RESEARCH
ADVANTAGE

HEALTH PROFESSIONALS RESEARCH EDUCATION PROGRAM –

Session 2: CLINICAL TRIALS

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

NSW GOVERNMENT Health Hunter New England Local Health District

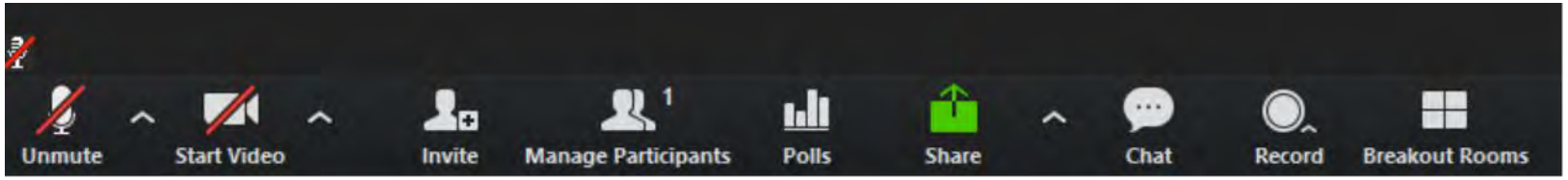
NSW GOVERNMENT Health Central Coast Local Health District

12.30 – 2.00pm Thursday 13 June 2019
HOST: Gosford Hospital – Conference Centre
***Alternative site*: John Hunter Hospital – Small Lecture Theatre [6067]**
Zoom – ID: 825 404 357 https://uonewcastle.zoom.us/j/825404357

RESEARCH ADVANTAGE
connecting and empowering

ZOOM ETIQUETTE

- **This Education session is being recorded**
- **If you are joining us from a remote location – WELCOME**
- **May I ask you to complete login – then MUTE YOUR MICROPHONE & turn off your video**



ACKNOWLEDGEMENT OF COUNTRY

We acknowledge and pay respect to the Darkinjung People, traditional custodians of the land on which Gosford Hospital is situated

and also pay respect to the Awabakal People, traditional custodians of the land on which the John Hunter Hospital is situated.

We further acknowledge and respect all other Aboriginal and Torres Strait Islander Nations joining us today

MS FIONA WILKINSON

Director - Quality, Strategy and Improvement
Central Coast Local Health District [CCLHD]

GUEST SPEAKER INTRODUCTION

NSW GOVERNMENT Health Hunter New England Local Health District

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NSW GOVERNMENT Health Central Coast Local Health District

DOCTOR BERNADETTE ALIPRANDI-COSTA

Manager, Safety and Quality Improvement Systems and Intergovernmental Relations
Australian Commission on Safety and Quality in Health Care

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS
A better way to care

NSW GOVERNMENT Health
Hunter New England Local Health District

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NSW GOVERNMENT Health
Central Coast Local Health District

The National Clinical Trials Governance Framework project

Central Coast LHD Meeting 13 June 2019

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

The Commission

The Australian Commission on Safety and Quality in Health Care (the Commission) was established in 2006 to lead and coordinate safety and quality improvements nationally. The functions of the Commission are specified in the *National Health Reform Act 2011* and include:

- Formulating standards, guidelines and indicators relating to healthcare safety and quality matters
- Advising health ministers on national clinical standards
- Promoting, supporting and encouraging the implementation of these standards and related guidelines and indicators
- Monitoring the implementation and impact of these standards
- Formulating model national schemes that provide for the accreditation of organisations that provide healthcare services and relate to healthcare safety and quality matters
- Collecting analysing, interpreting and disseminating information relating to healthcare safety and quality matters.

Project purpose

To develop the National Clinical Trials Governance Framework as the first step towards the accreditation of health services undertaking clinical trials that is:

- Aligned with existing national and jurisdictional guidance materials with which trials must comply
- Aligned with the National Safety and Quality Health Service Standards (second edition) for hospital accreditation and the National Model Clinical Governance Framework.

Reduce duplication, increase efficiency, cohesion and productivity across the clinical trials sector.

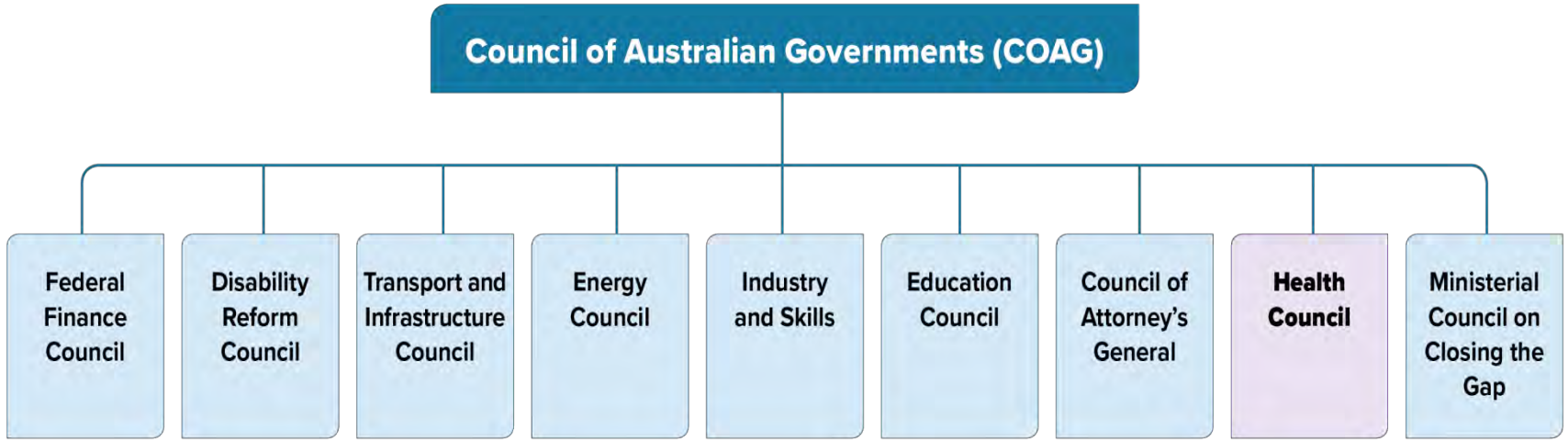
Background

- The Australian Health Ministers' Advisory Council (AHMAC) was tasked to work up options for the development of models of best practice to improve administered efficiencies, better engage sponsors and improve trial start up times

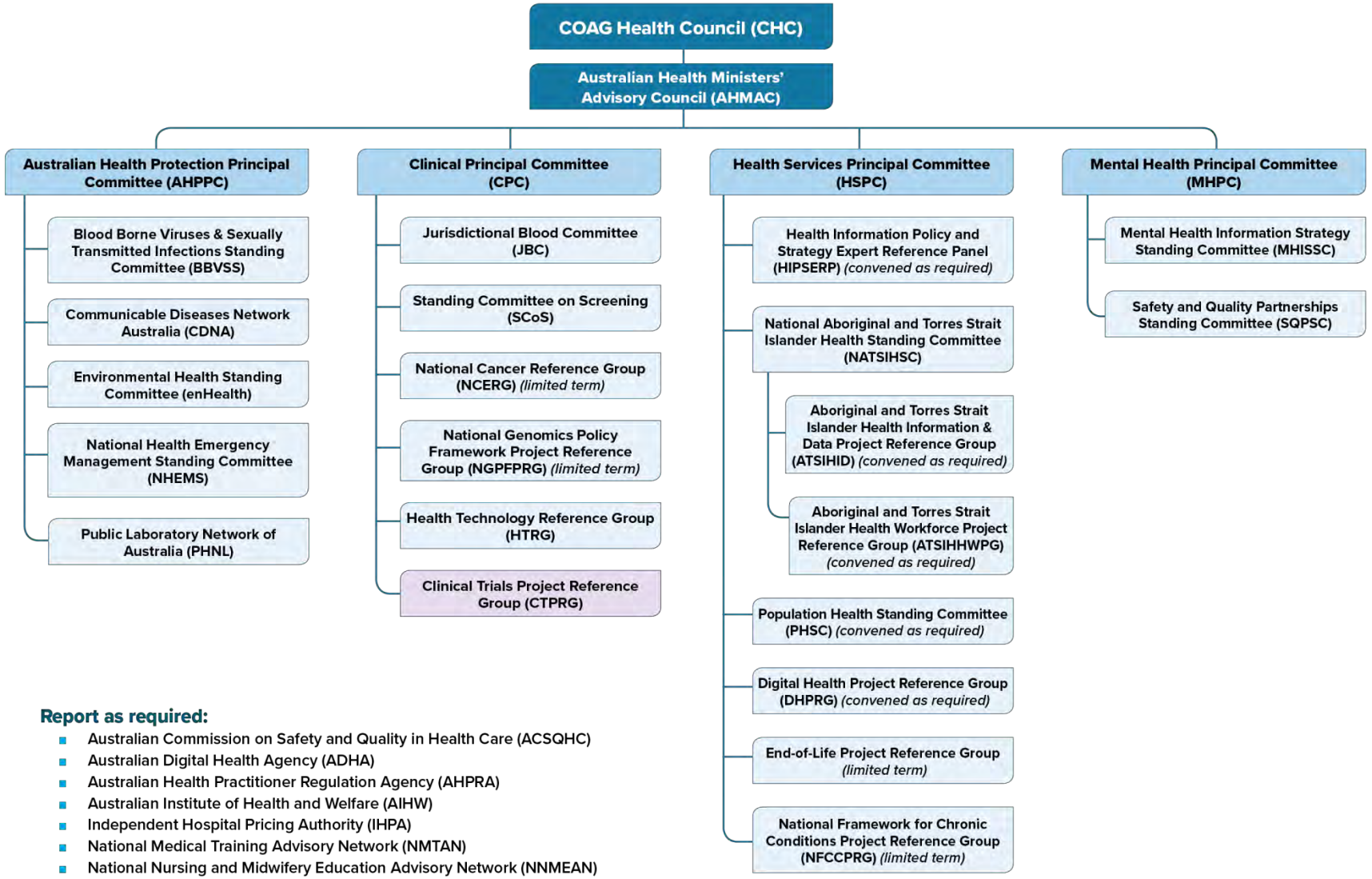
- The full AHMAC response, developed on its behalf by the Clinical Trials Jurisdictional Working Group (CTJWG), which included a recommendation for a National Clinical Trials Governance Framework, was endorsed by the CHC in 2017

- The Clinical Trials Project Reference Group (CTPRG) is the expert advisory sub-group within the Clinical Principal Committee under the Australian Health Ministers' Advisory Council (AHMAC) who are tasked with progressing the CHC clinical trials agenda.

COAG Health Council



AHMAC



Report as required:

- Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Australian Digital Health Agency (ADHA)
- Australian Health Practitioner Regulation Agency (AHPRA)
- Australian Institute of Health and Welfare (AIHW)
- Independent Hospital Pricing Authority (IHPA)
- National Medical Training Advisory Network (NMTAN)
- National Nursing and Midwifery Education Advisory Network (NNMEAN)

Benefits for the community

Clinical trials:

- Provide early access to innovative treatments and interventions for patients
- Improve the overall standard of medical care provided in Australian hospitals through the uptake of evidence into practice
- Improve outcomes for patients participating in clinical trials
- Support the retention of clinicians and medical researchers in our healthcare system through the provision of technical skills and global recognition of their contribution to international research

Under the National Health Reform Agreement 2011, Jurisdictions committed to 'plan and deliver teaching and training and support research provided through public hospitals'

Limitations of Australia as a trial location

- Australia has a small geographically dispersed population
- Australia's capacity to recruit patients to clinical trials in some therapeutic areas is overstretched due to:
  - administrative inefficiencies
  - competing ongoing trials
  - limited avenues for clinicians for refer patients to a clinical trial
  - unpredictable participation rates
- Australia is more expensive for Phase II and III trials than markets in Asia and Eastern Europe and is overall less competitive in cost and efficiency
- Commercial trial sponsors have reported up to 845% cost variation between separate trial sites for the same activity on the same trial.

Australia is less competitive on metrics of cost, timeliness of trial start-up, capacity to recruit to target and the quality of the trial data.

National initiatives

- $1.3 Billion over ten years from 2017-18 for a **National Health and Medical Industry Growth Plan** to improve health outcomes and develop Australia as a global destination for medical sector jobs, research and clinical trials including:

    - $206M program extension for the Rare Cancers, Rare Disease and Unmet Need program, and $42M for the International Clinical Trials Collaborations program

- $7 million *Encouraging More Clinical Trials in Australia* budget measure over four years from July 2017 to 30 June 2021 has incentivised a number of jurisdictional activities to improve their local clinical trial environments

- The Australian Department of Health is developing a concept for a potential national clinical trials platform, the ‘clinical trials front door’.

National reference groups

- Clinical Trials Project Reference Group (CTPRG)
  - advisory group within the Clinical Principal Committee under AHMAC
  - members from jurisdictions and the Australian Government Department of Health
  - development of processes to streamline HREC review and approval
  - developed the National Aggregate Statistics (NAS)

- Clinical Trials Forum
  - members from jurisdictions, Australian Government Department of Health, industry and the private sector

- Australian Clinical Trials Alliance (ACTA)
  - networking across the research sector, fostering collaboration between co-operative clinical trial groups

- Advanced Health Research Translation Centres (AHRTCs)
  - building collaborations across the university, health and research sectors.

Literature review

Purpose: to provide evidence on governance frameworks for clinical trials in Australia and internationally, with focused insights from three developed countries:

- **Australia**
- **Canada**
- New Zealand
- **United Kingdom**
- United States of America
- **South Korea**
- European Union
- Nordic region

Literature review key findings

- A national strategic plan for change with clearly articulated guiding principles for the implementation of a governance framework, realistic objectives and measurable outcomes
- A national (or bi-national, as in the EU) legislation and policy framework
- National independent accreditation to assess local-level providers to confirm they have implemented the nationally harmonised approach to clinical trials governance
- A national or central coordinating agency or reference group
- A national or central IT platform
- A national and local site-capability framework.

Mapping exercise

- Map current clinical trials governance processes within each jurisdiction
- Describe governance processes at the research hospital/institute level
- Incorporate the policies identified during the literature review
- Reflect upon the work already undertaken aimed at providing consistent and standard processes across sites
- Undertake key stakeholder interviews:
  - Interview participants representing the public and private health sector, researchers, research governance officers, clinical trial investigators, research coordinators and managers, hospital administrators, government and non-government agencies.

Mapping exercise key findings

- Absence of nationally consistent standard operating procedures leading to inconsistent work-flow arrangements for trial sites
- Lack of a national approach to managing workflow and national reporting on operational performance metrics
- Absence of a consistently applied definition of ‘governance’ and confusion regarding the role and function of the research governance office by trial sponsors, investigators and site staff
- Lack of a uniform approach to site staff training and certification, limiting a health service’s capacity to engage and retain a skilled and reliable workforce.

Definition of Governance

Governance is a set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled.

Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal and HR) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance.

Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives.

In the National Safety and Quality Health Service (NSQHS) Standards, governance includes both corporate and clinical governance.

Advantages of the NSQHS Standards

- The National Safety and Quality Health Service (NSQHS) Standards is agreed by all Jurisdictions and approved by AHMAC
- The NSQHS Standard has a strong governance structure
- Each component of the NSQHS Standards has a **safety and quality** and **consumer** focus
- Health service organisations have used the NSQHS Standards as a framework for investing in safety and quality improvement activities
- Assessment against the Standards is a nationally consistent and accepted process – mandatory for all health services conducting clinical trials
- The process for assessment ensures all actions are being met.

The NSQHS Standards has a nationally agreed and accepted mechanism for implementation and assessment

NSQHS Standards (second edition)


Clinical Governance Standard


Partnering with Consumers Standard


Preventing and Controlling Healthcare-associated Infection Standard


Medication Safety Standard


Comprehensive Care Standard


Communicating for Safety Standard


Blood Management Standard


Recognising and Responding to Acute Deterioration Standard

National Model Clinical Governance Framework

Five components

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

Every item within the Standard is assessable under the Australian Health Service Safety and Quality Accreditation Scheme

Clinical Trials Governance Framework

The National Clinical Trials Governance Framework is aligned with the *National Model Clinical Governance Framework* to provide:

- The set of relationships, roles and functions established by a health service organisation between its:
  - state or territory department of health
  - governing body
  - executive
  - workforce
  - patients
  - consumers
  - clinical trial sponsors
- The actions against which health service organisations will be assessed for accreditation
- Suggested strategies to meet the actions
- Examples of evidence for accreditation assessors

Implications for health services

- More than half of the 47 actions within the NSQHS Standards 1 and 2 apply to clinical trial services
- Embedding accreditation into routine health service organisation accreditation optimises organisational strategic planning to deliver clinical trial services and will deliver more efficient trial operations such as:
  - trial selection
  - pre-trial assessment of a trial site (eg: trial site selection, feasibility assessment)
  - pre-recruitment activities (HREC review and time-to-decision timeframes, SSA review and sign-off)
  - recruitment activities
  - trial management
  - workforce management and workforce training
  - trial related financial management

Benefits for the sector

Governing bodies, hospital administrators, clinician trial investigators, clinical and non-clinical site staff working in partnership with patients, trial sponsors, regulators, and consumers have **individual** and **collective responsibilities** for ensuring clinical trial service provision.

- Nationally consistent approach to clinical trial governance across health service organisations
- Clarity on roles, functions and actions which are reflected in the NSQHS Standards
- Opportunities for organisational strategic planning for clinical trial service provision in collaboration with trial networks and AHRTCs
- Measureable operational outcomes

Greater predictability, transparency, cohesion and productivity

Next steps…

- Final draft Governance Framework and User Guide in June 2019
- Pilot in health service organisations to commence in January 2020, implementation in January 2021

Contact the Commission project team on (02) 9126 3517 or at:
CTGovernance@safetyandquality.gov.au

Safetyandquality.gov.au

Twitter.com/ACSQHS

Youtube.com/user/ACSQHC

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Summary of feedback

- Overall, there was broad support for a National Clinical Trials Governance Framework and accreditation standard for health services undertaking clinical trials
- Limited awareness of the accreditation process by the clinical trials sector- more information needed on to process for assessment against the NSQHS standards
- Ambitious time frame for implementation and clashes with the implementation of new national guidelines
- Disconnect regarding strategic planning to deliver clinical trial services as an organisation and selecting trials, undertaking trials within a clinical department
    - o accreditation of a HSO vs *audit* of a trial (TGA process)
    - o trial sites don't understand how to undertake strategic planning, or how to engage with their hospital administrators to do this

Summary of feedback

- Standard metrics and KPIs required
- It was not clear that the roles and functions provided were already in place in most clinical trial sites (as per jurisdictional policy documents gathered during the mapping exercise)
    - o some participants thought these were provided in too little detail
    - o others suggested the framework mandated the roles and functions and thought more flexibility was needed
- Engaging consumers will be difficult, no resources to access training programs to educate consumers (no awareness of how this is done to meet the accreditation standard currently) - "*can't make consumers participate"*
- Impact of implementation on cost , time and resources
- Resource allocation to support the workforce. If HSOs contribute to funding then they could also have a say in how research funds are spent.

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Director - Quality, Strategy and Improvement
Central Coast Local Health District [CCLHD]

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MS ANITA VAN DER MEER

Manager - Clinical Trials Support Unit
Office for Health and Medical Research
NSW Ministry of Health

NSW GOVERNMENT Health Hunter New England Local Health District

RESEARCH ADVANTAGE

NSW GOVERNMENT Health Central Coast Local Health District

CLINICAL TRIALS NSW

Anita van der Meer
Manager, Clinical Trial Support Unit
NSW HEALTH Office for Health and Medical Research
June 2019

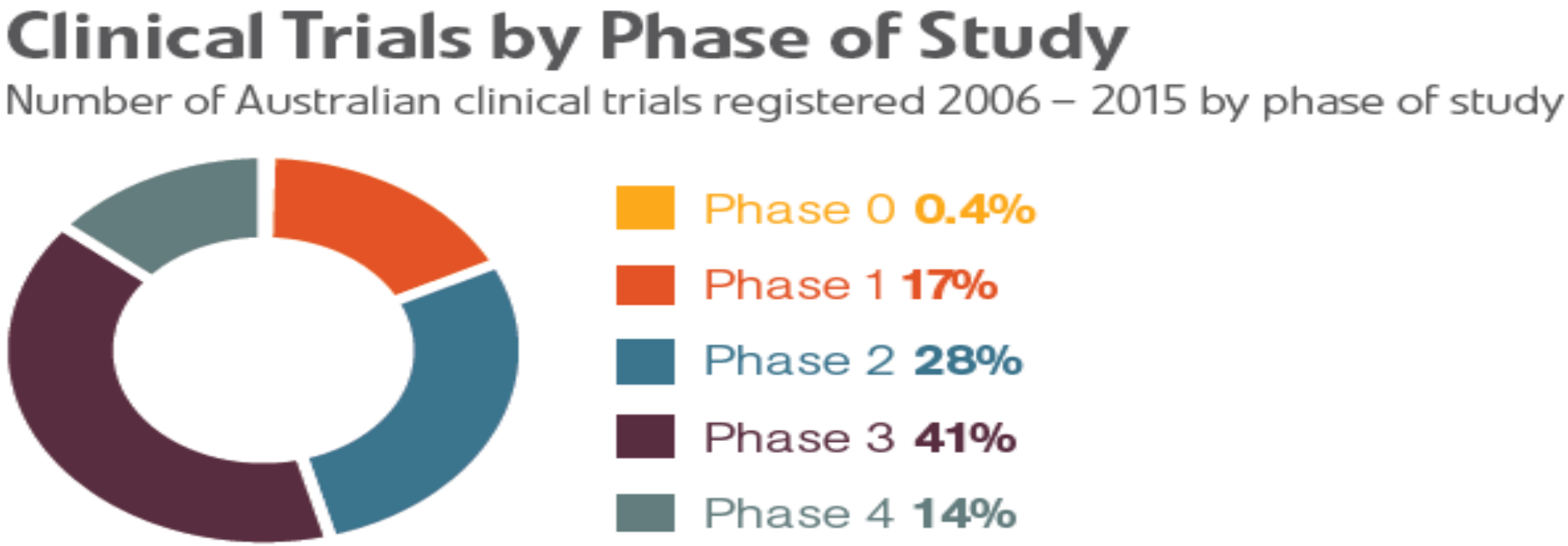
NSW GOVERNMENT

Australian Clinical Trials

Clinical trials are part of a robust and diverse health ecosystem in Australia

AusTrade Why Australia for Clinical Trials 2019

Australian Clinical Trials

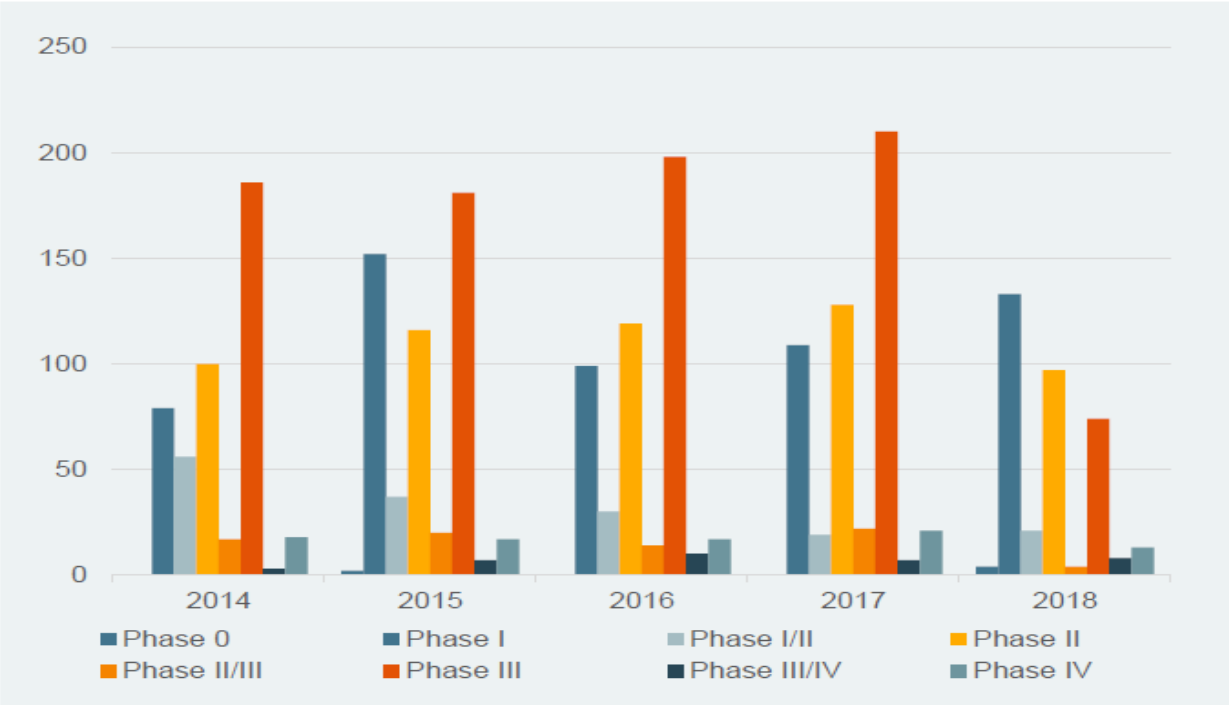


AusTrade Clinical Trials Fact Sheet 2018

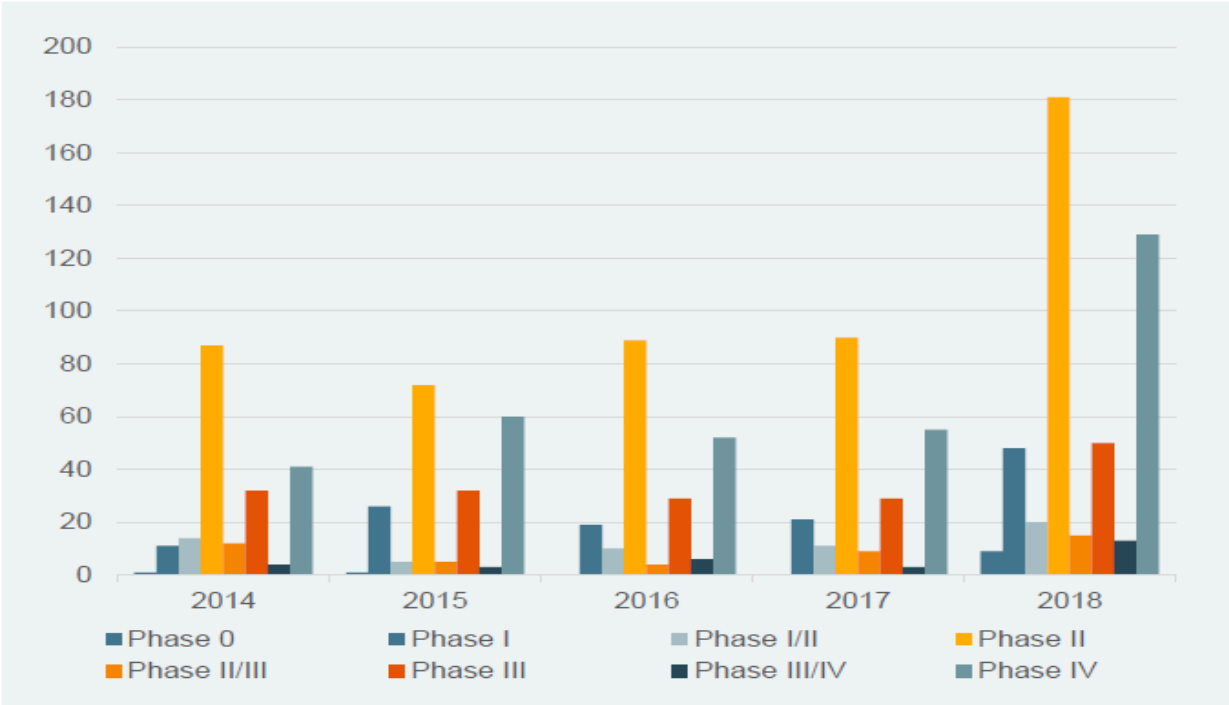
Australian Clinical Trials

Clinical trials started in Australia by phase, 2014 –18

2,348
industry–sponsored trials started in Australia in 2014-18



1,298
non-industry–sponsored trials started in Australia in 2014-18



AusTrade Why Australia for Clinical Trials 2019

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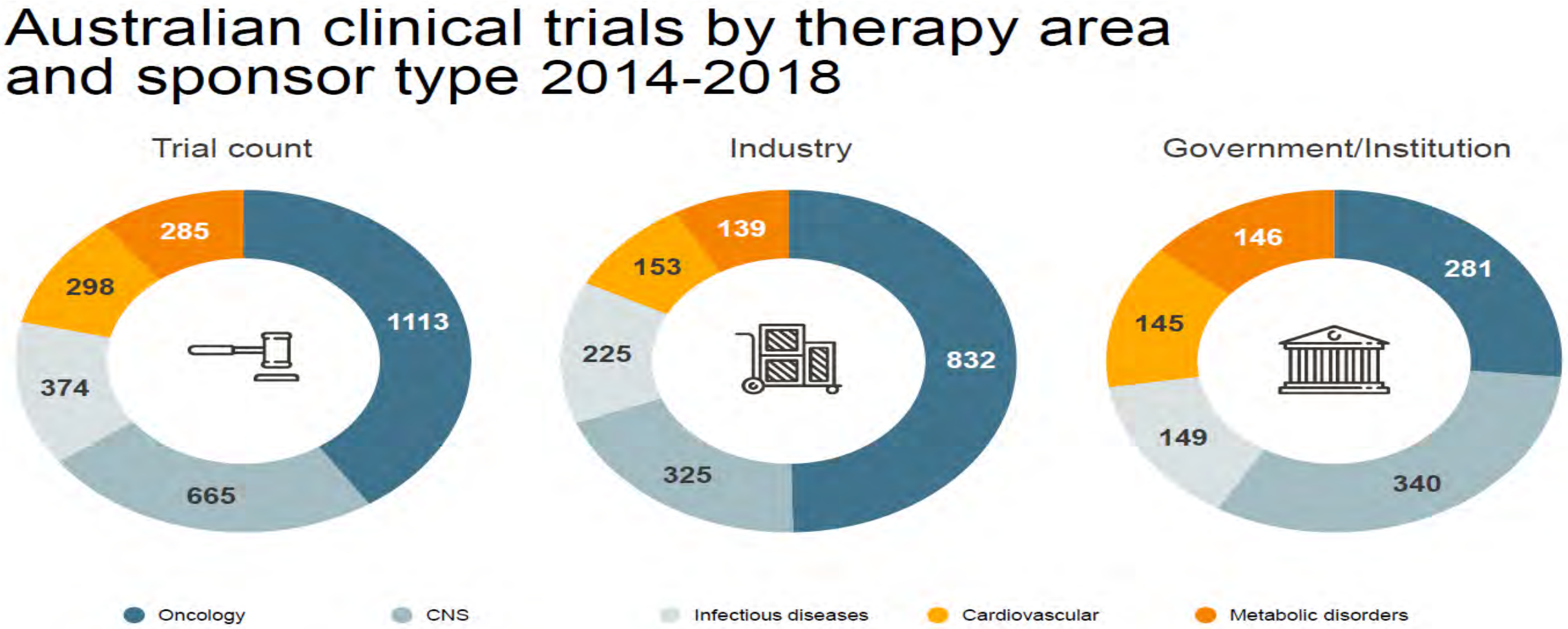
Australian Clinical Trials



AusTrade Why Australia for Clinical Trials 2019

Clinical Trials NSW

- ~30% of clinical trials in Australia are conducted at NSW centers
- ~30% of early phase clinical trials are conducted at NSW centers

- >90% of clinical trials submitted to a NSW HREC are approved within 60 days
- >90% of clinical trials at NSW centers are authorized within 30 days

- Specialist NSW EPCT HREC review within 20 days

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Australian MTP Snapshot

$5.0 billion GVA in 2010

-2.6% compound annual growth rate 2010–2015

$4.6 billion manufactured exports in 2015

$4.4 billion Gross Value Added (GVA) in 2015

48,000 jobs

- 10,000 Medical technologies
- 22,000 Pharmaceutical and biotech
- 16,000 Health and medical research

Companies

- 50 pharmaceutical
- 400 biotechnology
- 500 medical technology

$775 million
public spending on R&D

$630 million
industry spending on R&D

Australia contributes
3% of the world's biomedical research

NSW GOVERNMENT

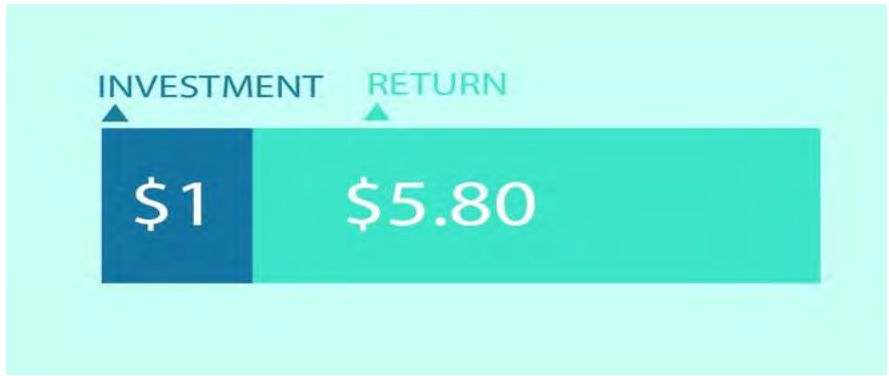
Medical research delivered $78 billion in net gains to the Australian economy.

$78B in net gains to the Australian economy[6]*

$52B health gains

$26B wider economic gain

Every **$1** invested in medical research ▶ returns **$3.90** in benefits to the population[6]



KPMG, *Economic Impact of Medical Research in Australia*, released 16 October 2018

ACSQHC Economic evaluation of investigator-initiated clinical trials conducted by networks 2017

Clinical Trials Support Unit OHMR NSW

NSW Health Clinical Trial Support Unit

enabling clinical trial capacity and capability across NSW

Who we are:

Tony Penna
Executive Director, OHMR

Anita van der Meer
Manager, CTSU

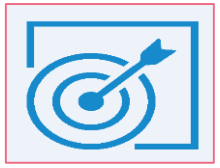
Ashika Kumar
Sr. Project Officer

Shelley Burnett
Sr. Project Officer

Clinical Trial Support Unit: Key Functions

Establish an entry point for MTP clinical trials in NSW

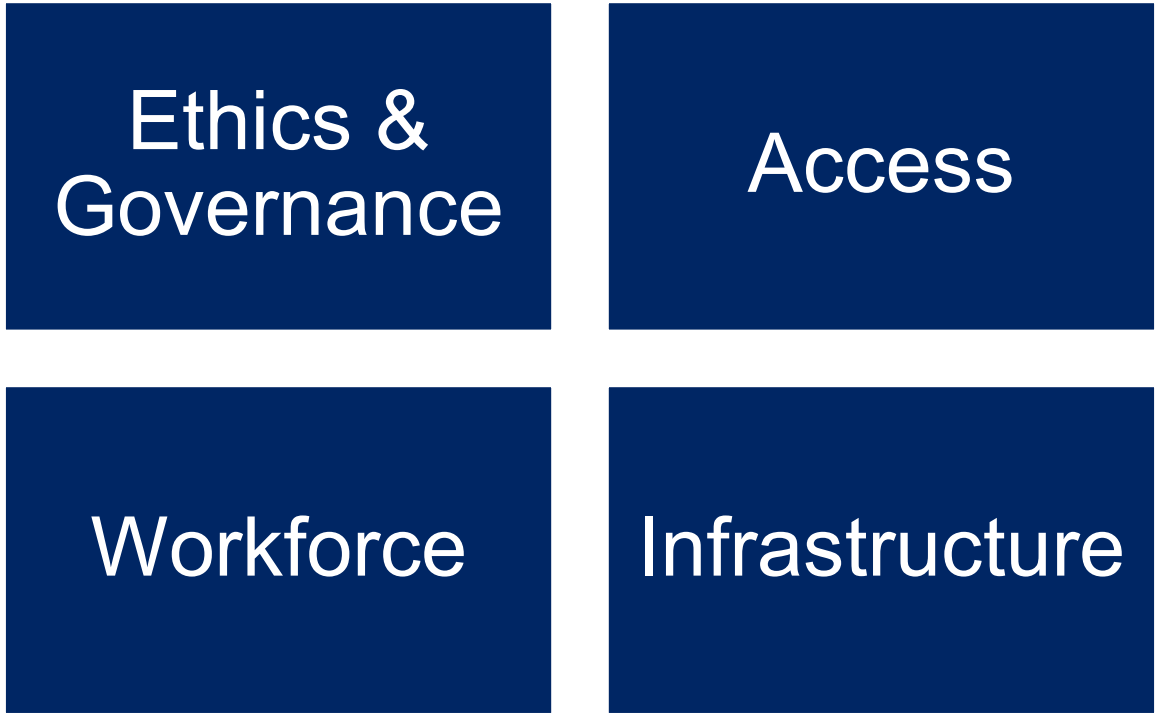
Maintain policy directives, drawing on national and international best practice



Drive transformational change and improvements across the clinical trial sector

Monitor and evaluate outcomes of clinical trial initiatives

NSW Clinical Trials Strategy – 4 pillars



NSW Clinical Trials Strategy

Ethics and Governance

- Portfolio Management
- Research Governance
- Site specific Assessment

Access

- Knowledge hub & connector
- Clinical Trials triage
- Linkage and support for funding
- Patient access, teletrials and PHNs

Expertise

- Certified training
- Communities of practice
- Peer support program (experienced sites mentoring emerging sites)

Infrastructure

- Data management
- Quality Improvement
- Specialist support services/enablers

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Benefits to NSW Health

- scale the model across all types of clinical trials in NSW
- support decision making for public health organisations
- leverage our existing expertise

Multiplier effects

- enable capacity and capability, enhance collaboration
- foster a culture of clinical trial excellence
  → research & innovation *pull-through*

- create a connected, self-sustaining clinical trial ecosystem
- *embed* into the health system and *translate* into clinical practice

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Early Phase Clinical Trials NSW

Why focus on Early Phase Clinical Trials?

17%

FIGURE 15: AUSTRALIAN CLINICAL DEVELOPMEN

Increased activity

Global market
$56b 2020

CSIRO MTP Roadmap 2017

NSW Health Early Phase Clinical Trials HRECs

NSW Health Early Phase Clinical Trials HRECs Scheme

- a consistent, high quality ethics approval process
- that supports Phase I and First-in-Human clinical trials
- at all sites in NSW

NSW Health Early Phase Clinical Trials HRECs

2 EPCT HRECs

- **Bellberry Limited**
- **Sydney Children's Hospital Network (SCHN) HREC**

- Submissions 'business as usual' through REGIS
- target to review all applications within 20 working days

NSW Health Early Phase Clinical Trials QRS

EPCT Quality Recognition Scheme

- high quality operational conduct of PhI & FiH trials
  - application process – all clinical trial sites, units and Investigators in NSW are invited to apply
  - Assessment and certification
  - Quality Improvement Program

Clinical Trials Triage Service

MOH-OHMR@health.nsw.gov.au

Further information

w www.medicalresearch.nsw.gov.au

t 02 9391 9228

e MOH-OHMR@health.nsw.gov.au

@MedResearchNSW

QUESTIONS


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Clinical trials income can be counted for HERDC as follows:

Activities that meet the above definition of R&D include:

a) professional, technical, administrative or clerical support staff directly engaged in activities essential to the conduct of R&D
b) the activities of HDR[4] students enrolled at the HEP
c) the development of HDR training and courses
d) the supervision of HDR students enrolled at the HEP
e) R&D into applications software, new programming languages and new operating systems

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[2] OECD (2015), *Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development*, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris, pp 44-45.
[3] *Ibid*. pp 46-48.
[4] Higher degree by research (HDR) training is training undertaken by students to achieve a Research Doctorate or Research Masters. A Research Doctorate means a Level 10 Doctoral Degree (Research) qualification as described in the Australian Qualifications Framework and a Research Masters means a Level 9 Masters Degree (Research) qualification as described in the Australian Qualifications Framework. Professional Doctorates may be included but only where at least two-thirds of the qualification is research.

f) prototype development and testing
g) construction and operation of a pilot plant where the primary objective is to make further improvements
h) trial production where there is full scale testing and subsequent further design and engineering
i) phases I to III of clinical trials.

Source: https://docs.education.gov.au/node/51966

WHAT'S NEXT

Health Professionals Research Education Program: *Session 3:* ***Implementation***
Thursday 29 August 2019 [Host: John Hunter Hospital – 6067 Lecture Theatre, Alternative location: Gosford Hospital – Conference Centre or via Zoom]

Grant Accelerator Program: *Session 5:* ***Linkage Projects***
Thursday 27 June 2019 [Host: ATC 210 – Advanced Technology Centre, Callaghan Campus and via Zoom]

http://www.newcastle.edu.au/research-and-innovation/resources/research-advantage