

ACTA International Clinical Trials Conference, Sydney
3 October 2019

Why and how NHMRC supports clinical trials

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Chief Executive Officer



NHMRC

BUILDING
A HEALTHY
AUSTRALIA

National Health and Medical Research Council

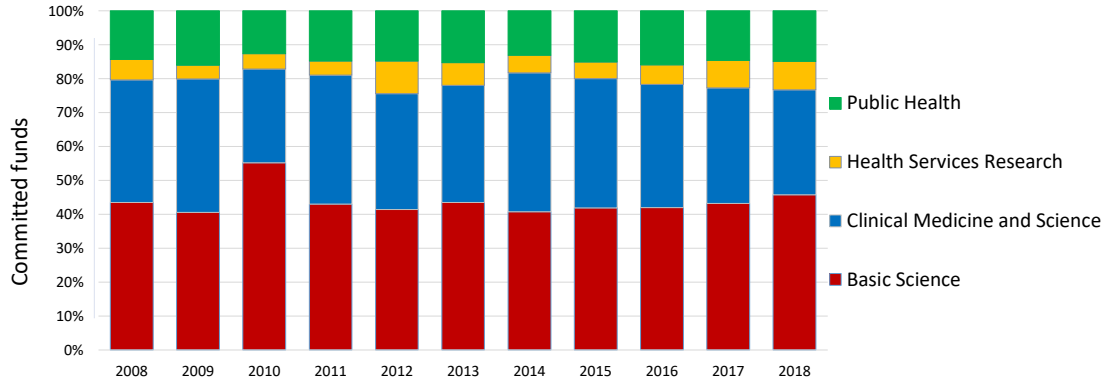
- NHMRC is the Australian Government's lead funding agency for health and medical research.
- NHMRC delivers about \$840 million funding per annum:
 - goal of all funding is improvement of human health
 - about 5000 applications and 4000 active grants each year
 - various schemes, mostly investigator-initiated
 - contestable based on independent peer review.
- NHMRC is also responsible for:
 - national codes of research conduct and ethics
 - regulation of research with human embryos
 - clinical, public health and environmental health guidelines and information statements.



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Why NHMRC supports clinical trials

- NHMRC has a broad remit to raise the standard of individual and public health in Australia.

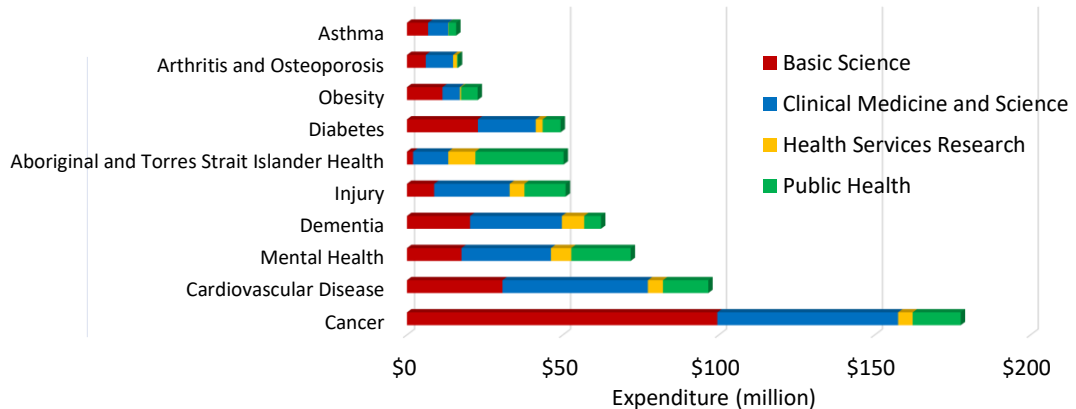


*Broad Research Area is selected by applicant.



Why NHMRC supports clinical trials

- NHMRC has a broad remit to raise the standard of individual and public health in Australia.



Note: Some grants may cover more than one priority area, so the values cannot be summed.



Why NHMRC supports clinical trials

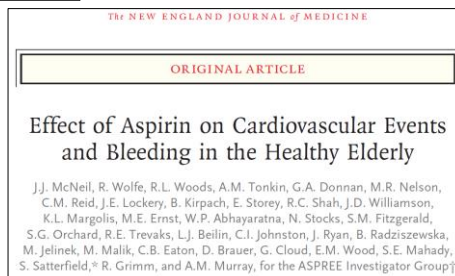
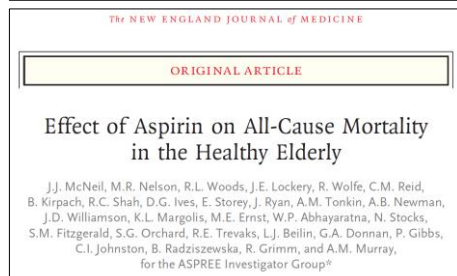
- NHMRC has a broad remit to raise the standard of individual and public health in Australia.
- Clinical trials are a critical step in the journey from idea, discovery or invention to improved health – and therefore a key element of NHMRC’s grant program.
- NHMRC-funded clinical trials have made substantial contributions to improvements in individual and public health:
 - high-quality evidence to support or change standard practice
 - participation in international multicentre trials, increasing statistical power and relevance across populations and health systems
 - leverage of funds from other sources
 - patient involvement
 - savings for health system and wider economy.

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Why NHMRC supports clinical trials



**2019 ACTA Clinical Trial of the Year:
ASPREE Study**



18 October 2018

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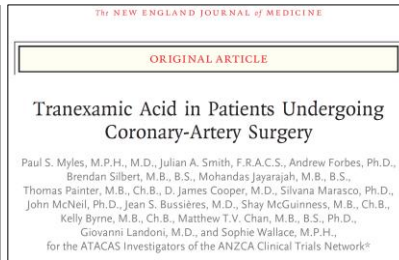
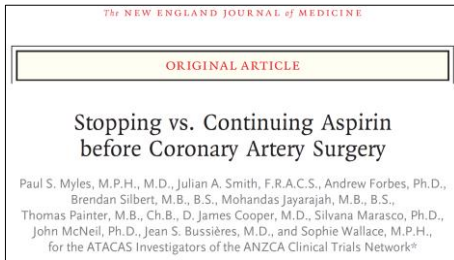
Why NHMRC supports clinical trials

2017 ACTA Clinical Trial of the Year: APT Study

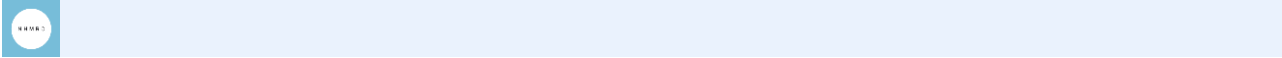


21 December 2017

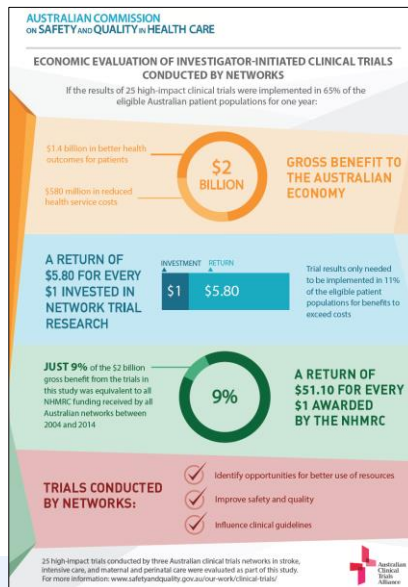
2018 ACTA Clinical Trial of the Year: ATACAS Trial



25 February 2016
12 January 2017



Why NHMRC supports clinical trials



How NHMRC supports clinical trials

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NHMRC's new grant program – principles

- Primary goal: improve health through research.
- Achieve by supporting a diversified portfolio of investigator-initiated and priority-driven projects across the breadth of health and medical research – laboratory, clinic, community.
- Meet structural priorities by supporting:
 - the best people at all career stages
 - the most innovative ideas
 - multi-disciplinary and diverse research teams and networks
 - research at different scales
 - clinical trials and cohort studies
 - partnerships with end-users (healthcare sector/policy makers)
 - early-stage commercial research
 - international collaboration.

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NHMRC's new grant program – structure

Investigator Grants	Synergy Grants	Ideas Grants	Strategic and leveraging grants
Support the research program of outstanding investigators at all career stages *NEW*	Support outstanding multidisciplinary teams to work together to answer major questions that cannot be answered by a single investigator *NEW*	Support innovative research projects addressing a specific question *NEW*	Research that responds to national priorities: <ul style="list-style-type: none"> Centres of Research Excellence Partnership Projects Development Grants Targeted Calls for Research International schemes Clinical trials and cohort studies *NEW*
Salary + research support package	Research costs (\$5 million)	Research costs	Research costs
One per investigator*	One per investigator*	Two per investigator*	No caps

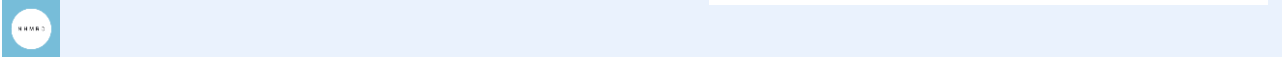
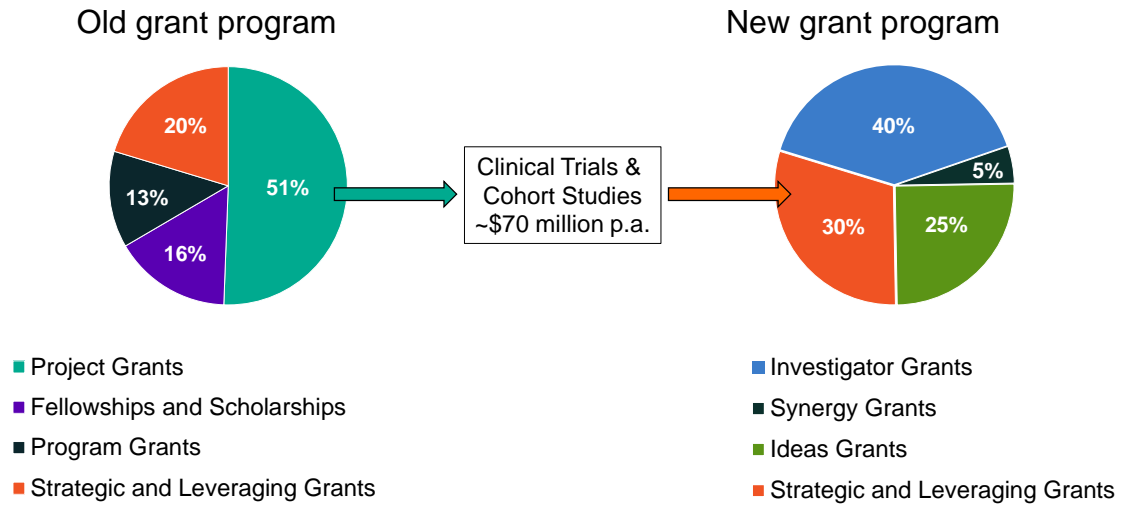
* Researchers may hold one Investigator Grant or up to two Ideas Grants

Clinical Trials and Cohort Studies Scheme

- Objective: support high-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health
- Open to research proposals for clinical trials and/or cohort studies of any size, up to 5 years, including:
 - applications for new clinical trials and/or cohort studies
 - proposals to answer research questions using findings from existing trials or cohort studies.
- Assessment criteria:
 - Significance (40%)
 - Research Quality (40%)
 - Team Quality and Capability (20%)

- Greater visibility and no caps
- Focus on rationale (systematic review)
- Design: SPIRIT and STROBE checklists
- Milestone reporting

NHMRC's new grant program – redividing the pie



Clinical Trials and Cohort Studies Scheme – first round



Clinical Trials and Cohort Studies Scheme – first round

- At application close (May 2019):
 - 571 applications received; one withdrawn; 570 underwent peer review
 - ~69% applications involved a clinical trial
 - Total \$1,013 million requested (range \$117,000 – \$10.7 million)
 - Total budget available: \$70 million
- Peer review:
 - 3 independent reviews of each application
 - 195 applications (~34%) proceeded to Grant Review Panel (total request \$415 million)
 - 8 Grant Review Panels: 6 for trials, 2 for cohorts; 23-26 grants per panel
- Outcomes: announcement expected in November



Issues in the first round

- High application numbers across all new schemes, including CTCS:
 - Anticipate low success rates
 - Applications to CTCS scheme will remain uncapped for now (number per CI and budget)
 - Watching brief
- Trials versus cohorts: open competition rather than fixed allocation
- Submission of CTCS applications to Ideas Grant scheme:
 - Generous approach to eligibility in first round
 - Working on stronger definition of boundary between the schemes
 - Applicants will need to pay attention to eligibility in future rounds



The future of clinical trial funding by NHMRC

- Clinical trials are a critical element of NHMRC's grant program, now highlighted through the new Clinical Trials and Cohort Studies Scheme.
- NHMRC will continue to support investigator-initiated clinical trials across all disease areas.
- This support will complement priority-driven funding for clinical trials by the Medical Research Future Fund.
- Budgets for each grant scheme will be reviewed annually as usual, but significant changes are not anticipated during the transition to the new grant program.
- Scheme guidelines and peer review processes will evolve over time – please give us feedback and watch out for changes.

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Australian Government

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Thank you

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