



## ACTIVITY WORK PLAN

<b>Activity</b>	<b>Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance</b>
<b>Program</b>	Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program
<b>Organisation</b>	Australian Clinical Trials Alliance Ltd
<b>Activity Plan Timeframe</b>	July 2018 to June 2019

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## ACTIVITY PLAN SUMMARY

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### OVERVIEW

**Department of Health Program Name:** Medical Research Future Fund (MRFF) - Lifting Clinical Trials and Registries Capacity - Clinical Trials Networks Program

**Activity Name:** Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance

**Activity Start Date:** 16 June 2017

**Activity End Date:** 30 September 2020

#### Objective:

ACTA is expanding and strengthening its **strategic leadership** and practical support for Clinical Trials Networks (CTNs), and the coordinating centres (CCs) and clinical quality registries (CQRs). This leadership includes:

- the development and implementation of a **national capacity-building framework** (the framework) to provide a comprehensive, evidence-based foundation and strategic roadmap to expand the capacity, capability, efficiency and effectiveness of CTNs in Australia; and
- building on **strategic partnerships** with stakeholders, including Government, working with members and Alliance partners to address clinical priorities for CTNs, and
- facilitating effective **sharing of experience, capacity and resources** between CTNs to accelerate the impact of research as a core part of a self-improving health system.

This Activity Plan outlines key activities to be undertaken in 2018–19 through the *Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance* program (the Program). The Activity Plan has been developed in consultation with the Australian Clinical Trials Alliance (ACTA) Board, ACTA Reference Group Leadership Teams and the Department of Health.

The scale of work described in this Activity Plan reflects the size and potential impact of the opportunity ahead. ACTA is committed to working closely with Government, our members and the broader health and research sector in Australia to help develop the CTNs as core components of a self-improving health system.

The Activity Plan, which builds on the sector's significant strengths and expertise, will be led by and informed by the sector but conducted in close consultation with the Federal Department of Health to ensure relevance and co-ordination with other key activities being undertaken across the broad health community. ACTA will:

- provide the **central coordination and program support** required to progress key priorities;
- maintain an active program of **engagement with the sector** to ensure that the work program informs and is informed by member priorities, expertise and needs;
- provide direct **one-to-one support and mentoring** to support the development of new CTNs;
- accelerate the dissemination and adoption of **guidance and best practices** among existing CTNs; and
- **revise and refine our approach** over time, building on and learning from early sector consultation and mapping activity, and ensuring that our strategic work programs lead to practical outputs that can be implemented across the sector.

The Activity Plan defines key activities and proposed approaches to collaboration, engagement and dissemination.

## KEY PRIORITIES AND PROGRAMS OF WORK

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### PROGRAMS OF WORK- YEAR 2

In 2017, through a process of sector consultation and Board review, ACTA identified seven key **program areas**. In 2018 an additional work program was identified. These program areas are supported by ACTA program staff and overseen by multidisciplinary cross-sector Reference Groups drawn from the ACTA membership and a multitude of key stakeholders. Within program areas, time-limited projects will be undertaken, supported by standing Reference Groups, or by time-limited Working Groups, as required.

These **eight program areas** for Year 2 are:

- A. Efficient and Effective CTNs**
- B. CTN Sector Expansion**
- C. Impact and Implementation of CTN trials**
- D. Embedding Clinical Trials in Healthcare**
- E. Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials**
- F. Research Prioritisation: Tools and Criteria**
- G. Innovative Trial Design**
- H. Innovative Outcome Data** (to commence in the 2018-2019 period)

Some of these programs of work will be conducted over multiple years of program funding. Priorities will be reviewed on an annual basis and informed by stakeholder views and consultation including with Federal agencies. Program areas are mapped to the Funding Agreement priorities (see Appendix A). Note that some funds have not yet been allocated – these funds will be utilised to address emerging issues as they arise, with the approval of the Department of Health.

### OVERARCHING PRINCIPLES

ACTA has developed a set of core principles that will underpin its approach to priority programs and activities. These principles will be refined through member consultation and activity will be reviewed on a regular basis to ensure alignment.

Core principles include:

- **Collaborative and inclusive:** inviting all to participate.
- **Effective and efficient:** recognising that public monies support this activity.
- **Equitable:** addressing gaps and areas of need within Australia.
- **Flexible and responsive:** able to respond to changing needs of patients, the sector and Governments as views mature.
- **Evidence-based:** using best available information.
- **Patient-centred:** involving consumers in all stages of the research continuum.
- **Innovative:** looking for novel methods that minimise cost.
- **Robust:** effective governance within a clear operating framework.
- **Defensible:** providing the evidence of impact of funding on sector capacity.

## 2018–2019 ACTIVITIES AND DELIVERABLES

### GROUP A: EFFICIENT AND EFFECTIVE CTNS

#### Goal:

Enable CTNs to operate in an effective and efficient manner.

#### Objectives:

- Describe activities undertaken by current networks.
- Identify factors critical to success and failure of networks.
- Identify unmet needs to enhance effectiveness and efficiency of networks.
- Promote linkage between networks and the sharing of expertise and tools.

#### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 2,3

#### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Identification of currently active CTNs in Australia.
- Formation of a working group to explore and describe key structural, operational and sustainable aspects associated with successful CTNs across the sector; critical component mapping.
- Documentation of identified network structures and models and operational processes that are critical success factors in building a sustainable CTN as well as consumer engagement, success in funding projects, patient recruitment and implementation of research findings.
- Engagement with network managers and executive officers to understand the essential processes and tools required to maintain network activities.
- Foundation work to establish 'peer-to-peer' and 'mentor' network linkage between executive officers and network managers; corporate knowledge sharing.

Year 2 Activities and Deliverables	
A.4	<p>Sector-wide <b>consultation</b> using <b>survey</b> and <b>focus groups</b> of leaders and managers of CTNs to identify structures/models and operational processes/activities, focussing on identifying elements that are critical to effectiveness and efficiency. <b>Review</b> of Terms of Reference, operational manuals, and strategic plans of existing CTNs.</p> <ul style="list-style-type: none"> <li>• Report on activities undertaken by CTNs that are critical to success and sustainable growth.</li> </ul>
A.5	<p>External consultation to <b>identify</b> opportunities and options for increased CTN efficiency in current practices and through shared services.</p> <ul style="list-style-type: none"> <li>• External business process review of several CTNs.</li> </ul>
A.6	<p><b>Identification</b> of unmet needs, barriers, and enablers in relation to the enhancement of the effectiveness and efficiency of CTNs.</p> <ul style="list-style-type: none"> <li>• Workshop of leaders and managers of CTNs.</li> <li>• Guidance document on best practice options for CTN operation, management, and governance.</li> </ul>
A.7	<p><b>Dissemination</b> and <b>sharing</b> through a <b>community of practice</b> the best practice options for CTNs.</p> <ul style="list-style-type: none"> <li>• Templates for CTN Terms of Reference.</li> <li>• Linkage, including mentor-mentee relationships, with newly established networks (linking with Reference Group B).</li> </ul>

### Leading to Year 3

Guideline dissemination and implementation to enhance network operations

Development of tools enabling networks to improve effectiveness, share services and resource; and foster collaboration

Support tool(s) implementation and review

Define and Identification of “Networks of Concern”

Evaluation of implementation: lessons learned

## GROUP B: CTN SECTOR EXPANSION

### Goal:

The establishment of efficient, effective, and sustainable CTNs in areas of major importance to public health and the healthcare system.

### Objectives:

- Identify and prioritise areas of need for the establishment of new CTNs.
- Develop and disseminate guidance framework for facilitating the formation of effective, efficient, and sustainable new networks.
- Assist and facilitate the formation of new networks, focusing on areas of need.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,3,5
- Leadership and collaboration: 1,4

### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Sector-wide gap analysis: preliminary report.
- Guidance document and process to facilitate the formation of a new CTNs.
- Meetings with leaders who may form new CTN.

Year 2 Activities and Deliverables	
B.6	<p><b>Sector-wide gap analysis:</b> explore issues raised in a preliminary report, including limitations with methodology and data sources.</p> <ul style="list-style-type: none"><li>• Presentation to Department of Health on a preliminary report.</li><li>• Final Report on Sector Gaps.</li></ul>
B.7	<p><b>Validate, finalise and disseminate</b> the Final Guidance for the formation of new CTNs.</p> <ul style="list-style-type: none"><li>• Report on consultations with stakeholders and experts through the facilitation experience of new network formation.</li><li>• A public communications plan will outline mode of publication of the Final Guidance.</li><li>• Final Guidance.</li></ul>
B.8	<p><b>Consolidation</b> of networks established and being established during year 1.</p> <ul style="list-style-type: none"><li>• Ongoing support and mentoring of new CTNs.</li><li>• Linkage of new CTNs to work outputs from Reference Group A to enhance effectiveness and efficiency as well as other Reference Groups where relevant.</li></ul>

B.9	<p>Targeted <b>establishment of new CTNs</b> with a focus on Indigenous health, primary care, dementia, and surgical specialities.</p> <ul style="list-style-type: none"> <li>• Liaison with clinical and research leadership in areas of need.</li> <li>• Workshops, utilising the Final Guidance, to facilitate the formation of new CTNs.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Exploration of seed funding for the establishment of CTNs in priority areas, develop guidance for harnessing alternative funding sources e.g. in-kind support, philanthropic donations.</p> <p>Exploration of models for shared services to support CTN (linkage with program area A).</p> <p>Formation of new CTN in areas of need.</p> <p>Evaluation of implementation: lessons learned.</p>	

## GROUP C: IMPACT AND IMPLEMENTATION OF CTN TRIALS

### Goal:

Maximise, and measure the value of clinical trials to the community and the healthcare system, including the consideration of implementation of trial results into standard care

### Objectives:

- Establish a community of practice involving both clinical trial networks, experts in implementation science, and end-users to grow capacity in networks to facilitate effective implementation of the results of trials.
- Disseminate and promote methods to clinical trial networks:
  - to facilitate the design of trials that optimises capacity for implementation.
  - to facilitate appropriate implementation of trial results.
  - to allow measurement of change in practice, coordinated with the conduct of trials.
  - to measure impact on practice, including economic impact, following implementation of trial results.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 3,4,6
- Leadership and collaboration: 1,2,3,4

### Year 2 Priorities:

Year 2 will build on achievements from Year 1 including

- Review and refinement of objectives for this Reference Group.
- Identification of end-users of trial results as critical to optimisation of impact of clinical trials.
- Planning for a workshop on optimisation of capacity for implementation of trial results.

## Year 2 Activities and Deliverables

C.5	<p><b>Identification</b> of factors in trial design and conduct that optimise the value of clinical trials to end-users i.e. ‘implementability’ of the results of clinical trials.</p> <p>Identify factors that enhance the value of trials to the healthcare system, including implementation of within-trial intervention matching actual practice, appropriateness of control or comparator groups, and acceptability of trial end-points to end-users.</p> <ul style="list-style-type: none"> <li>• Production and distribution of a Scope and Definitions document ensuring consistency of nomenclature.</li> <li>• Literature review of factors that optimise ‘implementability’ of trials.</li> <li>• Survey of CTNs to identify barriers and enablers to the measurement, optimisation of implementation of trial results, and measurement of implementation.</li> <li>• Workshop on features of trial design optimising implementation capacity</li> </ul>
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	<ul style="list-style-type: none"> <li>Guideline Document: Optimisation of ‘Capacity for Implementation of Results’ of CTN Trials.</li> </ul>
C.6	<p><b>Engagement</b> with experts in a systematic review and evidence synthesis and literature <b>review</b> to provide guidance to CTNs to evaluate if trial results should be implemented into practice.</p> <ul style="list-style-type: none"> <li>Guideline Document for CTNs: After the trial – should, and if so how should, results be implemented?</li> </ul>
C.7	<p><b>Identification</b> of processes to measure the implementation of trial results. Likely to include recommendations for measurement of practice before and after trial and how registries can contribute to implementation measurement.</p> <ul style="list-style-type: none"> <li>Guideline Document for CTNs: What is next after a trial that should be implemented? Measuring implementation and impact.</li> </ul>
C.8	<p>Creation of a <b>community of practice</b> to engage CTNs, AHRTCs, experts in implementation science, and leaders in the healthcare sector to optimise and implement trial evidence.</p> <ul style="list-style-type: none"> <li>Key stakeholder workshops exploring cross-sectoral optimisation, implementation and impact.</li> <li>Presentation to Department of Health on optimisation of implementation of trial results and impact measurement.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Development and dissemination of tools for impact measurement of CTN trials, including the return-on-investment.</p> <p>Generic policy advice to research funding bodies on mechanisms for evaluation of capacity for implementation and impact measurement in applications for new clinical trial projects.</p> <p>Evaluation of implementation: lessons learned.</p>	

## GROUP D: EMBEDDING CLINICAL TRIALS IN HEALTHCARE

### Goal:

Reduce the cost and shorten the duration of clinical trials by integrating trial processes as a routine component of the healthcare system.

### Objectives:

- Define embedding of clinical trials within routine healthcare delivery
- Describe and report examples of successful embedding
- Develop a comprehensive model of embedding
- Identify enablers and barriers to successful embedding
- Create a community of practice among trialists who utilise embedding
- Develop and implement a strategy to remove barriers and promote enablers
- Develop metrics to evaluate embedding

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4,6
- Leadership and collaboration: 2,3

### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Formulate an operational definition of ‘embedding clinical trials in healthcare’ with specific focus on sector activities.
- International scoping review to identify best practice to achieve routine clinical trial embedding.
- Survey instruments and focus group questions identifying barriers and enablers of successful embedding.

Year 2 Activities and Deliverables	
D.5	<p><b>Definition</b> of embedding, <b>identification</b> of examples of successful embedding, and development of <b>model</b> that identifies components necessary for successful embedding.</p> <ul style="list-style-type: none"> <li>Viewpoint article identifying the importance of embedding, citing examples of success, and presenting a comprehensive framework of components to achieve embedding.</li> </ul>
D.6	<p><b>Consultation</b> with health service providers (health system leaders, hospital CEOs, hospital directors of research and State or Territory Departments of Health and Colleges) to understand barriers and enablers of embedding.</p> <ul style="list-style-type: none"> <li>Guideline document for healthcare providers identifying factors necessary and sufficient to achieve embedding of clinical trials within the healthcare system.</li> </ul>
D.7	<p><b>Consultation</b> with networks and clinical trialists, including those who have achieved embedded trials, to understand barriers and enablers of embedding.</p> <ul style="list-style-type: none"> <li>Guideline document for CTNs identifying factors necessary and sufficient to achieve embedding of clinical trials within the healthcare system. Factors including easy-to-apply clinical trial entry criteria, design of trial interventions that can be implemented within routine care, simplified and relevant trial end-points, and automated extraction from existing sources of data.</li> <li>Identify public policy goals to facilitate embedding, eg, simplified information provision and opt-out consent to evaluate comparative effectiveness of variants of standard care and better public understanding of clinical trials (in conjunction with Reference Group E).</li> </ul>
D.8	<p>Assist ACSQHC Clinical Trials Governance Framework.</p> <ul style="list-style-type: none"> <li>Response to the call for submissions from the ACSQHC Clinical Trials Governance Framework Steering Committee and provide any additional liaison.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Dissemination of best practices guidelines to achieve implementation of embedding clinical trials within routine care.</p> <p>Development of metrics for measurement of embedding (in conjunction with Reference Group G).</p> <p>Promotion of 'Learning Health System' model.</p> <p>Evaluation of implementation: lessons learned.</p>	

## GROUP E: STRENGTHENING CONSUMER ENGAGEMENT IN DEVELOPING, CONDUCTING AND REPORTING CLINICAL TRIALS

### Goal:

Strengthen the CTN sector's capacity and ability to involve consumers in all activities across the research continuum.

### Objectives:

- Identify and disseminate best practice options for the involvement of consumers in CTN activities.
- Develop and disseminate messages to the general community about the value of clinical trials, particularly around comparative effectiveness trials.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 1,2

### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Working group review of current approaches and international best practice of consumer-involvement in CTN activities.
- Sector-wide (CTN) consultation of consumer involvement in clinical trial activities both at a network and trial-specific level.
- Development of a Direct-Consumer consultation framework, to understand engagement across the CTN sector and detailed CT activities.

Year 2 Activities and Deliverables	
E.5	<p><b>Consultation</b> of consumer and investigator members of CTNs and coordinating centres to identify the range of current practices and barriers and enablers to consumer involvement.</p> <ul style="list-style-type: none"> <li>• Report on existing consumer involvement in CTN activities from consumers' and triallists' perspectives.</li> </ul>
E.6	<p><b>Engagement</b> with consumers, CTNs and coordinating centres, and literature <b>review</b> of international practice to identify <b>best practice options</b> for the involvement of consumers in CTN activities and CTN trials.</p> <ul style="list-style-type: none"> <li>• Workshops including CTN and consumer participants.</li> <li>• Guidance document for CTNs: Best practice options for the involvement of consumers in CTN activities and trials.</li> </ul>
E.7	<p><b>Consultation</b> with consumers and literature <b>review</b> to identify messages to the general community about role and value of clinical trials conducted by CTNs.</p> <ul style="list-style-type: none"> <li>• Workshop on messages to the general community.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Consultation with culturally and linguistically diverse (CALD) and primary care communities</p> <p>Dissemination and implementation of best practice options guideline for consumer involvement across the sector.</p> <p>Development of tools to support best practice of consumer involvement e.g. education and training, impact measurement, communication strategies.</p> <p>Dissemination strategy for messages to the general community about the value of clinical trials.</p> <p>Feasibility assessment of the expansion of current teletrial models beyond cancer trials.</p> <p>Explore of the role of Medicare and health insurance funds in supporting experimental CTs.</p> <p>Evaluation of implementation: lessons learned.</p>	

## GROUP F: RESEARCH PRIORITISATION: TOOLS AND CRITERIA

### Goal:

To ensure that trials conducted by networks identify research questions with the greatest possible impact on health outcomes.

### Objective:

- Development and dissemination of best practice guidelines for prioritisation of clinical trials conducted by CTNs.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 3
- Leadership and collaboration: 1

## Year 2 Priorities:

Year 2 build on achievements from Year 1, including:

- Working group review of approaches to CTN research prioritisation.
- Engagement with stakeholders to identify current processes and future needs (survey).
- Further development of a Principles Framework for CTN research prioritisation.

Year 2 Activities and Deliverables	
F.2	<p><b>Validation</b> of the prioritisation Principles Framework v0.1 developed in Y1. Relevant factors include criteria that should determine prioritisation and methods and tools for prioritisation.</p> <ul style="list-style-type: none"> <li>• Stakeholder and expert workshop evaluating prioritisation from CTNs', Governments' and research funders' perspectives.</li> <li>• Prepare revised Framework (v0.2).</li> </ul>
F.3	<p>Further exploration of <b>sector needs</b>, including best practice guidance, as part of D2.</p> <ul style="list-style-type: none"> <li>• Report: identification of additional sector needs.</li> </ul>
F.4	<p>Framework v0.2 <b>Implementation Pilot</b> (stage 1): CTNs selected ranging from small to large, including established and developing networks.</p> <ul style="list-style-type: none"> <li>• Report on the pilot: lessons learned.</li> <li>• Prepare revised Framework (v0.3).</li> <li>• A public communications plan.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Development of additional support tools identified in D.4 and D.7: Framework update.</p> <p>Costing ongoing maintenance of the Framework.</p> <p>Full implementation of final prioritisation tools, representing stage 2 of F.4 and leading to a final Framework v1.0.</p> <p>Development of a process for linkage of CTNs with policy makers (such as federal and state and territory departments of health, MSAC, PBAC) to identify and evaluate priority research questions.</p> <p>Evaluation of implementation: lessons learned.</p>	

## GROUP G: INNOVATIVE TRIAL DESIGN

### Goal:

CTNs transition from use of conventional trial designs to use of innovative trial designs.

### Objectives:

- Facilitate availability, dissemination, uptake, and evaluation of innovative methods of trial design.
- Influence policy and promote the development of shared infrastructure to support innovative trial design.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities:1,2,4,5
- Leadership and collaboration: 2,3

## Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Establishment of linkage among key clinical trialists and statisticians conducting trials using innovative designs.

- Conduct of workshop/seminar on innovative trial design.

Year 2 Activities and Deliverables	
G.3	Develop a <b>community of practice</b> to enable sharing of code for trial simulations, expertise in design and analysis of innovative designs, and development of template protocols. <ul style="list-style-type: none"> <li>• Introduction to innovative trial design' workshops.</li> <li>• Workshops on expertise in coding of simulations of adaptive trials.</li> <li>• Workshops to evaluate the suitability of innovative trial designs for emerging trial questions.</li> <li>• Novel trial designs Hackathon.</li> <li>• Policy proposals for workforce and expertise development to support innovative trial designs.</li> </ul>
G.4	Development and application of <b>methods</b> to calculate the 'cost-effectiveness' of innovative and conventional trial designs. <ul style="list-style-type: none"> <li>• Publication of methods used to evaluate the economic efficiency of alternative trial designs.</li> </ul>
G.5	<b>Dissemination</b> of awareness of Studies Within A Trial to enhance trial method efficiency. <ul style="list-style-type: none"> <li>• Workshop/webinar on Studies Within a Trial.</li> <li>• Presentations to CTNs on Studies Within a Trial.</li> </ul>
<b>Leading to Year 3</b> Development and dissemination of protocol templates for adaptive multifactorial trials. Application of methods to calculate the 'cost-effectiveness' of current innovative trial designs. Survey of biostatistics workforce capacity and needs. Facilitation establishment of centres of expertise in innovative trial design. Evaluation of implementation: lessons learned.	

## GROUP H: INNOVATIVE OUTCOME DATA

### Goal:

Widespread uptake of the use of linked data, automated PROMs, and registry datasets by CTN trials.

### Objectives:

- Facilitate availability, dissemination, and uptake of innovative methods for trial outcome data collection.
- Influence policy and promote the development of shared infrastructure to support innovative methods for collection of trial outcome data relevant to real-world populations.

### Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 2,3

### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Establishment of linkage with experts in methods for efficient and automated ascertainment of outcome data.

Year 2 Activities and Deliverables	
H.2	<p><b>Dissemination</b> of awareness about and methods of access, as well as <b>needs analysis</b> for use of linkage to administrative datasets to obtain outcome measures for clinical trials.</p> <ul style="list-style-type: none"> <li>• Webinar series on the use of linked data conducted by the Population Health Research Network.</li> <li>• Guidance document for CTNs: Use of linked administrative data in clinical trials.</li> </ul>
H.3	<p><b>Dissemination</b> of awareness and sharing of <b>tools</b> that can be used for automated collection of Patient Reported Outcome Measures (PROMs) using text messaging and email reminders.</p> <ul style="list-style-type: none"> <li>• Presentations to CTNs on systems for automated PROMs.</li> <li>• Guidance Document for CTNs: Use of automated PROMs.</li> <li>• Policy paper on the use of automated PROMs including standardisation of PROMs, development of shared infrastructure, and integration with measurement of PROMs.</li> </ul>
H.4	<p><b>Identification</b> of enablers and barriers to greater use of registry data in conduct of clinical trials.</p> <ul style="list-style-type: none"> <li>• Workshop on registry randomised trials.</li> <li>• Report on enablers and barriers to registry-randomised trials in Australia.</li> </ul>
<p><b>Leading to Year 3</b></p> <p>Policy paper on the utilisation of My Health Record data in clinical trials.</p> <p>Policy proposal on shared infrastructure for automated PROMs.</p> <p>Policy proposal on registry randomised trials.</p> <p>Evaluation of implementation: lessons learned.</p>	

## ACTA CENTRAL: LEADERSHIP AND COLLABORATION

### Goal:

To expand and strengthen ACTA's capacity to provide collaborative and strategic leadership and practical support for CTNs, CCs and CQRs.

### Objectives:

- Ensure sustainable growth of ACTA capacity and expertise.
- Promote effective and cost-effective health care in Australia through investigator-initiated clinical trials.
- Provide a forum to facilitate communication and collaboration between clinical researchers, Governments, policy makers, healthcare providers, industry and consumers, and identify areas for further development or activity.
- Measure ACTA's impact in the sector.

### Year 2 Priorities:

Year 2 will build on achievements from Year 1, including:

- Review of the governance structures and processes to ensure flexibility during growth.
- Engagement with stakeholders to identify future needs.
- Further develop and implement a communications strategy.

Objectives	Year 2 Activities and Deliverables	
	Ap.17	<p>Conduct Governance review.</p> <ul style="list-style-type: none"> <li>• Development of a governance framework.</li> </ul>

<p>Ensure the sustainable growth of ACTA.</p> <p><i>Funding Agreement Leadership &amp; collaboration 1</i></p>	Ap.18	<p>Explore the sector needs for further special interest groups.</p> <ul style="list-style-type: none"> <li>• Report on any identified needs for additional special interest groups.</li> <li>• Development of Terms of Reference and work plans for approved special interest groups.</li> </ul>
	Ap.19	<p>Review ACTA membership models.</p> <ul style="list-style-type: none"> <li>• Report on ACTA membership model and growth.</li> </ul>
	Ap.20	<p>Board Strategy Planning.</p> <ul style="list-style-type: none"> <li>• Publication of ACTA's medium-term strategy.</li> </ul>
	Ap.21	<p>Review ACTA's Information and communication technology (ICT) needs, including member database and internal systems, to increase staff efficiency.</p> <ul style="list-style-type: none"> <li>• ACTA ICT Business needs analysis and plan.</li> </ul>
<p>Promote investigator-initiated clinical trials</p> <p><i>Funding Agreement Leadership &amp; collaboration 2, 3, 4</i></p>	Ap.22	<p>Partner with key stakeholders to celebrate International Clinical Trials Day.</p> <ul style="list-style-type: none"> <li>• Annual Trial of the Year Awards.</li> </ul>
	Ap.23	<p>Develop reference material for consumers and raise awareness about ACTA and investigator initiated CTs.</p> <ul style="list-style-type: none"> <li>• Brochure on ACTA and the importance of investigator initiated CTs.</li> </ul>
<p>Provide a forum for stakeholders</p> <p><i>Funding Agreement Leadership &amp; collaboration 2, 3, 4</i></p>	Ap.24	<p>Hold Advisory Council meetings.</p> <ul style="list-style-type: none"> <li>• Digital publication of Advisory Council meeting minutes.</li> </ul>
	Ap.25	<p>Hold Special Interest Group meetings.</p> <ul style="list-style-type: none"> <li>• Summary reports and recommendations published on ACTA's website.</li> </ul>
	Ap.26	<p>Review and develop ACTA's Stakeholder Engagement and Communication Strategy.</p> <ul style="list-style-type: none"> <li>• Stakeholder Engagement and Communication Strategy v2.0.</li> </ul>
	Ap.27	<p>Review ACTA's website and perform a needs analysis to increase member engagement.</p> <ul style="list-style-type: none"> <li>• Major website and digital asset upgrade.</li> <li>• ACTA website development plan.</li> <li>• Launch the improved website.</li> </ul>
	Ap.28	<p>Hold annual scientific meeting.</p> <ul style="list-style-type: none"> <li>• Digital publication of scientific meeting report.</li> </ul>
	Ap.29	<p>Hold bi-annual Clinical Trial Forum Meetings.</p> <ul style="list-style-type: none"> <li>• Publication of bi-annual Clinical Trial Forum digital newsletter.</li> </ul>
<p>Measure ACTA's impact in the sector.</p> <p><i>Funding Agreement Priority Activity 6</i></p>	Ap.30	<p>Develop and review a consolidated Program Evaluation Plan to measure the impact of ACTA's activity in expanding and enhancing the clinical trials and registries sector.</p> <ul style="list-style-type: none"> <li>• Program Evaluation Plan and Preliminary Report.</li> </ul>

## **APPENDIX A: MRFF FUNDING AGREEMENT PRIORITIES**

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The delivery of the Activity will include, but not be limited to, the following:

### **PRIORITY ACTIVITIES:**

1. Identifying, agreeing and implementing best-practice guidelines to achieve optimal operational standards.
2. Facilitating knowledge sharing and professional development.
3. Identifying and addressing gaps and strategic opportunities in the CTN sector.
4. Developing and sharing tools and resources to enhance the quality, efficiency, and effectiveness of CTNs.
5. Cultivating thought leadership to drive contemporary models for research prioritisation and design.
6. Facilitating a robust approach to measuring the impact of ACTA's activity in expanding and enhancing the clinical trials and registries sector in accordance with the agreed Activity Work Plan.

### **LEADERSHIP AND COLLABORATION**

1. Strengthening governance, advisory and working group structures.
2. Creating strategic collaborations and partnerships.
3. Fostering a culture of collaboration around areas of mutual interest and synergy.
4. Maintaining appropriate and widespread communication between ACTA members, and the broader health community through a range of publications, website and digital media, webinars and forums and communiques and policy briefs.