

HEALTH+MEDICAL  
RESEARCH

# *Moving early phase trials forward in NSW*

 *clinicaltrialsNSW*



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# Contents

1. OHMR and clinicaltrialsNSW

2. NSW clinical trial sector

3. clinicaltrialsNSW initiatives

Focus on:

- Statewide Clinical Trials Management System (CTMS)
- Early Phase Clinical Trial Quality Recognition Scheme
- Clinical Trial Workforce Analysis

# OHMR and ctNSW

The Office for Health and Medical Research (OHMR) was established to implement the NSW Government's strategic plan to build research capability in NSW.

Key areas include

- Grants & Funding
- Ethics & Governance
- Translation & Commercialisation
- Advanced Therapeutics
- Clinical Trials - *clinicaltrialsNSW*

<https://www.medicalresearch.nsw.gov.au/>

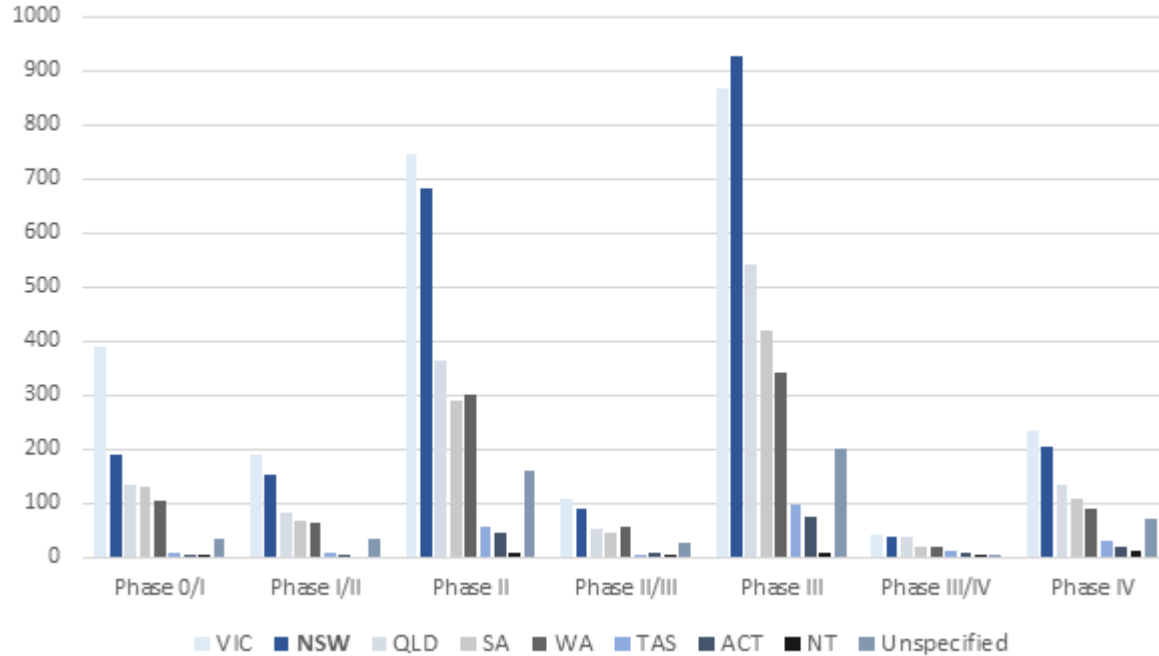
## ***clinicaltrialsNSW***

Remit to enable clinical trial capacity, capability and collaboration across New South Wales

- Foundation
- Quality
- Workforce
- Access
- Responsive



## Pharma Trials by Phase and State, 2015 - 2018



**2425** new trials commenced 2015-2018

**95%** of NSW clinical trials are in pharma and biotech



**20%** of all PhI and I/II trials in Australia are conducted in NSW



**30%** of Australian pre-clinical & discovery research activity in NSW



**45%** of trials in NSW are early phase PhI and PhII trials (early development and proof of concept trials)



**17.7%** increase in NSW Ph0/I trials since 2016

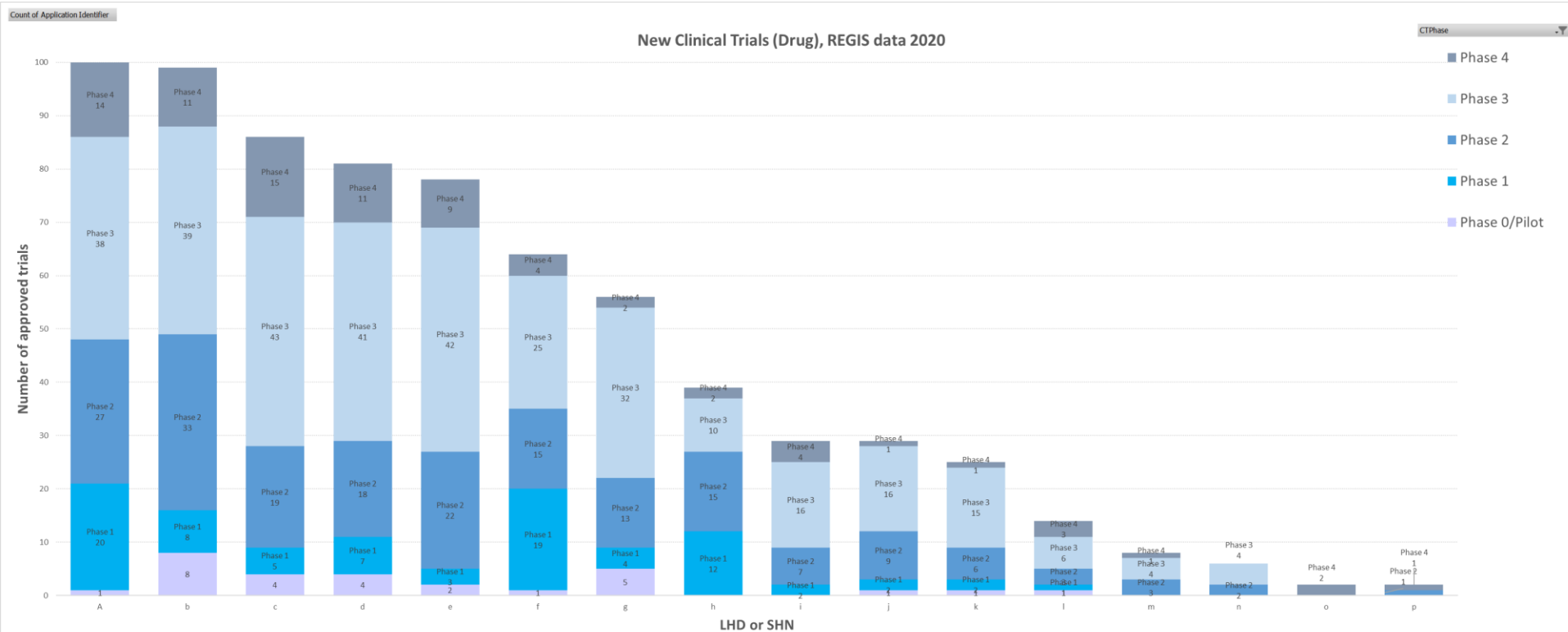


**41%** of trials in NSW are Ph III (registration-enabling trials)

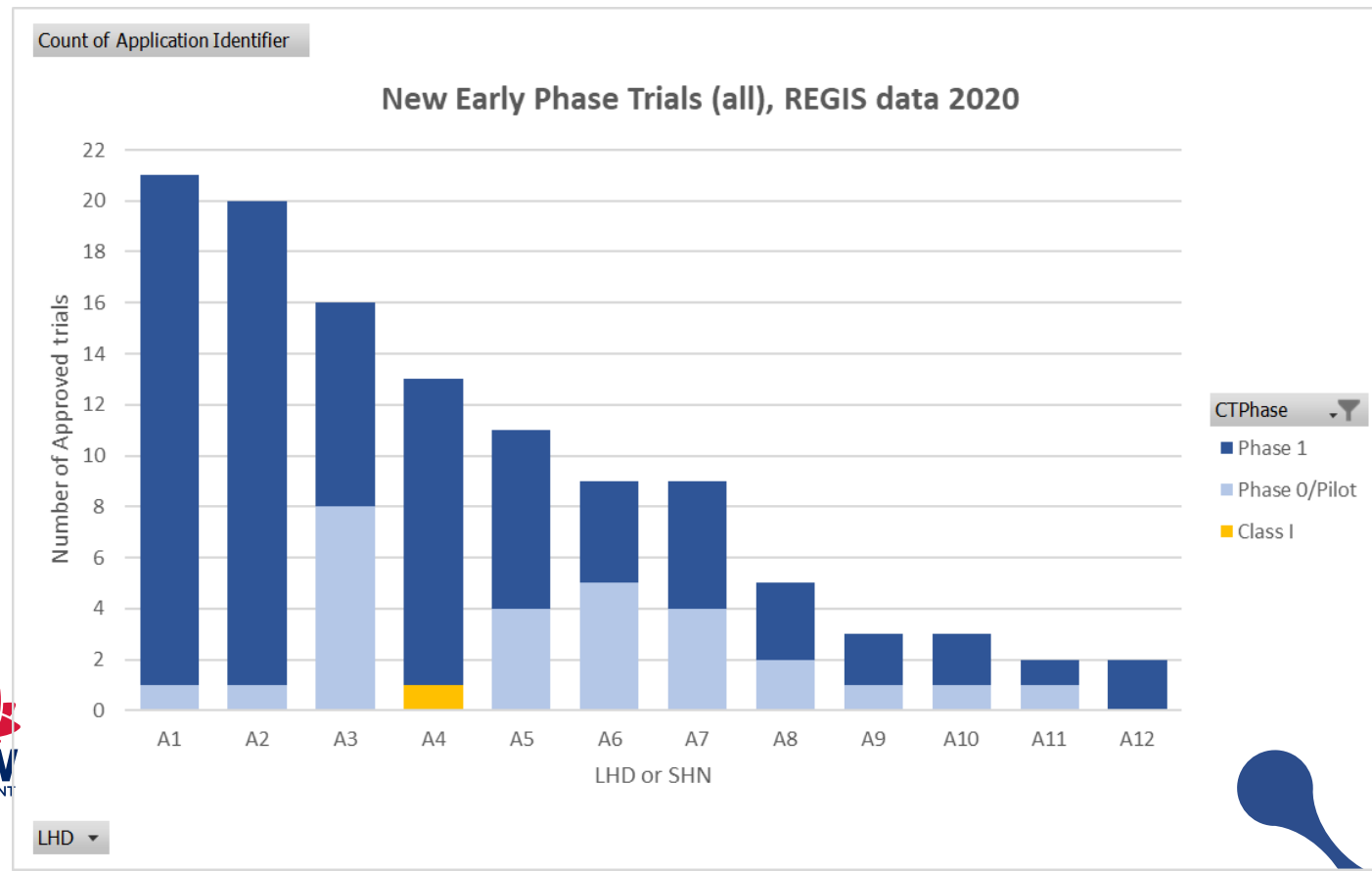


Global Data. 2019. A comparative analysis between NSW clinical trial performance and rest of Australia.

# Clinical Trials in NSW



# Clinical Trials in NSW



# clinicaltrialsNSW

*Established 2018 to enable clinical trial capacity, capability and collaboration across NSW*



Establish an entry point for MTP clinical trials in NSW



Maintain policy directives, drawing on national and international best practice



Drive transformational change and improvements across the sector



Monitor and evaluate outcomes of clinical trials initiatives

# clinicaltrialsNSW Concierge

Core programs – supporting clinical trials across NSW LHDs and MRIs

## Clinical Trial Connect

Connecting your trial to the right site and service

[Get started >](#)



364 connections to

- Investigators & sites
- CROs
- NSW Health services eg: Biobank

## Clinical Trial Triage

A solution service for researchers, sponsors and administrators

[Learn more >](#)



221 requests for assistance with

- Ethics & governance
- Regulatory
- Finance

## Clinical Trial Toolkit

The essential tools to conduct your clinical trial

[View the toolkit >](#)



Standards Operating Procedures

GCP & ISO Guidance

Protocol and trial document templates

Contracts, finance & IP templates



# Clinical Trial Toolkit

## Supporting clinical trials at site

### Standard Operating Procedures for sites

- Clinical Trial Training and Qualification
- Hosting an Audit or Regulatory Inspection
- Sub-Contracting of External Vendors
- Trial Feasibility & Start-Up
- Delegation of Duties by the Principal Investigator
- Informed Consent
- Managing and Reporting Safety Events
- Reporting Non-Compliance and Suspected Breaches of GCP or the Protocol
- Investigational Medicinal Product Management and Emergency Unblinding
- Source Data and Case Report Form Completion
- Handling and Transporting Biological Specimens
- Investigator Site File & Essential Documents
- Close-Out at a Trial Site
- Clinical Trial Archiving
- Work Instruction Site Templates

### Teletrials Standard Operating Procedures



# Clinical Trial Toolkit

## Supporting clinical trials at site

### GCP guidance

- GCP E6 (R2) and ISO14155
- National Statement on Ethical Conduct in Human Research 2007 (updated 2018)
- TGA CTN/CTX guidelines
- Australian Clinical Trials Handbook
- NHMRC Safety Monitoring and Reporting in Clinical Trials
- NHMRC Guidance of Reporting Serious Breaches

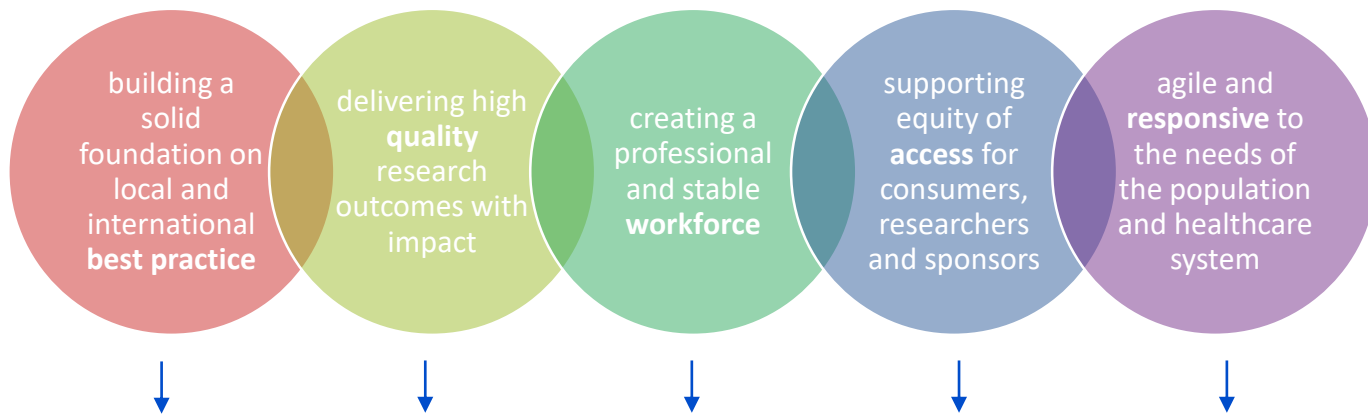
### Templates and guidance

- Protocol
- Investigator Brochure
- CONSORT, SPIRIT & GRACE statements
- International Committee of Medical Journal Editors Policy on Trial Registration guidelines
- National Participant Information and Consent Form (PICF) and Participant ID card template

### Finance, Contracts and Intellectual Property guidance

- NSW Health Clinical Trial Budget Costing Tool
- NSW Health Pathology Pricing Tool
- Clinical Trial Research Agreements
- Indemnity and compensation guidelines
- Insurance guidelines
- IP Australia non-disclosure agreement

## *transforming clinical trials in NSW*



mature, interconnected clinical trials sector  
embedding research into health service delivery  
providing equity of access to innovative healthcare

# clinicaltrialsNSW



building a solid  
foundation on  
local and  
international  
best practice

Clinical Trial Management System

Trial Funding and Site Financing

# Current State

## Clinical trials in NSW PHOs attract an annual revenue of ~\$50M - \$70M and employ 700+ staff

- Depending on hospital size, clinical trials are managed by dedicated trial units, individual therapeutic departments or clinicians.
- Managing a trial is complex – feasibility, risk assessment, budget negotiation & invoicing, patient management, interdepartmental relations, and milestone tracking for trial and patients over several years.
- Enormous variability in trial management. Site staff create their own excel trackers, hard copy files, databases, post-it notes and calendars.
- Due to current management there is limited oversight of clinical trials activity, it is challenging to identify number of trials open, or number of patients enrolled.
- As a result there is significant revenue leakage from clinical trials, estimated at 10-30% depending on the site.

**Estimated \$5 - 15M lost annually across NSW PHOs**



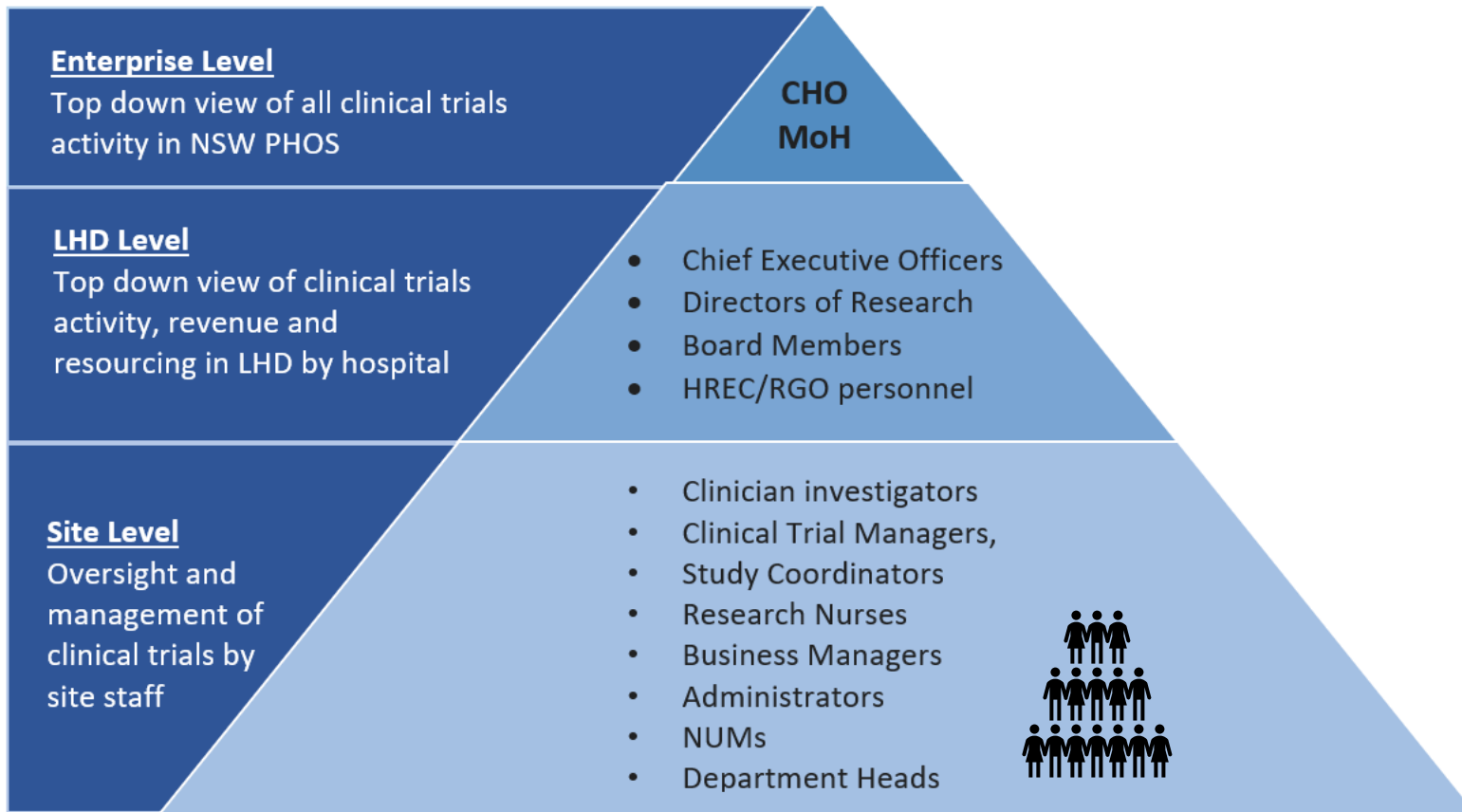
<sup>1</sup> Staff figure from 2020 Clinical Trial Workforce Analysis and revenue estimate based on confidential discussion with sponsors and sites

# What is a CTMS?

**A Clinical Trial Management System (CTMS) is a specialised, commercially available software system**

- Provides a shared online repository for clinical trials management which can organise & store all of NSW Health's clinical trial operational data in one location.
- Replaces electronic and hard copy user-created documents and files for clinical trial management with a single system
- A CTMS fulfils different functions at the:
  1. **Site level:** *Clinical trial unit and/or therapeutic department*
  2. **LHD level:** *Chief Executive, Research Director, Senior Exec*
  3. **Enterprise level:** *Ministry of Health, NSW Govt*

# NSW Health Statewide CTMS - Users



# Why Implement a CTMS?

## NSW Health strategic plan to be a global leader in clinical trials

- Current clinical trial processes & systems are manual, paper-based and non-standardised
- Facilitate ACSQHC Clinical Trial Governance Framework Accreditation
- Improve revenue capture and financial oversight
- CTMS use identified globally as best practice
- Risk mitigation and quality management for early phase clinical trials
- Dashboard and automated reporting on NSW clinical trials
- Central online repository enabling remote working and collaboration
- Increase NSW's appeal to international trial sponsors



# Benefits of a CTMS for Investigators

- Central, online electronic document management and remote access capability
- Oversight of participant visit and enrolment status
- Audit trail and document revision history compliant with FDA 21 CFR Part 11
- Template study designs available – easier to build IIS studies into system
- Low or no cost remote monitoring
- Study data and document archiving
- e-consenting options



# Benefits of a CTMS for other depts.

## **Trial Pharmacists**

- Central repository of all clinical trial participants
- Option for IP management within system
- Invoicing system – automate billing when IP dispensed

## **Business/Finance Managers**

- Oversight of trials activity, revenue, costs, staff
- Invoicing system

## **HREC/RGO**

- Oversight of clinical trials activity within LHD
- Option for automatic notification on first participant enrolment
- Potential to obtain reports and metrics not currently addressed by REGIS

# How will a CTMS change staff workflows?

**A CTMS provides a central online platform to manage clinical trials**

## **Current Clinical Trial Workflow**

1. Participant attends clinic visit– [scheduled via eMR](#)
2. Refer to protocol to see what needs to be done at that visit – [check off manually \(if at all\)](#)
3. After participant visit, staff enter data in eCRF or trial database
4. Invoicing is either automatic by the sponsor based on data entered/verified or by the site based on visit/evaluations completed – [Sites currently using ad hoc tracking via Excel, MS Access](#)

## **Clinical Trial Workflow with CTMS**

1. Participant attends clinic visit– [scheduled via CTMS](#), [automatic reminders sent via SMS or email](#)
2. CTMS identifies required evaluations/scans and can be checked off within system
3. After participant visit, staff enter data in eCRF or trial database
4. Invoicing is automatic based on the checked off evaluations/scans – [print off or save invoice as pdf](#)

# How will a CTMS change billing?

## Initially CTMS will be a standalone piece of software –integration with Oracle is a later phase

- CTMS will generate summary invoices by participant or study as requested
- Can print off or save as pdf – upload into eDocs repository if required
- Enter invoice into Oracle as per current processes

## Benefit of CTMS

- Automatic calculation of invoice based on agreed items in CTRA
- Reduces user error and miscalculation – *e.g. GST, uncheduled visits, invoicing for full value of evaluations, etc.*
- Tracking of completed invoices in central online repository
- Clearer oversight of costs and revenue associated with each trial and across the clinical trial site

## Issues

- Cannot resolve existing challenges with Oracle system – lack of transparency when invoices paid
- Invoicing is still reliant on CTMS users to check off visits and evaluations performed

# How will a CTMS impact patient care?

**From the patient/participant viewpoint the implementation of a CTMS may not be noticeable**

- Automated reminders for visit scheduling
- Option for eConsent and online access to Participant Information Sheet and Consent Form (PISCF)
- May increase protocol adherence through checklist of evaluations

**What about data protection and privacy?**

- CTMS to be locally hosted via eHealth Azure cloud for data protection and privacy
- User restricted access to data – use of stafflink ID for login
- eHealth penetration and security testing at highest level - equivalent of eMR

# Risks and Mitigation

## Risks

- **Poor user acceptance and use of system**
  - Increased burden on clinical trial staff to build studies into system
  - Cultural change from current user-based trial management to central online software
  - Technology challenges
  - Clinician and site concerns around oversight
- **Risk of another standalone ICT software**
  - Duplication of work
  - Multiple passwords/logins to manage across software
- **System not financially viable**
  - Cost of CTMS not covered by trial revenue
  - No increase in trial revenue capture

## Mitigation

- **Focus on Change Management and Stakeholder engagement**
  - Start early, promote benefits of CTMS
  - Each LHD to have access to local support staff over first 3 years of CTMS use
  - Webinars, training videos and on-site sessions
- **CTMS must have integration capability**
  - First integration with Stafflink/Active Directory
  - Subsequent integrations with EMR, Oracle and REGIS as able
- **CTMS very likely to result in financial benefits**
  - Clarity of trials revenue and expenditure
  - Increase in overall portfolio
  - Ability to forecast and strategically manage portfolio

# Implementation Timeline

2021											
Q1			Q2			Q3			Q4		
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Procurement Process - RFP											
				Contract Negotiation & Agreement							
				CTMS Project Office Creation							
				eHealth pen/sec test							
				Pilot implementation at 2 LHDs							
				Change Management - education, training and promotion for sector							
				Integration with Active Directory (Stafflink)							
2022											
Q1			Q2			Q3			Q4		
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Change Management - education, training and promotion for sector											
Implementation at 3 LHDs											
			Implementation at 3 LHDs								
						Implementation at 3 LHDs					
									Implementation at 3 LHDs		
2023											
Q1			Q2			Q3			Q4		
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Integration with existing systems e.g. eMR, Oracle, and/or REGIS											
Timeline and budget pending vendor selection and pilot implementation											

# clinicaltrialsNSW



delivering high  
quality  
research  
outcomes with  
impact

ACSQHC Clinical Trials Governance Framework

NSW Early Phase Clinical Trials Framework



# ACSQHC Clinical Trials Governance Framework

Australian Commission on Safety and Quality in Healthcare has introduced a clinical trials component to the National Safety and Quality Health Service (NSQHS) Standards accreditation for institutions

The National Clinical Trials Governance Framework is aligned with the NSQHS Standards, in particular, the Clinical Governance Standard and the Partnering with Consumers Standard.

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

# ACSQHC Clinical Trials Governance Framework

In 2020, clinicaltrialsNSW set up a working group with LHD/SHNs to share their experience with the pilot accreditation process and collaborate on developing processes to better support NSW PHOs to meet accreditation requirements

In collaboration with clinicaltrialsNSW, the aim of the working group is to:

- Support NSW Health LHDs in preparing for the implementation of the Governance Framework
- Facilitate engagement with NSW LHDs about the implementation of the Governance Framework
- Facilitate sharing of information and processes within NSW LHDs for the implementation of the Governance Framework
- Identify processes which OHMR can drive

# NSW Health EPCT

**OHMR developed the Early Phase Clinical Trials Framework to support early phase clinical trials across NSW. Extensive stakeholder consultation was conducted between May 2016- Feb 2017.**

**Vision:** NSW is a centre of excellence that provides a high quality and efficient environment to conduct early phase clinical trials with the ultimate aim of improving health outcomes for NSW residents.

The Framework is one component of a broader suite of initiatives to build capacity to make NSW a centre of excellence for all phases of clinical trials

The Framework comprises of two key elements:

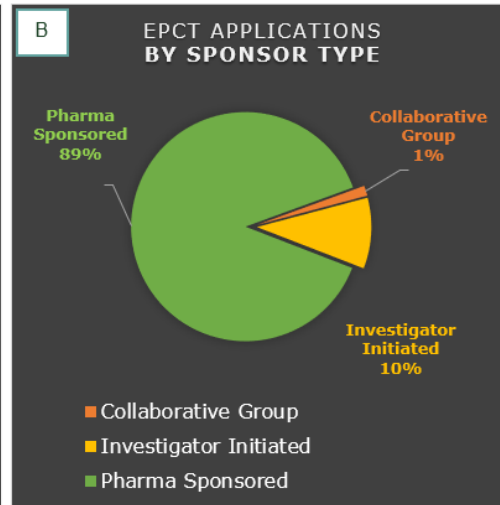
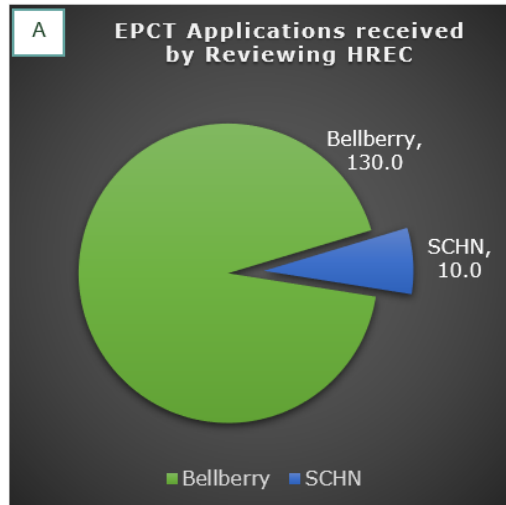
1. NSW Health Early Phase Clinical Trials Human Research Ethics Committee to provide rapid and high-quality approval process to commence early phase trials.
2. Quality Recognition Scheme to ensure high quality operational conduct of early phase trials.

# EPCT HREC

- The Early Phase Clinical Trials (EPCT) Human Research Ethics Committees (HRECs) Scheme was established to further support NSW's consistent, high quality scientific and ethics review and approval process for early phase clinical trials in NSW, while supporting the welfare and safety of trial participants.
- Began 29 April 2019, following the appointment of Bellberry Limited and Sydney Children's Hospitals Network (SCHN) in November 2018.
- All early phase clinical trials HREC applications must be submitted to one of the two NSW Health Early Phase Clinical Trial HRECs for review and approval before it can be accepted by an NSW Public Health Organisation (PHO) site, unless under current arrangements of the scheme involving paediatrics early phase clinical trials.
- NSW non-PHOs are also encouraged to use NSW Health Early Phase Clinical Trial HRECs for review and approval of early phase clinical trials.
  
- **In 2020, 100 applications received ethics approval with an average review time of 21.5 working days**
- **The average total review time (including both HREC and researcher time) for EPCT applications was recorded as 65 days.**

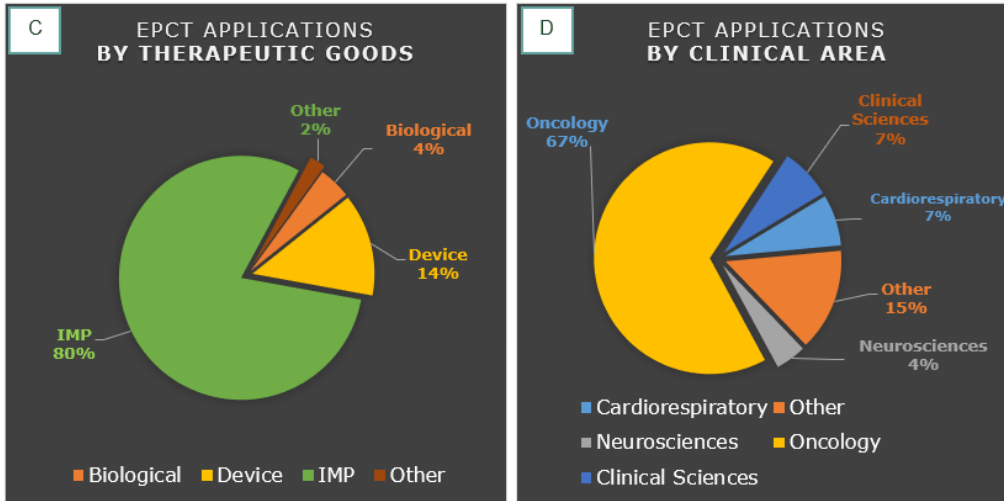
# EPCT HREC – 2020 Snapshot

- Majority of EPCT applications (93%) were for adult patients, and were reviewed by Bellberry.
- Only 7% of the applications were registered as first in paediatric and reviewed by SCHN
- The majority of the EPCT applications (89%) were sponsored by commercial entities (e.g. pharmaceutical companies or other industry bodies).
- The remaining 11% of applications received were sponsored by collaborative groups or investigators, however many were found ineligible by the reviewing HRECs and withdrawn reducing investigator-led study count to 3%



# EPCT HREC – 2020 Snapshot

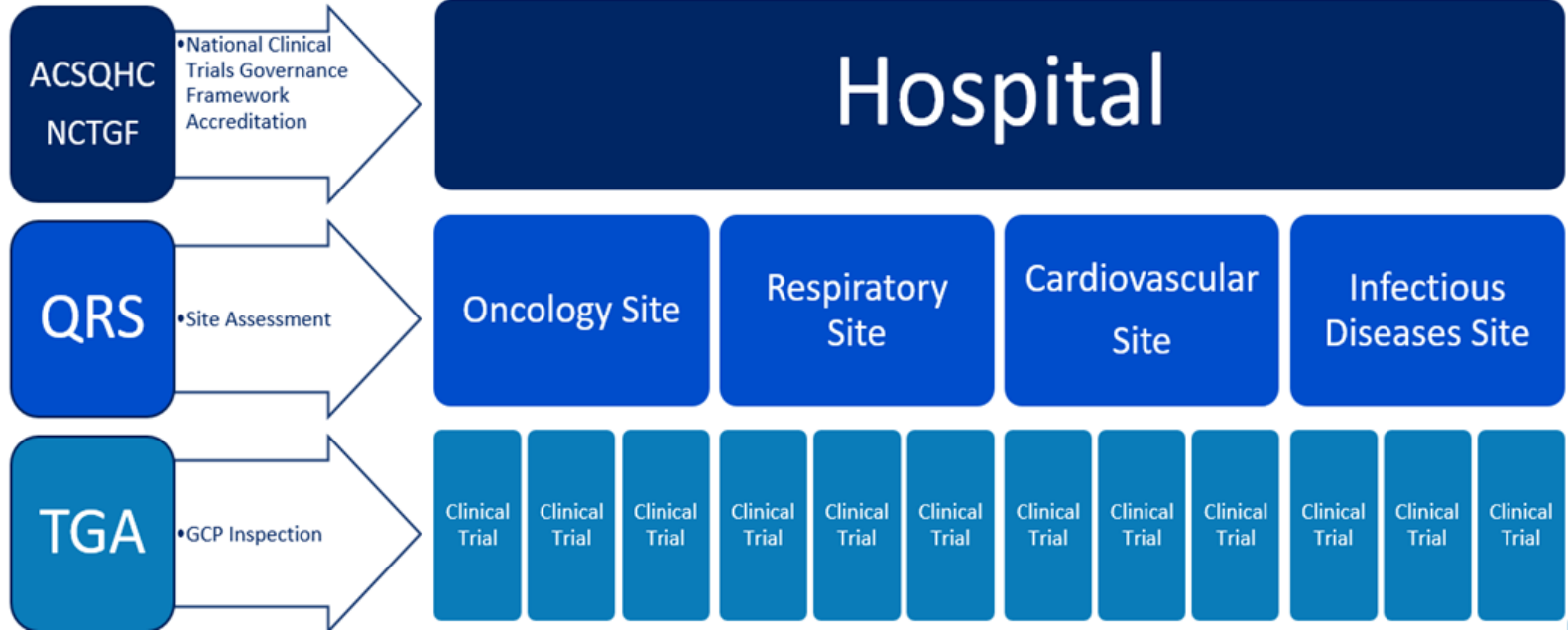
- Investigational medicinal products (IMPs) formed the most common type of therapeutic goods proposed to be used in EPCT applications followed by medical devices and biologicals.
- Oncology trials formed two thirds of the applications received.
- Most EPCT applications involve multiple sites. While more than 15 NSW-based sites were registered, 5 sites collectively accounted for 50% of the EPCT studies (Figure 3).



# EPCT Quality Recognition Scheme (QRS)

- Second part of the Early Phase Clinical Trials Framework
- Recognises sites which have the capability to conduct high quality early phase trials
- Value to the health sector:
  - ✓ Support decision making for Public Health Organisations: Confidence that a trial site meets a high standard of conduct.
  - ✓ Supports sites in meeting the ACSQHC Clinical Trial Governance Framework accreditation
  - ✓ Increase attractiveness of the site to sponsors

# EPCT QRS





# EPCT QRS

- Aligned with the ACSQHC National Clinical Trial Governance Framework and the TGA GCP inspection program
- Does not address the conduct of individual trials, but rather site operations, facilities, and staff skills and experience.
- Sites must demonstrate that they exceed basic regulatory GCP standards by having additional procedures that pertain to early phase trials.
- These must include the highest standards for avoiding harm to trial participants including their ability to handle medical emergencies. Sites should also maintain data quality, including adherence to trial protocol and should be skilled at assessing the appropriateness of the study design.

**The QRS aims to ensure that site conduct of trials is safe and of high quality and strengthen public confidence with early phase clinical trials in NSW.**

# Eligibility

- ✓ Site based in NSW
- ✓ Sites within public or private organisations with demonstrated experience in conducting early phase clinical trials
- ✓ Good Clinical Practice compliance: no unresolved critical or major findings from previous GCP audits or Regulatory inspections.
- ✓ Site has relevant SOPs and Policies that are current and active.

# QRS Process Summary



# QRS Standards

## Quality Recognition Scheme Standards

1. Adequate Medical and Clinical Governance Oversight at site level
2. Efficient and effective systems and processes to ensure quality
3. Risk Assessment and Management Procedures in place demonstrating that the site continuously verifies and assesses all aspects of the early phase clinical trials.
4. Appropriate research team experience and qualification for early phase clinical trials
5. Adequate infrastructure and resources to conduct clinical trials and appropriately respond to medical emergencies

# EPCT Quality Recognition Scheme (QRS)

## 1. Adequate Medical and Clinical Governance Oversight at site level

Clinical/Medical governance accountability at sites including clear lines of responsibilities for investigators and other medical staff

- Head of Site oversight and involvement in risk assessment and management of clinical trials
- Process for allocation of PI and sub-investigators to facilities/research teams especially for FTIH
- Mechanism for delegating responsibilities and tasks by PI to another appropriately qualified medical staff (for example sub-investigator) especially when the PI is not available onsite during dose escalation days.
- Process to assess visiting researchers and their suitability to act as PIs or sub-investigators (including mentoring processes)
- Staff delegated to perform risk assessment i.e. PI, qualified delegate or Medical Director of the site.

# EPCT Quality Recognition Scheme (QRS)

## 2. Efficient and effective systems and processes to ensure quality

- Core Standard Operating Procedures at the site, to ensure compliance with relevant processes and GCP requirements including additional early phase trial requirements and procedures for Trial Documentation Management.
- Oversight of SOP creation, implementation, internal monitoring and review of current processes in place to ensure SOPs are current and active at site.

# EPCT Quality Recognition Scheme (QRS)

## 3. Risk Assessment and Management Procedures

Early phase trial sites have always performed risk assessment and contingency planning both in the context of subject safety and resource management. However, this should be a formalized process which is clearly documented.

- An established Risk Management Plan or equivalent due diligence procedures in place for critical review of the relevant sources (protocol, IB, etc).
- There should be an evaluation and management plan of identified risks for a specific trial and a risk monitoring plan during the study

# EPCT Quality Recognition Scheme (QRS)

## 4. Appropriate research team experience and qualification for early phase trials

*Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s), (ICH GCP 2.8).*

- The QRS seeks to confirm site governance procedures ensure sufficient appropriately qualified staff for management of early phase clinical trials
- Evidence of an appropriately composed, managed and led study team with the relevant collective knowledge to meet specific study requirements.
- CVs are expected to be
  - current (within 2 years), personally signed and dated (electronic signature accepted).
  - evidence the staff member affiliated to the clinical trial site
  - include relevant qualifications and training (GCP, ALS, etc),
  - list clinical trial involvement.

<https://www.transceleratebiopharmainc.com/assets/site-qualification-and-training>



# EPCT Quality Recognition Scheme (QRS)

## 5. Adequate infrastructure and resources to conduct clinical trials and appropriately respond to medical emergencies

- To assess “adequate and appropriate” early phase facilities, the site is first asked to describe the facilities and equipment used in the management of early phase studies.
- For those in a hospital setting, there is likely multiple locations involved, whereas others may have a single self-contained suite.
- Based on the number of beds/chairs and the layout of the site, there must be sufficient emergency trolleys (or acceptable alternative) to ensure easy and rapid access.
- The emergency trolley contents should reflect the current PHO/LHD guidelines or applicable emergency service guidelines to ensure staff easily locate required items on the trolley.

# Challenges and Benefits of QRS

## Challenges

- Additional workload for site staff in collating documents and completing application
- Need to develop new SOPs, CVs and supplementary documents
- Time taken for interviews and site visit

## Benefits

- Aligns sites with best practice standards
- Assists in preparing for NCTGF accreditation
- 3yr certification and promotion through OHMR website
- Increase site appeal to sponsors

# Statewide Implementation

- The EPCT QRS suffered major delays due to COVID staff re-prioritization
- Application form transferred from pdf to online
- Improved clarity of guidance information provided to sites and ease of application completion
- **Due for Statewide roll out in mid-2021**
- Assessment and certification planned initially to be free of charge for NSW based sites

# clinicaltrialsNSW



creating a  
professional  
and stable  
workforce

Clinical Trials Workforce Analysis

clinicaltrialsNSW Community of Practice

GCP & ISO14155 Training

# NSW Health Clinical Trials Workforce Analysis

## Background

- Recruitment and retention reported as a longstanding issue within the Australian clinical trials sector – not yet formally evaluated
- OHMR received direct Ministerial request to conduct analysis of barriers to attraction and retention

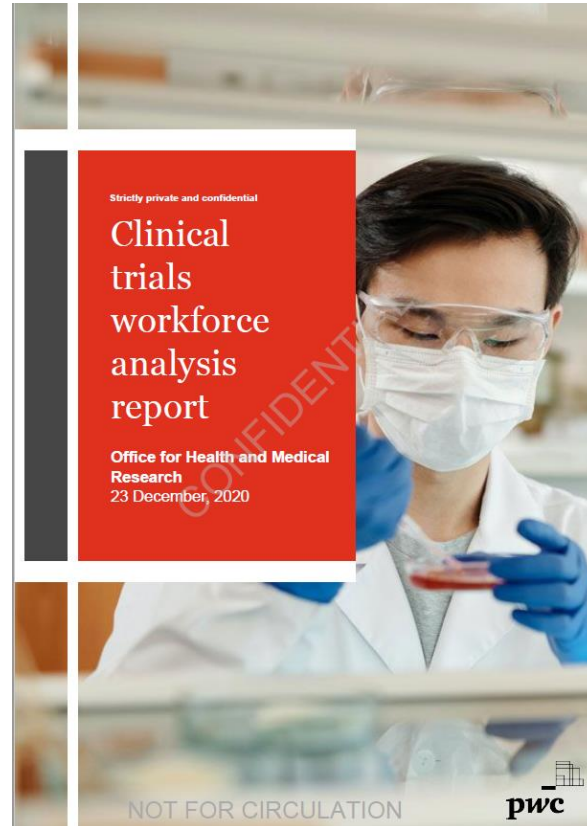
## Purpose of Analysis

1. Understand and analyse the current state of the clinical trials workforce
2. Define the desired state of the clinical trials workforce
3. Analysis of workforce gaps, opportunities and barriers

## Method of data capture

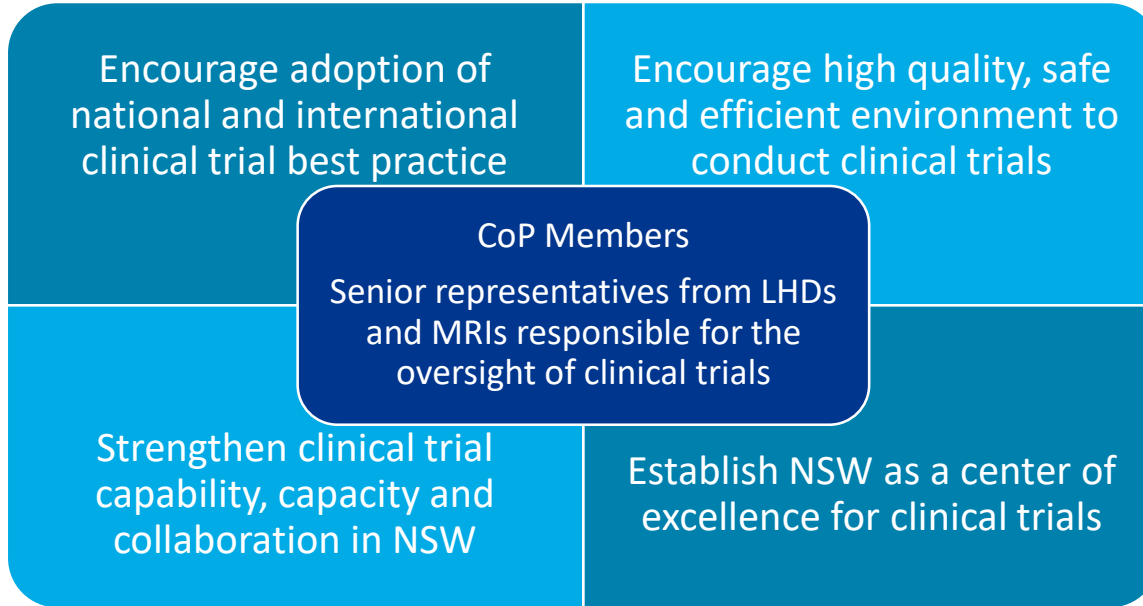
- ✓ **Data request:** Workforce datasets received from 12/18 LHDs and SHNs and 3 other organisations working within PHOs
- ✓ **1:1 Interviews :** 11 interviews conducted with Principal Investigators, Clinical Research Managers, Study Coordinators and Research Nurses from across NSW Health (metro and rural/remote)
- ✓ **Focus groups:** 9 focus groups with a total of 33 participants from NSW Health's clinical trial workforce (metro and rural/remote), as well as representatives from MoH, CINSW, AHTRCs, RDTF, and ACTA
- ✓ **Online survey:** ctNSW emailed 700+ contacts and received 562 survey responses

# NSW Health Clinical Trials Workforce Analysis



# clinicaltrialsNSW Community of Practice

Facilitating connection and information sharing across NSW LHDs and MRIs



# Education, Training and Professional Development

## Supporting the NSW clinical trials sector

- Free online GCP training to over 1000 registrants
- TransCelerate recognized training for staff employed by NSW Health or a NSW MRI
- Funded conference passes for 46 study coordinators and research nurses to attend ARCS and ACTA conferences
- Developing a clinical trials training program for 2021





# clinicaltrialsNSW



supporting  
equity of  
access for  
consumers,  
researchers  
and sponsors

RRR Clinical Trial Enabling Program \$30M

eConsent

Consumer Involvement & Engagement

# MRFF RRRCTEI Grant

Rural, Regional & Remote Clinical Trial Enabling Infrastructure

**NSW Health \$30.6M**

*'Improving access to innovative healthcare in rural, regional and remote NSW and ACT'*

NSW/ACT RRR Clinical Trial Program outcomes:

- Promote **equity of access** to novel therapies through clinical trials **relevant to the needs** of patients in our rural, regional and remote communities
- Deliver more **trials** with increased **patient recruitment** and **clinician participation**
- Improve the **speed and coordination** of clinical trials and maintain high **quality** trial conduct
- Develop a local, clinical trial capable **workforce**
- Ensure **sustainability** of a rural, regional and remote clinical trials network.



Medical Research  
Future Fund

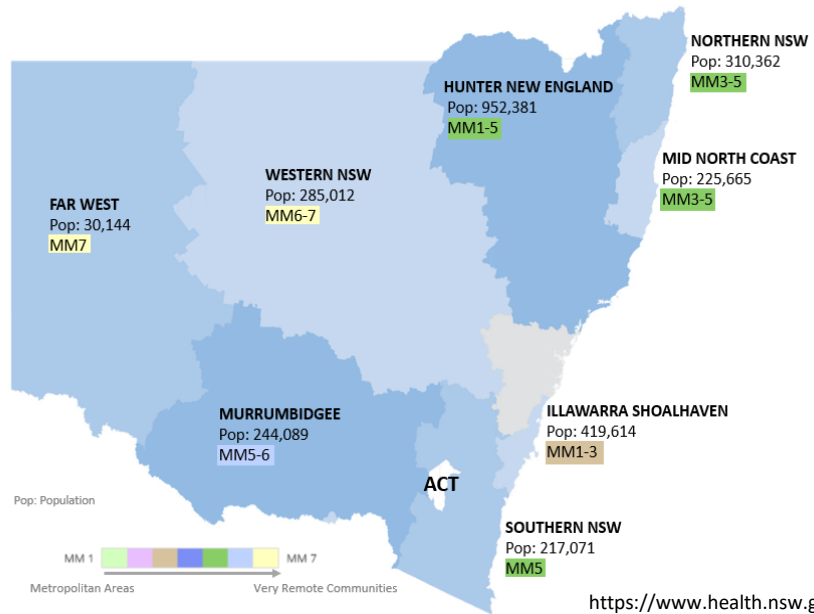


Medical Research Future Fund -  
National Critical Infrastructure Initiative

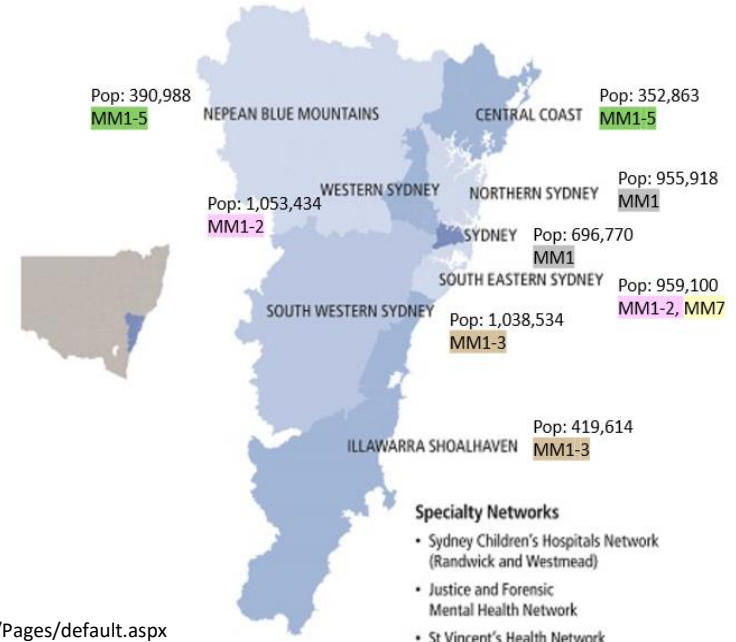
2019 Rural, Regional and Remote Clinical  
Trial Enabling Infrastructure Grant  
Opportunity Guidelines

# RRR Clinical Trial Support Units - collaborative network delivering a growing and diverse clinical trial portfolio with increased and equitable access to clinical trials for patients in rural, regional and remote in NSW and ACT

## Rural and Regional NSW LHDs



## Metropolitan LHDs



### Specialty Networks

- Sydney Children's Hospitals Network (Randwick and Westmead)
- Justice and Forensic Mental Health Network
- St Vincent's Health Network

<https://www.health.nsw.gov.au/lhd/Pages/default.aspx>

# Program Partners

## 34 State and National partners across health, research, private and community sectors

**Health organisations:** NSW Rural Health Research Alliance (including 7 R3 LHDs), ISHLD, CINSW, NSWHP, ACI, CAH, NSWHSB, eHealth NSW, NSW Rural Doctors Network, Canberra Health Services

**Academic organisations:** HMRI, George Institute, NHMRC CTC; NHMRC accredited Centre for Innovation in Regional Health (NSW Regional Health Partners) and advanced health research translation centres (SPHERE and Sydney Health Partners), Australian Clinical Trials Alliance, Melanoma Institute of Australia

**Consumer organisations:** Health Consumers NSW, & Health Care Consumers Assoc. ACT

**Industry:** Medicines Australia, Roche, IQVIA, Novartis; Baxter Healthcare Pty Ltd; Praxis Australia Ltd; ARCS Australia Ltd; Tonic Health Media, ClinTrial Refer



# RRR CT Program: Key Activities

1. Developing decentralised clinical trials capacity and capability

*delivering clinical trials directly to the community*

2. Delivering locally through rural, regional and remote clinical trial support units

*supporting and developing the local workforce*

3. Clinical trial awareness, engagement, recruitment and retention

*involving communities in clinical trials*

4. Professionalising clinical trial services

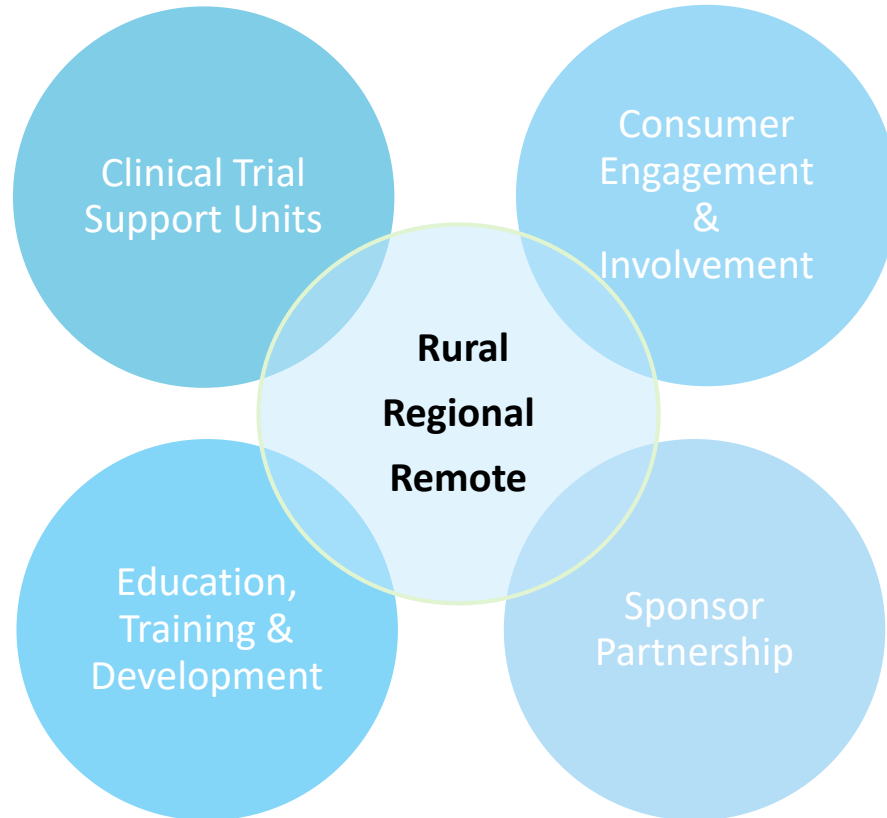
*conducting trials to international best practice standard*

5. Program Evaluation

*framework to assess translational research impact*



# Enabling RRR clinical trials



# clinicaltrialsNSW



agile and  
responsive to  
the needs of  
the population  
and healthcare  
system

COVID-19 Clinical Trials Guidance

Waratah Vaccine Alliance

Adaptive Platform Trials for COVID-19

# clinicaltrialsNSW

## ***Benefits to NSW Health system & stakeholders***

- fosters a culture of clinical trials excellence that supports research and innovation
- supports quality academic & investigator-initiated clinical trials which translates research into clinical practice & embeds outcomes into the health system
- facilitates access to and participation in clinical trials, including rural, regional and remote communities
- improves health outcomes through development of and access to innovative medical therapies and technologies, and provision of comparative evidence.



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HEALTH+MEDICAL RESEARCH

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 *transforming clinical trials in NSW*

