

NIH TABA Consulting Services Program Webinar Transcript

June 9, 2023

Chris Sasiela: My name is Chris Sasiela. I am the lead of the Innovator Support Team in the SEED office. SEED stands for Small Business, Education, and Entrepreneurial Development. We are the office that coordinates the small business and several other translational programs across NIH. You are on this webinar today because you received an e-mail telling you about the Technical and Business Assistance Consulting Services Program. We have a relatively short presentation planned, after which we will be taking questions and hopefully providing some answers. Joining me on today's webinar is the project manager for SEED who oversees this program and that is Pablo Gersten and our contractor project manager, Sowmya Sreekanth. My apologies, with Guidehouse.

And, we also have the PI of a small business awardee company that went through the program recently, Jessica Ochoa Hendrix, and she will be answering ... hopefully, you guys will have questions specifically for her by the end of this webinar. So, a few housekeeping items, this webinar is being recorded. The recording and the materials will be made available 7 to 10 business days after this ends, hopefully closer to 7 rather than 10 because we do recognize you may want to review it as you prepare your own requests.

Then secondly, please submit all questions in the Q and A box located in your control panel, which for most people is going to be along the bottom of your screen. With those few housekeeping tasks taken care of, I am going to invite Pablo Gersten to take over control and tell you about the nuts and bolts of our consulting services program. Pablo.

Pablo Gersten: Thank you, Chris. The small business space to Technical and Business Assistance, TABA, Consulting Services program provides select NIH Phase II small business awardees with consulting services worth up to \$50,000 from independent vendors. This \$50,000 is a hard limit established by statute, we cannot exceed it. Program participants select one emergent need to address from the following four areas: Intellectual Property Strategy and Services, Market Analysis, Regulatory Strategy and Services, Reimbursement Strategy and Services. Some

examples of services requested in previous TABA Consulting services cohorts include for Intellectual Property: an IP landscape analysis, IP portfolio strategy, or a request to draft and submit a patent application.

For Market Analysis: a commercial launch strategy, customer or market discovery, or maybe even an influencer identification. For Regulatory Consulting Services: gap analysis or regulatory strategy and roadmap development, or an action plan for a 510(k) data development. For Reimbursement Consulting Services: a reimbursement landscape analysis, a reimbursement plan or playbook, or a payer market access strategy documents. Which NIH funded companies are eligible for the program, companies with an active Phase II award within 2 years of the date of the TABA Consulting Service request, which in this case is June 7th, 2021, that neither received TABA funding in the original Phase II or phase IIB award, nor received TABA funding as an administrative supplement to the original Phase II or Phase IIB award, are eligible to request one consulting service.

Companies may only request one service upon receiving an e-mail inviting them to participate in this program. Regardless of how many eligible awards they may have, you should have received this invitation to participate in this year's program on June 1st. Companies that are not selected in the current cycle may submit the same or a different request in a future cycle if they receive another e-mail invitation for that project. So, how do you request participation in the TABA Consulting Services Program? Well, participation is a two-step process.

Step one, eligible companies request participation. You should have received an invite with a link to request consulting services on last Thursday, June 1st. If you have not received an invitation, but believe you have an eligible award, please reach out at the conclusion of this webinar. After the request for service period closes at 5 p.m. on July 7th, NIH staff reviews submissions and may e-mail company leadership with any questions that arise. Prompt responses are required. Some helpful information to have at hand when completing this request include award ID, concise update on the award progress, justification for the request, or proposed deliverable. As I mentioned previously, this year's submission period is open for 1 month, from June 7th through 5 p.m. July 7th.

The second step of this process includes NIH selecting and notifying companies of their participation status. SEED works with NIH program officers to ensure requesting companies are fully eligible and to prioritize companies into current cohort based on multiple criteria including, but not limited to, feasibility of the TABA program to meet the company's stated need and equity of representation across NIH interest areas. Companies may be assigned to or wait listed for a cohort or denied participation in the current cycle.

Companies typically receive a status message within 2 months of the end of the request period. Waitlisted companies receive their final determination within an additional 2 months, so it may take up to 4 months for some companies to receive their final determination. And finally, it is possible that some companies initially accepted may be identified as a [Indistinct] program during the statement's award defining thought. Here is a sample application for a fictitious company we created called Fake Hats. Some examples of information requested include company name, support area requested, CEO and PI, website, sponsoring NIH institute or center, a brief description of your technology, market area, technology stage, and primary regulatory path.

Some additional questions we asked in the application, you will be asked to describe the public health impact of the product or project for which you are requesting consulting services, why are you requesting the specific consulting service selected and how will this contribute to the development of the NIH funded project or program, what one specific outcome are you seeking through the TABA Consulting Services Program, what interim and final deliverables do you expect to receive through the program, what qualifications and experience should a vendor possess, you will be asked to include any work your company has done towards the goal of this request and, finally, if you have received ... If you have a preferred vendor, you could submit contact information to include consideration in the vendor matching process.

All of these fields are limited to a specific amount of words you cannot exceed. If your company is accepted into the TABA Consulting Services Program, you will work with NIH and its contractors to develop a statement of work document for vendor recruitments. Companies are expected to finalize this SOW and return it to NIH within 3 weeks of the SOW development call. This SOW and development goal includes SEED Subject Matter Experts who work to refine the

request and create a formal scope of work documents. Your application will be used to generate this initial draft SOW, and prior to the call all attendees will receive that draft SOW. During the 1 hour call the NIH team will refine in real time the vendor support request.

That information that is useful for the company leadership to have in hand when preparing for the SOW call include a brief presentation on the project. It does not have to be slides; it can be informal. Preliminary information about the topic area that TABA Consulting Services Program will focus on, and proposed deliverables and an anticipated timeline, if you know it. Key contact for potential vendors if there are specific vendors you would like to include in the program.

The NIH team will provide your company leadership with a draft SOW document within a week of your intake call, and company leadership is asked to return that finalized SOW within 2 weeks of the ... To initiate vendor selection. A finalized SOW is expected within 3 weeks of your intake call. So here are some sample SOWs developed from the sample application you saw previously in this presentation for the Fake Hats company. We will make these example documents available after today's webinar, and additional sample materials to assist you in this process. This first example is for an IND submission.

Preparing and submitting an IND is likely unlikely to fit within the allowable program budget, so a request of this kind is likely to be declined. However, a pre-IND request, preparing the gap analysis, developing and supporting that pre-IND is likely to fit within the allowable program budgets. At this point, I'd like to turn it over to Sowmya Sreekanth, our colleague with Guidehouse, to walk you through the vendor selection process, surface provision and close out of the TABA Consulting Services Program.

Sowmya Sreekanth: Thank you, Pablo. Hello, everyone. I am Sowmya Sreekanth, lead program manager at the Guidehouse. We are global consulting leaders to help specialize in integrating commercial and public sectors. Our mission is to simplify challenging programs. So we execute the TABA Consulting Service Program logistically on a day-to-day basis to create successful projects within the life sciences space. We focus on the four primary TABA program areas and also offer additional relevant expertise, which allows us to tailor our services to meet the needs of all small businesses. We identify and provide the best internal and external consultants,

subject matter experts in these niche areas to support a wide range of innovative and creative project scopes we created in this program, which you just saw earlier in this presentation.

To accomplish this, we manage and maintain a diversified portfolio of vendors, [Indistinct] the number changes annually, but currently we have about 100 vendors dedicated for the TABA program. We continuously monitor their performance metrics to include in the program.

However, we also welcome, if you have a preferred vendor and you want them to be included in the program, we welcome them. They have to undergo the vendor vetting process. Some of the definitive requirements are the need to be able to sign a non-disclosure agreement and they need to follow federal regulations, [Indistinct]. So, this is a step-wise onboarding on to the program, so we request all these records to be made to us as early as possible if you're selected to the program. In the next few slides, I will provide a brief overview of the process and the main takeaways. So, once we receive the scope of work, we just created within the program and approved by the small business, we initiate the vendor selection.

Our choice to ... Of the vendors depends mainly on the subject matter expertise, the past performance which is demonstrated in various case studies and similar projects or even later projects, we considered that the value proposition of each vendor team and mainly the subject matter experts they can provide us. Guidehouse also internally has two experience teams, the subcontractors and the procurement teams, who always see this process from the beginning toward any possible hurdles with these vendors you have chosen.

Moving on, our vendors solicitation process is a 28-day phase approach with three distinct segments. The first 7 days is SOW acceptance period. The vendors will use this time to review the project scope, especially with the vendor qualification criteria, and confirm if they're interested. Once they submit that interest, it's the time for all pre-proposal meetings with the small businesses. We introduce the interested vendors and encourage them to conduct an in-depth review of the project scope and about the company.

The last 7 days is a proposal submission phase. Initially all proposals are submitted to the Guidehouse. We give you the proposals primarily to make sure the period of performance and the budget are within the program requirements, and then submit all these proposals to the

small businesses. The small business teams have 2 weeks to decide a vendor and select them. In the meantime, if you have questions, we are ... We will ... You can reach out to us, ask questions about the vendors, proposal or any elements. Once you decide the vendor, the winning proposal will be submitted to the Guidehouse legal team. This is the longest phase of the program. It can range up to, from 2 weeks all the way up to 6 weeks.

This time, in my experience, it can be very valuable advice for small businesses to create your goals, what you want to see and define your deliverables and prepare your internal data room, organize the necessary documents as we are gearing up for the kick-off meeting. Okay. Once the contract is initiated the vendors will have 2 weeks for a kick-off meeting and to initiate the service. This will be the official hand off of every project. We'll confirm the milestones, define the deliverable dates, and also discuss expected contributions needed from both small business and vendors to accomplish the project goals.

Although we have handed over, the Guidehouse still will oversee all the project activities, we monitor the compliance of milestones and deliverables, we submit the monthly status report to the NIH SEED office in this time. If there are any unexpected scope changes or timeline changes, we work with you, take relevant steps as it's a case-by-case for every project and be subject as changes to NIH and the move forward to make sure your project is successful.

Finally, we schedule the close-out meeting and invite all the relevant NIH SEED office and also IC team members. After the close-out meeting you will have an opportunity to provide your experience and access our survey and discuss what you've learned. Overall, all demonstrative responsibilities will be handled by the Guidehouse and we will be your partners throughout from the inception of the service project to the end, until the close-out meeting. At this point, I'll hand it back to Pablo to review the CS timeline.

Pablo Gersten: Thank you, Sowmya. So, really quickly, I just wanted to note a generalized timeline. At this point today requests are open, you can click on that link in the invitation and submit your application, and we are having our webinar. By July 9th all requests will be due. By August 9th, status notification, SOW calls should be scheduled. August through September is the SOW development period and September through November is the vendor selection

period. There is some overlap there because October through December includes the vendor contract execution. And October 2023 through January 2024, we expect accepted projects to kick off. At some point March through October '24, we expect those projects to be completed and we will be conducting close-out calls with these small business and vendor and NIH between March and October '24. At this point, I will turn it back to Chris and Jessica.

Question and Answer Session

Chris Sasiela: Excellent. Thank you, Pablo. So, we are now at the Q and A section for today's webinar. And, I have been answering some questions that came in through the Q and A, and you should be seeing those answers posted. There are two that I've left up that I am going to start with while you guys come up with even more questions.

And Pablo, Sowmya and Jessica, come on video and unmute themselves so we can little contribute to the conversation and help you understand this program as fully as possible so you understand the attributes and limitations of it. So one of the questions that I've left unanswered in the chat is, does receiving TABA funding as a supplementary request to an existing award create any obstacles to subsequently receiving CRP funding? So, one of the reasons I didn't answer this online is that I want to clarify what CRP funding is for those who may not be familiar. The CRP is another funding mechanism, it's the Commercialization Readiness Pilot Program and it allows for a different type of support than an R award, the R41, 42, 43, 44 series with which most small businesses are familiar.

The funding mechanism is actually called an SB1. Because it is an SB1 and not an R mechanism in funding, what that allows is a greater percentage of outsourcing of activities. So where a Phase II award in the SBIR/STTR program allows for between 40 and 50 percent outsourcing, the CRP allows for up to 90 percent outsourcing. And that is intended to support the type of technical development that you really don't want to need to have to develop in the house as a small business. Things like IND-enabling studies, GLP [Indistinct] stuff. Scale up with manufacture, which you noted on a ... You're going to farm it out anyway to a CDMO, right? So, that is what the CRP funding opportunity supports. Now, for the question of does receiving TABA funding interfere with your ability to subsequently receive CRP funding, the answer is no.

Those are totally separate mechanisms, totally separate applications. There are small TABA ... There is a small CRP and a large CRP, they're all one CRP this year, but they do support small projects for technical assistance in the form of administrative assistance as opposed to manufacturing and testing assistance. The smaller award amount is not ... You would not be blocked from applying for that because you have received TABA funding or TABA support services through this program if you end up applying for the CRP. They are independent. So.

And then, the second question is does the TABA application require a preliminary budget? If so, then how is this determined if we do not know which Guidehouse consultants will be chosen based on the SOW? So, no. You do not need to have a budget. If you have a general idea of how much something you're asking for is going to cost, that is helpful. But I can assure you that when the government says we will pay up to \$50,000, the vast majority of proposals will come in maximizing that budget. So, if you come in asking for less, then the vendor discussions you have will likely be optimized to your benefit to get the most out of this program.

If you come in with a request that is well beyond the scope of the budget supported by the program, then you will have that reverse conversation with vendors where they will say, "There's no way we can do this within that amount of money, here is what we can do." So, it's not important for you to fully understand or even attempt to build a budget. You will not have access to that information. Jessica, can you talk about the experience you had in terms of working with the vendors and coming up with the optimal balance?

Jessica Ochoa Hendrix: Yes, I'd love to. So, first, my name is Jessica Ochoa Hendrix. I am the CEO and cofounder of Killer Snails, and Killer Snails went through this process last year. And the process was actually very smooth. The folks at Guidehouse are incredible experts and extremely organized. So, when we applied, the process to apply was straightforward and did not take a lot of time, and we were just given a lot of support.

So we wanted to apply for a patent, and as part of that we wanted the folks that we would work with, the vendors, to propose what that would look like to go through the patent to do an IP search to see what else is out there and to see who else was working in this space. Based off the proposals that were received by Guidehouse, Guidehouse handled everything. So it was not

an enormous time suck as the PI. After our initial discussion we came up with the scope of work and she put out the call to the vendors. I was trying to look up and remember how many vendors. We ... Actually, I want to say, like, maybe five.

Chris Sasiela: Four, five.

Jessica Ochoa Hendrix: Yeah. I think it was about five vendors, and I did schedule time to speak with them. And so, that took a little bit more of my time, but I thought that was an important step to actually get a sense of who they were and what working with them would be like. So, it's not that Guidehouse just kind of sticks you with somebody and best of luck to you. It is a partnership where they find the people, they help you to write the scope of work to be as clear as possible, and then they allocate five different potential partners and you meet with them and then you make a decision after having those interviews to say which one you'd like to work with. The folks that we ended up working with were great.

They were super responsive. They were very organized. The way that we personally handled it was we scheduled, I think it was two meetings a month, and they would send the agenda and readings in advance. I am somebody who really enjoys reading documents in advance, so I appreciated them always sending it several days so that I would have time to read it and I would come prepared with questions. So when we met we would usually meet for about an hour and we were able to get through everything we needed to get through during that time. There were many back and forths during the process of the folks that we were working with would, they'd draft it up, I'd take them through exactly what it was that we were working on and then we would highlight the areas in which we thought would be patentable, and then they would go and they would do keyword searches and they would come back with a variety of documents.

And they ended up presenting us with some super helpful information about the landscape and who else was working on the same kinds of things, who had filed other applications, where those were, and then they helped us to submit ours. We are still in the process, because those of you on the video who may have done the patent process before, it takes kind of a while. So we are still in the process, but we are hopeful that that's going to end within the next couple

months. We've had to do one office action since originally submitting, and we have hopes that with the clarification that that will go through.

And the close-out meeting was really nice because it, when you end the relationship with the partners, essentially the organize everything really nicely in terms of like here are all the folders of things we worked on, here is like the IP landscape, here is what the competitive set looked like, here's where all of the different patent analyses that we did, here is your proposal, here are all the figures from your proposal, here is the initial response in the filing. So it was a super smooth and incredibly helpful process. I would rate it very highly. With that, I'll stop talking and see if anyone has any questions.

Chris Sasiela: So, there have been a few questions posted. I am going to take the first one and then, Pablo, perhaps you'll take the second and third that are currently in the queue. So, the first question is, if our proposed consulting needs exceed \$50,000, can an applicant be accepted for two TABAs over, say, 2 to 3 years? Splitting up the SOW over multiple TABAs? This assumes continued funding for TABA in 2024 and beyond obviously. So, thus far we are entering year three of the full program. We have not funded the same company in cohort one and cohort two. I'm not saying it's impossible.

It is possible if companies have multiple awards, and different institutes or even the same institute are willing to prioritize them year over year for this program. I don't have a preference one way or the other. I leave the prioritization largely to the institutes to help make that decision. However, there is no way to guarantee service in a future year and you are only eligible for one TABA Consulting Services provision per Phase II award. So, selecting a program or proposing a service that would run multiple years and cost significantly more than \$50,000 would not be a good fit for this program. There would be other ways that you should seek funding for that project. So, that is my answer for question number one. Pablo?

Pablo Gersten: Stephen asked does the grant PI need to lead the communication with Guidehouse and vendor, or can other company personnel lead? The answer to that question is no, the grant PI does not need to lead communication. It can be other company personnel. Quite frequently we have a company CEO or CTO, we have company officers. In the application

process you can designate your point of contact for this program. Obviously it makes some sense to include the PI on some of these calls and some of these communications, but it is not a requirement of this program. And lastly, we have a question, so can we only choose or apply for one of the services offered? And the answer to that is yes, you may only request one service per award, per year.

Chris Sasiela: Excellent. So, as you were talking earlier, Pablo, about the program, you were very clear, as was Sowmya, about the timelines that we have, the expectations for responsiveness about this program. I'd like to just offer a comment about why that is, at this point. The reason those timelines are so tight is because in the government money expires. So this program can provide support for a finite amount of time. It's part of why we're starting the program a little earlier this year to try and gain a few months for some of those things that take longer to complete, such as IP filings or regulatory meetings or filings. And so, we are quite strict about these timelines. And if you are not responsive initially, you will get an e-mail from Pablo or Sowmya.

If you are not responsive secondarily, you will get a phone call from Pablo or Sowmya. And then, if they come to me and say we still are wondering what's going on with this company, we are very concerned that there's been a health issue or some other crisis come up, you will actually get a call from me. And, usually it's exactly that, that there's been some significant event that is diverting the attention of the leadership team and we do our best to work within that. But I do want to make sure that you are aware that when we say we're going to get something to you within 5 business days, we do it.

And when we want it back from you in 10 business days, we really want that to happen. It's only for your benefit. We know it takes time and you have other priorities, but it is important. And then the second part of that, is Jessica, you did an IP filing, right? But your office action is still ongoing. You've graduated from the program, right?

Jessica Ochoa Hendrix: Yes.

Chris Sasiela: So some of the relationships that this program will support will go longer than the program just by the nature of what is being asked for. Can you talk a little bit, Jessica, about

how Killer Snails is managing that since the TABA Consulting Services program money has run out for your IP support?

Jessica Ochoa Hendrix: Yes. It's a great question. It's one of the things that we talked about in our close-out was in our scope of work we specified that they would file the patent. We knew that the timeline was not going to include that we would get the patent or even that a final decision would be made on the patent because the patent office is backlogged a lot, so when, if you are applying for a patent, you do need to realize that the funds that are coming through TABA will help you to file it, but they will not help you with any of the response, because even if you pay for the expedited filing, you're still likely not going to hear anything for at least 6 months, at which time your TABA funding has ended.

So, the way that we chose to handle that was we put a lot into the scope of work of what we hoped to get from our partners during that time so that we could use the full budget to get useful information that could help us strategically as we move forward knowing that we would also need to budget from our own funds for the expected office actions. And also, you know., with the patent you still have to, you know, every few years you have to refile, you have to maintain your claim, and there are funds associated with that too that are not going to be covered by TABA.

That is something that you're own company funds will need to cover if you are doing the patent route. However, the relationship that they set up for us was great and otherwise I don't know if I would have found this particular law firm because I am based in New York and this company is based in Arizona. So they probably never would have come across my radar if it hadn't been for the help of Guidehouse.

Chris Sasiela: And that is ... Thank you for bringing that up, that's something that we do try to stress during that initial SOW defining call, is that this is a relationship in many cases that will live beyond the TABA project itself. If it's a simple market analysis, then maybe not. But many of the other services, it's a way to try a vendor and hopefully have an excellent outcome. But there is an end date and a dollar amount that is associated with it. So hopefully we get the combos right, and in most cases we have. Not all. We could have easily also brought on at least

one PI who was not as thrilled with the outcome of their service provision, but strangely we chose to go with a happy person. Pablo, I see there's a question in the Q and A box, would you like to address it?

Pablo Gersten: Sure. So, limited to one service per award means, for example, SOW cannot include both assistance with patent filing and FDA regulatory approval and you are correct. It cannot. Patent filing would be an IP strategy and service and FDA regulatory approval would be a regulatory strategy and service and you cannot slip them across.

Chris Sasiela: And the reason for that is that it costs time and overhead to develop the SOW and to identify and gauge the vendors and then execute contracts. And doing that in two different areas is much ... Is very burdensome, and is just not part of how we are running our program, but if you choose to simply develop your own SOWs, go out and find your own vendors, you can request TABA funding when you apply for your Phase II award in any distribution of ways that meets your business needs. Existing trademark renewal, Ronnie wants to know if that is an acceptable IP request.

Absolutely. That would be any IP request would be completely appropriate and reasonable. I'm very good at the uncomfortable silence, just so that you know. I guess one thing I'd like to ask Jessica, who, she's the only person who doesn't report to me, who's on this call. So Jessica, you know, what would you caution people about coming into this program?

Jessica Ochoa Hendrix: I would caution, I guess two things. The first one is that I would caution you to think about what is actually doable during this timeline. So for the folks in here like can I do this and this? Even if you had more money I don't know that you necessarily could because there are timelines that are just long, and if you're trying to accomplish too much, that's not going to be possible. And if you start on the path of accomplishing something, you're going to be really sad when the time runs out and you weren't able to do it. So I would caution you to think about what you could realistically do during the length of this application process and the program itself.

The other thing that I would encourage you to think about is that the person or teams that you're going to be working with, you're going to be working with other partners. So having

somebody like Sowmya from Guidehouse partner you with work with, interview these different people is important because it would have been easy to say, "I'm really busy, I cannot meet with five different people and interview them about this thing. I'm just going to go with the first one off this list." But if you do that you are really missing an opportunity to see the quality and how they work.

I think all of the folks that I spoke with would have done a good job, but the ones that I chose were really good partners for us because of their particular interest in the kind of work that we do. So you can't ... It would be hard to have done that without putting the time in. And I do think that you putting the time in as the applicant and as the person who's going to be leading this work matters a lot in terms of the end results that you'll get.

Chris Sasiela: Thank you. There is a question about TABA funding. If requesting TABA funding as part of the grant, does that amount go on top of the budget cap or is it included in the budget cap? So I'd like to answer this in a couple of different ways. First, NIH has budget waivers for the vast majority of projects that we support. So the concept of a budget cap is a little bit different at NIH than it is with other agencies that also have small business programs. However, the National Institute of Health's 24 different funding institutes and centers, each of which has its own approach to funding and some of whom have very limited budgets.

So if you are applying to an institute that says the maximum amount that we will allow for a Phase I or a Phase II SBIR is this dollar amount, then that 50,000 is going to be included in that amount or the 6,500 will be included in that amount because they will not fund above that amount and they would just cut your budget down to that amount, percentage wise across the board if you come in higher than that. So, that is always a question as with any funding question, you should talk to your program officer as you're putting together your application.

There is a question about the supporting documents and video for this presentation. I believe that perhaps Laura can address this. I know she loves it when I put her on the spot in the middle of an event.

Laura Bonilla: Hello, everyone. Yes, we will be making the recording and materials available within 7 to 10 business days right after this session. So they will be available and we will share that with all of you via e-mail.

Chris Sasiela: Excellent. Pablo, I believe the next question would be good for you. Do we want to go backwards in the slide deck?

Pablo Gersten: We can. I am going to reverse it now to that point. So I believe we are talking about these requirements.

Chris Sasiela: Yeah.

Pablo Gersten: So, the question, the core question ... and to answer the last part, is there a word limit? Yes, there is a word limit. It is shown in the application itself, but you can also see it on your screen here. And, these questions include, describe the public health impact of the project or project for which you are requesting consulting services, you have 50 words to respond to that. Why are you requesting the specific service selected above and how will this contribute to the development of your NIH funded project or program?

You get 150 words for that. What one specific outcome are you seeking through the TABA Consulting Services Program? You get 100 words for that. What interim and final deliverables do you expect to receive through the TABA Consulting Services Program? There's 150 words for that. What qualifications and experience should a vendor possess and highlight to demonstrate their capability to create your desired deliverable?

This is a really important one. Response is limited to 100 words there. And then, include any work your company has done towards the goal of this request, include examples. And finally, you will have an opportunity to provide a contact information for a preferred vendor. So part of this question was, you know, how much details required, is there word limits? So yeah, there's a word limit. Obviously as much detail as you could provide within that word limit, that would be very, very helpful. Hopefully that answers this question.

Chris Sasiela: Excellent. And Pablo, while I take the next question, I'm going to let you figure out the conundrum of the next one.

Pablo Gersten: Yes.

Chris Sasiela: [Indistinct]. How are we seeing companies handle projects where they have an existing vendor but want to take advantage of TABA? So the example is an IP related project and you already have an IP vendor. So Peter, in that case you would simply have your vendors put a proposal together of what you can get for \$50,000, and/or less, hopefully, if they're working with you and already have all of that background in place, and then you would submit that as a TABA funding request with your Phase II application.

That is if you already have an existing vendor relationship, that is the best way to ensure you get the money. This program is competitive and if you know who you want to work with and you know what you want to do and they can get it done for \$50,000 or less. Or even more, but you can get at least \$50,000 of it done through your grant award, then by all means please submit that request with a letter of support from your selected vendor or vendors with your Phase II application. Over to you, Pablo.

Pablo Gersten: Okay. So the question is the website says the deadline is July 7th, but the presentation said July 9th. My apologies, the deadline is July 7th, that is a Friday. July 9th is a Sunday; we do not expect and or anticipate anybody to be working on the weekends. So the deadline is 5 p.m. July 7th, not July 9th. My apologies.

Chris Sasiela: And in fact, the system is set to close. So the system is automated. It is open right now and it will close at 5 p.m. Eastern Daylight Time on Friday the 7th. We require you to take the weekend off. Okay. We are at 1:45, that's probably about as long as I thought this was going to run. If people have more questions, please pop them in right now, because otherwise I'm going to return 15 minutes to people's time.

It is a Friday afternoon. I know I was at Bio this week and I have a whole lot I need to try and trunk through. Okay. Seeing nothing else ... Oh, wait. Something came in. We already included \$50,000 consulting fee from a vendor to work on regulatory, can we still apply to TABA? No. You can receive one or the other, money or consulting services program. You cannot get more than \$50,000 TABA and you cannot get money and services. It's an either/or. The question of

whether materials are going to be e-mailed to us, we are certainly going to post them on a website and, Pablo, take it away.

Pablo Gersten: Yes. So as I believe Laura mentioned, we will be posting and making the materials available on the website and send a link to all participants today.

Chris Sasiela: Including those who registered and were perhaps unable to actually make it to the event itself.

Pablo Gersten: Sure.

Chris Sasiela: Okay. With that, have a wonderful weekend, folks. We look forward to seeing excellent applications or requests for consideration in our program and having a heck of a hard time deciding who we are able to support and supporting as many as we can. Have a wonderful weekend.