Please stand by for real time captions.

Thank you everyone for joining. This webinar will begin shortly. Before we do begin, we wanted to go through a few housekeeping items. One, we are recording the session and we will be sharing the slides after the presentation. We also want to make this interactive and we encourage you to share your questions and comments. We have a Q&A feature on the side of your screen. Please send your questions throughout the webinar and we will be responding during the Q&A session. We also offer closed captioning and technical support. You see the links there on your screen. In addition, following this session, we would like to get your feedback. It helps us to provide and improve webinars that we do in the future. Please take a few minutes to fill out the feedback form before you sign off for the day.

With that, I would like to welcome you to the National Center for Advancing Translational Sciences’ Small Business Funding Early-Stage Support to Commercialize Your Translational Science Innovation webinar. We will have a few featured speakers today. Lili Portilla, Director of Strategic Alliances of the Office of Strategic Alliances at NCATS. We’ll also have Maria Thacker. She is CEO of Georgia Bio as well as Executive Director of the Georgia BioEd Institute. I would like to thank our partner, Georgia Bio, for being a part of the session today. I would like to now turn it over to Maria Thacker for remarks.

Thank you so much. I will be brief. Georgia Bio is pleased to partner with NCATS for this wonderful opportunity and we are thrilled to have this astounding group of people joining us for this very informative webinar. Thank you to our members that have chosen to join us today as well. Georgia Bio looks forward to continuing to offer these and other opportunities to grow our community, not only in Georgia but in the Southeast. Please check our website out for future events. One housekeeping note, the slideshow will be made available on our website at gabio.org. It will be under the resources tab shortly after the webinar. And with that I will turn it back over to the NCATS team and thank you all again, we are pleased to partner on this event.

Thank you, Maria. Now joining me is Lili and she will be leading our presentation.

Hi. This is Lili Portilla from the NCATS Office Of Strategic Alliances. I will go ahead and start off with the webinar. I want to thank again our partners at Georgia Bio for opening up this opportunity for us and at the end of the presentation, there is contact information in case you need to reach me, and as Monique stated, we very much value your feedback and hope if you have comments about the webinar and the information provided, that you will give us your comments on that.

So, the National Center for Advancing Translational Sciences, NCATS, is one of the 27 Institutes at the National Institutes of Health. We conduct research around the operation of how translation and the idea here is how these translational bottlenecks can be addressed to get treatments to patients more quickly. And, we focus on what is common across the various diseases and the translational process. NCATS, unlike some of the other NIH Institutes, is not a disease-specific Institute. We are disease-agnostic; however I will say that we have a great interest in rare diseases and I will be highlighting a program at the end of the presentation that touches upon that particular program that we have here at NCATS that is available for academics and small businesses. Next slide, please.

So, there are other programs too that NCATS manages and funds. One of those is the Clinical Translational Award Program which is about 62 academic medical centers that are funded by this particular network and they provide clinical support to these academic universities. I believe there's actually one in, that is situated at Emory University that we fund. We also have the Rare Disease Clinical Network and the New Therapeutic Uses Program which is our program where we try to pair up investigators with shelved assets that Pharma has that has failed for a particular indication but then to repurpose them for other indications since they are rich with clinical information and hopefully addressing a new use for that particular asset. And their applications that come are available every year under that particular program. We also have, we also have the National Chemical Genomics Center here that does a lot of screenings and the next two programs, Therapeutic for Rare and Neglected Diseases program, the TRND program, and the BrIDGs program are ones that I’m going to be talking about as part of this presentation, we also have other initiatives here that we run out of the center. Next slide.

So, again NCATS, being one of the 27 Institutes here at the NIH, participates in the SBIR/STTR program. We have several areas of research priorities that we want to cover under the program. If you go to our website, at the very end of the slide, you'll see specifically the types of topics we are looking for. But they fit into three buckets which are pre-clinical drug discovery development tools and technology, biomedical and clinical health research informatics tools, and also, clinical dissemination and implementation research tools and technologies that we find under the program. The SBIR/STTR program at the NIH has three submission dates every year. They are, for 2020, there is, we just had one that passed in January, the next one is coming up on April 6 and the one after that is April 7. Next slide.

There are funding opportunities under the NIH SBIR/STTR program. The majority of the applications that come to the NIH come under what is called the Omnibus Solicitation. The Omnibus Solicitation covers all topics of interest across the 24 participating Institutes here at the NIH as well as our sister agencies, the CDC and FDA. And, again the standard deadlines are April 5, September 5 and January 5 that is what they are every year with three submission dates. Then, there are also targeted grant solicitations we have on various research priorities. And you can see, if you go to the NIH website, you’ll be able to see those particular specific targeted solicitations. NCATS had a few, but if there is a priority that we want to highlight, we may do it again, one of these targeted solicitations. The due dates typically track the Omnibus Solicitation standard deadlines. But with that said, some of them have different deadlines, so it’s always good to check out that particular funding announcement date. And once a year, there is a contract solicitation for the SBIR program and these are topics that the NIH deems to be high priority. We use a contracting mechanism because we expect there to be a deliverable at the end of the day with these contract topics. Those are topics which usually close in the November-October-November time frame. Next slide.

At the NIH. SBIR is one of the largest sources of early-stage financing. And the budget for the program tracks with the agencies on the budget. At the NIH, that is 1.15 billion dollars that is set aside specifically for small businesses across all of the NIH centers. And it is a significant amount of money that every year must be designated and provided to small businesses under the SBIR/STTR program. Next slide.

So, when I said that the budget tracks with— the agencies are indeed budgeted. So, Congress has said there is a percentage set-aside that we must do for this. So, it’s 3.2% for the SBIR program and it is 0.45 for the STTR program. As you can see, the majority, the lion’s share of the budget for the small businesses fall under SBIR, that is not to say we're still not looking for good STTR applications. It is good to see that the differences in terms of what the set-asides for these budgets looks like. Next slide.

The benefits of the program, there are multiple benefits. One is, this tracks with the agency's budget and it is a congressionally mandated program which means we have to set the money aside so it is pretty stable and predictable. The other reason is it is not diluted. We, the government, does not ask for IP rights back after funding. We recognize that the IP belongs to the small business or the academic that was participating in the program. And, once you're into the program, you can get access to other technical assistance and commercialization programs that the NIH offers to its SBIR or STTR applicants -- excuse me, awardees. I will briefly touch on those towards the end of the presentation. Another reason that it is important too is that your project undergoes rigorous scientific peer-review processes here at the NIH. We know that many of our awardees will use, they will use that peer-review and the summary statement that is from the review as a way of leverage and trying to attract more dollars for their company because they are able to say that the science has been validated by the NIH.

So, it is a three-phase program. When I say Phase I, I want to make sure that everyone understands that I'm not referring to clinical phases here, it’s just that those are the various phases of this particular program. Phase I SBIR/STTR is typically what we classify as feasibility studies and, the budget guideline here at the NIH is $225K for a Phase I SBIR/STTR grant. The project period can last anywhere between six months to a year. But with that said, about the budget, there are projects at the NIH, that believe there should be higher dollar amounts associated with them. So, at NCATS, we have several topics that we deem to be, that fall under this category. You are able to get a waiver and apply up to $325,000 for a Phase I. Phase II is more full R&D research. The NIH budget cap is $1.5 million. Projects run anywhere between 2-3 years depending on what you're doing and there is a -- when we refer to something called a Fast Track application, that is when applicants apply not only for Phase I but also Phase II. Typically the types of projects that apply to that are ones that have some preliminary data and so they are able to make a compelling case as to why NIH should not only fun Phase I but the Phase II. And then there are some instances where applicants feel, I have that feasibility already, and I would like to skip the Phase I and go directly to the Phase II. That is the Direct-to-Phase II program that we also participate in. Some Institutes and that includes the NCATS have a Phase IIB program and that is additional funding that you can request for a project. For example, there is additional regulatory studies that need to happen to get to IND filing or you are developing a device and there's some complex instrumentation that needs to happen. We could also consider funding what is called the Phase IIB program. At our Institute you could request up to $1 million per year but the caveat is we must have funded the Phase II in order for you to be considered for the Phase IIB award. And Phase III is what we typically, here, consider to be commercialization or graduation from this particular program, and recognizing that NIH generally is not going to be a customer to anything you are developing. Again, because this is considered to be seed funding, early-stage seed funding to kind of get your project going and for you to leverage that funding with other sources and strategic partnerships that you can develop. Next slide.

So, who is eligible for SBIR? The eligibility criteria, keep in mind, is not something that the NIH dictates, it’s something that the small business, the U.S. small business administration, they put the parameters around what makes someone eligible to receive SBIR or STTR funding. An SBIR eligible company would be one that has 500 or fewer employees, the PI’s primary employment has to be with the small business at the time of award and during the entire duration of the project, the company can be more than 50% U.S. owned by individuals or independently operated or more than 50% owned and controlled by other small businesses, other business concerns that are greater than 50%, only controlled by one or more individuals or the company can also participate in the SBIR program if you have multiple venture capital investments and ownership if your company is no more than 50%. Next slide.

For STTR, it’s a little different. Here, you have to be collaborating with a nonprofit research institution or U.S. college or university or what is called it a federally funded R&D center (FFRDC). And 40% of the work must be done by the small business and a minimum of 30% must be done by that research institution. If you need IP rights, for example, let's say you want to partner with a faculty at a particular university, that faculty has developed an intellectual property that you would like to use as part of your small business. At the time of award, you’re going to have to demonstrate to us that you either have a license or some kind of option that allows you to use those intellectual property rights as part of the company. Here, unlike the SBIR, the primary employment of the principal investigator can be either with the small business or with the research institution. Next slide.

Here is a recap of the differences between the two programs, SBIR and STTR. As I said, the PI was in SBIR has to be with the company, with the STTR the PI should be working for the research institution or for the company but keep in mind that the award is always made to the small business. If you are partnering with the research institution, you can sub award to them but NIH will make the award to that small business.

So, I talked a little about the Omnibus Solicitation which, again, is the bulk of -- this is the funding announcement that most of the applications for the NIH come under. These are the two solicitations that are currently open for SBIR and STTR, if you go to the solicitations, there is a hot link to what is called the program descriptions and research topics. If you click on that document, it is several hundred pages but you will be able to see, across the NIH and our sister agencies, exactly what topics we fund here at the NIH and what we consider to be priorities for our respective Institutes, etc. I did talk about the standard deadline. Next slide.

So, the next couple of slides are specific funding announcements that NCATS is participating in. Here is one of them. It is related to the illuminating the druggable genome initiative that the NIH has. Several NIH Institutes participate here and if you are interested in learning more about what is covered under the illuminating -- the IDG program, I encourage you to look at this funding announcement that we have open for SBIR and the next deadline for that is April 6. Next slide please.

The other funding opportunity that we have, once you receive an NIH grant, you can also ask for administrative supplements. This is one that we have specifically to promote diversity and research and development in small businesses. We will, if you have for instance a particular student that falls within the criteria of the type of individual we would fund under this diversity supplement, we will fund their salary for the duration of their, for a couple of years and the idea is these individuals get to learn what it is to run a small business, but they’re also there to provide scientific support to the particular program that you have in your small business. Also, under the NIH HEAL initiative, the initiative that NIH currently has to deal with the opioid crisis, there are two open requests for applications. This is specific money that has been set aside for small businesses to respond to this particular crisis. And, the next application deadline is April 9 and you'll notice it is different than the April 6 deadline that I've been talking about. That is why it is really important to look at these individual funding announcements to see when applications are due and also if you have NIH funding or had NIH funding in the last couple years, you could also apply for the Commercial Readiness Pilot program which is technical assistance that we would fund under this. For example, let's say that you wanted to get a market analysis done under specific technology or a patent landscape done, those are things that typically NIH does not fund under a regular SBIR/STTR grant. But, this particular program or funding announcement does allow us to fund that type of work. And as I said, you could have been an NIH awardee in the last 2 years or you can be a current awardee and apply for this program. And the next deadline for that is April 6. Next slide.

How long does it take to get an award? Both these programs are not things I would consider to be quick turnaround times. The time period can be between the time of submission of an award to, excuse me, submission of an application to the time you get an award could be anywhere between six or nine months. For example, if you're going to be applying to the next April 5 deadline, you would submit then and then the applications would typically get reviewed in a June, July timeframe. We will have our scores by then and then our respective Institute advisory councils will look at those applications and provide their concurrence for an approval for funding the application. The earliest award date that we would be making would be late August, early September depending on, for example, if the money has been spent down, we may have to actually consider funding into the next fiscal year. Those are all things that you can talk to me or another NIH program officer about in terms of the timing for this, the timing for the award depending on the due date, the application date that you submit to. As you can see, it is not something we turnaround in several months. There are several, as I said, 7-9 months between the time you submit and the time you could possibly get an award. Next slide.

Okay, the next couple of slides will be around developing our successful application, next slide, please. I apologize for the lag in the slides coming up.

So, if you’ve applied to the NIH before, you will see that some of these criteria look very familiar. And, they are except there is an additional one around commercialization which is the focus of this particular program. When we look at the significance and the approach we’re taking, I think NIH review wants to know what you're developing here actually has commercial potential and what your potential market could be for this product. Are you a first in class product or is it a first in class therapeutic you are developing or device? Is it something that is an improvement on what currently is in the market? That’s the kind of focus that these applications have as opposed to if you are familiar with NIH funding, what a R 1 grant looks like, SBIR/STTR grants have a focus around commercialization. We want to understand who it is, what your project is, market potential and how this grant will help you to move the project to the point where you can leverage and potentially develop strategic partnerships or attract additional investment in your company. One of the other things is some of the questions we get is I'm a virtual company, can I apply for NIH-SBIR/STTR funding? My response to you is it depends. If you are virtual company and you are doing, maybe IT work or something you can do that you don't need a lab or something like that, there may be flexibility in that. I think every case is unique and we have to talk to about what you will be doing. Remember, there is an expectation that a certain amount of the work must be done by the small business. We are going to make sure that if you're contemplating on doing wet lab work, that you have access to a wet lab whether it be through an arrangement that you have the University, with a bio incubator or you actually have wet lab space in your company. This issue of virtual companies is one we deal with frequently and my best advice is to talk to your program officer about what NIH can and will fund. Next slide.

The SBIR/STTR submission is done electronically. Before you submit your application, there are five important registrations that need to be done before you can submit and they need to be done in this particular order. You have to have a Duns number and if you want to get any kind of payment from the government, you have to be registered in what is called the system of award management. That registration can take up to 4-6 weeks because that system is checking with for instance an EIN number, a tax ID number to make sure your company has a tax ID number registered with the IRS. These things take a while to do and I can't stress that enough that if you're going to be applying or thinking about applying, work on these registrations early because you will not be able to submit your application until these registrations are completed. Next slide.

There are also special designations. The NIH and the small business administration that oversees the overall SBIR/STTR initiative wants to know about economically disadvantaged small businesses and women-owned small businesses that are applying to the program. There are certain criteria that would distinguish one from being socially, economically disadvantaged small business. SBA makes these criteria and what we consider to be a woman owned small business. If you meet these criteria, the NIH would appreciate that you would self-designate, make that designation on the application so we can track who is applying to the program and also, this helps us to do outreach to these particular groups as well. Next slide.

Here some top tips in applying for the program. Mentioned this before it is really important for you to review that funding announcement and really understand, first of all, are you eligible? What special criteria there are, what types of applications that we are looking for and making sure your project aligns with what those areas of interest are under the funding announcement. NIH has a couple of successful applications on the website made publicly. If you want to see what does a successful application look like? You can go to that website and pull those applications up. We have examples of Phase I and Phase II SBIR/STTR applications. I encourage you to talk to an NIH program officer before you submit to make sure the application is a good fit for that Institute but by talking to program officers you can also find out about what those research priorities may be for that particular center and NIH is a big place and for me, personally, I can't claim to know everything and every priority going on across the NIH, but that’s why talking to individual program officers will provide you with more information. Register early and as I said, if you submit to the program, you need to have those registrations done. If you’re a first time NIH submitter, there is an application tool called the NIH assist which allows you that annotates the application and helps you understand what it is that we are looking for in the application and a lot of our first-time applicants use the NIH assist to help them out. We also, if you're talking to an Institute, for instance, NCATS, and I say to you, I think your application perfectly fits fine for us and I encourage you to list us as a primary assignment on the application, you can specify that on the application. You can also specify the study section you think your application should be reviewed by. These are suggestions you make and many times they will be honored. Sometimes, the folks that make these determinations feel that other study sections may be more appropriate but you certainly have that opportunity to designate the appropriate Institute and study section that you think your application should be assigned to. And, again, submit early and not hours or minutes before the application deadline. Many times, this happens every time, without fail. There are a couple of emails I get at 5:01 PM EST from people who submitted an application and ran into an error who are now unfortunately precluded from submitting the application. So, submitting early is a great way of making sure you will not run into errors, deal with any error messages or pagination problems with your application at the very last minute. Please submit early. Next slide.

And, here are common application problems that we have collected with the assistance of the folks that run the reviews for the applications. As you can see, they kind of run the gamut here in terms of not making a very good or compelling case about the commercial potential and the impact that your technology is going to have on patients. Sometimes, lack of innovation, applicants want to show they can do everything and by doing that, the application also becomes very diffuse and unfocused. And the reviewers will pick that up and say that it is a big risk for NIH to fund something that is so all over the place so they will not fund that. And, proposing a large amount of work for the budget that correspond to the Phase I and Phase II, it is really important too to understand who your competition is the reviewers, they will know that and they will point that out that maybe you did not do a good job explaining how your product differentiates itself from a competitor. These are some of those application problems we see on a pretty consistent basis. Next slide.

Important fact to remember before submitting is that eligibility is determined at the time of the award. For example, we will do these re-checks with you to make sure you are eligible to receive the application. And, certainly the time of award, that is going to be done. Your PI, principal investigator, in the application is not required to have an M.D. or PhD when you apply to the NIH. However, we are expecting you to have the right team assembled to get the specific aims of the grant done. If you are working in a specific clinical area and do have a proper clinician that can, as a consultant or providing advice on your project, you know, review will pick that up and say that your, you do not have an adequate team assembled. We want to make sure you have the right people on your team to get the specific aims addressed. You can submit applications to different agencies for similar work however, just keep in mind that if you're doing that, we are able to check and see, if you being funded by other agencies, what will make sure is that NIH is not duplicating efforts in terms of what is funding. If there applications you have at other agencies are pending that are looking to be in the same area, we will look at those to determine whether there is overlap and if there is, we will come back to you and tell you why we may not be able to fund the applications. So, please keep that in mind. We are the government. We know what other people are doing in this air and space. Next slide.

So, yes, sometimes your application will not get reviewed. 50% of the applications that get submitted to the NIH will not get a score. But, with that said, they still get a summary statement and a review. The reviewers will provide feedback on the application. We encourage that you use that summary statement, even though you may have not gotten the score or maybe your score was not, did not get funded by that particular NIH Institute. We encourage you to use that summary statement as your road map to improving your application. Very much so, if you don't get find it the first time, please, please resubmit as your chances will increase. If you want to understand what the review process and the dynamics of the review look like, the Center for scientific review, here’s a link to their website and you can look and see what a study section does. How study sections review applications. And, I talked about the fact you could also designate what study section you want your application to go to. You can do that and, it will tell you exactly what those study sections are and also the roster of reviewers on the CSR website that we have listed here. Next slide.

So, very quickly. I wanted to talk about the types of applications that we fund these are, I will give you a couple of examples here. We have an initiative around tissue chips and using those tissue chips as a way of testing drugs as opposed to testing them directly on animals. Because we know sometimes animal data does not translate to humans and how they react to drugs. So, we have developed this tissue chip program and AxoSim is a small business out of Louisiana that applied to the program and has been able to leverage their grants that they received from us to receive additional funding. The company has been able to acquire other funding and they were also a company that we were able to, through this program at the NIH support, to go to a conference, a capital conference and do a pitch contest and they were able to talk about their technology and tried to secure additional partnerships as well. So, that is an example of something we funded and is very much of a success story. Next slide please.

The next slide, the next company is Lyndra Therapeutics out of Cambridge which is a novel drug delivery technology. It is a pill that expands and then stays in the gut for a longer period of time. We funded a specific project around using Ivermectin, delivering it through this pill for malaria. And, the company has been able to leverage this grant that it got from NCATS to figure out how to manufacture the drug and the company now has been able to raise additional funds as well too. This is a great example of how they will able to leverage what they did here with this grant and again, develop strategic partnerships and expand this platform, drug delivery system to other applications. Next slide.

So, again if you want to talk to me, I encourage you to reach me here’s our email. FAQs also online if you want to look at those. And our current funding opportunities can be found on this link. Next slide.

So, I did talk to you about a couple of other resources that the NIH has for existing applicants. Once you get an award, there are other opportunities for you to apply to certain programs and initiatives we have here for SBIR companies. This is one of them. This is the I-Corps program. The I-Corps program teaches our SBIR companies how to do customer discovery; allows them to pivot and perhaps submit a better Phase II when they are ready to do so. So, we will pay for the team, the company to go through the training. It is a supplement we provide in the grant. Next slide.

There are also a couple of technical assistance programs we have. There is a Niche Assessment that does like a market analysis to determine which your competitive advantage is it is report that we can provide to you. We use contractors to help us with that. That is an offering we give our small business awardees. And also, the Commercial Accelerator Program, the CAP program which helps you with how to do pitch coaching, also, facilitates investor partnerships, how to deal with regulatory issues and those are – it’s a training that we offer them. Again, you apply for the program and we pay for you to go through the program. Next slide.

So, very quickly. I will talk about a couple of other resources we have here at NCATS. These resources are offered through the NCATS Therapeutic Development Branch. This particular branch offers different ways of collaborating. They are able to offer some of the services and opportunities to collaborate around med/chem if you need some kind of tox study done, GMP manufacturing, particular kind of formulations for your therapeutic that you're working on. A menu of the different things that they offer and the idea here is to kind of get you across the valley of death that many of our applicants face that they've gotten funding but they are kind of stuck because they need very specific things and those specific things are not typically things NIH would fund so you could leverage your grant with this particular offering that Therapeutic Development Branch offers. Specifically - next slide --

There is the BrIDGs program. Here you identify whether -- you enter when you have a clinical candidate to identify. You can identify any disease they’re eligible to participate in. The idea here is to do a gap analysis to determine what you need in order to get to an IND filing. They work with various modalities, small businesses – I’m sorry -- small molecule, large molecule, gene therapy and it is open to academic as well as SBIR eligible companies. Next slide.

Here is, this is on the website. I’m not going to spend too much time on it. I want to give you a sense of the types of projects that we have funded as you can see, some of these are small businesses. But, we've been pretty successful at getting our collaborations under this program to an IND filing. Next slide.

The next program is the TRND program. Here, you must be working in either FDA orphan designated disease or some disease that meets the WHO neglected tropical disease criteria. We can actually take you past an IND filing out of this program. It is a very small, a gap analysis is done. We work closely with you. If you need certain kinds of studies done, we can partner with our CROs that we have working with us to get that data to you so you can get your, you know, a key inflection point and get that IND filing. We work with academics and small businesses. We pretty much work with everyone under this program.

The next slide I believe, these are the different TRND programs and the folks we have been collaborating with and basically how far we took -- when these programs came in, some of them have come in in the lead-off stage. Others, we helped out with IND enabling studies. And, you can get a sense of how we've been working with the companies here. Next slide.

Here is a quick example of an applicant that developed a new molecular entity, a new compound for a rare disease. She has cobbled together RO1 and STTR funding that added up to about $3.5 million. And she was doing well and then she had a pre-IND meeting with the FDA and they determined she needed to get these two tox studies done in order to file her IND. The tox studies totaled about, I believe it was a rat and a dog study that totaled about half a million dollars, which would be very difficult on its own to get that type of funding at the NIH. So, she applied to the BrIDGs program. We talked to her, again, we did that gap analysis to determine that yes indeed, we could help her with providing access to our services and providing with the data she needed in order to file the successful IND. As a result, she raised, after filing the IND, she was able to raise $50 million in VC funding. Both these programs do not give you money but they give you access to resources and expertise we have here at the NCATS.

And submissions, if you want to apply to any of those programs, please go to the website because they're on a rolling submission basis. If you have any questions, you can talk to me and with that, that concludes my talk and here are all the different ways you can engage with NCATS and I hope you sign up for our newsletter, Twitter, and stay in touch with us about finding new funding opportunities out there. So, that's it.

Thank you, Lili and thank you to all our participants. We have been receiving your questions. If you do have other questions to share, please use the Q&A feature and we will show up on the right-hand side or bottom of your screen. And with that I will start with the questions we've received so far. There some folks who like us to help understand what a PI is. Just to find that a bit more and have a follow up question on that.

So, the PI is going to be the primary point of contact for the grant. The principal investigator is in charge of making sure that the specific gains are being addressed. He/she kind of leads the team that is assembled, whether that team be other employees or consultants are needed to get the project done. For example, if I have questions, I will be talking to that principal investigator about the progress the grant is making.

Thank you, Lili. We have some academic researchers who are in the different phases spinning out companies. This question applies to that scenario. We have a PI who is the process of building a therapeutic targeting a mechanism of action for a particular disease. And, this person wants to create a startup around it so they can apply for an SBIR.

Does he or she have to be the PI on the SBIR application or can anyone that wants to own the company and use the therapeutic be the PI on the application?

Sure. There are a couple of ways that could work out. For example, if you had a student in your lab who wants to work at being more entrepreneurial in what they do. They could be the one that is a PI for the company, or you can also arrange to do work with a small business and find a way of licensing that invention to the small business for them to work on it. You can stay engaged, but not necessarily be the person running the company or that PI on the grant.

Thank you Lili. To follow that thread, one of the questions received. So, if the PI is 100% dedicated to the research at a public university, that is a 25% owner of the small business. Should that person apply for an STTR or an SBIR? One other note, the CEO of the small businesses is 100% dedicated to the small business.

Under an STTR, the academic could be a PI on the grant. But, again, funding is going to always go to the small business, and they would be required to do a percentage of the work. Absolutely, there is a way to stay engaged and not be the PI the company, but you can stay engaged and collaborate with the small business. With that said, if that academic also wants to be involved in an SBIR, that is possible as a “key personnel” and also you are allowed to have multiple PIs under an SBIR grant. You may not be the principal PI of the small business, but you can be like a co-PI that is working closely with the small business as well.

Thank you.

Let me just add that these kinds of questions are great questions that you can ask me, the program officer or somebody else at NIH that works in the program so we can kind of brainstorm with you about the different ways that this could work.

Thank you. I am going to move to a couple of questions about the phases of applications. So, can I apply to NCATS Phase II if I've received a Phase I from another Institute?

You can and, with that said, I want to make sure it was a good fit for NCATS. Having a discussion with me ahead of time to help make that determination might be good. You know, there are situations where we may feel that you are staying at a particular Institute is a better fit than coming to NCATS. I know I said we were a disease agnostic Institute, but if you're working in oncology and working on prostate cancer, I think that the National Cancer Institute will be a much better fit for your application than NCATS is. And the other point that I don't believe we addressed during the presentation was, NCATS has made the decision that it will not fund clinical trials under the SBIR program. We are happy to fund free clinical work and we can fund clinical research as long as it does not meet the definition of the FDA considers to be a clinical trial. Some of the other disease-specific Institutes will be funding clinical trials under their programs. That is another reason why talking to different Institutes about your project will help determine which one is a good fit for what you're doing. Spent a great pair, along those line, I have some questions about FastTrack. Does NCATS offer FastTrack through Phase II? When is it appropriate to apply?

Yes to both. We do fund both mechanisms. FastTrack, you know, I think the success rates for FastTrack versus just submitting a Phase I are pretty equal these days. My advice always is if you're going to be applying for a FastTrack, if you have preliminary data, it is important to include that to demonstrate to the reviewers that it is a good risk for the NIH to consider funding through Phase I or Phase II project. Under direct Phase II, you will basically be able to skip that Phase I and that is demonstrating that you already have that data and you're able to get that data through another source that was not the NIH program. So, here, you will have to demonstrate that you got that feasibility data placed and that is what makes you eligible to apply to the Direct-to-Phase II program.

Thank you. I just wanted to call attention: the link is on your chat I want to encourage everyone to please fill that out as we answer these questions.

The other question received is what is the best way for a company to go – when it is right to apply to NCATS versus some of the other Institutes?

I talked about this and I think it was one of the slides that had the Omnibus Solicitation on it. There are two links to that. You can go to the Omnibus Solicitation. There is a link to the program description guide and you can open that up. Applicants will open that document up and just basically search topically to see what Institutes are funding, do they have interest in what they're funding. That is one way of determining who to talk to. Another thing you can do is use the NIH RePORTER tool that is a public database that is available, searchable and it tells you pretty much everything that the NIH has funded. So, you can do a search by topic and see what other Institutes are funding similar types of research. That is another great way for you to determine what your competition is at the NIH—what else is being funded in your area. All the information is publicly available through the NIH RePORTER tool.

Thank you, Lili. I wanted to note that NCATS does make itself available to folks who want to talk about their research topics ideas before submitting an application. So, Lili and her team are accessible and we did include a note about the email and also how it sends a follow-up to you. I want to know we'll send you a link to the research topics which is also on the website. That will help you see if the research you are thinking about aligns with NCATS funds.

A couple of questions about the research programs that NCATS and the NIH offer. I will put you with 2 questions here. Do you need to be awarded that SBIR grant to be eligible for the I-Corps? What other opportunities are available to non-SBIR grantees does the NCATS offer?

So, the eligibility for I-Corps, you have to have an active Phase I SBIR or an active NIH contract. You can apply to the program via those programs. You have to have these mechanisms that are open and your grant has to be active during the entire time you are applying. You're participating in the I-Corps program. I believe the supplement is $55,000 that we will give your team for registration of the program and also to cover your travel as well and some money to do market analysis or whatever it is you need in order to meet the goals of the program. You have to have an active Phase I grant in place. And, okay, what was a second question? Sorry about that.

It was just one example would be BrIDGs and TRND or any other programs across the valley of death be open to non-SBIR grantees?

Thank you. Thank you. BrIDGs and TRND are one of those programs that you don't need an SBIR to participate in. That is open to everyone. The National Cancer Institute has the next program which runs very similarly to TRND and BrIDGs. You have to be clearly working in the oncology space in order to be eligible for that one part. There is a Neuro NXT program. That program, it is based out of the Neurology Institute. And you need to be working, it is pretty broad, in some neurodegenerative diseases, neurology issues, brain issues, those are some programs that support applicants in, you don't necessarily have to have an SBIR. There are de-risking programs and certainly worthwhile looking into.

Thank you. We have four more questions which we will allow. I wanted to know, I know we are at the top of the hour. There are good questions we want to get to. I also wanted to note that in your chat feature, we have included a link to a webinar at the NCATS is leading with the U.S. Patent and Trade office. We will also provide information on how to protect your IP. That is a very important webinar that is coming up on the 29th of this month. Well I, have another question about these research programs. If someone has participated in the NCATS program in the past, would they be able to participate in the Commercialization Assistance Program or the Niche Assessment Program in the future?

If it is for a different project. If it is for the same project, I think that might be the restriction. But if you're working in a different area, different project, than what you originally applied to NCATS for, I think that would be okay.

Okay, thank you. This next question relates to eligibility. They want to know if I sent a link to eligibility in the chat box. This is about U.S. companies that may have some ownership in other places. The question is did the U.S. companies with foreign investments up to 25% of the ownership qualify for SBIR funding?I think that would be a great discussion to have offline so, I could provide you guidance with that. I should've mentioned there are a lot of the eligibility issues we will defer to our colleagues at the Small Business Administration on. Because, again, they are the ones that define what eligibility for the program is. So, that may be one where we need to work with the SBA to get clearance on that one.

Perfect. And, I know there are a couple questions about TRND and BrIDGs. I want to know that on our site we have a link with eligibility and how to apply for those. There is a question about the typical funding rate, what percentage of applications typically get funded?

So, if you go to the NIH website you will be able to get those different funding success rates for both programs. For NCATS, we track with what the NIH does. For example, for Phase I grants, I think success rate is 21%. And ours is pretty close. For the Phase II, I think it is something like in the high 30s or 40s. I think we are close to that as well.

Thank you. And then the last question**,** how do we know about the contracts in 3D medicine or rare disease drug development?

About contracts in those areas? So, just very quickly, contract topics are submitted, it is a special solicitation that is put out in the street around the July – August timeframe and applications are due to the NIH October-November. Those same topics can also be, are available under the grant topics. If you want to submit a grant, you can also submit at those three submission dates that I talked about. If there was a specific contract topic, those are once a year and that solicitation typically comes out between mid to late summer. And if you have any questions, send me an email.

Thank you. And, thank you to Georgia Bio. Thank you to all of our participants here today. I know there may be some questions that come through. Please do email us. Will be happy to do that and if there any unanswered questions we have, will funnel those to NCATS. Thank you for your time. Please take a look at the feedback form we sent as well as the NCATS website. Have a wonderful afternoon.

This concludes our presentation. [Event Concluded]