NIH Proof of Concept Network Common Metrics and Outcomes Tracking

Session Transcript:
2021 Proof of Concept Network Annual Meeting: NIH Proof of Concept Network Common Metrics and Outcomes Tracking

>> Alan O'Connor: Thank you very much for that Krishan, I hope everyone's doing well. This is usually one of my favorite things to do during our annual get-togethers to just have that opportunity to connect with everyone and report out on the success of our network. One of the exciting things about this particular year is of course that we have a full and open public meeting, and that means that it's a great opportunity to report out on what we're doing across the network, in terms of what our outcomes are, the processes that we use, and to share some of the ideas and insights that we have accumulated over the past seven years that we've been running the NCAI and REACH programs. So for those of you who are not familiar with me, my name is Alan O'Connor. I am an economist and a program evaluator based at RTI international with a particular focus on evaluating science and innovation programs. These are something that it's been kind of a hallmark of my career, something that I've really focused in on. And I joined this network in 2015 to help with developing strategies for tracking the overall outcomes and performance for our particular, for this particular network.

So what I thought I would do today would be to share some thoughts on why do we go about doing, monitoring evaluation, have a few highlights about our evaluation program overall, touch on some of the metrics that we use for tracking technology progression market, thinking a little bit and sharing some insights about the infrastructure and the overall approach that we use. And then summarize with some of the current status of the portfolio with respect to progress to market overall. Including such things as follow-on funding, start ups, small business support via STTRs, SBIRs and of course, market approvals. Market approvals is being probably one of the most important things for NIH because the overall mission of the NIH in general is to turn discovery into health. And these programs are great mechanisms for working with academic innovators on how to go about the process of taking their great discovery and their ideas and moving them towards the bedside to assist patients.

I will note that today I'm probably going to be focusing on funded projects and also technologies as outcomes. There's a portfolio of around 386 projects that have been collectively supported by the 11 NCAI and REACH sites, we're going to be talking about the progression to market and outcomes for those funded projects. I want to emphasize that a big portion of the overall goal of these programs is around culture change. It's around stimulating and engaging academics and translational science. It's about building capacity. It's about connecting institutions more strongly with their regional innovation ecosystems. There really is a broader focus to these programs that's very important to keep in mind. I'm only going to be talking today about a small portion of what we're doing to kind of report out and track outcomes and that's mainly those that are associated with the funded projects. Okay.

Those primarily stem from two of the programs so NCAI and REACH both 2015 and 2019. Also the NIGMS Tech Transfer Hubs, they're an important part of this network, but they only have a very small number of projects, they're still being incorporated into our metrics. So I'm not going to present on those today. But will at a later date. So just as a quick refresher, for those of you who may not have been able to attend yesterday, but the NCAI and REACH sites are distributed across the country. Going from Maine to California. The states here in which there is a REACH or NCAI institution are highlighted in blue. There are 11. Some of the sites are consortia, namely, M Bark, the University of Kentucky, UC-CAI in California, NCAI-CC in Michigan, Illinois and Ohio. And B-BIC is largely concentrated in the Boston area, but also includes institutions in Maine and Rhode Island. Other programs are single sites. So that would be WEREACH which is based out -- WEREACH based out of the University of Washington. SPARK/REACH at the University of Colorado and Rutgers Health Advance, which is based at Rutgers University. Collectively, there are 70, more than 70 institutions included in the next work. The largest numbers are from MBArC and kinetic, MBArC has the large connection of institutions across any state and Nebraska. But the kinetic program also includes the technical and community college system for Kentucky. So that's a quick overview of the network, just the kind of reminding everyone of some of the details that Matt reviewed yesterday morning.

So here I just want to touch on and remind everybody about why it is that we do this. And, I'm on the faculty of the international school for research impact assessment. We also tell our funders and research performing entities that it's really the four As okay. So there's analysis, which is really where we're thinking about learning so that we can make evidence informed strategy, program design and policy decisions going forward. There's also an accountability function. That's particularly important in this program because although the NIH and Congress have provided a substantial amount of resources for NCAI and REACH, there's also matching support coming from the institutions that are part of these networks. Those institutions committed their own resources either from their state governments or from institutional XLerator programs, to kind of support and encourage the overall progress within their own communities. So it's really important that we're not only accountable to the federal stakeholders being NIH, but it's also important that we're accountable to the institutions that have allocated very scarce resources to support these projects and to further these programs. Because they're that invented in the mission.

So, accountability is really something that's very important to us. Of course there's also allocation decisions. How do we allocate a marginal dollar? So if I have a certain pot of money that I can put into a translational science program, what's my programmatic mix? What are the types of levers that I want to play with? Where do I put that marginal dollar? Sorry I'm a economist, I'll use terms like that. But that's really important for helping to shape strategy and to make effective decisions. Lastly, it's really about advocacy, which S it tends to be more about providing data, information, lessons, insights. So we can talk about the importance of these programs, so that we can share best practices and lessons learned, also to say hey, this is what we're learning from this experience. This is why this was valuable. And this is what you should be taking away from this. How can we implement this into our formal culture or organizational structures, or other aspects that kind of characterize our research ecosystems.

So RTI's approach. We designed this in close collaboration I would say probably 2015/2016 working with NHLBI in particular as well as representatives from other parts of the NIH to come up with a holistic evaluation plan that would be meaningful, useful and provide value for all the reasons that I was just describing. In a nutshell, it really involves kind of engagement with the site teams who are developing and implementing strategies and approaches for managing translational science and encouraging academic entrepreneurship. That also means that they're developing strategies for cultivating application pipelines. Likewise, we're really interested in the profiles of applicants who are attracted to these programs. One of the things that's always been amazing to me is both REACH and NCAI have been able to reach those innovators that really don't have a whole lot of experience in commercialization. And yet, they have an idea, they're attractive, they want to try it, especially those earlier career investigators, they're postdocs and associates teams who get excited about the program. It is interesting to learn what the experience is. You get this diversity of perspective from those who are more the kind of usual cast of characters, those tenured professors who really know how to move technology. They have a lot of experience in commercialization. Then you have the other apps who have very little experience.

What's interesting is that the outcomes are largely the same. So it's been great over the years to see these innovators grow and mature as entrepreneurs. Some of them are now CEOs. We spend a lot of time working with the funded innovators just understanding the program experience, get suggestions, insights, how things can be improved, what works well, what doesn't work well, is there a secret sauce for the particular site from their perspective. Because they are the target customer in many ways. What I'll focus most of my talk today which is on tracking projects over time. And this really relates to what's the technology's progression, what are the commercialization milestones and outcomes? I don't want to move on without saying that a big part of what we're doing is also thinking about skills development and engagement. And of course, throughout this whole process, there has been sustained collaboration between RTI and NIH and all the sites. So there are papers being published, data shared freely across the network, and so that's really been one of the things that has kind of characterized this particular network. It's the fact that it's very much been a place where people can collaborate. They can share their insights. They can share best practices, troubleshoot challenges and have a sustained dialogue where it's focused on the particular issues in academic innovation, especially as it starts to connect entrepreneurship. What are some of the summary metrics categories that we care about right? So that's the title of my talk about common interests.

So here's a quick little review as Matt was saying yesterday at the beginning there were about 400 ideas for different metrics to capture. I remember getting a call one day from one of the Deloitte team, and they were just like, Alan, we have this list. It's about 400 things long, we're trying to sort out what's meaningful, what's the best approach to hear? Can you help? (Laughter). I'm like, yeah! I want to do this, this is exciting stuff. What we did is we started like streamlining everything down to what would be meaningful? So, first we start thinking about the innovator profile. What is their commercialization experience? Have they licensed something before? Have they been a start up? Have they engaged with industry before? That's important to know. Because you have your usual cast of characters like you mentioned before. You also had those newbies. And those are many ways kind of like the targets. Then there's also demographics, gauze you would be thinking about what is our representation? How does that compare to the broader innovator community overall? So, we think about race. We think about ethnicity. We think about academic rank. Gender and other issues. We also track technology profiles. So what's the technology type? Such as the diagnostic, assay, therapeutic. We also track disease areas, cancer, cardiovascular. So those are some of the high-level things that are really important to us.

Now when it comes to funding projects, and we're tracking progression, our ultimate goal is a market availability, right. So the mission here is how can we take these discoveries that we've invested so much basic science a dollar in, and push them out to solutions that will help patients? So, market availability, at the bottom here is the number one thing that we're paying attention to. Now, there are other metrics that we can use as signals along that path right. Because we know it can take in you're in the private sector ten years, most translational science programs, 17 years. So it takes awhile to really move a lot of these technologies along to the market. So, some of the things that we track on an ongoing basis would be start up formation and growth. Intellectual property status. It's the licensing status. Are there SBIRs or STTR applications or awards? How much follow-on funding? Who's finding that follow-on funding? Is it something that's coming from NIH? A strategic partner? Is it a venture round involved for a particular concern? Those are things we really pay attention to. And likewise we pay attention to technology maturity. So, DoD and ARDA have done everyone a favor, they've come up with a basic rubric for biomedical technology around technology readiness levels or TRLs. And we had adapted that to the clinical and translational science setting that we can use to essentially track the maturity of the technology over time. So, one of the other things that I'm a big fan of is AUTM, so I'm stoked that they're presenting later on today. Because AUTM has worked really hard for the past couple of decades coming up with some common definitions. So why reinvent the wheel, they have great definitions for everyone to leverage. They're well understood, they're well characterized. So we use those.

And of course we also track the regulatory pipeline, because that's what allows us to say well, how close are we getting to potentially having a product on the market? So how do we collect the data? So we have a tool that we created in collaboration with the sites over the past few years. It's called the update tracker which is really just technology update tracker. We were not feeling particularly creative. It just stuck. So that's how that came about. But it's a web-based infrastructure , we jokingly say it's like Turbo Tax for technology development projects. There are Wizards, reporting features. There's a business logic. All of that is probed in by a stellar team that essentially sees the world as an endless series of databases they characterize and post questions in such a way that it's easy for the sites who are collaborators in this to provide information. We can ingest data from Salesforce and other CRM tools, there's other role-based access security features. The way we go about doing this is the project managers each of the sites were overseeing the technology development projects themselves. They'll meet with their staff during update meetings, ask them a few questions by using an iPad or maybe have the screen open. Something like that. And they will ask them the questions, they will just populate the data as they move through the milestone meetings. Sometimes it takes a minute, sometimes it leads to a broader conversation about commercialization strategy. So it's also an educational goal.

And then we go through a process of validating the data chargely using a whole host of third party data sources. Generally speaking, this has been an approach that's well testified by the team. So we're really happy that over the past several years that this has made it relatively easy for us to collect technology outcomes data. If you were to talk to a individual person on the sites, they are saying we still have to collect information from innovators. We still need to plan this into our workflow. So it's not a lift. But it's not painful. We're not necessarily asking for a whole bunch of stuff that no one will ever look at or use, which is part of the strategy. So basically just to give people a little show and tell. We have a website where it's called the update tracker where everyone can create an account or log in. Once you're there, essentially you'll be able to enter details about a project. So there will be a project abstract, a lot of metadata information. And then a running timeline about what's going on with the project so that, the technology manager, the tech transfer offices, whoever can go into the site later and review with what the progress is and have an informed conversation. The other thing that's kind of nice about all of this is once it's in the database, there are ways that we can visualize the data so that people can essentially run queries down the graphics, prepare for presentations. So that's really important. But what's great about it is that it saves the NIH and the sites from a constant stream of one-off emails and conversations asking for updates and it really starts to drive people a little crazy. So here's a project update. And then here's kind of an example of the application pipeline where we have an application what the total demands so to speak for the programs are. So that gets visualized. We have follow-on funding, interactive reports. So there's just a variety of tools that we have made available using this infrastructure that has really kind of made it easy for us to track so many projects over time involving both the sites so they see all the data that we have. Any data that we find out using third-party sources we populate in here so everybody can stay on the same page to how the projects are doing. I want to just kind of offer a quick additional editorial remark about metrics tracking.

You know, again I mentioned earlier that it's really important that everyone be always mindful about whether each metric that's provided contributes to meaningful situational awareness. If you're not going to do anything with it, if a metric is being proposed but you're just like, how am I going to make a decision with that? -- how am I going to make a decision with that, what is it going to tell me? It's probably not something you need to collect. I mentioned the critical importance of harmonizing common clear definitions. Something that Kathleen shared with me who's a program officer for NCAI, she's like Alan, make sure you tell them that it's really important to start early, plan and prepare. So the last thing that you want to do is to have to go back and collect information when you're five years into a program. One of the other things that we've done here is that we've also provided resources and tools. We always strive to kind of create the same value for the user community. We have a monthly development cycle to make sure we're meeting everyone's needs because we want to keep our customer base, which is the sites, happy. So we will make tweaks and adjustments to suit their purposes to kind of help sustain engagement. And honestly we've grown and adapted over time. This is not like a one-time engineering solution we kept growing and morphing to make sure our infrastructure and our evaluation program are as dynamic as the technologies and the programs that we are tasked with providing monitoring and evaluation for.

The last thing before I start launching into some kind of overview of our high level metrics is that I just want to remind everyone that these metrics are just a snapshot in time. I do not reflect important intangibles. Okay. So these would include things such as culture change, learning and demonstration effects, professional development, whether there are insights to these programs that inform one's tech transfer and innovation management strategies. The data also tend not to really show a good picture about what is the underlying institutional research strength, mission or portfolio composition. So if you're only looking at the summary metrics. You're kind of looking at the outputs and outcomes and you're forgetting about what am I working with. Why is it like that there can also be some regional contacts? But I will tell you regional contact is not as important as people think. The Midwest, the upper Midwest in particular punches way above its weight class when it comes to innovation performance. It's not necessarily something someone would expect when you think about the concentrated ecosystems of Boston, or San Francisco Bay area or San Diego.

So as I touched -- there's just a couple of things I want to remind everybody from Matt's talk the other day. So the first thing is that remember when we talk about the NCAI program, it's focused on heart, lung, blood, sleep. Okay. REACH 2015 and 2019 an NIH mission. Something that I didn't put on the slide is that there's also a resource difference between NCAI and REACH. So the REACH sites generally have about $2 million of capital that they're working with per year. And they were funded for about the first cohort for about three years with some extensions, it ended up going a little bit longer. For the current cohort of sites I believe it's four or five years. So you have to keep that in mind. The NCAI is funded for a full seven years. So there are some programmatic differences. And that of course will show up in the results when we start talking about the numbers. So I don't want everyone to really focus on this slide too much, the main takeaway is that the overall composition of the funded projects between NCAI and REACH when it comes to technology type is more or less comparable. What I've noticed is that the big difference is around NCAI with it's larger resource base, was more likely to have additional therapeutic devices. So across therapeutic areas, again, NCAI has a real focus on heart, lung, blood, sleep. And then for REACH, you have a strong weighting towards cancer. But there's also cardiovascular technologies in that portfolio as well. There's also a large number of research tools, apps, health IT that really don't have a specific disease or indication. That's something that's been really interesting about the research REACH portfolio in particular. Because of our innovators have put out apps, they have put out new APIs, and other health technologies for example first responders can use. So it's a real difference in kind of the technology composition. That relates also to the underlying research strengths of the institutions where these projects, from which these projects emerge.

In terms of follow-on funding, right now, across the whole network, we are approaching $1.9 billion in follow-on funding. The vast majority of this was from the private sector. In 2021 alone, there was $980 million worth of follow-on funding invested in this technology portfolio. And it's been increasing over time. There were a couple of early investments that were quite substantial. Some of the earliest projects, you know, basically picked off low-hanging fruit, really accelerated technologies forward. There was kind of a large amount of follow-on funding secured. But there's also a lot of technology that are attracting additional investment. Across 386 projects in 2021 alone there were 43 investments of less than $1 million, okay. There were, you know, 19 investments of more than $1 million. And there is also new strategic partner funding totaling more than $700 million. It is quite substantial the amount of interest that this portfolio has attracted. Keep in mind, many of our innovators had very little commercial experience prior to participating in this program. So as would be expected, some of the earliest projects funded back in 2014 are those that kind of attracted have had more time to germinate so to speak. A couple of those have led to quite significant investments from partners.

As you look across the years, there's actually kind of a nice distribution of follow-on funding events. So, for example, in 2019, you know, out of that particular funded project year, you know, 15 of those 31 projects are already getting follow-on investment. 2020 projects, 17 of them. So we're really seeing a lot of interest in investors in projects that have been selected in this portfolio. Here is a high-level summary of our summary by source. Most notably some Amgen some of the large biotech companies have really invested in technologies that were rooted in this particular portfolio. So if I were to kind of sensor out some of like that big money for a couple of projects, this is what the balance looks like. So you still have something like $300 million in venture capital that's been attracted. You have a lot of other follow-on NIH funding for either clinical work, translational, further translational work, contracts, et cetera. And then other parts of the federal government are investing heavily. There's about $36 million comes from the SBIR program, about $4 million from the STTR program. In terms of success rates, when it comes to the application for SBIR programs, STTR programs. We're seeing a pretty healthy SBIR success rate around somewhere between 40 and 50% success rate, which is really high. The typical would be about half that, if that. So, the SBIR success rate is really great. That's important because we're trying to kind of connect these technologies in the start ups that were formed so SBIR portfolio. There's some kind of other data here that people can look at later, I'm going to keep moving for time.

In terms of cumulative start ups and jobs created, we're now at 101 start ups overall. 48 projects have either a start-up and SBIR and STTR app. So there's really kind of like that, there's a lot of connections between these different programs which is great to see. Somebody else that I observe when we're looking at the latest data is that, the median time from project start to start of formation is about 7 months. So most teams are learning pretty early on what is the best commercialization mechanism for their particular technology? Should they try licensing? Should they try to start up formation? For licenses and options, you know, we have some small businesses are actually coming in, licensing technologies which is really great to see. But we're noticing it takes a couple of years between when a project is started where someone is kind of picking up on that and kind of optioning our licensing the technology. Right now we're at 16 licenses and then there are 11 options.

So I mentioned earlier around how do we track technology progression? In high level BARDA had a structure where basically it goes all the way from kind of a review of -- BARDA goes from a review of the scientific base and ends with FDA approval. So, along this trajectory, in collaboration with the sites and using some tools, we have developed a plan whereby a lot of the sites are now trained to kind of identify and track and demarcate what the status of the particular technology is. And then there are resources and tools available to help them with that process. But what I find to be particularly interesting is that, if you focus kind of on the right hand side is that, typically, the time progression to market for a translational science program is truly 17 years. This is based on meta-analysis that was kind of done several years ago. But that's like a really like well-known kind of reference point for how long it takes to get some projects from an academic lab onto the marketplace. And what we have seen with this program is that in fewer than 8 years, there are products on the market. And so, what this particular graph in front of you is showing is that, in general, depending upon how long ago your project was funded, so that's a project age along the X axis. We're seeing broad progression. So if it's blue it means that these one TRL advancement for a project from that particular cohort, oh are that particular year of support. And so you see most of the technologies they're going to at least once. The interesting thing is that the technologies are between 4 and 7 years old. The outcomes in terms of progression are similar. Kind of implying that once you get going, that you know, that really, there's that momentum can be sustained, and that depending upon what the broader kind of characteristics or market dynamics are, there can be you know, a substantial or a strong pathway to the next, to stages of technology maturity. I think I've had one technology that went from TRL 2 kind of very early proof of concept all the way to market approval.

So speaking of market approval, here is kind of some updates about where we are. I mentioned at the beginning of my talk that we really care about market stress. So on the market today, there are 18 tech, there are 4 technologies that have regulatory clearance for clinical use. There are 3 additional technologies in the market that are not requiring regulatory approval. And then there are an additional 18 technologies that are either in clinical trials or research settings right now. So that's a phenomenal success after only 8 years. I have not seen such a strong rate of progress in other programs. A couple of highlights would be some pulmonary stents. There's also this great first responder toolkit that received a lot of attention because of its use in application for healthcare workers who are struggling with the trauma and the challenge of the pandemic. So really, there are some of these tools have really had quite an impact on the community. So, a couple of parting remarks, then I'm going to open things up for questions. There's some things that these teams have done very, very well. So one is on-site team composition. They've chosen leaders that have a strong track record of academic entrepreneurship. They have good visibility. They're supported by really strong teams around them. They also have empathetic project managers with industry project development expertise and empathetic is really important.

Because remember, a lot of the innovators in this particular community, they've gone kindergarten to postdoc, to a faculty position. They're very good at the science. They're very good at science. But many of them have never kind of moved a technology or a concept into the translational pipeline before. And so be paired with a industry-trained project manager who has really good communication skills can coach that innovator, can really help kind of add a lot of value and ensure that that kind of technology development project doesn't drift into hypothesis driven research but stays on track towards what do we need to do to add value, to get your great idea into a product or service to help somebody. Somebody else that kind of characterizes sites is close integration with technology transfer offices. In some cases the tech transfer offices are part of the leadership teams. Or, in a couple, the leadership teams themselves. They also leverage resources from their CTSAs and local innovation ecosystems. Somebody else that was particularly effective was kind of leveraging external advisory boards and proposal selection boards. We saw a couple, we had one instance where a board for choosing applications for funding, the composition was just basically a lot of like university administrators and senior faculty leads. People were like these are the wrong people to be evaluating technologies for commercial merit and scientific promise and relevance for the market. And so what we saw is that a lot of proposals, the selection boards were retooled using life science executives, entrepreneurs and people from the broader community.

Something else that kind of characterizes the sites was active outreach to the research community. So the more that the site teams were engaged interacting with faculty, the more likely that they would ask questions about the program, increase the propensity to apply. So active engagement, not just passive engagement through newsletters, but actually going to meetings, championing the program and sustaining that proved to be particularly significant. Something else that's just a signal, it's a N of 1. I believe Paula Bates shared in a University of Louisville a couple of years ago, the full innovator team from the University of Louisville site program were women, in the end, 63% of funded PIs or co-PIs were also women. They said that representation in an interview with innovators, seeing someone like themselves in a leadership position as an entrepreneur inspired this epito take the next step further with their idea. So I think that's probably themes that Monique and team will pick up on when they talk about diversity and inclusion shortly.

Something else that was kind of a great practice was application processes as an opportunity for learning feedback. So watching innovators struggle filling out a kind of market plan, a business development plan, was also an opportunity that kind of coach and provide feedback. Something kind of related to this is for educational programming many of the sites were starting to time all of their seminars or boot camps with the application cycles. And that proved to be particularly useful to help those innovators as they muddled through their application for technology development funding. Of course once the projects were funded, a lot of the innovators said well the most important training was my one-on-one training with the site team and the project manager. Because they basically counseled me, they were my sounding board. They helped me solve some of these challenges about how to add value to my technology when this is the first time I've ever gotten it. So this was a real common anecdote we heard across the board. They also were effective in implementing milestone based project management tools. So tranched funding, fast-fail strategies, use of target product profiles and other tools. The things that I tended to be fairly new to an academic investigator that have proven to be particularly helpful in building out their knowledge about how to move these projects forward. So high level takeaways for me, this has been -- I think this is the sixth time I've given a talk like this. I really love it. The thing that always strikes me, is that really there's a lot of evidence about how these types of programs can transition those basic science discoveries to help patients. And as a science policy nerd, I really think about the return on basic science investment.

NIH is a $40 billion a year enterprise. A large proportion of that is going to basic science research to help patients and people and discover new knowledge and technologies. And it's great to have programs that kind of disks the probability that a great idea is a great idea doesn't make it to a patient. It's exciting to see how this fuels our small business innovation programs. There's some great technology both to existing small start ups, but then also forms new ones such as what we've seen with the 101 that have started in these two programs in particular.

I'll mention it again, products to market less than 8 years typical 17 from a translational setting. Some of you are likely to run a small fund either at a university or maybe a state-based innovation fund. Your Pittsburgh life sciences greenhouse, or one of the other Ben Franklins for example, you're probably saying, I really want a 10X on the return. This program right now for, if you apply those typical rates of return measures that are used by the broader venture community either public or private, you're basically looking at 35X for NCAI and reach combined. That's not bad. And then I guess the other kind of parting note that I just want to share is that there's a strong base of program managers emerging from these teams. Within the past year alone, I think 3 or 4 new publications have emerged. From Colorado spark, from B-BIC in Boston, there's one from the NCAI-CC team. We put together an overview so there are resources available, particularly in the journal of clinical and translational science. If you're really interested in this stuff about how you can improve program delivery, what are the types of metrics you should use, what are the key insights and perspectives from the leaders and these really great site teams. These journals are the place to go to kind of check out what the take-aways are. And with that, I will take any questions.

>> Thank you Alan for a great presentation. It is always good to hear you give sort of an overview of the network, but also, talking about why these outcomes and metrics and selection and standardization is so important. So we have been answering a bunch of questions. But there's one that it might be helpful for you to weigh on. Someone is asking if we have looked at innovator demographics in terms of that follow-on funding, gender, race, all of those factors. Do we have if I break-out of that if you can comment on that?

>> That's a really great question. We have started to investigate that data. In general, I can tell you that, once innovators reach the SBIR portfolio, just as a reference point, once you have your Phase I SBIR outcomes are the same for phase two transition and thereafter. There's no difference by gender or race. So, that means that really what we need to be focusing on when it comes to broader inclusion when it comes to these types of commercialization outcomes is getting the innovator to that first milestone. And in this program, largely we're seeing strong results, the hard part is that we have noticed that there are differences in the technology profiles by gender. So, we have a lot of the therapeutics are largely from men, and we have a strong base of research tools, diagnostics and assays from women. That's the only thing that I've observed. But we are starting to look across the portfolio. It's just hard to draw inferences because we have 186 projects. Take this with a grain of salt, it's just a signal nothing you can take

>> Thanks Alan we're trying to look at some of the data on the non-NIH side as well. That's a little tricky, it's always challenging to sort of figure out the attribution and all. Someone was asking about, you were talking about that milestone-driven work and fail-fast philosophy versus hypothesis driven research. So just wanted, there was a question about what does that mean? Can you clarify why hypothesis driven research should be avoided. Before I pass it to you I want to make a clarify indicates, we're not saying you should avoid hypothesis driven research, that's what most of NIH does, the kind of work we are supporting with the NIH Proof of Concept Network for those products development work, the milestone driven approach is what we are advocating for. But Alan, I'll let you comment on that.

>> Alan O'Connor: I think you're touching on it really well, there's a time and place for everything. This particular program is focused on the additional validation and maturation of a known technology. It's filling a gap. Because a lot of the basic science funding is looking at hypothesis driven research, generation of knowledge, right. It's not hard validating and further developing something that you've already discovered. The focus of this particular program is to do that validation and additional technology development work so that the idea moves forward into something that's a practical, usable tool, therapeutic device, et cetera. So that's a picture here. Hypothesis driven research, that is bread and butter for NIH. This program is distinct from that. Because it has a very particular lens on trying to essentially move that technology forward. That's the difference here.

>> Thank you. I think one -- let's see. I wanted to ABG knowledge Paula and Claire, they have put the link for some of the articles. Please take a look at those. Definitely a great resource. Someone was asking about some of the metrics that we are using and collecting. So is it possible for people to access those? I will try to think, I think some of those articles we might have those. But we can also think of ways to pull it out. Nothing is proprietary. We want everyone to use the same information.

>> Alan O'Connor: That's right. That's right. In response to this, I would say that all the papers that I mentioned we can go to the journal of clinical and translational science, or Paula Bates dropped in if you're on the news article she can get that to you. There's also a paper in nature reviews, drug discovery. So when it comes to this evaluation program, I'm in the process right now of crafting a full paper that describes our entire evaluation program as a reference tool. So if you drop me an email, I am more than happy to share with you the evaluation plan that I've already produced. And other materials. I can email it to you. But there's also a paper that's currently in development.

>> Thanks Alan, that 35X return on investment. How do you calculate that? Can you talk about how we are measuring it?

>> Absolutely. So basically it's a ballpark, it's a moving picture at any point in time. Essentially it's the kind of non-federal follow-on funding as a numerator. With the federal support for these programs as the denominator. So, the denominator, the full cost, so all like, I don't forget the -- I forget the number off the top of my head. But I think that REACH is -- the current cohort is like $4 million per site per year, or $1 million per site per year for four years. So basically we have that then for NCAI's it's a bit larger. So what we do is lump all of that together, that becomes the denominator, the numerator is the federal follow-on funding, that is about 35X, it changes that's the ballpark.

>> In terms of how do we know if the REACH project was evaluated, there's a lot validation, we check with the program and project managers at each of the Hubs, we validate with the innovator, we want to make sure we get the right attribution, we're very careful in making sure we have the correct attribution.

>> That's right. We have a lot of data science teams on our side that are essentially running crawls, they're getting all the validation data. Really the sites in collaboration with RTI at NIH, I mean, we've done a phenomenal job over the years getting all of this stuff down. And every now and then there will be something that we'll miss, that they'll remind us or vice versa. But largely we feel pretty good about our broader situational awareness.