NIH's Seed Fund: Submitting Successfully to the Small Business Program - Transcript and Helpful Chat Links

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Transcript

Adam Sorkin: We'll start over with a quick bit of housekeeping. Please use the Q and A function to ask questions. We will address them after the presentation, but you can ask them anytime. Slides and a recording will be available in about seven business days at SEED.nih.gov, at our Events page. And with that, I will introduce our speaker, Stephanie Fertig, like, director of NIH's Small Business Program. Take it away, Stephanie.

Stephanie Fertig: Thank you so much, Adam, and hopefully there's no concern with my audio. But great to see all of you today virtually. And today we're going to talk about how to best fund your startup, using an NIH grant. And we're really going to be focusing today on the NIH grant process. And you can really find more information on the Small Business Program Management website, the seed.nih.gov. Today, I'm going to be really focusing this presentation on potential applicant pitfalls. So, throughout the presentation, I want you to look for this little warning sign, with the exclamation point. That is a potential pitfall. So today we're going to focus on those potential pitfalls that can stop you from being able to successfully submit your application.

Now for those who don't know, the Small Business Program really helps NIH meet its mission of turning discoveries into help and getting those great innovations out there throughout the country into the hands of the patients, clinicians, caregivers, and researchers that need them. These are congressionally mandated programs. It's approximately $1.4 billion dedicated to early-stage capital, and specifically in Life Sciences across the United States. This is one of the largest sources of that capital in the US. There are two programs: the Small Business Innovation Research, or SBIR Program, and Small Business Technology Transfer, or STTR Program. They're very similar programs. We're going to get into a little

bit of the differences in a minute. But the big difference between the two, SBIR allows partnering, but the STTR Program requires partnering with a US research institution.

So, some of the benefits of NIH funding -- well, really, we sit in that point after company formation, where we're really there to help provide capital, and it's non-dilutive, so it's not alone. We don't take a piece of the company, but really, we're here to help you derisk your technology, and many of our recipients leverage that funding to attract investors and partners that are needed really to bring something fully to market in the biomedical space. And a number of our companies have done that. I do encourage you to take a look at our small business success stories.

This really helps show the depth and breadth of the kinds of different modalities and different technologies that we can support, not just diagnostics and therapeutics, but research tools, digital learning -- so there's a number of things that we can really support through this program. In addition, it really shows the wide variety and the different institutes and centers that are associated, and that have small business programs within NIH. There are 24 different institutes and centers, each of them has a slightly different mission space, so you can check out some of the things that they have supported previously.

One of the questions we do often get is around eligibility criteria. I encourage you to take a look at the website, again, seed.nih.gov. This eligibility is determined at the time of award, and really there are generally questions around eligibility criteria, but there is an eligibility guide, and I do encourage people to take advantage of that on the website. But again, a number of our questions are associated with eligibility, specifically around it being a US for-profit business. So, you do need to have a for-profit business, a US for-profit business, and the work needs to be done within the United States. There are a few exceptions there, but really, the work needs to be done within the US.

We have funding opportunities on our website, front and center. You can see those open funding opportunities. But the majority of the funding does go to investigator-initiated grant applications. Again, these are our standard receipt dates, and really we're doing this with the idea that many of you may be looking to that January 5th receipt date. Now when we talk about investigator-initiated, we're talking about those projects that are going to our general Omnibus Solicitations.

These are our open-topic solicitations. And as you can see, there are four different solicitations, depending on if you're an SBIR or STTR, or you're proposing a clinical trial, or you're not proposing a clinical trial within that application. We also have some targeted solicitations, and you can see a list of those targeted solicitations here. At times we also may have contract solicitations open as well. I want to point out two examples of some targeted solicitations; one is a Notice of Special Interest, the Women's Health Research, note it's a special interest. You would come in for those notices of special interest. You would come in, in this case, under the Omnibus Solicitations, but you would note that notice within your application. There is a specific box where you would be putting that information.

The Small Business Transition Grant, on the other hand, is a specific program announcement that you would come in and actually apply under, and that transition grant is for new entrepreneurs. We have a whole webinar, and we have a limited amount of time today, but we do have a whole webinar on the Small Business Transition Grant. I would encourage you to take a look at that as an option as well.

When we talk about a Notice of Funding Opportunity, what are we talking about here? Well, I would encourage you all to read the Notice of Funding Opportunity. That is one of our main tips. One of the things, particularly for specific Notice of Funding Opportunities that can be a caution -- and you can see our first caution here -- that to look at the participating institutes and centers. Not all institutes and centers participate in every Notice of Funding Opportunity, so it's important to take a look at what kind of research is supported through that Notice of Funding Opportunity, who are the participating institutes and centers. In addition, there's information about the purpose and objectives, as well as the budgetary guidance and review criteria. So, I would take a look, and again, read through the Notice of Funding Opportunity. A big thing that we do see people do that is a potential pitfall -- not reading that Notice of Funding Opportunity.

One of the things you'll see in the Notice of Funding Opportunity is what phase the Notice of Funding Opportunity supports. When you're thinking about phases, in this case, the phase -- it's a phased program. This is not related to clinical trial spaces, that's an unfortunate similarity in nomenclature. The Phase I is a feasibility study, Phase II is for further research and development. And then we have a number of bridging programs after the Phase II to support our recipients, and help them get to the

commercial market, partner or investor. What you'll see on those Notice of Funding Opportunities is whether or not they support a Phase I, a standard Phase II, a Fast-Track, which is Phase I and Phase II in one proposal, or a Direct to Phase II, which is SBIR only, allows you to skip over that Phase I and go directly to getting Phase II support.

We also do have, and this is a hallmark of our Program, is the flexibility associated with not just these different ways of entering the program, but also budgeting. So, I do encourage you, again, to read through the budgeting, read through the Program descriptions in the Omnibus, and-or in specific NOFOs to make sure that you're asking your budget request is something that can and would be within the scope of what the institute or center, or that specific NOFO supports.

Now one of the things -- and you can see here, again, caution, that there is a pitfall here, is around the which Phase -- how should I fill out the application to determine phase, and again around that only some institutes and centers participate in some of these bridging programs. So, things like the Phase IIB or the CRP. But I really want to focus on that Phase I to Phase II, and Fast-Track, and Direct to Phase II and Phase I, because one of the things that we really do see as a pitfall is, in the application when it asks about application types, and particularly for those individuals who are looking at doing a Phase II, either a standard Phase II -- so a standard Phase II that comes after the Phase I, a Direct to Phase II, or if they're in that point where they're going to a Phase IIB. It's really important you read the instructions to make sure you're selecting the correct type of application, because the first page of the application you see here is Type of Application, and then the second time you'll see Application Type is on the SBIR-STTR information form.

Oftentimes, one of the things that we will see as an individual who would like to submit a Phase II that is coming after a Phase I -- so you have completed your Phase I and you're doing a standard Phase II, the appropriate thing to do there would be to do a Renewal Phase II. If you want to do a Direct to Phase II, you will click New, and then make sure to select Direct to Phase II; not Standard Phase II, but Direct to Phase II. And again, this is all spelled out in the instructions about what the allowable types are. And it's important to read through those instructions to make sure you're making the correct Application Type selection.

Now some of the critical differences between SBIR and STTR, we get a number of questions about this, and again, really, it boils down to that partnering requirement where the SBIR permits partnering, STTR requires a nonprofit research institution partner, like a university. But regardless, the award is always made to the small business. And I could have put a pitfall here, but usually we tend to catch those. People do ask that question. The award has to be made to the small business, even if the principal investigator in the STTR is employed primarily by that nonprofit research institution.

Now if you remember, I was talking about that Notice of Funding Opportunity, and we were talking about clinical trials versus not clinical trials, SBIR versus STTR. You do have to indicate, and some Notice of Funding Opportunities will only allow for clinical trials, or clinical trials may be required, they may be optional, so you do need to know whether or not you're a clinical trial. We get a number of questions associated with, am I a clinical trial, or individuals who don't realize that they're a clinical trial, submit using the wrong Notice of Funding Opportunity. I would really encourage you to read the NIH definition of a clinical trial. It is different, and it may be broader than what you might think.

What you might see in this definition of a clinical trial is that risk -- so how risky a study is does not factor into the definition, nor does the number of patients. So, in this case, even one patient, one human subject could be considered -- that could still be considered a clinical trial. So, I really do encourage you to please take use of the website, read that definition, and utilize the decision tool to help determine if you are proposing a clinical trial within your application. Now I should note, we do get a number of questions asking us, well, wait a minute -- I want to do a clinical trial later, not in this proposal, but much, much later. I know that my therapy will require eventually a clinical trial. What do I do? What we're trying to determine is, are you proposing a clinical trial in this project? Are you requesting to use SBIR or STTR funds in this application to do a clinical trial?

Now really, today we're going to focus a lot on the submission process, and that does utilize electronic submission. So, we're going to walk through the application and review process, but really, again, focus on submission today. And I'd encourage you to take advantage of the resources on the website. Really, we do have a How to Apply, kind of step-by-step through the process on our website. We also have links to application instructions, which I've already referenced, the annotated form set, which is great, it walks you line by line through that application form, sample applications, so you can see what a

completed application looks like, as well as different links to state resources that might be available through the Small Business Administration's FAST Program. So again, I really encourage you to take a look at this and take advantage of those resources, including your state and local resources.

Now electronic submission is something that does catch people. Do make sure that you have all of your required registrations in-hand. Now is the time, you need to start doing those required registrations as soon as possible. If you are hoping to submit in January, and you do not have your required registrations, you need to start doing that immediately. These are required registrations. They are required in order for you to apply. Now you have to submit electronically, we really encourage you to use ASSIST. Why ASSIST? Because there are alerts, there are warnings. It does assist you. It provides alerts, it provides warnings as you're -- to make sure that you are able to submit. So, if there's a potential error, it doesn't catch everything, but it can catch a number of common errors and issues. So, it's so important, we really do encourage the use of ASSIST to submit. You can use the grants.gov workspace, but we really do recommend ASSIST for submission.

Now one of the required registrations that does cause some issue, when submission is eRA Commons. Specifically, the company needs a separate eRA Commons account than the PI, so you need two separate eRA Commons accounts. Not only all, now all the senior and key personnel need to have eRA Commons accounts. And this is really important, that you need to have all senior and key personnel need to have that eRA Commons accounts. So, make sure. This is a fairly easy process. We really do encourage you to get those accounts now.

Another pitfall is the Data Management and Sharing Plan. This is a fairly new requirement, but we are seeing a number of applications that are not able to be submitted because they lack this Data Management and Sharing Plan. This is required for all SBIR and STTR applications. We do now have an optional format page to help you write this Data Management and Sharing Plan, so it has all the required sections. Why this is important is because even if you submit a Data Management Sharing Plan, but if it's missing some component, that may delay, if you are selected to potentially to get funded, that may delay you getting funding as you try to address any questions around the Data Management and Sharing Plan. Now it's really important to note that you can retain the rights to data generated during the performance of the award for up to 20 years after the award date, and

acceptable plans can absolutely reference and incorporate these data rights. So, you can absolutely incorporate the data rights, the 20-year data exclusivity, but you do need to indicate that in your Data Management and Sharing Plan. It's also important that NIH may make these plans public, so make sure not to put any proprietary information in those plans. And again, as I'm sure many of you may know, don't put proprietary information in your abstracts, either. Those are made public. And you can see more information about the Data Management and Sharing Plan on the Data Management and Sharing Plan webpage.

Another big issue that we do see is these hyperlinks in the application. So quick dos and don'ts -- do include hyperlinks when they're explicitly requested. So, if there is a specific situation where it's requested that there's a hyperlink, you can certainly use them there. Do use hyperlinks and relevant citations in publications, included in the bio-sketch and publication list attachments. But don't use them anywhere else. And I'd encourage you, there is a specific notice about these hyperlinks -- do make sure you review that if you're planning to put hyperlinks in the application. Again, we don't want a situation where your application isn't able to move forward because of the use of hyperlinks.

Some other application tips -- and again, make sure that you're building a solid team. Have those people review your application. Make sure that they're really providing, they're really a member of the team. They're providing that additional feedback and guidance. Talk to people about your innovation. I hear this a lot, and this is something that I do see, some companies are a little bit nervous about talking to people, but you need that feedback. You need that information to help make your project and your innovation stronger. And be prepared to pivot, be prepared to take that feedback and really move in maybe a potential tangential or different direction. Read the Notice of Funding Opportunity -- I said it before, I'm going to say it again -- definitely read the Notice of Funding Opportunity.

It has a lot of information in there that's really critical towards the submission of your application. Follow the instructions. This is so important. Make sure you follow the instruction. I do realize that they are long, but they really do walk you step-by-step as to what you need to do in order to submit that application. Again, we do have successful grant applications online. You can take a look at those. You can also really make sure that others review your application. And look at that Notice of Funding Opportunity when those other individuals are reviewing your application; you want to make it as easy

as possible to read. You want to make sure that it's addressing the review criteria. Really, it's written for both individuals who are extremely high experts in your field, as well as those people who may be in scientifically tangential fields as well.

But the big application tip is, please submit early. Days, not hours. It's one of the most difficult things that we have to deal with in our office, is to try to explain to individuals who, for a variety of reasons, their application didn't go through, there may have been some kind of technical issue, and we have to explain that, unfortunately, there's nothing our office can do. It's so difficult, particularly given the amount of time and effort it takes to write a great application. We want to make sure that you succeed in the submission process.

The most important piece of advice -- talk to a Program Officer. And I have a pitfall here -- at least a month before the application deadline. Please, while you certainly can reach out to a Program Officer right before submission, as you can imagine, things get very busy towards the submission deadline. We simply run out of hours in the day. It's so important to reach out early. Now I would even add, particularly for the January 5th receipt date, it's even more important for you to reach out a little earlier, given the end of the calendar year. We have a list of Small Business Program Managers, so they're for each of those 24 different institutes and centers, as well as the other operating divisions within HHS. We have specific points of contact. However, if you're not sure who to contact, you can go to NIH RePORTER, and I'll show you a little bit on how to use that -- a fantastic tool -- in a minute. But you can also email us here at seedinfo@nih.gov.

So, a little bit about NIH RePORTER -- for all those projects that end up getting funded by the NIH, we put their abstracts and basic information on the NIH RePORTER, so you can look and see what small businesses may have been funded in your scientific area. One of the great tools is that you can use Matchmaker, and I highlighted it here to the right. That Matchmaker, you can actually put in your abstract, and you can find potential program officers, what institutes and centers have supported this kind of technology or that kind of research in the past, so it's an easy way to determine where you might be assigned.

I do want to touch on the peer review process, because I think it is so important, and really something that we do want to make sure to focus on. We do utilize the standard review criteria, but if you look, the standard review criteria is more focused and tailored on commercialization, on trying to do that product development, and support product development through this program. Again, I would really encourage you to take a look at the review criteria and the specific Notice of Funding Opportunity. One questions that we often get is around budget and period of support, so I do want to note that under Additional Review Consideration, where is budget and period of support? It's way over here. It is not factored in the overall score. So, it's an additional review consideration, not factored into the overall score.

Now when we're talking about the review process, again, we do have those scored review criteria and the specific questions associated with that review criteria. What I really want to highlight is that all applications receive reviewer comments, and it's so important that those reviewer -- that you review those reviewer comments, take a look even if you were not discussed. Even if you're not discussed, you'll receive reviewer comments. And in fact, and you can revise your application and resubmit. Even if you receive a "not discussed," you can revise your application and resubmit.

Some common problems that we definitely see -- again, I would encourage you to take a look -- one of the things we do see that the team lacks experience, or expertise in a key area, or that you have somebody on your team, but it's clear they didn't review or read the application, they didn't really provide adequate feedback, particularly when we have a situation where there's relevant published work that is not included or not considered, and it's kind of clear that that was not considered. Beyond the lack of either significance because there's a non-convincing case for commercial potential or societal impact, or lack of innovation, or advantage over technologies or products -- so this is really how are you, and how is your product better than what's currently out in the market, or what's being developed?

There are a number of common problems and approach -- I'm not going to hit on all of them, but I will tell you the failure to consider potential pitfalls and alternatives is really something that we do see. Oftentimes individuals are a little worried about going out and saying, "Look, this is a potential pitfall," but it's often better to state that and be open and say, "Yes, this is the potential pitfall, but here's how

we're going to deal with it. Here's the alternatives. Here's how we're going to address that and be proactive with regards to those pitfalls and concerns.

But again, the most important piece of advice I can provide here is to be prepared to resubmit. Regardless of your score, whether you score or get a "not discussed," you can resubmit. And resubmission is part of the NIH process. If you are not sure, if you don't want to believe me, I would encourage you to believe others who have been through the process. I have a quote here from Dr. Carter, who I think provides a great example of the importance of really taking that feedback and incorporating it into the application and emerging with impact scores in the Excellent range.

So, to close out before we enter into some questions, I do really want to talk a little bit about some of the other ways that we can provide support, either through technical and business assistance, or others. And one of the things I would really encourage you to take a look at is the Technical and Business Assistance Programs. Again, a pitfall that I see is not taking advantage of these Technical and Business Assistance Programs. First, Phase I's, you can request a needs assessment of your project. And this is something that you request post-award, so when you receive your Phase I, you can request a needs assessment.

And that can help a Phase I think about what to request in their application for Phase II, Technical and Business Assistance Funding, because in the Phase II, you can request up to $50,000 to hire either one or more vendor for technical and business assistance. So again, I think this is a great example of where it's not just about the research and development funding, but this is additional technical and business assistance support that you can receive.

Finally, we do have a number of entrepreneurial support programs. Pre-SBIR and STTR, you will see the NIH Entrepreneurship Boot Camp, and that is something that is open now. I would take a look at that if you are really in that SBIR-STTR space. It is similar in some ways, for those who are familiar with I-Corps, it helps introduce the teams to customer discovery in that business model validation. Post-award for Phase I SBIR-STTR awards, we do have the I-Corps program, and both pre- and post-SBIR, we have something called the Concept to Clinic: Commercialization Innovation Program, and that's specifically focused on medical device innovators. And finally, we do have supplements to SBIR-STTR

awardees to provide research and entrepreneurial experiences. So, one of the pitfalls we see is that individuals don't take advantage of some of these other programs that we provide.

So, with that, I'm going to end with this -- although I should have had a pitfall here, because one pitfall I see is that individuals don't sign up for the listserv. So, you can see here, the signup for NIH and feed updates -- I really encourage you to do that. That is a great way to keep up to date with the different programs and opportunities that are available. I'd also encourage you to follow us either through social media, and make sure to check out our webpage.

So, with that, I'm going to stop here, that hopefully leaves us with plenty of time for questions. And I do see a number of the questions in the chat. So, Adam, I can't wait to answer some of these questions that we have.

Question and Answer Session

Adam Sorkin: Yeah, keep those questions coming in. We've got a lot of great questions already. So, let's get rolling. A couple of good questions to start with, about finding a good fit for their project. If somebody's not sure where to start, or what the best institute or center might be to really target their project to, how would they go about doing that?

Stephanie Fertig: That's a great question. Again, I would encourage you to take a look at the NIH RePORTER -- and I'm going to click back, I'm going to definitely use the slides here, I won't lie, because I do think it's a great way to kind of point out that specific information. We do have -- so some of our institutes and centers are focused on specific disease areas, things like, say, the National Heart, Lung and Blood Institute -- they're interested in heart, lung, blood, and sleep. So sometimes the name of the institute really gives you a great idea of what they cover. But they could cover, but they could cover a couple of other things that might be maybe a little tangential. We do have a number of other institutes and centers that may have a broader focus, or a mission space.

For example, we have the National Institute on General Medicine, or the National Center for Advancing Translational Sciences. So, each of them has a little bit of a different mission. I would encourage you,

again, you can utilize the RePORTER, this RePORTER tool that I talked about where you can pop your specific abstract into that Matchmaker and see what institutes or centers may have funded similar technology in the past. But if you're still not sure, this is where reaching out to us and talking with us can be a really great option. Again, that's seedinfo@nih.gov, so here on this slide, seedinfo@nih.gov, and you can put a brief description of what you're hoping to propose, and we can help connect you.

Adam Sorkin: Great. Thanks so much. Let's see, a lot of interesting questions about eligibility. What kind of credentials do our PI's typically hold?

Stephanie Fertig: Great question. And the answer is, you don't need a PhD. So that's a big question that we often get, do I need to have a PhD in order to be the principal investigator? You do not. You need to be qualified to manage the project, but again, this is where teams are so important, particularly for our small business grantees. Really, what we find is, no one can know everything. No one is an expert in everything. So many of our successful recipients really are successful because they pull together a team of individuals. So, you may not have a PhD, but you have somebody else on your team that is providing that bit, has a PhD in a specific area and is providing expertise. And again, we make plenty of awards to individuals who don't have PhDs, but who have other extremely important and relevant experience to getting that project done and getting it out to the market.

Adam Sorkin: Fantastic. Let's see, oh, good question. What do our success rates look like? How do they change across mechanisms or faces, maybe resubmissions?

Stephanie Fertig: Great question. Great question. And really, so we're usually looking for the -- with regards to our success rates -- and it can vary from year to year, it does depend on the NIH budget. But usually, we're looking at somewhere between the mid-teens to twenties, twenty percent. So somewhere in there. Resubmissions -- it again really does depend, but what we find is that usually, if individuals are addressing the questions that are raised in the prior review, that is seen generally very favorably. However, it is not a guarantee, so just because you're resubmitting, it doesn't automatically mean you're going to get a better score. But we find that there have been a number of cases where someone may get a lower score, even a "not discussed," but then end up addressing those concerns, and are able to really move into a range where they can be considered for funding.

One of the myths that's out there is that the study section makes funding decisions. They don't. Institutes and centers take that into consideration, but the study sections do not determine and make funding decisions.

Adam Sorkin: Great. Let's see, here's a good question. Do you have to have a lab to submit the grants? I'm with a new company that's just getting started across this program.

Stephanie Fertig: Ooh, that's a great question! So, you don't need to have space -- you don't need to sign a lease, you don't need to be in a space and moved in. You can talk -- you can utilize and really talk about if we get the grant funding, this is where we are going to be. Now I really do generally encourage applicants that you really identify the space, that you're going to do the work. Provide information about that space that should be as tangible as possible, even if you have not -- you haven't signed the lease yet, you haven't signed on the dotted line yet.

But you really need a clear idea of where you're going to do the work, where that's going to take place, and that you're going to have the appropriate resources. Similarly, say you may want to bring somebody on board full-time, but only if you get the grant. You can indicate that. "Hey, this person will work us full-time if they are -- this person will work for us 20 percent, if we get the grant." That doesn't mean that that person needs to be on your payroll right now, but they do need to -- you do need to indicate that they would move to be on your payroll at the time of award. Again, this is where the eligibility is really determined, at the time of award. And that's so important.

Adam Sorkin: Great. It seems we're getting a couple of questions asking about [INAUDIBLE] SAM Small Business Program, too. And that is a separate program, it's a separate federal agency. But we do overlap a fair amount in the biomedical and health sciences space and can consider an application that was also submitted to NSF as well. Just be sure to disclose on your application that it was also submitted to that agency. It's important to note that we will not provide duplicate funding if that's also being funded by another agency as well.

Let's see. A lot of questions about Fast-Track applications. Can you talk a little bit more about that mechanism? What does a company need to submit a successful application? Are there any specific requirements, like a previous award?

Stephanie Fertig: Absolutely. And I'm actually going to click back to talk a little bit more about those phases, because I did gloss over those a little bit. But I think they're really important. So, I like to think about it, there's three different ways to come into the Program; there's the Phase I, the Fast-Track, and the Direct to Phase II. A Phase I is really that feasibility study. And again, it's important to note for a Phase I, you do not submit a commercialization plan. You actually cannot submit a commercialization plan, otherwise, your application might get rejected. So, you can't submit a commercialization plan with a Phase I, it's a much smaller page limit, smaller grant size. And really, that's the feasibility study. A Fast-Track combines the Phase I and Phase II into one application.

For a Fast-Track, and anyone can submit a Fast-Track, you don't need to have been a successful recipient in order to try for a Fast-Track, so you can come in and ask to do a Fast-Track. Again, it combines the Phase I and Phase II into one proposal, so you need to be able to write a full and complete Phase II without having done the work for the Phase I. And there needs to be kind of clear, quantitative goal or goal milestones between the Phase I and the Phase II. There's administrative review by program staff that allows for that transition between the Phase I to Phase II, so instead of it going to peer review, it's going to be administratively reviewed by the NIH staff.

Then finally, there's something called the Direct to Phase II, that allows you to skip over the Phase I feasibility and go directly to Phase II, but that's only for SBIRs. Now one of the big differences between these is the preliminary data requirement. So, a Phase I doesn't require preliminary data. You do need to have scientific rationale, but no preliminary data is required. For a Fast-Track, preliminary data isn't required, but it's expected that a successful Fast-Track will have some preliminary data. So, in order to be competitive, most Fast-Tracks will have some preliminary data. Then finally, a Direct to Phase II, you really need to have put in all the data as if you had already done a Phase I. So, you need a significant amount of preliminary data compared to the other two options.

Both the Fast-Track and the Direct to Phase II have a commercialization plan. You need to submit that commercialization plan as part of the application. Phase I, you cannot submit a commercialization plan. Not allowed to submit a commercialization plan. So that's some of the differences between the three, and you can see it's kind of a sliding scale as to the maturity of the innovation and where you are on that product development pipeline.

Adam Sorkin: Great. I'm seeing a number of questions about the resubmission process, and how to get some help with confusing reviewer feedback. So, I wonder if you might discuss some good resources about processing that feedback, and then what the options are for, coming back with a revised or updated application.

Stephanie Fertig: Great question. So, I would state a first thing to do is, getting that feedback and really reading it through maybe once or twice, really digest that feedback. Oftentimes there may be questions. You might get conflicting feedback, and these are individuals, they each have their own scientific opinion, so there may be some conflicting feedback. I would encourage you to reach out to your Program Officer with any questions that you might have about the Summary Statement. Program Officers do have a significant amount of experience reading through a Summary Statement. And you can see your assigned Program Officer in the left-hand corner of your Summary Statement; you will get a specific individual who is your Program Officer, who is assigned that specific grant application.

So, I would encourage you to review the Summary Statement, write a list of questions that you may have for your Program Office, and then reach out and ask to schedule a call. But again, it's important to do that well in advance of the application deadline, because as you can imagine, you're not the only one trying to reach out, and there are only so many hours in the day.

Now I would also add one other thing that people may not be aware of. So, within your Reviewer comments, you will receive individual -- and I'm going to move to the Review section here -- but you're going to receive individual comments about each of those individual scores for each of those individual review criteria. And you're going to get those individual criteria scores for each of the assigned reviewers. And generally, you have three or more assigned reviewers. One of the mistakes that I do see people make is that you get a number of specific scores, and individuals really like to average those scores -- I would caution you against averaging the scores.

Really, what you should do is use those individual criteria scores to determine what your strengths and what your weaknesses are. Two reviewers may have the exact same criteria scores all the way down the line, but their overall score may have been very different, because their overall score was driven by one of the review criteria over another. So, I would -- again, it's really important to reach out and talk

with your program official about the Summary Statement, and if you have any specific questions about the score and what your next best options are.

Adam Sorkin: And so, yeah, you do have a couple options there, too. You can either revise and resubmit that application, or if you want a clean break, you do have the opportunity to just come in with the same idea but submit a new application that follows up on that idea. And your Program Officer can help you sort through those different options as well, and what your best step forward may be. Let's see.

Stephanie Fertig: I do see a question about clinical trials --

Adam Sorkin: Ah, yes.

Stephanie Fertig: -- and a specific question about, hey, what if your Phase I application doesn't include a clinical trial, but you're unsure if you want to perform a clinical trial in the Phase II? Well, it all depends on what you're asking for. If you're just asking for the Phase I and what you're asking to do does not include a clinical trial, that it would be not a clinical trial. However, if you're, say, doing a Fast-Track, where the Phase II does include a clinical trial, that means the application would include a clinical trial. You are requesting to do a clinical trial as part of the overall application. So, it really depends on what you're specifically doing.

Generally, what I tell individuals to do -- if you are not sure if you're doing anything with human subjects, you're not sure if you're considered a clinical trial, that's, again, a great question to reach out and ask a Program Officer.

Adam Sorkin: Let's see. Let's see, I'm seeing a couple of questions about the budget guidelines you showed, and how the budget works. Can you tell them a little bit more on what the guidelines were again, and maybe what happens if you want to exceed them?

Stephanie Fertig: Absolutely. Clicking back over to those because they're just so important. And we do get a number of questions around the budgetary guidelines. So first off, it's important to note that institutes and centers do have different budgetary guidelines. So, an individual institute and center at NIH can choose to fund either at ease, at the Small Business Administration's guidelines that you see

here, or even less. So, they may not choose to fund the full, if you ask for $314,000; they may not give you that entire amount. So, institutes and centers, as part of the program description, if you go to our omnibus solicitation and you see the program description, what you would be able to see is that individual institutes and centers do provide guidance on the amount of money that they're willing to provide for either a Phase I or a Phase II, and how much they're willing to exceed that amount. And you can also see the specific waiver topics, and I have a link to the slides as well, but you can find those on our webpage.

So, for specific topics, we do allow -- we can make awards that are larger than these -- but we don't have to. So just because you're under a specific topic doesn't automatically mean that you're going to get a larger amount of money. It means that there is the potential to do so, because we recognize that for some topics, it just takes more money, more time to be able to get that work done. So again, it really depends on if you have questions about your specific budget, this is another question that you can reach out and talk to a Program Officer about.

Adam Sorkin: Let's see, I'm seeing a couple of pretty specific questions about how regulatory processes align and figure in with these applications. I don't know if we can get into those, but what kinds of resources do we have that our awardees might be able to take advantage of, to answer those questions?

Stephanie Fertig: Great question. So first off, I would say I'd encourage you again to reach out and look at our webpage. We do have some resources that are available on the SEED website, specifically associated around the different regulatory and reimbursement. And that is, there are some -- we do really offer some of those resources, particularly for our recipients. We can provide consults, either regulatory or reimbursement consultants for individuals who have received SBIR and STTR support. A number of the institutes and centers may have specific notices or funding opportunities that really do look at the requirements of going to the FDA. So, either you have got to get either an IND or IDE, and I'm throwing those out there, but really getting their product through the FDA regulatory process and have specific Notice of Funding Opportunities that help companies get through that process, provide support so that they can do the research and development necessary to be able to submit the

appropriate paperwork to the FDA, in order to then start and get the ability to do a clinical trial. So, there are a number of specific Notice of Funding Opportunities that help you through that.

But again, I would state you can start by first reaching out to your Program Officer and saying, hey, are there any specific resources at the institute or center level that can help? Many institutes or centers may have other resources beyond the SBIR program to help companies; either they may not be grant programs, but maybe access to resources. So again, this is where reaching out and talking to someone in advance can be really helpful.

Adam Sorkin: Great. I'm seeing a fair amount of questions about partnering with a university. I wonder if you might just go back and sort of highlight the options for partnering with a university, particularly what the PI requirements look like in the SBIR Program versus STTR.

Stephanie Fertig: Ooh, I think I went one too --

Adam Sorkin: [INAUDIBLE].

Stephanie Fertig: Did I go one to quick? I think I went back one too much. So, I'm going to go -- oh, there he is. All right, there's the slide that I needed. I thought it was. There we go.

Adam Sorkin: Perfect.

Stephanie Fertig: So really, it's about the SBIR and STTR, and some of the critical differences there. Now regardless -- again, the award is always made to the small business -- really important. The university is a sub-awardee in this case. For the SBIR, you can have a university partner, we often do have universities working with small business in the SBIR Program. However, it's important to note that the primary employment of the principal investigator should be with the small business. There are some situations in a Phase I where we do allow for some deviations there, but again, the primary employment should be with the small business of the principal investigator. In addition, there are some work guidelines, there's a work requirement that the majority of the work in an SBIR is going to be done by the company, and not the university.

In an STTR, there's a requirement to have that university, that nonprofit research institution partner, it's often a university. And really, again, because there's that requirement, the difference is in the work

requirement and the principal investigator kind of come out. So, with regards to the principal investigator, they can be employed by either the institution partner, or the small business. And for the work requirement, there is a minimum work requirement where 40 percent of the work needs to be done by the small business, and 30 percent needs to be done by that research institution partner. So, there is more of this set, there's a specific amount that needs to be done either by the small business or the research institution partner in the STTR. But again, at the end of the day, the award is always made to the small business.

And it's really important to note -- SBIR -- you're not required to do partnering, either. I do get this question, where small businesses say, "Well, what if I don't have a partner? Can I still come in?" Absolutely. Absolutely, you can. And so, and we fund a number of businesses that are very, very small, or that may not have a university partner. Many of our companies are under 10 people, some are even smaller than -- under five. That is perfectly acceptable. We do fund a large number of individuals, companies that are brand new to the Small Business Program. So certainly, don't let that stop you in looking at this as a viable option.

Adam Sorkin: Great. And we're getting really close to the end of our hour. Do you have anything else you want to highlight in particular for our audience before we wrap things up?

Stephanie Fertig: Absolutely. Please do reach out and talk to someone. It's so important to reach out and talk to a Program Officer. Don't let the perfect be the enemy of the good there, it's really important just to start that conversation, ask those questions. Do make sure to sign up to our listserv, so that you have the most up-to-date information on the Small Business Program and all the different options that might be available, and different programs that might be available right now.

Finally, I would encourage you to take a look at our NIH Boot Camp, Entrepreneurship Boot Camp. The registration is going to open on Monday, November 25th. That is certainly another option as well, if you are really in that pre-SBIR space, and looking and thinking about, hey, is this something -- is this innovation really ready to go to that next step? This could be a good option as well.

So, we encourage you to take a look at that program. And with that, all I'll say is, it's great to see everyone. Do reach out if you have specific questions, seedinfo@nih.gov.

Adam Sorkin: Great. Well, thank you so much, Stephanie, for a fantastic hour. As Stephanie mentioned, if we didn't get to your question, and we have a lot of them, we're very happy to address the matter at Help Desk, again at seedinfo@nih.gov. Also, a very big thank you to our team behind the scenes, Vicki in particular, for helping manage all the links and managing the webinar, as well as our captioner, helping to make sure that everything is accessible. As we mentioned at the beginning, all the materials from this webinar, including the recording, transcription, slides, and I believe helpful links will be available at our website, seed.nih.gov, in about seven business days. Thanks to everybody for joining us today and looking forward to hearing from you very soon.

Helpful Chat Links

Website: https://seed.nih.gov/
About SEED: https://seed.nih.gov/aboutseed
Contact: seedinfo@nih.gov
Sign up for SEED emails: https://public.govdelivery.com/accounts/USNIHOER/signup/23029
X (@nihseed): https://twitter.com/nihseed
LinkedIn (NIH SEED): https://www.linkedin.com/company/nihseed

SBIR and STTR Program

SBIR and STTR differences: https://seed.nih.gov/small-business-funding/small-business-program-basics/understanding-sbir-sttr#comparing-SBIR-and-STTR

Eligibility criteria: https://seed.nih.gov/small-business-funding/small-business-program-basics/eligibility-criteria

How to apply: https://seed.nih.gov/small-business-funding/how-to-apply

Phases: https://seed.nih.gov/small-business-funding/small-business-program-basics/understanding-sbir-sttr#Application-types-and-program-phases

Funding opportunities: https://seed.nih.gov/small-business-funding/find-funding

General omnibus grants: https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities#omnibus-solicitations

Specific grants: https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities#nonparenttable

SBIR contracts: https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

Transition grant: https://seed.nih.gov/small-business-funding/open-funding-opportunities/small-business-transition-grant

TABA: https://seed.nih.gov/product-development-support/technical-business-assistance-program

Foreign disclosure and risk management: https://seed.nih.gov/small-business-funding/small-business-program-basics/foreign-disclosure-and-risk-management

Success stories: https://seed.nih.gov/portfolio/stories

Small Business Program Managers: https://seed.nih.gov/aboutseed/contact-us/hhs-small-business-program-managers

Support for Grantees
Product development consultations: https://seed.nih.gov/product-development-support/consulting

Entrepreneurial Support Programs
Webpage: https://seed.nih.gov/entrepreneurial-training

Other
NIH RePORTER: https://report.nih.gov/