



## **Australian Clinical Trials Alliance**

Advisory Council Meeting Report

28 July 2017

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## 1. Introduction

In May 2017, the Australian Clinical Trials Alliance (ACTA) was awarded funding by the Australian Government Department of Health to expand and strengthen its capacity to provide collaborative and strategic leadership and practical support for Clinical Trials Networks (CTNs), and the coordinating centres (CCs) and clinical quality registries (CQRs) that enable, support, and inform their work.

The *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program* places CTNs at the centre of enhancing capacity and capability in the sector. The program is funded through the Medical Research Futures Fund (MRFF), which aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability through targeted strategic investment across the research pipeline.

The purpose of the *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program* is to strengthen sector capability and collaboration with the aim of embedding evidence-based care in the health system. Funding of \$5m will be provided to ACTA to manage the *Strengthening* over the period 2017–2020 to work with its membership to develop and implement a program of strategic activities that will strengthen and grow the capacity, capability and effectiveness of the clinical trials sector in Australia.

### Workshop overview

ACTA held an Advisory Council workshop on 28 July 2017 to canvass input and ideas on how the sector can work collectively to build the future and achieve transformational change in clinical research in Australia. The workshop was attended by 39 participants, including Terrie O'Brien, Director – Health and Medical Research – Clinical Trials Section, Department of Health. A list of workshop participants is provided in Appendix I.

The workshop agenda is provided at Appendix II. The key question considered during the workshop was: '*if it is critical to delivery of quality healthcare that research is embedded within the system, how can we work collectively to achieve that?*'.

Opening presentations covered:

- a history of ACTA and achievements to date
- a summary of the Australian Commission on Safety and Quality in Healthcare report *Economic evaluation of investigator-initiated clinical trials conducted by networks*, prepared by ACTA and Quantum Health Outcomes (to be released 1 August 2017)
- an overview of the objectives of the *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program* and the opportunity afforded by the *Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance*.

A Q&A session provided members with the opportunity to raise and clarify questions regarding ACTA's history and the intent and scope of the funding program.

The remainder of the workshop focused on gathering, theming and prioritising ideas for consideration in the program of work, with a focus on what should be started in year 1.

Attendees were asked individually to identify ideas, which were then collected and grouped through a process of facilitated group discussion. Following a brief thematic analysis of the ideas, a further process of plenary discussion was used to prioritise activities for the first year of funding. Small groups were then assigned to provide ideas for how the agreed priority programs could be approached.

This report lists the questions raised and ideas presented during the workshop. The ideas have been themed and grouped since the workshop to align with overarching program goals and inform the activity plan.

## 2. The opportunity: strengthening the capacity of the clinical trials sector in Australia

### *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program objectives*

The Objectives of the *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program* as stated in the funding agreement are to:

- **analyse the current CTN landscape**, including identification of key opportunities and priorities for enhancement and efficiencies to support a vibrant research sector
- identify **critical success factors** for establishing and operating efficient high-impact CTNs
- develop a **national capacity building framework for CTNs**
- develop and implement **best practice standards and guidance** to bolster the capability of the sector
- conduct **multi-stakeholder forums** for improving quality and efficiency of trials in Australia
- facilitate **cross-sector collaboration**, including between CTNs and large trial coordinating centres, to support the investigator-led clinical research sector in adapting to novel methodologies and technologies tailored to support the needs of individual CTNs and CQRs
- build and support the **formation of new networks and capacity of existing networks and/or registries** in areas of priority to key stakeholders, the Australian health system and the health and medical research sector in Australia
- assist **CTNs and CQRs to work productively** and with central points of contact being established through jurisdictional redesign of trial operating systems
- provide **support to relevant Government initiatives** and agendas
- show progress towards a **self-sustaining Clinical Trials Network** to support the health and medical research sector into the future.

### *About the Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance program*

Funding has been provided to ACTA to provide a means of coordinating, connecting, sharing and ultimately improving the clinical trials and registries sector in Australia.

ACTA's program: *Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance* will support coordinated programs of work and activities designed to increase capacity and capability to conduct clinical trials across all disciplines. ACTA will draw on the significant expertise and experience of our members to provide guidance and leadership around the optimal use of the available resources to facilitate the effectiveness and efficiency of the sector.

The Program aims to expand and strengthen the capacity of the ACTA to provide collaborative and strategic leadership and practical support for Clinical Trials Networks (CTNs), and the coordinating centres (CCs) and clinical quality registries (CQRs) that enable, support, and inform their work through:

- facilitating 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
- building on **strategic partnerships** with stakeholders, including Government, working with members and Alliance partners to address clinical priorities, 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.

The broad priority activities and approach to leadership and collaboration against which ACTA will be required to deliver are listed below.

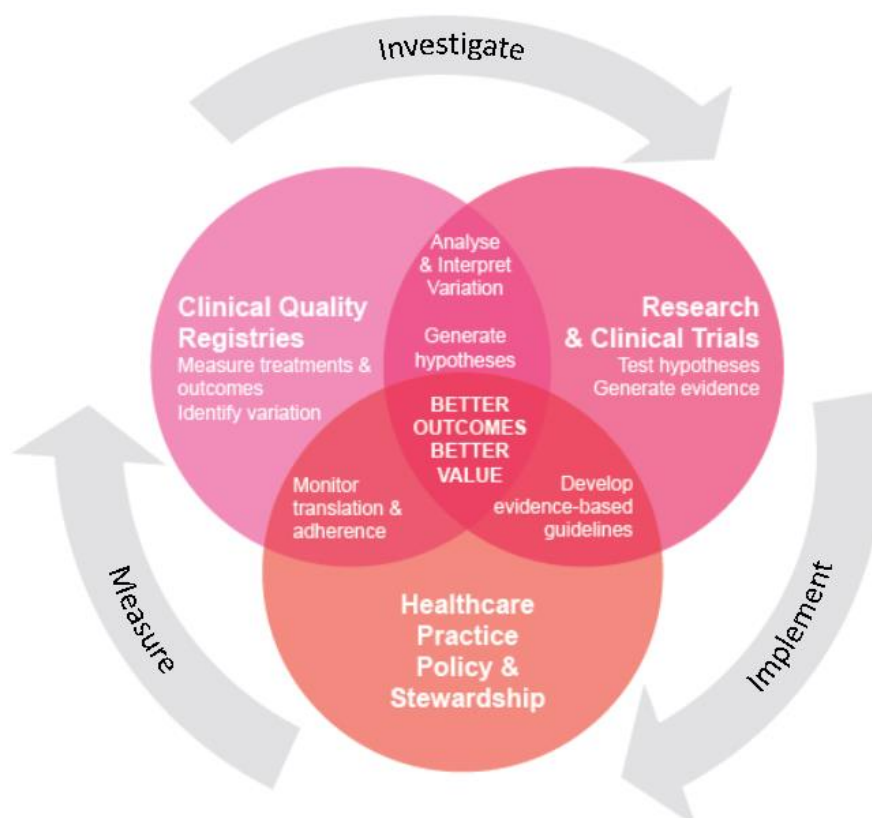
### Priority activities

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

Central to the activity will be the concept of the 'self-improving health system', which has underpinned ACTA's approach and activity to date.



## Questions about ACTA's activity and the program scope

The following table summarises the main points from a Q&A session during the Advisory Council workshop regarding the scope and direction for the *Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance* program.

Question	Answers / discussion	Implications for activity plan
<p><b>Economic report</b> If the analysis focused on the best networks and best trials, how will we respond to possible criticism that the benefits will not be reflected across the sector?</p>	<ul style="list-style-type: none"> <li>• Analysis presents what is possible through high performing networks</li> <li>• Only 25 trials have paid for the funding to 35 networks over 10 years.</li> <li>• ROI is for 1 year of implementation; implementation is actually over many years so the ROI will likely be greater than presented</li> </ul>	<ul style="list-style-type: none"> <li>• How can ACTA help the rest of the sector to perform at this level?</li> </ul>
<p><b>ROI</b> How to use the information on ROI</p>	<ul style="list-style-type: none"> <li>• Economic analysis is critical for prioritisation and for identifying where to invest in the future</li> <li>• We have good studies showing what could achieve if we change practice; we need to ensure and demonstrate that these studies can change practice – e.g. look at translation plans as part of clinical trial protocols.</li> </ul>	<ul style="list-style-type: none"> <li>• Seek input and advice from the sector on what to consider around prioritisation</li> <li>• Incorporate measurement of impact and translation into practice as key elements for review (to identify models/approaches) and sharing across the sector</li> </ul>
<p><b>ACTA grant</b> How will ACTA achieve the grant objectives with only 1 FTE?</p>	<ul style="list-style-type: none"> <li>• Activity plan will identify programs of work and the staffing required to support priority activities; funding will be used to employ people to support the nominated activities</li> <li>• Over the last 4 years, ACTA has built the case for sector capacity building; now ACTA has centralised funding for centralised staff to achieve this capacity building</li> <li>• Some work will require dedicated staff and some will be able leverage existing skills and expertise of the networks</li> </ul>	<ul style="list-style-type: none"> <li>• Identify achievable projects supported by project staff and working groups drawn from the networks to oversee and drive project activity</li> <li>• Define the required program support and other staffing required to support key activities</li> <li>• Define how existing resource, including network staff and expertise, will be leveraged</li> </ul>
<p><b>ACTA membership</b> ACTA has come a long way in a very short time. How is the membership growing and what is the current profile? Is there a plan for raising the profile?</p>	<ul style="list-style-type: none"> <li>• ACTA had good early sector engagement – including a large proportion of the sector, and continued engagement has been good</li> <li>• ACTA's growth has been relatively slow</li> <li>• Currently membership includes approx. 40 CTNs, 15 CQRs and 15 CTCs as well as individual organisations</li> </ul>	<ul style="list-style-type: none"> <li>• Use communications to share between networks – i.e. how does ACTA work to support sector growth and capacity?</li> <li>• Current membership model may benefit from review. Have we got the model right?</li> </ul>

Question	Answers / discussion	Implications for activity plan
	<ul style="list-style-type: none"> <li>• Registries space is more complex as the DoH is actively developing a policy framework but today we have the majority of CTNs represented</li> <li>• Opportunity now for leadership and collaboration is critical</li> </ul>	
<p><b>Engagement with industry</b> Does ACTA envisage engaging with industry?</p>	<ul style="list-style-type: none"> <li>• Recognise the range of perspectives on industry engagement</li> <li>• Industry-led trials share many common issues with the investigator-initiated trials</li> <li>• Where issues overlap there may be priorities that are relevant to both – and we can work together on those priorities</li> <li>• MTP is an industry growth sector hub and represents interests of industry in bringing trials to Australia - another key stakeholder in trying to improve healthcare in Australia</li> <li>• Industry are not members of ACTA but ACTA is open to working with them on areas of mutual interest</li> <li>• Kieran is on the ACTA Board and that has been very beneficial</li> <li>• Both CROs and pharmaceutical sector are important ‘industry’ partners</li> <li>• Affiliate member model supports CROs but have never had members from the pharmaceutical industry</li> </ul>	<ul style="list-style-type: none"> <li>• Consider industry engagement models and how to work with them to effect change in areas of mutual interest</li> <li>• May be an option to include industry on Working Groups where relevant</li> <li>• Start a discussion with members about membership structure</li> </ul>
<p><b>ACTAs role – from advocate to leader</b> ACTA started as a coalition of active trials groups and ended up as a representative group advocating for goals and needs National priorities now need to be agreed – should ACTA think about identifying the priorities and advising government about how it should be investing in clinical trials? What is the role of membership in supporting that? And is there a need to</p>	<ul style="list-style-type: none"> <li>• Funding has imposed a pivot point by posing the question – how should we build capacity in high impact clinical trials?</li> </ul>	<ul style="list-style-type: none"> <li>• Consider ACTA’s evolution from advocate to leader</li> </ul>

Question	Answers / discussion	Implications for activity plan
consider any additional members to be able to do that?		
<p><b>Enhancing trial activity in rural and regional settings and in Aboriginal &amp; Torres Strait Islander health</b></p> <p>Can ACTA in its supporting and enabling role look at linking CTCs and research institutes with a track record in rural/regional and Aboriginal health -and find ways of enabling high quality research</p> <p>Can ACTA play a leadership role – i.e. not just waiting for ideas to emerge but directing members to think about how to address key gaps; e.g. Aboriginal health – and linking up the groups that are active in the space to bring the relevant expertise together</p>	<ul style="list-style-type: none"> <li>• This is a good example of how to think in a stepwise fashion from a longer-term goal. What are the fundamental building blocks of a network? There is lots of knowledge re: the decision tree - but no tools to support that.</li> <li>• Important principle is that we have amazing networks but no network does everything perfectly</li> <li>• COSA tele-trials initiative will allow rural and regional centres to participate; important to be able to share that knowledge</li> </ul>	<ul style="list-style-type: none"> <li>• Before establishing new networks, identify the key elements of a network so that new networks are established appropriately</li> </ul>
<p><b>Establishing optimal governance structures for networks – to support interaction and engagement with stakeholders</b></p> <p>Networks have a range of structures and governance arrangements</p> <p>Sometimes structures aren't flexible enough to support collaboration with different stakeholder groups</p> <p>Can ACTA help to identify the governance and structures and framework that will support better interactions?</p>	<ul style="list-style-type: none"> <li>• Agree there are a range of governance models for networks models of governance with variation based on size, maturity and focus for networks</li> <li>• When thinking about sector sustainability it is important to think about the operating model(s) that will best support that CTN</li> <li>• Sector is broad and there is a lot that can be learned from different networks</li> <li>• Some of the most enjoyable research is at the nexus between organisations – so will be good to think about cross-cutting clinical issues</li> </ul>	<ul style="list-style-type: none"> <li>• Aim is to build capacity: the funding will allow ACTA to look for areas of duplication across the sector and optimal models</li> <li>• Funding will allow the sector to be able to identify structures and funding needed to support this, and allow it to act nimbly when funding becomes available</li> </ul>
<p><b>New Zealand</b></p> <p>Is NZ in scope for today's discussion given this is an Australian government funding agreement?</p>	<ul style="list-style-type: none"> <li>• ACTA is looking at a governance review, and NZ engagement and reach will be part of that</li> <li>• Many Colleges are bi-national as are networks (registries less so)</li> </ul>	<ul style="list-style-type: none"> <li>• Keep on the agenda – but may be outside scope for deliverables within the funding agreement</li> </ul>



Question	Answers / discussion	Implications for activity plan
	<ul style="list-style-type: none"> <li>• Pragmatic decision made around a funding model that relies on state and federal support; becomes complicated to think about bi-national issues and will need more thought</li> <li>• New Zealand has a keen interest and HRC came to last ACTA summit; New Zealand can learn from the work happening in Australia</li> <li>• If networks are stronger it will flow to NZ</li> <li>• If issues come up in relation to New Zealand, they will need to be considered; may be appropriate to think about engagement with NZ in due course</li> </ul>	

### 3. Building the roadmap: prioritising activities to strengthen the sector

The items listed in the following tables represent a synthesis of the ideas offered by Advisory Council members during the Advisory Council meeting on 28 July 2017. The list of unedited ideas, grouped as they appeared on the white boards is presented at Appendix III.

The ideas have been synthesised as follows:

- ideas have been grouped by theme area
- ideas have been categorised according to whether they identify a) an area of need or b) an idea for something ACTA could do / support
- suggestions for 'Activity plan options' have been added based on discussions during the workshop and prior planning activity by ACTA around use of program fund.

#### Emerging program priorities and directions

The ideas provided support and reinforce the need for activity in the following key areas:

- **identifying and sharing 'good practice' for CTNs** – to be used both to improve and strengthen existing networks, as well as providing a framework for new networks as they are established
- **scoping current gaps in the sector**, including resource, network and trials gaps, and considering equity of access to clinical trial activity (and using this analysis to plan and prioritise future activities to address key gaps)
- defining and establishing approaches to **measurement of trial and network activity and impact** including how to measure translation of research outcomes into clinical practice
- identifying and implementing activities to **embed research as a core part of the health system**
- working effectively with relevant stakeholders to influence **ethics and governance issues**
- strengthening the **role of consumers** in trial design, conduct and reporting, and in broader awareness of the benefits of research participation
- providing **leadership in novel and innovative trial design** and in **factors to consider in prioritisation of research questions** and approaches.

The opportunity for ACTA to work with the membership and to provide central coordination and resource to progress these areas was discussed, and ideas proposed for how this could be achieved.

Suggested activities for ACTA to undertake included:

- establishing **working parties and other advisory structures** to develop and oversee programs of work
- providing **central program and operational support** for projects and centralised services
- facilitating **sharing and networking** across the sector
- developing and disseminating **templates, tools and resources** to improve efficiency and reduce duplication
- coordination of **professional development and mentoring activities** across the sector.

A central theme of the discussion was the need to:

- **review and learn** from what has been done elsewhere
- undertake **appropriate engagement** with the membership and key stakeholder groups
- maintain an **efficient and appropriate governance structure** for ACTA
- **measure the impact** of funded activities on sector capacity, efficiency and effectiveness.

## Overarching considerations

In discussing models and approaches to enhance sector capacity and effectiveness it was noted that:

- models should be sufficiently flexible to meet the needs of different disease groups, geographies and demographics and to be adaptable to trials networks of differing sizes and levels of maturity
- models should be appropriate for the Australian context but should also support international collaborative research
- the bi-national membership of many networks is important to note; while funding is provided by the Australian government, lessons can be learned and benefits will flow to New Zealand centres.

## Priorities and programs: synthesised ideas

### 1. National capacity building framework

A key funding agreement requirement is for ACTA to develop a comprehensive, evidence-based foundation and strategic roadmap to expand the capacity, capability, efficiency and effectiveness of CTNs in Australia.

This piece of work is likely to be undertaken as a standalone piece of consultancy activity and will focus on identifying opportunities, potential models and resource requirements for significant sector growth. The work will include sector-wide consultation as well as reviews of international models.

Ideas from the workshop that may be included as key areas for this consultation activity included:

- **funding models:**
  - including government, industry, philanthropy
- **network structures and models:**
  - including effective structures used internationally, e.g. NIHR
- innovative approaches to drive **patient recruitment**
- approaches for **centralised and effective trial coordination:**
  - including how to avoid duplication and opportunities for centralised academic CROs
- models to **establish and maintain a sustainable trial workforce:**
  - such as including research as a mandatory component of training for health professionals
- models for **consumer engagement** in research
- mechanisms to **embed research within the health system**
- **translation of research into practice**
- **metrics for monitoring impact.**

## 2. Program priorities

Synthesised ideas under each of the main emerging program priority areas are listed below (but not in any specific order).

### *Identifying, agreeing and implementing good practice for networks to achieve optimal operational standards*

Area of practice	What needs to happen / key issues	How could ACTA help?	Activity plan options
Trial efficiency	Reducing waste / becoming more efficient Identifying what's needed and what can be discarded	<ul style="list-style-type: none"> <li>National support system</li> <li>Review and advise networks on efficient network functioning and use of personnel and resources</li> <li>Identify where resources are duplicated and work to reduce this</li> </ul>	<ul style="list-style-type: none"> <li>See <b>plan 1 – good practice for networks</b></li> <li>Draw from consultation findings in <b>National Capacity Building Framework</b></li> </ul>
Network design and operation	Identify the minimum and optimal structure for an efficient CTN? Prepare CTNs for increased investment Identify opportunities for sharing	<ul style="list-style-type: none"> <li>Review range of 'structures' of networks – what works? What doesn't work?</li> <li>Identify key characteristics of 'highly performing networks'</li> <li>Define a minimum 'good practice' / business model for networks</li> </ul>	

### *Identifying and addressing gaps and strategic opportunities in the CTN sector*

Gap	What needs to happen / key issues	How could ACTA help?	Activity plan options
Networks	Address network gaps don't duplicate Encourage engagement and provide support	<ul style="list-style-type: none"> <li>Undertake an inventory of CTNs / CQRs, including: size, features, expertise, contacts</li> <li>Provide advice and guidance for new networks as needs emerge</li> </ul>	<ul style="list-style-type: none"> <li>See <b>plan 2 – gap analysis</b></li> <li>Establish <b>Gap analysis Working Group</b> <i>Will link to / draw from prioritisation activity</i></li> </ul>
Trials	Help inform and respond to priorities for government	<ul style="list-style-type: none"> <li>Gap analysis of trials based on burden of disease, available treatments etc</li> <li>Include consideration of equity of access to clinical trials by population group, geography and disease / health area</li> </ul>	

### Measuring trial and network activity and impact

Theme	What needs to happen / key issues	How could ACTA help?	Activity plan options
Data linkage	Data linkage for outcome measures / metrics for trials, including simplified access Systems for use of routinely collected clinical data for research (screening / feasibility for trials comparative effectiveness, health outcomes)	<ul style="list-style-type: none"> <li>Investigate links with non-medical registries (data collections)</li> <li>Enhance enabling links for outcome information between different registries</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
Supporting translation	Develop mutual objectives with health services and measure success based on these Develop meaningful rewards for translatable outcomes	<ul style="list-style-type: none"> <li>Identify barriers and enablers to driving the implementation of trial results through networks</li> <li>Develop sector-wide knowledge and expertise in translating knowledge into care in our setting(s)</li> <li>[Support for] end of active trial translational activities (i.e. post-publication activities to increase uptake)</li> </ul>	<ul style="list-style-type: none"> <li><b>AHTRC engagement</b></li> <li>Models likely to emerge from consultation activity for <b>National Capacity Building Framework</b></li> <li>Option for topic for <b>ACTA innovation hub</b></li> <li>Option for <b>centralised ACTA support</b> around post-publication/translation activity</li> </ul>
Measuring impact	How do we measure the success of a network or registry?	<ul style="list-style-type: none"> <li>An investigation of how to measure network impact – what data are currently available? What data would be ideal?</li> </ul>	<ul style="list-style-type: none"> <li>See <b>plan 3 – measure and optimise implementation of trial results</b></li> <li>Establish a <b>Measurement/metrics working group</b></li> </ul>

### Embedding research into the health system

Theme	What needs to happen / key issues	How could ACTA help?	Activity plan options
Investment / funding models	Need to define how this will be implemented and measured. How to fund embedding clinical network in Australian healthcare will follow	<ul style="list-style-type: none"> <li>Identify models for adaptive trials embedded in service delivery</li> <li>Pilot use of existing data in trials embedded in health service delivery</li> </ul>	<ul style="list-style-type: none"> <li>See <b>Plan 4 – Embedding</b></li> <li><b>Engagement activity at hospital / health service level</b></li> </ul>

Theme	What needs to happen / key issues	How could ACTA help?	Activity plan options
		<ul style="list-style-type: none"> <li>• Look at successful international models</li> </ul>	<ul style="list-style-type: none"> <li>• <b>AHTRC engagement</b></li> </ul>
Engagement	Need to change perception that clinical research is an optional extra	<ul style="list-style-type: none"> <li>• Engagement with hospitals and health services</li> </ul>	
Metrics	<p>Clinical trial metrics / KPIs embedded in health care and linked to health care funding</p> <p>Make clinical trials reportable at a hospital CEO level</p>	<ul style="list-style-type: none"> <li>•</li> </ul>	

**Informing and influencing approaches to overcome ethics and governance barriers**

Theme	What needs to happen / key issues	How could ACTA help?	Activity plan options
Ethics and governance	<p>Ethics and governance is a roadblock</p> <p>Streamlining ethics processes</p> <p>Expand / modify national statement to streamline ethics</p> <p>Look at opt out models using implied consent for quality / audits / registries</p>	<ul style="list-style-type: none"> <li>• Work with Government to inform issues and approaches to improving ethics processes</li> <li>• Identify opportunities to support networks to streamline governance and ethics based on national priorities</li> <li>• Engagement with HREC organisations</li> </ul>	<ul style="list-style-type: none"> <li>• Establish an <b>Ethics and Governance Reference Group</b> to provide advice to Government and to Networks on key issues</li> </ul> <p><i>Note: ACTA advised not to undertake specific programs of work around ethics / governance until current national programs have been completed</i></p> <ul style="list-style-type: none"> <li>• <b>Government engagement activity</b> (Federal and State/Territory)</li> </ul>
Governance	<p>Guardianship processes are different for each state</p> <p>Remove barriers to clinical trial governance (institutional, state, health district)</p>		

## Consumer engagement

Theme	What needs to happen / key questions	How could ACTA help?	Activity plan options
Models for consumer engagement	<p>Increased role of consumers in ensuring research relevance</p> <p>Consumer engagement on research priorities, endpoints</p> <p>Encourage consumers to drive change</p>	<ul style="list-style-type: none"> <li>• Scoping study to identify international models on consumer engagement in clinical trials and to test in Australian settings</li> <li>• Development of a consumer strategy (i.e. development of principles, operating standards and implementation mechanisms to support consumer participation in trials)</li> <li>• Develop a model for community engagement with vulnerable groups</li> </ul>	<ul style="list-style-type: none"> <li>• Establishment of <b>Consumer Engagement Reference Group</b></li> <li>• <b>Key element of consultation activity</b> for <i>National Capacity Building Framework to identify models used elsewhere – including models for vulnerable groups</i></li> <li>• <b>Key element of mapping / gap analysis work</b> to identify what resources already exist</li> <li>• Link to <b>ACTA Communications plan</b></li> </ul>
Supporting networks	<p>What are the support needs of registries / networks to support consumer participation?</p>	<ul style="list-style-type: none"> <li>• Scope consumer groups interested in research</li> <li>• Centralise and improve consumer engagement activity across the sector, including education, training and support</li> <li>• Work with existing consumer networks and shared knowledge</li> </ul>	
Building awareness	<p>Raise awareness of benefit of trials amongst patients and community</p> <p>Bottom-up approach to build public awareness of benefits</p>	<ul style="list-style-type: none"> <li>• Promote and awareness activities of clinical trials</li> <li>• Public awareness campaign</li> <li>• Support networks around mechanisms to enhance patient recruitment e.g. social media campaigns</li> </ul>	

## Cultivating thought leadership to drive contemporary models for research prioritisation and design

Theme	Issues	Ideas / solutions	Activity planning
High-value care	Clinical trials program linked to health care funding (MBS/PBS)	<ul style="list-style-type: none"> <li>• Research into more efficient trial designs – support for methodological research</li> <li>• Support research into innovative trial design including how trials can inform implementation of high-value care</li> </ul>	<ul style="list-style-type: none"> <li>• See <b>plan 5 – advancing trial methodology</b></li> </ul>
Trial design	Identify barriers to multicentre research		

Theme	Issues	Ideas / solutions	Activity planning
Support for networks in how to prioritise research questions	Model for research priority and funding – return on investment and quality	<ul style="list-style-type: none"> <li>• Develop processes for identifying the questions that matter</li> <li>• Facilitate development of efficient pathways to establish feasibility in trials</li> </ul>	<ul style="list-style-type: none"> <li>• See <b>plan 6 – models for prioritising clinical trials/research</b></li> </ul>

### 3. ACTA's activity and structure

#### *Facilitating sector-wide sharing and collaboration*

Theme	What needs to happen / key questions	How could ACTA help?	Activity plan options
Collaboration	Create a means for sector-wide collaboration and sharing across areas of mutual interest	<ul style="list-style-type: none"> <li>• Identify how groups can collaborate, especially regarding personnel and reducing duplication</li> <li>• Develop a network of networks</li> <li>• Facilitate/establish links between CTN and CTN</li> <li>• Establish mentoring networks – EON, CTCN</li> </ul>	<ul style="list-style-type: none"> <li>• See <b>plan 7 – running better trials</b> (was written from perspective of collaborative approach)</li> <li>• Bring together <b>working parties and reference groups</b> to work on areas of mutual interest</li> <li>• Use of <b>ACTA website</b> to facilitate information and knowledge sharing</li> <li>• <b>Trials in registries special interest group?</b></li> </ul>
Communication	Meaningful communication	<ul style="list-style-type: none"> <li>• Regular meetings/communications to highlight best practice and examples</li> <li>• Check out LSE blog – very useful ideas</li> <li>• Newsletters</li> </ul>	<ul style="list-style-type: none"> <li>• <b>ACTA Communications plan</b> to establish and implement ongoing communications activity</li> </ul>



**Developing and sharing tools and resources to enhance the quality, efficiency and effectiveness of CTNs**

Topic	What is needed / what is the issue?	How could ACTA help?	Activity plan options
Standard forms and templates	Simple e-CRF used across different networks with standard data fields for common disciplines	<ul style="list-style-type: none"> <li>• Identification of tools / resources within networks</li> <li>• Standardise and consolidate templates, documents and processes</li> <li>• Connect networks with resources and services</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Program of work</b> to be agreed and resourced with central ACTA team support and working party oversight (e.g. working with EOs to identify examples and standardise for sharing)</li> <li>• See <b>plan 7 – running better trials through collaboration</b></li> </ul>
	Trial document templates		
	Trial budget/costing templates		
	Governance templates/advice		
Standard processes	Quality assurance/control resources		
Tools	Template patient recruitment tools		

**Opportunities for centralised services**

Topic	What is needed / what is the issue?	How could ACTA help?	Activity plan options
Support for trial coordination	Resource costs of trial coordination	<ul style="list-style-type: none"> <li>• Shared coordination resources</li> <li>• Shared / central resource service, i.e. buying monitors in different states to reduce travel costs</li> </ul>	<ul style="list-style-type: none"> <li>• Would require further scoping – draw from <b>National Capacity Building Framework</b> consultation activity to identify options and costs</li> </ul>
	Increase trial coordination options		
Trial governance processes	Common infrastructure elements – quality assurance/monitoring; legal	<ul style="list-style-type: none"> <li>• Provide resources such as legal</li> <li>• Shared insurance resources</li> <li>• Umbrella / no fault compensation insurance</li> <li>• Support for network legal/governance</li> </ul>	<ul style="list-style-type: none"> <li>• Look at existing examples of shared resource (e.g. through the Cancer trials networks)</li> </ul>
Biostatistics	More support/recognition of biostatistics; data analysts; using routine data	<ul style="list-style-type: none"> <li>• Shared statistical services</li> <li>• Support national network of trial statisticians</li> </ul>	<ul style="list-style-type: none"> <li>• Role for <b>ACTA STInG</b> to work up plan / ideas</li> </ul>
Communication and secretariat functions	How to support grant writing and milestone based reporting of grant progress under a revised NHMRC framework	<ul style="list-style-type: none"> <li>• Grant writing support</li> <li>• Communications support – trial outcomes (lay and technical language)</li> </ul>	<ul style="list-style-type: none"> <li>•</li> </ul>

Topic	What is needed / what is the issue?	How could ACTA help?	Activity plan options
		<ul style="list-style-type: none"> <li>Establish central secretariat – scribing, meeting management, web development</li> </ul>	
Centralised support – health economics	Health economics – feasible built-in endpoints in trial design	<ul style="list-style-type: none"> <li>Central service for modelling benefits as per commission paper, consider worst/best case ranges</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>

### Facilitating knowledge sharing and professional development

Audience	What needs to happen / key issues	How could ACTA help?	Activity plan options
All	Improve education and training	<ul style="list-style-type: none"> <li>Research workshops</li> <li>Professional development activities for early career researchers</li> <li>Improve member learning, skills</li> <li>Develop a plan for supporting and developing junior researchers and research coordinators re: research processes</li> <li>Increase opportunities for clinical trial training</li> </ul>	<ul style="list-style-type: none"> <li>See plan 8 – professional development</li> <li>Option for <b>Education and training Reference group / Working group</b> <i>Priorities likely to emerge from gap analysis and other workstream activities</i></li> <li>Link to <b>Professional College engagement</b></li> </ul>
Junior researchers	Career pathways for individuals across all roles		
Study coordinators	Training systems to rapidly develop skills for study coordinators		

### Strengthening ACTA's governance, advisory and working group structures

ACTA governance / operations aspect	Issues / questions	What can ACTA do differently?	Activity plan options
ACTA governance	What corporate structure is required?	<ul style="list-style-type: none"> <li>Governance review</li> </ul>	<ul style="list-style-type: none"> <li><b>ACTA governance review</b></li> </ul>
ACTA name		<ul style="list-style-type: none"> <li>Change name to ACTRA?</li> </ul>	<ul style="list-style-type: none"> <li>Board business</li> </ul>
ACTA processes	Consider watching costs	<ul style="list-style-type: none"> <li>Longer timeframes for member consultation</li> <li>Try to limit expense of membership, meeting attendance etc to maximise participation and engagement</li> </ul>	<ul style="list-style-type: none"> <li>Operations business</li> </ul>

ACTA governance / operations aspect	Issues / questions	What can ACTA do differently?	Activity plan options
Sustainability	How can ACTA become self-sustaining?		<ul style="list-style-type: none"> <li>• <b>Key element of consultation activity</b> for <i>National Capacity Building Framework</i></li> </ul>

### **Creating strategic collaborations and partnerships**

Stakeholder groups	What needs to happen / key questions	How could ACTA help?	Activity plan options
Government	Closer working with state/Federal Government to understand priorities and link to health policy making	<ul style="list-style-type: none"> <li>• Government engagement</li> <li>• Support member understanding of policy directions and how to respond</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b> <i>Draw from issues identified by priority working groups</i></li> </ul>
Professional bodies	Sector working with professional bodies	<ul style="list-style-type: none"> <li>• Professional College engagement</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b> <i>Draw from issues identified by priority working groups</i></li> </ul>
Industry	How can we make Australia an attractive / competitive place for pharma to conduct their research through CTNs?	<ul style="list-style-type: none"> <li>• Industry engagement</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b></li> <li>• Option for <b>Industry reference group / working group</b> <i>and/or</i></li> <li>• <b>ACTA round table on joint issues/priorities</b></li> </ul>
Universities	Cross-sector collaborations with university partners - joint appointments in research roles		<ul style="list-style-type: none"> <li>• Consider as part of <b>National Capacity Building Framework</b></li> </ul>
International organisations	Shared knowledge from international organisations	<ul style="list-style-type: none"> <li>• Register of [international] expertise</li> <li>• Identification of EOs, Chairs, Boards to facilitate collaboration</li> <li>• Consider building / facilitating international linkages with other networks</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b> <i>Draw from issues identified by priority working groups</i></li> <li>• <b>Key element of consultation activity</b> for <i>National Capacity Building Framework</i></li> </ul>

Stakeholder groups	What needs to happen / key questions	How could ACTA help?	Activity plan options
Health services	How to engage with ALL hospitals/health institutes	<ul style="list-style-type: none"> <li>• AHRTC engagement</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b> <i>Key element of 'embedding' activity</i></li> </ul>
AHRTCs		<ul style="list-style-type: none"> <li>• Engagement with AHRTCs</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Engagement plan</b> <i>Key element of 'translation / implementation' activity</i></li> </ul>

## 4. Activity planning

### Plan 1: Research to define 'good practice for networks': optimal business models

Question	Steps / considerations
Overarching principle	Needs to reflect and support the variation between networks
What needs to happen	<ol style="list-style-type: none"> <li>1. Scope current practice for ACTA members to identify current business models</li> <li>2. Define the common principles for 'good practice', e.g.               <ol style="list-style-type: none"> <li>a. Governance structure</li> <li>b. membership</li> <li>c. Reporting systems / measuring success</li> <li>d. Mechanisms for dissemination / communication</li> <li>e. Consumer engagement</li> <li>f. Finances / funding models</li> <li>g. Translation findings into practice</li> <li>h. ROI</li> </ol> </li> <li>3. Develop recommendations / checklist (ensuring they provide flexibility)</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>• Working group of ACTA members               <ul style="list-style-type: none"> <li>○ Ensure inclusive of networks with different models (new/mature; industry involved / not; infrastructure funded / not; registry representation)</li> </ul> </li> <li>• Project management by ACTA</li> </ul>
What / who can we learn from?	<ul style="list-style-type: none"> <li>• 2015 ACTA Profiling Networks Report (interviews with ACTA members to update)</li> <li>• Undertake literature review</li> <li>• International networks</li> <li>• Private industry (CRO) perspective</li> </ul>
Where is partner / member input needed	<ul style="list-style-type: none"> <li>• Network member input needed to define current models and practice</li> <li>• Private CROs and industry sponsor input</li> </ul>
How will we measure success	<ul style="list-style-type: none"> <li>• Network change in structure/business models as a consequence of implementing recommendations</li> </ul>
Other comments / issues	<ul style="list-style-type: none"> <li>• Aiming to share corporate knowledge</li> <li>• Ensure 'minimum standard'</li> <li>• Option to allow 'ACTA accreditation' of a network</li> </ul>

### Plan 2: Gap analysis

Question	Steps / considerations
Note	Approach taken below overlaps with plan 1
What needs to happen	<ol style="list-style-type: none"> <li>1. Update previous Profiling Networks Report:           <ol style="list-style-type: none"> <li>a. What do we have and what don't we have?</li> <li>b. What are networks doing well / less well</li> </ol> </li> <li>2. SWOT analysis to review:           <ol style="list-style-type: none"> <li>a. National health needs</li> <li>b. How networks are collecting / using metrics</li> <li>c. Barriers to success (funding / recruitment / ethics)</li> <li>d. Government / jurisdiction issues</li> <li>e. Workforce gaps (e.g. biostatistics)</li> </ol> </li> </ol>

Question	Steps / considerations
	<ol style="list-style-type: none"> <li>3. Develop guidelines for setting up a network</li> <li>4. Identify what ACTA could provide to address gaps</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>•</li> </ul>
What / who can we learn from?	<ul style="list-style-type: none"> <li>• Review what has been done by others</li> <li>• Review UK NIHR system – how does this integrate with a federated system?</li> </ul>
Where is partner / member input needed	<ul style="list-style-type: none"> <li>• Members need to be engaged</li> <li>• Government</li> <li>• Industry – inform networks what works well for them</li> <li>• Consumers</li> </ul>
How will we measure success	<ul style="list-style-type: none"> <li>• How gaps are being addressed – e.g. more QoL / cost: benefit / health economic analysis for studies</li> </ul>
Other comments / issues	<ul style="list-style-type: none"> <li>•</li> </ul>

### Plan 3: Metrics / data to better understand the sector

Question	Steps / considerations
What needs to happen	<ol style="list-style-type: none"> <li>1. Late phase trials should include a program for pre–post trial results to measure practice change</li> <li>2. Linkage with registries to measure practice change</li> <li>3. Trials of different approaches to optimise implementation</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>• <b>Measurement working group</b>, covering: <ul style="list-style-type: none"> <li>○ trial activity: recruitment; funding to recruitment time</li> <li>○ metrics around trial implementation: measurement of trial impact; ROI and actual implementation</li> <li>○ development of guidelines for practice</li> </ul> </li> <li>• <b>IT systems</b> / integration with clinical information systems</li> <li>• <b>Health economics support</b></li> </ul>
What / who can we learn from	<ul style="list-style-type: none"> <li>• Registries</li> </ul>
Where is member/partner input needed	<ul style="list-style-type: none"> <li>•</li> </ul>
How will we measure success	<ul style="list-style-type: none"> <li>•</li> </ul>
Other comments / issues	<ul style="list-style-type: none"> <li>•</li> </ul>

### Plan 4: Embedding (NZ writing up this one)

Question	Steps / considerations
What needs to happen	<ol style="list-style-type: none"> <li>4.</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>•</li> </ul>

Question	Steps / considerations
What / who can we learn from	•
Where is member/partner input needed	•
How will we measure success	•
Other comments / issues	•

### Plan 5: Advancing trial methodology

Question	Steps / considerations
What needs to happen	<ol style="list-style-type: none"> <li>1. Scoping of people / resources / opportunities of those working with novel methods</li> <li>2. Map expertise</li> <li>3. Facilitate upskilling and training workshops and exchange programs</li> <li>4. More statistical research into novel methodologies</li> <li>5. Encourage collaboration and discussion forums</li> <li>6. International collaboration and engage with similar efforts elsewhere</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>• Project manager and working party to undertake scoping and map</li> <li>• Consultation with stakeholders</li> <li>• Facilitate opportunities to interact with EMR and registries</li> <li>• Educational activities for researchers</li> <li>• Engaging with ethics committees</li> </ul>
What/who can we learn from?	<ul style="list-style-type: none"> <li>• International researchers with similar interests and expertise</li> <li>• ? CRE</li> </ul>
Where is member / partner input needed?	<ul style="list-style-type: none"> <li>• Member input at all stages</li> <li>• Methodologists and investigators / biostatisticians</li> <li>• Consumers, reviewers</li> <li>• Data systems people</li> </ul>
How will we measure success?	<ul style="list-style-type: none"> <li>• Securing funding for trials with novel methodologies</li> <li>• Number of trials with new methods and platform trials</li> <li>• Publications related to novel methodologies</li> <li>• Attendance at suggested workshops and related programs</li> </ul>
Other comments	<ul style="list-style-type: none"> <li>• Explore overlap with 'embedding research' plan</li> <li>• Challenging funding statistical research</li> <li>• Lobby for methodology research funding</li> </ul>

### Plan 6: Models for prioritising clinical trials research

Question	Steps / considerations
What needs to happen	<ol style="list-style-type: none"> <li>1. Identify models and factors for consideration when prioritising: <ol style="list-style-type: none"> <li>a. availability of networks / other capacity for coordination of research (see capacity working group)</li> <li>b. criteria for specific studies: burden of illness, quality of research, return on investment, equity</li> <li>c. value of investment – linkage to PBS/MBS funding decisions</li> <li>d. engagement of stakeholders (practitioners / consumers)</li> </ol> </li> </ol>

Question	Steps / considerations
	e. implementation/translation plan
What is needed to make this happen?	<ul style="list-style-type: none"> <li>• Develop brief white paper (draft) – high-level points</li> <li>• Round table meeting (including issues and questions) (ACTA to host)</li> <li>• Develop more detailed white paper</li> <li>• Consult with the sector</li> </ul>
What/who can we learn from?	<ul style="list-style-type: none"> <li>• UK (NIHR)</li> <li>• Australia (Government, MBS e.g. Paul Glasziou)</li> <li>• Other ACTA groups</li> <li>• NHMRC – important to see how it fits with NHMRC structural review / trials framework</li> <li>• AAMRI review</li> </ul>
Where is member / partner input needed?	<ul style="list-style-type: none"> <li>• Important to include ACTA groups in development and consultation</li> <li>• Others to be included: <ul style="list-style-type: none"> <li>○ PBAC/MSAC/MBS review representatives</li> <li>○ Government (state and federal)</li> <li>○ Professional bodies – practitioners across different areas</li> <li>○ Consumers</li> </ul> </li> </ul>
How will we measure success?	<ul style="list-style-type: none"> <li>•</li> </ul>
Other comments	<ul style="list-style-type: none"> <li>• Define / clarify overlaps with other groups – e.g. embedding research, linkage group, capacity building group, models for registries and CTNs</li> </ul>

### Plan 7: Running better trials by better member collaboration

Question	Steps / considerations
Overarching principle	ACTA members need to learn from each other's strengths and experiences
What needs to happen	<ol style="list-style-type: none"> <li>1. Review large corporate experience and resources (human and technological)</li> <li>2. Share: <ol style="list-style-type: none"> <li>a. Processes / SOPs</li> <li>b. Software</li> <li>c. Social media experience</li> <li>d. Relationships with network 'homes'</li> <li>e. Approach to philanthropy / funding</li> <li>f. Videoconference subscriptions</li> <li>g. Reimbursement models</li> <li>h. Mentoring processes for young investigators</li> </ol> </li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>• Identify key topics</li> <li>• Explore ways to connect and share knowledge/experience: <ul style="list-style-type: none"> <li>○ Newsletters</li> <li>○ Conferences</li> <li>○ Meetings of CEOs/Chairs</li> <li>○ Workshops – virtual meetings</li> <li>○ Central problem hotline and 'chat room'</li> </ul> </li> </ul>
What/who can we learn from?	<ul style="list-style-type: none"> <li>• Cancer trials groups have Executive Officers Network</li> <li>• Pharma</li> <li>• <a href="#">TransCelerate</a></li> </ul>



Question	Steps / considerations
Where is member / partner input needed?	<ul style="list-style-type: none"> <li>All members needed to input into the 'issue box' and preferred method of collegiality</li> </ul>
How will we measure success?	<ul style="list-style-type: none"> <li>Increased activity</li> <li>Cross-network collaboration – specific examples</li> <li>Attendance at for a etc</li> </ul>
Other comments	<ul style="list-style-type: none"> <li>Lowest hanging fruit – pluck it!</li> </ul>

### Plan 8: Professional development – Executive Officers, Managers and Research Co-ordinators

Question	Steps / considerations
What needs to happen	<ol style="list-style-type: none"> <li>Linking network EOs</li> <li>Facilitate information sharing and mentoring of new EOs</li> <li>Opportunity to share insights on activities done well</li> <li>Provide support / facilitate secretariat support for networks (scheduling, agenda development, scribe)</li> <li>Provide meeting support (travel and teleconferencing)</li> </ol>
What is needed to make this happen?	<ul style="list-style-type: none"> <li>Scope support needs and interest</li> <li>Identify champions</li> <li>Terms of reference</li> <li>Funding to identify and address support needs</li> </ul>
What/who can we learn from?	<ul style="list-style-type: none"> <li>Executive Officers Network (oncology)</li> <li>Government</li> <li>Industry (Medicines Australia?)</li> <li>Institute Managers and Leaders</li> <li>CTCN</li> </ul>
Where is member / partner input needed?	<ul style="list-style-type: none"> <li>Draw from learnings from Executive Officers Network (oncology)</li> <li>Survey the sector (EOs and CEOs)</li> </ul>
How will we measure success?	<ul style="list-style-type: none"> <li>Growth in member engagement</li> <li>Growth in research activity</li> <li>Reduction in staff turnover</li> <li>Efficiencies in operating costs</li> </ul>
Other comments	<ul style="list-style-type: none"> <li></li> </ul>

## APPENDIX I: Advisory Council meeting participants

Name	Member organisation represented
Stephen Ackland	Australia & New Zealand Breast Cancer Trials Group
Ross Andrews	Menzies School of Health Research
Chris Bertinshaw	Australasian Spinal Cord Injury Network Ltd
Allison Bourne	Australia and New Zealand Musculoskeletal Clinical Trials Group (ANZMUSC)
Linda Brown	Palliative Care Clinical Studies Collaborative (PaCCSC)
Ellie Brown	Centre for Innovation in Mental and Physical Health and Clinical Treatment (IMPACT) SRC
Hamish Campbell	Multiple Sclerosis Research Australia Clinical Trials Network (MSRA CTN)
Denise Caruso	Australasian Sarcoma Study Group (ASSG)
Alan Cass	ACTA Board / Menzies School of Health Research
Russell Conley	Australasian Gastro Intestinal Trials Group (AGITG)
Andrew Davidson	Melbourne Children's Trials Centre
Ian Davis	Australian & New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
Chris Fraser	Australian and New Zealand Children's Haematology-Oncology Group (ANZCHOG)
Craig French	Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG)
Donna Goldsmith	Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG)
Liddy Griffith	South Australian Health and Medical Research Institute (SAHMRI)
Katie Groom	ACTA Board / Interdisciplinary Maternal Perinatal Australasian Collaborative Trials (IMPACT) Network
Ian Harris	Australia and New Zealand Musculoskeletal Clinical Trials Group (ANZMUSC)
Ross Haslam	Australian & New Zealand Neonatal Network (ANZNN)
Rebecca James	ACTA Board
Mustafa Khasraw	Cooperative Trials Group for Neuro-Oncology (COGNO)
Kurt Lakovic	Cancer Trials Australia
Kate Lee	ACTA STInG / Melbourne Children's Trial Centre (MCTC)
Rebecca Lennon	Paediatric Trials Network Australia (PTNA)
Nicole Marsh	Alliance for Vascular Access Teaching and Research (AVATAR) group
Ed Oakley	Paediatric Research in Emergency Departments International Collaborative (PREDICT)
Terrie O'Brien	Department of Health
Elizabeth Paton	Australian and New Zealand Melanoma Trials Group (ANZMTG)
Vlado Perkovic	ACTA Board / The George Institute / Australasian Kidney Trials Network (AKTN)
Philip Peyton	Australia & New Zealand College of Anaesthetists (ANZCA) CTN
Gillian Ray-Barruel	Alliance for Vascular Access Teaching and Research (AVATAR) group
Kieran Schneeman	ACTA Board
John Simes	ACTA Board / NHMRC Clinical Trials Centre
Delaine Smith	Australasian Leukaemia and Lymphoma Group (ALLG)
Rhiannon Tate	ACTA CEO
Niall Tebbutt	Australasian Gastro Intestinal Trials Group (AGITG)

Name	Member organisation represented
Steve Webb	ACTA Board / Monash School of Public Health and Preventive Medicine (SPHPM) / Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG)
John Zalcberg	ACTA Board / Monash School of Public Health and Preventive Medicine (SPHPM) / Australasian Gastro Intestinal Trials Group (AGITG)
Nik Zeps	ACTA Board / Primary Care Collaborative Cancer Clinical Trials Group (PC4)
<i>Alison Evans</i>	<i>Alison Evans Consulting – workshop scribe</i>

## APPENDIX II: Workshop agenda

### Agenda

Time	Topic	Presenter
10.00am	Welcome, introductions & outline of meeting objectives	John Zalcborg
10.15am	<b>The opportunity</b> Overview of the <i>Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program</i>	Rhiannon Tate
10.45am	<b>Q&amp;A</b>	
11.20am	<b>Planning day overview</b> <i>Overview of the day's planning activities</i>	Rhiannon Tate
11.30am	<i>Morning tea</i>	
11.45am	<b>Building the roadmap: prioritising activities to strengthen the sector</b> <i>What are the key priorities that will drive sector growth and impact and how should we be working together to achieve this?</i>	Facilitated group discussion
1.00pm	<i>Lunch</i>	
1.45pm	<b>Building the roadmap: reviewing the year 1 priorities</b> <i>What can we start now? What are the key questions we need to know more about?</i>	Steve Webb
2.30pm	<b>Activity planning: what does year 1 look like?</b> <i>What do we need to do to start work on key priorities? What resources do we need? Who can we learn from? How will we measure our progress?</i>	Small group discussion focused on agreed year 1 priorities
3.15pm	<i>Afternoon tea</i>	
3.30pm	<b>Making it happen</b> <i>Small group feedback and agreement on next steps</i>	Rhiannon Tate and John Zalcborg
4.00pm	<i>Close</i>	

## APPENDIX III: RAW DATA – POST-IT NOTE GROUPINGS AND THEMES FROM WHITEBOARDS

### Red group

Theme	Post-it
Partnerships	Cross-sector collaborations with university partners – joint appointments in research roles
	Sector working with Government, professional bodies, industry, community
Governance	ACTA Structure – governance review
Communication/knowledge sharing	Create a means for networks and network coordinators to communicate and learn from each other
	Regular meetings/communications to highlight best practice and examples
	Meaningful communication -check out LSE blog – very useful ideas
ACTA running trials	In the future should ACTA fund clinical trials?
Reduce costs of ACTA engagement	Consider watching costs; try to limit expense of membership, meeting attendance etc to maximise participation and engagement
Industry engagement	How can we make Australia an attractive/competitive place for pharma to conduct their research?
	Industry engagement
Linking trials to MBS and PBS – high value care	How to link to the health policy making and implementation mechanisms
	Clinical trials program linked to health care funding (MBS/PBS)
Public awareness	Bottom up approach to build public awareness of benefits Public awareness campaign
Rare diseases	Need to ensure that model developed supports participation in international collaborative research, particularly rare diseases
	Need to ensure that framework developed takes into consideration the unique challenges faced by networks who treat rare diseases
Professional development	Develop meaningful rewards for clinicians involved in research
	There is an issue with funding continuity which affects staffing and retention of staffing. How can ACTA possibly assist to advocate for increasing funding duration
	Improve education and training
	Training systems to rapidly develop skills for study coordinators
	Will ACTA offer research workshops? Impact of investment – w/s enrolments, conference attendance, invited speakers to overseas
	Plan for supporting and developing junior researchers and research coordinators re: research processes
	Importance of ACTA to facilitate clinical trials education for early career researchers, doctors, integrate with Colleges and the ACTA members. Improve member learning, skills and engage people in their careers for lifelong contribution
	Career pathways for individuals across all roles
Funding – site level, coordination, network level	Identify sector-wide funding opportunities and models
	Advocate for expansion of the successful ones
	Simple e-CRF used across different networks

Capacity for trial coordination/conduct	Standard data fields for common disciplines eg onc, ICU etc
	Quality assurance/control resources
	Trial document templates Trial budget/costing templates
	Connecting networks with resources and services
	Resource costs of trial coordination
	Shared statistical / coordination/ insurance resources
	Cost of monitoring/CRO costs are often considerable. Should there be investment in establishing academic research organisations or building networks own capacity to conduct the activity
	Capacity building – including biostats, health economics, translation
	Reducing waste
	Shared / central resource service i.e. buying monitors in different states to reduce travel costs
Sustainability	How can ACTA become self-sustaining? What corporate structure is required?
Network best practice	Different clinical trials networks have different funding models. How to support those without a funding stream from philanthropy or pharma
	Discover, develop and advise networks on efficient functioning and use of personnel and resources
	What's needed and what can be discarded?
	Monash registry has significant interest groups. What's available, can we build on this?
	Standardise and consolidate templates, documents and processes
	What does a trial network do?
	Networks – define a minimum set of activities – work out best practice
	Look globally – e.g. OMG study (418 hospitals, 51 countries, 15 languages)
	Scope of successful models of networks e.g. Cancer Council Australia, Monash, NIHR, WA HTN
	Identify networks and review network structures/ governance
Identify key characteristics of 'highly performing networks'	
Ethics/governance	Expand/modify national statement to streamline ethics
	Ethics and governance is a roadblock – time consuming, complex, all different requirements
	Quality / audits / registries needs to be implied consent on admission to hospital (opt out model)
	Guardianship processes are different for each state
	Lobby for improving ethics processes (lead HREC review and approval, national acceptance)
	Invest in resources to streamline governance and ethics (it drowns some networks)
Value of information/prioritisation	Model for research priority and funding – return on investment and quality
	How can clinical trials inform implementation of high-value care, i.e. through the MBS / PBS Does ACTA have a role in this?

Consumers	Consumer strategy i.e. development of principles, operating standards and implementation mechanisms to support consumer participation in trials
	Scoping study to identify international models on consumer engagement in clinical trials and to test / trial these in Aust / NZ settings
	What are the support needs of registries / networks to support consumer participation
	Role of ACTA to centralise and improve consumer services, education, training and support. Role of consumers to ensure research relevance and monitor outcomes / efficiencies
	Scoping consumer groups interested in research, e.g. WH HTN model
Embedding	Develop 'ideal models for each aim e.g. embedding research into practice
	Capture data from electronic health records – trials and registries
	Embed clinical research into all health degrees
	Embed KPIs in health care quality framework
	Clinical trial metrics embedded in health care and linked to health care funding
	How to fund embedding clinical network in Australian healthcare
	Embedding research into care means – trials, translation, quality monitoring; we need to invest in all three
	Where research is not done where most patients are seen means translation becomes more important
	Need to change perception that clinical research is an optional extra
	Make clinical trials reportable at a hospital CEO level
Implementation	Results dissemination Closing the loop Practice change
	Implementation – identify barriers to implementation science
	How do we measure the success of a network or registry?
	Develop meaningful rewards for translatable outcomes
	Develop sector-wide knowledge and expertise in translating knowledge into care in our setting(s)
Trial methods	Terminology, Snomed etc Still too much variation in many trials
	Identify variation in clinical research
Linkage between groups	Inventory of CTNs/CQRs (complete) – including: size, features, expertise, contacts etc
	Identify duplication of resources
	Identify how groups can collaborate, especially regarding personnel and reducing duplication
	Recognise cross-cutting themes: indigenous health, data management etc and minimise duplication
	Develop a network of networks
	Facilitate/establish links between CTN and CTN / CTN and CQR

	Registries linkages between each other and new CQRs
Funding pilots and preliminaries	Identify barriers to multicentre research

### Green group

Theme	Post-it
Advocating for ethics and governance	HREC associations - ? presentations
	Guardianship considerations between states
	National Ethics – 1 approval per trial
	National clinical trial governance – remove barriers (institutional, state, health district)
	Identify barriers and enablers to driving the implementation of trial results through networks
	Complete overhaul of governance – philosophy is inimical to trials
	Can we push back against governance obstacles? (a major obstacle to clinical trial engagement)
	ACTA to develop a framework to deliver a national standard for ethics and governance as practiced overseas (Korea and China)
ACTA facilitating accessibility to health providers	State presentations / forums by ACTA. Aim – to increase ACTA’s profile/accessibility; increase state government (not just health department) understanding and support
Community / consumer engagement	Consumer engagement – research priorities; endpoints etc
	What do consumers think? Can we encourage consumers to drive change?
	Working with existing consumer networks
	Consumer engagement / education re: medical research need and value – start in schools, medical schools, adult ??
	Global consumer engagement in clinical trial research – how?
Funding	Prioritising available clinical trial research funds
Collaboration and linkage – within ACTA and outside (barriers and enablers)	More working together – learning from each other (coordinated approach)
	Create opportunities for collaboration
	Requirements for CTNs, CIs and CQRs to establish links with each other within their discipline
	Enhance enabling links for outcome information between different registries
	Investigate (at least) links with non-medical registries (data collections) eg education, employment and industry, even ATO!
How to measure impact outcome (start now)	An investigation of how to measure network impact – what data is currently available? What data would be ideal?
	How do we measure CTN/Clinical trial success?
National framework	Achieving 100% implementation
	CQR-RCT-Implement (cycle) ACTRA
	Health economics – feasible built-in endpoints in trial design; central service for modelling benefits as per commission paper, consider worst/best case ranges



	National support system
	National 'CRO' to support IITs – do we need multiple coordinating centres, reproducing processes?
	Health data linkage systems – PHR, cross/trans service referrals for trials, government registries (e.g. cancer, BAM, HHS, PBS – simplify access!)
Hospital / clinical service / primary care interaction with CTNs / research	Develop mutual objectives with health services – measure success based on these – enhance implementation
	How to engage with ALL hospitals/health institutes – KPI for health leaders/hospital managers/CEOs
	Medical and allied health and nursing education – mandatory research component
Trial design	Research into more efficient trial designs – support for methodological research
	Sharing innovation in trial design – becoming more efficient
New CTNs	Project leading to establishment of an Aboriginal health CTN: review trial activity in indigenous health; discussion about barriers and enablers; consultation on possible models; implement; evaluate
Gaps	National support / development system for CALD/ATSI research – link to NZ for Maori
Prioritisation	Prioritising which clinical trials and which networks – quality of outcomes not quality of academic research
	Facilitate development of efficient pathways to establish feasibility in trials
How to identify potential remit	Developing systems to identify patients suitable for trials and for recruitment – embed into routine system; improve recruitment (reduce timeline and increase efficiency)
	Systems for use of routinely collected clinical data for research – screening/feasibility for trials; comparative effectiveness; health outcomes. Same for excess tissue!
Research staff infrastructure at all hospitals – integrated into clinical workload	Network of trial capable staff throughout health system – professional development
	Getting research staff and trial infrastructure into all hospitals
	More support/recognition of biostatistics; data analysts; using routine data
Sustainability	Funding model: salaried trial staff – RCs a'la 'NIHR'
Critical success factors for CTNs and shared resources	Provide resources such as legal
	Common infrastructure elements – quality assurance/monitoring; legal; comms / marketing / fundraising expertise and support
Reviewing other networks	What is the structure of an efficient CTN? (and CQR/CC)
	Identify best practice models of network operation
	International engagement – how is research supported in other leading countries in research?
	International expertise – shared knowledge; register of expertise?
	Involvement of NZ: note key deliverable for many ACTA groups – needs NZ policy change on funding all costs of treatment from trial budgets
	Links to / learning from international networks
Reviewing ACTA networks	Model for a quality clinical trial network – what might it look like; would assist organisations with a gap analysis; would help identify common infrastructure needs

	Are all CTNs ready for more investment? Governance, infrastructure? What is the minimum? Can we share?
	An assessment of the ranges of 'structures' of networks – what works? What doesn't work? What would you do differently?

## Yellow group

Theme	Post-it
International collaboration	Identification of Eos, Chairs, Boards to facilitate collaboration
	Sharing ideas across disciplines: mental health – physical health
	Complement NIHR examples / successes
	Consider building / facilitating international linkages with other networks
Communication	How to communicate what is happening nationally – newsletters
	Involving those that don't know about ACTA – how?
Industry	Make Australian trial networks attractive for industry
Process	Longer timeframes for member consultation
New trial design	Support research into innovative trial design
Regional/rural	Enhancing capacity and capability at rural sites
Back of office support	Grant writing support
	Support for network legal/governance
	Establish central secretariat – scribing, meeting management, web development
	Umbrella / no fault compensation insurance
Workforce	Support national network of trial statisticians
	Increase trial coordination options
	Establish mentoring networks – EON, CTCN
	ACTA's role in professional development and/or education
	How to support grant writing and milestone based reporting of grant progress under a revised NHMRC framework
	Increase opportunities for clinical trial training – subsidise fees? Scholarships?
Ethics/governance	Lobby for changes /improvements in governance processes
	Governance templates/advice
	How to help reduce timelines to start trials at HREC / Governance levels
Standards/KPIs	Embed – hospital KPI via quality standard – regular reporting and monitoring
Public health / government agencies	Willingness of states and territories to participate in population-level public health trials – for example school-based influenza vaccination programs
	Pilot use of existing data in trials embed in health service delivery
	Role of adaptive trials embedded in service delivery
	Work to remove the demarcation between clinical care and clinical research
Outcomes	How to minimise wastage in research?
	Communications support – trial outcomes (lay and technical language)
Priorities / impact	Develop processes for identifying the questions that matter

	End of active trial translational activities – ie post publication activities to increase uptake *policy*
Funding models	Outline optimal funding framework for trial funding
Registries/EMR	Enhance registries capacity – find out current gaps; fund capacity drivers; value registry data
	Trials in registries special interest group
AHRTCs	Partner with AHRTCs and health districts to develop consistent network: site approach and relationship
Consumer/recruitment	Consumer involvement – training, central body for consumer review
	Raise awareness of benefit of trials amongst patients and community
	A piece on equity of access to clinical trials – ie it is unethical that vulnerable groups such as Aboriginal and Torres Strait Islander peoples, CALD groups do not have the same opportunity to participate in trials
	Model of community engagement with vulnerable groups that: feeds into co-design; feeds into recruitment; feeds into translation (working party task?)
	Template patient recruitment tools
	Project on recruitment to trials – best practice and innovative approaches
	Mechanisms to enhance patient recruitment – eg social media
	Increased awareness to increase recruitment
	Promote and awareness activities of CTs generally, benefits etc
Groups – networks and trials	Help streamline ethics
	Aboriginal health CTN connecting with other CTNs
	Increase CTNs but ensure don't duplicate networks – therefore promote current support and engagement
	Identify 'missing' networks and facilitate establishment
	Gap analysis of trials based on burden of disease, available treatments etc – priorities for government
Tools and resources	Reducing duplication – shared resources
	Facilitate communication between networks – share experiences, share resources, eg database software
	Identification of tools / resources within networks (survey?)
Data	Facilitating data linkage for outcome measures / metrics for trials
Workforce	Staff retention and continuity of employment