Beyond Funding: NIH Support for Innovators

Elyse Sullivan: All right. We can get started. I wanted to introduce myself and say welcome to our session. It's called "Beyond Funding: NIH Support for Innovators." My name is Elyse Sullivan. I will be moderating today's session, and I have a few housekeeping items to note before we get started, so you should see a button on the bottom of your Zoom window that says Q and A. If you have questions that come up over the course of the presentation, please enter them in the Q and A box. That's the one that we're going to be monitoring, and we're going to be collecting those questions, and we're going to go through them after the presentation, and we're going to try and get to as many as we can, so please go ahead and pop anything in there that comes to mind. There is closed captioning available for this session. There's a link that I believe we just put in the chat box that will give you that closed captioning, and we also have interpreters with us, so this session will be recorded, and that recording will be made available along with the slides used within the next couple of days, so that's a resource for you guys. All right. With that, thank you again for joining us, and I would like to introduce our panelists. We have Chris Sasiela. She's our senior regulatory specialist and the innovator support team lead. We also have John Sullivan joining us, and he's an NIH entrepreneur in residence, so with that, I'm going to turn it over to our panelists.

Chris Sasiela: Thanks, Elyse, so good afternoon again and congratulations for making it nearly all the way through the NIH virtual conference. We really appreciate your willingness to sit here in front of your screens for yet another hour on a Friday afternoon. My name is Chris Sasiela, and I'm the innovator support team lead in the Small Business Entrepreneurial Education and Development Office, or SEED office, at NIH, and today John Sullivan, one of SEED's entrepreneurs in residence, and I are going to tell you about the great value our team brings to the NIH innovator community and how you can access our people, programs and resources. John.

John Sullivan: Thanks, Chris. I've been focused on healthcare innovation throughout my career, and one overarching consistent theme that emerges is that it takes a really broad and experienced team with complementary skills and networks to successfully move a technology from the bench to the bedside, or as NIH likes to say, "from discovery to health." The SEED office can help with this by working across the NIH to support our small businesses in a wide variety of ways providing outside team members and active support so you can have the best chance to successfully grow your company and get your technology to the market. We've assembled some great subject-matter experts in key areas with long track records in the life sciences industry. This includes experts with both business and entrepreneurial acumen, especially for those small businesses and academic entrepreneurs that are new to starting companies and all the decisions and complexities that that requires. Commercialization guidance experts, not just about building companies, but launching new innovations into the market with an understanding importantly of target markets, market research, evidence building, go-to market strategies, business models, strategic partners and financing plans. A full understanding of the regulatory issues around your product is critical to ensure that you can chart an efficient path to the market and prove your technology is safe and effective, and once your technology is on the market, it's helpful for you to get paid too, and our experienced experts can help you navigate the wonderful world of payers from [Indistinct] consumers to private insurers to government payers such as Medicare and Medicaid, and beyond working with our team of experts, we have an ability to sponsor companies so they can and then several of the top industry conferences, which we call showcase events and explore conversations with a large number of potential investors and strategic partners and grow your industry network. We can help you prepare for the event as well with pitch coaching, make sure that your story is clear, powerful and well received, so we can also put on some regulatory ... some regular interactive workshops and webinars, including regulatory, in all the areas that are listed above to grow your knowledge and allow you to ask some specific questions tailored to your businesses, so again, all this is with the goal to ensure that you're successful and can turn your technology from discovery into health.

Chris Sasiela: Thanks. Next slide, please, so I know I used to think of the government as soon as sort of this big black box. I'd send an e-mail or leave a voicemail, and it would be fairly obvious someone somewhere might have received my message, but I had no real idea who that person was or what their drivers were that would keep them from getting back to me, or eventually I might get a response, so one of the things that I like to do is to make sure that people know who's on the other end of the communication when they reach out to the innovator support team. As John mentioned, we really have a very strong set of professionals on our team, and these are people who have expertise and experience and all those different things that you never learned when you were in graduate, medical, dental school or wherever. This slide doesn't show everyone who's on our team, but these folks represent our core competencies. We have a serial entrepreneur and active angle investor who helps us advise our awardees on many of the beginning steps of starting a business and getting that first tranche of third-party funding. It can be really hard to get that very first check written. Our entrepreneurs in residence and our business analysts offer their experience working with start-up and everyone from start-up to Fortune 500 companies, in drugs, devices and diagnostic development, and these people really educate our NIH entrepreneurs on developing and recruiting company leadership and advisory teams, talking to investors and strategic partners and truly communicating the value proposition of what they're developing, be it either as an academic entrepreneur or as a small business. We also have access to a incredible colleague, a gentleman I've been working with for nearly a decade at this point at the U.S. Patent and Trademark Office. He has provided insights into intellectual property portfolio development and management, how to understand how to interact with the USPTO during an examination, and he's been doing this for quite some time and focused specifically on the innovator community, such as the NIH innovator community, although he has worked with multiple programs. We also have experts who are very experienced in the regulation of small molecules, medical devices, biologics, vaccines and diagnostics, as well as the development and deployment of laboratory development tests. These people have worked at FDA, at large regional healthcare systems. They've led regulatory contractor teams. They've worked with and for CMS. Their expertise spans the spectrum of early development and optimization, preclinical and clinical development and all the way through and beyond initial market authorization for a new technology, so with this team in mind, we really want you to know who we are and what these people can do for you. Next slide, please. So one of the things that you can get as John mentioned earlier through the innovator support team in SEED is a subject-matter expert consultation, and Ben here is one of our regulatory experts. In order to request a consultation, all you need to do is currently hold an award from NIH, any award from NIH, a training grant, basically a search award, a small business award, a program project grant, whatever. It just needs to be a current award, and your program officer, that person that you talk to about your research plan or your training plan basically just needs to support your access to our team, and I've got to tell you, it's not hard to get their approval. I've pretty much never met a program officer who said, "No, no, no, no. We don't want them talking to you." It doesn't happen. They not only want you to talk to us, but many of the program officers at NIH will proactively reach out to myself and my team because we know we have the expertise that their awardees could really use in terms of ad hoc consults. Once we get connected, which is usually done by e-mail, we're going to ask you a couple of questions. We're going to ask you to give us a little bit of information about our project, where you are compared to when you originally applied. We're going to ask you what specific topic you are interested in talking about with our team so that we know we can get the right person on the phone with you. We try to focus on a single topic at a time, so if you just come in saying, "Oh, I need everything," we're going to break that down to a couple of different calls because we want to be able to give full attention and appropriate focus to each aspect of your product-development work, so what are some of the questions that people might ask? People might ask, "Oh, I have an innovation that is going to need to go to FDA, and I don't understand how to develop a research plan that is compliant with the FDA," so we'll have a conversation about that, or they may have a plan that they've already developed, and now they want to make sure that it's on target, so they want to meet with the FDA. Well, how do I prepare for that? What does that look like? Those are the types of questions that we'll have. In all, that's really what's written up on this slide, and I know that all of you can read on your own, so I'm just going to view a case study or two. One thing about the NIH portfolio is that we love to serve the underdog, so we have a lot of companies and innovators in our portfolio who are developing technologies to meet small market areas, and this can be a very challenging space for a company that's looking for investors, so we've been working with one such company who is working on a technology that can identify environmental pollutant levels. For example, to provide health alerts to people who have asthma or a lung disease or who may be sensitive to certain chemicals, and this company sought a consultation with our entrepreneurs and residents to help them identify investor groups that would be open to their type of technologies. It's not a drug. It's not a medical device. It's a little bit different. It's out of the norm for NIH, and so we pulled in the program officer. We talked to the company leadership. We had a nice conversation, and we ended up being able to connect them with a local investment group that was extremely interested in their technology and that was a reasonable drive away so they could actually pitch to and talk with those investors. There's a second company that I have worked with that is developing a new cell therapy, and cell therapies are a little bit unique in that to get a cell therapy into human clinical trials, you need to not only submit to the Food and Drug Administration, or FDA, but also to the Recombinant Advisory Committee, or RAC, and you can submit at the same time to both of these regulatory bodies, or you can submit first to the RAC, get their approval for your clinical protocol and then file with FDA, and I had an initial conversation with the company leadership. We talked about the risks and benefits of waiting to submit to the RAC until they were ready to put in their application with FDA, and was it a bit more of risk or less of a risk? How did they want to manage that with their investors, with their development time line? They chose to wait and submit to both bodies simultaneously, and unfortunately, that ended up delaying them a little bit because they did get called up for a public review from the Recombinant Advisory Committee, and it's not common for that to happen, so they didn't really have any experts who had that experience. They didn't know what to expect or the time lines or things like that, and what I was able to do with that company was actually get someone on the phone with them who helped set up the Recombinant Advisory Committee in the first place when it was first formed many years ago and help them then sort of understand what to expect and how to proceed, everything went really well. The review went smoothly, and they were able to start their clinical trial very soon thereafter. I could talk about examples like this all afternoon. I've been at NIH for a while, but, A, you're going to get bored, and, B, we're going to run out of time, so I think we should move on, and John, I believe, is going to talk to you about what you can expect as you prepare for an investor event. John.

John Sullivan: Thanks, Chris. Yeah. Showcase event attendance, as we mentioned earlier, it's a great opportunity for our small business awardee companies, and they've really, I think, relished that chance, and they've really taken good advantage of it, which strong reviews from these entrepreneurs that they were able to build their networks, meet investors, form strong partnerships and help their company continue to grow and learn. The process is pretty continuous throughout the year where our companies fill out these company information forms which provides to us an overview on their company, their development stage, their interest rates, and then the SEED team really goes to work along with gathering input from the NIH institutes and centers that are funding these companies. We look to match the companies to the most appropriate showcase opportunities that best fit their market sectors and where they are as a company. It also includes free registration and access to the events' partner platform, and you'll get pitch coaching from our subject-matter experts who have started companies themselves, raised money, invested in companies and formed strategic partnerships throughout their careers, and along the way they've seen a lot of pitch presentations as well, so a really good partner to have for you across the table. We can help you prepare for the conference itself too, whether it's virtual or hopefully one of these days in person again. The preparation can include things like, which company should they, your partner, should they look to target? Who can they reach out to as potential partners, both from the launch of the products as well as potential vendors as well as elevator pitches? How do they do an elevator pitch if they run into somebody or have an off meeting that's a secondary topic in another meeting? How do they respond in a quick way to give a brief overview of their company? And frequently after building a relationship with these companies through this pitch coaching and understanding their needs better, then we as the innovator support team and follow up with them throughout the year to assist them with these same issues that we've been talking about, business strategy, commercialization and other strategic issues. Three good example, Chris gave some great case studies. I have three ones that come to mind. One, we worked with a company that was developing a great solution for both heart and brain ischemia, and we started with an EIR consultation with them to really get to know them and their main strategic issue, and then we were able to match them and help to prepare them for the Life Sciences Summit in New York City last fall. There, they made some great investor contacts. They met with strategic partners, and also they were able to meet a potential CEO candidate, and after the conference, we were able to discuss next steps with them, including market strategy, fundraising strategy and also supported them in the discussion they were having with one of their early investors and cofounders. We were also able to hook them up with a consultation with our great regulatory strategy team, so it's really nice that the CEO saw us as a good entrepreneurial business thought partner. The next example I'll give is a company that was doing a product for the dialysis market. We did an initial EIR consult to help them with their overall business and fundraising strategy, and then we sent them to a really large MedTech strategic meeting that's sponsored by AdvaMed every year in the fall, and since then, we've had a couple of great follow-up discussions with them on building their financial model and even assisted them on evaluating a couple of their term sheet offers that came across [Indistinct] for the company. One was for a potential investment, and another was for a [Indistinct]. The last example I'll give is a cancer therapy company that we actually met at a conference that one of the institutes was sponsoring them to, and we were actually at the same conference. The company had a really strong technical founding team, and we were able to set up an initial EIR consult for them, pitch coach them for another conference that we sent them to, and then help them think about their fundraising strategy, and in addition, we even helped them think about potential ways they could form a business and scientific advisory boards that could guide them on a regular basis moving forward, so I hope that shows you a variety of ways that we can really help these companies and build a relationship with them and how the showcase pitch coaching can be a really important, integral part of it. Chris.

Chris Sasiela: Thanks. Next slide, please. So thus far, we've talked about what you can access as academic awardees or as small business awardees and what those different populations can get from SEED, but both of those populations really require a specific NIH award to get tied to them. What if you don't have a current award, but you're interested in doing something innovative and entrepreneurial? So what you can get without a specific award if aren't either ready to talk to someone about a specific business issue or you serve a larger population and you aren't just dealing with one innovation. For the rest of us, as I like to say, there are active and archived learning opportunities that the innovator support team members develop and deliver, so in a very human fashion, we really like to talk if you haven't figured that out yet, and one other point we really like to talk about, what we do and what we're good at. We're all very passionate about supporting life science innovation using the experience that we can bring to the table. I often call myself a translator, much more so than an expert, because you are the expert in your technology or your product or your service. I just help you understand how to talk to people who are in the regulatory field. John helps you understand how to talk to people who are in the business field, and there are times that we do that one-on-one with a consult and the showcase event preparation, but there are also times where we do this in rooms, obviously virtual for now, but hopefully again some time in person, and we will deliver webinars. We will run workshops. We will develop online content that does not require time-dependent interaction, so we have held internal and external educational events to explain to both scientists and the NIH program officers also the difference between a scientific research program and a product development program and how to move effectively from one to the other. We've delivered webinars to academic and small business awardees to help them understand how to develop a regulatory plan, what sorts of information is available to them for free before they have to reach out to a consultant or ask for a meeting with the FDA. We've talked to investor groups about regulation of drugs and devices and diagnostics, helping them understand realistic milestones for exits and how to explore the different types of risks that come along with different types of technologies, what to look for as obvious red flags as they begin to evaluate a potential investment, so we have all of these different audiences that we are perfectly excited and happy to talk with, and if you are not just an individual researcher, but if you're at an economic development center or an incubator or a university, or if you are with an investment group and you want to hold a larger-scale event to help propel your community forward, please reach out. We really enjoy and miss the interactive nature of these larger events. We've told you about all these really great things that we feel are great anyway that we've been doing, and I want to have John come back on for a moment before we start taking some questions to remind you how to get a hold, so, John, next slide, please.

John Sullivan: Yes, I'll definitely echo what Chris was saying in terms of we do really want to talk with you, so in terms of how to connect with us, the most important thing is to be proactive. Please don't be shy. The SEED office loves to hear from our portfolio companies early and often, and it's one of the main points you should really take away from this presentation. Please take advantage of all these great programs we tried to lay out for you throughout the presentation. There's several specific ways that you can contact us. One is to connect to us through your NIH program officer. As Chris said earlier, they're very open to having you working with us. Just let them know that you're interested in working with the innovator support team in the SEED office. You've obviously built a great relationship with your program officer over time, and this is another resource that they can bring to bear to help your company. Another way is to respond to our outreach e-mails. Please keep an eye out for these communications from NIH as these innovator support opportunities really become available throughout the year, and when you get them, we'd ask please respond as quickly as possible so that you don't miss important deadlines as they come along. Another way is you can reach out to us directly via e-mail at sbir@od.nih.gov, and I think Chris mentioned this earlier as well. Please include in your message the specifics like award number, NIH program officer name, brief background on your project and the specific topics and questions that you need assistance with. That way, we can, one, pull the right team together and also prepare the right information for the call to make sure that it's really a productive experience for you, so that's, I think, the quick summary of it. I look forward to working with you and answering any questions that you have.

Chris Sasiela: Thanks.

Elyse Sullivan: Great. I will pop back on here. Thank you both. We've got a number of questions coming in, and why don't we start with ... I'm just going to bring this over. Chris, your first piece was about the subject-matter experts or contacting for regulatory business, etc. The question is, how can we get in touch with those SMEs, and how far into the grant award can we start this given that it requires an active award.

Chris Sasiela: So how is simply send us an e-mail or ask your program officer to connect you with us. They obviously will know how to reach us internally in NIH, and how far into an award? Pretty much as soon as you have that communication onboard with your program officer. If you were to put in an award application rather and in your summary statement, for instance, you got some feedback that you might want to strengthen up your commercialization plan or better understand your market area or develop a stronger regulatory approach or validate something of that nature, then that might be part of that first conversation you have with your program officer and say, "Hey, got this feedback from my reviewers, and I'd like to talk to someone who has a little bit of knowledge in this area. Can you connect me with the SEED team?

Elyse Sullivan: Great, so there's another question along the lines if you're applying for an award, but you don't have an award yet. Is it still ... Can we still contact you, or is there any ... Or who else would you recommend contacting preaward?

Chris Sasiela: So preaward, we always encourage you to reach out to your program officer. In order for us to provide service to the NIH community, we do need to have a limit on how many people can contact us, and so we do require the active award, but that being said, your program officer is often very useful, and there are quite a few online resources that are available to you that they can point you towards that can help you with understanding the business aspects. For instance, if you're wondering what a commercialization plan looks like written out, the National Institute of Allergy and Infectious Diseases has posted example successful applications online, and you can see what that looks like. Several institutes have videos or webinars posted. The NHLBI has a whole series of what are called small biz hangouts that talk about intellectual property development, market research, regulatory affairs, these types of things, so there are resources available to you already online, and a program officer should be able to point you towards those.

Elyse Sullivan: So another question is, could an NIH program officer make a connection where small businesses can get outside opinions for unmet needs? So I guess that's asking, do they need to come to you or can folks use outside services?

Chris Sullivan: I can take a shot at that. I think ... And Chris is really the expert in terms of the NIH and the processes and how to work with your program officer, so please correct me if I'm wrong on this, Chris, but I think from a ... What I hear you saying is we really want to understand our unmet market needs. Where is ... How do we talk to our customers, and how do we evaluate where this technology fits within the marketplace? And as Chris said earlier, I think ... I really do echo her comments on reach out to us as early possible once you receive your grants, right, your award, excuse me, so that we can help you with these issues. In terms of is there inside versus outside the NIH ways to get this help. Through an EIR consult, we can help you evaluate both sides of the equation. We can help you think through what are broad ways to look at your market as well as what are ways you can use both primary and secondary market research firms to really help you in a capital-efficient way to get those important answers that you're looking for.

Chris Sasiela: In addition to what John mentioned, there's also the opportunity in your application for small business funding at least to request funding to support technical and business assistance, so you can, with a phase one award request up to $6,500 per year of award and for a phase two award, in your application, you can request up to $50,000 per project to help you with some of those things, and for phase one awardees, NIH has several customer discovery programs. There is the C3I program and the I-Corps at NIH program that you can apply for. Those are competitive programs, so it's not a guarantee, but you can certainly ... If you know how you want to use to do your market research, you can justify that in your budget with your original application. Put that in there. It will go through peer review, and you can request up to those different tablet funding amounts. You are not required to reach out to the NIH resources.

Elyse Sullivan: Another question about accessing you all in the SEED office. Can investor groups get in touch with you all? They don't have program officers, so how do you want investor groups to go about this?

Chris Sullivan: Yeah. I'll take a crack at that too. I was a venture capitalist for 7 years, so I'm experienced in being an investor and trying to find great companies that fill our portfolios when you're investor, and when you think about these NIH small business awardee companies, there's really a lot of benefits to working with those NIH portfolio companies. They are certainly a little reduced risk because the NIH has sort of evaluated them, had a national team, a panel of expert, really look at these companies, and they've given some early seed capital and maybe even some more extensive capital, $5, $10, $20 million in some cases to companies to really help them de-risk their projects and their technologies so ... And they also play in really important markets. NIH, our whole thing is discovery to health, and NIH wants to make from their mission a big impact on the healthcare in the U.S., and so, Elyse, the question that you raised from the audience about how does an investor get the opportunity to work with these companies, what I would say is absolutely, please, contact us. We're constantly at these conferences trying to build our investor networks on top of what we already have, but if we can help understand the investors, I would say reach out to the SEED office directly through that e-mail address. If we can understand what the investor is looking, the types of companies, we can help them think through the types of companies. They can look at how to connect with them at conferences as well as to use our great public available fate website, which is called projectreporter.nih.gov, which lists a lot of these companies that investors should really be paying attention to.

Elyse Sullivan: Wonderful, so there's a couple of questions about some of these, about TABA funding and the C3I program that we just spoke about, so I'm going to go through those, and then we'll circle back to some of the earlier questions. I'm not going to forget you all. Okay. Question is, should I include TABA in the SBIR? So I'm not 100 percent sure what the question. Is the question asking should they include their request for technical business assistance in their SBIR application?

Chris Sasiela: So I will tackle that: yes. It's a best practice if you're going to ask money from NIH to do that in an application, and certainly if you know in advance who you want to work with ... The thing is, you can't just request the money, just like you can't just request money to do research. You need to justify your budget, so let's say that you have a desire to do some market research, and you have identified John Sullivan, an absolutely stellar consultant with whom you want to work to do market research on your very innovative program. You would negotiate with Mr. Sullivan, and he would say, "Oh, I'm very expensive. I will cost you $6,500 to do a market research analysis for your technology in this field, and here's what I will give you, and this is my hourly rate and how many hours I anticipate it taking you, and this is the deliverables." You'll have that all written out, and then you'll be able to include it in your budget justification page with your application on those lines eight, nine or 10 of the budget justification pages.

Elyse Sullivan: Another question about the budget. Can your TABA funding exceed the budget caps for your SBIR award?

Chris Sasiela: That's an excellent question. At NIH, we have waivers for the hard caps that Congress sets for the small business program, so what we encourage you to do is to take a look at the waiver topics and take a look in the solicitation, typically the omnibus solicitation, that you are applying to, and talk to a program officer because across the 24 different funding institutes and centers of NIH, there are 24 different approaches to whether or not that money is above the cap, under the cap, part of the total request, et cetera, so that is a question that needs to be answered by the program officer at the institute where you are most likely to be funded.

Elyse Sullivan: Wonderful. I wanted to circle back to a question. This may require more of a one-on-one consult with you, Chris, the regulatory expert, but the question is, what are the reimbursement and payer players and requirements for cell and gene therapies.

Chris Sasiela: Oh, that's definitely not a question that can be answered in the few moments we have remaining. Specialty medicines have a very complex and evolving payment strategy in place, and so it's going to be very dependent upon the prevalence of the disease, the ask that you have in terms of first pricing, the durability of the response. John, you can pipe in here. You know.

John Sullivan: Yeah. Medical pharma benefit, it depends on whether it's in hospital, inpatient specialties cell therapy or whether it's an outpatient cell therapy, so it's a whole mix of ... I agree with Chris. It's a hard topic to answer in this kind of a forum, but [Indistinct].

Chris Sasiela: [Indistinct] specifics.

John Sullivan: Reach out to us, and we can help you work through those issues, and bring in ... There's a good example though of this is something you would send to us with that very specific question, and then we would at the SEED team bring in some of our specific experts that have specific expertise in that particular topic area, so we make the most efficient use of your time.

Elyse Sullivan: Great, and there is a question about the conflict of interest policy, and that's probably an off-line question, so I'm going to acknowledge the question, but what we can do is probably send you ... If you do a quick Google search, we have a web page on our conflict of interest policy. If you have any additional questions there, you can come to us or the policy office, so I did want to get down to a question of, can you explain a little more about the C3I program?

Chris Sasiela: So the C3I, which is the Culture Commercialization Center for Innovation?

John Sullivan: Yeah.

Chris Sasiela: You think? It's akin to the Innovation Corps or I-Corps program. Both are customer discovery based. They are finite times with X number of anticipated customer discovery interviews to be conducted during that time, so it might be an 8-week course of events or a 10-week course of events. It might be 4 months. I'm not 100 percent sure. Each program and each node or center might have a slightly different approach, and it is expected that what you'll do is you'll identify the key stakeholders and what is called your business canvas, your business model canvas, and there are seven different areas, including who is going to buy your product, who is going to use your product, who are the key stakeholders for getting your product to market, things of that nature, so for instance, you might have interviews with clinicians and with FDA and with CMS and with leading key opinion leaders and with investors and with patient advocacy groups, and so this is really a great way for people to understand the true market need because ideally you would like a market pull versus a market push for your technology, and this can help you get to that point to understand what those key drivers are.

John Sullivan: And, Chris, correct me if I'm wrong, but I think it's just for medical devices as well. Is that correct?

Chris Sasiela: Yeah, the C3I program is focused on medical devices where the I-Corps program is agnostic to technology type.

Elyse Sullivan: And can you tell us ... So this question is, can companies apply for the I-Corps if they've already received TABA funding in their award, or can you do only one or the other?

Chris Sasiela: The I-Corps is separate from the TABA funding, so you can apply if your IC participates in that program, and you have a phase one award. I don't believe it's open to phase two awardees, but you can look at the I-Corps at NIH website and find out a little more information there.

Elyse Sullivan: So we probably have time for just one more question. Let's see. We have an active phase one SBIR award, and I was wondering if you have anything to help us with the phase two commercialization program. I'm assuming that you do.

John Sullivan: So when you say anything to help you with, yeah, so if you're an active phase one award and you're preparing for that, Chris already mentioned up-front that there's a great NIAID sort of form, or they have some examples of successful commercialization plans. I would certainly look through that. Depending on your institute and center, they might have other examples that are directly relevant to your topic market of interest. As an EIR, we can do a consult with you to sort of think through some of those important commercialization plan efforts in terms of a lot of the things even Chris talked about for the C3I and the I-Corps programs on, who are your customers? What's your go-to-market strategy? How are you going to price this? What are the channels you're going to use? All the very important questions, we can help walk you through those important topic areas and sort of be a thought partner around the table for what areas you know already and what are areas you need to explore and learn more about in order to have a successful commercialization plan.

Chris Sasiela: And in addition, there was a recent webinar that was delivered by Todd Haim, who was at the National Institute on Aging, that talks about how to develop a strong commercialization plan. I encourage you to watch that also because although certainly an EIR consult would be very helpful and very informative, I think many times for a phase two application, unless there is a unique, specific concern that you're trying to address in your application, it's ... For most phase two applicants, it's really understanding the breadth and scope of what reviewers are looking for, and he did a really great job in that webinar describing how to put an effective plan together.

Elyse Sullivan: Wonderful. Well, we've only got 1 minute left, so I think we should wrap it up. Thank you to our panelist.

John Sullivan: Thank you. Thanks very much.

Chris Sasiela: Thank you.

John Sullivan: Thanks very much, Elyse, for moderating and doing such a great job.

Chris Sasiela: And thank you to everyone who stayed so late on a Friday afternoon. Don't forget. There's one more panel. We have a number of small business awardees who've really been very successful through the NIH program and come from diverse backgrounds and diverse areas, and that is starting in about 15 minutes, so I hope that you'll stick around and enjoy that session also.