

Day One Summary and Introductory Remarks: Product Development at the NIH – Introduction to the Proof-of-Concept Network

Wednesday, December 7, 2022

Session Transcript:

>>Matthew McMahon: Alright, thank you everyone for coming back and joining us for day 2 of our Proof-of-Concept Network Annual Meeting, yesterday, we had an excellent day.

I really enjoyed all the sessions, the Keynote address by Ian McClure I thought was a great way to kind of set the high-level perspective around how this program fits into the broader innovation, landscape, and how that landscape is shaping up over this coming year. So that's super exciting. Then we had a panel on career development transition to small business and early commercialization resources. So, in those panels, we're really talking about, more of the kind of nuts and bolts of how this network works and how it would really assist these innovators to do what they need to do to be successful and bringing their technologies to patients.

Today, I'm excited, because today, we're going to hear about the impact of the program. We're starting to get to the place now where we can really see the fruits of this labor paying off. Then we're going to have a panel on Equity, Diversity and Inclusion Across the Proof-of-Concept Network. This is our "PACE" committee, the Proof-of-Concept Network Action Committee on EDI and then we're going to have our Innovator Showcase. So, what I want to do here at the beginning is just, Alan is going to tell you about all the exciting metrics, that really show that this network is accelerating the pace of technology development and commercialization. But I wanted to tell you a very brief story that I think really reinforces that point, and this is a story about the NIH RADx program.

So RADx stands for "Rapid Acceleration of Diagnostics" and in 2020, the US Congress gave NIH 1.5 billion dollars to rapidly come up with diagnostics tests for Covid and NIH sprang into action and developed the RADx Program which, in it of itself, was built out on one of the Proof-of-Concept type programs at NIH called 'POCTRN' – the Point of Care Technology Research

Network – so they sprang into action and they said we want proposals from people who can develop covid tests. We're going to take applications in April of 2020, and we need those tests available to people by the end of the calendar year and we have the money and the resources to make that happen. So, when they got those applications, they found that there were tons of projects that were super exciting technologies, but that were super promising but there was no way, that they could be developed into usable products by the end of the year and NIH in the National Institute of Biomedical Imaging and Bioengineering was running that program, they really were caught in a bind, because they wanted to support those technologies, but they knew that they weren't on the critical path to be available as marketed tests by the end of the year. So, they had a bit of an 'a-ha' moment.

They said wait a second, we see some of these applications coming from these institutions that are supported through our national network of Proof of Concept Centers, and they realized they could go out and specifically advertise across this network because what better place to find innovators who would know how to turn these ideas into products than within the network that is designed to do that. So, I'm going to share my screen now and I'm going to show you a few slides and tell you what happened.

So, what happened was they came to SEED, and they said, why don't you – so you can see in the upper left– this is just a schematic that shows the overall structure of the RADx program. But what the leadership of RADx did is they said, why don't we take a bunch of these submissions, that that are not really viable to go through our normal funnel and bounce them out, manage them through the Proof-of-Concept Network, leverage the Entrepreneurs-in-Residence, and our commercialization resources that SEED can bring to bear instead of leaving those projects on the cutting room floor. We'll create another pathway, for these exciting technologies, that maybe by the time the next pandemic comes around, or later, or in another phase of the pandemic. We will have some super exciting technologies that that are available for use. So, the SEED Office in collaboration with the Proof-of-Concept Network for Centers and Hubs. We started supporting 20 RADx Diagnostic Projects, and those projects each received a significant amount of funding, most of them \$250,000 each plus access to the local resources of the centers and Hubs, plus the SEED team support through our Entrepreneurs-in-Residence and our commercialization advisors and I'm happy to say that so far, we've had 10 of those projects that have made Emergency Use Authorization submissions, and more than 10 of those projects have received significant follow-on funding to continue development totaling over \$33 million. So, I think this is an example of this is proof that the Proof-of-Concept Network is a valuable resource that can be leveraged to rapidly commercialize technologies.

I mean, this is really– the RADx program is unprecedented and at speed, and its commitment to get products on the market immediately. And I think that the fact that we were able to take extremely young technologies and you heard yesterday in the panel on small business from Steve Soper about his project and the BioFluidica project, that's an example of one of those projects. So okay, so this is RADx Tech, but there's a whole other part of RADx called RADx-rad, which is looking at even more kind of early-stage technologies, and different types of technologies, and when the RADx-rad people heard about what we were doing with RADx Tech,

they said, why don't you work together with our coordinating center to assist our portfolio also. So, the RADx-rad portfolio has about 49 projects in the portfolio and you can see in the upper left here the different types of projects that are in the RAD Portfolio. It's things like wastewater surveillance, looking at MIS-C the rare side effect in children, novel biosensing strategies, lots of different technologies. So, they came to us, same thing, can you help our projects. And when we started helping their Projects, we realized that 7 of those projects, were living at institutions that were already a part of the Proof of Concept Network. So, we started assisting – we've assisted 25 of those projects out of the RADx-rad portfolio to really help them think through the commercialization and the business development aspects of their projects.

And many of them are just like the projects that come through the Proof of Concept Network normally, they're very early-stage science projects that really need to think about what that business case is and how to develop that project in a way that maximizes their chance of success. So through our efforts, we've been able to get these projects that we're assisting an extra 5 million dollars of funding through the RADx-rad program, and also access to many of the resources of the RADx program that are provided by outside sources, like clinical validation, usability, testing, regulatory support and commercialization support and even these very early-stage projects, 4 of them have submitted pre-emergency use authorization submissions to the FDA to begin discussing their regulatory path. I just love this example, because it really goes to show that this network can— which we claim, and we tell people— this is a network that's helping turn these scientific ideas into products. When push came to shove and we really needed it for COVID, the Network was able to spring into action and accelerate these technologies that would have just not been accelerated at all. They would have been left on the cutting room floor.

So, I want to really thank the Centers and the Hubs who worked together on this. There were a lot of administrative snafus that we had to work out; there were a lot of hard problems we needed to solve, but the Centers and the Hubs have done just as much work on this project as SEED in supporting these innovators to move the technologies forward and I think it's a tremendous example of the power of this Network.

So, I just wanted to mention that because this information will not be contained in Alan's overall presentation. This is just like an extra bonus of the Proof-of-Concept Network. So, with that, I want to hand things over to Alan to talk about the overall outcomes of the Network. But first, I'll just remind you of a few of our housekeeping issues. Please type your questions into the Q&A and we'll try and answer them as best as we can either during or after the speaker is finished; and don't forget that we're going to have a networking session at 4:30 PM ET and we're going to have 3 separate zoom rooms that are basically associated with the different breakouts – or different panels that we had the other day based on interest. So, thanks a lot and I'll turn it over to Alan.