CSBA Webinar Transcript

Christie Canaria: Good morning everyone. Hi. My name is Christie Canaria and before we get started with today's webinar I'd like to go over a few housekeeping rules. First, you guys are all muted but you are welcome to submit throughout the webinar today your questions via the Q&A box. If you go up to the top tab and you don't see the Q&A box go to that little right hand side caret and pull down and you can find the Q&A box there, you can send us your questions, then we'll collect them throughout the webinar. And then we will address them towards the end around 1:30. And as another reminder we will not be answering any question specific to your projects and if you want those kind of questions answered you can e-mail either for contract topics Elizabeth Shanahan at the e-mail here or for grants questions you can e-mail us at NCIsbir@mail.nih.gov. So, I'm here today at the NCI SBIR Development Center. I'll be your moderator. We are joined by Brian Stoker from the Council of State Bioscience Associations. He will share two opening remarks with us. We thank Brian and the CSBA for helping promote this webinar today. And we have our talk from Director Michael Weingarten and Lead Program Director Andy Kurtz. But first, a few words from CSBA's Brian O'Connor. Brian, are you there?

Brian Stoker: I am thanks. This is actually Brian Stoker. I work with the Biotechnology Industry Organization and the Council of State Bioscience Associations. And I really just wanted to say welcome to all of bios members who are on this webinar and to members of any of our affiliated state associations. Bio is really pleased to be able to partner with National Cancer Institute. Again, this is the--one of the second or third or fourth year that we've done this in a row and really are happy to be able to partner with them in bringing such a great educational event to you guys. Thanks especially to Michael Weingarten and Dr. Andy Kurtz for the time and have everyone else at NCI who made this possible. And yeah, we just really grateful to be able to have such a great event. And with that I'm actually just going to turn it straight over to Michael.

Michael Weingarten: OK. Thanks very much Brian. We want to also thank the--thank bio and the Council of State Bioscience Associations for sponsoring this event. We really looked at this as an opportunity for connecting with both state bioscience associations across the country and also small businesses that are interested in applying the program or academics that are considering spending all for company in order to apply. Essentially today what we're going to try to do is give you a full overview of the SBIR and STTR programs at the National Cancer Institute then a lot of new things with the program that we hope would be of interest. We're going to kind of walk though that with you today and I encourage you, you know, as we're going through please, you know, e-mail us questions and we'll be happy that set aside time at the end of each of our talks in order to answer questions that come up. And if you do have a specific question about like a--lets say you have a proposal that you are working on or you're thinking about a specific proposal that you might--you might want to apply to the NCI for--encourage you to send us an e-mail about that and we'll set up a separate time to discuss that with you in more

detail. But again, thank you again for the opportunity to speak with you today. So, I'm going to cover--in my talk, I'm going to cover the overview in--on the program as a whole and also who is eligible for both the SBIR and STTR programs. I'll talk about the program both at the National Cancer Institute and also across the NIH and then I'll also talk about some of the other resources that NIH offers for translating technologies from the lab and try to move it towards that commercial product and then going to be followed by Andy Kurtz and Andy is going to spend some good time with you really talking about our different funding opportunities. And also offer you some practical strategies for--for applying just based on, you know, our experiences. I'm working with the companies who are applying the program and our sense have also have a peer review process, works at the NIH and he'll be offering you some valuable tips on things that you should be considering as you put together your free application.

So, just first, a brief overview of the SBIR and STTR programs, these are what are known government set aside programs. So, with that means is we actually get a percentage of the National Cancer Institute are in the budget for the SBIR program that set aside percentage each year equates the 2.8 percent of the NCI's RND budget and for the sister program of SBIR which is down as a small business technology transfer program or STTR about this year it's 0.4 percent of the RND budget goes towards STTR projects. So, if you look across the budget in our program at the NCI for SBIR and STTR this year that's about 110 million dollars in terms of total budget and then across the NIH as a whole, NCI represents one of 27 different institutes. So, if you look at the SBIR program across NIH as a whole the budget for the entire program is at about 700 million dollars. So, this program was actually reauthorized back in 2011 by congress and one of the nice attractive aspects to the program with the congress authorized at the budget set aside percentage for both SBIR and STTR would increase from 2011 through 2017 so that that's what you can see in this chart here. The set-aside percentage back at 2011 was that a total of 2.8 percent of our RND budget and that's going to increase up to 3.65 percent of the RND budget in 2017.

There are some other changes that the congress made of the program that were very excited about one that many of you probably heard about is that at the NIH venture back companies are now eligible to apply for the program. That's the first time that that changes been in effect for the--really the last 10 years now. So, that specifically applies for the SBIR program that this feedback companies can now apply STTR as they are not eligible for STTR but what qualifies as a venture back company would include a venture capital operating company the hedge fund or private equity firms. The other key requirement is that SBIR and STTR applicants must also register at a small business administration company registry which is that SBIR.gov and that requirement has been put in place just so we can start tracking some of the metrics coming out of the program more easily. And another change was that hard caps on award sizes were put in place.

So, I'll be talking to you about the different phases of SBIR just a second but first phase I SBIR project that cap is at 225,000 dollar and for phase II that cap is at 1.5 million dollars. And we're getting some indications that there is going to be some--some relief on those caps for projects at certain areas. So, I would stay tuned for more information to come on that but we're hoping over this next year that we--we get a little bit more flexibility again on award sizes. But at least for right now those caps are advice. In addition, there's another important change to that applicants to the programs can now request 5,000 dollars and technical assistance beyond the reward--beyond the award cap this should be for activities to assist you for example with developing your regulatory strategy or your commercialization strategy or business strategy around the program.

So, if you are interested, we have more information on our website about which you can request with that 5,000 dollars and that can--that would just be a part of your application. In addition, the other option is if you can also tap into different technical assistance programs that the NIH offers as opposed to requesting the 5,000 dollar yourself and I'll be giving you some examples of our technical assistance program a little bit latter in the talk. Some new provisions that are not yet implemented but that we expect to be implemented in the coming year. Right now your--you can't yet switch between SBIR and STTR mechanisms. So, what I mean by that is for example, once you applied for the STTR initially for phase I project and you receive funding for an STTR lets say the goals or the make up of your--your company has changed.

So, if you a have special case where you wanted then switch from an STTR to an SBIR for phase II application we expect you'll be able to do that in this coming year but that--that change is not yet in place. So, again, stay tuned on that one. The other thing that we're going to--we're going to probably start offering this next year is we will have specific solicitation that will allow for direct to phase II SBIR applications is will come out as pilot funding opportunity announcements. These are not yet available but again that is, that is to change that we expect to have over this next year.

Now, if you are interested in kind of tracking, you know, some of the changes with the reauthorization of SBIR, I encourage you to go up to the NIH-SBIR reauthorization website which will kind of give you the latest on, in all these changes that are being made and we're going to make these slides available to everyone who's signed-up for the call so you don't to copy this down right now but that's just a resource for your right there.

So, why should you as a company or someone who is thinking about starting up a company be interested in applying for SBIR and STTR funding, what we were probably that the largest source of early stage funding right now on the country particularly in the biotechnology space, you know, most companies when they are first get started up they look different in family for their initial stage of funding and then pass friends and family they looked at SBIR for potential funding in order to help find your innovation. So, some of the benefits are that SBIR

funding is not a lone so there is no repayment required and it doesn't impact the stock of your company or shares in any way. It's all non-dilutive funding. So, we offer our program either through grants that we make to companies or through contracts. The other benefits are that the intellectual property rights are retained by the small business. The government doesn't take an IP interest in the technology that we fund. And the other thing is all projects, all applications that are submitted to the program go through the NIH Peer Review Process which is pretty competitive and if you do get an award from the NCI that will help provide recognition and verification of the strength of your--of your idea and of your project which can then help your attract funding from other sources down the road which is venture capital or from strategic partners or from angel investors.

So, just a little bit of information on how SBIR is set up. It's a three phase program, phase I SBIRs are feasibility studies typically those are 6 to 12 month long projects. The guideline for a phase I SBIR or the STTR award is 150,000 dollars over that time frame. But we do allow companies to apply for up to 225,000 dollars for phase I projects. Phase II is typically a 2 to 3 year project and that's for the--the full research and development of the technology. It's you know, typically is a follow on to phase I. And again, 2 to 3 year project, the guideline is 1 million dollars in total costs over that the full term of the project but we are allowed to go up to 1.5 million dollars in terms of total funding for phase II awards. In addition to a description of your, your specific aims and your technology approach which you lay out as part of your application, there is a commercialization strategy and plan that you require as part of that application and that is one of the key components of review, of the review process. We want to see what your commercialization strategy is and we want to--we want to know that you put a fair amount of thought into actually not only how you going to develop the technology but how are you going to commercialize it. You know, what is--what is your plan for actually how you are going to bring this technology to the marketplace. And then phase III is the commercialization phase of the technology, that's done with non SBIR funds and we have some programs to help assist with that which I'll talk about in a minute.

Now, one nice program that the NIH offers as a whole is what we call our Fast Track Application and that's what we offer the opportunity for companies to actually to what's called a Fast Track which is a combined phase I and phase II application together. The benefit of a fast track is because it's a combined application you go through a peer review at one time. So, you don't--you know, you don't have to--you don't have to go to the peer review process between the phase I and phase II level if you get a fast track application. You simply achieve the goals of your phase I, your Program Director here at the NCI would be monitoring and overseeing your project and once that individual agrees that you achieved your phase I milestones then you can transition to a phase II. The thing about fast tracks is that they are very competitive, peer review likes to see a lot of preliminary data as part of that application. So, you know, if you've done a lot of work on your technology before and you add that data which you can share as part of your

application then, you know, it might make sense to consider a fast track but in all of the cases before you would go that route we encourage you to contact us ahead of time and just, you know, share your ideas for your project with us. And then we can get your feedback and whether we, you know, we would suggest that as a fast track application or whether we--we instead recommend that you just come in for a regular phase I application. And again, at the bottom of the slide those are the hard caps and award sizes right now.

Eligibility requirements, the applicant has to be a small business concern, you have to be organized for profit here in United States. 500 or fewer were employees including affiliates. The principle investigators primary employment meaning over 50 percent of their time must be with the small business at the time of the award and also for the duration of the project. And this is the change that I mention before. This is where the change in eligibility that was just made recently with the reauthorization of program. So, to be eligible for the program, you have to either be 50 percent US owned by individuals and independently operated or a 50 percent owner control by another business concern that itself is 50 percent owned in control by one or more individuals. Or majority owned greater than 50 percent owned by multiple venture capital operating companies, hedge funds, private equity firms or a combination of the above. So, again, that last point is regarding venture capital internship that's with the key change that was made. And again, the key is it can't just be for example a single venture capital firm that's got to be multiple venture capital firms that have a majority ownership.

For the small business technology transfer program eligibly requirements are that the applicant has to be a small business concern, again, organize for profit here in the US. But the goal of program is actually to transfer technology that wash originally developed typically in academia to transfer that technology for the academic world to a small business. So, because of those goals, there has to be a formal cooperative research and development effort between the small business and between the US research institution. So, at least 40 percent of the dollars should go to the small business under an STTR but also at least 30 percent of the dollar should go to the US research institution that's a partner with a small business. And a US research institution can be a college or university. It can be a not for profit research organization or it can be Federally-Funded Research and Development Center. We actually fund FFRD--one FFRDC here at the NCI and that's a laboratory out in Frederick for cancer research. The other requirement is that the principle investigator's primary employment maybe either with a small business or the research institution. So, this could be a real benefit to--to a company working collaboration with the university, let’s say the PI does not want to leave the university, no one wants to stay there and continue to do the research, you have the ability to do that under the STTR program where the PI can be at the university. The small business still has to be the one submitting the application but they, you know, they can do it with a partnership with the university and the PI can stay there. The other possibility under about this program and also the SBIR program is that you can have co-PIs or multiple PIs, you know, with the PI at the

university and also PI at the small business. But there does have to be an intellectual property agreement in place at the time of application in terms of how the IP is going to be treated.

So, which program is best for you? I kind of summarized this just as I was discussing it but, you know, again the key for STTR is that the PI is that at the university that's, you know, STTR can be a good mechanism for you, they do have to commit at least 10 percent of effort to the project. And then it really depends on the level of effort so if the research institution is going to be doing let's say more than a third of their work on the project. Let's say, you know, 40--50 percent or even higher of the amount of work on the project then STTR is probably the right, the right vehicle for you to use because under SBIR for phase I about two thirds of the work is supposed to be done at the small business and for phase II SBIR half of the work is supposed to be done at the small business and this is in terms of the budget.

So, currently I can tell you that we--we have been experiencing a shortage of applications under the STTR program over the last two years. So, we are encouraging people to take a hard look at the STTR program if you fit the requirements of it because, you know, we're not getting enough strong applications under that program and we'd like to improve the number and the quality of applications. So, the success rate for STTR right now is a little bit higher than under the SBIR program.

So, just a quick summary of the program across the NIH as I mentioned NCI is one of 27 different institutes. We have the largest institute at the National Institutes of Health and as you can see from this chart, you know, there are 27--26 other institutes and this just gives you a sense of, you know, the different--disease focus areas of the other institutes, you know, for example National Institute of Heart, Lung and Blood as well as the National Institute of Allergy and Infectious Diseases, those are two of the other larger institutes at the NIH.

What's a timeline for applications? So, if you are applying for a grant in a response to a grant solicitation, the solicitation that most of you are probably aware of is what's called the NIH Omnibus Solicitation that comes out in January of every year with three different receipt dates. Those receipt dates are April 5th, August 5th and December 5th and this chart just gives you a little bit of a sense of the timeline for--for review and ultimately award of projects. So, as you can see the applications come in April, they typically go through scientific review in July that's the Peer Review study section that will review your application. They then come to us on the program side after they go through peer review. We discussed applications that come in and on the program side we then make decisions based on the peer review on which applications we would like to fund. Then those go through council review at each of the different institutes at the NIH and the award date, typically the earliest award date is going to be about--about eight or nine months after the application has been received. So, that just gives you a little bit of a sense of the timeline. So, now I'm going to talk just a little about some of the initiatives that we have launched at the National Cancer Institute. We--one of the most important things I think we did

with the program at the NCI starting five years ago now is that we actually set-up a center. His only responsibility was to manage this program and then we, we went out, we recruited the right talent in order to come and actually manage projects under this program. So, as you can see by--by this chart, each of our different Program Directors on the program they come to us with different technology areas of expertise and focus and almost everyone on the team comes to us with prior industry backgrounds. And, you know, our goal is really to bring on people who had experience out on the private sector in managing projects on the technology development side and moving projects towards commercialization really so this Program Directors would be able to share those experiences with companies that they were managing through in their portfolios. So, in terms of, you know, who you should, who you can reach out to this gives you some--some phases to connect kind of with the different technology or is of expertise under the program. In this pie chart just give you sense of, you know, what areas that were funding as you can see therapeutic projects represent about a third of the projects that we're funding, in vitro diagnostics are 21 percent of the projects we're funding, imaging also a 20 percent cancer imaging projects and then the next largest category is digital health and software tools at 12 percent.

So, what are some of the different things that we're able to offer because we--we have set up this Center in order to work with the small business community, well, one of the things that we do is, you know, we do a lot of very active outreach events where our folks get out in the field and they meet with companies and we try to put on these workshops similar to what we're doing with you today where we can provide an overview of the program to the small business communities and local areas around the country. And then we'll actually, you know, spend a good amount of time meeting one on one with individual companies and learning about their project, ideas and really try to help advice you on your project and how that, you know, how to develop a stronger application when you are applying for the funding at the NCI. The other thing that we're able to do is that we can couch applicants, you know, through the word process, we provide over side in active management or projects and we can really help mentor and guide companies throughout the award period just based on the backgrounds of the folks on our team. And as our companies are maturing and, you know, they're--they've gone through phase I SBIR, they're into their phase II projects. Their technology, you know, is that kind of at a key inflection point where they're ready to--to talk with other investors and raise other funding, we can help facilitate match making with potential third party investors and strategic partners. So, the way we do that is we--about, once every year and a half, we hold what we call our NCI, SBIR Investor Forum. This is really the unique opportunity for the NCI to showcase the top companies in our portfolio and typically what we do is the way we did that is we pull together an external panel of investors and strategic partners and they help us review our portfolio and identify the top 15 to 20 companies that we're funding and then what we'll do is we'll showcase those companies to the investor and strategic partner community and the goal is to really help, help our companies make those connections that will facilitate raising follow on capital to SBIR funding. We've held this event three times now, 2009, 2010 and then just last year 2012. Last

two events we've done out in San Francisco and as you can see in 2010 we had a total of 14 companies that presented at our investor company, our Investor Forum and eight out of those 14 companies we're able to close deals with investors. Those deals are collectively valued at 200--over 213 million dollars. So, you know, that the--this effort is working and, you know, we really see it as kind of an important role for the NCI to play. This gives you just a brief overview of just four of the eight deals that were concluded. Two of these were actually therapeutics companies, one was company called Zacharon out of a San Diego area, a company focused in developing therapeutics for rare diseases and cancer. Coming out of our Investor Forum they were able to finalize their partnership with Pfizer and went up to 200 million dollars. And then Zacharon was actually purchased just in the past year by another company called BioMarin. The other company we funded a company called Lpath who's able to raise just under million dollars and then equity financing round for the continued development of their two drug candidate. And also had one of our diagnostics companies MagArray which closed a deal. And another company in the imaging area, developing imaging agents ImaginAb was able to raise 12 and a half million dollars coming out of the Investor Forum.

Another program that we put on is what we call our Workshop on Federal Resources to Accelerate Commercialization. This is an event, our goal is to hold this probably about once every year and a half, we invite all of our grantees and contractors to it and we try to make information available on other programs at the National Cancer Institute, across the NIH and really across the government that are available to companies that we're funding that, you know, resources that they can tap into in order to really help facilitate the development of their technologies in advancing their technologies further. So, at this event we had representative from the Food and Drug Administration, from CMS, from the patent and trade mark office and also from the White House. And each of them, you know, give overviews of the different programs that they offer, you know, what kinds of advice they can provide to small business, as you know, they're developing their projects, you know, as their advancing for example towards clinical trials. And these folks are actually available over the course of that day to meet one-on-one with the companies that are attending. So, we got a lot of positive feedback on the first time that we held this just back in May and it's something we plan on continuing to do again just to make all of these other resources across the government available to our companies.

In addition to, you know, the state or program that I just mentioned I also mentioned earlier that we have this technology assistance programs for our awardees. The first program is known as the Niche Assessment Program. Eventually, this is open to phase I, SBIR and STTR awardees. Essentially we--we fund a contractor that will--if you apply to this program and if you are accepted, a contract will actually develop the market analysis around your technology and provide that market analysis to your company free of charge. We have found that that often times is provided companies valuable information as they're developing their phase II applications and

they are trying to develop the commercialization strategy around their technology. So, that--that's something again that's open to all phase I awardees under the program.

There's another program we offer for phase II awardees, this is called our Commercialization Assistance Program. Essentially, we link companies under this program with mentors to guide them as they are trying to implement their commercialization strategy at the phase II level. So, these are mentors from across--across industry or for example, you know, a regulatory, the regulatory roles. It really depends on the needs of the specific company, there's a fair amount of flexibility here but this is really to help--help our phase II companies advance their technologies and really implement their--their commercialization strategies. And then I also had mentioned earlier, you know, if you rather just fund the technical assistance yourself, you have the ability to request 5,000 dollars through a Technical Assistance Supplement and just, you know, fund this type of work yourself.

So, in addition to the programs, we offer--there are other programs that the NCI that I'll just mention briefly here and this are resource type programs and this are not funding programs. And again, these slides will be available so you can--you can explore these in more detail. First program is known as the NExT program or the NCI Experimental Therapeutics Program and this is essentially is a program where NCI, you apply to this program and if NCI is really interested in an early stage drug that you are in the process of developing NCI can make resources available to your company in order to help advance that drug towards--towards an NID and ultimately into the clinic. That's just one example of one program we offer, we also offer other programs like our Clinical Assay Development Program, our PREVENT program. And then I've also provided links here to the programs offered by another institute known as the National Center for Advancing Translational Science.

We give you one quick piece of information on just the company that we consider to be a success story. This is the company we funded under our program called Insight Genetics. They're molecular diagnostics company that was established in 2007, a spin off from Genetic Assays and they're in the business of developing companion diagnostic assays. So, we've actually funded the development of several different companion diagnostic assays of these companies just provide you just a brief overview of those three different projects but first is a real time PCR test that detects mutations and fusions of the ALL gene that are linked to multiple cancer types including non-small cell lung cancer, colorectal and breast cancer. This provides an accurate result that inform whether a patient will respond to an ALK inhibitor treatment such as Pfizer's Xalcori. And this just shows you the funding history on the project, we gave--we provided the first award to this company back in 2010. It was a phase I award, they received a phase I in 2011 and then in 2012 they actually received a phase 2 award from us. What we're really excited about is, you know, we feel that the NCI SBIR funding helped the company develop the technology to a point that, it became a strong interest to strategic partners. So, just last year, they were able to conclude a partnership with QIAGEN on the technology that we funded. And that's

where the manufacturing commercialization of insights ALK screen kit as a companion diagnostic. And as many of you know QIAGEN is global leader in personalized healthcare. And so, they're actually with that agreement with QIAGEN, they're going to actually be commercializing the test kit that was developed by Insight. Insight also closed a commercializing agreement with Clarient which is a GE healthcare company and that's going to be for the use of Insight, the Insight ALK screen for genetic testing, for non- small cell lung cancer. They've also closed a partnership with Kindstar Global Chain, that's for laboratory testing services in greater China. And then finally, just this year QIAGEN licensed exclusive worldwide rights to--from Insight generics for the--for three other biomarkers for the detection of non-small cell lung cancer. And in addition we've been able to tie Insight into another program that NCI offers which is our Clinical Assay Development Program and in this program is going to help facilitate optimization and analytical performance as well as establishing the clinical validity of assays to providing Insight Genetics with access to--for example clinical samples as well as services of two CLIA-certified labs. So, that concludes my portion of the presentation, we're now going to move this on to Andy Kurtz. He's going to talk about specific funding opportunities and practical strategies for applying.

Christie Canaria: So, thank you Michael, you just heard from Michael Weingarten, our Director here at the NCI SBIR Development Center. Before we move on, Andy's portion of the webinar I'd like to remind everyone listening in today to please submit your questions through the web--software and we will address them at the end. Andy Kurtz.

Dr. Andy Kurtz: Thanks Christie. So, taking a look at some of the questions that have come in since we've been on the line and we'll try to address some of those as we go along and then certainly we can take more specific questions as we get to the end. So, what I'd like to do now is shift gears a little bit and add some color to some of the things that Michael explained about the program in terms of providing information on specific resources for you as the applicant. So, just a start with the funding opportunities that are available there are three primary categories of SBI. Our funding opportunities at the NIH, the first is what's called the SBIR and STTR Omnibus Solicitation for Grant Application. These are the primary funding opportunity announcements that most SBIR and STTR grants are funded under these announcements come out in January of each year, they have standard receipt dates on April 5th, August 5th and December 5th. You can find more information about all funding announcements in several places so for announcements that are specific to the NCI we have our own website at sbir.cancer.gov. You can use this site, as I said to find information on these funding opportunities.

You can also sign up for updates to be notified when new funding opportunities become available. There is also a general NIH SBIR website that provides a great deal of information not just about funding opportunities but also other events and resources that are available to all of the--across all of the institutes and centers for applicants in all areas. And then there is also

something called the NIH Guide which is a searchable database of all current NIH Funding Opportunities which includes SBIR Funding Opportunities across the agency. Again, the Omnibus is the primary announcement for most grant applications but there are number of other special grant announcements that are released periodically. These are updated weekly in NIH Guide. Sometimes those announcements follow the standard receipt dates and sometimes they follow special receipt dates. So, you need to take a look closely at the announcement.

I like to give you a little bit of information about a few of those specific funding opportunities here at the NCI just to give you a flavor of some of the things of interest to us. One of those is titled Innovative Health IT for Broad Adoption by Healthcare Systems and Consumers. The goal of this announcement is to accelerate development and commercialization of evidence-based consumer health IT to help prevent and reduce the risk of cancer, facilitate patient provider communication and improve disease outcomes in consumer and clinical settings. This announcement is really geared toward projects that are poised to relatively quickly bring a product to market. So, we're looking specifically for either phase II applications that are predicated on phase I award that was already completed in this are or else a fast track application that, again, is poised to move relatively quickly from proof of concept work into development work into the phase II. The expectation under this program is that competitive applicants will have partnership arrangements with large businesses. This could be commercial IT firms, electronic medical records, vendors, other healthcare systems, organizations and other groups like that, again, with the goal of moving a product to market relatively quickly. This announcement is following the standard receipt dates. The next receipt date for applications is on December 5th and our office contact for this opportunity is Dr. Patty Weber and you can find her information here.

Another announcement that we recently joined onto is called the Development of Highly Innovative Tools and Technology for Analysis of Single Cells. The goal here is to develop next-generation tools to better define cell heterogeneity in situ, with substantially increased sensitivity, selectivity, spatiotemporal resolution, scalability, or non-destructive analysis of multiple global or functional measures of single cells. This is actually something that is cross-cutting across the NIH. It's affiliated with a larger program called the Single Cell Analysis Program that supported through the NIH Common Fund. The goal is to develop new analytical measures and manipulations of cellular contents to look at structure and activity beyond those methods that are currently available in single cells. And this would include first-in-class or cross-cutting technologies that had multiple applications for variety of different disease areas and disease states. This announcement is also following the standard receipt dates again, the next opportunity to submit an application is December 5th. And the contact in our office is Dr. Jian Lou. And she can stick with you more if you have questions about this announcement.

And then the last targeted announcement I'll highlight is something called the Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care

announcement. The goal here is to support development, maturation and dissemination of novel and potentially transformative next-generation technologies through an approach of balanced but targeted innovation to support clinical, laboratory or epidemiological research on cancer. Again, this is focused on molecular and cellular analytical technologies for cancer detection and/or characterization in vitro, in situ, or in vivo. This announcement has special receipt dates so be sure to look closely at the dates for receipt of proposals. The next opportunity to submit under the IMAT announcement is May 28th of next year. And our program contact for this announcement is Amir Rahbar.

I wanted to mention special funding opportunity that we launched here at the NCI going back about five or six years which is called the SBIR Phase IIB Bridge Award. The thinking behind this program is that for many of our projects that proceed through the Phase I and Phase II Development phase, many of these projects achieved their goals and produced promising results. But there's often a funding gap between that point and when a third-party investor or strategic partner would be willing to come in to help advance the full commercialization of the technology. And so, what we've done to help address that funding chasm which is sometimes called the Valley of Death is to provide some additional funding through this Phase IIB Bridge Award. But there are number of sort of special caveats to being competitive for that funding. So, it does provide up to a million dollars per year for up to three years following the phase II award. It is open to any NIH funded phase II awardee with the project that is relevant to NCI's mission and more specifically that falls within the technical scope of that funding announcement which is somewhat selective as far as things that it covers. But it's designed to really accelerate commercialization by incentivizing partnerships with other third-party investors and strategic partners earlier in the development process than might otherwise happen. And so, the way that we do that is we provide competitive preference and funding priority to companies that can secure matching funds for that Bridge Award portion--for that Bridge Award funding. So, again, here we're looking for a minimum dollar for dollar match from outside third-party investors. And the idea here is that we as the NCI would be sharing some of the investment risk with those other outside partners to sort of bridge this gap between the Phase II Development phase and full commercialization. This slide summarizes 13 of those Bridge Awards. We've actually made 16 awards to date. So, this is a little bit out of date. But this just gives you a sense for the amount of funding that the NCI has provided in aggregate through the Bridge program and then the amount of funding that each of those companies has raised. So, the blue bar has showed the level of the NCI award. Orange shows the third-party investment funds. And in aggregate, you'll see that even though our goal is a dollar for dollar match, we're actually achieving closer to 2 to 1 in leverage as far as the third-party investments that match the Bridge funding. As far as where those dollars come from, in rough numbers about a third of that money comes from traditional venture capital, about a third from strategic partners, and about a third comes from other individual investors and other investors that don't fit those other two categories. We are relatively agnostic as far as where those third-party investments come from under this program.

But again, it's up to the company that puts together those deals in wherever way makes sense for the project.

Finally, on the list of different types of funding announcements, there is this solicitation for SBIR contract proposals that comes out once a year. Typically, this is in mid to late August. This year the receipt date for contract proposals is November 25th. So, it's coming up quickly. I will say just a few more words about how we think about using contract solicitations at the NCI and then give you a little more information on how the contracts are structured. So, over about the last six years, we have used the contract mechanism more extensively here at the NCI to really drive areas that we think are emerging opportunities technical areas for development by the small business community. And the way we think about that is just sort of think generally about the various scientific and technology priorities of the institute. It's also to think about areas that are of interest to the commercial sector based on market opportunity and other things like investment activity. And then when there is overlap in this Venn diagram, really focused on those areas where we think there's an overlap between NCI's priority and an opportunity for commercial success. And so you'll see that as a percentage of our overall SBIR portfolio, these more focused areas of development represent a larger fraction of bar activity over about the last six years. Currently, it's about a third--represents about a third of our portfolio in these targeted areas.

So, few words about how grants and contracts are different, so I just alluded to this for most grants in general those funding opportunities allow you and the investigator to define the scope of the problem and the solution to that problem whereas under a contract, the NIH or the NCI in this case is essentially defined the scope of the problem for you as the company and you're expected to bring an innovative solution to that problem. An important administrative difference between grants and contracts, if you're considering a grant submission not only is it allowed is very much encouraged for you to get on the phone and talk with the program officer before you submit your application. Under contracts, the rules are quite a bit different. Once that announcement hits the street, the intent is that everyone would be competing for an award with the same information. And so, you're not permitted to have detailed conversations back and forth with the program officer. You are allowed to contract the--contact the contracting officer if you have questions about clarification for what's being submitted. But in general, those interactions are relatively brief and are limited to answering questions about clarification. Again, for most grant opportunities, you're allowed three times per year to submit applications. Again, contracts come in only once a year. The reporting requirements are quite a bit more honors for contracts than they are for grants. In general, there's a kickoff presentation. There are quarterly progress reports, final report, as well as a commercialization plan. Most grant opportunities do not have a set-aside funds associated with them. But for contracts which again have been pretty identified as priorities by the NCI. We do tie a set-aside of funds to those particular areas. In general, program staff involvement once a grant award has been made tends to be relatively low,

although it really depends on a project in how proactive you may be in terms of wanting some interaction with your program officer along the way. For contracts, there is a high level of program staff involvement along the way. You receive regular feedback on your progress reports. And in situations where the project may need to pivot or make some sort of technical turn, that wasn't written into the original contract. Those are all things that have to be pre-approved and discussed not only with your program officer but also a contracting officer.

Few more notes on differences between grants and contracts. For most grants the review of those applications is conducted at the NIH Center for Scientific Review which is the locus of review for most of the basic research applications and SBIR proposals that come to the NIH. For some of the more targeted announcements including SBIR contracts, those proposals are reviewed at the institute level. And what that means in a practical sense is that our office works much more closely with the review office to help recruit reviewers that have specific expertise around the topic areas that we pre-identified in these specific activities and deliverables in those topic areas. The--again, related to review, most of the study sections over at CSR, they review applications for different programs that have some overlap in similar topic areas. But again, study sections that are assembled by the NCI are specifically recruited and selected around individual specific topics. Very important difference between grants and contracts, by and large although not entirely, but by and large, the peer review score is largely drives your competitive--competitiveness for funding under a grant, although there is also some consideration given to program relevance and balance. For contracts, the peer review process really is only the first step. After you've received a competitive score, there's a fairly involved negotiation process where you will work not only with the contract office, but also our program office to answer number of technical questions that may have come up with--in review to help refine and define the specific activities that you'll deliver during the course of that project. A lot of that time is also spent really just to find the particulars of the budget to make sure it's very clear what the government will receive under the terms of that contract. Another consideration relative to the fast track mechanism that Michael discussed, when you submit a fast track grant, it's important to realize that the phase I and phase II pieces of that fast track are reviewed as a single package and considered as a single project. And that's important because, in cases where--it may be a very innovative and interesting project and idea, if you don't have a lot of preliminary data such that there appears to be a fair a bit of technical risk, you may submit a very strong phase I work plan. But there may just be too much risks associated with it such as the phase II plan is very difficult to evaluate. And in situations like that, it can end up pulling down your overall score such that nothing ends up being funded. So, in contrast, when you submit a fast track contract proposal, phase I and phase II, those sections are considered a separate proposals. So, in some ways, there's less risks there. If the phase I scores well and the phase II of course doesn't score well, we have some latitude to consider just funding the phase I proposal and to negotiate only that section of the award such that you could compete for a phase II at some point in the future.

Just to let you know with some of the specific opportunities are right now, again, these are for the November 25th receipt date coming up. We've bend these into three general categories. The first is Therapy and Diagnosis. I won't read through all of these for you but you can see we have a number of areas around different topics associated with, again, both novel therapeutics, as well as diagnostic technologies. Some topic areas that we've went under what we call Advancing Cancer Research which are largely focused on facilitating research or developing new tools to facilitate research. And then one topic this year focused around Health IT to develop specific software tools for development of environmental measures related to cancer health behaviors and resources.

Again, just some summary information, I've went through most of these already. But the contract opportunity is an annual announcement. This was published in August 29th of this year. The original deadline was November 13th, but that was extended partially due to the government shutdown to give folks several extra time that was sort of lost during the month of October. We've provided links here to the request for a proposals as well as an amendments that was issued to that original RFP. You can find more information about the various NCI topics that I just spoke about on our website. Although, I'll mention that several of the other institutes have included a number of other topics which I've not mentioned. So, you may want to take a look to see if there's overlap with your company's core-competencies in address.

Another quick note about the review criteria for contract proposals. So, I won't read through the details here, you'll notice that if you're familiar with the grant review process, these are the same general categories that are used to evaluate any SBIR proposal. But it's important to recognize that the contract proposals have a particular weighting associated with each of those areas. So, for example, when reviewers are considering the soundness of the technical merit of the proposal, that's worth 40 percent of the overall score for your proposal. Again, qualifications of the principal investigator, 20 percent, and so on down the list. So, as you're putting together each of those applications not to say that any one has more or less important but when it comes to calculating the final score, sometimes it's helpful to make sure you understand the weighting that's given to each of those areas. Similarly for phase II, the areas focused for review are similar but they have slightly different weighting in particular, there's a heavier weighting on the commercial application of the technology. So, by that stage in the project, the expectation is that you're really flushing out things like regulatory strategy, downstream financing and the market opportunity that you're proposing to address with the technology.

Just as a reminder, at this point in the presentation, please remember you can submit your questions at any time using the Q&A box on the right hand of your screen. And if you don't see that, you can expand it by hovering over the green bar at the top of your screen. We would ask-- as you're thinking about your questions during the talk today, please try to submit things-- questions that are of a general nature. Please don't provide any proprietary information. We won't be answering specific questions about your project today. But again, if you have questions

about the contract opportunities that I just mentioned, Elizabeth Shanahan is your point of contact for those. Or any questions about grant opportunities can be directed to our general mailbox at NCIsbir@mail.nih.gov. Again, just as a reminder, the webinar slides including a recording of today's talk and the Q&A section will be published to our website after today is completed. In here, again, is Betty Shanahan's contact information here at the NCI.

So, in terms of the grant application process, Michael mentioned a moment ago that the overall timeframe from the time that you submit an application until you would receive funding is in the range from six to nine months. Sometimes that can be a little bit longer than nine months. It really depends on the budget cycle and what round that you submit for. If you submit for the earlier April round, it tends to take slightly longer to receive your funding that it does if you submit in August or December, and again that's due to the federal budget funding cycle. But once you've decided to apply and you put together an application, it takes about two to three months after you submit it for the peer review process to take place, within a day or two of the peer review, your numerical score is available to you through your eRA commons account. But it can take up to six to eight weeks before you'll receive written comments in the form of a summary statement from the reviewers. At that point, it's usually a good idea to contact your sign program officer depending on your score; they may be able to give you a sense for your competitiveness for funding. Although that again depends on the number of factors including where we are in the budget year and where your score is on the overall scale. At that point, based on that discussion, you should have a relatively good idea about whether or not you want to resubmit the application. So, you have one opportunity to submit any application with revisions. After that, if the application is unsuccessful a second time, the expectation is that you would substantially retool that application and revise the specific games in submitting new application for consideration. Again, if you successfully go through this process, somewhere between six to nine months after submission is when you would see money.

Few words about deciding to apply for this program. So, it's worth mentioning I think that these days, SBIR and STTR awards are very competitive here at the NIH. It has not always been that way over the years. But these days, the funding success rates for SBIR and STTR are really hovering around the same levels as they are for RO1 awards. It's somewhere in the 10 to 15 percent range. It's important to realize that particularly if you are a new applicant, you should go into this expecting that you may need to resubmit and respond to an initial round of comments before you'll be competitive for funding. It's important to realize that the folks that you are competing against are very bright, skilled, accomplished, and they come from top institutions. Many SBIR awards involved collaborations with universities even though that's not a requirement. It is the norm for many companies to be working with very accomplished academic investigators with a great deal of specific expertise around their topic area. We do see a lot of great ideas. So, the best way to combat this competition is obviously to prepare a strong application. And the best way to do that is to use all the help and the resources and the people

that are available to you. When is an appropriate time to consider submitting an SBIR/STTR application? Obviously, we are looking for innovative solutions to significant unmet clinical needs. The SBIR program really is the engine of innovation for commercializing a lot of the technologies that have some foundation in other basic research that's been funded by the NIH. So, we're really looking for projects that not only address significant problems but also have significant commercial potential in order to deliver products and services to patients.

All right, it's important to really think carefully about how you're leveraging your specific companies and founders expertise to solve these innovative or these significant problems. Think about using this funding to produce feasibility data that's really going to be key in order to perform downstream development of a product or a service. In cases where maybe the technology is a little bit more advanced with some feasibility, you may want to consider a fast track proposal to really accelerate the development of that technology. In many cases, folks that apply to the program are start-up companies. So, these maybe companies that are a little too early stage for private investment and they focus on SBIR and STTR as a way to secure seed funding. To sort of contrast that previous example, we also see a number of applications from established small businesses that do not currently have resources available to pursue new approaches or new technologies. But their Board or the other leadership of the companies supports using SBIR as a way to sort of pilot new programs within the established company.

There are also some situations in which we would recommend that you not apply. We don't ever encourage chasing solicitations. Why not? Really, we look for companies that are applying their core-competencies in a way that can best deliver on the problems and the unmet needs of the NIH and in our case, the NCI. I would say, in particular for the contract topics, we sometimes see companies that are really trying to bend or pivot, you know, some of their core-competencies in a way that's really not aligned with their business model and their core-expertise. And that's really not what we're looking for. We're looking for folks that really are aligned with--well, with the problems and the solutions that they're tackling. We do not encourage companies to chase "cool" technologies or for that matter to develop a cool technology and chase solutions or problems that may not be well aligned with that technology. It's not appropriate to consider SBIR if you are really in need of cash and have to get your hands on it quickly. Again, the timeframe for securing your funding can be anywhere from six to nine months or upwards of that. The funding for an SBIR Phase I is in a range of 225K. So, there's a substantial time investment or even a Phase I award and for obviously for downstream Phase II or Bridge Funding. So, it really shouldn't be approached with the idea that you would get your hands on money quickly, but really as part of a larger overall financing strategy for the company. Again, we're really looking for innovative solutions to significant unmet needs, solutions that represent sort of incremental upgrades without any change in clinical paradigms tend to not do very well in peer review. Also, products that are really sort of follow on "Me too" products without any substantial value proposition really tend not if they were in peer review. We are not

looking for projects that are going to require a great deal of basic research in order to demonstrate commercial and clinical feasibility. A lot of that work we would hope would have been accomplished under some previous basic research funding. And it's not appropriate to consider SBIR as a surrogate for a lost RO1. So, again, sort of summarizing some of the things I mentioned. Before you write your application, really consider your company's strength as well as your weaknesses. It's helpful to review other similar currently funded NIH projects and the best way to do that is to view--do a search in the NIH Project RePORTER database. I can't emphasize this point enough. It's always helpful to contact your NIH Program Director early and often to discuss what you're thinking about including some of the details of your specific aims so that you can get their feedback. We see a ton of technology on a daily basis and have a pretty good sense for whether or not what you're proposing is one of this sort of "Me too" projects, whether sort of the innovative aspects of the proposal relative to other things that you might see and how you might present that in order to be most competitive. This is a screenshot of the NIH Project RePORTER database that I just mentioned. You can use this to go in and actually search with specific fields to look at the SBIR and STTR funding mechanism specifically you can search by a specific institution if you're interested in limiting it to the NCI for example and you can then enter keywords which will pull a project specifically in that area. So, that's one helpful way to take a look at things that maybe similar to what you're contemplating.

A few words about what it takes to get funded at the NIH and at the NCI. So, in terms of building the application again we'd encourage you to start as early as possible. Strong applications take time to develop. It's important that you handle all of the administrative registrations that are required very far in advance we suggest that at least two months if not more than that in order to get all of your registrations in line to be able to complete the electronic submission. You can find more information on that at the NIH, SBIR page under the electronic submission heading. Again, make sure that you carefully read the particular solicitation that you're responding to. There are some key differences between for example the Omnibus solicitation and some of the other targeted grant opportunities. So, you really need to go through. Make sure you understand the receipt dates. The review criteria, sometimes there are particular budget constraints. So, make sure you have a handle on all of that information. Also in support to start early to make sure that you have time to fill in the gaps in the proposal what we would call gaps. These could be--gaps on the team could be a matter of going out and recruiting an appropriate collaborator. It might involve making sure that you have access to all the equipment and resources that you're going to need or it could mean going out and securing letters of support either from those collaborators or other folks that might be able to lend validation to the overall approach. Most of the--or all of the information that you're going to need to actually submit the application is contained in something called the SF424 application guides. This is listed as a URL in all SBIR applications. It's a very large PDF file. And this is a--what it looks like. Key number two as far as preparing your application. Again, building off of the previous slide, it's important to take time to refine and explain your vision for the project.

So, as you think about what you're going to tackle its always important to have a formal discussions about the products and what that will eventually look like. The way to think about that is through interactions with potential customers, other folks that have technical expertise in the area. And again, since this is SBIR really thinking long term about who are going to be the downstream, potential investors and commercialization partners up to and including full commercialization and distribution. A good way to approach this is to seek help from folks to have previous experience and being successful with this. So, who are folks that you know that have successfully competed for SBIR funding in the past. Very often it's helpful to talk with your academic collaborators who have experienced with the grant writing process at the NIH. In general, even though they may or may not have specific expertise with SBIR, they can often help you with general grantsmanship approaches. It is helpful to sometimes engage professional grant writers if you have access and resources to do that. But again, none of those things should substitute for engaging early and often with SBIR program staff. The funding climate can change. You want to make sure you're very up to date on the most current opportunities. So, leverage all of these other things but make sure you also get on the phone and talk with your program officer.

Another thing that folks sometimes forget is that with any project, there is some risk associated with that project, sometimes that's technical risk, sometimes that can be administrative or programmatic risk in terms of access to resources or samples or other things that you may need. So, make sure that as you put your application together, you identify what those risks are. Be very clear about not only your study design but also any alternative approaches that you're going to consider to mitigate those risks if you have to pursue contingencies along the way. Obviously very important to build the right team, the principal investor is key to the proposal. They must have the appropriate expertise to oversee all of the activities that are going to be carried out under the project. Sometimes, it's appropriate to consider building a team that would include multiple principle investigators particularly in situations where you're taking a multi-disciplinary approach to solve a problem you want to make sure that you're covering all of the key areas of expertise. Other things related to the team involve establishing appropriate academic collaborations. Very importantly, consider whether or not you're going to need to engage outside consultants. For example, in the area of drug development, very often it's key to go out and recruit regulatory expertise to fill in gaps that may not be part of the key personnel within the company. And in other situations it may even be appropriate to consider partnerships or strategic alliances with other companies particularly in the area of manufacturing for example that can be very beneficial. Sometimes it's even helpful to think about the SBIR funding opportunity as an engagement tool to initiate some of these collaborations. As I mentioned academic researchers have by and large a great deal of experience with NIH funding process. So, they understand grants and what's involved there. Business executives and other business and industry professionals understand areas of product development and marketing. So, SBIR in

many ways can be leveraged as a tool to bring some of those folks together to help solve significant on that needs.

Very important thing to remember when you're putting your application together is that the only thing the reviewers have to go on is what is actually written in your application. They will not have the benefit of being able to get on the phone with you and ask questions the way program staff will. So, it's very important that you'd be as clear and as focused as possible about what you're going to do. That really starts with the one page specific aims section of the grant. You want to make sure that you use that one page to grab their attention in a positive way. In many ways it's sort of the focal point of the application. You want to use it to highlight the strengths of your technology to describe your goals. Hopefully, say a word or two about what are some of the milestones that will indicate success particularly for a phase I feasibility study. And to essentially really highlight the problem that you are uniquely able to solve and what sets you apart from your competition in terms of meeting significant unmet medical needs. That then sets the stage for the research strategy section of the application which is really the meat of the application that starts off with the background sections. It sort of set the stage for what you're going to accomplish. You want to make sure you provide a very detailed technical plan that you're going to pursue to achieve those specific aims. The budget section is actually a separate section but you want to make sure that the budget aligns with all of the activities and the resources that you're going to need to achieve those specific aims. The question that we often get is whether or not preliminary data are required. The preliminary data aren't required for a phase I proposal but they are very powerful. And I will say that in almost all cases applications really need to have preliminary data in order to be competitive in the peer review process. And again, very often those preliminary data are--have been accumulate and assembled under other previous basic research funding often that happens during academic lab but not always. Again, I already mentioned to make sure to describe potential pitfalls and the risk and make sure that you communicate alternative angles of attack or other contingencies in case things take twist and turns.

Other components in the application that you want to make sure you pay attention to. Letters of support are very critical particularly from consultants and collaborators just to make sure that those people are firming their interest and desire to work with you on a project. Letters of support can also be very powerful even if they don't come from folks that are going to work directly on a project but have something that they can say about the value proposition of the technology. So, for example, anything that may have a very direct clinical application, if you're working with physicians that work in that area and can speak to that need, very often it's helpful to use--to include a letter of support from them to indicate their desire and eventually using a product that may look like that one day. And for that matter, you know, any other end user or potential investor, or partner that can really speak to that commercial potential providing letters from those folks can also be very powerful. It's important to remember a phase II application

that represents follow and development from feasibility work that has been done in phase I. So, phase II involves 12 page commercialization plan that would really flash out in more detail of how you're going to bring up a product or technology to market. Another component of the application is a cover letter that you're allowed to submit that makes usually specific administrative request once the application gets to the NIH. So, that's really--cover letter has really addressed two key issues. One is the assignment of that application to a particular institute or institutes. So, there maybe situations where, for example, you're developing a technology that has an application to a cancer field and perhaps also something related to infectious disease. So, in that situation you may want to request that your application be assigned primary to the NCI and then receive a secondary assignment to the Institute for Allergy and Infectious Disease. In case one Institute may have greater funding latitude as the year goes on and after your application is scored. The other thing that you can use your cover letter for is to request a specific study section at the NIH. They are a number of standing SBIR study sections that the SBIR and STTR applications are assigned to. If you would like you can visit the Center for Scientific Review website and identify one or more study sections that you think maybe appropriate and then use your cover letter in order to specifically request that your application be assigned to one of those. Biosketches for the key personnel are very important in order to make sure that you demonstrate that the key personnel have all the expertise that is going to be required to achieve the aims of the projects. The budgets for each project period should be very clearly spelled out and justified in the budget section. Again, descriptions of facilities and equipment are very important. Any project that is going to involve human research or vertebrate animals requires a specific section on either one of those areas to make sure that assurances either are in place or will be in place before that work is undertaken, as well as to ensure that all the studies are done in accordance with NIH policy. And then again, make sure you read through the application or the solicitation to make sure that there isn't any other specific information that's required for that opportunity.

Before you submit, it's always a good idea to try to do your own peer review. Try to recruit folks who can help you poke holes in the idea and identify what are some of the weaknesses that may come out during the discussion of the review. I think it's very important to say that you shouldn't try to hide those weaknesses. It's always better to bring those to the forefront and then identify ways that you're going to address them. You should assume that your application is going to be seen by experts in the field and that if there are underlying weaknesses you should assume that they will be discussed during the review. So, again, best way to address that is to confront them head on and let the reviewers know that you thought about these things and you have a way to tackle those. Again, you can ask collaborators to review the application. Another good way to get some feedback is to try to find someone who is technically trained, but perhaps not in the area in which you are presenting. Just to try to determine, do they understand the overall goal of the proposal and are they excited about it. I think these are some of the same things that the reviewers are going to ask themselves. So, if you can get some preliminary

feedback from some of your own contacts then that can often help you shape the proposal before you submit.

Make sure that you know and understand what are the key NIH review criteria. There are five key review criteria across all NIH applications. These are Significance, Approach, Innovation, the background and expertise of the Investigators and the Environment. There has been a sixth consideration for SBIR proposals which again is the potential for commercialization of the technology. I won't read all of the description to you but make sure you know and understand the core NIH review criteria as well as anything else specific that's being called for in a particular announcement. I already talked about the use of a cover letter so I won't go through this again other than to say there is a roster index of SBIR study sections on the CSR website. So, this is where you can go to take a look at those study sections, what they're focuses on, and what expertise of those panels gives to see if it aligns with your application. And here is the main landing page for the Center for Scientific Review.

So, you've worked late into the night, you submitted your proposal, what happens next? So, once you receive your summary statements, again, I already mentioned that that's a good idea to get on the phone with your program officer and have a discussion about what that might mean for your prospects of funding. In terms of receiving awards, so once applications come in about half of those applications goes through an initial review process by a set of primary reviewers. And then they are bend into either the top half or the bottom half of applications. Those that are in that bottom 50 percent, well, they will receive a written summary statement. They are not discussed any further at the in-person peer review meeting nor are they considered any further for funding. So, applications that fall into that not discussed category, those will need to be resubmitted in order to be considered for funding. And in all of those cases, I would say it's key to get on the phone as quickly as you can with your program officer to talk about some of the key weaknesses and how you can address them in a resubmission.

So, for applications that are scored again about 10-15 percent of the overall applications that come in are successful in getting an award. Those other 35-40 percent of scored applications. Those also will need to be resubmitted. And many of those scores, it's hard to know exactly where you will fall in terms of the competitive range until it gets relatively late in a year. So again, same message over and over again. Make sure you're in constant communication with your program officer who can give you feedback on the best decision as far as resubmitting. Make sure that you remember that if you're not successful the first time, that even though rejection can be painful, once you do have some written feedback from your reviewers, you do then have something to work with as far as making improvements for the next go round. The written comments in your summary statement really provide a road map for the things you need to think about most carefully in terms of resubmitting that application for future consideration. Make sure you use those peer review comments, not only to improve the way you present what you're doing, but also to make key changes that may be gave come through some of

the comments of some of these key technical experts. Again, discuss these things with your Program Director.

When you do revise and resubmit the application, you are allowed a one page introduction that gives you the opportunity to discuss at a high level. What are the primary critiques that came out of that initial review and how are you responding to those reviewer critics. Again, it's helpful to discuss those responses with your program officer. We would request that you do that early since we get a lot of calls. So, at least one month before the resubmission date. Try to get in touch with your Program officer and have a discussion. It's very important to remember to be constructive with those responses, but not defensive. So, remember that the folks that are reviewing your application, they are technical experts in the field. It's not uncommon for scientists to have a difference of scientific opinion. So, it's very important to address those concerns in a constructive way that lets the reviewers know that you consider them but you're addressing them in ways that you think are appropriate. Do make sure that you learn more about the SBIR and STTR process in general, that can help you in terms of understanding how the process works when it comes time for your own application to be reviewed. One way to do that is to explore opportunities for you yourself to participate on NIH peer review panels. You can talk with your program officer about opportunities to do that. Again, talk with other successful applicants and review the CSR website to understand at a high level how the review process works and what are the dynamics on the peer review study sections.

So, at this point, we'll make just a final reminder to you that you can submit your questions now and we'll be having a Q&A session here between now and the end of the call. You can do that by clicking on the Q&A box on your screen. Again, just another reminder, please focus your questions on general issues, general topics that don't involve any specific information about your project, specific questions about contract opportunities. It should be directed to Betty Shanahan at the e-mail listed here, grant opportunities, you can come to us at NCI or grant inquiries, you can come to us at NCIsbir@mail.nih.gov. And this is some additional general contact information or e-mail inbox, our website and please feel free to follow us on Twitter @NCIsbir. So, with that, I will turn it back over to Christie and we will start the Q&A session.

Christie Canaria: Yes, thank you. You just heard from Lead Program Director, Andy Kurtz. So, before we begin our Q&A session--and thank you for everyone who's been submitting questions throughout the webinar, I want to advise you that we are about to launch our poll and if you please take a minute to answer a few of our questions for you we'd really appreciate it. So, that should be going on live now and to begin with our first question--oh, so the purpose of our poll is just to gather feedback from you on how you found today's webinar, if it was useful. We appreciate all your feedback as we endeavor to make these presentations useful for you, our audience members. So, thanks again.

Michael Weingarten: OK, so I'm just going to start or we're going to start going to the questions here and try to answer as many as we can with the time that we still have. So, I'll just post the question and see if I could also answer. So, first question is just to confirm, it is not yet possible to go above the 225,000 dollar phase I cap.

Answer is yes. You cannot go above the 225,000 dollar cap. We do expect this next year to be given some relief, but I don't know what the timing of that is so for now you have to live within 225,000 dollar cap for phase I and 1.5 million dollar cap for phase two.

Let's see, the second question, "Can you switch from a phase I specific application to a fast track, which is the phase I, phase II joint application, if reviewed but not funded after the first submission?"

The answer is yes. You can switch to a fast track after your phase I submission. That could be--that would be a separate application.

Andy Kurtz: Yeah. I would mention now that more often, the reverse is true that a company may submit a fast track and maybe because of too much technical risk associated with the phase two, the reviewers may recommend that you come back and submit a phase I only. So, that change--that's happened quite often.

Michael Weingarten: OK, next question. Can NIH NCI laboratories serve as the academic partner on an STTR--let's see in this case the IT is going to be co-developed with the NCI. So, academic partners have to fit the certain roles around the program so that could be a college, it could be university, it can be a federal, an FFRDC, in this case if your partner, for example, NCI has laboratories at NCI at Frederick that is actually a FFRDC or Federally Funded Research And Development Center so if your collaborator is our contractor at NCI Frederick, then yes, they can be your partner on the STTR and be classified as such. If your partner is actually a government employee, then no. They would not be classified as the academic partner. However, we do have cases where companies are looking to license a technology from the NCI and develop it using SBIR funds. That is something that is allowed under the program. And in fact this year, we actually have one of our contract funding opportunity announcements that is open this year involves that type of technology. So, there are opportunities to collaborate with NCI researchers, but just in case of this question, they would not be considered the academic partner.

Andy Kurtz: Yeah, and just to follow up on that, I mean there are situations where SBIR funding or STTR funding can be leveraged in combination with other opportunities for collaborations. So, for example, we have situations where companies have an SBIR award perhaps to develop a technology that's maybe going to be beta tested or otherwise used in an NIH laboratory, the SBIR funds cannot flow to the government, but in many of those of cases the company will set up a separate CREDA agreement with the NIH in order to have a collaboration that has separate but related activities to the grant. So, I think the take-home message is that every collaboration

between a company and the NIH is different and if you have something that you're thinking about. The best thing to do is get on the phone with us. Sometimes the solution--the administrative solution may involve something through our office or sometimes through the tech transfer office, but we can certainly talk through those things and help determine the appropriate arrangement.

Michael Weingarten: OK, thanks Andy. So, the next question is when is the next NCI SBIR Investor Forum? We're currently looking at that for about a year from now. It's probably going to be next October or November and probably will be in the San Francisco area. We'll be deciding on that by the beginning of the year, so probably in January we'll have a date set. And actually one thing I would encourage everyone on the line to do is to actually go online to our website at sbir.cancer.gov and register to receive updates on the program. If you do that then you'll automatically get, for example, when we come out with new funding opportunity announcements or for offering, you know, a special new program to the community. If you sign up on the website, you'll automatically get information about that. So again, just go to sbir.cancer.gov and right there on the home page there is a link to sign up for updates on the program and you just have to give us your e-mail and other contact information. And then you'll also find out when our next Investor Forum is.

So, what is the best strategy for resubmitting and addressing review or comments? I think that Andy largely covered that question in his discussion. So, I probably go on to the next one. Do any of these programs apply to companies with an NCI contract not grant SBIR?

So, I think some of the programs that we talked about, for example, like our Technical Assistance programs, like the Niche Assessment program where we in effect provide a contractor that will provide a market analysis for your company if you're receiving funding from us under the SBIR program. Yes, contractors are eligible for that program as our grantees. And like our Investor Forum and our Workshop on Federal Resources, those are all available to contractors as well as grantees.

Let's see, more details. Someone was asking for more details on the NExT program. Andy, do you want to talk a little bit about that maybe or--

Andy Kurtz: Well, I generally, you know, the NExT program and resources available to provide essentially CRL-type activities to accompany this developing early stage therapeutic--this is through a network of CROs that the NCI has relationships with and manages, under that program the resources actually don't flow to the company, but they are dedicated on the company's behalf for a specific project. I won't say any more on the details of the program other than that the program is administrated out of a different office and if you have specific questions and want to send an inquiry to our inbox, we can connect you with the NExT program staff and they can

provide you more information. And also if you go to next.cancer.gov, they also have an e-mail address. You can contact them directly as well.

Michael Weingarten: And if you have other questions, you know, this can be for any question you have. Again, there is our NCI SBIR mailbox addresses right there at the top of that last slide that is currently being shown. Let's see.

So, next question is can some of the research be formed or be performed in a different country?

In most cases the internet is going to be no. The dollars is supposed to be spent here in the United States and some rare cases if there is a special capability, for example, let's say there's a cell line that we don't have here in the US that is available in a different country and you need access to that cell line in order to conduct your research, you know, in a very specific case like that. You know, that can be possible, but in most cases it's the same capability that you're looking for is available here in United States then it would not--we not--we would not be allowed to fund that work in a different country.

Let's see, what are the details around the other category for matching funding with the bridge award?

So, Andy do you want to say something about that, wonder what--what's candidates other?

Andy Kurtz: Yeah. Again--we--we'll accept a pretty broad range of investment types in arrangement. So, I'm not--I think we divided it out by traditional venture capitals, strategic partners and others. So, the biggest piece of other would be angel investors, an individual angel investors, but it could include other private equity firms that don't exactly sort of fit within sort of a traditional venture framework. In some cases it includes state by technology funds which are--there are several of these across the country that provide investments at the state level or sometimes in the case of universities. There are maybe opportunities for investments through university funds. So, we deliberately cast a fairly broad net in terms of what we would expect. But what I would say is that in all cases I think, you know, money is not always created equal. And by that, I mean, the expertise and the level of sophistication of the investors is something that we would consider as part of that overall investment strategy. So, you know, money coming from, you know, a very wealthy person, you may have expertise in the oil industry for life science project may not be considered quite as valuable as a company like Third Rock Ventures that does a great deal of work venture capital investment in the life science phase. So again, when emphasized that if you're considering a Bridge project, get on the phone with us early and we can talk through the details of what you're thinking about.

Michael Weingarten: And Andy, do they need the funds from their investor in the bank at the type of--at the time of application? Do they actually have to receive the funds already?

Andy Kurtz: Right. So, this is the other question that often comes up in. So, what we expect at the time that you apply for a bridge award is a plan for raising an equal level of funds to that which you're requesting from the NCI over the course of the project as well as some letters to collaborate that plan from your investors. It does not necessarily mean that you--if you're requesting 3 million dollars in a bridge award that you have to have 3 million dollars in the bank. However, we would trounce the NCI portion over three years to a million--up to a million dollars per year. Before we would initiate the NCI award, we would expect you to have raised at least that first years worth of private investment before we would initiate the award. So, at that point, it would be a million and you're one. We would expect you to have close a million before we would initiate the award and then similarly in years two and three.

Michael Weingarten: OK. Thank you. Next question is, how many resubmissions can I have and does the success rate improve with the resubmission?

The answer is you can have one application and one resubmission. And then at that point, if you're not funded then you have to change your aims on the project fairly significantly in order to reapply.

Does the success rate does it improve with the resubmission? The answer is yes. I don't know what the exact numbers are there, but they do improve. Companies often benefit a lot from that first submission and we encourage them, you know, do not be discouraged just 'cause you weren't funded on the first try because it is a very competitive program and we encourage you to resubmit and to use the comments that you got from the reviewers because everyone who is--who goes to peer review will receive a summary statement that gives you input on the strengths and the weaknesses of your application.

If we are deemed unresponsive for a contract submission, does that mean we would likely not be a good candidate for an SBIR grant?

That's actually a really good question which you'll find with our contract topics is that they are very targeted. They are very focused. So, just because you--you're not--you're deemed unresponsive it doesn't--it does not mean that you want to be a good candidate for an SBIR grant, the--our grants Omnibus Solicitation is a much broader funding opportunity announcement and really would capture almost all areas of cancer research that fit the goals of the SBIR program so that they are--they're focused on developing a commercial product. So, you know, again, just because if you did apply for the contract, I would encourage you talk to us before you make that decision on submitting for a grant, but, you know, grant could be a really good way for you to go.

Andy Kurtz: Yeah. I would just follow up on that by saying that, you know, the Omnibus announcement, the intent there is to really solicit any investigator initiated proposal that follows within the broader mission and scope of the various participating Institutes and Centers. We do list some high level areas of interest in the Omnibus announcement. That's not to say that if you don't see your technology type listed there that it would be considered unresponsive essentially anything that would again fall within that broader mission and scope would be considered responsive.

Michael Weingarten: OK. I think we can do one last question because we are coming up to the end of our time here. So, the question is, how does the NCI define market opportunity and significant commercial potential?

So, what I would suggest there is a number of different items, but I think, you know, we would like to see that you define the market or the potential market in terms of numbers of patients that can be served by the technology that you're developing. You'll also need to address, are there are current treatment options or existing products in this area? And what are the competitive advantages that your product will offer over existing or competing technologies or products? And how are--how is your company and your team uniquely able to meet the needs of the patient or cancer community in that product area? And then finally, what is the track record of the team that's actually proposing on the project? So, and do they have a prior track record of actually developing technologies in this area and in bringing products to market so that we would have confidence that you got the knowledge base and the capability on your team in order to commercialize?

Andy Kurtz: One other point to consider on that question is that, you know, we are not a four profit investment firm and so, you know, some private investors that you may engage maybe disinterested in anything that is not a billion dollar opportunity and that's not the approach that we take necessarily. If it's a large opportunity then that's great, we are interested in addressing significant unmet needs in cancer treatment and diagnosis and so forth. So, if that clinical need is significant just in terms of current standard of care even if the overall number of patients that you maybe impacting is relatively small compared to perhaps some other indications, we would still be very interested in the technology and seeding that technology so that perhaps some things that are not being developed and approached by the larger private sector could actually be accomplished by you as a small business.

Christie Canaria: OK. And with that I'd like to thank again Michael and Andy for presenting today at our webinar. I want to thank you too, those of you who have stayed on the line, thank you again for filling out our poll. We hope to have this presentation and up on the website with slides and audio. And again, I'd also like to thank again Brian Stocker from the CSBA for helping us promote this event. So, thank you all. If you have any more questions, please feel free to e-mail us, NCIsbir@mail.nih.gov. Thank you.

[End of Recording]