Product Development at the NIH – Introduction to the Proof of Concept Network

Session Transcript:
2021 Proof of Concept Network Annual Meeting: Product Development at the NIH – Introduction to the Proof of Concept Network

>> Matt McMahon: Thank you so much, Ashim for the introduction. We're really excited to have everybody here today at this meeting. This meeting is really a combination of many of our oldest friends from the very beginning of this proof of concept experiment, and many newcomers inside of the government, outside of the government, across the academic innovation space. So, we're really excited to make sure to share all this information with people and really help you to understand how we're stimulating the academic innovation system. And I start with this slide, because I really, I really would like to point out that it's really about turning discovery into health. The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems, but also to apply that knowledge to enhance health, length of life and reduce illness and disability. I'm going to start by giving a little historical perspective and also, try to weave into that gratitude and recognition for some of the people who have made this network possible. But behind every name that I'm going to mention there's usually a whole supporting cast behind that person who really makes it all possible. So, let's jump right in here.

So we can start with a little walk down memory lane. So this NIH journey really started at the National Heart, Lung, and Blood Institute. And it started because NHLBI was trying to squeeze more strategic benefit out of their small business programs, the SBIR and STTR programs. Also advance more of the cutting edge science that they were funding out of the lab and actually try to move that closer to patients. So they convened an outside group of experts from a broad range of stakeholder communities. This was back in 2010. So, I pulled out some slides from the historical archive here and you can see some of the names and some of the people that were involved in these initial discussions. And this slide, which also is from back in that time, really lays out the challenge that that group was trying to solve. You can see this bridge right here that's connecting basic research and discovery with validation pre-clinical development and R&D companies. And that bridge was designed to try to compensate for the fact that NIH was funding lots of R01 and basic science research. But there was a gap between that research and the funding and the support that was available through the small business program.

You can see down below some of the NIH programs that were in existence at the time. And you can see with this red arrow here where this program is designed to sit. So this is back in 2010-2012. So, so it's kind of interesting to take a look at the goals here that were laid out to educate an academic workforce, to enhance multi-stakeholder partnerships. Develop collaborative transfer relationships and develop adoptable best practices. So, in the next few days, we can reflect on these goals and we can try and have a discussion about what things are working well, where there are gaps and spaces where we need to fill things in, and how can we work together to advance science toward a patient.

So, what is the NIH Proof of Concept Network? What really defines the NIH Proof of Concept Network. What Proof of Concept Network is, it's three collaborative programs that have shared goals and common elements. And those three programs are the NIH Centers for Accelerated Innovation, the research evaluation and commercialization Hubs, and the idea, state, regional technology transfer accelerator Hubs. I'll talk about each of them and the history going forward. Some of the common elements that exist between those programs are funding for product validation studies, Ashim talked about that. He talked about training and resources. Industry style milestone driven project management, which is really quite different from the style of academic research that most investigators are used to. And personalized feedback and assistance to help people really develop those projects and turn a science project into a product development project.

So I'm going to start out with a little description of the NCAI program that was launched in 2013. But I want to say from the beginning, it's really important to note that every NIH dollar is precious. There's tremendous internal competition for resources. So, every new program really requires an internal champion to just relentlessly advocate and evangelize for the funding of resources that are necessary to make it happen. In this case, the early stage, Jodi black played a pioneering role in not only convening these working groups, but really implementing the vision of these working groups. And that implementation was really put if place in September of 2013, when NHLBI through a joint seven year commitment of $42 million by NHLBI and $23 of matching funding from non-federal partners stood up these initial three NCAI centers. And you can see here on this map, the three centers that were in Boston, Boston Biomedical Innovation Center, the Cleveland Center for Accelerated Innovation, and the California NCAI center, which was a collaboration of all of the UC medical schools. In total, it was 28 institutions and seven states. So, this really was a true collaboration between NIH and these sites. It was not really the usual kind of hands off leadership style that you usually see in a NIH program. The centers and the NIH staff really work very closely together to develop processes and procedures and ways of starting up this program in a real way. I want to acknowledge the PIs of those first NCI programs, Mike from California, I think he's on the life. Jeff Vince from Cleveland, and Joe Loscalzo from Boston, not just them but their staff. It really was not easy in the early days. I give a lot of credit to those centers because, we worked out a lot of issues and iterative ways to strength the program very early on. I also want to mention Kathleen Rousche, the original program office through the NCAI program. Also the Deloitte team who's provided support for our Proof of Concept Network from the very beginning.

So, moving along from there, oh, I see, I'm going to keep one eye on the Q&A in the chat and while I'm doing my presentation, I zoo he a question. Are these Centers for Accelerated Innovation applicable to certain agencies are the NIH, or for all of them across the board? So this particular program, the NCAI, was funded by the heart, lung, and blood institute. So it supported only technologies in the NHLBI mission space, that's heart, lung, blood Insititute. So in this next iteration partly based on the success of NCAI in appreciation for what we were trying to do, Congress authorized NIH to use STTR funding small business program funding to assist this pilot. And some of that money was originally available to supplement the NCAI program, but that authorization allowed us to launch three more Hubs in 2015, there were search evaluation commercialization Hubs. Those Hubs support projects across the entire NIH mission space. And another, a few special recognitions here, it's important to understand that this congressional authorization was very important to facilitating the funding that was necessary to establish these programs and Dan Lipinski, a House representatives member from Illinois was one of the critical people in really pushing this authorization forward. So there were three Hubs, six institutions across three states. You can see them listed here in this graph, in this figure. I also want to call out here Kurt Marek, who was the initial program officer for the REACH program. So at this point, we were now developing a collaborative partnership between the three NCAI centers and the three Hubs that were the three REACH Hubs that were formed in 2015. Now let's jump ahead a little bit.

In 2018, the National Institute of General Medical Sciences in an effort to really commit to geographical diversity and entrepreneurial education formed a program called the idea state Regional Tech Transfer Accelerator Hubs. And Jon Lorsch, who you'll hear from next, his team with Ming Lei and Krishan Arora, they really wanted to build upon this proof of concept methodology and spread some of those best practices and those abilities across the United States. It's not just the coasts, or those usual suspects in Boston or California, or at the big research institutions that NIH is trying to assist. We really want to spread these methods and these practices and this know-how across the country. And I give NIGMS a lot of kudos for pushing this program forward. It was a very innovative program that used STTR small business funding to advance the shared goals of technology acceleration. So, these four Hubs are a partnership between four small businesses and 48 institutions across 23 states and Puerto Rico. Moving forward from here, but jumping back a little bit to the REACH Program, in 2019, we were able to form five more REACH Hubs in 2019, this was a congressional authorization, this was based on a string of advocacy from NIH and the broader NIH stakeholder community. So now you can see that we're starting to get a much broader REACH of these programs and services across the country, the number of institutions and innovators who have access to these programs, and also, I think a broader appreciation for the value of the shared goals that were advanced, just taking a quick look at the chat Q&A.

Also, at this point, I want to really thank Ashim Subedee who gave the intro today. He's the academic innovation within the SEED office, he's really now the primary coordinator and he's really responsible for managing and tying this network together. He's doing a great job and you're going to hear a lot more from Ashim moving into the future.

But I want to shift a little bit now and talk about some of the things that we learned, some of the important lessons that we've learned. We've been doing this now for a number of years, we have these meetings every year. And we often talk about one of the best practices that we came up with, and, there's just a few examples that I want to take you through because I think they're kind of informative. So the first one I want to talk about is the evolution of outcomes. Defining metrics is really an iterative process. And as far back as the beginning of the program, this is really around 20 -- this is a slide from 2013. And, at this time we did realize that we needed to balance the evolution of the program with lessons learned and stakeholder feedback, in 2013, we were starting out with a whole universe of metrics, we kind of whittled it down to 93 priority metrics. I have to tell you at this time there was a lot of oh anxiety about outcomes tracking metrics. The administrative burden to track 93 metrics, a lot of discussions about what the most important metrics were, the usual challenges that we deal with, and this innovation cycle where it talks so long from initial scientific discovery to patient impact. These are all very difficult problems. We were working very hard to try and come up with solutions.

And over the years, mainly through a very strong and ongoing collaboration with RTI that's been led by Alan O'Connor, we have done a lot of trial and error to strike the right balance between administrative burden and usable metrics that can really help to show that not only show the impact of what we're doing, but help us understand what parts of the program work well, and what parts of the program require improvement. So, this dashboard you can see on the right is a dashboard that all of the centers and departments utilize to report their outcomes and their metrics. And we have a very streamlined approach. We have a streamlined reporting structure. We have selected metrics that are very meaningful both to the centers and Hubs themselves, at NIH, at Congress. And we take it as one of our responsibilities to facilitate that reporting and to help use that information to evangelize and really explain the success of -- Evangelize and explain the success of the network. You can see on the left the reports and outcomes that are easy to generate of all the years and efforts defining these metrics and finding an infrastructure to support them.

So, this is also important to mention because this issue of outcomes metrics is one that spans not just this program but many of the translational research programs across NIH and in fact, across the country. And, this program and our approach, that we've converged upon over the years, is really setting an example across NIH. And many of the translational research programs are taking a look at this, and under a trans-NIH working group that Ashim Subedee is managing, we're trying to bring some uniformity across NIH to the tracking of the outcomes of these early stage product development programs. This next slide you can see here is an update on the current indicators of success. This framework is really a living system. So I'll give you one example.

So right now we're embarking on an expansion, a slight expansion and modification of this metrics collection. With the help of NIGMS, to really better track -- our success in entrepreneurial education. That's a core aspect of the program, it's a core way to track educational activities. There's more activity now on tracking diversity and inclusion. And we're also in the ongoing struggle of how to quantify healthcare and economic impact. And this is a really big one, super important. There are some really promising examples from the NCI's impact study, where we took a look at the outcomes from the late stage small business program. It's so labor intensive to tie the links between these early stage innovations and the late-stage impact that there's a lot more work to be done there. That's an area that's going to be very important going into the future. And I encourage you all to attend the metrics and outcomes tracking session tomorrow at 12:15 to learn more.

Another area is integration with local tech transfer ecosystems, this is a really important topic that's been on the radar screen since the initial design of the network. Over 30 years ago we formed a social contract between the government and research institutions with the Bayh-Dole Act, the Bayh-Dole Act gave the ownership of the fruits of the federally funded R&D a to the institutions as a financial incentive to turn discoveries into societal balance. One of the first things that we did, to integrate this local tech transfer ecosystem is we work hard to harmonize with the employee metrics that the honor metrics that the universities already use. That is one of the first things that we did.

I also want to call out a specific example from the Kentucky team. So KYNETIC, the Kentucky network for innovation and commercialization, that team lead by Paula Bates and Linda has really had a strong integration with the tech transfer ecosystem from the very beginning. Ian is a KYNETIC co-investigator, Pre COVID cook with the Kentucky commercialization ventures is also a KYNETIC co-investigator, they've done a excellent job of integrating technology transfer and entrepreneurial support services not just into the KYNETIC Hub, but more broadly speaking across institutions all across Kentucky. I hope that you get a chance to talk to them more about that at this meeting because they've really been doing some excellent work there.

Another thing to call out in 2018, we had a panel at all that was really about industry-style mile-stone driven project management and how that strategy could be used within the academic environment. We created a kind of toolkit to help institutions understand how to help academic innovators manage the projects in this way, which is a really unique way for those academic innovators to think about how to manage the projects. I want to call out if you're interested in this topic please attend our joint session with all tomorrow at 2:30 which is about mastering entrepreneurship and -- fostering entrepreneurship and indicating healthcare products. We're happy to have this partnership with all year. This is partly with our partnership with Ian, the incoming board President for AUTM.

I want to talk a little bit about diversity. At NIH we have a very broad definition of diversity. Our definition of diversity encompasses underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, women, diversity in geography, and, we care about diversity because diversity leads to more innovative and better products. If we learned anything from COVID, we really learn that COVID has laid bare the striking health disparities across this country. From my personal perspective, I really feel like diverse innovators focus on topics that affect their own communities. It's a natural tendency. And many of the areas that we see these health disparities in are areas that don't get their fair share of attention from the innovation ecosystem or from NIH. And so by expanding the pool of innovators that participate in these programs, we really hope to expand the sphere of projects and the sphere of healthcare challenges that we have.

I'll calm out a few really interesting developments in the Proof of Concept Network. The first is the Proof of Concept Network Action Committee on EDI (PACE) committee. This is a self organized committee led by Monique Quarterman, who I mentioned before, and Julius from the University of Delaware, he's associated with the NIGMS DRIVEN Hub. And that committee has over 30 attendees across this network. And they regularly meet, they share best practices, they make plans. And they discuss really innovative solutions to diversity challenges that are coming from Hubs all across the country. I'm really excited about that group. And you'll be able to hear more about them tomorrow in a diversity session. But, the other thing I want to mention is that this promotion, this EDI group, promotion, innovation and entrepreneurship and tenure, you might think what does promotion and tenure entrepreneurship have to do with diversity? It actually has a lot to do with that. There's an intersection of innovation and entrepreneurship with diversity and inclusion with team science, with community engagement. These are part of the evolving system of rewards for faculty members in the 21st Century. It going to be so important to really redefine what it means to be a successful university faculty member in the future and part of that is going to be a broader appreciation for innovation and entrepreneurship and hand in hand with that is going to be a broader appreciation for diversity of perspective, diversity of topics that are addressed, diversity of R&D outputs considered for promotion and tenure. We're really excited about this effort. They've had some interaction with the PACE committee, I'm looking forward to some more interesting results soon.

So we also have some upcoming activity in the small business program, we have a diversity cell. Which funds small businesses to hire people from underrepresented groups. And in the future, we're going to be trying to use the Proof of Concept Network as a kind of a matchmaking way to bring young investigators who are interested in innovation and entrepreneurship into the small business program utilizing these diversity supplements that can pay for their time and effort. So if you want to hear more about EDI, you can attend tomorrow's session at 1:15.

So I've told you a little bit about how this program works. And I just want to shift a little bit now and talk to you about how we can leverage this network. We know that it works now. So how can we leverage this network to really have a big impact? I'm going to tell you one really exciting story on how we've done that. So the story starts out, this is a story about COVID's impact and about the rapid acceleration of the diagnostics program. So the RADx initiative was launched in April of last year to speed the development validation and commercialization of patient care and home-based tests for COVID-19. It was established with a $1.5 billion-dollar commitment of the U.S. Congress to NIH. And, this program was built on the back of another existing NIH Proof of Concept Network called the point of care technology research network that's managed by the National Institute of Biomedical Imaging and Bioengineering. And there are many common aspects to the network and to our proof of concept centers and Hubs that allow them to really rapidly launch this program. They receive many hundreds of applications. They quickly put them through a kind of a Shark Tank selection process. They took projects in a kind of a phased way to an early stage of validation and risk review then through a later stage for those successful projects of manufacturing scale-up. And that program has been really successful. To date the projects in that program are responsible for 841 million COVID tests that have been produced. And 32 emergency use authorizations, the first home-use test. And three other at-home tests. So that's basically what RADx is.

But you think what does that have to do with our Proof of Concept Network? Well, one of the issues with this program is when they opened the floodgates for this program they got lots of applications for super exciting novel technologies. But those technologies were in a much overstated the develop. It was really no hope or little hope that those projects that we're using those advanced technologies that were in such an early stage could reach the point of having a test in the commercial marketplace by the end of fall, by the end of 2020. And, NIDID and the director was looking at these projects and was saying, I hate to leave these projects on the cutting room floor. There's some super exciting new technologies that have never seen the lane of a commercial product. We hate to leave those projects behind. So what we did was we decided to take the most promising projects from that field and incubate them within our proof of concepts under network within the NCAI, REACH and NIGMS ecosystem. So we took 25 additional RADx projects and six more that were from a related program to develop advanced biosensing techniques and we supported them through the Proof of Concept Program, our Proof of Concept Network.

What did that look like? We combined three things. So the first thing we did is, we utilized the Hubs to provide training and entrepreneurial support and to help provide project management for those 30 projects. From the NIH side, from our office, the SEED office, we provided an entrepreneurial residence who assisted every single one of those projects. We also provided very, very integrated regulatory support. So part of key to the RADx program's success was a super tight collaboration with the FDA, weekly meetings with the NIH and the FDA, these 30 projects benefited from the early real-time feedback between the FDA in vitro diagnostics group and the NIH RADx team to help them understand what they needed to do to achieve emergency use authorization. Then the RADx program provided project funding and also more resources like support for clinical validation, support for engineering design, prototype development, and also, commercial relationship assistance.

So, just in a short period of time, we've had some real successes from the redirect programming. I'm just going to mention two here. One is Anavasi, RT-LAMP based technology, it was incubated through this redirect program, all of the redirect projects received around $200,000 of funding. Along with the support that I described before. But those projects leverage that funding with private sector funding that they were able to collect. And, most of them rapidly developed an association with a spin-out or a start-up company, all of them actually. And, the Anavasi project developed so quickly that they were able to acquire $15 million of different RADx support to scale-up and prepare for manufacturing. So they are anticipating filing an EUA any day now. And they're hoping to be in the market early next year. Rapid than Nano technology, a carbon nanotube immuno-resistive sensor technology, both of these projects are developing tests comparable to the PCR level test, the accuracy is comparable to PCR level test, be you the cost and time to get a result are comparable to about Antigen tests, the rapid nanosensing test has received a additional $400K funding of support, with we're hoping that project will advance to commercialization soon. So it's part of this collection of projects, so far we've been able to support 13 of these projects to move toward emergency use authorization. And these projects have garnered $38 million in follow-on funding beyond what we've provided for them. We're very happy about these projects. We think they really illustrate the power of this network to combine feedback and expertise from the local ecosystem, financing for early stage product validation, milestone driven project management, all of these essential elements were really required for success.

And if you want to hear more success stories, well more success stories from the network, you can attend the session at 2:15 today or check our our website where we have about 75 success stories on our website and a little while ago we decided most of those success stories in fact all of them were from a small business program. Small businesses who had received SBIR / STTR funding. We realized wait a second. We had so many successes coming out of our Proof of Concept Network we need to start including stories from these academic projects as well. So now there are nine success stories that are directly attributable to the Proof of Concept Network, and we're developing more every single day. So, I want to kind of wrap it up by talking about some of the ongoing challenges and opportunities. And, to kind of get them out in the open so that we can talk about them over the next few days and maybe we can come up with some solutions.

So, you can decide which of these are challenges, which of these are opportunities. Maybe challenges and opportunities are the same thing. But the first one I want to mention is, this idea of virtualizing a product development support to innovators from any institution. So most of the time when we get talks about the Proof of Concept Network somebody says hey, wait a second, I'm at institution X. And I don't see a dot on the map, or from my institution, can I benefit from this network? And usually what we say to that is, well, much of the education and training has been virtualized. And a lot of that is available to people at any institution. But there are real challenges that have prevented us from coming up with a good model to provide funding and project management to innovators that are not at partner institutions. And part of that is due to the fact that we require matching funds for these projects. And it's just been a challenging nut to crack. I think we can use more discussion about how to solve that problem.

A slightly related problem is the financial model for how this program works. Which I'll call the piggy bank model. The piggy bank model NIH throws in a bunch of money to each center. The center or Hub turns in matching funds from their local ecosystem, sometimes there's a state economic development agency, their university, wherever it comes from. And then from that pot of money, individual R&D projects are funded in support. And we like that model in many ways. But there are a few issues that could use some refinement. One is, it's been kind of difficult to do charged funding of these academic research projects. We like to do milestone- driven project management. But one of the reasons why milestone driven project management works well is because, you don't waste money doing things that once you know a project is not likely to be successful. And we have some models from within the Proof of Concept Network particularly from Kentucky that help to solve that problem. There's also the issue of obtaining matching funds. We want to be about to support innovators to do early stage product development work, we don't want to have those investigators on the hook for coming up with those matching funds. It's been difficult to figure out a way to obtain that leveraging money in those matching funds in a way that really allows us to expand the usability of this model. Then finally, the sustainability issue from the very beginning of this Proof of Concept Network experiment, we've been talking about okay, what happens after say five years when this NIH funding goes away? How are these centers or Hubs going to be able to maintain their operations and sustain their ability to fund projects and provide education and training? And I think that's a really challenging one that we know a number of potential solutions that do not work well. But I think it's been challenging to come up with robust solutions that will allow these programs to persist and continue their activities after the NIH support ends. And I would love to have some more discussion about that in the next few days.

On the right side of this graph, some potential opportunities. So partnering with other similar programs, this is other NIH translational research and product development programs, or non-NIH programs like other incubators and accelerators were really excited to have people here at this meeting really for the first time who come from outside of our network and outside of our ecosystem. And I think, I think there's some really power to think about maybe it's education and training, support services, how they can really be leveraged more broadly across the entire biomedical innovation ecosystem across the country and how we can build on what's already out there to strengthen everybody's activities. So I think that's a real area of opportunity, addressing emerging healthcare challenges. The RADx example was a really great example. I think there are more to come. There is certainly no lack of healthcare challenges that we have to address in this country. I think RADx and the support that the network provided for the COVID response a really showed that with some additional funding and some dedication and real concerted effort, we can bring this network to bear on other powers, equally effectively.

Then the last one is, many of you are aware that, on the horizon is discussion of a new advanced research project agency for healthcare, this is a kind of healthcare version of DARPA. That, if and when that agency is stood up, it's likely that that agency will be living within the NIH ecosystem. And what we've been trying to do is develop a more continuous pipeline between basic science discovery and early stage product development and later stage product development and private sector commercialization and I'm really looking forward to thinking about how all of the things that we've built up in this NIH Proof of Concept Network can work together with ARPA-H to make ARPA-H more successful. And for our network to be able to leverage the resources and the activities that are likely to happen at the NIH. So that's a kind of a big picture overview, a little bit of history, some things to think about in the days ahead. And I just want to thank everyone for being here. I'm so excited about this meeting and all about all of these people who are joining us. And, I'm looking forward to the discussions in the next few days. I'll turn it back over to Ashim.

>> Ashim Subedee: I think we have a couple of minutes, with us a couple of minutes, let me see this. One thing that might be helpful to do, I saw a few questions on that is a little bit of clarity on the scope of the different programs right. This area, so you made it clear NCI, heart lung and blood, if you could just clarify a little bit about the three programs and what business area they cover.

>> Matt McMahon: The NIH Centers for Accelerated Innovation, they focused on heart, lung, blood and sleep capabilities, but the REACH program covers all areas that are all healthcare areas that are supported by NIH, essentially all healthcare areas. And we work really hard to make sure that that program has supported projects across a real diversity of topic areas, and I think that we've done a pretty good job of that. So there are projects that are related to environmental health, there are projects related to digital healthcare projects. There are pediatric projects. There's a pretty good split between drugs, devices, diagnostic. So we really try to make sure that the network is representing all innovation space that NIH supports. The NIGMS Hubs are primarily focused on entrepreneurial education and training and support. But they have also kind of tested out some of those educational and training resources by funding some R&D projects. Those R&D projects also span the whole NIH mission space. Thank you. Ashim Subedee speaks at question, EU-related think this might be helpful to provide a little context and clarity. These resources, are they only for academic entrepreneurs? How can other partners like in a small business, leverage these resources and work together with the entrepreneurs now?

>> Part of these programs is to serve as a bridge between academic innovation and small business innovation. And, in fact, you may have noticed that some of the outcome measures are around the number of start up companies and the number of small business program applications and awards. So, we're really hoping to strengthen the connection between academic institutions and small businesses in these programs. So, although these programs only support proof of concept projects within the academic environment, it's really a goal of these programs to support the transition into early stage product development and small businesses. We primarily do that through the small business program which at NIH, is $1.2 billion a year. It's the largest source of early stage product development funding in biomedical space in the world. So, that's how those programs work together. I hope that's helpful.

>> Ashim Subedee: That was helpful and clear. I think that was most of the questions. Thank you again for providing the sort of background and history of the program. And definitely some of the challenges and opportunities more so on the opportunities side that you mentioned are definitely exciting and worth exploring, I'm really hopeful that we will be able to interact with a number of you in these meetings and some of those opportunities and how it can work together. I think we have a little break now. Our next session will start at 1:15. We will be hearing the keynote speaker from Dr. Jon Lorsch, the Director of The National Institute of General Medical Sciences. So please, do stay on the line, we'll get started in less than 15 minutes.