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Future Fund

**Stem Cell Therapies Mission
National Consultation on the Roadmap and Implementation
Plan**

Webinar



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Introduction

- Welcome
- No microphones will be active, only hosts are able to speak
- All questions can be sent via the interactive Q&A input
- One hour has been allocated at the end of the presentation to answer questions
- A copy of this presentation will be made available on the MRFF website

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Slide 3

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are we going to put it also on the Consultation hub or can that not be done when a consult is open?

Author, 21/01/2021

A97

Can it be put on the consultation hub through a link, and if it can, how long after the webinar will the presentation be provided to us?

Author, 4/02/2021



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MRFF Background

- Established in 2015, the \$20 billion Fund is a long-term sustainable source of research funding
- The MRFF aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability
- Complementary Government funding of health and medical research in Australia:
 - MRFF - awards funding for national priority areas that address gaps in research with a focus on research translation and commercialisation to improve the health and wellbeing of Australians
 - NHMRC - awards funding through a range of investigator-initiated schemes to build capacity and advance health and medical knowledge



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MRFF 10-year investment plan

- The Australian Government announced a \$5 billion, 10-year investment plan for the MRFF, as part of the 2019-20 budget.
- There are 20 initiatives under four themes, funded over 10 years to harness innovation, provide vital infrastructure, improve patient outcomes, and generate jobs and economic growth.

 Patients	Funding innovative treatments, supporting clinical trials, and delivering more advanced health care and medical technology to improve the health of all Australians
 Researchers	Supporting our researchers to make breakthrough discoveries, develop their skills and progress their careers in Australia
 Research missions	Helping researchers think big to tackle significant health challenges through investment, leadership and collaboration
 Research translation	Moving research ideas from the lab to the clinic, so that medical discoveries become part of clinical practice for GPs, specialists and hospitals





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MRFF Missions

- MRFF missions:
 - focus on an area of unmet need or a technology with transformational potential (priority led)
 - are planned and coordinated 10 year programs of work (strategic, Roadmap, Implementation Plan)
 - bring together key researchers, health professionals, consumers, stakeholders, industry partners (outcome focused)
 - harness resources across the system (investment, leadership and collaboration)
 - use innovative research approaches (new grant models)





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Purpose of consultation

- **Focus:** Mission design (Roadmap and Implementation Plan)

- **Questions:**

- As designed, will the Mission generate the knowledge required to develop, safe innovative and effective treatments using stem cells, that are accessible to all Australians?
- Will the proposed grant opportunities elicit the research required to generate the knowledge needed to improve practice/policy and outcomes?
- In 10 years time, will we know if the Mission has succeeded (evaluation measures)?



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Stem Cell Therapies Mission

- Forms part of the MRFF 10 Year Investment Plan announced in 2019
- The Mission will support world-leading translational stem cell research that develops and delivers innovative, safe and effective stem cell medicines to improve health outcomes, in partnership with patients and carers
- \$150 million over 9 years from 2019–20 as outlined below



2019–20 \$m	2020–21 \$m	2021–22 \$m	2022–23 \$m	2023–24 \$m	2024–25 \$m	2025–26 \$m	2026–27 \$m	2027–28 \$m	Total \$m
6.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0	18.0	150.0



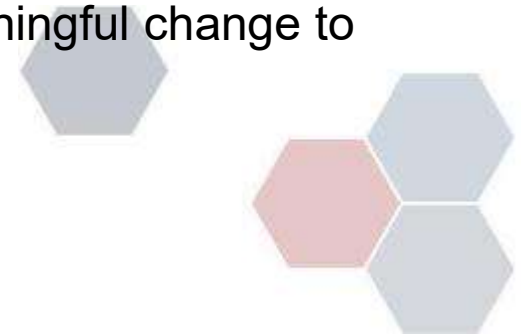


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Expert Advisory Panel

- 11 panel members, comprising eminent researchers and clinicians in stem cell therapy research
- Role to advise the Minister on the strategic priorities for research investment through the MRFF Stem Cell Therapies Missions by defining:
 - Sectoral gaps to be addressed to transform health care and health outcomes for individuals and communities
 - Key priority activities that if addressed will deliver meaningful change to patients through the translation of research.





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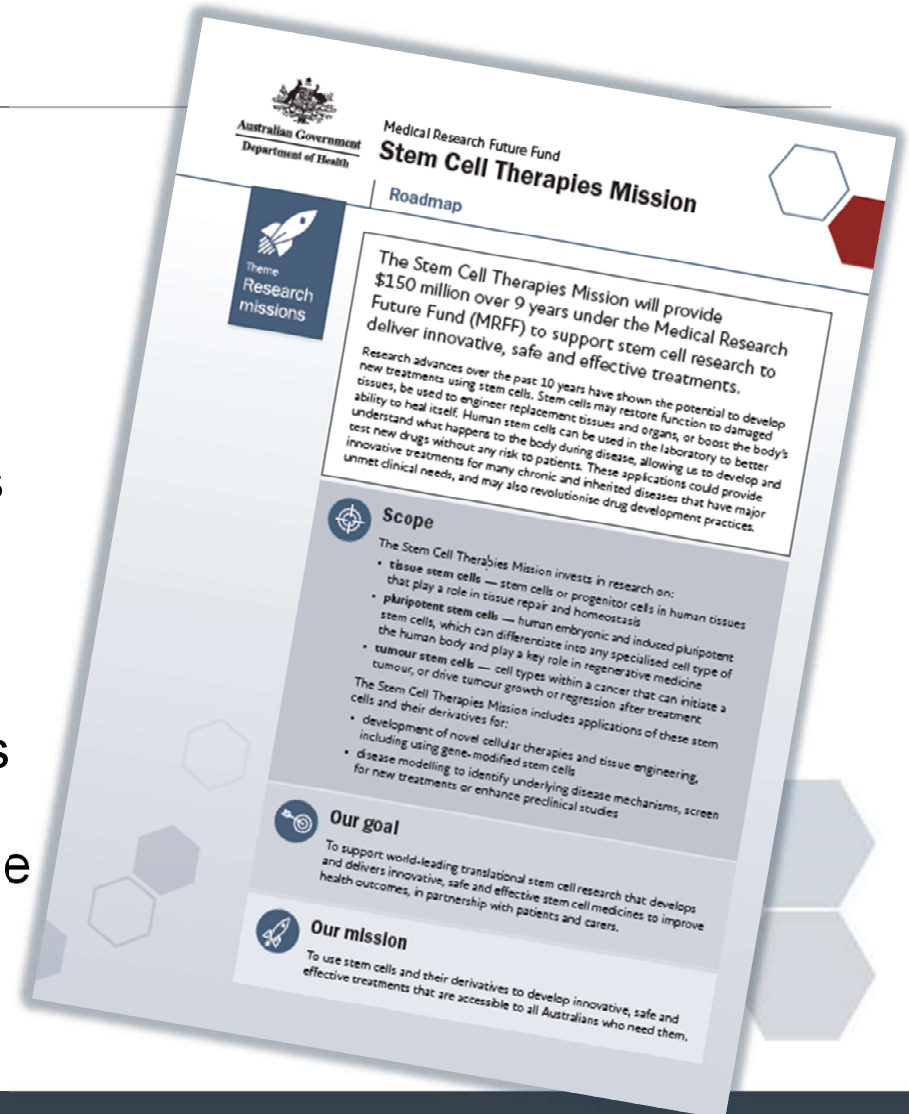
Roadmap – Goal and Mission

Our goal

To support world-leading translational stem cell research that develops and delivers innovative, safe and effective stem cell medicines to improve health outcomes, in partnership with patients and carers.

Our mission

To use stem cells and their derivatives to develop innovative, safe and effective treatments that are accessible to all Australians who need them. A98



Slide 10

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After this slide, can you include a snapshot of the roadmap scope?

Author, 5/02/2021

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Roadmap – Scope

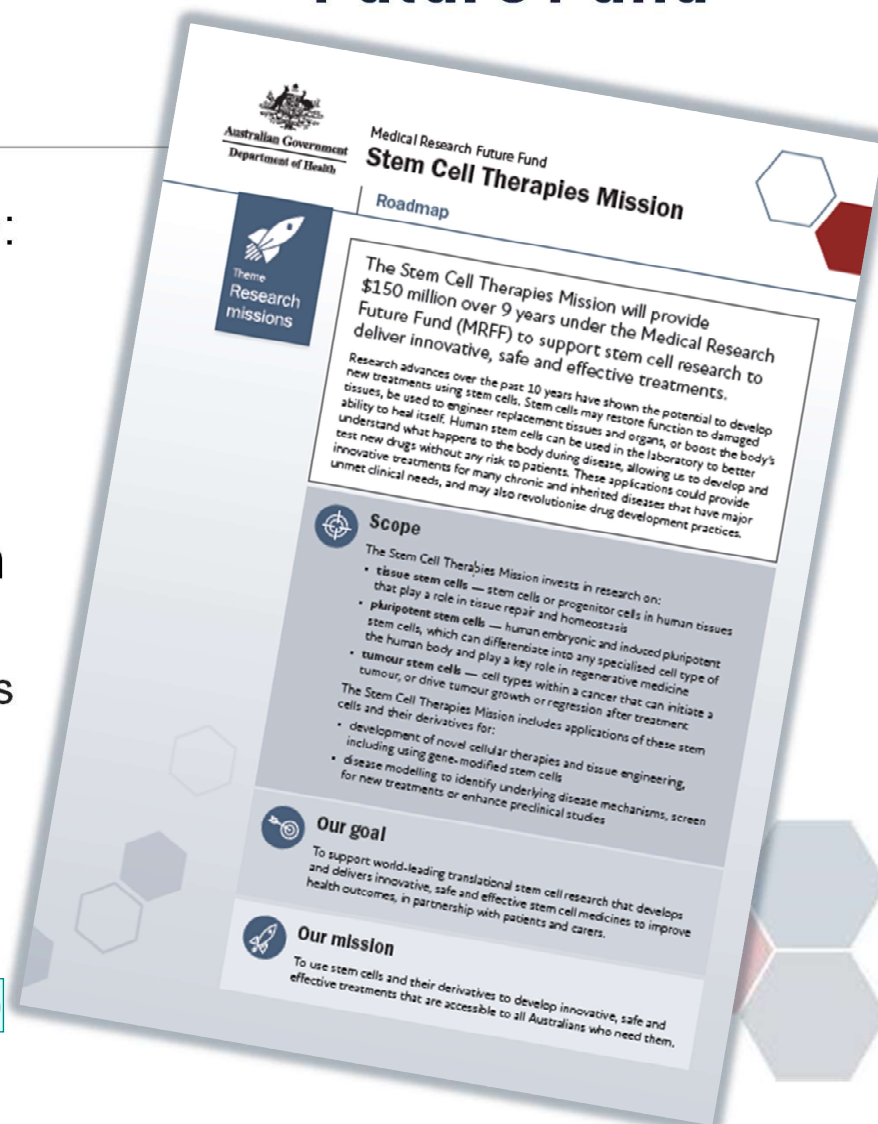
The mission will invest in research on:

- tissue stem cells
- pluripotent stem cells
- tumour stem cells

Funding the application of these stem cells and their derivatives for:

- Development of novel cellular therapeutics and tissue engineering, including gene-modified stem cells
- Disease modelling to identify underlying disease mechanisms, screening new treatments or enhance preclinical studies

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Slide 11

A99 After this slide, can you include a snapshot of the roadmap scope?

Author, 5/02/2021

A100 done

Author, 11/02/2021

Roadmap – Priority areas for investment

- Funding will focus on:
 - accelerating the development of safe, effective and affordable stem cell-based therapies
 - generating new treatments using human tissues made from stem cells (disease modelling for drug development)
 - building the health system and commercial sector to deliver these transformative treatments for the community.





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Implementation Plan

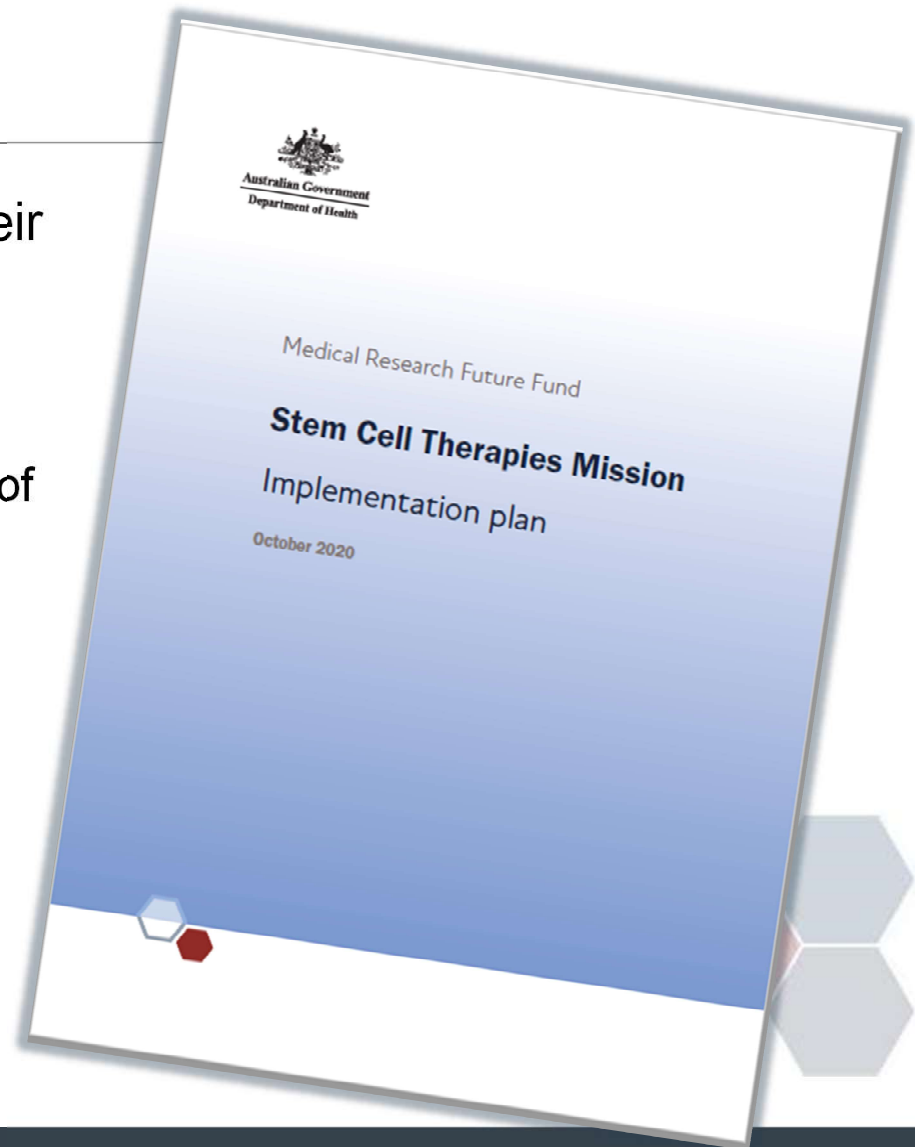
- Implementation strategy to guide research investment over the life of the Mission
- Priority areas for investment allocated across the short, medium and long term time-frames
- Establishes how the outcomes from each priority will be evaluated in terms of benefit to Australian patients and facilitate tracking of the mission's progress towards its objectives



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Implementation Plan

- Based on the priority areas and their goals, proposed to:
 - Identify the investment activities required to achieve these goals
 - Identify additional activities outside of the Mission that will be required to achieve success
 - Identify opportunities to leverage additional investment
 - Define what success will look like, how this might be measured and across what timeframe

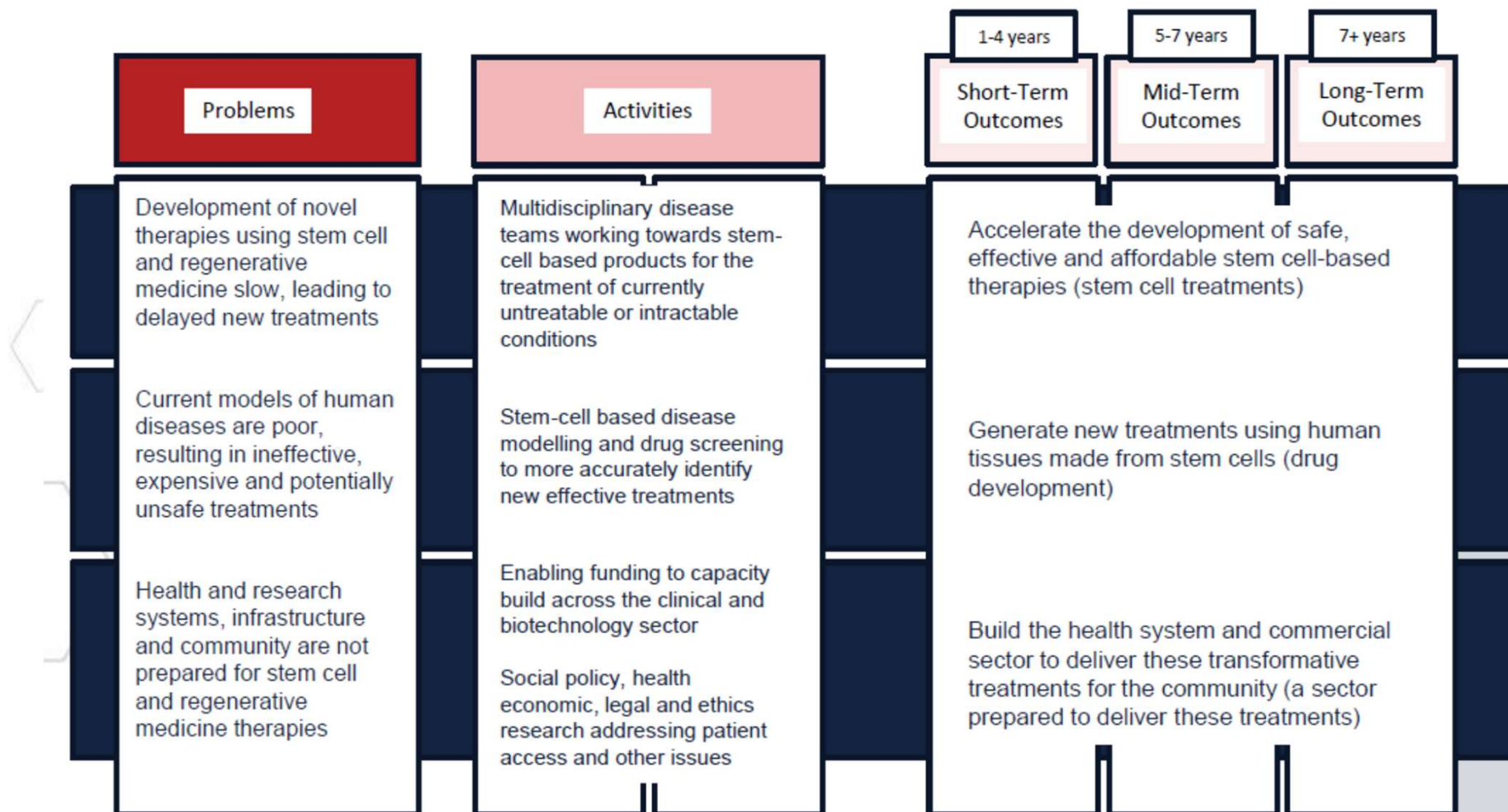




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Outcome / Logic Model



Slide 15

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snapshot taken of slide in IRP presentation pdf and pasted in as a picture

Author, 15/03/2021



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Implementation Plan: Priority Area 1

Accelerate the development of safe, effective and affordable stem cell-based therapies

Priority Area	Short term (1-2 years)	Medium term (2-5 years)	Long term (6-10 years)
1.1	Proof of concept studies to develop novel stem cell-based treatments 5 grants awarded (2019-20)		
1.2		Develop novel stem cell-based treatments by disease focused, multidisciplinary teams	
1.3	Conduct Phase 1 Clinical trials of novel stem cell-based treatments		

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Implementation Plan: Priority Area 2

Generate new treatments using human tissues made from stem cells for pre-clinical development

Priority Area	Short term (1-2 years)	Medium term (2-5 years)	Long term (6-10 years)
2.1 Developing platforms		Develop disease model platforms	
2.2 Evaluation and screening stem cell derived tissue models by multi-disciplinary teams	Application of stem cell based screens for the development of treatments for inherited disease, complex disease, infectious disease and cancer 5 grants awarded (2019-20) including a response to COVID-19	Large scale projects focusing on preclinical screening of new treatments using human tissues made from stem cells	



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Implementation Plan: Priority Area 3

Build the health system and commercial sector to deliver these transformative treatments for the community

Priority Area	Short term (1-2 years)	Medium term (2-5 years)	Long term (6-10 years)
3.1	Research the ethical, social, regulatory, health economics and legal issues associated with the development, availability, regulation and application of stem cell therapies and treatments		





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Stem Cell Therapies Mission - early investments

- In 2019-20 eight initial projects totalling \$5.73 million were funded for research designed to:
 - accelerate the development of safe, effective and affordable stem cell-based therapies; or
 - generate new treatments using human tissues made from stem cells.
- An additional \$1m was provided for 2 grants focusing on the use of stem cell models to screen approved drugs for repurposing for COVID-19





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Stem Cell Therapies – current open grant opportunity

- 2020-21 grant opportunity - \$17 million (closed 3 March 2021)

➤ Five streams:

- i. generating novel approaches to stem cell-based therapies that have the potential to transform clinical care
- ii. enabling faster access to promising stem cell treatments
- iii. making available new treatments for inherited disease, complex disease, infectious disease and cancer
- iv. building the evidence base to improve community trust, acceptance, and adoption of stem cell-based therapies
- v. facilitating rapid implementation of existing drugs for clinical use against COVID-19





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Stem Cell Therapies Mission Roadmap and Implementation Plan Consultation

- The Stem Cell Therapies Roadmap and Implementation Plan underwent international review in late 2020.
- The international review panel comprised experts who provided advice in the context of relevant activities occurring internationally, which can inform the strategic direction of the Stem Cell Therapies Mission's Roadmap and Implementation Plan.
- The panel was supportive of the Roadmap and the identified priorities, noting the challenge of implementation when these aspects are not directly enabled by the MRFF. There was encouragement to soften evaluable outcomes to those which are directly linked to MRFF Mission research
- The panel identified the need to have ELSI activities embedded in large teams within particularly Priority area 1.2
- The panel agreed that clinical trial funding should be Phase 1 only and limited in funding total.

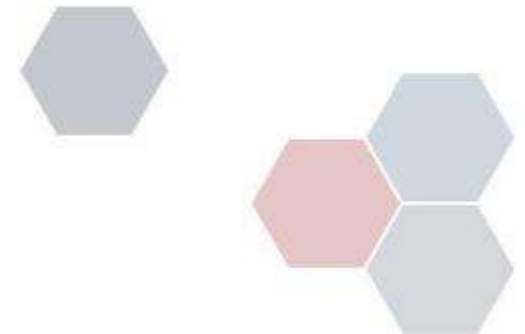


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Stem Cell Therapies Mission Roadmap and Implementation Plan Consultation

- Consultation on the Stem Cell Therapies Mission Roadmap and Implementation plan is now subject to national review.
- Written submissions may be made at:
www.consultations.health.gov.au
- The Minister for Health is interested in your comments on the Stem Cell Therapies Mission Roadmap and Implementation Plan, which will guide future MRFF investments.



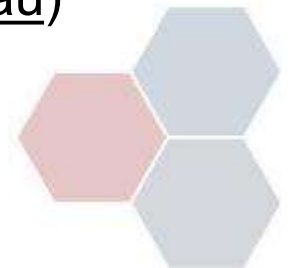


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Consultation – open discussion

- One hour allocated
- Please type questions in the Q&A box provided on the screen
- Questions and feedback will be collated for the presenters to note or discuss
- All submissions can be made through the Consultation Hub on the Department of Health website (www.consultations.health.gov.au)
- **Reminder - online submissions close 23rd April 2021**



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Consultation questions

- Are the priority areas for investment identified in the implementation plan the most effective way for delivering on the Mission's goal and aims?
- Are there existing research activities which could be utilised to contribute to the Stem Cell Therapies Mission Roadmap and/or Implementation Plan aims and priority areas for investment? How can these be leveraged?
- Are the 'Evaluation approach and measures' appropriate for assessing and monitoring progress towards the mission's goal and aims?
- Other?





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More information:

www.health.gov.au/MRFF
www.consultations.health.gov.au



Interested in accessing MRFF grants:

Register with **GRANTCONNECT** (www.grants.gov.au)

Thank you

