ATTACHMENT A

SCHEDULE OF DOCUMENTS – FOI 2421

Document No.	Date	Pages	Description	Decision on access[1]	Exemption/s applied
1	30/9/20	13	Supporting the national COVID-19 vaccine and therapeutics strategy	E	section 33 – full section 47 – full section 47C – part section 47G – part
2	17/12/20	14	COVID-19 vaccine rollout: implementation planning progress and sentiment. Country profiles: US, UK, Canada	RE	section 47C – part
3	15/12/20	9	Vx uptake intent trends v2	R	
4	11/12/20	3	COVID-19 Australian vaccine pipeline summary vF	R	
5	09/12/20	53	COVID-19 Therapeutics and Vaccines Landscape Overview December 9 2020	R	
6	26/11/20	47	COVID-19 Therapeutics and Vaccines Landscape Overview November 26 2020	R	
7	26/11/20	4	COVID-19 Australian Vaccine Pipeline Summary vF	R	
8	19/11/20	3	COVID-19 Australian Vaccine Pipeline Summary vShare vF	R	
9	16/11/20	35	COVID-19 Therapeutics and Vaccines Landscape Overview November 16 2020	R	
10	06/11/20	3	COVID-19 Australian vaccine pipeline summary	R	
11	29/10/20	35	COVID-19 Therapeutics and Vaccines Landscape Overview October 29 2020	R	
12	8/01/21	61	Request for Tender – COVID-19 Vaccine Training Program	R	
13	15/12/20	63	Request for Tender – Vaccination Administration Support	R	
14	18/11/20	56	Request for Proposal - Logistics and Distribution Services	R	
15	17/11/20	63	Request for Proposal – Provision of a COVID-19 Vaccine Data Solution	R	

[1] E = Exempt in full, R = Release in full, RE = Release with exempt material removed.

COVID-19 vaccine rollout: implementation planning progress & sentiment

Country profiles: US, UK, Canada

DEC 2020

Contents

Executive summary

Context & approach

As requested, we sought to **understand the level of implementation planning / readiness and associated stakeholder sentiment** across three peer countries that have recently commenced rollout: **the US, the UK and Canada.** Our approach included:

1. Reviewing publicly available documents
2. Interviewing select international experts/stakeholders
3. Conducting press and media searches (including social media sources)

High level findings

There appeared to be more stakeholder criticism where implementation plans were less transparent; noting this finding is limited by accessibility to information (e.g., only statements/sentiment in the public domain) and a targeted sample of countries.

- **Implementation plans comparison**

Beyond the obvious fact of an earlier rollout launch, all three countries are **more progressed in implementation planning than Australia.** However some of the plans have not been released to the public.

- The **US is most progressed**, with implementation planning efforts beginning **5 months ahead of Australia.**
- These countries may hold **valuable lessons** on:
  - **Governance** (e.g. close collaboration with defence and other agencies to leverage their logistics expertise)
  - **Vaccine sites** (e.g. hospital vaccination sites may be at risk of capacity constraints and risk of infection during outbreaks)
  - **Close collaboration** between Federal and Jurisdictional governments enabled faster, more effective implementation planning

- **Key stakeholder sentiment analysis**

Sentiment towards the implementation plans across the three countries' key stakeholders is **mixed overall**, **but not out of line with pre-COVID-19 sentiment**

- **Canada's** key stakeholder sentiment **outside of the opposition parties is either positive or neutral**
- In the **US**, **key stakeholders have a mixed sentiment towards the implementation plan**, with stakeholders such as ASTHO expressing negative sentiment towards the lack of information available, whilst the AMA is openly supportive and positive
- In the UK, **stakeholders such as the BMA appear to have negative sentiment** towards the lack of clarity and visibility of information regarding COVID-19 vaccine rollout

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DRAFT

Country profiles: USA

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- **Plans were made early -** all 64 jurisdictions submitted implementation plans by September 2020. This was a requirement of the federal Operation Warp Speed, which set a target jurisdictional readiness date of November 15, 2020. For example:
  - Massachusetts (full document, executive summary)
  - California (full document, executive summary)
  - Illinois (full document, executive summary)
- **Plans are comprehensive and evolving**
  - Covering governance (incl. program monitoring), distribution and logistics (incl. inventory management), admin site SOPs (incl. provider onboarding, training, second dose reminders), systems and data, public comms plan
  - Spanning all 3 phases of rollout
  - Plans were reviewed by at least 3 CDC experts, and feedback returned by October 26. The CDC released updated guidelines on October 29, requiring the jurisdictions to refresh their interim plans (source)

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Country profiles: UK

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- **UK's approach heavily leverages existing centralised control of delivery via the NHS,** reducing the need for new planning/documentation (e.g., on coordination mechanisms)
  - Plans are therefore not necessarily labelled/published as COVID-19 specific
  - On COVID-specific requirements, internal planning is further progressed than published documentation (e.g., non-public guidance on establishing mass vaccination sites)
  - Distribution & logistics planning is currently reliant on vaccine-specific needs (i.e., use of Pfizer's supply chain)
- **Administration sites planning is most progressed** (relying on Pfizer for Phase 1 on other areas). Public Health England has published information on administration site processes:
  - For consumers - COVID-19: The green book, which contains details on:
    - Priority groups (with no indication of timing of when each group will be vaccinated)
    - Recommendations for the use of the specific vaccines i.e. contra-indications, adverse events
  - For providers: COVID-19 vaccination programme - Information for healthcare practitioners

There may be unpublished information available

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Country profiles: Canada

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- **Jurisdictions are responsible for implementation planning**
  - Health Canada have released guidance on the governing principles of an implementation plan (source), in addition to guidance on priority populations (source)
  - Implementation plans have been published by Provinces and Territories, generally at an architecture only, consumer-oriented level of detail. Selected examples:
    - Ontario
    - British Columbia
    - Manitoba
- **Initial/pilot implementation plans have been shaped by Pfizer,** e.g., stipulating sites for cold chain reasons.

There may be unpublished information available

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Example learnings on logistics and administration sites

Logistics

Canada: The vaccines taskforce includes a multidisciplinary team of experts, including the Canadian Armed Forces

US: Collaboration between DOH and DOD at a Federal level, leveraging Defense's strong logistics capability, a key enabler of success

Admin sites

US: Node reduction strategy adopted to reduce risk of cold chain breaches (e.g. no storage in warehouses; direct distribution from factory to admin sites)

US: Mass admin sites encouraged to form a part of every Jurisdiction's plans, enabling vaccination of the population in <6 months

US: Hospitals deprioritised as vaccination sites via contingency planning - capacity constrained, carry high infection risk during outbreaks

US: Federal Government supporting vaccination in long term care through CVS and Walgreens, providing clinics in every facility

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Vaccine uptake intent is volatile, but has fallen over time

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

Preliminary; data as of 11 Dec 2020

	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20
Australia	-	86	-	68	88	88	85	71	-
US	75	-	49	66	66	62	50	58	60
UK	-	79	-	77	64	85	49	79	67
France	74	62	-	-	68	59	-	54	-
Germany	-	70	-	61	70	67	-	69	53
Canada	-	60	72	77	-	76	-	76	64
Switzerland	60	80	-	63	-	46	54	49	-
Singapore	-	-	-	80	-	-	-	-	-
Japan	-	-	-	-	-	75	-	69	-
New Zealand	-	-	65	-	74	-	76	-	76

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: See following slides

BACKUP: Sources

Sources: vaccine uptake intent over time (1/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Australia	-	**Sydney Health Literacy Lab COVID-19 group**: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7326391/ 'https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(20)30559-4.pdf	-	**Finder (comparison website):** https://www.news.com.au/lifestyle/health/health-problems/only-68-per-cent-of-australians-would-get-a-covid19-vaccine-if-it-was-available-a-survey-has-found/news-story/67a760fe18624771a99b3a5bba2852d9	**Ipsos**:https://www.ipsos.com/en-au/9-10-australians-say-they-would-get-vaccinated-covid-19	**Ipsos**:https://www.ipsos.com/en-au/9-10-australians-say-they-would-get-vaccinated-covid-19	**Vox Pop Labs for the ABC:** https://www.abc.net.au/news/2020-10-29/covid-19-vaccine-attitudes-in-australia/ 12819470	**BehaviourWorks** Australia (part of the Monash Sustainable Development Institute) 'https://timesnewsgroup.com.au/surfcoasttimes/living/most-australians-coronavirus-vaccine/ 'Melbourne Institute:https://melbourneinstitute.unimelb.edu.au/__data/assets/pdf_file/0008/3518468/Taking-the-Pulse-of-the-Nation-5-10-October.pdf (Page 2)	-	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: vaccine uptake intent over time (2/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
US	**NBCLX/Morning Consult** Poll: https://www.nbcsandiego.com/news/coronavirus/poll-less-than-a-third-of-america-will-rush-to-get-coronavirus-vaccine/2298088/	-	**The Associated Press**-NORC Center for Public Affairs Research: https://www.npr.org/sections/coronavirus-live-updates/2020/05/27/863401430/poll-shows-only-a-quarter-of-african-americans-plan-to-get-coronavirus-vaccine 'Associated Press and the University of Chicago: https://www.sciencemag.org/news/2020/06/just-50-americans-plan-get-covid-19-vaccine-here-s-how-win-over-rest	**Gallup**: 'https://www.nytimes.com/2020/11/17/health/gallup-poll-coronavirus-vaccine.html 'https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx	**Gallup**: 'https://www.nytimes.com/2020/11/17/health/gallup-poll-coronavirus-vaccine.html 'https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx	**Gallup**: 'https://www.nytimes.com/2020/11/17/health/gallup-poll-coronavirus-vaccine.html 'https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx	**Gallup**: 'https://www.nytimes.com/2020/11/17/health/gallup-poll-coronavirus-vaccine.html 'https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx	**Gallup**: 'https://www.nytimes.com/2020/11/17/health/gallup-poll-coronavirus-vaccine.html 'https://news.gallup.com/poll/325208/americans-willing-covid-vaccine.aspx	**Pew Research Center:** 'https://www.webmd.com/lung/news/20201207/americans-increasinglyi-say-theyll-get-covid-vaccine	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: vaccine uptake intent over time (3/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
UK	-	79	-	76.9	64	85	49	79	67	-
	-	**Erasmus** University Rotterdam: 'https://link.springer.com/article/10.1007/s10198-020-01208-6	-	**Sheffield** Hallam University: https://psyarxiv.com/fs9wk/	**Keele** University (survey online, on Qualtrics): https://www.medrxiv.org/content/10.1101/2020.08.13.20174045v1.full.pdf	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	**The Guardian:** https://www.theguardian.com/world/2020/sep/24/a-fifth-of-people-likely-to-refuse-covid-vaccine-uk-survey-finds	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	**New YouGov**: https://yougov.co.uk/topics/health/articles-reports/2020/11/16/how-many-britons-are-willing-take-coronavirus-vacc	-
France	74	62	-	-	68	59	-	54	-	-
	The COCONEL Group: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30426-6/fulltext	**Erasmus** University Rotterdam: 'https://link.springer.com/article/10.1007/s10198-020-01208-6	-	-	**YouGov**: https://www.connexionfrance.com/French-news/One-in-three-French-people-would-not-get-Covid-vaccination-as-France-sceptical-of-vaccination-in-general	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: vaccine uptake intent over time (4/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Germany	-	70	-	61	70	67	-	69	53	-
	-	**Erasmus** University Rotterdam: 'https://link.springer.com/article/10.1007/s10198-020-01208-6	-	University of **Hamburg**: https://www.dw.com/en/coronavirus-vaccine-germany/a-54146673	**German Institute for Economic Research**: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3717703	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	**Barmer**: https://www.deutschland.de/en/news/coronavirus-in-germany-informations	-
Canada	-	60	72	76.5	-	76	-	76	64	-
	-	**Leger and the Association for Canadian Studies:** https://globalnews.ca/news/6932834/mandatory-coronavirus-covid-19-vaccine-ipsos/	**Ipsos**: https://globalnews.ca/news/6932834/mandatory-coronavirus-covid-19-vaccine-ipsos/	**Statistics Canada:** https://www150.statcan.gc.ca/n1/pub/45-28-0001/2020001/article/00073-eng.htm	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	**Ipsos/Radio-Canada**: https://www.cbc.ca/news/canada/montreal/poll-finds-majority-of-canadians-open-to-getting-covid-19-vaccine-but-many-want-to-wait-1.5824067	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: vaccine uptake intent over time (5/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Switzerland	60	80	-	63	-	45.8	54	49	-	-
	Sotomo research institute: https://www.swissinfo.ch/eng/scepticism-against-anti-covid-vaccine-grows/46190500	**ORB** International: https://www.politico.eu/article/why-a-future-coronavirus-vaccine-may-go-to-waste/	-	**CSS** at the Sotomo Institute: https://www.rts.ch/info/suisse/11544436-deux-tiers-des-suisses-se-disent-prets-a-etre-vaccines-contre-le-covid19.html	-	**Bern** University of Applied Sciences: https://lenews.ch/2020/08/20/coronavirus-a-quarter-of-swiss-employees-dont-want-to-be-vaccinated-suggests-survey/	**SonntagsZeitung** and Le Matin Dimanche: https://www.swissinfo.ch/eng/half-of-swiss-would-get-vaccinated-against-covid-19/46075298	**Sotomo** research institute: https://www.swissinfo.ch/eng/scepticism-against-anti-covid-vaccine-grows/46190500	-	-
Singapore	-	-	-	80	-	-	-	-	-	-
	-	-	-	**ISGlobal**: https://www.nature.com/articles/s41591-020-1124-9 https://static-content.springer.com/esm/art%3A10.1038%2Fs41591-020-1124-9/MediaObjects/41591_2020_1124_MOESM1_ESM.pdf 'https://www.medrxiv.org/content/10.1101/2020.08.23.20180307v1.full.pdf	-	-	-	-	-	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

Sources: vaccine uptake intent over time (6/6)

% of respondents likely to get a COVID-19 vaccine when available[1]

DRAFT

	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020	October 2020	November 2020	December 2020
Japan	-	-	-	-	-	75	-	69	-	-
	-	-	-	-	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	**Ipsos**: https://www.ipsos.com/en/global-attitudes-covid-19-vaccine-october-2020	-	-
New Zealand	-	-	65	-	74	-	76	-	76	-
	-	-	**Stickybeak** survey: https://thespinoff.co.nz/science/20-05-2020/new-poll-shows-16-of-new-zealanders-dont-want-to-be-covid-19-vaccinated/	-	**Massey** University: https://mro.massey.ac.nz/bitstream/handle/10179/15567/Aotearoa%20New%20Zealand%20Public%20Attitudes%20to%20COVID-19%20Vaccine.pdf?sequence=1	-	**1 NEWS** Colmar Brunton Poll: https://www.tvnz.co.nz/one-news/new-zealand/most-kiwis-would-likely-get-covid-19-vaccine-if-one-becomes-available-1-news-poll	-	**1 NEWS** Colmar Brunton Poll: https://www.tvnz.co.nz/one-news/new-zealand/one-fifth-kiwis-would-not-probably-get-covid-19-vaccine-1-news-poll-finds	-

1. For surveys where responses lie on a scale (e.g., from very unlikely to very likely), all positive responses are considered likely. Unsure and negative responses are considered not likely (i.e., not included in the percentage displayed).

BACKUP: useful reports

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- “Global attitudes towards a COVID-19 vaccine” (Jul 24 – Aug 7), a Ipsos survey for the World Economic Forum with insights on attitudes towards a COVID-19 vaccine across various countries (Link)
- “Global attitudes towards a COVID-19 vaccine” (Oct 8 – Oct 13), a Ipsos survey for the World Economic Forum with insights on attitudes towards a COVID-19 vaccine across various countries (Link)
- “Once we have it, will we use it? A European survey on willingness to be vaccinated against COVID-19” (Apr 2 – Apr 15), a survey conducted for 8 European countries. (Link)

Key changes since our last update

Canada became the third country to approve Pfizer/BioNTech's BNT162b2 vaccine[1]

- Pfizer/BioNTech submitted their vaccine for approval in early October, and Health Canada announced on Wednesday that it has now issued an interim order authorising use in people 16 years or older.
- Canadian provinces plan to commence vaccination next week, prioritising health care workers and long-term care workers. Priority populations were agreed nationally, on advise of the National Advisory Committee on Immunisation. 2nd doses will be scheduled at the time of first dose administration. Pfizer is responsible for distributing the vaccine, and is requiring Alberta begin administering the vaccine only at the site of delivery (and thus not in continuing care facilities), as experience in handling the vaccine grows.

UK has begun deployment Pfizer's vaccine, but the UK MHRA advises against use in those with history of severe allergic reactions[3]

- The UK began vaccine delivery this week, with prioritization to residents of long-term care facilities and healthcare staff. Deployment is via the UK's NHS with vaccine administration by GPs at 50 approved hospitals. Vaccination cards are in use to record doses and to provide a reminder to receive the second dose (top left).
- Pfizer's trials excluded people with a "history of severe adverse reaction associated with a vaccine", according to data released by the US FDA on Tuesday.
- The UK MHRA is investigating two incidents of allergic reactions after two health workers received the vaccine. Both had histories of allergic reactions.
- BioNTech and FosunPharma have launched a Phase II trial of the vaccine in China to generate data support potential approval there.

Russia has begun deployment of its Sputnik V vaccine[3]

- Sputnik V is a Russian-made vaccine, which according to Russia, is 92% effective and has no serious side effects associated with it, and has received domestic regulatory approval despite clinical trials being incomplete
- Russia began vaccine delivery this week, prioritising medical workers, teachers, and social workers. Recipients must volunteer and be aged 60 years or less, and without particular health conditions.
- The Russian Direct Investment Fund also announced that generics manufacturer Hetero has signed an agreement to produce more than 100 million doses per year of the vaccine in India starting in 2021.

China continues deployment of experimental vaccines, including those by Sinovac and Sinopharm[4]

- Vaccine candidates under development by Sinovac and Sinopharm were approved for emergency use in July. The efficacy and safety of these vaccines remain unclear. Clinical trials are ongoing in multiple jurisdictions.
- More than 1 million health care workers and high-risk groups have already received vaccinations.

US FDA continues to consider EUAs for Pfizer's BNT162b2 and Moderna's mRNA1273[5]

- Review meetings are to take place on Dec 10 and 17. If authorised, shipments are expected to commence Dec 15 and 22 respectively, according to a document from the federal government's Operation Warp Speed.
- US DoD released first images of vaccination record card last week (bottom left). "Everyone will be issued a written card that they can put in their wallet that will tell them what they had and when their next dose is due," Dr Kelly Moore of the Immunization Action Coalition said.

1. AAP, TCP, TCP
2. Gov. UK, Gov.UK, Reuters, FN London, FiercePharma, UK Finance , Starherald, BioNTech, The Sun, AP
3. Reuters, ABC, SBS
4. AP
5. CNN

Australia has agreements in place that potentially provide access to five leading COVID-19 vaccines candidates

Manufacturer supply agreement | Possible COVAX supported supply[1]

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Vaccine candidate	Trial Phase	Platform	Efficacy	Thermostability requirements	Doses to be supplied if successful[1,2]	Manufacturing
Oxford University /AstraZeneca (AZD1222)	Ph 3*	Non-replicating viral vector	70% average[3]	**2-8°C** for up to 6 months	**3.8M** by March 2021, additional **30M** by September Plus purchase option up to **50% population** coverage, via COVAX	**Offshore** via AZ (3.8M); **onshore** manufacturing agreement via CSL (30M doses)
UQ/CSL (Seqirus) V451	Ph 1	Protein subunit	TBC	**2-8°C** for up to 6 months	**51M** from mid-2021 Purchase option up to **50% population** coverage, via COVAX	**Onshore** manufacturing agreement via CSL
Novavax (NVX-CoV2373)	Ph 3	Protein subunit	TBC	**2-8°C,** duration not yet confirmed	**40M** early-mid 2021 (TBC), option to purchase additional 10M Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
BioNTech/Pfizer mRNA (BNT162)	Ph 3* (Completed)	mRNA	95%	**-70°C** for up to 6 months **2-8°C** for up to 5 days[4]	**10M** early-mid 2021 (TBC) Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
Moderna (mRNA-1273)	Ph 3 (Completed)	mRNA	94-95%	**-20°C** for up to 6 months **2-8°C** for up to 30 days[5]	Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX

* TGA Provisional Determination received (i.e., eligible to apply for approval under the Provisional Approval pathway)

1. COVAX options are additional to directly negotiated Advance Purchase Agreements, with the option for purchase of doses sufficient for up to 50% of the population (across all candidates cumulatively).
2. Information to date indicates that all five vaccine candidates are likely to require two doses per person (subcutaneous or intramuscular injections, administered three to four weeks apart).
3. 62% efficacy on 2 full doses taken 4 weeks apart (n=8,895), 90% efficacy with 1 half dose followed by a full dose 4 week apart (n=2741)
4. When thawed but not yet reconstituted; must be used within 6 hours (at room temperature) once reconstituted
5. When thawed but not yet reconstituted; must be used within 12 hours (at room temperature) once reconstituted

There are additional candidates in Phase 3 trials that are not covered by Australian/COVAX supply agreements

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Vaccine candidate	Platform	Thermostability requirements	Notes
Johnson & Johnson (Ad26.COV2.S)*	Non-replicating viral vector	2-8°C refrigerated cold chain in storage and at administration sites for 3 months, 2 years at - 20°C	Only leading candidate with single-dose regimen Phase III trial underway to assess a two-dose regimen BARDA-supported
Sinopharm	Inactivated virus	Unclear[1]	Chinese government supported

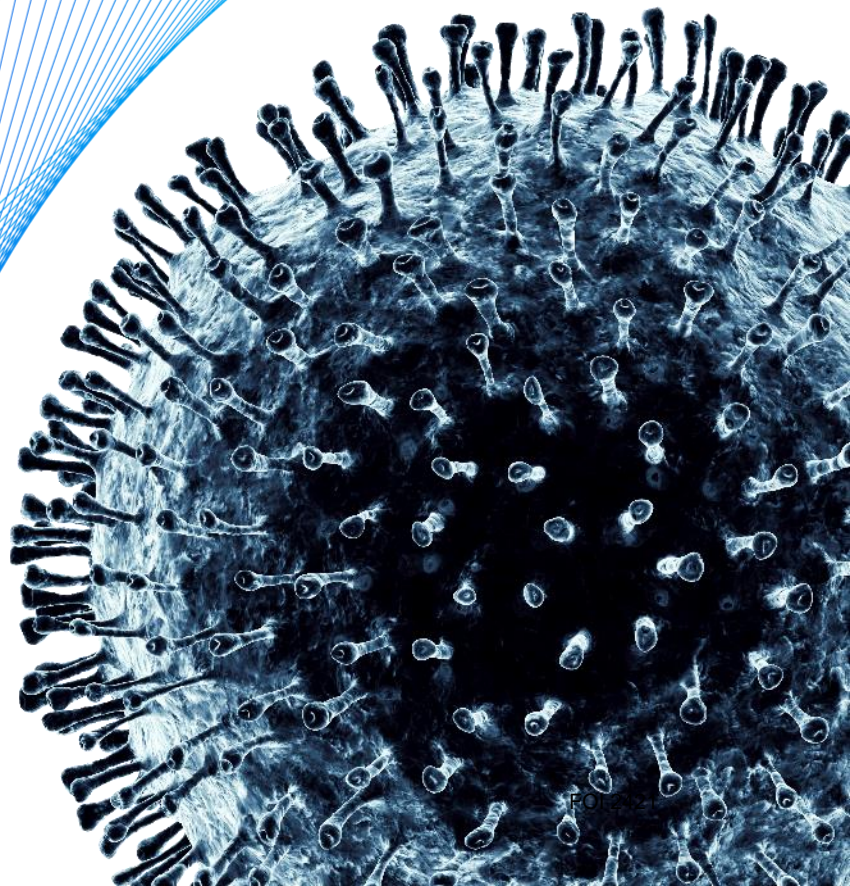
Two further candidates are currently in Phase III clinical trails, manufactured by CanSino Biological (China) and Gamaleya (China/Russia), however limited data are available

* TGA Provisional Determination received (i.e., eligible to apply for approval under the Provisional Approval pathway)

1. Likely 2-8°C refrigerated cold chain based on technology platform

McKinsey & Company

COVID-19 Therapeutics and Vaccines Landscape Overview



December 9, 2020

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED PURELY ON CURRENT, PUBLICLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE

Document overview

To date, there is no **globally approved COVID-19 vaccine or treatment** available.

There are **over 275 vaccine candidates** and **over 455 therapeutics candidates** in consideration.

This document provides a **current snapshot of vaccine and therapeutic efforts for COVID-19.** It is based on **publicly available data** across candidate lists, clinical trial data and trial results.

Sources of insight:

- Multiple candidate lists (e.g. Milken Institute, BioCentury, WHO)
- Clinical trial registries (mainly CT.gov and ChiCTR)
- Press and literature searches

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5 key points on the status of vaccines

1 Recent evidence on COVID-19 vaccines is encouraging[1]

- 8+ vaccine candidates in or through late-stage clinical trials; tracking towards <1 year overall development vs. fastest prior at 4.5 years[1a,b]
- Completed Phase III results for Pfizer/BioNTech and Moderna's vaccine candidates show respectively 95% and 94% efficacy[2,3] ; interim Phase III analysis suggests suggests 62% - 90% efficacy depending on dosing regimen for Oxford/AstraZeneca's vaccine[4], and 91% efficacy for Russia's Sputnik V vaccine[5], with data from J&J expected to follow[6]

2 Pfizer/BioNTech's vaccine received emergency approval in the UK; US EUA decision expected after Dec 10[7]

- Decision on emergency approval for Moderna's vaccine is expected after Dec 17 in the US[8], with reviews by European authorities ongoing
- Full licensure of the first COVID-19 vaccines is expected in Mar / Apr 2021[9]
- In US, EUA likely to focus on healthcare and frontline workers, patients with chronic conditions, elderly[10], full roll-out to broader populations targeted for Q2 / Q3 2021

3 While early signals are promising, challenges need to be overcome

- Resolving clinical unknowns: full safety and efficacy data from Oxford/AZ and others, duration of vaccine protection, pediatric testing[1]
- Manufacturing capacity: multiple players need to be successful to meet global demand[11]
- Complex supply chain: cold chain requirements and two-dose regimen for several products[12]
- Consumer adoption: vaccine acceptance levels range from 40 to 60% of the population[13]

4 In high-income countries, herd immunity is likely to be reached around Q3 / Q4 2021, with gradual transition back to normal in Q2 2021 (including use of broader public health interventions)[14]

- Vaccines are only one tool – need to be complemented with improved testing, therapeutics, and public health measures
- COVID-19 unlikely to be fully eradicated - ongoing immunization and treatment of cases likely needed

5 Vaccine roll-out will vary by geography. While the WHO's COVAX program and others are focused on equitable access, capacity challenges mean the pandemic is likely to extend into 2022 in some parts of the world[15]

1.Nature a Nature b 2.Pfizer, Pfizer 3.Moderna 4.AZ 5.Sputnik 6.WSJ 7.Pfizer 8.Reuters 9.NYT, CNBC 10.CDC 11.Nature 12.Reuters 13.Gallup 14.Politico 15.COVAX

COVID-19 vaccine update: Phase III trial analysis

Context

Pfizer/BioNTech, Moderna and Oxford University/ AstraZeneca's COVID-19 vaccine candidates are 3 of 4 candidates in the first wave of development, alongside Johnson & Johnson[1,2]

The announce-ments of results come at about the expected time (late October / early November and by end of 2020)[3]

Positive news

94-95% vaccine efficacy and EUA requests submitted for Pfizer/BioNTech[4] and Moderna's[5] mRNA candidates – 2-month safety data for both candidates appears positive[4,5]

70% vaccine efficacy on average for Oxford University/AstraZeneca's viral vector candidate – 90% efficacy when given as a half dose, followed by a full dose min. 4 weeks later; 62% efficacy when given as two full doses min. 4 weeks apart[6]

170 (Pfizer/BioNTech), 196 (Moderna) and 131 (Oxford/AZ) cases of COVID-19 – each represent more than the initial threshold for (interim) analysis, suggesting that the results are relatively robust[4,5,6]

Efficacy in elderly population – Pfizer/BioNTech >94% efficacy in adults over age 65[7]

Efficacy against severe disease – Moderna 100% efficacy against severe COVID-19[5]

Supply chain complexity – Pfizer/BioNTech vaccine two doses and ultra-cold chain (-70 degrees C); specially designed thermal shippers can be used for temporary storage for 15 days by refilling with dry ice, Moderna two doses at 2-8º C for 30 days and -20º C for 6 months; Oxford/AZ two doses at 2-8º C for 6 months[6,8,9]

Big outstanding questions

Optimal dosing regimen (Oxford/AZ) – pending full readout of all trial arms/dosing regimens and subgroup analyses[6]

Duration of efficacy – pending longer-term data to assess duration of vaccine-mediated protection[4,5,6]

Data for other demographics – pending efficacy data on pediatrics (<18 y/o), and subpopulations with comorbidities (e.g., HIV positive)[10]

Vaccine hesitancy – public confidence in COVID-19 vaccines poses adoption challenges[11]

Potential implications

Timeline for EUA submission and vaccine availability in line with expectations (by end of 2020)

Higher than expected efficacy could enable herd immunity with lower rates of coverage

Overall timeline to herd immunity may not be accelerated because manufacturing, supply chain, and rate of adoption likely to be rate limiting

High efficacy with lower dosing regimen (Oxford/AZ) could potentially allow for vaccination of a larger population with the current planned supply – to be further validated with additional data

Potential positive indication for mRNA and viral vector platforms - to be further validated with other candidates (e.g., Curevac, J&J)

1.Nature 2. WSJ 3. Pfizer, Pfizer 4. Pfizer 5. Moderna 6. AstraZeneca 7. Pfizer 8. Pfizer 9. Moderna 10. Pink Sheet 11. Gallup

COVID-19 vaccine update: summary of recent data

Overview of available data on Phase III trials of select COVID-19 vaccine candidates

	moderna	Pfizer BioNTech	The Jenner Institute, University of Oxford, AstraZeneca
MoA	mRNA	mRNA	Viral vector
Dose schedule	2 doses, 4 weeks apart	2 doses, 3 weeks apart	1 or 2 doses of a half or full dose 4-12 weeks apart, depending on trial arm
Dose levels	1 dose level, 100 micrograms	1 dose level, 30 micrograms	COV002 trial (UK): one or two doses of a half or full dose COV003 trial (Brazil): one or two full doses
Efficacy target	60%	60%	50%
Efficacy in clinical trial	94%	95%	90% for half dose + full dose 62% for 2 full doses 70% across both dosing regimens
Thermostability	-20°C shipped /stored for 6 months; 2-8°C for 30 days	-70°C shipped /stored for 6 months; 2-8°C for 5 days	2-8°C for 6 months
Announced manufacturing capacity	30m doses by year-end 2020 1b doses in 2021	50m doses by year-end 2020 1.3b doses in 2021	200m doses by year-end 2020 3b doses in 2021

Source: ClinicalTrials.gov, Moderna press release, WBUR, Pfizer, Pfizer , The Guardian, AstraZeneca, Oxford University; Moderna

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COVID-19 vaccines development effort overview (1/2)

Recent developments – Nov 25 – Dec 9, 2020

UK's MHRA authorized Pfizer / BioNTech's COVID-19 vaccine for emergency use [1]

- The approval is the first for a COVID-19 vaccine globally, while the mRNA platform is also a first for vaccines more broadly.
- The UK began vaccine delivery this week, with prioritization to residents of long-term care facilities and healthcare staff.
- Pfizer and BioNTech have now also submitted their vaccine data to the EMA, which has planned a review for Dec 29th, but has said it can move up the date if data comes in early.
- BioNTech and FosunPharma have launched a Phase II trial of the vaccine in China to generate data support potential approval there

Moderna filed for emergency approvals with US and European regulatory authorities for its COVID-19 vaccine, mRNA1273 [2]

- The company released additional data from its completed Phase III trial, showing 94.1% efficacy.
- The FDA expects to review the vaccine at its Dec 17th VRBPAC meeting, while the EMA has planned its review meeting for January 12th.

Oxford/AstraZeneca will await results from their US Phase III trial, expected by end of January, before submitting an EUA to the FDA [3]

- The UK government has asked the MHRA to consider granting fast track review to the vaccine
- The **Serum Institute of India** will continue its trial of Oxford/AstraZeneca's vaccine with a full two-dose regimen as planned, despite recent data showing an initial half-dose primer might spark greater efficacy. SII said any efficacy above 50% is acceptable, and a change in dose would result in trial delays.
- AstraZeneca plans to launch a separate Phase III trial to validate the higher efficacy of the half-dose initial primer.
- Meanwhile, a SII trial participant is seeking compensation and suspension of the study, claiming he suffered serious 'neurological and psychological' symptoms after receiving the vaccine. The Indian Council of Medical Research is looking into the claim.

Novavax delays its US Phase III trials, pushing the start date to late December at the earliest [4]

- The company has received additional questions from the FDA over its partnership with Fijifilm Diosynth Technologies for manufacturing of the vaccine for the trial
- Meanwhile, Novavax's UK and South African' Phase III trials are ongoing, including 245 participants who are HIV-positive and medically stable. Interim datafrom these trials is expected by Q1 2021

1.Gov. UK, Gov.UK, Reuters, FN London, FiercePharma, UK Finance , Starherald, BioNTech 2. Moderna, Endpoints 3. CNBC, Reuters, Endpoints, Reuters 4. Novavax, Fierce Pharma End Points

COVID-19 vaccines development effort overview (2/2)

Recent developments – Nov 25 – Dec 9, 2020 (continued)

Sinopharm filed a request for marketing approval with Chinese regulatory authorities. This follows earlier approval of one of its candidates for use in frontline workers in Bahrain. [1]

The EMA has launched a rolling review of Johnson and Johnson's COVID-19 vaccine candidate, Ad26.COV2-S[2]

Brazil, Ecuador and Peru have jointly entered a deal to purchase up to 140 million doses of Covaxx's UB-612 vaccine for $2.8 billion, pending regulatory approval. The drug is still in Phase I clinical trials, and is expected to enter Phase II/III testing in the US, Asia and Latin America in the coming months. [3]

South Korea has agreed to purchase an undisclosed amount of Oxford/AstraZeneca's vaccine candidate, in addition to its agreements with Pfizer/BioNTech and Johnson & Johnson. [4]

CureVac has partnered with Whacker to produce its vaccine candidate, with the goal of adding production capacity of 100 million doses per year. [5]

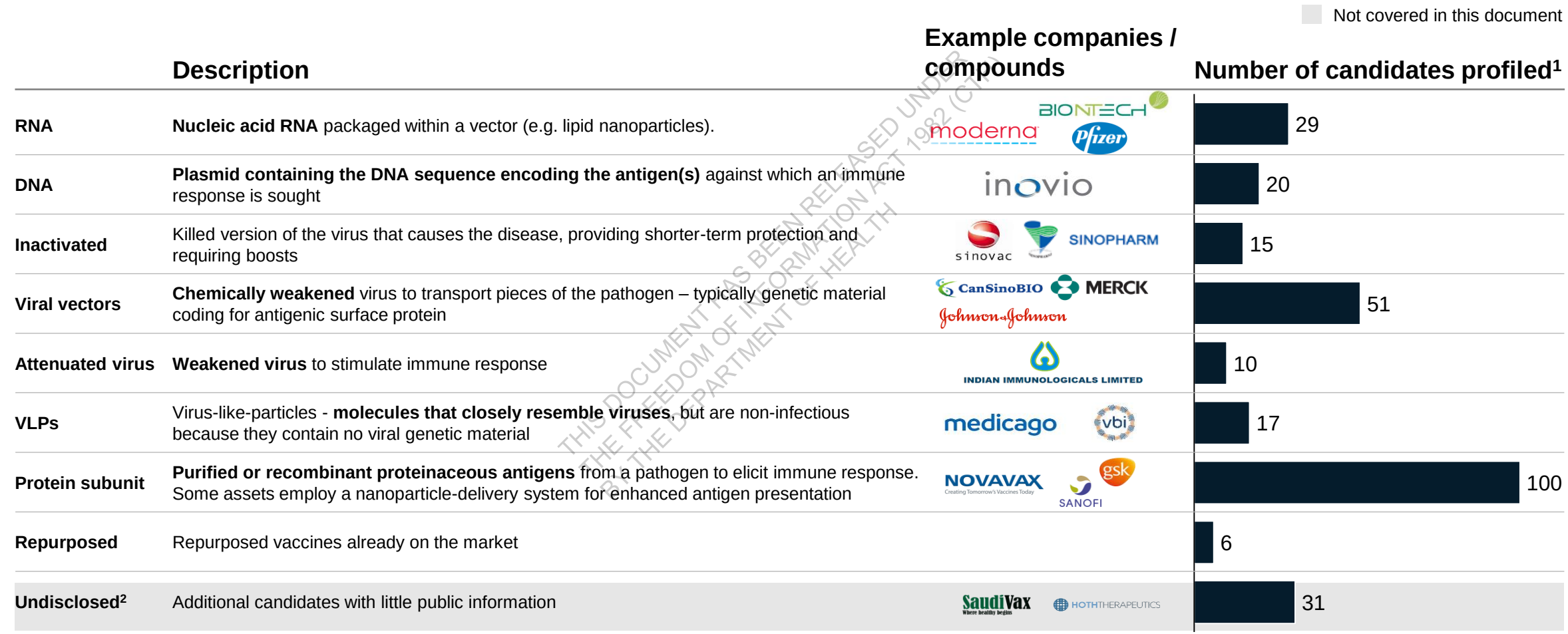
Russia is kicking off a mass vaccination campaign, with teachers and doctors likely among the first to be offered the country's Sputnik V vaccine. The Russian Direct Investment Fund also announced that generics manufacturer Hetero has signed an agreement to produce more than 100 million doses per year of the vaccine in India starting in 2021. [6]

The CDC's Advisory Committee for Immunization Practices (ACIP) recommended prioritizing healthcare workers and long-term care residents for vaccination, along with nursing home residents and staff. [7]

Sanofi and GSK aim to announce the price of their COVID-19 vaccine candidate with the release of their phase I/II trial results, which is expected by end of the year.

1. SCMP 2. Reuters 3. Businesswire 4. Korea Biomed 5. CureVac 6. Reuters, Gamaleya Institute 7. CNN 8. Reuters

There are 279 candidates in the pipeline for COVID-19 vaccines



1. Compiled across multiple lists (Milken Institute, BioCentury, WHO, Nature) and supplemented with press
2. Not profiled moving forward. Vaccine type cannot be delineated due to lack of public information; typically in research setting or small biotech

Source: Milken Institute, BioCentury, WHO, Nature

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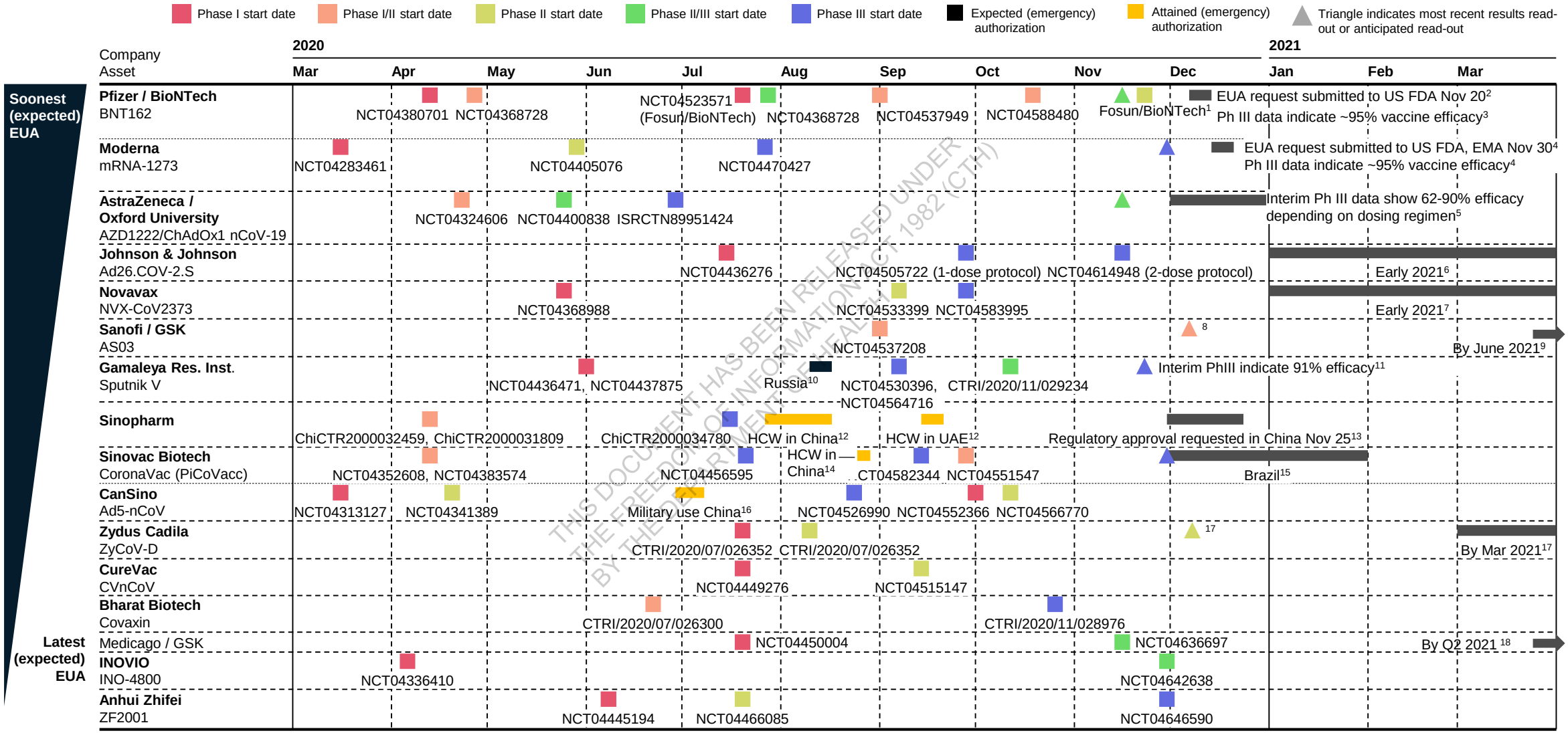
CURRENT AS OF DECEMBER 9, 2020
NONEXHAUSTIVE - EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Select vaccine candidates currently in Phase II/III or III or have announced potential EUA timelines



1. Pharmaceutical Technology
2. Pfizer
3. CIDRAP, Pfizer, Pfizer
4. Moderna
5. Reuters, AstraZeneca, Aljazeera
6. FiercePharma, Johnson & Johnson
7. Biospace
8. Sanofi
9. SEC filing
10. BioPharma
11. Gamaleya Center
12. Reuters; NPR
13. SCMP
14. Reuters
15. FiercePharma, Lancet
16. Reuters
17. Reuters, Business Standard
18. India Times, DNA India

Design elements for select vaccine candidates in late-stage efficacy trials (non-exhaustive, 1/2)

Based on public information; trials and timing are estimates and subject to change

	Pfizer BioNTech	moderna	AstraZeneca	J&J	NOVAVAX
	Phase I/II/III	**Phase III**	**Phase II/III**	**Phase III**	**Phase III**
Start	Completed	Completed	May/June 2020	Sept/Nov, 2020	Sep 28, 2020
MoA	mRNA	mRNA	Viral vector	Viral vector	Protein subunit
Dose schedule	2 doses	2 doses	1 or 2 doses for adults, ped, elderly	1 dose or 2 doses	2 doses
Dose levels	1 dose level 30 micrograms	1 dose level 100 micrograms	1 dose level for adults and ped., 2 for elderly	1 dose level 1x10^11 viral particles	1 dose level
Efficacy target	60%	60%	50%	60%	Unknown
Efficacy attained	95%	94%	70% (interim analysis)	n/a	n/a
Trial size	43,998	30,000	49,430	90,000	39,000
Site geography	Germany, USA, S. Africa, Argentina, Brazil Turkey, China, Japan	USA	UK, USA, Brazil, S. Africa, India	USA, Argentina, Brazil, Chile, UK, Colombia, France, Mexico, Peru, Philippines, S. Africa, Ukraine, Belgium, Germany, Spain	UK, US, Mexico, S. Africa
Temperature conditions	-70°C shipped / stored for 6 months; 2-8°C for 5 days	-20°C shipped / stored for 6 months; 2-8°C for 30 days; 12 hours at room temp	2-8°C for 6 months	2-8°C for 3 months; 2 years at -20°C	Unknown
Special populations	Ex-EU: 12yrs+, EU: 18yrs+, Phase 3 incl. HIV patients	None (adults 18+)	Elderly, pediatric	Adults 18+; planned inclusion of pediatric population 12-18yrs	Stable HIV+ patients

Source: clinicaltrials.gov, press search

Design elements for select vaccine candidates in late-stage efficacy trials (non-exhaustive, 2/2)

Based on public information; trials and timing are estimates and subject to change

	Gamaleya Institute	SINOPHARM	sinovac	CUREVAC	BHARAT BIOTECH	INOVIO
	Phase III	**Phase III**	**Phase III**	**Phase II/III**	**Phase III**	**Phase II/III**
Start	August 25, 2020	July 16, 2020	July/Sept/Oct, 2020	Sept 29, 2020	Sept 29, 2020	Nov, 2020
MoA	Viral vector	Inactivated virus	Inactivated virus	mRNA	Inactivated virus	DNA, delivered directly into the skin via CELLECTRA device
Dose schedule	1 dose each of 2 components	2 doses	2 doses	2 doses	2 doses	2 doses
Dose levels	1 dose level per component,0.5ml	1 dose level	1 dose level	1 dose level, 12 micrograms	1 dose level, 6 micrograms	2 dose levels, 1 and 2mg
Efficacy target	Unknown	Unknown	Unknown	Unknown	50-60%	Unknown
Efficacy attained	91% (interim analysis)	n/a	n/a	n/a	n/a	n/a
Trial size	40,000	45,000	26,248	30,000	25,800	6,578
Site geography	Russia	UAE, Bahrain	Brazil, Indonesia, Turkey, China	TBC	India	USA
Temperature conditions	-18ºC	Unknown	Unknown	2-8ºC for 3 months; room temperature for 24 hours	Unknown	Stable at room temp for ~1 year, does not require cold chain shipping/ storage
Special populations	TBC	None (adults 18+)	Adult, elderly & pediatric arms, healthcare workers	TBC	TBC	TBC

Source: clinicaltrials.gov, press search

Compilation of published or pre-released clinical trial results (1/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Pfizer / BioNTech BNT 162	RNA	Phase II/III	Randomized triple blind placebo controlled trial	Interim Germany Phase I/II readout	July 20, 2020	• BNT162b1 elicited strong CD4+ and CD8+ T cell responses against SARS-CoV-2-receptor binding domain (RBD) compared to baseline • The RBD-specific, interferon-γ+, IL-2+, CD8+ T cells elicited by BNT162b1 in immunized participants indicate a strong potential for cell mediated anti-viral activity • T cell cytokine profile shows vaccine elicited T cells exhibit a Th1 phenotype, which is associated with antiviral properties	NCT04368728
				Interim US Phase I/II readout	Aug 20, 2020	• BNT162b2 elicited SARS-CoV-2–neutralizing GMTs in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times • Well tolerated with mild to moderate fever in fewer than 20% of participants	NCT04368728
				Phase III readout	Nov 18, 2020	• BNT162b2 was 95% effective across >41,000 participants who received the two-dose vaccine regimen • 170 cases of COVID-19 occurred in trial participants, 162 in the placebo group and 8 in the vaccine group • Efficacy was consistent across demographics, including 94% efficacy in older adults (65+) • The vaccine was well tolerated; the most common Grade 3 adverse events were fatigue (3.8%) and headache (2.0%)	NCT04368728

Compilation of published or pre-released clinical trial results (2/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Moderna mRNA1273 moderna	RNA	Phase III	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 29, 2020	• By day 57, among the participants who received the low dose, the geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 and 1,128,391 among those who were 71+ years • Among the participants who received the high dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively • Binding- and neutralizing-antibody responses appeared to be similar to those among vaccine recipients between the ages of 18 and 55 • The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells	NCT04283461
				Phase III read out	Nov 30, 2020	• 94.1% efficacy overall, with 196 cases of COVID-19 occurring in the study population: 185 in the placebo arm and 11 in the vaccine arm. • All 30 severe COVID-19 cases occurred in the placebo group, including one COVID-19-related death • Safety profile as per interim Phase III readout on Nov 16 —The most common grade 3 event after the first dose was injection site pain (2.7%), with smaller numbers of participants experiencing grade 3 headache, pain or redness at the injection site. —After the second dose, fatigue (9.7%), muscle pain (8.9%) and joint pain (5.2%) were the most common SAEs	NCT04283461

Compilation of published or pre-released clinical trial results (3/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
CureVac CVnCoV	RNA	Phase I	Randomized blinded placebo-controlled, dose-escalation trial	Interim Phase I readout	Nov 9, 2020	• Two doses of CVnCoV ranging from 2 µg to 12 µg per dose, administered 28 days apart were safe • Seroconversion (defined as a 4-fold increase over baseline titer) of virus neutralizing antibodies two weeks after the second vaccination occurred in all participants who received 12 µg doses • Preliminary results in the subset of subjects who were enrolled with known SARS-CoV-2 seropositivity at baseline show that CVnCoV is also safe and well tolerated in this population, and is able to boost the pre-existing immune response even at low dose levels • Based on these results, the 12 µg dose is selected for further clinical investigation	NCT04449276
Inovio INO-4800	DNA	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	Aug 10, 2020	• 100% of trial participants demonstrated overall immune responses • 95% had seroconverted by antibody response overall • Nearly 90% generated strong T cell responses, including CD8+ T cell responses	NCT04336410
Sinopharm BBIBP-CorV	Inactivated	Phase I/II	Randomized double blind placebo controlled trial	Interim Phase I/II readout	Aug 14, 2020	• The trial linked the vaccine to increases in antibody titers. It is not clear whether the response is likely to confirm immunity as the study did not include a comparison arm featuring serum samples from patients previously infected with the coronavirus	ChiCTR-2000032459
Sinovac CoronaVac (PiCoVacc)	Inactivated	Phase I/II	Double blind prospective RCT	Peer-reviewed Phase I/II results	Nov 17, 2020	• Phase I/II results indicated that a 2-dose regimen with 14 days between doses successfully induced an antibody production	NCT04383574

Compilation of published or pre-released clinical trial results (4/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
AstraZeneca/ Oxford AZD1222	Viral vector	Phase III	Single blind prospective RCT	Interim Phase I/II readout	July 20, 2020	• "Neutralizing antibodies were generated in over90% of participants across different assays. Responses were sustained up to 56 days." • "No serious adverse events occurred."	NCT04324606
				Peer-reviewed Phase II/III data	Nov 18, 2020	• Local and systemic reactions were similar in nature to those previously reported, but were less common in older adults (aged ≥56 years) than younger adults • Median anti-spike SARS-CoV-2 IgG responses 28 days after the boost dose were similar across the three age cohorts	NCT04400838
				Interim Phase III readout	Nov 23, 2020	• Interim analysis pooling data from COV002 (UK), COV003 (Brazil) • 90% efficacy when given as a half dose, followed by a full dose at least 4 weeks later (n=2,741); 62% efficacy when given as two full doses at least 4 weeks apart (n=8,895); 70% vaccine efficacy on average across both dosing regimens (n=11,636) • No hospitalized or severe cases in anyone who received the vaccine	NCT04324606
J&J JNJ-78436735	Viral vector	Phase III	Randomized triple blind placebo controlled trial	Interim Phase I/II readout	Sept 28, 2020	• After a single dose, seroconversion rate at day 29 after immunization reached 92% with GMTs of 214 and 243 for the low and high dose levels, respectively	NCT04436276

Compilation of published or pre-released clinical trial results (5/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Gamaleya Research Institute	Viral vector	Phase III	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 4, 2020	• All trial participants (76 adults) elicited an antibody response within 21 days and no serious adverse events after 42 days • The vaccine also produced a T-cell response within 28 days, a secondary outcome	NCT04436471, NCT04437875
			Non-randomized, open label prospective trial	Interim Phase III readout	Nov 24, 2020	• Interim analysis triggered by reaching 39 cases • 91.4% efficacy based on analysis of 18,794 participants at 7 days after the second dose (28 days after the first dose); efficacy above 95% at 21 days after the second dose (42 days after the first) • "There were no unexpected adverse events"	NCT04436471, NCT04437875
CanSino Ad5-nCoV	Viral Vector	Phase II	Non-randomized, open label prospective trial	Interim Phase I readout	May 22, 2020	• Reported mean neutralizing titers of 34 in high-dose group, below FDA recommendation (160) • Single dose elicited a four-fold increase in binding antibodies to RBD in 94–100% of participants, and a four-fold increase to live virus in 50–75% of participants	NCT04313127
			Randomized, observer-blinded prospective trial	Interim Phase II readout	July 20, 2020	• One injection of non-replicating adenovirus-vectored COVID-19 vaccine with two concentrations • "Seroconversion occurred in more than 96% of participants, and neutralizing antibodies were generated in about 85%. More than 90% had T-cell responses."	NCT04398147

Compilation of published or pre-released clinical trial results (6/6)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Novavax NVX-CoV2373 NOVAVAX Creating Tomorrow's Vaccines Today	Protein subunit	Phase I/II	Randomized quadruple blind placebo controlled trial	Full Phase I readout	Sept 2, 2020	• 100% of participants developed wild-type virus neutralizing antibody responses after Dose 2 • Both 5 and 25mcg doses generated GMT greater than 300 • Anti-spike IgG & viral neutralization compared favorably to responses from patients with clinically significant COVID disease. Cellular immune responses were demonstrated in a subset of patients. No severe AEs reported	NCT04368988

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Public announcements indicate global vaccine manufacturing capacity of ~12 billion doses by end of 2021 (non-exhaustive)

Asset category	Asset	Company	Collaborators	YE 2020 (M)	YE 2021 (M)	Insource	Outsource	Partnerships
RNA	mRNA-1273	Moderna	NIAID, Lonza	20 [1]	500-1,000 [1]	✓	✓	Lonza, Catalent, ROVI, Takeda, recipharm
	BNT162	BioNTech	Pfizer and Fosun Pharma	50 [2]	1,300[2]	✓	✓	Pfizer, Rentschler[2] (for downstream purification), Polymun
	CVnCoV	CureVac	European Commission; BMGF		300 [3]	✓		Wacker, Tesla
Viral vectors	Ad26.COV-2.S	J&J	Beth Israel, HHS		1,000 [4]	✓	✓	Catalent, Emergent Biosolutions, Biological E, Aspen
	AZD1222 / ChAdOx1 nCoV-19	AstraZeneca	University of Oxford (Jenner Institute), Advent SRL, MilliporeSigma, Cobra Biologics	200 [5]	3,000 [6]		✓	SII, Oxford Biomedica, Emergent Biosolutions, Catalent, Scotland Symbiosis, Wockhardt, BioKangtai
	Sputnik V	Gamaleya	N/A	200 [7]	1,000 [8]	✓		Binnopharm, RDIF, GL Rapha, Hetero Biopharma
VLP-based	CoVLP	Medicago	GSK, Laval Univ. Infectious Disease Research Centre		80 [9]	✓		N/A
Protein-subunit	AS03	Sanofi Pasteur	GSK		1,000 [10]	✓		N/A
	NVX-CoV2373	Novavax	Emergent BioSolutions, Praha Vaccines, Serum Inst. of India	100 [11]	2,000 [12]	✓		Praha Vaccines, Takeda, Fujifilm, SK Biosciences, Serum Institute of India
	UB-612	Covaxx	UNMC, Dasa		1,000 [13]	✓		Maersk
Inactivated	VLA2001	Valneva	Dynavax		200 [14]	✓		N/A
	PiCoVacc	Sinovac Biotech	Dynavax		100-500 [15]	✓		BioPharma
	[several]	Sinopharm	Wuhan Institute of Biological Products		300–1,000 [16]	✓		Beijing Institute of Biological Products
Total				**570**	**11,780-12,380**			

1. Moderna press release, WBUR, Moderna
2. Pfizer, Fierce Pharma
3. CureVac; Expected capacity in 2022: 600m
4. J&J press release, FiercePharma
5. Reuters
6. AZ press release, Reuters
7. MedicalExpress
8. Reuters, Sputnik
9. Standard
10. Sanofi
11. FiercePharma
12. FiercePharma, Novavax
13. FiercePharma
14. Valneva
15. BusinessWire, EuroNews
16. Chinadaily.com.cn, Reuters

Source: Milken Institute, BioCentury, WHO, Nature, clinicaltrials.gov, press searches as noted above

Governments & organizations are creating supply contracts with rights to an allocation of doses (non-exhaustive)

Value ($) / **Doses**
Unk for unknown

	AstraZeneca	Novavax	Sanofi GSK	Pfizer BioNTech	J&J	Moderna	Gamaleya Institute	CureVac	COVAXX	Sinovac	Medicago	Valneva	**Total**
USA	$1.2B / 300M[1]	$1.6B / 100M[2]	$2.1B / 100M[4] (+500M)	$1.95B / 100M (+500M)[3]	$1B+ / 100M (+300M)[6]	$1.525B / 100M (+$6.6B / 400M)[5]							$9.3B+ / 800M+
UK	Unk / 100M[7]	Unk / 60M[8]	Unk / 60M[11]	Unk / 40M[9]	Unk / 30M[13]	Unk / 7M[12]						$558M / 60M[10]	$558M+/ 357M
EU	$843M / 300M (+100M) [14]		$380M / 300M[16]	$3.7B / 200M (+100M) [15]	Unk / 200M (+200M) [18]	Unk / 80M (+80M)[17]		$2.7B / 225M (+180M) [19]					$7.6B+ / 1.3B+
Brazil	$356M / 100M[20]						Unk / 50M[22]		*$2.8B / 140M*[58] Together with Ecuador, Peru	Unk/46M[21]			$3.2B / 336M
Middle East				Unk / 8M[23] Israel		Unk / 6M[24] Israel	Unk / 25M[25] Egypt						$73M+ / 39M+
Japan	Unk / 120M[26]	Unk / 250M[27] via Takeda		Unk / 120M[28]		Unk / 50M[29] via Takeda							Unk / 540M
Canada	Unk/ 20M[30]	Unk/ 76M[31]	Unk / 72M[33]	Unk / 20M (tbc)[32]	Unk / 38M[35]	Unk / 56M[34]					$173M / 76M[36]		$173M+ / 358M
China	Unk / 300M[37] via BioKangtai			Unk / 10M[38] via Fosun, tbc									Unk / 310M
LatAm	Unk / 150M (+100M) [39] Argentina, Mexico			Unk / 10M[40] Chile			Unk / 32M[41] Mexico						Unk / 192M+
Other Europe						Unk / 4.5M[42] Switzerland				Unk/20M[43] Turkey			Unk / 24.5M
Other APAC	Unk / 26M[59] Thailand Unk / 100M[44] Indonesia			Unk / 30M[45] Taiwan Unk / 1.5M[46] New Zealand			Unk / 100M[48] India Unk / 37 (+5M)[49] Kazakhstan, Belarus, Uzbekistan			Unk / 40M[47] Indonesia			Unk / 334.5M+
Australia	Unk / 34M[50]	Unk / 40M[51]		Unk / 10M[52]									Unk / 84M
COVAX (LMIC)	$750M / 300M[53]		Unk / 200M[54]										$750M+ / 500M
Serum Inst. of India (LMIC) (mfg tech transfer)	Unk / 1B[55]	Unk / 1B[56]											Unk / 2B
Total	$3.1B+ / 2.9B+	$1.6B+ / 1.5B+	$2.4B+ / 732M+	$5.65B+ / 549.5M+	$1B+ / 368M+	$1.6B+ / 303.5M+	Unk / 244M+	$2.7B / 225M+	$2.8B / 140M	Unk / 106M	$173M / 76M	$558M / 60M	**$22B+ / 7B+**

4. "over half of $2.1B for dev., other for doses" 37. "(…) required to produce at least 100 million doses by the end of the year, and at least 200 million doses by the end of 2021" 58. $2.8B, 140M doses total supply to Brazil, Ecuador, Peru

CURRENT AS OF DECEMBER 9, 2020
NONEXHAUSTIVE - EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Overview of publicly announced supply contracts (non-exhaustive)

Course[2] / Population ratio:
- > 1.5
- 0.5 – 1.5
- <0.5
- Unknown

Value ($) / Doses
Unk for unknown

USA

AstraZeneca	$1.2B / 300M
Novavax	$1.6B / 100M
Pfizer BioNTech	$1.95B / 100M (+500M)
Sanofi GSK	~$2.1B / 100M[1] (+500M)
Moderna	$1.525B / 100M (+$6.6B / 400M)
J&J	$1B+ / 100M (+300M)
Total	$9.3B+ / 800M+

Canada

AstraZeneca	Unk / 20M
Novavax	Unk / 76M
Pfizer BioNTech	Unk / 20M (tbc)
Sanofi GSK	Unk / 72M
Moderna	Unk / 56M
J&J	Unk / 38M
Medicago	$173M / 76M
Total	$173M/358M

UK

AstraZeneca	Unk / 100M
Novavax	Unk / 60M
Pfizer BioNTech	Unk / 40M
Valneva	$558M / 60M
Sanofi GSK	Unk / 60M
Moderna	Unk / 7M
J&J	Unk / 30M
Total	$558M / 357M

EU

AstraZeneca	$843M / 300M (+100M)
Pfizer BioNTech	$3.7B / 200M (+100M)
Sanofi GSK	$380M / 300M
Moderna	Unk / 80M (+80M)
J&J	Unk / 200M (+200M)
CureVac	$2.7B / 225M
Total	$7.6B+ / 1.3B+

Other APAC

AstraZeneca	Unk / 100M (Indonesia)
	Unk / 26M (Thailand)
Pfizer BioNTech	Unk / 30M (Taiwan)
	Unk / 1.5M (New Zealand)
Sinovac	Unk / 40M (Indonesia)
Gamaleya Institute	Unk / 100M (India)
	Unk / 37M (+5M) (Kazak., Belarus, Uzbekistan)
Total	Unk / 335M

LatAm

AstraZeneca	Unk / 150M (+100M) (Argentina, Mexico)
Pfizer BioNTech	Unk / 10M (Chile)
Gamaleya Institute	Unk / 32M (Mexico)
COVAXX	Ecuador, Peru sharing $2.8B/140M with Brazil[3]
Total	Unk / 192M+

Middle East

Pfizer BioNTech	Unk / 8M (Israel)
Gamaleya Institute	Unk / 25M (Egypt)
Moderna	$73M / 6M (Israel)
Total	$73M/ 39M

China

AstraZeneca	Unk / 300M
Pfizer BioNTech	Unk / 10M (via Fosun)
Total	Unk / 310M

Japan

AstraZeneca	Unk / 120M
Novavax	Unk / 250M (via Takeda)
Pfizer BioNTech	Unk / 120M
Moderna	Unk / 50M (via Takeda)
Total	Unk / 540M

Brazil

Sinovac	Unk / 46M
Gamaleya Institute	Unk / 50M
AstraZeneca	$356M / 100M
COVAXX	$2.8B / 140M[3]
Total	$3.2B / 336M

Other Europe

Sinovac	Unk / 20M (Turkey)
Moderna	Unk / 4.5M (Switzerland)
Total	Unk / 24.5M

Australia

AstraZeneca	Unk / 34M
Novavax	Unk / 40M
Pfizer BioNTech	Unk / 10M
Total	Unk / 84M

LMIC countries/COVAX AMC

COVAX (LMIC)

AstraZeneca	$750M / 300M
Sanofi GSK	Unk / 200M
Total	$750M / 500M

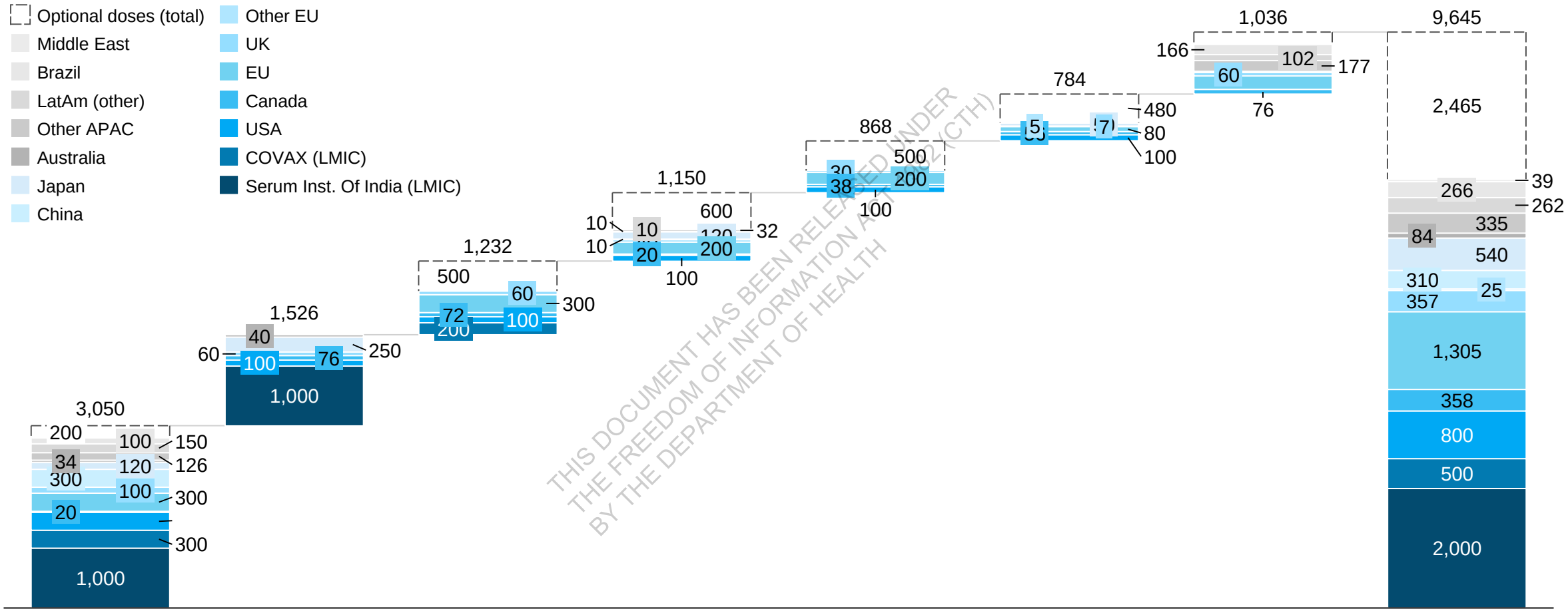
Serum Inst. of India (LMIC)

AstraZeneca	Unk / 1B
Novavax	Unk / 1B
Total	Unk / 2B

1. Sanofi press release – "over half of $2.1B for dev., other for doses"
2. Calculation assumes 1 course equals 2 doses; optional doses not included in calculation. COVAX and SII doses averaged over population of associated LMIC
3. $2.8B, 140M doses total supply to Brazil, Ecuador, Peru

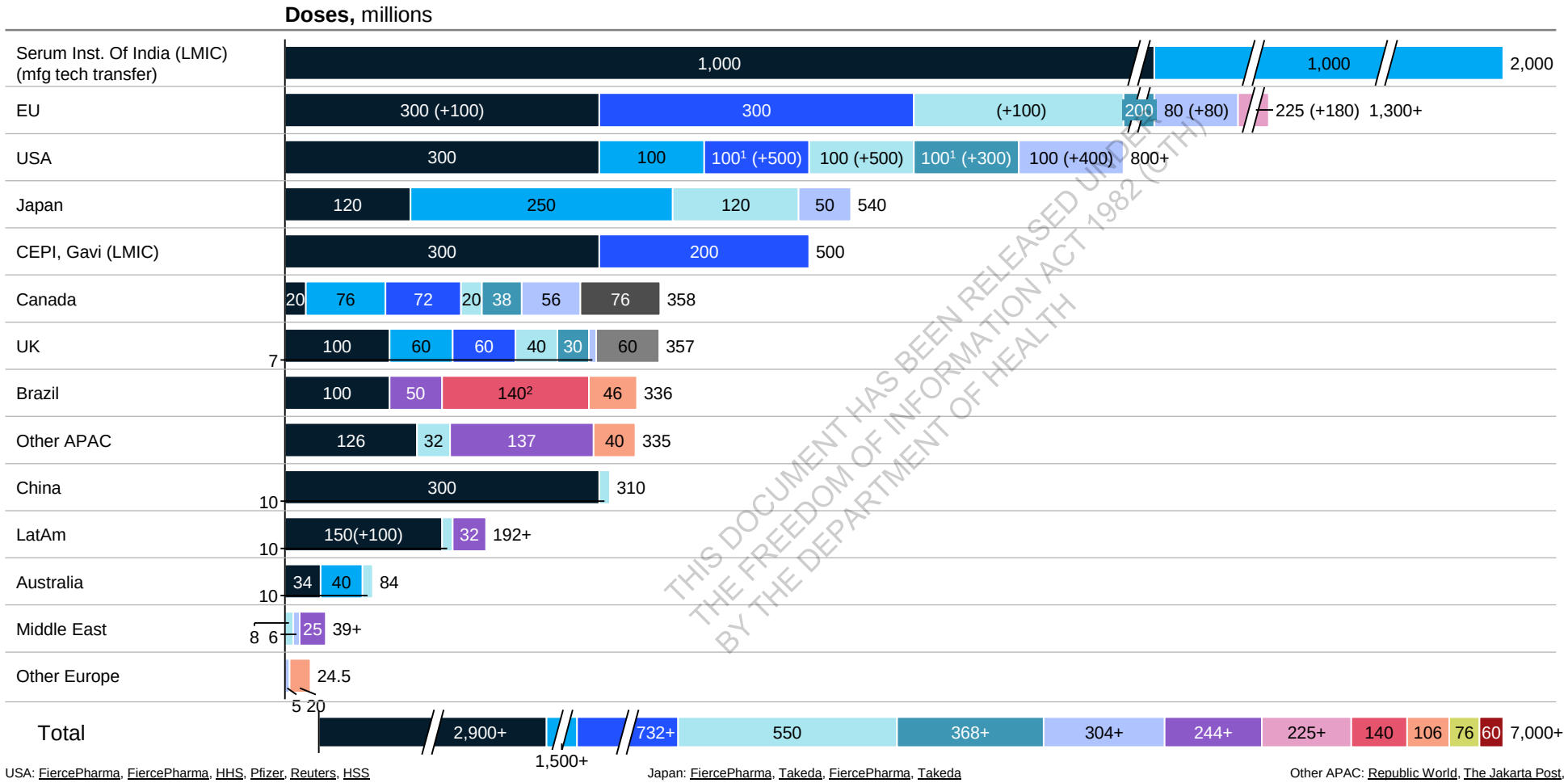
Source: Economist, Reuters, FiercePharma, BBC, The Marker, Pharmaceutical Technology, GlobalNews, Bloomberg, FOPH Switzerland, UPI, Company press releases

Overview of publicly announced purchase commitments by manufacturer (non-exhaustive, millions of doses)



Source: Economist, Reuters, FiercePharma, BBC, The Marker, Pharmaceutical Technology, GlobalNews, Bloomberg, FOPH Switzerland, UPI, Company press releases

Overview of publicly announced purchase commitments by geography (non-exhaustive, millions of doses)



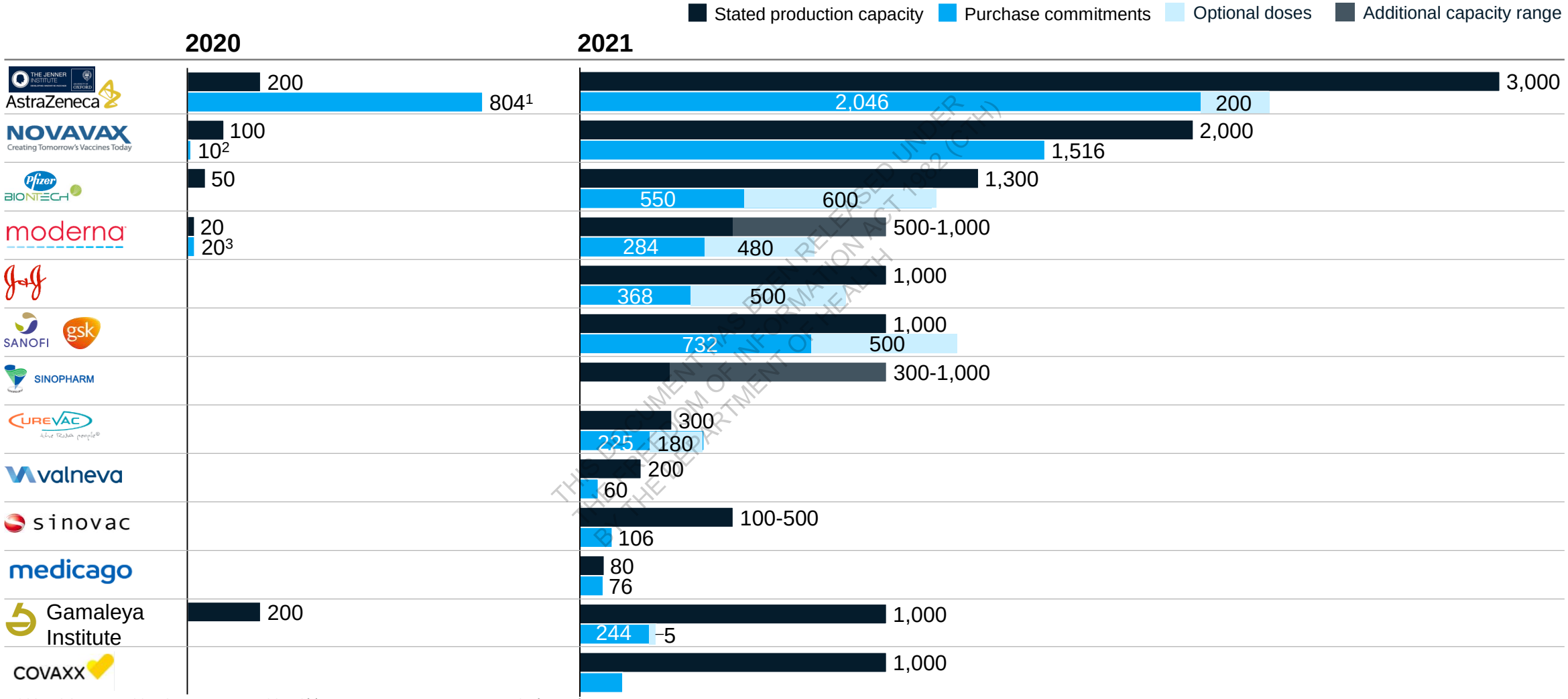
USA: FiercePharma, FiercePharma, HHS, Pfizer, Reuters, HSS
UK: FiercePharma, AP News, GSK, Gov UK, J&J, Moderna, Valneva
EU: FiercePharma, Sanofi, EC, J&J, Moderna, CureVac
Brazil: FiercePharma, Precision Vaccinations, FiercePharma, Reuters
Middle East: Times of Israel, Jerusalem Post, Reuters

Japan: FiercePharma, Takeda, FiercePharma, Takeda
Canada: Medical Xpress, CNBC, GSK, Freight Waves, J&J, CNBC, Medicago
China: BioSpace, BioNTech
LatAm: FiercePharma, Reuters, Reuters
Other Europe: CNBC, Reuters

Other APAC: Republic World, The Jakarta Post, BioSpectrum Asia, Reuters, Reuters, Reuters, Business Wire
Australia: ABC, Novavax, Gov AU
COVAX: FircePharma, Sanofi
Serum Inst. Of India: Novavax, Economic Times

1. Sanofi press release – "over half of $2.1B for dev., other for doses"
2. 140M doses total supply to Brazil, Ecuador, Peru

Comparison of stated COVID-19 vaccine production capacity and purchase commitments (non-exhaustive, millions of doses)



1.300M COVAX + 400M SII + 4M UK + 100M China
AZ press release, FiercePharma, FiercePharma

2.FiercePharma

3.CNBC

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Only a few select assets are in late stage development or have successfully gained approval for use (non-exhaustive)

Not comprehensive

	Company	Asset	Origin	Trial status	Approval status	COVID-19 indication
Virus-directed small molecule	GILEAD	Veklury *(remdesivir)*	Repurposed	Completed Phase III	Approved in US; provisional approval in EU, Japan, UK & others; excl. from WHO list[1]	Severe disease; hospitalized adult and pediatric patients ≥12 yrs
	FUJIFILM	Avigan *(Favipiravir)*	Repurposed	Completed Phase III	Provisional approval in China, Japan, Russia, India[2]	Mild-to-moderate disease
Virus-neutralizing monoclonal antibodies (mAbs)	VIR gsk	VIR-7831/2	Novel	Ongoing Phase II/III	n/a	n/a
	REGENERON	Casirivimab+imdevimab *(REGEN-COV2)*	Novel	Ongoing Phase II/III	EUA in US; emergency approval in Canada [3]	Mild-to-moderate disease Adult and pediatric patients ≥12 yrs
	Lilly	Bamlanivimab *(LY-CoV555)*	Novel	Ongoing Phase II	EUA in US[4]	Mild-to-moderate disease Adult and pediatric patients ≥12 yrs
Polyclonal antibodies	N/A	Convalescent plasma	Repurposed	Ongoing Phase II/III	EUA in US[5]	Hospitalized patients
Immune modulators	Biocon	ALZUMAb *(Itolizumab)*	Repurposed	Phase III plans withdrawn[6]	Emergency approval in India[7]	CRS[8]
	Roche	Actemra *(Tocilizumab)*	Repurposed	Ongoing Phase III	Pre-COVID approval for CRS[8] Emergency approval in UK[9]	Severe disease; ICU patients requiring respiratory support[9]
	Lilly	Olumiant *(Baricitinib)*	Repurposed	Ongoing Phase III	n/a	n/a
Cell, gene and RNA therapies	*No assets in late stage clinical development/ trials*					
Other	Generic	Dexamethasone	Repurposed	Completed Phase III	Approved in UK & Japan[10]	Pts requiring ventilation or oxygen
Combination therapy	GILEAD + Lilly	Veklury + Olumiant *(remdesivir + baricitinib)*	Repurposed	Completed Phase III	EUA in US[11]	Hospitalized adults and pediatric patients ≥2 yrs requiring suppl. oxygen, IMV, or ECMO[12]

1. US, Japan, Taiwan, India, UAE, Singapore, Australia , Canada, UK, EU, FiercePharma
2. RDIF, HospiMedica, Pmlive, Fujifilm
3. US: FDA; Canada: HRES
4. FDA
5. FDA, STATNews
6. Equillium
7. Biocon
8. Cytokine Release Syndrome, Oncologist
9. MHRA
10. Fiercepharma; Reuters
11. FDA
12. IMV: Invasive Mechanical Ventilation; ECMO: extracorporeal membrane oxygenation

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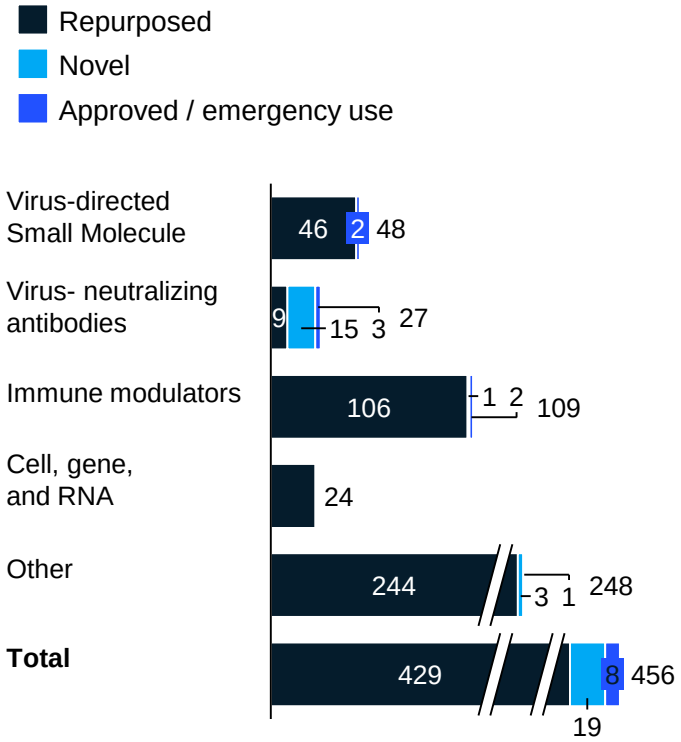
COVID-19 Therapeutics landscape update (1/2)

Pipeline snapshot

Number of candidates under active investigation, Phase 2 onwards[1]



Recent developments – Nov 25 – Dec 09, 2020

Virus-directed small molecule

Following WHO's recent recommendation on Veklury (remdesivir), the **FDA has issued a response claiming that results** from the SOLIDARITY trial **do not refute the clinical benefits of the drug**, and that its approval for treatment of patients hospitalized with COVID-19 met both legal and scientific standards. [1]

NIAID has started another iteration of its **COVID-19 trial investigating leading treatments for moderate-to-severe symptoms**. Patients in one arm of the study will receive a **combo of dexamethasone and Veklury (remdesivir)**, while the second arm will receive **Veklury (remdesivir) and Olumiant (baricitinib)**. [2]

Appili Therapeutics launched a Phase III trial evaluating the efficacy of Fujifilm's flu medication Avigan (favipiravir) in patients with mild to moderate COVID-19. Preliminary results are expected in the first half of 2021. [3]

Virus- neutralizing antibodies

A trial of hospitalized patients with severe pneumonia showed no clinical benefit nor improved mortality for treatment with convalescent plasma.[4]

SAB Biotherapeutics received $57.5 million from BARDA **to help manufacture its experimental polyclonal antibody, SAB-185 for treatment of COVID-19**. Currently, the antibody has two ongoing phase I trials. [5]

The UK has established a **conditional agreement with AstraZeneca to buy 1 million doses** of its cocktail treatment, AZD7442, **if it succeeds in Phase III trials**. [6]

The US purchased 650 thousand additional doses of Eli Lilly's monoclonal antibody treatment **Bamlanivimab** (LY-CoV555), totaling its purchase at 950 thousand doses. The doses included in the **$812.5 million deal will be delivered through January 31, 2021**, with at least 350 thousand additional doses delivered in December 2020. At the same time, CVS announced it has signed an agreement to pilot administration of the drug to severely at-risk patients in longt-term care facilities or at home. [7]

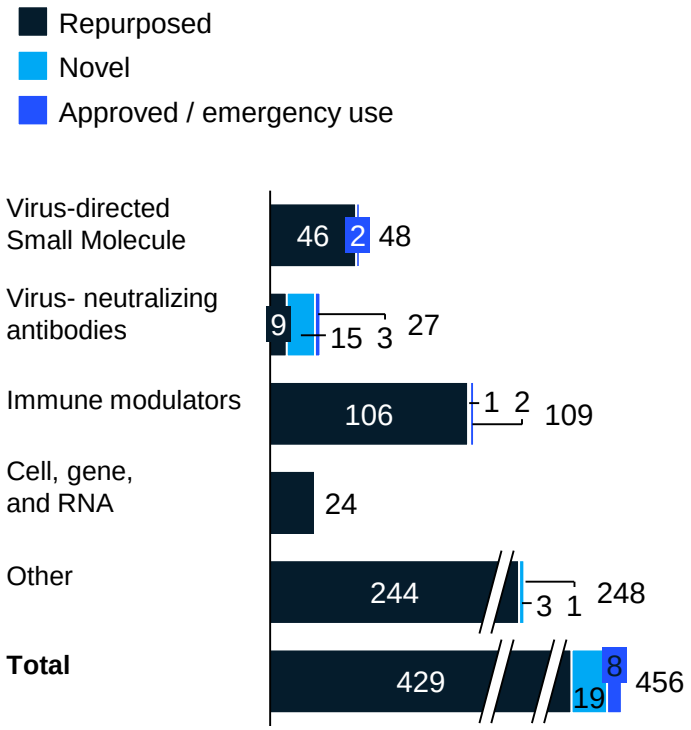
Regeneron entered a collaboration agreement with Penn Medicine to explore delivery of its **REGN-COV2** antibody cocktail (casirivimab and imdevimab) **via intranasal spray.** A go, no-go decision is expected in January. [8]

1.FDA, MPR
2.NIH
3.Appili Therapeutics
4.CT.gov, NEJM
5.Business Wire, CT.gov, CT.gov
6.Bloomberg
7.PRN, CVS
8.Penn Medicine

COVID-19 Therapeutics landscape update (2/2)

Pipeline snapshot

Number of candidates under active investigation, Phase 2 onwards[1]



Recent developments – Nov 25 – Dec 09, 2020 (continued)

Immune modulators

The UK has issued guidance on off-label prescription of Actemra (tocilizumab) for COVID-19. Patients in intensive care with severe pneumonia requiring respiratory support would be eligible under this guidance. [1]

Equillium, Biocon's partner in the **development and commercialization of ALZUMAb (itolizumab), has withdrawn plans for its phase III trials**. The company will instead prioritize development of the asset for acute graft-versus-host disease, one of its original indications. [2]

Amgen, Takeda, and UCB announced the **kick-off of their joint COMMUNITY trial** this week, which aims **to study an array of therapeutic candidates in hospitalized COVID-19 patients**. The first round of assets are immunomodulators, and include Amgen's psoriasis and psoriatic arthritis drug Otezla (apremilast), Takeda'sIV formula of its hereditary angioedema therapy Takhzyro (lanadelumab), and UCB's experimental autoimmune drug zilucoplan. [3]

Cell, gene, RNA and other therapeutics

Canada has signed a $32.5 million agreement with Eli Lilly for the supply of 26 thousand doses of baricitinib, to be supplied **between December 2020 and February 2021**. [6]

Mesoblast's mesenchymal stem cell therapy, **Ryoncil (remestemcel-L), was granted fast track designation by the FDA** in order to expedite its development **for treatment of ARDS due to COVID-19**. [5]

Colchicine, an anti-inflammatory drug typically used to treat gout and Behçet's disease, **was added to the UK's RECOVERY trial**. At least 2,500 patients are expected to be enrolled into the colchicine arm to evaluate its ability to reduce dangerous immune overreactions in hospitalized patients, and the effect on mortality, length of hospitalization and need for ventilator support.[4]

AB Science secured an $18 million loan from the European Investment Bank to begin evaluating masitinib, its tyrosine kinase inhibitor developed as treatment for cancer and amyotrophic lateral sclerosis, as a Covid-19 therapeutic. [7]

1.MHRA
2.Equillium
3.Takeda
4.Canada
5.Acute respiratory distress syndrome, MarketScreener
6.Recovery Trial
7.AB Science

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CURRENT AS OF DECEMBER 9, 2020
NONEXHAUSTIVE - EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

There are over 450 candidates in the pipeline for COVID-19 therapeutics

F | Not covered in this document

		Description	Assets profiled	Example candidates/companies
A | **Virus-directed small molecule**		**Largely repurposed** compounds, including **antivirals** (HIV, Influenza), **antimalarials**, **antiprotozoals**, and more	**48**	Remdesivir Kaletra Chloroquine
B | **Virus-neutralizing antibodies**	**Monoclonal antibodies** (mAbs)	**New development** using **survivor samples**, **genetically engineered** mice and **synthetic routes**; often a cocktail	**27**	
	Polyclonal antibodies (incl. plasma)	**New development** using **survivor plasma** (convalescent plasma) or **genetically engineered** cows for hyper-immunized globulin. Also called plasma-derived therapy or IVIG		
C | **Immune modulators**		**IL inhibitors**, alpha or beta-**interferon** and other therapies often **repurposed**. Targets host immune response with severe and critical disease (e.g. cytokine release syndrome)	**109**	Actemra Kevzara
D | **Cell, gene and RNA therapies**		**Stem cells**, **T-cells**, cord blood cells and **RNA-based** therapies	**24**	remestemcel-L siRNA
E | **Other**		**Steroids, surfactants**, **oxygen carriers, immunotherapies,** and other modalities not included in the above	**248**	Losartan Methylprednisolone Bevacizumab
F | **Traditional Chinese Medicine**		Traditional **herbal formulas and medicines**	**n/a**	maxingshigan-yinqiaosan

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (1/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Remdesivir *Veklury* (Repurposed) GILEAD	Antiviral agent that impedes replication of viral genetic material. Previously trialled in MERS, Ebola and RSV.	Treatment, predominantly of hospitalized patients	Approved for COVID-19 in US [2] Provisional approval in EU, Japan, UK, Taiwan, India, Singapore, Australia and UAE.[2] Excluded from WHO's COVID-19 drug list, pending further evidence [2]	30	Full results of recent NAID-funded ACTT-1 trial of 1026 patients indicated that a 10-day course of remdesivir in hospitalized patients led to modest but significant clinical improvement and reduced mortality (11.4% in remdesivir, 15.2% in placebo at day 29)[3] Interim results from the WHO SOLIDARITY trial suggested minimal benefit in hospitalized patients, in terms of mortality, initiation of ventilation and duration of hospitalization[4] Improvement in compassionate use cases in US and other countries[5] Trial for paediatric use and inhalant version pending[6]
Hydroxy-chloroquine (Repurposed)	Established antimalarial, also used in autoimmune conditions including SLE. Mechanism in COVID-19 unclear, hypothesised to impede viral replication.	Prophylaxis, treatment	Used off-label for COVID-19. EUA revoked (US)[7]	202	In-vitro data promising, however in-vivo trials have not found significant consistent benefit in treating hospitalized or non-hospitalized patients; no evidence of prophylactic benefit[8] Some improvement demonstrated in small studies[9] Authorization revoked in France,[10] use outside of clinical trials banned in Italy and the UK has put limits on the use[11] WHO, NIH and others have halted HCQ trials[12]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov) 2. Gilead, Reuters, Reuters, Reuters, Press , FDA, EMA, health.gov.au, Reuters; 3. NEJM; 4. medRxiv; 5. CDC. Gilead; 6. Endpoint News; 7. FDA; 8. NEJM; 9. Pharma Japan, The Scientist; 10. France24; 11. Pharmafile; 12. STAT, Fierce Pharma

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (2/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Chloroquine (Repurposed)	As per hydroxy-chloroquine (analogue).	Prophylaxis, treatment	Phase III ongoing	**26**	In-vitro data promising, however in-vivo trials have not found significant consistent benefit. One study showed increased mortality and cardiac arrhythmias, with or without macrolide, but was subsequently retracted[2]
Azithromycin (Repurposed)	Antibiotic, widely used for bacterial respiratory infections. Mechanism in COVID-19 unclear, may have antiviral, immuno-modulatory effects.	Treatment	Phase III ongoing	**73**	In-vitro data promising, however Brazilian COALITION II RCT found no benefit in clinical condition at day 15 in patients receiving azithromycin (in addition to standard of care, including hydroxychloroquine)[3] Some benefit demonstrated in retrospective French study of azithromycin-hydroxychloroquine combination therapy[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Lancet, FDA; 3. Lancet, NEJM; 4. NCBI

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (3/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Lopinavir, ritonavir *Kaletra* (Repurposed) abbvie	Antiretroviral agent used in treatment of HIV, impedes viral replication.	Treatment	Phase III ongoing	41	Two Chinese trials, the RECOVERY trial, and the WHO SOLIDARITY trial all failed to demonstrate efficacy; both the RECOVERY and SOLIDARITY trials dropped Kaletra arms after concluding no benefits to severe / hospitalized patients[2] Some improvement in patients in Australia and Thailand[3] Licensed for import by Israel Health Ministry
Favipiravir *Avigan* (Repurposed) FUJIFILM	Antiviral agent that impedes replication of viral genetic material. Developed for treatment of influenza	Treatment	Not commercially available in US Conditional approval in China, Japan, Russia, India [6,7,8,9] Phase III completed ex-US; Phase II ongoing in US	34	Phase III demonstrated faster time to viral clearance vs placebo (11.9d vs 14.7d, respectively) and modest but significant improvement in symptoms of patients with non-severe COVID-19 pneumonia, reducing time to symptom resolution by 2.8 days[4] Positive results on viral load and clinical recovery in Chinese, Russian, and the 'Dhaka Trial'; but mixed results in several Japanese trials Test dosages effective in mild and asymptomatic cases[5] Conditional approval for COVID-19 in China.[6] Russia temporarily approved favipiravir for hospitalized cases.[7] India approved for mild to moderate for restricted emergency use[8] General approval being sought in Japan and China[9]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Recovery trial press release, WHO, NEJM; 3. The Scientist; 4. Fujifilm; 5. GenEng News, MedRxiv 6. HospiMedica; 7. RDIF; 8. GlenmarkPharma; 9. Japan Times

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – Selected candidates deep dive (1/2)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Bamlanivimab (LY-CoV555), LY-CoV016 (Novel)	Neutralizing IgG1 mAb directed against complementary regions of the spike protein of SARS-CoV-2 designed to block viral attachment and entry into human cells	Prophylaxis, treatment of mild-mod COVID-19	Emergency use approval in US and Canada for LY-CoV555 monotherapy in mild-mod COVID-19 [2] Phase II trials ongoing	8	BLAZE-1 trial of LY-CoV555 demonstrated significant reduced the rate of hospitalization in patients with mild-moderate COVID-19 (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose[3] ACTIV-3 NIAID trial of bamlanivimab monotherapy in hospitalized (moderate-severe COVID-19) was discontinued after no significant benefit was demonstrated[4] For combination antibody arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[5]
REGN-COV-2 (Novel)	Cocktail of two different mAb from COVID-19 survivors and genetically engineered mice	Treatment	EUA granted in US Phase II/III trials ongoing	5	REGN-COV2 reduced viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. The antibody also reduced medical visits by 57% overall compared to placebo, with a 72% reduction reported in high risk populations[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. HRES; 3. Lilly; 4. Lilly; 5. Lilly; 6. Regeneron

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – Selected candidates deep dive (2/2)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
VIR-7831/2 (Novel)	Isolated mAb from SARS survivors, developed by coalition inc. GSK	Treatment	Phase II/III ongoing	**1**	Phase II/III trial for early treatment to prevent hospitalization (initiated Aug 2020), early results expected late 2020[2]
AZD7442 (Novel)	2 mAb cocktail, licensed from Vanderbilt. Working with BARDA and DARPA	Prophylaxis, treatment	Phases I (treatment) and III (prophylaxis) ongoing	**3**	Phase I trial launched in Aug 2020 with expected results by end of year[3]
CoVIg-19 (Novel)	Hyperimmune globulin (H-IG), developed by Plasma Alliance coalition inc. Takeda, CSL	Treatment	Phase III ongoing	**0**	Phase III trial of hospitalized patients (ITAC trial, NIH-sponsored) commenced in October 2020[4]
Convale-scent plasma (Repurposed)	Human plasma containing anti-SARS-CoV-2 antibodies	Treatment	EUA granted in US Phase II/III trials ongoing	**158**	Preliminary observational studies indicate that convalescent plasma may improve outcomes among severely ill and hospitalized patients with COVID-19 (e.g., reduced need for supplemental oxygen and mechanical ventilation, and reduced mortality)[5] A trial of hospitalized patients with severe pneumonia showed no clinical benefit nor improved mortality[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Pharmatimes; 3. Fiercebiotech; 4. CSL, Takeda; 5. NIH; 6. NEJM

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (1/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Tocilizumab *Actemra* (Repurposed) Roche	IL-6 inhibitor used in treatment of autoimmune conditions inc. RA	Treatment, esp. of cytokine release syndrome (CRS)	Approval for use in CRS[2] Emer-gency use in UK [3] Phase III ongoing	**46**	Reduced relative progression to mechanical ventilation by 44% through 28 days compared to placebo (12.2% vs. 19.3%, respectively) in one RCT. However, several secondary endpoints were not met (including time to hospital discharge and mortality)[4] The EU has struck a deal to secure supply for its member countries[5]
Sarilumab *Kevzara* (Repurposed) REGENERON SANOFI	IL-6 inhibitor used in treatment of autoimmune conditions inc. RA	Treatment, esp. of cytokine release syndrome (CRS)	Phase III complete	**17**	Sanofi, Regeneron shut down trial after failed Phase III study[6]
Rebif (Repurposed) MERCK	Interferon beta-1a used in treatment of multiple sclerosis	Treatment	Phase III ongoing	**13**	Currently being tested in combination with remdesivir as part of NIH's ACTT 3 trial[7] The EU has struck a deal to secure supply for its member countries[5]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Cytokine Release Syndrome;
3. For eligible COVID positive patients in the intensive care setting; MHRA; Pharmaceutical Journal; 4. Roche; 5. Reuters; 6. Sanofi; 7. NIAID

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (2/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Lenzilumab (Novel) Humanigen	Anti-GM-CSF IgG1 mAb	Treatment	Phase III ongoing	**3**	Promising results in a trial of 12 patients with severe COVID-19, however trial was small and observational only.[2] Selected for the NIH's ACTIV-5 Big Effect trial. Early results expected in Q4 2020[3] Humanigen has partnered with Lonza, Thermo Fisher, and Catalent to manufacture drug[4]
Baricitinib *Olumiant* (Repurposed) Lilly	JAK inhibitor, used in treatment of autoimmune conditions inc. RA	Treatment	US EUA for combi-nation treatment with Veklury (rem-desivir) Mono-therapy: Phase III ongoing	**15**	Lilly study of baricitinib + remdesivir vs. remdesivir alone met primary endpoint yielding ~1 day reduction in median recovery time, also met a key secondary endpoint comparing patient outcomes at day 15 using an ordinal 8-point scale ranging from fully recovered to death[5] When treated with baricitinib, hospitalised COVID-19 patients showed improvement in cough, fever, and a reduction in inflammatory markers and SARS-CoV-2 viral load[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. NCBI; 3. Clinicaltrials.gov; 4. Reuters, Fiercepharma; 5. Lilly; 6. PharmaPhorum

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (3/3)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
ALZUMAb *Itolizumab* (Repurposed) Biocon	Humanized anti-CD6 monoclonal antibody, approved for treating chronic plaque psoriasis and only available in India	Treatment	Emergency approval granted in India to treat CRS[2] Phase III plans withdrawn[3]	**2**	In a Phase II trial involving 30 hospitalized COVID-19 patients aged >18 years with moderate to severe ARDS, all patients receiving itolizumab recovered fully, whereas 30% of patients in the control arm died. The itolizumab arm also showed significant improvement in key lung function parameters without increasing oxygen flow, along with clinically significant suppression of clinical markers of inflammation[4] A separate single-arm, non-controlled trial of 80 COVID-19 patients treated with itolizumab appeared to have similar results, but detailed data on this study is still pending[4] Phase III trials are planned to start in Colombia by end of November 2020,with additional trials authorized for the USA, Mexico and Brazil[5]
Anakinra *Kineret* (Repurposed) sobi SWEDISH ORPHAN BIOVITRUM	IL-1R antagonist used in treatment of autoimmune conditions inc. RA, hypothesized to reduce inflammatory cascades in COVID-19	Treatment, especially of CRS and ARDS	Phase II/III ongoing	**27**	A cohort study of 96 patients indicated that anakinra was associated with a significant reduction in likelihood of progression to IMV, and mortality[6] A study of 120 patients with severe pneumonia and hyperinflammation showed that treatment with anakinra and methylprednisolone reduced mortality[7] Case reports have also been encouraging[8]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov) ; 2. Cytokine Release Syndrome; 3. Equillium; 4. NCBI, CB; 5. CT.gov , Biospace; 6. Lancet ID; 7. DocWire News; 8. IJID

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

D: COVID-19 Cell, Gene, RNA therapy – Selected candidates deep dive (1/2)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Non-stem cell therapy	**CYNK-001** (Repurposed) celularity sorrento THERAPEUTICS	Placenta-derived natural killer cell therapy, previously in development for treatment of hema-tological malignancies	Treatment	Phase I/II ongoing	**1**	Pre-clinical (in vitro and mouse model) studies demonstrated promising antiviral activity against cells infected with influenza[2] Estimated completion of 86 participant Phase I/II trial December 2020[3] Other NK cell based-therapies are also being investigated
	RAPA-501-ALLO (Novel) RAPA THERAPEUTICS	TREG cell therapy, also being trialled for haematological malignancies and ALS	Treatment	Phase I/II ongoing	**1**	Estimated completion of Phase I/II trial of 86 participants Q3 2021[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Blood; 3. Clinicaltrials.gov; 4. Clinicaltrials.gov; 5. PBR;
6. For treatment of acute respiratory distress syndrome (ARDS) due to COVID-19; MarketScreener; 7. Mesoblast

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

D: COVID-19 Cell, Gene, RNA therapy – Selected candidates deep dive (2/2)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
RNA therapy	**VIR-2703** (Novel) Alnylam VIR	Inhaled siRNA therapy, impedes replication of viral genetic material	Treatment	Preclinical development ongoing	**n/a**	Successfully inhibited viral production in mouse models[5]
Stem cell therapy	**Remestemcel-L** *Ryoncil* (Repurposed) mesoblast	Mesenchymal stem cell therapy developed for treatment of graft-vs-host disease	Treatment, especially of ARDS & cytokine release syndrome	Granted fast track designation by FDA[6] Phase III ongoing	**2**	Currently in Phase III trials; enrolment anticipated to be completed by the end of 2020 A recent readout indicated that there were early signs of positive developments in the trial[7]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Blood; 3. Clinicaltrials.gov; 4. Clinicaltrials.gov; 5. PBR;
6. For treatment of acute respiratory distress syndrome (ARDS) due to COVID-19; MarketScreener; 7. Mesoblast

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (1/4)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Anti-inflam-matories	**Dexamethas-one** (Repurposed)	Corticosteroid, reduces lung damage that occurs due to inflammatory processes in COVID-19	Treatment, especially of moderate and severe COVID-19	Approved in UK & Japan US Phase III ongoing	**18**	The RECOVERY trial demonstrated that dexamethasone reduced mortality in patients with COVID-19 requiring respiratory support by 35% in patients requiring MV and 20% in those requiring oxygen[2]
	Methyl-prednisone (Repurposed)	As per dexamethasone	Treatment, especially of moderate and severe COVID-19	Phase III ongoing	**20**	In an RCT of 400 patients in Brazil, there was a slight but not statistically significant reduction in mortality in older COVID-19 patients; no reduction of overall mortality[3] Associated with significant reduction of the mortality risk in patients with ARDS in a Chinese cohort study[4] Was inferior to dexamethasone in a meta-analysis by the WHO[5]
	Colchicine *Colcrys* (Repurposed) Takeda	Anti-mitotic drug widely used to treat gout. Downregulates multiple inflammatory pathways	Treatment	Phase II/III ongoing	**20**	Associated with clinical improvement in a small RCT[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. NEJM; 3. Clinical Infectious Diseases; 4. JAMA Internal Medicine; 5. JAMA; 6. MedRxiv

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (2/4)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
RAAS modulators	**Losartan** *Cozaar* (Repurposed) MERCK	Antihypertensive, blocks angiotensin receptors in the RAAS system, which hmay play a multifactorial role in COVID-19	Treatment	Phase II ongoing	**19**	The ACE-2 receptor was demonstrated to be a receptor for the SARS-CoV virus in 2005[2]
	Telmisartan (Repurposed)	As per losartan	Treatment	Phase II ongoing	**8**	The ACE-2 receptor was demonstrated to be a receptor for the SARS-CoV virus in 2005[2]
Anticoag-ulants and anti-platelets (1/2)	**Aspirin** (Repurposed)	Antiplatelet agent, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II/ Phase III ongoing	**16**	A retrospective cohort study of 412 patients (98 receiving aspirin) found that aspirin use was associated with a reduction in likelihood of mechanical ventilation and ICU admission, but not mortality[3]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Nature; 3. DocWire

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (3/4)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Anticoag-ulants and anti-platelets (2/2)	**Enoxaparin** (Repurposed)	Anticoagulant, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II ongoing	**24**	A study published by Thrombosis Research suggests enoxaparin improves gas exchange and decreases the need for mechanical ventilation in patients with severe COVID-19. No statistical differences were seen between groups in all-cause 28-day mortality rate, in-hospital mortality rate, and ICU-free days[2]
	Heparin (Repurposed)	Anticoagulant, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II/ Phase III ongoing	**70**	A large retrospective cohort showed lower mortality in COVID-19 patients treated with heparin, even after adjustment for age and gender and use of concomitant medication[3]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Clinical Infectious Diseases; 3. JAMA Internal Medicine

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (4/4)

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Vitamins, minerals and supplements	**Vitamin D** (Repurposed)	Vitamin, hypothesised to have some antiviral effect (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase III ongoing	**22**	An analysis of vitamin D levels among asymptomatic and critically ill COVID-19 patients indicates a significant correlation, translating into increased mortality in vitamin D deficient patients[2]
	Vitamin C (Repurposed)	Vitamin, hypothesised to have some anti-inflammatory effects (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase II ongoing	**42**	Research carried out before the pandemic found no significant evidence that giving high doses of vitamin C to patients suffering from respiratory failure and sepsis (conditions which can occur in severe Covid-19 cases) would reduce organ failure. Clinical trials in COVID-19 currently underway[3]
	Zinc (Repurposed)	Vitamin, hypothesised to have some antiviral effect (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase II ongoing	**19**	The US National Institute of Health warned against taking high doses of zinc to prevent Covid-19, pointing to lack of evidence and potential side effects, including irreversible neurological conditions from long-term use[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Nature; 3. JAMA, CT.gov; 4. NIH

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

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Public announcements indicate global manufacturing capacity of ~3.3M doses for approved therapeutics in 2020 (non-exhaustive)

Asset category	Asset	Company	Collaborators	YE 2020 ('000)	YE 2021 ('000)	In-source	Out-source	Manufacturing partnerships
Virus-directed small molecule	**Veklury** *(remdesivir)*	Gilead		2,000 [1]	TBC		✓	Cipla, Dr. Reddy's Laboratories, Eva Pharma, Ferozsons Laboratories, Flamma SpA, Hetero Labs, Jubilant Life Sciences, Mylan, Syngene (Biocon), Zydus Cadila Healthcare, Pfizer, Saptagir Laboratories (Saptagir Group), with Jubilant Life Sciences, Hikma, Uquifa Group [1]
Virus-neutralizing monoclonal antibodies (mAbs)	**Bamlanivimab** *(LY-CoV555)*	Eli Lilly	AbCellera	1,000 [2]	TBC	✓	✓	Samsung Biologics, Amgen, Fujifilm [3]
	Casirivimab + imdevimab *(REGEN-COV2)*	Regeneron	N/A	280 [4]	2,000 [5]	✓		Roche [6]
Total				**3,280**	**2,000**			

1. Gilead 2. Reuters 3. Amgen, Fujifilm 4. PMLive, 80k by end of Nov 2020 + 300k by end of Jan 2021 (incl. 200k by 1st week of Jan)
5. Bloomberg 6. FiercePharma

Source: Milken Institute, BioCentury, WHO, Nature, clinicaltrials.gov, press searches as noted above

CURRENT AS OF DECEMBER 9, 2020
NONEXHAUSTIVE - EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Overview of publicly announced supply contracts (non-exhaustive)

Value ($) / Doses (K='000)
Unk for unknown

USA

AstraZeneca

AZD7442	$486M / 100K in 2020 (+1M in 2021)[1]

REGENERON

Casirivimab + imdevimab *(REGEN-COV2)*	$450M 70K-300K doses for treatment OR 420K-1.3M doses for prevention[2]

Lilly

Bamlanivimab *(LY-CoV555)*	$1.2B / 950K (650K in 2020; 300K in 2021)[3]

GILEAD

Veklury *(Remdesivir)*	Unk[4] / 500K[5]

Total $2.1B+ / 1.6B-1.85B+

Canada

Lilly

Bamlanivimab *(LY-CoV555)*	$32.5M[6] / 26K[7]

UK

AstraZeneca

AZD7442	Unk / 1M[8]

EU

GILEAD

Veklury *(Remdesivir)*	Unk[4] / 500K[5]

1. Cision
2. Reuters
3. Lilly, PRN
4. FiercePharma, Gilead (US list price: $520 per vial, 5-day treatment using six vials, $3,120; Developed countries: $390 per vial, or $2,340 per course)
5. BMJ, Gilead
6. Reuters
7. Canada (over the three-month period between December 2020 and February 2021)
8. Bloomberg (if it succeeds in Phase III trials)

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Public resources for pipeline compounds and clinical trials

Live lists of vaccine and therapeutic candidates

BioCentury

Milken Institute

Linksbridge (vaccine only)

Biorender

Live clinical trial aggregators

ReDo Project

Anticovid by Inato

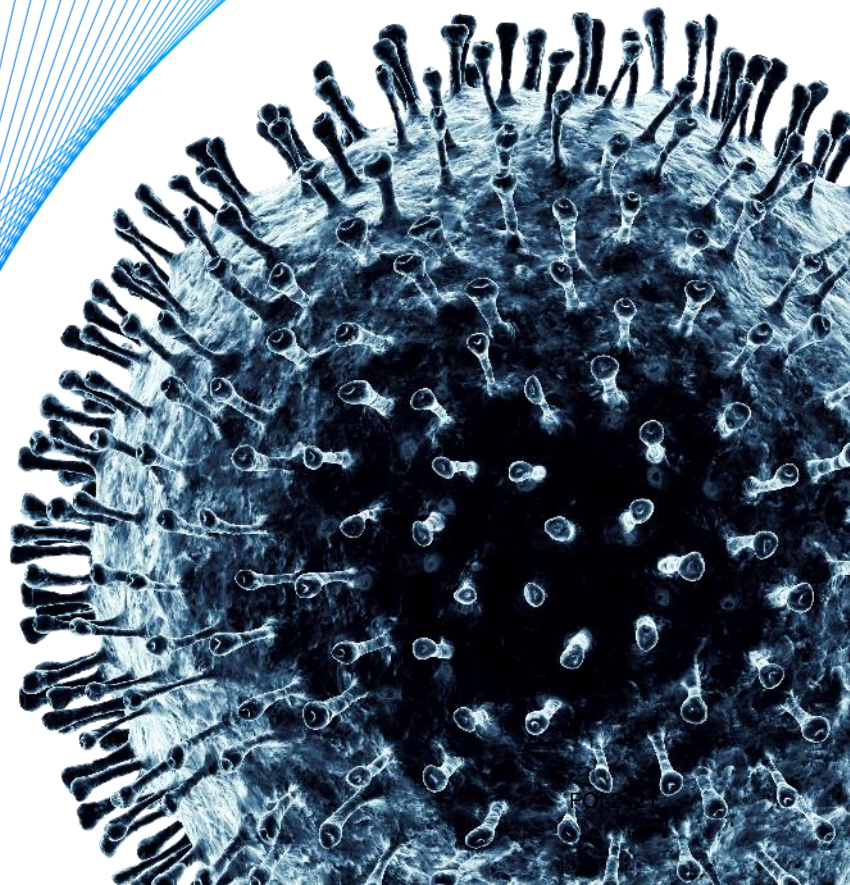
COVID-Trials.org

IDM visualization of trial dates

COVID-19 Therapeutics and Vaccines Landscape Overview

November 26, 2020

Document intended to provide insight based purely on current, publicly available information for consideration and not specific advice



Document overview

To date, there is no **globally approved COVID-19 vaccine or treatment** available.

There are **over 275 vaccine candidates** and **over 450 therapeutics candidates** in consideration.

This document and accompanying Excel trackers provide a **current snapshot of vaccine and therapeutic efforts for COVID-19.** They are based on **publicly available data** across candidate lists, clinical trial data and trial results.

Sources of insight:

- Multiple candidate lists (e.g. Milken Institute, BioCentury, WHO)
- Clinical trial registries (mainly CT.gov and ChiCTR)
- Press and literature searches

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5 Key points on the status of vaccines

1 Recent evidence on COVID-19 vaccines is encouraging[1]

- 8+ vaccine candidates in or through late-stage clinical trials; tracking towards <1 year overall development vs. fastest prior at 4.5 years[1a,b]
- Complete phase 3 results for Pfizer/BioNTech and and interim phase 3 results for Moderna's vaccine candidate showing ~95% efficacy[2,3] , Oxford/AstraZeneca's vaccine showing 62% - 90% efficacy depending on dosing regimen[12], and Russia's Sputnik V vaccine showing 91% efficacy[13], with data from J&J expected to follow[4]

2 US Emergency Use Authorization for Pfizer/BioNTech and Moderna's candidates likely in December, with full licensure in Mar / Apr[5]; unclear timing for Oxford/AstraZeneca given the different dosing regimens

- In US, EUA likely to focus on healthcare and frontline workers, patients with chronic conditions, elderly[6]
- Full roll-out to broader populations targeted for Q2 / Q3 2021

3 While early signals are promising, challenges need to be overcome

- Resolving clinical unknowns: full safety and efficacy data from Moderna, Oxford/AZ, and others, duration of vaccine protection, pediatric testing[1]
- Manufacturing capacity: multiple players need to be successful to meet global demand[7]
- Complex supply chain: cold chain requirements and two-dose regimen for several products[8]
- Consumer adoption: vaccine acceptance levels range from 40 to 60% of the population[9]

4 High income countries, highest probability of functional end to the pandemic in Q3 / Q4 2021, with gradual transition back to normal in Q2 2021 (including use of broader public health interventions)[10]

- Vaccines are only one tool – need to be complemented with improved testing, therapeutics, and public health measures
- COVID-19 unlikely to be fully eradicated - ongoing immunization and treatment of cases likely needed

5 Vaccine roll-out will vary by geography. While the WHO's COVAX program and others are focused on equitable access, capacity challenges mean the pandemic is likely to extend into 2022 in some parts of the world[11]

1. Nature a, Nature b
2. Pfizer, Pfizer
3. Moderna
4. WSJ
5. NYT, CNBC
6. CDC
7. Nature
8. Reuters
9. Gallup
10. Politico
11. COVAX
12. AstraZeneca
13. Gamaleya Center

COVID-19 vaccine update: Phase III trial analysis

Current as of November 26, 2020

Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only

Context

Pfizer/BioNTech, Moderna and Oxford University/ AstraZeneca's COVID-19 vaccine candidates are three of four candidates in the first wave of development, alongside Johnson & Johnson[1,2]

The announcements of results from the three companies come at about the expected time (late October / early November and by end of 2020)[3]

Positive news [3,4,8]

~95% vaccine efficacy for Pfizer/BioNTech and Moderna's mRNA candidates – higher than most projections

70% vaccine efficacy on average for Oxford University/AstraZeneca's viral vector candidate – 90% efficacy when given as a half dose, followed by a full dose min. 4 weeks later; 62% efficacy when given as two full doses min. 4 weeks apart

170 (Pfizer/BioNTech), 131 (Oxford/AZ) and 95 (Moderna) cases of COVID-19 – each represent more than the initial threshold for (interim) analysis, suggesting that the results are relatively robust

Efficacy in elderly population – Pfizer/BioNTech >94% efficacy in adults over age 65

Safety data – 2-month safety data from Pfizer/BioNTech appears positive; Moderna and Oxford/AZ no severe adverse events reported so far

Supply chain complexity – Pfizer/BioNTech vaccine two doses and ultra-cold chain (-70 degrees C); specially designed thermal shippers can be used for temporary storage for 15 days by refilling with dry ice, Moderna two doses at 2-8º C for 30 days and -20º C for 6 months; Oxford/AZ two doses at 2-8º C for 6 months

Big outstanding questions[1,5,6,7]

Optimal dosing regimen (Oxford/AZ) – pending full readout of all trial arms/dosing regimens and subgroup analyses

Duration of efficacy – pending longer-term data to assess duration of vaccine-mediated protection

Data for other demographics – pending efficacy data on pediatrics (<18 y/o), and subpopulations with comorbidities (e.g., HIV positive)

Vaccine hesitancy – public confidence in COVID-19 vaccines poses some challenge to adoption rates

Potential implications

Timeline for EUA submission and vaccine availability in line with expectations (by end of 2020)

Higher than expected efficacy could enable herd immunity with lower rates of coverage

Overall timeline to herd immunity may not be accelerated because manufacturing, supply chain, and rate of adoption likely to be rate limiting

High efficacy with lower dosing regimen (Oxford/AZ) could potentially allow for vaccination of a larger population with the current planned supply – to be further validated with additional data

Potential positive indication for mRNA and viral vector platforms - to be further validated with other candidates (respectively e.g., Curevac, J&J)

1.Nature 2. WSJ 3. Pfizer, Pfizer 4. Moderna 5. Reuters 6. Gallup 7. Moderna 8. AstraZeneca, Oxford University

COVID-19 vaccine update: summary of recent data

Overview of available data on Phase III trials of select COVID-19 vaccine candidates

	moderna	Pfizer BioNTech	AstraZeneca (The Jenner Institute, University of Oxford)
MoA	mRNA	mRNA	Viral vector
Dose schedule	2 doses, 4 weeks apart	2 doses, 3 weeks apart	1 or 2 doses of a half or full dose 4-12 weeks apart, depending on trial arm
Dose levels	1 dose level, 100 micrograms	1 dose level, 30 micrograms	COV002 trial (UK): one or two doses of a half or full dose COV003 trial (Brazil): one or two full doses
Efficacy target	60%	60%	50%
Efficacy in clinical trial	94.5%	95%	90% for half dose + full dose 62% for 2 full doses 70% across both dosing regimens
Thermostability	-20ºC shipped /stored for 6 months; 2-8ºC for 30 days	-70ºC shipped /stored for 6 months; 2-8ºC for 5 days	2-8ºC for 6 months
Announced manufacturing capacity	30m doses by year-end 2020 1b doses in 2021	50m doses by year-end 2020 1.3b doses in 2021	804m[1] doses by year-end 2020 3b doses in 2021

1. Based on production commitments

Source: ClinicalTrials.gov, Moderna press release, WBUR, Pfizer, Pfizer , The Guardian, AstraZeneca, Oxford University

COVID-19 vaccines development effort overview (1/2)

Recent developments – Nov 13 – 26, 2020

Pfizer/BioNTech's completed Phase III results demonstrate 95% efficacy for their BNT162b2 vaccine candidate[1]

- Observed efficacy in adults >65 years was >94%; safety data indicate that the vaccine was well tolerated, with no serious safety concerns observed
- Based on these results, the company submitted an EUA request to the US FDA on Friday, November 20th
- Additionally, Pfizer and BioNTech have reached an agreement to supply he EU with 200 million doses and an option to request additional 100 million doses, with deliveries anticipated to start by the end of 2020
- Pfizer says it is poised to start shipping doses within hours of an authorization. The company has designed special thermal shippers, that can serve as temporary storage for 15 days by replenishing with dry ice.

Interim analysis of Moderna's mRNA-1273 vaccine candate Phase III trial shows 94.5% efficacy[2]

- Ninety cases of COVID-19 occurred in the placebo arm, including all 11 observed severe cases, versus 5 in the vaccine arm
- The most common grade 3 event after the first dose was injection site pain (2.7%), while fatigue (9.7%), muscle pain (8.9%) and joint pain (5.2%) were the most common SAEs occurring after the second dose
- The company also issued a statement indicating its vaccine is stable at standard refrigeration temperatures for 30 days, compared to its earlier estimate of 7 days
- Moderna and the EU finalized a deal to supply 160 million doses of the vaccine. The EMA and Swiss drug regulator have begun rolling reviews of the candidate, and Moderna is expected to file for an EUA with the FDA by end of November, which could potentially review the data on December 17th.

AstraZeneca and Oxford University have released interim Phase III results for their vaccine candidate AZD1222[3]

- The results pool data from trials in the UK and Brazil
- Efficacy ranged between 62 and 90% depending on the dosing regimen, averaging at 70% across the two regimens analysed (n=11,636).
- The higher efficacy of 90% was reached in a subset of patients (n=2,741) who mistakenly received a half dose for their first shot, followed by a full dose at least 4 weeks later. If validated, this could potentially mean more people could be vaccinated with the planned vaccine supply.
- Additional data from Phase II clinical trials found that AZD1222 delivers similar immune responses in people aged over and under 70 years.
- AstraZeneca expects a 'relatively fast approval' in the EU thanks to an ongoing rolling review by the EMA, and is planning to seek an Emergency Use Listing (EUL) from the WHO.
- The company also announced that AZD1222 can be stored, transported and handled at standard refrigeration temperatures for at least 6 months.

1. Pfizer, Sky News, FiercePharma, Pfizer, Pfizer 2. Moderna, Moderna, EMA, ABC, Swissmedic 3. AstraZeneca, FiercePharma, FierceBiotech, Oxford University, EuroNews, Lancet

Sources for pipeline overview: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 20, 2020

COVID-19 vaccines development effort overview (2/2)

Recent developments – Nov 13 – 26, 2020 (continued)

Sinovac could potentially unveil interim Phase III data in early December

- The study passed the threshold of infections needed for interim analysis in its Brazil trial. Brazilian health officials expect a possible approval in December or January.
- The company also published Phase II/III data showing its vaccine sparked a swift immune response but with lower antibody levels compared to convalescent patients.1

Johnson & Johnson launched a Phase III trial to assess a two-dose regimen of its vaccine candidate

- The new study will run in parallel to its ongoing single-dose study.
- The company has also received an additional $454 million from BARDA and is partnering with UnitedHealth to accelerate participant enrolment. Low enrolment, partly due to a pause earlier this year to review a safety concern, is potentially pushing out the company's initial goal of having data this year. 2

Baharat Biotech initiated Phase III trials of its Covaxin vaccine candidate

- The trial will enrol 26,000 participants across India, and the company expects at least 60% efficacy, with plans to launch the shot in Q2 2021.3

Inovio is preparing to initiate the Phase II segment of its phase II/III clinical trial for its DNA vaccine candidate INO-4800

- The announcement follows FDA approval to proceed with the trial. The company is aiming to resolve remaining questions about the device that will be used to deliver its candidate directly into the skin.4

Russia's Gamaleya research center claims interim data from its vaccine's Phase III trials demonstrate >91% efficacy

- The analysis is based on 39 COVID-19 cases. There were no 'unexpected' side effects. The trial will continue for another 6 months, with the next analysis to be triggered when the study reaches 78 COVID-19 cases.
- Russia has expressed an interest in applying for an EUL from the WHO. 5

The US federal government aims to distribute 6.4 million vaccine doses within 24 hours of a candidate receiving emergency approval, with a goal to distribute 40 million doses by the end of the year. Sixty-four jurisdiction and 5 agencies received allocation numbers, based on the per capita population for residents 18 years and older. The CDC's ICAP will make recommendation on who should get the first doses, but ultimately the decision will be up to the governors. Groups currently considered include: healthcare workers, essential workers and people in high-risk health categories or 65 years and older. 6

The COVID Collaborative is partnering with the Ad Council to launch a $50 million vaccine education campaign, aimed at countering concerns and scepticism about coming vaccines. A recent survey by the Collaborative indicates that while a majority of Americans (86%) believe a vaccine will be effective in curbing the pandemic, only 34% say they will get vaccinated themselves. 6

1. FiercePharma, Lancet; 2. J&J, BMJ News, Bloomberg, Endpoints; 3. India Times, DNA India; 4. Inovio; 5. Gamaleya Center, Reuters; 6. FierceHealthcare
Sources for pipeline overview: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 20, 2020

There are 279 candidates in the pipeline for COVID-19 vaccines

Not covered in this document

	Description	Example companies / compounds	Number of candidates profiled[1]
RNA	**Nucleic acid RNA** packaged within a vector (e.g. lipid nanoparticles).	moderna, BIONTECH, Pfizer	29
DNA	**Plasmid containing the DNA sequence encoding the antigen(s)** against which an immune response is sought	inovio	20
Inactivated	Killed version of the virus that causes the disease, providing shorter-term protection and requiring boosts	sinovac, SINOPHARM	15
Viral vectors	**Chemically weakened** virus to transport pieces of the pathogen – typically genetic material coding for antigenic surface protein	CanSinoBIO, MERCK, Johnson & Johnson	51
Attenuated virus	**Weakened virus** to stimulate immune response	INDIAN IMMUNOLOGICALS LIMITED	10
VLPs	Virus-like-particles - **molecules that closely resemble viruses**, but are non-infectious because they contain no viral genetic material	medicago, vbi	17
Protein subunit	**Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response. Some assets employ a nanoparticle-delivery system for enhanced antigen presentation	NOVAVAX, SANOFI, gsk	100
Repurposed	Repurposed vaccines already on the market		6
Undisclosed[2]	Additional candidates with little public information	SaudiVax, HOTHTHERAPEUTICS	31

1. Compiled across multiple lists (Milken Institute, BioCentury, WHO, Nature) and supplemented with press
2. Not profiled moving forward. Vaccine type cannot be delineated due to lack of public information; typically in research setting or small biotech

Source: Milken Institute, BioCentury, WHO, Nature

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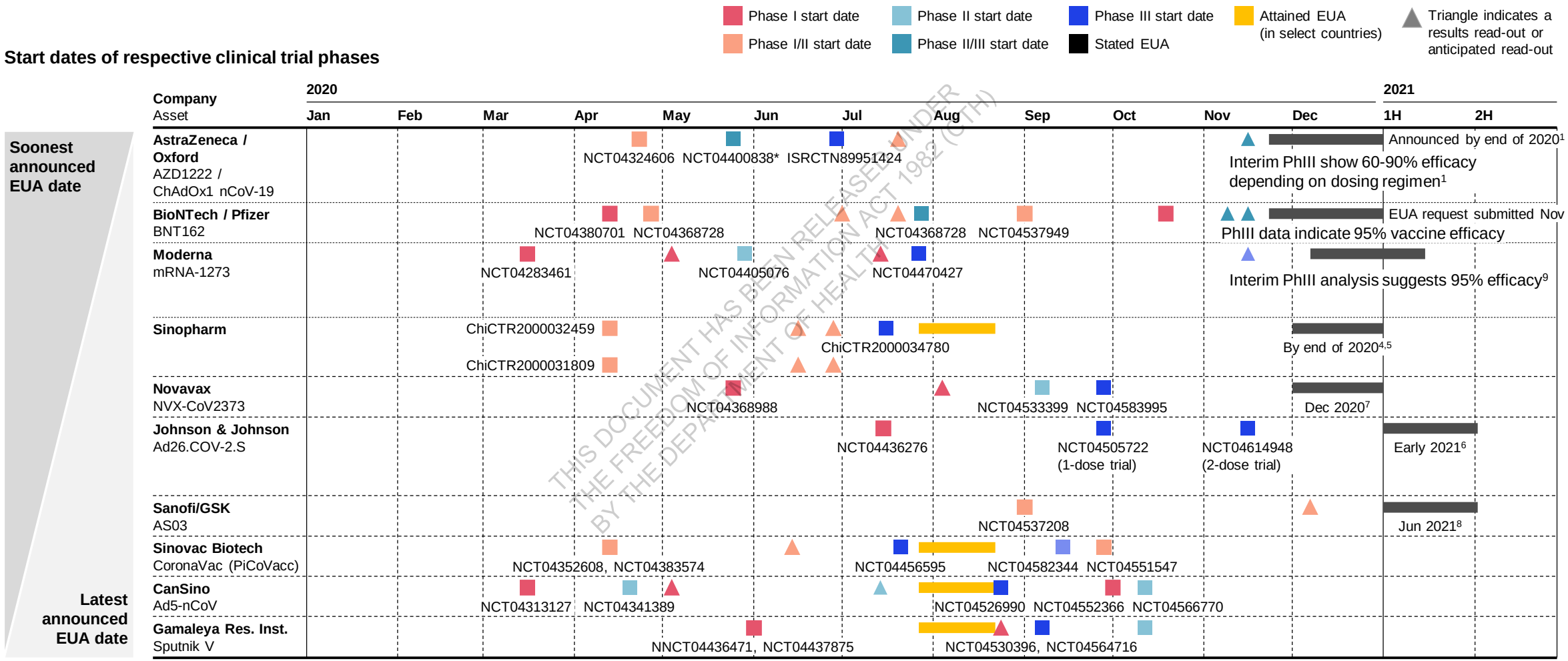
Select vaccine candidates currently in Phase III or Phase II/III or have announced potential EUA timelines



1. Reuters, AstraZeneca; 2. CIDRAP, Pfizer, Pfizer, Pfizer; 3. Moderna; 4. Reuters; 5. PBR; 6. FiercePharma, Johnson & Johnson; 7. Reuters; 8. SEC filing; 9. Moderna

Source: Milken Institute COVID-19 Tracker, clinicaltrials.gov, BioCentury, press search

Design elements for select vaccine candidates in late-stage efficacy trials (Non-exhaustive)

Outside-in view based on media coverage and published trial design if available; trials, timing, and EUA are estimates and subject to change

	moderna	Pfizer BioNTech	AstraZeneca	J&J	sinovac	SINOPHARM	NOVAVAX	CureVac
	Phase III	**Phase I/II/III**	**Phase II/III**	**Phase III**	**Phase III**	**Phase III**	**Phase III**	**Phase II/III**
Start	July, 2020	Completed	May/June 2020	Sept/Nov, 2020	July/Sept/Oct, 2020	July 16, 2020	Sep 28, 2020	Sept 29, 2020
MoA	mRNA	mRNA	Viral vector	Viral vector	Inactivated virus	Inactivated virus	Protein subunit	mRNA
Dose schedule	2 doses	2 doses	1 or 2 doses for adults, ped, elderly	1 dose or 2 doses	2 doses	2 doses	2 doses	2 doses
Dose levels	1 dose level, 100 micrograms	1 dose level, 30 micrograms	1 dose level for adults and ped., 2 for elderly	1 dose level (1x10^11 viral particles)	1 dose level	1 dose level	1 dose level	1 dose level, 12 micrograms
Efficacy target	60%	60%	50%	60%	Unknown	Unknown	Unknown	Unknown
Trial size	30,000	43,998	49,430	90,000	26,248	45,000	39,000	30,000
Site geography	USA	Germany, USA, S. Africa, Argentina, Brazil Turkey, China, Japan	UK, USA, Brazil, S. Africa, India	USA, Argentina, Brazil, Chile, Colombia, Mexico, Peru, Philippines, UK, S. Africa, Ukraine, Belgium, France, Germany, Spain	Brazil, Indonesia, Turkey, China	UAE, Bahrain	UK, US, Mexico	TBC
Temperature conditions	-20°C shipped / stored for 6 months; 2-8°C for 30 days; 12 hours at room temperature	-70°C shipped / stored for 6 months; 2-8°C for 5 days	2-8°C for 6 months	2-8°C for 3 months; 2 years at -20°C	Unknown	Unknown	Unknown	2-8°C for 3 months; room temperature for 24 hours
Special populations	None (adults 18+)	Ex-EU: 12yrs+, EU: 18yrs+, Phase 3 incl. HIV patients	Elderly, pediatric	Adults 18+; planned inclusion of pediatric population 12-18yrs	Adult, elderly & pediatric arms, healthcare workers	None (adults 18+)	None (adults 18+); seasonal flu vaccine	TBC

Source: clinicaltrials.gov, press search

Compilation of published or pre-released clinical trial results (1/5)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Sinovac CoronaVac (PiCoVacc) sinovac	Inactivated	Phase I/II	Double blind prospective RCT	Peer-reviewed Phase I/II results	Nov 17, 2020	• Phase I/II results indicated that a 2-dose regimen with 14 days between doses successfully induced an antibody production	NCT04383574
AstraZeneca/ Oxford AZD1222 AstraZeneca	Viral vector	Phase III	Single blind prospective RCT	Interim Phase I/II readout	July 20, 2020	• "Neutralizing antibodies were generated in over90% of participants across different assays. Responses were sustained up to 56 days." • "No serious adverse events occurred."	NCT04324606
				Peer-reviewed Phase II/III data	Nov 18, 2020	• Local and systemic reactions were similar in nature to those previously reported, but were less common in older adults (aged ≥56 years) than younger adults • Median anti-spike SARS-CoV-2 IgG responses 28 days after the boost dose were similar across the three age cohorts	NCT04400838
				Interim Phase III readout	Nov 23, 2020	• Interim analysis pooling data from COV002 (UK), COV003 (Brazil) • 90% efficacy when given as a half dose, followed by a full dose at least 4 weeks later (n=2,741); 62% efficacy when given as two full doses at least 4 weeks apart (n=8,895); 70% vaccine efficacy on average across both dosing regimens (n=11,636) • No hospitalized or severe cases in anyone who received the vaccine	NCT04324606
Gamaleya Research Institute	Viral vector	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 4, 2020	• All trial participants (76 adults) elicited an antibody response within 21 days and no serious adverse events after 42 days • The vaccine also produced a T-cell response within 28 days, a secondary outcome	NCT04436471, NCT04437875

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (2/5)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Gamaleya Research Institute (continued)	Viral vector	Phase I	Non-randomized, open label prospective trial	Interim Phase III readout	Nov 24, 2020	• Interim analysis triggered by reaching 39 cases • The vaccine shows 91.4% efficacy based on analysis of 18,794 participants at 7 days after the second dose (28 days after the first dose) • Preliminary data indicate an efficacy above 95% at 21 days after the second dose (42 days after the first) • "There were no unexpected adverse events"	NCT04436471, NCT04437875
Moderna – mRNA1273	RNA	Phase III	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 29, 2020	• By day 57, among the participants who received the low dose, the geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 and 1,128,391 among those who were 71+ years • Among the participants who received the high dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively • Binding- and neutralizing-antibody responses appeared to be similar to those among vaccine recipients between the ages of 18 and 55 • The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells	NCT04283461
				Interim Phase III read out	Nov 16, 2020	• 94.5% efficacy overall, with 95 cases of COVID-19 occurring in the study population: 90 in the placebo arm and 5 in the vaccine arm. • The most common grade 3 event after the first dose was injection site pain (2.7%), with smaller numbers of participants experiencing grade 3 headache, pain or redness at the injection site. • After the second dose, fatigue (9.7%), muscle pain (8.9%) and joint pain (5.2%) were the most common SAEs	NCT04283461

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (3/5)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Inovio INO-4800	DNA	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	Aug 10, 2020	• 100% of trial participants demonstrated overall immune responses • 95% had seroconverted by antibody response overall • Nearly 90% generated strong T cell responses, including CD8+ T cell responses	NCT04336410
CanSino Ad5-nCoV	Viral Vector	Phase II	Non-randomized, open label prospective trial	Interim Phase I readout	May 22, 2020	• Reported mean neutralizing titers of 34 in its high-dose group, below FDA recommendations of 160 • Single dose elicited a four-fold increase in binding antibodies to RBD in 94–100% of participants, and a four-fold increase to live virus in 50–75% of participants	NCT04313127
			Randomized, observer-blinded prospective trial	Interim Phase II readout	July 20, 2020	• One injection of non-replicating adenovirus-vectored COVID-19 vaccine with two concentrations • "Seroconversion occurred in more than 96% of participants, and neutralizing antibodies were generated in about 85%. More than 90% had T-cell responses."	NCT04398147
Novavax NVX-CoV2373	Protein subunit	Phase I/II	Randomized quadruple blind placebo controlled trial	Full Phase I readout	Sept 2, 2020	• 100% of participants developed wild-type virus neutralizing antibody responses after Dose 2 • Both 5 and 25mcg doses generated GMT greater than 300 • Anti-spike IgG & viral neutralization compared favorably to responses from patients with clinically significant COVID disease. Cellular immune responses were demonstrated in a subset of patients. No severe AEs reported	NCT04368988

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (4/5)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Pfizer / BioNTech BNT 162	RNA	Phase II/III	Randomized triple blind placebo controlled trial	Interim Germany Phase I/II readout	July 20, 2020	• BNT162b1 elicited strong CD4+ and CD8+ T cell responses against SARS-CoV-2-receptor binding domain (RBD) compared to baseline • The RBD-specific, interferon-γ+, IL-2+, CD8+ T cells elicited by BNT162b1 in immunized participants indicate a strong potential for cell mediated anti-viral activity • T cell cytokine profile shows vaccine elicited T cells exhibit a Th1 phenotype, which is associated with antiviral properties	NCT04368728
				Interim US Phase I/II readout	Aug 20, 2020	• BNT162b2 elicited SARS-CoV-2–neutralizing GMTs in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times • Well tolerated with mild to moderate fever in fewer than 20% of participants	NCT04368728
				Phase III readout	Nov 18, 2020	• BNT162b2 was 95% effective across >41,000 participants who received the two-dose vaccine regimen • 170 cases of COVID-19 occurred in trial participants, 162 in the placebo group and 8 in the vaccine group • Efficacy was consistent across demographics, including 94% efficacy in older adults (65+) • The vaccine was well tolerated; the most common Grade 3 adverse events were fatigue (3.8%) and headache (2.0%)	NCT04368728

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (5/5)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Sinopharm BBIBP-CorV	Inactivated	Phase I/II	Randomized double blind placebo controlled trial	Interim Phase I/II readout	Aug 14, 2020	• The trial linked the vaccine to increases in antibody titers. It is not clear whether the response is likely to confirm immunity as the study did not include a comparison arm featuring serum samples from patients previously infected with the coronavirus	ChiCTR-2000032459
J&J JNJ-78436735	Viral vector	Phase III	Randomized triple blind placebo controlled trial	Interim Phase I/II readout	Sept 28, 2020	• After a single dose, seroconversion rate at day 29 after immunization reached 92% with GMTs of 214 and 243 for the low and high dose levels, respectively	NCT04436276
CureVac CVnCoV	mRNA	Phase I	Randomized blinded placebo-controlled, dose-escalation trial	Interim Phase I readout	Nov 9, 2020	• Two doses of CVnCoV ranging from 2 µg to 12 µg per dose, administered 28 days apart were safe • Seroconversion (defined as a 4-fold increase over baseline titer) of virus neutralizing antibodies two weeks after the second vaccination occurred in all participants who received 12 µg doses • Preliminary results in the subset of subjects who were enrolled with known SARS-CoV-2 seropositivity at baseline show that CVnCoV is also safe and well tolerated in this population, and is able to boost the pre-existing immune response even at low dose levels • Based on these results, the 12 µg dose is selected for further clinical investigation	NCT04449276

Source: Company press releases & associated published literature

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Public announcements indicate global vaccine manufacturing capacity of ~12+ billion doses by end of 2021

Non-exhaustive

Asset category	Asset	Company	Collaborators	YE 2020 (M)	YE 2021 (M)	In-source	Out-source	Partnerships
RNA	mRNA-1273	Moderna	NIAID, Lonza	20[1]	500-1,000[1]	✓ 1	✓ 1	Lonza, Catalent, ROVI, Takeda, recipharm
	BNT162	BioNTech	Pfizer and Fosun Pharma	50[2]	1,300[2]	✓ 2 1	✓ 2 1	Pfizer, Rentschler[2] (for downstream purification), Polymun
	CVnCoV	CureVac	European Commission; BMGF		300[3]	✓ 1		Wacker, Tesla
Viral vectors	Ad26.COV-2.S	J&J	Beth Israel, HHS		1,000[4]	✓ 1	✓	Catalent, Emergent Biosolutions, Biological E, Aspen
	AZD1222 / ChAdOx1 nCoV-19	AstraZeneca	University of Oxford (Jenner Institute), Advent SRL, MilliporeSigma, Cobra Biologics	200[5]	3,000[6]		✓ 1	SII, Oxford Biomedica, Emergent Biosolutions, Catalent, Scotland Symbiosis, Wockhardt, BioKangtai
	Sputnik V	Gamaleya	N/A	200[7]	1,000[8]	✓		Binnopharm, RDIF, GL Rapha
VLP-based	CoVLP	Medicago	GSK, Laval Univ. Infectious Disease Research Centre		80[9]	✓		N/A
Protein-subunit	AS03	Sanofi Pasteur	GSK		1,000[10]	✓ 1		N/A
	NVX-CoV2373	Novavax	Emergent BioSolutions, Praha Vaccines, Serum Inst. of India	100[11]	2,000[12]	✓ 1		Praha Vaccines, Takeda, Fujifilm, SK Biosciences, Serum Institute of India
Inactivated	VLA2001	Valneva	Dynavax		200[13]	✓ 1		N/A
	PiCoVacc	Sinovac Biotech	Dynavax		100-500[14]			BioPharma
	[several]	Sinopharm	Wuhan Institute of Biological Products		300–1,000[15]	✓ 1		Beijing Institute of Biological Products
Total				**570**	**10,289-12,380**			

1. Moderna press release, WBUR, Moderna
2. Pfizer, Fierce Pharma
3. CureVac; Expected capacity in 2022: 600m
4. J&J press release, FiercePharma
5. Reuters
6. AZ press release, Reuters
7. MedicalExpress
8. Reuters, Sputnik
9. Standard
10. Sanofi
11. FiercePharma
12. FiercePharma, Novavax
13. Valneva
14. BusinessWire, EuroNews
15. Chinadaily.com.cn, Reuters

Source: Milken Institute, BioCentury, WHO, Nature, clinicaltrials.gov, press searches as noted above

Governments & organizations are creating supply contracts with rights to an allocation of doses

Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only

Non-exhaustive

	AstraZeneca	Novavax	Pfizer BioNTech	Valneva	Sanofi	GSK	Moderna	J&J	Sinovac	Gamaleya Institute	Medicago	CureVac	**Value** ($) / **Doses** Unk for unknown **Total**[3]
USA	$1.2B / 300M	$1.6B / 100M	$1.95B / 100M (+500M)		$2.1B / 100M[1] (+500M)		$1.525B / 100M (+$6.6B / 400M)	$1B+ / 100M (+300M)					$9.3B+ / 800M+
UK	Unk / 100M	Unk / 60M	Unk / 30M	$558M/ 60M	Unk / 60M		Unk / 5M	Unk / 30M					$558M+/345M
EU	$843M / 300M (+100M)		$3.7B / 200M (+100M)		$380M / 300M		Unk / 160M	Unk / 200M (+200M)				$2.7B / 225M (+180M)	$7.6B+ / 1.4B+
Brazil	$356M / 100M								Unk/46m	Unk / 50M			$356M / 196M
Middle East			Unk/8M Israel				$66M / Unk Israel & Qatar			Unk / 25M Egypt			$66M+ / 33M+
Japan	Unk / 120M	Unk / 250M via Takeda	Unk / 120M				Unk / 50M via Takeda						Unk / 540M
Canada	Unk/ 20M	Unk/ 76M	Unk / 20M (tbc)		Unk / 72M		Unk / 56M	Unk / 38M			$173M / 76M		$173M+/358M
China	Unk / 300M[2] via BioKangtai		Unk / 10M via Fosun, tbc										Unk / 310M
LatAm	Unk / 150M (+100M) Argentina, Mexico		Unk / 10M Chile							Unk / 32M Mexico			Unk / 192M+
Other Europe							Unk / 4.5M Switzerland		Unk/20m Turkey				Unk / 24.5M
Other APAC	Unk / 100M Indonesia		Unk / 30M Taiwan Unk / 1.5M New Zealand						Unk / 40M Indonesia	Unk / 100M India Unk / 37M (+5M) Kazakhstan, Belarus, Uzbekistan			Unk / 308.5M+
Australia	Unk / 34M	Unk / 40M	Unk / 10M										Unk / 84M
COVAX (LMIC)	$750M / 300M				Unk / 200M								$750M+ / 500M
Serum Inst. of India (LMIC)	Unk / 1B	Unk / 1B											Unk / 2B
Total[3]	$3.1B+ / 2.8B+	$1.6B+ / 1.5B+	$5.65B+ / 539.5M+	$558M / 60M	$2.4B+ / 732M+		$1.6B+ / 375.5M+	$1B+ / 368M+	Unk / 106M	Unk / 244M+	$173M / 76M	$2.7B / 225M+	**$19B+ / 7B+**

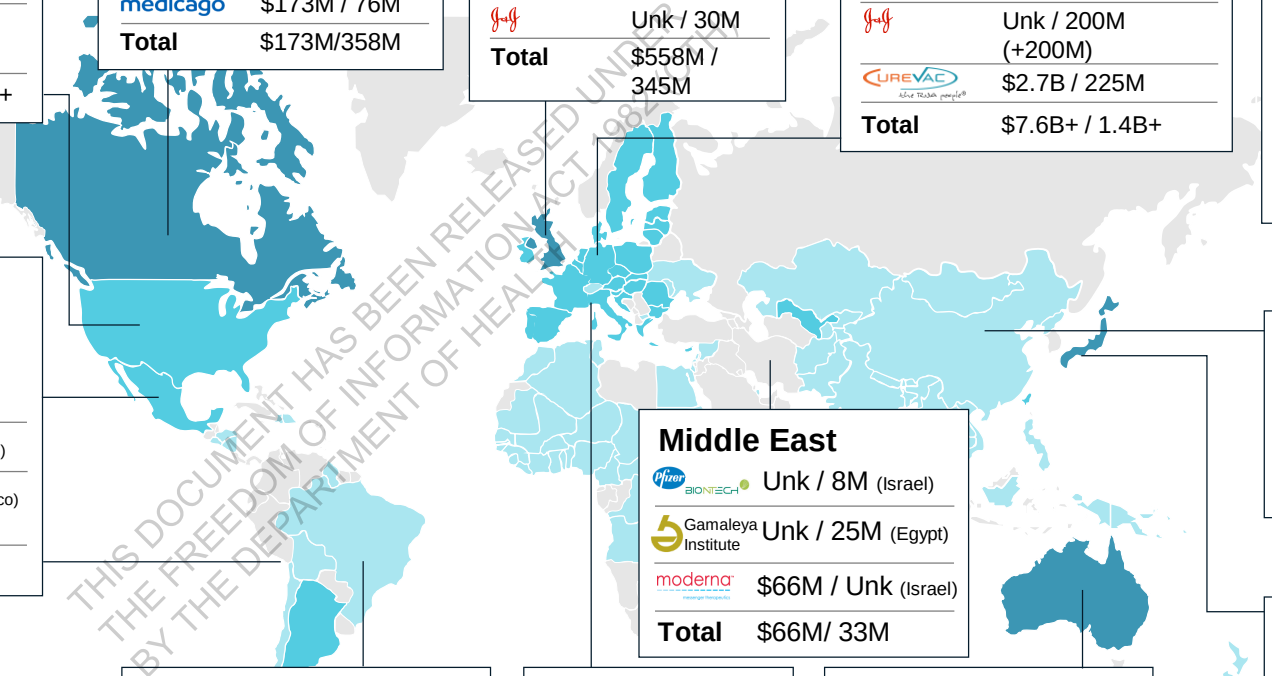
1. Sanofi press release – "over half of $2.1B for dev., other for doses"; 2. "(…) required to produce at least 100 million doses by the end of the year, and at least 200 million doses by the end of 2021"; 3. Excludes optional commitments
Source: Economist, Reuters, FiercePharma, BBC, The Marker, Pharmaceutical Technology, GlobalNews, Bloomberg, FOPH Switzerland, UPI, Company press releases

Overview of publicly announced supply contracts

Non-exhaustive

Course[2] / Population ratio:
- > 1.5
- 0.5 – 1.5
- <0.5
- Unknown

Value ($) / Doses
Unk for unknown



USA

AstraZeneca	$1.2B / 300M
Novavax	$1.6B / 100M
Pfizer BioNTech	$1.95B / 100M (+500M)
Sanofi GSK	~$2.1B / 100M[1] (+500M)
Moderna	$1.525B / 100M (+$6.6B / 400M)
J&J	$1B+ / 100M (+300M)
Total	$9.3B+ / 800M+

Canada

AstraZeneca	Unk / 20M
Novavax	Unk / 76M
Pfizer BioNTech	Unk / 20M (tbc)
Sanofi GSK	Unk / 72M
Moderna	Unk / 56M
J&J	Unk / 38M
Medicago	$173M / 76M
Total	$173M/358M

UK

AstraZeneca	Unk / 100M
Novavax	Unk / 60M
Pfizer BioNTech	Unk / 30M
Valneva	$558M / 60M
Sanofi GSK	Unk / 60M
Moderna	
J&J	Unk / 30M
Total	$558M / 345M

EU

AstraZeneca	$843M / 300M (+100M)
Pfizer BioNTech	$3.7B / 200M (+100M)
Sanofi GSK	$380M / 300M
Moderna	Unk / 160M
J&J	Unk / 200M (+200M)
CureVac	$2.7B / 225M
Total	$7.6B+ / 1.4B+

Other APAC

AstraZeneca	Unk / 100M (Indonesia)
Pfizer BioNTech	Unk / 30M (Taiwan) + Unk / 1.5M (New Zealand)
Sinovac	Unk / 40M (Indonesia)
Gamaleya Institute	Unk / 100M (India) Unk / 37M (+5M) (Kazak., Belarus, Uzbekistan)
Total	Unk / 40M

LatAm

AstraZeneca	Unk / 150M (+100M) (Argentina, Mexico)
Pfizer BioNTech	Unk / 10M (Chile)
Gamaleya Institute	Unk / 32M (Mexico)
Total	Unk / 192M+

Middle East

Pfizer BioNTech	Unk / 8M (Israel)
Gamaleya Institute	Unk / 25M (Egypt)
Moderna	$66M / Unk (Israel)
Total	$66M/ 33M

China

AstraZeneca	Unk/300M
Pfizer BioNTech	Unk / 10M (via Fosun)
Total	Unk / 310M

Japan

AstraZeneca	Unk / 120M
Novavax	Unk / 250M (via Takeda)
Pfizer BioNTech	Unk / 120M
Moderna	Unk / 50M (via Takeda)
Total	Unk / 540M

Brazil

Sinovac	Unk / 46M
Gamaleya Institute	Unk / 50M
AstraZeneca	$356M / 100M
Total	$356M / 196M

Other Europe

Sinovac	Unk / 20M (Turkey)
Moderna	Unk / 4.5M (Switzerland)
Total	Unk / 24.5M

Australia

AstraZeneca	Unk / 34M
Novavax	Unk / 40M
Pfizer BioNTech	Unk / 10M
Total	Unk / 84M

LMIC countries/COVAX AMC

COVAX (LMIC)

AstraZeneca	$750M / 300M
Sanofi GSK	Unk / 200M
Total	$750M / 500M

Serum Inst. of India (LMIC)

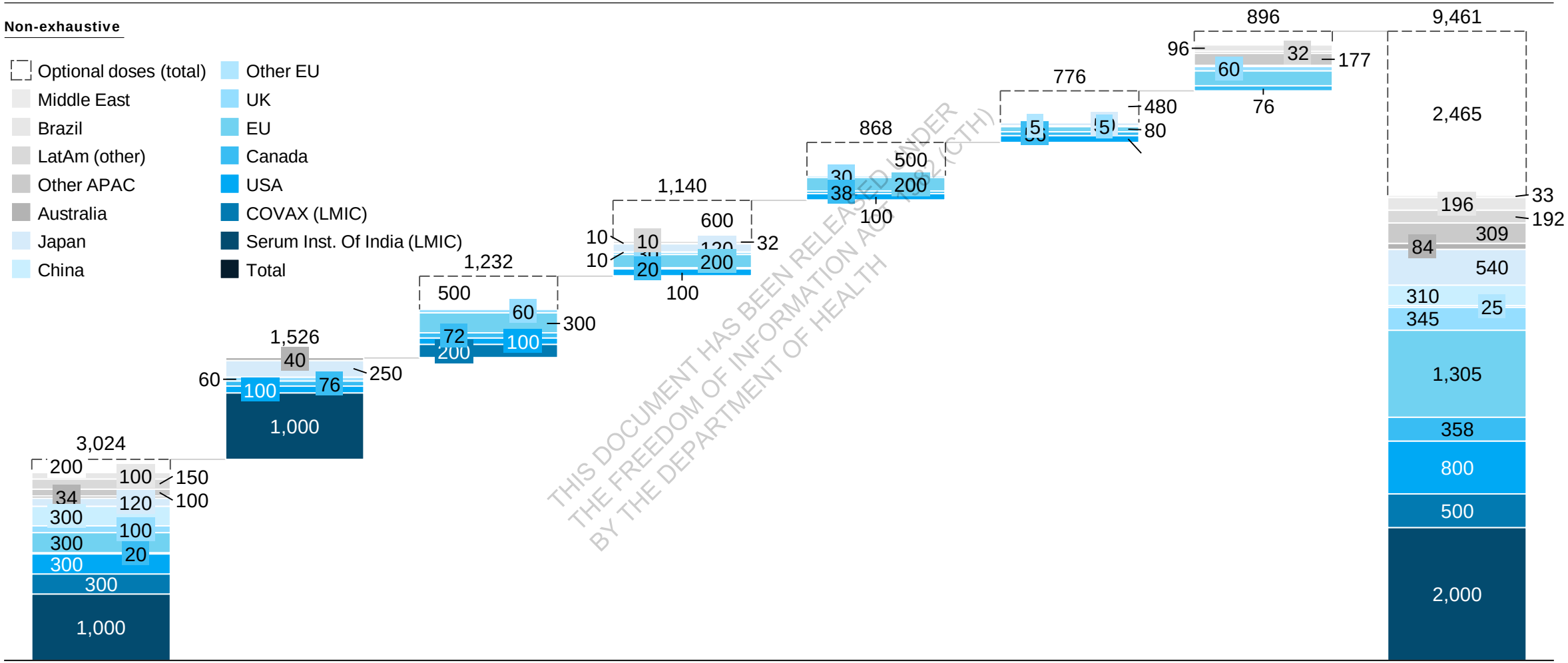
AstraZeneca	Unk / 1B
Novavax	Unk / 1B
Total	Unk / 2B

1. Sanofi press release – "over half of $2.1B for dev., other for doses"
2. Calculation assumes 1 course equals 2 doses; optional doses not included in calculation. COVAX and SII doses averaged over population of associated LMIC

Source: Economist, Reuters, FiercePharma, BBC, The Marker, Pharmaceutical Technology, GlobalNews, Bloomberg, FOPH Switzerland, UPI, Company press releases

Overview of publicly announced purchase commitments by manufacturer (Millions of doses)

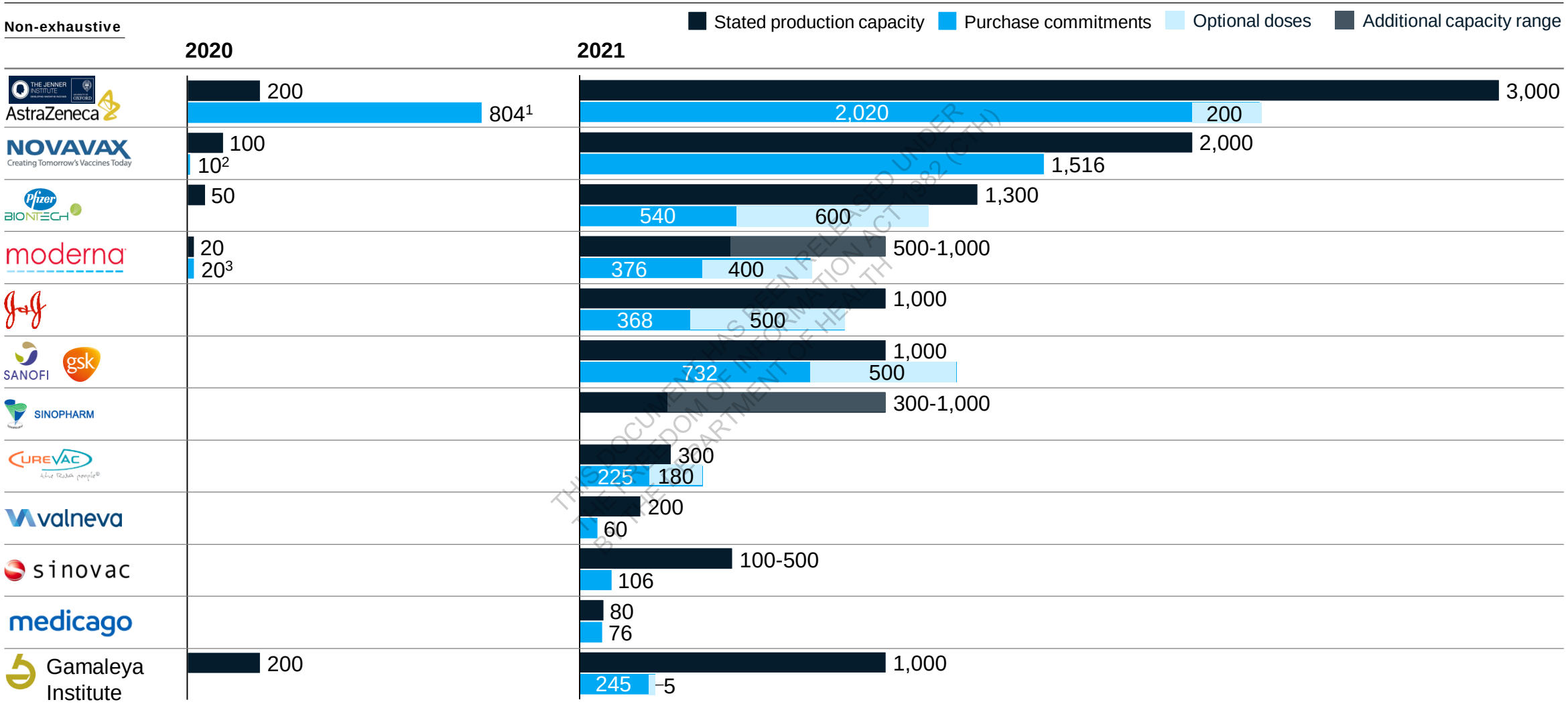
Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only



Source: Economist, Reuters, FiercePharma, BBC, The Marker, Pharmaceutical Technology, GlobalNews, Bloomberg, FOPH Switzerland, UPI, Company press releases

Comparison of stated COVID-19 vaccine production capacity and purchase commitments (Millions of doses)

Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only



1. 300M COVAX + 400M SII + 4M UK + 100M China AZ press release, FiercePharma, FiercePharma
2. FiercePharma
3. CNBC

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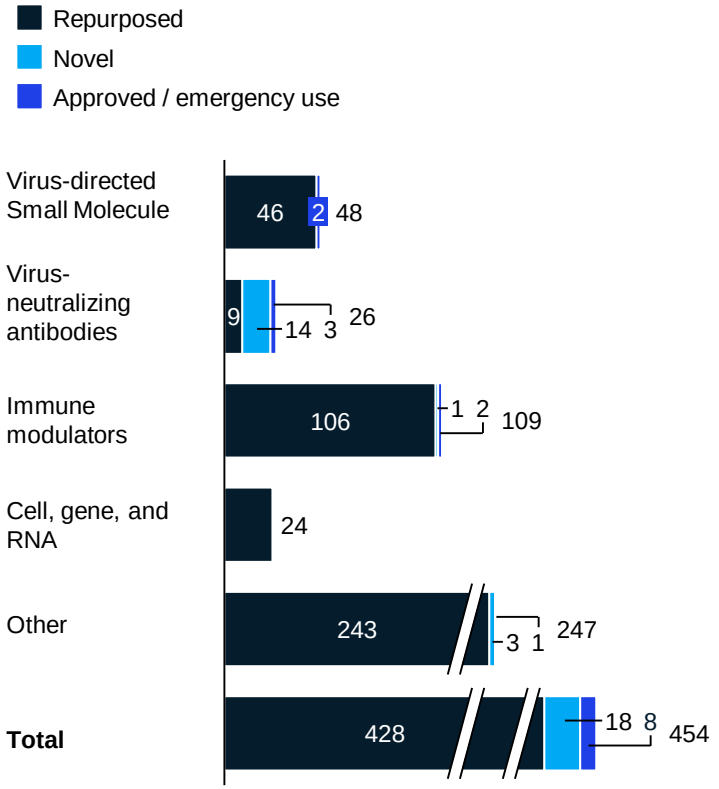
COVID-19 Therapeutics landscape update (1/2)

Pipeline and recent developments – Nov 13 – 26, 2020

Pipeline snapshot

Number of candidates under active investigation, Phase 2 onwards[1]



Recent developments – Nov 12 – 26, 2020

WHO's Guideline Development Group has advised against routine use of Veklury (remdesivir) for hospitalized COVID-19 patients, regardless of disease severity, based on a review of data from four international randomized trials involving over 7,000 patients hospitalized for COVID-19. The panel found no evidence of improved patient outcomes, and came to their recommendation based on the "remaining possibility of important harm, relatively high cost and resource implications". The Group did find that those with non-critical disease might benefit from remdesivir, in line with previous findings, but judged the credibility of the subgroup analysis insufficient to allow for recommendations. The Group supports further clinical studies with remdesivir and intends to update its 'living guideline' on COVID-19 as new evidence becomes available. [2]

A combination of Lilly's Olumiant (baricitinib) and Gilead's Veklury (remdesivir), received an FDA emergency use authorization (EUA) for hospitalized COVID-19 patients needing oxygen. The FDA's decision follows data from the NIAID's ACTT-2 trial, showing that the combined treatment reduced hospitalized patients' recovery time by 12.5% over Veklury alone. [3]

Following the FDA's EUA on November 9th, Lilly's bamlanivimab (LY-CoV555) has now also received interim authorization from Health Canada as a treatment for COVID-19. Meanwhile, US doctors, fearing shortages – at the current infection rate, the US supply of 300,000 doses is estimated to be correspond with a week's worth of new infections –, are calling for more conservative criteria on treatment eligibility. [3]

Regeneron's casirivimab and imdevimab antibody cocktail (REGN-COV-2) was granted an EUA for treatment of mild to moderate adults, and pediatric patients at high risk for progression to severe COVID-19 and/or hospitalization. Following the approval, the Department of HHS announced plans to distribute 30,000 doses immediately, with allocation based on case count and hospitalizations. Roche has successfully tested its ability to manufacture the antibody combo at scale and is expected to start production in Q1 2021, with 300,000 doses already committed to the US by January, and a total goal of 2M doses in 2021. Additionally, Regeneron is considering investigating lower doses to allow it to meet demand. [4]

Celltrion aims to pursue emergency approval for its monoclonal antibody,CT-P59, currently in Phase II trials, in South Korea in December. Earlier this year, the company announced that its antibody could shorten patients' recovery time with no reported side effects, and could potentially protect patients with mild symptoms from developing severe disease. [5]

Hummingbird Bioscience expects to roll out its experimental antibody, HMBD-115, in Singapore and other countries by early 2021. On October 27th, the company received authorization to initiate a Phase I/II clinical trial; Phase 3 studies are slated to start in December. [6]

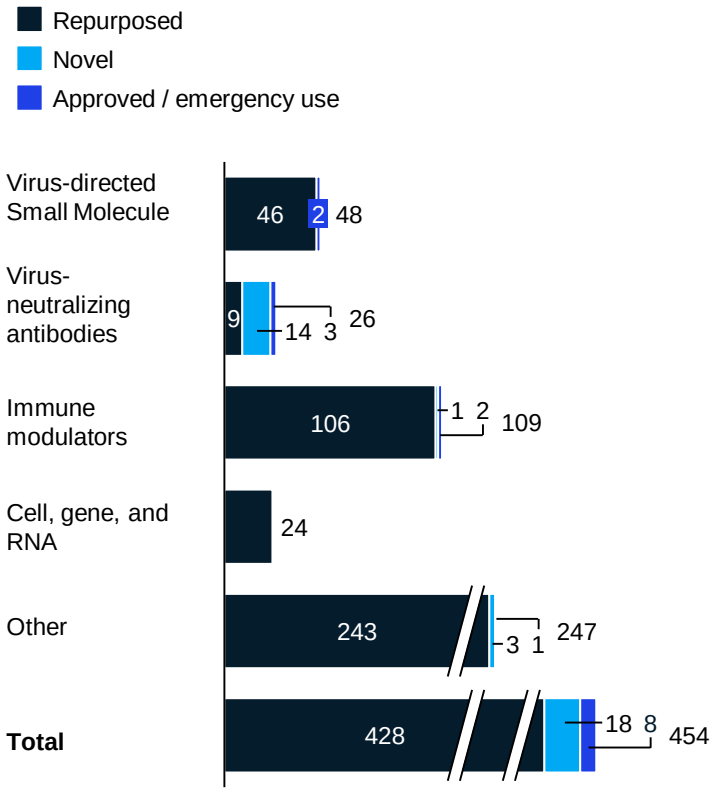
1. Based on publicly available data: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 20, 2020. Snapshot reflects assets in late-stage trials (Phase II+), excluding those suspended, terminated, withdrawn and unknown
2. FiercePharma, MedRxiv, BMJ
3. FiercePharma, Reuters, Lilly
4. Regeneron, Reuters, FierceHealthcare, FiercePharma
5. Yonhap News
6. CNBC, Hummingbird Bioscience

COVID-19 Therapeutics landscape update (2/2)

Pipeline and recent developments – Nov 13 – 26, 2020 (continued)

Pipeline snapshot

Number of candidates under active investigation, Phase 2 onwards[1]



Recent developments – Nov 12 – 26, 2020

Early data indicate that Roche's Actemra (tocilizumab) reached a "key efficacy endpoint" for severe COVID-19 patients in its REMAP-CAP trial. It is currently unclear whether Actemra kept people alive or shortened how long they needed ICU care, or both; those results are expected in the next few weeks. [2]

A pre-engineered version of Adagio's lead drug candidate, ADG20, protected against SARS-CoV-2 in mouse models. The drug also protected against other related coronaviruses, potentially indicating a broad-spectrum therapeutic range. [3]

Novartis secured a global license to Mesoblast's candidate cell therapy remestemcel-L. The treatment, which was recently rejected by the FDA for treatment of children with steroid-resistant graft-versus-host disease, is being repurposed for COVID-19 patients with acute respiratory distress syndrome (ARDS); phase III trials started in May following positive results in a 12-patient compassionate use program. [4]

Merck is acquiring OncoImmune and its COVID-19 treatment candidate CD24Fc, a fusion protein linked to improvements in clinical status in a Phase III trial of severe and critical patients requiring supplemental oxygen support, noninvasive ventilation, high flow oxygen devices, invasive ventilation or extracorporeal membrane oxygenation. Alongside CD24Fc, Merck has two vaccines and an antiviral drug in development against COVID-19. [5]

A study by the Washington University School of Medicine in St Louis suggests that fluvoxamine, a common SSRI antidepressant, potentially reduces the risk of respiratory deterioration in COVID-19, if taken within seven days of symptom onset (n=152). The COVID-19 Early Treatment Fund is sponsoring an 880-person trial to confirm the findings. [6]

Synairgen's inhaled **IFN-beta-1a therapy, SNG001**, reduced likelihood of progression to severe COVID-19 disease by 79% in a pilot study. The Phase II double-blinded RCT included 101 patients hospitalized with COVID-19 in the UK. [7]

Over 175 US patients with critical COVID-19 respiratory failure and a severe comorbidity have entered into an EAP with NeuroRx and Relief's aviptadil (RFL-100). A previous study indicated aviptadil might improve survival rates compared to standard of care. [8]

A group of 13 African countries are joining a clinical trial to test whether drugs for malaria, HIV, certain cancers and other diseases could prevent moderate COVID-19 cases from becoming more severe. The trial will be carried out by ANTICOV, a consortium of 26 African and European clinical institutions. The countries include the Democratic Republic of Congo, the Equatorial Guinea, Ethiopia, Ghana, Guinea, Kenya, Mali, Mozambique, Sudan and Uganda. [9]

1. Based on publicly available data: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 20, 2020. Snapshot reflects assets in late-stage trials (Phase II+), excluding those suspended, terminated, withdrawn and unknown
2. Reuters
3. bioRxiv
4. Novartis
5. Businesswire
6. JAMA
7. Lancet
8. PRN
9. NYT

Only a few assets are in late stage development or have successfully gained approval for use

Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only

Non-exhaustive

	Company	Asset	Origin	Trial status	Approval status	COVID-19 indication
Virus-directed small molecule	GILEAD	Veklury *(remdesivir)*	Repurposed	Completed Phase III	Approved in US; provisional approval in EU, Japan, UK & others; excl. from WHO list[1]	Severe disease; hospitalized adult and pediatric patients ≥12 yrs
	FUJIFILM	Avigan *(Favipiravir)*	Repurposed	Completed Phase III	Provisional approval in China, Japan, Russia, India[2]	Mild-to-moderate disease
Virus-neutralizing monoclonal antibodies (mAbs)	VIR gsk	VIR-7831/2	Novel	Ongoing Phase II/III	n/a	n/a
	REGENERON	Casirivimab+imdevimab *(REGEN-COV2)*	Novel	Ongoing Phase II/III	EUA in US[3]	Mild-to-moderate disease Adult and pediatric patients ≥12 yrs
	Lilly	Bamlanivimab *(LY-CoV555)*	Novel	Ongoing Phase II	EUA in US[4]	Mild-to-moderate disease Adult and pediatric patients ≥12 yrs
Polyclonal antibodies	N/A	Convalescent plasma	Repurposed	Ongoing Phase II/III	EUA in US[5]	Hospitalized patients
Immune modulators	Biocon	ALZUMAb *(Itolizumab)*	Repurposed	Phase III planned	Emergency approval in India[6]	CRS[7]
	Roche	Actemra *(Tocilizumab)*	Repurposed	Ongoing Phase III	Pre-COVID approval for CRS[7]	n/a
	Lilly	Olumiant *(Baricitinib)*	Repurposed	Ongoing Phase III	n/a	n/a
Cell, gene and RNA therapies	*No assets in late stage clinical development/ trials*					
Other	Generic	Dexamethasone	Repurposed	Completed Phase III	Approved in UK & Japan[8]	Pts requiring ventilation or oxygen
Combination therapy	GILEAD Lilly	Veklury + Olumiant *(remdesivir + baricitinib)*	Repurposed	Completed Phase III	EUA in US[9]	Hospitalized adults and pediatric patients ≥2 yrs requiring suppl. oxygen, IMV, or ECMO

1. US, Japan, Taiwan, India, UAE, Singapore, Australia , Canada, UK, EU, FiercePharma
2. RDIF, HospiMedica, Pmlive, Fujifilm
3. FDA
4. FDA
5. FDA, STATNews
6. Biocon
7. Cytokine Release Syndrome, Oncologist
8. Fiercepharma; Reuters
9. FDA
10. IMV: Invasive Mechanical Ventilation
ECMO: extracorporeal membrane oxygenation

Table of contents

There are over 390 candidates in the pipeline for COVID-19 therapeutics

Current as of November 26, 2020
Non-exhaustive
Examples for illustration purposes only

F| Not covered in this document

		Description	Assets profiled	Example candidates/companies
A| Virus-directed small molecule		**Largely repurposed** compounds, including **antivirals** (HIV, Influenza), **antimalarials**, **antiprotozoals**, and more	48	Remdesivir, Kaletra, Chloroquine
B| Virus-neutralizing antibodies	**Monoclonal antibodies** (mAbs)	**New development** using **survivor samples**, **genetically engineered** mice and **synthetic routes**; often a cocktail	26	
	Polyclonal antibodies (incl. plasma)	**New development** using **survivor plasma** (convalescent plasma) or **genetically engineered** cows for hyper-immunized globulin. Also called plasma-derived therapy or IVIG		
C| Immune modulators		**IL inhibitors**, alpha or beta-**interferon** and other therapies often **repurposed**. Targets host immune response with severe and critical disease (e.g. cytokine release syndrome)	109	Actemra, Kevzara
D| Cell, gene and RNA therapies		**Stem cells**, **T-cells**, cord blood cells and **RNA-based** therapies	24	remestemcel-L, siRNA
E| Other		**Steroids, surfactants**, **oxygen carriers, immunotherapies,** and other modalities not included in the above	247	Losartan, Methylprednisolone, Bevacizumab
F| Traditional Chinese Medicine		Traditional **herbal formulas and medicines**	n/a	maxingshigan-yinqiaosan

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (1/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Remdesivir *Veklury* (Repurposed) GILEAD	Antiviral agent that impedes replication of viral genetic material. Previously trialled in MERS, Ebola and RSV	Treatment, predominantly of hospitalized patients	Approved for COVID-19 in US [2] Provisional approval in EU, Japan, UK, Taiwan, India, Singapore, Australia and UAE.[2] Excluded from WHO's COVID-19 drug list, pending further evidence [2]	29	Full results of recent NAID-funded ACTT-1 trial of 1026 patients indicated that a 10-day course of remdesivir in hospitalized patients led to modest but significant clinical improvement and reduced mortality (11.4% in remdesivir, 15.2% in placebo at day 29)[3] Interim results from the WHO SOLIDARITY trial suggested minimal benefit in hospitalized patients, in terms of mortality, initiation of ventilation and duration of hospitalization[4] Improvement in compassionate use cases in US and other countries[5] Trial for pediatric use and inhalant version pending[6]
Hydroxy-chloroquine (Repurposed)	Established antimalarial, also used in autoimmune conditions including SLE. Mechanism in COVID-19 unclear; hypothesised to impede viral replication	Prophylaxis, treatment	Used off-label for COVID-19 EUA revoked (US)[7]	202	In-vitro data promising, however in-vivo trials have not found consistent significant benefit in treating hospitalized or non-hospitalized patients; no evidence of prophylactic benefit.[8] Some improvement demonstrated in small studies[9] Authorization revoked in US and France[7,10]; Use outside of clinical trials banned in Italy; the UK has limited its use[11] WHO, NIH and others have halted HCQ trials[12]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov) 2. Gilead, Reuters, Reuters, Reuters, Press , FDA, EMA, health.gov.au, Reuters, FiercePharma; 3. NEJM; 4. medRxiv; 5. CDC. Gilead; 6. Endpoint News; 7. FDA; 8. NEJM; 9. Pharma Japan, The Scientist; 10. France24; 11. Pharmafile; 12. STAT, Fierce Pharma

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (2/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Chloroquine (Repurposed)	As per hydroxy-chloroquine (analogue).	Prophylaxis, treatment	Phase III ongoing	26	In-vitro data promising, though benefit not consistently significant. One study showed increased mortality and cardiac arrhythmias, with or without macrolide, but was subsequently retracted[2]
Azithromycin (Repurposed)	Antibiotic, widely used for bacterial respiratory infections. Mechanism in COVID-19 unclear, may have antiviral, immuno-modulatory effects.	Treatment	Phase III ongoing	73	In-vitro data promising, however Brazilian COALITION II RCT found no benefit in clinical condition at day 15 in patients receiving azithromycin in addition to standard of care[3] Some benefit demonstrated in retrospective French study of azithromycin-hydroxychloroquine combination therapy[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Lancet, FDA; 3. Lancet, NEJM; 4. NCBI

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – Selected candidates deep dive (3/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Lopinavir, ritonavir *Kaletra* (Repurposed) abbvie	Antiretroviral agent used in treatment of HIV, impedes viral replication.	Treatment	Phase III ongoing	41	Two Chinese trials, the RECOVERY trial, and the WHO SOLIDARITY trial all failed to demonstrate efficacy. Both the RECOVERY and SOLIDARITY trials dropped Kaletra arms after concluding no benefits to severe / hospitalized patients[2] Some improvement in patients in Australia and Thailand[3] Licensed for import by Israel Health Ministry
Favipiravir *Avigan* (Repurposed) FUJIFILM	Antiviral agent that impedes replication of viral genetic material. Developed for treatment of influenza	Treatment	Not commercially available in US Conditional approval in China, Japan, Russia, India[6,7,8,9] Phase III completed ex-US; Phase II ongoing in US	34	Phase III demonstrated faster time to viral clearance vs placebo (11.9d vs 14.7d, respectively) and modest but significant improvement in symptoms of patients with non-severe COVID-19 pneumonia, reducing time to symptom resolution by 2.8 days.[4] Positive results on viral load and clinical recovery in Chinese, Russian, and the 'Dhaka Trial'; but mixed results in several Japanese trials. Test dosages effective in mild and asymptomatic cases[5] Conditional approval for COVID-19 in China.[6] Russia temporarily approved favipiravir for hospitalized cases.[7] India approved for mild to moderate for restricted emergency use[8] General approval being sought in Japan and China[9]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Recovery trial press release, WHO, NEJM; 3. The Scientist; 4. Fujifilm; 5. GenEng News, MedRxiv 6. HospiMedica; 7. RDIF; 8. GlenmarkPharma; 9. Japan Times

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – Selected candidates deep dive (1/2)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Bamlanivimab (LY-CoV555), LY-CoV016 (Novel)	Neutralizing IgG1 mAb directed against complementary regions of the spike protein of SARS-CoV-2 designed to block viral attachment and entry into human cells	Prophylaxis, treatment of mild-mod COVID-19	US EUA for LY-CoV555 monotherapy in mild-mod COVID-19 Phase II trials ongoing	8	BLAZE-1 trial of LY-CoV555 demonstrated significant reduced the rate of hospitalization in patients with mild-moderate COVID-19 (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose.[2] ACTIV-3 NIAID trial of bamlanivimab monotherapy in hospitalized (moderate-severe COVID-19) was discontinued after no significant benefit was demonstrated.[3] For combination antibody arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[4]
REGN-COV-2 (Novel)	Cocktail of two different mAb from COVID-19 survivors and genetically engineered mice	Treatment	EUA granted in US Phase II/III trials ongoing	5	REGN-COV2 reduced viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. The antibody also reduced medical visits by 57% overall compared to placebo, with a 72% reduction reported in high risk populations.[5]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Lilly; 3. Lilly; 4. Lilly; 5. Regeneron

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – Selected candidates deep dive (2/2)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
VIR-7831/2 (Novel)	Isolated mAb from SARS survivors, developed by coalition inc. GSK	Treatment	Phase II/III ongoing	1	Phase II/III trial for early treatment to prevent hospitalization initiated Aug 2020; interim results expected late 2020[2]
AZD7442 (Novel)	2 mAb cocktail, licensed from Vanderbilt. Working with BARDA and DARPA	Prophylaxis, treatment	Phase I ongoing	3	Phase I trial launched in Aug 2020 with results expected by end of year[3]
CoVIg-19 (Novel)	Hyperimmune globulin (H-IG), developed by Plasma Alliance coalition inc. Takeda, CSL	Treatment	Phase III ongoing	1	Phase III trial of hospitalized patients (ITAC trial, NIH-sponsored) commenced in October 2020[4]
Convale-scent plasma (Repurposed)	Human plasma containing anti-SARS-CoV-2 antibodies	Treatment	EUA granted in US Phase II/III trials ongoing	156	Preliminary observational studies indicate that convalescent plasma may improve outcomes among severely ill and hospitalized patients with COVID-19 (e.g., reduced need for supplemental oxygen and mechanical ventilation, and reduced mortality)[5]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Pharmatimes; 3. Fiercebiotech; 4. CSL, Takeda; 5. NIH

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (1/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Tocilizumab *Actemra* (Repurposed) Roche	IL-6 inhibitor used in treatment of autoimmune conditions inc. RA	Treatment, esp. of cytokine release syndrome (CRS)	Approval for use in CRS[2] Phase III ongoing	46	Reduced relative progression to mechanical ventilation by 44% through 28 days compared to placebo (12.2% vs. 19.3%, respectively) in one RCT. However, several secondary endpoints were not met (including time to hospital discharge and mortality)[3] The EU has struck a deal to secure supply for its member countries[4]
Sarilumab *Kevzara* (Repurposed) REGENERON SANOFI	IL-6 inhibitor used in treatment of autoimmune conditions inc. RA	Treatment, esp. of cytokine release syndrome (CRS)	Phase III completed	17	Sanofi, Regeneron shut down trial after failed Phase III study[5]
Rebif (Repurposed) MERCK	Interferon beta-1a used in treatment of multiple sclerosis	Treatment	Phase III ongoing	13	Currently being tested in combination with remdesivir as part of NIH's ACTT 3 trial[6] The EU has struck a deal to secure supply for its member countries[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Cytokine Release Syndrome; 3. Roche; 4. Reuters; 5. Sanofi; 6. NIAID

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (2/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Lenzilumab (Novel) Humanigen	Anti-GM-CSF IgG1 mAb	Treatment	Phase III ongoing	3	Promising results in an observational trial of 12 patients with severe COVID-19[2] Selected for the NIH's ACTIV-5 Big Effect trial. Early results expected in Q4 2020.[3] Humanigen has partnered with Lonza, Thermo Fisher, and Catalent to manufacture the drug.[4]
Baricitinib *Olumiant* (Repurposed) Lilly	JAK inhibitor, used in treatment of autoimmune conditions inc. RA	Treatment	US EUA for combination treatment with Veklury (remdesivir) Monotherapy: Phase III ongoing	14	Lilly study of baricitinib + remdesivir vs. remdesivir alone met primary endpoint yielding ~1 day reduction in median recovery time, and also met a key secondary endpoint comparing patient outcomes at day 15.[5] When treated with baricitinib, hospitalized COVID-19 patients showed improvement in cough, fever, and a reduction in inflammatory markers and SARS-CoV-2 viral load[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. NCBI; 3. Clinicaltrials.gov; 4. Reuters, Fiercepharma; 5. Lilly; 6. PharmaPhorum

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

C: COVID-19 immune modulators – Selected candidates deep dive (3/3)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
ALZUMAb *Itolizumab* (Repurposed) Biocon	Humanized anti-CD6 monoclonal antibody, approved for treating chronic plaque psoriasis and only available in India	Treatment	Emergency approval granted in India to treat CRS [2] Phase III planned [2]	2	In a Phase II trial involving 30 hospitalized COVID-19 patients aged >18 years with moderate to severe ARDS, all patients receiving itolizumab recovered fully, whereas 30% of patients in the control arm died. The itolizumab arm also showed significant improvement in key lung function parameters without increasing oxygen flow, along with clinically significant suppression of clinical markers of inflammation [3] A separate single-arm, non-controlled trial of 80 COVID-19 patients treated with itolizumab appeared to have similar results, but detailed data on this study is still pending.[3] Phase III trials are planned to start in Colombia by end of November 2020,with additional trials authorized for the USA, Mexico and Brazil [4]
Anakinra *Kineret* (Repurposed) sobi SWEDISH ORPHAN BIOVITRUM	IL-1R antagonist used in treatment of autoimmune conditions inc. RA, hypothesized to reduce inflammatory cascades in COVID-19	Treatment, especially of CRS and ARDS	Phase II/III ongoing	26	A French cohort study of 96 patients indicated that anakinra was associated with a significant reduction in likelihood of progression to IMV, and mortality.[5] Case reports have also been encouraging. [6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov) ; 2. Cytokine Release Syndrome; CT.gov 3. NCBI, CB; 4. CT.gov , Biospace; 5. Lancet ID; 6. IJID

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

D: COVID-19 Cell, Gene, RNA therapy – Selected candidates deep dive

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Non-stem cell therapy	**CYNK-001** (Repurposed) celularity sorrento THERAPEUTICS	Placenta-derived natural killer cell therapy, previously in development for treatment of hema-tological malignancies	Treatment	Phase I/II ongoing	1	Pre-clinical (in vitro and mouse model) studies demonstrated promising antiviral activity against cells infected with influenza[2] Estimated completion of 86 participant Phase I/II trial December 2020[3] Other NK cell based-therapies are also being investigated
	RAPA-501-ALLO (Novel) RAPA	TREG cell therapy, also being trialled for haematological malignancies and ALS	Treatment	Phase I/II ongoing	1	Estimated completion of Phase I/II trial of 86 participants Q3 2021[4]
RNA therapy	**VIR-2703** (Novel) Alnylam VIR	Inhaled siRNA therapy, impedes replication of viral genetic material.	Treatment	Preclinical development ongoing	n/a	Successfully inhibited viral production in mouse models[5]
Stem cell therapy	**Remestemcel-L** *Ryoncil* (Repurposed) mesoblast	Mesenchymal stem cell therapy developed for treatment of graft-vs-host disease	Treatment, especially of ARDS & cytokine release syndrome	Phase III ongoing	2	Currently in Phase III trials; enrolment anticipated to be completed by the end of 2020 A recent readout indicated that there were early signs of positive developments in the trial[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Blood; 3. Clinicaltrials.gov; 4. Clinicaltrials.gov; 5. PBR; 6. Mesoblast

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (1/4)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Anti-inflammatories	**Dexamethasone** (Repurposed)	Corticosteroid, reduces lung damage that occurs due to inflammatory processes in COVID-19	Treatment, especially of moderate and severe COVID-19	Approved in UK & Japan US Phase III ongoing	17	The RECOVERY trial demonstrated that dexamethasone reduced mortality in patients with COVID-19 requiring respiratory support by 35% in patients requiring MV and 20% in those requiring oxygen.[2]
	Methylprednisone (Repurposed)	As per dexamethasone	Treatment, especially of moderate and severe COVID-19	Phase III ongoing	20	In an RCT of 400 patients in Brazil, there was a slight but not statistically significant reduction in mortality in older COVID-19 patients; no reduction of overall mortality .[3] Associated with significant reduction of the mortality risk in patients with ARDS in a Chinese cohort study.[4] Was inferior to dexamethasone in a meta-analysis by the WHO.[5]
	Colchicine *Colcrys* (Repurposed) Takeda	Anti-mitotic drug widely used to treat gout. Downregulates multiple inflammatory pathways	Treatment	Phase II/III ongoing	20	Associated with clinical improvement in a small RCT.[6]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. NEJM; 3. Clinical Infectious Diseases; 4. JAMA Internal Medicine; 5. JAMA; 6. MedRxiv

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (2/4)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
RAAS modulators	**Losartan** *Cozaar* (Repurposed) MERCK	Antihypertensive, blocks angiotensin receptors in the RAAS system, which hmay play a multifactorial role in COVID-19	Treatment	Phase II ongoing	18	The ACE-2 receptor was demonstrated to be a receptor for the SARS-CoV virus in 2005[2]
	Telmisartan (Repurposed)	As per losartan	Treatment	Phase II ongoing	8	The ACE-2 receptor was demonstrated to be a receptor for the SARS-CoV virus in 2005[2]
Anticoag-ulants and anti-platelets (1/2)	**Aspirin** (Repurposed)	Antiplatelet agent, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II/III ongoing	16	A retrospective cohort study of 412 patients (98 receiving aspirin) found that aspirin use was associated with a reduction in likelihood of mechanical ventilation and ICU admission, but not mortality[3]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Nature; 3. DocWire

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (3/4)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Anticoag-ulants and anti-platelets (2/2)	**Enoxaparin** (Repurposed)	Anticoagulant, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II ongoing	**23**	A study published by Thrombosis Research suggests enoxaparin improves gas exchange and decreases the need for mechanical ventilation in patients with severe COVID-19. No statistical difference was seen between groups in all-cause 28-day mortality rate, in-hospital mortality rate, and ICU-free days[2]
	Heparin (Repurposed)	Anticoagulant, may reduce risk of blood clot formation in COVID-19	Treatment	Phase II/III ongoing	**70**	A large retrospective cohort showed lower mortality in COVID-19 patients treated with heparin, even after adjustment for age and gender and use of concomitant medication[3]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Clinical Infectious Diseases; 3. JAMA Internal Medicine

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

E: Other COVID-19 therapeutics – Selected candidates deep dive (4/4)

Not Comprehensive

Directionally positive result | Neutral result or mixed results | Directionally negative result | Results not yet released

Asset sub-category	Asset (Novel or repurposed)	Description	COVID-19 use case	Status	Registered trials on CT.gov[1]	Results and progress
Vitamins, minerals and supplements	**Vitamin D** (Repurposed)	Vitamin, hypothesised to have some antiviral effect (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase III ongoing	21	An analysis of vitamin D levels among asymptomatic and critically ill COVID-19 patients indicates a significant correlation, translating into increased mortality in vitamin D deficient patients[2]
	Vitamin C (Repurposed)	Vitamin, hypothesised to have some anti-inflammatory effects (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase II ongoing	42	Research carried out before the pandemic found no significant evidence that giving high doses of vitamin C to patients suffering from respiratory failure and sepsis (conditions which can occur in severe Covid-19 cases) would reduce organ failure[3]
	Zinc (Repurposed)	Vitamin, hypothesised to have some antiviral effect (mechanism inconclusive)	Prophylaxis, treatment, prevention	Phase II ongoing	18	The US National Institutes of Health warned against taking high doses of zinc to prevent Covid-19, pointing to lack of evidence and potential side effects, including irreversible neurological conditions from long-term use[4]

1. Based on COVID-19 trials registered on clinicaltrials.gov (CT.gov); 2. Nature; 3. JAMA; 4. NIH

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

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Public announcements indicate global manufacturing capacity of ~3.3M doses for approved therapeutics in 2020

Non exhaustive

Asset category	Asset	Company	Collaborators	YE 2020 (K)	YE 2021 (K)	In-source	Out-source	Manufacturing partnerships
Virus-directed small molecule	**Veklury** *(remdesivir)*	Gilead		2,000 [1]	TBC		✓	Cipla, Dr. Reddy's Laboratories, Eva Pharma, Ferozsons Laboratories, Flamma SpA, Hetero Labs, Jubilant Life Sciences, Mylan, Syngene (Biocon), Zydus Cadila Healthcare, Pfizer, Saptagir Laboratories (Saptagir Group), with Jubilant Life Sciences, Hikma, Uquifa Group [1]
Virus-neutralizing monoclonal antibodies (mAbs)	**Bamlanivimab** *(LY-CoV555)*	Eli Lilly	AbCellera	1,000 [2]	TBC	✓	✓	Samsung Biologics, Amgen, Fujifilm [3]
	Casirivimab + imdevimab *(REGEN-COV2)*	Regeneron	N/A	280 [4]	2,000 [5]	✓		Roche [6]
Total				**3,280**	**2,000**			

1. Gilead 2. Reuters; 3. Amgen, Fujifilm; 4. PMLive, 80k by end of Nov 2020 + 300k by end of Jan 2021 (incl. 200k by 1st week of Jan); 5. Bloomberg 6. FiercePharma

Source: Milken Institute, BioCentury, WHO, Nature, clinicaltrials.gov, press searches as noted above

Overview of publicly announced supply contracts

Value ($) / Doses
Unk for unknown

Non-exhaustive

USA

AstraZeneca

AZD7442	486M / 100K in 2020 (+1M in 2021)[1]

REGENERON

Casirivimab + imdevimab *(REGEN-COV2)*	450M$ 70K-300K doses for treatment OR 420K-1.3M doses for prevention[2]

Lilly

Bamlanivimab *(LY-CoV555)*	375M / 300K in 2020 (+650K in 2021)[3]

GILEAD

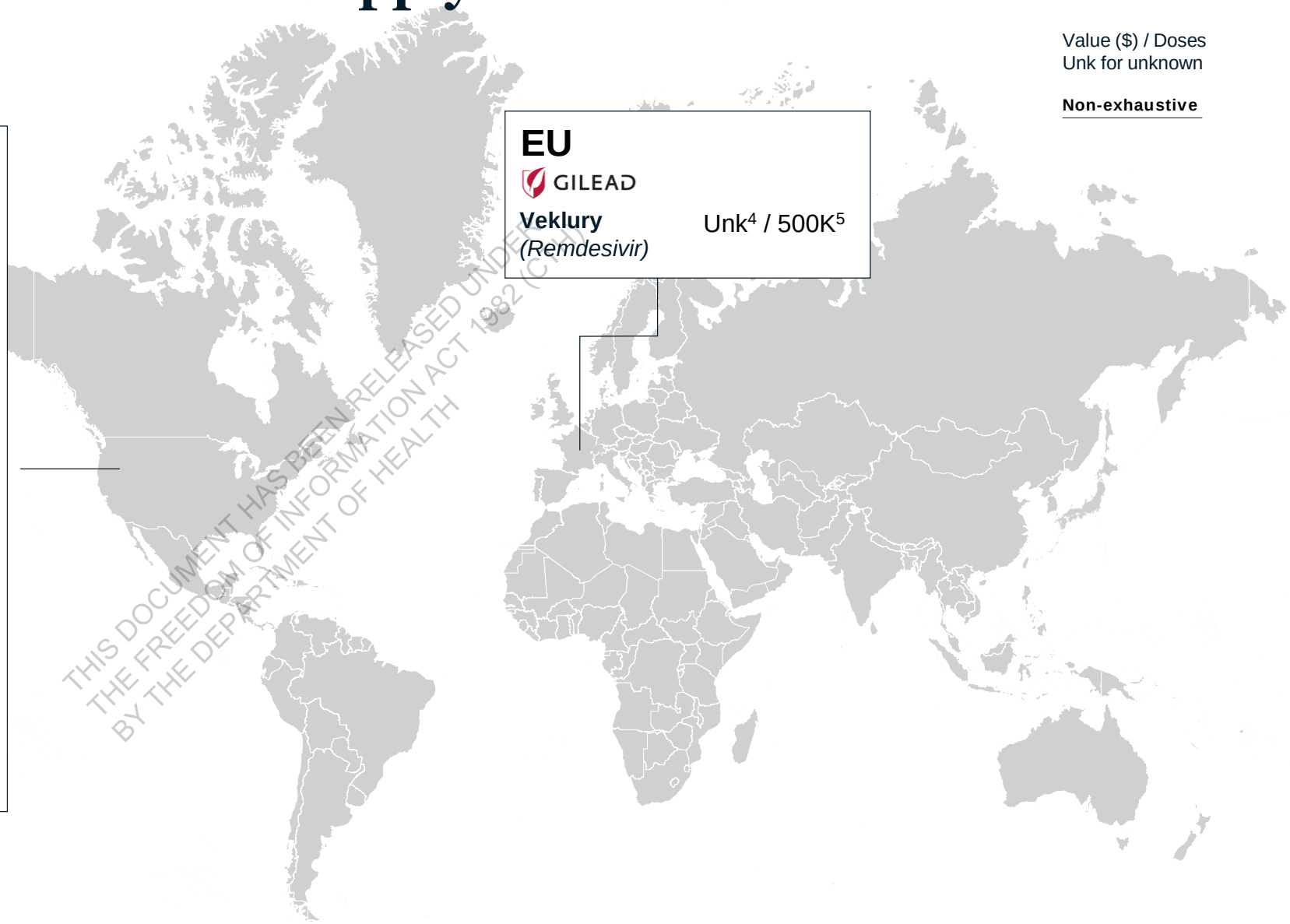
Veklury *(Remdesivir)*	Unk[4] / 500K[5]

Total	1.3B+ / 970M-1.32B+

EU

GILEAD

Veklury *(Remdesivir)*	Unk[4] / 500K[5]



1. Cision 2. Reuters 3. Lilly 4. Fierce , Gilead (US list price: $520 per vial, 5-day treatment using six vials, or $3,120; Developed countries: $390 per vial, or $2,340 per course) 5. BMJ, Gilead

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Public resources for pipeline compounds and clinical trials

Live lists of vaccine and therapeutic candidates

BioCentury

Milken Institute

Linksbridge (vaccine only)

Biorender

Live clinical trial aggregators

ReDo Project

Anticovid by Inato

COVID-Trials.org

IDM visualization of trial dates

DRAFT

Key changes in the vaccine landscape since last update (1/2)

AstraZeneca/Oxford released interim Phase III results for vaccine candidate AZD1222 [1]

- Efficacy 62% to 90% depending on the dosing regimen. Average 70% (n=11,636). 90% was reached in patients who mistakenly received a half dose for their first shot (n=2,741), then a full dose 4+ weeks later.
- NB Phase II found similar immune responses in people aged over and under 70 years.
- AstraZeneca expects a 'relatively fast approval' from an ongoing rolling review by EU's EMA, and is planning to seek an Emergency Use Listing (EUL) from the WHO.
- Can be stored, transported and handled at standard refrigeration temperatures for at least 6 months.

Pfizer/BioNTech completed Phase III results show 95% efficacy for vaccine candidate BNT162b2 [2]

- Efficacy consistent across age, gender, ethnicity (>94% in adults >65 years). No serious safety concerns observed.
- Submitted US FDA EUA request on November 20.
- Reached agreement to supply the EU with 200M doses, with option for additional 100M, anticipated to start by the end of 2020.
- Pfizer says it is poised to ship doses within hours of an authorization. The company has designed special thermal shippers, that can serve as temporary storage for 15 days by replenishing with dry ice.

Moderna released interim Phase III analysis shows 94.5% efficacy for vaccine candidate mRNA-1273 [3]

- 90 COVID-19 cases in placebo arm (incl. all 11 severe cases), vs. 5 cases in vaccine arm.
- Most common grade 3 event after the first dose was injection site pain (2.7%), while fatigue (9.7%), muscle pain (8.9%) and joint pain (5.2%) were the most common SAEs occurring after the second dose.
- Moderna states thermostability at standard refrigeration temperatures for 30 days (vs prior 7 day estimate)
- EMA and Swiss regulator have begun rolling reviews, and Moderna is expected to file for an EUA with US FDA by end of November, which could potentially review the data on December 17th.
- Reached agreement to supply the EU with 160 million doses.

1. AstraZeneca, FiercePharma, FierceBiotech, Oxford University, EuroNews, Lancet
2. Pfizer, Sky News, FiercePharma, Pfizer, Pfizer
3. Moderna, Moderna, EMA, ABC, Swissmedic

Key changes in the vaccine landscape since last update (2/2)

Sinovac could unveil interim Phase III data in early December

- Brazil trial has passed the threshold number of infections needed for interim analysis.
- Brazilian health officials expect a possible approval in December or January.
- Also published Phase II/III data showing its vaccine sparked a swift immune response but with lower antibody levels compared to convalescent patients.[1]

J&J launched a Phase III trial to assess a two-dose regimen of its vaccine candidate

- To be run in parallel with the ongoing single-dose study.
- Low enrolment potentially pushing out the company's initial goal of having data this year.[2]
- Also received additional $454 M from BARDA, and partnering with UnitedHealth to accelerate enrolment.

Baharat Biotech initiated Phase III trials of its Covaxin vaccine candidate

- The trial will enrol 26,000 participants across India, and the company expects at least 60% efficacy, with plans to launch the shot in Q2 2021.[3]

Inovio is preparing to initiate its Phase II/III trial for its DNA vaccine candidate INO-4800

- The announcement follows FDA approval to proceed. The company is aiming to resolve remaining questions about the device that will be used to deliver its candidate directly into the skin.[4]

Russia's Gamaleya research centre claims interim Phase III data shows >91% efficacy

- The analysis is based on 39 COVID-19 cases, with no 'unexpected' side effects.
- The trial will continue for another 6 months, with next analysis triggered when 78 COVID-19 cases reached.
- Russia has expressed an interest in applying for an EUL from the WHO. [5]

1. FiercePharma, Lancet
2. J&J, BMJ News, Bloomberg, Endpoints
3. India Times, DNA India
4. Inovio
5. Gamaleya Center, Reuters
6. FierceHealthcare

Australia has agreements in place that potentially provide access to five leading COVID-19 vaccines candidates

Manufacturer supply agreement | Possible COVAX supported supply

DRAFT

Vaccine candidate	Trial Phase	Platform	Efficacy	Thermostability requirements	Doses to be supplied if successful[1]	Manufacturing
Oxford University /AstraZeneca (AZD1222)	Ph 3	Non-replicating viral vector	70% average[3]	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**3.8M** doses by March 2021, additional **30M** doses by September Plus purchase option up to **50% population** coverage, via COVAX	**Offshore** via AZ (3.8M); **onshore** manufacturing agreement via CSL (30M doses)
UQ/CSL (Seqirus) V451	Ph 1	Protein subunit	TBC	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**51M** doses from mid-2021 Purchase option up to **50% population** coverage, via COVAX	**Onshore** manufacturing agreement via CSL
Novavax (NVX-CoV2373)	Ph 3	Protein subunit	TBC	**2-8°C** refrigerated cold chain in storage and at administration, duration not yet confirmed	**40M** doses, early-mid 2021 (TBC), option to purchase additional 10M Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
BioNTech/Pfizer mRNA (BNT162)	Ph 2/3	mRNA	95%	**-70°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 5 days	**10M** doses, early-mid 2021 (TBC) Purchase option up to **50% population** coverage, via COVAX (TBC – EOI only)	**Offshore** manufacturing via COVAX
Moderna (mRNA-1273)	Ph 3	mRNA	94.5%	**-20°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 30 days; 12 hours at room temp	Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX

1. Information to date indicates that all five vaccine candidates are likely to require two doses per person (subcutaneous or intramuscular injections, administered three to four weeks apart). COVAX option for AZD1222 is additional to directly negotiated supply agreement
2. When thawed but not yet reconstituted; must be used within 6 hours (at room temperature) once reconstituted
3. 62% efficacy on 2 full doses taken 4 weeks apart (n=8,895), 90% efficacy with 1 half dose followed by a full dose 4 week apart (n=2741)

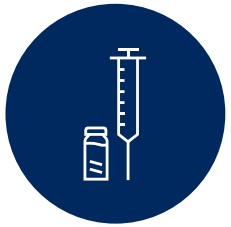
There are additional candidates in Phase 3 trials that are not covered by Australian/COVAX supply agreements

DRAFT

Vaccine candidate	Platform	Thermostability requirements	Notes
Johnson & Johnson (Ad26.COV2.S)	Non-replicating viral vector	2-8°C refrigerated cold chain in storage and at administration sites for 3 months, 2 years at - 20°C	Only leading candidate with single-dose regimen Phase III trial underway to assess a two-dose regimen BARDA-supported
Sinopharm	Inactivated virus	Unclear[1]	Chinese government supported

Two further candidates are currently in Phase III clinical trails, manufactured by CanSino Biological (China) and Gamaleya (China/Russia), however limited data are available

1. Likely 2-8°C refrigerated cold chain based on technology platform



Key changes in the vaccine landscape since last update

Moderna released an interim analysis of their Phase III COVE trial results, which demonstrated **94.5% efficacy**. 95 cases of COVID-19 occurred in the study cohort (90 in the placebo arm, 5 in the active arm), including 15 among elderly and 20 among candidates from minority ethnic backgrounds. Safety data indicate that the 2-dose **regimen was well tolerated**.[1]

Pfizer released additional data from their Phase III trial analysis. Final results demonstrated **95% efficacy**, which were consistent across participants from diverse demographics, including those >65 years old. Safety data indicate that the 2-dose regimen was well tolerated, with **minimal side effects**. Pfizer plans to submit for an EUA in the coming days, as well as for approval with other regulatory agencies around the world.[2]

EU Commission President Ursula von der Leyden indicated that the **EU could approve Moderna and Pfizer's vaccine candidates by as early as mid-December.** Both companies have sent data to the EMA for evaluation.[3]

Cold chain requirements were clarified for several vaccine candidates following new stability assessments:

- **Moderna**'s candidate can be refrigerated at 2-8ºC for up to 30 days (previous projection 7 days) once thawed from -20ºC[4]
- **Pfizer**'s candidate can be refrigerated at 2-8ºC for up to 5 days (previous projection 1-2 days) once
- thawed from -70ºC[5]

  CureVac's candidate does not require any freeze chain distribution, can be refrigerated at 2-8C for up to 3 months, and stored at room temperature for 24 hours[6]

The **TGA** granted **provisional determination to Janssen** (J&J), giving the company eligibility to apply to have their COVID-19 vaccine candidate added to the Australian Register of Therapeutic Goods (ARTG). Provisional determination has previously also been granted to AstraZeneca and Pfizer for their COVID-19 vaccine candidates.[7]

Pfizer commenced a pilot delivery program for its COVID-19 vaccine. The trial includes urban and rural areas in four US states, and seeks to overcome challenges in logistics and distribution posed by the Pfizer/BioNTech candidate's freeze chain requirement.[8]

1. Moderna
2. Pfizer
3. France24
4. Reuters
5. Reuters
6. CureVac
7. TGA
8. Reuters

Australia has agreements in place that potentially provide access to five leading COVID-19 vaccines candidates

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DRAFT

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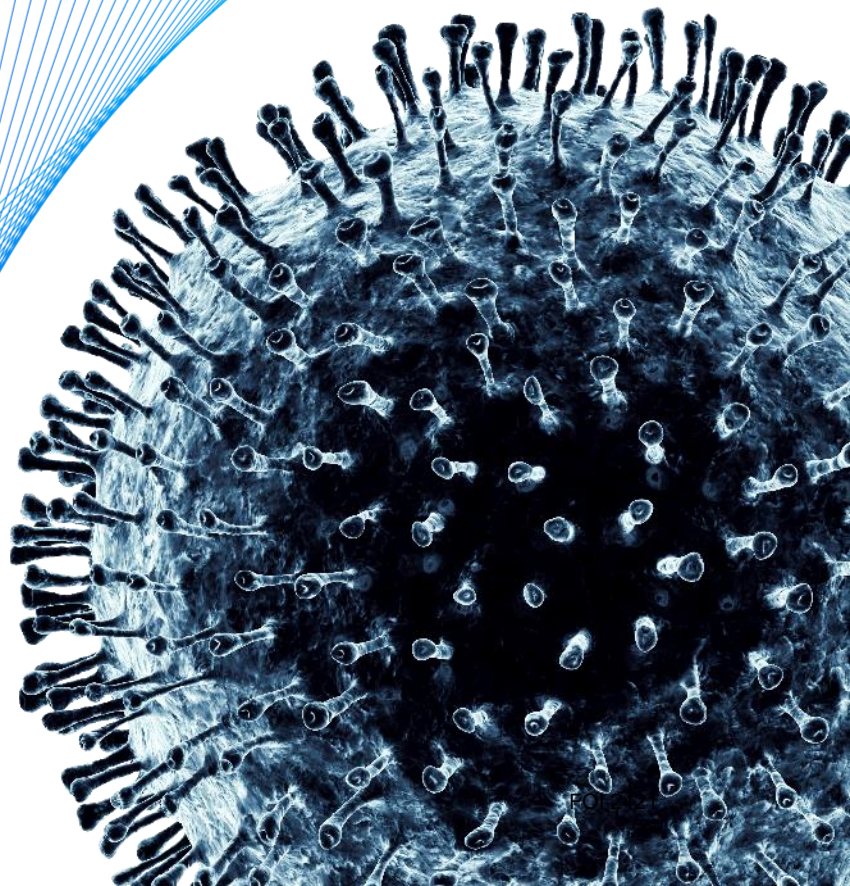
COVID-19 Therapeutics and Vaccines Landscape Overview

November 16, 2020

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED PURELY ON CURRENT, PUBLICLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE



Document overview

To date, there is no **globally approved COVID-19 vaccine or treatment** available.

There are **over 275 vaccine candidates** and over **390 therapeutics candidates** in consideration.

This document and accompanying Excel trackers provide a **current snapshot of vaccine and therapeutic efforts for COVID-19.** They are based on **publicly available data** across candidate lists, clinical trial data and trial results.

Sources of insight:

- Multiple candidate lists (e.g. Milken Institute, BioCentury, WHO)
- Clinical trial registries (mainly CT.gov and ChiCTR)
- Press and literature searches

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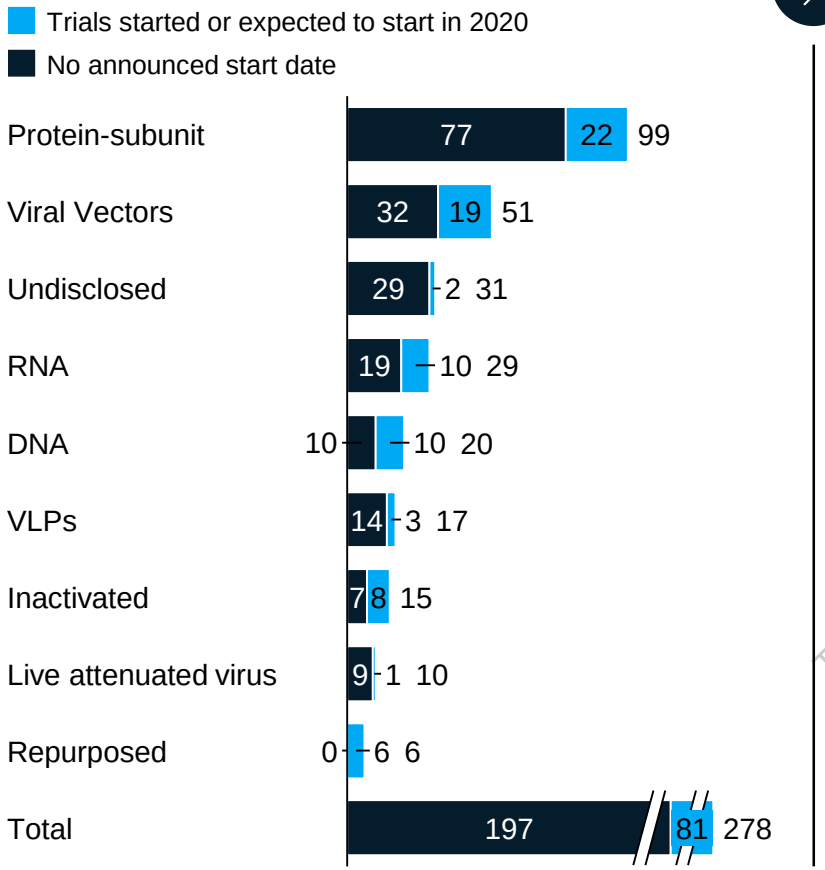
COVID-19 vaccines development effort overview

278 vaccines are currently in development

Pipeline overview



Recent developments – Oct 30 – Nov 12, 2020

Pfizer reports over 90% efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection with a 2-dose schedule, based on the first interim efficacy analysis. The company expects to file for Emergency Use approval in the third week of November[1]

Moderna has reached the target number of cases required for interim analysis earlier than projected as a result of increased rates of infection across its sites. Results are expected in the next few weeks[2]

Russia's Sputnik V vaccine is 92% effective, according to the National Research Center for Epidemiology and Microbiology in Moscow, while China's Sinopharm claimed its late-stage data are "better than expected" – though it is unclear which of the two assets generated this data[3]

Bahrain granted emergency approval to (one of) Sinopharm's vaccine candidates, and has started inoculating frontline workers[4]

AstraZeneca intends apply for an EUA in the US once it has reached the required targets in its ex-US trials, in hopes to circumvent the 3-month delay to its US trials[5]

Novavax's recombinant nanoparticle-based vaccine won fast track designation from the US FDA. The company expects to begin Phase 3 clinical trials in the US and Mexico by end of November, with interim data from its ongoing UK phase 3 trial expected in Q1 2021[6,7]

Medicago announced it is starting phase 2/3 clinical trials of its plant-derived vaccine, with plans to recruit 30,000 participants in North America, Latin America and/or Europe[8]

J&J announced plans to start testing its COVID-19 vaccine in youths aged 12 to 18 as soon as possible, weeks after Pfizer gained approval to do the same[9]

Sinovac resumed its Phase 3 trials in Brazil, less than 48h after the trial was paused due to a participant suicide[10]

CureVac presented more data from its Phase 1 trial, with antibody titers comparable to those in convalescent era from COVID-19 patients. The company plans to enter phase 2b/3 trial by end of the year.[11]

1. Pfizer
2. Moderna
3. Russia
4. Bahrain
5. Endpoints, Reuters
6. GlobeNewsWire
7. Reuters
8. Medicago
9. BusinessInsider
10. CNBC
11. MedRxiv, FiercePharma

Sources for pipeline overview: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 9, 2020

There are 278 candidates in the pipeline for COVID-19 vaccines

Not covered in this document

	Description	Example companies / compounds	Number of candidates profiled[1]
RNA	**Nucleic acid RNA** packaged within a vector (e.g. lipid nanoparticles).	moderna, BIONTECH, Pfizer	29
DNA	**Plasmid containing the DNA sequence encoding the antigen(s)** against which an immune response is sought	inovio	20
Inactivated	Killed version of the virus that causes the disease, providing shorter-term protection and requiring boosts	sinovac, SINOPHARM	15
Viral vectors	**Chemically weakened** virus to transport pieces of the pathogen – usually antigen coding surface proteins	CanSinoBIO, MERCK, Johnson & Johnson	51
Attenuated virus	**Weakened virus** to stimulate immune response	INDIAN IMMUNOLOGICALS LIMITED	10
VLPs	Virus-like-particles - **molecules that closely resemble viruses**, but are non-infectious because they contain no viral genetic material	medicago, vbi	17
Protein subunit	**Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response. Some assets employ a nanoparticles-delivery system for enhanced antigen presentation	NOVAVAX, gsk, SANOFI	99
Repurposed	Repurposed vaccines already on the market		6
Undisclosed[2]	Additional candidates with little public information	SaudiVax, HOTHTHERAPEUTICS	31

1. Compiled across multiple lists (Milken Institute, BioCentury, WHO, Nature) and supplemented with press
2. Not profiled moving forward. Vaccine type cannot be delineated due to lack of public information; typically in research setting or small biotech

Source: Milken Institute, BioCentury, WHO, Nature

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56 COVID-19 vaccine candidates are currently undergoing clinical trials (1/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
RNA	Moderna	mRNA-1273	NIAID, Lonza, Catalent, ROVI	USA	CEPI, NIAID, BARDA	Phase III	Jul-20	30,720
	BioNTech	BNT162	Pfizer and Fosun Pharma, Polymun	Germany, USA,S. Africa Argentina, Brazil Turkey, China, Japan		Phase I/II/III	Jul-20	44,880
	Imperial College London	LNP-nCoVsaRNA	UK Government	UK		Phase I	Jun-20	320
	CureVac	CVnCoV	CEPI, European Commission; Gates Foundation; DARPA	Germany, Panama, Peru	German gov.	Phase II	Sep-20	859
	Walvax Biotechnology	ARCoV	People's Liberation Army, Academy of Military Sciences	China		Phase I	Jun-20	168
	Arcturus Therapeutics	LUNAR-COV19	Duke-NUS Medical School	Singapore	Singapore	Phase I/II	Aug-20	92
	Chulalongkorn University	ChulaCov19		Thailand		Phase I	Sep-20	96
DNA	Genexine	GX-19	Binex, GenNBio, Korea Advanced Institute of Science and Technology, Pohang University of Science and Technology	South Korea	IVI	Phase I/II	Jun-20	210
	Aivita Biomedical, Inc.	AV-COVID-19		USA		Phase I/II	Jul-20	280
	Inovio	INO-4800	Beijing Advaccine Biotechnology, Ology Bioservices	USA, S. Korea	CEPI, BMGF	Phase I/II	Jun-20	280
	Zydus Cadila	nCov vaccine		India		Phase I/II	Jul-20	1048
	AnGes	AG0301-COVID19, AG0302-COVID19	Osaka University and Takara Bio	Japan		Phase I/II	Aug-20	60
	Symvivo	bacTRL-Spike		Australia		Phase I	Oct-20	12
	Entos Pharmaceuticals	Covigenix VAX-001	Cytiva, CIHR	Canada		Phase I/II	Nov-20	72

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (2/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Inactivated	Sinovac Biotech	CoronaVac (previously PiCoVacc)	Dynavax	Brazil, Indonesia, Turkey, China	Bank of Beijing	Phase III	Jul-20	26,248
	Sinopharm		Beijing Institute of Biological Products, Wuhan Institute of Biological Products	UAE, Bahrain, Jordan		Phase III	Jul-20	48,584
	Chinese Academy of Medical Sciences		Institute of Medical Biology,	China		Phase I/II	Jul-20	1,413
	Republic of Kazakhstan		Research Institute for Biological Safety Problems, National Scientific Center for Pulmonology	Kazakhstan	Kazakhstan government	Phase I	Sept -20	244
	Bharat Biotech	BBV152		India		Phase I/II	Jul-20	879
	Beijing Institute of Biological products Co. Ltd	Vero cell	China National Biotec Group Company Ltd, The Huesped Foundations, Universidad Peruana Cayetano Heredia	Argentina, Peru		Phase III	Sep-20	9,000
	Shenzhen Kangtai Biological Products Co.,Ltd.; Beijing Minhai Biotechnology Co., Ltd.	Vero cell	Jiangsu Provincial Center for Disease Control and Prevention(Public Health Research Institute of Jiangsu Province)	China		Phase I	Oct-20	180
Viral vectors	University of Oxford (Jenner Institute)	AZD1222 / ChAdOx1 nCoV-19	AstraZeneca, Advent SRL manufacturer, MilliporeSigma, Cobra Biologics, Emergent Biosolutions, Catalent	UK, Brazil, S. Africa[1] , India, US, Russia, Japan	UK gov't	Phase III	Jun-20	55,532
	CanSino Biologics	Ad5-nCoV	Institute of Biotechnology at China's Academy of Military Medical Sciences	China, Russia, Pakistan	Chinese government	Phase III[3] Phase III[4]	Sept -20 Sept -20	42,285 168
	Gamaleya Research Institute	Sputnik V		Russia, Belarus[2]		Phase III	Aug- 20	40,286

1. Reuters 2. Two formulations of the same asset in trials in two separate locations 3. Approved for Military use in China; total participants includes pediatric Ph Iib trial 4. Trial for 2 dose regimen CT.gov

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (3/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Viral vectors (cont.)	Johnson & Johnson	Ad26.COV-2.S	Beth Israel Deaconess Medical Center	Argentina, Belgium, Brazil, Chile, Colombia, France, Germany, Mexico, Peru, Philippines, Spain, S. Africa, Ukraine, UK, USA	BARDA	Phase III	Sept-20	91,295
	Shenzhen University	COVID-aAPC	Shenzhen Second and Third People's Hospitals	China	Chinese gov.	Phase I	Feb-20	100
	Institut Pasteur	TMV-083	Themis (Merck)	Belgium, France	CEPI	Phase I	Aug-20	90
	ReiThera	GRAd-COV2	LEUKOCARE, Univercells	Italy		Phase I	Aug-20	90
	Merck/MSD	V591	Themis	Belgium		Phase I/II	Aug-20	260
	Merck/MSD	V590	Themis			Phase I	Oct-20	252
	Beijing Wantai Biological Pharmacy Enterprise	DelNS1-2019-nCoV-RBD-OPT1		China		Phase I	Sep-20	60
	Vaxart	VXA-COV2-1		USA		Phase I	Sep-20	48
	Jiangsu Province Centers for Disease control	Adeno Type 5 virus		China		Phase I	Sep-20	89
	Universitätsklinikum Hamburg-Eppendorf	MVA-SARS-2-S	German Center for Infection Research, Philipps University Marburg Medical Center	Germany		Phase I	Oct- 20	30
	ImmunityBio	hAd5-S-Fusion+N-ETSD	NantKwest	USA		Phase I	Oct-20	35
	Institute for Biological Research	IIBR-100	Dyadic, Weizmann Institute	Israel		Phase I/II	Oct-20	1,040
VLPs	Medicago		Laval University's Infectious Disease Research Centre	Canada	Canadian gov't	Phase I	Jul-20	180
	SpyBiotech	HBsLVP	Serum Institute of India	Australia		Phase I/II	Sep-20	N/A

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (4/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Protein-subunit	Anhui Zhifei Longcom Biopharmaceutical		Institute of Microbiology, Chinese Academy of Sciences	China		Phase II	Jul-20	1,000
	Clover Biopharmaceuticals[1]	SCB-2019	GSK/Dynavax	Australia		Phase I	Jun-20	150
	Vaxine Pty Ltd		Flinders University, Oracle	Australia		Phase I	Jun-20	40
	Novavax	NVX-CoV2373	Emergent BioSolutions, Praha Vaccines, Serum Institute of India	Australia, S. Africa, USA, UK, Mexico	CEPI	Phase III[2]	Aug- 20	42,035
	University of Queensland		GSK, Dynavax, CSL (Parkville, Australia), Viroclinics Xplore	Australia	CEPI, Queensland, Austrialian gov't, Paul Ramsay Foun.	Phase I	Jul-20	216
	Federal Budgetary Research Institution "Vector"	EpiVacCorona		Russia		Phase I/II	Jul-20	100
	Sanofi Pasteur		GSK	USA		Phase I/II	Sept-20	440
	Jiangsu Province Centers for Disease Control	Sf9 Cell	West China hospital	China		Phase I	Aug-20	168
	AdImmune	AdimrSC-2f		Taiwan		Phase I	Aug-20	70
	Medigen	MVC-COV1901	NIAID & Dynavax	Taiwan		Phase I	Aug-20	45
	University Hospital Tuebingen	pVAC		Germany		Phase I	Sept-20	36
	United Biomedical Inc. Asia	UB-612	COVAXX	Taiwan		Phase I	Sept-20	60
	Finlay Vaccine Institute			Cuba		Phase I/11	Sept-20	676

1. Clover is testing three different versions of the vaccine, including two that use unique adjuvants, in this trial
2. Phase III in UK, US, Mexico

Source: clinicaltrials.gov, press search

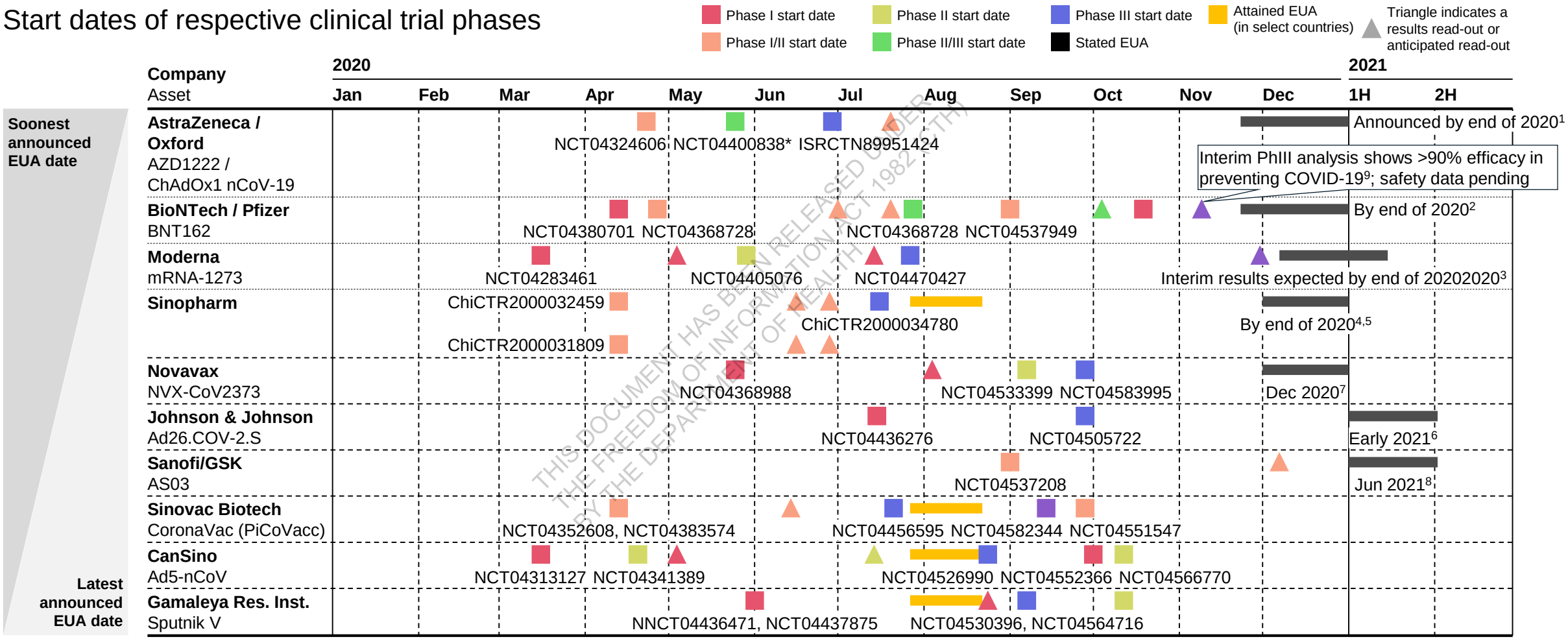
56 COVID-19 vaccine candidates are currently undergoing clinical trials (5/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Repurposed	Several	BCG vaccine		Australia, Brazil, Colombia, Denmark, Egypt, France, Netherlands, S. Africa, USA		Phase III/IV	March-20 to Sep-20	20,090
	Kasr El Aini Hospital	Measles vaccine		Egypt		Phase III	May-20	200
	Immunovative Therapies	AlloStim	Mirror Biologics	USA		Phase I/II- Delayed	Oct-20	40
	Canadian Cancer Trials Group	IMM-101	Immudolon Tx, BioCan Rx, CSSRI, AtGen, ARCC	Canada		Phase III	Jul-20	1500
	Oklahoma Medical Research Foundation	Shingrix vaccine		USA		Phase I	Sep-20	250
	NeuroActiva Inc. & Biomed Industries Inc.	Oral Polio vaccine		USA		Phase III	Nov-20	3600

Source: clinicaltrials.gov, press search

Select vaccine candidates currently in Phase III or Phase II/III or have announced potential EUA timelines

Start dates of respective clinical trial phases



1. Reuters
2. CIDRAP
3. Moderna
4. Reuters
5. PBR
6. FiercePharma
7. Reuters
8. SEC filing
9. Pfizer

* indicates an estimated start date as trial has not yet officially commenced

Source: Milken Institute COVID-19 Tracker, clinicaltrials.gov, BioCentury, press search

Design elements for select efficacy trials (e.g., Phase 2/3 or 3)

Outside-in view based on media coverage and published trial design if available; trials, timing, and EUA are estimates and subject to change

	moderna	Pfizer BioNTech	AstraZeneca	J&J	sinovac	SINOPHARM	NOVAVAX	CUREVAC
	Phase III	**Phase I/II/III**	**Phase II/III**	**Phase III**	**Phase III**	**Phase III**	**Phase III**	**Phase II/III**
Start	July, 2020	July, 2020	May/June 2020	Sept/Nov, 2020	July/Sept/Oct, 2020	July 16, 2020	Sep 28, 2020	End 2020 (tbc)
MoA	mRNA	mRNA	Viral vector	Viral vector	Inactivated virus	Inactivated virus	Protein subunit	mRNA
Dose schedule	2 doses	2 doses	1 or 2 doses for adults, ped, elderly	1 dose or 2 doses	2 doses	2 doses	2 doses	2 doses
Dose levels	1 dose level, 100 micrograms	1 dose level, 30 micrograms	1 dose level for adults and ped., 2 for elderly	1 dose level (1x10^11 viral particles)	1 dose level	1 dose level	1 dose level	1 dose level, 12 micrograms
Efficacy target	60%	60%	50%	60%	Unknown	Unknown	Unknown	Unknown
Trial size	30,720	44,880	49,430	90,000	26,248	48,584	39,000	30,000
Site geography	USA	Germany, USA, S. Africa, Argentina, Brazil Turkey, China, Japan	UK, USA, Brazil, S. Africa, India	USA, Argentina, Brazil, Chile, Colombia, Mexico, Peru, Philippines, UK, S. Africa, Ukraine, Belgium, France, Germany, Spain	Brazil, Indonesia, Turkey, China	UAE, Bahrain	UK, US, Mexico	TBC
Temperature conditions	-20°C shipped /stored for 6 months; 2-8°C for 7 days	-70°C shipped /stored for 6 months; 2-8°C for 24-48 hours	2-8°C; normal cold chain	2-8°C; normal cold chain for 3 months; 2 years at -20°C	Unknown	Unknown	Unknown	2-8°C for 3 months; room temperature for 24 hours
Special populations	None (adults 18+)	Ex-EU: Age 12+ EU: Age 18+ Phase 3 includes HIV patients	Elderly, pediatric	Adults 18+; planned inclusion of pediatric population age 12-18	Adult, elderly & pediatric arms, healthcare workers	None (adults 18+)	None (adults 18+); seasonal flu vaccine	TBC

Source: clinicaltrials.gov, press search

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Compilation of published or pre-released clinical trial results (1/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Sinovac CoronaVac (previously PiCoVacc)	In-activated	Phase I/II	Double blind prospective RCT	Interim Phase II readout	August 10, 2020	• Reported that the vaccine candidate appeared to be safe and induced detectable antibody-based immune responses	NCT04383574
AstraZeneca/ Oxford AZ1222	Viral Vector	Phase III	Single blind prospective RCT	Interim Phase I/II readout	July 20, 2020	• "Neutralising antibodies were generated in more than 90% of participants across different assays. Responses were sustained up to 56 days of observation."[4] • "No serious adverse events occurred."	NCT04324606
Gamaleya Research Institute	Viral vector	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 4, 2020	• All trial participants (76 adults) elicited an antibody response within 21 days and no serious adverse events after 42 days. The vaccine also produced a T-cell response within 28 days, a secondary outcome[3]	NCT04436471, NCT04437875
Moderna mRNA1273	RNA	Phase III	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 29, 2020	• Follow-up results showed promising data for older adults – by day 57, among the participants who received the low dose, the geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 years and 1,128,391 among those who were 71+ years • Among the participants who received the high dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively • Binding- and neutralizing-antibody responses appeared to be similar to those among vaccine recipients between the ages of 18 and 55 years • The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells.	NCT04283461

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (2/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Inovio INO-4800	DNA	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	August 10, 2020	• 100% of trial participants demonstrated overall immune responses • 95% had seroconverted by antibody response overall • Nearly 90% generated strong T cell responses, including CD8+ T cell responses	NCT04336410
CanSino Ad5-nCoV	Viral Vector	Phase II	Non-randomized, open label prospective trial	Interim Phase I readout	May 22, 2020	• Reported mean neutralizing titers of 34 in its high-dose group, below FDA recommendations of 160 • Single dose elicited a four-fold increase in binding antibodies to RBD in 94–100% of participants, and a four-fold increase to live virus in 50–75% of participants	NCT04313127
			Randomized, observer-blinded prospective trial	Interim Phase II readout	July 20, 2020	• One injection of non-replicating adenovirus-vectored COVID-19 vaccine with two concentrations • "Seroconversion occurred in more than 96% of participants, and neutralising antibodies were generated in about 85%. More than 90% had T-cell responses."	NCT04398147
Novavax NVX-CoV2373	Protein subunit	Phase I/II	Randomized quadruple blind placebo controlled trial	Full Phase I readout	Sept 2, 2020	• 100% of participants developed wild-type virus neutralizing antibody responses after Dose 2; Both 5 and 25mcg doses generated GMT greater than 1:3,300; Anti-spike IgG & viral neutralization compared favorably to responses from patients with clinically significant COVID disease. Cellular immune responses demonstrated in a subset of patients. No severe AEs reported	NCT04368988

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (3/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Pfizer / BioNTech BNT 162	RNA	Phase II/III	Randomized triple blind placebo controlled trial	Interim Germany Phase I/II readout	July 20, 2020	• BNT162b1 elicited strong CD4+ and CD8+ T cell responses against SARS-CoV-2-receptor binding domain (RBD), compared to baseline[2] • The RBD-specific, interferon-γ+, IL-2+, CD8+ T cells elicited by BNT162b1 in immunized participants indicate a strong potential for cell mediated anti-viral activity • T cell cytokine profile shows vaccine elicited T cells exhibit a Th1 phenotype, which is associated with antiviral propertie	NCT04368728
				Interim US Phase I/II readout	August 20, 2020	• BNT162b2 elicited SARS-CoV-2–neutralizing GMTs in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times • Well tolerated with mild to moderate fever in fewer than 20% of participants	NCT04368728
				Interim Phase III readout	November 9, 2020	• The case split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90%, at 7 days after the second dose base on evaluable case count of 94	NCT04368728
Sinopharm BBIBP-CorV	In-activated	Phase I/II	Randomized double blind placebo controlled trial	Interim Phase I/II readout	August 14, 2020	• The trial linked the vaccine to increases in antibody titers. It is not clear whether the response is likely to confirm immunity as the study did not include a comparison arm featuring serum samples from patients previously infected with the coronavirus	ChiCTR-2000032459

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (4/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
J&J JNJ-78436735	Viral vector	Phase III	Randomized triple blind placebo controlled trial	Interim Phase I/II readout	Sept 28, 2020	• After only a single dose, seroconversion rate at day 29 after immunization in cohort 1a already reached 92% with GMTs of 214 and 92% with GMTs of 243 for the low and high dose levels, respectively.	NCT04436276
CureVac CVnCoV	mRNA	Phase I	Randomized blinded placebo-controlled, dose-escalation trrial	Interim Phase I readout	November 9, 2020	• Two doses of CVnCoV ranging from 2 µg to 12 µg per dose, administered 28 days apart were safe. • Seroconversion (defined as a 4-fold increase over baseline titer) of virus neutralizing antibodies two weeks after the second vaccination occurred in all participants who received 12 µg doses. • Preliminary results in the subset of subjects who were enrolled with known SARS-CoV-2 seropositivity at baseline show that CVnCoV is also safe and well tolerated in this population, and is able to boost the pre-existing immune response even at low dose levels. • Based on these results, the 12 µg dose is selected for further clinical investigation	NCT04449276

Source: Company press releases & associated published literature

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Public announcements indicate global vaccine manufacturing capacity of 10+ billion doses by end of 2021

Manufacturing type	Asset	Asset category	Company	Collaborators	YE 2020 (M)	YE 2021 (M)	In-source	Out-source	Partner
Specific-assets	mRNA-1273	RNA	Moderna	NIAID, Lonza	30 [1]	1,000 [1]	✓	✓	Lonza, Catalent, ROVI
	BNT162	RNA	BioNTech	Pfizer and Fosun Pharma	50 [2]	1,300[2]	✓	✓	Pfizer, Rentschler[17] (for downstream purification)
	INO-4800	DNA	Inovio	Beijing Advaccine Biotechnology, Ology Bioservices	1 [4]		✓	✓	Richter-Helm,
		Viral vectors	Themis	Merck, Institut Pasteur and Uni. of Pittsburgh		1,000 [5]	✓	✓	
	AAVCOVID	Viral vectors	Mass. Eye and Ear and Mass. General Hospital	Novartis	Millions [6]			✓	Novartis
	Ad26.COV-2.S	Viral vectors	J&J	Beth Israel, HHS		1,000 [7]	✓	✓	Catalent, Emergent Biosolutions, Biological E
	AZD1222 / ChAdOx1 nCoV-19	Viral vectors	University of Oxford (Jenner Institute)	AstraZeneca, Advent SRL MilliporeSigma, Cobra Biologics	800 [8,3]	2,000 [9]		✓	SII, Oxford Biomedica, Emergent Biosolutions, Catalent, Scotland Symbiosis, Wockhardt, BioKangtai
	AS03	Protein-subunit	Sanofi Pasteur	GSK		1,000 [10]	✓		
	NVX-CoV2373	Protein-subunit	Novavax	Emergent BioSolutions, Praha Vaccines, Serum Inst. of India	100 [15]	2,000 [11]	✓		Praha Vaccines, Takeda (250M doses), Fujifilm
	CVnCoV	RNA	CureVac	CEPI; European Commission; Gates Foundation; German gov		1,100 [16]	✓		
Other	PiCoVacc	Inactivated	Sinovac Biotech	Dynavax		100 [12]			N/A
		Inactivated	Sinopharm	Beijing Institute of Biological Products	100 [13]				N/A
		Inactivated	Sinopharm	Wuhan Institute of Biological Products	100 [13]				N/A

1. Moderna press release, WBUR
2. Pfizer, The Guardian
3. FiercePharma
4. Inovio press release
5. FierceBiotech
6. Masseyeandear.com
7. J&J press release
8. AZ press release
9. AZ press release
10. FiercePharma
11. FiercePharma
12. BusinessWire
13. Chinadaily.com.cn
14. HHS press release
15. FiercePharma
16. Nature
17. Fierce Pharma

Source: Milken Institute, BioCentury, WHO, Nature, clinicaltrials.gov, press searches as noted above

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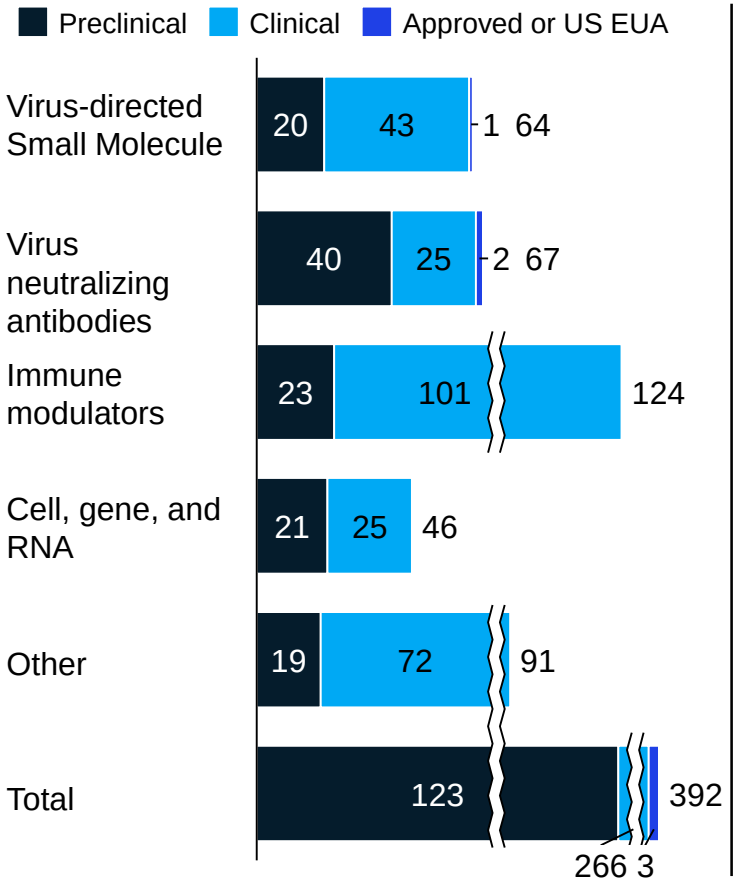
COVID-19 Therapeutics landscape update

Pipeline snapshot

Number of candidates under active investigation[1]



Recent developments – Oct 29 - Nov 12, 2020

Eli Lilly's bamlanivimab (LY-CoV555) received an EUA for treatment of COVID in ambulatory patients[2] . Separately, data from NIH's ACTIV-3 trial suggested bamlanivimab was unlikely to improve clinical outcomes in hospitalized patients.[3]

UK's RECOVERY trial continued to recruit patients for its treatment arms containing Regeneron's REGN-COV2, less than a week after recruitment was paused to allow review of safety and efficacy data by the Independent Data Monitoring Committee.[4]

The RECOVERY trial began investigating aspirin as a therapy to prevent blood clots in patients with COVID-19.[5]

A randomized Phase II clinical trial found that convalescent plasma did not reduce progression to severe disease or mortality in hospitalized patients with moderate COVID-19.[6]

Novartis' canakinumab (Ilaris) did not meet its Phase III primary endpoint of improving patient survival rates without the need for invasive mechanical ventilation. The trial also did not meet its secondary endpoint of reducing COVID-19-related mortality[7]

AstraZeneca's acalabrutinib (Calquence) did not reduce respiratory failure in a Phase II randomized trial of hospitalized COVID-19 patients[8]

1. Based on publicly available data. Snapshot updated to reflect assets under active investigation, excluding those where preclinical development has been suspended
2. FDA
3. Lilly
4. RECOVERY
5. RECOVERY
6. BMJ
7. Novartis
8. AstraZeneca

Sources for pipeline snapshot: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, as of Nov 9, 2020

Only a few select assets are in late stage development or have successfully gained approval for use

Not comprehensive	Company / Asset		Stage of development	EUA / approval status
Virus-directed small molecule	GILEAD	Remdesivir	Completed Phase III	Approved in US, EU, Japan, UK & others[1]
	FUJIFILM	Avigan	Completed Phase III	Provisional approval in China, Japan, Russia, India[2]
Monoclonal antibodies (mAbs)	VIR	VIR-7831/2	Ongoing Phase II/III	
	REGENERON	REGEN-COV2	Ongoing Phase II/III	Submitted for EUA in US[3]
	Lilly	Bamlanivimab (LY-CoV555)	Ongoing Phase III	EUA in US[4]
	Biocon	Itolizumab	Phase III planned	EUA in India[5]
	N/A	Convalescent plasma	Completed Phase III	EUA in US[6]
Immune modulators	Roche	Actemra	Ongoing Phase III	Prior approval for use in CRS[7]
	Lilly	Olumiant	Ongoing Phase III	
Cell, gene and RNA therapies	*No assets in late stage clinical development/ trials*			
Other	Generic	Dexamethasone	Completed Phase III	Approved in UK & Japan[8]

Final read-outs from several key Phase II/III trials (e.g., Lilly & Regeneron mAb trials) **expected in late 2020**

Many currently marketed drugs for indications such as HIV, malaria, RA, etc. have failed to show efficacy in Ph III trials

1. US, Japan, Taiwan, India, UAE Singapore, Australia , Canada, UK, EU
2. RDIF, HospiMedica, Pmlive, Fujifilm
3. Biopharma
4. Lilly
5. Biocon
6. FDA, STATNews
7. Cytokine Release Syndrome
8. Fiercepharma; Reuters

There are over 390 candidates in the pipeline for COVID-19 therapeutics

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

F| Not covered in this document

		Description	Candidates profiled	Example candidates/companies
A| Virus-directed small molecule		**Largely repurposed** compounds, including **antivirals** (HIV, Influenza), **antimalarials**, **antiprotozoals**, and more	64	Remdesivir Kaletra Chloroquine
B| Antibodies (to neutralize virus)	**Monoclonal antibodies** (mAbs)	**New development** using **survivor samples**, **genetically engineered** mice and **synthetic routes**; often a cocktail	67	
	Polyclonal antibodies / plasma	**New development** using **survivor plasma** (convalescent plasma) or **genetically engineered** cows for hyper-immunized globulin. Also called plasma-derived therapy or IVIG.		
C| Immune modulators		**IL inhibitors**, alpha or beta-**interferon** and other therapies often **repurposed**. Targets host immune response with severe and critical disease (e.g. cytokine release syndrome)	124	Actemra Kevzara
D| Cell, gene and RNA therapies		**Stem cells**, **T-cells**, cord blood cells and **RNA-based** therapies	46	remestemcel-L siRNA
E| Other		**Steroids, surfactants**, **oxygen carriers, immunotherapies,** and other modalities not included in the above	91	Losartan Methylprednisolone Bevacizumab
F| Traditional Chinese Medicine		Traditional **herbal formulas and medicines**	n/a	maxingshigan-yinqiaosan

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech

A: COVID-19 virus-directed small molecule – selected candidates deep dive (1/2)

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Directionally positive result | Directionally negative result

Not comprehensive

Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date[2]	Initial clinical evidence[3]	Efficacy in isolated use?	Additional information
Remdesivir (Antiviral) GILEAD	**Approved for COVID-19**	Treatment	**29**	**May 2020**	Positive Gilead and NIAID-sponsored results in hospitalized patients; interim results from WHO SOLIDARITY trial suggested little or no effect on hospitalized pts	Improvement in compassionate use cases in US and other countries[4]	Approved in US, EU, Japan, Taiwan, India, Singapore, Australia and UAE[5] Planning a trial for paediatric use and inhalant version[6]
Chloroquine (Antimalarial)	**Marketed** (Malaria)	Prophylaxis, Treatment	**26**	**Apr 2021** (prophy) **Apr 2020** (treatment)	A large observational study showed increased mortality and cardiac arrhythmias, with or without macrolide		In-vitro SARS-CoV-2 efficacy data Used off-label for treatment and prophylaxis of Zika
Hydroxy-chloroquine (Antimalarial)	**Marketed** (Malaria)	Prophylaxis, Treatment	**200**	**May 2020** (prophy) **May 2020** (treatment)	Randomized trials in general have not found significant benefit in treating hospitalized or non-hospitalized patients; no evidence of prophylactic benefit	Improvement in Japanese patient and patients in Australia[7,8]	FDA revoked EUA for COVID patients.[9] France also revoked its authorization of HCQ.[10] Italy also banned the drug's use outside of clinical trials and the UK has put limits on the use[11] WHO and NIH halted HCQ trials[12]
Azithromycin (Antibiotic)	**Marketed** (Bacterial infection)	Treatment	**71**	**May 2020**	Mixed results on viral clearance from small-mid size French studies and Brazilian study		Widely used for chest infections, pneumonia

1. Based on CT.gov registered trials related to COVID-19 2. From CT.gov trial end dates. Actual read-out may be sooner 3. See "Compilation of published results" for full set of references 4. CDC. Gilead 5. Gilead, Reuters, Reuters, Reuters, Press , FDA, EMA, health.gov.au, Reuters 6. Endpoint News 7. Pharma Japan 8. The Scientist, Tech Times 9. FDA 10. France24 11. Pharmafile 12. STAT, Fierce Pharma

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – selected candidates deep dive (2/2)

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Directionally positive result
Directionally negative result

Not comprehensive

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Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date[2]	Initial clinical evidence[3]	Efficacy in isolated use?	Additional information
Kaletra lopinavir, ritonavir (Antiviral) abbvie	**Marketed** (HIV)	Treatment	41	**Mar 2020**	Two Chinese trials, the RECOVERY trial, the Solidarity trial all did not show any evidence of efficacy	Improvement in patients in Australia and Thailand[4]	Both the RECOVERY and SOLIDARITY trials dropped Kaletra arms after concluding no benefits to severe / hospitalized patients[5]
Avigan favipiravir (Antiviral) FUJIFILM	**Investigational** (Influenza)	Treatment	34	**Mar 2020**	Positive results on viral load and clinical recovery in Chinese, Russian, and the 'Dhaka Trial'; but mixed results in several Japanese trials	Test dosages effective in mild and asymptomatic cases[6]	Conditional approval for COVID-19 in China[7] Russia temporarily approved favipiravir, for hospitalized cases[8] India approved for mild to moderate for restricted emergency use[9]

1. Based on CT.gov registered trials related to COVID-19 2. From CT.gov trial end dates. Actual read-out may be sooner 3. See "Compilation of published results" for full set of references
4. The Scientist, Tech Times 5. Recovery trial press release, WHO 6. GenEng News, MedRxiv 7. HospiMedica 8. RDIF 9. GlenmarkPharma 10. Japan Times

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – selected candidates overview

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

Compound/company		Description	Target/actual trial start date[1]
Monoclonal antibodies	VIR, WuXi Biologics, Biogen, gsk	Isolated monoclonal antibodies from **SARS survivors** to develop **VIR-7831 and VIR-7832**	Phase II/III for VIR-783 began in Aug[2]
	REGENERON	Cocktail of two different monoclonal antibodies (**REGN-COV2**) from COVID-19 survivors and genetically engineered mice.[3]	**Began phase II/III treatment trials** and phase III preventive trials in July[3]
	Lilly, AbCellera	Testing **Bamlanivimab (LY-CoV555)** and **LY-CoV016,** with several study designs in prevention and treatment of COVID. Previously announced plans for large-scale manufacturing (6/1/2020)[4,5]	**Phase III preventative trial** in nursing homes and assisted living facilities initiated in Aug 2020. **Phase II/III treatment** trials also launched in Aug 2020[4]
	CELLTRION	mAb candidate **CT-P59**; finished Phase I trials and plans to start manufacturing at-scale in September 2020[6]	**Phase II trials to begin late 2020**[6]
	AstraZeneca	2 mAb cocktail (**AZD7442**) licensed from Vanderbilt for both prophylaxis & treatment. Working with BARDA and DARPA, which includes manufacturing support for Ph I[7]	**Phase I trial launched in Aug 2020** with expected results by end of year[7]
	Lilly, 君实生物 TopAlliance	Antibody cocktail of **JS016** (incl. CB6) for both prophylaxis and treatment; the company announced they have secured capacity to serve 100,000 people by the end of 2020[8]; licensed Lonza's gene expression system GS Xceed[9]	**Phase I trial in China ongoing** **US phase I completed in October**; Phase II/III to start before end of 2020[8]
Polyclonal antibodies / plasma	Takeda, CSL Behring, ADMA BIOLOGICS, bpl, LFB, GC Pharma, Biotest, octapharma, Sanquin, biopharma	A coalition of 10 companies, led by Takeda and CSL, to develop a hyperimmune globulin (H-IG) based COVID-19 treatment called **CoVIg-19**	**Phase III trial started in October 2020**[10]

1. Publicly stated targets or actual start date of human trials 2. Pharmatimes 3. Fiercepharma, Fiercepharma 4. Eli Lilly, Lilly, NIAID, Medscape 5. Reuters 6. Reuters 7. Fiercebiotech 8. Reuters, Lilly 9. AP 10. CSL

Source: Milken Institute, BioCentury, CT.gov

B: COVID-19 virus-neutralizing antibodies – selected candidates deep dive

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

FDA Emergency Use Authorization issued | Directionally positive result | Directionally negative result

Company/Collaboration (Asset)	Description	Current Trials	Trial size (status)	Latest results
Lilly AbCellera **Bamlanivimab (LY-CoV555)** **(LY-CoV016)**	Neutralizing IgG1 monoclonal antibodies **directed against complementary regions of the spike protein of SARS-CoV-2** designed to block viral attachment and entry into human cells	**Phase II treatment trial (LY-CoV555 monotherapy arm)** in ambulatory patients (initiated June 2020)	2,400 patients (recruiting). Data from 452 mild/moderate patients	**US Phase II PoC data (Sept 2020):** LY-CoV555 significantly reduced the rate of hospitalization (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose.[1] **EUA granted on 11//9/2020[2]**
		Phase II treatment trial (LY-CoV555 + LY-CoV016 combination therapy arm) in ambulatory setting (initiated June 2020)	800 mild/moderate patients (recruiting). Data from 268 mild/moderate patients	For combo antibody arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[3]
REGENERON **(REGN-COV2)**	Cocktail of **two different monoclonal antibodies** (REGN-COV2) from **COVID-19 survivors** and genetically engineered **mice**	**Phase III preventative trial** for household contacts (initiated June 2020)	2,000 participants (recruiting)	**Analysis from ambulatory Ph I/II/III trial (Sept and Oct 2020):** REGN-COV2 reduced viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. The antibody also reduced medical visits by 57% overall compared to placebo, with a 72% reduction reported in high risk populations. **Applied for EUA on 10/7/2020[4,5]**
		Parallel phase I/II/III trials in hospitalized & ambulatory patients	2,970 moderate to severe hospitalized patients; 2,104 ambulatory patients (recruiting)	
VIR WuXi Biologics Biogen gsk **(VIR-7831/2)**	Isolated monoclonal antibodies from **SARS survivors** used to develop two assets: **VIR-7831 & VIR-7832**	**Phase II/III trial** for early treatment to prevent hospitalization (initiated Aug 2020)	1,360 patients with early symptoms (recruiting)	Early results of Ph II/III trial **expected late 2020**

1. Lilly 2. Lilly 3. Lilly 4. Regeneron 5. Regeneron

Source: Company press releases, CT.gov

C: COVID-19 immune modulators – selected candidates deep dive

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

Directionally positive result | Directionally negative result

Compound (Primary mode of action)	US Status (Licensed indication)	Use case[1]	Registered trials on CT.gov[2]	Earliest trial end date[3]	Initial clinical evidence[4]	Efficacy in isolated use?	Additional information
Actemra Tocilizumab (IL-6 inhibitor)	**Marketed** (RA)	Treatment - CRS	46	**May 2020**	Mixed. Some evidence of reducing progression to MV, mixed results in reduction of mortality	-	Prior approval for CRS; EU struck a deal to secure Actemra supplies for its member countries[5]
Kevzara Sarilumab (IL-6 inhibitor)	**Marketed** (RA)	Treatment – CRS, ARDS	10	**Jun 2020**	Correlated with worse outcomes for severe patients; No meaningful benefit for critical patients	-	Sanofi, Regeneron shut down trial after failed Ph III study[6]
Rebif (Interferon beta-1a)	**Marketed** (Multiple sclerosis)	Treatment - CRS	10	**Nov 2023**	-	-	Being tested in combination with remdesivir as part of NIH's ACTT 3 trial.[7]
Lenzilumab (anti-GM-CSF mAb)	**Under development** (multiple indications)	Treatment	2	**Sept 2020**	Topline data announcement expected in Q4 2020	-	Began Phase III trials in May 2020. Humanigen has partnered with Lonza, Thermo Fisher, and Catalent to manufacture drug.[8]
Olumiant baricitinib (JAK inhibitor)	**Marketed (**Rheumatoid Arthritis)	Treatment – COVID-19, CRS	11	**Apr 2020**	Study met primary endpoint yielding ~1 day reduction in median recovery time for patients treated with baricitinib in combination with remdesivir vs. remdesivir alone	-	Lilly launched Ph III in May 2020 to test baricitinib + remdesivir vs. remdesivir alone. Study also met a key secondary endpoint comparing patient outcomes at Day 15 using an ordinal 8-point scale ranging from fully recovered to death[9]

1. CRS - Cytokine Release Syndrome; ARDS - Acute Respiratory Distress Syndrome
2. Based on CT.gov registered trials related to COVID-19 as of July 13, 2020
3. Actual read-out may be sooner than CT.gov trial end date
4. See "Compilation of published results" for full set of references
5. Trieste All News
6. Sanofi
7. NIAID
8. Reuters, Fiercepharma
9. Lilly

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov

D: COVID-19 Cell, Gene, RNA therapy – selected candidates deep dive

Not comprehensive

Directionally positive result | Directionally negative result

	Compound (Primary mode of action)	US Status (Licensed indication)	Use case[1]	Registered trials on CT.gov[2]	Earliest trial end date[3]	Initial clinical evidence[4]	Efficacy in isolated use?	Additional information
Cell therapy	CYNK-001 (NK cells (placenta-derived)) sorrento THERAPEUTICS celularity	Under Development	Prophylaxis, Treatment – COVID-19	1	**Nov 2021**	-	-	Investigated to treat solid and hematological malignancies; shows potential against virally infected cells
	NK cells (various originators)	Under Development	Prophylaxis, Treatment – COVID-19	4	**Jun 2020**	-	-	-
	RAPA-501-ALLO *Rapa Therapeutics*	Under Development	Treatment – COVID-19	1	**Dec 2021**	-	-	-
RNA therapy	VIR-2703 VIR Alnylam	Under Development	Treatment – COVID-19	0	**-**	-	-	-
Stem cells	Mesenchymal Stem Cells	Under Development	Treatment – COVID-19, ARDS	46	**June 2020**	Improved outcomes in severe patients	7 patients in China (all discharged)[5]	Efficacy shown in human COPD study (same biomarker as COVID-19)
	Ryoncil remestemcel-L (MSC) mesoblast	Under Development	Treatment – ARDS	3	**April 2021**	Positive outcome in isolated use	-	-
	Adipose-derived mesenchymal stem cells Personalized Stem Cells CALiDi	Under Development	Treatment	0	**-**	-	-	Efficacy shown in human COPD study (same biomarker as COVID-19)

1. CRS - Cytokine Release Syndrome; ARDS - Acute Respiratory Distress Syndrome
2. Based on CT.gov registered trials related to COVID-19 as of July 13, 2020
3. Actual read-out may be sooner than CT.gov trial end date
4. See "Compilation of published results" for full set of references
5. IEEE Spectrum

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, Irish News, IEEE Spectrum

E: COVID-19 other therapeutics – selected candidates deep dive

CURRENT AS OF NOVEMBER 16, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

Directionally positive result | Directionally negative result

Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date	Initial clinical evidence[2]	Efficacy in isolated use?	Additional information
Cozaar (and Gx) MERCK Losartan (Antihypertensive)	**Marketed** (hypertension)	Treatment	10	**Oct 2020**	-	-	-
Dexamethasone (Steroid)	**Marketed** (inflamm-ation, allergy)	Treatment	16	**Jun 2020**	A large RECOVERY platform show reduced mortality; separate meta-analysis showed similar results[3,4]		UK approved the drug after the favourable RECOVERY trial result[3] Approved in Japan[5]
Methylprednisolone (Steroid)	**Marketed** (inflammation)	Treatment	19	**May 2020**	-	-	In Chinese study of n=200, seemingly reduced risk of death for ARDS patients
Prednisone (Steroid)	**Marketed** (various)	Treatment	6	**July 2020**	-	-	-
Colcrys Takeda Colchicine (Anti-mitotic)	**Marketed** (gout)	Treatment	20	**May 2020**	A small trial showed effect on preventing progression of the disease		-
Avastin Roche Bevacizumab (Angiogenesis inhibitor)	**Marketed** (cancers)	Treatment	3	**May 2020**	- -	- -	- -
Vitamin D	**Marketed**	Treatment	19	**Dec 2020**	-	-	-
Heparin (Anticoagulant)	**Marketed**	Treatment	18	**Jan 2021**	-	-	-
Nitric oxide (Vasodilator)	**Marketed** (PPHN, ARDS)	Treatment	18	**Sep 2020**	-	-	-

1.Based on CT.gov registered trials related to COVID-19 as of July 13, 2020 2. See "Compilation of published results" for full set of references 3. FiercePharma 4. StatNews 5. Reuters

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov

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Recent clinical trial results (1/2)

Not comprehensive

Directionally positive result Directionally negative result

Compound	Location	Publish Date	Size	Trial type	Study population	**Arms:** Dosing schedule	Results	Trial ID
Avigan (Favipiravir) FUJIFILM	Japan	September 2020	**156**	Randomized, controlled	COVID-19 patients with non-serious pneumonia	**Drug**: Favipiravir **Control**: Placebo	Favipiravir led to faster time to viral clearance vs placebo (11.9d vs 14.7d, respectively)[1]	
Actemra (Tocilizumab) Roche	USA	September 2020	**389**	Randomized, controlled	Hospitalized COVID-19 patients, 18 years or older, SpO2 <94% on room air, did not require noninvasive or invasive ventilation	**Drug**: tocilizumab **Control:** placebo	In a randomized, controlled trial, IL-6 inhibitor Actemra reduced relative progression to mechanical ventilation by 44% through 28 days compared to placebo (12.2% vs. 19.3%, respectively). However, several secondary endpoints were not met (incl. time to hospital discharge and mortality)[2]	NCT04372186
Bamlanivimab (LY-CoV555) **LY-CoV016** Lilly	USA	September and October 2020	**2,400**	Randomized, controlled	Patients in the outpatient setting with mild-to-moderate recently diagnosed COVID-19	Arm 1: **Drug**: LY-CoV555 (4 dose categories) **Control:** placebo	In PoC data of the Phase 2 randomized, double-blind, placebo-controlled trial (n=452), LY-CoV555 significantly reduced the rate of hospitalization (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose.[3]	NCT04427501
					Patients in the outpatients setting with mild-to-moderate recently diagnosed COVID-19	Arm 2: **Drug**: LY-CoV555 + LY-CoV016 **Control:** placebo	In interim Phase 2 data (n=268) for the combination antibody treatment arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[4]	
Bamlanivimab (LY-CoV555) **Remdesivir** Lilly	USA	October 2020	**326**	Randomized, controlled	Hospitalized patients with COVID-19, symptomatic for ≤12 days	**Intervention**: Remdesivir + LY-CoV555 **Control:** Remdesivir + placebo	On 10/26/2020, the Data and Safety Monitoring Board (DSMB) reviewed data (n=326) from the ACTIV-3 trial in hospitalized patients with COVID-19 on and recommended no further participants be randomized to receive LY-CoV555. This recommendation was based on a low likelihood that the intervention would be of clinical value in this hospitalized patient population[5]	NCT04501978

1. Fujifilm 2. Roche 3. Lilly 4. Lilly 5. NIH

Recent clinical trial results (2/2)

Not comprehensive

Directionally positive result Directionally negative result

Compound	Location	Publish Date	Size	Trial type	Study population	**Arms:** Dosing schedule	Results	Trial ID
REGN-COV2 REGENERON	USA	September 2020	**3,000**	Randomized, controlled	Patients with symptomatic recently diagnosed COVID-19 infection with symptoms ≤10 days, who have been hospitalized for ≤72 hours	**Drug**: REGN-COV2 + SoC **Control:** Placebo + SoC	In a preliminary descriptive analysis (n=275) of its adaptive Phase 1/2/3 randomized, controlled trial, the REGN-COV2 antibody cocktail treatment arm rapidly reduced viral load through Day 7 and reduced associated symptoms in infected COVID-19 patients[1] In prospective results from ongoing Phase II/III trials (n=799), Regeneron found that 2.8% of patients who received REGN-COV2 had a medical visit related to COVID-19 through Day 29, compared to 6.5% of individuals in the placebo group (p-value 0.024). In individuals older than 50 years old or BMI>30, the antibody produced a 72% reduction in medical visits. It was also noted that results indicated no significant difference in virologic or clinical efficacy between low and high doses (2.4g vs. 8g)[2]	NCT04426695

1. Regeneron 2. Regeneron

Public resources for pipeline compounds and clinical trials

Live lists of vaccine and therapeutic candidates

BioCentury

Milken Institute

Linksbridge (vaccine only)

Biorender

Live clinical trial aggregators

ReDo Project

Anticovid by Inato

COVID-Trials.org

IDM visualization of trial dates

Key changes in the vaccine landscape since last update

CSIRO published new research indicating that COVID-19 vaccines developed using the strains of the coronavirus that predominated in early 2020 are still **efficacious against newer, mutated strains** of coronavirus that are currently dominating transmission

The **CDC** plans to actively monitor for adverse events of a COVID-19 vaccine through a **digital surveillance program**, V-SAFE, which will include text messages and online surveys sent at intervals across the first six weeks following vaccine administration

AstraZeneca expanded its Phase 3 trial of AZD1222 further in the Americas. In the USA, the University Hospitals Cleveland Medical Centre joined a network of sites with a collective target of 30,000 participant enrollments in the study. The governments of Chile and Peru also approved commencement of Phase 3 AZD1222 clinical trials in their countries

Israel commenced Phase 1 clinical trials of its vaccine, **BriLife**, with the first doses administered to healthy volunteers to evaluate safety and immunogenicity. BriLife is a non-replicating viral vector vaccine, and Phase 2 trials are anticipated to commence in December

[Therapeutic] **Lilly** discontinued trials of an experimental **monoclonal antibody** therapy, bamlanivimab, as a stand-alone therapy in patients with mild to moderate COVID-19 after a review of results determined that it was not significantly helping patients. It will be continued as part of a trial of dual-antibody therapy with another Lilly candidate, etesevimab

Australia has agreements in place that potentially provide access to five leading COVID-19 vaccines candidates

Manufacturer supply agreement

Possible COVAX supported supply

DRAFT

Vaccine candidate	Trial Phase	Platform	Thermostability requirements	Doses to be supplied if successful[1]	Manufacturing
Oxford University /AstraZeneca (AZD1222)	Ph 3	Non-replicating viral vector	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**3.8M** doses by March 2021, additional **30M** doses by September Plus purchase option up to **50% population** coverage, via COVAX	**Offshore** via AZ (3.8M); **onshore** manufacturing agreement via CSL (30M doses)
UQ/CSL (Seqirus) V451	Ph 1	Protein subunit	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**51M** doses from mid-2021 Purchase option up to **50% population** coverage, via COVAX	**Onshore** manufacturing agreement via CSL
Novavax (NVX-CoV2373)	Ph 3	Protein subunit	**2-8°C** refrigerated cold chain in storage and at administration, duration not yet confirmed	**40M** doses, early-mid 2021 (TBC), option to purchase additional 10M Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
BioNTech/Pfizer mRNA (BNT162)	Ph 2/3	mRNA	**-70°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 1-2 days	**10M** doses, early-mid 2021 (TBC) Purchase option up to **50% population** coverage, via COVAX (TBC – EOI only)	**Offshore** manufacturing via COVAX
Moderna (mRNA-1273)	Ph 3	mRNA	**-20°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 7-14 days	Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX

1. Information to date indicates that all five vaccine candidates are likely to require two doses per person (subcutaneous or intramuscular injections, administered four weeks apart). COVAX option for AZD1222 is additional to directly negotiated supply agreement.
2. When thawed but not yet reconstituted; must be used within 6 hours (at room temperature) once reconstituted

There are additional candidates in Phase 3 trials that are not covered by Australian/COVAX supply agreements

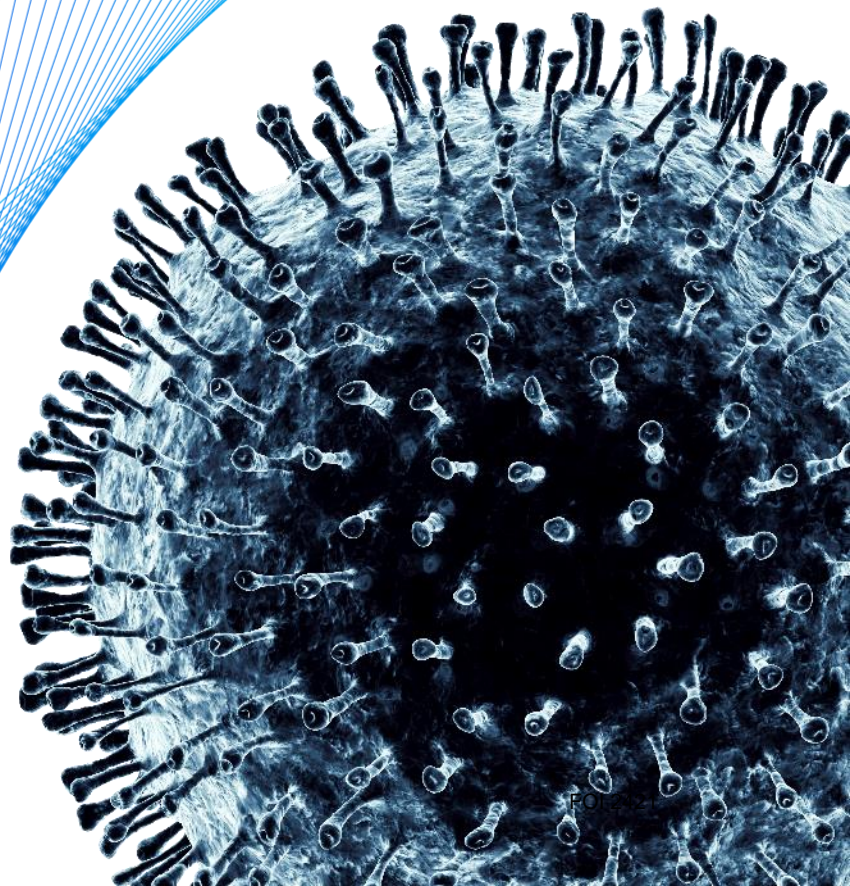
DRAFT

Vaccine candidate	Platform	Thermostability requirements	Notes
Johnson & Johnson (Ad26.COV2.S)	Non-replicating viral vector	2-8°C refrigerated cold chain in storage and at administration sites for 3 months	Only leading candidate with single-dose regimen BARDA-supported
Sinopharm	Inactivated virus	Unclear[1]	Chinese government supported

Two further candidates are currently in Phase III clinical trails, manufactured by CanSino Biological (China) and Gamaleya (China/Russia), however limited data are available

1. Likely 2-8°C refrigerated cold chain based on technology platform

COVID-19 Therapeutics and Vaccines Landscape Overview



October 29, 2020

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED PURELY ON CURRENT, PUBLICLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE

Document overview

To date, there is no **globally approved COVID-19 vaccine or treatment** available.

There are **over 275 vaccine candidates** and over **425 therapeutics candidates** in consideration.

This document and accompanying Excel trackers provide a **current snapshot of vaccine and therapeutic efforts for COVID-19.** They are based on **publicly available data** across candidate lists, clinical trial data and trial results.

Sources of insight:

- Multiple candidate lists (e.g. Milken Institute, BioCentury, WHO)
- Clinical trial registries (mainly CT.gov and ChiCTR)
- Press and literature searches

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Key changes in the vaccine landscape since last update

Preliminary results from the **AstraZeneca** trial, which are yet to be confirmed in detail, demonstrated that the vaccine **induced antibody production in older adults** comparable to that induced in younger adults, which may indicate efficacy in older populations.

The **AstraZeneca trial was resumed** in the US after pausing to investigate an unexplained illness in a trial participant. It was reported that a participant experienced a “neurological event”, but an investigation determined that this was unlikely to be related to the vaccine administered.

A 28-year-old Brazilian man enrolled in the **AstraZeneca** trial died unexpectedly. It was reported that he received a placebo, rather than the active dose of the vaccine being tested, and the trial was not paused to investigate this further.

The **Johnson & Johnson trial was resumed** in the US after pausing to investigate an unexplained illness in a trial participant. It was reported that a participant suffered a stroke, but an investigation determined that this was unlikely to be related to the vaccine administered.

Moderna completed enrollment of 30,000 participants in its Phase 3 clinical trial. The trial slowed enrollment in order to recruit **participants from diverse backgrounds**, reflecting the broader population and ensuring that key populations disproportionately at risk from COVID-19 (including minority ethnic groups and older adults) are adequately represented. All participants have received their first vaccine dose, and most have received their second.

An **intranasal COVID-19 vaccine** in development by the **University of Alabama** effectively induced an immune response in **mice**. However, this vaccine remains in very early stages of trials, and has not yet been tested in humans.

Chinese government officials reported that the **SinoPharm** vaccine has been tested on 60,000 people, including students and government employees, with only “slight adverse events”. Detailed results data were not provided.

Australia has agreements in place that potentially provide access to five leading COVID-19 vaccines candidates

Manufacturer supply agreement

Possible COVAX supported supply

Vaccine candidate	Trial Phase	Platform	Thermostability requirements	Doses to be supplied if successful[1]	Manufacturing
Oxford University /AstraZeneca (AZD1222) AstraZeneca UNIVERSITY OF OXFORD	Ph 3	Non-replicating viral vector	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**3.8M** doses by March 2021, additional **30M** doses by September Plus purchase option up to **50% population** coverage, via COVAX	**Offshore** via AZ (3.8M); **onshore** manufacturing agreement via CSL (30M doses)
UQ/CSL (Seqirus) V451 THE UNIVERSITY OF QUEENSLAND AUSTRALIA CSL	Ph 1	Protein subunit	**2-8°C** refrigerated cold chain in storage and at administration sites for 6 months	**51M** doses from mid-2021	**Onshore** manufacturing agreement via CSL
Novavax (NVX-CoV2373) NOVAVAX Creating Tomorrow's Vaccines Today	Ph 3	Protein subunit	**2-8°C** refrigerated cold chain in storage and at administration, duration not yet confirmed	Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
Moderna (mRNA-1273) moderna	Ph 3	mRNA	**-20°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 7-14 days	Purchase option up to **50% population** coverage, via COVAX	**Offshore** manufacturing via COVAX
BioNTech/Pfizer mRNA (BNT162) BIONTECH Pfizer	Ph 2/3	mRNA	**-70°C** freeze chain in storage for 6 months, 2-8°C[2] refrigerated cold chain at administration sites for 1-2 days	Purchase option up to **50% population** coverage, via COVAX (TBC – EOI only)	**Offshore** manufacturing via COVAX

1. Information to date indicates that all four vaccine candidates are likely to require two doses per person (subcutaneous or intramuscular injections, administered four weeks apart). COVAX option for AZD1222 is additional to directly negotiated supply agreement.
2. When thawed but not yet reconstituted; must be used within 6 hours (at room temperature) once reconstituted

There are additional candidates in Phase 3 trials that are not covered by Australian/COVAX supply agreements

Vaccine candidate	Platform	Thermostability requirements	Notes
Johnson & Johnson (Ad26.COV2.S)	Non-replicating viral vector	2-8°C refrigerated cold chain in storage and at administration sites for 3 months	Only leading candidate with single-dose regimen BARDA-supported
Sinopharm	Inactivated virus	Unclear[1]	Chinese government supported

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1. Likely 2-8°C refrigerated cold chain based on technology platform

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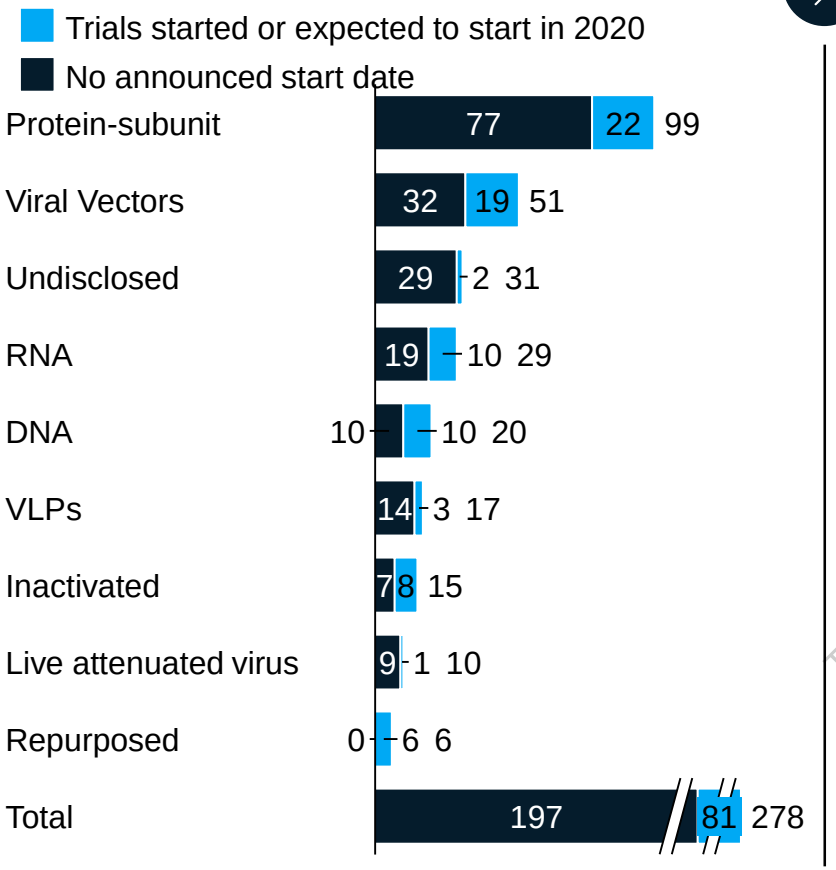
COVID-19 vaccines development effort overview

278 vaccines are currently in development

Pipeline overview



Recent developments – Oct 8 - 29, 2020

J&J announced it is resuming its late-stage vaccine trial, which had been paused earlier this month over safety concerns. Results from that study are expected by end of the year.[1]

AZ has received approval from the FDA to continue the US arm of its Phase 3 trial. This follows previous authorizations to restart clinical trials in the UK, Brazil, India, Japan and South Africa. [2]

Novavax is delaying the start of its late-stage study in the US to November, due to delays in manufacturing scale-up. Interim data from its UK phase 3 trial is expected by early 2021.[3]

A lower-than-expected number of COVID-19 infections in Pfizer's phase 3 vaccine trial means data aren't yet ready for an interim analysis, pushing a readout into the first week of November at the earliest. CEO Albert Bourla said the company still hopes to launch its vaccine by year-end. [4]

The European Medicines Agency (EMA) may accept a vaccine that works in less than 50% of patients, as long as the benefits outweigh the safety risks. The EMA guidance differs from that of the FDA, which requires at least 50% efficacy for EUA approval.[5]

California, Washington, Oregon, Nevada and New York are planning to conduct independent evaluations of FDA-approved vaccines, citing public concern over the FDA approval process.[6,7]

Russia has approved a second Covid-19 vaccine, developed by the Vector State Virology and Biotechnology Center. No clinical trial data have been released.[8]

1. Endpoints
2. AstraZeneca
3. Reuters
4. FiercePharma
5. WSJ
6. Reuters
7. NYT
8. The Moscow Times

Source: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR

There are 278 candidates in the pipeline for COVID-19 vaccines

	Description	Example companies / compounds	Number of candidates profiled[1]
RNA	**Nucleic acid RNA** packaged within a vector (e.g. lipid nanoparticles).	moderna, BIONTECH, Pfizer	29
DNA	**Plasmid containing the DNA sequence encoding the antigen(s)** against which an immune response is sought	inovio	20
Inactivated	Killed version of the virus that causes the disease, providing shorter-term protection and requiring boosts	sinovac, SINOPHARM	15
Viral vectors	**Chemically weakened** virus to transport pieces of the pathogen – usually antigen coding surface proteins	CanSinoBIO, MERCK, Johnson & Johnson	51
Attenuated virus	**Weakened virus** to stimulate immune response	INDIAN IMMUNOLOGICALS LIMITED	10
VLPs	Virus-like-particles - **molecules that closely resemble viruses**, but are non-infectious because they contain no viral genetic material	medicago, vbi	17
Protein subunit	**Purified or recombinant proteinaceous antigens** from a pathogen to elicit immune response. Some assets employ a nanoparticles-delivery system for enhanced antigen presentation	NOVAVAX, gsk, SANOFI	99
Repurposed	Repurposed vaccines already on the market		6
Undisclosed[2]	Additional candidates with little public information	SaudiVax, HOTHTHERAPEUTICS	31

Not covered in this document

1. Compiled across multiple lists (Milken Institute, BioCentury, WHO, Nature) and supplemented with press
2. Not profiled moving forward. Vaccine type cannot be delineated due to lack of public information; typically in research setting or small biotech

Source: Milken Institute, BioCentury, WHO, Nature

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56 COVID-19 vaccine candidates are currently undergoing clinical trials (1/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
RNA	Moderna	mRNA-1273	NIAID, Lonza, Catalent, ROVI	USA	CEPI, NIAID, BARDA	Phase III	Jul-20	30,720
	BioNTech	BNT162	Pfizer and Fosun Pharma, Polymun	Germany, USA,S. Africa Argentina, Brazil Turkey, China, Japan		Phase1/ II/III	Jul-20	44,880
	Imperial College London	LNP-nCoVsaRNA	UK Government	UK		Phase I	Jun-20	320
	CureVac	CVnCoV	CEPI, European Commission; Gates Foundation; DARPA	Germany, Panama, Peru	German gov.	Phase II	Sep-20	859
	Walvax Biotechnology	ARCoV	People's Liberation Army, Academy of Military Sciences	China		Phase I	Jun-20	168
	Arcturus Therapeutics	LUNAR-COV19	Duke-NUS Medical School	Singapore	Singapore	Phase I/II	Aug-20	92
	Chulalongkorn University	ChulaCov19		Thailand		Phase I	Sep-20	96
DNA	Genexine	GX-19	Binex, GenNBio, Korea Advanced Institute of Science and Technology, Pohang University of Science and Technology	South Korea	IVI	Phase I/II	Jun-20	210
	Aivita Biomedical, Inc.	AV-COVID-19		USA		Phase I/II	Jul-20	280
	Inovio	INO-4800	Beijing Advaccine Biotechnology, Ology Bioservices	USA, S. Korea	CEPI, BMGF	Phase I/II	Jun-20	280
	Zydus Cadila	nCov vaccine		India		Phase I/II	Jul-20	1048
	AnGes	AG0301-COVID19, AG0302-COVID19	Osaka University and Takara Bio	Japan		Phase I/II	Aug-20	60
	Symvivo	bacTRL-Spike		Australia		Phase I	Oct-20	12
	Entos Pharmaceuticals	Covigenix VAX-001	Cytiva, CIHR	Canada		Phase I/II	Nov-20	72

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (2/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Inactivated	Sinovac Biotech	CoronaVac (previously PiCoVacc)	Dynavax	Brazil, Indonesia, Turkey	Bank of Beijing	Phase III	Jul-20	25,208
	Sinopharm		Beijing Institute of Biological Products, Wuhan Institute of Biological Products	UAE, Bahrain, Jordan		Phase III	Jul-20	48,584
	Chinese Academy of Medical Sciences		Institute of Medical Biology,	China		Phase I/II	Jul-20	1,413
	Republic of Kazakhstan		Research Institute for Biological Safety Problems, National Scientific Center for Pulmonology	Kazakhstan	Kazakhstan government	Phase I	Sept -20	244
	Bharat Biotech	BBV152		India		Phase I/II	Jul-20	879
	Beijing Institute of Biological products Co. Ltd	Vero cell	China National Biotec Group Company Ltd, The Huesped Foundations	Argentina		Phase III	Sep-20	3,000
	Shenzhen Kangtai Biological Products Co.,Ltd.; Beijing Minhai Biotechnology Co., Ltd.	Vero cell	Jiangsu Provincial Center for Disease Control and Prevention(Public Health Research Institute of Jiangsu Province)	China		Phase I	Oct-20	180
Viral vectors	University of Oxford (Jenner Institute)	AZD1222 / ChAdOx1 nCoV-19	AstraZeneca, Advent SRL manufacturer, MilliporeSigma, Cobra Biologics, Emergent Biosolutions, Catalent	UK, Brazil, S. Africa[1] , India, US, Russia, Japan	UK gov't	Phase III	Jun-20	55,532
	CanSino Biologics	Ad5-nCoV	Institute of Biotechnology at China's Academy of Military Medical Sciences	China, Russia, Pakistan	Chinese government	Phase III[3] Phase III[4]	Sept -20 Sept -20	42,285 168
	Gamaleya Research Institute	Sputnik V		Russia, Belarus[2]		Phase III	Aug- 20	40,286

1. Reuters 2. Two formulations of the same asset in trials in two separate locations 3. Approved for Military use in China; total participants includes pediatric Ph IIb trial 4. Trial for 2 dose regimen CT.gov

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (3/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Viral vectors (cont.)	Johnson & Johnson	Ad26.COV-2.S	Beth Israel Deaconess Medical Center	USA, Japan Belgium, Brazil	BARDA	Phase III	Sept-20	61,295
	Shenzhen University	COVID-aAPC	Shenzhen Second and Third People's Hospitals	China	Chinese gov.	Phase I	Feb-20	100
	Institut Pasteur	TMV-083	Themis (Merck)	France, Belguim	CEPI	Phase I	Aug-20	90
	ReiThera	GRAd-COV2	LEUKOCARE, Univercells	Italy		Phase I	Aug-20	90
	Merck/MSD	V591	Themis	Belgium		Phase I/II	Aug-20	260
	Merck/MSD	V590	Themis			Phase I	Oct-20	252
	Beijing Wantai Biological Pharmacy Enterprise	DelNS1-2019-nCoV-RBD-OPT1		China		Phase I	Sep-20	60
	Vaxart	VXA-COV2-1		USA		Phase I	Sep-20	48
	Jiangsu Province Centers for Disease control	Adeno Type 5 virus		China		Phase I	Sep-20	89
	Universitätsklinikum Hamburg-Eppendorf	MVA-SARS-2-S	German Center for Infection Research, Philipps University Marburg Medical Center	Germany		Phase I	Oct- 20	30
	ImmunityBio	hAd5-S-Fusion+N-ETSD	NantKwest	USA		Phase I	Oct-20	35
VLPs	Medicago		Laval University's Infectious Disease Research Centre	Canada	Canadian gov't	Phase I	Jul-20	180
	SpyBiotech	HBsLVP	Serum Institute of India	Australia		Phase I/II	Sep-20	N/A[1]

1. SpyBiotech

Source: clinicaltrials.gov, press search

56 COVID-19 vaccine candidates are currently undergoing clinical trials (4/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Protein-subunit	Anhui Zhifei Longcom Biopharmaceutical		Institute of Microbiology, Chinese Academy of Sciences	China		Phase II	Jul-20	1,000
	Clover Biopharmaceuticals[1]	SCB-2019	GSK/Dynavax	Australia		Phase I	Jun-20	150
	Vaxine Pty Ltd		Flinders University, Oracle	Australia		Phase I	Jun-20	40
	Novavax	NVX-CoV2373	Emergent BioSolutions, Praha Vaccines, Serum Institute of India	Australia, South Africa, USA, UK	CEPI	Phase III	Aug- 20	12,035
	University of Queensland		GSK, Dynavax, CSL (Parkville, Australia), Viroclinics Xplore	Australia	CEPI, Queensland, Austrialian gov't, Paul Ramsay Foun.	Phase I	Jul-20	216
	Federal Budgetary Research Institution "Vector"	EpiVacCorona		Russia		Phase I/II	Jul-20	100
	Sanofi Pasteur		GSK	USA		Phase I/II	Sept-20	440
	Jiangsu Province Centers for Disease Control	Sf9 Cell	West China hospital	China		Phase I	Aug-20	168
	AdImmune	AdimrSC-2f		Taiwan		Phase I	Aug-20	70
	Medigen	MVC-COV1901	NIAID & Dynavax	Taiwan		Phase I	Aug-20	45
	University Hospital Tuebingen	pVAC		Germany		Phase I	Sept-20	36
	United Biomedical Inc. Asia	UB-612	COVAXX	Taiwan		Phase I	Sept-20	60
	Finlay Vaccine Institute			Cuba		Phase I/11	Sept-20	676

1. Clover is testing three different versions of the vaccine, including two that use unique adjuvants, in this trial

Source: clinicaltrials.gov, press search

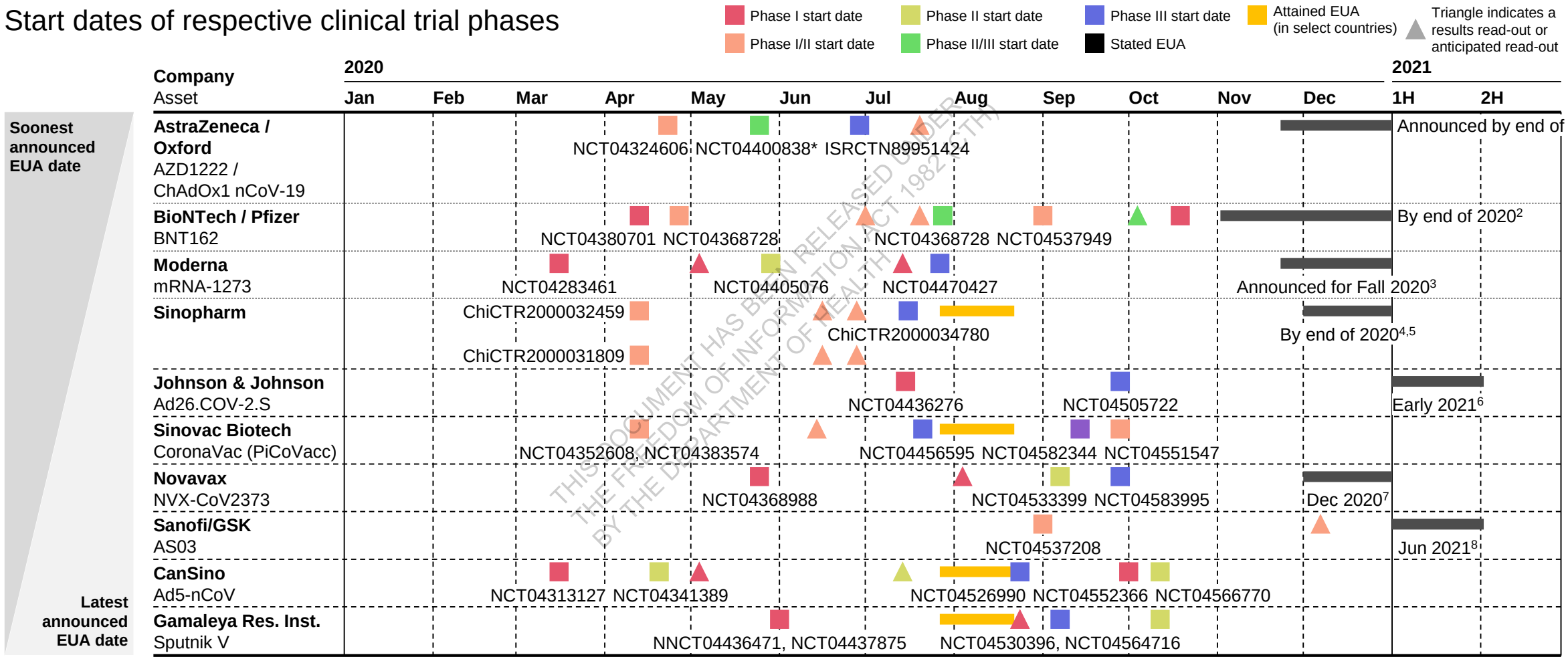
56 COVID-19 vaccine candidates are currently undergoing clinical trials (5/5)

Platform	Company / group	Asset	Collaborators	Country	Other funding / govt' involvement	Current dev. phase	Official start date	Cum. trial participants
Repurposed	Several	BCG vaccine		Australia, Brazil, Colombia, Denmark, Egypt, France, Netherlands, South Africa, USA		Phase III/IV	March-20 to Sep-20	20,090
	Kasr El Aini Hospital	Measles vaccine		Egypt		Phase III	May-20	200
	Immunovative Therapies	AlloStim	Mirror Biologics	USA		Phase I/II- Delayed	Oct-20	40
	Canadian Cancer Trials Group	IMM-101	Immudolon Tx, BioCan Rx, CSSRI, AtGen, ARCC	Canada		Phase III	Jul-20	1500
	Oklahoma Medical Research Foundation	Shingrix vaccine		USA		Phase I	Sep-20	250
	NeuroActiva Inc. & Biomed Industries Inc.	Oral Polio vaccine		USA		Phase III	Nov-20	3600

Source: clinicaltrials.gov, press search

Select vaccine candidates currently in Phase III or Phase II/III or have announced potential EUA timelines

Start dates of respective clinical trial phases



1. Reuters
2. CIDRAP
3. Moderna press release
4. Reuters
5. PBR
6. FiercePharma
7. Reuters
8. SEC filing

* indicates an estimated start date as trial has not yet officially commenced

Source: Milken Institute COVID-19 Tracker, clinicaltrials.gov, BioCentury, press search

Design elements for select efficacy trials (e.g., Phase 2/3 or 3)

Outside-in view based on media coverage and published trial design if available; trials, timing, and EUA are estimates and subject to change

	moderna	Pfizer BioNTech	The Jenner Institute, University of Oxford	AstraZeneca	J&J	sinovac	SINOPHARM	NOVAVAX Creating Tomorrow's Vaccines Today
	Phase III	**Phase I/II/III**	**Phase II/III**	**Phase III**	**Phase III**	**Phase III**	**Phase III**	**Phase III**
Start	July 27, 2020	July 27, 2020	May 2020	June 28, 2020	Sept 5, 2020	July 2, 2020 Sept 14, 2020	July 16, 2020	Sep 28, 2020
MoA	mRNA	mRNA	Viral vector		Viral vector	Inactivated virus	Inactivated virus	Protein subunit
Dose schedule	2 doses	2 doses	1 or 2 doses for adults, ped, elderly	1 dose	1 dose	2 doses	2 doses	2 doses
Dose levels	1 dose level, 100 micrograms	1 dose level, 30 micrograms	1 dose level for adults and ped., 2 for elderly	1 dose level	1 dose level (1x10^11 viral particles)	1dose level	1 dose level	1 dose level
Efficacy target	60%	60%	50%	50%	60%	Unknown	Unknown	Unknown
Trial size	30,720	44,880	12,330	37,100	60,000	19,490	48,584	9,000
Site geography	USA	Germany, USA, S. Africa, Argentina, Brazil Turkey, China, Japan	UK	US, Brazil, S. Africa, India	USA, Argentina, Brazil, Chile, Colombia, Mexico, Peru, Philippines, S. Africa, Ukraine	Brazil, Indonesia, Turkey	UAE, Bahrain	UK
Temperature conditions	-20°C shipped /stored for 6 months; 2-8°C for 7 days	-70°C shipped /stored for 6 months; 2-8°C for 24-48 hours	2-8°C; normal cold chain		2-8°C; normal cold chain for 3 months	Unknown	Unknown	Unknown
Special populations	None (adults 18+)	Ex-EU: Age 12+ EU: Age 18+ Phase 3 includes HIV patients	Elderly, pediatric	Pediatric	None (adults 18+)	Adult, Elderly & pediatric arms, healthcare workers	None (adults 18+)	None (adults 18+); seasonal flu vaccine

Source: clinicaltrials.gov, press search

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Compilation of published or pre-released clinical trial results (1/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Sinovac CoronaVac (previously PiCoVacc)	In-activated	Phase I/II	Double blind prospective RCT	Interim Phase II readout	August 10, 2020	• Reported that the vaccine candidate appeared to be safe and induced detectable antibody-based immune responses	NCT04383574
AstraZeneca/ Oxford AZ1222	Viral Vector	Phase III	Single blind prospective RCT	Interim Phase I/II readout	July 20, 2020	• "Neutralising antibodies were generated in more than 90% of participants across different assays. Responses were sustained up to 56 days of observation."[4] • "No serious adverse events occurred."	NCT04324606
Gamaleya Research Institute	Viral vector	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 4, 2020	• All trial participants (76 adults) elicited an antibody response within 21 days and no serious adverse events after 42 days. The vaccine also produced a T-cell response within 28 days, a secondary outcome[3]	NCT04436471, NCT04437875
Moderna mRNA1273	RNA	Phase III	Non-randomized, open label prospective trial	Interim Phase I readout	Sept 29, 2020	• Follow-up results showed promising data for older adults – by day 57, among the participants who received the low dose, the geometric mean titer (GMT) was 323,945 among those between the ages of 56 and 70 years and 1,128,391 among those who were 71+ years • Among the participants who received the high dose, the GMT in the two age subgroups was 1,183,066 and 3,638,522, respectively • Binding- and neutralizing-antibody responses appeared to be similar to those among vaccine recipients between the ages of 18 and 55 years • The vaccine elicited a strong CD4 cytokine response involving type 1 helper T cells.	NCT04283461

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (2/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Inovio INO-4800	DNA	Phase I	Non-randomized, open label prospective trial	Interim Phase I readout	August 10, 2020	• 100% of trial participants demonstrated overall immune responses • 95% had seroconverted by antibody response overall • Nearly 90% generated strong T cell responses, including CD8+ T cell responses	NCT04336410
CanSino Ad5-nCoV	Viral Vector	Phase II	Non-randomized, open label prospective trial	Interim Phase I readout	May 22, 2020	• Reported mean neutralizing titers of 34 in its high-dose group, below FDA recommendations of 160 • Single dose elicited a four-fold increase in binding antibodies to RBD in 94–100% of participants, and a four-fold increase to live virus in 50–75% of participants	NCT04313127
			Randomized, observer-blinded prospective trial	Interim Phase II readout	July 20, 2020	• One injection of non-replicating adenovirus-vectored COVID-19 vaccine with two concentrations • "Seroconversion occurred in more than 96% of participants, and neutralising antibodies were generated in about 85%. More than 90% had T-cell responses."	NCT04398147
Novavax NVX-CoV2373	Protein subunit	Phase I/II	Randomized quadruple blind placebo controlled trial	Full Phase I readout	Sept 2, 2020	• 100% of participants developed wild-type virus neutralizing antibody responses after Dose 2; Both 5 and 25mcg doses generated GMT greater than 1:3,300; Anti-spike IgG & viral neutralization compared favorably to responses from patients with clinically significant COVID disease. Cellular immune responses demonstrated in a subset of patients. No severe AEs reported	NCT04368988

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (3/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
Pfizer / BioNTech BNT 162	RNA	Phase II/III	Randomized triple blind placebo controlled trial	Interim Germany Phase I/II readout	July 20, 2020	• BNT162b1 elicited strong CD4+ and CD8+ T cell responses against SARS-CoV-2-receptor binding domain (RBD), compared to baseline[2] • The RBD-specific, interferon-γ+, IL-2+, CD8+ T cells elicited by BNT162b1 in immunized participants indicate a strong potential for cell mediated anti-viral activity • T cell cytokine profile shows vaccine elicited T cells exhibit a Th1 phenotype, which is associated with antiviral propertie	NCT04368728
				Interim US Phase I/II readout	August 20, 2020	• BNT162b2 elicited SARS-CoV-2–neutralizing GMTs in younger adults (18-55 years of age) that were 3.8 times the GMT of a panel of 38 sera of SARS-CoV-2 convalescent patients, and in older adults (65-85 years of age) the vaccine candidate elicited a neutralizing GMT 1.6 times • Well tolerated with mild to moderate fever in fewer than 20% of participants	NCT04368728
Sinopharm BBIBP-CorV	In-activated	Phase I/II	Randomized double blind placebo controlled trial	Interim Phase I/II readout	August 14, 2020	• The trial linked the vaccine to increases in antibody titers. It is not clear whether the response is likely to confirm immunity as the study did not include a comparison arm featuring serum samples from patients previously infected with the coronavirus	ChiCTR-2000032459

Source: Company press releases & associated published literature

Compilation of published or pre-released clinical trial results (4/4)

Sponsor / Asset	Platform type	Development phase	Trial type	Results type	Results date	Results	Trial ID
J&J JNJ-78436735	Viral vector	Phase III	Randomized triple blind placebo controlled trial	Interim Phase I/II readout	Sept 28, 2020	• After only a single dose, seroconversion rate at day 29 after immunization in cohort 1a already reached 92% with GMTs of 214 and 92% with GMTs of 243 for the low and high dose levels, respectively.	NCT04436276

Source: Company press releases & associated published literature

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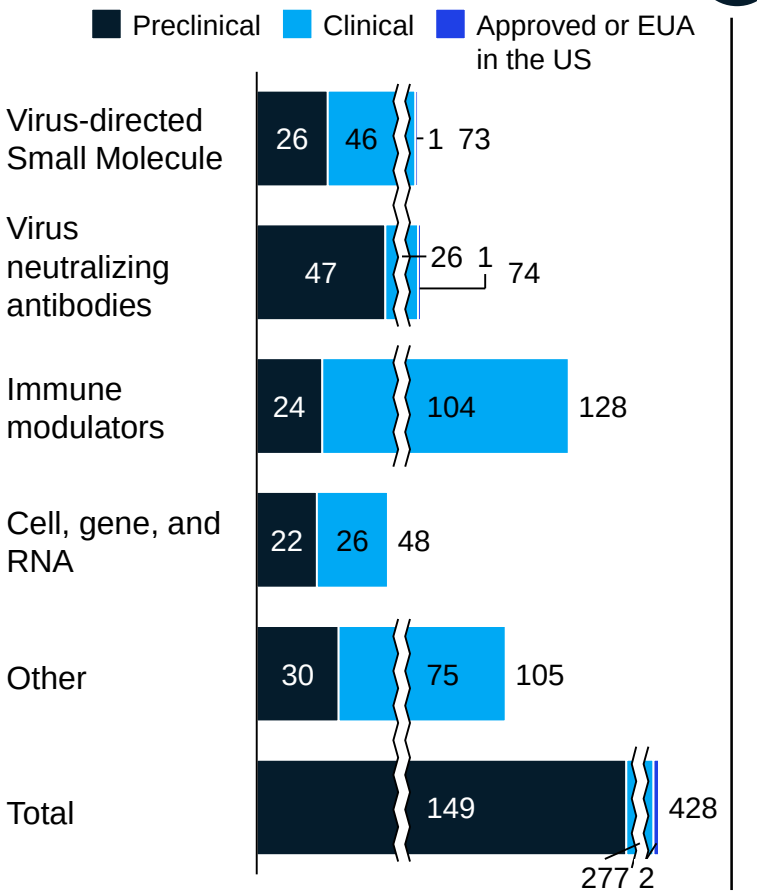
COVID-19 Therapeutics landscape update

Pipeline snapshot

Number of candidates[1]



Recent developments – Oct 8 - Oct 29, 2020

Phase II/III data from Regeneron REGN-COV2 indicate that the drug **decreased COVID-related medical visits by 57%** in 29 days post-treatment (2.8% vs. 6.5% in placebo group).[2]

The NIH halted its combination trial of Eli Lilly's LY-CoV555 antibody and Remdesivir citing a lack of benefit in hospitalized patients. The decision comes after the trial was paused earlier in October over safety concerns, although an independent review found similar safety outcomes for intervention and placebo arms of the trial[3]

The US government and Eli Lilly agreed to a $375M USD deal to supply 300,000 vials of LY-CoV555. The agreement is contingent on EUA approval and contains an option to purchase 650,000 more vials through June 2020[4]

Gilead obtained FDA approval for Veklury (remdesivir) in the treatment of adult and pediatric COVID-19 patients requiring hospitalization. The FDA referenced data from three randomized, controlled clinical trials, including an NIAID trial showing that Veklury significantly improved time to recovery as compared to placebo. Interim results from the WHO SOLIDARITY trial had previously suggested that remdesivir 'appeared to have little or no effect on hospitalized COVID-19'[5,6,7]

Key takeaways

Over 425 candidates are being considered across a range of modalities and use cases. **Remdesivir and Dexamethasone** are two drugs with clinically proven benefits.

None have been approved globally for COVID-19, but some countries approved specific drugs (not comprehensive):

- **Veklury (remdesivir)** is approved in the US,[6] EU, Japan, Taiwan, India, UAE, Australia, and Singapore, UK, and Canada[8]
- **Favipiravir** is approved in China, India, and Russia[9]
- **Coronavir** is approved in Russia[10]
- **Dexamethasone** is approved in Japan and the UK and provisionally approved in Taiwan[11]
- **Itolizumab** is approved for emergency use in India[12]
- **Convalescent plasma** from COVID-19 patients received emergency use authorization in the US[13]

1. Clinical trial information may not have been captured if not registered at CT.gov or published otherwise
2. Regeneron 3. NIH 4. Lilly 5. Gilead 6. FDA 7. medRxiv
8. Gilead, Reuters, Reuters, Reuters, Press, Department of Health , Reuters, gov.uk 9. RDIF, HospiMedica, PMlive
10. CGTN 11. Fiercepharma; Reuters 12. Indiatvnews 13. FDA, STATNews

Source: Milken Institute, BioCentury, WHO, Nature, CT.gov, ChiCTR, press as of July 14, 2020

There are over 425 candidates in the pipeline for COVID-19 therapeutics

CURRENT AS OF OCTOBER 29, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

F| Not covered in this document

		Description	Candidates profiled	Example candidates/companies
A| Virus-directed small molecule		**Largely repurposed** compounds, including **antivirals** (HIV, Influenza), **antimalarials**, **antiprotozoals**, and more	73	Remdesivir, Kaletra, Chloroquine
B| Antibodies (to neutralize virus)	**Monoclonal antibodies** (mAbs)	**New development** using **survivor samples**, **genetically engineered** mice and **synthetic routes**; often a cocktail	74	
	Polyclonal antibodies / plasma	**New development** using **survivor plasma** (convalescent plasma) or **genetically engineered** cows for hyper-immunized globulin. Also called plasma-derived therapy or IVIG.		
C| Immune modulators		**IL inhibitors**, alpha or beta-**interferon** and other therapies often **repurposed**. Targets host immune response with severe and critical disease (e.g. cytokine release syndrome)	128	Actemra, Kevzara
D| Cell, gene and RNA therapies		**Stem cells**, **T-cells**, cord blood cells and **RNA-based** therapies	48	remestemcel-L, siRNA
E| Other		**Steroids, surfactants**, **oxygen carriers, immunotherapies,** and other modalities not included in the above	105	Losartan, Methylprednisolone, Bevacizumab
F| Traditional Chinese Medicine		Traditional **herbal formulas and medicines**	n/a	maxingshigan-yinqiaosan

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech

A: COVID-19 virus-directed small molecule – selected candidates deep dive (1/2)

CURRENT AS OF OCTOBER 29, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Directionally positive result | Directionally negative result

Not comprehensive

FDA Emergency Use Authorization issued

Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date[2]	Initial clinical evidence[3]	Efficacy in isolated use?	Additional information
Remdesivir (Antiviral) GILEAD	**Under development** (Ebola, SARS)	Treatment	28 *2 terminated due to low enrollment[8]*	**May 2020**	Positive Gilead and NIAID-sponsored results in moderate / severe patients, conflicting with the earlier Chinese trial	Improvement in compassionate use cases in US and other countries[4]	Approved approval in US, EU, Japan, Taiwan, India, Singapore, Australia and UAE[5] Planning a trial for paediatric use and inhalant version[6]
Chloroquine (Antimalarial)	**Marketed** (Malaria)	Prophylaxis, Treatment	26	**Apr 2021** (prophy) **Apr 2020** (treatment)	A large observational study showed increased mortality and cardiac arrhythmias, with or without macrolide		In-vitro SARS-CoV-2 efficacy data Used off-label for treatment and prophylaxis of Zika
Hydroxy-chloroquine (Antimalarial)	**Marketed** (Malaria)	Prophylaxis, Treatment	199	**May 2020** (prophy) **May 2020** (treatment)	Randomized trials in general have not found any benefit in treating hospitalized or non-hospitalized patients; no evidence of Prophylactic benefit However, mixed results from a couple of studies	Improvement in Japanese patient and patients in Australia[7,8]	FDA revoked EUA for COVID patients.[9] France also revoked its authorization of HCQ.[10] Italy also banned the drug's use outside of clinical trials and the UK has put limits on the use[11] WHO and NIH halted HCQ trials[12]
Azithromycin (Antibiotic)	**Marketed** (Bacterial infection)	Treatment	70	**May 2020**	Mixed results on viral clearance from small-mid size French studies and Brazilian study		Widely used for chest infections, pneumonia

1. Based on CT.gov registered trials related to COVID-19 2. From CT.gov trial end dates. Actual read-out may be sooner 3. See "Compilation of published results" for full set of references 4. CDC. Gilead 5. Gilead, Reuters, Reuters, Reuters, Press , FDA, EMA, health.gov.au, Reuters 6. Endpoint News 7. Pharma Japan 8. The Scientist, Tech Times 9. FDA 10. France24 11. Pharmafile 12. STAT, Fierce Pharma

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

A: COVID-19 virus-directed small molecule – selected candidates deep dive (2/2)

CURRENT AS OF OCTOBER 29, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Directionally positive result
Directionally negative result

Not comprehensive

Licensed for Gx import by Israel Health Ministry

Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date[2]	Initial clinical evidence[3]	Efficacy in isolated use?	Additional information
Kaletra lopinavir, ritonavir (Antiviral) abbvie	**Marketed** (HIV)	Treatment	41	**Mar 2020**	Two Chinese trials, the RECOVERY trial, the Solidarity trial all did not show any evidence of efficacy	Improvement in Thai patient and patients in Australia[4]	Both the RECOVERY and SOLIDARITY trials dropped Kaletra arms after concluding no benefits to severe / hospitalized patients[5]
Avigan favipiravir (Antiviral) FUJIFILM	**Investigational** (Influenza)	Treatment	33	**Mar 2020**	Positive results on viral load and clinical recovery in Chinese, Russian, and the 'Dhaka Trial'; but mixed results in several Japanese trials	Test dosages effective in mild and asymptomatic cases[6]	China aproved for COVID[7] Russia temporarily approved Avifavir, for hospitalized cases[8] India approved for mild to moderate for restricted emergency use[9]

1. Based on CT.gov registered trials related to COVID-19 2. From CT.gov trial end dates. Actual read-out may be sooner 3. See "Compilation of published results" for full set of references
4. The Scientist, Tech Times 5. Recovery trial press release, WHO 6. GenEng News, MedRxiv 7. HospiMedica 8. RDIF 9. GlenmarkPharma

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, CDC, Gilead, Pharma Japan, The Scientist, Tech Times, GenEng News

B: COVID-19 virus-neutralizing antibodies – selected candidates overview

CURRENT AS OF OCTOBER 29, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

Compound/company		Description	Target /actual trial start date[1]
Monoclonal antibodies	VIR, WuXi Biologics, Biogen, gsk	Isolated monoclonal antibodies from **SARS survivors** to develop **VIR-7831 and VIR-7832**	Phase II/III for VIR-783 began in Aug[2]
	REGENERON	Cocktail of two different monoclonal antibodies (**REGN-COV2**) from COVID-19 survivors and genetically engineered mice.[3]	**Began phase II/III treatment trials** and phase III preventive trials in July[3]
	Lilly, AbCellera	Testing **Bamlanivimab (LY-CoV555)** and **LY-CoV016,** with several study designs in prevention and treatment of COVID. Previously announced plans for large-scale manufacturing (6/1/2020)[4,5]	**Phase III preventative trial** in nursing homes and assisted living facilities initiated in Aug 2020. **Phase II/III treatment** trials also launched in Aug 2020[4]
	CELLTRION	mAb candidate **CT-P59**; finished Phase I trials and plans to start manufacturing at-scale in September 2020[6]	**Phase I trials initiated in July 2020**[6]
	AstraZeneca	2 mAb cocktail (**AZD7442**) licensed from Vanderbilt for both prophylaxis & treatment. Working with BARDA and DARPA, which includes manufacturing support for Ph I[7]	**Phase I trial launched in Aug 2020 with expected results by end of year**[7]
	Lilly, 君实生物 TopAlliance	Antibody cocktail of **JS016** (incl. CB6) for both prophylaxis and treatment; the company announced they have secured capacity to serve 100,000 people by the end of 2020[8]; licensed Lonza's gene expression system GS Xceed[9]	**Began its China study in June; plan to begin its US study in 2Q of 2020**[8]
Polyclonal antibodies / plasma	Takeda, CSL Behring, ADMA BIOLOGICS, bpl, LFB, GC Pharma, Biotest, octapharma, Sanquin, biopharma	A coalition of 10 companies, led by Takeda and CSL, to develop a hyperimmune globulin (H-IG) based COVID-19 treatment called **CoVIg-19**	**September 2020**[10]

1. Publicly stated targets or actual start date of human trials 2. Pharmatimes 3. Fiercepharma, Fiercepharma 4. Eli Lilly, Lilly, NIAID, Medscape 5. Reuters 6. Reuters 7. Fiercebiotech 8. Reuters 9. Reuters 10. Reuters

Source: Milken Institute, BioCentury, CT.gov

B: COVID-19 virus-neutralizing antibodies – selected candidates deep dive

Not comprehensive

Directionally positive result | Directionally negative result

Company/ Collaboration (Asset)	Description	Current Trials	Trial size (status)	Latest results
Lilly AbCellera **Bamlanivimab (LY-CoV555)** **(LY-CoV016)**	Neutralizing IgG1 monoclonal antibodies **directed against complementary regions of the spike protein of SARS-CoV-2** designed to block viral attachment and entry into human cells	**Phase II treatment trial (LY-CoV555 monotherapy arm)** in ambulatory patients (initiated June 2020)	2,400 patients (recruiting). Data from 452 mild/moderate patients	**US Phase II PoC data (Sept 2020):** LY-CoV555 significantly reduced the rate of hospitalization (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose.[1] **Applied for EUA on 10/7/2020**[2]
		Phase II treatment trial (LY-CoV555 + LY-CoV016 combination therapy arm) in ambulatory setting (initiated June 2020)	800 mild/moderate patients (recruiting). Data from 268 mild/moderate patients	For combo antibody arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[2]
REGENERON **(REGN-COV2)**	Cocktail of **two different monoclonal antibodies** (REGN-COV2) from **COVID-19 survivors** and genetically engineered **mice**	**Phase III preventative trial** for household contacts (initiated June 2020)	2,000 participants (recruiting)	**Analysis from ambulatory Ph I/II/III trial (Sept and Oct 2020):** REGN-COV2 reduced viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. The antibody also reduced medical visits by 57% overall compared to placebo, with a 72% reduction reported in high risk populations. **Applied for EUA on 10/7/2020**[3,4]
		Parallel phase I/II/III trials in hospitalized & ambulatory patients	2,970 moderate to severe hospitalized patients; 2,104 ambulatory patients (recruiting)	
VIR WuXi Biologics Biogen gsk **(VIR-7831/2)**	Isolated monoclonal antibodies from **SARS survivors** used to develop two assets: **VIR-7831 & VIR-7832**	**Phase II/III trial** for early treatment to prevent hospitalization (initiated Aug 2020)	1,360 patients with early symptoms (recruiting)	Early results of Ph II/III trial **expected late 2020**

1. Lilly 2. Lilly 3. Regeneron 4. Regeneron

Source: Company press releases, CT.gov

C: COVID-19 immune modulators – selected candidates deep dive

Not comprehensive

Directionally positive result | Directionally negative result

Compound (Primary mode of action)	US Status (Licensed indication)	Use case[1]	Registered trials on CT.gov[2]	Earliest trial end date[3]	Initial clinical evidence[4]	Efficacy in isolated use?	Additional information
Actemra Tocilizumab (IL-6 inhibitor) Roche	**Marketed** (RA)	Treatment - CRS	46	**May 2020**	Improved outcomes in France, China, and in Global study; mixed evidence in Italy, US, retrospective studies	-	Prior approval for CRS; EU struck a deal to secure Actemra supplies for its member countries[5]
Kevzara Sarilumab (IL-6 inhibitor) REGENERON SANOFI	**Marketed** (RA)	Treatment – CRS, ARDS	10	**Jun 2020**	Correlated with worse outcomes for severe patients; No meaningful benefit for critical patients	-	Sanofi, Regeneron shut down trial after failed Ph III study[6]
Rebif (Interferon beta-1a) MERCK	**Marketed** (Multiple sclerosis)	Treatment - CRS	10	**Nov 2023**	-	-	Being tested in combo with remdesivir as part of NIH's ACTT 3 trial.[7]
Lenzilumab (anti-GM-CSF mAb) Humanigen	**Under development** (multiple indications)	Treatment	3	**Sept 2020**	Topline data announcement expected in Q4 2020	-	Began Phase III trials in May 2020. Humanigen has partnered with Lonza, Thermo Fisher, and Catalent to manufacture drug.[8]
Olumiant baricitinib (JAK inhibitor) Lilly	**Marketed (**Rheumatoid Arthritis)	Treatment – COVID-19, CRS	11	**Apr 2020**	Study met primary endpoint yielding ~1 day reduction in median recovery time for patients treated with baricitinib in combination with remdesivir vs. remdesivir alone	-	Lilly launched Ph III in May 2020 to test baricitinib + remdesivir vs. remdesivir alone. Study also met a key secondary endpoint comparing patient outcomes at Day 15 using an ordinal 8-point scale ranging from fully recovered to death[9]

1. CRS - Cytokine Release Syndrome; ARDS - Acute Respiratory Distress Syndrome
2. Based on CT.gov registered trials related to COVID-19 as of July 13, 2020
3. Actual read-out may be sooner than CT.gov trial end date
4. See "Compilation of published results" for full set of references
5. Trieste All News
6. Sanofi
7. NIAID
8. Reuters, Fiercepharma
9. Lilly

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov

D: COVID-19 Cell, Gene, RNA therapy – selected candidates deep dive

CURRENT AS OF OCTOBER 29, 2020
NONEXHAUSTIVE
EXAMPLES FOR ILLUSTRATION PURPOSES ONLY

Not comprehensive

Directionally positive result | Directionally negative result

	Compound (Primary mode of action)	US Status (Licensed indication)	Use case[1]	Registered trials on CT.gov[2]	Earliest trial end date[3]	Initial clinical evidence[4]	Efficacy in isolated use?	Additional information
Cell therapy	CYNK-001 (NK cells (placenta-derived)) sorrento THERAPEUTICS celularity	Under Development	Prophylaxis, Treatment – COVID-19	1	**Nov 2021**	-	-	Investigated to treat liquid and solid tumors; shows potential against virally infected cells
	NK cells (various originators)	Under Development	Prophylaxis, Treatment – COVID-19	4	**Jun 2020**	-	-	-
	RAPA-501-ALLO *Rapa Therapeutics*	Under Development	Treatment – COVID-19	1	**Dec 2021**	-	-	-
RNA therapy	VIR-2703 VIR Alnylam	Under Development	Treatment – COVID-19	0	**-**	-	-	-
Stem cells	Mesenchymal Stem Cells	Under Development	Treatment – COVID-19, ARDS	44	**June 2020**	Improved outcomes in severe patients	7 patients in China (all discharged)[5]	Efficacy shown in human COPD study (same biomarker as COVID-19)
	Ryoncil remestemcel-L (MSC) mesoblast	Under Development	Treatment – ARDS	3	**April 2021**	Positive outcome in isolated use	-	-
Stem cells	Adipose-derived mesenchymal stem cells Personalized Stem Cells CALiDi	Under Development	Treatment	0	**-**	-	-	Efficacy shown in human COPD study (same biomarker as COVID-19)

1. CRS - Cytokine Release Syndrome; ARDS - Acute Respiratory Distress Syndrome
2. Based on CT.gov registered trials related to COVID-19 as of July 13, 2020
3. Actual read-out may be sooner than CT.gov trial end date
4. See "Compilation of published results" for full set of references
5. IEEE Spectrum

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov, Irish News, IEEE Spectrum

E: COVID-19 other therapeutics – selected candidates deep dive

Not comprehensive

Directionally positive result | Directionally negative result

Compound (Primary mode of action)	US Status (Licensed indication)	Use case	Registered trials on CT.gov[1]	Earliest trial end date	Initial clinical evidence[2]	Efficacy in isolated use?	Additional information
Cozaar (and Gx) MERCK losartan (Antihypertensive)	**Marketed** (hypertension)	Treatment	9	**Oct 2020**	-	-	-
Dexamethasone (Steroid)	**Marketed** (inflamm-ation, allergy)	Treatment	15	**Jun 2020**	A large RECOVERY platform show reduced mortality; separate meta-analysis showed similar results[3,4]		UK approved the drug after the favourable RECOVERY trial result[3] Approved in Japan[5]
Methylprednisolone (Steroid)	**Marketed** (inflammation)	Treatment	18	**May 2020**	-	-	In Chinese study of n=200, seemingly reduced risk of death for ARDS patients
Prednisone (Steroid)	**Marketed** (various)	Treatment	6	**July 2020**	-	-	-
Colcrys Takeda colchicine (Anti-mitotic)	**Marketed** (gout)	Treatment	19	**May 2020**	A small trial showed effect on preventing progression of the disease		-
Avastin Roche bevacizumab (Angiogenesis inhibitor)	**Marketed** (cancers)	Treatment	3	**May 2020**	- -	- -	- -
Vitamin D	**Marketed**	Treatment	19	**Dec 2020**	-	-	-
Heparin (anticoagulant)	**Marketed**	Treatment	18	**Jan 2021**	-	-	-
Nitric oxide (Vasodilator)	**Marketed** (PPHN, ARDS)	Treatment	17	**Sep 2020**	-	-	-

1.Based on CT.gov registered trials related to COVID-19 as of July 13, 2020 2. See "Compilation of published results" for full set of references 3. FiercePharma 4. StatNews 5. Reuters

Source: Milken Institute, BioCentury, FiercePharma, FierceBiotech, CT.gov

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Recent clinical trial results (1/2)

Not comprehensive

Directionally positive result | Directionally negative result

Compound	Location	Publish Date	Size	Trial type	Study population	**Arms:** Dosing schedule	Results	Trial ID
Avigan (Favipiravir) FUJIFILM	Japan	September 2020	**156**	Randomized, controlled	COVID-19 patients with non-serious pneumonia	**Drug**: Favipiravir **Control**: Placebo	Favipiravir led to faster time to viral clearance vs placebo (11.9d vs 14.7d, respectively)[1]	
Actemra (Tocilizumab) Roche	USA	September 2020	**389**	Randomized, controlled	Hospitalized COVID-19 patients, 18 years or older, SpO2 <94% on room air, did not require noninvasive or invasive ventilation	**Drug**: tocilizumab **Control:** placebo	In a randomized, controlled trial, IL-6 inhibitor Actemra reduced relative progression to mechanical ventilation by 44% through 28 days compared to placebo (12.2% vs. 19.3%, respectively). However, several secondary endpoints were not met (incl. time to hospital discharge and mortality)[2]	NCT04372186
Bamlanivimab (LY-CoV555) **LY-CoV016** Lilly	USA	September and October 2020	**2,400**	Randomized, controlled	Patients in the outpatient setting with mild-to-moderate recently diagnosed COVID-19	Arm 1: **Drug**: LY-CoV555 (4 dose categories) **Control:** placebo	In PoC data of the Phase 2 randomized, double-blind, placebo-controlled trial (n=452), LY-CoV555 significantly reduced the rate of hospitalization (1.7% vs. 6% for placebo). Primary endpoint of viral load change at 11 days was met for the middle dose, but not low or high dose.[3]	NCT04427501
					Patients in the outpatients setting with mild-to-moderate recently diagnosed COVID-19	Arm 2: **Drug**: LY-CoV555 + LY-CoV016 **Control:** placebo	In interim Phase 2 data (n=268) for the combination antibody treatment arm, significant viral load reduction met primary end endpoints at day 11. Rate of COVID-related ED and hospitalization visits decreased (0.9% vs. 5.8% in placebo group)[4]	
Bamlanivimab (LY-CoV555) **Remdesivir** Lilly	USA	October 2020	**326**	Randomized, controlled	Hospitalized patients with COVID-19, symptomatic for ≤12 days	**Intervention**: Remdesivir + LY-CoV555 **Control:** Remdesivir + placebo	On 10/26/2020, the Data and Safety Monitoring Board (DSMB) reviewed data (n=326) from the ACTIV-3 trial in hospitalized patients with COVID-19 on and recommended no further participants be randomized to receive LY-CoV555. This recommendation was based on a low likelihood that the intervention would be of clinical value in this hospitalized patient population[5]	NCT04501978

1. Fujifilm 2. Roche 3. Lilly 4. Lilly 5. NIH

Recent clinical trial results (2/2)

Not comprehensive

Directionally positive result Directionally negative result

Compound	Location	Publish Date	Size	Trial type	Study population	**Arms:** Dosing schedule	Results	Trial ID
REGN-COV2 REGENERON	USA	September 2020	**3,000**	Randomized, controlled	Patients with symptomatic recently diagnosed COVID-19 infection with symptoms ≤10 days, who have been hospitalized for ≤72 hours	**Drug**: REGN-COV2 + SoC **Control:** Placebo + SoC	In a preliminary descriptive analysis (n=275) of its adaptive Phase 1/2/3 randomized, controlled trial, the REGN-COV2 antibody cocktail treatment arm rapidly reduced viral load through Day 7 and reduced associated symptoms in infected COVID-19 patients[1] In prospective results from ongoing Phase II/III trials (n=799), Regeneron found that 2.8% of patients who received REGN-COV2 had a medical visit related to COVID-19 through Day 29, compared to 6.5% of individuals in the placebo group (p-value 0.024). In individuals older than 50 years old or BMI>30, the antibody produced a 72% reduction in medical visits. It was also noted that results indicated no significant difference in virologic or clinical efficacy between low and high doses (2.4g vs. 8g)[2]	NCT04426695

1. Regeneron 2. Regeneron

Australian Government
Department of Health

REQUEST FOR TENDER FOR THE PROVISION OF *COVID-19 VACCINATION TRAINING PROGRAM*

REQUEST FOR TENDER FOR THE PROVISION OF *COVID-19 VACCINATION TRAINING PROGRAM*

Health/20-21/295888

ISSUED BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH

Lodgement Closing Time: 8 January 2021 2:00pm (local time in Canberra, ACT)

PLEASE NOTE:

- **Tenders must be lodged electronically via AusTender (see clause 8)**
- **Tenders should be lodged in the format described in clause 10.**

The Department adheres strictly to Commonwealth policy on late tenders. The Department therefore recommends that Tenderers plan to lodge their Tender well before the Closing Time to minimise the possibility of any unforeseen circumstances arising that may cause the Tenderer to miss the Closing Time.

Commonwealth Contact: COVID19VaccineProcurement@health.gov.au

CONTENTS

SCHEDULE 7 – DRAFT CONTRACT **60**

PART 1 – OVERVIEW, BACKGROUND, SERVICES SPECIFICATIONS AND TENDER LODGEMENT

1. REQUEST FOR TENDER

1.1 This Request for Tender (**RFT**) comprises:

a. Part 1 – Overview, background, services specifications and Tender lodgement;
b. Part 2 – Information to be provided by Tenderers;
c. Part 3 – Evaluation of Tenders;
d. Part 4 – Conditions of tendering;
e. Part 5 – Glossary;
f. Schedule 1 – Statement of Requirement;
g. Schedule 2 – Tenderer Deed;
h. Schedule 3 – Tenderer Response Information;
i. Schedule 4 – Statement of Non-Compliance;
j. Schedule 5 – Pricing Schedule;
k. Schedule 6 – Indigenous Participation Plan Template Response Form; and
l. Schedule 7 – Draft Contract.

1.2 Tenderers' attention is also drawn to the:

a. Conditions for Participation set out in clause 12;
b. Minimum Content and Format Requirements set out in clause 13; and
c. Essential Requirements set out in clause 14.

2. THE DEPARTMENT

2.1 The Commonwealth of Australia acting through the Department of Health (**Department**) is responsible for better health and wellbeing for all Australians. The Department aims to achieve its vision through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.

2.2 Australia's COVID-19 Vaccine and Treatment Strategy aims to support access to, and delivery of, safe and effective COVID-19 vaccines and treatments for all Australians, as soon as they are available.

2.3 The Department of Health is seeking to engage a partner to design and deliver training modules for individuals involved in the administration of COVID-19 vaccines to ensure timely and safe access to COVID-19 vaccines in line with best practice and government guidance.

2.4 The Initial Term of the Contract will be up to 1 year. The Department also requires 2 optional extensions each to be 6 months in duration.

3. SERVICES THE DEPARTMENT REQUIRES

3.1 The Department is seeking Tenders for the following Services:

(a) To develop the curriculum for modular trainings in line with the learning objectives for COVID-19 vaccination

(b) To digitise and produce training content for delivery on an e-learning platform (hosted by the Tenderer, or other relevant platforms including peak bodies)

(c) To identify and design practical training and/or assessments for training modules

(d) To rapidly include new training material (as described in 1-3 above) for COVID-19 vaccines as they are developed

Modular trainings are required to provide additional formal training to ensure competency standards are met for the administration of COVID-19 vaccines.

Training modules can be considered in two groups: core COVID modules and additional vaccine specific modules. Core COVID modules involve training that is consistent across vaccine candidates and applies to COVID-19 vaccination broadly. Additional vaccine specific modules are for individual vaccine candidates, where the core content for training is provided by vaccine manufacturers.

The detailed specifications and requirements for the Services are set out at Schedule 1 - Statement of Requirement. The Department proposes to engage the successful Tenderer to provide the Services in accordance with the Draft Contract set out in Schedule 7.

4. RFT TIMETABLE

4.1 The following is an indicative timetable for this RFT process:

Activity	Timing
Release of RFT	24 December 2020
Enquiry Cut-Off Date	7 January 2021 12:00pm
Closing Time	8 January 2021 2:00pm
Negotiation with preferred Tenderer(s)	w/c 11 January 2021
Execution of Contract with successful Tenderer	w/c 11 January 2020
Notification of unsuccessful Tenderers	w/c 11 January 2021
Commencement of Services	w/c 11 January 2021 (estimated)

5. ENQUIRIES ABOUT THIS RFT

5.1 Enquiries about this RFT should be made by email addressed to:

Title:	***Director, COVID-19 Vaccine Taskforce***
Email:	***COVID19VaccineProcurement@health.gov.au***

5.2 The Department will provide answers to any reasonable enquiry from a prospective Tenderer that is received by the Department before the Enquiry Cut-Off Date set out in clause 4, in which case:

a. questions and related answers may be disclosed to all prospective Tenderers via AusTender (without disclosing the source of the questions); and

b. any Tenderer Confidential Information contained in a question (that is expressly nominated as such by the relevant Tenderer and agreed to by the Department) will be removed prior to disclosure on AusTender.

5.3 All communications related to this RFT should be addressed to the Contact Officer (via the contact details specified above) and not to other Departmental officers or other persons. The Department may not respond to any enquiry not made in accordance with the requirements of clause 5.1. A Tenderer who communicates other than to the Contact Officer may be excluded from participating further in this RFT process.

6. GOVERNMENT PROCUREMENT (JUDICIAL REVIEW) ACT 2018 (CTH)

6.1 This RFT process is not a covered procurement for the purposes of the Commonwealth Procurement Rules and the *Government Procurement (Judicial Review) Act 2018* (Cth).

6.2 Not used

6.3 Not used

7. AUSTENDER, THE AUSTRALIAN GOVERNMENT TENDER SYSTEM

7.1 AusTender is the Australian Government's procurement information system. Access to and use of AusTender is subject to terms and conditions. In participating in this RFT process, Tenderers agree to comply with those terms and conditions and any applicable instructions, processes, procedures and recommendations as advised on the AusTender website at https://www.tenders.gov.au/?event=public.termsOfUse.

7.2 All queries and requests for technical or operational support must be directed to:

AusTender Help Desk

Telephone: 1300 651 698

International: +61 2 6215 1558

Email: tenders@finance.gov.au

7.3 The AusTender Help Desk is available between 9am and 5pm ACT local time, Monday to Friday (excluding ACT and national public holidays).

8. ELECTRONIC LODGEMENT

8.1 Tenders must be lodged electronically via AusTender before the Closing Time and in accordance with the Tender response lodgement procedures set out in this RFT and on AusTender.

8.2 If Tenderers need to lodge material that cannot be submitted via AusTender, Tenderers should contact the Contact Officer prior to Closing Time to make arrangements for its submission.

9. TENDER CLOSING TIME AND DATE

9.1 Submissions must be lodged before ***2:00pm***, local time in the ACT on the ***8 January 2021***, (the **Closing Time**).

9.2 The Closing Time will also be displayed in the relevant AusTender webpage together with a countdown clock that displays in real time the amount of time left until Closing Time (For more information please see AusTender Terms of Use). For the purposes of determining whether a Tender has been lodged before the Closing Time, the countdown clock will be conclusive and will be the means by which the Department determines whether a Tender has been lodged by the Closing Time.

9.3 Any attempt to lodge a Tender after the Closing Time will not be permitted by AusTender. Such a Tender will be deemed to be a Late Tender. Late Tenders will be excluded from consideration unless the Tender is late as a consequence of mishandling by the Department.

9.4 Where electronic submission of a Tender has commenced prior to the Closing Time but concluded after the Closing Time, and upload of the Tender file(s) has completed successfully, as confirmed by AusTender system logs, the Tender will not be deemed to be a Late Tender. Such Tenders will be identified by AusTender to the Department as having commenced transmission prior to, but completed lodgement after, the Closing Time.

9.5 Where a Tender lodgement consists of multiple uploads, due to the number and/or size of the files, Tenderers must ensure that transmission of all files is completed and receipted before the Closing Time and clause 8.4 will only apply to the final upload.

10. PREPARING TO LODGE A TENDER

Tender File Formats, Naming Conventions and Sizes

10.1 The Department will accept Submissions lodged in Microsoft Word, Microsoft PowerPoint and PDF formats. Supplementary materials/attachments may be also be provided in one of these formats, or in formats compatible with Microsoft Excel. If the Tenderer believes elements of their Submission are best represented in a file format not listed here, queries may be directed to the Contact Officer.

10.2 The Tender file name/s should:

a. incorporate the Tenderer's company name; and
b. reflect the various parts of the Tender they represent, where the Tender comprises multiple files.

10.3 Tender response files should not exceed a combined file size of 5 megabytes per upload.

10.4 Tenders must be completely self-contained. No hyperlinked or other material may be incorporated by reference.

11. SCANNED OR IMAGED MATERIAL, INCLUDING STATUTORY DECLARATIONS

11.1 In the event that the Department requires clarification of the Tenderer's Tender, the Tenderer may be required to courier or security post the originals of the signature and/or initialled pages to the Department at the address notified by the Department within the period notified by the Department.

PART 2 – INFORMATION TO BE PROVIDED BY TENDERERS

12. CONDITIONS FOR PARTICIPATION

12.1 Subject to clause 13, if the Department considers that a Tenderer does not satisfy all of the following Conditions for Participation, that Tender will be excluded from further consideration under this RFT:

Item	Conditions for Participation
1	The Tenderer must not have had any judicial decisions against it (excluding decisions under appeal) relating to employee entitlements and have not satisfied any resulting order.
2	The Tenderer, its personnel, and any Subcontractors proposed in the Tender must not, at the Closing Time, be listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).
3	The Tenderer (and any Subcontractor proposed in its Tender) must not be named in the Consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).
4	(a) The Tenderer either: i. holds a Valid and Satisfactory Statement of Tax Record by the Closing Time; or ii. has a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office by the closing time, and holds a Valid and Satisfactory Statement of Tax Record no later than 4 business days from the Closing Time; and (b) the Tenderer holds a Valid and Satisfactory Statement of Tax Record from any Subcontractor that it proposes, as part of its Tender, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive). [Note to Tenderers: Tenderers should apply for a Statement of Tax Record and should ensure that their Subcontractors apply for a Statement of Tax Record within sufficient time to meet this Condition for Participation.]

13. MINIMUM CONTENT AND FORMAT REQUIREMENTS

13.1 Subject to clause 13, if the Department considers that a Tender does not satisfy all of the following Minimum Content and Format Requirements, that Tender will be excluded from further consideration under this RFT:

Item	Minimum Content and Format Requirements
1	The Tender must be in English and measurements must be expressed in Australian legal units of measurement.
2	The Tender must include a completed, signed and scanned Tenderer Deed substantially in the form at Schedule 2.

Item	Minimum Content and Format Requirements
3	Tenderers must substantially complete and submit the Pricing Schedule in Schedule 5 in accordance with the instructions provided in Schedule 5.
4	The Tenderer must include an Indigenous Participation Plan in its Tender.
5	The Tender must include either: (a) a Valid and Satisfactory Statement of Tax Record for the Tenderer; or (b) a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office for the Tenderer and the Tenderer then provides a Valid and Satisfactory Statement of Tax Record within 4 business days from the Closing Time.

Unintentional Errors of Form

13.2 Without limiting the Department's other rights in this RFT, the Department may allow the Tenderer to correct any error of form in a Tender that appears to be unintentional, by lodging a correction or additional information, in writing in accordance with the direction of the Department, but will not permit any material alteration or addition to the Tender.

13.3 If the Department provides any Tenderer with the opportunity to correct errors of form, it will provide the same opportunity to all other Tenderers that are in the same position.

14. ESSENTIAL REQUIREMENTS

14.1 If the Department considers that a Tenderer does not satisfy all of the following Essential Requirements, that Tender will be excluded from further consideration under this RFT:

Item	Essential Requirements
1	The Tenderer must offer to provide all the Services described in this RFT.
2	The successful Tender must be able to ensure the confidentiality and integrity of any systems or data and meet industry security standards
3	The Tenderer must already have, or be in the process of undertaking national accreditation for their immunisation education program by the Health Education Services Australia (HESA) and be on track to achieve this no later than January 31, 2021

14.2 Notwithstanding the use of the words “must”, "shall", "minimum", "required to" or similar language or anything to the contrary in Statement of Requirement or elsewhere in this RFT, there are no other Essential Requirements for this RFT besides those set out in the table above (if any).

15. FORMAT OF TENDERS

15.1 Tenders should be completed in accordance with Schedule 3, noting the following:

a. all applicable information should be provided in response to the information requirements set out in Schedule 3;
b. where a response to a particular requirement is covered in another section of the Tender, a cross reference to that section should be provided; and
c. Tenderers may include additional or supporting materials (as supplements or attachments to the Tender Response Information) noting that Tenderers are discouraged from including

generic marketing information that does not relate to the information requested in this RFT and/or does not address the Evaluation Criteria.

15.2 Tenderers should also complete the statement of non-compliance in accordance with Schedule 4 in relation to:

a. any of the provisions of the Draft Contract with which the Tenderer is partially compliant or non-compliant; or
b. any claim of confidentiality in relation to any aspects of their Tender.

16. PRICING

16.1 Tenderers should provide full details of their proposed price structure in Schedule 5. This document should be included in a separate electronic file when the Tender is lodged and no pricing should be included in any other part of the Tender.

16.2 Tendered prices should include all charges necessary and incidental to the proper delivery of the Services.

16.3 Prices should be fixed for the duration of the Contract unless otherwise indicated by the Department in this RFT.

16.4 Prices should be in Australian dollars (inclusive of GST).

17. WORKPLACE GENDER EQUALITY

17.1 Commonwealth policy prevents the Department from entering into contracts with Tenderers who are non-compliant under the *Workplace Gender Equality Act 2012* (Cth) (the **WGE Act**).

17.2 The Draft Contract requires that, in performing any contract, a successful Tenderer must:

a. comply with its obligations, if any, under the WGE Act; and
b. if the term of any resultant Contract exceeds 18 months, the successful Tenderer must provide a current letter of compliance within 18 months from the Contract Commencement Date and following this, annually to the Department's Contract contact officer.

17.3 Tenderers should note that if during the term of any resultant Contract, the successful Tenderer becomes non-compliant with the WGE Act, the successful Tenderer must notify the Department's Contract contact officer.

17.4 For further information about coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

17.5 Tenderer's must indicate as part of the Tenderer Deed at Schedule 2 whether or not the Tenderer's organisation is a 'relevant employer' under the WGE Act and, if applicable, provide a current letter of compliance as part of their Tender, or prior to entering into any resultant Contract (if successful).

18. ILLEGAL WORKERS

18.1 It is Commonwealth policy not to contract with providers engaging Illegal Workers.

18.2 The Tenderer's Deed in Schedule 2 contains a statement from the Tenderer confirming that it meets this obligation.

19. INDIGENOUS PROCUREMENT POLICY

19.1 It is Commonwealth policy to stimulate Indigenous entrepreneurship and business development, providing Indigenous Australians with more opportunities to participate in the economy (see Indigenous Procurement Policy for further information).

19.2 If any resultant Contract is a High Value Contract, the mandatory minimum requirements for Indigenous participation will apply.

19.3 If a component of any resultant Contract will be delivered in a Remote Area, this creates an opportunity for that resultant Contract to deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

19.4 In its Indigenous Participation Plan, the Tenderer should detail how it will ensure that its provision of the Services will deliver a significant Indigenous employment or supplier use outcomes in the Remote Area.

[Note to Tenderers: Refer to section 4.4.1 of the Indigenous Procurement Policy for examples of options available to ensure any resultant Contract will deliver significant Indigenous employment or supplier use outcomes in the Remote Area.]

20. *MODERN SLAVERY ACT 2018* (CTH)

20.1 T Tenderers should note that any resultant Contract will require the successful Tenderer to provide all assistance reasonably requested by the Department to comply with its obligations under the Modern Slavery Act 2018 (Cth).

PART 3 – EVALUATION OF TENDERS

21. EVALUATION CRITERIA

21.1 The Department will use the following Evaluation Criteria in the evaluation of Tenders:

Category	Considerations	Weighting
Capability	The Tenderer's ability to deliver the Services within the Department's timeframes and requirements, as demonstrated by: a) the Tenderer's proposed solution and approach to meet the requirements described in Schedule 1, including the extent to which it is fit for purpose in delivering a training curriculum of sufficient scale, accessibility and flexibility; b) the Tenderer's past performance and/or demonstrated commitment in meeting the essential requirements; c) the Tender's proposed solution to delivering practical training digitally; and d) the experience of the Tenderer and its key personnel in delivering similar Services. This should be supported with case studies of relevant experience within the Commonwealth Government and/or the Health sector, where available.	50%
Capacity	The organisational capacity (with relevant experience) of the Tenderer to undertake and deliver the Services in accordance with the specified requirements and timeframes, including: a) qualifications and experience of key Tenderer personnel, including their skills and knowledge in the design and delivery of training modules and/or the Health sector; b) availability of key personnel to meet the specified timelines, including approaches to manage the continuity of services and ability to scale resources to meet requirements; c) use of qualified and experienced subcontractors (as required); and d) other resources offered by the Tenderer..	30%
Collaboration and responsiveness	The methods, capability and expertise of the Tenderer to provide agile and responsive services in complex and evolving operating environments, as well as to work collaboratively with the Commonwealth, states and territories, peak bodies other service providers and any other required stakeholders in the delivery of the Services. This should be supported with examples of demonstrated experience, where available.	20%

Category	Considerations	Weighting
Pricing	The Tenderer's pricing information as specified in its response to Schedule 5 (Pricing Schedule).	Not weighted
Security and compliance	The extent to which the Tenderer does or will meet all specified security requirements The degree of the Tenderer's overall compliance with the RFT and Draft Contract and the likelihood of any non-compliance meaning the Department is unable to agree a contractual arrangement with that Tenderer.	Not Weighted
Risk	Any risks inherent in, or associated with, the Tenderer's Submission that have not otherwise been considered under other Evaluation Criteria including, but not limited to: a. the Tenderer's financial viability; b. the Tenderer's compliance with Statement of Requirement and the Draft Contract; and c. any conflicts of interest. The Department will assess Tenderers on any risks identified in Submission and any other risks identified in the Evaluation Process that have not been considered as part of another Evaluation Criteria. The Department is concerned to ensure that all conflicts of interest are identified, and any risks are properly managed.	Not weighted
Economic Benefit	The Tenderer's proposed approach to providing benefits to the Australian economy as specified in its response to this RFT.	Not weighted
Indigenous participation	The Tender's response to the Indigenous participation plan.	Not weighted

21.2 The Department may:

a. consider any part of a Tender in the evaluation of any or all of the Evaluation Criteria; and
b. use material provided in response to one Evaluation Criterion in its evaluation of other Evaluation Criteria.

22. EXCLUSION OF TENDERS

22.1 Without limiting any other provision of this RFT that gives the Department the right to exclude Tenders on other grounds, the Department may at any time exclude a Tender from further consideration if:

a. the Tender is incomplete or contains insufficient information to allow evaluation of the Tender;
b. prices are not clearly and legibly stated;

c. the Tenderer or Tender does not comply with this RFT;
d. the Tenderer is not fully capable of undertaking a contract in the form of the Draft Contract;
e. the Tender is clearly uncompetitive when compared with the other tenders received;
f. the Tender is rated unsuitable or unsatisfactory against one or more of the Evaluation Criteria;
g. the Tender contains statements that qualify or are contrary to the Tenderer Deed at Schedule 2 to this RFT:
h. in the Department's opinion the Tender contains a false declaration;
i. the Tender contains false or misleading information or statements;
j. the Tenderer, or a director or officer of the Tenderer, is insolvent or bankrupt;
k. the Tenderer has an actual, potential or perceived conflict of interest that cannot be managed to the satisfaction of the Department acting in its absolute discretion; or
l. there has been a significant deficiency in the performance of a substantive requirement or obligation under a prior agreement.

23. TENDER EVALUATION PROCESS

23.1 Tenders will be evaluated against the Evaluation Criteria to determine the Tender that represents the best overall value for money on a whole-of-life basis.

23.2 As part of its evaluation of Tenders, the Department may, in its sole and absolute discretion:

a. ask Tenderers to undertake presentations;
b. shortlist one or more Tenderers at any time;
c. ask Tenderers to provide written clarification of various aspects of their Tenders;
d. ask Tenderers to provide further information to confirm their financial viability and commercial stability;
e. have discussions or interviews with Tenderers in order to seek further clarification of their Tenders;
f. visit Tenderers' sites; and
g. have discussions with or undertake visits to customers of Tenderers and their Subcontractors, whether or not those customers are listed as referees in the Tenderers' Tenders.

23.3 The Department may choose to undertake the activities set out in clause 23.2 in relation to some Tenderers only. Presentations, interviews and site visits may be subject to additional terms and conditions that are advised by the Department to Tenderers who have been invited to participate in each activity.

23.4 Any costs incurred by the Tenderer in complying with this clause 23 will be borne by the Tenderer.

24. CLARIFICATION

24.1 Where the meaning of a Tender is unclear or there is an apparent error of form, the Department may seek clarification from the Tenderer.

24.2 Any clarification provided by a Tenderer in response to a request for clarification is not to contain any new material additional to that included in the Tender unless specifically requested by the

Department. Failure to supply clarification to the satisfaction of the Department may cause the Tender to be excluded from consideration.

25. TENDERED PRICES

25.1 The Tenderer agrees to provide access to such information as is determined by the Department to be necessary in order to evaluate the reasonableness of their Tendered prices.

25.2 In the evaluation process, the Department may make certain adjustments to the Tendered price, including adjustments to account for the following matters, which may need balancing in order to establish a common basis for the comparison of Tenders, including (without limitation):

a. Tendered prices as per the completed Schedule 5;
b. pricing flexibility;
c. any other costs or discounts which form part of the Tenderer's offer;
d. normalised and discounted cash flow;
e. any alternative proposals or financial incentives offered by the Tenderer;
f. implementation costs;
g. any risk relating to the Tendered prices;
h. transition out costs;
i. cost of administering the resultant Contract; and
j. whole of life costs and benefits.

26. NEGOTIATIONS

26.1 Negotiations may be undertaken with one or more Tenderers (including in relation to prices, terms and conditions of the Draft Contract or any other matters).

26.2 During the negotiation phase of this RFT process, the Department may engage in detailed discussions and negotiations, including parallel negotiations, with the goal of maximising the benefits of the project, as measured using the Evaluation Criteria. As part of this process, those Tenderers participating in the negotiation phase may be asked to improve any or all aspects of their Tender. The Department's intention is that it will select a preferred Tenderer after all material issues have been resolved.

26.3 The Department may seek best and final offers from Tenderers participating in the negotiation phase of this RFT process.

26.4 Without limiting its other rights under this RFT, in the event that the Department concludes that during negotiations a Tenderer has retracted, or attempts to retract, any part of its tendered offer, the Department reserves the right to:

a. exclude that Tenderer's Tender from further consideration;
b. terminate this RFT process;
c. re-enter negotiations or parallel negotiations with other Tenderers; or
d. exercise any other right reserved to the Department under law or elsewhere in this RFT.

27. DEBRIEFING

27.1 After the award of any resultant Contract, the Department will notify all unsuccessful Tenderers of the outcome of the RFT process.

27.2 All Tenderers will be offered the opportunity for a debriefing on their Tender.

27.3 Tenderers will be debriefed against the Evaluation Criteria contained in this RFT. Tenderers will not be provided with information concerning other Tenders.

28. COMPLAINTS PROCEDURE

28.1 Complaints in relation to this RFT process should be made in writing and directed to the Complaints Officer at procurement.advice@health.gov.au.

28.2 Complaints will be handled by the Department in accordance with the Department's Procurement Complaints Procedures which are available at About Us

PART 4 – CONDITIONS OF TENDERING

29. OWNERSHIP AND USE OF TENDER DOCUMENTS

29.1 All Tender documents (including paper and electronic copies) become the property of the Department on submission.

29.2 Without prejudice to anything agreed in any resultant Contract, clause 27.1 does not affect any intellectual property rights that may exist in a Tender.

29.3 Without prejudice to any other right of the Department under this RFT or at law, the Department may copy, amend, disclose or allow the disclosure of, or otherwise deal with, a Tender or any information contained in or relating to any Tender (at any time) for any of the following purposes:

a. the RFT process, evaluating and clarifying Tenders;
b. negotiation of the resultant Contract with the Tenderer or any other Tenderer;
c. managing any resultant agreement with the Tenderer or any other Tenderer;
d. addressing any dispute concerning the RFT process;
e. audit, governmental and Parliamentary reporting requirements; and
f. responding to any disputes about this RFT process or requests from Parliament or a Parliamentary Committee.

29.4 The Department may make copies of the Tender as necessary for its purposes.

30. INTELLECTUAL PROPERTY RIGHTS IN RFT

30.1 All intellectual property that exists in the information contained in this RFT, or any related or attached material, remains the property of the Department.

30.2 Each Tenderer is permitted to use this RFT for the purpose only of compiling its Tender and, in the case of the Tenderer(s) selected through this RFT process, for negotiating the resultant Contract with the Department.

31. SMALL TO MEDIUM ENTERPRISES (SMES)

31.1 The Australian Government is committed to *Public Governance, Performance and Accountability Act 2013* (Cth) non-corporate Commonwealth entities sourcing at least 10 per cent of their purchases by value from SMEs. For the purpose of this clause an SME is an Australian or New Zealand firm with fewer than 200 full-time equivalent employees.

31.2 Tenderers are encouraged to include the participation of SMEs in their Tenders.

32. AUDIT AND ACCESS

32.1 The attention of Tenderers is drawn to the *Auditor-General Act 1997* (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.

32.2 In addition to the Auditor-General's powers under the *Auditor-General Act 1997* (Cth), if a Tenderer is chosen to enter into a resultant Contract, the Tenderer will be required to provide the Auditor-

General or an authorised person with access to information, documents, records and Department assets, including those on the Tenderer's premises. This will be required at reasonable times on giving reasonable notice for the purpose of carrying out the Auditor-General's functions and will be restricted to information and assets which are in the custody or control of the Tenderer, its employees, agents or Subcontractors, and which are related to the resultant Contract. Such access will apply for the term of the Contract and for a period of 7 years from the date of expiration or termination of the Contract.

32.3 Tenderers should obtain, and will be deemed to have obtained, their own advice on the impact of the *Auditor-General Act 1997* (Cth) on their participation in the Tender.

33. FREEDOM OF INFORMATION AND OTHER RIGHTS TO ACCESS INFORMATION

33.1 The attention of Tenderers is drawn to the *Freedom of Information Act 1982* (Cth), which gives members of the public right of access to documents in the possession of the Commonwealth and its agencies.

33.2 The Act extends as far as possible the right of the community to access information (generally documents) in the possession of the Commonwealth, limited only by exceptions and exemptions necessary for the protection of essential public interests and the private and business affairs of persons in respect of whom information is collected and held by departments and public authorities.

33.3 Rights of access also exist under other legislation, including the *Ombudsman Act 1976* (Cth). Courts also have legal rights to access a wide range of information.

33.4 Tenderers should also be aware of the *Australian Information Commissioner Act 2010* (Cth), which established the Office of the Australian Information Commissioner to perform freedom of information, privacy and information policy functions.

34. PRIVACY

34.1 Tenderers are advised that it is Commonwealth policy to ensure that there is no loss of privacy protection when a Commonwealth entity contracts for the delivery of services.

34.2 Without limiting any obligations under the *Privacy Act 1988* (Cth), successful Tenderer(s) will be required under the Contract to agree not do an act, or engage in a practice, that would breach an Australian Privacy Principle under the *Privacy Act 1988* (Cth) if done or engaged in by a Commonwealth entity to which the Australian Privacy Principles apply. Tenderers selected as a result of this RFT process will also need to agree to impose those same obligations on any Subcontractor engaged by the Tenderer.

35. CONFIDENTIALITY

35.1 The Department will, subject to this RFT, including clauses 33.2 and 33.3, endeavour to treat the following information as confidential:

a. all Tenders received prior to the award of a resultant Contract;
b. all unsuccessful Tenders, following the award of a resultant Contract;
c. all successful Tenders, following the award of a resultant Contract but only to the extent that:
   i. the successful Tenderer requests that specific information in their Tender be kept confidential; and

ii. the Department has determined that specific information is to be kept confidential in accordance with the Confidentiality Throughout the Procurement Cycle from the Department of Finance and has agreed, pursuant to the resultant Contract with the successful Tenderer, to keep that information confidential.

35.2 The Department will not be taken to have breached any obligation to keep information provided by Tenderers confidential to the extent that the information:

a. is disclosed by the Department to its advisers, officers, employees or subcontractors solely in order to conduct this RFT process or to prepare and manage any resultant Contract;
b. is disclosed to the Department's internal management personnel, solely to enable effective management or auditing of this RFT process;
c. is disclosed by the Department to the responsible Minister;
d. is disclosed by the Department in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
e. is shared by the Department within the Department's organisation, or with another Commonwealth entity, where this serves the Commonwealth's legitimate interests;
f. is authorised or required by law to be disclosed;
g. is disclosed as agreed by the Tenderer;
h. is disclosed to meet the Department's reporting or accountability requirements, including, without limitation:
   i. under the Public Governance, Performance and Accountability Act 2013 (Cth) or other legislation;
   ii. to the Australian National Audit Office or any other auditor appointed by the Department;
   iii. in accordance with the provisions that require notification of Commonwealth contracts on the AusTender website;
   iv. to the Commonwealth Ombudsman; or
   v. is in the public domain otherwise than due to a breach of the relevant obligations of confidentiality.

35.3 Tenderers should be aware that the Department, as a non-corporate Commonwealth entity, is subject to specific accountability requirements, which support internal and external scrutiny of its tendering and contracting processes. These include:

a. the policy of the Commonwealth to publish details of relevant entity agreements, contracts and standing offers with an estimated value of $10,000 or more on the AusTender website;
b. the requirement to report details of Commonwealth contracts valued at $100,000 or more in accordance with the *Senate Order on Departmental and Agency Contracts*, including:
   i. name of the service provider and the subject matter of the Contract;
   ii. total value of the Contract; and
   iii. whether the Contract contains clauses that are confidential, and if so, the reasons for confidentiality;
c. the requirement to publish information about certain procurements in Annual Reports; and
d. the requirement to make available, on request, the names of any subcontractors engaged to perform services in relation to a Commonwealth contract (as such, Tenderers should inform all potential Subcontractors that their participation in fulfilling a Commonwealth contract may be publicly disclosed).

36. ENVIRONMENTAL POLICY AND PROCUREMENT

36.1 The Commonwealth aims to improve the implementation of ecologically sustainable development (**ESD**) within its agencies.

36.2 In support of this aim, the Department is committed to fostering the sustainable use of the Earth's resources and will implement and maintain an environmental management system to ISO14001, with the following key areas:

a. compliance with all relevant environmental legislation, regulations, policies and other initiatives to which it subscribes;
b. integrating environmental management into business decision making at all levels;
c. reducing cost through better resource usage and waste management;
d. setting objectives and targets for continuous improvement;
e. monitoring, reporting and reviewing achievements;
f. exploring best practice and innovative environmental management approaches to the use of technology, property and related resources; and
g. building an environmentally aware business culture.

36.3 The Department's procurement activities are a key means of implementing its environmental policy.

37. MATERIAL CHANGE TO TENDERER

37.1 A Tenderer must notify the Department if, following lodgement of its Tender, there occurs:

a. an event that has the effect of materially altering either the composition or control of the Tenderer or the business of the Tenderer; or
b. any material change to the compliance status of the Tenderer against this RFT; or
c. any material change to the proposed basis on which the Tenderer will deliver the Services, or have access to the necessary and appropriate skills, resources, nominated key personnel, nominated Subcontractors or corporate or financial backing to provide the Services, on the terms of the Draft Contract.

37.2 If the Department receives notice, or becomes aware of an event under clause 37.1a, the Department may allow (on terms it considers appropriate) the substitution of the Tenderer with another legal entity upon receipt of a joint written request from or on behalf of the Tenderer and the other legal entity. If the Department allows the substitution, it will evaluate the Tender in its original form prior to the event, except that the impact of the event on the information provided in the Tender may be taken into account.

37.3 If the Department receives notice, or becomes aware of an event under clause 37.1b or 37.1c, or the Commonwealth does not allow substitution, or substitution is not requested, under clause 37.1a, the

Department may either exclude the Tender from consideration or consider the Tender taking into account the impact of the changed circumstances on the information provided in the Tender.

38. CONFLICT OF INTEREST

38.1 Tenderers should represent and declare in the Tenderer Deed any conflict of interest that exists at the time of lodging their Tender.

38.2 If at any time prior to entering into a resultant Contract for the Services, an actual or potential conflict of interest arises or may arise for any Tenderer, other than that already disclosed, that Tenderer should immediately notify the Department in writing.

38.3 If any actual or potential conflict is notified, or the Department becomes aware of any actual or potential conflict, the Department may:

a. disregard the Tender submitted by such a Tenderer;
b. enter into discussions to seek to resolve such conflict of interest; or
c. take any other action it considers appropriate.

39. TENDERER BEHAVIOUR

39.1 Tenderers must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of Tenders:

a. Engage in misleading or deceptive conduct or make any false or misleading or deceptive claim or statement;
b. improperly obtain Confidential Information;
c. receive improper assistance from any existing or former officer or employee of the Department;
d. engage in collusive tendering, anti-competitive conduct, unlawful, unethical or other similar conduct with any other Tenderer or other person;
e. attempt to improperly influence an officer or employee of the Department or violate any applicable laws regarding the offering of inducements; or
f. approach any officer or employee of the Department other than in the manner set out in this RFT;
g. engage in, procure or engage others to engage in, any activity that would result in a breach of the Lobbying Code of Conduct 2013 published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
h. otherwise act in an unethical or improper manner or contrary to any law.

39.2 The Department may exclude a Tender from consideration if the Tenderer fails to comply with the requirements set out in this clause 39.

40. COST OF PREPARING AND SUBMITTING TENDER

40.1 To the extent permitted by law, participation in this RFT process is at the Tenderer's sole risk, cost and expense, and in no circumstances will the Department be responsible for any costs incurred by a Tenderer in preparing a Tender, or associated expenses related to this RFT.

41. TENDERERS TO INFORM THEMSELVES

41.1 Tenderers are deemed to have:

a. examined this RFT, and any other documents referenced or referred to in this RFT, and any other information made available in writing by the Department to Tenderers for the purposes of submitting a Tender;
b. examined all other information which is obtainable by the making of reasonable and timely inquiries and relevant to the risks, contingencies and other circumstances having an effect on their Tender;
c. satisfied themselves as to the correctness and sufficiency of their Tender, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
d. satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at Schedule 4;
e. obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFT process;
f. made their own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments; and
g. examined AusTender, including the AusTender Terms of Use.

41.2 It is the responsibility of Tenderers to obtain all information necessary or convenient for the preparation of their Tender.

41.3 Tenderers must not rely, and are deemed not to have relied, upon any statement or representation by the Department, whether before or after the date of this RFT, in connection with this RFT or this RFT process, unless that statement or representation is made in writing by the Contact Officer for this RFT.

41.4 Tenderers should obtain their own legal and other professional advice on this RFT and its requirements including in respect of the potential rights and obligations in respect of the Draft Contract and should not construe this RFT as investment, legal, tax or other advice.

42. NO CONTRACT OR UNDERTAKING

42.1 Nothing in this RFT or in any Tender or by the submission of a Tender (in part or together) creates, or is to be construed to create, any binding contract or other understanding (including any form of contractual, quasi-contractual, restitutionary rights or other legal relationship (express or implied)

between the Department and any Tenderer unless and until a resultant Contract (if any) is signed by the Department and a successful Tenderer.

42.2 Clause 40.1 does not apply to a Tenderer Deed executed by a Tenderer.

43. ACCEPTANCE

43.1 Selection of the preferred Tender will be subject to the execution of a Contract between the Commonwealth and the successful Tenderer substantially in the form of the Draft Contract at Schedule 7.

43.2 Neither the lowest priced Tender, nor any Tender, will necessarily be accepted by the Department.

44. THE DEPARTMENT'S RIGHTS

44.1 The Department reserves the right to:

a. vary the timing and processes, if any, referred to in this RFT;
b. change or suspend the RFT process;
c. amend or vary this RFT or the RFT process, including the Draft Contract;
d. allow any Tenderer to change its Tender at any time;
e. shortlist Tenders;
f. terminate the RFT process where it is, in the opinion of the Department, in the public interest to do so;
g. exclude any Tender from consideration where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. the Tenderer does not meet a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. the Tenderer is not fully capable of undertaking the Contract substantially in the form of the Draft Contract;
    iv. this RFT otherwise allows for the exclusion of the Tenderer; or
    v. the Tender does not represent value for money;
h. enter into a contract or other binding relationship outside the RFT process with a person on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. no Tenderer is fully capable of undertaking the Contract substantially in the form of the Draft Contract; or
    iv. no Tender represents value for money;
i. enter into a contract on terms different to that specified in this RFT;
j. add a Tenderer or select and negotiate with a third party who has not submitted a Tender on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a mandatory requirement;
    iii. no Tenderer is fully capable of undertaking the Contract; or
    iv. no Tender represents value for money;
k. call for new Tenders;
l. publish or disclose the names of Tenderers (whether successful or unsuccessful);
m. allow or not allow a Related Body Corporate to take over a Tender in substitution for the original Tenderer;

n. enter into negotiations with any Tenderer; or
o. cancel, add to or amend the information, requirement, terms, procedures or processes set out in this RFT.

44.2 To the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFT process, including instances where:

a. a Tenderer is not engaged to undertake the provision of the Services;
b. the Department decides not to enter into any resulting Contract with any Tenderer or at all;
c. the Department exercises or fails to exercise any of its other rights under or in relation to this RFT (whether or not the Department has informed a Tenderer of its exercise of the rights);
d. a Tender or any other material or communication relevant to this RFT is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
e. the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements.

44.3 If the Department does vary this RFT or process, the Department will endeavour to inform any prospective Tenderers who have sought, or been issued with, this RFT of that change. A notice of the issue of an addendum will be published in the same manner as the original information about this RFT, including by notification on the AusTender website. Tenderers should regularly check the AusTender website for any updates or addenda to this RFT.

44.4 If clause 6.1 provides that this RFT process is a 'covered procurement', the Department will issue an addendum notifying Tenderers of any suspension of the RFT process.

44.5 To the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFT or any other matter arising by the Department exercising any of its rights.

45. COORDINATED PROCUREMENT

45.1 The Commonwealth has agreed to establish a coordinated procurement contracting framework to deliver efficiencies and savings from goods and services in common use by non-corporate Commonwealth entities who are subject to the *Public Governance, Performance and Accountability Act 2013* (Cth) or other legislation.

45.2 It is therefore possible that the Commonwealth may approve the procurement by the Department of some or all of the same goods or services as the Services under a coordinated process:

a. before the Closing Time; or
b. after the Closing Time but before any resultant Contract is signed with the successful Tenderer(s); or
c. during the period of any resultant Contract entered into as a result of this RFT.

45.3 If clause 45.2a applies, the Department reserves the right to discontinue this RFT process.

45.4 If clause 45.2b applies, the Department reserves the right to discontinue the Tender process and not proceed to enter any contract as a result of this RFT.

45.5 If clause 45.2c applies, the Department may exercise its rights under any resultant Contract to terminate for convenience, without compensation for loss of potential profits.

46. COOPERATIVE PROCUREMENT (PIGGYBACKING)

Not used

47. INTERPRETATION

47.1 If any part of this RFT conflicts with another part, the part higher in the following list will take precedence:

a. Part 1 – Overview, Background, Services Specifications and Tender Lodgement, Part 2 – Information to be provided by Tenderers, Part 3 – Evaluation of Tenders and Part 4 – Conditions of Tendering;
b. Part 5 - Glossary;
c. SCHEDULE 7 – Draft Contract;
d. SCHEDULE 1 – Statement of Requirement;
e. SCHEDULE 2 – Tenderer Declarations, SCHEDULE 3 - Tenderer Response Information, SCHEDULE 4 – Statement of Non-Compliance, SCHEDULE 5 – Pricing Schedule and SCHEDULE 6 – Indigenous Participation Plan Template Response Form; and
f. any other document forming part of this RFT.

47.2 In this RFT, except where the contrary intention is expressed:

a. a reference to time, unless specified otherwise, is to the time in the Australian Capital Territory;
b. words importing a gender include each other gender;
c. words in the singular include the plural and vice versa;
d. a reference to A$, $A, dollar or $ is to Australian currency;
e. if any word or phrase is given a defined meaning, any other part of speech or other grammatical form of that word or phrase has a corresponding meaning;
f. a reference to a clause, paragraph, schedule or annexure is to a clause, paragraph, schedule or annexure to this RFT;
g. a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority, agency or other entity;
h. a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
i. the meaning of general words is not limited by specific examples introduced by including, ‘for example’ or similar expressions and the word ‘include’ is not a word of limitation; and
j. the term 'may' when used in the context of a right exercisable by the Department means that the Department may exercise that right in its sole and absolute discretion and the Department has no obligation to any Tenderer.

PART 5 - GLOSSARY

Term	Definition
ACT	Australian Capital Territory
AusTender	means the Australian Government online tendering system, located on the AusTender website
AusTender Terms of Use	means the terms of use for AusTender available at https://www.tenders.gov.au/?event=public.termsOfUse.
Black Economy Procurement Connected Policy	means the *Black economy – increasing the integrity of government procurement*: *Procurement connected policy guidelines March 2019* available at https://treasury.gov.au/publication/p2019-t369466.
Commonwealth	Commonwealth of Australia
Contract	means a contract substantially in the form of the Draft Contract provided with this RFT, to be executed by the Department and the Contractor, as amended from time to time, and includes its schedules, annexures and attachments.
Closing Time	means the closing time and date of this RFT as specified at clause 9.1 of this RFT
Conditions for Participation	means the mandatory conditions (if any) identified in clause 12 of this RFT
Confidential Information	means information (whether or not owned by the Commonwealth) that: (a) is by its nature confidential; or (b) the receiving party knows or ought to know is confidential, but does not include information which: (c) is or becomes public knowledge other than by breach of contract or any other obligation of confidentiality; (d) is in the possession of a party without restriction in relation to disclosure before the date of receipt; or (e) has been independently developed or acquired by the receiving party
Contact Officer	means the contact person for all matters pertaining to this RFT process, as identified at clause 5 of this RFT
Department	means the Department of Health
Draft Contract	means the document attached as Schedule 7 to this RFT being the proposed Contract to be entered into between the Department and the successful Tenderer(s)
Essential Requirements	means the mandatory conditions (if any) identified at clause 14, and which a Tenderer must comply
Evaluation Criteria	means the criteria set out in clause 21 of this RFT that will be used to evaluate the Tenders received.

Term	Definition
High Value Contract	means a contract where: (a) the Services will be delivered in Australia; (b) the value of the Services is $7.5 million (GST inclusive) or more; and (c) more than half the value of the contract is being spent in one or more of the following industry sectors: (i) building, construction and maintenance services; (ii) transportation, storage and mail services; (iii) education and training services; (iv) industrial cleaning services; (v) farming and fishing and forestry and wildlife contracting services; (vi) editorial and design and graphic and fine art services; (vii) travel and food and lodging and entertainment services; or (viii) politics and civic affairs services.
Illegal Worker	means a person who: (a) has unlawfully entered and remains in Australia; (b) has lawfully entered Australia, but remains in Australia after his or her visa has expired; or (c) is working in breach of his or her visa conditions.
Indigenous Enterprise	means an organisation that is 50 per cent or more Indigenous owned that is operating a business.
Indigenous Participation Plan	means a plan detailing how the Tenderer will meet the minimum mandatory requirements for the Indigenous Procurement Policy (see template at SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM – Indigenous Participation Plan Template Response Form).
Indigenous Procurement Policy	means the policy of that name, as amended from time to time, available on the Indigenous Procurement Website.
Indigenous Procurement Website	means the website at **www.dpmc.gov.au/ipp**.
Late Tender	means any Tender not received by Closing Time
Minimum Content and Format Requirements	means the mandatory content and format requirements identified in clause 13 of this RFT

Term	Definition
Related Body Corporate	has the meaning given in section 9 of the *Corporations Act 2001* (Cth)
Remote Area	means the areas identified in the map on the Indigenous Procurement Website, as updated from time to time.
RFT	means this Request for Tender
Satisfactory	means meets the conditions set out in Part 6.b of the Black Economy Procurement Connected Policy or, if the circumstances in Part 6.c of the Black Economy Procurement Connected Policy apply, the conditions set out in Part 8.b of the Black Economy Procurement Connected Policy.
Schedules	means all or any of the schedules to this RFT
Services	means the Services described in the Statement of Requirement and clause 3 of this RFT
Statement of Requirement	means the description of the Services as set out in Schedule 1 of this RFT
Statement of Tax Record	means a statement of tax record issued by the Australian Taxation Office following an application made in accordance with the process set out at https://www.ato.gov.au/Business/Bus/Statement-of-tax-record/?page=1#Requesting_an_STR.
Subcontractors	means an entity that the Tenderer proposes to enter into a contract with to provide goods or services to the successful Tenderer(s) in relation to the Services or in order for the Tenderer to meet obligations under the resultant Contract
Tender	means a response submitted by a Tenderer to this RFT
Tenderer	means an entity that submits a Tender, and includes a potential Tenderer.
Tenderer Deed	means the deed to be completed and submitted by Tenderers as part of their Tender, as set out in SCHEDULE 2 – Tenderer Declarations of this RFT
Valid	means valid in accordance with Part 7.e of the Black Economy Procurement Connected Policy.

SCHEDULE 1 – STATEMENT OF REQUIREMENT

1. Context and objective of the services required

1.1 Objective

The Australian Government aims to ensure the delivery of safe and effective COVID-19 vaccines to all Australians, as soon as they are available. The Department of Health is seeking to engage a partner to design and deliver training modules for individuals involved in the administration of COVID-19 vaccines to ensure timely and safe access to COVID-19 vaccines in line with best practice, vaccine manufacturer guidance and government guidance.

1.2 Context

The Australian Government is building a diverse portfolio of investments to secure early access to promising vaccines. First doses of some of these candidates are expected to be delivered from early 2021, should they be found to be safe and effective, with further doses delivered in batches throughout 2021 and 2022. The list of COVID-19 vaccines that will be available and administered in Australia is evolving as candidates progress through clinical trials (further detail on the Australian Government's current portfolio is in section 2(h)).

The content covered by existing accredited immunisation programs is broadly applicable to COVID-19 vaccination; however additional formal training is required to ensure competency standards are met for the administration of COVID-19 vaccines (see Table 2). COVID-19 vaccination will likely differ from existing vaccination programs including the administration of novel vaccine candidates, delivery mechanism, populations targeted, , use of digital systems to support track and trace, and handling and cold chain requirements. Such differences will require the development and delivery of COVID-19 vaccination specific training modules. These modules are intended to supplement existing training/basic accreditation for immunisation, and are not intended to replace nor act as a refresher for the vaccination practices and requirements of the National Immunisation Program (NIP).

There are a broad range of existing authorised immunisation providers that may require access to COVID-19 vaccination training modules. These include (but are not limited to) general practitioners, appropriately qualified nurse immunisers, pharmacists, Aboriginal and Torres Strait Islander Health Practitioners and ambulance officers. Some modules may need to be accessed by other individuals that are not authorised immunisation providers, but who undertake defined tasks in the context of a multi-disciplinary team delivering COVID-19 vaccinations (e.g., those who may be involved in the storage and handling of vaccines, but not their administration to individuals).

2. Description of services and scope

2.1 Overview of services required

The Department of Health is seeking to engage a partner to:

1. **Develop the curriculum** for all COVID-19 vaccination training modules, in line with the learning objectives for each module.
2. **Deliver digital training content.** I.e., develop a digital implementation of the curriculum for each (and every) module, producing training content for delivery on an **e-learning** platform, inclusive of CPD-accredited modules, at no additional cost to the trainee/participant.
3. **Deliver practical training.** I.e., identify which COVID-19 vaccination modules may require practical components of training to be delivered digitally if feasible for appropriate assessment and develop such practical training for the relevant modules.

The above includes the requirement to rapidly include new training material (as described in 1-3 above) as and when needed (e.g., where further COVID-19 vaccines are planned for use in Australia which have different requirements to those already in use).

Training modules can be considered in two groups: core COVID-19 modules and additional vaccine-specific modules. Core COVID-91 modules involve training that is consistent across vaccine candidates and applies to COVID-19 vaccination broadly. Additional vaccine specific modules are for individual vaccine candidates, where the training module will be developed by the successful Tenderer(s) based on content or specific requirements provided by vaccine manufacturers.

Table 1 details the scope of work that Tenderers are required to fulfil. Table 2 details the training modules required, noting where there is existing guidance that may be used to inform curriculum development.

The curriculum should made up of the training modules listed in Table 2 in the first instance, noting that flexibility to add or adapt training is required (see Section 2.2(g)). Training should be developed such that modules can be flexibly bundled into multi-module training programs to suit the training needs of those involved in immunisation appropriate for their role, as defined by the Department.

The Department intends to make the training available to participants free of charge, therefore a participant-facing payment platform will not need to be included in the scope of the service.

Table 1. Scope of work for Tenderers

	Core COVID-19 modules[1]	Additional specific COVID-19 vaccine modules[2]	Additional future core COVID-19 modules
Curriculum development			
Course curriculum creation	All core modules	As required	As required
Digital delivery platform (e-learning)			
Build (and transfer as needed)	All core modules	As required	As required
Operate and maintain	All core modules	As required	As required
Practical delivery[3]			
Practical development incl. trainer guidance	Tenderer to propose	As required	As required
Trainer training	Tenderer to propose, if relevant	As required	As required
Immuniser training	Tenderer to propose, if relevant	As required	As required

[1] Core COVID modules: handling and storage, multi-dose vial training, delivery mechanism, administrative reporting, safety and surveillance monitoring for AEFI, communication

[2] Additional specific COVID vaccine modules: candidate specific training for vaccines in Australia. Note advance purchase agreements currently in place with Oxford University/AstraZeneca AZD 1222, Novavax (NVX-CoV2373), BioNTech/Pfizer mRNA (BNT162)

[3] The Tenderer should propose which modules require practical or hands on training. This may or may not involve in-person delivery of training and/or assessment

Table 2. Training elements in scope for Tender (not exhaustive)

Group	Training module	Existing guidance or materials available to inform curriculum development	Sources[4]
Core COVID-19 modules	(a) Handling and storage	Yes – information available on thermostability and handling requirements by vaccine, vaccine storage and cold chain management (including handling, storage and transport) for vaccines stored at 2–8°C.	Individual vaccine manufacturers (provided by the Department) Accredited nurse immuniser program NSW Health Education Training Institute (HETI) training module on cold management (publicly available)
	(b) Multi-dose vial (MDV) training	Yes – advice available on the key issues associated with the use of MDVs, and clinical guidance in the administration of COVID-19 vaccines from MDVs	ATAGI (provided by the Department)
	(c) Delivery mechanism	Yes – advice available from Beckton Dickinson on their consumables including the soloshot mini. Product information and Consumer Medicines Information from Therapeutics Goods Administration (TGA) when available	Beckton Dickinson, TGA
	(d) Administrative reporting including eligibility checking	Yes – advice available on workforce competencies required for documentation and reporting of COVID-19 vaccines	ATAGI/Services Australia/Australian Digital Health Agency
	(e) Safety and surveillance monitoring and reporting for AEFI	Yes – high level guidance on gaps in vaccine safety training from a workforce perspective	ATAGI (provided by the Department) TGA advice when available
	(f) Communication	Yes – advice available on workforce competencies required for communication of COVID-19 vaccines	ATAGI (provided by the Department)
Additional specific COVID-19 vaccine modules	(g) Candidate-specific training	Yes – requirements/guidance to be made available	Individual vaccine manufacturers (provided by the Department)

[4] The successful Tenderer(s) may need to approach the relevant provider unless otherwise stated

Details on the requirements are provided below, for each of the three services required in turn.

2.2 Curriculum development

The following information may be helpful context in developing the curriculum for the training modules.

Core COVID-19 modules

(a) Handling and storage

Learning objective(s)

- Understand the general storage, handling, and transporting requirements for COVID-19 vaccines including relevant national guidelines.
- Understand what to do when a breach occurs ad how to report breaches and wastage
- Demonstrate appropriate handling and storage of vaccines and how to maintain cold chain.
- Demonstrate monitoring and use of temperature monitoring equipment relevant to COVID-19 vaccines

Content

COVID-19 vaccines are known to have different thermostability requirements, examples of these are detailed in Table 2. It is anticipated that individuals at administration sites may need to be equipped to handle multiple different storage and handling requirements, to ensure that different vaccines are maintained at their required temperatures.

Table 2. Example thermostability requirements of vaccine candidates

Thermostability requirements			
In storage	**At administration sites**	**Platform**	**Example vaccine**
2-8°C refrigerated cold and chain	2-8°C refrigerated cold chain for 6 months[2]	Non-replicating viral vector	Oxford University/AstraZeneca AZD 1222
		Protein subunit	Novavax (NVX-CoV2373)
-20°C freeze chain for 6 months	2-8°C for 30 days[5]	mRNA	Multiple potential candidates
-70°C freeze chain for 6 months	Dry ice thermal shippers for 15 days 2-8°C storage for 5 days[2]	mRNA	BioNTech/Pfizer mRNA (BNT162)

As vaccine-specific stability data will become available over time, and training requirements around thermostability may need to be updated (see Additional specific COVID vaccine modules). Thermostability after dilution will also be required to be included in the training, however data is not yet available. In addition to the above, the Australian Government has invested in the COVAX facility for up to 50 per cent

[5] Subject to ongoing stability leading

population coverage. This could include multiple vaccine types that may have different and currently unknown thermostability requirements to those detailed in Table 2.

As stability data is being continually tested and determined by manufacturers and the Therapeutic Goods Administration (TGA), it is likely that the TGA will have continuous updates for expiry dates against batches on their website. As COVID-19 vaccinations will be provided in multi-dose vials the label will include space for the user to note the time of opening to enable vaccination providers to determine the correct time of expiry. Providers will need to be educated on these nuances of additional expiration date checks. Information relating to the expiry date applying after opening will need to be further outlined in the candidate specific training.

(b) Multi-dose vial (MDV) training

Learning objective(s)

- Understand the risk of infection associated with MDV use
- Understand the risk of potential wastage associated with the use of multi-dose vials, and how to minimise this wastage
- Demonstrate safe and appropriate use of multi-dose vials for COVID-19 vaccination (including practices relating to infection control and aseptic techniques to prepare, store and administer vaccines from MDVs)

Context

The use of multi-dose vials is unfamiliar to the vast majority of immunisation providers and is not covered under any existing training programs for immunisation providers (including those qualified to administer BCG vaccines, which are provided in multi-dose vials). There are risks associated with the use of multi-dose vials that can be mitigated through proper training and support. Without training, there is a higher chance of administration errors and possible contamination of vaccine vials and transmission of infection, which could lead to a loss of confidence in the vaccination program. In addition to training, the successful Tenderer(s) will be required to provide written resources. Other resources, such as videos demonstrating proper aseptic techniques, may be considered, dependent on time and resources available. The use of multi-dose vials also comes with the increased risk of wastage, vaccine providers will need to be trained on the correct techniques to reduce wastage.

(c) Delivery mechanism

Learning objective(s)

- Demonstrate ability to use new administration devices (e.g., soloshot mini) appropriately and safely for vaccination
- Understand the risks and potential adverse events use of these devices may cause

Context

The Commonwealth has procured a number of consumables from Becton Dickson (BD) including a new device, the BD Soloshot Mini. BD will provide material to support the training and education on use of these consumables. However, given the use of both MDVs and a new delivery device, it likely that Tenderers will need to be retrained on the delivery mechanism for COVID-19 vaccines. The Soloshot Mini is a drawing and administering combination consumable (allowing providers to administer a vaccine with the same needle used to draw the dose).

(d) Administrative reporting including eligibility checking

Learning objective(s)

- Demonstrate ability to identify the vaccine recipient, check their eligibility and suitability for the vaccine (prior to vaccination); using relevant systems and specific to each setting (e.g. aged care facilities, mass clinics, hospitals etc)
- Demonstrate ability to report vaccine administration details to the AIR, potentially through a number of reporting channel options dependent on the setting

- Demonstrate ability to record wastage at administration site, and to monitor, record and report accurate stock levels at administration sites; using the appropriate system(s) and specific to each setting

Context
Vaccines may become available at different times and be most suitable for specific populations. Individuals must be aware of how to check eligibility and suitability for a vaccine candidate prior to vaccination.

Under-reporting and poor data completeness are known issues, it will be critical that accurate and complete data is captured for the administration of COVID-19 vaccines. Accurate and timely reporting to AIR will be essential for monitoring and evaluating the vaccination program, and for tracking the status/use of each dose of COVID-19 vaccine deployed in Australia. AIR reporting will be a mandatory requirement for COVID-19 vaccination.

Providers may need to preparatory take steps to be able to report to AIR (e.g. register with PRODA, activate Immunisation Provider Numbers, update practice management software). It is likely that there will be a number of digital systems available that can support providers reporting to AIR.

Additionally, training on stock and wastage management and reporting will also be required, including on the use of any systems associated with this requirement.

The successful Tender(s) will need to liaise with Services Australia, the Australian Digital Health Agency and the Therapeutics Goods Administration to ensure end to end training on the digital services and platforms available.

(e) Safety and surveillance monitoring and reporting for AEFI

Learning objective(s)
- Understand the likely symptoms of an adverse event following vaccination (for specific candidate if available, see Additional specific COVID vaccine modules)
- Understand the appropriate monitoring, managing and reporting of adverse events following immunisation (AEFI) for COVID-19 vaccines; including understanding the minimum observation period post-vaccination (for specific candidate if available, see Additional specific COVID vaccine modules)
- Understand and be able to advise patients how they can access advice and support if they are concerned they are experiencing an adverse event, including the appropriate digital channels they can use.

Context
Due to the new and novel COVID-19 vaccines it is vital that any adverse events are monitored and reported in an accurately and timely fashion, to ensure the appropriate investigation can be undertaken and any resulting actions occur rapidly. Providers will require education on how to effectively monitor and report an adverse event within the requirements of their jurisdiction, while also ensuring the adverse event is reported nationally and to the Therapeutic Goods Administration. This includes consideration for legal obligations and preferred reporting methods.

The minimum observation period post vaccination may need to be initially extended, until the safety of COVID-19 vaccines in population-scale vaccination programs is better established. Providers will need to be informed, and training refreshed, if new adverse event reporting requirements are introduced.

(f) Communication

Learning objective(s)
- Understand and demonstrate appropriate communication relating to common consumer concerns relating to COVID-19 vaccinations, other COVID-19-specific vaccination concerns (e.g., concerns related to vaccine-induced disease enhancement, the use of MDVs), and measures to manage these concerns/risks.

- Understand and demonstrate appropriate communication on priority populations and vaccine eligibility in relation to the COVID-19 vaccination program rollout, including communication specific to particular settings.
- Understand and demonstrate appropriate communication on risks and suitability of COVID-19 vaccination for relevant population groups. This includes concerns relating to the use of vaccines with live viruses, particularly in certain population groups (e.g. immunocompromised, pregnant)
- Understand the relevant vaccination schedules, including recommended intervals between doses, the need to provide reminders on timing of second doses, and the appropriate spacing or co-administration with other vaccines

Context
Front-line providers will likely be faced with a range of questions, particularly around the safety of COVID-19 vaccines. Training must address the issues likely to be of greatest concern to patients, as well as build providers' confidence to respond to these concerns.

The public will require reassurance that any COVID-19 vaccines used in Australia have been thoroughly assessed for safety, having undergone clinical trials and assessment as rigorously as all other vaccines used in Australia. Communications with the public should include an explanation on where the timeline of development has been compressed, how this has been possible, and why the compressed timeline does not compromise the safety of the vaccines.

Some relevant information will evolve over time (e.g., information on the safe co-administration of COVID-19 vaccines with other NIP vaccines).

Providers will need to be aware when to direct patients if they have concerns at a later time. It is also imperative that vaccine administration providers are aware of how to communicate and manage culturally diverse populations (including some populations where English is not the primary language spoken).

Additional specific COVID-19 vaccine modules

(g) Candidate specific training

Learning objective(s)
- Understand the appropriate dosing and schedule for administration
- Understand of the contraindications, warnings, adverse reactions, and (in)appropriate usage with other vaccines
- Demonstrate appropriate storage and handling of the specific vaccine candidate; including handling of vaccines prior to time of use, thawing, dilution, and storage following dilution
- Demonstrate appropriate dose preparation including dilution and verification prior to administration
- Understand appropriate administration of the vaccine, including in relation to appropriate (bodily) sites of administration

Context
Vaccine manufacturers will develop and provide training materials specific to the relevant candidate. The successful Tenderer(s) is expected to draw on these to develop training modules.

The approach to providing COVID-19 vaccines in Australia is outlined in 'Australian COVID-19 Vaccination Policy'. To date, the Commonwealth has entered into advance purchasing agreements with the following developers[6]:

- AstraZeneca for the supply of 53.8 million doses of the Oxford vaccine
    - 3.8 million doses will be delivered to Australia in early 2021
    - 50 million doses will be manufactured in Australia between from early 2021 in monthly batches through to January 2022 in monthly batches

[6] Australia's vaccine agreements, last updated 13 November 2020, https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/vaccines-and-treatments/australias-vaccine-agreements

- Pfizer for the supply of 10 million doses
    - 10 million doses will be available in Australia in monthly batches commencing from early 2021
- Novavax for the supply of 51 million doses
    - 51 million doses will be made available in Australia during 2021

This amounts to a total of over 114 million COVID-19 vaccine doses if each of the vaccines if proven safe and effective. The Commonwealth has also joined the global COVAX Facility to purchase up to 25.5 million doses (50% population coverage) of safe and effective vaccines from a diverse global portfolio of vaccine candidates.

Current information indicates that successful vaccine candidates will be presented in multi-dose vials and administered by injection in a 2-dose regimen. Reconstitution of vaccines will be required in some instances. Training will need to reiterate the importance of completing the 2-dose regime in the specified timeframes.

2.3 Digital delivery platform (e-learning)

Tenderers are required to digitise/produce training content for all modules for delivery on an e-learning platform, to meet the learning objectives detailed above.

It is anticipated that, for some (but not all) training participants, these training programs will be accessed via the websites of the professional bodies/peak bodies relevant to the participants. Tenderers should propose an approach for two scenarios, noting that a combination of these scenarios may be required across the relevant professional/peak bodies.

- Scenario 1: participants access training via peak bodies that have existing e-learning platforms
- Scenario 2: participants either do not hold membership/access with a relevant peak body, and/or the peak body does not have an e-learning platform

Requirements

(a) Export of training modules

(i) For scenario 1: training modules must be exportable such that they can be incorporated into an existing learning platform

(b) Hosting of training modules

(i) For scenario 2: training modules must be accessible via links on the peak body portal but hosted by the Tenderer

(ii) For scenario 2: e-learning portal hosted by the Tenderer should be able to display the branding of any relevant peak body

(c) Capacity of platform

(i) For scenario 2, a high volume of users is anticipated following the launch of the training program and in the initial months of operation. The Tenderer must demonstrate their ability to host large volumes of traffic on their platform.

(d) Security of platform

(i) For Scenario 1 and 2: any platform hosting training information must have the appropriate security and privacy requirement's to protect individuals information and the content held within the training as per industry standards.

(e) Availability

(i) Tenderers must configure the training environment in a highly available and redundant fashion in order to minimise the potential impact of any outage

(ii) Tenderers must make the training program available on a 24 x 7 basis, except during agreed downtime and maintenance windows

(f) User Support

(i) Scenario 2: must provide user support to manage and resolve platform or use related issues for the training program

2.4 Practical delivery

Training for core and/or additional specific vaccine candidate modules may require a digital practical training component for participants to meet the learning objectives successfully.

Tenderers must identify and design the necessary practical training for such modules to ensure appropriate assessment and understanding of the learning objectives

Practical modules may or may not be delivered in person, Tenderers should detail their approach to practical training noting that it must be able to be delivered at sufficient scale and speed to meet the timelines required for rollout of the COVID-19 vaccination program.

Where practical training via a digital platform is not feasible the successful tenderer(s) will provide alternative options as to how practical training can be delivered and distributed to ensure training can be undertaken I a timely and safe manner, following relevant COVID-Safe rules and regulations.

Further advice on practical training may be uncovered through engagement with peak bodies and medical experts.

Requirements

(a) National training availability and accessibility

(i) Tenderers must ensure equity of practical training availability across Australia, i.e. access for those in rural/remote areas

(ii) Tenderers must ensure the training delivery meets any accessibility requirements for online and potential in-person practical training (where digital practical training is not feasible)

2.5 Cross-cutting requirements

(a) Reporting:

(i) Reporting requirements for the platform/practical training (including the nature, frequency and detail of reporting provided to the Department).

(ii) Maintaining a register of accredited/trained participants (including for the purposes of verification by third-parties and regulators) noting the Department's right to access and use training data

(b) Service Standards

(i) Service levels will need to be developed by the successful Tenderer(s) and agreed with the Department as part of implementation planning to ensure quality, availability and timing of the delivered solution.

(c) Identification of participants

(i) Tenderers must be able to uniquely identify the individual undertaking the training, irrespective of scenario, either through the participant's membership, unique student identifier or other methods to be outlined by the tenderers.

(d) Assessment of eligibility

(i) Tenderers must ensure all participants undertaking the training are appropriately qualified to do so. I.e., they hold current registration to provide vaccination services (other than COVID-19 vaccines).

(ii) Tenderers must propose how they intend to assess candidates' eligibility. The Department anticipates that this would, at a minimum, entail checking participants' AHPRA registration number, and (where appropriate for the health practitioner type) self-certification that the participant has undergone the necessary vaccination training.

(e) Assessment and proof of training

(i) Tenderers must provide evidence of successful training completion by individual module, and overall program.

(ii) Tenderers should propose an approach to evaluating participant learning such by conducting post-test assessments for each module.

(f) Accreditation

(i) Tenderers must successfully accredit the training program through the Health Education Services Australia (HESA) in advance of rollout.

(ii) Tenderers should account for accreditation processes in the timeline to commence delivery of the training programs by the end of January 2021.

(g) Consultation with peak bodies, universities and State and Territory Health Departments

(i) Tenderers must consult with relevant peak bodies to ensure buy-in for the training program (i.e., to maximise the chances of high training uptake).

(ii) Tenderers must consult with relevant peak bodies to design an appropriate approach digital training delivery through existing platforms.

(iii) Tenderers must work with relevant professional bodies to ensure training modules meet the requirements for CPD points, where applicable.

(h) Flexibilities and assurances

(i) Tenderers must be able to adapt in designing and rolling out additional training modules or updates as required within a reasonably agreed timeframe

(ii) Tenderers must be able to flex if roll-out is required earlier or later than forecast, depending on vaccine availability and/or approvals

(iii) Tenderers must be able to flex if multiple vaccine types are available, either launched together or at different times

(iv) Tenderers must be able to adapt to new individuals/workforces undertake training and eligibility for training must be verified

(i) Stable launch date

(i) The training modules must be operational by late January 2021, in advance of when the first doses of a COVID-19 vaccine are projected to be delivered to the Department.

(ii) Tenderers are to advise the Department if there are any implementation considerations or issues for the timing or availability of training program functions

3. Expected deliverables

The outcome of this RFT will be the selection of a successful Tenderer(s) who must:

- Develop the curriculum for modular training in line with the learning objectives for core COVID and additional specific vaccine modules
- Digitise and produce training content for delivery on an e-learning platform hosted either by peak bodies or by the Tenderer
- Identify and design practical training and assessments for training modules
- Rapidly include new training material (as described in 1-3 above) for COVID-19 vaccines as they are developed and prior to them being made available in Australia

4. Proposed timetable for performance of service

Activity	Timing
Commonwealth Execution of Contract	w/c 11 January 2021
Commencement of Services	On signing
Services definition	From Commencement of Services.
"Operate" stage	From late January / early February 2021 (earliest anticipated commencement of Phase 1 of vaccine rollout, pending availability of suitable vaccines(s))

5. Responsibilities of the Department

The Department will be responsible for provision of reasonable access to information as requested by the Tenderer(s).

The Department will provide an internal resource to act as a point of contact for the duration of the contract, including supporting engagement with required stakeholders across the Commonwealth e.g., ATAGI, HESA.

The Department will approve the training programs to be provided by the Tenderer.

6. Term of the Contract including any options to extend

The Initial Term of the Contract will be up to 1 year. The Department will retain the option of also requires 2 optional extensions each to be 6 months in duration (in the Department's favour).

7. Specific insurance requirements particular to the procurement

The Tenderer will need to hold standard insurances as per industry standards such as public liability and professional indemnity insurance, refer to Schedule 1 of the draft contract for further information.

8. Monitoring and reporting

Tenderers will be required to produce reports for the Department at least weekly in order for the Department to review the effectiveness of the contract, and to assist with decisions on improvements that could increase the utility of the service to end users.

The reports will also assist the Department to monitor the quality and effectiveness of the provision of the Services by the successful Tenderer(s).

The reports produced by the successful Tenderer which must be delivered to the Department are required to:

- support the Tenderer's contractual obligations to the Department;
- provide details about the Tenderer's management of the Services with respect to agreed Service Levels; and
- support reporting requirements of the Department.

It is expected that the Tenderer will also produce reports for the Tenderer's own purposes to:

- support the day-to-day operations of the Services provided; and
- allow the Tenderer to monitor the quality of the training and to manage continual improvement of the training modules and the overall training program..

Other Reporting may be required as set out in the Contract.

SCHEDULE 2 – TENDERER DECLARATIONS

The Tenderer must complete, sign and scan the declaration set out below and submit the declaration as part of its Tender. This is a Minimum Content and Format Requirement.

THIS DEED POLL is made on the day of 2018

by

Name

ACN/ABN/ARBN

Short form name **Tenderer**

1. Declaration

The Tenderer declares that this deed is for the benefit of the Commonwealth of Australia as represented by the Department of Health (Department).

2. Definitions

In this deed terms have the same meaning as in Request for Tender for COVID-19 Vaccination Training Program (Health/20-21/XXXX) (**RFT**).

3. Offer and Change of Circumstance

The Tenderer offers to supply the Services described in this RFT on the conditions set out in this RFT for the price tendered. The Tenderer undertakes not to withdraw, vary or otherwise compromise this offer for a period of no less than six months from the Closing Time.

The Tenderer undertakes to promptly notify the Department of any change, after submission of its Tender, to the basis upon which it will have access to the necessary skills or resources, or corporate or financial backing, to supply the Services.

4. Tenderer's Conduct

The Tenderer confirms that this Tender:

- does not contain any false or misleading claim or statement; and
- has been compiled without the Tenderer:
  - engaged in misleading or deceptive conduct;
  - improperly obtaining Confidential Information;
  - engaging in any collusive bidding, anti-competitive or other unethical, improper or unlawful conduct;
  - violating any applicable laws or Commonwealth policies regarding the offering of inducements;
  - communicating with or soliciting information from any Department employee (or contractor) or ex-employee (or ex-contractor) other than the Contact Officer;
  - obtaining improper assistance from any Commonwealth employee or using Confidential Information improperly obtained;
  - approaching any officer or employee of the Department other than in the manner set out in the RFT;
  - engaging in, or procuring others to engage in, any activity that would result in a breach of the *Lobbying Code of Conduct 2013* published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or

- otherwise acting in an unethical or improper manner or contrary to any law.

The Tenderer warrants that it has not attempted and will not attempt, through its officers, employees or agents, to influence improperly any officer or employee of the Department in connection with the assessment of the Tender.

The Tenderer warrants that it has complied with all relevant laws and with Commonwealth policy, in preparing and lodging its Tender and in taking part in this RFT process.

5. Conflict of Interest

[Note to Tenderers: Strike through whichever option does not apply. Tenderers should refer to clause 38 of the RFT for further information

The Tenderer represents and declares that, having made all reasonable enquiries, it does not have any known actual or potential conflicts of interest concerning itself or a related entity in respect of this RFT, its Tender or the provision of the Services referred to in the Statement of Requirement other than those specified below.

OR

The Tenderer

- represents that, having made all reasonable enquiries, the following represents its only known actual or potential conflicts of interest in respect of this RFT, its Tender or the provision of the Services referred to in the Statement of Requirement:

[Insert details]

- advises that its proposed mitigation approach to manage this conflict of interest is as follows:

[insert details]

6. Further representations

The Tenderer makes the following further representations to the Department:

- it is authorised to sell and/or support all products required in the performance of the Services relating to this Tender;
- it has examined the AusTender Terms of Use which are obtainable on the AusTender website;
- it has examined this RFT, all documents referred to in this RFT and all other information made available to it and all applicable legislation and policies;
- it has examined all further information which is obtainable by making reasonable enquiries relevant to the risks, contingencies and other circumstances having an effect on its Tender;
- it has satisfied itself as to the correctness and sufficiency of its Tender, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
- it has satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at SCHEDULE 4 – Statement of Non-Compliance;
- it has obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFT process;
- it has made its own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments;
- it has relied entirely on its own enquiries and has not relied on any representation, warranty or other conduct by or on behalf of the Department, except as expressly provided in this RFT or in notices received by it; and

- it has accepted and has fully complied with the provisions of this RFT.

7. Acknowledgements

The Tenderer acknowledges that:

- the Department may exercise any of its rights set out in this RFT, at any time;
- the statements, opinions, projections, forecasts or other information contained in this RFT may change;
- this RFT is a summary only of the Department's requirements and is not intended to be a comprehensive description of it;
- neither the lodgement of the Tender nor the acceptance of any Tender nor any agreement made subsequent to this RFT will imply any representation from or on behalf of the Department that there has been no material change since the date of this RFT or since the date as at which any information contained in this RFT is stated to be applicable;
- to the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFT process, including instances where:
  - a Tenderer is not engaged to undertake the provision of the Services;
  - the Department decides not to enter into any resulting Contract with any Tenderer or at all;
  - the Department exercises or fails to exercise any of its other rights under or in relation to this RFT (whether or not the Department has informed a Tenderer of its exercise of the rights);
- a Tender or any other material or communication relevant to this RFT is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
- the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements
- to the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFT or any other matter arising by the Department exercising any of its rights; and
- the Department will have received this Tender in reliance on this deed and that the Department may suffer loss if any of the representations, undertakings, consents or other statements in this Declaration or the Tenderer's Tender are misleading or deceptive.

8. Corporate capacity

The Tenderer confirms that:

- it has the capacity to respond to this RFT;
- there are no restrictions under any relevant law to prevent it from so responding;
- it is financially viable; and
- the Tenderer:
  - being a corporation – is not under one of the forms of external administration referred to in Chapter 5 of the *Corporations Act 2001* (Cth) and has not had an order made against it for the purpose of placing it under external administration; or
  - being an individual – is not bankrupt and has not entered into a scheme of arrangement with creditors.

9. Security, probity and financial checks

The Tenderer:

- consents to the Department performing (and will procure all necessary consents to enable the Department to perform) such security, probity and financial investigations and procedures as the Department may determine are necessary in relation to the Tenderer, any consortium member, their employees, officers, partners, associates, Subcontractors or related entities; and
- agrees to provide at its cost, all reasonable assistance to the Department and its nominees in this regard.

10. Workplace Gender Equality Act 2012 (Cth)

Under Australian Government procurement the Tenderer is obliged to indicate whether or not it is covered by the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act). The Tenderer is covered by the WGE Act if it is a 'relevant employer', defined as being a non-public sector employer (including higher education institutions, trade unions and not-for-profit organisations) of 100 or more employees in Australia. For more information about the coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

[Note to Tenderers: Check the relevant box below. If you check box (a), please ensure your letter of compliance is attached to this declaration.]

☐ (a) Yes, the Tenderer is a relevant employer. The Tenderer has attached a current letter of compliance as part of this Tender which indicates my compliance with the *Workplace Gender Equality Act 2012* (Cth).

☐ (b) Yes, the Tenderer is a relevant employer. The Tenderer will be providing a current letter of compliance prior to entering into any resultant Contract.

☐ (c) No, the Tenderer is not a relevant employer.

11. Terrorism

The Tenderer declares neither it, nor any of its personnel or any Subcontractor proposed in its Tender, are listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

12. Trade sanctions

The Tenderer declares neither it, nor any Subcontractor proposed in its Tender, are named in the consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

13. Employee entitlements

The Tenderer represents that, having made all reasonable enquiries, there are currently no unsettled judicial decisions against the Tenderer (excluding decisions under appeal) relating to employee entitlements for which the Tenderer has not satisfied any resulting order.

14. Illegal Workers

The Tenderer declares that is does not engage Illegal Workers.

Note: see definition of "Illegal Workers" in the Glossary in Part 5 of this RFT.

15. Survival

This deed survives the termination or expiry of the RFT process.

16. Indigenous Procurement Policy

The Tenderer declares the following:

The Tenderer has or has had _____ [NIL OR SPECIFY NUMBER] contracts with the Commonwealth that included the Indigenous Procurement Policy mandatory minimum requirements.

For the contracts referred to in the para above (if any), the Tenderer has:

- fully met /
- partially met /
- not met /
- not applicable as Nil contracts undertaken,
- the Indigenous Procurement Policy mandatory minimum requirements.

[Note to Tenderers: Strike out the options that do not apply.]

The Indigenous enterprises referred to in the Indigenous Participation Plan submitted as part of Tenderer's Tender are 50 per cent or more Indigenous owned.

[Note to Tenderers: If you are an incorporated joint venture, where the joint venture is at least 25 per cent Indigenous owned, include the following. If it does not apply you may strike it out.]

The Tenderer is a joint venture that is 25 per cent or more Indigenous owned.

17. [Note to Tenderers: Supply Nation maintains a list of enterprises that meet the definition of "Indigenous enterprises". If an enterprise is not listed with Supply Nation refer to section 1.8.1 of the Indigenous Procurement Policy for ways of ensuring an enterprise is an Indigenous enterprise.]Black Economy Procurement Connected Policy

Note to drafters: Where the RFT is for a contract, insert the wording below. This wording should be removed if the RFT is for a panel arrangement.

There are no mandatory clauses in the Black Economy Procurement Connected Policy for a Tenderer declaration for an approach to market for a panel arrangement. Refer to the Black Economy Procurement Connected Policy for optional clauses and seek advice from Legal and General Counsel Division or Procurement Advisory Services if required.

The Tenderer represents that:

- it holds a Valid and Satisfactory Statement of Tax Record from each Subcontractor that it proposes, as part of its Tender, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive); and

if it is the successful Tenderer, it will ensure that any Subcontractor not included in its Tender that it subsequently engages to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive), will provide it with a Satisfactory Statement of Tax Record that is Valid at the time of entry into the subcontract.

Executed as a **deed poll**

Execution by a company incorporated in Australia

The following execution block should be used by a Tenderer that is a company incorporated in Australia.

Executed by **[**Name of company**]** in accordance with Section 127 of the *Corporations Act 2001*

Signature of director	Signature of director/company secretary (Please delete as applicable)
Name of director (print)	Name of director/company secretary (print)

Execution by an attorney

Where the Deed of Undertaking is executed by an attorney under a power of attorney on behalf of a company incorporated in Australia, the Tenderer should submit with its executed Deed of Undertaking a copy of the relevant power of attorney. Powers of attorney must be in the form of a deed executed in accordance with section 127 of the *Corporations Act 2001* (Cth).

Signed sealed and **delivered** by **[**company name**]** by its attorney under power of attorney [dated [date of power of attorney] registered number [registered number] book number [book number], who warrants that, as at the date of this deed, they have had no notice of revocation of the power of attorney

Signature of attorney	Signature of witness
Name of attorney (print)	Name of witness (print)

SCHEDULE 3 – TENDERER RESPONSE INFORMATION

Tenderer's Profile

1.1 Tenderer's contact officers

Tenderers should provide details of their nominated contact officers in the following table:

Tenderer's primary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	
Tenderer's secondary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	

1.2 Tenderer's details

Tenderers should complete all details in the following table:

Tenderer's details	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
Is the Tenderer registered for GST?	Yes / No
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Date and place of incorporation or registration of business (if applicable)	

2. Subcontractor details

Where Tenderers are proposing to use Subcontractors to deliver some of the Services, Tenderers should complete all details in the following table for each nominated Subcontractor.

(a) Tenderers should note that, under paragraph 7.21 of the Commonwealth Procurement Rules, the names of Subcontractors may be publicly disclosed and that it is the responsibility of Tenderers to secure Subcontractors' agreement to this.

Subcontractor 1	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

Subcontractor 2	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

3. Tenderer's insurance

Tenderers should complete all details in the following table:

General liability insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Professional indemnity insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Workers' compensation insurance	
Name of insurer	
Policy number	
Expiry date	

Where the Tenderer's proposed Personnel are operating as an individual and/or include volunteers, Tenderers should also complete all details in the following table:

Disability income insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Voluntary workers' insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	

4. Tenderer's Financial Viability

(a) The Tenderer should provide a summary of their financial viability.

(b) This may include data from or for a financial analysis of its operations including profitability, liquidity, insolvency, bankruptcy actions, working capital management efficiency, financial structure, debt coverage and return on investment.

(c) The Department may also request further information and undertake its own independent enquiries and assessment in relation to the Tenderer's financial viability.

5. Actions or Investigations

(a) The Tenderer should provide particulars of any petition, claim, action, judgement or decision that is likely to adversely affect its capacity to provide the Services.

(b) Tenderers should provide details of whether or not they are aware that they are under investigation, or the subject of court proceedings, in relation to a possible or actual breach of any relevant legislation, and if applicable, provide details of the same.

6. Service Delivery and Management

Tenderers should provide an overview of their proposed approach to delivering the Services outlined in Schedule 1 – this should be presented across the 3 areas (curriculum development, digital delivery platform (e-learning), and practical delivery) and for each of the training modules detailed in Schedule 1.

6.1 Approach to service delivery

The Tenderer should clearly state whether they can meet all of the Service requirements as set out in the Statement of Requirement, and if not, which they are unable to meet.

Tenderer's should detail:

(a) Curriculum development

(i) how they propose to develop the curriculum for all stated modules, including but not limited to, approach for validating the inclusion of course material, course structure, learning outcomes, length of course

(ii) any additional modules the Tenderer feels would be required to ensure the adequate training and upskilling of COVID-19 immunisers

(b) Digital delivery platform (e-learning)

(i) the plan to deliver training digitally, including their platform strategy and technology choices, mix of media and level of interactivity

(ii) approach to meet the requirements including for both scenarios

(c) Practical delivery

(i) Identify training modules most in need of practical training to ensure adequate training and upskilling

(ii) the planned approach to deliver practical training in a digital setting, outline where this is not feasible and provide an alternative approach to ensure timely accessibility of practical training

(iii) where in person practical training is proposed Tenderers should include their sites, resourcing, and approach for ensuring delivery across Australia. Noting this could be provided by the Tenderer or through an alternative party, options for both should be specified

(d) Cross-cutting requirements

(i) Their proposed approach for identifying individuals and ensuring they are eligible to undertake training

(ii) how courses will be assessed to demonstrate impact to knowledge base and skill of trainees and how proof of training will be provided

(iii) their proposed approach to seeking accreditation from HESA in advance of rollout

(iv) proposed consultation approach with peak bodies

(v) how they propose to adapt to the flexibilities and assurances outlined in schedule 1

(vi) their proposed approach to reporting requirements and register maintenance of accredited/trained participants

6.2 Timeline execution and readiness

Tenderer's should propose a path to readiness including timelines and flagging key risks to service delivery. Tenderer's should detail the expected ramp up time for current and potential training modules including both digitally delivered and practical modules, including requirement to seek and achieve accreditation. Tenderers should set out their organisational capacity to deliver the Services.

6.3 Collaboration and responsiveness

Tenderers should detail their methods, capability and expertise to provide agile and responsive services in complex and evolving operating environments, as well as to work collaboratively with the Commonwealth, peak bodies other service providers and any other required stakeholders in the delivery of the Services.

6.4 Security and compliance

Tenderers should detail the extent to which it does or will meet all specified security requirements in the RFT.

7. Pricing

In line with the pricing sheet, Tenderers should detail any assumptions or constraints associated with their proposed pricing, such as for fixed price limits. If relevant Tenderers should ensure they detail expected in person training group sizes, including number of individuals that can be trained to deliver COVID-19 vaccine training by a single individual (trainer training), and the number of trainees that can be trained by a single trainer (immuniser training).

8. Performance management

Tenderer's should outline:

(a) details of how the performance standards for the Services will be maintained, monitored and reported to the Department;

(b) how the Tenderer will respond to requests from the Department for performance related information

(c) a list of the daily, weekly, and monthly metrics that will be reported to demonstrate effectiveness and completeness of process, including in what format these reports will be delivered and how they can be accessed

9. Past Performance

To assess the Tenderer's capability to deliver the Services, Tenderers should provide details of similar services provided within the last three years (if any). In addressing this requirement, Tenderers should include:

(a) the organisation(s) for whom the services were undertaken, including contact details;

(b) the nature of the project and the outcome achieved by the Tenderer;

(c) the period over which the work was undertaken; and

(d) the value of the work undertaken.

10. Risk management

Tenderers should set out in their Tender response:

(a) the key issues and risks they consider are relevant to the provision of the Services;

(b) the Tenderer's suggested approach to the issue and risk;

(c) the Tenderer's and Department's roles in the suggested approach; and

(d) the Tenderer's risk management systems currently in place or proposed.

11. Personnel

The Tenderer should, in the table below, provide details of the personnel who will be used for the supply of the Services.

Name and position of Personnel	Role in the provision of the Services	Experience / qualifications	Availability

12. Referees

(a) Tenderers should provide details of at least two referees which can be contacted regarding work undertaken by the proposed personnel. References will be evaluated based on relevance of work completed as well as comments from the referee contacts.

(b) A Tenderer may provide contacts within the Department as referees. However, where a Department contact is involved in evaluating Tenders or advising the Tender evaluation team they will be unable to provide a reference, in which case the Department may ask the Tenderer to provide details of an alternate referee.

(c) Without limiting paragraph 10.2, the Department reserves the right to contact persons other than those provided as referees by Tenderers.

13. Indigenous Participation Plan

(a) Each Tenderer must submit an Indigenous Participation Plan with its Tender using the template in Schedule 6. The Indigenous Participation Plan should address:

(i) how the Tenderer intends on meeting the mandatory minimum requirements for the Indigenous Procurement Policy;

(ii) the Tenderer's current rate of Indigenous employment and supplier use;

(iii) the Tenderer's commitment to Indigenous participation. Some examples of the activities an organisation can take to demonstrate its commitment to Indigenous participation are set out in paragraph 4.7.1 of the Indigenous Procurement Policy; and

if any part of the Contract will be delivered in a Remote Area, how the Tenderer will ensure that its provision of the Services will deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

(b) The mandatory minimum requirements can be met at:

(i) the contract-based level (see paragraph (c) below); or

(ii) the organisation-based level (see paragraph (d) below).

(c) To meet the mandatory minimum requirements at the contract-based level, by the end of the Initial Term of the ***Contract***:

(i) at least 4 per cent of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, on average over the Initial Term of the ***Contract***; or

(ii) at least 4 per cent of the value of the work performed under the ***Contract*** must be subcontracted to Indigenous enterprises, on average over the Initial Term of the ***Contract***; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, and a minimum percentage of the value of the work performed under the ***Contract*** must be subcontracted to Indigenous enterprises, so that both minimum percentages add up to 4 per cent, on average over the Initial Term of the ***Contract***.

(d) To meet the mandatory minimum requirements at the organisation-based level, by the end of the Initial Term of the ***Contract***:

(i) at least 3 per cent of the full time equivalent Australian-based workforce of the contractor must be Indigenous Australians, on average over the Initial Term of the ***Contract***; or

(ii) at least 3 per cent of the value of the contractor's Australian supply chain must be subcontracted to Indigenous enterprises, on average over Initial Term of the ***Contract***; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce must be Indigenous Australians, and a minimum percentage of the value of the contractor's supply chain must be subcontracted to Indigenous enterprises, such that both minimum percentages add up to 3 per cent on average over the Initial Term of the ***Contract***.

(e) The mandatory minimum requirements can be met directly or through subcontracts.

(f) The successful Tenderer's Indigenous Participation Plan will be attached to the resultant ***Contract***, and the successful Tenderer will be required to comply with and report against the Indigenous Participation Plan during the term of that ***Contract***.

14. Economic Benefit to the Australian Economy

Respondents should answer the questions below to enable the Department to consider the economic benefit of the procurement to the Australian economy.

RESPONDENT PROFILE

Does the Respondent have an Australian Business Number (ABN)	Y/N

Is the Respondent incorporated in Australia? If No, is the Respondent a foreign company registered in Australia	Y/N Y/N
How many current (full time equivalent) employees of your organisation are based in Australia?	

Describe any strategies you consider relevant to your proposed supply's economic benefit to the Australian economy
[max 300 words] *Examples of information potential suppliers might include, but are not limited to:* • *Lowest price, saving the tax payer;* • *Building, leasing or procuring infrastructure that supports Australian communities;* • *Providing skills and training that benefits Australian communities;* • *Employing workers in Australia;* • *Paying taxes in Australia;* • *The environmental benefit of the proposed solution to Australia, for example, low environmental impact through energy efficient inputs such as computers, air conditioning, telephones and paper;* • *Contributing to positive social outcomes in Australian communities;* • *Using of indigenous business;* • *Using SMEs in delivering goods and services, such as a subcontractor or supplier;* • *Sharing knowledge, skills and technology with SMEs; and* • *Using goods and services from a business that provides services of persons with a disability*

15. Other information

Tenderers should provide any other information that addresses the Evaluation Criteria set out in clause 21 of this RFT.

Note to drafters: If you have changed or supplemented the Evaluation Criteria in clause 21 of the RFT you should consider whether you need to change or add paragraphs to this Schedule so that you are requesting enough information to allow the Department to assess Tenders.

SCHEDULE 4 – STATEMENT OF NON-COMPLIANCE

1. Statement of Non-Compliance

Where the Tenderer wishes to negotiate any provisions of the Draft Contract (Schedule 6), it should include in its response below details of:

- the provision that it wishes to negotiate;
- the alternative words that it proposes; and
- any increase in its Tender price if the Department does not agree to the amendment.

The Department will consider any non-compliances or partial compliances in its evaluation of other risks.

If Tenderers do not submit a response to this Schedule they will be evaluated on the basis that they agree with all the provisions of the Draft Contract.

The Department does not intend to permit a Tenderer to re-open any provision of the Draft Contract in negotiations that was not identified as an area of non-compliance or partial compliance in a Tender.

Item reference	Nature of compliance (partially complies, does not comply)	Reasons for non-compliance or partial compliance and proposed alternative wording

2. Confidential Information

The Tenderer should specify any information which is contained in its Tender, or which may be provided by it during this RFT process, that it considers should be protected as Confidential Information by the Department in respect of any resultant Contract. The Tenderer should also provide appropriate reasons why any such information should be protected as Confidential Information.

Tenderers should review the information available from the Department of Finance's website for further detail about what information may be protected as Confidential Information (see the Department of Finance's Confidentiality Throughout the Procurement Cycle).

Proposed Confidential Information (refer to RFT or Schedule clause)	Reason why this information should be protected as Confidential Information

SCHEDULE 5 – PRICING SCHEDULE

1. Pricing Schedule

1.1 The Tenderer should indicate, using the attached .xlsx file as a template, all fees, charges, and other costs which it would seek to be paid for the Services and discounts offered.

1.2 A breakdown of assumptions, variations or other qualifications relied upon for generating the price should be provided.

1.3 The Department prefers that Tenderers lodge their pricing in Australian currency. Any pricing lodged in foreign currency amounts will be converted to Australian currency for evaluation purpose.

1.4 All amounts are to be expressed as GST inclusive.

1.5 Tenderers should provide itemised pricing information and proposed payment schedules detailing all fees, prices and charges related to each milestone or deliverable of the Services.

1.6 Competitive neutrality requires that government business activities should not enjoy net competitive advantages over their private sector competitors simply by virtue of public sector ownership. Accordingly any Tenderers from the public sector must demonstrate in the pricing of their Tender that the requirements of competitive neutrality have been met, including payment of relevant taxes and charges, rates of return and cost of funds. Compliance with the requirements of competitive neutrality may be verified by the Department.

2. Other Pricing Information:

2.1 Tenderers are encouraged to provide any discount Tenderers are prepared to allow for payment within the standard Commonwealth 30-day period for payment of invoice.

2.2 Tenderers are encouraged to provide financial details of any alternative pricing structures or pricing control mechanisms they would be prepared to use to ensure good cost controls (for example, volume discounts, rebates, fee credits, other alternatives to hourly rates, capped, fixed or success fee pricing mechanisms). Tenderers are to state when such control mechanisms would be applicable.

SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM

INDIGENOUS PARTICIPATION PLAN

[INSERT NAME OF TENDERER]

1. This is an Indigenous Participation Plan submitted as part of the Tender in response to [INSERT RFT NUMBER] (**RFT**).

2. If selected as the Contractor following evaluation of Tenders received in response to the RFT, [TENDERER] will meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy:

   at the contract-based level, in which regard at least:

   - [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians over the Initial Term of the [***Contract/Deed of Standing Offer***]; and

   - [INSERT] percentage of the value of the work performed under the Contract will be subcontracted to Indigenous enterprises over the Initial Term of the [***Contract/Deed of Standing Offer***]; or

   at the organisation-based level, in which regard at least:

   - • [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce will be Indigenous Australians over the Initial Term of the [***Contract/Deed of Standing Offer***]; and

   - • [INSERT] percentage of the value of [TENDERER'S] Australian supply chain will be subcontracted to Indigenous enterprises over the Initial Term of the [***Contract/Deed of Standing Offer***].

[Note to Tenderers: Select which option(s) above apply based on the requirements set out in paragraphs 12(b), (c) and (d) in Schedule 3 of this RFT.]

3. To meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy, [TENDERER] will undertake the following:

[Note to Tenderers: Tenderer to insert details of how it will meet the mandatory minimum requirements (which may include details of its current workforce / supply chain) at either / both the contract / organisation level and how it will go about meeting the requisite percentages to meet the mandatory minimum requirements. Tenderers should note that the mandatory minimum requirements are averages over the Initial Term of any resultant [***Contract/Deed of Standing Offer***], and will accordingly need to detail their approach to achieving the specified targets over the Initial Term.]

_____

_____

_____

_____

4. [TENDERER's] rate of Indigenous employment and supplier use as at the Closing Time is:

_____

_____

_____

_____

5. [TENDERER] demonstrates its commitment to Indigenous participation as follows:

_____

_____

_____

_____

6. [TENDERER] will meet the mandatory minimum requirements: directly; or through subcontracts.

[Note to Tenderers: Tenderer to detail its approach to meeting the mandatory minimum requirements directly or through subcontracts.]

_____

_____

_____

_____

Note to drafters: Include section 7 where a component of any resultant Contract/Deed of Standing Offer will be delivered in a Remote Area.

Remote Area Contracts

7. A component of any resultant [***Contract/Deed of Standing Offer***] will be delivered in a Remote Area. [TENDERER] proposes to ensure the [***Contract/Deed of Standing Offer***] will deliver a significant Indigenous employment or supplier use outcome in that Remote Area as follows:

_____

_____

_____

_____

SCHEDULE 7 – DRAFT CONTRACT

See separate document titled 'Schedule 7 – Draft Contract'.

Note to drafters: Attach a copy of the draft contract.

Australian Government
Department of Health

Lodgement Closing Time: ***15 December 2020 2:00pm*** **(local time in Canberra, ACT)**

REQUEST FOR TENDER FOR THE PROCUREMENT OF COVID-19 VACCINATION ADMINISTRATION SERVICES

Health/20-21/20-287846

ISSUED BY THE AUSTRALIAN GOVERNMENT

DEPARTMENT OF HEALTH

PLEASE NOTE:

- **Submissions must be lodged electronically via AusTender (see clause 8)**
- **Submissions should be lodged in the format described in clause 10**.

The Department adheres strictly to Commonwealth policy on late submissions. The Department therefore recommends that Tenderers plan to lodge their submission well before the Closing Time to minimise the possibility of any unforeseen circumstances arising that may cause the Tenderer to miss the Closing Time.

Commonwealth Contact: COVID19VaccineProcurement@health.gov.au

CONTENTS

PART 1 – OVERVIEW, BACKGROUND, SERVICES SPECIFICATIONS AND SUBMISSION LODGEMENT

1. REQUEST FOR SUBMISSION

1.1 This Request for Tender (**RFT**) comprises:

a. Part 1 – Overview, background, services specifications and Submission lodgement;
b. Part 2 – Information to be provided by Tenderers;
c. Part 3 – Evaluation of Submissions;
d. Part 4 – Conditions of tendering;
e. Part 5 – Glossary;
f. Schedule 1 – Statement of Requirement;
g. Schedule 2 – Tenderer Deed;
h. Schedule 3 – Tenderer Response Information;
i. Schedule 4 – Statement of Non-Compliance;
j. Schedule 5 – Pricing Schedule;
k. Schedule 6 – Indigenous Participation Plan Template Response Form; and
l. Schedule 7 – Draft Contract.

1.2 Tenderers' attention is also drawn to the:

a. Conditions for Participation set out in clause 12;
b. Minimum Content and Format Requirements set out in clause 13; and
c. Essential Requirements set out in clause 14.

2. THE DEPARTMENT

2.1 The Commonwealth of Australia acting through the Department of Health (**Department**) is responsible for better health and wellbeing for all Australians. The Department aims to achieve its vision through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.

2.2 Australia's COVID-19 Vaccine and Treatment Strategy aims to support access to, and delivery of, safe and effective COVID-19 vaccines and treatments for all Australians, as soon as they are available.

2.3 The Department of Health is seeking to engage a partner(s) to provide targeted vaccine administration capacity to ensure timely and safe access to COVID-19 vaccines in line with the Australian COVID-19 Vaccination Policy.

2.4 The Initial Term of the Contract will be up to 1 year. The Department also requires 4 optional extensions each to be 6 months in duration.

3. SERVICES THE DEPARTMENT REQUIRES

3.1 The Department is seeking Submissions for the following Services:

a. A Tenderer(s) that can provide flexible and scalable vaccine administration support covering all potential locations and streams with capacity operational by late January 2021.
b. Administration support is anticipated to focus on three streams;

i. **Priority populations** as identified by the Australian Technical Advisory Group on Immunisation (ATAGI) (e.g., vulnerable groups, those with high exposure risk, critical services, see SCHEDULE 1 1.2) where the Tenderer(s) may be required to have sole responsibility for vaccine administration. This should focus on Q1 and Q2 2021.

ii. **High throughput**, surge capacity provided by the Tenderer(s) to support existing efforts, or in the event more doses are available and supplementary workforce is required. This should be a focus as more supply becomes available through Q2-Q3 2021.

iii. **Hard to reach communities defined by vulnerability or location** (e.g., rural and remote communities, outreach for homeless) where the Tenderer(s) may be required. This should be a focus in Q2 and Q3 2021.

c. Administration support including all aspects of vaccine administration detailed in SCHEDULE 1. Examples of this support include a trained workforce; stock and inventory management including eligibility checking; scheduling of appointments to manage supply and demand; reporting including adverse event monitoring, follow-up for second dose, and record of immunisation into the AIR; cold chain, physical security, and wastage.

d. A Tenderer(s) that is able to adapt, pivoting to deploy extra capacity to areas of need, within a lead time as directed by the Commonwealth.

3.2 The detailed specifications and requirements for the Services are set out at Schedule 1 - Statement of Requirement. The Department proposes to engage the successful Tenderer to provide the Services in accordance with the Draft Contract set out in Schedule 7.

4. RFT TIMETABLE

4.1 The following is an indicative timetable for this RFT process:

Activity	Timing
Release of RFT	4 December 2020
Industry briefing	11 December 2020
Enquiry Cut-Off Date	14 December 12:00pm
Closing Time	15 December 2020 2:00pm
Negotiation with preferred Tenderer(s)	w/c 11 January 2021
Execution of Contract with successful Tenderer	w/c 11 January 2020
Notification of unsuccessful Tenderers	w/c 11 January 2021
Commencement of Services	w/c 11 January 2021 (estimated)

4.2 The Department may at any time vary the table in clause 3.1 in accordance with the process for varying this RFT at clause 44.3. The timetable in clause 3.2 is subject to change and the Department will not give notice if this changes.

5. ENQUIRIES ABOUT THIS RFT

5.1 Enquiries about this RFT should be made by email addressed to:

Title:	***Director, COVID-19 Vaccine Taskforce***
Email:	***COVID19VaccineProcurement@health.gov.au***

5.2 The Department will provide answers to any reasonable enquiry from a prospective Tenderer that is received by the Department before the Enquiry Cut-Off Date set out in clause 4, in which case:

a. questions and related answers may be disclosed to all prospective Tenderers via AusTender (without disclosing the source of the questions); and
b. any Tenderer Confidential Information contained in a question (that is expressly nominated as such by the relevant Tenderer and agreed to by the Department) will be removed prior to disclosure on AusTender.

5.3 All communications related to this RFT should be addressed to the Contact Officer (via the contact details specified above) and not to other Departmental officers or other persons. The Department may not respond to any enquiry not made in accordance with the requirements of clause 5.1. A Tenderer who communicates other than to the Contact Officer may be excluded from participating further in this RFT process.

6. GOVERNMENT PROCUREMENT (JUDICIAL REVIEW) ACT 2018 (CTH)

6.1 This RFT process is not a covered procurement for the purposes of the Commonwealth Procurement Rules and the *Government Procurement (Judicial Review) Act 2018* (Cth).

6.2 Not used

6.3 Not used

7. AUSTENDER, THE AUSTRALIAN GOVERNMENT TENDER SYSTEM

7.1 AusTender is the Australian Government's procurement information system. Access to and use of AusTender is subject to terms and conditions. In participating in this RFT process, Tenderers agree to comply with those terms and conditions and any applicable instructions, processes, procedures and recommendations as advised on the AusTender website at https://www.tenders.gov.au/?event=public.termsOfUse.

7.2 All queries and requests for technical or operational support must be directed to:

AusTender Help Desk

Telephone: 1300 651 698

International: +61 2 6215 1558

Email: tenders@finance.gov.au

7.3 The AusTender Help Desk is available between 9am and 5pm ACT local time, Monday to Friday (excluding ACT and national public holidays).

8. ELECTRONIC LODGEMENT

8.1 Submissions must be lodged electronically via AusTender before the Closing Time and in accordance with the Submission response lodgement procedures set out in this RFT and on AusTender.

8.2 If Tenderers need to lodge material that cannot be submitted via AusTender, Tenderers should contact the Contact Officer prior to Closing Time to make arrangements for its submission.

9. SUBMISSION CLOSING TIME AND DATE

9.1 Submissions must be lodged before ***2:00pm***, local time in the ACT on the ***15 December 2020***, (the **Closing Time**).

9.2 The Closing Time will also be displayed in the relevant AusTender webpage together with a countdown clock that displays in real time the amount of time left until Closing Time (For more information please see AusTender Terms of Use). For the purposes of determining whether a Submission has been lodged before the Closing Time, the countdown clock will be conclusive and will be the means by which the Department determines whether a Submission has been lodged by the Closing Time.

9.3 Any attempt to lodge a Submission after the Closing Time will not be permitted by AusTender. Such a Submission will be deemed to be a Late Submission. Late Submissions will be excluded from consideration unless the Submission is late as a consequence of mishandling by the Department.

9.4 Where electronic submission of a Submission has commenced prior to the Closing Time but concluded after the Closing Time, and upload of the Submission file(s) has completed successfully, as confirmed by AusTender system logs, the Submission will not be deemed to be a Late Submission. Such Submissions will be identified by AusTender to the Department as having commenced transmission prior to, but completed lodgement after, the Closing Time.

9.5 Where a Submission lodgement consists of multiple uploads, due to the number and/or size of the files, Tenderers must ensure that transmission of all files is completed and receipted before the Closing Time and clause 8.4 will only apply to the final upload.

10. PREPARING TO LODGE A SUBMISSION

Submission File Formats, Naming Conventions and Sizes

10.1 The Department will accept Submissions lodged in Microsoft Word, Microsoft PowerPoint and PDF formats. Supplementary materials/attachments may be also be provided in one of these formats, or in formats compatible with Microsoft Excel. If the

Tenderer believes elements of their Submission are best represented in a file format not listed here, queries may be directed to the Contact Officer.

10.2 The Submission file name/s should:

a. incorporate the Tenderer's company name; and
b. reflect the various parts of the Submission they represent, where the Submission comprises multiple files.

10.3 Submission response files should not exceed a combined file size of 5 megabytes per upload.

10.4 Submissions must be completely self-contained. No hyperlinked or other material may be incorporated by reference.

11. SCANNED OR IMAGED MATERIAL, INCLUDING STATUTORY DECLARATIONS

11.1 In the event that the Department requires clarification of the Tenderer's Submission, the Tenderer may be required to courier or security post the originals of the signature and/or initialled pages to the Department at the address notified by the Department within the period notified by the Department.

PART 2 – INFORMATION TO BE PROVIDED BY TENDERERS

12. CONDITIONS FOR PARTICIPATION

12.1 Subject to clause 13, if the Department considers that a Tenderer does not satisfy all of the following Conditions for Participation, that Submission will be excluded from further consideration under this RFT:

Item	Conditions for Participation
1	The Tenderer must not have had any judicial decisions against it (excluding decisions under appeal) relating to employee entitlements and have not satisfied any resulting order.
2	The Tenderer, its personnel, and any Subcontractors proposed in the Submission must not, at the Closing Time, be listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).
3	The Tenderer (and any Subcontractor proposed in its Submission) must not be named in the Consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).
4	(a) The Tenderer either: i. holds a Valid and Satisfactory Statement of Tax Record by the Closing Time; or ii. has a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office by the closing time, and holds a Valid and Satisfactory Statement of Tax Record no later than 4 business days from the Closing Time; and (b) the Tenderer holds a Valid and Satisfactory Statement of Tax Record from any Subcontractor that it proposes, as part of its Submission, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive). [Note to Tenderers: Tenderers should apply for a Statement of Tax Record and should ensure that their Subcontractors apply for a Statement of Tax Record within sufficient time to meet this Condition for Participation.]

13. MINIMUM CONTENT AND FORMAT REQUIREMENTS

13.1 Subject to clause 13, if the Department considers that a Submission does not satisfy all of the following Minimum Content and Format Requirements, that Submission will be excluded from further consideration under this RFT:

Item	Minimum Content and Format Requirements
1	The Submission must be in English and measurements must be expressed in Australian legal units of measurement.
2	The Submission must include a completed, signed and scanned Tenderer Deed substantially in the form at Schedule 2.

Item	Minimum Content and Format Requirements
3	Tenderers must substantially complete and submit the Pricing Schedule in Schedule 5 in accordance with the instructions provided in Schedule 5.
4	The Tenderer must include an Indigenous Participation Plan in its Submission.
5	The Submission must include either: (a) a Valid and Satisfactory Statement of Tax Record for the Tenderer; or (b) a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office for the Tenderer and the Tenderer then provides a Valid and Satisfactory Statement of Tax Record within 4 business days from the Closing Time.

Unintentional Errors of Form

13.2 Without limiting the Department's other rights in this RFT, the Department may allow the Tenderer to correct any error of form in a Submission that appears to be unintentional, by lodging a correction or additional information, in writing in accordance with the direction of the Department, but will not permit any material alteration or addition to the Submission.

13.3 If the Department provides any Tenderer with the opportunity to correct errors of form, it will provide the same opportunity to all other Tenderers that are in the same position.

14. ESSENTIAL REQUIREMENTS

14.1 If the Department considers that a Tenderer does not satisfy all of the following Essential Requirements, that Submission will be excluded from further consideration under this RFT:

Item	Essential Requirements
1	Immunisation providers must meet accreditation standards as per their relative health professional qualification and registrations and ensure they meet Commonwealth, State and Territory legislation requirements to provide authorised immunisations to the deployed location.
2	The partner must be able to comply with cold-chain management requirements as per the Commonwealths Strive for 5 national vaccine storage guidelines. Requirements outside of the standard guidelines will be worked through in consultation and relevant stakeholders.
3	Security services must be provided only by licensed security industry participants as required in each State and Territory in Australia.
4	The successful Tender must be able to ensure the confidentiality and integrity of any systems or data through conformance with Commonwealth IT Security Standards as published by the Australian Cyber Security Centre, including but not limited to the Australian Government Information Security Manual.

14.2 Notwithstanding the use of the words “must”, "shall", "minimum", "required to" or similar language or anything to the contrary in Statement of Requirement or elsewhere in this

RFT, there are no other Essential Requirements for this RFT besides those set out in the table above (if any).

15. FORMAT OF SUBMISSIONS

15.1 Submissions should be completed in accordance with Schedule 3, noting the following:

a. all applicable information should be provided in response to the information requirements set out in Schedule 3;
b. where a response to a particular requirement is covered in another section of the Submission, a cross reference to that section should be provided; and
c. Tenderers may include additional or supporting materials (as supplements or attachments to the Submission Response Information) noting that Tenderers are discouraged from including generic marketing information that does not relate to the information requested in this RFT and/or does not address the Evaluation Criteria.

15.2 Tenderers should also complete the statement of non-compliance in accordance with Schedule 4 in relation to:

a. any of the provisions of the Draft Contract with which the Tenderer is partially compliant or non-compliant; or
b. any claim of confidentiality in relation to any aspects of their Submission.

16. PRICING

16.1 Tenderers should provide full details of their proposed price structure in Schedule 5. This document should be included in a separate electronic file when the Submission is lodged and no pricing should be included in any other part of the Submission.

16.2 Tendered prices should include all charges necessary and incidental to the proper delivery of the Services.

16.3 Prices should be fixed for the duration of the Contract unless otherwise indicated by the Department in this RFT.

16.4 Prices should be in Australian dollars (inclusive of GST).

17. WORKPLACE GENDER EQUALITY

17.1 Commonwealth policy prevents the Department from entering into contracts with Tenderers who are non-compliant under the *Workplace Gender Equality Act 2012* (Cth) (the **WGE Act**).

17.2 The Draft Contract requires that, in performing any contract, a successful Tenderer must:

a. comply with its obligations, if any, under the WGE Act; and
b. if the term of any resultant Contract exceeds 18 months, the successful Tenderer must provide a current letter of compliance within 18 months from the Contract Commencement Date and following this, annually to the Department's Contract contact officer.

17.3 Tenderers should note that if during the term of any resultant Contract, the successful Tenderer becomes non-compliant with the WGE Act, the successful Tenderer must notify the Department's Contract contact officer.

17.4 For further information about coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

17.5 Tenderer's must indicate as part of the Tenderer Deed at Schedule 2 whether or not the Tenderer's organisation is a 'relevant employer' under the WGE Act and, if applicable, provide a current letter of compliance as part of their Submission, or prior to entering into any resultant Contract (if successful).

18. ILLEGAL WORKERS

18.1 It is Commonwealth policy not to contract with providers engaging Illegal Workers.

18.2 The Tenderer's Deed in Schedule 2 contains a statement from the Tenderer confirming that it meets this obligation.

19. INDIGENOUS PROCUREMENT POLICY

19.1 It is Commonwealth policy to stimulate Indigenous entrepreneurship and business development, providing Indigenous Australians with more opportunities to participate in the economy (see Indigenous Procurement Policy for further information).

19.2 If any resultant Contract is a High Value Contract, the mandatory minimum requirements for Indigenous participation will apply.

19.3 If a component of any resultant Contract will be delivered in a Remote Area, this creates an opportunity for that resultant Contract to deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

19.4 In its Indigenous Participation Plan, the Tenderer should detail how it will ensure that its provision of the Services will deliver a significant Indigenous employment or supplier use outcomes in the Remote Area.

[Note to Tenderers: Refer to section 4.4.1 of the Indigenous Procurement Policy for examples of options available to ensure any resultant Contract will deliver significant Indigenous employment or supplier use outcomes in the Remote Area.]

20. *MODERN SLAVERY ACT 2018* (CTH)

20.1 Tenderers should note that any resultant Contract will require the successful Tenderer to provide all assistance reasonably requested by the Department to comply with its obligations under the *Modern Slavery Act 2018* (Cth).

PART 3 – EVALUATION OF SUBMISSIONS

21. EVALUATION CRITERIA

21.1 The Department will use the following Evaluation Criteria in the evaluation of Submissions:

Category	Considerations	Weighting
Proposed solution and approach	The extent to which the proposed Submission meets the requirements described in Schedule 1 and the Tenderer's approach to developing the approach. Factors to be taken into account are: a) The extent to which the proposed plan addresses potential target populations listed in Schedule 1. b) Whether the Tenderer's plan for flexible and adaptive delivery is fit-for-purpose, particularly considering mechanisms to scale capacity up or down as needed c) The robustness of the proposed quality assurance and quality control processes that the Tenderer will implement to ensure patient safety, maintain cold chain, minimise vaccine wastage, and maximise second dose completion. d) Whether the Tenderer has clearly outlined mechanisms for monitoring and reporting throughout administration (as detailed in Schedule 1 including administration details, stock levels, wastage, temperature). e) Whether the Tenderer has a fit-for-purpose plan for demand management (including managing booking and scheduling of appointments, and follow up to ensure second dose completion). f) Proposed approach to manage interoperability with other systems, stakeholders, and handover points (e.g., receipt of vaccines).	30%
Timeline and execution readiness	g) The extent to which the Tenderer's Submission provides a feasible path to readiness of the administration network within required timelines. h) The scale and capacity with which the Tenderer is able to cover potential populations in the time required including consideration of both geographical coverage across jurisdictions and from metropolitan to very remote areas. i)	30%

Category	Considerations	Weighting
Past experience	j) The extent to which the Tenderer's past performance providing similar services demonstrates its ability to provide the Services.	30%
Collaboration	k) How conducive the Tenderer's proposed interaction model is to working with the Commonwealth and any required stakeholders to ensure successful delivery. l) The strength of the proposed team's experience and skills relevant to delivering the solution.	10%
Pricing	The Tenderer's pricing information as specified in its response to Schedule 5 (Pricing Schedule).	Not weighted
Security and compliance	The extent to which the Tenderer does or will meet all security requirements The degree of the Tenderer's overall compliance with the RFT and Draft Contract and the likelihood of any non-compliance meaning the Department is unable to agree a contractual arrangement with that Tenderer.	
Risk	Any risks inherent in, or associated with, the Tenderer's Submission that have not otherwise been considered under other Evaluation Criteria including, but not limited to: - the Tenderer's financial viability; - the Tenderer's compliance with Statement of Requirement and the Draft Contract; and - any conflicts of interest. The Department will assess Tenderers on any risks identified in Submission and any other risks identified in the Evaluation Process that have not been considered as part of another Evaluation Criteria. The Department is concerned to ensure that all conflicts of interest are identified, and any risks are properly managed.	Not weighted
Economic Benefit	The Tenderer's proposed approach to providing benefits to the Australian economy as specified in its response to this RFT.	Not weighted
Indigenous participation	The Tender's response to the Indigenous participation plan.	Not weighted

21.2 The Department may:

a. consider any part of a Submission in the evaluation of any or all of the Evaluation Criteria; and
b. use material provided in response to one Evaluation Criterion in its evaluation of other Evaluation Criteria.

22. EXCLUSION OF SUBMISSIONS

22.1 Without limiting any other provision of this RFT that gives the Department the right to exclude Submissions on other grounds, the Department may at any time exclude a Submission from further consideration if:

a. the Submission is incomplete or contains insufficient information to allow evaluation of the Submission;
b. prices are not clearly and legibly stated;
c. the Tenderer or Submission does not comply with this RFT;
d. the Tenderer is not fully capable of undertaking a contract in the form of the Draft Contract;
e. the Submission is clearly uncompetitive when compared with the other Submissions received;
f. the Submission is rated unsuitable or unsatisfactory against one or more of the Evaluation Criteria;
g. the Submission contains statements that qualify or are contrary to the Tenderer Deed at Schedule 2 to this RFT;
h. in the Department's opinion the Submission contains a false declaration;
i. the Submission contains false or misleading information or statements;
j. the Tenderer, or a director or officer of the Tenderer, is insolvent or bankrupt;
k. the Tenderer has an actual, potential or perceived conflict of interest that cannot be managed to the satisfaction of the Department acting in its absolute discretion; or
l. there has been a significant deficiency in the performance of a substantive requirement or obligation under a prior agreement.

23. SUBMISSION EVALUATION PROCESS

23.1 Submissions will be evaluated against the Evaluation Criteria to determine the Submission that represents the best overall value for money on a whole-of-life basis.

23.2 As part of its evaluation of Submissions, the Department may, in its sole and absolute discretion:

a. ask Tenderers to undertake presentations;
b. shortlist one or more Tenderers at any time;
c. ask Tenderers to provide written clarification of various aspects of their Submissions;
d. ask Tenderers to provide further information to confirm their financial viability and commercial stability;
e. have discussions or interviews with Tenderers in order to seek further clarification of their Submissions;
f. visit Tenderers' sites; and
g. have discussions with or undertake visits to customers of Tenderers and their Subcontractors, whether or not those customers are listed as referees in the Tenderers' Submissions.

23.3 The Department may choose to undertake the activities set out in clause 23.2 in relation to some Tenderers only. Presentations, interviews and site visits may be subject to additional terms and conditions that are advised by the Department to Tenderers who have been invited to participate in each activity.

23.4 Any costs incurred by the Tenderer in complying with this clause 23 will be borne by the Tenderer.

24. CLARIFICATION

24.1 Where the meaning of a Submission is unclear or there is an apparent error of form, the Department may seek clarification from the Tenderer.

24.2 Any clarification provided by a Tenderer in response to a request for clarification is not to contain any new material additional to that included in the Submission unless specifically requested by the Department. Failure to supply clarification to the satisfaction of the Department may cause the Submission to be excluded from consideration.

25. SUBMISSION PRICES

25.1 The Tenderer agrees to provide access to such information as is determined by the Department to be necessary in order to evaluate the reasonableness of their Tendered prices.

25.2 In the evaluation process, the Department may make certain adjustments to the Tendered price, including adjustments to account for the following matters, which may need balancing in order to establish a common basis for the comparison of Submissions, including (without limitation):

a. Submission prices as per the completed Schedule 5;
b. pricing flexibility;
c. any other costs or discounts which form part of the Tenderer's offer;
d. normalised and discounted cash flow;
e. any alternative Submissions or financial incentives offered by the Tenderer;
f. implementation costs;
g. any risk relating to the Tendered prices;
h. transition out costs;
i. cost of administering the resultant Contract; and
j. whole of life costs and benefits.

26. NEGOTIATIONS

26.1 Negotiations may be undertaken with one or more Tenderers (including in relation to prices, terms and conditions of the Draft Contract or any other matters).

26.2 During the negotiation phase of this RFT process, the Department may engage in detailed discussions and negotiations, including parallel negotiations, with the goal of maximising the benefits of the project, as measured using the Evaluation Criteria. As part of this process, those Tenderers participating in the negotiation phase may be asked to improve

any or all aspects of their Submission. The Department's intention is that it will select a preferred Tenderer after all material issues have been resolved.

26.3 The Department may seek best and final offers from Tenderers participating in the negotiation phase of this RFT process.

26.4 Without limiting its other rights under this RFT, in the event that the Department concludes that during negotiations a Tenderer has retracted, or attempts to retract, any part of its tendered offer, the Department reserves the right to:

a. exclude that Tenderer's Submission from further consideration;
b. terminate this RFT process;
c. re-enter negotiations or parallel negotiations with other Tenderers; or
d. exercise any other right reserved to the Department under law or elsewhere in this RFT.

27. DEBRIEFING

27.1 After the award of any resultant Contract, the Department will notify all unsuccessful Tenderers of the outcome of the RFT process.

27.2 All Tenderers will be offered the opportunity for a debriefing on their Submission.

27.3 Tenderers will be debriefed against the Evaluation Criteria contained in this RFT. Tenderers will not be provided with information concerning other Submissions.

28. COMPLAINTS PROCEDURE

28.1 Complaints in relation to this RFT process should be made in writing and directed to the Complaints Officer at procurement.advice@health.gov.au.

28.2 Complaints will be handled by the Department in accordance with the Department's Procurement Complaints Procedures which are available at About Us

PART 4 – CONDITIONS OF TENDERING

29. OWNERSHIP AND USE OF SUBMISSION DOCUMENTS

29.1 All Submission documents (including paper and electronic copies) become the property of the Department on submission.

29.2 Without prejudice to anything agreed in any resultant Contract, clause 27.1 does not affect any intellectual property rights that may exist in a Submission.

29.3 Without prejudice to any other right of the Department under this RFT or at law, the Department may copy, amend, disclose or allow the disclosure of, or otherwise deal with, a Submission or any information contained in or relating to any Submission (at any time) for any of the following purposes:

a. the RFT process, evaluating and clarifying Submissions;
b. negotiation of the resultant Contract with the Tenderer or any other Tenderer;
c. managing any resultant agreement with the Tenderer or any other Tenderer;
d. addressing any dispute concerning the RFT process;
e. audit, governmental and Parliamentary reporting requirements; and
f. responding to any disputes about this RFT process or requests from Parliament or a Parliamentary Committee.

29.4 The Department may make copies of the Submission as necessary for its purposes.

30. INTELLECTUAL PROPERTY RIGHTS IN RFT

30.1 All intellectual property that exists in the information contained in this RFT, or any related or attached material, remains the property of the Department.

30.2 Each Tenderer is permitted to use this RFT for the purpose only of compiling its Submission and, in the case of the Tenderer(s) selected through this RFT process, for negotiating the resultant Contract with the Department.

31. SMALL TO MEDIUM ENTERPRISES (SMES)

31.1 The Australian Government is committed to *Public Governance, Performance and Accountability Act 2013* (Cth) non-corporate Commonwealth entities sourcing at least 10

per cent of their purchases by value from SMEs. For the purpose of this clause an SME is an Australian or New Zealand firm with fewer than 200 full-time equivalent employees.

31.2 Tenderers are encouraged to include the participation of SMEs in their Submissions.

32. AUDIT AND ACCESS

32.1 The attention of Tenderers is drawn to the *Auditor-General Act 1997* (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.

32.2 In addition to the Auditor-General's powers under the *Auditor-General Act 1997* (Cth), if a Tenderer is chosen to enter into a resultant Contract, the Tenderer will be required to provide the Auditor-General or an authorised person with access to information, documents, records and Department assets, including those on the Tenderer's premises. This will be required at reasonable times on giving reasonable notice for the purpose of carrying out the Auditor-General's functions and will be restricted to information and assets which are in the custody or control of the Tenderer, its employees, agents or Subcontractors, and which are related to the resultant Contract. Such access will apply for the term of the Contract and for a period of 7 years from the date of expiration or termination of the Contract.

32.3 Tenderers should obtain, and will be deemed to have obtained, their own advice on the impact of the *Auditor-General Act 1997* (Cth) on their participation in the Submission.

33. FREEDOM OF INFORMATION AND OTHER RIGHTS TO ACCESS INFORMATION

33.1 The attention of Tenderers is drawn to the *Freedom of Information Act 1982* (Cth), which gives members of the public right of access to documents in the possession of the Commonwealth and its agencies.

33.2 The Act extends as far as possible the right of the community to access information (generally documents) in the possession of the Commonwealth, limited only by exceptions and exemptions necessary for the protection of essential public interests and the private and business affairs of persons in respect of whom information is collected and held by departments and public authorities.

33.3 Rights of access also exist under other legislation, including the *Ombudsman Act 1976* (Cth). Courts also have legal rights to access a wide range of information.

33.4 Tenderers should also be aware of the *Australian Information Commissioner Act 2010* (Cth), which established the Office of the Australian Information Commissioner to perform freedom of information, privacy and information policy functions.

34. PRIVACY

34.1 Tenderers are advised that it is Commonwealth policy to ensure that there is no loss of privacy protection when a Commonwealth entity contracts for the delivery of services.

34.2 Without limiting any obligations under the *Privacy Act 1988* (Cth), successful Tenderer(s) will be required under the Contract to agree not do an act, or engage in a practice, that would breach an Australian Privacy Principle under the *Privacy Act 1988* (Cth) if done or

engaged in by a Commonwealth entity to which the Australian Privacy Principles apply. Tenderers selected as a result of this RFT process will also need to agree to impose those same obligations on any Subcontractor engaged by the Tenderer.

35. CONFIDENTIALITY

35.1 The Department will, subject to this RFT, including clauses 33.2 and 33.3, endeavour to treat the following information as confidential:

a. all Submissions received prior to the award of a resultant Contract;
b. all unsuccessful Submissions, following the award of a resultant Contract;
c. all successful Submissions, following the award of a resultant Contract but only to the extent that:
   i. the successful Tenderer requests that specific information in their Submission be kept confidential; and
   ii. the Department has determined that specific information is to be kept confidential in accordance with the Confidentiality Throughout the Procurement Cycle from the Department of Finance and has agreed, pursuant to the resultant Contract with the successful Tenderer, to keep that information confidential.

35.2 The Department will not be taken to have breached any obligation to keep information provided by Tenderers confidential to the extent that the information:

a. is disclosed by the Department to its advisers, officers, employees or subcontractors solely in order to conduct this RFT process or to prepare and manage any resultant Contract;
b. is disclosed to the Department's internal management personnel, solely to enable effective management or auditing of this RFT process;
c. is disclosed by the Department to the responsible Minister;
d. is disclosed by the Department in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
e. is shared by the Department within the Department's organisation, or with another Commonwealth entity, where this serves the Commonwealth's legitimate interests;
f. is authorised or required by law to be disclosed;
g. is disclosed as agreed by the Tenderer;
h. is disclosed to meet the Department's reporting or accountability requirements, including, without limitation:
   i. under the Public Governance, Performance and Accountability Act 2013 (Cth) or other legislation;
   ii. to the Australian National Audit Office or any other auditor appointed by the Department;
   iii. in accordance with the provisions that require notification of Commonwealth contracts on the AusTender website;
   iv. to the Commonwealth Ombudsman; or
   v. is in the public domain otherwise than due to a breach of the relevant obligations of confidentiality.

35.3 Tenderers should be aware that the Department, as a non-corporate Commonwealth entity, is subject to specific accountability requirements, which support internal and external scrutiny of its tendering and contracting processes. These include:

a. the policy of the Commonwealth to publish details of relevant entity agreements, contracts and standing offers with an estimated value of $10,000 or more on the AusTender website;
b. the requirement to report details of Commonwealth contracts valued at $100,000 or more in accordance with the *Senate Order on Departmental and Agency Contracts*, including:
   i. name of the service provider and the subject matter of the Contract;
   ii. total value of the Contract; and
   iii. whether the Contract contains clauses that are confidential, and if so, the reasons for confidentiality;
c. the requirement to publish information about certain procurements in Annual Reports; and
d. the requirement to make available, on request, the names of any subcontractors engaged to perform services in relation to a Commonwealth contract (as such, Tenderers should inform all potential Subcontractors that their participation in fulfilling a Commonwealth contract may be publicly disclosed).

36. ENVIRONMENTAL POLICY AND PROCUREMENT

36.1 The Commonwealth aims to improve the implementation of ecologically sustainable development (**ESD**) within its agencies.

36.2 In support of this aim, the Department is committed to fostering the sustainable use of the Earth's resources and will implement and maintain an environmental management system to ISO14001, with the following key areas:

a. compliance with all relevant environmental legislation, regulations, policies and other initiatives to which it subscribes;
b. integrating environmental management into business decision making at all levels;
c. reducing cost through better resource usage and waste management;
d. setting objectives and targets for continuous improvement;
e. monitoring, reporting and reviewing achievements;
f. exploring best practice and innovative environmental management approaches to the use of technology, property and related resources; and
g. building an environmentally aware business culture.

36.3 The Department's procurement activities are a key means of implementing its environmental policy.

37. MATERIAL CHANGE TO TENDERER

37.1 A Tenderer must notify the Department if, following lodgement of its Submission, there occurs:

a. an event that has the effect of materially altering either the composition or control of the Tenderer or the business of the Tenderer; or
b. any material change to the compliance status of the Tenderer against this RFT; or

c. any material change to the proposed basis on which the Tenderer will deliver the Services, or have access to the necessary and appropriate skills, resources, nominated key personnel, nominated Subcontractors or corporate or financial backing to provide the Services, on the terms of the Draft Contract.

37.2 If the Department receives notice, or becomes aware of an event under clause 37.1a, the Department may allow (on terms it considers appropriate) the substitution of the Tenderer with another legal entity upon receipt of a joint written request from or on behalf of the Tenderer and the other legal entity. If the Department allows the substitution, it will evaluate the Submission in its original form prior to the event, except that the impact of the event on the information provided in the Submission may be taken into account.

37.3 If the Department receives notice, or becomes aware of an event under clause 37.1b or 37.1c, or the Commonwealth does not allow substitution, or substitution is not requested, under clause 37.1a, the Department may either exclude the Submission from consideration or consider the Submission taking into account the impact of the changed circumstances on the information provided in the Submission.

38. CONFLICT OF INTEREST

38.1 Tenderers should represent and declare in the Tenderer Deed any conflict of interest that exists at the time of lodging their Submission.

38.2 If at any time prior to entering into a resultant Contract for the Services, an actual or potential conflict of interest arises or may arise for any Tenderer, other than that already disclosed, that Tenderer should immediately notify the Department in writing.

38.3 If any actual or potential conflict is notified, or the Department becomes aware of any actual or potential conflict, the Department may:

a. disregard the Submission submitted by such a Tenderer;
b. enter into discussions to seek to resolve such conflict of interest; or
c. take any other action it considers appropriate.

39. TENDERER BEHAVIOUR

39.1 Tenderers must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of Submissions:

a. Engage in misleading or deceptive conduct or make any false or misleading or deceptive claim or statement;
b. improperly obtain Confidential Information;
c. receive improper assistance from any existing or former officer or employee of the Department;
d. engage in collusive tendering, anti-competitive conduct, unlawful, unethical or other similar conduct with any other Tenderer or other person;
e. attempt to improperly influence an officer or employee of the Department or violate any applicable laws regarding the offering of inducements; or
f. approach any officer or employee of the Department other than in the manner set out in this RFT;
g. engage in, procure or engage others to engage in, any activity that would result in a breach of the Lobbying Code of Conduct 2013 published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or

h. otherwise act in an unethical or improper manner or contrary to any law.

39.2 The Department may exclude a Submission from consideration if the Tenderer fails to comply with the requirements set out in this clause 39.

40. COST OF PREPARING AND SUBMITTING SUBMISSION

40.1 To the extent permitted by law, participation in this RFT process is at the Tenderer's sole risk, cost and expense, and in no circumstances will the Department be responsible for any costs incurred by a Tenderer in preparing a Submission, or associated expenses related to this RFT.

41. TENDERERS TO INFORM THEMSELVES

41.1 Tenderers are deemed to have:

a. examined this RFT, and any other documents referenced or referred to in this RFT, and any other information made available in writing by the Department to Tenderers for the purposes of submitting a Submission;
b. examined all other information which is obtainable by the making of reasonable and timely inquiries and relevant to the risks, contingencies and other circumstances having an effect on their Submission;
c. satisfied themselves as to the correctness and sufficiency of their Submission, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
d. satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at Schedule 4;
e. obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFT process;
f. made their own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments; and
g. examined AusTender, including the AusTender Terms of Use.

41.2 It is the responsibility of Tenderers to obtain all information necessary or convenient for the preparation of their Submission.

41.3 Tenderers must not rely, and are deemed not to have relied, upon any statement or representation by the Department, whether before or after the date of this RFT, in connection with this RFT or this RFT process, unless that statement or representation is made in writing by the Contact Officer for this RFT.

41.4 Tenderers should obtain their own legal and other professional advice on this RFT and its requirements including in respect of the potential rights and obligations in respect of the Draft Contract and should not construe this RFT as investment, legal, tax or other advice.

42. NO CONTRACT OR UNDERTAKING

42.1 Nothing in this RFT or in any Submission or by the submission of a Submission (in part or together) creates, or is to be construed to create, any binding contract or other

understanding (including any form of contractual, quasi-contractual, restitutionary rights or other legal relationship (express or implied) between the Department and any Tenderer unless and until a resultant Contract (if any) is signed by the Department and a successful Tenderer.

42.2 Clause 40.1 does not apply to a Tenderer Deed executed by a Tenderer.

43. ACCEPTANCE

43.1 Selection of the preferred Submission will be subject to the execution of a Contract between the Commonwealth and the successful Tenderer substantially in the form of the Draft Contract at Schedule 7.

43.2 Neither the lowest priced Submission, nor any Submission, will necessarily be accepted by the Department.

44. THE DEPARTMENT'S RIGHTS

44.1 The Department reserves the right to:

a. vary the timing and processes, if any, referred to in this RFT;
b. change or suspend the RFT process;
c. amend or vary this RFT or the RFT process, including the Draft Contract;
d. allow any Tenderer to change its Submission at any time;
e. shortlist Submissions;
f. terminate the RFT process where it is, in the opinion of the Department, in the public interest to do so;
g. exclude any Submission from consideration where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. the Tenderer does not meet a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. the Tenderer is not fully capable of undertaking the Contract substantially in the form of the Draft Contract;
    iv. this RFT otherwise allows for the exclusion of the Tenderer; or
    v. the Submission does not represent value for money;
h. enter into a contract or other binding relationship outside the RFT process with a person on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. no Tenderer is fully capable of undertaking the Contract substantially in the form of the Draft Contract; or
    iv. no Submission represents value for money;
i. enter into a contract on terms different to that specified in this RFT;
j. add a Tenderer or select and negotiate with a third party who has not submitted a Submission on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a mandatory requirement;
    iii. no Tenderer is fully capable of undertaking the Contract; or
    iv. no Submission represents value for money;

k. call for new Submissions;
l. publish or disclose the names of Tenderers (whether successful or unsuccessful);
m. allow or not allow a Related Body Corporate to take over a Submission in substitution for the original Tenderer;
n. enter into negotiations with any Tenderer; or
o. cancel, add to or amend the information, requirement, terms, procedures or processes set out in this RFT.

44.2 To the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFT process, including instances where:

a. a Tenderer is not engaged to undertake the provision of the Services;
b. the Department decides not to enter into any resulting Contract with any Tenderer or at all;
c. the Department exercises or fails to exercise any of its other rights under or in relation to this RFT (whether or not the Department has informed a Tenderer of its exercise of the rights);
d. a Submission or any other material or communication relevant to this RFT is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
e. the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements.

44.3 If the Department does vary this RFT or process, the Department will endeavour to inform any prospective Tenderers who have sought, or been issued with, this RFT of that change. A notice of the issue of an addendum will be published in the same manner as the original information about this RFT, including by notification on the AusTender website. Tenderers should regularly check the AusTender website for any updates or addenda to this RFT.

44.4 If clause 6.1 provides that this RFT process is a 'covered procurement', the Department will issue an addendum notifying Tenderers of any suspension of the RFT process.

44.5 To the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFT or any other matter arising by the Department exercising any of its rights.

45. COORDINATED PROCUREMENT

45.1 The Commonwealth has agreed to establish a coordinated procurement contracting framework to deliver efficiencies and savings from goods and services in common use by non-corporate Commonwealth entities who are subject to the *Public Governance, Performance and Accountability Act 2013* (Cth) or other legislation.

45.2 It is therefore possible that the Commonwealth may approve the procurement by the Department of some or all of the same goods or services as the Services under a coordinated process:

a. before the Closing Time; or
b. after the Closing Time but before any resultant Contract is signed with the successful Tenderer(s); or

c. during the period of any resultant Contract entered into as a result of this RFT.

45.3 If clause 45.2a applies, the Department reserves the right to discontinue this RFT process.

45.4 If clause 45.2b applies, the Department reserves the right to discontinue the Submission process and not proceed to enter any contract as a result of this RFT.

45.5 If clause 45.2c applies, the Department may exercise its rights under any resultant Contract to terminate for convenience, without compensation for loss of potential profits.

46. COOPERATIVE PROCUREMENT (PIGGYBACKING)

Not used

47. INTERPRETATION

47.1 If any part of this RFT conflicts with another part, the part higher in the following list will take precedence:

a. Part 1 – Overview, Background, Services Specifications and Submission Lodgement, Part 2 – Information to be provided by Tenderers, Part 3 – Evaluation of Submissions and Part 4 – Conditions of Tendering;
b. Part 5 - Glossary;
c. SCHEDULE 7 – Draft Contract;
d. SCHEDULE 1 – Statement of Requirement;
e. SCHEDULE 2 – Tenderer Declarations, SCHEDULE 3 - Tenderer Response Information, SCHEDULE 4 – Statement of Non-Compliance, SCHEDULE 5 – Pricing Schedule and SCHEDULE 6 – Indigenous Participation Plan Template Response Form; and
f. any other document forming part of this RFT.

47.2 In this RFT, except where the contrary intention is expressed:

a. a reference to time, unless specified otherwise, is to the time in the Australian Capital Territory;
b. words importing a gender include each other gender;
c. words in the singular include the plural and vice versa;
d. a reference to A$, $A, dollar or $ is to Australian currency;
e. if any word or phrase is given a defined meaning, any other part of speech or other grammatical form of that word or phrase has a corresponding meaning;
f. a reference to a clause, paragraph, schedule or annexure is to a clause, paragraph, schedule or annexure to this RFT;
g. a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority, agency or other entity;
h. a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
i. the meaning of general words is not limited by specific examples introduced by including, ‘for example’ or similar expressions and the word ‘include’ is not a word of limitation; and
j. the term 'may' when used in the context of a right exercisable by the Department means that the Department may exercise that right in its sole and absolute discretion and the Department has no obligation to any Tenderer.

PART 5 - GLOSSARY

Term	Definition
ACT	Australian Capital Territory
AusTender	means the Australian Government online tendering system, located on the AusTender website
AusTender Terms of Use	means the terms of use for AusTender available at https://www.tenders.gov.au/?event=public.termsOfUse.
ATAGI	means the Australian Technical Advisory Group on Immunisation
Black Economy Procurement Connected Policy	means the *Black economy – increasing the integrity of government procurement*: *Procurement connected policy guidelines March 2019* available at https://treasury.gov.au/publication/p2019-t369466.
Commonwealth	Commonwealth of Australia
Contract	means a contract substantially in the form of the Draft Contract provided with this RFT, to be executed by the Department and the Contractor, as amended from time to time, and includes its schedules, annexures and attachments.
Closing Time	means the closing time and date of this RFT as specified at clause 9.1 of this RFT
Conditions for Participation	means the mandatory conditions (if any) identified in clause 12 of this RFT
Confidential Information	means information (whether or not owned by the Commonwealth) that: (a) is by its nature confidential; or (b) the receiving party knows or ought to know is confidential, but does not include information which: (c) is or becomes public knowledge other than by breach of contract or any other obligation of confidentiality; (d) is in the possession of a party without restriction in relation to disclosure before the date of receipt; or (e) has been independently developed or acquired by the receiving party
Contact Officer	means the contact person for all matters pertaining to this RFT process, as identified at clause 5 of this RFT
Department	means the Department of Health

Term	Definition
Draft Contract	means the document attached as Schedule 7 to this RFT being the proposed Contract to be entered into between the Department and the successful Tenderer(s)
Essential Requirements	means the mandatory conditions (if any) identified at clause 14, and which a Tenderer must comply
Evaluation Criteria	means the criteria set out in clause 21 of this RFT that will be used to evaluate the Submissions received.
High Value Contract	means a contract where: (a) the Services will be delivered in Australia; (b) the value of the Services is $7.5 million (GST inclusive) or more; and (c) more than half the value of the contract is being spent in one or more of the following industry sectors: (i) building, construction and maintenance services; (ii) transportation, storage and mail services; (iii) education and training services; (iv) industrial cleaning services; (v) farming and fishing and forestry and wildlife contracting services; (vi) editorial and design and graphic and fine art services; (vii) travel and food and lodging and entertainment services; or (viii) politics and civic affairs services.
Illegal Worker	means a person who: (a) has unlawfully entered and remains in Australia; (b) has lawfully entered Australia, but remains in Australia after his or her visa has expired; or (c) is working in breach of his or her visa conditions.
Indigenous Enterprise	means an organisation that is 50 per cent or more Indigenous owned that is operating a business.
Indigenous Participation Plan	means a plan detailing how the Tenderer will meet the minimum mandatory requirements for the Indigenous Procurement Policy (see template at SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM – Indigenous Participation Plan Template Response Form).

Term	Definition
Indigenous Procurement Policy	means the policy of that name, as amended from time to time, available on the Indigenous Procurement Website.
Indigenous Procurement Website	means the website at **www.dpmc.gov.au/ipp**.
Late Submission	means any Submission not received by Closing Time
Minimum Content and Format Requirements	means the mandatory content and format requirements identified in clause 13 of this RFT
Related Body Corporate	has the meaning given in section 9 of the *Corporations Act 2001* (Cth)
Remote Area	means the areas identified in the map on the Indigenous Procurement Website, as updated from time to time.
RFT	means this Request for Submission
Satisfactory	means meets the conditions set out in Part 6.b of the Black Economy Procurement Connected Policy or, if the circumstances in Part 6.c of the Black Economy Procurement Connected Policy apply, the conditions set out in Part 8.b of the Black Economy Procurement Connected Policy.
Schedules	means all or any of the schedules to this RFT
Services	means the Services described in the Statement of Requirement and clause 3 of this RFT
Statement of Requirement	means the description of the Services as set out in Schedule 1 of this RFT
Statement of Tax Record	means a statement of tax record issued by the Australian Taxation Office following an application made in accordance with the process set out at https://www.ato.gov.au/Business/Bus/Statement-of-tax-record/?page=1#Requesting_an_STR.
Subcontractors	means an entity that the Tenderer proposes to enter into a contract with to provide goods or services to the successful Tenderer(s) in relation to the Services or in order for the Tenderer to meet obligations under the resultant Contract
Submission	means a response submitted by a Tenderer to this RFT
Tenderer	means an entity that submits a Submission, and includes a potential Tenderer.
Tenderer Deed	means the deed to be completed and submitted by Tenderers as part of their Submission, as set out in SCHEDULE 2 – Tenderer Declarations of this RFT

Term	Definition
Valid	means valid in accordance with Part 7.e of the Black Economy Procurement Connected Policy.

SCHEDULES

SCHEDULE 1 - STATEMENT OF REQUIREMENT

1. Context/objectives of the services

The Australian Government aims to ensure the delivery of safe and effective COVID-19 vaccines to all Australians, as soon as they are available. The Department of Health is seeking to engage a collaborative partner(s) to provide targeted and flexible vaccine administration capacity to ensure timely and safe access to COVID-19 vaccines in line with the vaccination policy.

1.1 Current portfolio of vaccine candidates

The approach to providing COVID-19 vaccines in Australia is outlined in 'Australian COVID-19 Vaccination Policy' (attached). The Australian Government is building a diverse portfolio of investments to secure early access to promising vaccines. To date, the Commonwealth has entered into advance purchasing agreements with the following developers[1]:

- AstraZeneca for the supply of 33.8 million doses of the Oxford vaccine
    - 3.8 million doses will be delivered to Australia in early 2021
    - 30 million doses will be manufactured in Australia between from early 2021 in monthly batches through to September 2021 in monthly batches
- Pfizer for the supply of 10 million doses
    - 10 million doses will be available in Australia in monthly batches commencing from early 2021
- CSL for the supply of 51 million doses of the University of Queensland vaccine
    - 51 million doses will be manufactured in Australia by CSL and available from mid-2021
- Novavax for the supply of 40 million doses
    - 40 million doses will be made available in Australia during 2021

This amounts to a total of over 134 million COVID-19 vaccine doses if each of the vaccines if proven safe and effective.

First doses of some of these candidates are expected to be delivered from early 2021, should they be found to be safe and effective, with further doses delivered in batches throughout 2021 and 2022.

The Commonwealth has also joined the Gavi COVAX Facility to purchase up to 25.5 million doses (50% population coverage) of safe and effective vaccines from a diverse global portfolio of vaccine candidates.

Current information indicates that successful vaccine candidates will be presented in multi-dose vials and administered by injection in a 2-dose regimen. Reconstitution of vaccines will be required in some instances.

COVID-19 vaccines are known to have different thermostability requirements, examples of these are detailed in Figure 1. It is expected that the successful supplier(s) will be equipped to handle different storage and handling requirements to ensure that vaccines are maintained at required temperatures.

[1] Australia's vaccine agreements, last updated 13 November 2020, https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/vaccines-and-treatments/australias-vaccine-agreements

Table 1: Example thermostability requirements of vaccine candidates

Thermostability requirements					
In storage	**At administration sites**	**Platform**	**Example vaccine[2]**	**Purchase agreement***	**Manufacturing location**
2-8ºC refrigerated cold and chain	2-8°C refrigerated cold chain for 6 months[2]	Non-replicating viral vector	Oxford University/AstraZeneca AZD 1222	Direct purchasing agreement in place for 3.8M doses by March 2021, additional 30M doses by September	Offshore via AZ (3.8M); onshore manufacturing agreement via CSL (30M doses)
		Protein subunit	UQ/CSL (Seqirus) V451	Direct purchasing agreement in place for 51M doses from mid-2021	Onshore manufacturing agreement via CSL (Seqirus)
		Protein subunit	Novavax (NVX-CoV2373)	40M doses, early-mid 2021 (TBC), option to purchase additional 10M	Offshore manufacturing
-20°C freeze chain for 6 months	2-8°C for 30 days[3]	mRNA	Multiple potential candidates	No purchase arrangements in place at this time*	Offshore manufacturing
-70°C freeze chain for 6 months	Dry ice thermal shippers for 15 days 2-8°C storage for 5 days[2]	mRNA	BioNTech/Pfizer mRNA (BNT162)	10M doses, early-mid 2021	Offshore manufacturing

*The Australian Government has invested in the COVAX facility for up to 50 per cent population coverage. This will include multiple vaccine types - possibly in small quantities.

[2] Successful vaccines candidates will require policy decisions before confirmed for rollout

[3] Subject to ongoing stability leading

1.2 Proposed vaccine roll-out

Consistent with the Australian COVID-19 Vaccination Policy, vaccine rollout is expected to follow three phases;

1. Identified priority population groups;
2. Wide scale vaccination of the general population (excluding those to whom the vaccine is contraindicated) and
3. Regional support across the IndoPacific.

Key vaccination sites are expected to initially include hospitals, GP respiratory clinics, vaccination clinics and general practises.

When vaccines are available, supplies will initially be limited and directed towards priority groups for vaccination (Table 1). The Australian Technical Advisory Group on Immunisation (ATAGI), has provided preliminary advice to the Australian Government on the priority groups for the first doses of a COVID-19 vaccination outlined in 'Preliminary advice on general principles to guide the prioritisation of target populations in a COVID-19 vaccination program in Australia' (attached). This advice supports planning for the deployment of any safe and effective vaccine(s) as soon as approval is obtained from the Therapeutic Goods Administration (TGA) for use in Australia[4].

ATAGI will review these groups as new public health, medical and epidemiological data becomes available, including taking into account any current outbreaks.

Table 1. Possible priority population groups

Group	Vulnerable groups	High exposure risk	Critical services
Description	Those who have an increased risk, of developing severe disease or dying from COVID-19	Those who are at increased risk of exposure and hence of being infected with and transmitting SARS-CoV-2 to others at risk of severe disease or are in a setting with high transmission potential	Those working in services critical to societal functioning
Example sub-populations *Illustrative and non-exhaustive*	Older people (e.g., people aged >65 years) People with pre-existing underlying select medical conditions (e.g., immunocompromised) Aboriginal and Torres Strait Islander people	Healthcare workers (e.g., general practitioners, ambulance staff, paramedics, ICU and emergency department staff) Aged care workers (e.g., group residential care workers) Disability care staff People in settings with increased risk of virus	Groups critical for managing the pandemic response e.g., public health personnel, police, emergency services, defence forces, staff managing quarantine facilities, clinical laboratories, pathology and diagnostic services

[4] ATAGI – Preliminary advice on general principles to guide the prioritisation of target populations in a COVID-19 vaccination program in Australia, https://www.health.gov.au/resources/publications/atagi-preliminary-advice-on-general-principles-to-guide-the-prioritisation-of-target-populations-in-a-covid-19-vaccination-program-in-australia

		transmission (e.g., correctional and detention facilities, staff at ports of entry, sites where disease clusters have occurred, hotel quarantine staff)	Occupations required for societal functioning (e.g., people working in supply and distribution of essential goods and services including food, water, electricity, telecommunication, other critical infrastructure)

1.3 Circumstances where Administration Support is Required

Targeted vaccine administration support is anticipated to focus on three service streams:

- **Priority populations as identified in preliminary ATAGI advice**

When vaccines are available, supplies will initially be limited and directed towards priority groups for vaccination (as detailed in Table 1), for which the Tenderer(s) may be required to have sole responsibility for vaccine administration in specified location(s)(detailed in Section 2). This phase of the roll out is likely to occur in Q1 and Q2 2021.

- **High throughput**

As more supply becomes available through 2021, vaccination will continue with mass vaccination for more of the general population. In this context surge capacity provided by the Tenderer(s) may be required to support existing efforts. This should be a focus as more supply becomes available through Q2 and Q3 2021.

- **Hard to reach communities defined by vulnerability or location**

As more supply becomes available through 2021, more vaccination sites will be required. In this context the Tenderer(s) may be required to support existing efforts in regional, rural, and/or remote locations. Specific populations or communities, such as homeless, may also need targeted support. This should be a focus as more supply becomes available through Q2 and Q3 2021.

1.4 Roles and responsibilities of key stakeholders

On 13 November 2020, National Cabinet has endorsed the Australia's COVID-19 Vaccination Policy (Vaccination Policy) which outlines the roles and responsibilities of the Commonwealth and State and Territory Governments in the roll-out of a vaccination program.

The Commonwealth has responsibility for regulation of vaccines, their acceptance from manufacturers, storage and transport to specified sites within States and Territories, setting funding policy, ensuring that appropriate data collection and monitoring systems are in place, and the national communications and information effort.

The Commonwealth will also define particular requirements for vaccination in residential aged care and residential disability settings; Aboriginal and Torres Strait Islander peoples; culturally and linguistically diverse communities; and vulnerable groups.

States and Territories, in partnership with the Commonwealth will ensure availability of appropriately qualified and trained workforce for vaccines delivered at their vaccination sites,

providing sites where vaccinations can safely take place, and ensuring that immunisation providers at state and territory vaccination sites remain compliant at all times with their safety, ethical, and reporting obligations.

The Commonwealth's distribution and logistics provider(s) are being contracted by the Commonwealth to hold full distribution responsibility for the roll-out of a COVID-19 vaccine or vaccines from point of vaccine acceptance from manufacturers, to sites of vaccine administration (administration sites). The distribution and logistics provider(s) will also be responsible for the receipt, storage, transport, distribution and management of ancillary vaccination supplies including, but not limited to, needles, syringes, personal protective equipment and other consumables such as saline and adrenaline. There will be a handover point of responsibility from the distribution and logistics provider at the administration sites.

The ATAGI is responsible for providing advice on the medical administration of vaccines and providing evidence-based advice to the Department of Health on COVID-19 vaccination in Australia. This includes guidance on administration site requirements, training guidance and pharmacovigilance.

1.5 Objective of the RFT

The objective of this RFT is to select a Tenderer(s) to act as a collaborative partner(s) to provide support and additional capacity where required across the country to assist in the administration of COVID-19 vaccines under required cold chain conditions and dose regimens to target populations as defined by the Commonwealth, across Australia from January 2021 to ensure timely and safe access to COVID-19 vaccines.

2. Description of Services/Scope

The Commonwealth is seeking to engage a collaborative partner(s) to provide targeted and flexible vaccine administration capacity to ensure timely and safe access to COVID-19 vaccines. The tenderer will be required to provide support for all aspects of administration (principally including workforce management, eligibility checking, scheduling of appointments to manage supply and demand, reporting, refrigerated storage capacity and management, physical security, follow-up for second dose) provided over and above the core vaccination administration capacity provided by the States and Territories. As and when required by the Commonwealth, the successful Tenderer(s) will be responsible for the administration of vaccines at locations Australia-wide, including metro, regional and remote locations, to populations defined by the Commonwealth, and in partnership with jurisdictions. In some instances, the Tenderer will have primary responsibility for vaccination sites. In other instances, they will be required to work collaboratively with or under the supervision of, staff employed by a jurisdiction or other healthcare provider to deliver vaccination services. This could be to supplement existing workforces where capacity constraints are identified.

The successful Tenderer(s) will be required to train (or ensure appropriate training has occurred) and provide a suitably qualified workforce that can be scaled and deployed as required to vaccinate target populations across Australia, within a lead time agreed in partnership with the Commonwealth. The minimum training and qualification requirements will be outlined in the Commonwealth's implementation plan, will align with the National Immunisation Education Framework for Health Professionals and will include training on multi-dose vials, management of adverse events, clinical content and record requirements. The COVID-19 vaccination program will enable vaccination coverage to all Australians, including rural, remote and very remote and otherwise hard to reach populations. Tenderers should detail their ability to flex their available workforce (including by provider type and utilising multi-disciplinary teams) up and down with time and across geographical locations. Demonstrated case studies of previous vaccination work are to be included in the Submission.

In the rapidly evolving context of the COVID-19 pandemic and its public health response, a number of uncertainties limit the ability of the Department to fully pre-specify the necessary target populations and location (including uncertainty on which vaccine candidate(s) will prove successful in obtaining regulatory approval, and when or where outbreaks may occur).

The Tenderer's administration capacity should be operational by late January 2021.

2.1 Cross cutting requirements

(a) Workforce

Tenderer(s) must provide a flexible number of well-trained staff for administration and be able to ramp up at short notice when required (the required number will depend on the anticipated size of the clinic or patient volume, with provisions for emergency scenarios). Workforce must include:

- Staff to manage vaccination patient bookings
- Eligible vaccination workforce to prepare and administer vaccines
- Authorised immunisation provider subject to different state and territory legislation (e.g. medical officer or fully trained immunisation registered nurse/nurse practitioner to assess patients and authorise other appropriately trained clinical staff (vaccinator) to administer and record the vaccine in the Australian Immunisation Register (AIR))
- Concierge or team leader (to direct clinic flow)
- Clerical staff
- First aid staff, additional to vaccinating staff as per jurisdictional requirements
- Security staff (if required)
- Staff to follow-up patients for second doses

Tenderer(s) must demonstrate that they are not sourcing this workforce from the public health system to meet the scale and skill in this RFT.

Tenderer(s) must ensure vaccine providers and administrators are compliant with, and meet the necessary requirements within, State and Territory legislation to administer vaccines at the location they are deployed.

Tenderer(s) are required to ensure administration staff have access to and have a clear understanding of the clinical guidelines for administering COVID-19 vaccines from multi-dose vials including the mandatory reporting to the AIR.

(b) Stock and inventory management

Tenderer(s) must be able to take responsibility for the management and reporting of vaccine stock on hand to ensure stock levels are accurately recorded and used to inform supply/demand planning (see Record keeping and reporting).

Tenderer(s) must be able to ensure the optimised use of vaccine stock including, but not limited to, monitoring vaccine expiration dates, checking eligibility in advance of vaccination to ensure the appropriate vaccines are supplied to the correct populations, and completion of second dose.

The successful Tenderer(s) may be required to ensure availability of sufficient ancillary consumables at administration sites, such that availability and/or safe disposal of consumables does not become a bottleneck to administration. This includes, needles, syringes, sharps disposal containers, personal protective equipment, saline, adrenaline and any other consumables required to support administration.

This may require the Tenderer to organise the redistribution of products between vaccine administration sites, if required, by the distribution and logistics provider and in line with the Australian Government's agreed vaccine administration plan.

(c) Cold chain compliance

COVID-19 vaccines must be kept at the appropriate temperature throughout storage to ensure thermostability requirements are met and vaccines remain effective, until point of administration by vaccine administrators. This is a critical requirement to minimise wastage. Temperatures should be tracked and reportable at all times.

Tenderer(s) are required to provide an adequate number and capacity of refrigerators and freezers if relevant to store vaccines for the vaccine to be used. The quantum of this requirement will be specified as part of the defined services.

Tenderer(s) must be able to monitor in real time or near real time the temperatures of the refrigerator(s) and freezer(s) where vaccines are stored (whether those refrigerators or freezers are provided by the successful Tenderer(s) or other administration site participants), including appropriate equipment and systems to monitor ultra-low temperatures according to national vaccine storage guidelines and additional guidelines for storage at -80°C. This may also include management and monitoring of other vaccine storage solutions including, but not limited to, temporary cold storage boxes. Monitoring data must be retained in accordance with guidelines specified by the Department and be provided to the Department on request.

Tenderer(s) must have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator/freezer and responding at times the administration site may not have any staff present.

It is expected that if a cold chain breach should occur, the successful Tenderer(s) will be able to perform a thorough root cause analysis to prevent future breaches and cooperate in any and all enquiries by the Department in relation to such breaches.

Tenderer(s) must be able to provide appropriate refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared until the time they are administered.

(d) Wastage

Given the social, economic and public health importance of a COVID-19 vaccination program, and the anticipated constrained supply of vaccines, there will be a low tolerance for vaccine damage, wastage or loss during administration.

Tenderer(s) must be able to endeavour to minimise wastage of vaccine doses at administration sites via closely monitoring expiry dates, appropriate stock management, minimising cold chain breaches, specific training of staff and minimising damage in storage or handling.

Wastage, including deviation from cold-chain requirements, must be reported against relevant KPIs as agreed with the Department.

Tenderer(s) must also be able to manage returns, including destruction of medical waste as required and associated protocols required for regulated waste destruction.

(e) Record keeping and reporting

Tenderer(s) must be able to comply with all record keeping and reporting requirements as defined by the Department.

Tenderer(s) must be able to implement clear procedure for identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand of vaccine received), and recording immunisation encounters (electronically except in exceptionally circumstances agreed with the Department).

Tenderer(s) must be able to implement a process of labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry.

Tenderer(s) must be able to have access to AIR via Provider Digital Access (PRODA) and have a process to manage vaccination data and report immunisation records to AIR.

Tenderer(s) must be able to report all adverse events following immunisation (AEFI) in line with guidance provided by the Department. This may include reporting to state and territory health departments, the Therapeutic Goods Administration and utilising the Commonwealth funded platform for the active monitoring of adverse events following immunisation known as AusVaxSafety.

Tenderer(s) must be able to record vaccines used and those discarded, including reasons for discarding.

(f) Physical security

Tenderer(s) must have demonstrated procedures in place, and access to trained and licensed personnel, to ensure the physical security of staff, consumers and vaccines at administration sites both when staffed and not staffed.

(g) Data and cybersecurity

The successful Tenderer(s) must have the capability to monitor and report on the stock levels and cold chain compliance of all doses at the vaccine administration sites in their control at all times. KPIs including wastage or other damage, must be reported directly into relevant reporting systems.

The successful Tenderer(s) may need to work with existing Commonwealth, State and Territory systems, or may be required to establish and manage administration site level systems and data management arrangements.

To support data, tracking and cyber security activities the successful Tenderer(s) must work with the Australian Cyber Security Centre (ACSC) as required.

Historic data should be accessible to enable tracking of doses, in case of a later quality or security issue that needs to be traced to point of administration and or recipients of relevant doses.

Data should be provided to the Department daily and on demand. Data may be required to be compatible with other Australian Government reporting systems, including state and territory reporting systems.

Tenderer(s) must ensure their systems are compatible with the Data Solution being developed by the Department to support an end-to-end of the vaccine journey in Australia, and work with the Data Solution vendor as required.

The successful Tenderer(s) will be responsible for maintaining the physical and cyber security of all electronic data systems that relate to the receipt, distribution and storage of vaccines and ancillary consumables as required. Tenderer(s) are expected to have suitable strategies in place to mitigate against threats that may compromise vaccine availability or tracing e.g. ransomware, DDOS attacks. The Tenderer must comply with Australian Privacy Law requirements in relation to all data and records.

(h) Communications

The successful Tenderer(s) must communicate and promote information in relation to COVID-19 vaccines in line with the materials provided by the Commonwealth in accordance with the Commonwealth COVID-19 Vaccine Communications Strategy.

Table 2. Anticipated minimum requirements for immunisation service provider sites for the administration of COVID-19 vaccines.

Set up of the physical environment	Minimum requirements
	• Have adequate space for patients waiting to be vaccinated that is not congested, observes physical distancing requirements, and is sheltered from weather elements. • Have a private space for consultation with patients and vaccinator (including obtaining informed consent, answering patient questions and assessment of any conditions that may preclude vaccination or require further assessment) • Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for patients and vaccinator(s). • Have space for patients to wait and be observed post-vaccination, separate from the area for administering the vaccine. • Have safe, risk free and directed access in clinical areas to allow movement of staff between areas while minimising the risk of workplace incidents (e.g. moving doses from preparation area to patient administration area, accessing refrigerators or cool boxes, etc.). • Have a dedicated clean and well-lit area, separate from areas that provide other clinical services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration. • Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available. • Have antimicrobial /disinfectant wipes to clean stations between patients. • Have visual reminders and cues in place to reduce the risk of errors. • Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements. • Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needle stick injuries.
Cold chain management	• Have adequate number and capacity of refrigerators, and freezers if relevant (-80°C and/or -20°C, as required for the specific vaccine), to store vaccines for the vaccine to be used. • Able to monitor the temperatures of the refrigerator(s) and freezer(s) where vaccines are stored, including appropriate equipment and systems to monitor ultra-low temperatures according to national vaccine storage guidelines and additional guidelines for storage at -80°C. • Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator/freezer and responding at times where clinic may not have any staff present. • Have appropriate refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared till the time they are administered.
Immunisation record keeping and reporting to the Australian Immunisation Register (AIR)	• Have a clear procedure for identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand product received), and recording immunisation encounters (electronic records are preferable). • Have a process of labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry. • Have access to AIR via Provider Digital Access (PRODA). • Have a process to manage vaccination data and report immunisation records to AIR.

	• Have a process to record vaccines used and those discarded, including reasons for discarding. • Have a process of obtaining informed consent.
Management of the clinic	• Standardised screening process to exclude patients who display symptoms of COVID-19 disease, and refer for appropriate assessment for COVID-19 or other conditions (as per guidance provided in the ATAGI Guiding Principles for Maintaining Immunisation Services During the COVID-19 Pandemic. • Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements). • Clear record of patients vaccinated (to inform ordering of vaccines). • Clear assignment of duties and responsibilities of all staff and clear plan of workflow, particularly regarding drawing up from a multi-dose vial and administering individual vaccine doses drawn from a particular vial for each clinic session. • Knowledgeable about procedures and able to report adverse event following immunisation to the appropriate health authorities. • Incident management in place, with staff knowledgeable about procedures and able to report any clinical incident (e.g. injury in workplace) to the appropriate health authorities. • Has process in place to manage injuries to workforce (e.g. needle stick injury). • Process in place to prevent and manage violence or aggression in the workplace.

2.2 Flexibilities / assurances

Tenderer(s) must;

a) Provide assurance of workforce availability, capacity and skill level to enable the Department to manage capacity planning
b) Be able to adapt, pivoting to deploy extra capacity to areas of need, within a reasonably agreed timeframe
c) Be open to covering all potential locations and populations outside those referred to specifically in this RFT, including those that are difficult to reach (e.g., homeless population).

Tenderer(s) should demonstrate the ability to have contingency plans prepared for:

a) Where roll-out is required earlier or later than forecast, depending on vaccine availability and/or approvals
b) Where there is an active outbreak in one or more delivery areas: i.e., Tenderers ability to deliver using the proposed approach should there be ongoing community transmission
c) Where multiple vaccine types are available, either launched together or at different times, in single or multiple sites

Tenderer(s) acknowledge that the requirements and obligations detailed in this Schedule 1 are based on projected future requirements and are subject to variation.

3. Expected deliverables/outcomes

The outcome of this RFT will be the selection of a successful Tenderer(s) who must:

- work closely with the Department and relevant stakeholders to define a detailed administration program for a future COVID-19 vaccine or vaccines;
- deliver and commence operation of the program from January 2021; and
- scale or adapt the program as required during operation to address the likely service streams (see Section 1.3).

4. Proposed timetable for performance of Services

Activity	Timing
Commonwealth Execution of Contract	w/c 11 January 2021
Commencement of Services	On signing
Services definition	From Commencement of Services.
"Operate" stage	From late January / early February 2021 (earliest anticipated commencement of Phase 1 of vaccine rollout, pending availability of suitable vaccines(s))

5. Responsibilities of the Department

The Department will be responsible for provision of reasonable access to information as requested by the Tenderer(s).

The Department will provide an internal resource to act as a point of contact for the duration of the contract, including supporting engagement with required stakeholders across the Commonwealth, and States and Territories.

The Department will approve the approach for the vaccine administration services to be provided by the Tenderer.

6. Term of the Contract including any options to extend

The Initial Term of the Contract will be up to 1 year. The Department also requires 4 optional extensions, each to be 6 months in duration.

7. Specific insurance requirements particular to the procurement

Immunisation Providers will be required to hold relevant professional and/or medical indemnity insurance as a registered Australian Health Practitioner Regulation Agency member or equivalent. Evidence of such insurance will be required.

Public liability insurances held by the successful tenderers must include specific provisions necessary for the provision of security services. Evidence of such insurance will be required.

8. Monitoring and reporting

The Tenderer will be required to produce reports for the Department in order for the Department to review the effectiveness of the contract, and to assist with decisions on improvements that could increase the utility of the Solution to end users.

The reports will also assist the Department to monitor the quality and effectiveness of the provision of the Services by the successful Tenderer.

The reports produced by the Tenderer which must be delivered to the Department are required to:

(a) support the Tenderer's contractual obligations to the Department;

(b) provide details about the Tenderer's management of the Services with respect to agreed Service Levels; and

(c) support reporting requirements of the Department.

It is expected that the Tenderer will also produce reports for the Tenderer's own purposes to:

(a) support the day-to-day operations of the Services provided and

(b) allow the Tenderer to monitor quality of services and to manage continual improvement of the Services.

Other Reporting may be required as set out in the Contract.

SCHEDULE 2 – TENDERER DECLARATIONS

The Tenderer must complete, sign and scan the declaration set out below and submit the declaration as part of its Submission. This is a Minimum Content and Format Requirement.

THIS DEED POLL is made on the day of 2018

by

Name

ACN/ABN/ARBN

Short form name **Tenderer**

1. Declaration

The Tenderer declares that this deed is for the benefit of the Commonwealth of Australia as represented by the Department of Health (**Department**).

2. Definitions

In this deed terms have the same meaning as in Request for Submission for the procurement of a COVID-19 vaccination administration services (Health/20-21/ 287846) (**RFT**).

3. Offer and Change of Circumstance

The Tenderer offers to supply the Services described in this RFT on the conditions set out in this RFT for the price tendered. The Tenderer undertakes not to withdraw, vary or otherwise compromise this offer for a period of no less than six months from the Closing Time.

The Tenderer undertakes to promptly notify the Department of any change, after submission of its Submission, to the basis upon which it will have access to the necessary skills or resources, or corporate or financial backing, to supply the Services.

4. Tenderer's Conduct

The Tenderer confirms that this Submission:

- does not contain any false or misleading claim or statement; and
- has been compiled without the Tenderer:
  - engaged in misleading or deceptive conduct;
  - improperly obtaining Confidential Information;
  - engaging in any collusive bidding, anti-competitive or other unethical, improper or unlawful conduct;
  - violating any applicable laws or Commonwealth policies regarding the offering of inducements;
  - communicating with or soliciting information from any Department employee (or contractor) or ex-employee (or ex-contractor) other than the Contact Officer;
  - obtaining improper assistance from any Commonwealth employee or using Confidential Information improperly obtained;
  - approaching any officer or employee of the Department other than in the manner set out in the RFT;
  - engaging in, or procuring others to engage in, any activity that would result in a breach of the *Lobbying Code of Conduct 2013* published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
  - otherwise acting in an unethical or improper manner or contrary to any law.

The Tenderer warrants that it has not attempted and will not attempt, through its officers, employees or agents, to influence improperly any officer or employee of the Department in connection with the assessment of the Submission.

The Tenderer warrants that it has complied with all relevant laws and with Commonwealth policy, in preparing and lodging its Submission and in taking part in this RFT process.

5. Conflict of Interest

[Note to Tenderers: Strike through whichever option does not apply. Tenderers should refer to clause 38 of the RFT for further information

The Tenderer represents and declares that, having made all reasonable enquiries, it does not have any known actual or potential conflicts of interest concerning itself or a related entity in respect of this RFT, its Submission or the provision of the Services referred to in the Statement of Requirement other than those specified below.

OR

The Tenderer

- represents that, having made all reasonable enquiries, the following represents its only known actual or potential conflicts of interest in respect of this RFT, its Submission or the provision of the Services referred to in the Statement of Requirement:

[Insert details]

- advises that its proposed mitigation approach to manage this conflict of interest is as follows:

[insert details]

6. Further representations

The Tenderer makes the following further representations to the Department:

- it is authorised to sell and/or support all products required in the performance of the Services relating to this Submission;
- it has examined the AusTender Terms of Use which are obtainable on the AusTender website;
- it has examined this RFT, all documents referred to in this RFT and all other information made available to it and all applicable legislation and policies;
- it has examined all further information which is obtainable by making reasonable enquiries relevant to the risks, contingencies and other circumstances having an effect on its Submission;
- it has satisfied itself as to the correctness and sufficiency of its Submission, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
- it has satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at SCHEDULE 4 – Statement of Non-Compliance;
- it has obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFT process;
- it has made its own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments;
- it has relied entirely on its own enquiries and has not relied on any representation, warranty or other conduct by or on behalf of the Department, except as expressly provided in this RFT or in notices received by it; and
- it has accepted and has fully complied with the provisions of this RFT.

7. Acknowledgements

The Tenderer acknowledges that:

- the Department may exercise any of its rights set out in this RFT, at any time;
- the statements, opinions, projections, forecasts or other information contained in this RFT may change;
- this RFT is a summary only of the Department's requirements and is not intended to be a comprehensive description of it;
- neither the lodgement of the Submission nor the acceptance of any Submission nor any agreement made subsequent to this RFT will imply any representation from or on behalf of the Department that there has been no material change since the date of this RFT or since the date as at which any information contained in this RFT is stated to be applicable;
- to the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis

whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFT process, including instances where:
  - a Tenderer is not engaged to undertake the provision of the Services;
  - the Department decides not to enter into any resulting Contract with any Tenderer or at all;
  - the Department exercises or fails to exercise any of its other rights under or in relation to this RFT (whether or not the Department has informed a Tenderer of its exercise of the rights);
- a Submission or any other material or communication relevant to this RFT is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
- the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements
- to the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFT or any other matter arising by the Department exercising any of its rights; and
- the Department will have received this Submission in reliance on this deed and that the Department may suffer loss if any of the representations, undertakings, consents or other statements in this Declaration or the Tenderer's Submission are misleading or deceptive.

8. Corporate capacity

The Tenderer confirms that:

- it has the capacity to respond to this RFT;
- there are no restrictions under any relevant law to prevent it from so responding;
- it is financially viable; and
- the Tenderer:
  - being a corporation – is not under one of the forms of external administration referred to in Chapter 5 of the *Corporations Act 2001* (Cth) and has not had an order made against it for the purpose of placing it under external administration; or
  - being an individual – is not bankrupt and has not entered into a scheme of arrangement with creditors.

9. Security, probity and financial checks

The Tenderer:

- consents to the Department performing (and will procure all necessary consents to enable the Department to perform) such security, probity and financial investigations and procedures as the Department may determine are necessary in relation to the Tenderer, any consortium member, their employees, officers, partners, associates, Subcontractors or related entities; and
- agrees to provide at its cost, all reasonable assistance to the Department and its nominees in this regard.

10. Workplace Gender Equality Act 2012 (Cth)

Under Australian Government procurement the Tenderer is obliged to indicate whether or not it is covered by the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act). The Tenderer is covered by the WGE Act if it is a 'relevant employer', defined as being a non-public sector employer (including higher education institutions, trade unions and not-for-profit organisations) of 100 or more employees in Australia. For more information about the coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

[Note to Tenderers: Check the relevant box below. If you check box (a), please ensure your letter of compliance is attached to this declaration.]

☐ (a) Yes, the Tenderer is a relevant employer. The Tenderer has attached a current letter of compliance as part of this Submission which indicates my compliance with the *Workplace Gender Equality Act 2012* (Cth).

☐ (b) Yes, the Tenderer is a relevant employer. The Tenderer will be providing a current letter of compliance prior to entering into any resultant Contract.

☐ (c) No, the Tenderer is not a relevant employer.

11. Terrorism

The Tenderer declares neither it, nor any of its personnel or any Subcontractor proposed in its Submission, are listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

12. Trade sanctions

The Tenderer declares neither it, nor any Subcontractor proposed in its Submission, are named in the consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

13. Employee entitlements

The Tenderer represents that, having made all reasonable enquiries, there are currently no unsettled judicial decisions against the Tenderer (excluding decisions under appeal) relating to employee entitlements for which the Tenderer has not satisfied any resulting order.

14. Illegal Workers

The Tenderer declares that is does not engage Illegal Workers.

Note: see definition of "Illegal Workers" in the Glossary in Part 5 of this RFT.

15. Survival

This deed survives the termination or expiry of the RFT process.

16. Indigenous Procurement Policy

The Tenderer declares the following:

The Tenderer has or has had _____ [NIL OR SPECIFY NUMBER] contracts with the Commonwealth that included the Indigenous Procurement Policy mandatory minimum requirements.

For the contracts referred to in the para above (if any), the Tenderer has:

- fully met /
- partially met /
- not met /
- not applicable as Nil contracts undertaken,
- the Indigenous Procurement Policy mandatory minimum requirements.

[Note to Tenderers: Strike out the options that do not apply.]

The Indigenous enterprises referred to in the Indigenous Participation Plan submitted as part of Tenderer's Submission are 50 per cent or more Indigenous owned.

[Note to Tenderers: If you are an incorporated joint venture, where the joint venture is at least 25 per cent Indigenous owned, include the following. If it does not apply you may strike it out.]

The Tenderer is a joint venture that is 25 per cent or more Indigenous owned.

17. [Note to Tenderers: Supply Nation maintains a list of enterprises that meet the definition of "Indigenous enterprises". If an enterprise is not listed with Supply Nation refer to section 1.8.1 of the Indigenous Procurement Policy for ways of ensuring an enterprise is an Indigenous enterprise.]Black Economy Procurement Connected Policy

The Tenderer represents that:

- it holds a Valid and Satisfactory Statement of Tax Record from each Subcontractor that it proposes, as part of its Submission, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive); and
- if it is the successful Tenderer, it will ensure that any Subcontractor not included in its Submission that it subsequently engages to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive), will provide it with a Satisfactory Statement of Tax Record that is Valid at the time of entry into the subcontract.

Executed as a deed poll

Execution by a company incorporated in Australia

The following execution block should be used by a Tenderer that is a company incorporated in Australia.

Executed by **[**Name of company**]** in accordance with Section 127 of the *Corporations Act 2001*

Signature of director	Signature of director/company secretary (Please delete as applicable)

Name of director (print)	Name of director/company secretary (print)

Execution by an attorney

Where the Deed of Undertaking is executed by an attorney under a power of attorney on behalf of a company incorporated in Australia, the Tenderer should submit with its executed Deed of Undertaking a copy of the relevant power of attorney. Powers of attorney must be in the form of a deed executed in accordance with section 127 of the *Corporations Act 2001* (Cth).

Signed sealed and **delivered** by **[**company name**]** by its attorney under power of attorney [dated [date of power of attorney] registered number [registered number] book number [book number], who warrants that, as at the date of this deed, they have had no notice of revocation of the power of attorney

Signature of attorney	Signature of witness
Name of attorney (print)	Name of witness (print)

SCHEDULE 3 – TENDERER RESPONSE INFORMATION

1. Tenderer's Profile

1.1 Tenderer's contact officers

Tenderers should provide details of their nominated contact officers in the following table:

Tenderer's primary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	
Tenderer's secondary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	

1.2 Tenderer's details

Tenderers should complete all details in the following table:

Tenderer's details	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
Is the Tenderer registered for GST?	Yes / No
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	

Tenderer's details	
Date and place of incorporation or registration of business (if applicable)	

2. Subcontractor details

(a) Where Tenderers are proposing to use Subcontractors to deliver some of the Services, Tenderers should complete all details in the following table for each nominated Subcontractor.

(b) Tenderers should note that, under paragraph 7.21 of the Commonwealth Procurement Rules, the names of Subcontractors may be publicly disclosed and that it is the responsibility of Tenderers to secure Subcontractors' agreement to this.

Subcontractor 1	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

Subcontractor 2	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a	

Subcontractor 2	
trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

3. Tenderer's insurance

Tenderers should complete all details in the following table:

General liability insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Professional indemnity insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Workers' compensation insurance	
Name of insurer	
Policy number	
Expiry date	

Where the Tenderer's proposed Personnel are operating as an individual and/or include volunteers, Tenderers should also complete all details in the following table:

Disability income insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Voluntary workers' insurance	
Name of insurer	

Policy number	
Expiry date	
Amount of current cover	

4. Tenderer's Financial Viability

(a) The Tenderer should provide a summary of their financial viability.

(b) This may include data from or for a financial analysis of its operations including profitability, liquidity, insolvency, bankruptcy actions, working capital management efficiency, financial structure, debt coverage and return on investment.

(c) The Department may also request further information and undertake its own independent enquiries and assessment in relation to the Tenderer's financial viability.

5. Actions or Investigations

(a) The Tenderer should provide particulars of any petition, claim, action, judgement or decision that is likely to adversely affect its capacity to provide the Services.

(b) Tenderers should provide details of whether or not they are aware that they are under investigation, or the subject of court proceedings, in relation to a possible or actual breach of any relevant legislation, and if applicable, provide details of the same.

6. Service Delivery and Management

Tenderers should provide the following information:

6.1 Overall approach

Tenderers should outline their proposed overall approach to delivering the Services outlined in Schedule 1 – including reference to the workforce, infrastructure, procedures, equipment and facilities, if applicable, to be utilised in the delivery of the Services. This should include details of the strategies for resourcing, in terms of staff, equipment and facilities where required. This should be presented across the 3 service streams detailed in SCHEDULE 1 1.3.

The Tenderer should clearly state whether they can meet all of the Service requirements as set out in the Statement of Requirement, and if not, which they are unable to meet.

Tenderer's should also detail their capacity and proposed approach to deliver vaccination services to the following populations:

- Aged care residential facilities
- Disability services
- Regional / rural / remote communities
- Any other populations listed in SCHEDULE 1 1.2, Table 1

Tenderer's should detail:

(a) A proposed schedule for how staff will be adequately trained to support vaccine administration as per the National Immunisation Education Framework for Health

Professionals and additional minimum requirements outlined in implementation planning

(b) the plan for demand management (including managing booking and scheduling of appointments, and follow up to ensure second dose completion)

(c) the plan to optimise use of stock to individuals

(d) how staff will report an individual's administration of a vaccine to the AIR and any associated wastage and/or spoilage in a timely manner

(e) how staff will monitor and report adverse reactions

(f) how staff will ensure the 2-dose regime for patients is optimised

6.2 Current and potential future additional capacity

Tenderer's should detail the expected ramp up time for current and potential capacity. The pricing sheet assumes a 4-week notice period for administration requirements. Please include additional pricing tabs to reflect price based on different notice periods.

In line with information provided in the pricing sheet, Tenderers should outline in greater detail the origin and status of their potential future additional capacity, including whether this is in progress or proposed.

6.3 Performance management

Tenderer's should outline:

(a) details of how the performance standards for the Services will be maintained, monitored and reported to the Department;

(b) how the Tenderer will respond to requests from the Department for performance related information

(c) a list of the daily, weekly, and monthly metrics that will be reported to demonstrate effectiveness and completeness of process, including in what format these reports will be delivered and how they can be accessed

7.2 Contingencies

Tenderer's should outline the mechanisms that will be used to ensure delivery of the service is adaptive and fit-for-purpose given the evolving context.

Furthermore, Tenderers should outline their approach to contingencies/adaptation to ensure services can be delivered under the following circumstances:

- Where roll-out is required earlier or later than forecast, depending on dose availability and/or approvals
- Where there is an active outbreak in one or more delivery areas: i.e., Tenderers ability to deliver using the proposed approach should there be ongoing community transmission
- Where multiple vaccine types are available, either launched together or at different times, in single or multiple sites

7. Timeline execution and readiness

Tenderer's should propose a path to readiness including timelines and flagging key risks to service delivery.

Tenderers should set out their organisational capacity to deliver the Services, in addition to the scale and capacity with which Tenderer's are to cover potential populations in the time required including consideration of both geographical coverage across jurisdictions and from metropolitan to very remote areas.

Tenderer's should specifically detail their capacity to enhance or pivot the existing network during operation.

8. Past Performance

To assess the Tenderer's capability to deliver the Services, Tenderers should provide details of similar services provided within the last three years (if any). In addressing this requirement, Tenderers should include:

(a) the organisation(s) for whom the services were undertaken, including contact details;

(b) the nature of the project and the outcome achieved by the Tenderer;

(c) the period over which the work was undertaken; and

(d) the value of the work undertaken.

9. Risk management

Tenderers should set out in their Tender response:

(a) the key issues and risks they consider are relevant to the provision of the Services;

(b) the Tenderer's suggested approach to the issue and risk;

(c) the Tenderer's and Department's roles in the suggested approach; and

(d) the Tenderer's risk management systems currently in place or proposed.

10. Personnel for supplier representatives

The Tenderer should, in the table below, provide details of the personnel who will be used for the management and leadership of the Services.

Name and position of Personnel	Role in the provision of the Services	Experience / qualifications	Availability

11. Referees

(a) Tenderers should provide details of at least two referees which can be contacted regarding work undertaken by the proposed personnel. References will be evaluated based on relevance of work completed as well as comments from the referee contacts. Tenderer(s) must specify programme of work that the referee was involved with.

(b) A Tenderer may provide contacts within the Department as referees. However, where a Department contact is involved in evaluating Submissions or advising the Submission evaluation team they will be unable to provide a reference, in which case the Department may ask the Tenderer to provide details of an alternate referee.

(c) Without limiting paragraph 10.2, the Department reserves the right to contact persons other than those provided as referees by Tenderers.

12. Indigenous Participation Plan

(a) Each Tenderer must submit an Indigenous Participation Plan with its Submission using the template in Schedule 6. The Indigenous Participation Plan should address:

(i) how the Tenderer intends on meeting the mandatory minimum requirements for the Indigenous Procurement Policy;

(ii) the Tenderer's current rate of Indigenous employment and supplier use;

(iii) the Tenderer's commitment to Indigenous participation. Some examples of the activities an organisation can take to demonstrate its commitment to Indigenous participation are set out in paragraph 4.7.1 of the Indigenous Procurement Policy; and

(iv) if any part of the Contract will be delivered in a Remote Area, how the Tenderer will ensure that its provision of the Services will deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

(b) The mandatory minimum requirements can be met at:

(i) the contract-based level (see paragraph (c) below); or

(ii) the organisation-based level (see paragraph (d) below).

(c) To meet the mandatory minimum requirements at the contract-based level, by the end of the Initial Term of the Contract:

(i) at least 4 per cent of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 4 per cent of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, on average over the Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous

Australians, and a minimum percentage of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, so that both minimum percentages add up to 4 per cent, on average over the Initial Term of the Contract.

(d) To meet the mandatory minimum requirements at the organisation-based level, by the end of the Initial Term of the Contract:

(i) at least 3 per cent of the full time equivalent Australian-based workforce of the contractor must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 3 per cent of the value of the contractor's Australian supply chain must be subcontracted to Indigenous enterprises, on average over Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce must be Indigenous Australians, and a minimum percentage of the value of the contractor's supply chain must be subcontracted to Indigenous enterprises, such that both minimum percentages add up to 3 per cent on average over the Initial Term of the Contract.

(e) The mandatory minimum requirements can be met directly or through subcontracts.

(f) The successful Tenderer's Indigenous Participation Plan will be attached to the resultant Contract, and the successful Tenderer will be required to comply with and report against the Indigenous Participation Plan during the term of that Contract.

13. Economic Benefit to the Australian Economy

Respondents should answer the questions below to enable the Department to consider the economic benefit of the procurement to the Australian economy.

RESPONDENT PROFILE

Does the Respondent have an Australian Business Number (ABN)	Y/N
Is the Respondent incorporated in Australia? If No, is the Respondent a foreign company registered in Australia	Y/N Y/N
How many current (full time equivalent) employees of your organisation are based in Australia?	

Describe any strategies you consider relevant to your proposed supply's economic benefit to the Australian economy
[max 300 words] *Examples of information potential suppliers might include, but are not limited to:* • *Lowest price, saving the tax payer;* • *Building, leasing or procuring infrastructure that supports Australian communities;*

- *Providing skills and training that benefits Australian communities;*
- *Employing workers in Australia;*
- *Paying taxes in Australia;*
- *The environmental benefit of the proposed solution to Australia, for example, low environmental impact through energy efficient inputs such as computers, air conditioning, telephones and paper;*
- *Contributing to positive social outcomes in Australian communities;*
- *Using of indigenous business;*
- *Using SMEs in delivering goods and services, such as a subcontractor or supplier;*
- *Sharing knowledge, skills and technology with SMEs; and*
- *Using goods and services from a business that provides services of persons with a disability*

14. Other information

Tenderers should provide any other information that addresses the Evaluation Criteria set out in clause 21 of this RFT.

SCHEDULE 4 – STATEMENT OF NON-COMPLIANCE

1. Statement of Non-Compliance

Where the Tenderer wishes to negotiate any provisions of the Draft Contract (Schedule 6), it should include in its response below details of:

- the provision that it wishes to negotiate;
- the alternative words that it proposes; and
- any increase in its Submission price if the Department does not agree to the amendment.

The Department will consider any non-compliances or partial compliances in its evaluation of other risks.

If Tenderers do not submit a response to this Schedule they will be evaluated on the basis that they agree with all the provisions of the Draft Contract.

The Department does not intend to permit a Tenderer to re-open any provision of the Draft Contract in negotiations that was not identified as an area of non-compliance or partial compliance in a Submission.

Item reference	Nature of compliance (partially complies, does not comply)	Reasons for non-compliance or partial compliance and proposed alternative wording

2. Confidential Information

The Tenderer should specify any information which is contained in its Submission, or which may be provided by it during this RFT process, that it considers should be protected as Confidential Information by the Department in respect of any resultant Contract. The Tenderer should also provide appropriate reasons why any such information should be protected as Confidential Information.

Tenderers should review the information available from the Department of Finance's website for further detail about what information may be protected as Confidential Information (see the Department of Finance's Confidentiality Throughout the Procurement Cycle).

Proposed Confidential Information (refer to RFT or Schedule clause)	Reason why this information should be protected as Confidential Information

SCHEDULE 5 – PRICING SCHEDULE

1. Pricing Schedule

1.1 The Tenderer should indicate, using the attached .xlsx file as a template, all fees, charges, and other costs which it would seek to be paid for the Services and discounts offered.

1.2 A breakdown of assumptions, variations or other qualifications relied upon for generating the price should be provided.

1.3 The Department prefers that Tenderers lodge their pricing in Australian currency. Any pricing lodged in foreign currency amounts will be converted to Australian currency for evaluation purpose.

1.4 All amounts are to be expressed as GST inclusive.

1.5 Tenderers should provide itemised pricing information and proposed payment schedules detailing all fees, prices and charges related to each milestone or deliverable of the Services. The first payment milestone must be delivery to the Department an implementation plan for services within contracted timeframes.

2. Other Pricing Information:

2.1 Tenderers are encouraged to provide any discount Tenderers are prepared to allow for payment within the standard Commonwealth 30-day period for payment of invoices

2.2 Tenderers are encouraged to provide financial details of any alternative pricing structures or pricing control mechanisms they would be prepared to use to ensure good cost controls (for example, volume discounts, rebates, fee credits, other alternatives to hourly rates, capped, fixed or success fee pricing mechanisms). Tenderers are to state when such control mechanisms would be applicable.

SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM

INDIGENOUS PARTICIPATION PLAN

[INSERT NAME OF TENDERER]

1. This is an Indigenous Participation Plan submitted as part of the Submission in response to [INSERT RFT NUMBER] (**RFT**).

2. If selected as the Contractor following evaluation of Submissions received in response to the RFT, [TENDERER] will meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy:

   at the contract-based level, in which regard at least:

   - [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians over the Initial Term of the Contract; and

   - [INSERT] percentage of the value of the work performed under the Contract will be subcontracted to Indigenous enterprises over the Initial Term of the Contract; or

   at the organisation-based level, in which regard at least:

   - • [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce will be Indigenous Australians over the Initial Term of the Contract; and

   - • [INSERT] percentage of the value of [TENDERER'S] Australian supply chain will be subcontracted to Indigenous enterprises over the Initial Term of the Contract.

[Note to Tenderers: Select which option(s) above apply based on the requirements set out in paragraphs 12(b), (c) and (d) in Schedule 3 of this RFT.]

3. To meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy, [TENDERER] will undertake the following:

[Note to Tenderers: Tenderer to insert details of how it will meet the mandatory minimum requirements (which may include details of its current workforce / supply chain) at either / both the contract / organisation level and how it will go about meeting the requisite percentages to meet the mandatory minimum requirements. Tenderers should note that the mandatory minimum requirements are averages over the Initial Term of any resultant Contract, and will accordingly need to detail their approach to achieving the specified targets over the Initial Term.]

4. [TENDERER's] rate of Indigenous employment and supplier use as at the Closing Time is:

5. [TENDERER] demonstrates its commitment to Indigenous participation as follows:

6. [TENDERER] will meet the mandatory minimum requirements: directly; or through subcontracts.

[Note to Tenderers: Tenderer to detail its approach to meeting the mandatory minimum requirements directly or through subcontracts.]

Remote Area Contracts

7. A component of any resultant Contract will be delivered in a Remote Area. [TENDERER] proposes to ensure the Contract will deliver a significant Indigenous employment or supplier use outcome in that Remote Area as follows:

SCHEDULE 7 – DRAFT CONTRACT

See separate document titled 'Schedule 7 – Draft Contract'.

Australian Government
Department of Health

REQUEST FOR PROPOSAL FOR THE PROVISION OF COVID-19 VACCINE LOGISTICS & DISTRIBUTION SERVICES, INCLUDING ANCILLARY CONSUMABLES

Health/20-21/D20-2484457

ISSUED BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH

Lodgement Closing Time: 2.00pm on the 18 November 2020 (local time in Canberra, ACT)

PLEASE NOTE:

- **Proposals must be lodged electronically via AusTender (see clause 19)**
- **Proposals should be lodged in the format described in clause 21**.

The Department adheres strictly to Commonwealth policy on late proposals. The Department therefore recommends that Tenderers plan to lodge their Proposal well before the Closing Time to minimise the possibility of any unforeseen circumstances arising that may cause the Tenderer to miss the Closing Time.

Commonwealth Contact: COVID19VaccineProcurement@health.gov.au

CONTENTS

PART 1 – OVERVIEW, BACKGROUND, SERVICES SPECIFICATIONS AND PROPOSAL LODGEMENT

1. REQUEST FOR PROPOSAL

1.1 This Request for Proposal (RFP) comprises:

a. Part 1 – Overview, background, services specifications and Proposal lodgement;
b. Part 2 – Information to be provided by Tenderers;
c. Part 3 – Evaluation of Proposals;
d. Part 4 – Conditions of tendering;
e. Part 5 – Glossary;
f. Schedule 1 – Statement of Requirement;
g. Schedule 2 – Tenderer Deed;
h. Schedule 3 – Tenderer Response Information;
i. Schedule 4 – Statement of Non-Compliance;
j. Schedule 5 – Pricing Schedule;
k. Schedule 6 – Indigenous Participation Plan Template Response Form; and
l. Schedule 7 – Draft Contract.

1.2 Tenderers' attention is also drawn to the:

a. Conditions for Participation set out in clause 23;
b. Minimum Content and Format Requirements set out in clause 24; and
c. Essential Requirements set out in clause 25.

2. THE DEPARTMENT

2.1 The Commonwealth of Australia acting through the Department of Health (**Department**) is responsible for better health and wellbeing for all Australians. The Department aims to achieve its vision through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.

2.2 Australia's COVID-19 Vaccine and Treatment Strategy aims to support access to, and delivery of, safe and effective COVID-19 vaccines and treatments for all Australians, as soon as they are available.

2.3 The Department is seeking to engage a partner(s) to co-design and deliver logistics and distribution services for the roll-out of a potential COVID-19 vaccine and associated consumables (including needles, syringes, personal protective equipment) for Australia; from point of acceptance from manufacturers, to sites of vaccine administration (vaccination), including potential consumer management system.

3. SERVICES THE DEPARTMENT REQUIRES

3.1 The Department is seeking Proposals for the following Services:

a. **Co-design** of a logistics and distribution network to support the delivery of a potential COVID-19 vaccine or vaccines to all Australians, including the

transport, storage and management of both the vaccine and ancillary consumables (such as the needles, syringes, and personal protective equipment) necessary for vaccination service providers to administer the vaccine(s) to the point of vaccination;

b. **Establish** the co-designed logistics and distribution network, including consumer management systems;

c. **Operate** the co-designed logistics and distribution network to transport and store potential COVID-19 vaccine(s).

3.2 The detailed specifications and requirements for the Services are set out at Schedule 1 - Statement of Requirement. The Department proposes to engage the successful Tenderer to provide the Services in accordance with the Draft Contract set out in Schedule 7.

4. RFP TIMETABLE

4.1 The following is an indicative timetable for this RFP process:

Activity	Timing
Release of RFP	5 November 2020
Industry briefing	11 November 2020
Enquiry Cut-Off Date	2 PM, 16 November 2020
Closing Time	2 PM, 18 November 2020
Negotiation with preferred Tenderer(s)	23 - 27 November 2020
Execution of Contract with successful Tenderer	30 November 2020
Notification of unsuccessful Tenderers	30 November 2020
Commencement of Services	Upon signing

5. ENQUIRIES ABOUT THIS RFP

5.1 Enquiries about this RFP should be made by email addressed to:

Name:	Bec Sykes
Title:	Director, COVID-19 Vaccine Strategy Taskforce
Email:	COVID19VaccineProcurement@health.gov.au

5.2 The Department will provide answers to any reasonable enquiry from a prospective Tenderer that is received by the Department before the Enquiry Cut-Off Date set out in clause 15, in which case:

a. questions and related answers may be disclosed to all prospective Tenderers via AusTender (without disclosing the source of the questions); and

b. any Tenderer Confidential Information contained in a question (that is expressly nominated as such by the relevant Tenderer and agreed to by the Department) will be removed prior to disclosure on AusTender.

5.3 All communications related to this RFP must be addressed in writing to the Contact Officer (via the contact details specified above) and not to other Departmental officers or other persons. The Department may not respond to any

enquiry not made in accordance with the requirements of clause 5.1. A Tenderer who communicates other than to the Contact Officer may be excluded from participating further in this RFP process.

6. GOVERNMENT PROCUREMENT (JUDICIAL REVIEW) ACT 2018 (CTH)

6.1 This RFP process ***is not*** a covered procurement for the purposes of the Commonwealth Procurement Rules and the *Government Procurement (Judicial Review) Act 2018* (Cth).

6.2 Not used

6.3 Not Used

7. AUSTENDER, THE AUSTRALIAN GOVERNMENT TENDER SYSTEM

7.1 AusTender is the Australian Government's procurement information system. Access to and use of AusTender is subject to terms and conditions. In participating in this RFP process, Tenderers agree to comply with those terms and conditions and any applicable instructions, processes, procedures and recommendations as advised on the AusTender website at https://www.tenders.gov.au/?event=public.termsOfUse.

7.2 All queries and requests for technical or operational support must be directed to:

AusTender Help Desk

Telephone: 1300 651 698

International: +61 2 6215 1558

Email: tenders@finance.gov.au

7.3 The AusTender Help Desk is available between 9am and 5pm ACT local time, Monday to Friday (excluding ACT and national public holidays).

8. ELECTRONIC LODGEMENT

8.1 Proposals must be lodged electronically via AusTender before the Closing Time and in accordance with the Proposal response lodgement procedures set out in this RFP and on AusTender.

8.2 If Tenderers need to lodge material that cannot be submitted via AusTender, Tenderers should contact the Contact Officer prior to Closing Time to make arrangements for its submission.

9. PROPOSAL CLOSING TIME AND DATE

9.1 Proposals must be lodged before 2 PM, local time in the ACT on the 18th November 2020, (the **Closing Time**).

9.2 The Closing Time will also be displayed in the relevant AusTender webpage together with a countdown clock that displays in real time the amount of time left

until Closing Time (For more information please see AusTender Terms of Use). For the purposes of determining whether a Proposal has been lodged before the Closing Time, the countdown clock will be conclusive and will be the means by which the Department determines whether a Proposal has been lodged by the Closing Time.

9.3 Any attempt to lodge a Proposal after the Closing Time will not be permitted by AusTender. Such a Proposal will be deemed to be a Late Proposal. Late Proposals will be excluded from consideration unless the Proposal is late as a consequence of mishandling by the Department.

9.4 Where electronic submission of a Proposal has commenced prior to the Closing Time but concluded after the Closing Time, and upload of the Proposal file(s) has completed successfully, as confirmed by AusTender system logs, the Proposal will not be deemed to be a Late Proposal. Such Proposals will be identified by AusTender to the Department as having commenced transmission prior to, but completed lodgement after, the Closing Time.

9.5 Where a Proposal lodgement consists of multiple uploads, due to the number and/or size of the files, Tenderers must ensure that transmission of all files is completed and receipted before the Closing Time and clause 8.4 will only apply to the final upload.

10. PREPARING TO LODGE A PROPOSAL

Proposal File Formats, Naming Conventions and Sizes

10.1 The Department will accept Proposals lodged in Microsoft Word, Microsoft Powerpoint and PDF formats. Supplementary materials/attachments may be also be provided in one of these formats, or in formats compatible with Microsoft Excel. If the Tenderer believes elements of their proposal are best represented in a file format not listed here, queries may be directed to the Contact Officer.

10.2 The Proposal file name/s should:

a. Begin with the date in YYYYMMDD format (e.g., 20201030); and
b. incorporate the Tenderer's company name; and
c. reflect the various parts of the Proposal they represent, where the Proposal comprises multiple files.

10.3 Proposal response files should not exceed a combined file size of 5 megabytes per upload.

10.4 Proposals must be completely self-contained. No hyperlinked or other material may be incorporated by reference.

11. SCANNED OR IMAGED MATERIAL, INCLUDING STATUTORY DECLARATIONS

11.1 In the event that the Department requires clarification of the Tenderer's Proposal, the Tenderer may be required to courier or security post the originals of the signature and/or initialled pages to the Department at the address notified by the Department within the period notified by the Department.

PART 2 – INFORMATION TO BE PROVIDED BY TENDERERS

12. CONDITIONS FOR PARTICIPATION

12.1 Subject to clause 13, if the Department considers that a Tenderer does not satisfy all of the following Conditions for Participation, that Proposal will be excluded from further consideration under this RFP:

Item	Conditions for Participation
1	The Tenderer must not have had any judicial decisions against it (excluding decisions under appeal) relating to employee entitlements and have not satisfied any resulting order.
2	The Tenderer, its personnel, and any Subcontractors proposed in the Proposal must not, at the Closing Time, be listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).
3	The Tenderer (and any Subcontractor proposed in its Proposal) must not be named in the Consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).
4	(a) The Tenderer either: i. holds a Valid and Satisfactory Statement of Tax Record by the Closing Time; or ii. has a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office by the closing time, and holds a Valid and Satisfactory Statement of Tax Record no later than 4 business days from the Closing Time; and (b) the Tenderer holds a Valid and Satisfactory Statement of Tax Record from any Subcontractor that it proposes, as part of its Proposal, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive). [Note to Tenderers: Tenderers should apply for a Statement of Tax Record and should ensure that their Subcontractors apply for a Statement of Tax Record within sufficient time to meet this Condition for Participation.]

13. MINIMUM CONTENT AND FORMAT REQUIREMENTS

13.1 Subject to clause 13, if the Department considers that a Proposal does not satisfy all of the following Minimum Content and Format Requirements, that Proposal will be excluded from further consideration under this RFP:

Item	Minimum Content and Format Requirements
1	The Proposal must be in English and measurements must be expressed in Australian legal units of measurement.
2	The Proposal must include a completed, signed and scanned Tenderer Deed substantially in the form at Schedule 2.
3	Tenderers must substantially complete and submit the Pricing Schedule in Schedule 5 in accordance with the instructions provided in Schedule 5.

Item	Minimum Content and Format Requirements
4	The Tenderer must include an Indigenous Participation Plan in its Proposal.
5	The Proposal must include either: (a) a Valid and Satisfactory Statement of Tax Record for the Tenderer; or (b) a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office for the Tenderer and the Tenderer then provides a Valid and Satisfactory Statement of Tax Record within 4 business days from the Closing Time.

Unintentional Errors of Form

13.2 Without limiting the Department's other rights in this RFP, the Department may allow the Tenderer to correct any error of form in a Proposal that appears to be unintentional, by lodging a correction or additional information, in writing in accordance with the direction of the Department, but will not permit any material alteration or addition to the Proposal.

13.3 If the Department provides any Tenderer with the opportunity to correct errors of form, it will provide the same opportunity to all other Tenderers that are in the same position.

14. ESSENTIAL REQUIREMENTS

14.1 If the Department considers that a Tenderer does not satisfy all of the following Essential Requirements, that Proposal will be excluded from further consideration under this RFP:

Item	Essential Requirements
1	Storage and transportation facilities proposed and supplied meet all Therapeutic Goods Administration registration and / or regulatory requirements as well as hold applicable state and territory warehousing / wholesaling licences.
2	Storage and transportation facilities are GMP certified and/or meet the Australian Code of Good Wholesaling Practices or can be upon the commencement of the contract.
3	Work with the Australian Cyber Security Centre (ACSC) and become an ACSC partner through the Partnership Program upon commencement of the contract.

14.2 Notwithstanding the use of the words “must”, "shall", "minimum", "required to" or similar language or anything to the contrary in Statement of Requirement or elsewhere in this RFP, there are no other Essential Requirements for this RFP besides those set out in the table above (if any).

15. FORMAT OF PROPOSALS

15.1 Proposals should be completed in accordance with Schedule 3, noting the following:

a. all applicable information should be provided in response to the information requirements set out in Schedule 3;

b. where a response to a particular requirement is covered in another section of the Proposal, a cross reference to that section should be provided; and
c. Tenderers may include additional or supporting materials (as supplements or attachments to the Proposal Response Information) noting that Tenderers are discouraged from including generic marketing information that does not relate to the information requested in this RFP and/or does not address the Evaluation Criteria.

15.2 Tenderers should also complete the statement of non-compliance in accordance with Schedule 4 in relation to:

a. any of the provisions of the Draft Contract with which the Tenderer is partially compliant or non-compliant; or
b. any claim of confidentiality in relation to any aspects of their Proposal.

16. PRICING

16.1 Tenderers should provide full details of their proposed price structure in Schedule 5. This document should be included in a separate electronic file when the Proposal is lodged and no pricing should be included in any other part of the Proposal.

16.2 Tendered prices should include all charges necessary and incidental to the proper delivery of the Services.

16.3 Prices should be fixed for the duration of the Contract unless otherwise indicated by the Department in this RFP.

16.4 Prices should be in Australian dollars (inclusive of GST).

17. WORKPLACE GENDER EQUALITY

17.1 Commonwealth policy prevents the Department from entering into contracts with Tenderers who are non-compliant under the *Workplace Gender Equality Act 2012* (Cth) (the **WGE Act**).

17.2 The Draft Contract requires that, in performing any contract, a successful Tenderer must:

a. comply with its obligations, if any, under the WGE Act; and
b. if the term of any resultant Contract exceeds 18 months, the successful Tenderer must provide a current letter of compliance within 18 months from the Contract Commencement Date and following this, annually to the Department's Contract contact officer.

17.3 Tenderers should note that if during the term of any resultant Contract, the successful Tenderer becomes non-compliant with the WGE Act, the successful Tenderer must notify the Department's Contract contact officer.

17.4 For further information about coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

17.5 Tenderer's must indicate as part of the Tenderer Deed at Schedule 2 whether or not the Tenderer's organisation is a 'relevant employer' under the WGE Act and, if

applicable, provide a current letter of compliance as part of their Proposal, or prior to entering into any resultant Contract (if successful).

18. ILLEGAL WORKERS

18.1 It is Commonwealth policy not to contract with providers engaging Illegal Workers.

18.2 The Tenderer's Deed in Schedule 2 contains a statement from the Tenderer confirming that it meets this obligation.

19. INDIGENOUS PROCUREMENT POLICY

19.1 It is Commonwealth policy to stimulate Indigenous entrepreneurship and business development, providing Indigenous Australians with more opportunities to participate in the economy (see Indigenous Procurement Policy for further information).

19.2 If any resultant Contract is a High Value Contract, the mandatory minimum requirements for Indigenous participation will apply.

19.3 If a component of any resultant Contract will be delivered in a Remote Area, this creates an opportunity for that resultant Contract to deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

19.4 In its Indigenous Participation Plan, the Tenderer should detail how it will ensure that its provision of the Services will deliver a significant Indigenous employment or supplier use outcomes in the Remote Area.

[Note to Tenderers: Refer to section 4.4.1 of the Indigenous Procurement Policy for examples of options available to ensure any resultant Contract will deliver significant Indigenous employment or supplier use outcomes in the Remote Area.]

20. MODERN SLAVERY ACT 2018 (CTH)

20.1 Tenderers should note that any resultant Contract will require the successful Tenderer to provide all assistance reasonably requested by the Department to comply with its obligations under the *Modern Slavery Act 2018* (Cth).

PART 3 – EVALUATION OF PROPOSALS

21. EVALUATION CRITERIA

21.1 The Department will use the following Evaluation Criteria in the evaluation of Proposals:

Category	Considerations	Weighting
Vaccine end-to-end delivery	a. The extent to which the Tenderer's **existing and proposed infrastructure and distribution network meets the requirements** in Schedule 1. [Including consideration of both geographical coverage across jurisdictions and from metropolitan to very remote areas; and the capabilities of the provider to enhance or pivot the existing network] b. Whether the Tenderer has a fit-for-purpose plan for **receiving, managing and responding to demand signals/orders** c. Whether the Tenderer can **manage key handover points** such as acceptance of vaccines at port of entry / receipt, between supply chain nodes, and at point of administration d. The robustness of the proposed **quality assurance and quality control processes** that the Tenderer will implement to maintain cold chain and minimise the risk of breaches occurring e. The robustness of the Tenderer's plan to ensure **physical security of vaccines** throughout the distribution network, including precautions against wastage, counterfeiting and theft	40%
Collaboration and flexibility	f. How conducive the Tenderer's **proposed interaction model** is to working with the Commonwealth to ensuring successful co-design and delivery g. The strength of the **proposed co-design team's experience and skills** relevant to delivering the solution h. Whether the Tenderer's plan for **flexible and adaptive delivery** is fit-for-purpose, particularly considering ability to scale capacity up or down as needed	20%
Data tracking and cybersecurity	i. Whether the Tenderer has clearly outlined mechanisms for **tracking and monitoring** (including temperature) goods throughout their distribution network j. Whether the **metrics** that the Tenderer will monitor throughout vaccine delivery are appropriate, including their proposal for regular reporting	5%

Category	Considerations	Weighting
	k. The extent to which the Tenderer has indicated what controls are in place to protect **confidentiality, integrity and availability of data** l. Whether the Tenderer's approach to meeting **information security requirements** is fit-for-purpose, including mitigating against cybersecurity threats and a robust **business continuity and response plan**	
Timeline and execution readiness	m. The extent to which the Tenderer's proposal provides a **feasible path to readiness** of the distribution network within required timelines	15%
Past experience	n. The extent to which the Tenderer's **past performance** providing similar services demonstrates its ability to provide the Services.	20%
Pricing	o. The **assessed value to the Commonwealth** of the tenderer prices (in Schedule 5 (Pricing Schedule)).	Not weighted
Risk	p. **Compliance** with Statement of Requirement and the Draft Contract; q. **Financial viability** of the Tenderer; and r. **Any other risks** identified in the evaluation process that have not been considered as part of another Evaluation Criterion.	Not weighted
Economic Benefit	s. Paragraphs 4.7 and 4.8 of the CPRs requires the Department to consider the **economic benefit to the Australian economy** for procurements estimated to be above $4 million for non-construction goods and services and above $7.5 million for construction services.	Not weighted
Indigenous participation	t. The Tenderer's past performance and/or demonstrated commitment in relation to **increasing Indigenous participation**, including, where relevant, by having regard to the Tenderer's past compliance with any mandatory minimum requirements; and u. The extent to which the Tenderer's **proposed Indigenous Participation Plan** will meet the mandatory minimum requirements.	Not weighted

21.2 The Department may:

a. consider any part of a Proposal in the evaluation of any or all of the Evaluation Criteria; and

b. use material provided in response to one Evaluation Criterion in its evaluation of other Evaluation Criteria.

22. EXCLUSION OF PROPOSALS

22.1 Without limiting any other provision of this RFP that gives the Department the right to exclude Proposals on other grounds, the Department may at any time exclude a Proposal from further consideration if:

a. the Proposal is incomplete or contains insufficient information to allow evaluation of the Proposal;
b. prices are not clearly and legibly stated;
c. the Tenderer or Proposal does not comply with this RFP;
d. the Tenderer is not fully capable of undertaking a contract in the form of the Draft Contract;
e. the Proposal is clearly uncompetitive when compared with the other proposals received;
f. the Proposal is rated unsuitable or unsatisfactory against one or more of the Evaluation Criteria;
g. the Proposal contains statements that qualify or are contrary to the Tenderer Deed at Schedule 2 to this RFP:
h. in the Department's opinion the Proposal contains a false declaration;
i. the Proposal contains false or misleading information or statements;
j. the Tenderer, or a director or officer of the Tenderer, is insolvent or bankrupt;
k. the Tenderer has an actual, potential or perceived conflict of interest that cannot be managed to the satisfaction of the Department acting in its absolute discretion; or
l. there has been a significant deficiency in the performance of a substantive requirement or obligation under a prior agreement.

23. PROPOSAL EVALUATION PROCESS

23.1 Proposals will be evaluated against the Evaluation Criteria to determine the Proposal that represents the best overall value for money on a whole-of-life basis.

23.2 As part of its evaluation of Proposals, the Department may, in its sole and absolute discretion:

a. ask Tenderers to undertake presentations;
b. shortlist one or more Tenderers at any time;
c. ask Tenderers to provide written clarification of various aspects of their Proposals;
d. ask Tenderers to provide further information to confirm their financial viability and commercial stability;
e. have discussions or interviews with Tenderers in order to seek further clarification of their Proposals;
f. visit Tenderers' sites; and
g. have discussions with or undertake visits to customers of Tenderers and their Subcontractors, whether or not those customers are listed as referees in the Tenderers' Proposals.

23.3 The Department may choose to undertake the activities set out in clause 23.2 in relation to some Tenderers only. Presentations, interviews and site visits may be

subject to additional terms and conditions that are advised by the Department to Tenderers who have been invited to participate in each activity.

23.4 Any costs incurred by the Tenderer in complying with this clause 23 will be borne by the Tenderer.

24. CLARIFICATION

24.1 Where the meaning of a Proposal is unclear or there is an apparent error of form, the Department may seek clarification from the Tenderer.

24.2 Any clarification provided by a Tenderer in response to a request for clarification is not to contain any new material additional to that included in the Proposal unless specifically requested by the Department. Failure to supply clarification to the satisfaction of the Department may cause the Proposal to be excluded from consideration.

25. PROPOSAL PRICES

25.1 The Tenderer agrees to provide access to such information as is determined by the Department to be necessary in order to evaluate the reasonableness of their Tendered prices.

25.2 In the evaluation process, the Department may make certain adjustments to the Tendered price, including adjustments to account for the following matters, which may need balancing in order to establish a common basis for the comparison of Proposals, including (without limitation):

a. Proposal prices as per the completed Schedule 5;
b. pricing flexibility;
c. any other costs or discounts which form part of the Tenderer's offer;
d. normalised and discounted cash flow;
e. any alternative proposals or financial incentives offered by the Tenderer;
f. implementation costs;
g. any risk relating to the Tendered prices;
h. transition out costs;
i. cost of administering the resultant Contract; and
j. whole of life costs and benefits.

26. NEGOTIATIONS

26.1 Negotiations may be undertaken with one or more Tenderers (including in relation to prices, terms and conditions of the Draft Contract or any other matters).

26.2 During the negotiation phase of this RFP process, the Department may engage in detailed discussions and negotiations, including parallel negotiations, with the goal of maximising the benefits of the project, as measured using the Evaluation Criteria. As part of this process, those Tenderers participating in the negotiation phase may be asked to improve any or all aspects of their Proposal. The

Department's intention is that it will select a preferred Tenderer after all material issues have been resolved.

26.3 The Department may seek best and final offers from Tenderers participating in the negotiation phase of this RFP process.

26.4 Without limiting its other rights under this RFP, in the event that the Department concludes that during negotiations a Tenderer has retracted, or attempts to retract, any part of its tendered offer, the Department reserves the right to:

a. exclude that Tenderer's Proposal from further consideration;
b. terminate this RFP process;
c. re-enter negotiations or parallel negotiations with other Tenderers; or
d. exercise any other right reserved to the Department under law or elsewhere in this RFP.

27. DEBRIEFING

27.1 After the award of any resultant Contract, the Department will notify all unsuccessful Tenderers of the outcome of the RFP process.

27.2 All Tenderers will be offered the opportunity for a debriefing on their Proposal.

27.3 Tenderers will be debriefed against the Evaluation Criteria contained in this RFP. Tenderers will not be provided with information concerning other Proposals.

28. COMPLAINTS PROCEDURE

28.1 Complaints in relation to this RFP process should be made in writing and directed to the Complaints Officer at procurement.advice@health.gov.au. The Complaints Officer is able to receive complaints under the *Government Procurement (Judicial Review) Act 2018* (Cth).

28.2 Complaints will be handled by the Department in accordance with the Department's Procurement Complaints Procedures which are available at About Us

PART 4 – CONDITIONS OF TENDERING

29. OWNERSHIP AND USE OF PROPOSAL DOCUMENTS

29.1 All Proposal documents (including paper and electronic copies) become the property of the Department on submission.

29.2 Without prejudice to anything agreed in any resultant Contract, clause 27.1 does not affect any intellectual property rights that may exist in a Proposal.

29.3 Without prejudice to any other right of the Department under this RFP or at law, the Department may copy, amend, disclose or allow the disclosure of, or otherwise deal with, a Proposal or any information contained in or relating to any Proposal (at any time) for any of the following purposes:

a. the RFP process, evaluating and clarifying Proposals;
b. negotiation of the resultant Contract with the Tenderer or any other Tenderer;
c. managing any resultant agreement with the Tenderer or any other Tenderer;
d. addressing any dispute concerning the RFP process;
e. audit, governmental and Parliamentary reporting requirements; and
f. responding to any disputes about this RFP process or requests from Parliament or a Parliamentary Committee.

29.4 The Department may make copies of the Proposal as necessary for its purposes.

30. INTELLECTUAL PROPERTY RIGHTS IN RFP

30.1 All intellectual property that exists in the information contained in this RFP, or any related or attached material, remains the property of the Department.

30.2 Each Tenderer is permitted to use this RFP for the purpose only of compiling its Proposal and, in the case of the Tenderer(s) selected through this RFP process, for negotiating the resultant Contract with the Department.

31. SMALL TO MEDIUM ENTERPRISES (SMES)

31.1 The Australian Government is committed to *Public Governance, Performance and Accountability Act 2013* (Cth) non-corporate Commonwealth entities sourcing at least 10 per cent of their purchases by value from SMEs. For the purpose of this

clause an SME is an Australian or New Zealand firm with fewer than 200 full-time equivalent employees.

31.2 Tenderers are encouraged to include the participation of SMEs in their Proposals.

32. AUDIT AND ACCESS

32.1 The attention of Tenderers is drawn to the *Auditor-General Act 1997* (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.

32.2 In addition to the Auditor-General's powers under the *Auditor-General Act 1997* (Cth), if a Tenderer is chosen to enter into a resultant Contract, the Tenderer will be required to provide the Auditor-General or an authorised person with access to information, documents, records and Department assets, including those on the Tenderer's premises. This will be required at reasonable times on giving reasonable notice for the purpose of carrying out the Auditor-General's functions and will be restricted to information and assets which are in the custody or control of the Tenderer, its employees, agents or Subcontractors, and which are related to the resultant Contract. Such access will apply for the term of the Contract and for a period of 7 years from the date of expiration or termination of the Contract.

32.3 Tenderers should obtain, and will be deemed to have obtained, their own advice on the impact of the *Auditor-General Act 1997* (Cth) on their participation in the Proposal.

33. FREEDOM OF INFORMATION AND OTHER RIGHTS TO ACCESS INFORMATION

33.1 The attention of Tenderers is drawn to the *Freedom of Information Act 1982* (Cth), which gives members of the public right of access to documents in the possession of the Commonwealth and its agencies.

33.2 The Act extends as far as possible the right of the community to access information (generally documents) in the possession of the Commonwealth, limited only by exceptions and exemptions necessary for the protection of essential public interests and the private and business affairs of persons in respect of whom information is collected and held by departments and public authorities.

33.3 Rights of access also exist under other legislation, including the *Ombudsman Act 1976* (Cth). Courts also have legal rights to access a wide range of information.

33.4 Tenderers should also be aware of the *Australian Information Commissioner Act 2010* (Cth), which established the Office of the Australian Information

Commissioner to perform freedom of information, privacy and information policy functions.

34. PRIVACY

34.1 Tenderers are advised that it is Commonwealth policy to ensure that there is no loss of privacy protection when a Commonwealth entity contracts for the delivery of services.

34.2 Without limiting any obligations under the *Privacy Act 1988* (Cth), successful Tenderer(s) will be required under the Contract to agree not do an act, or engage in a practice, that would breach an Australian Privacy Principle under the *Privacy Act 1988* (Cth) if done or engaged in by a Commonwealth entity to which the Australian Privacy Principles apply. Tenderers selected as a result of this RFP process will also need to agree to impose those same obligations on any Subcontractor engaged by the Tenderer.

35. CONFIDENTIALITY

35.1 The Department will, subject to this RFP, including clauses 33.2 and 33.3, endeavour to treat the following information as confidential:

a. all Proposals received prior to the award of a resultant Contract;
b. all unsuccessful Proposals, following the award of a resultant Contract;
c. all successful Proposals, following the award of a resultant Contract but only to the extent that:
   i. the successful Tenderer requests that specific information in their Proposal be kept confidential; and
   ii. the Department has determined that specific information is to be kept confidential in accordance with the Confidentiality Throughout the Procurement Cycle from the Department of Finance and has agreed, pursuant to the resultant Contract with the successful Tenderer, to keep that information confidential.

35.2 The Department will not be taken to have breached any obligation to keep information provided by Tenderers confidential to the extent that the information:

a. is disclosed by the Department to its advisers, officers, employees or subcontractors solely in order to conduct this RFP process or to prepare and manage any resultant Contract;
b. is disclosed to the Department's internal management personnel, solely to enable effective management or auditing of this RFP process;
c. is disclosed by the Department to the responsible Minister;
d. is disclosed by the Department in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
e. is shared by the Department within the Department's organisation, or with another Commonwealth entity, where this serves the Commonwealth's legitimate interests;
f. is authorised or required by law to be disclosed;
g. is disclosed as agreed by the Tenderer;
h. is disclosed to meet the Department's reporting or accountability requirements, including, without limitation:
   i. under the Public Governance, Performance and Accountability Act 2013 (Cth) or other legislation;

ii. to the Australian National Audit Office or any other auditor appointed by the Department;
iii. in accordance with the provisions that require notification of Commonwealth contracts on the AusTender website;
iv. to the Commonwealth Ombudsman; or
v. is in the public domain otherwise than due to a breach of the relevant obligations of confidentiality.

35.3 Tenderers should be aware that the Department, as a non-corporate Commonwealth entity, is subject to specific accountability requirements, which support internal and external scrutiny of its tendering and contracting processes. These include:

a. the policy of the Commonwealth to publish details of relevant entity agreements, contracts and standing offers with an estimated value of $10,000 or more on the AusTender website;
b. the requirement to report details of Commonwealth contracts valued at $100,000 or more in accordance with the *Senate Order on Departmental and Agency Contracts*, including:
   i. name of the service provider and the subject matter of the Contract;
   ii. total value of the Contract; and
   iii. whether the Contract contains clauses that are confidential, and if so, the reasons for confidentiality;
c. the requirement to publish information about certain procurements in Annual Reports; and
d. the requirement to make available, on request, the names of any subcontractors engaged to perform services in relation to a Commonwealth contract (as such, Tenderers should inform all potential Subcontractors that their participation in fulfilling a Commonwealth contract may be publicly disclosed).

36. ENVIRONMENTAL POLICY AND PROCUREMENT

36.1 The Commonwealth aims to improve the implementation of ecologically sustainable development (**ESD**) within its agencies.

36.2 In support of this aim, the Department is committed to fostering the sustainable use of the Earth's resources and will implement and maintain an environmental management system to ISO14001, with the following key areas:

a. compliance with all relevant environmental legislation, regulations, policies and other initiatives to which it subscribes;
b. integrating environmental management into business decision making at all levels;
c. reducing cost through better resource usage and waste management;
d. setting objectives and targets for continuous improvement;
e. monitoring, reporting and reviewing achievements;
f. exploring best practice and innovative environmental management approaches to the use of technology, property and related resources; and
g. building an environmentally aware business culture.

36.3 The Department's procurement activities are a key means of implementing its environmental policy.

37. MATERIAL CHANGE TO TENDERER

37.1 A Tenderer must notify the Department if, following lodgement of its Proposal, there occurs:

a. an event that has the effect of materially altering either the composition or control of the Tenderer or the business of the Tenderer; or
b. any material change to the compliance status of the Tenderer against this RFP; or
c. any material change to the proposed basis on which the Tenderer will deliver the Services, or have access to the necessary and appropriate skills, resources, nominated key personnel, nominated Subcontractors or corporate or financial backing to provide the Services, on the terms of the Draft Contract.

37.2 If the Department receives notice, or becomes aware of an event under clause 37.1a, the Department may allow (on terms it considers appropriate) the substitution of the Tenderer with another legal entity upon receipt of a joint written request from or on behalf of the Tenderer and the other legal entity. If the Department allows the substitution, it will evaluate the Proposal in its original form prior to the event, except that the impact of the event on the information provided in the Proposal may be taken into account.

37.3 If the Department receives notice, or becomes aware of an event under clause 37.1b or 37.1c, or the Commonwealth does not allow substitution, or substitution is not requested, under clause 37.1a, the Department may either exclude the Proposal from consideration or consider the Proposal taking into account the impact of the changed circumstances on the information provided in the Proposal.

38. CONFLICT OF INTEREST

38.1 Tenderers should represent and declare in the Tenderer Deed any conflict of interest that exists at the time of lodging their Proposal.

38.2 If at any time prior to entering into a resultant Contract for the Services, an actual or potential conflict of interest arises or may arise for any Tenderer, other than that already disclosed, that Tenderer should immediately notify the Department in writing.

38.3 If any actual or potential conflict is notified, or the Department becomes aware of any actual or potential conflict, the Department may:

a. disregard the Proposal submitted by such a Tenderer;
b. enter into discussions to seek to resolve such conflict of interest; or
c. take any other action it considers appropriate.

39. TENDERER BEHAVIOUR

39.1 Tenderers must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of Proposals:

a. Engage in misleading or deceptive conduct or make any false or misleading or deceptive claim or statement;
b. improperly obtain Confidential Information;
c. receive improper assistance from any existing or former officer or employee of the Department;
d. engage in collusive tendering, anti-competitive conduct, unlawful, unethical or other similar conduct with any other Tenderer or other person;
e. attempt to improperly influence an officer or employee of the Department or violate any applicable laws regarding the offering of inducements; or
f. approach any officer or employee of the Department other than in the manner set out in this RFP;
g. engage in, procure or engage others to engage in, any activity that would result in a breach of the Lobbying Code of Conduct 2013 published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
h. otherwise act in an unethical or improper manner or contrary to any law.

39.2 The Department may exclude a Proposal from consideration if the Tenderer fails to comply with the requirements set out in this clause 39.

40. COST OF PREPARING AND SUBMITTING PROPOSAL

40.1 To the extent permitted by law, participation in this RFP process is at the Tenderer's sole risk, cost and expense, and in no circumstances will the Department be responsible for any costs incurred by a Tenderer in preparing a Proposal, or associated expenses related to this RFP.

41. TENDERERS TO INFORM THEMSELVES

41.1 Tenderers are deemed to have:

a. examined this RFP, and any other documents referenced or referred to in this RFP, and any other information made available in writing by the Department to Tenderers for the purposes of submitting a Proposal;
b. examined all other information which is obtainable by the making of reasonable and timely inquiries and relevant to the risks, contingencies and other circumstances having an effect on their Proposal;
c. satisfied themselves as to the correctness and sufficiency of their Proposal, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
d. satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at Schedule 4;
e. obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFP process;

f. made their own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments; and
g. examined AusTender, including the AusTender Terms of Use.

41.2 It is the responsibility of Tenderers to obtain all information necessary or convenient for the preparation of their Proposal.

41.3 Tenderers must not rely, and are deemed not to have relied, upon any statement or representation by the Department, whether before or after the date of this RFP, in connection with this RFP or this RFP process, unless that statement or representation is made in writing by the Contact Officer for this RFP.

41.4 Tenderers should obtain their own legal and other professional advice on this RFP and its requirements including in respect of the potential rights and obligations in respect of the Draft Contract and should not construe this RFP as investment, legal, tax or other advice.

42. NO CONTRACT OR UNDERTAKING

42.1 Nothing in this RFP or in any Proposal or by the submission of a Proposal (in part or together) creates, or is to be construed to create, any binding contract or other understanding (including any form of contractual, quasi-contractual, restitutionary rights or other legal relationship (express or implied) between the Department and any Tenderer unless and until a resultant Contract (if any) is signed by the Department and a successful Tenderer.

42.2 Clause 42.1 does not apply to a Tenderer Deed executed by a Tenderer.

43. ACCEPTANCE

43.1 Selection of the preferred Proposal will be subject to the execution of a Contract between the Commonwealth and the successful Tenderer substantially in the form of the Draft Contract at Schedule 7.

43.2 Neither the lowest priced Proposal, nor any Proposal, will necessarily be accepted by the Department.

44. THE DEPARTMENT'S RIGHTS

44.1 The Department reserves the right to:

a. vary the timing and processes, if any, referred to in this RFP;
b. change or suspend the RFP process;
c. amend or vary this RFP or the RFP process, including the Draft Contract;
d. allow any Tenderer to change its Proposal at any time;
e. shortlist Proposals;
f. terminate the RFP process where it is, in the opinion of the Department, in the public interest to do so;
g. exclude any Proposal from consideration where in the opinion of the Department:
   i. it is in the public interest to do so;

ii. the Tenderer does not meet a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
iii. the Tenderer is not fully capable of undertaking the Contract substantially in the form of the Draft Contract;
iv. this RFP otherwise allows for the exclusion of the Tenderer; or
v. the Proposal does not represent value for money;

h. enter into a contract or other binding relationship outside the RFP process with a person on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
i. it is in the public interest to do so;
ii. no Tenderer meets a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
iii. no Tenderer is fully capable of undertaking the Contract substantially in the form of the Draft Contract; or
iv. no Proposal represents value for money;

i. enter into a contract on terms different to that specified in this RFP;

j. add a Tenderer or select and negotiate with a third party who has not submitted a Proposal on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
i. it is in the public interest to do so;
ii. no Tenderer meets a mandatory requirement;
iii. no Tenderer is fully capable of undertaking the Contract; or
iv. no Proposal represents value for money;

k. call for new Proposals;

l. publish or disclose the names of Tenderers (whether successful or unsuccessful);

m. allow or not allow a Related Body Corporate to take over a Proposal in substitution for the original Tenderer;

n. enter into negotiations with any Tenderer; or

o. cancel, add to or amend the information, requirement, terms, procedures or processes set out in this RFP.

44.2 To the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFP process, including instances where:

a. a Tenderer is not engaged to undertake the provision of the Services;

b. the Department decides not to enter into any resulting Contract with any Tenderer or at all;

c. the Department exercises or fails to exercise any of its other rights under or in relation to this RFP (whether or not the Department has informed a Tenderer of its exercise of the rights);

d. a Proposal or any other material or communication relevant to this RFP is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or

e. the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements.

44.3 If the Department does vary this RFP or process, the Department will endeavour to inform any prospective Tenderers who have sought, or been issued with, this RFP of that change. A notice of the issue of an addendum will be published in the

same manner as the original information about this RFP, including by notification on the AusTender website. Tenderers should regularly check the AusTender website for any updates or addenda to this RFP.

44.4 If clause 6.1 provides that this RFP process is a 'covered procurement', the Department will issue an addendum notifying Tenderers of any suspension of the RFP process.

44.5 To the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFP or any other matter arising by the Department exercising any of its rights.

45. COORDINATED PROCUREMENT

45.1 The Commonwealth has agreed to establish a coordinated procurement contracting framework to deliver efficiencies and savings from goods and services in common use by non-corporate Commonwealth entities who are subject to the *Public Governance, Performance and Accountability Act 2013* (Cth) or other legislation.

45.2 It is therefore possible that the Commonwealth may approve the procurement by the Department of some or all of the same goods or services as the Services under a coordinated process:

a. before the Closing Time; or
b. after the Closing Time but before any resultant Contract is signed with the successful Tenderer(s); or
c. during the period of any resultant Contract entered into as a result of this RFP.

45.3 If clause 45.2a applies, the Department reserves the right to discontinue this RFP process.

45.4 If clause 45.2b applies, the Department reserves the right to discontinue the Proposal process and not proceed to enter any contract as a result of this RFP.

45.5 If clause 45.2c applies, the Department may exercise its rights under any resultant Contract to terminate for convenience, without compensation for loss of potential profits.

46. COOPERATIVE PROCUREMENT (PIGGYBACKING)

Not used.

47. INTERPRETATION

47.1 If any part of this RFP conflicts with another part, the part higher in the following list will take precedence:

a. Part 1 – Overview, Background, Services Specifications and Proposal Lodgement, Part 2 – Information to be provided by Tenderers, Part 3 – Evaluation of Proposals and Part 4 – Conditions of Tendering;
b. Part 5 - Glossary;
c. SCHEDULE 7 – Draft Contract;

d. SCHEDULE 1 – Statement of Requirement;
e. SCHEDULE 2 – Tenderer Declarations, SCHEDULE 3 - Tenderer Response Information, SCHEDULE 4 – Statement of Non-Compliance, SCHEDULE 5 – Pricing Schedule and SCHEDULE 6 – Indigenous Participation Plan Template Response Form; and
f. any other document forming part of this RFP.

47.2 In this RFP, except where the contrary intention is expressed:

a. a reference to time, unless specified otherwise, is to the time in the Australian Capital Territory;
b. words importing a gender include each other gender;
c. words in the singular include the plural and vice versa;
d. a reference to A$, $A, dollar or $ is to Australian currency;
e. if any word or phrase is given a defined meaning, any other part of speech or other grammatical form of that word or phrase has a corresponding meaning;
f. a reference to a clause, paragraph, schedule or annexure is to a clause, paragraph, schedule or annexure to this RFP;
g. a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority, agency or other entity;
h. a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
i. the meaning of general words is not limited by specific examples introduced by including, ‘for example’ or similar expressions and the word ‘include’ is not a word of limitation; and
j. the term 'may' when used in the context of a right exercisable by the Department means that the Department may exercise that right in its sole and absolute discretion and the Department has no obligation to any Tenderer.

PART 5 - GLOSSARY

Term	Definition
ACT	Australian Capital Territory
AusTender	means the Australian Government online tendering system, located on the AusTender website
AusTender Terms of Use	means the terms of use for AusTender available at https://www.tenders.gov.au/?event=public.termsOfUse.
Black Economy Procurement Connected Policy	means the *Black economy – increasing the integrity of government procurement*: *Procurement connected policy guidelines March 2019* available at https://treasury.gov.au/publication/p2019-t369466.
Commonwealth	Commonwealth of Australia
Contract	means a contract substantially in the form of the Draft Contract provided with this RFP, to be executed by the Department and the Contractor, as amended from time to time, and includes its schedules, annexures and attachments.
Closing Time	means the closing time and date of this RFP as specified at clause 9.1 of this RFP
Conditions for Participation	means the mandatory conditions (if any) identified in clause 12 of this RFP
Confidential Information	means information (whether or not owned by the Commonwealth) that: (a) is by its nature confidential; or (b) the receiving party knows or ought to know is confidential, but does not include information which: (c) is or becomes public knowledge other than by breach of contract or any other obligation of confidentiality; (d) is in the possession of a party without restriction in relation to disclosure before the date of receipt; or (e) has been independently developed or acquired by the receiving party
Contact Officer	means the contact person for all matters pertaining to this RFP process, as identified at clause 5 of this RFP
Department	means the Department of Health
Draft Contract	means the document attached as Schedule 7 to this RFP being the proposed Contract to be entered into between the Department and the successful Tenderer(s)
Essential Requirements	means the mandatory conditions (if any) identified at clause 14, and which a Tenderer must comply
Evaluation Criteria	means the criteria set out in clause 21 of this RFP that will be used to evaluate the Proposals received.
High Value Contract	means a contract where: (a) the Services will be delivered in Australia; (b) the value of the Services is $7.5 million (GST inclusive) or more; and (c) more than half the value of the contract is being spent in one or more of the following industry sectors: (i) building, construction and maintenance services;

Term	Definition
	(ii) transportation, storage and mail services; (iii) education and training services; (iv) industrial cleaning services; (v) farming and fishing and forestry and wildlife contracting services; (vi) editorial and design and graphic and fine art services; (vii) travel and food and lodging and entertainment services; or (viii) politics and civic affairs services.
Illegal Worker	means a person who: (a) has unlawfully entered and remains in Australia; (b) has lawfully entered Australia, but remains in Australia after his or her visa has expired; or (c) is working in breach of his or her visa conditions.
Indigenous Enterprise	means an organisation that is 50 per cent or more Indigenous owned that is operating a business.
Indigenous Participation Plan	means a plan detailing how the Tenderer will meet the minimum mandatory requirements for the Indigenous Procurement Policy (see template at SCHEDULE 6– INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM – Indigenous Participation Plan Template Response Form).
Indigenous Procurement Policy	means the policy of that name, as amended from time to time, available on the Indigenous Procurement Website.
Indigenous Procurement Website	means the website at **www.dpmc.gov.au/ipp**.
Late Proposal	means any Proposal not received by Closing Time
Minimum Content and Format Requirements	means the mandatory content and format requirements identified in clause 13 of this RFP
Related Body Corporate	has the meaning given in section 9 of the *Corporations Act 2001* (Cth)
Remote Area	means the areas identified in the map on the Indigenous Procurement Website, as updated from time to time.
RFP	means this Request for Proposal
Satisfactory	means meets the conditions set out in Part 6.b of the Black Economy Procurement Connected Policy or, if the circumstances in Part 6.c of the Black Economy Procurement Connected Policy apply, the conditions set out in Part 8.b of the Black Economy Procurement Connected Policy.
Schedules	means all or any of the schedules to this RFP
Services	means the Services described in the Statement of Requirement and clause 3 of this RFP
Statement of Requirement	means the description of the Services as set out in Schedule 1 of this RFP

Term	Definition
Statement of Tax Record	means a statement of tax record issued by the Australian Taxation Office following an application made in accordance with the process set out at https://www.ato.gov.au/Business/Bus/Statement-of-tax-record/?page=1#Requesting_an_STR.
Subcontractors	means an entity that the Tenderer proposes to enter into a contract with to provide goods or services to the successful Tenderer(s) in relation to the Services or in order for the Tenderer to meet obligations under the resultant Contract
Proposal	means a response submitted by a Tenderer to this RFP
Tenderer	means an entity that submits a Proposal, and includes a potential Tenderer.
Tenderer Deed	means the deed to be completed and submitted by Tenderers as part of their Proposal, as set out in SCHEDULE 2 – Tenderer Declarations of this RFP
Valid	means valid in accordance with Part 7.e of the Black Economy Procurement Connected Policy.

SCHEDULES

SCHEDULE 1 STATEMENT OF REQUIREMENT

1. Objectives of the Services

The Department of Health aims to ensure the delivery of safe and effective COVID-19 vaccines to all Australians, as soon as they are available.

The Australian Government is building a diverse portfolio of investments to secure early access to promising vaccines. To date, the Australian Government has entered into advance purchasing agreements with a number of manufactures to access doses of their vaccine should they be found to be safe and effective. This includes agreements with:

- AstraZeneca for the supply of 33.8 million doses of the Oxford vaccine;
- CSL for the supply of 51 million doses of the University of Queensland vaccine;
- Pfizer for up to 10 million doses of its mRNA vaccine; and
- Novovax for up to 40 million doses of its vaccine.

The Australian Government has also joined the Gavi COVAX facility to purchased up to 25.5 million doses of safe and effective vaccines from a diverse global portfolio of vaccine candidates.

Pending the success of vaccine candidates it is expected that the first doses will be available in January 2021, with doses delivered in batches throughout 2021 and 2022.

The Department is seeking proposals by a potential partner (or partners) to co-design and deliver logistics and distribution services for the roll-out of a potential COVID-19 vaccine or vaccines for Australia from point of vaccine acceptance from manufacturers, to sites of vaccine administration (administration sites). The successful Tenderer will also be responsible for the receipt, storage, transport, distribution and management of ancillary vaccination supplies including, but not limited to, needles, syringes, personal protective equipment and other consumables such as saline and adrenaline, as required.

In the rapidly evolving context of the COVID-19 pandemic and its public health response, a number of uncertainties limit the ability of the Department to fully pre-specify the necessary distribution network (including uncertainty on which vaccine candidate(s) will prove successful in obtaining regulatory approval). Furthermore, the Department recognises the role of industry expertise in informing the development of the many interdependent design decisions to be made in relation to the distribution of vaccines to administration sites. As such, the Department wishes to select a partner to co-create the distribution and logistics network over the life of the vaccination program. The solution may evolve and change as the pandemic progresses, and as such the chosen partner must be experienced, agile and fully collaborative in their approach.

Working collaboratively with the Department of Health, the successful supplier(s) would be expected to take lead responsibility for the design, establishment and operation of a logistics and distribution network to support the delivery of future COVID-19 vaccine(s) to all Australians, including the delivery of both the vaccine and the ancillary consumables necessary for vaccination service providers to administer the vaccine (injecting equipment, such as needles and syringes, and

personal protective equipment) and supporting products such as saline and adrenaline, as required.

2. Description of Services

2.1 Requirements by vaccine thermostability and rollout phase

The Tenderer will be responsible for the distribution of vaccines and the ancillary consumables Australia-wide, to the relevant vaccine administration sites, under appropriate cold chain requirements consistent with a vaccination distribution plan determined by the Australian Government.

Proposals should articulate the Tenderer's ability to deliver future COVID-19 vaccine(s) under each of three thermostability scenarios (cold chain temperature requirements), across each major phase of roll-out (see Figure A).

Please note that these scenarios and phases are indicative only, based on currently available information, and are subject to change.

Figure 1

	2-8ºC Standard cold-chain requirements	**-20ºC**	**-70ºC**
1. **Phase 1: Priority populations**[1]	In schedule 5, Tenderers are requested to provide an outline of the following capabilities across phases and thermostability requirements: • Current capacity - Baseline - Any seasonal reductions in capacity • Potential future capacity - In a centralised administration model - In a decentralised administration model - Timing of bringing additional capacity online		
2. **Phase 2: General population**[1]			
3. **Phase 3: Catch-up campaigns** (operations targeted to low coverage groups/locations to reach herd immunity)			

[1] Tenderers should be aware that there may be some population groups for which the vaccine isn't indicated. Thus, there may be some exclusions from the general population. The general population may also be separated into sub-phases for receiving the vaccine.

Current information indicates that successful vaccine candidates will likely be presented in multi-dose vials, and administered in a 2-dose regimen (for example, delivered 3 or 4 weeks apart) by intramuscular injection. In addition to the distribution of vaccines, Tenderers will also be expected to distribute the consumables required for administration, including syringes, needles, and sharps disposal containers, adrenaline, saline and personal protective equipment.

The distribution network must be operational by at least the end of January 2021, when the first doses of a COVID-19 vaccine are projected to arrive. Supply is

expected to be initially constrained, with priority populations vaccinated in the first phase, before rollout to the general population of all (or a majority) of Australians. The distribution network should enable vaccination service providers to cover all Australians, including rural, remote and very remote and otherwise hard to reach populations.

2.2 Cross-cutting requirements and service standards

Given the social, economic and public health importance of a COVID-19 vaccination program, and the anticipated constrained supply of vaccines, there will be a low tolerance for vaccine damage, wastage or loss throughout the supply chain. The successful Tenderer(s) will be responsible for meeting the following requirements.

Acceptance

The successful Tenderer(s) must take responsibility for receipt and acceptance of vaccines and consumables on behalf of the Australian Government.

This includes visual inspection of vaccines to ensure they are delivered consistent with the required specifications, undamaged and have been stored correctly. Tenderers may also be required to support Therapeutic Goods Administration (TGA) testing processes through the provision of documentation and samples to the TGA.

Cold chain

Vaccines must be kept at the appropriate temperature throughout storage and distribution to ensure thermostability requirements are met and vaccines remain effective, until point of receipt by vaccine administrators. Temperatures should be tracked and reportable at all times.

It is expected that if a cold chain breach should occur, the successful Tenderer(s) will perform a thorough root cause analysis to prevent future breaches, and cooperate in any and all enquiries by the Department in relation to such breaches.

Inventory management

Vaccines and ancillary products should be available for use at administration sites such that a bottleneck is not created, and inventory should be monitored to ensure agreed service levels can be achieved. Service levels will be agreed during the co-design phase, and may be refined as the vaccination program moves between phases.

Vaccines should be delivered in line with just in time principles to reduce waste and support stock management. Consumables should be delivered to ensure that vaccination is not delayed and that vaccines are not wasted.

The successful Tenderer(s) must ensure availability of sufficient ancillary consumables at administration sites, such that availability and/or safe disposal of consumables does not become a bottleneck to administration. This includes, needles, syringes, sharps disposal containers, personal protective equipment, saline, adrenaline and any other consumables required to support administration.

This may require the supplier to redistribute products between vaccine administration sites, if required, in line with the Australian Government's agreed vaccine administration plan.

Physical security

The successful Tenderer(s) must ensure physical safety and security of vaccines at all times whilst within its distribution network (from point of acceptance to point of administration). This includes undertaking reasonable precautions against counterfeiting and theft of product.

Wastage

The distribution network must endeavour to minimise wastage of vaccine doses via closely monitoring expiry dates, appropriate stock management, minimising cold chain breaches, and minimising damage in transit or storage.

Tenderer(s) must also manage returns, including destruction of medical waste as required and associated protocols required for regulated waste destruction.

Data, tracking and cybersecurity

The successful Tenderer(s) must have the capability to track and report on the location and cold chain compliance of all doses in the distribution network at all times, including monitoring of stock levels of vaccines and consumables across vaccine administration sites. KPIs including delivery in full, on time (DIFOT), breakages or other damage, must be reported directly into relevant tracking systems.

To support data, tracking and cyber security activities the successful tenderer(s) must work with the Australian Cyber Security Centre (ACSC) and become an ACSC partner through the Partnership Program.

Historic data should be accessible to enable tracking of doses, in case of a later quality or security issue that needs to be traced to point of administration and or recipients of relevant doses.

Data should be provided to the Department daily and on demand. Data may be required to be compatible with other Australian Government reporting systems, including state and territory reporting systems. The successful Tenderer(s) will be responsible for maintaining the physical and cyber security of all electronic data systems that relate to the receipt, distribution and storage of vaccines and ancillary consumables. The Tenderer is expected to have suitable strategies in place to mitigate against threats that may compromise vaccine availability or tracing e.g. ransomware, DDOS attacks.

The solution must be fully compliant with GS1 system standards, a set of standards for the unique identification of all trade items, services, logistic units, consignments, assets, documents, relationships, parties and locations at every point in the chain of distribution and administration of vaccines.

The successful tenderer(s) must consider options to support the end to end user journey, including managing consumer demand for services, in consultation with the data solution supplier.

2.3 Collaboration model

Due to the tight time frames required to establish a fit-for-purpose distribution network by mid-January 2021, and the potentially novel nature of the vaccine distribution program, the Department wishes to collaborate with the successful Tenderer(s) on an initial co-design phase.

This initial co-design phase will involve transparent, open and outcomes-focused collaboration between the required parties, with initial co-design to occur in the first three weeks after appointment of the successful Tenderer. During this time, the working relationship between parties will be evaluated, alongside the proposed vaccine distribution program.

The successful Tenderer may also be required to participate in additional co-design projects throughout the duration of the agreement to assist the Department in making changes to the distribution network, inclusive of state and territory requirements, which the successful Tenderer will be required to deliver.

(a) Responsibilities of the Tenderer(s)

The successful Tenderer(s) will be responsible for delivering a fit-for-purpose design in consultation with the Department that can be implemented to receive, store and deliver vaccines and associated consumables to administration sites by the end of January 2021 and delivering updates to that design as required by the Department during the contract period.

(b) Responsibilities of the Department

The Department will be responsible for provision of reasonable access to information as requested by the Tenderer or Tenderers throughout the design process.

The Department will make available a resource to act as single point of contact for the successful Tenderer(s) throughout the co-design phase.

The Department will approve the design at the end of the co-design phase.

2.4 Contingencies and flexibility

Due to the evolving nature of the pandemic, the solution must be able to adapt to shifting supply and demand dynamics, including pivoting to deploy extra doses to areas of need, within a reasonably agreed timeframe.

In particular, Tenderers should have contingencies prepared for:

1. Where roll-out is required earlier or later than forecast, depending on vaccine availability and/or approvals
2. Where there is an active outbreak in one or more delivery areas: i.e., Tenderers ability to deliver using the proposed approach should there be ongoing community transmission
3. Where multiple vaccine types are available, either launched together or at different times

Tenderers acknowledge that the requirements and obligations detailed in this Schedule 1 are based on projected future requirements, and are subject to variation.

3. Expected deliverables

The outcome of this RFP will be the selection of a delivery partner or partners who will work closely alongside the Department to co-design a detailed distribution program for a future COVID-19 vaccine or vaccines and ancillary consumables, and to build or acquire necessary infrastructure and operate the distribution program.

3.1 Proposed timetable for performance of the Services

Activity	Timing
Commonwealth Execution of Contract	30 November 2020
Commencement of Services	On signing
Initial “Co-design” stage	From Commencement of Services.
Initial “Build” stage	TBD, as design decisions allow. This stage may overlap with “co-design” and “operate” stages.
“Operate” stage	From January 2021 (earliest anticipated commencement of Phase 1 of vaccine rollout, pending availability of suitable vaccines(s))

4. Term of the Contract including any options to extend

The overall duration of the contract is anticipated to be 2 years, with the option to extend if required (e.g., if due to delays in an approved COVID-19 vaccine becoming available to Australia).

The arrangement will be subject to a probationary period of 4 weeks from Commencement of Services, after which the Department may choose (at its sole discretion) to terminate the services of the successful Tenderer and make another approach to market, propose a variation, or proceed to full design and delivery with the successful Tenderer.

SCHEDULE 2 TENDERER DECLARATIONS

The Tenderer must complete, sign and scan the declaration set out below and submit the declaration as part of its Proposal. This is a Minimum Content and Format Requirement.

THIS DEED POLL is made on the day of 2020
by

Name

ACN/ABN/ARBN

Short form name **Tenderer**

1. Declaration

The Tenderer declares that this deed is for the benefit of the Commonwealth of Australia as represented by the Department of Health (**Department**).

2. Definitions

In this deed terms have the same meaning as in Request for Proposal for the provision of COVID-19 vaccine logistics & distribution services, including ancillary consumables (Health/20-21/D20-2484457) (**RFP**).

3. Offer and Change of Circumstance

The Tenderer offers to supply the Services described in this RFP on the conditions set out in this RFP for the price tendered. The Tenderer undertakes not to withdraw, vary or otherwise compromise this offer for a period of no less than six months from the Closing Time.

The Tenderer undertakes to promptly notify the Department of any change, after submission of its Proposal, to the basis upon which it will have access to the necessary skills or resources, or corporate or financial backing, to supply the Services.

4. Tenderer's Conduct

The Tenderer confirms that this Proposal:

- does not contain any false or misleading claim or statement; and
- has been compiled without the Tenderer:
  - engaged in misleading or deceptive conduct;
  - improperly obtaining Confidential Information;
  - engaging in any collusive bidding, anti-competitive or other unethical, improper or unlawful conduct;
  - violating any applicable laws or Commonwealth policies regarding the offering of inducements;
  - communicating with or soliciting information from any Department employee (or contractor) or ex-employee (or ex-contractor) other than the Contact Officer;
  - obtaining improper assistance from any Commonwealth employee or using Confidential Information improperly obtained;

- approaching any officer or employee of the Department other than in the manner set out in the RFP;
- engaging in, or procuring others to engage in, any activity that would result in a breach of the *Lobbying Code of Conduct 2013* published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
- otherwise acting in an unethical or improper manner or contrary to any law.

The Tenderer warrants that it has not attempted and will not attempt, through its officers, employees or agents, to influence improperly any officer or employee of the Department in connection with the assessment of the Proposal.

The Tenderer warrants that it has complied with all relevant laws and with Commonwealth policy, in preparing and lodging its Proposal and in taking part in this RFP process.

5. Conflict of Interest

[Note to Tenderers: Strike through whichever option does not apply. Tenderers should refer to clause 38 of the RFP for further information

The Tenderer represents and declares that, having made all reasonable enquiries, it does not have any known actual or potential conflicts of interest concerning itself or a related entity in respect of this RFP, its Proposal or the provision of the Services referred to in the Statement of Requirement other than those specified below.

OR

The Tenderer

- represents that, having made all reasonable enquiries, the following represents its only known actual or potential conflicts of interest in respect of this RFP, its Proposal or the provision of the Services referred to in the Statement of Requirement:

[Insert details]

- advises that its proposed mitigation approach to manage this conflict of interest is as follows:

[insert details]

6. Further representations

The Tenderer makes the following further representations to the Department:

- it is authorised to sell and/or support all products required in the performance of the Services relating to this Proposal;
- it has examined the AusTender Terms of Use which are obtainable on the AusTender website;
- it has examined this RFP, all documents referred to in this RFP and all other information made available to it and all applicable legislation and policies;
- it has examined all further information which is obtainable by making reasonable enquiries relevant to the risks, contingencies and other circumstances having an effect on its Proposal;

- it has satisfied itself as to the correctness and sufficiency of its Proposal, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
- it has satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at **SCHEDULE 4** – Statement of Non-Compliance;
- it has obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFP process;
- it has made its own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments;
- it has relied entirely on its own enquiries and has not relied on any representation, warranty or other conduct by or on behalf of the Department, except as expressly provided in this RFP or in notices received by it; and
- it has accepted and has fully complied with the provisions of this RFP.

7. Acknowledgements

The Tenderer acknowledges that:

- the Department may exercise any of its rights set out in this RFP, at any time;
- the statements, opinions, projections, forecasts or other information contained in this RFP may change;
- this RFP is a summary only of the Department's requirements and is not intended to be a comprehensive description of it;
- neither the lodgement of the Proposal nor the acceptance of any Proposal nor any agreement made subsequent to this RFP will imply any representation from or on behalf of the Department that there has been no material change since the date of this RFP or since the date as at which any information contained in this RFP is stated to be applicable;
- to the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFP process, including instances where:
  - a Tenderer is not engaged to undertake the provision of the Services;
  - the Department decides not to enter into any resulting Contract with any Tenderer or at all;
  - the Department exercises or fails to exercise any of its other rights under or in relation to this RFP (whether or not the Department has informed a Tenderer of its exercise of the rights);
- a Proposal or any other material or communication relevant to this RFP is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or

- the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements
- to the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFP or any other matter arising by the Department exercising any of its rights; and
- the Department will have received this Proposal in reliance on this deed and that the Department may suffer loss if any of the representations, undertakings, consents or other statements in this Declaration or the Tenderer's Proposal are misleading or deceptive.

8. Corporate capacity

The Tenderer confirms that:

- it has the capacity to respond to this RFP;
- there are no restrictions under any relevant law to prevent it from so responding;
- it is financially viable; and
- the Tenderer:
  - being a corporation – is not under one of the forms of external administration referred to in Chapter 5 of the *Corporations Act 2001* (Cth) and has not had an order made against it for the purpose of placing it under external administration; or
  - being an individual – is not bankrupt and has not entered into a scheme of arrangement with creditors.

9. Security, probity and financial checks

The Tenderer:

- consents to the Department performing (and will procure all necessary consents to enable the Department to perform) such security, probity and financial investigations and procedures as the Department may determine are necessary in relation to the Tenderer, any consortium member, their employees, officers, partners, associates, Subcontractors or related entities; and
- agrees to provide at its cost, all reasonable assistance to the Department and its nominees in this regard.

10. Workplace Gender Equality Act 2012 (Cth)

Under Australian Government procurement the Tenderer is obliged to indicate whether or not it is covered by the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act). The Tenderer is covered by the WGE Act if it is a 'relevant employer', defined as being a non-public sector employer (including higher education institutions, trade unions and not-for-profit organisations) of 100 or more employees in Australia. For more information about the coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

[Note to Tenderers: Check the relevant box below. If you check box (a), please ensure your letter of compliance is attached to this declaration.]

☐ (a) Yes, the Tenderer is a relevant employer. The Tenderer has attached a current letter of compliance as part of this Proposal which indicates my compliance with the *Workplace Gender Equality Act 2012* (Cth).

☐ (b) Yes, the Tenderer is a relevant employer. The Tenderer will be providing a current letter of compliance prior to entering into any resultant Contract.

☐ (c) No, the Tenderer is not a relevant employer.

11. Terrorism

The Tenderer declares neither it, nor any of its personnel or any Subcontractor proposed in its Proposal, are listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

12. Trade sanctions

The Tenderer declares neither it, nor any Subcontractor proposed in its Proposal, are named in the consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

13. Employee entitlements

The Tenderer represents that, having made all reasonable enquiries, there are currently no unsettled judicial decisions against the Tenderer (excluding decisions under appeal) relating to employee entitlements for which the Tenderer has not satisfied any resulting order.

14. Illegal Workers

The Tenderer declares that is does not engage Illegal Workers.

Note: see definition of "Illegal Workers" in the Glossary in Part 5 of this RFP.

15. Survival

This deed survives the termination or expiry of the RFP process.

16. Indigenous Procurement Policy

The Tenderer declares the following:

The Tenderer has or has had _____ [NIL OR SPECIFY NUMBER] contracts with the Commonwealth that included the Indigenous Procurement Policy mandatory minimum requirements.

For the contracts referred to in the para above (if any), the Tenderer has:

- fully met /
- partially met /
- not met /
- not applicable as Nil contracts undertaken,

- the Indigenous Procurement Policy mandatory minimum requirements.

[Note to Tenderers: Strike out the options that do not apply.]

The Indigenous enterprises referred to in the Indigenous Participation Plan submitted as part of Tenderer's Proposal are 50 per cent or more Indigenous owned.

[Note to Tenderers: If you are an incorporated joint venture, where the joint venture is at least 25 per cent Indigenous owned, include the following. If it does not apply you may strike it out.]

The Tenderer is a joint venture that is 25 per cent or more Indigenous owned.

17. [Note to Tenderers: Supply Nation maintains a list of enterprises that meet the definition of "Indigenous enterprises". If an enterprise is not listed with Supply Nation refer to section 1.8.1 of the Indigenous Procurement Policy for ways of ensuring an enterprise is an Indigenous enterprise.]
Black Economy Procurement Connected Policy

There are no mandatory clauses in the Black Economy Procurement Connected Policy for a Tenderer declaration for an approach to market for a panel arrangement. Refer to the Black Economy Procurement Connected Policy for optional clauses and seek advice from Legal and General Counsel Division or Procurement Advisory Services if required.

The Tenderer represents that:

- it holds a Valid and Satisfactory Statement of Tax Record from each Subcontractor that it proposes, as part of its Proposal, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive); and
- if it is the successful Tenderer, it will ensure that any Subcontractor not included in its Proposal that it subsequently engages to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive), will provide it with a Satisfactory Statement of Tax Record that is Valid at the time of entry into the subcontract.

Executed as a deed poll

Execution by a company incorporated in Australia
The following execution block should be used by a Tenderer that is a company incorporated in Australia.

Executed by **[**Name of company**]** in accordance with Section 127 of the *Corporations Act 2001*

Signature of director	Signature of director/company secretary (Please delete as applicable)
Name of director (print)	Name of director/company secretary (print)

Execution by an attorney
Where the Deed of Undertaking is executed by an attorney under a power of attorney on behalf of a company incorporated in Australia, the Tenderer should submit with its executed Deed of Undertaking a copy of the relevant power of attorney. Powers of attorney must be in the form of a deed executed in accordance with section 127 of the *Corporations Act 2001* (Cth).

Signed sealed and **delivered** by **[**company name**]** by its attorney under power of attorney [dated [date of power of attorney] registered number [registered number] book number [book number], who warrants that, as at the date of this deed, they have had no notice of revocation of the power of attorney

Signature of attorney	Signature of witness
Name of attorney (print)	Name of witness (print)

SCHEDULE 3 – TENDERER RESPONSE INFORMATION

1. Tenderer's Profile

1.1 Tenderer's contact officers

Tenderers should provide details of their nominated contact officers in the following table:

Tenderer's primary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	
Tenderer's secondary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	

1.2 Tenderer's details

Tenderers should complete all details in the following table:

Tenderer's details	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
Is the Tenderer registered for GST?	Yes / No
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	[*Please include street address, telephone*]
Date and place of incorporation or registration of business (if applicable)	

Tenderer's details	
TGA registration/licence numbers / and or applicable state and territory warehousing / wholesaling licence numbers (if applicable)	

2. Subcontractor details

(a) Where Tenderers are proposing to use Subcontractors to deliver some of the Services, Tenderers should complete all details in the following table for each nominated Subcontractor.

(b) Tenderers should note that, under paragraph 7.21 of the Commonwealth Procurement Rules, the names of Subcontractors may be publicly disclosed and that it is the responsibility of Tenderers to secure Subcontractors' agreement to this.

Subcontractor 1	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	
TGA registration/licence numbers / and or applicable state and territory warehousing / wholesaling licence numbers (if applicable)	

Subcontractor 2	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory	

Subcontractor 2	
authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	
TGA registration/licence numbers / and or applicable state and territory warehousing / wholesaling licence numbers (if applicable)	

3. Tenderer's insurance

Tenderers should complete all details in the following table:

General liability insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Professional indemnity insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Workers' compensation insurance	
Name of insurer	
Policy number	
Expiry date	

Where the Tenderer's proposed Personnel are operating as an individual and/or include volunteers, Tenderers should also complete all details in the following table:

Disability income insurance	
Name of insurer	
Policy number	

Expiry date	
Amount of current cover	
Voluntary workers' insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	

4. Tenderer's Financial Viability

(a) The Tenderer should provide a summary of their financial viability.

(b) This may include data from or for a financial analysis of its operations including profitability, liquidity, insolvency, bankruptcy actions, working capital management efficiency, financial structure, debt coverage and return on investment.

(c) The Department may also request further information and undertake its own independent enquiries and assessment in relation to the Tenderer's financial viability.

5. Actions or Investigations

(a) The Tenderer should provide particulars of any petition, claim, action, judgement or decision that is likely to adversely affect its capacity to provide the Services.

(b) Tenderers should provide details of whether or not they are aware that they are under investigation, or the subject of court proceedings, in relation to a possible or actual breach of any relevant legislation, and if applicable, provide details of the same.

6. Co-design

Tenderers should detail how they plan to partner effectively with the Department to collaborate during the co-design phase.

In presenting their approach, Tenderers should consider outlining the following:

(a) Which elements of the scope are most in need of co-design;

(b) Which stakeholders should be involved in the co-design;

(c) The proposed interaction model with the Department and any other relevant stakeholders, including both working arrangements and how visibility/status updates will be provided;

(d) How the codesign process will be managed to ensure minimum time to viable solution design;

(e) How the Tenderers will bring the best of their expertise to the codesign phase, and profiles of the proposed team that the Tenderers would allocate to the co-design phase, including their relevant expertise and roles.

7. Service Delivery and Management

Tenderers should provide the following information:

7.1 Overall approach

Tenderers should outline their proposed overall approach to delivering the Services outlined in figure 1 – including reference to the infrastructure, procedures, staffing, equipment and facilities, if applicable, to be utilised in the delivery of the Services. This should be presented across the 3 thermostability scenarios and 3 phases outlined in figure 1.

7.2 Contingencies

Furthermore, Tenderers should outline their approach to contingencies/adaptation to ensure services can be delivered under the following circumstances:

1. Where roll-out is required earlier or later than forecast, depending on vaccine availability and/or approvals
2. Where there is an active outbreak in one or more delivery areas: i.e., Tenderers ability to deliver using the proposed approach should there be ongoing community transmission
3. Where multiple vaccine types are available, either launched together or at different times

the Tenderer should clearly state whether they can meet all of the Service requirements as set out in the Statement of Requirement, and if not, which they are unable to meet.

7.3 KPIs:

A list of the **daily, weekly, and monthly metrics** that will be reported to demonstrate effectiveness and completeness of process, including in what format these reports will be delivered and how they can be accessed;

7.4 Data interfaces:

(a) An overview of the **data that would be collected and tracked** as part of ongoing operations, and how this might be available to Commonwealth systems under development;

(b) How **order processing and inventory management interfaces** would be managed, including how orders would be received from the Commonwealth and/or vaccination sites, and how vaccination sites would have line of sight of incoming deliveries;

7.5 Quality assurance

How **quality and fidelity of cold chain** under each of the 3 thermostability scenarios will be ensured;

7.6 Remote reach

How the Tenderer will ensure distribution will be **accessible for regional and remote populations** in addition to metropolitan populations;

7.7 Potential future additional capacity

In line with information provided in the bid sheet, Tenderers should outline in greater detail the origin and status of their potential future additional capacity, including whether this is owned or leased, in progress or proposed;

8. Past Performance

To assess the Tenderer's capability to deliver the Services, Tenderers should provide details of similar services provided within the last three years (if any). In addressing this requirement, Tenderers should include:

(a) the organisation(s) for whom the services were undertaken, including contact details;

(b) the nature of the project and the outcome achieved by the Tenderer;

(c) the period over which the work was undertaken; and

(d) the value of the work undertaken.

9. Risk management

Tenderers should set out in their Tender response:

(a) the key issues and risks they consider are relevant to the provision of the Services;

(b) the Tenderer's suggested approach to the issue and risk;

(c) the Tenderer's and Department's roles in the suggested approach; and

(d) the Tenderer's risk management systems currently in place or proposed.

10. Personnel

The Tenderer should, in the table below, provide details of the key personnel who will be used for the supply of the Services.

Name and position of Personnel	Role in the provision of the Services	Experience / qualifications	Availability

11. Referees

(a) Tenderers should provide details of at least two referees which can be contacted regarding work undertaken by the proposed personnel. References will be evaluated based on relevance of work completed as well as comments from the referee contacts.

(b) A Tenderer may provide contacts within the Department as referees. However, where a Department contact is involved in evaluating Proposals or advising the Proposal evaluation team they will be unable to provide a reference, in which case the Department may ask the Tenderer to provide details of an alternate referee.

(c) Without limiting paragraph 10.2, the Department reserves the right to contact persons other than those provided as referees by Tenderers.

12. Indigenous Participation Plan

(a) Each Tenderer must submit an Indigenous Participation Plan with its Proposal using the template in Schedule 6. The Indigenous Participation Plan should address:

(i) how the Tenderer intends on meeting the mandatory minimum requirements for the Indigenous Procurement Policy;

(ii) the Tenderer's current rate of Indigenous employment and supplier use;

(iii) the Tenderer's commitment to Indigenous participation. Some examples of the activities an organisation can take to demonstrate its commitment to Indigenous participation are set out in paragraph 4.7.1 of the Indigenous Procurement Policy; and

(iv) if any part of the Contract will be delivered in a Remote Area, how the Tenderer will ensure that its provision of the Services will deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

(b) The mandatory minimum requirements can be met at:

(i) the contract-based level (see paragraph (c) below); or

(ii) the organisation-based level (see paragraph (d) below).

(c) To meet the mandatory minimum requirements at the contract-based level, by the end of the Initial Term of the Contract:

(i) at least 4 per cent of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 4 per cent of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, on average over the Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, and a minimum percentage of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, so that both minimum percentages add up to 4 per cent, on average over the Initial Term of the Contract .

(d) To meet the mandatory minimum requirements at the organisation-based level, by the end of the Initial Term of the Contract:

(i) at least 3 per cent of the full time equivalent Australian-based workforce of the contractor must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 3 per cent of the value of the contractor's Australian supply chain must be subcontracted to Indigenous enterprises, on average over Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce must be Indigenous Australians, and a minimum percentage of the value of the contractor's supply chain must be subcontracted to Indigenous enterprises, such that both minimum percentages add up to 3 per cent on average over the Initial Term of the Contract .

(e) The mandatory minimum requirements can be met directly or through subcontracts.

(f) The successful Tenderer's Indigenous Participation Plan will be attached to the resultant Contract, and the successful Tenderer will be required to comply with and report against the Indigenous Participation Plan during the term of that Contract.

13. Economic Benefit to the Australian Economy

Respondents should answer the questions below to enable the Department to consider the economic benefit of the procurement to the Australian economy.

RESPONDENT PROFILE

Does the Respondent have an Australian Business Number (ABN)	Y/N
Is the Respondent incorporated in Australia? If No, is the Respondent a foreign company registered in Australia	Y/N Y/N
How many current (full time equivalent) employees of your organisation are based in Australia?	

Describe any strategies you consider relevant to your proposed supply's economic benefit to the Australian economy
[max 300 words] *Examples of information potential suppliers might include, but are not limited to:* • *Lowest price, saving the tax payer;* • *Building, leasing or procuring infrastructure that supports Australian communities;* • *Providing skills and training that benefits Australian communities;* • *Employing workers in Australia;* • *Paying taxes in Australia;* • *The environmental benefit of the proposed solution to Australia, for example, low environmental impact through energy efficient inputs such as computers, air conditioning, telephones and paper;* • *Contributing to positive social outcomes in Australian communities;* • *Using of indigenous business;* • *Using SMEs in delivering goods and services, such as a subcontractor or supplier;* • *Sharing knowledge, skills and technology with SMEs; and* • *Using goods and services from a business that provides services of persons with a disability*

14. Other information

Tenderers should provide any other information that addresses the Evaluation Criteria set out in clause 21 of this RFP.

SCHEDULE 4 – STATEMENT OF NON-COMPLIANCE

1. Statement of Non-Compliance

Where the Tenderer wishes to negotiate any provisions of the Draft Contract (Schedule 6), it should include in its response below details of:

- the provision that it wishes to negotiate;
- the alternative words that it proposes; and
- any increase in its Proposal price if the Department does not agree to the amendment.

The Department will consider any non-compliances or partial compliances in its evaluation of other risks.

If Tenderers do not submit a response to this Schedule they will be evaluated on the basis that they agree with all the provisions of the Draft Contract.

The Department does not intend to permit a Tenderer to re-open any provision of the Draft Contract in negotiations that was not identified as an area of non-compliance or partial compliance in a Proposal.

Item reference	Nature of compliance (partially complies, does not comply)	Reasons for non-compliance or partial compliance and proposed alternative wording

2. Confidential Information

The Tenderer should specify any information which is contained in its Proposal, or which may be provided by it during this RFP process, that it considers should be protected as Confidential Information by the Department in respect of any resultant Contract. The Tenderer should also provide appropriate reasons why any such information should be protected as Confidential Information.

Tenderers should review the information available from the Department of Finance's website for further detail about what information may be protected as Confidential Information (see the Department of Finance's Confidentiality Throughout the Procurement Cycle).

Proposed Confidential Information (refer to RFP or Schedule clause)	Reason why this information should be protected as Confidential Information

SCHEDULE 5 – PRICING SCHEDULE

1. Pricing Schedule

1.1 The Tenderer should indicate, using the attached Pricing Schedule.xlsx file as a template, all fees, charges, and other costs which it would seek to be paid for the Services and discounts offered.

1.2 A breakdown of assumptions, variations or other qualifications relied upon for generating estimates should be provided.

1.3 The Department prefers that Tenderers lodge their pricing in Australian currency. Any pricing lodged in foreign currency amounts will be converted to Australian currency for evaluation purpose.

1.4 All amounts are to be expressed as GST inclusive.

1.5 Tenderers should provide itemised pricing information and proposed payment schedules detailing all fees, prices and charges related to each milestone or deliverable of the Services.

SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM

INDIGENOUS PARTICIPATION PLAN

[INSERT NAME OF TENDERER]

1. This is an Indigenous Participation Plan submitted as part of the Proposal in response to [INSERT RFP NUMBER] (**RFP**).

2. If selected as the Contractor following evaluation of Proposals received in response to the RFP, [TENDERER] will meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy:

   at the contract-based level, in which regard at least:

   - [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians over the Initial Term of the Contract ; and
   - [INSERT] percentage of the value of the work performed under the Contract will be subcontracted to Indigenous enterprises over the Initial Term of the Contract ; or

   at the organisation-based level, in which regard at least:

   - [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce will be Indigenous Australians over the Initial Term of the Contract ; and
   - [INSERT] percentage of the value of [TENDERER'S] Australian supply chain will be subcontracted to Indigenous enterprises over the Initial Term of the Contract .

[Note to Tenderers: Select which option(s) above apply based on the requirements set out in paragraphs 12(b), (c) and (d) in Schedule 3 of this RFP.]

3. To meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy, [TENDERER] will undertake the following:

[Note to Tenderers: Tenderer to insert details of how it will meet the mandatory minimum requirements (which may include details of its current workforce / supply chain) at either / both the contract / organisation level and how it will go about meeting the requisite percentages to meet the mandatory minimum requirements. Tenderers should note that the mandatory minimum requirements are averages over the Initial Term of any resultant Contract , and will accordingly need to detail their approach to achieving the specified targets over the Initial Term.]

4. [TENDERER's] rate of Indigenous employment and supplier use as at the Closing Time is:

5. [TENDERER] demonstrates its commitment to Indigenous participation as follows:

6. [TENDERER] will meet the mandatory minimum requirements: directly; or through subcontracts.

[Note to Tenderers: Tenderer to detail its approach to meeting the mandatory minimum requirements directly or through subcontracts.]

Remote Area Contracts

7. A component of any resultant Contract will be delivered in a Remote Area. [TENDERER] proposes to ensure the Contract will deliver a significant Indigenous employment or supplier use outcome in that Remote Area as follows:

SCHEDULE 7 – DRAFT CONTRACT

See separate document titled ‘Schedule 7 – Draft Contract’.

Australian Government
Department of Health

REQUEST FOR PROPOSAL FOR THE PROVISION OF A COVID-19 VACCINE DATA SOLUTION

Health/20-21/277038

ISSUED BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH

Lodgement Closing Time: 2.00 pm on the 17 November 2020
(local time in Canberra, ACT)

PLEASE NOTE:

- Proposals must be lodged electronically via AusTender (see clause 8)
- Proposals should be lodged in the format described in clause 10.

The Department adheres strictly to Commonwealth policy on **Late Proposals.** The Department therefore recommends that Tenderers plan to lodge their Proposal well before the Closing Time to minimise the possibility of any unforeseen circumstances arising that may cause the Tenderer to miss the Closing Time.

Commonwealth Contact: COVID19VaccineProcurement@health.gov.au

CONTENTS

PART 1 – OVERVIEW, BACKGROUND, SERVICES SPECIFICATIONS AND PROPOSAL LODGEMENT

1. REQUEST FOR PROPOSAL

1.1 This Request for Proposal (**RFP**) comprises:

a. Part 1 – Overview, background, services specifications and Proposal lodgement;
b. Part 2 – Information to be provided by Tenderers;
c. Part 3 – Evaluation of Proposals;
d. Part 4 – Conditions of tendering;
e. Part 5 – Glossary;
f. Schedule 1 – Statement of Requirement;
g. Schedule 2 – Tenderer Declarations;
h. Schedule 3 – Tenderer Response Information;
i. Schedule 4 – Statement of Non-Compliance;
j. Schedule 5 – Pricing Schedule;
k. Schedule 6 – Indigenous Participation Plan Template Response Form; and
l. Schedule 7 – Draft Contract.

1.2 Tenderers' attention is also drawn to the:

a. Conditions for Participation set out in clause 12;
b. Minimum Content and Format Requirements set out in clause 13; and
c. Essential Requirements set out in clause 14.

2. THE DEPARTMENT

2.1 The Commonwealth of Australia acting through the Department of Health (Department) is responsible for better health and wellbeing for all Australians. The Department aims to achieve its vision through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.

2.2 Australia's COVID-19 Vaccine and Treatment Strategy aims to support access to, and delivery of, safe and effective COVID-19 vaccines and treatments for all Australians, as soon as they are available.

2.3 The Department is seeking to engage a partner to design, develop and implement a data solution to enable the tracking and reporting of COVID-19 vaccines across the vaccination delivery chain. The end-to-end tracking for each vaccine will start on the delivery of the vaccine dose to the Department from the relevant manufacturer through to post-administration monitoring.

2.4 The Initial Term of the Contract will be 2 years. The Department also requires 3 options extend the Contract Term, and each option is to be of 1 year.

3. SERVICES THE DEPARTMENT REQUIRES

3.1 The Department is seeking Proposals for a full stack software solution to utilise data from existing systems to enable the Department to have granular and point-in-time visibility of end-to-end tracking of COVID-19 vaccines data (the Solution), including all software, design

and implementation services, and ongoing maintenance and delivery support, and other related services that meets the requirements in SCHEDULE 1 (Statement of Requirement).

3.2 The end-to-end tracking for each vaccine is to start on the delivery of the vaccine dose to the Department from the relevant manufacturer, through logistics and distribution stages (i.e. the transportation and storage of the vaccine), to vaccine administration (i.e. receipt of the vaccine by the provider and the vaccination of a consumer, including management of consumer demand) and then to post-administration monitoring (i.e. adverse event monitoring).

3.3 The Solution will need to, on an ongoing basis, extract and link data from existing systems and data sources. The data extracted from these sources may include vaccination data made available to the Department from the Australian Immunisation Register (AIR), and vaccine stock and flow data from the Department's logistics/distribution service provider.

3.4 The Solution will need to use extracted data from existing systems and collate that data (i.e. the successful Tenderer is not required to collect primary sources of data – e.g. the Department's logistics service provider will be responsible for collecting the tracking data on each vaccine dose and vial while the vaccine is in its custody). The Solution must collate data from various sources and create a seamless tracking view for each dose and each vial (noting there will be multiple in each vial) from the time that it is delivered to Health to the time that the vaccine dose is administered, and then post administration.

3.5 Further details on the systems and data sources that the Solution will need to integrate with and the kinds of data that will need to be extracted are in SCHEDULE 1 (Statement of Requirement).

3.6 The Solution is intended to support the Department's efforts to enhance its analytic capabilities to proactively and responsively manage the implementation of the COVID-19 vaccination program.

3.7 The successful Tenderer is required to provide the necessary training and knowledge transfer to allow Department Authorised Users to competently operate the Solution independently of the successful Tenderer.

3.8 The detailed specifications and requirements for the Services are set out at Schedule 1 - Statement of Requirement. The Department proposes to engage the successful Tenderer to provide the Services in accordance with the Draft Contract set out in Schedule 7.

4. RFP TIMETABLE

4.1 The following is the timetable for the initial stages of this RFP process:

Activity	Timing
Release of RFP	5 November2020
Industry briefing	11 November 2020
Enquiry Cut-Off Date	12 PM, 16 November 2020
Closing Time	2 PM, 17 November 2020

4.2 The following is the indicative timetable for the later stages of the RFP process:

Evaluation of tenders	18-22 November 2020
Negotiation and Execution of Contract with successful Tenderer	23 - 27 November 2020
Notification of unsuccessful Tenderers	23 - 27 November 2020
Commencement of Services	30 November 2020 (estimated)

4.3 The Department may at any time vary the table in clause 3.1 in accordance with the process for varying this RFP at clause 44.3. The timetable in clause 3.2 is subject to change and the Department will not give notice if this changes.

5. ENQUIRIES ABOUT THIS RFP

5.1 Enquiries about this RFP should be made by email addressed to:

Name:	Sarah Sinclair
Title:	Director, COVID-19 Vaccine Strategy Taskforce
Email:	COVID19VaccineProcurement@health.gov.au

5.2 The Department will provide answers to any reasonable enquiry from a prospective Tenderer that is received by the Department before the Enquiry Cut-Off Date set out in clause 4, in which case:

a. questions and related answers may be disclosed to all prospective Tenderers via AusTender (without disclosing the source of the questions); and
b. any Tenderer Confidential Information contained in a question (that is expressly nominated as such by the relevant Tenderer and agreed to by the Department) will be removed prior to disclosure on AusTender.

5.3 All communications related to this RFP should be addressed to the Contact Officer (via the contact details specified above) and not to other Departmental officers or other persons. The Department may not respond to any enquiry not made in accordance with the requirements of clause 5.1. A Tenderer who communicates other than to the Contact Officer may be excluded from participating further in this RFP process.

6. GOVERNMENT PROCUREMENT (JUDICIAL REVIEW) ACT 2018 (CTH)

6.1 This RFP process is not a covered procurement for the purposes of the Commonwealth Procurement Rules and the Government Procurement (Judicial Review) Act 2018 (Cth).

6.2 Not Used

6.3 Not Used

7. AUSTENDER, THE AUSTRALIAN GOVERNMENT TENDER SYSTEM

7.1 AusTender is the Australian Government's procurement information system. Access to and use of AusTender is subject to terms and conditions. In participating in this RFP process, Tenderers agree to comply with those terms and conditions and any applicable instructions, processes, procedures and recommendations as advised on the AusTender website at https://www.tenders.gov.au/?event=public.termsOfUse.

7.2 All queries and requests for technical or operational support must be directed to:

AusTender Help Desk

Telephone: 1300 651 698

International: +61 2 6215 1558

Email: tenders@finance.gov.au

7.3 The AusTender Help Desk is available between 9am and 5pm ACT local time, Monday to Friday (excluding ACT and national public holidays).

8. ELECTRONIC LODGEMENT

8.1 Proposals must be lodged electronically via AusTender before the Closing Time and in accordance with the Proposal response lodgement procedures set out in this RFP and on AusTender.

8.2 If Tenderers need to lodge material that cannot be submitted via AusTender, Tenderers should contact the Contact Officer prior to Closing Time to make arrangements for its submission.

9. PROPOSAL CLOSING TIME AND DATE

9.1 Proposals must be lodged before 2 PM, local time in the ACT on the 17 November 2020 (the Closing Time).

9.2 The Closing Time will also be displayed in the relevant AusTender webpage together with a countdown clock that displays in real time the amount of time left until Closing Time (For more information please see AusTender Terms of Use). For the purposes of determining whether a Proposal has been lodged before the Closing Time, the countdown clock will be conclusive and will be the means by which the Department determines whether a Proposal has been lodged by the Closing Time.

9.3 Any attempt to lodge a Proposal after the Closing Time will not be permitted by AusTender. Such a Proposal will be deemed to be a Late Proposal. Late Proposals will be excluded from consideration unless the Proposal is late as a consequence of mishandling by the Department.

9.4 Where electronic submission of a Proposal has commenced prior to the Closing Time but concluded after the Closing Time, and upload of the Proposal file(s) has completed successfully, as confirmed by AusTender system logs, the Proposal will not be deemed to be a Late Proposal. Such Proposals will be identified by AusTender to the Department as having commenced transmission prior to, but completed lodgement after, the Closing Time.

9.5 Where a Proposal lodgement consists of multiple uploads, due to the number and/or size of the files, Tenderers must ensure that transmission of all files is completed and receipted before the Closing Time and clause 8.4 will only apply to the final upload.

10. PREPARING TO LODGE A PROPOSAL

Proposal File Formats, Naming Conventions and Sizes

10.1 The Department will accept Proposals lodged in Microsoft Word, Microsoft PowerPoint and PDF formats. Supplementary materials/attachments may be also be provided in one of these formats, or in formats compatible with Microsoft Excel. If the Tenderer believes elements of their proposal are best represented in a file format not listed here, queries may be directed to the Contact Officer.

10.2 The Proposal file name/s should:

a. Begin with the date in YYYYMMDD format (e.g., 20201030); and
b. incorporate the Tenderer's company name; and
c. reflect the various parts of the Proposal they represent, where the Proposal comprises multiple files.

10.3 Proposal response files should not exceed a combined file size of 5 megabytes per upload.

10.4 Proposals must be completely self-contained. No hyperlinked or other material may be incorporated by reference.

11. SCANNED OR IMAGED MATERIAL, INCLUDING STATUTORY DECLARATIONS

11.1 In the event that the Department requires clarification of the Tenderer's Proposal, the Tenderer may be required to courier or security post the originals of the signature and/or initialled pages to the Department at the address notified by the Department within the period notified by the Department.

PART 2 – INFORMATION TO BE PROVIDED BY TENDERERS

12. CONDITIONS FOR PARTICIPATION

12.1 Subject to clause 13, if the Department considers that a Tenderer does not satisfy all of the following Conditions for Participation, that Proposal will be excluded from further consideration under this RFP:

Item	Conditions for Participation
1	The Tenderer must not have had any judicial decisions against it (excluding decisions under appeal) relating to employee entitlements and have not satisfied any resulting order.
2	The Tenderer, its personnel, and any Subcontractors proposed in the Proposal must not, at the Closing Time, be listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).
3	The Tenderer (and any Subcontractor proposed in its Proposal) must not be named in the Consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).
4	(a) The Tenderer either: i. holds a Valid and Satisfactory Statement of Tax Record by the Closing Time; or ii. has a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office by the closing time, and holds a Valid and Satisfactory Statement of Tax Record no later than 4 business days from the Closing Time; and (b) the Tenderer holds a Valid and Satisfactory Statement of Tax Record from any Subcontractor that it proposes, as part of its Proposal, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive). [Note to Tenderers: Tenderers should apply for a Statement of Tax Record and should ensure that their Subcontractors apply for a Statement of Tax Record within sufficient time to meet this Condition for Participation.]

13. MINIMUM CONTENT AND FORMAT REQUIREMENTS

13.1 Subject to clause 13, if the Department considers that a Proposal does not satisfy all of the following Minimum Content and Format Requirements, that Proposal will be excluded from further consideration under this RFP:

Item	Minimum Content and Format Requirements
1	The Proposal must be in English and measurements must be expressed in Australian legal units of measurement.
2	The Proposal must include a completed, signed and scanned Tenderer Deed substantially in the form at Schedule 2.

Item	Minimum Content and Format Requirements
3	Tenderers must substantially complete and submit the Pricing Schedule in Schedule 5 in accordance with the instructions provided in Schedule 5.
4	The Tenderer must include an Indigenous Participation Plan in its Proposal.
5	The Proposal must include either: a. a Valid and Satisfactory Statement of Tax Record for the Tenderer; or b. a receipt demonstrating that a Statement of Tax Record has been requested from the Australian Taxation Office for the Tenderer and the Tenderer then provides a Valid and Satisfactory Statement of Tax Record within 4 business days from the Closing Time.

Unintentional Errors of Form

13.2 Without limiting the Department's other rights in this RFP, the Department may allow the Tenderer to correct any error of form in a Proposal that appears to be unintentional, by lodging a correction or additional information, in writing in accordance with the direction of the Department, but will not permit any material alteration or addition to the Proposal.

13.3 If the Department provides any Tenderer with the opportunity to correct errors of form, it will provide the same opportunity to all other Tenderers that are in the same position.

14. ESSENTIAL REQUIREMENTS

14.1 If the Department considers that a Tenderer does not satisfy all of the following Essential Requirements, that Proposal will be excluded from further consideration under this RFP:

Item	Essential Requirements
1	Ability to comply with and adhere to the Department of Health cloud security standards (Annex A to Schedule 1), demonstrated through prior experience and/or evidence.
2	Willingness to work with the Australian Cyber Security Centre (ACSC) and become an ACSC partner through the Partnership Program, as outlined in the requirements in Schedule 1.

14.2 Notwithstanding the use of the words “must”, "shall", "minimum", "required to" or similar language or anything to the contrary in Statement of Requirement or elsewhere in this RFP, there are no other Essential Requirements for this RFP besides those set out in the table above (if any).

15. FORMAT OF PROPOSALS

15.1 Proposals should be completed in accordance with Schedule 3, noting the following:

a. all applicable information should be provided in response to the information requirements set out in Schedule 3;
b. where a response to a particular requirement is covered in another section of the Proposal, a cross reference to that section should be provided; and
c. Tenderers may include additional or supporting materials (as supplements or attachments to the Proposal Response Information) noting that Tenderers are

discouraged from including generic marketing information that does not relate to the information requested in this RFP and/or does not address the Evaluation Criteria.

15.2 Tenderers should also complete the statement of non-compliance in accordance with Schedule 4 in relation to:

a. any of the provisions of the Draft Contract with which the Tenderer is partially compliant or non-compliant; or
b. any claim of confidentiality in relation to any aspects of their Proposal.

16. PRICING

16.1 Tenderers should provide full details of their proposed price structure in Schedule 5. This document should be included in a separate electronic file when the Proposal is lodged and no pricing should be included in any other part of the Proposal.

16.2 Tendered prices should include all charges necessary and incidental to the proper delivery of the Services.

16.3 Prices should be fixed for the duration of the Contract unless otherwise indicated by the Department in this RFP.

16.4 Prices should be in Australian dollars (inclusive of GST).

17. WORKPLACE GENDER EQUALITY

17.1 Commonwealth policy prevents the Department from entering into contracts with Tenderers who are non-compliant under the *Workplace Gender Equality Act 2012* (Cth) (the **WGE Act**).

17.2 The Draft Contract requires that, in performing any contract, a successful Tenderer must:

a. comply with its obligations, if any, under the WGE Act; and
b. if the term of any resultant Contract exceeds 18 months, the successful Tenderer must provide a current letter of compliance within 18 months from the Contract Commencement Date and following this, annually to the Department's Contract contact officer.

17.3 Tenderers should note that if during the term of any resultant Contract, the successful Tenderer becomes non-compliant with the WGE Act, the successful Tenderer must notify the Department's Contract contact officer.

17.4 For further information about coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

17.5 Tenderer's must indicate as part of the Tenderer Deed at Schedule 2 whether or not the Tenderer's organisation is a 'relevant employer' under the WGE Act and, if applicable, provide a current letter of compliance as part of their Proposal, or prior to entering into any resultant Contract (if successful).

18. ILLEGAL WORKERS

18.1 It is Commonwealth policy not to contract with providers engaging Illegal Workers.

18.2 The Tenderer's Deed in Schedule 2 contains a statement from the Tenderer confirming that it meets this obligation.

19. INDIGENOUS PROCUREMENT POLICY

19.1 It is Commonwealth policy to stimulate Indigenous entrepreneurship and business development, providing Indigenous Australians with more opportunities to participate in the economy (see Indigenous Procurement Policy for further information).

19.2 If any resultant Contract is a High Value Contract, the mandatory minimum requirements for Indigenous participation will apply.

19.3 If a component of any resultant Contract will be delivered in a Remote Area, this creates an opportunity for that resultant Contract to deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

19.4 In its Indigenous Participation Plan, the Tenderer should detail how it will ensure that its provision of the Services will deliver a significant Indigenous employment or supplier use outcomes in the Remote Area.

[Note to Tenderers: Refer to section 4.4.1 of the Indigenous Procurement Policy for examples of options available to ensure any resultant Contract will deliver significant Indigenous employment or supplier use outcomes in the Remote Area.]

20. MODERN SLAVERY ACT 2018 (CTH)

20.1 Tenderers should note that any resultant Contract will require the successful Tenderer to provide all assistance reasonably requested by the Department to comply with its obligations under the Modern Slavery Act 2018 (Cth).

PART 3 – EVALUATION OF PROPOSALS

21. EVALUATION CRITERIA

21.1 The Department will use the following Evaluation Criteria in the evaluation of Proposals:

Description	
Proposed Solution and approach: The extent to which the proposed Solution meets the purposes, and functional, non-functional and other requirements described in Schedule 1 and the Tenderers approach to developing the Solution. Factors to be taken into account are: a. The extent to which the proposed Solution has architecture that aligns the requirements in Schedule 1 including compliance with cyber requirements (Annex 1). b. The extent to which the proposed Solution characteristics are modular, decoupled, standardised, configurable, performant, reliable, secure, manageable, accurate, and reusable. c. The extent to which the proposed Solution has the ability to meet the Department's current and future performance and data management requirements in Schedule 1. d. The quality and suitability of the proposed warranty and support and maintenance arrangements. e. The quality and suitability of the Tenderer's proposed approach to managing and facilitating the transfer of skills and knowledge to Department staff. f. The extent to which the Tenderer's proposed collaboration model supports the successful design and development and implementation of the proposed Solution. g. The extent to which the proposed Solution meets any other requirements in Schedule 1. h. The assessed level of overall technical risk of the proposed solution.	50%
Timeline and execution readiness: a. The extent to which the Tenderer's proposed delivery plan is assessed as meeting the project deadlines in Schedule 1, and the extent to which this is supported by a defined delivery methodology and credible delivery schedule (with quantifiable assumptions where necessary). b. The extent to which the Tenderer is assessed as having the organisational capacity and capability to deliver the Solution from day 1 post-contract execution (e.g. timely resource availability and capability).	25%
Past experience: a. The extent to which the Tenderer's past performance providing similar services demonstrates its ability to provide the Services. b. The extent to which the Tenderer is assessed as having proven experience in end-to-end execution of data and tracking system platforms of a comparable complexity, size and scale.	25%

Description	
c. The extent to which the Tenderer is assessed as having proven experience working with Australian health industry stakeholders or stakeholders of an equivalent or similar nature. d. The extent to which the Tenderer is assessed as having proven experience in BOT (build, operate, transfer) IT systems of a comparable complexity, size and scale.	
Pricing: The assessed value to the Department of the tendered prices, and pricing structure for the Services. Factors to be taken into consideration are: a. The assessed value to the Commonwealth of the tenderer prices (in Schedule 5 (Pricing Schedule)). b. The extent to which the proposed pricing structure and the Tenderer's proposal in relation to allocation of liability reflects an appropriate shared risk profile for the Services, including the Solution.	Not weighted
Risk: The extent to which the Tenderer's proposal represents risk to the Department: a. The level of compliance with Statement of Requirement and the Draft Contract. b. The extent to which the proposed corporate structure, and financial and corporate viability, of the Tenderer (and its proposed Subcontractors) will support the provision of the Services. c. The legal and commercial risks associated with the Tenderer's response. d. Any other risks identified in the evaluation process that have not been considered as part of another Evaluation Criterion that are associated with the Tenderer's response.	Not weighted
Economic Benefit Paragraphs 4.7 and 4.8 of the CPRs requires the Department to consider the economic benefit to the Australian economy for procurements estimated to be above $4million for non-construction goods and services and above $7.5 million for construction services.	Not weighted

21.2 The Department may:

a. consider any part of a Proposal in the evaluation of any or all of the Evaluation Criteria; and
b. use material provided in response to one Evaluation Criterion in its evaluation of other Evaluation Criteria.

22. EXCLUSION OF PROPOSALS

22.1 Without limiting any other provision of this RFP that gives the Department the right to exclude Proposals on other grounds, the Department may at any time exclude a Proposal from further consideration if:

a. the Proposal is incomplete or contains insufficient information to allow evaluation of the Proposal;
b. prices are not clearly and legibly stated;
c. the Tenderer or Proposal does not comply with this RFP;
d. the Tenderer is not fully capable of undertaking a contract in the form of the Draft Contract;
e. the Proposal is clearly uncompetitive when compared with the other proposals received;
f. the Proposal is rated unsuitable or unsatisfactory against one or more of the Evaluation Criteria;
g. the Proposal contains statements that qualify or are contrary to the Tenderer Deed at Schedule 2 to this RFP:
h. in the Department's opinion the Proposal contains a false declaration;
i. the Proposal contains false or misleading information or statements;
j. the Tenderer, or a director or officer of the Tenderer, is insolvent or bankrupt;
k. the Tenderer has an actual, potential or perceived conflict of interest that cannot be managed to the satisfaction of the Department acting in its absolute discretion; or
l. there has been a significant deficiency in the performance of a substantive requirement or obligation under a prior agreement.

23. PROPOSAL EVALUATION PROCESS

23.1 Proposals will be evaluated against the Evaluation Criteria to determine the Proposal that represents the best overall value for money on a whole-of-life basis.

23.2 As part of its evaluation of Proposals, the Department may, in its sole and absolute discretion:

a. ask Tenderers to undertake presentations;
b. shortlist one or more Tenderers at any time;
c. ask Tenderers to provide written clarification of various aspects of their Proposals;
d. ask Tenderers to provide further information to confirm their financial viability and commercial stability;
e. have discussions or interviews with Tenderers in order to seek further clarification of their Proposals;
f. visit Tenderers' sites; and
g. have discussions with or undertake visits to customers of Tenderers and their Subcontractors, whether or not those customers are listed as referees in the Tenderers' Proposals.

23.3 The Department may choose to undertake the activities set out in clause 23.2 in relation to some Tenderers only. Presentations, interviews and site visits may be subject to additional terms and conditions that are advised by the Department to Tenderers who have been invited to participate in each activity.

23.4 Any costs incurred by the Tenderer in complying with this clause 23 will be borne by the Tenderer.

24. CLARIFICATION

24.1 Where the meaning of a Proposal is unclear or there is an apparent error of form, the Department may seek clarification from the Tenderer.

24.2 Any clarification provided by a Tenderer in response to a request for clarification is not to contain any new material additional to that included in the Proposal unless specifically

requested by the Department. Failure to supply clarification to the satisfaction of the Department may cause the Proposal to be excluded from consideration.

25. PROPOSAL PRICES

25.1 The Tenderer agrees to provide access to such information as is determined by the Department to be necessary in order to evaluate the reasonableness of their Tendered prices.

25.2 In the evaluation process, the Department may make certain adjustments to the Tendered price, including adjustments to account for the following matters, which may need balancing in order to establish a common basis for the comparison of Proposals, including (without limitation):

a. Proposal prices as per the completed Schedule 5;
b. pricing flexibility;
c. any other costs or discounts which form part of the Tenderer's offer;
d. normalised and discounted cash flow;
e. any alternative proposals or financial incentives offered by the Tenderer;
f. implementation costs;
g. any risk relating to the Tendered prices;
h. transition out costs;
i. cost of administering the resultant Contract; and
j. whole of life costs and benefits.

26. NEGOTIATIONS

26.1 Negotiations may be undertaken with one or more Tenderers (including in relation to prices, terms and conditions of the Draft Contract or any other matters).

26.2 During the negotiation phase of this RFP process, the Department may engage in detailed discussions and negotiations, including parallel negotiations, with the goal of maximising the benefits of the project, as measured using the Evaluation Criteria. As part of this process, those Tenderers participating in the negotiation phase may be asked to improve any or all aspects of their Proposal. The Department's intention is that it will select a preferred Tenderer after all material issues have been resolved.

26.3 The Department may seek best and final offers from Tenderers participating in the negotiation phase of this RFP process.

26.4 Without limiting its other rights under this RFP, in the event that the Department concludes that during negotiations a Tenderer has retracted, or attempts to retract, any part of its tendered offer, the Department reserves the right to:

a. exclude that Tenderer's Proposal from further consideration;
b. terminate this RFP process;
c. re-enter negotiations or parallel negotiations with other Tenderers; or
d. exercise any other right reserved to the Department under law or elsewhere in this RFP.

27. DEBRIEFING

27.1 After the award of any resultant Contract, the Department will notify all unsuccessful Tenderers of the outcome of the RFP process.

27.2 All Tenderers will be offered the opportunity for a debriefing on their Proposal.

27.3 Tenderers will be debriefed against the Evaluation Criteria contained in this RFP. Tenderers will not be provided with information concerning other Proposals.

28. COMPLAINTS PROCEDURE

28.1 Complaints in relation to this RFP process should be made in writing and directed to the Complaints Officer at procurement.advice@health.gov.au. The Complaints Officer is able to receive complaints under the *Government Procurement (Judicial Review) Act 2018* (Cth).

28.2 Complaints will be handled by the Department in accordance with the Department's Procurement Complaints Procedures which are available at About Us

PART 4 – CONDITIONS OF TENDERING

29. OWNERSHIP AND USE OF PROPOSAL DOCUMENTS

29.1 All Proposal documents (including paper and electronic copies) become the property of the Department on submission.

29.2 Without prejudice to anything agreed in any resultant Contract, clause 27.1 does not affect any intellectual property rights that may exist in a Proposal.

29.3 Without prejudice to any other right of the Department under this RFP or at law, the Department may copy, amend, disclose or allow the disclosure of, or otherwise deal with, a Proposal or any information contained in or relating to any Proposal (at any time) for any of the following purposes:

a. the RFP process, evaluating and clarifying Proposals;
b. negotiation of the resultant Contract with the Tenderer or any other Tenderer;
c. managing any resultant agreement with the Tenderer or any other Tenderer;
d. addressing any dispute concerning the RFP process;
e. audit, governmental and Parliamentary reporting requirements; and
f. responding to any disputes about this RFP process or requests from Parliament or a Parliamentary Committee.

29.4 The Department may make copies of the Proposal as necessary for its purposes.

30. INTELLECTUAL PROPERTY RIGHTS IN RFP

30.1 All intellectual property that exists in the information contained in this RFP, or any related or attached material, remains the property of the Department.

30.2 Each Tenderer is permitted to use this RFP for the purpose only of compiling its Proposal and, in the case of the Tenderer(s) selected through this RFP process, for negotiating the resultant Contract with the Department.

31. SMALL TO MEDIUM ENTERPRISES (SMES)

31.1 The Australian Government is committed to *Public Governance, Performance and Accountability Act 2013* (Cth) non-corporate Commonwealth entities sourcing at least 10 per cent of their purchases by value from SMEs. For the purpose of this clause an SME is an Australian or New Zealand firm with fewer than 200 full-time equivalent employees.

31.2 Tenderers are encouraged to include the participation of SMEs in their Proposals.

32. AUDIT AND ACCESS

32.1 The attention of Tenderers is drawn to the *Auditor-General Act 1997* (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.

32.2 In addition to the Auditor-General's powers under the *Auditor-General Act 1997* (Cth), if a Tenderer is chosen to enter into a resultant Contract, the Tenderer will be required to provide the Auditor-General or an authorised person with access to information, documents, records and Department assets, including those on the Tenderer's premises. This will be required at reasonable times on giving reasonable notice for the purpose of carrying out the Auditor-General's functions and will be restricted to information and assets which are in the custody or control of the Tenderer, its employees, agents or Subcontractors, and which are related to the resultant Contract. Such access will apply for the term of the Contract and for a period of 7 years from the date of expiration or termination of the Contract.

32.3 Tenderers should obtain, and will be deemed to have obtained, their own advice on the impact of the *Auditor-General Act 1997* (Cth) on their participation in the Proposal.

33. FREEDOM OF INFORMATION AND OTHER RIGHTS TO ACCESS INFORMATION

33.1 The attention of Tenderers is drawn to the *Freedom of Information Act 1982* (Cth), which gives members of the public right of access to documents in the possession of the Commonwealth and its agencies.

33.2 The Act extends as far as possible the right of the community to access information (generally documents) in the possession of the Commonwealth, limited only by exceptions and exemptions necessary for the protection of essential public interests and the private and business affairs of persons in respect of whom information is collected and held by departments and public authorities.

33.3 Rights of access also exist under other legislation, including the *Ombudsman Act 1976* (Cth). Courts also have legal rights to access a wide range of information.

33.4 Tenderers should also be aware of the *Australian Information Commissioner Act 2010* (Cth), which established the Office of the Australian Information Commissioner to perform freedom of information, privacy and information policy functions.

34. PRIVACY

34.1 Tenderers are advised that it is Commonwealth policy to ensure that there is no loss of privacy protection when a Commonwealth entity contracts for the delivery of services.

34.2 Without limiting any obligations under the *Privacy Act 1988* (Cth), successful Tenderer(s) will be required under the Contract to agree not do an act, or engage in a practice, that would breach an Australian Privacy Principle under the *Privacy Act 1988* (Cth) if done or engaged in by a Commonwealth entity to which the Australian Privacy Principles apply. Tenderers selected as a result of this RFP process will also need to agree to impose those same obligations on any Subcontractor engaged by the Tenderer.

35. CONFIDENTIALITY

35.1 The Department will, subject to this RFP, including clauses 33.2 and 33.3, endeavour to treat the following information as confidential:

a. all Proposals received prior to the award of a resultant Contract;
b. all unsuccessful Proposals, following the award of a resultant Contract;

c. all successful Proposals, following the award of a resultant Contract but only to the extent that:
   i. the successful Tenderer requests that specific information in their Proposal be kept confidential; and
   ii. the Department has determined that specific information is to be kept confidential in accordance with the Confidentiality Throughout the Procurement Cycle from the Department of Finance and has agreed, pursuant to the resultant Contract with the successful Tenderer, to keep that information confidential.

35.2 The Department will not be taken to have breached any obligation to keep information provided by Tenderers confidential to the extent that the information:

a. is disclosed by the Department to its advisers, officers, employees or subcontractors solely in order to conduct this RFP process or to prepare and manage any resultant Contract;
b. is disclosed to the Department's internal management personnel, solely to enable effective management or auditing of this RFP process;
c. is disclosed by the Department to the responsible Minister;
d. is disclosed by the Department in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
e. is shared by the Department within the Department's organisation, or with another Commonwealth entity, where this serves the Commonwealth's legitimate interests;
f. is authorised or required by law to be disclosed;
g. is disclosed as agreed by the Tenderer;
h. is disclosed to meet the Department's reporting or accountability requirements, including, without limitation:
   i. under the Public Governance, Performance and Accountability Act 2013 (Cth) or other legislation;
   ii. to the Australian National Audit Office or any other auditor appointed by the Department;
   iii. in accordance with the provisions that require notification of Commonwealth contracts on the AusTender website;
   iv. to the Commonwealth Ombudsman; or
   v. is in the public domain otherwise than due to a breach of the relevant obligations of confidentiality.

35.3 Tenderers should be aware that the Department, as a non-corporate Commonwealth entity, is subject to specific accountability requirements, which support internal and external scrutiny of its tendering and contracting processes. These include:

a. the policy of the Commonwealth to publish details of relevant entity agreements, contracts and standing offers with an estimated value of $10,000 or more on the AusTender website;
b. the requirement to report details of Commonwealth contracts valued at $100,000 or more in accordance with the *Senate Order on Departmental and Agency Contracts*, including:
   i. name of the service provider and the subject matter of the Contract;
   ii. total value of the Contract; and
   iii. whether the Contract contains clauses that are confidential, and if so, the reasons for confidentiality;
c. the requirement to publish information about certain procurements in Annual Reports; and

d. the requirement to make available, on request, the names of any subcontractors engaged to perform services in relation to a Commonwealth contract (as such, Tenderers should inform all potential Subcontractors that their participation in fulfilling a Commonwealth contract may be publicly disclosed).

36. ENVIRONMENTAL POLICY AND PROCUREMENT

36.1 The Commonwealth aims to improve the implementation of ecologically sustainable development (**ESD**) within its agencies.

36.2 In support of this aim, the Department is committed to fostering the sustainable use of the Earth's resources and will implement and maintain an environmental management system to ISO14001, with the following key areas:

a. compliance with all relevant environmental legislation, regulations, policies and other initiatives to which it subscribes;
b. integrating environmental management into business decision making at all levels;
c. reducing cost through better resource usage and waste management;
d. setting objectives and targets for continuous improvement;
e. monitoring, reporting and reviewing achievements;
f. exploring best practice and innovative environmental management approaches to the use of technology, property and related resources; and
g. building an environmentally aware business culture.

36.3 The Department's procurement activities are a key means of implementing its environmental policy.

37. MATERIAL CHANGE TO TENDERER

37.1 A Tenderer must notify the Department if, following lodgement of its Proposal, there occurs:

a. an event that has the effect of materially altering either the composition or control of the Tenderer or the business of the Tenderer; or
b. any material change to the compliance status of the Tenderer against this RFP; or
c. any material change to the proposed basis on which the Tenderer will deliver the Services, or have access to the necessary and appropriate skills, resources, nominated key personnel, nominated Subcontractors or corporate or financial backing to provide the Services, on the terms of the Draft Contract.

37.2 If the Department receives notice, or becomes aware of an event under clause 37.1a, the Department may allow (on terms it considers appropriate) the substitution of the Tenderer with another legal entity upon receipt of a joint written request from or on behalf of the Tenderer and the other legal entity. If the Department allows the substitution, it will evaluate the Proposal in its original form prior to the event, except that the impact of the event on the information provided in the Proposal may be taken into account.

37.3 If the Department receives notice, or becomes aware of an event under clause 37.1b or 37.1c, or the Commonwealth does not allow substitution, or substitution is not requested, under clause 37.1a, the Department may either exclude the Proposal from consideration or consider the Proposal taking into account the impact of the changed circumstances on the information provided in the Proposal.

38. CONFLICT OF INTEREST

38.1 Tenderers should represent and declare in the Tenderer Deed any conflict of interest that exists at the time of lodging their Proposal.

38.2 If at any time prior to entering into a resultant Contract for the Services, an actual or potential conflict of interest arises or may arise for any Tenderer, other than that already disclosed, that Tenderer should immediately notify the Department in writing.

38.3 If any actual or potential conflict is notified, or the Department becomes aware of any actual or potential conflict, the Department may:

a. disregard the Proposal submitted by such a Tenderer;
b. enter into discussions to seek to resolve such conflict of interest; or
c. take any other action it considers appropriate.

39. TENDERER BEHAVIOUR

39.1 Tenderers must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of Proposals:

a. Engage in misleading or deceptive conduct or make any false or misleading or deceptive claim or statement;
b. improperly obtain Confidential Information;
c. receive improper assistance from any existing or former officer or employee of the Department;
d. engage in collusive tendering, anti-competitive conduct, unlawful, unethical or other similar conduct with any other Tenderer or other person;
e. attempt to improperly influence an officer or employee of the Department or violate any applicable laws regarding the offering of inducements; or
f. approach any officer or employee of the Department other than in the manner set out in this RFP;
g. engage in, procure or engage others to engage in, any activity that would result in a breach of the Lobbying Code of Conduct 2013 published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
h. otherwise act in an unethical or improper manner or contrary to any law.

39.2 The Department may exclude a Proposal from consideration if the Tenderer fails to comply with the requirements set out in this clause 39.

40. COST OF PREPARING AND SUBMITTING PROPOSAL

40.1 To the extent permitted by law, participation in this RFP process is at the Tenderer's sole risk, cost and expense, and in no circumstances will the Department be responsible for any costs incurred by a Tenderer in preparing a Proposal, or associated expenses related to this RFP.

41. TENDERERS TO INFORM THEMSELVES

41.1 Tenderers are deemed to have:

a. examined this RFP, and any other documents referenced or referred to in this RFP, and any other information made available in writing by the Department to Tenderers for the purposes of submitting a Proposal;
b. examined all other information which is obtainable by the making of reasonable and timely inquiries and relevant to the risks, contingencies and other circumstances having an effect on their Proposal;
c. satisfied themselves as to the correctness and sufficiency of their Proposal, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
d. satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at Schedule 4;
e. obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFP process;
f. made their own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments; and
g. examined AusTender, including the AusTender Terms of Use.

41.2 It is the responsibility of Tenderers to obtain all information necessary or convenient for the preparation of their Proposal.

41.3 Tenderers must not rely, and are deemed not to have relied, upon any statement or representation by the Department, whether before or after the date of this RFP, in connection with this RFP or this RFP process, unless that statement or representation is made in writing by the Contact Officer for this RFP.

41.4 Tenderers should obtain their own legal and other professional advice on this RFP and its requirements including in respect of the potential rights and obligations in respect of the Draft Contract and should not construe this RFP as investment, legal, tax or other advice.

42. NO CONTRACT OR UNDERTAKING

42.1 Nothing in this RFP or in any Proposal or by the submission of a Proposal (in part or together) creates, or is to be construed to create, any binding contract or other understanding (including any form of contractual, quasi-contractual, restitutionary rights or other legal relationship (express or implied) between the Department and any Tenderer unless and until a resultant Contract (if any) is signed by the Department and a successful Tenderer.

42.2 Clause 42.1does not apply to a Tenderer Deed executed by a Tenderer.

43. ACCEPTANCE

43.1 Selection of the preferred Proposal will be subject to the execution of a Contract between the Commonwealth and the successful Tenderer substantially in the form of the Draft Contract at Schedule 7.

43.2 Neither the lowest priced Proposal, nor any Proposal, will necessarily be accepted by the Department.

44. THE DEPARTMENT'S RIGHTS

44.1 The Department reserves the right to:

a. vary the timing and processes, if any, referred to in this RFP;
b. change or suspend the RFP process;
c. amend or vary this RFP or the RFP process, including the Draft Contract;
d. allow any Tenderer to change its Proposal at any time;
e. shortlist Proposals;
f. terminate the RFP process where it is, in the opinion of the Department, in the public interest to do so;
g. exclude any Proposal from consideration where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. the Tenderer does not meet a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. the Tenderer is not fully capable of undertaking the Contract substantially in the form of the Draft Contract;
    iv. this RFP otherwise allows for the exclusion of the Tenderer; or
    v. the Proposal does not represent value for money;
h. enter into a contract or other binding relationship outside the RFP process with a person on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a Minimum Content and Format Requirement, Condition for Participation or Essential Requirement;
    iii. no Tenderer is fully capable of undertaking the Contract substantially in the form of the Draft Contract; or
    iv. no Proposal represents value for money;
i. enter into a contract on terms different to that specified in this RFP;
j. add a Tenderer or select and negotiate with a third party who has not submitted a Proposal on such terms as the Department accepts without prior notice to any Tenderer where in the opinion of the Department:
    i. it is in the public interest to do so;
    ii. no Tenderer meets a mandatory requirement;
    iii. no Tenderer is fully capable of undertaking the Contract; or
    iv. no Proposal represents value for money;
k. call for new Proposals;
l. publish or disclose the names of Tenderers (whether successful or unsuccessful);
m. allow or not allow a Related Body Corporate to take over a Proposal in substitution for the original Tenderer;
n. enter into negotiations with any Tenderer; or
o. cancel, add to or amend the information, requirement, terms, procedures or processes set out in this RFP.

44.2 To the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFP process, including instances where:

a. a Tenderer is not engaged to undertake the provision of the Services;
b. the Department decides not to enter into any resulting Contract with any Tenderer or at all;

c. the Department exercises or fails to exercise any of its other rights under or in relation to this RFP (whether or not the Department has informed a Tenderer of its exercise of the rights);
d. a Proposal or any other material or communication relevant to this RFP is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
e. the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements.

44.3 If the Department does vary this RFP or process, the Department will endeavour to inform any prospective Tenderers who have sought, or been issued with, this RFP of that change. A notice of the issue of an addendum will be published in the same manner as the original information about this RFP, including by notification on the AusTender website. Tenderers should regularly check the AusTender website for any updates or addenda to this RFP.

44.4 If clause 6.1 provides that this RFP process is a 'covered procurement', the Department will issue an addendum notifying Tenderers of any suspension of the RFP process.

44.5 To the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFP or any other matter arising by the Department exercising any of its rights.

45. COORDINATED PROCUREMENT

45.1 The Commonwealth has agreed to establish a coordinated procurement contracting framework to deliver efficiencies and savings from goods and services in common use by non-corporate Commonwealth entities who are subject to the *Public Governance, Performance and Accountability Act 2013* (Cth) or other legislation.

45.2 It is therefore possible that the Commonwealth may approve the procurement by the Department of some or all of the same goods or services as the Services under a coordinated process:

a. before the Closing Time; or
b. after the Closing Time but before any resultant Contract is signed with the successful Tenderer(s); or
c. during the period of any resultant Contract entered into as a result of this RFP.

45.3 If clause 45.2a applies, the Department reserves the right to discontinue this RFP process.

45.4 If clause 45.2b applies, the Department reserves the right to discontinue the Proposal process and not proceed to enter any contract as a result of this RFP.

45.5 If clause 45.2c applies, the Department may exercise its rights under any resultant Contract to terminate for convenience, without compensation for loss of potential profits.

46. COOPERATIVE PROCUREMENT (PIGGYBACKING)

Not Used

47. INTERPRETATION

47.1 If any part of this RFP conflicts with another part, the part higher in the following list will take precedence:

a. Part 1 – Overview, Background, Services Specifications and Proposal Lodgement, Part 2 – Information to be provided by Tenderers, Part 3 – Evaluation of Proposals and Part 4 – Conditions of Tendering;
b. Part 5 - Glossary;
c. SCHEDULE 7 – Draft Contract;
d. SCHEDULE 1 – Statement of Requirement;
e. SCHEDULE 2 – Tenderer Declarations, SCHEDULE 3 - Tenderer Response Information, SCHEDULE 4 – Statement of Non-Compliance, SCHEDULE 5 – Pricing Schedule and SCHEDULE 6 – Indigenous Participation Plan Template Response Form; and
f. any other document forming part of this RFP.

47.2 In this RFP, except where the contrary intention is expressed:

a. a reference to time, unless specified otherwise, is to the time in the Australian Capital Territory;
b. words importing a gender include each other gender;
c. words in the singular include the plural and vice versa;
d. a reference to A$, $A, dollar or $ is to Australian currency;
e. if any word or phrase is given a defined meaning, any other part of speech or other grammatical form of that word or phrase has a corresponding meaning;
f. a reference to a clause, paragraph, schedule or annexure is to a clause, paragraph, schedule or annexure to this RFP;
g. a reference to a person includes a natural person, partnership, body corporate, association, governmental or local authority, agency or other entity;
h. a reference to a statute, ordinance, code or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
i. the meaning of general words is not limited by specific examples introduced by including, ‘for example’ or similar expressions and the word ‘include’ is not a word of limitation; and
j. the term 'may' when used in the context of a right exercisable by the Department means that the Department may exercise that right in its sole and absolute discretion and the Department has no obligation to any Tenderer.

PART 5 - GLOSSARY

Term	Definition
ACT	Australian Capital Territory
AusTender	means the Australian Government online tendering system, located on the AusTender website
AusTender Terms of Use	means the terms of use for AusTender available at https://www.tenders.gov.au/?event=public.termsOfUse.
Commonwealth	Commonwealth of Australia
Contract	means a contract substantially in the form of the Draft Contract provided with this RFP, to be executed by the Department and the Contractor, as amended from time to time, and includes its schedules, annexures and attachments.
Closing Time	means the closing time and date of this RFP as specified at clause 9.1 of this RFP
Conditions for Participation	means the mandatory conditions (if any) identified in clause 12 of this RFP
Confidential Information	means information (whether or not owned by the Commonwealth) that: (a) is by its nature confidential; or (b) the receiving party knows or ought to know is confidential, but does not include information which: (c) is or becomes public knowledge other than by breach of contract or any other obligation of confidentiality; (d) is in the possession of a party without restriction in relation to disclosure before the date of receipt; or (e) has been independently developed or acquired by the receiving party
Contact Officer	means the contact person for all matters pertaining to this RFP process, as identified at clause 5 of this RFP
Department	means the Department of Health
Draft Contract	means the document attached as Schedule 7 to this RFP being the proposed Deed of Standing Offer and Official Order to be entered into between the Department and the successful Tenderer(s)
Essential Requirements	means the mandatory conditions (if any) identified at clause 14, and which a Tenderer must comply
Evaluation Criteria	means the criteria set out in clause 21 of this RFP that will be used to evaluate the Proposals received.
High Value Contract	means a contract where: (a) the Services will be delivered in Australia;

Term	Definition
	(b) the value of the Services is $7.5 million (GST inclusive) or more; and (c) more than half the value of the contract is being spent in one or more of the following industry sectors: i. building, construction and maintenance services; ii. transportation, storage and mail services; iii. education and training services; iv. industrial cleaning services; v. farming and fishing and forestry and wildlife contracting services; vi. editorial and design and graphic and fine art services; vii. travel and food and lodging and entertainment services; or viii. politics and civic affairs services.
Illegal Worker	means a person who: (a) has unlawfully entered and remains in Australia; (b) has lawfully entered Australia, but remains in Australia after his or her visa has expired; or (c) is working in breach of his or her visa conditions.
Indigenous Enterprise	means an organisation that is 50 per cent or more Indigenous owned that is operating a business.
Indigenous Participation Plan	means a plan detailing how the Tenderer will meet the minimum mandatory requirements for the Indigenous Procurement Policy (see template at SCHEDULE 6 – INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM – Indigenous Participation Plan Template Response Form).
Indigenous Procurement Policy	means the policy of that name, as amended from time to time, available on the Indigenous Procurement Website.
Indigenous Procurement Website	means the website at **www.dpmc.gov.au/ipp**.
Late Proposal	means any Proposal not received by Closing Time
Minimum Content and Format Requirements	means the mandatory content and format requirements identified in clause 13 of this RFP
Related Body Corporate	has the meaning given in section 9 of the *Corporations Act 2001* (Cth)
Remote Area	means the areas identified in the map on the Indigenous Procurement Website, as updated from time to time.
RFP	means this Request for Proposal
Satisfactory	means meets the conditions set out in Part 6.b of the Black Economy Procurement Connected Policy or, if the circumstances in Part 6.c of the Black Economy Procurement Connected Policy apply, the conditions set out in Part 8.b of the Black Economy Procurement Connected Policy.
Schedules	means all or any of the schedules to this RFP

Term	Definition
Services	means the Services described in the Statement of Requirement and clause 3 of this RFP
Statement of Requirement	means the description of the Services as set out in Schedule 1 of this RFP
Statement of Tax Record	means a statement of tax record issued by the Australian Taxation Office following an application made in accordance with the process set out at https://www.ato.gov.au/Business/Bus/Statement-of-tax-record/?page=1#Requesting_an_STR.
Subcontractors	means an entity that the Tenderer proposes to enter into a contract with to provide goods or services to the successful Tenderer(s) in relation to the Services or in order for the Tenderer to meet obligations under the resultant Contract
Proposal	means a response submitted by a Tenderer to this RFP
Tenderer	means an entity that submits a Proposal and includes a potential Tenderer.
Tenderer Deed	means the deed to be completed and submitted by Tenderers as part of their Proposal, as set out in SCHEDULE 2 – Tenderer Declarations of this RFP
Valid	means valid in accordance with Part 7.e of the Black Economy Procurement Connected Policy.

SCHEDULES

SCHEDULE 1 - STATEMENT OF REQUIREMENT

1. Context

The Commonwealth Department of Health aims to ensure the delivery of safe and effective COVID-19 vaccines to all Australians, as soon as they are available.

The Australian Government is building a diverse portfolio of investments to secure early access to promising vaccines. To date, the Commonwealth has entered into advance purchasing agreements with AstraZeneca for the supply of 33.8 million doses of the Oxford vaccine, with CSL for the supply of 51 million doses of the University of Queensland vaccine, Novavax for the supply of 40 million doses and Pfizer for the supply of 10 million doses should they be proven to be safe and effective. The Commonwealth has also joined the Gavi COVAX facility to purchase up to 25.5 million doses of safe and effective vaccines from a diverse global portfolio of vaccine candidates. The Department is negotiating agreements with additional vaccine suppliers.

Pending the success of vaccine candidates, it is expected that the first doses will be available in January 2021, with doses delivered in batches throughout 2021 and 2022.

2. Objectives of the Services

The Department is seeking to engage a collaborative partner to design, develop, and implement a software solution to enable granular and point in time visibility of COVID-19 vaccines across the vaccination delivery chain and to support the end to end user journey.

The end-to-end tracking for each vaccine is to start on the delivery of the vaccine dose to the Department from the relevant manufacturer, through logistics and distribution stages (i.e. the transportation and storage of the vaccine), to vaccine administration (i.e. receipt of the vaccine by the administer and the vaccination of a patient) and then to post-administration monitoring (i.e. adverse event monitoring). Note that this will require close engagement with distribution and logistics provider(s).

The Solution will need to use extracted data from existing systems and collate that data (i.e. the successful Tenderer is not required to collect primary sources of data – e.g. the Department's logistics service provider will be responsible for collecting the tracking data on each vaccine dose and vial while the vaccine is in its custody). The Solution must collate data from various sources and create a seamless tracking view for each dose and each vial (noting there will be multiple doses in each vial) from the time that it is delivered to Health to the time that the vaccine dose is administered, and then post administration.

The successful Tenderer must:

a. design and document the architecture of a full stack software solution to utilise data[1] from existing systems to enable visibility of end-to-end tracking of vaccines by the Department through a front -end user interface, and associated reports;
b. Identify gap in the data landscape to assist the Department in ensuring these gaps are filled or a solution is identified
c. develop and implement the designed Solution, which must be operational or "live" by early January 2021; and
d. provide maintenance, user support services and capability skills transfer for the Solution.

[1] The Department does not anticipate the underlying data systems themselves to be integrated, rather their data outputs to be integrated

e. Consider options to manage consumer demand for services, in consultation with the logistics and distribution supplier(s).

In the rapidly evolving context of the COVID-19 pandemic and its public health response, the Department recognises the role of industry expertise in informing the numerous interdependent design decisions to be made. As such, the Department wishes to select a successful Tenderer who must design, develop, implement, support, and maintain the Solution as collaborative partner with the Department. As the Department may need the Solution to evolve and change as the both epidemiological and public health responses to COVID-19 evolve, the chosen partner must be experienced, agile and fully collaborative in their approach.

Australian Cyber Security Centre Partner Program

- **The successful Tenderer must become an ACSC partner, if not already, before commencing work with the Department on the Solution (further information can be found at https://www.cyber.gov.au/acsc/register/large-organisations-and-infrastructure#no-back).**

3. Description of Services

3.1 Functional requirements

Purpose and functionality

A successful Solution would fulfil the purposes defined in Exhibit 1 (see section below). In particular, the three critical purposes are to:

a. Inform targeting of **public policy** interventions to increase **voluntary** uptake **of the vaccinations** (including by reviewing coverage and accessibility of chosen administration sites, timing, and funding), of both first and second doses;
b. Enable operational decisions to **flexibly adjust the distribution** of vaccination stock to match supply and demand for the vaccines (e.g., in the case of outbreaks, to redirect the vaccines to hotspot locations or to send fewer vaccine doses to locations that are proving to be bottlenecks); and
c. Inform interventions to **reduce wastage / improve efficiency** at administration sites (e.g., identify training needs, adjust inventory flow model, maintain appropriate target stock levels).

Tracking will be required at the dose level and at the vial-level, noting that there will be multiple doses in each vial. Also noting this may vary by vaccine candidate due to differences in labelling.

In outlining their approach to ensuring the above purposes of the Solution are met, Tenderers should detail how the functionality of their proposed Solution will enable the above purposes to be achieved. Exhibit 2 provides illustrative examples of functionality that may be suitable (note that these examples are illustrative only, – the primary marker of a successful solution remains its ability to meet the purposes in Exhibit 1).

For purposes 2-12 (Exhibit 2), the Solution may need to incorporate dynamic demand forecasts/ signals and static target population size data (e.g., from the Australian Bureau of Statistics); to allow supply-demand comparisons.

Exhibit 1: Purpose of data solution by objective and stage in value chain to be fulfilled by solution

[xx] Critical requirements

Solutions for vaccine and vaccination data consolidation and tracking can serve to inform 3 key areas across the value chain: policy and program design, program implementation, and public communications

	Policy and program design	Program Implementation	Public communications
Distribution and logistics	Inform ongoing vaccine platform choices/switching, with real-world information on cold-/freeze- chain integrity and performance Similarly, inform ongoing supply chain choices (e.g., capacity expansion or consolidation, vendor selection).	Inform interventions to reduce wastage / improve efficiency in distribution (e.g., to identify areas of weakness in the supply chain and target interventions) **Enable operational decisions to flexibly adjust the distribution of vaccination** stock to match supply and demand for the vaccines (e.g. redirect in the case of outbreaks or bottlenecks)	Enable communication of the progress/efficiency of vaccine rollout to stakeholders (and, where necessary, where bottlenecks are occurring) Provide transparency and confidence in availability of vaccines
Administration	**Inform targeting of public policy interventions to increase voluntary uptake** (including reviewing coverage, accessibility of chosen sites, times, funding), of both first and second doses Inform approach for subsequent waves of roll-out (i.e., population sequencing, scale, timing) Inform broader public health measures (e.g., restrictions), with uptake/expected immunity levels during roll-out progress	**Inform interventions to reduce wastage** / improve efficiency at administration sites (e.g. training needs, inventory flow model, target stock levels) Inform operational decisions to flex workforce (and demand generation activities) to match supply and demand Assurance that consumers are vaccinated with the correct vaccines, at the correct time	Provide consumer and business confidence in progress of vaccination towards herd immunity Inform targeting of interventions to maximise compliance to dose regimen Increase public awareness of how to get vaccinated
Post-administration	Inform ongoing vaccine selection in procurement decisions, with real-world safety information	Inform post-administration observation protocols Enable management of adverse events (e.g., research needs, health and social services)	Generate public confidence in safety of COVID-19 vaccines

Exhibit 2: Functionality of data solution by purpose and stage in value chain to be fulfilled by solution

Data solutions must be able to meet stated functionality requirements

	Purpose	Functionality (indicators; granularity; frequency; linkages)
Distribution and logistics	1. Inform ongoing vaccine **platform choices/switching**, with real-world information on cold-freeze- chain integrity and performance	Dose **wastage**, cold-freeze-chain **breaches**, **on time** delivery, delivery **in full**; by vaccine platform, by supply chain step, by geographic location, by vendor; low frequency (weeks-months)
	2. Similarly, inform ongoing **supply chain choices** (e.g., capacity expansion or consolidation, vendor selection).	Dose **wastage**, cold-freeze-chain **breaches**, **on time** delivery, delivery **in full**; by vaccine platform, by supply chain step, by geographic location, by vendor; low frequency (weeks-months)
	3. Inform interventions to **reduce wastage**/improve efficiency in distribution (e.g., to identify areas of weakness in the supply chain and target-interventions)	“” Dose wastage, cold-freeze-chain breaches, on time deliver, delivery in full; by vaccine platform, by supply chain step, by geographic location, by vendor; but moderate frequency (weekly)
	4. Enable operational decisions to **flex flow of stock** to match supply and demand (e.g., redirect in the case of outbreaks or bottlenecks)	**Dose volumes**; by vaccine platform, by supply chain step, by geographic location, by vendor, linked to scheduling requirements. intended end point; high frequency (hours-days)
	5. Enable **communication of the progress**/efficiency of vaccine rollout to stakeholders (and, where necessary, where bottlenecks are occurring)	[Combination of above]
	6. Provide transparency and **confidence in availability** of vaccines	**Dose volumes**; by vaccine platform, by geographic location; high frequency (daily); linked to scheduling requirements, intended end point
Administration	7. Inform targeting of interventions to **increase uptake** (including reviewing coverage, accessibility of chosen sites, times, funding), of both first and second doses	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time frequency; linked to stock availability, population data
	8. Inform **approach for subsequent waves** of roll-out (i.e., population sequencing, scale, timing)	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time

	Purpose	Functionality (indicators; granularity; frequency; linkages)
		frequency; linked to stock availability, population data
	9. Inform broader **public health measures** (e.g., restrictions), with uptake/expected immunity levels during roll-out progress	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time frequency; linked to stock availability, population data
	10. Inform operational decisions to **flex workforce** (and demand generation activities) to match supply and demand	**Number of individuals requiring vaccination**; by wave or consumer segment, by administration location, by vaccine platform; near real time frequency; linked to stock availability, scheduling requirements
	11. Inform interventions to **reduce wastage** / improve efficiency at administration sites (e.g., training needs, inventory flow model, target stock levels)	**Dose wastage**; by reason for waste, by vaccine platform, by administration location, by type of administration site, by administrator; near-real time frequency; linked to stock availability
	12. **Assurance** that consumers are vaccinated with the correct vaccines, at the correct time	**Dose timing and vaccine**; linked by individual
	13. Provide consumer and business **confidence** in progress of vaccination towards **herd immunity**	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time frequency; linked to population data
	14. Inform targeting of interventions to maximise **compliance to dose** regimen	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time frequency; linked to population data
	15. Increase **public awareness** of how to get vaccinated	**Number of individuals** by started and completed dose regimen, by vaccine; by demographic information, by administration location; near real time frequency; but linked to stock availability
Post-administration	16. Inform ongoing vaccine selection in procurement decisions, with real-world safety information	**Adverse events, by number** of people vaccinated; linked to batch number, by vaccine; linked to type/severity of adverse event, demographic information, relevant medical history; weekly

	Purpose	Functionality (indicators; granularity; frequency; linkages)
	17. Inform post-administration observation protocols	**Adverse events, by time elapsed** since administration; by batch number, by vaccine; by type/severity of adverse event, by demographic information, by relevant medical history; weekly
	18. Enable management of adverse events (e.g., research needs, health and social services)	**Adverse events, by type**/severity of adverse event, demographic information, relevant medical history; weekly
	19. Generate public confidence in safety and effectiveness of COVID-19 vaccines	[Combination of above]

Landscape of existing systems

The Solution will need to, on an ongoing basis, extract and link data from existing systems and data sources. For the Draft Contract (i.e. the Official Order that will be executed with the draft Deed of Standing Offer) the data sources and systems are:

- the Australian Immunisation Register (AIR) data in Health's Enterprise Data Warehouse
- the Department's logistics/distribution service provider(s) supply chain management system.

The proposed Solution will need to collate the relevant data to provide a consolidated view of the end-to-end tracking as described in the "Objectives of the Services" section above. This will require the use of identifiers at the batch, vial, dose, and delivery and location administration, to fulfil the purposes stated in Exhibit 1.

The proposed Solution does not require the vendor to fill gaps in the existing data landscape (i.e., it does not need to collect new primary data). However, the Solution must link the data so that it provides an end-to-end view of each vaccine dose and vial, and the successful Tenderer will be required to work with the Department and other agencies as required to identify such data gaps in order assist the Department in ensuring these gaps are filled (Exhibit 1).

The current systems that have vaccine related information are set out in Exhibit 3 below. With the exception of the AIR data in Health's Enterprise Data Warehouse (which is included as part of the Official Order), extracting data from these sources and integrating that information into the Solution, may be required by Health in accordance with a Service Order under the Official Order. Tenderers should provide costed options for that work.

Note: No personal identifying information will be required for the Solution, all information of a personal nature will be de-identified and/or aggregated and/or anonymised.

Exhibit 3: Current vaccine and vaccination system and data landscape (not exhaustive and may not be required for Solution).

System name	Operator	Policy owner	Purpose	Data collected
Australian Immunisation Register (AIR)	Services Australia	Department of Health - Immunisation & Communicable Diseases Branch AIR policy team	National register of vaccinations	Date of vaccination, vaccine brand, dose number, vaccination provider who administered the vaccine, vaccination provider who reported the vaccine to AIR, Medicare/AIR provider number, vaccination provider name, vaccination provider address, batch number (optional reporting), date the vaccination record was received by AIR, name of the school (optional – only applicable for school/adolescent vaccines). DOB of patient, patient address, Full Medicare card number including individual reference number, patient name, Indigenous status, gender. The AIR also records: - medical contraindications - natural immunity - if an individual is on a vaccine catch up schedule - if an individual is participating in a clinical trial
Vaccine Administration System (VAS)	Department of Health, Vaccine Suppliers, States and territories	Department of Health - Immunisation & Communicable Diseases Branch Immunisation procurement and contract management	Vaccine order management for the National Immunisation Program (NIP)	Supplier information; vaccine forecasts, fully vs partial order fill, monthly stock on hand, number ordered, details of delivered orders, cold chain breaches, shelf life, batch number, presentation. State/territory orders; volumes and vaccinations ordered
My Health Record	Australian Digital Health Agency	Digital Health and Services Australia Branch, Department of Health	Capture health information about an individual	DOB of patient, patient address, Healthcare Identifier Number (unique ID) Provider and organisation Healthcare Identifiers

System name	Operator	Policy owner	Purpose	Data collected
				Event summaries, hospital discharge summaries Immunisation history Pathology and Diagnostic Imaging reports Medication charts
AIR data in Health's Enterprise Data Warehouse	Department of Health	Department - Immunisation & Communicable Diseases Branch Immunisation Register Policy team	Australian Immunisation data	Date of vaccination, vaccine brand, dose number, vaccination provider who administered the vaccine, vaccination provider who reported the vaccine to AIR, Medicare/AIR provider number, vaccination provider name, vaccination provider address, batch number (optional reporting), date the vaccination record was received by AIR, date the record was last updated by AIR. DOB of patient, patient address, Full Medicare card number including individual reference number, patient name, Indigenous status, gender
Medirecord	Healthdirect	Department of Health, Preventative Health Section	Record reason for call to National COVID helpline MBS medicine wise support line	Numbers of call, reason for calls, number of follow up calls Adverse event call numbers
Database of Adverse Event Notifications (DAEN)	Information to be provided when available, if required for solution			
State and territory monitoring	Information to be provided when available, if required for solution			

System name	Operator	Policy owner	Purpose	Data collected
systems				

3.2 Non-functional requirements

Given the social, economic and public health importance of a COVID-19 vaccination program, and the anticipated limited initial supply of vaccines, there will be a low tolerance for system malfunction of the Solution or unavailability of the Solution during vaccine rollout.

The successful Tenderer will be required to meet the following requirements.

Stable release date

- The Solution must be operational (i.e. go "live") by early January 2021, in advance of when the first doses of a COVID-19 vaccine are projected to be delivered to the Department. At a minimum, functionalities for the three critical purposes described in clauses 1.1(i) to (iii) above must be achieved.
- Tenderers are to advise if there are any implementation considerations for the timing or availability of Solutions functions – for example, if it is expected that full functionality may not come online immediately but be phased in over time.

Secure Cloud Strategy

- The Department is obliged to comply with the Australian Government's position on cloud computing (Secure Cloud Strategy) (further information can be found at https://www.dta.gov.au/what-we-do/policies-andprograms/secure-cloud/).
- Subject to legislative and regulatory requirements, the Department is required to use cloud services for new ICT services whenever cloud services:

  (i) are fit for purpose;

  (ii) offer the best value for money; and

  (iii) provide adequate management of risk to information and ICT assets as defined by the Protective Security Policy Framework.

- To the extent that the Solution is hosted in the cloud, the successful Tenderer must comply with the Department's Secure Cloud Strategy at Annex A.

Security Management

- Security Management includes the processes, procedures, policies and tools that ensure the confidentiality and integrity of all information, data and IT services.
- The successful Tenderer must not and must ensure that specified personnel and any Subcontractor personnel do not, without the Department's prior written consent, transfer or disclose data or allow data to be transferred or disclosed outside of Australia.
- The successful Tenderer must cater for additional security requirements as may be required by the Department from time to time.
- The successful Tenderer must report any cyber security incidents to the department within 48 hours and provide the department with a robust Cyber Security Incident Management Plan
- The successful Tenderer must provide Security Management Services to ensure the confidentiality and integrity of the Solution is maintained in compliance with the Australian Government Information Security Manual (ISM) [https://www.cyber.gov.au/acsc/view-all-content/ism]
- The Solution must comply with the IT Security Policy and relevant Australian Government policies including, but not limited to the:

  - Australian Government Protective Security Policy Framework (PSPF)
  - Information Security Manual (ISM);
  - National Identity Security Strategy (NISS);
  - Australian Signals Directorate (ASD) Essential Eight at maturity level 2 at a minimum; and
  - Australian Security Intelligence Organisation (ASIO) T4 Protective Security Standards.

- The Solution must comply with all laws applicable to the processing of and access to data used in or created on the Solution and information including the:
  - Privacy Act 1988 (Cth) including as amended by the Privacy Amendment (Notifiable Data Breaches) Act 2017 (Cth);
  - Electronic Transactions Act 1999 (Cth);
  - Archives Act 1983 (Cth); and
  - Cybercrime Act 2001 (Cth).

- All Solution support and administration functions for the Solution must occur within Australia and must be accessed only by those explicitly authorised to work on the Solution account.

Timeliness of data availability

- The successful Tenderer will be required to design, develop, implement support (operate), transfer and maintain a Solution which enables fast transfer of data from existing sources.
- Data must be collected and made available at a frequency suitable to fulfil each of the purposes detailed (in clauses 1.1(i) to (iii))
- Data must be made available through ad-hoc reporting which can be generated by end users, with an option to include standardised reporting where required
- The successful Tenderer will be required to provide resourcing to provide reporting services initially, with long term capability anticipated to sit within the Department
- In responding to this requirement, Tenderers are to presume a high level of automation of data provision into the centralised system on a cyclical (e.g. overnight or more often) basis, and indicate on what timing data could be collated and made available to users (daily, weekly, etc) and any assumptions that have been made around limitations or considerations.

Data sources, integration & system architecture

- The Solution is required to provide a top-layer system to integrate data[2] from existing systems (Exhibit 3)
- The Solution must be decoupled from existing systems as much as possible (for example, an API based framework that enables data requests from individual Department systems), such that modifications of any individual system does not necessarily require modification of other systems.
- The Solution is required to function and utilise information from across Australia including rural and remote locations noting some of this information may need to be provisioned by the states and territories where required
- The Tenderer must support the Department in identifying novel sources of data that may be required to provide the functionality detailed above

Data quality

- The Solution must include data quality control and completeness measures

[2] The Department does not anticipate the underlying data systems themselves to be integrated, rather their data outputs to be integrated

- The successful Tenderer will be required to manage, to the extent possible, the quality of the data reported in the Solution. This will require the validation of data extracted by the Solution from relevant existing systems through appropriate processes
- The Solution must provide data validation for all data, no matter how it is sourced, at the time of capture. This includes, but is not limited to:
    - data completeness;
    - conformity to approved data formats and structures; and
    - referencing existing data to ensure integrity of the information being captured.

- This includes, for example:
    - ensuring that dates conform to an acceptable date range; and
    - ensuring when creating a new record that an existing record does not already exist; and
    - errors that are apparent from the data (including by reference to other existing data)

- The successful Tenderer must also have processes for notifying Health and any other person nominated by Health of any apparent error with the data.
- The successful Tenderer will not be liable or responsible for the accuracy of the data extracted from existing systems.

Availability

- The Solution environment must be configured in a highly available and redundant fashion in order to minimise the potential impact of any outage.
- The Solution must be available on a 24 x 7 basis, except during agreed downtime and maintenance windows.
- The Solution must have the ability to support testing of any of the Solution components with minimal or no disruption to business operations.
- When operating under a Disaster Recovery event, the Solution must continue to meet all agreed Service Levels.
- The Solution must be able to recover any lost data in order for business to continue unaffected.
- Components of the Solution must remain operational where those components are unaffected during scheduled maintenance windows, i.e. the Solution must remain operational with degraded components.

Backup and restore

- The Solution must provide backup capability that enables all data and software to be backed up and retrievable.
- The Solution must provide or support ability to perform scheduled and ad-hoc backup.
- The Solution must support backup processes that are configurable to vary which data and files are backed-up and how often (e.g. hourly, daily, weekly, monthly, quarterly, yearly, Mondays only etc.)
- The Solution must support backup processes that are non-disruptive to the Production Environment.
- The Solution must provide or support capability to enable restore of data and files.
- The Solution must be able to restore the data to the recent backup.
- The Solution must backup data frequently to prevent any data loss in an unexpected disaster and/or failure event.

Maintenance and User Support

- The successful Tenderer must be able to provide user support to manage and resolve ICT related issues for the Solution where the issues raised require IT assistance to resolve

- The successful Tenderer must be able to provide ongoing maintenance (e.g., bug fixes, resolving defects)

4. Collaboration model

Given the evolving nature of the COVID-19 pandemic, the Department wishes to select a partner to create, operate and transfer the Solution. The successful Tenderer will be required to collaborate with the Department and other agencies as deemed necessary by the Department to deliver the Solution.

a. **Responsibilities of the Tenderer**
The successful Tenderer will be responsible for designing, delivering and implementing a fit-for-purpose data Solution, along with associated maintenance and services, to meet the objectives and purposes stated above.

b. **Responsibilities of the Department**
The Department will be responsible for reasonable provision of access to systems and information as requested by the Tenderer or Tenderers throughout the design process.

The Department will provide an internal resource to act as a point of contact through the refinement of the design process, including supporting engagement with required stakeholders across the Commonwealth and State and Territory.

5. Ownership models

The Department is interested in comparing alternative ownership scenarios for the solution and the associated price implications. The two scenarios are:

- Ongoing ownership by the successful Tenderer (where the solution is hosted and provisioned by the vendor)
- Or a "build-operate-transfer" (BOT) approach (where ownership of the solution is handed over to the Commonwealth after an initial period of vendor-supported operations).

6. Deliverables/outcomes

The outcome of this RFP will be the selection of a successful Tenderer who must:

- work closely with the Department and relevant stakeholders to refine the design and document the architecture of for the proposed Solution, which includes an appropriate user interface (UI) to enable easy data extraction to meet the stated purposes;
- deliver and implement the Solution by early January; and
- provide ongoing maintenance and support of the Solution for the duration of the Draft Contract.

7. Proposed delivery dates for performance of the Services

Activity	Timing
Commonwealth Execution of Contract	Approx. 30 November 2020
Commencement of Services	On execution
Refined the design of the proposed Solution with input of the Department and other stakeholders as required (e.g., ADHA, Services Australia)	23-30 November
Usable system stress test	21 December 2020
Solution launched (deployment to live/production environment)	4 January 2021

Activity	Timing
Maintenance and support services	From 4 January 2021

8. Monitoring and reporting

- The Solution will be required to produce reports for the Department in order for the Department to review the effectiveness of the Draft Contract, and to assist with decisions on improvements that could increase the utility of the Solution to end users.
- The reports will also assist the Department to monitor the quality and effectiveness of the provision of the Services by the successful Tenderer.
- The reports produced by the Tenderer which must be delivered to the Department are required to:
    - support the Tenderer's contractual obligations to the Department;
    - provide details about the Tenderer's management of the Services and System administration with respect to agreed Service Levels; and
    - support reporting requirements of the Department.

- It is expected that the Tenderer will also produce reports for the Tenderer's own purposes to:
    - support the day-to-day operations of the Solution; and
    - allow the Tenderer to monitor the Solution for quality of service and to manage continual improvement of the Services.
    - The Solution must be able to provide ad-hoc reporting of any details of the Draft Contract, and/or any details of operation of the Solution to the Department.

- Other Reporting may be required as set out in the Draft Contract.

9. Additional Optional Functionality

If agreed by the parties, the Services may also include:

- The design, development and implementation of flexible dashboards, and other decision support tools
- Data availability to a third-party provider to develop flexible dashboards, reporting, and other decision support tools

Future addition of features to existing Solution

10. Term of the Contract including any options to extend

The Initial Term of the Contract will be 2 years. The Department also requires 3 options extend the Contract Term, and each option is to be of 1 year.

11. Annex A to Schedule 1 – Department's Coul

See separate document titled 'Cloud Security Policy'.

SCHEDULE 2 – TENDERER DECLARATIONS

The Tenderer must complete, sign and scan the declaration set out below and submit the declaration as part of its Proposal. This is a Minimum Content and Format Requirement.

THIS DEED POLL is made on the day of 2020

by _____

Name

ACN/ABN/ARBN

Short form name Tenderer

1. Declaration

The Tenderer declares that this deed is for the benefit of the Commonwealth of Australia as represented by the Department of Health (**Department**).

2. Definitions

In this deed terms have the same meaning as in Request for Proposal for the provision of a COVID-19 vaccine data solution (Health/20-21/7038) (**RFP**).

3. Offer and Change of Circumstance

The Tenderer offers to supply the Services described in this RFP on the conditions set out in this RFP for the price tendered. The Tenderer undertakes not to withdraw, vary or otherwise compromise this offer for a period of no less than six months from the Closing Time.

The Tenderer undertakes to promptly notify the Department of any change, after submission of its Proposal, to the basis upon which it will have access to the necessary skills or resources, or corporate or financial backing, to supply the Services.

4. Tenderer's Conduct

The Tenderer confirms that this Proposal:

- does not contain any false or misleading claim or statement; and
- has been compiled without the Tenderer:
    - engaged in misleading or deceptive conduct;
    - improperly obtaining Confidential Information;
    - engaging in any collusive bidding, anti-competitive or other unethical, improper or unlawful conduct;
    - violating any applicable laws or Commonwealth policies regarding the offering of inducements;
    - communicating with or soliciting information from any Department employee (or contractor) or ex-employee (or ex-contractor) other than the Contact Officer;
    - obtaining improper assistance from any Commonwealth employee or using Confidential Information improperly obtained;
    - approaching any officer or employee of the Department other than in the manner set out in the RFP;

- engaging in, or procuring others to engage in, any activity that would result in a breach of the *Lobbying Code of Conduct 2013* published by the Department of the Prime Minister and Cabinet and available at http://lobbyists.pmc.gov.au/conduct_code.cfm; or
- otherwise acting in an unethical or improper manner or contrary to any law.

The Tenderer warrants that it has not attempted and will not attempt, through its officers, employees or agents, to influence improperly any officer or employee of the Department in connection with the assessment of the Proposal.

The Tenderer warrants that it has complied with all relevant laws and with Commonwealth policy, in preparing and lodging its Proposal and in taking part in this RFP process.

5. Conflict of Interest

[Note to Tenderers: Strike through whichever option does not apply. Tenderers should refer to clause 38 of the RFP for further information

The Tenderer represents and declares that, having made all reasonable enquiries, it does not have any known actual or potential conflicts of interest concerning itself or a related entity in respect of this RFP, its Proposal or the provision of the Services referred to in the Statement of Requirement other than those specified below.

OR

The Tenderer

- represents that, having made all reasonable enquiries, the following represents its only known actual or potential conflicts of interest in respect of this RFP, its Proposal or the provision of the Services referred to in the Statement of Requirement:

[Insert details]

- advises that its proposed mitigation approach to manage this conflict of interest is as follows:

[Insert details]

6. Further representations

The Tenderer makes the following further representations to the Department:

- it is authorised to sell and/or support all products required in the performance of the Services relating to this Proposal;
- it has examined the AusTender Terms of Use which are obtainable on the AusTender website;
- it has examined this RFP, all documents referred to in this RFP and all other information made available to it and all applicable legislation and policies;
- it has examined all further information which is obtainable by making reasonable enquiries relevant to the risks, contingencies and other circumstances having an effect on its Proposal;
- it has satisfied itself as to the correctness and sufficiency of its Proposal, including quoted prices which are deemed to cover the cost of all matters necessary for the due and proper performance and delivery of the Services described in the Statement of Requirement;
- it has satisfied themselves as to the terms and conditions of the Draft Contract and its ability to comply with the Draft Contract (including by obtaining independent legal advice on the effect of its terms where appropriate), subject to its response at SCHEDULE 4 – Statement of Non-Compliance;

- it has obtained independent advice on the effect of all relevant legislation in relation to the Tenderer's participation in the RFP process;
- it has made its own independent assessments of actual workload requirements under any resultant Contract and all prices will be presumed by the Department to have been based upon the Tenderer's own independent assessments;
- it has relied entirely on its own enquiries and has not relied on any representation, warranty or other conduct by or on behalf of the Department, except as expressly provided in this RFP or in notices received by it; and
- it has accepted and has fully complied with the provisions of this RFP.

7. Acknowledgements

The Tenderer acknowledges that:

- the Department may exercise any of its rights set out in this RFP, at any time;
- the statements, opinions, projections, forecasts or other information contained in this RFP may change;
- this RFP is a summary only of the Department's requirements and is not intended to be a comprehensive description of it;
- neither the lodgement of the Proposal nor the acceptance of any Proposal nor any agreement made subsequent to this RFP will imply any representation from or on behalf of the Department that there has been no material change since the date of this RFP or since the date as at which any information contained in this RFP is stated to be applicable;
- to the extent permitted by law, neither the Department nor its officers, employees or advisers will be liable to any Tenderer on the basis of any promissory estoppel, quantum meruit or on any other contractual or restitutionary ground or any rights with a similar legal or equitable basis whatsoever or in negligence as a consequence of any matter or thing relating or incidental to a Tenderer's participation in the RFP process, including instances where:
    - a Tenderer is not engaged to undertake the provision of the Services;
    - the Department decides not to enter into any resulting Contract with any Tenderer or at all;
    - the Department exercises or fails to exercise any of its other rights under or in relation to this RFP (whether or not the Department has informed a Tenderer of its exercise of the rights);
- a Proposal or any other material or communication relevant to this RFP is not received in time, is corrupted or altered or otherwise is not received as sent, cannot be read or decrypted, or has its security or integrity compromised; or
- the Department makes information available or provides information to a Tenderer relating to projected future, current or historical requirements
- to the extent permitted by law, the Department will not be liable or in any way responsible for any failure to inform a potential Tenderer of a change relating to this RFP or any other matter arising by the Department exercising any of its rights; and
- the Department will have received this Proposal in reliance on this deed and that the Department may suffer loss if any of the representations, undertakings, consents or other statements in this Declaration or the Tenderer's Proposal are misleading or deceptive.

8. Corporate capacity

The Tenderer confirms that:

- it has the capacity to respond to this RFP;
- there are no restrictions under any relevant law to prevent it from so responding;
- it is financially viable; and

- the Tenderer:
    - being a corporation – is not under one of the forms of external administration referred to in Chapter 5 of the *Corporations Act 2001* (Cth) and has not had an order made against it for the purpose of placing it under external administration; or
    - being an individual – is not bankrupt and has not entered into a scheme of arrangement with creditors.

9. Security, probity and financial checks

The Tenderer:

- consents to the Department performing (and will procure all necessary consents to enable the Department to perform) such security, probity and financial investigations and procedures as the Department may determine are necessary in relation to the Tenderer, any consortium member, their employees, officers, partners, associates, Subcontractors or related entities; and
- agrees to provide at its cost, all reasonable assistance to the Department and its nominees in this regard.

10. Workplace Gender Equality Act 2012 (Cth)

Under Australian Government procurement the Tenderer is obliged to indicate whether or not it is covered by the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act). The Tenderer is covered by the WGE Act if it is a 'relevant employer', defined as being a non-public sector employer (including higher education institutions, trade unions and not-for-profit organisations) of 100 or more employees in Australia. For more information about the coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

[Note to Tenderers: Check the relevant box below. If you check box (a), please ensure your letter of compliance is attached to this declaration.]

☐ (a) Yes, the Tenderer is a relevant employer. The Tenderer has attached a current letter of compliance as part of this Proposal which indicates my compliance with the *Workplace Gender Equality Act 2012* (Cth).

☐ (b) Yes, the Tenderer is a relevant employer. The Tenderer will be providing a current letter of compliance prior to entering into any resultant Contract.

☐ (c) No, the Tenderer is not a relevant employer.

11. Terrorism

The Tenderer declares neither it, nor any of its personnel or any Subcontractor proposed in its Proposal, are listed as terrorists under section 15 of the *Charter of the United Nations Act 1945* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

12. Trade sanctions

The Tenderer declares neither it, nor any Subcontractor proposed in its Proposal, are named in the consolidated list referred to in Regulation 40 the *Charter of United Nations (Dealing with Assets) Regulations 2008* (Cth).

Note: The list is available from the *Department of Foreign Affairs website*.

13. Employee entitlements

The Tenderer represents that, having made all reasonable enquiries, there are currently no unsettled judicial decisions against the Tenderer (excluding decisions under appeal) relating to employee entitlements for which the Tenderer has not satisfied any resulting order.

14. Illegal Workers

The Tenderer declares that is does not engage Illegal Workers.

Note: see definition of "Illegal Workers" in the Glossary in Part 5 of this RFP.

15. Survival

This deed survives the termination or expiry of the RFP process.

16. Indigenous Procurement Policy

The Tenderer declares the following:

The Tenderer has or has had _____ [NIL OR SPECIFY NUMBER] contracts with the Commonwealth that included the Indigenous Procurement Policy mandatory minimum requirements.

For the contracts referred to in the para above (if any), the Tenderer has:

- fully met /
- partially met /
- not met /
- not applicable as Nil contracts undertaken,
- the Indigenous Procurement Policy mandatory minimum requirements.

[Note to Tenderers: Strike out the options that do not apply.]

The Indigenous enterprises referred to in the Indigenous Participation Plan submitted as part of Tenderer's Proposal are 50 per cent or more Indigenous owned.

[Note to Tenderers: If you are an incorporated joint venture, where the joint venture is at least 25 per cent Indigenous owned, include the following. If it does not apply you may strike it out.]

The Tenderer is a joint venture that is 25 per cent or more Indigenous owned.

[Note to Tenderers: Supply Nation maintains a list of enterprises that meet the definition of "Indigenous enterprises". If an enterprise is not listed with Supply Nation refer to section 1.8.1 of the Indigenous Procurement Policy for ways of ensuring an enterprise is an Indigenous enterprise.]

Black Economy Procurement Connected Policy

There are no mandatory clauses in the Black Economy Procurement Connected Policy for a Tenderer declaration for an approach to market for a panel arrangement. Refer to the Black Economy Procurement Connected Policy for optional clauses and seek advice from Legal and General Counsel Division or Procurement Advisory Services if required.

The Tenderer represents that:

- it holds a Valid and Satisfactory Statement of Tax Record from each Subcontractor that it proposes, as part of its Proposal, to engage to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive); and

- if it is the successful Tenderer, it will ensure that any Subcontractor not included in its Proposal that it subsequently engages to deliver the Services, where the estimated value of the Services to be undertaken by that Subcontractor is over $4 million (GST inclusive), will provide it with a Satisfactory Statement of Tax Record that is Valid at the time of entry into the subcontract.

Executed as a deed poll

Execution by a company incorporated in Australia

The following execution block should be used by a Tenderer that is a company incorporated in Australia.

Executed by **[**Name of company**]** in accordance with Section 127 of the *Corporations Act 2001*

Signature of director	Signature of director/company secretary (Please delete as applicable)
Name of director (print)	Name of director/company secretary (print)

Execution by an attorney

Where the Deed of Undertaking is executed by an attorney under a power of attorney on behalf of a company incorporated in Australia, the Tenderer should submit with its executed Deed of Undertaking a copy of the relevant power of attorney. Powers of attorney must be in the form of a deed executed in accordance with section 127 of the *Corporations Act 2001* (Cth).

Signed sealed and **delivered** by **[**company name**]** by its attorney under power of attorney [dated [date of power of attorney] registered number [registered number] book number [book number], who warrants that, as at the date of this deed, they have had no notice of revocation of the power of attorney

Signature of attorney	Signature of witness

Name of attorney (print) Name of witness (print)

SCHEDULE 3 – TENDERER RESPONSE INFORMATION

1. Tenderer's Profile

1.1 Tenderer's contact officers

Tenderers should provide details of their nominated contact officers in the following table:

Tenderer's primary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	
Tenderer's secondary contact officer	
Name	
Position	
Telephone number	
Mobile phone number	
Email address	
Postal address	

1.2 Tenderer's details

Tenderers should complete all details in the following table:

Tenderer's details	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
Is the Tenderer registered for GST?	Yes / No
ACN (if applicable)	
Details of principal place of business / head office	Please include street address, telephone

Tenderer's details	
(including street address and telephone)	
Date and place of incorporation or registration of business (if applicable)	

2. Subcontractor details

(a) Where Tenderers are proposing to use Subcontractors to deliver some of the Services, Tenderers should complete all details in the following table for each nominated Subcontractor.

(b) Tenderers should note that, under paragraph 7.21 of the Commonwealth Procurement Rules, the names of Subcontractors may be publicly disclosed and that it is the responsibility of Tenderers to secure Subcontractors' agreement to this.

Subcontractor 1	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

Subcontractor 2	
Business or trading name	
Full legal name	
Entity type (e.g. company, sole trader, incorporated association, statutory	

Subcontractor 2	
authority, partnership, trustee on behalf of a trust, or other (as specified))	
ABN (if applicable)	
ACN (if applicable)	
Details of principal place of business / head office (including street address and telephone)	
Details of the part(s) of the Services which will be delivered by the Subcontractor	

3. Tenderer's insurance

Tenderers should complete all details in the following table:

Public liability insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Professional indemnity or errors and omissions insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Workers' compensation insurance	
Name of insurer	
Policy number	
Expiry date	
Product liability insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Cyber Incident insurance	
Name of insurer	
Policy number	

Expiry date	
Amount of current cover	

Where the Tenderer's proposed Personnel are operating as an individual and/or include volunteers, Tenderers should also complete all details in the following table:

Disability income insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	
Voluntary workers' insurance	
Name of insurer	
Policy number	
Expiry date	
Amount of current cover	

4. Tenderer's Financial Viability

(a) The Tenderer should provide a summary of their financial viability.

(b) This may include data from or for a financial analysis of its operations including profitability, liquidity, insolvency, bankruptcy actions, working capital management efficiency, financial structure, debt coverage and return on investment.

(c) The Department may also request further information and undertake its own independent enquiries and assessment in relation to the Tenderer's financial viability.

5. Actions or Investigations

(a) The Tenderer should provide particulars of any petition, claim, action, judgement or decision that is likely to adversely affect its capacity to provide the Services.

(b) Tenderers should provide details of whether or not they are aware that they are under investigation, or the subject of court proceedings, in relation to a possible or actual breach of any relevant legislation, and if applicable, provide details of the same.

6. Collaboration model

Tenderers should detail how they plan to partner effectively with the Department to collaborate during the refinement of design process.

In presenting their approach, Tenderers should consider outlining the following:

(a) Which elements of the scope are most in need of input from the Department and other stakeholders;

(b) Which stakeholders should be involved in the process;

(c) The proposed interaction model with the Department and any other relevant stakeholders, including both working arrangements and how visibility/status updates will be provided;

(d) How the design process will be managed to ensure minimum time to viable solution design;

(e) How the Tenderers will bring the best of their expertise to the design phase, and profiles of the proposed team that the Tenderers would allocate to the design phase, including their relevant expertise and roles.

7. Service Delivery and Management

Tenderers should provide the following information:

7.1 Overall approach

A proposal on the overall approach the Tenderer will take into delivering the Services outlined in Schedule 1 – including reference to the infrastructure, software, including any COTS software, delivery methodology, procedures, staffing, and other support, if applicable, to be utilised in the delivery of the Services. This should address the three critical purposes in clauses 1.1(i) to (iii) of Schedule 1.

In presenting their proposed Solutions, Tenderers should include the following:

- the proposed high-level conceptual architecture of the Solution;
- the proposed technology choices, including and software, hardware, and/or cloud service, for each component of the architecture and considerations given to other alternative technology choices;
- the proposed licensing model for the software; and
- a brief explanation of the rationale behind the architecture and the choices made.

Tenderers should also include their proposed approach to supporting and maintaining the Solution.

Tenderers should also outline their proposed approach to managing the development of the Solution, including collaborating with the Department and other stakeholders.

The Tenderer should clearly state whether they can meet all of the Service requirements as set out in the Statement of Requirement, and if not, which they are unable to meet.

The Tenderer should include clear timelines and milestones for delivery, and state any deviations from the delivery dates set out in clause 7 Schedule 1 (State of Requirement).

7.2 Service Levels

Tenderers should include a list of the daily, weekly, and monthly metrics that will be reported to demonstrate effectiveness and completeness of process, including in what format these reports will be delivered and how they can be accessed;

7.3 Quality assurance

Tenderers should outline their approach to ensuring the quality, completeness, and availability of data will be maintained in the proposed Solution.

7.4 Contingencies

Tenderers should outline their approach to adapting to ensure the Services can be delivered, including;

- how flexibility will be incorporated into the Solution to manage the inclusion of new COVID-19 vaccines in the future;
- where solution roll-out of a set of vaccine doses is required earlier or later than forecast, depending on first vaccine availability and/or approvals;
- where one or more logistics and distribution partners are involved in the delivery chain;

- where data from a costed option is exercised for one or more existing systems to be integrated with the Solution

7.5 Ownership models

The Tenderer should also explain how their proposal differs under two solution ownership scenarios: ongoing ownership by the successful Tenderer (where the solution is hosted and provisioned by the vendor), and under a "build-operate-transfer" (BOT) approach (where ownership of the solution is handed over to the Commonwealth after an initial period of vendor-supported operations).

Tenderers should detail in their response their preferred option and advantages and disadvantage of that option for the Department.

7.6 Suggested Day 1 support

The Tenderer is welcome to provide a list (with explanation, where required) of requirements that should be in place in order for the Tenderer to be well positioned to commence work on Day 1. For example, access to systems and relevant documentation.

7.7 Extension to analytical/decision-support services

The minimum requirement for the data solution is for integrated/linked data and an appropriate UI to facilitate data querying/extraction. However, Tenderers should also detail how the following additional services could be supported by their solution (or be directly provided by their solution):

- Development and implementation of flexible dashboards, enhanced reporting, [reporting is covered in the base requirements] and other decision support tools
- Data availability to a third-party provider to develop flexible dashboards, enhanced reporting, and other decision support tools

8. Capacity

Tenderers should set out their organisational capacity to deliver the Services by providing details of the strategies for resourcing, in terms of staff, equipment and facilities, including the resources to be allocated for the delivery of the Services.

9. Past Performance

To assess the Tenderer's capability to deliver the Services, Tenderers should provide details of similar services provided within the last three years (if any). In addressing this requirement, Tenderers should include:

(a) the organisation(s) for whom the services were undertaken, including contact details;

(b) the nature of the project and the outcome achieved by the Tenderer;

(a) the resourcing and team provided on the project;

(c) the period over which the work was undertaken; and

(d) the value of the work undertaken.

10. Risk management

Tenderers should set out in their Tender response:

(a) the key issues and risks they consider are relevant to the provision of the Services;

(b) the Tenderer's suggested approach to the issue and risk;

(c) the Tenderer's and Department's roles in the suggested approach; and

(d) the Tenderer's risk management systems currently in place or proposed.

11. Personnel

The Tenderer should, in the table below, provide details of the personnel who will be used for the supply of the Services.

Name and position of Personnel	Role in the provision of the Services	Experience / qualifications	Availability

12. Referees

(a) Tenderers should provide details of at least two referees which can be contacted regarding work undertaken by the proposed personnel. References will be evaluated based on relevance of work completed as well as comments from the referee contacts.

(b) A Tenderer may provide contacts within the Department as referees. However, where a Department contact is involved in evaluating Proposals or advising the Proposal evaluation team they will be unable to provide a reference, in which case the Department may ask the Tenderer to provide details of an alternate referee.

(c) Without limiting paragraph 10.2, the Department reserves the right to contact persons other than those provided as referees by Tenderers.

13. Indigenous Participation Plan

(a) Each Tenderer must submit an Indigenous Participation Plan with its Proposal using the template in Schedule 6. The Indigenous Participation Plan should address:

(i) how the Tenderer intends on meeting the mandatory minimum requirements for the Indigenous Procurement Policy;

(ii) the Tenderer's current rate of Indigenous employment and supplier use;

(iii) the Tenderer's commitment to Indigenous participation. Some examples of the activities an organisation can take to demonstrate its commitment to Indigenous participation are set out in paragraph 4.7.1 of the Indigenous Procurement Policy; and

(iv) if any part of the Contract will be delivered in a Remote Area, how the Tenderer will ensure that its provision of the Services will deliver significant Indigenous employment or supplier use outcomes in that Remote Area.

(b) The mandatory minimum requirements can be met at:

(i) the contract-based level (see paragraph (c) below); or

(ii) the organisation-based level (see paragraph (d) below).

(c) To meet the mandatory minimum requirements at the contract-based level, by the end of the Initial Term of the Contract:

(i) at least 4 per cent of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 4 per cent of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, on average over the Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians, and a minimum percentage of the value of the work performed under the Contract must be subcontracted to Indigenous enterprises, so that both minimum percentages add up to 4 per cent, on average over the Initial Term of the Contract.

(d) To meet the mandatory minimum requirements at the organisation-based level, by the end of the Initial Term of the Contract:

(i) at least 3 per cent of the full time equivalent Australian-based workforce of the contractor must be Indigenous Australians, on average over the Initial Term of the Contract; or

(ii) at least 3 per cent of the value of the contractor's Australian supply chain must be subcontracted to Indigenous enterprises, on average over Initial Term of the Contract; or

(iii) a minimum percentage of the full time equivalent Australian-based workforce must be Indigenous Australians, and a minimum percentage of the value of the contractor's supply chain must be subcontracted to Indigenous enterprises, such that both minimum percentages add up to 3 per cent on average over the Initial Term of the Contract.

(e) The mandatory minimum requirements can be met directly or through subcontracts.

(f) The successful Tenderer's Indigenous Participation Plan will be attached to the resultant Contract, and the successful Tenderer will be required to comply with and report against the Indigenous Participation Plan during the term of that Contract.

14. Economic Benefit to the Australian Economy

Respondents should answer the questions below to enable the Department to consider the economic benefit of the procurement to the Australian economy.

RESPONDENT PROFILE

Does the Respondent have an Australian Business Number (ABN)	Y/N
Is the Respondent incorporated in Australia?	Y/N
If No, is the Respondent a foreign company registered in Australia	Y/N

How many current (full time equivalent) employees of your organisation are based in Australia?	

Describe any strategies you consider relevant to your proposed supply's economic benefit to the Australian economy
[max 300 words] *Examples of information potential suppliers might include, but are not limited to:* • *Lowest price, saving the tax payer;* • *Building, leasing or procuring infrastructure that supports Australian communities;* • *Providing skills and training that benefits Australian communities;* • *Employing workers in Australia;* • *Paying taxes in Australia;* • *The environmental benefit of the proposed solution to Australia, for example, low environmental impact through energy efficient inputs such as computers, air conditioning, telephones and paper;* • *Contributing to positive social outcomes in Australian communities;* • *Using of indigenous business;* • *Using SMEs in delivering goods and services, such as a subcontractor or supplier;* • *Sharing knowledge, skills and technology with SMEs; and* • *Using goods and services from a business that provides services of persons with a disability*

15. Other information

Tenderers should provide any other information that addresses the Evaluation Criteria set out in clause 21 of this RFP.

16. Draft Official Order

Tenderers are to provide as an attachment to their response to this RFP a draft Official Order, in the form of Schedule 4 to the Draft Contract (Official Order), including a draft Statement of Work for the Official Order. While the draft Statement of Work may take any form, it should be consistent with the content in Schedule 1 to the RFP (the Statement of Requirements) and the Tenderer's response. The draft Official Order should also attach any relevant usage or licensing conditions (eg cloud services usage / COTS licensing conditions) noting that (1) it is intended that the terms and conditions in the Draft Contract will take precedence to any such terms in accordance clause 1.3 (Order of Precedence), and (2) the incorporation of any such terms is subject to negotiations between the successful Tenderer and the Department.

SCHEDULE 4 – STATEMENT OF NON-COMPLIANCE

1. Statement of Non-Compliance

1.1 Where the Tenderer wishes to negotiate any provisions of the Draft Contract (Schedule 6), it should include in its response below details of:

- the provision that it wishes to negotiate;
- the alternative words that it proposes; and
- any increase in its Proposal price if the Department does not agree to the amendment.

1.2 The Department will consider any non-compliances or partial compliances in its evaluation of other risks.

1.3 If Tenderers do not submit a response to this Schedule, they will be evaluated on the basis that they agree with all the provisions of the Draft Contract.

1.4 The Department does not intend to permit a Tenderer to re-open any provision of the Draft Contract in negotiations that was not identified as an area of non-compliance or partial compliance in a Proposal.

Item reference	Nature of compliance (partially complies, does not comply)	Reasons for non-compliance or partial compliance and proposed alternative wording

2. Confidential Information

The Tenderer should specify any information which is contained in its Proposal, or which may be provided by it during this RFP process, that it considers should be protected as Confidential Information by the Department in respect of any resultant Contract. The Tenderer should also provide appropriate reasons why any such information should be protected as Confidential Information.

Tenderers should review the information available from the Department of Finance's website for further detail about what information may be protected as Confidential Information (see the Department of Finance's Confidentiality Throughout the Procurement Cycle).

Proposed Confidential Information (refer to RFP or Schedule clause)	Reason why this information should be protected as Confidential Information

SCHEDULE 5 – PRICING SCHEDULE

1. Pricing Schedule

1.1 The Tenderer should indicate, using the attached "Pricing Schedule.xlsx" file as a template, all fees, charges, and other costs which it would seek to be paid for the Services and discounts offered.

1.2 A breakdown of assumptions, variations or other qualifications relied upon for generating estimates should be provided.

1.3 The Department prefers that Tenderers lodge their pricing in Australian currency. Any pricing lodged in foreign currency amounts will be converted to Australian currency for evaluation purpose.

1.4 All amounts are to be expressed as GST inclusive.

1.5 Tenderers should provide itemised pricing information and proposed payment schedules detailing all fees, prices and charges related to each milestone or deliverable of the Services.

SCHEDULE 6 : INDIGENOUS PARTICIPATION PLAN TEMPLATE RESPONSE FORM

[INSERT NAME OF TENDERER]

1. **This is an Indigenous Participation Plan submitted as part of the Proposal in response to [INSERT RFP NUMBER] (RFP).**

2. **2If selected as the Contractor following evaluation of Proposals received in response to the RFP, [TENDERER] will meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy:**

at the contract-based level, in which regard at least:

- [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce deployed on the contracted project must be Indigenous Australians over the Initial Term of the Contract; and
- [INSERT] percentage of the value of the work performed under the Contract will be subcontracted to Indigenous enterprises over the Initial Term of the Contract; or

at the organisation-based level, in which regard at least:

- [INSERT] percentage of [TENDERER'S] full time equivalent Australian-based workforce will be Indigenous Australians over the Initial Term of the Contract; and
- [INSERT] percentage of the value of [TENDERER'S] Australian supply chain will be subcontracted to Indigenous enterprises over the Initial Term of the Contract.

[Note to Tenderers: Select which option(s) above apply based on the requirements set out in paragraphs 12(b), (c) and (d) in Schedule 3 of this RFP.]

3. **To meet the mandatory minimum requirements on and from 1 July 2016 for the purposes of the Indigenous Procurement Policy, [TENDERER] will undertake the following:**

[Note to Tenderers: Tenderer to insert details of how it will meet the mandatory minimum requirements (which may include details of its current workforce / supply chain) at either / both the contract / organisation level and how it will go about meeting the requisite percentages to meet the mandatory minimum requirements. Tenderers should note that the mandatory minimum requirements

are averages over the Initial Term of any resultant Contract, and will accordingly need to detail their approach to achieving the specified targets over the Initial Term.]

4. [TENDERER's] rate of Indigenous employment and supplier use as at the Closing Time is:

5. [TENDERER] demonstrates its commitment to Indigenous participation as follows:

6. [TENDERER] will meet the mandatory minimum requirements: directly; or through subcontracts.

[Note to Tenderers: Tenderer to detail its approach to meeting the mandatory minimum requirements directly or through subcontracts.]

Remote Area Contracts

7. A component of any resultant Contract will be delivered in a Remote Area. [TENDERER] proposes to ensure the Contract will deliver a significant Indigenous employment or supplier use outcome in that Remote Area as follows:

SCHEDULE 7 – DRAFT CONTRACT

See separate document titled 'Schedule 7 – Draft Contract'.