Helping Academics Address Unmet Medical Needs

Ashim Subedee: Great. We will get started. Okay, perfect. Good afternoon, or good morning, depending on where you are joining us from. My name is Ashim Subedee. I'm the Academic Innovation Lead in the new [Indistinct]. It's relatively new, the Small Business Education and Entrepreneurial Development with the NIH Office of Director. I'm joined today by Matt McMahan, who is the director of the office, who is serving as a moderate, but also jumped in with his comments, and answer your questions as we get them. I know it's a different world these days, right? So if we were all together, we would be in Baltimore. You see the temperature there is around 40 to 50 degrees. So you probably are all glad, unless you are in Anchorage, Alaska, that you are not here. So you could pick your place. You can be anywhere in the country. You can think you are in San Diego and enjoying the 87 degree weather. But today we'll be talking about academic innovation, and how we can help academics really meet unmet medical needs and challenges. So to make it a little more interesting in this virtual setting, I have a number of polls. So what we'll do is, we'll put the polls out. You'll have 30 seconds to answer, and it will be a good way to really get to know the audience so we can tailor the presentation that way. So the first question, you have 30 seconds. If you are an academic and have received any NIH academic awards ... maybe a couple of more seconds, and then we can end the poll so you don't have to wait around. Okay. Let's see the answer. Whoa, that's surprising. So it looks like only about 22 percent of folks are academics. The others are not. Don't worry. We'll be talking about other aspects of NIH ecosystem and how other people can get information as well. So the next question is, just sort of to build on that question, Cameron, if we could have that question. So I wanted to get a sense for what your roles are. Are you faculty postdoc student, administration, administrator, small business or other? So we will put that up for another 15 seconds or so. This would happen so much better and easier if it was in person. I could see your hands, but unfortunately we have to do it this way, but at least we'll to know each other. We'll know who is here. Okay, we can end this poll as well. Let's see. So we have a pretty good mix. A number of faculty and university administrators. A bunch of others, which we don't know what they are, and a few postdocs and grad students as well. So exciting. One more question before I get into the presentation. So let's see the third poll. So this is the question that would help us identify what you think the role of research is. Do you believe your research has potential to develop into a technology, either therapeutic diagnostic devices to help cure diseases, or improve human health. Okay, 10 more seconds. Okay, that's great. So most of you believe, and which is what you should I think as your research does have a potential to be lead into exciting technologies. So based on the answer, it was very clear that you all believe, and that is true that the majority of innovations really come from basic research and academia, right? So NIH is the biggest funder of research in general in the US, and in fact, in the whole world in biomedical space. NIH gives about $30 billion each year as grants and contracts and other research funding to really do this basic research projects with the goal of understanding science and human life. This leads to creation of all of these ideas and knowledge, but what eventually the goal of NIH is, is to really convert these discoveries into help improve human health, to improve the lifespan of everyone. The problem is turning these discoveries that are sort of at the university level and early stage into tangible products is a really slow and inefficient process. There are a number of reasons for this. One is lack of funding for these academic innovators to really take these discoveries and ideas from idea to a product. So that includes doing these really early studies to figure out, is there feasibility of doing these studies or definitely some [Indistinct] and development studies to take it forward? There's also a lack of knowledge. A lot of these academic innovators don't really have the know-how of the commercial [Indistinct] process. They know their science really well. They what the technical and scientific aspect is, but oftentimes they don't know, "Okay, what do I need to do? What sort of experiments and things do I need to do now to take my idea and develop into a product?" Then on top of that, there is a lack of access. So even if, say, sort of no, okay, I kind of know vaguely that this is what I should be doing. A lot of times they don't have access to expertise, and so that really hampers development and really slows it down. And a lot of times there's also lack of incentive to do this, and there is sort of a lot of stigma around, okay, you don't really need to do this kind of product-development focus studies or translation studies. Just do your basic research, and that is what is needed. So that's not what we want. So because of that, to really change that mind-set, and also to provide resources and really help not just academics, but the NIH ecosystem in general, to take these discoveries and convert it into tangible products to really improve healthcare. A little over a year ago, NIH started a new office called Small Business Education and Entrepreneurial Development Office, and the goal of the office is to really provide all of the NIH funded innovators, and the community in general with not just funding, but also other additional resources that you need to really take this idea and build it into a product, and improve human health. So we do it with sort of three aspects in mind. So one is, as I mentioned, academic innovators are the biggest group of people we really support and fund at NIH. So we have one team within our office that is focused on really helping these academic innovators take their discoveries and convert it into product. Then we also have at NIH, it's also the biggest funder of small business research. So in terms of really funding that [Indistinct] space for a company, or startup, or to take a technology and build it into a product. NIH every year gives out more than $1 billion to provide that early stage capital to take that idea and develop it into a product. So that's the second aspect of the office where we are really trying to help these small businesses really improve upon their product development, and take these technologies and build it into a product. And then to tie it all together, we have a third team with a number of experts, entrepreneurs and residents or regulatory experts or commercializing experts who have done it, and they have the know-how, how to do it. They are there to then provide support beyond just the funding we're providing, both to the academic innovators, as well as to the small business innovators. Okay, so that now I've told you a little bit about what the office is about, the different aspects, I wanted to ask a question about the NIH proof of concept network to kind of get a sense of how many of you have heard about it and know it about the proof of concept network that we have. We will wait 15 seconds. Okay, let's see. So, unfortunately, a vast majority of haven't heard about the program, so my hope and goal for this session is to really educate and empower you, so now you will all know about the NIH proof of concept network so you'll be able to go and tell people about the programs. Just knowing that you didn't really ... A lot of people don't know about it. I'll skip this poll because I think I was going to ask about if you have heard about it, have you received any funding from the NIH proof of concept, but I don't think we need to do it. So I'll move on and tell you more about the NIH proof of concept network. So I mentioned how we have the academics really taking their discoveries. We have identified some really innovative idea. They want to now think, "Okay, is my idea good enough to be developed into a product?" So if we want to do that, we have to really help at that early stage to define the proof of concept. Is this idea even worth something developing into product around? So what we have done is we have created this NIH proof of concept network to help you, one, providing you with funding support with grants. But then as I mentioned, grants or funding alone is not enough. You also need this know how of how do we really commercialize technology and build it into a product and bring it to patients. So for that we then put together educational packets, mentoring, and created a network to really help you do that. One critical aspect that was integrated into this whole philosophy was figuring out how do we let these innovators know really early if it's not something worth developing. So the whole idea around fail fast philosophy. So you give funding in tranches, so you'll get a certain amount of money. You need to show feasibility of proof of concept, and then you get additional capital if you made the milestones. That way you know really early if something is going to fail or not, or you don't waste your effort and time on that, and the ones that are working, you provide them with more support to take it forward. Then providing all the other resources to then take them forward. So there are four components. There's the funding component, so you get up to $200,000 in private funding. There's the educational component to really train you about product management and train you in terms of the commercial assets and resources that you need. Regulatory planning, financing and fundraising, and partnerships and business developments and all of those aspects. Then we also then worked with other federal partners at FDA, CMS and USPTO with our private sectors including pharma and med tech. Then with our payer partners, so Kaiser Permanente being one, where these innovators at the really early stage get feedback from them as to if they're thinking about regulatory and reimbursement components, about business development components back early on so that can help them with their technology development. So here the extent of the NIH proof-of-concept network. So I'll go in order as to how do I start it. So the first network or the centers were created with the NIH Center for Accelerated Innovations. So these were three centers that were funded in 2013 with a focus on heart, lung and blood diseases. So there was one in Boston, one in Cleveland and one in California with all of the medical schools in California being part of that network. In 2015, once we saw over 2 years that this program was really working, there was a lot of value. We then expanded it to include all of the busiest areas that NIH covers. So not just heart, lung and blood. These were trans-NIH covering all different disease areas, and we funded three different centers, one in Louisville, one in Minnesota and one in Long Island, bio medical hubs including Stony Brook and other universities. Then in 2019 we were able to then expand it to five additional centers. So as you see, we have covered extensive networks. This network of just this NCIA and Reach hubs cover almost 40 to 50 universities across the country. Then on top of that, we also have the NIGMS STTR regional technology transfer accelerator hubs. So these hubs are focused on IDeA states, the states where there is not as much NIH funding going to these states. So the idea was to really foster innovation and NIH support in these states. So there were four centers that were funded in these four IDeA state networks. So southeast, northeast, central and western hubs, and what these hubs provide is ... Some of these hubs provide some small funding, but a vast majority of their focus is on providing entrepreneurship and commercialized resources and expertises. So you are really training the innovators in these IDeA states to think about product development, and providing them with all of the educational and entrepreneurial components needed for them to then start thinking about building their technology and moving it forward. To date, we have fund 289 projects using the NCIA and the Reach network. These 289 projects were selected from thousands of letters of intent and applications that were submitted. So these go through an intensive review process, both at the hub center network and also then at NIH, including review from our external partners. So then, out of these 289 projects that we have funded, already up to date, 74 companies have been established. So just based on this sort of very early stage ideas where they got funding to really explore their idea and do some of these really critical studies to demonstrate feasibility, they were then, based on that, able to say, "Okay, my idea, I have demonstrated the proof-of-concept. There is value in it. We'll start a company around it." Of those 74 companies, 29 of them gone on to receive SPR STTR awards, which is a really good success rate if you sort of consider the overall success rate for SPR STTR. From these 289 projects, 69 technologies have already either been licensed or optioned to license already. So there is potential that these technologies will now ... Other small business or larger companies are going to take this technology and build it into a product. These projects have also received $800 to $1 million in follow-on funding already, both from the federal sector, including SPR STTR, and also from private sectors. From MedTech, from VCs, from pharma. The other key component is we have used with this center networks already trained more than 2,000 innovators. So now we have these 2,000 innovators who know how do you really take an idea from the lab and think about product development, and build a product around it and take it forward. So it's not just about those 289 projects that we have funded. It's about this network that we're building of innovators who know how to take an idea and build it into a product. So I wanted to talk about one of the success stories of the program so far. So this is one of the innovators we funded with the NCIA program in Boston. So Jonathan Thon, he had received K99 award and so that really helped him believe that the technology was working on pluripotent stem cells. It has a potential to now manufacture, using that technology, and of course [Indistinct] platelets. So Jonathan, once he got that sort of basic research figured out, he went to the NCIA hub in Boston, the [Indistinct] hub, and applied for NCIA funding to take this idea and then see, "Okay, is there a potential to build it into a product?" So he used the NCIA funding to build a platelet by reactor. So I mentioned when the applications come in, they are reviewed by NIH, but also by our external partners, including our federal partners at FDA. During that review process, he got connected directly with our partners at CBER, Center for Biological Evaluation Research at FDA. He was able to, through that interaction, discuss the regulatory path that he would need. So that really helped him really at that early stage how he should be thinking about that regulatory pathway. He then went on to spin out a company in 2016, and that received a direct phase II SBIR award. They also applied for commercializing assistance program award. That really helped them with that IP development. In 2017, there was $10 million in Series A venture capital financing. They then came back to NIH, and with one of the program we offer, which I'll talk about a little bit later on, and I mentioned earlier the EIR, Entrepreneur-in-Residence. He was able to get mentoring and [Indistinct] coaching support from these EIRs, and then he attended BIO and presented his technology, and was able to really leverage that interaction to then raise funds. 2018, they received additional $3 1/2 million as a DoD, and then in 2019 they received $1 of $26 million and a $5 million contract from Barda with a potential to reach up to $56 million. So as you can see here, and this is a direct quote that Jonathan said, "If not for acceleration effect of BBIC," this is part of the NCIA hub based in Boston, "This would have been a continuation of just an academic project." So it's a really good story as you think about taking this idea from the basic research lab. So using the K99 funding to build on that basic idea and research further, then using the NCIA funding through the proof-of-concept network to demonstrate that feasibility so that it works, and then he went on to get all of these awards and take the technology forward. So I wanted to say this so you know that there are stories like this, and this is just one of the many stories, and we really hope that after this talk and presentation, it will really get you excited so you could be Jonathan, and you could take your idea and then build it into a product just like this using all the NIH resources that are available. If you want to hear from innovators like Jonathan, from 4 o'clock to 4:45 today in this same Hall B, you'll be able to listen to other innovators in action. So we'll have three innovators talk about how they took their idea and built it into a product, leveraging all of the NIH researches. So definitely attend that session. It's from 4 o'clock to 4:45. So I think this is the last question. So I talked about the NIH proof-of-concept network and centers. So I wanted to ask if you had heard about other early stage product development resources and programs that are available at NIH. So I listed some of them here, but there others as well. So I wanted to get a sense for how many of you know about all the other product development resources we've provided at NIH. Fifteen more seconds. So again, unfortunately, the vast majority of you haven't heard about it. So again, my hope is after this presentation that you will learn more about it. So I will just give you a very brief snapshot of some of the programs. This is by no means comprehensive listed. In fact, it's a very small number of programs that I've listed here. But if you see here, so I talked about NIH funds, academic grants, R01s and U01s and all of the different grants. Then I talked about the proof-of-concept network with more than a hundred institutions around the country where you'll able to, if you're part of those institutions, apply for this feasibility award through some of the studies to demonstrate proof of concept. But those are not the only programs, even if you are not part of one of the network universities, you are somewhere else. But also you have some sort of idea that you want to think like, "Hey, I want to build a product around it, there is potential." There are all these programs at NIH that you are able to leverage and use to take it forward. And there are different flavors of the program. So some of them are funding based programs. Some of them are resource-based programs. So what they will do is they will not give you money, but they will do the work for you. So it's almost as good, or even better as getting money, and some of them are [Indistinct] where they'll give you funding as well, but they'll also provide all the other resources that you need. So the commercialized resources, including regulatory feedback, and reimbursement guidance, and business development, and competitive landscape analysis and all of those aspects. So if you look here, when you have, in terms of a drug development or devise a diagnostic development, you start at figuring out the target and identifying that, and then in the device, the diagnostics, there's coming up with the concept. There are a number of steps that are required for you to move it forward. So there are a number of programs that are at all the different stages. So as I mentioned, this is just a snapshot. What we are working on at the SEED office is in fact creating one central webpage with information to all of these relevant programs. So that is coming soon. We understand that a lot of people either haven't heard about all of these resources, or even if they might have, it's really difficult to navigate the 24 institutes and centers at NIH that provide funding and have programs like this. So we want to provide you with one stop and you can go and say, "I am working on developing a drug," or "I am working on disease indication. I am at this stage of development. What are the resources that are available right now?" And you'll be able to then see all of the programs and resources that you can leverage. On top of that, we'll also work on creating someway to then give you some guidance as to how do you then develop using these programs. How do you then develop the product further? So product development learning modules, or regulatory guidance and all of those resources. So keep an eye out that. That will definitely be coming. You can go to our website, seed.nih.gov, and you will see, whenever this is launched. You'll see it there, but you'll also get e-mails and information about it. So it's coming out soon. So I've talked a lot about the academic innovation, what are the different programs that academics can use and leverage right now, including the proof-of-concept network, and even within the proof-of-concept network, there are other similar kinds of network programs that I didn't talk about. So I talked about the Reach hubs, NCIA hubs and the NIGMS technology transfer hubs and the IDeA states. We also have programs like Apoctrine, point of care technology research network, CTSS, Clinical and Translational Science Award network. So there are a number of other programs like that that are existing at NIH, where academic innovators can go and leverage the network to get support and resources. So I mentioned our office has that academic innovation focus, but then we also really work very closely, and we have the whole team focused on small business side of things. And I told you that NIH gives out more than $1 billion each other in supporting small businesses in terms of helping take their technology and then move it forward to build it into products. So with the small business innovation, there are a number of funding opportunities and other resources. So definitely if you go to spir.nih.gov, you'll be able to get all the information there as well. Then I mentioned the innovative support team within our office. So the academic innovators, as well as the small business innovators, on top of funding, they will need other entrepreneurial training and resources, commercialized resources and regular consult and all of those aspects. So our innovator support team is there to provide you with all of the guidance and resources that you need to take your technology and build it into a product and take it forward. So that's the third aspect of the office, and all of these programs and teams really are integrated well and work together to really help NIH innovator community across NIH to take their idea from lab to market. So you heard all about the academic innovation resources. From 2 o'clock to 2:45 today, we have our small business focus session where you'll able to hear all about all of our small business program and all of the resources. The small business innovation team lead from our office, Stephanie Furtick, will be there. She will have a number of meets that she will [Indistinct], so you will hear all about how can you leverage the program, what are the resources that are available. Then from 3 o'clock to 3:45, you can hear from our innovator support team with Chris Sasiela, and one of our entrepreneurial residents, John Sullivan. They'll talk about all of the support that our innovators can get and receive from NIH. So definitely tune in to those sessions. You will definitely learn much more about the small business support and the innovator support than what I just briefly mentioned here. So that's all I had. So I have a number of links here, so definitely visit those webpages if you have questions. Subscribe to receive alerts from us on and reach out to us if you have any questions. Over the next 15 minutes, we can take any questions you have and answer any of the questions and things you have. I see Matt has already answered a number of questions. So if you want to type all of the questions, please type it using either the chat function or the Q & A function, and then we will answer all of those questions. So let's see. Looks like Matt has answered most of the questions. So I'll pick some of the questions and try to answer here. So one question I see was not answered was do you have to be an academic staff or faculty to apply. Can a trainee apply for these funds? So for the NIH proof-of-concept network, if you are affiliated to the universities that are part of the network, you can apply. You have to work with the faculty, but you can apply even if you are not a faculty. It's intended you definitely work with your faculty and team, but you can be part of the team to then apply for those funds. For the small business and other funding opportunities, again, for the small business funding opportunity, small businesses have to apply. But even if you are not a small business and you are at the university, you can work closely with the small business and apply for funding as well. If there any other questions, please feel free to type questions if you have any. Would a funding belong solely to the inventor or to the academic institution with which the inventor is employed? So Matt answered the question. It is awarded to the institution, and in terms of the IP, for the institution, the institution hosts the IP, but usually the inventors are either ... They get the royalties from the IP, but they are also able to license it out a lot. A lot of times the innovators get the first option to license the technology out if they want to build a startup or technology around those IP. Does NIH support innovation from nonprofit product development, and Matt answered the question. Absolutely. The SPIR program is intended for for-profit small businesses. So for that, you have to have a small business, but we have other support and funding opportunities for not-for-profit institutions as well. Can you get funded to develop medical education technology product? Yes, absolutely. We have a number of those projects and products in our portfolio, and depending on if you are an academic innovator in one of the NIH proof-of-concept networks, you are able to apply for funding to build those, or if you're a small business, you use the small business funding obviously to do that. What do the recent NCIA centers offer that allow institutional office of innovation commercialized, et cetera, wouldn't already offer? Development pitches, funding investors, developing business funds, et cetera. How would it work for an innovator in one institution, not an NIH funded hub to use resources at NIH or NIH funded groups? That's a great question. So the first question about what do they offer that some of the universities [Indistinct]. There's a variety of things. One of them is that funding aspect. Right? So they are providing this proof-of-concept funding that a lot of the tech transfer offices might not be providing. So you get this up to $200,000 to do some of these key studies to demonstrate feasibility. So that's one thing. The other aspects are all ... entrepreneurial, education and training. There are also a number of these regulatory consults and other people on staff. What most of the Reach hubs also have is they leverage their local ecosystem as well. So each of these Reach hubs and NCIA hubs have external advisory board that consists of a number of experts from their local community who are either volunteering their time to really provide guidance on a number of these commercialized and related factors and resources. So there is that aspect. I think the other critical piece is that partnership with NIH, and our partnership with our federal partners at FDA and CMS and Kaiser, they are able to get feedback from these really critical partners really early in the development pathway that a lot of these academic transfer centers might not be able to provide. So in terms of innovators who are not part of these hubs, how can they access these resources? So as Matt mentioned, a number of these educational resources are already online, but a lot of these hubs also partner with other institutions in their network. Also the NIGMS tech transfer hubs have resources that anyone can access. You have to be part of the network to get access to the funding, but educational materials and components that have been developed, anyone can access. Then I talked about all the other NIH program product development resources that we have available that you are able to use. So even if you are not part of the NIH proof-of-concept network, I would encourage you to explore the NIH product development resources and programs and funding opportunities that we have, and pretty soon we'll have a website where you'll get all of the information, but you can already go and find out information about all of these programs and use those programs as well. Are there any specific funding mechanisms that would be more ideal than others for nonprofit development? I think that depends on what kind of work you're doing. Is it developing drug, or device or whatever? So based on all of that, based on the business indications you'll have to check out its individual IC and figure out which one is the appropriate funding opportunity and mechanism for you. Then someone asked about the success rate of applications, and Matt posted a link there. So I see a few other questions. Can you please give some examples ... So a little more about international development projects that develop products, including international development? So there are a number of funding opportunities that are focused on international development. So again it all depends on the disease area the institute that I see. So for the Center for International Development, I think that's what it's called. But there is an institute that is focused on international work, so you can definitely check out resources from there. A number of institutes have programs that are focused on these international development work and resources. So NIAD, National Institute on Allergy and Infectious Disease have a big international component and presence where they do fund a number of projects that are based in other parts of the world. National [Indistinct] have a center for global health where they're focused on cancer-related work around the globe and world as well. There are a number of these funding opportunities and programs that are available, so I would encourage you to check out a number of these programs. Unfortunately, we don't have one place where you can get all of this information, but we do have a number of these programs that are available. Any other questions. We have a few more minutes.

Matt McMahon: I'll just chime in here for a second, Ashim. There's a few people who have been asking about whether they can get support through the various centers or hubs for their project, and the best way to know that is to first take a look and see if your institution is a part of one of these proof-of-concept centers or hubs. The easiest way to do that is to go to the website for the program that I just put in the chat, and in the navigation bar there's a tab called "centers or hubs," and if you go down there you can see those centers and hubs listed. And you can just take a look and see if there's one that you think is in your area, or close by to you, you can click on that one and see if your institution is a member of that center or hub. I see Ashim has tabbed back here, and you can see most of the partner institutions there. So those are the institutions where you can receive product development funding for your project, but one of the nice things about the centers and hubs is that many of the educational offerings that they have are online, or they're available to anyone. So if you're looking for guidance and support on entrepreneurship or early stage product development, a lot of these centers or hubs have online resources that could be helpful for you, even if you can't get money to do your project.

Ashim Subedee: Thank you, Matt. So someone asked how can you schedule a meeting or phone call to discuss further. Please send us an e-mail at SPIR@od. I can in fact just type in the chat box. Just send us a note and we'll make sure that someone is going to reach back out to you and schedule a call. Okay, I don't see any other questions, so thank you so much for tuning in. I'm glad that you're all able to join and I'm really hopeful that I was able to change the answer on some of those poll questions. So I hope that you all learned that NIH has a number of these proof-of-concept networks and hubs around the country that we're supporting. There are all these other product development programs and resources we support. NIH also supports small businesses to really develop the technology further, a billion dollar each year. NIH is not just about funding. We provided all these other entrepreneurship training and commercializing resources that you need to take your idea and build it into a product, and bring it to market and to patients. So please check out the websites that we talked about. If you have any questions, please reach back out and we're happy to answer any other questions and talk. Let me go to this right here. Definitely check out the upcoming sessions, from 2 o'clock to 2:45, From Bench to Boardroom. You will learn all about small business program in way more detail than I talked about. Beyond Funding: NIH Support for Innovators. You will learn about all of the support that we provide to innovators beyond just funding. Then from 4 o'clock to 4:45, Innovators in Action. You will hear from innovators like Jonathan who have leverage of the NIH resources and taken their ideas and built it into products to bring to market. Thank you again, and I hope you have a great rest of the meeting and a good day. Thank you.