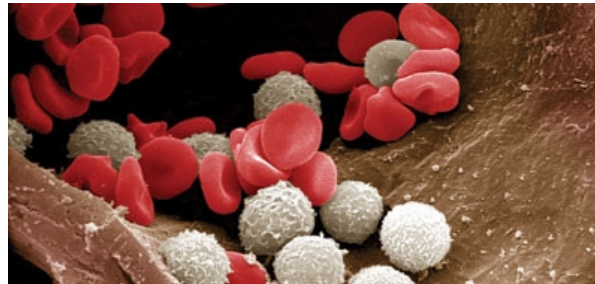
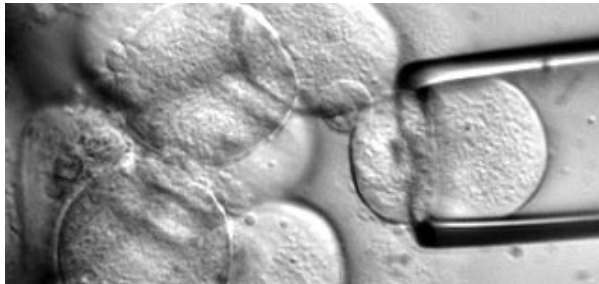
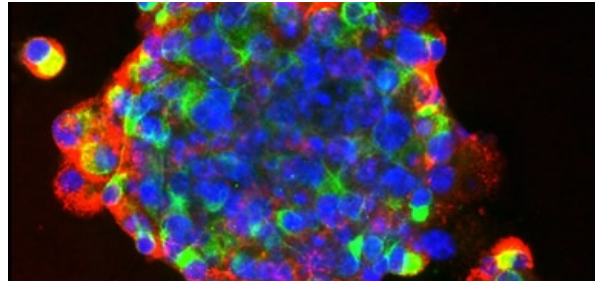
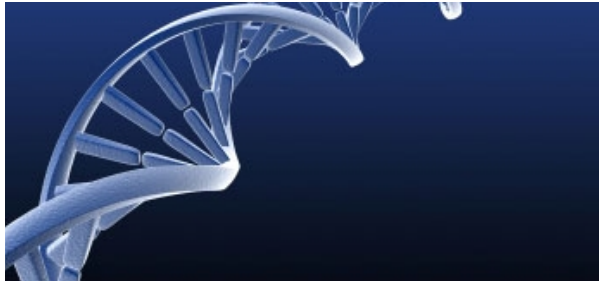
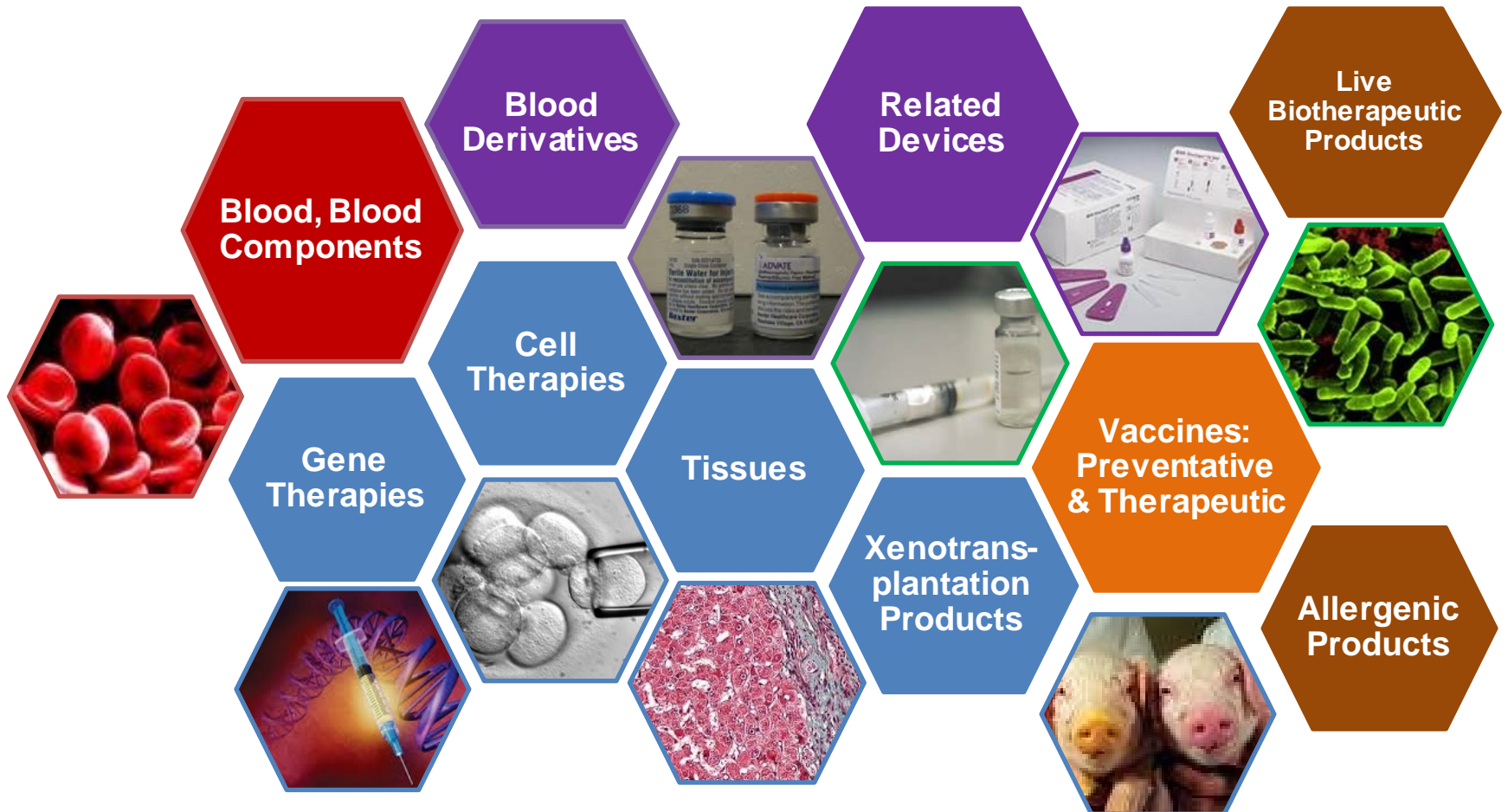


# Overview of CBER Research Programs

**Karen Elkins, Ph.D.**  
**Associate Director for Science**  
**Center for Biologics Evaluation and Research**  
**U.S. Food & Drug Administration**



# CBER Regulates Complex Biological Products





# 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 Research-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



# CDER's Research-Reviewers: Role in Regulatory Review Teams

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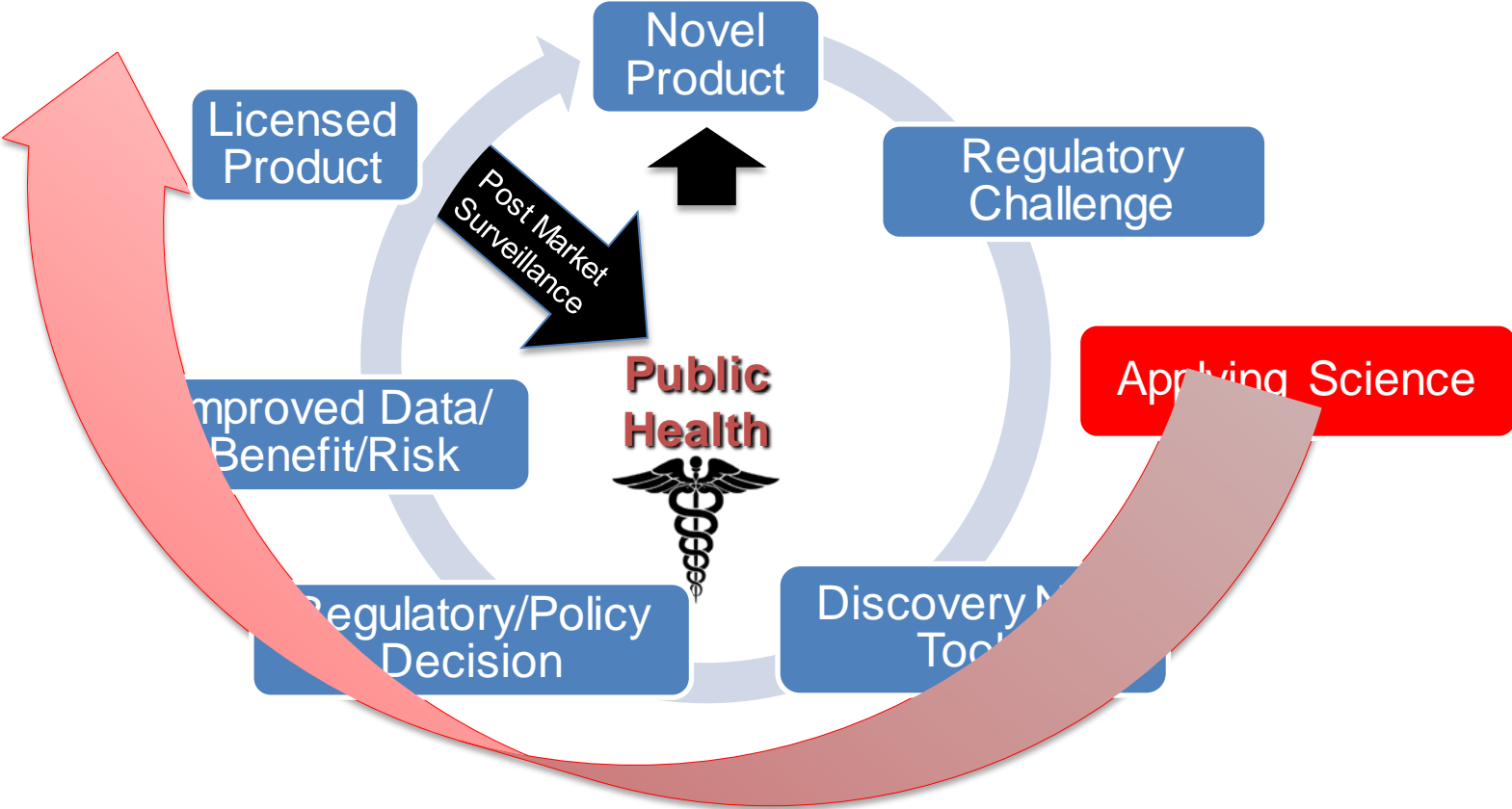
- Chemistry, manufacturing, and control (CMC) product reviewer:
  - Scientific rationale, data for proof-of-concept
  - Production techniques and resulting product
  - Quality control testing
  - Clinical assays
  - *Up to ~ 50% of time for PIs and staff*

## Other review team members:

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



# Using Science and Regulation to Advance Product Development



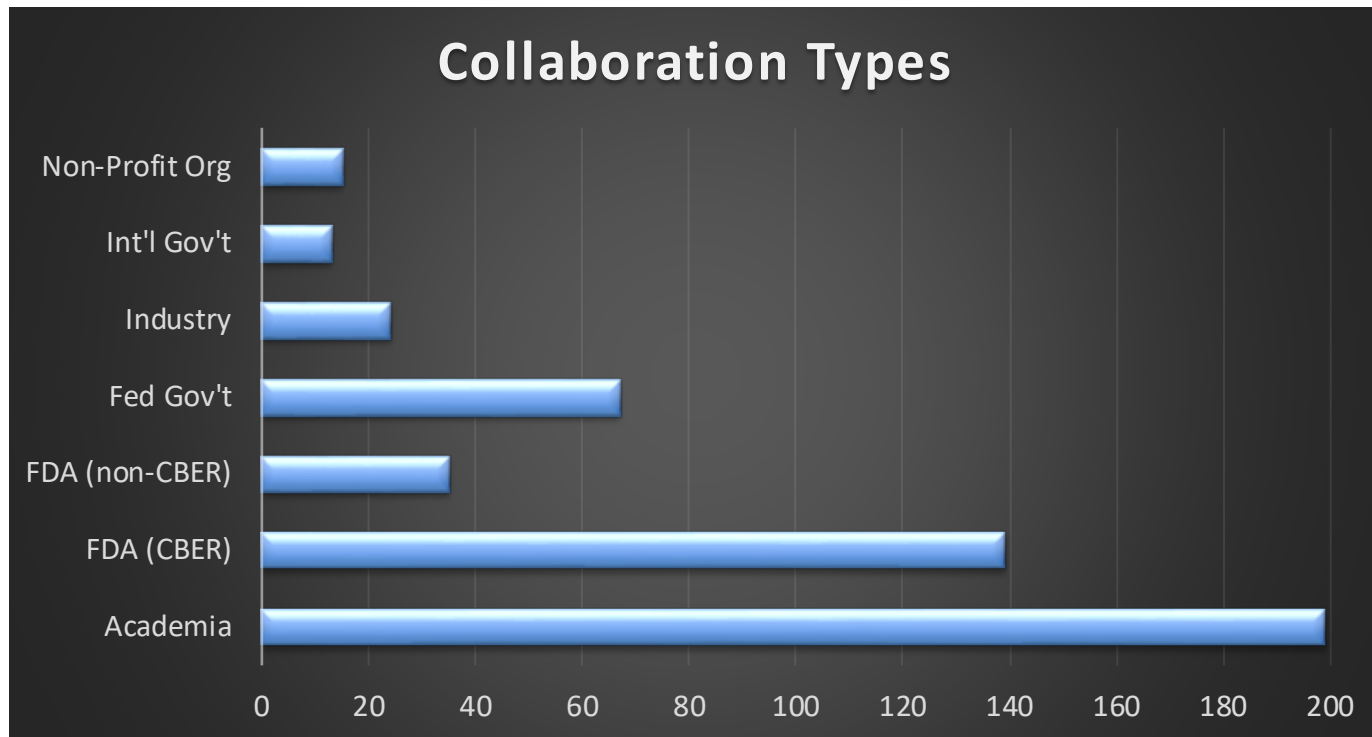
# White Oak Lab Facility

- 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





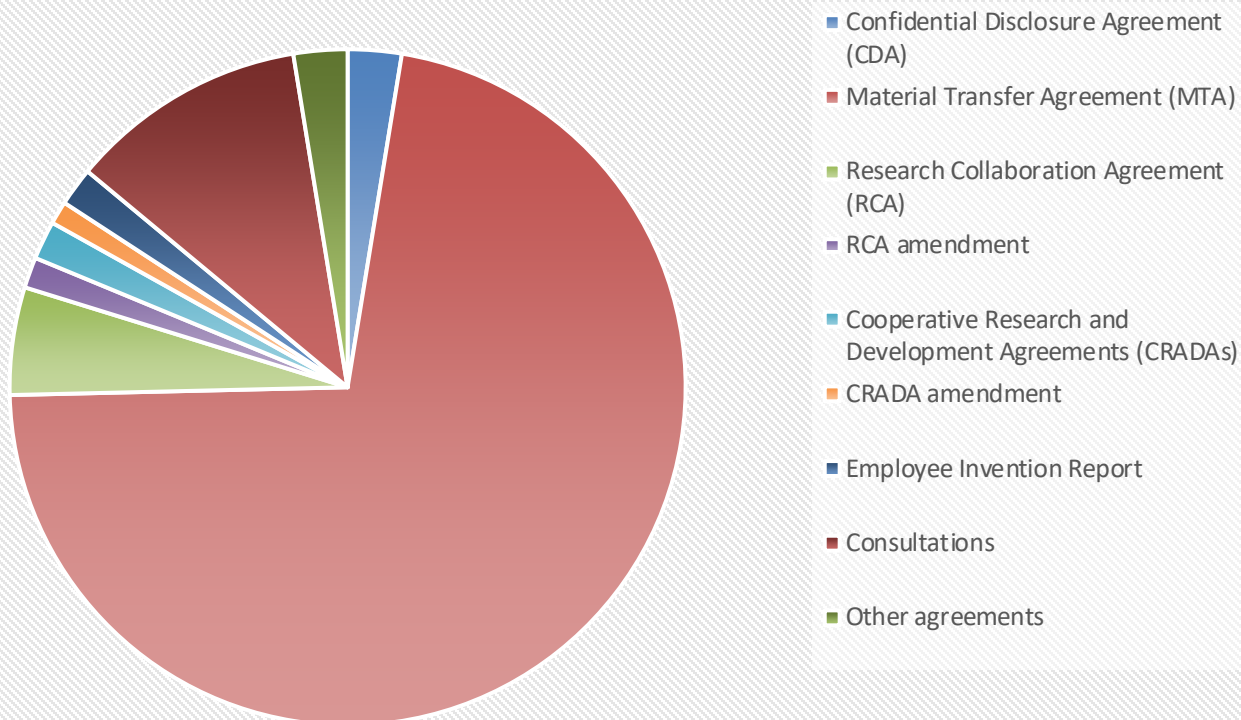
# CBER Advances Applied Science through External Collaborations-I



*Data from FY21 CBER Research Reporting Database*

# CBER Advances Applied Science through External Collaborations-II

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



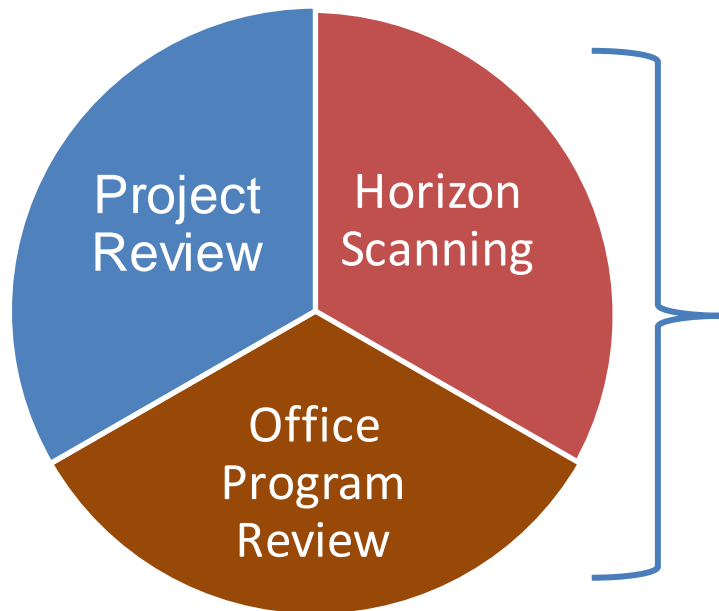
# Benefits of CBER Research Program

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- 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

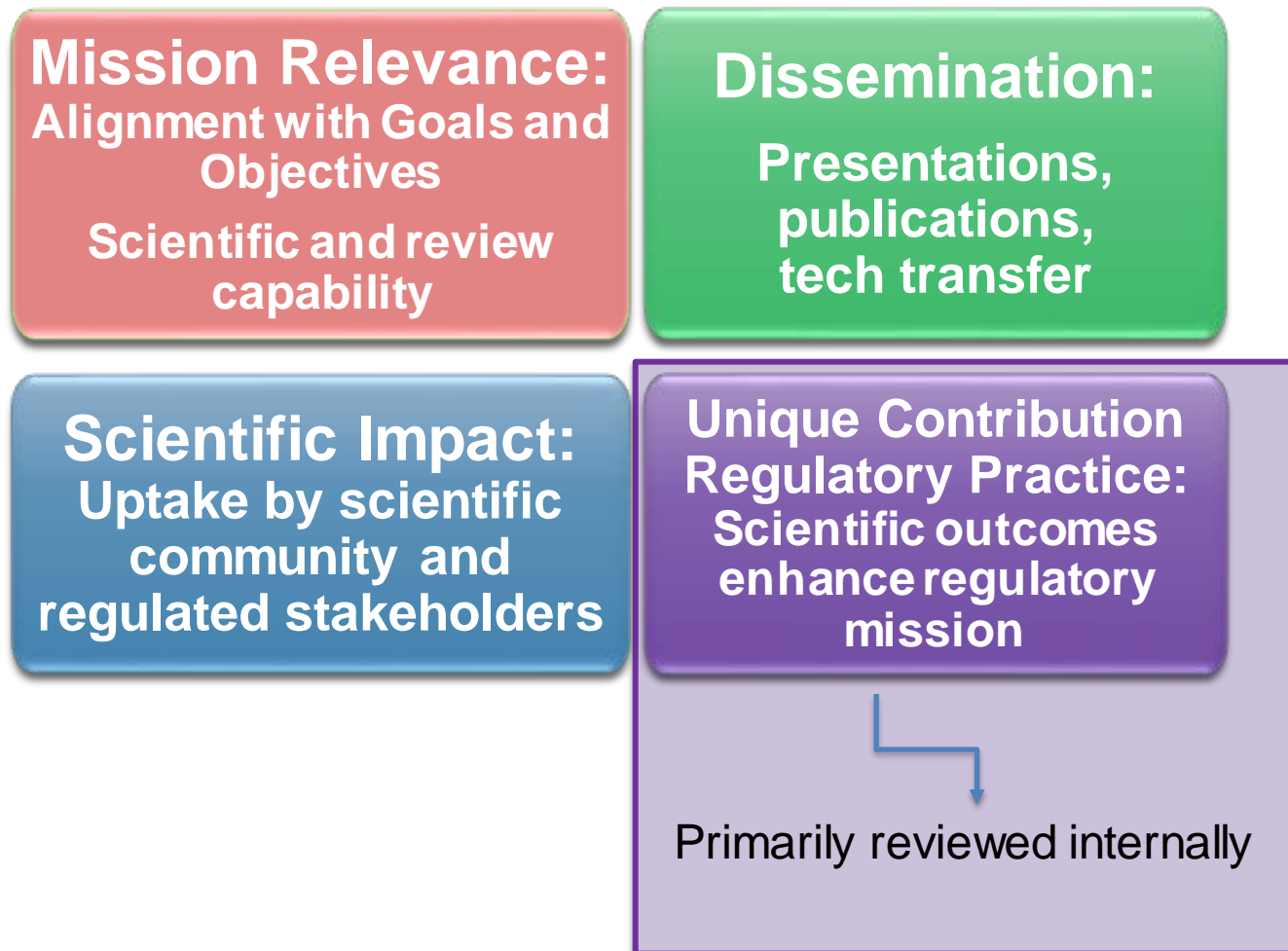


# Overview of CBER Research Evaluation



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

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- 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!**