Introduction to the National Clinical Trials Governance Framework

Coordinating Office for Clinical Trial Research (COCTR)

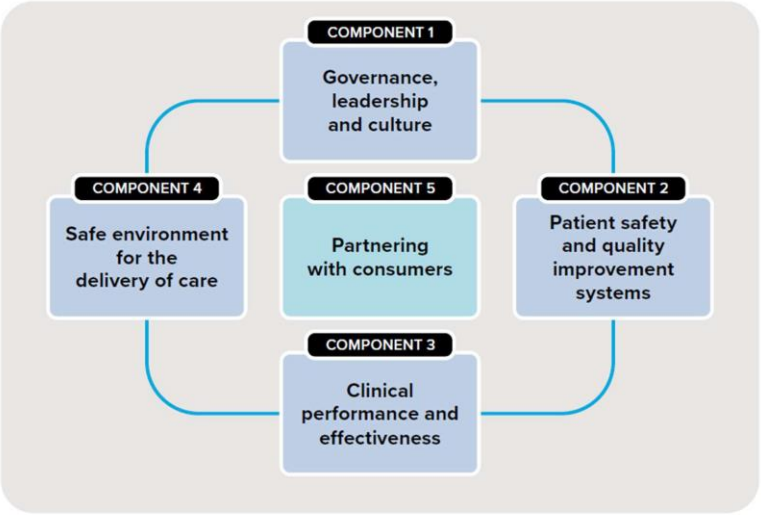
VICTORIA State Government | Department of Health

Background to the National Clinical Trials Governance Framework

- As of May 2023, all health services conducting clinical trials will be assessed against the National Clinical Trials Governance Framework.
- The assessments are aligned to the National Safety and Quality Health Service (NSQHS) Standards accreditation surveys.
- Effective from July 2023, health services are subject to short notice accreditation assessments which can occur at any time (with 24 hours' notice)
- This means clinical trial sites must be compliant with the Framework at all times.

Background to the National Clinical Trials Governance Framework

- The purpose of the Framework is to ensure that clinical trials are conducted in a safe environment and in a high-quality manner for improved health outcomes for patients and the community.
- The Framework was introduced to ensure that the governance of clinical trials is integrated within a health service's corporate and governance system and embed clinical trials into practice.
- The Framework intersects with the NSQHS Standards, in particular:
  - Clinical Governance Standard
  - Partnering with Consumers Standard



Components of the National Clinical Trials Governance Framework

1. ***Governance, leadership and culture*** – corporate and clinical trials governance systems are established, and used to improve the safety and quality of clinical trial service provision for patients, their carers and consumers

2. ***Patient safety and quality improvement systems*** – are established and used to manage and improve patient safety in clinical trials.

3. ***Clinical performance and effectiveness*** – the workforce has the right qualifications, skills and supervision to provide safe, high-quality clinical trial services to patients

4. ***Safe environment for the delivery of care*** – the environment in which clinical trials are conducted, is safe and promotes high-quality clinical trials to patients

Components of the National Clinical Trials Governance Framework

5. ***Partnering with consumers*** – systems are designed and used to support patients, carers, families and consumers to be partners in planning, design, measurement and evaluation of clinical trial services.

   Elements of this component include clinical governance and quality improvement systems to support partnering with consumers

   − partnering with patients in their own care, and in trial participation

   − health literacy

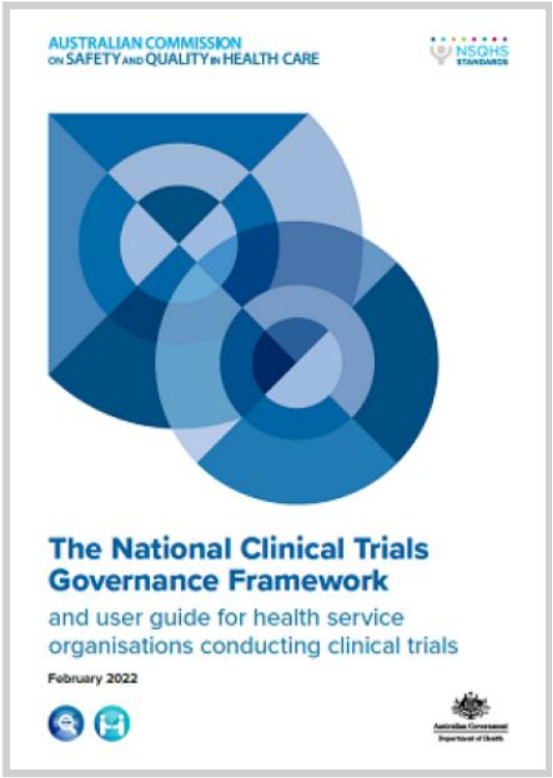
   − partnering with consumers in organisational design and governance of clinical trial services.

The National Clinical Trials Governance Framework & User Guide

The National Clinical Trials Governance Framework and User Guide provides:

1. Roles and functions for identified positions relating to clinical trial service provision within a health service

2. Actions against which health services with a clinical trial service will be assessed for accreditation
   - Suggested strategies health services may implement to meet the actions within the NSQHS Standards
   - Examples of evidence a health service may provide that demonstrate they have met the action for clinical trial service provision.



Actions

National Clinical Trials Governance Framework

27 unique actions are addressed in the accreditation process.

In the first three years the actions will be scored against a maturity scale.

Maturity Scale

- Initial systems - Evidence to demonstrate that the requirements of the action are yet to be commenced or implemented
- 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
- Established systems - Evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service.

Map for assessment preparation

COCTR supported activities for regional health services

COCTR support for Regional Health Services through meeting with the key regional stakeholders to outline the program of work, discuss roles and responsibilities within the health services, addressing the following:

- Gap Analysis– what do you have and what do you need for assessment?
- Workplan development – key information and informed by the gap analysis to guide implementation activities to meet the new standards for clinical trials.
- Implementation – prioritise activities and resources identified in the workplan, including examples of evidence.
- Post Assessment – address any actions that need further implementation.

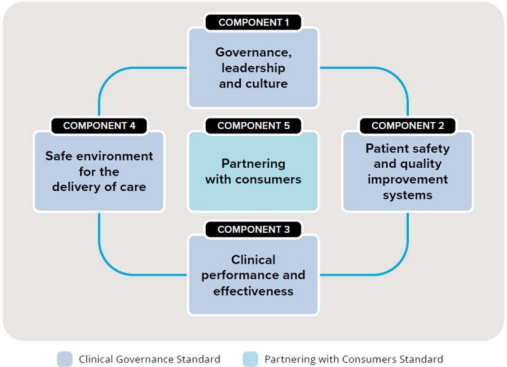
Governance Framework structure for assessment

Components of the National Clinical Trials Governance Framework

Components have specific list of actions, evidence, processes and systems

PICMoRS – PICMoRS can be used as a tool to review clinical trial services ahead of assessment

PICMoRS - six elements to guide preparation for assessment e.g. questions, scenarios, practice for assessment



P	*Process*
I	*Improvement*
C	*Consumer participation*
Mo	*Monitoring*
R	*Reporting*
S	*Systems*

Preparation for short notice assessment

Be aware of the six PICMoRS elements that identify safety and quality systems and where improvements are needed in each component.

PICMoRS – six elements are as follows:

P	***Process***
I	***Improvement***
C	***Consumer participation***
Mo	***Monitoring***
R	***Reporting***
S	***Systems***

PICMoRS

General Guidance applicable to each of the six PICMoRS elements

Process

When reviewing a particular process, it is important to ensure that members of the workforce:

- Understand the elements of the process
- Know what their role and responsibilities are
- Know where to find information about the process.

Examples of questions:

- How does this process work in your health service?
- Is the process documented?
- How do you access this information?

Improvement

To implement change, it is important the workforce be aware of, and participate in, quality improvement strategies, and for results and recommendations to be reported. It is important:

- Identify the areas for change
- Participate in making changes that are required
- Participate in evaluating the effectiveness of changes.

Examples of questions:

- How did you determine if changes are needed?
- Has the process been reviewed?
- Were there issues that led to the change?

PICMoRS

General Guidance applicable to each of the six PICMoRS elements

Consumer Participation

Consumers are partners in their own care and partners in the planning, design, monitoring and evaluation of healthcare services.

Examples of questions:

- How are consumers informed about or involved in the process?
- How do you provide consumers with feedback on this process?
- What reports do you provide to consumers on the outcomes of this process?

Monitoring

It is important to check that implemented processes are monitored to:

- Identify areas of under and high-performance
- Prioritise areas for improvement
- Evaluate the effectiveness of changes that are introduced.

Examples of questions:

- How is this process monitored?
- Where is this documented?
- What prompted the process to be changed?

PICMoRS

General Guidance applicable to each of the six PICMoRS elements

Reporting

Systems should be in place to ensure that reporting on processes occurs to those involved, which may include:

- The individual with accountability (e.g. Board, Management, Workforce)
- Consumers

Examples of questions:

- Where is information on the process reported?
- How often does this occur?
- Where does the information go?

Systems

The Systems element is a test of clinical governance. It tests whether information learnt from one process is used to inform and guide other processes.

Examples of questions:

- Is the information from this process or system used to inform other processes, such as training or quality improvement?
- Does the information from any other process or system influence how you use or change this process?
- Where is this documented?

Accessibility statement and publisher information

To receive this presentation in another format phone 0493 244 168, or email Nicole.Charles@health.vic.gov.au

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

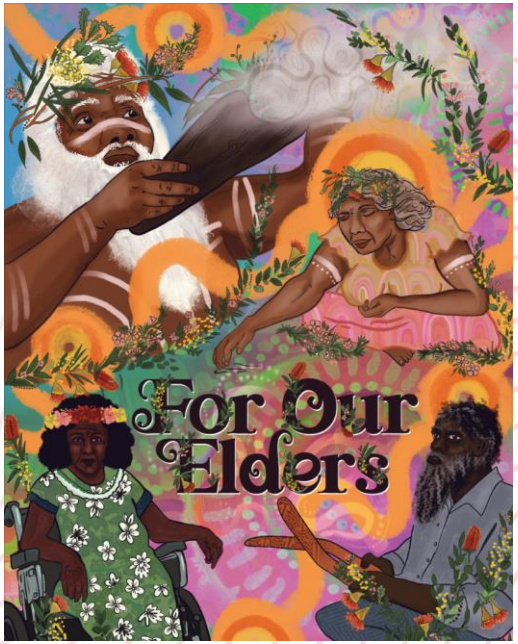
Adrian Costa
CLINICAL TRIALS CENTRE

Implementing the National Clinical Trials Governance Framework

A department of Barwon Health

Acknowledgement of Country

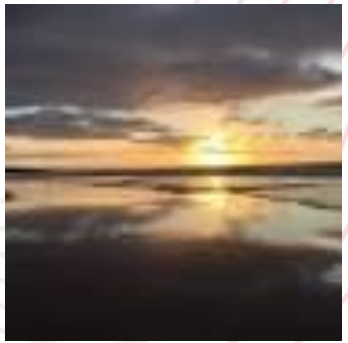
We, respectfully acknowledge the Traditional Owners of the land, the Wadawurrung, Wurundjeri Woi-Wurrung and the Bunurong/Boon Wurrung peoples of the Kulin Nation. We pay our respects to the Elders past, present, and emerging

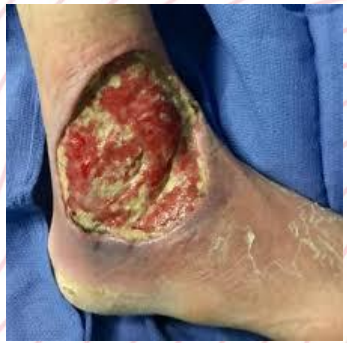


Thank you to Nicole Charles who travelled far and worked hard with us to achieve our outcome

Who are we?

- Barwon Health is a large regional health service
- 1000-bed tertiary hospital and 23 sites
- 17 separate trial units, now ACCTC
- 180 – 200 open trials
- 70 : 30 commercial to Investigator Inititated trial ratio
- 53 EFT in trial teams plus ~ 40 PIs
- 1800 participants @ 31/12/23
- Trials units are self-funded





12 Weeks from Accreditation

- 2021 Gap Analysis
- Core pillars in place
    1. Research Director
    2. Research Office
    3. Some established units
    4. Research Strategic Plan
- Skilled teams, fragmented system

A two-fold strategic approach

1. Highway to Heal**th**

2. **K**eep **I**t **S**imple - KISS

Project of Unity – Trials + Health Service

- Hospitals have been doing this a long time
- Build a narrative
- Hub and spoke
- Build links from you to the existing system
- Town Hall training
- Cheat sheets for staff

The Suits Arrive

- July 2023
- 8 Assessors for 5 days
- 8am to 5pm
- NCTGF had Lead Assessor
- Interviews with 60 people over 4 days
- 30 trials listed for sampling
- All relevant corporate reports and papers

Corporate, Clinical Governance, Consumers

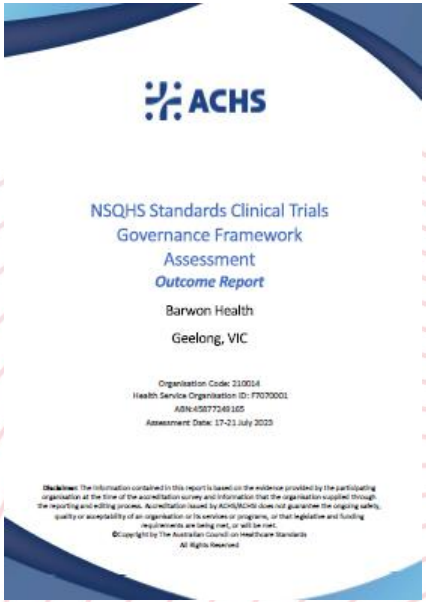
- Strategic Plans and Org Charts
  - For Barwon Health and Research
- Registers: GCP, Staff Training, Projects
- All Board, Clinical Governance, Research, Risk, Finance, New Tech, Consumers Committees
  - Terms of Reference
  - All Frameworks and Reports
  - All Management Plans
  - All Meeting Papers, last three meetings
  - Last three safety items

Trial Sampling

- Phases 1 – 4
- Drug, device, behavioural, surgical technique
- All Sponsor types
- All documents HREC, RGO, New Tech, meeting notes
- Trial Site Files – consent
- Participants
- Trial team, PIs and coordinators

ACHS Suggestions for Improvement

1. Include First Nations peoples in Hospital and Research Strategic Plans.
2. Improve quarterly reporting systems to the Board.
3. Translate strategic plans into operational plans with goals and timelines.
4. Add NCTGF KPIs into deliverables in university partner agreements.


ACHS

NSQHS Standards Clinical Trials Governance Framework Assessment

Outcome Report

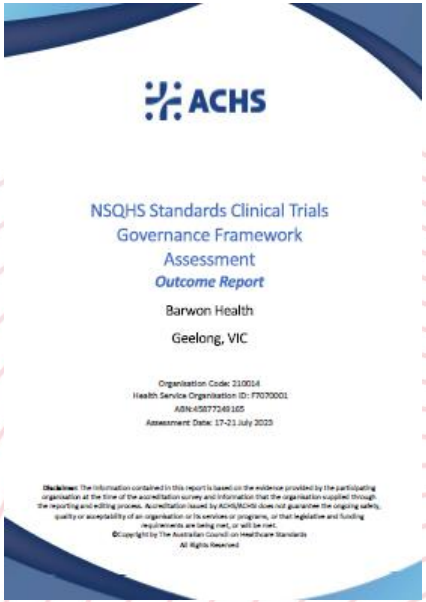
Barwon Health

Geelong, VIC

Organisation Code: 210014
Health Service Organisation ID: F7070001
ABN:45877249165
Assessment Date: 17-21 July 2023

ACHS Suggestions for Improvement

5. Develop an organisational research infrastructure plan.
6. Ensure trials have a risk management framework to identify, assess, manage and monitor research related risks.
7. Implement the marra ngarrgoo, marra goorri
8. Ensure all patient facing trial materials are reviewed by consumers at Barwon Health



Final Score - 2.6 / 3.0

- Some units are well established
- Some units are growing
- More time needed to embed new organisational structure
- Upper end of growing

Adrian Costa
CLINICAL TRIALS CENTRE

Thank You!

Come and visit Barwon Health

A department of Barwon Health

Adrian Costa
CLINICAL TRIALS CENTRE

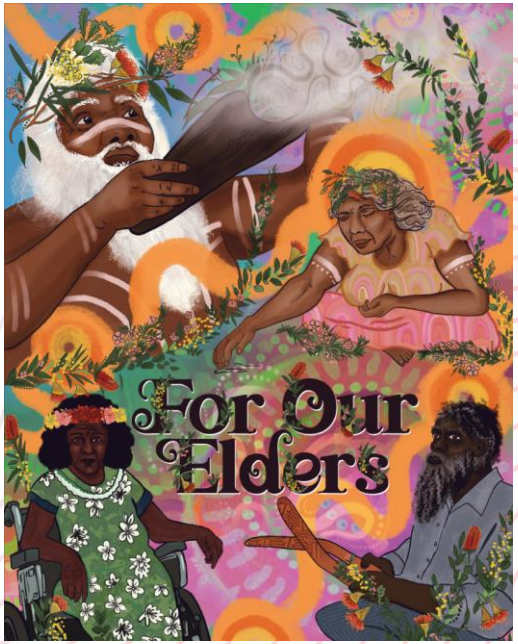
The P.A.V.I.N.G Project

Partnering With Consumers To Produce **A** Participant Initial **V**isitation Package And Effectively Utilise Consumer Feedback **I**n Line With The **N**ational **G**overnance Framework

A department of Barwon Health

Acknowledgement of Country

We, Barwon Health, acknowledge the Traditional Owners of the land, the Wadawurrung, Wurundjeri Woi-Wurrung and the Bunurong/Boon Wurrung peoples of the Kulin Nation. We pay our respects to the Elders past, present, and emerging.



What is a vccc skilled intern?

A VCCC intern is a graduate with a Masters or PhD degree in the Sciences who is undergoing training as a Clinical Trial Coordinator, or Clinical Trial Assistant, usually in regional or rural health services like Barwon Health

Each Intern must complete a site development project

PAVING was my site development project

How was paving conceived?

- In 2021 an Assessment report against the NCTGF (pilot) was conducted
- Gaps at Barwon Health were identified
- The NCTGF was compared to the identified gaps
- A list of actions were designed to address these gaps

How does this bring sites in line with the National Clinical Trial Governance Framework?

- Action 1.8 – through identifying areas for improvement based on safety and quality reflected through analysis of data from the participant feedback survey;
- Action 1.9 – Ensuring a timely report on safety and quality systems and performance are provided through evaluation of survey results;
- Action 1.13 – Establishes a process to seek regular feedback from participants and carers;
- Action 1.14 – Establishes a complaints management system that encourages participants and carers to report complaints, resolves complaints in a timely fashion, uses information from analysis of complaints to inform safety and quality improvements, regularly reviews and acts to improve effectiveness of complaints management;
- Action 1.15 – Identifies the diversity of consumers using the service, identifies consumers who are at higher risk of harm, and establishes systems that use this information to improve the delivery of care for these at risk groups;
- Action 1.29 – Provide clearly marked signs, maps and instructions to help participants and visitors navigate the clinical trial service within the health service organisation;
- Action 2.1 – Partners with consumers to explore opportunities make improvements based on consumer experiences;
- Action 2.2 – routinely implementing necessary improvements as determined through participant feedback;
- Action 2.3 – Provides consumers with clear information regarding their healthcare rights; and
- Action 2.14 – involves consumers in the process of identifying areas for improvement and training of staff.

So what does PAVING look like?

PAVING comes in two parts:

THE WELCOME PACK

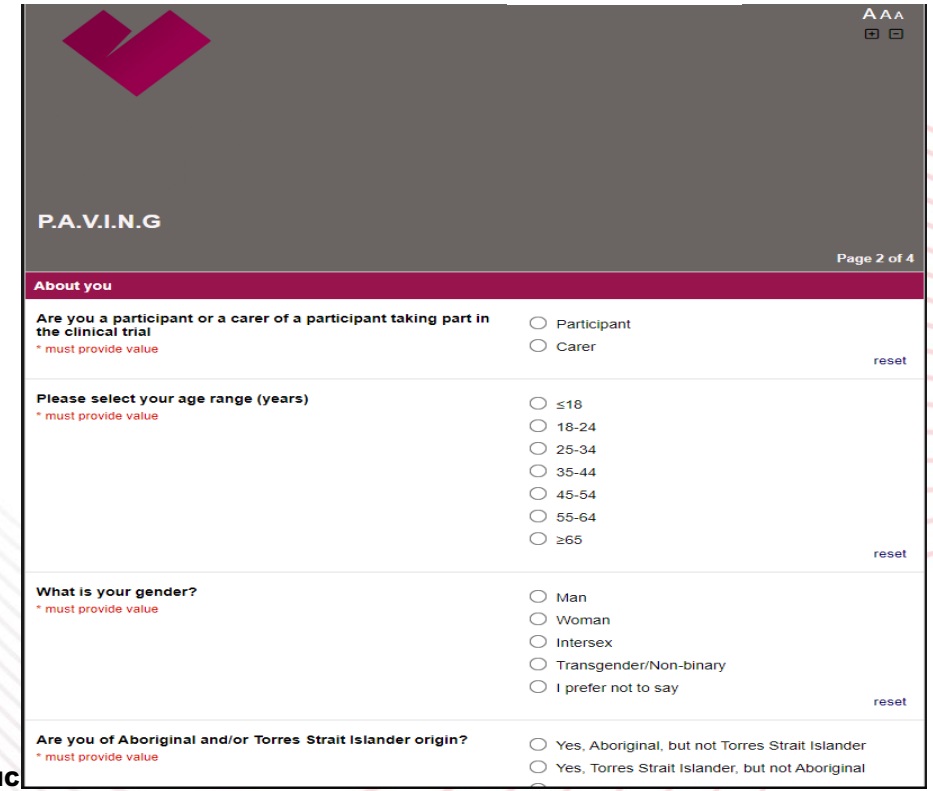
INFORMS AND EDUCATES

PREPARES THE PARTICIPANT TO JOIN A TRIAL

The Standardised Trials Experience Participant Surveys

Scan Me!

- Based on TransCelerate, ACSQHC Your Healthcare Experience, and RACGP standards, Follows the guidelines of MACH clinical trial participant guidelines
- Developed with consumer groups
- Given after consent, and then every 3 months



Our Consumer Partners

Aboriginal Health Unit

Barwon Health

VCCC Alliance

ReViTALISE's Every Voice Consumer Group

The Community And Research Network

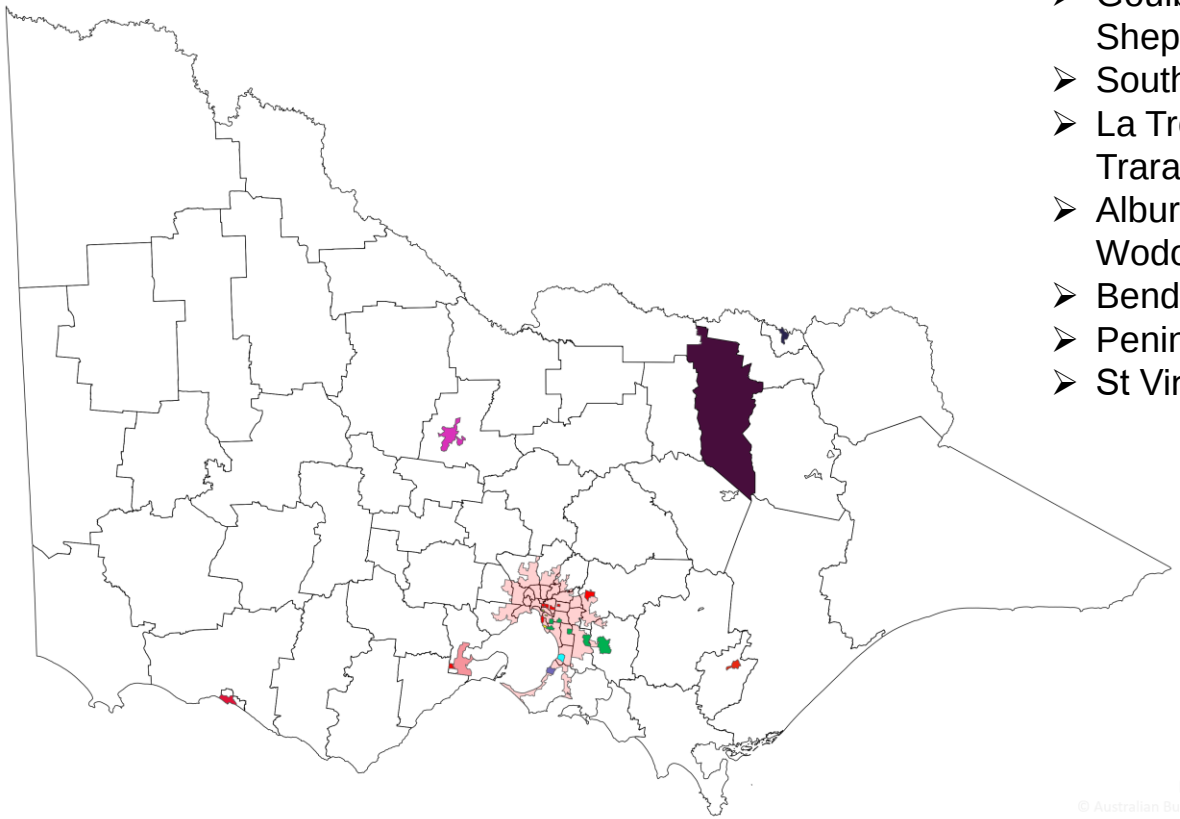
PAVING Aims

Make service improvements based on consumer feedback

Standardise the participant experience

Set a benchmark for trials in the hospital, and across the state, potentially even the country

PAVING's Reach



- Barwon Health, Geelong
- Northeast Health, Wangaratta
- Goulbourn Valley Health, Shepparton
- Southwest Healthcare, Warrnambool
- La Trobe Research Hospital, Traralgon
- Albury Wodonga Health, Albury-Wodonga
- Bendigo Health, Bendigo
- Peninsula Health, various
- St Vincent's Hospital Melbourne

Interested in getting involved?

To express your site interest to join the pilot program

Please email

Chiara.bortolasci@barwonhealth.org.au

Subject line: PAVING

Acknowledgements

VCCC Alliance SKILLED Internship Program, supported by MTP Connect and Victorian Department of Health.

The Authors would like to acknowledge and thank the members of the Community and Research Network (CARN), representatives of the ReViTALISE Every Voice consumer group, and the Barwon Health Aboriginal Health Unit for their valuable time and consultation in the production of the Frequently Asked Questions and Participant Experience Survey.

Adrian Costa
CLINICAL TRIALS CENTRE

Questions?

A department of Barwon Health

Clinical Trials Research

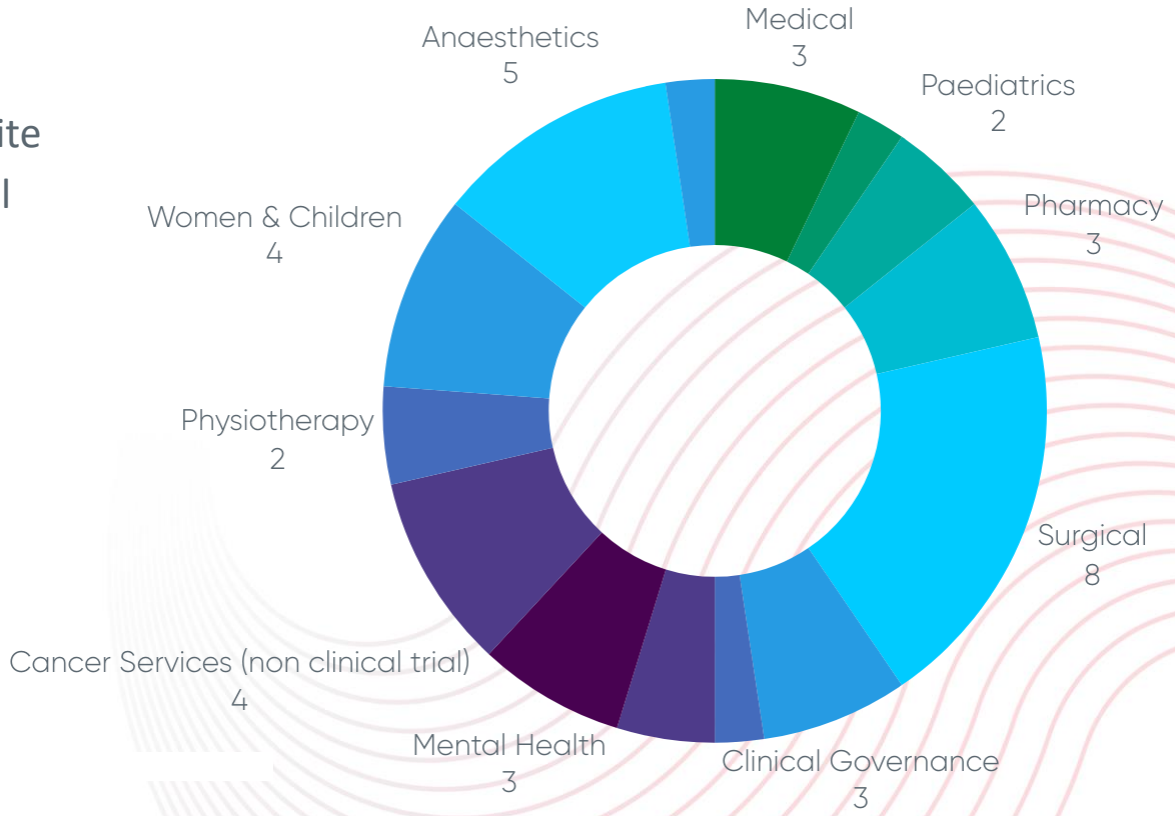
Accreditation 2023

Albury Wodonga Health
Library & Research

Research in 2022

45 Projects

- 25 AWH Initiated | 20 Multisite
  - 4 Non-trial interventional
  - 6 Clinical Trials
  - 11 Qualitative studies
  - 24 Retrospective data



NCTGF Prep...

Thank you to DoH for support

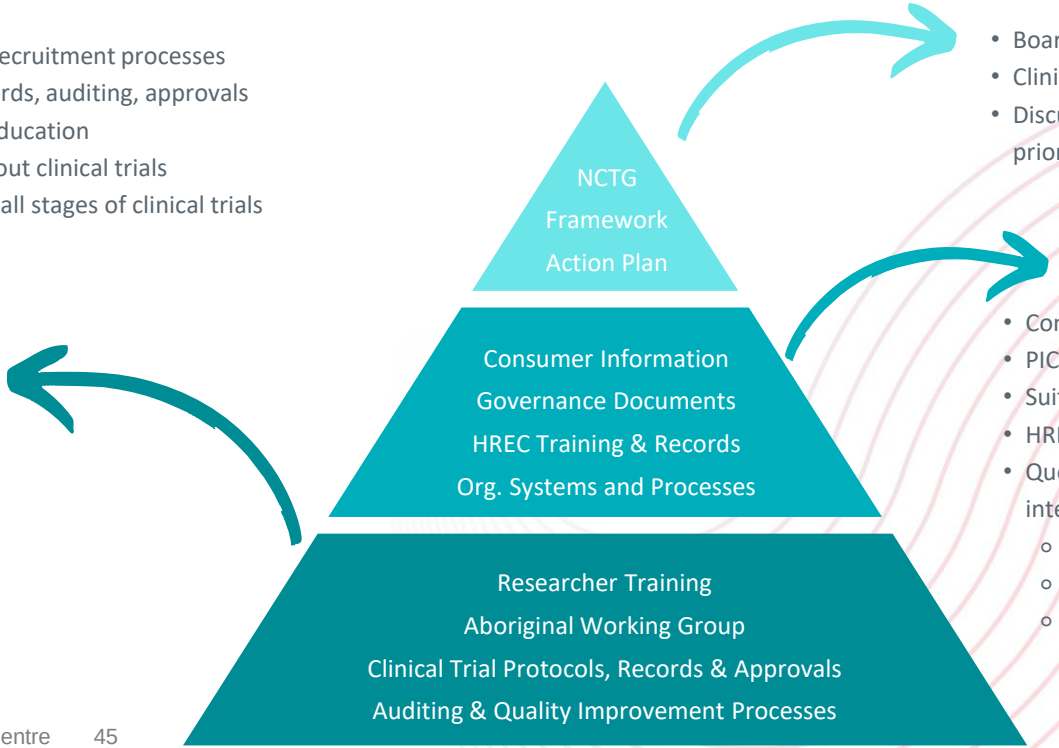
Albury Wodonga Health

Adrian Goldstein Clinical Trials Centre

Short Notice Accreditation

October 2023 ACHS | 3 Assessors over 6 hours

- Trial design and consent/recruitment processes
- Research governance records, auditing, approvals
- Researcher training, PD, education
- Clinical staff education about clinical trials
- Consumer involvement at all stages of clinical trials
- QI cycles recommended



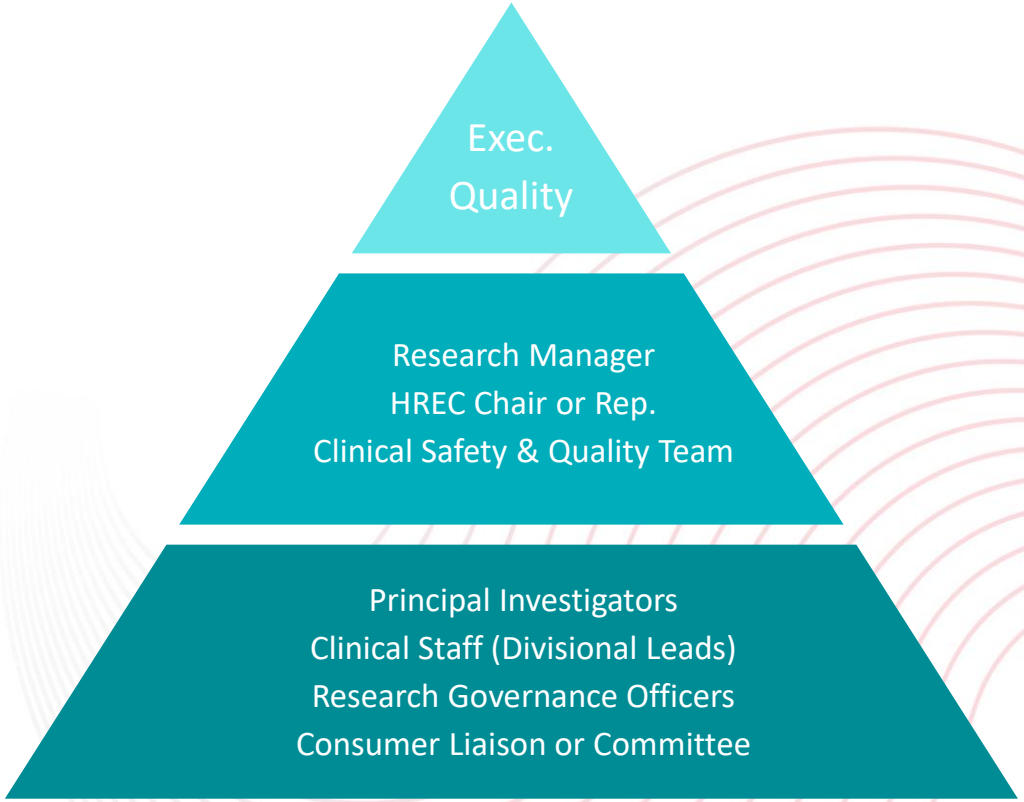
- Board Attestation confirmed
- Clinical trials noted in Strategic Plan
- Discussion on each Action item (not viewed prior to the meeting)

- Consumer information on AWH website
- PICF and trial websites viewed
- Suite of governance documents noted
- HREC not discussed in detail
- Queries about how clinical trial information interfaces with existing systems:
  - Patient records (Aboriginal status)
  - RiskMan
  - Complaints

Short Notice Accreditation

Outcomes & Reflections

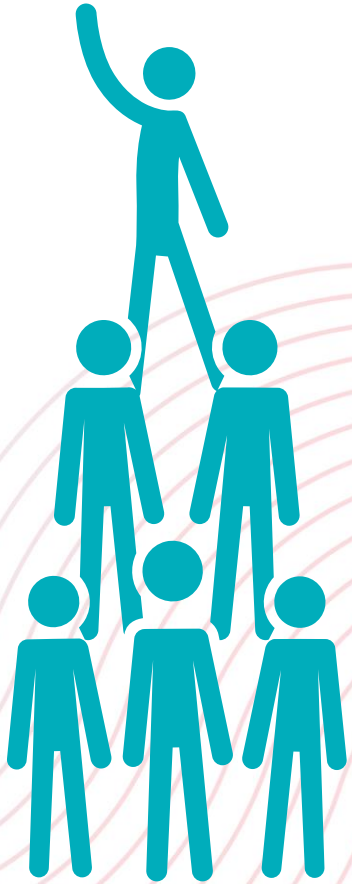
- AWH received a 1.5 for Initial Systems
- Low clinical trial activity made it difficult to demonstrate all Action items
- Team of people was required to toggle between the levels of information required



Where to next?

Outcomes & Reflections

- Accreditation process elevated the status of clinical trials at AWH
- Systems, processes and resourcing has started
- Very positive networking & menteeship experience!



Smart Governance and You

06 Februrary 2024 || Dr Heidi Gaulke || Office for Research

Acknowledgement of Country

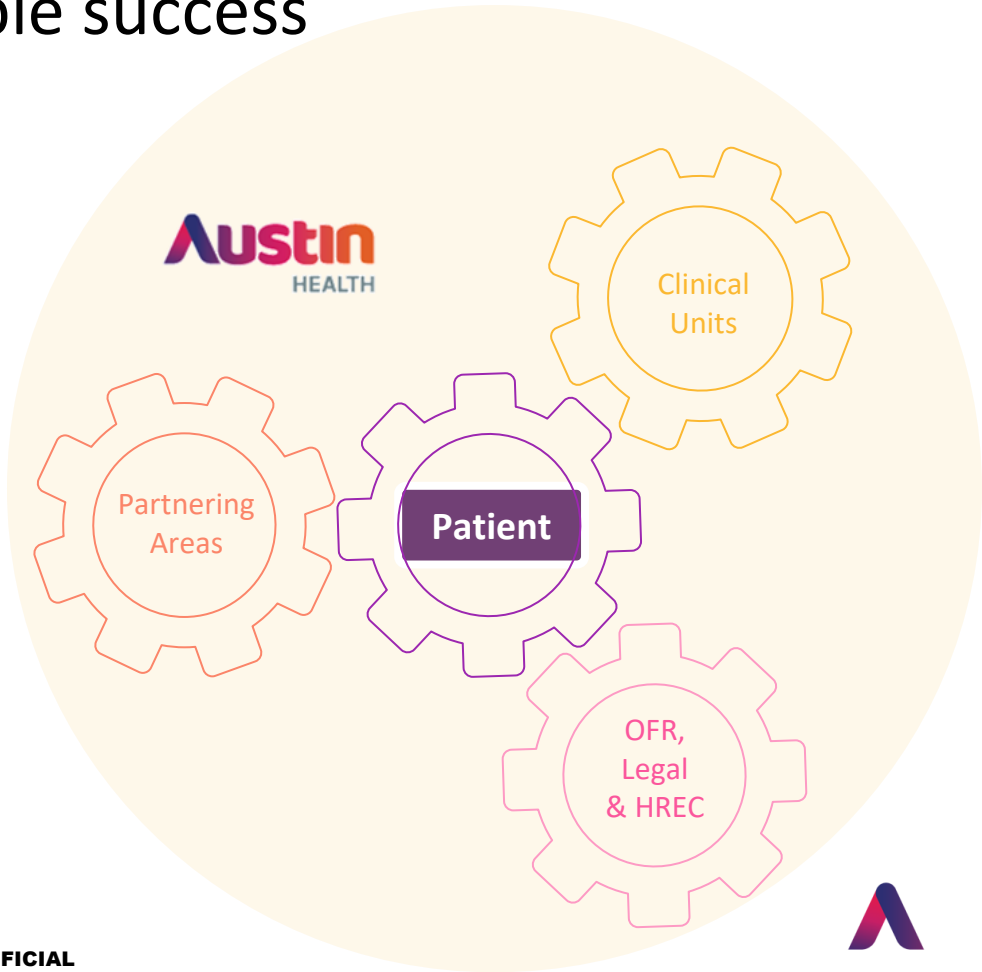
We acknowledge the Traditional Owners of the unceded land on which we work, learn and live across Australia.

We acknowledge the history and impact of health and wellbeing research on Aboriginal and Torres Strait Islander Communities. We are grateful to the Traditional Owners, Elders and Knowledge Holders of all Indigenous nations and clans who continue to help us understand, appreciate, and uphold your unique and beautiful knowledges, needs and aspirations.

We pay our respect to the importance of Indigenous Knowledge by acknowledging Elders past and present. This means we will forever ensure all Aboriginal and Torres Strait Islander research is self-determined. As a community of researchers and professional staff we can think of no greater privilege than to work, learn and live by the principles of the world's oldest culture.

Three PRIORITES to enable success

1. Use existing Clinical Governance IT system
2. Improve Governance
3. Reporting to the Board & our Community



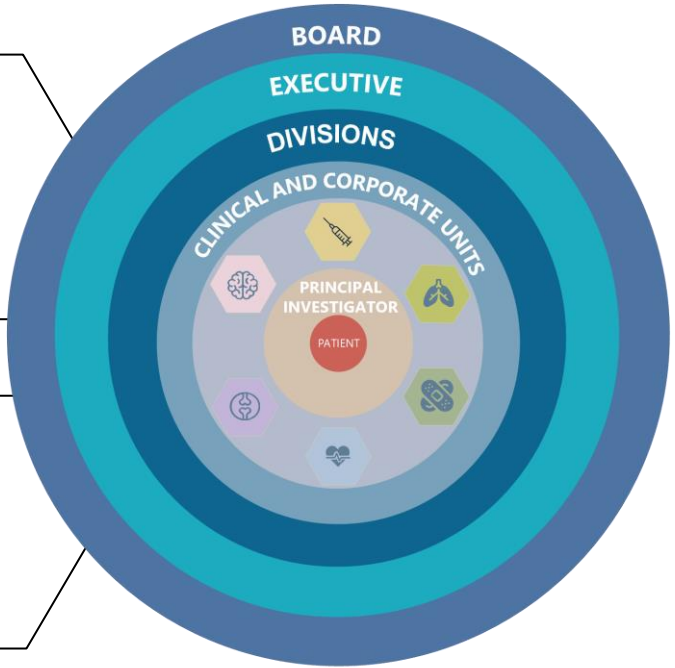
Improving VISIBILITY & REPORTING

IT system

- Automated notifications
- Track requests
- Board reporting
- Improved visibility & transparency

SNAP accreditation

- To ensure we, as part of Austin Health, are prepared for short notice accreditation assessment
- Understanding your role



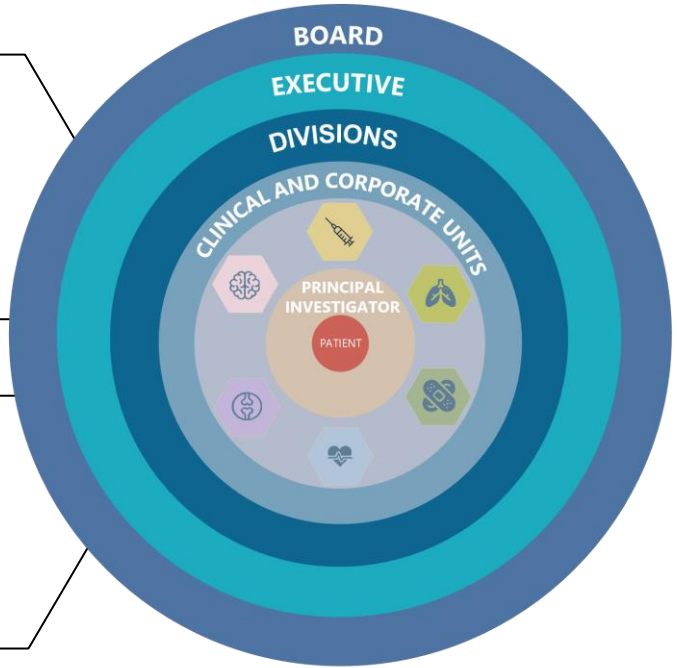
Improving GOVERNANCE

Risk Mitigation Strategies

- Clinical Governance drives the process
- Automatic alerts to Research Office
- Research Office can manage parallel process
- Research competency framework

Reporting

- Board reporting against Austin Health Risk Appetite Statement
- Reporting to Sponsors
- Emerging risks
- Current risks



Improving quality of INFORMATION

Who was impacted?

What happened?

Why did this happen?

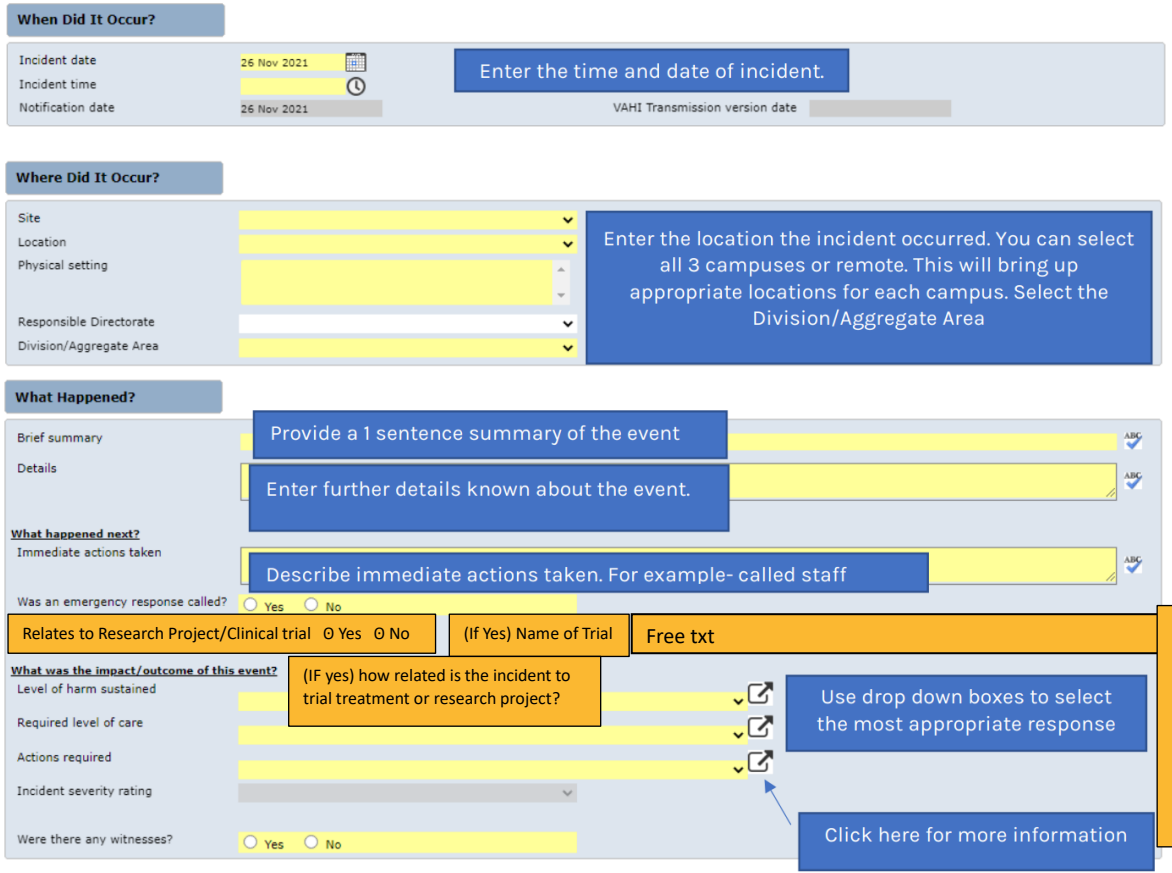
How did this happen?

When did this happen?

Who needs to know?

What happens next?

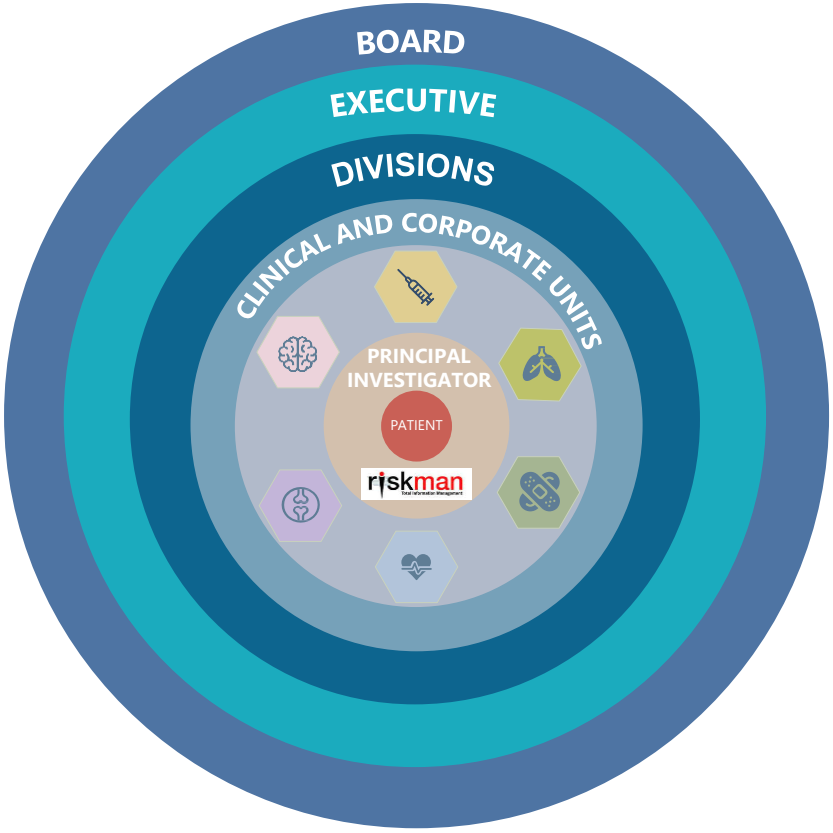
Providing a single source of truth in RiskMan



Drop down list:

- Incident definitely related to clinical trial treatment.
- Incident may be related to clinical trial treatment.
- Unsure
- Too early to tell if the incident is related to clinical trial treatment.
- Unrelated to clinical trial treatment.

Transparency of information & automated reporting



Competency is knowing your role

RESEARCH COMPETENCY FRAMEWORK

		Principal Investigator	Associate Investigator	Registrars/Research Fellow/ Intern/ Student/ Medical Officer	Clinical Research/Trials Manager	Clinical Research Coordinator
Role	Your role in the Clinical Workforce	You are a responsible, qualified and skilled leader overseeing all aspects of the research project. You are responsible for the conduct of all research activities from start to finish.	You are a qualified senior research professional (clinical or non-clinical) being supervised by the Principal Investigator. You are part of a team undertaking research.	You are undertaking professional experience at a health service under supervision of a mentor or manager. You are an honorary employee of the organisation or under placement.	You have a leading role in planning, coordinating and completing the study to time and to target, as part of a multidisciplinary team.	Manages and conducts the day-to-day activities of a clinical trial/clinical research. The Principal Investigator determines the specific responsibilities and works closely with the Clinical Research Coordinator. In general, the Clinical Research Coordinator ensure the clinical study maintains accordance with the protocol, applicable regulations, Good Clinical Practice and Human Research Ethics Committee (HREC) requirements.
Research Type training	Case Study/Systematic review/scoping review/narrative review	Level 1	Level 1	Level 1	Level A	Level A
	Audit: Retrospective/ Prospective	Level 2 Mentor + Completed Post-Graduate Research degree	Level 2 Mentor + enrolled in Post-Graduate Research degree	Only by exception	Level B	Level A
	Clinical Research	Level 3	Level 2 Mentor + enrolled in Post-Graduate Research degree	Only by exception	Level B	Level B
	Clinical Trial	Level 3	Level 2 Mentor + enrolled in Post-Graduate Research degree	Only by exception	Level B	Level B
	Novel/ First-In-Human	Level 3	Level 3 Mentor + enrolled in Post-Graduate Research degree	Only by exception	Level B Mentor + Recommended Advanced Training	Level B Mentor + Recommended Advanced Training

Training	Minimum Training Requirements for each level and role					
		Annual Training (mandatory regardless of level) - All research staff must comply with Austin Health's Core Education Training and Development Policy: • Austin Health mandatory ATLAS training modules • Austin Health Research Induction Training **Level 1** • Valid Professional registration • ACTEC Trial Regulatory Requirements in Australia • Ethics and Governance Application Process • Library - How to develop a strategic publishing strategy • Library - Endnote for beginners • Library - Develop your literature searching skills • Library - Using Library resources and services • Library - How to create a researcher profile **Level 2** **ACTEC – Research Ethics and Governance Process** • Key Concepts • Initial Submissions • Post Approval Reporting • ACTEC - Introduction to Clinical Trials • Running a Clinical Trial from start to finish • ACTEC - Good Clinical Practice Training • ACTEC - Trial Feasibility & Start-Up Process • ACTEC Protocol Compliance and Serious Breaches • ACTEC - Monitoring and Auditing **Level 3** ACTEC Trials Essentials for Investigators • Trial regulatory requirements in Australia • Trial Feasibility & Start-up Process • Protocol Compliance & Serious Breaches • PI Oversight & Trial management **Free extension training** • Research for Impact • Introduction to Good Clinical Practice • Healthcare Data Security, Privacy & Compliance • Risk Management (HCA Australia Paid Course) • Design & Conduct of Clinical Trials • Data Analysis • Clinical Trial Operations Specialization • Understanding Clinical Research: Behind the Statistics (John Hopkins) • Data Management for Clinical Research (Vanderbilt Uni) • Understanding Research Methods (University of London) • Design and Interpretation of Clinical Trials (John Hopkins Uni) • Introduction to Systematic Review & Meta-Analysis (John Hopkins) • Understanding Medical Research: Your Facebook Friend is Wrong (Yale Uni) Researcher Management and Leadership (University of Colorado) **Paid extension training** • Methods and Implementation Support for Clinical and Health (MISCH) Hub & MCRI • MCRI Workshops • Monash University Professional Education Program	**Annual Training (mandatory regardless of level) -** All research staff must comply with Austin Health's Core Education Training and Development Policy: • Austin Health mandatory ATLAS training modules • Austin Health Research Induction Training **Level 1** • Valid Professional registration • ACTEC Trial Regulatory Requirements in Australia • Ethics and Governance Application Process • Library - 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Smart reporting Improves CARE

Using Clinical Governance ecosystem keeps our patients safe by

- smarter and faster reporting
- removing duplication
- keeping information to a single source of truth

Moving Melbourne

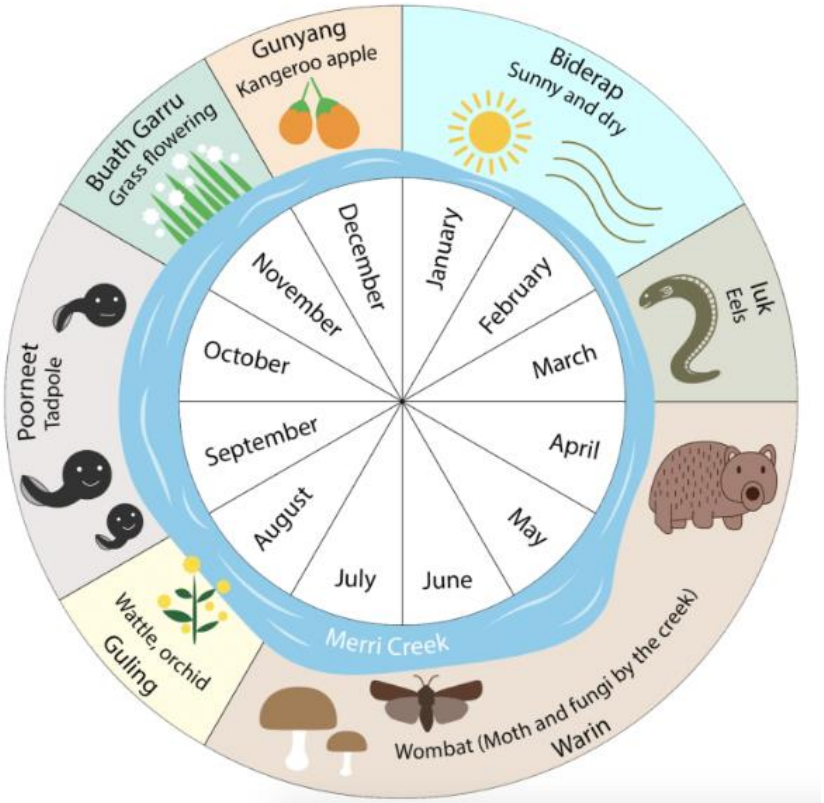
Royal Melbourne Hospital Governance Framework Experience

06 Feb 2024

Dr Jacqui Waterkeyn, Director Office for Research

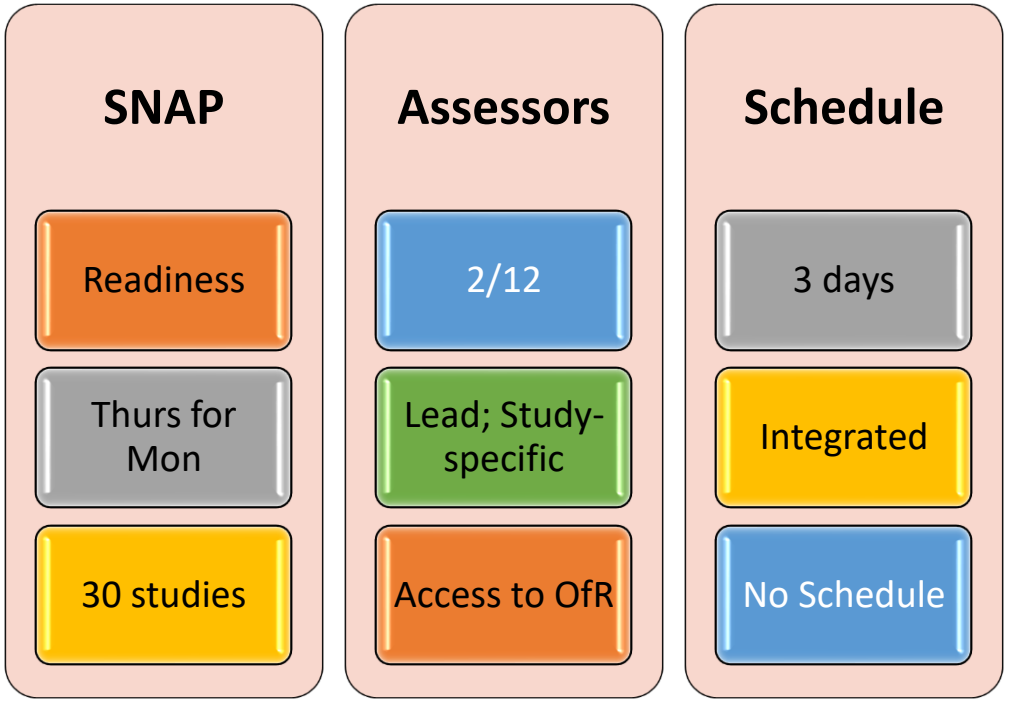
The Royal Melbourne Hospital

Acknowledgement of Country

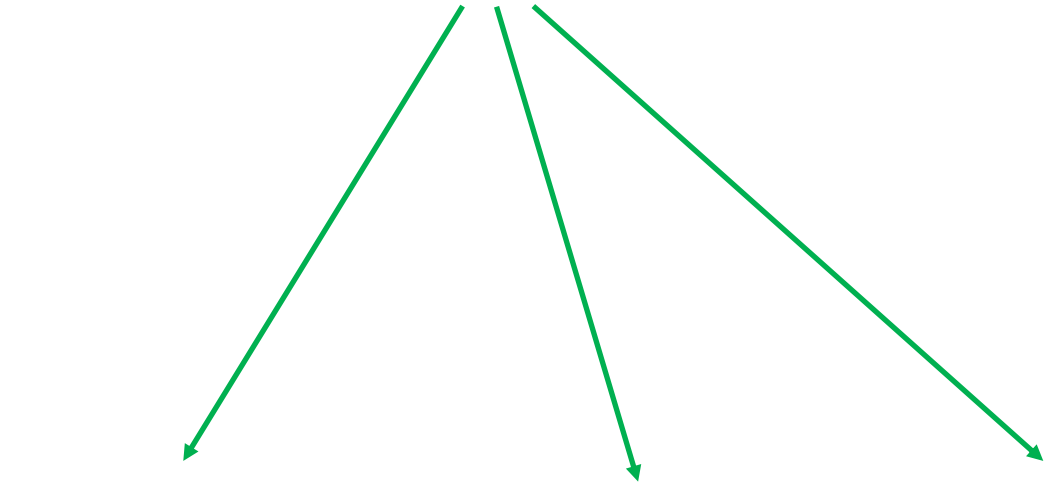


http://www.morelandps.vic.edu.au/from-waring-to-guling-the-seasons-of-the-merri-creek/

Overview of Assessment Week 27 – July to 4th August 2023



National Clinical Trials Governance Framework



Clinical Trial Notifications
Clinical Trial Approvals

+ Non CTN/CTA trials

+ Clinical Research

Assessors embedded with broader RMH accreditation

RMH did not differentiate

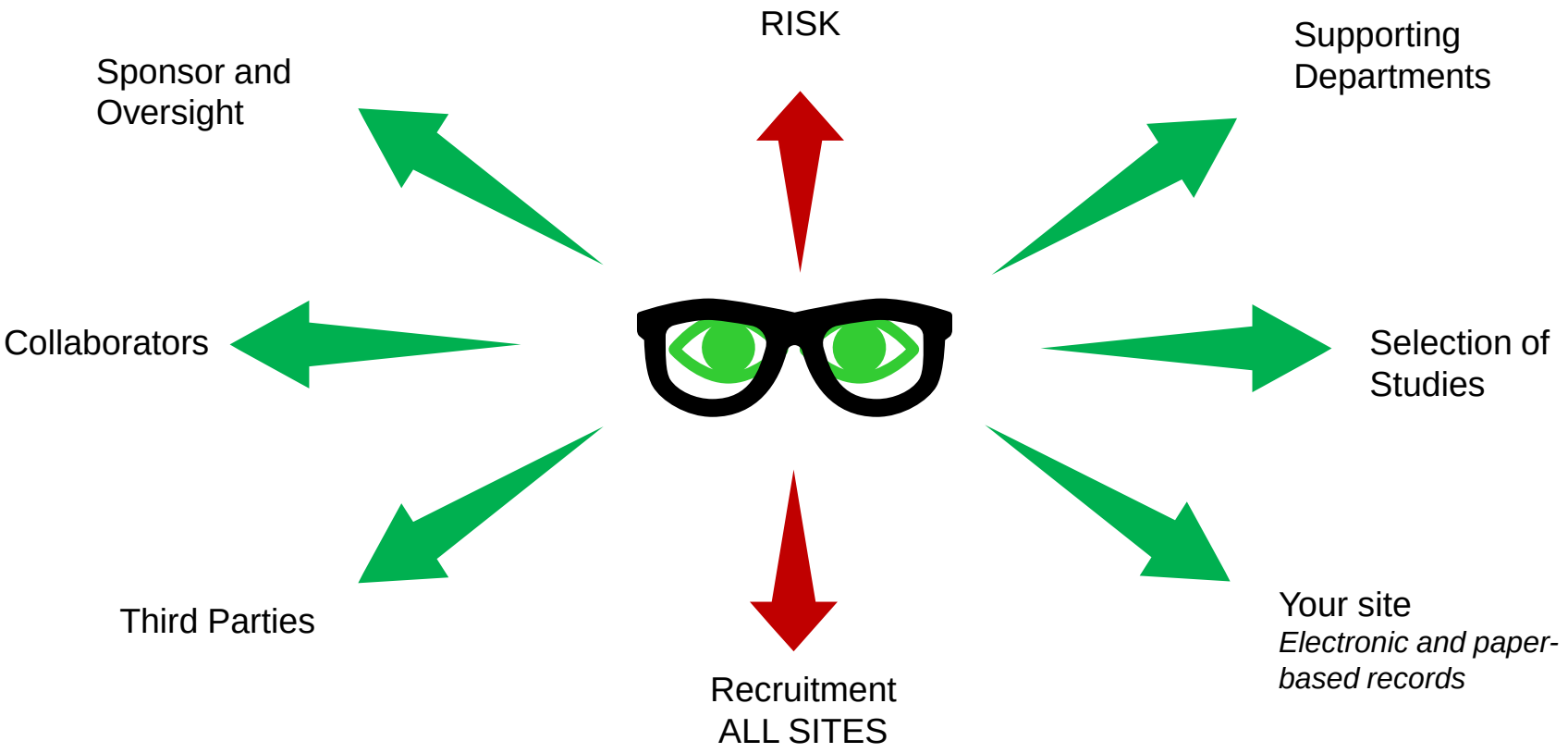
Working with Assessors

EXPERIENCE WITH CLINICAL RESEARCH

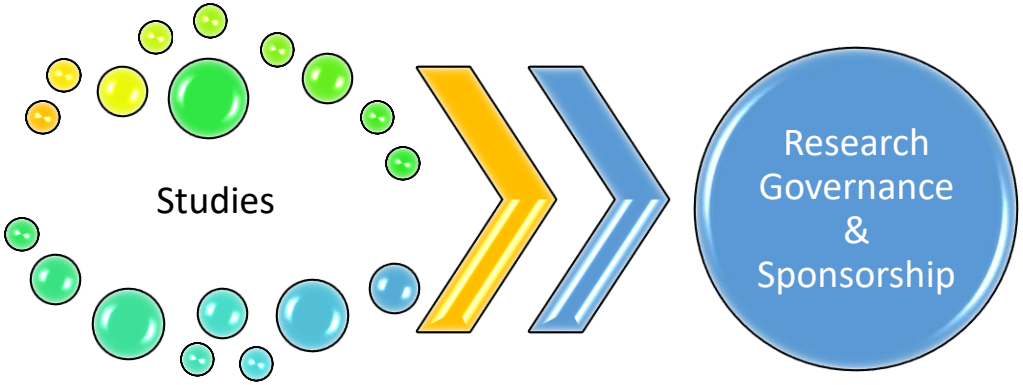
- Human Research Ethics Committee process and approvals
- Research Governance process and approvals
- Research Operations (Site and Facilities)

NCTGF

- Reporting in Clinical Research **ICH-GCP meets Accreditation**


RISK
Sponsor and Oversight
Supporting Departments
Collaborators
Selection of Studies
Third Parties
Your site
Electronic and paper-based records
Recruitment ALL SITES

COLLABORATORS AND RISK



Based on risk

Research Governance & Sponsorship

- Oversight
- Regulatory

Universities

Medical Research Institutes

Other health services

COLLABORATOR PANIC AND PACIFICATION

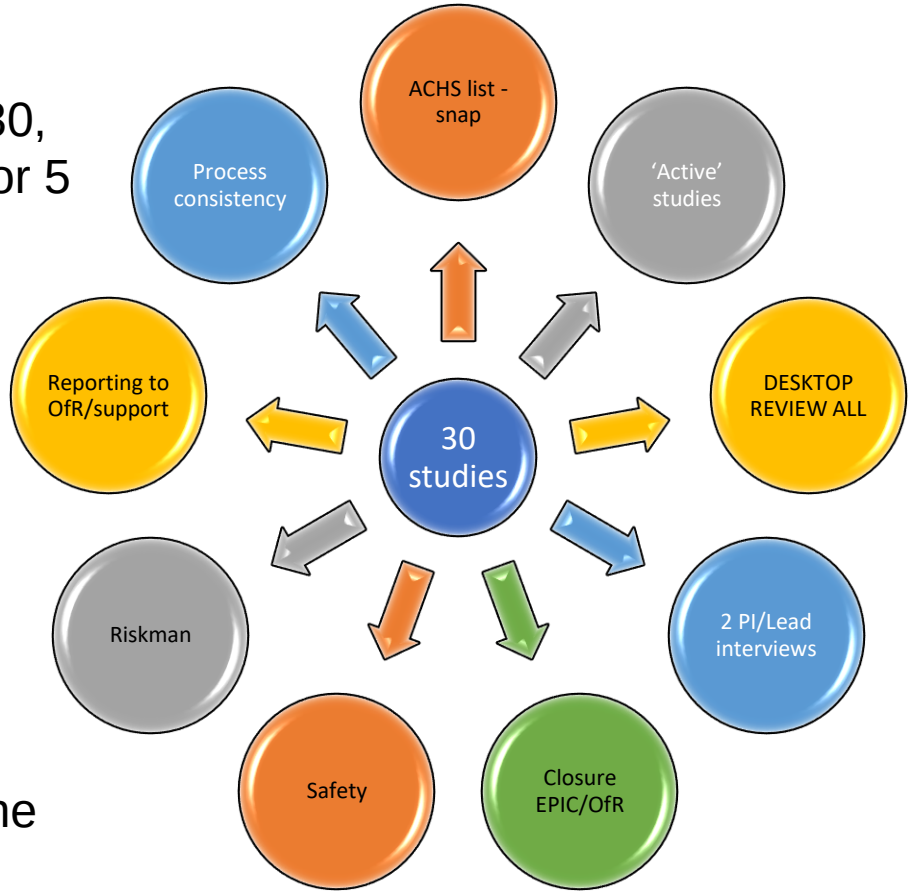
Key collaborator preparation:

- ❑How do you routinely do business with them?
- ❑How do you oversee them from a governance perspective
- ❑What are their responsibilities?
- ❑**CONTRACTING**
- ❑Make sure they have their study files ready and contemporaneously maintained
- ❑Prep KEY collaborators early. Consider them part of the research teams

When you have the 30 studies:

- ❑Let them know which study
- ❑Confirm they understand responsibilities
- ❑Confirm they have the agreements
- ❑Let them know they may be needed. Don’t need to schedule

Review all 30, interviews for 5



PI meetings together with study lead

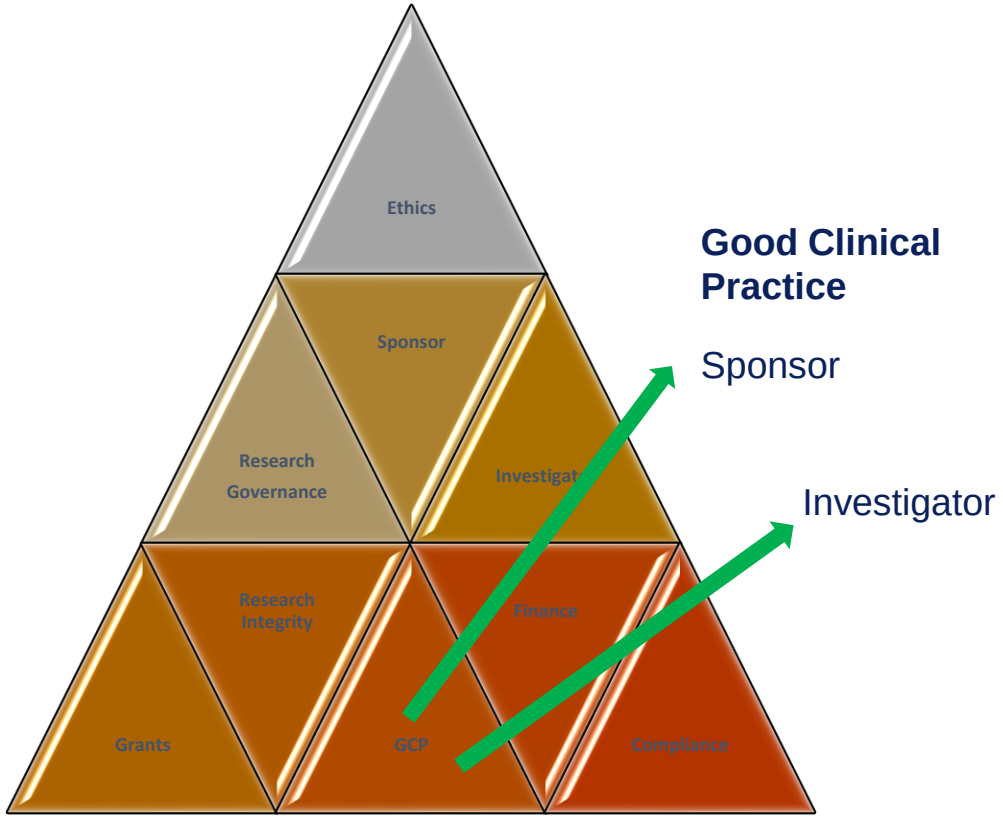
Spread of study types

Interested in the Clinical Trials Centre

NEW REQUIREMENT IN A HIGHLY REGULATED AREA

Office for Research (OfR)

Research Oversight



Infrastructure & Embedding of CTS – SUPPORTING DEPARTMENTS

– Process of oversight for governance purposes

– Departmental Statements of Approvals

– How governance and process fits (seamlessly) into Institution and RGO

– How do they work with the Research Office?

– Website user friendliness (assessors sought opinion from Investigators)

– Integration of study data collection into medical record and study data

REPORTING – ACTION 1.1 METRICS

YAY!!!

- How does the Research Directorate report to the Governing Body?
- How and when are these reviewed?
- How does the Research Directorate get the data to begin with?
  - Research workforce
  - Study metrics

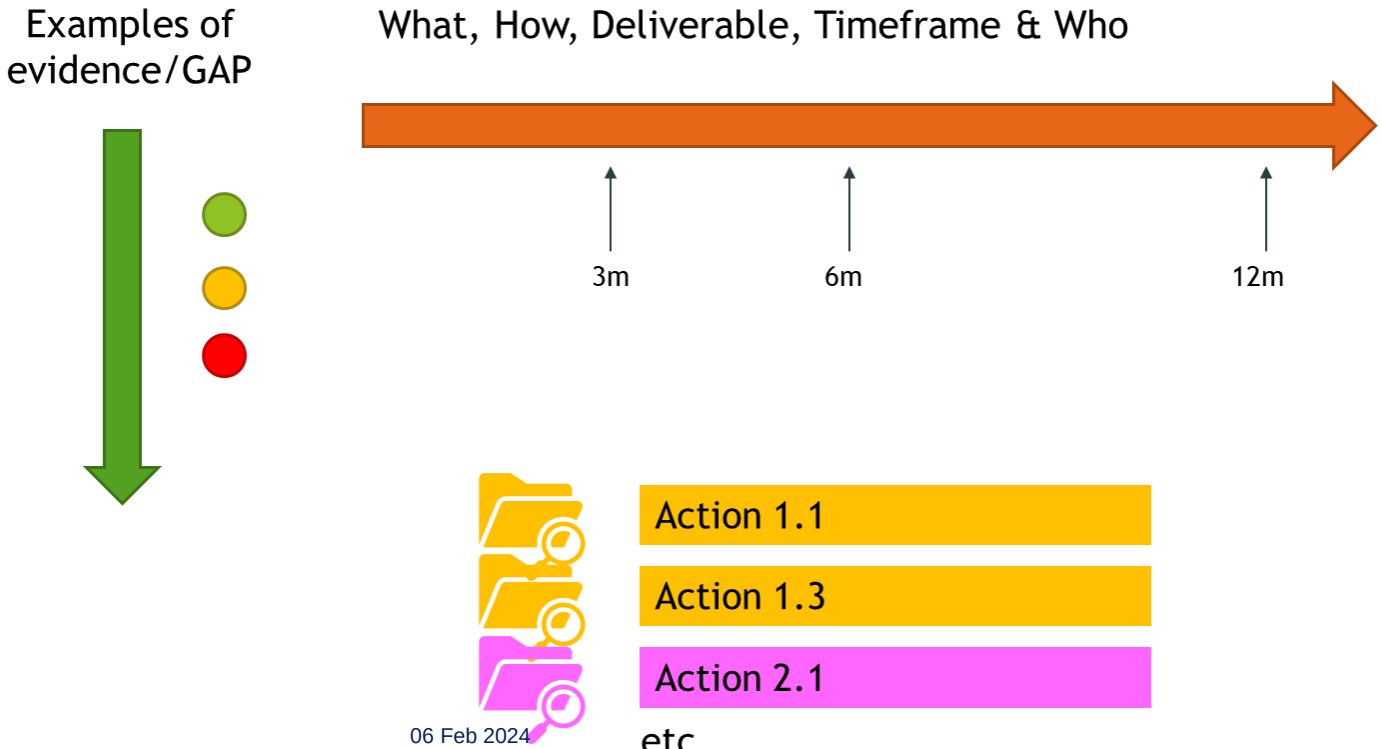
BASICALLY –

LEARN AND SPEAK TO:

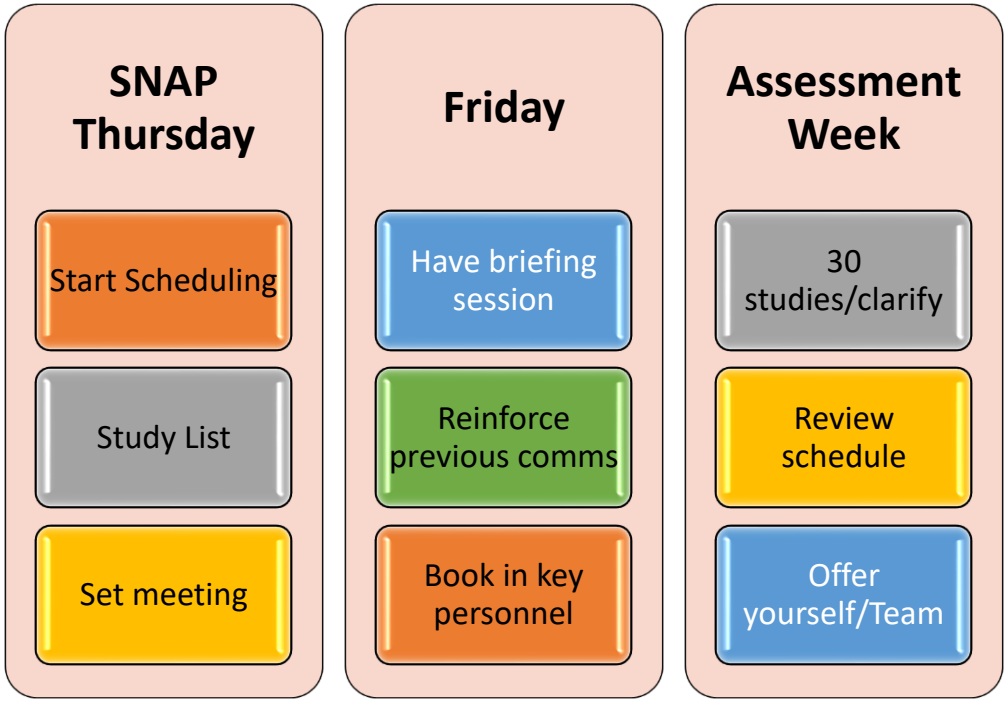
- **YOUR REPORTING OBLIGATION**
- **HOW YOU REPORT IT**
- **WHEN AND TO WHO YOU REPORT AND**
- **WHO ACTUALLY CARES WHAT THE RESULT SHOWS**

Quality Improvement Plan and Gap Analysis

ACTION REFERENCE – EXCEL SHEET



SNAP ASSESSMENT



Up to the assessors but help steer

Keep comms channel open with updates as the week progresses

Key Learnings - SUMMARY

- ✓ Know your processes
- ✓ Know your reporting lines (metrics and organisational)
- ✓ Bring in your Subject Matter Experts early
- ✓ Ensure Position Descriptions of SMEs reflect the framework requirements
- ✓ Know your gaps
- ✓ Continuous Improvement Plan/Action Plan (up to 12 months out)
- ✓ START YOUR EVIDENCE FOLDER EARLY ON

During assessment week:

- ✓ Get to know your assessors and their focus area
- ✓ Keep your workforce updated ESPECIALLY the 30 study PI/Lead
- ✓ Don’t forget collaborators and broader study stakeholders

Thanks to:

OfR Team
RMH Quality Team
Many RMH Departments

E: research@mh.org.au
T: 9342 8530

National Clinical Trials Governance Framework: You've been SNAP'ed

Associate Professor Tam C. Nguyen *FRSM FAIM FRSPH PhD MBA*

Deputy Director of Research, St Vincent's Hospital Melbourne

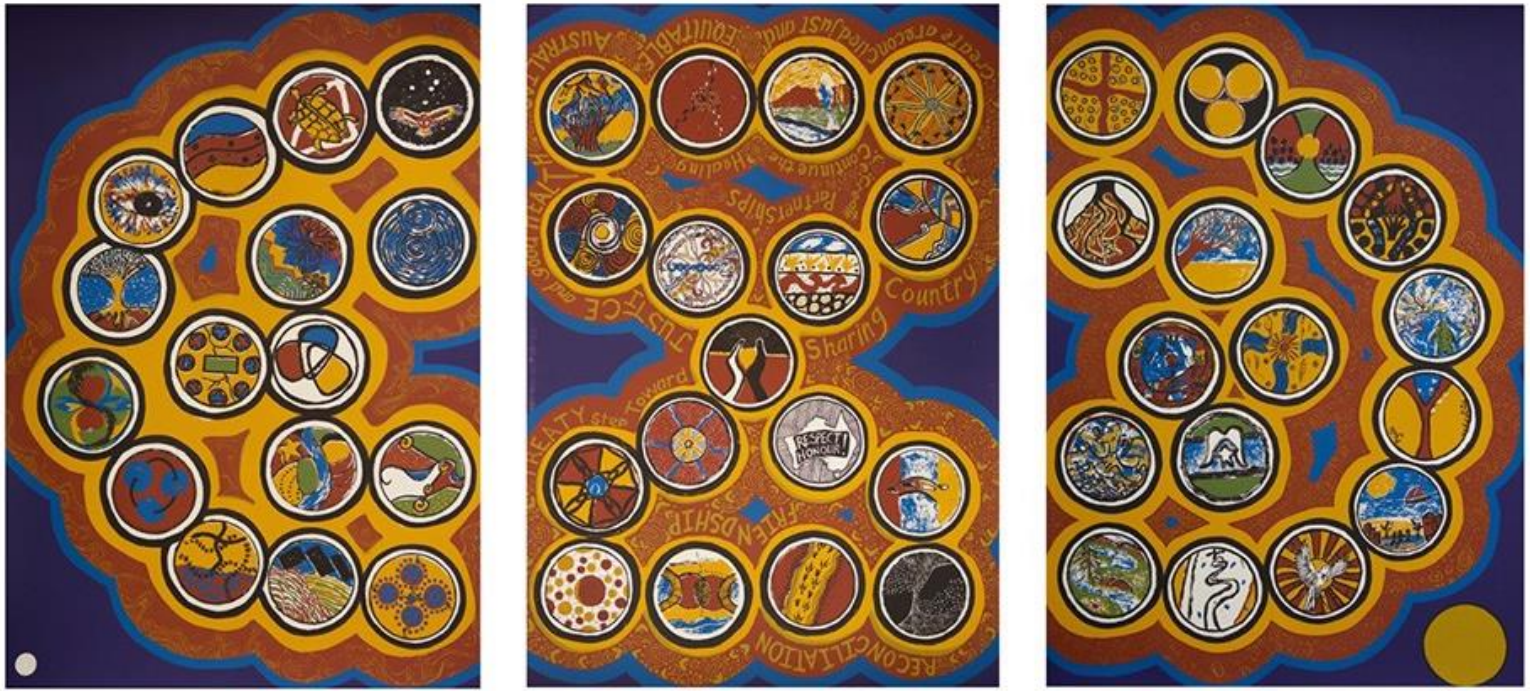
Associate Professor, Melbourne Medical School

Adjunct Assoc Prof (Research), Monash Medical School | RMIT University

UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

I acknowledge the people of the Kulin Nation, the traditional custodians and pay my respects to their culture and their Elders past, present and future. Being inclusive and providing equitable healthcare is our commitment at St Vincent's

ST VINCENT'S HOSPITAL MELBOURNE



Artists: Bianca Beetson, Vicki Couzens and Jeffery Samuels in collaboration with 48 SVHA staff members

Clinical Trials in Australia

ST VINCENT'S HOSPITAL MELBOURNE

Metric	2015*	2019**	CAGR (2015–19)
Expenditure	$1.1 billion	$1.4 billion	5%
Employment	6,900 employees	8,000 employees	4%
Patient participation	Not reported	95,000	N/A
Number of trials started	c.1,360	c.1,880	7%
Share of global industry sponsored trials	c.5%	c.5%	Nil

Note: * As calculated in *Clinical Trials in Australia* (2017) report; ** As calculated in this report

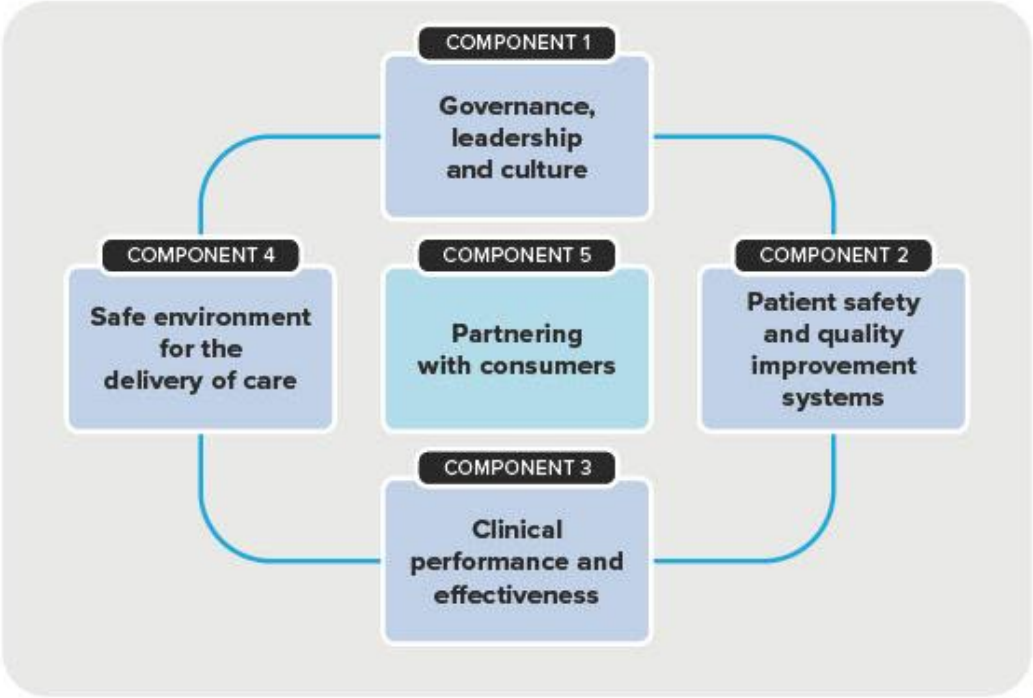
MTPConnect Report updated 2021

- Updated figures through to 2019
- Approx 1800 interventional clinical trials in Australia in 2019
  - Two thirds investigator initiated
  - 80% funds generated through commercially sponsored trials
  - Reported $1.4B expenditure
  - 5% global commercial trial market
- National standard for clinical trials proposed as means of improving Australia's competitiveness in the global clinical trials market
- Reassurance for global sponsors and pharma that Australia had established standards of practice for clinical trials

What is the National Clinical Trials Governance Framework

- Developed to address issues of fragmentation and inefficiency that impact on Australia's attractiveness as a preferred location for clinical trials
- The Governance Framework aligns with the Commission's existing National Safety and Quality Health Service standards for hospital accreditation.
- Aims to assist hospitals to embed clinical trial services into routine practices of health service organisations

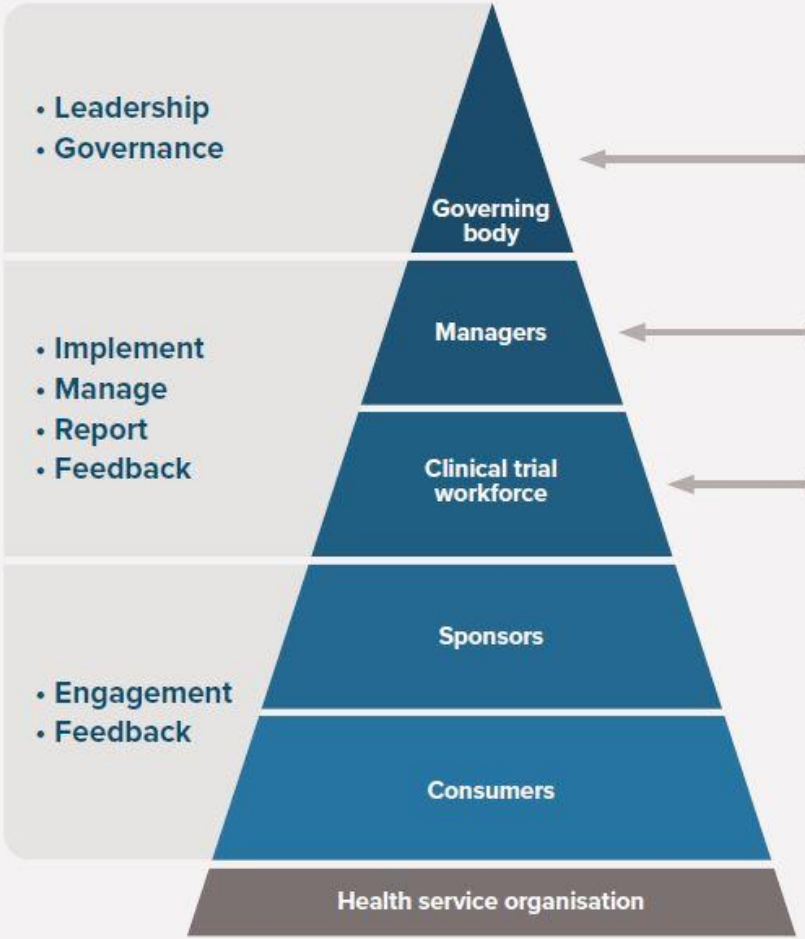
Key Components of the Governance Framework



Standard 1 – Clinical Governance

- **Governance Leadership and Culture**
- **Patient Safety and Quality Improvements Systems**
- **Clinical Performance and Effectiveness**
- **Safe Environment for Delivery of Care**

Standard 2 – Partnering with Consumers



Governing bodies – establish strategic policy and frameworks, lead organisational culture, oversee management performance, monitor organisational performance and ensure organisational accountability for clinical trial service provision.

Managers – lead and coordinate the workforce and implement well-designed systems for the delivery of clinical trials.

Clinical trial workforce – work to deliver high quality clinical trial services. They maintain their skills and performance and are confident their colleagues and the organisation will support them in the delivery of high quality clinical trials.

ST VINCENT'S HOSPITAL
MELBOURNE

ST VINCENT'S HOSPITAL MELBOURNE

Governing body

- Board
- Health Service Organisation/ trial site
- Chief Executive Officers
- Heads of Departments
- Director of Research

Managers

- Managers (clinical and non-clinical)
- Finance
- Human Resources
- Business Operations

Clinical trial workforce

- Principal and Sub-investigators
- Clinical Trials Liaison Officer
- Study Coordinators
- Supporting departments
- Trial Managers
- Trial Pharmacists
- Trial Nurses
- Site Specific Assessment Officer
- HREC Executive Officers

Patients and consumers

- Patients
- Consumers
- Trial Participants, their carers and families

Sponsors

- Commercial
- Clinical Research Organisations
- Health service organisations
- Academic research organisations
- Collaborative clinical trial groups
- Investigators
- Universities

Questions to consider

Are you familiar with the Governance Framework?

Are you familiar with the suggested strategies you could implement to demonstrate you meet the actions in the Governance Framework?

Who is your health service organisations' accrediting agency?

Approximately, when is your next assessment due?

Who is your Risk, Safety and Quality Officer?

Who coordinates assessment against the NSQHS Standards in your organisation?

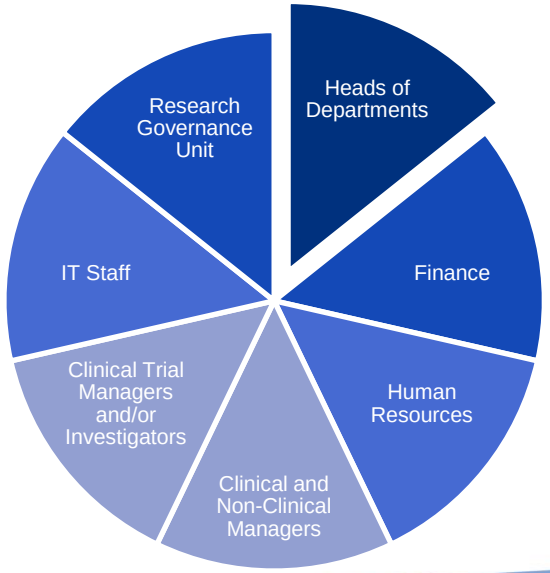
National Clinical Trials Governance Framework Working Group

SVHM Working Group Responsibilities Include:

Advising on matters related to clinical trials services

- systems support clinical trial service delivery
- business, strategic and operational plans relevant to clinical trial service provision
- risk relating to clinical trials
- Maintain organisational culture

SVHM Working Group Composition



Departmental Requirements

National Clinical Trials Governance Framework:
Departmental Checklist

NOMINATED DEPARTMENT CONTACTS (PLEASE INCLUDE MINIMUM OF 2)

Department:			
[Name], [Role]		**[Name],** [Role]	
[Contact Number]		[Contact Number]	[E-Mail]

DEPARTMENTAL CHECKLIST

**Please note: the term 'clinical trials' has been used throughout to describe any activity that is related to any research conducted. The Research Directorate may contact departments to collect specific data on interventional trials separately to this Checklist.*

Clinical Trial Workforce		
Related action/s	**Item**	**Due date**
☐ 1.1	**How many clinical trials/research coordinators are there within your department?** Please provide a log of all clinical trials coordinators/research coordinators and research staff within your department *using the spreadsheet template provided*.	**16 OCT**
☐ 1.6	**Are there position descriptions for Clinical Leaders include safety and quality roles/responsibilities related to clinical trial services?** Please provide copies.	**16 OCT**
☐ 1.6	**Has a performance review been completed or scheduled for all clinical trial staff that discusses and requests feedback on their role in clinical trials?** Staff should have at least 1 performance review each year. Visit the Workday for Managers site for more information.	**16 OCT**

- **Complete the Departmental Checklist and Workforce Register Form by the due date**
- **Assist with the clinical trials data collection process using the clinical trials portal (select departments will be contacted for this)**
- **Work with the Research Directorate to to make amendments to submissions in preparation for accreditation**
- **Work with the Research Directorate to identify and implement changes at a departmental level**

National Clinical Trials Governance Framework:
Departmental Checklist

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Clinical Trial Workforce Training		
Related action/s	**Item**	**Due date**
☐ 1.6 1.20	**Ensure all staff involved in research are up to date with all their Required Training in Workday and have completed their GCP certification.** Please provide a log of GCP certification *using the spreadsheet template provided.* Please contact the RGU at research.ethics@svhm.org.au if you would like more information on how to obtain GCP certification.	**16 OCT**
☐ 1.4 1.6 1.8 1.20	**What training (additional to GCP) does your department implement for clinicians/staff involved in research? (Can include specific training for research involving Aboriginal and Torres Strait Islanders / the informed consent process / etc)** Please provide evidence.	**16 OCT**
☐ 1.20	**Do you have employment records that detail the skills and competencies required of the individuals undertaking clinical trials?** Please provide evidence.	**16 OCT**

- Departmental data checklist
- Departmental Workforce register with GCP
- Document pack used by Quality team for NSQHS
- All evidence uploaded to ACSQHC website
- Uploading issues frequent

National Clinical Trials Governance Framework: Departmental Checklist

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Departmental Clinical Trials Policies, Procedures, and Operations		
Related action/s	**Item**	**Due date**
☐ 1.7	**Are there departmental policies and procedures specific to clinical trial/research conduct, or are clinical trial provisions embedded in the departmental procedures?** Please provide evidence.	**16 OCT**
☐ 1.11	**What is the departmental process for incident reporting within clinical trials?** Please explain and provide evidence.	**16 OCT**
☐ 1.10	**Is the risk register contributed to when necessary, and are there departmental SOPs guiding this process?** Please provide evidence.	**16 OCT**
☐ 1.8	**Is there a Quality Improvement Plan for clinical trials that includes actions to deal with identified risks and issues as they arise?** Please provide evidence.	**16 OCT**
☐ 1.5	**Is there a departmental clinical trials strategy plan, operation plan, and/or business plan?** Please provide evidence.	**16 OCT**
☐ 1.3 1.10	**Are there any departmental clinical trials meetings / committees? Do these meetings discuss clinical trial issues and safety concerns?** Please provide evidence, including minutes and terms of reference.	**16 OCT**
☐ 1.8	**Is there a process in place for more active monitoring of trials that have problems? (E.g. poor recruitment, underfunded, under-resourced, etc).** Please provide evidence.	**16 OCT**
☐ 1.6	**Are there documented workforce performance appraisals for the clinical trials workforce that include review of safety and quality responsibilities, feedback from staff on their performance?** Please provide evidence.	**16 OCT**
☐ 1.6	**Do clinical trial investigators actively supervise their clinical trial team?** Please provide evidence. (e.g. minutes from regular meetings with investigators and the clinical trial workforce, safety and quality are standing items on the agenda – both from training and monitoring perspective)	**16 OCT**
☐ 1.4	**Have strategies been implemented to meet the needs of Aboriginal and Torres Strait Islander people to access and/or participate in a clinical trial? Are ATSI liaison officers engaged in the process? Are there performance indicators for ATSI enrolment?** Please provide evidence.	**16 OCT**
☐ 1.9	**Does monitoring of clinical trial service delivery take place? Is clinical trial performance data collected and disseminated within the department? How often is this data collected and presented?** Please provide evidence.	**16 OCT**
☐ 1.8	**How are reports on clinical trial service provision and results disseminated? How often are these reports generated?** Please provide evidence.	**16 OCT**
Trial Participants Feedback / Engagement		
Related action/s	**Item**	**Due date**
☐ 1.8	**Are there mechanisms in place for monitoring trial participant and consumer satisfaction on the quality of clinical trial service provision within the department?** Please provide evidence.	**16 OCT**

SVHA NCTGF Pilot Assessment

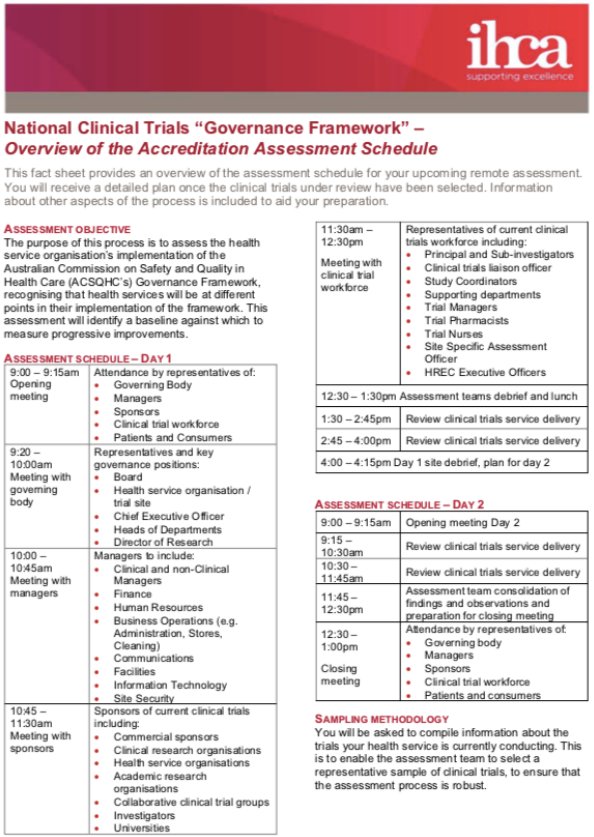
Assessment over 1.5 days

Combined sessions:

- Introduction
- Governing body – SVHA Board / Exec
- Managers – relevant operational staff
- Sponsors – pharma, biotech, univ, MRIs
- Clinical trial workforce

In-depth assessment of 3 selected trials at each site

- Via zoom with departmental staff
- Research Directorate staff also attended
- Some uploading of documents
- Some holding documents/files up to camera
- At SVHNS – walk around the facility



ihca supporting excellence

National Clinical Trials "Governance Framework" –
Overview of the Accreditation Assessment Schedule

This fact sheet provides an overview of the assessment schedule for your upcoming remote assessment. You will receive a detailed plan once the clinical trials under review have been selected. Information about other aspects of the process is included to aid your preparation.

ASSESSMENT OBJECTIVE

The purpose of this process is to assess the health service organisation's implementation of the Australian Commission on Safety and Quality in Health Care (ACSQHC's) Governance Framework, recognising that health services will be at different points in their implementation of the framework. This assessment will identify a baseline against which to measure progressive improvements.

ASSESSMENT SCHEDULE – DAY 1

9:00 – 9:15am Opening meeting	Attendance by representatives of: • Governing Body • Managers • Sponsors • Clinical trial workforce • Patients and Consumers
9:20 – 10:00am Meeting with governing body	Representatives and key governance positions: • Board • Health service organisation / trial site • Chief Executive Officer • Heads of Departments • Director of Research
10:00 – 10:45am Meeting with managers	Managers to include: • Clinical and non-Clinical Managers • Finance • Human Resources • Business Operations (e.g. Administration, Stores, Cleaning) • Communications • Facilities • Information Technology • Site Security
10:45 – 11:30am Meeting with sponsors	Sponsors of current clinical trials including: • Commercial sponsors • Clinical research organisations • Health service organisations • Academic research organisations • Collaborative clinical trial groups • Investigators • Universities
11:30am – 12:30pm Meeting with clinical trial workforce	Representatives of current clinical trials workforce including: • Principal and Sub-investigators • Clinical trials liaison officer • Study Coordinators • Supporting departments • Trial Managers • Trial Pharmacists • Trial Nurses • Site Specific Assessment Officer • HREC Executive Officers
12:30 – 1:30pm	Assessment teams debrief and lunch
1:30 – 2:45pm	Review clinical trials service delivery
2:45 – 4:00pm	Review clinical trials service delivery
4:00 – 4:15pm	Day 1 site debrief, plan for day 2

ASSESSMENT SCHEDULE – DAY 2

9:00 – 9:15am	Opening meeting Day 2
9:15 – 10:30am	Review clinical trials service delivery
10:30 – 11:45am	Review clinical trials service delivery
11:45 – 12:30pm	Assessment team consolidation of findings and observations and preparation for closing meeting
12:30 – 1:00pm Closing meeting	Attendance by representatives of: • Governing body • Managers • Sponsors • Clinical trial workforce • Patients and consumers

SAMPLING METHODOLOGY

You will be asked to compile information about the trials your health service is currently conducting. This is to enable the assessment team to select a representative sample of clinical trials, to ensure that the assessment process is robust.

Clinical Governance Standard

ST VINCENT'S HOSPITAL MELBOURNE

Clinical Governance Standard

Leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their clinical trial services, and ensuring that they are patient centred, safe and effective.

Intention of this standard for clinical trial services

To implement governance for clinical trial services that ensure patients and consumers receive safe and high-quality clinical trial services.

Criteria

- Governance, leadership and culture
- Patient safety and quality systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care.

Key resources

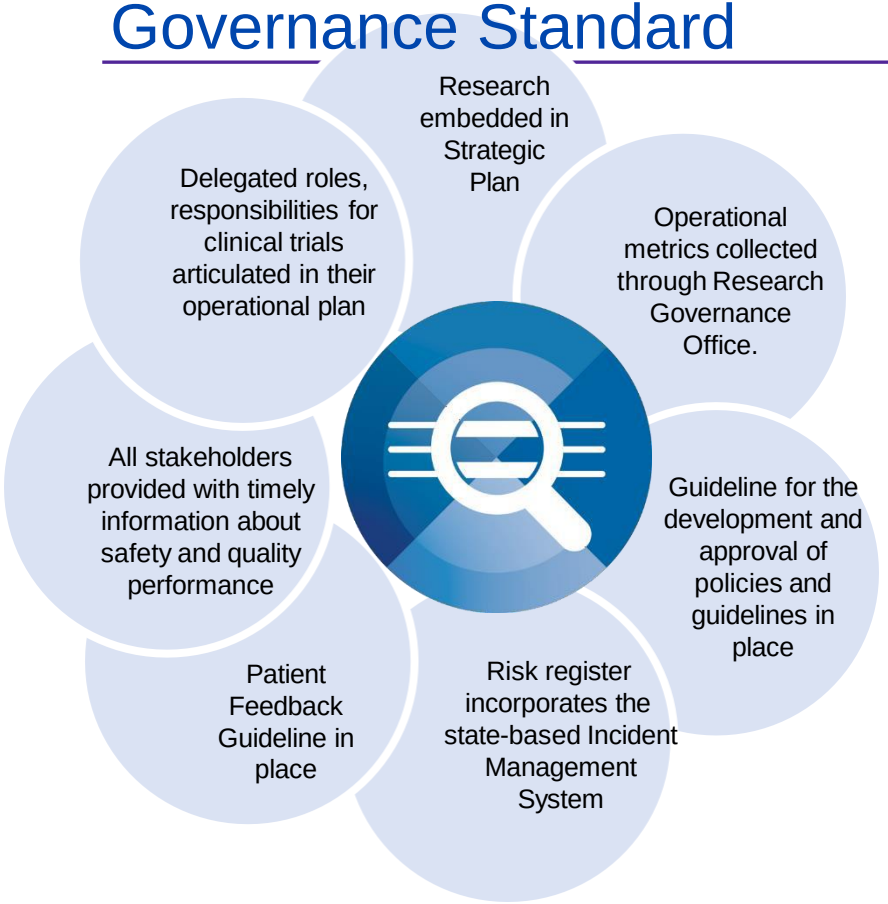
- *National Model Clinical Governance Framework*
- *NSQHS Standards Guide for Governing Bodies*
- *NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health*
- *Australian Open Disclosure Framework.*

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 organisation
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 health service organisation's progress on safety and quality performance.

Example of Strategies to implement Clinical Governance Standard



- Governance, leadership and culture
- Patient safety and quality systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care

Partnering with Consumers Standard

Partnering with Consumers Standard

Leaders of a health service organisation develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement and evaluation of care. The workforce uses these systems to partner with consumers.

Intention of this standard for clinical trial services

To create an organisation in which there are mutually beneficial outcomes by having:

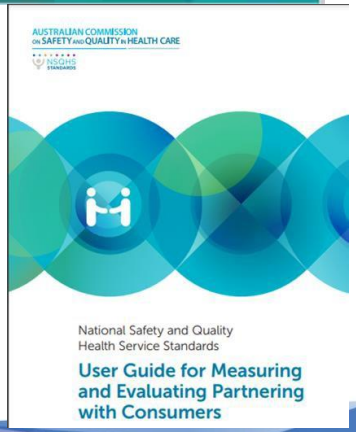
- Consumers as partners in planning, design, delivery, measurement and evaluation of systems to deliver clinical trial services
- Trial participants and patients as partners in their own care, to the extent that they choose.

Criteria

- Clinical governance and quality improvement systems to support partnering with consumers
- Partnering with patients in their own care
- Health literacy
- Partnering with consumers in organisational design and governance.

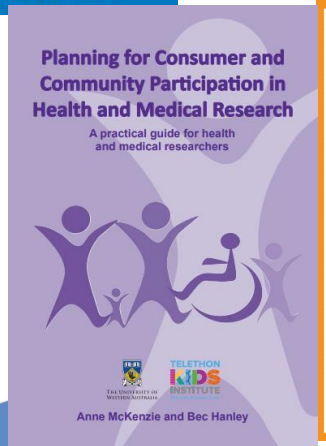
Partnering with Consumers resources

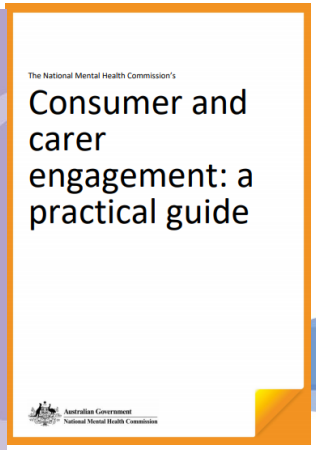
- Partnering with consumers in the NSQHS Standards
- Australian Charter of Healthcare Rights
- Decision support tools for patients
- Top Tips for Safe Health Care
- Health Literacy
- Review of attributes of high-performing person-centred organisations
- Person-centred care
- Measuring partnerships with consumers
- Informed consent



Partnering with Consumers resources

- NHMRC - Toolkit for Consumer and Community Involvement in Health and Medical Research
- VCCC - Consumer Involvement and Engagement Toolkit
- Cancer Australia – Consumer involvement toolkit
- National Mental Health Commission - Consumer and Carer Engagement: a Practical Guide
- NHMRC National Institute for Dementia Research - Becoming involved in research – A guide for people living with dementia, their care partners and family members
- AHHA - Experience Based Co-Design Toolkit
- Monash Partners – Consumer and Community Involvement
- Telethon Kids Institute – Planning for Consumer and Community Participation in Health and Medical Research





Examples of strategies used to implement the Partnering with Consumers Standard

Community Advisory Committee in place

Consumer register of 100 consumers

Patients centred strategy and plan developed

KPIs developed to monitor consumer involvement

Guidelines to support effective partnership with consumers established

Patient Information Working Group established to improve communication with consumers

Catalogue of patient stories

Examples of strategies used to implement Aboriginal and Torres Strait Islander peoples specific actions

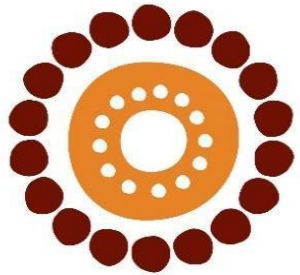
Reconciliation Action Plan in place

Patient experience KPIs for Aboriginal and Torres Strait Islander people

Aboriginal health policies and guidelines in place

Aboriginal Health Advisory Group established

Aboriginal and Torres Strait Island specific network established to enable collaborative activities to strengthen indigenous research capacity



SUMMARY

- **Planning and be Prepared**
- **People (Research, Quality & Risk)**
- **Policy / SOP**
- **Process**
- **Patients / Trial Participants**
- **Principal Investigators**

THE NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK AND THE CLINICAL TRIALS REFORM AGENDA

– ENABLING AN EFFICIENT AND EFFECTIVE OPERATING ENVIRONMENT

Dr Bernadette Aliprandi-Costa
Clinical Trials Policy Section
Australian Government Department of Health and Aged Care

HOW FAR WE HAVE COME…

2009 - Clinical Trials Action Group – Co-chaired by the (now) Minister for Health and Aged Care, the Hon Mark Butler and the Hon Richard Marles

2014 - Clinical Trials Jurisdictional Working Group

2017 - Revitalised Clinical Trials Agenda

2016 - Clinical Trials Project Reference Group

2017- Encouraging More Clinical Trials in Australia Agreement

2018 - National Clinical Trials Governance Framework

2019 - National Clinical Trials and Tele-trial Compendium

2021 - Development of an Accreditation Scheme for National Mutual Acceptance (NMA) Human Research Ethics Committees

Expansion of the National Mutual Acceptance scheme
Ethical and Scientific Review of Multi-Centre Research

2021 - Consultations on the National One Stop Shop for Clinical Trials and Health-Related Human Research.

2023 - Establishment of the Inter-Governmental Policy Reform Group to drive the national reform agenda and the National One Stop Shop

INTER-GOVERNMENTAL POLICY REFORM GROUP (IGPRG)

- Chair, Professor Ian Chubb AC FAA FTSE

- Cross-jurisdictional collaboration with key Commonwealth agencies to to drive the national clinical trial and health related research reform agenda and strengthen the clinical trial and health research operating environment to position Australia as a global leader

- The reform agenda seeks to build Australia's sovereign capacity across the research pipeline and place clinical trials and health research at the forefront of a sector-wide research investment and innovation drive.

NATIONAL INITIATIVES

EMBEDDING RESEARCH INTO ROUTINE HEALTH CARE

Nationally consistent accreditation under the AHSSQA Scheme

National Clinical Trials Governance Framework

HARMONISING SYSTEMS AND PROCESSES

National One Stop Shop

National SSA

Public facing website

IMPROVING SAFETY, QUALITY AND EFFICIENCY

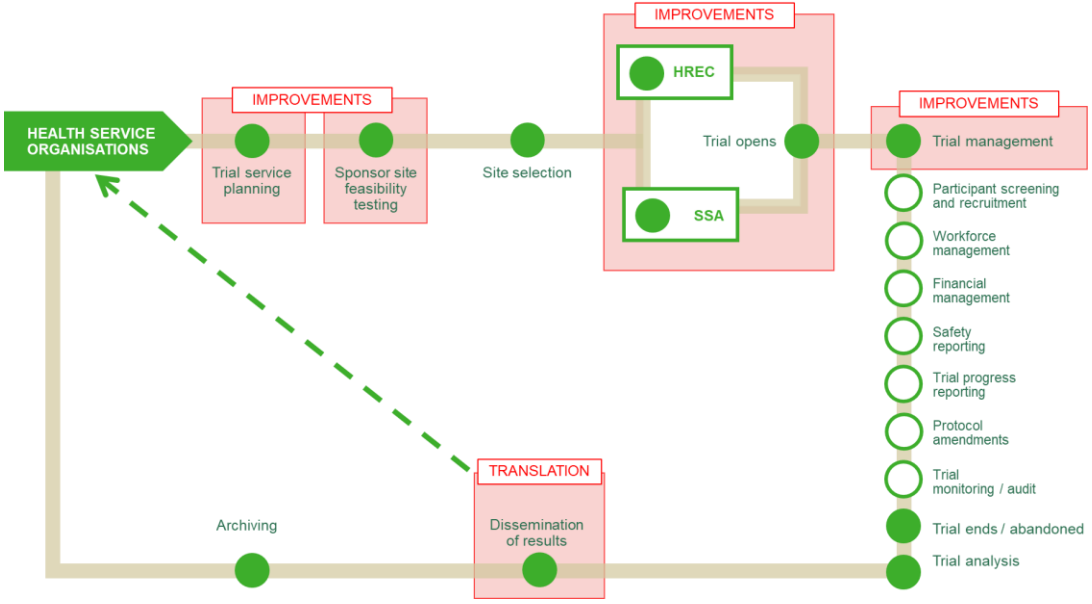
Quality standard and accreditation of HRECs under the National Mutual Acceptance Scheme

DEVELOPING STANDARDS AND GUIDELINES

National Clinical Trials and Tele-trials compendium

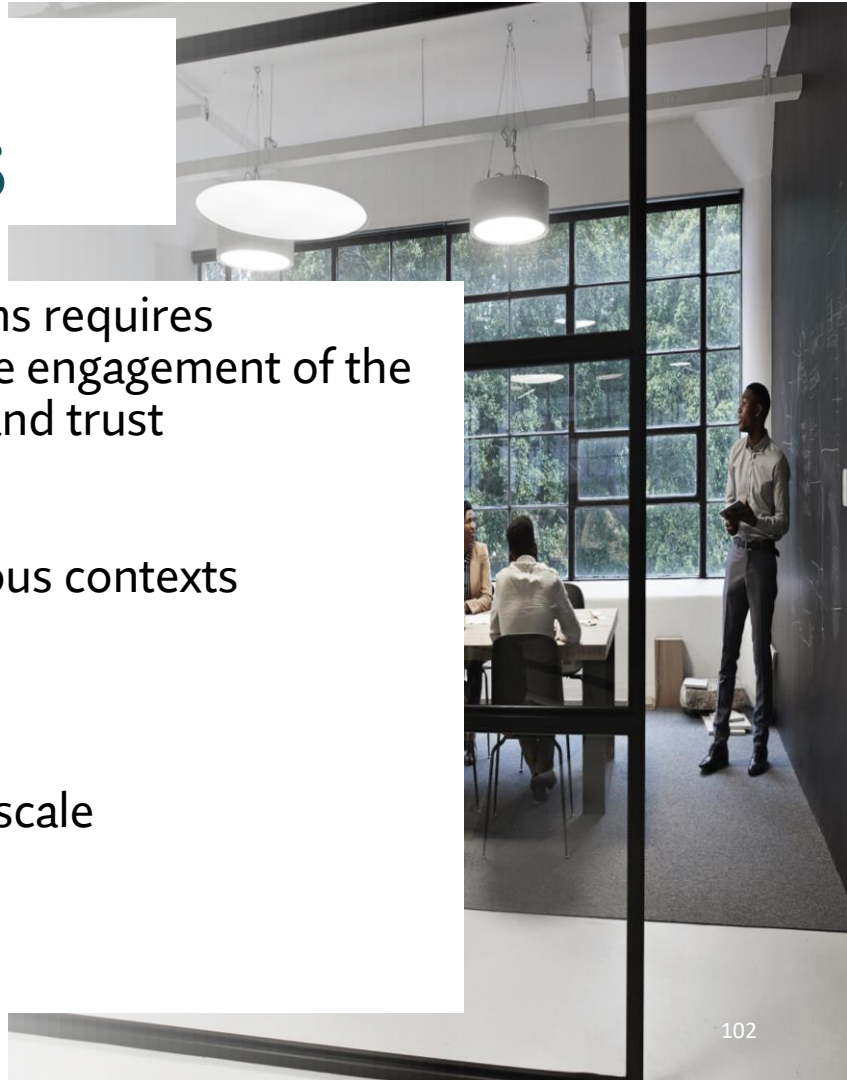
NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK

Nationally consistent accreditation of health services for clinical trial service provision.



KEY ROLES FOR INDIVIDUALS

- Embedding clinical trials into governance systems requires collaboration across the health service – genuine engagement of the executive; regular reporting; clinical leadership and trust
- Roles and responsibilities for individuals
- Conducting a self-assessment – services in various contexts
- Contracts with accrediting agencies
- Costs associated with implementation
- Flexibility in the assessment process – maturity scale
- Independence of the assessment process
- Confidence in the assessment process



THANK YOU

Visit:

https://www.australianclinicaltrials.gov.au/

Contact the team at:

ClinicalTrialsPolicy@health.gov.au

NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK

Nationally consistent accreditation of health services for clinical trial service provision.

- Strengthens governance arrangements for clinical trial services under the Australian Health Service Safety and Quality Assessment Scheme
- Ensures clinical trial services are embedded in health service clinical governance systems and are considered core health service business
- Ensures clinical trials governance is a fundamental part of the health services governing body's responsibilities and accountabilities
- Aligns with the Good Clinical Practice Site Inspection Program of the TGA.