





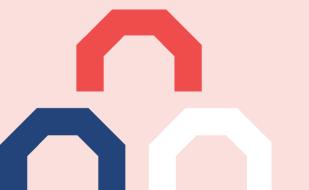


## **2025 Australia-UK Platform Studies** in Areas of Unmet Clinical Need

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A live Q&A will be held at the end of the webinar

Please submit your questions via the Q&A icon



Vote for the ones you want answering by clicking the thumb icon







## Housekeeping

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- You can turn on the live transcript by clicking on the 'live transcript' button and then selecting 'show subtitle
- You may send in questions by clicking on the Q&A button and upvoting your favourites by clicking the thumb icon
  - Please use the chat feature to indicate if you having any connection problems

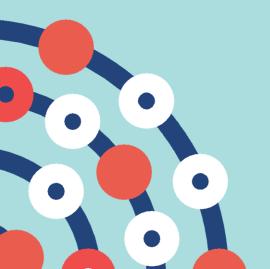
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## 2025 Australia-UK Platform Studies in Areas of Unmet Clinical Need



Applicant Webinar 19 November 2024 08:00 – 09.30 UK (UTC+0) 19:00 – 20.30 AEDT (UTC +11)

### Agenda

- Housekeeping and introduction to presenters
- Background to the call
- Scope of Funding Opportunity
  - Eligibility and Key requirements
  - Assessment criteria
- Overview of the application and assessment process
  - Australian
- Available national support for UK and Australian leads
- Application hints and tips
- Question and Answer session





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### **Presenters**

- Inesa Thomsen UK Department of Health and Social Care
- Anika Prabhu MRFF Acting Director, Patients and Infrastructure, Health and Medical Research Office
- Andrew Farmer NIHR Health Technology Assessment (HTA) Programme Director
- Sarah Puddicombe NIHR Assistant Director Research Programmes, Global Health and International
- Christy Nixon MRFF Acting Assistant Director Patients and Infrastructure, Health and Medical Research Office

### **Q&A Panel**

- Chris Jennaway NHMRC Director, Research Strategy and Engagement, Research Partnerships Branch
- Cherie Atkinson MRFF Director
- Michelle Bailey MRFF Assistant Director
- John Simpson MRC/NIHR Efficacy and Mechanism Evaluation (EME) Programme Director
- Andrew Cook NIHR Consultant Advisor
- Lisa Douet, Debbie Willis, Gemma Bashevoy, Charlotte Minter NIHR Senior Research Managers





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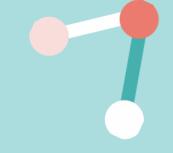
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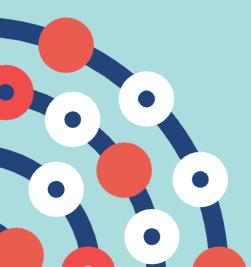






## **Background to the call**

Inesa Thomsen (DHSC, UK) and Anika Prabhu (MRFF, Australia)



### Background

• International collaborations can support the efficient funding and advancement of clinical studies aiming to prevent, detect, or treat disease in areas of shared priority.

 Clinical trials often require the recruitment of patients beyond national borders, additional expertise and equipment from abroad to boost the scope and effectiveness of clinical studies.

 The Medical Research Future Fund (MRFF), the National Health and Medical Research Council (NHMRC) and the National Institute for Health and Care Research (NIHR) are pleased to announce the launch of this joint funding opportunity, with a deadline for Stage 1 outline applications on 23 July 2025.

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# Extending our long standing funding collaboration between Australia and UK

- NIHR HTA and NHMRC have collaborated to jointly commission research in areas of shared priority by supporting collaborative Australia and UK research projects since 2012.
- This leveraged existing NIHR HTA prioritisation and assessment processes but gave limited flexibility to maximise all emerging priorities within annual budget commitments.
- Over 10 years NIHR HTA and NHMRC have jointly commissioned 16 awards; funding research in the respective jurisdictions. We continue to monitor and support these awards to their completion.
- Recognising the importance of international trials but also the challenges associated with undertaking them, we have committed to supporting and extending our ongoing international collaboration and are working to further reduce barriers to the successful delivery of impactful international studies.
- Through this collaboration we are supporting both collaborative research and clinical trials
  research capacity strengthening and are streamlining our assessment to avoid double
  jeopardy.



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### **Australia-UK Platform Studies Collaboration**

 This joint call between the MRFF (Australia), the NHMRC (Australia) and the NIHR (UK), will support funding for new collaborative research to establish platform studies in areas of unmet clinical need in Australia and the UK.

• With a single joint funding assessment and coordinated financial approvals we aim to facilitate and support new collaborations for joint Australia-UK platform trials.

 The Australian-based component will be funded through the MRFF or the NHMRC, and the UK-based component will funded through the NIHR UK, (EME or HTA programmes) where applications align to the call and these programme remits.

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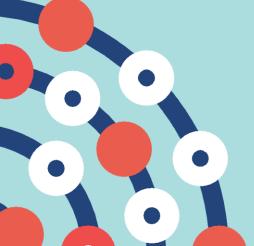




## **Scope of Funding Opportunity**

**Andrew Farmer** 

NIHR HTA Programme Director, UK



### **Areas of interest**

- Areas which can be justified through their strategic interest (e.g strategic national/federal policy documents from payers and commissioners of health at a national level and from national charities and third sector bodies) including areas which cannot be adequately addressed without collaboration across Australia and the UK.
- Areas of particular interest include, but are not limited to:
  - Childhood, brain and prostate cancers
  - Stroke and traumatic brain injuries
  - Neurodegenerative diseases
  - Cardiometabolic conditions, including obesity
- Applicants are still required to **provide justification for the platform approach.**





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### Scope of the platforms (1)

- For this call, a platform is defined as a multi-arm study employing a master protocol and shared infrastructure to simultaneously evaluate multiple interventions.
  - Arms may be terminated early, based on interim analyses, or added as new candidates are identified and mature.
  - A platform should realise efficiencies in conduct and management, which may include statistical efficiencies due to a shared control group and early termination of arms which do not show any positive effect.

#### A platform approach may be justified where:

- There are multiple technologies requiring evaluation, with others likely to arise within the anticipated lifetime of the platform.
- Relevant outcomes/endpoints may be observed in the short- and medium-term, allowing the platform to adapt and focus on the most promising interventions.
- A collaborative, multi-disciplinary team and multi-centre recruitment plan can support the delivery of a platform.



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### Scope of the platforms (2)

We will fund...

- *Either* a new sole Phase 2 or a sole Phase 3 focussed platform, where there is a convincing evidence of a promising pipeline of technologies which justifies a platform approach. The range of and inclusion of each technology within the platform must be well justified (2-3 sentences) and support a coherent platform trial approach.
- This call **will not** support funding for studies aiming to run platforms seamlessly from Phase 2 into Phase 3.

#### Phase 2 platforms

- Should focus on establishing the **efficacy of multiple interventions** in a defined patient group or circumstance (which may include sub-groups).
- The study must focus on interventions with **convincing human clinical proof of concept** which suggests they may be efficacious.
- By robustly evaluating efficacy, the study should have the potential to inform future Phase 3 (comparative and cost-effectiveness) trials.





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### Scope of the platforms (3)

#### Phase 3 platforms

- Should aim to efficiently generate high-quality evidence around the clinical and costeffectiveness of multiple interventions in a defined patient group or circumstance.
- The focus must be on candidate therapies which have demonstrated some clinical efficacy but which require further testing in a multi-centre, pragmatic trial to compare against current best practice.

It is expected that proposals will be to set up a platform to evaluate a pipeline of most promising current candidates but will have the potential to adopt additional interventions at a later date through an adaptive protocol.

Funding for addition of further technologies will need to be secured from other sources to support future sustainability.







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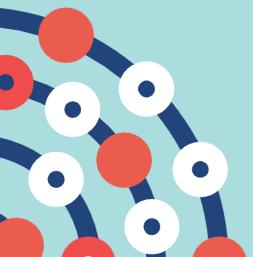






## Eligibility and key requirements

Sarah Puddicombe (NIHR, UK) and Christy Nixon (MRFF, Australia)



### General

- Applications to this funding opportunity must describe a new platform study seeking to evaluate a number of specified technologies.
  - Each Phase 2 technology must have sufficient clinical, human proof of concept to justify a definitive efficacy study.
  - Each Phase 3 technology must have some evidence that already exists to show that a technology *can* be effective
  - Consideration should be given to experience and capacity building amongst early and mid- career researchers (EMCRs)
  - Sustainability of the platform beyond the initially funded work should be considered
- The proposed study must be **multi-centre and collaborative**.
  - Recruitment must be split across both countries but needn't be apportioned equally, with a minimum of 20% of the total number of participants being recruited in each country.
  - Further international recruitment involving other countries may be proposed, where justified, however the MRFF,
     NHMRC and NIHR are not able to pay recruitment costs for other countries through this call.
- Applicants must ensure they meet **eligibility requirements** specified by their respective governmental funding bodies.
  - Australian based applicants must follow the MRFF and NHMRC Grant Opportunity Guidelines for this grant opportunity
  - UK based applicants must follow the NIHR Funding Opportunity Guidance





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### **Research team**

- NIHR applications must be jointly led, with an Australian and United Kingdom (UK) Lead. For practical purposes (e.g. application portals, regulators, ethics) there must be one named UK 'Chief Investigator' and one named Australian lead collaborator (i.e the Australian Chief Investigator A) listed on the NIHR UK application as a co applicant.
- Consideration must be given to a strategy that allows collaborators to join and exit the platform as appropriate, a publications plan that enables recognition of collaborators' contribution, and the development of a succession plan to allow the leadership of the platform to change over time if sustained.
- The study should support capacity building amongst Early and Mid-Career Researchers (EMCRs), through experience and training in the conduct and leadership of clinical trials and to support placements/visits to facilitate knowledge and skills exchange. EMCRs will become members of the <u>NIHR Academy</u>, with access to online career development events, training and support resources.
- A Named Point of Contact for Training and Development (NPC) should be included in the application. Training and support should be in line with the principles and best practice set out within the <u>Researcher Development Concordat</u>.





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### **Early and Mid Career Researcher eligibility**

- For in this funding opportunity:
- Early Career Researchers are generally postdoctoral researchers working towards early independence usually within 5\* years of the PhD award date, or clinicians/practitioners with equivalent demonstrable years of research experience.
- Mid Career Researchers are those who are establishing their independence and are as yet without substantial independent grant funding, these are usually between 5-10\* years of the PhD award date (\*excluding any career disruptions or time spent on non research activity).
- EMCRs must have been awarded their PhD or MD or equivalent experience by the time the award starts.
- Each EMCR post should be competitively awarded, include a training plan and have a defined end point, and be funded > 25% via these awards to be a member of the NIHR Academy.
- EMCR are **not eligible to be named as a Joint Chief Investigator** (in UK or Australia) and leadership should be supported through other research team roles. We encourage applications to include EMCR in the research team, with lead applicants to support appropriate career and leadership development.

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### Costs

- Total combined funding available is equivalent to a max of 30m AUD = £15.5 m GBP.
- MRFF, NHMRC and NIHR are aiming to fund 1-3 platforms for up to 7 Years.
- There is no set upper limit for the cost of applications however, value for money will be a key consideration.
- The maximum grant amount that can be requested for an Australian component is up to \$5 million AUD over up to 7 years.
- NIHR estimates approximately £2.6m per award over 7 years. The total UK contribution is up to £7.8 million GBP to support all the components of projects based in the United Kingdom.
- NHMRC or MRFF will fund the Australian research components and the NIHR will fund the UK research component of successful applications.
- Each national funder will support selected individual awards and there will be no shared or split Australian funding arrangements between NHMRC or MRFF.





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### Not eligible for this opportunity

- Existing platforms are not eligible to apply for further funding under this call, and should apply through other existing MRFF, NHMRC and NIHR funding schemes
- Applications which do not meet the eligibility criteria and scope for this call
- Applications which do not involve an Australian and UK collaboration.
- Australian and UK CI's cannot be named as a CI on more than one application.
- Applications which significantly replicate trials funded by any of the research funders.
- Please refer to <u>NIHR Funding Opportunity guidance</u>
- For NHMRC and MRFF to Grant Opportunity Guidelines for full details



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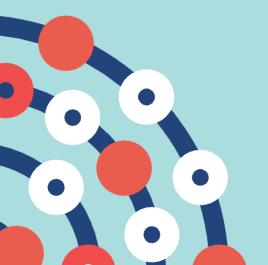






## **Assessment Criteria**

### Sarah Puddicombe (NIHR, UK)



### **Criteria for Assessment (1)**

- The study design would answer the research question proposed
- How well the proposal matches the call specification
- Scientific rigour:
  - The study design would answer the research question proposed
  - The proposed study would be feasible and deliverable
- Value for money:
  - The proposed costs of the research are reasonable and commensurate with the proposed work involved
  - The costs to health and care services in supporting the research are reasonable in relation to the likely benefits of the research to decision-makers, patients and the public
- Demonstration of experience in the team of delivering multi-centre interventional studies in the UK/Australia. Experience of innovative adaptive designs, particularly platform studies, is likely to be particularly relevant







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### **Criteria for Assessment (2)**

- Demonstration within the proposal, and/or prior track record, of working with members of the public, and people who draw on services and are in locations of greatest need, and how these needs, priorities, views and values have informed the research plans and will continue to be embedded across the planned research lifecycle
- Inclusive research approaches that target underserved populations and demonstrate how outcomes will benefit these populations and contribute to their improved health outcomes
- Evidenced plans to work closely in partnership, both with local healthcare organisations and across the international collaboration
- Ability to establish and coordinate data input from all proposed sites
- Ability to work effectively with industrial partners, if appropriate, and deliver robust, independent and industrially relevant research

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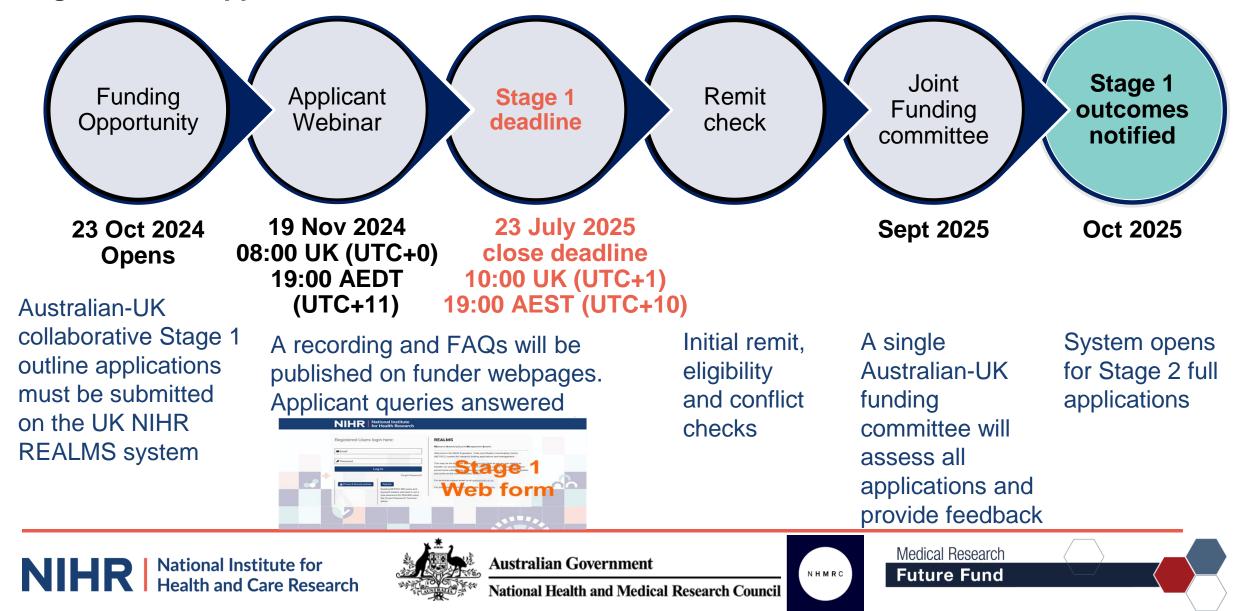
## Overview of Application and Assessment process

### Sarah Puddicombe (NIHR, UK) and Anika Prabhu (MRFF, Australia)



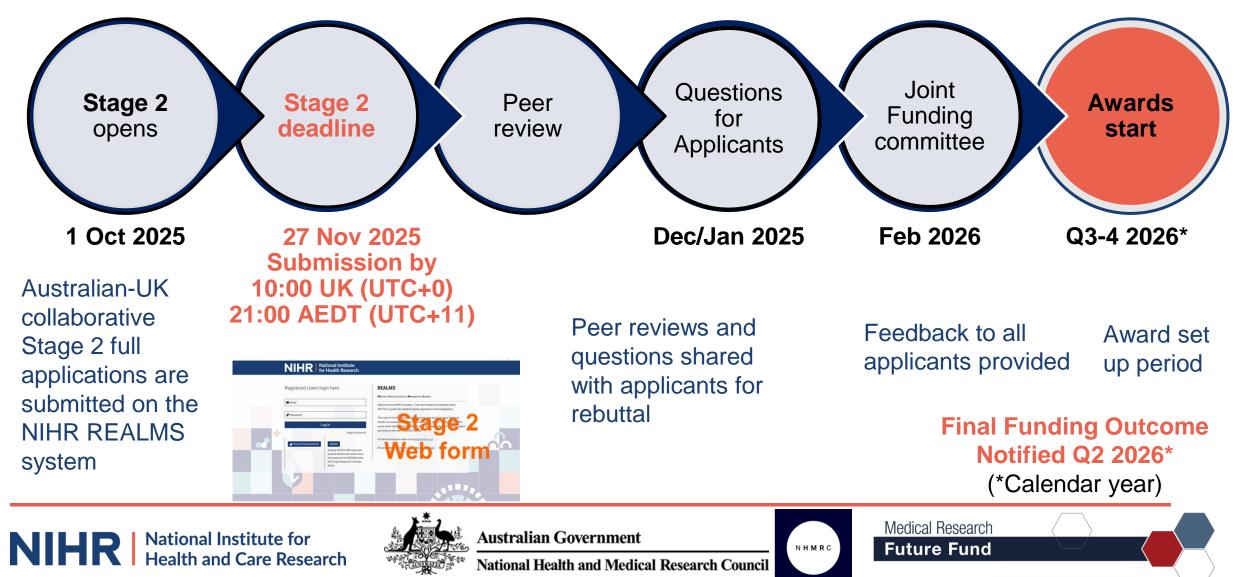
### **Timeline for application and awards - two stages (1)**

#### **Stage 1 Outline application**



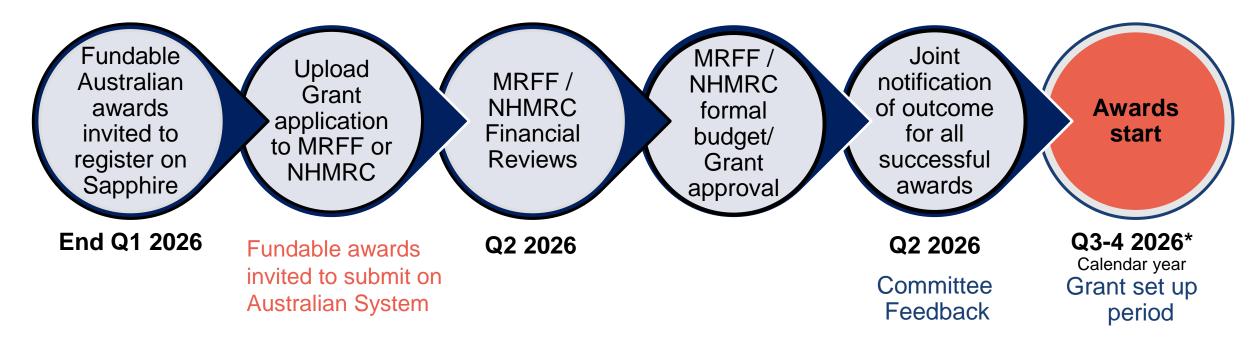
### **Timeline for application and awards - two stages (2)**

#### **Stage 2 Full application**



### Final application and funding approval process for fundable Australian component of awards only by MRFF/NHMRC

**Stage 2 Fundable Australian applications** 



The MRFF and the NHMRC grant program administer grants according to the Commonwealth Grants Rules and Principles (<u>CGRPs</u>). Refer to <u>NHMRC website</u> and <u>GrantConnect</u>. NHMRC will undertake administrative review processes to ensure that your application meets NHMRC-specific eligibility requirements and budgetary limits.





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### **Timelines**

Applications to this call will follow a two-stage application process:

- Stage 1 outline submission:
  - O 23 July 2025 10:00 UK (UTC+1) / 19:00 AEST (UTC+10)
- Shortlisted applications invited for Stage 2 full submission:
  - O 27 November 2025 10:00 UK (UTC+0) / 21:00 AEDT (UTC+11)
  - Fundable awards invited to apply for Australian budget review Q1 2026
- All applicants receive a final outcome notification in Q2 2026
- Awards/Grants estimated to start Q3-Q4 2026

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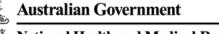
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### Submitting your Stage 1 application

- You must submit your application online via REALMS
  - Apply Now
- Uploads at Stage 1
  - Mandatory
    - Flow diagram
    - References
    - Australian team member details and declaration of potential conflicts of interests
  - $\circ$  Optional
    - Papers in press

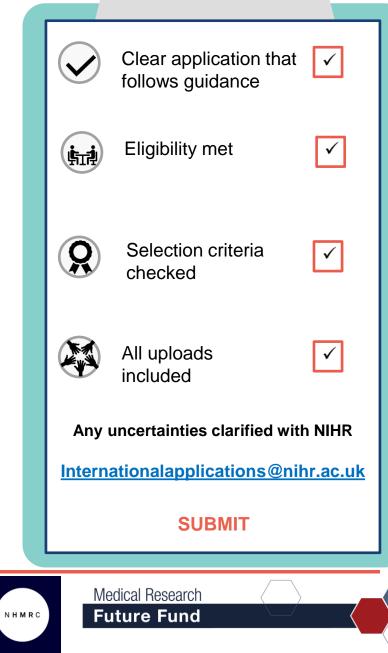






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### **Available support for UK applicants**

#### • Research Support Service

- The <u>NIHR Research Support Service (RSS</u>) provides free and confidential support for researchers to apply for funding and develop and deliver clinical and applied health and care research. The experts in the RSS can help you to formulate your idea into a research question. Available to applicants based in England, or with a project partner based in England.
- Research support for applicants from Devolved Administrations in the UK
  - Scotland may access NHS Scotland Innovation Hubs and/or NHS <u>Research Scotland</u>
  - Northern Ireland may access <u>The Northern Ireland Clinical Research Network</u>
  - Wales may access <u>Health and Care Research Wales</u>

#### • Study Support Service

- The <u>Study Support Service</u> helps researchers and the life sciences industry plan and deliver high quality research to time and target. It supports researchers across England in the NHS and the wider health and social care environment.
- We provide this service for all studies eligible for support on the <u>Research Delivery Network</u> (<u>RDN</u>) Portfolio, regardless of location, study type, study size, therapy or research area.







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### **Available support for Australian applicants**

- Applicants requiring assistance should direct enquiries to their Research Administration Officer. Research Administration Officers can contact NHMRC's <u>Research Help Centre (RHC)</u> for further advice.
- Applicants are encouraged to consider utilising research infrastructure projects such as those funded by the Australian Government through the National Collaborative Research Infrastructure Strategy (<u>NCRIS</u>).
- The NCRIS projects encompass a variety of infrastructure relevant to health research such as the Translating Health Discovery (THD) project and the Population Health Research Network (PHRN) project. Further information, including access and pricing, is available on the Department of Education website see <u>NCRIS</u>.

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# Tips on planning for Success

Andrew Farmer (NIHR HTA Programme Director, UK) and Sarah Puddicombe (NIHR, UK)

### **Specific application Tips**

- Read funding opportunity guidance!
- What is the evidence gap/unmet need you are addressing and how your approach will address this gap
- Justify the need/gap for the inclusion of each intervention arm (2-3 sentences per arm) and the existence
  of a coherent pipeline of interventions to warrant a platform approach
- Platform trials either a solely Phase 2 or solely Phase 3 focussed but not a seamless transition between P2-P3 studies
- Ensure you select the most appropriate study design to meet the identified needs
- Ensure inclusive approaches to address inequities and maximise the benefit from collaborative Australian -UK studies
- Involve the wider research and patient community
- Seek to build clinical trials research capacity and expertise for EMCRs
- Justify deliverability and value for money
- Consider sustainability to support funding for addition of future interventions







### **Consider and do prepare for common trial issues**

- Ensure you justify a sufficient pipeline of interventions to warrant a platform and coherence for inclusion of each intervention within the platform
- Rigorous statistics and data management are needed for cross country platform studies
  - consider innovative adaptive designs
  - $\circ$   $\,$  consider use of Bayesian analysis  $\,$
- Consider deliverability and value for money
  - seek efficient and less complex designs for cost effective deliverability
- Consider insurance and the optimal model for sponsorship
  - single sponsor for both countries or
  - $\circ$   $\,$  one sponsor in each jurisdiction
- Regulatory Approvals
  - differing complexity of cross-national approvals e.g. Auxiliary Medicinal Products (AMPs), device and Investigational Medicinal Product (IMP)
- Clinical Trials Unit (CTU) support or equivalent
  - the CTU readiness, available capacity and required support within each country
- Consider sustainability plans for the future
  - engage commercial companies or other funders to fund future arms
  - the set up of supply agreements for future commercial providers







### Please contact us for advice

- We can advise on whether an outline of your planned proposal is in remit for the call specification
- Please send in a PICO summary. This stands for:
  - Patients/Population who/what
  - Intervention how
  - Comparator placebo/treatment as usual etc
  - Outcome this should be a patient-centred effect

For work relating to mechanism of action of an intervention, please describe any hypothesis being tested

- Proof of concept (Phase 2 platforms)
  - Please cite any evidence that the intervention(s) could work. How much evidence is needed will vary depending on the size of the translational step, the scale of the study and the nature of the intervention(s)
- Evidence of efficacy (Phase 3 platforms)
  - Please cite any evidence which demonstrates efficacy for the intervention(s)





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### Feedback

• You will get feedback at every stage of the assessment process

- Please provide a robust response to the feedback from:
  - External Reviewers
  - Funding Committee Members
- Clearly describe any changes made
- If you disagree with any feedback, explain your justification

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#### **Any Questions?**

- Recording and slides will be made available shortly
- FAQs will be posted on our respective websites
- Queries submitted within a week of the submission deadline will definitely be answered.
- Please do not leave your application submission to the last minute!





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## Thank you!

Good luck with your application and please do contact us if you have any further questions at:

#### Email: Internationalapplications@nihr.ac.uk

See <u>NIHR Funding Opportunity Guidance</u> and this link to <u>apply now</u>

For Australia applicants please also refer to <u>Grant Opportunity Guidelines</u> Specific Australian grant condition questions - <u>help@nhmrc.gov.au</u>

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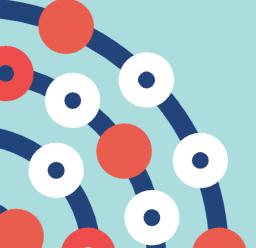






# Appendix of additional guidance

Additional applicant reference information



## **Overview of application and assessment process**

- Stage 1 outline application for a platform trial (comprising plans for both Australian and UK arms) submitted through the NIHR UK system. The NIHR REALMS system requires the Australian lead to be named as a co-applicant (with no costed FTE for the UK component)
- 2. A joint Australian and UK committee will assess applications against the advertised assessment criteria and will provide feedback to all applicants
- 3. Shortlisted stage 1 applicants invited to submit a stage 2 full application external peer review comments and an opportunity for rebuttal followed by committee feedback.
- 4. Stage 2 full applications considered 'fundable' by the NIHR UK-Australian Funding Committee will be recommended for funding through the required funder processes: for the UK component to the UK Department of Health and Social Care and for the Australian component an additional short assessment of budget is required prior to recommendations to the Australian Government Department of Health and Aged Care.
- 5. The Australian leads of 'fundable' applications will be invited by either MRFF or NHMRC to apply for funding to support the Australian-based component of the trial. The application and costs for the Australian components uploaded onto the NIHR system at Stage 2 must be the same as those submitted to the MRFF/NHMRC for final funding assessment and approval. Full details on this assessment and budget approval steps for any Australian components of trials please refer to the <u>Australian Grant Opportunity Guidelines</u>.
- 6. Final outcomes will be notified to the UK and Australian joint leads of all applications.





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#### **Research Question**

- Describe unmet clinical need being addressed in the context of current practice and provide the size of the incident or prevalent patient population in the UK / Australia
- Ensure the question has not already been answered. Look at what we have already funded:
  - <u>https://fundingawards.nihr.ac.uk/</u>
  - <u>https://www.nhmrc.gov.au/funding/data-research/outcomes</u>
- Public and Patient Involvement work is required to ensure it is relevant to patients/the public and please also ensure the plain language summary is clear
- Is it timely and will it make a difference?
- Can it be delivered by the health and social care system?
- Ensure all hypotheses being tested for the clinical study and any mechanistic work are clearly defined including how you will confirm or refute them. Phase 2 applications must be hypothesis-driven, i.e. funding will not be available for studies where the main aim is hypothesis generation.



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#### **Study Design**

- Ensure the design is optimised to answer the question
- Choose the most robust research method and fully describe it clearly
- Describe the planned inclusion/exclusion/withdrawal criteria, how participants will be allocated to trial groups and any methods to protect against bias
- Describe and justify the choice of primary outcome, and any secondary outcomes
- Explain the dose and any side effects of the intervention
- Include a statistical analysis plan and ensure the sample size/power calculation be replicated
- Use existing infrastructure support, e.g. UK (RSS, CTU) Australia (NCRIS)

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## Study design and other support available for UK applicants

- UK Clinical Research Collaboration Registered Clinical trial units network
   For more information contact UKCRC Registered CTU Network
- <u>NIHR HealthTech Research Centres</u> (HRCs): Can help medical device, digital technology and diagnostic companies (collectively known as healthtech) to develop, evaluate and validate new innovative health technologies to address pressing healthcare challenges. This includes help to generate evidence to demonstrate financial value (health economics) or improve operational efficiency in the NHS (real-world evidence generation).
- <u>NIHR's Business Development Team</u>: Help with finding and making great partnerships to strengthen your work. This service is available to all UK-based applicants and you may wish to contact them if you are seeking a partner.

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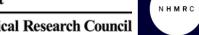
#### **Research Team**

- Does your team have the multi-disciplinary expertise you need?
- Ensure the roles are clearly defined and appropriate
- Consider the level and range of expertise required; use Clinical Trial Units
- Consider and cost for early career and mid-career researcher development in relation to clinical trials capacity strengthening and exchanges
- Ensure that Public and Patient Involvement and research inclusion is demonstrated at all stages
- We would usually expect at least two of the following organisation types to be involved: National Health Service (NHS UK) / health and care service Australia, academia and industry
- Please note for UK component your collaborators must accept <u>NIHR</u> terms and conditions
- For Australian components they must accept <u>NHMRC</u> and <u>MRFF</u> the grant terms and conditions

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## **Academic Training and Research Capacity Strengthening**

Provide a short summary of your overall approach for increasing clinical trial research capacity within the award; including through the provision of training which supports diverse career paths and promotes equality, diversity and inclusion.

Detail the plans to support capacity building amongst Early and Mid-Career Researchers (EMCRs), through experience and training in the conduct and leadership of clinical trials. This includes the number and type of career development posts you intend to support, costs for training and any plans for exchange visits between UK and Australian based EMCRs to facilitate knowledge and skills exchange.

Please consider:

- key stages within the academic career pathway (in particular current pinch points and where clinical trial expertise may be limited)
- broadening out to a wide variety of groups, disciplines and professions; including methodologists and under-represented disciplines and professions in research
- relevant sectors and particular geographies/places where there may be a low research base and a need for building clinical trial research capacity
- the costs for research capacity building (as a general rule approximately 10-20% of the overall award budget). Funds can be for staff salary/stipend costs, time commitment, and as appropriate academic tuition fees and exchange visits within the overall 'costs for the research'.
- provide a "Named Point of Contact for Training and Development (NPC)" responsible for overseeing the academic career development of those ECMRs undertaking training within this Australia-UK award. The NPC can be the Lead Applicant, a Co-Applicant with relevant experience, or an existing dedicated career lead from the contracting or collaborating institutions. The NPC should ideally be different from the Academic supervisor.



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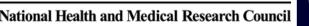
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## Deliverability

- Have you ensured your research is credible?
- Recruitment: have you made a convincing case that your recruitment plan is realistic and addressed any research inclusion issues
- Is your timeline manageable?
- Does your application provide value for money, and are the costs correctly allocated?
- For UK see the AcoRD guidance for how to allocate treatment costs: <u>https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research</u>
- For Australia refer to Grant Opportunity Guidelines finance section 4



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#### **Dissemination and Impact**

- Describe the deliverables of the project
- Is there a clear pathway to dissemination and impact?
- What are the next steps involved after the project has completed?
- How will the research impact current practice?
- Are there any barriers for further research, development, adoption and implementation?
- What are the measures of success?





#### **Proof of concept for applications to EME programme**

For full details on what is required as proof of concept see https://www.nihr.ac.uk/proof-concept-applications-eme-programme

These include:

- Studies backed by epidemiological data or large case series
- Study based on pilot data
- Study based on data from other large trials
- Study following on from positive early phase human trial
- Study based on promising early indications of an effective diagnostic



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## **Please refer to NIHR International Funding Guidance**

NIHR funding for recruitment is only applicable to research in UK institutions. International recruitment is funded from other sources

- UK-based Chief Investigators and institutions must lead the UK aspects of any international studies to be funded by NIHR and the contract must be held by a UK organisation.
- Modest allowances for the extra central UK administration associated with international recruitment and collaboration will be considered.
- Applicants must demonstrate that they are seeking funding for recruitment at international centres from other sources when applying.
- Applicants should identify how the project will mitigate or allow for delays to international centre funding with clear stop/go criteria for the funding of international centre(s) and contingency plans if international funding is not approved.
- NIHR funding for recruitment is only applicable to research in UK institutions. International recruitment must be funded from other sources. There may be multiple funding sources for the international recruitment costs.
- Apart from the NIHR Global Health Programme it would be very unusual for NIHR programmes to fund recruitment internationally.

See <u>NIHR International funding</u> for further general information





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#### Please refer to NIHR Funding and Awards for examples of previously funded Platform Trials

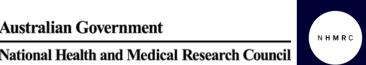
https://fundingawards.nihr.ac.uk/award/NIHR158714 https://fundingawards.nihr.ac.uk/award/NIHR133719

Examples of development awards used to plan a future platform application: https://fundingawards.nihr.ac.uk/award/NIHR154383 https://fundingawards.nihr.ac.uk/award/NIHR153811 https://fundingawards.nihr.ac.uk/award/NIHR153955 https://fundingawards.nihr.ac.uk/award/NIHR156028





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#### **Industry involvement**

- We welcome applications with industry involvement, this involvement can range from interventions being provided at a discount or free of charge, or other forms of in kind support, through to arms fully funded by industry.
- Provide evidence of your ability to work effectively with industrial partners and to deliver robust, independent and industrially relevant research. Do consider and mitigate for possible barriers to the inclusion of industry assets, and ensure there are efficiencies and benefits arising from the proposed platform approach.
- Develop and maintain appropriate industry stakeholder engagement, to explore industry assets and support a pipeline of potential future candidates interventions for use within the adaptive platform design, which must allow for interventions to be dropped and new candidates to be added as new technologies mature. Industrial partners often required evidence that the platform is appropriately designed and working well before engaging, so ongoing plans to continue to engage further industry partners throughout the award as part of the platform approach may be beneficial and required to support future sustainability.
- Funded research awards need to demonstrate their independence when working with Industry. As funders we have clear expectations
  on publication and IP ownership that will need to be communicated in advance with any potential industry partners. The <u>NIHR contract</u>
  and the Australian <u>Grant Opportunity Guidelines</u> outline the funder requirements so do please share these with potential industry
  partners in advance.

Industry may apply for funding as co-applicants with NHS or academic (Higher Education Institute) partners to this 2025 Australia-UK Platform call. Our NIHR Industry team can assist you in finding suitable partners for collaborative applications or inform you about alternative funding programmes available. <u>Contact the NIHR Industry team</u> for more information.



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#### **NIHR** National Institute for Health and Care Research







## 2025 Australia-UK Platform Studies in Areas of Unmet Clinical Need

Webinar and additional content end

