TTRA Drugs and Devices Information Session - Transcript

Please note, this is adapted from an automated transcript and may not be completely accurately.

Welcome, Acknowledgement of Country and Housekeeping

SLIDE 6

Lauren Kelly: Hello and welcome to the Targeted Translation Research Accelerator Information Session focused on the new funding opportunity for the commercialisation of drugs and devices. I am really glad that you could join us today. For those that don't know me, my name is Lauren Kelly, and I am the Senior Director for the TTRA program at MTPConnect, and I will be your facilitator this afternoon.

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Lauren Kelly: Before we begin, I'd like to acknowledge the Traditional Custodians of the many lands that we are meeting on today and recognise Aboriginal and Torres Strait Islander people as the first innovators, the first healers, first engineers and technologists. I'm personally on Bunurong Country and pay my respects to their elders, past and present, and I also extend that respect to Aboriginal and Torres Strait Islander people joining us today for this information session.

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Lauren Kelly: Now, before we launch into the session, I'd like to run through a few pieces of housekeeping. Today's session will include a presentation providing context setting with a broad overview of the inaugural TTRA program, which was established back in 2020 and then drilling down into the key details of the new drugs and devices funding opportunity which you're all very interested in hearing. This will be followed by a dynamic panel discussion around how to prepare a competitive application. Following this, we'll then open up the session to answer any questions you, as the audience may have that were unanswered.

To submit questions, please use the Q&A box which should be available at the bottom of your screen in your Zoom toolbar. If you have the same question as someone else, you can upvote, which will raise the question to the top of the list. Questions can be submitted anonymously, but if there is any need for follow up, we unfortunately won't be able to reach you. So the TTRA team can be contacted via our accelerator email, which is just displayed at the bottom of this slide.

We do request that audience members hold off on submitting questions until the end of the presentation and panel discussion. As your questions may be answered during the course of the session content. This will also allow us to work through any unanswered questions more efficiently at the end.

For audience members who have a question about whether the innovation is within scope or aligns to the objectives of the scheme, we would appreciate if you can contact us directly via our accelerator email address. This is so we can gather the relevant information from you to make an informed assessment. Unfortunately we can't have the necessary two-way dialogue via a webinar.

For those who wish to view 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. We will notify all registrants when it is published. We'll also be turning the session into a podcast episode as well, for listening on the go.

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Lauren Kelly: I'd now like to introduce the wider TTRA team at MTPConnect, Dr Dharmica Mistry, who is our medical device specialist, Dr Mana Liao, who brings to the program life sciences commercialisation and IP expertise, and Dr Erin McAllum, a strategy specialist with a passion for turning ideas into impact. And you'll hear from both Erin and Mana during today's information session.

So before we move into the details of the TTRA program, I'd now like to introduce MTPConnect's Chief Operating Officer, Lisa Dubé, who will provide an overview of MTPConnect and what we do to support Australia's vibrant medical products sector.

Welcome, Lisa.

MTPConnect Background

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Lisa Dubé: Thank you, Lauren and thank you, everyone. I'm, as Lauren mentioned, the Chief Operating Officer at MTPConnect. I'm delighted to be here discussing this funding opportunity for companies tackling diabetes and cardiovascular disease.

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Lisa Dubé: First, I'm going to share a little bit about MTPConnect and the benefits of investing in medical innovations. MTPConnect is Australia's Life Sciences Innovation Accelerator, an independent, not-for-profit organisation established by the Australian Government to champion the continuing growth of Australia's vibrant medical products sector. We've been operating for almost nine years now.

MTPConnect forges stronger connections between research and industry to help maximise opportunities for Australians to not only make scientific and technological breakthroughs, but to see them develop through the proof-of-concept stage and be successfully translated and commercialised.

We achieved these outcomes with a focus on improving collaboration and commercialisation, funding innovations, improving management and workforce skills, optimising the regulatory and policy environment, and improving access to global supply chains and strategic international markets.

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Lisa Dubé: MTPConnect operates accelerator programs to support the development of cutting-edge medical technology, biotechnology and pharmaceutical innovations with more than $182 million invested so far, in over 200 projects. Here are some of the successful accelerator programs we have run before.

If you haven't already looked at the impact reports for these accelerator programs, I encourage you to download a copy on our website. There are some fantastic outcomes from these programs, including the recently released REDI workforce skills impact report.

Of course, TTRA and CTCM are still progressing, and we are now able to support further diabetes and cardiovascular innovations in this new accelerator program of $28.5 million.

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Lisa Dubé: With its programs and follow on investments, connect has so far contributed $1.7 billion into Australia's medical product sector. Using KPMG's impact multiplier for medical research, MTPConnect's overall impact shows a return of $6.5 billion. A very strong return on investment.

MTPConnect is an important innovation accelerator supporting the development and translation of Australia's health and medical research into valuable and clinically important medical products that directly benefit Australians and provide access to cutting edge clinical trials and medical innovations.

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Lisa Dubé: MTPConnect's outcomes to date include 1,585 new technologies invented or progressed, 849 new patent and trademark applications or licenses, 300 products launched, 2,294 new jobs created in the awardee companies that we've been able to fund, 199 new startup companies have been formed and 740,975 patients treated. I'm sure you'll agree, these are some pretty impressive key performance indicators.

And now that I've shared a bit about MTPConnect. I'll hand you back to Lauren to learn a bit more about our audience.

Inaugural Targeted Translation Research Accelerator – Background

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Lauren Kelly: Thank you, Lisa.

So we have over 100 people joining us online today, which is a fantastic turnout, and I think really does underscore the importance of this investment for the sector. So to find out a little bit more about you, we'll run four quick polls, and they should pop up shortly for you to start to input. The first is to find out which indication your product is addressing, the second is around which modality your research aligns with, and you can tick all that apply with these. The third is which organisation type you are from, and lastly, your experience with involving and embedding lived experience and community perspective in your research. So I'll give you a few moments to complete those polls.

Can we see the outcomes of those polls now and move on to the second two questions if they haven't already been displayed?

Excellent. So it's looking like we've got pretty even interest in CVD and diabetes complications (CVD 49%, Diabetes complications 22%). And there are also about a third interested in both indications (30%).

We've got more people interested in developing medical devices (58%) there is 30% interested in drug development, and interestingly, about 18% in combos.

We will get to how applicants who are developing super novel combos of drug/device products can submit their applications.

So can we have a look at the second two polls? So, this is focused on the organisation you're from and engagement and involvement of people with lived experience in your work today.

It's probably enough time for everyone to have responded, so it'd be good to have a look at those results.

Excellent. So, we've got a lot of people who are looking to spin out (36%). This is an exciting opportunity for all the recent spin outs and startups (37%) as well as established SMEs (24%). A few 'others' too (7%).

And then we have a good majority, so over two thirds of our audience joining us today who have already been engaging with people with lived experience of CVD or diabetes in the development of their products and solutions (70%). We've got Renza Scibilia as part of our panel discussion, who will be able to provide you with some more tips and advice on how to further engage for those that haven't already done so (30%).

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Lauren Kelly: So moving on. As just, I guess a little history lesson, in 2020 MTPConnect was awarded the delivery of the inaugural $47 million TTRA program to support the development of innovative products and solutions for diabetes and cardiovascular disease, as well as their associated complications over a period of 5 years. And this program has focused on supporting both commercial product development as well as non-commercial health equity projects and health service innovations.

The inaugural TTRA program has been delivered with the support of five specialist partners ANDHealth, the Australian Centre for Health Services Innovation, the Lowitja Institute, the Medical Device Partnering Program and UniQuest.

And in the four years since, we've established two research centres, the Australian Centre for Accelerating Diabetes Innovations (ACADI) and the Australian Stroke and Heart Research Accelerator (ASHRA), along with providing direct investment for 22 other individual research projects.

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Lauren Kelly: At last count, which was 30 June 2023, the midway point of the program, $38 million injected to the awarded entities had leveraged $46.5 million in co-contributions, and this in turn had resulted in the exceptional outcomes that you can see on the right hand side of this slide, and we know that these outcomes and impacts will only grow as the products developed are further translated.

So, if you'd like to learn more about the inaugural TTRA program, you can read our interim Impact Report, which was published at the beginning of this year.

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Lauren Kelly: So building on the legacy of the inaugural TTRA, MTPConnect was successful this year with our bid to the Medical Research Future Fund (MRFF) to deliver a new investment for cardiovascular disease and complications of diabetes, focused this time just on the commercialisation of drugs and devices, and which is designed to accelerate into practice promising

products that will reduce the burden for people living with these conditions, their carers, families, and the communities.

And in September, which is only a month and a bit ago now, we were thrilled to announce to the sector the new $28.5 million opportunity along with our partnerships with CSL and Roche Diagnostics Australia – industry giants who will bring global drug and device development knowledge to the program and funded companies, and we are pleased to have two representatives on the line this afternoon for the panel discussion.

So I'd now like to welcome Erin McAllum to take us through the details of the drugs and devices funding opportunity. Welcome.

TTRA Drugs and Devices – Opportunity Overview

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Erin McAllum: Thanks, Lauren. So now that you all have some background on the foundations that the inaugural TTRA program has established, and how the new Drugs and Devices investment will build on this, I'm now going to take you through the specifics of the opportunity itself.

The scheme can provide up to $1.5 million in non-dilutive investment to help SMEs, including spinouts and startups, develop and accelerate innovative preventative, diagnostic, therapeutic and disease management drugs and devices for diabetes complications, and cardiovascular disease.

So, this is an important point to emphasise here – the scheme can fund products and solutions addressing cardiovascular disease broadly, so that could be a drug or device for the prevention or diagnosis of cardiovascular disease as well as treatment and management. But the scheme can only fund products and solutions addressing the complications of type 1 and type 2 diabetes. So that could include the diagnosis, prevention, treatment, or management of those complications, but not the diagnosis or prevention of diabetes itself.

The TTRA investment will be divided into two tranches, and I'll go into detail on that on the next slide, but the maximum funding term across both tranches is 42 months or three and a half years.

TTRA Drugs and Devices is principally seeking to support products and solutions that will reach a commercial value inflection point by the end of their TTRA funded activities. So that's a point that positions your product or solution more attractively to garner that next investment be that another grant, industry partnership or license, or investment from venture capital, for example. As such, this position at the end of the TTRA funding term will be unique to each project, and it's really your job to articulate what that will be within your application.

Generally speaking, though, blue sky discovery or ideas and concepts that have no technical validation are too early and therefore out of scope for the program.

As with other MRFF funded programs that we deliver, we're also seeking to build capabilities and capacity around translation and commercialisation for the Australian research and clinical sectors. To that end, in addition to this non-dilutive investment, the MTPConnect accelerator model provides extensive wrap around acceleration support and development opportunities. This is through things such as regular mentoring, access to a network of experts for specialist advice, opportunities to participate in capability building programs, communication support to publicise successes and connections to further funding and investment opportunities.

An additional value add aspect of the TTRA Drugs and Devices opportunity will be support to participate in flagship events, such as the MTPConnect-led delegations to the BIO and Medtech conferences in North America.

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Erin McAllum: To deliver this investment, we're using MTPConnect's bespoke accelerator model. You can see that laid out here end to end.

As I've just covered Australian SMEs, including recent spinouts and startups, can apply for up to $1.5 million in non-dilutive TTRA investment through our multi-stage application and assessment process, which I'll cover shortly. There are separate application streams for drugs and devices, and the EOI form is tailored to each. So it's really important that you do submit your EOI through the correct stream.

For funded companies, the TTRA investment will be divided into those two tranches, A and B, and each will support an activity work package. Each of these activity work packages should result in you reaching a value inflection point for your product or solution, and these work packages will be finalised with you during contracting should you be awarded funding.

Funded companies that successfully complete Tranche A activities and can demonstrate high commercial potential will then be able to access, through a competitive process, additional investment for Tranche B activities. Noting that this is up to $1.5 million in total across both Tranche A and B. We would expect Tranche B activities to allow you to then reach a further value inflection point or to finalise preparations for private investment.

It's important to note this is a competitive process. So not all funded companies will receive both Tranche A and Tranche B investment. That is, not all funded companies will receive the full funding request.

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Erin McAllum: In terms of eligibility, this is laid out in detail from page 7 of the Funding Guidelines, along with a comprehensive list of eligible and ineligible expenditure which can be found in the appendices.

The lead applicant must be an Australian-based for-profit organisation incorporated here with an active ABN. Large corporations are not eligible, and we define that as having 200 or more employees. Organisations that act as a technology transfer office or mechanism for a university or medical research institute are also not eligible to be the lead applicant, even if they do have a separate ABN.

While universities and MRIs are not themselves eligible lead organisations, if you are a researcher within a university or MRI, your innovation can be spun out into an incorporated for-profit entity to be eligible to apply for this opportunity. So, in this case you would need an active ABN to be established for the spin out and provided at EOI submission. And should your application then progress to the next step, which is Due Diligence Consultation, you would need to provide a binding conditional commitment from the University or MRI to transfer IP to the incorporated entity if funded. This would have to be provided to MTPConnect by 3 February 2025. Similarly, a startup company may be formed for the purposes of applying for this opportunity. So just to emphasise that there is no minimum amount of time that a company needs to exist for it to be eligible.

You must be able to match the co-contribution requirements for the scheme which are proportionate to the TTRA investment request, and I'll explain that in more detail on the next slide.

As already discussed, the product or solution must be a drug or device that addresses cardiovascular disease or the complications of diabetes.

Your product or solution must be at the minimum required stage of development for drugs or devices.

So, for drugs, you must at least be entering the formal pre-clinical development stage. So that is, your lead has been optimised and you're entering the testing phase to assess things like safety, formulate dosing and other things you would do for an IND application.

For devices, you must meet the TGA definition of a medical device and be at least entering TRL4. So that is technical proof-of-concept and safety of candidate devices or systems demonstrated in defined laboratory or animal models.

For both drugs and devices, this is the minimum stage that you need to be at when the TTRA funded activities begin. So, you might not quite be there yet, but you might have a high level of confidence that you will get there during the application process, and you would need to clearly outline that within your application.

Software is a medical device if it fits within the TGA definition of a medical device, and it would therefore be eligible for this opportunity. This includes products and solutions that are specifically exempt from regulation by the TGA. However, software that is excluded from regulation is not eligible for this opportunity.

Combination drug/devices are absolutely eligible for this investment. And if you are developing a combination drug device, you should submit your EOI through the stream that aligns with the novelty and core differentiation of your innovation. So, say you're developing a novel device that functions in combination with a known and available drug, you would submit this through the devices stream. In the EOI form, you will be asked to provide brief details on that secondary, non-novel aspect of the innovation.

In the scenario that you're developing a combination that has novelty and differentiation in both the drug and device components, we ask that you submit your application through the drugs stream. The EOI form will ask you to indicate this novelty in both components, and that will then enable you to fully explain both components within the form. So just to emphasise, you would submit through the drugs stream, and that's an administrative thing on our end.

In terms of IP eligibility, it is imperative that applicants control or have the legal right to access relevant IP. We have included an IP eligibility flowchart, on page 10 of the Funding Guidelines, and this allows you to self-assess the IP status of your project to determine if it meets this eligibility requirement. Please take a close look at that, but if you're still unsure, feel free to get in touch with the team, just noting that we're not able to give you IP advice.

Projects for strict repurposing where there is no novel IP are not eligible for this opportunity.

Applicants and organisations can submit multiple applications for TTRA Drugs and Devices so long as they are different projects. You can also submit projects that have been submitted for other pending opportunities. We just ask that you declare that in your application. If your project was to be submitted for multiple opportunities, you would just need to be mindful that you cannot be funded for the same activities twice.

And finally, there is nothing precluding you from applying for this opportunity if you have applied or received funding from the inaugural TTRA as long as you do meet the requirements of the scheme.

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Erin McAllum: So, the co-contribution for TTRA Drugs and Devices must be cash, and the required amount is relative to your TTRA investment request on a sliding scale.

If you are requesting between $200,000 and $500,000 from the TTRA Program, the co-contribution to TTRA funding ratio is one-to-four. So, say you are requesting $450,000 in TTRA funding, you would be required to provide a cash co-contribution of $112,500.

For requests of $500,001 to $1 million the ratio is one-to-two, and for anything over $1,000,001 the ratio is one-to-one.

Additional cash and in kind above this are obviously not required, but they will be viewed favourably.

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Erin McAllum: The application and selection process is a multi-stage leaky funnel. Initially, applications are obviously submitted as an EOI, and they are closing on 4 November 2024.

Once submitted, these will firstly be checked for eligibility by MTPConnect and then reviewed by the selection panel, which includes MTPConnect and other organisations with relevant expertise, including lived experience perspective. We anticipate communicating EOI outcomes and providing feedback around 20 December 2024.

It's expected that a significant proportion of applications will then move forward to the next stage, which is Due Diligence, Consultation. And this is where the selection panel will undertake a consultative due diligence process, allowing the applicant to address any of the feedback that's come through the EOI review, as well as take a deeper dive into the project under a confidentiality agreement.

This phase will take place from 3 February next year, and for those applicants that are creating a spin out from a university or MRI, this is the date that you would need to provide MTPConnect with official confirmation that should you be awarded funding, the relevant IP will be transferred from the university or MRI to this new Co.

I'd like to emphasise that this due diligence consultation process is not only valuable for developing your TTRA application, but can also generally add value to your project ss you're thinking about commercialisation. Following this stage, the selection panel will reassess the applications, and a short list of projects will move forward to the final stage and submit a full proposal. This will happen around mid-March with full proposals due mid-April.

An independent international and national investment panel of experts will review these full proposals and make recommendations for funding award, and we expect outcomes to be communicated around mid-May next year.

The successful applicants will enter into a formal funding agreement with MTPConnect and it's during that contracting process that the activity work packages for Tranche A and Tranche B funding will be finalised.

And at each phase all applicants will receive feedback on their applications.

So Tranche A activities can start from 1 July 2025, and once underway funded companies will have regular reporting obligations to MTPConnect. As already covered, Tranche B funding will be dependent on successfully completing Tranche A activities and demonstrating high commercial

potential. But all TTRA funded activities across both tranches will need to be completed by 31 December 2028.

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Erin McAllum: And finally, I'll briefly mention the selection criteria. But I won't go into detail, as this is what the panel is going to discuss next.

Applications will be assessed against five broad selection criteria themes. These being challenge and solution, technical merit, project plan, translation and commercialisation, and team and capabilities.

Do note that these are not weighted equally. The themes that are weighted more highly are not because these are more important, or because they are themes that you should be putting more effort into. Rather these are things that are looking more at the historical context of your project. So, there are things that should really already be in place and are essential for project success. The themes that are weighted lower cover activities that are more future thinking and things that can and will be shaped by the support that the program offers. However, we'd still like to see the same level of effort put into these sections of the application form.

I'd also like to note here that MTPConnect recognises the importance of people with lived experience being engaged and embedded in research, and that this leads to products and solutions that are much more likely to be implemented successfully. This is really an essential part of product development, it's not just the nice to have. So, in line with this community and consumer engagement is embedded in every selection criteria theme.

The selection criteria are quite comprehensive. They can be found from page 15 of the funding guidelines. But with that I'll now hand back to Lauren, who will facilitate the panel discussion.

Panel Discussion

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Lauren Kelly: Thank you so much, Erin. That was a lot of detail, and I hope that's answered a lot of questions that the audience may have. But just on questions, because this is a webinar, if you've raised your hand as an audience member, we can't actually call on you. So if you have a question, just jump into the Q&A box and type it in, and we will get to it after the panel discussion.

So I'd now like to introduce our panellists, 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 really competitive application. So I will be joined by Mana Liao from MTPConnect and representatives of our TTRA impact partners, Perdita Cheshire from CSL and Kenny Lean from Roche Diagnostics Australia, and a friend of the TTRA program and advocate for people living with diabetes and their inclusion in research, Renza Scibilia.

So thank you to our panellists for coming on camera and to unmute yourselves. And then I'll ask you to introduce yourselves and to provide a bit of an overview of either your respective organisations or the perspective that you're bringing for our audience's benefit. So I'll start with you first Mana.

Mana Liao: Great. Thank you, Lauren. Hi, I'm Mana Liao. I'm the Director of the TTRA Program at MTPConnect and today I'm joining you from the land of the Darug and the Guringai people in Sydney. Thanks.

Lauren Kelly: Thanks, Mana. I'll move on to Perdita.

Perdita Cheshire: Hi, thanks for the invitation to participate today. My name is Perdita Cheshire. I'm a director at CSL in the Research Innovation team. So CSL is a global biotech company focused on developing and delivering medicines for patients with rare and life-threatening illnesses. And in the research innovation team, we are particularly focus on partnering with early-stage companies and academic groups.

Lauren Kelly: Thank you, Perdita. Kenny?

Kenny Lean: Thanks, Lauren. Hi! Well, a pleasure to be here. So Kenny Lean, I'm the head of Access and Innovation here at Roche Diagnostics Australia. Roche Diagnostics is particularly keen in advancing diagnostics and improving patient outcomes, and particularly in access innovation. We're looking at new innovative products, business opportunities as well. And yeah, looking forward to working with the with the team here.

Lauren Kelly: Thanks, Kenny. And last, but not least, Renza.

Renza Scibilia: Hi, everybody! My name is Renza Scibilia. I'm coming to you today from beautiful Wurundjeri land. I am here today as a person with lived experience of type 1 diabetes. I've been living with type 1 diabetes for the last 26 and a half years. I've got 20 or more than 20 years' experience working in diabetes organisations specifically around making sure that that lived experience community engagement piece is front and centre. I'm absolutely thrilled to be here today. Thank you.

CHALLENGE AND SOLUTION

Lauren Kelly: Thank you. Thank you all. So we're going to use as a framework for the panel discussion, the selection criteria. So we'll start with Challenge and Solution. And as a reminder to everyone, this has a weighting of 25%. So here you'll be asked to link your proposed product or solution to an area of unmet need. And you'll note just as an overview for the entire EOI. There are tips throughout the form for nearly every single question and they're really helpful and will guide you on what to include in your response.

So, Renza, how about I start with you. The challenge and solution is going to be about people. How can an applicant demonstrate that they are addressing a community identified unmet need?

Renza Scibilia: Yeah, I think that's such a brilliant place to start, really. And I'll explain why I think it's such a great place to start. So often I hear about research projects or devices that are in development, and I always think you really haven't spoken with anybody living with that condition. Have you made sure that this is something that is critically important to those of us with lived experience? So I think that often community engagement is seen as a nice to have, and it's a bit of an add on, or even worse, you rush to do it at the end because you realise you've got to do it. But if you don't have that community engagement from the very, very beginning, there's absolutely no way that you're going to know whether or not what is in development if it's going to be successful at all. So I think that it's really critical that we think about this as something that happens way, way, way, before pretty much anything else happens is that community engagement piece. It really will change the outcome of whatever it is that is in development.

Lauren Kelly: Thanks, Renza. And that's really speaking to the importance of innovation pull rather than technology push. And we do see a lot of researchers with a solution looking for a problem. But we need it to be the other way around.

Renza Scibilia: Yes, that happens so frequently. And I think everybody wants to develop something that's new and shiny. And of course we do. You know, we love new technology. But is that actually going to be something that is really relevant, and that people are going to want to use? Or is it something in your mind that you think this is what people are going to want. Is it actually going to be practical in our everyday lives? So ask those questions, really early on.

Lauren Kelly: Thanks, Renza.

So, Mana, what advice do you have for applicants tackling this section.

Mana Liao: Sure. So, my advice, really is to consider Challenge and Solution to be where you make your first impression to the selection panel. They say, first impressions count right? So this is where you describe how your product solution addresses an unmet need, and you get the opportunity to really hook the reviewers in with your unique value proposition. The selection panel would be looking for a clear demonstration of a problem to be solved. For a specific patient group or a solution that is meaningfully different from existing care options, for example, they will be looking for tailored novel interventions to address a serious and unmet need or a solution that solves a problem for people living with the complications of diabetes or cardiovascular disease, the carers, or healthcare professionals, delivering clear health outcomes.

From our experience, competitive applications are those that can articulate the existing market environment and can explain how their product or solution is differentiated or has an advantage over the competition. We are also looking for how the product or solution will achieve or enhance equitable health service delivery on top of everything else that Renza mentioned as well.

Lauren Kelly: Thanks, Mana.

So with value proposition, and differentiation, I might pass to you, Perdita, to talk to how an applicant can craft a strong application for a drug with respect to value proposition and differentiation.

Perdita Cheshire: Yeah. And look, I would echo the earlier comments that you really need to start with your community unmet need. So this will really help you articulate your target product profile. So you know, if you're talking about patients with cardiovascular disease, for example, are you talking about all patients with a particular diagnosis of a specific cardiovascular disease? Or any patients with a particular clinical presentation, or those with specific biomarkers or genetic background, or those not managed well with current standard of care?

So once you've really identified, who are the patients that you're trying to engage, then that will help you identify what is the problem that you're trying to solve? Is it that there aren't any treatments? Or is the treatment available not particularly efficacious? Or does it have a poor safety or tolerability profile? And then this will really help you articulate, what is your value proposition? What is the specifics that you're trying to differentiate? And then this will help you have a really clear target product profile, which is part of the application process is a target product profile section. So I think, being really clear around what it is that you need to demonstrate in terms of differentiation is a really good starting point.

Lauren Kelly: Thanks, Perdita.

And Kenny, from your perspective with device development, how would an applicant craft a strong application with respect to the value proposition, and differentiation for devices?

Kenny Lean: Thanks, Lauren. Look! I think I'll echo what the others have said earlier. So from a device perspective, is no different right? The device should solve a genuine problem, that the people with a condition face right, whether it's addressing an unmet need, and it has to offer a significant improvement over the existing solutions. I mean for devices specifically, we want to look at unique features and benefits. So you know, highlight, what's the innovative features that differentiate the device from others in the market? You know, what are the technological advancements, what's the ease of use? What's the enhanced effectiveness? And you know what's the value to users as well, you know? Explain how the device improves a user's quality of life, you know. Whether is it better health outcomes, is it reducing the burden of the disease or condition? And yeah, if you can also look at the clinical economic benefits as well, I think that would be quite a good application for this area.

Lauren Kelly: Thanks, Kenny. So it is really about surveying the landscape now. But also what's in development? Because we know that as your product is being developed, that landscape is changing. So, having a good understanding of what is in clinical develop at this point now, should also be reflected in your application too.

TECHNICAL MERIT

Lauren Kelly: So moving on to Technical Merit. This is again worth a quarter of your mark, and this is where we are seeking to understand your product or solution at its technical level. So the approach that you've taken in developing and validating your innovation to date.

So, Kenny, I'll start with you from a device perspective. How would you approach this section?

Kenny Lean: So I guess as mentioned at the start, the device needs to be meeting a minimum stage of development, which is TRL4, that means technical proof of concept and safety demonstrated in defined laboratory and animal models. So I guess that from the technical aspect we will ask for an overview of the existing data package. Basically, what is the data that you are presenting here, you know in terms of pre-clinical data? Is it animal studies? What are the studies that validates the technology and demonstrates its safety?

The other important thing to highlight as well, we would want to see technical and stakeholder engagement in terms of the product development pathway, you know. So basically, how has early feedback informed the product design? Is there, for example, has there been voice of consumer studies done? Has there been needs analysis? And, I'm sure Renza can speak to this a bit more, what's the engagement with people with lived experience? That's absolutely crucial. Engagement with key opinion leaders and also other stakeholders, right advocacy group and other end users like the hospital.

So those will be our key things to sort of look at from a technical perspective. I guess just one other point to touch on is software as a medical device. Or SaMD. These we want to specifically look at the software's functionalities. You know, what are the algorithms, the data inputs, the outputs? What are the validation verification processes that's been done? We're going to look at what has ensured that the software performs as it intended in various conditions.

Lauren Kelly: Thanks, Kenny for the detail there.

And Perdita for drug applicants, how would they approach this section?

Perdita Cheshire: Yeah. So look, I think Kenny gave a really nice overview. And it's not dramatically different for a drug. So I guess maybe a practical tip would be, there's not a lot of space, and it is non-confidential. So I really encourage that high level overview of what data is available. And then where are you in your current stage of development? And then where will you be at the two inflection points? So avoid trying to get into too much detail around a particular piece of data, and really make sure that you're articulating the whole data package, and where you are in in terms of your development. What stage you are is going to be really critical.

And perhaps the one thing to add from a drugs perspective is really your understanding of the mechanism of action. Because even if you've got some, you know, great efficacy data, if we really don't understand the mechanism that can be really challenging from a regulatory perspective. So making sure that you don't neglect some of those sort of early understanding of mechanism as well, making sure that you articulate what data is available, there.

Lauren Kelly: Thanks, Perdita, some great tips there.

So, Renza, I'll jump to you now. So heard from Kenny that there are some obvious spaces for innovators to be engaging with people with lived experience in community around voice of customer studies. What other types of engagement should innovators have undertaken, and how important is it for them to demonstrate that they have engaged people with lived experience?

Renza Scibilia: I mean, I think it's critically important. It's a requirement as part of the application. So I think that it can't simply be something that is, Oh, look! Look how great we are! Because we did this. It actually has to be done very deliberately, and in a very meaningful way, and it should have happened yesterday.

And I think maybe we need to start to reframe the way we think about people with lived experience. Because I've already heard people use the word patients, and instead, let's consider people as partners rather than patients. Right? I really object to being called a patient, you know we look at what the definition of a patient is. It's somebody who is, you know, waiting to be told what to do. It's a passive recipient of care. Right? And the last thing that very many people are is passive. They want to be really active in their care, and that starts from really early on.

So you know, my comments around this would be bring in people with lived experience as partners really early on. Because then, when you're also starting to look at data collection. That's where people start to remind you that perhaps part of that data needs to also include quality of life measurements. And that's really, critically important. Because if you're developing something that is actually going to add to the considerable burden of living with a condition like diabetes people aren't going to want to do it. They're simply not. There's already so much that we do. Our emotional labour is already so high. So if you're telling me that you've got this whiz, bang device or this brilliant drug but it's going to really impact and increase, you know, the burden of living with diabetes or reduce my quality of life, the chances of me wanting to be engaged with a new something like that is pretty low. But you're not going to know that unless you're talking with people who are going to actually be the end users.

So bring people on early, find the right people. Don't just bring on one person. Please, please don't just bring on one person, you know. Bring on a selection of people to work with you on this, but partners rather than patients.

Lauren Kelly: Thanks, Renza, thank you for helping shift and reframing that. So it's not passive. It's active, it's ownership. It's being involved, being embedded in research. And, as you said, we don't

want it to be tokenistic. So not having one person involved to satisfy the requirements, because that's not doing that at all. And, as you said, it's never too early to be engaging people with lived experience in product development. And that really gets to the point that we're talking about in challenge and solution as well, is that it's you've defined that there is a community identified unmet need and then you're working with community to develop that product.

Renza Scibilia: That!

Lauren Kelly: So, Mana, we appreciate that EOIs are brief, and Perdita highlighted that as well. But there is an opportunity to upload a single page to support your submission. So what would be your tips around this supporting information document?

Mana Liao: Sure. So this supporting document is not mandatory. But I highly recommend you using it strategically. This upload can include data, figures, images, etc, that you have generated yourself or it can be taken from the literature. So please ensure that you use appropriate referencing for the reviewers benefit and provide a link back to your in-text responses in the application portal to discuss the data and its significance. The upload can be used to support your whole submission from providing benchmarking or evidence of differentiation in the Challenge and Solution section through your Technical validation, to demonstrate your most compelling data which Perdita and Kenny previously mentioned. Or to outline a Project Plan workflow.

However, please note that this one-page upload is not a place to get an additional 500 words into your EOI - it is for supporting information in the form of data, figures, or images. And also, another reminder here is that the supporting material, like the rest of the EOI, is to be non-confidential.

PROJECT PLAN

Lauren Kelly: Thanks, Mana.

So the description of your TTRA funded project plan does sound fairly straightforward, but we do see some traps that applicants might fall into when addressing this section. So I'll come back to you, Mana, to kick us off. Can you articulate what assessors will be keeping a close eye on as part of the project plan section of your EOI. And as a reminder, this is worth 15% of the mark.

Mana Liao: I guess, going back to the goal of the TTRA Program, which is to move translational research towards commercial reality and health impact. So it is important that applicants can clearly articulate what stage they're at and where they want to get to and support that with evidence, and then define both major and incremental milestones of the proposed project. Being vague, will only hurt you in the Project Plan section, unless you can clearly justify why you are unable to plan a certain stage.

The funding is for up to 42 months. If you are successful, the funding will be divided into two tranches which Erin mentioned previously, with each tranche supporting a package of activities. So we want you to define these work packages in your application and explain how each leads to a value inflection point for your product or solution. For a funded company to access the second tranche, they will need to not only complete this first package of activities but will also need to demonstrate high commercial potential. So it's important to note that not all funded companies will receive both tranches of investment! And in the application, we want to see what the expected outcomes are and impact of the project activities on your solution’s ability to be commercialised.

Remembering that overall, it is essential that the proposed activities place the applicant on a critical path towards key translational milestones and/or commercial proof of concept. Another hint here is to be clear about the risks to the development of your solution, and how the proposed project will be will address these. An “all green risk register” does not indicate a strong project. For example, if for your application, understanding exactly what data is required to achieve regulatory approval is a risk, don't pretend that you know, and put “data gathering for regulatory approval” as an activity alone. This is the chance to put a task around “engaging a contractor to understand data required for regulatory approval” and “expert review of clinical trial structure towards regulation” ahead of the trial, and to get budget for such activities. That would indicate a well thought out project where the TTRA program can make real impact. Also, don't forget your project risk as well.

It is also important that the amount requested is realistic - that requested amounts generally match the tasks at hand. If it does not pass the back of the envelope test, then it is unlikely to pass the selection committees either. Those are some tips, Lauren.

Lauren Kelly: Thanks, Mana. So, I might start with you, Kenny, around providing some examples of an activity work package for Tranche A and Tranche B for devices.

Kenny Lean: Hello, Lauren. I guess, you know, what's been mentioned before, in terms of a product. You probably want to have a clear, defined project plan, right? What are the proposed activities, as mentioned on the critical path towards the commercial proof of concept? What are the, you know, the inflection points that you want to achieve? What are the deliverables? Milestones? Go/no-go decisions and outcomes as well? You know it should also include a plan for consumers and lived experience as well, for sure.

And you know, I guess the other thing is, you know, identify the key risk and management and mitigation strategies that you know that could result from this device as well. So what is the plan around that? And I guess, just to add specifically again on, I guess as an example around software, you know, we want to look at the development lifecycle. So the project plan should include stages specific to the software development. What is the requirement analysis? What's the design testing deployment and maintenance of that software? And you know, the risks again, are different for software compared to implantable or device. For example, you want to look at cybersecurity, risks of software bugs and failures, user error. So what are the risk management strategies around all those components?

Lauren Kelly: Thanks, Kenny. and as a reminder for the devices, we'll be expecting a minimum stage of development as TRL4. So activities aligned with TRL4 and up from that will all be eligible within the scheme as long as that you're putting it on the path towards value inflection, and those critical commercial milestones.

So Perdita for a drug development project, what would activity work packages look like as some examples.

Perdita Cheshire: Yeah, I think it's been covered, really? Well, I think the specific details are going to be very specific to your stage of development as well as the modality. So you know, work packages for gene therapy, for example, might look quite different to a small molecule. And so what I would suggest as a tip to think about is just trying to articulate and think about what needs to be done sequentially versus what can be done in parallel in order to accelerate timelines. So, you know, are there later work parts of your work package that you know are going to be challenging, or take a bit longer to develop that you could think about starting earlier on at risk, even if you haven't quite got the go on a different experimental outcome to really try and move along some of these timelines. So

I would encourage people when they're talking about their work packages to really make it clear what's being done sequentially? And where might there be opportunities to do things at risk or earlier on, or do things in parallel to contract timelines.

Lauren Kelly: Thanks, Perdita.

And again, if you've got any specific questions about your project at hand, your product, you can get in touch with the TTRA team at our accelerator email. And we can provide some advice there.

So, Renza, what would some examples be for our innovators embedding community and consumer engagement in their project plans?

Renza Scibilia: So I would suggest that in your research group or in your group that you're working with, that, you have a couple of people with lived experience very central to the work that you're doing. So, you know, I think that this has got to do with the bringing people on super early.

Consider setting up, and I'm not a massive fan of advisory committees, you know, patient advisory committee, because they're often very token. But I would consider, I would say that having something where there is an easy mechanism for you to connect with a number of people is really important.

Think of the thre R's, which I constantly come back to, which is recognition, reimbursement, and representation. So representation is about not just having one person, making sure that you've got people from diverse backgrounds to make sure that you're hearing different lived experience examples in what you're doing.

People with lived experience need to be paid because in most instances this isn't our day job. And so our expertise, nobody else has our expertise, and it is just as critical to the work that you're doing so when you're looking at budgets, make sure that there is reimbursement built in there. And recognition as well, so how are the people who are involved going to be recognised. And this is a little bit down the track, but if you're looking at publications, you would want to make sure that you're including people with lived experience in that as well.

So I mean, I think that these are really simple. It sounds a bit scary, but they're actually very simple ways to, you know, make sure that you've got people with lived experience, front and centre all the time, and just constantly, you know, just sense checking that a lot to make sure. You know, when was the last time that we actually sat down with people with lived experience to speak about what it is that we're doing. And I know that for a lot of people you will think, but this is so early on, it's too early on, you know we can't even really speak with people because it's so technical. You're absolutely wrong. Bring people in and talk with them about it. And I always talk about this in terms of you've got to work out what it is that you're doing, and how you can explain that so that people will get what it is that you're doing. I used to say, can you say it in a tweet? But really Twitter's a cesspool now, so let's go back to the elevator pitch. You know. Can you explain it going up one flight in an elevator? Because that's the sort of thing that you need to be able to do, and then you'll find that people are very, very eager to be involved, and to have a chat with you.

Lauren Kelly: Absolutely great tips, Renza.

TRANSLATION AND COMMERCIALISATION

Lauren Kelly: So as we've discussed, it's important to not only provide an overview of the big picture which is focused on the Challenge and Solution section, your technical work done today to the Technical Merit and your project at hand, which is the Project Plan. But also we need to understand the later stages of development of your solution or product, and how, as it moves through clinical work which might be part of your TTRA activities, or it might be beyond your TTRA activities and towards end user adoption.

So within the Translation and Commercialisation section of the EOI (10%), we are seeking a clear understanding of the commercial potential of your proposed product or solution.

So Mana, I might get you to kick us off around the IP section as our in-house IP specialist. While it's not a requirement to have already been granted IP protection for this scheme, it is important to outline the strategy behind securing a strong IP position. So what advice do you have for applicants here?

And I'm conscious we're running a little bit behind time. So if you can tweak your response, here, so it's nice and snappy. That'd be great.

Mana Liao: Sure. IP protection and IP strategy are critical for the successful commercial outlook. So the first thing I would say as a priority before you go too deep in crafting your application, I highly recommend you to conduct a self-assessment on your IP eligibility, using the flowchart on page 10 of the Funding Guidelines to avoid disappointment down the track based on what Lauren says. There's also different ways IP can be protected. So that can include patents, trademarks, design - those are the legal registration that you're familiar with. But there are other also other non-legal registration forms protection that you could use, include trade secret and know how, and copyright. So competitive application in the past, we could see they could really articulate the strategic value of the IP and the strategy to protect their innovation which encompass a mixed form of IP protection.

In general, for drugs and devices which result in more tangible products will place more emphasis on patents and design registration, whereas for software as medical device, the more the traditional patent may not be appropriate for the business model. So if an applicant has filed a patent, reviewers will be seeking favourable terms in the application. For example, does it consist of a broad patent, claim, clear freedom to operate. A common weakness that we've seen in the past applications, there's insufficient articulation of how they are going to secure market share and protect their innovation in the absence of a patent. So it's important that you fully expand your IP protection mechanism, such as trade, secret, first mover advantage, or exclusive access agreements to provide reviewer with the confidence in your commercial outlook. Applications will only be considered when there's a viable IP or commercialisation plan can be demonstrated.

Also, I just want to emphasise if you're using third party IP, especially in the event that the innovation is a drug and device combination technology, for example, in the instance that the drug is provided by the pharmaceutical company, or you're using an off the shelf software make sure you have obtained a legal right or agreement to conduct the work and keeping a clean chain of titles of any future Project IP. You would not want to be in a situation of infringing other's IP after you've done all the hard work! And one more thing just to mention that again, that strict drug repurposing where there's no novel IP is not eligible.

Lauren Kelly: Thanks, Mana.

Perdita or Kenny, did you have anything to add to that? That was pretty extensive IP advice.

Lauren Kelly: So moving on to the second half of this section, it relates to the clinical and regulatory development pathway and the commercialisation strategy. So really, what's coming next in your project, like after you finish your TTRA project. And what do you need to complete after or in conjunction with the project to keep your innovation moving along the commercialisation pathway. So, Perdita, I'll start with you for drugs. What would reviewers be looking for with a clinical development and regulatory pathway?

Perdita Cheshire: Yeah, so look, both are highly complex. And they're also deal breakers in terms of the commercial viability of the program. So what we would really be looking to understand is, what is your strategy for accessing the relevant expertise to guide you on these parts?

So what expertise do you have in your team if that's relevant. But really, do you have a strategy for engaging external consultants, for example, what work have you already done in this regard? And who are you getting guidance from? So there's no expectation that you already know all this. As I said, it's highly complex, and it requires a lot of expertise. So what we would really be looking for is your strategy and approach. And how much of that you've already started in terms of clinical development and regulatory pathways, and you should have a bit of an outline to start with. You know what is the regulatory framework that what you're working on falls under and perhaps mapped out. Certainly you know the phase one trial, for example, if that's relevant. So you know, it depends on what stage you're at as to how far down those pathways you should be, but you should certainly have a strategy for accessing the right advice.

Lauren Kelly: Thanks, Perdita.

And Kenny, for devices, any advice around the clinical development pathway and/or reg strategy?

Kenny Lean: Yeah, look, I think Perdita covered that quite thoroughly, and it'll be the same for devices. I guess the only thing to add, is just to make a note that there are recent TGA guidelines on software as medical devices. So just this has been recently updated, I believe, as of May this year. So just make sure you have that on your radar as well in terms of the regulatory pathway and sort of clearly articulating that pathway. So make sure you are aware of that updated guidelines.

Lauren Kelly: Thank you. And I think we will pop some links into the chat just around guidelines with respect to medical devices and software as a medical device to keep up to date there.

And I guess we also want to understand in this section the commercialisation pathway, the model. So partnering or licensing, or having an acquisition or things like that. These can in some ways look similar for drugs and devices. But they can also be differences.

So perhaps, Perdita, you can kick off with some examples of realistic commercialisation pathways for a drug product. And then I'll come to you, Kenny, for some examples with the device.

Perdita Cheshire: Yeah. So I mean, for a drug, you know, realistically, you might not be able to take it all the way through to market. So the question is, at what point do you want to take it to, you know? And then what is the pathway that you want to go down? Do you want to license to industry? Is your plan to raise money and take it through, let's say to Phase II? I don't think there's a right or a wrong answer. What's important is that you have an understanding of what is the path that you want to take.

And then, you know, for example, if your plan is to take a drug through a Phase I trial, for example, what's your fundraising strategy to get through that? If your plan is to partner with an industry partner early on, then have you already engaged some potential industry partners? Have you already

got feedback as to the attractiveness of this from potential industry partners. And if not, what's the timeframe that you would think of approaching potential partners, VCs and so on? So and going back to the earlier point, you know, the clear IP strategy is going to underpin all that. So making sure that section is really well articulated as well.

Lauren Kelly: And Kenny anything to add there from a device, perspective?

Kenny Lean: Yeah, thanks. Lauren. So I think, yeah, definitely, we want to see the commercialisation plans for the device. And as Perdita mentioned for drugs, is there a plan to sort of partner with a medtech company, for example, do you plan to take this device all the way by yourself? How are you positioning your product to achieve this?

The other thing to add is, we would like to see some user adoption plans as well. What does that look like? What are your plans for educating and training end users? This could be healthcare professionals, it could be persons living with the condition. What's the plans for your device to ensure proper adoption? I guess the other things are fairly generic in terms of you know you want to look at competitive landscape as well, you know. Discuss the competitive advantage of your device, and how your device addresses the gaps in the current market.

Lauren Kelly: Thanks, Kenny, and I guess on market understanding who will pay for the drug or device is important. A lot of the times it is the person living with diabetes or cardiovascular disease. But sometimes it's not so, Renza, how should applicants consider this in their application?

Renza Scibilia: Yeah, I think that's really critical that we do think about that living with a chronic health condition is expensive, even though we have truly remarkable systems here in Australia, I live with diabetes, and we have our national diabetes services scheme which significantly and heavily subsidises the products that I need to stay alive. But in most cases things that are launched onto the market are not subsidised. Which means that it's people who are very fortunate, who can afford them who are able to use them. But the vast vast majority of people simply can't.

I mean, what's that doing? That's really, you know, broadening that gap of people who end up with the best care, with the best devices and the best drugs, and those who simply can't afford it. So, being very, very, I guess progressive about and thinking about that from early on is critically important. We simply can't have a situation where only very few people are actually able to use something because they can afford it. I mean that works for absolutely nobody. So I think that that's certainly something that does need to be considered very, very early on, having a look at what subsidy schemes are available, and what the process for something getting onto the PBS or getting onto the NDSS, or whatever it may be, what that looks like. And thinking about that really early, not once the product has been launched and is available. It's just it's crazy that it, that it takes that long and just be very mindful, I think as well that these things do take time. So it is something that needs to be considered very early.

TEAM AND CAPABILITIES

Lauren Kelly: Yeah, thanks, Renza.

So conscious of time. So I'm going to bring us to the final theme, which is team and capability. This is worth 25% of the score. And we know that multidisciplinary approaches require diverse teams and diverse teams are successful teams.

So I would like to whip around our panel and ask each of our panellists to provide one tip around team and capability for the audience just to keep us on time and moving this along. So, Renza, I'll start with you.

Renza Scibilia: Okay, you need to have people with lived experience from day one. It's too late, actually, at day one. Start even earlier than that. There you go.

Lauren Kelly: Thanks. Renza, Perdita.

Perdita Cheshire: I would say, your team is going end up much bigger than what you're starting with. And the further along you go, the more you're going to have to engage with other groups. So CROs, for example, regulators, external consultants. So you know, really articulate what core competency do you already have and where are you going to need support? And what's your strategy for bringing in that support?

Lauren Kelly: Thanks Perdita, Kenny.

Kenny Lean: I would just say diversity would be really important, you know, if you can, highlight diversity. You know, this could be anything from gender, career stage, lived experience backgrounds, you know. If your team is not yet diverse, then what is the strategy around increasing that diversity to provide the necessary expertise, you know, build the capacity. And also, you know, in improve collaboration within the team.

Lauren Kelly: Alright, thanks Kenny. And Mana.

Mana Liao: I guess my tip here is there isn't an expectation from the panel that all the work needs to be done in-house, so also remember to list your external partners as well when you're writing your team section.

Lauren Kelly: Yeah. And I guess my tip would be that we don't want to see a long list of informal advisors. You know, you've got 20 people with a combined FTE load of one. I think, that raises concerns about who is driving the project. We want to know who's driving the project there, so that would be my tip.

So that draws our panel discussion to a close. I'd like to thank all our panellists, Mana, Perdita, Kenny, and Renza for providing some really rich colour to the funding guidelines and passing on practical tips for those applying.

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So if you haven't already started to drop down any questions into the Q&A box that were unanswered. I'll now invite everyone to start doing that.

And while you are quickly typing in some questions which we'll hopefully get to. I'll just remind everyone that EOIs for the drugs and devices investment are now open. They will close on 4 November at 4pm Australian Eastern Daylight-Savings Time. So just be mindful of that time zone change.

We don't accept late submissions. The system's sensitive to word count and other errors. So please get in there and make sure that you're working to the system requirements. It won't let you submit, and that's not a valid excuse for a late submission. We are always on hand. Our accelerator platform help desk is on hand. Our numbers and emails are in the Funding Guidelines.

And I think if anyone has to duck off before the end of Q&A. There'll be an anonymous survey for you to complete. This just really helps us to know what worked well and where we can improve the next time.

Q&A

Lauren Kelly: So I will now jump into the Q&A and we'll see what we can do to launch through this. So you can uptick any questions that you would like.

So we've got an IP question. Are there any minimum requirements on the transfer of IP into the eligible company? So a field based license versus full assignment. So, Mana, maybe you can quickly address this?

Mana Liao: There's no preferences. As long as there's a legal agreement, it could be a licensing form or other forms. As long as you have a legal transfer of the usage. That's the main thing.

Lauren Kelly: Thank you.

So we have another question around health economics assessment, and whether we would require that being conducted at the time of applying, or would it strengthen the application? So perhaps I might throw this initially to Kenny, and then Perdita.

Kenny Lean: Sorry, Lauren. I missed that. Yeah. Sorry.

Lauren Kelly: That's okay. Maybe Perdita can kick us off, and then you can add to that. So that was about whether it's required to conduct a health economics assessment at the time of applying? Or would it strengthen the application?

Perdita Cheshire: I would say it's not required, but it certainly would strengthen the application. It could also be an activity, I think, that's part of the funded activities. It depends on what stage you're at as to how accurately you can assess that.

Lauren Kelly: Thank you. Okay.

Kenny Lean: Yeah, I would agree, Lauren. So it's, you know, economics analysis would definitely strengthen the application at any stage.

Lauren Kelly: Thank you. We've got a question around whether a case manager is provided during the application process.

So I can answer this. It's definitely not at EOI, though the TTRA program and our team members are on hand if you've got any questions and we can help guide you as you progress. If you're shortlisted to consultation, you'll be matched with our in-house specialists. So the medical device and our therapeutic specialists and they will conduct the due diligence process, as Erin explained. And then, if you are shortlisted to full proposal, you'll actually get a couple of opportunities to engage further with those specialists, and they will be providing you with advice on how to craft a competitive application. Then, once you are funded, you will be paired with these amazing specialists who will be your mentor, your sounding board and your touch point throughout the activities that you conduct with the TTRA program. So it's really just not at EOI that you do not have a case manager.

We've got a question around whether the $28.5 million in MRFF funding is allocated equally amongst drugs and device development.

So this was actually two separate opportunities from the MRFF. There was the delivery of a drug stream and the delivery of a device stream, and the funding allocation was slightly different, with slightly more funding in the drug stream. And so we will be conscious of ensuring that that ratio is preserved moving forward, but it will be broadly equal. A little bit more funding will be going to the drug stream to keep in alignment with what the MRFF set out.

So I think, Kenny, here, we've got a question for you around, can you provide more details regarding what type of data should be provided to demonstrate that a software is already at TRL4?

Kenny Lean: Yeah, you'll probably need to demonstrate that it is in that TRL, that proof of concept and safety of that system is at that stage. There, are some guidelines available which you can look up that will guide you on what to demonstrate.

Lauren Kelly: Thank you. I might just jump down and see if we can take off a couple of other questions.

Somebody's asked are listed companies, SMEs eligible? They most definitely are eligible. The company limit is with respect to employees.

We have had a question, Renza, you might be able to address this. There's a lot of emphasis on people with lived experience engagement. Does this mean that the product must be used directly by people with lived experience? Or we've got questions about whether software as a medical device is used by physicians for diagnosis as an example. So that's definitely in scope. It doesn't have to be the person that's using it. But you might want to speak to the importance that engagement with people with lived experience is still important, because it's ultimately linked to their health outcomes.

Renza Scibilia: Absolutely so. What is it that this is actually, you know, is it collecting data? And what is that data? What does it look like. I absolutely would make sure that you are engaging still. And I think that that's something to be really mindful of. You know, there are devices that are developed, and often in the first instance, perhaps they might be a clinician only device, but then they actually become something that does end up being used by the person living with the condition. And by the time they get to us we're looking at them going, why was this developed like this? Why does it do this, you know. So I would be really mindful of that. And also if it's software that's being used by clinicians that is containing information for us or data about us at some point, we're going to want to see that. So having it presented in a way that makes sense to us is really really important.

Lauren Kelly: Thank you. We've got a question around TTRA co-contributions, and whether it is acceptable for contributions to come from industry. Most definitely, the contributions, they have to be cash, they can come from anywhere. So I think that that generally answers that question. All cash contributions are eligible as the contribution.

We can't speak to specific projects, sorry. So if you've got any specifics, please get in touch with us separately, and if you haven't submitted anonymously, we can reach out to you.

The matched funds we need to have evidence of that being provided at full proposal with your letters of support. That's when you'll need to provide evidence of matched funds.

We've got a question about, is there a stage of development that is too late for this scheme?

Probably, if it's already on market, it's too late, because this is a development program. But perhaps Perdita and Kenny, you can quickly speak to, if there's anything that's too late, and that would probably wrap up our Q&A because I'm conscious of time.

Kenny Lean: Yeah, look, I don't believe there is a stage that's too late, I think. Yeah, if the product's not on market yet, and it's a developing stage. I think it's all within scope.

Perdita Cheshire: Yeah, I agree. Nothing to add.

Lauren Kelly: Yeah. And I guess there's just a couple of quick questions, and if I can whip through them we're finished.

Project plan section yes, EOI is completely brief, and risks take a lot of time to outline. We're just looking for high level risks at EOI. You'll get a bigger opportunity to talk through risks if you progress to the next stages. You can always use dot points to keep things brief.

The prevention of type 2 diabetes was not included in this opportunity. This was directed by the government, and the Government felt that complications of diabetes, type one complications and type 2 diabetes complications is where this funding should be flowing to.

The funding cannot go beyond 42 months. That is the limit to our program's timeframe.

So I think that that draws us to a close. I'd love to thank our presenters and panellists today, Lisa, Erin, Mana, Renza, Kenny and Perdita, and our behind the scenes whizzes Deb and Nat.

We thank you, the audience for joining us. Sorry that we went over time. We hope that this information session provided practical tips and advice for you as you progress the development of your EOI. If you need to reach out, to ask a question, or if we didn't get around to all of the questions that you had, or you've got a project specific one about eligibility or project alignment, please, email. We are always happy to help and have a lovely afternoon. Thank you.