# Australian Clinical Trials Alliance

# Business review of Clinical Trial Networks

# Final report

## May 2021

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# LIST OF ABBREVIATIONS

| Acronym | Definition |
|---------|------------|
| ACTA | Australian Clinical Trials Alliance |
| CC | Coordinating Centres |
| CQR | Clinical Quality Registries |
| CRF | Case Report Form |
| CTN | Clinical Trial Network |
| DGR | Deductible Gift Recipient |
| FTE | Full Time Equivalent |
| FY | Financial Year |
| FYE | Financial Year Ended |
| SOP | Standard Operating Procedures |
| TMD | Trial Management Database |

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# ACKNOWLEDGEMENTS

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# EXECUTIVE SUMMARY

## CONTEXT

This project forms part of a broader program of activities being undertaken by ACTA through a Medical Research Futures Fund (MRFF) grant to 'Strengthen the capacity, efficiency and effectiveness of Clinical Trial Networks'. Consistent with the focus of the MRFF grant, the current project is explicitly focused on enabling CTNs to operate in an efficient and effective manner.

## OBJECTIVES

The scope of the project involved a business review of six CTNs and the following specific objectives:

- **Efficiency and sustainability** – what are the opportunities for improved efficiency/sustainability including through and increased scale or capacity?
- **Collaboration** – what are the opportunities for shared services to increase scale or capacity?
- **Development and growth** – what is the potential impact and associated costs if a CTN had greater scale or capacity?
- **Performance and innovation** – what are CTNs doing well and what learnings could be applied to the greater network?

## SELECTION OF CTNs

Expressions of interest were sought from CTNs by ACTA. This yielded the following group of CTNs for the review:

- **CTN1 –** Established and coordinating
- **CTN2 –** Established and facilitating/coordinating
- **CTN3 –** Established and facilitating/coordinating
- **CTN4 –** Emerging and facilitating
- **CTN5 –** Emerging and facilitating
- **CTN6 –** Established and facilitating.

Additionally, these CTNs covered a diverse range of disease areas/network types including cancer, surgery, emergency, paediatrics, and infectious diseases. In agreement with each CTN, and given that detailed and potentially sensitive, financial information has been provided as part of this review, specific identities of the CTNs that participated in this review have been anonymised.

## COSTING SURVEY

Financial and activity information was collected from six CTNs and included:

- Revenue sources
- Direct costs by type
- Revenue and costs for CTN infrastructure/overheads
- Workforce/volunteerism by role and FTE or hours
- Resource use by CTN activities.

## CONSULTATIONS

Consultations were held with each CTN to discuss barriers and enablers to efficiency and effectiveness as well as future opportunities and challenges. Key themes that emerged were:

- **Constraints of limited resourcing** – All CTNs identified securing funding as a high priority and as a major challenge. Even established CTNs held concerns about sustaining ongoing funding sources to secure key roles and positions in their network. Many different approaches to securing funding have been adopted by CTNs with some applying a more commercial bent, others investing seed funding with the aim of building a base for growth and leveraging fund-raising capabilities.
  - > **Implication:** The limited resource base of some CTNs is a key barrier to organisational development and sustainability.

- **Importance of a clearly defined strategic focus** – Notwithstanding the different contexts, each CTN espoused the importance of having a clear strategic direction articulated in a strategic plan. What was clear is that for CTNs with a more tenuous resource base, the priority given to strategic planning was understandably overshadowed by the difficulties associated with a barely adequate or inadequate resource base.
  - > **Implication:** There is broad consensus on the importance for all CTNs to define their strategic purpose with a clear strategic plan, supported by a business operating plan.

- **Workforce optimisation** – There were three main workforce themes identified: the criticality of a program manager role; development of a recruitment and retention strategy; and striking the right balance between volunteer staff time and funded staff time.
  - > **Implication:** Workforce optimisation is critical to all CTNs, and volunteers are highly relevant but should not substitute for core organisational workforce roles, the most critical of which is an Executive Officer position.

- **Efficiency and sustainability** – Scale appears to play a significant role in determining the types of efficiencies being sought by the CTNs. Emerging CTNs operate with very small budgets and their priority revolved around a more efficient use of a limited resource base. Larger established CTNs were seeking to realise greater value and organisational effectiveness and operational improvement initiatives including: redesigning team structures for enhanced productivity; business improvement processes including systems for performance reporting and financial monitoring; exploring innovations such as registry trials; and use of emerging online collaborative technologies.
  - > **Implication:** There is greater scope for mainstream efficiency improvement opportunities initiatives as CTNs transition to a larger scale including 'lean' redesign principles, performance measurement and management systems and collaborative technologies.

- **Strategic contracting and vendor management** – CTN operating above a threshold scale can gain a step-change increase in network effectiveness and efficiency. More established CTNs sought value for money through negotiations with existing vendors or through a competitive tender process.
  - > **Implication:** Enhanced efficiency and effectiveness may be gained through more strategic contracting and vendor management, with opportunities currently only realised within CTNs not between CTNs.

- **Partnerships and collaboration** – The nature of collaboration has taken on many different forms across the CTNs including: international partnerships to increase knowledge-sharing and scope of trials and funding streams; partnering with other CTNs to share resources and staff in the form of secondments; shared use of infrastructure.
  - > **Implication:** There is limited evidence of partnerships and collaboration between CTNs to achieve advantages of scale economies.

# STRATEGIC OPPORTUNITIES

Based on an assessment of the financial context of the CTNs and the feedback from the consultations, this review identified ten strategic response opportunities to improve efficiency and effectiveness across the following five domains:

1. Resource optimisation
2. Strategic focus
3. Workforce optimisation
4. Efficiency and sustainability
5. Collaboration.

Whilst many of the findings were consistent across the sampled CTNs, some of the challenges and opportunities varied with the scale and the CTN's stage of development. In other words, context matters when considering the applicability of these strategies. It should also be recognised that the six CTNs selected for this review are effectively case studies – the findings are not necessarily representative of all CTNs in operation. Nonetheless, the findings are suggestive and many are also aligned with previous findings of ACTA review that have explored critical success factors for CTN development.[1]

Table 1 summarises the main issues/challenges, identified strategic responses and key enablers relating to the each of the development themes.

**Table 1:** Key issues, strategic responses and enablers

| THEME | KEY ISSUE OR CHALLENGE | STRATEGIC RESPONSE | ENABLERS |
|---|---|---|---|
| **Resource optimisation** | ■ Narrow revenue base<br>■ Cessation of previous funding grants. | 1. Diversify revenue streams:<br>  > Develop fundraising capacity<br>  > Membership fees. | ■ Case studies of resource diversification<br>■ Deductible Gift Recipient Status. |
| **Strategic focus** | ■ Lack of clear development pathway. | 2. Develop and implement strategic plan<br>3. Develop and implement operational plan. | ■ Strategic plan and operating plan template<br>■ Balanced scorecard and KPIs for strategic plan and operational plan. |
| **Workforce optimisation** | ■ High reliance on volunteers<br>■ Lack of resourced Executive Officer roles<br>■ Teams lack role clarity. | 4. Establish workforce structure aligned with development stage<br>5. Review role clarity of team structures<br>6. Building flex capacity through secondments. | ■ Position description templates for all senior roles<br>■ Workforce recruitment and retention strategy<br>■ Partnership agreements for cross-CTN secondments. |
| **Efficiency and sustainability** | ■ Business processes lack rigour<br>■ Lack of value for money in contracted services. | 7. Implement performance management systems<br>8. Implement competitive processes for vendor management. | ■ Standardised business processes and templates. aligned to strategic objectives<br>■ Tender specifications and contract performance management systems. |
| **Collaboration** | ■ Inefficient and unreliable systems<br>■ Cost to develop systems may be prohibitive for individual CTNs. | 9. Identify opportunities for shared services with other CTNs<br>10. Adaptation of successful CTN development pathways. | ■ Trial of shared IT platform/ database development between CTNs<br>■ Case studies of CTN business improvement strategies. |

## RESOURCE OPTIMISATION

All emerging CTNs face the challenge of how to secure ongoing funding to enable the organisation to grow and develop. Acknowledging that this is perhaps the most difficult aspect of CTN development, emerging CTNs in this situation may need to look to diversify their revenue streams by leveraging partnerships to assist with:

- Fundraising opportunities, and/or
- Development of their membership base.

**Strategic response 1:** Diversify revenue streams through developing fundraising capacity with a fundraising plan, and membership fees.

**Key enablers include:** Case studies of resource diversification; and Deductible Gift Recipient Status.

**Suggested practical example:**

- Continue to develop more case studies of successful CTNs and how they have diversified their revenue streams.

## STRATEGIC FOCUS

A starting point in the development of emerging CTNs is to develop a strategic plan and a governance structure to provide a basis on which to plan the CTN's future roadmap. This allows a CTN to clearly articulate its mission and develop an operational plan to achieve its strategic purpose.

**Strategic response 2:** Encourage the development and implementation of strategic plans by CTNs.

**Strategic response 3:** Encourage the development and implementation of operational plans by CTNs.

**Key enablers include:** Strategic plan and operating plan templates; balanced scorecard and KPIs for strategic plan and operational plan.

**Suggested practical examples:**

- Provide examples and templates of strategic plans and operating plans, and
- Provide sample balanced scorecard and KPI reports for CTNs to adopt.

## WORKFORCE OPTIMISATION

Workforce optimisation takes on a different form depending on a CTN's stage of development. For emerging CTNs, a couple of threshold development steps are:

- The appointment of an Executive Officer to act as the driving force behind the strategic plan and leads the implementation of operational planning goals
- To develop an organisational workforce structure and develop position descriptions as the organisation develops. This would assist with maintaining operational efficiency.

For larger CTNs the focus shifts more to team effectiveness with key factors being:

- The established flex capacity through secondment agreements between CTNs.

**Strategic response 4:** Establish workforce structure aligned with development stage.

**Strategic response 5:** Review role clarity of team structures.

**Strategic response 6:** Building flex capacity through secondments.

**Key enablers include:** Position description templates for all senior roles; workforce recruitment and retention strategy, and partnership agreements for cross-CTN secondments.

**Suggested practical examples:**

- Share position description templates for common CTN roles to minimise HR time requirements
- Assist with enabling cross CTN secondments through 'internal' advertising across partner CTNs.

## EFFICIENCY AND SUSTAINABILITY

Efficiency and sustainability initiatives become a more compelling proposition for CTNs as scale increases. The CTNs in the sample have implemented a number of efficiency and sustainability initiatives including:

- Activity tracking software to ensure time is used effectively and to support appropriate budget determination for funding grants
- Monthly performance reporting to enable responsive management
- Establishing a business case template and process which is tied to the strategic plan to ensure asset utilisation is optimised.

**Strategic response 7:** Encourage the implementation of performance management systems.

**Strategic response 8:** Encourage the implementation of competitive processes for vendor management.

**Enablers:** Encourage the adoption of standardised business processes and templates aligned to strategic objectives; tender specifications and contract performance management systems.

**Suggested practical examples:**

- Set up vendor agreements for shared insurance, IT contracts, and HR by leveraging buying power of multiple CTNs to ensure a competitive price can be achieved for even smaller CTNs.

## COLLABORATION

Understanding the challenges for CTNs that are in a competitive environment, it became evident that some CTN's limited strategic outlook and outward orientation would likely become a limiting factor in their future sustainability. This underscores the need to develop strong partnerships. Benefits from open collaboration can be achieved in a few ways:

- Learning the lessons from other successful pathways, and
- Leveraging economies of scale and purchasing power to develop and upgrade infrastructure.

Partnership enhancement is another important factor. The partnerships and alliances which are built need to be more than superficial and more than transactional. In this, ACTA plays a central enabling role in the sector, building bridges between CTNs and facilitating opportunities for CTNs to strengthen their partnerships through conferences, training programs and facilitation.

**Strategic response 9:** Identify opportunities for shared services with other CTNs.

**Strategic response 10:** Facilitate adaptation of successful CTN development pathways.

**Enablers:** Facilitate the trialling of shared IT platform/database development between CTNs; and case studies of CTN business improvement strategies.

**Suggested practical example:**

- Share resources and back of house functions such as business software, website development and promotion.

## IMPLEMENTATION

Some of the strategies identified will have a relatively straightforward implementation process, whereas others may have a longer-term horizon, but will also bring greater benefit. Figure 4 (on page 34) shows the anticipated relative complexity versus expected benefits for each of the strategic responses.

# BACKGROUND AND OBJECTIVE

## BACKGROUND

### Australian Clinical Trials Alliance

The Australian Clinical Trials Alliance (ACTA) is the national peak body for supporting and representing the networks of clinician researchers that conduct investigator-initiated or 'public-good' clinical trials within the Australian health system.

ACTA's Vision is for better health through best evidence. Specifically, ACTA's Mission is: 'To promote effective and cost-effective healthcare in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decisions made by health practitioners, policy-makers and consumers.'

ACTA's membership includes more than 70 CTNs, Coordinating Centres (CCs) and Clinical Quality Registries (CQRs).

### Clinical Trial Networks

A CTN is a collaborative group of practising clinicians and clinical researchers that come together to identify important clinical questions and design large multi-centre clinical trials to answer them. Networks all vary slightly in the way they are structured and how they operate but in general, they can be categorised into two groups: Facilitating Networks and Coordinating Networks. The core functions of each are provided in Table 2.

**Table 2:** Core functions of clinical trial networks[2]

| CLINICAL TRIAL FACILITATION | CLINICAL TRIAL COORDINATION |
|---|---|
| Identification of important clinical questions | Direct trial coordination and management* |
| Collaborative study protocol development | Site management* |
| Peer review and formal endorsement of trials | Data management* |
| Scientific meetings | Recruitment of trial participants* |
| Grant writing* | Monitoring* |
| Education/training/mentoring of researchers* | Statistical analysis* |
| Advocacy and industry/consumer liaison | Regulatory affairs* |
| Site selection and trial oversight* | May or may not act as study sponsor |
| Clinical guideline development | |

* Activities that are often undertaken in partnership with clinical trial coordinating centres.

It is widely considered that one of the key benefits of a CTN is that they facilitate more rapid translation of trial results into practice because they have the engagement or buy-in of a large and broadly distributed group of practising clinicians, those that participate in the trial being more likely to translate the results of the trial into practice.

## CONTEXT

### How ACTA supports CTNs to become more efficient and effective

ACTA received funding from the Medical Research Future Fund (MRFF) to undertake a three-year project to 'Strengthen the capacity, efficiency and effectiveness of Clinical Trial Networks'. The Project commenced in June 2017 and is currently in its final year. To achieve the objectives of the project, ACTA identified key priorities and established eight key program areas. Each program area is supported by ACTA staff and is overseen by an Expert Reference Group comprising of multidisciplinary, cross-sector representatives drawn from ACTA members and sector leaders.

The program of work supporting the key priority of Efficient and Effective CTNs is incorporated into Program Area A, which aims to enable CTNs to operate in an effective and efficient manner. The specific objectives of Program Area A are to:

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

## OBJECTIVE

The scope of the project involved a business review of six CTNs. The objectives of the business review were as follows:

- **Efficiency and sustainability** – what are the opportunities for improved efficiency/sustainability including through and increased scale or capacity?
- **Collaboration** – what are the opportunities for shared services to increase scale or capacity?
- **Development and growth** – what is the potential impact and associated costs if a CTN had greater scale or capacity?
- **Performance and innovation** – what are CTNs doing well and what learnings could be applied to the greater network?

# APPROACH

This section describes the approach undertaken for the review.

## SELECTION OF CLINICAL TRIAL NETWORKS

A number of selection criteria were developed to ensure that a representative cross-section of CTNs was represented in the review. Ideally, the selection criteria would have:

- A selection of six CTNs
- Of the six, four established and two emerging
- Of the four established, two of both facilitating networks and coordinating networks
- Of the two emerging CTNs one of both facilitating networks and coordinating networks
- A diverse coverage of disease areas.

In this context, 'established' refers to a CTN that has been in operation before 2017 and 'emerging' refers to a CTN that has been established in or after 2017.

Expressions of interest were sought from CTNs by ACTA. This yielded the following group of CTNs for the review:

- **CTN1 –** Established and coordinating
- **CTN2 –** Established and facilitating/coordinating
- **CTN3 –** Established and facilitating/coordinating
- **CTN4 –** Emerging and facilitating
- **CTN5 –** Emerging and facilitating
- **CTN6 –** Established and facilitating.

Additionally, these CTNs covered a diverse range of disease areas/network types including cancer, surgery, emergency, paediatrics, and infectious diseases as well as population sub-groups. In agreement with each CTN, and given that detailed and potentially sensitive, financial information has been provided as part of this review, specific identities of the CTNs that participated in this review have been anonymised.

## DEVELOPMENT OF COSTING SURVEY

Financial and activity information was collected from six CTNs and included:

- Revenue sources
- Direct costs by type
- Revenue and costs for CTN infrastructure/overheads
- Workforce/volunteerism by role and FTE or hours
- Resource use by CTN activities.

Some of the CTNs opted to provide financial information in place of completing the survey. These financial statements were then converted into a standard format to allow for comparability of results.

CTNs were unable to readily report resource use by CTN activity type and so this line of inquiry could not be pursued through the survey and instead was informed by qualitative information gained from interviews with CTNs.

## DEVELOPMENT OF DISCUSSION GUIDE

A discussion guide was developed to frame the consultations with the CTNs and covered the following broad questions:

1. Are there any opportunities currently being undertaken in relation to efficiency and effectiveness improvement?
2. Describe barriers your CTN has faced? Do those barriers persist or have they been overcome?
3. Has your CTN recently implemented any strategies to increase efficiency and effectiveness?
   > What were these strategies and were they effective?
   > Are there (additional) strategies planned in the near term?
4. Has your CTN reviewed its infrastructure support costs?
5. Is the current distribution of resourcing of your CTN's activities giving the most efficient allocation?
   > How have you been able to engage volunteers?
6. What are the opportunities for efficiencies with infrastructure support and/or shared services?
7. What challenges can you foresee in the future? Have any strategies been put in place to address these challenges?
8. What are the main changes to activities that you consider would deliver the greatest gain in efficiency and effectiveness?
9. What collaboration opportunities are there with other CTNs to jointly improve efficiency and effectiveness, particularly in relation to infrastructure support?

The CTN representatives who Aspex consulted with were Chief Executive Officers, Heads of Finance, Chiefs of Critical Care, and Research Coordinators.

# CLINICAL TRIAL NETWORK SUMMARIES

## CLINICAL TRIAL NETWORK 1

This CTN defines itself as:

- Established
- Coordinating.

### Context

This CTN is one of the more long-standing networks and has been in existence for over 40 years. It is the only network in the sample with recognised fundraising revenue, which represents 42% of its total revenue. The high proportion of fundraising is partly a function of the maturity of this network which achieved a scale and profile that enable dedicated staffing resources to be allocated to this function. Additionally, 34% of its overheads are for advertising and promotion expenses, a further indication of the organisation's resource commitment to fundraising.

This CTN also has the lowest percentage (35%) of salaries and wages compared to total costs. However, 56% of the direct costs also fund salaries and wages at other organisations to conduct clinical trials.

The results below (Table 3) are exclusive of investment activities and only show operating performance.

**Table 3:** Financial results year ended 31 March 2020 (from annual report)

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $6,867,000 |
| Fundraising | $5,056,000 |
| **Total revenue** | **$11,933,000** |
| S&W | $4,197,000 |
| Direct expenses | $4,096,000 |
| Overheads | $3,671,000 |
| **Total costs** | **$11,964,000** |
| **Profit/(Deficit)** | **($41,000)** |

### Consultation summary

**Efficiency and sustainability**

One of the main efficiency challenges identified by this CTN was the time-consuming processes involved in clinical trial research governance: that is, the processes involved in preparing ethics applications and clinical trial governance requirements. These challenges were particularly compounded by multi-site and cross-border trials.

Notwithstanding the challenge of clinical trial research governance, this CTN identified two main areas in which efficiency and sustainability improvements had been realised:

- Increased adoption of new technology
- Asset optimisation.

*Technology*

The impact of COVID has accelerated the pace of adoption of beneficial technologies including remote monitoring of trials and remote access to medical records using eConsenting and signatures where sites are no longer requiring hard copies of contracts. Further technology which this CTN is looking to leverage includes cloud-based solutions for their accounting system and a Trial Management Database (TMD).

*Asset optimisation*

Previously, one of the major challenges for this CTN was its location on two sites. They have since consolidated onto a single site. This has achieved greater collaboration and efficiencies in the business. The new site (a single floor of a building) was purchased outright and has eliminated the need to pay rent. The decision to purchase was justified through a business case which identified the cost-effectiveness of this option. Additionally, having IT on-site has been identified as a clear benefit to the CTN allowing for greater flexibility and responsiveness. This is one of the benefits of scale implemented by the CTN.

**Development and growth**

Opportunities for development and growth which have been identified by this CTN were:

- IT systems
- Staff recruitment and retention.

*IT systems*

This CTN has developed its IT systems over several years and it now has a fit-for-purpose and sophisticated IT platform that supports its core database and systems. The CTN opted to develop on-site IT systems and capability rather than rely on an entirely outsourced provider. This has delivered key benefits in terms of meeting organisational requirements, flexibility and agility. An example of the latter is the recent implementation of electronic Case Report Forms (eCRFs).

*Staff recruitment and retention*

Given the cost of labour is the highest cost category in the Network, being able to attract staff with adequate pay is vital to the success of the CTN. This CTN has sought to ensure attractive and competitive remuneration arrangements through salary packaging and offering income protection and death and disability insurance.

**Performance and innovation**

A key focus for this CTN has been ensuring financial sustainability of its operations and investment decisions. To this end, the CTN has developed comprehensive business case processes to inform all major financial decisions.

To support this focus, the CTN developed a business case template with input from the CTN's Board. The template identifies the key evidence and information requirements relevant to the approval of any business case. This has not only provided a basis for a leaner organisational finance strategy, but each business case has been required to align with the CTN's strategic plan. This ensures that resources are not only allocated efficiently but are focused on strategic medium to longer-term objectives.

**Collaboration**

This CTN has identified a range of benefits from partnering with a number of different organisations:

- Executive Officers Network, which has banded together in a number of cases to push for common goals
- Australian and New Zealand Academy of Periodontists (ANZAP) have shared costs for a joint trial
- International support – partnering with various international groups for trials.

## CLINICAL TRIAL NETWORK 2

This clinical trial network defines itself as:

- Established
- Facilitating and coordinating.

This CTN's method of operating is that they prefer to undertake a coordinating role if they are sponsoring the trial.

### Context

The cost survey (Table 4) showed that this CTN produced a small surplus in the 2019 calendar year with 61% of the total costs funding salaries for 13.8 FTE staff. This CTN also reported one of the highest levels of volunteerism at 5.6 FTE recorded.

**Table 4:** Financial results 2019 calendar year

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $2,463,616 |
| Fundraising | — |
| **Total revenue** | **$2,463,616** |
| S&W | $1,494,234 |
| Direct expenses | $649,516 |
| Overheads | $303,902 |
| **Total costs** | **$2,447,652** |
| **Profit/(Deficit)** | **$15,965** |

### Consultation summary

**Efficiency and sustainability**

This CTN identified four efficiency and sustainability challenges:

- Clinical trial resourcing
- External stakeholder communication
- Contractors and vendor management
- Workforce recruitment and retention.

*Clinical trial resourcing*

A major financial risk for CTNs is the potential for under-quoting for clinical trials. This CTN identified this as a key challenge. It cited the example of a clinical trial that was originally funded for an anticipated three-year period, but subsequently required follow-up for six to ten years. This trial extension is ultimately unfunded.

Scope creep is a further key risk that CTNs confront in clinical trial resourcing. This occurs when the scope of activities that are planned at the outset of a trial are broadened during the actual implementation of the trial, with the un-planned additional activities contributing additional, un-funded, resource commitments.

One of the options this CTN has identified to improve the estimation of resource requirements for clinical trials involves the use of activity and time tracking software. This is designed for ongoing monitoring of trial performance and is intended to identify areas where processes may be inefficient. This software, which is currently being rolled-out, will enable the CTN to better manage resource inputs and will ultimately provide a more accurate basis for the estimation of resource requirements for undertaking future clinical trials.

*External stakeholder communication*

The challenge here relates to communication with stakeholders external to the CTN. The core of this issue is that the CTN's processes are not well understood by external stakeholders. In turn, this leads to delays and subsequently greater costs. The CTN has activities currently underway to address this issue which continues to persist.

*Contractor and vendor management*

Trial efficiency can be adversely affected by high contractor costs associated with specialised industry inputs. A significant portion of funding is allocated to these expenses, which can include:

- Drug logistics – transport and labelling
- Database management
- Other specialist software
- Statistical analysis costs.

This CTN identified that it had achieved a substantial efficiency improvement through a review of its outsourced HR services. This review yielded a 50% saving in the contract costs and also significantly increased the value the CTN was achieving from these services.

*Workforce recruitment and retention*

The CTN also identified staff succession planning as a key issue and had experienced difficulties in finding suitable replacements. The CTN has high levels of maternity leave that are required to be covered. The CTN considered that options for more flexibility in recruitment could include secondments and/or sharing of staffing resources between CTNs. This could not only cover short-term workforce gaps, but also provide professional and career development opportunities for staff.

**Development and growth**

A key challenge identified by the CTN for its future development is the increasing level of competition in the sector. This has not only led to a reduced success rate for competitive funding but also generated intense competition for donations and fundraising.

Two opportunities for development and growth have been identified:

1. Trial management database
2. Alternative models for clinical trials.

*Trial management database*

The CTN is in the process of designing a trial management database. Existing databases in the market were identified as not fit for purpose. It is intended that the new database will replace a reliance on Excel spreadsheets to manage data on clinical trial management.

*Alternative models*

Alternative models for clinical trials, such as registry trials, are being explored. These are considered more cost effective as they use existing registries rather than having to develop them for each new trial, thereby significantly reducing administrative costs.[3] This is seen as an opportunity to increase the capacity of the CTN while also decreasing the costs to run trials.

**Collaboration**

Collaborative opportunities identified by the CTN include:

- IT synergies
- Policies, templates and financial management tools.

*IT synergies*

The main benefits to collaboration identified by this CTN are the potential to generate IT synergies. There could be economies of scale if multiple CTNs were using the same third-party provider for specified services. An example considered was the appointment of preferred suppliers for clinical trial database design and the development or use of similar platforms for website build and hosting.

*Policies, templates and financial management tools*

Further opportunities identified to develop shared approaches between CTNs included:

- Legal templates for trials involving international collaboration
- Standard Operating Procedures (SOPs) and policies such as the recently developed Vendor Management Policy and Trials Chairs Responsibilities Guidance Document
- Tools to assist with financial management such as quoting templates, project tracking or income tracking.

**Performance and innovation**

Examples of performance and innovation included:

- Team structure
- Operational reporting
- Fee model.

*Team structure*

The effectiveness of the CTN was improved following a change to its team structure. To improve role clarity, the CTN was divided into two distinct teams: development activities; and trial operations activities. This provides the teams with greater focus and the ability to dedicate staff to specific primary roles.

*Operational reporting*

Implementation of monthly reporting allowed the CTN to react much sooner to internal developments and to readily highlight areas of under-performance. This was done in conjunction with monthly income tracking to monitor compliance with annual targets. Combined, this change in reporting allowed for improved transparency and greater accountability across the organisation.

*Fee structure*

The CTN has introduced a two-tier membership model consisting of a free membership and a paid membership. This model allows for the recruitment of members at no cost for an initial period. Members transition to fee-paying once the benefits of membership become evident.

# CLINICAL TRIAL NETWORK 3

This clinical trial network defines itself as:

- Established
- Facilitating and coordinating.

## Context

This CTN operates within the context of a broader medical research institute and is operated as a Special Purpose Fund (SPF). The CTN was initially funded on a grant basis and has secured a second five-year grant.

The CTN has three funded staff roles including 0.8 EFT for a network coordinator, 0.6 for a research coordinator and a further 0.4 EFT for a research translation role. Operating within another organisation means that there are limited overhead costs – these are primarily the costs to operate and maintain a website.

**Table 5:** Financial results 2019/20

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $249,919 |
| Fundraising | — |
| **Total revenue** | **$249,919** |
| S&W | $143,989 |
| Direct expenses | $95,100 |
| Overheads | $10,830 |
| **Total costs** | **$249,919** |
| **Profit/(Deficit)** | — |

## Consultation summary

### Efficiency and sustainability

The challenges and opportunities to efficiency and sustainability identified by this CTN include:

- Funding continuity
- Development of shared IT
- Transient patients.

### Funding continuity

Sourcing an ongoing revenue stream to support this CTN has been the most challenging aspect. It is run primarily on members' good-will and free time.

### Shared database

Development of a shared database between CTNs may have the potential to improve efficiency. However, this CTN does not currently have any specific plans to advance this concept.

### Transient patients

The CTN's emergency specialty focus means that most of their patients are transient. Accordingly, it is more challenging from a research follow-up perspective to engage and sustain these patients' participation in clinical trials.

**Development and growth**

Development and growth opportunities to increase scale or capacity include:

- Appointment of a network coordinator
- Some minor revenue opportunities.

*Network coordinator*

Since appointing a network coordinator this CTN has identified a number of benefits: volunteer time has increased, and the network has the capacity to develop policy and guidelines.

*Revenue*

Some smaller revenue opportunities have been considered including charging member fees, which has to this point been ruled out due to the limited number of members. The other revenue opportunity involves allocation of a portion of a trial's budget to cover a component of CTN costs where it is appropriate and feasible to do so.

**Collaboration**

Many partnerships have been developed and considered by this CTN which are primarily with hospitals, research institutes and CTNs which had a similar field of study such as ICU and Anaesthetics. However, they have also considered the potential to work with other networks outside their field of study.

**Performance and innovation**

They key performance and innovation learning that is implemented successfully by this CTN is its ability to leverage the network's track record and branding. This was established by a requirement "to have our name on the research" if they are endorsing the trial. The CTN's members are required to be on the steering committee of a sponsored trial. This forms a positive loop – more brand awareness brings more trials for endorsement.

# CLINICAL TRIAL NETWORK 4

This CTN defines itself as:

- Established
- Facilitating.

## Context

This CTN functions within a broader, parent organisation and was created in 2006 for a specific group of trials. With the cessation of these trials, a lack of ongoing funding means that most of their work is now being done in-kind. Currently, there are six endorsed trials. As such, the CTN has a limited revenue stream and only has a limited expenditure capacity.

Much of the work done by the CTN is in-kind by the members of the parent organisation. There is only a minimal spend on salaries and wages to facilitate face-to-face meetings for all members. While there are no overheads specifically allocated to this function by the parent organisation, the parent organisation itself would incur overheads to provide this function.

**Table 6:** Financial results 2019/20

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $4,000 |
| Fundraising | — |
| **Total revenue** | **$4,000** |
| S&W | $2,900 |
| Direct expenses | $1,100 |
| Overheads | — |
| **Total costs** | **$4,000** |
| **Profit/(Deficit)** | **—** |

## Consultation summary

### Efficiency and sustainability

The CTN has implemented a new system of endorsing trials rather than supporting. The aim of endorsement is to provide credibility to the trial and in turn to enable the trial to raise its own funding.

### Development and growth

Challenges faced by this CTN in terms of development and growth include:

- Lack of funding
- Unsure on how to progress as a CTN
- Lack of promotion of the network.

The common thread to the challenges faced by this CTN are primarily related to the lack of direct funding. After the end of the initial "five big trials" there has been a lack of direct staff working for the CTN. While there is a desire to continue to grow and develop as a CTN, there is no articulated strategic direction to identify their future development pathway.

Communication and promotion was identified as very important, and the parent organisation has created a new media role in January 2021 with the aim that part of that role will include promotion of the CTN.

Some opportunities for development and growth have been identified:

- Engaging younger and more regional researchers
- Shift to Deductible Gift Recipient (DGR) status.

The CTN is seeking to approach younger researchers and regional researchers with a view that this is where there is further potential to engage the medical community and grow. Recently the CTN has been recognised as a Deductible Gift Recipient (DGR) to support fundraising. The expectation is that the fundraising could be used to fund administration staff to help drive the organisation or at least provide ongoing support.

**Collaboration**

The partnership which has been beneficial to the CTN is its relationship with ACTA. The CTN is seeking to coordinate their face-to-face meetings with the ACTA conference to be able to leverage international guest speakers. Furthermore, attending training sessions has also proven beneficial.

**Performance and innovation**

The current primary challenge for this CTN is the fragility of its funding stream and the uncertainty of its strategic direction. This has overshadowed issues relating to CTN performance.

## CLINICAL TRIAL NETWORK 5

This CTN defines itself as:

- Emerging
- Facilitating.

### Context

This organisation is primarily supported by a specialist college. In 2020, its staff comprised 0.2 EFT for a director role and 0.2 EFT for an administrative officer. This CTN also reported the highest level of volunteerism of 9.6 EFT in the 2020 calendar year compared to other CTNs in this review.

**Table 7:** Financial results 2020 (calendar year budget)

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $112,003 |
| Fundraising | — |
| **Total revenue** | **$112,003** |
| S&W | $97,003 |
| Direct expenses | $15,000 |
| Overheads | — |
| **Total costs** | **$112,003** |
| **Profit/(Deficit)** | **—** |

### Consultation summary

#### Efficiency and sustainability

The challenges and opportunities for efficiency and sustainability identified by this CTN included:

- Funding source
- Workforce mix.

*Funding source*

The main challenge faced by this CTN is being able to establish an ongoing funding source. Several other challenges were also identified but all stemmed from not having sufficient funds: 'You need to do something "big" before you get funding, but you need funding to do something "big"'.

*Workforce mix*

Attracting the right people was identified by the CTN as a key priority. It would be optimal to engage a clinical trials coordinator/nurse role within the CTN. It was also identified that certain expertise is missing from the organisation and that more people with expertise in ethics submissions would increase efficiency.

#### Development and growth

Development and growth opportunities to increase scale or capacity include:

- Coordination of more face-to-face meetings
- Generation of new studies and trials.

One of the enablers of development and growth has been the co-ordination of face-to-face meetings to support greater collaboration through building the network. If additional funding could be secured this would be one of the strategies which would be further deployed.

A further development and growth opportunity is the commencement of new trials with MRFF funding having been granted for a wound dressing trial. This trial had failed to recruit sufficient trial participants internationally but in Australia this trial has over-recruited. Additionally, the COVID pandemic has enabled some newer studies to be developed and the CTN has the belief that a lot more traction is coming within the next 12–18 months and that they are on the cusp of generating some local trials.

**Collaboration**

This CTN has found further benefits from partnering with different organisations:

- International collaboration such as participating in UK trials
- ACTA is useful in providing a set of resources, and the conference is invaluable
- Partnerships with other CTNs which have a similar focus such as the Anaesthetic Group and ICU Group. However, it must be for the 'right project, and with groups with a similar track record'.

Other partnerships are formed with organisations who are the lead, and their infrastructure is leveraged to conduct the trials.

**Performance and innovation**

This CTN's focus on performance and innovation learnings is built around adoption of an established pathway and seeking to seed-fund trials. It has adopted the learnings and the growth pathway from a UK model. The UK model has grown in scale to the extent that it now has four designated sites with statistics and logistics undertaken in-house and some generic infrastructure to support trials.

This pathway relies on investment in the research capabilities of surgical trainees. Often there is limited research scope – for example, the scope of research is often limited to conducting retrospective reviews of clinical notes. With some seed funding, the students would be able to engage in more meaningful studies, increasing the prospect for expanded scope of research, the development of opportunities to undertake clinical trials and in turn expand CTN membership. In turn, the CTN's visibility and exposure would be enhanced, potentially generating improved opportunities for ongoing funding streams.

# CLINICAL TRIAL NETWORK 6

This clinical trial network defines itself as:
- Emerging
- Facilitating
- Regional.

## Context

This CTN was previously run as a project but has recently secured two funding grants. One is from the MRFF to support the expansion of existing services and another $2.3m over a three-year period has been secured from the Department of Health and Human Services (DHHS) to develop organisational sustainability. Currently, revenue is primarily used to fund 0.7 EFT of a Program Manager with site fees, travel,marketing and IT expenses being the other major cost items incurred.

Currently, this CTN supports six clinical research sites with plans to expand to seven sites across regional Victoria.

**Table 8:** Financial results – average revenue and expense per annum since funding commencement (30 April 2017)

| ACCOUNT GROUP | AMOUNT |
|---|---|
| Revenue | $210,667 |
| Fundraising | — |
| **Total revenue** | **$210,667** |
| S&W | $155,032 |
| Direct expenses | — |
| Overheads | $55,635 |
| **Total costs** | **$210,667** |
| **Profit/(Deficit)** | **—** |

## Consultation summary

### Efficiency and sustainability

The challenges and opportunities for efficiency and sustainability identified by this CTN include:
- Strategic direction
- Regional context.

*Strategic direction*

Even though this CTN has secured some ongoing funding it is unclear on how to proceed to develop its operational capability. Despite having a board of governance, there are currently no executive roles within the organisation. As a result, the CTN lacks an organisational capacity to undertake some of the routine business and planning activities. By establishing an executive role within the organisation, this would strengthen the organisation's capability: it would assist to 'drive' the organisation, enabling the creation and implementation of a strategic plan. Progress has been made on this front and the CTN is now seeking to formalise the Network and has had some planning discussions on sustainability and the development of a strategic plan.

*Regional context*

Another key challenge faced by this CTN is that most trials have a 'city-centric' focus. This CTN is located in a regional context and there is a sense that it is difficult to raise awareness for regionally located trials.

**Development and growth**

A number of development and growth opportunities have been identified by this CTN:

■ Online collaborative technology
■ Increase in the number of sites.

*Online collaborative technology*

COVID has increased acceptance of the use of on-line collaborative technology such as Zoom and Microsoft Teams conferencing. This has several benefits including decreased travel time between sites and for training. There is also increased acceptance of tele-trials.

*Increased number of sites*

The increased number of sites the CTN has access to has enabled the CTN to have greater visibility and engagement. The CTN has built greater capability and capacity at smaller sites.

Other future strategies that are also being considered are:

■ Increasing promotion activities
■ Establishing a more appropriate operating structure
■ Increasing volunteerism levels
■ Increased EFT to establish capability in the fundraising function as they have now become a DGR.

**Collaboration**

This CTN identified a number of collaborative opportunities beneficial to continued success:

■ Victorian Comprehensive Cancer Centre (VCCC) in using its infrastructure and the site itself as a place to conduct trials
■ ACTA for conferences, network building and training opportunities.

Building close partnerships helps to avoid duplication of processes in that each organisation becomes familiar with the other's processes. Support will be provided by linking and facilitating education and training opportunities to the VCCC and the University of Melbourne.

**Performance and innovation**

Several performance and innovation initiatives through operational efficiencies have been developed to support sites:

■ Assistance with capability and capacity building through site process mapping enabling consistent processes across sites and reducing the administrative burden
■ Streamlining operational documents by building on already developed suite of Standard Operating Procedures (SOPs) and Work Practice Guidelines (WPGs) for sites
■ Tele-trial establishment assistance
■ To assist sites with National Clinical Trials Governance Framework compliance when initiated.

# THEMATIC SUMMARY

This chapter presents a thematic summary from the review of six CTNs.

## RESOURCE CONTEXT

The resource context was perhaps the most prominent theme. All CTNs commented on securing funding as a high priority and this was consistently identified as a major challenge. Even established CTNs held concerns about sustaining ongoing funding sources to secure key roles and positions in their network.

The resource context often defined the opportunities available to the CTN. Some commented that the competitive landscape had become even more difficult with increased competition for not only grants and trial funding but also charitable donations.

CTNs have been applying different approaches to securing funding. Some CTNs have applied a more commercial model to their membership fee; some have applied seed funding of some trials now as investment for future growth; and others have attained DGR status to assist with fundraising.

**Implication:** The limited resource base of some CTNs is a key barrier to organisational development and sustainability.

## STRATEGIC FOCUS

The importance of strategic focus was underlined during the consultations with the sample of CTNs positioned at various stages of organisational planning and development. Some had clearly defined strategic objectives and well-developed business models, and routinely used business case methodologies to assess and implement value-adding initiatives. Some emerging CTNs were clearly on a transition path. One had recently been successful with a large funding grant and was now seeking to develop a strategic plan to enable organisational growth and development. Other CTNs had no strategic plan and their development pathway was unclear.

Notwithstanding the different contexts, each CTN espoused the importance of having a clear strategic direction, articulated in a strategic plan. What became clear is that for CTNs with a more tenuous resource base, the priority given to strategic planning was understandably overshadowed by the difficulties associated with a barely adequate or inadequate resource base.

**Implication:** There is broad consensus on the importance for all CTNs to define their strategic purpose with a clear strategic plan, supported by a business operating plan.

## WORKFORCE

Optimising workforce and HR issues was a prominent theme across the CTNs, particularly in relation to:
- Key staff roles
- Recruitment and retention
- Volunteerism.

Many CTNs had either appointed a program manager or were actively seeking to recruit a program manager role. The benefits that were hoped to be achieved by those hiring was being realised by those who had already implemented the role. This role is seen as fundamental to enacting the role of the CTNs and as a conduit between the board and operations.

A well-conceived and executed recruitment and retention strategy is pivotal to successful CTN development and growth in addition to the program manager role. Key considerations included: increasing the attractiveness of the remuneration package; managing a part-time workforce with high rates of parental leave; and use of alternative sourcing strategies including secondments to flex up their staffing complement when there were sufficient trials underway.

The importance of volunteerism was underlined by all CTNs. As shown in Figure 1, the levels of volunteerism form a significant portion of the workforce with much of the work being done in-kind as well. Whilst access to volunteers is a useful basis for managing a constrained salary and wage budget, it is not a substitute for an effective organisational workforce.

**Implication:** Workforce optimisation is critical to all CTNs and volunteers are highly relevant but should not substitute for core organisational workforce roles, the most critical of which is an Executive Officer position.
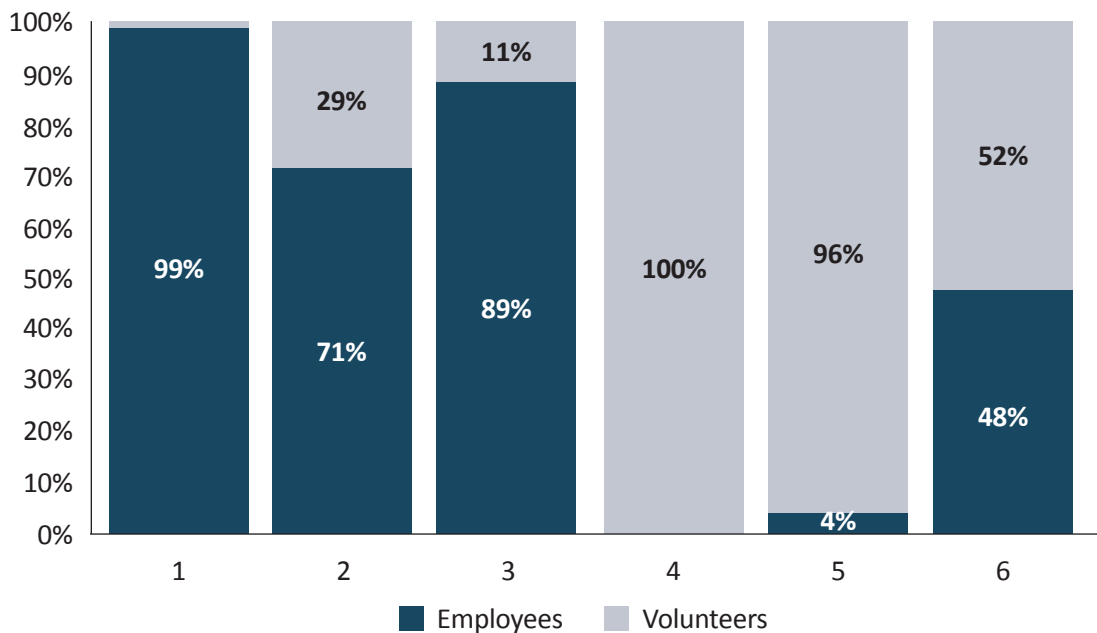
**Figure 1:** Levels of volunteerism by CTN

## EFFICIENCY AND SUSTAINABILITY

Scale appears to play a significant role in determining the types of efficiencies being sought by the CTNs. Emerging CTNs operate with very small budgets and their priority revolved around a more efficient use of a limited resource base. Larger established CTNs were seeking to realise greater value and organisational effectiveness – their strategies included workforce optimisation; more efficient operational delivery models; and productivity improvements through technology.

Operational efficiencies being explored or undertaken by CTNs included:

- A change in team structures to ensure staff were being used to their full capacity
- Using established business processes rather than re-inventing a process
- Performance reporting and financial monitoring
- Exploring different avenues for clinical trials such as registry trials
- Taking advantage of emerging online collaborative technologies.

**Implication:** There is greater scope for mainstream efficiency improvement opportunity initiatives as CTNs transition to a larger scale including 'lean' redesign principles, performance measurement and management systems, and collaborative technologies.

## CONTRACTING AND VENDOR MANAGEMENT

Once a CTN has achieved sufficient scale there is a step-change increase in the opportunities to expand network effectiveness and efficiency. The relationship between scale and IT expenditure is an example as shown in Figure 2.
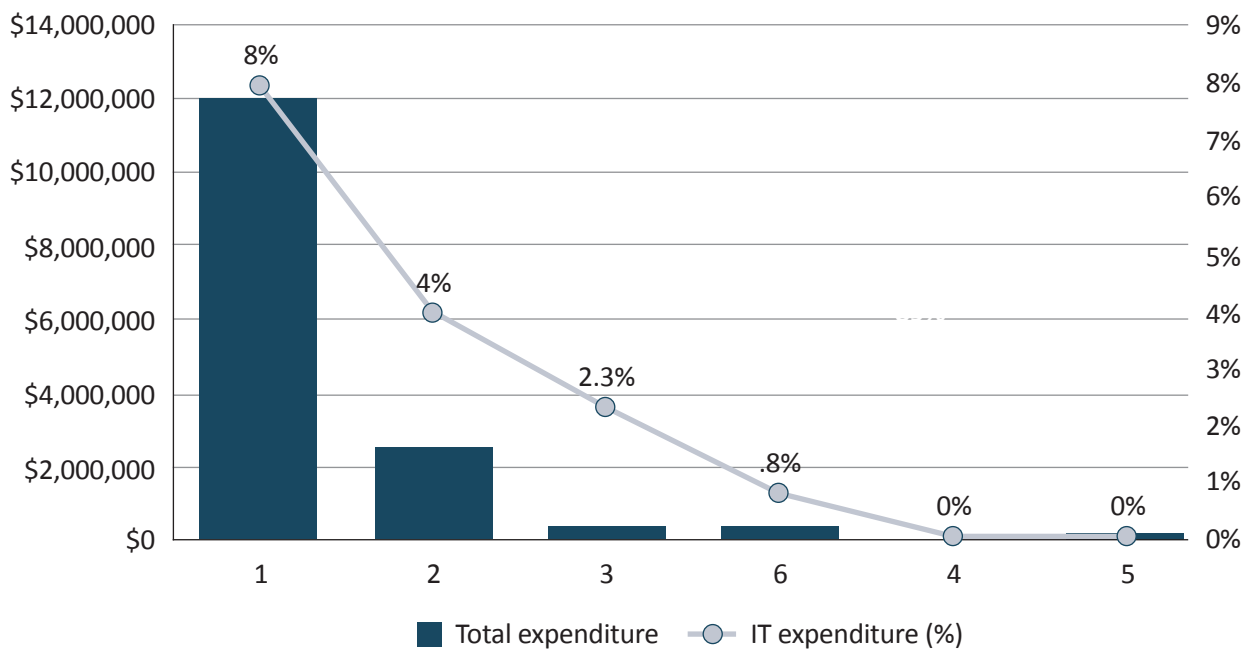
**Figure 2:** Total expenditure vs IT expenditure as a percentage of total expenditure

Two of the established CTNs were focused on achieving value for money out of their third-party contractors. This was achieved either through negotiations with existing vendors to ensure value was generated or through a competitive tender process. Both had already considered the possibility of using the collective buying power of the CTNs to achieve value for money. The areas that were focused on in particular were:

■ IT and database management
■ HR
■ Statistics
■ Logistics.

**Implications:** Enhanced efficiency and effectiveness may be gained through more strategic contracting and vendor management, with opportunities currently only realised within CTNs **not between** CTNs.

## PARTNERSHIPS AND COLLABORATION

Partnerships were a common point of discussion with the nature of collaboration taking many different forms including:

■ International partnerships to increase knowledge-sharing, increase the scope of trials, and to also provide access to international funding streams
■ Partnering with other CTNs to share resources and staff in the form of secondments
■ Encouraging students to engage in more meaningful studies with the view to increase the potential number of trials in the future
■ ACTA was identified in many cases as a key partner through the support provided through education and conferences
■ Pharmaceutical companies in some cases were utilised to provide additional funding streams and the supply of pharmaceuticals
■ Trial sites such as hospitals were partners for use of infrastructure in conducting trials.

**Implications:** There is limited evidence of partnerships and collaboration between CTNs to achieve advantages of scale economies.

# STRATEGIC RESPONSE OPPORTUNITIES

This chapter outlines the recommended strategic response opportunities identified to improve efficiency and effectiveness across the following domains:

- Resource optimisation
- Strategic focus
- Workforce optimisation
- Efficiency and sustainability
- Collaboration.

Whilst many of the findings were consistent across the sampled CTNs, some of the challenges and opportunities varied with scale and the CTN's stage of development from emerging to established. Figure 3 shows which factors were deemed to be important at each stage of development for a CTN.
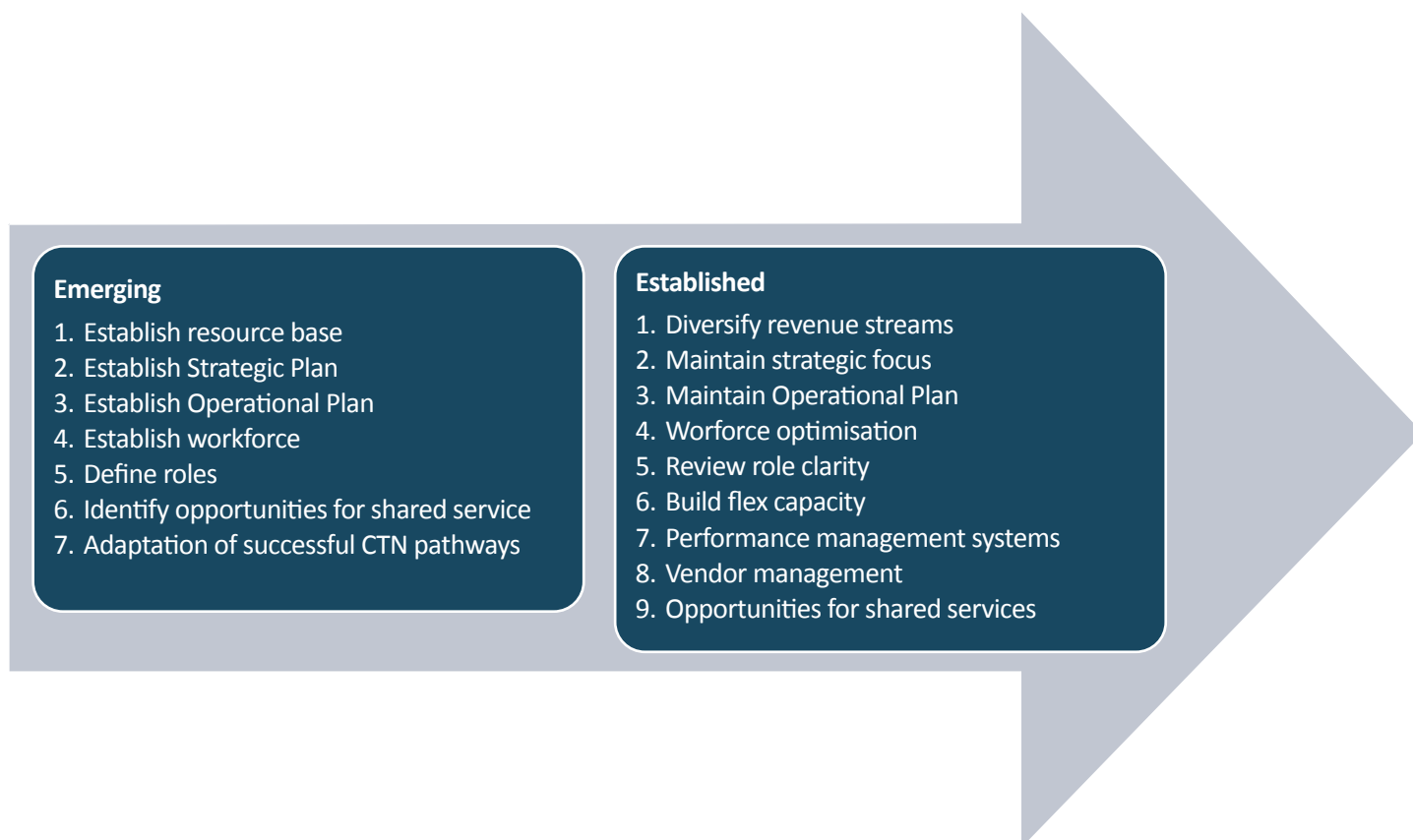
**Emerging**

1. Establish resource base
2. Establish Strategic Plan
3. Establish Operational Plan
4. Establish workforce
5. Define roles
6. Identify opportunities for shared service
7. Adaptation of successful CTN pathways

**Established**

1. Diversify revenue streams
2. Maintain strategic focus
3. Maintain Operational Plan
4. Worforce optimisation
5. Review role clarity
6. Build flex capacity
7. Performance management systems
8. Vendor management
9. Opportunities for shared services

**Figure 3:** CTN development progression

Table 9 summarises the main issues/challenges, identified strategic responses and key enablers relating to each of the development themes.

**Table 9:** Key issues, strategic responses and enablers

| THEME | KEY ISSUE OR CHALLENGE | STRATEGIC RESPONSE | ENABLERS |
|---|---|---|---|
| **Resource optimisation** | ■ Narrow revenue base<br>■ Cessation of previous funding grants. | 1. Diversify revenue streams:<br>　> Develop fundraising capacity<br>　> Membership fees. | ■ Case studies of resource diversification<br>■ Deductible Gift Recipient Status. |
| **Strategic focus** | ■ Lack of clear development pathway. | 2. Develop and implement strategic plan<br>3. Develop and implement operational plan. | ■ Strategic plan and operating plan template<br>■ Balanced scorecard and KPIs for strategic plan and operational plan. |
| **Workforce optimisation** | ■ High reliance on volunteers<br>■ Lack of resourced Executive Officer roles<br>■ Teams lack role clarity. | 4. Establish workforce structure aligned with development stage<br>5. Review role clarity of team structures<br>6. Building flex capacity through secondments. | ■ Position description templates for all senior roles<br>■ Workforce recruitment and retention strategy<br>■ Partnership agreements for cross-CTN secondments. |
| **Efficiency and sustainability** | ■ Business processes lack rigour<br>■ Lack of value for money in contracted services. | 7. Implement performance management systems<br>8. Implement competitive processes for vendor management. | ■ Standardised business processes and templates. aligned to strategic objectives<br>■ Tender specifications and contract performance management systems. |
| **Collaboration** | ■ Inefficient and unreliable systems<br>■ Cost to develop systems may be prohibitive for individual CTNs. | 9. Identify opportunities for shared services with other CTNs<br>10. Adaptation of successful CTN development pathways. | ■ Trial of shared IT platform/ database development between CTNs<br>■ Case studies of CTN business improvement strategies. |

## RESOURCE OPTIMISATION

All emerging CTNs face the challenge of how to secure ongoing funding to enable the organisation to grow and develop. Often the challenge is intensified as there is little in the way of a strategic plan making the way forward difficult to see. Acknowledging that this is perhaps the most difficult aspect of CTN development, emerging CTNs in this situation may need to look to diversifing their revenue streams by leveraging partnerships to assist with fundraising opportunities and development of their membership base.

Established CTNs have typically reached an advanced stage of organisational governance, workforce development and systems implementation. Their developmental maturity enables many of the benefits of growth and development to be realised. The challenge for these organisations is framed in terms of efficiency and effectiveness. Established CTNs are typified by:

- Greater security of ongoing funding
- A clearly defined organisational strategy
- Established organisational processes
- Established key roles and functions.

**Strategic response 1:** Diversify revenue streams through developing fundraising capacity with a fundraising plan and membership fees.

**Key enablers include:** Case studies of resource diversification and Deductible Gift Recipient status.

**Practical suggestions:**

- Continue to develop more case studies of successful CTNs and how they diversified their revenue streams.

### Strategic focus

A starting point in the development of emerging CTNs is to develop a strategic plan and a governance structure to provide a basis on which to plan the CTN's future roadmap. This allows a CTN to clearly articulate its mission and develop an operational plan to achieve its strategic purpose.

**Strategic response 2:** Encourage the development and implementation of strategic plans by CTNs.

**Strategic response 3:** Encourage the development and implementation of operational plans by CTNs.

**Key enablers include:** Strategic plan and operating plan templates, balanced scorecard and KPIs for strategic plan and operational plan.

**Practical suggestions:**

- Provide examples and templates of strategic plans and operating plans.
- Provide sample balanced scorecard and KPI reports for CTNs to adopt.

## Workforce optimisation

For emerging CTNs, a threshold development step is the appointment of an Executive Officer. This executive acts as the driving force behind the strategic plan and leads the implementation of operational planning goals. Many CTNs identified these as key roles for their success. There could be potential to build on the training provided by ACTA to provide CTN management training. It is also prudent to develop an organisational workforce structure and develop position descriptions as the organisation develops. This would assist with maintaining operational efficiency.

While team effectiveness is important across all stages, the larger an organisation, the greater the importance of effective team structures, role clarity and good communication channels within the organisation. Given fluctuations in CTN workforce requirements, the opportunity to build flex capacity through secondment agreements between CTNs is an efficient way to manage this workforce and to cover leave arrangements.

**Strategic response 4:** Establish workforce structure aligned with development stage.

**Strategic response 5:** Review role clarity of team structures.

**Strategic response 6:** Building flex capacity through secondments.

**Key enablers include:** Position description templates for all senior roles, workforce recruitment and retention strategy and partnership agreements for cross-CTN secondments.

**Practical suggestions:**
- Provide examples and templates of strategic plans and operating plans
- Provide sample balanced scorecard and KPI reports for CTNs to adopt.

## Efficiency and sustainability

With increased scale, the case for investment in performance management systems to support CTN operations becomes more compelling. The CTNs in the sample have implemented a number of performance management systems including activity tracking software to ensure time is used effectively and to support appropriate budget determination for funding grants, together with monthly performance reporting to enable responsive management.

A key to the continued success of these CTNs is to ensure that the assets are optimised and that there are processes to verify optimisation. One of the CTNs in this sample has established a business case template and process which is tied to the strategic plan. This enables the CTN to evaluate all investments and expenditure to ensure alignment with organisational goals and achievement of value for money.

**Strategic response 7:** Encourage the implementation of performance management systems.

**Strategic response 8:** Encourage the implementation of competitive processes for vendor management.

**Enablers:** Encourage the adoption of standardised business processes and templates aligned to strategic objectives; tender specifications and contract performance management systems.

**Practical suggestions:**
- Provide examples and templates of strategic plans and operating plans
- Provide sample balanced scorecard and KPI reports for CTNs to adopt.

## Collaboration

Whilst not understating the challenges for CTNs that are operating in a competitive environment, it became evident from this review that the strategic outlook and outward orientation of some CTNs was likely to be a limiting factor in their future sustainability. This underscores the need to develop strong partnerships. It entails learning the lessons from other successful pathways, including lessons from international groups. An opportunity exists to document the various CTN growth pathways which have proven successful so that learnings from successes can be adopted.

Developing and upgrading internal systems such as IT, database management and HR is a key step to achieving efficiencies in operations. An opportunity exists to develop partnerships with CTNs and IT providers to develop a standard database where new CTNs, or existing CTNs with limited databases, could upgrade their database, or provide a common starting point that the emerging CTNs can leverage. Using a single, or set of referred IT providers, would reduce this cost across the Networks and mitigate the risks.

Partnership enhancement is another important factor. The partnerships and alliances which are built need to be more than superficial and more than transactional.

*"Active collaboration takes place when companies develop mechanisms – structures, processes and skills – for bridging organisation and interpersonal differences and achieving real value from the partnership. Multiple ties at multiple levels ensure communication, coordination and control. Deploying MORE, rather than fewer people to relationship activities helps ensure that both partners resources are tapped and that both companies own need and goals are represented."*[4]

ACTA plays a central enabling role in the sector, building bridges between CTNs and facilitating opportunities for CTNs to strengthen their partnerships through conferences, training programs and facilitation.

**Strategic response 9:** Identify opportunities for shared services with other CTNs.

**Strategic response 10:** Facilitate adaptation of successful CTN development pathways.

**Enablers:** Facilitate the trialling of shared IT platform/database development between CTNs; case studies of CTN business improvement strategies.

**Practical suggestion:**

■ Sharing of resources and back of house functions such as business software, website development and promotion.

## IMPLEMENTATION

Some of the strategies identified will have a relatively straightforward implementation process, whereas others may have a longer-term horizon, but will also bring greater benefit. Figure 4 shows the relative complexity versus expected benefits for each of the strategic responses. It should also be reiterated that the expected benefits would be different for each CTN dependent on their stage of development.
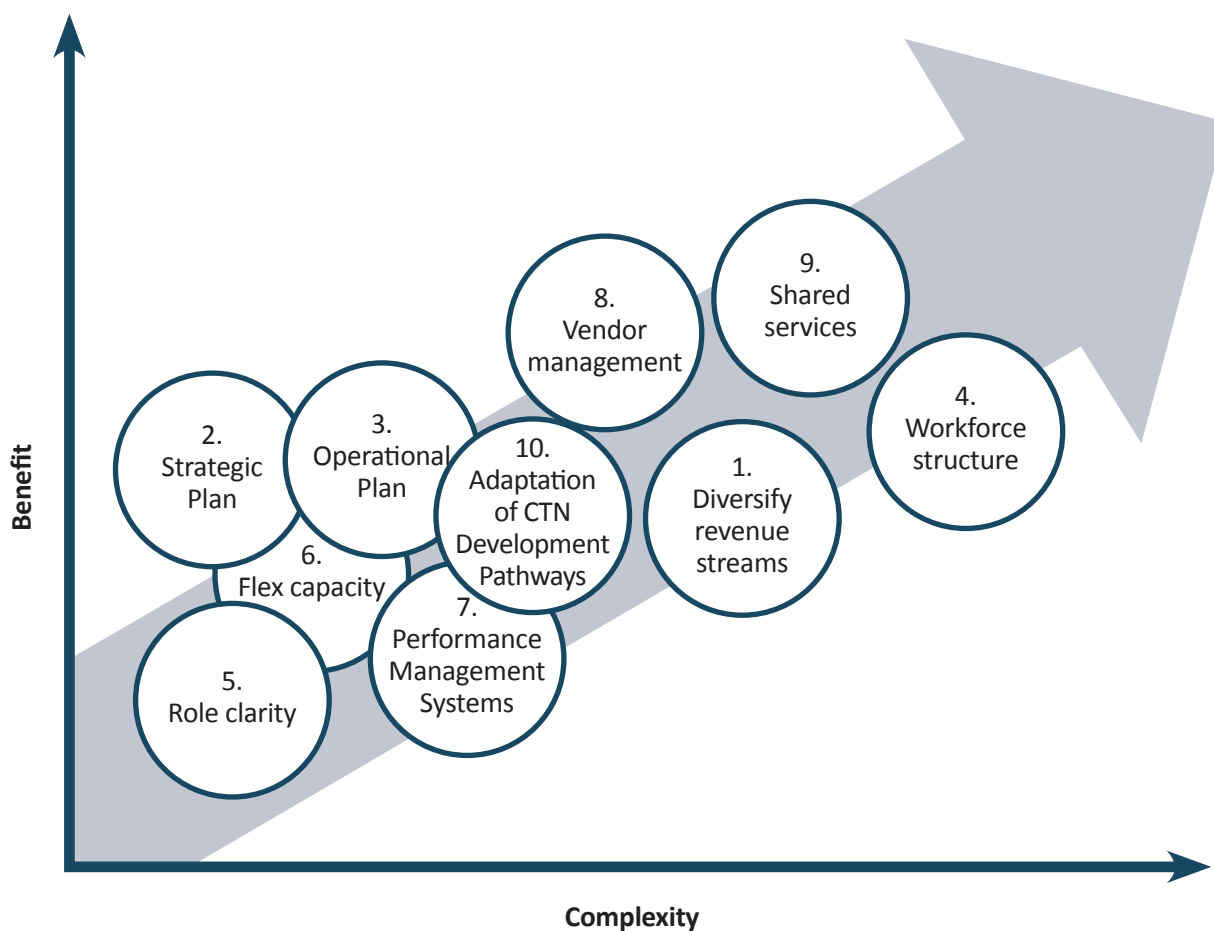


**Figure 4:** Implementation benefits versus complexity

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# APPENDICES – FINANCIAL REVIEW

A basic financial review was undertaken to provide context for each of the CTNs. It was intended to provide a more detailed comparative analysis between the CTNs, however, only limited comparisons were able to be done due to:

- Differences in granularity of data
- Differences in scale and scope of the organisations.

## A.1 FINANCIAL RESULTS

Table A1 shows a comparative summary of each of the CTNs. It should be noted that not all the time periods are the same, some relate to the 2019/20 financial year, some relate to the 2019 calendar year, and some use the financial year ending March 2020. Despite this, each result is still comparable as they represent a full 12 months of operation.

**Table A1:** Financial results summary

| ACCOUNT GROUP | CTN 1 | CTN 2 | CTN 3 | CTN 4 | CTN 5 | CTN 6 |
|---|---|---|---|---|---|---|
| Revenue | $6,867,000 | $2,463,616 | $249,919 | $4,000 | $112,003 | $210,667 |
| Fundraising | $5,056,000 | — | — | — | — | — |
| **Total revenue** | **$11,923,000** | **$2,463,616** | **$249,919** | **$4,000** | **$112,003** | **$210,667** |
| S&W | $4,197,000 | $1,494,234 | $143,989 | $2,900 | $97,003 | $155,032 |
| Direct expenses | $4,096,000 | $649,516 | $95,100 | $1,100 | $15,000 | — |
| Overheads | $3,671,000 | $303,902 | $10,830 | — | — | $55,635 |
| **Total costs** | **$11,964,000** | **$2,447,652** | **$249,919** | **$4,000** | **$112,003** | **$210,667** |
| **Profit/(Deficit)** | **($41,000)** | **$15,965** | — | — | — | — |

## A.2 COST BREAKDOWN

Figure A2 shows the cost breakdown as a percentage of total costs. This seems to indicate that as CTNs get larger that salaries and wages become a smaller portion. However, there appears to be very little consistency in overheads. This is most likely due to the various structures (function of an organisation, standalone entity or somewhere in between).
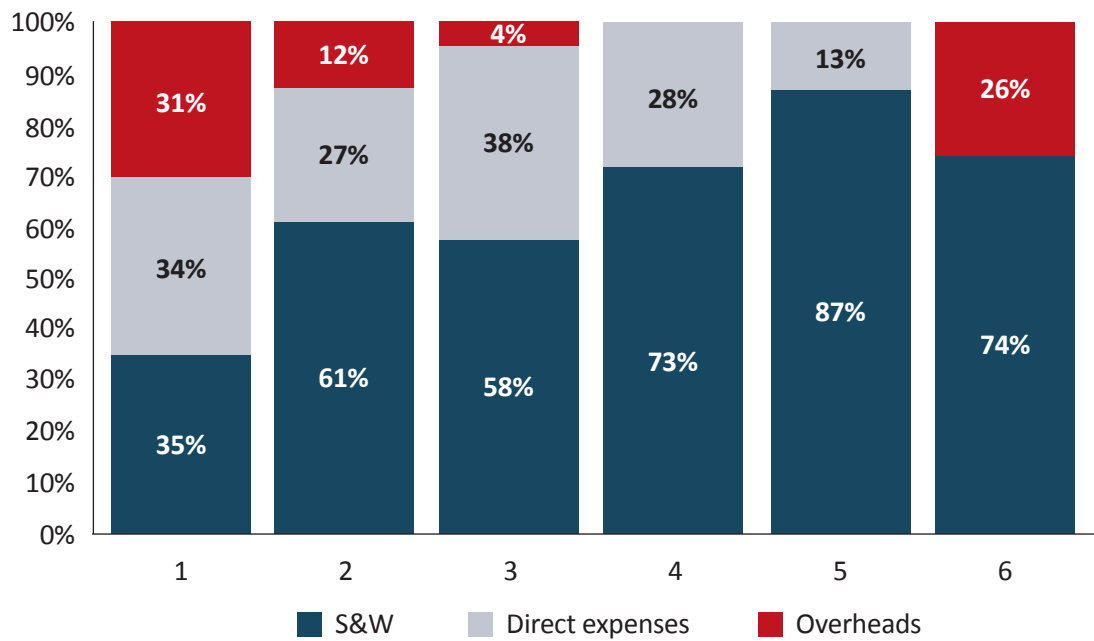


**Figure A2:** Cost breakdown (% of total cost)

## A.3 IT EXPENDITURE

The data from the sampled CTNs confirms the expected increase in focus on IT expenditure as a CTN grows, with CTN 1 spending a total of 8% of their total costs on IT related expenditure.
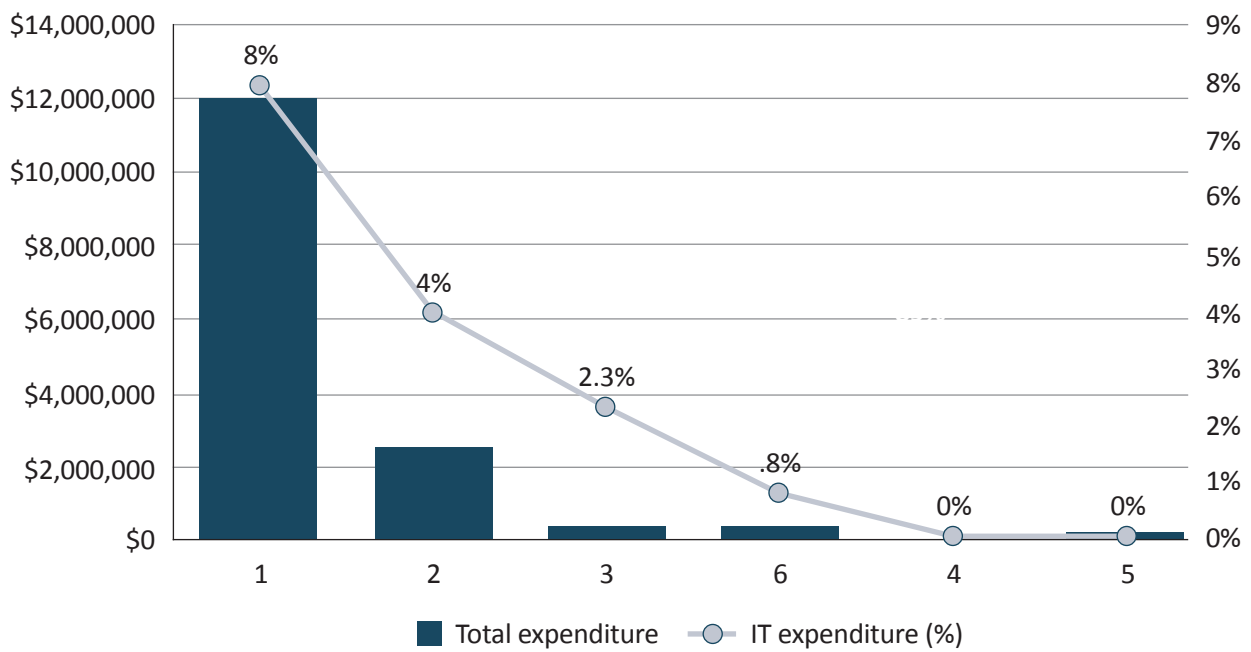


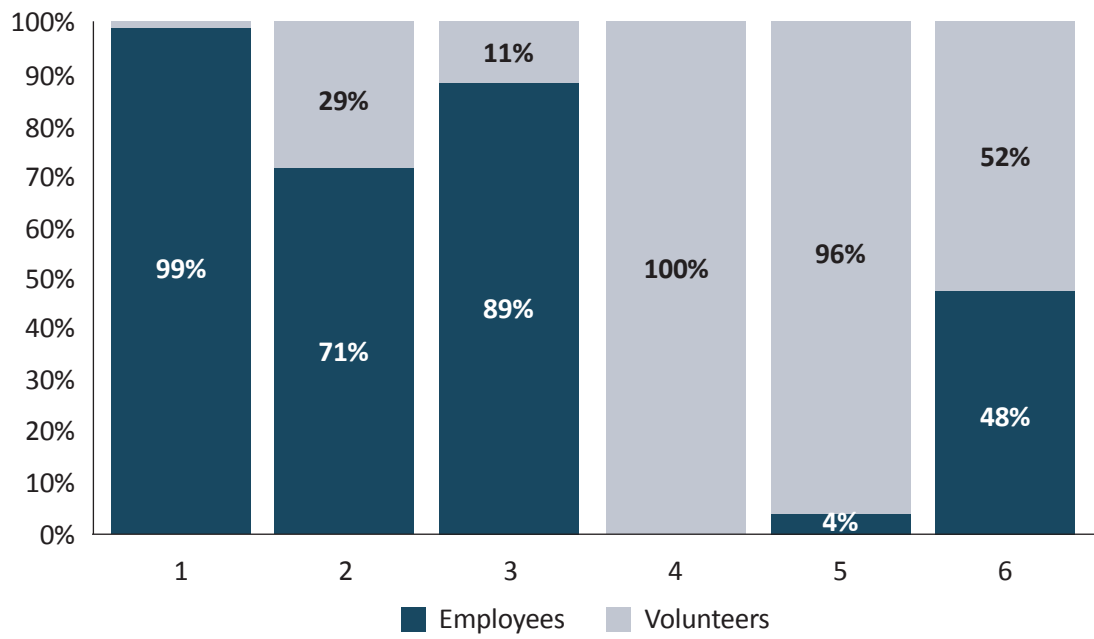**Figure A3:** IT expenditure by CTN (% total costs)

## A.4 VOLUNTEERISM



**Figure A4:** Volunteerism vs employees (%)

# Australian
# Clinical
# Trials
# Alliance

**www.clinicaltrialsalliance.org.au**