SEEDing Biomedical Innovation: Supporting Entrepreneurs at NIH

Session Transcript: 2022-2023 Grants Conference

Matt McMahon: We're happy to have everyone joining us here today for this after-hours session. My -is Matt McMahon, and I'm the director of the SEED Office at the National Institutes of Health, and the SEED Office is basically NIH's commercialization acceleration unit. What we're trying to do is we're trying to help investigators that are supported by NIH convert more of their basic science discoveries into early-stage product development. So we're here to help people when they come up with those scientific discoveries, and they get the idea that perhaps they can be actually useful to people somehow. We want to help people find out how they can get started, what they need to do, and how that whole process works. So we've got a number of people from our team here to talk to you today about this. What we're going to do is... I'll just give you a little overview of how our office is set up and what we do, and then I'll tell you a little bit about the services that we provide for academic innovators. From there, I'll turn it over to Stephanie Fertig, and Stephanie is the lead of the small business programs, the SBIR and STTR programs across all of the Department of Health and Human Services. So Stephanie will talk to you about those small business programs and a little bit about diversity and product development support, and then from there, we're going to turn it over to Eric Padmore who's going to talk a little bit about product development programs and resources. He'll talk about entrepreneurial training and some of the other programs that we support, and then we'll have Chris Sasiela talk about some of the services that we provide for small businesses to help them be more successful in bringing their products and services through early stage development and out to people where they can see the benefit of these projects. So I told you a little bit about the SEED Office. We are sitting in the Office of the Director, so we're basically a trans-NIH coordinating office. So many of you are used to dealing with the individual institute or center that provides your funding, but the type of activities that we support and the services that we provide are spanning the NIH institutes and centers, so you can think of us as the one-stop shop for the types of things that we're going to be talking about today, and we can always point you to your colleagues and the people that you're going to want to be speaking to within your institute and center. So I said I was going to start out by talking a little bit about how we support academic innovators, and I expect, actually, that most of the people in the audience are probably academic innovators as opposed to representatives from small businesses. So I just wanted to start by telling you a little bit about the NIH Proof of Concept Network and how that works. So that program is designed to help academic innovators through those early stages of product validation and proof of concept work. So if you're sitting in your lab and you have an idea that you're discovering might be useful as a product, you need to do some initial studies just to test the idea that that could be feasible, and that type of funding is very difficult to obtain. So NIH supports a national network of proof of concept centers that contains over 80 institutions all around the country, and we'll put in the chat a link to this program. You can see it there. There's a map that shows you where these individual institutions are, and if you are at one of these institutions, I'm going to tell you a little bit about the services you can receive. So the proof of concept centers and hubs provide, first of all, funding for proof of concept or product validation studies. That's really important because that funding is pretty hard to come by, but the other things that are provided through those centers and hubs are an industry-style way of managing and supporting your projects. So those projects are managed and supported in a milestone-driven way. That's different from the normal R01 grant where you get your funding and you just go off and do your work. We really help the investigators to lay out a product development plan so that they can march through the steps that would be necessary for them to prove that their product is viable, and not only do we provide that, we provide feedback and guidance from industry-experienced experts, people who have worked in industry, people who have experience in the regulatory world or in the insurance payment world. So that program is really a great way to help people make that jump from doing basic science research in their laboratory to early-stage product development. So that's really the main way that we support those programs or we support those types of projects at NIH. There are many other translational and product development programs across NIH that live in the institutes and centers, and we encourage you to work with those program officers and those program staff to also take advantage of their programs and their services that they provide. In our office, we're also really trying to change the culture of academic innovation so that the types of early-stage product development work that we do is really valued within the academic environment, and I'll just mention there is a nationwide effort called Promotion and Tenure Innovation and Entrepreneurship, PTIE, and they have a website, ptie.org, and what that organization is trying to do with assistance and funding from the National Science Foundation is trying to get universities to modify their tenure and promotion guidelines so that product development work and innovation is valued just as much as publications and basic science progress. So that's a really important effort because it's a way to kind of change the incentive structure to really encourage people to take advantage of the types of services and programs that we support within SEED. So that's kind of a quick overview and introduction to the office and to the Proof of Concept Network, and I'm going to turn it over to Stephanie Fertig now to talk about the support for small businesses and small business program funding. Stephanie.

Stephanie Fertig: Thank you, Matt, and good evening, everyone. Great to see so many people have joined us today to learn about the different resources that we have to really support entrepreneurs and small businesses here at NIH. The NIH's America's SEED Fund, also known as SBIR and STTR, supports small businesses to take those great innovations that are within the lab and bring them to market to get them into the hands of the patients, clinicians, caregivers and researchers that need them. We provide over $1.2 billion in SEED funding for small business, and this is dedicated to small businesses. This is congressionally mandated to be specifically for small businesses to do the research and development they need to get those great innovations to marketplace. Now, the small business programs are some of the largest sources of early-stage SEED funding for small businesses that are developing life science product. Now, our programs here .. . There's two programs. You might have heard SBIR and STTR, so that's the Small Business Innovation Research and Small Business Technology Transfer programs. Those are two different programs, but their very similar, and in one the SBIR allows partnering with academic or nonprofit research institutions versus the STTR requires partnering, but regardless it always goes to the small business and that partner as a subaward. This is a great way, particularly the STTR, where academic, nonprofit research institutions can partner with small businesses to, again, get those innovations into the hands of the people that need them. I know we don't have slides. We're trying to leave plenty of time for questions, so I want to get a couple of tips out there because there's a lot of information out there about the small business programs. So first, there's more flexibility than you think. Get a lot of questions about what can come in, what stage things need to be at, and we're fairly flexible with regards to what we can support, and so I encourage you to reach out and talk to somebody about your project. Talk to one of our program officers, and in fact, if you take nothing from today, I hope you can take that we're here. We're approachable, and we really would like to speak with you about that great innovation. So talk to us. Talk to a program officer. We'll put a link into the chat to give a list of all the different program officers that each institute and center that's specifically there and coordinates the SBIR, STTR programs. If you're not sure who to talk to, you can always e-mail us at seedinfo@nih.gov. One of the other big tips I always beg people to do is start early, particularly if this is your first application and your first time having and being in a small business. It's really important to start that process early. There are a number of registrations that are required, and it can take some time to put together that first solid application. The majority of our applications come in through what we call the omnibus solicitations. Those are the general solicitation for an investigator-initiated applications. So even though we do have some specific funding opportunities, it's okay if we don't see one that specifically matches what you're doing. That's what that investigator- initiated omnibus is there for. And finally, the biggest tip I have is, it's important to realize that not everyone may get that SBIR or STTR on the first try. Most people do have to resubmit at least once, and so it's really important to take a look at the feedback that you receive, reach out to a program officer, and they can help guide you on what the next best steps are, and oftentimes that resubmission, and that's part of the process. So we really want to make sure that people are aware of the entire process, and you can find information about that process online on our website, seed.nih.gov. We're going to put some links in the chat about understanding SBIRs, understanding the SBIR process as well as a huge number of resources that are available on our web page that walk through how to apply, all the registrations that are required, annotated form set and even sample application, which are really helpful if you're trying to figure out exactly what that application should look like. Now, once a small business has and receives an SBIR or STTR, there are opportunities for them to receive an additional funding to support research and entrepreneurial experiences from individuals from diverse backgrounds, and they can do this through an administrative fund through our Diversity Supplement Program. So I would encourage you, if you are interested in having one of those entrepreneurial experiences, or you're a small businesses that has received SBIR or STTR funding, we're going to put a link in the chat, and I encourage you to take a look at our diversity supplement. It's a great way to get individuals that experience in being part of a small business both, again, with regards to research but also with regards to entrepreneurship. In addition to funding, we also provide different ways of supporting our awardees with product development, technical and business assistance. For many of our applicants and awardees, this is their first company, may not have been trained in business, may not have been trained in what it takes to bring something to market, but that's okay, and we've got a number of resources that can help. So one of the things that individuals can do, if you are aware and you already know that there's a specific technical and business assistance you need, maybe market research, intellectual property development, there's a number of options. You can ask for that as far as technical and business assistance funding within your application, and that is one option, and there are instructions on how to do that within the application instructions, and so I encourage you to read those, and again, you can always reach out to your program officer and ask for advice and help on how best to proceed, but in addition to asking for technical and business assistance funding, we have a number of other product development programs and resources, and so I'm going to now hand it over to Eric. Should be coming on shortly, and he's going to talk about some of the product development programs and resources for some of our Phase 1 SBIR or STTR awardees.

Eric Padmore: Thank you, Stephanie, and good evening, everybody, and thank you for joining us in this program. As Stephanie mentioned, I'm going to talk to you now about some of the programs that are specifically targeted to our Phase 1 SBIR awardees, and I want to start by talking about, again, referring back to our Technical and Business Assistance program, which we refer to by the acronym TABA, and the purpose of the TABA program is really to help you and your business identify and address your most pressing product development needs. Just by way of clarification, I want to point out that the TABA programs that we offer, and these are all listed again on our website under the Support for Small Businesses tab, is really kind of a three-legged stool. So we have the TABA funding, which Stephanie just referred to, which allows you or provides you, rather, funding in your grant to use your own vendors for those aspects of your technical and business assistance that you already know that you require, and that TABA funding is available for both Phase 1 and Phase 2 grants, and in a few moments you're going to hear from our colleague Chris Sasiela who's going to talk to you about the TABA Consulting Services, which is specifically targeted for Phase 2 awardees, and I'm going to talk to you now about TABA Needs Assessment, which is purely for Phase 1 awards. So those are sort of the three aspects of the overall TABA program that it's helpful to understand. So TABA Needs Assessment Program provides third-party unbiased assessment of areas that are critical to your success in the competitive marketplace, and again, these are for SBIR, STTR Phase 1 or Phase 1 fast track recipients that have had that in either a grant, cooperative agreement or a contract within the last 2 years, and that assessment is provided by a third-party contractor, RTI Innovation Advisors, and they help you to identify those most product development needs in four specific areas: the business model profitability, your market needs or competitive advantages, regulatory manufacturing or your clinical planning implementation and your intellectual property or other various entry. And then that assessment will allow you to understand the high priority steps you need to improve the commercial potential of your potential product. Again, going back to, and we're going to keep repeating this for the rest of the program, going to our website under that Support for Small Businesses tab, you will find a sample report that we ask you to review before making your requests so that you understand the structure and the scope of the program, and then there is a link there to request an assessment, and that link is open all year round. So unlike most programs or funding opportunities at NIH, which have fixed application or receipt dates, this is 24/7 ongoing process, and once you complete the request, we will give you some notification of the status of your request submission within 60 days, and it outlines the process there for .. . I'm going to speed through this just a little bit, but essentially what you need to know is that once you make a request, you will potentially get a phone interview with RTI within 60 days. Then they have 3 to 4 months to complete their assessment. They will send back a preliminary report which you and your business entity have about 10 business days to review and respond to accuracy if there are any issues there. RTI then has another 10 days to incorporate that feedback and then deliver the final needs assessment report, and the reason that I went through that is because many times people want to use that needs assessment and report to inform their Phase 2 application. So if that is what you're thinking about, you need to understand that development timeline in planning for your Phase 2 application. So again all of that is on our website, and Chris will talk to you about kind of the Phase 2 TABA consulting piece of that. I want to move on now very quickly to the other piece of our Phase 1 support, and that is around the I-Corps at NIH program, and that is an entrepreneurial immersion course for both NIH and select CDC-funded small businesses, and you can see which of the NIH institutes and CDC offices are participating in the I-Corps at NIH program, and that's all listed in PAR-22-073, which is the funding opportunity announcement for this program for 2023. And you can see a comprehensive list there of all the participating institutes, and the goals for this program are for your business to understand your knowledge or increase your knowledge and your understanding of market opportunities through in-depth interviews with your potential customers. So this is really about customer discovery and moving your team towards funding success, and customers is broadly defined, right? So in terms of perhaps an exit strategy, your reimbursement potential. It's really just understanding where the downmarket potential for your product is, and that happens through about 100 interviews that you're asked to do over the course of an 8-week program. It starts with a 3-day onboarding, and we're doing all of this virtual at present. In prior years, in the before times, as we used to like to refer to prior to COVID, it was an on-site meeting, but we've been doing it virtually for the past 2 to 3 years, and we will continue to do so virtually until things change. But you conduct those interviews, and then you have weekly webinar classes working with your cohort of 18 to 24 other teams and building relationships with those teams to help you understand the commercialization potential of your product. Just a quick note about the eligibility for I-Corps: This is restricted to active Phase 1 SBIR, STTR, grantees, and that active period must include the period of the particular cohort that you're applying for. So for example, today, actually, about 26 minutes ago was the closing of the application period for our next cohort of I-Corps participants, which will occur in May through June. It's that application deadline, just in case anybody is on the west coast, is usually closed at 5 o'clock your time, so if you're on the west coast you still got a couple of hours left, but it comes forward in, though, in an administrative supplement, which then pays for that education process and walks you through all those things, and again, there is an immense amount of detail on our website and in the funding announcement, which I believe probably got loaded into the chat as I was talking about it. So with that, let me pass it on to Chris who's going to talk to you about the TABA Consulting Services.

Chris Sasiela: As soon as I find that unmute button, absolutely. So what I'm going to talk to you about today is actually a number of things that are available for support. I will talk about the TABA Phase 2 program, and I'll start there since that was the cue in for me. So the Phase 2 program that we offer utilizes that $50,000 that Congress has enabled us to provide us support for our Phase 2 awardees, and it can provide what we call the TABA Consulting Services program. What it can provide is for a company access to a vendor who will give a deliverable at the end of an engagement of either an intellectual property assessment, a market analysis, a regulatory development plan, or a reimbursement landscape analysis, something along those lines, and we are going to drop a link to the details of the program right there. I see it just dropped into the chat. The way the program works is, there is a single cohort per year right now, and if you request participation in that, you will find out within about 2 months whether you have been accepted or not accepted into the program. If you are accepted into the program, you work with NIH people to develop a scope of work document that is then used to solicit multiple vendor proposals to meet your need. You will have the final say on how that scope of work looks. You will have the final say on which vendor you select, and once you have selected a vendor, then the contract is executed by our contractor, and service begins. Depending on the type of request you put in, service is typically complete somewhere between 3 months for a simple market analysis to up to a year for some longer-term regulatory filings, meeting requests, things of that nature that have external deadlines that are associated as waiting points within them. It is a competitive program. Not everyone who requests is accepted, but for those who do get in, what we've been hearing is that these are absolutely valuable services. The vendors are top quality. In addition to the TABA Consulting Services Program, there are other ways that you can access expertise through the SEED Office. One is that we have a team of experts, people who have subject matter expertise in business concepts and intellectual property, in regulatory and in reimbursement. Those may sound a little familiar right now because that's the same areas as the TABA Consulting Services Program. That's because those are really the areas where we have found our innovator community or entrepreneur community needs the most assistance. You guys are already super smart at the science. So the ad hoc consults are provided by this team of subject matter experts, people who have worked for Fortune 500 companies, worked at FDA or CMS or similar health care systems, and these are a really great way to get a sounding board as you are learning how to be an entrepreneur, as you are looking for your first investment, developing a term sheet, a pitch deck, trying to figure out the right studies to do or how to contact the right office at FDA, how much your technology can be worth at the end of the day based on current reimbursement costs that are published online, right? So the Ad Hoc Consult Program is a pretty quick program. Basically we complete all requests generally within 3 weeks. We strive for 2. And then there is one more program, which is sort of the end of the funding line, sort of, for NIH. You've heard about all the great money, the $1.2 billion that go into the small business programs, but each company and each project has a finite amount of that pie that they can take a bite of. So we recognize that it's really important for you as innovators to make connections with and engage with investors who will carry forward with you or partners who will codevelop with you, with codevelopers such as manufacturing organizations or testing organizations. So what we do to enable that is that twice a year we open a request for support to attend partnering and investing events, and our most recent cycle of closing the door on that until next time ended on January 20th. We're currently looking through all of the people who requested that program, and we're going to do our best to match as many of them as possible to events so that we can help you go out there and make those connections. It's not just the registration support. We pay for registration, presentation fees or kiosks as appropriate for the event. What we don't pay is your travel costs, but in addition to paying for that registration, your entry into the room, we also pair you with an entrepreneur in residence, one of these business experts that we have in SEED, and they'll really help you understand how to enter that room, how to enter that event and make the most of that opportunity. If you are successful in engaging with an investor or a partner and those conversations progress, you can come back and ask for a consult, and we'll go ahead and we'll help you understand how to take those next steps also. It's a very personalized process. This is not a cohort program. We work with .. . At this point this year I think we're aiming for a dozen different organizations and events. We send over 100 companies per year out to these events. So it's a very personal and hand-to-hand connection to help you get out there and be successful and move forward beyond the NIH funding that we can provide. Those are the three topics I really wanted to make sure you guys heard today. I'd like to invite Matt to come back into the room now and either close up the conversation or we can have some live Q and A.

Matt McMahon: Great. Thanks, Chris. Thanks, Eric, and thanks, Stephanie, for your comments, and I've been furiously typing away in the Q and A, and I see we've been doing a pretty good job of keeping up here with the questions. We're happy to take more questions. Feel free to type them into the chat. We also want to make sure that people know that they can reach out to us by going to our website. We're putting the contact information into the chat here. You can reach us from the website. You can also e-mail us, and we also have a pretty active social media presence on Twitter and LinkedIn. So you can get a pretty good idea of what we're up to and what's going on, including the places where you can come and meet up with us live at various conferences and meetings around the country by following us on LinkedIn and Twitter. So let's see what we've got in the .. . It looks like we're doing pretty good on the Q and A. Does anybody want to jump in and ask a question live? I think we can probably handle that.

Stephanie Fertig: Well, Matt, I'm going to jump in, and I noticed a couple of questions are in the chat about what is supported, and what specifically can we support through these small business programs? So, again, as I mentioned, there are .. . The small business program is a phased mechanism. So there's a Phase 1 that's feasibility, and Phase 2, which is full research and development. And those terms are vague, and that's great because one person's feasibility study is another individual's research and development, and so we really support a wide variety of modalities from everything from therapeutics to research tools to digital technology as well as things all along the product development pathway, proof of concept, that early-stage development of a prototype, all the way through to clinical trials. And so this idea of, is a specific item covered? This is why it's to important to reach out and talk with a program officer, and, again, we did put the program officer links in the chat, but if you're not sure which institute or center is the best fit, you can always reach out to us, seedinfo@nih.gov, and we're happy to .. . Provide us a brief description. We're happy to connect you to the most appropriate individual within NIH. So I know I've answered a couple of questions around, what's the best fit? And again, reach out and talk with a program officer. That's the best way to get that information. Talk with them about your specific situation, your specific collaboration, and they will be able to help best assist you. So I do see a question about medical versus veterinary science and health. I think we're really here .. . The mission of NIH is turning discoveries into health, and so our main goal is really trying to help those patients, clinicians and caregivers but also researchers, and this is where veterinary sciences can play a role. We have certain and have had situations where there have been specific technologies where the .. . instead of first in human, it may involve .. . The first individuals may be animal subjects, but I think it really depends again on that specific project. Now, our mission, though, is really focused on turning discoveries into health and trying to support the best ways to do that and the best ways .. . the best research and development necessary to take that innovation and get it to market for the patients and clinicians with a human population.

Eric Padmore: Stephanie, I was going to jump in here because I see a question about the Phase 1 award and how that is defined, and I think that the best answer to that question is that you really need to talk to a program officer at the institute or center where you're thinking about applying because that definition varies very widely depending on what type of technology you're talking about and the particular scientific area of application, and even within NIH, if, for example, you get a Fast Track award, it's not really intuitive in most cases to understand when you're transitioning from that Phase 1 or Phase 2. Sometimes it's not even easy for us to do it, so it's a very nuanced area, a situation to try and figure out. It's best not to try and figure that out yourself because you will drive yourself crazy. So again, talking to the program officials, and we have put those links into the chat, or contacting us at the SEED Office directly to help guide you through that analysis, if you will, is really your best way to do it. There's no pat answer for that.

Stephanie Fertig: And I'll just add that, again, we tend .. . The SBIR, STTR program tends to be much more focused on product development than hypothesis-driven research, and this is the difference between the SBIR, STTR program and, say, the standard R01 or R21 mechanism that NIH uses. The Phase 1 is really to do feasibility, and again, that could be building a prototype, but it could also be animal work, or it could be developing a model, or it even could be early-stage human clinical trials because that's what's necessary for that feasibility study for the Phase 2 full research and development. So we really see a wide variety of projects coming to us, and that's why, again, it's so important to reach out. Don't make those assumptions and say, "I do" .. . I've received a lot of questions, and a lot of people assume that they know what .. . how that Phase 1 is defined, but I would say, don't limit yourself. Reach out. Talk to a program officer and provide a brief description of what you're planning or you'd like to propose and go from there. Ah, the question about, can the Phase 1 .. . This was a question that just came in. Can a Phase 1 be used for secondary use of a commercial drug? Potentially. Potentially, and again, different individual institutes and centers or even for different disease areas, that may make sense from a commercial perspective, but for others it may not, or there may be reasons why the institute or center might be less excited about that, so if you are thinking that you've got a secondary use for a commercial drug, one of the big questions is around intellectual property. You'd have to talk a little bit about how you would prevent barriers to entry and prevent someone else from taking on that if it is in generic form, for example. So there's some business thoughts that need to be happening around any secondary use of a commercial drug. So that's something you may want to talk to a program officer about, and maybe the SBIR, STTR program isn't the best fit, but there are other programs as well. Here's the other thing, and I did answer this in one of the questions was, well, if you're a small business, can you apply to some of the other programs within NIH? And you certainly can. Businesses, both small businesses as well as businesses that wouldn't be considered eligible for the small business program, can be either applied to other programs at NIH. You should look at the eligibility. Oftentimes you can see that businesses are eligible to apply, or they can be collaborators with an academic or nonprofit research institution on different awards. However, the small business program, for those who are small businesses and are eligible, it's a congressionally mandated set aside just for small businesses, so we really do encourage you to take a look at at the program and see if it's a good fit for your project.

Matt McMahon: Great. Well, thank you, everyone, for joining us. We're at the end of our time. We're glad that we got a chance to answer lots of questions, but if there are any more questions, or if you got one in there at the last minute that you didn't get an answer to, please feel free to e-mail us or take a look at our website, and we're always happy to help people out. So thank you very much for attending the session, and we hope you enjoy the rest of the meeting.