NCATS Wisconsin & NIH Webinar Transcript

MODERATOR:
Welcome everyone. This webinar will begin shortly. Before we proceed, we wanted to go over a few items with you. We want this to be an interactive session. We have some great content to share with you and great tips about the programs and resources of a variety of NIH programs with some of our partners. But we want you to share your questions with us. So even while we're talking, feel free to drop a Q and A question and we'll answer it during the Q and A.

We are offering closed captioning and Zoom Technical Support, and we'd like to make sure we collect your feedback. This helps us to improve our programming and find out what more you need to know to be successful. You'll be able to see the feedback form link in chat, and then we also invite you to join the conversation and follow us on Twitter, which is now X. So, during this webinar we're going to have a variety of resources that we'll put in the chat box.

Don't worry about copying them all. We will send an email with several of these resources, and we'll also have them on our respective websites. However, if you would like to save the chat, you can do so by clicking on the... which are the three dots in chat, and you'll be able to save them to your computer.

With that, I'd like to welcome you to the Entrepreneurial and product development support for academic and small business innovators. We have a wonderful webinar planned. We have a variety of cohosts, and this is an opportunity to bring you feedback and top tips from 4 institutes across NIH, the NCATS Office of Strategic Alliances, the National Heart, Lung and Blood Institute Small Business Program, the National Cancer Institute Small Business Development Program and we also have the National Institute on Aging Small Business Programs.

You'll hear from more of that, more about them and the resources shortly. We're also very thankful for our cohosts today. We are joined by the Center for Technology Commercialization in Wisconsin as well as the Wisconsin Women in Bio Health. Today, we have a variety of featured speakers. You'll hear from Margaret Ramey – she's the Interim Director of the Wisconsin Center for Technology Commercialization. April Hughes – she's BioForward's Woman in Biohealth. Meena Rajagopal – Dr. Rajagopal is the Program Officer at the NCATS Small Business Team. You'll also hear from Stephanie Davis – she leads the small business programs at NHLBI. In addition to Dr. Davis and the others I mentioned, you will be joined by Dr. Joshua Hooks – he is the program Officer at the Office of Strategic Extramural Programs at the National Institute on Aging. Dr. Saroj Regmi – Program Director at the SBIR Development Center at NCI. And my name is Monique LaRocque Ashton. I'm from Ogilvy Health and I'll be a moderator for today.

Just to give an overview of the information you'll be receiving; we'll be learning more about CTC Wisconsin and Bioforward's Women in Biohealth. We'll be going specifically through each of the NCATS, NHLBI, NIA and NCI SBIR and STTR programs and then we'll be leading a moderated Q and A.

With that, I'd like to welcome Margaret Ramey.

MARGARET RAMEY:
Hi, good afternoon. I'm Margaret Ramey with the Wisconsin Center for Technology Commercialization. I want to thank you so much for joining us today. I have so much representation from NIH today. It is very important to us to spread the word about the SBIR program and how helpful it is. So also thank you

program managers and coordinators from the from NIH that'll be speaking during this webinar too. Next slide.

So, my organization, the Center for Technology Commercialization is Wisconsin's No Cost SBIR Resource. We are a part of UW System and are partially funded by the Wisconsin Economic Development Corporation. So, all of our consulting, all of our programs and all of our events are free. So, this organization provides training programs. Events and grants to Wisconsin small businesses pursuing SBIR funding. So, if you're a Wisconsin researcher, innovator or small business considering the SBIR program, definitely come and talk to one of us first.

So, you might ask why is that? Well, we provide grants like I said, so small businesses in Wisconsin are eligible for up to three, almost up to $300,000 in grants that we manage to pursue Phase 1 and Phase 2 programming. So, those come in forms of grants that you can use to hire a grant consultant to help you write, and then also in in the form of SBIR match grants.

So, once you have a Phase 1 in hand, we will, it's a competitive program but you could be awarded up to $275,000 to cover costs that the SBIR program doesn't allow. So definitely come to us and we'd be happy to talk to you about NIH or other agencies that also participate in the program, and we'd be happy to help you get your program going. So next slide please.

OK. So, like I said, one of our free services is to provide training and events. These are a couple of exciting events we have coming up this fall. It's a busy fall for us. So, if you'd like to attend again, they're free. Sign-up for our newsletter. The link is right there on the slide. We'd be happy to have any or all of you join. You can go to the next slide, please.

And then again, if you go to our website and click on the request for counseling, it is a form that will also establish an NDA. So, doing this process will get you in touch with one of our consultants and then also make sure we're confidential. So, we would love to have any questions come to us via email or contact us through the request for counseling. That's all I have. Now we can get on to more interesting things. I'll hand things to April. Thank you so much for your time.

APRIL HUGHES:
And thanks again for joining today Margaret and for sharing the information about CTC. My name is April Hughes, and I am here to represent Women in Biohealth. I'm one of the cofounders of the organization. On next slide please. And one more.

All right, So, what is Women in Biohealth? So, Women in Biohealth essentially is an affinity group, the community affinity group. It is not a nonprofit. We are not a membership organization. You don't need to pay dues or need to be part of the membership to attend. But we are using BioForward Wisconsin as our fiscal agent to represent Women in Biohealth. So, we can get sponsorship for events and stuff like that. But we are, we're connected, but we are not necessarily owned or anything like that by BioForward Wisconsin. You do not need to be a BioForward member to attend. And again, because we are not a nonprofit, we're not a membership. All of our events are free as well.

The mission of our organization is to connect and empower women in the biohealth community. So biohealth is a pretty broad area. It's biotech, biopharma, digital health or healthcare technologies, healthcare systems, med devices, diagnostics. So, biohealth in general, anything that just kind of touches biohealth. But again, we have several individuals who aren't necessarily part of the biohealth that also

attend our events just because they are geared towards women-identifying individuals, but it is inclusive of all genders. So, we do see gentlemen at our events as well for engagement.

We do offer both professional development events as well as networking events for the community in Wisconsin. We're based out of Madison, but we do have some individuals in Milwaukee that are pretty engaged in our program. We offer mentoring circles as well as a mentoring program specifically and you can also find us on LinkedIn. We have I think it's up to 600 plus members now because of our events, so feel free to follow us on LinkedIn or subscribe to our email list and the things that we've been working on for 2023, we are revamping just a little bit, and we formed four leadership teams that are dedicated to four different areas. Those areas are community outreach, which also encompasses the educational system. So, if we have individuals that are reaching out for representation in in biohealth to come and do something for the schools, that would go through our community outreach group, and we're also launching an advocacy group which is currently focused on trying to elevate more women-identifying individuals into board positions at both for profit and nonprofit organizations. We also have a membership leader or excuse me, a mentoring leadership team, which covers our mentorship program as well as our mentoring circles or networking circles. And then we also have our professional development and leadership team that plans our professional development and our networking events. So those are all ways that you can get involved in the organization. If you want to go above and beyond just attending some of the events, we are always recruiting for those four leadership teams. If you are based in the Wisconsin area, more specifically in in the Madison area, you'll have plenty of opportunities to get involved. Next slide please.

This is our steering committee for Women in Biohealth. We have several people on the steering committee that are part of the industry in general. So, this was a grassroots effort that was brought together by industry professionals because there was a need in the community to represent women identifying individuals. I'm so just calling out our wonderful steering committee that helps with the leadership teams and helps the organization and they've really brought it from. The next slide, please.

So, thank you again for joining this talk and I hope that you enjoy the rest of the presentations that are to come. If you want more information about Women in Biohealth, you can connect with us on our LinkedIn group or you can go to womeninbiohealth.org and you can sign up for our mailing list.

So, thank you so much and we look forward to seeing you in the area. Thanks, everyone.

MODERATOR:
Thank you. Now welcome Doctor Meena Rajagopal from NCATS.

MEENA RAJAGOPAL:
Thank you, Monique. Hi everyone. Thanks for joining us today. I want to start off by saying that NCATS is very happy to partner up with the Wisconsin Center for Technology Commercialization and BioForward's Women in Biohealth in this webinar. And I'm absolutely delighted to have my colleagues from the National Heart, Lung and Blood Institute, the National Cancer Institute and the National Institute on Aging to speak about their Institute's specific small business program interests and funding opportunities. Next, go to the next slide please.

So, I am the program officer for the Small Business Program within the Office of Strategic Alliances at the National Center for Advancing Translational Sciences, NCATS for short. And NCATS is one of the 27

institutes at the NIH, and our mission is to promote research that would ultimately result in the development of more treatment options being made available to all patients more rapidly.

We are a little different from the other institutes and what I mean by that is we are not focused towards a particular disease or a body organ and our interest lies in accelerating the translational science process again to make sure that more treatments are made available to all patients more rapidly. Let's go to the next slide.

So, you've heard quite a, you know, several times now me mentioning translational sciences, right. So, what is translational science? Translational science as we define it here at NCATS is the conversion of a basic science discovery that happens in a lab setting into health solutions that are made available to patients at the clinic or the market. So, as you can imagine, this process is not straightforward or simple, while there may be N number of putative therapeutics that have been identified in a lab setting. Only a fraction of this actually makes it to the other end of the pipeline to reach patients, as shown in this animation here.

The different components that make up this translation science spectrum include, say, for instance, developing new approaches demonstrating their utility before disseminating the findings, right? And there are a number of roadblocks identified in each of those components. And NCATS wants to basically facilitate programs that not only identifies bottlenecks in the translational science pipeline but also mitigates them. So, ultimately leading to the development of more treatment options being made available to all patients more rapidly.

So, in the next slide, I just wanted to highlight a few of the solutions to these roadblocks that NCATS is currently working on. And by number means this is an exhaustive list, right? For instance, NCATS would like to see if we can understand what is similar across a number of human diseases that can help us develop multiple treatments at the same time. Can we develop models to predict how a patient responds to treatment? And how can we better design clinical trials to make it more inclusive and diverse so that it accurately reflects the patient population? NCATS' mission is to clear the path to translational research. Projects move more quickly and easily on their way to becoming health solutions. Next slide please.

So, towards this goal, NCATS manages and funds a number of initiatives, some of which are listed on this slide. In the interest of time, I'm not going to get into the details of it. And if you would like to learn more about these programs, please visit our NCATS website and read about them. Next slide, please.

One more, okay, now that I've talked about who we are and what we do at NCATS, I will dive into the small business program. So SBIR, which stands for the Small Business Innovation Research and STTR, an acronym for the Small Business Technology Transfer Research, are both what's called America's Seed Fund. It is a congressionally mandated program and is one of the largest sources of early-stage funding available to eligible US-based small businesses. A number of agencies participate in this program including the FDA and the CDC, and the budget for the program typically tracks the agency's budget. So, what this means that the NIH is that it totals to about $1.2 billion. That's billion with a B as in boy that is shared among the participating institutes of the NIH. Next slide please.

So, there are a number of advantages or reasons why a small business should apply to the NIH small Business Program, right? Like I said earlier, the budget tracks the agency's budget, hence it is stable and predictable. The funds are non-dilutive, meaning the IP rights belong to the company and once awarded,

there are several resources that me and my colleagues will talk about that the small businesses can leverage to further develop the technology or product. One additional benefit to applying to the NIH small business program is the peer review process. So, every application that comes to the small business program undergoes a rigorous peer review at the Center for scientific review. And what this allows for the small business is a chance or an opportunity to go outside of the NIH looking for funds and other collaborations because now your science of work is validated by guess who, the National Institutes of Health, right. So, just wanted to highlight some of those benefits and applying to the NIH Small Business program, let's go to the next slide.

So, I want to quickly touch upon the eligibility for small businesses to apply to the SBIR and STTR program. And I want to make you aware that the NIH has nothing to do with this eligibility criteria, right. It is, in fact, set forth by the US Small Business Administration, so according to the US Small Business Administration, a US based small business with few 500 or fewer employees can apply to the SBIR program. On the STTR program, the company should be owned by 50% or more. Should be owned 50% or more by individuals who are either U.S. citizens or permanent residents of the United States. If there are multiple venture capitalist investments, these should not be more than 50% and there are also some of the requirements when it comes to the primary employment of the principal investigator which I'll get to in just a second. Next slide please.

So, under the STTR program, the small business can collaborate with the US-based college or university, and it is very important that the small business has the proper paperwork in terms of licenses to use the technology that has been developed in a lab at the university for, for its commercialization purpose, right. And there are some additional requirements again which I will go over in my next slide.

So, here I just wanted to highlight some of the key differences. I'm sorry, Sanjana, is this the next slide? Okay. Okay. Yeah, I'm sorry, I think it is okay. So, So, here I just wanted to highlight a few of the key differences between the two programs, So, under the SBIR, the small business is allowed to partner with the US based college or university like I said earlier and however this is an absolute requirement if you want to apply under the STTR mechanism. There are also some work-related requirements that differentiate between the two programs. For instance, under the SBIR, the small business can outsource up to about 33% under a Phase 1and up to about 50% under a Phase 2.

I will explain what these four phases are in just a bit in just a little bit. But under the STTR mechanism, a minimum of 40% of the proposed work has to be carried out at the small business and at least 30% of the work should be done at the Research Institute. There are also differences in the primary employment of the principal investigators. So, under the SBIR program, the primary employment, which is at least 50% of time and effort, has to be with of the principal investigator has to be with the small business. While there is some flexibility if you're coming under the STTR program where the primary employment of the principal investigator can be either with the small business or the nonprofit research institute, please note that irrespective of what program you apply to, the award or the money always goes to the small business program. Next slide please.

So, with this one, I just wanted to quickly make you aware of these special designations given to small businesses, right. And we highly encourage our applicants to self to please self-identify because this information is actually tracked mainly to see if there needs to be more outreach done targeting these specific groups. So, just wanted to bring it to your awareness that these special designations have been given to small businesses by the US Small Business Administration. Next slide, please.

So, now getting into the NIH small business program, right, like I said, it's a phased program and we are looking for applications under the Phase 1. I'm sorry, we are actually looking for applications that typically talk about a proof of concept or a feasibility study. The SBA said hard cap budget, hard cap for a Phase 1 is about $296,000, but each institute, each institute have their own topics of high interest that is within our mission space, and we have what's called waiver topics and if you wish to apply under one of those waiver topics you can actually request a budget that is slightly above the SBA said hard cap. So, at NCATS you know if you apply under one of those NCATS waiver topics you can request up to about 350K for the Phase 1 and about up to about $2.15 million for the Phase 2. So, the Phase 2 again is a full-blown R and D type of application that has a commercialization plan built into it. We also have what's called the Phase 2B, and not all institutes participate in this program. NCATS does and this is where we would like to support our awardees.

Or applicants get through a key inflection point like say you need a state-of-the-art instrumentation or you're filing for an Ind. We can provide those extra funds of up to $1,000,000 per year for three years. The only caveat being in NCATS should have funded your Phase 2. We are also participating in Phase 2B funding opportunities led by NHLBI and I will let my colleague Dr. Stephanie Davis talk about it. Then there's the Phase 3, which is the more commercialization part of the program, right. So, this is where, say, if you were to apply to a different agency like the DoD, they would actually buy the tool or the technology from you. But NIH is never the customer. So, at NCATS, we want our awardees to think of an exit strategy and graduate out of the program. Let's go to the next slide.

So here I just wanted to highlight some of the different funding mechanisms that are available to small business entrepreneurs. Over 80% of the applications to the NIH small business program comes under the Omnibus Solicitation and this is an investigated initiated grant funding mechanism and there are typically 3 standard deadlines due dates. The upcoming one is actually next week, September 5th, which is next week and each institute also you know they put out targeted funding announcements that are of high priority to them. So, please check out our websites to learn more about it and I will get to the last two. You know funding opportunities on contract solicitations and commercialization readiness pilot in just a few minutes. So, let's go to the next slide please. So, here I wanted to give you a sense of the type of projects that NCATS' small business program has funded in the past. Our interest can broadly fall under these three buckets that's listed on the slide here. And each one of these three topics have multiple subtopics, so please visit our website to learn more about them. My colleague Melissa is chatting out the link, so please check it out. The pie chart on the right shows that a majority of the projects where with the tools that we funded fall under the tools for drug discovery and development, but we've also funded projects in artificial intelligence and machine learning, rare diseases devices and clinical research tools. Next slide please.

So, with this one, I just wanted to spotlight a few of the targeted funding announcements that is out there on the streets, and we are currently accepting applications for. Again, in the interest of time, I'm not going to go into each of those in detail, but please check out our funding, the funding announcements, and if you have any questions, please reach out to the point of contacts listed in those NOFOs. Next slide please.

So, I also want to make you aware of the SBIR contract solicitation, right. So, one, in addition to the grant funding mechanism, the program also has SBIR contract solicitations. And this is a little different from the grant mechanism. And what I mean by that it's since it is a contractual agreement, there deliverables that have to be met. Please note that the SBIR contract solicitation is actually out now, and the proposals are due in November. The 14th and also a point to note is that not all institutes participate in the SBIR

contract mechanism, but I believe NCATS, NHLBI, NCI and NIA participate in it. And in fact, I would strongly encourage you to please again check out the website and reach out to the point of contacts. Next slide please.

In this slide, you know, I just wanted to give you a sense of the time that is involved in this funding mechanism, right. So, once you put in your application, the division for division of receipt and referral at the Center for Scientific Review assigns your application to a study section and peer review happens. So, let's pick actually for instance, let's pick the September 5th deadline, right. So, applications are due on September 5th. The peer review happens sometime in October, November time frame and then a second level of review actually happens at the institute level, and this is called Council meeting and at NCATS, this typically happens in January and by the time a notice of award is sent out by the Grants Management Office to our awardees, it is already probably in late March or April, early April. So, as you can tell it takes anywhere from 6 to 8 months from the time of application to when you will get to know of a decision on it, and this is because a number of institutes, divisions and offices work towards this, right. So, nobody likes the waiting game, but I would ask that you keep the benefits of applying to the small business program like the non-dilutive one that I mentioned earlier and do consider applying to it. Let's go to the next slide. Next one more please. Yeah.

So, if you have applied to the NIH grant, you are probably familiar with the number of these review criteria. However, given that it is a small business application, our reviewers will look for the commercialization potential of your technology or product. So, just wanted to flag that for your reference. Next slide please.

So, for our those timers note that all applications will be received only electronically and there are specific registrations that needs to be completed prior to submitting the applications. And these registrations have to be done in a certain order and each one could take anywhere from up to about two weeks. So, the time to have all these registrations in place in itself would take you about a month or two. So, we strongly encourage you to start with these registrations really early on if you are looking to apply to the SBIR program, SBIR and STTR program, let's go to the next slide please.

So, just wanted to share on behalf of my colleagues here some tips for our applicants and the first and foremost advice is for you to read the funny announcement carefully. And please reach out to program officers prior to submitting an application to make sure that your proposed work is a good fit for the institute. We are here to help you out. And at the very least, you know, if we don't think it's a good fit for our Institute, we would be more than happy to connect you with our colleagues from the other ICs whom we might think would be more interested in your application. Then there are also some handy dandy tools that we have, like the NIH Reporter tool to learn about projects that are funded by the ICs at the NIH, and you can see if something similar to your work has been funded or applied to a specific institute. And I do also want to let you know at this point that we have links to some of the sample applications that have been funded by other Institutes on our web page that the applicants have graciously let NIH share to benefit applicants, so please go check out those sample applications just to get a sense of how high the bar is and what that rigor is like, especially if you're first time applying to the program. And please submit applications early, right? Don't wait for 4:49, 4:59, sorry PM on September 5th to hit the submit button just to find out that there is a glitch. I've had numerous last minute panicky emails saying something has gone wrong and they're not able to submit the application. So please, you know, we strongly encourage you to submit. The applications early on just to you know avoid these last-minute tense situations and before I move on to the next slide, I do want to reiterate that it is very

important that you talk to program and make sure that your application is of interest to the institute, right. So, with that let's go to the next slide.

So, now so some of the, you know with this one I just wanted to flag. We do get a number of questions from potential applicants, right? So, I just wanted to touch up on a few here. So, first of all, you know, we people, you know, applicants reach out to us and ask us, hey, does the PI have to have an M.D. or a Ph.D.? And the short answer is no. But that said, if you're proposing a work that is that requires a Ph.D. level of expertise and experience, then yes, of course it's recommended that one of your team members brings in that qualification. So again, in the interest of time, I'm just going to skip through the slide and then go past to the next one please.

But please take a look at it and if you have any questions reach out to me, OK. In my earlier slide, I did say that it takes about 6 to 8 months or even 9 months to hear a decision on your application. And you know if your application is selected to move forward and you know funding is an award, notice of award is sent. Then that's great, but the other side to this is you know, you get a rejection and we do understand. Trust me, we do understand that this can be a painful process. But what I would recommend is that you take the summary statement and comments noted by the reviewers in your summary statement as a roadmap to put in a stronger application the next time around. And it is not uncommon for us to see that new applicants or the first-time applicants usually are not successful at the first attempt. However, when they address the criticism or the weakness is noted by the reviewers in the summary statement, excuse me somebody's statement and put in a resubmission, their chances are much higher because the review team will actually look for if the critics have been addressed or not. Also, it's a good idea to talk to your program officer to brainstorm ideas for your resubmission. Next slide please.

So now that now I want to switch gears a little bit and talk about some resources that are available to small business entrepreneurs. Next slide please. So, there are a number of resources that are available to both our applicants and awardees. While I will be talking about the Commercialization Readiness Pilot program in just a minute, my colleagues from the other ICs will be speaking of a few other of these resources. So please stay tuned for that. So now going on to the Commercialization Readiness Pilot program, right, this is a program for those for awardees with the NI, you know SBIR or STTR Phase 2 or Phase 2B contracts or grant awardees. From any of the participating Institutes or Centers, CRP provides additional technical assistance and late-stage research and development support that is not typically covered within the small business awards to help products get to the market. So, for a list of technical assistance and late-stage research development activities. Covered within the CRP program and you know get to know about the budget limits and the participating ICs information. Please refer to the funding announcement. Also, I want to let you know that NCATS budget does not allow us to support clinical trials. So, we are participating only in the CRP that does not allow clinical trials. Next, let's go to the next slide please.

So, with NCATS, within NCATS, we have other resources that are available to not just our small business entrepreneurs but also to academics that they can leverage to help them get to a point where they can be successful. Let's say for instance filing an IND. So, the slide here list some of the expertise of our NCATS therapeutic team has to offer. Let's go to the next slide.

And the two programs, so towards this there are actually two programs, the Bridging Interventional Development Gaps program and the Therapeutics for Rare and Neglected Diseases that small business entrepreneurs and academics can leverage to cross the Valley of Death. So, you can enter the BrIDGs

program after identifying a clinical candidate and our team will do the gap analysis and provide you support to get to you know, say, successfully file an IND. Let's go to the next slide please.

So, the TRND is very similar to the BrIDGs program, but you can enter at any stage of the preclinical development. The only requirement is that you must be working with an FDA-defined orphan disease or the World Health Organization-designated neglected tropical diseases. Please note that both these programs are currently accepting applications and if you're interested, please reach out to me and I'll be more than happy to connect you with the right folks in these two programs. Next slide please.

Here I just wanted to, you know, just show you some of the ways that you can stay connected with NCATS. We would be very happy if you sign up to our list so that you can stay up to date on finding opportunities and resources that are available to you. And always, please feel free to send us an email. Happy to have a one-on-one conversation with you to talk about the appropriateness of your proposal to NCATS. And like I said earlier, I'll be happy to refer you to my colleagues at the other ICs if I think that they would be more interested in your proposed work. Can we go to the next slide? So. So before I hand over the virtual mic to my colleague, Stephanie, Dr. Stephanie Davis at NHLBI, I just wanted to, you know, share a few words about NIMHD, which is the National Institute of Minority Health Disparities. I do want to say that Dr. Michael Banyas, who is in charge of the Small Business program at NIMHD is not able to join us today. But we are happy to share a few slides with you regarding the program interests from his institute. And I believe this deck is going to be made available to all attendees. So please go over this information on NIMHD's Small Business program and reach out to Dr. Banyas if you need more information or have any questions for him. With that, I pass the baton to my colleague Dr. Stephanie Davis from NHLBI.

STEPHANIE DAVIS:
Thank you everyone, thank you so much Meena. So, good afternoon, everyone. My name is Stephanie Davis, and I am the Small Business Program Coordinator at the National Heart, Lung and Blood Institute. And it is lovely to be with you all here today. Next slide please.

So, as our name would suggest, the NHLBI small business program is very interested in funding innovative and commercially promising products to prevent, treat and diagnose heart, lung, blood and sleep related diseases. There is one very minor caveat, although we cover a very wide range of conditions, if you are interested in either lung or blood cancers, you're going to want to talk to my good friend and colleague Suraj Regmi at the National Cancer Institute. But anything else is likely going to fall in our mission space and we find a pretty wide variety of technologies as shown by this pie chart here. So, we fund approximately 328 active projects. We have about 33% of our portfolio consists of therapeutics, which includes both small molecule drugs, peptides, monoclonal antibodies, other biologics. And we are also a very device-heavy institute. So about 36% of our portfolio consists of supportive devices which include both surgical and therapeutic devices. We have about 7% of our portfolio consists of monitoring devices, about 5% in vitro diagnostics, 5% imaging devices. We have a growing portion of our portfolio dedicated to software's apps and digital health technologies and then the remainder goes to research tools. But just keep in mind that most of the applications we get are going to be through those omnibus notebooks. So, this breakdown will change from year to year depending on what meritorious applications we receive. Next slide please.

So, the small business program at the NHLBI is housed within the NHLBI Innovation and Commercialization office also known as the INC. So, in addition to providing monetary support and

supplements for training programs which are shown via the red bars on this graphic, we also provide very important non-monetary resources, services and activities. And the goal of providing both of these types of support is to help advance companies and researchers for developing promising technologies. Or diseases within our mission space to support them all the way from their basic and early-stage translational research all the way up to when their technologies are adopted by both patients and providers. So, you know we participate in several training programs including I-Corps at NIH, which I believe NCI is going to be covering. We also participate in the commercialization readiness pilot program which Meena mentioned. We offer other training mechanisms through the commercial of the C3i program, which provides training opportunities for medical device innovators. And we also provide competing renewal Phase 2B awards, which I'm going to talk about in a few slides. Next slide please.

So, here is a table of some of the targeted funding opportunities and notices of special interest that the NHLBI participates in. As I mentioned before, most of the applications we get are going to be through one of those Omnibus NOFOs, but we do have several funding opportunities that have special review and set aside funds that I wanted to highlight within the next few slides. Next slide please.

So, Meena referenced this earlier in her presentation and one of these RFAs that we offer is one that is a joint program with NCATS. But we have two Phase 2B RFAs that are available to companies that have previously been awarded a Phase 2 grant or contract and they need to have additional funding to help meet their regulatory milestones, connect with investors and strategic partners and commercialize their technologies. So, the two programs we have are called the Bridge and the Small Market programs. These both offer up to $3,000,000 in total cost over three years and the Bridge program funds all technologies that could potentially fall within the NHLBI mission space, while the Small Market program is specifically designed for technologies that address rare diseases and or pediatric indications, which is part of the reason why NCATS partners with us on that RFA because they have a very strong rare disease interest. So, although the funding is the same for both of these RFAs, there is a different matching fund expectation for both, so as a condition of award. We do expect our Bridge Award applicants to bring in a one-to-one match of private funds. So, what that means is if they get a $3,000,000 award, we expect them to bring in $3,000,000 in matching funds. The small market awardees do have a matching requirement, but it is lower, so the small market awardee gets a $3,000,000 grant. We're expecting them to bring in $1 million in matching funds. So, the next due date for our Phase 2B RFAs is going to be February 28th, 2024. You do not have to have gotten your Phase 2 award from the NHLBI to be eligible. You could have gotten your Phase 2 award from another institute, even another agency. As long as your technology requires regulatory approval and it falls within our mission space, we are interested in having your submission, so please feel free to reach out if you'd like to learn more about our face to be programmed. Next slide please.

So, another RFA that I wanted to highlight is the Innovations for Healthy Living Small Business RFA. So, this is an RFA that is led by our friends at the National Institute for Minority Health and Health Disparities. So, the focus of this RFA is to provide funding to innovators that are developing technologies, tools and devices for decreasing health disparities in historically underserved low-resource and health disparity communities. So, we are interested in pretty much any sort of technology that can help alleviate health disparities in heart, lung, blood and sleep deletions. So, this has a different due date than the omnibus. It's going to be September 6th, 2023. But I strongly recommend anybody who is developing a device or a software program or something that relates to a heart, lung, blood or sleep health disparity to apply through this RFA. Next slide please.

Another RFA that I wanted to highlight that has its own pool of money is going to be the HEAL RFA. So, this RFA is a part of the Helping End Addiction long-term program and the goal of both the SBIR and STTR RFAs are to fund the development of new nonaddictive therapeutics and theme management strategies. So, as you can imagine, the NHLBI is interested in new therapeutics that are not addictive and pain management strategies for patients who have heart, lung, blood or sleep conditions. So, the next due date for this one is actually going to be scheduled for September 4th. But since September 4th falls on Labor Day, it will actually be September 5th. So, this is another funding opportunity where if you have a technology that falls within the scope of this RFA, I would strongly recommend applying. Next slide please. So, the NHLBI as well as all of the other institutes that participate in the small business program provide a limited allowance for awardees to be able to support activities that relate to technical and business assistance, also known as TABA activities. So, some of the activities that are supported by TABA funds can include but are not limited to IP protection, market research, development of regulatory and manufacturing plans. Assistance with product sales or access to technical and business databases. So, awardees have to have a couple of options for their TABA support. They can either request they can request the support directly in their application under section F. Other direct costs and so Phase 1 applicants can request up to 6.5 K per year for their project. Phase 2 applicants can request up to $50,000 for their project. Some institutes allow companies to request these after the fact be an admin supplement. So, it's important to check out notice OD 21062 to show to see which institutes and centers allow this because some of them do, but others do not. And then finally when NIH, Small Business, Entrepreneurial Education and Development or SEED Office provides centralized programs that are available to both Phase 1 and Phase 2 grantees, and these are the needs assessment program and the consulting services. So, companies that have not requested TABA in their application or through an administrative supplement can take advantage of these programs, but I strongly recommend if you are applying to request it in your application. Even if you don't really know what you're going to be using it for at when you apply that information to be provided during just in time, but it is easiest to get those to have funds if you request them at the time of the application. Next slide please.

So, in the innovation and commercialization office as I mentioned, we provide both monetary support and non-monetary support. So, I have a really wonderful team of entrepreneurs and residents who I get to work with, and they are here to not only provide their subject matter expertise to various projects, but they are also there to provide pitch coaching services and provide one-on-one consults with our companies. And these services do not just aren't just limited to small business grantees, they can also provide their expertise on product commercialization for teams and investigators who are receiving funding through other mechanisms of support. Next slide please.

So, one of the things that I like to do in outreach presentations is I always love to highlight companies that are located within the geographical area of the partner in question. So, I wanted to highlight just a few companies that are based in Wisconsin. So, the first company that I wanted to highlight is called Cellular Logistics. So, this is a spinout company from the University of Wisconsin at Madison. So, they are developing a therapeutic biomaterial called CFX that promotes cardiac regeneration after acute myocardial infarction. So, they have gotten two SBIR fees, won awards from the NHLBI and they recently won an $850,000 SBIR grant advance grant from the state of Wisconsin. So, I've included a picture of Doctor Schmuck, who is a faculty member at UW Madison as well as the cofounder and CSO of Cellular Logistics. Next slide please.

Another company that I wanted to highlight is a spin out from the University of Wisconsin at Milwaukee is the Milwaukee Institute for Drug Discovery. So, this company was founded by Doctor Doug Stafford, and it's called Pantherics. So, they are developing a GABA-A receptor agonist called PI-301 for the

treatment of asthma. So, they have been awarded Phase 1 awards from the NHLBI, and they have also received the grand prize for the 2022 Milwaukee Tech Week Healthcare Innovation Pitch Event grand prize. Next slide please.

And finally, I wanted to highlight our last company. This one is our leader stage company that I wanted to highlight InVivo Sciences, which is a precision medicine-focused company based in Madison. So, they are developing both therapeutics and tools to improve drug screening that can help accelerate the development of therapeutics for heart failure. So, one of their signature products is an iPSC-derived micro heart tissue called new heart. So, they have been both awarded SBIR Phase 1 and two awards from a NHLBI and they've also received a Phase 1 award from the National Institute on Aging. And in 2022, they were selected as the Innovation Challenge winner for the Redefining Early-Stage Investment conference. And there is the cofounder, CEO, Ayla Annac with their technology. Next slide please.

So, one funding opportunity that is not small business, but I wanted to highlight for this presentation is the Catalyze program. So, Catalyze is very similar to the small business program and that it funds technology development, but it is open to academic investigators and nonprofit institutions as well. So, you do not have a company to apply for Catalyze. So, there are several RFA's that make up the Catalyze funding opportunities and they are grouped by different technology types. So, the next application deadline for Catalyze is going to be November 21st, 2023. But if you do not yet have a company and you're interested in getting some early-stage funding to develop your technology, I would strongly recommend looking into some of these RFAs. Next slide please.

And so, I strongly recommend to follow us on Twitter or X as it's now called at @NHLBI_SBIR if you'd like to get updates on what's going on with our small business program and the I and C. If you need to email us, you can reach us at nhlbi_sbir@mail.nih.gov And please feel free to scan the QR codes if you'd like to visit our website or sign up for our monthly newsletter. And that concludes my session. I'm going to be turning it over to my colleague Dr. Joshua Hooks.

JOSHUA HOOKS:
Good afternoon, everyone. Really glad to be here again. My name is Joshua Hooks. I'm a program officer in the Office of Strategic Extramural Programs at the National Institute on Aging. Next slide please. So, as my colleagues have gone over in a lot of detail, in all of every institute at NIH provide small business funding to kind of spur innovation within their field. NIA is now the third largest institute and provides roughly $150 million annually to nonprofit and nonprofit businesses to end to fund their innovation. Next slide, please.

Unlike National Heart, Lung and Blood or National Cancer Institute, aging is a pretty broad term and so we are willing to fund a variety of different disease indications in in this in how they interact with aging, specifically by Congressional mandate. A large portion of our budget is dedicated to funding innovations around Alzheimer's disease and related dementias. And broadly age-related changes in brain function, but outside of that we're also interested in technologies to improve aging in place and independence in aging, age-related diseases and conditions and research tools in order to conduct aging research. And so, these can be a variety of kind of companion diagnostics, bioinformatic, public health informatics and other data science technologies selling gene therapies so on and so forth. The chart on the right shows just kind of our current funding by portfolio classification. You can see roughly 30% of our budget goes to therapeutics, but one of the fastest growing segments is on digital and mobile health. And this chart on the right is kind of just an indication of what is currently funded, not necessarily an indication of priorities. We're open to meritorious applications and all technologies. Next slide please.

So, you've heard now NIH's funding is broken down into various phases, the Phase 1 being primarily focused on discovery and feasibility. I bring up the slide primarily just to show NIA-specific funding caps. So, for a Phase 1 award, they're typically up to one year in length and will award 400,000 for we consider general aging projects. That's pretty much everything other than projects related to Alzheimer's disease and dementia and up to 500. 2004 projects that do address Alzheimer's disease and dementia. And this stage again is to kind of establish the technical merit and feasibility of your approach. Phase 2 funding is typically up to two years in length. The budget goes up to 2.25 million for general aging projects and 2.5 million for Alzheimer's disease and dementia related projects. For this phase, you will need to have a commercialization plan to really show where your technology fits in the market and this is for somewhat more advanced research and development efforts. In addition to those two phases, NIA participates in fast-track awards. So, combining both your Phase 1 and Phase 2 proposals into one application Direct to Phase 2. For SBIR applications, NIA participates in the commercialization readiness pilot. So, this is a unique kind of Phase 2 be like program where you can in addition to funding the late-stage research and development, you can also request for those fundings to be used for technical assistance activities. Things such as developing commercialization plan, manufacturing plan, scaling up your technology and that award is up to 3.94 million and you have to have had an active Phase 2 award and or have or have had recently an active Phase 2 award. And then there's also the Phase 2B award for continuing research efforts on a Phase 2 award and that's up to 3 million they can spread out over three years. Next slide please.

So, again as we've outlined, there's the Omnibus Solicitation. Again, NIA treats that as kind of our general aging funding and then targeted solicitations of which NIA participates in a variety. Next slide, again the Omnibus is kind of the general aging projects depending on your kind of employment and the terms of your project, you can apply either through the SBIR or STTR mechanisms. And we do participate in clinical trials, so you know, make sure that you apply to the correct notice of funding, so that you apply to the one that allows for clinical trials if you need a clinical trial or to the one that does not allow clinical trials if you are not using human participation. And then our primary targeted funding opportunity is that opportunity in Alzheimer's disease and related dementias that has the slightly higher budget caps because that is a high priority area for us. But we also are signed on to a lot of the other funding opportunities that have been outlined today, including the HEAL initiative for pain management techniques for chronic conditions and the Innovations for Healthy Living for technologies on the intersection of health disparities and aging research or aging innovation. We also have put out a Notice of Special Interests for digital technologies for early detection, characterization and monitoring of senescence related changes. So, if you're researching in that space, you're really interested in providing funding for those technologies. Next slide.

So again, NIA participates in a lot of the additional kind of entrepreneurial training programs that have been outlined by my colleagues at NCATS and NHLBI. But I just wanted to highlight a few of those in green to go into a little bit more detail. But please reach out for questions about any of these other support programs that we provide to our awardees and to potential applicants. Next slide.

So, the first program I wanted to talk about is the REDI program or the Research and Entrepreneurial Development Immersion program. It is a series of funding opportunities aimed at providing entrepreneurial training that is within the NIA mission space and kind of allowing trainees to acquire additional non-academic skills. So, we take a really broad definition of entrepreneurship and are interested in providing early-stage researchers. This can be graduate students, postdocs and junior faculty depending on the awards. Forward skill sets in bio entrepreneurship, IP, drug discovery,

regulatory affairs, and even things that might not be traditionally considered entrepreneurship, like science communication and science policy, or on consulting career pathways recognizing that more and more researchers are moving into fields outside of academic research. Next slide.

The four primary awards that are currently encompassed under this REDI umbrella are the REDI SBIR-STTR awards, the REDI R25 award and the REDI K01 award. They are all currently active and are accepting applications throughout mid to late October. So, the REDI starting with the REDI R25, this is an entrepreneurial educational award, so it's to provide funding for an institute, nonprofit or for-profit business to provide. Educational programs for graduate students and or postdocs around how to pursue entrepreneurship, IP and all those topics that I outlined previously and then the REDI K01 award. I think of this as for postdocs or early-stage faculty that are interested in in gaining those skill sets but still want to maintain their primary responsibilities within a kind of academic research lab typically and this would allow them to provide salary in addition to some extra funding to do work. Workshops and trainings and attend conferences in those topics outside of academic research. Next slide.

The two awards that I thought would be most relevant to this audience are the REDI SBIR and REDI STTR awards. So, I'll spend a little bit more time on those mechanisms. These are novel SBIR-STTR mechanisms for which the PI must be within 10 years of their terminal research degree. This can be a PhD, an MD, or a science-focused master's degree. The applicant can have never cannot have successfully competed for a NIH small business or major research grant such as an R01. It requires the PI to identify a dedicated entrepreneurial mentor and to create a career development plan that really outlines, in addition to being the PI for an SBIR project, how they will use some of the funding on that award to attend trainings, go to conferences and receive certifications in the entrepreneurial space, realizing that they're really early to this entrepreneurial to entrepreneurship and would need some additional training and career development. And please reach out for any additional questions. Those awards have a 500,000 cap for a Phase 1 award. You can also apply for a Fast Track award for up to 2.5 million. Next slide, please. Another unique program at the National Institute on Aging is our Startup Challenge and Accelerator program of which we're in our second year of running this program. Its focus is fostering entrepreneurial diversity. It addresses challenges faced by diverse innovators and IT to kind of provide additional training for innovations impacting health disparities. It is set up as a roughly 5-month entrepreneurial boot camp where we have additional pieces of mentorship and a cash prize that the participants will compete for so, a major component again is this in-depth entrepreneurial training. We cover a wide variety of topics. We really see this as an accelerator program to cover both how to successfully compete for SBIR funding, but in addition, how to conduct customer discovery, how to innovate for HealthEquity, navigating entrepreneurship as an adverse founder, going to market strategies, IP, so on and so forth. And another great piece of this program is the fact that it will match these early-stage founders with one-on-one mentoring. And those mentors have really agreed to tap the participants into their networks to really help them flesh out their ideas and figure out how to best bring them to market. Next slide.

And I just wanted to quickly highlight our 2022 cohort. So, we are currently running the 2023 cohort, but the 2022 cohort was our founding cohort. They're great. You can see here just the full diversity of research topics that the cohort was addressing and happy to talk to anyone who might be interested in potential future iterations of this program. Next slide.

Finally, I wanted to outline the NIH Applicant Assistance Program. This is a program that several institutes, but not all institutes that NIH have participated in, but all of the institutes that are presenting here are signed on to this Applicant Assistance Program. You can see the full list at the top of this line. It provides 10 weeks of application preparation assistance. So, it helps with Phase 1 preparation, support,

and review of the materials that you will ultimately submit to help you work through your specific aims. Page has been giving additional review and advice for that in addition to just broad coaching. This is not a branch writing program, so the if you get accepted into this program, no one is going to write the grant for you. But they really kind of work with you to help make a strong of a proposal as possible. They don't develop your research plan; they simply give advice, and they help work with you. They helped talk you through some of the registration steps, but you have to ultimately register your small business. Next slide.

And it's a little bit more information. To be eligible, you have to have never received a small business grant, or at least not in the last 10 years. There's a strong interest in applicants who are currently underrepresented in Biosciences and life science entrepreneurship, including women-owned small businesses, minority-owned small businesses. And small businesses operating in idea states or underrepresented states, they're currently accepting applications until September 12th. And if you get accepted through this application, it will be to prepare you for the January 5th submission on the Omnibus Solicitation. And again, please reach out with any questions. Next slide.

Just wanted to emphasize that we're here as a resource to all potential applicants. The best one of the best first steps you can take is simply sending me or one of my colleagues an email just to get a sense of if your technology is a good fit and that what I instituted might be a good fit for. And please reach out, we're here to help. And if you go to the next line, I have our email address here for any questions. And with that I will turn things over to my colleague, Saroj Regmi.

SAROJ REGMI:
Thank you very much, Doctor Hooks. My name is Saroj Regmi and I'm one of the program Directors at the NCI SBIR Development Center. First of all, I'd really like to thank all the organizers for this great opportunity to talk about the NCI's SBIR program. These virtual outreach events are great. They're fantastic. And I do want to highlight today the fact that we program officers are really approachable. We're federal employees and our job is to demystify the SBIR and STTR application process for you, so don't hesitate to reach out to us. Yeah, reach out to us via email. We're more than happy to schedule one-on-one if your technology aligns with our institute and talk to you. So definitely think of us as your resource in your SBIR journey along with your state-specific resources, which Wisconsin does a fantastic job off. So, I just wanted to start with that. So, in terms of the NCI's SBIR-funded portfolio, we're pretty broad in our coverage of cancer specific technologies we fund. Small molecules, cancer biology research tool, imaging devices, almost anything and everything to do with cancer. And we have, we have the largest SBIR budget within the NIH. So, for fiscal year 2023, we had a budget of $203,000,000 for startups involved in oncology specific areas. Next slide please.

So, this was mentioned previously as well. So, the SBIR our CTR program is organized into three different phases. There's a Phase 1 which is a proof-of-concept work which affords up to $400,000 at the NCI for 6 to 12 months of work once you go through a Phase 1 for furthering your research and development, once you have a commercialization plan and you've thought about that commercialization piece, you can apply for what is called a Phase 2. This is a $2,000,000 award at the NCI for two years. Definitely check out each and every institute and what their budget limits are they do change depending on the institute. So, there are some subtle differences to the budget amount. Now if you've already done some of the you know groundwork, if you've already done some of the preliminary work and if you want to come in directly at Phase 2, you can do that as well. And that is what we call the directive Phase 2 that is for that, that is again that $2,000,000 award and if you wanted to combine both the Phase 1 and Phase 2 get a sort of a two-fer-one application where you really have good milestones that you know you're going to

achieve at the end of your year one. Then, you can definitely consider what is called a Fast Track that combines a Phase 1 with a Phase 2 at the end of a Phase 1, there's a go no go decision with your program officer and that's a $2.4 million award with a $400,000 for Phase 1 and $2,000,000 for that Phase 2-part of your project. At the National Cancer Institute, we also have what is called the Bridge award. Now this is to help you cross the Valley of Death and if you're really looking into regulatory framework, looking into validation of technology and current clinical translation, this is a great program for you. This provides follow on funding for SBIR Phase 2 awardees from any of the federal agencies, provided that you're working in the space of oncology. The expectation is that you will secure substantial third-party investor funds. This is a $4.5 million award for over 2 to three years. So, the goal is that you bring in at least $4.5 million from different investor sources from third party and NCI will provide you $4.5 million. Unlike some of the other federal agencies, NCI and NIH does not have a Phase three program. We will not buy the product. We do not think of ourselves as a customer for that Phase 2. So, we hope that you graduate from the program and you're able to commercialize and utilize your non SBIR-STTR funds for that for that Phase three. Next slide.

Yes, so right off the bat, as I mentioned, definitely check out every institute and their budget limits. At the National Cancer Institute, we have a waiver wherein we can allow $400,000; up to $400,000 total cost including both direct and indirect cost for your Phase 1 work. For your Phase 2, you can request up to $2,000,000. Like I said, again, this is very institute specific, so definitely check out each institute and their rules when it comes to waiver topics. If you go to the next slide, you will see that the waiver topic coverage for NCI is pretty exhaustive and broad. So, if you're working in the realm of therapeutics, if you're working in invitro and in vivo diagnostics, if you're working with imaging modalities and technologies, devices for cancer therapy agents, for cancer prevention and if you're also looking at developing digital health tools or technologies, low-cost technologies for low resource settings and cancer and global health, you will qualify for that waiver topic. You will be able to request $400,000 for that Phase 1 and $2,000,000 for that Phase 2. So, this is this I think is a really interesting graph that I really like to use just to show you tell you the story about the SBIR STTR program. So, basically what we found out in fiscal year 2021 when we look at all of our portfolio, when we look at success rate is that we found out that original submission. So, if it's an application that was submitted the first time around, the success rate was around 7 to 8%. And if the application had been resubmitted, what we call an A1, we found out that the success rate had gone up now to up to 20% and our overall success rate was around 10%. And so, what this graph really tells you is that there are definitely merits to resubmitting. So, it's really a good idea to think about that. And it's submitting that initial application early on, getting that review of feedback and then being prepared to resubmit. Resubmission is really helpful because your odds of success really tend to improve. And so, if you have not been successful the first time around, I definitely urge you to think about resubmission. I definitely cannot highlight enough the fact that you should come talk to us. We're a resource for you and we're always available to talk to you about your resubmission process as well. Next slide.

So, let me just quickly talk about some of the funding opportunities through the NCI. So, this is an exhaustive list of all the funding opportunities. We participate in the Omnibus Solicitation, both the SBIR and STTR. We do fund clinical trials and we also have a couple of notice of special interest around low resource settings as well as a liquid biopsy assay validation. There are also other couple of other awards that I'd like to quickly go over in the next couple of minutes. Next slide.

So, one thing that we were really interested in at the NCI was a small business transition grant. So, we're thinking about an entrepreneurial training path for graduate students and postdocs that are thinking about a career in entrepreneurship. So, for the aficionados, we're familiar with the K99-R00 pathway

where in the postdoc remains at the educational institution for a number of years before they transition to a faculty position at that institution, we wanted to create something similar and so we wanted to create that entrepreneurial path for trainees. And so, this is the general idea behind the small business transition grants. Our goal is that post docs or graduating students that are thinking about entrepreneurship can spin out their technologies and also be empowered to do so by this grant. Next slide.

So, this is a really unique mechanism given the fact that at a Phase 1 it is an STTR. We believe that the STTR at a Phase 1 affords extra flexibility for the individual, the PI, who is a postdoc or a graduating PhD student to continue working on their innovation while remaining at the educational institution. So, majority of the time the PI will be a postdoc, they can be graduating PhD student, they can be folks with a Master's degree. And what we require for this is 2 mentors. There is a mentoring plan that is required. They are required to have a technical mentor who is most likely their research mentor. And they're also required to have a business mentor who can guide them through the business path pathway and also provide them with advice as needed. So, we'll also pay for them to participate in the I-Corps program, which is a customer discovery program at the NIH. And then I'm happy to talk about that in a couple of slides. And so, you're at a Phase 1 STTR and once the technology is ready to transition into a small business, once all the milestones have been met, all the IP agreement is in place, then the Phase 2-part of that award begins and the expectation now is that the trainee, the PI, the postdoc or a graduate student moves to the small business as a PI. So, the PI is not transferable. It's going to be the same individual. The mentoring is continuing and now they're really working on that innovation. Small pivots are allowed, but the goal is that what they started with early on, they will keep working on and commercialize their product. So yeah, so that's the award, the application recently. These four recently expired, but we hope to launch it again in a couple, in a year. The other award that I'd like to talk to you about is a concept award. So, this is a really cool mechanism to fund disruptive technologies to address rare and pediatric cancer. The application process is very different.

We utilize the contract mechanism. So, it's a short application around 20 pages versus your traditional SBIR-STTRs that require more than 50 pages. We do encourage you to submit a white paper wherein you submit a short idea about your technology. We will have an internal review wherein we will provide you feedback and then we will request that you submit a full application. A lot of focus is on innovation. Around 40% of the review criteria will be on innovation, how innovative, how disruptive the technology is and we're looking to fund experiments really early, so that we can de risk early-stage technology. So, these are going to be high risk, high reward kind of approaches that we're really interested in. We aim to make awards really rapidly within six months and we'll also expect that the award is enrolled in I-Corps programs so that they can learn about customer discovery. So, this also expired recently on August 21st. So, the next solicitation hopefully will come out next year. The other thing that I'd like to mention is I think we've talked quite a bit about contract topics. So, contract topics are really great. If you have a, if you have an innovation that aligns really well with contract topic, then I really encourage you to think about it and submit a contract application. NCI is one of the heaviest users of contract topics. Each year these topics change and this year we have around 11 topics to be included in the solicitation. I believe the deadline will be sometime in November or so. They're pretty diverse in terms of the subject area encompassing all aspects of cancer but they are they are pretty narrow in their focus.

So, for example, ultra-fast dose rate (FLASH) Radiation, technologies for detecting tumor-derived cell clusters; cancer prevention and treatment, clinical trial tools for recruitment and retention of diverse populations; and things like that. So, you know, really things that we want to see at the SBIR center so that there will be future commercialized innovations out there. Next slide, I talked a little bit about the

Bridge Award. So again, just to reiterate whether you've gone through a SBIR Phase 2 either through NCI or NIH or any of the federal agencies, if you have a technology that aligns well with the mission of the National Cancer Institute, definitely think about submitting an application. This again is a once-a-year funding opportunity that just expired. So, the next receipt date will hopefully come out next year. The goal here is to really accelerate commercialization and incentivize partnership. We expect that at least one to one match and we provide $4.5 million, not $4 million in additional funding over a span of two to three years. Next slide. So, I just wanted to highlight one of the recent success stories. I think the biggest success story of NCI actually is a company called Illumina, which I'm sure all of you have heard of.

But a recent success story is this company called Immunomedics. They developed an antibody drug conjugate directed against a protein called Trop-2, which is a cell surface protein expressed in many solid cancers. And so, this antibody drug conjugate was conjugated with topoisomerase in a bitter for the aficionados. And the goal was to really, you know, hone this drug and then and treat triple negative breast cancer. So in 2012, Immunomedics received their SBIR award and they used it to fund the first in-human trial of Trodelvy. In 2020 they received FDA approval and in September of 2020, they were actually acquired by Gilead for $21 billion. So, you really can start small with your SBIR, and you can really take it to market. So definitely think about think about that piece as well. Next slide.

I think I've said this a lot of times, but I cannot highlight this enough. Definitely reach out to a program director. We're really here to help you out with your SBIR journey. If you have any questions, be sure to email if you have an idea you'd like to discuss. If you'd like to discuss fit. If you are unsure about which particular funding opportunity is a good way, reach out to one of us. We're more than happy to have a one-on-one with you. We're more than happy to respond to you via email. The only caveat is please don't ask us questions two days before the deadline. We may not have bandwidth in that case. So definitely give us ample time and we're happy to help you out. Next slide.

So, I'll focus a couple of minutes on talking about some of the initiatives that we have at the NCI SBIR development center. Some of them were mentioned in pretty big, pretty in detail through from one of from my colleagues at other institutes, but in the next slide, you'll see a list of different programs. So, before Phase 1, NCI participates in the application assistance program. This was covered really well. We at the NCI, we also have a lot of different programs such as the I-Corps, which is a customer discovery focused program. The investor initiatives, I'll talk a little bit about it, peer learning webinars that are for everybody. We also have resources for commercialization workshops. We have executive round tables. We also have a really good relationship with FDA. So, we are able to connect our awardees to regulatory experts at FDA so that they can ask these important questions early on and get answers. We also have an industry mentoring and assistance program, and we have a women's innovation network. A majority of these programs are once you get the award unfortunately, but I'm happy to talk about a couple of them. So, if you go to the next slide.

So, I-Corps at NIH is, is a really intensive entrepreneurial immersion course. The goal is customer discovery. You will have to do around 100 interviews in a span of eight weeks and with each interview you learn more about your innovation. So, it's an experiential learning focus. This was designed by the NCI SBIR and now it's managed by the NIH. There are 24 institutes at NIH and CDC participate and this is available for Phase 1 awardees. So, there's more information on that link at the bottom of the slide. Next slide please.

So, the requirement is that SBIR-STTR grantees can assemble 3-member team that work collaboratively. They need to have a principal investigator, they need a C-level executive with decision-making authority,

and they also need an industry expert who has some business development expertise, so that they can guide them through this customer discovery process. There are instructors that are experienced business-savvy and that work closely with the project team to help them explore their market and also help them think about the question a little bit. They have domain expertise in the major product areas that comprise the Biomedical industry. The NIH will pay up to $55,000 to support entrepreneurial training, mentorship and collaboration opportunities. To be eligible, you have to be an active Phase 1 SBIR or STTR grantee. If you have a Phase 1 grant or a contract as well, you are eligible and the predicate Phase 1 must have project and budget timeline that are active from application date through the end of I-Corps, so that's really important. So, if you have an award with us, if you're interested in customer discovery, definitely consider applying for the I-Corps quote. I'm at NIH next slide.

The other valuable resource is the PLAN Webinar series, pure learning and networking webinar series. The goal here is that we will create a prerecorded panelist presentation on a small on a specific topic area. The goal is that you will watch that webinar, you will write down your questions and then you'll attend a real time panel session where wherein we'll invite these panelists and there will be a moderated a Q and A session to ask the questions. So, some of the topics that we've covered are how to write a good specific aims page, the video content is available, how to implement a QMS quality management system, what are the first steps for starting a small business. And so, all of these contents are available online, so definitely go on our website and have a look at the PLAN webinar series. This may be really useful as you're thinking about either submitting an application or if you aren't awarding. Next slide.

The other program that I'd like to highlight is Investor Initiatives Program at the NCI. So, this is a great program in that if you're a current or recent NCI awardee, you can apply once a year. We generally get around 80 to 100 applications. Once you submit your short one-to-two-page application, it gets reviewed by pharma and venture partners from you know, J and J, Pfizer, GE, and MPM just to name a few. All of the applications that you submit you will get constructive feedback from these investors from the space, and the next step is based on these reviews, we will select about 25 to 30 companies. And will assist them with presentation fees for our conference. It could be bio, it could be med tech, anything that is relevant. And so, we will pay for you to go to these conferences and then present your work and will support your pitch. NCI will also provide training for pitches. So, we'll pitch coach these companies. There might be there might be other mentoring that programs that might be involved as well. There's also industry mentoring that that will happen for these companies. And sometimes these may result in introductions to investors as well. We will create a booklet of the companies that have been selected for the year and they will be shared via newsletter to all of our investor network. And when investors request, we're also happy to do direct introductions to our SBIR. So this is a really great program as well for our awardees. Next slide please.

So, definitely there are a lot of events I really encourage you to think about. Signing up for our mailing list, you'll be aware of a lot of resources and opportunities, funding opportunities that are available through the NCI SBIR Development Center. We also host an SBIR monthly office hours, so if you have a short question, consider signing up for that as well wherein you'll be able to connect one-on-one with an NCI SBIR program director. And if you just want to reach out, I'm more than happy to take an email and take any questions from you as well. There are upcoming events that are listed and that once again. Definitely think about signing up for our mailing list. Next slide. Thank you very much.

MODERATOR:

Thank you everyone. We really appreciate all of the feedback and it's fantastic to have so many institutes here to share more about the resources and specific program opportunities that are available. I think you know that every institute wants you to be successful because we want new innovative products to come to market.

We appreciate all of your questions. We're going to do a moderated Q and A now. If you do have any other questions, feel free to drop in the chat and in the Q and A feature. And I'll also note that we want you to fill out the feedback form. We'll include that again in the in the chat links. But before you sign off, please do fill out that feedback form.

So, I'm going to go through some general topics and then we I will call on some of the specific institutes. OK. So, generally speaking, there are some folks here who are outside of Wisconsin. I just wanted to let you know that all of the institutes that spoke today, the resources are available to the entire nation. It's not one specific state. However, Wisconsin resources and nonprofits that have been presented here today are related to Wisconsin. So, I'll just check in to see if Women in Bio or any others have anything to say about that question.

APRIL HUGHES:
Yeah, the only thing I would add is if you go to sbir.gov there is a page that lists all the support organizations and all of the FAST grant awardees in each state. So many of these organizations like us can only service their state because we are state funded as well. So, I would suggest going to sbir.gov looking for the support organization by state. I think that's how they do it, but I'll try to find the website and put in the chat, but that is what I would suggest. Look for your state's support organization and they'll have the similar programs to us that I went over.

MODERATOR:
Wonderful. The next question is for NCATS. Does NCATS use a Payline score and how do you select grants for awards?

MEENA RAJAGOPAL:
Great question. Well, it actually depends and it varies from cycle to cycle. So, I would say probably you know this, we have typically funded applications that have scored anywhere from 20s to. It’s gone as high as 38, I would say, but again it just depends on the cycle in the pool of the application that we receive for that round.

MODERATOR:
Fantastic. Thank you. So, for NIA, can you share does the SBIR STTR program Phase 1 at NIA offer an extension over the budget cap of 400 or 500 like other ICS do and if so, under what conditions?

JOSHUA HOOKS:
No. So, the budget caps outlined are keeping in mind the budget waivers. NIA has a kind of liberal or broad budget waivers to cover most projects, but be sure to review those budget waivers and that's how you qualify for that either 400,000 to 500,000 budget cap.

MODERATOR:
Thank you. And another question for you related to REDI. Can participant apply for the REDI KO1 as a STEM MBA with over 8 years of experience in biotech and healthcare?

JOSHUA HOOKS:
No. The individual would need a doctoral degree in order to qualify for the ready K01.

MODERATOR:
Thank you. So, the next question relates to resubmission, and this is open to anyone of you who want to start first, but how many times can you resubmit an SBIR grant?

JOSHUA HOOKS:
So, you can go for it.

STEPHANIE DAVIS:
So, I could take that one. So, officially you can only submit an application once. So, when you resubmit, it's going to be called an A1 as opposed to an A0, which is a new submission package. If your A1 application package is not scored, you can technically resubmit it, but it has to be formatted as an A0 or a new application package, so you're not allowed to reference your previous solution.

JOSHUA HOOKS:
Thank you. Yeah, I will add, I will add a couple of things. One is that you know obviously you're only allowed to resubmit once, but even if you're not successful during a resubmission, definitely think about getting that feedback and submit a new application. You can submit your application multiple times. It's just that the resubmission will allow you to have that one page wherein you're able to, you know, address some of the reviewers' concern. With that application, you also have to resubmit within 37 months. And officially you're allowed one resubmission within 37 months from the time of your initial submission.

MODERATOR:
Thank you. And Stephanie, just a follow up on that question. Does resubmission for grants mean that this would be for the next grand cycle, or would it be with that current deadline? I just want to understand the timing perspective of resubmission.

STEPHANIE DAVIS:
Yes. So, the rule of thumb is that when you submit. When you're submitting 2 overlapping applications, obviously a resubmission is going to be scientifically overlapping with the initial submission. The rule of thumb is you have to wait until the summary statement from the first submission is back before you could submit the other. So sometimes you are able to. For example, if you submit an application for the September deadline, it's probably going to be reviewed in November. Your summary statement is likely going to be back in December.

Once that summary statement is back, you are cleared to submit for the January deadline. However, sometimes, especially if you submit for the January deadline, the summary statement from that January submission does not come back before the April 5th deadline. So, the rule of thumb is that if your summary statement is not back yet, you cannot resubmit.

MODERATOR:
Thank you and the follow up for Saroj Regmi is on this very same topic. When submitting A resubmission grant application, is it allowed to change from a Phase 1 submission into a Phase 2 or Fast Track submission?

SAROJ REGMI:
Yeah, when you do that, it might be better to just submit it as a fresh application, get that review of feedback you utilize that, and then submit a fresh application.

MODERATOR:
And one more question for you, Saroj, like the K99, can international postdocs apply for R41-R42? Or it only for permanent residents or citizens?

SAROJ REGMI:
I'm guessing the question is for the Small Business Transition Grant. For the grant that just expired, you have to be a permanent resident or a or a citizen. For traditional SBIR STTR grants, there's no stipulation for the residency status of the PI as long as the small business concern is primarily owned and operated by US-based individuals. DPI can be an international provided that they have a valid visa to conduct the work for the duration of the time in the US.

MODERATOR:
Thank you. The next question is for NIA. Has NIA considered targeting older researchers or is age ever a disqualifier age?

SAROJ REGMI:
So, age is not a disqualifier. We don't look at the applicants' chronological age in any capacity. There's just for like the REDI program there is a consideration for kind of early stage in their career for some for that particular award, but that's just for that REDI program.

MODERATOR:
Thank you. So, who is the first contact that a participant should reach out to assess fit for a company or research focus area for each programmer institute?

JOSHUA HOOKS:
So, there is a web page that outlines a point of contact for every institute across NIH, but generally if you if send that person in in an email or if you send any program officer an email, they can help point you in the right direction if they are not the appropriate program officer to discuss your application. There also will generally be points of contact in the Notice of Award at the bottom of that web page as well.

MODERATOR:
And a participant is asking what's the best way to find waiver amounts per institute.

MEENA RAJAGOPAL:
I can take that question. So, I believe the waiver topics and the amounts are actually included in the program description within the Omnibus Solicitation. So, I would definitely, you know, suggest that you refer to the program description again in the funny announcement.

MODERATOR:
Thank you. Another question for you, Meena, at NCATS, do applications go to usual study sections or are there specialized study sections where people have expertise in a particular type of research or business?

MEENA RAJAGOPAL:

Yeah, there's actually a panel for -- to review the SBIR and STTR applications and these members are recruited based on the expertise needed for each of the meetings. So, they can vary. The members can vary, but again, there is a dedicated team to look into the SBIR STTR applications.

MODERATOR:
Thank you. Here's an easy question for you all I'll start off with Joshua at NIA, what time are applications due on due dates? Is it 5:00 PM ET or a midnight deadline,

OSHUA HOOKS:
5:00 PM Eastern.

MODERATOR:

Wonderful, Thank you. And then the other question relates to can someone apply for SBIR funding to reanalyze their existing data in a newly? acquired scientific knowledge and if so, what are the mechanisms for getting funded. So, do you want to take that one?

SAROJ REGMI:

Sure. I think it really depends on whether you know if it has commercialization potential, if the data is going to be a product that has a market. In that case that may be that may work. But a lot of the time, you know, you may think about other traditional R grants such as R21, RO3s, and things like that that will you know, take you towards you know. More data generation and not particularly commercialization per se.

MODERATOR:
Thank you. There was mention of during some of your presentations of matching funds. Does that mean that a company has to match funds or partnering university has to match it?

STEPHANIE DAVIS:
No. So general. So technically matching funds are not required especially through the Omnibus. For the Phase 2B programs, the Bridge program, the NCI mentioned, and the Bridge in the Small market program, the NHLBI mentioned, the matching funds cannot technically be required to apply, but they are written to the review criteria. So, for example, if an applicant organization applies for a Phase 2B RFA award through our bridge RFA and they didn't have any matching funds. The application would be accepted, it just probably wouldn't be reviewed very well since one of the specialized review criteria includes did the applicant organization bringing commitment to those matching funds.

MODERATOR:
Thank you. If there is an applicant who has a project idea that had me overlap with multiple institutes, what do you suggest in terms of deciding which institute when? Saroj, do you want to take that one?

SAROJ REGMI:
Sure. I think, you know, definitely think about, you know, what might be the most relevant one and, you know, reach out to the program officer, talk to them. The other thing you can do is always go to the NIH reporter, put in your abstract and see what are the institutes that have funded, you know, innovations in your space, which institute might be more receptive to funding your type of technology. The reporter does a really good job of, you know, showing you what are some of the projects that have been funded.

There's also that matchmaker. When you can copy and paste your abstract and then that, that helps as well.

MODERATOR:
Thank you. And Meena, did you want to add anything from an NCATS perspective given that it's somewhat disease agnostic?

MEENA RAJAGOPAL:
Yeah, I just wanted to quickly chime in on to what Saroj said that you know, you can actually list multiple institutes to consider funding and that actually opens up a possibility for these institutes to come together and cofund your application. So, you know, I od fit for multiple ICs, reach out to all those ICs and program officers and talk to them and see if one of them would be willing to take primary assignment on it. And you can list the others as a secondary or a tertiary [choice].

MODERATOR:
Wonderful. I want to thank everyone for your time today. We appreciate hearing from all the institutes and our partners. And thank you to all the participants who stayed on with us to listen to all the presentations. We will make this presentation available. We will also send out an email with various links that we've been sharing on the chat. Thank you and we wish you much success in your future application.

PANELISTS:
Bye, everyone. Thank you. Thank you. Thank you. Thank you.