Making the Most of Your NIH Phase II Small Business Award - Webinar Transcript

November 7, 2023

Chris Sasiela: Good afternoon, or good morning, depending on where you are, and welcome to today's webinar. My name is Chris Sasiela. I am the Director of SEED Innovator Support Services here at NIH, and you are here today to learn how to make the most out of your NIH Phase II Small Business Award. Joining me in today's webinar is Ms. Stephanie Fertig, who is the Director of the NIH Small Business Program, and two of our NIH Phase II awardees, Ana Moreno, Founder and CEO of Navega Therapeutics, and Mo Chen, Founder and CEO of WNT Scientific. We have the next 90-ish minutes for you to learn a whole heck of a lot and to ask a lot of questions, so please, as questions come up, feel free to post them in the Q and A.

We may not actually address them in real-time, but if they are completely relevant only to that section of content, we will try to. Of note, a little bit of housekeeping, this webinar is being recorded. The recording and materials will be made available to all registered parties seven business days after the session, and we would like to ask that you please submit all of your questions in the Q and A box located in your control panel. The Q and A box is the appropriate place, not the chat function but the Q and A box. So, with that, I'm going to turn the webinar over to Ms. Fertig, who's going to tell you a little bit about SEED. Stephanie?

Stephanie Fertig: Great. Well, welcome, everyone. Lovely to see so many people on our webinar today. We're going to be talking about a lot of information in the webinar today, and we're going to be going fairly quickly, but we're going to provide a lot of time for Q and A. If there is additional information, things that you might have missed or not quite gotten, as was noted, don't worry. The webinar-recorded materials will be made available on our website, seed.nih.gov, which is a wealth of information, not just about the information here from this webinar but about the programs in general, so really encourage you to utilize the website moving forward. The main mission of NIH can really be summarized as turning discoveries into health, and we see that this program helps to get those great innovations out there across the country and get some into the hands of the patients, clinicians, caregivers and researchers that need them.

And so, a lot of the resources today and things that we discuss, programs we discuss today are going to be focused on, how do we get those great innovations to those individuals that really do need them? Now, the NIH Small Business Program is really in that early stage of supporting companies. We're often some of the first funding, and that's why we do call ourselves America's Seed Fund. We're that first tranche of funding that some of our companies get. This is free money. It's non-dilutive. It's not a loan, and awardees can really leverage that funding to attract investors or partners, and we realize that investors and partners are often what's going to be required to take those great innovations and get them to market. So, as one of the largest sources of early-stage capital, how does our program work? Well, as many of you already know, since your recipients, we have a Phase I and we have a Phase II.

We have a variety of ways to get to that Phase II, that full research and development. You can go the standard pathway. We have something called a Fast-Track, which combines the Phase I and Phase II together, and then we have a Direct to Phase II. But regardless of how you get to that Phase II, oftentimes our companies need a bridge between that gap of the Phase II funding and the commercial market partner or investor. And that's where some of the resources and programs that we're going to talk about today fit in.

So, we're going to talk a little bit about the competing renewal award or a Phase IIB. Some institutions also call it a bridge award. We're going to talk about the Commercialization Readiness Pilot, or CRP. Regardless of which one of these, one of the things that we really want to emphasize is, as we're talking about some of these programs, we're going to talk about those things. Some things are NIH-wide, but some things are only specific to an individual Institute or Center. So, let's talk about the Phase IIB and the CRP.

Now, these are both for Phase II recipients only. Phase IIB is only allowed, and there are some specific differences between the two, so they both fill that gap between the Phase II and the commercial market or partner or investor, but they're a little bit different, so we're going to talk a little bit about those differences, but both of them are awards that you will apply. So, you're going to submit an application through a notice of funding opportunity for either of these awards. You have to have a Phase II. For a Phase IIB, it's a Phase II award. You have to have it after the Phase II award, so you cannot have a Phase IIB at the same time as your Phase II is active. Versus the CRP, that can be concurrent with or after a Phase II award, so you can have a CRP and an active Phase II at the same time or even a Phase IIB.

Phase IIs do follow, so it's basically a step back into Phase II. So, a Phase IIB follows those Phase II outsourcing guidelines because it's just like you're basically asking for a second Phase II, so that's what the Phase IIB issue, a second Phase II, to do some additional work that you need in order to move, again, closer to that investor or partner, versus a CRP. Significant outsourcing is allowed. It's a fundamentally different program where we recognize that you're going to be using more of your

funding for maybe CROs or other subawards in order to, again, do some of that work necessary to get further down the product development pipeline. A CRP also allows you to do other items, things beyond just research and development. It allows for some different kinds of technical assistance that's not normally allowed with any Phase II. How Phases ... Phase IIBs and how CRPs are accepted are also different. In Phase IIBs, some Institutes and Centers accept Phase IIB through the omnibus, not all, and some allow them through specific funding opportunities, versus a CRP is only through specific funding opportunities, and you can see the two trans-NIH funding opportunities here, one for clinical trials and one where clinical trials are not allowed.

Finally, the Phase IIB does encourage matching funding, and there is language in the omnibus around matching funding and how to really show that ... and that's really based on focusing on looking to show that you are moving towards, again, that partner or investor so that that encouragement of matching funding really does show that you're moving that, getting that commercial potential. But at the end of the day, only some Institutes and Centers participate, and that ... and different Institutes and Centers participate in different versions of these, and so it's really important to make sure that if you're at the Phase II, and you're looking and seeing where ... when can I ... what other award or program can I be part of to get some additional funds to do either additional research and development or research and development as well as commercialization and technical assistance?

You should ask the program officer that's assigned to your Phase II to determine, one, if your Institute or Center does participate in either the Phase IIB or the CRP, and if so, which one, and what's your next best steps? What are the kinds of things that that Institute or Center normally supports through these different programs? So, as you can imagine, it's so important to contact well in advance of submission. You don't want to be having that conversation just before you hit the submit button. It's not a great idea. So again, not all Institutes and Centers participate in these, but they do provide that additional support and funding that is necessary in order to move forward.

We also have another ... a little bit of a different way of getting add support once your recipient, is the NIH SBIR/STTR Diversity Supplement, and this is an administrative supplement that really helps support companies that want to enhance the diversity of the research and development and research and entrepreneurial workforce. It supports those small businesses. You have to have an active small business, either an SBIR or STTR award, to recruit and support individuals from a diverse and wide variety of backgrounds and individuals who are really going to, again, enhance that diversity of the research and entrepreneurial workforce.

We do encourage you to go to our website. There's all sorts of information about this program including sample components for the mentorship plans that are required as part of the supplement and additional information that might be helpful as you're putting together the supplement request. As you can see, we support a wide variety of career levels and really supported a number of individuals to

date, about 100 already, and continuing to grow. So, we do encourage you to look at a Diversity Supplement. It's a great way to grow your business and really support and get some additional funding for that. So, with that, I'm going to now turn it over to Chris Sasiela, who is going to talk a little bit about our other Technical and Business Assistance programs.

Chris Sasiela: Absolutely. Thank you so much, Stephanie. So, you may be aware that you are allowed to request Technical and Business Assistance funding as part of your funding application, your original application. Certain Institutes and Centers may allow for those requests to come in post-award, but certainly every Institute and Center allows them in the original application. If you had ... If you did not know about the TABA funding when you were writing your application, we do have some post-award TABA programs that you're going to hear about a little bit later on.

For the Phase I, that is a Needs Assessment, a general report that provides a high-level sort of gap analysis for year company, and for Phase II, there is a vendor-matching program that supports a small number of companies per year. Unfortunately, it's a relatively expensive program, but nonetheless, does help make that one-to-one connection.

But what I'm going to talk about most right now is how to effectively ask for TABA funding in your application. The reason that I really want to go into this with you is that whether you're coming in with a Phase II application or Phase IIB application, or if you're going to submit a supplement, an administrative supplement, it's really important for you to know the types of information that program staff are going to be looking for in that application and how you can get that information to justify your request.

So, there are some best practices that we've identified. First off, just for clarity, you must use a third-party vendor. You cannot use TABA funding to support personnel within your own company, so if you are seeking TABA funding to support your intellectual property development, and you have a lawyer on your team that you want to support, someone who's already in your company, that is not an allowable cost. That is something that must be used with a third-party vendor, okay? In the application itself, it's very important that you look at that SF424 Application Guide and follow the instructions in there. If you don't follow those instructions properly, your request may be denied, okay?

In your original application, you're going to label the requested cost technical assistance on one of the lines, eight, nine or ten. Those are the other lines on that budget justification form. You should include a detailed description of the technical or business assistance that your vendor is going to provide. You should provide the name of a given vendor and the expected milestones or deliverables that you're going to get as part of your request. So how do you get that?

One very effective way to do that is to put out bids for proposal. And one way that you can do that is to develop a Scope of Work document. Now, this is obviously a ... not a non-trivial thing to do, so one of

the things that the SEED office has done is the Innovator Support Team has a specific type of consultation called the SOW consult. So, this is the Scope of Work consult, and we have some examples of contrived companies that we've made up that have examples of a number of different types of knowledge areas and requests that you might make. The common things that you want to make sure are you want a clear ask. You want clear, developed deliverables, and you want to understand your vendor's qualifications to do the work. When you are building out that budget, you want to solicit multiple vendor quotes so that you have comparisons to understand just how much you're going to be able to get from each of the vendors and their different approaches and then evaluate which vendor you would prefer to go with. Include them.

Get a letter of commitment and put them into your application for the funding. So, I mentioned those SOW consults, and you're probably wondering, "Consults: What does that mean?" The Innovator Support Team in the SEED office has eight, as I can count, Entrepreneurs in Residence. These people are amazing. They are all very seasoned business executives. They have worked at Fortune 200 companies. They have been part of corporate or private venture funds. They have been C-suite leaders. They have all been entrepreneurs in at least one business and several in serial businesses, and they bring their expertise to our NIH community.

And the consult programs are a one-on-one conversation that you get to have with these people. So, you would request a consult. We'll get back to you, and we'll ask you to please identify two or three key topics or key questions that you'd like to address, and then we will assign appropriate expertise based on your request and your technology to give you that expert guidance. This is a program that typically turns around a request in two to three weeks. So, if you were to compare that to a funding request, that can take six to nine months. This is just a few weeks. And as you really work on understanding the commercial potential and the business aspects of your specific project, product or service, this ... These are really great people to talk with, to do some brainstorming, some ideation.

Sometimes they will have ideas about specific funds that are being raised or investors that you may want to talk to or development partners. So, their expertise is tremendous and very wide-ranging. I encourage you to take advantage of them. In addition to the business expertise, we also have subject matter experts, people who provide ad-hoc consultations focused on regulatory or reimbursement topics. And again, this is a team of people who come with extensive experience either in industry or in government, working with CMS, working as nurses or as entrepreneurs or as investigators or at FDA.

They have a tremendous set of experience that they bring to there, and the conversations will range everything from, "I don't even understand if I'm a regulated product," to, "Wow. I have to have a meeting with FDA. I want to make sure that I'm asking the right questions in order to get the information I need to move forward with my product development work." These types of consults, especially with your Phase II award, can be extremely meaningful, and if you are at the point where

you are looking to develop a CRP application or a Phase IIB application, and you don't already have, for instance, your regulatory plan in place, meeting with this team can be an excellent starting point. So, I want to encourage you all to take great advantage of the people that we have in these programs.

Then, as Stephanie was mentioning earlier, what our greatest desire is for our companies is for them to truly become commercially viable, for those products to get out there and positively impact the health of the nation. We know that NIH money probably won't bring you all the way there, and so what we do is we also support your attendance at a variety of different conferences, and you can see some of the conferences, I think potentially all of the conferences that we participated in this year, and I think we're missing one or two. But we send over 100 companies a year to these different meetings, and the way that we do that is, twice a year, in January and June, we send out as broadly and as widely and as often as we can information to you saying, "We're going to be evaluating companies for these opportunities on a certain day.

Please get your request in if you are interested, if you are actively partnering, if you're looking for investors, if you're looking for development partners," right? So please respond to those. Fill out a request form. The form itself should take you about fifteen minutes to complete. We have that metric by the form, the program we use to collect the information. It takes most people about fifteen minutes.

It could get you registration and a speaking spot at one of these events. If you are matched and you are offered a spot and you accept that spot, then you actually automatically get paired with an Entrepreneur in Residence to help you refine your value proposition, your pitch statement for that event, right? And that EIR will meet with you at least once, often twice, sometimes three times to help review and refine that pitch and any additional collateral to make sure you understand how to use the partnering or networking opportunities of the event that you are being sent to and really to ... just helping have the most successful event possible.

The SEED office also has a tremendous social media team, and we promote your attendance through various approaches on LinkedIn, through X, through e-mails, and through our partners in these events where we have copromotion and branding of you as an NIH company. Again, I think. It's a tremendous program. I ... This office has existed for 4 years. We've sent well over 400 companies out, and I encourage you to request consideration for the program.

And of course, you know this wouldn't be an NIH webinar if we didn't tell you the most important thing, which is, talk to your program officer. The funding opportunities that Stephanie mentioned earlier and the resources that I just described are only part of what come with your NIH award. Your program officers are going to know within your IC, do they have clinical trial networks? Are there specific other events or other programs that they participate in or they have developed that help

enhance your product development work? So, please make sure to stay in touch with your program officer. If, for whatever reason, you're not sure who that is, maybe that person recently left NIH, and you tried to reach them. You got a bounce back. We do have a contact list for all of the Small Business Program Managers, and you can find it right on our website. Okay?

I also encourage you to sign up for our newsletter, and if you have any specific questions that we don't get to either today or that come to your mind later, please e-mail us at SEEDinfo@nih.gov. We are now at the point where we really want you to hear from your peers, right? So, we are very blessed today to have two entrepreneurs, people who have received these two awards online with us. First, I would like to introduce Ana Moreno. Ana is the CEO of Navega Therapeutics. Navega is developing a patented, non-permanent gene therapy to target pain. This is a therapy that is not addictive, highly specific, and long-lasting.

On this slide, I have listed what I know of the programs that Ana and Navega have taken advantage of, although she probably knows of even more. And we also have Mo Chen, CEO of WNT Scientific. Wnt is developing therapeutics, therapeutic products for musculoskeletal disorders. I managed to say that without tripping over my tongue. I'm quite proud of myself. I've done the same thing with WNT and Mo and listed both the awards that the company has received as well as the SEED interactions that Mo has experienced or that I am aware that Mo has participated in through our office. So, welcome, Ana, and welcome, Mo. Mo, can you please come off mute? Thank you.

Mo Chen: Thank you.

Chris Sasiela: So, what I'd like to do is I'd like to ... I'm going to just ask a few questions to get the appetites whetted of our audience here today, and so I'm going to start with asking Mo to answer first and then Ana. Second question, we'll reverse that. Third question, whoever gets to the button first gets to answer first. And then we will open this up to general questions. So, Mo, could you sort of talk about, how many times did you need to apply before getting your first award? And did you need to resubmit for your Phase II award and your CRP award, or did it become easier because you were a little more familiar with how NIH reviewers look at things?

Mo Chen: Yes, so thank you for the opportunity to share my experience with other awardees. So, regarding this question, I have to say luckily our first [Indistinct] grant allocation was funded after first submission. However, all other grants including other Phase I, Phase II CRP awards were funded after resubmission. So, I want to talk to the audience that a few grant was not a [Indistinct] for funding after first submission. My suggestion is to read as a summary or statement to talk to your program official, revise your application and submit again to [Indistinct].

Chris Sasiela: Excellent. Ana?

Ana Moreno: So just to give some additional color, I applied for my first two Phase I SBIRs while I was

still finishing up my Ph.D. So, I submitted the applications, and January ... I graduated in April, and I was ... We were lucky to get them in September, and that was actually thanks to a program called the Applicant Assistant Program, the AAP. Just, I think it's something that maybe others haven't heard of, and it helps first-time grant writers to kind of understand the process, and that was really helpful for us. One of the applications we did have to resubmit and one that we did not, and as Mo mentioned, it's understanding where there are various concerns.

Maybe we're not clear in a certain section, and just recent meeting, our Phase II, we received right away as well as a CRP. And what I think made our CRP program really unique, I felt like it was a lot of getting to know our program officer and them understanding what are the needs that awardees have. And specifically, for us in the pain field, it's really difficult to find funding through investors, and so the CRP program was focused on business development assistance to the company to allow us to get towards that investment or partnering of the program. So again, a lot of support, as you can see, all the things that I've taken advantage of for the seed program, and I find that the NIH are our investors, really. That's how I think that they're our investors, and they're here to support us throughout the process.

Chris Sasiela: And can you also talk just for a second about your ... when you submitted your request for the Diversity Supplement? First, how did you find out about it, and then, how did that process work for you?

Ana Moreno: Sure. I think for me, it was really exciting to see this kind of Diversity Supplement because, myself, I'm female, Mexican in background, and not a lot of us ... as CEOs of companies, and so we have this ... I'd be on our company to be obviously very open and very diverse. And for us, we learned about it through e-mails, so SEED sends e-mails, I don't know how often, but pretty often, right, with ...

Chris Sasiela: Every 2 weeks.

Ana Moreno: Yeah, every 2 weeks, with programs coming up, deadlines. And we were really excited about that, especially as a small company. I think that this is really important for career development, and it's supporting our employees and thinking about what they're focused on. So, it's not just us asking them to do science, but also, how can I help you grow in your career? And so, these diversity supplements were really helpful in terms of, are there certain conferences that they wanted to attend to or certain skills that they wanted to learn? And we've been really grateful. We have two different awardees that have now been raising ... They've been advancing in their specific areas in the company. So, yes, through the e-mails that we get biweekly, I guess.

Chris Sasiela: Excellent. See, what? This is advertising. You can't fake this. So, can you talk a little bit

about what the differences are between your Phase II award and your CRP award?

Ana Moreno: Sure, so for our Phase II, the idea is really clearly scientific, getting our lead candidate into IND, right, getting into IND to start initiating clinical trials, so really focused on the science itself. And our CRP was specifically part of the HEAL Initiative, which is focused on non-addictive long-lasting therapies for pain, and it was this chicken-and-egg problem of pain companies not having this difficulty of raising funds from investment and trying to support our company in finding a good partner to take our program into the clinic, so from a pharma partner, or from the investment side.

So, it was actually focused on hiring a chief business officer, so really helping build out the team and supporting that, so that valley of death, right, so the actual drug gets to the clinic and gets ... starts helping patients. So, it's very focused on business development, and everyone is really surprised when I mention that we have this grant, even investors, because it's unique, right, the fact that there are supporting business development efforts that are really important in science, obviously.

Chris Sasiela: Excellent. And, Mo, you also ... WNT also has a CRP in addition to a Phase II. What ... Did you bring in a CEO also or how ...

Mo Chen: Yes, so I'm working on the CRP project, so basically, our CRP is to outsource the manufacturing process to the CDMO, so ... I can briefly review the project we're working on. So, we're developing therapeutic product for osteoarthritis, mandibular-joint osteoarthritis treatment, and so this modifying drug to alleviate joint pain in the wrist or joint function. In the Phase I study, we did not have the sustained release formation, and in the Phase II studies, we examined the therapeutic accuracy in animal models and the animal efficacy the data together with mechanistic study was published in "Cell Stem Cell" in September. And after we proved the efficacy, the CRP project is focusing on manufacturing, and so because our product is therapeutic protein, so our current effort is to generate a cell line producing therapeutic protein and develop the purification protocol and, eventually, produce a GMP-grade protein for clinical and preclinical studies.

So, the current study founded by CRP will mitigate the technical risk and leading to substantial private investment. So yeah, in short, Phase II was to prove the animal efficacy, and the current CRP is about manufacturing. Thank you.

Chris Sasiela: Excellent. And if you don't mind my asking, how did you identify the manufacturing partner?

Mo Chen: Well, so we ... Actually, so at first, Matt, the CDMO, at its BIO Convention sponsored by the SEED office. Yeah, so it's definitely a great opportunity to discover the industry resources, so I do encourage people to apply to attend these business conferences.

Chris Sasiela: Excellent.

Mo Chen: Yeah.

Chris Sasiela: Well, thank you. So, at this point, you've already both touched a little bit on some of the interactions you had with the SEED Office and the innovator-support programs that we have. If I were one of the CEOs sitting in the audience right now, a PI on a Phase II award, what would you want to tell me about when and how to access those programs, your experience in NIH's responsiveness to keeping you aware of your status of yes, no, maybe so, timing, things of that nature?

Ana Moreno: So, I guess I'll ... Yeah, I'll get to it first. So, I've had a few consults, as you can see. One of the initial, I guess, opportunities that we took advantage of was attending the BIO Conference in San Diego, and I think what made it really unique was the support and perfecting our pitch. So, we had a consult with SEED to help us finalize our pitch. I get the feedback that I see fast as well as the fact that I'm very scientifically focused, as a scientist as background, so really helped me perfect my pitch to make it more of a business case and, I think, more relatable potential investors that might not be as scientifically focused.

So that has been really, really helpful, but there's been other opportunities that, again, are unique to what we're focused on. And one was a skill-partnering meeting that they made new this year, and that was bringing together companies that had been funded by the NIH that are in pain space. Like I mentioned, it's a difficult space to be in, and they brought in investors as well as pharma experts to listen to our pitches, give us feedback, and that was really unique. The fact is I've also been able to keep some of those relationships with the people that were part of the judges, judging our pitches, and I actually have a consult after because we won first place, so additional support in terms of, again, how do we perfect that pitch to get towards investors?

Does the business case make sense? So that's more on the pitching, but we have a call next week on regulatory, so we have a regulatory consult coming up because we have an idea of what we're thinking of starting our Phase I 2a clinical trial, but we have questions in terms of, does it make sense to then do a Phase 3 in a different indication? So, some questions that we still have that they can provide a lot of support. So, I see it as an extension of our team. We are small, 10 people in our team, and we have a lot of advisors, but it's just a great way of finding experts in the field that can be an extension of your current team.

And I would say the responsiveness is really quick. There's always a program manager that helps you find the right time and has everyone ... sends the invitation to everyone, so it's not a burden to you as a company. And I would say it's really, really quick turnaround.

Chris Sasiela: Great, and Mo?

Mo Chen: Oh, yes, so regarding our experience with the SEED programs, so basically when we should start this, applying for the programs, the innovator-supporting program I think as early as possible.

So, when looking at our history in 2018, so a side of the company was awarded the first NIH Small Business grant, and by then, I didn't know the grant gave us access to so many resources until I received the email from SEED office regarding the business conference presentations sponsored by NIH. So, after receiving the email, I applied, and a few months later I was informed that I was selected to present at a BIO Convention in San Diego in 2020. So, then pandemic happen, and then ...

Chris Sasiela: Yeah, so it became the first digital BIO.

Mo Chen: Yes, it was the first digital BIO.

Chris Sasiela: The office had just formed back then, actually. That was our first BIO, also.

Mo Chen: Yeah, so our conference went virtual, and even the presentation was prerecorded. I still scheduled over forty eight one-on-one meetings, virtual meetings, with a lot of pharma [Indistinct] consulting firms. And again 2022, so when I attend the BIO Convention in person, so as opposed to pandemic, still I had a chance to follow up with the people I met online two years ago to present our progress, so it's a great experience. Yeah, so other than that, I want to mention the coaching program is fascinating and very inspiring. And unless that's changing, it's a great opportunity to learn how to present a company to impress general audience. Yeah.

So ... Yeah, so also getting to the TABA Needs Assessment to receive a comprehensive assessment on the market needs and technical-regulatory hurdle in 2021. In 2022, we also applied for TABA Consulting. With the help of SEED office, we drafted the scope of work, as I mentioned, so you have very good advisor team to provide other guidance how to assemble a scope of work for the TABA Consulting Services. And so, the project started in 2023 and working with NIH-contracted consulting firm, result over one hundred pages briefing package and then submitted the meeting request to FDA in July.

So, our meeting request was granted 2 weeks ago. Had a first regulatory meeting with FDA, so it's great experience. In the meeting, we presented the TDP, IND [Indistinct] Phase I clinical trial and had very productive discussion with FDA of clinical [Indistinct] and the regulatory pathway, so very helpful. So, the FDA official also gave us twenty five pages, very thoughtful, thorough comments on the product developing. Yeah, so ... Yeah, so that's our experience. A lot of things happened in the last five years.

Question and Answer Session

Chris Sasiela: What I'd like to do now is, first, I want to offer Ana and Mo the opportunity, if there's anything that you want to share that we haven't covered in these sort of planned questions, please do so. Other than that, I'm going to ask Stephanie to come back online, off mute and on-screen, and I am going to start running through some of these questions. We have quite a few of them in the Q and A box, but please continue to add more because we have some that I know are repeats. Okay. So, the

first thing, Stephanie, that I think it would be helpful to talk about is, how does the CRP review differ from a traditional SBIR/STTR review?

Stephanie Fertig: That's a great question, and I have been trying to answer some of those questions, particularly those that might not be ... that might be focused on some more general SBIR topics. I have been trying to make sure that those get answered in the Q and A, so I'll try to keep up with that, even though I'm now off mute and on camera again. We'll see how well I can multitask this afternoon. So, the CRP is reviewed differently from a standard Phase II or even a Phase IIB, and I would really encourage applicants to take a look at the review criteria and specifically the different questions that are under each of the review criteria.

So, if you'll note, the CRP does have significance, investigators, innovation, approach and environment, just like a standard NIH SBIR/STTR review, but the questions that are located under each of those individual review criteria different, because there's a recognition that the CRP is really going to be much later in the product-development pipeline than many of the other SBIRs and STTRs.

So, for example, if you look at that scored criteria, you'll see under significance, things like, to the extent appropriate for the maturity of this project, how compelling is the value proposition? To what extent does the application demonstrate a substantial market pull for the technology under development? How well has the applicant described market segments and customers in the product and technology? So, you could see these are very commercialization-focused questions, and so those are the kinds of things that the reviewers are going to ask. Great tip, and this is just in general, when you're looking at a program, when you're looking at a Notice of Funding Opportunity, we give you the questions in advance.

You have the questions beforehand. Take a look at those questions. These are the questions that we're telling the reviewers to ask themselves. So again, it's a much commercially focused. It's more a late-stage, and that's the nature of that review.

Chris Sasiela: Excellent. Thank you. And there's also a question about the timing of applying for different awards. So, you mentioned earlier that you cannot have a Phase II and a Phase IIB simultaneously, but can you apply for the Phase IIB while you are still finishing the work of your Phase II, to minimize that funding gap that might otherwise happen?

Stephanie Fertig: Absolutely. Really, and this is actually true of even going from your Phase I to Phase II, you can apply for that Phase II before you've completed your Phase I. You can apply for a Phase IIB before you've completed your Phase II. Just make sure that you're really able to show that you've made enough progress, so you should be far enough along that you can show that you met the goals of that other award and that you're ready to move on to the next section. So usually, individuals are

generally in their last year or on their last portion because then, they can show that they've really done the work. They've moved forward. They've been successful, and now, they're ready to go to the next step.

Chris Sasiela: Great. Thank you. So, Ana, there's a question here that I think you might be able to address, and the question is, "When you apply for a Diversity Supplement, first, do you need to apply on standard SBIR receipt dates, or is it a rolling submission? And about how long does it take for that request to be reviewed and for a decision to be made?"

Ana Moreno: Yes, so it is definitely a rolling submission. What we've done is that we have close contact with the NIH asking for feedback. "Does this make sense what we're trying to apply for?" We actually did get feedback on one of our applications that we needed more information in terms of the applicant and what they're thinking in five years. What are their goals? So that was really helpful. So that's ... It is rolling, and in terms of how fast, I have a really bad memory, but I would say ... Correct me if I'm wrong, I would say maybe a quarter. It was 3 months, maybe. I honestly ... I'm the worst in terms of memory.

Chris Sasiela: I think the answer to the timing is really something where you talk to your program officer and understand how they make those decisions because institute may have a different approach to when they make decisions about supplements.

Stephanie Fertig: I will state, though, that these are administrative supplements, so they're a little bit different from a standard NIH grant application. It doesn't have to go through that peer review process, and so oftentimes, there is some additional flexibility. And it's really encouraged, again, and I think you're going to hear this over and over again in this Q and A today, but reaching out to that program officer that's assigned to your application is really important. I did get a question in the chat about, "Well, wait a minute. What's the difference between a program officer and a small-business program manager, and how does all that work?"

So, your grant or your grant application has an assigned program officer, and you can find that program officer. If you look at your summary statement, they're going to be in that top, left-hand corner of your summary statement. You can also find that individual on your eRA Commons account, and they're going to be the assigned program officer. You can always reach out to your assigned program officer. Now each Institute and Center, in addition, also has a program manager that's a small-business program manager, who really helps coordinate the small-business programs for an individual Institute and Center. Now, sometimes those individuals are the same individuals that are assigned the small-business projects, so they might be your assigned program officer, project officer. They might not be. It's often helpful, and they really work in concert together. So, if they are different people, don't worry. NIH is a large place, but it's also a pretty small place. We all do know each other, and we do

work together as a team. And so, if you're not sure who to contact, it's not at all insulting to add the small-business program officer as a copy, but also, you can reach out. Always reach out to your program officer because even if ... As an ex-program officer, if I didn't know the answer, I knew who to ask, so I could get you that information that you needed. So, a great person to start with is your assigned program officer.

Chris Sasiela: Absolutely. NIH has 40,000 employees, and it's amazing how many of the ones that you interact with and you just know, or if you don't know, you know someone who knows. So please use the network that you have instant access to. There is another question I saw that seemed a policy-ish, and I wanted to ask Stephanie if she could address this. So, the question is, "Can I use my SBIR/STTR fee to pay for grant writing? So, let's say we hire a grant writer to write a Phase I or a Phase II, can we use the fee to pay the grant writer?" What can you use that fee for?

Stephanie Fertig: That's actually an even bigger question. What is that fee, and what can we use it for? So, so glad you're asking about the fee because I think as we're talking about different Technical and Business Assistance, one of the things that does come up is the seven-percent fee, and that's considered profit. So, the small-business grants, both SBIR and STTR, they're really different compared to the other grants in NIH in that they allow for this seven-percent fee, and that's profit for the company.

And there's a lot of flexibility with regards to what you can use that fee for. People use that fee for different technical assistance or business assistance they might need. You can use it for intellectual property. You can use it for doing some work that you didn't include in the grant. You can also use it to help with other company-based projects or company things, like helping write the next levels of GRACE. We really ... there isn't that ... There's a lot of restrictions. There's a lot of ... There are restrictions and requirements, not a lot, but there are restrictions and requirements with regards to what you can use your funding for, for a grant.

The fee doesn't have those, and so it's really unique. Now, obviously, I would always say in the federal government, it is better to ask for permission than ask for forgiveness, and I'm going to say that again because it's the exact opposite of what we normally think. It is better to ask for permission than ask for forgiveness. If you're not sure if you can do an activity, that's why you should ... something you can ask. You can ask, "Hey, is this something that's an allowable cost, either in my standard grant or with through technical or business assistance or through my fee?" And we're happy to help. I used to get those questions all the time as a program officer. Was happy to help out and was also happy to point where you can find that information for the future because, oftentimes, that's just as valuable when you're like, "Wait a minute. I remember this." So, you can find that information. I'm going to pop that into the chat here. You can find a lot of the information on what's allowable from a cost perspective versus what's not allowable in our instructions. I do know they are fairly lengthy, but part of the reason

they're lengthy is they have all the answers. So, I'm going to pop that into the chat as well as tell you what page that fee information is on, but you got to give me one second. So, Chris, I hope the next question is for the other panelists because I'm going to need a minute.

Chris Sasiela: Not a problem. Actually, I see that there are quite a few questions in the Q and A about the investor-event program, and so what I want to do is I'm just going to take a little bit of time and talk a bit more about that. So, some of the questions that have come across, basically come to me as, "Tell me more." So, the request cycles is always happen. So, when you have the request here button or link that will come in the slide desk when this is circulated, or that might already be posted in the meeting chat, you can go, and you can complete a request at any point in time. There is not a point during the year where you cannot submit. However, we only evaluate those companies that have requested participation twice a year. It is an extremely intensive process that takes all of those EIRs, plus myself and several project managers' time. So, we don't just do that on a rolling basis. A, it would be impossible to manage. B, it would not be fair because companies would be coming in, and we would not be able to match them effectively. It would lead to an imbalance.

What we do once we receive your request, is we divide up the companies amongst the EIRs, and we give them criteria that we have developed in collaboration with those event organizers. So, the matching criteria for the Angel Capital Association Summit of Investing is very different than the matching criteria for the Med Tech Conference or for BIO, right? There are things that come in, but level of investment that you are seeking, or are you seeking a partnership or networking instead of investment? How mature is your technology? What does your leadership team look like? Do you have a fully developed website? We're not going to send you to BIO without a website, usually, right? There are certain criteria that we work with the organizers, so we understand what their investor audience or their partners are looking for, and then each company that requests participation, we try to match you to as many of those possible because every year, I negotiate agreements with each of these organizations to send X number of companies to their events.

And sometimes I will send an email out ... Let's say I'm reaching out to Ana, and I'm saying, "Ana, I've got this great event. It's an ACA event. It is for founders of color. It's coming up in October." Real-life example, as it turns out. Ana comes back to me. She says, "Oh, wow, I've just been on this fundraising binge for the past 5 months. I don't have it in me. I need to spend dedicated time with my company and doing the work. Thank you so much for that opportunity. Please continue to consider me for other things. Right now, isn't a good time." This is a 2019-2020 sort of interaction that Ana and I had, whether she remembers it or not. That's perfectly fine. However, obviously moving forward, still great company, great CEO. She has gone to BIO, right, so when the timing was correct. So I need enough of a bench to be able to have those people who say now isn't a good time and then reach back and fill those slots. So, you don't get matched to just one event. You usually would get matched to multiple

events. It is also the case that quite a few companies that request participation may not get matched in a given cycle. Now, we match you to twelve months' worth of events. We don't just match you to the next six months. We match to a full year's worth of events, but there are companies where they just don't have enough of a development to ... of a developed product or leadership team to be attractive to an investor yet. Keep requesting participation. You and your company are going to grow. You're not making it one cycle doesn't mean you won't make it the next.

The time for you to find that out, typically, my intent is that within three months of the date that I tell you I'm going to make the cutoff and start that evaluation process, within three months you will know if you're a match to an event that's coming up in the next six months. And let's say that you apply in January, and I'm matching events through July at that point. I'm going to let you know by April whether you're going to BIO or not, but if you're not going to BIO, and you're going to the MedTech conference, which happens in September/October time frame, you'll get a letter saying you weren't matched to anything within the six-month time frame, but you're still being considered for the remainder of the year.

You don't need to reapply just because you didn't get matched in that six-month cycle, and sometimes it really is that plain. It's not the right technology type. I have BIO in June, but I have MedTech in October, right? I'm not sending an on-market device to BIO. I'm sending them to MedTech. So hopefully that answered a number of the questions about the investor-conference support. One more thing that I do want to clarify, when we support a company, what we support is their registration and, if possible, a presentation spot, right? Sometimes that comes with a kiosk. Sometimes it comes with a table. Sometimes it comes with a poster. Sometimes it is just you entering a room, right? Each event is a little bit different. What we do not support is your travel. That is something that you must find the money to support within your company, within your award. So although we will cover your registration and your speaking slot, and I do my best to negotiate speaking spots in every event where we support companies. I can't always do it, but it's 90 percent of the time there's a speaking slot if I'm offering you an opportunity.

So, you don't have to apply to speak. You already have the NIH badge of approval. You went through peer review. You have your award. We're going to coach you up, and you're going to get a speaking slot. So, it's not the competitive speaking slot consideration that you might have if you were coming in on your own trying to get to that event. Okay. Hopefully that gave Stephanie enough time to add that.

Stephanie Fertig: Plenty of time. It actually gave me enough time to answer a couple of questions as well as flag one I would love to answer live, because I think, Chris, it's a question that we get a lot, which is ... And this person was asking, "Well, wait a minute. Can you apply for a CRP you've requested TABA funding? I thought there was a rule where this wasn't allowed?" And so I really want to talk and take a minute about these different resources and how they do and how they may not conflict with

Technical and Business Assistance. So Technical and Business Assistance, or TABA, is a very specific program within the small-business programs here. So the Technical and Business Assistance, it allows companies to ask, as Chris noted, for up to $6,500 for a Phase I per year and up to $50,000 for a Phase II. Now, that's specifically for these Technical and Business Assistance programs, and if you don't ask for that funding, there are these centralized programs that you can take advantage of, Needs Assessment or, in some cases, as Chris noted, there is that ... Another centralized service around Consulting Services. All the other resources we're talking about here today are not ... do not fall under Technical and Business Assistance. CRP, Phase IIB, some of the great resources and experts that Chris talked about, none of that falls under Technical and Business Assistance.

So, if you've received Technical and Business Assistance funding, say through your grant, you still have the ability to come in and get a CRP, utilize some of those great resources that Chris was talking about. Ask and request to be part of a conference. You have all those opportunities available to you. What you can't do is, you're restricted with regards to the TABA centralized program, so things that are specifically labeled TABA, and we do try to label those. We try to put TABA in big caps just to try to make it as easy as possible. So the good news is, if you got Technical and Business Assistance funding in your Phase II, you can absolutely come in for a Phase IIB. You can come in for a CRP. You still have all of those resources and programs available to you.

Chris Sasiela: We have a few questions that have come in very specifically focused for Mo and Ana. I'm going to ask two of them at the same time, and either of you, please, both of you come off mute and feel free to respond. So, the first question is, did you apply for the NIH I-Corps, and that would have been during your Phase I award? And then secondly, did you apply for CRP in parallel to your Phase II or Phase IIB, or did you do that separately on a different receipt date, et cetera, et cetera?

Ana Moreno: So, I actually participated in the NSF I-Corps while I was in grad school, so I did not participate at the NIH level, and the CRP for me was really interesting because my program officer emailed me to send me the opportunity. And so again, keeping that relationship close with the program officer, I think, is really important because when these opportunities come to mind, they'll reach out to you, and it was a really exciting opportunity for us. So it was not concurrently, and it was, I would say, a year into our Phase II.

Mo Chen: Yeah, so for us, we applied for I-Corps. We, because of medical emergency of a key team member, so we have to jump it. So that's our experience with I-Corps, and regarding the CRP, we applied for the CRP a year after the Phase II grant was awarded, and so ... Yeah, so according to the application policies once a Phase II grant is awarded and [Indistinct] can start applying for the CRP program. That's my understanding. And also regarding ... So some more information regarding CRP. So when I go to my CRP grant application, I was a little bit confused because I used to write like a grant [Indistinct] hypothesis-driven, and asked the program officials like, "How can we draft something like a

hypothesis-driven CRP?" And then the program officials there instructed that a CRP doesn't need to be hypothesis-driven. It's more like as we discussed this, it's bridge money to drive the project out of the [Indistinct] so it's more technical, yes.

Chris Sasiela: And there is another question for the two of you which is, did you raise investments from private investors before your CRP award, and how important was third-party funding to the success of your CRP applications?

Ana Moreno: So, we have raised a little funding through angel investments. So for us, it was ... When we think about grants, there are certain aspects of the business, right, that are difficult to fund with grants, such as you can use a fee for IP, but IP is really expensive. It usually doesn't cover with the seven percent. So, we did raise ... a little capital before we applied for the CRP.

Mo Chen: Yeah, so we had a similar experience. So, we raised angel investment a while ago. So when we were awarded the Phase I grant, and the large quantity, with a large chunk of the private investment, it was used ... [Indistinct] public traded company, tech company and not about the tech company executives.

Chris Sasiela: So, I think Stephanie may want to also contribute to this question. I'm not going to read her mind [Indistinct].

Stephanie Fertig: Oh, no! I think this is ... It's extremely helpful to hear, and I think it's interesting. There was a question that I was going to type an answer to, but since I'm here. Somebody asked, "Wait a minute, is this a bridge to investment or a bridge to active marketing?" And my comment is, it depends on the project. I think one of the great benefits of the small business programs, these seed funds within NIH, is their flexibility. Not all projects are the same, so some individuals do really use this. They know they're going to need additional partnership and investment in order to bring their great innovation to market, while some projects, and admittedly maybe fewer than those that might need those partners or investors, but some can really utilize the Phase IIB and the CRP and get that far enough down the line that then they're able to transition either through a licensing agreement which is a partner, but really able to transition out and maybe even go to market, and we do have ...

We support everything from research tools to therapeutics, diagnostics, biologics, software. We support all sorts of different technologies. So there are some that can really utilize this to transition to market. It really depends on the specific needs of the program, and what's great is, there is that flexibility, and there are these different programs to help get you there.

Chris Sasiela: So, Stephanie, can you also talk about whether a match, an external investment, is a requirement for the CRP? Because it can be for the Phase IIB for some institutes but not for all and ... Sure.

Stephanie Fertig: So, it's never ... We don't require it, but it is strongly encouraged for some Institutes, and you can imagine strongly encouraged is strongly encouraged. For many Institutes, they really do want to see that matching funding for those companies that are trying to come in and do a Phase IIB, and they're utilizing that matching funding again to really show the commercial potential. They want to see because oftentimes that Phase IIB is really to help bridge that gap, and so they want to see that there's a commercial potential there.

Chris Sasiela: But that was ...

Stephanie Fertig: With regards ... Yeah, with regards to the CRP, you don't need to have that match. Again, that is not ... there's less of an emphasis there for the CRP, and one of the ... Again, one of the interesting components of the CRP is that it can run at the same time as your active Phase II or Phase IIB. It can really be a way to get, again, that ... It's meant to be a commercialization readiness program. So, it's there to help not just with research and development, although that's certainly part of the program and can be part of the program, but it's really also there to provide that technical assistance, and that technical assistance is a really important component.

And many individuals are ... Utilize the CRP to really focus on that business and commercialization and technical assistance and doing some of the things that are normally not allowable costs within a Phase II. So I would take a look at that list, and the Notice of Funding Opportunity has a great list of what the kinds of things that are allowed through the CRP. Take a look at that list, reach out to your program officer if there's some specific things you'd like to do, and you can talk with them about how best to proceed.

Chris Sasiela: Excellent. There is another question that I think you could probably answer pretty quickly. There is a CEO who recently received a Direct to Phase II award, and they are looking to apply for the CRP. Are those receipt dates the same as the traditional SBIR receipt dates, or are there different receipt dates?

Stephanie Fertig: Great question, and it's always a good idea ... And I love that people ask the questions about the receipt dates. So always a good idea to look at the Notice of Funding Opportunity. You can see the application due dates. Now, the good news for the CRP is it does follow the standard receipt dates. Standard receipt date, September 5th, January 5th, and April 5th every year.

Chris Sasiela: Or the first business day thereafter.

Stephanie Fertig: Or the first business day thereof. Particularly in the fall, there's a couple of ... There's a couple of holidays that sometimes catch us, and I always have to remember, "Wait a minute, next business day." But you shouldn't be waiting until the last minute to apply. Don't wait until the last minute to apply! Apply early!

Chris Sasiela: Give yourself a relaxing holiday weekend.

Stephanie Fertig: Please apply early only because, particularly for the CRP and the Phase IIB, they are applications. You do have to go through the NIH application process, and I always ... I'm going to use this opportunity to remind everyone to please make sure to go start the submission process early. It is a computer system. Things do happen. I saw Ana smiling. I think both Mo and Ana could talk about that it is not a trivial process to submit, and it's important to give yourself a little bit of extra time.

Ana Moreno: I'm laughing because I think that I've had an application that I submitted thirty minutes before deadline, super stressed, so don't do that. But, yeah, that's ...

Stephanie Fertig: So, see? This is a situation we could learn from others.

Ana Moreno: And it wasn't going through. That's why ... Yeah, so it was really stressful. Do it a day in advance at least.

Mo Chen: Yep, so had a similar experience. The last day is very stressful to submit a grant.

Chris Sasiela: Yeah, I think of the NIH application as your Wi-Fi at your house. If you have teenagers, and they like to play "Fortnite," and then you're trying to just get some emails out for work, and your emails are going, "Maybe someday we'll send, maybe there's just too much going on here." The NIH systems also tend to get a bit overloaded on the actual receipt date. So bandwidth becomes an issue. As much as we try to not have that be a challenge, it still is. There is a question about whether there are examples of CRP applications. I don't actually know the answer to that. I know for Phase I, Phase II, Phase IIB, but I don't know about CRP.

Stephanie Fertig: We don't, or at least I'm not aware of any specific examples for another Institute or Center. It can often be difficult, I have to say. We do really rely on the recipients to allow us to put up those sample applications, so I always like to give an extra thank-you to any recipient who allows us to put up their sample applications because I do know, again, it is something that they ... not everybody is comfortable doing. We completely understand that. For those who are willing, we're happy and more than thrilled that they're willing to do that. So unfortunately we don't have a CRP right now, and CRPs can vary significantly. They can even vary in size.

I have been seeing a couple of questions about, "Well, wait a minute, the CRP is only this big," or "The CRP amount reduced." Each individual institute and center sets their own CRP budget guidelines, and that's actually true across the board. Each individual Institute and Center can set their own budgetary guidelines. So it's important to reach out and talk with an Institute or Center, with your specifically assigned Institute or Center.

One of the other big questions that I have answered a couple of times now, so we might as well mention it here, there was a question of, "Wait a minute, if I've got my Phase II with one Institute and Center, can my CRP be with another?" So if you look at the CRP, you'll see the Institutes and Centers

generally say things like ... And I'm just going to pick on ... "This Institute or Center only accepts basically CRPs from their own Phase IIs." And that's because, again, that CRP can run at the same time as the Phase II. So it's going to be directly related to that project that was assigned to that Institute or Center. So some Institutes and Centers don't allow for Phase IIBs that are CRPs, but they have other ways that they provide support, particularly when you're talking about clinical trials. They have other ways that they provide that kind of support, and again as Chris was talking about, there are other ways that we can give you that support outside even a Phase IIb or a CRP. There are other ways that we can help you as you're again moving towards that ... moving towards the marketplace.

Chris Sasiela: And there is a question of timing in here. There is a question, "Can you apply for a Phase IIB after a CRP?"

Stephanie Fertig: You can! So it's interesting. Again, it's a little like, what makes the most sense for your project, right? So it is very much a situation where you can ... You have your Phase II. Then you can have a Phase IIB, and you can apply for the CRP at the same time of ... You can apply for it. You can have a Phase II and apply for a CRP at the same time and then realize, "Gosh, I need some additional research and development," and do a Phase IIB. You can do a Phase II, Phase IIB and then a CRP. You can do a CRP at the same time as a Phase IIB. There's a lot of flexibility here, and I think that's what great about it. It does mean that sometimes it's helpful to talk to your program officer to talk around, "What makes the most sense for what I'm trying to do?" Because it can be a little complicated.

I just want to second ... and I think we mentioned it a couple of times here, is signing up for updates, having ... Oftentimes people learn about some of these different resources and different programs because they look at our listserv. They look at our emails. I'm always surprised. We have a number of opportunities that cost nothing that are very low lifts to come in and take advantage of, and people don't do that, and I'm always surprised by that. So do make sure that if you receive an email from NIH, read that email. It might be important for your specific grant. There might be some issue that you do need to address, but in addition, it could be a great opportunity. It could be a brand-new program or resource that you can now take advantage of. So make sure that you're really reading those emails, at least give them a good solid skim to make sure, "Hey, is this something that I can really take advantage of?"

Chris Sasiela: Absolutely. There is a question that asks, do we have any examples of companies going to market using only SBIR grant money without needing private funding? And I know Stephanie will no doubt also have examples from her time when she was at NINDS. From my time, when I was at the National Heart, Lung, and Blood Institute, I actually at one point was contacting prior awardees to understand why they chose not to apply for a Phase II award. So these were people who had only come in, gotten Phase I money, and then we never heard from them again, and I was trying to understand. Were there technical issues? Were there knowledge gaps? And I spoke to at least one

company during that time who said, "Well, we got our money. We built our widget, and we sold it." So they didn't even need Phase II money, but obviously that would not be the case for a full therapeutic development program, right? This was a digital app, a digital solution, but, yeah, I certainly have examples like that in my history, Stephanie. How about yourself?

Stephanie Fertig: Well, I think a great example that utilized the CRP, we had a company that was developing a bicycle helmet, and they ended up utilizing ... They had a partnership they had started talking about. So I get this isn't investment. This is more on the partner side. They had a partnership. They had a situation where they had a potential license that they were working on with Trek bicycles. So again, it was a bicycle helmet, so they were working with Trek, well-known bicycle manufacturer, to get their technology into Trek bicycle helmets, and they realized one difficult thing in particular when we were talking about manufacturing. They needed to work on some of the manufacturing to make it really fit within the Trek process, within the price points as well as making sure that ... There's price points. There's how it's manufactured.

There's a lot of different pieces that go into taking something that maybe you were doing on a lab bench versus we're going to make a lot of them and sell them at Trek stores worldwide, right? That's a difference of scale. It's a difference of manufacturing, and they utilized the CRP to really help them with that, so that they could then use ... Instead of getting other investors to help them figure out that manufacturing, they were able to use the CRP program to help them figure out that manufacturing and then use that and then move on and do a license with Trek. And you can now get those helmets in Trek stores worldwide. So sometimes there is a combination, too.

I think it's okay to think about ... It's not an all or none. There's the beauty of, you can do both. You can have both sometimes, and sometimes both are needed. There are things that you really may need other investment or partners. I think it might just be investment. It could also be needing a partner or needing ... Who are you going to license to?

Chris Sasiela: So there are a number of questions in here asking about sample applications, so in addition to the one we had earlier about the CRP. What I often encourage people to do if they're looking for sample applications is, go to the Internet. Go into your favorite browser and say, sample NIH SBIR application. You can make it Phase I, Phase II, Phase IIB. You can make that search stream be whatever you want, and the reason that I encourage people to use that resource as opposed to providing a link is because there are multiple institutes and centers across NIH that have examples out there. So your project may be very well-aligned with the National Institute on Aging which has a series of examples, or it might be close to the National Institute on Allergy and Infectious Diseases, or the National Cancer Institute, and there are multiple examples out there. So please use the Internet. It is powerful, and search engines get better every day. So for sample applications, that is really an

excellent way to identify them.

Stephanie Fertig: And ... but we did on the SEED website ... and I did put that link in there. We have assembled the three Institutes and Centers that do have sample applications, so you can go Io that link, and you can see those three institutes and centers. Another option and just something to consider as you're writing your application ... And I did see a couple of individuals indicate, "Wait a minute, I've never done a Phase II before. I've never done a CRP before." So we do have resources. You can see those individuals that have received funding from the NIH, and you can reach out to individuals in your community, in your ecosystem. See those individuals who have been through the process before, ask for their tools and tips.

Always a great tip, have someone else read your application, particularly individuals who have been through it before. Ask them to give ... Use a big red pen, go to town. So really getting that other feedback from your network is really important. Don't be afraid, but this is another reason why you can't wait until the last minute because if you want somebody to read and give you input, you can't wait until the last minute. But I've often found that the small business community is very open to providing information, providing feedback to fellow colleagues. I think in part because they were there once, too, so everyone ... everybody knows what it's like to be ... To have gone through the process. Also, don't be afraid to reach out to your ecosystem and others in your community.

Ana Moreno: I would add that we've had the opportunity to be reviewers as well. So if you are asked to be a reviewer, I think it really gives you insight and understanding what reviewers are looking for and how to write a better grant. Our Diversity Supplement, we were asked to share that, so that's also available, I think, somewhere on the Internet, if you want to take a look at that. So ... and lastly, the small business ... SBA in San Diego actually, it's a free consultation. You can go in there with your application, and they can read it for you. So I'm sure not just San Diego, but other cities might have that opportunity as well.

Stephanie Fertig: And I'm going to put a couple of links again for some local resources. There are different organizations throughout the country that are supported from the Small Business Administration. The FAST Network helps SBIR/STTR applicants, so you can certainly connect up with that. So I'll pop that link into the chat as well. And then lastly, I would say not only should you say yes if you're asked to be a reviewer, but you can volunteer to be a reviewer so please do volunteer. You can reach out to the ... If you have gone through the review process, you know where you were assigned, that scientific review officer, they're looking for reviewers, right?

That is the backbone of the NIH process. Don't be afraid to reach out and say, "Hey, I'm willing to review. Here's my CV where I'm more than willing to help out." So I'm going to put that link to the FAST Network in the chat here. That's also a great resource that's more local.

Chris Sasiela: Excellent. We are getting close to time for our webinar. So what I'd like to do is, I'd like to note that there have been a number of questions posted that we have not had time to answer. Many of the ones that we have not addressed have related to specific challenges that you are having with your award. Perhaps you received FDA feedback, and there's been a pivot you need to make in the size of your clinical trial, or you have had challenges with personnel turnover or COVID interfered with your ability to complete your award. When that happens, the very first thing that you should do and the very first piece of advice that we should be providing, as well as the last piece of advice as we close out this webinar, is please reach out to your program officer. Talk to them, explain your situation. They are the people who are going to most intimately know what resources are and are not available to you at any point in time. Okay?

So, we started out with how to make the most out of your SBIR or STTR Phase II award. I certainly hope this hour and a half have been useful for you. I think we had some really great conversations. I want to thank Ana and Mo and Stephanie for joining me today and all of you. This has been a tremendous experience. I've really enjoyed our time together. I hope you have, too, and please be on the lookout. Sometime within the week you should receive an email with the link to the recording as well as the materials we've presented today. Thanks so much and have a wonderful remainder of your afternoon.

Mo Chen: Thank you.

Ana Moreno: Good luck.

Stephanie Fertig: Thank you.