“I want NSW to have a vibrant early phase clinical trials environment so that our trials are high quality, our processes are efficient and that NSW becomes a destination of choice for early phase trials”

Dr Kerry Chant – Chief Health Officer, NSW Ministry of Health
Overview of the Stages to Develop and Implement the Early Phase Clinical Trials Framework for NSW
Why focus on Early Phase Clinical Trials?

We will create a high quality and efficient environment to conduct early phase trials in NSW

- To increase the speed and reduce the administrative burden for early phase trial approval to commence

- To ensure the operational conduct of early phase trials is aligned with best practice nationally and internationally.

- To make NSW a destination of choice for early phase trials because it will benefit residents, industry, healthcare and the research community in NSW.
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 comprises two key elements:

- NSW Health appointed specialist early phase clinical trial Human Research Ethics Committees
- Voluntary quality recognition scheme for early phase clinical trial sites and investigators in NSW
NSW Health appointed specialist early phase clinical trials Human Research Ethics

- Specialist committees will be appointed to review all early phase clinical trials
  - Mandated for use where NSW Public Health Organisation sites are involved
  - Criteria include guaranteed review time and core specialist skills
  - All Human Research Ethics Committees in Australia are eligible to apply through an Expression of Interest process
  - Likely that only a small number of committees will meet criteria
  - Funding support for specialist review and committee capability development

- Value to the health sector:
  - Support decision making for public health organisations as sites can have confidence in specialist ethics review
  - Streamline ethics application timelines – 20 day timeline
  - Build early phase trial capability
  - Increase attractiveness of NSW to sponsors
Voluntary quality recognition scheme

- Quality recognition scheme will recognise sites and investigators that have the capability to conduct early phase trials at a high standard
  - All clinical trial sites and units, and associated investigators, in NSW eligible to apply
  - Support provided by an Expert Oversight Committee to set standards and monitor performance
  - Clinical trial sites and units, and associated investigators will be awarded recognition and provided support to work towards recognition.

- Value to the health sector:
  - Support decision making for Public Health Organisations who can have confidence that a trial site meets a high standard of conduct, built in requirements for good clinical governance
  - Streamline research governance timelines – 10 day Site Specific Assessments review
  - Increase attractiveness of site to potential sponsors
Implementation Process and Timeline Early Phase Clinical Trials Framework for NSW – 2018

Voluntary Quality Recognition Scheme (VQRS) for Early Phase Clinical Trial Sites in NSW

Framework development

Jan
Feb

Implement initiation and governance
- Project Governance, and Technical Working Groups
- Stakeholder engagement

Mar
Oct

Appoint Central Office
- Seek EOI for a Central Office to manage the VQRS
- Appointment of a central office to run the VQRS

May
Dec

Finalise Voluntary Quality Recognition Scheme criteria
- Establish criteria for the recognition of sites/units and investigators
- Establish SOPs and international standards
- Consultation with clinical trials sector

Mar
Jun

Finalise criteria for NSW Health appointed Specialist Early Phase Clinical Trials HREC
- Refine the criteria for Specialist HRECs
- Develop Risk Assessment Tool
- Consultation with clinical trials sector

Jun
Sep

Appoint NSW Health Specialist Early Phase Clinical Trials HRECs
- EOI process for Specialist HRECs
- Formally appoint

2017
2018
2018
2018
2019

NSW Health Appointed Specialist Early Phase Clinical Trials Human Research Ethics Committees (HREC) Scheme

Operational future
- VQRS open for EOI
- HREC scheme operational with transition measures
- Early review

* Timeline is indicative only and subject to change.
Governance Structure - Implementation Phase - 2018

Executive sponsor
Chief Health Officer, Deputy Secretary
Population and Public Health
Dr Kerry Chant

Expert Oversight Committee

Project Sponsor
Executive Director, Dr Antonio Penna
Office for Health and Medical Research

Implementation Project Control Group
- OHMR Team
- External Consultants
- Other Experts

NSW Health Appointed
Specialist Early Phase
Clinical Trials
Human Research Ethics
Committees (HRECs)
Scheme
Technical Working Group

Voluntary Quality Recognition Scheme (VQRS) for Early Phase Clinical Trial Sites in NSW
Technical Working Group

Appointed VQRS Central Office (Oct 2018)

Time limited - Implementation period only