2021

HEALTH+MEDICAL RESEARCH

Rural, Regional and Remote Clinical Trials Program

Guidelines for Rural, Regional and Remote Clinical Trials Support Unit Expression of Interest

NSW GOVERNMENT

NSW Health

1 Reserve Rd

St Leonards NSW 2065

(02) 9391 9228

www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

Further copies of this document can be downloaded from the NSW Health website: www.medicalresearch.nsw.gov.au

SHPN: (OHMR) 210066

Contents

Abbreviations

CRO	Clinical Research Organisation
EOI	Expression of Interest
LHD	local health district
MMM3-7	Modified Monash Model (areas classified MM3-7 are rural or remote)
MRFF	Medical Research Future Fund
NHMRC	National Health and Medical Research Council
OHMR	Office for Health and Medical Research
KA	Key Activity
RRR CT Program	Rural, Regional and Remote Clinical Trial Program
R_3CTSU	Rural, regional and remote clinical trial support unit
SME	Small and medium-sized enterprises

Contact Information

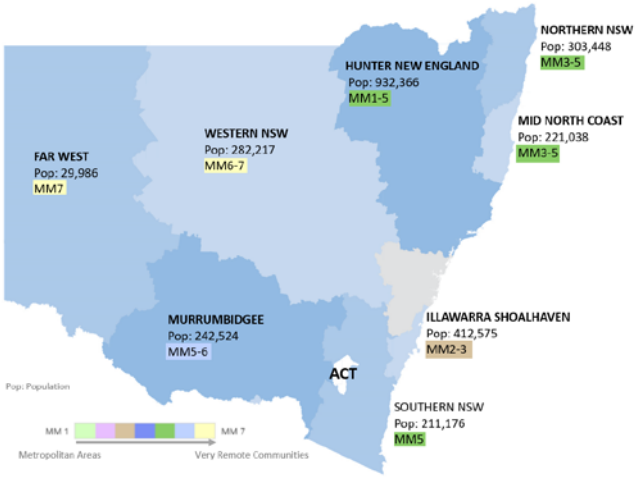
Please contact clinicaltrialsNSW, The Office for Health and Medical Research, at clinicaltrialsNSW@health.nsw.gov.au for any queries related to the Rural, Regional and Remote Clinical Trials Support Unit Expression of Interest or the Rural, Regional and Remote Clinical Trial Program generally.

Section 1: Background

NSW Health is focused on providing researchers, clinicians, managers and policy makers with the tools they need to translate research into innovative policy and practice to create healthier communities and deliver better patient care. clinicaltrialsNSW is an initiative of the Office for Health and Medical Research (OHMR) to enable clinical trial capacity, capability and collaboration across NSW and provide equity of access to innovative healthcare to our NSW communities.

The NSW Rural, Regional and Remote Clinical Trial Program (RRR CT Program) is funded under the 2019 Medical Research Future Fund (MRFF) National Critical Infrastructure Initiative – Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant. The RRR CT Program project plan, *Improving access to innovative healthcare in rural, regional and remote NSW and ACT* is available here.

The RRR CT Program is managed through clinicaltrialsNSW, OHMR, NSW Health. A Key Activity of the Program is the establishment of a network of up to three regional, rural and remote clinical trial support units (R_3CTSUs) across all local health districts (NSW) and health services (ACT) covering MMM3-7 populations (see NSW Health classification of rural and regional local health districts).



For the purposes of this Program, a clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. (WHO). Commercial trials are those where the Sponsor is a commercial entity such as a multinational company, Clinical Research Organisation (CRO) or small-medium enterprise (SME). Non-commercial trials are those where the Sponsor, for instance is an LHD or Collaborative Trials Group, is not a commercial entity, and/or where funding is primarily provided through a non-commercial source such as NHMRC or MRFF grant funding or philanthropic sources.

Section 2: Call for Expressions of Interest

NSW Health invites LHDs, and ACT health services covering MMM3-7 populations to apply for funding to establish and implement a R_3CTSU in up to three clusters covering the northern, western or southern NSW/ACT region.

Each cluster must be representative of all local health districts (NSW) and health services (ACT) within these regions. **Each Host Organisation, either an LHD (NSW) or health service (ACT), may apply for funding up to $6 million over 4 years per region.** The maximum funding available for the network of R3CTSUs in up to three clusters is a total of up to $18 million over 4 years.

Eligible Host Organisations and their partners will be responsible for submitting an expression of interest, which includes a proposal for the R_3CTSUs addressing two key areas:

1. Demonstration of the clusters **current clinical trial capacity, capabilities and collaborative relationships.**
2. A proposal outlining **how the R_3CTSU will be developed and delivered** within the cluster in line with KA4 of the RRR CT Program project plan and the responsibilities outlined in Section 4 of these Guidelines, leveraging and building on current capacity and capabilities and clearly demonstrating strong collaboration.

NSW Health will determine the funding amount awarded based on several factors, including but not limited to population covered, clinical trial portfolio, potential for growth, and clinical trial support unit staffing and infrastructure required. The level of funding will not be fixed but will be reviewed annually

based on performance and could be increased or decreased.

Preference will be given to agencies based in rural, regional and remote areas, and which have clear links to clinical trials delivery expertise.

These guidelines provide information about the expression of interest application procedure, selection process, as well as reporting and evaluation requirements. The guidelines should be read in conjunction with the RRR CT Program project plan – *Improving access to innovative healthcare in rural, regional and remote NSW and ACT* prior to completing the Expression of Interest.

For any queries please contact clinicaltrialsNSW@health.nsw.gov.au.

Applicants are strongly encouraged to consult with clinicaltrialsNSW to discuss their approach, particularly regarding governance and sustainability, to ensure alignment with the RRR CT Program.

Section 3: The vision: A rural, regional and remote clinical trial support network delivering a growing and diverse clinical trial portfolio

clinicaltrialsNSW, OHMR is responsible for delivery of the Program to NSW Health and the Commonwealth. To limit duplication and fragmentation, the R3CTSUs will be required to work closely with clinicaltrialsNSW to ensure successful operationalisation of the Program Key Activities and delivery of the Program intended outcomes. R3CTSUs will also be required to align with the broader continuous improvement initiatives of clinicaltrialsNSW across the State.

3.1 Program Key Activities

1. Developing decentralised clinical trials capacity and capability - *delivering clinical trials directly to the community*
2. Delivering locally through rural, regional and remote clinical trial support units - *supporting and developing the local workforce*
3. Clinical trial awareness, engagement, recruitment and retention - *involving communities in clinical trials*
4. Professionalising clinical trial services - *conducting trials to international best practice standard*
5. Program Evaluation

3.2 Program Intended Outcomes

- Promote **equity of access** to novel therapies through clinical trials **relevant to the needs** of patients in our rural, regional and remote communities
- Deliver more **trials** with increased **patient recruitment** and **clinician participation**
- Improve the **speed and coordination** of clinical trials and maintain high **quality** trial conduct
- Develop a local, clinical trial capable **workforce**
- Ensure **sustainability** of a rural, regional and remote clinical trials network.

NSW Health is interested to receive EOIs that outline innovative approaches to clinical trial strategy which develop the current site-centred, individual model of trial delivery to a maturing, interconnected trial network that utilises economies of scale and seeks to embed clinical trials in core clinical care delivery or public health in any setting.

The R3CTSUs will be responsible for facilitating and delivering clinical trials across a predefined geographical area, and collaborating across clusters to support clinical trials in rural, regional and remote NSW more generally.

In the implementation of the Program Key Activities, a R3CTSU may be asked to lead on a specific project or pilot a specific initiative. A R3CTSU may also lead a specific responsibility of behalf of the network eg: business development activities.

Section 4: R3CTSUs Responsibilities

In addition to partnering with clinicaltrialsNSW to ensure successful operationalisation of the Program Key Activities and to support delivery of the Program intended outcomes, each R3CTSU will be responsible for:

1. **Growing the clinical trials portfolio in their respective cluster** including increasing the
    a. number of clinical trials
    b. range of therapeutic areas in which trials are conducted
    c. number of trials sites

d. community awareness of clinical trials and the number of participants enrolled in trials
e. range of trial types by Sponsor – commercials trials (multinational and SME Sponsors) and non-commercial trials (Collaborative Group trials, Investigator-initiated trials and other Sponsor types)
f. range of trial delivery methods – face-to-face, teletrials, out-of-hospital visits, primary care and other decentralised trial modalities

2. **Increasing the return on investment for clinical trials and the value proposition of the trial portfolio for the health system and for Sponsors**, including:
    a. collating the contract value of the current clinical trials portfolio within the cluster
    b. developing financial acumen of the trial workforce to support realisation of contract value

3. **Supporting trial administration activities to enable Sites to deliver on trial execution, participant consent, enrolment, study visits and patient care**, including:
    a. trial start-up activities such as feasibility assessments, budget development and CTRA execution, HREC and Site-specific Assessment applications, CTN and CTA submissions, essential document collection and Site activations,
    b. supporting/coordinating participant recruitment activities including recruitment campaigns and pre-screening services to ensure contracted enrolment targets are met
    c. Ongoing administration such as HREC and SSA reporting, SAE reporting and deviation reporting
    d. Close-out activities such as TMF review and archiving

4. **Supporting quality conduct of clinical trials including**;
    a. maintaining current working knowledge to ensure all trials are conducted in accordance ICH-GCP, ISO14155, National Health and Medical Research (NHMRC) guidelines, relevant Australian and NSW laws and regulations, and Standard Operating Procedures (SOPs).
    b. Providing trial monitoring and trial auditing services for non-commercial trials
    c. building and continuously developing a network of trained and skilled staff based directly in R_3 areas including providing a pool of trial staff to support developing or at-risk sites or trials
    d. specifically developing Lead Investigator expertise within R_3 areas so that trials can increasingly be conducted in R_3 areas and designed for the needs of R_3 communities.
    e. supporting the development, review and amendment of policies and SOPs to ensure compliance with relevant laws, regulations and guidelines.
    f. Preparing sites for the ACSQHC Clinical Trial Governance Framework and the NSW Health Early Phase Clinical Trial Framework

4.1 Timeframe

At a minimum and in line with the Milestones in the RRR CT Program project plan, it is expected the three R3CTSUs will be fully resourced and operational by January 2022. The Program will conclude in June 2025 and it is expected the three R_3CTSU will have a sustainability model in place by that time.

Section 5: Eligibility criteria

Applications must meet ALL eligibility requirements:

5.1 Host Organisation requirements

Up to three R_3CTSUs will be established covering northern, western and southern NSW/ACT, and must be representative of the local health districts (NSW) and health services (ACT) covering MMM3-7 populations within these areas.

- A single Host Organisation must lead the EOI and manage the proposed R_3CTSU. The Host Organisation must be a NSW local health district covering MMM3-7 populations or ACT health service supporting MMM3-7 populations

(see NSW Health classification of rural and regional local health districts).

- The Host Organisation will be required to justify why they should lead the R3CTSU based on the MMM3-7 classification in the EOI.
- The Host Organisation will enter into an agreement with OHMR to deliver the outcomes of the Program and will be responsible for managing the Program in partnership with clinicaltrialsNSW, OHMR and reporting Program milestones and deliverables to clinicaltrialsNSW, OHMR.
- The Host Organisation must identify the local health districts (NSW) and health services (ACT) to be included within the cluster and provide justification for their inclusion based on the MMM3-7 classification in the EOI.
- R3CTSU must be representative of the local health districts (NSW) and health services (ACT) covering MMM3-7 populations within these areas.
- the R3CTSU can be co-located across the Cluster.
- the R3CTSU must support all local health districts (NSW) and health services (ACT) within the Cluster.

The following organisations are out of scope as Hosting Organisations for the R3CTSU EOI, but may be considered as partnering organisations in proposals:

- Private organisations
- Advanced Health Research and Translation Centres/Centres for Innovation in Regional Health (AHRTC/CIHR)
- Medical Research Institutes
- Universities
- Non-government organisations

Inclusion of Partner Organisations in the Proposal is optional. Partner organisations must clearly support a specific Cluster responsibility/ies. Partner organisations must not duplicate partner responsibilities already identified in the Program Key Activities.

5.2 Clinical Trials Champion/Research Director

- An LHD Research Director or a Clinical Trials Champion within a cluster and nominated by the Host Organisation should lead the development and submission of the EOI. This individual will be responsible for delivery of the Program on behalf of the Host Organisation. The role can be funded within the Program for up to 0.1-0.2 FTE. It can be co-located within a Cluster.

5.3 Submit a complete EOI

- the Host Organisation must submit a complete EOI with relevant attachments, including certification by the Chief Executive of the Host Organisation.
- the Chief Executive of the Partner local health districts (NSW) and/or health services (ACT) must also co-sign the application, noting the contents of the Proposal.
- By certifying/co-signing the application, the partner LHD (NSW) and/or health service (ACT) Chief Executives are agreeing to support the proposed model of trial delivery, the R3CTSU responsibilities and the associated outcomes.
- Partner organisations that are not a local health district (NSW) /health service (ACT) must provide a letter of support signed by the CEO or Managing Director.

Section 6: Selection Criteria

1. **Demonstrated evidence of current clinical trial capacity, capabilities and collaborative relationships within the Cluster (40%)**

This criterion relates to the current actual state of clinical trials in the proposed cluster LHDs (NSW)/ health services (ACT) with relevance to MMM3-7 areas.

Questions relating to this component of the Selection Criteria must be completed in the excel template provided.

1.1. Demonstrates a strong current governance structure for managing clinical trials (commercial and non-commercial). The clinical trial governance structures of cluster LHDs (NSW)/ health services (ACT) should be described, and diagrams provided.

1.2. Demonstrates that current staffing for delivering clinical trials (commercial and non-commercial) within the Cluster are established.

1.3. Demonstrates that current infrastructure for delivering clinical trials within the cluster is established. A description of office space, clinic space and supporting infrastructure should be provided.

1.4. Demonstrates a track record in the delivery of clinical trials (commercial and non-commercial) within the Cluster. Trial portfolio for the last 3 years should be provided. Any experience in the delivery of teletrials or decentralised trials within the cluster should be also be clearly described.

1.5. Demonstrates strong existing collaborations that directly benefit clinical trials (e.g. other local health districts in the cluster, academic centres, sector bodies such as ACTA, commercial sponsors and consumer organisations).

2. Proposal for the development and delivery of the Cluster R_3CTSU (60%)

This criterion relates to Key Activity 4 of the Project Plan and Section 4 of these Guidelines (R_3CTSU Responsibilities). Criteria must be addressed in sufficient detail and supported by a detailed budget using the EOI form provided.

2.1. Identifies areas of unmet needs within the cluster in sufficient detail

2.2. Clearly articulates how development and delivery of the RRR CT Program through the R_3CTSU will tangibly benefit their rural, regional or remote community/ies. Explains how areas of unmet needs within the cluster will be addressed and how funding will be directed to MMM3-7 areas

2.3. Considers equity of access by researchers and potential participants to clinical trials within the Cluster

2.4. Proposes how the R_3CTSU will leverage *and build on* existing capacity, capabilities and collaborative relationships to deliver the R_3CTSU responsibilities, specifically

2.4.1. Proposes a strong and practical governance structure for the R_3CTSU across the LHDs (NSW) and/or health services (ACT) in the Cluster. Includes evidence of partnerships where appropriate and explains how those partnerships will add value to the R_3CTSU in supporting the R_3CTSU responsibilities.

2.4.2. Proposes an appropriate staff structure for the R_3CTSU and Cluster

2.4.3. Proposes appropriate infrastructure (office and clinic space, etc) for the R_3CTSU and Cluster

2.5. Proposes a model for collaborating and communicating within the R_3CTSU Cluster and with other R_3CTSUs to create a rural, regional and remote clinical trials network across NSW.

3. Timeframe

3.1. Ability of the proposed R_3CTSU to be operational by January 2022 including a detailed plan of how this will be achieved, addressing any known risks such as staff recruitment challenges and contract/agreement execution timelines.

3.2. Demonstrated alignment with delivery of current milestones in the RRR CT Program project plan.

4. Budget

4.1. Extent to which the budget is reasonable and well-justified. The budget should include all anticipated funding required (each Host Organisation, either an LHD (NSW) or health service (ACT), may apply for **funding up to $6 million over 4 years per region**). The maximum funding available for the network of up to three clusters is a total of up to $18 million over 4 years.

For salaries, please specify the FTE, salary level, maximum on-costs (package) and anticipated increases over the 4-year Program period. Reference to costing sources should be included where possible. A detailed budget should be developed using the EOI form provided. Funding conditions are outlined in Section 8 of these Guidelines.

5. Sustainability

5.1. Proposes how the R_3CTSU will integrate clinical trials within the rural, regional and remote health system on an ongoing basis, beyond the life of the Program in sufficient detail

5.2. Proposes a model for financing and resourcing of the R_3CTSU on an ongoing basis beyond the life of the Program.

Section 7: Application and selection process

Timelines for the application and selection process are outlined below:

Stage	Date
Call for Expressions of Interest	1 February 2021

Sign off period by Chief Executive of Host Organisation and Partner local health districts	8 March 2021 – 12 March 2021
EOIs submitted to NSW Ministry of Health	15 March 2021
Assessment of EOIs by the Selection Panel	April 2021
Notification of outcomes	May 2021

7.1 Application process

1. Completing the expression of interest

The EOI involves two key components.

Component 1: Demonstration of the cluster's current clinical trial capacity, capabilities and collaborative relationships

This component of the EOI must be completed in the excel template provided.

Component 2: A proposal outlining how the R_3CTSU will be developed and delivered within the cluster in line with KA4 of the RRR CT Program project plan and the responsibilities outlined in Section 4 of these Guidelines, leveraging and building on current capacity and capabilities and clearly demonstrating strong collaboration.

This component of the EOI must be completed in the EOI form provided.

2. Obtaining Chief Executive endorsement prior to submitting the expression of interest

The Host Organisation must obtain authorisation and sign off from the Chief Executive of the Host Organisation and partner local health districts (NSW) and/or health services (ACT) in advance of the submission deadline. Additional time has been built into the EOI preparation phase to allow this to occur.

3. Submitting the expression of interest

The point of contact at the Host Organisation (listed in the EOI form) must submit the EOI form by email to clinicaltrialsNSW@health.nsw.gov.au by 5pm 15 March 2021.

The EOI is not complete until a confirmation email is received by the person submitting the EOI.

If the person submitting the EOI does not receive a confirmation email, it is their responsibility to follow up within 24 hours, by emailing clinicaltrialsNSW@health.nsw.gov.au or calling 02 9461 7120. Please do not include attachments within the follow up email.

Please save the confirmation email as this will need to be provided to NSW Health if required as evidence of submission. If an email confirming receipt of the EOI is not available, no further correspondence regarding the EOI will be entered into.

Please note NSW Health will ONLY accept:

1. Submission of the EOI by email to clinicaltrialsNSW@health.nsw.gov.au
2. EOI forms that have been endorsed by the Chief Executive of the Host Organisation and Partner local health districts (NSW) and/or health services (ACT). EOIs without a signed declaration by the Host Organisation and Partner local health districts (NSW) and/or health services (ACT) will not be reviewed. Late submission of signature pages is not permitted.
3. Files less than 20MB in size. Please note emails larger than 20MB will be blocked.

7.2 Review process

1. Eligibility check

Expressions of Interests will undergo initial review by NSW Health to ensure eligibility criteria are met.

2. EOI review

All Expressions of Interest will be reviewed against the selection criteria in Section 6 of these Guidelines by the RRR CT Selection Panel, chaired by the Executive Director, Office for Health and Medical Research, NSW Ministry of Health. The Selection Panel may contact applicants in order to clarify or confirm information in the application. Shortlisted applicants will be required to virtually present their proposal to the Selection Panel. Applicants may additionally be required to discuss their proposal to NSW Health or independent reviewers, and address any issues raised, before a final funding decision is made.

a. Recommendation to NSW Health

The review process will result in recommendations to NSW Health who will make a final decision on funded applicants and amounts. All applicants will be informed as to whether they have been awarded funding. This decision is final and may not be appealed.

b. Funding arrangements

The NSW Ministry of Health will contact the Host Organisation to establish a funding agreement between the Host Organisation and NSW Ministry of Health.

A standard, non-negotiable funding agreement will be used.

The Host Organisation will be required to report quarterly against key milestones and deliverables and provide funding acquittals as outlined in the agreement.

Funds may not be drawn down until the Funding Agreement is reviewed and certified by the Chief Executive of the Host Organisation. The admin contact of the Host Organisation, specified within the EOI, will be responsible for submitting the signed Funding Agreement to the NSW Ministry of Health.

Funding will be provided as per arrangements in the Funding Agreement.

Section 8: Funding Conditions

- R_3CTSU must be managed must by an eligible Host Organisation
- R_3CTSU must be led by a LHD Research Director or Clinical Trials Champion to be employed by the host organisation
- Funding must be expended within NSW or the ACT
- Funding can be spent on R3CTSU staff, programs, IT support, rent and associated costs for premises (office space or clinical space) directly related to the delivery of responsibilities outlined in Section 4. Costs must be reasonable and detailed in the proposal budget.
- Some funding can be allocated towards staff (e.g. resource nurses and study coordinators) for local clinical trial delivery.
- The funding must not be spent on capital works, or overheads.
- The funding cannot be spent on the execution of any individual clinical trial.
- Funding is conditional on the Chief Executive of the Host Organisation and Partner local health districts (NSW)/ health services (ACT) signing the declaration on the R_3CTSU proposal, which outlines the organisations' obligations.
- The NSW Ministry of Health reserves the right to reduce, withhold or stop funding if the Host Organisation does not achieve the milestones and deliverables outlined in the Funding Agreement.

Section 9: Reporting requirements

clinicaltrialsNSW, OHMR is responsible for delivery of the Program to NSW Health and the Commonwealth. Reporting requirements of the R_3CTSUs will align with and be used to inform the Program reporting to NSW Health and the Commonwealth.

The successful Host Organisation will enter into a Funding Agreement with NSW Health. The Funding Agreement will include a schedule for reporting detailing requirements to provide:

- a quarterly progress report demonstrating progress against milestones and deliverables
- a quarterly financial report
- a final report and final financial report following the conclusion of the term of the Program.

Reports will be reviewed by clinicaltrialsNSW and the Program Steering Committee and will be used to inform recommendations to the Executive Sponsor for continuation, change or termination of the Program or components thereof, including the R_3CTSUs and/or their funding allocation.

NSW Health reserves the right to seek any updates throughout the course of the Program, to ensure ongoing alignment with the Program objectives and priorities.

Section 10: Program monitoring, quality assurance and auditing

Program monitoring, quality assurance and auditing will be managed by clinicaltrialsNSW, OHMR and issues escalated to the Program Steering Committee

or Executive Sponsor according to the Governance Plan and other Program Plans.

Program monitoring, quality assurance and auditing will be undertaken in collaboration with the successful Host Organisations managing the R_3CTSUs. A representative from the Host Organisation may be asked to meet with NSW Health from time to time during the funding period and following the completion of the RRR CT Program. Meetings with recipients will facilitate feedback and inform the future direction of the R_3CTSU network and RRR CT Program generally.

Program monitoring, quality assurance and auditing should not be confused with Program Evaluation, which is a Key Activity of the Program and will be undertaken in collaboration with Hunter Medical Research Institute as a project partner.