Phase I Commercialization Support: I-Corps at NIH and TABA Needs Assessment Programs Webinar – January 2023

Eric Padmore: Good afternoon, and welcome to the Phase I Commercialization Support webinar for I-Corps at NIH, and our Technical and Business Assistance Needs Assessment program. My name is Eric Padmore, and I am the Program Director for I-Corps at NIH, and we will be joined this afternoon by my colleague, Stephanie Fertig, who is the Health and Human Services Small Business Program Lead.

Just as a matter of housekeeping, I ask that if you do have questions, and we'll be addressing those questions at the end of this webinar, please enter them into the Q and A, which you will see is part of your screen, and we will address those once we get through our slide presentation. And as always, we'd like to direct you to our Small Business Program website, which is at seed.nih.gov. And we're going to go through the specifics of the resources available to our Phase I SBIR and STTR awardees, but there are a number of other resources that you will find on this website, including the information that we're about to share with you this afternoon, and depending on your status, you can see those three boxes at the bottom of the screen, which will contain a plethora of information about those support services that we do offer.

So, to jump right in, we're going to start talking about the I-Corps program at NIH, which is a Phase I SBIR supplement. And we will define those terms for you in a minute. But just to let you know that you can always find all the information about this program through the Funding Opportunity Announcement -- that is the FOA -- which is PAR-22-073, which you see at the top of the screen. And the easiest way to get to that is simply to enter that into any search engine, and it will pop right up. And in that FOA contains all of the dates, which are also included in the notice that you see below. But for purposes of our discussion this afternoon, we want to highlight that the application deadline for the next cohort is February 1st at 5:00 p.m., in your local time. So please make a note of that if your intention is to try and get into our cohort for 2023. And again, the contact email for any questions, you can email us at icorps@mail.nih.gov.

So, jumping right in, the question comes up, what is I-Corps at NIH. And let me start by saying, our mission really is to empower entrepreneurs in developing and validating your strategic business model through a diverse customary discovery process, in order to meet unmet clinical needs. So, our goal here is to enable and accelerate the transformation of your inventions and innovations to impact public health and, quite frankly, to improve the odds of success for your small businesses. We know that the biggest reason for failure of startups in the healthcare sector within five years is a lack of customers. So, the customer identification process, we understand, is crucial to your ongoing success and the success of your technologies.

So how will I-Corps help people who participate in the program? And specifically, it's around the definition of your value proposition, helping you to assess and understand your intellectual property and regulatory risk, as I said before to understand your core customers, and in addition, really identify potential partnerships with customers or purchasers. And finally, identifying financing vehicles, or in some cases, exit strategies that ultimately are going to lead to the commercialization of your product.

Who is eligible? And we're going to spend a little time on this, but the eligibility is restricted to those who currently have a Phase I SBIR/STTR grant from the participating ICs of NIH, and I'll say that those, most of the comprehensive list is at the beginning of the FOA that I spoke about earlier, and of certain offices within the Centers of Disease Control, which are also listed on the FOA. Also, Phase I components of the Fast Track awards -- of our Fast Track awards, I should say -- are also eligible.

Phase II, Direct-To-Phase II or Phase II component of Fast Track is not eligible, and if you're unclear of your status, whether you're in Phase I or Phase II, the best way to sort that out, it is not always immediately obvious, please contact your Program Officer, and they will help you to be able to identify whether or not you're eligible for this program as a Phase I. Contractors, as opposed to grantees at the NIH must apply through their acquisition offices and get a modification of their existing contract. But that happens after the selection process, so the Contracting Officer will be your point of contact initially.

The program requirements, and we entertain a lot of questions on this, is really putting together three-member teams who consist of a C-level officer, so that's either the CEO, COO, Chief Financial Officer, or anybody in the C-Suite, a technical lead, who's normally the PI on the Phase I award, but as we'll talk about in a moment, can be substituted for others, and an industry expert, which is normally an individual with prior business development expertise in the target area of your technology.

In terms of the flexibility of how you fill those roles, what you see on this screen here is an example where the PI on the grant may actually be serving also as the CEO of the startup, so the person we have listed here is Sue Scientist, who, her role category initially is the PI on the grant. But she also serves as the CEO, so in terms of her team role in I-Corps, she comes in as the C-level executive. A Co-Investigator, who we have listed here as Robin Researcher, then serves as the technical lead or the expert on the grant, and then the industry expert is an entrepreneur, Consultant, third party member, if you will, who they're bringing to that role. Again, that industry expert needs to be someone experienced with some proximity to the firm that can be serving either as a board member, or as an outside, third-party resource, like a consultant, but we're really looking for people who have prior experience in the development and commercialization of other products in your technology space.

So, the format for the program, which you can see there on the left of the slide, begins with a three-day kick-off event, six weekly web classes, and then a close-out, which consists of a two-day program of lessons learned, which you will essentially do a case presentation, a two-minute video, and then ten minutes lessons learned for the rest of your members in your cohort. Teams, to the best that we are able, are streamed into one of three tracks: a therapeutics track, a diagnostics tools track, and a medical devices track. In some cases, folks don't fit neatly into one box or another, in which case we do our best to sort of even out each of the three rooms, so that there is a relatively equal distribution. But the teaching teams within each of those tracks are known instructors who, themselves, are experts in one of those three domain areas. And as a side note, the curriculum, for those of you who may be familiar with I-Corps in other venues, whether it be universities or the National Science Foundation, our curriculum is specifically tailored to the life sciences. So those I-Corps Node Instructors will have a wealth of

expertise and information to share, depending on which of those three modalities you participate in.

In terms of expectations of your participation, I cannot stress enough that our expectation is, if you were to receive this supplemental award to participate in the I-Corps program, we are looking for 20 to 25 hours per week of each of the three members of your team to fully participate in the kick-off, the Wednesday webinars and the close-out, and that time is required in order to conduct the minimum of a hundred customer discovery interviews that we want you to do in order to meet the goals. So, we get a lot of questions about, well, can one of us be there, or only two of us there? The answer is, it is better that you are all committed and present to the extent humanly possible for the full duration of the program at that level of effort.

In terms of the budget, if you are selected for the program, each of your participating ICs will provide a $55,000 administrative supplement award, or in the case of contractors, a modification to the contract which includes $22,000 for the registration fees to pay for the course. So, the remaining $33,000 is then available for -- and it's up to you to budget personnel time for team members who are going to be involved, any travel or conference registrations directly related to the customer discovery efforts, and those meetings as noted on the slide here, should occur within the cohort dates of your participation. In some cases, membership to disease-specific foundations or societies, again, where you're going to be able to have direct interface and contact with potential customers around your technology, and licensing fees and indirect costs related to your efforts.

So that's a very general guideline for kind of the allowable costs that are part of the supplement, but again, once you're accepted into the program, you will work with the Grants Management Officers within the sponsoring ICs, and each of those ICs, in many cases, are going to have internal protocols or policies that will govern what they will deem you allowable to do or not to do. But that'll be clear once you go through that process.

So again, this is just a table of the cohort dates. Highlighted there at the top of Cohort 2, as you can see Cohort 1 is already closed, but that program will start to kick off within the second

week in March. Application due dates for Cohort 2 are February 1st, and then throughout May and into June will be when we actually deliver the program.

So, with that, let me hand it over to my colleague, Stephanie, to talk about the Technical and Business Assistance Needs Assessment program.

Stephanie Fertig: Thank you so much, Eric. And good afternoon, everyone. Great to virtually meet with you all today. So, if we go to the next slide -- let's see if I can get that to -- there we go. As noted on this slide, the purpose of the Technical and Business Assistance program is to help small businesses identify and address the most pressing product development needs. Now this is part of the statute, and NIH uses the program to help get those great innovations that you all have into the hands of patients, clinicians, caregivers, and researchers that need them.

NIH currently has three core components to our Technical and Business Assistance, or TABA programs. Needs Assessment for Phase I, consulting services for Phase II, and TABA Funding, which is an option for either phase. The Needs Assessment and Consulting Services are what we call "centralized" by TABA resources, while TABA Funding is requested in the application and provides specific funding if a small business has identified vendors and knows the assistance that it needs. Today we're going to be focusing on the Needs Assessment program, and we'll be diving into Consulting Services or TABA Funding. There was a recent webinar on the TABA Consulting services, and you can find that on our website. If you're interested in that program, I encourage you to watch the webinar. If you're interested in -- we also did a recent webinar on the TABA Needs Assessment and TABA Funding, so if you would like more information, you can also take a look at that webinar as well on our website and reach out to us if you have any questions.

So, the TABA Needs Assessment program provides third party unbiased assessment, and this is provided by RTI Innovation Advisors, to help small businesses identify their most pressing product development need. What we find is that while some Phase I's or some small businesses really do know what the next step in their need is with regards to Technical and Business Assistance, others may not know -- may not know what's the best next step; what are those major gaps that they should be really focusing on first. And this is particularly important if, as

you're a Phase I, you're looking at submitting that Phase II, and you're thinking, well, what should I spend, what should I put in there and indicate for my Technical and Business Assistance for the Phase II, because for the Phase II, you can request, just part of TABA Funding up to $50,000. And so, what this TABA Needs Assessment can help you do is see what are those gaps, what should I be looking to make sure that I'm filling in the Phase II? Or what are those highest priority steps that I need to take, regardless if I get a Phase II SBIR/STTR grant?

The four areas that we look at is intellectual property, barriers to entry, regulatory manufacturing and clinical plan, marketing needs, competitive advantages, and business model profitability.

In order to come in and request a Needs Assessment, you do need to have had, or have, a Phase I with either a straight Phase I SBIR or STTR, or a Phase I Fast Track, and you have had to have had an active Phase I grant, cooperative agreement, or contract within the last two years of request. So, it's really based on the Phase I. And that Phase I had to have been active within the last two years. If you received TABA Funding within your Phase I, you are ineligible, and that's because you can do either TABA Funding or one of these centralized services. So, if you received TABA Funding in your Phase I, you are not eligible to get a Needs Assessment.

The good news is, though, you can participate in our other support programs, such as I-Corps. So, you can do I-Corps and the Needs Assessment program -- that's totally fine. So, there's the great news here, is if you're a Phase I, both of these are potentially good programs for you to participate in.

The request process is simple. You should review the sample report before requesting, because the structure and the scope are fixed, so it's really important to look at that report, because we want you to know the kind of report that you're requesting. It's open all year, but you have to request an assessment at our website. And you can see the website here, and I'm sure it's going to show up in the Chat shortly. Requests have to be complete. We will confirm your eligibility, and we'll notify you of your status.

Now once it's time to get that assessment, we will confirm that you've reviewed and acknowledged the deliverable, that you're ready to proceed and to receive appropriate contact.

Now RTI's going to perform that analysis, they're going to have an initial interview with you, and work to identify information, verify that information, and then deliver a draft. Now a draft's going to take three to four months, so do keep that in mind when thinking about planning and thinking about, again, submission, if you're planning to use this to help inform your Phase II, make sure that you work that into your submission plan. And then the company has 10 business days to review, and RTI will then deliver the final Needs Assessment report, incorporating any questions or feedback.

But the most important piece of advice is to talk to us. Talk to your Program Officer. We talked about two great programs here, but if you do have any questions about these or any other resources, reach out and talk to the Program Officer that's assigned to your Phase I. They're a great resource. You can also talk to us. If you're not sure who to contact, you can always reach out to us at SEEDinfo@nih.gov, we're happy to help.

And with that, we're open for questions. We have plenty of time for questions. I see a number of them in the Chat. So, let's get started. Well, I think this was a question, and I'm looking at the question from the Chat; I do see a question here specifically, I think, for I-Corps, although you could probably ask this of the Needs Assessment program as well -- why are active Phase IIs excluded from I-Corps?

Eric Padmore: Well, very good question. Let me say that these programs are really tailored to complement the activities in the Phase I feasibility studies of these funded projects. But the goal is really to strengthen the structure and design of the Phase II portion of the research effort, right? So, it's a recognition that the earlier this process we get you to look at these questions and answer the things in terms of the goals that I outlined earlier, the better your Phase II is, and then the better your commercialization plan will be. So, it's structured deliberately in that way.

Stephanie Fertig: And I will say with regards to the Needs Assessment program, this is really, again, an opportunity for you to utilize the program to look at those gaps, see what those gaps may be, and what your next steps should be with regards to this specific project. And the idea is that we're going to assess those needs, we're going to assess your project within those four

areas, and then hopefully that will help inform you with regards to what you might want to put in a Phase II, or what you might want to make sure you looked at and addressed prior to that Phase II. So, these are things that will help you as you're looking at going forward, and really receive the sweet spot for that, is the Phase I.

We have been getting a lot of questions around the slides, and again, the great news is if you go to our Events -- and thank you for moving that forward -- if you go to our NIH SEED events, you can see past events, and you'll see not only recordings, but also transcripts and slides from many of our past webinars -- that's where this will be at the end, in several weeks. So, you'll be able to look at this recording, share it with others, as well as look at the slides and transcripts.

So, what are the next rounds of the program, or I-Corps, after this one?

Eric Padmore: So, there will be in those dates for FY 2023, again, are listed on the FOA PAR-22-073. There is a third round, which is scheduled later in the summer, but that round will be specifically sponsored by the National Cancer Institute and will involve cancer technologies only. So, the last round for FY23 in a disease agnostic way, is the upcoming deadline, February 1st. We have not yet established the dates for the FY 2024 I-Corps rounds.

Stephanie Fertig: And where can people find a list of the institutes that allow I-Corps eligibility under an extension of the grant?

Eric Padmore: Again, that's in at the very beginning of the Funding Opportunity Announcement, PAR-22-073. So just pop that into your browser in Google, and it should come right up.

Stephanie Fertig: We have an interesting question that I think is one that I've definitely seen before with regards to I-Corps. Is I-Corps a fit for biotech companies who don't need to do a lot of customer interviews, like reagent company? And this individual could see using this platform to talk to industry experts, to figure out target product profiles, etcetera, but they're not sure that I-Corps would be a good fit if they kind of know what they've got to do.

Eric Padmore: So, I think there are two ways to look at it, and obviously there are some entities who are much mature, let me say it that way, in terms of the development of their product and their business model. However, one of the things that I think I-Corps does is to help you

understand better the definition of the term "customer," right? So, when you say "customer" to many people, they're thinking of kind of a retail end user, but in the case of a platform technology, you are probably looking at more, shall we call them "middle men," whether those are distributors, large other pharmaceutical entities that are going to buy your product from you. So absolutely, yes, I think that helping you to understand that market and who those customers might be that you have not yet thought of is one of the absolute benefits of a program like this. And more to the point, we have a number of platform technologies that have gone through this program rather successfully.

Stephanie Fertig: And I think that's a -- I would concur wholeheartedly with that assessment. I've certainly seen -- I've had when I was a Program Officer, I had a number of projects go through the I-Corps program. And I think there's always some points of discovery, even if people thought they were very comfortable with what their next steps were. I had a number of companies find it to be very helpful. And they discovered something that they hadn't actually anticipated during the I-Corps process. So, I would encourage you to take a look at I-Corps, and I would say I'm going to answer it also for the Needs Assessment program, we've found that while certainly, I think, companies that are in earlier stages of development, really do benefit from a Needs Assessment program. Even some of our later-stage companies find it helpful to get that verification and kind of -- that verification that they're on the right track, but they are really hitting those major things that they need to be looking at next. So that can be very helpful on the particular sense it is available at no cost for our Phase I's.

With that, what stage of development should technology be in for a strong I-Corps application? Is there earlier or later? Does it matter?

Eric Padmore: Again, I don't think it does matter, so long as you are in an active Phase I. So that defines itself, right?

Stephanie Fertig: Yeah, I think that --

Eric Padmore: If you're in Phase II, no. If you're in Phase I, yes. I mean, it's fairly straight-forward.

Stephanie Fertig: But I think obviously one person's feasibility study is another person's full research and development. But I found people in a variety of different stages in the product development have really taken advantage of the I-Corps program. I've definitely seen that as well.

Eric Padmore: Sure.

Stephanie Fertig: So, there's a question, would a hospital administrator in the target industry count as an industry expert? Or does that person have to be an entrepreneur?

Eric Padmore: So, you're asking an ex-hospital administrator if hospital administrators are relevant -- the answer is yes. So again, it's thinking in terms of who your customers are, and who your markets are, right? So, whether or not -- let's say you devise some sort of surgical technology, and you want to talk to hospital administrators, surgical department administrators, nursing administrators -- all of these are people who are going to have some impact in the market potential of your product. So even somebody in Purchasing, right? So yes, all of those people are good in helping you define the marginal utility of what you're bringing to the market, assuming that you're developing something where the end use case is going to be in hospitals -- then yes, hospital administrators are clearly the part of people, or part of the mix of people, that you're going to want to talk to, because ultimately they will have a say in the adoption of your technology in its use case.

Stephanie Fertig: We have a couple of questions around I-Corps and eligibility.

Eric Padmore: Okay.

Stephanie Fertig: I'm going to bundle those together a little bit. There was one question on, in order to be eligible, do you have to be -- is it only on that application due date? Or how does that eligibility work? And then, does it have to be -- so does it have to be active for the entire time, or just on the application due date? And is there some flexibility there? And I think you mentioned this a little bit in the presentation, but maybe you can walk through that, because I know that's a sticking point.

Eric Padmore: Yes. So, your Phase I award needs to be active through the course close-out date. So, in the case of this upcoming February 1st cohort, you need to be active through June 27th, right, which is the last day of the close of that course close-out date. Now that being said, depending on the policies of your sponsoring institute or center, they may be willing to provide you with a no-cost extension, which will essentially keep your award alive for the duration of the program. Or in the case where you're applying to some date in the future; if, for example, your award is going to expire at the end of the month, which is cutting it close, but talk to your Program Officer at your sponsoring institution, and in some case -- not all cases -- those institutions will allow you to participate in I-Corps with a no-cost extension. But it is ultimately at the discretion of your Program Officer and Grants Management Officer at that institution to make that determination.

Stephanie Fertig: And I think one of the reasons why we really wanted to present these two programs together, if your Phase I has ended, or you're not able, you're no longer eligible to submit to do I-Corps, you can still potentially submit for a Needs Assessment, because the eligibility window for that is a little bit more flexible. So, if you are unable to do I-Corps, you may still be able to do the Needs Assessment program. So, I would certainly take a look at that. And again, reach out if you have any specific questions.

We are getting a question, if I-Corps is restricted to one per company, so if somebody had multiple awards, are you limited to participating in I-Corps only once per company? I will tell you because this was also a question around Technical and Business Assistance. For Technical and Business Assistance, or the Needs Assessment program, you are not restricted to one per company. But I'd be interested to hear your answer with regards to I-Corps.

Eric Padmore: Yeah, so I think that's a little bit of a nuanced answer. Typically, if you have multiple awards from different institutes, so for example, if you have an active Phase I from mental health, the National Institute of Mental Health, and you also have a Phase I award from NINDS, you can certainly apply for both of those. Ultimately, if you're going to participate in a cohort, you can only participate as one entity, right? So, at some point, you're going to move forward with one or the other. It would be very difficult to have essentially two teams of three people participating in the same cohort, so that might want to be staggered.

The other instance in which this comes up is, let's say you were to participate in cohort number one, which is going to kick off at the beginning of March with your NIMH technology, then yes, you could apply for cohort number two with your NINDS technology and go through sort of the same evaluation process that we do to pick members of those teams. But again, if we try to have key individuals overlap in both of those cohorts, then we're going to ask you some pretty pointed questions about whether or not they truly have the time to dedicate on the 20 to 25 hour a week basis to do both of those. So it is, in a nutshell -- it was a long-winded answer -- you're certainly not excluded for applying for both, but it comes down to a question of prioritization, and then again, the actual logistics, if you will, of participating in a concentrated program like that.

Stephanie Fertig: So, we are getting some questions around the faculty and staff. So, please provide some additional details regarding the faculty or staff leading the program, or other resources. Is there information about individuals who have graduated from this program?

Eric Padmore: Yes. And so, we can -- there are links, and those will be on our website, if they are not already, to prior participants. I would also refer anybody who's interested in I-Corps in general to look at the National Science Foundation I-Corps page, because we do, essentially, mine a number of our instructors from their I-Corps network. Theirs is a much older, much more established program than ours. But again, although we do mine their network of instructors and mentors, our curriculum is specifically tailored to the life sciences, so between our website and their website, you will see examples of a number of companies that have successfully gone through those programs, as well as some additional detail around the curriculum that you might expect to encounter.

Stephanie Fertig: Somebody is asking, do we bring the expert, or do you provide them?

Eric Padmore: You will bring an industry expert, as I mentioned, as a member of your team. We provide experts as instructors, but again, the person that you are bringing as a member of your team should be expressly familiar with the innovation space that your technology exists in, and preferably have some additional experience in commercializing technologies in that space. So, as I said earlier, typically those are people who are serving on your board, who may be serving

as scientific advisors, or in some cases even paid consultants to your firm. But they are folks who are engaged with you and understand your technology and your market space.

Stephanie Fertig: I'm getting a couple of questions about that timing between notice of award and when you can come in for I-Corps. So, I have one here that talks about, we haven't received our notice of award yet, it's still in Just-In-Time. Can we still apply if we don't have it by that February 1st? And then another question that's somewhat related is, we just got our notice of award. Do you think we can manage to slip in an application for February 1st?

Eric Padmore: So, I would say certainly, if you've already gotten a notice of award, that should not be an issue. But in both cases, I will say please reach out to your Program Officer at your sponsoring institute. We're well aware that there are always these sort of timing issues -- I'm almost there, I'm not quite there -- and we work with those on a case-by-case basis to look at the particulars of your situation and make a determination. Our goal is, if you are in the process of, or queued up to get a Phase I award, we want to help you be successful. So, we're not going to throw up, to the extent possible, any administrative barriers or technicalities to say, oh no, you can't participate because your wait's still pending. We're going to work with you to try to make that happen as best we can, but again, it's best to reach out to your Program Officers and let them help you -- or let them help guide you through that process, working with us.

Stephanie Fertig: What's the success rate of I-Corps applications?

Eric Padmore: So that's a loaded question. It depends on how you define success rate. Some people talk about success rates in terms of getting funding, right? So, if you already have a Phase I, that's one metric that people typically apply in looking at NIH grant success rates, did you get an award as a result of your application? If you're asking me, what is the success rate for folks who apply for this supplement, I will say that the limiting factor really is the size of the cohort, which is limited to 24 participants per cohort. In some cases, after the evaluation process, your application may not be successful for the cohort for one of several reasons; either there is a restriction on your existing Phase I award in terms of financial restriction, or some other bar that has come up as a result of your progress report, your grant may be about to expire and your participating IC chooses not to issue a no-cost extension, or the cohort is over-

subscribed, so we may have 35 applicants for 24 slots. And in many cases, in that situation, what we will try to do is to move the surplus, if you will, into a future cohort, assuming that they continue to be eligible for that application period. So again, our goal is to help you succeed. We will accommodate as many teams as we possibly can, and if we can't accommodate them in a given cohort, we try to move them forward. If that works, and assuming that they do well in our review and interview process, which in all but a few cases, everybody does.

Stephanie Fertig: We're getting other questions about whether or not to do the TABA Needs Assessment versus I-Corps, can we do them simultaneously or not? I'm going to jump in and answer kind of -- so one, we had a question about, we're a very, very, very small company, we don't have a lot of staff, kind of earlier stage. Would it make sense to apply for TABA instead of I-Corps? Is it better to do I-Corps first, and then TABA? Can you do -- what is the timing with regards to applying for, or requesting that TABA Needs Assessment? I will say that again, you can certainly do both. You can request a TABA Needs Assessment as well as come in for the I-Corps program. They're very different programs, and I think they both provide valuable information. I would encourage you -- I would certainly encourage you to come in for the TABA Needs Assessment. It's a very simple request, it doesn't take a lot of effort, and it is always open, and it is available to you. And I think it's a low-lift, particularly if your company doesn't have a lot of staff, or you may not have a lot of ability to put the time into I-Corps.

That said, although I-Corps is more of a time commitment, we have heard nothing but good things from those companies that have gone through the process. And as a Program Officer, I've certainly seen a lot of companies get some great input and feedback, and really used that I-Corps experience to include their project. So, I don't know if, Eric, you want to add anything. I would say do both, but I'm sure you'd have some additional things to add as well.

Eric Padmore: Yeah, no, I agree with everything you said, Stephanie. I think particularly smaller companies, as you said, where they may not have a lot of staff -- again, you're going to want to look at, what are your priorities in terms of your time and your commitment? I-Corps is very time-intensive, and if you only have three people in your company and you're going to be doing 20 hours a week for 8 weeks, that may not be workable for you. But only you can make that

assessment, in which case, I think the TABA Technical Assistance may be the way to go. But you have to make that determination based on your own priorities and based on your own sense of what you can physically do with the time that you have available.

Stephanie Fertig: Great. So, there was another question around both the Technical and Business Assistance, as well as I-Corps. So, is this looking at the company overall, or is this really focused on an individual project? And I'll say for the Technical and Business Assistance, it's focused on the project, although obviously there are aspects of the overall company that they are going to be looking at as it relates to that project. But Eric, do you want to talk about it? Is it project-specific or company-specific?

Eric Padmore: Yeah, so for I-Corps, it's really project-specific, right? So, you're taking your technology and really looking at the market space and the commercialization potential of that particular technology.

Stephanie Fertig: So, I am going to say, there was one I just saw. And that was specifically looking at the time that it takes. For the 20 hours a week, how is the hours distributed? How is that going to work? Because, again, is some of that outside of normal working hours? Or is that all within business hours?

Eric Padmore: So, the 20 to 24, 25 hours a week is an estimate, an educated estimate, based on prior experience, of the time it's going to take you to conduct the interviews that you need to conduct over the eight-week period, right? So that all depends on who you're talking to and where they are, and where you are. If you're doing that over remote platforms and you're on the West Coast and you're talking to people on the East Coast, because that's where the people that you need to talk to are, obviously that may happen outside of your business hours. If the market that you are looking at is entirely within a time zone that you live in, then you might be able to conduct that entirely within business hours. It's entirely up to you. Again, we are just putting those hours out there as guidelines, in terms of what you should anticipate you're going to need to do in order to complete this program.

Stephanie Fertig: So, there was a clarification, if you don't have a business development person, or if you are a smaller company, how can you apply to I-Corps? There's a lot of questions about how to find individuals, how do you get some of those teams together?

Eric Padmore: Again, those hopefully are contacts that you have within your ecosystem, either existing board members, advisors, mentors. If you are coming out of an academic environment, mining that network within that space to -- and I'm assuming people are talking here primarily about industry experts, which is where we tend to get the most of these kinds of questions. So, it's a question of really sort of looking around in your own environment and trying to find people who understand your space in that ecosystem. In some cases, the SBIR/STTR program offices of your sponsoring institutes may have mentor networks that they can help you identify those kinds of individuals, so again, speaking to your Program Officers, they may be able to help you find the kind of people that can supplement your team in that way.

Stephanie Fertig: What makes a good technical lead team member for I-Corps?

Eric Padmore: Technically. So, as I mentioned in one of the earlier slides, those are typically, in many cases, co-investigators, people who are part of your small business concern as Chief Scientific Officer, Chief Technical Officer, but somebody who is intimately familiar with the technology at hand with the project that you are trying to advance. So, it's simply not going out and finding somebody who knows a little bit about heart catheters; if you are specifically developing some kind of new heart catheter technology, we would hope that it's somebody who's been intimately involved in the development of that technology in an active way.

Stephanie Fertig: I have a question here about how to apply for I-Corps. Is this something you need to include with the application assist? Is it a six-page application, budgets, bio-sketches? How does all of that work?

Eric Padmore: So, all of that information is included on the Funding Opportunity Announcement -- I'm going to say it again, I know you're tired of me saying it -- PAR-22-073, and the instructions for submitting an application are contained in exhaustive detail in that Funding Announcement. So, I'd refer you to that.

Stephanie Fertig: And for those who are familiar with the supplement process -- it is a supplement, and so it will look very familiar if you've done supplements in the past.

So, there is a question here, we have a therapeutic. It works very well in a specific animal model, and we did an exit strategy. How would TABA help with that? And I would even add, how would I-Corps help with that? I would say TABA would help you identify some of the potential gaps in being able to bring that technology to market, and so it's really going to help you kind of identify, what are the next big things you need to tackle with regards to on the more business development side. But Eric, how would I-Corps help with that?

Eric Padmore: So, I think, and we addressed this a little earlier -- in terms of an exit strategy, then you're really sort of defining your customer in a different way, right? Presumably, you're looking for either an investor or some sort of acquisition by a larger entity. So, the I-Corps process is going to help you figure out who those potential either licenses or acquires may be, as well as to help identify those elements of your intellectual property, that you either need to shore up or that are particularly attractive to the marketplace. So that's absolutely one of the things that you could get out of participation in the I-Corps program.

Stephanie Fertig: Is I-Corps all virtual?

Eric Padmore: Yes. So, for FY 2023 -- and thank you for asking that question, because I did not mention that -- it will continue to be virtual as it has been since the start of the pandemic, going forward and in the past. We will evaluate whether or not we can make it an in-person event once again, or whether or not that's actually even desired by potential participants. It was previously, to 2020, in-person for all of the education sessions and so forth, it was an in-person event. The value to that was helping to build those within-cohort relationships, which I'm going to take a minute to stress, because that is one of the key benefits of this program that we have seen in the past, is that a relationship that you are going to build within your cohort by participating with those other 23 teams, right? So even though they may not be in your technology space, there is a great deal of cross-pollenization, sharing of learning and personal relationships that get made and built and strengthened that help you down the road for reasons that you may not be able to anticipate at the moment. But in terms of our evaluations

of the program, that is one of the key things that people always come back to, once they have kind of come out the other end and say, you know, I have these relationships now with people all across the country who may not be in my space, but because we have gone through this together, they understand what I'm trying to do, they bring fresh eyes to the problem, and they've been of great help to me in working out whatever issues I'm trying to work out. So, all that said, for the foreseeable future, it'll continue to be virtual. But I anticipate at some point we'll be looking at that closely to see if it's possible to do it in-person once again.

Stephanie Fertig: I know we are running out of time, but I do think this is a really important question, so I'm going to kind of slip this one in. And this was a question on, who is doing those customer interviews? Does it have to be those three team members?

Eric Padmore: Yes.

Stephanie Fertig: Or can it be others in the company?

Eric Padmore: No. It's the three team members.

Stephanie Fertig: And I think that's a really important thing to know. I mean, again, it's extremely important that the individuals that have been identified are ready and able to really be part of the whole I-Corps process.

Eric Padmore: Yeah. And again, the teams are constructed in that way, because if you think about it, the technical person, the corporate lead and then the industry expert who's an advisor really need to hear those things from the folks downstream, who are going to help develop the commercialization of that project, right? So, it's about educating those three key leaders within a small business concern, to help them understand how to move their project forward. So, it's not something that you want to delegate, because then you're reading a report, or you're hearing feedback from somebody within your company, and you're missing the nuances of those one-on-one conversations, or two-on-one, whatever the case may be, conversations that you're having with the folks who are potentially your markets.

Stephanie Fertig: Well, I know we are out of time. And I have to say there's a number -- while I have been trying to address some of those, I'm typing some of the answers to the questions in

the Chat. I know we do have a number of questions that still remain unresolved. I would encourage you to reach out to either us or your Program Officer. If you have additional questions, you can always email us at SEEDinfo@NIH.gov. in addition, you can always reach out to your Program Officer, the assigned Program Officer on your Phase I, or your Phase II if you have specific questions about what resources are available to you, given the fact that you're a recipient of an SBIR or STTR. And with that, Eric is there any closing words?

Eric Padmore: Other than to thank everybody for joining us this afternoon. Thank you, Stephanie for acting as moderator, expertly done as always and thank you to our technical team for getting us through this webinar without crashing, which is always something to applaud, so, applaud to those folks. And again, I would also say that if you have specific questions about the I-Corps program you can always direct those via email to Icorps@mail.nih.gov and we will endeavor to answer those. And again, this video and the accompanying slides will be posted in a couple of weeks to our website for any of those of you who wish to refer back to it. So, thank you everybody for joining us and I think that will conclude our program for today.

Stephanie Fertig: Thank you.