U.S. FOOD & DRUG ADMINISTRATION

Overview of CBER Research Programs

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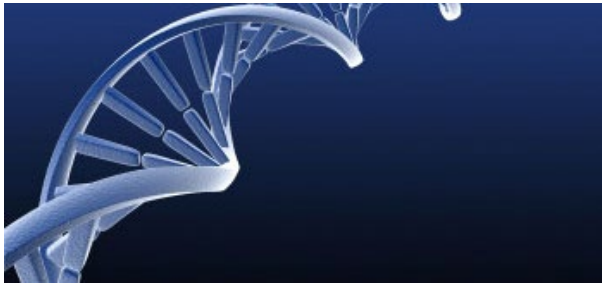
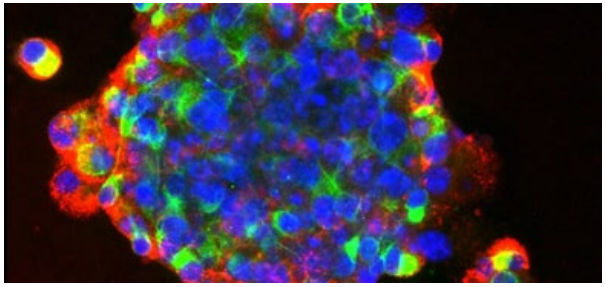
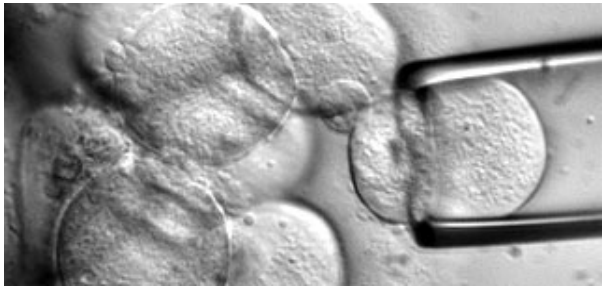
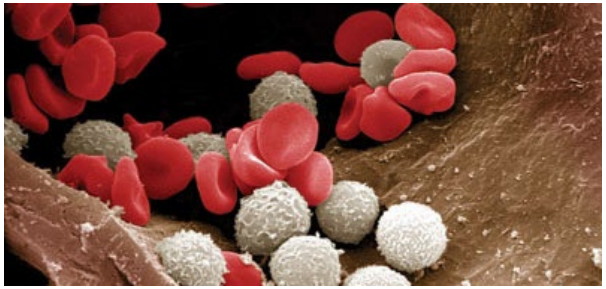
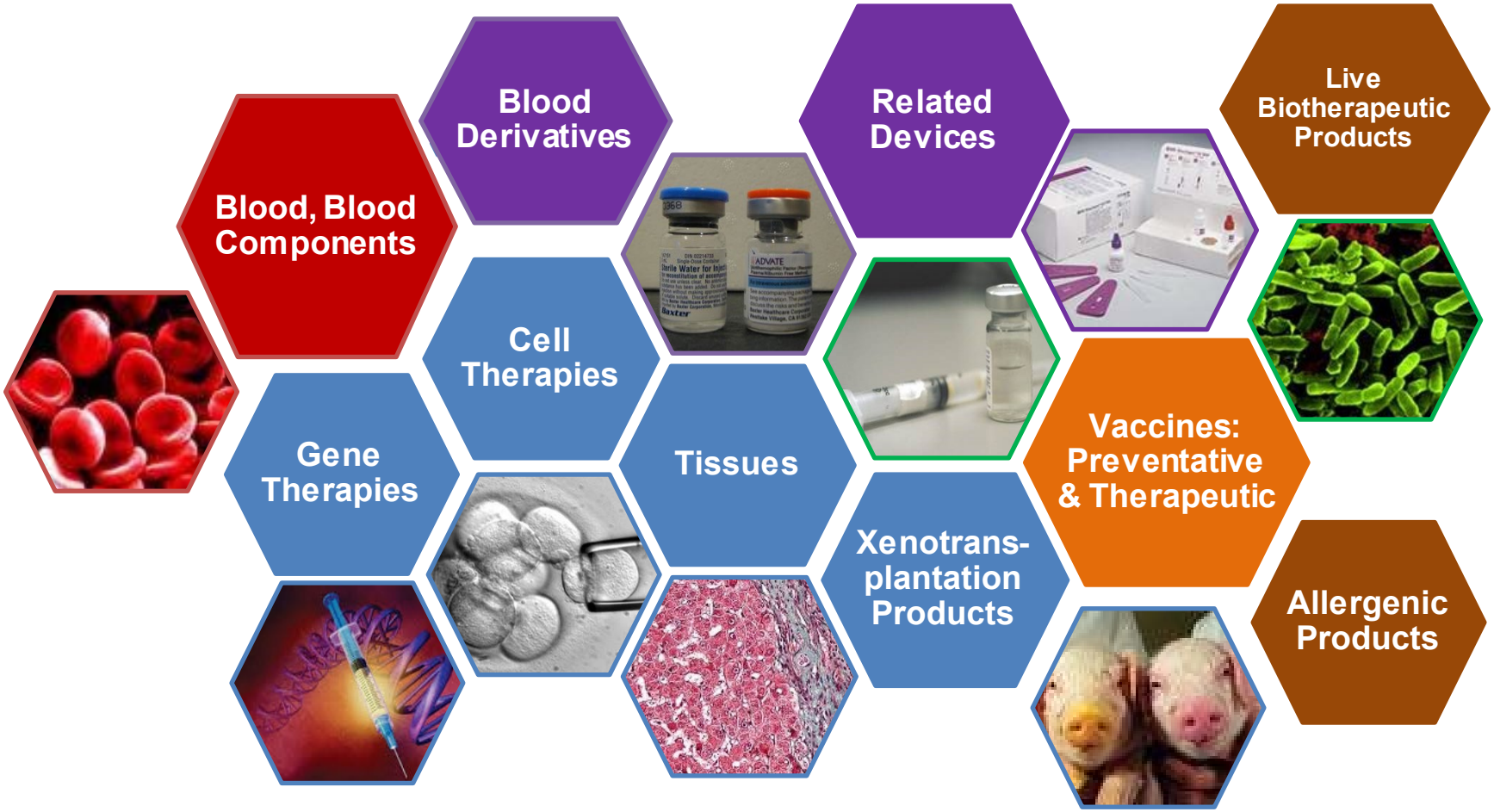
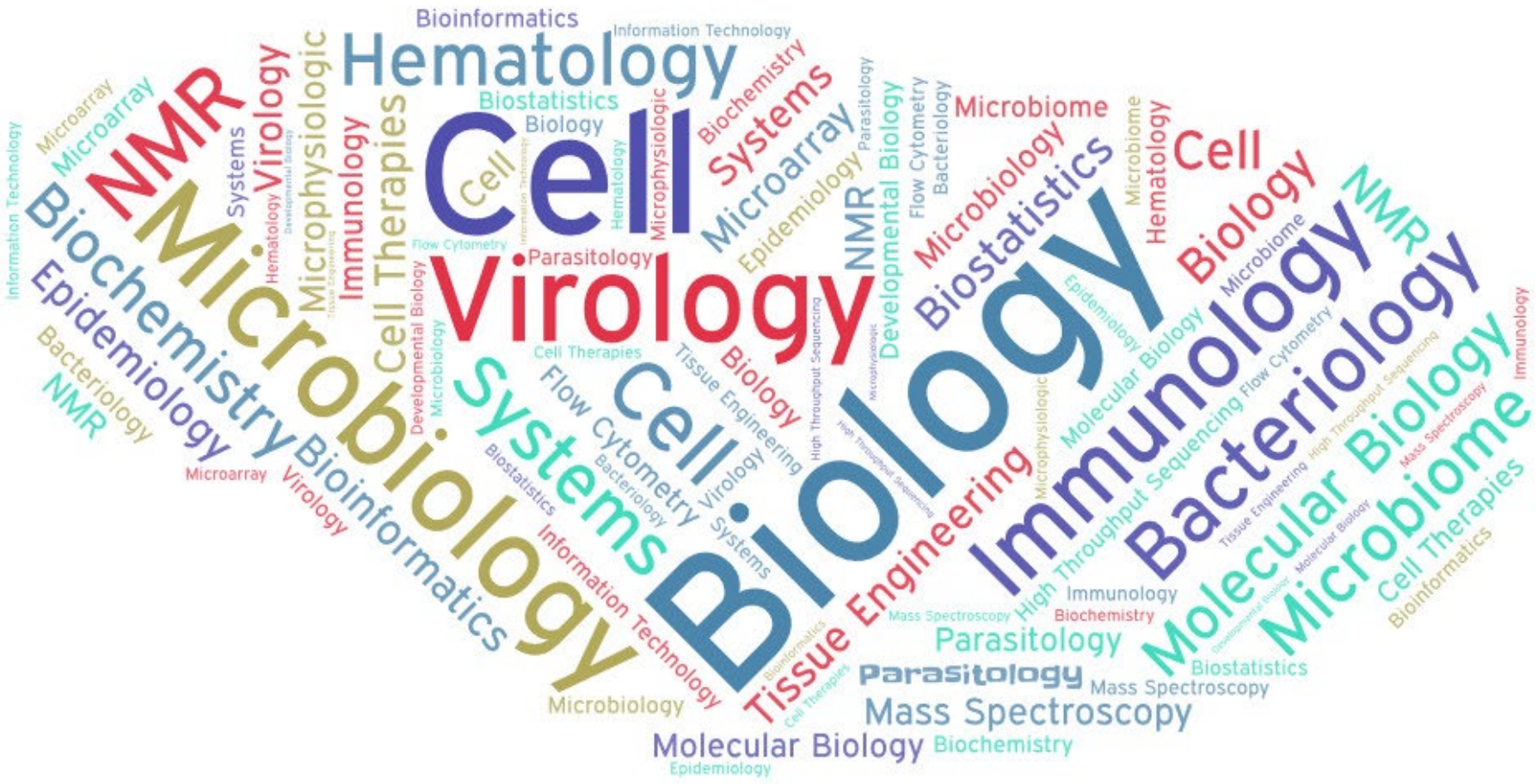




CBER Regulates Complex Biological Products



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 in the context of regulatory review work
- 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

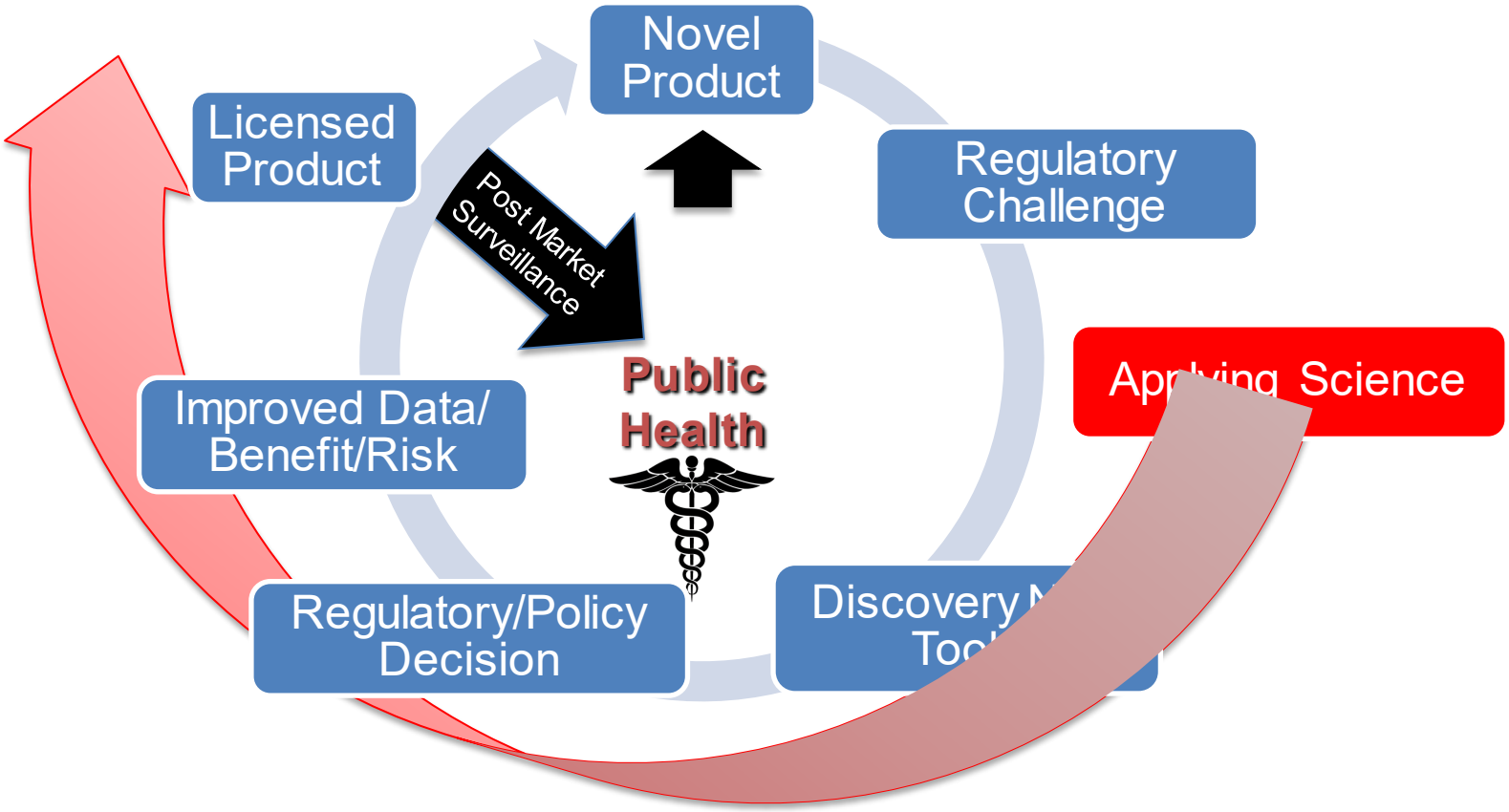
CBER's Researcher-Reviewers: Role in Regulatory Review Teams

- Chemistry, manufacturing, and control (CMC) product reviewer:
  - Scientific rationale, data for proof-of-concept
  - Production techniques and resulting product
  - Quality control testing
  - Clinical assays
  - *Up to ~ 50% of time for PIs and staff*

Other review team members:

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

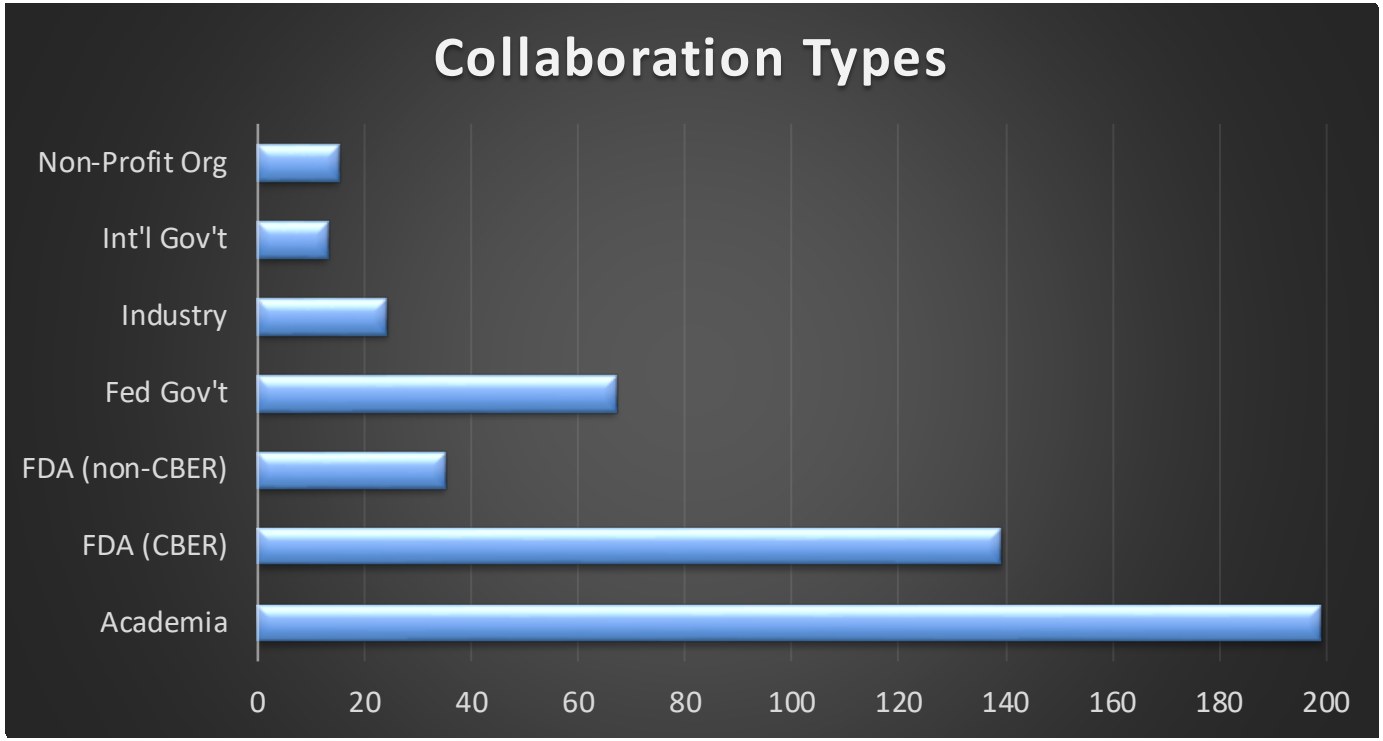
Using Science and Regulation to Advance Product Development



White Oak Lab Facility

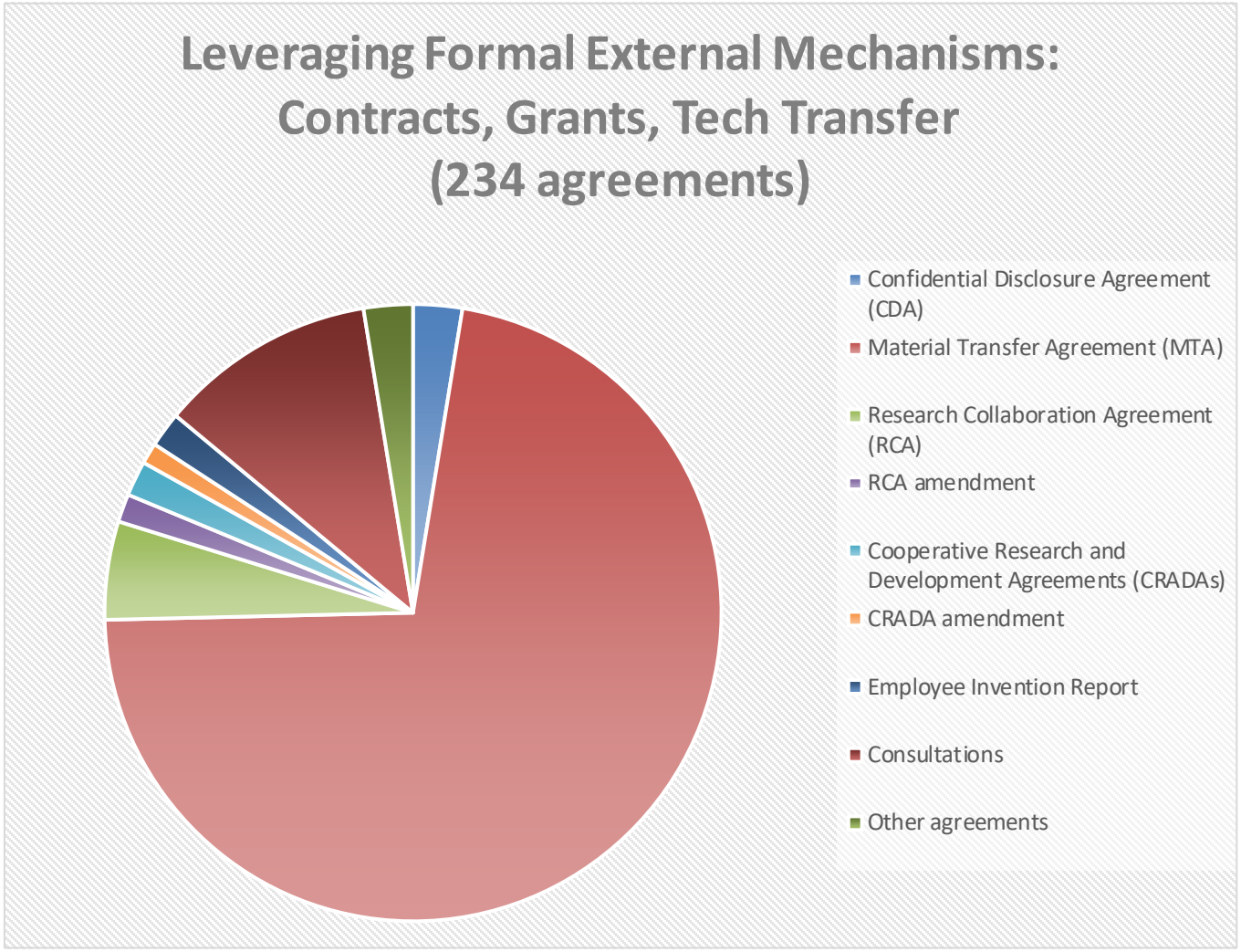
- 450,000 square feet for ~ 150 BSL-1 to BSL-3 laboratories and offices for > 500 research staff
- Core technologies:
  - Flow cytometry
  - Confocal microscopy
  - High-performance Integrated Virtual Environment (HIVE)
  - Biotechnology core facility:
    - Oligonucleotide, siRNA, PNA, and peptide synthesis
    - 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

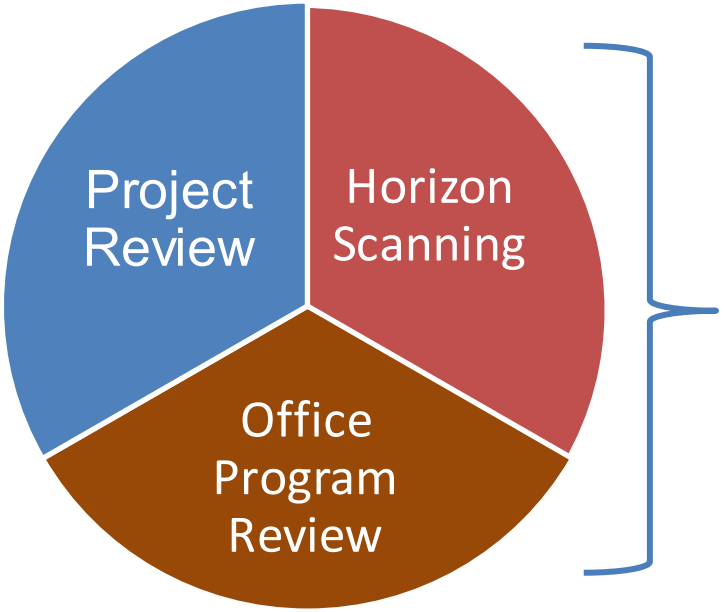


Data from FY21

Benefits of CBER Research Program

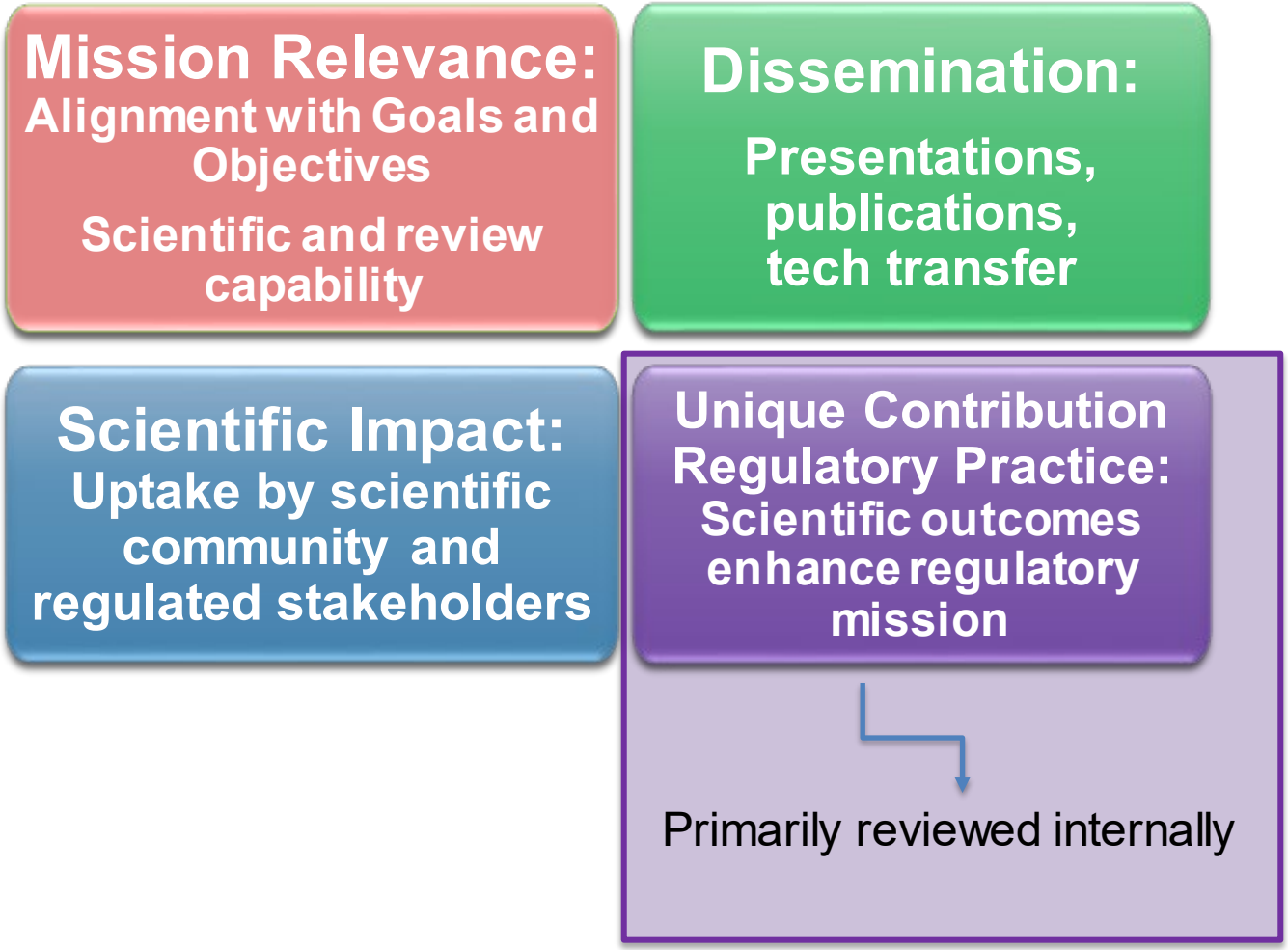
- Prepares for future innovative products and public health challenges
- Develops data and tools that support development of classes of products
- Fills knowledge gaps that inform policy development and regulatory decision-making
- Facilitates recruitment and retention of highly trained scientists, with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

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!

Your input via external review is critical to ensure CBER maintains high quality research programs and thereby fulfills CBER's regulatory mission!