NIH Resources Beyond the Proof of Concept Network

Session Transcript:
2021 Proof of Concept Network Annual Meeting: NIH Resources Beyond the Proof of Concept Network

Stephanie Fertig: Thank you, Kathleen. So it is great to be with you today on this last day of the conference, it's so -- I'm so glad to have some distinguished panelists with me today Dr. Amir and Dr. Kimberly Taylor.  I'll kick this off and turn it over so they can provide some of the other resources that are available in their institutes. We'll have plenty of time for questions. So give me one second I'm going to share my screen. Excellent. And hopefully, everyone can see the screen here. So it appears my video is a little off, it's okay you don't need to see me, what you do need to see is the screen. It seems I'm having a little bit of technical trouble here. Ashim can you hear me?

Ashim Subedee: Yes, I do hear you fine.  If you want to try not like -- turning the video off in the setting.  The screen is not showing anywhere.  Now we do see a bit.

Stephanie Fertig: Do you just see the slides?

Ashim Subedee: Yes.

Stephanie Fertig: Perfect. Okay. You know what, we're just going to go with that, we're not going to share video, as much as I'd love to be able to see you all.  (Laughter), have you guys virtually see me, I think this is the best bet.  So today I'm just going to briefly touch on some of the funding and support that small businesses can get through the NIH to support their small business as well as then pass it off to Amir and Kim to talk about some of the other programs that are available to innovators and companies at NIH. I would be remiss if I didn't talk about our new website.  We're going to be going through a large of -- our new website.  We're going to go through a lot of information, I won't go in-depth through each piece of information, I encourage you to visit other website for more information. We recently launched the seed.nih.gov website for the small business program. It has a -- seed.nih.gov website. Particularly for those who this may be the first time coming in and applying for the small business award.

In addition, as Eric Padmore mentioned yesterday, we had a recent, well, recent as of last spring, virtual conference that specifically focused on diverse perspectives seeding impactful innovations. This conference has a lot of material that's really focused on those individuals who may be again, new to the program, first time applicants, this provides step by step in-depth information on the grant application process including review, how to write a good Phase I or Phase 2 proposal.  We'll get to what that means.  That's seed.nih.gov/events, I encourage you to take a look at more information. More than I can touch on in the ten minutes we have in this day. So let's discuss the mission of NIH to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge. And really, the small business programs helps with this by taking those great innovations that are in the academic institutes help them get those innovations into the hands of the patients, the clinicians, the caregivers and researchers that need them. When we say small business programs, that's really the SBIR and the STTR programs. Together, it's about $1.2 billion of dedicated funding for small businesses. The SBIR and STTR are very similar, big difference is that while the SBIR program allows for partnering, the STTR requires partnering between small business and a U.S. research institution. One of the big myths that we do see is that because that STTR program budget is smaller than the SBIR, people are often hesitant to come in and submit an STTR. I would encourage you to really look at the STTR program if you look across NIH and again some institutes may vary, but if you look across NIH, the STTR program, many companies are very successful in getting funding from the STTR. And the size of the budget there, since we get so far fewer applications means that the success rate is looking across NIH.  So one of the myths I might do a little myth busting today, one of the myths I hear is that it's not coming into the STTR program. But I disagree. I think it is a really good option particularly for those individuals where it might be a good fit.  The NIH programs are one of the largest sources of early-stage capital for life sciences in the United States. And apart from the fact it's non-diluted capital, a lot of our awardees do leverage that funding to attract investors and partners. So, if you're looking at the little bottom timeline here, it's similar to what Ashim showed in the first day. Where, you have these research grants, this Proof of Concept Centers can really help connect those research grants with potential SBIR and STTRs with those companies and help them start on that journey again to get things into the hands of the individuals that need them. The SBIR and STTR program can help companies get to that inflection point to attract the investors and partners that are often required for marketing.

This is a very complicated slide and I'm not going to go into all of the details. But really what I wanted to emphasize here is that as long as these programs -- the small business programs are phased. These phases aren't clinical trial phases. The Phase 1 is a feasibility study. Phase 2 is full research and development. It's really important to note that one person's definition of a feasibility study is another person's full research and development. They are really broad terms. And so, there's a lot of flexibility there, we take a wide variety of modalities, and companies and projects that are in different stages. So, again, don't make assumptions if you take nothing else from this. Reach out and talk with us. We can help guide you and determine what's the best fit for your project and your company. We have a number of ways to get to that Phase 2 funding, standard Phase 1, Phase 2 fast track, which combines that Phase 1 and Phase 2 together, and then finally, a direct to Phase 2 which allows companies to skip over the Phase 1 if they've already done feasibility-style work and are ready to start that Phase 2. Regardless of how you get to Phase 2, however, we recognize that there may be more support that's necessary to get to that inflection point, get to that market or partner or investor. That's why we do have the Phase 2B, the second Phase 2 to help bridge that gap, as well as the specialization readiness pilot or CRP program. Now, it's important to note that not all institutes and centers participate in every program that you hear about and again, this is why it's so important to reach out and talk with us. I hope you take from this workshop that, and this conference, how approachable NIH is and we do really want you to come and speak with us.

The last thing I'm going to talk about on this slide is around the budgets. We do get a lot of questions about budgets. And I put the Small Business Administration guidance on here, however, we do have the ability to exceed these budgetary amounts for many topics. And we've got a specific waiver that allows us to do that. Again we do have flexibility. It is very institute and center dependent, but it's important to reach out and talk with us again if you have any questions. Our standard receipt date is coming up. The next one is in January. The majority of our funding the does go to investigator-initiated applications. We do have specific Funding Opportunity Announcements and I'm sure Amir and Kim will talk about those today. But, it's important to note that it's okay if you don't find the exact fit, because again, we do have those general what we call "omnibus" solicitations. I would also note that you want to take a look, this is a snapshot of our website here. We have a box specifically focused on those who are new to the SBIR and STTR process. And I put a snapshot here in the bottom left-hand corner. We now have, on the new website, the detailed step by step process on how to apply, to help applicants again through that process. Even if an individual has been part of the academic submission process, oftentimes they're doing that application in conjunction with their Grants Office.  Small businesses on the other hand in many ways play both the role of the principle investigator as well as having to do what the Grants Office does, and so, it can be very daunting for first time individuals. But that's okay, we're here to help walk you through the process, with this step by step guide as well as resources. An know visited form sets, grant application instructions, and sample applications. There's also an applicant assistance program for those applicants, and again this is something Eric mentioned yesterday, there's an applicant assistance program to help those who have never received an SBIR or STTR award from NIH submit an application. So, I encourage you to take a look at that program as well. Finally, most important piece of advice, talk to a program officer, I encourage you to do it at least a month before the application deadline. There's a list on our website of all the different program officers. There is a small business program manager at each of the different institutes and centers. I encourage you to reach out to them. If you're not sure who to talk to, that's okay, please contact the SEED office. We're happy to help you at SEEDinfo@NIH.gov, more than willing to help connect you with the right individual. I'm also tell you that oftentimes it takes persistence to get that first SBIR. I put a couple of quotes up here from some of our successful awardees. And, most of the individuals share that it can be very difficult and long to get that first application funded. But both of them found it was a very worthwhile journey and helped them improve the product and improve what they were able to do. I think both of them would agree, don't give up. And actually one quote was don't give up because of a depressing review, we encourage you to please resubmit.

I want to finally mention something about our new NIH SEED office and how we really recognized that it's not just the SBIR and STTR programs, it's not just that funding. But that we needed more than just funding to help support our applicants. The SEED office really supports the entire NIH innovator community. And, you all know Ashim very well, he's part of our office, but we also have support for those individuals who have received small business grants to help again get those companies through the process and get them to that hand off, get them to the point where they're getting that product onto the market.  Chris Sasiela is the individual who helps run our Innovator Support Team who really provides that help and guidance. We have a number of different programs, specifically focused for awardees. There's the technical and business assistance programs, different educational opportunities that you heard throughout the meeting, I-Corps, C3I, the commercial, regulatory consults as well as the company showcases. For this innovator support, that regulatory and business development consults we found are really critical and helpful for a lot of our companies who this may be the innovators first time the developing and bringing something to market. So, our innovators our regulatory and business consultants can help use their expertise to coach our innovators and companies and support them, and to help them present at different partnering and investing events. So providing that coaching and providing that mentoring, presenting at a company showcase is very different from presenting at a scientific meeting. Our office can also provide help to get those companies at those partnering and investment events. So, as I said, Chris Sasiela who is not only -- who not only runs our innovator support team but is also a regulatory and support, support regulatory expert, helping coordinate those efforts for us.

I see a question, I'm going to take it and answer it live. Is the innovator support specific to individuals who have received NIH funding and support? So that is specific to those individuals who are recipients of the SBIR or STTR program. With that, I'm going to -- I want to make sure that I leave plenty of time for my other co-panelists here.  But I encourage you to get connected with us. Speak with us. Reach out, talk with us if you have any questions, we're certainly here to help. With that, I'm going to turn it over to Dr. Amir Tamiz, hopefully he has better luck than I do with regards to the technical issues.

Amir Tamiz: Thanks Stephanie. I don't know if people can hear me or see me. But I am here. Stephanie, can you hear me?

Stephanie Fertig: I can hear you and I can see you, you're one better than I did.

Amir Tamiz: Awesome. So I'm back in the office, which is really really amazing. And I want to thank everybody for joining this panel today and obviously everybody who's helped us organize the meeting. So, just as a way of quick introduction, my name is Amir Tamiz. I'm the associate director at the National Institute of Neurological Disorders and Stroke.  And I head up the Division of Translational Research. So I'm going to try to parachute you into our institute and tell you more about what we do and the type of resources we have available for us for our translation, and specifically advancing therapies from discovery to clinical trials all the way to the Phase 2 type of trials that we routinely fund at NINDS. The mission is to seek fundamental knowledge about the brain and the nervous system and reduce the burden of neurological disorders. Fairly simple. But it's actually really complicated as you can imagine. We do things through funding. And we are on the extramural side, utilizing 90%, a little bit over $2 billion annual budget to do basic research, translational research and clinical research. Most of us focus on Phase 2 and Phase 1 clinical trials well we three scientific divisions listed on the cartoon, division of neuroscience, division of translational research, which I head up, and I'll tell you much more about, and the division of clinical research.

Stephanie Fertig: We're not getting any slides. I see you, but no slides. So maybe -- (Laughter).

Amir Tamiz: Let me show the slides. All right. Can you see them now?

Stephanie Fertig: Yes, we can see them now.

Amir Tamiz:  Awesome. All right. Thank you for the heads up Stephanie. NINDS actually uses about a quarter of the funds available within NIH to do neuroscience, it turns out that neuroscience actually gets a whole lot of money as part of the larger NIH, we do the work through a number of institutes, but NINDS is actually one of the institutes among 25 centers and institutes here at NIH. So the funding the way it's allocated is that, roughly 60%, unsolicited grants which would pie you with pay line. There are 20% of selected programs that includes the Phase 3 clinical trials and new investigators, supplements, and grants that we decide to pay outside of pay line. We have PARs and RFAs and clinical trial networks. We also have many activities like the BRAIN Initiative and the HEAL initiative, where there's actually congressional line for these type of activities we have a separate budget to do separate work. As Stephanie mentioned, with we a set aside fund for the SBIR program, and, roughly between SBIR and training, we spend about 10% of our budget to accomplish that goal. Roughly 25% of our total budget is available for compete quote on quote. So essentially we can fund to up about 25% of our budget with new money every year. And that's actually much higher for SBIR program. We have a lot of flexibility within SBIR, not only do we have the omnibus SBIR program announcement. We have actually been quite creative, and this credit goes a lot to Stephanie when she was actually here at NINDS leading up the SBIR program where we are actually using our SBIR dollars very wisely to fund cooperative agreements. And cooperative agreements are such that we are essentially partners with you, and, you get access to our resources in kind. I'll tell you much more about those resources. Next slide.

So, I promised to parachute in! Here it is. It's a pretty complex web of activities we do. I'm going to spend a few minutes on this slide, so I'm going to orient you a little bit better. On the left, pre-clinical readiness, proof of concept all the way to dissemination and implementation there are many more steps as you can imagine, taking you from left-hand side to the right-hand side. We have Proof of Concept studies, therapeutics development, clinical trial readiness. Then we have a benchmark for an IND or IDE that leads us to first in human clinical trials. We have additional funds available for Phase 1B and Proof of Concept Phase 2 clinical trials, preliminary efficacy trials and definitive efficacy trials. So demarcation for what you see in dark orange brown versus blue are the type of activities we do within our division, the Division of Translational Research. And in blue, the work that's been led by my colleague Clinton B. Wright, in the Division of Clinical Research. So I'll tell you a lot more about the efforts within our division before I jump into the clinical efforts. So, we have a number of activities to achieve our mission. At NINDS we are very mission-oriented. So we are trying to make sure that we advance discoveries and force clinical trials. And so, as part of this, we do have early preliminary type activities for pre-clinical studies that includes screening, Proof of Concept studies and model development. These are the applications that you can submit under the IGNITE program. We do have two pretty large, big resources that are provided for free for testing and animal studies and pre-clinical studies for epilepsy under ETSB and for pain for PSPP.

Once the Proof of Concept is in place and there is enough data to move into optimization studies, we do have demarcation from the type of modalities we use. I'll go through it one by one, the blueprint of the therapeutics network is to specialize in small molecules, this program is actually funded by Blueprint, which are 15 institute and centers that are really interested in brain CNS disorders at NIH. We do this on behalf of everyone. If you have any interest in diseases that perhaps are not covered within NINDS but perhaps are covered under other institutes that are interested in CNS disorders we still cover those, we can actually work through those grants for you. The biologics program it used to be called CREATE Bio, we sunsetted that program. Now we use a very similar infrastructure as Blueprint small molecules for Blueprint biologics. We just launched a brand new network to do gene based therapies for diseases called URGENT, there are two program announcements that were published just three-weeks ago. I encourage you to look at them very carefully. One is to do cooperative agreements were the funding can come to you and have access to our resources. And the other one is a XO 1 mechanism which we're fairly new to which essentially allows you to have free access to all of our resources without any funding. The review for XO 1 is a very quick review from a time that was submitted until the email that we receive is essentially instantaneous. We are doing the reviews internally in-house. Within very few weeks we can actually give you a go-no-go decision as to whether you can have access to our resources. And, that covers essentially all the modalities except devices.

Now for devices historically, we have a translation on your device program in NINDS. But as of last year we are also offering a MedTech program which is very similar program to Blueprint. It's funded by Blueprint institutes, and are really focused on initial discovery and YNS disorders. The bottom is small businesses, reach for small businesses, is much larger, it goes all the way from pre-clinical to phase two, we have a pretty extensive program. We also have a biomarker discovery and validation program. This is a fairly new effort for NINDS, it's a consolidated centralized effort. At NINDS we're really excited about, if you are interested in biomarkers, I really encourage you to look at our website. We have funding announcements for discovery, and we have funding announcement for validations. Retrospective studies of samples, identify and validate your analytical methods, prospective studies in patients actually get to some type of remember administration and qualification with the FDA.

So, I will go to next slide to describe the way we typically do our clinical trials. So we typically use networks systems for doing clinical trials. This is run out of our Division Clinical Research. So we already have our Clinical Centers and data centers in place. We have already identified clinical sites and a lot of this information is actually readily available on our website. So it's a ready to go turn-key type of program. We can do this for a number of efforts that are listed on this screen. But I just want to identify a couple of the advantages of coming to this system. People don't want to save half their resources, it allows them to get direct access, the data is pretty well established within our networks, and, it's a centralized IRB, which means once you have an IRB up and running, all of our sites can use them very quickly and we have a history of being able to get trials up and running very quickly and actually finishing trials which is quite important to all of us. We do also offer a platform program for stroke, and that's described within StrokeNet. And that's something that we launched just this year, and we're a quite excited about it. I do want to focus on the HEAL initiative, helping end addiction long-term. We have established a clinical network all across the U.S. to actually do, identify and study knowledge into pain medicines. If you have a interest in that area, Dr. Barbera Carp one of my colleagues within the division of clinical research is the contact person, and she will be more than happy to discuss any assets that you would like to study with an EpicNet. With that I would like to stop and I'll give the stage back to Stephanie. Thank you so much.

Stephanie Fertig: Thank you, Amir. So, Kim, I'm hoping you have better luck than I did. Kim you're on mute.

Kim Taylor: There's always a technical issue or button you need to push that you didn't push, (Laughter) so thanks for hanging in there. All right. So thanks so much for inviting me today, to the SEED program, the SEED program really appreciate the time of everyone, that we have today to hear more about NIAD's resources. Let me go ahead and share my slide deck. Let's see if this is working. All right. Are you able to see my screen?

Stephanie Fertig: I am.

Kim Taylor: Fantastic.  All right. So again, thank you so much for inviting me, appreciate everybody's time. Today I want to tell you a little bit about what we do at NIAID then talk about the various resources that we have. So, looking at Amir as slides I was impressed that you had a nice mission slide, I wish I had thrown one in there as well. But I think everyone's kind of well versed and seen NIAID in the mainstream these days. But our mission is really to conduct and support basic and applied research to better understand, treat, and ultimately treat infectious, immunologic and allergic diseases. We have a pretty broad scope. What I'll focus on today is more on infectious disease, because that's the division I come from, the Division of Microbiology and Infectious Diseases. So it's really product development oriented towards infectious disease. As you can see, here's the product development pathway from very early hit to lead, lead optimization, discovery of new products, all the way out to Phase 3 and registration. So we have a number of funding mechanisms that are currently available for this type of work. Many of you may already know about our grant mechanisms. So what I was going to focus on today was really what's highlighted in green, our preclinical services, clinical services and product development contracts, or omnibus BAAs. Then I'll talk a little bit about the concept acceleration program resources we have as well.

All right, so I'm going to kick this off with our NIAID preclinical services. These are a little different than grants and contract mechanisms. These services do not provide direct funding to the product developers, however, what they do is they provide a service to get them that really critical gap to link data to advance the candidate product. The deliverables would include data, reports, materials that would really help advance your candidate product. We have a wide variety of services, therapeutics, vaccines are highlighted here as well as we have some diagnostics within the therapeutics that are also standing up additional diagnostic resources and hope to get those online soon. So let me just run through, we have a lot on this slide that I did want to cover. This full suite of capabilities allows us again to address key gaps, it also helps with our outbreak response. So we have really leveraged these across the board for Ebola, Zika and SARS-2 and for the pandemic resource, I couldn't tell you how many requests have come in and we've leveraged these services across the board. One of the things you may -- one the things you may already know about is our DEI resources or the repository, this is a central repository that awe supplies organisms and agents to the broad scientific community of microbiology and infectious disease researchers. There's an online website you can go to with the catalog. You can peruse the inventory, then these are actually free materials to you. So, we have you know, thousands of items within that. We also have our preclinical models of infectious disease, which is shown there on the bottom, and this is really for the development and refinement of animal models and animal replacement technologies, such as organoid systems, and will provide that initial pre-clinical screening or testing data proof of concept data all the way through GLP. And more focuses on therapeutic testing.

As far as therapeutics, what we have there is in vitro assessment for antimicrobial activity. These services provide the capability a broad range of in vitro assessments to evaluate promising candidates for antimicrobial activity against a number of microbial pathogens, vectors, we can test clinical samples specimens from that as well. There's also the interventional agents, program, these services include lead identification and development of chemistry and manufacturing safety and talks, pharmacology KYNETIC’s preclinical development and also development of product development plans which is really popular with academics or you know, start-up industry that are really looking to layout a plan of how do I get my product from early on into Phase I.  We also have a number of services for bio-pharmaceutical products that supports biological therapeutics, for example, monoclonal antibiotics, common proteins, peptides nucleic acid-based acids, etc., so a ton of stuff there, supporting the testing and evaluation of these as well as manufacturing product release, regulatory CMC documentation support as well. Then also for the vaccine testing and manufacturing service we have a huge suite, that's actually the space that I'm working in. So we have leverage that tremendously well for the SARS-COVID-2 outbreaks for the nonclinical and clinical testing, nonclinical immunogeneity and efficacy studies, clinical and nonclinical sample testing and safety and TOX for the testing. Then manufacturing we have all the way from feasibility and gap analysis, product development plans, product optimization, development formulation product release, CDMP manufacture audits, regulatory. So it really spans the whole spectrum of how do I get into Phase I, I'll show you at the very end of the website, that will take you to the resources so you can look at the details.

Okay, so what do the services provide? So this is really key. These do not provide frequent funding but they provide a service to you with key deliverables to really move your product along and lower that risk for other developers to come in and partner or allow future funding opportunities. And, what we do at DMID is leverage our expertise and internal capabilities and product development. So we have a number of SMEs across the board, subject matter experts in preclinical, clinical manufacturing, regulatory, that span really the spectrum that can help you and that we pull into each project that we work on. We really work as a team with the product development to design studies and move things along. Again, this is gap filling. Also as part of these services in order to access them, we have agreements that are already established, templates that are provided to the product developers to kind of streamline the process of access and this covers you know, it's kind of like an MTA but with some additional confidentiality IP that allows you to get into that particular service.

So who is eligible for the support? So, really, it's product developers across the board, academic nonprofit industry, government, partners as well. Domestic or foreign, you don't need to already have a NIH grantor funding to access or request. It is a simplified process which is available year-round. Meaning you can come and talk to me or come and talk to another program officer with the DMID, within DMID about a project that you would like to do. Then work very closely to submit the request, and then we have an internal process that will go ahead and review and prioritize based on a number of items that are listed here on this slide. Okay. Now jumping over to our clinical services. Again, these are services provided to you. We have two different funding mechanisms. One is actually a network which is a grant mechanism. And one is a contract mechanism also a network. So this allows us flexibility for different types of clinical studies all focused around vaccine and therapeutics. You can see that we have a number of areas spanning from very early phase 0 all the way to Phase 3. I would say typically our bread and butter areas are these Phase 1 and early Phase 2 clinical trials. And again, what you would do is really work with all the program officers within the division, or one of the concept accelerators which I'll get to in a moment, to figure out how best to put in your request for this. Again, it gets reviewed by internal committees prior to moving on. And also for the IDCRC this actually has a external review board or scientific committee that it comes through. Okay.

So lastly, I just wanted to touch on the Concept Accelerator Program or what we call CAP. And, there are three of us, diagnostic, therapeutics and vaccines, I'm with on of the vaccine contacts, we talk to one of the product developers quite frequently. And then work on trying to figure out how can we access or how can we accelerate some of these technologies, get them that proof of concept data that they would really need to fill a gap or help them write a grant, or write a contract application to get them that opportunity for future funding? We also tap in to our regulatory colleagues as well as a lot of us are very well versed in industry for a a number of years and came to the NIH. We bring a depth of knowledge there as well. Okay.

One more thing I want to talk about today, was the NIAID omnibus broad agency announcement. So once you've established proof of concept with your technology platform, we have a funding opportunity that would really just kind of be soup to nuts from clinical all the way through Phase 1 is our typical contract to cover those activities. And what we do is we focus on the technology platform. So for example, for vaccines, enhancement of you know, what are the new technology platforms out there, as far as improvements on immunogeneity, stability and other aspects there. We also have, this has actually changed recently. It is focused on NIAID priority pathogens A-C it has been expanded to include infectious diseases. As you've seen with pandemic, recent outbreaks in Zika this list is becoming longer and longer. It is posted annually, typically it does come out in Q1, so keep your eyes out for that. The research areas that we focused on get tweaked a bit.  It always calls out vaccines, therapeutics, and diagnostics, however that topic gets refined, as to what pathogen is targeted and it might call out different technology platforms of interest. I've attached the links to the previous omnibus BAAs you can take that example from last year. One more slide here, I did want to post the website there for the resources for researchers for NIAID. When I clicked on it this morning it had a wealth of resources. What we can do and search for these preclinical searches, it's search for DMID and preclinical. You can run another search for just the clinical services, that will bring you up to the ones we spoke about today. Thank you very much for your time. Feel free to reach out to me or any of the other CAP folks on the line, thank you.

Stephanie Fertig: Excellent. Thank you so much.

Kim Taylor: Sure thing.

Stephanie Fertig: So, we have some time for questions, I do see a number of questions have come into the Q&A. I encourage you if you do have questions, please feel free to put your questions in the Q&A that is in the bottom of the Zoom here. One of the questions that I did receive that I wanted to make sure to address was about sharing those resources that are available to small businesses before they receive their first SBIR or STTR, and the great news here is that there are a number of things that you do have access to prior to the SBIR or STTR and I tried to touch on a couple of those in the presentation. Certainly our website has a wealth of resources, sample applications and information on the application process. The second thing that I the did touch on briefly was the applicant assistance program, and helping provide again for those who are new to the SBIR process, that applicant assistance program can help you through that first submission to guide you and get you to successfully submit. Then finally, I would really encourage you to contact NIH prior, well advance of that first, submitting that first proposing. Again, I hope you take from the meeting how much we're interested in helping and talking with you, answering questions, and helping guide you through that process. So again, I really encourage you to reach out to us, and as I said before, if you're not sure who to reach out to, that's okay. You can always send the SEED office an email at SEEDinfo@NIH.gov and we can help connect you.

Amir Tamiz: If I can add something too?

Stephanie Fertig: Absolutely I was going to segue into that anyway.

Amir Tamiz: I - your last point is of a desperate need for underlining. One of the most valuable resources that you have as grantees are actually are directors. They understand the scope of the programs that they run. They have written the program announcements. And they routinely have conversations with the PIs and actually adamantly are there during the the review of applications. And ultimately, make recommendations to IC directors and council for the funding. So a 15 minute call with a director describing your specific aims, making sure what you try to do is within the scope, making sure what you're proposing is within the mission of the given institute is going to be really critical and significantly improves the success rate for you. You'll be amazed how many calls a program director will take during a given day. And we have seen all sorts of modalities, all sorts of stages of development, and we do this for a living. So if you write up a one-pager describing a specific aim, just submitting it in through email, asking for a quick call, you would be amazed how much you can learn about how best to structure your program and how best to also organize your application.

Stephanie Fertig: That's a great point, Amir.  I was going to ask, one of my questions was, because both of you presented a number of different programs and I know I did, but what is the best way for people to really learn about the various resources and programs across NIH. What I'm hearing is contact the program officer. I don't know, Kim if you want to add anything?

Kim Taylor:  Yeah, I think that's the best way. If you're already working with the program officer, I would suggest reaching out to them first. If you're not sure who they are, for DMID, I would reach out to the CAP person, typically we're the first line of contact. And then we engage our various branches. So our pathogens are kind of split out into viruses, respiratory diseases, parasitic and then we have bacterial and fungal. So we have different branches that handle different types of pathogens. Our office actually works across the board with all of the offices. So, we know best how to direct your request. And then what we do is we form small teams within DMID to really work on your request, figure out, maybe a group will come in and request the toxicology study, then you realize oh you know what, you're really missing a key preclinical study, then we need to go back and do a NHPC study or do the tox, maybe this material wasn't quite ready for tox. Something else needs to be addressed within the engineering round or the manufacturing. We do really take a holistic approach. I think it's best to, if you're not sure who to speak to, go ahead contact one of the CAP offices. We're happy to direct and get these small teams together. One thing I did see a question in the chat, how much does it cost if we want to get those services at NIAID. The services are actually free into the product developers. The key is, you know, the product developers also have to supply the materials for testing. And, of course what we have agreements that are put in place that allows that and allows confidentiality and retaining the IP. What the deliverables are again are are the reports, the data, perhaps your request might even be for a manufacturing run, that we would provide the material back to you to run a clinical trial. So I hope that helps answer that question as well. That's great.

Stephanie Fertig:  That's great. I want to do a follow-up question. Amir you touched on it. What's the best information to have ready when you're contacting that program officer particularly that first time?

Amir Tamiz: Specific aims, I think those need to be pretty well fleshed out and having the conversation, sharing it with a program officer, having a conversation about them is going to be really critical. What I also look for is information about a team. Have you as an investigator thought about who needs to be on your team, what type of resources do you need from us and what type of resources do you have that you feel comfortable bringing to the table. With that information, I think our program officers are in a really good shape to figure out. They may not have manufacturing capabilities but does it match with something that we have to offer them. How do we make sure you're successful. That's ultimately my goal. You have to know how whether it's biology, chemistry or pharmacology, we can give you the resources that puts together synergy, puts together a holistic team that can look at everything to go forward. Translational research is really complicated. Even the best of teams do fall a part that's the reality of it. In our case we've tried to build as much resources as possible to make sure that we give it a good try. We can only do that if you feel like we're partners, and we are in it so that you are successful, that's the bottom line for us. Because if you're successful, we are successful.

Kim Taylor:  If I can just add on a bit more here about the process of engaging NIAID. So again, I mentioned feel feel free to reach out to me or one of the other CAP folks or a program officer, what we typically would do is schedule a very brief call first to find out what the request is. Similar to what Amir said, it's often very helpful to put a one-pager together with really what exactly you're requesting, and what's the justification for that.  And really, the stages of product development that you're at. And also, timelines help too a bit to know, is it an urgent need that needs to be filled right away? Is it somebody that's going to happen six months from now. I will tell you, it's better to engage DMID earlier rather than later so we know it's coming, so that we really prepare and help work with you to figure out the best path forward. You know, what services are most appropriate to respond to your request. They do get prioritized internally and, they also get prioritized by the branches as well. So not all of the requests go forward when many, many of them do. One more thing, after we have sort of the initial request flushed out. What we do is put a small team together and have the product developer come in and present say a 30-45 minute slide deck on their program. And then, allow enough time for Q&A and sort of next steps to refine that concept. And it's a bit of an iterative process. Especially if you haven't been through it for. It might take a few times to flush things out. Certainly a lot of back and forth emails as well.

Amir Tamiz: Yeah, actually, I'll give another sort of a tidbit of or a hint on how you be successful. So based on everything I've seen over the last nine years, eight years I've been here suggest that investigators that are really dedicated and really want to get the funding, typically do end up with the funding. It's not the first trial, definitely the first or second trial. You learn a lot about your program, your grantsmanship and your project if you actually go through the review one time. The second application is typically much better. The second application you actually get a chance to clarify some of the questions that were raised be I the reviewers the first time around. You've had a chance to sort of regroup and think about what you can do based on what your peers told you. So, it's a long process. We appreciate it. We want to make sure we can do this as fast as possible. But, I can assure you that the success rate for the second applications are actually quite high.

Stephanie Fertig: I could not -- that's a great point. I think that's something that needs a little bit more emphasis.  Particularly, I think this is true of all programs across the NIH, but this is also true in the SBIR/STTR program. We often find that it's that resubmission, does have a higher success rate and many of our companies find that the information they get from those reviews help them craft and hone their idea, hone that innovation so that it ends up being a much better product at the end. So, if you get that first review back, it's maybe not what you had hoped it would be.  I always encourage people look at it very carefully, but then reach out and talk to your program officer, program officers, this is part of what the program officers are here to help you do, is to better understand the review process and understand what your next best steps might be. So there is a question that I think is a really important one, which is, how can an academic innovator try to figure out what programs and resources are available at NIH that are relevant to them. It seems, the question was, NIH seems very large. How do we figure that out? And then another question that is related is okay, NIAID has free contract services but what about other institutes. So how would someone try to navigate that? What would you recommend to people as they're trying to figure out what their next best steps might be?

Kim Taylor: The broader NIH, I know the SEED program was thinking about putting together a list. I don't know if Ashim you can talk about that at all?  What's going on in that space, or maybe Arthur?

Ashim Subedee: I think one thing I would say is, the OER grants page, so any grants and contracts are all in one central place, a way for you to go and search for all the active grants. So definitely you can take advantage of that. In terms of the sort of the pre-clinical services kind of resources that Kim is talking about, a number of other institutes do have those kind of programs as well. It's a little tricky, there's no one place where you can go and find out information. And we understand, you know, the pain, NIH is definitely really large, it's 27 different institutes and centers, often times it can get quite tricky. We are trying to simplify it a little bit, like we're working towards that. Talking to your program officer, talking to the institutes is great. I know for NINDS, the difficulty, I'll let Amir speak to it, the translational program at NINDS is trying to make it better, they have a flowchart you try to answer some questions it will guide you to the right place. We hear this from a lot of folks out there who are trying to make it simple and easy and so, it's a work in progress. Hopefully, by the next meeting we can tell you hey, here's a place you can go and find out all that information.

Amir Tamiz:  Yeah, NINDS if you visit our website for translational research, I actually put the link in the chat, what you see is, in the blue box, it's a decision tree. So you essentially, it's an interactive decision tree, we'll ask you a couple of questions about what it is we're trying to do and present to you a couple of program announcements that would fit just at the very high level. And give you the contact information for the program officer who can then certainly direct you to perhaps not, if it's not even a fit for their program to someone else. We have a very small group at NINDS. We work very closely together. We're thinking very carefully about how much synergy and where the lines are in between these programs. And if you just get a good idea for where you fit in our institute and in our sort of global picture as I depicted in my cartoon in any talk, we'll find you a home. We feel pretty strongly that we've covered all the bases. If there are gaps, we can always try to figure out how best to answer them. We have a history of partnering with other institutes also. If there are things that perhaps we don't offer but perhaps some other institute offers, we'll work behind the scenes to make sure that you get the resources you need.

Stephanie Fertig: I want to second that, and that's not just true of NINDS, I think that's true across the NIH, we're a large organization, we all work very closely together. When I was a program officer at NINDS, I see this with other processes across NIH, if you approach this, they're not the right person, we'll get you to the appropriate individual, to get you to the appropriate institute and get connected with the program that are available around your scientific research area.  And so, we are again, this is why reaching out can be so helpful, it's so important because it can help guide the next best steps. I do see a number of questions around the resubmissions and how to resubmit, what that looks like. And, specifically the question that was raised was, how to deal with inconsistent reviews, what you do when you get a review.  I can answer this one pretty easy. That's contact your program officer. Program officers have a lot of experience reading those summary statements. I know I've read my fair share and time. We can again, program officers can really help guide you on what the next best step would be.  I would encourage regardless of what you decide to do with getting that summary statement, take some time to read that summary statement. Look at your application, make the appropriate adjustments. I do know for some of our small business grantees in particular, we try to turn that over as quickly as possible. It is really important to make sure that you've addressed the comments in your resubmission. That helps you be successful. That helps you get to that point that Amir was talking act where you get that successful next score.

One of the questions that was raised that I think it would be helpful to know is thinking about how do you see the individuals utilize your programs, how are you able to leverage the resources and move the product forward. Having the NIH support, supporting product development, how are these programs leveraged. What kind of successes have you seen?  I like to end on successes. (Laughter)

Kim Taylor: To give an example of one of the Ebola vaccines that's now approved from the EMEA that initial proof of concept study that was initially done through NIAID preclinical services, we took one component in another, did a heterologuos prime boost to show it works.  At the time we had a contract with one of the product developers, both of them. We were able the get them to partner together, and they were able to get future funding opportunities and within our clinical program, and within our sister organization where we typically pass product development through a lot of the bio-defense pathogens or BARDA, now it's a licensed product. So that's just one of many that we talk about. So, Amir, I don't know if you wanted to add anything?

Amir Tamiz: I don't want to be really product-specific. But we have been compiling many of our success stories and I've been tracing back how programs received funding and investigators navigated through the funding mechanisms to go from initial concept discovery to development. That's actually readily available on our website. I encourage you to look at that. I think, there is no one PI that got funding and went all the way to commercialization. I can think of a few of them actually. But they're not that many. The majority of them have navigated very carefully through the initial preclinical studies, and that got another grant to do perhaps optimization, manufacturing, and then even got additional grants to do clinical trials. At least the early clinical trials before they either partner up with a bigger industry partner, or exit the company. So, a lot of this is actually listed. It will also give you a good flavor of the type of path that you can go through at NINDS.

Kim Taylor: I will say NIAID also does something that's very similar, the NIAID impacts, I think it's called, which also tracks from you know, how it got the original funding in some cases, outline the services or from services it got passed over to another grant mechanism, it went to a contract.  So, these product developers were able to really navigate through all of this. I think one of the keys was really working very closely with the program officers to understand what opportunities are going to be best suited for them to apply to.

Stephanie Fertig: And that I think is a great message to end on with this idea that it really is a journey. The development, product development isn't just one grant, or one award, it's often being able to pull together the multiple resources that are available across NIH both those that are focused on the support of the research and development as well as those for companies that are supported on that business development component which is equally as important and really bringing together all of those different programs and helping bring some of these great innovations that we're supporting at NIH and getting them into the hands of those individuals that need them. So, I want to thank both of you again. Wonderful to have you speak and talk about some of the fantastic programs that are happening at NIH. With that, I believe we are on a break until 1:30.  You can correct me if I'm wrong.

Ashim Subedee: Yes.

Stephanie Fertig: Thank you.