

# 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



Health

# Chief Health Officer

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*“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?

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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

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## **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

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- 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

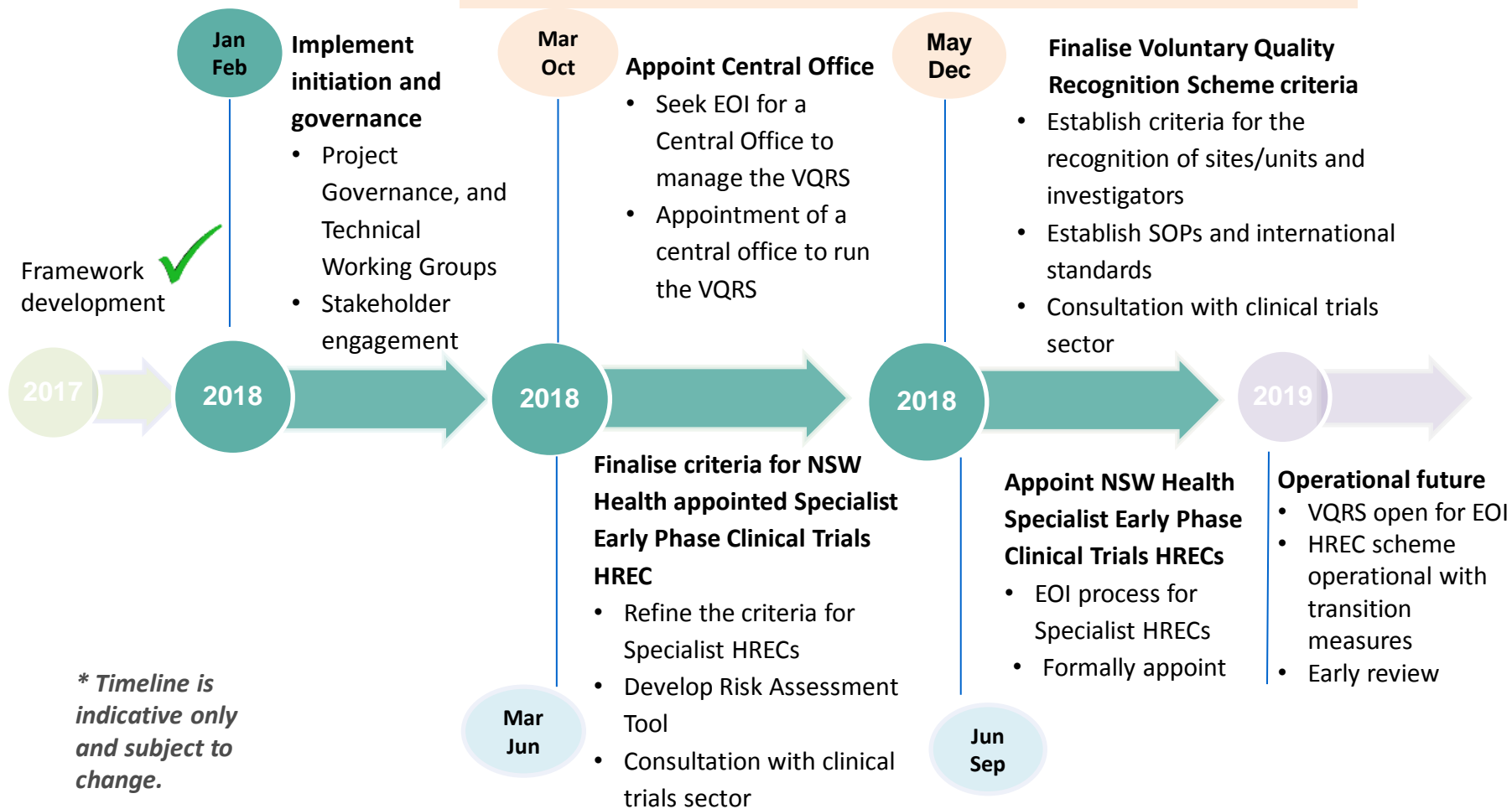
# Voluntary quality recognition scheme

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- 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

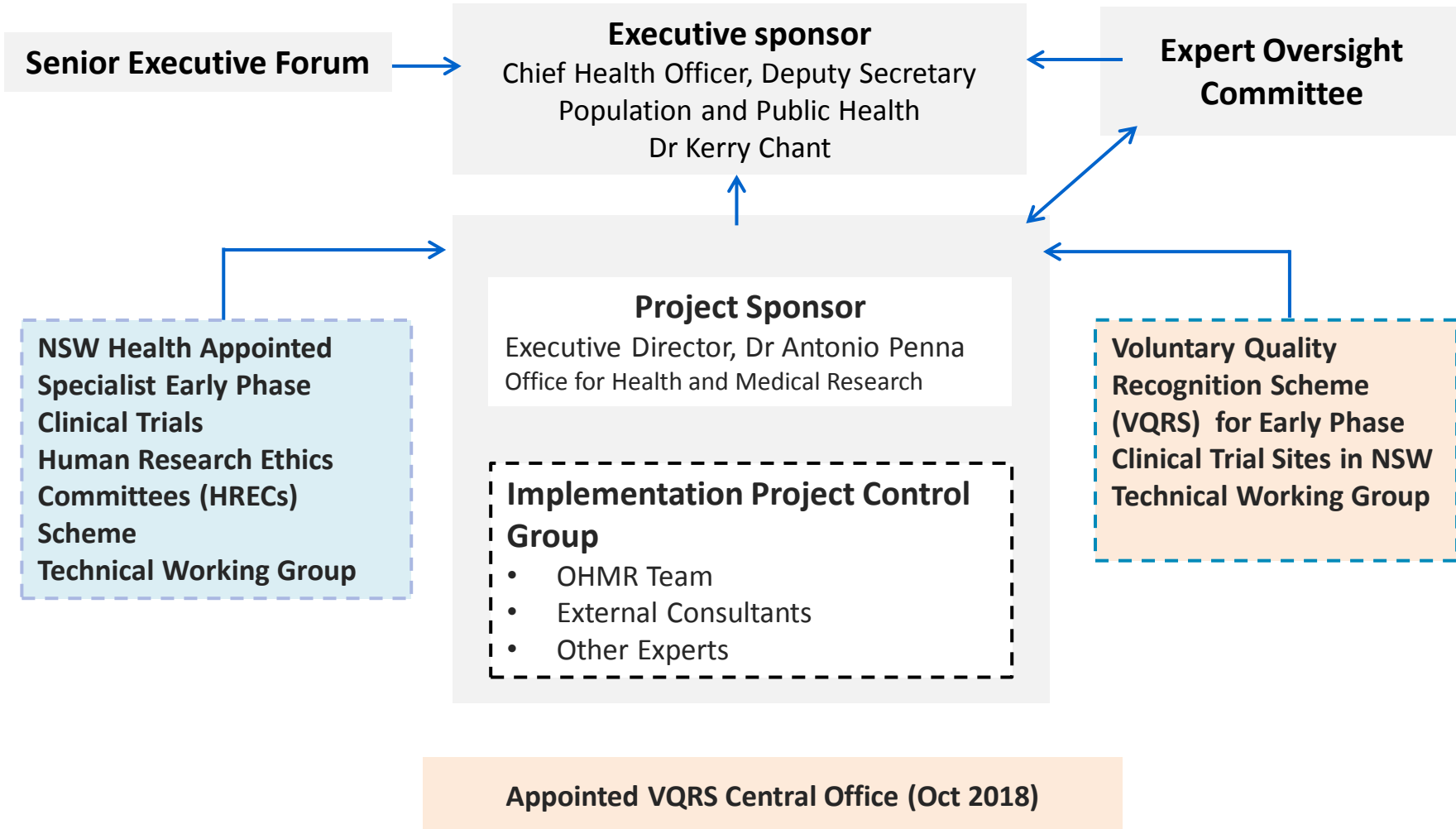
# Implementation Process and Timeline Early Phase Clinical Trials Framework for NSW – 2018

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





## Governance Structure- Implementation Phase - 2018



Time limited - Implementation period only