WEBVTT

1
00:00:16.120 --> 00:00:31.180
Kinnera.Chada@fda.hhs.gov: Hello, everyone! Welcome to the Fy. 25 FDA broad agency announcement, question and answer session. I'm Kinara Chadha, and I'm the program lead for Baa. Team from office of regulatory and emerging science ors. At FDA

2
00:00:33.080 --> 00:00:46.280
Kinnera.Chada@fda.hhs.gov: I am joined by Yin Wise, who is the contracting officer for the BA. Program from office of acquisitions and grant services on behalf of the BA. Team. We wish you all a happy New Year

3
00:00:48.160 --> 00:00:49.549
Kinnera.Chada@fda.hhs.gov: next slide, please.

4
00:00:52.430 --> 00:01:12.450
Kinnera.Chada@fda.hhs.gov: So our agenda for today is that I would be going over some updates related to the announcement for FDA, Baa. That was posted recently and also go over some reminders followed by QA. Session that would cover previously received questions, and followed by live questions.

5
00:01:12.900 --> 00:01:21.609
Kinnera.Chada@fda.hhs.gov: Please note that this event is being recorded, and will be posted on the Fi, 25 Q. And a session website

6
00:01:21.730 --> 00:01:26.099
Kinnera.Chada@fda.hhs.gov: on or by January 23, rd 2,025.

7
00:01:26.580 --> 00:01:27.890
Kinnera.Chada@fda.hhs.gov: Next slide, please.

8
00:01:30.410 --> 00:01:49.730
Kinnera.Chada@fda.hhs.gov: With respect to FDA updates. In the recent solicitation that was posted in December, you would see that updates have been made to the concept paper template. We have added an additional question in the cover table that, as if the proposal involves dual use, research of concern.

9
00:01:49.740 --> 00:02:09.539
Kinnera.Chada@fda.hhs.gov: or any pathogens with enhanced pandemic potential and or nucleic acid synthesis, this question has been added in order to comply with United States government policy for oversight

related to dual use, research of concern as well as pep and nucleic acid synthesis.

10
00:02:09.900 --> 00:02:15.189
Kinnera.Chada@fda.hhs.gov: So please make sure to answer this question. In the cover table of the concept paper.

11
00:02:17.430 --> 00:02:21.759
Kinnera.Chada@fda.hhs.gov: we have received some questions regarding feedback

12
00:02:22.340 --> 00:02:37.999
Kinnera.Chada@fda.hhs.gov: timeline for optional early concept paper, and when the recommendations are due, please be informed that with respect to the optional early concept papers, all recommendations were communicated to the applicants on December 16th of last year.

13
00:02:38.020 --> 00:02:53.620
Kinnera.Chada@fda.hhs.gov: and any feedback that was received from the program officers was also communicated to the applicants. If we did not receive any feedback from the program officers. The field for feedback related to your concept paper was left blank.

14
00:02:55.370 --> 00:03:23.079
Kinnera.Chada@fda.hhs.gov: Please note that there would be an updated solicitation that would be posted on sam.gov for the FDA. BA. Announcement on January 17, th which is tomorrow. This Friday. It does not have any updates related to the scope in part one of the research areas, but it would have minor updates related to. So in order to address some of the questions that were asked ahead of this Q. And a session

15
00:03:23.360 --> 00:03:24.700
Kinnera.Chada@fda.hhs.gov: next slide, please.

16
00:03:27.730 --> 00:03:47.470
Kinnera.Chada@fda.hhs.gov: So on the slide, I just would like to go over some of the documents and details related to the application. Submission of stage one package that would be due February 24, th 2,025. Please note that stage one package would include freestanding Pdf. Documents of checklist

17
00:03:47.600 --> 00:03:55.600
Kinnera.Chada@fda.hhs.gov: concept paper and a full proposal that would be sent by a single email to fdaba@fda.hhs.gov.

18

00:03:56.170 --> 00:04:08.610
Kinnera.Chada@fda.hhs.gov: Irrespective of receiving a submit recommendation based on an optional early concept, paper submission. Or if it is a new application, please make sure that you submit all these 3 documents

19
00:04:09.850 --> 00:04:15.930
Kinnera.Chada@fda.hhs.gov: for checklist. Please see attachment. 3 of the announcement on sam.gov

20
00:04:16.110 --> 00:04:22.220
Kinnera.Chada@fda.hhs.gov: for concept paper that would include cover, table and overview of your proposal.

21
00:04:22.720 --> 00:04:28.269
Kinnera.Chada@fda.hhs.gov: See template attachment. See for the for the template. Please see attachment 4.

22
00:04:29.850 --> 00:04:49.519
Kinnera.Chada@fda.hhs.gov: For the full proposal. We have Volume one and volume 2. Volume one is the technical proposal, and for the template please see attachment. 5 of the announcement on sam.gov. And for Volume 2. Please look into the details for cost proposal. This would also include a statement of work.

23
00:04:50.120 --> 00:04:51.450
Kinnera.Chada@fda.hhs.gov: Next slide, please.

24
00:04:54.810 --> 00:05:01.900
Kinnera.Chada@fda.hhs.gov: These are some of the timelines with respect to due dates or communication related to your submission.

25
00:05:02.440 --> 00:05:24.550
Kinnera.Chada@fda.hhs.gov: February 24th is when the stage one package is due for submission for Fy. 25 funding consideration. Once again, as a reminder, stage one re stage, one package required. Documents are checklist concept, paper and full proposal that comprises of technical as well as the cost proposal volumes one and 2.

26
00:05:26.250 --> 00:05:34.389
Kinnera.Chada@fda.hhs.gov: On March 6, th 2025 applicants will receive an acknowledgment of receipt of their

27
00:05:34.560 --> 00:05:41.730

Kinnera.Chada@fda.hhs.gov: applications, irrespective of they're receiving a submit recommendation, or if it is a new application.

28
00:05:42.510 --> 00:05:56.159
Kinnera.Chada@fda.hhs.gov: If you have submitted an optional early concept paper and have received a recommendation to submit from FDA, then stage one review will be initiated for your full proposal on March 6.th

29
00:05:56.260 --> 00:06:14.580
Kinnera.Chada@fda.hhs.gov: If you have submitted a new application or a revised based on A, do not submit recommendation, then review of concept papers would be initiated on March 6, th where the concept papers would be sent to FDA offices for their review for program relevance

30
00:06:16.970 --> 00:06:20.189
Kinnera.Chada@fda.hhs.gov: by April 7, th 2025.

31
00:06:20.340 --> 00:06:47.479
Kinnera.Chada@fda.hhs.gov: Regret notification for applications not moving forward for stage one review will be informed. This is relevant to any of the new applications. If you have submitted an early optional concept paper and a submit recommendation was made. Then you would not receive this regret. Notification. This would be only applicable for any new applications that would have their concept papers reviewed by the program officers on March 6th

32
00:06:49.030 --> 00:07:05.029
Kinnera.Chada@fda.hhs.gov: after stage one review. If your proposal would be moving forward for Stage 2 request, then a revised full proposal. Submittal package would be requested from FDA, and the applicants would have 14 calendar days to submit a revised proposal.

33
00:07:06.220 --> 00:07:18.659
Kinnera.Chada@fda.hhs.gov: Any decisions for notification for applications moving forward for an award or regret would be informed no later than September 32,025.

34
00:07:20.130 --> 00:07:24.809
Kinnera.Chada@fda.hhs.gov: Please note that after February 24, th

35
00:07:25.690 --> 00:07:35.569
Kinnera.Chada@fda.hhs.gov: we would still be accepting applications, but your submission would be considered for Fy. 26. Funding rather than Fy. 25.

36

00:07:35.810 --> 00:07:52.810
Kinnera.Chada@fda.hhs.gov: Please note that Bas is a rolling submission, and irrespective of February 24, th or after February 24, th we still require that applicants submit checklist concept paper and full proposal in order for your submission to be complete

37
00:07:54.340 --> 00:08:15.409
Kinnera.Chada@fda.hhs.gov: any of the applications that were reviewed, and have been favored for an award, but due to funding consideration. We are not able to inform you by September 30th those applications a decision notification would be confirmed no later than December 1, st 2025.

38
00:08:16.240 --> 00:08:17.530
Kinnera.Chada@fda.hhs.gov: Next slide, please.

39
00:08:20.610 --> 00:08:33.369
Kinnera.Chada@fda.hhs.gov: So those were the updates that we wanted to, and reminders that we wanted to present to you prior to discussing the previously received questions via email. And through the registration process.

40
00:08:33.820 --> 00:08:34.650
Kinnera.Chada@fda.hhs.gov: Thank you.

41
00:08:40.510 --> 00:08:48.710
Kinnera.Chada@fda.hhs.gov: Jessica. Please go ahead and we can. You can start asking the questions and we can provide answers.

42
00:08:49.000 --> 00:08:49.950
Jessika.Alfaro@fda.hhs.gov: Sounds good.

43
00:08:50.080 --> 00:08:55.220
Jessika.Alfaro@fda.hhs.gov: So these are the questions we've received ahead of time through the Baa inbox.

44
00:08:55.370 --> 00:08:58.989
Jessika.Alfaro@fda.hhs.gov: And the 1st question is, Can you guys hear me.

45
00:09:00.370 --> 00:09:01.450
Ian.Weiss@fda.hhs.gov: Yep. Sure can.

46
00:09:01.590 --> 00:09:26.499

Jessika.Alfaro@fda.hhs.gov: Okay, great. So on the being announcement on page 45 and page 46, for the AI machine learning and Llm based solutions. Does the FDA provide access to the data, including but not limited to the electronic health record or quality defect report? Or does the bidder bring in their own data

47
00:09:26.650 --> 00:09:28.570
Jessika.Alfaro@fda.hhs.gov: think this would be for Canara.

48
00:09:29.000 --> 00:09:44.219
Kinnera.Chada@fda.hhs.gov: We would recommend that you have your own data, but once the proposal is reviewed by FDA, and if there is any requirement for data that is specifically provided by FDA. Then that can be discussed on a case by case basis.

49
00:09:44.510 --> 00:09:45.290
Kinnera.Chada@fda.hhs.gov: Thank you.

50
00:09:45.680 --> 00:09:46.819
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

51
00:09:46.950 --> 00:09:47.669
Jessika.Alfaro@fda.hhs.gov: Next week.

52
00:09:47.670 --> 00:09:53.468
Kinnera.Chada@fda.hhs.gov: I wanted to make sure that you I am audible because I did see some messages that

53
00:09:53.920 --> 00:09:55.840
Kinnera.Chada@fda.hhs.gov: presenter cannot be heard.

54
00:09:57.340 --> 00:09:58.180
Jessika.Alfaro@fda.hhs.gov: I can hear you.

55
00:09:58.180 --> 00:09:58.680
AV Support | Markus Allen: Yes, yes.

56
00:09:58.680 --> 00:10:00.469
Ian.Weiss@fda.hhs.gov: Yeah, I can hear you as well.

57
00:10:00.470 --> 00:10:01.220
Kinnera.Chada@fda.hhs.gov: Sounds good.

58
00:10:02.400 --> 00:10:09.889
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara. Next question are support letters allowed in the application package, and this would be for Ian.

59
00:10:10.830 --> 00:10:12.560
Ian.Weiss@fda.hhs.gov: Yes, they are absolutely allowed.

60
00:10:13.880 --> 00:10:19.170
Jessika.Alfaro@fda.hhs.gov: Great. Thank you. Ian, next question, if we develop a technical solution

61
00:10:19.280 --> 00:10:24.170
Jessika.Alfaro@fda.hhs.gov: that can be used to address multiple topics, for example, charge one

62
00:10:24.330 --> 00:10:35.779
Jessika.Alfaro@fda.hhs.gov: C. 9 d. 5 and J. 4. Can we include all in one proposal, or shall we submit one proposal for each of the topics? Canara.

63
00:10:36.620 --> 00:10:53.530
Kinnera.Chada@fda.hhs.gov: So our recommendation would be to submit one proposal and identify a primary research area that is closest to the focus of the research topic and list all other relevant topics that you have listed as part of the secondary research areas.

64
00:10:54.320 --> 00:10:55.260
Kinnera.Chada@fda.hhs.gov: Thank you.

65
00:10:55.480 --> 00:10:56.490
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

66
00:10:56.780 --> 00:10:58.399
Jessika.Alfaro@fda.hhs.gov: Next question

67
00:10:58.530 --> 00:11:11.510
Jessika.Alfaro@fda.hhs.gov: on page a hundred 3 of the BA. Announcement, can a teaming agreement be used for contractal agreements? If so, what specific terms are typically required by the client?

68
00:11:11.630 --> 00:11:12.440
Jessika.Alfaro@fda.hhs.gov: Ian.

69

00:11:13.140 --> 00:11:33.319
Ian.Weiss@fda.hhs.gov: Yeah, you can absolutely use a teaming agreement in in a contractual environment. As far as the specific terms the the FDA doesn't necessarily have any specific terms on what that teaming agreement looks like, and it's more of a business decision for the for the 2 commercial parties involved.

70
00:11:34.760 --> 00:11:35.740
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

71
00:11:36.360 --> 00:11:47.069
Jessika.Alfaro@fda.hhs.gov: Next question. It's also on page 103 of the BA. Announcement, can we keep intellectual property? But the FDA has the right to use it. Ian.

72
00:11:47.730 --> 00:11:55.239
Ian.Weiss@fda.hhs.gov: Yeah. So if you have intellectual property, that's you know you've already generated, or is

73
00:11:56.760 --> 00:12:02.528
Ian.Weiss@fda.hhs.gov: generated in in part with this? With the effort. Yeah, you can

74
00:12:03.130 --> 00:12:11.729
Ian.Weiss@fda.hhs.gov: market as such. And you know the FDA has unlimited right to use it. But you can keep the intellectual property. Yes.

75
00:12:12.500 --> 00:12:13.010
Jessika.Alfaro@fda.hhs.gov: Great.

76
00:12:13.010 --> 00:12:13.929
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

77
00:12:15.010 --> 00:12:30.120
Jessika.Alfaro@fda.hhs.gov: In the introduction. Section page 7, states, the FDA will be giving preference to proposals that use a cost. Reimbursable model vice, a firm, fixed price model. What does vice mean in that sentence? Ian.

78
00:12:30.793 --> 00:12:34.336
Ian.Weiss@fda.hhs.gov: Just means that we prefer due to the research

79
00:12:35.080 --> 00:12:47.651

Ian.Weiss@fda.hhs.gov: nature of this of this work. We just prefer a cost reimbursement model as opposed to a a firm, fixed price. That's not to say that if a firm, fixed price isn't

80
00:12:51.619 --> 00:13:02.700
Ian.Weiss@fda.hhs.gov: eligible or or applicable to your proposal that we wouldn't accept it. It's just that A lot of research tends to lend itself to a cost reimbursement model.

81
00:13:04.980 --> 00:13:07.770
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question

82
00:13:09.030 --> 00:13:20.000
Jessika.Alfaro@fda.hhs.gov: in the introduction section page 7, States. In the future the FDA may move to an only utilizing a call, start model for this? BA, a word.

83
00:13:20.150 --> 00:13:25.309
Jessika.Alfaro@fda.hhs.gov: Can you please clarify what is mean by a cost type, model.

84
00:13:26.100 --> 00:13:40.489
Ian.Weiss@fda.hhs.gov: So that refers to a cost reimbursement model in accordance with far part 16. And you know, if you were to go to far. 16, 3 0, 1 dash one and I'll just kind of read this verbatim.

85
00:13:40.490 --> 00:14:00.709
Ian.Weiss@fda.hhs.gov: Real quick cost. Reimbursement types of contracts provide for the payment of allowed incurred costs to the extent prescribed in the contract. These contracts establish an estimate for total cost, for the purpose of obligating funds and establishing a ceiling, that the contractor may not exceed, except at its own risk, without the approval of the contracting officer.

86
00:14:03.540 --> 00:14:04.590
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

87
00:14:05.320 --> 00:14:06.640
Jessika.Alfaro@fda.hhs.gov: Next question.

88
00:14:07.428 --> 00:14:24.779
Jessika.Alfaro@fda.hhs.gov: This would be for Canara. In part one research areas of interest. On page 9, the Bea states, FDA aims to target innovation in regulatory science that advances the health of the following demographic groups and populations.

89
00:14:24.870 --> 00:14:54.499
Jessika.Alfaro@fda.hhs.gov: some of which have clinical characteristics that maybe frequently preclude their participation in clinical research or bear disproportionate burden of tobacco, product, risk and harm, racial and ethnic minority, population, women's health persons with cancer and persons with rare diseases. We note here that inclusion of women's health. The 3 charges in this section also emphasizes women's health.

90
00:14:54.770 --> 00:15:02.030
Jessika.Alfaro@fda.hhs.gov: However, the second full paragraph on page 9 seems to emphasize men as well as women

91
00:15:02.250 --> 00:15:09.310
Jessika.Alfaro@fda.hhs.gov: should proposed research focus only women's health, or both women and men.

92
00:15:10.470 --> 00:15:24.840
Kinnera.Chada@fda.hhs.gov: So our recommendation would be that any of the areas or research topics on table one that you have, that you see as listed as a priority for women's health. The proposals can focus on women's health.

93
00:15:24.980 --> 00:15:34.010
Kinnera.Chada@fda.hhs.gov: and any other areas of the scope can be directed towards other demographics. Men, women, children, elderly population.

94
00:15:35.100 --> 00:15:36.280
Jessika.Alfaro@fda.hhs.gov: Thank you, Clara.

95
00:15:37.000 --> 00:15:41.180
Jessika.Alfaro@fda.hhs.gov: Thank you. Canara. Next question is, for you as well. Canara

96
00:15:41.320 --> 00:15:50.769
Jessika.Alfaro@fda.hhs.gov: in preparation. Volume one. Technical proposal, page 68. Mandates the use of aerial font with point size as follow.

97
00:15:50.960 --> 00:16:01.320
Jessika.Alfaro@fda.hhs.gov: 12 point for main proposal, narrative, and 10 point for tables, charts, references, and figures. Please confirm that the text box

98
00:16:01.470 --> 00:16:03.899
Jessika.Alfaro@fda.hhs.gov: can also be a 10 point.

99
00:16:04.940 --> 00:16:17.209
Kinnera.Chada@fda.hhs.gov: So if it is text box that is part of the table figure shot, then it could be a font size of 10. But if it is part of the main text or the proposal.

100
00:16:17.550 --> 00:16:19.400
Kinnera.Chada@fda.hhs.gov: then it should be 12.

101
00:16:20.790 --> 00:16:21.330
Jessika.Alfaro@fda.hhs.gov: Great.

102
00:16:21.330 --> 00:16:22.560
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

103
00:16:22.660 --> 00:16:40.249
Jessika.Alfaro@fda.hhs.gov: Next question is also for you as well. Canara in preparation of volume one technical proposal, page 68, provides one through 15 list. Of all components of the technical proposal. The last component

104
00:16:41.030 --> 00:17:05.420
Jessika.Alfaro@fda.hhs.gov: 15 is the table of acronyms in terms of proposal presentation. Could the proposal move the acronym of the list to be presented right after the table of contents. We believe that, showing the acronym at the beginning of the proposal rather than at the end, will improve proposal. Readability for proposal evaluators.

105
00:17:06.619 --> 00:17:34.089
Kinnera.Chada@fda.hhs.gov: Thanks, Jessica. Thank you for the suggestion. So you will see in the updated announcement that will be posted tomorrow that the attachment 4 for technical attachment 5 for technical proposal volume one has been updated and you will see table of acronyms to appear as Number 4 after the table of contents. It would not be listed at the end anymore. Thank you once again for the suggestion.

106
00:17:34.720 --> 00:17:35.749
Jessika.Alfaro@fda.hhs.gov: Thank you. Canaro.

107
00:17:36.610 --> 00:17:48.089

Jessika.Alfaro@fda.hhs.gov: Next question is also for you. Canara, in section submission of full proposal. Page 76. Calls for submission of checklist attachment? 3.

108
00:17:48.260 --> 00:18:09.199
Jessika.Alfaro@fda.hhs.gov: Our questions about the checklist. Should the checklist be submitted as a standalone document? Or should the checklist be submitted as an appendix to the technical proposal. If the checklist should be submitted as an appendix to the technical proposal, is it also subject to the page limit of the technical proposal appendices.

109
00:18:10.260 --> 00:18:32.949
Kinnera.Chada@fda.hhs.gov: So so the checklist is a standalone document as presented at the beginning of the meeting today session. Today, you will see that these are all freestanding standalone documents, checklist concept paper, and also the full proposal. They can go as separate Pdf attachments in a single email to FDA, BA at

110
00:18:33.490 --> 00:18:35.429
Kinnera.Chada@fda.hhs.gov: fda.hhs.com.

111
00:18:35.710 --> 00:18:36.550
Kinnera.Chada@fda.hhs.gov: Thank you.

112
00:18:37.020 --> 00:18:59.140
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara. So there's a follow up to that question, and it says, attachment. 5. Technical proposal, template. Page 101 also includes a proposal checklist. Should we submit this attachment? 5 checks as well? If so, can you please clarify that it would not be subject to the page limit of the technical proposal appendices.

113
00:18:59.780 --> 00:19:22.249
Kinnera.Chada@fda.hhs.gov: So if you see the proposal checklist that is listed in attachment 5 is specific to the volume, one technical proposal, and that would be different from the checklist that is listed at the beginning. The checklist, that is a free standing document that is provided as attachment. 3 of the announcement

114
00:19:22.330 --> 00:19:44.260
Kinnera.Chada@fda.hhs.gov: verifies or confirms that the technical proposal concept paper, the charges and all these areas are completed, whereas the checklist that is provided to you as part of the attachment file technical proposal, make sure that the component of the technical proposal are covered and have been provided.

115
00:19:45.670 --> 00:19:46.739

Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

116
00:19:47.610 --> 00:19:51.440
Jessika.Alfaro@fda.hhs.gov: Next question. Ian. This question would be for you

117
00:19:51.570 --> 00:20:04.899
Jessika.Alfaro@fda.hhs.gov: in Section B volume one, technical proposal appendices, pages a hundred 5 to 106. Reference key personnel from both the contractor and the subcontractor

118
00:20:05.110 --> 00:20:09.150
Jessika.Alfaro@fda.hhs.gov: and key subcontractor employees are questions.

119
00:20:09.390 --> 00:20:21.119
Jessika.Alfaro@fda.hhs.gov: how are key personnel defined? Should there be a minimum or a maximum number of key personnel's? What is the difference between key personnel and key employees?

120
00:20:22.920 --> 00:20:49.730
Ian.Weiss@fda.hhs.gov: So key personnel are generally primary points of contact and and those whose expertise is critical to the contracts requirements. Right? So typically the primary investigator, the pi of the of the proposal. There's no limit, necessarily. As to how many key personnel you can have, but we always recommend kind of leaning towards a smaller number. And there's really no difference in terms between key personnel and key employees.

121
00:20:51.120 --> 00:20:52.220
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

122
00:20:52.580 --> 00:21:07.370
Jessika.Alfaro@fda.hhs.gov: Next question is also for you as well. Ian, in section B, volume one, technical proposal appendices, biographical sketches on page 106. One C. Calls calls for a list of related projects.

123
00:21:07.520 --> 00:21:23.259
Jessika.Alfaro@fda.hhs.gov: Is this list for the individual being proposed, or is it for the offer and any potential subcontractors. The requester list of related projects asks that the offer for a list

124
00:21:23.660 --> 00:21:36.599

Jessika.Alfaro@fda.hhs.gov: of the last 3 related contracts of similar size and scope during the past 3 years. Would the FDA also consider work performed under a corporate agreement?

125
00:21:37.470 --> 00:21:59.376
Ian.Weiss@fda.hhs.gov: So, yeah, essentially, what we're asking for here is is past performance. Right? We're we're asking to see. If you've done things of, as it says, of similar size and and scope, so it can be for the individuals proposed, it can be for the offer and potential subcontractors. We definitely recommend that if the offer and or subcontractors

126
00:21:59.730 --> 00:22:07.525
Ian.Weiss@fda.hhs.gov: have that past performance that you lean, you lean more heavily on that, and then, you're as to the other question as to

127
00:22:08.299 --> 00:22:19.470
Ian.Weiss@fda.hhs.gov: work performed under a cooperative agreement. Yes, absolutely. What we're look looking to see here is ha! Have you managed a project of of this size and scope. It helps. It helps the Government

128
00:22:20.050 --> 00:22:24.959
Ian.Weiss@fda.hhs.gov: gain confidence that you could manage the the project in your proposal.

129
00:22:27.190 --> 00:22:28.450
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

130
00:22:28.620 --> 00:22:31.120
Jessika.Alfaro@fda.hhs.gov: Next question is also for you.

131
00:22:31.844 --> 00:22:56.100
Jessika.Alfaro@fda.hhs.gov: Cost annex number one requires that Naics code. However, the previously listed, Ni naics code 5, 4, 1, 7, 1, 4 appears to be to being removed in the last update on sam.gov with the FDA. Please confirm that naics code.

132
00:22:57.070 --> 00:23:13.889
Ian.Weiss@fda.hhs.gov: So I wanted to say, Thank you for pointing that out. Yeah, we weren't aware that it was indeed removed on the last update. So we're gonna be moving to naics. Code 5, 4, 1, 7, 1, 5. And you'll see that in tomorrow's update to the BA announcement on sam.gov.

133
00:23:16.040 --> 00:23:17.059
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

134
00:23:17.320 --> 00:23:24.790
Jessika.Alfaro@fda.hhs.gov: Next question is also for you. Also in calls to annex one. The solicitation requests

135
00:23:25.120 --> 00:23:41.100
Jessika.Alfaro@fda.hhs.gov: they offer dunce number. As this number has been replaced by the unique, identify identifier number. Should the offer submit their Ue. I. Instead of their outdated dunce.

136
00:23:42.506 --> 00:23:50.019
Ian.Weiss@fda.hhs.gov: Short answer is, yes, and you'll see, update update to that language in tomorrow's update as well. In the in the BA announcement.

137
00:23:52.290 --> 00:24:14.809
Jessika.Alfaro@fda.hhs.gov: Great. Thank you, Ian. Next question. It's also for you as well. Ian. In part 3. Proposal preparation and submission. Table, 2. Submission deadlines for Fy. 25 Baa. Requires revised full proposal to highlight any revisions within 14 calendar days of FDA request.

138
00:24:15.150 --> 00:24:37.669
Jessika.Alfaro@fda.hhs.gov: Can you please clarify if this is the same guidance for Fy. 24. Full proposal resubmission specifically, should Fy. 24. Full proposal, resubmission also use Strikethrough and highlight revisions to denote what has changed versus the previous year's submission.

139
00:24:37.770 --> 00:24:47.709
Jessika.Alfaro@fda.hhs.gov: If so, should this practice apply equally to both the technical proposal and the budget budget narrative.

140
00:24:48.740 --> 00:24:53.537
Ian.Weiss@fda.hhs.gov: So if what if what is being asked here is whether or not the

141
00:24:54.391 --> 00:25:08.310
Ian.Weiss@fda.hhs.gov: a new proposal for Fy 25 is actually a resubmission of Fy. 24, then. No, you wouldn't wanted to use the strike through and and track changes and highlights. If

142
00:25:08.380 --> 00:25:24.160
Ian.Weiss@fda.hhs.gov: now, if you are asked to put. Ask for resubmission on your Fy. 25 submission, and yes, those would be required, and it would

be equally applicable to the technical proposal and the Budget narrative, as well.

143
00:25:26.230 --> 00:25:42.420
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. It appears that the ordering, numbering, and references, references appearing on page 73 of the Baa. May contain mistakes or require further clarification.

144
00:25:42.510 --> 00:26:03.420
Jessika.Alfaro@fda.hhs.gov: For example, under item 4. Subcontract, there is in sentence stating that a cost proposal confirming to all requirements of this section 4 c. Should be provided. However, there's No. Section 4 c. On this page, nor on the pages immediately above and below. To this page

145
00:26:03.520 --> 00:26:23.520
Jessika.Alfaro@fda.hhs.gov: there is only 4 a and 4 B. Could FDA please indicate precisely where this reference. Section 4 C appears in the Baa. Similarly near the top of page 74. There's a list and numbered as follows.

146
00:26:24.260 --> 00:26:31.160
Jessika.Alfaro@fda.hhs.gov: fee for profit, including percentage certified cost and pricing data

147
00:26:31.870 --> 00:26:36.359
Jessika.Alfaro@fda.hhs.gov: data other than certified cost or pricing data.

148
00:26:37.355 --> 00:26:41.079
Jessika.Alfaro@fda.hhs.gov: shall be provided for proposals under 2 million.

149
00:26:42.310 --> 00:27:00.040
Jessika.Alfaro@fda.hhs.gov: This list, number one through 3, does not relate to the sentence above above it, nor, it is clear under which header section it. It belongs. It is misnumbered and supposed to be a continuation of the previous list.

150
00:27:01.945 --> 00:27:07.610
Jessika.Alfaro@fda.hhs.gov: For example, it should be 5, 6, 7, following on item 4. Subcontracts

151
00:27:08.050 --> 00:27:17.069

Jessika.Alfaro@fda.hhs.gov: instead of 1, 2, 3, or or this their text missing from this page, please confirm, clarify.

152
00:27:18.470 --> 00:27:31.600
Ian.Weiss@fda.hhs.gov: So that was a a long question. And I have a very short answer. It looks as though those were typos. When we went and looked at that. And you'll see updates to that in the updated announcement tomorrow.

153
00:27:32.380 --> 00:27:35.019
Ian.Weiss@fda.hhs.gov: So, Lana, thank you. Thank you for pointing those out.

154
00:27:37.670 --> 00:27:58.049
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is also for you as well for proposals. Over 70 750 K. For large businesses. Are there specific small business businesses, subcontracting goals? Percentage target is the FDA is requesting.

155
00:27:59.420 --> 00:28:05.634
Ian.Weiss@fda.hhs.gov: So they're not published yet for Fy 25. And I did check in with our small business

156
00:28:06.433 --> 00:28:18.380
Ian.Weiss@fda.hhs.gov: program folks earlier today on this but they are expected to mirror Fy 24 goals. And so that would be a total small business percentage of 31%

157
00:28:18.843 --> 00:28:44.879
Ian.Weiss@fda.hhs.gov: small disadvantaged businesses, including Ada. Program participants, Alaska, native contribution or corporations. Pardon me, and Indian tribes would be 5%. Women owned small business. 5% service disabled veteran owned small business, 5% and hubzone of 3%. And so again, those aren't published as of yet. But those are those are the expected goals for this year.

158
00:28:46.340 --> 00:28:47.700
Jessika.Alfaro@fda.hhs.gov: Great. Thank you, Ian.

159
00:28:48.234 --> 00:28:57.309
Jessika.Alfaro@fda.hhs.gov: Next question is for you as well. Are there any restrictions on the percentage of work that can be performed by international subcontractors.

160
00:28:58.030 --> 00:29:17.530

Ian.Weiss@fda.hhs.gov: So there's no specific limitation on work for international subcontractors. But there is the the requirement that 51% of the the total work needs to be done by the prime contractor. So it doesn't matter so much if it's a domestic or an international subcontractor. But we just have to adhere to that 51%

161
00:29:17.770 --> 00:29:20.500
Ian.Weiss@fda.hhs.gov: of the work performed by the prime.

162
00:29:22.060 --> 00:29:34.670
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. Is there an expected minimum frequency for meetings with FDA? Subject matter experts, or the contracting officer representative.

163
00:29:35.673 --> 00:30:05.009
Ian.Weiss@fda.hhs.gov: No, and it really kind of varies and depends on the pro on the project. We see some where there's bi-weekly meetings, monthly meetings, quarterly meetings it. It really kind of depends, and you can. You can pitch the the frequency of those meetings in your proposal. So if you have an idea about how often you think on your particular project meeting with the the program and core folks would be beneficial. Then, then, certainly. Put that in your proposal.

164
00:30:06.970 --> 00:30:18.379
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. Ian FDA has asked to provide feedback on survey instruments to be used in this proposed project.

165
00:30:18.660 --> 00:30:27.700
Jessika.Alfaro@fda.hhs.gov: how much time should be allocated in the timeline for FDA Review 30 days, as it's stated, for manuscript review.

166
00:30:30.251 --> 00:30:41.178
Ian.Weiss@fda.hhs.gov: It varies. And it's case by case. I don't really have a a definitive answer on that. And yeah, really, really, just kind of depends on the case by case basis.

167
00:30:42.100 --> 00:30:48.609
Ian.Weiss@fda.hhs.gov: 30 days is a good, a good benchmark, but I I wouldn't necessarily plan on that for for every review.

168
00:30:50.190 --> 00:30:51.239
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

169
00:30:51.520 --> 00:31:04.929

Jessika.Alfaro@fda.hhs.gov: Next question is for you as well. Will the FDA allow any consideration for proposals that are within the staged page limits, but may exceed 2 MB limit.

170
00:31:06.185 --> 00:31:17.910
Ian.Weiss@fda.hhs.gov: No, that's that's a hard limit on those on on those submissions. So please make sure that you adhere both to the page limit and to the the size limit of the file.

171
00:31:19.520 --> 00:31:20.549
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

172
00:31:20.670 --> 00:31:37.499
Jessika.Alfaro@fda.hhs.gov: Next question is also for you as well. Appendix 8 is referenced in the Rfp. As the pre-award survey accounting system checklist, but it's not uploaded to Sam. Will the FDA upload this appendix.

173
00:31:38.160 --> 00:31:46.139
Ian.Weiss@fda.hhs.gov: Yes, absolutely. And I thank you for pointing that out, and we will get that uploaded with tomorrow's update on sam.gov.

174
00:31:47.460 --> 00:31:54.569
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. What is the average length of accepted proposals.

175
00:31:56.550 --> 00:31:57.390
Ian.Weiss@fda.hhs.gov: So

176
00:31:58.290 --> 00:32:23.499
Ian.Weiss@fda.hhs.gov: the the timeline is generally one to 3 years the project length really isn't a primary concern for acceptance. We could. We've seen them as short as 6 months and as long as 5 years it. It really kind of depends on a realistic timeline for your project. What I what I would say is, you know, if you think your project is is, you know.

177
00:32:23.500 --> 00:32:29.154
Ian.Weiss@fda.hhs.gov: one year, 5, 5 years, 4 years, whatever whatever it's going to be. Please write your proposal as such.

178
00:32:30.050 --> 00:32:51.079
Ian.Weiss@fda.hhs.gov: what we, what we see often is kind of overly optimistic timelines on the length of time these projects are gonna be, and you know, it might get proposed as a a 1 year project. And then we're

doing multiple rounds of of modifications to the contract in order to facilitate

179
00:32:51.377 --> 00:33:06.830
Ian.Weiss@fda.hhs.gov: changes and changes in the timeline. When you know kind of turns out, we we might have known at the beginning that you know something that was pitched as a 1 year project was really a 2 or 3 year project. So just know that the timeline isn't a primary concern.

180
00:33:07.564 --> 00:33:29.150
Ian.Weiss@fda.hhs.gov: you know, funding definitely is. But the timeline is not so. Please try to be realistic with your timelines and not not too overly optimistic. We tend to error on what I would say is, we tend to error on the the longer side. If you. If you have a timeline, a variable timeline of, say, one to 3 years, you might want to write it more. Towards that 3 year timeline.

181
00:33:30.970 --> 00:33:41.900
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian, next questions for you as well. If we get a contract, how long on an average, till it's funded or and works begins.

182
00:33:42.983 --> 00:33:48.316
Ian.Weiss@fda.hhs.gov: That really depends on the project and the funding availability, and when it when is awarded?

183
00:33:49.460 --> 00:33:54.416
Ian.Weiss@fda.hhs.gov: we we had some. We had some BA. Contracts awarded as early as April

184
00:33:54.960 --> 00:34:13.410
Ian.Weiss@fda.hhs.gov: last year, and as late as the begin. You know the the beginning and middle of September so, and and everything in between. So I'd love to give you a hard, hard answer to that. But it could be anywhere from anywhere in the 3rd and 4th quarter of the fiscal year.

185
00:34:15.040 --> 00:34:16.160
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

186
00:34:16.719 --> 00:34:18.769
Jessika.Alfaro@fda.hhs.gov: Next question is for Canara.

187
00:34:19.120 --> 00:34:23.649
Jessika.Alfaro@fda.hhs.gov: When will I hear back about the decision on my submitted concept? Paper.

188
00:34:25.560 --> 00:34:38.800
Kinnera.Chada@fda.hhs.gov: So as discussed as part of the timelines for communication. If you have submitted an early concept paper, you should have already heard from FDA regarding the recommendation.

189
00:34:39.310 --> 00:34:56.709
Kinnera.Chada@fda.hhs.gov: If once you have submitted a new application which is not just the concept paper, but the full stage one application that is due February 24, th then you would be receiving a notification for

190
00:34:57.840 --> 00:35:02.560
Kinnera.Chada@fda.hhs.gov: acknowledgement of your application by March 4th and

191
00:35:03.390 --> 00:35:20.059
Kinnera.Chada@fda.hhs.gov: After that, if the concept paper has been marked as indicated as aligned with FDA's priorities. Then it would move forward for stage one review, or else you will be notified by mid-april.

192
00:35:21.070 --> 00:35:26.099
Kinnera.Chada@fda.hhs.gov: that your concept paper or your application would not be moving forward for stage. One review.

193
00:35:27.460 --> 00:35:28.740
Jessika.Alfaro@fda.hhs.gov: Thank you. Canara.

194
00:35:28.740 --> 00:35:29.120
Kinnera.Chada@fda.hhs.gov: Thank you.

195
00:35:29.577 --> 00:35:37.359
Jessika.Alfaro@fda.hhs.gov: Next question is for Ian, can an FDA employee be a subcontract, a subcontractor on this program?

196
00:35:38.380 --> 00:35:45.649
Ian.Weiss@fda.hhs.gov: So I'll answer this from the perspective of just kind of any government employee, not just an FDA employee, and

197
00:35:45.980 --> 00:36:09.299
Ian.Weiss@fda.hhs.gov: that, more than likely, is gonna cause a conflict of interest situation. So what I would say is, in general, the answer is probably going to be No, if you want a more definitive and and targeted answer to the specifics of of your specific scenario. What I would say

is, check with your ethics office on that. You know whether it's FDA or any other agency.

198
00:36:10.630 --> 00:36:11.560
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

199
00:36:12.270 --> 00:36:24.490
Jessika.Alfaro@fda.hhs.gov: Next question is for you as well. Can FDA provide a potential start, date, or other guidance for the contractor for the purpose of developing the proposed budget.

200
00:36:24.600 --> 00:36:29.160
Jessika.Alfaro@fda.hhs.gov: Would, October 1, st 2025, be appropriate.

201
00:36:31.241 --> 00:36:51.028
Ian.Weiss@fda.hhs.gov: If if in your proposal you were looking at a start, date again, kind of, as I said earlier these are these BA. Contracts are generally awarded anywhere from 3rd and 4th quarter. So it, it depends. But if you wanna propose a start date of October first, st I think that that probably is appropriate.

202
00:36:51.370 --> 00:37:03.490
Ian.Weiss@fda.hhs.gov: And you know, if we we get into discussions with your particular organization on on your proposal, you know that that may or may not be updated. But I'd say that that's a fair, a fair date to to propose.

203
00:37:05.630 --> 00:37:22.209
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian, next questions for you as well. Are subcontractors with a proposed budget under 250,000 required to submit a separate cost proposal? Or is it sufficient for the prime contractor to include their cost in their budget?

204
00:37:24.447 --> 00:37:30.340
Ian.Weiss@fda.hhs.gov: No, it's yeah. It's sufficient for the prime to include that in their budget. If it's under the 250 k.

205
00:37:32.690 --> 00:37:39.949
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. Should the volume 2 cost proposal and volume

206
00:37:40.740 --> 00:37:51.040
Jessika.Alfaro@fda.hhs.gov: and volume to cost proposal appendices be submitted as a single Pdf. Document, or should they be provided as separate files.

207
00:37:52.239 --> 00:38:01.839
Ian.Weiss@fda.hhs.gov: We don't necessarily say one way or the other. But I think the preferences for separate files for those for those documents is preferred.

208
00:38:03.740 --> 00:38:19.540
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian, next questions for you as well. And FDA, can FDA please confirm that the salary limitations for this opportunity is the Executive level to cap effective. January 2025.

209
00:38:20.440 --> 00:38:21.690
Ian.Weiss@fda.hhs.gov: Yes, that is correct.

210
00:38:23.270 --> 00:38:24.479
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

211
00:38:28.500 --> 00:38:42.209
Jessika.Alfaro@fda.hhs.gov: and next questions for you as well. Can FDA please confirm. If a certificate of current cost or pricing data needs to be submitted by both the prime and the subcontractors.

212
00:38:42.780 --> 00:38:44.488
Ian.Weiss@fda.hhs.gov: Yeah, if it's again, it's

213
00:38:47.220 --> 00:38:51.830
Ian.Weiss@fda.hhs.gov: applicable to your proposal, then. Yes, it would be. It would be

214
00:38:53.850 --> 00:38:56.810
Ian.Weiss@fda.hhs.gov: required to be submitted by both the prime and the subcontractor.

215
00:38:59.520 --> 00:39:11.930
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. This is a 2 part questions I'll ask you. Ian. This part. This is part of the volume. One technical proposal and volume appendices.

216
00:39:12.160 --> 00:39:20.000
Jessika.Alfaro@fda.hhs.gov: and it's an under security. It is unclear. What information should be provided

217
00:39:21.790 --> 00:39:27.429

Jessika.Alfaro@fda.hhs.gov: under 6, 8, 2, security that isn't already addressed.

218
00:39:28.160 --> 00:39:33.460
Jessika.Alfaro@fda.hhs.gov: Risk medication, plan and security planning. Could this be clarified.

219
00:39:35.350 --> 00:39:53.995
Ian.Weiss@fda.hhs.gov: So in general, the information in the risk, mitigation, plan and security planning should be sufficient. There may be some clarifications asked for on a case by case basis by the technical review panel but in general, those that security

220
00:39:54.790 --> 00:40:00.260
Ian.Weiss@fda.hhs.gov: documents should be should be covered under your risk, mitigation, plan, and your security planning.

221
00:40:01.550 --> 00:40:12.770
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian and follow up to this question would be for Canara canara. It says in volume one technical proposal and volume one appendes, so

222
00:40:13.320 --> 00:40:16.320
Jessika.Alfaro@fda.hhs.gov: it says, the the under the gantt chart.

223
00:40:16.670 --> 00:40:30.939
Jessika.Alfaro@fda.hhs.gov: How should this be included in the proposal? Is a separate Ms. Project file, allowable, if not. Should the gantt chart be inserted into a word document as a picture table, or some other way.

224
00:40:32.170 --> 00:40:57.380
Kinnera.Chada@fda.hhs.gov: Yes, our suggestion would be to include the Gantt chart as a picture or a table into the proposal itself, because that would be helpful for the reviewers to look at the timeline. If it is submitted as a separate chart, then it might take time for the reviewers to go ahead and open that separate file, so our recommendation would be to include it as a picture or a table as part of your technical volume. One

225
00:40:57.720 --> 00:40:58.640
Kinnera.Chada@fda.hhs.gov: proposal.

226
00:40:59.500 --> 00:41:00.450
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

227
00:41:00.710 --> 00:41:07.239
Jessika.Alfaro@fda.hhs.gov: Next question is for Ian. This is under volume 2 cost proposal and volume 2 appendixes.

228
00:41:07.380 --> 00:41:20.260
Jessika.Alfaro@fda.hhs.gov: Our work would require a non servable cost for data purchasing and management, with no associated deliverables and severable work would be 2 different aims. Using that data.

229
00:41:20.460 --> 00:41:24.959
Jessika.Alfaro@fda.hhs.gov: the statement of work instructions have the example of if

230
00:41:25.090 --> 00:41:38.220
Jessika.Alfaro@fda.hhs.gov: and aim one can be completed, separate and distinct from aim. 2 aim one, and its associated tasks should be proposed as based period tasks

231
00:41:38.540 --> 00:41:45.579
Jessika.Alfaro@fda.hhs.gov: and aim to, and its associated tasks would be identified as option. One tasks

232
00:41:46.140 --> 00:42:00.119
Jessika.Alfaro@fda.hhs.gov: in our case would aim one, then be option one, and aim to be option 2 or still aim, one being base and aim to being option. One.

233
00:42:03.010 --> 00:42:14.662
Ian.Weiss@fda.hhs.gov: So yeah, without going into more detail, just kind of with this general information here. What I would say is that aim? One would be the base and aim. 2 would be an option. There's there's

234
00:42:16.290 --> 00:42:26.857
Ian.Weiss@fda.hhs.gov: other scenarios that we could get into depending on the the details of these of these aims where you know, maybe it's not an option period. It's an optional item

235
00:42:27.350 --> 00:42:43.453
Ian.Weiss@fda.hhs.gov: but in general, yeah, it's it sounds like aim. One would be would be your base. If we're just talking about a base and an option period aim, one would be your base and aim. 2 would be your would be your option. But just know that you can absolutely have a

236
00:42:44.630 --> 00:42:57.340

Ian.Weiss@fda.hhs.gov: absolutely have a hybrid model. And you can. You can suggest optional items within the option years. And we're we're very flexible with that, in fact. In some cases that might almost be preferred.

237
00:42:58.930 --> 00:43:00.050
Ian.Weiss@fda.hhs.gov: Thank you, Ian.

238
00:43:00.941 --> 00:43:07.110
Jessika.Alfaro@fda.hhs.gov: Next question. If several tasks are in the it are to be listed in base

239
00:43:07.270 --> 00:43:10.610
Jessika.Alfaro@fda.hhs.gov: last year hybrid proposals were acceptable.

240
00:43:10.780 --> 00:43:14.780
Jessika.Alfaro@fda.hhs.gov: For example, some costs were severable and some were not severable.

241
00:43:15.050 --> 00:43:23.549
Jessika.Alfaro@fda.hhs.gov: Is the is that also acceptable this year, with a summary table showing separable and non severable cost under the base period.

242
00:43:23.930 --> 00:43:25.729
Ian.Weiss@fda.hhs.gov: Yes, that's absolutely acceptable.

243
00:43:27.570 --> 00:43:33.659
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question is for you as well. This would be under supplementary material. One.

244
00:43:34.020 --> 00:43:39.209
Jessika.Alfaro@fda.hhs.gov: Would this be the appropriate category to include letters of support.

245
00:43:41.056 --> 00:43:42.050
Ian.Weiss@fda.hhs.gov: Yes, absolutely.

246
00:43:45.090 --> 00:43:48.899
Jessika.Alfaro@fda.hhs.gov: Great. Thank you, Ian. Next question would be for you.

247
00:43:49.730 --> 00:43:54.230

Jessika.Alfaro@fda.hhs.gov: does the FDA have any preference for pi terminology?

248
00:43:54.350 --> 00:43:58.090
Jessika.Alfaro@fda.hhs.gov: For example, multiple pi versus co-pis.

249
00:43:59.423 --> 00:44:08.389
Ian.Weiss@fda.hhs.gov: We don't have any preference on that on that terminology just as long as it's as as it's defined. In your proposal.

250
00:44:11.710 --> 00:44:18.059
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. So that concluded that questions that we received through the Va inbox.

251
00:44:18.170 --> 00:44:23.119
Jessika.Alfaro@fda.hhs.gov: and I'm just gonna go to the QA part.

252
00:44:23.730 --> 00:44:26.929
Jessika.Alfaro@fda.hhs.gov: And 1st question is.

253
00:44:27.510 --> 00:44:34.599
Jessika.Alfaro@fda.hhs.gov: think it's similar to the one that was asked before. But this a different clause clarify HH.

254
00:44:34.820 --> 00:44:45.670
Jessika.Alfaro@fda.hhs.gov: SAR. Clause 3 5 2.2 3 1 slash, 70 salary rate limitation. What is the salary limit?

255
00:44:48.058 --> 00:44:59.469
Ian.Weiss@fda.hhs.gov: I'll have to double check that. But it should be equal to that Executive level cap. Effective. January 2025 of 225,700.

256
00:45:03.640 --> 00:45:06.870
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question.

257
00:45:09.531 --> 00:45:16.570
Jessika.Alfaro@fda.hhs.gov: Does FDA accept added fees, or ir, and d to the budget.

258
00:45:19.140 --> 00:45:37.197
Ian.Weiss@fda.hhs.gov: it. It depends on it really depends on the proposal. It's that's not to say that we don't accept fees in general,

what I've seen for the Baa. Contracts is they are in general kind of just cost reimbursement without fees. So

259
00:45:37.770 --> 00:45:42.200
Ian.Weiss@fda.hhs.gov: I would say, factor that into your proposal development.

260
00:45:43.350 --> 00:45:47.069
Ian.Weiss@fda.hhs.gov: that we we tend to award to proposals without fees.

261
00:45:49.830 --> 00:45:51.079
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

262
00:45:53.170 --> 00:46:09.190
Jessika.Alfaro@fda.hhs.gov: Are there guidance, guidelines concerning the balances between award amount and duration of award? Can you describe what the breakdown is on the previous awards between total estimated contract value and obligated.

263
00:46:11.750 --> 00:46:12.580
Jessika.Alfaro@fda.hhs.gov: Pm.

264
00:46:13.020 --> 00:46:15.339
Ian.Weiss@fda.hhs.gov: Yeah, let's see here.

265
00:46:17.620 --> 00:46:29.899
Ian.Weiss@fda.hhs.gov: So I think we Canara correct me if I'm wrong. I think we published our the Con total contract value and the amount obligated as to oh, I see what they're asking here. Okay.

266
00:46:32.440 --> 00:46:39.089
Ian.Weiss@fda.hhs.gov: the total estimated contract value. And then what we actually obligated? No I in in general.

267
00:46:39.580 --> 00:46:42.940
Ian.Weiss@fda.hhs.gov: it should be should be the same

268
00:46:44.138 --> 00:46:49.465
Ian.Weiss@fda.hhs.gov: we've definitely had somewhere. We've we've conducted modifications and added additional funding

269
00:46:50.640 --> 00:47:02.969

Ian.Weiss@fda.hhs.gov: but what you see in the posting as far as the the Fy. 2024 awards, and or Fy. 23 awards we we post all that on sam.gov

270
00:47:03.760 --> 00:47:09.920
Ian.Weiss@fda.hhs.gov: the all, all of that should be should be publicly accept accessible.

271
00:47:13.800 --> 00:47:25.300
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question. Should we list in the IP insertion of rights only patents or or patent licenses?

272
00:47:27.500 --> 00:47:28.120
Jessika.Alfaro@fda.hhs.gov: Sorry.

273
00:47:28.120 --> 00:47:31.259
Ian.Weiss@fda.hhs.gov: Yeah, I would say, list all, all. IP,

274
00:47:33.770 --> 00:47:35.534
Ian.Weiss@fda.hhs.gov: it's definitely been a a

275
00:47:36.950 --> 00:47:53.599
Ian.Weiss@fda.hhs.gov: bone of contention for here and there. When there's this, this disagreements on IP. So if you know upfront that it's that it's your proprietary, IP, whether it's a license or whether it's just generalized IP, I would say, please please list that in your proposal.

276
00:47:54.610 --> 00:47:55.190
Jessika.Alfaro@fda.hhs.gov: Hmm.

277
00:47:55.380 --> 00:48:07.829
Jessika.Alfaro@fda.hhs.gov: thank you, Ian. Next question for sub awards subcontracting are additional documents, such as such award budget, key persons.

278
00:48:07.940 --> 00:48:15.239
Jessika.Alfaro@fda.hhs.gov: subaward equipment, etcetera, needed in the submission from the intended sub awardee.

279
00:48:17.450 --> 00:48:18.520
Jessika.Alfaro@fda.hhs.gov: Hmm!

280
00:48:19.520 --> 00:48:20.907

Ian.Weiss@fda.hhs.gov: Let's see here.

281
00:48:26.300 --> 00:48:30.349
Ian.Weiss@fda.hhs.gov: no, I don't think you need to necessarily

282
00:48:32.920 --> 00:48:39.410
Ian.Weiss@fda.hhs.gov: differentiate between the between the Subawardee and the and the Awardee.

283
00:48:48.070 --> 00:48:49.220
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

284
00:48:49.540 --> 00:49:01.940
Jessika.Alfaro@fda.hhs.gov: Next question, can you please advise what is meant? On page 109 of the Va. Announcement relative to section 5, contractual agreements.

285
00:49:02.670 --> 00:49:03.889
Jessika.Alfaro@fda.hhs.gov: no problem.

286
00:49:04.690 --> 00:49:26.689
Ian.Weiss@fda.hhs.gov: Yeah, I think for that one we may have to table that one. And I'll have to go in and and read read that specifically on page under 9. I don't. I don't have that open in front of me. But maybe if we can table that one and and either come back to it or answer it in the in. When this gets posted to the BA. QA. Day.

287
00:49:28.380 --> 00:49:29.880
Jessika.Alfaro@fda.hhs.gov: Sounds good. Thank you, Ian.

288
00:49:31.240 --> 00:49:37.150
Jessika.Alfaro@fda.hhs.gov: Next question is the base period limited to a specific time?

289
00:49:37.310 --> 00:49:40.480
Jessika.Alfaro@fda.hhs.gov: Can the base period last more than a year?

290
00:49:40.650 --> 00:49:44.850
Jessika.Alfaro@fda.hhs.gov: Are there options limited to one year each.

291
00:49:45.960 --> 00:50:00.710

Ian.Weiss@fda.hhs.gov: So in general. Yeah. In general, base periods are generally one year option. Periods are generally one year. It really has to do with the on on our end, the the source of the funding

292
00:50:01.330 --> 00:50:09.280
Ian.Weiss@fda.hhs.gov: as to how that and and how how it's funded, and what type of funding it is so what I would say. If you're

293
00:50:10.290 --> 00:50:15.852
Ian.Weiss@fda.hhs.gov: for in your proposal, the majority of of the funds used for these

294
00:50:16.700 --> 00:50:31.690
Ian.Weiss@fda.hhs.gov: BA contracts are generally what we call budget authority or or annual appropriations and they're they're good for a year at a at a time. So what I would say is in your proposal. You are safest planning on one year periods of time.

295
00:50:35.500 --> 00:50:36.600
Jessika.Alfaro@fda.hhs.gov: Thank you. Ian.

296
00:50:38.379 --> 00:50:46.559
Jessika.Alfaro@fda.hhs.gov: Next question on page 108. What is meant by contract number and subcontract number.

297
00:50:48.050 --> 00:50:54.002
Ian.Weiss@fda.hhs.gov: So again. I'd have to go in. And this one, the the contract number will be provided to you.

298
00:50:54.600 --> 00:51:09.796
Ian.Weiss@fda.hhs.gov: if if you're selected, and if you're awarded a contract I'll have to go in and look at page 108 and see what we're we're talking about there as far as subcontract number. Again, we'll either post that or either come back to it or

299
00:51:10.260 --> 00:51:14.859
Ian.Weiss@fda.hhs.gov: post in the Q, and a answers when we post it online.

300
00:51:16.890 --> 00:51:18.520
Jessika.Alfaro@fda.hhs.gov: Sounds good. Thank you, Ian.

301
00:51:19.720 --> 00:51:30.089

Jessika.Alfaro@fda.hhs.gov: What are the main changes between the updated announcement to be posted tomorrow and the one we have now, maybe, Canara.

302
00:51:37.660 --> 00:51:47.890
Kinnera.Chada@fda.hhs.gov: I was on mute answer, for that would be to. There would be a template change where we are moving the table of acronyms, and then the next code.

303
00:51:48.040 --> 00:51:54.679
Kinnera.Chada@fda.hhs.gov: and some changes in language for the part 2

304
00:51:55.260 --> 00:51:58.769
Kinnera.Chada@fda.hhs.gov: related to contract clauses. Is that correct? Again.

305
00:51:59.220 --> 00:52:00.040
Ian.Weiss@fda.hhs.gov: Yes, that's correct.

306
00:52:00.040 --> 00:52:06.619
Kinnera.Chada@fda.hhs.gov: It could be formatting changes and then adding attachment. 8 to the announcement.

307
00:52:09.230 --> 00:52:16.630
Kinnera.Chada@fda.hhs.gov: Those would be the changes. No major changes with respect to scope or part one of the research areas of interest.

308
00:52:18.520 --> 00:52:19.520
Jessika.Alfaro@fda.hhs.gov: Thank you. Canara.

309
00:52:19.660 --> 00:52:20.160
Jessika.Alfaro@fda.hhs.gov: 8.

310
00:52:20.160 --> 00:52:39.496
Ian.Weiss@fda.hhs.gov: Jessica before we move on. I did. I was able to get get into here this question about page 108, and what it was referring to was projects of similar size and scope. So the contract number they're referring to there is the contract. If they had a Federal Government contract number

311
00:52:40.550 --> 00:52:57.574
Ian.Weiss@fda.hhs.gov: to provide that. And then for purposes of the BA a major subcontract. If they have the provide the basically, for

subcontracts provide the prime contract number and and subcontract number it's this was in relation to

312
00:52:59.090 --> 00:53:01.149
Ian.Weiss@fda.hhs.gov: the the past performance.

313
00:53:01.750 --> 00:53:06.529
Ian.Weiss@fda.hhs.gov: So the the vendors or the the entity should have, should have that information available.

314
00:53:08.130 --> 00:53:09.140
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

315
00:53:10.140 --> 00:53:28.729
Jessika.Alfaro@fda.hhs.gov: Next question on page 106 for Section 8, under resources in Section B. There is a reference reference to licensure and agreements. Can you define? What do you mean by licensure?

316
00:53:31.460 --> 00:53:41.099
Ian.Weiss@fda.hhs.gov: I believe that, like, I believe we're referring there to. Licensing with, with respect to, you know, software things things of that nature.

317
00:53:48.250 --> 00:53:51.301
Jessika.Alfaro@fda.hhs.gov: Thank you. Ian. This is

318
00:53:52.040 --> 00:53:55.600
Jessika.Alfaro@fda.hhs.gov: The same question that has been asked before.

319
00:53:57.480 --> 00:53:58.549
Jessika.Alfaro@fda.hhs.gov: So I just

320
00:53:59.368 --> 00:54:07.709
Jessika.Alfaro@fda.hhs.gov: move on to the next question should we budget to meet with FDA for an in person meeting.

321
00:54:09.520 --> 00:54:12.895
Ian.Weiss@fda.hhs.gov: I think that that depends on on the proposal.

322
00:54:13.670 --> 00:54:39.339
Ian.Weiss@fda.hhs.gov: Now, prior to contract award. No, as far as I, as far as I'm aware, and Canira, keep me honest on on that one, if I'm mistaken. But as far as I'm aware, there's no in person meetings prior to

contract award. If there's value in an in person meeting after contract award, should that be budgeted for? I think that that's a business decision on on your end in your, in your proposal.

323
00:54:40.180 --> 00:54:40.890
Ian.Weiss@fda.hhs.gov: Oh, great.

324
00:54:43.930 --> 00:54:44.999
Jessika.Alfaro@fda.hhs.gov: Thank you both.

325
00:54:45.290 --> 00:54:51.929
Jessika.Alfaro@fda.hhs.gov: Next question, is FDA open to working with industry sector under Baa.

326
00:54:52.610 --> 00:54:58.291
Ian.Weiss@fda.hhs.gov: Absolutely small business, large business educational institutions. We're open

327
00:54:59.030 --> 00:55:15.679
Ian.Weiss@fda.hhs.gov: th, this is all about innovation and and trying to solve problems that the government doesn't even necessarily know that we have. So we're open to working with with any sector that that might have a creative solution to to a problem

328
00:55:16.770 --> 00:55:19.310
Ian.Weiss@fda.hhs.gov: in these research areas of interest absolutely.

329
00:55:20.860 --> 00:55:21.800
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

330
00:55:22.310 --> 00:55:27.310
Jessika.Alfaro@fda.hhs.gov: Next question. In the event that the methodology includes.

331
00:55:28.370 --> 00:55:37.880
Jessika.Alfaro@fda.hhs.gov: The use of AI. Are there any disclosures that the FDA requires. Regarding the AI used, for example, Llm.

332
00:55:43.383 --> 00:55:46.740
Ian.Weiss@fda.hhs.gov: I'll have to look into that one. I

333
00:55:46.930 --> 00:55:54.159

Ian.Weiss@fda.hhs.gov: I cannot cannot answer that at this time, and I'll have to. We'll have to get back to the group on that on that one.

334
00:55:56.690 --> 00:55:58.539
Jessika.Alfaro@fda.hhs.gov: Sounds good, Ian, thank you.

335
00:55:58.820 --> 00:56:05.499
Jessika.Alfaro@fda.hhs.gov: Next question, is there a possibility of a no-cost extension like we have on grants?

336
00:56:07.600 --> 00:56:17.634
Ian.Weiss@fda.hhs.gov: So the answer is, yes, but like I said earlier try to keep your as as best you can. Try to keep your proposal timelines realistic.

337
00:56:18.327 --> 00:56:39.459
Ian.Weiss@fda.hhs.gov: We all know that in in research, in, you know any any of these R&D type contracts. Sometimes we don't know what we don't know. And and things just happen. And we have to do no cost extensions. But we're we're really trying to minimize those so the answer is, yes, but kind of put an asterisk on that that we'd we'd prefer not to.

338
00:56:42.090 --> 00:56:43.150
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

339
00:56:43.900 --> 00:56:59.520
Jessika.Alfaro@fda.hhs.gov: Next question, if we have not submitted a concept paper ahead of time with the application be negatively impacted. Even if the proposed research aligns with the published published research priorities.

340
00:57:03.170 --> 00:57:18.550
Kinnera.Chada@fda.hhs.gov: No, please note that submission of an optional early concept. Paper, as it indicates, is optional step of the BA process only. It is to receive feedback from FDA. That's just an opportunity.

341
00:57:18.690 --> 00:57:21.550
Kinnera.Chada@fda.hhs.gov: and to encourage small businesses

342
00:57:21.870 --> 00:57:50.510
Kinnera.Chada@fda.hhs.gov: to determine if they would like to put in additional resources to submit a full proposal without knowing if the proposal would align with FDA's research priorities. So it is not required for you to submit an optional early concept paper, which was due

in November you are free to submit an application stage one application that would include a checklist concept paper and a full proposal.

343
00:57:50.510 --> 00:58:04.069
Kinnera.Chada@fda.hhs.gov: On February 24, th 2025 for Fy. 25. Funding consideration, and after February 24th for Fy. 26, funding consideration. So there would not be any negative impact.

344
00:58:04.420 --> 00:58:17.519
Kinnera.Chada@fda.hhs.gov: The only difference or change that you would experience is if you have not submitted an optional early concept paper, then you would have not received FDA's recommendation for submit or do not submit.

345
00:58:18.430 --> 00:58:36.880
Kinnera.Chada@fda.hhs.gov: For example, if you had submitted an optional early concept paper in November and FDA, after the review, has provided you a recommendation for submit, then what would happen in February is, once we receive a complete application as presented on the Timeline slide.

346
00:58:37.160 --> 00:58:43.209
Kinnera.Chada@fda.hhs.gov: March 6, th we would initiate stage one review of your full proposal.

347
00:58:43.400 --> 00:59:04.149
Kinnera.Chada@fda.hhs.gov: If you have not submitted an optional early concept paper, and it was a new submission that we were receiving on February 24.th Then, if your application is marked as complete, then what we, the next step would be is, we would be sending the concept paper of your application

348
00:59:04.150 --> 00:59:19.849
Kinnera.Chada@fda.hhs.gov: for review to the program offices to see if that aligns with their program priorities. If it is in alignment with their program priorities, then we would move forward with initiating the stage one review of your application.

349
00:59:19.870 --> 00:59:28.680
Kinnera.Chada@fda.hhs.gov: so you would not be penalized or negatively impacted for not submitting an optional early concept paper in November.

350
00:59:29.940 --> 00:59:30.860
Kinnera.Chada@fda.hhs.gov: Thank you.

351

00:59:31.260 --> 00:59:32.370
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

352
00:59:32.690 --> 00:59:34.330
Jessika.Alfaro@fda.hhs.gov: Next question.

353
00:59:35.171 --> 00:59:52.009
Jessika.Alfaro@fda.hhs.gov: is the ability to conduct centennial projects include under the Baa. Could industry also be allowed to submit a centennial focus proposal under the post marketing surveillance focused area areas.

354
00:59:53.480 --> 00:59:58.939
Ian.Weiss@fda.hhs.gov: So I guess the short answer is, maybe if if there's

355
01:00:00.391 --> 01:00:07.440
Ian.Weiss@fda.hhs.gov: if there's a project that that relates to sentinel that the government already has a requirement for then no

356
01:00:08.870 --> 01:00:16.619
Ian.Weiss@fda.hhs.gov: that. That's kind of kind of defeats the the spirit of the the Baa mechanism. If if it's a

357
01:00:17.010 --> 01:00:35.809
Ian.Weiss@fda.hhs.gov: solution to a problem that we don't know that we have, perhaps so the the question is, maybe. And you know, could, are you allowed to submit a sentinel focus proposal. Absolutely. You can submit that. Whether or not it's an acceptable projects really gonna depend on what's in your proposal.

358
01:00:37.600 --> 01:00:52.410
Kinnera.Chada@fda.hhs.gov: I would add that the attendee look into part one charge to research area of interest, to see if that is listed as a priority for FDA in order to submit a proposal as well.

359
01:00:54.460 --> 01:00:55.100
Kinnera.Chada@fda.hhs.gov: because.

360
01:00:55.100 --> 01:00:55.570
Ian.Weiss@fda.hhs.gov: Very much.

361
01:00:55.570 --> 01:00:58.189
Kinnera.Chada@fda.hhs.gov: Experience focus area would be charged too.

362
01:00:59.690 --> 01:01:00.819
Jessika.Alfaro@fda.hhs.gov: Thank you both.

363
01:01:01.710 --> 01:01:03.783
Jessika.Alfaro@fda.hhs.gov: I think this question was asked, but

364
01:01:04.080 --> 01:01:11.347
Ian.Weiss@fda.hhs.gov: I actually actually want to answer that one real quick and and we did say, the ex we definitely did speak about

365
01:01:11.770 --> 01:01:15.229
Ian.Weiss@fda.hhs.gov: expectation of a duration of of the

366
01:01:15.530 --> 01:01:34.729
Ian.Weiss@fda.hhs.gov: the the contracts. But I did want to put in a plug here, and I I do it most most of these BA days and question and answer days. I just want to differentiate that these are not grants. These are contracts, and there's some very definitive differences between a grant and a contract that I'm not gonna get into. But just

367
01:01:35.221 --> 01:01:42.520
Ian.Weiss@fda.hhs.gov: try to keep that in mind that these are the the results of the BA process are are contracts, not grants.

368
01:01:44.620 --> 01:01:45.749
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

369
01:01:47.030 --> 01:01:48.510
Jessika.Alfaro@fda.hhs.gov: Next question

370
01:01:48.710 --> 01:02:02.719
Jessika.Alfaro@fda.hhs.gov: regarding a previous question about supporting letters. If we want to provide supporting letters or reference letters, should we include them as set up as appendix, or in the main writing, subject

371
01:02:02.830 --> 01:02:03.859
Jessika.Alfaro@fda.hhs.gov: to page. Count.

372
01:02:08.790 --> 01:02:11.239
Ian.Weiss@fda.hhs.gov: Say, can you hear? I think we said in the appendix, right.

373
01:02:11.700 --> 01:02:12.440
Kinnera.Chada@fda.hhs.gov: Yes.

374
01:02:12.440 --> 01:02:14.899
Ian.Weiss@fda.hhs.gov: Yeah, yeah. And the appendix is fine.

375
01:02:16.860 --> 01:02:18.029
Ian.Weiss@fda.hhs.gov: Thank you. Ian.

376
01:02:19.053 --> 01:02:26.849
Jessika.Alfaro@fda.hhs.gov: Next question for subcontractor cost. Proposal. Baa. Page 75, says.

377
01:02:27.560 --> 01:02:38.150
Jessika.Alfaro@fda.hhs.gov: if the contractor subcontractor's work entails any unpredictable aspects, example includes experimentation, process, development, etcetera.

378
01:02:38.390 --> 01:02:45.369
Jessika.Alfaro@fda.hhs.gov: a cost proposal conforming to all requirements of this section. Foresee what is

379
01:02:45.770 --> 01:02:50.820
Jessika.Alfaro@fda.hhs.gov: 4 c. Section 4. CI think we think you already answered that.

380
01:02:52.535 --> 01:03:00.050
Ian.Weiss@fda.hhs.gov: Yeah, I was just looking in here on page 76. It's a it. There's a label. So from

381
01:03:01.980 --> 01:03:10.619
Ian.Weiss@fda.hhs.gov: Part 4 on page 75 into part 4. C, let's see your requirements of the section 4, c, 4,

382
01:03:11.230 --> 01:03:20.110
Ian.Weiss@fda.hhs.gov: actually, yeah, that might be a typo, because we have a 4, A and a 4 b, but I don't see a 4 c, so we'll go in and double check that for tomorrow's update.

383
01:03:23.060 --> 01:03:24.089
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

384
01:03:26.430 --> 01:03:36.250
Jessika.Alfaro@fda.hhs.gov: Next question, must all contractors, subcontractors, be definitely identified at a time of Baa submissions?

385
01:03:36.460 --> 01:03:44.969
Jessika.Alfaro@fda.hhs.gov: Is it appropriate to for the offer to put a fraction of the project out to bid at a later date

386
01:03:45.760 --> 01:03:59.609
Jessika.Alfaro@fda.hhs.gov: in the proposal we would provide letter of intent from highly qualified potential subcontractors who would be interested in bidding in this scenario what is the best approach to budget.

387
01:04:02.190 --> 01:04:28.650
Ian.Weiss@fda.hhs.gov: best out best effort on the budget would be the best approach. I mean, I certainly again, you know, looking at this as a contract and not a grant. We. We get letters of intent all the time. You know, in our standard contracts, and and sometimes those things are not definitized until the contract award. So we we understand that but best effort on on the budget, on the budget.

388
01:04:28.880 --> 01:04:31.021
Ian.Weiss@fda.hhs.gov: And yes, it is.

389
01:04:34.500 --> 01:04:38.280
Ian.Weiss@fda.hhs.gov: yeah, it. It is appropriate to to use letters of intent.

390
01:04:39.222 --> 01:04:40.820
Ian.Weiss@fda.hhs.gov: In your proposal.

391
01:04:43.030 --> 01:04:44.190
Jessika.Alfaro@fda.hhs.gov: Thank you. Ian.

392
01:04:45.072 --> 01:04:52.950
Jessika.Alfaro@fda.hhs.gov: Next question on page 90, under subcontracting plans, the Baa. Says that you need.

393
01:04:53.340 --> 01:05:08.170
Jessika.Alfaro@fda.hhs.gov: I'm sorry that you need to successfully submit your subcon subcontracting plan by the proposal due date to the link provided. But when the link was requested, we were told that the link would be provided in

394
01:05:08.360 --> 01:05:18.100
Jessika.Alfaro@fda.hhs.gov: selected for negotiation. Can you please clarify when and how the small business subcontracting plan should be provided.

395
01:05:19.140 --> 01:05:23.689
Ian.Weiss@fda.hhs.gov: Okay, let's go to page 90 here, real quick sub contract plans.

396
01:05:28.681 --> 01:05:48.990
Ian.Weiss@fda.hhs.gov: So yeah, it does say, successful contract proposal. So that means, when when your proposal selected for for contract award, you'll be sent a link at that time to the Sbcx system, which is Hhs small business customer experience system.

397
01:05:49.260 --> 01:05:52.180
Ian.Weiss@fda.hhs.gov: And that's that's when you would fill that out.

398
01:05:54.960 --> 01:05:56.069
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

399
01:05:56.070 --> 01:05:56.680
Ian.Weiss@fda.hhs.gov: Hmm.

400
01:05:56.680 --> 01:06:02.359
Jessika.Alfaro@fda.hhs.gov: Next question, what is the average page length of accepted proposals?

401
01:06:03.913 --> 01:06:18.800
Ian.Weiss@fda.hhs.gov: Just all I can say is, just stick to the the maximum number don't don't exceed the maximum number of pages. I don't. We don't really have A shorter proposal is not gonna go. Going to assist you in getting selected is what I would say.

402
01:06:20.880 --> 01:06:21.930
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

403
01:06:22.700 --> 01:06:33.639
Jessika.Alfaro@fda.hhs.gov: as a follow up. If the work is pre predictable, is the information on the subcontract letterhead. The only documentation needed.

404

01:06:37.970 --> 01:06:39.160
Ian.Weiss@fda.hhs.gov: I guess I'm not.

405
01:06:39.430 --> 01:06:44.460
Ian.Weiss@fda.hhs.gov: I'm not sure what what's being asked here. If the work is.

406
01:06:44.790 --> 01:06:50.583
Ian.Weiss@fda.hhs.gov: I mean, it's it's research, right? So I'm not sure how predictable it is. But,

407
01:06:51.620 --> 01:07:02.370
Ian.Weiss@fda.hhs.gov: if we're talking about just identifying the the subcontractor. Yeah, that should be sufficient outside of that answer. I'm not sure what else is is being asked here.

408
01:07:04.320 --> 01:07:05.219
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

409
01:07:05.470 --> 01:07:12.430
Jessika.Alfaro@fda.hhs.gov: Next question, what is the difference between base and option in the funding form.

410
01:07:15.250 --> 01:07:20.550
Ian.Weiss@fda.hhs.gov: So if we're talking about, let's see here, see if if we're talking about the

411
01:07:21.700 --> 01:07:26.002
Ian.Weiss@fda.hhs.gov: cost proposal, template the appendix. 7, let me just pull that up real quick.

412
01:07:29.170 --> 01:07:30.699
Ian.Weiss@fda.hhs.gov: So you've got base.

413
01:07:30.870 --> 01:07:40.930
Ian.Weiss@fda.hhs.gov: you? There's really, if if you're talking about that form, it's laid out pretty pretty pretty well in the tabs. You've got a base tab option, one through option. 4.

414
01:07:42.561 --> 01:07:45.378
Ian.Weiss@fda.hhs.gov: Pardon me, option 5. Because you you can have that

415
01:07:46.080 --> 01:07:54.560

Ian.Weiss@fda.hhs.gov: dash 8, 6 month extension there. But yeah, it's it's laid out by tabs in the in the appendix 7.

416
01:07:56.500 --> 01:08:06.470
Ian.Weiss@fda.hhs.gov: And that really to just talk about option periods. So like like we said earlier option. Option. P. Base and option periods are generally a year.

417
01:08:10.810 --> 01:08:11.850
Jessika.Alfaro@fda.hhs.gov: Thank you. Ian.

418
01:08:13.041 --> 01:08:16.620
Jessika.Alfaro@fda.hhs.gov: Next question, is it more advantage advantages

419
01:08:16.750 --> 01:08:25.750
Jessika.Alfaro@fda.hhs.gov: to apply to cross cutting or specific calls as our primary focus? If our proposal could address either.

420
01:08:28.250 --> 01:08:30.359
Kinnera.Chada@fda.hhs.gov: I think you are able to

421
01:08:30.620 --> 01:08:38.259
Kinnera.Chada@fda.hhs.gov: choose or have multiple sec selections if it is cross cutting, and also if it is a specific call.

422
01:08:39.630 --> 01:08:56.289
Kinnera.Chada@fda.hhs.gov: As long as you determine the primary research area focus, you could add multiple areas of FDA regulated products. You could use crosscutting if it falls under drugs. You could choose drugs, biologics, biosimilars.

423
01:08:56.290 --> 01:09:11.270
Kinnera.Chada@fda.hhs.gov: There is no restriction on choice of which area it is. The restriction is only on choice of your primary research area and any additional areas of focus. You could always list it under secondary research areas.

424
01:09:12.729 --> 01:09:13.600
Kinnera.Chada@fda.hhs.gov: Thank you.

425
01:09:13.800 --> 01:09:14.830
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara.

426
01:09:15.390 --> 01:09:25.320
Jessika.Alfaro@fda.hhs.gov: Next question, can you please advise what is meant? On page 109 of the BA. Announcement relative to section 5,

427
01:09:25.510 --> 01:09:27.629
Jessika.Alfaro@fda.hhs.gov: contractual agreements.

428
01:09:28.210 --> 01:09:34.599
Ian.Weiss@fda.hhs.gov: Pretty sure, we answered that already. Let me just take a look real quick. Was it? 100? Page 109.

429
01:09:34.930 --> 01:09:38.689
Jessika.Alfaro@fda.hhs.gov: 100 and 9 on section 5.

430
01:10:00.160 --> 01:10:09.799
Ian.Weiss@fda.hhs.gov: I think that's just any, any contracts that you have that. Yeah, it's speaking about subcontractor agreements, letters of intent, things of that

431
01:10:10.550 --> 01:10:16.030
Ian.Weiss@fda.hhs.gov: things of that nature. And then, if there's contracts for you know, software or any any of those kinds of things.

432
01:10:18.610 --> 01:10:19.580
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

433
01:10:20.340 --> 01:10:25.979
Jessika.Alfaro@fda.hhs.gov: Next question, is it beneficial to have around Robin partners.

434
01:10:28.630 --> 01:10:34.730
Ian.Weiss@fda.hhs.gov: I'm not sure what's being asked. There. I'll I'll take a guess and

435
01:10:34.940 --> 01:10:53.435
Ian.Weiss@fda.hhs.gov: having partners that do different different pieces of the work. I I think that you know that's a business decision. If you can break up the work and make it more efficient, or have better outcomes by having different partners do different different aspects of your proposal, then I'd say it is. It is beneficial.

436
01:10:53.890 --> 01:11:07.379

Ian.Weiss@fda.hhs.gov: is it? Is it beneficial? From a select, you know, being selected for a contract. I I don't believe that it is one way or the other. It's it's it's not detrimental either. So it's really more of a business decision on on your end.

437
01:11:10.170 --> 01:11:24.889
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question, is there a preference between a shorter award with a higher per year? Contract value versus a longer award with a lower per year. Contract value.

438
01:11:27.200 --> 01:11:47.959
Ian.Weiss@fda.hhs.gov: I would say traditionally so officially. Is there a preference? No but I think what is more palatable is a is a lower annual. A lower annual number, and perhaps a a longer period of performance is is probably more palatable from a selection standpoint.

439
01:11:49.800 --> 01:12:00.706
Ian.Weiss@fda.hhs.gov: And just looking at. You know our our previous years selection selection for for contracts we do tend to take, you know, kind of lower dollar value

440
01:12:01.990 --> 01:12:08.228
Ian.Weiss@fda.hhs.gov: lower dollar value contracts tend to be what's awarded. So yeah, I would say, I would say the the

441
01:12:09.200 --> 01:12:15.140
Ian.Weiss@fda.hhs.gov: lower lower war lower value per year, and maybe more years would be would be preferable.

442
01:12:16.780 --> 01:12:17.919
Ian.Weiss@fda.hhs.gov: It's a good question.

443
01:12:19.070 --> 01:12:20.069
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

444
01:12:21.630 --> 01:12:33.550
Jessika.Alfaro@fda.hhs.gov: Next question, is it desired within the scope of the project, to also have a dissimation exploitation, strategy, including a publication plan.

445
01:12:33.690 --> 01:12:38.200
Jessika.Alfaro@fda.hhs.gov: Additionally, can this be included in the cost.

446

01:12:47.010 --> 01:13:01.880
Kinnera.Chada@fda.hhs.gov: I think it wouldn't hurt to add that. But it is not a requirement I have seen in the past. Ba. Proposals or submissions that publication cost was included in as part of the cost. Proposal.

447
01:13:03.360 --> 01:13:05.130
Kinnera.Chada@fda.hhs.gov: Am I correct? Again.

448
01:13:05.310 --> 01:13:06.349
Ian.Weiss@fda.hhs.gov: Yes, that's correct.

449
01:13:08.150 --> 01:13:08.890
Kinnera.Chada@fda.hhs.gov: Thank you.

450
01:13:09.990 --> 01:13:11.859
Jessika.Alfaro@fda.hhs.gov: Thank you, Canara. Thank you, Ian.

451
01:13:12.080 --> 01:13:13.940
Jessika.Alfaro@fda.hhs.gov: Next question

452
01:13:14.110 --> 01:13:25.940
Jessika.Alfaro@fda.hhs.gov: for proposals accepted in 2024 Baa. But rejected due to lack of available funding. Are there any negative considerations for modifying and resubmitting.

453
01:13:30.359 --> 01:13:34.550
Ian.Weiss@fda.hhs.gov: No, there's no negative negative connotations that at all.

454
01:13:37.540 --> 01:13:38.400
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

455
01:13:39.490 --> 01:13:51.449
Jessika.Alfaro@fda.hhs.gov: Next question is the cost proposal template optional, as stated in the chart on page 78, under the section for the cost proposal appendices.

456
01:13:51.810 --> 01:13:56.390
Jessika.Alfaro@fda.hhs.gov: The Cost proposal instructions suggests otherwise.

457
01:13:56.850 --> 01:14:08.189

Ian.Weiss@fda.hhs.gov: So it's it's optional from the standpoint of. Do you? Do you have to use our template for your for your cost proposal? No, you do not. We just provide that as as a an easy tool to use

458
01:14:08.360 --> 01:14:17.392
Ian.Weiss@fda.hhs.gov: out. If you're providing. If if you're putting in for a cost type contract it is. It is required that you provide us a cost model.

459
01:14:17.910 --> 01:14:24.520
Ian.Weiss@fda.hhs.gov: we're just stating that you don't need to use our format to do that if you don't, if you don't like, we're just, we're just providing you a tool.

460
01:14:26.550 --> 01:14:27.520
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

461
01:14:29.010 --> 01:14:45.809
Jessika.Alfaro@fda.hhs.gov: Next question, can you please clarify? What is the difference in what is being asked for? On page 107, section 13, intellectual property, and on page 109, appendix, 4, intellectual property.

462
01:14:47.590 --> 01:14:49.330
Ian.Weiss@fda.hhs.gov: Let's see here.

463
01:14:53.950 --> 01:15:21.939
Ian.Weiss@fda.hhs.gov: So I mean, yeah. Looking at page 107 13, it says, for issued Pat. So intellectual property for issued patents or published patent applications that will be used in the performance of the contract, provide the patent number or patent application number, and a summary of the patent or invention title, and indicate whether the offer is the patent or invention owner. I think that's pretty straightforward. And then it was page 109. Let's go down there.

464
01:15:22.630 --> 01:15:23.740
Jessika.Alfaro@fda.hhs.gov: Appendix. 4.

465
01:15:26.620 --> 01:15:33.970
Kinnera.Chada@fda.hhs.gov: Maybe we are talking about the attachment for which is for the technical proposal. Again.

466
01:15:35.220 --> 01:15:36.930
Ian.Weiss@fda.hhs.gov: Yeah, there is a there is a

467
01:15:37.910 --> 01:15:48.570
Ian.Weiss@fda.hhs.gov: there is a number 4 on here. We may. We may need to research this one a little bit and come back to it. But what I would say is 100 page 107 is pretty

468
01:15:49.830 --> 01:16:02.473
Ian.Weiss@fda.hhs.gov: pretty straightforward. They're on page 109. There is it? Intellectual property is listed as required, and then it gives a a couple of far references.

469
01:16:03.110 --> 01:16:08.210
Ian.Weiss@fda.hhs.gov: yeah, I I'd like to research that a little bit then, and then answer that kind of at a later date.

470
01:16:10.480 --> 01:16:11.460
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

471
01:16:15.790 --> 01:16:25.189
Jessika.Alfaro@fda.hhs.gov: Next question, does the past performance information on contracts go under the Bio Biographical sketches? Section.

472
01:16:29.780 --> 01:16:30.460
Ian.Weiss@fda.hhs.gov: Let's see.

473
01:16:36.380 --> 01:16:40.169
Ian.Weiss@fda.hhs.gov: I don't believe so. I think that's its own, its own submission.

474
01:16:41.340 --> 01:16:42.900
Ian.Weiss@fda.hhs.gov: It's on file. Pardon me.

475
01:16:45.260 --> 01:16:46.219
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

476
01:16:47.150 --> 01:17:06.159
Jessika.Alfaro@fda.hhs.gov: Next question. We developed a device previously and licensed it to a company, and we want to propose something related to it. For this. Baa, we do not collect any financial benefit from the device, but we are listed as inventors on the patent.

477
01:17:06.360 --> 01:17:09.990
Jessika.Alfaro@fda.hhs.gov: Is this considered a conflict of interest.

478
01:17:11.590 --> 01:17:21.219
Ian.Weiss@fda.hhs.gov: No. In effect, we we've actually awarded some contracts using that scenario you'd wanna make sure that your device is listed as intellectual property

479
01:17:21.920 --> 01:17:26.992
Ian.Weiss@fda.hhs.gov: in your proposal. But no, it's not a. It's not a conflict of interest necessarily.

480
01:17:30.590 --> 01:17:31.650
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

481
01:17:32.110 --> 01:17:37.809
Jessika.Alfaro@fda.hhs.gov: Next question, is the FDA open to applications from overseas?

482
01:17:38.660 --> 01:17:42.374
Ian.Weiss@fda.hhs.gov: So that's a a common common question. That answer is, yes,

483
01:17:44.000 --> 01:17:46.550
Ian.Weiss@fda.hhs.gov: What I would say is,

484
01:17:47.770 --> 01:18:07.915
Ian.Weiss@fda.hhs.gov: and I'll put in a I'll put in a plug to everybody, and and I know I did this at BA day if you were at BA day but make sure that when you submit it. It's not required upon submitting your proposal, but it is required for contract award to be registered in. sam.gov make sure that that

485
01:18:08.570 --> 01:18:37.549
Ian.Weiss@fda.hhs.gov: that's the only thing that that holds you up from contract award at, I should say one of the one of the more common things that holds you up from contract award is not being properly registered in. sam.gov, that does take a little while, even if you're a domestic partner, if you're overseas, there's a whole another. You have to go through the Us. State Department to get registered in. sam.gov, and it it's kind of a lengthy process. So if you're not already registered in sam.gov.

486
01:18:37.780 --> 01:18:42.030
Ian.Weiss@fda.hhs.gov: and you're an overseas entity. You might want to get started on that now.

487

01:18:43.560 --> 01:18:50.140
Ian.Weiss@fda.hhs.gov: But the the short answer is, No, pardon me, yes, you can. You can absolutely apply if you're an overseas entity.

488
01:18:50.300 --> 01:18:52.139
Ian.Weiss@fda.hhs.gov: Just make sure you're in sam.gov.

489
01:18:55.360 --> 01:18:57.670
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question.

490
01:18:58.100 --> 01:19:10.800
Jessika.Alfaro@fda.hhs.gov: can you please clarify on the Paperwork Reduction act? Refer to A to it on page 110, and why this would be applicable or not applicable for a proposal.

491
01:19:13.750 --> 01:19:32.790
Ian.Weiss@fda.hhs.gov: I am not a a paperwork reduction act subject matter expert. But I can tell you, if you're conducting a study within the public and it. I'm not sure where this number comes from, but 9 or more people are involved. The Paperwork Reduction Act would apply to your proposal.

492
01:19:33.220 --> 01:19:34.340
Ian.Weiss@fda.hhs.gov: So

493
01:19:34.928 --> 01:20:02.659
Ian.Weiss@fda.hhs.gov: if if you determine, in looking at your proposal just another another plug here that the paperwork reduction act applies to you. I would count on a full year of time to get that Paperwork reduction act application approved. It's a it's a substantial process. We've had a number of people try to apply for waivers to that process, and during my time and my tenure here at the FDA, I have not seen a waiver granted yet, so

494
01:20:03.058 --> 01:20:10.880
Ian.Weiss@fda.hhs.gov: we. We don't own that process. Another agency owns that process. But yeah, it's it's that.

495
01:20:11.310 --> 01:20:21.130
Ian.Weiss@fda.hhs.gov: Any kind of study that involves the public. And collecting certain types of information. And it's 9 or more people. It's kind of an arbitrary number. But that's what the number is.

496
01:20:23.660 --> 01:20:24.320
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

497
01:20:27.070 --> 01:20:37.080
Jessika.Alfaro@fda.hhs.gov: Next question for cost. Proposal cost appendix 7. Can we use annual salary for base slash hours.

498
01:20:37.250 --> 01:20:44.290
Jessika.Alfaro@fda.hhs.gov: which is tab based column D for employees that are salaried not hourly rate.

499
01:20:46.030 --> 01:20:47.119
Ian.Weiss@fda.hhs.gov: Let me just take a look.

500
01:20:48.960 --> 01:20:50.450
Ian.Weiss@fda.hhs.gov: Oh.

501
01:20:56.470 --> 01:21:01.309
Ian.Weiss@fda.hhs.gov: yeah, you can absolutely use. Yeah, you can use salary right in there.

502
01:21:01.430 --> 01:21:02.720
Ian.Weiss@fda.hhs.gov: Annual salary.

503
01:21:05.050 --> 01:21:06.060
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

504
01:21:07.910 --> 01:21:09.330
Jessika.Alfaro@fda.hhs.gov: Next question.

505
01:21:09.770 --> 01:21:24.469
Jessika.Alfaro@fda.hhs.gov: can you please clarify on page 108 about the security appendix, and why this would be applicable or not applicable, and if applicable, what information and lever level of detail are you looking for.

506
01:21:32.750 --> 01:21:36.509
Ian.Weiss@fda.hhs.gov: I'd have to. I'd have to research that one. I don't. I don't know that

507
01:21:36.740 --> 01:21:39.023
Ian.Weiss@fda.hhs.gov: off the top of my head. And

508
01:21:39.800 --> 01:21:42.120

Ian.Weiss@fda.hhs.gov: yeah, we'll have to. We'll have to come back to that one.

509
01:21:44.700 --> 01:21:47.000
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question.

510
01:21:48.640 --> 01:21:54.769
Jessika.Alfaro@fda.hhs.gov: It appears that there are only one or 2 proposals funded by Cber in the last 2 years.

511
01:21:54.960 --> 01:22:02.399
Jessika.Alfaro@fda.hhs.gov: Is it due to the budget limitations? How about the budget condition for receiver in 2025.

512
01:22:04.850 --> 01:22:08.650
Ian.Weiss@fda.hhs.gov: So I I can't speak to Cber specifically.

513
01:22:09.086 --> 01:22:22.683
Ian.Weiss@fda.hhs.gov: But I do know the budget. The budget has been tight all around the last 2 years. And just looking at the climate going into this calendar year, I would say that the the budget's gonna be tight again. So

514
01:22:23.130 --> 01:22:30.420
Ian.Weiss@fda.hhs.gov: yeah, that's it's about all all we can say on that budget, I think, will continue to be a challenge this this calendar year.

515
01:22:32.150 --> 01:22:33.207
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

516
01:22:33.720 --> 01:22:38.380
Jessika.Alfaro@fda.hhs.gov: Who should the submission be directed to? Is it you, Mr. Weiss?

517
01:22:40.885 --> 01:22:44.354
Ian.Weiss@fda.hhs.gov: No, just direct. Yeah. It could be directed to me

518
01:22:45.570 --> 01:22:48.800
Ian.Weiss@fda.hhs.gov: as a contracting officer for certain.

519
01:22:51.570 --> 01:23:00.859

Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Next question. If the awardee changed institution, what would happen to the rest of the contract? Slash budget.

520
01:23:02.110 --> 01:23:09.920
Ian.Weiss@fda.hhs.gov: So if I understand the question correctly. So if the awardee is

521
01:23:10.810 --> 01:23:16.520
Ian.Weiss@fda.hhs.gov: I I think we're I. I think the question is asking if if a an individual

522
01:23:17.020 --> 01:23:22.310
Ian.Weiss@fda.hhs.gov: was awarded, the contract. If the individual was awarded, the contract, the contract would would

523
01:23:22.835 --> 01:23:33.264
Ian.Weiss@fda.hhs.gov: transfer with them, because the the contracts were tied to the individual, not the entity, if it's tied to the entity if it sites, you know. In this case

524
01:23:33.850 --> 01:23:36.280
Ian.Weiss@fda.hhs.gov: we had a principal investigator.

525
01:23:37.530 --> 01:23:47.979
Ian.Weiss@fda.hhs.gov: Who? Who left the institution, and the contract was tied to the institution, that the the institution is still on the hook to complete that contract.

526
01:23:48.610 --> 01:23:51.199
Ian.Weiss@fda.hhs.gov: So it kind of depends on the scenario there.

527
01:23:52.092 --> 01:24:07.379
Ian.Weiss@fda.hhs.gov: So the con the contract would stay. We'll just say you know the university of my house right. If if I were to leave the the that university still has that still has that contract, and would still be on the hook to to complete those contract objectives.

528
01:24:09.340 --> 01:24:10.259
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

529
01:24:11.570 --> 01:24:21.620
Jessika.Alfaro@fda.hhs.gov: Next question. On page 103 of the Baa. The proposal checklist there are, repeat repeats within the checklist

530
01:24:21.740 --> 01:24:32.529
Jessika.Alfaro@fda.hhs.gov: security plan and IP are included in one through 15, and also listed in the Appendix. Was this a typo.

531
01:24:32.650 --> 01:24:34.260
Kinnera.Chada@fda.hhs.gov: I can take this in.

532
01:24:35.110 --> 01:25:01.450
Kinnera.Chada@fda.hhs.gov: No, this is not a typo. This is because security planning and IP are part of your 50 page limit for the technical proposal volume one you would be able to provide preliminary information in these sections so that it does not take up too much of space in your page limit, and any additional information can be listed as part of the appendix.

533
01:25:03.610 --> 01:25:04.170
Kinnera.Chada@fda.hhs.gov: Thank you.

534
01:25:04.170 --> 01:25:17.969
Jessika.Alfaro@fda.hhs.gov: Thank you, Kinra. And next question, are universities viable as sub award partners? Or is there a preference on keeping award money on the industry side?

535
01:25:18.970 --> 01:25:40.560
Ian.Weiss@fda.hhs.gov: No, for the the BA mechanism there's there's no preference as to whether or not dollars for going to industry, or if it's going to educational institutions. Just the the only plug there would be, you know, making sure that the awardee the prime awardee is conducting 51% of that work is really the only the only qualifier there.

536
01:25:42.180 --> 01:25:43.109
Jessika.Alfaro@fda.hhs.gov: Thank you, Ann.

537
01:25:44.720 --> 01:25:46.110
Jessika.Alfaro@fda.hhs.gov: Next question

538
01:25:46.460 --> 01:25:55.809
Jessika.Alfaro@fda.hhs.gov: for the cost proposal, Baa. Page 73, says, to provide a narrative support for each cost element.

539
01:25:56.100 --> 01:26:05.210
Jessika.Alfaro@fda.hhs.gov: Is there a template for the narrative support, and is, and is the cost, summary reference on the same page.

540
01:26:05.660 --> 01:26:09.890
Jessika.Alfaro@fda.hhs.gov: Second, full sentence, the same as a narrative support.

541
01:26:11.430 --> 01:26:13.449
Ian.Weiss@fda.hhs.gov: Yeah, let me find that in the

542
01:26:22.580 --> 01:26:28.070
Ian.Weiss@fda.hhs.gov: alright, is there a template for the narrative support? No, there's there's not a template. We get.

543
01:26:28.799 --> 01:26:34.199
Ian.Weiss@fda.hhs.gov: Generally it's just a a straight word or Pdf document that's provided that kind of

544
01:26:34.820 --> 01:26:43.169
Ian.Weiss@fda.hhs.gov: just gives that in narrative format as far as cost summary reference on the same page. Second, full sentence

545
01:26:45.610 --> 01:26:46.760
Ian.Weiss@fda.hhs.gov: cost summary

546
01:26:52.971 --> 01:26:55.849
Ian.Weiss@fda.hhs.gov: no. The narrative and the cost summary are 2 different things.

547
01:26:59.070 --> 01:27:00.139
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

548
01:27:03.344 --> 01:27:12.040
Jessika.Alfaro@fda.hhs.gov: Next question I have. I have a follow up question on the past. Performance. Is the past performance an appendix.

549
01:27:15.293 --> 01:27:18.209
Ian.Weiss@fda.hhs.gov: Can you correct me if I'm wrong? I believe it was right.

550
01:27:26.870 --> 01:27:29.270
Ian.Weiss@fda.hhs.gov: Yeah, but I believe it is an appendix.

551
01:27:33.300 --> 01:27:34.310

Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

552
01:27:34.720 --> 01:27:40.259
Jessika.Alfaro@fda.hhs.gov: Next question, is there a preference regarding the project? Start?

553
01:27:41.050 --> 01:27:43.210
Jessika.Alfaro@fda.hhs.gov: I think that will go very fast.

554
01:27:43.490 --> 01:27:44.830
Ian.Weiss@fda.hhs.gov: Yeah. That was already asked.

555
01:27:47.898 --> 01:27:54.899
Jessika.Alfaro@fda.hhs.gov: Next question as a follow up to the subcontracting plan submission question earlier.

556
01:27:55.300 --> 01:28:02.259
Jessika.Alfaro@fda.hhs.gov: although page 90 indicates success, successful contract proposals

557
01:28:02.370 --> 01:28:10.709
Jessika.Alfaro@fda.hhs.gov: should request the form, the form through the Sbcx system at the beginning of the paragraph

558
01:28:10.860 --> 01:28:16.299
Jessika.Alfaro@fda.hhs.gov: the next page notes that if it is not confirmed

559
01:28:16.910 --> 01:28:27.169
Jessika.Alfaro@fda.hhs.gov: as it's not confirmed as received within Sbcx system by the proposal submission date. It will be considered late

560
01:28:27.390 --> 01:28:35.570
Jessika.Alfaro@fda.hhs.gov: for clarity should the Svp. Be submitted at the same time as the stage one proposal due date.

561
01:28:35.760 --> 01:28:39.359
Jessika.Alfaro@fda.hhs.gov: or is it expected at a later time.

562
01:28:42.810 --> 01:28:58.887
Ian.Weiss@fda.hhs.gov: Yeah, I'm just looking to see the languages definitely. It's confusing folks. The answer is, and and we did already

answer this. But we'll we'll we'll plug it again, because clearly, there's something in here that's that's confusing folks.

563
01:29:01.290 --> 01:29:10.571
Ian.Weiss@fda.hhs.gov: it's if you were selected for a contract you'll be given, and and and the small business subcontracting plan

564
01:29:11.350 --> 01:29:18.090
Ian.Weiss@fda.hhs.gov: applies to your submission. Then you will be sent a link to the Sbcx system.

565
01:29:19.000 --> 01:29:23.410
Ian.Weiss@fda.hhs.gov: Alright, officer. I just wanna read this real quick to make sure.

566
01:29:37.560 --> 01:29:38.610
Ian.Weiss@fda.hhs.gov: Oh, I see.

567
01:29:39.650 --> 01:29:51.404
Ian.Weiss@fda.hhs.gov: Offer shall then follow instructions outlined in Spcx Industry Guide listed to successfully submit their subcontracting plan by the proposal. Submission deadline that that is, that is a typo.

568
01:29:53.090 --> 01:29:56.348
Ian.Weiss@fda.hhs.gov: what? What? That's what. How that should read is

569
01:29:57.090 --> 01:30:14.789
Ian.Weiss@fda.hhs.gov: through the subcontracting plan. Submission deadline. You'll be given a deadline when you're sent the link, you'll be given a deadline as to when that can be filled out. And and that, I believe, is what this is referring to. So that is a typo on page 90. I understand why that's confusing folks and

570
01:30:15.480 --> 01:30:24.499
Ian.Weiss@fda.hhs.gov: can you? If you can make a note we'll we'll need to. I'll I'll pull up the language from Sbcx. But we we should change that for tomorrow's update.

571
01:30:30.740 --> 01:30:31.690
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

572
01:30:33.440 --> 01:30:42.110

Jessika.Alfaro@fda.hhs.gov: Next question, how would budget be potentially affected by new Presidency? Will the funding be potentially withdrawn?

573
01:30:44.065 --> 01:30:52.584
Ian.Weiss@fda.hhs.gov: Really can't answer that. If I if I could, I'd be much higher up in the in the budget planning process than than I am.

574
01:30:53.917 --> 01:31:10.432
Ian.Weiss@fda.hhs.gov: you're unfortunately not not to be flippant, but anyone's guess is as good as mine really. Like, I said earlier I would expect that budget will be tight this year. You know. Will the funding potentially be withdrawn? We we don't know.

575
01:31:11.291 --> 01:31:18.668
Ian.Weiss@fda.hhs.gov: We're we're continuing on as though there will be funding. There's there's a reason we don't publish those those numbers.

576
01:31:19.460 --> 01:31:21.419
Ian.Weiss@fda.hhs.gov: we we simply don't know.

577
01:31:22.150 --> 01:31:33.609
Ian.Weiss@fda.hhs.gov: So I I wish I had a better answer for you. Believe me, we we all do the when we have a when we have a firm budget. It's easier for us to to do our to perform our duties as well, so we wish we could answer you.

578
01:31:37.740 --> 01:31:39.940
Jessika.Alfaro@fda.hhs.gov: Not the award announcement.

579
01:31:39.940 --> 01:31:50.729
Kinnera.Chada@fda.hhs.gov: Let me clarify that. Jessica. There has been a question yin asking if we do publish the awards

580
01:31:50.960 --> 01:31:53.250
Kinnera.Chada@fda.hhs.gov: for Baa, and then just fine

581
01:31:53.250 --> 01:32:15.200
Kinnera.Chada@fda.hhs.gov: that. Yes, we do it on sam.gov. Because that was answered previously. But the attendee is clarifying saying that it's not the award announcement. But the project outcome specifically, I'm not aware if once the contracts are posted. Are the project outcomes posted on the contract, or is it just the

582

01:32:15.840 --> 01:32:22.139
Kinnera.Chada@fda.hhs.gov: initial primary objectives do we follow up on BA awards, or contracts.

583
01:32:22.140 --> 01:32:27.663
Ian.Weiss@fda.hhs.gov: No as I I think that some of them are published. But that's

584
01:32:28.590 --> 01:32:50.179
Ian.Weiss@fda.hhs.gov: not a contractual mechanism that's within the the different project offices that are program offices here at the FDA and and the interactions with the individual vendors. As to how how that gets published. I know, just from being in on the meetings that sometimes the FDA publishes it, sometimes the the vendor.

585
01:32:50.180 --> 01:33:02.550
Ian.Weiss@fda.hhs.gov: We'll we'll publish it, say, in an educational Institute Institutional publication. And sometimes it's not published at all. Or the data is, the data is used

586
01:33:03.128 --> 01:33:13.639
Ian.Weiss@fda.hhs.gov: for some other within some other mechanism. So it kind of it. It depends. But it's not. There's no single place where we put out where where those things are publicized.

587
01:33:15.700 --> 01:33:16.430
Kinnera.Chada@fda.hhs.gov: Thank you.

588
01:33:16.760 --> 01:33:17.890
Ian.Weiss@fda.hhs.gov: You're welcome. Thank you.

589
01:33:19.920 --> 01:33:21.489
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Can you hear him?

590
01:33:21.620 --> 01:33:27.260
Jessika.Alfaro@fda.hhs.gov: Next question, is there a template for security? Appendix document?

591
01:33:28.830 --> 01:33:36.070
Ian.Weiss@fda.hhs.gov: I thought there was. Let me take a look here. Real quick proposal template

592
01:33:56.054 --> 01:34:02.669

Ian.Weiss@fda.hhs.gov: I don't have any here, but we'll we'll take another look at that to see I I don't i i don't believe that we do.

593
01:34:06.380 --> 01:34:14.689
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian. Thank you, Kenira. So this is the questions we received. So far there's no more questions.

594
01:34:18.310 --> 01:34:26.770
Jessika.Alfaro@fda.hhs.gov: This is another question, for the cost proposal is the narrative support included in the 20 page limit.

595
01:34:27.900 --> 01:34:30.169
Ian.Weiss@fda.hhs.gov: Yes, yeah, I believe so.

596
01:34:35.070 --> 01:34:35.980
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

597
01:34:52.520 --> 01:34:59.400
Kinnera.Chada@fda.hhs.gov: I know we are over time, but if you have any other questions, please feel free to put those in the QA. Part.

598
01:35:06.540 --> 01:35:08.726
Ian.Weiss@fda.hhs.gov: Yeah, any any way, that we can help

599
01:35:09.140 --> 01:35:13.039
Ian.Weiss@fda.hhs.gov: facilitate quality proposals, you know, and that now's the time for sure.

600
01:35:13.330 --> 01:35:15.600
Ian.Weiss@fda.hhs.gov: Happy, happy to answer any questions you have.

601
01:35:23.710 --> 01:35:27.989
Kinnera.Chada@fda.hhs.gov: I don't see any questions in, and I think we can go ahead and end the call.

602
01:35:29.688 --> 01:35:35.060
Kinnera.Chada@fda.hhs.gov: Thank you. Once again we look forward to working with you this year. Good luck with your applications.

603
01:35:36.249 --> 01:35:39.240
Jessika.Alfaro@fda.hhs.gov: There's a couple one that just came up right now.

604
01:35:42.789 --> 01:35:48.300
Jessika.Alfaro@fda.hhs.gov: Can we email to ask questions leading up to the submission deadline.

605
01:35:51.150 --> 01:35:54.040
Kinnera.Chada@fda.hhs.gov: I would say, yes, correct, Ian, do you agree.

606
01:35:54.190 --> 01:35:55.030
Ian.Weiss@fda.hhs.gov: That's correct.

607
01:35:58.060 --> 01:36:02.750
Jessika.Alfaro@fda.hhs.gov: Thank thank you. Ian Guinera. Next question, what is the suggested

608
01:36:02.860 --> 01:36:19.659
Jessika.Alfaro@fda.hhs.gov: timeline for submission of initial of an initial concept paper for Fy. 26 funding. It appears that for Fy. 2626. Consideration, the final deadline for submission of stage one material

609
01:36:19.820 --> 01:36:26.099
Jessika.Alfaro@fda.hhs.gov: concept, paper and full proposal is September 2025.

610
01:36:26.270 --> 01:36:31.380
Jessika.Alfaro@fda.hhs.gov: But submitting a concept paper and getting feedback is the 1st step

611
01:36:31.690 --> 01:36:38.840
Jessika.Alfaro@fda.hhs.gov: given that this is a rolling submission. Some further suggestion on the timing would be most welcome.

612
01:36:40.280 --> 01:36:49.015
Kinnera.Chada@fda.hhs.gov: So I would like to clarify this information for the attendee, saying that

613
01:36:49.840 --> 01:37:01.980
Kinnera.Chada@fda.hhs.gov: receiving feedback for the concept paper is only a feature that is available for optional early concept papers that were due in November last year

614
01:37:02.310 --> 01:37:18.709
Kinnera.Chada@fda.hhs.gov: after the due date. Any submission would need to include concept, paper checklist, and also the full proposal that

comprises of technical proposal. Volume one, and the cost proposal, which is volume 2

615
01:37:19.150 --> 01:37:37.069
Kinnera.Chada@fda.hhs.gov: after February 24th or after November 8, th I think, which was the due date for optional early concept papers. Any submissions would be deemed incomplete if it does not. If a concept paper does not accompany a full proposal and checklist.

616
01:37:38.010 --> 01:37:41.720
Kinnera.Chada@fda.hhs.gov: So even after February 24, th

617
01:37:42.460 --> 01:37:52.730
Kinnera.Chada@fda.hhs.gov: you would see on the slides, and as part of the announcement that a complete application would include all these 3 required documents.

618
01:37:53.360 --> 01:38:01.820
Kinnera.Chada@fda.hhs.gov: checklist concept, paper, and a full proposal. Full proposal includes technical proposal as well as the cost proposal.

619
01:38:02.150 --> 01:38:13.279
Kinnera.Chada@fda.hhs.gov: The only difference with the the timeline and rolling submission is that if you submit stage one package on or before February 24, th

620
01:38:13.430 --> 01:38:19.400
Kinnera.Chada@fda.hhs.gov: your proposal or your submission will be considered for fiscal year 25 funds.

621
01:38:19.590 --> 01:38:22.359
Kinnera.Chada@fda.hhs.gov: If you make a submission from

622
01:38:22.510 --> 01:38:33.639
Kinnera.Chada@fda.hhs.gov: February 25th up to September 20, th you your proposal or your submission would be considered for Fy. 26 funding.

623
01:38:34.580 --> 01:38:49.620
Kinnera.Chada@fda.hhs.gov: That is the only difference. But the requirements still. Stay the same, and you will not be receiving feedback on concept paper for any submissions which have passed the November 8th 2024 deadline.

624
01:38:52.350 --> 01:38:53.289

Kinnera.Chada@fda.hhs.gov: Thank you.

625
01:38:53.820 --> 01:39:02.379
Jessika.Alfaro@fda.hhs.gov: Thank you. Canara. Last question. The appendix 7 cost proposal is a spreadsheet. Is that submitted as as it is.

626
01:39:03.180 --> 01:39:07.230
Ian.Weiss@fda.hhs.gov: Yeah. So if you again, it's a tool that we

627
01:39:07.629 --> 01:39:14.629
Ian.Weiss@fda.hhs.gov: give to you to just kind of help with the cost proposal. If you choose to use it. Yep, you just put it in as is.

628
01:39:16.550 --> 01:39:17.509
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

629
01:39:27.678 --> 01:39:34.370
Jessika.Alfaro@fda.hhs.gov: Next question is the topic of a digital twins still within scope for Fy. 26.

630
01:39:42.040 --> 01:39:52.519
Kinnera.Chada@fda.hhs.gov: So, for that we would have to wait to have the BA. Announcement for Fy. 26 to be published, which would happen around October 1st week.

631
01:39:55.650 --> 01:39:56.590
Jessika.Alfaro@fda.hhs.gov: Think it can air.

632
01:40:19.270 --> 01:40:25.150
Jessika.Alfaro@fda.hhs.gov: Next question, what were the most common reasons for rejection in the past?

633
01:40:27.060 --> 01:40:39.360
Kinnera.Chada@fda.hhs.gov: If it was for the concept paper review, then it was basically due to lack of alignment with priorities. That was the 1st reason, and the second reason was lack of funds.

634
01:40:42.300 --> 01:40:43.250
Jessika.Alfaro@fda.hhs.gov: Take a canoe.

635
01:40:46.820 --> 01:40:54.179
Jessika.Alfaro@fda.hhs.gov: Next question, do you include the cost spreadsheet as an Excel file, or submit as a Pdf.

636
01:40:56.270 --> 01:40:59.330
Ian.Weiss@fda.hhs.gov: You can include it as an excel, excel, file.

637
01:41:01.080 --> 01:41:01.919
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

638
01:41:38.410 --> 01:41:41.170
Kinnera.Chada@fda.hhs.gov: How about waiting until 2 45.

639
01:41:42.740 --> 01:41:49.039
Ian.Weiss@fda.hhs.gov: Sounds good in case you get any of those last minute questions in.

640
01:42:49.420 --> 01:42:50.333
Jessika.Alfaro@fda.hhs.gov: Next question.

641
01:42:50.920 --> 01:42:57.599
Jessika.Alfaro@fda.hhs.gov: European private research institution plus Us. Academic unit as a joint applicant.

642
01:42:57.870 --> 01:43:05.089
Jessika.Alfaro@fda.hhs.gov: then is it a formal consortium of private research, institution and academic unit required.

643
01:43:06.020 --> 01:43:11.322
Ian.Weiss@fda.hhs.gov: No formal formal consortium isn't required. It it can be it could be

644
01:43:15.120 --> 01:43:21.646
Ian.Weiss@fda.hhs.gov: listed as a primus of, I suppose, formal consortiums probably better.

645
01:43:23.800 --> 01:43:27.489
Ian.Weiss@fda.hhs.gov: but prime and sub would would suffice.

646
01:43:29.920 --> 01:43:30.830
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

647
01:43:33.560 --> 01:43:41.279
Jessika.Alfaro@fda.hhs.gov: In reviewing previous Baa Fy awards, I did not see much in the way of communications. Research

648
01:43:41.400 --> 01:43:52.580
Jessika.Alfaro@fda.hhs.gov: is that more to do? Lack of submission in the area or less of prioritization in the area for formative research, for health communications.

649
01:43:56.820 --> 01:43:58.289
Kinnera.Chada@fda.hhs.gov: I think it could be both.

650
01:44:04.510 --> 01:44:05.709
Jessika.Alfaro@fda.hhs.gov: Thank you. Canara.

651
01:44:12.250 --> 01:44:16.980
Jessika.Alfaro@fda.hhs.gov: What? What is the funding rate in the past years?

652
01:44:18.860 --> 01:44:25.538
Ian.Weiss@fda.hhs.gov: We've definitely published that. If you go to sam.gov and look up the BA.

653
01:44:26.930 --> 01:44:30.349
Ian.Weiss@fda.hhs.gov: I might. Let's see if I have a a link here.

654
01:44:32.130 --> 01:44:41.039
Ian.Weiss@fda.hhs.gov: we we definitely publish those on Samgov. So I don't. I don't have them off the top of my head, but that's all publicly available on on sam.gov.

655
01:44:41.450 --> 01:44:54.460
Ian.Weiss@fda.hhs.gov: if you Google their in their search tool, do Baa and FDA and make sure to include archived responses. You'll you'll see. You'll see those answers in there.

656
01:44:55.510 --> 01:45:00.799
Kinnera.Chada@fda.hhs.gov: We also have the historical data on BA. FDA web, page, public webpage.

657
01:45:03.730 --> 01:45:05.309
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian, and can hear you.

658
01:45:14.030 --> 01:45:19.990
Jessika.Alfaro@fda.hhs.gov: I guess the last question would be, What is what is very important for the cost description.

659
01:45:22.740 --> 01:45:28.409
Ian.Weiss@fda.hhs.gov: What is important. Really, the the making us understand why? That.

660
01:45:29.060 --> 01:45:36.557
Ian.Weiss@fda.hhs.gov: you know, that's put on to find a point on it. But make make us understand why the Government should pay that cost right?

661
01:45:37.450 --> 01:45:57.179
Ian.Weiss@fda.hhs.gov: so making us understand how that how that cost is important to the program or to your proposal, and and helps us helps us factor in and helps in our decision making process. Whether or not you know. We agree with that cost, and and whether or not we should be paying for it.

662
01:46:02.090 --> 01:46:03.040
Jessika.Alfaro@fda.hhs.gov: Thank you, Ian.

663
01:46:07.360 --> 01:46:09.309
Jessika.Alfaro@fda.hhs.gov: I think that's all the questions.

664
01:46:12.040 --> 01:46:14.179
Ian.Weiss@fda.hhs.gov: Like we had over between the the

665
01:46:15.700 --> 01:46:21.891
Ian.Weiss@fda.hhs.gov: questions we got ahead and the questions we answered live? I think we had well over well, over a hundred questions today. That's

666
01:46:22.880 --> 01:46:27.570
Ian.Weiss@fda.hhs.gov: yeah. That's pretty pretty good pretty good turnout.

667
01:46:32.230 --> 01:46:39.980
Kinnera.Chada@fda.hhs.gov: Thank you once again to all the attendees and the panelists for making it to this Q. And a session. Good luck, with the submission.

668
01:46:43.120 --> 01:46:43.719
Ian.Weiss@fda.hhs.gov: Absolutely.

669
01:46:44.590 --> 01:46:49.250

Ian.Weiss@fda.hhs.gov: Thank you, everyone. And thanks. Thanks for everyone's time and the questions.