FDA BAA Program Overview

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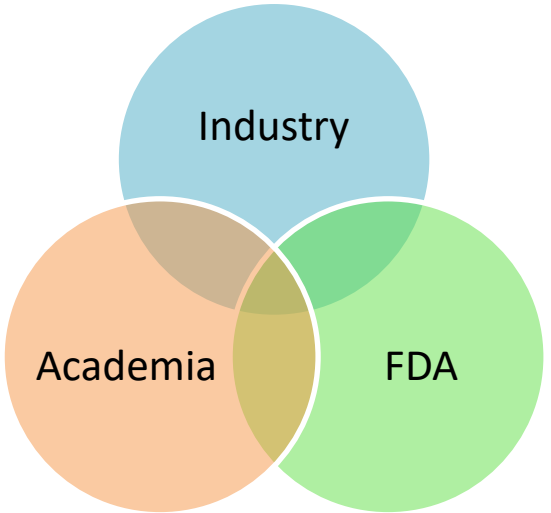
Presentation Topics

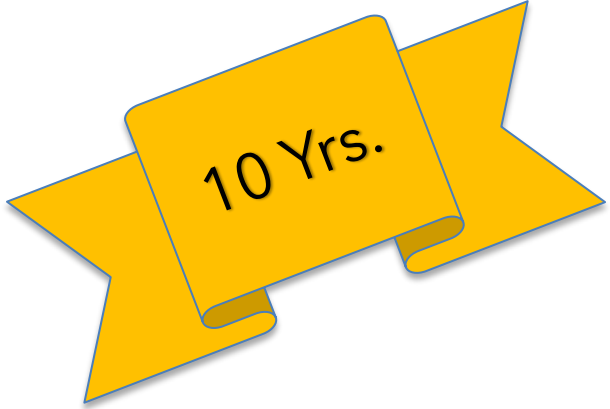
- Background
- BAA and RFP
- BAA and CERSI
- Solicitation Update
- Review Process
- Evaluation Criteria
- FY2023 Timeline
- Programmatic updates
- Outcome of Interest
- Success Story

What is a BROAD AGENCY ANNOUNCEMENT (BAA)?

Broad Agency Announcement (BAA) which sets forth research areas of interest for the Food and Drug Administration, is issued under FAR 35.016(c) of the Federal Acquisition Regulation (FAR)

BAA makes it possible for us to solicit innovative ideas and approaches by tapping into external knowledge and infrastructure in areas where FDA has limited expertise or capacities





Background

FDA BAA was launched in 2012 to advance and promote regulatory science within specified research areas of interest highlighted in the BAA solicitation

It is an extramural R&D contract mechanism for which FDA accepts whitepapers from any science and technology-based firms as well as academia within and outside of the country

BAA solicitation announcement is renewed on an annual basis to reflect FDA's scientific priorities for extramural research

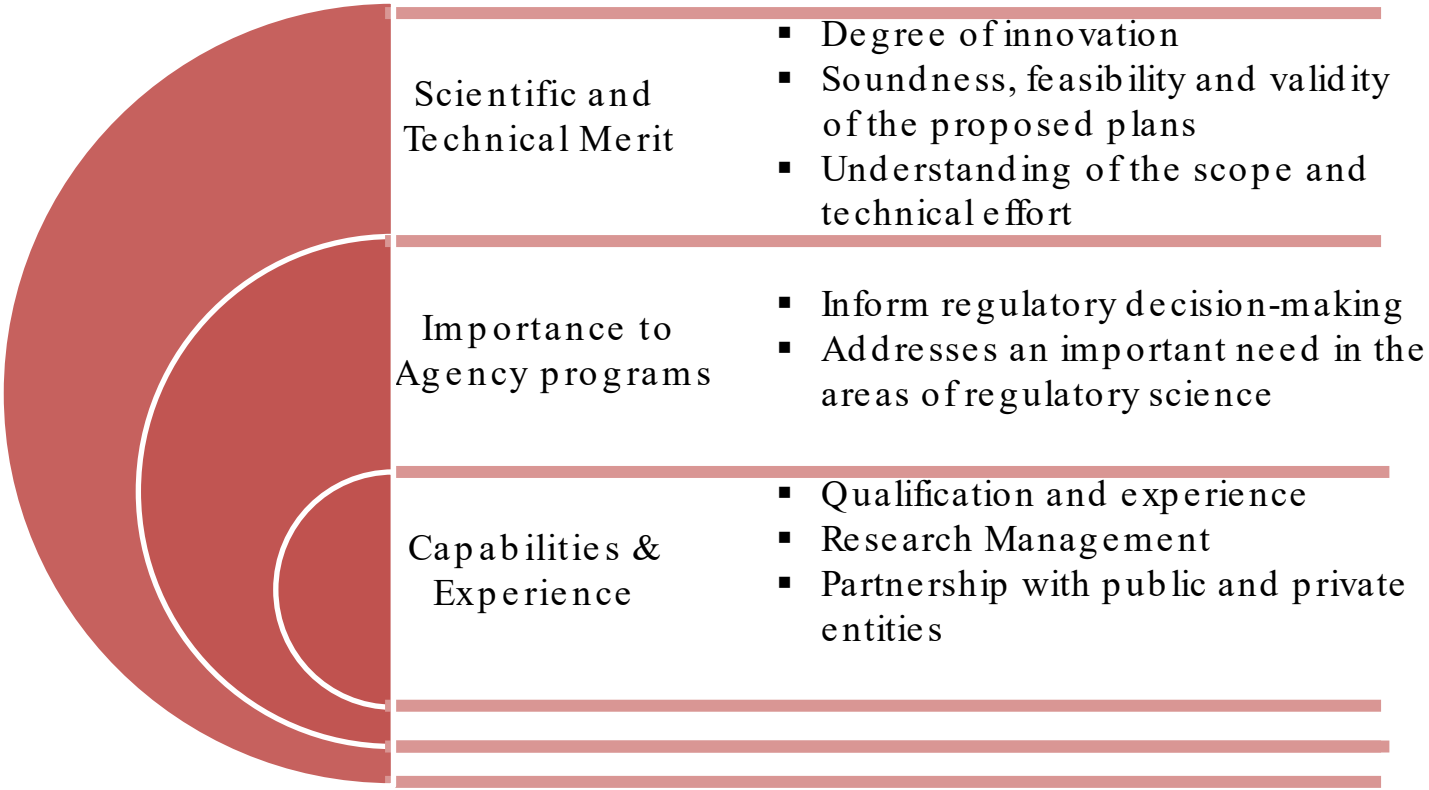
BAA Review Process

- Whitepaper & Quad Chart submission
- Panel evaluation
- Invitation/Do not Invite decision

- Full Technical proposal & Cost proposal submission
- Panel evaluation
- Funding consideration

- Contract negotiations
- Proposal resubmission
- Regret notifications

Evaluation Criteria



BAA vs. RFP (Request for Proposal)

Mechanism	Premise	The Statement of Work	Proposal Comparison	Review process
BAA	Scientific study and experimentation directed toward advancement of the art or increasing knowledge or understanding	The government drafts a statement of objective or general research interest/ statement of the regulatory challenge. The Offerors draft their own statement of work and technical approach.	Proposals contain stand-alone unique approaches. They are not compared to a common SOW	Streamlined regardless of the funding amount
Request for Proposal (RFP)	focuses on a specific requirement for system, hardware solution and services	The government drafts a common SOW to which all offerors propose	All proposals are intended to accomplish the same thing	It varies based on the funding amount and the type of acquisition

BAA and CERSI

CERSI and BAA can be used for FDA external collaborations to address regulatory science need. Research results from both should be disseminated publicly. Both uses the current Regulatory Science Framework.

BAA (Broad Agency Announcement)	CERSI (Centers of Excellence in Regulatory Science and Innovation)
R&D Contract mechanism	A cooperative agreement under a grant mechanism
BAA projects can be awarded to any entity as per the eligibility criteria	Projects are only awarded to the established CERSI's (can sub-award to other entities)
Deliverables and milestones are specific and must provide a direct benefit to the agency (program relevance)	Projects should address areas outlined in FDA's Regulatory Science Framework, results should benefit the public
BAA Announcement is renewed every year for solicitation purposes and awards are made on an annual basis	Funding Opportunity Announcement for CERSI Program is typically issued every 5 years (new funding opportunity is currently open, see RFA-FD-23-004)
BAA proposals are drafted independently without any FDA input and evaluated for merit, relevance and capability by the FDA Technical evaluation panel for an award	Research projects are conducted through collaborative interactions between CERSIs and FDA scientific experts from the funding Centers/Offices.
FDA is allowed to share confidential client information (CCI) under a BAA	No CCI can be shared under a cooperative agreement/grant mechanism

BAA Solicitation Update

Completed Activities

- ✓ BAA FY23 Solicitation Announcement is available on Sam.gov
- ✓ https://sam.gov/opp/6fd7bbaedd894978871de92ea572e354/view

Major Updates

- ❑ Research Area of Interest

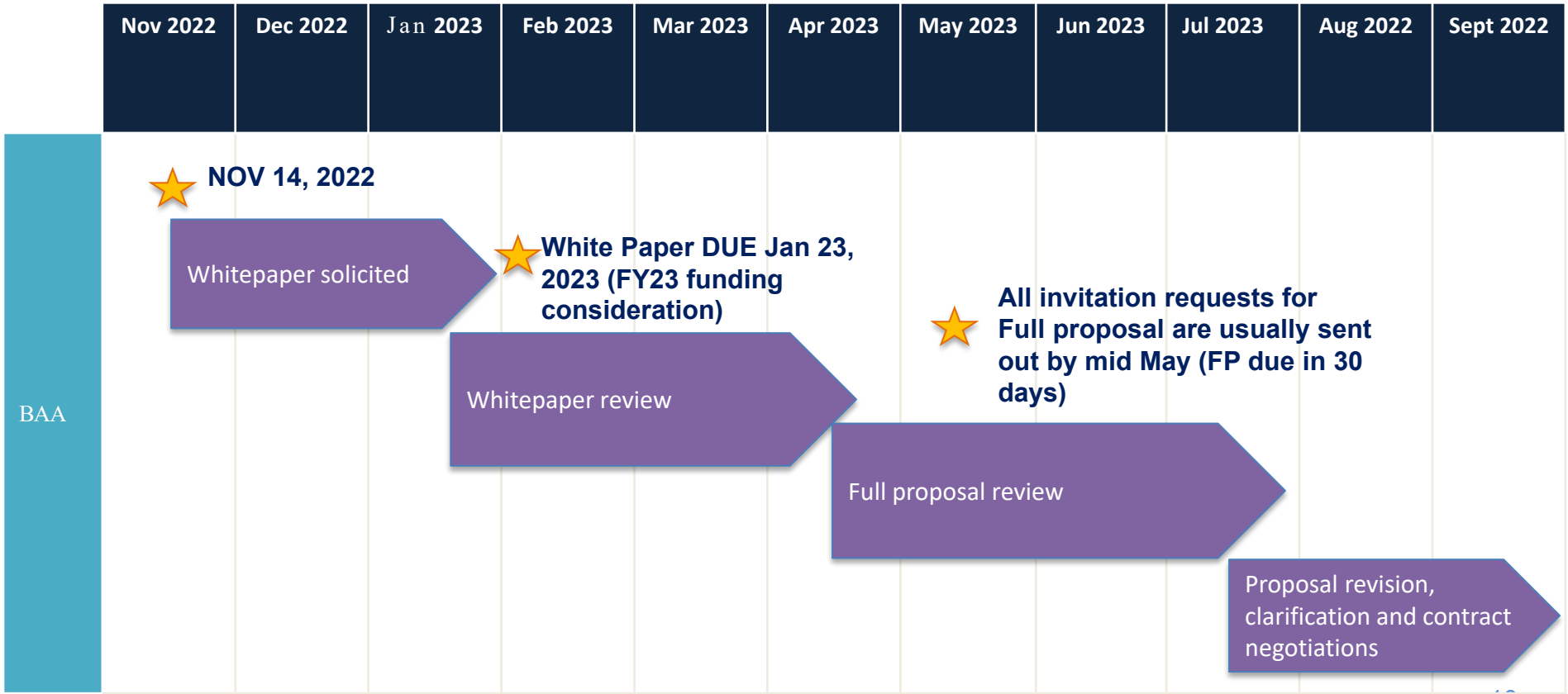
BAA Regulatory Science Categories
Area 1: Modernize Toxicology to Enhance Product Safety
Area 2: Stimulate Innovation in Clinical Evaluation & Personalized Medicine to Improve Product Development and Patient Outcomes
Area 3: Support New Approaches to Improve Product Manufacturing and Quality
Area 4:Ensure 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

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

BAA FY2023 Timeline

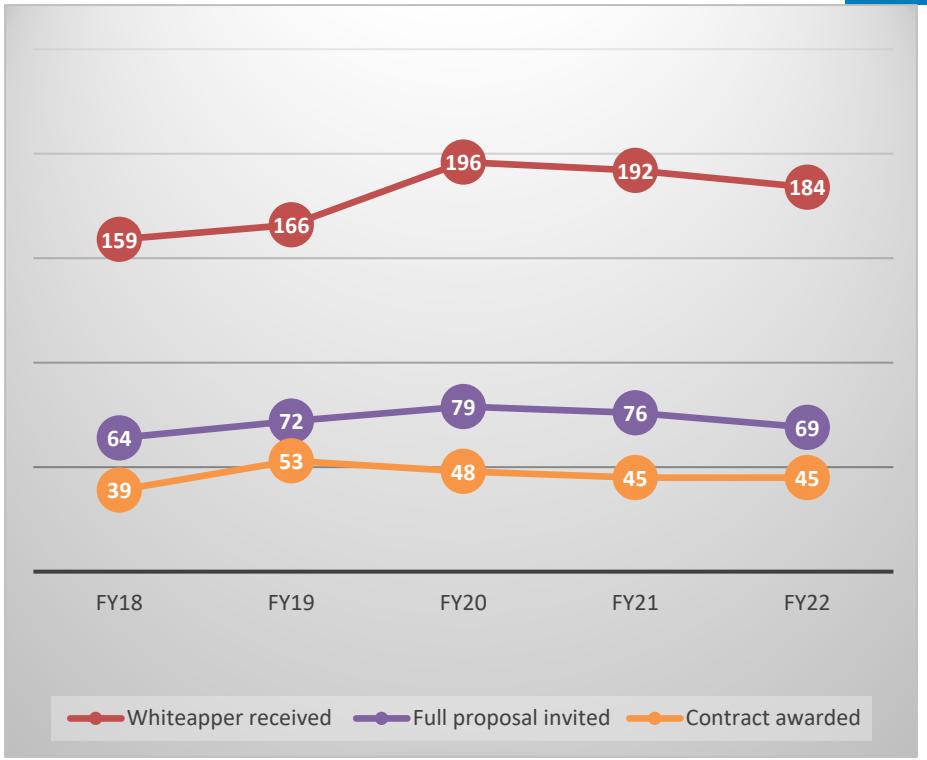


BAA proposals and awards

In FY2022, ORSI coordinated and facilitated reviews for

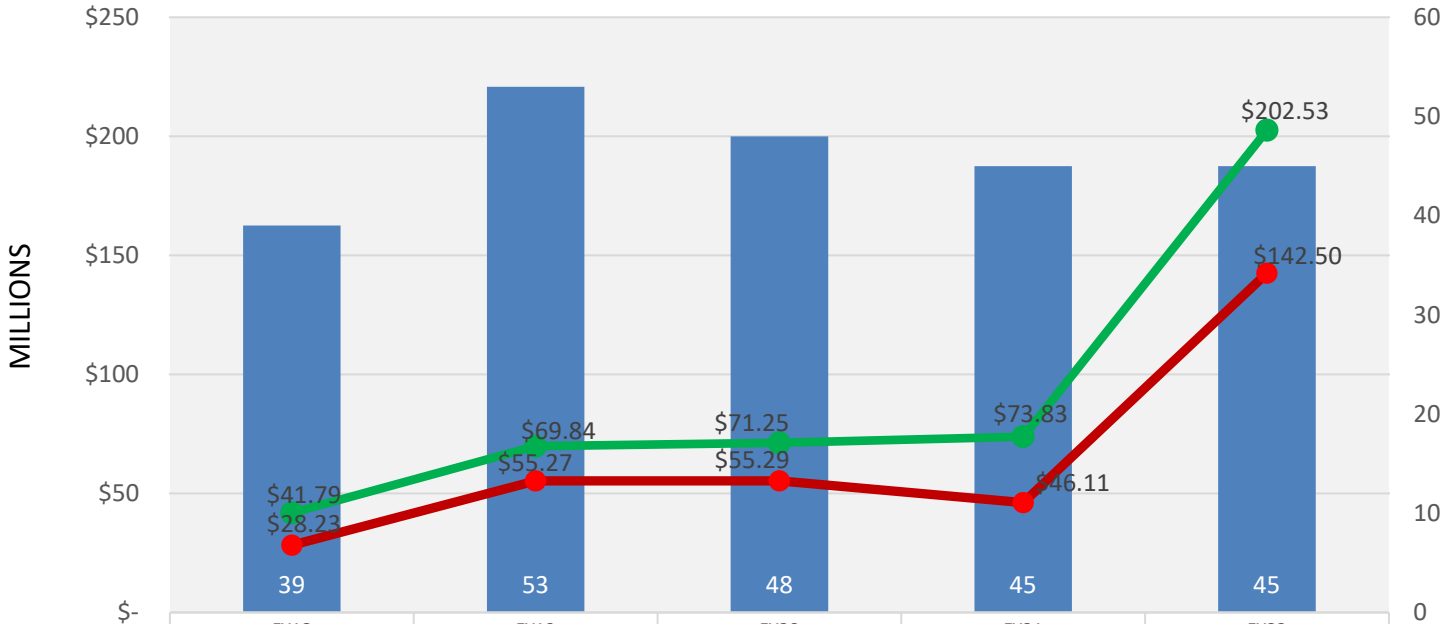
- 184 Whitepapers
- 69 Full Proposals
- 45 Full proposals were funded

FY18-FY22
Full Proposal Invite rate ~40%
Award rate ~64%



BAA Proposals and awards

FDA Investments in BAA (FY18-FY22)

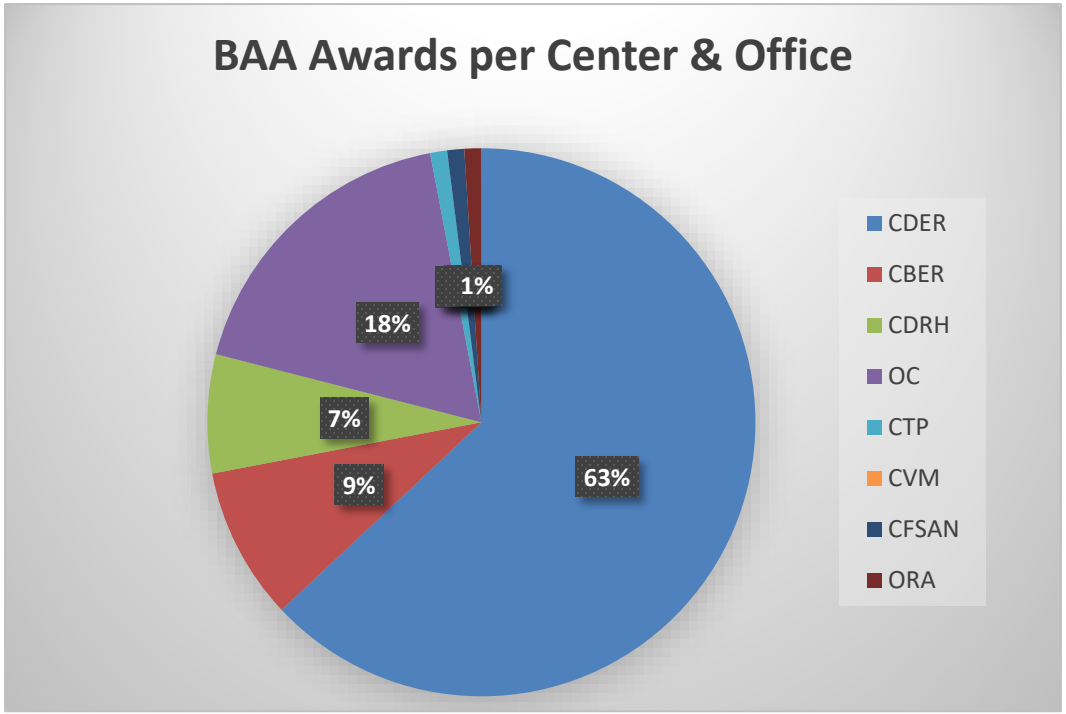


	FY18	FY19	FY20	FY21	FY22
Number of contracts	39	53	48	45	45
Obligated Dollar Amount	$28,230,765.55	$55,266,341.17	$55,289,690.12	$46,112,948.13	$142,495,425.15
Final Dollar Amount	$41,786,669.77	$69,839,526.94	$71,253,309.81	$73,834,242.13	$202,527,229.11

FY22 Awards: https://sam.gov/opp/e1455ea0c92c4b04b10d9c793ab0112c/view

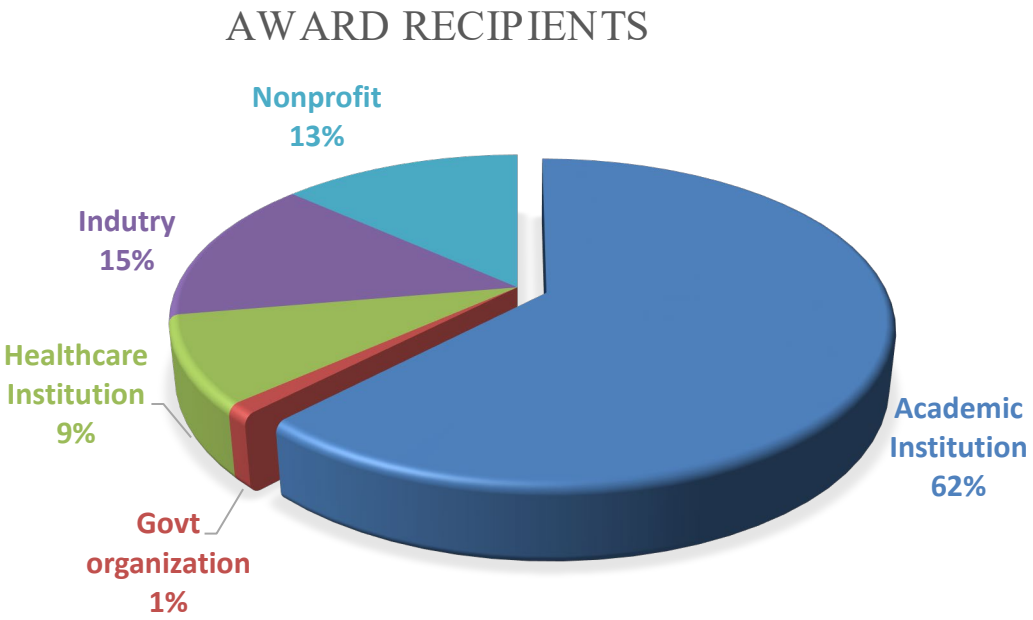
BAA Awards Per Center/Office (FY18 - FY22)

- CDER - Center for Drug Evaluation and Research
- CBER - Center for Biologics Evaluation and Research
- CDRH - Center for Devices and Radiological Health
- OC - Office of the Commissioner
  - OCE – The Oncology Center of Excellence
  - OCET - Office of Counterterrorism and Emerging Threats
  - OMHHE - Office of Minority Health and Health Equity
  - OWH - Office of Women's Health
  - National Center for Toxicological Research
- CTP – Center for Tobacco
- CVM- Center for Veterinary medicine
- CFSAN – Center for Food Safety and Applied Nutrition
- ORA - Office of Regulatory Affairs



BAA Awards (FY21-FY22)

- Offerors may include single entities or teams from private sector organizations, academic institutions and federally funded research and development centers
- Small Businesses are strongly encouraged to apply



BAA Award Alignment with Framework

BAA Charges with Topic Areas	FY21 awards	FY22 awards
I. Modernize development and evaluation of FDA-regulated products		
A. Alternative Methods	1	2
B. Advanced Manufacturing Approaches (includes MCMi)	3	5
C. Analytical and Computational Methods	5	6
D. Biomarkers	1	0
E. Clinical Outcome Assessment	3	1
F. Complex and Novel Clinical Trial Design	2	1
G. Predictive Toxicology	2	0
H. Methods for Assessing Behavioral, Economic, or Human Factors	0	0
I. Approaches to Incorporate Patient and Consumer Input	0	1
J. Methods to Assess Real-World Data to serve as Real-World Evidence	1	3
K. Methods to Assess Data Source Interoperability	0	0
II. Strengthen post-market surveillance and labeling of regulated products		
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	2	3
B. Using and Validating Artificial Intelligence Approaches	2	2
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	1	1
D. Automated Reporting Tools for Adverse Events and Active Surveillance	2	2
E. Methods to Improve Communication About Risk to Patients and Consumers	3	2
F. Approach to Expand Data Capacity, and Increase Data Quality and Use	0	2
G. Efforts to Harmonize Existing and Emerging Data Standards	0	1
III. Invigorate public health preparedness and response of the FDA, patients, and consumers		
A. Reinforce Medical Countermeasures Initiative (MCMi)	6	2
B. Antimicrobial Resistance	5	7
C. Patient and Consumer Engagement	0	0
D. Substance Use and Misuse	4	4
E. One Health Approaches	0	0
F. Global Product Safety net	1	0

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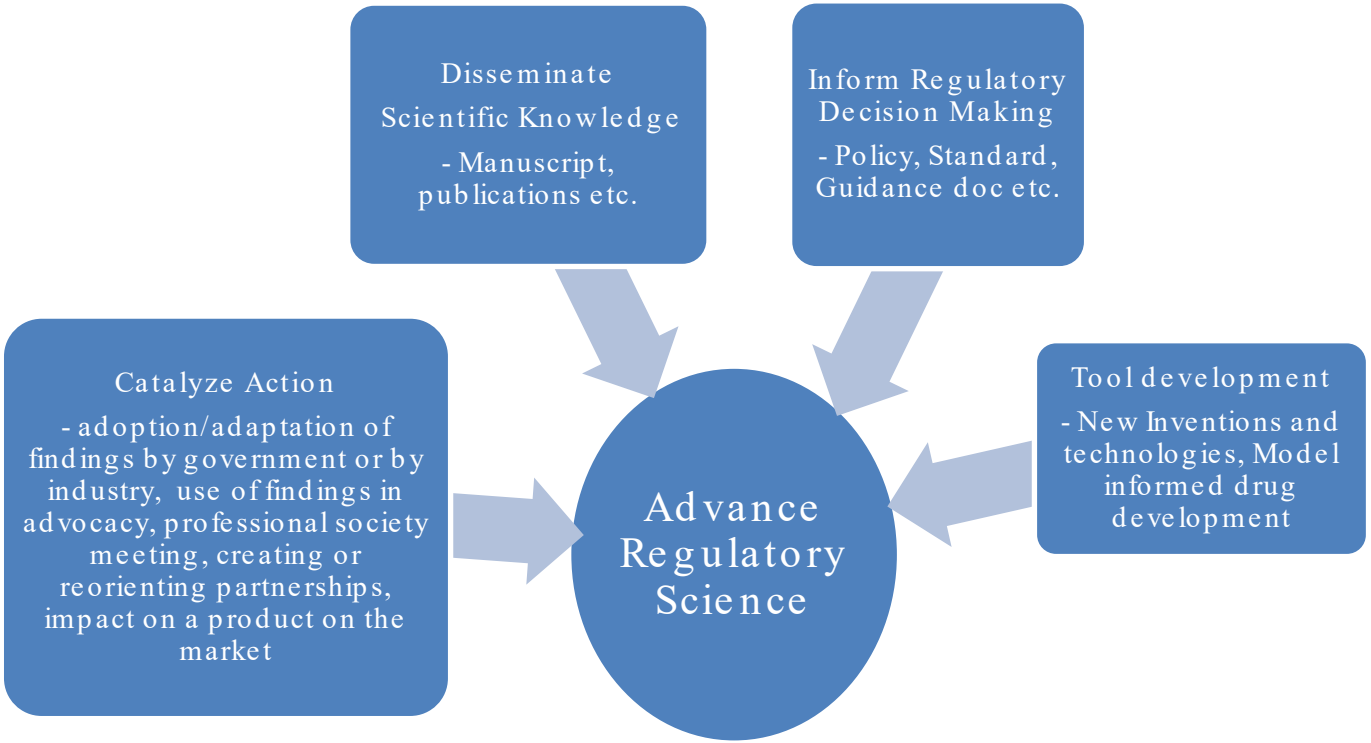
Outcome of Interest



A success story

21st Century Cures Act (2016)

FDA established a program to evaluate the potential use of real-world evidence (RWE)

Draft framework issued in December 2018:

https://www.fda.gov/media/120060/download

A success story

Regulatory Science Challenge: Use non-interventional (observational) study designs to generate real-world evidence (RWE). Factors may influence the clinical outcomes of such studies and bias the results.

Scientific Approach: In the absence of randomization, advanced epidemiologic and statistical methods have been developed to mitigate such bias, but these methods have not been extensively tested.

BAA collaborations: FDA CDER OMP launched a partnership with the Brigham and Women's Hospital/Harvard Medical School. Multiple non-interventional studies that investigated questions similar to clinical trials (30 phase 3/4 randomized) were designed and executed, and the results of these studies were compared to the corresponding clinical trials.

Summary Results: With data that are fit-for-purpose and proper design and analysis, non-randomized real- world evidence studies can come to similar conclusions about a drug's effect as randomized trials.

https://healthpolicy.duke.edu/events/findings-duplicate-demonstration-project

A success story

- Disseminate Scientific knowledge: Methods, objective, and initial results were published, Public workshop: Feb16, 2021, and May10, 2022

- Inform Regulatory Decision Making: lessons learned, and knowledge gained will inform a future FDA guidance document to address the use of non-interventional study design to assess drug effectiveness. Draft guidance for industry issued in Sep, Oct, Nov, & Dec 2021

- Catalyze Action: This project has catalyzed external action. Three other groups, OPERAND, OHDSI, and the Yale/Mayo CERSI have launched similar duplication projects. EMA have publicly endorsed this general approach.

Success Story Acknowledgements and References

Dr. Kenneth Quinto, CDER – Office of Medical Policy (OMP)
Dr. Dianne Paraoan, CDER – Office of Medical Policy (OMP)
Questions: CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov

- https://pubmed.ncbi.nlm.nih.gov/30636285/
- https://www.rctduplicate.org/
- https://healthpolicy.duke.edu/events/findings-duplicate-demonstration-project
- https://www.fda.gov/drugs/news-events-human-drugs/fda-issues-draft-guidances-real-world-evidence-prepares-publish-more-future
- https://pink.pharmaintelligence.informa.com/PS122984/Real-World-Data-Could-Get-Boost-From-Trial-Replication-Project
- https://www.fda.gov/drugs/news-events-human-drugs/real-world-evidence-safety-potential-tool-advancing-innovative-ways-develop-new-medical-therapies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