

FDA Broad Agency Announcement Industry Day

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- ❑ **The Food and Drug Administration (FDA) launched the Broad Agency Announcement (BAA) to spur regulatory science innovation in the scientific community and leverage its knowledge and infrastructure (regulatory science three charges)**
 - Modernize development and evaluation of FDA-regulated products
 - Strengthen post-market surveillance and labeling of FDA-regulated products
 - Invigorate public health preparedness and response of the FDA, patients, and consumers.
- ❑ **FDA is encouraging science and technology-based firms as well as academia to participate with us in developing innovative ideas and approaches to regulatory science.**
 - BAA is issued under the Federal Acquisition Regulation (FAR) part 35.016(c)
 - Opportunity to present ideas and proposals directly to FDA’s scientific thought leaders for consideration
- ❑ **OAGS posted the FY2 FDA BAA for Advanced Research and Development of Regulatory Science on www.Sam.gov on October 4th, 2024 (FDABAA-25-00123).**
 - Utilize industry and academia’s capabilities to advance the state of the art and achieve improvements in science and technology
 - Open to all responsible sources and Small Businesses are strongly encouraged to respond
 - Contracts will be the instrument used to make awards (not Grants) and based on the funding available
 - In FY24, there were 24 awards with an approximate total value of \$39 million dollars . We anticipate a similar number of awards and value this FY
- ❑ **Take advantage of this virtual event and the opportunities provided to understand our mission, meet, and network with the attending FDA staff (to include Contracting, Program)**



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- What is the purpose of this BAA?

The FDA solicits for advanced research and development proposals to support regulatory science and innovation. The FDA anticipates that research and development activities awarded under this BAA will serve to advance scientific knowledge to accomplish its mission to protect and promote the health of our nation.

The result of this process is that various proposals, based on scientific review and relevance, will be selected to be awarded contracts.



What is the difference between a contract and a grant?

- Federal Grants and Federal Contracts have significant differences. The government uses grants and cooperative agreements as a means of assisting researchers in developing research for the public good, whereas it uses contracts as a means of procuring a service for the benefit of the government. Grants are much more flexible than contracts. Typically in Federal Contracts, changes cannot easily be made to the scope of work or budget, whereas in grants these changes can usually be made with the governments approval. Failure to deliver under a Federal Contract can have potential consequences to the vendor , whereas in the case of a grant typically a final report explaining the outcome is sufficient.



What about severability vs nonseverability?

- "Severable" describes an action that can be divided into two or more parts that are not necessarily dependent upon each other. "Non-severable" describes an action that cannot be divided into two or more parts without negatively effecting performance of the task.
- Whether a contract is for severable or nonseverable services affects how the agency may fund the contract; severable services contracts may be incrementally funded, while nonseverable services contracts must be fully funded at the time of the award of the contract.



- Can we expect negotiations as a part of the contract award process?

The government will retain the right to negotiate with each offeror. It depends on a number of variables, but negotiations are always possible on BAA awards. This past year, approximately 50 % of the contracts issued required some level of negotiations.

- How can we improve our chances if we aren't selected this year?

While the reasons vary from incomplete packages to limitations in funding and relevance to the research areas, you may always request to speak to the CO for specific feedback.

- What about SAM registration?

SAM.gov gov registrations can be lengthy, and the government is PROHIBITED from issuing a contract to an entity not properly registered in SAM.gov for all awards. It is recommended your registration be current upon proposal submission.



- What if we are new to this process, and/or a small business?**

- WELCOME! The FDA is happy you are here, and we value your potential partnership!**

- Talk to your Contracting Officer (That's me).**

- What can we do for you? Point you towards resources, answer general questions, clarify points of federal contracting complexity.**

- What am we prohibited from doing? Reviewing your proposal before submission, answering “what should I research” or “what are my chances” kinds of questions. Especially not “what are other people submitting” questions!**



Questions on Contracting Matters?



THANK YOU FOR ATTENDING FDA BAA Day



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