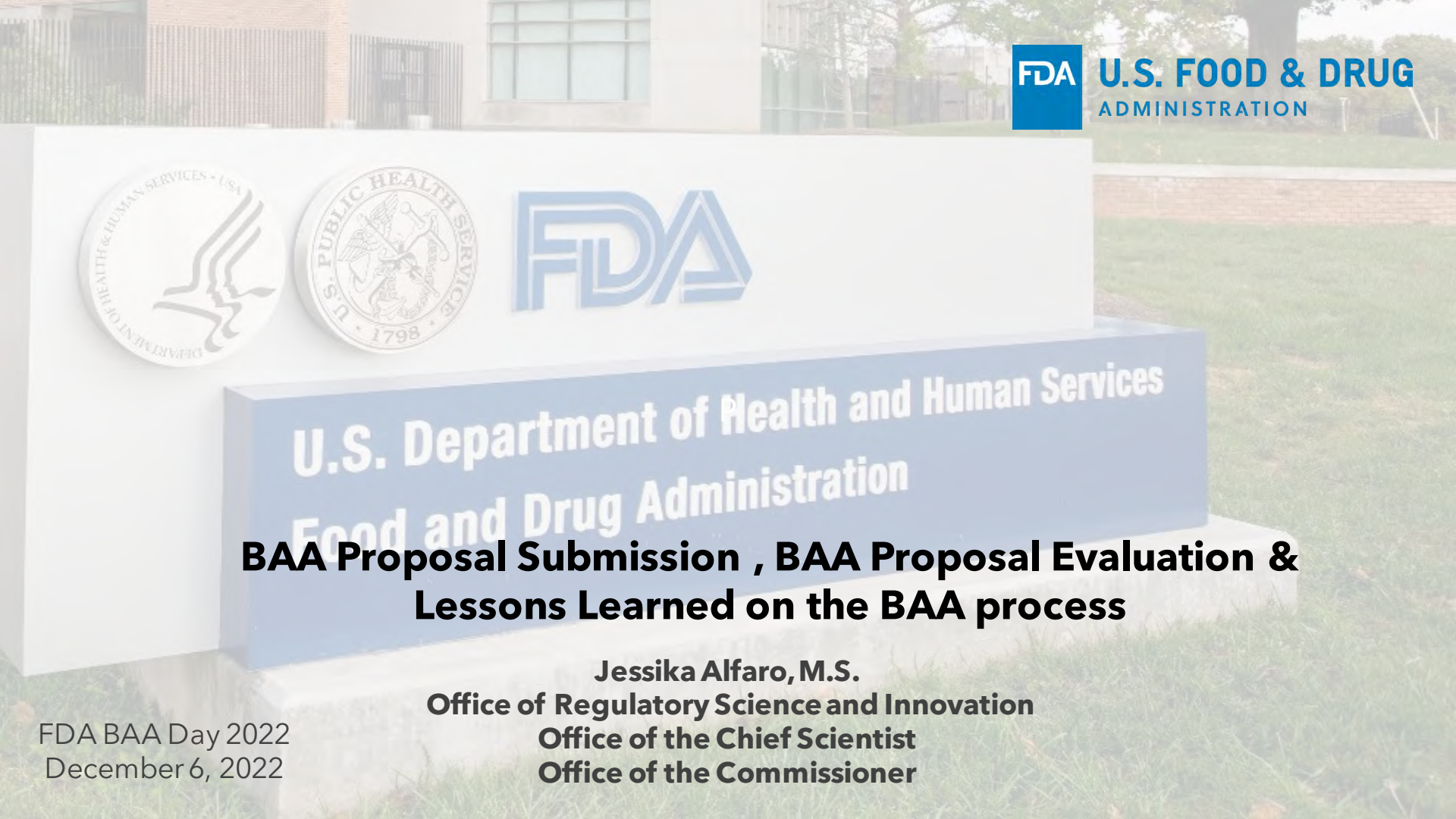


BAA Proposal Submission , BAA Proposal Evaluation & Lessons Learned on the BAA process

Jessika Alfaro, M.S.
Office of Regulatory Science and Innovation
Office of the Chief Scientist
Office of the Commissioner

FDA BAA Day 2022
December 6, 2022

Presentation Outline

1. BAA proposal submission
2. BAA Proposal Evaluation
3. BAA lessons learned

FY23 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission

Link to BAA solicitation FY23

- BAA is an open announcement
- For FY23 funding consideration white papers are due **January 23, 2023, 5:00PM Eastern Time**

Prospective Offerors are encouraged to submit **Stage I (White Paper & Quad Chart)** Submittal Packages with:

1. Cover Page (**1 page**)
2. Freestanding Quad Chart (**1 page**)
3. Freestanding White Paper aligned with the following (please assign the most closely aligned from each below if your proposal is applicable to more than one) (**up to 10 pages**)

   Update

   - Charge Area (i.e., I. modernize development and evaluation of FDA regulated products)
   - Regulatory Science Topic Area of Interest (i.e., A. Alternative Methods)
   - FDA Regulated Areas (i.e., Biologics) and/or Demographics and Populations (i.e., Racial and Ethnic Minority)
4. R&D justification (**1 page**)

FY23 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA Solicitation Update

Major Updates

✓ Research Area of Interest

BAA Regulatory Science Categories
Area 1: Modernize Toxicology to Enhance Product Safety
Area 2: Stimulate Innovation in Clinical Evaluation & Personalized Medicine to Improve Product Development and Patient Outcomes
Area 3: Support New Approaches to Improve Product Manufacturing and Quality
Area 4:Ensure FDA Readiness to Evaluate Emerging Technologies
Area 5: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security
Area 6: Harness Diverse Data through Information Sciences to Improve Health Outcomes
Area 7: Implement a New Prevention-Focused Food Safety System to Protect Public Health
Area 8: Strengthening Social and Behavioral Science at FDA by Enhancing Audience Understanding
Area 9: Strengthening the Global Product Safety Net

✓ Charge

I. Modernize development and evaluation of FDA-regulated products
A. Alternative Methods
B. Advanced Manufacturing Approaches
C. Analytical and Computational Methods
D. Biomarkers
E. Clinical Outcome Assessment
F. Complex and Novel Clinical Trial Design
G. Predictive Toxicology
H. Methods for Assessing Behavioral, Economic, or Human Factors
I. Approaches to Incorporate Patient and Consumer Input
J. Methods to Assess Real-World Data to serve as Real-World Evidence
K. Methods to Assess Data Source Interoperability

II. Strengthen post-market surveillance and labeling of FDA-regulated products
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making
B. Using and Validating Artificial Intelligence Approaches
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods
D. Automated Reporting Tools for Adverse Events and Active Surveillance
E. Methods to Improve Communication About Risk to Patients and Consumers
F. Approach to Expand Data Capacity, and Increase Data Quality and Use
G. Efforts to Harmonize Existing and Emerging Data Standards

III. Invigorate public health preparedness and response of the FDA, patients, and consumers
A. Reinforce Medical countermeasures Initiative (MCMi)
B. Antimicrobial Resistance
C. Patient and Consumer Engagement
D. Substance Use and Misuse
E. One Health Approaches
F. Global Product Safety net

FY23 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

Anticipated FY23 Funding for BAA Projects	FDA-Regulated Areas					Demographics & Populations			
	Biologics	Devices	Drugs	Veterinary Medicine	Tobacco Products	Racial and Ethnic Minority	Women's Health	Rare Diseases	Oncology
I. Modernize development and evaluation of FDA-regulated products									
A. Alternative Methods	X	X	X	X	X		X	X	X
B.Advanced Manufacturing Approaches (includes MCMi)	X	X	X						X
C. Analytical and Computational Methods	X	X	X		X	X	X	X	X
D. Biomarkers		X	X		X		X	X	X
E. Clinical Outcome Assessment		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		
H. Methods for Assessing Behavioral, Economic, or Human Factors			X						
I. Approaches to Incorporate Patient and Consumer Input		X						X	X
J. Methods to Assess Real-World Data to serve as Real-World Evidence	X	X	X				X	X	X
K. Methods to Assess Data Source Interoperability		X							
II. Strengthen post-market surveillance and labeling of 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		X		
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods		X	X						X
D. Automated Reporting Tools for Adverse Events and Active Surveillance	X	X	X				X		X
E. Methods to Improve Communication About Risk to Patients and Consumers		X	X				X		
F. Approach to Expand Data Capacity, and Increase Data Quality and Use		X				X			
G. Efforts to Harmonize Existing and Emerging Data Standards		X	X				X		
III. Invigorate public health preparedness and response of the FDA, patients, and consumers									
A. Reinforce Medical Countermeasures Initiative (MCMi)	X	X	X			X	X	X	
B. Antimicrobial Resistance			X						
C. Patient and Consumer Engagement		X	X			X	X		
D. Substance Use and Misuse		X	X		X				
E. One Health Approaches	X	X	X	X	X	X	X	X	X
F. Global Product Safety net	X	X	X						

REGULATORY SCIENCE FRAMEWORK – (Pg. 5*)

Please assign the most closely aligned from each below if your proposal is applicable to more than one –

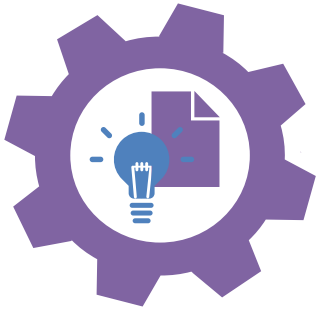
- **Charge Area**
  - (i.e., I. modernize development and evaluation of FDA regulated products)
- **Regulatory Science Topic Area of Interest**
  - (i.e., A. Alternative Methods)
- **FDA Regulated Areas**
  - (i.e., Biologics)

  and/or
- **Demographics and Populations**
  - (i.e., Racial and Ethnic Minority)

*FY23 BAA Announcement

FY23 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission Continued



Part III: Proposal Preparation and Submission,
Staring on Pg. 39*

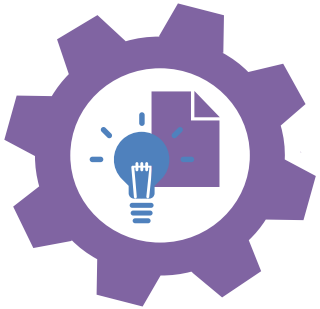
Section 1: The application process, Pg. 39*
Section 2: Stage 1 Quad Chart and White paper, Pg. 39*
Section 3: Quad Chart and White Paper Submission, Pg. 40*

Attachment 3: Quad Chart and white paper format template, found on page 63*
Attachment 4: Research and Development Justification, found on page 64*

*FY23 BAA Announcement

FY23 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission Continued



Part III: Proposal Preparation and Submission, Staring on Pg. 39*

Section 4: Stage II Full Proposal Submission, Pg. 41*
Section 5: Full Proposal Submission, Pg. 57*
Section 6: General information, Pg. 58*

Section 4: Stage 2 Full Proposal Preparation, Starting on Pg. 41

1. Cover Page
2. Official Transmittal Letter
3. Table of contents
4. Executive Summary
5. Introduction – Overview of the project.
6. Statement of Work (SOW)
7. Gantt Chart, Work Breakdown Structure and Milestones
8. Deliverable Schedule
9. Security Planning
10. Intellectual Property
11. Biographical Sketches
12. Volume I Appendices
13. Volume II Cost Proposal
14. Volume II Cost Proposal Appendices
15. Representation and Certification
16. Studies that involve Human Subjects
17. Animal Welfare

etc.

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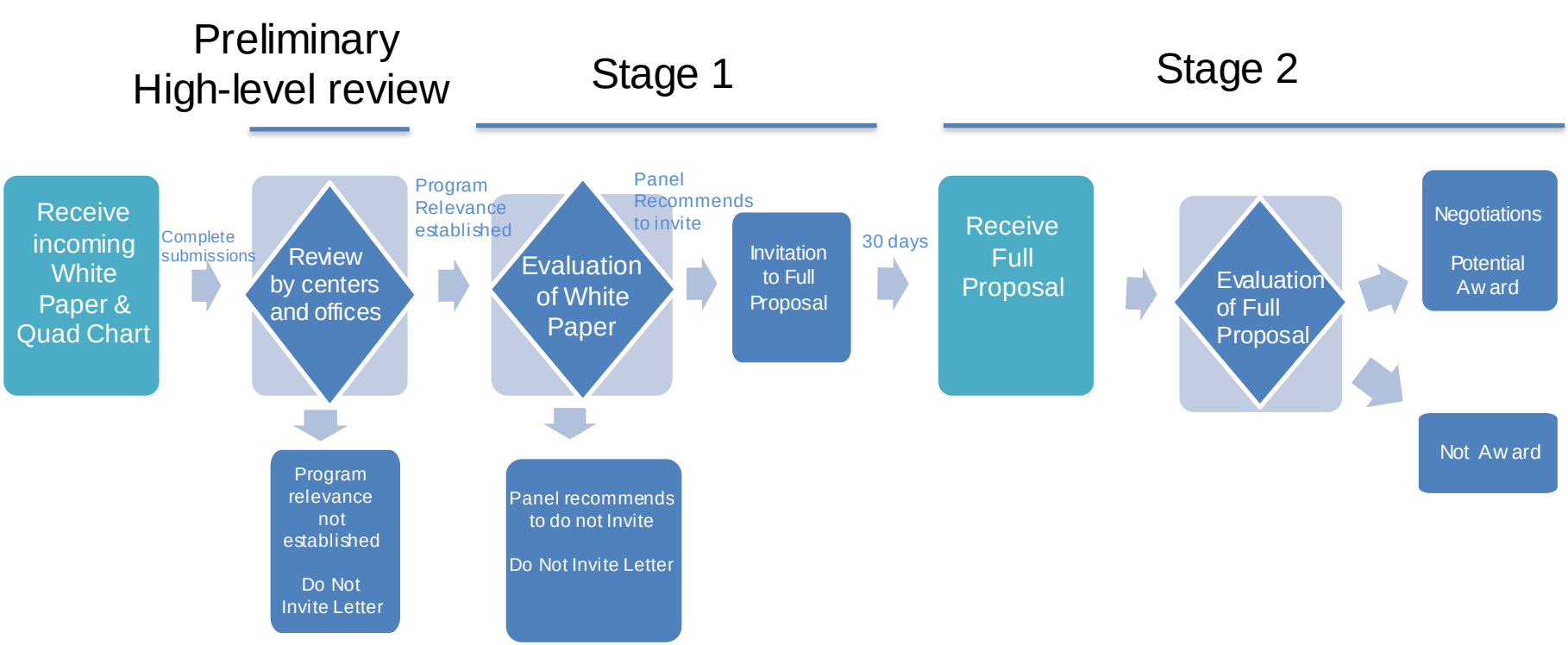
BAA Proposal Evaluation

Evaluation Points At Stage I & Stage II



Evaluation Points At Stage I & Stage II

Preliminary
Review of the proposal package for completion

Receive incoming White Paper & Quad Chart

complete submission moves forward to be reviewed by centers and offices

Incomplete submission

Prospective Offerors are encouraged to submit Stage One Submittal Packages with:
(Part III: Proposal Preparation and Submission, staring on Pg. 39*)

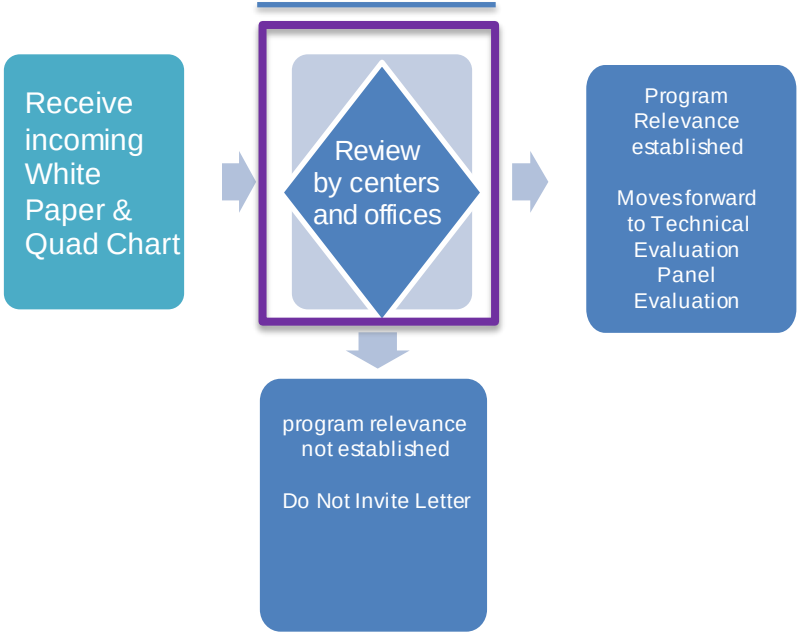
1. Cover Page (**1 page**)
2. Freestanding Quad Chart (**1 page**)
3. Freestanding White Paper aligned with the following (please assign the most closely aligned from each below if your proposal is applicable to more than one) (**up to 10 pages**)
   - •Charge Area (i.e., I. modernize development and evaluation of FDA regulated products)
   - •Regulatory Science Topic Area of Interest (i.e., A. Alternative Methods)
   - •FDA Regulated Areas (i.e., Biologics) and/or Demographics and Populations (i.e., Racial and Ethnic Minority)
4. R&D justification (**1 page**)

****A submission will be considered incomplete if any of these critical elements are missing**

*FY23 BAA Announcement

Evaluation Points At Stage I & Stage II

Preliminary
High-level review



Evaluation Points At Stage I & Stage II

Stage 1

Evaluation of White Paper

The following criteria are in descending order of importance (Sub-criteria listed under a particular criterion are of equal importance):

Starting on pg. 59*: Part IV: Proposal Evaluation

1. **Scientific and Technical Merit**
2. **Program Relevance**
3. **Capabilities and Experience**

*FY23 BAA Announcement

Evaluation Points At Stage I & Stage II

Section 4: Stage 2 Full Proposal Preparation, Starting on Pg. 41*

1. Cover Page
2. Official Transmittal Letter
3. Table of contents
4. Executive Summary
5. Introduction – Overview of the project.
6. Statement of Work (SOW)
7. Gantt Chart, Work Breakdown Structure and Milestones
8. Deliverable Schedule
9. Security Planning
10. Intellectual Property
11. Biographical Sketches
12. Volume I Appendices
13. Volume II Cost Proposal
14. Volume II Cost Proposal Appendices
15. Representation and Certification
16. Studies that involve Human Subjects
17. Animal Welfare

etc.

Stage 2

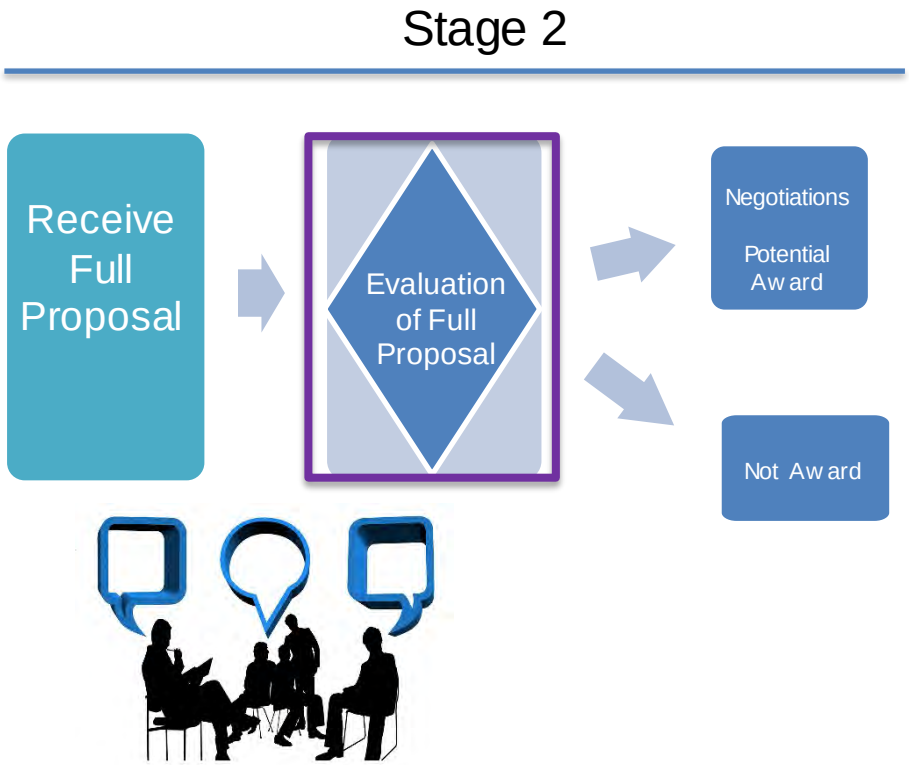
Receive Full Proposal

*FY23 BAA Announcement

Evaluation Points At Stage I & Stage II

The following criteria are in descending order of importance (Sub-criteria listed under a particular criterion are of equal importance):
Starting on Pg. 59*

1. **Scientific and Technical Merit**
2. **Program Relevance**
3. **Capabilities and Experience**



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BAA Lessons Learned

BAA Lessons Learned

Quad Chart

Follow Quad Chart Format Template	Concise, direct & consistent	Freestanding Quad chart

BAA Lessons Learned Continued

White Paper

Meaningful detail proposed work within the 10-page limit	Figures/Graphs	Background information limit to 1-2 pages	Proofread White paper	Consistent language	Provide information of previously awarded FDA contracts	Discourage to resubmit same proposal within the same fiscal year

BAA Lessons Learned Continued

Full Proposal

Address comments made by the review panel in the invite letter and provide additional clarity	Concise, direct & consistent	Include technical diagrams or graphical workflows for complex designs/processes	Describe the proposed work's applicability to the stated Charge & Topic Area & Relevance to FDA's goals and mission	Encourage to provide a risk management plan for overcoming potential challenges and scientific barriers	Provide Past awards contract information

Acknowledgements

- Thushi Amini, CDER/OND
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- Ellen Pinnow, CDER/OSE
- Vaibhau Kumar, CDER/OND
- Sam Raney, CDER/OGD
- Shaila Shaheed, OC/OCS/ORSI
- Ross Walenga, CDER/OGD
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