Center for Biologics Evaluation and Research

Applying Regulatory Science to Advance Development of Innovative, Safe and Effective Biologic Products

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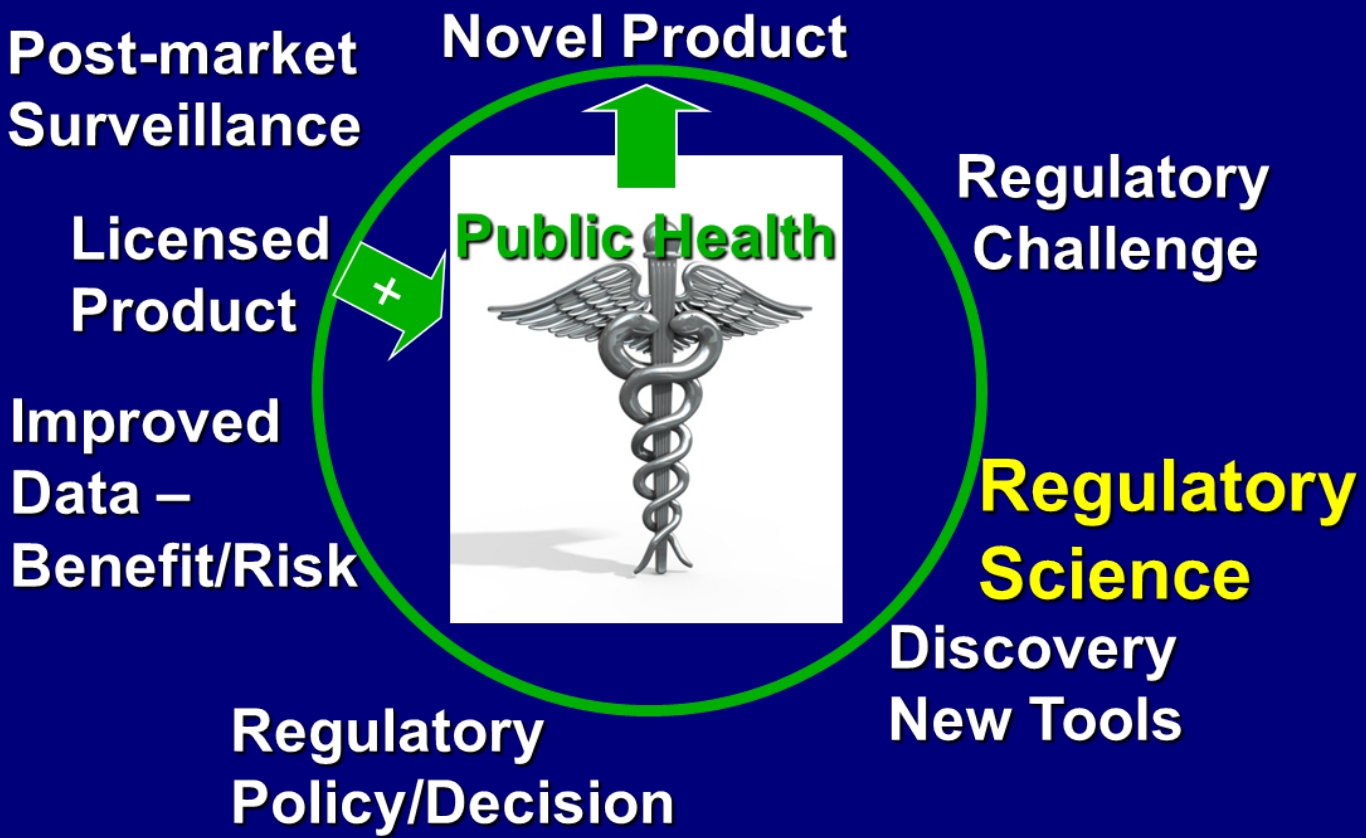
Associate Director for Research

Using Science and Regulation to Advance Product Development

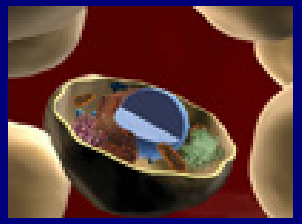


CBER researcher =
"Researcher-Regulator"
~20% CBER Staff

Integration of research and review ensures

Relevance, Expertise, Timeliness, and Usability

2016 CBER Regulatory Science and Research Goals



Goal 1. Advance the scientific basis for regulation of biologics, human tissues and blood to enhance safety, effectiveness, quality and consistency through development and evaluation of new concepts, methods, models, and reagents.

Goal 2. Develop and assess nonclinical models and methods with improved predictive value, and, as feasible, reduce, refine, or replace the use of animals, for evaluation of safety and effectiveness of CBER-regulated products.

Goal 3. Improve clinical evaluation related to CBER-regulated products through the use of new biomarkers, large scientific and healthcare datasets, and innovative design and analysis of clinical studies by applying new statistical, epidemiological, and mathematical modeling approaches, and considering patient input to inform benefit-risk assessment of general and special populations.

Goal 4. Prepare for future regulatory and public health challenges through investments in emerging science and technology, and develop and sustain varied scientific expertise.

CBER

Annual Review of Research

PI provides
For each project
- Progress report
- Future plans
- Budget Request

Presentations, Pubs
Other output

Information reviewed
- Lab chief, DD, ADR, OD
- Relevance
- Productivity
- Quality

Research Reporting Database

Funding Allocated
- Relevance to priority
- Scientific/Reg Output
- Feasiblity

CBER

Cyclic Peer Review of Every PI

External – Site Visits

peer review by scientific experts

Internal – Promotion, Conversion, Evaluation Committee

Research Impact Framework: Portfolio and Project Level Review

	Key elements	Applies to …	Primary use
Mission relevance and potential for impact	Alignment with **major Center- or Office-wide strategic initiatives** and priorities	**Portfolio** and individual projects	Consistent approach for portfolio management and communicating about CBER research to external stakeholders
	Building a world class review capability for current or anticipated pipeline	**Portfolio**	
	Maintenance of an **agile set of internal capabilities** for addressing unexpected, urgent public health needs	**Portfolio**	
Position to make a unique contribution	Using CBER's **unique perspective to address scientific gaps and questions** to enhance our ability to fulfill our regulatory mission	Individual **projects**	Annual Reporting and oversight of CBER research projects
	Scientific merit	Individual **projects**	
	PI's historical **productivity**	Individual **projects**	

Site-Visit Report

- Draft report is distributed to full Advisory Committee
- Final report is approved by full Advisory Committee
- Final report used in many ways:
  - Internal peer review of research/PI by Promotion, Conversion, Evaluation Committee (PCE) for personnel actions
  - By PIs for improving research program
  - By management, resource allocation decisions may be impacted by report (pending resource availability)
- Outcomes of Advisory Committee Meeting
  - Accept report
  - Amend report
  - Reject report and send back to Site Visit Team

Thank you!

To the Site Visit reviewers and
Advisory Committee

Your input improves CBER's research programs

External review is critical to fulfilling our
regulatory mission!