FY24 Broad Agency Announcement (BAA) Application Process

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BAA Day

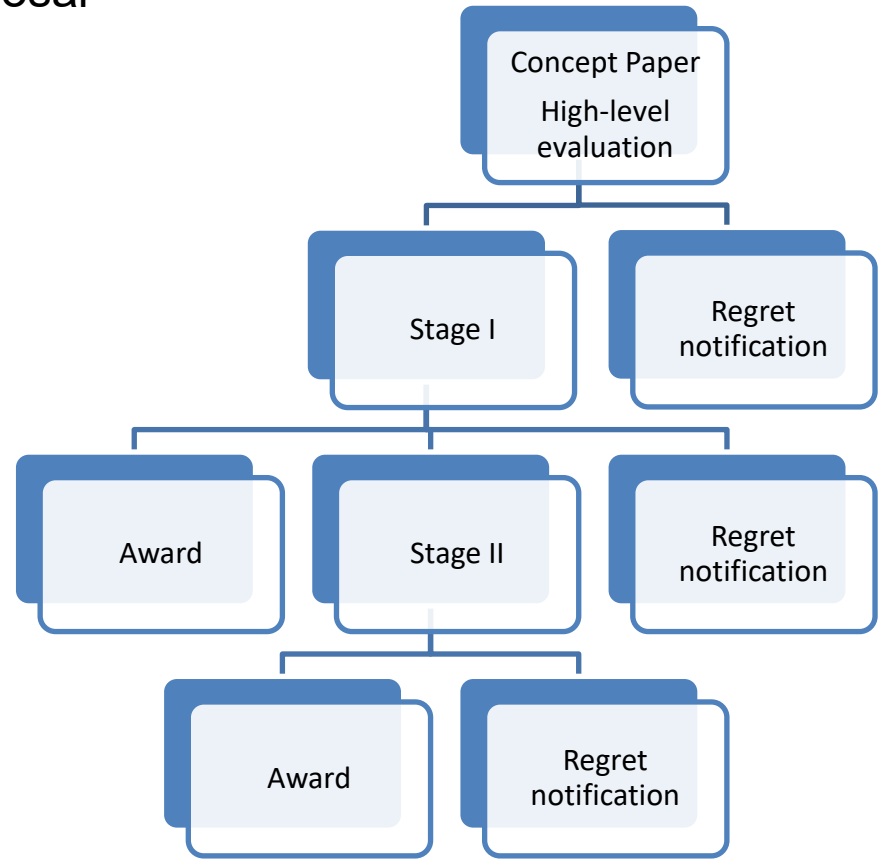
October 25, 2023

Overview

- Application process overview
- Application process updates
- Concept Paper
- Technical Proposal

BAA Application Process Updates

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



BAA Application Process Updates

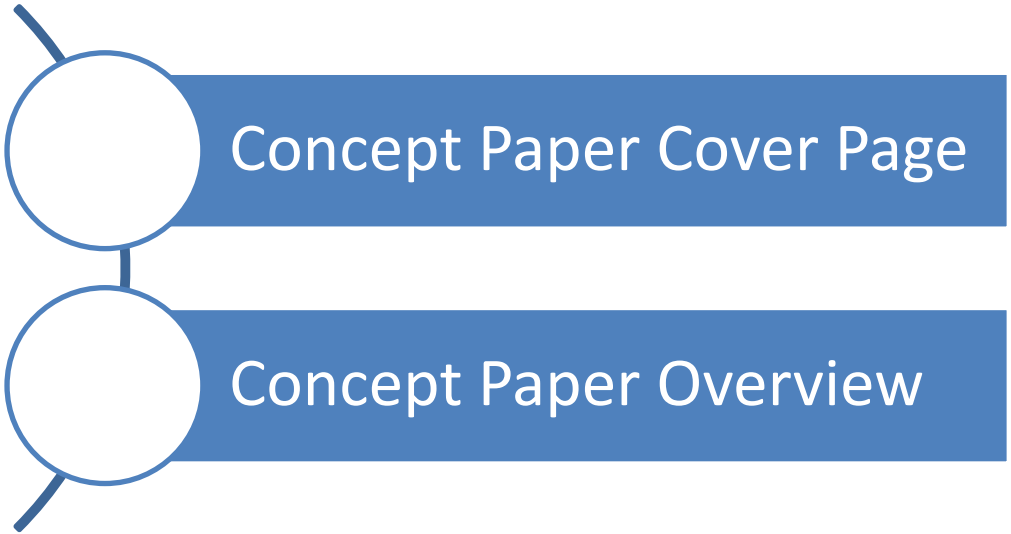
- All submission require a freestanding Concept Paper and freestanding Full Proposal

Process	Past	Current
High-Level Evaluation	Quad Chart	Concept Paper
Stage I	White Paper	Full Proposal
Stage II	Full Proposal	Revised Full Proposal (as needed)

- **Optional Early** Concept Paper

Concept Paper

- Concept Paper will be evaluated to conduct a High-Level review to determine potential program alignment with FDA priorities and mission
- See Attachment 4 of the FY24 Solicitation
- Optional Early Concept Paper



Concept Paper

Concept Paper Cover Page*

- 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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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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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		

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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		

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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
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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		

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						

www.fda.gov

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 met ... latory 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.

III.A.6.a

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.

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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:		

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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.

Full Proposal

- **Volume I Technical Proposal** and related Appendices
- See Attachment 5 of the FY24 Solicitation

	Volume I – Technical Proposal Checklist	
☐	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)
	☐	Intellectual Property (required)
	☐	Statement of Work (required)
	☐	Protection of Human Subjects (if applicable)
	☐	Animal Use (if applicable)
	☐	Use of Select Agents (if applicable)
	☐	Laboratory License Requirement (if applicable)
	☐	Security (if applicable)
	☐	Good Laboratory Practice (GLP) Compliance (if applicable)
	☐	Good Manufacturing Practices (GMP) Compliance (if applicable)
	☐	Good Clinical Practice (GCP) Compliance (if applicable)

Dates to Remember

Due Date	Description	Outcome
11/6/2023	Optional Early Concept Paper Submission	Communicate Recommend/Do Not Recommend stage I package submission
01/12/2024	Last date for FDA to post any amendments to the FY24 BAA solicitation	Communicate updated funding priorities for FDA
02/19/2024	Stage I package submission	Begin review for FY24 funding


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