TABA Consulting Services Webinar Transcript

Chris Sasiela: Good afternoon. I am Chris Sasiela. I am the innovator support team lead in the small business education and entrepreneurial development office at NIH. I am the primary person who is coordinating the technical and business assistance program for Phase II small business awardees at NIH. We call this our Consulting Services program. Over the next half hour-ish, I'm going to run through the program, how it's set up, how you become eligible, how you apply, what you can expect if you are accepted into the program. And then we are going to field some questions that either have been pre-submitted or that you're going to come up with throughout the event. Joining me for the Q&A session today will be the health and human services, small business program lead, Ms. Stephanie Fertig and the senior project manager for the SEED office who coordinates this program with me, Mr. Pablo Gersten. For now, let's just kind of jump in. Okay.

What I'm going to do today is I'm going to run through this website. So you see the URL at the top of your screen. You can join along if you'd like, or just watch me as I run through it, either way, you should be getting all the content you need. So the small business Phase II TABA Consulting Services program provides our awardees or some of our awardees with consulting services worth to up to $50,000 worth of value from independent vendors. In order to qualify for this program, you must have a small business award in Phase II that has been active no earlier- or no later than? I know, no longer than? Let's go with that- since September 1st, 2020. So this year's program, the date for your active award must be from September 1st, 2020, forward. Within the program, you are able to request an independent vendor perform a service in one of four areas, either intellectual property, market analysis, regulatory, or reimbursement space.

So those are pretty big spaces. And let's- let me give you a few examples. So for intellectual property for instance, you might request a freedom to operate analysis. You might ask for

strategy about how to expand your intellectual property portfolio that already exists. Or you might ask for some assistance in preparing and filing your patent applications. When we talk about market analysis, this is a very big space. Some examples for market analysis might be things like customer discovery research, primary customer research, partnership strategies, market entry playbook, it's a very wide variety of things. If you think it fits the bucket, check that box. You can ask for regulatory support. This could be anything from a gap analysis of where you are to where you need to be to engage with a regulatory agency. It need not be FDA, right? It could be a European agency. It could be a non-food and drug agency. It could be at the- you know, the FTC. It could be the NRC. There are a number of different regulatory agencies overseeing products within the NIH portfolio.

It could be a request for meeting support. It could be the development of a quality management system or a clinical trial design strategy support, things of that nature. For reimbursement, the types of support requests that we've seen so far have been payer analysis, which payers would be most interested, and what are the pricing strategies for those payers? What is a current payment or pricing strategy analysis? How does a company request a new code for coverage or is a new code required? So those are some of the things that you might ask for support in through this program.

Now, I've already touched a bit on eligibility, which as I scroll down the page, you'll see companies must have had an active Phase II award within two years of the date of the request. And we are calling that date September 1st, 2020, or forward. In addition, you must have not received TABA funding from your Phase II award that you're asking for the support on, and you must not have requested an administrative supplement of TABA funding if you didn't put a request in with your original application, your Phase II application. And finally, there was a predecessor Phase II Technical and Business Assistance program called the Commercialization Assistance Program or the CAP program, for the award that you're asking the support, you may not have participated in that program. Some of those things, we were able to validate before we sent out your- the email to you, making you aware of this program. However, some, we are only going to validate after we receive actual requests for consideration. So your email announcing the program is sort of a preliminary "Hey, you may be eligible to apply," full

eligibility will be determined only after requests have been received and are evaluated. So that is part one.

The second thing is, due to the limited number of opportunities we have per year for this program, regardless of how many active Phase II awards any company has, you may apply for only one service request. So if you have two, three, four, five active Phase II awards, you need to decide internally which program has the most emergent need, and you can request one of these four services within for that program. You might, if you have multiple ongoing programs that are active, still be eligible next year, at which point, the next year program, assuming that this program continues, you could apply for a different program, but each year you can only request participation for one award from your company.

So how does all of this work? First, you receive an email, that part's easy, no effort on your part. Hopefully, we got the list mostly right, and if you are eligible, you did receive an email from us. That email would've come either over my signature block or the signature block of your small business program manager or your NIH program official. Once you receive that email, there is a link in there where you can submit a request for participation in the program. We need information from you to understand what project you were requesting the support for, what your request is for, what topic area your request is for and what you're actually looking to do within that request. So you need to give us that information in order for us to be able to evaluate it. Okay?

If you can include some proposed deliverables, some companies are already at a point where they have well evolved leadership teams and are able to identify reasonable deliverables. If you don't understand what the appropriate deliverables would be, that does not disqualify you from the program. That is simply if you are included in the program, a conversation that we will have once you are included. Okay? Once all of the applications or all of the requests for participations have been received, and the closing date for that is September 9th at 5:00 PM Eastern time, the portal will close at that time. There will be no late submissions. So 5:00 PM on September 9th, East Coast time, we will review all of the requests that we have received. We will review the eligibility of the company at this point based on the criteria I mentioned earlier, as well as is the company still an eligible participant in the small business program? Sometimes

we have great successes where our companies are acquired and lose status in the small business program, and that may disqualify you from the program. So if that is your particular state, then please, you know, reach out to your program officer, reach out to me, reach out to Pablo, we'll be happy to answer that question or attempt to answer that question. It's always better to submit a request and find out later you're not eligible than to not submit it, find out you were eligible and not be able to participate in the program.

So in addition to all those eligibility criteria, as I mentioned, we do have a limited number of slots per year, and we do go for balance across the entire mission space of NIH. So the date by which you must submit your request for consideration is September 9th, and by November 9th, you will have received a status message. The status message will be one of three things. It'll be either "Congratulations, you are invited to participate in this year's cohort, thank you for requesting consideration, but at this point you are not being considered for support. Please reapply next year, if you are still eligible. Or thirdly, you are on a very short wait list." The reason we have a wait list is because we are not sure of full eligibility immediately, and that may take longer than October 9th to determine. That may be determined only once we start intake calls and really digging into the requests of companies. So you will receive a message no later than October 9th, you will hopefully receive one- I'm sorry, November 9th, but you will hopefully receive one much sooner than that. That is our intent.

If you are accepted into the program- and I'm certainly hoping you are, because I'm sure you are- what happens next is that we start to develop what is called a statement of work document. And this is a point where our contractor that coordinates this program for us, Medical Sciences and Computing, will coordinate a call with your company leadership team, your NIH program official, potentially the small business program lead at your institute, and the seed office, and of course, an MSC representative, and we will dig into what you proposed as the work that you would like to have accomplished. We will start with a draft document that is in a specific format, and we will refine that document together through that hour-long conversation. Okay? Once that hour-long conversation has been concluded, the internal NIH team will take one week to look through it one more time. Sometimes we have thoughts after a call ends about, "Oh, this would be a great thing to add in, or here's a, you know, another

opportunity." And so we'll include those comments. We will return then or send that draft scope of work document to you, the company leadership. You will have two weeks; we will ask you to return that document within two weeks. It is your responsibility as the leadership of the company to finalize that document, we do not finalize it. You do. It is your program. It is your service. It is your company. It is your product, right? We're providing this as a service to you.

If you have challenges in turning something around within two weeks, you may have a vacation plan, you may have some other deadlines going on, things come up. I mean, heck we just went through a global pandemic, right? There's a lot that happens in life. If you're not able to turn it around within two weeks, simply let us know and say, "Hey, we need another week. We need a few more days, et cetera, et cetera." We're reasonably flexible as long as it's on your desk, right? If we're not holding up the program, we're flexible with what you need in order to make this the best thing that it can be. When we have that first meeting, that SOW-defining meeting with the NIH staff and the MSC staff and your company team, if you already have an idea of a vendor you would like to work with, it would be useful if you can identify who that vendor is, what that vendor is, and if you have a contact person or people within that organization. We cannot guarantee that your preferred vendor is willing to work with our program, but we will do our best to get a proposal from them. It's easiest for us and quickest for you if you provide that information as early as possible once we- you know, as we begin this conversation, because there is some lead up work where confidentiality agreements need to be put in place between MSC and any vendor that is considering bidding on this work. Okay?

Once we have received the final SOW from company leadership, MSC will take that and provide it to no less than five vendors, including any vendor that you pre-identify as one that you would like to receive a bid from. Okay? We work very closely with our vendors. We currently have over a hundred vend.. . One moment, please. Okay. It went away.

Vicki VanArsdale: Chris, I can hear you now.

Chris Sasiela: Okay, thank you. I'm not quite sure what happened. I never get phone calls. I'm very unpopular. Anyway, once we receive that finalized scope of work statement, MSC will work with no less than five vendors, including any vendor you may pre-identify as one you

would like to get a proposal from. And we request that those vendors meet with you to clarify that scope of work statement so that they can put together the strongest proposal possible. Hopefully, you will be available during that time period to meet with the vendors and help them understand your needs so that they can build strong proposals. MSC will forward any viable proposal to you. What is a viable proposal? It needs to meet your requested deliverables and it needs to be within the financial constraints of the system. So pretty low bar, because we tell the vendors this upfront. It is up to you as company leadership to determine which vendor you wish to work with.

Now, before my phone rang, I was getting ready to share with you, we have over 100 vendors currently in the program, and some of them do meet multiple service areas or are able to address multiple service areas. So for instance, if you don't already have a pre-identified vendor that you would like to work with or are interested in getting a quote from, we have currently at least 20 intellectual property firms, 70 market analysis firms, 67 regulatory firms, and 41 reimbursement firms. We are constantly trying to grow the number of vendors available because the NIH mission space is very large and we want to get a best-fit match for you. So in addition to anyone that you may propose to us, we are also always actively vetting additional vendors for inclusion in this program. And we identify among those vendors, we have a matrix of these people specialize in pediatric indications or in mental health, or they are, you know, whatever the different things are. And that way, we're hoping to be able to provide you with five excellent matches from the very beginning. Okay?

Once you have made- once you have received all of the vendor proposals, and the vendors will tell us if they're going to or not going to submit a proposal, so you may get up to five, or you may get fewer. Once you have all of those proposals on hand, it is again, your company, your decision, who you choose as a vendor. Even if you asked us to go and get a quotation from a specific company, you are not committed to working with that company. You can choose one of the other vendors that we identified that also submitted a proposal. Once you have determined which proposal you want to accept, it takes about a month, plus or minus, depends on if it's the first time we've negotiated with this vendor or a number of other factors, but it takes approximately one month for a contract to be executed between MSC and the vendor. Okay?

Now, that is an important aspect. The contract is between MSC and the vendor. And so it is not with your company, it's not with NIH, it's between MSC and the vendor. And as part of the project management of this program, it is a requirement that we put in that there be a kickoff meeting between the vendor and your business within two weeks of that contract being executed. MSC will attend that meeting with the intent of ensuring that from the very beginning, all of the milestones are defined and clear, the deliverables are understood, and there is an agreement in place.

Beyond that first meeting, MSC will receive from each vendor, for each company, each project, we will receive an update every month on what progress has been made, what challenges exist and how close, how much progress has been made. Right? So we get monthly status update reports. Depending on the request you have, the service provision may take a few months, two months, three months, or it may take up to a year. Sometimes a request is for support, for instance, for a pre-IND meeting and development of the briefing packet to support that. So developing the packet may take several months and then actually getting the meeting in place with FDA also takes several months, right? So some of the services are more extended than others. Regardless of how long it takes for this service to be completed, at the end of service provision, there is sort of a project closeout meeting where all of the work and the deliverables are reviewed, at that meeting, everyone from NIH, who is invited to that initial meeting is also invited to the closeout meeting. This is our opportunity as NIH employees and as your program support members in the innovator support team and within the ICs themselves to learn alongside you and become better stewards of our portfolios. And so that is, our interaction is at the beginning, helping you understand how to develop a strong scope of work statement, and then at the end, seeing what resulted from the project itself.

That truly does complete- I told you it'd be about 20 minutes, I hope- that completes my overview of the TABA Consulting Services program. And at this point, I see that there are some questions in the chat and some Q&A, and what I want to do before I jump to those is I want to review some of the questions that came in prior to today's webinar. Once I do that, I will stop, actually, I can stop sharing screen now and I can ask Pablo, excellent, wonderful, to join me on screen. And I'm just going to read through some of the questions. One of the questions said, are

we allowed to select the consultant or is it required to go through the MSC selection process? And as I just mentioned during my overview of the program, you can certainly propose vendors and we will do our best to solicit proposals from those vendors. However, even if you have a preferred vendor, it is a requirement that you meet with multiple vendors if there are multiple vendors interested in and able to support the need of your company. This is not a pass-through mechanism where you can simply say, "I have this vendor, I've been working with them for 15 years on a bunch of different projects, and I want them to work on this. So give them $50,000." That is not this program, if that is what you have in place already, and you have an excellent relationship with a vendor, then I highly encourage you to either include that support in your application or look and see if your institute or center participates in the administrative supplements for Phase II TABA funding. And you can request that and submit a request with a justified budget for that purpose.

We have another question that talks about Fast-Track awards, and we actually received a number of questions about Fast-Track awards. If you have a Fast-Track award, and I will raise my hand as you may have received an email in error, and that was my fault in terms of my review of the emails that went out and the awards associated with them. I did try to catch as many Fast-Tracks as I could, but I did miss a few as it turns out. If you only just began your Fast-Track and you are still in Phase I, you are not eligible to participate in this year's TABA Consulting Services program. You may however request a needs assessment, which is the TABA program for Phase I awardees. When you transition to Phase II, you will receive an email if this program continues and you'll be invited to submit a request at that time. Stephanie, did you want to jump on for a second and talk about the needs assessment program just for a few seconds?

Stephanie Fertig: Sure. Happy to do that. There is a technical- oh, I was not going to start video, though. There is- here we go, there is a Technical and Business Assistance program for Phase Is, that's the TABA needs assessment program. That is our centralized TABA service. And again, this is a third-party assessment of some of those areas that are really important for companies as they're determining what their next steps should be. So if you are in the Phase I and you have not asked for technical or business assistance, you have not received technical and

business assistance as part of your application or as a supplement, you would potentially be eligible for the needs assessment program. I'm going to put a link to the Needs Assessment program in the chat, and I encourage you if you are an active Phase I and you might be in your Fast-Track and you're not quite eligible for this program, please take a look at the TABA Needs Assessment program. And that could be a great way to determine what your next step should be and prepare you better to take advantage of this or other programs at NIH.

Chris Sasiela: Great. Thanks so much, Stephanie. The next pre-submitted question, we have two Phase II grants that are eligible for this program. Can we apply for both or only for one? And I did mention this earlier, but for full clarification, you may only- you will only receive a service support for one award. If you submit more than one application, we will call you up. either Pablo or I will call you up and say, "We need you to make a choice because there are a limited number of slots per year for this program." In the emails that were sent, there is a link, and the first thing that is asked of you when you click that link is to identify your company and identify the award. You may notice that you have the same award but for multiple years, that you can select in that second section. It does not matter which one you choose. And again, I apologize, this is an iterative learning process for me in how to pull and manage this thing. I'm usually fairly competent, running the program is great, the communications sometimes get me though.

The next question that came in, I inadvertently submitted the form. Not to worry. We know that many people just want to click through the form, understand the information that they're going to need to have at hand when they sit down to fill it out for real, we will pre-vet anything that's essentially an empty form, you need to have the vast majority of the fields complete in order for us to consider your application. And so don't worry about empty forms. You can click back into that link, resubmit another form. This is not a problem. Okay? We will see the most filled out form, and we will use that as the form upon which we execute our evaluation.

Q&A Session

And now that is all of the pre-submitted questions. I see that there are a number of questions that have been coming up in the chat. Pablo, did you want to sort of go back and forth on these or would you like me to take them?

Pablo Gersten: I can read them and you can answer them if you would like

Chris Sasiela: Sounds great.

Pablo Gersten: So the first question we have from John Tepper is, "What if we think we are eligible but haven't received the email invitation presumably?"

Chris Sasiela: Well, Mr. Tepper, Dr. Tepper, if you believe that you are eligible for this program and you have not received an email, you may reach out to your program officer and ask them, or you can send an email to either myself or Pablo. There is an email seedinfo@nih.gov, where you can submit a request and say, "This is my award number, I believe I am eligible for this program." We do have a way for you to apply if you are eligible and did not receive an email.

Pablo Gersten: Excellent. Our next question comes from Emily Peak, "Other than the broad categories, are there any specific limitations on what we could use the funding for?"

Chris Sasiela: I'm not sure I understand the question. Those four areas really cover the vast majority of the acceptable activities for TABA funding. If you look on the seed website, at the technical and business assistance program overview, you will see that there are allowable and non-allowable uses of TABA funding. The four areas that we have identified are generally inclusive of, I would say at least 95 to 97% of that space. So if you are unclear, if your service request would meet one of those four areas, or which one they would fall into, I would encourage you to go ahead and submit your request. We have had- in the first year of program, we had situations where people selected one service area and in discussion with them, we realized really that there was a better fit in a different service area. So we just switch them over. It's not- we're flexible. We just need some box to start in to begin the conversation. Hopefully that's helpful.

Stephanie Fertig: And this is Stephanie, I just want to jump in just as a quick point of clarification that TABA Needs Assessment and the TABA Consulting Services is not- you're not receiving funds, you're receiving services. The TABA funding is a different program. That's where you ask for funds. So you're receiving funds to use your own vendor, and you're doing that either within the application or as a supplement. And so I know you asked about funding

and I just want to clarify, you're not receiving funding here, you're receiving access to services, but I will put a link to the funding, TABA funding, so you can check that out as well.

Chris Sasiela: Thanks again, Stephanie.

Pablo Gersten: Our next question is, is SBIR Phase II eligible for applying to TABA Consulting Services?

Chris Sasiela: Only Phase II awardees are eligible-

Pablo Gersten: Phase II B.

Chris Sasiela: Phase II B is also a Phase II award. So yes.

Pablo Gersten: Okay. We have a question. Is there a list of vendors available?

Chris Sasiela: There is not. At this point, we do not publicize the list of current vendors included in the program.

Pablo Gersten: And that covers the next question, which is, could you share a list of vendors that you have? And I guess the answer is no, we cannot.

Chris Sasiela: I can however tell you that it's an ever growing list, and I've been extremely impressed with the quality of the vendors that MSC and the NIH team and the companies have identified.

Pablo Gersten: Our next question is, how many companies usually apply for this program and how many spaces are available?

Chris Sasiela: The number of companies, there is no usual, this is year two of the program, so I don't have a number for you. I also cannot give you a number of slots available, that is dependent upon the cost of each individual project. I do have a total budget within which I am working, just like the small business program has an overall budget within which it works. However, the number of projects that we can complete within that budget is a moving target and is why we have a wait list. So we are hoping that not everything comes in at maximum budget and we're able to meet the needs of more companies.

Pablo Gersten: Okay. Next question is, We received a Fast-Track starting this September. It's a two-part question. One, do we get TABA for Phase I? And I read on the website, there is 6,500 for Phase I. And the second part of the question is, for Phase II, when can we apply?

Chris Sasiela: So again, this goes back to what Stephanie was mentioning in terms of if you want money versus in-kind services. If you wanted the $6,500 Phase I- $6,500 for your Phase I project, you would've needed to include that in your budget request when you put in your Fast-Track application. And the same would be true for Phase II if you have a vendor in mind for whatever that would cover in your Phase II award. Regarding your ability to request the in-kind services, the centralized programs, if you did not request the $6,500, then you may request a Needs Assessment report, and Stephanie already dropped the link in there. And when you transition to the Phase II program at the next request cycle, you will be eligible to request inclusion in the program, if you have not taken funds.

Pablo Gersten: Next question is, is the cost of consulting or your staff taxable income for the company?

Chris Sasiela: I truthfully do not have any idea; however, I would not believe so. This is a service provision. This is not a money transfer to the company. So this should not be, but I am not a tax accountant. I'm not any kind of accountant.

Pablo Gersten: We have another question. I apologize. I missed the first few minutes. Where and how do you apply?

Chris Sasiela: You- if you are eligible for the program, you should have received an email with a link to apply. If you did not receive that email and you believe that you should be eligible for the program, please send an email to seedinfo@nih.gov with the award number that you believe eligible, and we will be happy to send you a link.

Pablo Gersten: Next question is, my Phase I ends on September 17th, do we have to wait until next year to apply?

Chris Sasiela: Yes. If you do not have a currently eligible Phase II award, you may not apply for the program.

Pablo Gersten: Next question is, can I apply for TABA funds for a Phase II that ended earlier in 2022?

Chris Sasiela: If you are not in a no-cost extension, and even if you were in a no-cost extension, I'm not certain, but if you do not have a current active award, I do not believe you can request a supplement to an expired award. So no, you cannot generally request funding for an expired award.

Pablo Gersten: Next question is, if a technology niche analysis was performed in connection with a Phase I award, is the company eligible to apply for TABA for the continuation Phase II award?

Chris Sasiela: Having received a Niche Assessment or a Needs Assessment on a Phase I award does not in any way- pardon me, my light likes to blink out on me- does not impact your eligibility for the Phase II program. You are eligible to apply for the Phase II program, regardless of whether or not you received a Phase I report.

Pablo Gersten: Next question is, is it possible to apply for TABA consulting services and TABA funding, or should companies choose just one of the programs? And I believe you have addressed this.

Chris Sasiela: Yes, you must choose one or the other.

Pablo Gersten: Next question is, the PO is supposed to work with companies on TABA. If the Phase II is completed, is the PO called back to work on TABA even though the project is over?

Chris Sasiela: The program officer will be invited to the scope of work defining call and will be invited to the closeout project summary call. We do not require them to attend, but they will be invited.

Pablo Gersten: And then the last question we have currently in our Q&A is, we're very close to starting the Phase II of our Fast-Track grant. Can we apply now and receive TABA in Phase II by the time the review process is completed?

Chris Sasiela: You must be in Phase II of your award by September 1st of this year in order to be eligible for the TABA Consulting Services program in the current year cohort.

Pablo Gersten: And the follow up to the previous Phase II B question, our Phase II B ended a couple of months ago, are we eligible?

Chris Sasiela: If you received an email with a link, you are eligible to request inclusion in the TABA consulting services program.

Pablo Gersten: I got another one that just came in. We didn't include TABA funding in our application. Would you elaborate on how we can request TABA funding?

Chris Sasiela: Well, the easiest way is before you apply, obviously, and building it into your budget, you would justify that budget just as you would any other budget and you would include it on lines, I believe it's eight, nine or 10, the other lines of your overall budget build-out form. If- I'm going to ask Stephanie to help me here, if you could pull up the notice for the supplement, the administrative supplement for TABA funding, different institutes and centers across NIH, and, you know, there are 24 different funding institutes and centers, each have a different policy about their willingness to entertain requests for TABA funding after an award is made. And so Stephanie has just posted that link into the chat. I encourage you to hit that link and see if your funding institute or center does participate in supplement funding.

Stephanie Fertig: And you can always reach out and talk to your program officer because even if TABA funding isn't accessible, there may be other options, other resources available at the institute or center. So always a great idea to reach out to your program officer before submitting any supplement request and ask them if you- you know, if there are any other options that are available to you

Chris Sasiela: True that.

Pablo Gersten: Just received another question in the Q&A. Again, this is a TABA funding question, not so much TABA Consulting Services question, but is TABA funding separate from the budget limit specified in the funding opportunity announcement?

Stephanie Fertig: Great question. So, a TABA funding is- TABA funding is part of the overall budget when you put together your total budget. We do have SBA guidelines. Those are guidelines. When we're looking at whether or not something exceeds the overall budgetary

guidelines, for the purposes of our reporting to the SBA, we don't count TABA funding. However, and this is extremely important, individual institutes and centers have their own budgetary guidelines. I strongly recommend if it includes TABA and it's going to go over that specific budgetary guideline that's in the omnibus solicitation or in any solicitation, reach out and talk to your program officers. Some institutes and centers say, "Look, we're going to- this is the highest amount we're going to fund, inclusive of TABA fee, indirect cost, direct cost, TABA, everything. This is, you know, this is the amount we're going to go up to." And they can do that because individual institutes and centers have their own budgetary guidelines. So from your perspective, what is more important is to know and understand what are the budgetary guidelines of the institute and the center you are likely to apply to- and sorry, likely to be assigned during the application process.

Pablo Gersten: That is it for the questions in the Q&A portion, unless there are any more that come in.

Chris Sasiela: Okay. Well, again, I thank you all for taking time out of your very busy schedules to learn a little bit more about this program. Hopefully, this webinar has been helpful. We've been able to address quite a few questions, and I look forward to seeing a very robust response to this request for consideration and talking with a fair number of you in the months to come. Have a wonderful afternoon.