Go for the Gold: Path to a Fundable Fast-Track or Direct to Phase II

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2021 HHS Small Business Program Conference: Diverse Perspectives SEEDing Impactful Innovations

Todd Haim: So it's my pleasure to introduce our distinguished panelists. I am Todd Haim from the National Institute on Aging and I manage the Career Development and Small Business Programs at NIA. Christie, could you please introduce yourself?

Christie A. Canaria: Yes. Thank you, Todd, for leading us in today's session. Hi, everyone. My name is Christie Canaria. I'm a Program Director at the National Cancer Institute's SBIR development Center. I'm also the Program Director and Manager for the I-Corps program at NIH on behalf of the NIH and CDC. We look forward with engaging with you today.

Todd Haim: Thank you. And, Luis?

Luis T. Gutierrez: Good afternoon, everybody. My name is Luis Gutierrez. I serve as Entrepreneur in Residence at the National Heart, Lung, and Blood Institute in the Innovation Office that's the Division of Extramural Research. Before coming to the NIH, I walked in your shoes as the CEO of a start-up molecular diagnostics company, and before that spent most of my career advising small device, drug and diagnostic companies in their commercial strategies. How do we take cool science and turn it into a viable enterprise commercially? So I look forward to providing some feedback for you today.

Todd Haim: So you can see that I brought the experts here today. So in terms of panel format, we are going to start .. . I'm going to provide an overview in terms of how to submit competitive, Phase II.. . and Direct-to-Phase II applications, really focused on the commercialization process. And then, we will have some moderated question and answer, and then we will move quickly to the audience questions, and we will do our best to provide answers. So "Go for the Gold: Path to a Fundable Fast-Track or Direct-to-Phase II." We just showed you the three speakers. So developing the commercialization plan. One of the key components, one thing that differentiates Phase II type applications from Phase I's is the presence and the need for a commercialization plan. It's a 12-page section in those applications. It should be based on the company's business plan, and the goal is, really, to do a few things. To show that the product being developed meets a compelling need, that you know how to develop and commercialize a product, and that you have or can access the requisite expertise and resources. Sometimes you're not expected to know everything, but the key is being able to show that you know what you don't know and will be able to garner that expertise at the appropriate time. It is a maximum of 12 pages and it's required for several application types. The one application type where you cannot have a commercialization plan is the Phase I. But it is required for Fast-Track applications, Phase II Competing Continuations, Direct-to-Phase II applications and Phase IIB applications. The instructions are in the SF-424 Application Guide. It has specific instructions for the commercialization plan. So the commercialization plan really effects all the scoring criteria, but it contributes primarily to the significance score. The overall thing you really want to show there is that the product, or the project, has the potential to lead to a marketable product that will have a beneficial impact in the field of use. So for example, if you're developing a drug or a diagnostic that would end up in the clinical space, are you actually going to change a clinical paradigm? That takes a research tool. Are you going to change the research paradigm? Assuming that the data leading up to that point is positive and that the projects are successful. The scoring criteria may change with funding opportunity, but the commercialization plan will always have relevance and always be a part of the score in one way, shape, or form. The program officers and there is other resources that we can get to in this panel that serve as great resources as you think about how to write that commercialization plan. And it's important to note that the commercialization plan complements but does not replace the research strategy, and it can effect the four other review criteria. So there are seven components of the commercialization plan, as listed in the application guidance: the first is the value of project, expected outcomes and impact; number two, company; three, market, customer, and competition; four, intellectual property protection; five, finance plan; six, production and marketing plan; and seven, revenue stream. I'm going to talk about each of these real quickly. Sorry, I went the wrong way. So first, value of projects, expected outcomes and impact. So here the real focus is on the value proposition. What are the benefits of the product and why do those benefits matter? That essentially is a short way of telling you what a value proposition is. Then how do you intend to bring it to market? So the needs your trying to address, how does a product fit with your overall business goals, what hurdles will you encounter, and how will you address those hurdles and achieve your goals? One thing that we strongly recommend for this first section is the inclusion of a Gantt Chart. And, the Gantt Chart, like a product development plan, done in this way can actually help address multiple of the criteria in the sections of the commercialization plan. See in this one that I'm showing you right now, it's just a example. You can show the different steps that are going to be needed over time and then you can also show the financing that is expected over time and how you'll get there. So you can hit a couple of birds with one stone, so to say. So number two, company. So here's where you want to show: what are the core competencies of the company, who is the team, and elsewhere in the application with the biosketches and other sections, you'll talk about who's the team who is going to physically do the work. Who is going to conduct the aims, right? But in the commercialization plan, it's important to bring in those other team members that maybe are not involved in conducting that specific SBIR-funded project, but are essential to help guide that project and help advance that project and potential product, through commercialization. So that will include the leadership of the company, boards, staff, advisors, consultants. You can mention all of that in your commercialization plan. And then, important to demonstrate your corporate objectives. What do you want to be when you grow up? Transition .. . are you trying to transition from a R and D company to commercial entity or your corporate objective is to bring a product to licensing stage, and then describe the funds you receive to date, if any. And many of our companies the first time they have a Phase II don't have funds received date, and that's okay, other than your SBIR funds and what you've done with them. And then, again, the most important thing is there's no right answer to all the questions that I just mentioned, but it's about do you have a clear vision? So number three, market, customers and competition. So in terms of market, there are multiple ways, you could calculate backwards, you could calculate forwards in terms of the number of patients you're trying to address, what segment of those patients would your special product really address, what is going to be the rate of market penetration? Then you can estimate price. But you can also look backwards, look at other products that might have been similar that entered the market and what type of market did they see and did they address? Customers, and you really want to think about customers in different ways. It could be the end users. So if it's a research tool, it could be those researchers. If it's a product that's going to be in the clinic, then it could be the patient. But also your customers are going to be the physicians and going to be the payers. So think about what specialists diagnosis and treat the disease. How do they make money, so how would your product fit into that business model? Where is the disease diagnosed, monitored, and treated? Who buys the product? And then, is the product covered by insurance? So you could figure out who those payers might be. Competition, here's where you really want to focus on competitive advantage. Again, I think a chart here is really helpful. In terms of showing the different benefits and how those benefits are addressed by the competing products. And it's important to note that the reviewers may have seen other applications from other companies. They may be aware from news products and literature of other products that might be in development. So especially if products are maybe not on the market yet, but are ahead of you in development, really important to show how you're going to compete with those products as well. So the fourth part of the commercialization plan is intellectual property protection section. So this can include more than just patents. It can include trade secrets, copyrights. You want to list intellectual property covering the product. You want to describe the claims especially if you don't have a lot of patents in your hand. Important to demonstrate that you do have freedom to operate. You'll want to say who owns the patents. So if it's not the company, describe the rights to practice the patents. Let's say it's an academic university, it would be good to have a letter of support from the academic university demonstrating the access that you say that you have in the commercialization plan. How will you protect project-related inventions. How will you expand intellectual property after the project period. And what other options are there for commercial exclusivity? The finance plan. Now this really tends to focus more, not how are you going to get funding for the project that is in the SBIR application because the goal there would be the SBIR funds, right? But instead, it's really focused on how much funding will be needed to develop the product, so post award. Key development milestones, as I said, that Gantt Chart can help with that. Cost to achieve those milestones, how do you plan to secure the required funding, and more specific you could be, the better. If you've had discussions with potential investors or partners, that's a good place to do it. You can also include, and I strongly suggest you include, letters of support. So I always say letters of support are actually required for anyone that is getting paid through the grant, or anyone that you're going to use grant funds and pay them, you need to have a letter of support. But where letters of support are most powerful is, actually, people who have no tangible benefit from you getting the grant. So something like an external investor that can talk about their excitement of the product, maybe they need to see more data. But if you are able to achieve the data and the milestones that you're putting in this Phase II project, then that investor will seriously consider partnering with your company. A letter like that can really have an impact in the scoring and the funding potential of the application. Production and marketing plan, again, you want to show this over a scale of time, and you're going to probably touch on whatever features are most relevant. But you may touch on discovery activities if you're still at that stage, preclinical testing, again, if relevant, clinical testing, and then commercial launch. And finally, the revenue stream. How will you or the licenser generate revenues if the project is successful? You want to correlate that with everything else you're putting in that commercialization plan and then demonstrate that you understand the staffing requirements and expansion needed to obtain projected revenues. This will lead back to my first point about the commercialization plan. It's not about that you have to show in the commercialization plan that you know everything that it takes to get to commercialization and that your company has everything it needs to commercialize a product. That's probably not realistic at the Phase II stage, but the key is showing that you know what you need to eventually know and that you know how to get there. And, really importantly, if you weren't funded on the first try, don't give up. In fact, most companies are not funded on the first try. Most NIH applicants as a whole are not funded on the first try. So review that summary statement which has the written critiques, talk to us, discuss your summary statement with the assigned program officer, and then revise and resubmit. I put several application resources on this slide. Fortunately, actually, a few new sample applications have been posted on the web, including ones at the Phase II stage, so .. . From NIA and NCI, and there are also sample applications for NIAID. So definitely recommend looking at each of those, that can give you a .. . not that you want to copy anyone else's application, but just to give you an example of applications that were actually scored well and ultimately funded. NIDA has a great commercialization plan outlined on their website. That's another great resource, especially for those that have not applied before. So let's say you're considering a first Fast-Track or first Direct-to-Phase II, there's an application infographic on the NIH SBIR website, and then there is the SBIR and STTR Application Guides and Annotated Forms. If you want to get an idea of what other people have applied for and gotten funded, see if there any competitors there, you can use NIH RePORTER. And then, if you want examples of how companies use this to be successful, well there are some really great ones on the NIH Success Stories page. And then finally, as I said, really important to contact us. We're here for you before you apply. If you're thinking about Fast-Track or Direct-to-Phase II, you really want to talk to program staff first and get their recommendation for your specific project, what is right. So there's a list of contacts for each institute. That's also available through this link. So thank you. You can connect with all of us, and I now look forward to some Q and A. So the first question that I have for the panelists before we move to the audience questions is, I would like each of the panelists to come in and tell us how they think about the commercialization plan, and what types of perspective and things they would think about in writing that Phase II application? So let me start with you, Christie.

Christie A. Canaria: Yes. Thank you, Todd. You teed it up perfectly, and I liked what you said earlier, which was, "to demonstrate you know what you need to know." I thought that was really impactful. And so, when I think of that, I think of one of the programs that we provide at the NIH which is the I-Corps at NIH program, and if I can get a slide up on that I'll talk a little bit more on it. The I-Corps program is an entrepreneurial training program designed to help empower our entrepreneurs to better understand how their technologies can be utilized to meet clinical, unmet needs. And so one of the tools that we have in the I-Corps program is called the Business Model Canvas, and that's shown here. Now, Todd talked a little bit about the seven components that go into commercialization plan. But in programs like the I-Corps or the Lean Startup program on which it was based, there are actually nine components that you can think about when deconstructing your business model or your business thesis, and they're given here, and I'll just read through a few of them. Some of the key ones include understanding what your value proposition is for your technology, who the customer segments are, and that includes not just end users but people who are gatekeepers, decision-makers for getting a technology adopted. Other people include key partners, those who are involved in doing key activities, maybe that includes engaging with regulatory agencies, knowing what your key resources are, cost structures, revenue streams. All those can be thought of and should be thought of as you put together your commercialization plan. And so, I really like the Business Model Canvas because it's one kind of a tool that you can use to sort of deconstruct what your technology is and how it can be used and deployed for translational success. And so, as I mentioned, this is a program that's run for the NIH and the CDC. It's currently offered to Phase I awardees, but folks can access the curriculum itself freely online through portals like Udacity. And for the more than 200 teams that have already gone through the I-Corps program, they tell us that being able to conceive what a commercialization plan should be and what should go into it has been informed really greatly and really well through using something like the Business Model Canvas. So when I think of commercialization plans I think of this structure here, deconstructing it here, and then putting it back together into an application.

Todd Haim: Thank you. And it's important to mention that the I-Corps is one big example of the types of entrepreneurial training resources available at the NIH, and especially for Phase I companies, where those, for example, are the medical device-based. There's also the C3i program. And also, for everyone, there is the NIH has several Entrepreneurs in Residence, Luis being one of them, that's always there to provide guidance. We have two Entrepreneurs in Residence at the NIA, for example, to provide guidance. So Luis, from that perspective that you have as a serial entrepreneur, what advice do you have on putting together that commercialization plan?

Luis T. Gutierrez: Sure thing. Part of my duties at the NIH, I look at a lot of them and I go .. . I know reporters have who, what, why, where, what. I have two. I have the who and the how, and I'll start with the who because it really comes off of Christie's thing. Some scientific entrepreneurs, and the who is about self knowledge and knowing what you know, knowing what you don't know, and bringing in people. So I pay a lot of attention to the team. I'll draw a stark contrast in two I recently read, one good, one really bad, and it may be counterintuitive which is which. The first was a company that said point blank, "We are an R and D company. We have a R and D skill set. We are going to take this thing to human proof of concept and out license it." One of their letters of support was from Eli Lilly with serious support. So they didn't have to convince me about the reimbursement, and the business model, and the pricing. Yeah. They had somebody already who knows how to do that far better than they ever will. In stark contrast, another one was a solo entrepreneur, academic scientist. Real smart, I'm sure. Had no one else on the team. Out of one, and he was going to build a full integrated pharmaceutical company including hiring sales reps and launching it. I mean, not even close to quota. Then is the what, because at the NIH we see commercial opportunities of lots of different sizes, and an important thing about an economically viable, commercially viable progression is the cost of the path has to be proportional to the size of the pot of gold at the end of the rainbow. So not everything has to be a blockbuster. A blockbuster drug that's going to generate 10 billion dollars a year in sales, that's lovely, but not everything has to be that way. You can have a small product, perhaps a research tool, that has ultimate revenues of maybe 5 million, but if it's only going to cost half a million to get it to a commercial end point, that's a viable model. You can never get a drug anywhere close to a commercial end point for half a million dollars. You've got to add one, at least one, probably two zeroes to get there. So that scaling, and do they get that? Because, I do see applications that mismatch in both directions, they're under calling how long it's going to take in time and money and what's the commercial opportunity here on the back end which I equate to, will there be realistic access to this by patients down the line? And even for an orphan drug the answer can be yes, but you got to have a plan that makes some semblance of economic sense because we at the NIH, we can only take you so far. And if at the end of Phase II funding there's not something fundable in the private sector, it's going to die. And so, that doesn't do us any good to fund things that are going to die the minute our money gets spent.

Todd Haim: Thank you very much. So the next question that I have for both of you is, "What are the differences between and how should one decide between a Phase II Competing Renewal, or Competing Continuation, Direct-to-Phase II, and a Fast-Track application? We keep throwing these terms around, but it would be great to be able to define what's different between each one of those? And if I'm an applicant, how do I decide which one I should be applying for?"

Christie A. Canaria: I can take that one.

Luis T. Gutierrez: Please do.

Christie A. Canaria: So the options for you to think about are a continuing Phase II, a Direct-to-Phase II, or a Fast-Track, and I think the first question you should ask yourself is, "Have you done a Phase I and completed it? Do you have data from that that can help inform a new project?" If the answer is yes, then I would say go with a Phase II Continuing project, that make some sense. Now, let's say you have a Phase I completed and done, but you realize you need to pivot or refine some aspect of your application. Well then, maybe, a Direct-to-Phase II might make better sense if the aims really are deviating pretty far from where the original Phase I went. Or, maybe you want to go after a Fast-Track application because with your first Phase I you had some really good feasibility, proof of concept work done, and you know that a new Phase I coupled with a great Phase II could make a wonderful Fast-Track application. In either case, I strongly encourage you to reach out to the program officers at the appropriate institute center at the NIH and discuss your technology's position and your thoughts about how to go after it, and we can work together with you on helping you decide which is the best for you.

Todd Haim: Yes, exactly. We are here for you to help us, it really is a case-by-case basis, and that's there is no one size fits all or you should always do a Fast-Track or you should always do a Direct-to-Phase II, otherwise we wouldn't have both programs available to you. So definitely come talk to us and we can provide guidance. So I see a lot of great questions coming in, so I'd like to now get to some of those questions. Let me start with bringing a few questions together around the funding process, and there were some questions on what is a fundable score, how is the payline determined, is it published? And then there is also questions, "Let's say you got in low 20s but it wasn't funded, would it be carried over to the next council?" So I'll put my very short answer, and then turn it over to Christie and Luis to add, and most of it depends. Every institute is different. Some institutes publish their paylines, other institutes do not. At the NIA for small business we do not publish our paylines. Some institutes go straight by score. Other institutes, especially for Phase IIs, have, maybe, a range of scores where they can consider things on a case-by-case basis. And then in terms of moving things from one council to another, yes, at the NIA we would consider things one council back, but, again, that can vary from institute to institute. So, Christie and Luis, maybe you could talk to how things work at NCI and then NHLBI?

Christie A. Canaria: Yeah, sure. Thanks, Todd, and absolutely the same answer comes from NCI. It absolutely depends. For us, we don't put out publicly our payline but you can e-mail us and ask us what it is. The reason is it changes from year to year and it's really dependent on the applications that come in for us to do the calculations and math for what we set as a fundable range. But in addition to having a fundable range, we also have an extended range beyond that for which we will do additional discussions. And so it's really important after you get your summary statement back that you look in the top left-hand corner, look for the person who's listed as your program official, their name and their phone number are listed there, and you can reach out and have a discussion about what your summary statement means, what your score means, or if it's not discussed, what does that mean? We can really help guide you in understanding what your next steps would be moving forward.

Luis T. Gutierrez: From an NHLBI perspective, again, collectively, the three of us represent three institutes, that means there are 20 not on the call. Albeit, these are three of the five or six big ones. We also don't go with a strict payline. There is a zone of consideration. A lot of institutes have a multi-part mission. In our case it's heart, lung, blood, sleep, and there's some balance across those elements, which means that in some cases it's different lines. My one bit of advice, though, score in the low 20s, if don't get funded, by all means, come again. That's a good score.

Todd Haim: Definitely. So next question, "Does the demonstration of feasibility need to be stronger for a Direct-to-Phase II than it does for a typical Phase II?" So let me turn to Christie for that question.

Christie A. Canaria: So when you're talking about the data that would demonstrate your completion of feasibility and proof of concept, if you've already done the Phase I and you have the data in hand, you should certainly incorporate that into your Phase II, follow an application to demonstrate that you have met the milestones. If you have equivalent data that wasn't collected using a predicate Phase I award, you should still be including that equivalent data in your research plan for your Direct-to-Phase II application because reviewers in NIH will be looking to see that you've done the equivalence of proof of concept or feasibility, and so you certainly do want to have those in your applications in both cases.

Todd Haim: So the next question, "Other NIH resources, such as the application systems program which is for Phase I, are there such resources for Phase II or Fast-Track applications?" Do either of you know of such resources? And I can speak to a couple if not.

Christie A. Canaria: I will let you speak to those, Todd, and if I can add I will.

Todd Haim: Sounds great.

Luis T. Gutierrez: What are their resources once they're in, but for an application I'll let you handle it.

Todd Haim: Sounds good. So there may be somewhat specific ICs, for example, I believe that the National Institute for Allergy and Infectious Diseases does have such a program. But then the other thing is not .. . so the AAP .. . by the way, great program .. . Applicant Assistance Program to help applicants pre-Phase I understand the application process. Once you've gotten to Phase I and you understand the application process, you would have gotten that Phase I funded. So we don't have .. . mostly we don't have specific programs, but we do have resources, and you have .. . you're staring at one right now, which his Luis Gutierrez. So .. . and several ICs, pretty much all ICs, there is someone you can talk to to get guidance for a Phase II, and some ICs that maybe the program officer, and other ICs that maybe the program officer and the Entrepreneur in Residence, and the NIA and NHLBI are two examples that provide you that kind of two layers of separate people and expertise to help you with that Phase II application and that commercialization plan. Anything else that the panelists want to add on that?

Luis T. Gutierrez: Well, the one analytic point I would add is yeah, pick up the phone, call our small business office, have an interaction because we've done the analysis of applicants who did that versus those who didn't. Guess who has a much higher funding percentage? And it's not that we like them better, it's that there's a fundamental selection bias of "Yup, they got the necessary information," so it shouldn't be shocking that they succeeded. It's like did you have a coach or not? And if you didn't, well, you're not, on average, going to do as well.

Christie A. Canaria: I wanted to add another resource that isn't that isn't explicitly requested or asked around your question, Todd. But there is the needs assessment service that is available for active Phase I awardees through the NIH, and this is a wonderfully comprehensive deep dive into Phase I awards and their technologies and helping you understand some of those components that we talked about, the seven that are listed for the commercialization plan, the nine that were listed in the Business Model Canvas. We have services that will do the research and provide you with the report about your technology and it's potential in the space.

Todd Haim: Great. Thank you very much. So the next question, and I'll have Luis answer this first because it's a term that I'm sure he's very familiar with, "Is there a ROI that NIH likes to see, return on investment?"

Luis T. Gutierrez: Yeah.

Todd Haim: Luis, let me turn that you.

Luis T. Gutierrez: Yeah, again. For those who don't know a return on investment is, how much money does it take to get this product to the market as a function of how much are we going to make afterwards? And NIH absolutely doesn't because they don't calculate ROI in money, they calculate it in public health impact. And so .. . Plus, our mission is to fund those things that the private markets don't fund. So in some cases we don't have as much ROI as what a venture capitalist might see because our mission is to fund things that impact public health and de-risk them to a point where they become investable externally. So we're not looking for a hurdle rate. In fact, if anything, I've seen commercialization plans that try too hard by putting an inflated patient numbers, inflated pricing, and yeah .. . no, that's not going to happen. And so, as I said, a modest market is actually, if it's a big public health impact and a big imminent need, it is actually far more compelling than a me-too draw that's a no brainer ROI, which by the way we've got a very poor innovation score and scientific merit anyway, but that will be my response on an ROI. It's a very different notion of ROI on public health impact, not how much money will this entrepreneur make on the money we give them? That's just not the way that it's calculated.

Christie A. Canaria: I would like to share from the NCI SBIR perspective, we have made some greater attempts to understand what the impact is to public health. And in 2018, we published our Economic Impact Report demonstrating how our Phase II awardees have gone on to continued translating their technologies and getting them out to the market.

Luis T. Gutierrez: Yeah.

Christie A. Canaria: And a large part of that, really, is being able to celebrate and understand how the how the federal funds ultimately translate themselves into care that is available for patients and people around the world. And so I just wanted to show that NCI has some of those kinds of Economic Impact Reports. They both use some magic modeling, but really it's also about understanding how we can continue to push forward care for people with federal funds.

Luis T. Gutierrez: And to be clear, we do the same thing on the portfolio, but we don't evaluate it that way at the individual project or application level. But for the portfolio, absolutely, we have to justify our funding like anybody else. And as with any biotech VC portfolio, you'll fund 50 things, four will drive the entire ROI of the whole portfolio. We expect a lot of failure, a few brilliant successes commercially, and hopefully a few more than that in public health impact as well.

Christie A. Canaria: That's great to say, Luis. We think of the SBIR programs as America's SEED Fund and so it really is about trying to spread the resources and being hopeful that the technologies that are going to succeed have some roots with the federal resources and funds.

Todd Haim: Thank you. There is a quick question about, kind of, the interplay and the cost-up between traditional NIH research grant mechanisms, such as RO1, and then the SBIR and STTR mechanisms, and would it be okay to have feasibility data from research grants and then pursue Fast-Track and Phase II applications. Christie, do you want to take that?

Christie A. Canaria: That's a great question, and I would say that feasibility data comes from all sorts of different places and absolutely there are cases where that may come from your R01 research. Again, you'll hear this a lot and you'll talk to program directors about what you're considering using as justifications for your preliminary data which is not for Phase Is, which is not required by policy. But of course in Phase IIs, you have to demonstrate that you've got the data in hand. There are other places that may also provide equivalent data and those can be from other clinical trials, they can be with other partners using non-SBIR, STTR funds. Those are all still fair to use as justification.

Todd Haim: Thanks. And then, now, shifting to the other side, there's questions about private investment and how do those interplay? And I can get to those questions, but let me start by, I'm trying to explain how at least we at NIA look at the SBIR and STTR programs as that SEED fund? Sorry, it looks like my computer froze, but I think I'm back.

Luis T. Gutierrez: I was about to take over.

Todd Haim: So .. . you were ready. So we look at it at the NIA as we want to provide funding to small businesses, to start ups, that can then collect that key data, and it's that key data that meets value inflection points that will then bring in those external investors. So it's not that we require external investors at the front end, but the hope is that by being able to collect data through our funding you would be able to, downstream, secure the investments you need to get all the way to commercialization. We're slightly moving more than the amount of funding you can get from SBIR and STTR. Some of the questions come in to, well, what do you need to fund it? Do you need private financing at the front end when you first apply for SBIR, and there was a specific question about NCI. So Christie, I'll turn that to you.

Christie A. Canaria: So I want to address some of the things you said there because there is a lot of great commentary that you folded in there. Being able to get technology from lab to market, or from bench to bedside, is a long path and it's not right to expect that federal SBIR funds are going to get you all way there. One of the programs that we have at the National Cancer Institute is our Phase IIB program, which we call Bridge, and you'll see it across the NIH. There are other institutes, and I think the one's represented here too, that have Phase IIB programs, and that's our opportunity to really leverage federal funds from the NCI's perspective with matching against third party funds. And so for us, we will provide opportunities in a Phase IIB to match up to 4 million dollars in federal funds against third parties and we're able to provide it over a range of 2 to 3 years, we can tranche that, and your ability to show that you have imminently, or soon will, secure those funds into your company's accounts, are one of the criteria that we look for. Other eligibility criteria include having a Phase IIB. It doesn't matter from where in the federal government so long as you're looking forward with a cancer mission focus, we would consider you for Phase IIB. So thinking about how those private funds work with the federal funds, it's a long pipeline, right, to get there. So even in a Phase IIB, you may still be considered on the early side in terms of the long translation pipeline.

Todd Haim: And I'll add one more sub-question, Luis, before you take it.

Luis T. Gutierrez: Okay.

Todd Haim: Which is, does private investment help or hurt grant awards?

Luis T. Gutierrez: I would think it helps. Having been an entrepreneur myself, I view it as a balance. There's no question, the non-dilutive nature of NIH SBIR funds is beautiful. It's the best kind of money there is. If we're honest with ourselves though it's a little slow, and sometimes you need money now, right? You're in a .. . most medical development, you're in a race. There's other smart scientists out there too and there's a clock ticking on your patents, there's a clock ticking on the clinical viability of your drug, and so sometimes you have to look at your development program and something that's very much as a lead indication right at your critical path to company viability, that one may benefit from private funding from a speed perspective, whereas secondary indications, alternate populations, et cetera, aren't as time sensitive, and by all means fund them non-dilutively. So I view it that way as well. Our one drawback is our money is not as fast arriving in your bank account as private money, and sometimes you need fast money, but it's at a much higher cost in terms of dilution.

Todd Haim: Perfect. So we have two minutes left and I see a few questions I'm going to try to give really quick answers to, and then we'll go to close. So the first is, "What if we have Phase I and we want to apply to Phase II, do we have to convince the reviewers?" Well, that's part of your application, that you're ready to transition. You'll show that with the data in your application. There are questions about "What if .. . sorry, there are questions about, "How you could access the needs assessment report for active Phase I?" So that's .. . contact your program officer, they can make sure that you can apply to be a part of that program. There were also questions about the sample application, and someone said that they couldn't find the actual applications in RePORTER. That's correct, because they're not in RePORTER. But you'll get access to the slides and they are in the links. They're on the NCI website, NIAID sample application website and NIA's website. So those are the places to find those actual sample applications. And questions about "can an SBC that resubmitted a Phase II did not get funded, can you apply for Direct-to-Phase II?" You can, now the data shouldn't be a complete continuation of that Phase II. But let's say you've gone back, you've done some additional work, you have some additional data now. You're going to put that additional data in the application, then, yes, you would be able to apply for that Direct-to-Phase II. And the final question I'm going to be able to get to is fee for service. And, yes, you can talk to the institute, at several institutes, if you need to be partially virtual and you need to contract stuff out, there are ways that those might count as part of a company cost if the company is doing their analysis as fee for service activities. So I'd like to thank both of our great panelists for joining me today, and I would like to close by saying that, yes, we will be recording this panel, and we look forward to you accessing those recordings after the session. Hold on one second, and we also would ask you to fill out those feedback forms. Thank you for joining the session, and thank you. I look forward to hearing from you when you contact us about an application. Bye.