## Early Phase Clinical Trials Framework for NSW

**Launch the Implementation Design Phase 2018** 

Recap on the Framework and Implementation Process, Timeline and Governance

February 2018



### Chief Health Officer

"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

Framework Development

**2016/17 - Complete** 

Implementation Design

2018- Now

**Operational** 

**2019- Future** 

### 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.

### Early Phase Clinical Trials Framework

#### **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



Jan 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

17

Framework

development

change.

2018

2018

2018

Jun

Sep

2019

# 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

Appoint NSW Health
Specialist Early Phase
Clinical Trials HRECs

- EOI process for Specialist HRECs
- Formally appoint

#### **Operational future**

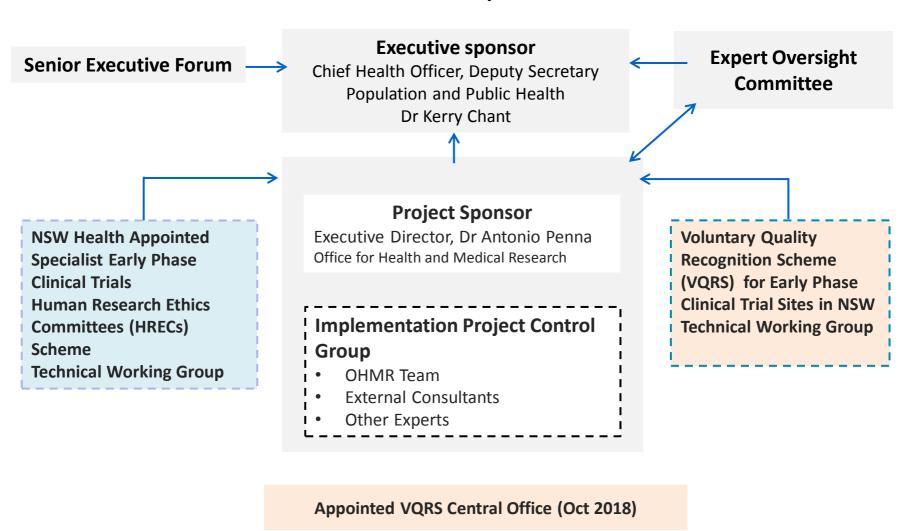
- VQRS open for EOI
- HREC scheme operational with transition measures
- Early review

\* Timeline is indicative only and subject to

Mar Jun

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

#### **Governance Structure-Implementation Phase - 2018**



Time limited - Implementation period only