Sponsored by the
Office of Regulatory Science and Innovation – Program Office
Office of Acquisitions and Grants – Contracting Office

U.S. FOOD & DRUG
ADMINISTRATION

Welcome to the FDA's
Broad Agency Announcement Day

December 6, 2022

FDABAA@fda.hhs.gov

BAA Day Overview

Morning Session

10:00 a.m.	Welcome and Opening Remarks • FDA regulatory science framework and an overview of the new BAA announcement	Dr. Tina Morrison, Director, ORSI Mr. Leonard D Grant, Director, OAGS
10:30 a.m.	Program Presentations • FDA BAA program overview • 2023 BAA updates • BAA proposal submission, evaluations and lessons learned	 Ms. Shaila Shaheed, ORSI Mr. Ian Weiss, OAGS Ms. Jessika Alfaro, ORSI
11:30 a.m.	Question and Answer Panel • Review of questions submitted via webinar Q&A pod, and in advance to FDABAA@fda.hhs.gov	 Panel Members: ORSI & OAGS
12:00 p.m.	Lunch	

BAA Day Overview

Afternoon Session

12:30 p.m.	Center for Drug Evaluation and Research (CDER) Presentation	
	• Office of Generic Drugs	Dr. Sammersingh Raney, OGD
	• Office of Pharmaceutical Quality	Dr. Neil Stiber & Dr. Thomas O'Connor, OPQ
1:00 p.m.	Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH) Presentation	
	• CBER	Dr. Emily Braunstein, CBER
	• CDRH	Dr. Christina Webber, CDRH
1:30 p.m.	Office of the Commissioner Presentations	
	• Office of Counterterrorism and Emerging Threats	Mr. Robert Orr, OCET
	• Oncology Center of Excellence	Dr. Julie Schneider, OCE
	• Office of Minority Health and Health Equity	Dr. Christine Lee, OMHHE
	• Office of Women's Health	Dr. Susan Bersoff-Matcha, OWH
2:30 p.m.	Special Consideration for BAA R&D Contract	
	• Intellectual Property (IP) and Data Rights	Dr. Alice Welch, TTP
	• Human Subject Protection Program Management Staff	Ms. Bridget Foltz, HSPPMS
	• Paperwork Reduction Act and Privacy	Ms. Domini Bean, PRA

House Keeping

- Presentations in the morning session will serve as an overview of the contents provided in the BAA solicitation on SAM.gov.
- The afternoon session will host a mix of recorded and live presentations. Not all presenters will be available for Q&A.
- There will be one live Q&A for the morning session – please enter your questions in the Q&A feature of zoom.
- Session will be recorded and a link to the recording and slides will be shared on the BAA Day event page.

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FDA Broad Agency Announcement Day

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CREATIVE CONNECTIONS

Office of Regulatory Science and Innovation's FDA-wide Programs for Advancing Regulatory Science

Tina Morrison, Ph.D.
Director, Office of Regulatory Science and Innovation
Office of the Chief Scientist
Office of the Commissioner

Tina.Morrison@fda.hhs.gov

6 December 2022

FDA Mission

PROTECT PUBLIC HEALTH by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. Regulate the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors

ADVANCE PUBLIC HEALTH BY HELPING TO SPEED INNOVATIONS that make FDA regulated products more effective, safer, and affordable and by helping the public get the accurate, science-based information they need to use medical products and food to maintain and improve their health

Play a significant role in Nation's counterterrorism capability by ensuring the security of food supply and fostering development of medical products to respond to deliberate naturally emerging public health threats.

https://www.fda.gov/about-fda/what-we-do#mission

FDA's Office of the Chief Scientist

The National Center for Toxicological Research

THE OFFICE OF
Regulatory Science and Innovation

THE OFFICE OF
Counterterrorism and Emerging Threats

THE OFFICE OF
Scientific Professional Development

THE OFFICE OF
Scientific Integrity

THE OFFICE OF
Laboratory Safety

Advisory Committee Oversight and Management

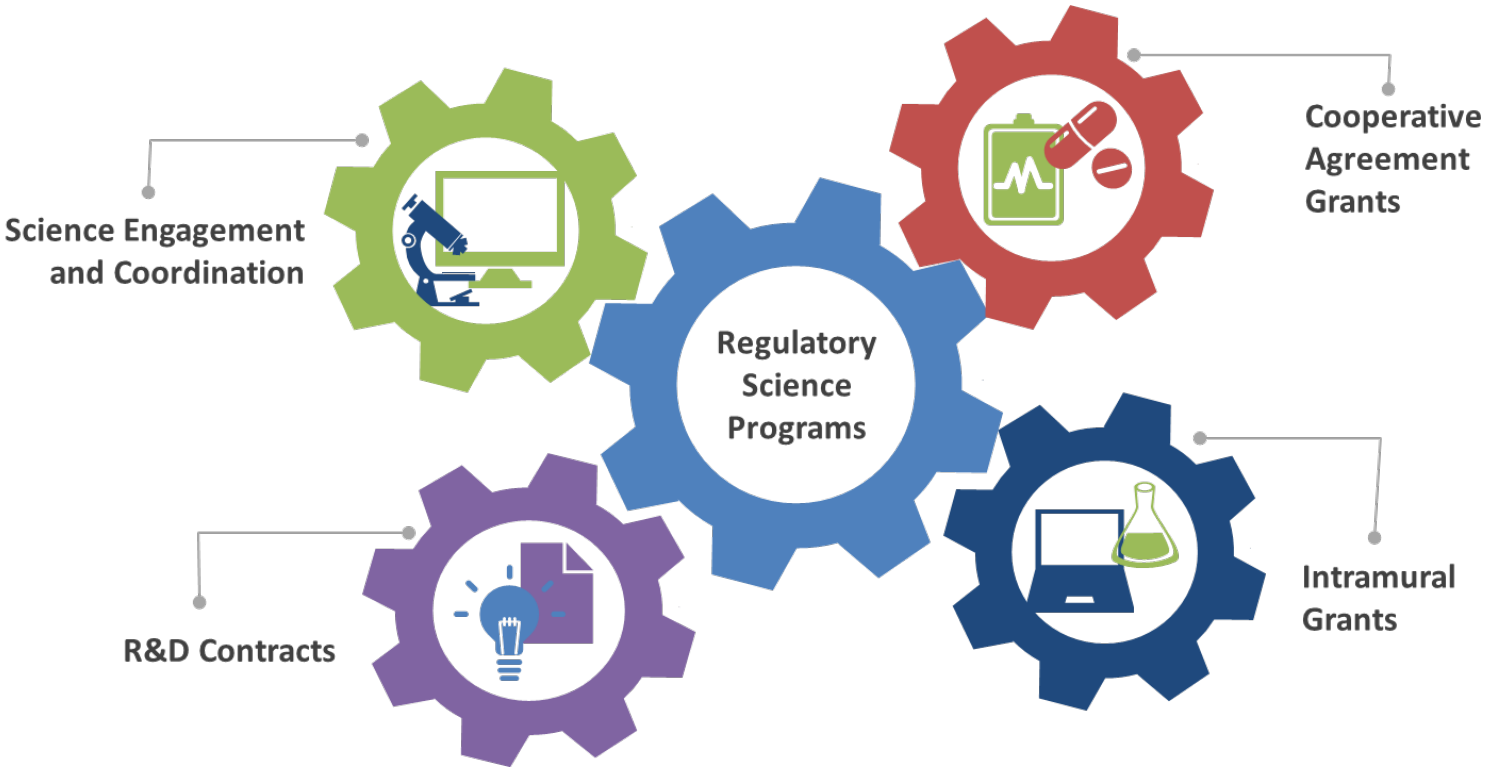
Technology Transfer Program

- supports the research foundation, science, and innovation that underpins FDA's regulatory mission;
- promotes scientific excellence and innovation to achieve FDA's mission; and
- provides research expertise and infrastructure to the FDA product centers.

ORSI's mission is to provide excellence and innovation in strategic leadership, collaboration, coordination, and infrastructure development to ensure FDA continues to have a strong regulatory science foundation to protect and advance public health.

ORSI's vision is to improve and advance public health by accelerating innovations through creative collaborations that harness the best science.

Office of Regulatory Science and Innovation



ORSI accelerates innovations through creative collaborations that harness the best science.

ORSI's Program Impact – FY22

$100+ Million
in FDA's regulatory science extramural research portfolio that ORSI supports

$2.2 Million
for intramural grant awards for FDA Scientists

800+
FDA Staff serve on

1100+
consensus standard committees

200+
Technical proposal evaluation and panel reviews

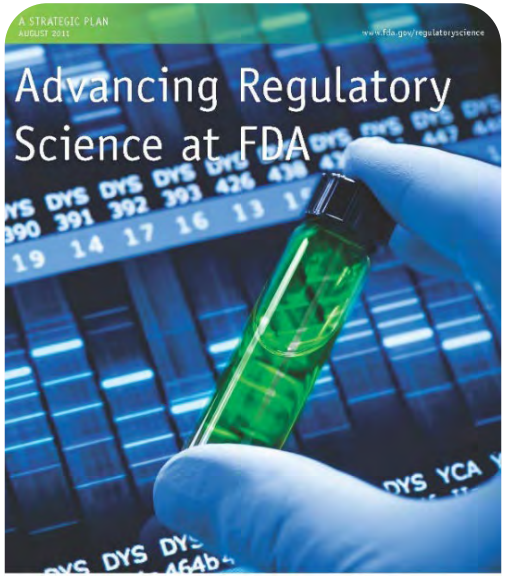
100+
Regulatory science projects with CERSIs

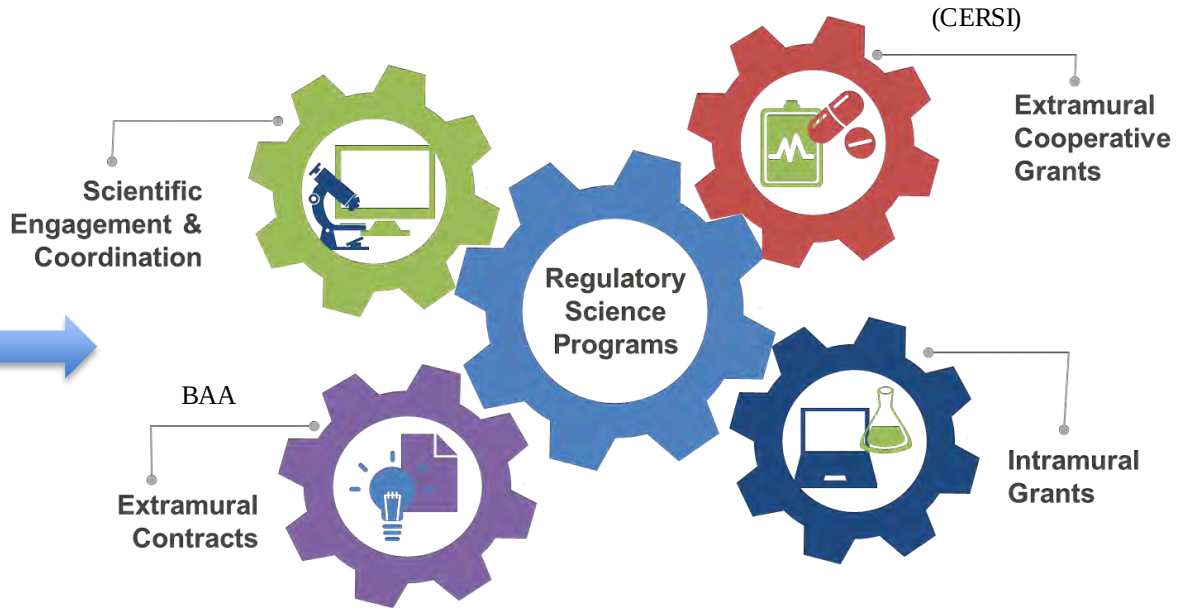
90+
seminars, training events and workshops ORSI facilitated and launched

1000+
FDA scientists that utilize ORSI's regulatory science programs

22
Focus Areas of Regulatory Science

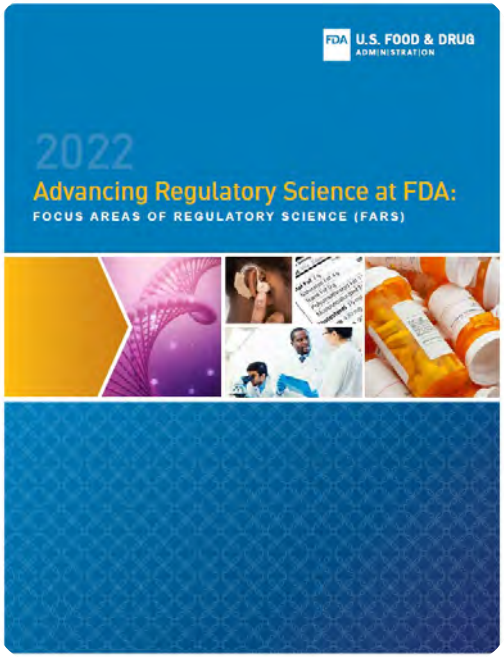
Since its inception, ORSI's regulatory science programs and their priorities have been shaped by the priority areas identified in the 2011 Strategic Plan for Advancing Regulatory Science.





Advancing Regulatory Science: FARS Report

First published in 2021; first update to FARS in 2022



www.fda.gov/FARS

- The "FARS report .. outlines topics that FDA has identified as needing continued targeted investment …"
- "The focus areas are not a comprehensive list of all of FDA's research needs, rather generally encompass research affecting more than one center or office."
- "The format is designed to be easy to update to accommodate frequent updates and revisions to align with the rapid pace of scientific advancement as well as evolving priorities and research activities."
- Each "focus area" has
  - an Importance Statement, which includes details on why that area of regulatory science requires continued investment;
  - Examples, which highlight on-going or completed work by FDA

2022 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers

2022 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers
Focus Area of Regulatory Science	• Medical Countermeasures and Preparedness for Emerging Infectious Diseases • Technologies to Reduce Pathogen Contamination • Substance Use Disorders • Antimicrobial Resistance • Food Safety • Quality of Compounded Drugs			

2022 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers

Focus Area of Regulatory Science	• Medical Countermeasures and Preparedness for Emerging Infectious Diseases
	• Technologies to Reduce Pathogen Contamination
	• Substance Use Disorders
	• Antimicrobial Resistance
	• Food Safety
	• Quality of Compounded Drugs
		• Individualized Therapeutics and Precision Medicine
		• Complex Innovative Trial Design
		• Microbiome Research
		• Novel Food and Food Ingredients
		• Regenerative Medicine
		• Advanced Manufacturing
		• Increasing Access to Generic Alternatives for Complex Drugs
		• Product Development Tools
		  ◦ Biomarkers
		  ◦ Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing
		  ◦ Model-Informed Product Development		

2022 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers

Focus Area of Regulatory Science	• Medical Countermeasures and Preparedness for Emerging Infectious Diseases
	• Technologies to Reduce Pathogen Contamination
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	• Antimicrobial Resistance
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		• Product Development Tools
		  ◦ Biomarkers
		  ◦ Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing
		  ◦ Model-Informed Product Development
			• Product Safety Surveillance
			• Diverse Data and Technologies
			  ◦ Artificial Intelligence
			  ◦ Digital Health
			  ◦ Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making	

2022 Focus Areas of Regulatory Science

Initiative	Public Health Preparedness and Response	Increasing Choice and Competition through Innovation	Unleashing the Power of Data	Empowering Patients and Consumers

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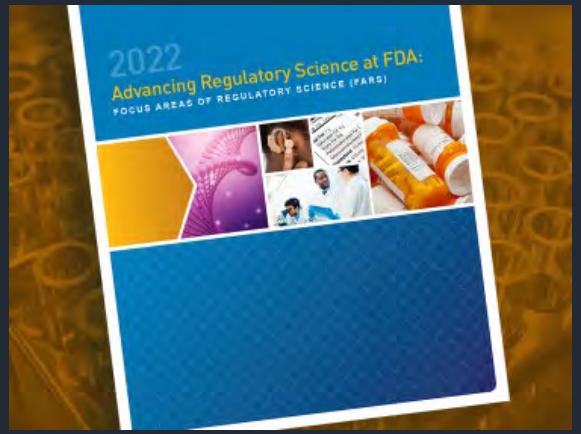
			• Product Safety Surveillance
			• Diverse Data and Technologies
			  • Artificial Intelligence
			  • Digital Health
			  • Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making
				• Patient and Consumer Preferences and Perspectives
				• Patient-Reported Outcomes and other Clinical Outcome Assessments
				• Empowering Patients and Consumers to make Better-Informed Decisions

FARS@fda.hhs.gov

Focus Areas of Regulatory Science

2022 Update



FDA aims to stay ahead of evolving regulatory needs, and thus we have reviewed each of the FARS from the 2021 report and provided important updates to the examples highlighted in the FARS.

Additionally, we bolstered our cross-cutting topics:

- women's health,
- minority health and health equity across diverse groups,
- pediatric health,
- rare diseases,
- oncology, and
- One Health.

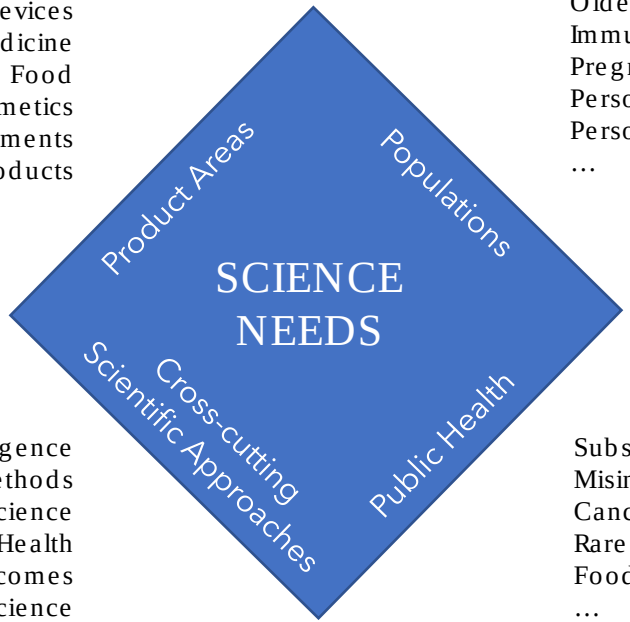
Created a new FARS website → https://www.FDA.gov/FARS

“FARS 2.0” – new Regulatory Science Framework

Communicating FDA's scientific needs can be challenging because there are different perspectives to consider.

Biologics
Combination products
Drugs
Medical Devices
Veterinary medicine
Food
Cosmetics
Dietary supplements
Tobacco products

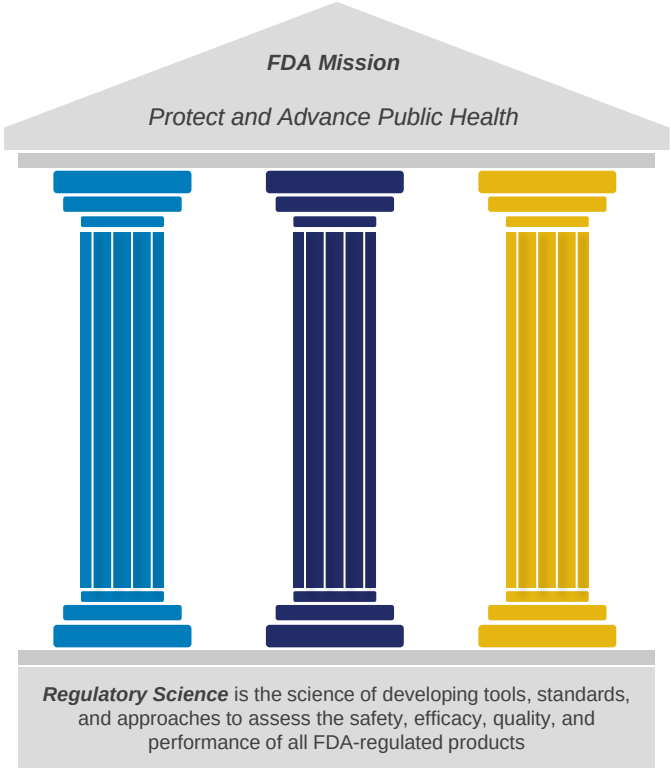
Racial & ethnic minorities
Sex and gender minorities
Children and adolescents
Older adults
Immunocompromised persons
Pregnant and lactating persons
Persons with cancer
Persons with rare diseases
…



Artificial intelligence
Alternative methods
Data science
One Health
Patient-centered outcomes
Behavioral & social science
…

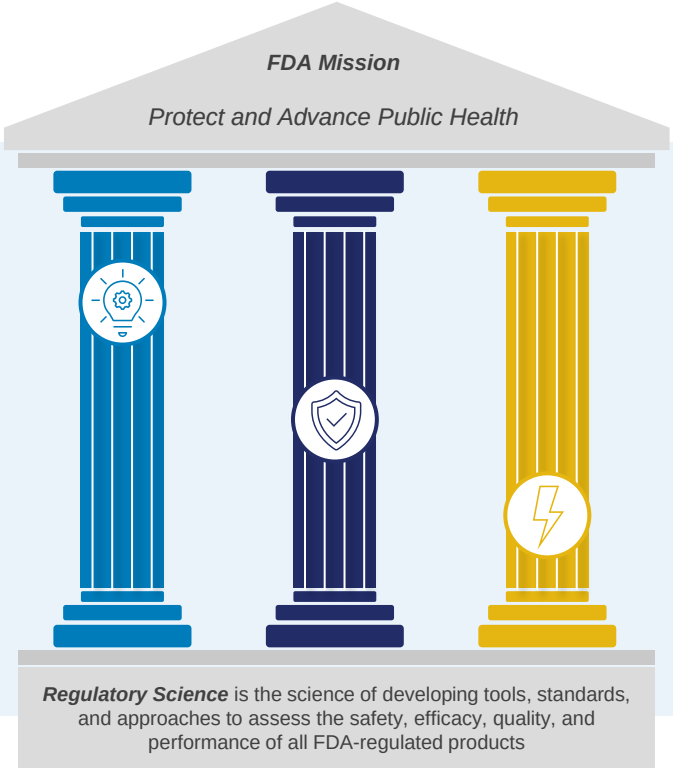
Substance use disorders
Misinformation/Disinformation
Cancer
Rare Diseases
Food Safety
…

Focus Areas of Regulatory Science
The New Framework



Regulatory Science is the science of developing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products

Focus Areas of Regulatory Science
The New Framework



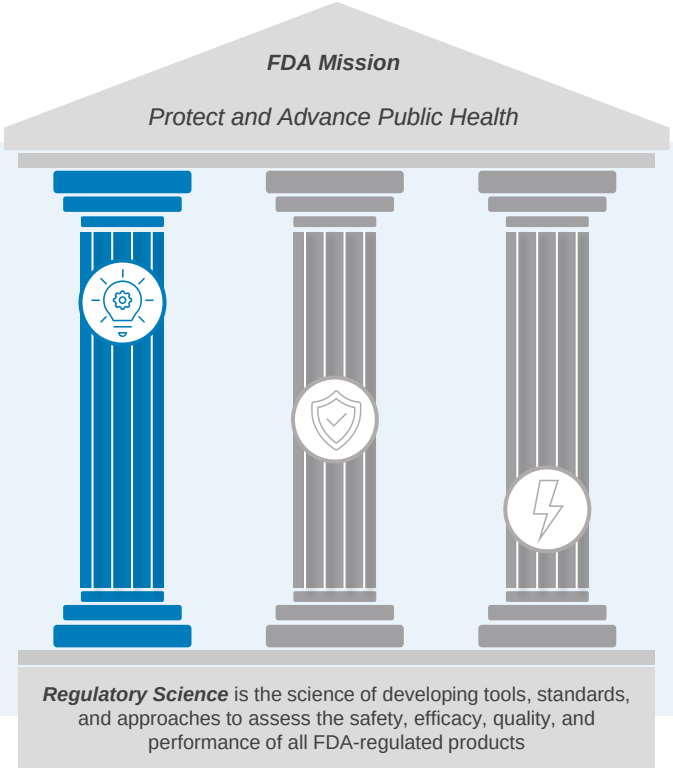
The goal of the framework is to harness regulatory science to advance FDA's mission.

Charge I:
Modernize development and ***evaluation*** of FDA-regulated products

Charge II:
Strengthen post-market surveillance and ***labeling*** of FDA-regulated products

Charge III:
Invigorate public health preparedness and ***response*** of FDA, Patients & Consumers

Focus Areas of Regulatory Science
The New Framework



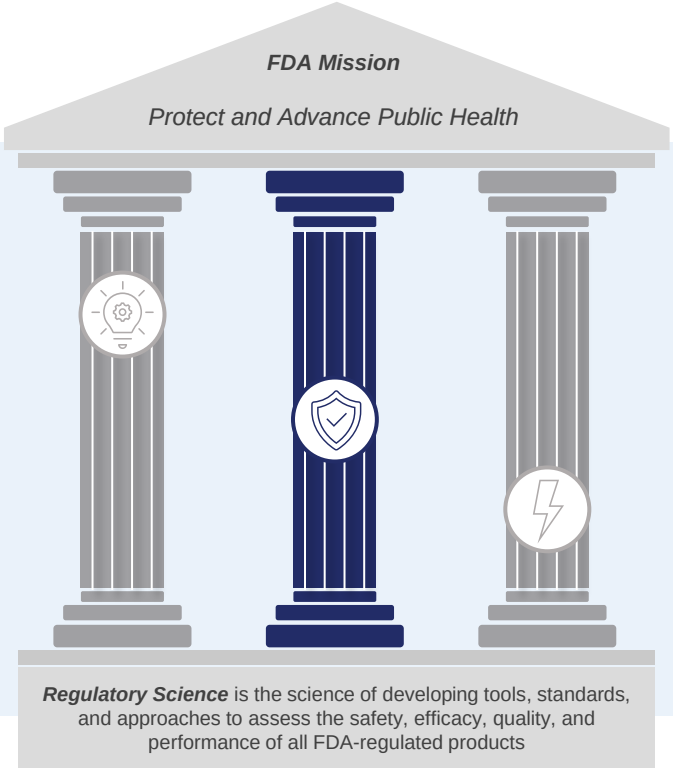
Regulatory Science is the science of developing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products

Modernize development and ***evaluation*** of FDA-regulated products

Focus Areas for Charge I:

A. Alternative Methods
B. Advanced Manufacturing Approaches
C. Analytical and Computational Methods
D. Biomarker tools
E. Clinical Outcome Assessment
F. Complex and Novel Clinical Trial Design
G. Methods for Assessing Behavioral, Economic, or Human Factors
H. Approaches to Incorporate Patient and Consumer Input
I. Methods to Assess Real-World Data to serve as Real-World Evidence
J. Methods to Assess Data Source Interoperability

Focus Areas of Regulatory Science
The New Framework



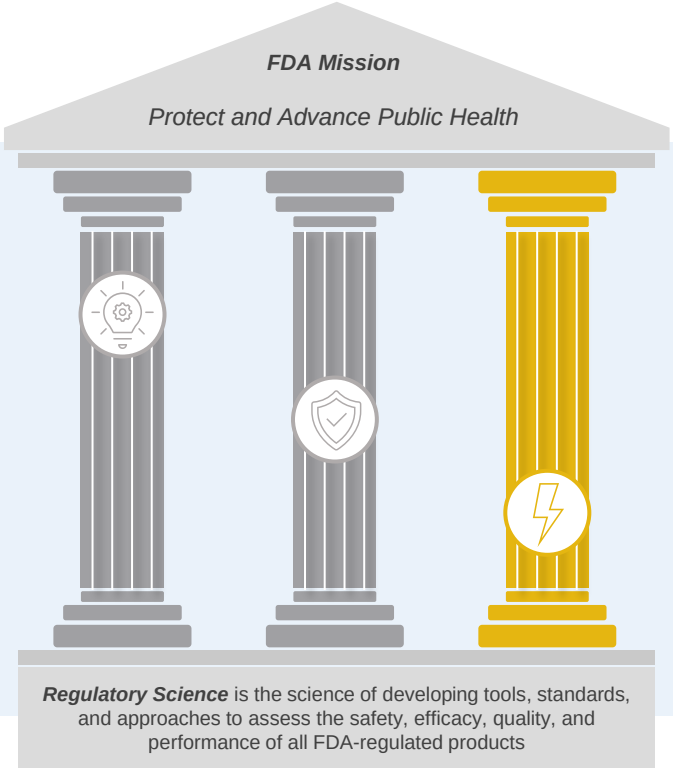
Regulatory Science is the science of developing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products

Strengthen post-market surveillance and ***labeling*** of FDA-regulated products

Focus Areas for Charge II:

A. Methods to Assess Real-World Data to Support Regulatory Decision-Making
B. Methods for 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 for Assessing Behavioral, Economic, or Human Factors
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

Focus Areas of Regulatory Science
The New Framework



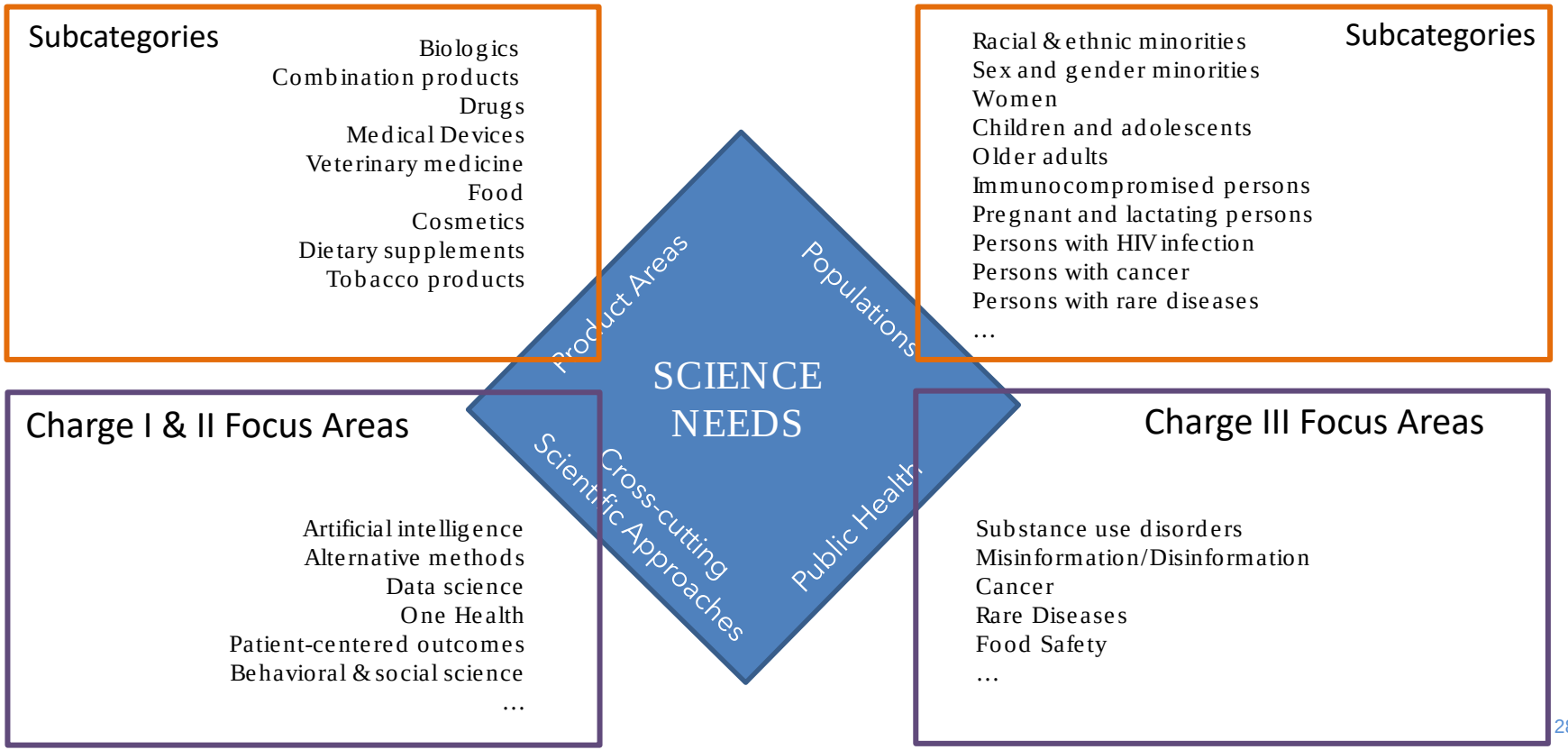
Regulatory Science is the science of developing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products

Invigorate public health preparedness and ***response*** of FDA, Patients & Consumers

Focus Areas for Charge III:

A. Reinforce Medical Countermeasures Initiative (MCMi)/Increase preparedness and response for emerging public health threats.
B. Mitigate Antimicrobial Resistance
C. Strengthen Patient and Consumer Engagement and Communication
D. Understand Substance Use and Minimize Misuse
E. Apply Population Approaches to Precision Medicine
F. Expand One Health Approaches
G. Identify and Harness Relevant Emerging Sciences & Technologies
H. Strengthen Global Product Safety Net

Each perspective is captured in the framework presented in the BAA solicitation, and priorities are presented for FY23.



ORSI is taking steps to incorporate the new cross-cutting Regulatory Science Framework into our Agency-wide regulatory science programs, as demonstrated by CERSI Request for Applications, and FY23 BAA Solicitation.

I. Modernize development and evaluation of FDA-regulated products
A. Alternative Methods
B. Advanced Manufacturing Approaches
C. Analytical and Computational Methods
D. Biomarker Tools
E. Clinical Outcome Assessment
F. Complex and Novel Clinical Trial Design
G. Methods for Assessing Behavioral, Economic, or Human Factors
H. Approaches to Incorporate Patient and Consumer Input
I. Methods to Assess Real-World Data to serve as Real-World Evidence
J. 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)/Increase preparedness and response for emerging public health threats.
B. Mitigate Antimicrobial Resistance
C. Strengthen Patient and Consumer Engagement and Communication
D. Understand Substance Use and Minimize Misuse
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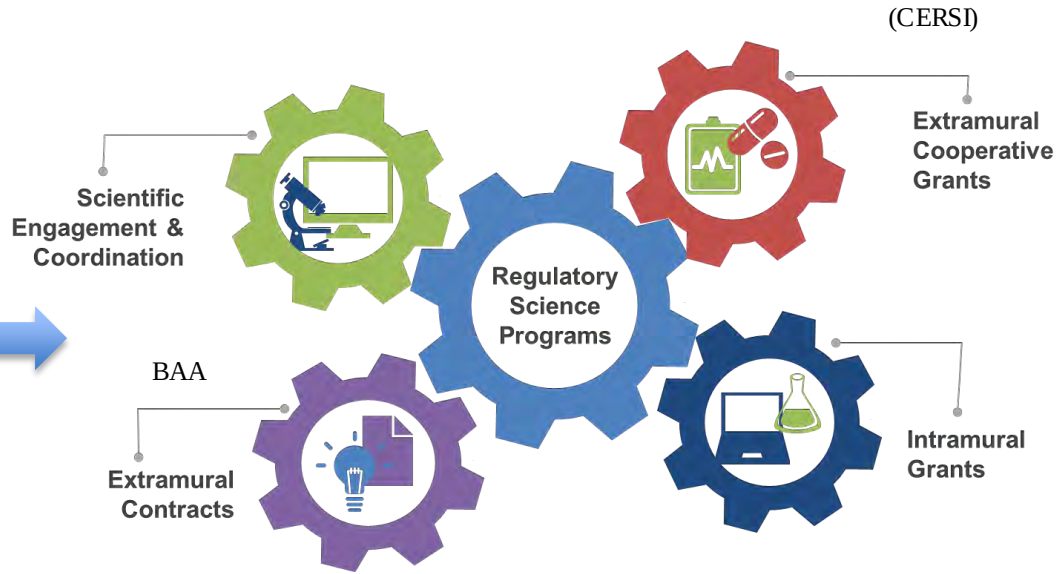

Three Key Takeaways

- ORSI manages two extramural regulatory science research programs: the Broad Agency Announcement (contract mechanism) and the Centers of Excellence in Regulatory Science and Innovation (CERSI cooperative agreement grant)
- ORSI has been facilitating research and development contracts through the BAA for 10 years, approximately $700M awarded contracts to advance regulatory science.
- The Office of the Chief Scientist created a new cross-cutting Regulatory Science Framework, which provided the new structure for the BAA solicitation for FY 23.

ORSI accelerates innovations through creative collaborations that harness the best science.

OAGS Partners:

- Leonard Sacks
- Ian Weiss

Thank You!