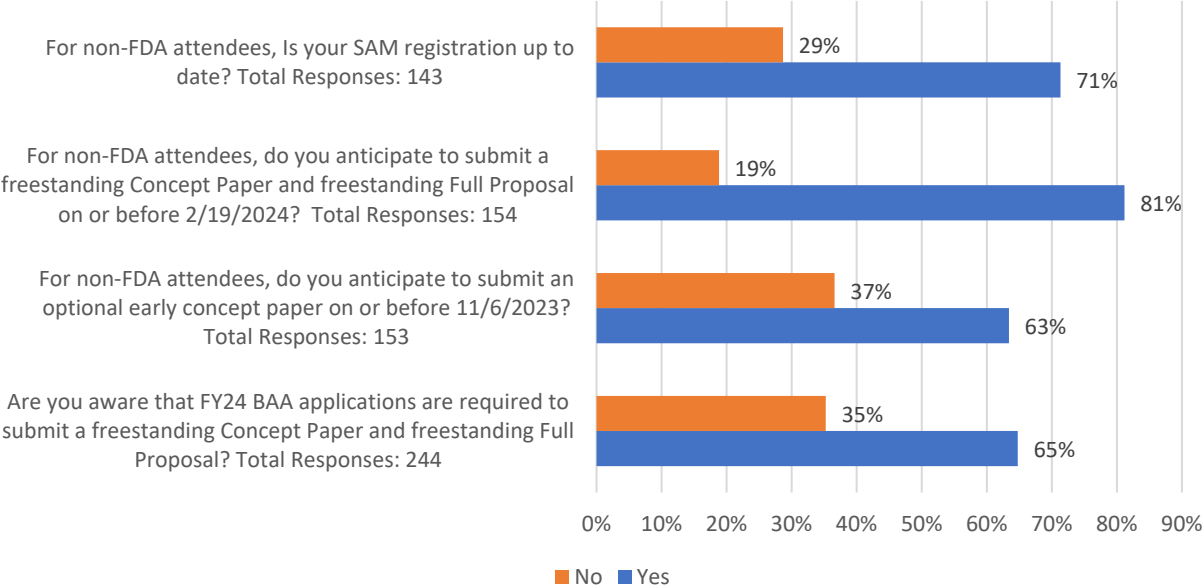


2023 BAA Day Poll Questions and Responses



Any topics of interest that need to be covered in the presentations or Q&A sessions	FDA Follow-Up
When will feedback be provided on the concept paper?	Answered Live
How can small consulting firm collaborate with larger medical device or pharma companies?	Answered Live
PPE supply, stock pile, innovation	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
past performance evaluation	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Any changes to the instructions for quad chart or white paper.	Presented and Answered Live
Recalls	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
My first time dealing with FDA grants. The more basic info is helpful.	Presented and Answered Live
How can we get more information on how to submit a BAA?	Presented and Answered Live
Formatting requirements for concept paper submission (optional)	Presented and Answered Live
The requirements for the paper and proposal	Presented and Answered Live
sickle cell disease	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Criteria of selection	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
What steps are needed to meet the deadline(s)? Are there topics related to substance abuse data that are of interest to the funding bodies?	See BAA solicitation for details
Biodefense activities	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
sucess rates for applications	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
When can we expect to hear back on the freestanding concept papers if they are submitted for review before Nov. 6th?	Answered Live
Interested in Procurement of Human Resources including Scientists, R&D Professionals and many more within the clinical research space.	Answered Live

Any topics of interest that need to be covered in the presentations or Q&A sessions	FDA Follow-Up
Sustainability	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Estimated budget that should be assumed for each concept presented	Answered Live
Can you explain the acquisition process, why initial concept papers in Oct, and full proposals in Feb?	Presented and Answered Live
How many pages do we need to write for the concept paper and full proposal? Do you have a template for both of them? Thanks!	Presented and Answered Live
what counts in the 3 page document	
Priority disease areas	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Specific topics for projects that are relevant	See BAA solicitation for details
Requirements related to digital manufacturing	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Budget limits, use of System Integrator	Answered Live
1. pandemic preparedness - FDA support 2. is there a possibility of delay in submissions expected on 03 November 2023?	Answered Live
Transdermal Topical GDUFA	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
How application should be prepared. What topics/scope can be included in the application.	Presented and Answered Live
financial limits, number of years, are propoals that address a certain center (for example generics), sent to that center for review, or to a central review team?	Presented and Answered Live
Budget limit for applications	Presented and Answered Live
Research Focus Areas	See BAA solicitation for details
Does the 3-page limit for the concept paper include the required cover page? When will FDA provide feedback on the optional concept papers submitted by 11/6?	Presented and Answered Live
The type of ideas being sought, he selection process, and any preferences for academia submissions, please.	Presented and Answered Live
FDAs research interests	See BAA solicitation for details
Can we collaborate with FDA scientists or pharma industry? Do the full proposals have to be team science or should have multiple PIs?	Answered Live
What is required to apply for funding? Are small teams acceptable? (3-5 people)	Answered Live
How many pages for the Concept Paper? and timeline?	Presented and Answered Live

Any topics of interest that need to be covered in the presentations or Q&A sessions	FDA Follow-Up
vaccines	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Timeline for feedback and format of feedback	Answered Live
AI/ML requirements	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Innovative manufacturing processes that overcome traditional drug manufacturing processes such as manufacturing in a zero gravity environment	Answered Live
AI/machine learning / mechanistic simulation / continuous manufacturing	Answered Live
AI/ML Medical Devices	Answered Live
Concept paper outlines and process	Presented and Answered Live
Clarity on the page requirements for the concept paper - is it a title page + 3 pages or 3 pages total WITH the title page	Presented and Answered Live
Does the 3 page limit include the cover page?	
technology support of FDA processes	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Digital twins	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
AI/ML	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Artificial intelligence?	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
What types or breadth of projects could be submitted and considered?	Answered Live
Can Canadian companies apply for this funding opportunity	Yes, a trade agreement country can apply for a contract awarded through the BAA Mechanism.
CQA for cell therapy	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
rare diseases	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
advanced manufacturing	Answered Live
Yes. Antimicrobial resistance	See BAA solicitation for details
Are there any funding limitations or requirements related to Small businesses?	Answered Live

Any topics of interest that need to be covered in the presentations or Q&A sessions	FDA Follow-Up
Does it support early stage researchers in PI or CoPI roles?	Yes
Priority research areas	See BAA solicitation for details
Please provide insight into funding priorities and examples of funded projects from previous years	Presented and Answered Live
advance manufacturint 3D printing.. Interested to know what are the knwoledge gaps that FDA like to see covered.	Presented and Answered Live
Concept paper details.	Presented and Answered Live
Specific diagnoses or patient populations that grant proposals should focus on?	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
Full application is needed by FEbruary 2024. Why the changes?	Answered Live
Common errors or mistakes to be avoided	Answered Live
would be good to learn if the question on prior submissions for this work apply to the PI or to the organization -- thank you!	Please provide experience of the PI and/or organization. Response is any experience and not specific to PI or organization.
Do you have to have an active IND to submit a concept paper and/or full proposal?	No
if we have a broad multi-part idea, is it better to submit multiple 3- page concept papers or a single concept paper covering multiple ideas?	Answered Live
How to submit/format focus are for preliminary proposal	Presented and Answered Live
Guidance on the concept paper	Presented and Answered Live
how much detail of budget and timeline is needed in the concept paper?	Answered Live
duration (PoP) and size recommendations	If any clarifying questions on this topic, please send them to FDABAA@fda.hhs.gov
I wonder whether BAA division has an opening for the graduate internship or any kind of career development program.	Please see usajobs.gov for job postings and opportunities related to FDA