

Question	Answer	Written Answer
could you also put the event page link in the chat?	Answered in Q&A Pod	2023 FDA Broad Agency Announcement Day <a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023</a>
Are co-principal investigators allowed on the application?	Answered Live	
Methods to Assess RWD to server as RWD		See Part I of BAA Solicitation for details
Can you give some insight on the amount of money available for awards through this BAA? What is the average size of an award?	Answered Live	
Using and Validating AI Approaches		See Part I of BAA Solicitation for details
What are the data sharing or publication requirements?	Answered Live	
Can you fund all phases of clinical trials?	Answered in Q&A Pod	Clinical trials to support regulatory research and development may be funded via the BAA Program. Please refer to Federal Acquisition Regulations (FAR) definitions for basic research (See FAR 2.101(b)(2)), applied research (See FAR 35.001) and development (See FAR 35.001). <a href="https://www.acquisition.gov/far/35.001">https://www.acquisition.gov/far/35.001</a>
Methods to Assess RWD to support Regulatory Decision-making		See Part I of BAA Solicitation for details
How many applications are anticipated for this round of funding?	Answered Live	
Where can we find the codes and explanation/definition of the FDA Primary Research Areas? Such as I.C.3.a. Secondary Research Area: I.F.4.b., Primary Research Area (i.e, II.B.7.e)	Answered in Q&A Pod	Please review Dr. Kinnera Chada's presentation
Looking for information on GDUFA initiatives on Topical products and characterization based approach	Answered in Q&A Pod	This was covered in the first presentation, thank you for your question!
Is there a limit of applications per institution?	Answered in Q&A Pod	There is no limit on applications per institution

Question	Answer	Written Answer
For this proposal, Can we assign co-PIs from 2 different institutions ?	Answered Live	
Will the slides be available after the meeting?		Yes, slides posted under event materials
Will proposals that address these items be sent to the Generics division for review or does it go to a central review team?	Answered Live	
Why we have not heard the feedback from the 2023 FDA BAA concept paper submission?	Answered in Q&A Pod	To our knowledge all feedback and rejection letters have been sent out. Please reach out to me directly at <a href="mailto:Ian.Weiss@fda.hhs.gov">Ian.Weiss@fda.hhs.gov</a> and we will get you the information you need.
I am a Univ faculty in AI and Machine Learning. To apply for FDA grant, do I have to partner with a MD or someone within FDA?	Answered Live	
Is developing IVPT skin penetration robustness an area of interest	Answered Live	
Are you looking for a proposal to cover multiple items thave you have listed (for example 1-3 under nitrosamines) or are you looking for a proposal to cover a single item	Answered Live	
For clarification, based on the topic area overview, the goal of this BAA for the FDA is to obtain new ways of testing and validating products that come through the FDA for clearance/approval, not for industry to share new devices or therapeutics?	Answered Live	
Are proposals for developing Methodology to improve clinical trial diversity of interest?	Answered Live	
Please provide the link to the detailed list of fields that we can apply in, mentioned by the Speaker	Answered in Q&A Pod	All details on research areas can be found in the BAA announcement on SAM.gov : <a href="https://sam.gov/opp/b4906ee0af3c48de9a793049a63695e5/view">https://sam.gov/opp/b4906ee0af3c48de9a793049a63695e5/view</a>

Question	Answer	Written Answer
Will other CDER offices present their priorities (OND?)		No, only the Centers and Offices listed on the Agenda will be presenting the priorities. See Part I of the solicitation on SAM.gov for details.
Recently, CRCG posted an opportunity on TDS patch adhesion. Would areas around adhesion assessment, still be encouraged in the BAA process.	Answered Live	
Can smartphone apps that track habits such as nicotine habits with data recording/AI/ML support etc be of some interest to current BAA? Just curious at this point..	Answered in Q&A Pod	Please refer to the FY24 BAA solicitation for scope under Tobacco Products. <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a>
Based on the feedback received last year, where our proposal was recognized as scientifically sound but had concerns about industry adoption and regulatory implementation, can we resubmit an enhanced proposal this year addressing these concerns? Additionally, can we reference the previous feedback in our revised concept paper?	Answered Live	
What is the website that all of these will be posted to?	Answered Live	
Can interchangeable processing of the same product be considered under this program?	Answered Live	
website for the recording and slides	Answered in Q&A Pod	Recording of the full event (including closed captioning and an audio transcript), presentation slides, and responses to all questions will be posted on the event page.
Given that this meeting is happening only 10 days prior the deadline for early concept submission (Nov. 6th), can that deadline be extended by a week?	Answered in Q&A Pod	The BAA Announcement was posted on 02 October 2023, and the FDA feels 6 weeks for an optional 3-page paper is a sufficient amount of time. As such, no extensions will be granted.

Question	Answer	Written Answer
what is the event page website?	Answered in Q&A Pod	<a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023</a>
Will you be covering Chare 3 and specifically Antimicrobial Resistance in this webinar?	Answered in Q&A Pod	Only the funding priorities listed by FDA Programs on the agenda will be presented. <a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-agenda">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-agenda</a>
What are the priorities in terms disease areas for the CDRH?	Answered Live	
Does the Concept Paper 3-page limit include the cover page?	Answered in Q&A Pod	Yes, the 3-page limit for Concept Paper includes cover page and overview.
Will FDA provide a link to this recorded session? Also, will it be posted on the FDA website or emailed to registered attendees?	Answered in Q&A Pod	Recording of the full event (including closed captioning and an audio transcript), presentation slides, responses to polls, and answers to all questions (received via email to FDABAA mailbox and live) will be posted on FDA BAA event page: <a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023</a>
For the MCM, are there modalities that are of priority? ie microbiome versus vaccine etc	Answered Live	
will advance manufacturing quality focuse on devices or also pharmaceutical manufacturing is of interest as well?	Answered Live	
Will CDRH support improvements to gene therapy manufacturing/supply chain specific proposals?	Answered Live	
Do you prefer to work with a single academic centre or a consortium of multiple?	Answered Live	
Can you clarify if CDER is also interested in MCM manufacturing?		See drug and cross-cutting sections on advanced manufacturing of the solicitation. There are no CDER specific topics related to

Question	Answer	Written Answer
		MCM manufacturing but we see a lot of advanced manufacturing proposals utilize candidates or model systems related to shortages, and emergency preparedness.
How are you addressing where there seems to be overlap in subjects between this BAA and other NIH announcements that uses very similar text?	Answered in Q&A Pod	Addressed live by the presenter
'@Julie Schneider: Significant part of Oncology CGTP products evaluation and long term monitoring relies heavily on Bioinformatics pipelines that support data analysis. Does OCE support "purely bioinformatics pipeline development proposals" that will facilitate regulatory data analysis for FDA reviewers ? Pipelines like Off-target, on-target, viral integration, AAV consistency of manufacturing, etc	Answered Live	
Hello! What if I have a proposal that could be relevant for two different centers (eg OCE and Office of Women's Health)?	Answered Live	For the Concept Paper, provide Persons with Cancer and Womens Health as entries for Demographics and Population
Under immunooncology are you interested in therapeutics that can alleviate side effects such as colitis ?	Answered Live	
Can multiple investigators from different institutions be on the same proposal?		Yes, this is acceptable to the Govt. However, please keep the 51% rule in mind with regards to subcontracting, as well as provide a primary POC.
'@Julie.Schneider@fda.hhs.gov, there seems to be similar language between some BAA topics and NIH solicitations, should this be complementary to those?	Answered Live	
Does non-radioactive imagents for LN mapping area of interest for OCE	Answered Live	
Does your center have interest in technologies that can aid in patient health evaluation under telehealth?	Answered Live	

Question	Answer	Written Answer
I thought I asked this already but don't see it here. This applies to all topic areas. I was wondering what the available funding is for this FY24 BAA and what the typical size award is through this funding mechanism. It really helps to know this as it impacts the size project/scope a company can propose.		Fundig has not been determined. Please see Prior year Award postings for historical data.
Do you require BSL3 strains for MCM research, or is use of BSL2 surrogate strains acceptable, if it can show proof of concept?	Answered Live	
Would on demand GCSF mfg be of interest?	Answered Live	
Do you support clinical trials of MCM's ?	Answered Live	
Does Covid-19 is still an interesting topic for FDA?	Answered Live	
Dose you center have interest in technology for distributed manufacturing of vaccine products?	Answered Live	
What types of supply chain resilience topics are of highest priority?	Answered Live	
Is 3D printing of countermeasure as a method for on-demand and decentralized countermeasure production method, of an interest?	Answered Live	
Would you consider proposals for development of novel NGS-based diagnostics. If not, can you give an example of the types of tools you are looking for that would enhance NGS-based diagnostics that may be applicable?	Answered Live	
How do you see Large Language Models impacting proposals	Answered Live	
Are you interested on modelling of advanced manufacturing?	Answered Live	Checking with Advanced Manufacturing Team
Are novel surrogate endpoints to advance MCM's of interest?	Answered Live	Checking with Advanced Manufacturing Team

Question	Answer	Written Answer
How do submit a concept paper	Answered in Q&A Pod	Please see Section 2: Stage 1 Concept Paper and Full Proposal of Part III: Proposal Preparation and Submission of FY24 BAA Solicitation. <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a>
How can we get information from the Advance manufactruing group?	Answered Live	Checking with Advanced Manufacturing Team
Which type of advanced manufactuirng process is of FDA interest?. Solid dosages or liquid dosages or both?	Answered Live	Checking with Advanced Manufacturing Team
Will the answers to the manufacturing questions be posted after you follow up with your colleagues?	Answered Live	Yes, answers will be posted
In the scope of real-world evidence, are there any specific areas of research that have more need than others?	Answered Live	
Related to the concept paper, is it possible to get an example of a good one?	Answered in Q&A Pod	Please see attachment 4 of FY24 BAA solicitation for a template for the Concept Paper. <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a>
Would evaluation of the mitigation and response efforts implemented during COVID and providing an evaluation and next steps on human and animal food supply chains. be of interest?	Answered Live	Evaluation of the mitigation and response efforts implemented during COVID and providing an evaluation and next steps on human and animal food supply chains are currently not a priority. We could be convinced that this would be of interest but only if the "next steps" part is the majority of the report and the steps are grounded in a lot of policy analysis, with all the pitfalls, challenges, and nuances that would entail.
Will tech that shows lower cost be of interest	Answered Live	Really like to see the research lower costs AND/OR (Help bring manufacturing back to the U.S. OR Move the ecosystem towards biomanufacturing and away from petrochemicals) - Parentheses for boolean grouping purposes.

Question	Answer	Written Answer
Which center focuses on substance use and misuse topics, especially around medication for opioid use disorder		Examples:
Is the length of the concept paper 1 Cover Page + 3 Pages of Concept paper or 1 Cover Page + 2 Pages of Concept Paper?	Answered in Q&A Pod	- A biomanufacturing method for polypropylene precursors that make them out from ecoli instead of oil.
Under OneHealth approaches 1. Crosscutting b. Develop methods to assess the impact of contaminants on human, animal, and environmental health, including the distribution and fate of contaminants in natural ecosystems, and develop tools to better assess risk and to predict how sources for human and animal exposures may affect the safety of medical products and human and animal food. If this looking for a monitoring tool, or would a review of biological contaminants distribution and fate in the environment be of interest?	Answered Live	- Automation / biomanufacturing that lowers the cost of making the key starting materials for certain active pharmaceutical ingredient (API), which makes it easier from domestic producers to compete.
What if the proposal address FDA's regulatory needs as well as CDCs mission. Can a proposal be co-submitted/co-funded by two agencies through some kind of interagency agreement ?	Answered in Q&A Pod	- A method that identifies new/different chemical pathways to make APIs (still using petrochemicals) but that increases the number of suppliers of Key starting Materials so that the supply chain becomes more resilient.
What if the proposal address FDA's regulatory needs as well as CDCs mission. Can a proposal be co-submitted/co-funded by two agencies through some kind of interagency agreement ?	Answered Live	
Intersex?	Answered Live	
Would breast cancer diagnostics be of interest	Answered Live	Breast cancer diagnostics could potentially be of interest; we would need to see the concept paper to fully evaluate.



Question	Answer	Written Answer
What is a SAM registration? Apologies for not knowing :)	Answered in Q&A Pod	<a href="https://sam.gov/content/home">https://sam.gov/content/home</a>
Are you interested in social media data analysis for monitoring tobacco product marketing and user behavior changes? Thanks!	Answered Live	Please see Part I of the solicitation for details.
What was the reason of asking for full proposals on February? FDA may get many more full proposals than before without a pre-screening	Answered Live	
Sorry, interrupted message: are concept papers due in November acting similarly as the white papers were previously?	Answered in Q&A Pod	The optional early concept papers that are due in November are 1. optional and 2. more similar to Quad Charts that were reviewed for high-level evaluation.
Are the approval, utility, and value of the technologies indicated for the pregnant women to determine congenital malformations within the scope of Women's health? other FDA center? or not covered by FDA in general since the laboratory tests are outside the scope of the FDA's authority?	Answered Live	Checking with Office of Womens Health
Does the three (3) page limit for the concept paper (specified on page 70 of the Broad Agency Announcement) include the Concept Paper Cover Page?	Answered Live	
Do international submitters need a SAM?	Answered Live	
Table 3: Overview of BAA Application Process on page 96 of the Broad Agency Announcement indicates that the FDA will notify submitters of the Optional Early Concept Paper of the interest or lack of interest for full proposal submission. Does the FDA have a target date or date range in mind for sending these notifications out?	Answered Live	

Question	Answer	Written Answer
Thanks, this means we most likely most will be sent as full proposal in February		No answer, this is a comment.
We still have a BAA submission from 2023 that has not been awarded or rejected. Should we re-submit the topic under the 2024 program, or wait for the 2023 program to complete?		This is a bussiness decision. However, you are allowed to re-submit.
If the US government shuts down will it affect your timelines?	Answered Live	
the FY24 BAA "solicitation for scope under tobacco products" website link is not working.	Answered in Q&A Pod	We did not find any links that are not operational. Please send an email to FDABAA@fda.hhs.gov an email with the website link that is not working.
I thought the concept paper was optional? Can you clarify this for us. Thanks	Answered Live	
There was no distinction in the BAA regarding early vs regular concept paper that I saw. What page? is there a page limit for the optional concept paper? I don't see that in the BAA but what should we be targeting?		
Is there a limit for requested yearly funding?		No, but historically, most BAA awards are 1 million per year or less.
When can we expect to hear back on a recommendation on the optional early concept paper?		yes, basic feedback and a recommendation will be given OOA 15 Nov.
When is the concept paper due date?		
If one submits an early concept will feedback be provided if modification of the proposal is desired?		
How much feedback will be provided about decisions for concept paper rejection or ways to better focus proposals for future submissions?	Answered Live	
when will the outcomes be communicated in slide 18 left hand column? E.g. early concept paper recommendations/feedback	Answered Live	
Is there an estimated timeframe that FDA will communicate recommend/do not recommend notices for the early Concept Paper submission?		yes, basic feedback and a recommendation will be given OOA 15 Nov.

Question	Answer	Written Answer
There was one slide which mentioned a question about whether we had recieved an invitation to submit a proposal in Oct-Nov 2024. I did not understand this commnet in the context of the optional concept paper.	Answered Live	
Can applicants of one proposal be from two different organizations, such as two different universities? In this case, through which entity to submit the proposal?	Answered Live	
Can one investigator submit multiple concept papers?	Answered in Q&A Pod	Multiple concept papers (for early optional concept paper) can be submitted, especially if the methodology and/or application is distinct.
Are the contracts cost sharing?		You can propose this.
Can the proposals that were not funded during the previous cycle be revised and submit as new or revised applications?		Yes.
From your experience, please provide some practical hints to prepare a good application. What are critical points to focus on? What are the most common deficiencs in the applications? What should be avoided, what to take care of particuraly, etc. Thank you	Answered Live	
Have all the awards been made for the BAA for FY2023 ?	Answered Live	
Are the deliverables intended for the public to use (e.g., statistical methods/designs) or they are more intended for the agency?	Answered Live	
Considering the BAA FY24's emphasis on advanced manufacturing approaches, and based on the feedback we received last year, can we resubmit a revised proposal that addresses the TEP's concerns by emphasizing our alignment with the BAA's objectives? Additionally, would it be	Answered Live	

Question	Answer	Written Answer
appropriate to reference the feedback from last year in our updated proposal?		
Is there a reason I did not receive a response to my proposal from June? I was invited to round two and I received positive feedback.	Answered in Q&A Pod	Please contact me (Ian.Weiss@fda.hhs.gov) directly, As far as I am aware all notices were sent out
What is the typical period of performance and a range of total contract value?	Answered Live	
What is the typical period of performance and a range of total contract value?	Answered Live	
What exactly is meant by remote monitoring? Is it to replace on-site inspections completely? Or complement them?	Answered Live	
Can you send link to event?	Answered in Q&A Pod	<a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023</a>
Who is a formal applicant in case of application from academia - a researcher or university?	Answered Live	
After submitting an optional early concept paper, when can I expect to hear back from the on a recommendation?	Answered Live	
What is your recommended way for getting in touch with you? Thank you.	Answered Live	
Is it mandatory to select a primary research area and secondary research area for the concept paper cover page?	Answered in Q&A Pod	Required to provide a primary research area but NOT required for secondary research area. We want to make sure that the concept paper is evaluated by appropriate program leaders. Feel free to include more than one primary research area.
What is the average project period? 2 - 3 years??		We have contract ranging from 6 months to 5 years. Most are 2-3 years.

Question	Answer	Written Answer
When looking the the SAM website, it asks about NCAGE number for some applications. WOUld we need one?		You need to be registered for all awards in SAM.gov. Cage codes are being phased out.
Who can apply? Small business? Academia (university)? Small business plus academic unit as a joint applicant? Then, is a formal consortium of business & academic unit required?	Answered Live	
Can a firm submit more than one concept paper and/or proposal provided they are stand alone documents?	Answered in Q&A Pod	For optional early concept paper, more than one concept paper per firm/institution can be submitted for distinct applications and/or methodology. Any time after 11/6/2023, more than one concept paper with full proposal per firm/institution can be submitted for distinct applications and/or methodology.
Where can you find the chart that includes the FDA-Regulated Areas and Demographics Populations from the Concept Paper slides? - Kinnera	Answered in Q&A Pod	Chart is available as Table 1 of FY24 BAA solicitation <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a> .
Please let us know if the reference list is iwithin 3 page limts?	Answered in Q&A Pod	the reference list is not part of the 3-page limit. Please review Part III. Proposal Preparation and Submission of the BAA Announcement
For the Cross-Cutting section of the chart, how do we know which office or center within FDA we should write to?	Answered Live	
As far as the size of the past awards, have the FY23 last cycle awards been posted to the BAA site yet?	Answered Live	
Is the \$2M guidance for 1 year or over the course of multiple years (for example for a total of \$6M over 3 years)	Answered Live	
Are we allowed to select more than one regulatory area, topic area, or demographic/population for one proposal?	Answered in Q&A Pod	only one charge area or regulatory topic area, but multiple product areas and demographic/population can be posted.

Question	Answer	Written Answer
		Please note that multiple primary and secondary research areas can be included.
Are there limits on direct and indirect costs?	Answered Live	
The concept letter asks for high-level budget (with total). If submitted in November, how much discretion do we have to modify for the final submission in February? thank you.	Answered Live	
Just to confirm- is it correct that if a vendor does not submit a concept paper by 11/6/23, they exclude from submitting a full proposal by February 2024?	Answered Live	
What do you mean performing 50% of the work? Sub vs prime.	Answered Live	
When do you expect to make award decisions?		The May - June 2024 timeframe.
If our organization submitted an FY23 full proposal and didn't hear back about an award decision, should we resubmit under the FY24 BAA, or should we wait to hear back under the FY23 BAA process?		This is a business decision. However, you are allowed to re-submit.
How can I attain feedback from my proposal last year? I was invited to stage two but never heard back again		Please contact us directly.
Does business size (SB, LB) come into play when making award decisions? Is any of this set aside for SBs?	Answered Live	
Could you please provide link for the FY23 results? The SAM page doesnt include the list of awrdees: <a href="https://sam.gov/opp/cee17d2a1ed84922a5a0392240a6f4e3/view">https://sam.gov/opp/cee17d2a1ed84922a5a0392240a6f4e3/view</a>	Answered in Q&A Pod	<a href="https://sam.gov/opp/832533a9e79e4de2b4d06c1131f70722/view">https://sam.gov/opp/832533a9e79e4de2b4d06c1131f70722/view</a>
Will the references for the concept paper count in the 3 pages?		
Is there a different way to send questions? I can't see questions that are presently been asked.	Answered in Q&A Pod	they can be sent to the BAA inbox, but only here live

Question	Answer	Written Answer
can a system integrator outside organization be used	Answered Live	
system integrator to provide management support		This is a bussiness decision. please keep the 51% subcontracting rule in mind
Do we need to submit the optional concept paper through our university representative or just send directly through email? Thanks!	Answered in Q&A Pod	Send to FDABAA@FDA.HHS.GOV Please see table 3 of FY24 BAA solicitation posting on <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a>
Whats the minimum amount that you could award through BAA?	Answered Live	
Are you less likely to receive funding if you recently received funding on a prior BAA?	Answered Live	
Does the SAM registration have to be complete at the time of the early concept paper submission or at the time of the full proposal?	Answered Live	
Would you recommend the non-primary applicants to also request a SAM number if they don't have one? For example in the case of subcontracting. Thanks!	Answered Live	
Can the purchase of equipment be included (with a justification) in the cost?	Answered Live	
please provide us the details for small business fair info. Thank you	Answered in Q&A Pod	<a href="https://sam.gov/opp/a9914d0313964d219e7c2ed278daf743/view">https://sam.gov/opp/a9914d0313964d219e7c2ed278daf743/view</a>
can budget be broken up into options so that fda can guide on what will be acceptable		yes.
Is it necessary to have proof of concept data for the proposed concept? or Is proof of principle based on published data/basic preliminary data enough?	Answered Live	
In the previous year, the WHITE Paper is condered as the Stage I propoal this year?	Answered in Q&A Pod	Please review Dr. Kinnera Chada's presentation and the FY24 BAA Announcement

Question	Answer	Written Answer
Do ODCs purchased by Prime count towards 51%?	Answered Live	
I apologize, I did not hear an answer to this question: After submitting an optional early concept paper, when can I expect to hear back from the on a recommendation?	Answered in Q&A Pod	On or about 15 Nov* depending on the shutdown
Are references included in the 3 page for concept paper	Answered Live	
How do you find the most current chart listed in the instructions for the concept paper?	Answered Live	
Can budget be submitted as options	Answered Live	
Where can we find the codes and explanation/definition of the FDA Primary Research Areas? Such as I.C.3.a. Secondary Research Area: I.F.4.b., Primary Research Area (i.e, II.B.7.e)	Answered Live	See "Slide 12" of the presentation covered for the topic "# Application Updates" on <a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023#event-materials">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023#event-materials</a> .
Where can we find the relevant codes/description information for the following sections for the Concept Paper submission? • Charge Area: • Regulatory Science Topic Area of Interest: • FDA Regulated Areas: • Demographics and Populations: • Primary Research Area: • Secondary Research Area:	Answered Live	See "Slides 7-12" of the presentation covered for the topic "# Application Updates" on <a href="https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023#event-materials">https://www.fda.gov/science-research/2023-fda-broad-agency-announcement-day-10252023#event-materials</a> .
We want to reconfirm about the concept paper page limit. Does the concept paper is limited to three (3) pages with single; Margins – 1 inch; Font – Arial; Font Size – 12?	Answered Live	The 3 page limit for the Concept Paper includes the Concept Paper Cover Page and Concept Paper Overview. Page Size: 8 ½ x 11 inches; Spacing – single; Margins – 1 inch; Font – Arial; Font Size – 12. For details, see description for "Preparation of Concept Paper", Section 2: Stage 1 Concept Paper and Full Proposal Preparation of Concept Paper of Part III: Proposal Preparation and Submission of the



Question	Answer	Written Answer
		solicitation on <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a> .
<p>Reconfirming - Within the limits of (3) three pages of the "Concept Paper" do we have to provide the below mentioned highlighted information? 1. Research Strategy:</p> <p>a. Aims: <i>Succinctly list the specific objectives of the proposed research (State the problem/objective and provide motivation for addressing that problem/objective) and primary scientific challenges being addressed.</i></p> <p>b. Methods: <i>Clearly describe the approach, description of level of effort, and the nature as well as extent of the anticipated results of the effort (one Figure that is a 508 compliant picture or graphic that illustrates the research or concept can be included)</i></p> <p>c. Considerations: <i>Brief description of the Offerors intellectual property ownership, data ownership, or licensure; statements on work experience for similar effort with FDA or another agency</i></p> <p>2.Regulatory Science Impact</p> <p>a. <i>How does this research address an unmet need or fill a critical knowledge gap to advance regulatory science and the program's priorities? How might FDA apply the research findings to the development of new tools, approaches, or standards? Please explain the benefits of proposed technology and challenges and how the</i></p>	Answered Live	The 3 page limit for the Concept Paper includes the Concept Paper Cover Page and Concept Paper Overview. The descriptive text (italicised red font) can be deleted or replaced. For details, see description for "Preparation of Concept Paper", Section 2: Stage 1 Concept Paper and Full Proposal Preparation of Concept Paper of Part III: Proposal Preparation and Submission of the solicitation on <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a> .

Question	Answer	Written Answer
<p><i>proposed project aligns with the objectives of FDA Regulatory Science</i></p> <p>3. Proposed Deliverables and Funding</p> <p>a. <i>List of the major goals, deliverables, or milestones and proposed funding by project year. Total proposed funding is the Base period cost plus each option period with no more than 5 years total.</i></p> <p>Milestones Timeline Funding</p>		
<p>on the Free standing Concept Paper Submission. I'm interested in apply for the following FY24 FDA BAA for Advanced Research and Development of Regulatory Science opportunity, but could not find the format of the Free standing Optional Concept Paper from the following website. I could not find the attachment 4.</p>	<p>Answered Live</p>	<p>See description for "Preparation of Concept Paper", Section 2: Stage 1 Concept Paper and Full Proposal Preparation of Concept Paper of Part III: Proposal Preparation and Submission of the solicitation. Attachment 4 is available in the solicitation and also as a document on <a href="https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view">https://sam.gov/opp/26fa501e9b4d4f1ba8e1c2a8314343cb/view</a>.</p>
<p>If we have several distinct ideas, would you prefer we combine them into one 3-page concept paper or submit them as separate proposals</p>	<p>Answered Live</p>	<p>If the proposal applications and/or research methodology are distinct, the recommendation is to submit separate submissions.</p>

Question	Answer	Written Answer
<p>Does the three (3) page limit for the concept paper (specified on page 70 of the <i>Broad Agency Announcement</i>) include the Concept Paper Cover Page? Table 3: Overview of BAA Application Process on page 96 of the Broad Agency Announcement indicates that the FDA will notify submitters of the Optional Early Concept Paper of the interest or lack of interest for full proposal submission. Does the FDA have a target date or date range in mind for sending these notifications out?</p>	<p>Answered Live</p>	<p>The 3 page limit for the Concept Paper includes the Concept Paper Cover Page and Concept Paper Overview. Recommendations for Optional Early Concept Paper submission will be communicated no later than December 15th (pending approval of either a continuing resolution or appropriations of funds for FDA).</p>
<p>1. Will funding be available for Phase 1, 2 or 3 clinical trial? 2. Will the BAA fund the development of surrogate endpoints that could be used as the basis for regulatory approval?</p>	<p>Answered Live</p>	<p>Broad Agency Announcements, as described in the Federal Acquisition Regulations (FAR), may only be issued for the procurement of Research and Development (R&amp;D). All acquisitions resulting from this announcement must meet one or more of the FAR definitions for basic research (See FAR 2.101(b)(2)), applied research (See FAR 35.001) and development (See FAR 35.001). Applications that describe how the project falls under the FAR requirements for R&amp;D work will be considered for review.</p>
<p>3. Are there limitations on the size of the award?</p>	<p>Answered Live</p>	
<p>I notice that the response date on SAM.gov is listed as February 14, 2024 for the FY24 FDA BAA but all of the supporting documents and attachments list February 19, 2024. Can you please clarify the date?</p>		<p>All applications are due by February 19th, 2024 for FY24 funding considerations. SAM.gov will be updated to reflect February 19, 2024.</p>

Question	Answer	Written Answer
<p>We have a question about the Concept Paper structure. Is it ok if we remove the descriptive parts in red?</p> <p>1. Research Strategy:  a. Aims: <b>Succinctly list the specific objectives of the proposed research (State the problem/objective and provide motivation for addressing that problem/objective) and primary scientific challenges being addressed</b></p>		<p>Yes, please remove the descriptive text (red font) suggested for the concept paper</p>
<p>for the early concept paper submission due 11/6, do we need to include budget within that submission?</p>		<p>Yes, please include the budget in Concept Paper Overview section for "Proposed Deliverables and Funding". Provide proposed funding by project year either as text or table provided in the template.</p>