

Num ber	Question	Task Assign to	Asker Name	Answer	Written answer
1	Will the presentations today be shared with participants afterwards?	ORSI	Martha De Cunha Maluf-Burgman	slides will be posted on the events page	
2	How can we be made aware of the BAAs when they are posted?	OAGS	Theresa Coles		The BAA announcement can be found both on the FDA website and on the SAM.gov website and any updates would be posted directly on Sam.gov. Once awards are made the award announcement will also be posted on Sam.gov linked to the original announcement
3	Will the services and products sourced directly or will there be RFI/RFP in the future	OAGS	Anonymous Attendee		If the results from the individual awards are a defined product or service and we had a continuing need for that product or service, then that would be put out for public competition via an RFI or RFP.
4	Will slides be provided at the conclusion of the event?	ORSI	Anonymous Attendee	slides will be posted on the events page	
5	what advice do you have clin pharm post doc fellows as the transition to faculty who are interested in an R&D contract for toxicity research in vulnerable/elderly populations? Are clinical instructors who are on NIH instructional K grants eligible to apply?	OAGS	Nabiel Mir	Nabiel.Mir@uchospitals.edu	If the individual is applying through an entity that is registered in SAM.gov they can submit a white paper for consideration. Please note that the offerors capability is an evaluation factor as well.
6	Will the participants get a copy of these slides?	ORSI	Maya Aridi	slides will be posted on the events page	

7	What will be the role of the In-Silico (computing modelling & simulation) technologies in this new framework?	<b>OAGS/ORSI</b>	Martha De Cunha Maluf-Burgman		See Charge Area I: Modernize development and evaluation of FDA-regulated products; Regulatory Science Topic Area of Interest C: Analytical and Computational Methods
8	What is the timeframe for decisions for each stage?	ORSI	Anonymous Attendee	live answered	Please refer to Ms. Shaheed's presentation. The BAA is an open solicitation. We are reviewing the new white papers that we are receiving. For FY23 Timeline, once we receive the white papers, they are initially triaged and then we follow through the stage I evaluation. Approximately, mid-May notification letters will go out to the applicant. For stage II approximately, mid-July notification letter will be sent to the applicants, but it may vary from proposal to proposal.
9	Do proposers have the ability to interact with scientific SMEs in advance of submission (e.g., similar to the CDC BAA)? Thanks!	OAGS	Anonymous Attendee		The research areas of interest are listed in the BAA as the announcement is crafted after consultations with the FDA centers on what their needs are in regard to the research areas.
10	What is the timeframe between submission of a white paper/quad chart should we expect a decision notification?	ORSI	Anonymous Attendee	live answered	Please refer to Ms. Shaheed's presentation. The BAA is an open solicitation. We are reviewing the new white papers that we are receiving. For FY23 Timeline, once we receive the white papers, they are initially triaged and then we follow through the stage I evaluation. Approximately, mid-May notification letters will go out to the applicant.
12	Is the technical evaluation panel the same for stage 1 and stage 2?	ORSI	Anonymous Attendee	live answered	Yes, it usually is. However, if additional Subject Matter Experts are needed for Stage II evaluation, which is a lot more robust and involved we do recruit additional members, or if they're unable to participate based on any commitment, we recruit additional reviewers. But this very rare.

13	Could you please send me a copy of the slides? Thank you.	ORSI	Rick Sciotti	slides will be posted on the events page	
14	Jan. 23rd seems like a tight timeline.	OAGS	Anonymous Attendee	live answered	The timeline is based off the whole two stage process of the BAA and the timelines are put into place in order for the FDA to be able to make awards in the corresponding fiscal year. We do accept white papers on a rolling basis they just might not be reviewed/evaluated in the present fiscal year.
15	What is the average budget and duration of projects awarded under the BAA?	<b>OAGS</b>	Guilherme Garcia	live answered	In general, they are all between the simplified acquisition threshold (\$250,000) to about \$2 million. However, there is not a minimum or maximum and it is just based off of what is put forth in the proposal and if it is determined to be fair and reasonable by the government when considering the proposal for award.  Duration is maximum five years.
16	Will the slide decks presented today be available to download? If so, could a link be sent in the chat?	ORSI	Thomas Miller	slides will be posted on the events page	
17	Wonderful and informative presentation—can you post the link to the list of past awards through the BAA mechanism? Thank you!	ORSI	Anonymous Attendee	live answered	Please go to Sam.gov and search the corresponding BAA announcement number. The announcement will show and the information of past awards will be listed in a pdf document.
18	Will proposals that can only be priced using FFP be negatively weighted?	OAGS	Anonymous Attendee	live answered	No, not at all. While there is a preference to the cost reimbursement contract type if the research that is being proposed lends itself to a firm-fixed price contract type and that can be properly articulated that is acceptable.

19	In the context of a tool development proposal, who would own the resulting intellectual property at the end of the contract period?	OAGS	Carson Mulligan	live answered	It depends on the individual requirements and the contract.
20	Can you please describe the BAA Stage 1 -Whitepaper and Quad chart requirements and templates if any. thank you.	ORSI	Anonymous Attendee		This can be found in the BAA announcement itself.
21	Are there guidelines for how much FDA can award for a typical BAA each year?	OAGS	Laura Jaeger	live answered	There is not a minimum or maximum amount for a BAA award it all depends on the proposal and what the work entails and if the government can find the amount and level of effort fair and reasonable to the government.
22	The 30-day timeline for developing the full proposal is a very tight turnaround for academic institutions. Would FDA consider a longer turnaround for the stage II proposals?	OAGS	Theresa Coles		You may request additional time if needed via the Contracting Officer. We will consider your request if feasible.
23	Can you please discuss academic areas of research that might qualify?	OAGS	Lisa Kearns	live answered	The research areas of interest are outlined in the BAA. You may also reference the BAA Day recording to view presentations from some of the FDA centers outlining their research areas of interest.

24	Can you propose a multi-year project/contract?	OAGS	Anonymous Attendee		Yes, you can propose a multi-year project timeline as long as the timeline is reasonable for the research being proposed.
25	On page 40 of the FDA BAA solicitation, in the section describing the instructions for the Stage 1 cover page, the following sentence appears to be incomplete, "The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and." Please confirm whether there are additional instructions after the word "and."	OAGS/ORSI	Natalia Cipolla		It has been addressed in the amendment document of the FY23 BAA announcement.
26	Are there limits on indirect cost rates?	OAGS	Sara Maloney		There is no limit on indirect cost rates however the indirect rates will need to be determined fair and reasonable by the federal government. If the entity has already negotiated their indirect rates with HHS or other federal government agency, we will request a copy of the negotiated rate agreement.
27	Are BAAs posted at the same week/month each year?	ORSI	Theresa Coles	live answered	We wrap up the fiscal year by end of September. October is where we are working with the centers to define their priorities for the next fiscal year and areas of interest are identified and then noted. We work with OAGS to have the announcement open. We target to post on November on Sam.gov.

28	Does the BAA program fund clinical trials?	OAGS	Anonymous Attendee		It depends on the proposed topic. As noted within the BAA we have a topic area, complex innovation of clinical trials which we receive a lot of submissions for. So short answer is, yes the BAA program can fund clinical trials depending on the research topic area.
29	The instructions between the FY 22 and FY 23 look inherently the same with regards to the Stage I proposal submission. What is the difference in the specification of a free-standing quad chart and free-standing white paper for FY 23, compared to FY 22?	OAGS	Anonymous Attendee		No specific changes for the white paper expect for the alignment is different. (please refer to page 1 of the FY23 BAA announcement)
30	If the team includes a large academic institution and a small business, does the small business need to be the lead organization in order to qualify as a small business submission?	OAGS	Kieran Richardson		If the large institution is the Prime and small institution is the subcontractor, then yes this would not qualify as a small business submission. However, it depends on the relationship between the two institutions
31	What is average duration of these awards? I understand that they are awarded/renewed annually, but do you have any recommendations for proposing a 1-year vs. 3-year vs. 5-year project, for example?	<b>OAGS/ORSI</b>	Will Richardson	live answered	The duration of the contract is all dependent of the timeline proposed and if that timeline is reasonable considering the research and deliverables being proposed. There is no recommended timeline.

32	<p>We have existing relationships with academic institutions and pharmaceutical compaies. Part of the proposal would involve collaborative work with these companies/institutions , but we may not be able to finalize contractual agreements for work specific to the FDA BAA before the Phase I or even Phase II proposals are due. Can we submit the proposals listing potential partnerships in progress and highlight prior work done with these institutions?</p>	OAGS	Yu Au		<p>Partnership is fine it will fall under subcontracting and applicable FAR Federal Acquisition Regulations subcontracting rules will apply.</p>
33	<p>I appreciate the response “The link for the awards are provided on the same page as the solicitation,” but I am on <a href="https://sam.gov/opp/52766923970840219c29d0ba2f0f4711/view">https://sam.gov/opp/52766923970840219c29d0ba2f0f4711/view</a> and see no such link. Can you share the actual link? Thank you!</p>	ORSI	Anonymous Attendee	<p>looks like it has been removed. I'll ask about that.</p>	<p>Please go to Sam.gov and search the corresponding BAA announcement number. The announcement will show and the information of past awards will be listed in a pdf document.</p>
34	<p>Are there any publicly available examples of prior White papers</p>	OAGS	Irene Bosch		<p>No, they are not shared. They are procurement sensitive</p>

	submitted? Thank you. Irene Bosch, IDx20 Inc.				
35	The SAM registration is required for lead institution. What about foreign subs for BAA with a US lead institution? Is State Department permission needed?	OAGS	Vadim Gurvich	live answered	No. SAM registration is required
36	Are previously submitted BAA white papers available to the public?	ORSI	Kathleen Harrigan	live answered	No, they are not shared. They are procurement sensitive
37	fpds.gov -> FDABAA-23-00123 ->  <a href="https://www.fpds.gov/ezsearch/search.do?indexName=awardfull&amp;templateName=1.5.3&amp;s=FPDS.GOV&amp;q=FDABAA-23-00123">https://www.fpds.gov/ezsearch/search.do?indexName=awardfull&amp;templateName=1.5.3&amp;s=FPDS.GOV&amp;q=FDABAA-23-00123</a> -> No Results found.	ORSI	Anonymous Attendee	live answered	List of FY22 awards has been added to the amendment of the BAA announcement
38	Oh: "23" is the fiscal year. Changing to "22" worked. Thanks!	ORSI/OAGS	Anonymous Attendee	live answered	
39	When Tina spoke earlier about reading the FARS Report, the Solicitation and then she mentioned reading an appendix. Where can the appendix be found?	ORSI	Anonymous Attendee	The appendix is on page 35 of the solicitation.	
40	Are clinical instructors who are on NIH	OAGS	Anonymous Attendee		Yes if They are registered in SAM.

	institutional K grants eligible to apply?				
41	Are there any limits on indirect rates?	OAGS	Sara Maloney		No.
42	Do you provide feedback for the BAA like the NIH?	<b>OAGS/ORSI</b>	Hadii Mamudu		Technical feedback will be provided to the offeror upon the completion of their evaluation in Stage I and Stage II. If the offeror received a 'Do Not Invite' letter after Stage I they will receive technical feedback in that memo and if they are receiving a 'Regrets Notice' after Stage II they will also receive technical feedback. If the offeror is being invited to submit a full proposal and the FDA has feedback/questions for the offeror to include in their submission that will also be provided.
43	How do I get feedback on my white paper	ORSI	Gunnar Boysen		Once the evaluation is complete you will receive an email notification that will include technical feedback, if permitted. The feedback may be limited depending on the reasons it was not chosen to move on to Stage II.
44	If we apply for CERSI and BAA with a similar topic in parallel, should we point that out in the proposals?	ORSI	Kristian Debus	It's worth mentioning.	Yes, it is highly recommended.
45	Thank you!	ORSI	Kristian Debus		
46	will the recordings be made available	ORSI	Manjeet Singh	yes, we plan to post recordings of this on the event page.	
47	slide 5- is there a separate data collection for subjects, in addition to patients? thank you.	This was live answered by the presenter	colleen lyons		
48	hi- would you kindly post the agenda? thanks	ORSI	colleen lyons	<a href="https://www.fda.gov/science-research/fda-">https://www.fda.gov/science-research/fda-</a>	

				<a href="#">broad-agency-announcement-day-2022-12062022</a>	
49	Would you please put the link to the Events Page?	ORSI	Doryn Chervin	<a href="https://www.fda.gov/science-research/fda-broad-agency-announcement-day-2022-12062022">https://www.fda.gov/science-research/fda-broad-agency-announcement-day-2022-12062022</a>	
50	Some of the solutions is applicable to many organizations in FDA. Do we need to solicit individually to these organization?	OAGS	Anonymous Attendee		All proposals for BAA should be submitted through the FDABAA inbox, listed in the BAA announcement. We will receive them and direct them to the appropriate centers/offices. Thank you
51	who are the reviewers for the application? are they from academics, industry, or fda? does each office have their own evaluation panel?	ORSI	Jaina		All voting panel members are subject matter experts and mostly FDA employees. We can recruit other agency members if needed.
52	Is there a maximum dollar limit for the award? is this amount different for oncology?	OAGS	Jaina		There is not a minimum or maximum amount for a BAA award it all depends on the proposal and what the work entails and if the government can find the amount and level of effort fair and reasonable to the government.
53	for cross cutting areas, does the proposer need to decide which office the application should go to?	OAGS	Jaina		Please review the BAA announcement. It includes specific instructions about how to submit a whitepaper and a quad chart. We also ask for the Charge, Topic area alignment and etc. Details are listed within the BAA announcement.

54	what advice do you have clin pharm post doc fellows inc oncology as the transition to faculty who are interested in an R&D contract for toxicity research in vulnerable/elderly populations? Are clinical instructors who are on NIH institutional K grants eligible to apply?	ORSI	Anonymous Attendee	Please review the current BAA (FY23) announcement. Research areas of interest for oncology is listed there. Eligibility criteria are also listed in the BAA announcement.	
55	A general question: earlier today it was mentioned that the FARS 2021 report was available online. Are there similar reports from years past on topics selected and awarded by BAA by the different agencies (CBER, CDER, etc.)?	<b>OAGS/ORSI</b>	Anonymous Attendee		<p>FARS report 2021 - <a href="https://www.fda.gov/media/145001/download">https://www.fda.gov/media/145001/download</a></p> <p>FARS report 2022 - <a href="https://www.fda.gov/media/161381/download">https://www.fda.gov/media/161381/download</a></p> <p>The awarded list from FY22 is added to the amendment of the BAA announcement.</p>
56	If software prototype is developed under contract. and later after contract is completed and full software is developed from the prototype with substantial difference. will the government still have license right to the full software	OAGS	Jaina		It depends, and this would be negotiated prior to award.
57	Is existing RW data collected by other entities before contract	OAGS	Jaina		No typically, but this may be negotiated if relevant.

	but used in the contract considered data property under contract?				
58	Is the license to IP the Government include all agencies?	OAGS	Keith Davis		Generally yes, but this could be negotiated.
59	Great session. Would you kindly send the agenda? thanks.	ORSI	Anonymous Attendee		<a href="https://www.fda.gov/science-research/fda-broad-agency-announcement-day-2022-12062022">https://www.fda.gov/science-research/fda-broad-agency-announcement-day-2022-12062022</a>