

## 2026 FDA BAA Day Q&A

	Question	Answer
1.	<p>Section 12 Security Planning (BAA page 87) doesn't have any instructions. BAA Page 97 says to refer to Appendix 8 for instructions, but Appendix 8 is not part of the BAA. Could you please provide instructions for preparation the Security Plan?</p>	<p>Security planning has been updated to remove appendix 8.</p>
2.	<p>Are cooperative agreements allowed for Past Performance?</p>	<p>Yes, work has to be similar size and scope</p>
3.	<p>The BAA specifies that only allotted 20 pages but also states that "Further, the offeror must also bear the burden of proof in establishing the reasonableness of proposed costs; therefore, it is in the offeror's best interest to submit a fully supportable and well-prepared cost proposal." To fully support our costs, we will need more than 20 pages, as we need to include items like payroll, NICRA, and BOEs, etc per FAR 15.403-4(a)(1).</p>	<p>The government will not deviate from the limit of 20 pages at this time.</p>
4.	<p>Solicitation page 58 states that 20 pages are allocated for Cost Proposal Appendices, which seems to be an additional 20 pages separate from the cost proposal. Is that correct? Also, the section for the Cost Proposal</p>	<p>The limit is 20 pages in total</p>

	Appendices is not clear on what can be included. Please clarify.	
5.	Please clarify if the Excel budget template should be at the task level or the subtask level.	Task level.
6.	<p>Do the 50 pages NOT include the content from the 30 pages below?  ^section included in 30-page limit  Volume I Appendices:</p> <p>*section included in 50-page limit</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 5. *Executive Summary</li> <li><input type="checkbox"/> 6. *Research and Development Justification</li> <li><input type="checkbox"/> 7. *Scientific and Technical Information</li> <li><input type="checkbox"/> 8. *Regulatory Science Impact</li> <li><input type="checkbox"/> 9. *Resources Proposed</li> <li><input type="checkbox"/> 10. *Gantt Chart, Work Breakdown Structure and Milestones</li> <li><input type="checkbox"/> 11. *Deliverable Schedule</li> <li><input type="checkbox"/> 12. *Risk mitigation plan</li> </ul> <p>^section included in 30-page limit  Volume I Appendices:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ^Intellectual Property (required)</li> <li><input type="checkbox"/> ^Contractual Agreements (if applicable)</li> <li><input type="checkbox"/> ^Protection of Human Subjects (if applicable)</li> <li><input type="checkbox"/> ^Animal Use (if applicable)</li> <li><input type="checkbox"/> ^Use of Select Agents (if applicable)</li> <li><input type="checkbox"/> #^DURC, PEPP</li> </ul> <p>(If applicable, see Part III, Section 9.1 for details)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> ^Regulatory or Compliance Approvals:</li> </ul>	That is correct.

	<p>Laboratory License Requirement (if applicable)</p> <p><input type="checkbox"/> ^Regulatory or Compliance Approvals: Good Laboratory Practice (GLP) Compliance (if applicable)</p> <p><input type="checkbox"/> ^Regulatory or Compliance Approvals: Good Manufacturing Practices (GMP) Compliance (if applicable)</p> <p><input type="checkbox"/> ^Regulatory or Compliance Approvals: Good Clinical Practice (GCP) Compliance (if applicable)</p> <p><input type="checkbox"/> ^Regulatory or Compliance Approvals: Paperwork Reduction Act (PRA) (if applicable)</p>	
7.	<p>The 50-page limit and 30-page limit are for different sections in <i>Volume I – Technical Proposal</i> and <i>Volume I – Technical Proposal Appendices</i>, respectively, right?</p>	<p>That is correct.</p>
8.	<p>Will the recording from BAA Day be available to anyone? If so, how soon after the event will it be available?</p>	<p>Yes, it is published on the <a href="#">2026 FDA Broad Agency Announcement Day</a>.</p>
9.	<p>The Cost Proposal Template, Appendix 7, instructs Offerors without a Forward Pricing Rate Agreement (FPRA), Forward Pricing Rate Recommendation (FPRR), or provisional billing rates to provide supporting information for proposed indirect rates. If the Prime Offeror has approved negotiated indirect rate agreements that expire in March 2026, should the Offeror still apply these provisional rates for the entire period of performance or propose forecasted indirect rates in the absence of FPRA/PFRR?</p>	<p>Yes, that is correct but note the date and the likelihood they will change.</p>

10.	If FDA requires the use of forecasted indirect rates rather than approved provisional billing rates, is submission of the forecasted indirect cost rates including the pools costs and base costs alone sufficient? Or are Offerors required to provide the underlying indirect cost rate structure and calculations supporting those rates?	Forecasted rates are acceptable, and if selected for an award they can be negotiated.
11.	Appendix 7 includes a Labor Overhead indirect cost category. In our accounting system, these costs are included within our G&A rate, which is applied only to labor and fringe. For completion of the FY2026 BAA Cost Proposal Template, should Offerors retain the Labor Overhead category name and map their G&A costs accordingly, or rename the category to reflect their internal cost structure with a brief explanation?	Rename the category to reflect their internal cost structure with a brief explanation
12.	Can FDA provide a potential start date or other guidance for the contract for the purposes of developing the proposed budget? Would 06/1/2026 or 07/01/2026 be appropriate?	Fourth Quarter FY26 would be appropriate.
13.	Since an official announcement for the 2026 rate is expected but not been made yet, likely from the Office of Personnel Management (OPM) and impacting HHS, can FDA please confirm that the salary limitation for this opportunity is the Executive Level II cap effective January 2025, set at \$225,700?	That is correct

<p>14.</p>	<p>For you FDA BAA for 2026, I am confused by the submission process. It looks like there is a pre-app of sorts (concept paper of 3 pages or so), which has to be reviewed favorably in order to have the full app (70 pages or so) be reviewed.</p> <p>However, it seems that both must be submitted together, but the 70 page full app wont be reviewed unless the concept paper passes review.</p> <p>I wasn't sure I understood correctly, since it seems strange to have to put in the effort to prepare a 70 page full application that may not even be looked at based on screening of the concept paper.</p> <p>In the past, the concept paper is submitted on kts own first, and then the full app if the concept paper was favorable. Is that supposed to be the procedure here?</p> <p>If not, what is the likelihood of getting the full app reviewed, so we can know if it is worthwhile before putting in a lot of time and effort on a 70 page contract doc that may not be seen at all?</p>	<p>They are submitted together this year due to the delay in posting caused by the Government shutdown.</p>
<p>15.</p>	<p>The BAA states that multiple awards are anticipated and that funding for individual awards will depend on the quality of proposals received and the availability of funds. To assist offerors in appropriately scoping proposed efforts, could FDA provide any additional information regarding:</p>	<p>A – 15-20 is likely but may be more or less and is funding dependent.  B- We do not know and do not publish the anticipated BAA budget as it is a fluid number each year.  C- historically 1 million dollars or less, but is proposal dependent.</p>

	<p>a) the anticipated number of awards FDA expects to make under this BAA;  b) the total anticipated funding available; and  c) the expected range of funding for individual awards.</p> <p>In addition, is funding expected to be allocated across specific research areas of interest or charges identified in Part I, or will funding decisions be made independent of topic area based solely on proposal merit and program relevance?</p>	
16.	<p>Historically, prior iterations of the FDA regulatory science BAA employed a phased submission process in which offerors were able to submit a Concept Paper for FDA review prior to preparing a full proposal. This has ranged from a mandatory gating approach to an optional submission. Through that process, applicants could receive feedback on the alignment of their proposed concept with FDA priorities and, in some cases, encouragement to submit a full proposal. Given the level of effort required to prepare a compliant full proposal under the current BAA, this phased approach was highly valuable to offerors and helped ensure that full proposals were well aligned with FDA's regulatory science needs. This is the first year that the Concept Paper is not submitted prior to the full proposal. The current approach increases applicant burden without ensuring alignment with FDA priorities.</p> <p>a) Is FDA considering any adjustments to the current submission process or timeline that would allow for a similar concept-level review and feedback prior to submission of a full proposal?</p>	<p>A - No. See question 14  B - due to the tight timeline, this is unlikely.</p>

	b) Alternatively, is there an established mechanism under this BAA for offerors to engage with appropriate FDA technical or program staff to receive non-binding feedback on the suitability and alignment of a proposed research concept prior to full proposal submission?	
17.	For the Biographical Sketches, should these follow the new SciENCv format?	please refer to Volume 1 technical proposal appendices starting on page 89
18.	<p>I have two questions related to the research area “Understanding Absorption Enhancement for Oral Peptides.”</p> <p>Q1: The solicitation mentions 'semaglutide/SNAC' as an example system. Would a proposal that focuses exclusively on the Semaglutide/SNAC system be viewed as higher priority or does the agency require data on other enhancers/peptides?</p> <p>Q2: The solicitation mentions 'in silico computer modeling approaches' to predict performance. Does the agency specifically expect the development of a PBPK model that integrates GI physiology with enhancer kinetics, or is the scope open to other mechanistic modeling approaches (such as quantitative IVIVC) that do not require full physiological mapping?</p>	<p>Please review the most current FY26 FYFDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a></p>
19.	<p>Hello,</p> <p>I am writing to request the recording (and any available slides and Q&amp;A document) for the FDA Broad Agency Announcement (BAA) Day held on January 20, 2026. I am preparing an application and would like to review the</p>	Recording is posted to the <a href="#">2026 FDA Broad Agency Announcement Day</a> .

	<p>portions covering the application process and FDA research priority areas.</p> <p>Could you please share where the recording will be posted (e.g., the event page or within the FY2026 BAA solicitation materials on SAM.gov), and any direct link if available?</p> <p>Thank you for your assistance</p>	
20.	<p>Dear FDA-</p> <p>Will the recording from BAA Day be available to anyone? If so, how soon after the event will it be available?</p>	<p>Yes, recording is available. It is posted to the <a href="#">2026 FDA Broad Agency Announcement Day</a>.</p>
21.	<p>Dear FDABAA team</p> <p>the SAM link is dead and I cannot find the document anywhere else. Where can I download it? Alternatively, could you please email me the PDF? Given that we are one month away from submission, I would appreciate hearing from you ASAP</p>	<p>Please note that SAM.gov webpage appears with a version log. Please ensure the version in the upper-right corner for the webpage is set to the most recent date.</p> <p><a href="https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view">https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view</a>.</p> <p>FY26 BAA Notice V3 has been posted January 16, 2026, on <a href="#">SAM.gov</a>. You will find it posted under attachments/links.</p>
22.	<p>Is there somewhere we can watch the 2026 FDA Broad Agency Announcement Day webinar if we missed it?</p> <p>Thanks!</p>	<p>Recording is posted to the <a href="#">2026 FDA Broad Agency Announcement Day</a>. To learn more information on how to apply for funding under the FY26 BAA please see FY26 BAA Notice published on <a href="#">SAM.gov</a>.</p>
23.	<p>During the BAA Day webinar, it was suggested that the slides would be uploaded here: <a href="#">2026 FDA Broad Agency Announcement Day - 01/20/2026   FDA</a></p> <p>I am having trouble finding the link and was wondering if I misheard. Thank you.</p>	<p>Presenter's slides are posted to the <a href="#">2026 FDA Broad Agency Announcement Day</a>.</p>

24.	How can I access the latest BAA solicitation; it has been deleted on SAM.gov.	<p>Please note that SAM.gov webpage appears with a version log. Please ensure the version in the upper-right corner for the webpage is set to the most recent date.</p> <p><a href="https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view">https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view</a>.</p> <p>FY26 BAA Notice V3 has been posted January 16, 2026, on <a href="https://www.sam.gov">SAM.gov</a>. You will find it posted under attachments/links.</p>
25.	could you please share the presentation slides for Jan 20th 2026 on BAA Advance research and development regulatory science opportunities.	Presenter's slides are posted to the <a href="#">2026 FDA Broad Agency Announcement Day</a> .
26.	Is there any required format for the personnel documents needed for this solicitation? Specifically, the Biosketch? Can SciENCv be used?	Please refer to Volume 1 technical proposal appendices starting on page 89
27.	Are all FDA "groups" participating in the BAA, or only those "groups" who presented in today's webinar? Specifically, is CBER participating in the BAA?	No, it is not limited to the centers/offices that presented in the 2026 BAA Day. Please refer to Table 1 which shows the priority across the agency for FY26 and Part I: Research Areas of Interest starting on page 9. Regarding Center for Biologics Evaluation and Research (CBER), please refer to Table 1:Fiscal Year 2026 Regulatory Science Research Area of interest for biologics and Part I of the <a href="#">FY26 BAA announcement</a> .
28.	<p>I have several questions for the Contraction office Branch Chief, Ian Weiss, about proposals I am representing a foreign company in Sweden who is fully registered in SAM.gov</p> <ol style="list-style-type: none"> <li>1. For indirect cost rate, I have seen 10% and 15% for de minimis. They do not have a negotiated rate with the USG. Which is acceptable for them to use in their budget.</li> </ol>	<ol style="list-style-type: none"> <li>1. 15% is the correct rate.</li> <li>2. You can request a fee, but this may impact a funding decision.</li> <li>3. Unsure what the question is here.</li> </ol>

	<p>2. Can they request a fee on this work, we are not sure if this allowable?</p> <p>3. They will perform two analysis, one in year one and 1 in year 2, should these be written as severable, base and option year activities. The data generated in year 1 and 2 is from identical assays but on two separate products.</p>	
29.	Are all FDA “groups” participating in the BAA, or only those “groups” who presented in today’s webinar? Specifically, is CBER participating in the BAA?	Please refer to Table 1 of the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a>
30.	Thank you for the informative session on FY26 BBA today. I have one follow-up question regarding the Firm Fixed-Price (FFP) contract: My original budget included Postdoc A, but we have since hired Postdoc B to complete the work. Based on your description of FFP agreements, my understanding is that we do not need to notify the FDA of this personnel change. In addition, since the invoice is based on completed deliverables—rather than the detailed effort reporting required for an NIH grant—I will not need to list individual personnel effort for each invoicing period, correct? I wanted to confirm if my interpretation is correct.	That is correct.
31.	Can a link be provided after the meeting recording has ended?	Recording is posted in the 2026 FDA BAA Day <a href="https://www.fda.gov/science-research/advancing-regulatory-science/2026-fda-broad-agency-announcement-day-01202026">https://www.fda.gov/science-research/advancing-regulatory-science/2026-fda-broad-agency-announcement-day-01202026</a>
32.	How much total funding is available for the BAA? Will the funding be allocated by Center or Office?	We do not have a firm number and do not publish it in advance. The budget is decided by center.

33.	Will the slides be posted as well?	Yes, they are available in the 2026 FDA BAA Day <a href="https://www.fda.gov/science-research/advancing-regulatory-science/2026-fda-broad-agency-announcement-day-01202026">https://www.fda.gov/science-research/advancing-regulatory-science/2026-fda-broad-agency-announcement-day-01202026</a>
34.	Could you pls clarify why the pdf of "BAA Notice V1" has been removed from the sam.gov page? Does that mean a new version is going to appear soon?	You need to click version in the upper right-hand box of the SAM.gov website and choose the most current date. You will then see all the updates to include the most current documents. Please review Mr. Ian Weiss's presentation.
35.	What was the name of the group based in Laurel, MD and their area of focus?	<a href="https://www.fda.gov/emergency-preparedness-and-response/innovative-technologies/innovative-technologies-and-advanced-manufacturing-i-team-hub">https://www.fda.gov/emergency-preparedness-and-response/innovative-technologies/innovative-technologies-and-advanced-manufacturing-i-team-hub</a>
36.	The BAA announcement that describes different research areas is deleted from your announcement site. are you going to repost the announcement instruction. <a href="https://sam.gov/workspace/contract/opp/803a5109fa3c49ebae21c22167a9a8d4/view">https://sam.gov/workspace/contract/opp/803a5109fa3c49ebae21c22167a9a8d4/view</a>	You need to click version in the upper right-hand box of the <a href="https://sam.gov">SAM.gov</a> website and choose the most current date. You will then see all the updates to include the most current documents. Please review Mr. Ian Weiss's presentation.
37.	Mr.Orr's contact info?	Robert Orr, <a href="mailto:robert.orr@fda.hhs.gov">robert.orr@fda.hhs.gov</a>
38.	How can we take advantage of your matchmaking with existing SBIR phase 2 awardees?	live answered
39.	Is the agency open to proposals that shift from periodic inspection toward continuous, system-level regulatory visibility—for example, real-time data access into manufacturing execution rather than episodic audits?	live answered
40.	Will questions that were submitted in writing in advance be discussed?	Yes, they will be addressed in the main Q&A session at the end of the presentations
41.	Can we get feedback from your program about the overview of our project?	live answered
42.	Why was biosimilars topic removed from the call as compared to last year's? It is going to be a focus area for the agency as far as we understand from the policies of the administration. Correct?	Please consult the FY26 BAA solicitation announcement for research area of interest priorities.

43.	Previous award recipients last year were predominantly academic institutions and hospitals. Would it be realistic for a proposal from a small business to be awarded?	There is always room for a small business to be awarded a contract. on average 20% of the awards are to private industry.
44.	Does this mean since NIH did reauthorize funding we can submit what would be Phase II to the FDA as we were told we would receive an invitation to Phase II and we have a strong proposal.	Hello, given the specific guidance that was provided, I would recommend following up directly to discuss the specifics of the program and phase II
45.	Are there any plans to extend the deadline since the concept paper and full proposal are due on the same day?	At this time, there is no room to extend the deadline.
46.	how to identify the right subject matter expert for 1-1 meeting?	live answered
47.	Curious why the Concept Paper is due at the same time as the Full Proposal this year?	That is correct, it was due to the impact to the timeline of the Government shutdown.
48.	Does the FDA work with National Institute for Defense Health Cooperation (NIDHC), Uniformed Services University (USU)?	live answered
49.	Is the agency open to proposals for a novel pharmacovigilance tool that uses AI, the FAERS database, and other real-world data sources or is all post-marketing surveillance off the table?	Please refer to the current BAA solicitation Announcement for FY26 research priorities.
50.	Can a project that was submitted before but was not funded because of lack of funds, be submitted again?	live answered
51.	And Defense Health Agency (DHA)?	live answered
52.	Would it be better for us to propose more modest topics, or consider partnering with European for profit companies if that increases the likelihood of being funded? Last year, many highly qualified U.S. institutions struggling for funding had their applications rejected, while the FDA awarded	There is no preference given to any type or location of proposal submitters for award. It is based on center priority and quality of proposal as they are submitted.

	<p>funding to several European for profit companies and private universities, even for topics that were not particularly novel, advanced, or unique to those organizations. E.g. <a href="https://govtribe.com/award/federal-contract-award/definitive-contract-75f40125c00073">https://govtribe.com/award/federal-contract-award/definitive-contract-75f40125c00073</a> and <a href="https://govtribe.com/award/federal-contract-award/definitive-contract-75f40125c00063">https://govtribe.com/award/federal-contract-award/definitive-contract-75f40125c00063</a></p>	
53.	How is the agency evaluating proposals that integrate regulatory-informed ML and real-time manufacturing data to support biologic development?	live answered
54.	Can we get more information on the topics of interest under biologics?	live answered
55.	If a government shutdown occurs at the end of January, will the BAA deadline be extended?	No, there will be no extension, the FDA was fully funded through FY26 in the last minibus.
56.	Would projects that include continuations / follow up / next steps to previously funded BAA contracts under this mechanism be considered for the FY26 BAA?	As long as there is no overlap, yes they could be considered.
57.	What role is the Concept Paper now playing given that it's due at the same time as the Full Proposal?	The role of the concept paper is still for an initial review of the proposal. A strong concept paper will assist your proposal getting a full review.
58.	Does the recommended length of the base period vary across program areas? Or is it generally 1-2 years for all program areas under this BAA?	Generally, options are one year in length and are preferred to multi-year contracts
59.	What is the FDA budget for BAA this year compared with previous two or three years? Any ballpark number of awards?	It is anticipated that the budget and number of awards to be similar to FY25.
60.	is a specific part for the overall funding set aside for ORES? if so, how much?	We do not publish budget in advance of awards, but it is anticipated that this year will be similar to last fiscal year.
61.	Thanks Shaila....is there a link for BAA FY2026 solicitation? Thanks.	FY26 BAA Notice V3 has been posted January 16, 2026, on <a href="https://www.sam.gov">SAM.gov</a> Please note that SAM.gov webpage appears with a version log. Please ensure the version in the upper-right corner for the webpage is set to the

		most recent date. <a href="https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view">https://sam.gov/workspace/contract/opp/5622acb8db634d37b3b55d607e6ba561/view</a>
62.	Are the proposal evaluated as soon as they are received and funding assigned to successful bids? Or does the reviewing process begin after the deadline?	Reviews can begin as the proposals come in, but it depends on center schedule.
63.	PFAS in dairy systems BAA call: is this a high priority for funding this year? Thanks!	Please consult the FY26 BAA announcement for PFAS related research area of focus.
64.	Sorry for admin Q. the baa notice pdf was taken down from Sam.gov? Can we see the requirements again	You need to click version in the upper right-hand box of the <a href="https://sam.gov">SAM.gov</a> website and choose the most current date. You will then see all the updates to include the most current documents. I will bring up a screenshot during my presentation.
65.	For this: Research to develop novel approaches to preserve the availability of drugs for which commercial developers have discontinued adult development that have strong potential in rare cancers but lack financial incentives for commercial development -- does the drug need to be FDA approved already?	live answered
66.	Will we receive confirmation the application was received?	Yes. A proposal ID is generated once a completed BAA application package is received and sent to the applicant for tracking purposes.
67.	How do OCE's current support mechanisms align with the FDA's Animal-Free Methods (NAM) initiatives under Acts 2.0 and 3.0	live answered
68.	Will the Tumor Organoid models will get funded?	live answered
69.	Is FDA interested in Radiation toxicity project for cardiac toxicity? of the focus is really just for drs?	live answered
70.	Will OCE will consider proposals on Tumor Organoids?	live answered
71.	What about evaluation of BBB penetration in metastatic breast cancer and other type using	live answered

	ML/AI and advanced artificial methods rather than in vivo ones	
72.	Is this topic relevant: Applying Large Language Models and Patient Knowledge Graphs to Predict Severe Adverse Events in Women with Breast Cancer on Real-World EMR and PRO Data from Routine Clinical Practice	live answered
73.	for Drugs	live answered
74.	When is a proposal ID generated? (i.e. Our group submitted an application late Dec 2025 but did not receive a BAA number.)	A submission received after the FY cutoff date would be considered late and would need to wait for the next FY review cycle. An incomplete submission is flagged, and a notification is sent to the applicant for a follow up.
75.	Before submitting, would OCE be open to answering general questions looking for alignment? And if yes, what would be the best way to set this up?	live answered
76.	the attachment for. checklist is not a fillable PDF. Can that be changed so it is?	The last update to the posting has already happened, but we will take that suggestion if there is another update and/or next year's announcement
77.	Would you say each OCE research topics in the are of same priority?	live answered
78.	FDA BAA Notice V1.pdf has been deleted from SAM. Will there be a new notice coming soon?	You need to click version in the upper right-hand box of the <a href="https://www.sam.gov">SAM.gov</a> website and choose the most current date. You will then see all the updates to include the most current documents. I will bring up a screenshot during my presentation.
79.	It is unfortunate and unfair that the standalone concept paper step has been removed. The announcement provides only a few high-level sentences per topic, while prior experience shows that internal FDA teams often have specific, well-defined research needs. Unlike other funding mechanisms, such as NIH announcements that devote multiple pages to a single topic, it is difficult to understand what is actually needed. This is particularly problematic because developing a full proposal requires	Unfortunately, the Government shutdown impacted the timeline, and the concept paper was a casualty of that. We anticipate the concept paper stage returning next fiscal year.

	substantial effort, and without an early concept stage, PIs may invest heavily only to later learn that a different direction would have been more appropriate	
80.	How much preliminary data do we need to show when suggesting a specific proposal?	live answered
81.	For proposal focus on AL/ML for NAMs, should the proposal be submitted to your center - Device?	live answered
82.	Michele, can you please share your contact info?	You can contact our team at <a href="mailto:CDRHRegScience@fda.hhs.gov">CDRHRegScience@fda.hhs.gov</a>
83.	if it not related to device	live answered
84.	Are CDRH interested in the intersection of cybersecurity and patient safety when it comes to emerging technologies and the health at home devices you mention?	live answered
85.	Is any center covered here confirmed to have funding? I'm asking given the challenges currently affecting CDER in particular	live answered
86.	Development and testing of a device that minimize animal testing would be suitable, for ex. an in vitro sytem that predicts human PK for inhaled therapeutics	live answered
87.	Would a purely software AI/ML solution be in scope?	live answered
88.	Would this be eligible?	live answered
89.	Can multiple proposals be submitted for emerging technologies?	live answered
90.	What is the max budget that can be proposed? I was given 2M as a standard answer, but in some cases could we ask for more? Also, What is the total award pool for the BAA?	live answered

91.	What is an acceptable budget? More or less than 1M per year?	Usually, a smaller budget is more acceptable, but it depends on center and proposal.
92.	Do cybersecurity proposals for medical devices need to focus on a specific device use case, or can they be written more generally to cover medical device cybersecurity overall?	live answered
93.	Can you speak more to your interest in patient perspectives and if they should be device specific or condition specific?	live answered
94.	General Q regarding your cost reimbursement model mentioned p.9 of the Notice: Can you offer general guidance as to the level of professional accounting support typically needed (say, per contract FTE) to support this?	You would need some assistance, but that said, if you propose a firm fixed price model, you would avoid that. Firm fixed price is the governments preferred contracting methodology.
95.	Are you interested in using AI/ML for analyzing consumer perceptions of regulated devices from social media data? To help inform post-market surveillance?	live answered
96.	For topics that are highly understudied given their newness, for example, would it still make for a competitive proposal if the proposal was largely descriptive and attempting to define the topic?	live answered
97.	Does organoid fit in the emerging technologies?	Please refer to the FY26 BAA solicitation announcement. Page 41: E. Emerging Technologies requirements.
98.	If we indicate a group or population on the cover sheet, will the application be reviewed by a particular relevant center only (regardless of primary research area)? For example, if I have a cross-cutting application, but include "patients with rare diseases" on the cover sheet, will all centers have a chance to review or will this only be reviewed by OOPD?	Submission of a freestanding Concept Paper and freestanding Full Proposal in accordance with the preparation guidance in Section 2 of Part III – see Table 2 for detailed timelines. Freestanding Concept Papers shall describe the effort in sufficient detail to enable a high-level evaluation of the concept's technical merit and its potential contribution as well as program alignment with FDA priorities and mission. Evaluation of Concept Papers will be conducted by scientific experts leading the various FDA Research Priorities (Table 1). Offerors whose freestanding Concept Paper did not receive a favorable evaluation will be notified by email regarding the outcome of high-level evaluation. Offerors whose freestanding Concept

		Paper will receive a favorable high-level evaluation will be forwarded on for an evaluation of a Full Proposal. Full proposal will follow a scientific review process described in Part IV and will be evaluated by a panel of subject matter experts (technical evaluation panel).
99.	great! thanks A LOT for sharing the rough numbers about available budgets historically. It'd be highly appreciated if other centers mention that too	Each year's awards are published on SAM.gov if you are looking for detailed historical information.
100	When are the projects supposed to start approximately?	Generally speaking, fourth fiscal quarter of each year is a good bet.
101	Just to clarify — so when you mention 1 million, is that for one year or multiple?	It depends on the proposal, we have seen both.
102	What is the expected TRL at the start and end of the project?	live answered
103	In terms of duration, you mentioned one year contracts would be preferred. Would FDA be interested in proposals that have a plan for base year, along with option years?	live answered
104	I apologize i must have missed the answer on this, and it's very important.. Hoping it can be addressed in the general session: What is the max budget that can be proposed? I was given 2M as a standard answer, but in some cases could we ask for more? Also, What is the total award pool for the BAA?	We do not publish the budget, but there is no max budget. 2 million or less is generally what we see.
105	Project Title: Open Phantoms and Metrics for 3D Breast Specimen Margin Assessment (OPM-3D); will it be a viable project?	live answered
106	Top of p. 9 of v2 of the Notice states "FDA will be giving preference to proposals that use a cost reimbursement model"	That was previously true, but due to shifting posture, an FFP proposal would be preferred.
107	can proposal submitted by internal employees, or can internal scientist act as collaborators for proposals?	For the first question, no. For the second, please check with your ethics office.
108	"By proposing a severable, cost reimbursable contract, risk is reduced to both the	That was previously true, but due to shifting posture, an FFP proposal would be preferred.

	government and the awardee. In the future, the FDA may move to only utilizing a cost type model for this BAA award."	
109	Is there any interest in understanding the cybersecurity/ result integrity issues with devices used in medical labs (e.g., mass spec, etc.).	live answered
110	In regards to start date, with applications due Feb, are you saying it's likely for funded projects to begin 7/1/26?	Yes, that is most likely, sometime between July and Sep.
111	Would CDRH consider an IVD in the immuno-oncology space for ovarian cancer as no diagnostic test is currently recommended in clinical guidelines because no reliable or established diagnostic methods exist? or whether this would instead be considered a cross-cutting area jointly involving CDRH and the Oncology Center of Excellence (OCE).	Please be aware that we cannot fund proposals intended to develop a specific medical device as BAAs are intended to fund pre-competitive research & development. I don't believe we have specific language regarding IVDs in the immuno-oncology space so this may be better suited for OCE.
112	Hi This is for Michelle, will the In Vitro model be fundable by CDRH replacing animals?	Reducing animal testing is part of our solicitation language under Charge I, Part A. NAMs. In vitro models are included
113	What is the process for assigning reviewers to cross-cutting proposals? Do all centers have a chance to review these proposals or are they assigned to specific centers by e.g. OAGS staff?	We will cover that during the BAA application and overview presentations.
114	what kind of preliminary data are you expecting for the IGA project?	We have no specific expectations. It would depend on the scope and aims of the project.
115	Can I ask a PFAS question?	live answered
116	Pharmacokinetics still the main interest?	If there is a specific question regarding PFAS in Veterinary food, please feel free to email me at david.longstaff@fda.hhs.gov and I will forward to the relevant group.
117	Is there a specific format for biographical sketches?	Please refer to Volume 1 technical proposal appendices starting on page 89.
118	OCE-specific Q for Rebekah Zinn: Does OCE's interpretation of BAA Charge I.F.1. include	Live answered.

	dose individualization trial designs? (Prior OCE Director had explicitly narrowed the scope of 'dose optimization' to "advocating a dose for a population.")	
119	Under section 1.J Methods to assess RWD for RWE generation, the narrative specifically mentions pediatric populations (i.e., "considerate of development, innovation, and labeling for the population"). Is the FDA prioritizing pediatric populations for this subsection, or would groups and populations (e.g., women) mentioned in the BAA for all Charges also be considered?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a> for research areas of interest/priorities. Please refer to Table 1 of the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a>
120	is women's health research focus also on methodology or more on the applications?	live answered
121	What are recently funded OWH activities?	live answered
122	Any interest in secondary literature review?	We are open to any type of proposal as long as it aligns with our strategic properties and the regulatory impact is clear
123	If our proposal idea is interested in understanding usage of unregulated drugs generally, but we are also interested in how that occurs differently by gender (for example), would we be considered for this grant? Or is it looking more at issues that would directly affect women only, like menopause?	We are interested in studies that address sex differences or areas that disproportionately affect women.
124	Are you able to share the monthly reporting template or comment on the content, i.e. scientific/deliverable updates vs financial/administrative information vs both? This will help determine the resources needed to prepare monthly reports.	Please see Part II: Reporting Requirements and Deliverables, page 45 of the BAA FY26 BAA Solicitation Announcement.
125	We are developing a novel in-line X-ray based probe for real-time monitoring polymorphous phase of API during the crystallization process,	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a> for research areas of interest/priorities. Please consider a proposal submission for FDA's review and consideration.

	which FDA center should I submit this BAA proposal?	
126	I did not see my topic listed. Are only the areas already covered on this talk of interest to the FDA?	If it falls under the research areas of interest in the announcement, you just need to show how it falls into that area in order to be considered.
127	Can we cost an internship (e.g. 3 months) to FDA to co-develop a solution?	No, that would not be allowable.
128	1. For proposal submissions, do concept paper (3 page limit) and full proposal (50 page limit) need to be submitted together by 2/24/2026? this seems to be different from previous process that concept paper (3 page) is submitted and reviewed first, and then FDA will only invite some concept papers to submit full proposal (50 pages).  2. What does "Stage I Submittal Packages for open period" (2/25/2026-9/21/2026) means? Will these proposals be reviewed in 2026 although they are submitted after 2/24/2026? Do concept paper and full proposal need to be submitted together too?	1. Yes, they need to be submitted together. 2. If they come in late, they will be reviewed for FY27.
129	would it be encouraged to be funded jointly across multiple FDA centers participating the BAA?	That depends on the proposed scope of the research and its relevance to FDA's mission and priorities.
130	you mentioned 15 awardees in 2025- how many proposals were submitted overall?	about 200 proposals were received.
131	You mentioned ~200 applications last year and 15 funded. Is that ratio pretty typical historically?	Last year was a dip in %, but we expect a similar number this year.
132	Is the entity on SAM.gov the investigator (me) or my institution (hospital)?	It would be the entity submitting, usually the institution.
133	So you are recommending that all risk be taken by the contractor with no risk to FDA?	Limiting risk to the government is always preferred. Remember, a contract has a firm deliverable and benefit to the government

134	Clarification on question: Is the entity *which needs to register* on SAM.gov the investigator (me) or my institution (hospital)? Thank you.	The institution would need to be registered.
135	Just to be sure - this BAA is open to academic entities; correct? Much of the discussion seems more geared towards companies/industry than academic scientists	Yes, absolutely academia is invited to submit.
136	The BAA on page 8 indicates that preference will be made to proposals that use a cost reimbursement model. That conflicts with what was just said which was that FFP is preferred. Can you clarify?	That was previously true, but due to shifting posture, an FFP proposal would be preferred.
137	The budget template for this BAA is structured by task and reflects projected labor allocations and subcontractor costs. We would appreciate clarification on whether contract payments are expected to be tied to labor allocations or to completion of defined tasks and milestones to ensure the proposed budget and cost tracking approach are aligned.	It depends on the type of contract. FFP is handled on a deliverable basis and a cost contract could bill labor.
138	We understood that early submission was preferred for the BAA, so we submitted our proposal to the designated BAA email inbox ahead of the deadline. However, we have not yet received a confirmation of receipt. Could you please advise whether we should continue to wait for a confirmation email or resubmit our application.	Please email the <a href="mailto:FDABAA@fda.hhs.gov">FDABAA@fda.hhs.gov</a> and attached your proposal and we will get back to you.
139	Ian, the BAA document states, "The FDA will be giving preference to proposals that use a cost reimbursement model vice a firm fixed price model." Are you saying that the FDA is now encouraging FFP contracts?	Yes, that is the case.
140	We would like to clarify whether the FDA generally considers it appropriate to build new projects upon the results of previous projects	live answered

	conducted with the FDA. If such an approach is viewed favorably, should this linkage be described within the Technical Proposal, or is it preferable to address it solely in the section 'Relevant Results from Previous Projects'?	
141	What fraction of FY25 awards were in Advanced Manufacturing Approaches?	You can review the BAA awarded list for FY25.
142	Q for Ian Weiss: Do international SUBCONTRACTORS also need to register with SAM.gov?	live answered
143	Evaluating RSV monoclonal antibody products in children <2 years of age. What topic area would that go under?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.fda.gov/sam">SAM.gov</a> for research areas of interest/priorities. Please refer to Table 1 of the most current FY26 FDA BAA Announcement: <a href="https://www.fda.gov/sam">SAM.gov</a>
144	where should we mentioned the revised proposal status? On the cover page as well?	Please include it under status of the concept paper cover table
145	Ian, I have a question regarding our firm fixed-price contract. My submitted budget originally included Postdoc A; however, we have since hired Postdoc B to deliver the project. Based on the nature of a firm fixed-price agreement, my understanding is that we do not need to notify the FDA of this personnel change, but I wanted to confirm if that is correct.	That is correct.
146	Is the table included in the three-page limit for the Concept Paper, and should it be placed on a separate page?	live answered
147	What is the timing for all the stages of review?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.fda.gov/sam">SAM.gov</a> Part III: Proposal Preparation and submission and table 2: Submission deadlines for FY26 BAA
148	For capabilities and experience, if the proposal is lead by more junior researchers by heavily supported by experienced advisors and technical experts, will that be looked upon negatively?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.fda.gov/sam">SAM.gov</a> for research areas of interest/priorities. Please consider a proposal submission for FDA's review and consideration.
149	Are we submitting to you Ian? As an email?	please submit to <a href="mailto:FDABAA@fda.hhs.gov">FDABAA@fda.hhs.gov</a>

150	To clarify, the max period of performance is 5 years but preferred is 1 year?	Max is 5 years but there is no preferred length of time.
151	Are all FDA "groups" participating in the BAA, or only those "groups" who presented in today's webinar? Specifically, is CBER participating in the BAA?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a> for research areas of interest/priorities. Please refer to Table 1 of the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a>
152	Are the 200 applications in FY25 referred to Stage I full proposals or concept papers?	The 308-applications received referred to the total application received stage I submittal packages and optional early concept papers
153	Even though academia is eligible, it is safe to assume that researchers from the private sector are eligible to apply as well?	Correct
154	Could you please confirm whether the Excel sheet is required as part of the cost proposal submission?	That is an optional template
155	How do we deal with subawards if we have partners? Should we budget to compensate them ourselves?	That is correct. The government does not have a relationship or ability to pay a subcontractor.
156	Does FDA plan to use AI in its process of evaluating the concept papers and full proposals?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a> for research areas of interest/priorities. We coordinate reviews based on the proposed research topics across the agency.
157	Do we attach "Intellectual Property" twice? It's #14 on technical checklist and listed under Appendix section.	No
158	Does the preference to FFP contracts reflect a shift in the type of projects that are preferred? The FAR leans towards cost reimbursement contracts for many R&D efforts given the inherent uncertainty often present in R&D projects.	No, we would just prefer a FFP type contract.
159	Question to Ian: If the more than 20 pages are submitted, is the proposal automatically disqualified or is the proposal truncated at 20 pages and whatever is in those truncated pages the only elements of the proposals that are considered?	It would be truncated.

160	Does the HHS subcontracting plan count towards cost proposal page limits.	No, and that is submitted if selected for award.
161	Could you please explain about contractual agreements. When are they required and what would they cover? I tried but could not yet find details in attachment 5. Thank you kindly.	live answered
162	Please clarify if the Excel budget template should be at the task level or the subtask level.	live answered
163	How important whether a fixed price vs cost reimbursement approach is proposed be in the evaluation criteria?	live answered
164	Dose BAA contract consider fee?	live answered
165	Is there a limitation for the numer of PIs?	live answered
166	Is the million dollars estimate for first year or total contract value on average?	live answered
167	Is there a template to use when preparing Volume II – Cost Proposal ? Specifically Cost Summary and Detailed Cost Breakdown	live answered
168	Can a contract be considered severable if the work can be divided into two parts with one part being performed first and the second part only performed if the first part is successful. The government would not fund the second part if the first part is not successful. Thank you.	live answered
169	what is the recommended duration of a projet?	live answered
170	can FDA subject area expert will be actively involved and collaborator in the proposal?	live answered
171	do we need to submit statement of work in the full proposal? How much details are needed?	live answered
172	If we are proposing a technical expert panel as part of our methods, would you recommend individual technical advisors be named? It's my	FDA conducts the technical panel evaluation based upon proposed topics and research areas of interest.

	understanding that they would be considered consultants and classified as subcontracts according to the BAA.	
173	Could you share the typical review timelines?	live answered
174	How does the spreadsheet template count toward the 30-page cap?	live answered
175	it previously funded BAA projects had been terminated by convenience, is it at a disadvantage if it is submitted in 2026	live answered
176	Can the contract support an internship hosted by FDA to co-develop a solution for example?	live answered
177	Are you accepting NIH Phase II proposals since there is no NIH funding?	It would need to be formatted per our instructions on SAM.gov
178	Are letters of support from unpaid or limitmally paid consulstntas needed if they are invited to joint the project?	live answered
179	But the PIs of those terminated projects would be qualified to propose new topics, right?	correct
180	How is the proposal submitted - via email?	Please submit to FDABAA inbox at FDABAA@fda.hhs.gov
181	Could you please elaborate what is meant by "Data Other Than Certified Cost or Pricing Data (see FAR 15.403- 3) shall be provided for proposals under \$2M." in the page 58 of the RFA.	That just means cost data that is not certified.
182	Does the proposed work need to be already engaged in some form of a regulatory approach with FDA?	No
183	How can we identify the point of contact for specific topics related to substance/opioids topics? The given topics are too broad, so we were wondering if we can consult with respective CDER researchers	Please consider submitting a proposal based on the research areas of interest that is published for FDA review and consideration.

184	Can the files (Volume I) and Volume II be more than 2 MB?	I don't believe there is a MB limit, but I would recommend 10 MG or less for the full proposal to be able to fit in a single email.
185	How important the file size is?	I don't believe there is a MB limit, but I would recommend 10 MG or less for the full proposal to be able to fit in a single email.
186	There are topics mentioned in the funding notice, e.g., substance use and misuse, however they were not discussed earlier, does it mean that they are not a priority for FDA?	Please review the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a> for research areas of interest/priorities. Please refer to Table 1 of the most current FY26 FDA BAA Announcement: <a href="https://www.sam.gov">SAM.gov</a>