FDA Broad Agency Announcement (BAA) Questions and Answers Session

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January 16, 2024

Overview

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 [FY24 FDA Broad Agency Announcement Question and Answer Session - 01/16/2024 | FDA]

- FDA Broad Agency Announcement
- FY24 Solicitation Updates
- Concept Paper
- Volume I of Technical Proposal
- Dates and Steps to Remember

FDA Broad Agency Announcement

- FDA has been soliciting proposals to advance the state of the art within the regulatory research areas through a specialized contract mechanism known as FDA's Broad Agency Announcement (BAA)

- FDA BAA Webpage: Regulatory Science Extramural Research and Development Projects | FDA

- BAA as described in the Federal Acquisition Regulations (FAR), may only be issued for the procurement of Research and Development (R&D). See Page 106 of the solicitation for additional details.
  - Basic research
  - Applied research
  - Development

FAR Definitions for R&D

Basic research - Research directed toward increasing knowledge in science. The primary aim of basic research is a fuller knowledge or understanding of the subject under study, rather than any practical application of that knowledge (FAR 2.101(b)(2))

FAR Definitions for R&D cont..

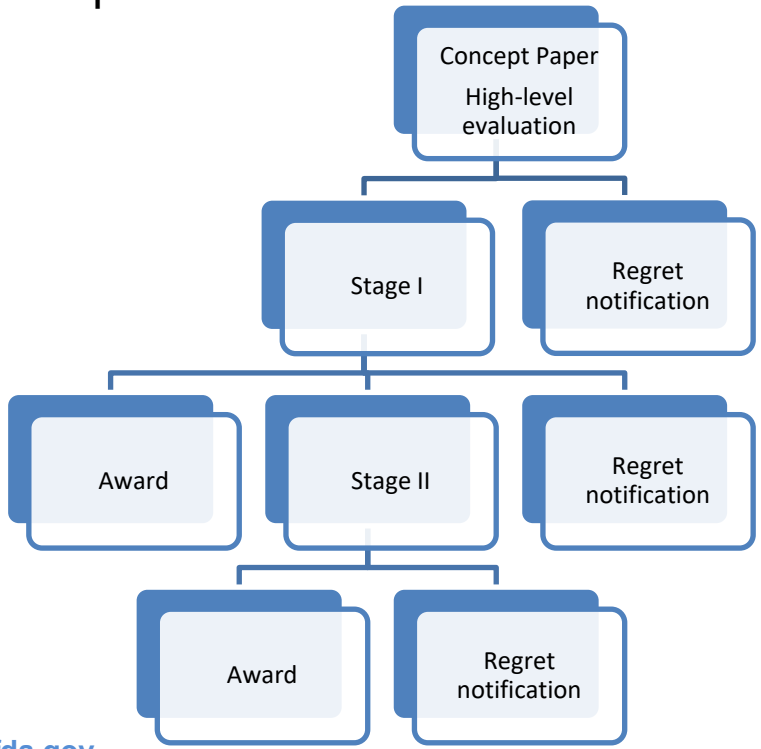
Applied research - The effort that (a) normally follows basic research, but may not be severable from the related basic research; (b) attempts to determine and exploit the potential of scientific discoveries or improvements in technology, materials, processes, methods, devices, or techniques; and (c) attempts to advance the state of the art. When being used by contractors in cost principle applications, this term does not include efforts whose principal aim is the design, development, or testing of specific items or services to be considered for sale; these efforts are within the definition of “development,” given below (See FAR 35.001).

FAR Definitions R&D cont..

Development - The systematic use of scientific and technical knowledge in the design, development, testing, or evaluation of a potential new product or service (or of an improvement in an existing product or service) to meet specific performance requirements or objectives. It includes the functions of design engineering, prototyping, and engineering testing; it excludes subcontracted technical effort that is for the sole purpose of developing an additional source for an existing product and the development of a specific system or hardware procurement (See FAR 35.001).

BAA Application Process Updates

- All submissions require a freestanding Concept Paper and freestanding Full Proposal



Concept Paper will be evaluated to conduct a High-Level review to determine potential program alignment with FDA priorities and mission

Technical Proposal will be evaluated by a panel of subject matter experts

Revised Full Proposal will be evaluated by panel of subject matter experts (same as Stage I)

FDA BAA FY24 Solicitation Updates

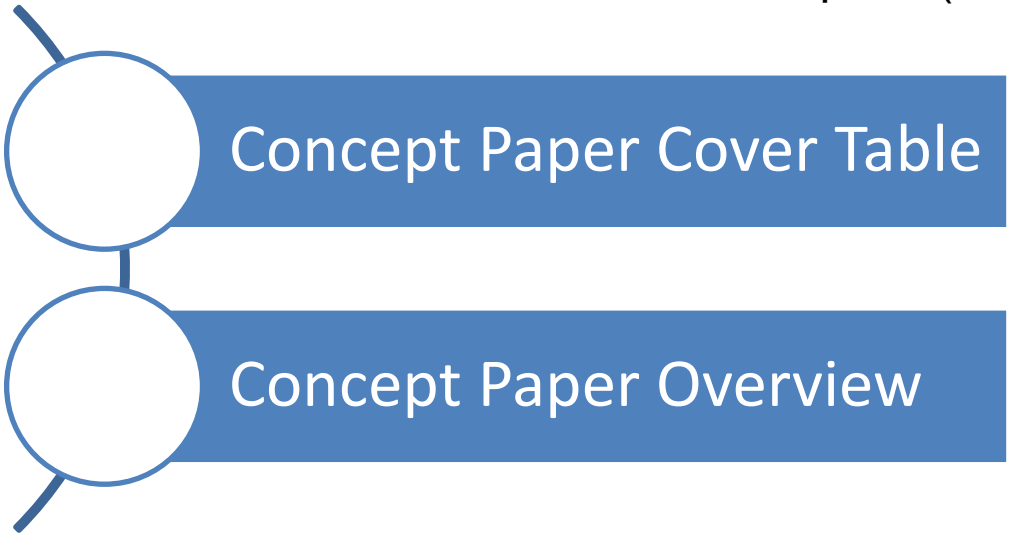
- Amendments
  - Charge I, Regulatory Research Topic I: Approaches to Incorporate Patient and Consumer Input, product area: Devices. See Page 34 for details.

- Optional Early Concept Papers
  - Optional Early Concept Paper: **Submission was NOT needed as a qualification step for consideration of a Stage One Package for FY24 BAA Applications**
  - Total applications received: 202 with Stage One package submit recommendation was made for 86 and Do Not Submit recommendation for 116. Numbers by charge are available on Regulatory Science Extramural Research and Development Projects | FDA
  - Reason for Do Not Submit recommendation was predominantly lack of alignment with FDA's program priorities.

Concept Paper

- See Part III of the solicitation for preparation details

- See Attachment 4 of the FY24 Solicitation for template (Pages 103-104)



Concept Paper

Concept Paper Cover Table*

- Charge Area
- Regulatory Science Topic Area of Interest
- FDA Regulated Areas
- Demographics and Populations
- Primary Research Area
- Secondary Research Area
- Offeror, Contact Information, Principal Investigator
- Research and Development Justification
- Optional Early Concept Paper Status

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FDA Regulated Areas:	**Demographics and Populations**:
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Offeror:	**Offeror Contact Information**: **Name-** **Email-** **Phone-**
Principal Investigator:	**Affiliations**:
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I. Modernize development and evaluation of FDA-regulated products										
A. Alternative Methods	X		X			X		X	X	
B. Advanced Manufacturing Approaches	X	X		X	X					X
C. Analytical and Computational Methods	X	X	X	X	X	X	X	X	X	X
D. Biomarkers	X				X	X		X	X	X
E. Clinical Outcome Assessment (COA)				X	X		X	X		X
F. Complex and Novel Clinical Trial Design				X	X	X	X	X	X	X
G. Predictive Toxicology	X				X	X		X		X
H. Methods for Assessing Be havioral, Economic, or Human Factors				X	X	X				
I. Approaches to Incorporate Patient and Consumer Input	X									
J. Methods to Assess Real-World Data to serve as Real-World Evidence	X	X	X			X		X	X	X
K. Methods to Assess Data Source Interoperability	X									
II. Strengthen post-market surveillance and labeling of FDA-regulated products										
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	X			X	X			X		X
B. Using and Validating Artificial Intelligence Approaches	X			X	X			X		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	X									X
D. Automated Reporting Tools for Adverse Events and Active Surveillance	X	X			X					X
E. Methods to Improve Communication About Risk to Patients and Consumers				X	X	X		X		
F. Approach to Expand Data Capacity, and Increase Data Quality and Use	X				X		X			
G. Efforts to Harmonize Existing and Emerging Data Standards	X									
III. Invigorate public health preparedness and response of the FDA, patients, and consumers										
A. Reinforce Medical Countermeasures Initiative to Increase Preparedness and Response for Emerging Public Health Threats				X			X	X	X	
B. Antimicrobial Resistance					X					
C. Patient and Consumer Engagement	X				X		X			
D. Substance Use and Misuse				X	X	X	X			
E. One Health Approaches	X									
F. Strengthen Global Product Safety Net	X	X			X					
G. Emerging Technologies				X						

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A. Alternative Methods	x		x			x		x	x	
B. Advanced Manufacturing Approaches	x	x		x	x					x
C. Analytical and Computational Methods	x	x	x	x	x	x	x	x	x	x
D. Biomarkers	x				x	x		x	x	x
E. Clinical Outcome Assessment (COA)				x	x		x	x		x
F. Complex and Novel Clinical Trial Design				x	x	x	x	x	x	x
G. Predictive Toxicology	x				x	x		x		x
H. Methods for Assessing Be havioral, Economic, or Human Factors				x	x	x				
I. Approaches to Incorporate Patient and Consumer Input	x									
J. Methods to Assess Real-World Data to serve as Real-World Evidence	x	x	x			x		x	x	x
K. Methods to Assess Data Source Interoperability	x									
II. Strengthen post-market surveillance and labeling of FDA-regulated products										
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	x			x	x			x		x
B. Using and Validating Artificial Intelligence Approaches	x			x	x			x		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	x									x
D. Automated Reporting Tools for Adverse Events and Active Surveillance	x	x			x					x
E. Methods to Improve Communication About Risk to Patients and Consumers				x	x	x		x		
F. Approach to Expand Data Capacity, and Increase Data Quality and Use	x				x		x			
G. Efforts to Harmonize Existing and Emerging Data Standards	x									
III. Invigorate public health preparedness and response of the FDA, patients, and consumers										
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B. Antimicrobial Resistance					x					
C. Patient and Consumer Engagement	x				x		x			
D. Substance Use and Misuse				x	x	x	x			
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F. Strengthen Global Product Safety Net	x	x			x					
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B. Advanced Manufacturing Approaches	x	x		x	x					x
C. Analytical and Computational Methods	x	x	x	x	x	x	x	x	x	x
D. Biomarkers	x				x	x		x	x	x
E. Clinical Outcome Assessment (COA)				x	x		x	x		x
F. Complex and Novel Clinical Trial Design				x	x	x	x	x	x	x
G. Predictive Toxicology	x				x	x		x		x
H. Methods for Assessing Be havioral, Economic, or Human Factors				x	x	x				
I. Approaches to Incorporate Patient and Consumer Input	x									
J. Methods to Assess Real-World Data to serve as Real-World Evidence	x	x	x			x		x	x	x
K. Methods to Assess Data Source Interoperability	x									
II. Strengthen post-market surveillance and labeling of FDA-regulated products										
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	x			x	x			x		x
B. Using and Validating Artificial Intelligence Approaches	x			x	x			x		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	x									x
D. Automated Reporting Tools for Adverse Events and Active Surveillance	x	x			x					x
E. Methods to Improve Communication About Risk to Patients and Consumers				x	x	x		x		

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B. Advanced Manufacturing Approaches	x	x		x	x					x
C. Analytical and Computational Methods	x	x	x	x	x	x	x	x	x	x
D. Biomarkers	x				x	x		x	x	x
E. Clinical Outcome Assessment (COA)				x	x		x	x		x
F. Complex and Novel Clinical Trial Design				x	x	x	x	x	x	x
G. Predictive Toxicology	x				x	x		x		x
H. Methods for Assessing Be havioral, Economic, or Human Factors				x	x	x				
I. Approaches to Incorporate Patient and Consumer Input	x									
J. Methods to Assess Real-World Data to serve as Real-World Evidence	x	x	x			x		x	x	x
K. Methods to Assess Data Source Interoperability	x									
II. Strengthen post-market surveillance and labeling of FDA-regulated products										
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	x			x	x			x		x
B. Using and Validating Artificial Intelligence Approaches	x			x	x			x		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	x									x
D. Automated Reporting Tools for Adverse Events and Active Surveillance	x	x			x					x
E. Methods to Improve Communication About Risk to Patients and Consumers				x	x	x		x		

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C. Analytical and Computational Methods	x	x	x	x	x	x	x	x	x	x
D. Biomarkers	x				x	x		x	x	x
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II. Strengthen post-market surveillance and labeling of FDA-regulated products										
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	x			x	x			x		x
B. Using and Validating Artificial Intelligence Approaches	x			x	x			x		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	x									x
D. Automated Reporting Tools for Adverse Events and Active Surveillance	x	x			x					x
E. Methods to Improve Communication About Risk to Patients and Consumers				x	x	x		x		

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Concept Paper

Example for Primary and/or Secondary Research Area

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III. Invigorate public health preparedness and response of the FDA, patients, and consumers										
A. Reinforce Medical Countermeasures Initiative to Increase Preparedness and Response for Emerging Public Health Threats				X			X	X	X	
B. Antimicrobial Resistance					X					
C. Patient and Consumer Engagement	X				X		X			
D. Substance Use and Misuse				X	X	X	X			
E. One Health Approaches	X									
F. Strengthen Global Product Safety Net	X	X			X					
G. Emerging Technologies				X						

III. Invigorate public health preparedness and response of the FDA, patients, and consumers

The following focus areas of regulatory science are identified to accomplish Charge III, *invigorate public health preparedness and response of the FDA, patients, and consumers*:

A. Reinforce Medical Countermeasures Initiative (MCMi) to Increase Preparedness and Response for Emerging Public Health Threats

Examples: Medical countermeasures, or MCMs, are FDA-regulated products (biologics, drugs, devices) that may be used in the event of a potential public health emergency. The FDA's ……

1. Develop and fully characterize ……. Animal Rule, Accelerated Approval, or Emergency Use Authorization (EUA):
   a. Advance the capability to conduct natural history studies necessary to support MCM development under the Animal Rule, ……
   b. Develop improved in-silico models to extrapolate pharmacokinetic/pharmacodynamic (PK/PD) data from animals to …
   c. Develop, qualify, and/or …and biological …
   d. Identify and qualify biomarkers and immune correlates …;
   e. Develop and qualify in …. of MCMs;
   f. Identify and evaluate biomarkers…… approaches (e.g. omics);
2. *Enhance the agility, quality, and utility of diagnostics and diagnostic data:*
   a. Support enhanced…… real-world evidence (RWE), etc.
   b. Support regulatory …. advanced manufacturing
   c. Support enhanced data agility of data collection using medical devices and through the use of enhanced data collection methods associated with medical products that could be harnessed during public health emergencies

III.A.2.c

3. *Modernize tools to evaluate MCM product safety, efficacy, and quality; and secure the MCM supply chain*
   a. Enhance capabilities …. including:
      i. Develop and refine tools and meth… tory and public health decision making,
      ii. Develop capabilities ….

III.A.3.a.ii

   b. Develop and validate …. diseases;
   ……
   g. Explore novel approaches… ….
4. *Advance the development of tools to enable the rapid development and availability of investigational MCMs*
   a. Develop and validate……. ……
   e. Evaluate methods for… within the U.S
5. *Devices*
   a. Develop …. populations.
6. *Rare Diseases*
   a. Develop ….f underserved populations e.g. neonates, pregnant and lactating women.
7. *Racial and Ethnic Minority Health*
   a.Evaluate strategies for …… treatment options.
8. *Women's Health*
   a. Develop tools …. focus on women.
   b. Assess whether …. of sex differences.

III.A.6.a

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Principal Investigator:	**Affiliations:**
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Between 10/3/2023 to 11/6/2023, has the Offeror submitted an Optional Early Concept Paper for FY24 BAA? Yes/No. **If Yes**, state **Primary Research Area** (i.e, II.B.7.e) and **Status** of previous submission (i.e., Recommended for Stage One Package Submission (BAA Number provided- Highlight revised sections), Not Recommended for Stage One Package Submission, Unknown).	

If Optional Early Concept Paper NOT submitted: NO

If Optional Early Concept Paper submitted: YES

If YES** and Optional Early Concept Paper **recommended for submission**: **Provide primary research area and BAA number

If YES and Optional Early Concept Paper **NOT recommended for submission**: **State primary research area and "Not Recommended"**

* Included in the 3 pages limit

Concept Paper

Concept Paper Overview#

- Research Strategy- Aims, Methods and Considerations
- Regulatory Science Impact
- Proposed Deliverables and Funding

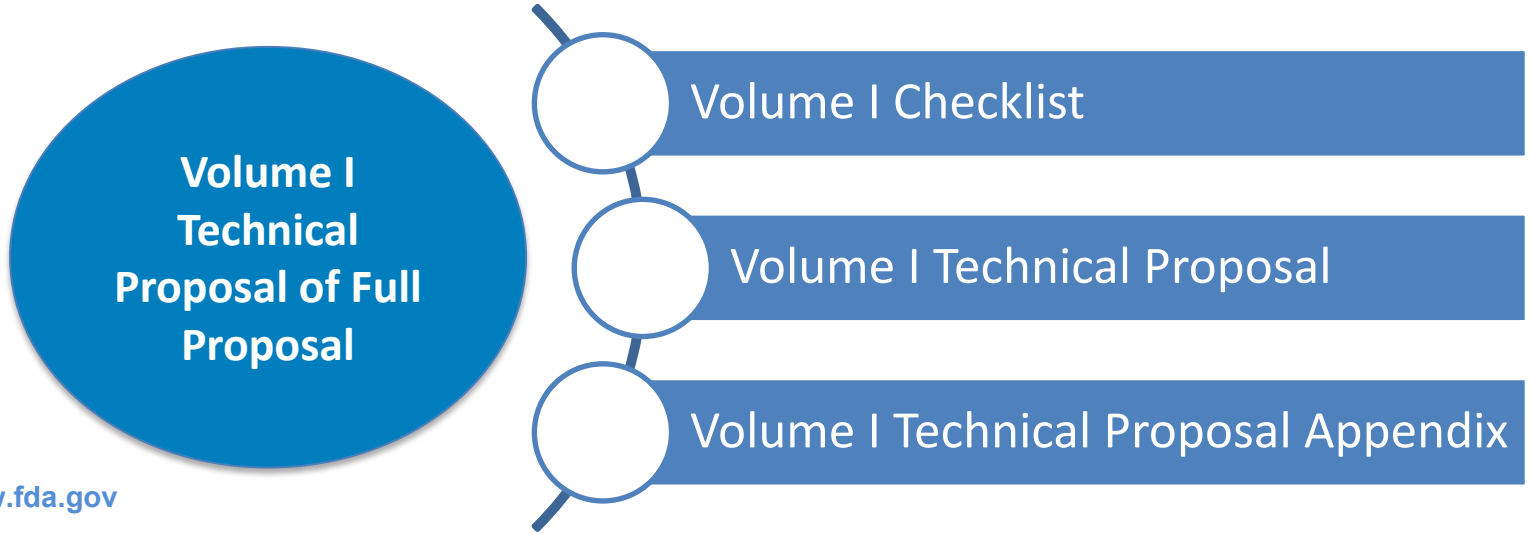
1. **Research Strategy**:
   a. **Aims:** Succinctly list the **specific objectives of the proposed research** (State the problem/objective and provide motivation for addressing that problem/objective) and **primary scientific challenges being addressed**
   b. **Methods:** Clearly **describe the approach, 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)
   c. **Considerations: Brief description of the Offerors intellectual property ownership, data ownership, or licensure; statements on work experience for similar effort with FDA or another agency**
2. **Regulatory Science Impact**
   a. 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 proposed project aligns with the objectives of FDA Regulatory Science
3. **Proposed Deliverables and Funding**
   a. 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.

Milestones	Timeline	Funding
Total Proposed Funding:		

#If FDA recommends a Stage One Package Submission for an Optional Early Concept Paper, a revised concept paper may be submitted, and the submitted version should **highlight** any fields that were revised from the version of the Optional Early Concept Paper.

Full Proposal

- Full Proposal expands on the information provided in the freestanding Concept Paper.
- Full Proposal must be prepared as two separate volumes: **Volume I Technical Proposal** and related Appendices and Volume II Cost Proposal and related Appendices.
- Volume I Technical Proposal: See Part III of the solicitation for preparation details
- See Attachment 5 of the FY24 Solicitation for template (pages 105-111)



Volume I- Technical Proposal of Full Proposal

- **Volume I Technical Proposal** and related Appendices

	Volume I – Technical Proposal Checklist *section included in 50-page limit ^section included in 30-page limit
☐	1. Cover page
☐	2. Official Transmittal Letter
☐	3. Table of contents
☐	4. *Executive Summary
☐	5. *Research and Development Justification
☐	6. *Scientific and Technical Information
☐	7. *Regulatory Science Impact
☐	8. *Resources Proposed
☐	9. *Gantt Chart, Work Breakdown Structure and Milestones
☐	10. *Deliverable Schedule
☐	11. *Risk mitigation plan
☐	12. Security Planning
	13.Intellectual Property
☐	14. Bibliography/References
☐	Appendix
☐	Biographic sketches (required)
☐	Security (if applicable)
☐	Statement of Work (required)
☐	^Intellectual Property (required)
☐	^Contractual Agreements (if applicable)
☐	^Protection of Human Subjects (if applicable)
☐	^Animal Use (if applicable)
☐	^Use of Select Agents (if applicable)
☐	^Regulatory or Compliance Approvals: Laboratory License Requirement (if applicable)
☐	^Regulatory or Compliance Approvals: Good Laboratory Practice (GLP) Compliance (if applicable)
☐	^Regulatory or Compliance Approvals: Good Manufacturing Practices (GMP) Compliance (if applicable)
☐	^Regulatory or Compliance Approvals: Good Clinical Practice (GCP) Compliance (if applicable)
☐	^Regulatory or Compliance Approvals: Paperwork Reduction Act (PRA) (if applicable)

Items 4-11 included in 50 page limit

Included in 30 pages limit

www.fda.gov, slide updated after presentation to reflect FY24 BAA Announcement version 6

Volume I- Technical Proposal

- **Volume I Technical Proposal: Scientific and Technical Information**

6. Scientific and Technical Information:

    a. Overview of the proposal
        i. Introduction and background to discuss (with reference citations) relevant literature to address rationale for research and/or issues or controversies, concise up-to-date status of the field, relevant current context of the study and gaps in current knowledge, significance of the study.
        ii. State all aims, goals, objectives, and proposed outcomes. Discuss hypothesis to be tested and/or research questions to be addressed.
        iii. Degree of innovation of the approach and potential to offer a revolutionary increase in capability after implementation.

➢ Volume I Technical Proposal: Scientific and Technical Information (Continued)

b. Research Methods and Approach: Provide clear and detailed description of overall research method, approach, and/or design, include scientific justification or rationale for the research design, method, and/or approach with reference citations, discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this proposal. Provide clear information and attach supporting material as Appendix for:
    i. Proposed Population, Biospecimens, and/or data such as study population; type and source; exclusion and inclusion criteria; time points for exposure and measurements; endpoints; dosing and administration with justification; recruitment, retention, and follow-up strategies; screening procedures; details for preparation, handling, storage, accountability, formulation, packaging, storage, and/or stability.
    ii. Proposed assessments, evaluations, and/or procedures such as statistical considerations (sample size and determination rationale, hypotheses, statistical analysis plan); measures for bias minimization; validation; quality control; data collection; safety assessments
    iii. Proposed regulatory, operational, and/or safety considerations such as informed consent; confidentiality and privacy; safety oversight; quality assurance, control, and monitoring; specimens and/or data management (collection, storage, access, sharing, handling, disposition, record keeping); plan for seeking approvals (e.g., IRB, PRA); compliance statements (GMP, GCP, GLP)

Volume I- Technical Proposal

- **Volume I Technical Proposal: Regulatory Science Impact**

7. Regulatory Science Impact:

    a. Relevance to the BAA program regulatory research areas of interest indicated in Table 1: Explain research alignment with the priorities and relevant scientific initiatives at FDA, benefits of proposed technology and challenges.

    b. Impact: Describe regulatory impact of research proposed. How does this research address an unmet need or fill a critical knowledge gap to advance FDA regulatory science? How might FDA apply the research findings towards advancement of regulatory research?

Volume I- Technical Proposal

- **Volume I Technical Proposal: Resources Proposed**

8. Resources Proposed:

   a. Personnel with role, responsibilities, field of expertise, expectations, experience overview, and efforts. Provide list of key personnel. Attach resumes and CV as appendix
   b. Licensure and agreements with sub-contractors, collaborators, and/affiliations proposed to work on the project, nature of agreements (Service Level Agreements, Letter of Intent, and/or any other formal agreements showing commitment for research participation). Provide details in appendix.
   c. Requirement for any regulatory or compliance approvals (IRB, PRA, MTA, etc.). Provide details in appendix.
   d. Communication management plan with ways of communication, frequency of communication, stakeholders identified for communication, extent of collaboration intended with FDA subject matter experts, research dissemination and information sharing, publications.

Dates to Remember

Due Date	Description	Outcome
02/20/2024	Stage One package submission *	Begin review for FY24 funding consideration
02/21/2024-09/20/2024	Stage One package submission *	Marked as late submissions and may be considered for FY25 funding

*Submissions in PDF format only and email (attachments in same email) to FDABAA@fda.hhs.gov by 11:59 pm, Eastern Standard Time. Stage One package submission includes:

1. Checklist- attachment 3
2. Freestanding Concept Paper- attachment 4
3. Freestanding Full Proposal- Part III for details

Steps to Remember

Description	Email Subject Line	Outcome
Optional Early Concept Paper Recommended for Stage One Package Submission	BAA Number_Concept Paper with Full Proposal" in pdf format (**highlight** any revised fields of the Concept Paper)	Begin review of Full Proposal
New Submission *	Charge Area_FDABAA-24-00123 Concept Paper with Full Proposal	Conduct high-level review of Concept Paper

*and/or Optional Early Concept Paper NOT Recommended for Stage One Package Submission with revisions

Contact FDABAA@fda.hhs.gov for any additional questions or clarifications