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**Moderator questions in Bold**, Respondents in Regular text.

**KEY: Unable to decipher** = (inaudible + timecode), **Phonetic spelling** (ph) + timecode), **Missed word** = (mw + timecode), **Talking over each other** = (talking over each other + timecode).

**Moderator: Well, thank you so much to all our panellists, and I hope that has whetted your appetite. I don't want to prolong visually looking at me, I want to prolong the engagement with everyone that's taken the time to attend this webinar. So, I encourage you all to submit any questions that you have, on any topic that you think our panellists, our wonderful panellists can answer. So, I will kickstart it with a question for Angela, in terms of best strategy to access the market, for example, in optometry specifically, or a med tech in the vision field, what would be your advice there Angela, or your guidance?**

F: Well thanks for that Suzanne, and good morning again to everybody, if I understand correctly just thinking about market access, very specifically you're saying optometry, but I guess it's right across in general. I mean, what we normally say to companies is first, actually look at home base, and actually think about your capacity and think about what you've achieved in the domestic market, and maybe even in some other export markets as well. And that won't necessarily translate into the Australian market, but it leads-, it gives you an idea of, you know, the lay of the land, the partners, the stakeholders etc. And then I would say look at the resources like yourself Suzanne at Invest NI, and who can assist with gathering market intelligence because that's going to be key. But if you think about the vision, market as it were, I would say, a couple of things, number one, there are so many agencies and institutes here that actually, look at international collaboration in that space. So groups like the Centre for Eye Research, they actually get involved in clinical trials, they're more than happy to look at partnering, whether it's with universities, or, you know, pharmaceutical companies, or biotech companies etc. globally. So agencies like that, the BHVI, what was the Brien Holden-, Brien Holden Visual Institute I believe, they actually have a focus on R and D in the sector as well, and there's other groups as well, like the Industry Association as well. If you're thinking about partners again, I mean, there are some good companies actively importing equipment in this space.

**Moderator: Yes.**

F: Companies like BNP (ph 02.28) Instruments would be one that comes to mind, Optimen (ph 02.31) is another, but my message is always don't go with the first one, actually identify all the players, look at what your competitors are doing as well, and see who your competitors might be partnering with. And then, qualify them and interview them to make sure that not only do they have the capacity, but that they're also interested-, they're also interested in collaborating with you. And of course, to Duncan and Adrian's comments, regulation compliance and TGA is really important as well, to make sure that you're aware of the compliance around TGA, and that you have a partner that will support you, you know, with

regard to compliance in country as well. So I hope that makes sense and answers the question for you.

**Moderator: Absolutely, thank you so much for that, and if I can expand slightly, you mentioned partnerships there, in your, sort of, experience, what would you say to companies that are looking at a partnership, what things should they consider, and I'm thinking here of the challenges-, sorry, I'm thinking here of the challenges, the pitfalls as you can see with my own camera. What guidance would you give in terms of making that process as smooth as possible, because obviously, Invest NI and all of the panellists, we're here to take the pain out of seeing Australia as an export market. So what would be your, I guess, your candid knowledge there?**

F: I look at-, I often will talk to companies and they tell us they have a partner in country and I might ask them, 'How did you find that partner, what was the connection?' And sometimes it's as simple as they'll tell us that they met them at a trade show, at Medica in Germany, or at Bio in San Diego, etc. they seem like they got on, they shook hands, and now it's happening. But sometimes, the next part of that conversation is, 'But we expected more from them, or we thought there would be more opportunity, or they're not moving as fast as we thought, or we're a little bit concerned about our compliance and making sure that we're actually meeting our obligations in country.' So, we usually encourage companies to really get a checklist in place, to really, don't agree anything on, you know, shaking hands and saying, 'Good, you can represent us, let's see how we go together.' Actually, figure out in advance, what type of partnership, whether you're going to appoint somebody in an exclusive, and what that means, that means they've got control over the market for you. Think about, you know, what rights you actually grant the supplier, if they are going to be your partner, and the territory, because often, these things are not discussed, if you're going to give them Australia-wide, then they're going to cover New Zealand as well if they've got a partnership there.

The length of the partnership and the responsibilities, and the responsibilities are the key one, what do you expect of them, but what are you going to commit to bring to the relationship as well? And that's the key one where we often see people fall down, they'll say, 'Things aren't happening.' But they're not providing collateral, technical support, information on pricing, all of that. So it's your responsibilities as well as the responsibilities of the supplier, and I guess, to wrap it up, if I think of a couple of others, sales targets, milestones, actually have milestones in place so you can revisit, have an end date on your agreement and have an opt-out clause. Because if you have an end date, at least you know we've got milestones, we've got a plan, this is where we want to be by 2025 for example, and discuss together as you go through, that's really key. But also, you need to have an opt-out clause if you're not happy, that you actually can then extrapolate yourself from the relationship, but then at that point you need to know who owns what, whether it's the customer database, whether it's the IP, all of that. So my final comment would be, if your signing an agreement and negotiating an agreement, make sure you actually have an agreement that's been created by good legal input because it's going to save you a lot of time and energy in the long-term as well.

**Moderator: Brilliant, thank you so much for that insightful comment, Angela. Duncan, can I come**

**to you, and just say, someone who has their feet on the ground, in that stakeholder engagement role, what would you likely, sort of, add on to what Angela has said, have you any insights there or any particular message that you want to share with the companies in Northern Ireland?**

M: Well I think what Angela has said has really, sort of, highlighted the importance of doing your homework and really understanding exactly also, how you're going to get paid, and we've had-, Angela gave a really good understanding of what the landscape looks like in Australia and who the various payers are for various things. But, you really have to pinpoint what your business model is going to be, it might not be the same as what you're doing currently in other countries. So really, clearly identify who the payer is going to be, and whether there is, for example, a reimbursement code for exactly what you want to do, that exists already, and understand that, and that's key, to really understand before you come to Australia, because it is a fantastic place to operate, but it's obviously not the same as what you're used to elsewhere.

**Moderator: Yes, yes, and can I also say to that, that Invest NI's obviously on the ground in Australia, we're here to act as that middle man to help you, you know, reduce those pain points, to help you manoeuvre those particular distributors that you should be looking for, or partners that you should not be looking for. So we are here to help with that, if I can move on, just changing tact a little bit to Adrian, I hear probably daily that the regulatory path to Australia is more difficult, now you touched on that in your presentation in the sense of the timelines have decreased, which I'm very happy to hear about. But, I always hear, you know, I hear commentary from companies saying, 'Well we can go to Europe, we can go to the FTN America, and Australia is challenging.' And I want to, with your help Adrian, I'm putting you on the spot a little bit here, I appreciate, but I want to help dispel that particular commentary today, because we are open for business, there's challenges in every market. But what would be your guidance on the typical time frames for reg approval in Australia, and if you can maybe touch on, break it into sectors, companies and even a few examples if you have them Adrian?**

M: Yes, well first of all, I'll talk about the success rate and the success rate with new indications is probably about 95%, and new medicine's about 90%, so it's a very high success rate for things reaching the market. And we sometimes have a slightly different opinion, but our opinion might be somewhere halfway between Europe and US. So I think we're very predictable in terms of outcome and we want to make sure that as many medicines as possible can reach the Australian consumer. In terms of timelines, medicines now are looking at, sort of, six months for something like a COVID vaccine, to twelve months or so for a medicine, and probably about ten, ten months or so for a new indication. So very predictable, very, very, tight time frames and very good, and having seven pathways means that you can for instance, give us an evaluation report from Europe, with your European dossier, and we can use that European evaluation report, and not ask too many questions either. So, it's not-, the regulatory burden is less as well. In terms of medicines, such as OTCs, you would probably see results within twelve months, and devices, they're currently going through a very busy period, because of all the rat tests and other things that have gone through. But again you would see, even for complex medical devices, probably an outcome in twelve months, so generally good. In terms of why, what the difficulty might be, I don't think it's so much a regulatory approval process, the difficulty which some people talk about is the difficulty to

get reimbursement, and that applies, perhaps more to prescription medicines, and perhaps more when companies are very ambitious in terms of what their return would be in that area. But definitely, to at least get an approval, it is quite predictable, quite fast, and I would encourage you to bring your medicines and devices to Australia with that in mind, and, and, consult early in terms of what you need to do, for the reimbursement space, for prescription medicines.

**Moderator: Great, thank you so much for that. I mean, we are living in a post-COVID world, and through that COVID process, there's been a lot of emphasis on, connected health products, indeed I myself have attended a lot of independent living conferences where you can see connected health, software, med device, demand shining through. And that was, sort of, burgeoning, before COVID even happened. Adrian what do you see that trend in softwares and med device, given that Australia has got a high rate of dementia which is increasing throughout the populous and only predicted to do, you know, increase more, do you see softwares and med device slash connected health, sort of, being a big sector moving forward?**

M: Oh absolutely, and in fact-, in fact TGAs probably it's most active area of development is developing guidance for softwares and medical device. It's clear that it's not only, sort of, an inherent software, that's in a medical device, but it's also diagnostic equipment, things that could be used in combination with their device and a medicine. It is extremely active area, and an opportunity for really, great bounds in healthcare, and self-management of health as well. So it's a thing we, as a country are very interested in, and I think there's lots of opportunities for us here.

**Moderator: Yes, and I'll just hover on you a little bit more Adrian, in the sense that another, sort of, commentary that I hear a lot of, is Australia is conceived to be one country in it's entirety, when actually it's broken down into different states with different regulations and indeed different technical capabilities. For a Northern Ireland company that's in connected health or softwares and med device, what guidance would you give and say, you know, you can only-, there's a, sort of, perception that you can only go to certain states. What would you say in that, you know, you can go nationally, there will be different regulations and expectations per state, but that isn't a deterrent, in fact that should be really something that you, you know embrace and continue on with. But what would be your, I guess, your opinion there?**

M: Yes, so most prescription medicines, OTCs and medical devices, there are health departments in each state, and a Commonwealth health department, but most of the powers have been vested in the Commonwealth department. So when you get an approval at the Commonwealth level, it applies to most states as well, occasionally, there is a small variation in, you know, which doctors are allowed to prescribe something, in, in particular states. Occasionally there are rules in terms of distributing to various hospitals and tendering processes, but the overall approval process is quite centralised in the Commonwealth now. So, you should not be having to go through seven sets of hands to get a generalised approval, you should generally be able to deal with the Commonwealth for most products, and then states sometimes have a, occasionally a minor role, or a minor input on it, and that's usually not a big barrier.

**Moderator: Okay, thank you for that, and talking about going through seven sets of hands, Angela if I can come to you regarding the procurement process that companies frequently encounter in terms of getting their product through public hospitals. What would be your opinion there in how to make that more streamlined or how-, what would be the time frame around that that you would suggest, why would it not put companies off, why should you just see that as something that, you know, you overcome, but should not be a deterrent to coming in market to Australia?**

F: My, my approach is often, because, when companies look at the market, they think of Australia and think we have to establish ourselves in Australia and they think country-wide. But often my approach is, especially if you're looking, say at the public health system, is to even start and think regional, because you want to get a foothold, you want to get that reference site, you want to actually establish a presence which you can then present to the rest of the country as it were. So even looking at, if I think of one region, the Gold Coast region in Queensland, South-East Queensland, it's probably got a population of, I don't know, about 700, 800,000 growing, growing as we have particularly the seniors demographic population shift going up the East Coast of Australia. Gold Coast Health, back, quite a few years ago, they actually developed their digital health roadmap, and they've got one currently that runs to 2024, and they're not unique, many other hospitals will have something similar. But my advice is start with something like this, look at the Gold Coast as a region, look at the health roadmap, look at the areas where they're really focussing, and from their perspective, it's virtual health, it's training of the workforce, patient care etc. They will have a number of priority areas, and see who they're partnering with. And using them as an example, I know they've partnered with Telstra Health for the delivery of a lot of services but there's also a health accelerator in the region, and they're really open to working with some of the companies, the start-ups, etc. in that accelerator on the Gold Coast, I think it's called LuminaX.

**Moderator: Yep.**

F: So one entry point might be to come in, potentially, if you're actually setting up yourself at a soft landing pad, maybe in one of the accelerators, to plug into the health ecosystem in that region, and use all the players in the region, to make that your entry point. And then you've got that, you can then look at the next and the next, whether it's in Queensland itself, in Brisbane further North or whether you go South to Sydney and on to Melbourne, etc. So really, from that perspective, it makes it much more manageable than thinking, 'We want to do health, let's start with health, you know, contracts and tenders.' But again, every company's different in Northern Ireland, we'll have small companies participating today, we'll have very large companies and the approach will differ depending on the size and scale as well. I mean, Duncan may have some insight as well I think through MTP Connect and the work you do with a lot of the accelerators and incubators as well Duncan.

M: Absolutely, look, I think Suzanne, as with every country, the pandemic has demonstrated the fragility of the supply chains in Australia, that has led to a focus on understanding our sovereign manufacturing capability and that has highlighted, for each state, the importance of them as-, their procurement. And it's really brought into sharp relief the opacity of some of those processes. So I know that all of the state

health groups are aware of the importance of-, that how they procure things, and they're all working to improve that. So, I've had conversations in the last month with New South Wales Health, Victoria Health, my colleague in Western Australia has been talking about the same thing. So yes, it can be complex, but there is a lot of work afoot to try and improve that as well.

**Moderator: Okay, alright, and I-, a question's just come through in terms of how can Invest Northern Ireland support you in terms of exporting into Australia. I specialise in, in market information as you can see, I would direct any companies with specific support questions back to our headquarters in Belfast. And this webinar will be uploaded shortly onto our website, with accompanying details, so you will find a signpost and pathway to how to contact HQ regarding specific support questions that will enable you to come here and export into Australia effectively. I just want to leave the panel with, I guess, the final comment, the final thoughts, I mean, I obviously will champion Australia as an export market, as I know my panellist will as well, I do hope to see you all come here, you know, from a travelling point of view, Australia might seem far away, but economically, it's right here on the map. And I encourage you to come and explore what we can offer. So I'll just go round the houses and say, Adrian, why should, in a final synopsis, why should companies come, or export into Australia, and indeed New Zealand?**

M: Yes, definitely, there's a lot of money put into health in Australia, there's high value put in medicines and medical devices, and certainly there isn't some of the competition that you will see in very large markets. So I think there are opportunities here, and desire to have the best products in Australia, so we've tried to facilitate that as a regulator, we've got more than \$13 billion a year paid for through our pharmaceutical benefits scheme, more than \$25 billion a year in our Medicare benefits scheme. There's a lot of money in that as well as in the accelerator programmes as well. So, health is considered a priority for our country, and we'd certainly like to have as many good options in our country as possible.

**Moderator: Thank you Adrian, well said, and over to you Duncan.**

M: Look, I'd really echo what Adrian said, we've seen in the last-, even the last just two months, a number of state budgets have come out with huge amounts of money, as Angela pointed out, to support the expansion and production of new and advanced medical products, whether they're therapeutics or medical devices. So there's a lot of investment coming in from state and federal governments to help make this work, to open up those pathways so that we can get the people here, and get medical innovations to patients.

**Moderator: Fantastic, thank you so much Duncan, and Angela, last but not least, I will give you the final word before we wrap up this webinar spotlight on Australia.**

F: Thanks so much Suzanne, I mean, my thought is, think about the historical relationship, think about the connections going right back, apart from the (inaudible 20.39) distance which is no more really, this is an

ideal place to do business, number one. Number two, if you look at the export stats coming from Northern Ireland, coming from the UK, coming from the region into Australia, if you're not doing business here already in your space, your neighbour is. The numbers are significantly high so the opportunity is there, and this is an opportunity for you to actually, grab a piece of that pie. As Duncan mentioned, when you look at the budgets, when you look at the money being allocated, right across the board, it's significant, and it's very easy to segment and see where you might fill in, what sector you're supplying, or sub-sector, and where you'll fit into a vertical etc. And of course, you're here sitting in Sydney as well Suzanne, able to provide that on the ground advice to be able to educate and provide the intelligence to help make the decisions.

**Moderator: Absolutely.**

F: So open for business, and the team here are ready to provide that support as well, thank you very much.

**Moderator: Well look, I hope we got the message across, I think we did, and I wish to just thank all of our panellists, Angela Fulley, Dr Duncan McGuinness and associate professor Adrian Boots, and I look forward to seeing you here, thank you so much to everyone.**