Compete Like a Pro: Path to a Fundable Phase I

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Monique Pond: Welcome, everyone. Thanks for joining us today for this session. We're going to be discussing some tips and recommendations for putting together your Phase I small business grant application for the NIH. I'm Monique Pond, and I'm a Program Director working in the SBIR Development Center at the National Cancer Institute, and I'm going to be your moderator for today's session. So thanks for joining the session today on "Compete Like a Pro: Path to a Fundable Phase I." I'm happy to introduce our panel for today's discussion. Miguel Contreras is the Small Business Program Manager in the Office of Research Infrastructure Programs within the NIH Office of the Director. And Lili Portilla is the Director of Strategic Alliances at the National Center for Advancing Translational Scientists, or NCATS, at NIH. So thanks again for joining. It's great to see so much interest in entrepreneurship. I'm going to turn it over now to Miguel, who will get us started.

Miguel Contreras: Thank you, Monique. Hello, everybody, and welcome. I'm going to talk about three essential tips that you should have in mind when you start your journey to prepare and submit a grant application to the small business program at NIH. Remember the title of the presentation or this session, "Compete Like a Pro." That means you need to be prepare and get ready for the journey. I can say that these are not probably the only three tips that you will need for the journey, but I think they are basically a good starting point. So the first one is, read the Funding Opportunity Announcement and follow the instruction of the Application Guide. Remember that there several type of FOA, and they have different flavors. You may have the one that has focus on a specific research areas and other that could be more broad. They may be different. As I mentioned, they may have different call for a specific topic of technology. They may have different budget, and they have different Institute, Center and Offices that are participating in that specific document. The second tip is, you have to identify which NIH Institute, Center or Office that align best with the project that you have in mind. For that, you can visit the different website to figure this out, but the idea here is for you to select the best home for your application or your project. The third tip is, don't be afraid and reach out to the program officer to discuss your project. At that time, you should have a document that usually is called a Specific Aims Page that should contain at least three or four parts. The first and perhaps the most important part is the background or abstract. The second part would be the aims, what you are proposing to do, and if you can add quantitative milestone to kind of sense the progress of your project, that would be really good. And, finally, a sentence that has the outcome, what you would like to achieve in this project. In addition of that, when you reach out to the program officer and get a time with him, try to use the time wisely. Also have ready a list of question, question like, "What are the budget? When are the due dates? How long will it take for me to know if my grant application was successful or not?" Now where you can find additional resources for regarding application? Next slide, please. So what I compiled here in this slide is some resources that are available online. The first one is the website for the NIH-wide small business program. If you apply to .. . I will strongly recommend that you stop by the web page about the question and answer. This is is a really good resource for you to familiarize about the program. The second website that I indicate here is for the office where I work with. That is ORIP, and I will encourage you to visit this place because we have two short animated videos, very entertaining, very short, will not take too much of your time, but one of those will give you an idea of how to create a small business company, and the second one will give you an overview of what the NIH small business program is about. In addition of that, if you visit our website of the ORIP, you will find that we have also the fact sheets that explain what kind of project we accept, but also, we have a flyer that compile resources for a small business applicant like you. In addition, this website that indicate there is for you to have a glimpse of the overall process of when you submit a grant application. Finally, I put the website for database resource that will allow you to search for applications like the one you have in mind that has been funded by NIH. Finally, you want to reach me, I put my e-mail there, too. Now I want to give the floor to my colleague Lili Portilla.

Lili Portilla: Hi. Thanks, Miguel, and good afternoon, everyone. So I'm going to talk about a few things. First thing I wanted to mention is, when you're putting your application together, there's a lot of steps that need to happen, but here keep in mind that the SBIR/STTR application process is an electronic process, so there's a little bit of homework that you're going to have to do before you even submit your grant, and this has to do with these five required registrations that must happen and in a particular order, as well, order that we've laid out here, and keep in mind that some of these registrations can take anywhere from between a month to a month and a half to successfully go through because we're talking to databases throughout the government. For example, your tax ID number has to be checked against the IRS files, and that takes time behind-the-scenes, so if you .. . And all these registrations are needed for some purpose, right, so eRA Commons is to access your grant. The System for Award Management is a way of getting your funding, so they all have a purpose, but please start early because we've seen this many times that applicants are ready to submit a grant but don't have these registrations, or there's an error that's come up in the context of getting the registration, so make sure you do that early and get those done so that you can submit your grant on time. Let's go to the next slide. Very briefly, I wanted to chat here about some common application problems that we see across the NIH and the SBIR/STTR program. They're in no particular order other than to say that these are things that we frequently see happen with our applications and applicants that submit. I think one of the ones that I can note that does happen somewhat frequently is that you didn't do a good job in discussing what the problem is that your technology is trying to solve or that you didn't do a convincing case of that, and as well and related to that is, maybe you didn't do your homework in understanding who your competitor is and how this technology fits in that competitive landscape. Remember, the review groups are looking at this, and they have experts in these respective fields that are looking at these applications, and they know who's out there and working in this area, so it's always good to do your homework and understand what your competitive landscape is for your technology. Sometimes we see lack of innovation or an application that perhaps overpromises but really can't deliver because the budget is not going to be sufficient enough, and I talked about being unfamiliar with certain published works or things that are out in the public domain around the technology, lack of experience with essential methodologies, understanding those and maybe, as well, some questions around your experimental approach that you will be using in the context of your specific aims of the grant. I think another thing to keep in mind here is that NIH on the website has a couple of resources that you can look at in terms of what a successful application looks like, and we'll be talking about those during our session, but there are links to successful applications that you can pull up. Granted, they may be in your technology area, but you can at least see what NIH considers to be a highly competitive application that hopefully will inform you in putting a good application forward for the program, so with that one, go to the next slide. Okay.

Monique Pond: Yeah, thanks, Lili. So definitely the issue of an unfocused application is something that we see a lot, so I just wanted to touch a little bit on what we mean about the focus of the application for this particular mechanism, so I know a lot of people in the audience are probably very familiar with the more academic NIH grants, your R01s, your R21s. With the focus there is a little bit different, and you're used to those mechanisms, so if you're new to the small business mechanisms, you want to keep in mind throughout the application that you want to focus on your eventual product and what you will be commercializing, maybe not at the end of your Phase I, but down the road your plan for that, and so this shows up in all of the five standard NIH review criteria, so for example, the team. Of course, you'll have your technical expert, your scientific expert in the technology itself. Leading the project is the PI, but when you start thinking about the rest of the team and who your collaborators should be and building that out, you want to start considering things like, "Does anybody have any business development experience?" or, "Have they previously worked for a company in this space and developed a technology that eventually became a commercial product?" It doesn't necessarily have to be someone .. . Especially early on if you're just starting your business now, in your Phase I, it doesn't have to be a full-time employee, but you want to start thinking about that team and if you can expand as far as advisors and consultants when you're thinking about putting together these SBIR/STTR grants. So we have had some questions about the slides. The slides are definitely available for you to download. If you go to the session details, so go into Agenda and then the sessions and click on this session title, you should be able to download the slides there. So, with that, I would like to get started with our discussion, so, Lili, I'll start with you. When you're talking to new applicants, what would you consider to be the main issue that you see people underestimate about the whole NIH SBIR/STTR application process?

Lili Portilla: I think I would say that one of the main things that's underestimated is the rigor of the scientific peer review process and what NIH is looking for in terms of grants that get funded, so I think that that sometimes takes our applicants aback, especially when they get a back a score that is not that great, or maybe their application didn't even get scored, but to that I want to say that .. . Can you .. . I'd like to say that .. . Can you guys hear echo, or is it okay?

Monique Pond: I can hear you well.

Lili Portilla: You can hear me fine? Okay.

Monique Pond: Mm-hmm.

Lili Portilla: I'd like to say that your .. . Even if you don't score well the first time, you are given a summary statement, and that summary statement is your guide for improving your application, so while you may not be successful in your first round, I do believe that NIH does give you the tools in improving the application, so I think keep that in mind, that while this is .. . It is going to be, to me, the largest hurdle that you're going to have to go through in order to get funding, which is to get a successful score in peer review. Know that that summary statement is your guide in improving your application should you have to resubmit.

Monique Pond: Mm-hmm, yup. That's a good point. I think I would agree. I think the summary statement can be very useful and is something that not all applicants know they have access to necessarily, and you should definitely take a look when you're considering resubmission, and talk to your program director, and get their take. We've seen a whole bunch of grants. We've read a lot of summary statements, and so set up a 30-minute meeting, and we're happy to go through that. There's .. .

Lili Portilla: Yeah, and .. .

Monique Pond: Mm-hmm.

Lili Portilla: Monique, I was just going to add another one is, the underestimation of how much time it takes to put the application together is the other thing,. Especially if you've never applied before, there's a lot of preparation that goes into that process, and I get a lot of calls from people who are about a month out from a submission date and are like, "Yeah, I'm going to put that grant together," and then they call me after the submission date and go, "We just couldn't get it together," so I think that underestimation of time is another thing that I see pretty frequently also with first-time applicants to the program.

Monique Pond: Mm-hmm. Yup, and, Miguel, what would you say to people in the audience who are hoping to submit to that September 5th deadline and are here today? When would you recommend that they get started on their application?

Miguel Contreras: I think that you need to be ready for the long haul. The process is little bit .. . I will not say that it's complicated, but as Lili mentioned, has a lot of step, need to have a lot of pieces that you need to bring together, and those pieces, you cannot put it together at the last minute.

Lili Portilla: Mm-hmm.

Miguel Contreras: The other issue that I would like to mention is that, with regard to summary statement, your work hard. You put a lot of effort, and sometime you don't get the result that you were expecting, okay? You need to have in mind that the review panel made for expert are trying to help you. If the outcome is not what you were expecting, don't take it personally. They are trying to help you. Those critique are for you to improve your project, so always make sure that you read it. If the outcome was good, be ready to celebrate, but if it wasn't, take a walk. Reach out for the phone number of your program officer and have a conversation with him.

Monique Pond: Mm-hmm, mm-hmm. And so when people reach out to a program director or a program officer .. . And I'll say we use those terms sort of interchangeably here at NIH. When people reach out, Lili, what would you say that they should do to make sure that they really have a fruitful discussion and make the most of their time with their program officer.

Lili Portilla: I think reading a cursory review of the funding announcement to make sure that what they're applying under is topically aligned with their project that they plan on submitting. If you're coming in under the omnibus solicitation, I still think it's a worthwhile read to look at the application and find out what NIH is looking for under the respective funding announcement.

Monique Pond: Mm-hmm.

Lili Portilla: And I'm surprised sometimes. It's hard to get us on the phone multiple times, especially when we get towards a submission date. Everyone is calling us. I'm not kidding. There's a 4-week period of time there where everyone wants to talk to us, and if you need to talk to us to get .. . Again, we're just saying these suggestions so that you maximize your time in front of the program officer, but knowing what the funding announcement at least is calling for, the due dates, budget limitations, having a working knowledge of that is fine, but then come armed with your questions. What do you want to talk about specifically? And I think that really .. . I find that when that happens, the calls are much more succinct. The applicant gets all of the questions answered ahead of .. . They know what they want because they've already put their question list, and I think it turns out to be a great use of time with your program officer.

Monique Pond: Mm-hmm, mm-hmm, and, Miguel, what would you say if someone was thinking about September 5th. I know I get a ton of calls in August, and you guys do, too, so early summer, is that when to contact you and want to maybe look at a draft of specific aims for September?

Miguel Contreras: I agree with you, Monique, the sooner the better. I would like to expand a little bit in the aims space. Is not only good that you have the idea that you would like to propose, but at the same time, it's good that you already know what is the gap or the need that you would like to solve based on your idea.

Monique Pond: Mm-hmm.

Miguel Contreras: Because that is an important issue to see the alignment when you discuss with the program officer, the alignment of the project with the mission of the institution, the Institute or Center.

Monique Pond: Mm-hmm.

Miguel Contreras: The other issue that most of the time we don't prepare or we don't consider too much is the aim. Be sure that you already elaborate what are going to be the pieces or what you want to achieve in your project, and as I mentioned before, most of the time is kind of complicated, right, to add metrics to those aims, how really I can see if my project is going to move along, how I can measure it. And, finally, talk about what is the outcome. You identify what is the need, what is the gap. You have an idea. Tell what you would like to have as a final product.

Monique Pond: Mm-hmm, mm-hmm. Yup, and what about a hypothesis statement? Would you say that .. . I know a lot of people in the audience are used to including hypothesis statements in their specific aims for their other grants at NIH, so is that something people should be trying to put into their small business Aims Pages, as well?

Miguel Contreras: From my point of view, because this is not what we call RPG, Research Program Grant, I think the most important is indicate what will be the commercial outcome. What is the potential for commercialization of the project?

Monique Pond: Mm-hmm, mm-hmm.

Lili Portilla: Yup. Yeah, I agree, Miguel. I think that's the distinguishing factor with this particular program is that the focus here is on commercialization, unlike other NIH grant mechanisms. There always has to be that eye towards commercialization, how your product is different from what's already in the marketplace, or is it a first-in-class type of project? I think those are all important points to make in your Specific Aims Page when it comes to understanding what the impact of the technology is, so yup.

Miguel Contreras: Yeah, let me add also that is not that we're not considering the science behind your project. The science is fundamental, but you are not trying to answer a biological question here. You are trying to take an idea and see how that idea can be brought to the marketplace.

Monique Pond: Mm-hmm, right, so if somebody is working in a space where they're at the point where they're asking basic science questions, they should probably focus on the academic grant mechanisms, but once they progress past that point, that's when they can come to SBIR or STTR and be more focused on the product, as we've been discussing.

Lili Portilla: Mm-hmm.

Miguel Contreras: Correct.

Monique Pond: Yeah, so I want to touch on preliminary data a little bit. We've got a lot of questions about how much preliminary data. Of course, the solicitations state that no preliminary data are required, but in practice and in what makes for a competitive grant, Miguel, let's start with you. From your perspective, are preliminary data required these days for someone to be competitive for a Phase I grant at NIH?

Miguel Contreras: As you mentioned, Monique, is not needed, but some kind of basic data or equivalent to information based on publication need to be present so the project can be evaluated by the expert in the Study Section.

Monique Pond: Mm-hmm.

Miguel Contreras: You should have .. . need to have all the elements, including what is the science behind, and that science behind, again, could be based on preliminary data. Although is not required, always is good to have some kind or based on publications.

Monique Pond: Mm-hmm, mm-hmm. Yeah, what about for NCATS, Lili? What are your thoughts for being successful?

Lili Portilla: Well, I think .. . I'm not .. . And I vacillate between having preliminary data and not having it because, again, it's not a requirement, and you should not be dinged in review for not having it either because it is not a requirement. But I think there's some mechanisms that we have out there that you really need to have data associated with them, and that's, for example, the Direct to Phase II program. That's the program where you skip the Phase I and go to a Phase II, but the premise there is that you have the data that you would have gotten under a Phase I already that may have been funded through a different source, another grant outside of the government or something like that, so there, you are expected to have data in order to support the fact that you're going to the Phase I. Another mechanism that I think all of us have had different experiences on this panel with the Fast-Track mechanism, right, and the Fast-Track is the one where you're not only applying for the Phase I but for the Phase II. You're going through one review that covers all that, and you can advance from Phase I to Phase II as long as you are meeting the specific aims of your grant, and I think sometimes you'll look, and you'll see that the success rates for getting a Phase I versus a Fast-Track are pretty similar, but I will say that in some instances, I think a Fast-Track, it might be good to show some preliminary data because, again, we're making a leap of faith that you are worth funding not only with the Phase I but the Phase II, so there .. . I think if you've got some data to support that, that's always going to be helpful, at least particularly for that particular mechanism that exists, so I don't know if the other panelists have any other suggestions on the Fast-Track, but I just throw that out there.

Miguel Contreras: Yeah, that is a good point, Lili. I would like to add that if you are considering a Fast-Track, you also need to be ready to provide a commercialization plan.

Lili Portilla: Right.

Miguel Contreras: That is one of the key element that is going to be evaluated by the review panel.

Monique Pond: Mm-hmm, mm-hmm.

Lili Portilla: It's true.

Monique Pond: Yeah, that's a good point that when we see Fast-Track applications at NCI, I agree with you, Lili, that sometimes those success rates can look pretty similar to Phase I, so some applicants might be thinking maybe they should just go for the Fast-Track, but I think to be successful, especially with the Fast-Track, you have to have some preliminary data. We've had some questions about preliminary data, and what does that mean? What are we talking about? So I'll give an example, just a common one we see at NCI. We find a lot of development of therapeutics for cancer, and I would say if you're at the stage where you have some in vitro preliminary data, you could potentially apply for a Phase I and be successful, but if you're at that stage, it's going to be really hard to be competitive for that Fast-Track. I think at least at NCI the last few years, reviewers tend to like to see at least a little bit of preliminary in vivo data for a Fast-Track and certainly for a Direct to Phase II that you mentioned, Lili, so that's just one example. Again, just to kind of put a few examples out there, I would say one other example is if you're working on device, if you are looking for funding to develop your prototype of your device, then that would be something that would fall in the Phase I range for NCI and I think most of the ICs or Institutes and Centers at NIH. If you've developed your prototype, and now you're really onto your validation studies for your device, that's great, and then that might be something that could make for a successful Fast-Track or Direct to Phase II. Yeah, so we've had a few questions come in as we've been talking about the PI themselves and what the requirements are for someone to be eligible to be a PI on either an SBIR or STTR grant. Are they required to have publications? How is that viewed? Especially, I know a lot of our people in the audience are coming from the academic world where publications are really important for grant success, so, Miguel, why don't we start with you, if you want to lead us off on that?

Miguel Contreras: Okay, so the PI has to be the person that can demonstrate that can move forward the project. Doesn't need to have a Ph.D., doesn't need to have a M.D., but he need to demonstrate that he's capable, has the expertise, the knowledge to assemble a team and be able, again, as I mentioned before, to move forward the project that they are proposing.

Monique Pond: Mm-hmm, yeah.

Lili Portilla: Right.

Monique Pond: Yeah. Yeah, I would say publications are always tricky. I've certainly seen comments from reviewers saying a PI doesn't have a large number of publications, but I'd also say I know I have grants in my portfolio that the PI is a postdoc, and so while it's not as common, it's certainly doable, and as you said, it's not a requirement to have a certain number of publications to be the PI. It's certainly not a requirement to have a Ph.D. or M.D. It just has to be the technical expert.

Miguel Contreras: Along those line, it's good to remind the audience that what really count is how the PI assembled the team that will develop the project.

Monique Pond: Mm-hmm, mm-hmm. Yup, yup, so thinking about the team a little bit more, Lili, what are your thoughts about how would you advise a new applicant to put together a strong team? Can you give some examples or some suggestions that you like to give for building out a strong team?

Lili Portilla: Yeah, I'll speak from experience about projects that we fund. We fund various rare diseases, right, and let's say that it's a particular technology that has a rare disease application. The PI may come to us, and he or she may say, "Hey, I'm the one developing the device, but I'm not the clinician. I don't have the patients," and that's where maybe talking to us is a really good idea because we might be able to give them ideas in terms of what PIs may be working in a particular area, and we know this. Just because it's rare diseases, we may be able to refer them to a particular network of PIs that may be able to help and provide that clinician expertise that's needed that's going to be needed in the grant. So talking to your NIH Program Officer sometimes leads to some great advice on maybe who to engage with, and remember that your company does not have to have all the expertise. You can go and look for consultants. You can also look for research institutions and investigators at those research institutions that have the expertise that you need, and I'll say that most universities and colleges in the U.S. know what SBIR/STTR are, and many of their PIs participate as key personnel in grants, so they've done this before. They know what the process is like. It's just you making the right connections in order to assemble that team that's going to focus on getting the specific aims of the grant done.

Monique Pond: Mm-hmm, mm-hmm.

Miguel Contreras: Yeah, I would like to add that the team need to cover all the ground in term of expertise and not necessarily, as Lili mentioned, need to be part of the company. You can have collaborator advisor that can be part of the team.

Monique Pond: Mm-hmm, mm-hmm. Yeah, I've seen some really successful teams that as far as company employees, there's two employees, but they've done a nice job of hiring consultants, as you said, and contacting and working with local academic institutions to find key opinion leaders, and especially at NCI, we see a lot of small businesses collaborate with the cancer centers in their area to kind of fill out that team and get that expertise. So we've been .. .

Lili Portilla: Yeah .. .

Monique Pond: Yeah, we've been throwing around SBIR/STTR a lot in this discussion, so let's just touch quickly for the audience the differences between SBIR, STTR, the main differences. Do all PIs who are also professors at academic institutions, do they have to go STTR, or how does a new applicant decide which program they should be applying to? Lili, you want to take that one?

Lili Portilla: Yeah, sure, and that's a good question. So the main difference between an SBIR and STTR is that the PI for an STTR can be either employed by the small business or by the research institution. There always has to be a research institution component in an STTR grant. So it's not to say that you cannot have an academic involved in some kind of co-PI relationship under an SBIR, but that is the distinguishing factor between the STTR and SBIR mechanism, is that PI and where they can be employed, so there's some flexibility there. I'll also add that if that PI, for example, is bringing some intellectual property that the company wishes to license or to use in the context of the grant, you have to demonstrate to the NIH that you have an ability to use that technology and that could be that you have a license or some kind of IP arrangement with the university to use that piece of intellectual property as part of the grant, and I think that would be another factor to consider with SBIR, doing an STTR or an SBIR. And then another distinguishing feature is the percentages of what you can subcontract out.

Monique Pond: Mm-hmm.

Lili Portilla: For example, under a Phase I SBIR, you cannot contract out more than, I believe, 33 percent of the grant. For an SBIR .. . I mean, STTR, you can subcontract up to, I think, is it 60 percent, I think? Is that right?

Monique Pond: Yeah, I think it's 60.

Miguel Contreras: Yeah.

Lili Portilla: Yeah, 60 percent, but just keep in mind that under both mechanisms, the money goes to the small business in both instances. Even though you may have an academic PI under an STTR, that funding will always go to the small business.

Monique Pond: Mm-hmm, mm-hmm.

Miguel Contreras: Yeah, I would like to reinforce something that Lili mentioned, that in the case of STTR a collaboration agreement need to be established between the small business and the academic institution. That is the only different with SBIR, and SBIR, you don't need that kind of established collaboration between both parties.

Monique Pond: So, for the SBIR, you can have a collaboration with an academic institution, but it's not required. With the STTR, it's required, and then if someone is trying to decide which way to go, another thing they should look at is the PI's employment. If it's primarily with the university, STTR is the route. I would say, too, that it's not one track or the other. It's not like your company applies for STTR, gets funded, and then it's always STTR. I've seen companies that actually have both. They have active SBIR and STTR, so I think there is a lot of overlap there, I think, if people just make sure that they follow the rules for eligibility that you both mentioned.

Lili Portilla: Yeah, and, Monique, I just want to amplify what you just said. Many of our applicants may start off in one mechanism, and they're Phase I and then say, "You know what? I'm not going to have the research institution involved at that level. I'm going to be doing something else," and then they switch over to the other mechanism. That's permissible. And you'd be surprised how many times that happens, so I just wanted to reinforce that. When you come in with one mechanism, you're not married to it through your entire time of getting grants at the NIH.

Miguel Contreras: Correct.

Monique Pond: Right, right. We do have some flexibility, right?

Lili Portilla: Yes.

Monique Pond: There are options. Yup, so there are a couple eligibility things that are coming up, so I just want to remind people in the audience that these programs are congressionally mandated for businesses that are organized for-profit, located in the U.S., and then if you're hiring consultants to do work on your grant, then those contractors should be located in the U.S., as well. So we have just a couple minutes left for our time today, so I think .. . Let's go ahead and take a couple minutes to wrap up, so I'd like to ask each of you for any last comments, or if there was one takeaway message that you hope everybody leaves here today with, what would it be? Lili, let's start with you.

Lili Portilla: I would say that talk to your program officer. I can't stress that enough, and start that conversation early. And don't talk to just one, maybe several from various institutes to get a sense of maybe your project is a better fit for one versus another, and the only way you're going to know that is by having that conversation with the program officer, so start those conversations early in the process. I'd also want to make a pitch for the NIH SBIR website. The FAQ page, while it is extremely comprehensive, there are a lot of questions there that I know will come up when you're putting your grant together or thinking about putting your grant, so use that as a resource, and you'd be surprised. I bet your question is on there already. Not to say that I'm not happy to answer it, but I might save you some time, and then maybe when we meet, we can focus on real .. . do a deeper dive on what you really want to talk about or your project.

Monique Pond: Mm-hmm. All right. Miguel, what about you?

Miguel Contreras: Well, I will just remind the audience the title of this session: "Compete Like a Pro." So get ready, get prepared. Don't be afraid to call us and share your idea or your project, and help us to advance the mission of NIH.

Monique Pond: Mm-hmm. Great, thank you. Just try to call us at least a month before one of those omnibus deadlines, right?

Miguel Contreras: Right.

Monique Pond: Right.

Lili Portilla: Yeah, please.

Monique Pond: Yup, you'll find a program officer who has more availability in time to really dive into your project with you. Well, thanks, everybody, for joining us today. Hopefully, you found this session useful. And if you have additional questions, or there were a few questions that came in that were really specific to a project, definitely reach out and visit the HHS and NIH Hub on the conference site and request a 15-minute appointment with a program officer. We're happy to meet with you, and like we said, we're happy to meet with you outside of the conference, as well. So, with that, don't forget to share your feedback on the session and overall conference. Thank you. Have a good afternoon.

Miguel Contreras: Thank you.