FDA Broad Agency Announcement (BAA) Overview and Updates

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BAA Day

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Overview

- Purpose and summary of FDA BAA
- Snapshot of FY24 FDA BAA Applications
- Optional Early Concept Papers
- Amendments
- FY25 Application process Do’s and Don’ts
- Due Dates & Timelines
- FAQs

FDA Broad Agency Announcement

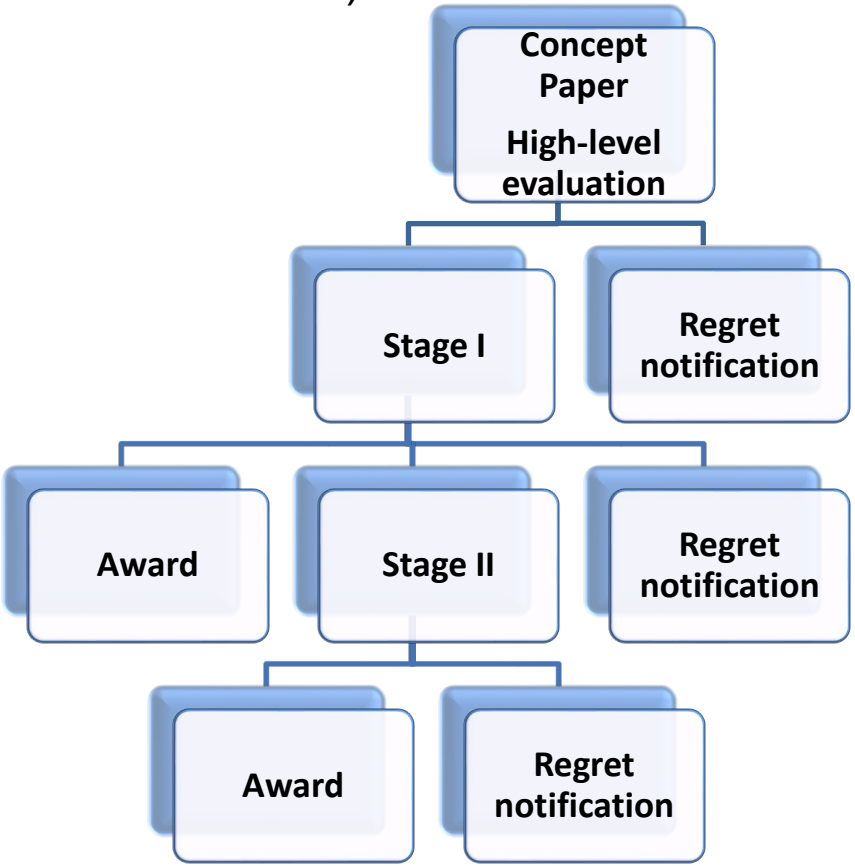
- FDA has been soliciting proposals to advance regulatory research areas through a specialized contract mechanism known as FDA's Broad Agency Announcement (BAA)
- FDA BAA Webpage: Regulatory Science Extramural Research and Development Projects | FDA
- BAA as described in the Federal Acquisition Regulations (FAR), may only be issued for the procurement of Research and Development (R&D).
  - Basic research FAR 2.101(b)(2)
  - Applied research FAR 35.001
  - Development FAR 35.001

FDA BAA Summary 2014-2024

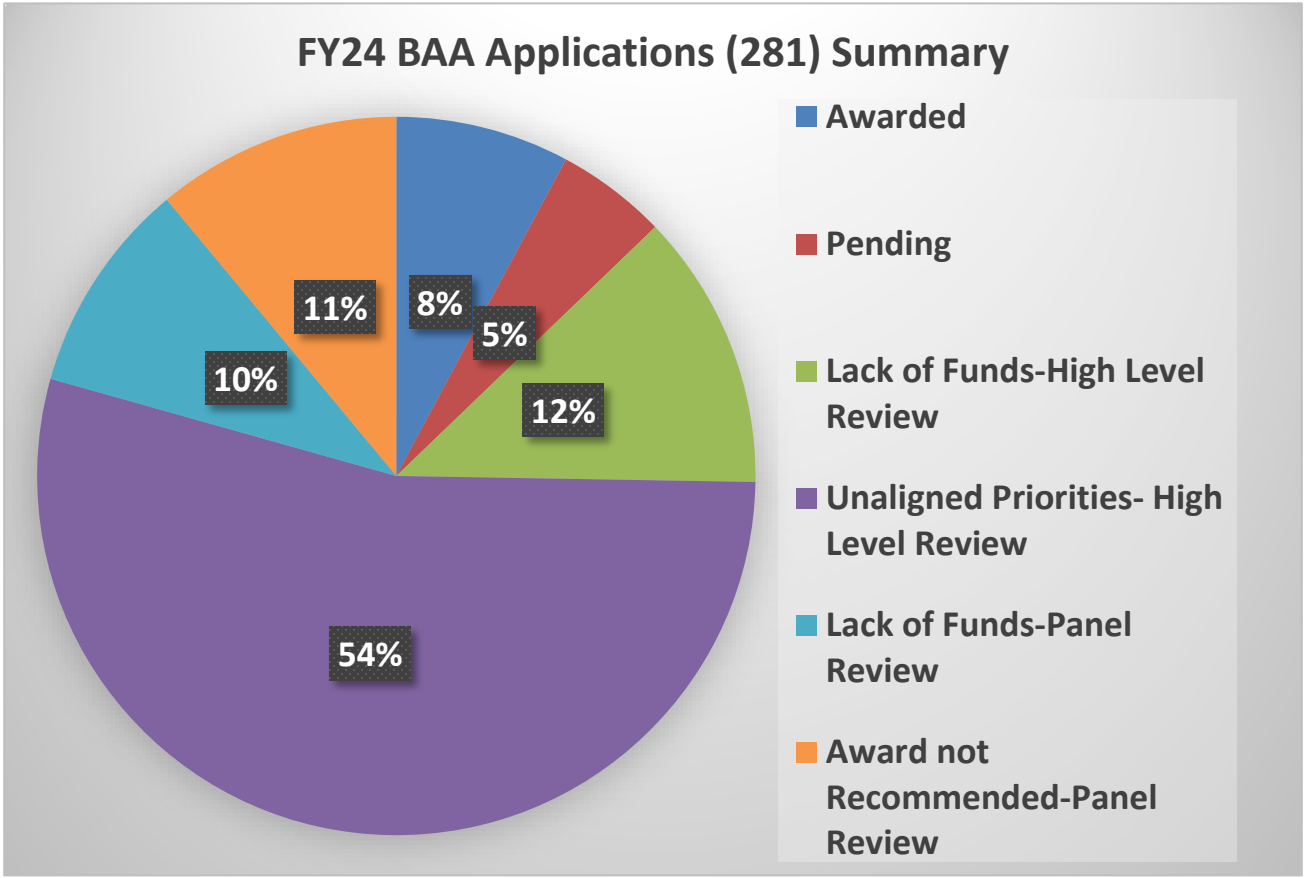
Fiscal Year	Applications Received	Awarded	Fiscal Year Total	Minimum	Maximum
2024	281	24	$24,597,676	$243,473	$2,982,375
2023	264	39	$26,606,697	$119,006	$2,949,902
2022	181	45	$142,495,425	$100,000	$82,182,000
2021	192	45	$46,112,948	$63,081	$5,000,001
2020	196	48	$55,289,690	$54,500	$11,106,465
2019	165	53	$55,266,341	$16,065	$5,500,000
2018	159	39	$28,230,766	$30,404	$5,733,684
2017	160	26	$29,315,334	$42,000	$2,492,907
2016	86	29	$25,272,636	$103,000	$4,400,000
2015	92	34	$24,055,857	$20,726	$4,288,633
2014	87	28	$20,651,357	$62,178	$4,911,531

BAA Application Review Process

- All submissions require a freestanding Concept Paper and freestanding Full Proposal (Part III of announcement)



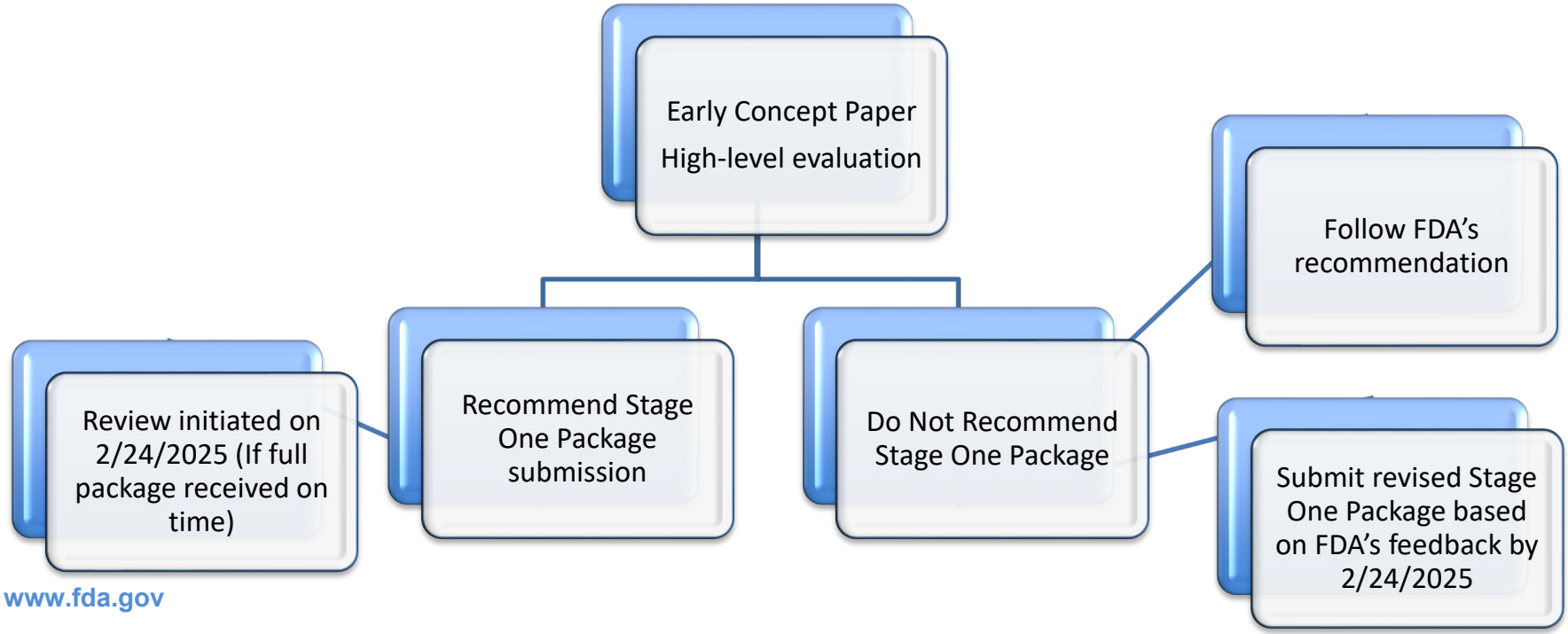
Snapshot of FY24 BAA



- Receipt acknowledgement sent within one week of application received
- Applicants informed about outcome by September 30th 2024
- Pending applications to receive decision by December 6th 2024

Optional Early Concept Papers

- FDA's recommendation for interest or lack of interest of Stage One Package submission. FDA's feedback for early Concept Paper is OPTIONAL.
- **Submission is NOT needed as a qualification step for consideration of a Stage One Package for FY25 BAA Applications**



FY25 Optional Early Concept Papers

- **Received 208 Optional Early Concept Papers by 11/8/2024**
- FDAs Recommendation for Early Concept Papers will be notified on 12/16/2024

I. Modernize development and evaluation of FDA-regulated products (135)	
A. Alternative Methods	12
B. Advanced Manufacturing Approaches	47
C. Analytical and Computational Methods	30
D. Biomarkers	14
E. Clinical Outcome Assessment (COA)	6
F. Complex and Novel Clinical Trial Design	5
G. Predictive Toxicology	3
H. Methods for Assessing Behavioral, Economic, or Human Factors	3
I. Approaches to Incorporate Patient and Consumer Input	4
J. Methods to Assess Real-World Data to serve as Real-World Evidence	10
K. Methods to Assess Data Source Interoperability	1

II. Strengthen post-market surveillance and labeling of FDA-regulated products (35)	
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	16
B. Using and Validating Artificial Intelligence Approaches	9
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	0
D. Automated Reporting Tools for Adverse Events and Active Surveillance	4
E. Methods to Improve Communication About Risk to Patients and Consumers	2
F. Approach to Expand Data Capacity, and Increase Data Quality and Use	2
G. Efforts to Harmonize Existing and Emerging Data Standards	2

III. Invigorate public health preparedness and response of the FDA, patients, and consumers (38)	
A. Reinforce Medical Countermeasures Initiative to Increase Preparedness and Response for Emerging Public Health Threats	3
B. Antimicrobial Resistance	3
C. Patient and Consumer Engagement	15
D. Substance Use and Misuse	4
E. One Health Approaches	2
F. Strengthen Global Product Safety Net	2
G. Emerging Technologies	0

Amendments to BAA

- Communicate updated funding priorities for FDA
- Potential dates for posting amendments to this announcement are 11/15/2024; 11/29/2024; 12/13/2024; 12/27/2024; 1/17/2025.
- Any amendments posted to the announcement will be highlighted and indicated with #
- Last date for FDA to post any amendments to the FY25 BAA solicitation is 1/17/2025
- #Amendments

11/15/2024: Added scope to #I.A.5.a, #III.D.1.i, and #III.E.2.a; Updated Table 1 to include Veterinary Medicine related priority research areas.

FY25 Application process Do's and Don'ts

Do	Don't
Submit all required documents for **Stage One Package (Checklist, Concept Paper, Full Proposal)**	Submit applications without full proposal, cost proposal, and/or statement of work
Submit PDF documents only for required files	Submit word or excel files for required documents
Contact FDABAA.fda.hhs.gov or BAA contracting Officer for any questions or clarifications	Contact any other FDA staff
Complete all fields of the Concept Paper (Cover Table and Overview; attachement 4) and Full Proposal (See attachment 5 for Volume I- Technical Proposal)	Exceed page limits

Take Home Information

Due Date	Description
12/16/2024	FDAs Recommendation notification to applicants for Early Concept Papers
01/17/2025	Last date for FDA to post any amendments to the FY25 BAA solicitation
02/24/2025	Stage I package submission due for FY25 funding consideration
03/06/2025	Application receipt acknowledgement notification
04/07/2025	Regret notification for applications not moving forward for Stage I review
14-calendar days	Stage II Revised Full Proposal Submittal Package request from FDA
09/30/2025	Decision notification for applications moving forward for Stage I/II review
2/25/2025-9/20/2025	Rolling Stage I package submission for FY26 funding consideration
12/01/2025	Decision notification for pending applications moving forward for Stage I/II review

BAA FAQs

- Is Optional early concept paper required step for FY25 BAA application consideration? **No**

- Is Concept paper required for stage one application? **Yes, concept paper is a REQUIRED document for stage one package (irrespective of optional early concept paper submission, submission for FY25-by 2/24 or FY26-after 2/24 funding consideration)**

- Does the 3-page limit for concept paper include cover table and overview? **Yes, the 3-page includes cover table and overview. Attachment 4 is the template for Concept Paper submissions (Optional or Required)**

- Can a previously submitted concept paper be revised? **Title , charge area, and regulatory science area fields CANNOT be revised. Any revisions need to be highlighted.**

BAA FAQs (Continued)

- Full proposal required for stage one application? **Yes, Full Proposal is a REQUIRED document for stage one package (irrespective of Stage One application recommendation, submission for FY25-by 2/24 or FY26-after 2/24 funding consideration)**

- Is volume II-cost proposal a required document for stage one application? **Yes**

- Can government employees collaborate and contribute to proposal development? **No. Please request the government employee to check with their Ethics office.**

- What is the average timeline to receive an application acknowledgement? **5 business days from date of submission or due date.**

- Is the review process for applications received after 2/24/2025 different? **No, the review process is the same. These applications will be reviewed after the review of applications received by 2/24/2025 have been initiated.**

Upcoming BAA Q&A Session

- FY25 FDA Broad Agency Announcement Question and Answer Session will be hosted on January 16th, 2025 from 1:00 PM- 4:00 PM Eastern Standard Time

- **Registration information will be provided by December 2nd, 2024**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