FDA Broad Agency Announcement Frequently Asked Questions for Oncology Researchers

Background information

1. **Where can I find the BAA announcement?**
   The BAA announcement is posted on beta.sam.gov. The FY 21 announcement is available here. Scientific interest areas in the BAA announcement are usually updated on an annual basis. Applicants should periodically search beta.sam.gov to find the updated BAA announcement.

2. **Who is eligible to apply?**
   As indicated in the BAA announcement, the BAA is open to all responsible sources, which includes single entities or teams from private sector institutions, academic and nonprofit institutions. Historically black colleges and universities and other minority institutions are encouraged to apply or join teams that submit applications.

   There are no specific educational or experience requirements for Principal Investigators, but capabilities and experience are considered as an evaluation criteria in review.

3. **Can international institutions submit proposals?**
   Yes, but institutions must be registered on www.sam.gov in time to receive funding if an application is successful. International applicants should ensure sufficient time to complete the sam.gov registration process, as FDA cannot make awards unless this registration is complete. FDA does not have authority over the sam.gov registration process.

4. **Does the BAA result in a contract or a grant? What reporting is required once a BAA is awarded?**
   The BAA results in a research and development (R&D) contract. There are regular reporting requirements to the FDA Contracting Office that are different to those typically required for grants. Reporting requirements are described in detail in the BAA announcement.

5. **What is the maximum length for a project supported by the BAA?**
   The BAA mechanism can support projects for up to five years.

6. **Does the FDA Oncology Center of Excellence (OCE) limit the amount of funding provided for an individual project?**
   There is no funding limitation specified by the BAA mechanism; however, individual FDA offices are limited by available budgets for research. It is most important for applicants to propose a cost that is reasonable to complete the research.

7. **Does OCE support basic and applied research under the BAA?**
   The BAA mechanism can fund both basic and applied research, but work funded under the BAA should have a direct impact to FDA. OCE prefers to fund applied research studies. OCE is most interested to support applied research that focuses on solving a specific, practical problem encountered in the review of oncology products rather than expanding general knowledge.

8. **How can I find out about previously awarded BAAs?**
   After awards are made each year, a brief summary is posted on beta.sam.gov under the BAA announcement for the appropriate fiscal year. The brief summary of awards can be found by clicking on "award details" and clicking on the pdf attachment.

Communicating with OCE staff about potential submissions

9. **How can I communicate with OCE staff about my research idea?**
   Prior to submission of a quad chart and white paper, you may contact individual OCE staff to seek clarification about the scientific interest areas described in the BAA announcement. Please note that FDA staff can *only discuss information that is included in the BAA announcement*. If you do not have a specific OCE contact, you may request input through FDAOncology@fda.hhs.gov.

   After a quad chart and white paper are submitted to FDA, all communications about the research proposal must go through the FDA Contracting Office at FDABAA@fda.hhs.gov.

10. **Can OCE staff comment on draft specific aims for a potential project?**
    No. OCE staff cannot comment on specific aims for a potential project or be involved in drafting or commenting on a research proposal.

11. **Can OCE staff stay involved in the research if a project is funded through the BAA?**
    Yes. OCE staff may provide regulatory perspectives about the research project, and may co-publish with BAA-funded investigators.

12. **Who can I contact about questions, details and logistics for submitting an application?**
    FDA contracting office representatives are the experts about the details of submitting applications. You can find specific contact names in the "Contact Information" section of the BAA announcement and/or may use the general BAA email inbox (FDABAA@fda.hhs.gov).

13. **Can I propose to analyze data submitted to FDA using the BAA mechanism?**
    Yes, because the BAA mechanism results in a research contract (rather than a grant), it is possible for Offerors to analyze data submitted to FDA. All FDA contractors (including funded BAA Offerors) are bound by Federal Acquisition Regulation rules about protecting commercial confidential information and can access data submitted to FDA on FDA-issued laptops.

Application and review

14. **When is the application deadline?**
    FDA accepts BAA submissions on a rolling basis, but posts a deadline to apply for consideration for funding in a specific fiscal year. For example, in order to be considered for funding in FY 21, applicants needed to submit a white paper and quad chart by January 28, 2021.

    Applicants may continue to submit white papers and quad charts after that deadline, but proposals submitted after the deadline will be considered for FY 22 funding.

15. **What do applicants submit?**
    For Stage 1 review, applicants submit a quad chart and a ~10 page whitepaper. Applicants who are invited to Stage 2 review submit a ~50 page full proposal. Details about preparing all of these submission materials are described in the BAA announcement, including templates in the appendix.

16. **What is a quad chart? I have received several NCI grants in the past, but have never heard of a quad chart.**
    A quad chart is a one-page summary of a research proposal that includes a heading with the project title, research area addressed, offeror point of contact, company/institution name. The four components of the quad chart are as follows:

    Upper left: Objective, description of effort
    Lower left: Benefits of proposed technology, challenges
    Upper right: Picture or graphic
    Lower Right: Milestones, cost, period of performance

    Detailed information about how to prepare a quad chart is included in the BAA announcement

17. **What is an Offeror?**
    In the Federal Acquisition Regulations, an "offer" means a response to a contract solicitation. For the BAA, an Offeror is the institution/ applicant who submits the research proposal to FDA for consideration.

18. **How are BAA submissions reviewed?**
    The review process is described in the BAA announcement and occurs in two stages. Both stages involve review by FDA internal scientific experts who consider the following factors: (1) scientific and technical merit; (2) program relevance; and (3) offeror capability and experience. Past performance and costs are also analyzed.

19. **When are applicants notified if they will be invited to submit a full proposal?**
    Since the BAA accepts submissions on a rolling basis, the timing of notifying applicants depends upon when the quad chart and white paper are submitted.

    For the FY 21 BAA announcement, applicants that submitted quad charts and whitepapers near the January 28, 2021 deadline were generally notified by the Contracting Office via e-mail sometime in spring to early summer. Those who were not invited to submit a full proposal are usually notified before the end of the fiscal year on September 30.

20. **How frequently are the scientific interest areas in the BAA updated?**
    FDA updates the scientific interest areas annually, with a new BAA announcement typically being issued each year. Applicants should periodically search beta.sam.gov to look for the updated BAA announcement.

OCE submits specific scientific interest areas in the BAA (which are further described on the OCE Scientific Collaborative website) but is also open to proposals in other areas relevant to oncology regulatory science research.