

Center for Biologics
Evaluation and Research
FDA

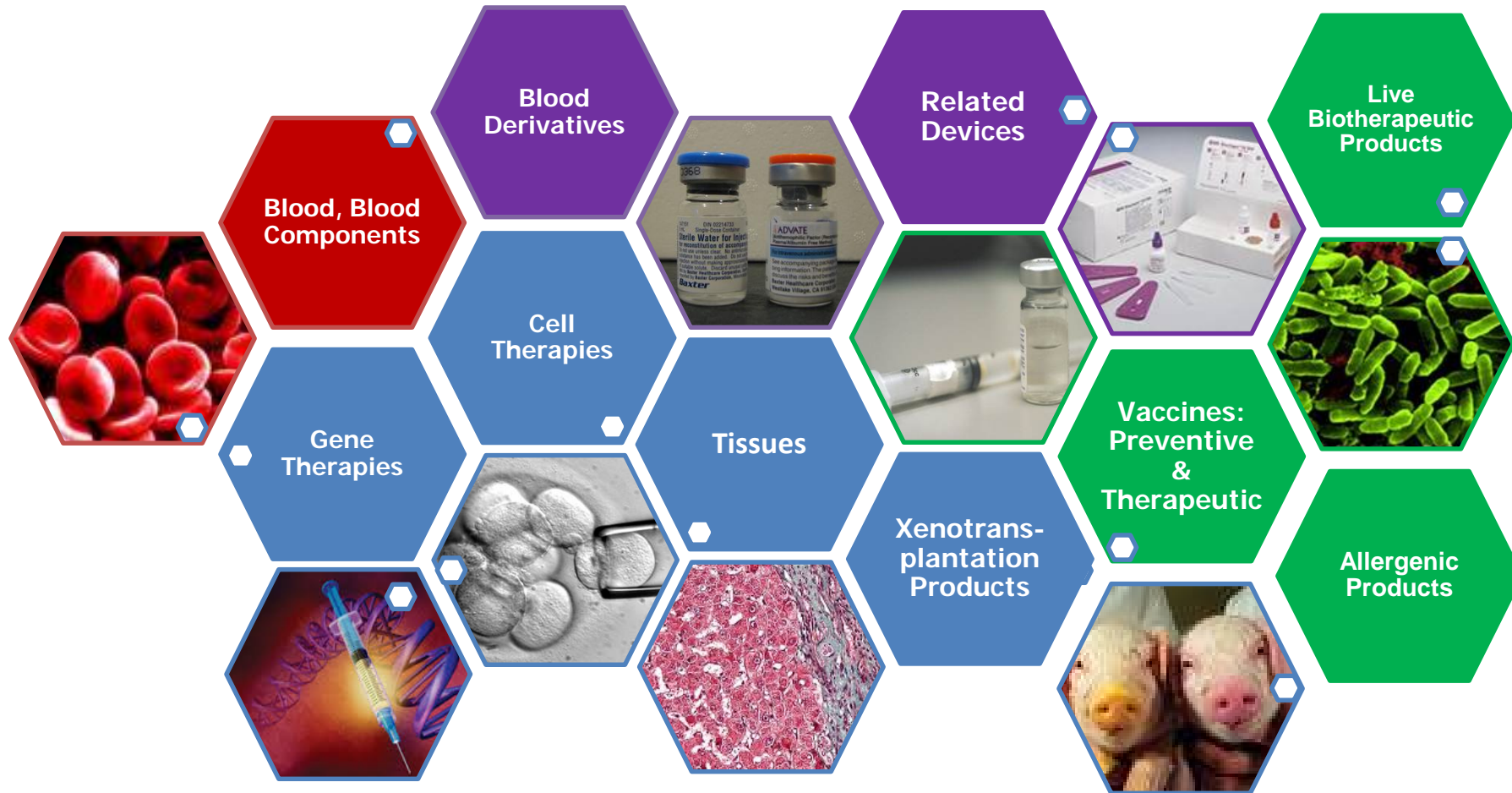
Overview

Monica L. Young, Ph.D.

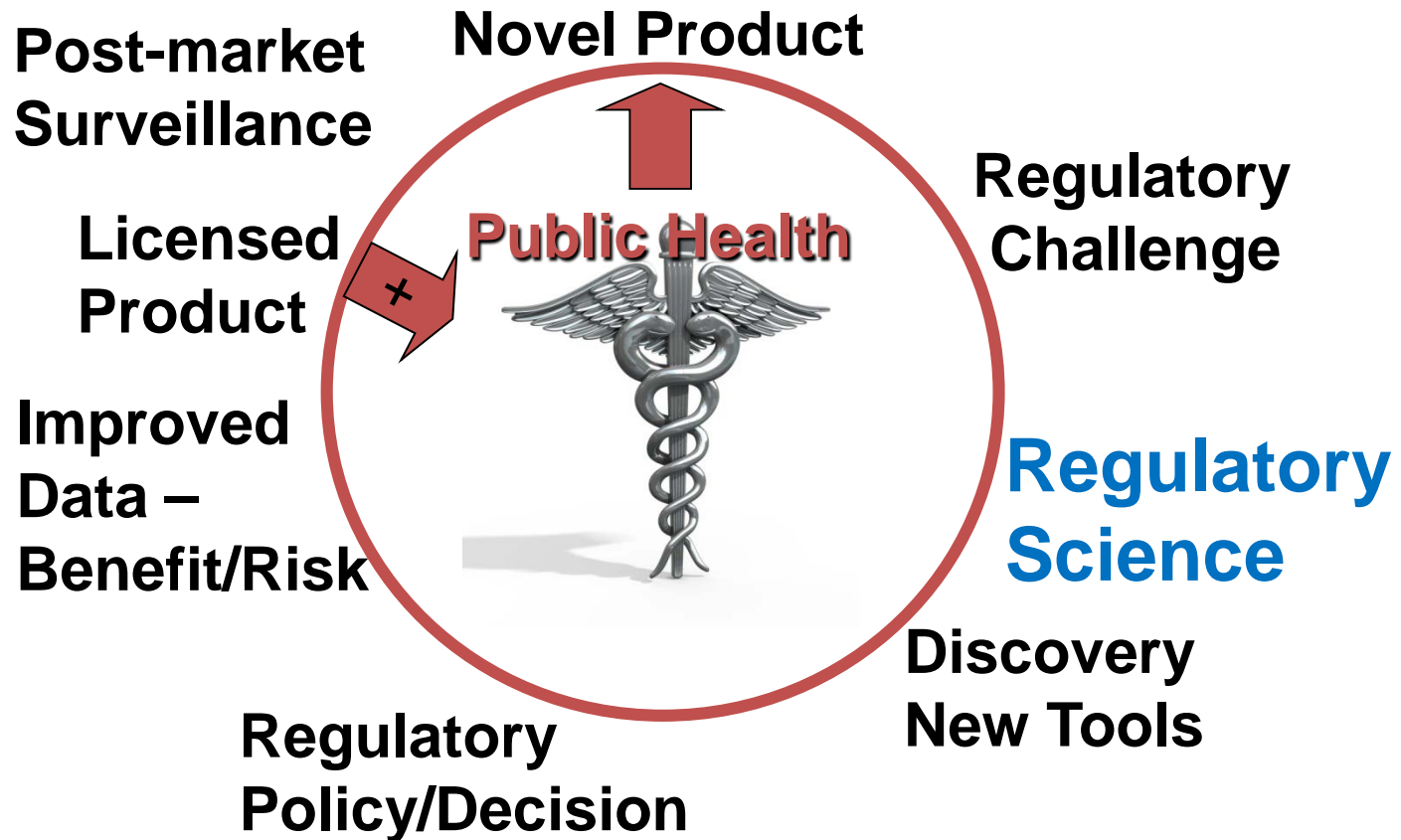
Senior Advisor to the Associate Director for Research



CBER Regulates Complex Products



Using Science and Regulation to Advance Product Development



Benefits of CBER Research Program



- The integration of research and review:
 - Ensures relevance, expertise, timeliness, usability
 - Fosters rational policy and decisions based on sound science, law, public health impact
- Prepare for future innovative products and public health challenges
- Develop tools and data that are available to all stakeholders and support development of product classes
- Recruit and maintain highly trained scientists with necessary expertise to review regulatory submissions

Scientific Expertise

- Applied technologies: NMR, mass spec, flow cytometry, microarray, high throughput sequencing and related bioinformatics/IT
- Microbiology: parasitology, bacteriology, virology, microbiome
- Immunology
- Biochemistry and molecular biology
- Cell and developmental biology, tissue engineering, and microphysiologic systems
- Epidemiology, meta-analyses of large healthcare databases
- Biostatistics
- Bioinformatics

White Oak Lab Facility

- Core Facilities:
 - Flow cytometry
 - Confocal and electron microscopy
 - Biotechnology
 - Illumina HiSeq and MiSeq
 - Oligonucleotide, siRNA, PNA, and peptide synthesis
 - Peptide and DNA sequencing (ABI, capillary)
 - Taqman probe synthesis
 - HPLC; Capillary electrophoresis
 - Mass Spectrometry/Proteomics
 - Amino acid analysis
 - Bioinformatics support for NGS data analysis and storage
- State-of-the-Art Vivarium
 - Imaging facility with MRI, digital X-ray, IVIS, ultrasound, CT
 - ABSL-2 and -3; procedure rooms
 - Transgenic derivation facility



CBER Peer Mentoring Group

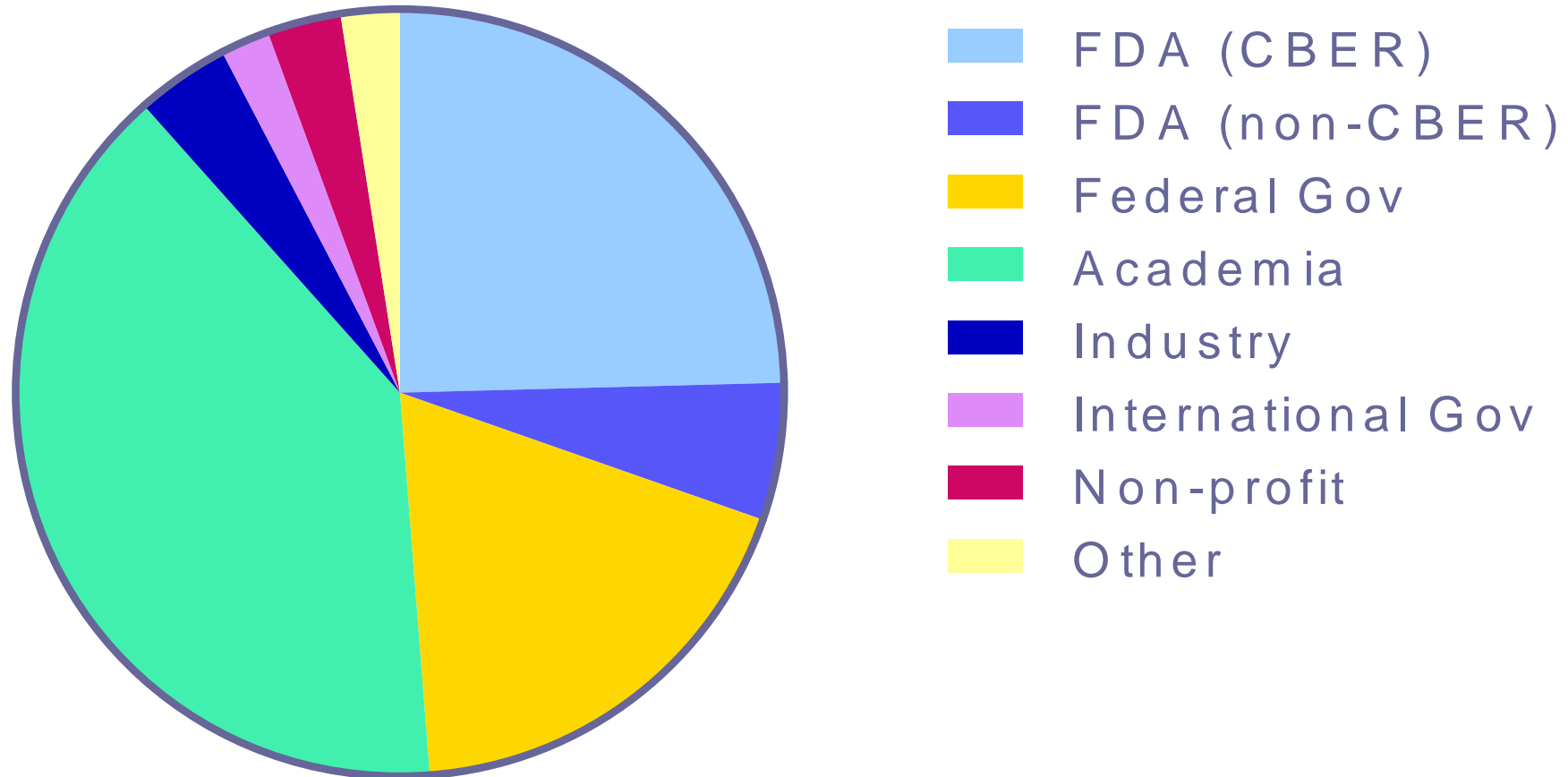
- CBER Peer Mentoring Group
 - Monthly meeting, open to all PI's
 - Discuss general issues, how to manage different responsibilities, eg, recruitment, budget, personnel issues, etc.
 - Informally mentored by senior PI volunteers

CBER Advances Regulatory Science



Collaborations by Sector

Total=484



Data from FY18 CBER Research Reporting Database

Research Management Processes

- CBER Regulatory Science Council develops
 - Research Goals and Objectives
 - Research evaluation framework and criteria to measure scientific and regulatory impact
 - Portfolio review of research program
- Evaluation of research program
 - Management (Office and Division level)
 - Internal and External Peer Review

CBER Research Goals



Advancing the scientific basis for regulation of biologics, human tissues and blood by:

Goal 1

Developing and evaluating technology, reagents, and standards to inform and improve chemistry, manufacturing, and controls (CMC).

Goal 2

Developing and assessing nonclinical models and methods predictive of clinical performance with respect to toxicity and effectiveness.

Goal 3

Improving clinical evaluation pre- and post-licensure through use of big data, innovative designs and statistical, analytical and modeling approaches.

Goal 4

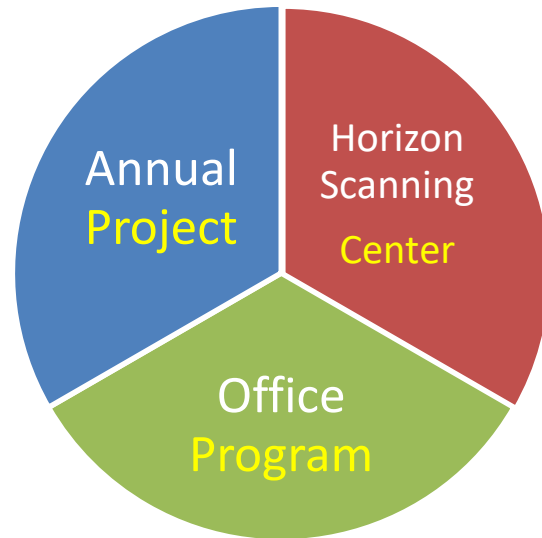
Preparing for future regulatory and public health challenges.

CBER Evaluation Framework

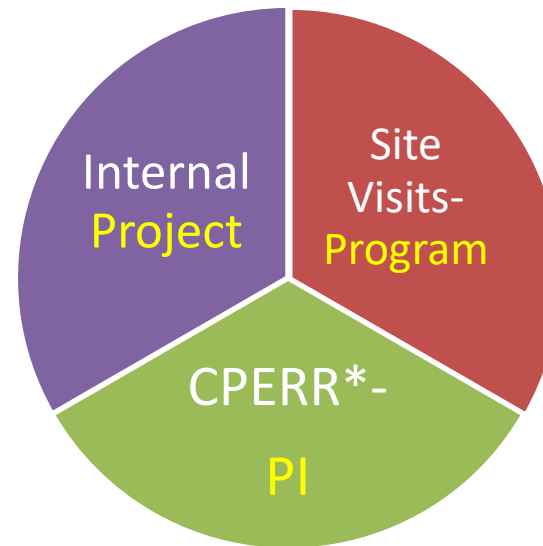


Overview of CBER Research Evaluation: Management and Peer Review

Management Review

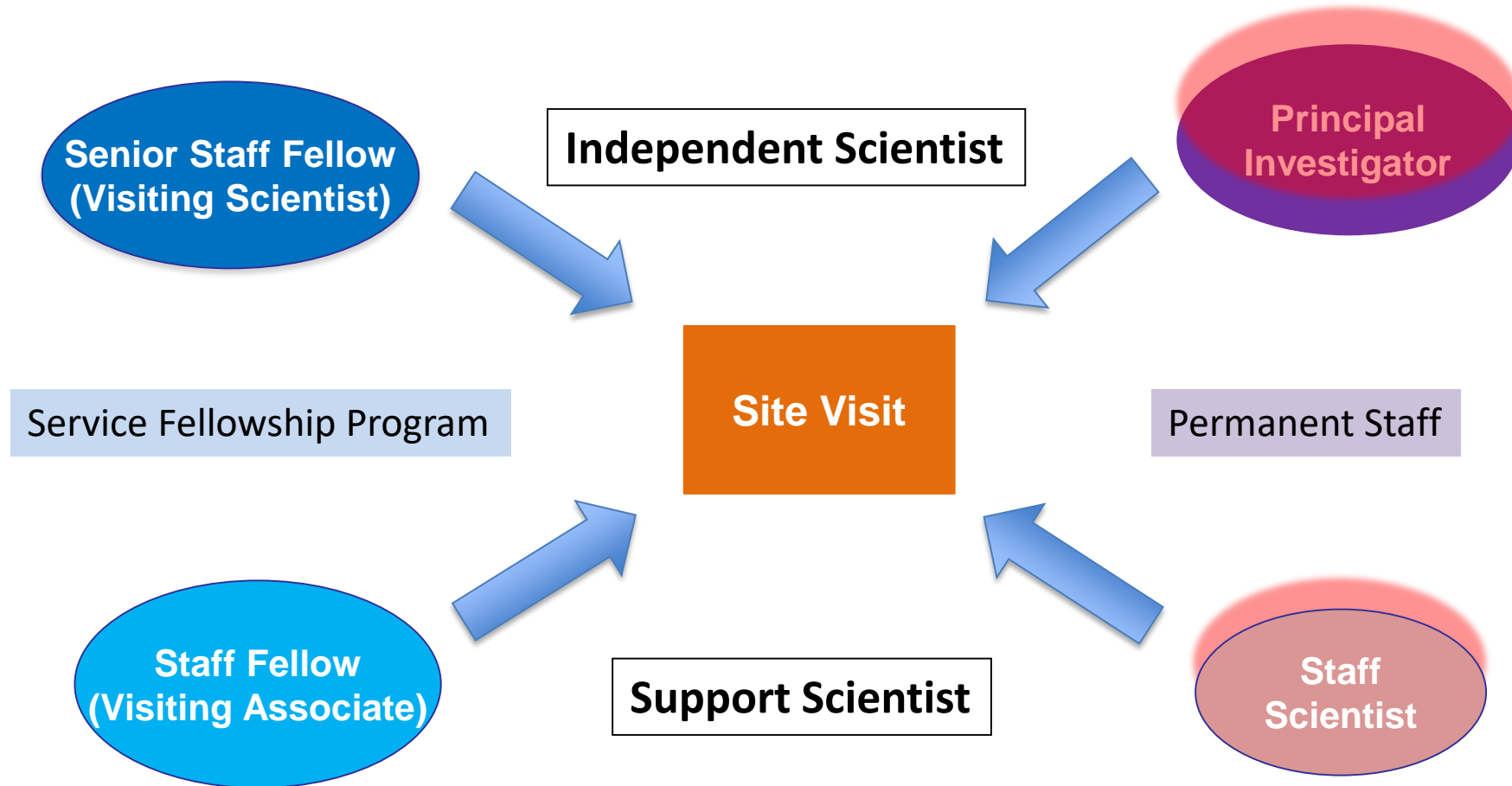


Peer Review



*CPERR:
Committee for
Promotion and Evaluation
of Researcher-Reviewers

Researcher-Reviewers Who Undergo External Peer Review



Site Visit Report

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

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!**