TTRA RESEARCH PROJECTS ROUND 2 INFORMATION SESSION - TRANSCRIPT

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INTRODUCTION

Libby Pearce: Well Hello everybody and welcome to today's TTRA session and welcome to MTPConnect. We still have a minute or two to go to before launching right on time so thanks for joining us Nice and early.

Go grab that coffee quickly and we will be launching soon so we'll be back in a minute thanks see you bye.

Hello everybody and welcome to today's MTPConnect webinar my name is Libby Pearce and I will be your zoom host for today so to launch the session officially I'm going to hand over to the lovely Lauren Kelly. Lauren do we have you on the line there.

Lauren Kelly: Yes, thanks Libby.

Hello everybody, welcome to the Targeted Translation Research Accelerator information session. The focus today is on round two of the research projects funding opportunity which is currently open.

We're really glad that you could join us today, as I said, my name is Lauren Kelly, I am the senior director for the TTRA Program at MTPConnect and I will be your facilitator this morning.

So, before we begin I'd like to acknowledge the traditional custodians of the many lands that we are meeting on today. I am personally on Bunurong Land and I pay my respects to elder's past, present and emerging. I also extend that respect to Aboriginal and Torres Strait Islander people joining us today for this information session.

So before we launch into the session I'd like to run through a few key pieces of housekeeping. Today's session will include, firstly, a presentation, providing a broad overview of the TTRA program in its entirety and then we'll be drilling down into the key details of the research projects funding opportunity. This will be followed by a panel discussion with representatives from our TTRA program partners, and they will give you advice and tips on how to prepare a competitive application. Following this we will then open up the session to the audience, so that you can ask us any remaining questions.

To submit your questions, please use the Q and A box, which should be available at the bottom of your screen in your zoom toolbar. And if you have the same question as someone else you can up vote it and that will raise the question to the top of the list and we'll be able to get to it quickly. Questions can be submitted anonymously, but if there is any need for follow up, we unfortunately won't be able to reach you so, you can contact us directly via our TTRA email address, which is displayed in the top right hand corner of the slide. We do request that audience members hold off on submitting questions until the end of the presentation and panel discussion as your question may be covered during the course of the

session content and then that will allow us to work through any unanswered questions at the end.

For audience Members who have a question about whether their research project is within scope or aligns to one of the priority areas identified, we would appreciate if you contact us directly via our TTRA email, so we can gather the relevant information from you to make an informed assessment. Unfortunately we can't have that two way dialogue during the webinar.

For those who wish to review this presentation at a later date or, if you have colleagues who couldn't attend, a recording will be made available as an on demand video on the MTPConnect website before the end of the week, and we will notify all registrants when it's published. We will also be turning this session into a podcast episode as well, so you can listen on the go.

Today I'll be joined by my TTRA colleagues at MTPConnect Dr Mana Liao, our TTRA director and Dr Erin McAllum, our TTRA project Manager. Additionally, we are obviously fortunate to also hear from representatives of our program partners. Grace Lethlean from ANDHealth. Olivia White from the Medical Device Partnering Program and Dr Leigh Ford from UniQuest. We also have Dr Amabel Tan from ANDHealth and Dr Andrew Harvey from UniQuest, who will be working behind the scenes and may respond to questions in the Q and A box for you.

So before we move into the TTRA program details I'd now like to introduce MTPConnect managing director and CEO Dr Dan Grant who will provide an overview of MTPConnect and what we do to support the Medtech, biotech, pharma and digital health sector in Australia. Welcome Dan.

MTPCONNECT BACKGROUND

Dan Grant: Thanks Lauren. As Lauren said, my name is Dan Grant, I'm the managing director and CEO of MTPConnect and I too want to thank you all for coming today to listen to this session on the TTRA Round 2 project grants.

We really appreciate your time and, as I look at the bottom of my screen, I can see, we have about 162 people online at the moment, so again, thank you very much for your time.

My role today is really to just remind you about who MTPConnect is, if we go to the next slide.

MTPConnect was established in 2015 as part of the Federal Government's Growth Centre Initiative. We're one of six growth centres and we are mandated with helping to accelerate the growth of the Medtech, biotech and pharmaceutical sector in Australia. We have offices in Melbourne, Perth, Brisbane and Sydney and we work at the nexus between companies, researchers, industry, associations, governments, universities, investors and regulators all focused on delivering key outcomes for the sector.

We're very much interested in increasing collaboration and commercialization across the sector, making sure that Australia is well positioned to capitalize on the research that's conducted within our research institutes and universities. We spend a lot of time working to

improve management and workforce skills in the sector, making sure those skills are fit for purpose, so the sector can grow. We run trade delegations and international missions to help improve access to global supply chains and international markets. And finally, we work very closely with State and Federal governments to help optimize regulatory and policy environments. Can we go to the next slide please.

We've been very fortunate to secure more than 180 million dollars of funding from the Growth Centre Initiative and the Medical Research Future Fund to help achieve these objectives. While I don't want to spend any time at all on the programs that we run you'd be familiar with our Growth Centre Initiative which has $15.6 million of funding committed to the sector. We have BioMedTech Horizons one through four, another $45 million focused on improving opportunities for medical technologies in Australia. Both of these programs are largely committed.

You'll know the Biomedical Translation Bridge program, another $22.3 million program again largely committed to 21 programs and we're delivering that with three of our key partners, including MDPP and UniQuest.

We have a program that is open it's called REDI. This is a training and education program. It's a $32 million program and I do want to spend just a minute talking to you about this because there is an opportunity for individuals to apply to REDI to secure fellowships. So clinicians, academics and other MTP professionals who would like to work for up to a year within an industry partner can apply to the ready program to secure a fellowship. I mentioned this now because just this week we relaxed the selection criteria for the REDI fellowship program, opening this program up to smaller, earlier stage companies to act as the sponsor. So, if you're interested in working in industry, if you've got a collaboration with a small company that you would like to work in for up to a year, please go to the REDI website and check out how you might apply for one of these fellowships. The fellowships will provide up to $250,000 in funding to allow you to do this.

But today we're here really to talk about the Targeted Translational Research Accelerator program, and this is one of our newest programs. It's a $47 million program that Lauren will tell you more details about in a few minutes, but today we're really here to talk to you about round two of our project fund.

And I'll pass back to Lauren now, and she can talk to you in detail about the program. I'll end by just again thanking you all for your attention today.

We look forward to receiving applications, both to the REDI fellowship program but also to the TTRA project grants from many of you in the near future, thanks Lauren.

TARGETED TRANSLATION RESEARCH ACCELERATOR - BACKGROUND

Lauren Kelly: Thanks Dan. Before we jump into the TTRA program we'd like to learn a little bit more about who's joining us today. As Dan said, we have over 150 people online today, which is a really fantastic turnout and thank you for joining us this morning.

So we'd like to run through a quick poll set up on your screen at the moment and you'll be able to complete them all. So the first question is to find out which modality your research aligns with so you can tick all that apply there. The second is to learn which priority area out of the five that we've prioritised that you are most interested in, again ticking all that apply and, lastly, which organization type you are from. I'll give you a few moments to complete that.

Libby Pearce: Yes, and just a reminder to once you've answered everything just to hit the submit button, so that comes through Thank you.

Got quite good participation Lauren.

It's coming through thick and fast, might just give everybody another 20 seconds or so.

Okay looks like they were all coming in, so I'm just going to end that poll and I'll pop those results up on the screen for everybody.

Lauren Kelly: Great so I'll run through these quickly. So we're actually seeing quite an even split with respect to the different modalities. So behavioural intervention about 33% of our audience Members are interested in BI. 47% in in digital health, 41% in medical devices and 52% in therapeutics. So that's fantastic to see that we're reaching a really broad audience base with this information session.

And I guess reflecting on round one we can actually see that there's been an increase in those that are that are interested in BI. We only had about 9% of applications that were BI focused in round one so it's great to see that that a big audience percentage is interested in that modality.

For this round with the priority areas, again we're seeing all of the audience interested across the two cardiovascular disease priority areas, as well as obesity, mental health, and glucose control.

Finally we're seeing again, probably, which is quite reflective of Round one with the largest audience base coming from medical research and university public research organization, and then 17% from corporations, another 17% or so from other corporate or other entities. I guess reflecting on round one we saw we had about 70% of applicants were from public research organizations, basically MRIs and universities. 28% was from corporations and then 2% from other corporate entities. So it's great to see that we're getting a broad audience base joining us today.

So we'll get into the main event. The TTRA is a $47 million program as Dan said, to support the development of innovative preventative, diagnostic, therapeutic and management approaches for diabetes and cardiovascular disease, as well as their associated complications and this is being run over five years.

The TTRA funding is drawn from the Public and Preventative Health Initiative of the MRFF, so, while there is a clear focus on health equity approaches, TTRA program also has commercialisation objectives.

The program funding is deployed across three pillars. The first is to establish through a competitive process two Research Centres one for diabetes and one for cardiovascular disease and their associated complications. Applications for these were called for at the beginning of the year and the outcome of this funding is imminent. The two Research Centres will be funded for four years through the TTRA and there is an expectation that they will be sustainable thereafter to continue to carry out the work.

The second pillar, which is what we're focused on today is to provide research project funding. Again, this is a competitive process. In January we called for the first round, which focused on common pathways, interactions and complexities for people experiencing comorbidities of diabetes and CVD, with the overlay of mental health, chronic kidney disease or other cardiac or vascular complications. So last month, the first round awardees were announced with $5.2 million flowing to seven projects addressing the three different priority areas, called for.

We are here today to talk about round two, which has just been opened. As you'll notice on this slide, there will be a third round of Research Projects which we expect to be announced in about mid 2022.

So underpinning both the Centres and the Research Projects, we will be fostering the translation of research and promoting collaboration with industry through Pillar 3.

We've partnered with preeminent organizations focused on research, translation and commercialization to support applicants and awardees of Pillar 2 Research Projects, as well as the Research Centres.

The Research Centres and Research Project awardees will have the opportunity to engage with one another. This will provide further opportunities for new collaborations to build, as well as access to training programs and workshops to aid in the translation of research through a series of annual partnering summits and Erin will be able to talk to these in more detail.

The TTRA is unique in comparison to some of the other programs that Dan highlighted earlier, in that we have an independent Expert Advisory Board, which has been nominated by the Minister for Health and Aged Care and chaired by Professor Ian Frazer. Our TTRA Board is diverse and highly experienced with deep expertise around diabetes and cardiovascular disease via advocacy and lived experience perspectives, clinical, biomedical and public health research strengths, as well as commercialisation and investment viewpoints.

As you'll recall on the TTRA Program overview slide just two slides ago, across both the Research Centres and the Research Projects funding opportunity, we have been, and we will continue to undertake a national, coordinated health sector needs assessment in diabetes and cardiovascular disease. This is to ensure that the funding opportunities that we call for supplement existing initiatives and fill emerging research and clinical gaps not currently addressed in the sector.

We partnered with Monash University's Behaviour Works, ANU and Research Australia to deliver on first identifying and then prioritizing the unmet needs for the TTRA funding rounds. The process of the needs assessment follows four key principles. First is scope. So for round two the

overarching question that was asked via a survey was what is the most critical unmet need in diabetes or CVD. This question was answered by 180 individuals representative of researchers, clinicians, other healthcare professionals, industry, knowledge of the lived experience, advocates, investors and other sectors stakeholders. Through the survey an exhaustive long list of over 500 potential priorities were identified. Then, as we moved through to principal three, a validated coding framework was used to turn this long list into a shorter list of unique topics to be discussed at a round table with a representative group of individual experts and consumers. This group use set criteria, which focused on clinical impact, quality of life, as well as commercial potential, economical productivity benefits and consumer expectations to prioritize the unique unmet needs that we've now called for as part of Round 2.

for those in the audience who participated in the roundtables, you may recall that there was significant discussion around health service delivery innovations and the need to address the inequity and barriers to accessing care that do exist in Australia. So while this type of research cannot be funded within the scope of the TTRA program, we acknowledge how important it is and, as such, all the applications in Round 2 will be assessed on how they will achieve or enhance equitable health service delivery or access in Australia, particularly for regional, rural and remote populations, Aboriginal and Torres Strait Islander communities, and other underserved groups.

You will no doubt be aware of the five priority areas for Round 2 Research Projects funding. These are atherosclerosis including cerebrovascular disease, cardiomyopathy and associated heart failure, and then obesity, mental health or glucose control as it relates to diabetes.

For those who applied for Round 1, you may recall that mental health was also a priority there. However, this was in the context of people living with both diabetes and cardiovascular disease. Through the second needs assessment, it became clear how significant an unmet need this is for people with diabetes, hence it's prioritization again here.

I'd now like to welcome Erin to take us through the details of the Round 2 Research Projects funding opportunity. Welcome Erin.

TTRA RESEARCH PROJECTS ROUND 2

Erin McAllum: Thanks Lauren. So now that you will have a background on TTRA program as a whole, the needs assessment process and it's outcomes which have informed those priority areas, I'll now run you through the specifics of the Research Projects funding opportunity.

The scheme can provide between $200,000 and $750,000 in cash to help eligible organizations develop innovative, preventative, diagnostic, therapeutic and disease management products and solutions addressing those priority areas.

The project term for funded TTRA Research Projects is a maximum of 24 months and to be eligible, applicants are required to provide a contribution to the value of 50% of the TTRA funding request. So, for example, if you're applying for $400,000 in TTRA funding, you will need to demonstrate a commitment of $200,000. This co-contribution can be cash

or in-kind or combination of both, and I see we've already had a question on that today, and a number of questions prior to the information session as well, so again, that can be cash or in-kind, or a combination. Additional cash or in-kind contributions above this threshold will be viewed favourably, but this is not a requirement. Examples of possible in-kind contributions that you may include could be salaries for key personnel that are actively engaged in the project, equipment or infrastructure that is used and can be valued, provision or manufacturer of a drug for a study or clinical trial, or other things of this nature.

The TTRA program will support a range of approaches or modalities and these include digital health solutions, medical devices, therapeutics and standalone behavioural interventions. The application form and selection criteria are specific to the different modalities so it's really important that you submit your application through the most appropriate modality stream. Ultimately, the modality you select depends on where your projects novelty and core differentiation lie and to help you determine this, we have included a decision making framework and descriptions of the different modalities on pages 13 and 14 of the funding guidelines which can be downloaded from the MTPConnect website. I'll just give you a brief overview of the different modalities now.

For digital health, these are digital technologies, represented either alone or in combination with physical products to treat, diagnose, cure, mitigate and/or prevent disease. Some examples include mobile health applications, connected wearable devices where the innovation or novelty lies in the software or the algorithm, telemedicine solutions which are delivering a clinical outcome for patients, care coordination systems with clear patient outcomes, clinical decision support tools and digital tools for evidence based behaviour change. The common denominator for all of these being that they have a clear impact on clinical outcomes and deliver improved care.

For medical devices, medical devices are any instrument, apparatus, appliance, material or other article, whether used alone or in combination, and including the software that's necessary for its application, that is intended to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease. Some examples include implantable devices, drug delivery devices, medical imaging, in vitro diagnostics, and assessment or monitoring devices.

For therapeutics, the therapeutic classes that are within scope for the TTRA program are fairly broad. Say, if you're working on an antibody, a peptide, a cell or gene therapy, a small molecule or constructs of any combination of these, you would fall within the therapeutic stream. Other categories may also fall within therapeutics. If your project involves repurposing a drug, we strongly encourage you to get in contact with the MTPConnect prior to submitting your expression of interest.

Behavioural interventions are interventions or lifestyle changes designed to affect the actions that individuals take with regard to their health in order to improve outcomes, with respect to prevention, treatment or management of disease. Some examples include structured education programs, for example quit smoking programs, healthy diets and exercise programs, psychological programs, health enablement using IT, and environmental restructuring. There are others, and you can find some of these listed within the application form.

The TTRA program is principally seeking to support projects that will reach a commercial or health economic value inflection point by the end of the TTRA funding term. So this will position your product or solution more attractively to garner that next investment, whether it is another grant, industry partnership or license, or investment from venture capital. As such, this position at the end of the TTRA funding term will be unique to each project and it is your job to articulate this in your application. Generally speaking though, blue sky discovery and ideas and concepts that have no technical validation will be too early and therefore out of scope for the Program.

The TTRA program, as with other MRFF funded programs that MTPConnect delivers, is also seeking to build capabilities and capacity around translation, commercialisation, implementation, and adoption for the Australian research and clinical sectors. To that end, we have partnered with ANDHealth, MDPP and UniQuest to provide guidance and support to applicants, both during the application process and post award. During the application process, this support comes in the form of the consultation phase, which follows EOI and I'll outline that shortly. Post award, the awardees can leverage the deep expertise of our partners to support successful delivery of their project plan.

An additional value add aspect of the TTRA program will be the annual partnering summit which Lauren mentioned and MTPConnect will co-host this with the successful Research Centres and the Research Project awardees will be invited to. The partnering summit will be an opportunity to access advice, assistance and training with respect to research translation, development pathways and commercialisation. We will also be exploring the opportunity to invite relevant external researchers, industry and investors to the events to increase potential for research and development and synergies in investment. This will also provide Research Project awardees with the opportunity to develop peer to peer and industry links with each other and the TTRA Research Centres.

In terms of eligibility, this is laid out in detail on pages 9 and 10 of the Funding Guidelines, along with a comprehensive list of eligible and ineligible expenditure. Eligible applicant organizations must have an ABN and must meet the MRFFs definition of an eligible organization. So this includes medical research institutes, universities and corporations, but please note that large corporations are ineligible and we define this as having 200 or more employees. Medical research institutes and universities are not impacted by this employee cap. Legally and financially separate Commonwealth or state government entities are also eligible, and I’d just like to point out that there is no preference given to any type of organization over another.

The proposal must be addressing one of the five priority areas that Lauren outlined and the product or solution must be applicable in markets beyond Australia.

Applicants and organizations can submit multiple applications for the Research Projects, so long as they are different projects. You can also submit projects that have been submitted for other pending grant opportunities and we ask that you declare this in your application. If your project was to be submitted for multiple opportunities you need to be mindful that you cannot be funded for the same activities or project twice as this is considered double dipping. There is nothing precluding

you from applying for this round if you applied in Round 1, as long as the project is addressing one of the Round 2 priority areas.

In terms of IP eligibility, is it imperative that applicants control or have the legal right to access relevant IP. So we've included an IP eligibility flow chart on page 10 of the funding guidelines to allow you to self assess the IP status of your project and determine if it meets the IP eligibility requirements of the funding opportunity. Please take a close look at this and if you're still unsure about the IP status of your project feel free to contact the TTRA team, but note that we are unable to give you IP advice.

The application and selection process is a multi stage leaky funnel. Initially, applications are submitted as expressions of interest and are first checked for eligibility by MTPConnect. They are then reviewed by MTPConnect and the TTRA program partners, as well as independent individuals representing consumer and public health perspectives. It is expected that a significant proportion of applications will then move forward to the consultation phase, which I mentioned earlier. Here they will be matched with an appropriate TTRA partner who will undertake a consultative due diligence process, allowing the applicant to address EOI review feedback and take a deeper dive into the project under confidentiality. I'd like to emphasize that this process is not only valuable for developing your TTRA application, but it can also generally add value to your project as you're thinking about commercialization and implementation. Following this, the selection panel will reassess the applications and a short list of projects will move forward to the final stage to submit a full proposal. An independent international and national investment panel of experts will review these full proposals and make recommendations for funding award. The successful applicants will then enter into a formal funding agreement within MTPConnect and will have regular reporting obligations. As outlined earlier, awardees will have the ongoing benefit of mentorship from the TTRA partner throughout the duration of their TTRA funding.

As a general guide for round 1, roughly half of applicants at each stage, made it through to the next stage in the process.

So finally I'll just briefly mentioned the selection criteria, which I think the panel will delve into a bit further. Applications will be assessed against five broad selection criteria themes. these being challenge and solution, technical merit, project plan, commercialization / implementation and team and capabilities. I'd like to point out that these are all weighted equally.

For technical merit and commercialisation / implementation, there are tailored questions and selection criteria for the different modalities so again, I stress the importance of selecting the correct modality for your innovation.

The selection criteria are quite comprehensive and can be found from page 18 of the guidelines.

I’ll now pass back to Lauren who will lead you through the panel discussion.

PANEL DISCUSSION

Lauren Kelly: Thanks so much Erin for providing all of that detail. So I'd now like to introduce our panelists who, through the course of our conversation will provide advice on how to best approach, the development of your expression of interest and produce a competitive application and we'll use the framework of the selection criteria to work through this.

So I'll be joined by Mana Liao from MTPConnect and representatives from TTRA partners, Grace Lethlean from ANDHealth, Olivia White from MDPP and Leigh Ford from UniQuest. So if you haven't already put your camera on please do.

So, can I ask you all to please introduce yourselves and for those who are not from MTPConnect also provide an overview of your respective organisations just for our audience's benefit, so I'll start with you Mana.

Mana Liao: Thank you Lauren. Hi everyone, as mentioned I'm Mana Liao, Director of the TTRA program. I have a background in medical research, intellectual property management and commercialisation. And in the last round of Research Project, we have received many high-quality applications and we're looking forward to support more in this round and I hope the tips we are providing you today will come handy you preparing your application so now I'll pass on to Grace.

Grace Lethlean: Thanks Mana. I've got a background in engineering and commercialisation and I'm co-founder of ANDHealth and we're thrilled to be a venture partner under TTRA.

ANDHealth specialises in digital health and Australia's only organisation which designs and delivers specialised technology identification, screening and commercialisation programs proven to accelerate the scale up and commercial growth of digital health companies. We have provided over 1700 hours of commercialisation support to over 460 companies since 2017 and we will be providing mentoring and commercialisation advice to digital health applicants and funding recipients under TTRA. But if you are not digital health and you own the medical device, you'll have the pleasure of working with Olivia and her team.

Olivia White: Thank you Grace. So I'm Olivia White. I'm from the Medical Device Partnering Program or MDPP and my background surprisingly is all centered around medical devices, encompassing everything from research and development, right through to sales marketing and management. So I bring this expertise to our team at MDPP and to our ideas incubator which fosters early stage collaborations between researchers, industry, end-users, government to help entrepreneurs and researchers develop novel medical devices with global market potential.

So MDPP is a national initiative and it's an initiative of the Medical Device Research Institute of Flinders University. It works with over 13 national partners across Australia and since commencing 13 years ago I had assessed over 720 ideas for new medical or assistive technologies. So if you choose medical devices, you'll have access to our team of innovation and commercialised experts, however, if it's therapeutics you're after, then it will be Leigh Ford and his team at UniQuest.

Leigh Ford: Thanks Olivia. So I'm Leigh Ford. My background is in therapeutic drug discovery and translation of academic research and I'm the Project Manager at UniQuest.

UniQuest is a leading university-based commercialisation company which manages the intellectual property of the University of Queensland. It's created more than 100 startups from UQ research and raised more than 812 million dollars to take UQ technologies to market. UniQuest's QEDDI is a small molecule drug discovery capability translating academic biomedical research into new drugs to deliver faster health benefits. In the context of TTRA, QUEDDI and UniQuest more broadly, provide expertise and mentoring, to the therapeutic modality.

Lauren Kelly: Thanks Leigh and for those that are behavioural intervention applicants and then awardees you'll have the pleasure of working with a combination of our TTRA partners and leveraging the complementary skill sets there. So diving into the first selection criteria theme which is Challenging and Solution. Here you'll be asked to link your proposal product or solution to the identified priority area that you're applying through, so Olivia what advice would you have for applicants tackling this section.

Olivia White: Well, I guess, the first thing I'd say is that all of the sections are weighted evenly at 20% but consider Challenging and Solution in this section to be where you can make your first impression to the reviewing panel. This is where you describe how your product or solution fits with one of the five priority areas, so you get the opportunity to hook the reviewers in with your unique value proposition. If you've ever penned an NHMRC application, think of this section as the first page of your grant.

So the selection panel will be looking for a clear demonstration of the problem to be solved for a specific patient group. And a solution that is meaningfully different for what is out there at the moment. So, for example with therapeutic or medical devices they'll be looking to a tailored novel intervention to address a serious unmet need. For digital health and behavioural interventions, a competitive application is a solution that solves a problem for patients, carers or healthcare professionals delivering clear patient outcomes and health economic benefits.

In round one the competitive applications with those that could also articulate the existing market environment and could explain how their product or solution is more competitive over those in the market at the moment or has an advantage over what might be in development. This round applications will also need to include information on how a product or solution that you're developing will achieve or enhance equitable health service delivery across Australia.

So, if you would like some extra tips on how to approach this section, MTPConnect put out a great webinar last year called 'Show me the money', so I would highly suggest you watch that. And I guess my final tip would be if you've got someone outside of your workplace or even a partner to have a read of this section if they understand what you're trying to achieve it's a great litmus test to know that you're on the right track for a successful commercialisation grant.

Lauren Kelly: Great thanks to Olivia and we will drop the 'Show me the money' webinar link into the chat box shortly, and it will also be distributed out to all registrants when we follow up and let you know that this on-demand video is available. So, moving on to the Technical Merit section and here we will be seeking to understand your product or solution at it's obviously technical level. And the approach we've taken in developing and validating your innovation to date. So, although there are some commonalities to this section across the different modalities, such as scalability of the solution or engagement stakeholders. It is recognised that due to the distinct R&D pathways required for progressing digital health solutions versus therapeutics versus medical devices or standalone behavioural interventions. The EOI form will therefore provide separate questioning and separate assessment of the different modalities. So Grace, from a digital health perspective, how would you approach this section?

Grace Lethlean: Thanks Lauren. So in this section for the digital health applicants, we're looking at the stage of development that the solution is at, so what the solution is, how it works and how it fits into clinical and patient work flow to make that impact. So digital health application that's successful, clearly address a number of core factors.

Let's go through them. I'd say that the end user, payer and beneficiary need to be clearly identified and that's pointed out in the tips, so do take the time to read the tips, they are there for your help and just like to really point that out. Also, that your product clearly solves a pain point for the clinician and the patient, and this is a place to put some clinical outcomes and that your product focuses on those clinical outcomes and not simply say, improved back end data management.

You need to have a clear articulation of how the solution will integrate into the current clinical workflow and patient journey or if implementation will require an entire new system regime change, spell out how that would work in practice. This is a place to provide evidence and explanation of your engagement and with key stakeholders throughout the whole value chain of your products. So you've got users and payers and beneficiaries and any demand your solution from any and all groups.

This is also a place to provide any evidence or data, demonstrating that the proposed solution is likely to deliver on the outcomes that you're intending and a bonus if the prototype or proof of concept has been tested with clinicians and patients and end users or maybe you've done a UX/UI study.

Finally, do show us that you've given consideration to the scalability and key integrations required, as well as job security and access, ownership and data privacy.

So I hope it's helpful for the digital health applicants out there and Olivia can help support the medical device applicants, how can they make a strong technical selection, Olivia?

Olivia White: Okay well in this section it's really your opportunity to show what technical or stakeholder engagement work you've completed to date. So take the panel on a journey from your preclinical bench top data right through to any animal or clinical studies you've completed that validate your technology. You'll also need to show evidence that your device is safe and that you understand what class of regulation it falls

under. So the TTRA aims to fund projects that will read to commercial inflection point by project end.

In round one device applicants were successful in reaching consultation phase, if they were at a Technical Readiness Level or TRL level of three and above. And most were projecting to trying reach TRL5 by the project end. So if you're not familiar with the TRL levels, it is in the EOI. And TRL5 is when a device is ready to be compared against existing modalities in its indication for use.

So early involvement from stakeholders is also really important and key to product design, so the reviewers will be interested to see what level of engagement you've undertaken so far. And if you've encompassed any early feedback from clinicians into the design of your product. So competitive applications from round one were able to provide this evidence, and this could have been in the form of voice of customer analysis or needs analysis documents. And it was really important that they were able to show that they could describe how the device could be incorporated into current clinical flow or existing clinical practice, so maybe take that on as a tip. And evidence of other stakeholder engagement is also looked on favourably so this could be engagement with groups such as end users, patients, local health networks, advocacy groups, manufacturers or supply chain partners.

And like Grace, scalability is really important, so there is a question on that in the EOI and it's also looking at the barriers to adoption that might exist into implementing your new device into the market, so be prepared to add some information about your intended manufacturing and implementation plans.

Leigh, how would therapeutic applicants approach this section.

Leigh Ford: Thanks Olivia. So in therapeutics you'll need to demonstrate that a biological target is sufficiently validated for the priority area and relevant disease states. The reviewers will be looking for links to disease, complementary approaches to target validation and a robust data set supporting translation of efficacy into the clinic. You'll also need to assess the safety risk of your approach in the relevant patient population.

Competitive applications will comprise reproducible, controlled and standardised data. Space is going to be really tight in the EOI, so a tip to demonstrate experimental robustness is a complete but concise list to experimental features, for example, after an in vivo ED50 include details such as species and strain, dose including route and regimen, group size, measures of significance and statistical method. The assessors will also be looking for things like controls and commercial benchmarks.

Mana, how will behavioural intervention applications be judged on their technical merit?

Mana Liao: Thanks Leigh. So for this section for the behavioural intervention, you will be assessed upon the evidence based biomedical and psychosocial benefits that can be implemented or adopted by end users, public and community. So the reviewers will seek interventions that can deliver clinical value and health economic benefits which can conveniently fit or complement within the existing clinical workflow, or fits the typical patient journey. Competitive applications will also

provide evidence of end user demand or clinical support over the existing solutions, and proof of principle use in the clinical or market setting. Also it's important for applicants to identify what are the key challenges in the uptake and the adoption and present a strategic approach in addressing them.

If your application incorporates a behavioural intervention in combination with any of the other modalities, as discussed previously. The modality stream to apply through will be dependent to 'where does your project's novelty and the core differentiation lie?'. For example, if you're using an off-the-shelf videoconferencing tool as a medium for delivering a novel psychological care to help to improve mental health in that case you should apply through the behavioural intervention stream. However, if your core innovation is in the actual design of a new software or device technology to allow the implementation and adoption of behavioural change then digital health or medical device will be more appropriate. But if you're still unsure which modality stream to apply, MTPConnect and the Partners are more than happy to meet with you to advise on your specific project.

Lauren Kelly: Thanks Mana. Yes, definitely just reach out and have a chat with us, we don't bite. So while it's appreciated that EOIs are brief, a single page upload can be attached to support your EOI submission, so this upload can include data, figures, images or other supporting information that you have generated yourself, or it can be taken from the literature. But please ensure that you use appropriate referencing for the reviewers' benefit and provide a link back to you in text responses in SmartyGrants to discuss the data and its significance. The upload can be used to support your whole submission, for example benchmarking or evidence of differentiation and to support the Challenge and Solution section through your Technical validation or to outline say a Project Plan workflow. However, please note that this one-page upload is not a place to just get an additional 500 words into your EOI, it is the supporting data only.

So, moving on to Project Plan, description of your TTRA funded project plan may sound very straightforward, but we do see some traps that applicants fall into when addressing this section. So grace, can you articulate what assessors will be keeping a close eye on in this section of the EOI.

Grace Lethlean: Thanks Lauren. Yes, I have to share my favourite part, I think it's the part we can be really creative and actually make a big impact on your innovation at this point. So the Project Plan, and the goal of TTRA is to move translational research and towards this commercial reality and community impact. And so it's important that you can clearly articulate what stage you're at, where you want to get to and support that with evidence and define both major incremental milestones of your proposed project. So being vague will only hurt you in a Project Plan, unless you can just clearly justify why you're unable to plan a certain stage right now. Just dot point it out, slabs of texts are actually less clear.

And remember that the funding is up for 20 to 24 months, so while some targets might extend beyond the 24 months, we really want to know how this funding will be used in the next two years, and what the expected outcomes and impact of those project activities will be on your solution's ability to be commercialised. So remembering that overall,

essentially proposed activities are on the critical path towards key translational milestones and commercial proof of concept.

Another hint is to be clear about the risks in the development of your solution and how that proposed project will address these, so an all-green risk register actually does not indicate a strong project but, for example, if your application and understanding exactly what data is required to achieve regulatory approvals is a bit of a risk for you guys, that's all right. Don't pretend that you know and just put data gathering for regulatory approval as an activity alone. This is actually a chance, an opportunity to put a task around engaging a contractor to understand the data required for every approval and expert review of clinical trial structure towards regulation. And then you can do your clinical trial. You can actually get budget for those activities. So that would indicate a well thought out project for TTRA Program to make a real impact. And note that the use of funds does cover many professional services to assist you on that critical path towards translation. So don't forget your project risks and do consider all the categories of risks.

Look, finally it's important, of course, that the amount requested is realistic and the requested amount generally match the task at hand. If it doesn’t pass the back of the envelope test, it probably won’t pass the review committees. So that’s my tip there.

Lauren Kelly: Thanks Grace. So what we've heard so far is that it's important to not only provide an overview of the big picture, which is your challenge and solution section, your technical work done to date and then your project at hand, but also we are looking at the later stages of development as your solution or product moves towards clinical work or end user adoption.

So, within the commercialization and implementation section of the EOI, we're seeking a clear understanding of the commercial potential or health economic benefit of the proposed product or solution. This will depend on if there is a commercialization pathway, so if you've got a therapeutic, a device, or a digital health solution, or an implementation / adoption pathway for behavioural interventions.

Please be mindful of the tips that we've provided throughout the EOI application form. They are there for nearly every single question and they're a really helpful guide to for what to include in your responses. So they've been tailored for the different modalities as appropriate so really we encourage you to use these to your advantage.

So the first section of commercialization / implementation is IP. While it is not a requirement to have already been granted IP protection or have applied for it for this scheme, it is important to outline the strategy behind securing a strong IP position. So Mana what advice, do you have applicants here?

Mana Liao: Thanks Lauren. So intellectual property or IP is a significant consideration in this section as Lauren has mentioned. IP is an intangible asset of innovation, meaning, it has value and can be sold licensed or traded. And not necessarily technological so it could be the knowledge or the staff expertise.

So IP protection, the IP strategy are both critical for a successful commercial outlook, but often overlooked in the academic setting. So, in the last round quite a number of applications didn't progress due to the lack of ownership or control rights of the IP.

For example, the tested drug use for the project is owned by a biopharmaceutical company and there's no IP arrangement between the applicant and the company. So as a priority, before you go too deep in crafting your application, I will highly recommend you conducting a self assessment or your IP eligibility using the flow chart on page 10 of the funding guidelines to avoid disappointment down the track.

So there are a number of ways IP can be protected against copying or other unfair usage by competitors. Patent, trademark, and design are the legal registration that many of you are familiar with. Other forms of IP protection that don't require legal registration that can sometimes be just as effective include trade secret, know-how and copyrights.

Across all the modalities competitive applications will be those that can articulate the strategic value of their IP and the strategies to protect the innovation which can encompass and mix the forms of IP protection.

In general therapeutics and medical devices which result in more tangible products will place more emphasis on patents and design registration, whereas for digital health and behavioural intervention, the traditional pattern may not be appropriate for the business model.

If the applicant has already filed a patent reviewers will be seeking favourable terms in the application. for example does it consists of a broad pattern plane, or does it have a clear freedom to operate or search report.

A common weakness will have seen in past applications was the insufficient articulation of how they're going to secure market share and how to protect the innovation in the absence of a patent. So it's really important for you to fully expand on your IP protection mechanism such as using trade secret, trademark, a first mover advantage, or exclusive access agreements so that you can provide your reviewer the confidence in your commercial outlook.

So in practice investors or venture capitals will not be interested in the work, even if it is brilliant science without a robust IP strategy behind it.

If you're using third party IP, for example, a drug provided by pharmaceutical company or an off the shelf software, make sure you have obtained the legal right or the agreement to conduct the work, and keeping a clean chain of titles of any future project IP. You will not want to be in a situation of infringing others IP after having done all the hard work.

So the top tip I like to give is to seek advice from your technology transfer office if you're from a university or a medical research institute because they manage the IP portfolios for your Institute, or a patent attorney or IP advisor if you're from a SME or company, so that you don't accidentally jeopardize your IP position and can leverage on their resources and expertise to build a stronger application.

So I'll now throw to Olivia to talk you through the clinical and regulatory aspects of the application.

Olivia White: Thanks Mana. So in this section you'll be asked about clinical and regulatory plans, so what the reviewers will be looking for is what comes next. what future studies or projects do you need to complete after or in conjunction with the TTRA project to keep you moving along the innovation and commercialization pathway. So, for some, but not all this will include talking about what future clinical studies need to be performed before your product or solution makes it to market.

For therapeutics or a drug device, this is the ideal section to include what you're going to do to complete that data package that you need to complete your target product profile.

For regulatory, the panel will be looking to see that you've clearly identified your pathway, including any barriers you might expect, regarding approval. So you'll need to cite the regulatory classification from the TGA and any other jurisdictions you're planning to target. For digital health applicants there's been some recent changes from the TGA to software as a medical device, so you should really consider this.

Information can be found on the TGA website, or you could connect with our partner ANDHealth for some advice in this space.

So the regulation in this environment is really complex. Some of you might not have ever engaged in this space before or you might have an external consultant helping you out. And so, if you are in that position or if you're in that early position at a university or research institution, this is also a good opportunity to work with the tech transfer office as Mana said before or maybe an internal business partner to collaborate on what you need to do. In the application, you can highlight this collaboration in this section.

And the other area that's obviously really important is understanding your target market. Grace, could you expand on this a little more for us.

Grace Lethlean: Yes, sure. Look, for the target market, the customer type should be identified. Who will be the ultimate payer for your product or if you don't intend to be taking it to market yourself, who will acquire or partner for your solution? Now careful here, if you intend for the government or a health system to pay. It's legitimate, but for this please articulate how they might pay, for example, are there reimbursement codes, is there specific funding to this kind of service or even a precedent funding for analogous products or services? If you've engaged with or spoken to any payers, this is the time to definitely let us know.

Market size should be realistically quantified. Step us through your workings and how you fit into the market, particularly in crowded markets. If marketer is small but growing it's worth taking the time to discuss that predictive growth.

And we noticed in the last round and a lot of people missed an opportunity in this market section, so please look at the tips they're there to guide you. For those who were successful in the last round, they were able to answer the questions thoroughly and obviously read the tips.

For those of you with a commercial partner or access to commercialisation office leverage their expertise and support for this section. It's equally weighted to all the other sections. You will need to describe your business model and the commercialisation strategy, so it's important that there is a clear commercialisation strategy and, at the center of that strategy is that there's evidence of market demand or a market need, and the potential paying customer or pathway has been identified. Strong applications may have even gone beyond the hypothetical and might, for example, have approach to potential commercialisation partner or developed a revenue model or have a plan to attract independent funding or revenue.

So Leigh, could you elaborate on these commercialisation strategies?

Leigh Ford: Sure Grace. As a building block in your commercialisation strategy for devices, digital health and therapeutics, the reviewers will be looking for a commercial proof of concept or value inflection point at the completion of your TTRA-funded project.

A common proof-of-concept in therapeutics could be a license the project to a pharma partner who has the expertise and resources to bring a product to market. Alternatively, the project could receive investment for clinical development in a newly formed startup. Some example value inflection points might be the selection of a preclinical candidate or promising efficacy data in an animal bundle that industry recognised as being transferable to the clinic.

Olivia could you give us an example of a commercial proof-of-concept or value inflection point in the digital sorry in the medical devices space?

Olivia White: Sure, so really I referred to the technology readiness level or TRL classification earlier and every time you move up that classification that could be seen as a value inflection point.

So, going back to TRL5 if you're able to show, safety and efficacy in the appropriate animal model that is a value inflection point, that you can go and get angel investment or maybe even do a series A capital raise so that's probably a good example to think about.

And Grace?

Grace Lethlean: Sorry Olivia, jumping in there, so excited. Digital health, you know, also has its own value inflection points and, for example, you know you might have planned your regulatory approval process and got the correct data for clinical trial data for TGA approval, that's a great inflection point.

Or maybe you've engaged with key stakeholders demonstrated your solution in real world setting and got some clinical and commercial pilot outcomes to drive uptake or investment.

Leigh Ford: Great thanks Grace, so I think one common feature that we would all agree on across all modalities is that highly scored EOIs will demonstrate evidence that prospective partners see promise in the projects and are willing to invest.

Mana, can you highlight why implementation, as opposed to commercialisation may be more relevant in the behavioural intervention modality?

Mana Liao: Sure Leigh. So for BI or behavioural interventions, it's quite different to the other modalities mentioned. We recognise that the core value of behavioural intervention opportunities may not be at its commercialisation but more in the significant economic health benefit from translation and implementation of the solution in the community.

So, for this reason in the EOI we purposely ask behavioural intervention applicants to expand on their business model in terms of implementation or adoption strategy for the targeted market or end users, after the completion of the TTRA funded project, without mandating for commercialisation as a strategy, like the other modalities. For example if it's a psychological program for tackling obesity to prevent type two diabetes, we would like to know how you will integrate the program into the existing clinical workflow. For example, is it going to be through a partnership, a license, or sale of solution or the IP.

We would also like you to identify the potential payer for the solution. Is that through the hospital's insurance or insurance company, for example, or evidence of willingness to pay through voice of customer studies or adoption of similar solutions.

Competitive applications will be ones that can demonstrate highly potent and maximally implementable behavioural interventions that improve health and well being and can be sustainable. In other words, articulate your approach in getting the buy in from the decision makers, or the gatekeepers that will pay or fund the implementation and continued availability of your solution.

Lauren Kelly: Okay, thanks everyone for that. So we appreciate that you may still be years away from these later stages of development and, indeed, you might not take your product through the clinic yourself. So if you have access to commercialization experts like a technology transfer office or business development groups within your medical research institute or your university, or if you're a SME and other commercialization consultants, we really strongly encourage you to discuss your application with them and to leverage their expertise and advice.

Another reminder that this section is worth 20% of the mark and we don't want you to put all your eggs in one basket, so to speak, with some of the earlier sections and then have this as underdeveloped and therefore jeopardize your position in the Program.

So, last but not least, we arrived at Team and Capabilities. Multi-disciplinary approaches really require diverse teams. It's important to list all the key personnel and external advisors, consultants and areas of expertise that will be required to successfully complete your TTRA project. Even those who may not be contracted or engaged yet so, for example, regulatory consultants to inform some of your downstream study designs.

So, Leigh what other tips, would you give to potential applicants.

Leigh Ford: Thanks Lauren. The first would be to remind everyone that this section, same as the others, is worth 20% of your total score. So I would encourage applicants not to leave this section to the last minute, or just to fill it in as an afterthought.

The reviewers are going to be looking for more than just CVs here. So competitive applications will be those that can articulate how their teams skill set, experience, combined track record, diversity and access to resources really sets them up for success.

The assessment of your team in the TTRA, will be quite different from other funding programs. So this is about really forming a holistic group with the required skill set to achieve your commercial or implementation goals, this is not just a list of superstars. We don't expect that all work is going to be done in House so make sure you list all your external partners.

Applicants should also justify each team member's contribution and role within the project. Reviewers don't want to see a long list of informal advisors. A team of 20 with a combined FT load of less than one is going to raise serious concerns about how the project is being driven. Also, you've got an opportunity to highlight your team members relevant experience or expertise outside of their job title.

Now we appreciate that small teams may not be diverse and you're not going to be penalized for this, but it will be imperative that you outline the strategy for increasing diversity within your team. It's clear that diverse teams are innovative teams. Finally for applicants from universities or research institutions there's going to be an expectation that a member from your tech transfer or commercialization office is part of the team.

Lauren Kelly: So thank you to all of our panellists, Mana, Grace, Olivia and Leigh for providing some colour to the funding guidelines and hopefully passing on really practical tips to those of you who are applying.

So that does conclude the formal part to the information session.

We have about 10 minutes left to go so I'll invite you now to ask any questions that remain unanswered, in the Q and A box.

I can already see that people have started to populate that and so, if you see a question that you also have you can upvote it and it will rise to the top.

There have also been some answered questions so if you toggle along to the answered tab you'll be able to read those and gain some insight.

So, while I give everyone a bit of time just to start populating their questions, I'll remind you that EOIs for Research Projects are open now, and they will close on the 4th of November at 4pm Australian Eastern daylight time.

We cannot accept late submission, so please be mindful of the time zones and don't leave entering your information into the SmartyGrants platform until the last minute. You'll be able to access the SmartyGrants platform from our Research Projects webpage on the MTPConnect website and it's just the 'apply here' button.

Please note that the SmartyGrant system is sensitive to word count and other areas and will not let you submit an application if any text field is over the word count or if a required field is left empty. Unfortunately, not leaving enough time to correct any errors is not a valid excuse for a late submission.

The MTPConnect team is on hand to help troubleshoot, as is the SmartyGrants help desk and both of our contact details can be found in the funding guidelines. But we will not be able to assist you if you contact us with only say 20 minutes to go.

I'd encourage you to start entering your responses into SmartyGrants early, especially those sections which are unlikely to change so filling in tables first, as these can be quite consuming, and all of your applicant administrative information.

Always remember to save as you go and while we don't encourage you to share login details, if you do, the system doesn't actually accommodate more than one user in the portal at the same time. So, if you do have two people in there, the work of one will actually override that of the other, and unfortunately that is not recoverable.

As a reminder, we will have a third round of Research Projects funding opening up in the middle of next year, and this will focus on new and different priority areas, following the third needs assessment.

If anyone has to duck off before we finish the Q and A, there will be an anonymous survey for you to complete upon exit. It's just really helps us to know what worked well and where we can improve next time.

Q&A

Lauren Kelly: So, let's get started on the questions. I'll invite Dan Mana, Grace, Olivia and Leigh to turn your cameras back on and to join me back on screen and we'll work through these questions.

The first question is from Rebecca, and she has asked us if it is eligible to be on more than one application and i'm assuming that she is also asking that so long as they're not the lead investigator on more than one application.

Yes, you can most definitely be listed on more than one application and I don't think there's anything wrong with being the lead on more than one application you just need to consider your capacity to deliver on multiple projects.

Okay, so the next question is from Emma, who's asked that the guidelines indicate that the research team should be diverse and possess the requisite skills to complete the project. Does MTPConnect have any preference regarding the size and composition of the team. For example, would you encourage early to mid career researchers lead applications or is there an expected range of people included in the team?

The team and its size should be appropriate to the research project I think that's the first and foremost point. I would also highlight that we don't want a long list of 50 team members, all of which are only providing 0.05 FTE because then we don't understand who was truly driving the project. Leigh would you add anything else?

Leigh Ford: Thanks Lauren I would just reiterate that this isn't a list of superstars and it's a holistic view of the team, so I don't think we have any preference for who is the lead applicant, or that they need to be the most senior person on the team. Regarding your question about diversity, I think, maybe Grace has got a little answer that she could provide for that.

Grace Lethlean: Diversity is not a box ticking exercise. In this program we've got government money, taxpayers money, we should be seeing representational teams of the types of people we would see in in the society of Australia. We have all seen the many economic studies showing a direct correlation between diversity and innovative and commercial outcomes.

If your team's not yet diversity with respect to gender, career stage or cultural background or other areas, you will be required to articulate a feasible strategy for achieving diversity. If you need help understanding diversity and creating your strategy there's innumerable government resources available to support you with that diversity and inclusion strategy.

Lauren Kelly: Thanks Grace. We've got an anonymous question asking if hospitals are eligible i'd suggest that they are an eligible entity, and they would fall under a corporate state government entity. It would also be important to ensure that you consider the IP ownership for the project, and that the hospital owns or controls the IP that is being progressed.

We have a question from Stephen asking if stroke would fit within the definition of cerebrovascular disease (within Priority 1)? Dan would you like to provide an answer to that question?

Dan Grant: So I think I think stroke does fit within the definition of cerebral vascular disease, as defined in the guidelines.

Lauren Kelly: So the next question is asking if there a specific partner for Behavioural Interventions (BI), as it looks to be represented in the leadership, but not in the supporting partners. For BI projects we leverage the complementary expertise of our ANDHealth, MDPP and UniQuest partners to support applicants and awardees progressing behavioural interventions.

Dan Grant: I might just add to that that. We will also outsource required skills were necessary, should any of our existing partners not have the capabilities or capacity to review and support any BI project or otherwise.

Lauren Kelly: Thanks Dan. So an anonymous audience member has asked if in-kind co-contributions come from organisations with more than 200 employees, or be a co-applicant, or cover part of the in-kind contribution with the supplement of the therapeutic drugs.

Organisations with 200 or more employees cannot be the applicant, but can be a named partner and be on the project team. However, if this organisation owns or controls the IP then you will need to consider the eligibility of your project. So you would need to consider what sort of arrangement, you have in the background, with respect to the IP around that therapeutic drug. Leigh, as our therapeutic modality expert, would you add anything to that?

Leigh Ford: you've covered all the points Lauren. Again I would encourage people if they not sure about eligibility to definitely get in contact.

Lauren Kelly: The next question is asking if you can have a team of academics and a corporation apply. This is definitely allowable, and you will need to determine who the lead applicant is based on who controls the IP. So if you have any questions, please just reach out to us directly.

The next question is how direct does the linkage have to be with a particular priority area? This is assessed and so maybe Olivia you would like to provide some advice here as you took on Challenge and Solution in the panel discussion.

Olivia White: It is a competitive process, so the closer you are to the priority area, the stronger your application will be and that's going to be how well you articulate the alignment and value proposition of your product or solution.

I would advise you to write and rewrite to try and ensure that you really nail this front section of the EOI.

Lauren Kelly: Thanks so we've been asked what if the organization more generally, is very diverse, but not necessarily the project team. Grace you spoke to diversity before and you pointed out that you won't be penalized if it's a small project team, but what is important is

outlining your strategy with respect to increasing diversity. Would you add anything to that Grace?

Grace Lethlean: Without knowing your organization I can't be specific. If you already have an existing organizational strategy around diversity, for example, you're from university, and this small team happens to not be diverse, but you plan to increase diversity as the team grows and presumably the TTRA funding helps you to grow and commercialize and translate. I think is important, to outline your organisation's strategy and their track record that demonstrates commitment to diversity as well.

Lauren Kelly: Great, thank you for that, so I'm conscious of time, we have about a minute left on our scheduled information session and there's still 10 unanswered questions. So we'll keep going through but we may need to close the session and get back to anybody who has left their name attached to a question and, if you have submitted it anonymously then, if you can get directly in touch with us we'll be able to answer any questions that you may have.

So we've got a question from an anonymous audience member asking if acute kidney injury or chronic kidney injury is within scope of atherosclerosis. Dan would you like to address this?

Dan Grant: I think I think we'd have to understand exactly what aspects of chronic kidney injury they're looking at to make that determination. Please note that kidney disease was prioritised in the last round. I'm happy to talk offline.

Lauren Kelly: Please get in touch with us to discuss this.

So, then, we had a question from Keeley who wanted to confirm that pediatric diabetes will be considered equally in this round. So yes, when it's broadly with respect to diabetes most definitely. And if you have a question specifically about your project again, please just get in contact with us and we can help you assess whether you've aligned to the priority area appropriately.

And it's a question from Rebecca asking is the lead of successful applications usually from an organization, for example, a small biotech rather than a than a scientist? So there is no preference given to the lead at all. When we're assessing team we're assessing the team in its entirety, and who makes up that team. We are also obviously wanting to make sure that there is a key driver of that project as well, but no preference given to the lead.

And the next question is would a combination of two modalities be accepted, for example, digital health and behavioural change. So this was discussed during the panel discussion, so perhaps Mana and Grace, would like to tackle this, as the examples are digital health and behavioural change.

Mana Liao: Sure as mentioned in the panel discussion when a project that has two modality components to it, the key aspect that you need to have a think about is where does your core innovation lie? So if your digital component is where the most innovative aspect of your project is, and where you are differentiating from the other products out in the market, then, you should definitely apply through the digital stream, and vice versa. If it's truly a combination of the two, then think about what

makes your project the strongest and most competitive as well. I'll throw to Grace.

Grace Lethlean: I'd also looks towards what an outcome of success would be for your project. Is it a commercial outcome or will it be implementation and a health economics benefit that will be your measure of success? If it's the latter, then you'll be able to answer the behavioural questions better because they have been framed around that. If you're trying to build a commercial product that might be on sold or reimbursed and then to be more able to strongly answer that section in a digital health stream. The key take away is, what does success look like in terms of your product's translation and commercialization?

Lauren Kelly: Right, thank you for that. I might just jump down a couple because i've seen there's a question around IP, which would be useful for everyone. This is from Johannes, who is asking for those who don't have full IP protection, for example just a provisional patent application at this point, would the EOI be considered a disclosure?

I would firstly highlight that EOIs are to be non-confidential in nature, so please do not include any enabling data and that could jeopardize your IP position. Would anybody else like to weigh in on this question?

Leigh Ford: I would just like to add that you should definitely, if you're at a university, talk to your tech transfer office get them to have a look at your EOI application, make sure you don't disclose anything that shouldn't be in the public domain.

Lauren Kelly: And we've been asked if the project fits a combination of two priority areas would it be acceptable to submit under both, for example, priority three and five. So you'll only be able to select one priority area, as the options are mutually exclusive. If you are unsure which priority area your project most aligs with, please get in touch and we'll talk you through this.

We've been asked, with a medical device that monitors blood pressure, would cardiomyopathy and heart failure be selected? Again it's probably best if you get in contact with us straightaway, so we can talk through this project in more detail and help you assess whether you will be eligible to apply.

Dan Grant: I might just add to that, what we don't want to see is people trying to force square pegs into round holes. So we often see that people will mention that priority area once in their application and then move on to their favourite research project and that's not the intent. So for example, if you're developing a device that has direct applicability to cardiomyopathy and heart failure, then you need to build that story in your application to make sure that it truly is aligned with what the priority area is.

Lauren Kelly: Great Thank you and we're at the final question, and we've gone five minutes over, so I apologise everybody. The question is, can a PhD candidate be the principal investigator? So we don't have any restrictions on who is named the principal investigator, and we do look at the team holistically as it's assessed.

Okay, well, thank you all again if you have any other questions that you would like answered please just get in touch with us directly. I'd like

to now thank our presenters and panelists today. Thank you, Dan, Erin, Mana, Grace, Olivia and Leigh, as well as our behind-the-scenes whizz Libby who you heard of heard from right at the beginning, as well as Amabel and Andrew and for your assistance in the Q & A box.

We also thank everyone for joining us and we hope that this information session has provided really practical tips and advice for you as you progress the development of your EOI. If you do need to reach out to us to ask a question about your eligibility or how your project aligns to a priority area, please email us, we're here to help. Thank you all and have a lovely rest of your afternoon.