



**Australian  
Clinical  
Trials  
Alliance**

**Pre Budget Submission 2017/18**

## About ACTA

The Australian Clinical Trials Alliance (ACTA) welcomes the opportunity to contribute to discussions regarding the 2017/18 Federal Budget.

ACTA is a coalition of more than 70 clinical trials networks, clinical trial coordinating centres and clinical quality registries across Australia (see appendix A for a full list of ACTA member organisations) with a combined membership of more than 10,000 individuals – the vast majority of whom have dual roles as researchers and clinicians working within Australia’s healthcare system

**Our mission is to promote effective and cost-effective healthcare in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decisions made by health practitioners, policymakers and consumers.**

As outlined later in this submission, there is now evidence of the magnitude of return on investment in investigator-initiated clinical trials and clinical quality registries.

Our submission focuses on key priorities for advancing the role and value of investigator-initiated clinical trials and registries as an integral component of Australia’s strategy for ensuring we have an effective, cost-effective healthcare system for generations to come.

## Summary of key priorities for the 2017/18 Federal Budget

- 1) Maintain the planned capital contribution to the MRFF and maintain the NHMRC budget in real terms.**
- 2) Develop a national capacity building framework for clinical trials networks.**
- 3) Develop and implement a national policy and funding framework for clinical quality registries.**
- 4) Support further policy development that enables the integration of evidence development and reimbursement.**
- 5) Establish a multi-stakeholder forum program for improving the quality and efficiency of trials conducted in Australia.**
- 6) Support leadership, coordination and collaboration across the investigator-initiated clinical trials and registries sector.**

## Background

Managing excessive growth in healthcare expenditure is, arguably, the biggest fiscal challenge that Australia faces.

ACTA is an alliance of clinician researchers who deliver healthcare at the coalface, and work to improve it, on daily basis. We believe it is possible to simultaneously improve healthcare quality and outcomes whilst controlling costs through relatively modest (in comparison to the costs of care delivery) targeted investment in two key activities - generating evidence of what treatments actually work (through clinical trials) and measuring, reporting and benchmarking patient outcomes across services (through clinical quality registries).

**A very substantial proportion of healthcare expenditure is spent on treatments for which there is insufficient evidence to tell us whether the treatment works, where there are alternative options, and which options result in the best outcomes for patients per dollar of expenditure. As such, there is enormous potential for investigator-initiated or 'public good' clinical trials and clinical quality registries to play a central role in helping to bend the health cost curve, drive better quality care and realise the wider economic benefits of a healthier Australian community.**

Two landmark studies commissioned by the Australian Commission on Safety and Quality in Health Care (the Commission) in 2015/16 demonstrate the sizeable returns that limited existing investment in clinical trials conducted by established clinical trial networks and clinical quality registries have delivered to the Australian economy. These returns substantially outweigh the widely quoted \$2.17 return on investment in health and medical research.<sup>1</sup>

The *Economic Evaluation of Clinical Quality Registries*<sup>2</sup> undertaken by Monash University and Health Outcomes Australia concluded that Australian clinical quality registries, when funded sufficiently and operating effectively, improve the value of care delivery at a relatively low cost.

Using conservative assumptions to assess the cost-effectiveness of five established registries in Australia, the study reported that **if registries achieve full national coverage, the minimum expected benefit to cost ratio is 4:1. That is, a \$4.00 return for every \$1 invested.**

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<sup>1</sup> Access Economics, *Exceptional Returns: The Value of Investing in Health R&D in Australia II*, Canberra, Australian Society for Medical Research, 2008.

<sup>2</sup> The Australian Commission on Safety and Quality in Health Care. *Economic evaluation of clinical quality registries: Final report*. Sydney: ACSQHC; 2016

Preliminary data from the *Economic Evaluation of Investigator-Initiated Clinical Trials Conducted by Networks*<sup>3</sup> undertaken by ACTA and Health Outcomes Australia indicates that investigator-initiated trials conducted by Australian networks have delivered substantial benefits through better health outcomes and avoided service costs.

**A \$2billion gross benefit was calculated to have been delivered if the findings of 25 trials conducted by three Australian networks were implemented in 65% of the eligible patient population FOR ONE YEAR.**

**The calculated benefit to cost ratio was 5.8:1. That is, \$5.80 for every \$1 invested.** Of this benefit, 30% was derived from reduced costs of healthcare delivery (avoidance of ineffective or harmful therapies) and the remaining 70% accrued as a consequence of improved survival and avoidance of disability among treated patients.

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<sup>3</sup> Preliminary data presented by the Australian Commission on Safety and Quality in Health Care at the ACTA 2016 Summit, Melbourne, 24 November, 2016. Available at <http://www.clinicaltrialsalliance.org.au/wp-content/uploads/2017/01/ACSQHC-Presentation-ACTA-summit-2016-16-9.pdf>

# Advancing the role and value of investigator-initiated clinical trials and clinical quality registries in Australia: Key priorities for the 2017/18 Federal Budget

## **1) Maintain the planned capital contribution to the MRFF and maintain the NHMRC budget in real terms.**

The MRFF represents a historic turning point for Australian healthcare and we commend the Australia Government for its vision in establishing the fund and subsequently delivering the *Australian Medical Research and Innovation Strategy 2016-2021* (the Strategy) and *Priorities 2016-2018* (the Priorities).

ACTA recognises the considerable pressure on the health budget and that MRFF funding must be directed towards initiatives that have demonstrated potential to deliver a measurable return on investment in terms of better health outcomes for patients and a better quality, more efficient health system.

As a sector that is deeply invested in achieving the same goal, we are tremendously encouraged to see that activities that embed the generation and implementation of evidence within the healthcare system—including fellowships for clinician researchers, investigator-initiated trials, clinical trials networks and clinical quality registries—have been prioritised for funding in the first two years of MRFF distribution.

At least until the MRFF is fully capitalised, the NHMRC will continue to be the primary source of resources to conduct investigator-initiated clinical trials. Moreover, the NHMRC is equipped and experienced at conducting high-quality peer review of clinical trials to ensure that the projects with the greatest potential to improve health are those that are supported. Over time, the optimal division of responsibilities between the MRFF and the NHMRC will become clear but it is ACTA's strong view that the interests of the nation and the broader health and medical research community will be best served by an ongoing commitment to the current level of budgetary support for the NHMRC in real-terms.

**We call on the Australian Government to uphold its commitment to fully capitalise the MRFF to \$20b by 2020/21, and to maintain its level of funding to the NHMRC in real terms in 2017/18 and over the forward estimates.**

## 2) Develop a national capacity building framework for clinical trials networks.

ACTA applauds the Australian Government's clear recognition of the value proposition for supporting clinical trials networks, evident in the inclusion of *"infrastructure support for existing and new national clinical trial networks to enhance innovation, collaboration, clinical research capacity and patient participation"* as a priority for funding in the first two-years of MRFF distribution<sup>4</sup>.

Through work conducted by ACTA, we know that there are approximately 40 established clinical trials networks in Australia in various stages of maturity<sup>5</sup>. We know that these geographically diverse, multidisciplinary collaborations of practicing clinician researchers provide a unique and highly effective and efficient mechanism for identifying major gaps in the evidence base and conducting well-designed clinical trials that have a high degree of influence on policy and practice. We also know that even highly successful networks report that their capacity to undertake important investigator-initiated trials could be expanded considerably, and that there are a number of high-burden areas of the health system where networks don't yet exist.

What we don't know, at a national level, is:

- what the critical success factors for establishing and operating efficient high-impact networks are;
- what type and level of investment in core infrastructure is needed;
- where opportunities exist to further enhance the efficiency and value of conducting trials through networks;
- how investment in networks should be prioritised and distributed; and
- how the impact of such investment should be measured.

A 'one size fits all' model for establishing and sustaining clinical trials networks is likely to limit success due to the complexities of building collaboration and expertise in different clinical areas. A model that works well in one field doesn't necessarily work for another. And whilst sizeable returns on investment have been demonstrated, the 'optimal' target for investment in core infrastructure that maximise the value of networks hasn't been evaluated. Only networks themselves can provide these insights.

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<sup>4</sup> Australian Medical Research and Innovation Priorities 2016-2018. Available at [http://health.gov.au/internet/main/publishing.nsf/Content/mrff/\\$FILE/Australian%20Medical%20Research%20and%20Innovation%20Priorities%202016.pdf](http://health.gov.au/internet/main/publishing.nsf/Content/mrff/$FILE/Australian%20Medical%20Research%20and%20Innovation%20Priorities%202016.pdf)

<sup>5</sup> Report on the Activities and Achievements of Clinical Trials Networks in Australia 2004-2014. Australian Clinical Trials Alliance, Melbourne 2015. Available at [http://www.clinicaltrialsalliance.org.au/wp-content/uploads/2015/12/ACTA\\_Networks\\_Report\\_2004-14\\_online.pdf](http://www.clinicaltrialsalliance.org.au/wp-content/uploads/2015/12/ACTA_Networks_Report_2004-14_online.pdf)

Furthermore, we believe that as new investment in network infrastructure becomes available, best-practice guidelines should support networks to achieve optimal standards of operation, including (but not limited to):

- Good governance practices
- Minimum standards for national collaborative development of trial questions
- Minimum standards for high-quality trial design, conduct and reporting
- Models of consumer and community engagement
- Models of registry linkage
- Pathways for driving translation of clinical trial results into clinical practice and policy.

**ACTA believes there is an urgent need to develop a national capacity building framework for clinical trials networks in order to ensure that funding via the MRFF to support networks is guided by a comprehensive, coordinated, evidence-based approach that is informed by the sector and broadly supported the sector.**

**We call on the Australian Government to ensure that an appropriate level of funding is allocated to undertake this critical work as part of a strategic, phased approach to delivering vital infrastructure support for networks.**

### **3) Develop and implement a national policy and funding framework for clinical quality registries.**

ACTA strongly supports the substantial body of early work led by the Commission to advance the clinical quality registry sector in Australia, including publication of the *Framework for Australian Clinical Quality Registries*, and more recently, the Australian Department of Health in coordinating efforts to develop a national clinical quality registry policy and funding framework.

**We call on the Australia Government to allocate an appropriate level of Commonwealth funding in the 2017/18 budget and over the forward estimates to continue critical areas of policy development that aim to:**

- **improve the quality and value of routinely collected data;**
- **expand the capture of existing registries;**
- **reduce fragmentation and improve interoperability across jurisdictions;**
- **provide funding sustainability to support efficient registry operation; and**
- **increase the capacity of national clinical quality registries to drive appropriate and efficient healthcare delivery.**

#### **4) Support further policy development that enables the integration of evidence development and reimbursement.**

ACTA commends the Australian Government for its work in undertaking the exhaustive Medicare Benefits Schedule (MBS) Review. In particular, we consider the establishment of the MBS Taskforce Clinical Research Working Group to explore ways that clinical trials and registries can and should be used to answer MBS-relevant questions an important, and potentially transformative, step forward.

**We urge the Australian Government to ensure that the Working Group is appropriately supported in the 2017/18 budget to deliver a comprehensive evaluation of the opportunities for embedding the generation of evidence (through both clinical trials and registries) into reimbursement policy and processes in Australia, and that adequate funding is ring fenced over the forward estimates to implement to the recommendations of the Working Group.**

#### **5) Establish a multi-stakeholder forum program for improving the quality and efficiency of trials conducted in Australia.**

ACTA acknowledges and supports the valuable work already undertaken by the Department of Health, the Department of Industry and Innovation, the NHMRC and Clinical Trials Jurisdictional Working Group (CTJWG) to improve the operating environment for conducting trials, particularly those conducted across multiple jurisdictions in Australia.

We believe it is critical that this program of work continues to be supported at the Commonwealth level, including as part of the Australian Government's \$7m commitment to make it easier for trials to take place in Australia. However, this program will not address all barriers and enablers to efficient trial conduct. In particular, greater linkage and engagement between individuals who conduct investigator-initiated trials and those who are responsible for managing the delivery of healthcare is a necessary pre-requisite for major improvements in the efficiency of trial conduct.

**We call on the Australian Government to establish a collaborative forum program equipped to bring together leaders from the key stakeholder groups in clinical trials—investigators, healthcare providers, consumers, government, industry and research bodies— to develop practical, evidence-based tools and recommendations for improving the quality and efficiency of trials conducted in Australia.**

**We believe the program should be structured to complement and leverage existing efforts, particularly those of the NHMRC and CTJWG, offering an agile mechanism for rapid distribution and implementation of recommendations among stakeholder networks.**



## **6) Support leadership, coordination and collaboration across the investigator-initiated clinical trials and registries sector.**

ACTA was established in 2014 to provide a national mechanism for supporting and advancing high-quality, public good clinical trials and clinical quality registries within the Australia health system. This was in response to an identified need to provide a single, coordinated pathway to link clinicians working collaboratively to improve the evidence base for high-quality care with each other as a cohesive sector, and with Government and key stakeholders.

With over 70 organisations now formally members of the Alliance, the Alliance has successfully engaged and brought together a large, clinically diverse and previously fragmented sector that represents well over 10,000 senior clinicians and researchers working to improve outcomes across a large proportion of the health system, including acute, sub-acute and primary care and across metropolitan, regional and rural centres.

The collective expertise and achievements of the organisations that come together under the ACTA umbrella are without parallel anywhere else in the world. Key work undertaken by ACTA in collaboration with our members has been instrumental in bringing focus to the role and value of investigator-initiated trials conducted by networks and clinical quality registries, together with the method centres that coordinate and manage trials and registries in Australia. In spite of these considerable achievements, ACTA's future remains uncertain.

**We call on the Australian Government to provide vital medium-term sustainability to ensure that ACTA can continue to develop as a piece of major national infrastructure supporting leadership, coordination and collaboration across the investigator-initiated clinical trials and registries sector.**

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## Appendix A. ACTA Member Organisations

### Full Members

- Australasian Gastro-Intestinal Trials Group
- Australasian Kidney Trials Network
- Australasian Lung Cancer Trials Group
- Australasian Rehabilitation Outcomes Centre, incorporating Palliative Care Outcomes Collaboration & Electronic Persistent Pain Outcomes Centre
- Australasian Sarcoma Study Group
- Australasian Stroke Trials Network
- Australia and New Zealand Breast Cancer Trials Group
- Australia and New Zealand Society of Cardiac & Thoracic Surgeons National Cardiac Surgery Database Program
- Australia New Zealand Gynaecological Oncology Group
- Australian & New Zealand Neonatal Network
- Australian & New Zealand Urogenital & Prostate Cancer Trials Group
- Australian and New Zealand Children's Haematology/Oncology Group
- Australian and New Zealand College of Anaesthetists Clinical Trials Network
- Australian and New Zealand Dialysis and Transplantation Registry
- Australian and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation
- Australian and New Zealand Intensive Care Society Clinical Trials Group
- Australian and New Zealand Melanoma Trials Group
- Australian Orthopaedic Association National Joint Replacement Register
- Australian Research Centre for Health of Women and Babies
- Bariatric Surgery Registry
- Cooperative Trials Group for Neuro-Oncology
- Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network
- Mater Misericordiae Health Services Brisbane Limited
- Melbourne Children's Trials Centre
- Menzies School of Health Research
- Neuroscience Trials Australia
- NHMRC Clinical Trials Centre
- Paediatric Research in Emergency Departments International Collaborative
- Palliative Care Clinical Studies Collaborative
- Primary Care Collaborative Cancer Clinical Trials Group
- Prostate Cancer Outcomes Registry Australia & New Zealand
- Psycho-oncology Co-operative Research Group

- School of Public Health and Preventive Medicine, Monash University
- South Australian Health and Medical Research Institute
- The George Institute for Global Health
- Therapeutic & Vaccine Development Research Group, The Kirby Institute
- Trans Tasman Radiation Oncology Group
- Victorian Ambulance Cardiac Arrest Registry
- Victorian Cardiac Outcomes Registry
- Victorian Orthopaedic Trauma Outcomes Registry and Victorian State Trauma Registry

### **Associate Members**

- Alliance for Vascular Access Teaching and Research Group
- ASPirin in Reducing Events in the Elderly (ASPREE) Clinical Trial
- Australasian Consortium of Centres for Clinical Cognitive Research
- Australasian Radiopharmaceutical Trials Network
- Australasian Spinal Cord Injury Network
- Australia and New Zealand Musculoskeletal Clinical Trials Group
- Australian Breast Device Registry
- Australian Epilepsy Clinical Trials Network
- Australian Paediatric Research Network
- BiNational Colorectal Cancer Audit
- Cancer Trials Australia
- Multiple Sclerosis Research Australia Clinical Trials Network
- Paediatric Trials Network Australia
- Queensland Centre for Mental Health Research

### **Affiliate Members**

- Australian Red Cross Blood Service, Research & Development
- Breast Cancer Research Centre – Western Australia
- Cancer Council Victoria
- Clinical Research Unit (Cancer Services), South East Sydney Local Health District, St George Hospital
- Commercial Eyes Pty Ltd
- Ingham Institute
- Melbourne Clinical and Translational Sciences Platform
- Research Path Pty Ltd
- T Symons Associates Pty Ltd