

ACTA International Clinical Trials Conference, Sydney 3 October 2019

Why and how NHMRC supports clinical trials

Professor Anne Kelso AO Chief Executive Officer







National Health and Medical Research Council

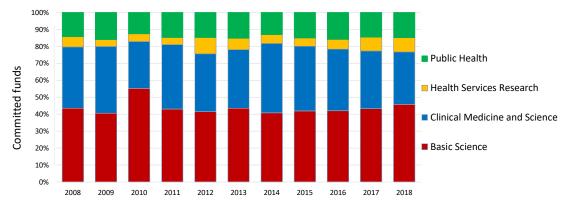
- NHMRC is the Australian Government's lead funding agency for health and medical research.
- NHMRC delivers about \$840 million funding per annum:
 - o goal of all funding is improvement of human health
 - o about 5000 applications and 4000 active grants each year
 - o various schemes, mostly investigator-initiated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





Why NHMRC supports clinical trials

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

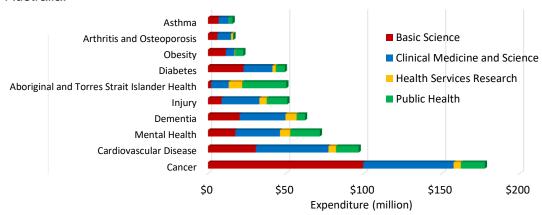


*Broad Research Area is selected by applicant.



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
 - o savings for health system and wider economy.



Why NHMRC supports clinical trials



2019 ACTA Clinical Trial of the Year: ASPREE Study

Effect of Aspirin on All-Cause Mortality
in the Healthy Elderly

J.J. McNeil, M.R. Nelson, R.L. Woods, J.E. Lockery, R. Wolfe, C.M. Reid,
B. Kirpach, R.C. Shah, D.G. Ives, E. Storey, J. Ryan, A.M. Tonkin, A.B. Newman,
J.D. Williamson, K.L. Margolis, M.E. Ernst, W.P. Abhayaratna, N. Stocks,
S.M. Fitzgerald, S.G. Orchard, R.E. Trevaks, L.J. Beilin, G.A. Donnan, P. Gibbs,
C.I. Johnston, B. Radziszewska, R. Grimm, and A.M. Murray,
for the ASPREE Investigator Group*

Effect of Aspirin on Cardiovascular Events and Bleeding in the Healthy Elderly

J.J. McNeil, R. Wolfe, R.L. Woods, A.M. Tonkin, G.A. Donnan, M.R. Nelson, C.M. Reid, J.E. Lockery, B. Kirpach, E. Storey, R.C. Shah, J.D. Williamson, K.L. Margolis, M.E. Ernst, W.P. Abhayaratan, N. Stocks, S.M. Fitzgerald, S.G. Orchard, R.E. Trevaks, L.J. Beilin, C.I. Johnston, J. Ryan, B. Radziszewska, M. Jelinek, M. Malik, C.B. Eaton, D. Brauer, G. Cloud, E.M. Wood, S.E. Mahady, S. Satterfield, R. Grimm, and A.M. Murray, for the ASPREE investigator Group?

18 October 2018



Why NHMRC supports clinical trials

2017 ACTA Clinical Trial of the Year: APT Study

Delayed versus Immediate Cord Clamping in Preterm Infants

W. Tarnow-Mordi, J. Moris, A. Kirby, K. Robledo, L. Askie, R. Brown, N. Evans, S. Finlayson, M. Fogarty, V. Gebski, A. Ghadge, W. Hague, D. Isaacs, M. Jeffery, A. Keech, M. Kluckow, H. Popat, L. Sebastian, K. Aagaard, M. Belfort, M. Pammi, M. Abdel-taff, G. Reynolds, S. Ariff, L. Sheikh, Y. Chen, P. Colditz, H. Liley, M. Prichard, D. de Luca, K. de Waal, P. Forder, L. Duley, W. El-Naggar, A. Gill, J. Newhan, K. Simmer, K. Groom, P. Weston, C. Gullam, H. Patel, G. Koh, K. Lui, N. Marlow, S. Morris, A. Sehgal, E. Wallace, R. Soll, L. Young, D. Sweet, S. Waller, A. Waldsins, I. Wright, D. Osborn, and J. Simes, for the Australian Placental Transfusion Study Collaborative Group®

2018 ACTA Clinical Trial of the Year: ATACAS Trial

ORIGINAL ARTICLE

Stopping vs. Continuing Aspirin before Coronary Artery Surgery

Paul S. Myles, M.P.H., M.D., Julian A. Smith, F.R.A.C.S., Andrew Forbes, Ph.D., Brendan Silbert, M.B., B.S., Mohandas Jayarajah, M.B., B.S., Thomas Painter, M.B., Ch.B., D. James Cooper, M.D., Silvana Marasco, Ph.D., John McNeil, Ph.D., Jean S. Bussières, M.D., and Sophie Wallace, M.P.H., for the ATACAS Investigators of the ANZCA Clinical Trials Network* ORIGINAL ARTICLE

Tranexamic Acid in Patients Undergoing Coronary-Artery Surgery

Paul S. Myles, M.P.H., M.D., Julian A. Smith, F.R.A.C. S., Andrew Forbes, Ph.D., Brendan Silbert, M.B., B.S., Mohandas Jayarajah, M.B., B.S., Thomas Painter, M.B., C.H.B., D. James Cooper, M.D., Silvana Marasco, Ph.D., John McNeil, Ph.D., Jean S. Bussieres, M.D., Shaw, McGuinness, M.B., Ch.B., Kelly Byrne, M.B., C.H.B., Matthew T.V. Chan, M.B., B.S., Ph.D., Giovanni Landoni, M.D., and Sophie Wallace, M.P.H., for the ATACAS Investigators of the ANZCA Clinical Trials Network® 21 December 2017

25 February 2016 12 January 2017



Why NHMRC supports clinical trials







How NHMRC supports clinical trials



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:
 - o the best people at all career stages
 - o the most innovative ideas
 - o multi-disciplinary and diverse research teams and networks
 - o research at different scales
 - o clinical trials and cohort studies
 - o partnerships with end-users (healthcare sector/policy makers)
 - o early-stage commercial research
 - o international collaboration.





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: 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

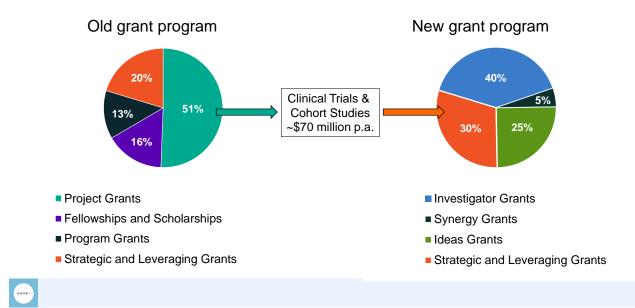


Clinical Trials and Cohort Studies Scheme

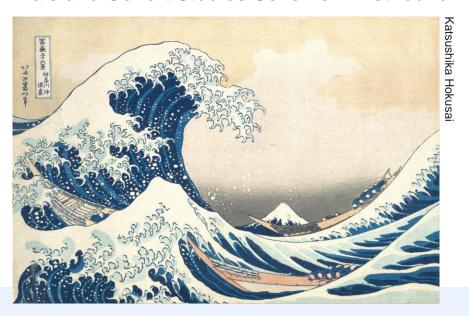
- Objective: support high-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health
- Open to research proposals for clinical trials and/or cohort studies of any size, up to 5 years, including:
 - o applications for new clinical trials and/or cohort studies
 - o proposals to answer research questions using findings from existing trials or cohort studies.
- · Assessment criteria:
 - Significance (40%)
 - Research Quality (40%)
 - o 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
 - o ~69% applications involved a clinical trial
 - Total \$1,013 million requested (range \$117,000 \$10.7 million)
 - Total budget available: \$70 million
- · Peer review:
 - o 3 independent reviews of each application
 - 195 applications (~34%) proceeded to Grant Review Panel (total request \$415 million)
 - o 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

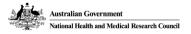
- · High application numbers across all new schemes, including CTCS:
 - Anticipate low success rates
 - o Applications to CTCS scheme will remain uncapped for now (number per CI and budget)
 - Watching brief
- Trials versus cohorts: open competition rather than fixed allocation
- Submission of CTCS applications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





Thank you



BUILDING A HEALTHY