HEALTH+MEDICAL RESEARCH

Improving access to innovative healthcare in rural, regional and remote NSW and ACT

NSW/ACT Rural, Regional and Remote Clinical Trial Enabling Program

NSW Health, Office for Health & Medical Research
clinicaltrialsNSW

NSW GOVERNMENT

PRAXIS Australia and clinicaltrialsNSW respectfully acknowledge Australia's First Peoples, the custodians of the lands we gather and work on. We respect their connections to lands, seas and culture and give our thanks to Elders, past, present and those paving the way for the future.

#alwayswasalwayswillbe

PRAXIS AUSTRALIA

Mission

Enhance the understanding and practice of ethical research for the benefit of the broader community

Vision

Enhance the welfare of research participants and improve the quality, efficiency and effectiveness of research and research ethics practice through education and training.

Values

Diversity. Leadership. Respect. Collegiality. Equity. Trust. Quality. Innovation.

Agenda

1. Welcome to Country
2. Speaker Introductions
3. Brief overview of the RRR CT Program and Expression of Interest for the Rural, Regional and Remote Clinical Trials Support Units
4. Purpose of today's webinar
5. Q&A session
6. Contact details for further support

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Speakers

Anita van der Meer, Manager of clinicaltrialsNSW, OHMR

Brigitte Fienberg, Policy Officer, OHMR

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NSW/ACT Rural, Regional & Remote Clinical Trial Program

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Contact List

To support NSW LHDs, ACT health services and Partner Organisations to connect with each other:

Could **all LHDs and ACT health services,** please provide **a point of contact for the RRR CT Program and their contact details to clinicaltrialsNSW@health.nsw.gov.au?**

We will publish the contact list on the Rural, regional and remote clinical trials webpage **Monday, 15 February 2021.**

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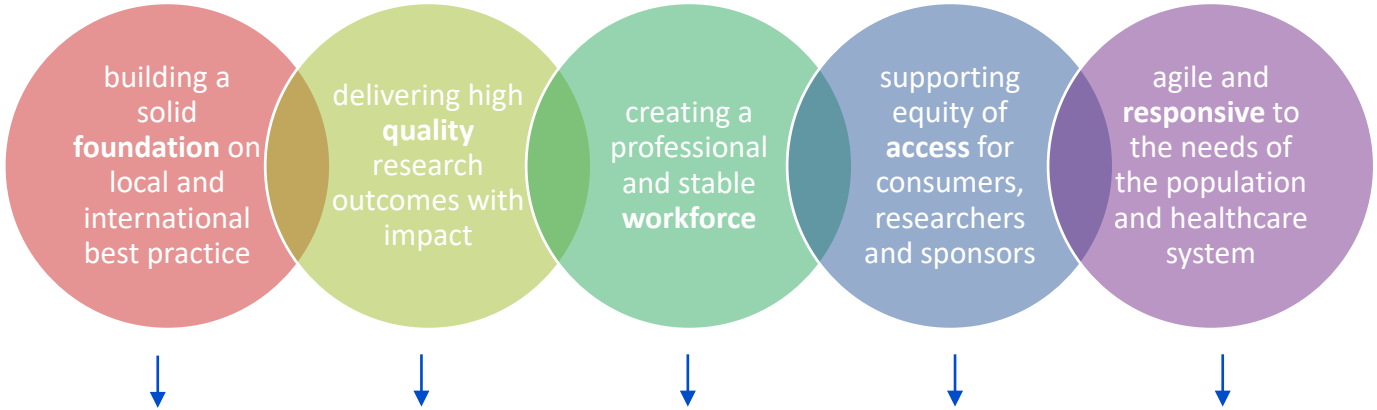
transforming clinical trials in NSW



mature, interconnected clinical trials sector
embedding research into health service delivery
providing equity of access to innovative healthcare

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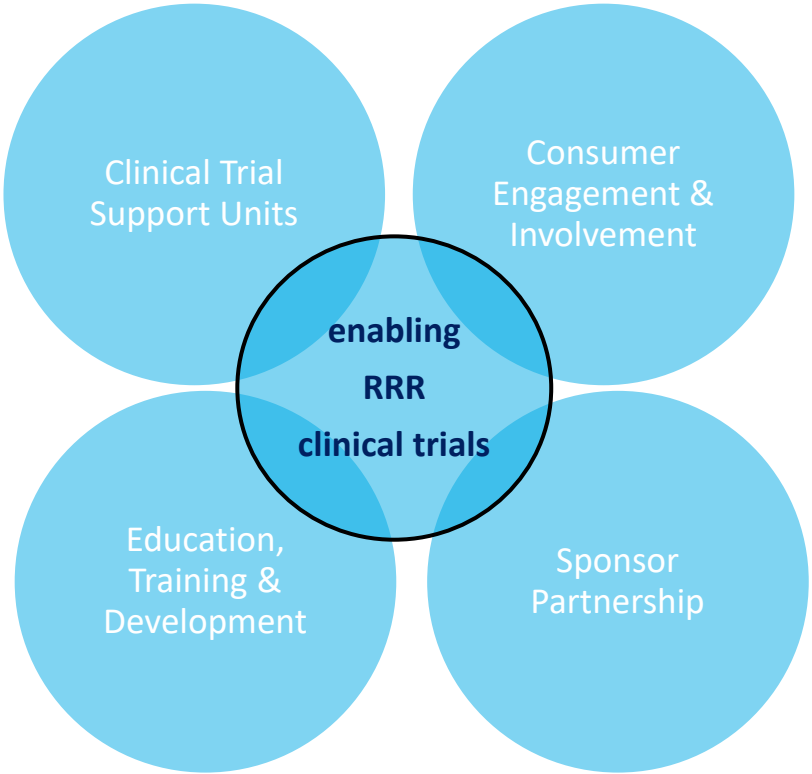
Program Vision



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RRR Clinical Trial Support Units Expression of Interest

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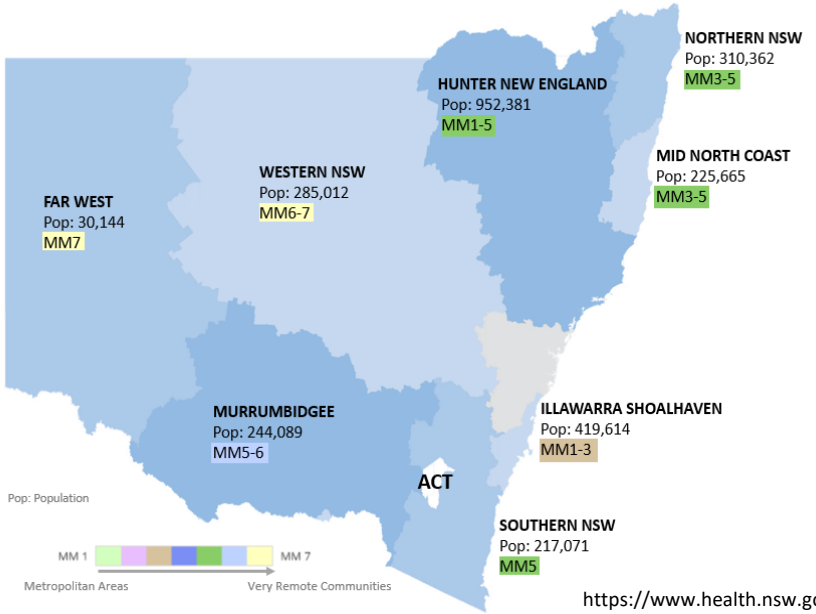
RRR Clinical Trial Support Units MMM3-7

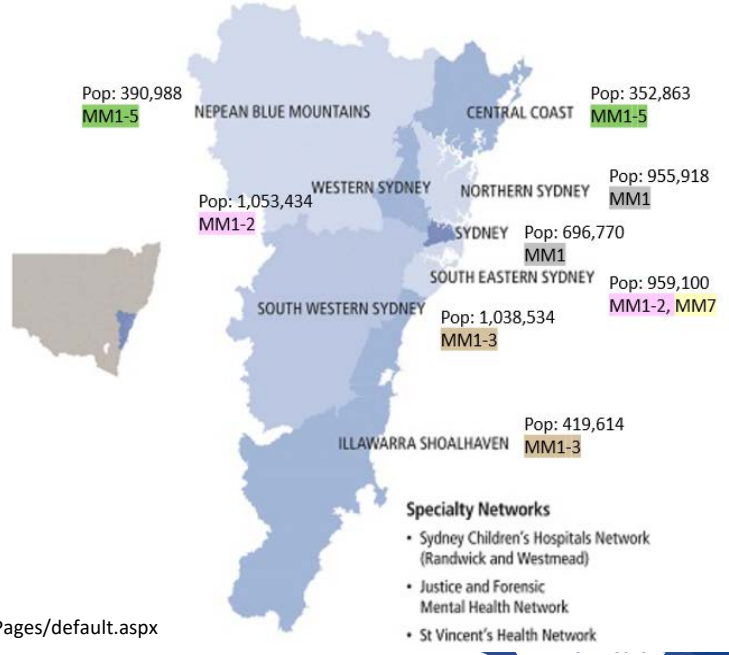
Collaborative network delivering a growing and diverse clinical trial portfolio

with increased and equitable access to clinical trials for patients in rural, regional and remote in NSW and ACT

Rural and Regional NSW LHDs



Metropolitan LHDs



https://www.health.nsw.gov.au/lhd/Pages/default.aspx

R_3CTSUs Expression of Interest

- NSW LHDs, and ACT health services covering MMM3-7 populations
  to establish and implement a Clinical Trial Support Unit
  in up to three NSW/ACT clusters covering the northern, western and southern region.
- **Funding of up to $6M over 4 years is available for each region covered in the cluster**
  $18M total (60% of MRFF award)

- clinicaltrialsNSW, OHMR is responsible for delivery of the Program to NSW Health and the Commonwealth.
- R_3CTSUs will be required to work closely with clinicaltrialsNSW to ensure successful operationalisation of the Program Key Activities and delivery of the Program intended outcomes.
- R_3CTSUs will also be required to align with the broader continuous improvement initiatives of clinicaltrialsNSW across the State.

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Purpose

To support applicants with the application process for the Rural, Regional and Remote Clinical Trials Support Unit EOI by:

- Answering questions submitted by applicants to clinicaltrialsNSW@health.nsw.gov.au
- Answering further questions related to the EOI in session

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Q & A Session

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But first a note about the RRR CT Project Plan

The Project Plan was:

- designed for submission to MRFF for the grant award, and
- is currently being updated to appropriately reflect the implementation phase of the Program.

While the Key Activities of the Program will remain largely unchanged from the Project Plan, the finer, specific detail of the Project Plan submitted to MRFF should not limit LHD clusters in their EOI for the CTSU.

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Eligibility Criteria Qs

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Eligible cluster LHDs

QUESTION:

Can metropolitan LHDs be a Host Organisation/lead applicant, partner LHD or involved in any way?

Eligible cluster LHDs

QUESTION: Can metropolitan LHDs be a Host Organisation/lead applicant, partner LHD or involved in any way?

ANSWER:

The Host Organisation/lead applicant must be:

- a NSW LHD covering MMM3-7 populations, or
- a ACT health service supporting MMM3-7 populations.

The partner LHD (NSW) or health service (ACT) within the cluster must be:

- a NSW LHD covering MMM3-7 populations, or
- a ACT health service supporting MMM3-7 populations.

Metropolitan LHDs that **do not cover MMM3-7 populations** can be a **Partner Organisation** and must provide a letter of support from the CE.

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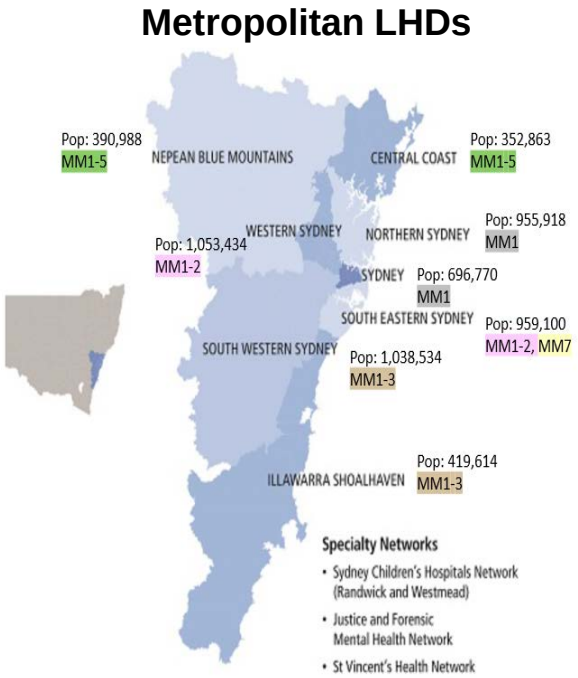
Eligible cluster LHDs

Metropolitan LHDs eligible to be a Host Organisation/Partner LHD within the cluster

Metropolitan LHDs	Population covered
Central Coast LHD	MM1-5
Nepean Blue Mountains LHD	MM1-5
South Eastern Sydney LHD	MM1-2, MM7
South Western Sydney LHD	MM1-3
Illawarra Shoalhaven LHD	MM1-3



MMM3-7 classification

QUESTION:

How do I determine whether my LHD covers MMM3-7 populations?

MMM3-7 classification

QUESTION: How do I determine whether my LHD covers MMM3-7 populations?

ANSWER:

- Please refer to the NSW Health website link in the Guidelines for classification of the rural and regional LHDs versus metropolitan LHDs
- Further information about the Modified Monash Model (MMM) can be found through this Department of Health link.
- The Department of Health's health workforce locator will help determine where a suburb sits within the classification.

Geographic location of clusters

QUESTION:

Does the cluster have to be geographically based?

Geographic location of clusters

QUESTION: Does the cluster have to be geographically based?

ANSWER:

- No the cluster does not need to be geographically based
- Seeking innovative proposals on how clusters can be arranged to meet the needs of R3 populations
- R3CTSU can be co-located or managed virtually

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Certification by partner LHDs/ACT health services

QUESTION:

Do partner LHDs (NSW) or health services (ACT) need to submit letters of support or would signature by their Chief Executive suffice?

Certification by partner LHDs/ACT health services

QUESTION: Do partner LHDs (NSW) or health services (ACT) need to submit letters of support or would signature by their Chief Executive suffice?

ANSWER: No, a signature from the Chief Executive will suffice.

Funding Agreements

QUESTION:

Will the Partner LHDs and/or ACT health services be expected to execute a formal agreement should the application be successful?

Funding Agreements

QUESTION: Will the Partner LHDs and/or ACT health services be expected to execute a formal agreement should the application be successful?

ANSWER:

- NSW Ministry of Health will enter into a Funding Agreement with the Host Organisation.
- We would encourage Host Organisations to enter into an Agreement with their Partners where appropriate.

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Funding Allocation

QUESTION:

Does the funding reside only with Host Organisation/lead applicant?

Funding Allocation

QUESTION: Does the funding reside only with Host Organisation/lead applicant?

ANSWER:

NSW Ministry of Health will:

- enter into a Funding Agreement with the Host Organisation, and
- transfer funding to the Host Organisation.

The Host Organisation is responsible for allocating the funding according to a budget approved by the NSW Ministry of Health.

Residence of staff employed in R3CTSU

QUESTION:

Do the staff need to reside/be employed by the Host Organisation/lead applicant?

Residence of staff employed in R3CTSU

QUESTION: Do the staff need to reside/be employed by the Host Organisation/lead applicant?

ANSWER: Staff employed in the R3CTSU do not need to reside or be employed in the Host Organisation, they can be co-located across the cluster.

National Registries

QUESTION:

Are National Registries out of scope?

National Registries

QUESTION: Are National Registries out of scope?

ANSWER: Yes, National Registries are out of scope but they could be a Partner Organisation for a cluster.

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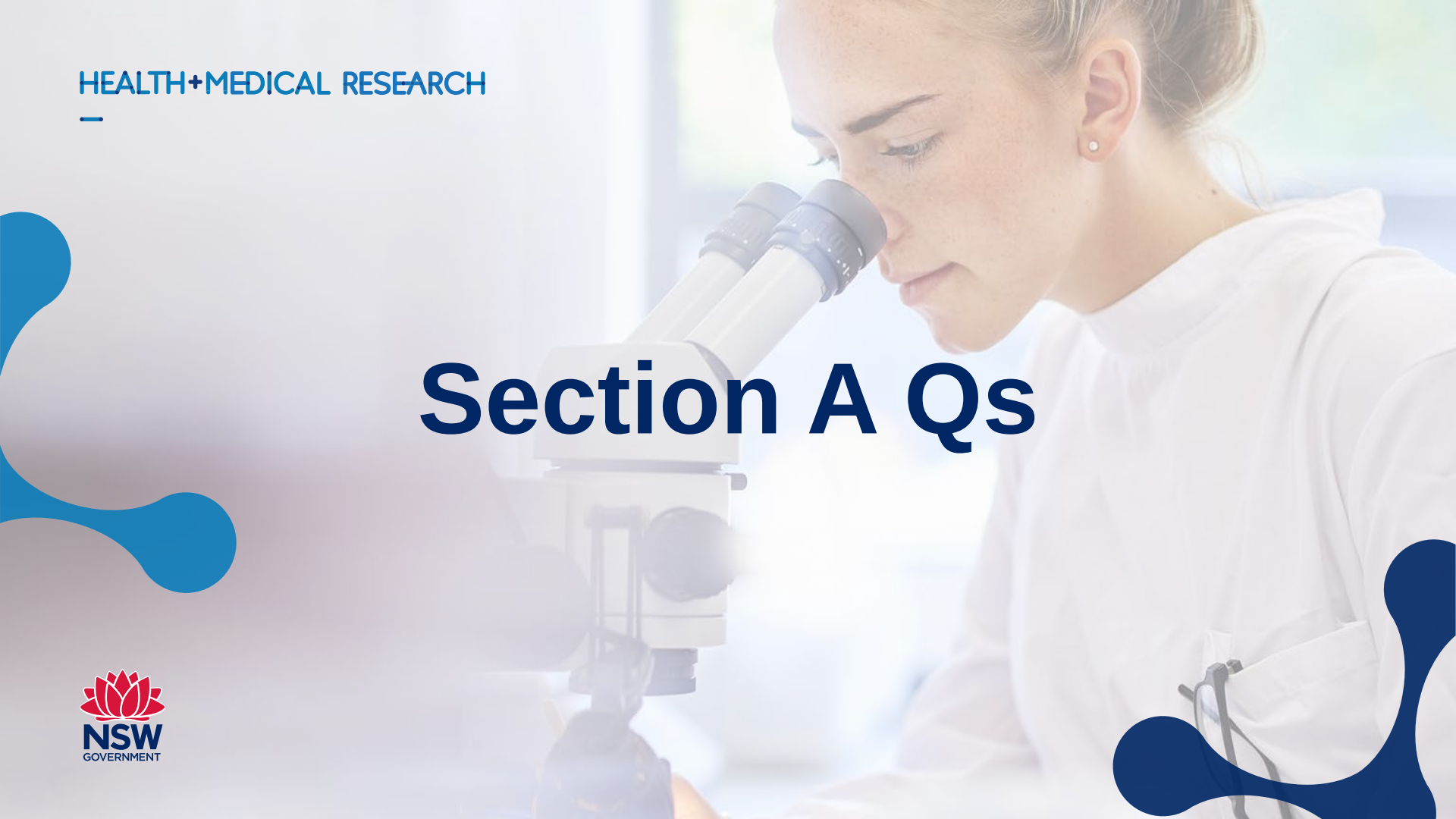
Section A Qs



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Question A3 & A5:Justification for Host Organisation and Cluster Partners

QUESTION:

Is there a word limit for question A3 and question A5, which asks applicants to justify the appointment of the Host Organisation and cluster LHDs and/or ACT health services based on the MMM3-7 classification?

Question A3 & A5:Justification for Host Organisation and Cluster Partners

QUESTION: Is there a word limit for question A3 and question A5, which asks applicants to justify the appointment of the Host Organisation and cluster LHDs and/or ACT health services based on the MMM3-7 classification?

ANSWER: There is no word limit for A3 and A5 of the EOI form.

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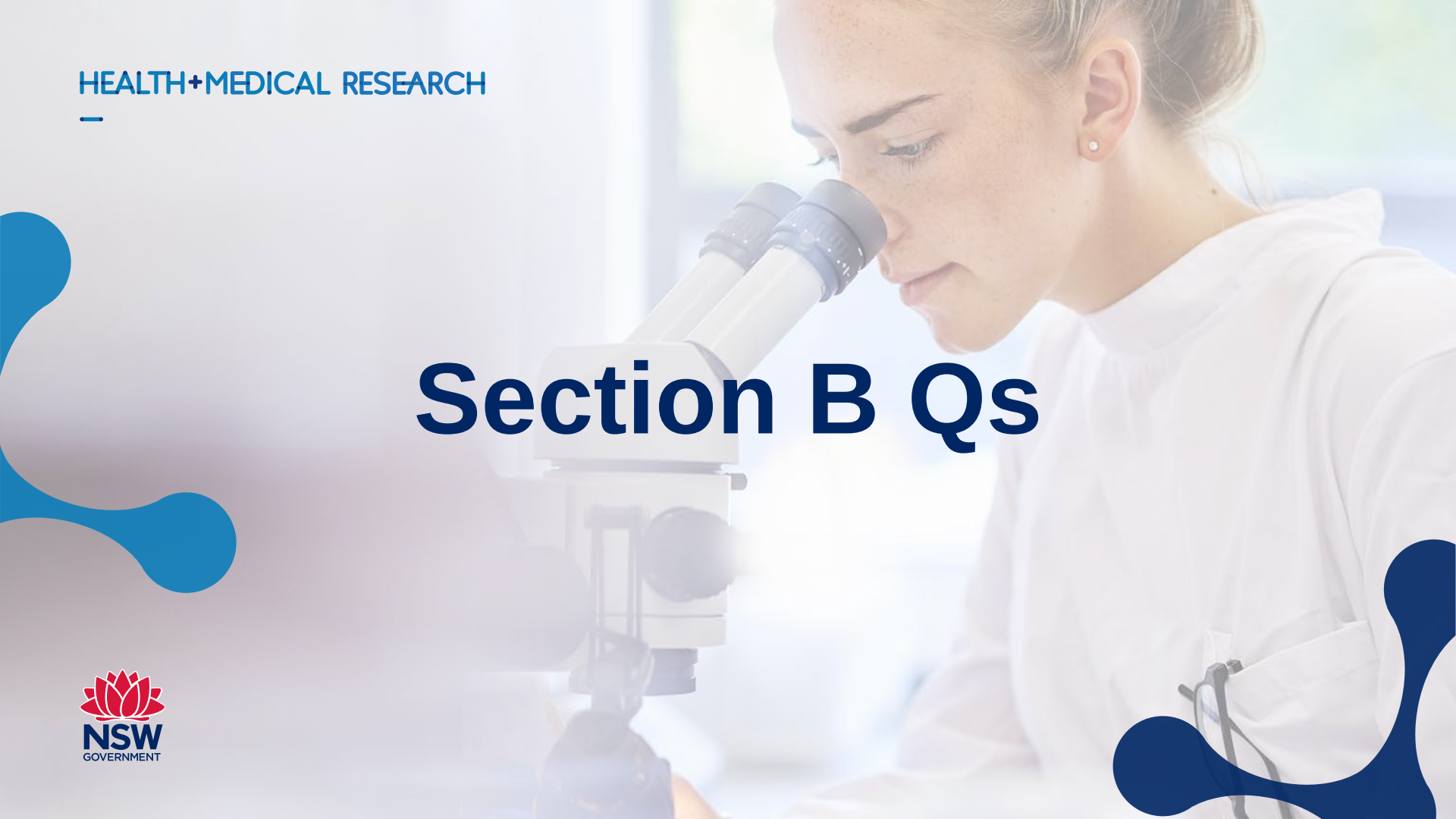
Section B Qs



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Section B: Data Collection

QUESTION:

Do we need to collect data from all trial sites within the cluster, including MMM1-2 trial sites that service MMM3-7 populations for Section B of the EOI (i.e. the data form)?

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QUESTION: Do we need to collect data from all trial sites within the cluster, including MMM1-2 trial sites that service MMM3-7 populations for Section B of the EOI (i.e. the data form)?

ANSWER:

Information provided in Section B of the EOI is required from trial sites **based in MMM3-7 areas** within:

- the Host Organisation, and
- Partner LHDs (NSW) and/or health services (ACT) within the cluster.

Data does not need to be collected from MMM1-2 trial sites for Section B of the EOI

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Section B: Data Collection

QUESTION:

Do we need to collect data from partner organisations for Section B of the EOI (i.e. the data form)?

Section B: Data Collection

QUESTION: Do we need to collect data from partner organisations for Section B of the EOI (i.e. the data form)?

ANSWER:

No, data collection is not required from partner organisations (MRIs, universities, commercial organisations, etc.) for Section B of the EOI.

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Question B1: Clinical Trials Governance Structure

QUESTION:

Do partner organisations (e.g. MRIs, universities, commercial organisations) need to be included in the current clinical trials governance structure for question B1 in the data form?

Question B1: Clinical Trials Governance Structure

QUESTION: Do partner organisations (e.g. MRIs, universities, commercial organisations) need to be included in the current clinical trials governance structure for question B1 in the data form?

ANSWER:

- **No**, partner organisations (e.g. MRIs, universities, commercial organisations) **do not** need to be included in the clinical trials governance structure for Q B1.
- Only the Host Organisation, partner LHDs and/or ACT health services within the cluster should be included in the clinical trials governance structure for Q B1.

Question B2: Staffing

QUESTION:

What is the extent of data required for staffing in question B2 of the data form and should ‘inactive staff’ be included under column J?

Question B2: Staffing

QUESTION: What is the extent of data required for staffing in question B2 of the data form and should ‘inactive staff’ be included under column J?

ANSWER:

- All clinical trials related staff must be listed for the **prior three years** (from February 2021 backwards) for Q B2
- Each staff member can only be listed once with their *current status as of today*, that being ‘active’ or ‘inactive’
- If ‘inactive’, please indicate why (e.g. secondment, redundancy, resigned, maternity leave or long service leave).

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Question B2: Staffing

QUESTION:

In addition to clinical trial delivery staff, do Investigators need to be included for current staffing in question B2 of the data form?

Question B2: Staffing

QUESTION: In addition to clinical trial delivery staff, do Investigators need to be included for current staffing in question B2 of the data form?

ANSWER: Yes please.

Question B2: Staffing

QUESTION:

What information is required in column O ‘position funded’ for question B2 of the data form?

Question B2: Staffing

QUESTION: What information is required in column O ‘position funded by’ for question B2 of the data form?

ANSWER: We are looking for the primary funding source (e.g. trial site or hospital department)

Question B3: Infrastructure

QUESTION:

How much detail and at which level should we be assessing existing supportive infrastructure for question B3 of the data form?

Question B3: Infrastructure

QUESTION: How much detail and at which level should we be assessing existing supportive infrastructure for question B3 of the data form?

ANSWER:

Highlight unmet need by identifying *current infrastructure,* including:

- office space for clinical trial staff
- clinic space to see and treat clinical trial participants, and
- trial related equipment (e.g. centrifuges, ECG machines, blood pressure monitors, calibrated weight and height measurement equipment, fridges, freezers and -20C freezers etc.)

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Question B4: Clinical Trial Portfolio

QUESTION:

Why is this level of information required for the Clinical Trial Portfolio for question B4 of the data form?

Question B4: Clinical Trial Portfolio

QUESTION: Why is this level of information required for the Clinical Trial Portfolio for question B4 of the data form?

ANSWER:

- please complete all sections of the clinical trial portfolio for Q B4 of the data form
- the track record will inform quarterly reporting and program evaluation

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Question B4: Clinical Trial Portfolio

QUESTION:

What is the definition of an “active clinical trial” for question B4 of the data form?

Question B4: Clinical Trial Portfolio

QUESTION: What is the definition of an “active clinical trial” for question B4 of the data form?

ANSWER:

- “Active clinical trials” refers to trials which are currently open i.e. the CTRA/contract has been executed and trial has not yet closed by the Sponsor with HREC – so actively enrolling, in follow up and reporting.
- Trials currently in scoping/feasibility stage or trials that have officially closed are *out of scope*

Question B4: Clinical Trial Portfolio

QUESTION:

When does the three-year timeframe start for all active clinical trials in the clinical trial portfolio for question B4 of the data form?

Question B4: Clinical Trial Portfolio

QUESTION: When does the three-year timeframe start for all active clinical trials in the clinical trial portfolio for question B4 of the data form?

ANSWER: Please work from February 2021 backwards - three years.

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Question B4: Clinical Trial Portfolio

QUESTION:

If trial sites are located in an MM1 or MM2 location, however the LHD cover/services MMM3-7 populations, do we include the data from those trial sites in MM1 or MM2 areas?

Question B4: Clinical Trial Portfolio

QUESTION: If trial sites are located in an MM1 or MM2 location, however the LHD cover/services MMM3-7 populations, do we include the data from those trial sites in MM1 or MM2 areas?

ANSWER:

- Please list trials for clinical trial sites in MMM3-7 areas only, which is shown in column M for Q B4 of the data form
- Data does not need to be collected from trial sites in MM1 and MM2 areas.

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Question B4: Clinical Trial Portfolio

QUESTION:

How important is it to include the ‘REGIS SSA reference number’ in column D for question B4 of the data form, if all other information is entered?

Question B4: Clinical Trial Portfolio

QUESTION: How important is it to include the ‘REGIS SSA reference number’ in column D for question B4 of the data form, if all other information is entered?

ANSWER: Please complete the data form in full.

Question B4: Clinical Trial Portfolio

QUESTION:

What is meant by ‘funding source’ in column S for question B4 of the data form?

Question B4: Clinical Trial Portfolio

QUESTION: What is meant by funding source in column S for question B4 of the data form?

ANSWER:

- Funding source refers to who is funding the trial.
- The funding source may be:
  - a commercial sponsor e.g. pharmaceutical company
  - a collaborative group, or
  - a grant e.g. OHMR, NHMRC or MRFF.

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Question B4: Clinical Trial Portfolio

QUESTION:

What information should be entered in column O ‘max target recruitment at this site (as per CTRA)’ for question B4 of the data form?

Question B4: Clinical Trial Portfolio

QUESTION: What information should be entered in column O ‘max target recruitment at this site (as per CTRA)’ for question B4 of the data form?

ANSWER: Maximum target recruitment per CTRA contract/agreement with the Sponsor is required.

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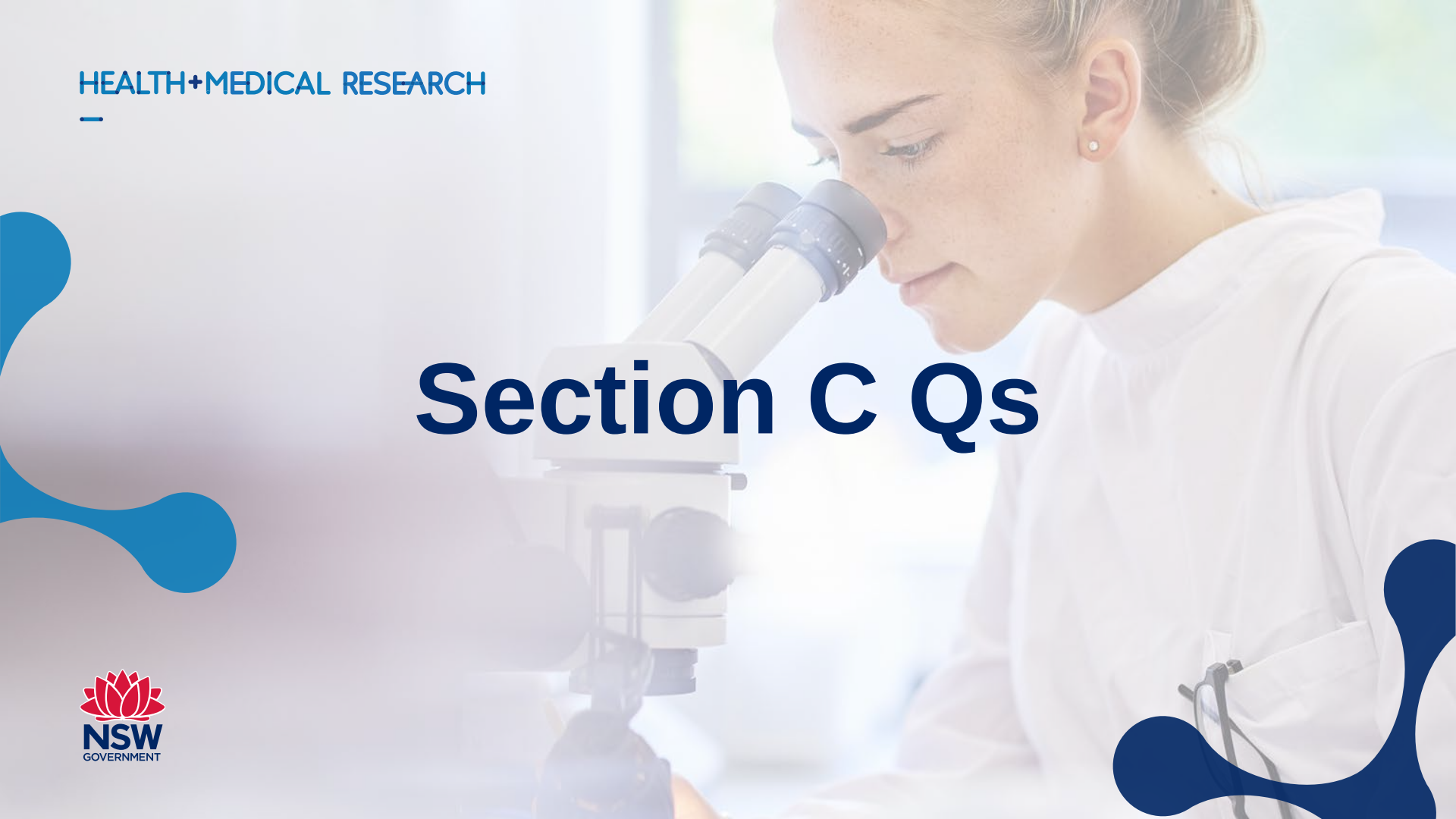
Section C Qs



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Question C1: Unmet need

QUESTION:

Can you clarify whether the question regarding unmet need is only directed towards disease types that require more research/medical needs or should we identify other unmet needs (e.g. clinical trial infrastructure, staffing etc)?

Question C1: Unmet need

QUESTION: Can you clarify whether the question regarding unmet need is only directed towards disease types that require more research/medical needs or should we identify other unmet needs (e.g. clinical trial infrastructure, staffing etc)?

ANSWER: Unmet need may refer to and is not limited to:

- research for certain disease types/ burden of disease
- infrastructure
- staffing, and/or
- capability in the delivery of clinical trials, etc.

Explain the **specific** unmet needs within the cluster.

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Question C3: Staffing for proposed R3CTSU

QUESTION:

Can you please clarify the staffing at R3CTSUs for question C3 of the EOI form. The RRR CT Program Project Plan states the following;

'…will on average be 5 full time equivalents (FTE)/CTSU:….In addition, there will be staff based outside the CTSUs in other recruitment sites, averaging initially per LHD 0.6FTE clinical nurse consultant and 0.6FTE trials assistant, and a part time clinical trial pharmacist:'

Does this mean those additional positions are not to be included/factored into the EOI?

NSW GOVERNMENT

Question C3: Staffing for proposed R3CTSU

QUESTION: Can you please clarify the staffing at R3CTSUs for question C3 of the EOI form. The RRR CT Program Project Plan states the following;

'…will on average be 5 full time equivalents (FTE)/CTSU:….In addition, there will be staff based outside the CTSUs in other recruitment sites, averaging initially per LHD 0.6FTE clinical nurse consultant and 0.6FTE trials assistant, and a part time clinical trial pharmacist:'

Does this mean those additional positions are not to be included/factored into the EOI?

ANSWER:

- All requests for staffing within the cluster must be included in Q C3 of the EOI form and the Budget (E1 of the EOI form).
- There will be no additional funding for staffing within the clusters outside of this EOI.

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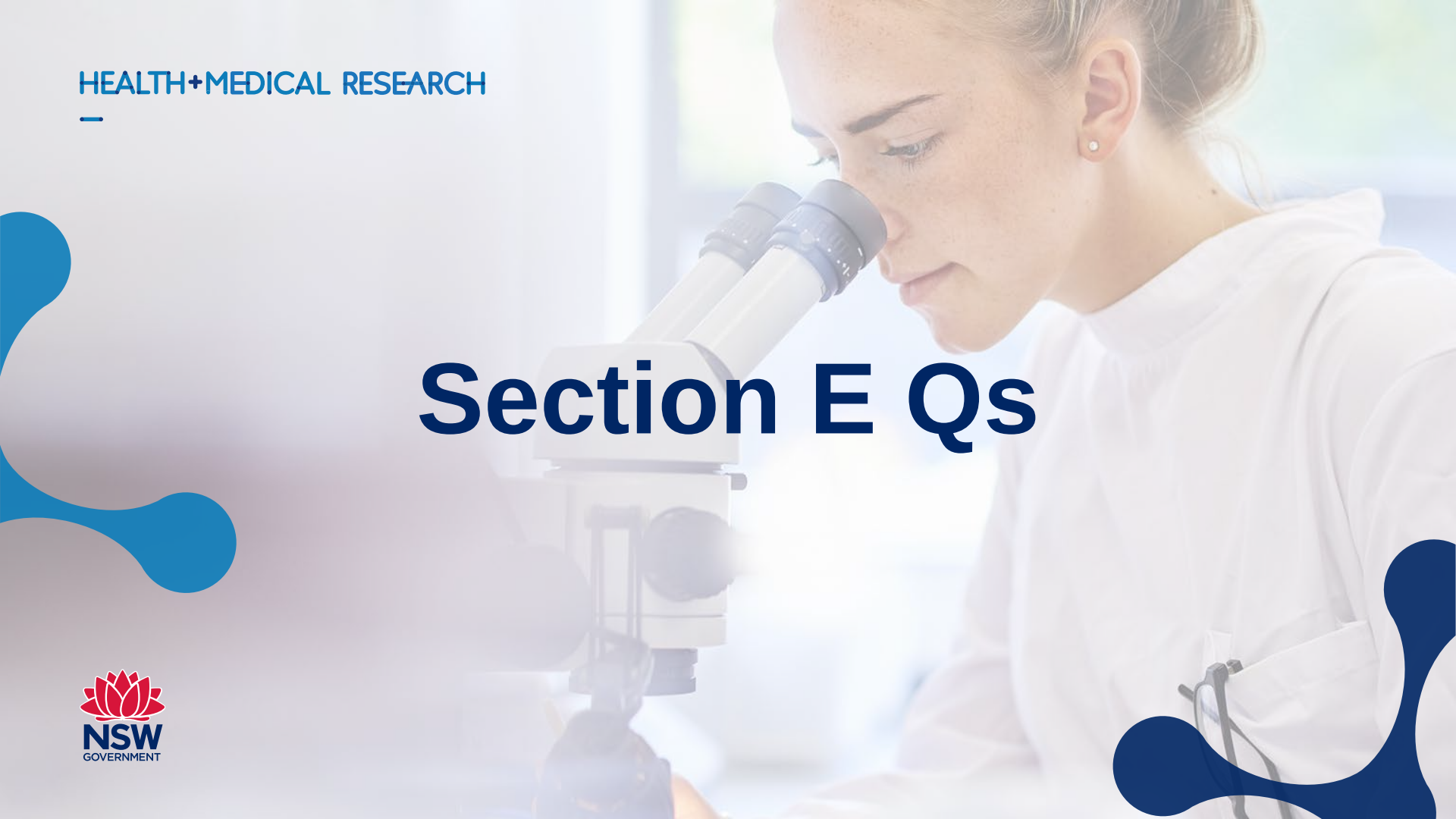
Section E Qs



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Question E1: Budget

QUESTION:

In terms of the budget in question E1 of the EOI form, can budget items be directed to partner organisations e.g. MRIs, if partners are directly related to the delivery of responsibilities as per Section 4 of the Guidelines?

Question E1: Budget

QUESTION: In terms of the budget in question E1 of the EOI form, can budget items be directed to partner organisations e.g. MRIs, if partners are directly related to the delivery of responsibilities as per Section 4 of the Guidelines?

ANSWER:

- Budget should be directed towards resourcing/headcount, facilities and equipment
- Budget items should:
  - facilitate the delivery of R3CTSU responsibilities, and
  - meet **specific** unmet needs across the cluster.
- The Host Organisation will administer the funding *across the partners* as outlined in your budget and proposal.

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Further support

Applicants are encouraged to contact clinicaltrialsNSW to discuss their proposed clinical trial governance structure and sustainability model.

Applicants are also welcome to contact clinicaltrialsNSW to discuss their approach to the EOI broadly.

Contact details

clinicaltrialsNSW:

clinicaltrialsNSW@health.nsw.gov.au

Anita van der Meer, clinicaltrialsNSW Manager:

Anita.VanDerMeer@health.nsw.gov.au

Tel (02) 9461 7044 | Mob 0419 728 487

Communication and partnership is key to success.

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