

Demonstrating the Impact of the NIH Proof of Concept Network

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Session Transcript:

>>Alan O'Connor: Hi! Good afternoon, or good morning everybody depending upon where you are. Alan O'Connor here from RTI. For those of you who do not know me, I'm an economist, and an evaluator based at RTI International in North Carolina. I've been working with the SEED office now for a few years and before that also NHLBI Providing Broad Overview and Evaluation Analysis and Assessment of accelerator programs, and one of the highlights of my year is usually being able to come to this meeting and talk, to you all about what we're seeing from the Proof of Concept network in terms of outcomes and results. I'm particularly excited this year because there's some great news to be sharing about products reaching patients as well, as some significant funding milestones, and the like, so let's dive into it. So, as you all know I mean, it's been I guess this is my seventh or maybe my seventh Proof of Concept network program meeting where I've just kind of highlighted some of the key outcomes and findings.

So, but I must remember that not everyone attends, each meeting. So, if for those of you who have been around for a while, just bear with me, as I bring our new newer colleagues up to speed on the programs, so that they're situated as we kind of start talking through the overall results that we're seeing today, so one reminder is obviously that the commercialization outcomes that we're going to cover today, relate to 3 programs so that's the NIH Centers for accelerated, Innovations, there were Research, Evaluation Commercialization, Hubs, both the 2015 and the 2019 cohorts part of the booker, NIH, Proof of Concept, network ecosystem or the NIGMS regional, tech transfer hubs, but those hubs largely focused on Entrepreneurship, Education Training, and Assistance, Programs, they're not necessarily focused necessarily focused on broader technology, development, and so although they've had a small number of pilot projects.

Largely, this program has really been around capacity building education and resource development. So, when while we recognize that they are in fact, part of the broader ecosystem, for NIH, we're really going to just focus in on NCAL and REACH today. So, for those of you who are kind of new to the NIH, Proof of Concept, model. I just want to take a minute here, just to overview some of the basics. Okay, so the overall premise is that we want to do several things. One, we want to de-risk, our you know, public investment in basic science, research, try to encourage, the promotion of entrepreneurship, or translation such that the good Science, and the discoveries, that results, from those science, kind of start moving towards the patient through the early stages of transition and commercialization.

We also want to build capacity and support to kind of ensure that there's comfort and knowledge, amongst innovators, in what the processes of research, translation, and academic entrepreneurship, are and then we want to try to seed, our SBIR STTR programs,. Prompting, startups and promising projects to really maximize the value that we're getting out of the substantial investment that we put into the small business programs in general. So how are we doing that so the NIH Proof of Concept models relatively straightforward. The concept is to surround an innovator with obviously funding for early-stage product development and concept validation. But also with that project management expertise, that's there to coach, that innovator through the early stages of how do I come up with my milestones? How do I develop my research, plan to help continue to add value to the technology? and also, like expert feedback, both from external review panels, largely composed from Industry, but then also from different subject matter experts, across the federal ecosystem, such that the Innovator, as they're going, into their technology development, project, they have a lot more information about what are the different pieces, of feedback, that different stakeholders in the medical product development ecosystem think about their product.

What are the things they need to be thinking about? What are the things they need to be cautious about so, this kind of idea of like having expert feedback through the review process and coaching around applicationsHow does one pursue itEarly-stage Proof of Concept funding is really a critical program component, the last piece is around education and training. So, this is providing skills, development webinars, other sorts of resources that build capacity in that innovator, whether or not their technologies, development project is ultimately funded and the idea, here, is that even if your technology, may not be selected you still have access to those training, resources you have benefited from these programs and your knowledge about the process of research transition the process of commercialization is more robust than it was before. One of the key things that we've noticed in fact, is that coaching the applicants at the early stages of approaching a Proof of Concepts program that is really like a significant value add to that innovator because they learn, so much about the commercialization process, that in their mind we have survey data that says hey this demystifies, this process to me. Okay, so the idea here, just in sum is that we have a Proof of Concept Center, where we're combining funding project management, mentorship and skills development surrounding that promising technology and helping it move forward in the translational pipeline one of the other things, is that not all projects will be successful. So, this is a great way through this this program. To, figure out well.hey? You know what from a social perspective, this technology had great promise.

But maybe it's not going to fit and so this is an or like a fast, approach. Conversely, this is a great technology, that and otherwise may never have made it into the commercialization pipeline. Well, this is the product, this is the type of program that can help the municipal that process for that innovator such that we get that promising discovery into that translational process on my slides here which will be available after this talk, I do have a link to a paper that kind of summarizes, some of the high-level observations that I'll review today, and has other information, about some of the product of the projects and other Successes, at our great

centers and hubs, around the country have facilitated. So, that's the NIH Centers for accelerated innovations, or the NCAI. This was a program that was launched in 2013.

There are 3 sites around the country, each have at least 5 institutions.

There's the Boston Biomedical Innovation Center, largely led out of the partners network, including the Brigham Women's Hospital, but also including institutions in Maine, and in Rhode Island. We also have the University of California center for accelerated, Innovation which would be UC Davis, San Francisco, UC Irvine, UCLA, UC San Diego, so it's a California ecosystem. Then we have the NIH, Center for Accelerated Innovations, at the Cleveland Clinic not just the Cleveland Clinic, but also 5 or 6 other institutions in Ohio, Michigan and Illinois, that were a part of that network.

The REACH cohort covers more states, so there are 2 cohorts, the 2015 Cohort includes the University of Louisville, University of Minnesota and then the Long Island Bioscience Hub Based Out of Stony Brook University. The REACH 2019, Cohort, consists of KENETIC, which is largely all the public institutions of higher Education in Kentucky, also University of Colorado, Spark at the Anchor's Medical Campus, as well as the University of Colorado Denver.

The Midwestern Biomedical Accelerator, Consortium, which is a group of multiple institutions, led by the University of Missouri and Kansas, University Medical Center and covers essentially all the planes states, and then there is also the Rutgers, Optimizes Innovation, or ROI out of a Rutgers, University and then WE-REACH which is the University of Washington and its ecosystems. So, these are the 8 reach sites, I would just kind of note that there's a current RFA that's Active for the 2023 Reach Cohort and I'm sure that people, might be interested, in knowing, that their upcoming, webinars next week to review.

That particular RFA and information and we found on the NIH website one of the big differences between NCAI and Reach. One was that the NCAI program largely ran from 2013, to 2020 REACH 2015, largely ended in 2021 and REACH 2019 is still ongoing in addition to it like a generally a longer period of performance for the NCAI Program, it really focused in on the heart lung, blood sleep, space, whereas the reach cohorts are really Pan NIH mission, So although there are some there are still some Cardiovascular technologies funded Out of REACH, a lot of the kind, of core heart, lung, blood, sleep technologies were largely with the NCAI program within the data that we're presenting today. So, let's talk a little bit about NCAI and REACH. The Portfolio composition overall after I talk a little bit about the portfolio, we'll Start Segway and into some of the Information that we're Seeing for outcomes and some of the high-level takeaways and observations for me in terms of progress today. So, there are just over 400 projects that have been funded, historically, they these projects were with the NCAI, but we're seeing more and more of the broader portfolio, being combined of projects, from the REACH sites largely because of the that, they continue, there are more sites, that obviously that are expected for 2023, and there are a larger number of institutions. So overall, right now we're at about 220 or 227 REACH Projects compared to about 190 from NCAI. In terms of overall distribution, some of this information is going to look like what I had last year. But the big, the big thing that I would note here is that REACH 2019, is continuing to fund projects. They are now at 100 projects across the 5 sites within the REACH 2019 network

In terms of the distribution of projects by technology type largely, we're seeing that there's you know, a similar portfolio composition, by different types of technology although one could say well, there's more diagnostics, in REACH and which is true I mean really in the grand scheme of things, these portfolio compositions, except for therapeutic Devices, and biological, drugs, more or less, one another so that's the portfolio composition in general.

So now let's segue and start talking about what we're seeing, for commercialization, outcomes. The first thing that I would note is that we're at about for those 420, or 400, and 17 Projects, were about 100, and 21 startups when looking across that startup, activity, there are 85 jobs, beyond the principle of the startup companies. There are 85 jobs that have been created with those small companies not surprising here given that you know early-stage companies usually have only just one or 2 employees. The interesting thing for us is that one of the big rationales for funding the REACH program in particular was to cultivate, more robust pipelines of SBIR and STTR Applications within these particular ecosystems, largely idea states, when we look back at the overall, composition of the startup portfolio, as well, as where they are with STTR, SBIR applications in awards we see that 64 of the startups have SBIR awards, we also see, that a 55 additional startups have applied for either. They weren't successful in their efforts, or they have applications that are outstanding as an economist, one of the things, I think a lot about is innovation speed.

When I look at data from other Proof of Concept networks or other programs. I say well, you know what our time to milestone is, like if I if I were an investor in this program, I'd want to know well how long I need to wait till I start seeing some activity. What's you know what does that return look like to me? Well, by looking at the all the data that we have to date. We've noticed that if a project is or excuse me, if a startup is going to emerge from a particular technology, development project we see that within about a year, and a half the median, the median, time to the startup is about a year and a half so that helps us, calibrate our expectations, right about what we would expect to see for those of you who have been around for a long time one of the challenges that we face was kind of benchmarking program performance because there's no data out, there. So, part of what we've been doing as a broader network is creating the data so we know what these performance measures are so it's nice to see performance measures such as this start to emerge, because this is what we can use to start thinking about the next program in the same domain area. So here's the basic information about our SBIR, an STTR applications, and awards. One thing, that I would note is that a success rate of about 35, so 63, STTR awards out, of a 180 applications, whose disposition we know. That's 35. So that's about double what the national average is. So it suggests that the technologies or the applications that are being submitted for SBIR are STTR funding are more robust, so they have more data they have more information perhaps they have more, detail about what the Research aims are or the commercialization fit or approach so I think we need to really be thinking about the success and the significance of these programs in helping to build a more robust SBIR and STTR success rate and pipeline.

Why is that important we program is a phase 0 program designed specifically to accomplish this, and so this suggests that the Phase 0 concept is successful in its endeavors to build that pipeline. Who are licenses and options? We have 14 projects that have been licensed to small companies, some of those small companies themselves go on to get SBIR, an STTR or awards. So, I think when we're looking at our total of 19 license technologies, it's interesting to note that there are small businesses that are licensing that technology, it's not necessarily a startup associated with the project but rather another small Business that said hey, you know this is something interesting. I will see, if I can further develop that technology add value and bring it closer to the market in terms, of overall cumulative, follow-on funding, we crossed a major milestone, this year we're at 2 billion dollars in follow-on funding overall last year we were flirting, with the 2 billion dollar mark, this year, we crossed it. What I would, note, when I look at this pattern on the on the screen. Here is that we're seeing a relatively consistent stepwise pattern.

We know that you know commercialization exits is they're lumpy don't expect a smooth curve that's not how markets work, particularly in early-stage technology, development so this stepwise pattern is what one would expect for a particular program such as this for those of you who are new also I would just highlight that we've had a couple of really significant events, for technologies, that resulted in the most significant steps from 2017 to 18 and then again, from 2020 to 2021 but if you were even when we take those data, out which I will, do in a couple of slides, we're still seeing broad follow-on funding success across support, portfolio, this past year, we had 6, private sector, investments of more than 1 million dollars. If you add in federal investments it goes up, to 12 at that same magnitude. Likewise We had 30 Private Sector, investments of less than 1 billion dollars, and if you were add, in a public sector, sources that number would go to 55. So, we're seeing it's not just a couple of projects that are achieving these types of funding milestones. It's a fair, a significant proportion of the overall portfolio. So, here's a little bit of information about the distribution of following funding my funding source. You know, I just gave you a preview. That's really a couple of those big investments that are sitting in the strategic partnership pool. So, I mean it's just a huge driver.

What I would note is that about 80% of all the follow-on funding is non-federal so that's coming from source system such as venture capital, angel investment, one IPO you know a prize and other sources. Here's, that same picture, without the outsize investments from a couple of strategic partners, and here you can see that really venture capital tends to be one of the most significant can sources of funding. I believe we have a couple of firms that in our portfolio that have gone through their B rounds. So were really seeing you know, great progress in terms of the attraction of capital to these, these technologies couple of highlights, just to share a little bit more about the follow-on funding. You know, we've heard from a couple people yesterday, so yesterday. Dr. Lyons talked about her experience. We also have other kind of notable is coming from MBArC with Dr. Lefield, having received a significant amount of venture capital from a variety of different sources for eclipse, for clinical testing of the Fasted Tech point of care, qPCR. System, so in addition, we are continuing to see, even though the program has largely has sunset we're continuing to see outcomes associated with the NCAL program. Here, I, highlighted Dr. Lawrence's Recent funding for a small molecule, therapeutic for treatment of

Idiopathic Pulmonary Fibrosis. So, one of the things that we do like to talk about is what are we seeing for technology, progression, we're talking about an accelerator, program, and so if we're going to be using that term that concept then we would expect to see that the technologies that we support would have fairly significant progress in terms of their time to milestones, or in terms of their overall technical progression.

So, one of the things that we did this year, was we looked at our technology readiness levels, and technology readiness levels are just a useful benchmark from which to gauge where technology, is in terms of what's, maturation at any given point in the commercialization process there, you know, there are a lot of gray areas that come with assigning TRLs, but on the flip side this process is useful for understanding relative progress. I'm putting up, on screen, here what the TRL levels, are going all the way, from reviewing of the basic scientific knowledgebase going down through product development and post licensure.

I think that you know the focus on the TRLs is less important than knowing that proceeding to each individual TRL itself is non-trivial in fact some of our Proof of Concept projects really focus on getting just a particular technology from one TRL, to the next and that can be the whole purpose of the process. So, what we've seen across the portfolio is that you know they're out of 420 some odd projects. You know, we have roughly, a 100, just over 130 that have advanced at least one TRL, all the way down to a handful of projects that have advanced you know 6 TRLs, now why, is this significant the timeframe with which this product with the which these projects have been funded is from 2014, to present what we know from the literature is that for what most academic projects, typical timelines to market is closer to 17 years.

What we're seeing now are rapid progress from early-stage products.

Early-stage projects to the market in less than 8 years. So right now, today there are 8 products, on the market, and there's another 11 that are at some stage of clinical testing, so we have 4 that have received regulatory clearances, we have 4 that are not in the market but didn't require regulatory approval, such as the first responder Toolkit, from Dr. Mendenhall, at the University of Minnesota, Minnesota, so you know, really, since 2014 to 2,000, and 2008, products on the market, that's a Phenomenal Rate of Progress 8 years from TRL 2 to something that's available that is just unheard of from you know, from my perspective, as someone who's studied academic innovation programs and Proof of Concept Centers around the country.

Here are some of the high level, like summary outcomes that I wanted to make sure that everybody had a chance to see so again. We're at 63, SBIR STTR awards. We're at about 187 SBIR Applications, 120 startups and over 2 billion dollars and total follow-on funding being secured. So, you know, what can we learn from this? I think the first thing that I want to kind of emphasize is that you know new products to help patients in about 8 years, instead, of 10 if you know typical industry, timelines, are often you know they'll say 8 to 10 you know, sometimes it's 5, to 7, if it's like a device, or a diagnostic, but from an academic setting, going to regulatory approval and 8 Years or less not 10 to 17. That's, a really profound rate, of progress and something that we would not otherwise expect so that is certainly probably the number.

One thing, that we should be paying attention to is because about helping people getting those promising discussions to improve patient health the other thing that's an interesting signal to me is that for every \$1 in NIH, investment there's about \$24 in private sector following on funding. So, if I were like in the angel space, or the venture, space I'd be like that's not bad that's like double my expectations, so that's significant overall, the other thing that I would note is just a 121 startups with like the robust, SBIR, STTR, and Pipeline.

I would imagine that next year we're going to see another significant number of new SBIR applications, or awards. probably you know the past is holds true. It's going to be somewhere between. You know, maybe 20 to 30 new applications will emerge. The success rate is about double the national average. So now, national average is roughly, like 18%, like 16 to 18%. And what we're seeing from this program is 35%. I would also note that we have 3,000 innovators that have been trained in academic entrepreneurship, and the last thing that I want to highlight that we didn't spend that much time talking through, but we have technology, advances, and funding successes, that are happening outside of the Boston and California gravity wells, you know, color commentary, but a lot of our historical Success, yes, the Boston Biomimicry Innovation Center, or B-BIC has been Phenomenally, Successful but also has the NCAI, the Cleveland Clinic in the Midwestern institutions that are part of that Hub, We're also seeing outstanding success across reach 2015 in 2019 which included in system, from across the prairies, or in America, across the plains, as well, as you know other institutions, that are outside of the typical corridors, and it's really showing that that these technologies, or these institutions, have a lot of promising, technology that is worthy of investment and it's also saying that these programs have help to build the capacity and provide the resources to those stakeholders in those ecosystems to provide the resources skills and training, that they're innovators need to kind of help overcome the fact that they're outside of the gravity well, ecosystems, of say you know San Francisco, or Boston.

I'm, going to stop my remarks here and take any questions, from the audience, but before I do, I want to say, thank you to the RTI team for all their hard work, on data Collection and analysis. I also want to thank the sites themselves, from across the NCAI, REACH 2015 and 2019. It's a lot of work to keep track of what's going on with our projects, with the innovators, and it takes us takes a team to get this happening. We have the sites, working with innovators. We have. RTI, also connecting with innovators, but also doing independent validation work. So, it really takes a village. So, I just want to thank everybody for all the hard work that they put into getting this data and yeah, it's really been a pleasure and a joy. To work with you all. So, I will take questions. Okay, I am, look going to start with I thought so.

Ethel Rubin: does RTI collect data on the jobs created?

Yes, we do. We do collect information on the jobs that are created we don't collect information that on quote, unquote sweat equity. We usually associate the innovator with the startup. So, the interface sweat equity is kind of baked in but we're really looking for net new hopefully, that answers your question at all.

Okay, next, okay, so we have a question for Doug Kelly. Do you know what the total combined revenues and earnings are the projects that have or excuse me of the products that have gone through the program? Investment is an interesting proxy for success, but earnings is the true interesting number of public health impact I would say yes, and no Doug. You know, for me, I think about it in 2 ways, like, yes, earnings, and returns per from a financial perspective, absolutely I think, I'm particularly keen on what are the public health, impacts, so we have Information about you know, what's the prevalence of disease in April conditions, and then to what extent are the medical interventions, I'm improving quality of life, and changing health outcomes, I think that's probably the number one. Next Year of Interest to me as an economist, so I would say that both of those are particularly important because in order to get a product, to that in our current system in order to get to that product where it's helping the patient where there really needs to be a return, so I'd be looking at those 2 particular metrics in parallel to help strike or develop some of opinion, about the broader, financial and public health impact of those technologies. That's a good question as the REACH program increased SBIR STTR grants from the idea states.

Yes, we're noticing, that we're seeing a good number of applications from the idea states. There will be more information on that that I can share after I didn't put it into my slide but we're we are seeing a slight habitat in the number of applications to those sites or excuse me to those states the choices that we face sometimes is that we know that applications to programs, such as SBIR and STTR, can be lumpy in general, so trying to really determine or trying to make a statistical inference on the pattern and the Impact of the program, on the pattern of applications, is still a little bit, challenging. Yet we need a little more time and more applications from these states in order to make such an assessment but in general my spidey sense would tell me yeah, we're seeing we're seeing more applications than we would otherwise have expected because we've interviewed those innovators and we know, where they were coming from and what they're alternatives were, and so that gives us from a qualitative perspective, some sense that there's, an influence

How to get training in academic entrepreneurship that's a great question.

I don't know in which state you're located, but the first thing that I would do is I would check to see if I have a state S and T Office and see if there's an entrepreneurship assistance program. There are navigators available from the Small Business Administration, most of the State Science and Technology Offices, will have Information on entrepreneurship support available you can go to the SEED Website, which will have, you know, a link to resources there and quite frankly, one of the best things that you can do, if you want to learn is to just go to YouTube, and just find a good program such as you could go to NHLBI's, catalyzed program, they have a YouTube playlist, and just you know read or choose we just watch those videos, learn about everything from held economics, to reimbursement to regulatory, to you know, what are the early stages of intellectual property, development, there's a lot of really great resources that have been curated by the SEED office, by other Niagara Falls that you can access that will provide some useful support, so good question.

Yes, from our colleague, Julia, she's saying, yes, check their different REACH centers, websites for available webinars, and courses, many of those programs, are available the recordings, are available free of charge, and you can also subscribe to the various newsletters from the v. from a. Different I see a particular interest to you, because those, I see part of their small businesses, office, they're a small business office, mission is to provide information on resources, to help build your knowledge base in commercialization so I would certainly check those small business, offices, as well, as the sites, the websites, for various programs, good question The best organization to encourage resort researchers. There must be some reason, as we have no biomarkers or cancer totally in Psafor prostate, and Ca 1, 25, for varying cancer. I think this is more of like a scientific policy and Funding Policy, question That I would recommend to the Cognizant Institute of or Center.

If this if your question relates to promotion, or encouragement of entrepreneurship for translation of a basic science discovery into such biomarkers and the like I then I Would Check the Small Business Office for the Cognizant or Institute or Center, within, the at NIH.

Other Questions? Alright great well, I think. Why, don't we check the chat. Alright! so why don't we hand things back over to our friends at Deloitte, who are doing a great job moderating our session today, and I believe we next up is another session. Or a short, break, so let's let them advise us.