Beyond Research: Building a Business

Session Transcript:
2021 HHS Small Business Program Conference: Diverse Perspectives SEEDing Impactful Innovations

Chris Sasiela: Welcome. Thanks for joining our session "Beyond Research: Building a Business." I'm Chris Sasiela, the Innovator Support Team Lead and Senior Regulatory Specialist in the Small business Education and Entrepreneurial Development Office. I'm the moderator of this session. What you're going to hear about in the next 45 minutes are the various resources and programs NIH has created to help you develop the business aspects of your company. Our panel members, in the order they present, are Robert Vinson, Small Business Program Manager with SEED, Michael Weingarten, Director of the National Cancer Institute SBIR Development Center, and Kwame Ulmer, Entrepreneur-in-Residence at NHLBI. If you have technical issues or would like to ask a question of the panel, please type it into the Q and A box on the right side of your screen. We're going to do our best to answer as many questions as possible, and we'll create an FAQ on many of these questions to share on this session page after the conference. If you need captioning, please use the link in the session description below. That will open a second window where you can see the ASL interpreter larger than on this screen. And finally, we want your feedback. Following the session please rate our session under the livestream box, and as the conference concludes, please complete the overall conference feedback form in the tab on your navigation bar. Thank you very much, and now let's get started with "Beyond Research: Building a Business." Rob?

Robert Vinson: Thank you, Chris. I'm Robert Vinson again from the SEED Office from the Office of the Director, NHLB .. . National Institutes of Health, excuse me. Next slide, please. All right. As part of a broader suite of resources, the SEED Office or NIH offers Technical and Business Assistance, and it's basically in two parts. You've got the first part that the TABA Needs Assessment, and then you also have the second part which is the TABA Funding Request. And TABA is just the acronym for Technical and Business Assistance. And as you can see it's in three sections. We divide it into education, funding and support, partnering and investment opportunities, and I'll talk about each of those divisions a little bit later on, but the important aspect of this slide is that you want to access this page or access this resource by going to sbir.nih.gov/ support-for-awardees. Next slide, please. Okay. The purpose of TABA is that the program is to help small businesses identify and address their most pressing product development needs. It helps the company to make better technical decisions, solve technical problems that are beyond the scope of the funded research and development and to minimize technical risk, and also to commercialize their product towards the end. Next slide, please. Under TABA funding, grantees may request TABA funding as part of their grant or as part of .. . or as a supplement. These costs cannot exceed $6,500 for Phase I per year and $50,000 additional funding per project period for Phase II award. It's important to understand that the institutes or centers can set individual budget and TABA guidelines. The projects that are awarded TABA funding cannot use centralized TABA programs, like the Needs Assessment program, for SBIR and STTR project phases. So it's important to understand that if you receive a supplement for your award under TABA, you cannot then change and get additional funding through the Needs Assessment through the centralized office. Next slide, please. Okay. A couple of guidelines that are very important to understand, what TABA .. . what you can and what you cannot .. . what TABA can and cannot support. The most important things are, as far as being able to support a subcontractor or consultants: assistance for product sales, intellectual property protection, market research and/or validation, development of regulatory plans, development of manufacturing plans and, of course, access to technical and business literature available through online databases. It's important to understand that funding from TABA you cannot .. . activities must be done by the recipient small business, affiliated investors, research and development subcontractors or consultants, contributions to the SBIR and STTR fee, activities outside the scope of the award, contingency costs or costs associated with the research and development and audit and bookkeeping services. Essentially your TABA funding must be something that is not within the original scope of the award, okay? Next slide, please. Okay, and under Needs Assessment and this is where you have access to the award or access to TABA funding through the process of having .. . applying for a Needs Assessment that's done by our vendor, which is Vikriti. And the Needs Assessment help businesses identify and address their most pressing product development needs, things like summary analysis for a company .. . summary analysis, company summary, target market attractiveness, technology and market needs, regulatory and clinical, business model profitability and so on. Other things like funding status, strategic partners - these are all things that the report would help you identify. And as of yesterday's date, we currently have 132 companies participating since we launched the program in November of 2020. It's important to understand that this validates the request for TABA funding and helps company write a strong Phase II commercialization plan. Next slide, please. Okay. Eligibility, it's very simple. SBIR and STTR recipients, grants or contracts, must have an active NIH Phase I or Phase II and within the last 2 years from the completion of the NIH Phase I, okay? So essentially you've got 2 years since the award has .. . the project period ended. If you have .. . And it's important to note if you've had a Niche Assessment or TABA funding in a Phase I, you are not going to be eligible. The Niche Assessment Program was a program that provided technical assistance that we had several year.. . Well, it sunsetted last year, but it was a program to help Phase I awardees over the last 15 years that the project was in place. And also participation in other support programs, as in the I-Corps program or the C3i program, does not make the company ineligible, and these are programs that provide additional assistance, but we will not disqualify an individual or make someone ineligible because they're participated in I-Corps or C3i, okay? Next slide, please. Something that's real important and a big distinction from previous Commercialization Accelerator Program and the Niche Assessment Program is that the TABA program is open year-round, okay, and to receive a TABA .. . a Needs Assessment report, this is the link that's listed below where you can access and fill out a registration to receive a Needs Assessment. All requests are reviewed, and they're reviewed monthly. Notification of your status with 60 days of submission and a report is to be completed with the 2 to 3 month range, depending on the availability of the company to schedule their interviews, okay? Next slide, please. All right, and with that, I'd like to pass it off to Dr. Michael Weingarten, and he will talk more about the I-Corps program.

Michael Weingarten: Thanks very much, Rob. I appreciate it. Hi. My name is Michael Weingarten. I'm the director of the SBIR Development Center at the National Cancer Institute, and I'm just going to take a couple minutes to talk about a program that we manage for the NIH. It's called Innovation Corps or I-Corps and how it's open to Phase I companies, both SBIR and STTR to apply. Next slide, please. So what's really interesting about the I-Corps program is it's an opportunity for you, soon after you get your Phase I award, to go through a program that really provides .. . It's an entrepreneurial immersion course, and by that I mean it teaches you as a small business how to build a business model around the technology that you're developing. And what's really different about I-Corps is it focuses on what we call a Business Model Canvas. I'm going to give you an overview of that in just a minute, but it really focuses on having you and your team members, team of three people, reach out to customers over the course of an 8-week program to really define the greatest market opportunity for your technology and where your technology can have the greatest patient impact overall. So teams are expected to actually go out and meet with either customers or stakeholders that are experts in the area that you're developing your technology in. You conduct 100 different interviews over 8 weeks, and by doing that, you're really doing your own market research to really define the market for your technology. Next slide, please. So really interesting to look at what are some of the key start-up mistakes that companies run into. Number one .. . The number one mistake is that a company or a start-up builds a product that nobody wants. So I-Corps is really geared toward addressing that. Next slide, please. So this is the organizing principle behind the I-Corps program called the Business Model Canvas, and it's geared .. . It has nine different components to the Canvas, but number one, you really need to identify what your value proposition is. Which customer needs are you helping to satisfy, and what is the specific product or service that you're going to develop to meet an unmet need in that area? So the very first part of the I-Corps program is really identifying what your key value proposition is, and then you go for that to the other key components of the Business Model Canvas, which are understanding what the key customer segments are. Who are your customers? Does your value proposition match their needs? What are the correct channels for reaching those customers? And then you spend a lot of time also through the course actually looking at what is your revenue model, and what are your cost structure? How much is it going to actually cost you to develop the technology that you're innovating and get it all the way through FDA approval into a commercial product? And also key partners. Who are some of the key partners that you could be working with that would be ideal partners for you as you move your technology through development and towards commercialization? You also start thinking about your regulatory strategy and your reimbursement strategy. So you can see, the Business Model Canvas really covers a lot of the key components for your company and what you're ultimately going to need to be successful. And the way that we structure the program, we actually have domain experts in the areas of therapeutics, devices, diagnostics and digital health who can help guide you on your journey as you're going through the program. Next slide, please. So Business Model Canvas, what we do for every team when you're going through the program is we actually do a survey at the beginning and after the program is over. And as you can see, most of the teams coming into I-Corps actually don't have a lot of background and knowledge in areas like value propositions and cost structure, who your key customer segments might be, but by the time they get through the program, they actually feel very comfortable. And I-Corps really sets you up to apply for your next award, but also it impacts your strategy overall as you move forward with your company, your overall strategy going forward. Next slide, please. So just one example of a company that went through I-Corps, a company called Medable. Medable was able to validate areas of unmet need that they should focus on by going out and doing their customer discovery work. They were actually able to identify more than four new commercial applications of their technology, and that work has actually enabled Medable to actually launch a new product which is called TeleVisit. And that's a mobile app that actually enables clinical trial research to progress even in a social distance setting like we're dealing with right now with COVID. It also helped them raise $91 million in Series C funding, because by doing customer discovery, they were able to help identify potential funders for the commercialization of their technology. Next slide, please. So I-Corps is one program that we offer across the NIH. At NCI we also offer a series of other programs that are available to our companies that we fund. Those include I-Corps, obviously, but we also offer an Investor Initiatives program where we help connect companies that are receiving funding from us with other private investors of both VCs and strategics like large pharmaceutical companies. We also offer a mentoring program that we call our CEO Roundtable where we pull peers of SBIR companies together to almost serve as an informal scientific and business advisory board. And then finally we offer a program called CARE where we help connect our awardees with the FDA to help them start thinking about their regulatory strategies. So if you're interested in learning more about those programs, I encourage you to go our website at sbir.cancer.gov, and it gives you information to all these different programs. Next slide, please. Finally, another new program that we launched at the NCI this past year, we called our Small Business Transition Grant. And what the Small Business Transition Grant really provides is an opportunity for a postdoc that's been developing a technology at a university, has created some valuable intellectual property around that technology and has decided they want to make the transition of moving that technology to a small business and developing that technology for patients. So the way the Small Business Transition Grant is structured, you apply for a Fast-Track grant. The Phase I part of the grant is actually going to be a STTR, so that the postdoc can receive the grant while they're still at the university and conduct research while they're in a university setting. One of the key components that really adds value to the Small Business Transition Grant is they're required to provide a mentoring plan where they actually have a technical mentor as well as a business mentor to really help facilitate and advise them on the development of their technology, and those mentors actually stay with the postdoc through the entire award. By the time they transition to the Phase II portion of a Small Business Transition Grant, they're supposed to have moved to a small business, and that really helps, again, with the transition as postdocs need the additional training and mentoring to be able to move that technology forward. Next slide, please. So again, if you're interested in getting more information about our program at the NCI, I encourage you go to sbir.cancer.gov, and happy to answer any questions in a few minutes. Thank you.

Kwame Ulmer: Thanks. It's a pleasure to be with you and speak with you for a few moments about the work we do at the National Heart, Lung and Blood Institute. I'm Kwame Ulmer. I'm an Entrepreneur-in-Residence and part of the team in the Innovation Office, and I'll spend some time discussing what we do to support NHLBI's mission. Next slide. Well, we are focused on providing and advancing research, training and education for technologies in the heart, lung, blood and sleep specialties. And our particular focus in the Innovation Office is to operationalize programs in each of those three areas to provide not just capital, but services to close gaps for innovators coming out of university with a prototype, potentially the pre-prototype and help them move along in their journey and develop a product that can get to patients. So I'm going to be spending some moments talking about what we do to advance translational research. Next slide. There's a really a continuum support, akin to what you've heard from other offices, with a few programs that may be new for you. One that I'll spend some time talking about is Catalyze, which focuses on extremely early stage entities, companies that are building a prototype or finding a prototype and what we do to help them move along in their journey. A little bit further along you heard about services like the program for TABA funding after you've received SBIR funding, and we focus also on products and companies that are somewhere in the middle gearing up for their first SBIR application. We support the Application Assistance Program. We review for commercialization potential, diversity supplements which is an additional source of capital, to hire staff from underrepresented groups to augment your company. So the main point of this slide is to communicate that we're with you at various points in your journey, from extremely early to even supporting commercialization. Next slide. So I'll talk a bit about some discrete programs we have within our Office of Innovation, and one is that we have a suite of experts that provide regular feedback to SBIR-funded companies in areas such as regulatory strategy, intellectual property and business development. And we have a network of mentors that, on demand, provide volunteer mentoring services to companies that are funded by NHLBI. We also spend a fair amount of time coaching companies to get their content and presentation at various top-tier conferences ready to attract funding from investors or other potential partners, from strategics to even potential angel investors and family offices. And there's also a video library for 101-type tutorials and educational content for early innovators. We also, in terms of education, will host webinars for companies focused on the heart, lung, blood and sleep space. Next slide. So this is one of the programs for folks early on in their journey that I talked about. It's Catalyze. It's a nationwide program that provides not only funding, but also support services to help a company build out a prototype, refine a prototype, validate or further verify a prototype, perhaps even characterize it with animal data. It is funding upwards of $300,000 to really get that innovator firmly at a university and building a prototype to which they could move onto the next meaningful milestone, typically pre-FDA. Another interesting aspect of the funding and the program is it's geared towards seeking nonfederal matching dollars, so you have that amplifying effect for your business as you're starting out. We support this by helping the companies think through very improvised services and various elements shown in this graphic. Next slide. So this is the innovation cadre of Entrepreneurs-in-Residence who support a lot of the programs that I discussed, from the Application Assistance Program to business coaching for the showcase to review of the commercialization potential for various SBIR applications. I am focused on regulatory strategy for early-stage companies, talking them through issues around when they might contact the FDA, what type of engagement they would want with the FDA and what are meaningful outcomes for engaging with the FDA. Steve Flaim is a Investor-in-Residence, so he advises companies on how to position their companies for financial backing, whether it be from an angel investor, an institutional investor, a family office, a strategic. He has deep expertise in that arena and gives thoughtful feedback on multiple occasions, as many sessions that are warranted, to get a company investor ready. Luis Gutierrez focuses on reimbursement, but also gives deep insights and feedback on commercialization of a business, leveraging his experience with running successful health care business. Gautam Prakash helps the company think through what makes for a strong IP portfolio, and he splits his time between the Patent Office and work with NHLBI. And last but not least, Renee Arnold leverages years of experience in actually founding a society focused on health economics outcomes to help companies clearly and effectively articulate the value proposition for potential payers. Next slide. I am so happy to have been able to spend some time talking about what we do at NHLBI, the National Health, Lung and Blood Institute, and I will turn it over to Chris for further comments.

Chris Sasiela: Thanks, Kwame. So as you've heard throughout this session and the conference overall, NIH not only wants to fund excellent and innovative science with its Small Business Program, but we've also created lots of resources and programs with the goal of helping you get some of that funding and grow as a young business. So what I'm going to do in the next couple of slides is cover a few additional programs. What I would like to do is start with some of the online resources that we have available. So as you can see on this slide, we .. . I don't know about you, but I really hate looking at a blank page, right? Several of the institutes and centers at NIH have posted redacted applications on their websites. You can use these applications to understand how to organize your thoughts, present your research and in many cases even see the comments that these applicants received from peer reviewers based on how they presented their research. You can also learn about the peer review process itself by viewing videos that were created by the Center for Scientific Review or by viewing the mock peer review panel posted within this conference or rewatching the Demyth-defying Review session that was presented yesterday. Next slide, please. There are also a wide range of online videos and some upcoming webinars where you can learn some of the fundamentals of being a business, from developing an intellectual property portfolio or target product profile to understanding what it costs to run a business and how to pitch your company to investors. The institutes at NIH have created content they hope will start you on the road to being not only a successful scientist but also a successful business. After all, our ROI is improving the health of the nation, and that can only happen if companies like yours have the resources both monetary and knowledge based to get your innovations to market. Next slide, please. Money! Yes. You've heard about the diversity supplement a few times during the conference, and here it is again. The diversity supplement is a way that small businesses funded by one of the institutes or centers noted here have the opportunity to request additional funding to support employees from groups that are underrepresented in the health-related research fields, or employees who have become disabled and are in need of accommodation to complete their work on a given project. One way that NIH has made the diversity supplement a bit more palatable for small businesses is by decreasing the required time remaining on an award from 1 year, as is for most funding mechanisms, to 6 months for small business awards. This enables even Phase I awardees to take advantage of this opportunity. Next slide, please. Just a few moments ago you heard Michael talk about the I-Corps program, and the I-Corps program is open to awardees from multiple institutes across NIH, but there is a second and very similar customer discovery program that is open not just to multiple institutes but also to some academic, as well as small business awardees. And that program is called C3i which stands for Concept to Clinic Commercializing Innovation. This program is focused on the development primarily of medical devices, whereas the I-Corps program is applicable to both drugs and devices. Next slide, please and finally the SEED Innovators Support Team, my personal favorite. Our team of subject-matter experts is available to consult with NIH awardees on a wide variety of nonscientific topics, things like understanding if, how and where your product may be regulated, understanding these strange little things called HCPCS codes or DRG codes or CPT codes, how to recruit an advisory board, talking to investors, and so much more. I know every time I sit in on a consult, I learn from the team, and I know if you join our family of companies, you will too. So at this point we are at the end of the slideshow, and we're ready to answer your questions. So I know that quite a few have come in, and what I'd like to do at this point is have my panel join me, and I'm going to just kind of go one by one. We don't have a whole lot of time, but we have about 10 minutes, so I'm hoping we can get maybe two questions per person in. So I'm going to start with Rob. One of the questions that's come in is, "Does the request for a Needs Assessment Report need to be for the specific Phase I project that was awarded, or can the Needs Assessment Report be for a different project where there is a need that the company is more curious about?"

Robert Vinson: That's a good question, Chris. The Needs Assessment Reports should be conducted on the application or the grant that was associated with that company. So if you come in and receive or request a Needs Assessment Report, it should be, and must be on that particular award that you were funded. Now, there are some cases where you decide to come in or are granted a Needs Assessment, and you realize that hey, maybe we would be .. . It would be a better or better fit if we looked at another application within that company, but that can be discussed at that time.

Chris Sasiela: Thanks, Rob. Michael, there is a question about .. . It's about I-Corps. It's a very popular topic. So I'm going to kind of group them together. Hopefully you can hit them all up at the same time. The first is, "Is I-Corps only for Phase I awardees?" The second is, "Is it only for NCI-funded companies?" And the third question is, "NSF requires this program of the I-Corps. Is it a required part of the NIH program to go through I-Corps in order to to apply for Phase II or .. . award?"

Michael Weingarten: Thanks, Chris. So let me try to address those in order. So yes, the program is .. . It's open to Phase I companies. That's the audience that is eligible to apply. There are 24 institutes that are now participating in the program, so most of the institutes across NIH participate in the program. It is not a requirement for every company to go through the I-Corps program. I guess we see it as an opportunity to really help better target the technology that you're developing in terms of what are the right market that you should be focused on where your technology can have the greatest impact, and is there an interest and a need for that technology among the stakeholders and the customers that you would be going after. So I-Corps actually gives .. . It provides a supplement of funding to your company to pay for the course, and it actually provides some funding so that you can put the time into doing customer discovery in order to really help hone in your overall business strategy for the company going forward.

Chris Sasiela: Thanks, Michael. Kwame, a question came in while you were talking about how might one of the participants of this conference get exposure to the EIR team at NHLBI? Are they able to get some of that advice and exposure as they're preparing their proposals?

Kwame Ulmer: Thanks, Chris. I think the best way as they're thinking about preparing their proposal is to enter into the Application Assistance Program, which is specifically designed to help you get ready for and have a complete and less error-prone SBIR application. And generally, we interact with innovators after they've received some level of funding. So the best path, I think, to ensure funding and interacting with us is to go through the AAP. Yep.

Chris Sasiela: Okay, great answer. Thank you very much. I'm going to circle back to Rob. We still have a few moments here. So there's a question about TABA, and it's phrased interestingly, so I'm going to be very specific in how I read it. "If we think we will want help from TABA," and I'm not sure if help is referring to if they want to receive a Needs Assessment, or if they want to request TABA funding, "Should we include that in the budget submitted with our application?" I think it might be useful to talk about whether someone could do both.

Robert Vinson: Okay. Essentially if a grantee or an applicant is thinking about receiving TABA funding, my first suggestion would be they speak with their program official, program officer, because you can receive TABA funding in your application or in your budget, but then you will not be able to get a Needs Assessment for that same grant application. Okay? So, and it's going to depend on how far along you are and whether or not you want to .. . Because you can receive TABA funding for Phase I, and then later on for your Phase II you can get a Needs Assessment, okay? So either way my best suggestion is to discuss that with your program official, because you don't want to shortchange yourself, and you want to take advantage of either program that's going to be best suited for your company.

Chris Sasiela: Great. Thank you very much, Rob. Michael, question number two, "All of the questions that you listed on that summary slide, the Roundtable, the CARE, et cetera, are they available only post-award, or are some open to companies that are looking to apply for Phase I funding?"

Michael Weingarten: Yes. So the program that is open to everybody is the Applicant Assistance Program. It's open to everyone who has not received an NIH SBIR award before. So Applicant Assistance Program is open to non-awardees who meet that requirement. The other programs that I mentioned, those are targeted at companies that have received funding from the NCI.

Chris Sasiela: So I'd like to dig into that just a little bit, Michael. I know some of the things that you talked about such as the PLAN webinar series, that is sort of more broadly .. . Parts of that are more broadly available. So I know in my presentation I included a variety of online resources and webinar series and things that are obviously available. How would someone find out about prior events that they might be able to gain from the knowledge that NCI has put out into the public realm?

Michael Weingarten: Sure. So one of the things that we, and I'm sure everyone that's part of this panel does, is we are all very active in doing outreach to the community to engage with either academic teams that are thinking of forming a company or to companies themselves. So at the NCI, if you want to find out some of our .. . the events that you could join in, and we're doing all those through webinars right now, I encourage you to go our website at sbir.cancer.gov, and we list all of our upcoming events, and we put on events where we'll give advice and tips on how to write stronger applications, as an example. And then also provide more information on some of the programs that I talked about today. And then there's also the opportunity to sign up for one-on-one meetings with us where we'll talk to you about your specific technology idea and give you some feedback on it. So best opportunity, well, during the conference this week, obviously you can use the conference platform to sign up for one-on-one meetings, and all of our folks are available for those. If it's outside the conference, then you can request a one-on-one meeting through our website at sbir.cancer.gov.

Chris Sasiela: Thanks, Michael, and, Kwame, we have a question that came in about Catalyze. "Is Catalyze restricted to small businesses, or is that something that's available to either people who are pre-award or may still be academic or postdocs? What are the parameters of the Catalyze program?"

Kwame Ulmer: It's open, and the funding sources on the website, if you look at it, do not have restrictions around whether you're coming from academia or need to have formed a business. It's really focused on trying to help you with a really good idea, get that prototype refined, and awards are up to $300,000 in addition to the services that I mentioned before.

Chris Sasiela: Okay, great, and then we have one final question that came in that I am going to tackle, and the question is, "Are you eligible for Technical Assistance .. . the Technical Assistance component in a CRP if you had TABA in Phase II?" So first let me say the CRP is the Commercialization Readiness Program, and it is not something where you .. . You cannot request TABA as part of the CRP. It is not allowed. It's a different type of funding, but you can certainly get .. . include in your TABA application whatever is appropriate to the .. . Or, I'm sorry, in your CRP application whichever type of assistance it is you are looking for. So there are two CRP applications. One is a smaller dollar amount for more technical assistance, and one is a larger amount for more of a manufacturing, scale-up IND-enabling study type of assistance. So you can ask for assistance in those ways, but TABA is not part of that, and if you have requested and received TABA in your Phase II award, that does not exclude you from applying for CRP funding. And we are now running up against the end of our session. We do have a few more questions. We'll do our best to answer those in the description after the session is over. I'd like to thank you for joining us today. We hope you found this session to be extremely useful. And if you have additional questions, please take the opportunity to meet with a Small Business Program expert for a 15-minute appointment this week. All those one-on-ones can be scheduled by visiting the HHS and NIH hub on the conference site. If you have any questions at all while you're doing that, please click the information tab to get help, and thank you so much for joining us this afternoon.