



**Australian  
Clinical  
Trials  
Alliance**

# ACTA Submission to the MRFF Advisory Board

Consultation on development of the Australian Medical  
Research and Innovation Strategy and Priorities

June 2016

# Australian Medical Research and Innovation Five Year Strategy

## Title: Better Evidence for Better Health: Embedding high-impact research into healthcare delivery.

The Australian Clinical Trials Alliance (ACTA) is a coalition of more than 60 individual Clinical Trials Networks, Clinical Quality Registries, and specialist coordinating centres 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.

### The Critical Gap

Improving the effectiveness and efficiency of healthcare is one of the greatest challenges facing societies and Governments. The most critical gap in current healthcare systems is their failure to be able to evaluate the effectiveness and cost-effectiveness of both existing and new approaches to prevention, diagnosis and treatment of illness. Australia is no exception. Endemic limitations in the way robust clinical evidence and real-world clinical data are generated and used to inform and manage healthcare in Australia have contributed to a system in which:

- There is substantial unwarranted variation in clinical practice and associated unacceptable variation in outcomes.
- The comparative effectiveness and cost-effectiveness of a large proportion of existing clinical practices has never been established.
- Many new (and expensive) clinical practices are being introduced without knowledge of their effectiveness or cost-effectiveness or both in the full range of patient categories in which such treatments are applied.
- Many clinical practices that have been proven to be effective are not being adopted and many clinical practices that are proven to be ineffective (or harmful) are still in practice.

**Successive reviews of Australia’s health and medical research (H&MR) efforts argue strongly the case for embedding clinical and health services research into frontline healthcare delivery (most recently recommended by the McKeon Review). Clinical Trial Networks and Clinical Quality Registries are the best examples of successful integration between research and healthcare delivery but a critical gap is that there is insufficient utilisation and coordination of these organisations to improve healthcare. The expansion of activities of these organisations offer the best available solution to the growing misalignment between the massive unmet need for better evidence and the capacity to generate and apply it within the health system.**

**Successive international reviews (and early analysis of Australian trials) of return-on-investment in large-scale public-good clinical trials and registries have shown combined health and health system returns in the order of \$3 to \$5, *per year*, for every dollar of one-off investment.**

### Critical gaps in Australia’s capacity to improve health and the health system include:

- Lack of embedded clinical research infrastructure to conduct high-impact research in areas that don’t attract commercial interest such as large-scale comparative effectiveness trials and studies designed to deliver significant innovations in healthcare delivery. Core components of the infrastructure include:
  - **People:** A stable workforce of skilled and experienced clinician researchers with protected time to design and conduct research as part of (and not separate to) their clinical service, along with skilled and experienced research coordinators and support staff based in hospitals and primary care facilities to recruit research participants and collect data for registries and trials.
  - **Platforms:** Adequately resourced coordinating centres that provide capability to coordinate and manage clinical trials and operate clinical quality registries within the health system. Central infrastructure to support national clinical research networks that unite whole communities of clinician researchers in identifying important clinical questions, conducting randomised trials and other studies that provide definitive answers to important clinical questions, and driving uptake of research evidence into practice.

- There are no funding pathways to build and sustain integrated clinical research infrastructure as a core component of the architecture necessary for a high-quality, self-improving health system.
- Current project funding mechanisms via the NHMRC often don't provide sufficient flexibility to adequately support large-scale clinical trials capable of providing definitive evidence to change practice and policy. These trials often require large sample sizes, involve multinational collaboration and take longer to complete.
- Current systems for managing and linking clinical and administrative data are unsuitable for undertaking analysis to provide important hypothesis generation or provide data on outcomes of trial patients. The absence of such real world data and risk-adjusted benchmarking impedes clinicians and health service providers delivering the best quality and most efficient clinical care.
- Implementation pathways to ensure that the evidence that emerges from H&MR becomes practice are not supported as part of a comprehensive national research investment strategy. Similarly, there is no requirement to evaluate and report the health and economic gains from public investment in H&MR.

## The Pathway Forward

The MRFF provides a critical opportunity to realise major improvements in the quality of health care and better health outcomes by investing in coordinated, collaborative needs-driven clinical and health services research (encompassing clinical trials, experimental medicine, translational research, epidemiological studies, public health, health services research, and healthcare quality improvement). ACTA's proposal identifies five critical pillars for generating *Better Evidence for Better Health* through the MRFF.

### 1. BUILD AND SUSTAIN THE EMBEDDED CLINICAL RESEARCH INFRASTRUCTURE NEEDED TO GENERATE AND IMPLEMENT EVIDENCE AS PART OF HEALTHCARE DELIVERY.

- a. This must be geographically distributed so to be representative of Australian patients and to maximise access to the largest possible sample size.
- b. It must be focused on
  - i. supporting clinical trials networks as an effective and efficient mechanism for conducting large-scale clinical trials and health services research. Many such networks exist already, but their effectiveness is limited critically by inadequate infrastructure.
  - ii. assuring the quality of research design and conduct
  - iii. dramatically increasing the number of patients participating in clinical research
  - iv. increasing the number of health services and healthcare professionals participating in clinical research
  - v. driving the implementation of research evidence into practice
  - vi. increasing the proportion of patients captured by clinical quality registries that measure and report clinical activity and health outcomes
- c. It must enable access to research coordination capabilities to support protocol development, study set up and management, data collection and analysis.

### 2. IDENTIFY AND DELIVER PRIORITY RESEARCH THAT IS IMPORTANT TO PATIENTS AND THE HEALTH SYSTEM.

- a. Develop new pathways for bringing patients, clinicians and health system leaders together to engage in priority setting, define research outcomes, select research methodologies, promote recruitment, interpret findings and disseminate results from MRFF-supported research.

### 3. SUPPORT AND COMMISSION THE HIGHEST-QUALITY RESEARCH BASED ON THE POTENTIAL TO DELIVER DIRECT BENEFITS TO PATIENTS AND THE HEALTH SYSTEM

- a. Establish a new competitive “response-mode” funding scheme that invites open applications from clinician-researchers for funding for large-scale, collaborative, investigator-led research to generate evidence of comparative effectiveness or testing innovative approaches.
- b. Establish a new competitive “development-mode” funding scheme for commissioning priority-driven research identified as being of high-value by patients, clinicians and the health system based on
  - i. Burden of illness
  - ii. Gaps in evidence
  - iii. Public, patient and stakeholder needs
- c. Proposals should be evaluated on using an evidence-based approach to assessing:
  - i. Feasibility and validity of the proposed research project
  - ii. Potential impact on changing practice for significant populations
  - iii. Expected value of information

### 4. DRIVE AND COORDINATE A NEW ERA OF RESEARCH PARTNERSHIP AND COORDINATION ACROSS THE HEALTH SYSTEM

- a. Establish a national body to coordinate, promote and support the generation and implementation of evidence within the health system. Such a body is needed because existing efforts are too important to continue to be neither efficient nor coordinated. Existing efforts are inefficient because methods and work processes (both to conduct research and manage networks and registries) are developed, expensively, by each group, whereas scalable generic solutions could be shared among all groups.

The remit for such a body would be to expand existing, develop new, and share methods for embedding research; develop and share solutions for network, registry, and coordinating centre work practices; facilitate linkage and sharing of clinical and administrative datasets to networks and registries; act as a linkage point between key agencies and stakeholders including Departments of Health, NHMRC, AHEC, ACSQHC, consumer groups, colleges and societies, clinical opinion leaders and others; build on current work to harmonise and minimise barriers to multijurisdictional clinical research; manage resources that provide shared site-level infrastructure for trials and registries; and facilitate the sharing of cutting edge methodologies for research design and conduct. The coordination of these activities by the National Institute for Health Research (NIHR) in the UK has been highly successful by a number of measures.

- b. Provide leverage funding that stimulates new partnership between Commonwealth and State and Territory Governments, health services, clinicians, researchers and industry to provide clinical research infrastructure and deliver high-impact projects.

### 5. ROUTINELY MEASURE AND REPORT THE TRANSLATION AND IMPACT OF MRFF-SUPPORTED RESEARCH.

- a. There must be a requirement for, and funding to support, planned translation measurement and health economic analysis alongside all major projects funded via the MRFF to be reported publically.

#### **Relevance to the building blocks.**

We believe ACTA’s proposed strategy will impact across all seven of the current challenges, all nine identified aims and objectives, all four of the mandatory considerations and provides a platform for direct linkage and engagement with all key interactions and stakeholders.

#### **Measures of Success.**

We believe that centering the strategy on the integration of clinical and health service research into frontline healthcare will deliver measureable benefits to patients and the health system and will, importantly, generate an axis shift in the culture that underpins clinical practice and the healthcare delivery towards one that truly values, seeks and rewards quality and continual improvement.

# Australian Medical Research and Innovation Two Year Priorities

## Title: Better Evidence for Better Health: Embedding high-impact research into healthcare delivery

*This document outlines priorities for funding in the first two years of the five year strategy titled “Better Evidence for Better Health: Embedding high-impact research into healthcare delivery” submitted to this consultation by the Australian Clinical Trials Alliance (ACTA). If feasible, we recommend that the two documents be considered in conjunction.*

### 1. What is the gap in Australia’s health system to be addressed by this priority?

This proposal addresses a critical gap in the capacity to generate and implement evidence for the effectiveness and cost-effectiveness of treatments and services provided by Australia’s health system.

### 2. How does your area of priority address either an existing or a new health or health system challenge?

The proposal creates and expands embedded research infrastructure within the health system that will be utilised to generate and implement high quality evidence of what treatment approaches work best so as to reduce unwarranted variation in clinical practice, establish comparative effectiveness and/or cost-effectiveness of clinical practices, and drive better implementation of new and existing evidence, particularly in high-burden, high-cost areas of the health system.

### 3. Comment on which aims and objectives your priority is likely to meet.

These priorities impact across all seven of the current challenges, all nine of the identified aims and objectives, all four of the mandatory considerations, and provide a platform for direct linkage and engagement with all key interactions and stakeholders identified in the building blocks.

### 4. Mandatory considerations – which of the mandatory considerations set out in the *Medical Research Future Fund Act (2015)* does your priority proposal address?

- Burden of disease on the Australian Community
- How to deliver practical benefits from medical research and medical innovation to as many Australians as possible
- How to ensure that financial assistance provides that greatest value for all Australians
- How to ensure that disbursements complement and enhance other assistance provided to the sector

### 5. Outline of priority proposal:

*ACTA proposes five coordinated areas of early investment that are highly synergistic and will provide a solid foundation upon which to build future activities. Nevertheless, each proposal could be considered for investment in isolation.*

#### 5.1 Commence funding flow to build and sustain embedded clinical research infrastructure.

Australia currently has approximately 50 Clinical Trials Networks and Clinical Quality Registries at various stages of maturity. This existing infrastructure is used to produce research that is of high quality and has had amongst the highest impact on health of any research conducted in Australia. These organisations have over 10,000 members, the vast majority of whom have dual roles as researchers and clinicians who provide healthcare. As such, these organisations are closely aligned with clinical care delivery.

In the last 10 years these groups have conducted more than 100 trials that have directly improved clinical practice or policy. However, as a consequence of limited opportunities for central infrastructure funding, many of these organisations have poor long-term sustainability (we are aware of several that have ceased to exist in the last 3 years despite broad clinical support) and could be substantially more effective and efficient if there was support for their core infrastructure requirements.

We propose that a priority for MRFF investment in the first two years should be the establishment of core national infrastructure to support clinical trial and registry activity embedded within the health system. Investment should target:

- **Platforms:** *Clinical Trial Networks* that typically require relatively modest levels of support (\$0.5 and \$1 M per year) for central coordination that represent high value–add in terms of significantly improving capacity to highly identify and prioritise clinical questions, design large randomised trials and other studies capable of providing definitive evidence to address such questions, train and mentor investigators and research coordinators, identify and integrate research sites for the network, and support peer-review processes that optimise the quality of research. Conducting trials within a network is more efficient (because infrastructure is shared across multiple trials) and the results of trials are more likely to be implemented because each network is a community of clinicians fully engaged in the process of generating and implementing clinical evidence.

*Clinical Quality Registries* typically require around \$1M per year for central coordination of their activities which include recruitment of participating sites, training sites in data collection, managing submitted data, and reporting on variation in practice and risk-adjusted outcomes. Registries play a critical role in measuring the implementation of best evidence and represent a largely untapped opportunity to establish greater interaction between research and quality activities.

*Specialist Coordinating Centres* that undertake central project and data management of clinical trials and registries and provide centres for innovation in design and conduct of trials and operation of registries. Current “project-by-project” funding models are insufficient to support such centres sustainably or allow them to investment in the capital and critical mass of personnel that could produce significant efficiencies across the sector.

- **People:** We propose that an early priority for MRFF distribution should be to support investigators and distributed site-level resources (research coordinators and registry data collectors). A stable workforce of skilled and experienced clinician researchers who have protected time to design and conduct research as part of (and not separate to) their clinical service are essential to effective embedding and high quality studies.

The major barrier to clinicians leading clinical trials and registries is that constrained healthcare systems are unable to release them from clinical service. Site-level resources for clinical research (research coordinators) are funded currently on a project-by-project basis. This is highly inefficient because downtime can't be used for other projects, experienced staff are lost at the end of each project necessitating retraining for each new project, and talented individuals are not attracted to the area because of the absence of job security.

One of the most effective components of the introduction of the National Institute for Health Research (NIHR) in the UK has been the employment of research coordinators who are allocated among funded projects (site-level resources are no longer included in project funding). We further submit that ‘support for people’ could be provided by the MRFF on a matched basis with the major beneficiaries of clinical research, which are State and Territory providers of healthcare.

## 5.2 Commence first rounds of “respond-mode” research calls

Clinical trials that provide definitive guidance to clinicians and policymakers can be expensive because of the need for large sample sizes or long-time frames or both. The budgets for large-scale trials funded by the NHMRC are typically between \$2 and 6 M. However, many of the most important clinical questions require much larger budgets. Moreover, greater value from research dollars may be achievable when budgets are capable of adapting as a trial progresses, where artificial trial duration is not required just for budgetary reasons, and where release of funding could be contingent on cofunding from industry or from overseas public funding. We believe that a high priority for MRFF funding should be regular calls for investigators to propose large-scale clinical trials that have the capacity to provide definitive evidence to clinicians and policymakers that will lead to direct health and economic gains – for example improvements morbidity, reduction in mortality or avoided healthcare costs.

### **5.3 Develop the necessary processes to support “development-mode” commissioned research**

An important pathway for policymakers to contribute to the effective embedding of research in the healthcare system is to create a process by which these organisations can engage in commissioning research to answer questions of high relevance to patients, clinicians and the health system. A priority in the first two years of MRFF disbursement should be to develop a nationally coordinated process for commissioning large-scale research projects based on established, evidence-based principles for prioritising research investment.

### **5.4 Development of metrics for measuring impact.**

We believe that activities funded by the MRFF should be evaluated comprehensively to understand their impact on health and their economic impact on the health system. As such, development of a rigorous and standardised process and template for such evaluations should be among the highest priorities for early MRFF resources and should be capable of evaluating not just clinical trials and registry activities, but any research that is supported by the MRFF.

### **5.5 Establish a national body to guide, coordinate, promote and support the generation and implementation of evidence within the health system**

Dedicated central funding should be allocated to catalyse and sustain the high level of national engagement, collaboration, partnership and leadership needed to realise the full potential for the MRFF to drive major improvements in health care and better health outcomes.

**Funding Allocation.** ACTA suggest that the allocation of resources by the NIHR provides a highly successful example upon which the MRFF funding allocation could be modelled. The NIHR budget allocates an annual total of £1 billion split between clinical research networks (£303m), clinical research coordinating centres and facilities (£340m), research projects and programs (£218m), clinical research training and workforce development (£98m), research governance and IT systems (£29m).

**Risk Mitigation.** A key consideration for early MRFF should be making strategic investment where there is a proven capacity to deliver impact. Investment in the first two years should focus on disciplines that can most effectively demonstrate the value of embedding high-impact research into healthcare delivery. This should be followed by investment in high-burden clinical areas that have no nationally coordinated clinical and health services research capability at present.

## **6. What measures of success do you propose and what will be the impact on health care consumers?**

The impact of these proposals will be to save and improve lives and enhance the productivity of the health system. The availability of registry data that measures implementation and outcomes, over-time, will allow the direct evaluation of the impact of these proposals. Economic impact will be evaluated by quantification of the impact of better health and by changes in healthcare delivery. Frequently, comparative effective evidence often provides the evidence necessary to allow disinvestment of harmful and ineffective therapies.

## **7. Please outline any linkages your proposal has with stakeholders, policy agendas and other health and medical research funding agencies.**

We believe that this is a highly integrated proposal that will create or strengthens linkages among all entities referred to in Figure 1. of the call for submissions document.





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