From: 522 s22 s22 :s47F :s 47F ; s22 To: s22

Subject: Dates for stakeholder consultation for the surgical guides and biomodels review with AHA

Good morning.

Please let me know if this time accommodates everyone. This meeting is to discuss the dates to stakeholder consultation/final report for the surgical guides and biomodels review with AHA.

I will not be able to attend however I have included my notes below.

My understanding is that stakeholders and sponsors should now be given a minimum 4 weeks to repond to the report. When taking into consideration shut down this would push the due date for responses out to 6 January.

Below is are some suggestions of new due dates to consider as a starting point for discussion. However this now runs into the new year and AHA capacity to accommodate any date changes needs to be discussed. It may be worthwhile noting this removes some urgency for the report to be

25 November: Report sent to stakeholders for comment (by AHA) with 4 weeks to respond + shutdown

15 December: draft report considered by PLAC

es provi Feedback from PLAC to AHA to incorporate changes to the report: date? verbal update from Jeff, with Minutes provided ASAP

(shutdown period 23 December to 3 January)

Friday 6 January (previously 9 December): Stakeholder comments on draft report due

Final report due 30 January (previously 22 December):

Kind regards,

s22

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From: s22

Sent: Tuesday, 22 November 2022 4:07 PM

To: \$22 ; \$47F ; \$ 47F Cc: ; \$22 ; \$22 ; \$22

Subject: RE: Feedback on SGBM draft report [SEC=OFFICIAL] **Attachments:** Draft report_PL review 21.11_s22 comments.docx

Hi All,

Please see attached my comments on the report.

Many thanks for a great report.

Kind regards,

s22

From: S22 @health.gov.au>

Sent: Tuesday, 22 November 2022 3:01 PM

To: safe @ahaconsulting.com.au>; safe @ahaconsulting.com.au>

Subject: Feedback on SGBM draft report [SEC=OFFICIAL]

c47E

s47F and s

As per meeting just now.

Thanks

s22

s22

Medical Adviser

Technology Assessment and Access Division

Health Resourcing Group

Australian Government Department of Health

Location: 595 Collins Street, Melbourne

GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.





From: s22

Sent: Tuesday, 22 November 2022 5:11 PM

To: s47F

Cc: s47E(d) ; s22 ; s22

Subject: RE: Feedback on SGBM draft report [SEC=OFFICIAL]

s47F and s

Further to our discussion and my feedback on your document, I think the following should also form part of stakeholder feedback:

I think \$\frac{s}{47F}\$, and other clinical experts as you see fit, should be asked to provide feedback on what item numbers listed in table 9 require guides and/or biomodels (and if so, a maximum number appropriate). They could also assist in defining simple and complex CMF surgery (which may be independent of MBS item numbers), and by so doing assist in improving Tables 18 and 19.

Thanks again for your ongoing hard work.

Best regards

s22

From: S22

Sent: Tuesday, 22 November 2022 4:00 PM

To: 947F @ahaconsulting.com.au>; 947F @ahaconsulting.com.au>

Cc: s47E(d) @Health.gov.au>; s22 @health.gov.au>;

@health.gov.au>; s22 @health.gov.au>

Subject: Feedback on SGBM draft report [SEC=OFFICIAL]

s^{47F} and s

As per meeting just now.

Thanks s22

s22

Medical Adviser

Technology Assessment and Access Division

Health Resourcing Group

Australian Government Department of Health

Location: s22 , 595 Collins Street, Melbourne

GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.





s22 From:

Sent: Tuesday, 22 November 2022 6:20 PM

To:

s47E(d) *s*²2 Cc: Subject: Feedback [SEC=OFFICIAL]

Attachments: Draft report_PL review 21.11_LB.docx

and splease find attached some edits in track changes. It is not essential you address my comments on the Lit Rev study findings - I think you have adequately covered the limitations of the clinical evidence in this report.

Kind regards,

s22

s22

THIS DOLLAR DE PARTINE DE PARTINE DE LA CONTROL DE LA CONT Director - Post-market Review Section Office of Health Technology Assessment and Policy Branch

Technology Assessment and Access Division | Health Financing Group

Australian Government Department of Health and Aged Care

@health.gov.au

Location: Sirius \$22

PO Box 9848, Canberra ACT 2601, Australia

s47F @ahaconsulting.com.au> From:

Monday, 21 November 2022 9:03 AM s22 s47E(d) s22 Sent:

To:

s 47F Cc:

Review of surgical guides and biomodels currently listed on the Prostheses List - Draft Report Subject:

Draft report PL review 21.11.docx Attachments:

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,

I am delighted to forward you a copy of the draft report.

We look forward to discussing this further at our meeting tomorrow.

Kind regards,

| Senior Consultant

Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

×

M: **s47**F E: **s47F** @ahaconsulting.com.au

W: www.ahaconsulting.com.au

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Self Right HEALTH AND ACED CARELY SILES OF THE ACED AND ACED CARELY SILES OF THE ACED ACED PLEASE NOTE: This email may contain confidential or legally privileged information. If you are not the intended recipient, any use, disclosure or copying of this email is unauthorised. If you have received this email in error, please advise the sender immediately and delete this email. From: s22

 To:
 s22
 ; s22
 ; s47F
 ; s 47F

 Cc:
 s22
 FLYNN, Elizabeth; s47F
 ; s47F
 ; s22

Subject: Canceled: Catch between the Department and AHA - Surgical Guides and Biomodels review

[SEC=OFFICIAL]

Importance: High

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

s22 From:

Sent: Friday, 11 November 2022 3:46 PM

@ahaconsulting.com.au; \$47F @ahaconsulting.com.au _s47E(d) To:

Cc:

Subject: Update analyses for Surgical Guides and biomodels

D1403 Updated tables Nov 22.xlsx **Attachments:**

Dear s47F

Would you find attached the updated data regarding patient level analyses of the utilisation report for Surgical Guides and Biomodels.

Please do not hesitate to contact us if you have further questions.

The additional data requested on Tuesday 08/11/22 during our meeting, will be provided next week.

Please note the attached sheet is considered Confidential Information covered by The Confidentiality, Conflict of

s22 From:

s22 :s47F : s22 ;s22 To: s22 :s47F

Cc: FLYNN, Elizabeth

Subject: Feedback from the Department to AHA on draft report for the surgical guides and biomodels review

[SEC=OFFICIAL]

Hello,

This meeting is for the Department to provide feedback to the AHA on the draft report for the surgical guides and biomodels review, in order to prepare the report to be sent to stakeholders for consultation on 25 November.

Please let me know if there is anyone that should attend that has been left off this invite.

Many thanks,

s22

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Page 1 of 1

to view host

From: s22

Sent: Tuesday, 8 November 2022 12:44 PM

To: S47F

Cc: 522 ; S22 ; S47E(d)

Subject: Quality assessment of studies included in the surgical guides and biomodels review

[SEC=OFFICIAL]

Hi s47F

One of your questions to the Department discussed on Friday regarded assessment of bias in studies. s22 may have mentioned quality assessment checklists can be used for studies included in the review. Those used in the past for post market reviews include checklists adapted from the NHMRC (2000), SIGN and GRADE assessment tools.

The link to the NHMRC website includes links to the tools suggested above and recommendations on which tool to use based on study type - <u>Assessing risk of bias | NHMRC</u>. Note: some of the links to SIGN tool are broken so here it is: Checklists (sign.ac.uk).

Please let me know if you have any further questions on this.

Many thanks,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care

Es22 | S22 @health.gov.au Location s22 160 Ann Street, Brisbane QLD 4000

PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

s22 From:

Sent: Tuesday, 8 November 2022 3:31 PM

To:

s47E(d) Cc:

Subject: Invoice for research protocol [SEC=OFFICIAL]

Hi ^{s47F}

I haven't seen an invoice for the research protocol yet. Have you sent one through? If so what email did you send it to?

Our departmental email to receive invoices has been updated to \$47E(d) . It is now an automated system so invoices should be sent as a PDF, with the subject line as the invoice number, and PO anyone

Ig Group

Jerams Branch

J Care

J 4000 number quoted on the invoice. I have also been told the system will fail if there is anyone cc'd as it is automated.

Cheers, s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

| **℃** s22 Location: s22 , 160 Ann Street, Brisbane QLD 4000

PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s22

Sent: Monday, 7 November 2022 3:52 PM

To: \$478

Cc: | s22 | s22 | s22 | s47E(d)

Subject: TRIM: RE: SGB review - additional data questions

Hi ^{s47F}

Thank you for this request.

I have forwarded it to our data expert ^{\$22} (Cced). ^{\$22} advises that we can provide this data from the HCM dataset. It should be available to you by this Friday at the latest.

I have also forwarded the invite to tomorrow's meeting to s22 and he will join at 10.15 to discuss any queries you may have. If we can't cover off on everything tomorrow you can arrange a subsequent meeting with him.

Best Regards

s22

From: ^{\$47F} @ahaconsulting.com.au>

Sent: Monday, 7 November 2022 10:31 AM

To: ⁸²² @health.gov.au>

Cc: SZZ @health.gov.au>; SATF @ahaconsulting.com.au>

Subject: SGB review - additional data questions

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi ^{s22}

Thanks for offering to facilitate an additional departmental data request. The following outlines the additional data sought to our previous extract (20220606 – Surgical guides and biomodels – Final Tables):

- 1. An update of the selected Surgical Guides and Biomodels, by Sponsor, by Financial Year table with Digital Dental Network data included
- 2. The Top 20 MBS codes for utilisation, separated for surgical guides and biomodels
- 3. Top 20 PMBS codes for utilisation, separated for surgical guides and biomodels
- 4. Utilisation by individual sponsor for top 20 MBS codes
- 5. Utilisation by individual sponsor for top 20 PMBS codes
- 6. Number of items used by top 20 MBS codes, separated for surgical guides and biomodels
- 7. Break down Private overnight hospital separations into:
 - a. Separations with a length of stay (LOS) of 1 day (or less)
 - b. Separations with a length of stay (LOS) of 1 or more days
 - c. Separations which included an admission to intensive care or high dependency unit (if possible)
- 8. Number of items used per hospital separation, separated by:
 - a. LOS of 1 day (or less)
 - b. LOS of 1 or more days.

We are happy to discuss this request further with your data team member if required.

Kind regards,

s47F

Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111 M: **s47F**

E: s47F @ahaconsulting.com.au

W: www.ahaconsulting.com.au

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From:

Sent: Friday, 4 November 2022 3:39 PM

To: \$47F

Cc: FLYNN, Elizabeth; s47E(d); s22

Subject: FW: Review of surgical guides and biomodels [SEC=OFFICIAL]

Attachments: Prosthesis letter2.docx

Hi s47F

Can you please confirm that AHA has received this correspondence (which was apparently sent to start and that it will be included as an input into the report?

Thanks

s22

From: FLYNN, Elizabeth

Sent: Friday, 4 November 2022 3:34 PM

To: \$22 ; \$22

Cc: \$22

Subject: FW: Review of surgical guides and biomodels [SEC=OFFICIAL]

FYI - could you ensure this gets to AHA

From:
@dayhospitalsaustralia.net.au

Sent: Friday, 4 November 2022 3:29 PM

To: FLYNN, Elizabeth < Elizabeth. Flynn@health.gov.au >

Cc: s47F

Subject: FW: Review of surgical guides and biomodels

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Elizabeth

As we discussed, on the phone, I received this important information regarding surgical guides, bio models and patient-specific plates from a key Oral and Maxillofacial surgeon after the due date.

I did forward the attached information on to s47F at AHA Consulting this morning.

Thank you for providing this opportunity to ensure that this information is received.

I'm sure s47F would be happy to speak to the consultants and or the DOHA on this issue

best contact via his PA s47F on s47F

Thank you

Kind regards

s 47F

Chief Executive Officer
BAppSc(Dist), MCNA, MAICD, AIMM, RN

mobile. s47F phone. s47F email s47F

email @dayhospitalsaustralia.net.au website. www.dayhospitalsaustralia.net.au mailing address. PO Box 102, Mitcham SA 5062





Day Hospitals Australia - Peak Body for the day hospital sector

From: s47F

s 47G

Sent: Wednesday, 2 November 2022 5:57 PM

<u>@daynospitaisaustralia.net.a</u>

Subject: Review of surgical guides and biomodels

From: s22

Sent: Friday, 4 November 2022 10:29 AM

To:

S47E(d) S22

Subject: FW: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Attachments: Biomodels and Surgical Guides - 20221031.xlsx

Hi s47F

Please find an updated dataset just forwarded to us.

Best Regards

s22

From: \$22 @health.gov.au>

Sent: Friday, 4 November 2022 10:26 AM

Subject: RE: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Good Morning all

Many apologies for the delay – please find attached the approved data for updating the tables mentioned below. As with the originally supplied data, the row level data is for internal use only.

Please let me know if you have any questions etcl

Cheers

s22

From: \$22 @health.gov.au>

Sent: Tuesday, 4 October 2022 5:10 PM

To: S22 @health.gov.au>; S22 @health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>;

@Health.gov.au>; s22 @health.gov.au>

Subject: RE: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Hi s22

I've discussed with s22 and the numbers from the admissions data can probably be updated fairly easily by the end of next week, if you are able to send the updated admissions data, or let me know if there's another way to access.

For the benefit of others, the paper included 2020-21 data from Qlik but the admissions data was up til June 2020.

Kind regards,

s22

Assistant Director – Drug Utilisation Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health Technology Assessment Policy Branch

Australian Government Department of Health and Aged Care

T: \$22 | M: \$22 | E: \$22 @health.gov.au

Location: Sirius Building s22

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: \$22 @health.gov.au>

Sent: Tuesday, 4 October 2022 2:56 PM

To: \$22 @health.gov.au>

@health.gov.au>

Subject: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Hi ^{s22}

I hope DUSC went smoothly last week. As you know we are involved in a review of surgical guides and biomodels for which you did a utilisation review for PLAC (attached with the original data tables). Do you have capacity to update the analyses with 2020-21 data?

In the 2020-21 FY there was a bug jump in utilisation (see below – note 2021-22 data is incomplete). It would be interesting to check if we can see what is driving this in patient level analysis (such as you have done for the 2018-19 and 2019-20 FYs in your original utilisation review). The overall analysis looks like it already included 2020-21 data.

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1	2018/2019	3,041	
2	2019/2020	3,867	
3	2020/2021	7,494	Chy Oby
4	2021/2022	6,087	90,69,0P

We have spoken to \$22 in HERD and the 2020-21 data is now complete to use.

Thanks, s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care

E s22 | ♣ s22 @health.gov.au Location s22 , 160 Ann Street, Brisbane QLD 4000

PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s22

Sent: Friday, 4 November 2022 11:00 AM

To: \$47F

S 47F ; s47E(d) ; s22

Subject: FW: SGB review meeting [SEC=OFFICIAL]

Attachments: Surgical guides and biomodels - Questions for the Department - 28.10.22 - GHAS Final.docx

Hi s47F

Ahead of your planned questions for our data people, please find attach responses to your previous questions (which I forwarded to \$22, our main data person, for input).

I incorrectly sent you a couple of emails earlier which I have recalled. Will call to discuss.

Thanks

s22

From: S22 @health.gov.au>

Sent: Friday, 4 November 2022 10:28 AM

To: s22 @health.gov.au>

Cc: SZZ @health.gov.au>; SZZ @Health.gov.au>

Subject: RE: SGB review meeting [SEC=OFFICIAL]

Hi ^{s22}

Please find attached our responses to the data questions – let me know if I have missed any or if you need more details etc

Cheers

s22

From: \$22 @health.gov.au>

Sent: Friday, 28 October 2022 1:19 PM

To: \$22 @health.gov.au>

Cc: SZZ @Health.gov.au>; S22 @Health.gov.au>

Subject: FW: SGB review meeting [SEC=OFFICIAL]

Hi s22

Please see attached list of questions from our consultant on the surgical guides and biomodels review.

There are a couple of data questions in there – if you have time could you provide some input as you see fit?

Cheers

s22

From: s47F @ahaconsulting.com.au>

Sent: Friday, 28 October 2022 11:54 AM

To: s22 @health.gov.au>

Cc: \$22 @health.gov.au>; \$47F @ahaconsulting.com.au>

Subject: SGB review meeting

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Hi s22

Thanks for forwarding the additional PHA submission information yesterday.

As discussed at our last meeting, we would like to take you up on the offer of a meeting with department representatives next week (preferably Friday 4 Nov) to discuss:

- emerging themes from the review
- some further questions we have (see the attached list of questions)

Could you let me know when it will suit the department to meet?

Kind regards,

s47F

s47F | Senior Consultant

Australian Healthcare Associates



Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

M:s47F E: 847F

@ahaconsulting.com.au

W: www.ahaconsulting.com.au



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s22 From:

; s22 ; s47F s22 ; s 47F ; s22 ; s22 To:

; s47F FLYNN, Elizabeth: \$47F Cc:

Subject: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join meeting S22

More ways to join:

Join from the meeting link

s22

Join by meeting number

Meeting number (access code): S22

Meeting password: S22

From: s22

Sent: Tuesday, 1 November 2022 12:31 PM

To: S4/F

S47E(d)

Subject: Timeframes for SGB review stakeholder consultation on draft report [SEC=OFFICIAL]

Hi ^{s47F}

Please see below timelines for after the draft report is due for stakeholder consultation, as was briefly mentioned in our meeting on 18 October. Let me know if there are any issues with timeframes for AHA.

- 18 November (or before start of business Monday 21 November): Draft report due to the Department
- 23 November: Department feedback on draft report to AHA
- 24 November: Meeting with the Department and AHA to discuss draft report and confirm suitability to be sent to stakeholders.
- 25 November: Report sent to stakeholders (by AHA). 2 weeks to respond limit 4 pages of text and 2 pages of tables.
- 9 December: Stakeholder responses due

Also when you send the draft report through, can you please cc s22 and s22 and PL review to ensure it gets to all relevant staff as soon as possible?

Kind regards,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

Es22 | S22 | Mealth.gov.au | Cocation | Coca

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: 522 s47F To s 47F Cc: · s22 SII Subject: RE: SGB review meeting [SEC=OFFICIAL] Date: Monday, 31 October 2022 12:27:00 PM Attachments: image001.png image002.jpg Thanks s47F I can see s22 is out of office until Wednesday which may be why you haven't heard a reply from him. I will check with the other Departmental attendee's on whether on whether the Thursday 3:30pm time would suit better, however is appears most can attend the Friday 9am time. Many thanks, s22 From: s47F @ahaconsulting.com.au> Sent: Monday, 31 October 2022 11:10 AM To: \$22 @health.gov.au> Cc: s47F @ahaconsulting.com.au>; s22 @Health.gov.au>; s22 @health.gov.au>; \$22 @Health.gov.au>: \$22 @health.gov.au>; s22 @health.gov.au> \$22 @health.gov.au> **Subject:** RE: SGB review meeting [SEC=OFFICIAL] REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe. Hi s22 The meeting wont go ahead tomorrow as it is a public holiday in Melbourne. I emailed on Friday to see if we could make a meeting for Friday. However, \$22 emailed back to say he could possibly make 9am Friday (although it is a clinic day for him). I responded that we could do after 3.30pm Thursday if that works better for the department. Could you confirm when best suits? Kind regards, s47F From: S22 @health.gov.au> Sent: Monday, 31 October 2022 12:05 PM To: S47F @ahaconsulting.com.au> Cc: S47F @ahaconsulting.com.au>: s22 @Health.gov.au>: s22 @health.gov.au>,s22 @Health.gov.au>;s22 @health.gov.au>; s22 @health.gov.au>: s22 @health.gov.au> **Subject:** RE: SGB review meeting [SEC=OFFICIAL] Hello all, I just wanted to check if the fortnightly catch-up between the Department and AHA will still go ahead tomorrow (I can see on the invite you are unable to attend s47F or will the meeting below be instead of the meeting tomorrow? and I will not make the Friday meeting, however s22 (who is acting for s22 this week) and s22 will be able to attend. Many thanks,

s22					
Post-market Review Section					
Location: \$22, 160 Ann Street, Brisb PO Box 9848, Brisbane QLD 4000, Austra Work hours: Mon, Tues, Wed 9a	nent Policy and Programs B Health and Aged Care nealth.gov.au ane QLD 4000 alia .m-3pm	ranch			
I acknowledge the traditional custorespects to elders past, present a		l waters where I live and work, and pay my			
From: s22		@health.gov.au>			
Sent: Friday, 28 October 2022 1	:35 PM				
To: ^{s47F}	@ahaconsulting	.com.au>			
Cc: s22	@health.gov.au>; s47	S- U			
@ahaconsulting.con	n.au>; ^{s22}	@Health.gov.au>; s22			
@health.gov.a	ı <u>u</u> >	1/2 Ch			
Subject: RE: SGB review meeting	g [SEC=OFFICIAL]	SED 198 CELL			
We can do 9am on Friday 4 Nov	– later is difficult for r	ne since I have clinical work that day.			
Does that work for you?		A A			
s22	17,47				
From: s47F	@ahaconsult	ng.com.au>			
Sent: Friday, 28 October 2022 1	1:54 AM	· -			
To: \$22	KY KY @	health.gov.au>			
Cc: s22	@health.gov.au>; s47	F			
@ahaconsulting.com	n.au>				
Subject: SGB review meeting) PK				
	his email originated from	outside our organisation. Only click links or open			
attachments if you recognise the sen Hi ^{\$22}	der and know the conten	t is safe.			
Thanks for forwarding the additi	onal PHA submission i	information yesterday.			
As discussed at our last meeting, we would like to take you up on the offer of a meeting with					
department representatives next week (preferably Friday 4 Nov) to discuss:					
 emerging themes from th 	e review				
 some further questions w 	e have (see the attach	ned list of questions)			
Could you let me know when it v	will suit the departmen	nt to meet?			
Kind regards,					
s47F					
Senior Consul					
	tant				
Australian Healthcare Associates					
Australian Healthcare Associates	5				

T: 1300 242 111 M: **s47F**

Page 2 of 3

W: www.ahaconsulting.com.au



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THIS DOUBLE OF ARTHUR OF THE PROPERTY OF THE P

From: s22

 To:
 \$22
 \$22
 \$47F
 \$ 47F

 Cc:
 \$22
 \$LYNN, Elizabeth; \$22
 \$47F
 \$47F

Subject: Canceled: Catch between the Department and AHA - Surgical Guides and Biomodels review

[SEC=OFFICIAL]

Importance: High

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

s22 From:

Sent: Monday, 24 October 2022 12:35 PM

To:

s47E(d) Cc:

TRIM: New due date for draft report [SEC=OFFICIAL] Subject:

Hi ^{s47F}

As discussed last week, the Department is happy to adjust the deliverable date for the draft report for the Surgical Guides and Biomodels review. The new date is Friday 18 November 2022 (or before start of business on Monday 21 November 2022).

Kind regards,

s22

s22

Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care
\$\frac{1}{2}\$ \$\f

s22 From:

Sent: Wednesday, 12 October 2022 1:17 PM

To:

s47E(d) s22 s22 Cc:

Subject: Updated data analysis [SEC=OFFICIAL] **Attachments:** PLAC 32 Surgical guides and biomodels.PDF

Hi s47F

As discussed, the Department is doing a small update to the data analysis for surgical guides and biomodels that was provided to you previously (I have attached again for reference). The update will include additional 2020-21 data in the second part of the report - the patient level analysis - which previously only used 2018-19 to 2019-20 data.

We are hoping to have the update completed before our catch-up next Tuesday.

Cheers,

past, present and future.

From: s22

Sent: Tuesday, 11 October 2022 10:33 AM

To: \$47F

S47E(d)

Subject: RE: SGB review [SEC=OFFICIAL]

Attachments: SGB review research protocol_Final.pdf JB feedback.pdf; Additional PL Contact List - SGBs.docx

Thank you s47F Please see attached some minor comments on the research protocol and additional stakeholders list to supplement the one originally provided.

Many thanks,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

Esc2 | September |

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

ERSED INDER

STITHAND ACED CARE

STITHAND ACED CARE

From: S47F @ahaconsulting.com.au>

Sent: Tuesday, 11 October 2022 8:44 AM

To: ^{S22} @health.gov.au>

Subject: RE: SGB review [SEC=OFFICIAL]

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Thanks 522

We have revised the Interview guides for the Clinical Experts to incorporate start our expert consultations today and am meeting with s47F this afternoon, so we may tweak it after we test it with s47F Of course, as mentioned, these are semi-structured guides and we will explore issues as we go.

I will arrange the invoice.

Kind regards, s47F From: S22 @health.gov.au>

Sent: Monday, 10 October 2022 3:59 PM

@ahaconsulting.com.au>

Cc: s47E(d) @Health.gov.au>; s22 @health.gov.au>;

s22 @health.gov.au>

Subject: RE: SGB review [SEC=OFFICIAL]

Hi s47F

I am just checking with the rest of the Department staff on the research protocol, however if s22 suggestions on the questions to stakeholders have been incorporated I think we are there. If you send the invoice, I will process once I have confirmation from the departmental delegate to pay the deliverable.

In regards to the COI, we had a question on whether a 'person' as referred to in your document could also mean an 'entity' such as a peak body or company. If not could you please make sure this is covered off in the document.

Many thanks,

s22

Post-market Review Section

RELEASED INDER

OR CARE

NATION AND AGED CAR Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

| 1 s22 **1** s22 @health.gov.au Location: s22 160 Ann Street, Brisbane QLD 4000 PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s47F @ahaconsulting.com.au>

Sent: Thursday, 6 October 2022 7:54 AM

To: \$22 @health.gov.au>

Subject: SGB review

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Hi ^{s22}

I am just following up on a couple of things:

- As we have now delivered the Research Protocol and it seems that it has been accepted, are you happy if I forward you our invoice for our first deliverable?
- Can you let me know when we might expect the Conflict of Interest form? Once we receive this, we can commence sending out forms and interview guides to the consults we have now scheduled.

Thanks and kind regards,

s47F | Senior Consultant

Australian Healthcare Associates

×

Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

M: **s47F** E:^{s47F}

@ahaconsulting.com.au

W: www.ahaconsulting.com.au

x x x

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s22 From:

Sent: Tuesday, 11 October 2022 4:01 PM

To:

s47E(d) s22 s22 Cc:

Subject: FW: Prosthesis List reforms - Post listing reviews - Biomodels and Surgical Guides

s22

[SEC=OFFICIAL]

Hi s47F

Please see below two additional clinical experts who wish to be contribute to the review.

Thanks,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

| 1 1 s22 @health.gov.au Location s22 , 160 Ann Street, Brisbane QLD 4000 PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s47F Sent: Thursday, 29 September 2022 9:18 AM To: s47E(d) @Health.gov.au> Cc: s47F @lh.org.au>

Subject: Prosthesis List reforms - Post listing reviews - Biomodels and Surgical Guides

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s47E(d) team,

s 47G

We would like to participate in consultations including the provision of product information as clinical experts. Please let us know how we might be able to make a submission for consultations.

Kind regards,

s47F

Head and Neck Cancer Research and Innovation Manager **Integrated Prosthetics & Reconstruction Operations and Project Manager**



119-143 Missenden Road Camperdown NSW 2050 PO BOX M33 Missenden Road NSW 2050

Phone: s47F

Email:s47F @lh.org.au Web: http://www.mylifehouse.org.au







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847F

Head & Neck Research & Innovation Manager

Phone: 847F

s22 From:

Sent: Monday, 10 October 2022 3:59 PM

To:

s22 Cc:

Subject: RE: SGB review [SEC=OFFICIAL]

Hi ^{s47F}

I am just checking with the rest of the Department staff on the research protocol, however if s22 suggestions on the questions to stakeholders have been incorporated I think we are there. If you send the invoice, I will process once I have confirmation from the departmental delegate to pay the deliverable.

In regards to the COI, we had a question on whether a 'person' as referred to in your document could also mean an 'entity' such as a peak body or company. If not could you please make sure this is covered off in the document.

Many thanks,

Post-market Review Section

ting Group ams Branch Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

| **1 S22** Location: s22 , 160 Ann Street, Brisbane QLD 4000 PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s47F @ahaconsulting.com.au>

Sent: Thursday, 6 October 2022 7:54 AM

To: S22 @health.gov.au>

Subject: SGB review

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Hi ^{s22}

I am just following up on a couple of things:

As we have now delivered the Research Protocol and it seems that it has been accepted, are you happy if I forward you our invoice for our first deliverable?

• Can you let me know when we might expect the Conflict of Interest form? Once we receive this, we can commence sending out forms and interview guides to the consults we have now scheduled.

Thanks and kind regards, s47F

| Senior Consultant | Australian Healthcare Associates



Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

M:s47F

E: s47F @ahaconsulting.com.au

W: www.ahaconsulting.com.au



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From: s22

Sent: Tuesday, 4 October 2022 11:09 AM

To:

S22 : S22 : S47E(d) : S22

Subject: FW: Clinical expert with industry links [SEC=OFFICIAL]

Hi ^{s47F}

Additional clinical expert as discussed.

s22

From: s47F @anzaoms.org>
Sent: Friday, 23 September 2022 6:18 AM

To: ⁵²² @health.gov.au>

Cc: s47F @gmail.com

Subject: Re: Clinical expert with industry links [SEC=OFFICIAL]

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Hi ^{s22}

Please meet s47F

. He is an Oral & Maxillofacial Surgeon with a commercial interest in a device company. He has agreed to be on the expert panel provided his conflict of interest is clearly declared.

Kind regards,

s47F

President of ANZAOMS

Oral & Maxillofacial Surgeon
BDSc (Melb), MBBS (Hons) (Melb),
PGDipSurg.Anat.(Melb), MDSc (OMS) (Melb)
FRACDS (OMS), FRCS (Edinburgh)



From: s22 @health.gov.au>

Date: Thursday, 15 September 2022 at 3:33 am

To: President s 47F

Subject: Clinical expert with industry links [SEC=OFFICIAL]

Medical Adviser

Technology Assessment and Access Division

Health Resourcing Group

Australian Government Department of Health

Location: \$22 595 Collins Street, Melbourne

GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

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s22 From:

Sent: Tuesday, 4 October 2022 1:42 PM

To:

s47E(d) s22 Cc:

Subject: CADTH review paper on 3D printing [SEC=OFFICIAL] CADTH 2019_3DPrinting overview of clinical use.PDF **Attachments:**

Hi s47F

Following on from the discussion in our catch up, attached is a CADTH review on clinical use of 3D printing that includes information on regulation in UK, US and Canada that may be useful.

Kind regards,

s22

From: @ahaconsulting.com.au>

Sent: Friday, 30 September 2022 3:51 PM

To: \$22

Cc: s47E(d) s22 s22 s 47F

Subject: SGB Review - Final research protocol and Conflict of Interest form

Attachments: SGB review research protocol_Final.pdf; Research protocol - Summary of changes.docx; Conflict

of Interest Declaration.docx; AHA Privacy Policy.pdf; AHA Confidentiality and conflict deed -

.pdf; AHA Confidentiality and conflict deed - S47F .pd

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Hi ^{s22}

Research protocol

Thanks for the very useful feedback session on the Research Protocol at our last meeting. I now attach an updated final version of the Research Protocol taking into account the suggested amendments. I have also attached a summary of changes made to the protocol for your reference.

Conflict of Interest form

Thank you for also sending through the Department's Conflict of Interest form. I have attached for your approval the AHA's adapted version of the Department form for your sign-off. As AHA is collecting this information, we have by necessity made some changes. We have also added a definition of conflict of interest and included the words perceived, potential or actual conflict of interest. We also refer to AHA's Privacy Policy (which I have attached for your information). Please let us know if you are happy for us to proceed using this form.

Additional Deeds of Confidentiality

I also attach the Deeds of Confidentiality for our newest team member, \$47F and our expert, \$47F

Communications

I have cc'd s22 into this email, as I am aware that you are not in the office today. I have also cc'd your requested email inboxes. Should I also include s22 or s22 in future emails?

Next meeting

I look forward to updating you with our progress at our meeting on Tuesday morning. Thank you for sending through the invite.

As always, please do not hesitate to contact me, if you wish to discuss anything further.

Kind regards,

s47F

| Senior Consultant

Australian Healthcare Associates



Level 6, 140 Bourke Street, Melbourne, VIC 3000

Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

M: **s47**F

E: @ahaconsulting.com.au

W: www.ahaconsulting.com.au



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From: s22

Sent: Tuesday, 13 September 2022 11:55 AM

To: \$47F

Cc: ; S22 ; S22

Subject: RE: Documents for AHA [SEC=OFFICIAL] **Attachments:** Report Template_PL review 12.9.22.docx

Hi s

I hope you are going well. Attached is the report template and below additional information for the review. I will send the COI form you requested through soon (we are just seeing if we can find a shorter form to use than our usual one).

In the template for the report there is a 'background' section. S22 has suggested the RFQ (introduction and background sections) has wording that can be used for the 'context for the review' and 'why review' sections. In addition, the PL reforms webpage and Post-listing review framework may provide some wording on the review process. If you have any questions about the report template please don't hesitate to ask.

Below are additional contact details for clinical experts.



Here is the Purchase Order (PO) number to reference when invoicing the Department: 4500149437

Research protocol feedback. For your information s22 (our medical advisor) is on leave next week so will be unable to attend the meeting on the 20th to provide feedback on the research protocol. If you find yourself in a position to send through the protocol or a draft this week (ideally before Friday), s22 has offered to send some comments through via email before he leaves. If you are unable that is ok (I know this is ahead of the due date), and we will provide feedback from other Departmental staff on the 20th. I will also set up a meeting when he is back on the 27th so that we can all check in.

If you have any questions or would just like to chat before \$22 goes on leave please let me know and I can organise.

Many thanks, s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

 Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: S22

Sent: Thursday, 8 September 2022 2:37 PM

To: \$ 47F ; \$22 ; \$47F

Cc: s47E(d) ; s22 ; s22 ; s22

Subject: RE: Documents for AHA [SEC=OFFICIAL]

Hi s 47F

We are reviewing the standard PBS medicine PMR template and making some changes so that it is more in line with this PL review. We will try and get this and the COI form to you early next week.

Kind regards

s22

From: ^{s47F} @ahaconsulting.com.au>

Sent: Thursday, 8 September 2022 2:26 PM

To: \$22 @health.gov.au>; \$47F

@ahaconsulting.com.au>

Cc: ^{s47E(d)} @Health.gov.au>; ^{s22} @Health.gov.au>; ^{s22} @Health.gov.au>; ^{s22}

@health.gov.au>

Subject: [ATTACHMENT UNSCANNED]RE: Documents for AHA [SEC=OFFICIAL]

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Hi s22

Received with thanks.

I think the only other item we discussed at the start-up meeting was the reporting template the department uses for post-listing reviews – if you could send through that would be great.

Also, if you have an example conflict of interest form that we could adapt for our consultations with experts that would be helpful.

Kind regards,

s4 7F

From: s22 @health.gov.au>

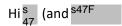
Sent: Wednesday, 7 September 2022 3:28 PM

To: 447F @ahaconsulting.com.au>; 547F @ahaconsulting.com.au>

Cc: s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22

@health.gov.au>; s22
@health.gov.au>;

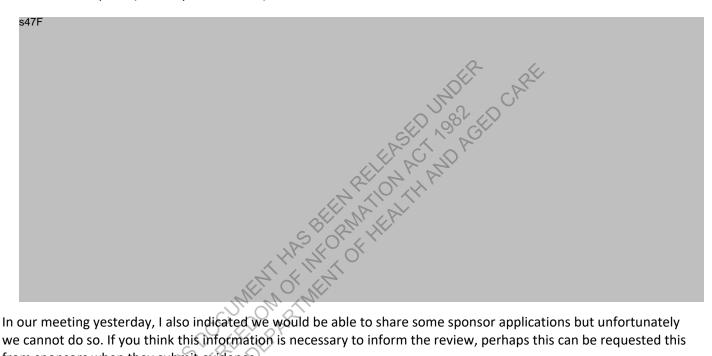
Subject: FW: Documents for AHA [SEC=OFFICIAL]



Please see attached initial background information from the Department. Please treat all information provided by the Department (that is not already publicly available) as confidential information.

- Prostheses List Post listing Review Framework
- List of billing codes and product names.
- Most recent correspondence with sponsors (email)
- Sponsor and stakeholder list
- Utilisation review (title: PLAC 32 Surgical Guides and Biomodels) and background tables
- Prosthesis list guide
- link to reforms webpage The Prostheses List reforms | Australian Government Department of Health and Aged Care.
- Published articles/papers for some background

List of clinical experts (this may be added to):



In our meeting yesterday, I also indicated we would be able to share some sponsor applications but unfortunately we cannot do so. If you think this information is necessary to inform the review, perhaps this can be requested this from sponsors when they submit evidence.

I hope you are feeling better soon s 47F

Kind regards, s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

₹ \$22 @health.gov.au Location: s22 , 160 Ann Street, Brisbane QLD 4000 PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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From: s22

Sent: Monday, 26 September 2022 1:08 PM

To: s47F : s22

Cc: s22 ; s47E(d)

Subject: RE: SGB review [SEC=OFFICIAL]

Thanks S47F

I will make some enquiries re whether there is a TGA contact that can provide more details on the ARTG issue. Also, have arrangements been made for a discussion with key departmental staff, including re eligibility criteria? I can flag this with the staff I nominated and try to gauge a suitable time, if this helps?

From: S47F @ahaconsulting.com.au> Sent: Monday, 26 September 2022 12:26 PM To: \$22 @health.gov.au>; \$22 @health.gov.au> Cc: S22 @health.gov.au>; s22 @Health.gov.au>; 🚉 @Health.gov.au> Subject: RE: SGB review [SEC=OFFICIAL] REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe. Thanks s22 We will proceed as per your suggestion. Kind regards, s47F From: s22 @health.gov.au> Sent: Monday, 26 September 2022 12:24 PM To: ^{S22} @health.gov.au>; s47F @ahaconsulting.com.au> Cc: \$22 @health.gov.au>; SZZ @Health.gov.au>; E(d @Health.gov.au>

Hi All

s22

Some of these devices will not have ARTG listings due to the stage they are at in the transitionary arrangements for personalised medical devices.

Perhaps the question/s they are asked should account for this. i.e....

1. Request ARTG

Subject: RE: SGB review [SEC=OFFICIAL]

2. If no ARTG, explanation for why not (+/- stage of the regulatory process they are at towards ARTG inclusion)

From: s22 Sent: Monday, 26 September 2022 1	<u>@health.gov.au</u> > 12:20 PM		
To: s47F	@ahaconsulting.com.	.au>	
Cc: \$22	@health.gov.au>; s22		@Health.gov.au>;
s22	@health.go	ov.au>; s47E(d)	@Health.gov.au>
Subject: RE: SGB review			
Hi ^{s47F}			
Thanks – we are on the mend.			
00	- '	r the ARTG listing and this see e let us know if you disagree?	
Kind regards, s22			
Post-market Review Section			
		,2-	4.
Technology Assessment and Access Division Office of Health and Technology Assessment Australian Government Department of Healt	Health Resourcing Group: Policy and Programs Branch th and Aged Care h.gov.au QLD 4000	1 SED JABLEED CAR	
PO Box 9848, Brisbane QLD 4000, Australia		CIE ROLL	
	<	55, 4, 7 k	
Work hours: Mon, Tues, Wed 9am-3	pm	MATERITY	
Technology Assessment and Access Division Office of Health and Technology Assessment Australian Government Department of Health s22 @health Location s22 , 160 Ann Street, Brisbane PO Box 9848, Brisbane QLD 4000, Australia Work hours: Mon, Tues, Wed 9am-3 I acknowledge the traditional custodic past, present and future. From: s47F Sent: Monday, 26 September 2022, 1	ans of the lands and wa	aters where I live and work, an	nd pay my respects to elders
From: s47F	@ahaconsulting.co	om.au>	
Sent: Monday, 26 September 2022 1	1:11 AM		
To:s	health.gov.au>		
Subject: SGB review	K,		
8			
REMINDER: Think before you click! This		tside our organisation. Only clic	k links or open attachments if
you recognise the sender and know the	content is safe.		
Hi ^{s22}			
_			
I hope you have recovered well.			
After our meeting, with s22 and s confirmation that the department co initial email to them. In our initial reask sponsors to provide the Australia As we are keen to get our request or	onsiders it reasonable t search, we were unable an Register of Therapeu	e to find listings for some pro- utic Goods (ARTG) reference r	ference from sponsors in our ducts. We are proposing to number for each product.
		_	
This would be most appreciated. Ple where we are at following our meeti	•	y mobile when you are free a	ına ı can update you on

Kind	regards	,
s47F		

s47F	Senior Consultant				
Australian Healthcare Associates					

Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003 T: 1300 242 111

1: 1300 242 M: **s47F**

E:s47F

@ahaconsulting.com.au

W: www.ahaconsulting.com.au

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From: s22

Sent: Monday, 26 September 2022 1:43 PM

To: s471

Cc: ; s47E(d) ; s22 ; s22

Subject: Further detains re ARTG inclusion [SEC=OFFICIAL]

Hi ^{s47F}

I have spoken to TGA re personalised medical devices (PMDs) and the ARTG.

Any sponsor supplying PMDs not included on the ARTG needed to register for transitionary arrangements by submitting a transition notification form to the TGA by 25 August 2022 (otherwise they cannot legally supply after this date).

Sponsors who applied were provided with a unique identification number.

Therefore, any sponsor of PMDs must either have their devices included on the ARTG, or have registered for the transitionary arrangements and hence be able to provide their transition notification form and unique identification number.

The TGA lead in this area is \$22 . She is willing to meet with you if you would like.

Happy to discuss further.

s22

s22

Medical Adviser

Technology Assessment and Access Division

Health Resourcing Group

Australian Government Department of Health

T: s22 | E: s22 @health:gov.au

Location: s22, 595 Collins Street, Melbourne

GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.





From: s22

Sent: Wednesday, 21 September 2022 9:13 AM

To: \$47F ; \$47F

Cc: \$47E(d)

Subject: FW: Review of surgical guides and biomodels - Research protocol [SEC=OFFICIAL]

Attachments: SGB review research protocol.LB PP Comments20Sept.pdf

and safe please see attached protocol with some comments in post-it notes for discussion this afternoon at 3pm. Unfortunately s22 is unwell this week.

Regards, s22

From: S22

Sent: Tuesday, 20 September 2022 1:29 PM To: \$22 ; \$22 ; \$47E(d)

Subject: RE: Review of surgical guides and biomodels - Research protocol [SEÇ€OFFICIAL]∕

Here are my marked up comments.

Cheers

s22

Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group

Australian Government Department of Health

T: \$22 | E: \$22 @health.gov.au

M: s22

Location: Sirius Building s22

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders past and present.



Building a stronger, healthier country

Yesterday today and tomorrow

From: @health.gov.au>

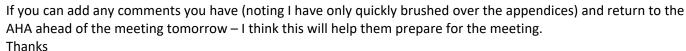
Sent: Tuesday, 20 September 2022 11:52 AM

To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22

Health.gov.au>

Subject: RE: Review of surgical guides and biomodels - Research protocol [SEC=OFFICIAL]

and s22 I have reviewed the protocol and quickly scanned the appendices. I have included comments on the protocol for discussion with AHA tomorrow.



From: s22 @health.gov.au>

Sent: Tuesday, 20 September 2022 8:19 AM

To: ^{s47E(d)} @Health.gov.au>; ^{s22} @health.gov.au>; ^{s22}

@Health.gov.au>

Subject: FW: Review of surgical guides and biomodels - Research protocol [SEC=OFFICIAL]

Hello all – please see attached the research protocol from AHA.

Apologies for not forwarding this yesterday I was out sick, I will remind s47F to include PL review in their correspondence with the Department.

From: 647F @ahaconsulting.com.au>

Sent: Friday, 16 September 2022 5:32 PM

To: \$22 @health.gov.au>

Cc: s22 @health.gov.au>; s47F

@ahaconsulting.com.au>

Subject: Review of surgical guides and biomodels - Research protocol

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 and s22

We are delighted to attach the Research protocol we have developed for the surgical guides and biomodels review. We look forward to discussing the research protocol further on Tuesday morning.

Thanks 522 for your advice on the departmental contacts to be involved in a consultation. I will follow this up on Monday. I hope you enjoy your break next week.

Kind regards, s47F

s47F | Senior Consultant

Australian Healthcare Associates

Level C 440 Davide Chart Malle come

Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111 M: **s47F**

@ahaconsulting.com.au

W: www.ahaconsulting.com.au

x x x

Please consider the environment before printing this email.

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THIS DELETED BY ARTHUR THE BELL OF THE BEL

s 22 From:

Sent: Tuesday, 20 September 2022 8:45 AM

To:

s 22 s 22 Cc:

RE: Review of surgical guides and biomodels - Research protocol [SEC=OFFICIAL] Subject:

Hi ^{s47F}

Thank you for sending this through. Can we reschedule the meeting today at 10am for tomorrow (3pm looks like it would suit everyone from the Department)? I have been out sick and \$22 is on leave, so I missed your email on Friday and was unable to forward it to others in the Department to review the protocol until this morning.

Can you include s47E(d) @health.gov.au and s47E(d) @health.gov.au when sending deliverables to the Department (and cc PL reviews when sending emails to the Department) to ensure nothing gets missed?

Kind regards,

s 22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group Office of Health and Technology Assessment Policy and Programs Branch Australian Government Department of Health and Aged Care

| **⁴** s 22 Location: s22 , 160 Ann Street, Brisbane QLD 4000 PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

ograms Branch and Care Seed Care I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

@ahaconsulting.com.au>

Sent: Friday, 16 September 2022 5:32 PM

To: ^{S 22} @health.gov.au>

Cc:S @health.gov.au>; s47F

@ahaconsulting.com.au>

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Kind regards, s 47F

s 47F | Senior Consultant

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Level 6, 140 Bourke Street, Melbourne, VIC 3000 Locked Bag 32005, Collins Street East, VIC 8003

T: 1300 242 111

M:s 47F

E: 847F @ahaconsulting.com.au

W: www.ahaconsulting.com.au

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s22 From: ;s22 ;s47F s22 s 47F To: ; FLYNN, Elizabeth; s47F ;s47F s22 Cc: Subject: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL] Hello AHA, Please let me know if this new meeting time doesn't work for you and I can reschedule. Apologies for the late notice. Kind regards, -- Do not delete or change any of the following text. -- When it's time, join your Webex meeting here.

Join meeting \$22 More ways to join: Join from the meeting link s22 Join by meeting number Meeting number (access code) \$22 Meeting password \$22 Tap to join from a mobile device (attendees only) \$22 Australia Toll Join by phone S22 Australia Global call-in numbers S22 Australia Toll Join from a video system or application You can also dial \$22 Join using Microsoft Lync or Microsoft Skype for Business Dial \$22 If you are a host, click here \$22 to view host information Need help? Go to https://help.webex.com https://help.webex.com

Sponsor	Primary contact	Email address
AA-Med Pty Ltd	s47F	© s47F @brandwoodbiomedical.com
Anatomics Pty Ltd		<u>@anatomics.com</u>
DIGITAL DENTAL		s47F @digitaldentalnetwork.com.au
NETWORK PTY LTD		<u>@digitaldentalnetwork.com.ad</u>
Johnson & Johnson		s47F @its.jnj.com
Medical Pty Ltd		<u>[wits.][i].com</u>
KLS Martin Australia Pty		s47F @klsmartin.com
Limited	_	
Maxoniq	_	s47F @maxoniq.com
More Group Pty Ltd	_	@misimplants.com.au
SPECIFICA PTY LTD	_	s4/F @specifica.com.au
Stryker Australia Pty Ltd		@stryker.com
İş .		s47F @specifica.com.au s47F @specifica.com.au s47F @stryker.com

Stakeholder	Type of organistation	Organisation Contact	Contact Info.	Notes
Carraman Haalib Farran	C	s 47F	s47F @chf org au	
Consumer Health Forum The Australian and New Zealand Association of Oral and Maxillofacial Surgeons (ANZAOMS)	Consumer representative	s 47F	s4 @anzaoms.org	
Medical Technology Association of Australia (MTAA)	Peak Body		MTAA Office hours are Monday to Friday 9am to 5pm Phone: (02) 9900 0600 Level 4, 97 Waterloo Road Macquarie Park, NSW 2113	s 47F
Private Healthcare Australia (PHA)	Peak Body	s 47F	s 47F @pha.org.au	
? Dentists - Orthpoadics		s 47F	s 47F @ada.org.au	https://www.ada.org.au/About/Our- Structure/leadership-team
Speech pathologist association	Peak Body	s 47F	s 47F @speechpathologyaustralia.org.au	https://www.speechpathologyaustralia.org.au/
National Health and Medical Research Council	Government body	s 47F	% @nhmrc.gov.au	
CSIRO	Biomedical Materials Translational Facility (BMTF)	s47F Communication Advisor	\$47F	https://www.csiro.au/en/research/health- medical/biomedical/bmtf
Biomedical engineers of Australia	Peak Body		s47F @bme.asn.au	ebme.asn.au
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Table 1 Qlik

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Figure 1 Qlik

Figure 2 Qlik

Figure 3 Qlik

Figure 4 Qlik

Table 3 Mean and median benefit amount per patient per admission for biomodels and surgical guides by Financial Year

Table 4 Number of biomodels or surgical guides per admission, 2018-19 to 2021-22

Table 5 Top 10 Number of biomodels or surgical guides, by PMBS item Clinical Category, 2018-19 to 2021-2022

Table 6 Patients, items and benefit by PMBS item number for 2020-2021 (Top 10 number of patients)

Table 7 Number of patients and devices by ICD label (Top 20 number of patients), 2018-19 to 2021-22

Table 8 Age of patients at first admission, 2018-19 to 2021-22

Source: HCP1

Notes:

The 2021-22 Financial Year data are preliminary, completeness compare to APRA data is provided in the table below

	2018-19	2019-20	2020-21	2021-22
Prostheses	90.6%	89.7%	91.1%	72.1%

	Benefit Amount	Benefit Amount	Benefit Amount	Benefit Amount
Financial Year	Mean	Median	Min	Max
2018/2019	8,460	7,118	1,950	36,272
2019/2020	8,023	5,168	1,950	56,944
2020/2021	6,991	4,534	1,950	101,506
2021/2022	6,428	4,534	956	72,496

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Name Is a second	ı
Number of	
biomodels or	
surgical	
guides per	Number of
separation	occurrences
1	2,362
2	1,856
3	737
4	739
5	415
6	354
7	301
8	176
9	41
10	38
11	17
12	11
13-36	73

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	2018/2019		2019/2020		2020/2021		202
PMBS Item Clinical Category	Number of Prostheses Items	Benefit Amount	Number of Prostheses Items		Number of Prostheses Items	Benefit Amount	Number of Prostheses Items
Plastic and reconstructive surgery. (medically							
necessary)	2,616	3,076,886	2,984	3,575,984	5,299	6,986,806	4,731
Blank	48	57,003	215	273,164	495	851,096	794
Bone, joint and muscle	227	373,804	424	515,272	778	845,521	516
Joint replacements			62	70,642	302	350,386	324
Support list	n.p.	11,028	38	65,964	126	219,102	207
Brain and nervous system	41	55,792	ZQ44	82,534	96	174,770	103
Ear, nose and throat	43	35,694	5 32	39,442	121	173,858	129
Joint reconstructions			10	14,236	101	126,222	14
Common list	16	17,454	n.p.	7,118	37	33,640	54
Other		12.47	$\mathcal{C}(X_k)$				

n.p. not publishable

1/2022	Total for four years		
	Number of		
Benefit	Prostheses	Benefit	
Amount	Items	Amount	
6,549,245	15,630	20,188,921	
1,390,237	1,552	2,571,500	
595,506	1,945	2,330,103	
399,530	688	820,558	
356,240	377	652,334	
192,954	284	506,050	
173,224	325	422,218	
12,968	125	153,426	
62,746	115	120,958	
	91	158,546	

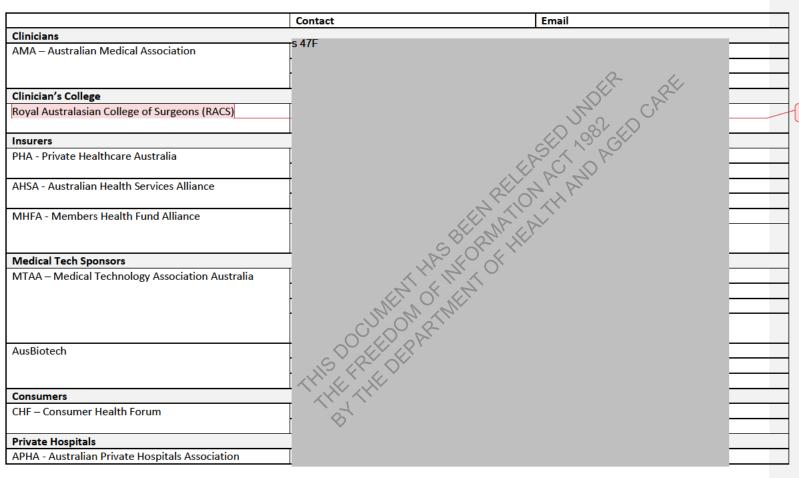
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Rank	Principal N	Patients	Items	Benefit
1	45841	373	592	1,439,508
2	Blank	257	497	1,192,808
3	45729	157	407	969,268
4	45738	135	480	1,181,992
5	45849	116	216	521,372
6	52375	105	650	1,558,698
7	45732	104	427	1,019,046
8	45752	93	436	1,056,884
9	52624	88	119	297,986
10	52363	72	346	813,546

ICD Label	Count Number of Patients	Sum Number of Prostheses Items
Dentofacial anomaly, unspecified	863	2,987
Loss of teeth due to accident, extraction or local		
periodontal disease	803	1,331
Anomalies of jaw-cranial base relationship	644	2,938
Anodontia	459	736
Disorder of teeth and supporting structures, unspecified	407	732
Malocclusion, unspecified	340	1,315
Hypoplasia of mandible	266	715
Hypoplasia of maxilla	261	1,126
Other dentofacial anomalies	240	848
Other specified disorders of teeth and supporting		SYN
structures	227	364
Other primary coxarthrosis	185	(A) (P) 436
Temporomandibular joint disorders	175	1,363
Dental caries, unspecified	141	278
Impacted teeth	5 124	248
Other specified diseases of jaws	102	348
Periapical abscess without sinus	85	131
Other major anomalies of jaw size	83	513
Other primary gonarthrosis	82	248
Anomalies of dental arch relationship	73	267
Primary arthrosis of other joints, other site	73	445

Age Range	Number of Patients
0-9 yrs	14
10-19 yrs	1,201
20-29 yrs	1,364
30-39 yrs	781
40-49 yrs	683
50-59 yrs	980
60-69 yrs	1,110
70-79 yrs	596
80-99 yrs	125

SGB Stakeholder contact list - PL Contact List



Commented S22]: In addition to RACDS

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