Clinical trial network strategic plan development

Guidance for CTNs

CONTENTS

PURPOSE OF DOCUMENT

This document will assist clinical trial networks (CTNs) to develop or revise their strategic plan.

ROLE OF ACTA IN DEVELOPING CLINICAL TRIAL NETWORK STRATEGIC PLANS

The Australian Clinical Trials Alliance (ACTA) is providing advice, which may assist a CTN in the development of their own strategic plan.

The generic advice provided by ACTA should be considered and applied by each CTN taking into account the specific individual circumstances and needs of the CTN. The following principles are integral to successful CTN operations.

- Decisions should reflect good governance practices including transparency, identification and management of conflicts of interest, and rules that are applied consistently.
- A recognition of the multidisciplinary roles in potential membership and their contributions to a successful CTN.
- The CTN membership structure should be both representative of and responsible to its members.

ACKNOWLEDGEMENTS

We acknowledge the contributions of ACTA CTN members and members of ACTA's Efficient and Effective CTNs Reference Group in the preparation, development and review of this document.

USE OF THIS DOCUMENT

ACTA requests that the following acknowledgement is included in any document that is developed using knowledge gained from this document. This will assist ACTA in identifying the usefulness and impact of this document in creating efficient and effective processes for clinical trial networks.

"[name of CTN] acknowledges the contribution of ACTA to the development of operational processes within our network (reference: Clinical Trial Network Strategic Plan Development)"

DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

DOCUMENT HISTORY

Version	Date	Changes made to document	Author
1.0	26 November 2018	Initial	MS, RJ, KL, KG, KGo

ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CTN	Clinical Trial Network
KPI	Key Performance Indicator
KRA	Key Result Area
SWOT	Strengths, weaknesses, opportunities, threats

THE STRATEGIC PLANNING PROCESS

The strategic plan:

- defines in practical terms what a CTN aims to achieve and how this will be achieved in terms of allocation of budget, resources, and time

- guides decision-making about future activities and priorities

- provides direction and structure to CTN activities

- describes the measures that will be used to evaluate success

Consider the people in your organisation who will contribute to the development of the strategic plan. This may extend beyond the CTN leadership group (e.g. Board of Directors, Executive Committee) and can include key stakeholders and/or external advisers. Identify who will be the 'director' of the strategic plan. Consider the time period that the strategic plan will span (usually 3 or 5 years). Outline the review and authorisation process once the plan is finalised for implementation.

A sample template for a strategic plan has been provided in APPENDIX 1, but you may also wish to consider reviewing the strategic plans of other CTNs.

Examples include:

https://www.anzup.org.au/content.aspx?page=strategicplan

http://pc4tg.com.au/resources/policies-and-reports/

https://impact.psanz.com.au/about/goals-and-strategies/

Determine where the organisation is now. One helpful way to do this is to conduct a SWOT analysis (see APPENDIX 2). Consider how this relates to the organisation's **vision** (the difference to the world you would like the organisation to make); **mission** (your core business, primary objectives and customer needs); and **values** to determine priority issues and focus the strategic plan. See relevant sections below if vision, mission and values have not already been articulated and consider how the CTN's present position relates to these. Key objectives and measurable goals (Key Performance Indicators) should then be developed.

Once the plan is near final, a **budget** should be drafted to align with the plan. Once the plan is finalised, the strategy needs to be **communicated** to the organisation, and **timelines** need to be set for progress and budget reviews against the strategic plan. Strategic planning may also benefit from development of an **action plan** to provide the detailed action steps necessary to execute and track progress against the strategic plan (see section entitled 'Establishment of an Action Plan').

DEVELOPING A CLINICAL TRIAL NETWORK VISION

The strategic plan document should include the CTN vision statement.

A *vision statement* is a source of inspiration and motivation. It communicates the values, purpose and core business of your organisation. Often it describes not just the future of the organisation but the future of the industry or society in which the organisation hopes to effect change. Consider "where do we want to be going forward?", "when do we want to reach that stage?", and "how do we want to do it?" The vision may address opportunities and challenges of the organisation. The vision should be achievable.

Some starting points are:

- An environment where high quality research translates into safe and effective practice in [health field]

- Access to clinical trials for all eligible patients
- Consistent use of best practice and research to extend evidence-based care in [disease/health area]
- An engaged medical and scientific community that participates in development, conduct, evaluation and promotion of clinical research in [disease area]
- A simplified process of clinical research
- A culture of multidisciplinary research in healthcare
- Embedding of high-quality research into routine care

The strategic plan document should include the CTN mission statement.

A *mission statement* is a concise explanation of the organisation's reason for existence and how it defines its success. A mission statement defines primary objectives related to customer needs and team values. It answers the questions "what do we do? what makes us different?". It should relate back to core values, customer needs and vision. The mission statement is timeless and therefore change should be kept to a minimum.

Some starting points are:

- To serve the community by providing high quality care that is informed by evidence-based research in [health field]
- To increase collaboration in clinical research or [disease]
- To provide opportunities in clinical research
- To provide education, training, and mentorship
- To engage with consumers
- To promote opportunities for translation research
- To publish and promote results of clinical trials to improve practices
- To raise funds for clinical trials

IDENTIFICATION OF VALUES

Identification of an organisation's values should include member representatives' opinions and ideally be undertaken during CTN formation. Values should identify the core beliefs that the organisation holds. Values are timeless and contextless and don't usually change unless the organisation changes its core business. The strategic plan should encompass these core values, but they should not be updated as frequently as the strategic plan.

Some examples of values that could be considered are:

- Collaboration, sharing, open communication, collegiate relationships
- Quality
- Innovation
- Creativity
- Respect, considerate of patients' needs, work in areas of agreed knowledge
- Integrity, trust, confidentiality, best practice
- Responsibility
- Accountability

- Curiosity
- Empathy
- Greatness
- Raising awareness
- Diversity
- Inclusive
- Considerate
- Equity
- Transparency

COMMON INCLUSIONS IN CLINICAL TRIAL NETWORK STRATEGIC PLANS

The main body of a strategic plan outlines main themes for the work of the organisation, along with specific objectives that the organisation aims to meet during the period covered by the plan.

The following list identifies some common themes in CTN strategic plans and objectives that could relate to the theme area. These are examples only, and should be adapted as appropriate, and other themes and objectives relevant to the CTN included. Some objectives could be classified under more than one theme.

Clinical Trial Portfolio

- Identify areas of need and actively seek trial concepts in this area
- Build evidence base to support improvements in health outcomes
- Deliver scientific outcomes through publication and presentations
- Identify and decrease barriers to trial setup
- Processes for prioritisation of research questions
- Specific focus areas – such as translation of results into practice
- Embedding of trial processes within delivery of routine healthcare

Consumers

- Develop and implement strategies for effective consumer involvement
- Establish or maintain consumer committee, and/or consumer representation on trial management committees
- Conduct training for consumers
- Development of resources to guide consumer participation
- Implement effective communication strategies

CTN Profile and Reputation

- Establish or adhere to publication guidelines outlining acknowledgement of CTN
- Develop and implement processes for endorsement of projects
- Effective internal and external communications
- Establish, maintain or re-develop website
- Increase awareness, participation and access to CTN clinical trials
- Establish CTN as global leader in disease area
- Establish communications strategy (newsletters, social media, directory)
- Marketing and branding of the CTN

Members

- Conduct meetings for membership
- Offer education and training awards and opportunities
- Support growth in membership
- Active expansion of membership in areas of expertise gap
- Introduce new membership categories e.g. life membership, honorary membership, associate membership
- Develop role and training opportunities for study coordinators
- Develop database for membership contacts

Governance and Operations

- Develop a quality framework, which includes monitoring, performance management, auditing and reporting
- Strategic planning and succession planning
- Establish or maintain committee Terms of Reference
- Support diversity in governance committees: gender, career stage, region, discipline
- Conduct Board and Advisory Committee meetings as per schedule
- Establish or maintain SOPs
- Develop database to manage clinical trial portfolio
- Staff professional development

- Maintain oversight of trial program

Collaboration

- Collaborate with international CTNs (Australian-initiated trials or internationally-initiated trials)
- Participate in clinical trials developed by similar international networks
- Identify projects that can be conducted in collaboration with other networks in Australia
- Increase collaboration with relevant national and international groups
- Continue relationship with major fundraising body in disease area
- Identify and decrease barriers to multidisciplinary research
- Joint grant applications

Sustainability

- Identify potential new funding sources from government, philanthropy and fundraising
- Business planning and management
- Develop a sustainable workforce (improve research capacity and capability across the CTN)
- Liaison with key funding bodies
- Succession planning

Translational Research

- Establish or maintain a biobank
- Include additional correlative studies in all clinical trial protocols
- Establish a Translational Research committee

RISK MANAGEMENT

For each objective in a strategic plan, risks that may prevent achievement of that objective should be identified, along with possible and relevant mitigations. As risk and mitigations may change more frequently than strategic plan objectives, they may be collated in a separate risk register to easily isolate updates to risks from updates to strategic plan themes or objectives.

ESTABLISHMENT OF AN ACTION PLAN

An action plan describes the way the organisation will meet its strategic objectives through detailed action steps that form the day-to-day tasks of the organisation. There are several reasons to develop an action plan within the 6 months following development of the strategic plan.

- To lend credibility to your organisation. An action plan shows members, the community and stakeholders that your organisation is well ordered and dedicated to achieving strategic objectives
- To adequately scope all strategic objectives
- To identify barriers to completing any strategic objectives with sufficient time to overcome them
- To maximise efficiency of resource and time
- To ensure accountability for the organisation
- To identify further activities associated with risk mitigation

Each activity will also require the identification of resources and support, responsible employee(s) and/or members who is/are to carry the activity through, a timeline, communication plans and an indication of how you will measure your success. An action plan should be a living document and viewed at least monthly to ensure alignment with the daily tasks of the organisation. An example is provided in APPENDIX 3.

REVIEW OF THE STRATEGIC PLAN

Strategic plan objectives should be reviewed within the lifetime of the strategic plan to ensure they are progressing according to timelines, remaining within appropriate scope, success measures remain relevant and that further risks have not emerged.

EVALUATION OF THE SUCCESS OF THE STRATEGIC PLAN

Key Result Areas

A key result area (KRA) is a strategic factor either internal or external to the organisation, where strong positive results must be realised for the organisation to achieve its strategic goal(s) for a given period of time, and therefore, move toward realising the organisation's longer-term vision of success. KRAs are sometimes referred to "critical success factors", "pillars", "strategic priorities", "key drivers of success" or "drivers". See APPENDIX 3 for examples. A mnemonic can be used, for example, ENGAGE, EXPAND, EMBED, NETWORKED, when developing KRAs (see APPENDIX 4).

Key Performance Indicators

The strategic plan should identify relevant measures of success for each objective. Metrics that help define whether the organisation is moving towards success in a particular objective are called Key Performance Indicators (KPIs) and should follow the SMART format – Specific, Measurable, Achievable, Realistic, Timebound. KPIs determine what the success will look like under each KRA in the given time frame.

COMMUNICATION OF THE STRATEGIC PLAN TO THE BROADER COMMUNITY

The strategic plan may be an aspect in CTN operations that requires communication to a wider stakeholder group e.g annual reports, websites, corporate presentations. Consider mnemonics or infographics for this purpose and consider using a professional graphic designer to format the document. An example is located here
http://pc4tg.com.au/resources/policies-and-reports/

MANAGEMENT OF THE STRATEGIC PLAN

Once the strategic plan is completed, it should be signed-off by the appropriate parties, usually the strategic plan 'director' and the Chair of the Executive, or the Board of the organisation.

Implement a version control system for the strategic plan. Revisions to the strategic plan should be versioned, reviewed and signed-off appropriately.

APPENDIX 1 FORMAT OF A STRATEGIC PLAN

Introduction

Description of your organisation and its purpose.

Vision

Mission

Values

Challenges and opportunities

What are the opportunities and challenges (e.g. from the SWOT analysis) that the clinical trial network currently faces and that may be addressed in the strategic plan?

About the strategic plan

Describe how the strategic plan was developed.

For example:

- Was a score card approach used or SWOT analysis undertaken?
- Who developed the plan and when?
- Which members or groups were consulted?
- Was this a revision of a previous version or a new plan?

Objectives and strategies (examples only)

Objective	Strategies
Grow pipeline of trials proposed for endorsement	Identify next generation trialists
	Provide education opportunities to next generation trialists
	Identify gaps in disease area research
	Prioritise areas for research
	Increase opportunities for brainstorming new ideas, peer review and mentoring new generation trialists
	Increase collaboration with relevant national and international groups
	Identify barriers to development of new clinical trial concepts and protocols
	Identify solutions to these barriers

APPENDIX 2 **TEMPLATE FOR SWOT ANALYSIS**

STRENGTHS List key strengths of your network and the aspects of your network you can rely on to deliver the essential requirements of your network	
WEAKNESSES List any aspects of your network that are either missing or not the way they should be at the moment	
OPPORTUNITIES List here any potential opportunities to grow and develop your network that you have not yet taken advantage of	
THREATS List here anything that might prevent the network from achieving its goals	

APPENDIX 3 SAMPLE TEMPLATE FOR AN ACTION PLAN

Strategy: Increase collaboration with relevant national and international groups

Action	Start date	End date	Resources	Responsible person	KPI	KRA	Risk	Mitigation
Identify areas where collaboration would be of benefit			Executive Committee	Network Chair	Six areas identified by end date	Participate in or conduct three international clinical trials	Networks identified for collaboration are not interested	Identify further collaborators
Identify key personnel in networks (international and national) for initiation of collaboration			Trial manager	CEO	Email addresses obtained for key contact in each of 6 collaboration areas			Conduct studies as pilot and once feasible, reconnect with collaborators for interest
Prepare 1 page document of key messages, activities, track record from network and attractiveness of network region for clinical trial conduct. Distribute to potential collaborators			CEO	CEO, Network Chair	1 page document approved by SAC and disseminated by end date			
Meet with network representative			Executive Committee	Network Chair	Establish CTN representative, possible dates and format of first meeting Conduct meetings			
Invite potential collaborators to attend ASM			Network Chair	CEO	Budget for invited speakers assembled and approved Invitations sent 3 months in advance of ASM			
Develop 3 clinical trial protocols for potential collaboration (led by collaborator or network)			Trial managers	CEO	Protocols approved by SAC by end date			
Develop and execute MOU for international collaboration			Business manager	CEO	Develop MOU for collaboration			

including allocation of responsibilities					MOU signed by end date		
Identify funding streams for trials run internationally			Executive Committee	Business manager	Lodge funding applications for each trial		

APPENDIX 4 EXAMPLE OF STRATEGIC PLAN OBJECTIVES USING A MNEMONIC

Example of KRAs using mnemonic ENGAGE

Excellence in clinical trial design and delivery

National and international network of collaborators

Growth and sustainability of clinical trials network

A well supported workforce in wellbeing, education, training and professional support

Geographic, sector and diversity of members

Evidence based research translated into safe and effective practice.

Example of key result objective under each KRA

Excellence in clinical trial design and delivery

- *To design three new clinical trials in (health field)*
- *To start three new pilot or feasibility studies*
- *To publish results of all clinical trials in peer-reviewed journals*

National and international network of collaborators

- *To establish Australian sites in internationally-initiated clinical trials.*
- *To run one or more Australian–initiated clinical trials overseas*

Establish CTN as global leader in health area

Growth and sustainability of clinical trials network

- *To get six new sites started in clinical trials*
- *To increase the EFT of research coordinators across the network*
- *To develop six new site investigators and associate investigators*
- *To identify new funding sources for sites (direct hospital funding for employment of research coordinators)*

A well supported workforce in wellbeing, education, training and professional support

- *To implement a mentorship program*
- *To develop training opportunities for site investigators and research coordinators*
- *To run regional networking sessions / events*

Geographic, sector and diversity of members

- *To get one new site in a rural / regional hospital started in clinical trials*
- *To get one new private hospital started in clinical trials*
- *To actively encourage and engage two new female site investigators*

Evidence based research translated into safe and effective practice.

- *To measure translation of research?*