Australian Clinical Trials Alliance

Australian Clinical Trials Alliance (ACTA) Update

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What is ACTA?

Australian Clinical Trials Alliance

- Call to stablish a national body in 2012
- Officially launched in March 2014
- National body to support and represent:
  - Clinical Trial Networks (CTN) that conduct investigator-initiated clinical trials (iiCT) in Australia
  - Clinical Quality Registries (CQR)
  - Co-ordinating Centres (CC) that support CTNs & CQRs
- Primary body to connect clinical researchers with Governments, health care policymakers and consumers
- Over 50 clinical trial networks

Aims & Objectives

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- Promote iiCTs & CQRs;
- Raise awareness of value of CTNs, CCs & CQRs;
- Highlight common issues impacting the conduct of CT & CQRs;
- Facilitate collaboration among CTNs, CCs & CQRs;
- Coordinate communication & consultation with clinician researchers;
- Provide expert advice & policy recommendations on iiCTs & CQRs to Governments and policymakers;

Aims & Objectives

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- Foster effective partnerships between clinician researchers & Governments, policy-makers, health care providers, industry & consumers;
- Support development of new CTNs & CQRs that conduct, or support the conduct of iiCTs;
- Encourage capacity building for the clinical research workforce;
- Promote education & training opportunities for clinical researchers.
- Coordinate projects, with the aim of improving all aspects of CTs and registries including efficiency;

Major Initiatives

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- Report on the Activities and Achievements of Clinical Trials Networks in Australia 2004–2014
- Economic evaluation of investigator-initiated clinical trials conducted by networks (2017).
- Submissions to the MRFF legislation as well as MRFF strategy and priorities document

Funding

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- Victorian Department of Health (2013)
- Western Australia Department of Health (2015)
- MRFF funding (2017) to enhance capacity and capability within the clinical trial network sector

MRFF strategies and priorities

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- 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.

MRFF strategies and priorities

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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.

MRFF strategies and priorities

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

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

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

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

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

Development of Activity Plan

Input from:

- Department of Health (MRFF)
- ACTA Advisory Council
- ACTA Board

Activities are the first priorities to develop, implement and support a national framework to expand the capacity, capability, efficiency and effectiveness of Clinical Trials Networks in Australia

Facilitate the development of a dynamic and responsive roadmap for the future

Three years of funding

- Secure for first year, subsequent two years dependent on satisfactory progress

ACTA's role

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- Central coordination
- Program support
- Identify and manage key priorities
- Engage with sector to ensure work program informs and is informed by member priorities, expertise, and needs

Core Principles

- Collaborative
- Inclusive
- Equitable
- Flexible
- Evidence-based
- Patient-centred
- Innovative

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Approach

- Seven Reference Groups
  - Designed to align with key priorities
  - Attempt to minimise overlap
- Substantial need for integration, coordination, management of demarcation
  - This is ACTA-central's job, but will be flexible and responsive
- Supported by:
  - Senior Program Manager
  - Multiple Project Officers
  - Capacity to engage external consults, as appropriate

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Reference Groups

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- Each group develops its own Terms of Reference and processes for working
- No limit to size of Reference Groups
- Expectation that an inner working group will define itself to drive delivery
- Referring to / seeking input from wider Reference Group as required
- Expectation of consultation with members and other sectors
- Sub-groups may form around specific activities
- Meetings
  - Video-conferencing
  - Face-to-face, as required
- Develop years 2 and 3 of Activity Plan for each Reference Group
- Defined pieces of work
  - Guidelines / recommendations / tools / software / workshops / policy

A. Efficient & Effective CTNs

- Year 1:
  - Scope & brief for consultation activity to identify critical success factors for CTNs
  - Publication on critical success factors for establishing and operating CTNs
  - Needs assessment for network tools

- Leading to:
  - Development of guidelines for CTN operations that describe options for efficient and effective conduct while allowing for flexibility according to models, availability of resources, and stage of evolution
  - Development and testing of network management software to facilitate reporting and conduct of network activity as informed by year 1 work

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B. CTN sector expansion

- Year 1:
  - Scope and brief for consultation activity to evaluate sector gaps
  - Report and presentation to Department of Health regarding sector-wide gap analysis
  - Publication of guidance for the formation of new CTNs

- Leading to:
  - Formation of new CTNs in areas identified by sector gap analysis
  - Identification of potential sources of seed funding for Executive Officers for new CTNs

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C. Impact and implementation of CTN trials

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- Year 1:
  - Draft guidelines for consultation on measuring and reporting impact of CTN trials
  - Presentation to Department of Health regarding measurement and reporting of CTN trial impact
  - Stakeholder map of potential program partnerships in implementation science
  - Workshop on policy proposals for measurement and reporting of key metrics
- Leading to:
  - Template for use to report return-on-investment of CTN trials
  - Development of guidance about how the healthcare system and CTNs should collaborate to optimise implementation of CTN trial results
  - Linkage with registries to optimise routine collection of data that reports implementation of CTN trial results

D. Embedding clinical trials in healthcare

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- Year 1:
  - Circulation for consultation of draft discussion paper on opportunities to embed clinical trials in the Australian health system

- Leading to:
  - Finalisation of discussion paper on opportunities to embed clinical trials in the Australian health system
  - Development of a discussion document regarding opt-out consent and simplified provision of information for comparative effectiveness trials

E. Strengthening consumer engagement in CTN trials

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- Year 1:
  - Map of current consumer engagement activity across the sector, including case studies
  - Workshops to harmonise with current work by Government to develop/release a clinical trials awareness campaign
- Leading to:
  - Development of a discussion document regarding opt-out consent and simplified provision of information for comparative effectiveness trials

F. Research Prioritization: Tools and Criteria

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- Year 1:
  - Circulation for consultation of best practice guidelines for determining value of information

- Leading to:
  - Finalisation of best practice guidelines for determining the value of information

G. CTN sector expansion

- Year 1:
  - Workshop on innovative clinical trial designs

- Leading to:
  - To be informed by Year 1 outcomes

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- Only things certain to be supported
  - Clinical fellowships
  - Clinical trials
- Optimistic that the *Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks* program is designed to make sector better ready for influx of funding
- Opportunity for dialogue / make case to MRFF and elsewhere about
  - Infrastructure requirements for networks
  - Infrastructure that will allow trials to be conducted faster and more efficiently e.g. registry randomised trials, data linkage, simulations to facilitate trial design
  - Policy e.g. governance requirements, who pays for interventions, opt-out consent for trials that compare variants of standard care

Keeping it coordinated

- Member networks, trial coordinating centres, registries
- Department of Health and MRFF
- NHMRC
- Jurisdiction governments
- AHRTCs
- MTPConnect
- CITI Australia
- ARCS, Medicines Australia, Oz Biotech
- Clinical Trials Collaborative Forum

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Key ACTA Staff

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- Simone Yendle, General Manager
- Tanya Symons, Acting Senior Program Manager
- Nicola Straiton, Senior Project Officer
- Madeleine Enright, Project Officer
- Further Project Officers currently being recruited