

Funding Opportunity: FDA Releases Updated BAA for Advanced Research and Development of Regulatory Science

Lewis-Burke Associates LLC – January 12, 2026

The U.S. Food and Drug Administration (FDA) has released an updated Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science. The BAA is a specialized contract mechanism used by the agency to solicit and fund extramural research concerning high-priority topics of concern to FDA's public health mission. For fiscal year (FY) 2026, FDA is soliciting both basic and applied research proposals on the following research topics:

1. Modernize development and evaluation of FDA-regulated products

- New Approach Methodologies
- Advanced Manufacturing Approaches
- Analytical and Computational Methods
- Biomarkers
- Clinical Outcome Assessment
- Complex and Novel Clinical Trial Design
- Predictive Toxicology
- Methods for Assessing Behavioral, Economic, or Human Factors
- Approaches to Incorporate Patient and Consumer Input
- Methods to Assess Real-World Data (RWD) to serve as Real-World Evidence (RWE)
- Methods to Assess Data Source Interoperability

2. Strengthen post-market surveillance and labeling of FDA-regulated products

- Methods to Assess Real-World Data to Support Regulatory Decision-Making
- Using and Validating Artificial Intelligence Approaches
- Novel Clinical Trial Design, Statistical and Epidemiologic Methods
- Automated Reporting Tools for Adverse Events and Active Surveillance Methods to Improve Communication About Risk to Patients and Consumers

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

- Medical Countermeasures (MCMs)
- Antimicrobial Resistance
- Substance Use and Misuse
- Global Product Safety net
- Emerging Technologies

To apply for FY 2026 funding under this BAA, applicants must submit both a freestanding Concept Paper and freestanding Full Proposal by the application deadline. Per FDA, “Offerors whose freestanding Concept Paper receives a favorable high-level evaluation will have their Full Proposal evaluated by a panel of subject matter experts (technical evaluation panel).”

Eligibility: This opportunity is open to “all responsible sources,” including single entities, small businesses, teams from other private sector organizations, Federally Funded Research and Development Centers, and academic institutions.

Total Funding and Award Size: FDA has not placed a limit on the number and size of research and development (R&D) contracts that will be awarded as part of the BAA mechanism. Total FY 2026 BAA funding availability will depend on the research budgets of individual FDA centers and offices, and resulting R&D contracts will be able to support projects for up to five years. In the FY 2025 BAA cycle, FDA obligated over \$14.3 million for projects, with the largest individual project being funded at approximately \$3.1 million.

Due Date: Both the freestanding Concept Papers and freestanding Full Proposals are due by **February 24, 2026**, at 5:00pm ET. FDA highly encourages early applications.

Virtual Events: On **January 20**, from 1:00pm-4:00pm ET, FDA is hosting a virtual event to answer BAA questions from potential applicants. Interested parties can register here:
<https://www.fda.gov/science-research/advancing-regulatory-science/2026-fda-broad-agency-announcement-day-01202026>

Additionally, on **January 21**, from 1:00pm-2:30pm ET, FDA is hosting a virtual event to answer questions specifically from academic researchers and other research organizations on BAA proposals involving generic drugs. Interested parties can join the event here:
<https://www.fda.gov/drugs/news-events-human-drugs/fda-information-session-generic-drug-research-needs-opportunities-fy-2026-01212026>

Sources and Additional Information:

- The full FY 2026 BAA is available here:
<https://sam.gov/workspace/contract/opp/fc0fe580a8224192850fdb5f2ac40c4e/view>
- General information on FDA's FY 2026 BAA process is available here:
<https://www.fda.gov/science-research/advancing-regulatory-science/regulatory-science-extramural-research-and-development-projects>