NIH Technical and Business Assistance (TABA) Program Webinar Transcript – October 2022

Stephanie Fertig: Welcome, everyone, again, good afternoon. Welcome to our webinar today focused on technical and business assistance. Specifically we're going to be spending a good amount of time on the new Needs Assessment Program. My name is Stephanie Fertig. I'm the HHS Small Business Program Lead here within the Small business Education and Entrepreneurial Development office, or SEED, within the office of Extramural Research here at NIH. Today we're going to dig into information about NIH's Technical and Business Assistance programs, so today we're going to ask for the Q&A. Please we welcome questions in the Q&A, and we're going to be also doing upvoting, so if you see a question that you also have, you can upvote that in the Q&A, and we're going to be providing links throughout the presentation in the chat but please feel free to ask your question, and we'll be answering those questions at the end of the presentation. All right. Let's get started. Okay.

Now we're going to be going through the specifics of the Technical and Business Assistance programs today, but we're not going to be going through the specifics regarding the SBIR and STTR programs or some of the other resources available to small-business awardees, so I encourage you to visit our website, has a wealth of information and resources particularly about the application process and the resources that we have available here. Now the Technical and Business Assistance program is part of the congressionally mandated SBIR and STTR programs. NIH and HHS as a whole dedicates about $1.2 billion of funding set aside from our research and development budget to help small businesses and help them transition their great innovations into health. The NIH small-business programs are one of the largest sources of early stage capital for life sciences.

Unlike other agencies, NIH is generally not the final purchasers of the technology that we support, and so the SBIR and STTR are programs also known as America's Seed Fund, really seed companies to help them do that proof of concept and research and development work that's needed to de-risk their technology. Now the Technical and Business Assistance programs that

NIH provides support for can really help companies move along this pathway. Many of our companies are in the early stage, and our awardees can leverage NIH funding and support to attract partners and investors that are needed to take their innovations to market. Now the programs, the SBIR and STTR programs are phased programs, and, again, very important to note that these phases are not related to clinical trials phases. It's an unfortunate similarity in nomenclature. We're going to be talking a little bit about phases when we're talking about what around eligibility for the different programs, but I'm not going to be going into specific details about these specific programs and all the different ways and how phases work today, so, again, I encourage you to visit our website as well as past webinars to learn more.

Today I want to really focus on those resources and additional programs that are available to our recipients. Regardless of how you get to a Phase II, and, again, we have a number of different ways to do that from the more traditional path as well as Fast-Track and Direct to Phase II, but we do have other options to help bridge the gap that often occurs between the Phase II, getting that funded Phase II and the commercial market partner or investor. Some Institutes and Centers participate in what we call second Phase II our Phase IIB. Others also may also participate in the Commercial Readiness Pilot Program.

Now it's important to note that for either of these programs which provides additional support and in some cases like the CRP some technical and business assistance, those programs do require that you have an awarded Phase II. You've received Phase II funds, and, again, not all institutes and centers participate. It's extremely important that you contact your program officer in advance of applying for either of these options and to see what might be available to you if you're in that Phase II. We also have other support options, and that's in addition to the Technical and Business Assistance programs, so these are separate from the Technical and Business Assistance programs we're going to discuss today.

We recognize that many of our innovators may have limited business experience and may be brand-new to entrepreneurship. The SEED Office has regulatory and business development consultants available to help support our entrepreneurs. We also have entrepreneurial support and education programs available to our Phase I recipients such as I-Corps and C3i, and finally we offer awardees opportunities to meet with investors and partners at conferences that occur throughout the country, and, again, I did put a link at the bottom of this website, the link at the bottom of this page for the website so you can take a look at some of these opportunities and, again, see if this might be of interest to you.

All right. Let's talk about TABA. Now as noted in the statute, the purpose of the Technical and Business Assistance Program is to really help small businesses identify and address their most pressing product-development need, and NIH really utilizes the program to help, again, get those great innovations that we're supporting into the hands of the patients, clinicians, caregivers and researchers that need them. So, here at NIH we have three core components to our Technical and Business Assistance program. We have the Needs Assessment for Phase I, Consulting Services for Phase II and the TABA Funding, which is an option for either phase. We're going to be discussing TABA Needs Assessment and TABA Funding today at a greater length, but we're not going to be delving into consulting services. There was a recent webinar on the TABA Consulting Services program. If you're interested, I would encourage you to watch that webinar, review our website and then reach out to us if you have any additional questions, and, again, you can find information on the website below on the slide.

So let's talk about the Technical and Business Assistance Funding. Applicants can request to get funding to use their own vendors for Technical and Business Assistance. Now this request really should be as part of the application. If you want to use your own vendors, you should actually request it in your budget as part of the application request as part of the overall proposed grant budget. Some institutes and centers do allow for administrative supplements after the award is made and allow you to get that funding as part of an administrative supplement, but not all institutes and centers allow this, and so it's really important to read the notice NOT-OD-21-062 to determine if your Institute and Center allows for administrative supplements or, again, you can always reach out to and talk to your assigned program officer.

It's important to note that TABA costs may not exceed $6,500 per year for Phase I or $50,000 per project period for a Phase II. All of the information about exactly how to put that in the application, where to put it, what you need to do, that's in our new Forms G instructions, so there are instructions for the SBIR and STTR applications, and there's a little box in there that specifically talks about Technical and Business Assistance Funding and talks about how to apply, where to put in your application and to make sure that there's an adequate budget justification. You need to tell us who, which vendor you're going to use and what you plan to do with that funding. And, again, one of the things we're going to say over and over and over again is the importance to talk to program staff before submission, and that's because one of the big questions that we get is around budget. How does this work with regards to the budget guidelines of an individual Institute and Center?

Since Institutes and Centers can set individual budget guidelines for their SBIR and STTR programs, it's important to reach out particularly as you're getting closer to a budget guideline for either the SBA's budget guidelines or for the Institute and Center's budget guidelines, so important to reach out and talk with them. It's also important to note that if you take advantage of funding specifically to do Technical and Business Assistance, you can't use the other NIH Technical and Business Assistance programs such as the Needs Assessment Program or the Consulting Services during that project phase. For example, if you ask for and receive funding to do Technical and Business Assistance in your Phase I, you cannot receive a Needs Assessment for that Phase I.

What can be included as part of Technical and Business Assistance Funding? And, again, this is taken from those instructions forms so extremely important, that form set. You can see here what the funding can support and what the funding can't support. I think the one thing I do want to highlight; I'm not going to read through all of these today, but I want to point out that the funding is really supposed to be for subcontractors or consultants to provide you with that Technical and Business Assistance. Funding cannot support investment in or maintenance of a division within a small business, an affiliate or investor of the small business or a subcontractor or consultant that's really required as part of the awarded Phase I or Phase II.

So, again, if you're not sure whether or not it's an allowable cost or whether or not it makes sense to do that activity as part of Technical and Business Assistance, as part of your application, I'd encourage you to reach out and talk to your program officer. Now there's a lot of pieces, and I've talked a lot about the different components and these three programs within Technical and Business Assistance. Well, how does this all fit with regards to Phase I and Phase

II? And what's your optimal path? What should you be taking advantage of when? And these are great questions. So I want to walk through that a little bit today.

Now you can see here that you have a number of different options for the Phase I or for the Phase II. What we think is the most optimal path for most companies, and, again, some of our more experienced companies or companies that have a clear and specific need in their Phase I, they may take advantage of and receive that funding in the Phase I application, but we really encourage our Phase I recipients to look and get a Needs Assessment Report. And that's because one of the big questions that we get and one of the things that we really see is that many of our innovators aren't sure what they should be asking for with regards to the Phase II funding, which is a larger amount of funding that you can receive. It's $50,000, so the Needs Assessment Report can really help guide you to what you might want to focus and address in your Phase II. It can also point you to maybe using some of the other resources that I talked about earlier in the presentation, so the Needs Assessment Report can really show you what needs you need to address, and then through your program officer or the SEED Office, you can identify the best options and get connected with the resources that make sense for you.

While TABA Consulting Services is a great program, the reason it's not on the optimal path is, it does have a limited participation, and so, again, for many of our companies, makes the most sense to do the Needs Assessment and then TABA Funding in the Phase II. So what is the TABA Needs Assessment since we do recommend that for our Phase Is? Well, that provides a third-party unbiased assessment, and that is currently provided by RTI Innovation Advisors to help small businesses identify their most pressing product development needs, and you're going to be hearing from RTI a little bit later in the presentation. They'll be able to talk to you about their capabilities and what they're able to do for our companies.

Now we're looking at your assessing the project in the following four areas: intellectual property and barriers to entry, market needs, competitive advantages, regulatory and manufacturing and/or clinical plan and business-model profitability. Now in addition to the assessment, RTI also provides an indication of the highest priority steps, so really they're going to help say, here's our assessment. Here are some of the things that you need to do, that we recommend based on that assessment that you might want to take a look at first. And the great news is, we support companies developing all types of technologies because, again, we recognize the wide breadth and depth of the NIH program, and we do have a notice that announced this program, and, again, we also have the website.

Now who's eligible? Well, first you have to have received a Phase I, and that can be either through the standard SBIR-STTR Phase I process or through a Fast-Track. That Phase I has to have been active within the last 2 years, and that's as of the request date, so it has to have been active as 2 years from the request, but it could be a grant, cooperative agreement, or contract. Now again as we stated with the TABA Funding, if you receive TABA Funding or for those who may have some of the older grants, we did have the prior program, the Niche Assessment Program. If you received one of those for your Phase Is, for that Phase I, for that specific Phase I that you're coming to us about, that would be ineligible.

However, projects can participate in other support programs such as I-Corps or C3i and remain eligible, so you can take advantage of some of those other resources I talked about earlier in the presentation. Now the request process is fairly straightforward. First and most importantly we really encourage you to review the sample report before making a request, and that's because the structure and the scope of this are fixed, so we can't modify the structure and scope for your individual project, so it is .. . The sample report that you see is the deliverable, the kind of deliverable you're going to receive, so it's important to review that and make sure that you recognize and understand that that's what you'll be receiving.

The good news is that this process is open year-round, but you must request the assessment at our website, and so you can see there's a big green button on our website that says request a Needs Assessment Report, and you can click on that and make that request. Requests must be complete, and NIH will be looking at eligibility and confirming that eligibility, and we'll notify you within 60 days of submission. If there is a queue, and there could be a queue based on the number of requests, we will also let you know that as well.

Now the general process, once we notify you that we're going to be moving forward with the report, you must confirm that you've reviewed and acknowledged the deliverable. We're going to ask if you're ready to proceed at this time and confirm they had appropriate contact. RTI is going to be performing the analysis. They're going to have that initial phone interview within 2 months, and they're going to be working with you to verify the information and make sure they have everything. It is right and correct, and they have all the information from you. They're going to deliver a draft probably within 3 to 4 months if not faster, and the company will have some time to review that for accuracy, and RTI will then incorporate those questions and the feedback they receive during that review and finally deliver that final Needs Assessment Report, so in a nutshell this gives you a rough idea of the process and some of the timing so that you can determine when makes the most sense for your company to request that Needs Assessment Report. And with that, I do want to turn it over to RTI to talk a little bit about their capabilities, introduce themselves and help you get an idea of who you'd be working with.

Moline Prak Pandiyan: Thank you, Stephanie. My name is Moline Prak Pandiyan, and we're going to segue a bit into introducing you to the team that will be executing the Needs Assessment Report and program. We are, as Stephanie had mentioned earlier, a third party. We're unbiased, and our goal is to provide review of your current state as a small business as well as identify needs and form recommendations for you. My name is Moline Pandiyan, and I lead the medical technology industry within RTI Innovation Advisors, but I also serve as the program manager for the RTI support specifically for the Needs Assessment Program.

Our team understands that taking your product to market is a very complex journey, especially in the medical industry, and we're here to help you navigate that complexity and also provide practical, actual recommendations on what you should be doing to improve your chances of communication success. As a quick intro to our team, RTI Innovation Advisors is a business unit of a larger organization, RTI International. RTI International is a nonprofit research institute with a global reach. Our mission is improving the human condition by turning knowledge into practice using evidence-based research, using our expertise, and our RTI Innovation Advisors team supports innovators directly or indirectly.

That can mean working with small businesses such as yourselves or the programs and the organizations that support them with the end goal of moving and turning your ideas, innovations and insights into practical use and application via new products, services and technologies. Here is a quick snapshot of the organizations that we serve. We provide services both to the public and private sector, so within industry in addition to working with small businesses like yourselves, we also work with very large well-known industries on the Fortune 500 list or midsize companies. Why is this important? This is important because oftentimes many of you as small businesses might have a goal getting acquired by some of these large businesses, so we have that perspective and understanding what their needs are in terms of finding other partners whether you're acquisition targets or technology development partnerships.

We also support programs similarly to the NIH. We also have a long history supporting NASA for over 55 years and their technology transfer programs as well as the DOD and other different groups and agencies. We also have experiences supporting academia NGOs and consortiums like the Medical Technology Enterprise Consortium, or MTEC. When you work with us, when you interact with our RTI Innovation Advisors team, you can trust that we understand that bigger picture of innovation and all the different perspectives that are a part of your ecosystem.

Our RTI Innovation Advisors team at a high level provides three different types of support to the clients that we serve, one that's at the organizational level where we provide innovation strategy services and help align stakeholders both internally and externally on any goals or initiatives that they may have. For example, sustainability is a key issue in many industries, and we help support the formation of goals and aligning your stakeholders and executing and achieving those goals. We also have experience providing insights, so, for example, we might be able to also for clients speak to end users as well or key opinion leaders to better understand the market and the market needs, but to emphasize for this specific program, the Needs Assessment Program under NIH TABA, we are providing that commercialization support, and while we have direct commercialization experience in executing, the Needs Assessment Program has our team focusing on specifically providing that unbiased view of your current state and perhaps more importantly identifying and forming recommendations of where and what you should be considering to overcome any unknowns we might uncover.

When you work with us, you tap into the internal and external network of RTI. RTI as a global institute has approximately 6,000 employees worldwide, and we have a variety of services and practice areas that we support. In addition to innovation advising and commercialization support, we also provide services in various practice areas with health being one of the key areas that we work with. So you might be asking, how does this impact your experience if you are an eligible or participating SBIR/STTR Phase I awardee? As an eligible participant as Stephanie had mentioned, you will be working very closely with RTI under the Needs Assessment Program, and your point of entry is the assessment lead who would reach out to you, have those initial interviews and go back and forth in terms of making sure that we understand where your business is and where your team is and the technology that you're working on.

The assessment lead is backed up by a large group of experienced subject-matter experts and also other team members, and together we form those recommendations for your Needs Assessment Report. That can mean helping to potentially validate that your approach is the right one but more often than not uncovering unknowns that perhaps your team has not yet identified or might not be aware of. We provide this needs assessment report to help you inform your commercialization pathway whether you are forming your commercialization plan in preparation for a Phase II application, or it might be you updating if you're a Fast-Tracked small business, updating your commercialization plan to strengthen it and making sure that you haven't missed a component of your strategy.

We hope that you are encouraged to submit an intake request into the program and that you have faith that the team that would be supporting you, our RTI Innovation Advisors team, can help you overcome some of those unknowns in terms of identifying it and also providing guidance as to making sure to look into other areas of things that you might not have known otherwise. At this point, I'd like to move it back over to Stephanie to open up the most important part of this webinar, which is the Q&A session. I also invite my colleague, Wout Salenbien, who serves as my deputy in the program management of this project and program to help answer any questions that you might have about the TABA Needs Assessment Program.

Question and Answer Session

Stephanie Fertig: Great, and we are getting a number of questions, which is fantastic, exactly what we were hoping for, but see .. . I think if we go to the next page, one of the most important things I do want to leave you with today, though, and this is a good segue and asking questions is the importance of reaching out and talking with us. As I mentioned, the Technical and Business Assistance programs can be .. . I saw it flash up briefly. There we go. The Technical and Business Assistance programs, which option is best? And what resources might be available to you? It can be complex, and so we do encourage you to reach out and talk with us in advance, certainly in advance of submission, always a strong idea, but even after you've received an award it's important to talk to your program officer to see what might be available to you.

There are a list of SBIR small-business program managers on our website, and, again, if you're developing an application, and you're not sure who to talk with, so if you have received funding, you know who your program officer is, and that can always be found through the eRA Commons. You can also find that individual. They're located on your summary statement in the upper-left-hand corner. But if you're still, you're not sure who to contact particularly if you're still in the application phase, we do have a list of all of those projects that have been supported in the past. You can find those at report.nih.gov. In addition, you can always e-mail the SEED Office a brief summary of what you're planning to propose, and we can make sure that you're connected with the appropriate individual.

So really the most important thing to do is to reach out and contact us, and I think on one of the last slides that we had was just all the ways to make sure to connect and contact the SEED office, and that includes SEED events. I did mention a couple of webinars today. We do put information and including about this information, this webinar, the slides, a transcript, and a recording of this video is all going to be on our SEED events website, so you'll be able to get access to this after the fact if you want to go back and make sure you listen to something we've said today.

You'll be able to do that including access to slides, so I do encourage you to reach out and to utilize these resources. So with that, I do see a number of questions, and I love the upvoting feature. I get to kind of start at the top and see the ones that you guys are voting for the most. So one of the first things I see is, can you apply for a Needs Assessment in Phase I and then TABA Funding, I'm assuming, in Phase II? And the answer is absolutely, and I think that is that optimal path where you figure out, what are the things that you really need to be focusing on in the Needs Assessment? And then that allows you to have a better use of what you want to propose and those funds in that Phase II, and so you can absolutely do that. When we talk about the Technical and Business Assistance program and being only able to kind of access one of the Technical and Business Assistance programs, it's per phase, so it's based on, you can basically do either TABA Funding or Needs Assessment in the Phase I, and then in the Phase II you can access TABA Funding if that is what you'd like to do.

Okay. The next upvote, if you're in the middle of an STTR Phase I and anticipate applying for a Phase II, what's the ideal time to request a Needs Assessment? Boy, that's a great question. I really like that, and I think it depends a little bit on the project, so, again, this might be something you want to discuss with your program officer. But ideally you're going to want to do it in enough time so that you'll have that assessment in hand and are able to utilize that to make a good plan for what you're going to request in your Phase II, so some of that depends on your timing with regards to when you think you're going to substitute your Phase II, and you should factor in the timing that it's going to take RTI to reach out to you, go through that process and, again, make sure that you provide adequate time there because the report does take time to make.

It's not instantaneous, but, again, what that can do is, if you provide yourself enough time there so that you can better integrate and integrate their feedback and make sure that, that part of what you're proposing, so I'm hoping that answers your question with regard to timing, and, again, some of it will be dependent on your specific project because obviously you want to provide RTI enough information so that they can give you a good assessment, be able to assess everything properly as well.

Moline Prak Pandiyan: And we've gotten this question before. We've already started in providing the Needs Assessment Reports, and we typically recommend approximately 6 months prior to when you think you might be applying to your Phase II. That gives you a chance to make sure that you share the information that you need with the RTI team. You go back and forth just a little bit in terms of making sure that we understand your current state but then also the most important piece is forming that recommendation as to what could be missing from your commercialization plan and also giving yourself a time to digest that report and also integrate it into your commercialization plan, so my blanket recommendation is approximately 6 months before you even think about applying.

Stephanie Fertig: With that said, say it's going to be shorter than that. I wouldn't stop you. Don't let that stop you from requesting the report. I think it's still extremely valuable, so you're asking us for the ideal time, but sometimes life isn't ideal, and I wouldn't let that stop you from requesting a report either.

Moline Prak Pandiyan: Absolutely, great point, Stephanie.

Stephanie Fertig: So we got the next question, and, again, I'm not surprised this one got a lot of upvotes either is TABA Funding on top of the award limit of approximately $275,000, and I think what we're talking about is the SBA guideline. So a couple of points about the SBIR and STTR budget guideline, so there is an SBA budget guideline, and above that guideline you do need .. . We do have .. . NIH has a waiver to exceed those budgetary amounts for specific topic areas that allows us to award some larger Phase Is in some topic areas.

Now each individual Institute and Center has their own budget guidelines. Some Institutes and Centers, again, and this is why it's so important to reach out to an individual Institute and Center because individual Institutes and Centers may say, look, we allow for our awards to be, and I'm just going to say for some topic areas allow our awards to be above the guideline, the SBA guideline, and we allow for TABA to be on top of that.

Some will say, look, this is the total amount that we will give any award, so really it's important once you start talking about that SBA guideline, that point where you need a waiver, you just need to reach out your program officer and ask for a specific individual Institute and Center, what is your guideline? How do you see these different budgets? What are you willing to fund? Because again, each individual Institute and Center does manage and handle their budget differently, and, again, this is why it's so important to reach out to us if you're not sure who to talk to. Again, the SEED office is happy to connect you. Send us a brief description of what you're planning to propose, and we can connect you with the right program officer just to make sure that before you go into all that effort and time to write that application, you have a clear idea. You know that the Institute and Center is likely to accept it as it is. Okay.

So there's a great question here. What are the differences between TABA Needs Assessment, the Niche Assessment and the I-Corps program? So I'm going to start. There's a little bit of background necessary to answer this question, and it's a great question. It's another one we get a lot. The Niche Assessment Program was a program that NIH no longer offers, and that was our program we did provide to Phase I awardees. We no longer offer the Niche Assessment Program. That is not available, and it was specifically focused on market research. TABA Needs Assessment is fundamentally different from the Niche Assessment Program. The TABA Needs Assessment also looks at not just market but really takes a holistic look across those different four factors and provides you an assessment within those four factors as well as recommendations on how best to proceed.

And so that assessment is very, very different from what used to be provided, and, again, the Niche Assessment is no longer an option. I-Corps is very, very different, and there was actually a recent webinar specifically targeted to the I-Corps program. The I-Corps program is an intensive program and in a very good way, and we actually have had individuals do a Needs Assessment and then do I-Corps or vice-versa. They're very complimentary, and the I-Corps program really helps you develop a business model canvas. It requires doing significant customer discovery, and it does require a significant time commitment on the part of the team. Again, it can be an extremely valuable experience. It's not the same thing as a Needs Assessment. I do think they go hand in hand.

Moline Prak Pandiyan: I'll also add that with the Needs Assessment, oftentimes that's one of your earlier steps of just defining and understanding what might be missing. Perhaps we'll come back and say you're thinking about all the different elements, but we know that getting a product to market is extremely complex whether it's related to regulatory concerns or IP or what have you. With that Niche Assessment that no longer exists, it focuses on getting some of that answers, but that's just one component of the Needs Assessment as well as with I-Corps. That's a little bit more tangible hands-on training so think of the Needs Assessment Program and that report as that first cornerstone to helping you understand what might be missing in the bigger picture.

Stephanie Fertig: Okay, next question: Does requesting a Needs Assessment Report in any way help you obtain Phase II funding? Well, it doesn't directly connect with Phase II funding. However, the TABA Needs Assessment Report can help you determine what you might want to focus on in your Phase II particularly with regards to the Technical and Business Assistance Funding. If you want to request Technical and Business Assistance support in your Phase II, a Needs Assessment can really help you determine what you should be focusing on and what your next step should be. In addition, individuals may look at the Needs Assessment and discover that they need to tailor what they were going to ask for more generally in their Phase II, and so it can really help you inform what your next step should be, but it doesn't directly connect to, hey, if you get a Needs Assessment Report, that automatically equals a certain percentage point increase.

Now we also don't have any data around that. This is a fairly new program, but, again, the connection is more to help you be able to write a Phase II that will help your company really get your product to the point where it's de-risked and can get to market. The next question, there are companies like Foresight… et cetera for Technical and Business Assistance. How can a small business choose the right consulting? Well, that's a great question, and, again, this is where when you're talking about Technical and Business Assistance Funding, and, again with the Needs Assessment Report, we have one contractor for that. TABA Consulting Services also has a specific contracting .. . You are coming to us for a resource, but if you want to select your own vendor, that is through the Technical and Business Assistance Funding. That's really up to the company, and, again, if you're not sure who the best individual is, that's why we generally do recommend you start with a Needs Assessment Report and then move to asking for funding because that Needs Assessment Report will help you determine what consulting services you might be really looking for.

On the other hand, some companies really know what they need to do, and, again, we get such a wide variety of different experiences and companies in the NIH, SBIR, STTR programs, and so some companies really know what they need and know that they're looking for a very specific kind of consultant, and so for those individuals, asking for TABA Funding and receiving TABA Funding allows them to select their own vendor to meet their own individual needs and so, again, you just get such a variety of different individuals into the program, so it really depends on their individual needs.

And so, again, you can always ask a program officer. You can always talk through your individual situation as well. Okay. This is a great question, and I think this one is a really important one, the next one on the upvote list: Do we have to select one of the four needs areas when applying to the Needs Assessment Report? Or is it open-ended? For example, will RTI hone in on one of the biggest needs there is? So I'm going to pass this to RTI because I think this is a great question, and I know you guys have gotten this one before.

Moline Prak Pandiyan: Absolutely, I'm going to invite Wout to also augment anything that I share but, yes, it does not have to zone in on any one particular thing. Actually the benefit of the Needs Assessment Program is that big picture, so in that experience of how you are interacting with the RTI team, you're going to be hearing a lot of different questions, a really nice conversation. I've been a part of several of them of just dissecting, where are you? Have you considered this? What did you do? So that will serve as a foundation of what we're looking at, but all four of those areas, I'm going to try to move over there, will be covered under the Needs Assessment.

There's a specific for IP, for market needs, for business model profitability and the regulatory manufacturing or clinical planning space. Each one will have an area where we cover, where are you now? We have built in some iterations where you take a look at what we learned just in case some topic does not come up during that initial interview just to make sure that we understand the bigger picture of your current state, but as you mentioned earlier, the biggest takeaway from this report are those recommendations. We do roll it up for you as well in terms of what are those priorities?

I'm actually going to move over to some of our backup slides. We understand that you have access to the sample Needs Assessment on the website. I'm going to move a little bit further, but we'll give you a dose there where we roll up the recommendations. There's going to be many different ways to slice and dice recommendations, but on this second page here where you see some of the items that are on bold, we do start to prioritize. This is what we think that you should be doing right now. We also list some long-term goals and recommendations as well, but if you take one thing away from the Needs Assessment, looking at that second page to say of all the things that I need to be focusing on right now in the short-term, those items will be bolded, and it does roll up all those four areas.

Stephanie Fertig: Great. Okay, so with regards to the .. . And we do have a number of questions here, which is fantastic, so I really love that everybody is engaging and asking these questions here. So the next question was, we did not include TABA in the Phase I request. Should it then be included in the Phase II proposal? Or can we apply for the funding as we move to a conclusion of the Phase I research, which is exceeding expectations? That's a great question, so you're in your Phase I, haven't yet received the Phase II. What should you do? Well, you have two different options. First you could request a Needs Assessment, and that would help you determine what you should be putting in that Phase II proposal, and that is again the optimal path that we do recommend.

Alternatively for some Institutes and Centers, you can request Technical and Business Assistance Funding through a supplement request, but, again, not all Institutes and Centers participate in that, and it is dependent on an Institute and Center determining that they're able to move forward with that administrative supplement request. You can then in your Phase II proposal ask for TABA Funding within the Phase II proposal as part of that Phase II, and you should certainly make sure that as you're preparing lecture proposal, you read through the instructions very carefully and making sure you read through how to designate in your budget the Technical and Business Assistance Funding and how to justify it.

Next question, is the TABA Needs Assessment funding request provided to all eligible applicants? Or does it undergo a review? Great question, so first you do have to request an assessment, and not everybody wants to request an assessment, and that's fine, so first you do have to go through and request that you get an assessment. Then NIH will confirm that you're eligible for the assessment. That is an important component. Now again we will .. . Sometimes there is a queue at this point. We are able to .. . We're going to be forwarding those assessments and providing a list to RTI on a regular rolling basis, but at this point we are really focusing on providing those assessments for the individuals that ask for them.

Now I did see a question further down asking questions about, well, wait a minute. If I have more than one project, can I ask for an assessment for each of those individual projects? You can, but I will tell you, we are prioritizing one assessment per company at this time, and so we're having you go through the assessment process for one of your projects, and you can then request an assessment for another project, but we are at this point prioritizing one per company, but obviously that may change, and certainly you can request other assessments for more than one project.

Next question, if I get more than one Phase I .. . Oh, that was that question. I answered that question. Is TABA only available for grantees or recipients? So meaning have to either have .. . And that depends when you say TABA. So the Technical and Business, the Needs Assessment Program is only available for individuals who've received a Phase I SBIR or STTR contract, grant or cooperative agreement.

TABA Consulting Services is open to Phase IIs that have received Phase II either through grant, contract or cooperative agreement. TABA Funding, you should be requesting that as part of your grant application, and then you would receive that when you receive the award. Again, there are some specific cases and some institutes and centers that do allow for administering supplements, but that's something you should reach out and talk to your program officer about. Now the next question is about Fast-Tracks, and I think this is another one that we do get a fair bit.

If you receive a Fast-Track, do you request the $6,500 or the $50,000? How do Fast-Tracks work? Well, you have to remember the Fast-Track is a Phase I and a Phase II in one proposal, so you can ask for $6,500 for the Phase I during the Phase I duration and then $50,000 for the Phase II. Alternatively you can come in, submit and expect to get a Needs Assessment Report, so you can request a Needs Assessment Report and then ask for the $50,000 of funding in the Phase II. So you do have some flexibility there with regards to the TABA because they really are seen as for the Phase I, it's the $6,500, and then the Phase II it's $50,000, so it's actually two separate .. . It is two separate phases.

Next question, can you apply for a Needs Assessment Report for a grant that has already been concluded? You can, provided it was active in the last 2 years, so at the time you request the Needs Assessment, and it's a request. You're going to request that Needs Assessment. If you were active within the last 2 years, you can request that Needs Assessment. So there's a question. We asked for $50,000 with our Phase II application. If funded, does that mean we get the TABA funds? Can we get a Needs Assessment to help us use our TABA funds as well? Well, that's a great question.

It does not automatically mean just because you ask for something, and this is true across the board within NIH budget. You can request a budget, but the Institute or Center and the review, peer review is going to review that request, and Institute and Center is going to review that request. Grants Management is going to look at it, and this is when I said, make sure it's well-justified in your application. That's why. We're going to look at that justification. We're going to look at what you're proposing. Does it make sense for the application? Does what you're proposing seem to fit and be in line with the overall project? So, no, it isn't guaranteed, but a well-justified request that makes sense for the proposal generally has a much higher chance of being accepted and being something that NIH is going to fund.

You could get a Needs Assessment, again, the Needs Assessment just to complete. The eligibility simply indicates that you need to have had a Phase I active over the last 2 years, so provided that you've been in with that eligibility, you can request it. That said, I'd encourage you to request it earlier rather than later because it can really help you determine what to do with those Phase II funds, so we generally encourage people prior to application to really look at reaching out and doing that Needs Assessment.

Can we get a Needs Assessment first then get Phase I TABA Funding and then apply for Phase II TABA Funding? And the answer there is no. You can either get .. . Again, you have to have had an active Phase I award in order to get a Needs Assessment Report. Once .. . You can either do Needs Assessment or receive TABA funds, but you can't do both for the Phase I. However, you could get a Needs Assessment Report and then apply for Phase II TABA Funding, and, again, the hope is, that, that Needs Assessment Report will help you understand what you should be trying to address within your Phase II application.

Oh, here's a great question. Does this mean that if we budget TABA Needs Assessment in our Phase I proposal budget that all that money will go to RTI? This is a great question, and I'm really glad this was brought up. If you want to use your own vendor, if you don't want to go through the Needs Assessment Program, that's when you do TABA Funding, but you do not put anything in your application if you're planning to do a Needs Assessment. Put another way, you wouldn't put anything in your funding. You wouldn't have a line item for $6,500 in your budget if you want to do the Needs Assessment.

TABA Funding is specifically to provide funds for you to use your own vendors for Technical and Business Assistance. So someone asked, and this is another really good question. If I received a Niche Program .. . So that's the older program that is no longer available .. . 5 years ago on an entirely different Phase I, can we receive the Needs Assessment for a different and current Phase I? And the answer is yes. It's per project, so if you received a Niche Assessment many, several years ago for a different project, but now you have a new Phase I, and you'd really like a Needs Assessment, you can absolutely request that Needs Assessment, and you can get that report for that project.

So there's another question, and there's a couple of questions here about I-Corps versus Technical and Business Assistance, and so I think that's very, very helpful. Do you need to have gone through the I-Corps program to get a Needs Assessment? And then another question was, does the Needs Assessment help us get I-Corps? So while they're complimentary programs, they're not that closely coupled, so the I-Corps program is not required for you to get a Needs Assessment, and the Needs Assessment is not required for you to get an I-Corps.

They're really different programs, and your company many use one or both depending on your individual needs and what you may specifically need for your project. So I'm going to answer this next one because I think it's really important. For TABA, you would talk about IP protection. Can the small business use it to pay the intellectual property licensing fee to a university? So when we're talking about, when you say intellectual property protection, again, in the Needs Assessment Program, it is really assessment, so I'm assuming you're talking about Technical and Business Assistance Funding and getting support directly through the grant, and, again, it would have to be .. . The university would have to be, and that's back to that whole question of what is and is not allowable.

If the university and if there's a subaward to the university that's a core component of the grant, so you're paying them to do some work within the SBIR and STTR. That would fall under the unallowable because they would be a subaward or a consultant already as part of the grant. However, if it's a completely separate .. . It is completely separate, and it's focused, again, it's not on licensing, and this is another important thing. If you're just talking about, hey, we're going to pay the licensing fee to the university. That's not a consultant or a subaward providing assistance. That's just the license.

If, on the other hand, you want to pay somebody to do intellectual property and really dive into freedom to operate or provide guidance or expertise around intellectual property, that would be acceptable. So if you're just paying the licensing fee, and that's what you're talking about, you have to think, is that technical and business assistance? And per the definition, likely, and, again, this is something you should talk to your program officer about but very, very likely just the licensing fee by itself would not be considered technical or business assistance.

All right. So I know we are at time, and there are a number of specific questions here. They start getting more specific about individual applications and inti requirements, and so what I would encourage you to do is to reach out and talk with your program officer about your specific situation, particularly if you've been awarded a grant or are looking to apply to one in the future, and, again, if you're not sure who your program officer is, if you're at that application phase, please feel free to reach out, send us a brief description.

We're happy to connect you to the right person, and I see thanks, a huge thanks to Vicki who's been putting a number of the links in the chat, and she certainly put a "contact us" link at the back of the chat, and, again, that's the most important link. I always say that's the most important one because when you have questions, and I'm sure many of you may have additional questions as you're developing either in this project or future projects, please feel free to contact us.

So with that, I want to thank you all for attending. We really appreciate it. Great attendance today, and we encourage you to reach out and talk with us if you have further questions about the Technical and Business Assistance Programs at NIH as well as the broader SBIR and STTR programs. Thank you so much and have a wonderful afternoon.