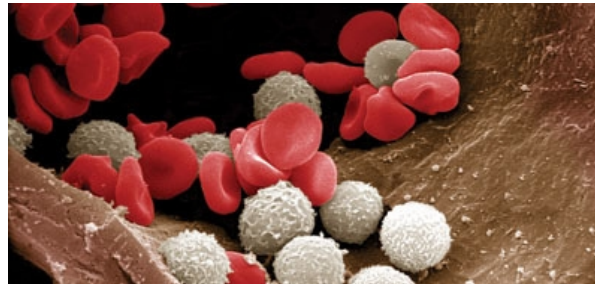
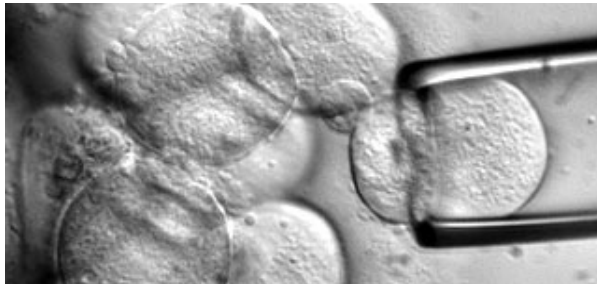
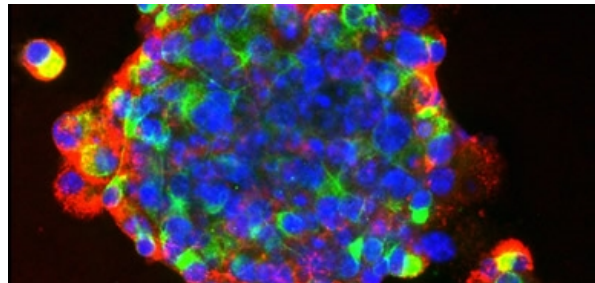
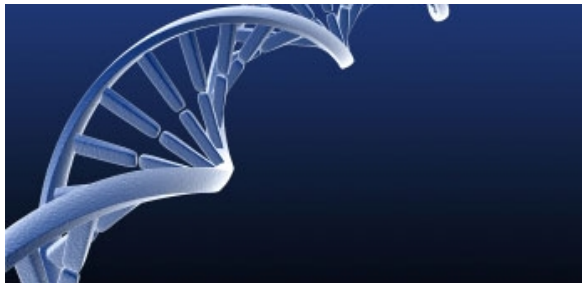


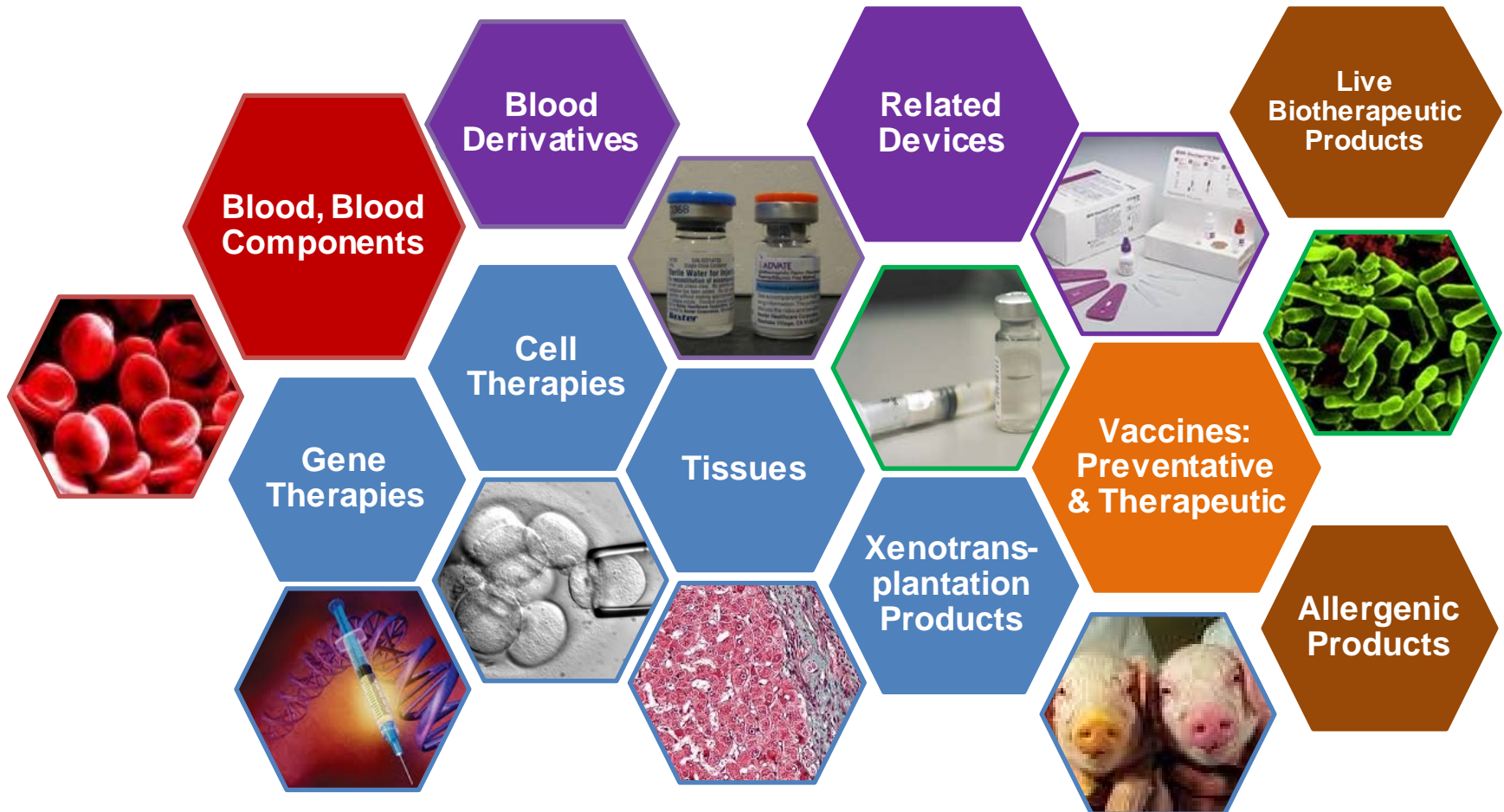
Overview of CBER Research Programs

Monica L. Young, Ph.D.

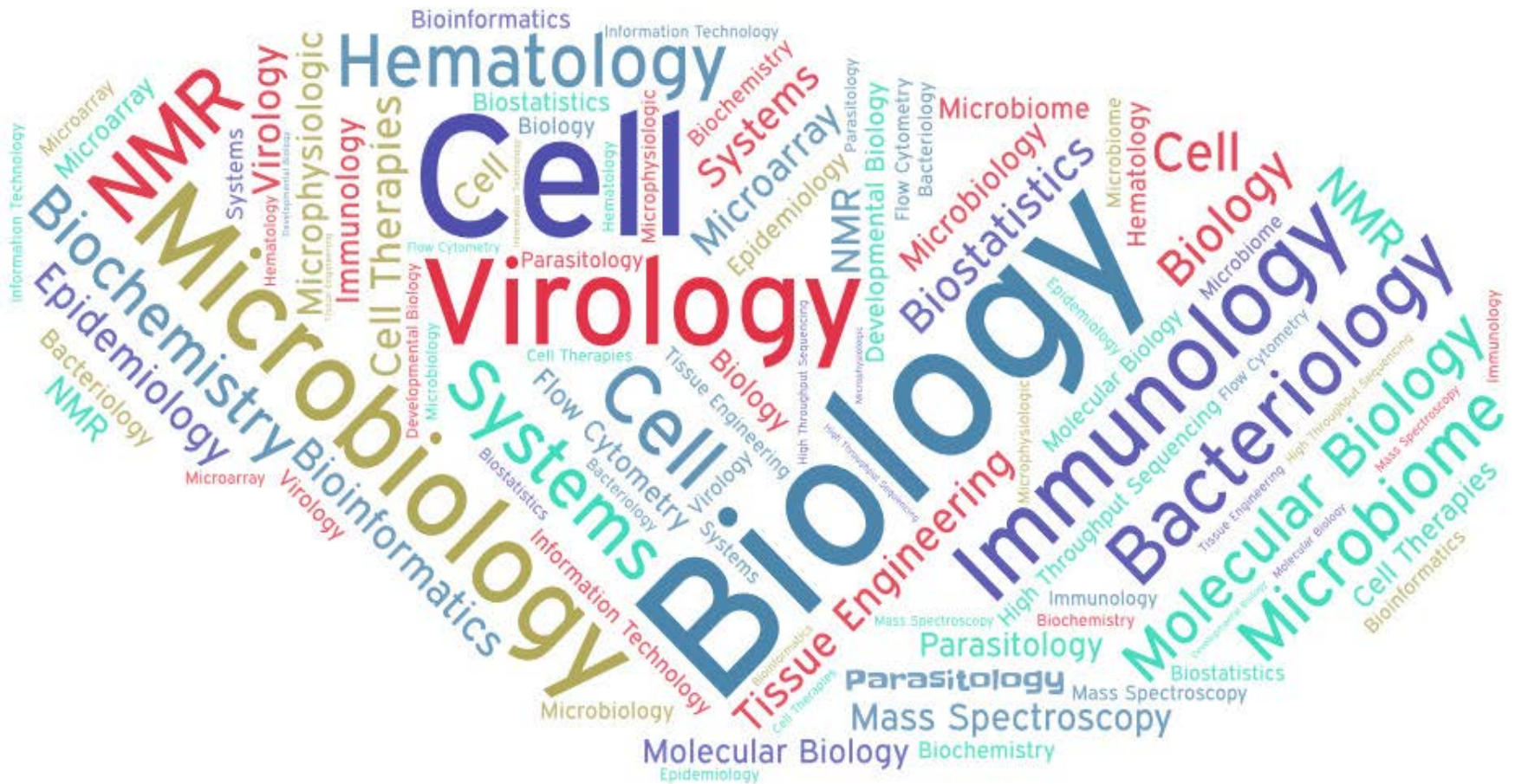
**Senior Advisor to the Associate Director for Research
Center for Biologics Evaluation and Research
U.S. Food & Drug Administration**



CBER Regulates Complex Biological Products



CBER Scientific Expertise



CBER Strategic Plan Goals

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

Goal 1

Facilitating the development and availability of safe and effective medical products through the integration of advances in science and technology

Goal 2

Conducting research to address challenges in the development and regulatory evaluation of medical products

Goal 3

Increasing preparedness for emerging threats and promote global public health

Goal 4

Managing for strategic excellence and organizational accountability

CBER's Researcher-Reviewers: The Approach to Regulating Biologics

- Investigator-initiated research
- Active research programs:
 - Range from basic to targeted studies related to regulated products
 - Ensures understanding state-of-the-art techniques that are the source of data in regulatory decisions
 - Ensures efficient, effective, credible review
 - Fosters decisions based on sound science
- CBER's research and review are integrated



CBER's Research-Reviewers: Role in Regulatory Review Teams

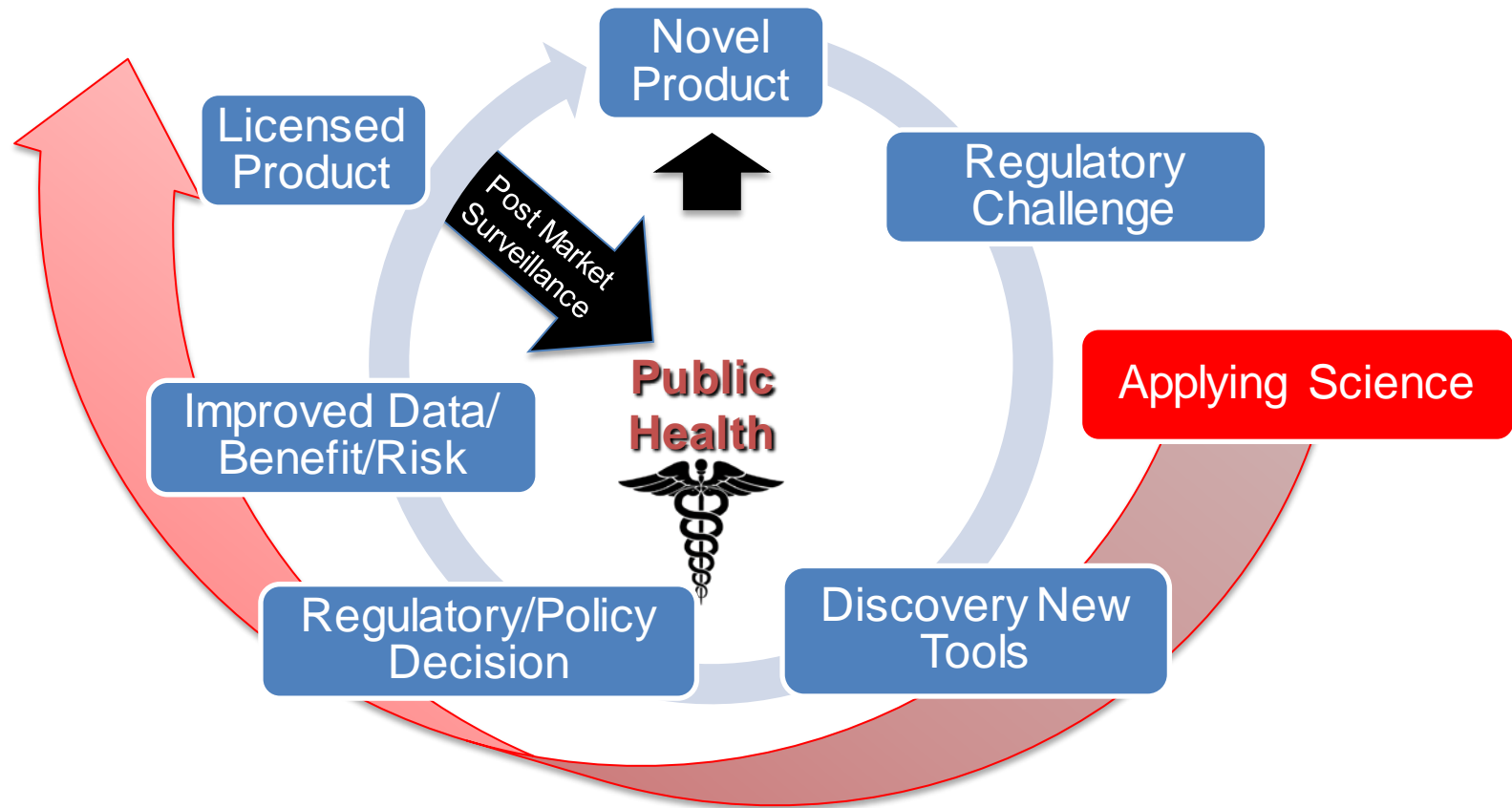
- Chemistry, manufacturing, and control (CMC) product reviewer:
 - Scientific rationale, data for proof-of-concept
 - Production techniques and resulting product
 - Quality control testing
 - Clinical assays

Other review team members:

- Regulatory Project Manager: oversight
- Pharmacology/toxicology reviewer
- Clinical reviewer
- Statistical reviewer



Using Science and Regulation to Advance Product Development

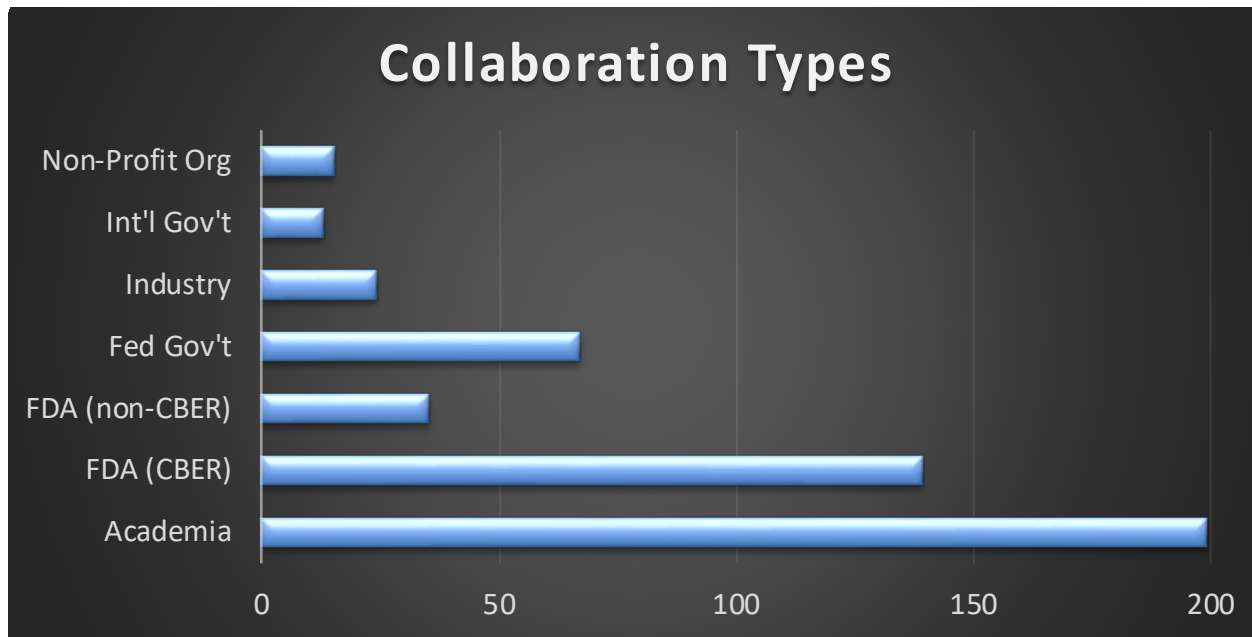


White Oak Lab Facility

- 450,000 square feet for ~ 150 BSL-1 to BSL-3 laboratories and offices for > 500 research staff
- Core technologies:
 - Flow cytometry
 - Confocal microscopy
 - High-performance Integrated Virtual Environment (HIVE)
 - Biotechnology core facility:
 - Oligonucleotide, siRNA, PNA, and peptide synthesis
 - Peptide sequencing, DNA sequencing, RNASeq
 - HPLC; capillary electrophoresis
 - Mass spectrometry and proteomics
- State-of-the-art Vivarium
 - Imaging facility with MRI, digital X-ray, IVIS, ultrasound
 - Transgenic derivation facility



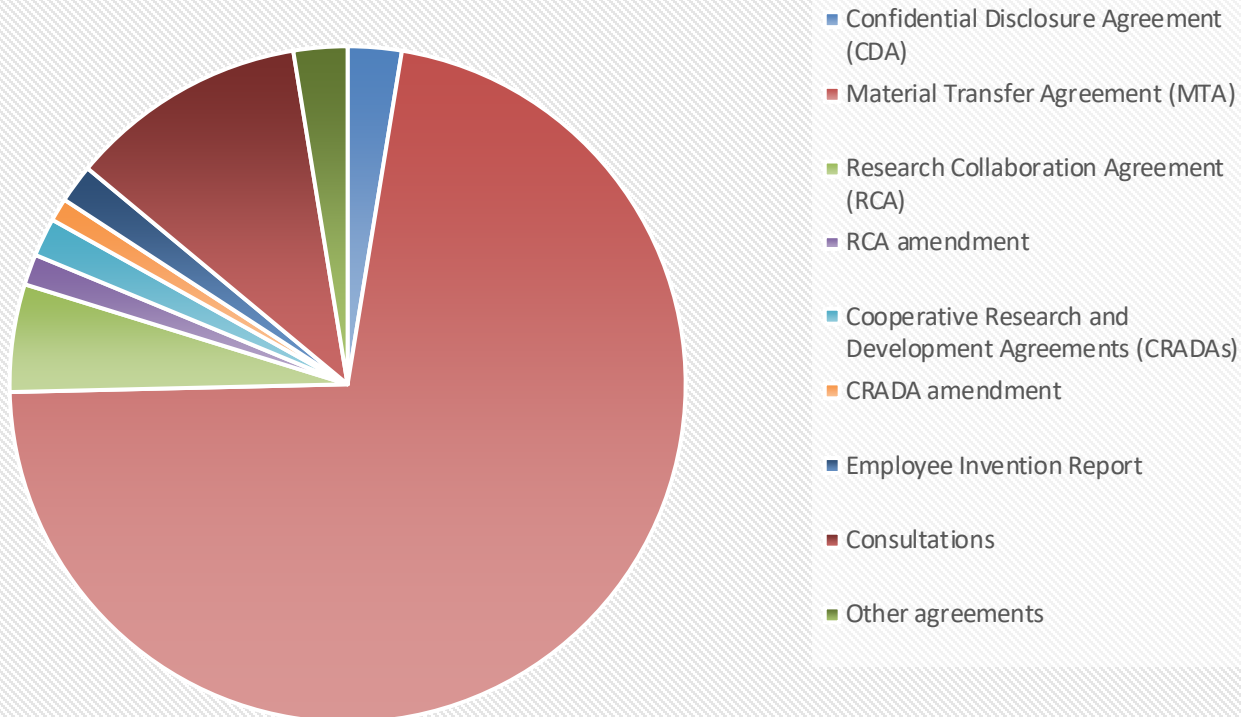
CBER Advances Applied Science through External Collaborations-I



Data from FY21 CBER Research Reporting Database

CBER Advances Applied Science through External Collaborations-II

Leveraging Formal External Mechanisms: Contracts, Grants, Tech Transfer (234 agreements)

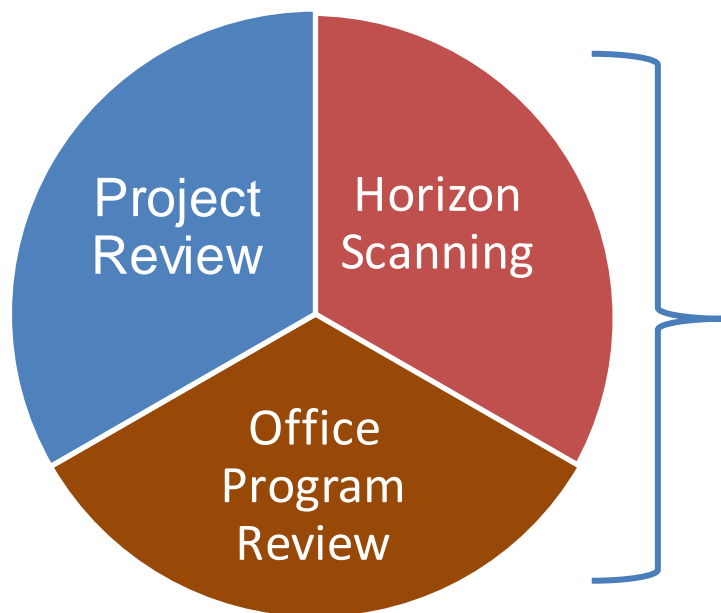


Benefits of CBER Research Program

- Prepares for future innovative products and public health challenges
- Facilitates recruitment and retention of highly trained scientists, with necessary expertise to review regulatory submissions
- Develops data and tools that support development of classes of products
- Fills knowledge gaps that inform policy development and regulatory decision-making

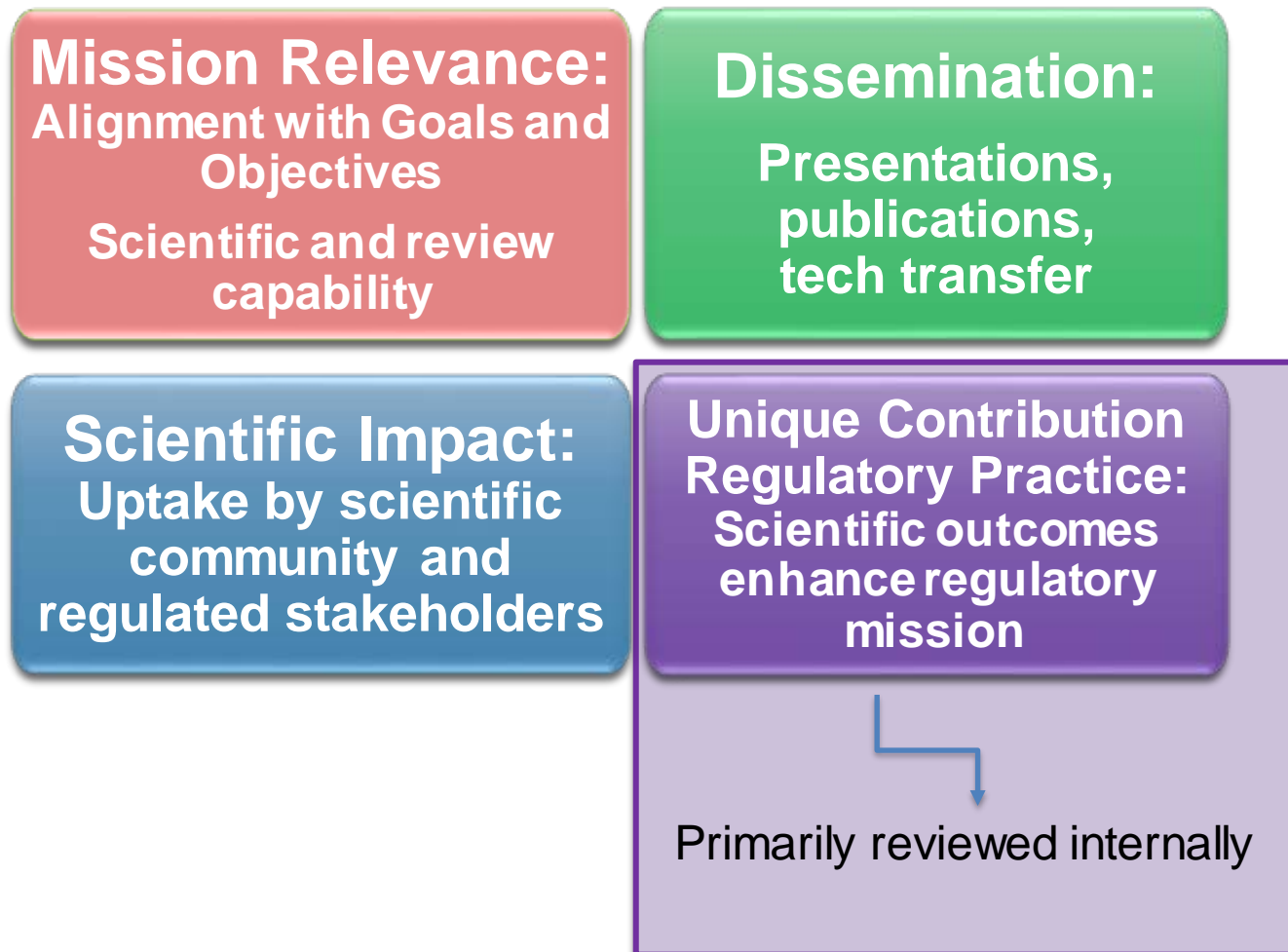


Overview of CBER Research Evaluation



| Evaluation | Frequency | By Whom |
|---------------------------|---------------|---|
| Project Review | Annually | Lab Chiefs, Division, Office Management |
| Horizon Scanning | Every 4 years | Office Staff & Center (RSC) |
| Office Review of Projects | New projects | Office & Center (RSC) |
| Site Visits | Every 4 years | External SME committee |

CBER Evaluation Framework



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:
 - By PIs for improving research program
 - By supervisors for internal review of the program's progress
 - By management, resource allocation decisions may be impacted by report (pending resource availability)

Thank you!

External review is critical to fulfilling CBER's regulatory mission!
Your input ensures CBER maintains high quality research programs.