SEEDing Healthcare Solutions

Matt McMahon: Well thanks everyone for joining us and welcome to this session, which is called "SEEDing Healthcare Solutions." I'm Matt McMahon and I'm the director of the relatively new SEED office at NIH. I know that it's the end of the day. I was looking outside today and thinking, we have this virtual meeting. I know everybody really misses the fact that we're not in Baltimore this year and we're all sitting in front of our computers, so I decided that maybe I would make you feel a little bit more at home and change my background here to Camden Yards for you. But let's get some slides going here and I can start telling you about all the exciting work that NIH is doing to SEED healthcare solutions. What do we mean by SEEDing healthcare solutions? Many people are aware that the National Institutes of Health is the largest funder of biomedical research. People are very much aware of the fact that NIH funds basic science research across the whole spectrum of the life sciences. But what many people don't know is that we're much more than funding basic science research. In fact, the tagline of NIH is turning discovery into health. NIH has had a much greater appreciation for the broad pipeline, the path that investigators have to take to get that basic science discovery in the laboratory and turn that into something that can actually affect people, can improve patients lives and really help to improve our healthcare system. About a year ago in recognition of that, NIH formed a new office within the NIH office of the director. The name of that office is SEED. SEED works as an acronym, but it also works as a word. The acronym SEED stands for Small Business Education and Entrepreneurial Development. But seed as a word is very much recognizable in the product development space as that earliest stage of work where you're actually turning those scientific discoveries into an early stage product development project. That's a huge shift. It's a shift in mind set. It's a shift in the skills and the expertise that people need and the type of resources. Over the years at NIH, a number of different institutes were trying out different types of programs and activities to help investigators be successful in making that shift. What they had done over time is bring together a combination of expertise and programs and different types of activities that can really help people along that initial part of the early product development pipeline. In recognition of that, NIH formed a central office called SEED. What we do is we coordinate those activities across the various institutes and centers, but we also centralize a number of activities that have been found to be very effective in this space so that those resources are available to investigators regardless of which NIH institute or center they're supported by. Investigators who are supported by smaller institutes that maybe have smaller budgets or have less staff can benefit from these types of programs and services that we've put together. So what exactly is the mission of this new office? The mission of the new office is to accelerate the conversion of scientific discoveries into impactful healthcare solutions. Really what we're going for, what the vision is there, is a world where scientists are empowered to actually improve the lives of patients and their families. I remember when I was in graduate school and I was working on the basic science of how retinal neurons function. I was in the lab one day doing intracellular recordings and I had this epiphany that one of the things I was working on in my preparation might be useful in retinal surgery. I remember, I went back to my PI and I told him this idea. I was so excited about it. His response was, "Get back into the lab. Get back to your experiments. This is not what we do. This is not what our lab is about." I was really shocked, but it actually was a real important point for me because it made me realize that the work that's done as basic scientists, there needs to be a pathway for those investigators. They need to be empowered to move those discoveries further along in that pipeline so that eventually they can affect patients. So what we've done in recognition of those needs is our office has three general components. There's an academic innovation component, there's a small business innovation component and there's an innovator support component. Those three components are intended to really overlap and work together to create a framework so that investigators can really move those projects forward in an effective way. I'll start out by kind of giving you an overview of each one of those three areas. This whole talk is really kind of an advertisement for a series of sessions tomorrow. We'll talk more about that at the end. But basically, we will have entire sessions tomorrow focused on our academic innovation, our small business innovation and our innovator support. But I'll give you a little snapshot now just to wet your appetites and entice you to come. So in the academic innovation space, what is that academic innovators really need? What is it that they need to be able to move those discoveries further forward? How can they prove a concept? That that concept, that discovery could have potential to create patient impact. What are the things they need? Well, lots of people have thought about this very hard and mainly the things that people need are funding to do those early stage product definition studies. That kind of funding is unique because as many of you know if you submit an R01 grant to do that kind of work it is often times not well received because it's not that kind of hypothesis driven discovery science. It's more entering into the applied world of trying to figure out whether those discoveries have potential as a product or service. So dedicated funding is something that's really necessary. Education and coaching is also really important because like I said before, the types of things that need to be done to strengthen a product development project are a world apart from the kinds of basic science research activities that people engage in in the laboratory on a daily basis. Along with that, training and resources. So how do you learn about the things you need to know? How do you learn about how to design a toxicology study? What kind of pre-clinical work is really necessary to convince the FDA that your idea has potential and could be effective and could be safe? Also, personalized feedback from people who really have done this before. Industry veterans or serial entrepreneurs live in the academic environment but have spun out companies and gone through this many times before. These are the kinds of components that can be really helpful. So what NIH did a number of years ago was they developed a network, a nationwide network of proof-of-concept centers. Each one of these centers provides those types of activities. They provide funding for these types of proof-of-concept studies. They provide expertise and support, industry style project management, milestone driven project management. They also provide feedback and guidance from industry veterans, both in the local ecosystem and directly from our colleagues at the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the US Patton and Trademark Office, the types of folks that are going to have to be involved in those projects eventually as they move forward into product development. So in 2013 NIH formed three centers and they were called the NIH Centers for Accelerated Innovation. You can see in the chat box a link to a website. The NCAI program was developed in 2013. It started out with a center in Boston, one based in the Cleveland Clinic and one that was composed of all of the UC medical schools. Then in 2015 that model was expanded to cover three more hubs that were formed in Minnesota, one based in Long Island and one based in Kentucky. Then at the end of last year we activated five of these new reach hubs. So as you can see, we're starting to spread this model and the availability of this model to investigators that are scattered all around the country. In addition to that, the National Institute of General Medical Sciences started a very similar set of hubs and they're called the idea state regional hubs. The idea states are the Institutional development award states. So these are regions that traditionally don't get as much NIH funding as some of the hot spots that everybody knows about across the country. These accelerator hubs are designed to provide the education and training and the support to help innovators be successful in those regions too. So now that we've expanded this network it's available to investigators now at over 100 institutions across the country. You can find more information about these centers and hubs in the links that Ashim has put in the chat box. So our office, the SEED office, coordinates and manages this network. We support the activities of the network. We make sure that the senders and hubs can work together. They benefit from the educational materials and the lessons learned that have been generated across the network. And our office really helps investigators obtain these resources and be successful as they move them forward. That's one of the things that we do in the academic innovation space. Another thing I'll mention, and this is kind of a work in progress, so NIH has many, many translational research programs. People generally know about translational research programs and they understand what translational research is, but there are also many programs across NIH that support early stage product development. And that's a little bit different from translational research. This is the jump into that stage where you're actually trying to convert that idea, that discovery into a product or a service. There are 27 different institutes and centers across the NIH, 24 of them that give out extramural research funding and many of them have programs that support this kind of work. So one of the things that our office is going to be trying to do in our centralized role is to kind of coordinate those efforts, collect up those different programs and make it easy for investigators who are doing this kind of work to understand the possibilities, understand the possible resources that are out there that could be available to them for their particular project. So that's a work in progress and you'll be seeing more about that soon. So let's make a shift over to the small business space now. Oh, actually, that's a good point. Ashim reminds me to mention RADx. Many of you may have heard of RADx. When the public health emergency was declared one of the very first things that we realized was that we needed access to rapid, cheap and accurate diagnostic tests for SARS-CoV-2. That was a critical need. Congress gave NIH $1.5 billion to develop these new diagnostic tests and to be able to scale our tests and capacity greatly across the United States by the fall, which is now or as soon as possible. And how could NIH do that? Well, one way the NIH could do that is they could actually benefit from these centers and hubs that were already set up to do this kind of work. In particular, another proof-of-concept center called POCTRN, a network of centers called POCTRN, the Point of Care Technology Research Network, which is managed by the National Institute of Biomedical Imaging and Bioengineering. These centers and hubs and the POCTRN centers are uniquely capable of rapidly taking these ideas and testing the proof-of-concept and moving them forward. So the RADx program, Rapid Acceleration of Diagnostics, was piggybacked on top of these research networks. You know, normally you might put out a funding announcement. It takes you a while to build your funding announcement, to get it published. It's on the street for a while. People apply. You get your applications. You review your applications. You make a funding plan. That takes a lot of time, but because we're able to leverage this network the RADx program was able to basically get started and fund projects extremely rapidly. Like, on the time scale of a few weeks as opposed to a number of months that it normally takes. So it's an example of how this type of a model where you're providing money and expertise for this product development work at the earliest stages can be applied to many different areas. We're hoping that it's not just COVID, but many of the different important public health needs that we have can leverage this network and bring therapies and cures to the forefront as fast as possible. And Ashim put some links into the chat. You can see Francis Collins has a Director's Blog post about that and also another press release that basically describes some of the projects that have been incubated through these proof-of-concept networks. And many of which have developed tests that will be available for you across the country to use soon. So shifting to the small business side, many people don't realize this, but NIH provides research funding, provides R&D funding to small businesses every year. In fact, NIH is actually the largest source of early stage capital for these life science product development projects in the United States. You can see here in the lower right, we give out $1.2 billion every year through the SBIR and STTR programs to small businesses across the country. That's $1.2 billion every year. So you might hear about an investor here and there and the venture capitalists and the big investments that they're making and this company or that company. Well, anytime you hear about those venture capitalists you can think to yourself, actually NIH is the largest funder in this space. We have 1,500 companies at any one time in our small business portfolio, and what are those companies getting? They're getting free money, it's not loans. We're not taking a piece of the company in exchange for the money that we give them. It's total non-dilutive unlike most investors. The companies get to keep all of the intellectual property and the data that they create as part of their work just like academic investigators. Their universities get to keep all the intellectual property and the inventions that they make. And more importantly, these small businesses can really leverage that funding and the work that they complete with that funding to attract the partners and the investors that are going to be necessary for them to move forward through later stages or product development. This little schematic here shows that this road from basic research discovery through proof-of-concept, research and development, scale-up and manufacturing, sales and distribution. This is a long road. The traditional kind of R01 basic research grants are shown over here on the left in this blue box. All of these other types of investments, friends and family money, once these small businesses spin out from a university or they're formed on their own, they're cobbling together money from friends and family, from angel investors. An angel investor is just an investor that's spending their own money. A venture capitalist is a person who is spending somebody else's money. They're investing in these companies. And strategic partners, large businesses, biotech firms, medical device companies. But the small business program, the SBIR and STTR programs, we're putting $1.2 billion into this part of the pipeline every year. And you can hear more about that in the small business presentations that are going to be happening tomorrow. But this piece of funding is really important and this small business program is really important because many of the academic research projects that are happening in universities when they start into this product development world, one of the main ways they keep going is by either spinning out small businesses from the university or in licensing their technologies to early stage small businesses. So what we're trying to do at NIH is we're trying to make a continuous pipeline of support. You can get funding and support in the earlier levels of project definition while you're in the academic world through the product development support programs that the institutes offer and also through our proof-of-concept network. But then once that technology is entering the small business space, they can continue to be supported by NIH through the small business programs. And it's really no small chunk of change. If you get one of these awards and you go through the various stages of these awards, you can get up to $5 million to $7 million for a project. I assure you that that is a significant amount of money in the product development world. And at the end of the day, these companies will have a lot of exciting results to show for it. Not only that, they haven't given away a part of their company to investors to get there. So this kind of funding and this type of small business support is really an important part of the product development pipeline. I'd like to encourage people to throw questions into the chat box if they have any. I'm happy to address questions and talk in more detail about things if you would like. Just pop them in there and our moderator, Ashim, who is actually the academic innovation team lead in our office will pass them along to me. So it's one thing to give people money, but money is just one thing that people need. I mentioned before that people also need expertise and support. And the third component of our office is our innovator support team. And what does that mean? Well, I mean, many of you are used to interacting with your program officers at NIH. The program officers at NIH have vast expertise. They're often times in their position because they have detailed subject matter expertise in the scientific area of their portfolio. What we're trying to do, what we've done in SEED is we've built a team of people that are also experts, but they have a specialized kind of expertise. Their expertise is in regulatory work. So we have Chris Sasiela as our senior regulatory specialist. They're in how to get financing, how to create your project and advance your project in a way that allows you to get investment and further funding. And we have Steve Flaim as our inverstor-in-residence who has a lot of experience. He's one of the founding members of the Tech Coast Angels in California and a board member of the Angel Capital Association. We also have a number of entrepreneurs and residents. So these are folks ... they're listed in the bottom left here. We have Ethel Rubin, John Sullivan and Steve Wolpe. Entrepreneurs and residents are people who have worked in industry. They've started small businesses. They've worked for companies. They've actually been out in the wild doing this work. And they come to NIH and they're working with us to share that expertise, to help our innovators. They do consults with people all the time. They give advice and support. We have an intellectual property expert, Gautam Prakash, who has actually loaned us from the US Patton and Trademark Office. All of the kind of interesting and important issues that investigators have to think about when they come up with an invention. And how do they work with their local tech transfer office to protect that invention and to make sure they can move that invention forward. Gautam and our team can help people work through those intellectual property issues also. So this team has really unique expertise that can be brought to bear on these important issues. And there are a number of activities that they participate in, which they will be talking about in a session tomorrow which I will let us know about in a minute. But one of the main things that they do is when our companies, when our small businesses are trying to get funding to move their projects even further along they have to go out into the private sector and try to get that money. It's a big challenge. We realize that the money that we're putting in at this very early stage of product development is actually just a drop in the bucket of what it takes to actually get that drug or that medical device all the way into the healthcare marketplace. It can take many billions of dollars to take a product all the way from an idea in somebody's head to availability to one of your family members in the doctor's office. And we realize that what we're doing is just helping those companies at the very beginning, but we don't want to just help them at the very beginning. We want to position them well so that when they're going on to compete for that money, to try and get funding in the private sector, they've derisked those projects, they've strengthened those projects in a way that makes it really easy for them to move forward. So many of you have probably seen the show "Shark Tank." So "Shark Tank" that's actually a real thing. That's how people go out there and communicate with potential investors. There are meetings, there are "Shark Tank" like meetings all over the country that are designed to match up investors with companies and projects that are looking for money. And what our team does is we coach investigators. We actually train them. We teach them the way to give the most effective pitch. Not only that, we collaborate with those meetings and those conferences so that we can send out people to those meetings. So we not only train up the investigators, but we support their participation in those meetings and a list of some of the meetings is here. The Bio International Convention, the Medtech Conference, RESI, Life Sciences Summit, the Angel Capital Association meeting ... these are all meetings where NIH has a relationship with those meetings and we have a certain number of slots at those meetings. We pick our investigators that are looking for money, we train them up to be professionals to really knock it out of the park on these pitches. And we send them there to try to get the next tranche of funding that they're going to need to move forward. And it's a really effective program. Right now, we're training and pitch coaching over 100 companies a year to go to these meetings. And the metric of success is are those companies able to get that funding that they need to move forward and development, and many times, they do. But actually, speaking of metrics, it's actually ... I'm going to switch back here a second to this proof of concept center slide because I want to tell you about some of the outcomes of this network. So we funded 289 projects through this network and not only have we funded 289 projects, those projects have spun out 79 new companies. And now that I've told you about the small business program, you'll be interested to know that of those 79 companies that spun out of these proof of concept centers, 29 of them have already gotten funding through SBIR or STTR grants. So we know that this system, that this pipeline approach is working. And not only that, those 289 projects have generated $802 million in follow-on funding to continue their work. So I told you that we're trying to position these projects to move forward in development. $802 million in follow-on funding is 13 times more than the total money that we have invested ... that NIH has invested in these programs. So it's a tremendous metric of success. The leveraging factor that we're getting ... we're investing money and we're getting back out of that ... these investors are getting back out of that 13 times more from the private sector. So we really think that these projects are uniquely positioned not only to compete in the small business program, but once they're in the small business program, we're hoping that these projects will continue to move forward into the private sector into products and services that you can see. And in fact, one of the things that you can ... that I can ... that we can tell you about is we have a website now where we have a catalog of success stories coming out of our small business program. And Ashim will put a link in the chat to that website. There are 57 stories there. We just launched the website a few months ago but there are 57 stories of examples of small business program projects that are having a positive effect on patients now. When you read those stories, which are written for a general audience, you can see how those projects advance and how the funding from our small business program's helped them to be successful. And not only that, there's also a story on that page on that first link that describes how a number of our small businesses within the SBIR and STTR portfolio were able to very rapidly pivot to address the COVID public health emergency. So some of these companies that were either developing therapeutics, or developing testing strategies, or developing IT platforms were able to really rapidly pivot to address COVID-19. And they were able to do that partly because NIH provided supplemental funding, very rapidly provided supplemental funding to companies to do that work. So it's another example of how NIH has leveraged the infrastructure and the capabilities that we have to really go after the COVID public health emergency. And we're really proud of that, and we think that at the end of the day, many of these projects are really going to play a critical role in developing therapeutics and testing strategies that will be necessary for moving the country forward. So I just want to kind of wrap it up by describing to you some of the sessions that are going to happen tomorrow. There's a whole track tomorrow, starts at 1:00. Ashim Subedee who is our moderator for today, who is answering your questions in the chat, will be giving a talk that describes in much more detail what the SEED office is doing to help academics address unmet medical needs, and that's at 1:00 tomorrow. At 2:00 tomorrow is a session called "From Bench to Boardroom: Supporting Small Businesses" and in that session, Stephanie Fertig, who is the HHS small business program lead will be talking about all the support that NIH provides to small businesses. And at 3:00 tomorrow, Chris Sasiela who is our innovator support team lead and also our regulatory affairs ... senior regulatory affairs specialist will be talking about all the different types of support that the innovator support team provides. But in addition to that, one of the really cool ... and I'm totally excited for this session. You know, I think we kind of saved some of the best stuff for last. There's a session tomorrow at 4:00 called "Innovators in Action: Case Studies" and you'll be able to hear directly from innovators, you'll be able to hear their stories, and hear about how they've used this type of NIH support. Whether it's from our proof of concept network or the small business program to really take their ideas and move them forward into potentially helpful healthcare solutions. So that session is going to be really exciting because you'll get to hear it right from those innovators' own mouths. They'll be able to tell you their stories, you can ask them questions, and you'll really get a much better personal feel for how these types of activities can help investigators like you move their projects forward in product development. So that's basically what I have for you today. If there are any questions that we haven't answered, you can throw them into the chat box now. We'd be happy to answer them. I'd also encourage you to attend these sessions that will describe much more in-depth the various types of things that we do. And I see a chat in the session, yes, tomorrow's "Bench to Boardroom" session will talk about the CRP, that's the the commercialization readiness pilot program. That's a great program, provides more support to small businesses than the base award. We'll also talk about a new set of activities that are provided that are under the topic of technical and business assistant. This is an addition to the funding for research activities, this is really to strengthen the technical and business aspects of projects in addition to the R&D that the SBIR program follows. So it's not just those grants. It's part of our more broad focused like it's not just the money, it's all of the things that we can wrap around that to make people be successful. Let's see if there are any other questions that pop up. Well, I don't see anything right now. I think Ashim has probably answered some questions that came in already, but again, I encourage you to ... Yep, go ahead.

Ashim Subedee: Matt, I'm going to pose a few questions to you.

Matt McMahon: Oh, great. All right, let's see what we have.

Ashim Subedee: Okay, so first question is for early stage small businesses ... Oh no, I answered that. So the difference between SBIR and STTR brands, you can find more answers tomorrow. But Matt, if you could quickly tell like what is the main difference between SBIR versus STTR?

Matt McMahon: Yeah, SBIR and STTR are almost identical programs. The only difference is the STTR program is funding a collaboration between usually a university and a small business. And a small business ... An SBIR grant is just providing funding for a small business. But other than that, they're almost identical. That's the main difference. But the other difference is that the SBIR program is a much larger program than the STTR program. But other than that, they're very similar. And Stephanie will be talking more about that tomorrow.

Ashim Subedee: Someone asked what's the nuances and differences between SBIR, SBIR versus ... Or NIH SBIR versus NSF SBIR, what are some of the differences there?

Matt McMahon: Oh, that's a great question. So actually, in the last few years, NSF has started funding more projects that are in the kind of life science and biomedical space. NSF is a broad agency that has a broad mandate. But many of the opportunities that they fund are around like platform technologies or things that have kind of broad applicability. Whereas NIH is covering anything in the life science space across all domains. So I would really encourage people to take a look at the NSF SBIR program. They have a great set of program officers, and they also have many support programs and they're very helpful. But the types of things they support are a little bit more restrictive and you have to take a look at the particular funding opportunities to see if your project is a good match for them.

Ashim Subedee: There was a good question about the requirement for I-Corps so they asked like NSF requires I-Corps, does NIH program require something like that as well, so it's ...

Matt McMahon: Yeah, good question. So that's an interesting part of the NSF program. We do not require participation in I-Corps but we love the I-Corps program. And in fact, the I-Corps program ... We have an I-Corps program at NIH that supports phase one small business program awardees. And I believe they just sent out an announcement a few days ago opening the application process for new applicants. So if you are a small business with a phase one award or you know somebody that is, I highly recommend that program. It's a really structured customer discovery program. My favorite thing about that is people say oh, scientists are used to validating their science, and it's like okay, well, the I-Corps program is all about validating the business case behind your project. You know, your R&D is about validating the technical case, but the I-Corps program is about validating the business case. I think Ashim can probably find a link to the NIH I-Corps program and throw it in the chat.

Ashim Subedee: Yes, I'll do that. While I'm doing it, another question was can you explain what a product means in this context? Can it be a new proof of concept methodology, not just a product, so not new agent but a method of doing certain things or [Indistinct].

Matt McMahon: Yeah, that's also a great question. You know, I ... In some ways, I don't like the word product because product implies something that is sold and that's not really what we're going for. We're mostly going for things that can ultimately have an effect on patients. We have institutes and centers that are much more focused on research tools, or the National Institute of Environmental Health Sciences that are working on other types of things. So I think I use that term but we are interested more broadly in services and projects that can have an effect on patients in the end. They could be research tools. They could be platform technologies. It's not just about pills and medical devices. It's much more broad than that.

Ashim Subedee: Another question, we have a couple of minutes. So this is regarding our EIRs and the innovator support team, are they available to to chat with academic innovators and small business owners even if they don't have SBIR funding, and is there any charge to meet with them?

Matt McMahon: That is a good question. So, Ashim is our innovator support team lead, and one of the things that we're working to do is to make our innovators and the other types of support staff much more available throughout our proof of concept network and those institutions that are available across the network. And they are available to applicants and awardees in the small business program. But I think as we go forward and we build our office, and we build our capacity, I think that there will be an opportunity for those types of resources to be available more broadly to academic innovators as well. But right now it's mostly through the proof of concept network that people have access to those kinds of services locally and that kind of expertise that lives locally and access to our centralized support team. And in the small business program right now, it's mostly available to awardees in the small business program. And all of those services are free.

Ashim Subedee: Okay, let's see. There is another question. Are there general business needs that you notice in companies with their first SBIR who come to help for you? That's a loaded question.

Matt McMahon: We see the full gamut of needs and in fact, if you go ... if you see ... if you go to our session tomorrow on innovator support and even in the small business program, you'll hear much more about those needs. But they can range from needs for understanding the regulatory aspects of their program, understanding how a product is going to get paid for in the end in the commercial marketplace. How to build your company, how to develop the right team, how to have the right business people involved, how to make a financial plan for your company. Basically the whole scope of things that are necessary are the type of things we can provide some guidance on.

Ashim Subedee: Okay, we are at time. There are a few questions so I'll try to type them there as well. These are more specific questions but one more minute, Matt, last words?

Matt McMahon: Well, I just want to thank everyone for attending and I want to point out that I'm glad that there's a lot of questions. Because like I said, these sessions tomorrow will cover everything that I talked about here but in much more detail. You'll be able to answer questions there and get more information about how we support academic innovators, how we support small businesses and the types of services we provide for everyone. And I just want to thank everyone for attending. I'm really glad that everybody could come. I know it's the end of the day so people can drop off and go to their virtual happy hours. And it was a real pleasure, and we hope to hear from you soon. You can reach us any time at SEED.nih.gov. Thank you very much.