

July 2, 2014 Webinar on I-Corps™ at NIH Program

Michael Weingarten: All right, so just a little bit of an overview of the program. This is a pilot program. It's a partnership between the NIH and the National Science Foundation. NSF has been running this program since 2011, and we're very happy that we have the opportunity to join them on this program.

It is a pilot, so initially there are going to be four participating institutes. That includes the NCI; the National Heart, Lung, and Blood Institute; National Institute for Neurological Disorders; and National Center for Advancing Translational Sciences.

And really, the goal of the I-Corps program is to help improve the commercialization of success of SBIR companies that go through the program. And specifically, to also help accelerate the development of the different technologies that are being funded through the SBR program at the four different institutes.

I liken I-Corps to a nine-week business strategy boot camp, where teams of scientists, SBIR teams, are taught and guided by a group of experienced faculty. Those will include accommodations to entrepreneurs as well as venture capitalists.

And really the goal of the nine-week program is to develop a viable business model around your technologies, focusing on key questions like what is the value proposition of your technology, and what is the revenue model that really supports the technology that you're developing.

I'll be getting into more details on that in just a minute. And really, the process that I-Corps uses to support really the fleshing out of this model, is to get, use the SBIR teams out of the lab and going out in the community and meeting with at least a hundred different customers or potential partners that will be critical players in either helping you develop a technology or be a customer for the technology.

And based on that feedback, you actually over the course of the nine weeks, you adjust your business strategy based on that direct customer feedback. And the format that is used is something called the business model canvas, which really is a framework for analyzing information to determine whether there's a product market fit between the technology you're developing and between what the market needs.

This should give you a little bit of an overview of what the business model canvas actually looks like. There are a total of nine different components. I'll just go over a couple of them right now, and Steve is going to be really delving into this as part of his presentation.

But probably one of the, probably the most important component of the business model canvas is the value proposition. Which one of your customer's problems are you trying to help solve? And which customer needs are you satisfying? And what are the features that are matched between the technology you're developing and the customer's needs?

Number two, who are the key customer segments that you're targeting? What are the problems that you're going to be fulfilling for those customers? And does the value proposition match those needs?

Who are the key partners, and what are the key activities that you need to follow to actually move your technology from the lab through development and ultimately to commercialization? And what is the revenue model? What are the pricing tactics?

I-Corps will also help SBIR companies assess the value of their intellectual property, develop strategies around reimbursement, but also deal with questions like regulatory risk.

And doing all these things is part of this nine-week class, so we think that will be very valuable based on really seeing the teams that have gone through this program in the past.

I-Corps will also help you evaluate the potential of your product for clinical utility at a very early stage, and identify finding these vehicles before they are needed.

So since July of 2007, over 300 teams from over a hundred universities across the country have actually gone through the I-Corps program at the National Science Foundation. NSF's program up until now has been focused on academic teams that are really at the pre-company phase, and more than 40% of those teams have gone on to start companies.

So teams have achieved a very high success rate also when competing for SBIR awards. So we're anticipating that one of the benefits of this program to your company is going to be it will really help inform your Phase II SBIR applications because of all the primary market research that you're going to be doing as part of the I-Corps program.

And the benefit, again, is the potential to improve your chances for competing for future SBIR awards.

So Steve Blank is the creator of the Lean Launch Pad and I-Corps methodology, we're really excited to have the opportunity to work with Steve on this program. Steve has actually been involved with eight different start-ups.

He is also currently offering courses on I-Corps at several different universities. And Steve's going to walk you through the I-Corps model now.

Steve Blank: Thank you, Michael. I assume you can hear me, everyone?

Christie Canaria: Yes.

Steve Blank: Great. So next slide, Christie. So the essential announcement that some of you might have read said the goal of the program is to accelerate the translation, go back one please, accelerate the translation of bio research for the marketplace by providing training to NIH funded SBIR and STTR grantees. Next slide.

So what that really means is we now know how to make early stage ventures more successful. This is a big idea because a few years ago, I don't think we could have made this claim because we didn't have enough evidence to support it.

And now after about 1500-plus teams, led by PIs, we actually know how to do this. And I'm going to share with you the insights of why, and then go through some of the details. Next slide.

As Michael said, this is a ten-week entrepreneurial emergent course to reduce commercialization risk, for therapeutics, diagnostics, devices, and other areas inside of NIH, SBIR, Phase I team. Next slide.

So let's talk a bit about what we know about commercialization. What we really now understand is, commercialization, that is translational medicine, actually has two components. One which you're probably intimately familiar with is advancing your science and technology.

But the other piece, the other piece that actually makes up commercialization, is the business model. Business model is a fancy word for we are customers, how will you get reimbursed, what are the IT issues, what are the regulatory risks? How and where and who is going to do clinical trials? What does it take to get your product out of the lab and to the bedside?

Greatly, commercialization efforts primarily focus on the science and technology. Our findings are that successful efforts that get through science to the bedside requires the team to do both. Next slide.

And the current thinking about translational medicines says we typically have centers or resources for you that help you focus on pushing the technology forward. You might be heavy in some facility or center that brings in experts for IT and regulatory issues and helps you with product development and product management, and you might even outsource some of the market research to consultants, and the goal is to either get something you could license or build a startup.

We now know that this is probably the least efficient way to commercialize technology. It's a big idea. It's not that we've been dumb before, not that anybody was trying to mislead us. It's just that we've now learned a lot more. Next slide.

Our insight is we need a formal path, a parallel path, for gathering evidence of commercialization. Next slide.

In the past, as I said, it started with realizing that for commercialization perhaps we should give teams physical space and equipment. And then as we got smarter over the time, let's give them some seed funding, and then let's give them mentorship and workshops and webinars, and then we would focus and pitch forward on technology process.

But what we now realize is this parallel path. Commercialization progress just hasn't been focused on as much of the technology progress. And that's what this class is about. We will teach you how to understand all the components necessary to commercialize your technology.

We will not make your technology better, except for the fact that what you learn, outside the building, will actually have an impact on what you think about how the technology is applied and used. Next slide.

So what we have found is that you definitely are the smartest person in your lab. Next.

But you're not smarter than the collective intelligence of your potential customers, partners, payors, and regulators. Next.

And you can't learn this by reading papers, listening to lectures. Next.

Or, and more importantly or, handing this off to proxy; whether the proxy is a consultant or a grant student, or anybody else. And here's the key idea about the class. You cannot do this learning by handing this to someone else and say, great questions, why don't you guys go figure it out and come back and tell it to me?

What we now know is that the team needs to be outside hearing the data first-hand. And the reason why is only the team that invented or is responsible for commercialization can make the decisions that's, wait a minute, we've now been hearing the same question fifteen times. Perhaps we ought to be asking some deeper one. Or perhaps, people have been asking for something we've had on the shelf in the lab; they don't like what we have now, but remember that thing that we worked on three years ago? Why don't we ask them if they'd be interested in that?

So what we need is a process for formalizing all these questions. And all these hypotheses about customers and regulation and reimbursement, etcetera. And we need a process for testing these hypotheses. Next.

I want to give you an example, before I get much deeper. We prototyped the class for UCSF, with twenty-five teams, 127 clinicians and researchers, last October. And one of the teams was headed up by Hobart Harris, the Chief of General Surgery for UCSF.

He wanted to prevent incisional hernias by having a device with some micro-particles like Fibrin Sealant. And his team also had another professor of surgery.

And of course, Hobart said, Steve, you know I've been working on this for three years, I'm the Head of Surgery, we'll take the class just so I can teach it to my students.

But obviously, it's not going to affect what I'm going to do because when I get out the building, we'll go through the process, this will be a no-brainer. Everybody will like just say it's a great idea, Hobart, you know, hope you go through the FDA process because we want to use it.

So let me show you what his team found out in Week Two, after talking to fourteen customers. This will just take two minutes. And play the video.

[Start of video]

So we're improving medical devices, and our product is going to treat hernias before they happen from people who have surgery. We had fourteen interviews, we changed our canvas a little bit, we are talking mostly with surgeons, so of the fourteen interviews that we did, over two-thirds surgeries were with actual surgeons.

What we said we had a product that might cost a \$1,000 that would prevent a hernia, that then they would pay actually \$20,000.00 to develop a product that would prevent a viral bio leak. So Hobart's pupils dilated at that point. Not the surgeons but his. If we could prevent the bio leak for that surgeon, they would pay a lot more money.

But for the product that we are proposing, they even thought that \$1,000 dollars might be too high for that, and that it would be too high a price to pay so these are things that we learned.

So do you feel like this was a worthwhile week? Did you learn something?

Oh it is, it probably saved us several years, no seriously, and our thought is that surgeons would embrace this, right. And so what we didn't realize was that they are not embracing it because they don't think that it is a problem that they have.

And what was the last phrase you used? You said it would save you several what?

Years.

[Applause]

[End of video]

Steve Blank: So for some of you, this might have been hard for you to see or hear, but the sum is that the team thought the reason the surgeons would use the product was because it was going to be a low cost device. But they found out literally in the second week of class, and this is something that I've been working on for years. That they found out that actually the real reasons surgeons would be interested is to prevent bio leaks and they would have paid 10x or 20x what the original team was thinking that they were going to offer.

I think this is kind of a dramatic example of what you'll find in the class. You will go in having a set of hypotheses about commercialization components, and you'll very quickly discover that some of them may be incorrect. And in the middle of the class, you'll get to change those hypotheses and pose new ones.

So the insight is commercialization requires outward focus and requires focus by the primary members of the team. Next slide.

So if you think about how we used to think about commercialization, with this internal focus, click, click, we're going to add a parallel outward-facing component to the commercialization process.

Like inward-facing versus outward facing. Next.

And basically, we're going to have you get out of the building, instead of bringing these experts in; we're going to have the team get out and personally, with first-hand evidence, acquire data which either validates or invalidates and requires evidence that validates or invalidates their hypotheses. Next.

And besides just changing your commercial hypotheses, the surprise to us actually was doing this process also affects your biological and clinical hypotheses. And that's a big idea. We just thought it would maybe reimbursement, etc.

But it affects actually all components, clinical utility, the data and quality of the data, how reimbursement works, and all this new data will actually make you go back and think about those biological and clinical hypotheses we started with. Next.

So let me give you one more last example. This was another UCSF team who was doing a magnetic compression device for [anesthestamosis], and it was led by Mike Harrison, the inventor of fetal surgery, along with a bunch of other surgery residents and device engineers.

Let's see if we can play this one and hopefully the audio's a bit better.

And they were mentioning Mike why PIs who'd been out of the building, rather than just proxies. Mike's been doing this for thirty years.

[Start of video]

The PIs whose invention this is, or idea this is, only you're capable of understanding how to pivot or iterate when someone says well how come you're not doing X? You go, really? There's a problem? I've been working on Y. Or, oh, I've had X on the shelf for twelve years; I never thought that would be a product or something we can offer.

Is there anybody else who now actually thinks back to what they were doing in Week One with like kind of shock, and have discovered they're on a different path?

We started in where we thought we were creating a device that was faster, cheaper, and better than what other people had. Meeting 10 to 15 patients and doing outreach to different associations that have colorectal cancer. Sitting with the patient and finding out, my God, I'm so afraid of the second operation, or I've had two operations, or my mother had a second operation and now she's demented or has Alzheimer's as a result of the anesthesia. That was a major change.

So for the rest of you, you want to understand because I hear this in almost every class the push back of I'm the darned PI, why do I have, you know, that's what my grad students are supposed to be doing. Or why on Earth should I be talking to a hundred customers; I could talk to three and get the same data.

And with three, you direct them in the direction that you want the results to go. So I would direct you and say well, if you could get this operation done and your recovery time would be four days instead of seven days, or you'd have less pain, and they all nod their heads. We really never got into well what happens if the device leaks because I never brought it up.

There's no magic in a hundred, in this class. But I got to tell you, the odds of you getting sufficient data out of three or ten customers is probably zero.

[End of video]

Steve Blank: So the goal of this I-Corps program is to help you and your team define clinical utility now, before you actually spend millions of dollars. You do this by understanding your core customers and the sales and marketing process required for initial clinical sales.

We help you personally assess IP and regulatory risk before you design and build, and to gather data essential to understand the customer partnerships with either pharma or device manufacturers, before doing the science. And identify financing vehicles, how hard, how easy, who they are, way before you're going to need them. And in doing so it will adequately prepare you and the potential investor for a fruitful collaboration.

Now let me talk about the classes in some detail. Next slide. The teams are teams of three, as Michael has said and I think the application describes, it's open to active NIH SBIR and STTR Phase I grantees. These will be teams of three; a C-level officer of your company, industry expert, and the program director or PI. Next slide.

The class details, the class starts with a three-day course October sixth through eighth in Bethesda, and then you'll be getting out of the building every week and talking to ten to fifteen customers a week.

But you'll also have six weekly follow along webinars where you stand and deliver a summary of the experiments you ran outside the building, and what you learned in talking to customers and partners.

There's another two-day get together talk in Bethesda, December ninth and tenth, where you'll present the summary of what you learned in those ten weeks. And as I said, it requires getting out of the lab.

There's at least fifteen hours of work per week, and every team will talk to a hundred customers and partners in those ten weeks. And the learning will be probably the fastest that you've been learning since grad school. Next.

Key design components of the class. What we now know is the best way to organize for commercialization is to have a framework to kind of keep score and measure our results. It's experiential. This is not a learn by lecture class; this is a learn by doing class. And for those of you who have been through that, you will remember what learn by doing is because you will be out every week getting your head spun around as you actually learn things about how to actually commercialize your technology.

It's evidence-based. You'll start with a series of hypotheses about the commercialization components, but what you're essentially doing is what you do in the lab. You're setting up hypotheses, running experiments, gathering data, getting some insight and either validating or modifying the hypotheses.

And this is taught by a team, and we'll explain who the team is, of experienced both entrepreneurs and more importantly domain experts; you know, like scientists. Next.

So let me just again repeat the framework, Michael mentioned this. We use something called the business model canvas to articulate your initial hypotheses and give you kind of a scorecard. We use a process of getting out of your lab called customer development, where you test these hypotheses in front of customers.

And three is we use active development to actually incrementally and iterably build either physical or virtual prototypes to put in front of customers to help test some of these hypotheses. Next.

Michael mentioned the business model canvas, this is just a visual diagram of all the components that you need to think about.

And for life sciences, for therapeutics and diagnostics and devices and digital help, we've modified it to talk about reimbursement and regulation of IP and clinical trials. But essentially, this is the framework you'll be going back to every week. Next.

And the experiential component, we keep mentioning the number of hours per week just so we can make sure no one's surprised. There's a formal methodology for customer interaction, and this focus is on what we call minimum viable product that is having a minimum either concept or physical prototype, if it's a device, in front of customers.

And as we accept the notion that they're hypotheses are more than likely incorrect. And when they are, instead of declaring failure of the commercialization, we typically do something called the pivot; which is just a subset of change from one or more of those components of that business model thing.

Well this might be the wrong customer, or as you've heard from the Vitruvian guys, it's, gee I guess customers don't really care about price, they actually care about bio leakage. Now those are some major insights that change your hypotheses.

And so getting out the building is a really big idea. It might seem obviously, or why should we do it; it literally accelerates the speed of translation in a way that you just can't imagine, so you do it. Next.

So teams present weekly, here's an example of a team's, one of their clients, they stand up, and you will stand up in front of your peers. One of the concerns we hear is, gee I don't want to disclose my IP. You're not disclosing IP; you're disclosing your learning about commercialization, about reimbursement, or about the fit between your product and the customer segments, etcetera.

And you're going to be doing this every week as we march through getting evidence about each component in the business model. Next.

And you will be updating this business model canvas, if you can see the boxes on the red, just simply show you what this team invalidated in the week. They thought their customer segments were farmer or probiotics manufacturers; they got enough data to kind of say perhaps those aren't customer segments, and they're moving on and explaining what they learned that week. And so week after week, the canvases kind of build up, so that you can actually see the buildup of your progress. Next.

So UCSF, as I mentioned, was the prototype for this class, life science teams, they spoke to an aggregate 2355 customers. They tested close to a thousand hypotheses, and actually changed about half of them, 423 what we call pivots. And these were just tremendous feats, and Karl will be going into detail about one of them. Next.

So, Karl, are you online?

Karl: Yes I am, Steve.

Steve Blank: Okay, let me mute my mike. And so what Karl's going to talk about is Zephyrus Biosciences, one of those UCSF teams, and I think we just want to give you a feel for, this is their final lessons learned presentation, of what they learned during the class.

Karl: Thank you, Steve. This is a great example of a team because it involved Amy, who is the PI from the lab; Kelly Gardner, a first-time entrepreneur outdoor lab; but most importantly, Josh is a fifteen-year, very experienced industry veteran. And I'll describe first what the company does. Next slide.

So we're all aware that there are separate techniques for measuring proteins; you can get bulk measurements or self-surface proteins. Next slide.

But what Zephyrus did is exploit a technology out of Amy's lab to look at the protein expression at the single-cell level by combining microfluidics with a device and with the technology.

And this was something that was well-worked out in the lab, and the question was how to commercialize it. And at the start, because Josh had built many devices before and exploited technologies like this, they were all set to build a big, fully integrated machine. Next slide.

But what they did is they started, as Steve mentioned, they started going out and talking to different people to find out who cares, how would they use it, and what would be the most useful way to develop the technology. Next slide.

And in this process, they actually generated a hypothesis, and they talked to people, and they would actively test this. And they had a pivot right away because some of the most interested parties actually didn't want a fully automated machine, even though they could build something at the right price point in terms of signing, it wasn't something that really created the type of value, the highest level of value. Next slide.

But we know that there's a huge scientific and also commercial need for this type of technology, because we can already measure RNA and DNA at the single-cell level, but we don't have a way to measure proteins at the single-cell level.

And we know that the expression of the proteins is the most critical thing in terms of generating, at the cellular level, what actually is going on inside the cell. You need to know what the proteins are doing. Next slide.

So there clearly was a need, but the need that I just stated is a broad need. There's no archetype, there's no specific type of customer that you can identify just because there's this broad need. Next slide.

So what they did is they focused in, finally, on stem cell researchers and cancer researchers as the most important, highest value type of customer. And as a good example of this, many of you know scientifically that the phosphorylation state of a different protein, you can have different antibodies; one which will recognize the phosphorylate state, one which won't.

So you can not only measure, using the technology at the cell level, the proteins, but you can actually measure differentiate between the phosphorylation state. And this was a very high need, and it was something that customers really would value. Next slide.

And at that point, they began to talk with the industry incumbents. Because the idea was, we're going to build this big integrated machine, we're going to need to get to a certain level of revenues, and having a fully integrated machine allows us to be industrial-relevant.

But what they found out, by talking to industry incumbents, is that there were already machines out there. And the level of revenues that they needed to reach to be important to these incumbents was actually not the tens of millions or hundreds of millions of dollars, but actually ten million dollars would make them quite important and would actually create value, rather than them needing a fully integrated machine. Next slide.

And just to give you an idea of, so the most important thing about this example is they thought they knew what they had to do, what the resources would be, and how much they would need to spend.

But by the end of the class, they'd clearly identified where they were starting and where they wanted to head. And were able to develop a path, advance through these slides, where they were able in just, next slide...

So here you see the timeline of what they're able to do after they took the course. They're able to get up to a very, very important financial point, and actually in eighteen months. Rather than raising the money and then figuring out what to do, they were able to raise the right amount of money and be able to have a clear operational plan from day one what they needed to execute and how they would create value in their company. Next slide.

And since the Lean Launchpad, they actually are closing this week on a one-half million dollar investment round, and importantly, they're able to attract someone to be chairman of the board who has been a CEO and founder of a company in their same state that reached a billion dollars in value.

And although this is not a therapeutic example, this approach of going out, getting out of the building, doing interviews, working with the Lean Launchpad, also will work for therapeutic programs to create value on a timeline of eighteen months, which is not what most people think is possible.

But using this process, you can find a path forward to develop your technology in a way, even for a therapeutic, we can create value within eighteen months and have a good operational plan which had a business case for investment.

So my background is fifteen years as a venture capitalist, dozens of companies, and this is the type of information that gets your funded. More importantly, once you get funded, helps you build a successful company.

Thank you.

Steve Blank: Let me just quickly mention who the teaching team is, Karl talked a little bit about himself. I'm Steve Blank, I did eight startups in twenty-one years; spent the last thirteen years teaching at Berkeley, Columbia, Stanford, and UCSF. I developed this methodology and was lucky enough to be associated with the rest of the teaching team. Next slide.

Karl just mentioned who he is. He runs the Therapeutic Curriculum. Founder of a couple of venture capital firms, and his specialty is the early-stage company formation and biotech. Next.

Allan May is the founder and chairman of Life Science Angels, managing partner was a managing partner with Emergent Medical Partners, VC firm, a founder, CEO, and was on the board of over thirty companies who have done over a hundred investments. And probably the leading device commercialization expert in the U.S. Next.

Bob Morrow is the Diagnostics Curriculum Director. He was the former head of corp and business development at Bio-Rad Labs. Personally founded three life science companies, has been teaching this class for the NSF for the last three years.

And so that's who we are. Next slide.

So how to apply, and I think Andrew's going to go into some detail here, but the course description is online, so is the application info. There's key dates, this webinar, but the applications are due August 7, the class starts October 6, and you get your life back on December 10. So Michael and I esteem thank you for the opportunity.

Andy Kurtz: Thanks, Steve, this is Andy Kurtz. So hopefully by now, Michael and Steve and Karl have convinced you that this is unlike anything you've ever seen so far in the area of entrepreneurship training.

And so at this point what I will do is take you through the process of what you need to do to actually apply to the program to participate in the upcoming pilot cohort, which will be the very first time we've offered this at the NIH.

The way that the program is going to be supported will be by way of administrative supplement awards to existing Phase I SBIR and STTR grants. The NIH will provide awards up to \$25,000 dollars, again to a pilot cohort of twenty-four currently funded SBIR and STTR Phase I grantees, to support entrepreneurial training as an I-Corps program.

As Steve mentioned, the program is set up to provide three member project teams with access to instruction and mentoring, that's really designed to accelerate the translation of these projects and technologies that we have funded through the SBIR and STTR program.

You must apply to participate in this program. The application is required and they are due by August seventh. You do not need to wait until August seventh to apply, and in fact, we would encourage folks to consider submitting early.

You do actually have to have an active award before you can apply, and we will not accept application beyond August seventh.

We will be selecting the course participants on a competitive basis. We expect that the folks that will be part of the first cohort will be notified sometime around mid-September.

We recently published the program announcement announcing the I-Corps program at NIH; we did that on June eighteenth. This provides you with the URL for that program announcement; the program announcement number is circled there at the bottom. P A R fourteen dash two six one.

Most of what I'll be going over today is taken directly from this announcement, but hopefully I'll be providing some additional information on some questions you may have. We also have a new website, or a new webpage on our NCI, SBIR website which provides an overview of the I-

Corps program at the NIH and will soon provide a number of links with some additional information about the program.

Currently we have a link to the funding announcement that I just provided to you. Very soon, we will have a link to the draft course syllabus. So you can take a look and see what each of the lectures will cover and how the course will be set up.

Who is eligible to participate in the program? So I already said it's open to currently funded SBIR and STTR Phase I grantees, only from one of the four participating institutes and centers that are part of this pilot. So those again are the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Institute for Neurological Disorders and Stroke; and the National Center for Advancing Translational Sciences.

Your predicate grant awards must extend at least through December 31, 2014 in order to be eligible, and that award should have remaining budget and R&D activities that extend at least through that date. We are not accepting applications from contractors as part of this pilot cohort.

Fast Track grantees are eligible to apply provided that the grant is currently in the Phase I portion of the award, and also that that Phase I grant meets the criteria of being active through December thirty-first of this year.

So first question you may be thinking about, if you have a current Phase I award, might be getting ready to end, you may be wanting to know may I apply for a no-cost extension to meet the eligibility requirements?

So grantees should not request an extension solely for the purpose of participating in the I-Corps program. You should only request a no-cost extension if you need additional time to extend your grant budget and complete R&D activities.

If this is the scenario that you're facing, I would encourage you to get on the phone with your program officer and discuss whether or not a no-cost extension is appropriate to your current award.

Another question, is the I-Corps training program only for new companies and/or inexperienced teams? So the answer to this question is no, not really, not necessarily. The pilot program is specifically set up and intended to instruct teams that are developing early stage Phase I projects in order to help inform the next steps along the pathway toward commercialization.

And although we do expect teams with limited commercialization experience to perhaps benefit the most, we fully expect that all of the teams will take away some valuable general lessons, as well as a number of specific insights around their particular technology and innovation.

And again, those insights will come through the customer discovery that Steve has explained.

Again, to participate in the program, you're required to designate a three-member project team. Those roles include a C-level corporate officer, an industry expert, and a principal investigator on the Phase I award.

Just to give you a little bit more background on the roles and responsibilities of each of those team members. So the C-level corporate officers should be either the Chief Executive Officer, the CEO, the Chief Operating Officer, or some other similar level corporate level officer within the company.

It's very important that that person has a relevant knowledge of the technology, as well as a very deep commitment to investigate the commercial landscape around the technology, and perhaps most importantly that that person has substantial decision-making authority within the company.

I think as Steve explained, the people that are out doing the interviews need to be the ones that have the power to pivot and to make those decisions and make substitute changes in the commercialization strategy based on the hypotheses that are being tested and the data that's being taken in.

The industry expert on the team really should be someone with experience in translating technologies to the marketplace. There is some flexibility here in terms of how that person is identified. It could be someone that already has an established relationship within the company.

So for example, it could be a senior, an experienced board member that might be able to fill that role, or in other cases, it could be someone that is selected that can identify from outside the company that is going to come and participate as a third-party resource and mentor, in a sense, to the team.

And again, the principal investigator, in general, should be the person who is formally listed on the Phase I award, formally listed on the NIH Phase I award.

Very important to reiterate this one more time. I think you've seen this two or three times already, but each of the three team members should plan to spend at least ten to fifteen hours per week on the I-Corps activities and learning exercises for the full duration of the program.

Again, the participants in the course are required to get out of the lab, and gather information by conducting a large number of interviews. Again, when we say large number, meaning a hundred or more interviews with potential customers, strategic partners, and other third-party stakeholders. And hopefully, by now you appreciate this last statement.

That this level of commitment and actually getting out and doing those interviews are absolutely required to reap the benefits of the I-Corps training program. So this is not something that can be negotiated.

A couple of questions about the teams. So who might make for a good industry expert on the team? One of the things to consider is that this ideally would be someone who has the right Rolodex that would include industry contacts in your area of commercialization. And this will

really become critical as you're getting out of the lab and trying to set up these interviews in order to flesh out the various elements of the business model canvas.

Ideally, this would be someone who has entrepreneurial experience previously, and someone who has all-systems specific business domain expertise within your sector.

Another question, is there any flexibility in how the three required roles are filled on the I-Corps team? The answer is yes. We fully expect that there may be some cases, for example, in which the principal investigator and the CEO may be the same person.

And so in those cases, we would recommend that you consider designated an alternate corporate level officer to lead the team. In other cases, it could be appropriate to do the opposite, just select another senior level scientist on the team to serve in the PI role, at least for the purpose of the I-Corps team.

We do expect that all of the teams will include three members, and that they will be led by someone within the company with decision-making authority, again, so that they would have the necessary authority to make pivots and to make changes to the commercialization strategy as they're needed.

And I would encourage you to considering applying to the program, if you have questions about the team, to reach out to NIH program staff to discuss your specific situation and who might be the most appropriate folks to fill these roles.

Who are those people? Depending on the institute that you received your Phase I award from, you can find the different institute and center contacts here. Christie Canaria, who is leading our call today, is our contact here at the NCI. Jennifer Shieh is the point of contact at the National Heart, Lung, and Blood Institute. Stephanie Fertig is the contact at NINDS. And Lili Portilla the contact for NCATS.

All of these folks are participating in the webinar today, and if you have specific questions for a particular institute, we can try to respond to those at the end.

Just a couple of notes about the actual written application that you need to submit to us. So there are four elements of what we call the research strategy section that is limited to six pages; relatively short application.

The first part of that should be a summary of the predicate Phase I grant, which really just includes a description of the project aims and a summary of the progress that you've achieved to-date.

The second section should include a description of the I-Corps team, which should include the rationale for the team members that you've selected, particularly noting their expertise and experience and why they are ready and appropriate to fulfill the role that you've designated for them.

We would like for you to provide some statements and any other evidence that you can provide to indicate your strong commitment to the very time-intensive program. And we really would like to see some evidence and hear some discussion from the team about the willingness to pivot kind of based on the knowledge that's gained during the course of the I-Corps program.

We ask that you also provide a section on the potential commercial impact of the technology, at least to the extent that you understand it today. That should include a brief profile of who you might expect might be a difficult customer, some description of that customer's needs, and how you expect that they're going to be met by your proposed innovation.

We also would like you to sort of explain to us how does customer currently meet those needs, and then describe in a little bit more detail the value proposition that's offered by your proposed innovation or your product.

And then finally, that section should include some forward looking plans for the overall project, describe to us the stage of development for your Phase I project, and explain at a high level at least the proof of concept that you will have demonstrated by the end of the Phase I. And then explain and discuss next steps that you believe will be necessary to advance the project closer to commercialization.

Another question about the budget that you'll be requesting to support the I-Corps activities; what should be included in the budget? The answer is that the budget should only include direct costs that are associated with completing the I-Corps program. Some of the things that should go in there will include a \$1500 dollar registration for each of the three team members, so that covers \$4500 dollars right off the bat.

You may request travel costs for the two trips that are required to the course site for the entire three-member team. So again, that will be at the beginning of the course, the three-day kick off event, and then the two-day wrap-up at the end.

You may also request travel costs to conduct interviews to travel to meet customers, partners, other key stakeholders that you'll need to talk to as part of the hypothesis validation to flesh out the business model canvas.

And then any additional budget that is remaining, up to \$25,000 total, can be allocated to personnel time for the team members that are participating.

A couple of things that you may not request. You may not request any indirect costs as part of this supplement award, and you also may not request any costs to cover R&D. All of the R&D that's being supported should come from the parent award on the grant.

So what will happen after we receive your application is a little bit of a unique review process for these supplement applications. So the first step involves, I should say that the applications will be reviewed in two stages.

The first step will involve evaluation by NIH staff of the written application, in which we will consider whether the team's participation in the I-Corps program will increase the parent award's overall impact. And as part of that we'll be looking at the things that I just mentioned to you about the rationale for who is on the team and the team's overall commitment to the program, and the willingness to pivot based on the information that's learned.

On this first section, I would direct you to the review criteria that we listed under Sections 5.1 and the Funding Announcement. We have identified each of the key points that we are looking for you to address, and set up provide essentially the road map for you to construct your application, making sure that you hit all of those key points.

In the second stage of the review, we will select what we think are the most responsive and best-qualified candidates for a follow-up stage of review, which will involve NIH staff contacting those candidates to seek clarification on some of the things that were within the written application, and then also to provide responses, to get responses from you, the applicant, some additional questions.

And again, we have listed some of these difficult questions under that same Section 5.1, and I would encourage you to consider your responses to those questions as you're drafting your application, as you're drafting your written application to us.

This is review at this point, but just to quickly go over the format again. The class will last from October sixth through December tenth. It includes a total of eleven sessions. The first kick-off session, the opening class, is three days long, will be held here in the Bethesda area at the Microsoft Building in Chevy Chase, Maryland.

The online classes will happen every Tuesday, nearly every Tuesday, during the months of October and November, and then the final presentation again will happen here in person on December ninth and tenth.

A couple of minutes about the online portion of the course. So during the course of the program, online content will be hosted either by the NIH or by a designee of the NIH, in order to track the progress of each of the teams. And it's also important to note that each team's progress will also then be shared with the entire cohort of I-Corps teams that are part of this pilot, in order to facilitate group learning.

And that really brings me to a couple of key points about the teaching philosophy of the course, the way it's been run and the way this iteration will be run. Which is that a key part of the class is not only about what you are doing, but also in seeing how each of the various teams solve similar problems through listening how the instructors and the teaching teams coach and critique the project teams that come through the class.

The success of the team in the end really is less about the original idea that you have coming into the course, and much more about the learning and the discovery and the execution as far as what happens during the course itself.

Another important part of the course is that the program is intended to provide a forum for you as a participant to bounce ideas off your peers. So you're not only learning through the customer interviews that you're doing, but you're also learning from each other.

This does sometimes bring up a question about confidentiality, so you may be wondering will my intellectual property be protected when I discuss my ideas with the class. So it's really important to emphasize that the customer discovery process does not require that you share the specifics of your IP.

But again you will be sharing with the class what you've learned on a weekly basis about reimbursement, regulation, customers, partners, and all the other elements of the business model canvas.

And you need to be aware that all of your presentations, customer discovery and validation notes, and your iterated business model canvas each week will be shared with the teaching team. So since we do not provide legal advice, if you have specific legal questions, we would encourage you to consult with an IP attorney before you engage in this course.

Some of the expected outcomes that we hope for by the end, certainly we expect that you'll have an enhanced understanding of your business model canvas. As you learn along the way, we expect that you may have some significantly refined commercialization plans by the end of the course, and perhaps there have been some well-informed pivots along the way in the overall commercialization strategy.

Ultimately, one of our very tangible goals with this pilot program is that will result in some stronger Phase II SBIR and STTR applications coming into the NIH after the program ends.

Again, this is a pilot program. We fully anticipate that we will be seeking some outcomes data from the pilot and that we'll be carefully evaluating those outcomes before the NIH would consider a possible continuation of the program.

Some of those outcomes data will be sought from you immediately following the course. Those activities may include doing some customer evaluation surveys, interviews, and possibly taking some other data both immediately following the course and then perhaps even at some later time point after the course is over.

It's very important for you to recognize that as part of the pilot cohort, your feedback will be critical to us, and so if you do participate, we will be very anxious to hear your thoughts and impressions. And not only that, but just see the very tangible progress that you've made as part of the course.

[End of Recording]