ACTIVITY WORK PLAN

Activity	**Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance**
Program	Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program
Organisation	Australian Clinical Trials Alliance
Activity Plan Timeframe	July 2017 to June 2018

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ACTIVITY PLAN SUMMARY

Overview

This Activity Plan outlines key activities to be undertaken in 2017–18 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) Advisory Council, ACTA Board and the Department of Health.

The activities described represent the first priorities required to develop, implement and support a national framework to expand the capacity, capability, efficiency and effectiveness of Clinical Trials Networks (CTNs) in Australia. By supporting and coordinating this strategic program of work, ACTA will facilitate the development of a dynamic and responsive roadmap for the future, that builds on the sector's significant strengths and expertise.

The programs of work will be led by and informed by the sector. ACTA will provide the central coordination and program support required to progress key priorities, and will 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. This will include the provision of direct one-to-one support and mentoring to support the development of new CTNs and accelerate the dissemination and adoption of guidance and best practices among existing CTNs.

The scale of ambition 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 achieve the aims of the Program. The Activity Plan defines key milestones and proposed approaches to collaboration, engagement and dissemination. Our approach will be revised and refined 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.

KEY PRIORITIES AND PROGRAMS OF WORK

Programs of work

Through a process of sector consultation and Board review, ACTA has identified a series of key **program areas** that will be started in 2017–2018. These program areas will be supported by ACTA program staff and will be overseen by multidisciplinary cross-sector Reference Groups drawn from the ACTA membership. Within program areas, time-limited projects will be undertaken, supported by standing Reference Groups, or by time-limited Working Groups as required.

These **program areas** 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 CTN trials**
F. **tools for research prioritisation**
G. **innovative trial design and conduct**.

Programs of work will be conducted over multiple years of program funding. Priorities will be reviewed on an annual basis and informed by consultation activity. 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 approval of the Department of Health.

ACTA's approach

ACTA's approach to supporting the planning, delivery and measurement of these programs of work will include:

- a review of **ACTA's governance** to ensure effective processes and decision making
- **program and project planning**
- establishment and support for **multidisciplinary cross-sector National Reference Groups** and **Working Groups**
- **provision of centralised operations and support** to advance priority projects and programs
- **strategic collaborations and partnerships**
- **development and sharing of tools and resources**
- **measuring the impact** of funding on sector capacity, effectiveness and efficiency.

Overarching principles

ACTA has developed 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
- inclusive
- equitable
- flexible
- evidence-based
- patient-centred
- innovative.

DELIVERABLES IN 2017–2018

Program activity

Program	Ref	Year 1 activities / milestones	Year 1 deliverables
A. Efficient and effective CTNs *Funding Agreement Priority Activities 1, 2, 4; Leadership & Collaboration 2, 3*	Year 1 activity		
	A.1	Appointment of **Efficient and Effective CTNs Reference Group** comprising clinical research leaders and CTN Executive Officers	Appointment of Reference Group Scope and brief for consultation activity to identify critical success factors for CTNs Publication of report on critical success factors for establishing and operating CTNs Needs assessment for network tools
	A.2	Development and conduct of a sector-wide consultation process to identify critical success factors for CTNs including: current structures, governance models, good practice operating principles, management processes, activities and approaches to measurement of trial activity	
	A.3	Understanding critical support tools for efficient and effective network administration and reporting	
	Leading on to:		
		Development of guidelines for CTN operations that describe options for efficient and effective conduct while allowing for flexibility according to models, availability of resources, and stage of evolution	
		Development and testing of network management software to facilitate reporting and conduct of network activity as informed by year 1 work	
B. CTN sector expansion *Funding Agreement Priority Activities 1, 2, 3, 4; Leadership & Collaboration 2, 3*	Year 1 activity		
	B.1	Appointment of a **CTN Sector Expansion Reference Group** comprising clinical research leaders and Executive Officers from new and established CTNs, and clinical research leaders from recognised under-supported areas with an interest in formation of new CTNs	Appointment of Reference Group Scope and brief for consultation activity to evaluate sector gaps Report and presentation to Department of Health regarding sector-wide gap analysis Publication of guidance for the formation of new CTNs
	B.2	Planning and conduct of a sector-wide gap analysis to identify disease entities, clinical disciplines, geographic locations, and vulnerable groups/communities not covered adequately by an existing CTN Estimate of public health impact of those diseases, clinical disciplines, geographic locations, and vulnerable groups/communities	
	B.3	Dialogue with clinical leaders (Colleges, Societies, academic leaders) and consumer organisations in areas identified by the sector-wide gap analysis to evaluate interest in formation of a CTN	

Program	Ref	Year 1 activities / milestones	Year 1 deliverables
		Dialogue with existing CTNs that have the potential to grow into identified sector gap areas about their interest in doing so	
	B.4	Development of guidance outlining options and decisions necessary to establish a new CTN	
	B.5	Facilitation of meetings of clinical leaders and clinician researchers from target areas to form new CTNs Establishment of collaboration and mentorship from existing CTNs	
	Leading on to:		
		Formation of new CTNs in areas identified by sector gap analysis	
		Identification of potential sources of seed funding for Executive Officers for new CTNs	
C. Impact and implementation of CTN trials *Funding Agreement Priority Activities 3, 4, 6; Leadership & Collaboration 2, 3*	**Year 1 activity**		
	C.1	Appointment of an **Impact and Implementation of CTN Trials Reference Group** comprising clinical researcher leaders, including researchers with expertise in health economics, health system management, and implementation of trial results into clinical practice	Appointment of Reference Group Draft guidelines for consultation on measuring and reporting impact of CTN trials Presentation to Department of Health regarding measurement and reporting of CTN trial impact Stakeholder map of potential program partnerships in implementation science Workshop on policy proposals for measurement and reporting of key metrics
	C.2	Development of guidelines for measuring and reporting impact of trials conducted by CTNs including: Recommendations regarding measurement of clinical practice before and after trial conduct	
	C.3	Conduct of workshop on optimisation of implementation of CTN trial results into clinical practice	
	C.4	Creation of linkages with experts in implementation science Planning for a workshop at ACTA Symposium on implementation science for clinical trialists	
	Leading on to:		
		Template for use to report return-on-investment of CTN trials	

Program	Ref	Year 1 activities / milestones	Year 1 deliverables
		Development of guidance about how the healthcare system and CTNs should collaborate to optimise implementation of CTN trial results	
		Linkage with registries to optimise routine collection of data that reports implementation of CTN trial results	
D. Embedding clinical trials in healthcare *Funding Agreement Priority Activities 2, 3, 4, 5; Leadership & Collaboration 2, 3*	**Year 1 activity**		
	D.1	Appointment of an **Embedding Clinical Trials in Healthcare Reference Group** comprising clinician researchers with representation requested from AHRTCs, National Digital Health Agency and Population Health Research Network along with consumer representation	Appointment of Reference Group Circulation for consultation of draft discussion paper on opportunities to embed clinical trials in the Australian health system
	D.2	Development of a discussion document on options to embed clinical trials in the Australian health system including: • consensus definition of 'embedding' • identification of elements of embedding (e.g. recruitment within existing healthcare processes and simplified and automated access to clinical and administrative data via linkage including registry-randomised trials) • identification of facilitators of embedding (e.g. enrolment criteria that can be interpreted easily and quickly by clinical staff, pragmatic trial end-points, 'front of door consent' for use of data) • Consideration of how trials link to and support the policy environment.	
	D.3	Availability of the Embedding Clinical Trials in Healthcare Reference Group to contribute to bi-directional dialogue with the Department of Health and other stakeholders, as appropriate, regarding impact of proposed reforms related to governance and ethics on capacity to embed trials within healthcare system efficiently and effectively	
	D4.	Development of scope for a discussion document regarding opt-out consent and simplified provision of information for comparative effectiveness trials (to be delivered in year 2)	
	Leading on to:		
		Finalisation of discussion paper on opportunities to embed clinical trials in the Australian health system	
		Development of a discussion document regarding opt-out consent and simplified provision of information for comparative effectiveness trials	
	Year 1 activities		

Program	Ref	Year 1 activities / milestones	Year 1 deliverables
E. Strengthening consumer engagement in CTN trials *Priority Activities 1, 2, 3, 4, 5; Leadership & Collaboration 2, 3*	E.1	Appointment of a **Strengthening Consumer Engagement in CTNs Reference Group** with representation from clinical researchers, consumer representatives from CTNs, and consumer representatives not associated with CTNs	Appointment of Reference Group Map of current consumer engagement activity across the sector, including case studies Workshops (NOTE: to harmonise with current work by Government to develop/release a clinical trials awareness campaign)
	E.2	Scoping activity to map current approaches to consumer engagement across the sector and identify examples of good practice	
	E.3	Conduct of workshop to discuss best practice principles for consumer involvement in the clinical trials sector (to inform year 2 activity to develop a guidance document)	
	E.4	Conduct of workshop to develop messages for the community about the role and value of CTNs and clinical trials that evaluate questions of comparative effectiveness	
	Leading on to:		
		Development of a discussion document regarding opt-out consent and simplified provision of information for comparative effectiveness trials (drawing from work conducted under D4)	
F. Tools for research prioritisation *Funding Agreement Priority Activities 2, 3, 4, 5; Leadership & Collaboration 2, 3*	**Year 1 activities**		
	F.1	Appointment of a **Clinical Trial Prioritisation Working Group**	Appointment of Working Group Circulation for consultation of best practice guidelines for determining value of information
	F.2	Development of best practice guidelines for determining value of information (to facilitate prioritisation of research questions by member networks)	
	Leading on to:		
		Finalisation of best practice guidelines for determining the value of information	
G. Innovative trial design and conduct *Priority Activities 2, 3, 4, 5; Leadership & Collaboration 2, 3*	**Year 1 activities**		
	G.1	Appointment of **Innovative Trial Design and Conduct Working Group**, including members of ACTA Statistics in Trials Interest Group (STInG)	Appointment of Working Group Workshop on innovative clinical trial designs
	G.2	Workshop on innovative clinical trial designs	
	Leading on to:		
		To be informed by Year 1 outcomes	

ACTA's approach

Focus area	Ref	Activities/milestones	Year 1 deliverables
Strengthening ACTA's governance *Funding Agreement Leadership & collaboration 1*	Ap.1	Board capability review and appointment of additional Board roles	Completion of Board capability and policy review Publication of Advisory Council meeting summary reports and recommendations Terms of Reference Formation of special interest groups and development of Terms of Reference and work plans ACTA membership growth
		ACTA policy review	
		Board sub-committee appointments including **Finance, Audit & Risk Committee**	
	Ap.2	Advisory Council meetings	
	Ap.3	Special interest groups: • Formalise **ACTA STInG** and develop 12-month activity plan • Establish **ACTA Health Economics Special Interest Group** • Establish **CTN Executive Officers Special Interest Group**	
	Ap.5	Review of ACTA membership models	
Program planning *Funding Agreement Leadership & collaboration 1,3*	Ap.6	Advisory Council meeting to canvass ideas on program priorities Agreement on year 1 program activity based on Advisory Council feedback and Board prioritisation	Report summarising Advisory Council ideas Submission of Activity plan 2017–2018
	Ap.7	Appointment of key ACTA Senior Program personnel to support priority programs	Appointment of ACTA Senior Program Team personnel
Establishment and support for multidisciplinary cross-sector Reference Groups and Working Groups *Funding Agreement Leadership & collaboration 1*	Ap.8	Review of optimal models for oversight of program areas (time-limited Working Groups vs Standing Reference Groups)	Reference Group and Working group processes reviewed and agreed Terms of Reference for Reference and Working Groups developed
		Development of terms of reference for agreed groups.	
Provision of operations and project support to advance priority projects and programs *Funding Agreement Leadership & collaboration 1*	Ap.9	Appointment of ACTA Operations and Program team personnel	Appointment of ACTA Operations and Program team personnel
	Ap.10	Onboarding and training of new personnel	

Focus area	Ref	Activities/milestones	Year 1 deliverables
Strategic collaborations and partnerships *Funding Agreement Leadership & collaboration 2*	Ap.11	Environmental scan to develop a stakeholder map relevant to increasing capacity and capability in the clinical trials sector including Professional Colleges and Societies, Federal and State / Territory Government and Health Departments, private hospital providers, Government bodies such as MSAC and PBAC, industry and commercial CROs	Stakeholder Map Stakeholder Engagement and Communication Strategy Publication of reports, newsletters and other communication collateral
	Ap.12	Development **of Stakeholder Engagement and Communication Strategy to intersect** between all Program activities and relevant stakeholders	
	Ap.13	Review and consolidation of ACTA central membership functions / support activities	
	Ap.14	Establishment of member engagement portal as part of ACTA website to encourage two-way member engagement	
	Ap.15	Ongoing release of relevant reports, newsletters and other collateral in line with Stakeholder Engagement and Communication Strategy and ACTA / program activities	
Measuring the impact of funding on sector capacity, effectiveness and efficiency *Leadership & collaboration 4*	Ap.16	Each of Reference and Working Groups outline proposals for measuring their impact which are consolidated into a **Program Evaluation Plan**	Program Evaluation Plan