

WEBVTT

1

00:00:05.130 --> 00:00:06.000

Monique LaRocque: Welcome everyone.

2

00:00:06.029 --> 00:00:07.890

Monique LaRocque: This webinar will begin shortly.

3

00:00:08.309 --> 00:00:14.280

Monique LaRocque: We want to make this very interactive and useful for you, so we have a dedicated Q&A period.

4

00:00:14.730 --> 00:00:20.940

Monique LaRocque: However, we're encouraging you to send us your questions throughout the presentation. If you hear something that you have questions about.

5

00:00:21.300 --> 00:00:28.380

Monique LaRocque: Please let us know, use the Q and A feature that you can find on Zoom. For some people it's in the right side, some people it's on the bottom of the screen.

6

00:00:28.710 --> 00:00:33.660

Monique LaRocque: Open that QA box and click it and drop your question and we'll answer it during the Q AND A.

7

00:00:34.260 --> 00:00:40.290

Monique LaRocque: We also wanted to share that we have some useful links for you, so we will have some things that will put in chat.

8

00:00:40.800 --> 00:00:52.050

Monique LaRocque: And you can open up your chat box and see some notes from my colleagues there so that you can see the links we are offering closed captioning and zoom technical support.

9

00:00:52.830 --> 00:01:00.780

Monique LaRocque: And we really well, I would like to request your feedback and so, if you can just click on the feedback link or type it.

10

00:01:01.500 --> 00:01:17.190

Monique LaRocque: If you're on chat you can click on it, if you are watching this online, you can type in that URL and let us know what you think. And join us on Twitter on the conversation. We have a dedicated hashtag feel free to use it throughout the presentation.

11

00:01:18.990 --> 00:01:20.160

Monique LaRocque: And please follow us.

12

00:01:22.080 --> 00:01:23.040

Monique LaRocque: Next slide please.

13

00:01:25.080 --> 00:01:36.390

Monique LaRocque: Just a note, because we always get this question, you can save the chat. So if you were to open your chat box you'll see at the end, there are three little dots on the right.

14

00:01:36.960 --> 00:01:49.410

Monique LaRocque: And you can save that chat. We'll also if you've registered for this presentation will share with you some of the links and then our website for those who are watching online have a lot of the links that will be discussing as well.

15

00:01:54.120 --> 00:02:03.870

Monique LaRocque: With that welcome. Today we're going to focus on how to leverage SBIR and STTR funding and other resources to create it diverse workforce and science and technology.

16

00:02:07.170 --> 00:02:18.480

Monique LaRocque: We have some great leaders with you today. Our experts from NCATS, which is really focus on translational science process and how to move new treatments and cures forward.

17

00:02:19.290 --> 00:02:34.890

Monique LaRocque: We're also joined by the National Heart Lung and Blood Institute both a part of NIH both have dedicated and strong small business programs and we're really delighted to also have partner XLerator Network and you'll hear from some of the leaders very soon.

18

00:02:38.220 --> 00:02:44.910

Monique LaRocque: Some of my esteemed colleagues are Dr. Stephanie Davis. She is a small business program coordinator from NHLBI.

19

00:02:45.540 --> 00:02:53.670

Monique LaRocque: you'll hear from Dr. Eugene Krentsel. He's the Chief Scientific officer and Vice President of Strategic Partnerships and Alliances at Accelerate Health.

20

00:02:54.600 --> 00:03:01.680

Monique LaRocque: Almesha L. Campbell. Dr. Campbell is the Assistant Vice President for Research and Economic Development at Jackson State University.

21

00:03:02.310 --> 00:03:12.510

Monique LaRocque: And Dr. Meena Rajagopal. She is a program officer at the Office of Strategic Alliances at NCATS. And I'll be your moderator for the first portion, and we'll also have a dedicated Q and A.

22

00:03:15.870 --> 00:03:31.020

Monique LaRocque: Today we'll go through some really important foundational elements to help you understand what is the SBIR STTR programs? What are the opportunities and resources for small business, both at NCATS and at NHLBI?

23

00:03:31.560 --> 00:03:41.790

Monique LaRocque: And then we'll talk a bit more about the Accelerated Network and EnRICH and then move into our Q and A period if you have questions. Again, feel free to use the Q and A chat feature.

24

00:03:45.810 --> 00:03:51.810

Monique LaRocque: And with that I'd like to welcome Dr. Meena Rajagopal is going to share information about NCATS.

25

00:03:55.380 --> 00:04:01.080

Meena Rajagopal: Hi everyone thanks Monique thanks for joining us today on this webinar.

26

00:04:01.860 --> 00:04:12.120

Meena Rajagopal: Before I start off, I want to say a big thank you to Stephanie, Eugene and Almesha for working, you know, collaborating with NCATS on this webinar.

27

00:04:12.750 --> 00:04:21.630

Meena Rajagopal: And, you know, Stephanie is a part of the NIH family so it's always great to have her and Eugene I know Eugene from, you know, the NIGMS-

28

00:04:21.960 --> 00:04:28.200

Meena Rajagopal: I had IDEa hubs meetings when I listened to his presentations and talks about, you know, very he.

29

00:04:28.770 --> 00:04:41.880

Meena Rajagopal: updates the NIH regularly on what the XLerator Network does for small businesses so it's good to have you, Eugene and I'm really looking forward to Almesha's talk and learn about, you know, resources that are.

30

00:04:42.480 --> 00:04:54.690

Meena Rajagopal: available to specifically increase diversity in small business workforce, I appreciate all your time and it's been an absolute pleasure, and, you know, great knowing great knowing you all.

31

00:04:55.410 --> 00:05:03.720

Meena Rajagopal: and working with you on this webinar collaboration. I think I'm now ready to dive into my talk. Let's go to the next slide please.

32

00:05:06.600 --> 00:05:15.660

Meena Rajagopal: Okay, so NCATS, which is short for the National Center for Advancing Translational Sciences, is one of the 27 institutes of the NIH.

33

00:05:16.560 --> 00:05:24.630

Meena Rajagopal: We were, we are a relatively new institute at the NIH. We just celebrated our 10th year anniversary this past December.

34

00:05:25.500 --> 00:05:32.040

Meena Rajagopal: And we are a little different when, you know, compared to the other Institutes at the NIH and what I mean by that is

35

00:05:32.610 --> 00:05:43.320

Meena Rajagopal: NCATS is not focused towards one particular disease. We are disease agnostic and our NCATS mission is to foster and promote

36

00:05:44.280 --> 00:05:54.000

Meena Rajagopal: translational science, so that, ultimately, that would lead to the development of more treatment options made available to all patients more rapidly.

37

00:05:54.330 --> 00:06:07.410

Meena Rajagopal: And the NCATS Small Business program is very much supportive and aligned with our mission statement that we found platform technologies that typically, you know, either identifies or mitigates

38

00:06:08.490 --> 00:06:26.460

Meena Rajagopal: a bottleneck in the translational science pipeline so again, leading to the development of, you know, providing more rapid and accurate diagnostics, more treatment options, and, you know, better management of various diseases and conditions. Let's go to the next slide please.

39

00:06:28.650 --> 00:06:38.670

Meena Rajagopal: So, to what's this mission, the NCATS has a number of initiatives that it manages and funds. A few of those are listed on this slide here.

40

00:06:39.030 --> 00:06:57.660

Meena Rajagopal: The first one is the Clinical and Translational Science Awards program within more than 50 institutes across the nation participate and are funded and again they all work together to speed up the translation of findings from basic science to improve patient care.

41

00:06:58.710 --> 00:07:05.370

Meena Rajagopal: Then we have the, you know, I did say -- I'm sorry I did say that we are disease agnostic but then,

42

00:07:06.510 --> 00:07:13.230

Meena Rajagopal: having said that, we do have a high interest in rare diseases and that's exactly why we have this Rare Disease.

43

00:07:13.920 --> 00:07:24.510

Meena Rajagopal: Research Network program to promote research in this specific area. We also have something called the New Therapeutic Uses program within NCATS. It tries to pair up

44

00:07:25.170 --> 00:07:31.440

Meena Rajagopal: investigators with shelf assets from Pharma that has probably failed for a particular indication right.

45

00:07:31.980 --> 00:07:42.030

Meena Rajagopal: But the purpose of this program is to see if that wealth of clinical information available on that shelf asset can be repurposed for a different disease.

46

00:07:42.840 --> 00:08:00.660

Meena Rajagopal: The application for the New Therapeutic Uses program is accepted yearly and on a rolling basis and gets also housed in the Chemical Genomic Center, which does a lot of high-throughput screening for drugs. And two of the programs that that we run out of our intramural.

47

00:08:02.400 --> 00:08:12.660

Meena Rajagopal: program are the BrIDGs and the TRND programs that I would like to touch upon a little bit more in detail towards the end of my talk, but NCATS also has these other cool re-engineering

48

00:08:12.990 --> 00:08:19.680

Meena Rajagopal: Initiatives like the Tissue Chip program that we run out of our Center. Let's go to the next slide please.

49

00:08:21.510 --> 00:08:34.200

Meena Rajagopal: So now going over a quick overview of the SBIR and STTR program in itself. SBIR is short for Small Business Innovation Research and STTR, which is

50

00:08:34.500 --> 00:08:41.820

Meena Rajagopal: Small Business Technology Transfer Research programs, are America's Seed Fund, and it is one of the largest.

51

00:08:42.600 --> 00:08:49.110

Meena Rajagopal: early-stage funding available for small businesses research and development. This is a congressionally mandated program.

52

00:08:49.470 --> 00:08:54.420

Meena Rajagopal: in which a number of other institutes participate, like the CDC and the FDA including NIH.

53

00:08:54.810 --> 00:09:10.140

Meena Rajagopal: And the budget for the small business program tracks, the agency's budget and what this means at the NIH is that it's about a billion dollars, that is shared among the 24 participating institutes within the NIH. Excuse me.

54

00:09:11.250 --> 00:09:22.320

Meena Rajagopal: And, you know, I do want to share a little bit of a tidbit information that a lion's share of this budget goes toward funding the SBIR program. This is not to say that the NIH.

55

00:09:22.590 --> 00:09:32.310

Meena Rajagopal: prefers the SBIR over STTR. Definitely not. But this is just how Congress had made a mandated or divided where the majority of the funds should go.

56

00:09:33.390 --> 00:09:43.200

Meena Rajagopal: So, the slide here does have the FY21 funds, but then we are still waiting on the reauthorization for the next fiscal year, which I hope.

57

00:09:43.950 --> 00:09:55.050

Meena Rajagopal: gets through it gets fast, but that's the hope. It's about a billion dollars a little over a billion dollars set aside for the small business program. Let's go to the next slide please.

58

00:09:57.210 --> 00:10:07.140

Meena Rajagopal: So, there are multiple advantages to applying to the NIH small business program. Right, one, like I said earlier, the budget tracks, the agency's

59

00:10:07.530 --> 00:10:19.560

Meena Rajagopal: budget, so what this means is the funding is stable and predictable and, second of all, it is non diluted, meaning the IP rights belong to the small business and NIH was never the customer.

60

00:10:20.130 --> 00:10:29.220

Meena Rajagopal: And once the awardee, there are other resources within the NIH that the small business can leverage to further develop and commercialize the product or technology.

61

00:10:29.910 --> 00:10:36.060

Meena Rajagopal: There is one of the added advantage to applying to the NIH program and that's the peer review process.

62

00:10:36.570 --> 00:10:49.950

Meena Rajagopal: Every application that comes in, through the SBIR STTR mechanism goes through a rigorous peer review process that is conducted by the Center for Scientific Review another Institute within the NIH and what this allows is

63

00:10:50.610 --> 00:11:05.250

Meena Rajagopal: the small businesses, an opportunity to go outside of NIH and look for other potential collaboration or funding opportunities right because guess what now your science or project has been validated by the National Institutes of Health.

64

00:11:05.850 --> 00:11:10.410

Meena Rajagopal: So that's one of the biggest advantages of applying to the NIH small business program.

65

00:11:11.430 --> 00:11:12.720

Meena Rajagopal: Let's go to the next slide please.

66

00:11:14.610 --> 00:11:19.530

Meena Rajagopal: So, with this slide I just want to highlight a few key differences between the two programs.

67

00:11:20.190 --> 00:11:30.390

Meena Rajagopal: So, within the SBIR, the small business is allowed to partner up with a nonprofit research institute, however, this is an absolute requirement under the STTR so, in other words.

68

00:11:30.660 --> 00:11:45.420

Meena Rajagopal: If you wish to apply under the STTR, then the small business has to partner up or work with a nonprofit research institute like a US college or university or other federally funded research and development centers. What we call FRDCs.

69

00:11:46.860 --> 00:11:52.200

Meena Rajagopal: The other major difference between the two program comes with the primary employment of the principal investigator.

70

00:11:52.530 --> 00:11:59.070

Meena Rajagopal: So, the primary employment of the principal investigator under the SBIR program has to be with the small business, obviously.

71

00:11:59.400 --> 00:12:11.430

Meena Rajagopal: But there is some flexibility when it comes to the STTR program so under the STTR program the primary employment of the principal investigator can be either with the small business or the nonprofit research institute.

72

00:12:11.880 --> 00:12:27.510

Meena Rajagopal: But I do want to drive home a very important message from this light and that's the line at the very bottom. Right. So, no matter which mechanism that you apply to, SBIR or STTR, all of the money always goes to the small business. Let's go to the next slide.

73

00:12:30.210 --> 00:12:38.430

Meena Rajagopal: So, to quickly go over the three phases of the SBIR or STTR program here, and please be advised that these three phases

74

00:12:39.210 --> 00:12:44.670

Meena Rajagopal: are not the same as the clinical phases of the clinical trial. This is completely different right and.

75

00:12:45.420 --> 00:12:52.950

Meena Rajagopal: For instance, in our-- under Phase I, we are actually looking for applications that talk about a proof of concept or a feasibility study.

76

00:12:53.910 --> 00:13:06.240

Meena Rajagopal: So, we do and create a few lines about the commercialization plan under Phase one but it's not a requirement and the budget that you can request under a Phase I is about 276 K.

77

00:13:06.750 --> 00:13:20.130

Meena Rajagopal: Again, this is the SBIR STTR set hard cap. However, each participating institutes like the NHLBI and NCATS have their own topics of interest, which we call Waiver Topics.

78

00:13:20.460 --> 00:13:36.300

Meena Rajagopal: And if you wish to apply under one of those way what topics, you can request over the SBIR budget hard cap of 276 K, so our NCATS are you can request up to about 325 K, if you wish to apply under the waiver topic.

79

00:13:37.410 --> 00:13:44.340

Meena Rajagopal: Then there's the Phase II, which is a more full-blown research and development plan, but in the commercialization.

80

00:13:45.030 --> 00:13:53.550

Meena Rajagopal: aspect or the plan is actually built into the application. Again, within the Phase II, there are two mechanisms: one the Fast Track, and the second is the.

81

00:13:54.150 --> 00:14:07.380

Meena Rajagopal: Direct-to-Phase II. In the Fast Track you basically combine the Phase I and the Phase II so you apply up contingent upon meeting the Phase I milestones, your Phase II award would be made.

82

00:14:07.830 --> 00:14:19.260

Meena Rajagopal: And, you know, Direct-to-Phase II, like the name suggests, you skip Phase I and directly apply for Phase II funding, and this is where, you know, you're very confident about your preliminary data that you want to apply to the next level.

83

00:14:19.740 --> 00:14:31.560

Meena Rajagopal: And the budget that you can request and Phase II is about \$1.8 million over the period of two years but, again, if you wish to apply under one of those waiver topics, you can request up to about \$2 million.

84

00:14:32.010 --> 00:14:45.210

Meena Rajagopal: Then there's the Phase IIB, and please note that not all participating Institutes within the NIH participate in the Phase IIB, but NCATS does and I'm gonna let Stephanie talk about the Phase IIB.

85

00:14:46.110 --> 00:14:54.540

Meena Rajagopal: In which NCATS is participating, and this is led by the NHLBI, so I will, you know, leave it for Stephanie to talk about it, but just to quickly mention,

86

00:14:55.260 --> 00:15:05.130

Meena Rajagopal: you know, at NCATS, we are looking to support projects under this Phase IIB so that, you know, we can help the small business get through the key inflection point like say.

87

00:15:05.430 --> 00:15:14.940

Meena Rajagopal: You know, you need to file an IND or you need and state-of-the-art complex instrumentation so that's when you can request up to about.

88

00:15:15.720 --> 00:15:18.990

Meena Rajagopal: A million dollars for about three years.

89

00:15:19.380 --> 00:15:27.600

Meena Rajagopal: Then there's the Phase III, which is the actual commercialization part of this program. Right. So, if you were to apply to a different agency like, say,

90

00:15:27.840 --> 00:15:38.460

Meena Rajagopal: The D o D, then the Phase II – Phase III is when the agency would actually buy the product or technology from you, but in NCATS, we want you to think.

91

00:15:39.270 --> 00:15:48.750

Meena Rajagopal: of an exit strategy to say graduate out of the program. So, those are the three phases of the NIH SBIR STTR program. Let's go to the next slide.

92

00:15:51.120 --> 00:16:02.160

Meena Rajagopal: Okay, there are different funding, you know, mechanisms available when you apply to the small business program at NIH and what I mean by that is there's the investigator-initiated Omnibus Solicitation.

93

00:16:03.210 --> 00:16:08.190

Meena Rajagopal: I do I'm very happy to let you know at this point of time that we do have

94

00:16:09.660 --> 00:16:26.760

Meena Rajagopal: The FY 22 Omnibus Solicitation out on the streets, you know, it's active I would strongly encourage you to please, you know, go give it a read and familiarize yourself with the Omnibus --new Omnibus Solicitation funding announcement and if you have any questions, please reach out to us.

95

00:16:27.780 --> 00:16:42.120

Meena Rajagopal: But then going back to the different funding mechanisms, you know, so there's the Omnibus Solicitation and then there is targeted grant solicitation, which is typically, you know, to promote a particular research area, or a techno-- excuse me, technology.

96

00:16:43.290 --> 00:16:51.540

Meena Rajagopal: The funding, the deadline for the Omnibus Solicitation is typically, you know, thrice a year and these are standard deadlines.

97

00:16:52.110 --> 00:17:05.730

Meena Rajagopal: In September, you know, January 5, April 5, and September 5 but this year I believe September 5 is a holiday, so the deadline, the upcoming deadline for the Omnibus Solicitation would be September 6.

98

00:17:06.660 --> 00:17:14.910

Meena Rajagopal: The deadlines for the targeted solicitation usually track the standard deadlines of the Omnibus Solicitation but depending on the topic of interest.

99

00:17:15.150 --> 00:17:24.030

Meena Rajagopal: It could vary, so again, I would strongly suggest that you familiarize yourself with the funding announcements and again if you have any questions reach out to us.

100

00:17:25.230 --> 00:17:37.740

Meena Rajagopal: Then we have the contract solicitations and, since these are contractual agreements, there are some deliverables that have to be met and the contract solicitations the applications are due sometime in October-November timeframe.

101

00:17:38.910 --> 00:17:40.440

Meena Rajagopal: Let's go to the next slide please.

102

00:17:43.380 --> 00:17:56.250

Meena Rajagopal: Okay, so like I said earlier, NCATS' mission is to catalyze translational sciences so more treatment options are available to all patients more rapidly and the small business program, you know, supports.

103

00:17:56.730 --> 00:18:07.110

Meena Rajagopal: supports or funds platform technologies that support our NCATS mission and research priorities and these would broadly fall under these three buckets right.

104

00:18:07.680 --> 00:18:20.130

Meena Rajagopal: The topics of interest could be, you know, under either preclinical drug discovery and development biomedical clinical and health research informatics or clinical dissemination and implementation research.

105

00:18:21.000 --> 00:18:31.890

Meena Rajagopal: I'm not going to get into the details of what sub-topics are included in each one of those, but I think Melissa was chatting it out, so if you can check out the PDF and, you know,

106

00:18:32.250 --> 00:18:43.230

Meena Rajagopal: read about those topics, and, you know, happy to have a conversation and see if your proposal is aligned with our research interests. Let's go to the next slide please.

107

00:18:47.340 --> 00:18:54.390

Meena Rajagopal: So, with this slide, I just wanted to spotlight, a few of the targeted funding announcements that are active and we are accepting applications for.

108

00:18:55.110 --> 00:19:10.800

Meena Rajagopal: Like I said I'm going to have Stephanie Davis talk about the NHLBI-led SBIR Phase IIB, which is Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood and Sleep Disorders.

109

00:19:11.220 --> 00:19:28.830

Meena Rajagopal: But then I do want to draw your attention to the new now funding announcement that we have, which is the Notice of Special Interest that is led by NIEHS that is specifically to promote Innovative Technologies for Research on Climate Change and Human Health.

110

00:19:29.970 --> 00:19:44.190

Meena Rajagopal: Human health. And both NHLBI and NCATS are participating in these NOSIs so again, please I would strongly encourage you to read the funding announcement and if you have any questions reach out to us. Next slide, please.

111

00:19:46.920 --> 00:19:59.130

Meena Rajagopal: Okay, with this one, I just wanted to give you all a sense of the timeline involved in this whole process right, so if you're looking for fast money, this is probably not the best route and I'll tell you in a second why.

112

00:19:59.880 --> 00:20:07.950

Meena Rajagopal: Let's pick the September deadline, I mean the deadlines mentioned in the slides are the standard like deadlines, but again this year.

113

00:20:08.310 --> 00:20:17.100

Meena Rajagopal: September 5 is holidays, so it would be the first September 6th. So let's pick the September deadline. Right. So, applications are due by September 6 this year.

114

00:20:17.580 --> 00:20:26.730

Meena Rajagopal: And the scientific review this that is conducted by the Center for Scientific Review happens sometime in October November timeframe and then each

115

00:20:27.690 --> 00:20:33.750

Meena Rajagopal: Institute has an internal review and at NCATS this happens some time around,

116

00:20:34.590 --> 00:20:49.860

Meena Rajagopal: You know January or late February and by the time the notice of award is sent to the applicant from the grants management office it's about, you know, it can be anywhere between in between April or, you know, March or April.

117

00:20:50.970 --> 00:21:00.330

Meena Rajagopal: So, it takes about six to eight months from the time of application to the time of, you know, know getting to know whether your project has been funded or not.

118

00:21:01.110 --> 00:21:07.590

Meena Rajagopal: I mean, this is a waiting game which, you know, can be pretty nerve-wracking and we totally get that right, but please.

119

00:21:08.010 --> 00:21:17.430

Meena Rajagopal: understand that there are a number of Offices, Divisions and Institutes that are working along in this process, so it does take quite a bit of time.

120

00:21:18.180 --> 00:21:28.140

Meena Rajagopal: But when you apply for this program do keep in mind the benefits that I went through earlier, which is, you know, the non-dilutive part of it.

121

00:21:28.710 --> 00:21:42.630

Meena Rajagopal: So, it's, you know, worth applying to the small business program so just keep that in mind that it does take eight to six, you know, anywhere from six to eight months for you to know the decision on your application. Let's go to the next slide.

122

00:21:45.450 --> 00:21:53.010

Meena Rajagopal: There are also some specially desig-, special designations set forth by the US Small Business Administration, you know.

123

00:21:53.910 --> 00:22:01.020

Meena Rajagopal: At the time when you register your company at [SAM.gov](https://www.sam.gov), you have the option to self-identify.

124

00:22:01.410 --> 00:22:11.130

Meena Rajagopal: And the eligibility criteria for these special designations of small businesses again is set forth by the US Small Business Administration. NIH has nothing to do with it.

125

00:22:11.790 --> 00:22:26.010

Meena Rajagopal: But the reason why I want to bring it up to your attention is because both SBA and NIH track the number of applications coming from these specially designated small businesses, and, you know, this would in turn help us.

126

00:22:27.510 --> 00:22:35.070

Meena Rajagopal: You know, see if we have to do outreach events specifically targeting these, you know, small businesses, so I would strongly encourage.

127

00:22:35.730 --> 00:22:48.810

Meena Rajagopal: If you if you can to self-identify your businesses when you register at SAM. [SAM.gov](https://www.sam.gov). And, you know, if you did not, that's okay. I believe there is a way that you can get in touch with the help desk and get that going.

128

00:22:50.340 --> 00:22:51.630

Meena Rajagopal: Let's go to the next slide please.

129

00:22:53.790 --> 00:23:02.820

Meena Rajagopal: So now, you know, I want to jump into some of the resources that are available within an NIH and also within NCATS.

130

00:23:03.210 --> 00:23:11.010

Meena Rajagopal: For small businesses and the first one that I want to talk about is the Applicant Assistance Program. So, if you're applying.

131

00:23:11.580 --> 00:23:27.840

Meena Rajagopal: To the SBIR or STTR program for the first time or say you have not been successful in your previous attempts, then you are eligible to apply and leverage this, um, you know free application preparation assistance program.

132

00:23:29.010 --> 00:23:35.580

Meena Rajagopal: They do help you with putting in a strong application for your Phase I for the Omnibus Solicitation.

133

00:23:36.120 --> 00:23:46.830

Meena Rajagopal: And the application portal is open about two months prior to the deadlines for the Omnibus Solicitation so you once you're you apply and you're selected --

134

00:23:47.250 --> 00:24:06.690

Meena Rajagopal: And I do want to mention here that not all again, not all Institutes within the NIH participate in the Applicant Assistance Program and both in NCATS and NHLBI participate, and we do have a limited number of slots, that has to be filled out filled in for each cohort.

135

00:24:07.710 --> 00:24:22.800

Meena Rajagopal: You know, for the three cohorts across the year, but then once selected, you will be us, you know, you will work with a coach from Eva Garland consulting services, [which] would provide you assistance in preparation and.

136

00:24:23.280 --> 00:24:34.710

Meena Rajagopal: submission of your grant application, you would also have the opportunity to, you know, talk to program officials, one-on-one and get their feedback on how good.

137

00:24:35.130 --> 00:24:45.480

Meena Rajagopal: Your proposal is a fit for their Institute and the main goal of the Applicant Assistance Program is to encourage small businesses.

138

00:24:46.560 --> 00:24:57.180

Meena Rajagopal: Participation in the SBIR's two-year program, particularly those that are owned by individuals who are traditionally underrepresented in the biomedical sciences research area.

139

00:24:57.690 --> 00:25:10.380

Meena Rajagopal: So, and I just strongly encourages applications from these women-owned businesses, socially and economically disadvantaged businesses that might be located in these underrepresented IDeA states.

140

00:25:11.730 --> 00:25:22.470

Meena Rajagopal: So that's a, you know, Applicant Assistance Program is an NIH-wide resource that again the small businesses can leverage to put in a strong application. Let's go to the next slide please.

141

00:25:25.590 --> 00:25:32.820

Meena Rajagopal: Another resource that we have available for our awardees is the Administrative Supplements to Promote Diversity.

142

00:25:33.390 --> 00:25:38.640

Meena Rajagopal: So, again I do want to stress that this is a, you know, early for our awardees.

143

00:25:39.300 --> 00:25:49.560

Meena Rajagopal: Basically, if you have a member in your team that would qualify for this award, then the Institute would pay for this salary and the purpose of this funding announcement is to again.

144

00:25:49.890 --> 00:26:02.730

Meena Rajagopal: enhance the diversity of the NIH-supported workforce. Both NCATS and NHLBI participate in this funding announcement, but again I do want to say that this is only open only to our current awardees.

145

00:26:03.750 --> 00:26:05.100

Meena Rajagopal: Let's go to the next slide please.

146

00:26:07.020 --> 00:26:17.430

Meena Rajagopal: Then we have the NCI-led I-Corps program and again our awardees can apply for this program and NCATS will basically pay for the company to go through.

147

00:26:17.820 --> 00:26:24.450

Meena Rajagopal: This training, which is about eight to nine week-long hands-on mentored program.

148

00:26:24.930 --> 00:26:36.750

Meena Rajagopal: With a, you know, with a lot of opportunity for the company to network and really do some customer discovery and understand the markets' needs and the goal again for the I-Corps program is to.

149

00:26:37.200 --> 00:26:43.980

Meena Rajagopal: equip the small businesses, so that they can, you know, successfully take their product or technology to the market.

150

00:26:45.330 --> 00:26:46.680

Meena Rajagopal: Let's go to the next slide please.

151

00:26:49.530 --> 00:26:54.630

Meena Rajagopal: So very similar program that runs out of the SEED Office here at the NIH is the TABA.

152

00:26:55.770 --> 00:27:08.190

Meena Rajagopal: Technical and Business Assistance program and here we try to connect our awardees with a third party that would provide an unbiased assessment of your technical and business plans and again.

153

00:27:08.610 --> 00:27:22.020

Meena Rajagopal: You know, they would help you make some wise decisions minimizing risk and the goal is to, you know, make sure that the small business are successful when they take their product or technology to the market.

154

00:27:23.040 --> 00:27:24.150

Meena Rajagopal: Next slide please.

155

00:27:26.550 --> 00:27:37.680

Meena Rajagopal: So, we have the TABA needs assessment that is out there. It's a funding announcement again for our current awardees who have not leveraged the TABA funding that I talked about.

156

00:27:37.950 --> 00:27:46.770

Meena Rajagopal: In my earlier slide, it is very similar, you know, the goal is again very similar, but the funding announcement is out on the streets, and please go check it out and,

157

00:27:47.340 --> 00:27:54.510

Meena Rajagopal: you know, if you have any questions reach out to the SEED office or any one of us. We will be more than happy to answer questions. Next slide please.

158

00:27:56.910 --> 00:28:07.410

Meena Rajagopal: Okay, now that I've talked about NIH-wide resources, I do want to touch upon some of the resources that we have at NCATS for small, you know, SBIR- STTR-eligible companies.

159

00:28:07.800 --> 00:28:17.730

Meena Rajagopal: Not just as SBIR- STTR-eligible companies -- I'm sorry -- but also to other you know, researchers, including academics. Right? So one such as some, you know, expertise.

160

00:28:18.090 --> 00:28:24.630

Meena Rajagopal: That our therapeutic development team has to offer, and many of which is listed on this slide.

161

00:28:25.320 --> 00:28:39.300

Meena Rajagopal: But again, the goal of this is to help our researchers both again academics and small business entrepreneurs to, you know, get through the key inflection point and cross the valley of death, so they could, you know,

162

00:28:39.810 --> 00:28:53.100

Meena Rajagopal: they can be good and help them achieve what they want to accomplish. This can be anywhere, there is a huge like I said, and, you know, listed in the slide there is a menu of services that you can leverage.

163

00:28:53.820 --> 00:29:08.790

Meena Rajagopal: From say optimization of your medicinal chemistry, evaluation of your PK-PD studies, you know, we can also connect you with the CROs to do your GMP studies and, you know, provide us some regulatory assistance and support.

164

00:29:10.020 --> 00:29:14.100

Meena Rajagopal: In addition to the one that is offered by the SEED office at the NIH.

165

00:29:14.820 --> 00:29:27.120

Meena Rajagopal: But again, you know, if you're interested in any of the services, please reach out to our office and we'll be more than happy to put you in touch with the right people within the Therapeutic Development team. Let's go to the next slide please.

166

00:29:30.420 --> 00:29:38.640

Meena Rajagopal: So, the other two programs that I want to touch upon a little bit more in detail or the BRIDGs and the TRND programs. So BRIDGs is short for Bridging Interventional

167

00:29:38.940 --> 00:29:46.320

Meena Rajagopal: Development Gaps program. Here the applicant actually comes in, when you have already identified a clinical candidate

168

00:29:47.190 --> 00:29:58.410

Meena Rajagopal: that, you know, we would look at your application, and, you know, probe, you know, specifically the Division of Preclinical Innovation team will look at the application and do the gap analysis and.

169

00:29:58.950 --> 00:30:09.840

Meena Rajagopal: We do help you out to say to put up strong application for an IND filing. They work with different modalities like small molecules therapeutics,

170

00:30:10.410 --> 00:30:21.240

Meena Rajagopal: recombinant proteins and again, you know, the goal of the BRIDGs program is to help you cross that valley of death and be able to successfully file an IND.

171

00:30:22.620 --> 00:30:23.940

Meena Rajagopal: Let's go to the next slide please.

172

00:30:27.300 --> 00:30:34.680

Meena Rajagopal: And then there is the very similar to BRIDGs program we have the TRND program, which is short for Therapeutics for Rare and Neglected

173

00:30:35.040 --> 00:30:41.880

Meena Rajagopal: Diseases. Right. The main difference between the TRND and BRIDGs is that, for the TRND program you don't need to have.

174

00:30:42.660 --> 00:30:48.660

Meena Rajagopal: You know, clinical candidate identified, you can come into the program at any of the preclinical stage develop, you know, development stage.

175

00:30:48.990 --> 00:30:59.850

Meena Rajagopal: And I do want to iterate that both the purchase and the trends program are available, or, you know, to all investigators SBIR- and STTR-eligible companies and academics.

176

00:31:00.510 --> 00:31:06.690

Meena Rajagopal: Please reach out to us and we will be more than happy to connect you with the folks at the Preclinical Development team.

177

00:31:07.890 --> 00:31:09.180

Meena Rajagopal: Let's go to the next slide please.

178

00:31:11.310 --> 00:31:17.820

Meena Rajagopal: So, in this slide, I just wanted to share a case study of wherein we had this academic investigator, who came to us.

179

00:31:19.020 --> 00:31:27.300

Meena Rajagopal: You know, through the BrIDGs program. She had identified a new molecular entity for treatment for a rare disease and she had cobbled up about.

180

00:31:27.780 --> 00:31:34.650

Meena Rajagopal: Three point five million with an RO1 and STTR combined, but when she went.

181

00:31:35.130 --> 00:31:45.180

Meena Rajagopal: To have this conversation with FDA during one of those pre-IND meetings, she found out that, you know, she needs to do tox studies on two animal models which would, which would easily cost about.

182

00:31:45.570 --> 00:31:51.780

Meena Rajagopal: You know, a half a million dollars and that's when she applied to the BrIDGs program at NCATS and our team.

183

00:31:52.200 --> 00:32:01.530

Meena Rajagopal: Looked at the application and we did determine that yes, she needs these resources to be able to, you know, file a successful IND. So we helped her out.

184

00:32:02.370 --> 00:32:18.390

Meena Rajagopal: Because of which she was, you know, able to put in an IND application that was very-- that was approved and, ultimately, was able to raise about \$50 million and VC funding so just wanted to, you know, share that case study with you.

185

00:32:19.440 --> 00:32:20.730

Meena Rajagopal: Let's go to the next slide please.

186

00:32:22.770 --> 00:32:26.160

Meena Rajagopal: I believe this is my last slide, so I just want to say that, you know,

187

00:32:27.000 --> 00:32:33.060

Meena Rajagopal: There are different ways that you can engage with NCATS and I would prefer that you send us an email to that mailbox.

188

00:32:33.330 --> 00:32:44.160

Meena Rajagopal: And, you know, there are actually real people checking that mailbox, believe it or not, you know, my supervisor, who is the director for the program, and I check the mailbox every day and respond to those emails.

189

00:32:44.670 --> 00:32:58.770

Meena Rajagopal: So please do get in touch with us and, at the very least, we will be able to, you know, we would be would definitely connect you with our colleagues like Stephanie and others at other institutes when we think that your project is probably better aligned to their mission and.

190

00:33:00.120 --> 00:33:12.270

Meena Rajagopal: better aligned to their research focus, but again I really hope to hear from some of you in the near future, but that I pass the baton to Stephanie Davis. Thank you all.

191

00:33:15.540 --> 00:33:24.960

Stephanie Davis: Thank you so much Meena and good afternoon, everyone. My name is Stephanie Davis, I am the small business program coordinator for the National Heart, Lung and Blood Institute.

192

00:33:25.260 --> 00:33:34.470

Stephanie Davis: So, I'm just briefly going to be going over some of the specific resources that are available for NHLBI grantees and applicants. Next slide please.

193

00:33:35.430 --> 00:33:47.310

Stephanie Davis: So, the NHLBI small business program -- as our Institute name would probably suggest - - we are very interested in funding the development of innovative and commercially promising products to prevent,

194

00:33:47.610 --> 00:34:00.750

Stephanie Davis: treat, research and diagnose heart-, lung-, blood- and sleep-related diseases. So there is one exception to this rule if you are interested in developing anything for longer blood cancers.

195

00:34:01.290 --> 00:34:09.510

Stephanie Davis: it'll probably be more of interest to our colleagues at the National Cancer Institute, but any non-oncological diseases in these areas, we are interested in funding.

196

00:34:09.780 --> 00:34:19.500

Stephanie Davis: So, our program is the fourth largest small business program at the NIH. We have approximately 120 million dollars to fund.

197

00:34:19.950 --> 00:34:31.410

Stephanie Davis: Just over 300 active projects, so, if you look at this pie chart. This shows examples of some of the types of technologies that the NHLBI small business program funds.

198

00:34:32.250 --> 00:34:41.220

Stephanie Davis: Just over a third of our portfolio goes towards funding therapeutics which include, of course, biologic, small molecules, gene therapies, etc.

199

00:34:41.550 --> 00:34:48.780

Stephanie Davis: About 30% of our portfolio goes towards supportive devices, which include both surgical and therapeutic devices.

200

00:34:49.200 --> 00:34:56.580

Stephanie Davis: About 8% each of our portfolio goes towards the development of research tools -- in vitro diagnostic tools.

201

00:34:56.850 --> 00:35:08.250

Stephanie Davis: and monitoring or diagnostic devices and then the remaining portion of our portfolio goes towards funding digital health and health IT-type technologies and imaging devices so.

202

00:35:08.580 --> 00:35:12.870

Stephanie Davis: In terms of the types of technologies we find we find just about everything and.

203

00:35:13.140 --> 00:35:24.030

Stephanie Davis: If you have any technology that is maybe in one of those smaller portions of the pie chart please do not be concerned and think that we are not interested in funding it. This distribution does change.

204

00:35:24.540 --> 00:35:31.980

Stephanie Davis: on a yearly basis, based on what applications we get through the Omnibus funding opportunity announcements. Next slide please.

205

00:35:33.900 --> 00:35:39.450

Stephanie Davis: So, as I mentioned in the previous slide our main mission space focuses on.

206

00:35:39.720 --> 00:35:53.100

Stephanie Davis: The development of new technologies, towards the treatment, diagnosis and research of heart, lung, blood and sleep disorders. So, while this does not include all of the conditions we are interested in at the NHLBI this does contain a.

207

00:35:53.610 --> 00:36:02.310

Stephanie Davis: broad overview of the type of conditions were interested in funding, so if you are developing a technology for a disease that you see listed here.

208

00:36:03.090 --> 00:36:13.380

Stephanie Davis: There than you are probably going to want to apply to us, and if you are in doubt of whether or not your technology fits in our mission space, we definitely recommend reaching out to us.

209

00:36:13.800 --> 00:36:26.790

Stephanie Davis: And in addition to funding these a heart, lung, blood and sleep conditions, the NHLBI is also interested in funding technologies that can improve the implementation of and dissemination of.

210

00:36:27.930 --> 00:36:38.670

Stephanie Davis: Evidence-based interventions for heart, lung, blood and sleep diseases, so if you have a technology that falls in that mission space, I would definitely recommend reaching out to us as well. Next slide please.

211

00:36:39.750 --> 00:36:53.610

Stephanie Davis: So here is a table that shows some of the different targeted funding opportunities that we participate in. So, like NCATS, we also participate in the Omnibus funding opportunity announcements, and we will fund clinical trials.

212

00:36:53.880 --> 00:37:07.860

Stephanie Davis: Through Phase I and Phase II for both SBIR STTR applications. So, while most of our applications that we get come in through those Omnibus applicant funding opportunities and they are investigator-initiated.

213

00:37:08.190 --> 00:37:18.060

Stephanie Davis: Here are some examples of targeted funding opportunity announce-, announcements that we are interested in. So, as Meena mentioned, we do have two different Phase IIB programs,

214

00:37:18.540 --> 00:37:28.980

Stephanie Davis: which are designed to provide additional support for former Phase II grantees who need additional funds to meet their commercial and regulatory milestones so.

215

00:37:29.280 --> 00:37:37.890

Stephanie Davis: The bridge award program provides funding for any heart-, lung-, blood- or sleep-related technology, but she specifically focused on the Small Market Award.

216

00:37:38.160 --> 00:37:52.680

Stephanie Davis: And that is one the NCATS co-funds applications with us the Small Market program. I will provide a little bit more details later, but those are specifically for applications that are for rare diseases and pediatric indications.

217

00:37:53.220 --> 00:38:02.580

Stephanie Davis: We also participate in the SBIR STTR Commercialization Readiness Pilot program, and this is designed to provide additional funding to.

218

00:38:02.790 --> 00:38:12.480

Stephanie Davis: Current and recent Phase II or Phase IIB awardees that need additional funds to cover activities that are not normally supported using small business funds.

219

00:38:13.290 --> 00:38:20.520

Stephanie Davis: We also participate, along with NCATS in the NIMHD Innovations for Healthy Living SBIR RFA.

220

00:38:20.820 --> 00:38:28.440

Stephanie Davis: So, if you are developing a technology or a device that is specifically focused on reducing health disparities.

221

00:38:28.710 --> 00:38:36.930

Stephanie Davis: And, you know, in this case the context is health disparities in heart, lung, blood and sleep disorders, this is a really great funding opportunity to apply to.

222

00:38:37.500 --> 00:38:41.670

Stephanie Davis: We also participate in the Technologies Directed at Enhanced Pain Management.

223

00:38:42.000 --> 00:38:47.250

Stephanie Davis: The HEAL Initiative RFS, which are run by the National Institute for Neurological Disorders and Stroke.

224

00:38:47.520 --> 00:38:55.950

Stephanie Davis: So, if you're working on something that focuses on pain management in the context of heart, lung, blood or sleep disorders, I would recommend checking these out.

225

00:38:56.580 --> 00:39:02.670

Stephanie Davis: We also participate in the Innovative Diagnostic Technology for Improving Outcomes for Maternal Health NOSI.

226

00:39:03.450 --> 00:39:18.030

Stephanie Davis: Just as NCATS does, and we also participate in I-Corps and I, ah, so current Phase I and early-stage Phase II grantees to the NHLBI are allowed to apply through I-Corps to work on their customer discovery.

227

00:39:18.840 --> 00:39:30.750

Stephanie Davis: And then, recently, we also signed on just like NCATS did to the Innovation-- Innovative Technologies for Research on Climate Change in Human Health, so if you're developing a technology that focuses on the intersection of.

228

00:39:31.050 --> 00:39:39.900

Stephanie Davis: Climate change-related health risks and heart, lung, blood, sleep health, this is an opportunity that might be of interest to you. Next slide please.

229

00:39:42.690 --> 00:39:53.460

Stephanie Davis: Another program that we participate in that is not a traditional funding opportunity announcement, but it is available to all SBIR and STTR grantees at the NHLB.

230

00:39:53.670 --> 00:40:05.790

Stephanie Davis: Is the Concept to Clinic: Commercializing Innovation or C3i program. So, this is a program that is specifically run by our colleagues at the National Institute for Biomedical Imaging and Bio-engineering.

231

00:40:06.120 --> 00:40:12.840

Stephanie Davis: And so, what it's designed to do is to allow medical device focused innovators to.

232

00:40:13.410 --> 00:40:25.830

Stephanie Davis: Access the tools and framework that are needed to commercialize their technologies or their devices, so this program specifically will provide up to 24 weeks of entrepreneurial training to current.

233

00:40:26.550 --> 00:40:31.620

Stephanie Davis: Small Business grantees as well as some non-small business grantees. So, if you have an RO1.

234

00:40:32.250 --> 00:40:44.730

Stephanie Davis: or have non-SBIR active award that focuses on the development of a medical device, and you're interested, I recommend reaching out to see if you're eligible, but the applications are due this August 5.

235

00:40:45.240 --> 00:40:52.620

Stephanie Davis: And it's a really great program and if you're a medical device innovator I highly recommend checking it out. Next slide please.

236

00:40:54.510 --> 00:40:59.370

Stephanie Davis: So, um, as I mentioned earlier, we have two different Phase IIBs.

237

00:41:00.750 --> 00:41:10.050

Stephanie Davis: um, SBIR RFAs, so the first one well that one is very broad and focuses on pretty much anything that is applicable under the NHLBI mission.

238

00:41:10.290 --> 00:41:19.350

Stephanie Davis: The small market award is the one that we both participate in with NCATS. So, in order to be eligible for a Phase IIB small market award.

239

00:41:20.160 --> 00:41:25.710

Stephanie Davis: You have to be a company that has previously received a Phase II

240

00:41:26.280 --> 00:41:32.880

Stephanie Davis: Award. It doesn't necessarily have to be through the NHLBI. It just-- the project has to be within our mission space.

241

00:41:33.240 --> 00:41:47.670

Stephanie Davis: The technology has to require regulatory approval and it has to fall under one of these three criteria: the first is that it must address a rare disease, as defined in the Orphan Drug Act Amendment of 1984.

242

00:41:48.480 --> 00:42:00.150

Stephanie Davis: The second criteria is that it must be a device that qualifies as a humanitarian use device or, it must be a technology that is targeted at a young pediatric population.

243

00:42:00.840 --> 00:42:09.750

Stephanie Davis: So, this program will provide grantees with up to \$3 million of funding in total costs over a three-year period.

244

00:42:10.290 --> 00:42:26.520

Stephanie Davis: And so, when we give out these awards, we do expect them to bring in matching funds so for the small market awardees since we understand that the awardees under this program are often dealing with technologies that have smaller markets or smaller patient populations.

245

00:42:26.970 --> 00:42:33.240

Stephanie Davis: We are expecting a lower match compared to what we expect from our bridge fees to be awardees.

246

00:42:33.570 --> 00:42:43.050

Stephanie Davis: And what we expect is a 1 to 3 match, so what that means is that, if a small market award he gets a \$3 million award from the NHLBI and/or NCATS.

247

00:42:43.350 --> 00:42:55.590

Stephanie Davis: We are expecting them to bring in an additional \$1 million to other sources of funding and that can include anything from non-dilutive funding to venture capital investment angel investment.

248

00:42:56.490 --> 00:43:03.330

Stephanie Davis: And we were pretty flexible in terms of the type of investment that we allow for interested, please contact us for more details.

249

00:43:03.990 --> 00:43:13.110

Stephanie Davis: And so, through this program since the interest is also very interested in rare diseases, they have funded several awards with us.

250

00:43:13.680 --> 00:43:22.560

Stephanie Davis: Where we act as the administering IC, but they will contribute up to \$500,000 every year, if this is a project that they're interested in.

251

00:43:23.040 --> 00:43:36.180

Stephanie Davis: So, the Phase IIB programs accept applications, only one time, a year, so the next due date is going to be February 28, 2023 So if you are a current Phase IIB.

252

00:43:37.770 --> 00:43:48.450

Stephanie Davis: If you're a current Phase II awardee and you're thinking that this program might be of interest to you and you'd like to apply for the next cycle, please feel free to contact me afterwards, and we can discuss. Next slide please.

253

00:43:50.670 --> 00:43:59.280

Stephanie Davis: So, our small business program is housed within the NHLBI Office of Translational Alliances and coordination within.

254

00:43:59.460 --> 00:44:09.930

Stephanie Davis: The Division of Extramural Research Activities, so our office does provide a lot of really great resources to small business grantees including commercialization programs.

255

00:44:10.590 --> 00:44:23.460

Stephanie Davis: awards to accelerate commercialization, such as the Phase IIB and the CRP awards we provide programs to support diversity, so we also participate in the Diversity Supplement program and the Applicant Assistance Program.

256

00:44:24.090 --> 00:44:34.080

Stephanie Davis: But we also provide resources to academic innovators, and these include programs, such as the Catalyze program, which provides support for both academics and small businesses.

257

00:44:34.440 --> 00:44:42.300

Stephanie Davis: And the CAPCaT program, which provides funding to companies that are developing point of care devices for heart, lung, blood or sleep disorders.

258

00:44:42.750 --> 00:44:52.350

Stephanie Davis: And then in our office, we also have several advisory staff members who are there to provide expertise to both communities.

259

00:44:52.620 --> 00:45:06.240

Stephanie Davis: And the goal of having these services available is that we can cater to both the academic and the small business innovators to help further into the development of heart, lung, blood and sleep related technologies. Next slide please.

260

00:45:08.040 --> 00:45:11.820

Stephanie Davis: And so, here is an overview of some of the advisory experts that we have.

261

00:45:12.060 --> 00:45:24.660

Stephanie Davis: We have a really fantastic team of entrepreneurs and residents at the NHLBI. So, if you are a current small business grantee or even if you are a translational research or that's being funded through another mechanism.

262

00:45:24.990 --> 00:45:35.550

Stephanie Davis: We have this team of experts who are available for one-on-one consults and also just to answer general questions so if you're interested in setting up a consult with any.

263

00:45:35.820 --> 00:45:49.410

Stephanie Davis: of my wonderful colleagues that are listed here, please feel free to email me, but they are extremely knowledgeable in what they do and they're here to answer any of your questions. Next slide please.

264

00:45:50.880 --> 00:46:05.400

Stephanie Davis: So that concludes my segment for the day if you would like to contact me it looks like my direct line has been put in the chat, so please feel free to reach out with any questions, and I would like to pass the baton over to my friend and colleague Dr. Eugene Krentsel.

265

00:46:06.540 --> 00:46:09.540

Eugene Krentsel: Thank you Steph. Appreciate your introduction.

266

00:46:11.430 --> 00:46:17.880

Eugene Krentsel: Good afternoon, everybody. For those of you on the west coast, who are still in the morning, part of the day.

267

00:46:18.990 --> 00:46:19.860

Eugene Krentsel: Next slide please.

268

00:46:21.990 --> 00:46:34.020

Eugene Krentsel: I will talk about Xlerator Health Xlerator Network and our EDI resources that are available. And, first, I will talk a little bit about who we are and what we do. Next slide please.

269

00:46:36.120 --> 00:46:40.140

Eugene Krentsel: XLerator Network is an NIGMS-funded

270

00:46:41.850 --> 00:46:50.520

Eugene Krentsel: hub for technology transfer acceleration. Ours – there are -- there are, there were four hubs of this.

271

00:46:51.060 --> 00:47:13.470

Eugene Krentsel: type of funded by NIGMS as covering different regions of the country. Ours covered the southeast part, which is Kentucky, West Virginia, South Carolina, Arkansas, Mississippi, Louisiana and Puerto Rico and um, there are three other hubs that cover other parts of the country. Next slide please.

272

00:47:15.390 --> 00:47:25.530

Eugene Krentsel: Their hub is led by a small business. We are, ourselves funded through the STTR mechanism and.

273

00:47:26.850 --> 00:47:36.420

Eugene Krentsel: We are small business, XLerateHealth, which is a healthcare focused accelerator founded in 2012 in Louisville Kentucky.

274

00:47:37.170 --> 00:47:45.060

Eugene Krentsel: Here is a photo of some of our core team members were using Steve Blank' Lean Startup Methodology to teach.

275

00:47:45.510 --> 00:47:56.970

Eugene Krentsel: Entrepreneurs learn how to build their businesses and scale. We run both bootcamp, 12-week boot camp and Intersession programs, we used to run those boot camp.

276

00:47:57.360 --> 00:48:13.590

Eugene Krentsel: programs in person, one in Louisville; one in Michigan where we have a satellite operation. But in pandemic, we decided that everything will be gone virtual so we're running to virtual programs.

277

00:48:14.490 --> 00:48:31.650

Eugene Krentsel: And we have a large number of mentors and coaches that provide -- and subject matter experts that are not only in our geographic space, but also across the country and internationally, will help mentor and coach startups. Next, please.

278

00:48:34.110 --> 00:48:52.470

Eugene Krentsel: This is their list of their institutions. The consortium constellation of 25 wonderful academic institutions across those six states and Puerto Rico led by XLateHealth and the University of Kentucky, which is our academic lead in this STTR-funded program.

279

00:48:53.910 --> 00:48:54.660

Eugene Krentsel: Next slide please.

280

00:48:56.190 --> 00:49:06.780

Eugene Krentsel: So those are some of the things that we do we're on various entrepreneurial programs and training. We have talent network, including XOR.

281

00:49:07.740 --> 00:49:29.970

Eugene Krentsel: It's an executives on roster program where we help startups that are coming from academic institutions to find their executives -- CEO and otherwise. Very interesting program. Would love to for you to take advantage of that. Feel free to reach out and ask questions.

282

00:49:31.230 --> 00:49:43.620

Eugene Krentsel: We do various webinars and podcasts to provide information about different things related to technology commercialization coming out of universities --- regulatory pathways and so on.

283

00:49:44.370 --> 00:49:54.960

Eugene Krentsel: We do have, a few funding programs that were in place, including the proof-of-concept Ideas to Products, I2P, which is no longer

284

00:49:56.910 --> 00:50:07.470

Eugene Krentsel: operational but we had that program funded by NIGMS as a supplement or grant and some of those technologies that we have developed pre-company are now.

285

00:50:07.860 --> 00:50:19.020

Eugene Krentsel: In SBIR-funded space they are already created companies and haven't gotten funded I just heard the yesterday from Steph that the NHLBI just funded one of those teams.

286

00:50:19.980 --> 00:50:28.530

Eugene Krentsel: And what is the topic of today's conversation we also have diversity programs: EnRICH, EnTRUST and EnGAGE. Next slide please.

287

00:50:29.970 --> 00:50:40.440

Eugene Krentsel: So those are authority the network signature diversity programs. EnRICH, which is a HBCU-focused, Engaging Researchers and Innovators for Commercialization at HBCUs.

288

00:50:40.830 --> 00:50:48.600

Eugene Krentsel: EnTRUST is focused on Hispanic serving institutions, Engaging Technologists and Researchers from Underrepresented Schools for Translation.

289

00:50:48.870 --> 00:50:58.800

Eugene Krentsel: And our new program that is just be shaped right now called EnGAGE. It's women-focused on entrepreneurial growth and acceleration with gender equity. Next, please.

290

00:51:01.620 --> 00:51:10.320

Eugene Krentsel: Just a couple of words about EnREACH. You have the whole full presentation after mine that Almesha will talk about this, it is an amazing

291

00:51:10.650 --> 00:51:24.540

Eugene Krentsel: program that is led by Jackson State, with the help and Jackson State as a part of the accelerator network and supported by XLerate Health and University of Kentucky. Great program. Next slide please.

292

00:51:27.510 --> 00:51:40.770

Eugene Krentsel: That was getting a lot of attention, including from Forbes magazine like I said. Almesha will go into all the details of this wonderful program and testimonies of the participants. Next slide please.

293

00:51:42.270 --> 00:51:57.240

Eugene Krentsel: Our next one is EnTRUST, as I mentioned, that is focused on Hispanic serving institutions and having Puerto Rico as a part of our region of IDEa states provided us with a very.

294

00:51:58.260 --> 00:52:10.500

Eugene Krentsel: rich consortium group of universities. Rich not in money and funding, but in wonderful ideas and great researchers at academic institutions in Puerto Rico.

295

00:52:11.610 --> 00:52:23.880

Eugene Krentsel: So, our goal is to impact equity, diversity and inclusion and innovation, train faculty and grad students, clinicians of those institutions and provide various resources to develop, validate

296

00:52:24.630 --> 00:52:34.170

Eugene Krentsel: New life and bioscience innovations. One of their most interesting programs that came out of that were Puerto Rico Science, Technology and Research Trust which is

297

00:52:34.950 --> 00:52:47.490

Eugene Krentsel: the state lead for a story of a network in Puerto Rico partnered with Columbia University in New York City piloted in 2021 and fully launched in January 2022 and

298

00:52:47.940 --> 00:52:56.040

Eugene Krentsel: a life science-focused accelerator program for Hispanic-serving institutions, and it is a fantastic program.

299

00:52:56.940 --> 00:53:12.120

Eugene Krentsel: Help participate in judging their technologists that were coming through it and mentoring and coaching the teams that went through it. Wonderful programming. Thank you, Columbia University, for being a great partner in that program. Next, please.

300

00:53:14.400 --> 00:53:33.330

Eugene Krentsel: The other one is our effort called SBIR/STTR Readiness Program. It's also focused on a HBCUs and minority entrepreneurs. It is led by XRateHealth with partnership from Jackson State, University of Kentucky, several INBREs

301

00:53:34.380 --> 00:53:37.590

Eugene Krentsel: in three states: in Kentucky, Mississippi, South Carolina.

302

00:53:38.430 --> 00:53:49.830

Eugene Krentsel: and South Carolina Research Authority as the feeder programs for it, and this is a five-week virtual course, it is funded by Small Business Administration Catalyst Award. We were

303

00:53:50.340 --> 00:54:06.240

Eugene Krentsel: very lucky to get funded by this very prestigious award in 2021. This one of seven of such awards, and that is a brand-new award. We also were recipients of SBA.

304

00:54:06.960 --> 00:54:19.050

Eugene Krentsel: Accelerator Awards for four years out of five that that program was running, primarily in the last couple of years for support towards SBIR programs. Next slide please.

305

00:54:22.560 --> 00:54:31.140

Eugene Krentsel: So that SBIR/STTR Readiness Program: We launched it in March, had the first cohort of seven participants.

306

00:54:32.400 --> 00:54:43.110

Eugene Krentsel: It's a five-week program that went through various background in the most foundational things for commercialization grants in general: customer discovery,

307

00:54:44.070 --> 00:55:05.040

Eugene Krentsel: reviewers' perspective at different agencies, how to form an entity, researcher perspective and budget preparation and helping participants frame how to move forward going into more intense programs that we have that are not just limited for minority participants but going through this.

308

00:55:06.420 --> 00:55:17.220

Eugene Krentsel: regional readiness program, our HBCU entrepreneurs are getting enough support that they may not have resources have their own institutions

309

00:55:17.610 --> 00:55:38.250

Eugene Krentsel: to get into a more intense 10-week program where we would expect them to actually file their – it's similar to AAP and they're targeting their stages of the researchers and informative the services that are provided to academic researchers and innovators.

310

00:55:39.390 --> 00:55:40.020

Eugene Krentsel: Next, please.

311

00:55:43.320 --> 00:56:00.240

Eugene Krentsel: So here is there a link to our website and my contact, please feel free to reach out, and I would like to pass the baton next slide please to Almesha to talk about this wonderful program called EnRICH.

312

00:56:01.470 --> 00:56:13.770

Almesha Campbell: Thanks Eugene. Next slide please. So, EnRICH, as Eugene mentioned and which is Engaging Researchers and Innovators for Commercialization at HBCUs. Next slide please.

313

00:56:15.120 --> 00:56:24.180

Almesha Campbell: So, the program was designed to basically focus on diversity and inclusion of HBCU faculty and students.

314

00:56:24.720 --> 00:56:35.340

Almesha Campbell: In innovation and commercialization, and this is led by Jackson State University, with support from XRate Health and the University of Kentucky. Next slide please.

315

00:56:36.270 --> 00:56:52.500

Almesha Campbell: So, the goals of the program, as I mentioned earlier, is to impact equity diversity and inclusion innovations and our goal is to train faculty and students at these institutions to critically evaluate the commercial potential of new healthcare innovations. Next slide please.

316

00:56:56.070 --> 00:57:06.660

Almesha Campbell: A word about Jackson State where can I get classified as high research activity in a university. We're the only research institution in the state of Mississippi.

317

00:57:07.170 --> 00:57:15.960

Almesha Campbell: And our mission is basically to provide quality teaching, research and service at all the different levels as well as support our communities.

318

00:57:17.010 --> 00:57:17.880

Almesha Campbell: Next slide please.

319

00:57:20.070 --> 00:57:30.090

Almesha Campbell: Initially, when, in which started, we focus on 31 HBCUs. Those are the HBCUs that are situated in the IDEa states but

320

00:57:30.510 --> 00:57:41.640

Almesha Campbell: after the first cohort we got a lot of interest from different HBCUs that are not in the network, and so we fully expand the program very quickly in the next by the next cohort.

321

00:57:41.940 --> 00:57:53.760

Almesha Campbell: To all HBCUs across the country and our very first cohort that was expanded included HBCUs and we have expanded since then. Next slide please.

322

00:57:54.690 --> 00:58:05.730

Almesha Campbell: So, our program outline is very simple: we want to introduce them to the goals and objectives of the program, talk about intellectual property, what that is, how to disclose.

323

00:58:06.570 --> 00:58:13.230

Almesha Campbell: Many of the agencies don't have established tech transfer offices, so we wanted to do a little bit of introduction to that.

324

00:58:13.830 --> 00:58:18.810

Almesha Campbell: As well as the Lean Startup Methodology, so we did some of the I-Corps-style training.

325

00:58:19.200 --> 00:58:27.900

Almesha Campbell: For four weeks of the program and then we talked about leveraging the TT and other support services, especially for those that don't have a tech transfer office on their campus.

326

00:58:28.080 --> 00:58:34.650

Almesha Campbell: What are some of the things that it can do? Who can they reach out for different supports whether it's within the XRate Network or other networks?

327

00:58:34.860 --> 00:58:47.280

Almesha Campbell: And we're able to share some of those resources to them and then we do a quick intro into startup formation and funding type, so this program is really trying to get their feet wet into this whole ecosystem and then.

328

00:58:47.610 --> 00:58:59.460

Almesha Campbell: guide them into other programs, so this is a pre-accelerator, and after they finish our 10-week program as you see week nine, we teach them how to perfect their pitch and we tend, we have a pitch competition.

329

00:58:59.880 --> 00:59:08.790

Almesha Campbell: And once we go through this, we make recommendations to them whether they need to pivot on the ideas or the need to go into other programs within the accelerator network.

330

00:59:09.330 --> 00:59:17.190

Almesha Campbell: NIH I-Corps, NSF I-Corps, different programs that are more suitable for them, based on what we've learned from them over the.

331

00:59:17.580 --> 00:59:30.630

Almesha Campbell: The 10-week program. The pitch competition was just supposed to be a fun thing but it ended up becoming very competitive, and then we end up having like four different categories and I mentioned that later on. Next slide please.

332

00:59:34.260 --> 00:59:39.570

Almesha Campbell: Our selection criteria is very simple, is the potentials of validation of the concept.

333

00:59:39.900 --> 00:59:48.390

Almesha Campbell: and potential impact of the stated goal and the clarity and effectiveness of the video presentation, so we asked them to do upload a brief.

334

00:59:48.780 --> 01:00:00.720

Almesha Campbell: Video letting us know who they are, what their technology or idea is even if they don't have an idea, why they want to participate in the program, and this provide us with some real good clarity about.

335

01:00:01.530 --> 01:00:06.570

Almesha Campbell: What their needs are and how we can support them through the program and so as you see we've had.

336

01:00:07.050 --> 01:00:22.230

Almesha Campbell: This is about two years old, but over 50 participants and the faculty -- both faculty and students -- and so far, we've had two SBIR submissions and three intellectual property disclosures. Next slide please.

337

01:00:25.170 --> 01:00:36.780

Almesha Campbell: So, some of our instructors from the national I-Corps program. We have Grant Water from Howard University and Marc Filerman from German Accelerator. They're the two that.

338

01:00:37.320 --> 01:00:48.300

Almesha Campbell: co-lead the full week of the I-Corps-style training. Myself, fill in most of the times, and then I have Angela Grayson and who does a really good job of breaking down.

339

01:00:49.140 --> 01:01:02.070

Almesha Campbell: The patent system IP and all that stuff making it easily understandable for these groups of innovators, who may not have been introduced to it before, so, very thankful for these coaches.

340

01:01:02.910 --> 01:01:15.480

Almesha Campbell: These coaches reached out to us and offer the support and we had our, we have other supporters that comes in, from time to time, but these are your core team of instructors. Next slide please.

341

01:01:16.860 --> 01:01:28.110

Almesha Campbell: And so, the key members on the terms of leadership: myself, University Kentucky would be Ian McClure and Tanya Philips. Very instrumental in helping us.

342

01:01:28.560 --> 01:01:45.210

Almesha Campbell: Make sure that we are meeting our goals and objectives, a lot of support to us to continue this program and, of course, Xlerate Health, Eugene is also on the board, and then we have Jackie Wilmott, who is the CEO and co-founder of XlerateHealth. Next slide please.

343

01:01:47.100 --> 01:01:59.100

Almesha Campbell: We do because of our program is partially funded to the Xlerate Network, we do have stuff where people can sponsor the program it can be to mentor in prices.

344

01:01:59.610 --> 01:02:08.520

Almesha Campbell: Patent expenses, entrance fees to accelerator programs. We try to support some of this, we were fortunate enough Jackson State President.

345

01:02:09.030 --> 01:02:17.940

Almesha Campbell: sponsored the mentoring prizes and also the prizes for the awardees for the pitch competition, so we were able to support with cash prizes.

346

01:02:18.600 --> 01:02:27.900

Almesha Campbell: To the winners. We had winners in different category, and of course I will – long-term goal, our objective is to make sure the program is sustainable.

347

01:02:28.200 --> 01:02:33.600

Almesha Campbell: And we want to ensure the longevity of EnRICH and its impact, as I told you, Xlerate Network.

348

01:02:33.930 --> 01:02:47.130

Almesha Campbell: My involvement, would mean that the sustainability plan in place, and if there was not one, then I wouldn't be involved, because it means a lot to me to have this program impacting the communities that I work in. Next slide please.

349

01:02:48.570 --> 01:02:50.130

Almesha Campbell: We do heavily promote.

350

01:02:51.180 --> 01:03:09.600

Almesha Campbell: The EnRICH program. We have social media pages, we also make sure that every success that we have is is publicized, reported to NIH and report it to the various HBCUs, so they are aware of what their faculty and students engage with the program. Next slide please.

351

01:03:11.130 --> 01:03:27.660

Almesha Campbell: And these are some of our program, some of our promotional pieces we've had the in which program picked up by different news articles to out as you see the ones before, but we also won a Visionary Prize.

352

01:03:28.740 --> 01:03:40.980

Almesha Campbell: From the lab to market for 25 K so some of those funds we'll use to help support some of our coaches, as well as support some of our prizes. So in our pitch competition we have first prize, second.

353

01:03:41.370 --> 01:03:46.770

Almesha Campbell: second place and third place for our faculty as well as our students and then our coaches select.

354

01:03:47.160 --> 01:03:58.110

Almesha Campbell: The Coaches' Choice, and it can be either faculty or student and then we have a student star who may not, you know, be in the top three in terms of the page, but because of where they are from.

355

01:03:58.920 --> 01:04:09.390

Almesha Campbell: What they've accomplished from day one of the program to week 10 so we just want to use this as a way of encouraged the participation and what we've had is.

356

01:04:09.690 --> 01:04:22.800

Almesha Campbell: That the passing on of information about the program to others, so he has been very easy to recruit because the participants enjoy the process so much that they encourage others from the campus to participate and just briefly.

357

01:04:23.700 --> 01:04:30.600

Almesha Campbell: One of our -- we do this on Fridays for 10 weeks and one Friday falls on Good Friday and I thought I would give them.

358

01:04:30.960 --> 01:04:43.980

Almesha Campbell: The day off because it's a holiday, but they all showed up, so I had to show up as well that shows the dedication of them in in learning what we provided to them through this program. Next slide please.

359

01:04:46.860 --> 01:04:51.090

Almesha Campbell: And this is just a brief video of testimonials from some of the participants.

360

01:04:59.250 --> 01:05:05.850

[VIDEO] Almesha Campbell: My name is Almesha Campbell and I serve as the assistant Vice President for research and economic development at Jackson State University.

361

01:05:06.180 --> 01:05:15.570

[VIDEO] Almesha Campbell: And I also serve as the executive director for the end which program there which program is designed to engage researchers and innovators in commercialization at HBCUs.

362

01:05:15.960 --> 01:05:30.840

[VIDEO] Almesha Campbell: And it's designed for all HBCUs -- both faculty and students, the idea came about when we talked about inclusion and diversity and how we get HBCUs involved in the commercialization space. I chose EnRICH to get my.

363

01:05:31.350 --> 01:05:42.360

[VIDEO]: Senior project idea off the ground, I knew that I didn't have the necessary knowledge to bring an application into the market, and I knew that EnRICH would me accomplish then.

364

01:05:43.080 --> 01:05:48.960

[VIDEO]: The name is Robin Williams, a licensed clinical psychologist and I'm a faculty Member at Jackson State University.

365

01:05:49.410 --> 01:05:53.820

Almesha Campbell: Working in psychology department, as part of the first cohort of EnRICH Program.

366

01:05:54.360 --> 01:06:04.440

[VIDEO]: They took me within a few weeks and educated me on the terminology, the processes, the software this needed to develop my idea and make it something that I can market to take to the next level.

367

01:06:05.160 --> 01:06:19.110

[VIDEO]: My favorite aspect of the program was being able to get my idea from up here and put it down on paper and because of EnRICH, I see myself in the future working with pharmaceutical companies on developing a product.

368

01:06:19.590 --> 01:06:28.440

[VIDEO]: My favorite aspect of the program was being able to get my idea from up here and put it down That allows individuals to take more control of their own health. The EnRICH program actually helped me to discover what the customer needs.

369

01:06:28.920 --> 01:06:33.120

[VIDEO]: My favorite aspect of the program was being able to get my idea from up here and put it down Oh, the things that were taught in which program helped me to build upon.

370

01:06:33.510 --> 01:06:48.750

[VIDEO]: My favorite aspect of the program was being able to get my idea from up here and put it down My initial idea that I came in with. Others should choose the EnRICH program because it's a program that provides you a platform to actually test your results, to actually test your research to know whether it is something that can be commercialized.

371

01:06:59.010 --> 01:07:01.530

Almesha Campbell: Thank you and I'll hand it over to the next person.

372

01:07:06.720 --> 01:07:12.840

Melissa Glim: Thank you so much, my name is Melissa and I'll be facilitating the Q and A right now.

373

01:07:14.370 --> 01:07:20.910

Melissa Glim: So, I will first of all I want to thank our speakers for providing such engaging and.

374

01:07:23.340 --> 01:07:30.630

Melissa Glim: Deep information about their program. It's really great. We do have some questions so I'm going to ask those now.

375

01:07:33.030 --> 01:07:34.350

Melissa Glim: The first question I.

376

01:07:35.430 --> 01:07:39.060

Melissa Glim: am going to answer myself: several people have asked about the.

377

01:07:40.140 --> 01:07:40.620

Melissa Glim: the.

378

01:07:42.030 --> 01:07:42.660

Melissa Glim: chat

379

01:07:43.890 --> 01:08:03.960

Melissa Glim: links and the presentation. We will be providing all of that information to you via email in the next day or two, so I just want everybody to rest assured if you didn't get everything down in your notes we're going to send it to you. You will have it. I have a question for Dr. Campbell.

380

01:08:05.160 --> 01:08:11.610

Melissa Glim: or Dr. Krentsel. The first is they wanted, one of our.

381

01:08:14.070 --> 01:08:18.810

Melissa Glim: viewers wanted to know more about the EnGAGE program. I know that that is.

382

01:08:21.750 --> 01:08:26.280

Melissa Glim: In development, right now, so they just want to get a little bit more information about that.

383

01:08:27.330 --> 01:08:47.070

Eugene Krentsel: Now this is, this is a brand-new thing that is being currently developed and if someone wants to help shape it, please reach out to us we'll be happy to, you know, to do that, and, you know, talk, talk with them about the best ways of doing it, this is, this is a program in development.

384

01:08:47.790 --> 01:08:49.200

Melissa Glim: Great. Thank you so much.

385

01:08:50.580 --> 01:08:55.260

Melissa Glim: The rest of our questions I think they're primarily going to be for Meena and Stephanie.

386

01:08:56.130 --> 01:09:10.320

Melissa Glim: In terms of the resources and programs for res-, researchers in smaller institutions and universities, it's often very difficult to perform high throughput screenings. What kind of assistance can NCATS provide on that front?

387

01:09:12.030 --> 01:09:18.030

Meena Rajagopal: Oh, sure happy to answer that. Um, well, first of all, the Genomic Center is run out of our.

388

01:09:18.450 --> 01:09:28.260

Meena Rajagopal: You know, ETB program, what we call the Early Translation Branch within NCATS, and this is a part of the NIH Common Fund and basically.

389

01:09:28.980 --> 01:09:37.680

Meena Rajagopal: Our intramural researchers, would, you know, collaborate with investigators outside of the NIH and within NIH.

390

01:09:38.310 --> 01:09:53.610

Meena Rajagopal: to generate probes I believe for studying a diverse cross section of human biology like focusing on new targets for untreatable diseases and I'll be more than happy, I mean if you want to reach out to me. I'll be more than happy to connect.

391

01:09:54.480 --> 01:10:01.110

Meena Rajagopal: The individual who has a specific question with the right person in the team.

392

01:10:02.400 --> 01:10:03.930

Melissa Glim: Great. Thank you so much.

393

01:10:05.370 --> 01:10:24.420

Melissa Glim: Um, this question is about eligibility and funding for SBIR STTR: when it says 40% of the work must be small business, can you tell us, it is OK, if the small business subcontracts that 40% of the work to CRO or.

394

01:10:27.480 --> 01:10:29.310

Melissa Glim: Contract Research Organization.

395

01:10:32.250 --> 01:10:46.380

Stephanie Davis: So, I can get that one, so this is something that will generally vary across institutes, what I can tell you the NHLBI policy, so we generally agreed that fee-for-service-work.

396

01:10:47.220 --> 01:10:51.180

Stephanie Davis: counts as small business costs, so one thing to keep in mind.

397

01:10:51.660 --> 01:11:00.630

Stephanie Davis: Especially if you are collaborating with an academic institution is that, you know, there is a difference between a sub-awardee and a fee-for-service-provider.

398

01:11:00.960 --> 01:11:13.110

Stephanie Davis: If you are going to be having somebody play a key role in the decision making of the project, so, for example, if you have a small business concern, and you have a piece of co-PI at an academic institution.

399

01:11:13.560 --> 01:11:20.700

Stephanie Davis: they're going to be considered a sub awardee and that's going to count towards your sub-contracting maximum, however.

400

01:11:21.540 --> 01:11:28.230

Stephanie Davis: If you're a company that's just getting started and you don't have, you know, a lot of equipment in house yet so it needs to be.

401

01:11:28.440 --> 01:11:41.220

Stephanie Davis: outsourced to CRM those are other fee for service providers and you're just having a CRM perform a service for you in exchange for a fee, and they give you back the data that we generally don't consider.

402

01:11:41.220 --> 01:11:47.250

Stephanie Davis: That subcontracted, we consider that to be fee-for-service and bus a small business cost.

403

01:11:48.420 --> 01:11:49.590

Melissa Glim: Great. Thank you Stephanie.

404

01:11:51.030 --> 01:12:08.670

Melissa Glim: This is another eligibility question. I think there's often a little bit of confusion here. Does the business itself, need to be a US company? Can a university in the US apply for an SBIR or STTR with a Canadian small business?

405

01:12:10.440 --> 01:12:12.000

Meena Rajagopal: I'm happy to take a stab at that.

406

01:12:13.230 --> 01:12:27.180

Meena Rajagopal: Yeah this is, you know, both the SBIR or STTR or other small business programs, and they are America's Seed Fund, right, so they fund small businesses based in the United States, but if you want to, you know,

407

01:12:27.690 --> 01:12:37.050

Meena Rajagopal: leverage a service outside of the country, then I think the there is a foreign component, that is allowed, but then it needs to have.

408

01:12:38.100 --> 01:12:43.230

Meena Rajagopal: You know, reason and justification to be able to do so, so I would strongly encourage.

409

01:12:43.980 --> 01:12:47.700

Meena Rajagopal: For the small business to have a conversation with the program official and see.

410

01:12:48.120 --> 01:12:54.870

Meena Rajagopal: You know if that is in fact the case, like say, for instance, that end caps right we get an application applicant and they.

411

01:12:55.170 --> 01:13:00.300

Meena Rajagopal: are working in a rare disease, and, you know, the samples for that particular rare diseases.

412

01:13:00.570 --> 01:13:14.580

Meena Rajagopal: Only available at a certain part of the world, and they do have to collaborate with that investigator outside of the United States then that's doable so again it's on a base case to case basis, but I would encourage you to have a conversation with the program official.

413

01:13:15.570 --> 01:13:16.890

Melissa Glim: Thank you so much Meena.

414

01:13:18.030 --> 01:13:30.090

Melissa Glim: um, this is about the application process can you self-certify or do you need to be officially certified by an independent party, and this is related to the small business.

415

01:13:30.840 --> 01:13:37.860

Melissa Glim: Administration designations as a woman owned small business or as a socially and economically disadvantaged small business.

416

01:13:42.270 --> 01:13:50.940

Meena Rajagopal: I can answer that one too. Yeah, the eligibility criteria, I do want to reiterate that, you know, it is set forth by the US Small Business Administration but having said that.

417

01:13:51.960 --> 01:14:00.240

Meena Rajagopal: You know, you do have you do have the opportunity to self-identify when you register at sam.gov I hope that clarifies the question.

418

01:14:01.710 --> 01:14:02.340

Melissa Glim: Thank you.

419

01:14:04.440 --> 01:14:13.800

Melissa Glim: And so, this is a intellectual property question if a small business identifies an idea that a.

420

01:14:15.210 --> 01:14:27.240

Melissa Glim: Primary investigator is working on a university does the small business need to get a license from the University in order to apply for all of these grants can talk a little bit about that process.

421

01:14:29.070 --> 01:14:43.620

Stephanie Davis: I can take that so, generally speaking, you know, if if you are, you know, according to the Bible act when a company, you know, when an academic investigator working at a university generates intellectual property.

422

01:14:43.950 --> 01:14:54.120

Stephanie Davis: The University is going to be the owner of that IP so what I recommend for any small business concerns who are collaborating with academic investigators, is that.

423

01:14:54.510 --> 01:15:03.180

Stephanie Davis: You know you, and this is something that's highly recommended for an STD tr applicant make sure that you have an IP agreement drafted up.

424

01:15:03.840 --> 01:15:13.290

Stephanie Davis: Basically, that lays out the fact that the small business is going to be the licensee of any technology that's generated by the University just because.

425

01:15:14.040 --> 01:15:27.720

Stephanie Davis: If I have seen cases where we're companies and collaborating academic investigators don't have an agreement drafted up, and, you know, you don't want to have to be involved with an IP dispute So yes, so generally if, you know, if the.

426

01:15:28.200 --> 01:15:38.880

Stephanie Davis: Technology is eventually going to go to the company and you're working with an academic investigator, you will want to work with your tech transfer office to make sure that that technology is licensed out to the company.

427

01:15:40.380 --> 01:15:42.240

Melissa Glim: Great Thank you so much Stephanie.

428

01:15:43.380 --> 01:15:48.660

Melissa Glim: I know that we're running up on time, so I just want to make sure that we.

429

01:15:50.340 --> 01:16:01.440

Melissa Glim: Get everybody's questions and really the last questions that we have here about contacting you for additional information, so we have questions, who for people who want to.

430

01:16:02.100 --> 01:16:05.010

Melissa Glim: learn more about targeted funding opportunities that and.

431

01:16:05.010 --> 01:16:13.230

Melissa Glim: NCATS and NHLBI as well as additional information in terms of getting in touch with the.

432

01:16:14.910 --> 01:16:25.020

Melissa Glim: Xerator Network and XerateHealth programs, so I just wanted to let everybody know we are going to share that information in a follow up email, but just for.

433

01:16:25.710 --> 01:16:37.140

Melissa Glim: People who are on the call right now, I know, email sometimes go into spam, can you share the best contact information for each of you? And we'll start with Meena:

434

01:16:40.440 --> 01:16:54.060

Meena Rajagopal: You can either email me at the, you know, email address that Sanjana just chatted out, which is NCATS hyphen SBIRSTTR dot mail dot NIH gov and I will also put in my

435

01:16:55.500 --> 01:17:06.150

Meena Rajagopal: email, if you want to reach out to me and have a one-on-one conversation as to whether you're in a proposal or intention to put a proposal would be a fit for NCATS.

436

01:17:08.580 --> 01:17:11.640

Melissa Glim: Thank you Meena Stephanie I saw that you put your

437

01:17:12.000 --> 01:17:23.310

Melissa Glim: Information in the chat and I'm just going to read that out is Stephanie got Davis that's definitely with an IE dot Davis number three at NIH dot gov.

438

01:17:25.830 --> 01:17:39.570

Melissa Glim: And I see Dr. Krentsel has put in Eugene at X L erate health dot com and Dr. Campbell has put hers. It's Alemsha dot L dot Campbell at.

439

01:17:39.870 --> 01:17:52.020

Melissa Glim: JSUMS.edu so we'll make sure that all that information is included in the emails as well and we've also included in the chat some information about XLerateHealth.

440

01:17:52.620 --> 01:18:01.260

Melissa Glim: coaching and readiness programs so with that I want to thank everybody who participated, I really especially want to thank.

441

01:18:02.490 --> 01:18:13.050

Melissa Glim: Dr. Campbell and Dr. Krentsel for their participation in putting this event together it's been really educational, and I think that we all got some very.

442

01:18:14.460 --> 01:18:23.910

Melissa Glim: Good information very exciting and very inspiring information. It's going to help a lot of people move forward with their ideas and, of course, I want to thank Stephanie.

443

01:18:24.150 --> 01:18:26.040

Melissa Glim: Davis at NHLBI.

444

01:18:26.370 --> 01:18:37.650

Melissa Glim: And Meena Rajagopal at NCATS for their presentations and the wonderful work that they do for all of us. So with that, thank you, if you do have any other questions get in touch with.

445

01:18:38.040 --> 01:18:50.310

Melissa Glim: Any of us, we've shared the contact information and again we will share the information in an email after this event as well and we'll let you know when there's a recording. Thank you so much and have a wonderful rest of the day.

446

01:18:53.670 --> 01:18:54.210

Melissa Glim: Bye-bye.