UIDP Strengthening University-Industry Partnerships

Partnership opportunities with FDA Center for Devices and Radiological Health Partners

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Collaborating with FDA

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It’s About the Patients

CDRH - Who We Are

CDRH is a team of dedicated, highly skilled, and internationally respected public health employees:

- **Physicians**
- **Biologists**
- **Chemists**
- **Physicists**
- **Engineers**
- **Statisticians**
- **Epidemiologists**
- **Microbiologists**
- **Nurses**
- **Pharmacologists**
- **Veterinarians**
- **Toxicologists**
- **Specialists in Public Health Education and Communication**

4

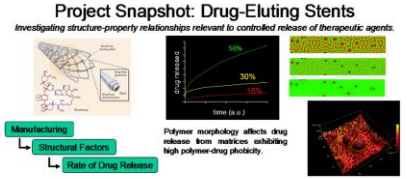
Our Vision

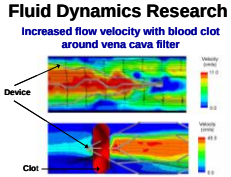
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

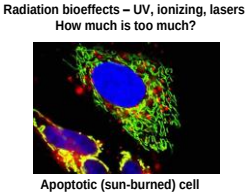
- The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.
- Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.
- Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

CDRH Regulatory Science

- Research – supports the Center's regulatory and scientific needs
  - Methods to determine safety and efficacy
  - Test methods to evaluate performance
  - Processes to improve manufacturing quality
  - Independent data for premarket, postmarket and compliance decisions
- Leveraging expertise
  - Collaborations (CRADAs, MOUs, etc.)
  - Medical Device Fellowship Program
- Standards development
- Public-private partnership to advance regulatory science







Collaboration is Imperative

As we look around us in a new century, we realize that businesses and non-profits in today's interconnected world will neither thrive nor survive with visions confined within the walls of their own organizations. They need to look beyond the walls and find partners who can help achieve greater results and build the vital communities to meet challenges ahead.

---Frances Hesselbein & John C. Whitehead of the PF Drucker Foundation & Harvard Business School

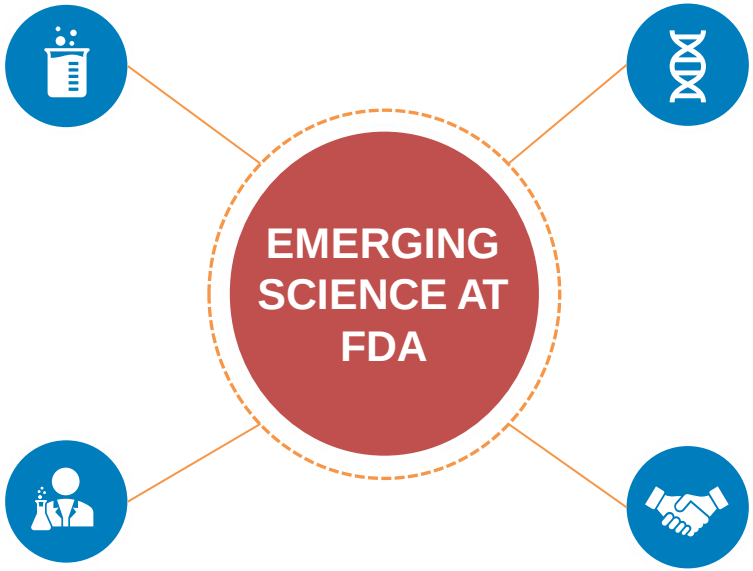
Scientific Partnership Mechanisms

FDA BAA

FDA solicits proposals for innovative ideas and approaches in developing and evaluating FDA-regulated products. This is a competitive contract mechanism.

CERSI Program

Under cooperative agreement grants, the Program supports collaborations between FDA and academic institutions to advance regulatory science through innovative research, training, and scientific exchanges.



CRADAs

Collaborative engagement to advance innovations in regulatory science. This mechanism is authorized under the Federal Technology Transfer Act.

MOUs

Declaration of shared initiatives and partnership goals between FDA and external academic or non-profit organization, or federal agency. This is not a legally binding mechanism.

Scientific Partnership Mechanisms

Advancing Regulatory Science Broad Agency Announcement (FDA BAA)

Since 2012, FDA has been soliciting proposals to advance the state of the art within prioritized regulatory science areas through a specialized **contract** mechanism. For more information, visit the FDA BAA webpage.

Centers of Excellence in Regulatory Science Program (CERSI Program)

FDA's CERSIs are partner institutions under **cooperative agreement grants** to collaboratively address promising areas of science and new methods of evaluation that contribute to tools, standards, and approaches required to assess the safety, efficacy, quality, and performance of innovative products. Visit the FDA CERSI webpage.

Cooperative Research and Development Agreement (CRADA)

The CRADA is an important tool for FDA and non-federal partners to collaboratively advance new technologies. Under a CRADA, FDA and its partners can exchange personnel, services, facilities, equipment, or other resources. No funds from FDA are awarded under a CRADA. Visit FDA Technology Transfer for more information.

Memorandum of Understanding (MOU)

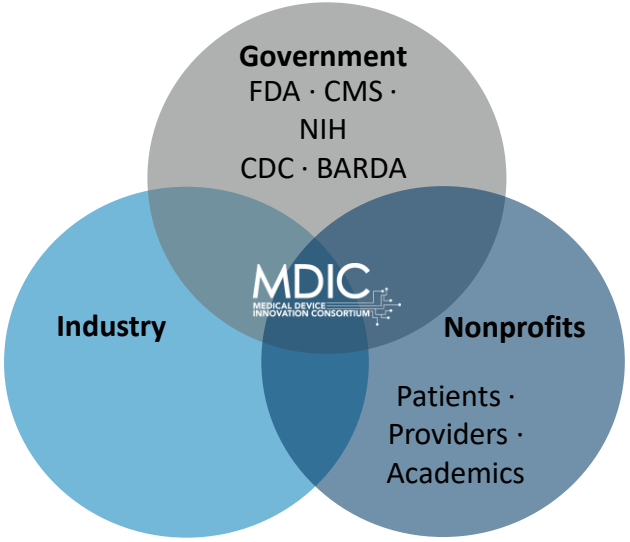
FDA enters into MOUs to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities. It is used to define lines of authority or responsibility or to clarify cooperative procedures. The MOU constitutes an understanding between the parties but is a non-binding agreement. Visit FDA MOUs.

Mechanisms Details

Mechanism	FDA Funds to Partner?	Legally Binding?	Other key features
FDA BAA	Yes through specialized competitive federal contract mechanism	Yes	
FDA CERSI Program	Yes through competitive cooperative agreement grant mechanism	Yes	Current FDA CERSIs are at the University of Maryland, University of California in a joint effort with Stanford, Johns Hopkins, and Yale in a joint effort with the Mayo Clinic.
CRADA Program	No	Yes	FDA is authorized to provide collaborator with an exclusive option to access inventions arising from the CRADA collaboration. FDA is authorized to accept funds from collaborator to use on the research project.
MOU	No	No	

Public-Private Partnerships

A 501 (c)(3) and public-private partnership created with the sole objective of advancing regulatory science of medical devices for patient benefit.

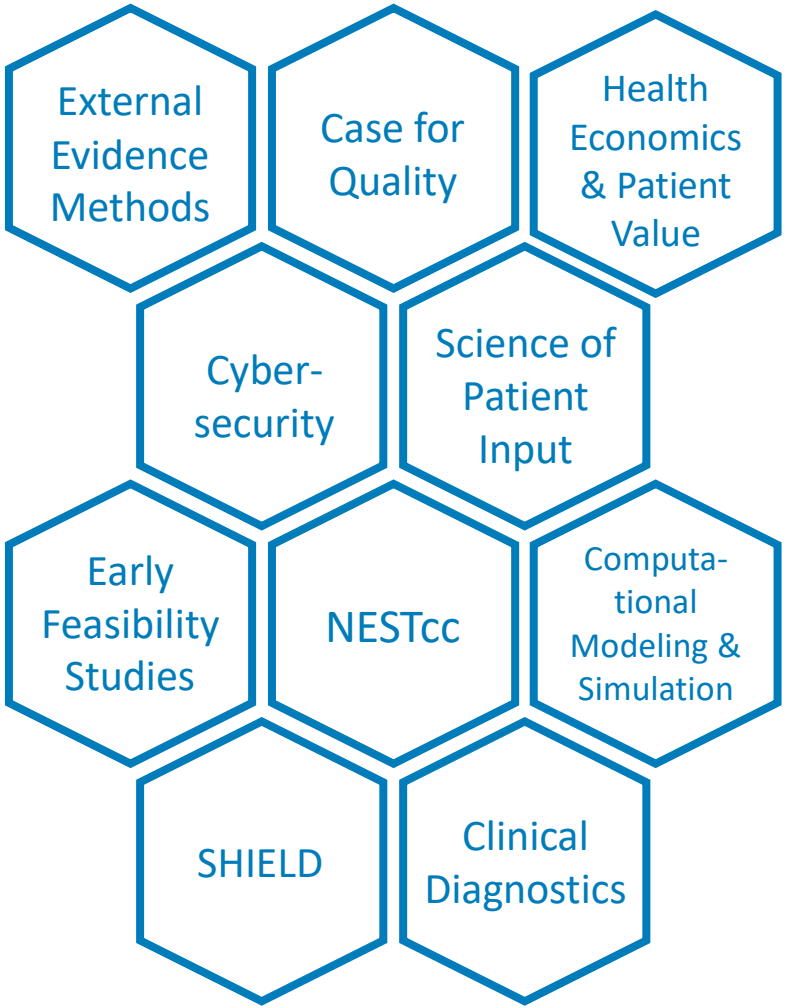


Resources · People · Intellectual Capital

HIGHLIGHTS

- 55 participating member organizations
- Leading resource on issues important to the Medtech innovation ecosystem
- 4 core initiatives housing 10+ program areas and projects
- Congressional testimony on modernizing clinical trials
- $35M + funding from grants and contracts for program initiatives

Collaboration between CDRH and MDIC has made a valuable impact on many areas of medical device regulatory science for patient benefit



What Is a Collaborative Community?

Collaborative communities are continuing forums where public and private sector members proactively work together to:

- Achieve common objectives and outcomes
- Solve shared challenges
- Leverage collective opportunities in an environment of trust, respect, empathy and openness.

What Collaborative Communities Are *Not*

- They are NOT led by the FDA.
- They are NOT convened by the FDA.
- They do NOT exist to advise the FDA.
- Their membership and governance are NOT directed by the FDA.
- They are NOT task forces, working groups, or commissions.

Collaborative Communities Toolkit

- A resource for stakeholders interested in establishing Collaborative Communities

- Please visit CDRH website (https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together)

Potential Outcomes of a Collaborative Community

- Tool Development
- Peer-reviewed publications
- Research Agenda & Projects
- White Papers
- Healthcare Coverage & Reimbursement Decisions
- Best practices
- Templates or Frameworks
- Improved Relationships

Thank You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