



# Developing Best Practice Guidance for Clinical Trial Network Operations

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# Clinical Trials Research

- › Translate basic scientific research findings and clinical observations to test them in clinical practice

- › A fundamental component of the process to generate evidence that informs clinicians, health consumers, and policy makers about the most effective and cost-effective ways to improve health outcomes



**Clinical Trials Networks provide sustainable support for clinical trials**

# Clinical Trials Networks



An organised group of clinicians and researchers who share infrastructure that enables them to collaborate to conduct multiple multi-centre trials

## ACTA CTN members

- › Defined area of research
- › Established governance processes
- › Conducted & published at least one investigator-initiated trial
- › Commitment to conduct further trials together

# Clinical Trial Networks in Australia



- › 37 networks identified in ACTA Profiling Report 2004-2014
- › Broad range of diseases/disciplines
- › Ever-growing number
- › More than half are bi-national, identifying as ANZ or Australasian
- › Two broad models:
  - **Facilitating Networks** (facilitate collaborative development, funding and execution of trials, not involved in day-to-day management of trials, often work alongside 1-2 preferred clinical trial co-ordinating centres)
  - **Co-ordinating Networks** (also take on role of clinical trial co-ordinating centre providing direct project management of network trials)

# Benefits of Clinical Trials Networks

The sum is greater than the parts

- › **Community:** shared sense of challenge and achievement in particular discipline/field
- › **Capacity:** complete trials with sufficient sample size that can be ‘practice changing’
- › **Conduct multiple sequential trials:** sustained infrastructure and retained workforce
- › **Shared intellect:** knowledge and expertise in trial design, conduct, analysis and reporting
- › **Participation:** academic/non-teaching, rural/metropolitan. Results applicable to population
- › **Track record:** brand value created
- › **Clinician-led, clinician-relevant:** enhance translation
- › **Partnerships:** wide variety of stakeholders, international networks



Better health through best evidence

# ACTA Reference Group A: Efficient and Effective Clinical Trial Networks



## Goal:

- Enable networks to operate in an efficient and effective manner

## Objectives:

- Describe structures/models and operational processes/activities of networks. *What we do and how we do it?*
- Identify structural and operational factors that are critical to success and sustainable growth
- Identify unmet needs that can enhance efficiency and effectiveness

**Develop a best practice guidance document and a portfolio of tools and resources to support network operations**

# Methods

- › **Sector-wide consultation** to identify common structural components of and operational activities performed by networks
- › **Focus group meetings** to explore these structures and functions to identify critical success factors and identify enablers and barriers to network operations
- › **Reference Group A review** to collate, construct and review a guidance document that can be used to benchmark, identify gaps, support future critical needs
- › **Key support tools** ranked and prioritised

# Sector-wide consultation

Communication to all ACTA network members Chairperson and Manager/Executive Officer

- › Core list of structural components and operational activities
- › Request to review and contribute
  - › **Structural:** organisation, membership, staff, physical space, governance
  - › **Operational:** databases, meetings, communications, website, guideline development, trial endorsement, consumer engagement, education and mentoring, trial management, financial activities, trial development

Informed Focus Group question development



# Focus Groups

Three groups established specific to their needs

- › Co-ordinating Networks
- › Facilitating Networks
- › Establishing/Newly Established Networks

Sample of convenience

- › ACTA members (except for establishing/newly established)
- › Geographical to encourage in person attendance
- › Variety of disease types

Chairperson and Manager/Executive Officer of each network invited



# Focus Group Contributing Networks



- › Australasian Stroke Trials Network (ASTN)
- › Australasian Lung Cancer Trials Group (ALCTG)
- › Paediatric Research in Emergency Departments International Collaborative (PREDICT)
- › Interdisciplinary Maternal Perinatal Australasian Collaborative Trials Network (IMPACT)
- › Palliative Care Clinical Studies Collaborative (PaCCSC)
- › Australasian Leukaemia and Lymphoma Group (ALLG)
- › Australasian Gastro-Intestinal Trials Group (AGITG)
- › Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA)
- › Australia and New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC)
- › Australian and New Zealand Alliance for Cardiovascular Trials (ANZACT)
- › Child and Youth Mental Health (CYMH)

## Coordinating Networks

- › 6 networks invited
- › 4 represented on the day
- › 1 chair and 4 network managers
- › 2 in attendance; 3 videoconference
- › 180 mins

## Facilitating Networks

- › 6 networks invited
- › 4 represented on the day
- › 3 chairs and 2 network managers
- › All in attendance
- › 165 mins

## Newly establishing Networks

- › 3 networks invited
- › 3 represented on the day
- › 3 network managers
- › All by videoconference
- › 120mins

All meetings facilitated by ACTA Project Officer  
Supported by Reference Group A leadership/ACTA Board

What makes your network successful?

Identify and describe essential tools that will allow a network to operate effectively?

Tell us about the governance structure of your network and what works well?

Using blue-sky thinking, how would your network look if there were no limitations?

Talk about the 'culture' that your network strives to promote?

Describe the factors which shape the goals of your network?

How does your network ensure different stakeholders feel engaged?

Identify one enabler and one barrier to running your CTN efficiently and effectively?

Is there anything that captures the essence of your network that you feel has not been discussed?

- > Few questions, lots of discussion
- > Exchange of ideas

# Analysis

- › All discussions were recorded and transcribed (intelligent verbatim)
- › Key themes were identified and organised across focus groups
- › Enablers, barriers and key tools were isolated from discussion

# Key themes

- › An engaged membership
- › Defined network structure
- › Network sustainability

# Network Membership

## Importance

- › ‘Champions’ of network promoting research culture that can improve health
- › Culture that promotes passion, goodwill and research
- › Generate new trials and collaborative opportunities
- › Peer review and trial endorsement
- › Participate in trials
- › Governance committees
- › Create track record and contribute to brand development

# Network Membership

## Factors and activities to promote an engaged membership

- › Actively encourage diverse representation and engagement
- › Transparent processes
- › Leaders with good 'people skills'
- › Scientific meetings and social events
- › Mentoring and education programmes
- › Regular communications - newsletters, website, social media
- › Smaller targeted workshops

# Network Structure

## Importance

- › Facilitate generation of new, relevant ideas and maintenance of pipeline of trials
- › Trial development services
- › Trial co-ordination services
- › Accountability and transparency

# Network Structure

## Factors and activities to support network structure

- › Strategic plan
- › Executive Officer/Network manager
- › Established organisational model and governance framework - ToR/regular meetings
- › Recognised consumer representation
- › Workshops and mentoring to facilitate development of new ideas
- › Authorship and publication policy
- › Site feasibility assessment/needs analysis/KPIs (co-ordinating CTNs)
- › Safety monitoring (co-ordinating CTN)
- › Trial conduct SOPs (co-ordinating CTN)

# Network Sustainability

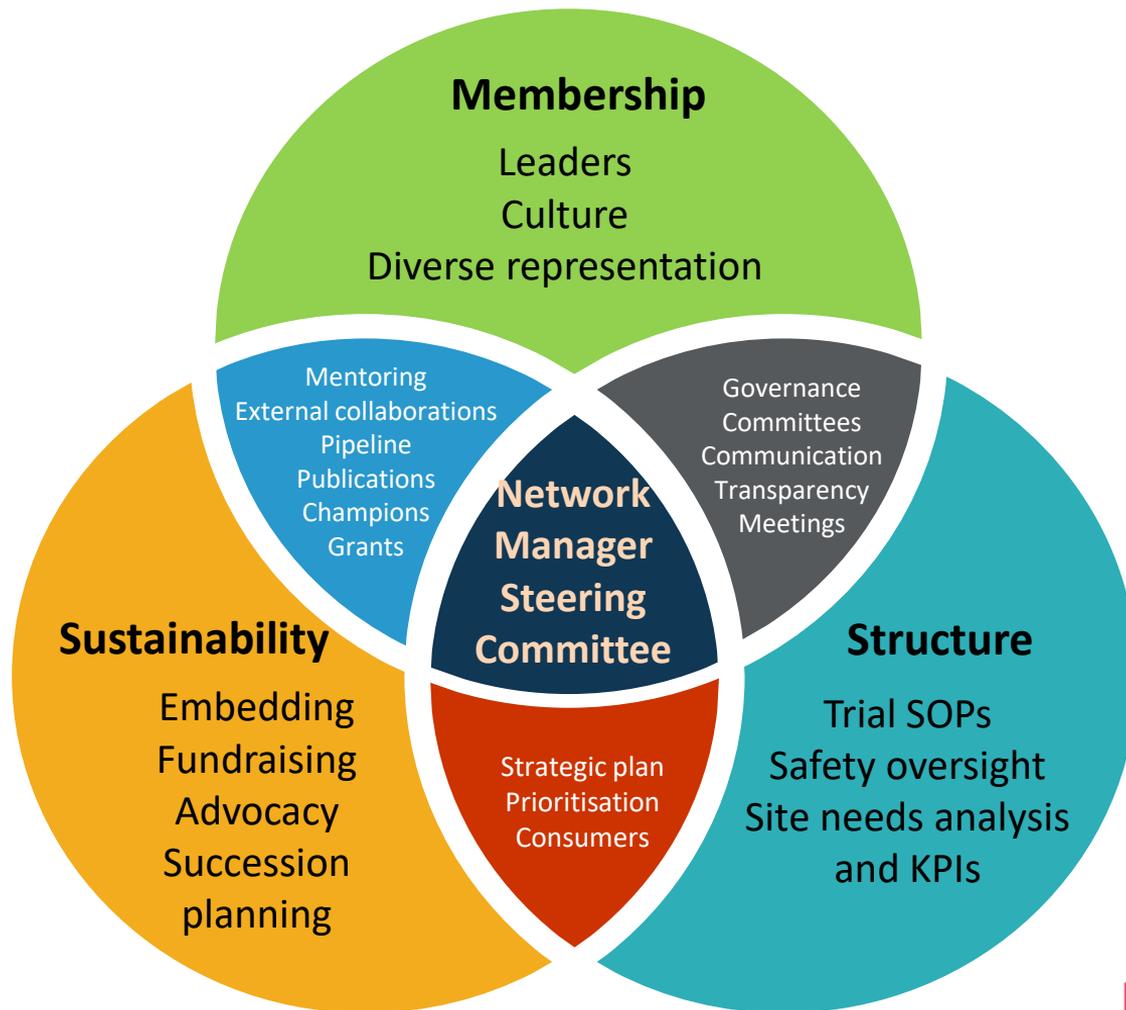
## Importance

- › Succession planning for network champions
- › Strong track record
- › Embedding research into healthcare
- › Community awareness, reputation and brand development
- › Strong pipeline of trials
- › Funding

# Network Sustainability

## Factors and activities to facilitate sustainability

- › Fundraising and marketing
- › ‘Generating ideas’ workshops or research prioritisation to areas of need
- › International collaboration
- › Trial endorsement and publications
- › Successful grant applications (pilot studies to increase chance of success)
- › Advocacy with community and policy makers
- › Engaged site staff
- › Defined career pathway for research co-ordinators



# Enablers for Efficient and Effective Network Operations

- › Engaged membership
- › Track record/brand development
- › Established recruiting sites
- › Formal consumer input (advisory board)
- › Network funded feasibility studies
- › Collaboration with other networks and international trials
- › Good governance
- › Infrastructure supplied by parent organisation

# Barriers to Efficient and Effective Network Operations

- › Individual networks struggle to engage policymakers
- › Lack of funding and resource
  - › Over reliance on site goodwill→ negatively affects recruitment
  - › Prevents expansion to newer sites
  - › No Executive Officer support
- › Competition
  - › In raising community awareness
  - › In conducting trials at a particular site
- › Trial design
  - › Mismatch between trial feasibility and actual trial recruitment rate
  - › Lack of 'embedded' trials; 'too parallel to the system which we're trying to influence'
- › Lack of understanding in parent organisation
- › No supported research time for clinicians

# Issues unique to establishing networks

## › Mission and vision

- › Established early
- › Diverse representation involved but must include ‘champions’
- › By agreement as an initial bonding exercise and then by evolution

## › Leadership

- › Identify early and ensure involvement in establishment meeting and succession planning
- › Lack of time in leaders may be a barrier

## › Establishing network culture

- › Flagship project to initially unite the network
- › Mentoring and welcoming younger members

## › Operations

- › Knowledge when making choice about organisational structures

# Key tools to facilitate network operations

- › Membership structure and guidelines
- › Consumer engagement guidelines
- › Assistance with funding applications
- › Governance documents (ToR)
- › Evaluation of site network capabilities
- › Strategic Plan
- › Trial review, endorsement and prioritisation process
- › Authorship and publication policy
- › MOU for collaboration with other CTN trials (international and local)
- › Operational staff position descriptions
- › Fundraising and marketing plan
- › Management of trial metrics- pipeline, active trials, impact of completed trials

# What does a successful network look like?

- › Shared vision, strong motivation to improve outcomes
- › Champions and strong leadership/governance
- › Effective communication
- › Diverse representation and consumer input
- › Transparent processes, especially trial endorsement and authorship
- › Pipeline, publications and strong track record
- › Strong network of sites, established site infrastructure, skilled study coordinators
- › Innovative and adaptable
- › Intrinsic evaluation of success

**Very strong recognition that one size does not fit all**



# Reference Group A sector consultation

## Focus Group Limitations

- › Not all networks were represented
- › Sample may not have reached saturation

## Outputs

- › Focus Group report
- › Best practice guidance document underway
- › Tools and resources to assist network operations

# Tools and resources to assist network operations



Informal sharing and collaboration has emerged from sector consultation activities

ACTA led development and sharing of documents and resources

Available on ACTA website:

- › Clinical Trial Network Governance Structure
- › Clinical Trial Network Membership Structure
- › Clinical Trial Network Strategic Plan Development

# Tools and resources to assist network operations



## Will become available throughout the next year

- › Committee terms of reference template
- › Network Manager duties/position description
- › Assessment of financial status and future projections
- › MOU template with parent organisation
- › Publication and authorship policy
- › Trial endorsement procedure
- › Trial milestone tracking spreadsheet
- › Lead investigator roles and responsibilities agreement
- › MOU and checklist for international trial collaborations
- › Communications strategies
- › Guidance for network meetings and workshops

## To be developed

- › Membership database
- › Website shell
- › SOPs for trial management
- › Trial management database

External business review 2019

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Donna Reidlinger

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