AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

The National Clinical Trials Governance Framework Pilot

Final Report for distribution

October 2021

Australian Government
Department of Health

Published by the Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: Has been requested

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework Pilot: Final Report. Sydney: ACSQHC; 2021.

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your health care provider for information or advice on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Contents

Using this report

This report provides the executive summary, key findings, pilot methodology and supporting data in the following sections:

Section 1: Background, pilot methodology, pilot aim and objectives, pilot population and pilot timeline

Section 2: Data collection, inputs activities and outputs

Section 3: Pilot outcomes

Section 4: Discussion and pilot limitations

Section 5: Case studies

Appendix 1: Level 2 pilot site mentoring participants by their role in the health service organisation

Appendix 2: Cost estimate data items.

Separate Addenda to this report include:

Addendum 1: Written submissions (15) tabulated by theme and the Commission's response.

Addendum 2: Examples of evidence provided to accreditation assessors mapped against the suggested evidence for each action in the National Clinical Trials Governance Framework and tabulated by the health service organisation self-assessment rating and, the pilot accreditation assessment outcome.

Addendum 3: Survey responses and general feedback on the National Clinical Trials Governance Framework and the supporting tools and resources and survey responses by each action in the Clinical Trials Governance Framework. For each question, responses to Likert Scale questions are tabulated by health service organisation participation level. That is, voluntary participants (Level 1) and targeted sites (Level 2). Responses for open-ended questions are also presented by health service organisation participation level (Level 1 and Level 2). The Commissions response is also provided.

Addendum 4: Accreditation assessment reports by health service organisation

Addendum 5: Revised National Clinical Trials Governance Framework incorporating suggested changes.

NOTE: Reported outcomes from pilot sites and the feedback received from contributing organisations has been coded. Several health service organisations are referred to separately and as part of a network, therefore several codes have been attributed.

Health service organisations HSO2, HSO3 and HSO16 are related.

Health services organisations HSO13, HSO17 and HSO18 are related.

Foreword

In 2019, all Australian Health Ministers agreed for the Australian Commission on Safety and Quality in Health Care (the Commission) to pilot the draft National Clinical Trials Governance Framework (the Governance Framework) in selected health service organisations with clinical trial services. Health Ministers requested that; all jurisdictions were represented in the selection of pilot sites, implementation of the Governance Framework allowed appropriate local tailoring to achieve requirements and, for the Commission to report back to Health Ministers on the pilot outcomes.

The Governance Framework is widely regarded as a significant and positive national reform for the clinical trials sector. The COVID-19 pandemic has highlighted the need for robust clinical trials to advance new drugs, medical devices and treatments and ensure the health system is self-improving and sustainable.

Under the National Reform Agreement (Addendum 2020–2025) all states and territory governments are responsible for system level management of public hospitals, including *planning, funding (with the Commonwealth) and delivering teaching, training and research*. Under the *National Health Reform Act 2011*, the Commission is responsible for the formulation of standards relating to health care safety and quality matters. This includes formulating the National Safety and Quality Health Service (NSQHS) Standards and coordinating the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme which provides for the national coordination of accreditation processes across public and private health service organisations, day procedure services and dental services.

The aim of the Governance Framework is to strengthen governance arrangements for health services that deliver clinical trials, consumers, patients, private companies, trial sponsors and trial investigators.

Assessment against the actions within the NSQHS Standards, Clinical Governance and Partnering with Consumers Standards (the Governance Framework), achieves this aim through the integration of clinical trial services into existing health service organisation corporate and clinical governance systems.

As with the NSQHS Standards, the Governance Framework does not specify how a health service organisation or trial site should develop or implement its governance systems. Rather, it describes the systems and processes that should be in place for effective clinical trials governance with consideration of local needs, values and the context in which services are provided.

The implementation of the Governance Framework under the NSQHS Standards and nationally consistent accreditation of clinical trial services under the AHSSQA Scheme will deliver measureable efficiencies in trial operations including:

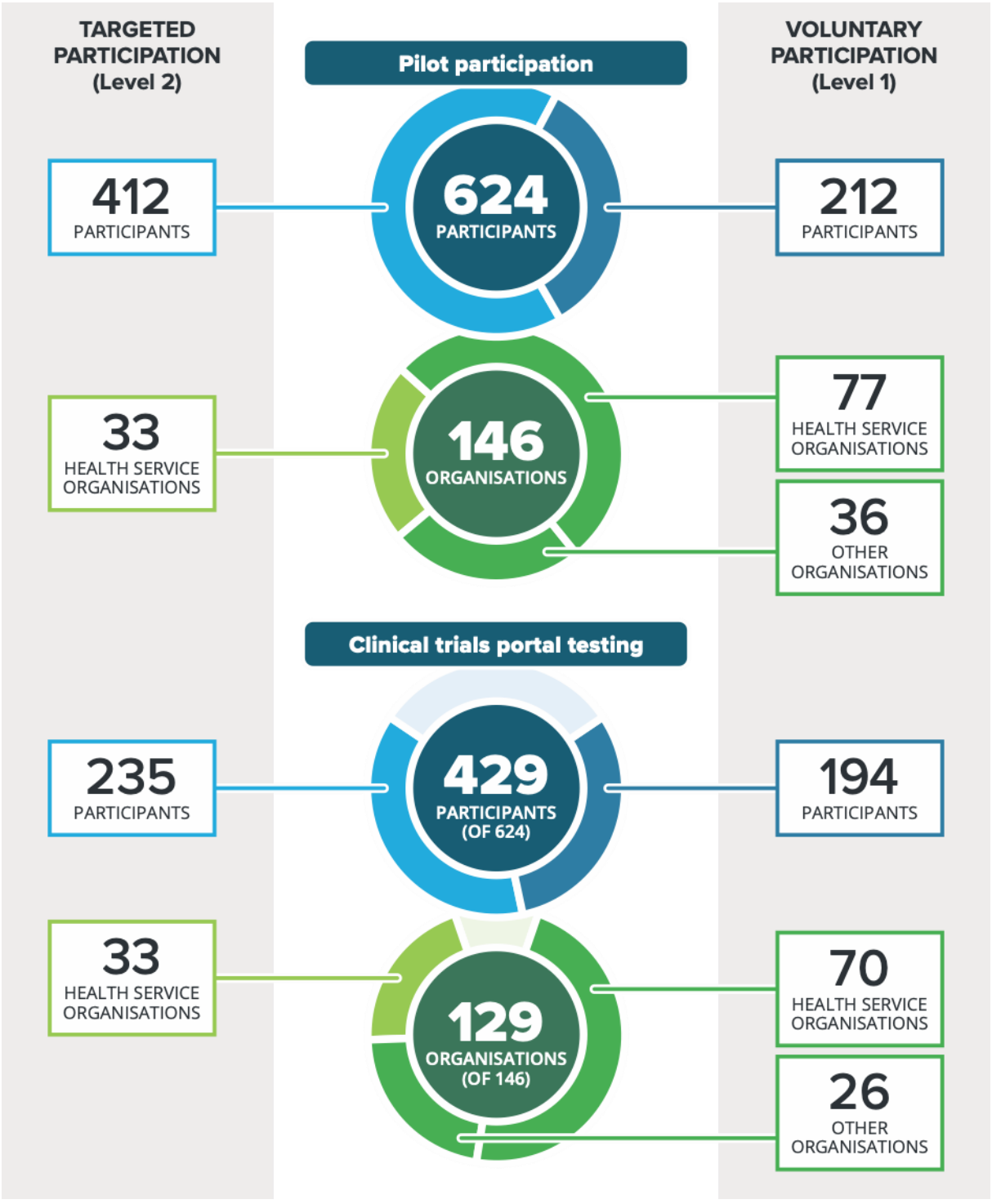
- Trial site feasibility assessment
- Pre-recruitment activities (ethics and local site review and time to approval decision)
- Participant recruitment
- Trial management
- Workforce management
- Trial related financial management

From 1 September 2020 to March 2021, the Commission conducted a national pilot of the Governance Framework to inform the approach to implementation. Thirty three health service organisations, including 412 individuals participated in the targeted pilot (Level 2) approach. Pilot sites were selected based on their geographic location; positioning within a Local Health District/Network; health service organisation specialisation; local population and whether or not they were public or private facility. These sites received mentoring and of these, 15 health services organisations underwent the pilot accreditation assessment (Figure I).

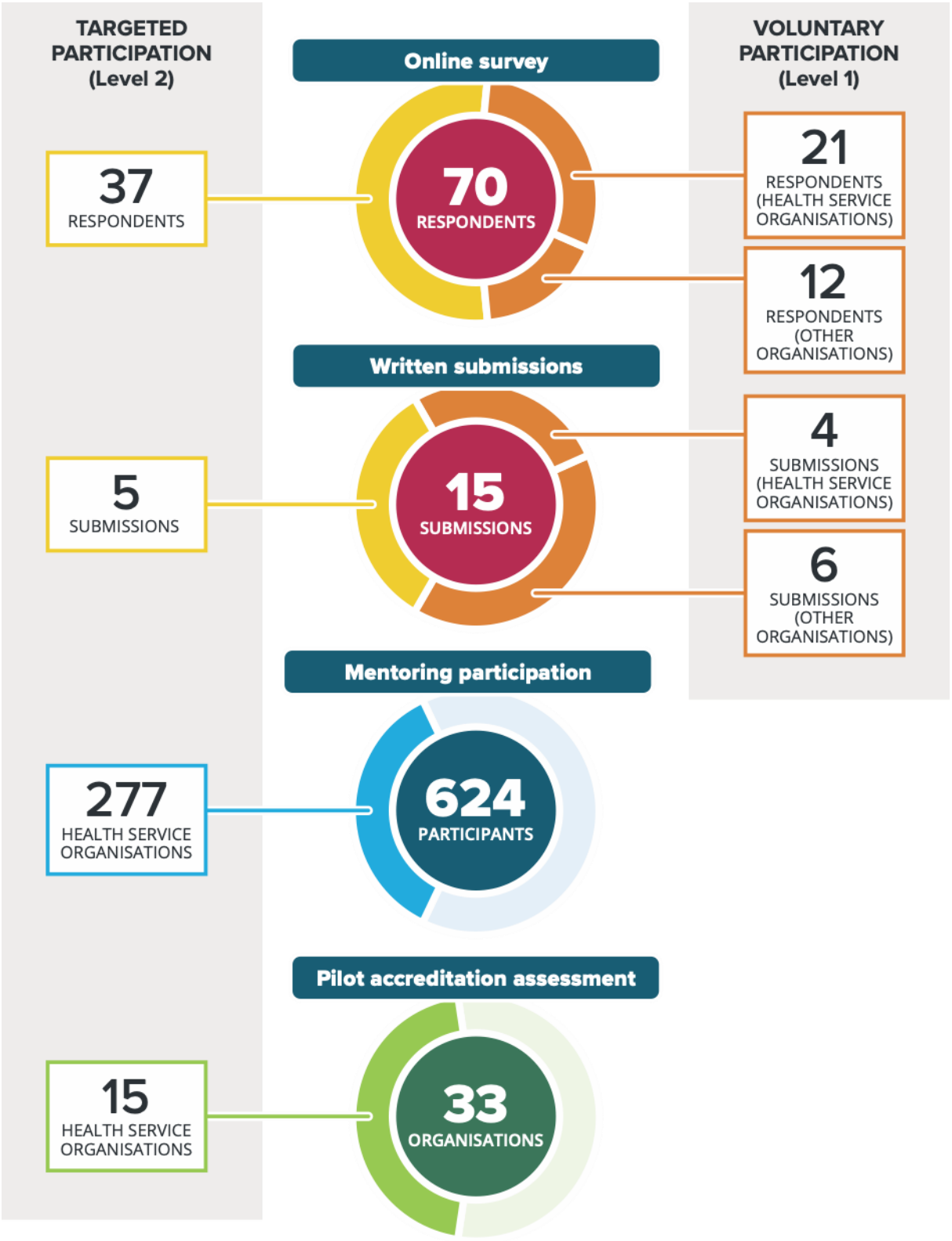
Another 212 individuals representing 113 health service and other organisations provided voluntary feedback on Governance Framework and the supporting tools and resources (Level 1). Overall, 624 individuals representing 146 organisations engaged in the national pilot (Figure II).

Figure I: Participating health service organisations

Figure II: Pilot participation



Continued over …


TARGETED PARTICIPATION (Level 2)
VOLUNTARY PARTICIPATION (Level 1)
Online survey
37
RESPONDENTS
70
RESPONDENTS
21
RESPONDENTS (HEALTH SERVICE ORGANISATIONS)
12
RESPONDENTS (OTHER ORGANISATIONS)
Written submissions
5
SUBMISSIONS
15
SUBMISSIONS
4
SUBMISSIONS (HEALTH SERVICE ORGANISATIONS)
6
SUBMISSIONS (OTHER ORGANISATIONS)
Mentoring participation
277
HEALTH SERVICE ORGANISATIONS
624
PARTICIPANTS
Pilot accreditation assessment
15
HEALTH SERVICE ORGANISATIONS
33
ORGANISATIONS

Key findings

Overall, health service organisations considered participation in the pilot as a valuable experience that provided the catalyst for collaboration across their organisation with their governing body, executives, quality officers, clinical and non-clinical managers and the clinical trial workforce. As with the NSQHS Standards, pilot participants reported that, the structure, sequence, intent and language of the Governance Framework is clear and logical and appropriate for clinical trial services:

> *"We found the Governance Framework and user guide documents were well-structured and clearly laid out, making navigation of the document easy. Of particular benefit was an outline of the supporting evidence required, which will enable researchers and the health service to understand how to meet the expectations and standards outlined within the Framework.*
>
> *"We believe that the intent of the Governance Framework is aspirational and appropriate, aiming to ensure excellence, safety and quality in delivery of clinical trial services."*

Enablers at the health service level included cross-organisational collaboration:

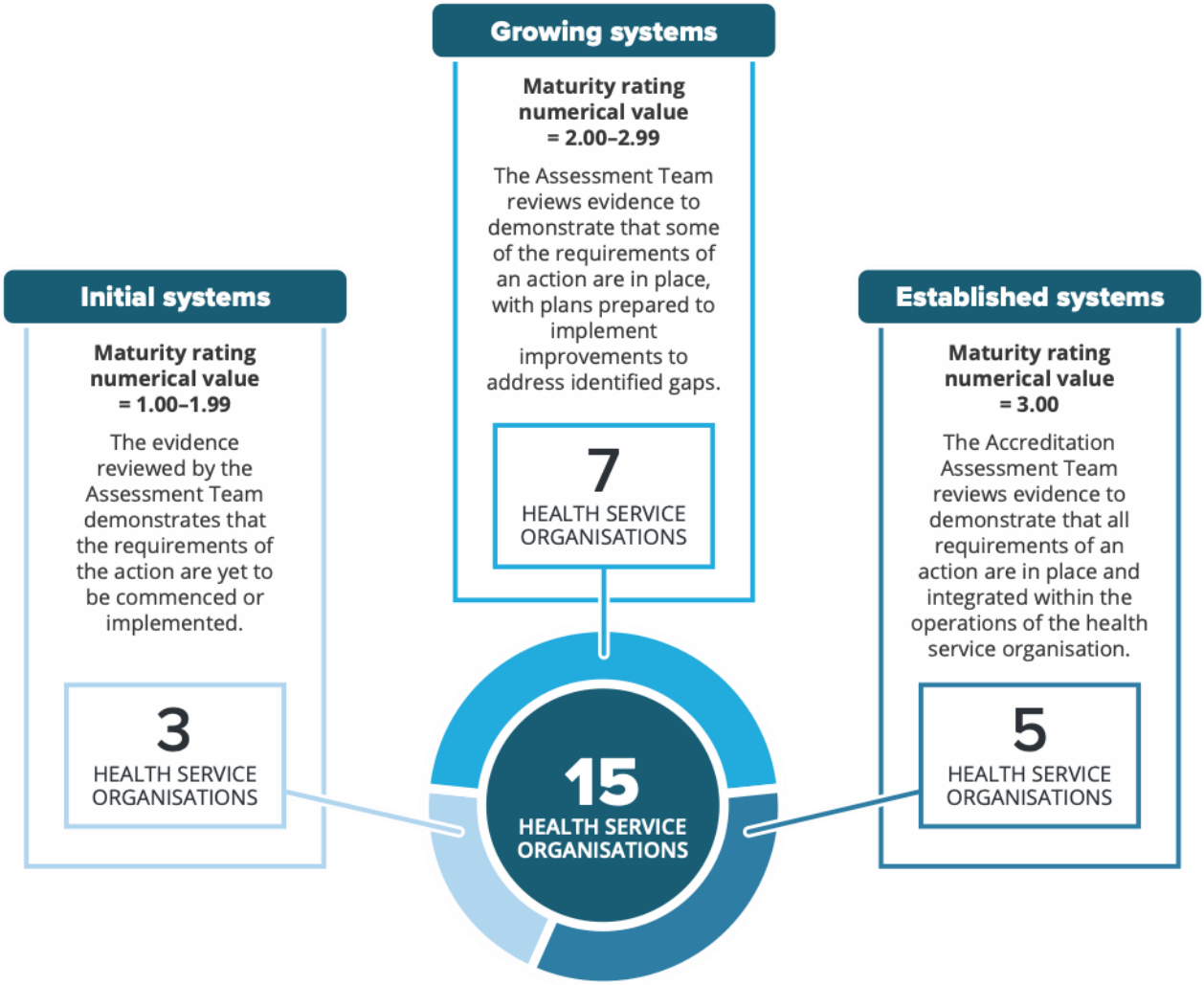
> *"Our hospital had, in more recent times, completed an accreditation process. This exercise provided fresh guidance. We also had:*
>
> - *Executive who fully supported the pilot*
> - *An excellent digital policy and procedure library – available to all staff – broken into sub sections focused on the key themes of the pilot. This enabled us to quickly drop all relevant documents into our own internal drive, in readiness to upload to the pilot system*
> - *A clinical trial unit that had previously undertaken a gap analysis regarding policy and procedures – addressing those gaps was well underway prior to the pilot*
> - *A governance structure which enabled us to complete the pilot requirements quickly. For example, our Clinical Trials Coordinator Network was able to meet on a weekly basis to discuss pilot related matters*
> - *An appreciation that clinical trials will form part of the next hospital accreditation round This assisted in focussing attention from clinical and non-clinical managers*
> - *A solid administrative team within the clinical trials environment who had various levels of accreditation experience."*

The pilot accreditation assessment process was consistent with the assessment of health service organisations to the NSQHS Standards, with adjustments for the pilot context and validation of the maturity scale. The maturity scale provided a qualitative and quantitative measure of success against each action in the Governance Framework. The approach and outcomes health service organisation accreditation assessment are provided in Sections 2 and 3 of this Report.

Of the 15 health service organisations assessed, 12 health service organisations received a rating of having either **Established** systems in place (met all actions) or, **Growing** systems in place to meet the actions in the Governance Framework. For those health services with **Growing** systems, ongoing engagement of the clinical trial workforce with their health service governing body, executive, safety, quality and risk management team, various clinical and non-clinical departments and/or steering committees, is expected to inform existing or planned transition projects to implement the Governance Framework (Figure III).

Those health services with **Initial** systems in place, were committed to full implementation of the Governance Framework.

Figure III: Accreditation assessment outcomes



The assessment of health service organisations against a maturity scale for each action in the Governance Framework provided a flexible and feasible measure of success to guide the improvements expected over a planning cycle of three years. Further, the pilot confirmed that as health services already have processes in place to meet the actions in the NSQHS Standards for clinical and corporate governance, the AHSSQA Scheme provides the appropriate mechanism for assessment and the awarding of accreditation to health service organisations for the provision of clinical trial services.

Support for implementation

As with the NSQHS Standards, the Commission provides support to health service organisations via a number of mechanisms including but not limited to; an advice centre, user guides, supporting tools and resources including training for and the registration of, accreditation assessors, advisories, fact sheets, workbooks and risk matrices.

To support implementation of the Governance Framework, jurisdictional health departments and health service organisations are key in facilitating:

- Greater engagement across the organisation between the executive and clinical trial services
- Broader understanding of the NSQHS Standards and the accreditation process

- The inclusion of patients and consumers in governance activities to support safe, high quality clinical trial service provision
- Engagement of the health service organisation's risk, safety and quality teams in the delivery of clinical services and clinical trial services
- Mechanisms for collating and maintaining accurate quality performance data about clinical trial services
- Executive oversight and arrangements for delivering investigator-initiated clinical trials
- Adopting a risk management approach in the development of policies and procedures to support clinical trial services, including the use of incident management systems
- Human and financial resources to support the delivery of clinical trial services
- Independence of the accreditation assessment process, particularly in respect to ensuring the accurate sampling of all trial units and trials conducted by the health service organisation.

Recommendations

- Implement the Governance Framework in health services organisations from 1 July 2022 and, for the first three-year accreditation cycle, assess health service organisations against the maturity scale. That is, health service organisations will be assessed as having either Established systems, Growing systems or Initial systems in place for clinical trial service provision.
- Incorporate the award of accreditation to health service organisations for the provision of clinical trial services, as an embedded approach (as clinical research is core health service business) under the AHSSQA Scheme. That is, health service should be assessed concurrently for clinical and corporate services and clinical trial service provision.
- Beyond the first three-year accreditation cycle, health service organisations should transition fully to the assessment of their clinical trial services under the AHSSQA Scheme, and be assessed as either having met or not-met the actions within the NSQHS Clinical Governance Standard and Partnering with Consumers Standard and receive 90 days to remediate.

Executive summary

In November 2019, all Australian Health Ministers endorsed the Governance Framework and agreed for the Commission to conduct a pilot in health service organisations conducting clinical trials throughout 2020–21. The pilot provided the first proactive opportunity for engagement between clinical trial services, their health service executive and governing bodies, to implement the Governance Framework.

Pilot aim and objectives

The aim of the pilot was to evaluate health service organisations with clinical trial services against the actions within the NSQHS Standards Clinical Governance Standard and Partnering with Consumers Standard, as provided in the Governance Framework and to familiarise the clinical trial workforce with the accreditation process. The objectives of the pilot were to evaluate:

- Health service organisations conducting clinical trials to understand the intent of the Governance Framework
- The Governance Framework enables health service organisations to identify and address gaps in safety and quality for clinical trial service provision
- The structure, sequence and format of the Governance Framework is logical and easily understood
- The language on the intent of the Governance Framework is specific and clear
- The Governance Framework can be implemented by health service organisations providing clinical trials and assessed for compliance
- Identification of additional resources that may be required to support national implementation of the Governance Framework.

Methodology

To assist health service organisations navigate the changes required to embed clinical trial service provision into existing clinical and corporate governance systems, Accelerating Implementation Methodology (AIM) informed the approach to pilot. The rationale for this approach was underpinned by two decades of evidence and findings from national consultation in 2019 that revealed, clinical trial services operate as siloed activities within health service organisations and, the trial workforce have low levels of awareness of the NSQHS Standards and accreditation process. AIM is a practical approach that takes into account the personal and cultural changes associated with the implementation of change.

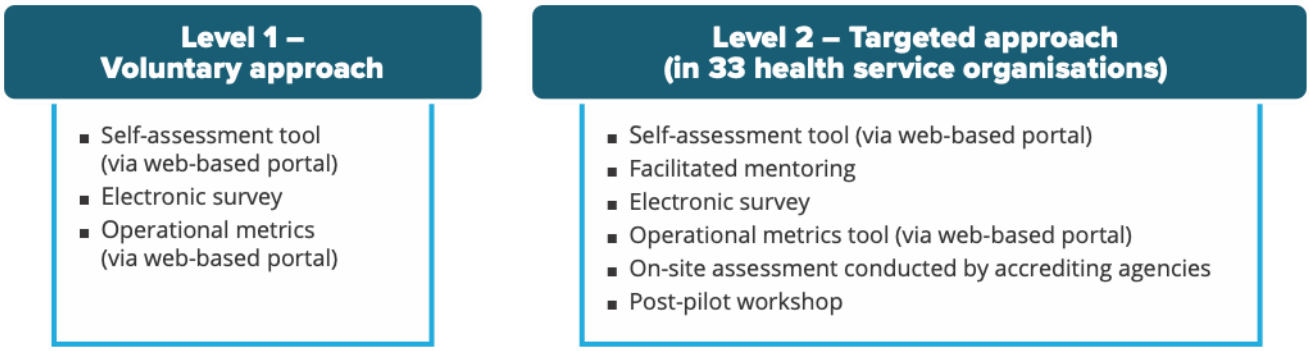
Pilot health service organisation selection

In February 2020, health service organisations were invited via an Expression of Interest (EOI) process to participate in the pilot. More than 92 health services, health networks/districts (including 274 individual health service organisations) responded to the EOI. Of those 274 health service organisations, 143 requested to be considered for participation in the targeted approach (Level 2) and all other health service organisations and key stakeholders were invited to provide feedback on the Governance Framework and supporting tools and resources on a voluntary basis (Level 1).

Thirty-three health service organisations, were selected to receive mentoring, undergo a pilot accreditation assessment and provide feedback on the supporting tools and resources (Figure 1). Health services were selected to ensure jurisdictional representation and the inclusion of private, public and specialty health services in rural and metropolitan locations:

- Alfred Health (The Alfred)
- Canberra Hospital
- Orange Heath Service
- Perth Children's Hospital
- Ramsay Health Care (14 health services)
- Royal Adelaide and Queen Elizabeth Hospitals
- Royal Brisbane and Women's Hospital
- Royal Darwin Hospital
- Royal Hobart Hospital
- St Vincent's Health Network, Sydney and Melbourne
- Sydney Local Health District (Royal Prince Alfred Hospital)
- The Royal Victorian Eye and Ear Hospital
- Townsville Hospital and Health Service
- Victorian Clinical Trial Research Support Service (Ballarat Health, Barwon Health, Bendigo Health, Goulburn Valley Health and Northeast Health Wangaratta).

Figure 1: Two levels of health service organisation participation



Evaluation method

A mixed methods approach using qualitative and quantitative measures sequentially was applied to evaluate the pilot. A logic model inclusive of a series of inputs (both human and material resources), activities and outputs (qualitative and quantitative data) underpinned the approach to data collation, evaluation of the pilot outcomes and the explanation of findings. Qualitative data sources included insights from mentoring; content and thematic analysis of survey data; accreditation outcomes; insights from the accreditation assessors and feedback on the supporting tools and resources. Quantitative data comprised estimates associated with implementation and compliance costs.

Mentoring

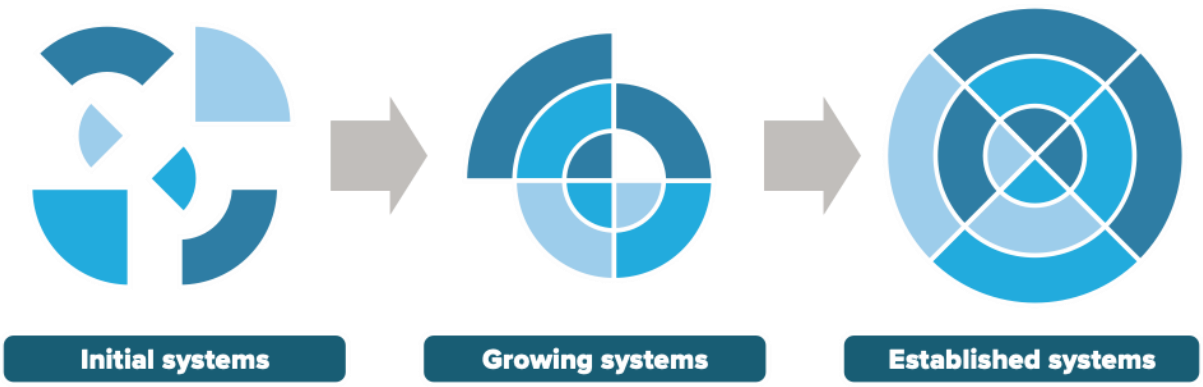
Mentors were engaged to assist health service organisations undertake a gap analysis to identify what needs to be in place to meet the actions in the Governance Framework; identify key people with whom to communicate to build capacity and to develop their approach to implementation. Mentors were also available to advise on mitigating strategies to manage the resistance to change they may encounter.

Accreditation assessment

The NSQHS Standards are already embedded in health service organisations, health services have already invested in policies and process. Therefore, the purpose of the pilot accreditation assessment was to familiarise the clinical trial workforce with the accreditation process and to assess the capacity of each health service organisation to meet the actions within the Governance Framework using a maturity scale (Figure 2). That is, whether the health service organisation had:

- **Established systems**: Evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation or,
- **Growing systems**: Evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps or,
- **Initial systems**: Evidence to demonstrate that the requirements of the action are yet to be commenced or implemented.

Figure 2: Maturity levels for pilot health service organisation assessment



To ensure inter-rater reliability of the assessment process, one team of four accreditation assessors from the Institute for Healthy Communities Australia (IHCA) was contracted to conduct the assessments. Two assessors conducted each assessment, the first assessment was conducted on site to confirm the process and the remainder were conducted using remote technologies (due to the COVID-19 pandemic).

Pilot sites comprising a network of health service organisations with a single governing body such as Ramsay Health Care were assessed as a single entity. For those networks such as the Victorian Clinical Trial Research Support Service, comprising several public entities, each with their own governing body, a sample of health service organisations (two) underwent the accreditation assessment.

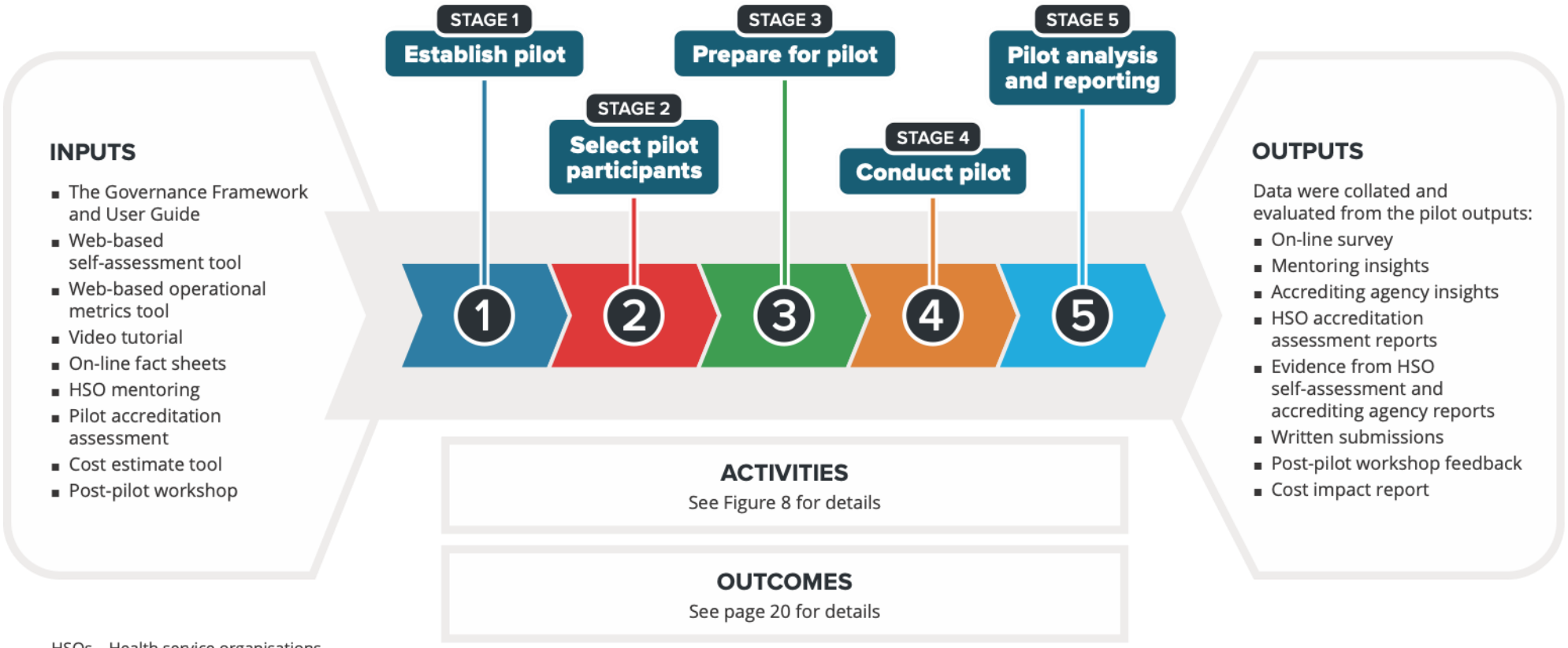
Overall, 15 of the 33 health service organisations were assessed on the maturity scale against the actions within the Governance Framework. The mean score for each action was calculated to determine the overall maturity rating for the health service organisation.

Supporting tools and resources

The following tools and resources were developed to facilitate the pilot activities, data collation and outcome evaluation:

- A comprehensive **online survey** enabled feedback on the Governance Framework
- **The web-based self-assessment tool** assisted health service organisations assess their readiness to meet the actions in the Governance Framework, identify gaps and track their progress
- **The web-based operational metrics tool** enabled the workforce within trial units, clinical departments, hospitals and health networks to collect and review clinical trial service operations through a series of automated reports. These reports may assist health service organisations with strategic planning to deliver clinical trial services. The operational report items are aligned to the National Aggregate Statistics (NAS) and the Commission has provided a user guide and detailed on-line training
- **Ten factsheets**, developed in plain language, explained the NSQHS Clinical Governance Standard and Partnering with Consumers Standard; the roles and functions of the governing body; managers (clinical and non-clinical); sponsors; principal investigators; clinical trial workforce; accrediting agencies and consumers
- **A video tutorial** provided the clinical trial workforce with information on the implementation of the Governance Framework and helps the clinical trial sector understand how to prepare for accreditation.

Pilot logic model



HSOs – Health service organisations

Outcomes

The pilot was conducted from 1 September 2020 to 31 March 2021. Thirty Three health service organisations participated in the targeted (Level 2) approach. Of these, 31 health service organisations received three mentoring sessions. Two health service organisations requested only one mentoring session. Participants commonly included members of the executive, directors, managers and the clinical trial workforce, research officers, secretaries of Human Research Ethics Committees (HRECs), safety, quality and risk officers, clinical service managers, head of clinical departments and business and clinical managers.

Five health service organisations were assessed as having **Established** systems in place. These health service organisations, located in metropolitan cities, met all the actions in the Governance Framework for clinical trial service provision. Seven health service organisations were awarded a maturity rating of **Growing** systems and three health service organisations were awarded a maturity rating of **Initial** systems. Two of these three health service organisations were located in regional Australia (Table 1).

Table 1: Maturity rating for pilot health services organisations

Maturity rating qualitative value	Maturity rating numerical value	Health service organisations (n=15)
Established systems: The accreditation assessment team reviews evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation.	3.0	5
Growing systems: The accreditation assessment team reviews evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps.	2.0–2.99	7
Initial systems: The evidence reviewed by the accreditation assessment team demonstrates that the requirements of the action are yet to be commenced or implemented.	1.0–1.99	3

Accreditation assessors noted that those health service organisations whose clinical trial teams had engaged early with the risk, safety and quality teams generally demonstrated a higher degree of maturity than those who were in the early stages of developing these relationships. Overall:

- Action 2.4 (informed consent) was the highest rated action (most frequently met)
- Actions 1.3 (the health service organisation has a clinical governance framework in place); 1.12 (the health service organisation has an open disclosure framework in place) and 2.5 (the health service organisation has a process to identify the capacity for patients to make decisions about their own care) were implemented in the majority of pilot sites
- The majority of pilot sites were awarded a rating of Growing or Initial systems in respect to Action 1.13, indicating that while health service organisations generally survey patients, families and carers, there was insufficient evidence available to confirm that clinical trial participants, families and carers were formally surveyed. Similarly, Actions 2.9 and 2.14, which require consumer involvement and partnership, challenged a large number of health services

- Eight organisations were awarded Growing systems for Actions 1.7 and 1.11. These actions relate to risk and incident management
- The pilot also highlighted for several health service organisations the need for greater visibility of investigator-led clinical trials.

Health service organisation observations

Health service organisations assessed as having Established systems were able to provide clear evidence that policies and procedures are implemented across the organisation that incorporate clinical trial services. There was evidence, supported through the interview process of regular engagement with and reporting to, the governing body and evidence of comprehensive and robust processes in relation to partnering with clinical trial participants and Aboriginal and Torres Strait Islander populations.

Participants from these health service organisations reported that pilot participation validated project roles or investment in the change journey to date, informed longer-term implementation and reform plans and identified priority actions. The pilot provided further information to inform the Board, executive, management team and third-party stakeholders and sponsors on the status of clinical trial services in their health service organisations.

Those health service organisations assessed as having Growing systems in place had evidence of policies and procedures, some of which may not be current or not completely implemented across clinical trial services and/or available. The most challenging areas included risk and incident management (Actions 1.7 and 1.11). These health service organisations are developing relationships with their risk, safety and quality team and reported that the pilot provided the momentum to develop a more comprehensive approach to update policies, procedures, operational plans, strategies, monitoring documents, risk assessments and communication plans.

Pilot participation provided another perspective on accreditation assessment to inform internal self-assessment and priorities and timelines for action. The pilot also raised awareness of key roles and responsibilities both internally and externally to assist with planning for a culture change, including identification of ‘champions’ to assist health services transition from the current state to the future state.

While health services assessed as having Initial systems in place were committed to full implementation of the Governance Framework, the majority of actions were yet to be commenced or implemented. These health services were generally smaller health services in regional locations, with fewer trials. They were particularly challenged by partnering with consumers in organisational design and governance. For these health services, the perceived benefits of pilot participation were the increased focus of health service executives on priorities for strategic planning and re-assessing the quantum of change required to align clinical trial services with existing clinical and corporate governance systems. It also provided the opportunity to increase engagement and raise awareness of the Governance Framework across the workforce and informed the development of communication and engagement plans with internal and external stakeholders.

Estimated business implementation and recurrent costs

The costs associated with the pilot implementation were estimated by nominated representatives from Level 2 health service organisations.

Profile domains were constructed for each health service organisation including: location and type of the health service organisation; number of trial units; number of active trials and the version of the NSQHS Standards (either, version 1.0 or 2.0) under which the health service organisation was currently accredited.

Cost estimates were provided for 18 cost items which were grouped into nine cost groupings then, categorised as implementation costs, compliance costs and additional costs. The cost estimates data collection tool is provided at Appendix 2.

18 Cost Items	9 Cost reporting groups	3 Cost categories
1. Policies, procedures, tools and resources	Policies and Procedures	Implementation Costs
2. Record keeping	Record Keeping	Implementation Costs
3. Staff training	Training	Implementation Costs
4. Training in Good Clinical Practice	Training	Compliance Costs
5. Notification / education / other training	Training	Compliance Costs
6. IT infrastructure	IT Infrastructure	Compliance Costs
7. Data collection tools	IT Infrastructure	Compliance Costs
8. Secure storage systems for record	IT Infrastructure	Compliance Costs
9. Secure storage systems for study/drug/device	Physical Resources	Compliance Costs
10. Education and training resources	Education Resources	Compliance Costs
11. Clinical trial work spaces	Physical Resources	Compliance Costs
12. Signage/instructions	Physical Resources	Compliance Costs
13. Maintenance costs	Physical Resources	Compliance Costs
14. Other	Other	Compliance Costs
15. Effort to review	Other	Additional Costs
16. Effort to update processes	Other	Additional Costs
17. Other direct/indirect costs	Other	Additional Costs
18. Costs for engaging consumers in National Clinical Trials Governance Framework	Consumer Engagement	Additional Costs

Descriptive analyses were undertaken to test the association between health service profile domain and cost items, cost groupings and cost categories. Estimated costs were calculated as total one-off and recurrent costs per annum.

Cost estimate data were confirmed by a nominated representative from the Level 2 pilot sites in discussion with the Commission, but were not validated through an independent audit process. One of the 33 health service organisations, assessed as having **Growing** systems reported no costs associated with implementation as they considered that the processes and people were already in place. There were a number of cost items with no cost entries recorded as no costs were estimated to be associated with these cost items. These items were entered into the consolidated spreadsheet as zero values. The summary of the estimated implementation costs are provided in Section 3.

The aggregate mean costs for implementation were estimated at $341,083.00 (StdDev $398,685.00). Recurrent costs, per annum were estimated at $261,777.00 (StdDev $238,639.00). The wide Standard Deviation reflects the variation in self-estimated costs and, multiple cost items in the costing tool were not attributed a financial value (Table 28).

Health service organisations that achieved a rating of **Established**, that is they met all the actions in the Governance Framework, estimated mean costs associated with implementation at $255,101.00 (StdDev $205,688.00) and $191,752.00 (StdDev $148,448.00) in recurrent costs per annum. These health service organisations were located in metropolitan cities.

The mean cost associated with implementation in health service organisations that achieved a rating of **Growing**, were estimated at $213,590.00 (StdDev $270,054) and $208,523.00 (StdDev $201,660.00) in recurrent costs per annum.

The mean cost associated with implementation in health service organisations that achieved a rating of **Initial**, were estimated at $781,871.00 (StdDev $665,154.00) and $502,743.00 (StdDev $351,119.00) in recurrent costs per annum. Two of these health service organisations are located in regional Australia. Mean costs for regional health service organisations were three times the estimated costs of larger metropolitan health service organisations which aligned with the difference, observed by the accreditation assessors in the level of resourcing and readiness to implement the Governance Framework between regional and metropolitan health service organisations.

Implementation costs

Of the 15 health service organisations that underwent the pilot accreditation assessment five health service organisations received an assessment rating of Established systems and these were public health facilities located in metropolitan cities. Two of the three health service organisations that received an assessment rating of Initial systems were located in regional centres and for these, the mean self-reported one-off costs for implementation equated to $781,871.00 (StdDev $665,154.00) and $502,743.00 (StdDev $351,119.00). These estimates are three times the level of financial investment estimated by larger metropolitan health service organisations and parallels the observed difference between the level of resourcing and readiness to implement the Governance Framework between regional and metropolitan health service organisations, reported by the accreditation assessors.

Summary

Overall, health service organisations considered participation in the pilot as a valuable experience that provided the catalyst for cross-organisational collaboration between the governing body, executives, quality officers, clinical and non-clinical managers and the clinical trial workforce. Health service organisations that were solutions focussed and achieved early executive and safety, quality and risk officer engagement, more easily and effectively met the actions within the Governance Framework. Strong executive support was essential for success.

Although resource intensive, building awareness of the Governance Framework through the pilot enabled health service organisations to undertake a gap analysis between what is currently in place and what needs to be in place, to meet the actions of the Governance Framework. The pilot provided the opportunity for health service organisation to collate the appropriate evidence that quality systems are integrated, embedded and evident in clinical trial operations.

Pilot participants reported that the structure, sequence, intent and language of the Governance Framework is clear and logical. The resources developed to support the pilot and implementation of the Governance Framework were also found to be helpful and easy to use, with recommendations for improved functionality of the web-based tools.

The self-assessment and the operational metrics tools were developed to ensure that every health service organisation is able to contribute to the collation of evidence against each action in the Governance Framework and report on trial operations.

There was a general lack of understanding on the purpose of performance measurement and requests for further guidance regarding reporting on trial operations were received through written submissions and survey responses. Shared operational reporting is a requirement of good clinical and corporate governance, it improves transparency and drives effective engagement between health service executive and the clinical trial workforce. The purpose of shared reporting is to enhance internal discussions using operational data that reflects the activity where it is occurring, that is, within the clinical trial unit. Throughout the trial process data should be progressively collated so that overtime these reports can inform quarterly internal service review.

The pilot revealed several larger jurisdictions and metropolitan health service organisations had a mechanism through which trial operations could be reported, however within the pilot cohort no health service organisation demonstrated they could report on the eight operational measures as required under Action 1.1 at the level of the clinical trial unit.

There was variable understanding by the clinical trial workforce of the accreditation process and the role of accreditation assessors. Accreditation assessors do not ‘lead’ the assessment process, they are neutral observers. Assessment is a fully independent process that should not be influenced by the preferences of the health service organisation, particularly in respect to trial service and trial sampling. For implementation of the Governance Framework, health service organisations will need to provide accurate information relating to all clinical trial services, the number of trials and participating trial populations.

For the purpose of the pilot, assessors assessed the maturity of participating health service organisations to meet the actions in the Governance Framework. The assessment team familiarised themselves with the Commission’s support material and participated in training prior to conducting assessments for the purpose of the pilot. Moving forward, all registered accrediting agencies will need complete the Commission led training on clinical trial service provision.

The pilot revealed confusion remains regarding the term ‘governance’ in relation to an organisational wide approach to implementing the Governance Framework as opposed to research review and authorisation as the role and function of a research office. Some participants noted that there are some actions under the NSQHS Standards which have not been included in the Governance Framework such as credentialing. This is because these actions are already addressed for all health service employees under the NSQHS Standards and did not need to be duplicated. The 27 actions specific to clinical trial services were determined on advice from the expert advisory committee and via national sector wide consultation in February 2019.

The pilot introduced the concept of clinical incident and risk reporting systems and processes, and clarified the difference between the reporting requirements at a trial level to a HREC or trial sponsor, and reporting incidents and risks associated with service provision. The pilot also broadened awareness by the clinical trial workforce of reporting lines, committee structures, committee memberships and the associated links with researchers and/or business partners. Additionally, the pilot increased sponsors’ awareness of their role and responsibilities in relation to the Governance Framework and the expectation that they will share information relating to the safety and quality of trial conduct and service provision with the health service executive, for the purpose of service provision improvement.

Those actions that received the highest assessment rating include: Action 2.4 (informed consent); Action 1.3 (the health service organisation has a clinical governance framework in place); Action 1.12 (the health service organisation has an open disclosure framework in place) and Action 2.5 (the health service organisation has a process to identify the capacity for patients to make decisions about their own care) were implemented in the majority of pilot sites.

The majority of pilot sites were awarded a rating of Growing or Initial systems in respect to Action 1.13, indicating that while health service organisations generally survey patients, families and carers, there was insufficient evidence available to confirm that clinical trial participants, families and carers were formally surveyed. Similarly, Actions 2.9 and 2.14, which require consumer involvement and partnership, challenged a large number of health service organisations. Eight health service organisations were awarded Growing systems for Actions 1.7 and 1.11. These actions relate to risk and incident management. The pilot also highlighted, for several health service organisations, the need for greater visibility of investigator-led clinical trials.

Jurisdictional health departments and health services have the overall responsibility to meet the actions in the NSQHS Standards, and there are a number of jurisdictional initiatives to support rural and regional health service organisations implement the Governance Framework including but not limited to the Australian Government investment of $125 million via *The Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program*. The focus of this funding is to improve the health of Australians in rural, remote and regional areas through access to innovative clinical trials by removing barriers to participating in clinical trials. It is anticipated this will be achieved by improving facilities, equipment and services in rural, regional and remote Australia, providing patients quicker and easier access to medical treatments, drugs, therapies and devices through participation in clinical trials; increasing research capacity; enhancing existing local and national organisations, facilities and the workforce. The effects are expected to be realised within health service organisations delivering clinical trials.

Conclusion

The pilot demonstrated that the systems and processes are already in place for health service organisations to meet the actions in the NSQHS Standards as provided in the Governance Framework and, as clinical research is core health service organisation business, the AHSSQA Scheme provides the appropriate mechanism for accreditation assessment. Effectively incorporating clinical trials into health service corporate and clinical governance systems requires health service organisations to consider the degree of cross organisational engagement and health service executive support for human and financial resources; a cross organisational understanding of clinical trial services; the accreditation process and greater awareness of consumer engagement and feedback strategies. As with accreditation of health service organisations for clinical and corporate governance, implementation of the Governance Framework under the NSQHS Standards will effectively strengthen national governance arrangements for clinical trial services..

Section 1:
Background and pilot methodology

Introduction

From 1 September 2020 to March 2021 the Commission piloted the implementation of the Governance Framework in 33 health service organisations with clinical trial services. This report provides the evaluation of the pilot and recommendations to support national implementation from July 2022.

The Governance Framework was developed on behalf of all jurisdictions, as the first step towards the accreditation of health service organisations for the provision of clinical trial services. The purpose of the Governance Framework is for a nationally consistent approach to governance of clinical trial services within health service organisations.

The Governance Framework is based on the National Safety and Quality Health Service (NSQHS) Standards 1: Clinical Governance Standard and 2: Partnering with Consumers Standard which are currently in place in all public and private hospitals, day procedure and dental services. It describes the actions that are essential for health service organisations to achieve integrated corporate and clinical governance systems for clinical trial service provision. As with the NSQHS Standards, the Governance Framework provides roles and functions for identified positions, actions against which health service organisations with a clinical trial service will be assessed for accreditation, and suggested strategies and examples of evidence demonstrating a health service organisation has met required actions.

Consistent with the NSQHS Standards, the Governance Framework does not specify how a health service organisation or trial site should develop or implement its governance systems. Rather, it describes the systems and processes that should be in place to implement an effective Clinical Trials Governance Framework considering local needs, values and the context in which services are provided.

Background

In 2017, the Commission commenced work to draft the Governance Framework on behalf of all jurisdictions via the (now) Clinical Trials Project Reference Group and the Australian Government Department of Health. Development of the Governance Framework was informed by a review of the national and international literature; a mapping exercise of national and jurisdictional regulation, legislation clinical trial polices and processes and national sector wide consultation.

The development and implementation of the Governance Framework is a key element of the *Revitalised Clinical Trials Agenda*, delivered *through the Encouraging More Clinical Trials in Australia* program. Development of the Governance Framework aligns with the Commission's functions as provided in the *National Health Reform Act 2011*. These functions include the formulation of model national schemes to accredit health service organisations. The Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme is such a scheme. It was endorsed by all Health Ministers in 2010 and has been implemented in all state and territory public and private health service organisations and day surgical procedure units.

Under the AHSSQA Scheme it is intended that, the Governance Framework will strengthen governance arrangements for governments, hospital administrators, health services that deliver clinical trials, private industry, trial sponsors and trial investigators. Importantly, it will do so in a way that aims to reduce duplication and increase efficiency, cohesion and productivity across the clinical trial sector.

In November 2019, all Australian Health Ministers agreed for the Commission to pilot the Governance Framework in health service organisations delivering clinical trial services throughout 2020–21.

Pilot methodology

To assist health service organisations navigate the changes required to embed clinical trial service provision into existing clinical and corporate governance systems, the Commission used Accelerating Implementation Methodology (AIM) as the underpinning approach to pilot. AIM provides a practical guide that takes into account the personal and cultural changes associated with the implementation of a change process. The rationale for this approach was underpinned by two decades of evidence and findings from national consultation in 2019, that the clinical trial workforce had low levels of awareness of the NSQHS Standards and health service organisation accreditation due in part, to the siloed business models of clinical trial services.

A mixed methods approach using both qualitative and quantitative measures in a sequential explanatory design, was applied to evaluate health service organisations pilot the implementation of the Governance Framework. The Commission developed a logic model inclusive of a series of inputs (including human and material resources), activities and outputs (qualitative and quantitative data) to assess the pilot outcomes. Qualitative data sources comprised: insights from mentoring; content and thematic analysis of survey data; accreditation outcomes; insights from the accreditation assessors and feedback on the supporting tools and resources. Quantitative data included estimates associated with business compliance costs assessed at each selected health service organisation following the pilot accreditation assessment.

Pilot aim and objectives

The aim of the pilot was to evaluate health service organisations with clinical trial services against the actions within the NSQHS Clinical Governance Standard and Partnering with Consumers Standard, as provided in the Governance Framework and to familiarise the clinical trial workforce with the accreditation process.

The objectives of the pilot were to assess the following:

- Health service organisations conducting clinical trials understand the intent of the Governance Framework
- The Governance Framework enables health service organisations to identify and address gaps in safety and quality for clinical trial service provision
- The structure, sequence and format of the Governance Framework is logical and easily understood
- The language on the intent of the Governance Framework is specific and clear
- The Governance Framework can be implemented by health service organisations providing clinical trials and assessed for compliance
- Identification of additional resources that may be required to support national implementation of the Governance Framework.

Pilot health service organisations

To facilitate broad engagement in the pilot, the Commission invited health service organisations via an Expression of Interest (EOI) process to participate in the pilot. More than 92 health services, health networks/districts (including 274 individual health service organisations) expressed their interest to provide either voluntary feedback on the Governance Framework tools and resources (Level 1) or to receive mentoring and undergo a pilot accreditation assessment (Level 2).

Level 1 participants

Any health service organisation, university, research organisation or interested stakeholder could register with the Commission to receive access to the web-based tools, and provide voluntary feedback via an on-line survey on the Governance Framework and supporting resources. Participants from these organisations were also invited to participate in the post-pilot workshop. One hundred and thirteen health service and other organisations (including 212 individuals) participated in Level 1 of the pilot. The number of voluntary health service organisations by jurisdiction is provided in Table 2.

Table 2: Voluntary health service organisation by state and territory

State / Territory	Level 1 organisations (n)
ACT	1
National	14
NSW	38
NT	2
QLD	14
SA	14
TAS	0
VIC	22
WA	8
Total	**113**

Level 2 participants

Participation as a Level 2 pilot site was by application to the Commission. The Commission purposively selected sites based on five published criteria (Table 3) to ensure representation of health service organisations across all states and territories. A total of 41 health services, health networks/districts (including 143 individual health service organisations) responded to the EOI requesting to participate in the targeted approach (Level 2), and 14 sites, inclusive of 33 health service organisations were selected. Pilot sites included single health service organisations, a national private health service provider (Ramsay Health Care), a private/ public partnership (St Vincent's Network) and a public health sector collaborative (Victorian Cancer Collaborative).

Following the receipt of agreement by the selected health service organisation's Chief Executive Officers, the list of participating health service organisations was published on the Commission's website. The location and profile of participating health service organisations and their associated hospitals are provided in Tables 4 and 5.

Table 3: Criteria for the selection of (Level 2) pilot health service organisations

Criteria	Criteria Description	Selection considerations
1	Geographic location	Ensure an appropriate mix of sites across all geographical areas (metro, inner regional, outer regional, rural, remote)
2	Positioning within a Local Health District/Network	Avoid multiple sites within the same local health district/hospital network
3	Health service organisation specialisation	Consider the type of health services / specialisation (e.g. paediatrics, maternity services, dedicated D&A/mental health)
4	Local population	Consider the demographics of the population served by the health service organisation.
5	Public or private facility	Consider a mix of public and private health service organisations

Table 4: Participating Level 2 health service organisations profile

No.	Level 2 health service organisations	State / Territory	Metropolitan / Regional / Rural	Public / Private	Single / Multi-site	Level 2 hospitals (n)
1	Canberra Hospital	ACT	Metropolitan	Public	Single	1
2	Ramsay Health Care	National	Various	Private	Multi	14
3	Sydney Local Health District	NSW	Metropolitan	Public	Multi	2
4	Orange Heath Service	NSW	Regional	Public	Single	1
5	St Vincent's Health Network	NSW, VIC	Metropolitan	Public, Private	Multi	2
6	Royal Darwin Hospital	NT	Regional	Public	Single	1
7	Royal Brisbane and Women's Hospital	QLD	Metropolitan	Public	Single	1
8	Townsville Hospital and Health Service	QLD	Regional	Public	Single	1
9	Royal Adelaide and Queen Elizabeth Hospitals	SA	Metropolitan	Public	Multi	2
10	Royal Hobart Hospital	TAS	Metropolitan	Public	Single	1
11	Victorian Clinical Trial Research Support Service	VIC	Regional	Public	Multi	5
12	Alfred Hospital	VIC	Metropolitan	Public	Single	1
13	The Royal Victorian Eye and Ear Hospital	VIC	Metropolitan	Public	Single	1
14	Perth Children's Hospital	WA	Metropolitan	Public	Single	1
Total						**33**

Table 5: Level 2 health service organisations and associated hospitals

Level 2 Health Service Organisations	No. of Clinical Trials	Hospitals (n=33)
Australian Capital Territory		
Canberra Health Services	~200	Canberra Hospital
National		
Ramsay Health Care	~200	Albert Road Clinic
		Border Cancer Hospital
		Greenslopes Private Hospital
		Hollywood Private Hospital
		John Flynn Private Hospital
		Lake Macquarie Private Hospital
		North Shore Private Hospital
		Peninsula Private Hospital
		Pindara Private Health
		Southern Highlands Private Hospital
		St George Private Hospital
		Sunshine Coast University Private Hospital
		Warringal Private Hospital
		Wollongong Private Hospital
St Vincent's Health Network	200–300	St Vincent's Hospital (Sydney)
		St Vincent's Hospital (Melbourne)
New South Wales		
Orange Health Service	~25	Orange Hospital
Sydney Local Health District	300-400	Royal Prince Alfred Hospital
Northern Territory		
Royal Darwin Hospital	~40	Royal Darwin Hospital
Queensland		
Royal Brisbane and Women's Hospital	>200	Royal Brisbane and Women's Hospital

Level 2 Health Service Organisations	No. of Clinical Trials	Hospitals (n=33)
Townsville Hospital and Health Service	>100	Townsville Hospital and Health Service
South Australia		
Royal Adelaide and Queen Elizabeth Hospitals	200–500	Royal Adelaide Hospital
		The Queen Elizabeth Hospital
Tasmania		
Royal Hobart Hospital	~150	Royal Hobart Hospital
Victoria		
Alfred Health	300–400	The Alfred
The Royal Victorian Eye and Ear Hospital	~50	The Royal Victorian Eye and Ear Hospital
Victorian Clinical Trial Research Support Service	135–200	Ballarat Health
		Barwon Health
		Bendigo Health
		Goulburn Valley Health
		Northeast Health Wangaratta
Western Australia		
Child and Adolescent Health Service	~100	Perth Children's Hospital

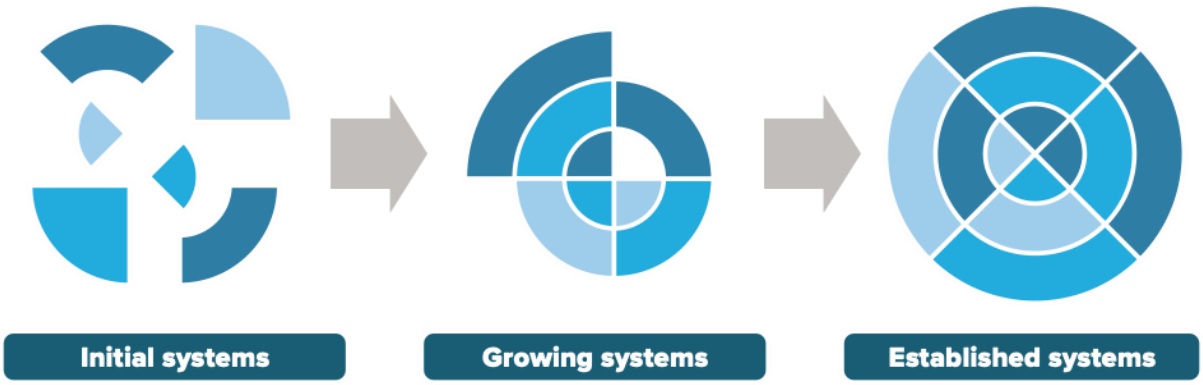
Approach to pilot

To guide Level 2 health service organisations through the pilot process the Commission engaged a mentoring team. Mentors assisted health service organisations undertake a gap analysis to identify what needed to be in place to meet the actions in the Governance Framework; identify key people with whom to communicate to build capacity and to develop their approach to implementation. Mentors were also available to advise on mitigating strategies to manage the resistance to change they may encounter.

The purpose of the pilot accreditation assessment was to familiarise the clinical trial workforce with the accreditation process and to provide feedback on the capacity of each health service organisation to meet the actions within the Governance Framework using a maturity scale (Figure 3). That is, whether the health service organisation has:

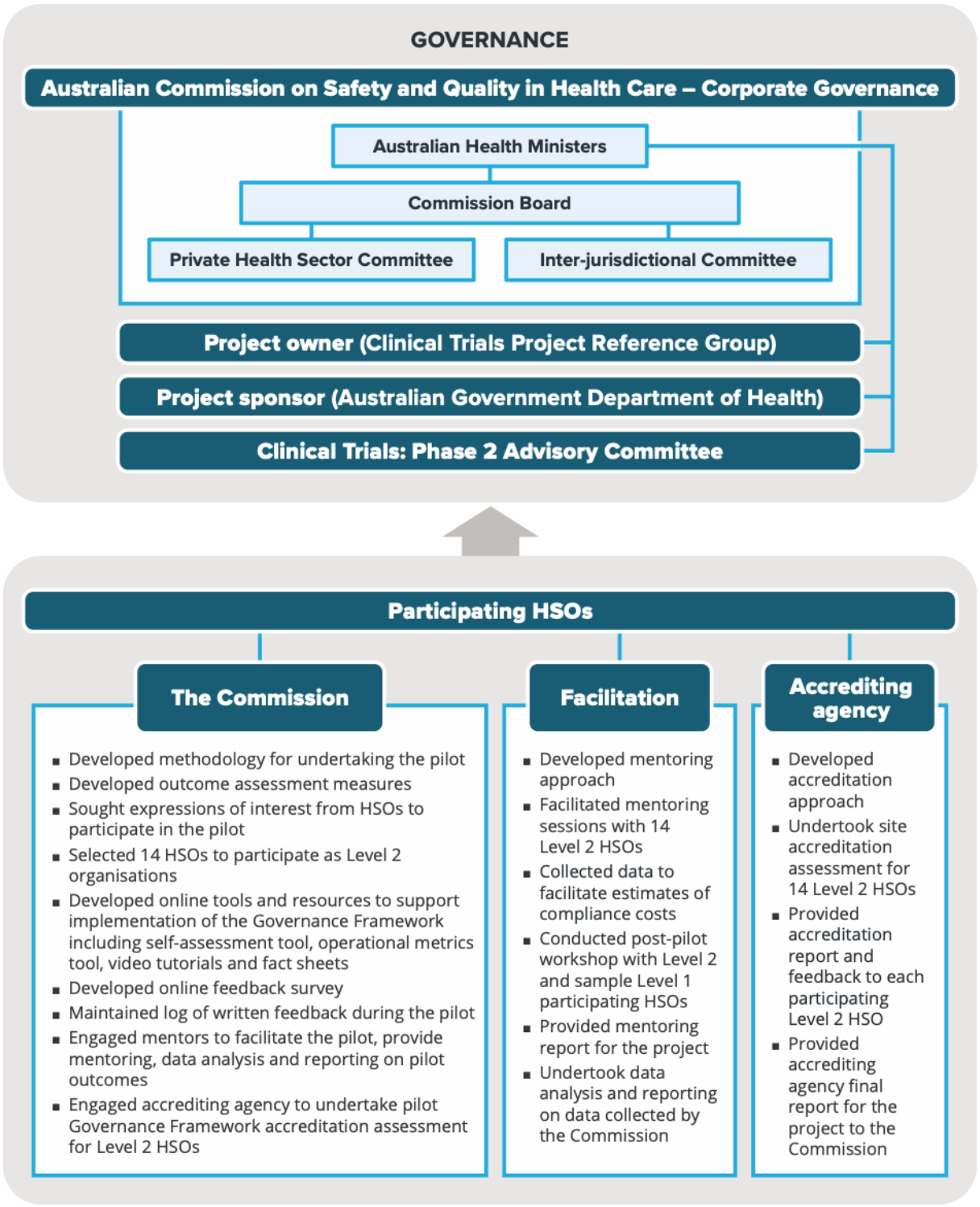
- **Established systems**: evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation or,
- **Growing systems**: evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps or,
- **Initial systems**: evidence that demonstrates the requirements of the actions are yet to be commenced or implemented.

Figure 3: Maturity levels for pilot health service organisation assessment



Pilot sites comprising a network of health service organisations with a single governing body such as Ramsay Health Care were assessed as a single entity. For those networks such as the Victorian Clinical Trial Research Support Service, comprising several public entities, each with their own governing body, a sample of health service organisations (two) underwent the accreditation assessment. Consequently, 15 of the 33 health service organisations where assessed on a maturity scale against the actions within the Governance Framework. The mean score for each action was calculated to determine the overall maturity rating for the health service organisation. The Institute for Healthy Communities Australia (IHCA) was engaged to undertake the pilot accreditation assessment in selected health service organisations. An overview of the roles and activities of each organisation working with the Commission to deliver the pilot are provided in Figure 4.

Figure 4: Pilot governance and project delivery roles

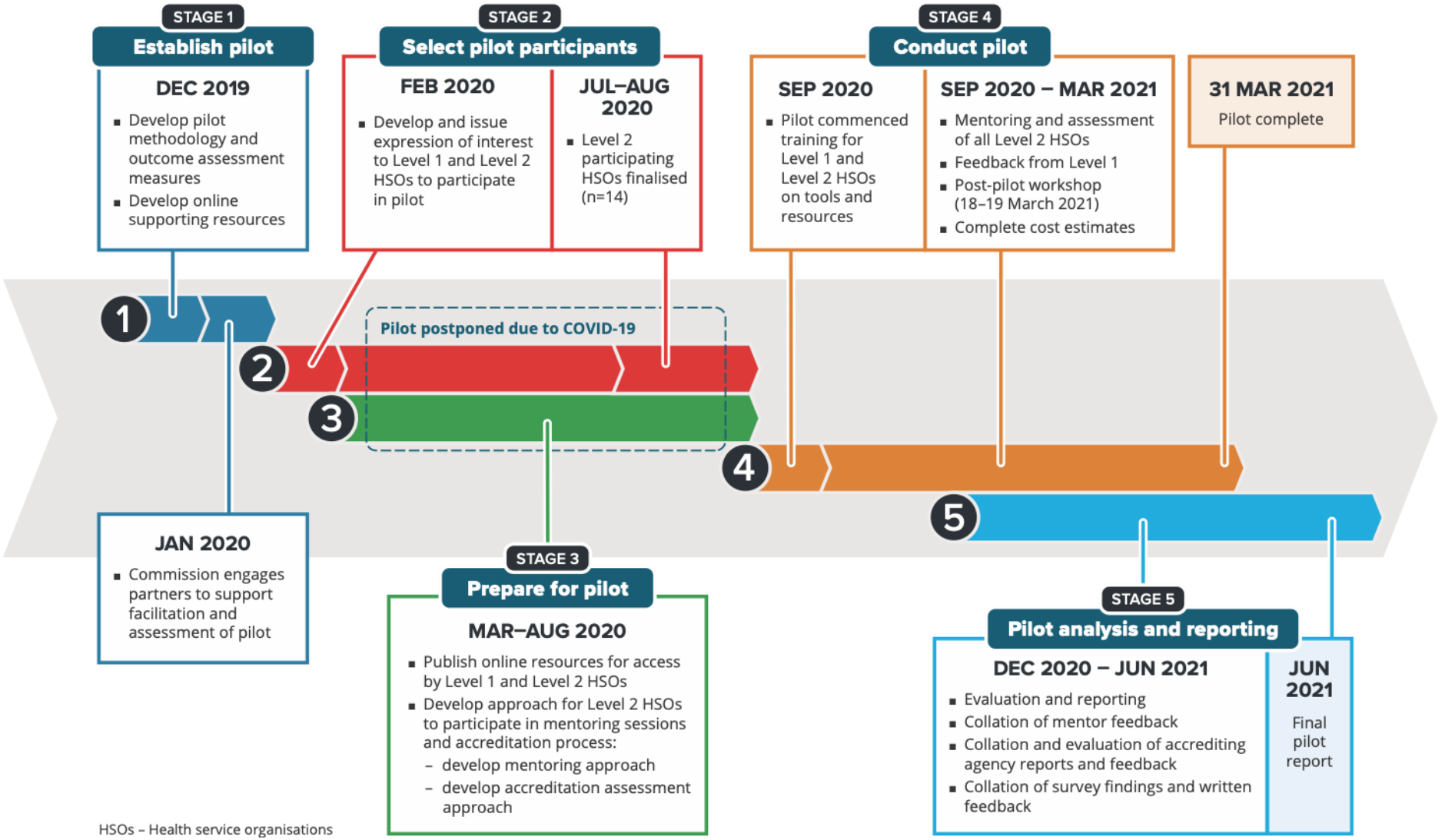


Abbreviations
Commission – Australian Commission on Safety and Quality in Health Care
HSOs – Health service organisations

Pilot timeline

The timeline for conducting the pilot was extended due to the COVID-19 global pandemic and the pause in routine accreditation assessment of health service organisations to the NSQHS Standards. The delayed commencement ensured the pilot progressed at the most appropriate time for health service organisations. On 1 September 2020, the supporting tools and resources were published on the Commission website and the pilot commenced. The pilot accreditation assessments were conducted sequentially through to 17 March 2021 and the post-pilot workshops were held on 18 and 19 March 2021 (Figure 5). Feedback on the tools and resources were sought from pilot participants via an on-line survey and/or written submissions until 1 December 2020.

Figure 5: Key timelines in delivering the Governance Framework pilot



Section 2:
Data collection, inputs activities and outputs

Data collection – inputs, activities and outputs

To evaluate the pilot outcomes data were analysed from the following sources: pilot inputs (including human and material resources); the evaluation of pilot activities and the assessment of outputs (qualitative and quantitative data).

Pilot inputs included:

- Input 1: National Clinical Trials Governance Framework (Governance Framework) and User Guide
- Input 2: Web-based self-assessment tool
- Input 3: Web-based operational metrics tool
- Input 4: Video tutorials
- Input 5: On-line fact sheets
- Input 6: Health service organisation mentoring
- Input 7: Pilot accreditation assessment
- Input 8: Cost estimate tool
- Input 9: Post-pilot workshop.

Data were collated and evaluated from the pilot outputs:

- Output 1: On-line survey
- Output 2: Written submissions
- Output 3: Mentoring report
- Output 4: Health service organisation accreditation assessment reports
- Output 5: Accrediting agency report
- Output 6: Evidence from health service organisation self-assessment and accrediting agency reports
- Output 7: Cost impact report
- Output 8: Post-pilot workshop feedback.

Inputs and outputs were either optional, required or not available depending on the level of participation by health service organisations.

Pilot inputs

A summary of pilot inputs and the requirements for completion by participating health service organisation is provided in Table 6 with an overview of each of the pilot inputs and their contribution to the pilot evaluation of outcomes.

Table 6: Pilot input requirements for Level 1 and Level 2 sites

No.	Pilot inputs	Requirements of health service organisations	
		Level 1	Level 2
1	**The Governance Framework and User Guide** Built on the National Model Clinical Governance Framework and the National Safety and Quality Health Service (NSQHS) Standards, this input has been developed to support the delivery of high-quality clinical trial services. It provides examples and strategies to monitor clinical trial service operations and self-assess against the actions defined in the Governance Framework. *Developed by the Commission.*	Optional	Required
2	**Web-based self-assessment tool** Self-assessment of current systems and processes using the Governance Framework, including identification of sources of evidence available to demonstrate actions have been met and identification of areas where actions are not met and where improvements are required. *Developed by the Commission.*	Optional	Required
3	**Web-based operational metrics tool** Data capture and reporting on clinical trial service operations, to facilitate reporting to the health service executive and governing body. *Developed by the Commission.*	Optional	Required
4	**Video tutorial** Explains what accreditation to the Governance Framework means for the clinical trial workforce. *Developed by the Commission.*	Optional	Optional
5	**On-line fact sheets** Ten fact sheets associated with the Governance Framework. *Developed by the Commission.* *Additional IHCA developed fact sheets.*	Optional	Optional

No.	Pilot inputs	Requirements of health service organisations	
		Level 1	Level 2
6	**Health service organisation mentoring** Remote facilitated mentoring provided by ZED to assist health service organisations assess their capacity to meet the actions within the NSQHS Standards as provided in the Governance Framework and to determine what needs to be in place to ensure actions are met.	Not available	Required
7	**Pilot accreditation assessment** Remote accreditation assessment conducted by IHCA accrediting agency to provide assessment against a maturity scale for each action item in the Governance Framework and for the health service organisation overall.	Not available	Required
8	**Cost estimate tool** A tool to capture cost estimates from health service organisations to implement the Governance Framework.	Not available	Required
9	**Post-pilot workshop** Post-pilot workshop to seek further insights and learnings from health service organisations regarding the findings of the pilot.	Optional	Required

Input 1: The Governance Framework and User Guide

The draft National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials: Draft for pilot 2020 was developed and published on the Commission website for use by all health service organisations, other organisations and individuals. The Governance Framework builds on the National Model Clinical Governance Framework and the NSQHS Standards to provide: the roles and functions for identified positions; 27 actions against which health service organisations with a clinical trial service were assessed for the pilot accreditation assessment; suggested strategies for health services and examples of evidence they might use to demonstrate they have met the to meet required actions. Feedback on the Governance Framework was provided via the on-line survey, written submissions and the mentoring and accreditation assessment process.

Input 2: Online survey

A comprehensive online survey was available for completion by all pilot participants to assess the Governance Framework and supporting tools and resources against the objectives of the pilot. The survey comprised 85 five to seven point Likert Scale and numeric scale questions:

- Questions 1 to 6 related to the organisational details of participants
- Questions 7 to 13 related to general feedback on the Governance Framework
- Questions 14 to 17 related to general feedback on the Clinical Governance Standard
- Questions 18 to 54 related to specific feedback for each action item of the Clinical Governance Standard
- Questions 55 to 58 related to general feedback on the Partnering with Consumers Standard
- Questions 59 to 77 related to specific feedback for each action item of the Partnering with Consumers Standard
- Questions 78 to 85 related to feedback on supporting resources for the Governance Framework
- Appropriateness of examples of evidence in the Governance Framework for each of the 27 action items, and primary sources of evidence used by organisations to indicate implementation of the action
- The utility of supporting tools and resources, and any additional resources which would be helpful for implementation of the Governance Framework.

Input 3: Web-based tools – operational metrics tool and self-assessment tool

The web-based self-assessment tool facilitated a whole of organisation approach – inclusive of the clinical trial workforce, clinical and non-clinical managers, human resources, finance and the executive – to review the organisation's readiness to meet the actions in the Governance Framework. The functionality of the tool supported the generation of reports at a trial unit and health service organisation level by action item, with self-rated measures as either met; mostly met with some exceptions; partially met or substantially not met. Health service organisations were able to assess their capacity to meet the actions in the Governance Framework; upload evidence to demonstrate each action had been met; create work plans; assign tasks relating to the collation of evidence and allocate a person responsible for completing each task.

The web-based operational metrics tool facilitated reporting on clinical trial service operations within trial units, clinical departments, hospitals and health networks. Report items align with the National Aggregate Statistics (NAS) and provide a mechanism to assist with strategic planning for delivery of clinical trial services and to ensure all health service organisations have a reporting mechanism in place as required under Action 1.1 of the Governance Framework. Operational measures include:

1. Number of new trials and breakdown by trial phase, and by sponsor type
2. Overall study start-up timeline (regulatory timeline)
3. Ethics and local site authorisation approval timeline
4. Human Research Ethics Committee (HREC) approval timeline
5. SSA/site assessment (local site authorisation) timeline
6. Trial recruitment: actual and planned number of participants recruited
7. Site recruitment: actual and planned number of participants recruited
8. Total inbound (internal and external) investment annually.

The operational metrics tool and the self-assessment tool were available to all health service organisations participating in the pilot, and will continue to be available following the pilot, with updates and enhancements, based on the pilot findings. The Commission provided a user guide and detailed on-line training via three webinars in the second week of September 2020. The webinars and tools remain accessible via the Commission's website.

Input 4: Video Tutorial

The Commission developed a video tutorial to assist health service organisations improve their understanding of the Governance Framework and the accreditation assessment process. The video tutorial explains what accreditation to the Governance Framework means for the clinical trial workforce.

The video tutorials are at https://youtu.be/tGXmj9ReeLw and https://www.youtube.com/watch?v=t_jkwgAmVy0&t=5s.

Input 5: On-line fact sheets

Ten fact sheets were developed by the Commission explaining the accreditation process, NSQHS Standards 1: Clinical Governance Standard and 2: Partnering with Consumers Standard and the roles and functions of the governing body, managers (clinical and non-clinical), principal investigators, clinical trials workforce, sponsors, accrediting agencies, and consumers:

Fact sheet 1: National Clinical Trials Governance Framework and accreditation overview

Fact sheet 2: National Clinical Trials Governance Framework – Clinical Governance Standard

Fact sheet 3: National Clinical Trials Governance Framework – Partnering with Consumers Standard

Fact sheet 4: National Clinical Trials Governance Framework – Roles and functions of the governing body

Fact sheet 5: National Clinical Trials Governance Framework – Roles and functions of managers (clinical and non-clinical)

Fact sheet 6: National Clinical Trials Governance Framework – Information for consumers

Fact sheet 7: National Clinical Trials Governance Framework – Roles and functions of clinical trial sponsors

Fact sheet 8: National Clinical Trials Governance Framework – Roles and functions for site principal investigators

Fact sheet 9: National Clinical Trials Governance Framework – Roles and functions for the clinical trial workforce

Fact sheet 10: National Clinical Trials Governance Framework – Information for accrediting agencies.

Additional online materials and fact sheets were also available such as the fact sheet 'Using PICMoRS for quality improvement and assessment preparation'.

Input 6: Health service organisation mentoring

Mentoring was offered to assist Level 2 health service organisations develop their approach to implementing the Governance Framework. Mentors worked with the health service organisation primary contact person to coordinate the mentoring approach, and advised on approaches to build connections with the clinical and non-clinical workforce, senior management and the executive to understand the systems and processes already in place to meet the NSQHS Standards and what was required to meet the actions within the Governance Framework. Mentors advised on the development and implementation of action plans in the weeks leading up to site accreditation assessment and coordinated review meetings following the accreditation assessment.

Mentors had capacity to provide up to seven formalised mentoring sessions of approximately one hour in duration for each Level 2 health service organisation, based on the needs of the organisation. However, no health service organisation required more than three sessions. The key focus of the three sessions (introductory, re-site assessment and post site assessment) are provided in Table 7 and the areas of focus for mentoring discussions are provided in Table 8.

The timing of sessions were aligned with the confirmed date of the accreditation assessment and included participation by health service organisation executives, quality officers, clinical and non-clinical managers, and members of the clinical trial workforce. The list of mentoring participants by health service organisation and role is provided in Appendix 1.

Mentors were also responsible for oversighting the completion of the self-assessment tool and Level 2 health service organisation gap analysis; ensuring health service organisations tested the operational metrics tool, provided business compliance costs estimates and completed the on-line survey.

Table 7: Overview of mentoring sessions

Mentoring session 1	Mentoring session 2	Mentoring session 3
Introductory session with broad range of stakeholders to introduce the pilot and ensure all key stakeholders were aware of their roles and responsibilities in participating in the pilot.	**Pre-site assessment sessions** to support timely completion of self-assessment tool and operational metrics tools, support engagement of clinical and non-clinical staff, and support development of systems and processes to address identified gaps.	**Post-site assessment sessions** to undertake debrief following accreditation assessment, check alignment with expectations, and to support sites to complete cost estimates tool and on-line survey.

Table 8: Mentoring focus areas

Mentoring focus areas	Aim	Standing items for mentoring
Compliance	Support the use of pilot tools and the development of action plans to address gaps	• Roles and responsibilities • Using tools • Self-assessment tool • Operational metrics portal • On-line survey • Cost-estimates • Tracking progress • Risks / issues • Agreed actions
Systems and processes	Support embedding of clinical trial services into strategic and operational planning processes	• Gaps identified • Potential solutions • Key stakeholders • Key changes • Action plan • Tracking progress • Risks / issues • Agreed actions
Engagement	Engage clinical and non-clinical workforce with senior management to meet requirements of Governance Framework	• Stakeholder identification • Understanding stakeholder needs • Stakeholder involvement • Manage stakeholder expectations • Communications • RACI (Responsible, Accountable, Consult, Inform) • Tracking progress • Risks / issues • Agreed actions

Input 7: Pilot accreditation assessment

The purpose of the pilot accreditation assessment was to familiarise the clinical trial workforce with the accreditation assessment process and provide feedback to all Level 2 health service organisations on their capacity to meet the actions within the Governance Framework.

To ensure inter-rater reliability of the assessment process, one team of four accreditation assessors from the Institute for Healthy Communities Australia (IHCA) was contracted to conduct the assessments. Two assessors conducted each assessment, the first assessment was conducted on site to confirm the process and the remainder were conducted using remote technologies (due to the pandemic). IHCA is an internationally accredited agency for the conduct of remote assessments and has well established processes for the conduct of remote assessments using remote technologies.

As with assessment to the NSQHS Standards, the assessment team required full contextual information about the health service organisation to facilitate relevant and accurate assessment planning. Preparatory activities prior to undertaking the first accreditation assessment included:

- Identification of key contextual planning information
- Determination of a methodology to sample trials

- Development of the definition of the maturity scale
- Identification of key roles to be interviewed
- Development of a method to include trial participants in the assessment process.

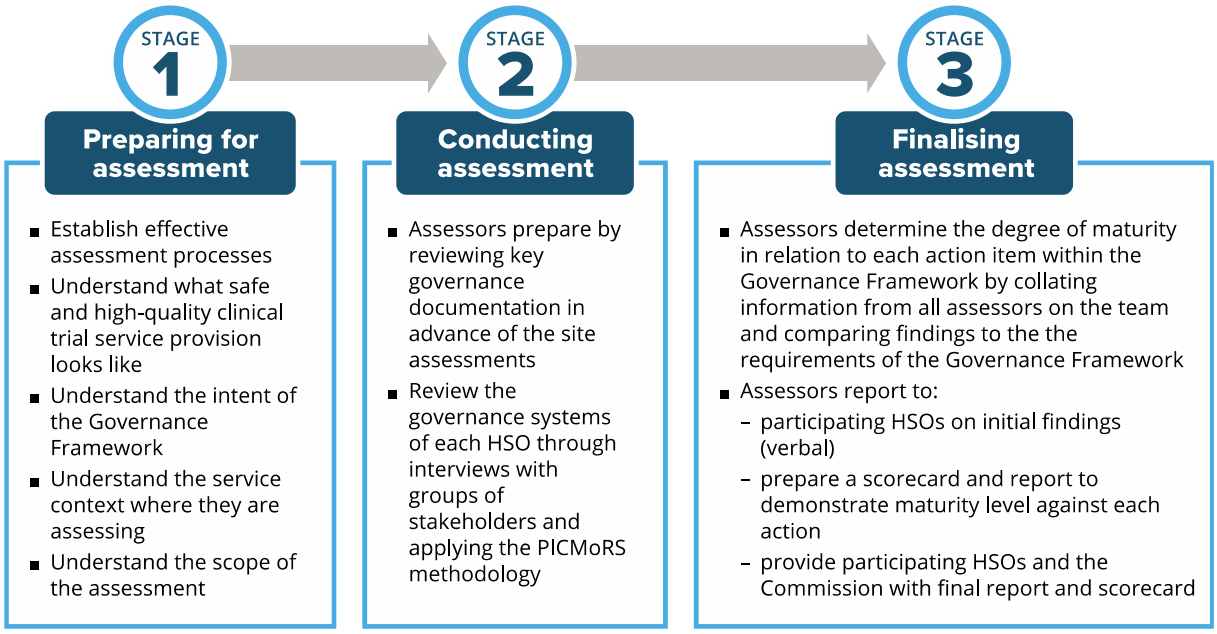
Additional fact sheets were also developed to support health service organisations prepare for the assessment process:

- Remote assessment fact sheet
- Accreditation assessment overview
- Information for patients and consumers
- Pre-assessment documentation
- Overview of assessment for sponsors
- Role of process observers.

The assessments were collaboratively planned and organised within the pilot timeframe as a three-staged approach (Figure 6). The process for engaging with health service organisations included:

1. A schedule of assessments was developed for each Level 2 pilot health service organisation.
2. Assessment teams were assigned to each health service organisation.
3. The assessment team developed a close working relationship with the pilot site staff to ensure that the scope of clinical trial services was captured. The assessment team also provided support for the collation of key documentation and answered questions about the assessment process.
4. The assessment team prepared an accreditation assessment plan for each health service organisation, in collaboration with the nominated staff members.
5. The assessment team reviewed key governance documentation ahead of each accreditation assessment.
6. The assessment team conducted remote assessments over 1.5 days.
7. The assessment team provided a verbal report to each health service organisation at the conclusion of site assessments.
8. The assessment team provided scorecards and detailed reports providing the assessment outcome against each action and overall for the health service organisation.

Figure 6: Accreditation assessment stages of engagement



HSOs – Health service organisations

Organisational information and sampling

Contextual information for each health service organisation was required by the assessment team included but was not limited to:

- Current organisational chart
- Site address/es
- Clinical trial phase
- Clinical trial name
- Department or specialisation in which the trial is being conducted
- Sponsor type and sponsor name
- Name and position of principal investigators
- Number of staff allocated to the trial
- Number of patients in the trial
- Number of Aboriginal and Torres Strait Islander patients in the trial.

The information was assessed and prioritised to optimise the representation of all clinical trial services across multiple clinical departments and the clinical trials underway. For the purpose of the pilot a sample of six clinical trials for each pilot site were selected. The sampling process took into account the trial phase; number of participants; clinical department specialisation; sponsor type and investigators.

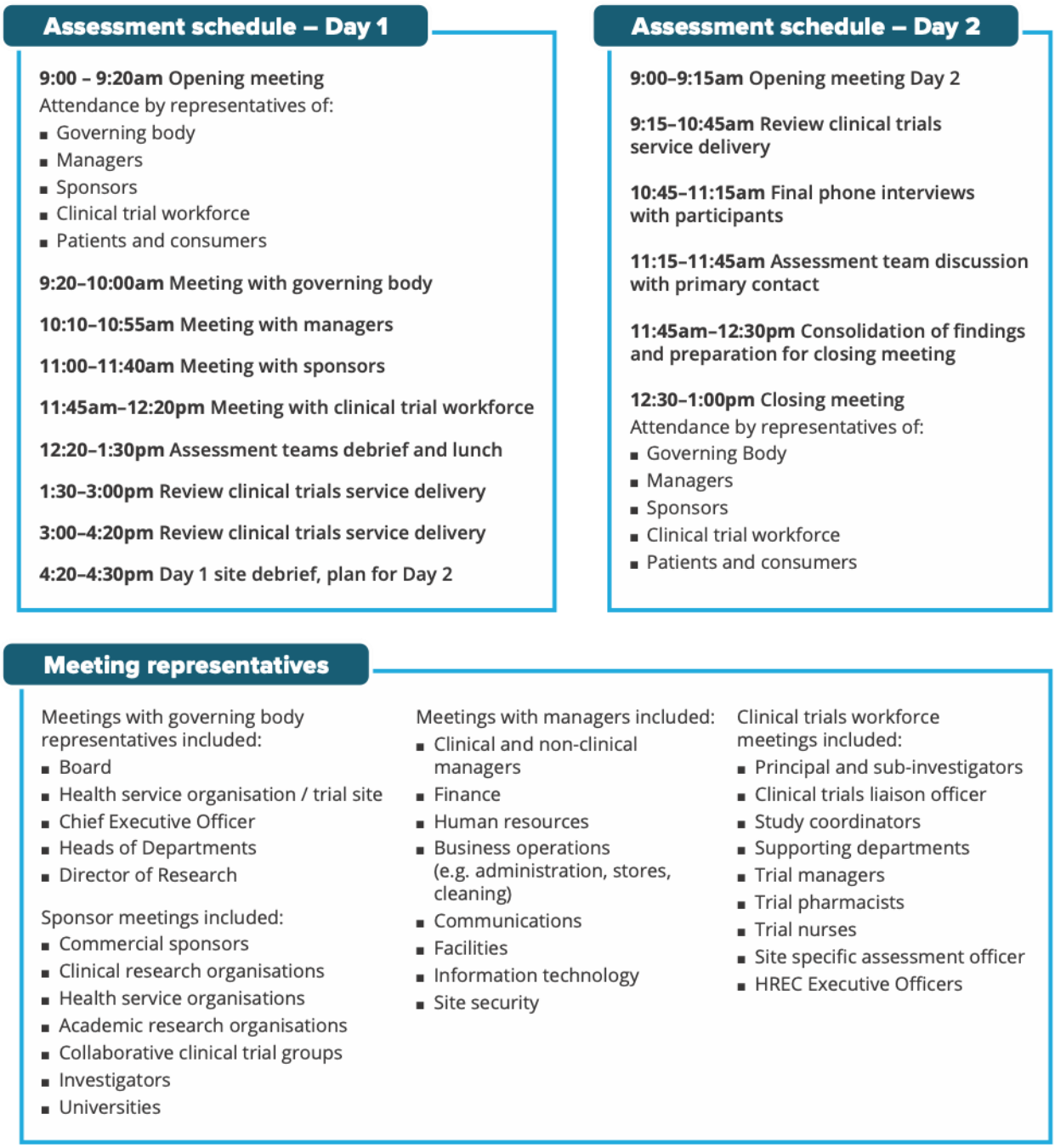
Due to the pilot timeframe, several health service organisations chose to provide the accreditation team with a selection of clinical trials from which to draw a sample for the assessment. A small number of sites were unable to provide more than six clinical trials to sample.* Health service organisations understood that following the pilot, it will be necessary for clinical trials services to accurately provide information about all clinical trial services and instances of clinical trials.

Assessment plan

Accreditation assessment planning commenced (at least) six weeks prior to the pilot accreditation assessment date, commencing with contact by the assessors requesting the health service organisation contextual information. The assessment team developed resources to assist them collate the contextual information including: a contextual information spreadsheet; an assessment plan template; a collated scorecard and a report template. This mitigated the risk of missing or requesting information multiple times. The assessment was conducted over two days and assessment team provided support and guidance to all participating health service organisations throughout the preparation period. The first pilot site was assessed on 20 October 2020 and the final site was assessed on 16 March 2021. A fact sheet providing an overview of the site accreditation assessment process is provided in Figure 7.

* Following implementation of the Governance Framework, health services will be required to provide the full list of all clinical trials being conducted to enable the accrediting agency to make a fully informed selection of trials to sample.

Figure 7: Assessment process – fact sheet for health service organisations



The assessment process

Prior to, and during the virtual site inspection, the assessment team reviewed policies, procedures, trial protocols, HREC approvals, contracts, and relevant records. A critical component of the accreditation assessment process were interviews with key stakeholders including the governing body, clinical and non-clinical mangers, sponsors, clinical trial workforce, patients and consumers.

The accreditation team used flexible methods of communication to accommodate each health service organisation's information and communication technology (ICT) preferences, such as, Microsoft Teams, Zoom and file sharing platforms such as Dropbox and SharePoint. Trial participants were interviewed by phone.

Assessment against the maturity scale

Pilot sites comprising a network of health service organisations with a single governing body such as Ramsay Health Care were assessed as a single entity. For those networks such as the Victorian Clinical Trial Research Support Service, comprising several public entities, each with their own governing body, a sample of health service organisations (two) underwent the accreditation assessment. Consequently, 15 of the 33 health service organisations were assessed on a maturity scale against the actions within the Governance Framework. The mean score for each action was calculated to determine the overall maturity rating for the health service organisation (Table 9).

Table 9: Maturity level and rating scale

Qualitative value	Numerical value	
Established systems: The Accreditation Assessment Team reviews evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation.	3.0	3
Growing systems: The Assessment Team reviews evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps.	2.0–2.99	2
Initial systems: The evidence reviewed by the Assessment Team demonstrates that the requirements of the action are yet to be commenced or implemented.	1.0–1.99	1

Input 8: Cost estimate tool

Costs estimates were developed based on the Office of Best Practice Regulation compliance costing tool. This tool provides an automated and standard process for quantifying regulatory costs on business, community organisation and individuals using an activity-based costing methodology.

Cost categories for compliance with the Governance Framework included estimates of compliance costs; implementation costs and additional costs. Table 10 itemises the categories and cost items. Cost data for each item were estimated as one-off costs and recurring costs. All key contacts were encouraged to test their costings with their site business units and seek acceptance for their cost estimates by senior management.

Table 10: Cost items, cost categories and descriptions

Cost items		Description
Category: Implementation costs		
1	Policies, procedures, tools and resources	Estimated cost of developing and updating policies, procedures, tools and resources to support implementation of the Governance Framework annually
2	Record keeping	Estimated cost associated with record keeping for compliance with the Governance Framework annually per trial – please list the nature of the costs

Cost items		Description
3	Staff training	Estimated cost of training staff in their roles and responsibilities annually to comply with the Governance Framework:
Category: Compliance costs		
4	Training in Good Clinical Practice	Estimated costs of training staff in Good Clinical Practice, annually
5	Notification/education/training	Estimated costs associated with notification/ education/training for compliance with the Governance Framework
6a	IT infrastructure	Estimated costs associated with IT infrastructure for compliance with the Governance Framework
6b	Data collection tools	Estimated costs associated with data collection tools for compliance with the Governance Framework
6c	Secure storage systems for record	Estimated costs associated with secure storage systems for records for compliance with the Governance Framework
6d	Secure storage systems for study/drug/device	Estimated costs associated with secure storage systems for study drug/device for compliance with the Governance Framework
6e	Education and training resources	Estimated costs associated with education and training resources for compliance with the Governance Framework
6f	Clinical trial work spaces	Estimated costs associated with clinical trial work spaces for compliance with the Governance Framework
6g	Signage/instructions	Estimated costs associated with signage/instructions within the health service organisation for compliance with the Governance Framework
6h	Maintenance costs	Estimated costs associated with maintenance for compliance with the Governance Framework
6i	Other	Other compliance related costs
Category: Additional data		
7	Effort to review	Hours spent on preliminary review/gap analysis
8	Effort to update processes	Estimated hours to update administrative processes such as committee structures, reporting schedules, and working groups
9	Other direct/indirect costs	Other estimated direct/indirect costs, either one-off or recurrent, anticipated from implementing the Governance Framework

Cost items		Description
10	Costs for engaging consumers	Additional estimated costs associated with engaging consumers in implementing the Governance Framework

Input 9: Post-pilot workshop

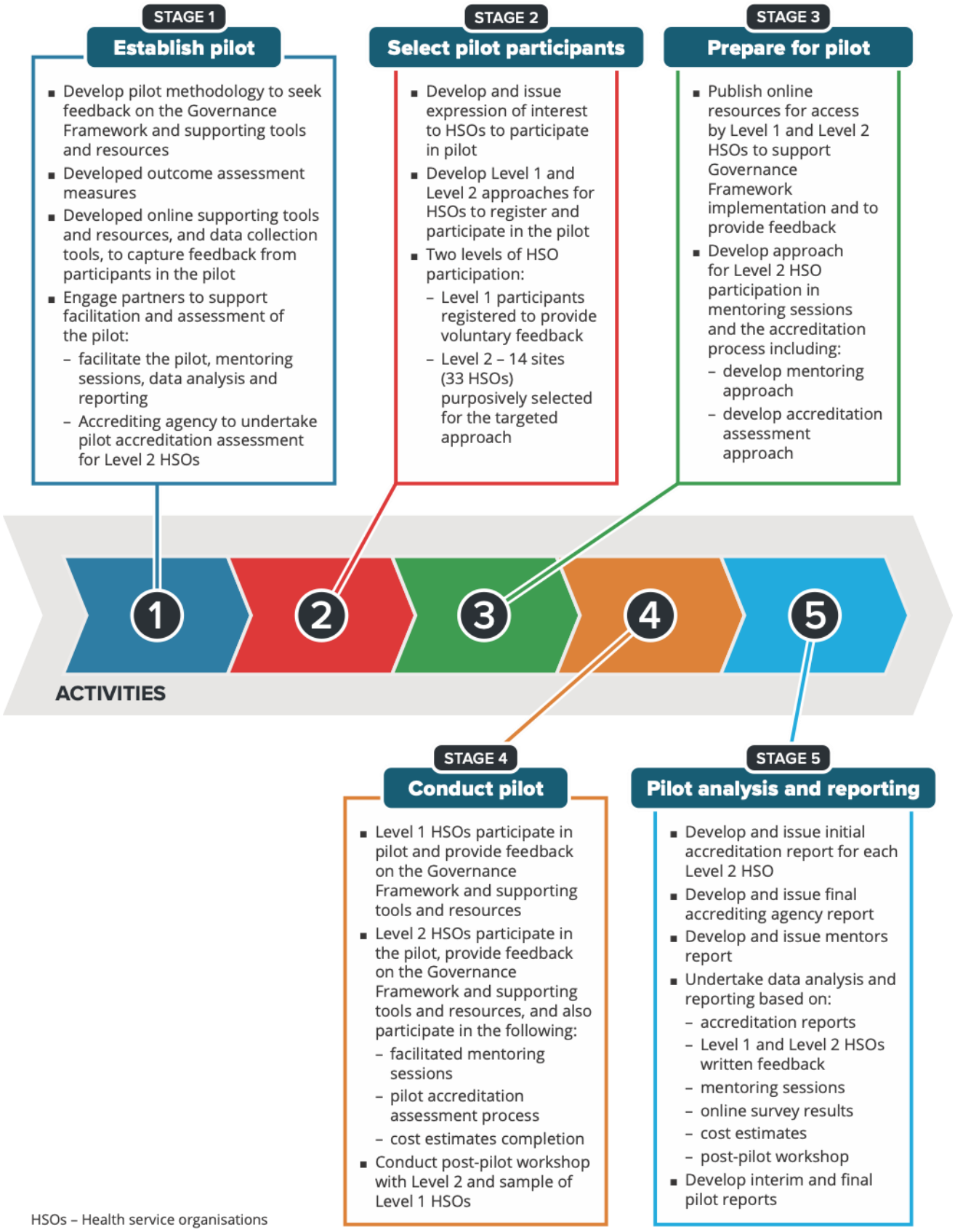
All Level 1 and Level 2 pilot participants were invited to attend the on-line post-pilot workshops. The purpose of the workshops was to provide an opportunity to share insights gained through the pilot process and present insights from the on-line survey, mentoring, pilot accreditation assessment process and, to seek further feedback on the Governance Framework and its associated tools and resources. The workshops provided the opportunity to share experiences of pilot participation. The post-pilot workshops were structured in four parts:

- Part one: insights from the online pilot survey
- Part two: insights from the mentoring process
- Part three: insights from the pilot accreditation assessments
- Part four: discussion on the tools and resources developed to support implementation of the Governance Framework.

Pilot activities

The pilot was conducted as a five-staged process (Figure 8). Following the receipt of written agreement by Level 2 health service organisations chief executive officers and commencement of the pilot, mentors contacted the pilot sites to schedule accreditation assessment date and the mentoring schedule. All resources were released via the Commission website and supported by a series of webinars on the web-based tools and resources. Over 300 stakeholders attended these webinars and at 31 March 2021, the on-line training was accessed via the Commission website 358 times. The schedule of activities is provided at Table 11.

Figure 8: Five-stage approach to National Clinical Trials Governance Framework pilot



HSOs – Health service organisations

Table 11: Schedule of activities

Schedule of activities	Level 2 health service organisations													
	Royal Brisbane and Women's Hospital	Royal Darwin Hospital	Royal Hobart Hospital	Royal Adelaide Hospital / The Queen Elizabeth Hospital	Orange Health Service	Canberra Hospital	Perth Children's Hospital	Ramsay Health Care	Townsville Hospital and Health Service	St Vincent's Health Network	Royal Victorian Eye and Ear Hospital	Victorian Clinical Trials Research Support Service	Alfred Health	Sydney Local Health District
Initial contact with site	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20	1 Sep 20
Mentoring session #1	24 Sep 20	22 Sep 20	17 Sep 20	Not taken up	6 Oct 20	28 Sep 20	24 Sep 20	6 Oct 20	21 Sep 20	25 Sep 20	23 Sep 20	7 Oct 20	23 Nov 20	28 Jan 21
Pre-assessment mentoring sessions #2–#5	From 1 Oct 20	From 12 Oct 20	From 30 Sep 20	Not taken up	From 16 Oct 20	From 12 Oct 20	From 13 Sep 20	From 16 Oct 20	From 16 Oct 20	From 15 Oct 20	From 21 Oct 20	From 9 Dec 20	From 20 Jan 21	From 4 Feb 21
Accreditation assessment	20 Oct 20	27 Oct 20	27 Oct 20	3 Nov 20	3 Nov 20	10 Nov 20	10 Nov 20	17 Nov 20	17 Nov 20	8 Dec 20	8 Dec 20	9 Feb 21 (Bendigo) 16 Feb 21 (Barwon)	16 Mar 21	3 Mar 21
Debrief mentoring discussion	Within 1–2 days post accreditation assessment													
Site report due	2 Nov 20	9 Nov 20	9 Nov 20	16 Nov 20	16 Nov 20	23 Nov 20	23 Nov 20	30 Nov 20	30 Nov 20	21 Dec 20	21 Dec 20	22 Feb / 29 Feb 21	29 Feb 21	16 Mar 21
Final mentoring sessions #6–#7	Within 1–2 weeks post site report receipt													
Post pilot workshop	18 Mar 21 (Level 2 sites)													

Pilot outputs

Table 12 provides a summary of the pilot outputs and the data sources used to evaluate the pilot by Level 1 and Level 2 pilot sites.

Table 12: Pilot outputs by Level 1 and Level 2 health service organisations

No.	Pilot outputs	Participating health service organisations	
		Level 1	Level 2
1	**On-line survey** On-line survey comprised of 85 questions used to capture feedback on the Governance Framework and supporting tools and resources (inputs 1–5).	✓	✓
2	**Mentoring insights** Report which captured the feedback, learnings and insights from health service organisations through facilitated mentoring, regarding their capacity to meet the actions within the Governance Framework.	✗	✓
3	**Accrediting agency insights** An over-arching accreditation report regarding feedback and insights by the accrediting agency in the assessment of Level 2 health service organisations.	✗	✓
4	**Health service organisation accreditation assessment reports** Accreditation reports for each Level 2 health service organisation which provides assessment results for each action item in the Governance Framework.	✗	✓
5	**Evidence from health service organisation self-assessment and accrediting agency reports** Reports for each Level 2 health service organisation which maps the accrediting agency's rating and evidence provided in the accrediting agency reports (Output 4) against each action in the Governance Framework against health service organisation's self-assessment rating.	✗	✓
6	**Written submissions** Direct written submission or feedback regarding the Governance Framework and supporting tools to the Commission (process not formalised).	✓	✓
7	**Post-pilot workshop feedback** Post-pilot workshop feedback report that provides summary of learnings and feedback from the post-pilot workshop conducted with Level 1 and Level 2 health service organisations.	✓	✓

No.	Pilot outputs	Participating health service organisations	
		Level 1	Level 2
8	**Cost impact report** A report that provides results from the cost estimates tool where health service organisations provided cost estimates for implementing and complying with the Governance Framework, including one-off and ongoing incremental costs.	✘	✓

Output 1: Online survey

Online survey participants

The online survey was accessed 103 times. Of these, 70 participants partially completed the survey and 38 participants provided a full response. All Level 2 participating health service organisations provided at least one response. All states and territories were represented in the responses received. The largest number of respondents were from within NSW (21 of 70) and Victoria (21 of 70). Fifty-one of the 70 respondents were from public health service organisations.

Forty-six of the 70 survey respondents (66%) were from metropolitan health service organisations, and 23 of the 70 (33%) respondents were from regional or rural health service organisations.

Of the 70 respondents, 47 represented health service organisations accredited to the NSQHS Standards (1st or 2nd edition); 4 respondents represented organisations that were not accredited to the NSQHS Standards and 19 respondents did not know their accreditation status.

The most common roles held by those responding to the survey on behalf of their health service organisation were the trial managers, trial coordinators, research governance officers and clinical or non-clinical managers. Table 13 provides the survey respondents by service type; Table 14 provides survey respondents by state and territory; Table 15 provides survey respondents by geographic location; Table 16 provides survey respondents by health service organisation accreditation status to either NSQHS Standards version 1 or 2 and Table 17 provides the survey respondents by role.

Table 13: Number of survey participants by type of service

Domain	Detail	No. survey respondents*		
		Level 1	Level 2	TOTAL
Type of service	Public hospital	16	35	51
	Private hospital	4	2	6
	Day procedure	1	–	1
	Other (NFP, Research Institute, University)	12	–	12
TOTAL		**33**	**37**	**70**

Table 14: Number of survey participant numbers by state or territory

Domain	Detail	No. survey respondents*		
		Level 1	Level 2	TOTAL
State / Territory	ACT	1	1	2
	NSW	13	8	21
	NT	–	3	3
	QLD	5	5	10
	SA	–	4	4
	TAS	1	2	3
	VIC	11	10	21
	WA	2	4	6
TOTAL		**33**	**37**	**70**

* Note that there may be more than one survey participant from each participating organisation.

Table 15: Number of survey participants by geographic location

Domain	Detail	No. survey respondents*		
		Level 1	Level 2	TOTAL
Geographic location	Metropolitan	23	23	46
	Regional	8	14	22
	Rural	1	-	1
	Not stated	1	-	1
TOTAL		**33**	**37**	**70**

Table 16: Number of survey participants by health service organisation accreditation status

Domain	Detail	No. survey respondents*		
		Level 1	Level 2	TOTAL
Accreditation status	NSQHS Standards v1	7	19	26
	NSQHS Standards v2	12	9	21
	Not accredited	4	-	4
	Don't know	10	9	19
TOTAL		**33**	**37**	**70**

* Note that there may be more than one survey participant from each participating organisation.

Table 17: Number of survey participant by role (n=70 respondents)

Survey participants' role	(n = 70)
Academic/university academic	1
Administration Officer	2
Associate/sub investigator	1
Chief Executive Officer	1
Clinical Trials Liaison Officer	4
Director of research	2
Head of Departments	3
HREC Executive Officer	1
Managers (Clinical & non-clinical)	5
Other	21
Principal investigator	3
Research Governance Officer	9
Safety and quality officers	3
Trial coordinator	7
Trial manager	6
Trial support officer	1

Output 2: Written submissions

The Commission received 15 written submissions from 12 organisations. The content of all submissions have been tabulated (Addendum 1) and addressed either through incorporation into the revised Governance Framework and fact sheets, enhancements of the web-based tools or the development of additional tools such as the accreditation assessor training guide. The Commission met with a number of key stakeholders throughout the pilot process to discuss their submissions and respond to questions.

The majority of written responses (9 out of 15) were submitted by public health service organisations. Three written responses were submitted by state and territory departments of health. Two written submissions were submitted by national and state-wide peak bodies. One written response was received from a private health service organisation.

Health service organisations that provided written submissions were located in NSW, NT, QLD and VIC.

Output 3: Mentoring support

Up to seven mentoring sessions were available to participating Level 2 health service organisations. Thirty-one of the 33 Level 2 health service organisations, participated in three mentoring sessions. Two health service organisations requested only one mentoring session. The roles held by participants varied between health service organisations, and commonly included executive, director, manager and project roles in areas including clinical trials, research, ethics, governance, quality, clinical services and business management. Table 18* provides a summary of attendance to mentoring sessions by health service organisation representatives. The list of attendees by role in the health service organisation is provided in Appendix 1.

In aggregate, 277 individuals attended at least mentoring session. The introductory (n=144) and pre-site assessment mentoring sessions (n=186) were most frequently attended, with lower attendances recorded at the post-site assessment mentoring sessions (n=29).

* Table 18, HSO2 and HSO 3 are related and reported as HSO16. HSO17 and HSO18 are related to and reported as HSO13.

Table 18: Number of mentoring session participants by health service organisation

Health Service Organisation	Introductory mentoring session	Pre-site assessment mentoring sessions	Post-site assessment mentoring session	Total number of attendances at mentoring sessions	No. of participants that attended at least 1 mentoring session
HSO1	7	0	0	7	7
HSO4	5	37	2	44	37
HSO5	13	3	2	18	13
HSO6	28	26	1	55	51
HSO7	8	3	1	12	8
HSO8	0	0	2	2	2
HSO9	7	4	2	13	5
HSO10	10	10	3	23	12
HSO11	8	2	2	12	8
HSO12	4	3	1	8	4
HSO13	25	30	0	55	46
HSO14	14	24	0	38	35
HSO15	6	2	2	10	6
HSO16	9	42	11	62	43
TOTAL	**144**	**186**	**29**	**346**	**277**

Output 4: Health service organisation assessments

Pilot accreditation assessments were conducted in 15 of the 33 participating health service organisations between October 2020 and March 2021. The first accreditation assessment, Royal Brisbane and Women's Hospital, was conducted onsite with all members (4) of the accreditation assessment team. Involvement of all assessors ensured contextual understanding of the clinical trial environment and ensured that all assessors were familiar with the application of the maturity rating scale.

The components of the assessment process were consistent across all pilot sites. Minor adjustments were made to accommodate local issues such as the availability of key cohort groups.

Site assessments commenced with a series of group meetings followed by the review of the clinical trial services across multiple clinical departments. Assessors reviewed at least 6 clinical trials per site and key governance documents for each clinical trial service prior to the assessment. These documents were accessed either through the Commissions clinical trials portal (self-assessment tool) or through the IHCA Citrix tool. Prior to conducting a virtual site inspection, the assessment team reviewed examples of evidence that related to individual clinical trials. Several health service organisations were prompted to provide additional evidence to demonstrate they had satisfied the requirements of the Governance Framework.

Health service organisations were advised of the initial findings at the closing meeting on Day 2 following which, detailed reports were prepared. A summary scorecard was provided with the maturity rating and detailed commentary on the evidence reviewed for each action. Reports were finalised and forwarded to chief executives within 8 working days of the assessment. While recommendations were not included, opportunities for improvement were highlighted for consideration by the health service organisation executive. A summary of the assessment outcomes against the maturity scale are provided in Table 19.

Table 19: Assessment outcome by health service organisation or network

Health service organisation	IHCA rating	Location type	Number of trials	Number of sites	NSQHS accredited version
HSO1	Established	Metropolitan	More than 300 (636)	Single-site	Version 2
HSO2	Initial	Regional	Less than 100 (50)	Single-site	Unknown
HSO3	Initial	Regional	Less than 100 (34)	Single-site	Version 2
HSO4	Growing	Metropolitan	100–300 (200)	Single-site	Version 1
HSO5	Growing	Regional	Less than 100 (25)	Single-site	Version 2
HSO6	Established	Metropolitan	100–300 (100)	Single-site	Version 1
HSO7	Growing	Various	100–300 (200)	Multi-site (14)	Version 2

Health service organisation	IHCA rating	Location type	Number of trials	Number of sites	NSQHS accredited version
HSO8	Growing	Metropolitan	More than 300 (550)	Multi-site (2)	Version 1
HSO9	Established	Metropolitan	100–300 (200)	Single-site	Version 2
HSO10	Established	Regional	Less than 100 (40)	Single-site	Version 1
HSO11	Growing	Metropolitan	Less than 100 (64)	Single-site	Version 2
HSO12	Initial	Metropolitan	Less than 100 (50)	Single-site	Version 1
HSO13	Growing	Metropolitan	100–300 (250)	Multi-site (2)	Version 1
HSO14	Established	Metropolitan	More than 300 (622)	Single-site	Version 1
HSO15	Growing	Regional	100-300 (100)	Single-site	Version 1

Output 5: Health service accreditation assessment reports

The accreditation assessment reports for 15 health service organisations that underwent the pilot accreditation assessment are provided at Addendum 1.

Output 6: Evidence mapping from health service organisations self-assessment and accrediting agency reports

Data from the assessment reports were collated in order to map the examples of evidence provided by health service organisations during the assessment process against the suggested evidence for each action as provided in the Governance Framework. Addendum 3 provides the accreditation assessment rating by action for each health service organisation and detailed evidence mapping of all examples of evidence provided by the participating health service organisations.

Case studies of selected health service organisations were developed (Section 5) and the Governance Framework updated with additional examples of evidence (Addendum 5). The health service self-assessment rating and the accreditation assessment rating, as a qualitative measure (Established, Growing or Initial) by action and health service organisation is provided in Table 20.

Table 20: Health service organisation self-assessment rating versus accreditation assessment team rating

Key	E	Established	G	Growing	I	Initial	M	Met	MM	Mostly met	PM	Partially met	NM	Not met	NS	Not stated

Region		National						NSW				VIC								QLD				WA		SA		TAS		ACT		NT	
Governance Framework		HSO7		HSO13		HSO17	HSO18	HSO5		HSO14		HSO1		HSO2		HSO3		HSO12		HSO9		HSO15		HSO6		HSO8		HSO11		HSO4		HSO10	
		Summary of IHCA Rating and Self-Rating by Level 2 Health Service Organisations as per legend																															
Action	Item	IHCA Rating	Self Rating	IHCA Rating	Self Rating			IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating	IHCA Rating	Self Rating
1. Clinical Trial Governance Standard																																	
Governance, leadership and culture	1.1	E	MM	E	M	MM	E	PM	E	NS	E	MM	G	NS	G	NS	G	M	E	MM	E	M	E	MM	G	NS	G	M	E	NS	E	NS
Organisational leadership	1.3	E	MM	E	M	PM	E	NM	E	NS	E	MM	G	NS	G	NS	I	MM	E	PM	E	MM	E	PM	E	NS	G	M	E	NS	E	NS
	1.4	E	MM	E	M	M	G	NM	E	NS	E	PM	I	NS	I	NS	G	PM	E	MM	E	MM	E	PM	E	NS	G	NM	E	NS	E	NS
	1.5	E	MM	E	M	PM	G	NM	E	NS	E	MM	G	NS	I	NS	G	PM	E	PM	E	M	E	MM	E	NS	G	NS	E	NS	E	NS
Clinical leadership	1.6	E	MM	E	M	MM	G	MM	E	NS	E	MM	G	NS	G	NS	G	PM	E	MM	E	M	E	PM	E	NS	G	NS	E	NS	E	NS
Policis and procedures	1.7	G	MM	G	M	M	G	NS	E	NS	E	MM	G	NS	G	NS	G	MM	E	MM	E	M	E	MM	G	NS	G	NS	E	NS	E	NS
Measurement and quality improvement	1.8	E	PM	E	M	NM	E	NS	E	NS	E	PM	I	NS	G	NS	I	PM	E	MM	E	MM	E	PM	G	NS	G	NS	G	NS	E	NS
	1.9	E	MM	E	M	NM	G	NS	E	NS	E	PM	I	NS	G	NS	I	NM	E	MM	E	M	E	PM	G	NS	G	M	G	NS	E	NS
Risk management	1.10	E	MM	E	M	PM	G	NS	E	NS	E	MM	G	NS	G	NS	G	MM	E	PM	E	M	E	PM	G	NS	G	M	G	NS	E	NS
Incident management systems and open disclosure	1.11	G	MM	E	M	PM	E	NS	E	NS	E	MM	G	NS	G	NS	G	MM	E	PM	G	M	E	PM	G	NS	G	M	G	NS	E	NS
	1.12	E	MM	E	M	NM	E	NS	E	NS	E	MM	G	NS	G	NS	I	MM	E	PM	E	M	E	PM	E	NS	G	M	E	NS	E	NS

Region		National					NSW				VIC								QLD				WA		SA		TAS		ACT		NT	
Feedback and complaints management	1.13	G	PM	G	MM	NS	G	NS	E	NS	E	PM	I	NS	I	NS	I	MM	E	NS	G	M	E	PM	G	NS	G	NS	G	NS	E	NS
	1.14	E	MM	E	M	M	G	NS	E	NS	E	MM	I	NS	I	NS	G	MM	E	NS	G	M	E	PM	G	NS	G	NS	G	NS	E	NS
Diversity and high-risk groups	1.15	E	MM	E	M	MM	G	NS	E	NS	E	MM	I	NS	I	NS	G	M	E	MM	E	M	E	PM	G	NS	G	NS	E	NS	E	NS
Healthcare records	1.16	E	MM	E	M	M	E	NS	E	NS	E	MM	G	NS	G	NS	I	PM	E	M	E	M	E	MM	G	NS	G	M	E	NS	E	NS
Safety and quality training	1.20	E	MM	E	M	NS	G	NS	E	NS	E	MM	G	NS	G	NS	G	M	E	MM	E	M	E	PM	E	NS	G	NS	E	NS	E	NS
Safe environment	1.29	G	MM	E	M	NS	G	NS	E	NS	E	M	G	NS	G	NS	I	MM	E	PM	E	M	E	M	E	NS	G	M	E	NS	E	NS
	1.33	E	M	E	M	MM	G	PM	E	NS	E	M	G	NS	G	NS	G	M	E	MM	E	M	E	M	E	NS	G	M	E	NS	E	NS
2. Partnering with Consumer Standards																																
Integrating governance systems into clinical trial service provision	2.1	E	PM	E	M	NS	G	NS	E	NS	E	PM	I	NS	G	NS	I	MM	E	PM	E	MM	E	MM	E	NS	G	NS	G	NS	E	NS
Applying quality improvement systems	2.2	E	MM	E	MM	NS	E	NS	E	NS	E	PM	I	NS	G	NS	I	NS	E	MM	E	MM	E	PM	G	NS	G	NS	G	NS	E	NS
Healthcare rights and informed consent	2.3	E	MM	E	M	M	G	NS	E	NS	E	PM	I	NS	G	NS	G	MM	E	MM	E	MM	E	MM	G	NS	E	NS	G	NS	E	NS
	2.4	E	MM	E	M	NS	E	NS	E	NS	E	MM	E	NS	E	NS	I	PM	E	MM	E	M	E	PM	E	NS	E	NS	E	NS	E	NS
	2.5	E	MM	E	M	NS	G	NS	E	NS	E	M	G	NS	E	NS	G	NM	E	MM	E	M	E	MM	E	NS	G	NS	E	NS	E	NS
Communication that supports effective partnerships	2.8	E	MM	E	M	NS	E	NS	E	NS	E	MM	G	NS	G	NS	G	MM	E	MM	E	M	E	MM	E	NS	G	NS	G	NS	E	NS
	2.9	E	MM	E	M	NS	G	NS	E	NS	E	MM	G	NS	I	NS	I	PM	E	NS	G	PM	E	MM	I	NS	G	NS	G	NS	E	NS
	2.10	E	MM	E	M	NS	G	NS	E	NS	E	MM	G	NS	I	NS	I	PM	E	NS	E	M	E	MM	I	NS	G	NS	G	NS	E	NS
Partnering with consumers in organisational design and governance	2.14	E	PM	E	MM	M	G	NS	E	NS	E	M	I	NS	I	NS	I	PM	E	NS	E	MM	E	MM	I	NS	G	NS	G	NS	E	NS

Output 7: Calculation of estimated business compliance costs

Cost estimates were self-reported by participating Level 2 health service organisations. Profile domains were constructed for each health service organisation to assess whether the cost estimates were associated with the characteristics of the service (Table 21). Using the available health service information, five domains and category values were assigned (Table 22).

Table 21: Health service organisation profile domains

Profile domain	Category values	Data source
IHCA rating	Initial, Growing, Established	IHCA Assessment Reports
Location type	Metropolitan, Regional	Expression of Interest Register for National Clinical Trials Governance Framework Pilot
Number of trials	Less than 100, 100–300, More than 300	
Number of sites	Single-site, Multi-site	
NSQHS accredited version	Version 1, Version 2	

Table 22: Assigned profile domain by health service organisation

Health service organisation	IHCA rating	Location type	Number of trials	Number of sites	NSQHS accredited version
HSO1	Established	Metropolitan	More than 300 (636)	Single-site	Version 2
HSO2	Initial	Regional	Less than 100 (50)	Single-site	Unknown
HSO3	Initial	Regional	Less than 100 (34)	Single-site	Version 2
HSO4	Growing	Metropolitan	100–300 (200)	Single-site	Version 1
HSO5	Growing	Regional	Less than 100 (25)	Single-site	Version 2
HSO6	Established	Metropolitan	100–300 (100)	Single-site	Version 1
HSO7	Growing	Various	100–300 (200)	Multi-site (14)	Version 2
HSO8	Growing	Metropolitan	More than 300 (550)	Multi-site (2)	Version 1

Health service organisation	IHCA rating	Location type	Number of trials	Number of sites	NSQHS accredited version
HSO9	Established	Metropolitan	100–300 (200)	Single-site	Version 2
HSO10	Established	Regional	Less than 100 (40)	Single-site	Version 1
HSO11	Growing	Metropolitan	Less than 100 (64)	Single-site	Version 2
HSO12	Initial	Metropolitan	Less than 100 (50)	Single-site	Version 1
HSO13	Growing	Metropolitan	100–300 (250)	Multi-site (2)	Version 1
HSO14	Established	Metropolitan	More than 300 (622)	Single-site	Version 1
HSO15	Growing	Regional	100-300 (100)	Single-site	Version 1

Costing analysis method

The set of 18 cost items reported via the cost estimate tool (Appendix 3) were grouped into ten cost groupings. The cost items and cost groupings were then categorised as implementation costs, compliance costs and additional costs (Table 23). The total one-off costs for implementation of the Governance Framework and recurrent costs, converted to a per annum cost, were then calculated and presented by health service organisation profile. A summary of compliance costs is provided at in Table 28.

Multiple statistical comparisons of high variability data were not possible due to small sample size. Cost items with no cost entries recorded, or with comments indicating that there were no additional costs associated with implementation of the Governance Framework, were entered into the consolidated spreadsheet as zero values.

Table 23: Cost items, cost groupings and cost categories

Ref #	Cost grouping	Cost item
Cost category: Implementation costs		
1	Policies and Procedures	Policies, procedures, tools and resources
2	Record Keeping	Record keeping
3	Training	Staff training
Cost category: Compliance costs		
4	Training	Training in Good Clinical Practice
		Notification/education/training
5	IT Infrastructure	IT infrastructure
		Data collection tools
		Secure storage systems for record
6	Physical Resources	Secure storage systems for study/drug/device
		Clinical trial work spaces
		Signage/instructions
		Maintenance costs
7	Education Resources	Education and training resources
8	Other	Other
Cost category: Additional data		
9	Pilot Participation Costs	Effort to review
		Effort to update processes
		Other direct/indirect costs
10	Consumer Engagement	Costs for engaging consumers in National Clinical Trials Governance Framework

Output 8: Post-pilot workshop feedback

Post-pilot workshop attendance

Two post-pilot workshops were conducted following the accreditation assessment of all pilot sites. Approximately 60 participants attended the Level 2 post-pilot workshop and 60 participants attended the Level 1 post-pilot workshop.

Method of analysis

Results from the post-pilot workshops were collated by:

- Engagement across the health service organisation
- Reflections on the accreditation process
- Resources to support implementation of the Governance Framework.

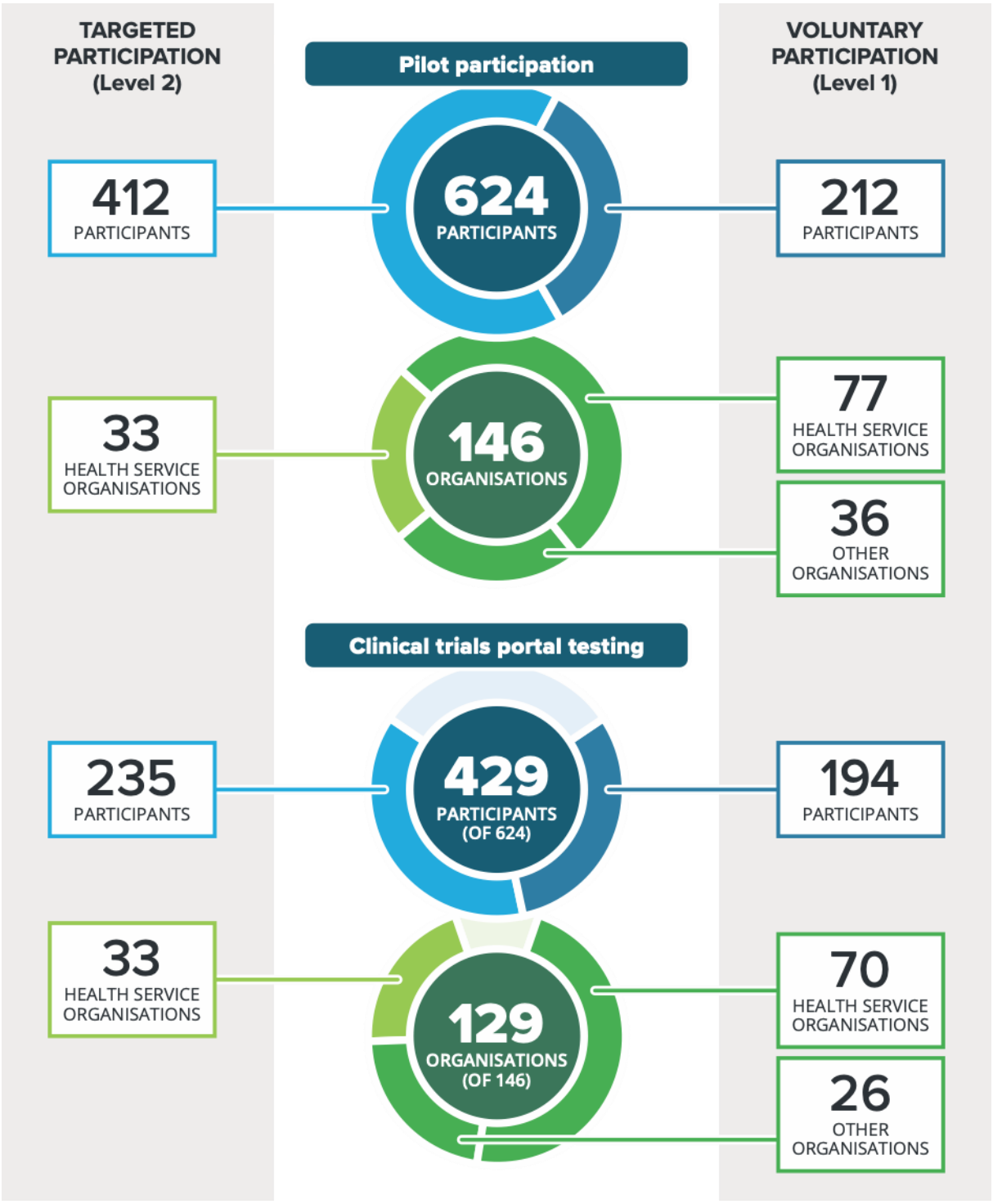
Participants had an opportunity to discuss their experience of participating in the pilot and provide additional feedback on the pilot. Additionally, participants were able to ask questions via the chat bar. Discussion during the post-pilot workshops was guided by the following questions:

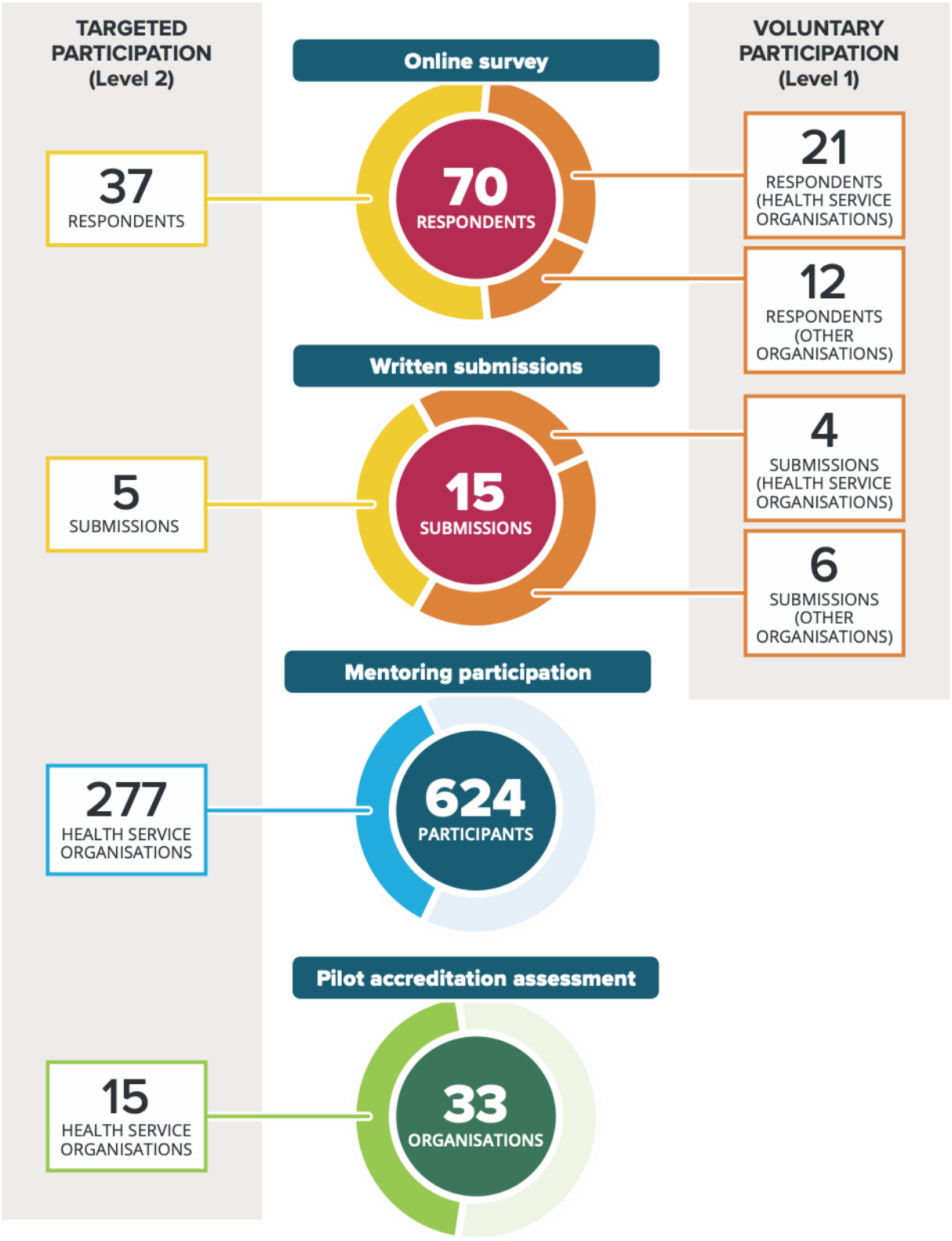
1. What would you recommend to sites, not involved in the pilot to help embed clinical trials into routine service provision?
2. How important are effective links between risk, safety and quality teams and clinical trials/ research teams for implementation of the Governance Framework?
3. Do you have any further feedback regarding how to embed clinical trials into routine services and accreditation processes?
4. Has the accreditation process further developed your health service organisation's understanding of how to integrate the Governance Framework?
5. How useful were the IHCA support tools to your organisation?
6. Which of the fact sheets and resources did your organisation use? Which of the fact sheets and resources were useful for your organisation?
7. Was the video tutorial explaining the Governance Framework and accreditation helpful? Was the webinar regarding use of the Clinical Trials portal helpful?
8. Do you think the online self-assessment tool as a shared resource will be useful to support your organisation implement the Governance Framework?
9. Do you think the online operational metrics tool as a shared resource will be useful to support your organisation implement the Governance Framework.

Section 3: Pilot outcomes

Outcomes

Figure II: Pilot participation




TARGETED PARTICIPATION (Level 2)
VOLUNTARY PARTICIPATION (Level 1)
Online survey
37
RESPONDENTS
70
RESPONDENTS
21
RESPONDENTS (HEALTH SERVICE ORGANISATIONS)
12
RESPONDENTS (OTHER ORGANISATIONS)
Written submissions
5
SUBMISSIONS
15
SUBMISSIONS
4
SUBMISSIONS (HEALTH SERVICE ORGANISATIONS)
6
SUBMISSIONS (OTHER ORGANISATIONS)
Mentoring participation
277
HEALTH SERVICE ORGANISATIONS
624
PARTICIPANTS
Pilot accreditation assessment
15
HEALTH SERVICE ORGANISATIONS
33
ORGANISATIONS

Fourteen sites comprising 33 health service organisations, including 412 individuals participated in the targeted pilot (Level 2) approach. Pilot sites were selected based on their geographic location; positioning within a Local Health District/Network; health service organisation specialisation; local population and whether or not they were public or private facility. These sites received mentoring and of these, 15 health services organisations underwent the pilot accreditation assessment. Another 212 individuals representing 113 health service and other organisations provided voluntary feedback on Governance Framework and the supporting tools and resources (Level 1). Overall, 624 individuals representing 146 organisations engaged in the pilot (Figure II).

The pilot outcomes reported in this section are derived from the qualitative content and thematic analysis of the survey data; observations from mentors; health service organisation accreditation outcomes; insights from the accreditation assessors and feedback on the supporting tools and resources. Quantified cost estimates are provided for each health service organisation for implementation and recurrent costs per annum.

Survey data were used to evaluate the pilot objectives and provide feedback on the Governance Framework and the supporting tools and resources (inputs 1, 2, 3, 4 and 5). A total of 70 respondents partially completed the survey and 38 respondents provided a full response. At least one participant from each Level 2 pilot site completed the survey.

Objective 1: Intent of the Governance Framework

Health service organisations conducting clinical trials understand the intent of the Governance Framework

Overall, 60 of 69 respondents (87%) of those who completed the online survey agreed, the intent of the Governance Framework is clear and easily understood (Figure 9). The views of Level 1 and Level 2 health service organisations were similar, with 29 of 32 pilot Level 1 survey participants and, 31 of 36 pilot Level 2 participants, agreeing that the intent of the Governance Framework is clear (Figure 10).

Figure 9: Survey reponses on the intent of the Governance Framework (Survey Question 8)

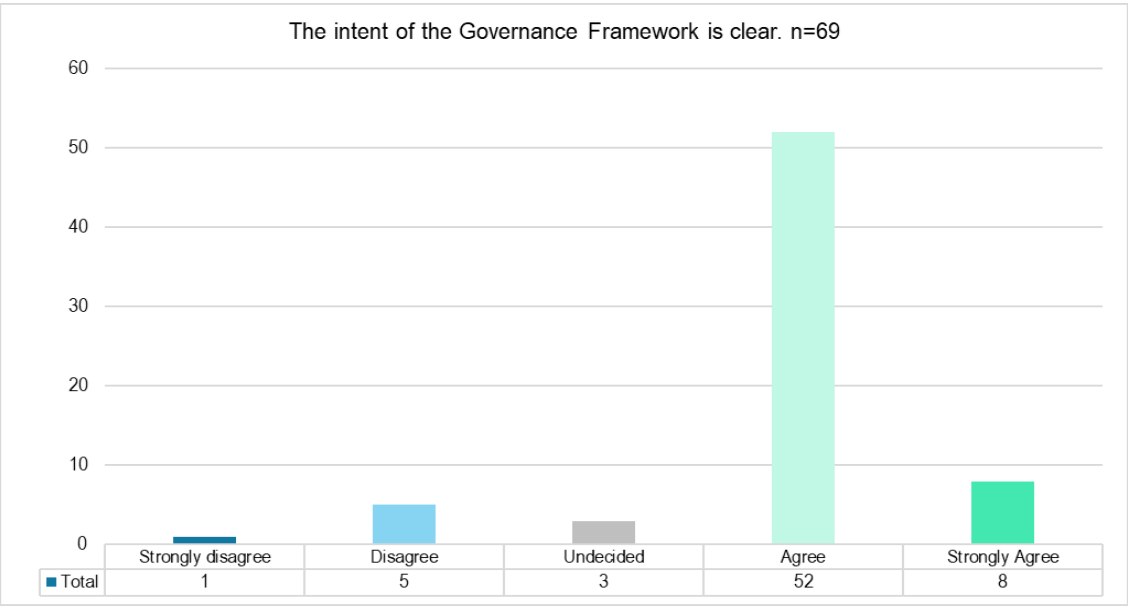
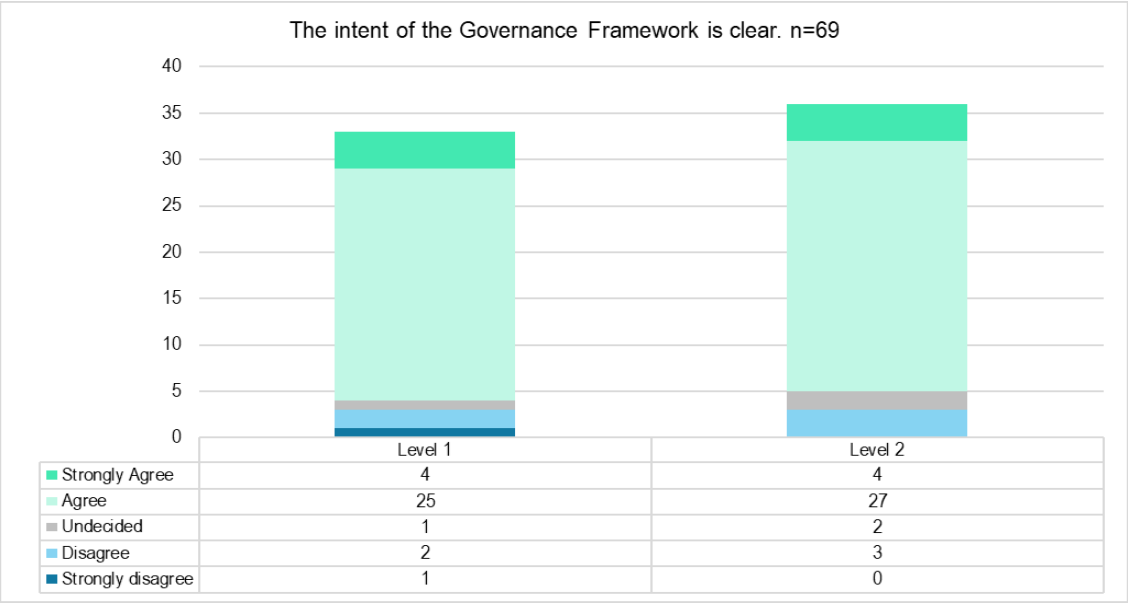


Figure 10: Survey responses on the intent of the Governance Framework, by Level 1 and Level 2 participants (Survey Question 8)



Thirty nine of the 46 survey participants providing a response to question 14, including 19 of 20 Level 1 participants and 20 of 26 Level 2 participants, responded that the intent of the Clinical Governance Standard is clear (Figures 11 and 12).

Figure 11: Survey responses on the intent of the Clinical Governance Standard (Survey Question 14)

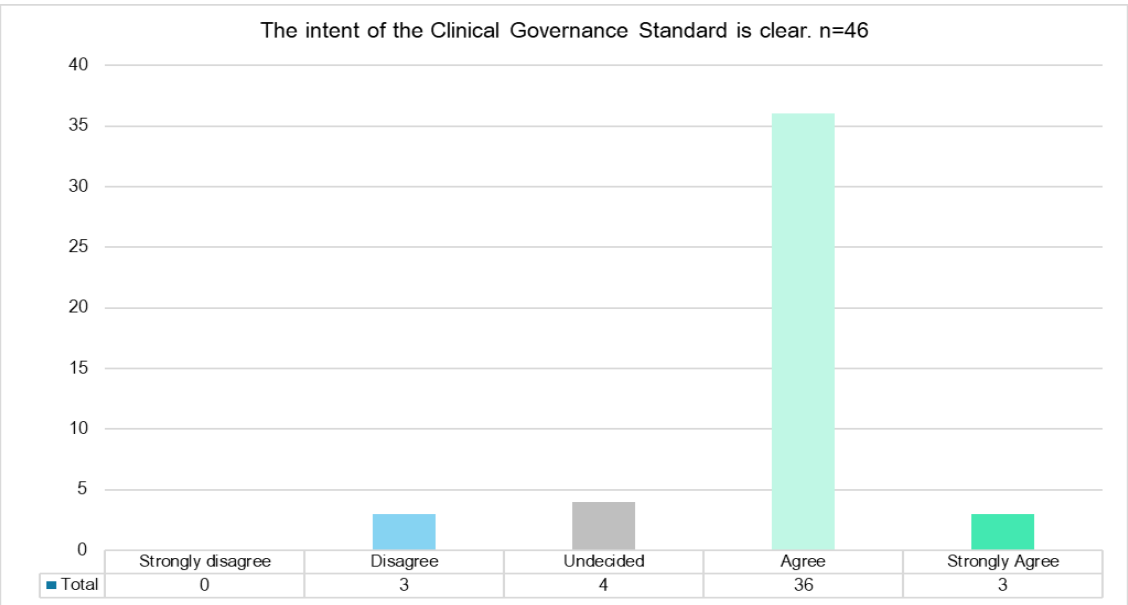
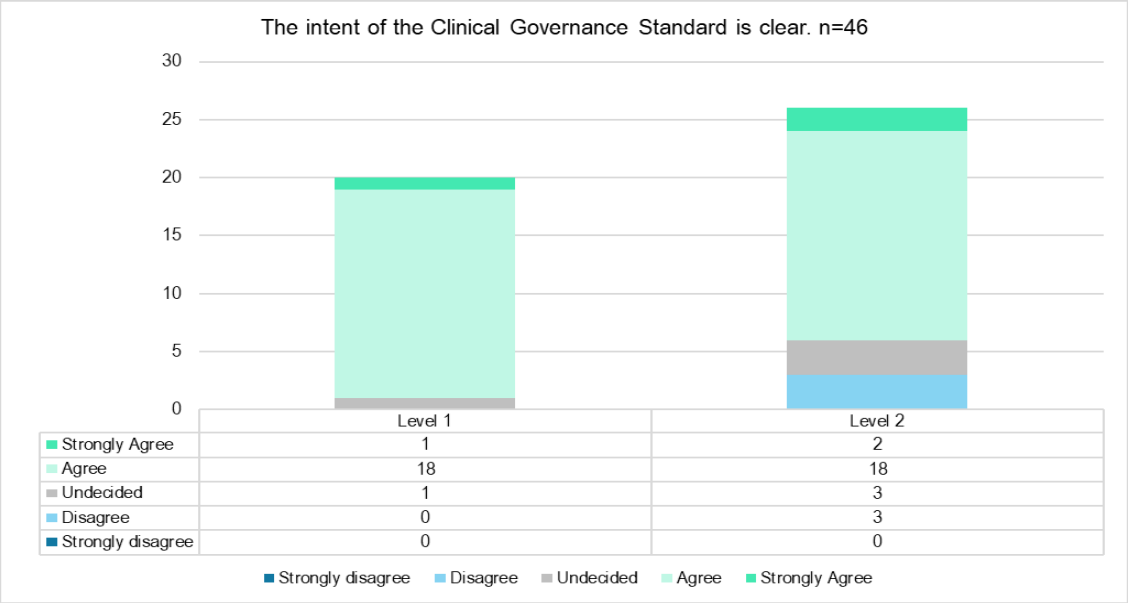


Figure 12: Rating on the intent of the Clinical Governance Standard, by Level 1 and Level 2 participants (Survey Question 14)



Thirty two of 35 survey respondents believed the intent of the Partnering with Consumers Standard is clear (Figure 13). Of these, 13 of 14 were Level 1 participants and 19 of 21 were Level 2 participants (Figure 14).

Figure 13: Rating on the intent of the Partnering with Consumers Standard, by all participants (Survey Question 55)

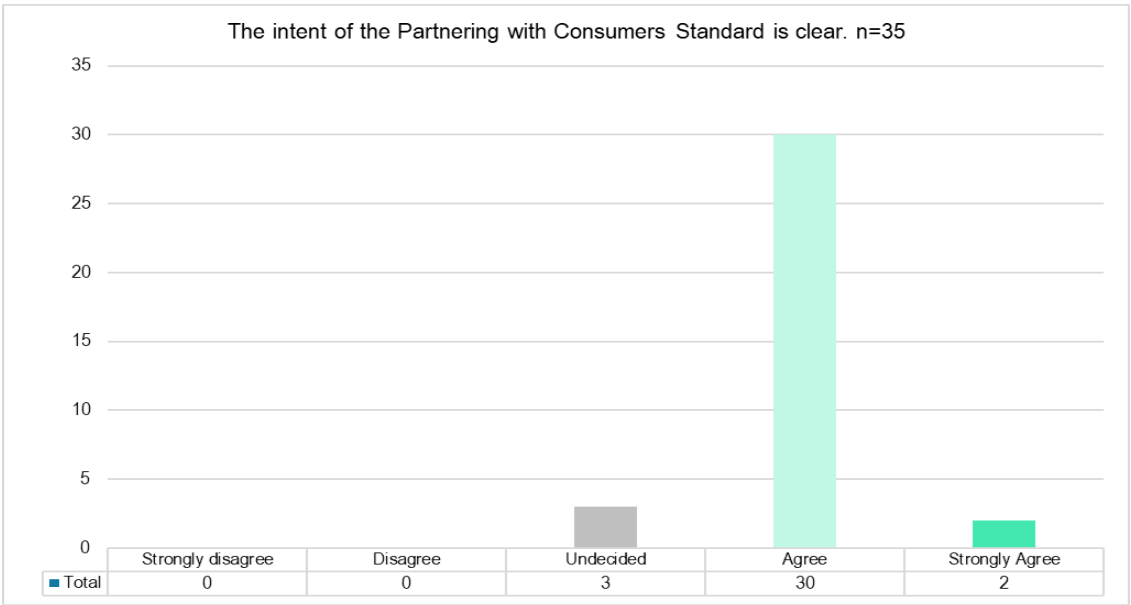
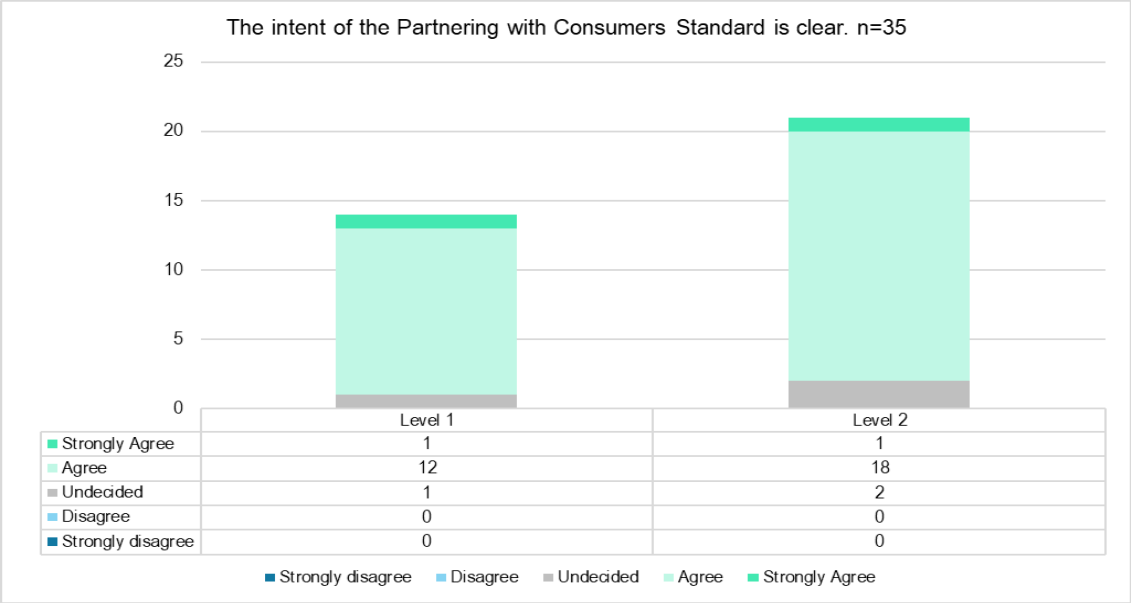


Figure 14: Rating on the intent of the Partnering with Consumers Standard, by Level 1 and Level 2 pilot participants (Survey Question 55)



While the overall intent of the Governance Framework was well understood, it was noted that the intent of each action required more clarity for some survey participants.

> "The intent of each action could be more specifically articulated"

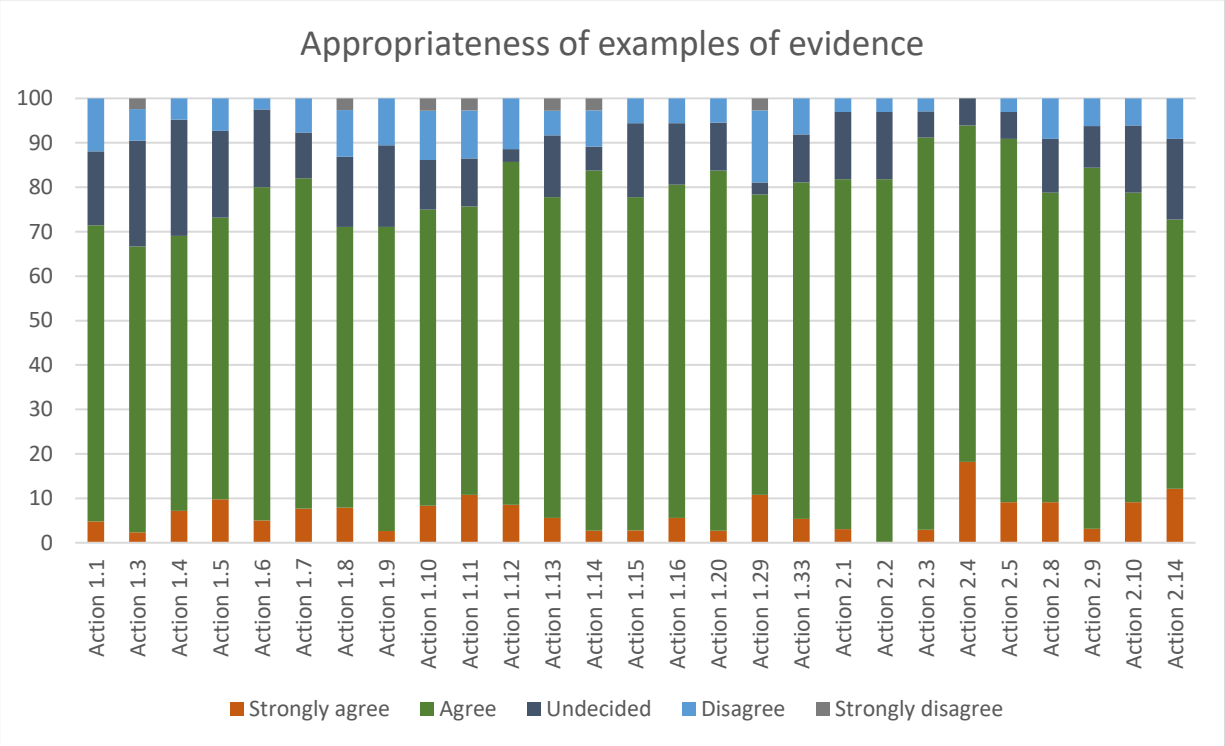
> "The key tasks and evidence required for each of the actions in Standards 1 & 2 are very good and clear. The overall intent of the Governance Framework and each of the Standards is clear, however the intent of each of the actions is not clear and could be expanded upon. The Governance Framework clearly describes the clinical governance requirements of health services against Standards 1 & 2"

Objective 2: The Governance Framework enables gaps in safety and quality for clinical trial service provision to be identified

The Governance Framework enables health service organisations to identify and address gaps in safety and quality for clinical trial service provision

Overall, the examples of evidence were found to be appropriate for all action items (Figure 15).

Figure 15: Appropriateness of examples of evidence for each of the action items in the Governance Framework



The actions for which survey participants were most undecided, where more than a third of respondents disagreed or were undecided about the appropriateness of examples of evidence, included:

- **Action 1.3**: The health service organisation establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality
- **Action 1.4**: The health service organisation implements and monitors strategies to meet the organisation's safety and quality priorities for Aboriginal and Torres Strait Islander people.

Objective 3: The Governance Framework is easily understood

The structure, sequence and format of the Governance Framework is logical and easily understood

While 39 of 65 of survey respondents agreed that the structure of the Governance Framework is easy to understand (Figure 16), 13 of 69 (20%) disagreed, and 13 of 65 respondents were undecided. The views of Level 1 and Level 2 health service organisations were similar with 58% of Level 1 participants (18 of 31) and 62% of Level 2 participants (21 of 34) agreeing that the structure of the Governance Framework is easy to understand (Figure 17).

Figure 16: Rating on the structure of the Governance Framework, by all participants (Survey Question 9)

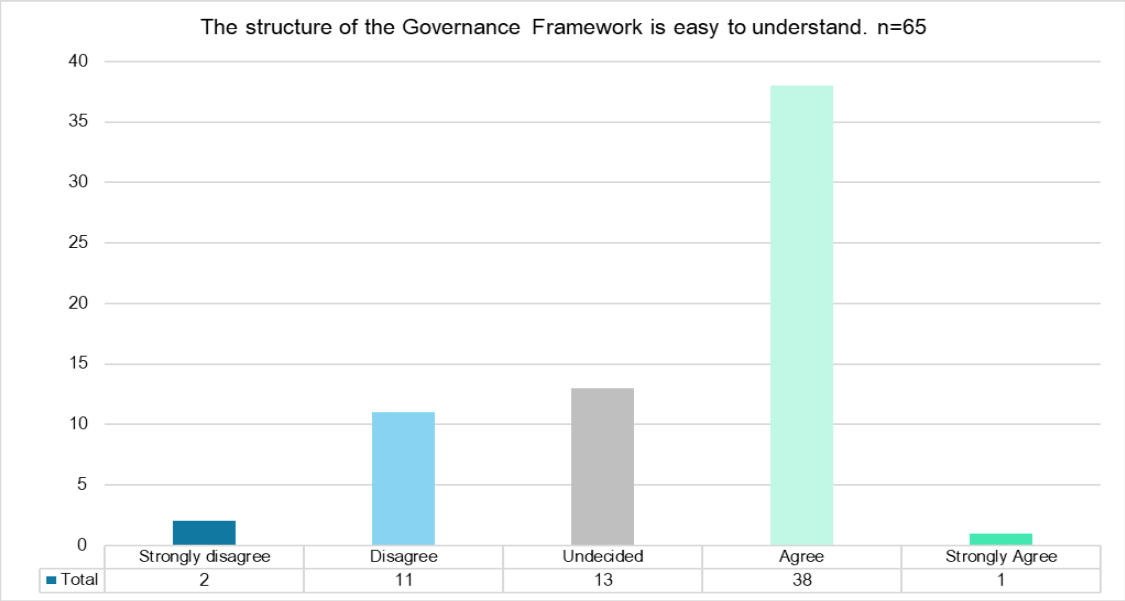
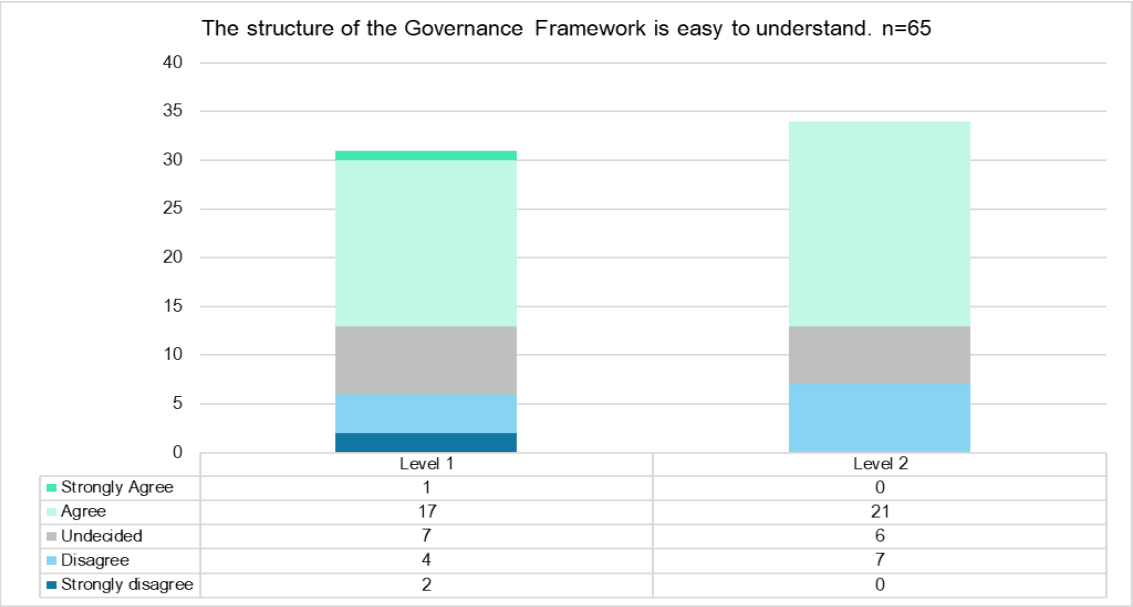


Figure 17: Rating on the structure of the Governance Framework, by Level 1 and Level 2 participants (Survey Question 9)



	Level 1	Level 2
Strongly Agree	1	0
Agree	17	21
Undecided	7	6
Disagree	4	7
Strongly disagree	2	0

Comments regarding the structure of the Governance included:

> "We found the Governance Framework and user guide documents were well-structured and clearly laid out, making navigation of the document easy. Of particular benefit was an outline of the supporting evidence required, which will enable researchers and the health service to understand how to meet the expectations and standards outlined within the Framework"

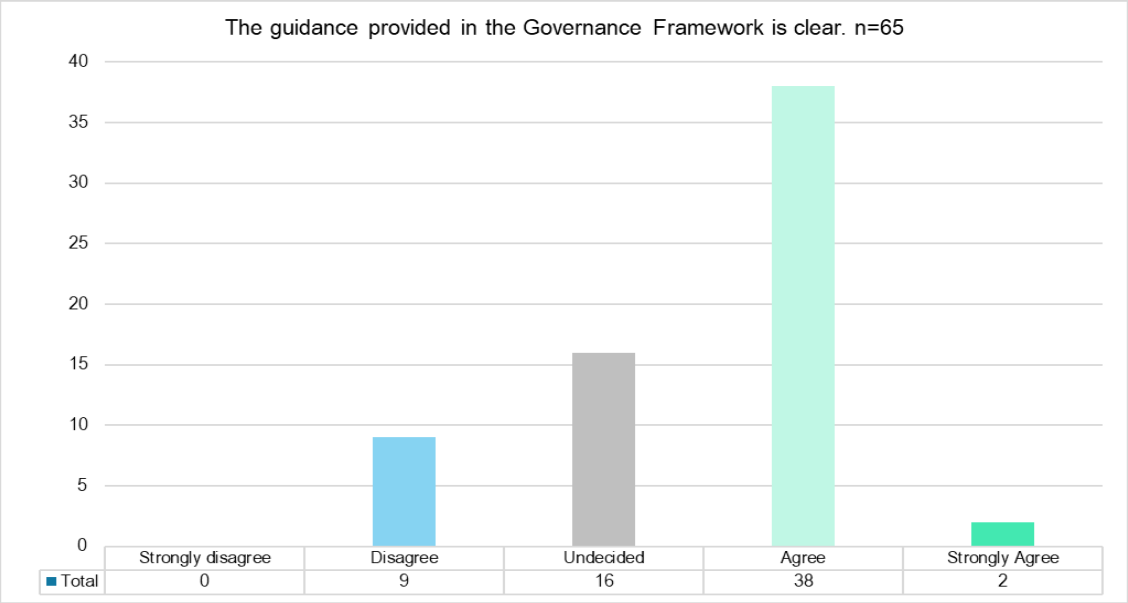
> "We believe that the intent of the Governance Framework is aspirational and appropriate, aiming to ensure excellence, safety and quality in delivery of clinical trial services."

Examples of comments from participants that did not find the structure of the Governance Framework easy to understand included:

> "A more succinct and structured Governance Framework document, which is targeted specifically at the establishment and conduct of clinical trials within an organisation. A lot of the information requested had no relevance to assessing of clinical trials are conducted in a safe environment and in a high-quality manner within an organisation"

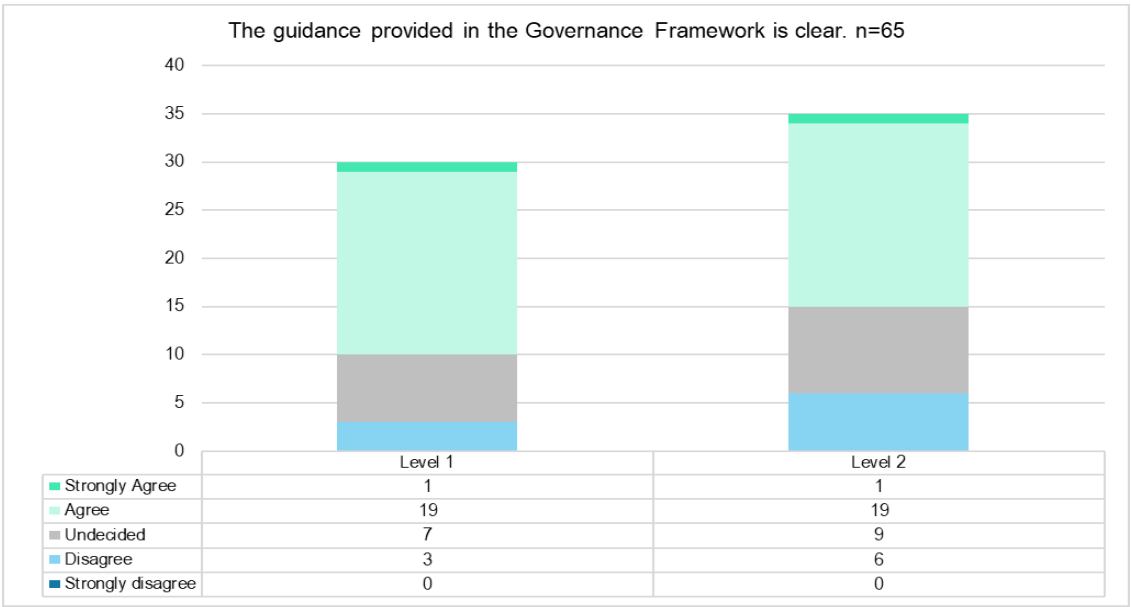
Sixty two percent of survey participants (40 of 65) agreed that the guidance provided in the Governance Framework is clear while 14 per cent (9 of 65) disagreed and 24% (16 of 65) were undecided (Figure 18).

Figure 18: Rating on the guidance provided in the Governance Framework, by all participants (Survey Question 10)



Sixty seven percent of Level 1 participants (20 of 30), and 57% of Level 2 participants (20 out of 35) agreed that the guidance provided in the Governance Framework is clear, with the remainder either disagreeing or undecided (Figure 19).

Figure 19: Rating on the guidance provided in the Governance Framework, by Level 1 and Level 2 participants (Survey Question 10)



A total of 72 per cent of survey respondents (33 of 46) reported they understood the requirements from their organisations for each of the actions in Standard 1: Clinical Governance (Figure 20). This includes 14 of 20 Level 1 participants and 19 of 26 Level 2 participants (Figure 21).

Figure 20: Response on understanding of health service organisations requirement for clinical trials for each action in the Clinical Governance Standard, by all participants (Survey Question 16)

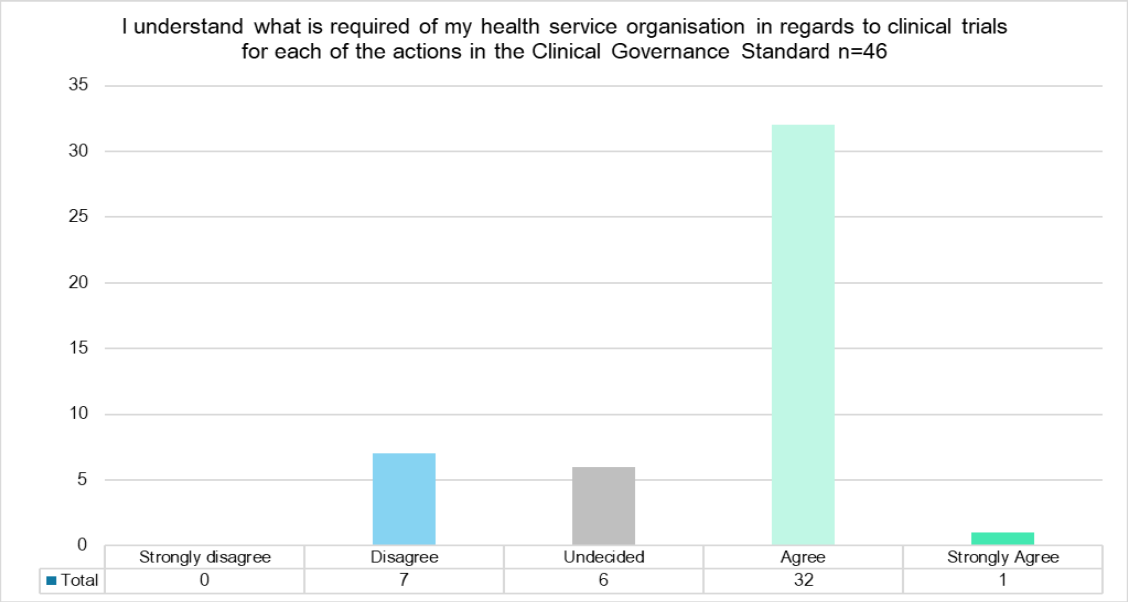
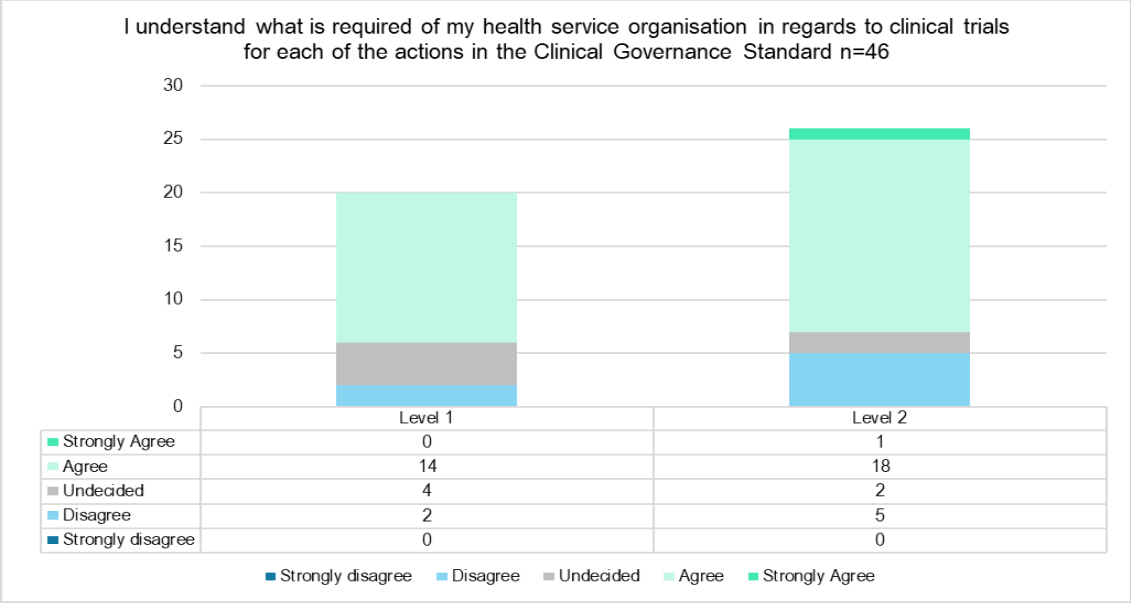


Figure 21: Response on understanding of health service organisations requirement for clinical trials for each action in the Clinical Governance Standard, by Level 1 and Level 2 participants (Survey Question 16)



Thirty of 35 survey respondents understood the requirements of their health service organisation for Standard 2: Partnering with Consumers in relation to clinical trial service provision (Figure 22). This includes 10 of 14 Level 1 respondents and 20 of 21 Level 2 respondents (Figure 23).

Figure 22: Response on understanding of health service organisations requirements for clinical trials for each actions in the Partnering with Consumers Standard, by all participants (Survey Question 57)

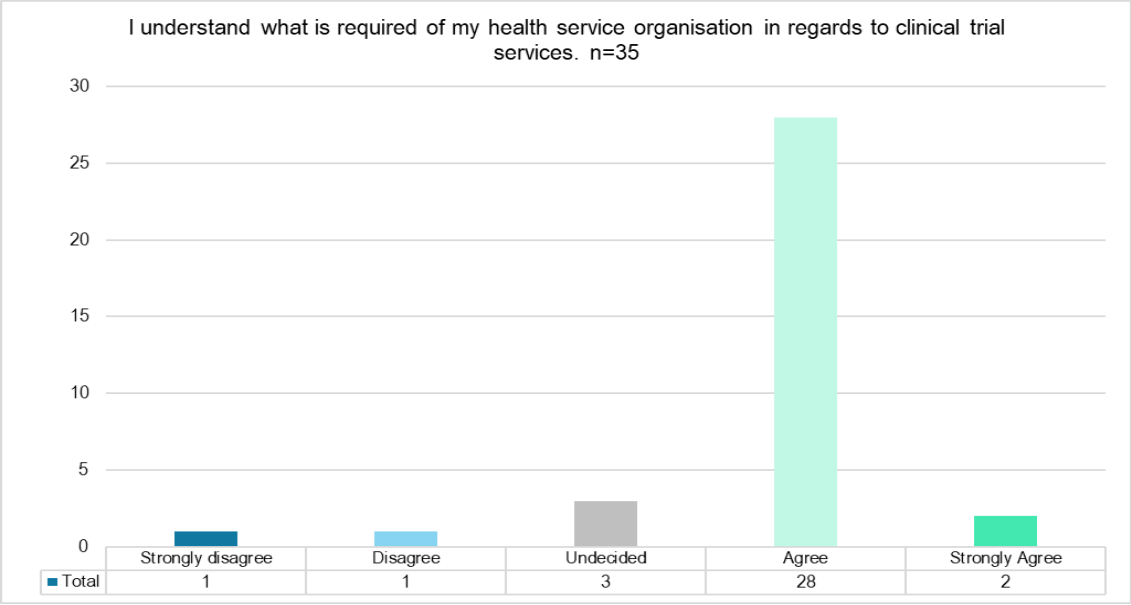
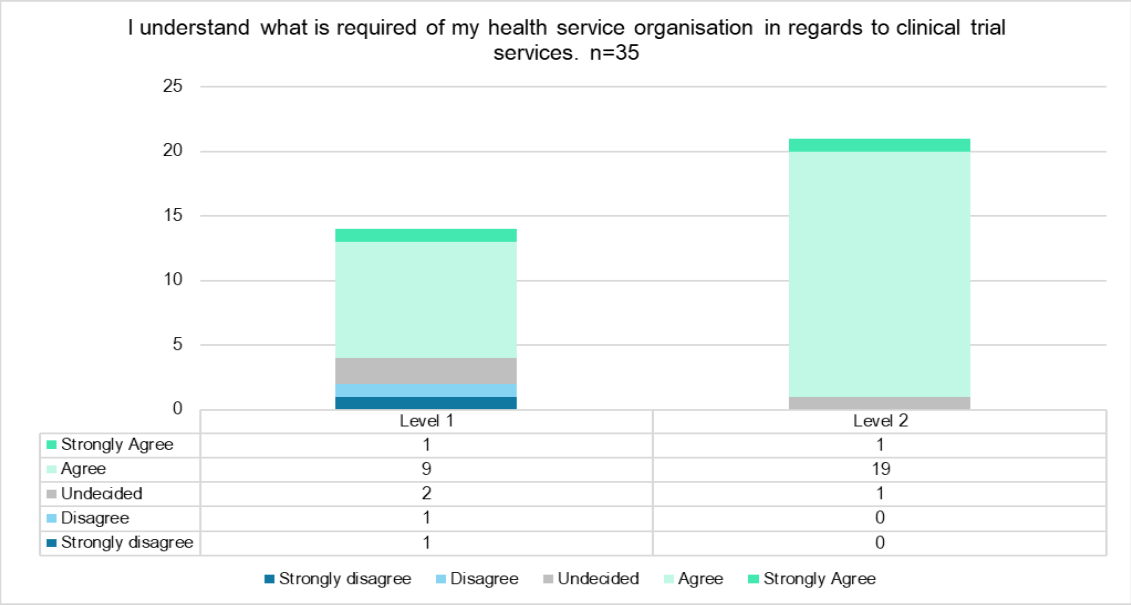


Figure 23: Response on understanding of health service organisations requirements for clinical trials for each actions in the Partnering with Consumers Standard, by Level 1 and Level 2 participants (Survey question 57)



Further guidance may be required to assist health service organisations understand reporting against key performance indicators listed in Action 1.1; the definition of risk and incident management; consumer engagement and feedback strategies, including for Aboriginal and Torres Strait Islander people.

For example:

> "In a private hospital setting where a patient journey can meander between different individual businesses of various natures (e.g. may be only a hospital patient, but could be on a trial visiting independent VMO private rooms, third party business running clinical trials entirely separately to the hospital who is only admitted to the hospital for IP administration), there needs to be clearer guidance on the expectations and extent to which the health organisation will be required to ensure businesses not under its control is meeting these standards or what evidence may be required to be provided."

> "HSO19 is an academic health sciences centre with a private hospital owned by the University, which brings complexity in addressing the requirements of the NCTGF. The governance structures, policy documents and clinical trials functions are distributed between the hospital, the clinics, the faculty-based Clinical Trials Unit (CTU) and central University functions. It will be challenging to streamline the policies, protocols, and SOPs across different areas within a short timeframe. When the Governance Framework is rolled out, there should be an opportunity to negotiate the timelines for clinical trials service accreditation"

> "The definition of 'risk' and 'incident' is required (Action 1.10 and 1.11). The definition of 'risk' and 'incident' in this context is required. Clinical trials have specific terminology and reporting requirements related to specific terms that may cause confusion."

> "Consumer engagement and systematic feedback tools targeting clinical trials participants is something that the sector is unlikely to be proficient with. The Governance Framework clearly highlights the intent and provides constructive steps as to the expectations. There is significant overlap with hospital accreditation Standard 2 compliance."

Objective 4: Language on the Governance Framework's intent

The language on the intent of the Governance Framework is logical and easily understood

Overall, 80% (55 out of 68) of survey respondents suggested the language of the Governance Framework is logical and clear (Figure 24). The results were similar for Level 1 and 2 participants (Figures 25, 26 and 27).

Figure 24: Rating on the language of the Governance Framework, by all participants (Survey Question 7)

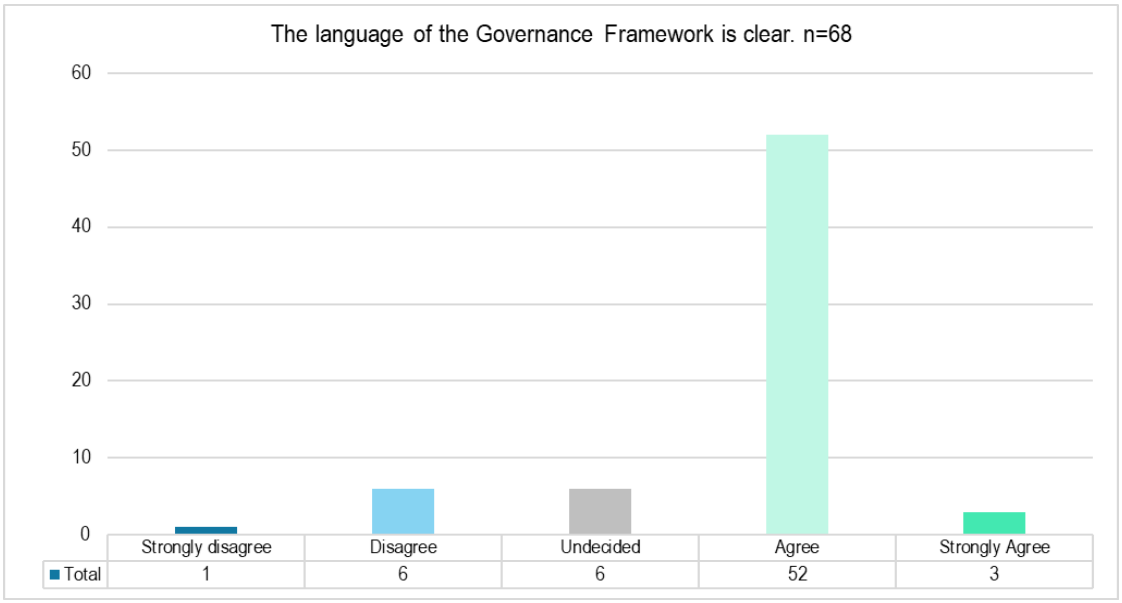


Figure 25: Rating on the language of the Governance Framework, by Level 1 and Level 2 participants (Survey Question 7)

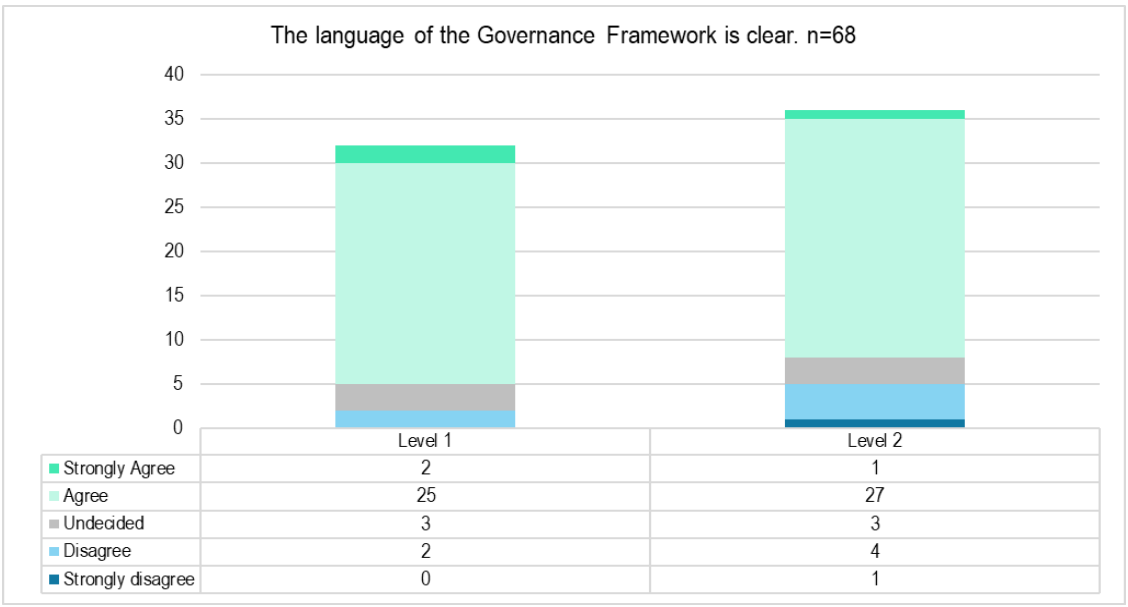


Figure 26: Rating on the intent of the Clinical Governance Standard, by Level 1 and Level 2 participants (Survey Question 15)

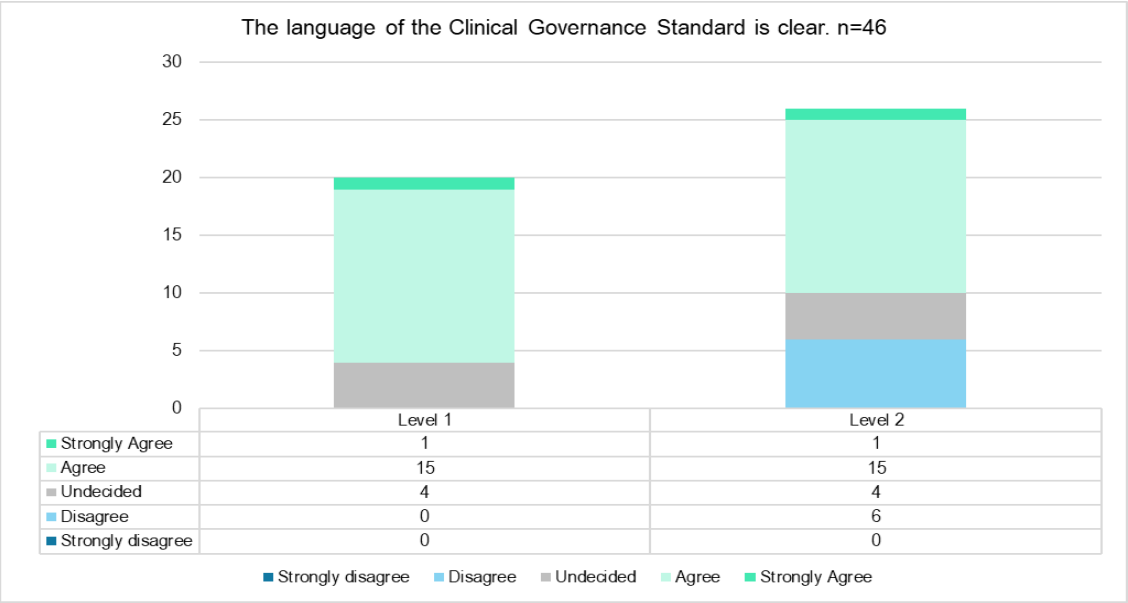
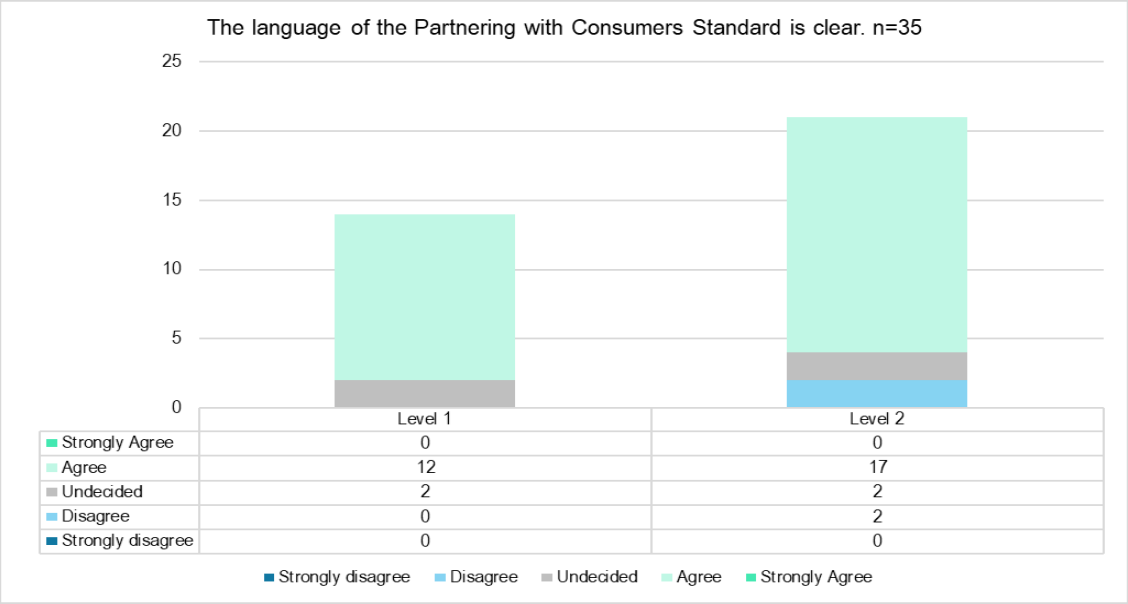


Figure 27: Rating on the language of the Partnering with Consumers Standard, by Level 1 and Level 2 participants (Survey Question 56)



Where survey respondents thought the language of the Governance Framework was not easy to understand, there were a variety of responses:

> "The Governance Framework is an extremely comprehensive document, well set out and written in clear concise language. It would be helpful to have a list of the links and references to the Fact Sheets built into this document at relevant sections. A summary version of the Framework listing the key action items for health service organisations including a checklist would also be helpful"

> "The Governance Framework is complex, the language and explanations included within it could be simplified. The intent of the standard is clear, however the intent of each action could be expanded upon."

"The Governance Framework was a bit long and the language a bit bureaucratic. It was also not tailored to research and trials."

"The language of the document was high level, and in some instances appeared to be targeted at senior members of a health service who may already be involved in the NSQHS Accreditation. Therefore, the provision of fact sheets was helpful as these documents described the key activities in a more concise, plain-language approach."

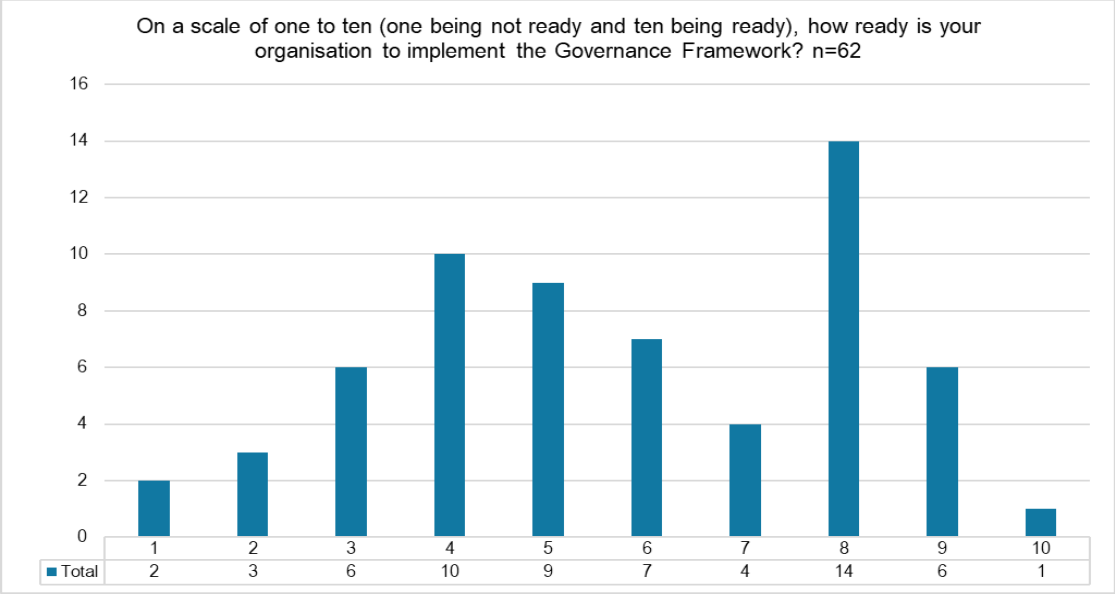
"The language in the Partnering with Consumers section was too complex for clinical trial services"

Objective 5: Implementation of the Governance Framework by health service organisations

The Governance Framework can be implemented by health service organisations providing clinical trials and assessed for compliance

Fifty two percent of survey participants (32 of 62) rated their organisation readiness to implement the Governance Framework at 6 or above (Figure 28).

Figure 28: Rating on organisation readiness to implement the Governance Framework, by all participants (Survey Question 11)



Some survey participants identified that the Governance Framework is aligned with the NSQHS Standards and that systems and processes are already in place in their health service organisations. For example:

"Some change will be required however the majority of activity will be in re-aligning to existing procedures/policy documents and other processes to ensure inclusion of clinical trials in the overarching clinical governance mechanics of HSO15."

"The Governance Framework mirrors the standard approach for the hospital's accreditation thus was relatively intuitive to follow. There were not any major surprises"

Potential barriers to implementation highlighted by survey respondents related to:

- Engagement across the organisation and executive buy-in
- Understanding of the accreditation process
- Understanding of clinical trials
- Consumer engagement and feedback strategies
- Human and financial resources.

Selected comments by theme, are provided in Table 24. All responses to the on-line survey are provided in Appendix 3.

Table 24: Selected comments regarding barriers to implementation

Theme	Comments
Engagement across the organisation and executive buy-in	"At present there is no central coordinated approach to clinical trial service provision as individual medical and surgical divisions manage their own trial services. Therefore, the level readiness to implement the Governance Framework is highly variable"
	"The Governance Framework requires strong buy in from the health service executive, clinical governance, the ethics and research governance office and clinical trials teams…"
	"My greatest concern would be insufficient engagement from the executive to enforce requirements that are essential to meet the standards for clinical trials."
	"There has been limited information generally at the grass roots level about the changes"
Understanding of the accreditation process	"The other factor is that many of the staff and researchers including trial sponsors have had very limited exposure to accreditation processes or the standards. A lot of our preparation work centred on NSQHS education to give them a baseline context of the standards and how these and the National Clinical Trials Governance Framework applied to their work … Currently, accreditation assessors would not visit or be aware of research areas. Building awareness will be required for implementation"
	"Working with research collaborators outside and inside the health service who are unfamiliar with the accreditation processes may be a barrier to implementation …"
	"There is a lack of knowledge or experience of research staff, sponsors etc in accreditation processes and the NSQHS Standards and how the Governance Framework needs to be implemented …"
Understanding of clinical trials	"There is a lack of understanding of clinical trials at the organisational level which may impact implementation. Additional guidance, specific to clinical trials not health care provision is needed."
	"Getting the executive management team to acknowledge and accept the importance of research to the organisation will be needed for implementation. "
	"Strong cultural issues with attitudes to consumers"

Theme	Comments
Consumer engagement and feedback strategies	"Consumer engagement is lacking and there is no process or local guidelines for this."
	"The biggest changes are needed in the clinical trial departments to ensure consumer involvement starts at the co-design stage etc. Consumer involvement has started at an organisational planning level, it now needs to commence at the clinical trials service level. Same as Standard one, improvement needed around the inclusion of people from non-English speaking backgrounds and also Aboriginal and Torres Start Islander people. "
	"We have consumers on the human research ethics committee and other organisational committees. However, integrating meaningful consumer involvement onto day-to-day clinical trial operations presents a challenge."
Financial and human resources	"There is a lack of resources and infrastructure, scale of clinical trial capacity in smaller regional hospitals compared to larger well developed organisations"

Objective 6: Additional resources to support national implementation of the Governance Framework

Identification of additional resources that may be required to support national implementation of the Governance Framework

Over 300 stakeholders attended the webinars on the on-line tools and resources. Additionally, as of 31 March 22021, the online training via the Commission website was accessed at least 358 times.

Overall, survey respondents reported that all resources were helpful, supported by clear guidance, easy to access and use (Table 25).

Table 25: Tools and resources utilised in the pilot (Survey Questions 78–83)

Resource	No. of respondents using the resource (n=34)	Response on effectiveness of the resource (Yes)				
		Language clear (n=34)	Intent clear (n=34)	Easy to access (n=34)	Easy to use (n=33)	Helpful (n=33)
Fact sheets	28	27	26	28	26	24
Self-assessment tool	25	23	26	20	14	18
Operational metrics portal	20	16	19	15	12	12
Video tutorial	15	15	15	16	14	11
Facilitated mentoring	20	30	17	19	18	17

Feedback regarding the operational metrics tool was extensive. The assessment process revealed that no Level 2 pilot health service organisation had a mechanism in place to report on the eight operational measures provided in Action 1.1 from the level of the trial unit through to the clinical department, health service executive and governing body. Several health service organisations had capacity to report at the level of the research office on the timeliness of HREC and local site authorisation. The operational metrics tool was supported by a user guide and hover notes over each field in the on-line tool however, survey respondents suggested the business rules for the completion of each field could be expanded. Future suggested enhancements included a request for more information on the scope of trials for inclusion and HREC and SSA process timelines and the income/investment information section.

Future capacity to upload data from existing clinical trials management systems was suggested and additional resources including:

- Information for clinical trials participants and sponsors on the Governance Framework and the accreditation process
- Organisations with established systems to mentor other health service organisations that have initial or growing systems in place
- Ongoing access to the already developed tools and resources.

There were a number of issues with the upload function of the self-assessment tool, which limited its use during the pilot and created some consternation among pilot sites.

Observations from mentoring

Insights obtained from the mentoring process aligned with the three mentoring domains:

- **Engagement** – engaging key stakeholders, including clinical and non-clinical workforce and senior management
- **Systems and processes** – embedding clinical trials into strategic and operational planning processes
- **Compliance** – supporting implementation of Governance Framework, use of tools and development of action plans to address gaps.

Up to seven mentoring sessions were available to participating Level 2 health service organisations. Thirty-one of the 33 Level 2 health service organisations participated in three mentoring sessions. Two health service organisations requested only one mentoring session. No health service organisation requested more than three.

Participants in the mentoring sessions commonly included the CEO, executive directors, clinical directors, managers, project officers and representatives of the clinical trial workforce, research office, ethics committee, clinical and corporate governance, business and finance management.

Collectively, over all Level 2 pilot health service organisations, 277 individuals attended at least one mentoring session. Ten of the 14 Level 2 pilot health service organisations had at least one representative attend each of the three of mentoring session offered.

Engagement

Throughout the pilot it was noted that research and clinical trial teams were generally not familiar with NSQHS Standards and the accreditation assessment process. Similarly, risk, safety and quality teams were generally not familiar with research and clinical trial services. Level 2 pilot health service organisation clinical trial teams that established strong support from their executive and engaged early with their risk, safety and quality staff more easily progressed through the pilot implementation. This collaboration was critical to building a shared understanding of requirements of accreditation assessment for clinical trial services.

Increasing sponsors' awareness of their roles and responsibilities in relation to the Governance Framework and the requirement to share information in relation to the safety and quality of trial conduct was identified throughout the pilot process.

Systems and processes

In preparing to undergo the pilot accreditation assessment, it became clear that understanding the existing health service organisation governance structures for all members of the workforce, including reporting lines, committee structures, committee memberships and links with research and/or business partnerships, supported successful implementation of the Governance Framework.

The pilot provided the opportunity to introduce the concept of clinical incident and risk reporting systems and processes and clarified the difference between the reporting requirements for a unique instance of a clinical trial to a HREC and trial sponsors, and the requirement to report risks and incidents at a health service organisation level. This realisation was reflected by several survey participants:

> "In relation to clinical trials and research specifically, integration of aspects such as incident management, complaints etc have historically been managed separately to the main hospital system/processes, so a bit more time is required to align all aspects".

"The definition of 'risk' and 'incident' in the context of clinical trials is required (Action 1.10 and 1.11). Clinical trials have specific terminology and reporting requirements related to specific events at a trial level, and the differences between the two may cause confusion."

Compliance

Pilot sites suggested more guidance could be provided regarding the requirements of health service organisations working in partnership with other organisations and groups. Various agreements often exist with academic partners, research alliances and third-party providers that have shared and/or independent governance structures. Additional guidance to clarify the potential impact on lease arrangements and service level agreements may support implementation.

Consumer engagement as part of 'Standard 2: consumers as partners in planning, design, delivery, measurement and evaluation of systems to deliver clinical trial services' was raised by several health service organisations as a key challenge for implementation. Compliance with the Governance Framework may require changes to current practices and workflows to incorporate clinical trial service provision into existing consumer engagement strategies.

Participation in the pilot

Level 2 pilot health service organisations noted that although participation in the pilot was an additional workload, overall it was a positive process. It facilitated an organisational-wide learning experience, increased engagement across various departments and members of the workforce and informed health service organisations' approach to implement the Governance Framework. It also leveraged traction of the clinical trial workforce with core teams and/or steering committees to manage the change required.

A summary of the benefits of pilot participation reported by Level 2 health service organisations are provided in Table 26 with summary tables of mentoring insights by health service organisation below.

Table 26: Reported benefits of pilot participation by accreditation assessment outcomes

Sites with initial systems	Sites with growing systems	Sites with established systems
• Pilot provided information on priorities for strategic planning and re-assessing quantum of change required • Provided opportunity to increase engagement and raise awareness of Governance Framework across governance groups and workforce • Informed current communication and engagement plans for internal and external stakeholders.	• Informed plans in place to move from current to future state • Raised awareness of roles and responsibilities internally and externally to assist with traction of planning and culture change, including identification of 'champions' • Provided another perspective of assessment to inform internal self-assessment and priorities / timelines for action.	• Informed longer term implementation and reform plans for any priority actions • Validated project roles or investment in change journey to date • Provided further information to inform Board, executive, management team and third-party stakeholders and sponsors on status of clinical trial services in their health service organisations.

Table 27: Summary of insights by health service organisation

HSO1	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	Public	Single	>300	Established
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• Substantial planning and resources dedicated to pilot preparation. • Recruited a dedicated Project Officer who coordinated pilot requirements at a site level. • In preparation, this site had conducted an initial desk top audit and identified consumer engagement and need for clarity regarding commercially sponsored trials (i.e. with international protocols) as key potential focus areas for attention.			• Formal introductory mentoring session only, with ongoing communication via dedicated Project Officer • Seven people participated in the introductory mentoring session • Mentor provided Commission developed fact sheets regarding roles and responsibilities of CT teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

<table>
<tr><th colspan="4">Mentoring insights</th></tr>
<tr><th>Engagement across organisation</th><th>Systems and processes</th><th>Governance Framework compliance</th><th>Pilot process and outcomes</th></tr>
<tr>
<td rowspan="2">Strong CEO, sponsor and executive support
Strong involvement and working relationship with risk safety and quality leads assisted meeting requirements of Governance Framework.
Early identification of research team lack of familiarity with NSQHS Standards accreditation approach allowed this to be addressed as part of engagement.</td>
<td rowspan="2">HSO1 had already established a steering committee which has regular planning meetings to transition requirements to business-as-usual ready for implementation.
Key challenge identified as the need to incorporate clinical trials into system and processes across organisation, with body of work to be undertaken around organisation-wide education / training needs analysis.</td>
<td rowspan="2">Despite being rated as established for all actions, key areas for improvement were identified during the process:
clinical trial incident reporting, requiring upgrade to Riskman system
Reporting at the trial unit level on clinical trial operations.</td>
<td>The pilot was useful to inform planning and next steps
As an established site with sound planning and project management, HSO1 would be able to provide case studies or exemplars.</td>
</tr>
<tr>
<td>Site self-rating generally not aligned to IHCA rating. For 22 of 27 items self-rated, site indicated that additional work was required to meet actions that IHCA rated as established.</td>
</tr>
</table>

HSO16	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Regional	**Public**	**Multi**	**<100**	**Initial**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• The Research Office is supporting HSO16 pilot and has allocated resources to build capacity and capability across sites. • Sites have been working on improvements to systems and processes for conducting and embedding clinical trials, nonetheless they expected a number of gaps to be identified as part of pilot participation. • Liaising with other sites to assist in preparation for the pilot accreditation.			• Mentoring was provided to HSO16 as a group at their request to facilitate shared learning, with HSO3 contact playing a coordinator role. • 2 sessions were conducted specifically for research and clinical trials teams, including individual site teams and mixed teams across HSO16.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• There was good executive engagement which increased as pilot progressed. • To address the gaps in understanding of accreditation process by research and clinical trial teams at HSO2, information sessions were held with the safety and quality manager/team, and insights were shared from HSO3 experience. • A communication strategy was suggested to build engagement across all stakeholders including IT and HR teams.	• HSO2 safety and quality manager became increasingly involved to provide support as the accreditation deadline approached and the number of queries increased across work streams.	• Key HSO16 challenge is understanding the scope of work required to implement the Governance Framework at each site, due to site variability. • Key gaps highlighted for future action: • Consumer engagement • Engaging commercial sponsors. • Reporting on trial operations at the trial unit level • More organisational oversight is required for internally sponsored and investigator-led trials.	• Despite the long lead-time for preparation the accreditation assessment process was a challenge for both sites. • Mixed views regarding the 'observing role' at accreditation. • The pilot raised the profile of the Governance Framework and improved engagement across the multiple health service organisations and their quality units. **HSO16 did not complete site self-assessment ratings for action items but reported general agreement with IHCA ratings during post accreditation mentoring session.**

HSO4	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Single**	**100–300**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO4 pilot team believe the system is mature. They have been working on policies and standard operating procedures for embedding clinical trials in strategic and operational planning processes. • Key site personnel have been involved in Governance Framework planning at National level, so familiar with requirements.			• Weekly mentoring sessions provided during core Clinical Trials Hub meetings. • Thirty-seven people were invited to participate in one or more mentoring sessions and regular contact was • Mentor provided fact sheets around roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**

• CEO and all staff involved have processes in place and are committed to achieving implementation of the Governance Framework into overall organisational governance.
• Clinical trial coordinators needed assistance from risk, safety and quality team to prepare for accreditation.
• Executive sponsor heavily involved in preparation for accreditation and research office encouraged clinical trial teams to provide feedback
	• Improved reporting processes established for governing body and executive around clinical trials to better embed in strategic and operational planning.	• Areas for additional work identified:
		  ○ Consumer engagement in co-design
		  ○ Incident and risk reporting within HREC and risk management system by clinical trial teams
		• Clarity sought re implications for academic partners and third-party agreements or service level agreements
			• Primary focus of mentoring was on preparation for accreditation
			• Increased awareness across health service post pilot will assist with planning initiatives.
			
			Initial IHCA assessment reviewed following disagreement by HSO4 around rating on some items (note that HSO4 did not complete self-rating).

HSO5	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Regional	**Public**	**Single**	**<100**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO5 had already commenced initial planning work for the Governance Framework with the Health and Medical Research Office. • Oversight of clinical trials reported to have been provided in recent years by the Health and Medical Research Office rather than local executive governance units within HSO5. • Organisational structure for research reported to be complex with varied reporting lines. • Challenge highlighted for regional site around capacity and capability, both in meeting Governance Framework requirements but also competing for commercial work.			• Thirteen people participated in one or more mentoring sessions. • Mentor helped to initiate discussion with executive sponsor and clinical trial director to expand engagement across HSO5 and LHD. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information. • Due to timelines, not able to hold specific sessions for clinical trial team.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**

• Key challenge was engagement of all parties across the various reporting lines for clinical trials both within the health service and across the LHD.
• Presentation by the Commission was useful to engage executives and broad stakeholder group and to discuss regional specific issues, including across LHD.
• Communication both internally (e.g; to engage finance and HR managers) and externally (e.g. CEO LHD) was important.
	• Key challenge was requirement for all protocols, guidelines and standard operating procedures to be developed in the context of the state-wide policy and implementation framework, but to also sit within HSO5 organisation structure and services.
	• Pilot facilitated robust internal discussions regarding how to embed clinical trials in current processes.
	• Challenge was differing reporting requirements and tools for LHD compared to unit level.
		• Provision of risk safety and quality staff resource to work with clinical trial team to assist with accreditation preparation worked well.
		• Key gaps to be addressed include:
		  ○ Clinical trial incident reporting policy within hospital
		  ○ Team roles and responsibilities as a team post accreditation.
		• Challenges in general with capacity and capability as a regional site.
			• Keen to learn from established sites for any strategies to assist them with planning post pilot process
			• Did not use portal tools for accreditation.
			• Post accreditation “the phone is now ringing off the hook” with interested parties wanting to know more.
			
			Initial IHCA assessment reviewed following disagreement by HSO5 around rating on some items (in particular, risk reporting).

HSO6	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Single**	**100–300**	**Established**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO6 had engaged a consultant to assist with accreditation, and to work closely with both clinical trial teams and risk safety and quality teams. • A draft research strategy had been developed incorporating Governance Framework requirements, but this needed to be finalised and planning progressed at the health service organisation level. • Existing online reporting systems via the jurisdictional Department of Health were not always reliable or verifiable.			• Fifty-one people were invited to participate in one or more mentoring sessions. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

<table>
<tr><th colspan="4">Mentoring insights</th></tr>
<tr><th>Engagement across organisation</th><th>Systems and processes</th><th>Governance Framework compliance</th><th>Pilot process and outcomes</th></tr>
<tr><td rowspan="2">Working group established by site to engage the research team, executive and other stakeholders worked well.
Following mentor session with clinical trial teams and research partners, site also provided further internal session and developed learning package on Governance Framework, accreditation requirements and roles and responsibilities to facilitate engagement of all stakeholders.
Specific engagement requirement for research partner organisations.</td><td rowspan="2">Addressing reporting and data provision requirements to Department of Health, and potential gaps in data was required to improve reporting to local governance body, executive and across HSO6.
Improved reporting noted as important to inform local finance, business support and HR decision making.</td><td rowspan="2">Clarification of commercial sponsors’ roles and responsibilities was a focus during accreditation preparation.
Fast tracking current plans to improve consumer engagement including consideration of future requirements under Governance Framework.</td><td>HSO6 is an established site with sound planning and initiatives developed during pilot to assist internal and external stakeholder engagement and may provide a valuable case study site.
Pilot contact planning to share learnings with colleagues across Department of Health.</td></tr>
<tr><td>Site self-rating generally not aligned to IHCA rating. For 25 of 27 items self-rated, site indicated that additional work was required to meet actions that IHCA rated as established.</td></tr>
</table>

HSO7	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Various	Private	Multi	100–300	Growing
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO7 have been working for around 12 months with clinical teams and management regarding structure and governance. • Already engaged project officer, undertaken gap analysis and progressed initial systems development work with the clinical trials network.			• Eight people participated in one or more mentoring sessions. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Planning led by small internal team with representation from risk, safety and quality, clinical trials and the Governance Framework project officer was valuable to support engagement across multiple sites. • Information provided by mentor for internal team to run education sessions with clinical trial teams and academic partners.	• HSO7 is a key pilot private sector site, and findings may act to provide guidance for other private sector sites. • Identified that education will be required across organisation to understand functions of clinical trials. • A key focus was to organise process for accreditation.	• Required some clarity from the Commission regarding third party trial coordinators who run clinical trials within HSO7. • Noted further work on consumers in relation to Governance Framework will be required.	• Process overall positive and has informed planning processes to address priorities such as data collection and reporting. • HSO7 reported that managers across sites were probably still not fully prepared for site inspection aspect of accreditation, hence area requiring further action in forward planning **Site self-rating generally not aligned to IHCA rating. For 22 of 27 items self-rated, HSO7 indicated that additional work was required to meet actions that IHCA rated as established.**

HSO8	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Multi**	**>300**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO8 has commenced the journey of formal strategic planning following the implementation of the new structure in which the Board is the Governing Body with oversight of HSO8's clinical and research service provision. • HSO8 has not yet undertaken accreditation as a LHN with multiple sites to date. • Formal mentoring sessions not taken up pre-accreditation.			• Introductory session provided to site, then site chose not to access further pre-accreditation mentoring. • Four people participated in initial and post-accreditation mentoring sessions. • Mentor provided one-on-one support with pilot primary contact and risk safety and quality lead as required. • Mentor provided fact sheets on roles and responsibilities of CT teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Key senior executive members attended the closing session and will develop and implement engagement plan moving forward. • Feedback from site that a post accreditation workshop with the Commission may be beneficial to help cement engagement required for future implementation, now that there is broad stakeholder awareness regarding the Governance Framework.	(No information obtained during mentoring process)	• Challenge reported by site was provision of body of evidence required to validate each of the action items.	• Felt that the accreditation process generally worked well. **HSO8 did not complete site self-rating using self-assessment portal. However, reported during post-accreditation mentor's debrief that IHCA rating generally aligned with self-assessment.**

HSO9	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Single**	**100–300**	**Established**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO9 has been working to develop research strategies and beginning work to ensure compliance with requirements of Governance Framework. • Requested broad attendance from Health Service at Commission's training sessions for use of online tools. • Plan to share learnings from pilot across the Health Service. • Identified internal working group for the pilot, with information shared as relevant with other research stakeholders across the Health Service.			• Seven people participated in one or more mentoring sessions. • Sessions focussed on assisting in preparation for accreditation and working on expanding team involvement to include key risk safety and quality leads. No direct mentor work with clinical trial teams or Steering Committee due to timelines. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Following initial work with mentor, key process for engagement was via: • Executive Sponsor briefing of senior executive team • Dissemination of information to HSO9 Research Council, HSO9 researchers and to Office of Research. • Early identification of research team lack of familiarity with NSQHS Standards accreditation approach allowed this to be addressed as part of engagement.	• HSO9 provided feedback that review of systems and process needs to include all research not just clinical trials as these are hard to separate. • A review of research and roles across HSO9 was already underway and part of the implementation transition and change plan for HSO9S, and this pilot has escalated this current planning process.	• To address challenges with use of portal in the pilot, the Department of Health was engaged to facilitate data collection to provide a comprehensive data set pertaining to current clinical trial activity at site. • Assistant Director Quality, Innovation and Patient Safety, worked with clinical trial teams to provide further relevant clinical trial level evidence.	• Short timeframes as first pilot site, so process felt rushed. • Process did increase awareness and engagement across site. Risk, safety and quality lead stated that pilot involvement is likely to strengthen current planning and risk reporting across health service. **Site self-rating generally not aligned to IHCA rating. For 21 of the 22 action items self-rated, HSO9indicated that additional work was required to meet actions that IHCA rated as established.**

HSO10	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Regional	**Public**	**Single**	**<100**	**Established**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• Executive sponsor is a member of the Governance Framework Advisory Panel. • Substantial pre-work already undertaken with clinical trial team. • Already considered governance across HSO10, Health service and external partners with respect to meeting Governance Framework requirements. • Challenge highlighted around capacity and capability in meeting Governance Framework requirements and competing for commercial work.			• Twelve people participated in one or more mentoring sessions. • Due to pilot and accreditation timelines, unable to hold specific session for clinical trial teams and academic partners. • Mentor provided fact sheets re roles and responsibilities of CT teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Strong involvement of executive sponsor in mentoring and leading engagement across organisation was effective. • Commission provided a useful presentation/discussion session to explore regional and remote specific issues including working with remote Aboriginal and Torres Strait Islander populations and dispersed health care workers • Involving risk safety and quality teams at HSO10 and Health Service in the mentoring process, plus representatives from research partner organisation ~~(Menzies School of Health Research)~~ helped to engage relevant stakeholders.	• Small internal working party already established with focus on engaging relevant stakeholders to embed clinical trial activity into current and new strategic and operational planning processes. • Increasing awareness within the hospital education team identified as a gap where additional information could help to increase understanding of requirements.	• Concern by regional sites that not all action items are equally as applicable to regional as metropolitan hospitals (feedback to be provided by site in online survey). • Work on Partnering with Consumer Standard key area for site, particularly with Aboriginal and Torres Strait Islander population and remote or isolated workers obtaining consent.	• Accreditation report content differed from expectations. • Rated as having 'established system' although site has some specific issues related to demographics or potential funding priorities which they felt still required work to progress. **HSO10 did not complete site self-rating using self-assessment portal. However, site reported during mentor's debrief that HSO10 perceived level of maturity was lower than the ratings provided by IHCA.**

HSO11	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Single**	**<100**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO11 Centre for Clinical Research has done background preparatory work with their jurisdictional Department of Health regarding implementation of the Governance Framework. • Director of Improvement given additional hours to dedicate to work associated with the pilot process and implementation of the Governance Framework.			• Eight people participated in one or more mentoring sessions. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information. • Due to pilot and accreditation timelines, unable to hold specific session for clinical trial teams and academic partners.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Engagement across the organisation was identified early as a challenge, and mentor provided communication and engagement strategy suggestions for implementation across HSO11 – this was reported as helpful and may support future implementation more broadly. • Local internal working team held in house workshops for research and clinical trials team and risk, safety and quality leads which was valuable in engaging these groups to work together to implement Governance Framework.	• Data collection and reporting identified as an issue in the context of current work being undertaken more broadly across the Health Service. • Focus on ensuring relevant HSO11 strategic documentation incorporates clinical trials (e.g. Aboriginal and Torres Strait Islander engagement strategic documents).	• Focus during mentoring on evidence required for Actions 1.29 and 1.33 plus Partnering with Consumers standards.	• Overall positive experience and excellent way to get increased engagement across health service. **HSO11 did not complete site self-rating using self-assessment portal. However, reported during post-accreditation mentor's debrief that IHCA rating generally aligned with self-assessment.**

HSO12	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Single**	**<100**	**Initial**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO12 research manager had been allocated four hours per week dedicated to Governance Framework implementation. • Due to the COVID-19 pandemic and "shutdown", HSO12 has not been able to continue many of the functions of the service. This shutdown required some staff to work from home and also impacted some clinical trials, as recruitment of participants to trials was interrupted or suspended. • Planning to provide updates on pilot process and learnings for members of Centre for Health.			• Updated executive sponsor via email as not able to attend introduction or subsequent mentoring sessions. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information. • Post-accreditation de-brief not taken up by HSO12.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Risk, safety and quality leads for National Standards included in mentoring and planning			

Mentoring insights			

• Governance Framework implementation was set up as a three-step approach following external review in 2018:
  ○ Step 1. Stakeholder engagement commencing with executive then senior clinical trial lead via information paper and series of meetings
  ○ Step 2. Use feedback from pilot to inform plan and next steps.
  ○ Step 3. Reassess organisation-wide implementation plan.
• Difficulty engaging remote/off site team whilst research office staff working from home during COVID-19.
	• Following discussion with project contact, communication ideas were provided by mentor to assist with developing strategy across the organisation, and pilot contact presented at key stakeholder and committee meetings prior to accreditation.
	• Data collection and reporting using state-based electronic records management tool needs to accommodate data reporting requirements for multiple systems and stakeholders.
		• Key gaps identified around consumer engagement.	**Site self-rating generally not aligned to IHCA rating. For 17 of the 26 action items self-rated, HSO12 rated their level of maturity higher than IHCA and one item was rated lower than IHCA. However, for eight of 26 items, the site rating matched the IHCA rating.**

HSO13	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public, Private**	**Multi**	**100–300**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO13 has had a journey of reform and have identified gaps – the pilot will confirm gaps to be addressed at individual sites and across HSO13. • HSO18 has been preparing for the Governance Framework and has a Steering Committee in place. HSO18 has also had some external consultancy input into planning for the Governance Framework. • HSO17 has already commenced planning and developing policies and procedures in line with the Governance Framework, and are looking at dedicated project roles to assist with the pilot.			• Forty-five people participated in one or more mentoring sessions. • Pre-accreditation mentoring focussed on preparing for accreditation and one session provided for clinical trial and risk safety and quality teams to prepare for accreditation coordinated by COO HSO13 Centre for Applied Research. • Mentor provided fact sheets on roles and responsibilities of CT teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• Board and Executive supportive of the pilot and attended mentoring and engagement sessions, which improved engagement across the organisation. • Strong risk, safety and quality engagement across organisation and involved in preparation for accreditation.	• Key challenge was how to manage requirements of the Governance Framework and optimise learning across two states and the four hospitals involved, each with individual research and academic partnerships – plan to have consistent practices across HSO13. • Need to ensure systems and processes do not duplicate reporting for the Governance Framework.	• Key priorities were identified up front around consumer engagement, particularly engagement with Aboriginal and Torres Strait Islander groups, noting that HSO18 has done some work with consumers in protocol design. • Issue for clinical trial teams and researchers is that they already work in a highly regulated industry, so need to ensure that reporting requirements and effort not duplicated to meet Governance Framework requirements. • Provided feedback that additional clarity required in user guide around what is minimal, optional or aspirational re maturity level.	• Assessed as one health service with multiple sites, however completed on-line tools as separate sites as they were unable to view other site's data in portal. • Reported that overall process will inform next steps in the planning process and change agenda. **Alignment of site self-rating to IHCA rating depended on site. For HSO17, 23 of 27 self-rated items matched IHCA maturity rating for HSO13. For HSO18, only five of the 17 self-rated items matched the IHCA rating for HSO13, and for 11 of 17 items HSO18 rated their level of maturity lower than IHCA.**

HSO14	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Metropolitan	**Public**	**Multi**	**>300**	**Established**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO14 appointed a risk, safety and quality and accreditation expert to lead the pilot project for implementation of the Governance Framework, and act as the key contact for the project. • Planning for pilot well underway, noting that HSO14 was one of the final sites to undergo accreditation during the pilot. • HSO14 CEO extremely engaged and HSO14 Research Strategy Plan in place • Implementation Committee established at executive level with working group led by director of research.			• Thirty-five people participated in one or more mentoring sessions. • Specific mentoring session conducted for research and clinical trials teams. • Mentor provided fact sheets on roles and responsibilities of clinical trial teams, commercial sponsors and academic partners, PICMoRs and other relevant information.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• The small implementation group established to lead the project and share information with the executive team and working group worked well to engage stakeholders across such a large organisation. • Early and strong involvement of risk, safety and quality and patient safety and family experience leads in mentoring sessions supported engagement. • 'Champions' identified in sessions with clinical trial teams to further assist in engagement across organisation.	• Early involvement and engagement across organisation helped identify any changes required to embed clinical trials into strategic and operational systems and processes.	• Process was helped by risk, safety and quality leads actively working with department leads to gain evidence and align planning with NSQHS Standards across the organisation. • Key challenge identified as different 'language' between NSQHS Standards and research and clinical trials terminology.	• Found involvement in the pilot to be a helpful process which validated work undertaken to date and several key areas for increased focus across HSO14. • As an established site, HSO14 may provide a valuable case study site. **Site self-rating generally not aligned to IHCA rating. Although only five action items were given a self-rating by HSO14, each of these reflected a lower level of perceived maturity than the IHCA rating for that item.**

HSO15	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	No. clinical trials	IHCA Rating (overall)
		Regional	**Public**	**Single**	**~ 100**	**Growing**
Description of organisation	**Status at pilot commencement**			**Summary of mentoring activity**		
	• HSO15 project lead is a member of the Governance Framework Advisory Committee and is therefore well-informed regarding Governance Framework requirements. • Site feels that they have a sound base for pilot as HSO15 received 'met with merit' rating for research at last accreditation. • Aiming to adopt the approach of 'mirroring real life' during the pilot as part of preparation for future implementation of the Governance Framework.			• Six people participated in one or more mentoring sessions. • Site lead had already accessed and made good use of fact sheets.		

Mentoring insights			
Engagement across organisation	**Systems and processes**	**Governance Framework compliance**	**Pilot process and outcomes**
• HSO15 project lead had already commenced process of engagement across the organisations and noted that key requirements included engagement with executive at the outset.	• Took a business as usual approach to the pilot process with aim to “mirror real life scenario” of clinical trials across the organisation. • Oncology clinical trial practice as a key exemplar. • HSO15 project lead had commenced work to explore embedding clinical trials into strategic and operational governance processes.	• Took a business as usual approach to the pilot process with aim to “mirror real life scenario” of CTs across the organisation.	**Site self-rating generally aligned to IHCA rating. For 17 of 27 action items self-rated, HSO15 maturity rating matched the IHCA rating for that item. For 7 of the 27 items, HSO15 rated their maturity lower than IHCA rated, and for three items HSO15 rated their maturity as higher.**

Outcomes from pilot accreditation assessment process

Outcomes of the accreditation process identified the level of maturity of pilot sites, actions that may require additional suggested strategies and examples of evidence to be provided in the Governance Framework and key observations from the accreditation assessment team.

Pilot sites level of maturity

Established systems

Five of the 15 health service organisations assessed achieved a maturity rating of Established systems. These public sector health service organisations, located in capital cities, were able to demonstrate that their clinical trial services are embedded in existing clinical and corporate governance systems, and there were processes for reporting on new requirements such as clinical trial operational activity. Each of these health service organisations had strong engagement between the safety and quality teams and clinical trial teams.

The assessors found that health service organisations awarded an overall rating of Established systems had comprehensive up to date documentation including policies, procedures, operational plans, strategies, monitoring documents, risk assessments and appropriate communication strategies. The assessment team evidenced regular engagement with and reporting to, the governing body about clinical trial services and they could also determine clear evidence of mature governance processes and effective implementation of the organisation's policies and procedures. The assessors also evidenced comprehensive and robust processes in relation to partnering with clinical trial participants, processes for obtaining participant consent and ongoing support for trial participants,

Growing systems

Seven of the 15 health service organisations were awarded a maturity rating of Growing systems. The actions that most challenged these health service organisations were in relation to risk and incident management (Actions 1.7 and 1.11).

For health service organisations awarded Growing systems, the assessment team identified some evidence of policies and procedures, however some may have been out of date or not completely implemented. For several actions, there was incomplete evidence available to review. In general, the assessment team noted that the clinical trial services were in the process of developing relationships with the organisation's risk, safety and quality team and in the early stages of developing strategies to partner effectively with consumers.

Initial systems

Two of the three health service organisations awarded a maturity rating of Initial systems are located in regional Australia and are seeking to improve the safety and quality of their clinical trial services through participation in relevant collaborative networks. These clinical trial services had fewer trials in comparison to the services awarded Growing and Established systems.

While it was clear that these health service organisations were committed to full implementation of the Governance Framework, the assessment team found that work to meet the majority of the actions was yet to commence or be implemented.

Performance against actions within the Governance Framework

Fourteen health service organisations were awarded Established systems in relation to Action 2.4, indicating that informed consent processes comply with legislation and best practice.

Eleven clinical trial services were awarded Established systems in relation to each of the following actions:

- Action 1.3 – The health service organisation establishes and maintains a clinical governance framework and uses the processes within the framework to drive improvements in safety and quality
- Action 1.12 – The health service organisation: (a) uses an open disclosure program that is consistent with the Australian Open Disclosure Framework (b) monitors and acts to improve the effectiveness of open disclosure processes
- Action 2.5 – The health service organisation has processes to identify: (a) the capacity of a patient to make decisions about their own care (b) a substitute decision-maker if a patient does not have the capacity to make decisions for themselves.

Growing systems was awarded to eight clinical trial services in relation to:

- Action 1.7 – The health service organisation uses a risk management approach to (a) set out, review, and maintain the currency and effectiveness of, clinical trial policies, procedures and protocols (b) monitor and take action to improve adherence to clinical trial policies procedures and protocols (c) review compliance with legislation, regulation and jurisdictional requirements
- Action 1.11 – The health service organisation or trial site has organisation-wide incident management information management and investigation systems.

Four clinical trial services were awarded Initial systems in relation to:

- Action 2.14 – The health service organisation works in partnership with patients and consumers to incorporate their views and experiences into training and education for the workforce.

The assessment teams noted there were few formal processes in place to seek feedback from clinical trial participants. Patient satisfaction surveys may have been in place in the wider health service organisation, however these were absent in the majority (ten of 15) of clinical trial services reviewed. Action 1.13 action was generally not well achieved by health service organisations.

Independence of the accreditation process

The accreditation assessment process is a fully independent process that should not be influenced by the preferences of the health service organisation, particularly in respect to trial sampling.

The assessment team noted that it was difficult for some pilot sites to collate the key contextual information necessary to develop an assessment plan and to sample clinical trial services and the individual trials they conducted. Some pilot sites chose to put forward their own sample of clinical trials from which the assessment team selected the trials to be reviewed. During implementation, health service organisations will need to provide accurate information relating to all clinical trial services, the number of trials and trial populations.

A number of sites were concerned about potential breaches of confidentiality agreements with their sponsors by making available clinical trial information to the assessors. It was clarified that all assessors are bound by confidentiality agreements, and where pilot sites required it, additional confidentiality declarations were signed.

In an onsite assessment, the engagement with patients and consumers of clinical trials would normally be opportunistic. Given the nature of remote assessment, patients and consumers needed to be engaged and provide consent to be interviewed. It was noted that, during the pilot, health service organisations were more likely to put forward only those trial participants, consumers and carers who were satisfied with the service.

The role of the assessor

Feedback on the role of the assessors was received from several pilot sites expressing concern that the assessment team did not appear to have a background in clinical trials.

The role of the assessor is to assess the maturity of participating health service organisations governance systems against actions of the NSQHS Standards for clinical service provision, and all assessors are suitably qualified. It is not the role of the assessor to review the conduct of a particular clinical trial. The assessment team familiarised themselves with the Commission's support material and participated in training prior to conducting assessments for the purpose of the pilot and moving forward, all registered accrediting agencies will need complete to the Commission developed training package on clinical trials.

Familiarity with the accreditation process

The majority of pilot sites were not familiar with the accreditation assessment processes. In some instances the purpose of an accreditation assessment had been misconstrued with clinical trial staff perceiving that the assessors were reviewing the people, performance and management culture of an organisation as opposed to assessing the systems, policies and procedures in place to ensure that clinical trials are conducted in a safe environment and in a high-quality manner.

Engagement with risk, safety and quality teams

The need to engage with the health service organisation's risk, safety and quality teams well in advance of the assessment was highlighted. The majority of clinical trial staff were not familiar with quality systems and processes and were in the process of building relationships with their organisational risk, safety and quality team.

Risk associated with investigator-initiated clinical trials

Investigator-initiated trials were handled differently within and between all health service organisations assessed. Of the 103 trials sampled, nine (less than 10%) were investigator-initiated. No governance issues were identified in the larger metropolitan health service organisations, however in regional health service organisations a number of practices were identified that would benefit from review:

- The principal investigator also acting as the trial monitor which may be perceived as a conflict of interest.
- Resourcing of health service organisation sponsored trials was limited with support provided largely as in-kind support
- The workforce was not supported due to budget restrictions and there was no opportunity to employ additional staff
- IT systems varied and there are consistent processes and systems to support the collation and reporting of clinical trial data.

Evidence of maturity level

Governance structure clearly defined

Pilot sites being assessed as having Established systems in place demonstrated that clinical trials were considered part of the health service organisation and local health districts/local health networks strategic planning.

> "HSO9 strategic planning is extensive, effective and comprehensive and the Health Service Strategic Plan includes safety and quality priorities, opportunities, strategic risks and four objectives including putting people first, improving access, equity, quality, safety and health outcomes. Research is included in Objective 3 to deliver value-based health services through a culture of research, education, learning and innovation." [HSO9]

> "There was sound evidence of research in the summary of the Strategic Plan and also in the HSO6 Strategic Plan 2018–2023." [HSO6]

> "The HSO14 Strategic Plan 2019-2024 demonstrates close linkages between clinical care and research with research specifically included in the Mission and Values. Research is one of the Strategic Plan's Focus Areas and the Peak Committees Structure has research embedded with links to HSO14 Executive Committee" [HSO14]

The governance structure is well defined for pilot sites with established systems in place and the workforce and consumers demonstrated a clear understanding of the governance and reporting structure.

> "The Organisational Structure clearly demonstrates a link from the HSO6 Board to Nursing Research. There is reporting to the Executive Director of Nursing Services, Research reporting to the Deputy Director Medical Services and the Centre for Neonatal Research reporting to the Co-Directors of Service Unit 6. It was evident during discussion with the Board Chair, the EDMS and the CEO that research at HSO6 is closely monitored. Evidence of this was also sighted in HSO6 Governance Committee Structure which includes Research at the top of the structure reporting directly to HSO6 Executive Committee." [HSO6]

> "The Organisational Structure December 2020 demonstrated the inclusion of research at multiple levels within the organisation and was sighted to include Clinical Chair Nursing Research, Chair of Medicine & A Director Research, Executive Officer HSO1 Research Alliance, and Research Governance Manager" [HSO1]

Roles and responsibilities and delegation of duties for the governing body, executives, managers and the clinical trial workforce are also clearly defined through position descriptions, Terms of Reference, guidelines and standard operating procedures.

> "The Executive Director of Research, Transformation & Change (EDRTC) advised that ELTs role includes identifying, monitoring, and managing strategic and critical risks as they relate to the Health Service. It was evident in ELT meeting minutes that HSO10 reports to ELT which monitors HSO10 progress on safety & quality performance. It was noted that confusion remained for staff around the definition of governance. In fact, a lot of the evidence provided for Standard 1: Clinical Governance Standard demonstrated the research governance processes in place as opposed to demonstrating the systems in place to embed clinical trial services in clinical and corporate governance." [HSO10]

Engagement across health service organisations

Mapping of the evidence revealed that pilot sites who had engaged broadly across their health service organisation achieved a better outcome for the pilot accreditation assessment. This was highlighted through the interviews conducted with Board members, executives, managers, clinical trial workforce and consumers. Interviews often revealed consistency between policies and processes implemented that could be described by all stakeholders involved.

Consumer engagement

Pilot sites with Established systems in place demonstrated defined strategies to involve consumers as partners in their own care and as partners in planning and delivery of clinical trial services.

Sites consistently demonstrated having a consumer engagement framework and/or policy.

> "The document titled "Developing the Consumer Engagement Strategy 2020–2022" provided evidence that the Consumer Engagement Strategy is a three- year plan for the HSO6 aimed at strengthening consumer engagement across all service areas […]. It was noted that the Strategy is complemented by a Consumer Engagement Framework to support the implementation of the goals and actions defined in the Strategy. […] HSO6 Consumer Engagement Strategy 2020–2022 was sighted to include measurable action items, including timelines, responsibility and form of engagement." [HSO6]

> "The Patients Come First Strategy and Plan 2016–2020 is the organisation's roadmap to supporting the best possible patient experience and engaging consumers in health service planning, design, and improvement. It is noted on the website that development of the third PCF Strategy is underway with a survey and an online forum held on 26 February 2021. According to the website, 155 patients, consumers and staff responded to the survey, and over 60 attended the virtual forum." [HSO1]

> "HSO14 Consumer and Community Participation Framework 2017–18 describes the demographics of the district, the aims of the Framework, how they will be achieved and the core values and principles of participation. A new framework for 2021–2026 is in draft form." [HSO14]

> "HSO17 Consumer & Community Participation & Carer Recognition Policy and Procedure Amendment date June 2020 describes HOS17's commitment to patient-centred care and organisational response to community, consumer and carer input and needs." [HSO17]

Consumers were systematically involved in the health service organisation committees as part of the Board, medical advisory committees, health council or as standalone consumer committees.

> "Interviews with Executive and the CT workforce confirmed the inclusion of consumers in Board membership and on various committees. Volunteers within hospitals are consulted as consumers. Although consumer participation varies between sites, HSO7 has a consumer on the Medical Advisory Committee (MAC) and any planned significant changes in business are presented to consumers who sit on Committees." [HSO7]

> "The Community Advisory Committee have a work plan. The sighted 2021 plan is noted to include the Patients Come First Strategy, integrated patient feedback report, and cultural diversity and inclusion. The Trial Hub Advisory Committee includes a consumer representative. The Terms of Reference (Review due: 21 September 2020) states the purpose is to establish an Advisory Group to contribute knowledge and expertise and provide advice on the implementation, evaluation, and sustainability of the Trial Hub Activity plan." [HSO1]

> "There is a consumer representative on the Research Council. It is noted that the Terms of Reference are not dated but state that they are to be reviewed annually." [HSO14]

Pilot sites also demonstrated they had developed information for consumers that is easily accessible with regards to their care but also on how to get involved in the planning and delivery of services.

> "Draft 2020 Consumer and Community Participation Handbook for prospective consumer representatives." [HSO14]

> "Role, Responsibilities and Eligibility Criteria for Regional Community Engagement Group Representatives (factsheet)." [HSO10]

"HSO17 Written Information for Consumers (Brochures and Information Sheets) Policy provides guidelines for staff developing or reviewing written health information for patients, families and carers. A flowchart was sighted for this process." [HSO17]

Observations relating to specific actions

Action 1.1: The governing body:

a) provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation
b) provides leadership to ensure partnering with patients, carers and consumers
c) sets priorities and strategic directions for the conduct of safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community
d) endorses the National Clinical Trials Governance Framework within the health service
e) ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce
f) monitors the action taken as a result of analyses of incidents
g) reviews reports and monitors the organisation's progress on safety and quality performance.

In addition to the examples of evidence described in the Governance Framework, evidence gathered for most pilot sites through interviews and documents reviewed focused on the approval processes and establishment of clinical trials. The following provides an example of a health service organisation's confusion between demonstrating that clinical trial services are embedded in organisational governance structures and processes versus research 'governance' or oversight processes.

"Interviews and observation of documents confirmed that processes relating to the approval process and establishment of CTs is consistent. The Executive Assistant Checklist included low negligible application, SSA application, CT, and research agreement and step by step tasks from creation of an eFILE to the saving of authorisation and agreement." [HSO5]

Sites that demonstrated having mature systems in place for this action, ensured the roles and responsibilities of the governing body, management, clinicians and clinical trials workforce are clearly defined through position descriptions, Terms of Reference and guidelines on essential training.

Action 1.3: The health service organisation establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality.

Pilot sites with established systems for Action 1.3 showed they had clear organisational structures with a comprehensive reporting line from the clinical trial services to the Board.

Additional evidence sighted for many pilot sites focused on research governance processes. For example:

> "Several members of the clinical trial workforce discussed the process prior to commencement of a trial. Once ethics and local site authorisation have been granted, the Sponsor meets with all involved, including the Principal Investigator and co-investigators and a separate meeting is held with pharmacy. The following is discussed: the protocol, safety requirements, path requirements, eligibility, training requirements and any equipment requirements" [HSO6]

Research monitoring processes (guidelines and standard operating procedures, description of monitoring visits, monitoring visit report) was also a strong component in the evidence provided by sites.

> "A Routine Monitoring Visit report by the sponsor for Plasma-Lyte 148 versus Saline (PLUS) Study included expected recruitment rate, current recruitment, reported infallible patients, reported protocol violations, recruitment and screening, eligibility, post-randomisation deviations from protocol, consenting issues, reconciliation and accountability, data collection/documentation, timeliness, accuracy and understanding, included follow up items as an action plan with allocated numbers, description, due by, person responsible and outcome status." [HSO9]

> "The Research: Monitoring Procedure was sighted and promotes the safety of research participants and best research practice through the confirmation of adherence to appropriate processes, collection of quality research data, appropriate record keeping, access and storage of research records. It also ensures relevant Human Research Ethics Committee (HREC), governance and regulatory compliance." [HSO10]

Action 1.4: The health service organisation implements and monitors strategies to meet the organisation's safety and quality priorities for Aboriginal and Torres Strait Islander people.

In addition to the examples of evidence provided in the Governance Framework for Action 1.4, most pilot site demonstrated that the hospital environment caters for and promotes the Aboriginal and Torres Strait Islander cultural diversity, evidenced by art and culturally appropriate displays.

Many pilot sites also showed they had a Reconciliation Action Plan in place.

> "Executive Committee Report cover sheet Reconciliation Action Plan – Annual Report advises the Executive Committee on the progress of the Reconciliation Action Plan. The report described the partnering of HSO1 and research Alliance Partners on the precinct, […] for the first time on an event related to an Aboriginal and Torres Strait Islander Day of Significance. The report focussed on NAIDOC Week- Celebration Event 9th of July" [HSO1]

> "HSO17 May Reconciliation Action Plan (RAP) Steering Committee Stretch RAP 2019–22 Targets describes a commitment that all facilities will reach out to local Aboriginal and Torres Strait Islander communities in order to improve healthcare outcomes". [HSO17]

Sites with Established systems in place often had Aboriginal and Torres Strait Islander representatives on the health service organisations Committees or had an Aboriginal and Torres Strait Islander Committee. Some health service organisations showed they used Aboriginal Health Research Committees for the review of research proposals.

> "Aboriginal Health Advisory Group Terms of Reference (TOR) define the purpose of the Aboriginal Health Advisory Group is to work in collaboration with Aboriginal and Torres Strait Islander people to support HSO1 in the planning, implementation and evaluation of initiatives, systems and processes to deliver safe, culturally appropriate, quality care and the best possible experience for all Aboriginal and Torres Strait Islander people who access HSO1 services locally and state-wide" [HSO1]

> "Sighted were an Aboriginal Health Ethics Committee approval letter August 2020, an Aboriginal Health Research summary May 2020, the inclusion of Indigenous Ethical Guidelines NHMRC in the CT space and Research training Involving the Aboriginal Community in research." [HSO6]

Additionally, some sites showed evidence of work and consultation with existing Aboriginal health services. For example:

> "HSO14 works closely with the Aboriginal Medical Service […]. Meeting minutes 19 February 2021 were sighted to include Strategic Priorities including Research Priorities, Strategic Priorities, Research Development Pathways, Engagement in Clinical Trials, Encouraging and Supporting Clinical Trial Participation, Workforce Strategies and Resources to Support AMS" [HSO14]

> "Evidence was sighted that an Indigenous Network was convened to discuss current Indigenous health research projects and determined priorities" [HSO1]

> "HSO10 works in conjunction with Aboriginal controlled health services […] and health sector to report against specific Aboriginal KPIs which are monitored through the Aboriginal and Torres Strait Islander forum. It was evident that effective collaborative partnerships exist between the Health Service, Aboriginal controlled health services and the primary health network within which a theme of continuous improvement was evident. The Health Service identifies specific issues such as childhood anaemia and the collaborative groups benchmark against each other for the purpose of continuous improvement." [HSO10]

Action 1.7: The health service organisation uses a risk management approach to:

a) set out, review, and maintain the currency and effectiveness of, clinical trial policies, procedures and protocols
b) monitor and take action to improve adherence to clinical trial policies, procedures and protocols
c) review compliance with legislation, regulation and jurisdictional requirements.

For Action 1.7, pilot sites with mature systems in place showed evidence of documents version control and date of revision. For some sites with growing systems in place, it was not always evident that policies and procedures were reviewed regularly. For example:

> "It was not always evident that HSO7 policies and procedures were reviewed when due and CT SOPs were not always formally approved and in current version. At the time of assessment, multiple CT SOPs were in draft, some since April 2020. The HSO7 Clinical Incident Reporting Policy, Guideline, Clinical Incident Management Policy and Guideline, all due for review in June 2018, had not been finally approved and released and the HSO7 Severity Rating by Degree of Impact for Clinical Incidents (V1 August 2011) did not include a date for review." [HSO7]

> "Multiple SOPs provided as evidence were in draft with an effective date of July 2019 and some included tracked changes." [HSO8]

Pilot sites that achieved established systems for this action showed they often had clear policies, processes and delegations in place for the development, review and update of policies.

> "HSO15 – policy, procedure and standing orders management Procedure, describes the process to approve, review, rescind or archive a document on behalf of HSO15. The Policy and Procedures Unit is responsible for facilitating the development, approval, review, rescission and archiving of a document and for monitoring and registering all such documents." [HSO15]

> "The Development and Approval of Policies and Guidelines Guideline details the process for the development, approval, implementation and review of all HSO1 policies and guidelines. It ensures the contents of policies and guidelines are contemporaneous, relevant to current practice and core business, underpinned by best practice principles, legislation and are evidence based." [HSO1]
>
> "HSO14 Policy Compliance Procedure – Governance and Development of Policy, Procedures and Guidelines describes the processes to ensure the development, review and management of quality policy, procedure, and guidelines at HSO14 within a robust governance framework. The framework ensures that high-quality, standardised documents are available and accessible to all staff in HSO14." [HSO14]

Some pilot sites use policies and procedures provided by their district or jurisdictions and adapt or develop additional policies as required by the health service organisation.

"HSO14 utilises policies and procedures provided by the Department of Health and develops any further site-specific documents in response to need." [HSO14]

"EDRTC advised that the DoH sets policies, not HSO10, and DoH establishes effective engagement and consultation around policy documents. Requests for additional policies and procedures go to governance and then to the Health Service Clinical Research and Innovation Committee." [HSO10]

Pilot site with established systems revealed a well-defined process for communicating updates on policies and procedures across the organisation.

> "With the Trials Docs program all relevant staff are notified by e-mail that a new document has been uploaded. Evidence was sighted of the program and there is a requirement that staff read and understand the document and an acknowledgement of this is generated in the system." [HSO9]
>
> "Interviewees advised that HSO6 has a formal approach of communicating new and/or revised documents, including policies, procedures and SOPs to staff which is more comprehensive if a document is new or more robust, such as Open Disclosure. Monthly newsletters are distributed to the workforce, headlines go out fortnightly and there is a research specific newsletter. It was evident that onsite or research partners' policies are communicated at regular meetings and an example provided was of HSO6 monthly meetings, at which policy changes and distribution are discussed. All policies and procedures are available to HSO6 workforce on the intranet site and emails are used as required for communication." [HSO6]

Action 1.11: The health service organisation or trial site has organisation-wide incident management information management and investigation systems, and:

a) supports the workforce to recognise and report incidents
b) supports patients, carers and families to communicate concerns or incidents
c) involves the workforce and consumers in the review of incidents
d) provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers
e) uses the information from the analysis of incidents to improve safety and quality
f) incorporates risks identified in the analysis of incidents into the risk management system
g) regularly reviews and acts to improve the effectiveness the incident management system and investigation systems.

With regard to Action 1.11, pilot sites that achieved established systems for this action showed all stakeholders could clearly describe the processes for risk and incident reporting in alignment with current policies and guidelines in place.

There was evidence of well-defined roles and responsibilities in the review of incidents with clear escalation and communication processes in place (Safety and Adverse Event Reporting Procedure, briefing notes on the monitoring and escalation of issues, terms of reference for relevant committees).

> "Executive, the Manager Research Ethics and Compliance and the CT workforce described the review of incident analysis and the inclusion of identified risks to feed into the continuous quality improvement of the organisation. The Chair of the Advisory Council is a consumer who identifies as Aboriginal and the HSO6 Board Chair described the inclusion of Board and Board subcommittees in the review of incidents. The Board Chair advised that the Board would send incident data back to Executives for clarification or further analysis to satisfy Board responsibilities. The Manager Research Ethics and Compliance advised that any incidents in the research/CT domain are entered into Datix and proceed through the chain of Executive and committees to the Board. It was evident that HSO6 will escalate, manage, and closely monitor any significant serious adverse events within a short time frame and will be considered by Executive committees and the Board out of session if necessary." [HSO6]

> "HSO10 involves the workforce in the review of incidents, and consistently provides timely feedback on the analysis of incidents to the governing body, the workforce, and consumers. Any information presented to consumers is deidentified. HSO10 demonstrated a structured reporting process up through CT steering committees for the reporting of outcomes and adverse events. Each trial has a Principal Investigator who is an employee of the Health Service" [HSO10]

> "The CEO described the process for engaging consumers in the review of incidents and advised that consumers are involved in incident analysis and receive training […]. Between six and eight will assist in the review of incidents." [HSO1]

Action 1.13: The health service organisation:

a) has processes to seek regular feedback from patients, carers and families about their experiences and outcomes of care
b) has processes to regularly seek feedback from the workforce on their understanding and use of safety and quality systems
c) uses this information to improve safety and quality systems.

The majority of the pilot sites demonstrated that patient satisfaction surveys were in place to seek regular feedback from consumers about their experiences and outcomes of care in the health service organisation, however, inclusion of clinical trial services was not evident.

Pilot sites that achieved established systems for this action demonstrated clear mechanisms for the collection of feedback from consumers evidenced by guidelines and procedures.

> "The Patient Feedback Guideline was sighted to provide guidance for the handling of patient complaints and the collection of routine and specific feedback from patient, families and carers" [HSO1]

> "Complaint Management Guidelines provide an operational framework for dealing with a complaint in accordance with the Complaints Management Policy […]." [HSO14]

> "The Consumer Feedback Management Guideline was sighted to provide guidance to promote a consistent approach to managing consumer feedback." [HSO10]

The clinical trial workforce also showed they had a close working relationship with clinical trial participants which enabled collection of informal feedback.

> "CT workforce described a close working relationship with the participants of some trials and explained that the majority of participants regularly and appear comfortable to deliver feedback." [HSO9]

> "CT workforce described a close working relationship with the participants of some trials and explained that the majority of participants are comfortable to deliver feedback. Interviews with four CT parents/consumer interviewed said they had never had reason to complain but were able to describe the process if they wanted to raise a complaint or provide feedback." [HSO6]

Information on how to provide feedback or lodge a complaint appeared to be readily available and accessible for consumers (information for consumers on website, brochures indicating how to make a complaint, information provided directly to all consumers on their first contact with the clinical trial service).

> "HSO6nwebsite includes information for consumers with regard to compliments and complaints and provides online and hard copy feedback forms as well as a phone number for the Child and Family Engagement team. […] HSO6 Feedback Form for Consumers with a post back option." [HSO6]

> "Brochures indicating how to make a complaint and Information provided directly to all consumers on their first contact with the service." [HSO10]

Reports on consumer feedback were also sighted to include research services.

> "HSO1 Integrated Feedback Report – January to June 2019 was sighted to include information with regard to patient feedback, complaints received, complaints by Pillar (HSO1 pillars of success) including but not limited to, communication, team, comfort and environment. […] People Matter Survey Results summary was sighted in HSO1 May–June 2019 survey." [HSO1]

Pilot sites with mature systems in place also demonstrated formal and informal collection of feedback from the workforce (staff satisfaction survey).

> "HSO9 promotes feedback from trial investigators, the clinical trial workforce, trial sponsors, trial participants, their families and carers are used to improve safety and quality. The health service collects feedback from the workforce and uses patient experience data to improve the quality of clinical trial service provision." [HSO9]

> "HS010 promotes that feedback from trial investigators, the clinical trial workforce, trial sponsors, trial participants, their families and carers and is used to improve safety and quality. Evidence was provided to confirm that the health service collects feedback from the workforce and uses participant experience data to improve the quality of clinical trial service provision." [HSO10]

> "Members of the CT workforce advised that staff satisfaction surveys have been conducted and results fed back to the staff." [HSO1]

Action 2.14: The health service organisation works in partnership with patients and consumers to incorporate their views and experiences into training and education for the workforce.

For all sites, the clinical trial workforce consistently expressed an understanding of clinical trials from the consumer's perspective.

Pilot sites with more mature systems in place demonstrated implementation of consumer engagement framework and policies where partnership in training is taken into account.

> "Draft 2020 Consumer and Community Participation Handbook for prospective consumer representatives." [HSO14]

> "The Education and Training Strategic Plan 2016–2020 includes the strategy, "where feasible, invite NGO partners and community participants to participate in health training programs."" [HSO14]
>
> "HSO6 Consumer Engagement Strategy Summary and Partnering with Consumers Policy." [HSO6]

Direct feedback from consumers interviewed as part of the accreditation confirmed their views and experiences were incorporated in training and education for the workforce through participation in committees, review of material or participation in focus groups.

> "An interview with one consumer demonstrated involvement in identifying and providing workforce education from a consumer aspect and was able to provide this feedback in the DoH Health Advisory Group." [HSO10]
>
> "An interview with one consumer demonstrated her involvement in identifying and providing workforce education from a consumer aspect." [HSO9]

Business compliance costs

Provide individual site context to support cost estimates data

Sites provided the local context for their rationale for cost estimates through consultation and in the rationale field of individual cost estimates values.

Document key observations from costing analysis

Cost estimate data are provided in Table 28. The 18 cost items were aggregated by cost grouping and cost category and presented by health service organisation profile. Estimated aggregate one-off costs and recurrent costs per annum by health service organisation/network are provided in Table 29. Two health service organisations did not provide an estimate of one-off implementation costs, as they considered the processes were already in place in their health service organisation as part of the NSQHS Standards. Overall, the mean one-off costs for implementation for the remaining 31 health service organisations, were estimated at $341,083.00 (StdDev $398,685.00). Recurrent costs, per annum were estimated at $261,777.00 (StdDev $238,639.00).

Health service organisations that achieved a rating of **Established**, that is they met the actions in the Governance Framework, estimated mean costs associated with implementation at $255,101.00 (StdDev $205,688.00) and $191,752.00 (StdDev $148,448.00) in recurrent costs per annum. These health service organisations were located in metropolitan cities.

Health service organisations that achieved a rating of **Growing**, estimated mean costs associated with implementation at $213,590.00 (StdDev $270,054) and $208,523.00 (StdDev $201,660.00) in recurrent costs per annum.

Health service organisations that achieved a rating of **Initial**, estimated a mean cost of $781,871.00 (StdDev $665,154.00) for implementation and $502,743.00 (StdDev $351,119.00) in recurrent costs.

Mean costs for regional health service organisations were twice the estimated costs of larger metropolitan health service organisations and there was an observed difference between the level of resourcing and readiness to implement the Governance Framework between regional and metropolitan health service organisations.

The estimated total costs by cost item and cost group are provided in Figure 29 and the estimated total one-off and recurrent costs by cost group and health service organisation /network are provided in Figure 30.

Table 28: Self-reported costs by health service organisation, cost item and cost group

Question	Cost item	Stage	HSO1	HSO13	HSO14	HSO11	HSO15	HSO5	HSO10	HSO3	HSO12	HSO8	HSO9	HSO6	HSO1	HSO2	HSO4
Implementation Costs																	
1.	Policies, procedures, tools and resources	One-off Costs	$ –	$ –	$17,802	$88,337	$ –	$ –	$91,199	$215,385	$40,000	$102,000	$ –	$52,570	$419,743	$119,403	$1,181
		Recurrent Costs	$42,672	$ –	$5,610	$39,851	$ –	$ –	$163,000	$143,591	$120,000	$5,900	$ –	$7,809	$138,162	$119,403	$1,181
2.	Record keeping	One-off Costs	$ –	$300,000	$4,314	$124,507	$ –	$ –	$ –	$91,187	$ –	$ –	$55,300	$7,520	$108,096	$78,110	$ –
		Recurrent Costs	$ –	$300,000	$ –	$104,507	$ –	$ –	$70,000	$96,768	$ –	$ –	$ –	$ –	$216,192	$78,110	$ –
3.	Staff training	One-off Costs	$38,223	$ –	$182,693	$30,000	$ –	$ –	$91,199	$13,316	$ –	$20,000	$ –	$9,569	$7,500	$142,235	$2,380
		Recurrent Costs	$10,000	$ –	$130,047	$30,000	$ –	$ –	$ –	$675	$ –		$ –	$6,677	$3,750	$139,235	$4,760
Compliance Costs																	
4.	Training in Good Clinical Practice	One-off Costs	$ –	$ –	$ –	$10,000	$ –	$ –	$ –	$21,800	$ –	$15,000	$ –	$6,238	$ –	$21,800	$ –
		Recurrent Costs	$ –	$ –	$9,000	$10,000	$ –	$3,000	$ –	$8,200	$15,000		$ –	$21,909	$ –	$8,200	$ –
5.	Notification / education / training	One-off Costs	$ –	$ –	$ –	$10,000	$ –	$ –	$ –	$57,436	$ –	$ –	$ –	$14,649	$10,000	$ –	$9,520
		Recurrent Costs		$ –	$ –	$10,000	$ –	$ –	$ –	$30,476	$ –	$ –	$ –	$13,355	$ –		$4,760
6a.	IT infrastructure	One-off Costs	$123,750	$150,000	$ –	$124,507	$ –	$ –	$1,000	$300,000	$ –	$ –	$ –	$ –	$20,000	$300,000	$ –
		Recurrent Costs	$217,500	$100,000	$ –	$104,507	$ –	$ –	$ –	$28,718	$ –	$200,000	$ –	$ –	$5,000	$140,000	$ –
6b.	Data collection tools	One-off Costs	$356	$ –	$ –	$ –	$ –	$ –	$ –	$46,070	$25,000	$ –	$ –	$ –	$15,000	$30,000	$ –
		Recurrent Costs	$4,267	$ –	$ –	$ –	$ –	$ –	$ –	$44,584	$ –	$ –	$ –	$ –	$ –	$56,250	$ –
6c.	Secure storage systems for record	One-off Costs	$15,000	$ –	$ –	$174,507	$ –	$ –	$30,000	$13,150	$ –	$ –	$ –	$ –	$3,750	$ –	$ –
		Recurrent Costs	$15,000	$ –	$ –	$154,507	$ –	$1,000	$ –	$1,700	$ –	$ –	$ –	$ –	$3,750	$ –	$ –
6d.	Secure storage systems for study/drug/device	One-off Costs	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$41,638	$ –	$ –	$ –	$ –	$ –	$ –	$ –
		Recurrent Costs	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –
6e.	Education and training resources	One-off Costs	$ –	$10,000	$ –	$ –	$ –	$ –	$ –	$114,872	$ –	$ –	$ –	$ –	$ –	$139,235	$865
		Recurrent Costs	$ –	$10,000		$ –	$ –	$ –	$ –	$60,952	$ –	$ –	$ –	$ –	$ –	$139,235	$6,940
6f.	Clinical trial work spaces	One-off Costs	$ –	$ –	$ –	$50,000	$ –	$ –	$60,000	$287,587	$ –	$ –	$ –	$8,952	$ –	$ –	$ –
		Recurrent Costs	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$30,000	$ –	$ –	$ –	$3,581	$ –		$ –
6g.	Signage/instructions	One-off Costs	$ –	$ –	$ –	$5,000	$ –	$ –	$17,500	$ –	$ –	$ –	$ –	$5,968	$ –	$2,000	$ –
		Recurrent Costs	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$1,000	$ –	$ –	$ –	$ –	$ –	$ –
6h.	Maintenance costs	One-off Costs	$ –	$ –	$ –	$80,000	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$18,930	$ –	$9,750	$ –
		Recurrent Costs	$ –	$ –	$ –	$30,000	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$8,869	$ –	$9,750	$ –
6i.	Other	One-off Costs	$ –	$ –	$564	$ –	$ –	$ –	$ –	$147,898	$ –	$ –	$ –	$2,507	$ –	$43,104	$ –
		Recurrent Costs	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$91,428	$ –	$ –	$ –	$ –	$ –	$97,868	$ –

Question	Cost item	Stage	HSO1	HSO13	HSO14	HSO11	HSO15	HSO5	HSO10	HSO3	HSO12	HSO8	HSO9	HSO6	HSO1	HSO2	HSO4
Additional Costs																	
7.	Effort to review	One-off Costs															
		Recurrent Costs															
8.	Effort to update processes	One-off Costs															
		Recurrent Costs	$ –														
9.	Other direct/indirect costs	One-off Costs	$ –														
		Recurrent Costs	$ –														
10.	Costs for engaging consumers in National Clinical Trials Governance Framework	One-off Costs	$ –	$10,000	$ –	$ –	$ –	$ –	$ –	$28,718	$ –	$ –	$ –	$8,442	$4,500	$15,920	$ –
		Recurrent Costs	$ –	$6,000	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$21,000	$1,000	$47,761	$13,310
Summary		**One-off Costs**	**$177,329**	**$470,000**	**$205,373**	**$696,858**	**$ –**	**$ –**	**$290,897**	**$1,379,057**	**$65,000**	**$137,000**	**$55,300**	**$135,345**	**$588,589**	**$901,557**	**$13,946**
		Recurrent Costs	**$289,439**	**$416,000**	**$144,657**	**$483,372**	**$ –**	**$4,000**	**$233,000**	**$537,092**	**$136,000**	**$205,900**	**$ –**	**$83,200**	**$367,854**	**$835,812**	**$30,951**
		Total	**$466,768**	**$886,000**	**$350,030**	**$1,180,230**	**$ –**	**$4,000**	**$523,897**	**$1,916,149**	**$201,000**	**$342,900**	**$55,300**	**$218,545**	**$956,443**	**$1,737,369**	**$44,897**

Table 29: Estimated one-off and recurrent costs (per annum) for implementation by health service organisation/network

Sum of Cost Estimate	One-off Costs	Recurrent Costs
HSO1	$588,589	$367,854
HSO2	$901,557	$835,812
HSO3	$1,379,057	$537,092
HSO4	$13,946	$30,951
HSO5	$ –	$4,000
HSO6	$135,345	$83,200
HSO7	$177,329	$289,439
HSO8	$137,000	$205,900
HSO9	$55,300	$ –
HSO10	$290,897	$233,000
HSO11	$696,858	$483,372
HSO12	$65,000	$136,000
HSO13	$470,000	$416,000
HSO14	$205,373	$144,657
HSO15	$ –	$ –
Mean Total Costs	**$341,083**	**$251,152**
StdDev Total Costs	**$398,685**	**$240,637**

Figure 29: Estimated one-off and recurrent costs by cost item and cost group for multiple health services

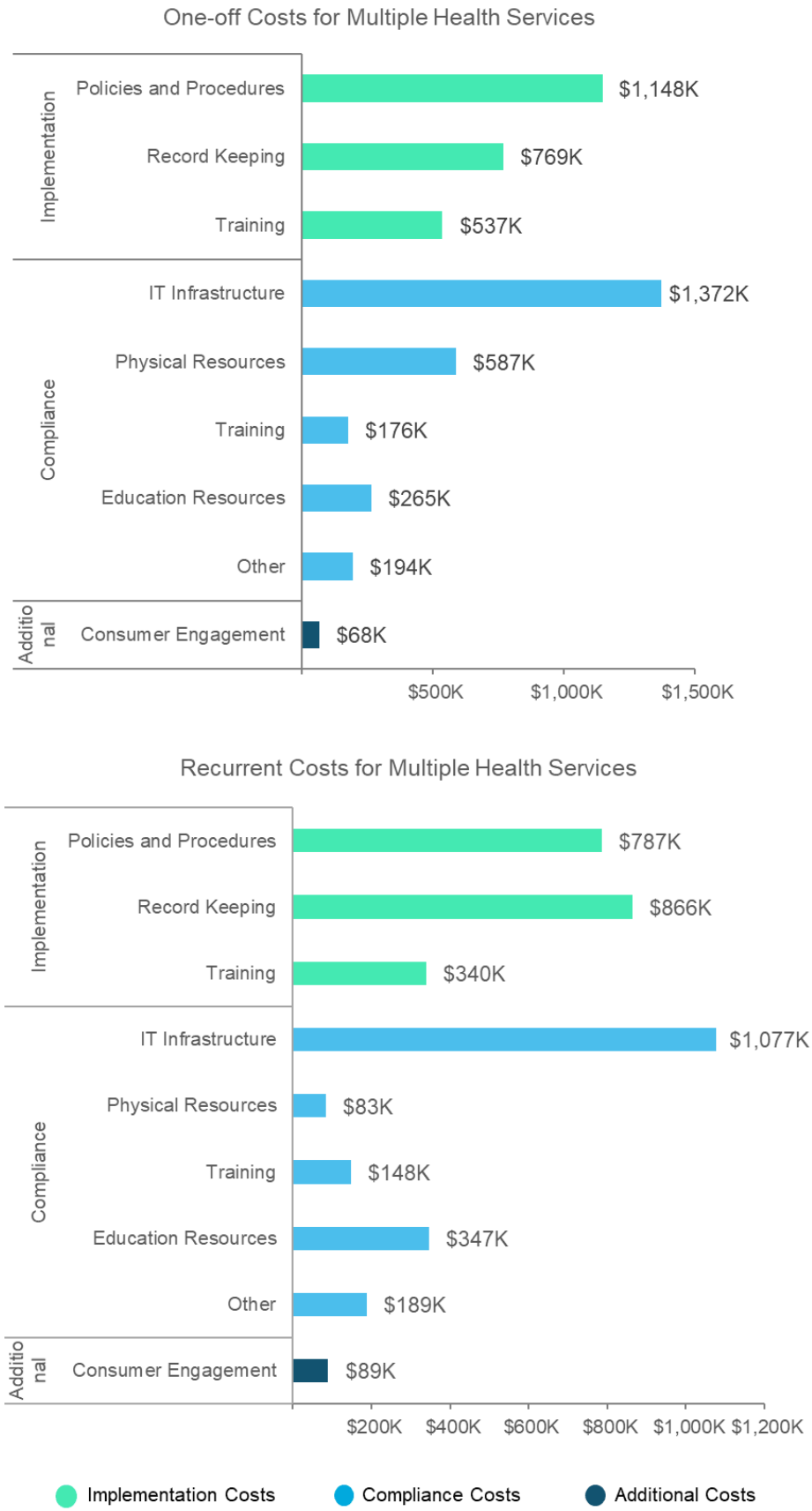
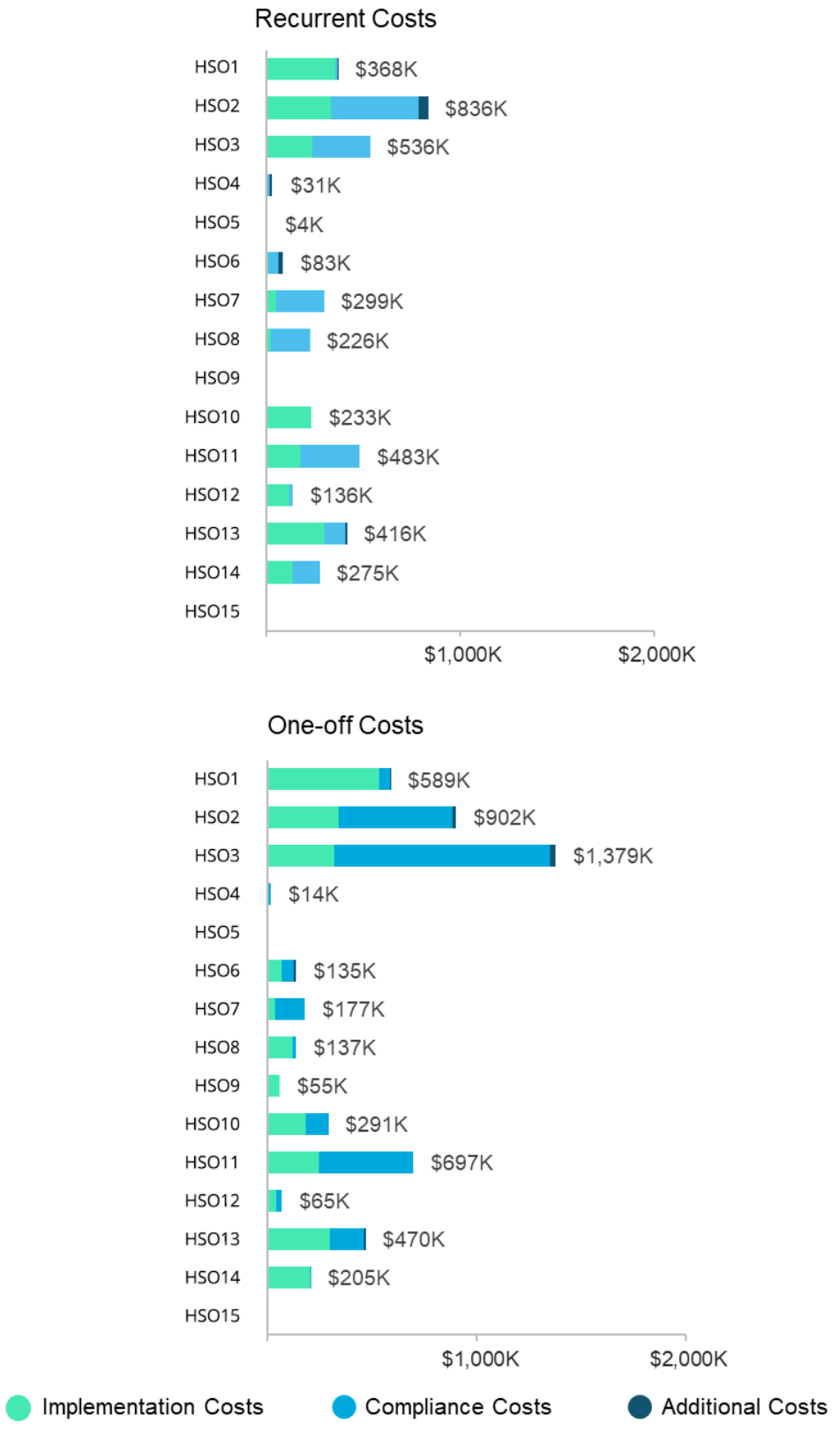


Figure 30: Estimated total one-off and recurrent costs by cost group and health service organisation/network



Insights from post-pilot workshops

Engagement across health service organisations

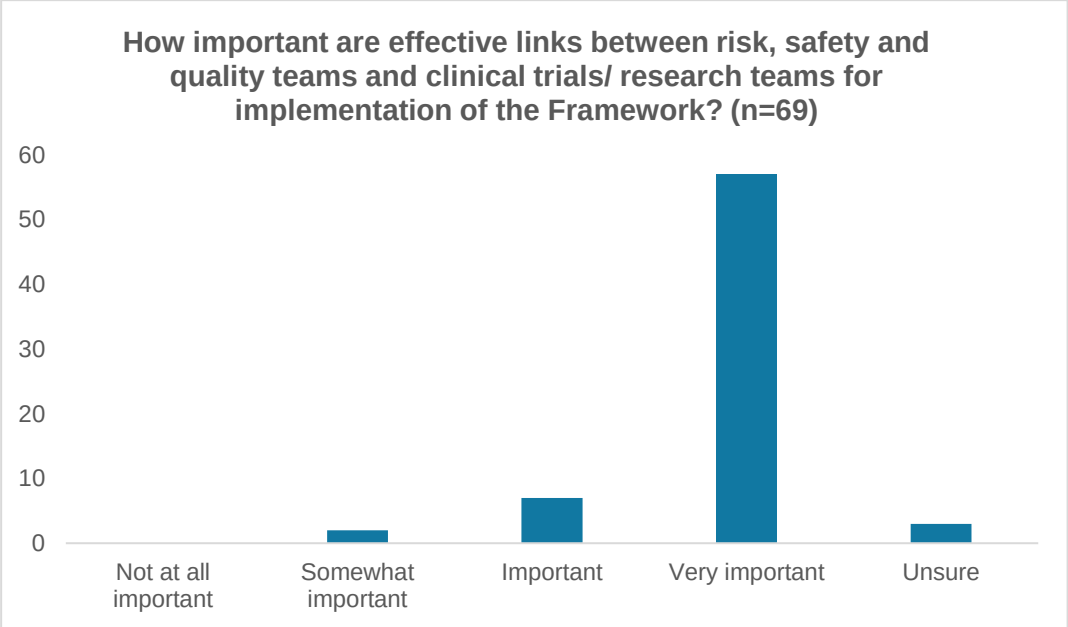
Overall, attendance of 120 participants was recorded across both post-pilot workshops.

In general, workshop participants (57 of 69 that provided a response) agreed that engagement between the safety and quality teams and clinical trials/research teams, and health service executive was key to successful implementation where participants thought they were very important (Figure 31).

Box 1: Examples of post-pilot workshop participants' recommendations to help embed clinical trials into routine service provision

Engagement across health service organisations
"Collaboration with your quality department"
"Engage with your executive and accreditation teams. Trial units do not have to work alone"
"Engage with people at your site who have done accreditation before"
"Engage clinical governance teams early and often; map research gaps regularly"
"Engage with key leaders as early as possible"
"Engage your leadership and quality teams early. Don't panic a lot of information is already available you just need to tweak for clinical trials"
"Engage with executives to ensure clinical trials are considered as important as surgical waiting lists etc"

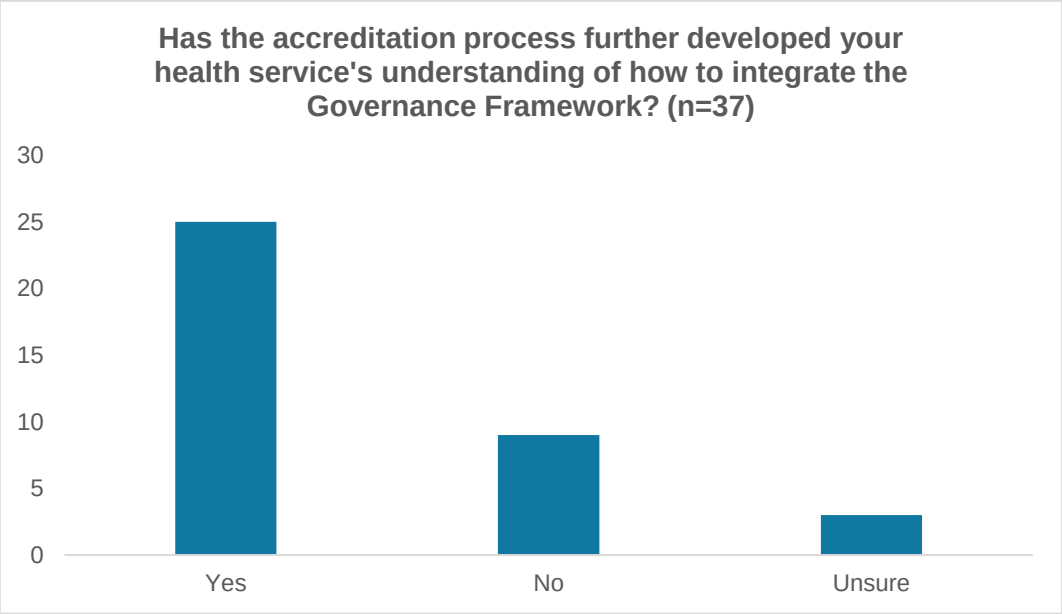
Figure 31: Importance of links between risk, safety and quality teams and clinical trials/research teams for implementation of the Governance Framework



Accreditation process

Participants (25 of 37 that provided a response) generally thought the accreditation process further developed their health service organisation's understanding of how to integrate the Governance Framework (Figure 32).

Figure 32: Participants thought on the accreditation process and their health service organisation's understanding of how to integrate the Governance Framework



Participants were encouraged to ask questions throughout the workshops. Questions were answered during the sessions and will be used to guide the update of the supporting resources. Examples of questions from participants are provided in Table 31 and largely related to:

- The experience of accreditation assessors
- The results of pilot accreditation assessments (qualitative and quantitative measures)
- The accreditation process.

Resources to support implementation of the Governance Framework

Fact sheets

Of the ten fact sheets developed by the Commission, Fact sheet 1 (National Clinical Trials Governance Framework and accreditation overview), Fact sheet 2 (National Clinical Trials Governance Framework – Clinical Governance Standard) and Fact sheet 3 (National Clinical Trials Governance Framework – Partnering with Consumers Standard), were considered the most useful fact sheets (Figure 33). In general, participants found the fact sheets useful (Figure 34) and suggested keeping the resources simple and concise.

Figure 33: Fact sheets used by health service organisations

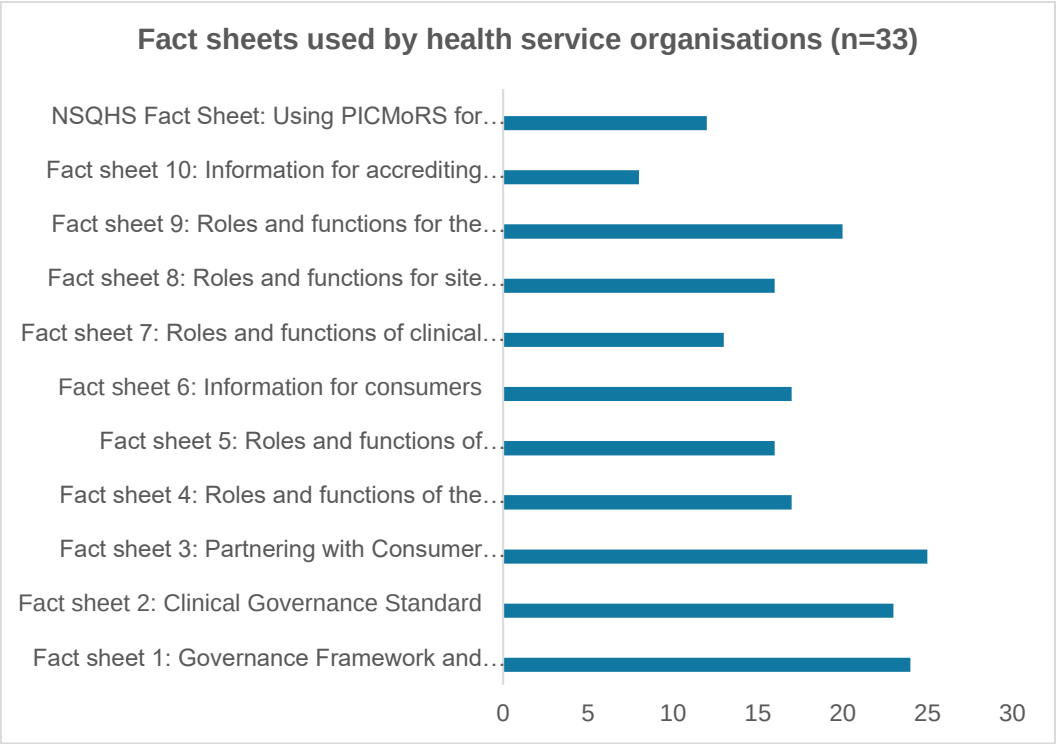
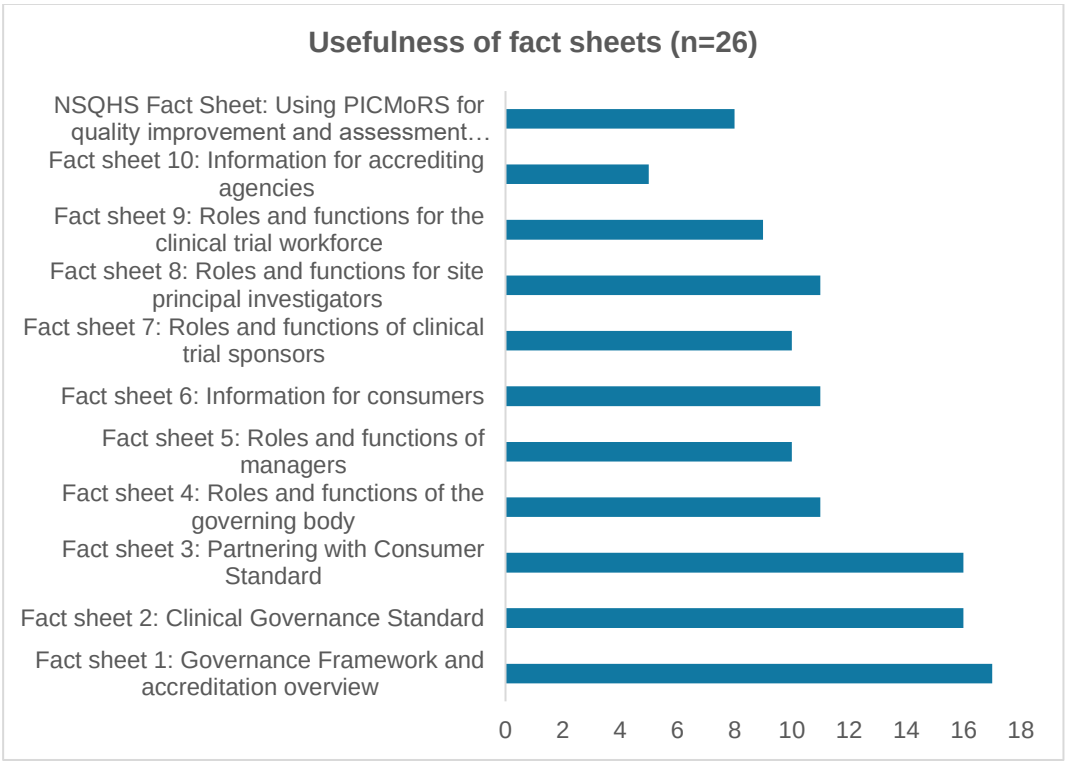


Figure 34: Usefulness of fact sheets



Suggested enhancements for the online self-assessment and operational metrics tools

Feedback from participants focused on system enhancement usability. Suggestions for enhancement of the self-assessment tool included the ability to upload website links and email formats as evidence and the ability to bulk upload. For the operational metrics tool, participants suggested including additional metrics regarding Aboriginal and Torres Strait Islander People specific clinical trials and overall participation in clinical trials and tele-trials.

Section 4: Discussion and pilot limitations

Discussion

Overall, health service organisations considered participation in the pilot as a valuable experience that provided the catalyst for cross-organisational collaboration between the governing body, executives, quality officers, clinical and non-clinical managers and the clinical trial workforce. Health service organisations that were solutions focussed and achieved early executive and safety, quality and risk officer engagement, more easily and effectively met the actions within the Governance Framework. Strong executive support was essential for success.

Although resource intensive, building awareness of the Governance Framework through the pilot enabled health service organisations to undertake a gap analysis between what is currently in place and what needs to be in place, to meet the actions of the Governance Framework. The pilot provided the opportunity for health service organisation to collate the appropriate evidence that quality systems are integrated, embedded and evident in clinical trial operations.

Pilot participants reported that the structure, sequence, intent and language of the Governance Framework is clear and logical. The resources developed to support the pilot and implementation of the Governance Framework were also found to be helpful and easy to use, with recommendations for improved functionality of the web-based tools.

The self-assessment and the operational metrics tools were developed to ensure that every health service organisation is able to contribute to the collation of evidence against each action in the Governance Framework and report on trial operations.

There was a general lack of understanding on the purpose of performance measurement and requests for further guidance regarding reporting on trial operations were received through written submissions and survey responses. Shared operational reporting is a requirement of good clinical and corporate governance, it improves transparency and drives effective engagement between health service executive and the clinical trial workforce. The purpose of shared reporting is to enhance internal discussions using operational data that reflects the activity where it is occurring. That is, within the clinical trial unit. Trial coordinators with trial investigators prepare to deliver the trials, seek the necessary approvals and recruit trial participants. Throughout the trial process data should be progressively collated so that overtime these reports can inform quarterly internal service review.

The pilot revealed several larger jurisdictions and metropolitan health service organisations had a mechanism through which trial operations could be reported, however within the pilot cohort no health service organisation demonstrated they could report on the eight operational measures as required under Action 1.1 at the level of the clinical trial unit.

There was variable understanding by the clinical trial workforce of the accreditation process and the role of accreditation assessors. Accreditation assessors do not ‘lead’ the assessment process, they are neutral observers. Assessment is a fully independent process that should not be influenced by the preferences of the health service organisation, particularly in respect to service and trial sampling. For implementation of the Governance Framework, health service organisations will need to provide accurate information relating to all clinical trial services, the number of trials and participating trial populations.

For the purpose of the pilot, assessors assessed the maturity of participating health service organisations to meet the actions in the Governance Framework. The assessment team familiarised themselves with the Commission's support material and participated in training prior to conducting assessments for the purpose of the pilot. Moving forward, all registered accrediting agencies will need complete the Commission lead training on clinical trial service provision.

The pilot revealed confusion remains regarding the term 'governance' in relation to an organisational wide approach to implementing the Governance Framework as opposed to research review and authorisation as the role and function of a research office. Some participants noted that there are some actions under NSQHS Standards which have not been included in the Governance Framework such as credentialing. This is because these actions are already addressed for all health service employees under the NSQHS Standards and did not need to be duplicated. The determination of the 27 actions specific to clinical trial services were determined on advice from the expert advisory committee and via national sector wide consultation in February 2019.

The pilot introduced the concept of clinical incident and risk reporting systems and processes, and clarified the difference between the reporting requirements at a trial level to an HREC or trial sponsor, and reporting incidents and risks associated with service provision. The pilot also broadened awareness by clinical trial workforce of reporting lines, committee structures, committee memberships and the associated links with researchers and/or business partners. Additionally, the pilot increased sponsors' awareness of their role and responsibilities in relation to the Governance Framework and the expectation that they will share information relating to the safety and quality of trial conduct and service provision with the health service executive, for the purpose of service provision improvement.

Those actions that received the highest assessment rating include: Action 2.4 (informed consent); Action 1.3 (the health service organisation has a clinical governance framework in place); Action 1.12 (the health service organisation has an open disclosure framework in place) and Action 2.5 (the health service organisation has a process to identify the capacity for patients to make decisions about their own care) were implemented in the majority of pilot sites.

The majority of pilot sites were awarded a rating of Growing or Initial systems in respect to Action 1.13, indicating that while health service organisations generally survey patients, families and carers, there was insufficient evidence available to confirm that clinical trial participants, families and carers were formally surveyed. Similarly, Actions 2.9 and 2.14, which require consumer involvement and partnership, challenged a large number of health service organisations. Eight health service organisations were awarded Growing systems for Actions 1.7 and 1.11. These actions relate to risk and incident management. The pilot also highlighted, for several health service organisations, the need for greater visibility of investigator-led clinical trials.

Perceived barriers to implementation include limited awareness of the NSQHS Standards, resistance to sharing resources within and between clinical departments; lack of executive and clinical trial workforce engagement to address the current state of siloed clinical trial service provision and a lack of understanding by trial sites of the role they play as participants in organisational governance.

Health service organisations along the maturity scale

Health service organisations assessed as having **Established** systems were able to provide clear evidence that policies and procedures are implemented across the organisation that incorporate clinical trial services. There was evidence, supported through the interview process of regular engagement with and reporting to, the governing body and evidence of comprehensive and robust processes in relation to partnering with clinical trial participants and Aboriginal and Torres Strait Islander populations.

Participants from these health service organisations reported that pilot participation validated project roles or investment in the change journey to date, informed longer-term implementation and reform plans and identified priority actions. The pilot provided further information to inform the Board, executive, management team and third-party stakeholders and sponsors on the status of clinical trial services in their health service organisations.

Those health service organisations assessed as having **Growing** systems in place had evidence of policies and procedures, some of which may not be current or not completely implemented across clinical trial services and/or available. The most challenging areas included risk and incident management (Actions 1.7 and 1.11). These health service organisations are developing relationships with their risk, safety and quality team and reported that the pilot provided the momentum to develop a more comprehensive approach to update policies, procedures, operational plans, strategies, monitoring documents, risk assessments and communication plans.

Pilot participation provided another perspective on accreditation assessment to inform internal self-assessment and priorities and timelines for action. The pilot also raised awareness of key roles and responsibilities both internally and externally to assist with planning for a culture change, including identification of ‘champions’ to assist health services transition from the current state to the future state.

While health services assessed as having **Initial** systems in place were committed to full implementation of the Governance Framework, the majority of actions were yet to be commenced or implemented. These health services were generally smaller health services in regional locations, with fewer trials. They were particularly challenged by partnering with consumers in organisational design and governance. For these health services, the perceived benefits of pilot participation were the increased focus of health service executives on priorities for strategic planning and re-assessing the quantum of change required to align clinical trial services with existing clinical and corporate governance systems. It also provided the opportunity to increase engagement and raise awareness of the Governance Framework across the workforce and informed the development of communication and engagement plans with internal and external stakeholders.

Of the 15 health service organisations that underwent the pilot accreditation assessment five health service organisations received an assessment rating of Established systems and these were public health facilities located in metropolitan cities. Two of the three health service organisations that received an assessment rating of Initial systems were located in regional centres and for these, the mean self-reported one-off costs for implementation equated to $781,871.00 (StdDev $665,154.00) and $502,743.00 (StdDev $351,119.00). These estimates are three times the level of financial investment estimated by larger metropolitan health service organisations and parallels the observed difference between the level of resourcing and readiness to implement the Governance Framework between regional and metropolitan health service organisations, reported by the accreditation assessors.

In summary, the pilot demonstrated that the systems and processes are already in place for health service organisations to meet the actions in the NSQHS Standards and, the AHSSQA Scheme provides the appropriate mechanism for accreditation assessment. Effectively incorporating clinical trials into health service corporate and clinical governance systems requires health service organisations to consider the degree of cross organisational engagement and health service executive support for human and financial resources, a cross organisational understanding of clinical trials and the accreditation process and familiarity of consumer engagement and feedback strategies. As with accreditation of health service organisations for clinical service provision, implementation of the Governance Framework under the NSQHS Standards will effectively strengthen clinical and corporate governance arrangements for governments, patients and consumers, hospital administrators, health service organisations, private companies, trial sponsors and trial investigators that deliver clinical trials.

Support for implementation

Jurisdictional health departments and health services have the overall responsibility to meet the actions in the NSQHS Standards as provided in the Governance Framework, and there are jurisdictional initiatives to support rural and regional health service organisations including but not limited to the Australian Government investment of $125 million via *The Rural, Regional and Remote Clinical Trial Enabling Infrastructure Program*. The focus of this funding is to improve the health of Australians in rural, remote and regional areas through access to innovative clinical trials by removing barriers to participating in clinical trials. It is anticipated this will be achieved by improving facilities, equipment and services in rural, regional and remote Australia, providing patients quicker and easier access to medical treatments, drugs, therapies and devices through participation in clinical trials; increasing research capacity; enhancing existing local and national organisations, facilities and the workforce. The effects are expected to be realised within health service organisations delivering clinical trials.

As with the NSQHS Standards, the Commission provides support to health service organisations via a number of mechanisms including but not limited to; an advice centre, user guides, supporting tools and resources including training for and the registration of, accreditation assessors, advisories, fact sheets, workbooks and risk matrices.

To support implementation of the Governance Framework, jurisdictional health departments and health service organisations are key in facilitating:

- Greater engagement across the organisation between the executive and clinical trial services
- Broader understanding of the NSQHS Standards and the accreditation process
- The inclusion of patients and consumers in governance activities to support safe, high quality clinical trial service provision
- Engagement of the health service organisation's risk, safety and quality teams in the delivery of clinical services and clinical trial services
- Mechanisms for collating and maintaining accurate quality performance data about clinical trial services
- Executive oversight and support for the delivery of investigator-initiated clinical trials
- Adopting a risk management approach in the development of policies and procedures to support clinical trial services, including the use of incident management systems
- Human and financial resources to support the delivery of clinical trial services
- Independence of the accreditation assessment process, particularly in respect to ensuring the accurate sampling of all trial units and trials conducted by the health service organisation.

Pilot limitations

A possible limitation of the pilot was the comparative short preparation time for health service organisations to implement the Governance Framework compared to the usual preparation time-frame of six months for accreditation assessment to the NSQHS Standards. The Governance Framework was released to the sector in February 2020. Level 2 pilot participating health service organisations were informed of their selection in July 2020, the pilot commenced in September 2020 and the first accreditation assessment was undertaken six weeks later. Therefore, while the Governance Framework was publicly available, those Level 2 pilot health service organisations who were assessed early in the pilot had approximately two to three months to prepare. For these health service organisations, preparing the relevant documentation and scheduling appointments with key stakeholders, the pilot created an additional workload particularly as some staff were still working remotely following the initial COVID-19 national lock-down period.

The requirement to use the supporting tools (operational metrics tool and self-assessment tool) through the pilot was to ensure the tools were fully tested by the sector. Level 2 pilot sites noted a potentially duplicative processes regarding data entry into existing systems for information required to facilitate reporting against the actions in the Governance Framework. The use of the web-based tools is optional once the Governance Framework is implemented, if the health service organisation has a mechanism and/or system to support clinical trial service performance reporting.

There were technological issues with the online self-assessment which created an additional workload for participating health service organisations. The IT development team responded early to correct issues relating to the document upload function and the Commission worked progressively with the health service organisations and the development team to resolve them. The subsequent enhancement of the self-assessment tool will ensure it is fit-for purpose to support health service organisations conduct a gap-analysis against the actions in the Governance Framework.

Section 5: Case studies

Alfred Health (the Alfred)

Table 32: Alfred Health at a glance

Alfred Health (the Alfred)	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	Population covered	No. clinical trials
	VIC	Metropolitan	Public	Single	>700,000	>600

Description of the organisation	Approach to implementation
• Alfred Health comprises three hospitals: The Alfred, Caulfield Hospital and Sandringham Hospital • The Alfred is home to the Alfred Research Alliance comprising Monash University, Baker Heart and Diabetes Institute, Burnet Institute, Deakin University, La Trobe University Nucleus Network and 360biolabs • Alfred Health is governed by the Alfred Health Board accountable to the Minister for Health • Committees established by the Board include Audit Committee, Community Advisory Committee, Finance Committee, Primary Care and Population Health Advisory Committee, People and Culture Committee, Quality Committee, Remuneration Committee	• Research Governance Framework Guideline developed and aligned with National Clinical Trials Governance, Quality and Clinical Governance Framework and the Alfred Health Strategic Plan • The Alfred Health Research Leadership and Governance Committee established to monitor implementation and compliance with the Clinical Trials Governance Framework • A project officer coordinates the implementation requirements of the Clinical Trials Governance Framework ensuring engagement across the organisation and integration with existing clinical governance processes • Close working relationship between risk, safety and quality staff and clinical trials staff fostered • Strong executive support established • Broad engagement across the organisation during the pilot accreditation assessment • Clear understanding of the governance structure, roles and responsibilities across all roles

Implementation of the Clinical Trials Governance Framework		
Clinical Governance Standards	**Partnering with Consumers Standards**	**Aboriginal and Torres Strait Islander specific actions**
• Research incorporated in the strategic plan and organisational structure • Processes in place to collect operational metrics to through Alfred Health's Ethics & Research Governance Office database (Access) and reported to the Research and Governance Committee • Delegated roles, responsibilities for clinical trials articulated in the Research Governance Framework. Development and Approval of Policies and Guidelines Guideline details the process for the development, approval, implementation and review of all policies and guidelines • There is a Risk Management policy, Framework & Guideline. The risk management framework and associated tools align with the Australian Standard for Risk Management (AS/NZS ISO 31000:2018) • All stakeholders provided with timely information about safety and quality performance • Patient Feedback Guideline outlines how routine and specific feedback from patient, families and carers is collected	• Strategy is overseen by the Community Advisory Committee and the Patients Come First Committee • Consumer register of over 100 consumers • Partnering with Consumers KPIs developed to monitor consumer involvement • Guidelines to support effective partnership with consumers established • Patient Information Working Group established to improve communication with consumers • Collecting Patient Stories is an important component in understanding how patients perceive the health care they receive and how services can improve. A number of online resources are available to support staff to collect and use patient stories	• Aboriginal Health policies and guidelines in place to ensure patients are provided with culturally safe, respectful, and appropriate patient care • Innovate Reconciliation Action Plan in place • Aboriginal Health Advisory Group supports the planning of initiatives to deliver safe, culturally appropriate and quality care for all Aboriginal and Torres Strait Islander people • Patient experience KPIs for Aboriginal and Torres Strait Islander people developed • Established Aboriginal Health Outcomes Working Group monitor the KPIs and develop actions to address the healthcare priorities • Ngarru Arweet Network enables discussions and collaborative activities to strengthen indigenous research capacity •

Alfred Health comprises three hospitals (The Alfred, Caulfield Hospital and Sandringham Hospital) and covers a population of more than 700,000 people in inner-southern Melbourne. Seven per cent of all patients speak a language other than English with the most common languages being Greek, Russian, Mandarin, Cantonese and Turkish. Alfred Health has identified the homeless as the most significant vulnerable population within the Alfred Health catchment.

The Alfred is a major metropolitan hospital including more than 7,800 staff and is home to the Alfred Research Alliance bringing together eight independent and diverse organisations including Monash University, Baker Heart and Diabetes Institute, Burnet Institute, Deakin University, La Trobe University Nucleus Network and 360biolabs. In 2019–20, Alfred Health had 636 clinical trials open.

Alfred Health is governed by the Alfred Health Board (the Board) which is accountable to the Victorian Minister for Health. The Board comprises nine independent non-executive directors who are appointed for a period of up to three years and can be re-appointed to serve up to nine years. The Board's role is to exercise good governance in achieving the objectives as outlined in Alfred Health's Strategic Plan and the Annual Statement of Priorities.

Governance, leadership and culture

Alfred Health has comprehensive, up to date and appropriate strategies, policies and procedures in place and shows regular engagement with and reporting to the governing body about clinical trial services.

Alfred Health has a mature governance structure in place. The Board understands and promotes safety and quality within the health service organisation and leaders at all levels in the organisation establish and use clinical governance systems to improve the safety and quality of health care for patients. The Board sets the strategic direction and research is incorporated in several goals of the Strategic Plan. Research is included at multiple levels of the organisational structure (Figures 35 and 36).

Figure 35: Alfred Health organisational structure (Please note: this figure is currently being updated to reflect the 2021 organisational structure)

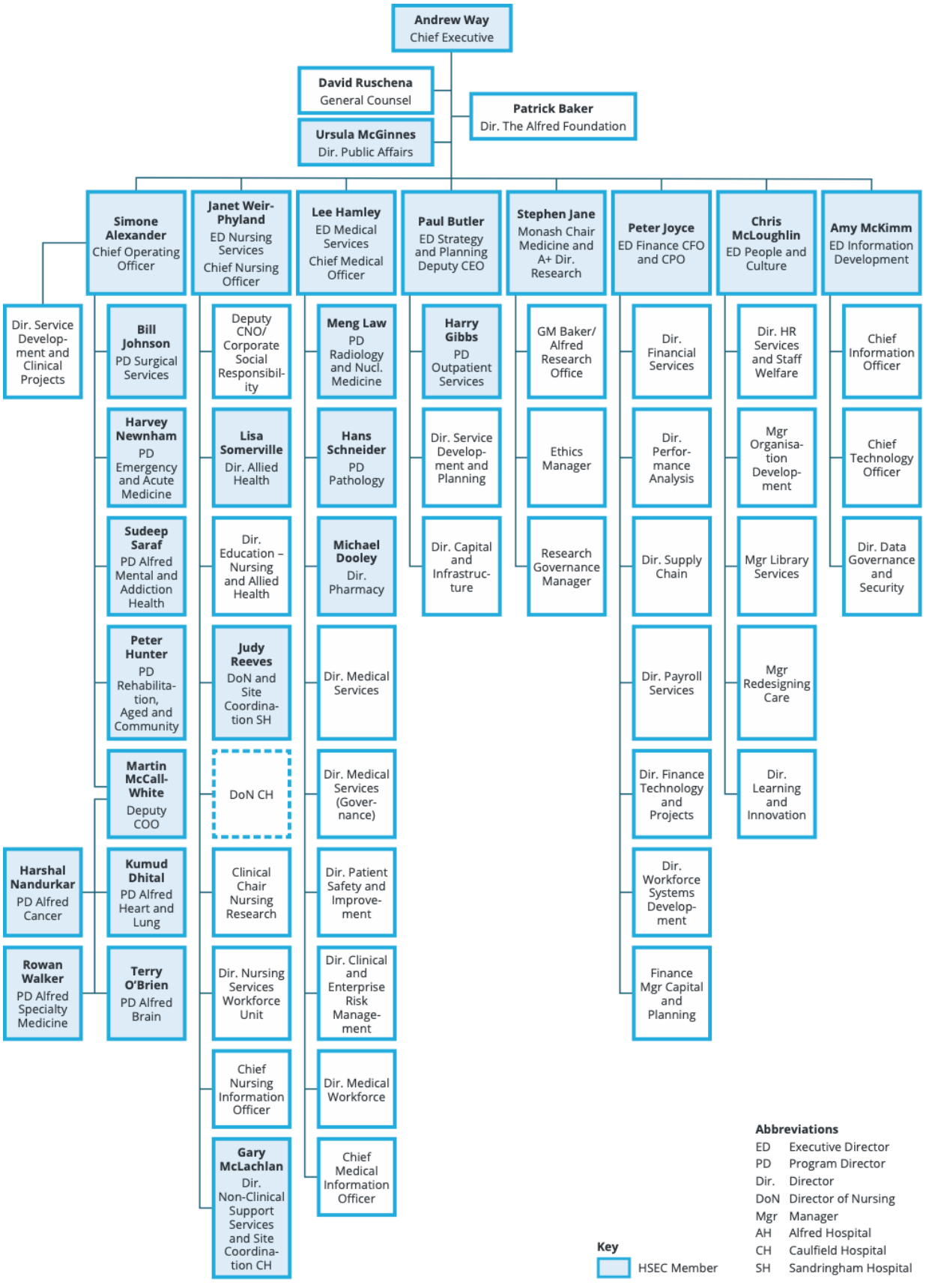
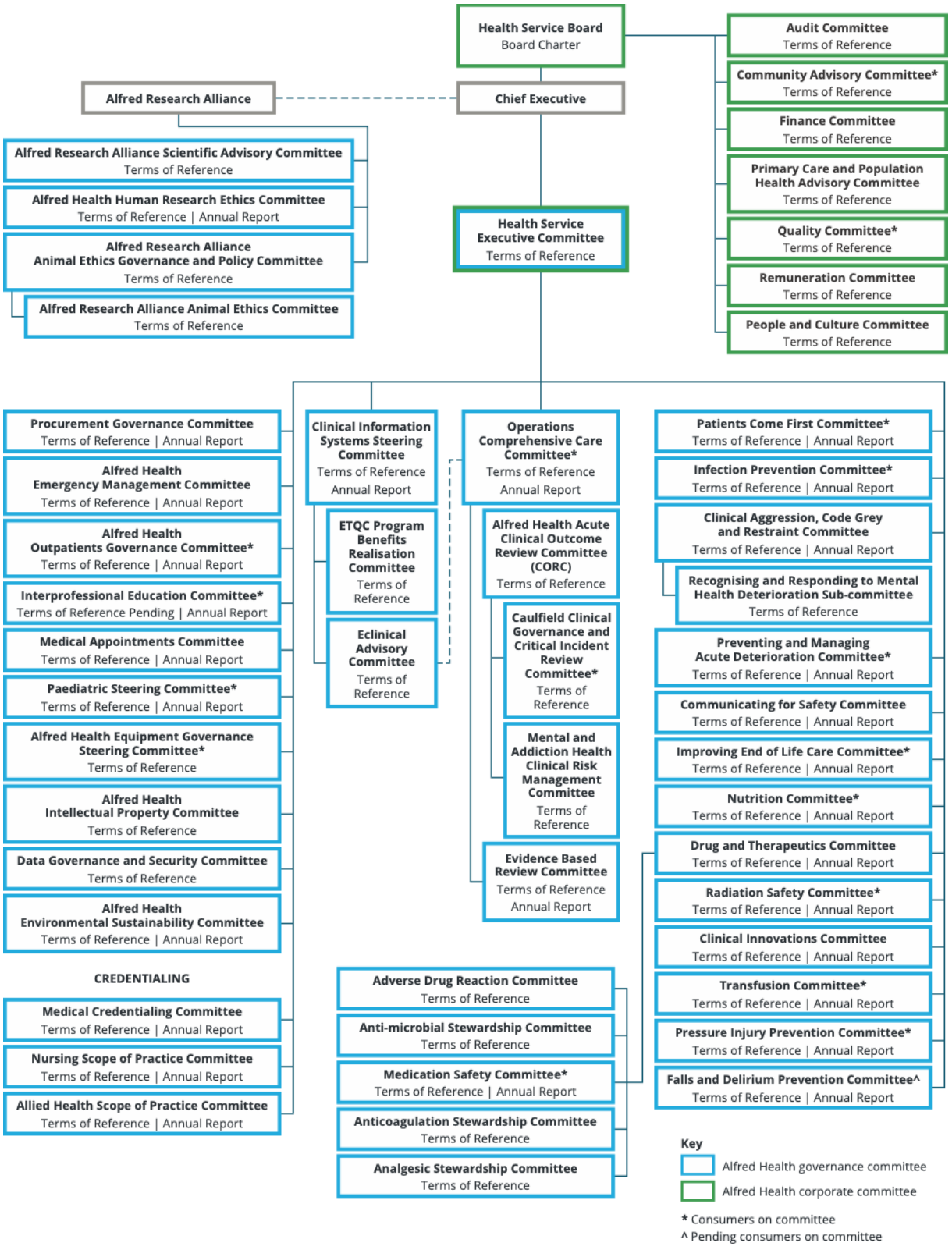


Figure 36: Alfred Health committee structure (Please note: this figure is currently being updated to reflect the 2021 governance and corporate committees' structure)



The Board has established a number of committees and advisory committees including:

- The Community Advisory Committee – provides advice to the Board on consumer, carer and community participation and other Alfred Health community initiatives
- The Quality Committee – established to ensure that effective and accountable systems are in place to monitor and improve the quality and effectiveness of health services.

The Board monitors variations in health care provision, complaints, compliments and the function of research and clinical trials to monitor progress and report on strategies for safe and high-quality clinical care. Summary reports containing pre-determined KPIs are provided to each meeting of the Board for review.

Alfred Health has processes in place to collect and use metrics to provide quality assurance.

The Alfred Health's Ethics & Research Governance Office collect and report on data covering the timeliness with which HREC and SSA applications are processed as well as:

- Recruitment at a site level
- Number of serious adverse events
- Deviations from protocols
- Amendments of protocols
- Number of audits carried out.

The data is collected through Alfred Health's Ethics & Research Governance Office database (Access) and reported annually to the Executive Committee, quarterly to Director of Research and the Alfred Research Alliance and provides data to the Commonwealth

Department of Health via National Aggregate Statistics (NAS).

The roles, responsibilities and accountabilities for safety, quality and clinical governance are clearly articulated in the Alfred Health Quality and Clinical Governance Framework and in workforce position descriptions. The Alfred Health Quality and Clinical Governance Framework aligns with the Alfred Health Strategic Plan. Delegated responsibilities for quality and safety for clinical trials and research are also articulated in the Research Governance Framework, the Code of Conduct of Researchers Policy, and the Principal Investigators Guideline.

Patient safety and quality improvement system

Alfred Health has developed guidelines to ensure the contents of policies and guidelines are current and relevant to current practice and core business, evidence-based, underpinned by best practice principles and compliant with all relevant legislation. For example, the Development and Approval of Policies and Guidelines Guideline details the process for the development, approval, implementation and review of all Alfred Health policies and guidelines while the Legislative Compliance Guideline provides guidance to ensure that Alfred Health is compliant with all relevant legislation.

Alfred Health has an integrated clinical and enterprise risk register. High and extreme risks are addressed by specific committees and data is used to support improvement in safety and quality. The responsibilities for risk management are included in The Risk Management Framework and Guideline. All staff are able to report incidents, hazards and near misses through the risk register which incorporates the Victorian Hospital Incident Management System, a data set which is reported monthly to Safer Care Victoria. All clinical incidents are screened and distributed to appropriate line managers for follow up. The incident data are routinely analysed for trends and reported to various committees including the Executive Committee and the Quality Committee. Consumers that have received training are also involved in incident review.

Alfred Health has developed processes to ensure that key stakeholders are provided with accurate and timely information about safety and quality performance in alignment with the

Alfred Health Quality and Clinical Governance Framework. Feedback is provided to the workforce on patient safety and quality and any system changes for implementation through various mechanisms:

- Monthly organisational/program/ward scorecards
- Clinical Governance report
- Monthly management pack
- Weekly staff e-Newsletters
- Regular executive roadshows
- Updates through Alfred Health social media platforms.

Feedback to consumers occurs through information boards, publications on Alfred Health website, the annual Alfred Health Quality Account and Alfred Health Annual Report.

Alfred health has a Patient Feedback Guideline in place to provide guidance to the workforce on handling patient complaints and collecting routine and specific feedback from consumers. A Clinical Trials and Research Patient Experience Survey Tool is currently in development to enable the collection of feedback specific to clinical trials participants and their carers.

Partnering with Consumers

Alfred Health has developed the Patients Come First Strategy and Plan, a roadmap to supporting the best possible patient experience and engaging consumers in health service planning, design, and improvement.

The Patients Come First Strategy is overseen by the Community Advisory Committee and the Patients Come First Committee. The Community Advisory Committee reports directly to Alfred Health Board. Five working groups report to the Patients Come First Committee:

- Aboriginal Health Advisory Working Group
- Diversity Working Group
- Patient Information and Feedback Governance Group
- Patient Information Consumer Working Group
- Vulnerable Persons Steering Group.

Alfred Health has a consumer register of about 100 consumers who help with service improvement and feedback.

Alfred Health has developed a Partnering with Consumers KPIs to monitors consumer involvement including but not limited to: number of trained consumer advisors and volunteers; consumer participation in Alfred Health projects and consumer involvement in patient information.

Health literacy

Alfred Health identifies the diversity of its consumers through daily reports of inpatients who require language services, inpatients who have identified as Aboriginal or Torres Strait Islander, as well as socioeconomic demographics and health outcome data.

Alfred Health has developed guidelines to support effective partnership with consumers:

- The Health Literacy Guideline provides strategies to reduce the impact of low literacy

- Guideline – Research with Participants Requiring Language Services sets out the Ethics Committee's requirements for the inclusion in research of people who require translated or interpreted information
- Supporting Vulnerable Patients Guideline identifies language requirements as contributing to vulnerability of consumers and provides guidance to staff to recognise patients and carers who may have increased vulnerability when accessing health services.

A Patient Information Working Group has been established to improve communication with consumers so they can access, understand, and use health information provided to them. Ten consumer representatives participate in the working group.

Alfred Health uses a consistent approach to the collection, utilisation, and governance of patient stories outlined in the Patient Stories Guideline. There is a catalogue of patient stories and approval is required to access them. These patient stories to bring the human dimension to health care and are considered a powerful patient feedback approach.

Aboriginal and Torres Strait Islander–specific actions

Alfred Health uses formal strategies to improve outcomes for Aboriginal and Torres Strait Islander patients.

Alfred Health has developed:

- The Aboriginal Cultural Heritage Policy which provides an operational framework for the protection of Aboriginal cultural heritage that is practical, legally appropriate, and fosters consistency across the organisation
- The Aboriginal Health Guideline which provides guidance to ensure patients who identify as Aboriginal or Torres Strait Islander are provided with culturally safe, respectful, and appropriate patient care. This guideline defines the roles and responsibilities of the Aboriginal Hospital Liaison Officers and the Aboriginal Access and Support Worker
- An Innovate Reconciliation Action Plan.

Alfred Heath has an Aboriginal Health Advisory Group which works in collaboration with Aboriginal and Torres Strait Islander people to support Alfred Health in the planning, implementation and evaluation of initiatives, systems and processes to deliver safe, culturally appropriate and quality care for all Aboriginal and Torres Strait Islander people who access Alfred Health services. The Aboriginal Health Advisory Group has developed a specific set of access, outcome, and patient experience KPI's for Aboriginal and Torres Strait Islander people in collaboration with the local Aboriginal community.

Alfred Health is also part of the Monash Partners, an Advanced Health Research Translation Centre. Monash Partners has established the Ngarru Arweet Network to enable discussions, collaborative activities and relationship building to strengthen indigenous research capacity and progress the priorities of health services.

Approach to implementation

Alfred Health has developed the Research Governance Framework Guideline which aligns to the Alfred Health Quality and Clinical Governance Framework Guideline. The National Clinical Trials Governance Framework and the Strategic Plan. This Framework outlines the safety and quality management systems that Alfred Health has implemented to support the undertaking of safe, high quality and patient-centred research.

- The Alfred Health Research Leadership and Governance Committee has been established to monitor implementation and compliance with the National Clinical Trials Governance Framework and will report annually to Alfred Health's Executive Committee.

A project officer coordinates the implementation requirements of the Governance Framework and engagement across the organisation. The project officer has fostered a close working relationship between risk, safety and quality staff and clinical trials staff and has established strong executive support.

Alfred Health ensured broad engagement across the organisation during the pilot accreditation assessment. Board members, executives, managers, clinical trial workforce sponsors and consumers were interviewed and revealed a clear understanding of the governance structure, roles and responsibilities across all roles and highlighted consistency between policies and strategies that are implemented

Royal Darwin Hospital

Table 33: Royal Darwin Hospital at a glance

Royal Darwin Hospital	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	Population covered	No. clinical trials
	NT	Regional	Public	Single	200–450	<100

Description of the organisation	Approach to implementation
• The Top End Health Services region includes: Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove Hospital, Top End Mental Health Services and numerous remote health clinics • The population is around 82% of the Northern Territory population • Around 26% of the population is from Aboriginal or Torres Strait Islander origin • The Royal Darwin Hospital is a university teaching hospital with 360-bed • Executive Leadership Team is the governing body and reports directly to the Department of Health • Some Committees established by the Executive Leadership team include the Health Advisory Committee, the Safety and Quality Committee, the Clinical Innovation and Research Committee, the Aboriginal Health Committee.	• Small internal working party established to oversee implementation of the Governance Framework • Working party focus on engaging all relevant stakeholders • Strong and effective support from executive • Risk safety and quality team engaged early in the implementation process • Educational opportunities identified early to increase awareness of the Governance Framework requirements across the organisation • Broad engagement across the organisation during the pilot accreditation assessment.

Implementation of the Clinical Trials Governance Framework		
Clinical Governance Standards	**Partnering with Consumers Standards**	**Aboriginal and Torres Strait Islander specific actions**
• Research incorporated in the Strategic Plan and organisational structure • Roles and responsibilities for safety and quality in clinical trials are included in clinical trials coordinator positions • Clinical Innovation and Research committee is chaired by an Executive member and reports to the Executive Leadership Team • Operational data and trial findings discussed at Clinical Trial Unit quarterly meetings • Quality improvement activities, risks and incidents reported through Riskman • Collection of patient experience through community meetings, patient surveys, Talk to Us Program, online form or feedback cards.	• Health Advisory Committees and Consumer Advisory Group established to promote and facilitate community consultation and engagement to shape the delivery of services • Participant satisfaction surveys appropriate to the different language groups of the Royal Darwin Hospital catchment area conducted • Participant Experience and Consumer Engagement and Stakeholder Communication Strategy established • Communication resources provide clinicians guidance and contact details for support services.	• Collaborative partnership with Aboriginal controlled health services and the primary health network • Aboriginal KPIs developed and reports monitored through the Aboriginal Health Committee. • Reconciliation Action Plan and Northern Territory Health Aboriginal Cultural Security Framework have been established • Cultural Awareness training provided to the workforce at orientation and repeated annually • A number of senior staff identify as Aboriginal and Torres Strait Islander.

Note: Top End Health Services as an entity has changed following an organisational restructure in July 2021. This change will be reflected in the final version of the pilot report.

The Royal Darwin Hospital is within the Top End Health Services region (TEHS). The TEHS region includes Royal Darwin Hospital, Palmerston Regional Hospital, Katherine Hospital, Gove Hospital, Top End Mental Health Services and numerous remote health clinics. The population in the region is estimated at 200 450, which is around 82% of the Northern Territory population. Around 26% of the population is from Aboriginal or Torres Strait Islander origin. The median age of the population is 33 years compared with the national median age of 37 years.

The Royal Darwin Hospital is a university teaching hospital with 360-bed and provides a broad range of services in all specialty areas.

The Executive Leadership Team is the governing body of Royal Darwin Hospital that leads and manages the business operations of TEHS (Figures 37 and 38). The Executive Leadership Team reports directly to the Department of Health.

Figure 37: Royal Darwin Hospital organisational structure (Please note: this figure is currently being updated to reflect request from Royal Darwin Hospital to remove names from the figure)

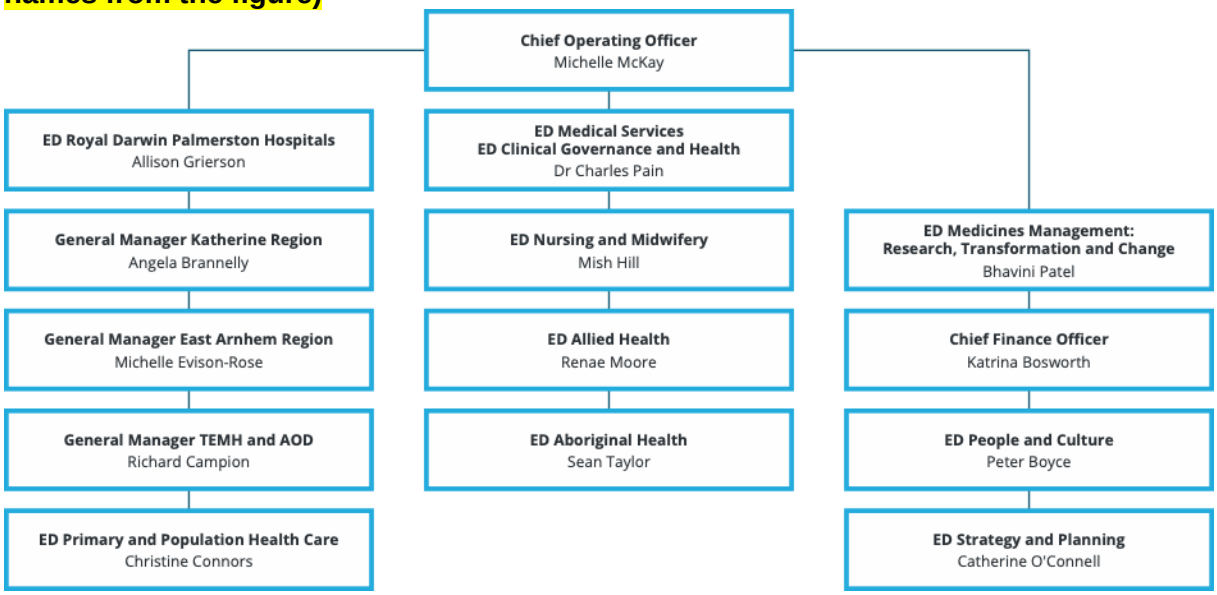
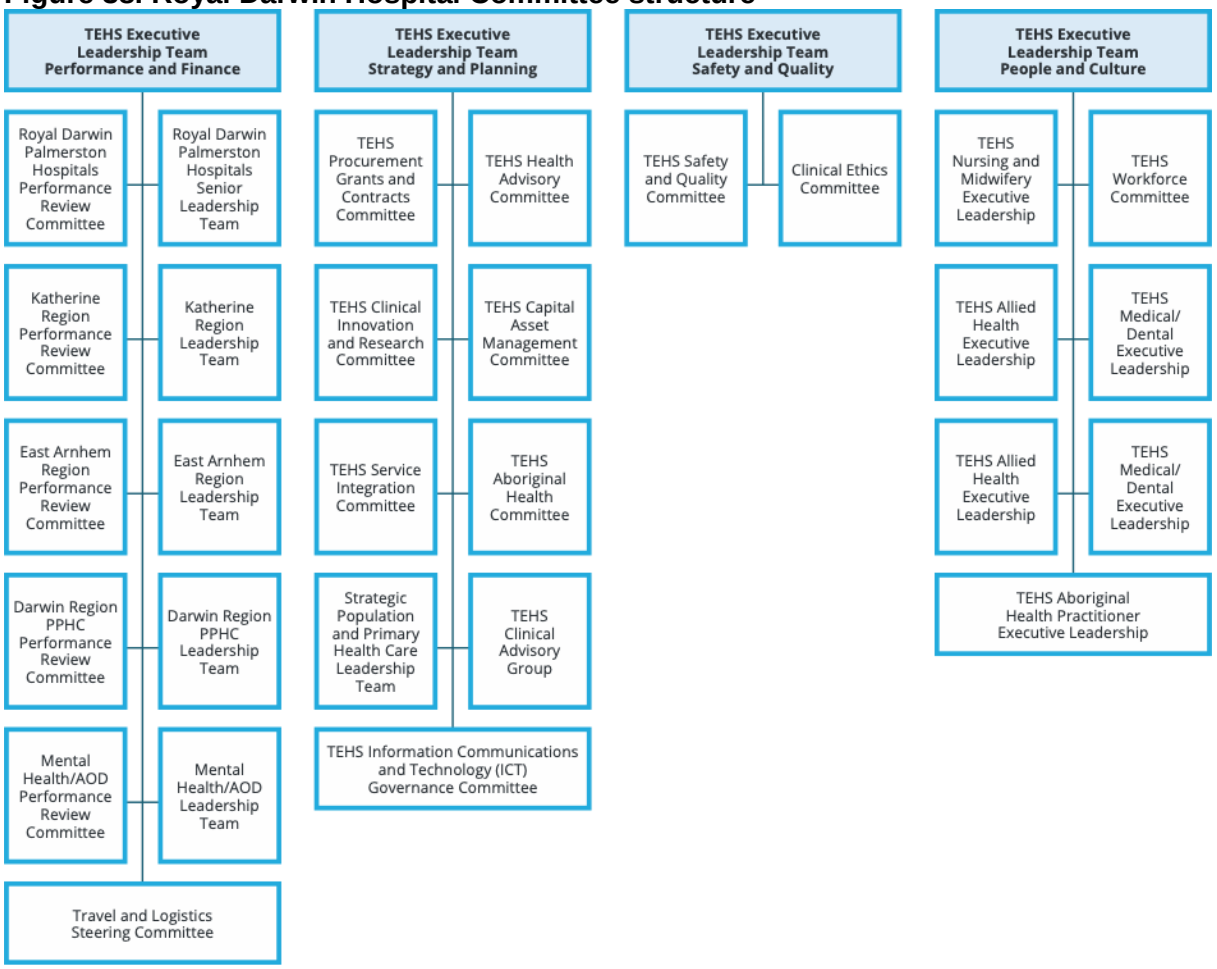


Figure 38. Royal Darwin Hospital Committee structure



Governance, leadership and culture

The Royal Darwin Hospital has established a set of policies and procedures to guide the conduct of a high-quality clinical trials that is appropriate to the size and context of the organisation.

The organisational structure demonstrates a comprehensive reporting line from research to the Executive Leadership Team and the Northern Territory Department of Health (NT Health) in which clinical trials are embedded.

The Chief Operating Officer is the Chair of the Executive Leadership Team. As the peak governance and decision-making body, the Executive Leadership Team is responsible for ensuring safe and high-quality care is delivered. The Executive Leadership Team has established a number of committees including but not limited to:

- The Health Advisory Committee supports the decision-making processes of the health service through consultation with, and advocacy on behalf of the community.
- The Clinical Innovation and Research Committee provides research governance leadership and supports the implementation of the TEHS Research Governance Framework
- The Safety and Quality Committee provides oversight of and leadership on the provision of high quality, safe clinical care and services and clinical governance systems for all of programs and services
- The Aboriginal Health Committee supports implementation of the Northern Territory Aboriginal Health Plan and Reconciliation Action Plan and seeks guidance from peak Aboriginal and Torres Strait Islander professional bodies and stakeholders.

The Alan Walker Cancer Care Centre, located at the Royal Darwin Hospital, is involved in national and international clinical trials and follows the Northern Territory Cancer Care Strategy. The strategy was developed by the Northern Territory Cancer Care Network on behalf of NT Health and provides a collaborative focus and direction for health care professionals, consumers and organisations involved to achieve improved patient experiences and optimal clinical outcomes for cancer patients. Clinical trials contribute to the key priority areas of quality and safety of the strategy:

> STRATEGIC OBJECTIVE – Delivery of high-quality cancer care based on contemporary evidence and data collection, application of optimal care pathways and increased participation in clinical trials.

The Royal Darwin Hospital strategic and business planning processes capture strategies and initiatives to deliver safe and quality clinical trial services. The TEHS Strategic Plan aligns with the NT Health and includes clinical trials in its strategic directions. The TEHS Clinical Governance Framework describes the arrangements that ensure TEHS sets, manages, monitors, and improves the delivery of safe, high-quality healthcare. The TEHS Clinical Governance Framework aligns with the NT Health Clinical Governance Quality and Safety Framework and includes research and innovation.

Roles and responsibilities for safety and quality in clinical trials is included in clinical trials coordinator positions. A Clinical Innovation and Research committee is chaired by an Executive member and reports to the Executive Leadership Team
. Safety and quality priorities and initiatives are also communicated to the workforce during orientation and affirmed at annual essential training.

The Royal Darwin Hospital has specific key performance indicators that require reporting to the NT Health. The Research: Monitoring Procedure promotes the safety of research participants and best research practice through collection of quality research data, appropriate record keeping, access and storage of research records. The TEHS Safety and Quality Plan includes priority areas, measurable outcomes, time frame and responsible positions. Clinical trials routinely collect, operational outcomes and trial findings and monitor data for trends. Data is discussed at Clinical Trial Unit quarterly meetings.

Patient safety and quality improvement systems

The TEHS Governance Document Framework articulates the process for the development, approval, implementation, and review of all governance documents. NT Health sets policies and establishes the consultation and engagement around new and revised policy documents. Requests for additional policies and procedures go to the TEHS Clinical Innovation and Research Committee.

All quality improvement activities are maintained within the quality improvement module on Riskman. Quality improvement education sessions are conducted and clinical trials units are encouraged to report any serious incidents via Riskman. Reports are run and analysed by the Executive Leadership Team and outcomes reported as a quality improvement standing agenda item in committees.

The Royal Darwin Hospital identifies one of the strategic risk associated with clinical trials as the inability to initiate, coordinate and embed research to support contemporary models of care.

The Risk Management Policy and Framework is a practical reference tool and sets out the processes for proactive identification, management, and timely resolution of risks and incidents. A structured process is in place to report outcomes and adverse events up through clinical trials steering committees. The Royal Darwin Hospital involves the workforce in the review of incidents which are reported via Riskman. Incidents receive an incident severity rating and relevant operational managers, members of executive team, the Chief Operating Officer and NT Health are alerted to facilitate visibility and enable appropriate review, action and monitoring. Timely feedback on the analysis of incidents is provided to the governing body, the workforce, and consumers. Any information presented to consumers is de-identified.

Feedback from trial investigators, the clinical trial workforce, sponsors, trial participants, their families and carers is used to improve safety and quality. TEHS uses learnings from patient experiences to guide service delivery and assist in identifying areas for improvement. TEHS collects information on the experience of patients, carers and families through:

- Community meetings
- Patient surveys
- Feedback through the Talk to Us Program, the NT Health online form or feedback cards
- Consumer participation on a range of advisory or operational committees.

The clinical trial workforce receives training on complaint management at orientation and annual essential training. The TEHS Consumer Feedback Management Guideline provides an approach and framework to ensure all consumer feedback is promptly acknowledged, investigated, reported and recorded.

Consumer focused evaluation and quality monitoring processes encompass regular and ad hoc processes. A feedback forum is held annually with all stakeholders. Feedback is collated and reported up through the committee structure to the Executive Leadership Team.

Clinical performance and effectiveness

The Royal Darwin Hospital has established an induction, orientation, mandatory training, and competency assessment relevant to clinical trials.

A programme for members of the workforce who are wanting to gain more experience in research is in place. The programme gives a general concept of research and provides opportunities to conduct research with guidance from senior roles and includes an annual forum for junior medical officers to present their projects.

Partnering with consumers

The Royal Darwin Hospital demonstrates a commitment to improve processes for partnering with consumers through the Health Advisory Committees. These committees have been established to promote and facilitate community consultation and engagement to shape the delivery of services. Members are appointed by the Minister for Health from a mix of background, skills and expertise to ensure appropriate local community input and engagement in health services planning.

The TEHS Consumer Advisory Group has been implemented and comprises a representative group of consumers, family members and carers to provide advice in the ongoing development of mental health services. An Indigenous Advisory Group has been established including Indigenous staff and consumer consultant to assist in the development of an Indigenous Consumer Advisory Group. TEHS currently has a consumer register which includes carers, family members and persons who wish to be involved, included and/or informed of developments and planning opportunities across the service.

Statistics are accessed to determine the demographics of the local population and to guide communication strategies to ensure the inclusion of all patients, consumers and clinical trials participants. The Executive Leadership Team ensures a culture of safety for staff and consumers and conducts participant satisfaction surveys appropriate to the different language groups of the Royal Darwin Hospital catchment area.

The Stakeholder Communication Strategy is a guide for the Research Governance Office in engaging with stakeholders. The Stakeholder Communication Strategy aligns with the NT Health and TEHS Strategic Plan and consumers are identified as one of the main target audience.

The Participant Experience and Consumer Engagement is a Framework which provide guidance to staff on how to build supportive relationships across the health service and support delivery of participant centred care.

Health literacy

Communication strategies are often determined by the sponsor. Trial information is only available in English, however interpreters are used when needed. Diagrams, pictures, and pictorial flowcharts are also used to aid discussions. Clinicians have access to communication resources that provide contact details for support services such as local consumer health advocates, interpreters, or cultural support and liaison services.

Aboriginal and Torres Strait Islander specific actions

An effective collaborative partnership exists between TEHS, Aboriginal controlled health services and the primary health network. The Royal Darwin Hospital is represented at these partnership committees where research is regularly discussed. In conjunction with Aboriginal controlled health services, the Royal Darwin Hospital reports against specific Aboriginal KPIs monitored through the Aboriginal Health Committee.

The TEHS Reconciliation Action Plan is in place which provides a holistic approach to create meaningful relationships, enhance respect and promote sustainable opportunities for Aboriginal people. The Northern Territory Health Aboriginal Cultural Security Framework focuses on the unique centrality of culture to health and the respect for Aboriginal people and culture necessary to enhance service access, equity, and effectiveness.

Cultural Awareness training is provided to the workforce at orientation and repeated at annual essential training. Additional interactive on-line modules are also being developed.

A number of senior staff identify as Aboriginal and Torres Strait Islander and work alongside Aboriginal and Torres Strait Islander people within Menzies School of Health Research who is a partner research organisation based on the Royal Darwin Hospital campus.

Approach to implementation

The Royal Darwin Hospital has established a small internal working party to oversee the implementation of the Governance Framework. The focus of the working party is on engaging all relevant stakeholders to embed clinical trial activity into current and new strategic and operational planning processes. There is a strong and effective involvement from the executive in leading engagement across organisation.

The risk safety and quality team has been engaged early in the implementation process and the requirements of the governance framework have been considered on multiple levels (across the Royal Darwin Hospital, TEHS and with research partners).

Educational opportunities have been identified early to increase awareness of the Governance Framework requirements across the organisation

The Royal Darwin Hospital ensured broad engagement during the pilot accreditation assessment. Clinical trial workforce, sponsors, managers, executives and clinical trials participants were interviewed.

Royal Prince Alfred

Table 34: Royal Prince Alfred Hospital at a glance

Royal Prince Alfred Hospital	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	Population covered	No. clinical trials
	NSW	Metropolitan	Public	Single	>700,000	>600

Description of the organisation	Approach to implementation
• SLHD is made of: Balmain Hospital, Canterbury Hospital, Concord Repatriation General Hospital, Royal Prince Alfred and Sydney Dental Hospital • Population covered in SLHD is >700,000 people and over 1 Million people work, study and visit SLHD each day • 55% of residents speak a non-English language with approximately 145 languages represented • Royal Prince Alfred Hospital has >4,500 staff • Complex interface between the district, the University of Sydney and the local medical research institutes • Royal Prince Alfred Hospital is governed by SLHD Board and Chief Executive.	• Risk safety and quality and accreditation expert appointed to lead implementation • Implementation Committee established at the Executive level • Strong support and engagement from the Chief Executive • Strong involvement of risk, safety and quality and patient safety experience team • 'Champions' identified in clinical trials teams to assist with engagement across the organisation • Early engagement across the organisation • A research strategy plan in place.

Implementation of the Clinical Trials Governance Framework		
Clinical Governance Standards	Partnering with Consumers Standards	Aboriginal and Torres Strait Islander specific actions
• Research is embedded in mission and strategic plan • Research strategic plan in place • Clinical Governance Standard Quality Improvement Plan supports provision of healthcare services through research, education, and the provision of tertiary and quaternary referral services • Research Clinical Governance Framework in place to improve safety and quality of health care during research studies. • Clinical Trials Steering Committee oversees clinical trials • Roles and responsibilities on the management and conduct of high-quality research in position descriptions and policy directives • Policies managed through Policy Committee and tabled at the Clinical Quality Council • Risk overseen by Risk Management Committee and Enterprise Risk Management System for Research identified • Patient Reported Measures Framework highlight the importance of feedback from clinical trials participants • National Carer Survey includes multiple references to research.	• More than 150 consumer representatives registered with SLHD • Patient Care Committee and Research Consumer Reference Group in place • Community Participation Coordinator engaged to and support consumer engagement • Importance of partnering with consumers highlighted in strategic plan and the Community and Consumer Participation Policy • Consumer and Community Participation Handbook for prospective consumer and community representatives • Consumer and community involvement in research project • Education and Training Strategic Plan and online training sessions for consumers and researchers in place • The Patient Reported Measures Framework.	• SLHD has a long-standing partnership with the Aboriginal Medical Service Redfern and the Metropolitan Aboriginal Land Council • Aboriginal Health Plan in place including a reporting dashboard with 18 indicators • Aboriginal Health Steering Committee established • Aboriginal Health Consultation held for the development of the Strategic Plan • Aboriginal Health Strategic Plan demonstrates commitment to incorporate strategies to deliver clinical trials to meet the priorities of Aboriginal and Torres Strait Islander people • SLHD works with the Aboriginal Medical Service Redfern in relation to research • Respecting the Difference Aboriginal cultural training framework in place.

SLHD is made up of five hospitals (Balmain Hospital, Canterbury Hospital, Concord Repatriation General Hospital, Royal Prince Alfred and Sydney Dental Hospital), health services and a range of associated support services. SLHD covers a population of more than 700,000 people in the centre and inner west of Sydney with over 1 million people who work, study and visit in the District each day. Fifty-five per cent of residents speak a non-English language with approximately 145 languages represented. The most common language groups include Arabic, Bangla, Chinese (Cantonese and Mandarin), Greek, Italian, Korean, Macedonian, Nepali, Vietnamese, Mongolian and Rohingya.

Royal Prince Alfred Hospital is a major metropolitan hospital including more than 4,500 staff.

The interface between the district, the University of Sydney and the local medical research institutes is complex. Research, teaching and clinical practice are integrated to support improved patient and community outcomes. Many senior researchers are specialist clinicians at both Royal Prince Alfred Hospital and Concord Repatriation General Hospital, while also lecturers/academics at The University of Sydney.

Royal Prince Alfred Hospital is governed by the SLHD Board and Chief Executive who are responsible for improving local patient outcomes, monitoring the performance of the district, delivering services and performance standards based on annual strategic and operating plans, ensuring services are provided efficiently and accountably and maintaining effective communication with local and state public health stakeholders.

Governance, leadership and culture

The Board oversees the SLHD strategic plan in which research is embedded and participates very actively with the development of strategic plans for facilities. Research is also included in the mission of the Royal Prince Alfred Hospital.

SLHD has a comprehensive research strategic plan which includes three strategic directions:

- To invest in and sustain research capacity across all district facilities, professions and disciplines.
- To create knowledge by leading quality biomedical, clinical, health services and population health research.
- To implement knowledge by rapidly translating research into best practice and policy.

Royal Prince Alfred Hospital Clinical Governance Standard Quality Improvement Plan describes the vision, mission and values developed to support the provision of healthcare services through research, education, and the provision of tertiary and quaternary referral services.

The Research Clinical Governance Framework describes the structures and systems in place to improve safety and quality of health care during research studies. The Framework outlines how the research community works toward improving consumer outcomes in relation to consumer safety, consumer experience, and research outcomes.

The Clinical Trials Steering Committee oversees clinical trials in regards to IT support, finance, expedition of approval, staffing and any identified issues for consideration.

The Safety Monitoring and Reporting for Clinical Trials conducted in NSW Public Health Organisations Policy Directive describes the regulatory and good practice requirements for safety monitoring and reporting for clinical trials conducted within NSW Public Health Organisations. It sets out the roles and responsibilities of public health organisations, investigators, Human Research Ethics Committees (HRECs) and clinical trial sponsors and provides a standard framework for all clinical trials. Position descriptions contain the roles and responsibilities in relation to the management and conduct/participation in high quality clinical and health services research. SLHD also has a booklet on staff management which includes guiding principles and outlines the management philosophy, key expectations of managers, and how this translates to everyday practice.

.

Patient safety and quality improvement system

SLHD Policy Compliance Procedure operationalises the requirements of NSW Health policies. Policies are managed through SLHD Policy Committee and all policies are tabled at the Clinical Quality Council. Policies are constantly reviewed by the Policy Manager, linked with the legal team to ensure they meet of legislative changes.

Risk is overseen by the SLHD Risk Management Committee and the Risk Management

Framework outlines the approach taken to integrate effective risk management into SLHD's culture and practices. The Enterprise Risk Management System for Research includes:

- Ineffective research governance management. Ethics and intellectual property must ensure compliance with standards and protection of intellectual property to avoid loss of opportunity and ensure benefits to SLHD
- Service agreements – business as usual risk. Budget overrun due to expired or incomplete service level agreements could result in unrecovered expenditure and disparate service expectations
- Drug and Clinical Trials – business as usual risk. Potential inadequate governance systems for reviewing clinical trial proposals including trial intervention design, conduct and reviewing of trials underway could result in adverse outcomes insurance claims and compensation to subjects.

The Royal Prince Alfred Hospital Strategic Plan highlights a culture of accountability through high-quality feedback and includes garnering feedback from patients/consumers and their families. The Patient Reported Measures Framework links to the strategic plan and promotes a patient and family-centred culture in which staff work collaboratively with patients and consumers in service planning, delivery, and evaluation. The Patient Reported Measures Framework states the importance of feedback from clinical trial participants.

A patient satisfaction survey has been developed and provides the opportunity for patients to identify their participation in a clinical trial. The National Carer Survey prepared by the Carers NSW Policy and research team includes multiple references to research.

Partnering with Consumers

Involvement of consumers and the community in clinical trials is seen as integral to providing excellent quality patient and family care.

More than 150 consumer representatives are registered with SLHD, and the Royal Prince Alfred Hospital Patient Care Committee includes consumers and community representatives. A community Participation Coordinator has been engaged to find consumer representatives and support their engagement with the health service.

The importance of partnering with consumers is highlighted in several strategic documents.

- One of SLHD Research Strategic Plan priority is to ensure consumer participation and community involvement in research.
- The Royal Prince Alfred Hospital Strategic Plan Priority 3 of research focus area is to promote patient/consumer involvement in the design and implementation of research projects and clinical trials.
- Royal Prince Alfred Hospital Community and Consumer Participation Policy outlines the mechanisms and processes involved in community participation at Royal Prince Alfred Hospital and the roles and responsibilities of staff and consumers.

SLHD has developed and implemented a Consumer and Community Participation Framework which describes the core values and principles of consumer participation. The Consumer and Community Participation Handbook for prospective consumer and community representatives provides information on the role description, committee reporting template, and National Safety and Quality in Health Services Standards information.

SLHD has proposed the establishment of a Research Consumer Reference Group to support initiatives such as:

- Development of guidelines on involvement in research
- Online website and registry
- Awareness campaign.

A consumer and community involvement in research project was initiated in 2020. The objectives of the project are:

- To raise awareness of best practice regarding involving consumers in research, among both consumers and researchers
- To raise consumer awareness about their potential role in research and increase their active involvement in the research process
- To develop a complement of structures, processes, roles and resources to support consumer involvement in research.

The Education and Training Strategic Plan states that “where feasible, invite NGO partners and community participants to participate in health training programs”. Online training sessions for consumers and researchers in partnership with Health Consumers NSW and Sydney Health Partners have been developed.

The Patient Reported Measures Framework links to the strategic plan and promotes a patient and family-centred culture in which staff work collaboratively with patients and consumers in service planning, delivery, and evaluation. Consumers have been involved in the development of the Patient Experience Survey tools.

Aboriginal and Torres Strait Islander–specific actions

SLHD has a long-standing partnership with the Aboriginal Medical Service Redfern and the Metropolitan Local Aboriginal Land Council and together, they work towards having the healthiest Aboriginal Community in the Country. An Aboriginal Health Plan is in place and includes a reporting dashboard with 18 indicators.

An Aboriginal Health Steering Committee has been established to provide leadership and support in addressing the directions and strategies of the Aboriginal Health Strategic Plan. This includes: ensuring that the implementation process is community driven, respectful of Aboriginal culture, supportive of ongoing partnerships, and committed to Closing the Gap between Aboriginal and non-Aboriginal people.

Aboriginal Health Consultation were held for the Strategic Plan: “Making Aboriginal Health Everybody’s Business” and included:

- Providing more opportunities for Aboriginal staff to learn research techniques and support to apply them
- Communicating outcomes and feedback related to research
- Ensuring research is culturally appropriate and collaborative
- Developing greater linkages to universities for Aboriginal research
- Involving Aboriginal workers on the ground in research

- Providing more Aboriginal Research Trainee positions.

The Aboriginal Health Strategic Plan demonstrates a commitment to incorporate the priorities and strategies to deliver clinical trial services to meet the priorities of Aboriginal and Torres Strait Islander people.

The Royal Prince Alfred Hospital works closely with the Aboriginal Medical Service Redfern in relation to research and strategic priorities, research development pathways, engagement in clinical trials and encouraging/supporting clinical trial participation.

Respecting the Difference is an Aboriginal cultural training framework which sets out the cultural training requirements for the NSW Ministry of Health, local health districts and other NSW health organisations to ensure that all staff are culturally competent and empowered to deliver more respectful, responsive, and culturally sensitive services for Aboriginal people, their families, and communities.

Approach to implementation

SLHD has appointed a risk safety and quality and accreditation expert to lead the implementation of the Governance Framework and act as the key contact. An Implementation Committee has been established at the Executive level led by Director of Research to oversee the implementation process and share information.

There is strong support and engagement from the Chief Executive as well as a strong involvement of risk, safety and quality and patient safety experience team

'Champions' have been identified in clinical trials teams to assist with engagement across the organisation. Early engagement across the organisation have helped identify any changes required to embed clinical trials into strategic and operational systems and processes.

A research strategy plan is also in place.

Ramsay Health Care

Table 35: Ramsay health care Health at a glance

Ramsay Health Care	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	Population covered	No. clinical trials
	National	Metropolitan	Private	Multi	>1 million	300+
Description of the organisation				**Approach to implementation**		
• Ramsay's global network covers 10 countries • Ramsay Australia has 72 private hospitals and day surgery • Ramsay Australia admits > one million patients annually • Ramsay Australia employs more than 31,000 people • National Clinical Trial Network established including 14 clinical trials units around Australia • Ramsay Australia is governed by the Risk Management Committee which reports to the Ramsay Global Board.				• Project officer appointed to undertake a gap analysis, progress work with the clinical trials network and support engagement across the sites • Planning led by a small team with representation from risk safety and quality, clinical trials and the project officer • Clinical Governance Committee responsible for overseeing implementation • Education opportunities identified across Ramsay Australia to understand functions of clinical trials and the accreditation process.		

Ramsay Health Care	State / Territory	Metropolitan / Regional	Public / Private	Single / Multi-site	Population covered	No. clinical trials
	National	Metropolitan	Private	Multi	>1 million	300+

Implementation of the Clinical Trials Governance Framework		
Clinical Governance Standards	**Partnering with Consumers Standards**	**Aboriginal and Torres Strait Islander specific actions**
• Strategic and business planning processes capture strategies and initiatives to deliver safe and quality clinical trial services • Regular report presented to Risk Management Committee including pre-determined KPIs, Riskman report, summary report on research specific policies • Clinical Policy and Forms Framework defines the governance structure and principles for developing, approving, reviewing and management of policies, guidelines, and forms • Position descriptions for clinical trials identified positions include reporting line, position summary and skill requirements • Patient Safety and Clinical Quality Framework in place • Comprehensive risk Management framework and clinical trial safety reporting policy in place • Clinical trial safety events collated and reported quarterly to facility Chief Executives. Chief Executives report incidents to the Medical Advisory Committee and the Patient Care Review Committee.	• Consumer Engagement Framework in place to assist facilities establish, maintain and enhance consumer engagement • Consumer Engagement Policy provides guidance on the engagement of consumers in broad operational and strategic decisions • Consumers included in the Board membership and various committees • Consumers participate in risk management and quality improvement activities • Pamphlets and videos regularly developed to orientate and inform participants about trials they may participate in.	• National Learning and Development Orientation and Mandatory Learning Framework includes mandatory training on Aboriginal and Torres Strait Islander Cultural Awareness • Cultural Diversity, Sensitivity and Responsiveness Policy comprises requirements for awareness of, and sensitivity to, the diverse needs of the patient populations • Aboriginal Support officer available at each facility to support.

Ramsay Health Care (Ramsay) provides health care through a global network of clinical practice, teaching and research. Ramsay's global network covers 10 countries in over 500 locations.

Ramsay Australia has 72 private hospitals and day surgery units and is Australia's largest private hospital operator. Ramsay Australia admits more than one million patients annually and employs more than 31,000 people.

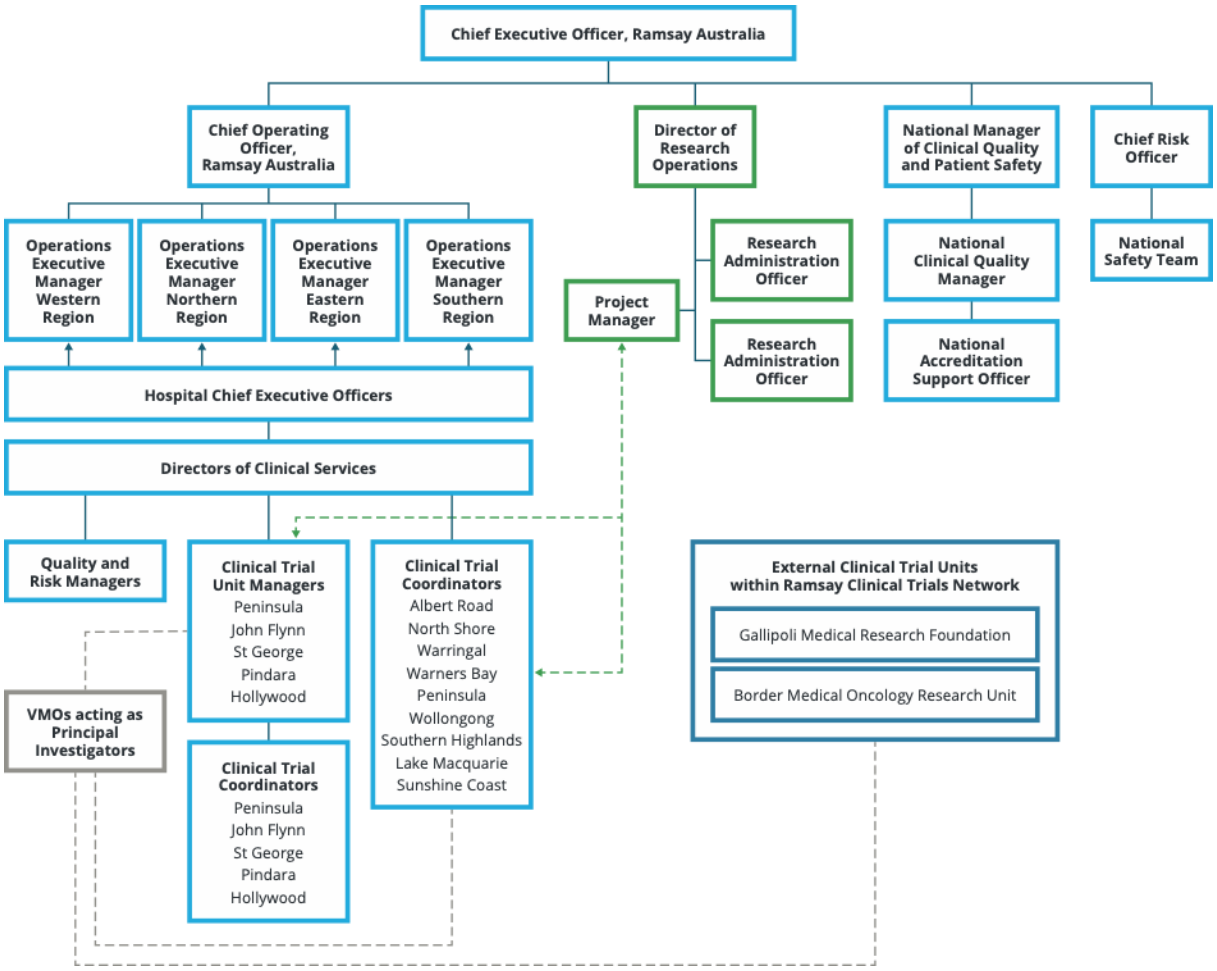
Ramsay Australia has established a National Clinical Trial Network which currently includes 14 dedicated clinical trials units around Australia.

The Risk Management Committee is the peak committee for all Australian Ramsay hospitals and reports directly to the Ramsay Global Board.

Governance, leadership and culture

Ramsay Australia's Clinical Trials Network shows a strong link between clinical trial unit managers, clinical trial coordinators, project manager, director of research operations, and Chief Executive (Figure 39).

Figure 39: Ramsay Australia's Clinical Trials Network structure



Ramsay Australia strategic and business planning processes explicitly capture strategies and initiatives to deliver safe and quality clinical trial services across multiple therapeutic areas. Performance across these areas is closely monitored by the Risk Management Committee which is the peak committee reporting to the Ramsay Global Board. Appointed members of the Risk Management Committee are oriented to individual corporate areas including patient safety and quality. Comprehensive regular reports are presented to the Risk Management Committee and include:

- Riskman report
- Unsatisfactory outliers according to clinical indicators, by hospital
- Pre-determined KPIs
- Unresolved complaint outside the 31-day closure requirement
- Policies endorsed by the Clinical Governance Committee
- Clinical Governance summary report including complaints, credentialing, policies and guidelines, research specific policies, and Safe Operating Procedures
- Australian Risk Management Committee dashboard

- NPS AHPEQS.

Clinical trial risks or issues are reported in the regular report to the Risk Management Committee.

Strategic and operational risks are considered at least annually by all operating divisions as part of Ramsay Australia's annual strategic planning, forecasting, and budgeting process. Each facility is responsible for the development and maintenance of a risk management plan identifying material risks, developing strategies for dealing with those risks and developing and testing controls.

The Ramsay Australia Clinical Policy and Forms Framework defines the governance structure and principles for developing, approving, reviewing and management of its clinical policies, guidelines, and forms. The Ramsay Australia national Clinical Governance Unit is responsible for the development of all clinical policies, guidelines, and forms. Facilities do not develop clinical policies but adhere to the mandatory use of Ramsay Australia clinical policies with supporting guidelines, facility work instructions and standard operating procedures. All clinical trial sites use standardised operating procedures and a standardised process to establish trial activity. All clinical trials operate under an ethical and governance framework that complies with the Australian Code of Research Conduct, Good Clinical Practice and ethical standards.

Position descriptions for clinical trial identified positions include reporting line, position summary and skill requirements. Good Clinical Practice training is mandatory for the clinical trial workforce.

Ramsay Australia Patient Safety and Clinical Quality Framework represents the systems and process through which patient safety and quality care initiatives are managed. The Patient Safety and Clinical Quality Framework is person-centred and consists of four other key areas including safety, structure, culture, and a culture of continuous improvement.

Ramsay Australia has developed a comprehensive Clinical Governance Framework based on:

- Clinical risk management (making sure their services are safe and minimising risk of error)
- Clinical effectiveness (making sure that the clinical services they provide are effective)
- Effective workforce (making sure their staff are competent and up to date)
- Consumer participation (involving their patients and carers in their care).

Patient safety and quality improvement system

Ramsay Australia's Governance Framework ensures that clinical trial services provided are effective by ensuring:

- Quality and safety indicators are used to measure and monitor performance
- Quality plans are initiated when significant issues are flagged
- Quality and safety indicators are benchmarked nationally
- Serious clinical incidents are reported and investigated
- Clinicians are represented on the Governance Committee and expert clinical advisory panels
- High risk areas are audited on a regular basis
- Quality performance and safety issues are reported to the Board.

Ramsay Australia has established a Risk Management Framework which includes comprehensive guidance on risk management and corporate governance, operational roles and responsibilities, risk escalation, risk management process and risk management tools. The process of managing risk is integrated into Ramsay Australia's overall governance, strategy, management, reporting process, policies, values and culture.

The Clinical Trial Safety Reporting Policy and Guideline provide comprehensive guidance to facilities on the management of safety monitoring and reporting requirements of clinical trials and includes clear definitions of multiple events and step by step management.

The number and severity of clinical trial safety events happening at a facility is collated and reported on a quarterly basis to the facility Chief Executive. The Chief Executive reports incidents to the Medical Advisory Committee and the Patient Care Review Committee.

The Patient Safety and Clinical Quality Framework also includes the garnering of patient and consumer feedback, involving consumers and patients in safety and quality, open disclosure, and complaints management. Ramsay Australia routinely collects and publishes data on patient and consumer experience. Action plans are developed from feedback received, and strategic and business planning are informed by patient and consumer experience. Ramsay Australia's surveying of patient, families and carers is comprehensive and robust, however, clinical trial participants, their families and carers are not regularly surveyed.

Partnering with Consumers

A Consumer Engagement Framework is in place and aims to assist facilities establish, maintain and enhance consumer engagement and participation at an individual, facility, governance and corporate level. The Consumer Engagement Policy provides guidance on the engagement of consumers in broad operational and strategic decisions. The Consumer Engagement Policy recognises that engaging consumers in the design, delivery and evaluation of health care can bring significant benefits to healthcare outcomes; the experience of care and the operations of delivering care.

Consumers are included in the Board membership and on various committees such as the Medical Advisory Committee.

Consumers participate in risk management and quality improvement activities and consumer feedback from patient satisfaction surveys informs strategic and business planning. Hospital volunteers are regularly consulted as consumers and any planned changes in business are often presented to consumers.

Health literacy

Pamphlets and videos are regularly developed to orientate and inform participants about trials they may participate in. The Resources Cultural Diversity, Sensitivity and Responsiveness Policy provides information for the workforce on participants' culture and diversity.

Aboriginal and Torres Strait Islander – specific actions

Ramsay Australia's National Learning and Development Orientation and Mandatory Learning Framework includes mandatory training on Aboriginal and Torres Strait Islander Cultural Awareness.

The Cultural Diversity, Sensitivity and Responsiveness Policy is in place and comprises requirements for awareness of, and sensitivity to, the diverse needs of the patient populations served in order to achieve safe and desired clinical care and outcomes. The document provides links to multiple videos, posters and podcasts.

An Aboriginal Support officer is available at each facility to support the participation of Aboriginal and Torres Strait Islander patients in clinical trials.

Actions assessed as growing systems

Policies and procedures (Action 1.7):

> It was not always evident that policies and procedures were reviewed when due and clinical trials Standard Operating Procedures were not always formally approved and in current version.

Incident management systems (Action 1.11):

> There was some uncertainty in regards to reporting lines and process for adverse events and serious adverse events in the workforce interviewed.

Feedback (Action 1.13):

> Overall the organisation's surveying of patient, families and carers is comprehensive and robust. However, there was insufficient evidence provided to confirm the survey of clinical trial participants, their families, carers and sponsors.

Safe environment (Action 1.29):

> Some equipment used for the care of clinical trial participants, were not serviced as required.

Approach to implementation

Ramsay Australia has engaged a project officer to undertake a gap analysis, progress work with the clinical trials network and support engagement across the sites. Planning is led by a small team with representation from risk safety and quality, clinical trials and the project officer.

Responsibility for overseeing the implementation of the National Clinical Trials Governance Framework sits with the Clinical Governance Committee.

Education opportunities have been identified across Ramsay Australia to understand functions of clinical trials and the accreditation process.

Glossary

Health service organisation: A separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body.

Health service/research organisation: All Level 2 participants were health service organisations, but Level 1 participants included health service organisations and research organisations.

Hospital: The level at which accreditation occurs.

Level 1: Those individuals and organisations that registered with the Commission to provide voluntary feedback on the Governance framework and supporting tools and resources

Level 2: Those health services that were selected to participate in the pilot, receive mentoring and undergo the pilot accreditation assessment.

Appendices

Appendix 1: Level 2 pilot site mentoring participants by their role in the health service organisation

Table 36: Summary of facilitated mentoring participants for each Level 2 health service organisation

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Alfred Health			
Senior Manager, Office of Ethics and Research	✓	–	–
Director, Clinical Trials Hub	✓	–	–
General Council	✓	–	–
Project Lead, National Clinical Governance Framework Trial	✓	–	–
Director, Patient Safety and Improvement. Clinical Governance.	✓	–	–
Senior Research Governance Officer, Office of Ethics and Research	✓	–	–
Head of Central Clinical School, Professor of Medicine, Monash University and Director of Research Alfred Hospital	✓	–	–
Canberra Hospital			
Head of Ethics and Governance	✓	✓	✓

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Clinical Trials Coordinator and Chair, Clinical Trials Coordinator Network	✓	✓	–
Manager (Finance) Clinical Trials	✓	✓	✓
Clinical Trials Manager	✓	✓	–
Director, Clinical Trials Unit	✓	✓	–
Trial coordinator	–	✓	–
Trial nurse	–	✓	–
Trial nurse	–	✓	–
Trial nurse	–	✓	–
Clinical Trials Group Clinical research lead for the Trauma and Orthopaedic Research Unit	–	✓	–
Trial coordinator	–	✓	–
Trial nurse	–	✓	–
Pathology	–	✓	–
Trial coordinator	–	✓	–
Pharmacist	–	✓	–
Trial coordinator	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Clinical Trials Group Trauma and Orthopaedics Fellow	–	✓	–
Trial coordinator	–	✓	–
Research Officer	–	✓	–
Registered nurse	–	✓	–
Administration assistant	–	✓	–
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Trial nurse	–	✓	–
Manager, office of research	–	✓	–
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Finance officer	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Trial nurse	–	✓	–
Trial coordinator	–	✓	–
Trial coordinator	–	✓	–
Orange Health Service			
Director of Cancer Services & Innovation	✓	–	–
Business Manager (Financial Controller) at Western NSW Local Health District – Orange Hospital	✓	–	–
Research Ethics & Governance Manager	✓	–	–
General Manager	✓	–	–
General Manager	✓	–	–
Quality, Education & Safety Manager	✓	–	–
District Director Pharmacy	✓	–	–
Executive Director of Operations	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Executive Director of Allied Health and Innovation Western NSW LHD	✓	–	–
Clinical Trials Manager	✓	–	✓
Director of Research Allied Health & Innovation Directorate | Western NSW LHD	✓	✓	–
Research Nurse / A Clinical Trials Manager	✓	✓	✓
Oncologist and CT Director	✓	✓	–
Perth Children's Hospital			
Child Development Services	✓	–	–
Community and Consumer Research, UWA	✓	–	–
Chair of Scientific/Safety Committee	✓	–	–
Safety and Quality – Accreditation point of contact	✓	–	–
Research Communications	✓	–	–
Nursing Research	✓	–	–
Research Facilitator	✓	–	–
Oncology Research	✓	–	–
Allied Health Research	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
RGO	✓	–	–
ED Safety and Quality	✓	–	–
Administrative assistant ethics/governance	✓	–	–
Emergency Department	✓	–	–
Community Health	✓	–	–
Telethon Kids Institute	✓	–	–
Director of Research	✓	–	–
Research Business Manager	✓	–	–
Research Business Manager	✓	–	–
Chief Registrar	✓	–	–
Mental Health	✓	–	–
ED Medical Services	✓	–	–
Research Facilitator	✓	–	–
Deputy Director of the Department of Child Health Research	✓	–	–
Senior Health Researcher/Governance oversight	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Co-Director Medical Services	✓	–	–
Safety and Quality – Accreditation point of contact	✓	✓	–
Ethics and Governance	✓	✓	✓
Accreditation Consultant	✓	✓	–
Trial manager	–	✓	–
Research coordinator	–	✓	–
Trial nurse	–	✓	–
Principal investigator	–	✓	–
University Western Australia	–	✓	–
Trial nurse	–	✓	–
Research nurse	–	✓	–
Telethon Kids institute	–	✓	–
Telethon kids institute	–	✓	–
Telethon kids Institute	–	✓	–
Research staff	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Research governance	–	✓	–
Telethon Kids Institute/Diabetes Research	–	✓	–
Research nurse	–	✓	–
Consultant Endocrinologist	–	✓	–
Principal investigator	–	✓	–
Telethon Kids Institute	–	✓	–
Telethon kids institute	–	✓	–
Telethon kids Institute	–	✓	–
Surgical Services	–	✓	–
Senior Policy Officer – Department of Health	–	✓	–
Telethon Kids Institute	–	✓	–
Telethon kids Institute	–	✓	–
Administration officer	–	–	–
Ramsay Health Care			

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
CT Coordinator Pindara Private Hospital	✓	–	–
Research Governance/Research Officer Ramsay	✓	–	–
Manager of Clinical trials at Peninsula Private Hospital,	✓	–	–
Research & Ethics Administration Officer QLD/VIC	✓	–	–
CEO Ramsay Hospital Research Foundation	✓	–	–
Project Officer	✓	✓	✓
National Clinical Quality Manager,	✓	✓	–
A/National Clinical Quality Manager	✓	✓	–
Royal Adelaide Hospital and The Queen Elizabeth Hospital, CALHN			
Manager, CALHN Research	–	–	✓
CALHN Research Governance & IP Contracts	–	–	✓
Royal Brisbane and Women's Hospital			
Executive Director, Research	✓	–	–
Nursing Director Research	✓	–	–
Business Manager, Research Services (Costing Session)	✓	–	✓

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Assistant Director – Quality, Innovation and Patient Safety Service	✓	✓	–
Research Coordinator Neurosurgery	✓	✓	–
Research Governance Officer	✓	✓	–
Research Coordinator	✓	✓	✓
Royal Darwin Hospital			
Acting Director of Nursing, Clinical Learning Education & Research Service	✓	–	–
Safety and Quality Manager RDPH	✓	–	–
Director, TEHS Safety and Quality Unit	✓	✓	–
Executive Director, Medicines Management | Research, Transformation and Change	✓	✓	✓
Change Maker, Clinical Innovation & Research	✓	✓	✓
Intensive Care Specialist	✓	✓	✓
Senior Clinical Trials Coordinator	✓	✓	–
Clinical Nurse Manager Alan Walker Cancer Care Centre	✓	✓	–
Clinical Nurse Educator	✓	✓	–
Executive Director of Nursing and Midwifery TEHs	✓	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Consultant Nephrologist RDH and Menzies School of Health	–	✓	–
Clinical Research Coordinator, Menzies School of Health	–	✓	–
Royal Hobart Hospital			
Director of Allied Health	✓	–	–
Executive Director, Medical Services South	✓	–	–
Safety and Quality Clinical Nurse Consultant	✓	–	–
ADON Research and Practice Development	✓	–	–
Clinical Research Coordinator at Royal Hobart Hospital	✓	–	–
Clinical Trials Nurse	✓	–	–
Director of Improvements for Quality and Patient Safety	✓	✓	✓
Research Governance Office, Department of Health	✓	✓	✓
Royal Victorian Eye and Ear Hospital			
Manager Planning and Patient Experience	✓	–	–
Research & Clinical Trials Manager	✓	✓	✓
Risk & Quality Manager	✓	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
HREC Secretary	✓	✓	–
Exec Director Medical Services and Exec Sponsor	–	–	–
St Vincent's Health Network (Sydney and Melbourne)			
Manager Patient Safety and Quality Unit	✓	–	–
Director of Innovation and Improvement -	✓	–	–
Director of Integrated Care	✓	–	–
Chief Executive Officer, Mater hospital	✓	–	–
Clinical Trials Steering Committee – Community Representative St Vincent's Sydney	✓	–	–
Director of Medical Services	✓	–	–
Research Governance Unit, St Vincent’s Melbourne	✓	–	–
Director of Clinical Services	✓	–	–
Director of Allied Health and Community Services	✓	–	–
Director of Aboriginal Health	✓	–	–
Manager, Health Services	✓	–	–
Director of Legal and Risk	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Chief Financial Officer & Director of Corporate Services	✓	–	–
Chief Executive Officer St Vincent's Private Hospital Sydney	✓	–	–
Director of Acute Care Services	✓	–	–
Professor Terry Campbell, Director of Research, St Vincents Hospital (Darlinghurst)	✓	✓	–
Senior Quality Manager/Network Accreditation Coordinator – St Vincent's Health Network	✓	✓	–
Group Chief Research Officer, St Vincent's Health Australia	✓	✓	–
Research Governance Unit, Clinical Trial Liaison Officer St Vincent's Melbourne	✓	✓	–
Low Risk and Quality Assurance Officer St Vincent's Melbourne	✓	✓	–
Research Officer Manager, St Vincent's Hospital Translational Research Centre Sydney	✓	✓	–
Associate Professor Philip Cunningham, OAM, Chief Operating Officer | St Vincent's Centre for Applied Medical Research	✓	✓	–
Clinical Research Manager, St Vincent's Centre for Applied Medical Research.	✓	✓	–
Deputy Director of Research St Vincents Melbourne	✓	✓	–
Director of Strategy, Planning and Partnerships	–	✓	–
Director of Nursing	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Head of Department, Medical Oncology	–	✓	–
Senior Staff Specialist	–	✓	–
Senior Staff Specialist	–	✓	–
Head, Department of Endocrinology and Diabetes Services	–	✓	–
Senior clinician	–	✓	–
Medical director	–	✓	–
Manager, Cancer Care Service	–	✓	–
Executive assistant	–	✓	–
Consultant haematologist	–	✓	–
Director of Mission and Inclusive Health	–	✓	–
Head of Clinical Haematology	–	✓	–
Staff specialist, Director of Haematology Clinical Trials Unit	–	✓	–
Staff specialist, Cardiology	–	✓	–
Trial manager	–	✓	–
Director of Nursing Research	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Director of pharmacy	–	✓	–
St Vincent's Centre for Applied Medical Research	–	✓	–
UNSW	–	✓	–
Chief Medical Officer, St Vincent's Private	✓	–	–
Sydney Local Health District			
Clinical Trials Business Manager.	✓	–	–
SLHD Executive Director Medical Services	✓	–	–
Patient and Family Experience Quality Manager RPAH	✓	–	–
A/Director Patient Safety and Quality Unit, RPAH	✓	–	–
Research Business Manager	✓	–	–
Associate Chief Nursing & Midwifery Information Officer for SLHD.	✓	–	–
General Manager, RPAH	✓	–	–
Clinical Trials Governance Consultant and Chairman of the Clinical Trials Steering Committee	✓	–	–
Chief Executive Officer	✓	–	–
SLHD Director of Operations	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Executive Director, Sydney Research	✓	–	–
SLHD Project Lead	✓	✓	–
SLHD Executive Research Manager	✓	✓	–
SLHD Research Director	✓	✓	–
Director of Clinical Services	–	✓	–
Clinical quality manager	–	✓	–
Trial nurse	–	✓	–
Trial manager	–	✓	–
Not stated	–	✓	–
Executive assistant	–	✓	–
Deputy Director of the Surgical Outcomes Research Centre	–	✓	–
Head of Department, chemical pathology	–	✓	–
Research nurse	–	✓	–
Manager	–	✓	–
Head of Department, Gastroenterology	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Research nurse	–	✓	–
Head of department, institute of haematology	–	✓	–
Research staff	–	✓	–
Executive director	–	✓	–
Trials Coordinator	–	✓	–
Operations manager	–	✓	–
Research nurse	–	✓	–
Head of Department, Cardiology	–	✓	–
Academic Head of the Department of Colorectal Surgery	–	✓	–
Head of cardiothoracic research RPA	–	✓	–
Townsville Hospital and Health Service			
Clinical Trials Pharmacist	✓	–	–
Acting Executive Director Clinical Governance	✓	–	–
Oncology Research Manager, Townsville	✓	–	–
Acting Nursing Director	✓	–	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Clinical Governance Coordinator Healthcare Standards	✓	✓	✓
Manager, Townsville Research Education, Support and Administration (TRESA) Unit & Townsville Institute of Health Research and Innovation	✓	✓	✓
Victorian Clinical Trial Research Support Service (Ballarat Health, Barwon Health, Bendigo Health, Goulburn Valley Health and Northeast Health Wangaratta)			
Project Officer Clinical Trials Research Support – Goulburn Valley Health (Shepparton)	✓	–	–
Clinical Trials Unit Manager Barwon Health	✓	✓	✓
Director Research and Innovation Bendigo Health	✓	✓	✓
Manager, Research & Partnerships at Ballarat Health Service	✓	✓	✓
Operational Director Education and Research · Northeast Health Wangaratta	✓	✓	✓
NCTGF Project Officer Barwon Health	✓	✓	✓
Clinical Trials Group – Clinical Trial Research Support Officer Wangaratta Health	✓	✓	✓
Quality Officer at Bendigo Health	✓	✓	✓
DJPR – Manager, Coordinating Office for Clinical Trial Research	✓	✓	–
Project officer	–	✓	–
Project officer	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Clinical Trials Group – Cancer Research Nurse Bendigo	–	✓	–
Clinical Trials Group – Infectious diseases physician	–	✓	–
Surgeon	–	✓	–
Clinical Trials Group – Clinical Trials Unit Manager Barwon Health	–	✓	✓
Trial coordinator	–	✓	–
Clinical Trial Manager Ballarat Health	–	✓	✓
Clinical Trials Group – Deakin University	–	✓	–
Clinical Trials Group – Cancer Research Nurse Bendigo	–	✓	–
Orthopeadic surgeon	–	✓	–
Clinical Trials Group	–	✓	–
Clinical Trials Group – Project officer Haematology Research	–	✓	–
Clinical Trials Group	–	✓	–
Clinical Trials Group	–	✓	–
Clinical Trials Group – Clinical Trials Unit Manager (Cardiology) Barwon Health	–	✓	–
Pathology	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Clinical Trials Group – Clinical Trials Unit Manager (Oncology) Barwon Health	–	✓	–
Clinical Trials Group – Research Fellow Anaesthesia at Barwon Health	–	✓	–
Clinical Trials Group -Director Deakin / Barwon IMPACT	–	✓	–
Clinical Trial Group Session – Cancer Research Manager Bendigo Cancer Research Unit	–	✓	–
Clinical Trials Session – Deakin / Barwon IMPACT	–	✓	–
Allied Health Research and Translation Lead Bendigo	–	✓	–
Director	–	✓	–
Director, Clinical Research, Goulburn Valley Health	–	✓	✓
Manager, Clinical Trials Research at Bendigo Health.	–	✓	✓
Medical Director Bendigo Cancer Centre Research Unit	–	✓	–
Lead, Clinical trials Bendigo Cancer Centre Research Unit	–	✓	–
Trial coordinator	–	✓	–
Clinical Trials Group – ICU Consultant	–	✓	–
Administration officer	–	✓	–
Trial manager	–	✓	–

Participant's position	Introductory mentoring session	Pre-site assessment mentoring sessions	Post site assessment mentoring session
Trial coordinator	–	✓	–
Clinical researcher	–	✓	–

Appendix 2: Cost estimate data items

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
Implementation costs							NOTE: These are NEW costs that are required to move The National Clinical Trials Governance Framework INTO the whole of hospital governance framework. This does not count costs that are already incurred for research governance. This does not count costs of existing hospital staff who would normally be expected to respond to ACSQHC changes.
	Policies, procedures, tools and resources	Estimated cost of developing and updating policies, procedures, tools and resources to support implementation of The National Clinical Trials Governance Framework annually	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.1 Action 1.3 Action 1.4 Action 1.5 Action 1.7 Action 1.12 Action 1.13 Action 1.14 Action 1.33 Action 2.1 Action 2.2 Action 2.3 Action 2.4 Action 2.5 Action 2.8 Action 2.9 Action 2.14	Are current policies, procedures, tools and resources capable of supporting the implementation of The National Clinical Trials Governance Framework? IF YES, implementation cost = $0. IF NO, calculate costs as per below. (One-off costs) Estimate cost of developing and updating policies, procedures, tools and resources to effectively support the implementation of The National Clinical Trials Governance Framework. (On going costs) Incremental costs which will be incurred on an ongoing basis in developing and updating policies, procedures, tools and resources to enable your hospital to comply with the National Clinical Trials Governance Framework. As mentioned above, this does not include costs which are already incurred for compliance to ACSQHC Standards.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
	Record keeping	Estimated cost associated with record keeping for compliance with The National Clinical Trials Governance Framework annually per trial – please list the nature of the costs	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.8 Action 1.9 Action 1.11 Action 1.13 Action 1.14 Action 1.16	Are current record keeping processes capable of keeping compliance with The National Clinical Trials Governance Framework annual per trial? IF YES, implementation cost = $0 IF NO, calculate costs as per below. (One-off costs) Estimate cost of improving record keeping processes to comply with The National Clinical Trials Governance Framework. (On going costs) Incremental costs which will be incurred on an ongoing basis to improving record keeping processes which enable your hospital to comply with the National Clinical Trials Governance Framework. As mentioned above, this does not include costs which are already incurred for compliance to ACSQHC Standards.
	Staff training	Estimated cost of training staff in their roles and responsibilities annually to comply with The National Clinical Trials Governance Framework:	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.6 Action 1.20 Action 2.10	Are staff currently currently capable of performing roles and responsibilities to implement The National Clinical Trials Governance Framework? IF YES, implementation cost = $0 IF NO, calculate costs as per below. (One-off costs) Estimate cost of developing and implementing training system (On going costs) Incremental costs which will be incurred on an ongoing basis to enable your hospital to comply with the National Clinical Trials Governance Framework. As mentioned above, this does not include costs which are already incurred for compliance to ACSQHC Standards.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
Compliance costs							NOTE: These are about incremental cost lift. That is, the margin above existing accreditation costs that needs to be included because of the The National Clinical Trials Governance Framework. For instance, if you already have appropriate secure storage systems for records, there will be no incremental cost lift. If you have a secure storage systems that need upgradeing to be appropriate, then there may be a one-off cost to upgrade, then an additional margin to existing costs to maintain it annually. If you do not have any secure storage systems, then you will have a large one-off cost, and then the whole additional cost annually.
	Training in Good Clinical Practice	Estimated costs of training staff in Good Clinical Practice, annually	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.6 Action 1.20 Action 2.10	Are all staff now covered by this accreditation trained in Good Clinical practice to comply with The National Clinical Trials Governance Framework annually? IF YES, compliance cost = $0. IF NO, calculate costs as per below. (One-off costs) Estimate cost of developing and implementing training system. (On going costs) Calculate the ADDITIONAL number of people who will now need training but did not before and multiply by unit training cost.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
	Notification/ education/training	Estimated costs associated with notification/ education/training for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.6 Action 1.20 Action 2.10	Are all staff involved in clinical trials receiving education training for compliance with The National Clinical Trials Governance Framework? annually? IF YES, compliance cost = $0. IF NO, calculate costs as per below. (One-off costs) Estimate cost of developing and implementing training system. (On going costs) Calculate the ADDITIONAL number of people who will now need training but did not before and multiply by unit training cost.
	Materials	Estimated costs associated with material purchased for compliance with The National Clinical Trials Governance Framework [including cost of adapting/ redeveloping facilities/environment]					NO INPUTS REQUIRED – ANSWER QUESTIONS 12a – 12i

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
12a	IT infrastructure	Estimated costs associated with IT infrastructure for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.11	Does your current IT infrastructure support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Speak to IT vendor and identify the cost of UPGRADE, or identify the cost of purchase and implementation of whole IT infrastructure. (On going costs) Speak to IT vendor and identify the ADDITIONAL margin
12b	Data collection tools	Estimated costs associated with data collection tools for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.10 Action 1.11 Action 1.15 Action 1.16	Does you currently have all the data collection tools to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase and implementation of data collection tools. (On going costs) Identify the ADDITIONAL costs to keep the data collection tools up to date.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
12c	Secure storage systems for record	Estimated costs associated with secure storage systems for records for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.10 Action 1.11	Do you currently have secure storage systems for records to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase (or updates) and implementation of secure storage system for records. (On going costs) Identify the ADDITIONAL costs to keep the secure storage systems for records up to date.
12d	Secure storage systems for study/drug/device	Estimated costs associated with secure storage systems for study drug/device for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.10 Action 1.11	Do you currently have secure storage systems for study drug/device to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase (or updates) and implementation of secure storage system for study drug/device. (On going costs) Identify the ADDITIONAL costs to keep the secure storage systems for study drug/device up to date.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
12e	Education and training resources	Estimated costs associated with education and training resources for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.6 Action 1.20	Does you currently have all the education and training to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase and implementation of education and training resources. (On going costs) Identify the ADDITIONAL costs to keep education and training resources up to date.
12f	Clinical trial work spaces	Estimated costs associated with clinical trial work spaces for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.8 Action 1.29	Does you currently have clinical trial work spaces that support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of securing or upgrading clinical trial workspaces. (On going costs) Identify the ADDITIONAL costs to keep the clinical trial workspaces compliant.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
12g	Signage/instructions	Estimated costs associated with signage/instructions within the health service organisation for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.29	Does you currently have all the signage/instructions support full compliance with the Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase and implementation of all signage/instructions. (On going costs) Identify the ADDITIONAL costs to keep the signage/instructions up to date.
12h	Maintenance costs	Estimated costs associated with maintenance for compliance with The National Clinical Trials Governance Framework	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT		Action 1.29	Does you currently have all the maintenance costs to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of ADDITIONAL maintenance costs required. (On going costs) Identify the ADDITIONAL ongoing costs tof maintenance.

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
12i	Other	Other compliance related costs	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT			Does you currently have any OTHER compliance costs to support full compliance with The National Clinical Trials Governance Framework? If YES, cost =$0. If NO, calculate costs as per below. (One-off costs) Identify the cost of purchase and implementation of other compliance costs. (On going costs) Identify the ADDITIONAL annual compliance costs.
Additional data							
	Effort to review	Hours spent on preliminary review/gap analysis			INSERT NUMBER OF HOURS		Track FTE or direct hours
	Effort to update processes	Estimated hours to update administrative processes such as committee structures, reporting schedules, and working groups			INSERT NUMBER OF HOURS		Track FTE or direct hours

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
	Other direct/indirect costs	What other direct/indirect costs, either one-off or recurrent, do you anticipate from implementing the CTFG?	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT			This is a second prompt questions additional to 12i
	Costs with engaging customers	What are the costs associated with engaging the consumers in implementing the CTGF?	INSERT DOLLAR AMOUNT	INSERT DOLLAR AMOUNT			This is the cost that is ADDITIONAL to what is currently being done
	Benefits to consumers	What are the benefits to consumers in implementing the CTGF?			INSERT TEXT		

Question number	Topic	Description	One off costs amount (refer to comments/explanation)	On-going costs amount (refer to comments/explanation)	Other data input (refer to comments/explanation)	Referenced Action item in The National Clinical Trials Governance Framework and User Guide	Comments / Explanation
	Other benefits	What benefits – financial, improved governance, improved trial operations, safety and quality, or other benefits – do you anticipate from implementing the CTFG?			INSERT TEXT		
	Current meeting of requirements	To what extent do you believe that your organisation is currently meeting the requirements of the CTGF?			INSERT TEXT		

Addenda

- **Addendum 1**: Written submissions
- **Addendum 2**: Evidence mapping and assessment outcomes
- **Addendum 3**: Survey results and general feedback
- **Addendum 4**: Accreditation assessment reports by health service organisation
- **Addendum 5**: Revised National Clinical Trials Governance Framework.

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au