July 2014 Webinar on I-Corps™ at NIH Program
Q&A

Christie Canaria: Thank you everyone for staying with us throughout the program today, I encourage you again to submit your questions using the Q&A chat box. We've been collecting them throughout the presentation today and we'll be answering a few of them here.

Michael Weingarten: This is Michael Weingarten again, and I'll just start going through some of the questions and we'll be providing answers. So the first question is, in addition to the Lean Start-Up Curriculum, will there be a separate component addressing regulatory issues as it relates to life sciences and medical device companies?

So the answer is yes, that is actually a part of the curriculum itself, Steve, could you address exactly, I know you have specific lectures on the topic of regulatory as well as reimbursement.

Steve Blank: Yes, obviously in life sciences, regulatory is a critical component of commercialization and specifically regulatory issues differ from therapeutics to devices to digital health, etc. And each one of the instructors will be addressing regulatory issues as an item as they go through the class, we cover it in activities, we cover it in resources, we cover it multiple times throughout the class, so the answer is yes.

Michael Weingarten: Okay, thank you very much. I'd also like to introduce the representatives from the other Institutes that are on the line in case anyone wants to pose questions that are Institute-specific. We have Lili Portilla, who is on the line from NCATS, the National Center for Advancing Translational Sciences, we have Jennifer Shieh and Kurt Marek from the National Heart, Lung and Blood Institute, and we also have Stephanie Fertig from the National Institute of Neurological Disorders and Stroke.

Next question, our university has participated several times in NSF I-Corp and has really seen a benefit for our PIs, even if they haven't started the company. Is there any thought to expanding the NIH version to allow academics that don't have an SBIR to participate in the program.

So actually, NHLBI has recently launched a program called REACH that addresses this. So Jennifer, she is on the line, can you address this question.

Jennifer Shieh: First, I just wanted to say that, right now, this is just a pilot program for the NIH SBIR and STTR Program but there are entrepreneurial educational opportunities for academics that aren't necessarily through I-Corp specifically but through programs, for example, NHLBI has the NIH Centers for Accelerated Innovation. It's aimed at pre-SBIR, pre-company stage innovators and then also the upcoming REACH Hubs (Research Evaluation and Commercialization Hub) Program will again be targeted towards pre-company stage innovators and will provide some educational opportunities but not necessarily through I-Corp.

Christie Canaria: This is Christie, again and I want to also remind you that we are going to run a poll and we'd appreciate if you answer the poll. It will help inform how the program runs in its next iteration as well as your feedback. It should be really quick.

Michael Weingarten: Okay so next question, who selects the group of 100 customers that are interviewed?

So the answer is that it is really done by the teams that go through the program, the 3-person teams. That is one of the reasons why having an industry expert as part of your team is so important, with some knowledge of the industry that is going to be targeted. One of the things that we are also looking at is trying to identify a set of advisors as part of this program that can be available to the teams that are going through it. And they can potentially provide advice on potential customers that teams might interact with. However, again, that identification is led by the teams.

Andy Kurtz: Steve, can you say a word about the expectations for the three-day kick off in terms of the initial interviews that they will be expected to conduct?

Steve Blank: We expect teams to come in with a list of potential interviewees but more importantly, we expect the teams to come in having been done ten interviews and while we understand that you won't exactly know the outcome of interview format it will actually have you show up to class going "well we got thrown out" or "we got answers we didn't like" or "we weren't sure what questions to ask." And so by the time you show up in class, you've already hit the ground running and we usually put you through a workshop on how to do efficient customer discovery interviews. But by then, you've already had some hands-on, having done it, seeing those best practices versus what you did. And ultimately that will hone your skills in both customer discovery and how to generate the right contact. In the meantime, your teaching team and your mentors are helping and guiding you to where the appropriate ex customers contact might be. I should also remind you that in your professional life, you run into tens if not hundreds of people at conferences and other areas that would be happy to talk to you. So getting the 100 interviews might be easier than you think.

Michael Weingarten: Thank you very much, Steve. So the next question is, the UCSF summary slide was great, it would be interesting to know, of those that were a go how many of the companies were funded or currently operational that went through the initial program at UCSF? Steve, let me throw that question back to you, do you have any sense of how many of the teams actually became companies out of that class?

Steve Blank: You know, I don't track that Michael. Karl, how many have you seen in the therapeutics area – were there about three or four?

Karl Handelsman: Yes, three of them. In addition to the three that are funded currently, counting the one this week, there are other ones that are continuing to iterate and work on certain things that they needed to develop more before they could eventually launch the company.

Steve Blank: And was that just in the therapeutics area, Karl or was that all 25?

Karl Handelsman: Yes, that is just therapeutics. Most importantly, I'd like to point out that funding is only useful if you have an operational plan that moves you forward to create real value. So many times, companies get funded and you convince the funder that you know what you're talking about but they are not your customer. So some of the teams that are continuing to work and not having done the funding is because they are actually building the business case so that they can generate not only the business case which then leads to the money.

Michael Weingarten: Okay, thanks very much, Karl that is very helpful. Okay, next question, will the first NIH I-Corp be held at UCSF and taught by this all-star team? Actually, as Andy mentioned, the first class will be taught here in Bethesda, MD. It will be taught by the team that Steve went through including Karl, Todd Morrill, and Allan May. So yes, we do have the all-star team that will be teaching.

Steve Blank: And a couple of other surprise guests.

Michael Weingarten: Yes, yes, right. Okay, next question, do the teams in the UCSF cohort have SBIR funding and have they found the pipeline still fit their goals?

So most of the teams that went through the UCSF cohort, I believe, and Steve correct me if I'm wrong, were still at the pre-company phase but there were several companies, we did have 1 or 2 SBIR-funded companies that did go through the program and gave us very positive feedback on what they learned coming out of it and did feel that it helped inform their future Phase 2 application based on all the customer discovery work and the business model strategy they developed. Do you have anything else to say to this, Steve?

Steve Blank: We have something like 78 applicants for the 25 slots. We discovered that two of the teams that were participating were teams sneaking out of Genentech at night so we had a variety of teams in various stages of commercialization. So unlike this program, Michael was correct, they varied from teams who were forming to teams who already had existing companies with existing hypotheses and existing funding. And I'd say across the board the results were about the same, meaning that everyone felt that they got a much deeper understanding of the commercialization process. The only issue that existing funding teams do find is that you already committed to both investors and the team itself about a direction and so getting out of the building and hearing data that contradicts the direction you've already picked is sometimes hard to do psychologically. There is no technical reason why it's harder but you mentally picked the path. So if you are not prepared to both test and abandon some preconceived hypotheses, this is probably the wrong class. This is not a class for execution; this is a class for learning and discovery, and gathering evidence that your hypotheses are right and if not, pivoting and changing them. Thank you, Michael.

Jennifer Shieh: Hey Michael, this is Jennifer with NHLBI, I just wanted to add one other note about that NIH doesn't currently have more I-Corp opportunities, but I see a lot of questions about are there ways that people can access this curriculum even if they are not an SBIR awardee or if they are not funded by NIH or one of the particular ICs that is participating. So I wanted to bring up that the NSF I-Corp Program has regional nodes, there are 5 I believe, there's an NYC regional innovation node, so all researchers, regardless of the funding source, universities that are from New York, New Jersey, Connecticut, Pennsylvania can apply for a free regional I-Corp cohort this fall. There is also a node in the DC/Maryland/Virginia area, in the Bay Area, in

Michigan, and in Georgia Tech. So if you look that up information, if you are not eligible for this specific pilot, you might be able to find some regional classes.

Michael Weingarten: Thank you, Jennifer. Just to bring up that point again, this is a pilot, so this will be the first cohort of SBIR companies that go through this; we'll be selecting a total of 24 companies across the four different Institutes. The goal at the end of the program is to assess how successful the program has been and if we are getting really positive feedback from the teams as we expect we will then the goal would be to continue this pilot going forward and to work to expand the current pilot to other Institutes.

Next question, what does currently funded SBIR and STTR Phase I mean? And does that not mean past recipients of a Phase 1? Andy, would you like to talk about the eligibility criteria again?

Andy Kurtz: Past recipients whose awards have ended are not eligible. So the award must be active, you must be currently working on the activities as part of the award and the end date for the award must extend beyond or at least to December 31 of this year. If you have specific questions about your particular award and whether or not an eligible predicate award, I would encourage you to reach out to your Program Officer.

Michael Weingarten: Okay, thank you. Some additional questions, does the submission go through Grants.gov.

Andy, can you answer that? Well, actually, we'll come back to that question in just a second.

So, why only these four Institutes?

Again, this is a pilot, so we are initially trying out with the four Institutes now and the goal, if it's successful, to expand from there.

Let's see, will NIH Program Officers be able to attend the course?

There are some limitations on seating; however, we are going to be inviting the Program Directors responsible for each of the different companies that are going to be going through the program. The Program Directors will all be invited to attend the program, in addition to the companies that are going to be participating.

Roughly, how many Phase I participants are currently eligible?

I actually don't know the exact number on that. I'm anticipating it's probably on the order of maybe about a hundred and fifty or so companies that would be eligible across the four different Institutes, but that is just an estimate.

Next question is would you consider a two person team if they had enough past experience at covering the three roles?

You know, I think we'd like to stick to the plan here in terms of the three person team requirement, each of those roles are really important. Both having the senior level executive from the company who is a decision maker, the principal investigator, and then also an industry expert. So I think we are going to be sticking to those guidelines. If you do want to discuss your specific situation with us, I encourage you to shoot us an email to the email address, which is NCISBIR@mail.nih.gov. We'd be happy to respond, but in general we're going to be sticking to those requirements.

Let's see… next question, are other NIH Institutes planning to partner with NSF for similar activities? Also which I-Corps site will coordinate the educational activities described in the presentation?

So, actually, all… as I mentioned this is a pilot activity with the four Institutes and I think it will expand after the pilot. All five NSF I-Corps Nodes will actually be involved in this initial pilot course. So, Maryland is providing a coordinating role but all of the different NSF I-Corps Nodes are going to be participating. And the reason that's being done is that the goal is to have a number of the Nodes also be going through a training from this course so that the course can then be expanded from just the initial course. Steve and Steve's team are going to be developing an educational curriculum from this class, which will enable us to offer the course more broadly in the future.

Andy Kurtz: We'll quickly come back to the question about the submission of the application. So, the supplement applications are submitted through Grants.gov. I would refer you to the program announcement under section 4.2, which is content and form of application submission. There is a section under there that is titled "instructions for submissions using Grants.gov/apply for electronic based submissions." You can find more instructions there, on the electronic submission process. If you still have additional questions I would encourage you to reach out to the grant management contact, who are listed in the funding announcement. They are listed near the end of the funding announcement, just after each of the scientific and programmatic contacts.

Michael Weingarten: Okay, so the final question that we have is can a technology transfer person with a rolodex and entrepreneurial experience serve as the industry expert on the three member team?

I think that can work as long as the technology transfer person has some contacts and experience in the industry area that's being targeted, because that's the role that that individual will be playing as part of the team.

So I think that those are all the questions that we have right now. Again, we want to thank everyone for joining us and for participating in the webinar. We encourage eligible companies to apply to the program. Again, the final receipt date, due date, for applications is August 7th. We encourage companies that are able to, to submit their applications early because we will be able to review them as soon as they come in. And also encourage you to talk with the point of contact at the Institute that you're being funded by to cover any questions that you might have. And to get any input on the application process that you might need. But we're really looking forward to launching the program, looking forward to working with the National Science Foundation, as well as Steve Blank, Karl Handelsman and the other instructors. And I think this is a great opportunity to offer a new service and a new program to SBIR companies that are being funded by the NIH and we're very much looking forward to going forward on the program.

Thank you all for participating.

Christie Canaria: Thank you all again for staying on the line with us, just as a final reminder we will be sending all the registrants to the webinar link, so that you will have access to all the slides and videos that were shown today. And those slides and materials will also be available at the I-Corps website.

That concludes today's presentation. Thank you very much.