## Office for Health and Medical Research

# NSW Clinical Trials Quality Recognition Scheme

## Information webinar

10 December 2024

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We acknowledge the traditional owners of the land we work on.

We honour the ancestors of yesterday, the custodians of today and those of tomorrow.

We recognise the continuing connection to land and waters and how culture is held, nurtured and shared.

We pay our respects to Elders past and present and extend that respect to other Aboriginal peoples here today.

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## Agenda

| Time | Agenda item |
|---|---|
| **1:30 to 1:50pm** | **What is the Quality Recognition Scheme (QRS)?** |
| 1:50 to 1:55pm | Break – please enter questions/queries into chat |
| **1:55 to 2:25pm** | **QRS High Level Standards and evidence expectations** |
| 2:25 to 2:30pm | Break – please enter questions/queries into chat |
| **2:30 to 2:45pm** | **QRS operation and application process** |
| 2:45 to 3:00pm | Q&A |

# Session 1:

# What is the NSW Clinical Trials Quality Recognition Scheme (QRS)

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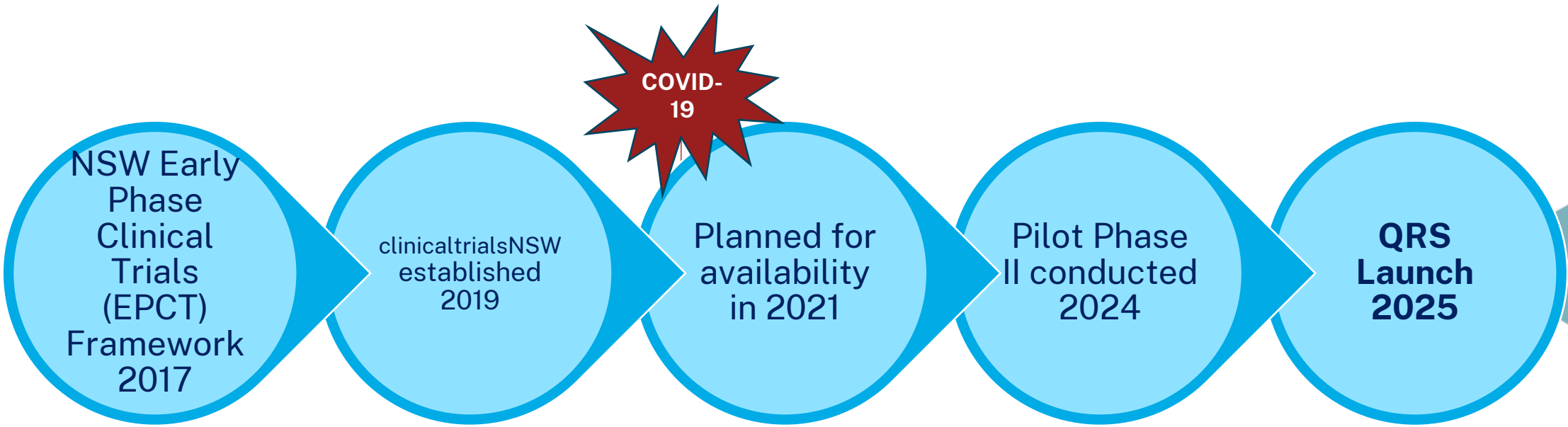
# Progression of the Quality Recognition Scheme




- Pilot Phase I

- Delays due to the pandemic response
- Program needed to adapt to sector wide changes

- Three sites; represented a diverse range of sites
- Applicability and capability building

- The Scheme will be **available from February 2025**
- Free and voluntary

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# Clinical trial sector changes

Changes in the sector impact on the operational process at site

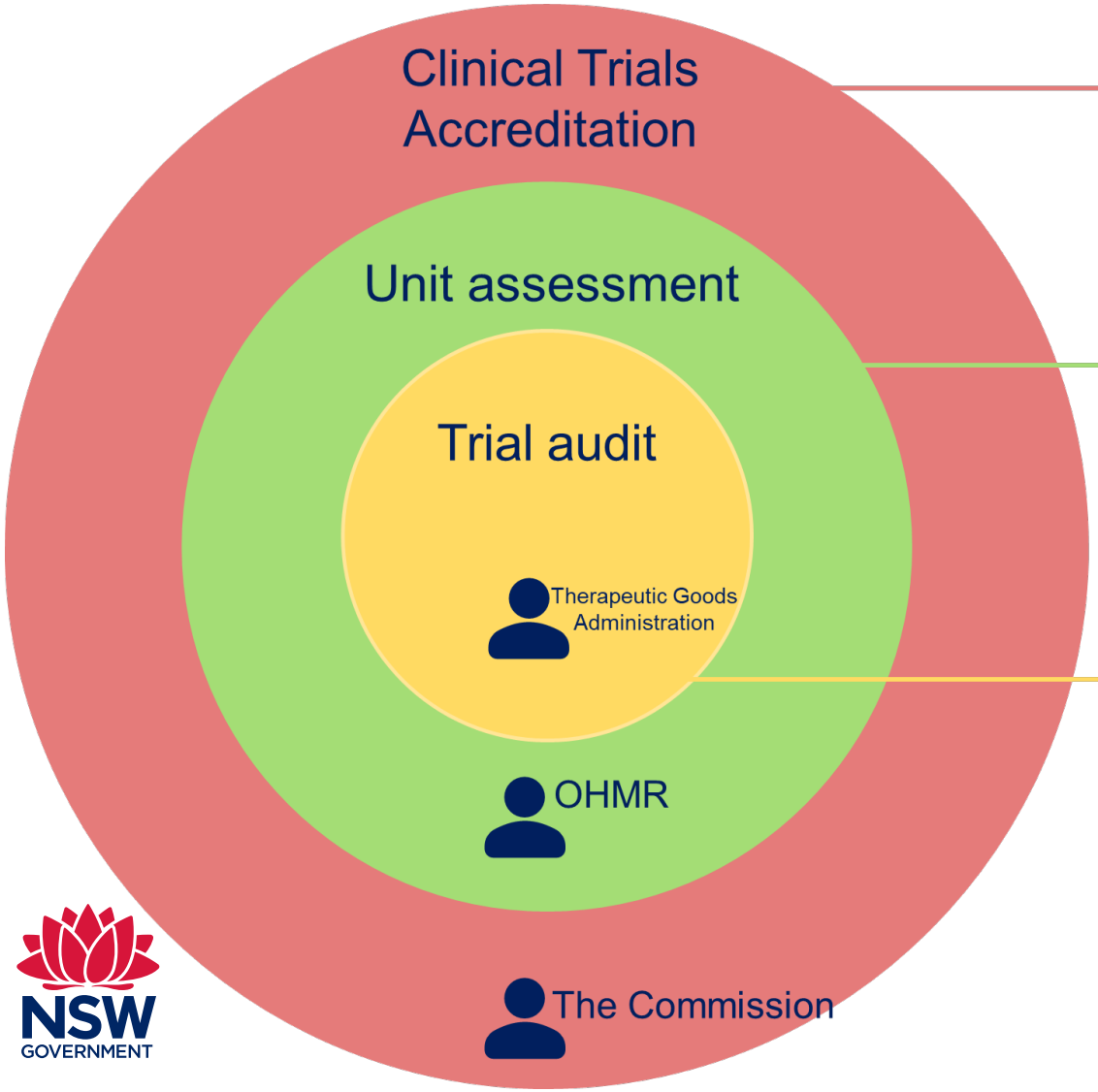
Trial units must adapt and be prepared → placing focus on risk assessment and continual improvement

- COVID-19 pandemic;
  - boosted shift towards decentralised trials, electronic applications, new ways of working
- National Clinical Trial Governance Framework;
  - accreditations commenced in 2023
- Upcoming ICH GCP E6 R3 due mid 2025;
  - encourages risk proportionality
  - more proactive, forward-thinking and considered approach to quality

# QRS Scope

- Founded on principles from the successful UK MHRA phase I accreditation scheme.
- Pilot confirmed QRS marking criteria can be adapted **to all phases** of clinical trials
- Sector changes reinforced the need for flexibility and relevance to all phases
- Site selection will be based on a risk prioritisation method

# Role of QRS in today's regulatory environment




## National Clinical Trials Governance Framework

- Hospital level assessment
- 5 key focus areas
- Mandatory program

## Quality Recognition Scheme

- Inspects clinical trial units
- Operational, facilities, and staff focus
- Voluntary program

## GCP Inspection Program

- Audit individual clinical trials for GCP compliance
- Will prioritise high risk trials
- For cause and random inspections will occur

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# How does the QRS add value?

## The QRS recognises a site's capability to conduct high quality clinical trials

- Creates an enabling environment
- Provides additional guidance for implementing ICH GCP requirement
  - ➢ Focus on risk and quality management procedures
- Aligning with draft ICH GCP E6 R3 updates due to be finalised in 2025
  - ➢ Shift from CApa ⟺ PAca



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# How does the QRS add value?

- Aligns sites with best practice standards
- Assessments will not incur a cost
- Capacity building –
  - OHMR will support sites to meet quality criteria
- Value based healthcare in NSW
- Recognised sites will be promoted through the OHMR website


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# Session 2:

# Quality Recognition Scheme (QRS) High level standards and evidence expectations

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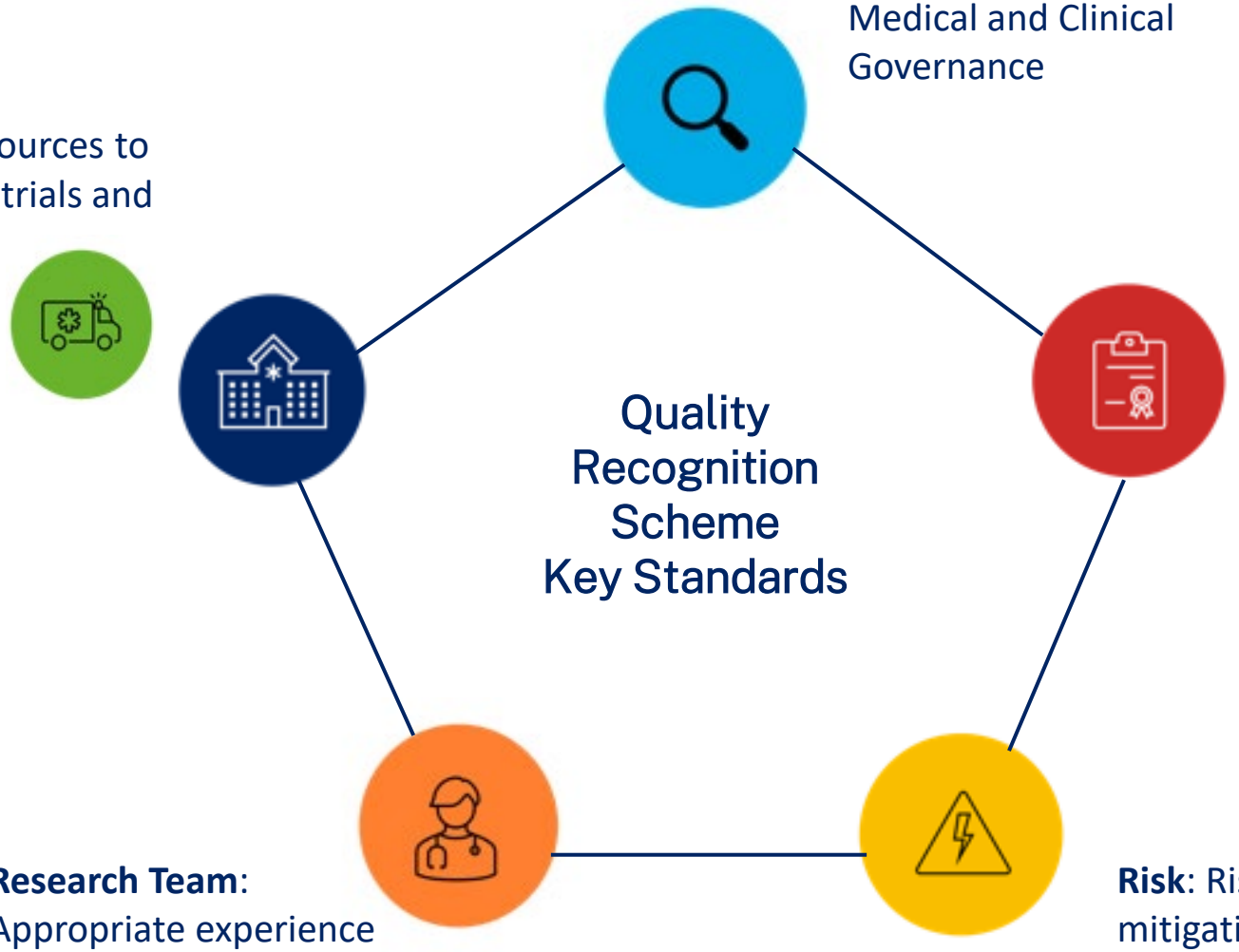
**Adequate oversight**: Medical and Clinical Governance

**Infrastructure**: Appropriate resources to conduct clinical trials and handle medical emergencies




**Quality**: Established systems and processes

**Research Team**: Appropriate experience and training

**Risk**: Risk assessment and mitigation procedures

# Governance

**Adequate Oversight**

Medical and Clinical Governance

- Clinical/Medical governance accountability at sites including clear lines of responsibilities
- Head of Site oversight and involvement in risk management
- Documented mechanism for delegating responsibilities and tasks by PI to another appropriately qualified medical staff
- Process to assess visiting researchers and their suitability to act as investigators
- Staff delegated to perform risk assessment i.e. PI, qualified delegate or Medical Director of the site.

# Example evidence requirements

- ✓ Site specific policies for medical (or clinical) governance, this may be dependent on the business structure of the site
- ✓ Trial unit organisational chart – showing reporting paths, can include roles, number of personnel in each role (FTE) etc
- ✓ Job descriptions or responsibility documentation (SOPs or equivalent)
- ✓ Documentation of management continuity process to ensure short term/long term planning for leadership team
- ✓ Records evidencing management oversight and communication strategies
  - ✓ Leadership meeting minutes, clinical trial management reports
  - ✓ Acknowledgement of receipt of critical information
  - ✓ Contingency procedures and issue escalation

# Quality Systems

**Quality**

Established systems and processes

- Core Standard Operating Procedures including additional early phase trial specific requirements and procedures
- Documented oversight of SOP creation, implementation, internal monitoring and review
- Example evidence includes:
  - SOPs and work instructions
  - Plans
  - Templates
  - Standard trackers and forms

# Example evidence requirements

- ✓ Active SOPs for all relevant study activities, medical and clinical governance and training for the facility
  - ✓ SOP Index
- ✓ Management of SOP life cycle
  - ✓ Internal monitoring and review plan of SOPs
- ✓ Non-compliance and quality issue management procedures and evidence of continual monitoring
  - ✓ Quality management procedures such as procedural QC checks i.e. 2nd person check at IP dispensing or administration (as required)
  - ✓ Non-compliance or/CAPA reports or registers to demonstrate action is taken against quality issues raised
  - ✓ Management  communication – email notification, minutes
- ✓ Electronic systems for management of study records
  - ✓ Detail on audit trail, back up, system security and BCP
  - ✓ Account management and access

# 3. Risk

**Risk**

Risk assessment and mitigation procedures.

- Formalised process for performing risk assessments and contingency planning both in the context of subject safety and resource management
- Established Risk Management Plan or equivalent due diligence procedures
- Examines the site's procedures for assessing risks:
  - From trial documents such as the Investigator's Brochure
  - To vulnerable patients
  - To identify medical emergencies

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# Example evidence requirements

- ✓ Risk Assessment and Management Plan template or equivalent checklist/ documentation
  - ✓ previously completed risk assessments (if applicable)
- ✓ Dose escalation/de-escalation assessment and implementation
- ✓ Safety management and reporting plan template
- ✓ Feasibility
  - ✓ process of assigning resources against protocol requirements
- ✓ process of assigning site responsibilities
- ✓ data review and risk decision making logs
  - ✓ Templates, email documentation, team and leadership meeting minutes

# 4. Research Team

**Research Team**

Appropriate experience and training

- Assess site governance procedures to ensure site staff are appropriately qualified
- Evidence of an appropriately composed, managed and led study team with the relevant collective knowledge to meet specific study requirements.

# Example evidence requirements

- ✓ Resource management plan with evidence of expertise (training, courses, studies, experience, etc.) and training plans
  - ✓ Minimum staffing requirements, adjustment by study design (overnight, intensive monitoring visits, out of hours etc)
- ✓ Staff training records and/or training matrix documenting training completion including GCP and emergency training
- ✓ Management oversight - training compliance review including regular competency assessments for routine procedures
- ✓ CVs, certifications and qualifications for all trial personnel
  - ✓ Job descriptions are important to understand role and experience required
- ✓ Site delegation logs (template and written process)
- ✓ Assessment process for visiting researchers
- ✓ Mentoring process: 1:1, on call support, shadowing…
  - ✓ Meeting minutes, email chains, site roster (junior/senior)

# 5. Facilities and Emergency management

**Infrastructure**
Appropriate resources to conduct trials

**Emergency Management**
Ability to respond to emergencies

- Adequate infrastructure and resources to conduct clinical trials and respond to medical emergencies.
- Sufficient emergency trolleys (or acceptable alternative) to ensure easy and rapid access.
- The emergency trolley contents should reflect current guidelines to ensure staff locate required items on the trolley.

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# Example evidence requirements

- ✓ Hospital accreditation for sites within Public Health Organisations (PHOs)
- ✓ On-site audit of facilities and equipment
  - ✓ Documentation for testing procedures
- ✓ Mock emergency scenarios performed and/or documented evidence of experienced emergency scenarios
- ✓ Life support training with standard refresher frequency (as appropriate).
- ✓ Third party - Service Level Agreement (SLA)/contract if applicable
- ✓ Operational procedures and/or templates
- ✓ 24hr medical cover for participants
  - ✓ staff roster, procedures, participant contact card templates or equivalent
- ✓ Participant database (if kept)



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# SOPs, work instructions and documentation

" ...if it is not documented, it didn't happen"

- Standard Operating Procedures (SOPs) **or equivalent** ensure a robust Site Quality Management System is in place
- Provide consistency
- Quality control measures

→ QRS can assist in identifying gaps in the current suite of process documents at site



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# Session 3:

# Quality Recognition Scheme (QRS) operation and application process

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# QRS Operation: eligibility and schedule

## Eligibility

- Based in NSW
- May be public or private with experience conducting clinical trials*
- Demonstrated GCP compliance
- Current control documents such as Standard Operating Procedures (SOPs)

## The Audit Schedule

- Up to 9 trial units across three rounds annually (Full recognition)
- Selection based on expressions of interest
- Site prioritisation

## Risk-based prioritisation

- Trial profile
- Access to tertiary services/infrastructure
- Emerging sites
- Population groups

*further expansion of the QRS to assist sites that are yet to perform clinical trials and in the early establishment phase of the trial unit is planned.



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# QRS capability building initiative - Partial and Full Recognition available

**Full recognition** = meeting criteria for 5 standards

- Certificate, three-year recognition cycle
- Recommend for established sites

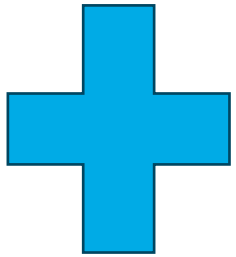
**Partial recognition** = standards completed in blocks

- Aim to receive full recognition over an extended period
- Encourage establishing sites to participate
- Suitable schedule will be determined

# QRS assessment overview: Site audit

A complete site assessment involves a desktop review and on-site audit

| Desktop review | On-site audit |
| --- | --- |
| • Off-site review<br>• SOPs, WIs, supporting evidence<br>• Assessor planning | • Operational review<br>• Process verification<br>• Staffing model<br>• Staff expertise |



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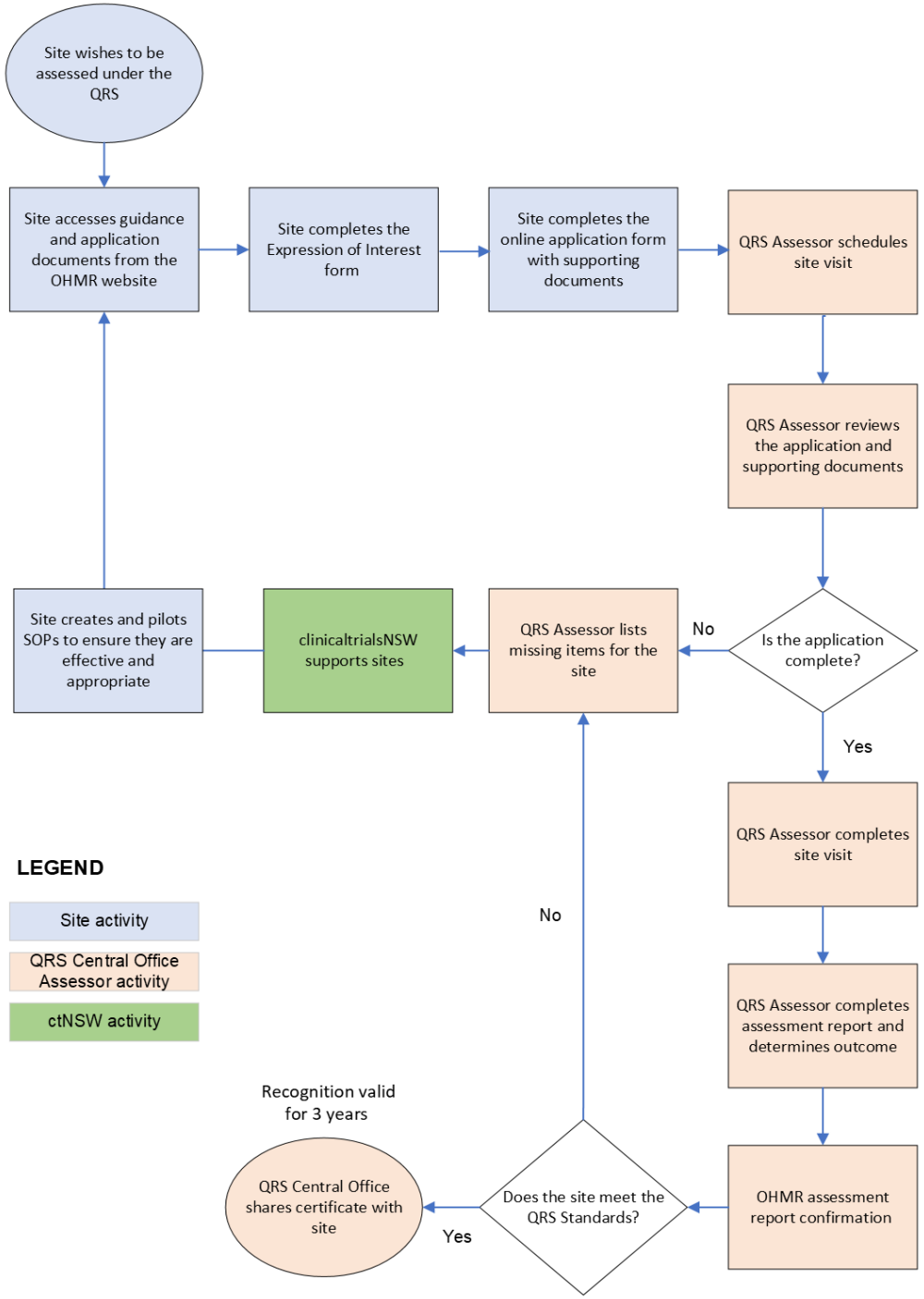
# QRS process flow

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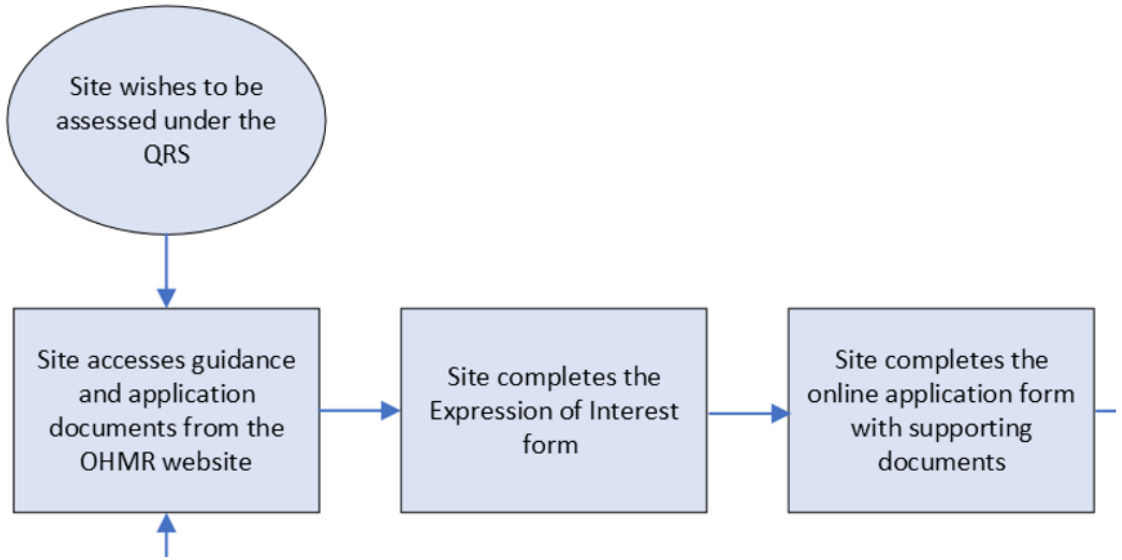
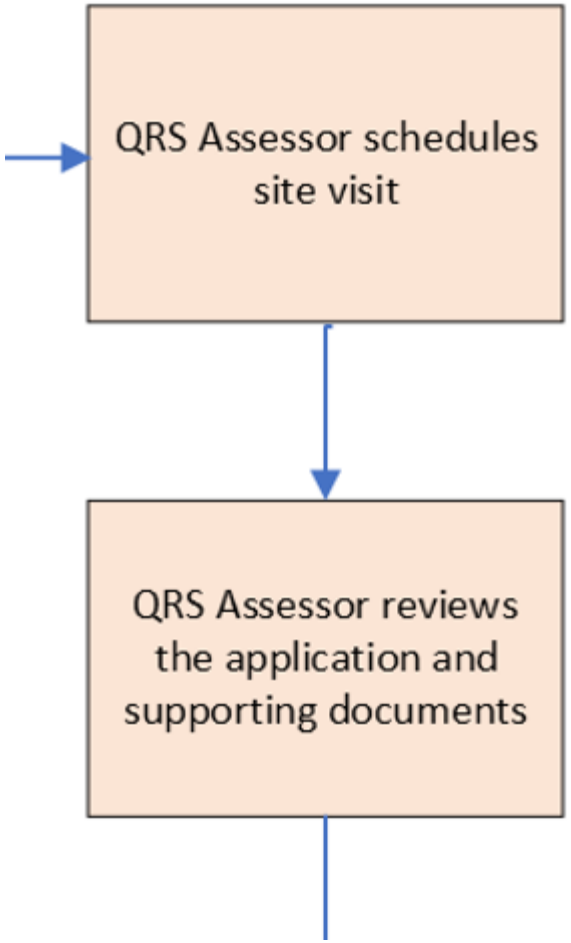
# QRS process flow



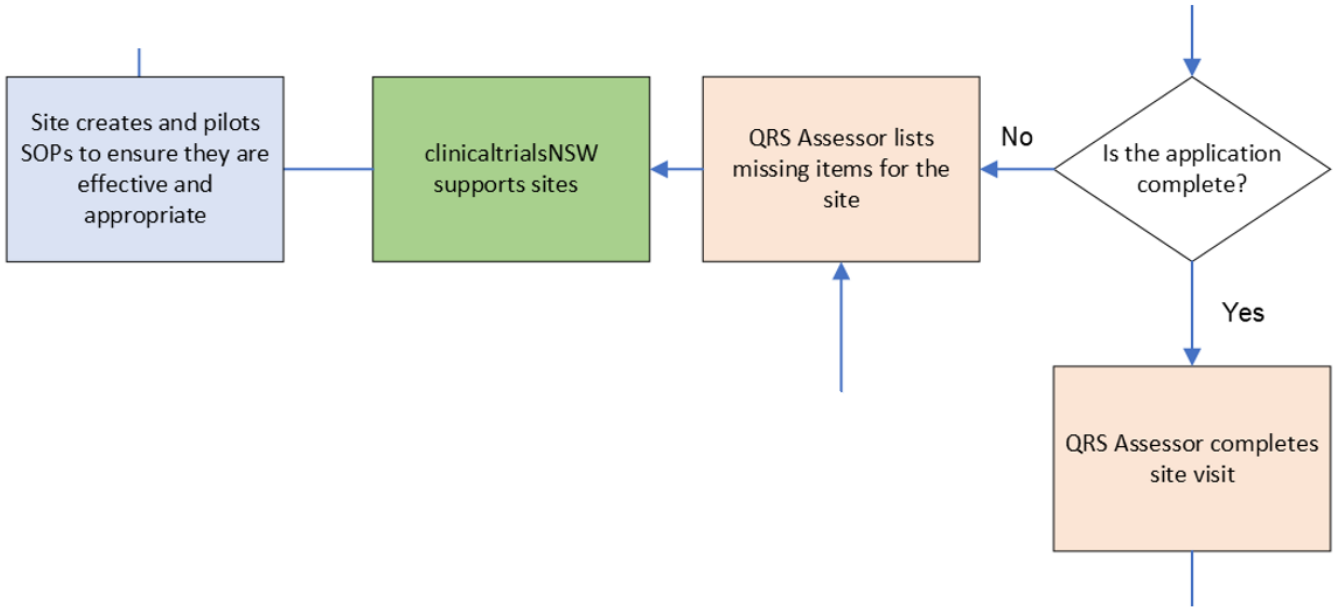

- EOI form – all rounds in 2025
- Application guidance and high-level standards can be found on the QRS website
- Application form will be sent to sites selected to participate in the upcoming round
- The Application form is completed in REDCap

# QRS process flow



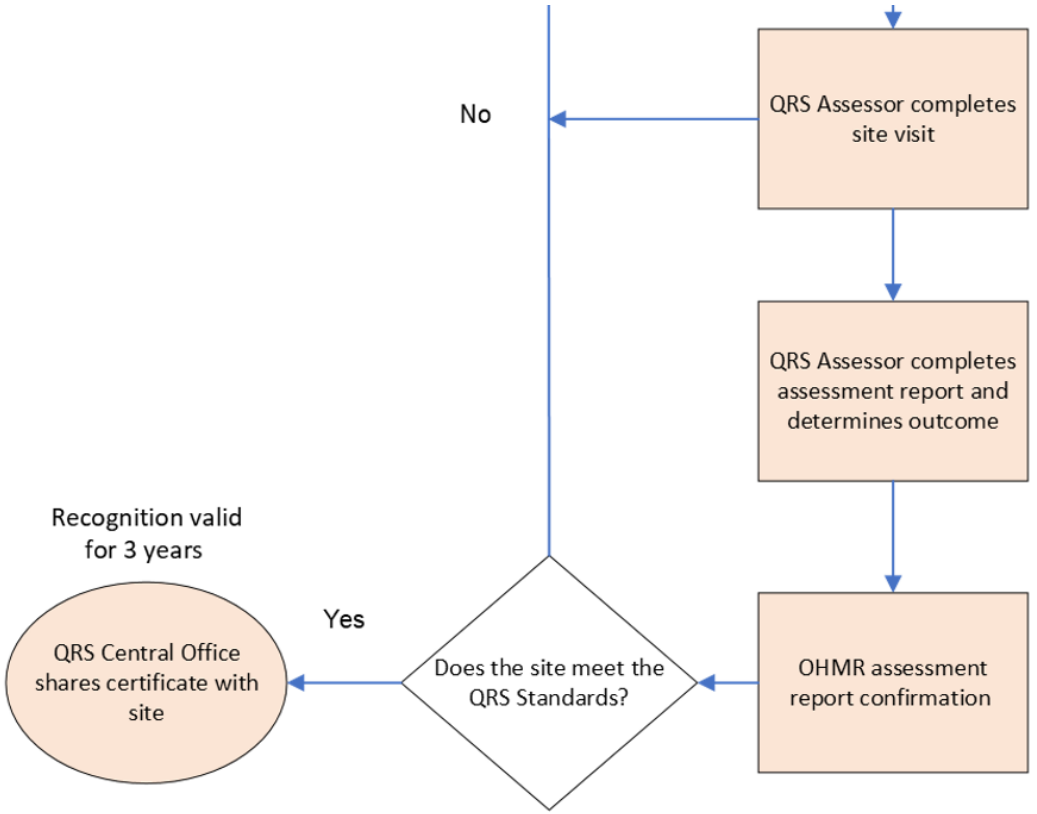

- On site audit scheduled
  - Minimum 1-day visit
- Application form review will determine visit
- When considering agenda, ensure appropriate team are available for agenda

# QRS process flow




- QRS Central Office and clinicaltrialsNSW will provide support for trial units
- Toolkit is being developed and will be available on the QRS website

# QRS process flow




- On site audit
- Initial feedback
- Assessor may request additional or clarification of information post visit
- Final report provided to site in 2 weeks

# Three-year recognition cycle

- Trial units will be notified of upcoming end of recognition cycle.
- Trial units will be required to complete and submit an updated application form in advance of the end of recognition cycle.
- Units are required to submit to the QRS Central Office any significant changes or variations within this 3-year period.
  - Relocation of unit or facilities
  - Significant changes in systems
  - Change in key personnel (leadership team – overall responsibility of trial unit etc)

# QRS Key Personnel

## Assessors

- From Office for Health and Medical Research
- Background in clinical trials
- Training required before conducting audits
  - Good Clinical Practice certification (required)
  - Lead Auditor in Quality Management Systems (ISO9001:2015) (required)
  - Clinical Research Auditing certification program (recommended)
  - Diploma of Quality Auditing (recommended)
- Ensure they are equipped to conduct robust assessments and provide valued findings

## Expert Advisory Panel

- Advise QRS central office
- To ensure program impartiality
- Provide areas of expertise as needed

# QRS key takeaways

- Creates an enabling environment for high quality trial conduct
- Provides consistency through a single set of quality standards for trial units across the State
- Educative, capability building role for the sector
- QRS assists sites in preparation for mandatory national clinical trial regulatory schemes
  - Identify improvement areas
- Be prepared for changes to international standards: GCP
- Free and voluntary, open from February 2025
- Recognised trial units will be published on the OHMR website

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# Next steps and key dates

| | Open | Close |
|---|---|---|
| **Expression of Interest** (all three rounds) | 10 December 2024 | Round 1 – 09 January 2025<br>Round 2 – 25 April 2025<br>Round 3 – 08 August 2025 |
| **Applications** Round 1 | 13 January 2025 | Based on visit dates |
| | | |

- Important dates and further updates will be listed on the QRS website: www.medicalresearch.nsw.gov.au/quality-recognition-scheme
- QRS will be available from February 2025

**Contact the QRS central office**: MOH-QRS@health.gov.au

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# Q&A

## Thank you for attending

Contact us: MOH-QRS@health.nsw.gov.au

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