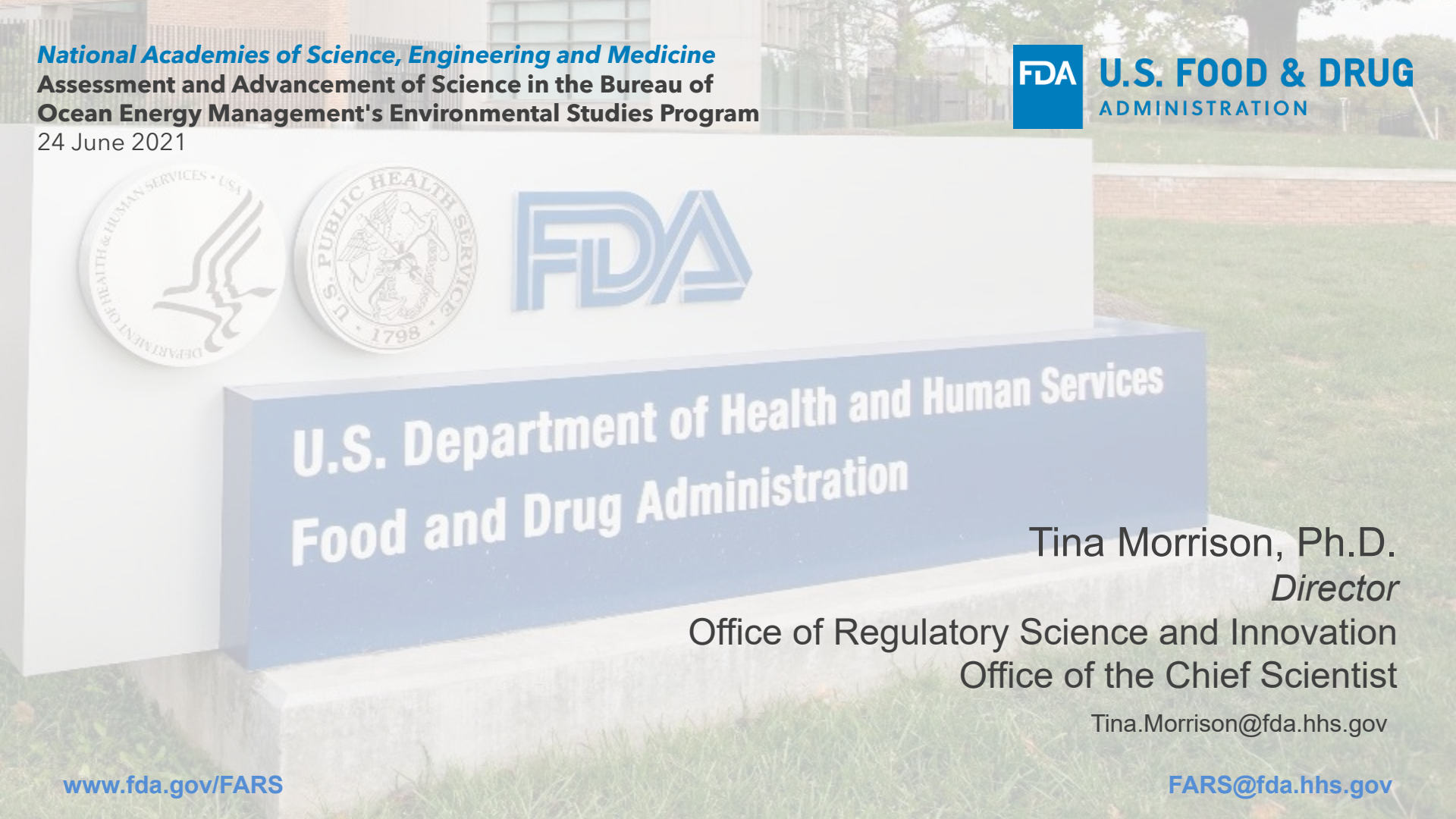
National Academies of Science, Engineering and Medicine

Assessment and Advancement of Science in the Bureau of Ocean Energy Management's Environmental Studies Program

24 June 2021

U.S. FOOD & DRUG ADMINISTRATION



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Office of the Chief Scientist
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FDA Mission

The Food and Drug Administration is responsible for protecting the 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.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

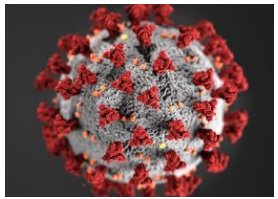
FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

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

The **Office of the Chief Scientist** (OCS) was established in 2007 in statute (FDAAA, Sec. 602)

to provide provides strategic leadership, coordination, and expertise, supporting scientific excellence, innovation and capacity to achieve FDA's public health mission.






https://www.fda.gov/about-fda/office-commissioner/office-chief-scientist

Office of the Chief Scientist (OCS) fosters scientific excellence across FDA.

The National Center for Toxicological Research

THE OFFICE OF
Regulatory Science and Innovation

THE OFFICE OF
Health Informatics

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

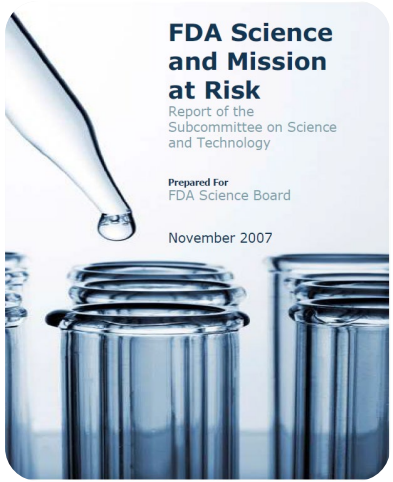
Examples of OCS's engagement:

1. We conduct scientific research and foster innovation and collaboration in support of FDA centers.
2. We preserve and promote integrity in scientific decision-making.
3. We support the common needs of scientists through state-of-the-art training and education.

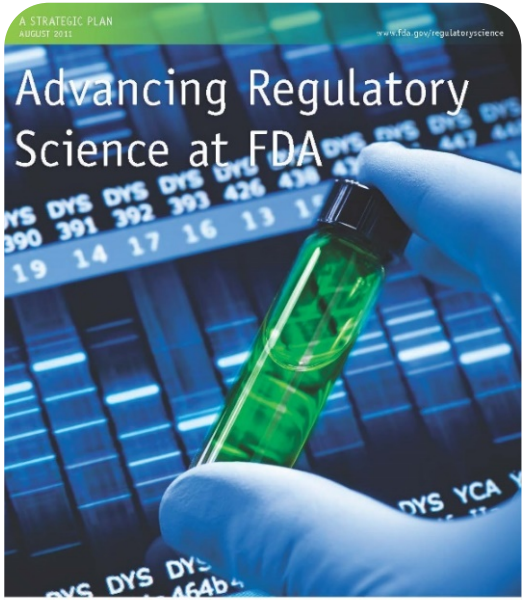
Regulatory Science

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

Agency Regulatory Science Priority Setting



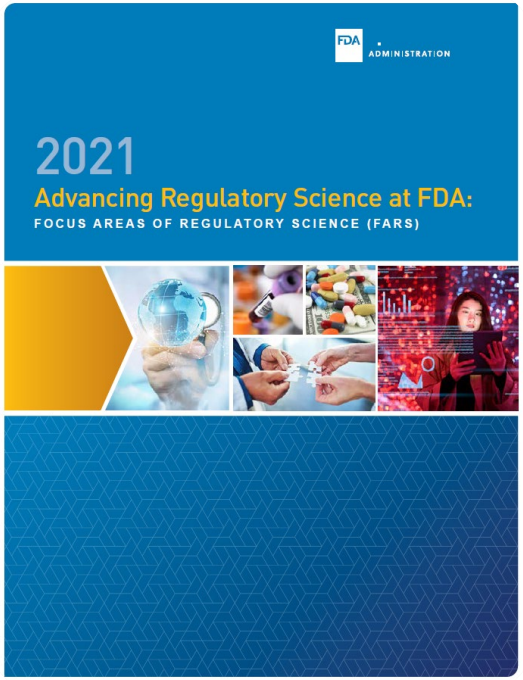
Science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.



- Identify opportunity areas of regulatory science importance to strength FDA's capacity to support its mission
- Develop/use 21st century regulatory science tools and approaches for evaluation of 21st century products
- Promote innovation through targeted and collaborative approaches to regulatory science that enable new technologies and product development
- Build FDA's scientific capacity, infrastructure, culture and collaborations, including through scientific and professional development of FDA's scientists

Agency Regulatory Science Priority Setting

Medical and technological advances continue to occur at a steady and relentless pace, and FDA must stay abreast if it is to remain the preeminent public health agency that the public expects.



- Formed an Agency-wide committee of senior scientific leadership to survey target areas.
- 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."

Office of the Chief Scientist provides scientific excellence across FDA.

The National Center for Toxicological Research

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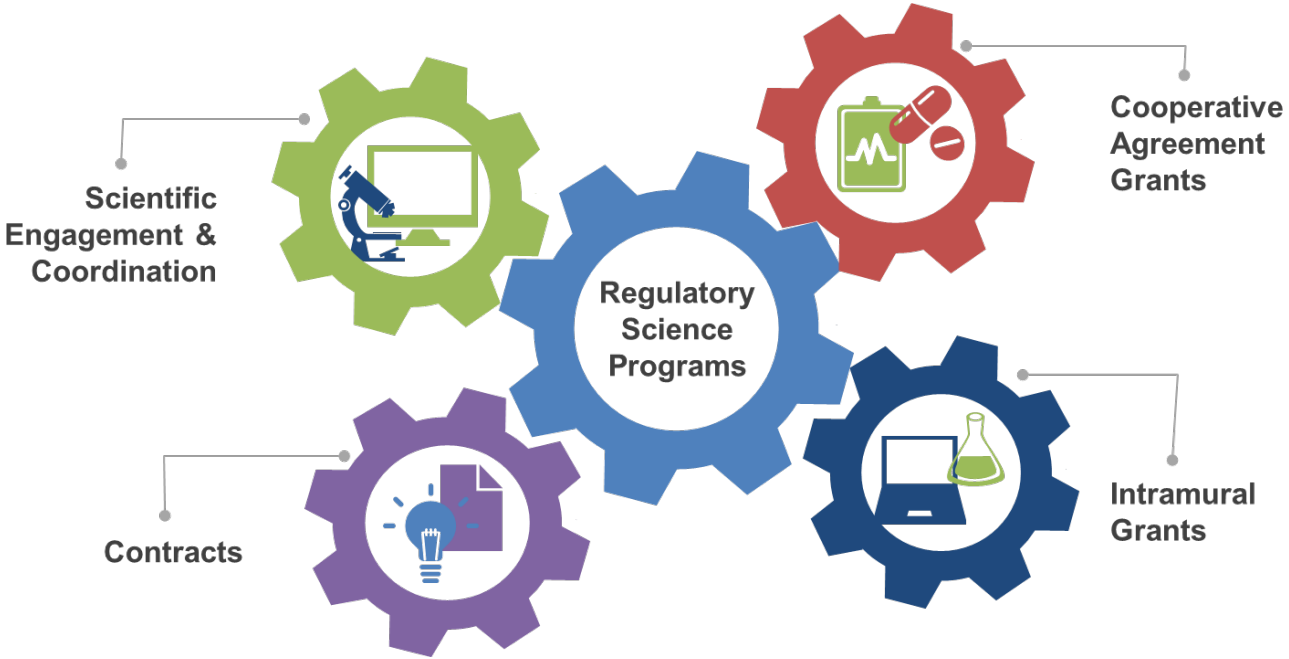
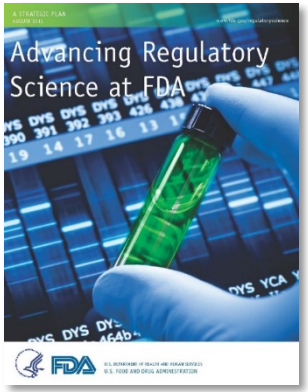
Office of Regulatory Science and Innovation (ORSI)

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.



Scientific Engagement and Coordination



- **FDA Science Board (external)** – link here
  - Official FDA advisory committee, comprised of external thought leaders from academia, industry, non-profits
  - Provides advice/recommendations on how FDA can keep pace with scientific/technical developments
  - Provides input into FDA's research agenda
  - Subcommittees provide expert review of intramural/extramural research
- **Senior Science Council (internal)**
  - Made up of senior scientific leadership
  - Provides advice and guidance to the agency on cross-cutting regulatory science planning, reporting, programs, policies, and communication.
- **Scientific Working Groups**
  - Made up of research and regulatory scientists
  - Collaborative platform that connects FDA scientists to harness expertise and create greater scientific efficiency in addressing cross-centers scientific and regulatory issues.

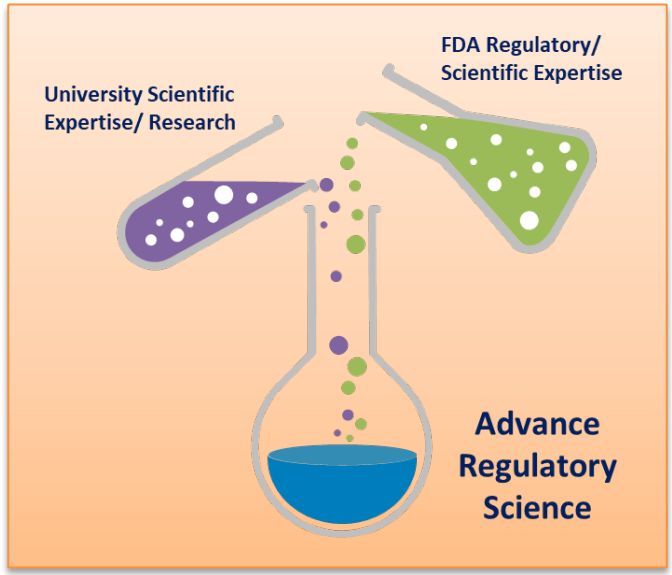
Scientific Working Groups

Cooperative Agreement Grants

Centers of Excellence in Regulatory Science and Innovation

FDA's CERSIs are collaborations between FDA and academic institutions to advance regulatory science through innovative research, training, and scientific exchanges:

- Regulatory Science Research with FDA Subject Matter Experts
- Visiting Scientist Program
- Workshops and Lectures
- Cross-CERSI scientific exchanges
- Certificate and Masters Programs
- Fellowships and CERSI Scholars



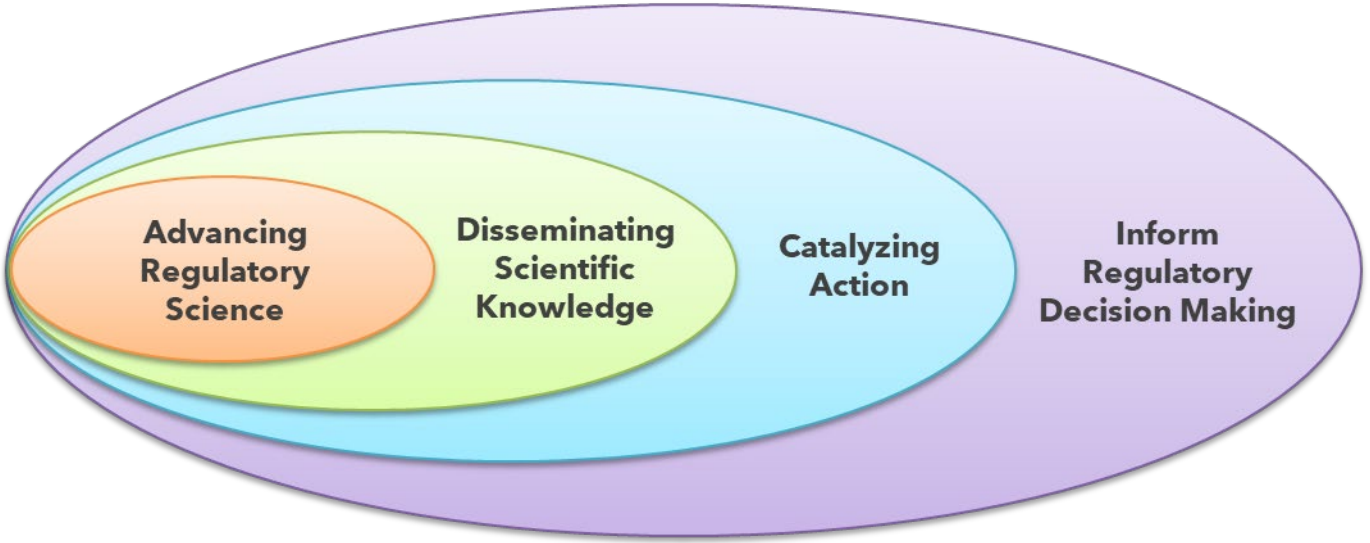
CERSI Regulatory Science Priorities

CERSI Johns Hopkins University | CERSI UCSF-Stanford | CERSI University of Maryland | CERSI Yale-Mayo Clinic

Each cooperative agreement grant is for 5-years.

We host a rigorous grant application and review process to identify and award the CERSIs.

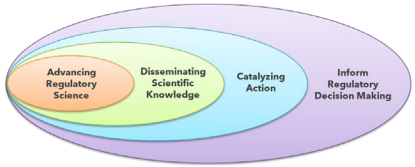
Metrics for Impact



Advancing Public Health from left to right

https://www.fda.gov/science-research/advancing-regulatory-science/**cersi-research-impact-metrics**

Metrics for Impact

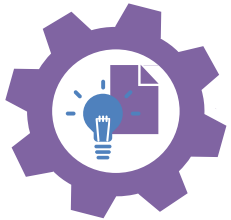


ADVANCE PUBLIC HEALTH

Advancing Regulatory Science	Disseminating Scientific Knowledge	Catalyzing Action	Inform Regulatory Decision Making
Alignment with FDA regulatory science priorities	Scientific publications and citations in literature	Adoption/ adaptation of findings by stakeholders	Development or change in: - Reference materials/ standards
Enhancement of FDA resources/ expertise/ capacity	Presentations at conferences, meeting, FDA Advisory Committees	Adoption/ adaptation of findings in advocacy	- Surveillance strategies - Guidelines/guidance
Facilitation of strategic relationships with expert groups	Incorporation into training and/or education curriculum	Technology transfer to stakeholders	- Regulations - Compliance/ enforcement strategies
Building FDA preparedness for rapid response health emergencies and new developments in emerging regulatory science	Medica coverage	Subject of professional society meeting	- inspection/sampling strategies
	Data-sharing with public	Catalyst for future research	- External communication strategies
		Improvements in consumer understanding	- Labeling
		Adoption for use into medical practice	- Agency policy

Contracts

Advancing Regulatory Science Broad Agency Announcement



To spur innovation in regulatory science, FDA funds extramural research using various contract mechanisms and grants to address broad Agency challenges within FDA's ***scientific priority areas***.

The BAA makes it possible for FDA to solicit innovative ideas and approaches to developing and evaluating FDA-regulated products by tapping into ***external*** knowledge and infrastructure in areas where FDA has limited expertise or capacities.

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

SAM.gov website here.

BAA Rigorous Review Process

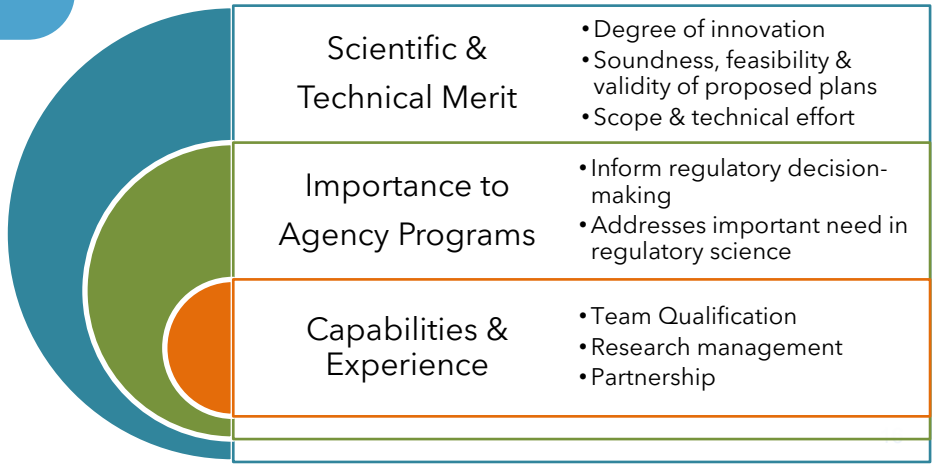
Stage I Review
- Whitepaper & Quad Chart submission
- Panel evaluation
- Invitation/Do not Invite decision

Stage II Review
- Full Technical proposal & Cost proposal review
- Panel evaluation
- Funding consideration

Decision: awarded, revised, rejected
- Contract negotiations
- Proposal resubmission
- Regret notifications

We utilize the Senior Science Council and our network of scientific expertise through the working groups to identify SME's and form the review panel; there is a panel chair that is designated to run the evaluation and prepare a memo to document the review panel's recommendation.

& Evaluation Criteria



Intramural Grants

FDA Chief Scientist's Challenge Grant Program

to foster opportunities ***for cross-cutting cooperation and collaboration*** in regulatory science. The funded research projects serve as an incubator for innovative ideas and enable FDA offices and centers to leverage the creative approaches of our investigators across the Agency to solve their priority challenges.

Five Target Areas:

1) **The MCMi Challenge Grants:** countermeasures against radiological/nuclear, chemical, and biological threats

2) **The Collaborative Nanotechnology (CORES) Challenge Grants**: supporting FDA cross-center and external collaborative nanotechnology regulatory research efforts since 2010.

3) **The Chief Scientist's Challenge Grants:** highly innovative and high-risk efforts that address scientific priority areas and are collaborative, i.e., involve external partners or more than one FDA center or ORA; display rigorous thought, be well focused and have excellent scientific merit. We are encouraging collaborative grants incorporating ***One Health*** approaches.

4) **The Office of Minority Health and Health Equity Challenge Grants:** contribute to identifying and understanding racial and ethnic differences pertaining to safety, efficacy, and effectiveness of FDA-regulated products.

5) **The Office of Women's Health Challenge Grants:** projects aimed at improving women's health.

Intramural Grants

FDA Chief Scientist's Challenge Grant Program

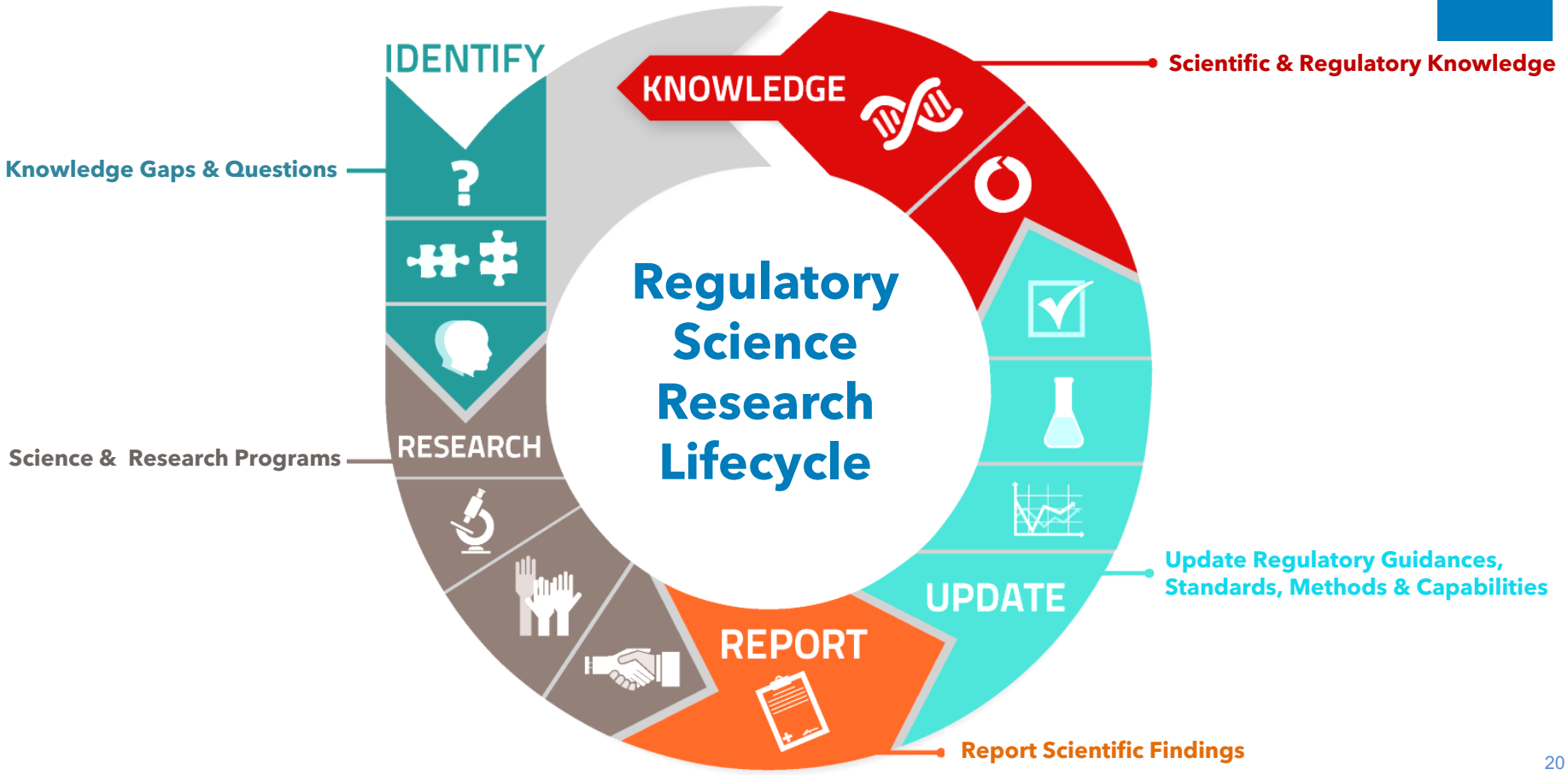
- These programs solicit reviewers through the Senior Science Council to identify SME from their Centers to review specific proposals based on their expertise and knowledge of the science topic areas.
  - Some may solicit both internal and external reviewers to review grants.
    - For external reviewers, they generally solicit reviewers from academia or other U.S. government agencies.

- For final selection, panel meetings are held, projects scored, ranked and then funding delegated accordingly.

FDA's Research Impact Working Group

FDA is continuously looking for expanded opportunities to convey impact. The RWIG is tasked to:

- Identify potential approaches for characterizing, evaluating and communicating the impact of FDA research;
- Identify and evaluate how best to capture and interpret meaningful data to address how FDA is meeting its regulatory science priorities;
- Host a larger learning environment, where feasible, by communicating outside the WG and the agency about efforts on identifying, evaluating, and communicating research impact.

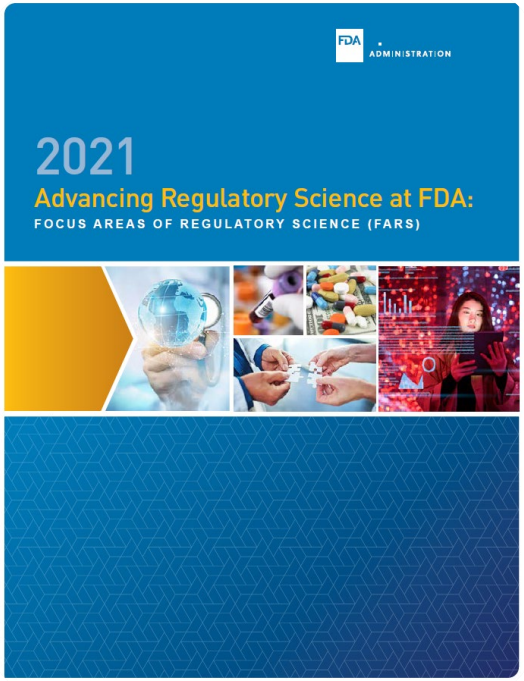


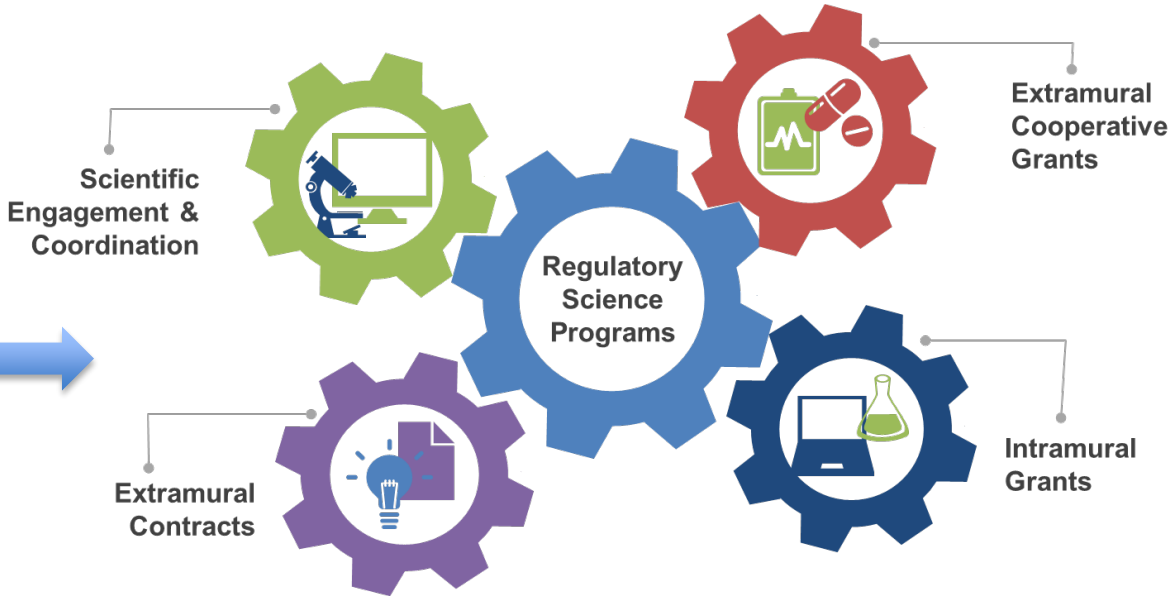
Adapted from CDER'S Science Program

Considerations for Program Evaluation

- FDA has a dedicated office that provides resources for program evaluation and process improvement.
- With respect to *regulatory science*, our key internal stakeholders are our scientists
  - Host roundtable discussion with scientists in the working groups
  - Input from senior scientific leadership and FDA science board
  - Engagement with partners, such as the Reagan Udall Foundation, National Center for the Advancement of Translational Science
  - Connecting with stakeholders that support FDA priorities through meetings, conferences, workshops

In the past, ORSI Program Priorities were structured by the 2011 Strategic Plan for Regulatory Science. Going forward, we're looking to be agile and dynamic using the Focused Areas of Regulatory Science.





As focus areas evolve, how do our programs evolve to meet stakeholders needs?

www.fda.gov

FARS@fda.hhs.gov