# Audio file

[Expression of Interest for Rural, Regional and Remote Clinical Trial Support Units(joebadolato@arcs.com.au) 1.mp4](https://nswhealth-my.sharepoint.com/personal/kate_mcgregor1_health_nsw_gov_au/Documents/Transcribed%20Files/Expression%20of%20Interest%20for%20Rural,%20Regional%20and%20Remote%20Clinical%20Trial%20Support%20Units(joebadolato@arcs.com.au)%201.mp4)

# Transcript

00:00:03 Speaker 3

Hi everyone, welcome to today's webinar.

00:00:06 Speaker 3

Its Joe Badolato, the Director of Education here at ARCS and ARCS is absolutely thrilled to be presenting this webinar in partnership with New South Wales Health.

00:00:20 Speaker 3

For those of you who aren't so familiar.

00:00:23 Speaker 3

With ARCS Australia, we are a national member based organization focused on the development and growth of the healthcare sector.

00:00:35 Speaker 3

And we provide education, career pathways, professional development at an advocacy to the health care sector.

00:00:45 Speaker 3

We are a member based organization as opposed to

00:00:50 Speaker 3

An institutional based organization and our typical members are in

00:00:55 Speaker 3

work across the whole gamut from regulatory affairs, clinical research, pharmacovigilance, health economics and medical information, and all the disciplines really to get quality use of medicines to the patients and our typical members

00:01:12 Speaker 3

come from industry, academia, medical research institutions, government, hospitals and patient groups.

00:01:19 Speaker 3

And on the next slide, most of you probably know,

00:01:25 Speaker 3

um most of you probably know us for our annual conference and we are very pleased to share with you that the annual conference this year will be on the 7th to the 9th of June at the ICC, Sydney.

00:01:42 Speaker 3

Registrations open quite very soon, and there's more information on our website.

00:01:48 Speaker 3

And with that I'll hand the meeting over to you, Tony.

00:01:52 Speaker 4

Thank you Joe. And so myself, Tony Penna, I look after the Office for Health and Medical Research in New South Wales and Anita’s team clinicaltrialsNSW.

00:02:02 Speaker 4

Is helping lead this extraordinary initiative.

00:02:06 Speaker 4

Firstly, I'd also like to acknowledge the traditional owners of the land on which we are all located in different places.

00:02:15 Speaker 4

Most of us it's the people of the Eora Nation and I pay my respects to their

00:02:22 Speaker 4

Elders past, present and emerging.

00:02:25 Speaker 4

This is an exciting time in in the area of research, especially as there's been an increasing focus and rightly

00:02:32 Speaker 4

so in clinical trials in the remote, rural and regional areas.

00:02:34

OK.

00:02:37 Speaker 4

It’s always been challenged in delivering.

00:02:39 Speaker 4

clinical trials to our patients in those areas, and I think with this initiative, I'm hoping that we’ll build the capacity and capabilities to drive clinical trials in those areas and to really ensure that the patients in those areas have opportunities to be able to access novel therapies via a clinical trial center.

00:03:00 Speaker 4

The whole initiative around clinical trials support unit is really a critical part of what we're on about, and I'm hoping that you'll have the opportunity to ask questions and have a better understanding of how the these clinical trials support units will assist in delivering clinical trials in the remote and rural, regional area.

00:03:21 Speaker 4

I think I would like to now hand over to Anita and will give you a better understanding of the work that we were going to be doing in this space.

00:03:31 Speaker 4

So over to you, Anita.

00:03:34 Speaker 1

Thanks Tony, thanks Joe and it's a pleasure to be partnering with ARCS on our rural, regional and remote clinical trial enabling program along with the 33 other partners that form part of this program.

00:03:50 Speaker 1

So just a little bit of housekeeping.

00:03:52 Speaker 1

Thank you to everyone for joining today.

00:03:54 Speaker 1

The purpose of today's presentation is to talk through the background of the rural, regional, and remote clinical trial enabling program with New South Wales ACT.

00:04:07 Speaker 1

And then to provide specific details around the current key activity, which is the expression of interest related to the clinical trial support units.

00:04:17 Speaker 1

Due to the amount of content we have to get through today, it's unlikely that we'll have time at the end of this webinar to have a live Q&A session. But please, if you have questions as we go along, submit those questions through the Q&A function available on the go to webinar system.

00:04:38 Speaker 1

We will be hosting another webinar on Friday this week which will be devoted to our Q&As and there is also a Q&A spreadsheet which will go live on our OHMR website. In addition, you are always welcome to contact us through the clinicaltrialsNSW email address or call me if you have a question regarding the program and you are a lead applicant.

00:05:09 Speaker 1

So to some background regarding the Rural, Regional and Remote program, the Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant was opened in December 2019 under the Medical Research Future Fund National Critical Infrastructure Initiative. The grant was originally proposed as $100,000,000 / 5 years.

00:05:30 Speaker 1

To provide initial stimulus funding for large scale, innovative approaches to enhancing an improving clinical trial infrastructure industry, addressing existing barriers such as distance, geographical isolation, cultural difference, low population density and workforce capacity so as to create better access to existing and new clinical trials in rural, regional and remote areas of Australia.

00:06:03 Speaker 1

The $125,000,000 in funding was announced for this MRFF program as part of the 2021 budget, which was released towards the end of September last year, and this included 30.6 million, which was the full requested allocation for the New South Wales Act submission.

00:06:24 Speaker 1

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

00:06:30 Speaker 1

And I would say that while NSW and ACT were approached to participate in the Queensland Health led National Consortium after considerable consultation and consideration of the proposed Queensland program and the funding structure, the decision was made for New South Wales to proceed with an

00:06:50 Speaker 1

independent submission and the reason for this was really to ensure that we could deliver within our own jurisdictional structure for the specific needs of our rural, regional and remote populations.

00:07:05 Speaker 1

And I hope you will see that as we proceed through today's presentation.

00:07:14 Speaker 1

So the New South Wales ICT Rural, Regional and Remote Clinical Trial Enabling Program is really a component of clinical trials NSW broader agenda to transform clinical trials across the state with the support of the Office for Health and Medical Research and the focus on clinical trials from New South Wales Health generally.

00:07:40 Speaker 1

Clinical trials NSW is implementing an agenda with five key pillars that really will build a solid foundation based on local and international best practice to deliver high quality research outcomes with impact for our New South Wales communities.

00:08:00 Speaker 1

This will do this by creating a professional and stable clinical trial workforce and supporting equity of access for our consumers, our researchers and our sponsors while maintaining agility and responsiveness to the needs of the population and our healthcare system.

00:08:20 Speaker 1

Really, the overall aim of this transformation program for clinical trials in New South Wales is to develop a mature, interconnected clinical trial sector that embeds research into health service delivery and provides equity of access to innovative health care.

00:08:40 Speaker 1

Before I talk more specifically about the Triple R Program, I just want to define the scope of what we mean by clinical trials.

00:08:48 Speaker 1

We are using the World Health Organization definition of a clinical trial as a prospective research study involving human participants that uses interventions that evaluates interventions that have a potential effect on health outcomes.

00:09:05 Speaker 1

The interventions being very broad, ranging from.

00:09:09 Speaker 1

Drugs through to preventative care.

00:09:11 Speaker 1

I want to make it very clear up front that when we're talking about clinical trials within this program, we are referring to our non-commercial clinical trials.

00:09:22 Speaker 1

So that's our academic investigator initiated, collaborative research type trials as well as our commercial clinical trials portfolio.

00:09:37 Speaker 1

The New South Wales Triple R CT program has the broader program outcomes of providing equity of access to clinical trials that are relevant to the needs of our communities in our triple R areas.

00:09:54 Speaker 1

To grow the breadth and depth of our trial portfolio so that we can bring more trials to our patients with increased patient involvement and recruitment and access to research for our clinician population.

00:10:08 Speaker 1

Focusing on improving the speed and coordination of our trials while maintaining high quality trial conduct.

00:10:17 Speaker 1

Developing a local, clinically clinical trial capable workforce that is based in our Triple R regions and ensuring the overall sustainability of the program.

00:10:29 Speaker 1

Post of current available funding and it's important here to

00:10:36 Speaker 1

Highlight that these program outcomes are very much in alignment with the overall outcomes of the MRFF program more broadly.

00:10:45 Speaker 1

And more broadly, and the deliverables of that program.

00:10:50 Speaker 1

I would like to focus here that the highlight here that the focus is on clinical trial operational capacity and capability and not specifically research ethics and governance per say or any particular research purpose or trial.

00:11:09 Speaker 1

And hopefully that focus will become clearer as we go through today's presentation.

00:11:16 Speaker 1

Again, thank you to our 34 state and national partners, which are part of our Triple R clinical trial enabling program including our health organisations across NSW and the ACT.

00:11:29 Speaker 1

Our academic organisations, industry partners and of course, and importantly, our consumer organisations and we're very pleased to have both health consumers NSW and Health Care Consumers Association ACT as partners of this program.

00:11:50 Speaker 1

To put some context on the milestones and timelines for the program, as I mentioned earlier, the announcement of the successful candidates from the MRFF Grant was made in September last year, meaning that at this point we are almost rapidly closing in on the end of year one.

00:11:55 Speaker 1

Man.

00:12:10 Speaker 1

That gives us essentially four years to deliver the 30.6 million in funding that we have available for this program, and hence we have quite a focused and assertive delivery of this program during that time.

00:12:31 Speaker 1

The overall program management for the Triple R program resides with clinical trials NSW, with OHMR ultimately responsible for the delivery of the program to New South Wales Health and to the Commonwealth.

00:12:45 Speaker 1

The program will be structured with a dedicated program team that sits within clinicaltrialsNSW in the Office for Health and Medical Research. That program team will work closely in collaboration with our Triple R clinical trial support unit and our other program partners to deliver the four key activities.

00:13:07 Speaker 1

Sorry, the five key activities of the program.

00:13:11 Speaker 1

In addition, the program team will be responsible for developing the architecture which allows the program to be implemented, monitored and evaluated.

00:13:18 Speaker 1

Yeah.

00:13:23 Speaker 1

That includes our stakeholder management and communication.

00:13:26 Speaker 1

Runs the risk and quality functions and the requirements and financial procurement components of the program.

00:13:33 Speaker 1

As everyone can appreciate, this is a large and ambitious program.

00:13:37 Speaker 1

We are focused on delivering the outcomes of the program to New South Wales Health and the Commonwealth.

00:13:46 Speaker 1

And that requires a structured approach with close partnership of our stakeholders.

00:14:00 Speaker 1

A summary of our five program key activities, and these represent the key activities as they are originally submitted to the MRFF.

00:14:12 Speaker 1

Focusing on improving or enabling clinical trial capacity, capability and collaboration.

00:14:19 Speaker 1

In our remote, rural and regional community.

00:14:22 Speaker 1

Is the first key activity is developing decentralized clinical trials, capacity and capability, so bringing the patient to the trials rather than the trials.

00:14:33 Speaker 1

Sorry, bringing the trials to the patients rather than the patients to the trials.

00:14:38 Speaker 1

Delivering locally through our rural, regional and remote communities.

00:14:42 Speaker 1

And I'll be focusing primarily on this key activity today.

00:14:46 Speaker 1

Improving clinical trial awareness, engagement, recruitment and retention within our communities.

00:14:52 Speaker 1

Professionalizing, our clinical trial services so that we conduct our trials to international best practice standard and finally evaluating the program so that we can create a sustainable future for clinical trials in our triple R communities.

00:15:09 Speaker 1

Another way to look at that is to focus on what we need to deliver to ensure that this is a successful program.

00:15:16 Speaker 1

So if our outcome is to enable clinical trials in our Triple R communities and therefore provide equity of access to innovative healthcare, we need to develop four key areas.

00:15:27 Speaker 1

The first is the capacity to undertake clinical trials in our Triple R areas and this is around resourcing, infrastructure in our clinical trial support units.

00:15:44 Speaker 1

Then developing the capabilities in those areas with a dedicated education, training and development program.

00:15:53 Speaker 1

Engaging with our consumers to codesign our approaches to clinical trials and to encourage participation, so we can ensure recruitment into clinical trials.

00:16:07 Speaker 1

And lastly, working with our sponsors, commercial and noncommercial, to ensure that we can provide an increased number of clinical trials that are appropriate for Triple R regions.

00:16:25 Speaker 1

So now we'll be moving to our clinical trial support units, expression of interest and I'll hand over to Brigitte, who is a team member from clinicaltrialsNSW who will talk through the application process and the selection criteria.

00:16:42 Speaker 1

Before Brigitte takes over, I want to highlight that if you are interested in applying as a clinical trial support unit within the Rural, Regional and Remote Clinical Trial Enabling Program, please reach out to clinicaltrialsNSW, either through our email address or please call me directly.

00:17:03 Speaker 1

To discuss the program in more detail and to discuss our expectations around governance and sustainability, there will also be an additional webinar on Friday, where we will go through Q&As related to the program and we encourage you all to join that.

00:17:21 Speaker 1

And with that Brigitte, I'll hand over to you.

00:17:27 Speaker 1

And I think you might be on mute Brigitte

00:17:30 Speaker 2

No, I think, I'm good.

00:17:32 Speaker 1

You're good to go.

00:17:34 Speaker 2

Yes so.

00:17:36 Speaker 2

Of course, we're talking about the expression of interest for the rural, regional, and remote clinical trial support units, which is a collaborative network that will deliver a growing and diverse clinical trial portfolio with increased an equitable access to clinical trials for patients in rural regional and remote areas, and this expression of interest will be open to all LHDs that cover Triple M 3 to 7 areas and as you can see in the map, there are some Metropolitan local health districts that cover these areas and.

00:18:13 Speaker 2

Of course, for a ACT health services that are supporting Triple M 3 to 7 populations.

00:18:23 Speaker 2

So as I said before, NSW local health districts and ACTT health services covering Triple M 3-7 populations can apply for this expression of interest to establish an implement a clinical trial support unit in up to three New South Wales ACT clusters covering the northern, western and southern region.

00:18:46 Speaker 2

I'm funding up to 6,000,000 /. 4 years is available for each region covered in the cluster.

00:18:52 Speaker 2

And and a total funding pool of 18 million is available, which is 60% of the MRFF award. The remaining funding is earmarked towards the delivery of the other key activities in the program, which will be done in collaboration with clinicaltrialsNSW, partners and also our clinical trial support units. So clinical trials NSW is responsible for the delivery of the triple R CT program to New South Wales Health and the Commonwealth and will be asking clinical trial support units to work closely with clinicaltrials NSW to ensure successful operationalization of the units, the key activities and the delivery of our program intended outcomes.

00:19:44 Speaker 2

And then they will also be required to align with our broader continuous improvement initiatives across the state.

00:19:52 Speaker 2

Right?

00:19:54 Speaker 1

So Brigitte, I'll take the next few slides, if you like.

00:19:58 Speaker 2

Yes, that would be great.

00:20:01 Speaker 1

So the next few slides focus on the purpose and responsibilities of the proposed triple R clinical trial support units, and it's really key to focus on these as essentially the requested deliverables of the CTSUs.

00:20:16 Speaker 1

These items align very closely with the deliverables that we are required to provide to the commonwealth.

00:20:25 Speaker 1

So broadly, in addition to partnering with clinicaltrialsNSW on the remaining key activities of the program, there are four areas that we are seeking. The clinical trials units to be responsible for.

00:20:45 Speaker 1

I'll take the next slide.

00:20:46 Speaker 1

Brigitte, thanks.

00:20:50 Speaker 1

The first is growing the clinical trials portfolio in their respective clusters, and this includes both the breadth and depth of the portfolio.

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So the number of clinical trials being conducted in our Triple R areas, as well as the range of therapeutic areas in which those trials are conducted.

00:21:07 Speaker 1

Increasing the number of clinical trial sites that are participating in those trials.

00:21:12 Speaker 1

Raising Community awareness of clinical trials and the number of participants enrolled in clinical trials as well as the range of trial types by sponsor.

00:21:22 Speaker 1

So ensuring that we are growing our noncommercial trial portfolio including collaborative group trials.

00:21:28 Speaker 1

Investigator initiated and other sponsored types.

00:21:32 Speaker 1

As well as our pharmaceutical and medical device Commercial sponsors.

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We are also keen to see an increase in a diversity or range of clinical trial delivery methods so that again we can bring the trials to the participants.

00:21:48 Speaker 1

This includes our traditional face to face models as well as tele-trials in home and primary care.

00:21:59 Speaker

The second responsibility of the CTSUs is to focus on increasing the return on investment for clinical trials, as well as the value proposition of trials to the health system and to sponsors, and this is a really important area that will be an area of increasing focus for clinical trials NSW more broadly.

00:22:20 Speaker 1

Understanding and delivering on the contract value of our clinical trials portfolio and developing the financial acumen and financial management of our clinical trials workforce.

00:22:34 Speaker 1

The third responsibility of the CTSUs is really around allowing our clinical trial sites to focus on ensuring high quality patient care.

00:22:48 Speaker 1

By leveraging economies of scale around trial administration activities, so this might look like focusing on startup activities in a more centralised fashion.

00:23:02 Speaker 1

Including feasibility assessments, budget development and CTRA negotiations, ethics and that specific assessment applications, regulatory submissions, etc.

00:23:14 Speaker 1

Also supporting and coordinating participant recruitment activities to ensure recruitment is aligned across clusters and patients have access to trials.

00:23:25 Speaker 1

Supporting ongoing administration, including annual ethics and governance reporting, adverse event reporting, etc.

00:23:33 Speaker 1

And supporting closeout activities associated with trials, and this is really around moving from a very site centered approach where sites are.

00:23:46 Speaker 1

very administration heavy, often duplicating the same activities across a range of sites participating in the same trial and leveraging our economies of scale with clinical trial support units which can

00:23:59 Speaker 1

Remove the heavy administrative burden of trials and allow our sites to focus on our patients and patient care.

00:24:09 Speaker 1

And the last responsibility is to support clinical trial conduct.

00:24:12 Speaker 1

So, of course, ensuring that trials are conducted in accordance with the appropriate guidelines and regulations, but also looking at providing trial monitoring and trial auditing services, particularly for our noncommercial trial portfolio.

00:24:28 Speaker 1

Building and developing our network of trained and skilled staff from our investigators through our study coordinators, research nurses and data managers.

00:24:38 Speaker 1

Specifically, focusing on developing our lead investigator expertise within our triple R areas so we can have more of our primary sites in our rural, regional remote communities.

00:24:49 Speaker 1

Supporting development of appropriate policies and standard operating procedures and, of course, preparing our sites for the commissions, clinical trials governance framework and our New South Wales Health Early Phase Clinical Trial Framework.

00:25:04 Speaker 1

So really, the highlight of these clinical trial support units are around ensuring that you have funding to grow your resourcing, your facilities, and your equipment across your LHD's where encouraging, innovative and virtual approaches to ensure that

00:25:24 Speaker 1

you are growing the breadth and depth of your portfolio across all of the LHD's moving away from what has traditionally been a very bricks and mortar site focused approach to clinical trials.

00:25:39 Speaker 1

And with that, I'll hand back to Brigitte to run you through the actual application process.

00:25:45 Speaker 3

Ah Brigitte, it’s Joe here, so just a quick soundcheck. We're at 1.04, so we've got about 25 minutes left in the webinar.

00:25:52 Speaker 2

That's perfect, thanks Joe.

00:25:54 Speaker 2

So just to give a quick outline of the eligibility criteria for this expression of interest, there's sort of three main criteria which relate to the host organisation, the Research Director or clinical trials champion, which is nominated by the host organisation and then completing submitting a complete expression of interest.

00:26:12 Speaker 2

And.

00:26:17 Speaker 2

So for the host organisation, there must be a single host organization that leads the expression of interest and manages the proposed clinical trial support unit.

00:26:28 Speaker 2

On behalf of the cluster, so a host organization would be either a New South Wales local health district covering Triple M 3-7 populations or in a see ACT health service that supports Triple M 3-7 populations.

00:26:45 Speaker 2

The host organization will be required to enter into an agreement with OHMR, the New South Wales from New South Wales Ministry of Health to deliver outcomes of the program on behalf of the partners within the cluster. They'll be responsible for managing the partnership in collaboration with clinical trials, NSW.

00:27:07 Speaker 2

To report program milestones and deliverables to clinicaltrialsNSW as well.

00:27:13 Speaker 2

The clinical trial support unit as mentioned by Anita, can be co-located across the cluster so they can be decentralized or manage virtually across the region or multiple regions.

00:27:27 Speaker 2

They must also support all local health districts and or ACT health services within that cluster.

00:27:36 Speaker 2

So part of the eligibility criteria is to justify why the host organiSation was selected to lead the clinical trial support unit and the expression of interest based on the Triple M 3-7 classification. We're also asking the host organization to predefine their cluster so to identify which local health districts and or AC T health services are within the cluster.

00:28:09 Speaker 2

And then to explain why these LHD's and or ACT health services have been selected within the cluster based on the Triple M 3-7 classification. And so this is completed in section A of the expression of interest form, there's no word limit for that justification.

00:28:29 Speaker 1

And I might add there Bridget that we are really seeking our Triple R communities to suggest OHMR are how they see these clusters forming and to focus on collaboration and partnership within the clusters. That is key to the success of this program.

00:28:51 Speaker 2

Thanks Anita, so the organisations that are out of scope as a host organization are listed here.

00:28:59 Speaker 2

However, they can be a partner organisation within the proposal, and we encourage these partner organisations to clearly support a specific cluster responsibility and this will be outlined in the expression of interest under Section C.

00:29:16 Speaker 2

So it's important to include that. So the organisations that are out of scope is host organisation include private organisations, Advanced Health Research and Translation Centers or Centers for Innovation in Regional Health, medical research institutes, universities and non government organisations.

00:29:37 Speaker 2

So as I said, they can be partners.

00:29:40 Speaker 2

They must support a responsibility and not duplicate the activities that have already been specified in the triple R CT program, as they've already been allocated to specific partners.

00:29:58 Speaker 2

The next criterion relates to the host organisation nominating a local health district Research Director or a Clinical Trials Champion within the cluster, and their responsibility is to lead the development and the submission of the expression of interests on behalf of the host organization.

00:30:19 Speaker 2

And the partner local health districts in and ACT health services.

00:30:23 Speaker 2

To deliver the program on the on behalf of the host organization as well. The role can be funded within the program for up to .1 to .2 FTE and can be co-located within a cluster. So as Anita had mentioned before, this can occur virtually, so we're not looking for a specific bricks and mortar clinical trial support unit within a specific location, so it can cross boundaries.

00:30:55 Speaker 2

The third criterion is to submit a complete expression of interest, so this includes the expression of interest form and the attachments

00:31:03 Speaker 2

So the Excel template, which is the data form within this expression of interest.

00:31:09 Speaker 2

I mean within this slide, sorry, a one page CV of the Research Director or clinical trials champion.

00:31:17 Speaker 2

You must also make sure that the expression of interest is certified by the Chief executive of the host organization and the Chief Executive of the partner.

00:31:27 Speaker 2

Local health districts and or AC T health services and so, by certifying this expression of interest, they are agreeing to the proposed model of trial delivery, the responsibilities and the outcomes associated.

00:31:43 Speaker 2

Partner organizations that are not NSW. Local health district or a ACT health service must provide a letter of support that's signed by the CEO or Managing Director.

00:31:56 Speaker 2

The timeline for the Rural, Regional Remote Clinical Trial Support Unit is to be fully resourced an operational by January 2022, so that means having staffing and infrastructure set up within the clinical trial support unit to facilitate the delivery of those responsibilities that Anita had mentioned earlier.

00:32:19 Speaker 2

The triple R CT program funding and the program itself will conclude in June 2025, so it is expected that the clinical trial support unit will have a sustainability model in place by that time and we will elaborate that on that a bit later in the slides.

00:32:42 Speaker 2

So the expression of interest will address 2 key areas.

00:32:46 Speaker 2

Firstly, the first component is to demonstrate the clusters current clinical trial capacity, capabilities and collaborative relationships, and the second part is to provide a proposal that outlines how the clinical trial support unit will be developed.

00:33:02 Speaker 2

And delivered within the cluster in line with key activity for of the triple R CT program project plan.

00:33:10 Speaker 2

And the responsibilities outlined by Anita, which are in section four of the guidelines.

00:33:16 Speaker 2

Based on that first component of the current clinical trial capacity, capabilities, and collaborative relationships.

00:33:25 Speaker 2

How are you going to leverage and build on this, is what we're after.

00:33:32 Speaker 2

So NSW Health is looking for innovative approaches to clinical trial strategy which build on the current site centered individual model of trial delivery to a maturing, streamlined and interconnected trial network that utilizes economies of scales and seek to embed clinical trials in core clinical care delivery, or public health in any setting.

00:34:03 Speaker 2

So the first selection criterion is to demonstrate evidence of current clinical trial capacity, capabilities and collaborative relationships within the cluster. So this is the first component of the expression of interest. It's weighted at 40%, and you must use the Excel template or data form to meet this criteria.

00:34:30 Speaker 2

So the first part of the data form is to demonstrate a strong current governance structure for managing clinical trials.

00:34:40 Speaker 2

So this governance structure relates to clinical trial operations as opposed to research and ethics.

00:34:49 Speaker 2

So what we've provided in the second tab is an organization chart which you can use to support your response.

00:34:57 Speaker 2

It's optional, you can use the one that we have there, or you could put your own organization chart in.

00:35:07 Speaker 1

And just to highlight there Brigitte that the governance structure for the CTSUs needs to align with the partnership with clinical trials NSW and I'm available to have those discussions with anyone who would like to know more detail around what we mean by that.

00:35:24 Speaker 2

Thanks Anita, and so the second criterion is current staffing for delivering clinical trials within the cluster.

00:35:32 Speaker 2

So here we are asking for the host organization, partner, local health districts and ACT health services within the cluster to identify the investigators and people currently employed to deliver clinical trials within the cluster.

00:35:51 Speaker 2

And so this is, we've formatted this table so that it closely aligns with the clinical trial workforce data that was submitted by local health districts late last year.

00:36:02 Speaker 2

So it should be just a matter of copying and pasting this information.

00:36:06 Speaker 2

The only additional information we require around investigators is the detail around the career stage of the researcher.

00:36:14 Speaker 2

And for all those employed, whether they have experience in commercial or noncommercial clinical trials.

00:36:23 Speaker 1

I might just add there Brigitte that the tab in particular around the trial portfolio very closely aligns with the information we are required to deliver to the Commonwealth, which is why we are seeking this information now.

00:36:40 Speaker 2

Yes, that's right.

00:36:41 Speaker 2

So yeah, the the next component of the data form is to complete a full track record and this is really important for us as we'll be reporting on those on those fields which are metrics for the Commonwealth so.

00:36:59 Speaker 2

It's really important that we gather that data and it will also help you in developing your proposal.

00:37:06 Speaker 2

Which one of the key responsibilities is to grow the portfolio of clinical trials.

00:37:14 Speaker 2

So you can build on this data template there.

00:37:19 Speaker 2

We also after the infrastructure for delivering clinical trials within the cluster, so this can be office space, clinic space and other supporting infrastructure.

00:37:31 Speaker 2

We want to know where it's located, the capacity and the facilities that are available on these sites and we've got some examples of equipment there.

00:37:43 Speaker 2

And this must be reported for both host organization, partner local health districts and/or ACT health services within the cluster.

00:37:55 Speaker 2

The next so we had mentioned about the track record before, so I won't go through that, but that is for the last three years, so all clinical trials within the cluster over the last three years, and it's important to also include any tele trials or decentralized trials within this spreadsheet.

00:38:22 Speaker 2

We're also after existing collaborations that directly benefit clinical trials, so these can be collaborations with other local health districts, academic sectors, commercial sponsors, and consumer organisations just to list a few, and how they successfully conduct clinical trials within the cluster so you can outline their contribution within the details of the collaboration, which is there on the screen.

00:38:56 Speaker 2

So the next component of this expression of interest is to propose the development and the delivery of the clinical trial support unit within the cluster, and it's weighted at 60%. So it is a significant weighting and I'll just go through each of the criteria now.

00:39:17 Speaker 2

So the first 3 criteria quite interrelated and they must be responded to in these two questions.

00:39:26 Speaker 2

So you need to identify any areas of unmet needs in the rural, regional and remote communities within your cluster.

00:39:34 Speaker 2

So here we could be talking about disease types that require more research.

00:39:40 Speaker 2

It could be in terms of staffing on infrastructure.

00:39:44 Speaker 2

It could be in terms of capability in the delivery of clinical trials, so you need to identify your unmet needs and then in the next response you need to be able to identify how your clinical trial support unit

00:40:01 Speaker 2

will benefit the rural, regional or remote communities in your cluster and how you're going to address the unmet needs within the cluster and how you're going to direct the funding to the Triple M 3-7 areas over that cluster.

00:40:18 Speaker 2

It's important here to consider equity of access by researchers and potential participants to clinical trials within the cluster to ensure that everyone across the Triple M 3-7 population is covered and their and their unmet needs are addressed.

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So an example here may be that you identify the unmet need as being a lack of stroke trials, and then in C2 you might justify the appointment of additional stroke trial nurses.

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So the next part of the expression of interest is to actually propose a clinical trial support unit within the cluster.

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So here you'll explain how the host organization, the partner local health districts and or ACT health services within the cluster will develop THE proposed clinical trial support unit and deliver the clinical trial support unit responsibilities which were outlined by Anita before and.

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In K activity, four of the triple RCT program project plan.

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How you will

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deliver these responsibilities based on that first component, which is the existing capacity, capabilities and collaborative relations to deliver those responsibilities.

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So here we're specifically asking for a strong and practical governance structure for the clinical trial support unit.

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Across the LHDs in the cluster and to include any partnerships and how they're going to add value to the clinical trial support unit you by supporting those clinical trial support unit responsibilities.

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We also need you to propose an appropriate staff structure for the clinical trial support unit.

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Appropriate infrastructure and to propose a model for collaborating and communicating within the clinical trial support unit and across the other clinical trial support units within the network.

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So here it might be worth speaking to clinicaltrialsNSW in relation to the governance structure to ensure that it aligns with the Triple R CT program.

00:42:46 Speaker 1

I might also add there Brigitte that in terms of staffing, you may want to consider roles such as more research nurses or clinical trial coordinators.

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Perhaps a recruitment support person, a finance or business development manager, quality and training manager, perhaps time in clinicians.

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schedules for research dedicated activities. Those sorts of roles across the cluster LHDs.

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And yes, that's exactly right.

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And it will need to be also supported by a budget, which I'll get to in a second.

00:43:26 Speaker 3

Brigitte your final time check we’re at 8 minutes left in the webinar, so I'll leave you with that.

00:43:33 Speaker 2

Great thanks Joe.

00:43:35 Speaker 2

So the next three components of the selection criteria are the timeframe, the budget and sustainability.

00:43:41 Speaker 2

So I'll just go into that in a bit further detail.

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So in terms of the time frame we want you to put together a detailed project plan which outlines the key, project milestones, the timeframe for execution, and how these will be achieved.

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We also want you to identify any known I guess risks that may prevent achievement.

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of the milestone and what strategies you're going to use?

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So it's important that this detailed project plan aligns with the milestones in the triple R CT program project plan, and to ensure that the clinical trial support unit is operational by January 2022.

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In terms of the budget, we need you to provide a really detailed budget, so this includes all salaries and all infrastructure.

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There is the opportunity for clinical trial delivery staff to be funded across a range of trials, however,

00:44:52 Speaker 2

it's important to note that funding cannot go towards an individual clinical trial, so really important to make sure that you read the funding conditions which are in Section 8 of the guidelines before completing this budget.

00:45:08 Speaker 2

So it's really important that the budget is reasonable and well justified and how you define the cluster is going to be really important for determining.

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The budget and also the unmet needs, so making sure that you're addressing the unmet needs mentioned early in the proposal through specific staffing or infrastructure or whatever is required that they are listed as budget items here.

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In terms of sustainability, as I mentioned before, the triple R CT program concludes in June 2025, so unfortunately our funding for the clinical trial support units is limited until this time. So to ensure that the program is viable on an ongoing basis.

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We do need applicants to

00:46:05 Speaker 2

answer some questions that relate to sustainability and to propose a sustainability model for the clinical trial support unit.

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So firstly, we need you to propose how the clinical trial support unit will integrate clinical trials within the rural, regional remote health care system on an ongoing basis beyond the life of the program.

00:46:27 Speaker 2

And to also propose a model for financing and resourcing the clinical trial support unit on an ongoing basis beyond the life of the program.

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So here we want you to focus on the future investment for your clinical trial portfolio and you can reach out to clinicaltrialsNSW in regards to your model for sustainability to seek any advice there and ensure that it's aligned with the program broadly.

00:47:00 Speaker 2

So here is a snapshot of the application and selection process timelines. So the expression of interest opens on the 1st of February, 2021. We've included a period for Chief Executive endorsement, but I would assume that a lot of Chief Executives would be engaged.

00:47:20 Speaker 2

Early in the process, in parallel with the development of the expression of interest. The expressions of interest need to be submitted to New South Wales Ministry of Health by 5:00 PM on the 1st of March 2021.

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And the expression of interest will be firstly assessed for eligibility and then they will be assessed by the triple R CT program selection panel in March 2021, and the panel may require some

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applicants to present their proposal or to answer any questions relating to their proposal or just address any issues prior to any funding decision being made.

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We are aiming to notify the outcomes in April 2021.

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And then we'll be executing funding agreements in June 2021 with funding administered in the next financial year to the successful rural, regional and remote clinical trial support units in August 2021.

00:48:28 Speaker 2

Anita, did you want to speak to this one?

00:48:31 Speaker 1

Thanks Brigitte and appreciate you covering off the application and selection criteria, so we're going to highlight the CTUSs may be funded up to $6 million / 4 years for up to three CTSUs in New South Wales ACT and that the total of 18 million represents 60% of the total MRFF award for this program.

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The remaining funding will be used to implement the other projects in the other key activities of the program in partnership with the CTSUs and our program partners.

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Yes.

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The funding amount that will be awarded to CTSUs will be based on several factors including the population, the portfolio, the potential for growth and the support unit, staffing and infrastructure that's required, as well as links to collect clinical trial delivery expertise.

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The funding will be provided on a quarterly basis.

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It will be reviewed annually by the Steering Committee in clinicaltrialsNSW and it's important to note that future funding is based on performance and may be increased, decreased or increased, or indeed terminated.

00:49:42 Speaker 1

I think you've gathered from today's presentation that this is an expression of interest for

00:49:49 Speaker 1

Up to $18 million in funding that is somewhat different to the grant programs that you may be used to engaging with through the office. This is really an opportunity to build an interconnected network of clinical trial capability across rural, regional, remote NSW and ACT, and the key here is around the partnerships.

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The partnerships across your LHD?

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And partner organisations within your cluster and the partnership in the delivery of the program with clinicaltrialsNSW.

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And lastly, if you have any follow up questions, please reach out to clinicaltrialsNSW either through our email address or feel free to call me directly.

00:50:37 Speaker 1

We do have a Q&A webinar this Friday and all questions are submitted before midday on Thursday will be addressed at that Q&A session.

00:50:48 Speaker 1

Lead applicants are also encouraged to contact me to discuss their proposal, particularly around governance and sustainability.

00:50:59 Speaker 1

So to this end, I just like to say thank you to ARCS for partnering with us on the presentation today, to Brigitte, the clinical trials and OHMR team for the work to support this program.

00:51:12 Speaker 1

And obviously to Tony Penna, the Executive Director of the OHMR. And to our Rural, Regional and Remote Program, Executive Advisor Prof Tom Walley, who's contributed significant input into the development of the expression of interest and to everybody on the webinar today. Thank you for your time.

00:51:32 Speaker 1

We look forward to partnering with you in the future.