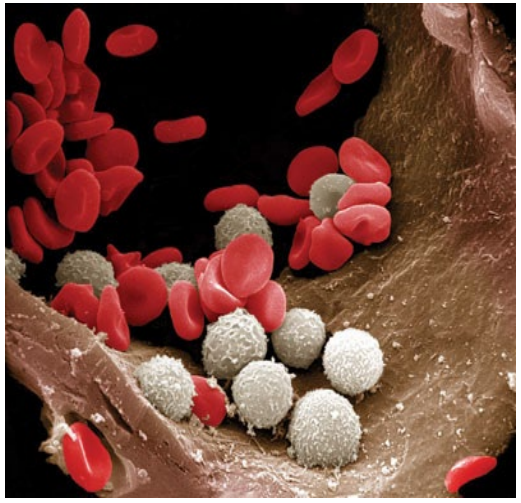
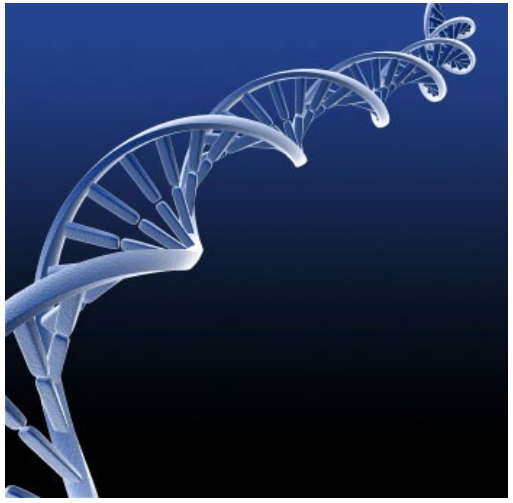
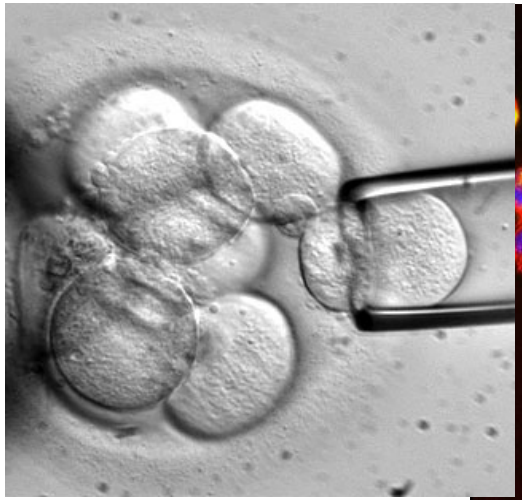
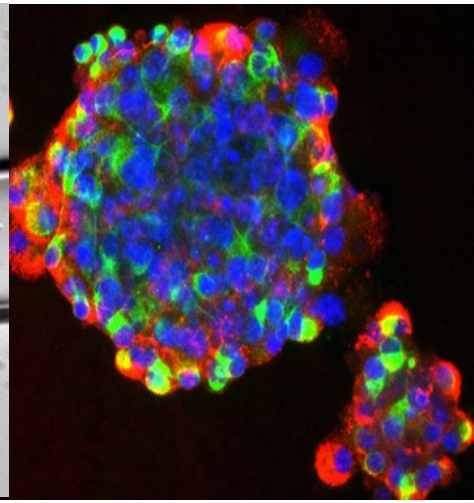
U.S. FOOD & DRUG ADMINISTRATION

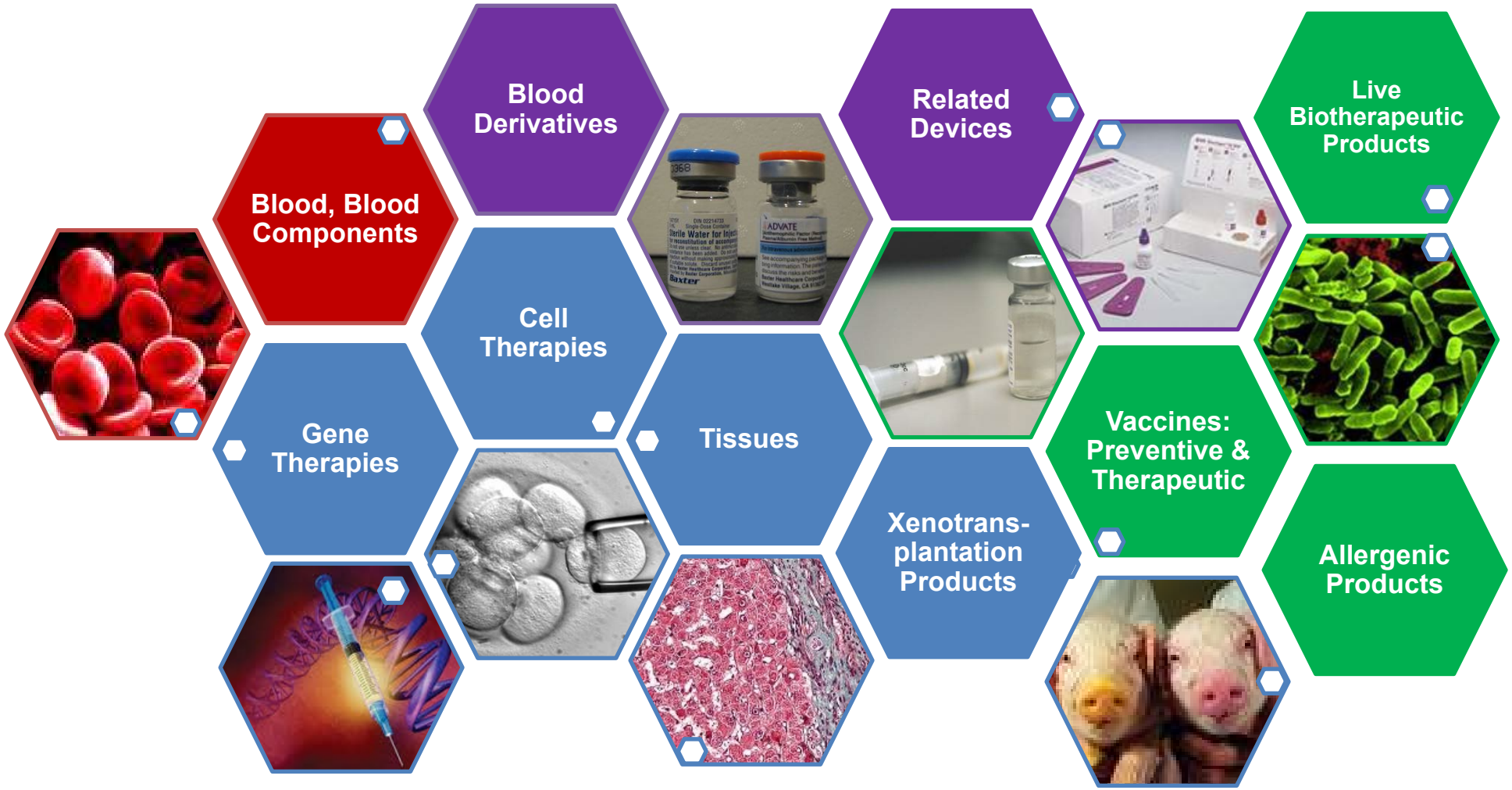
Center for Biologics Evaluation and Research, FDA

Overview of CBER Research and Site Visits

Karen Elkins, Ph.D.
Associate Director for Science

CBER Regulates Complex Biological Products



CBER Strategic Plan Goals, 2021 – 2025

CBER Intramural Research Resources

- Space comprises 450,000 square feet for ~ 150 BSL-1 to BSL-3 laboratories and offices for ~ 425 research staff, with research core facilities and a state-of-the-art vivarium
- Funding from annual federal appropriations, targeted CBER and FDA programs, and other external grants
- Staff is a mixture of permanent principal investigators, permanent staff scientists, technicians, and temporary research fellows

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

- Investigator-initiated research
- Topics of research include:
  - Basic to targeted studies, related to CBER-regulated products
  - Studies that develop data and tools that support development of classes of products
  - Studies to fill knowledge gaps that inform policy development and regulatory decision-making
- 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

Other review team members:

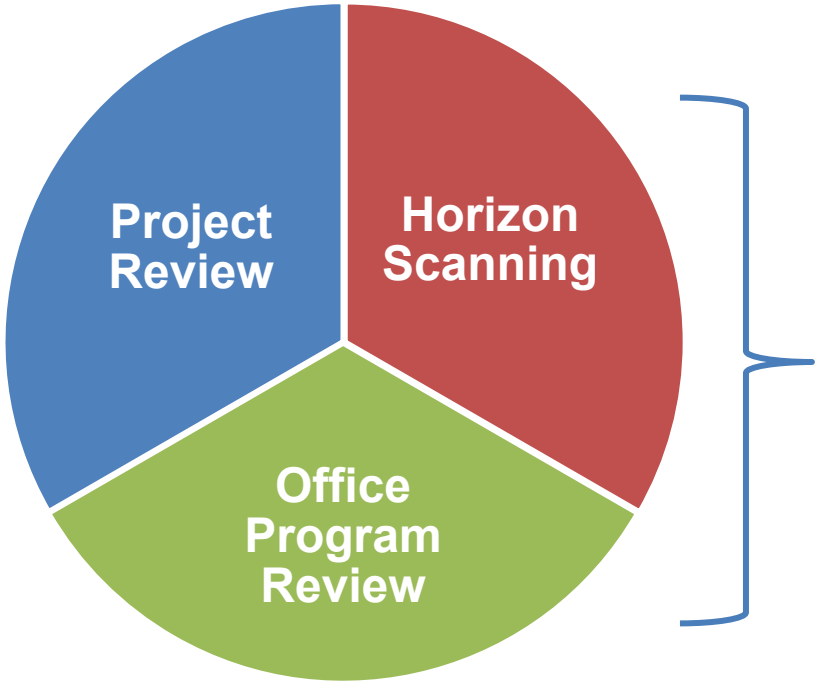
- Regulatory Project Manager: oversight
- Clinical reviewer
- Pharmacology/toxicology reviewer
- Statistical reviewer

Benefits of the CBER Research Program

- Develops knowledge and tools focused on supporting product development
- Ensures understanding state-of-the-art techniques that are the source of data in regulatory decisions
- Facilitates recruitment and retention of highly trained scientists
- Prepares for review of future innovative products and public health challenges

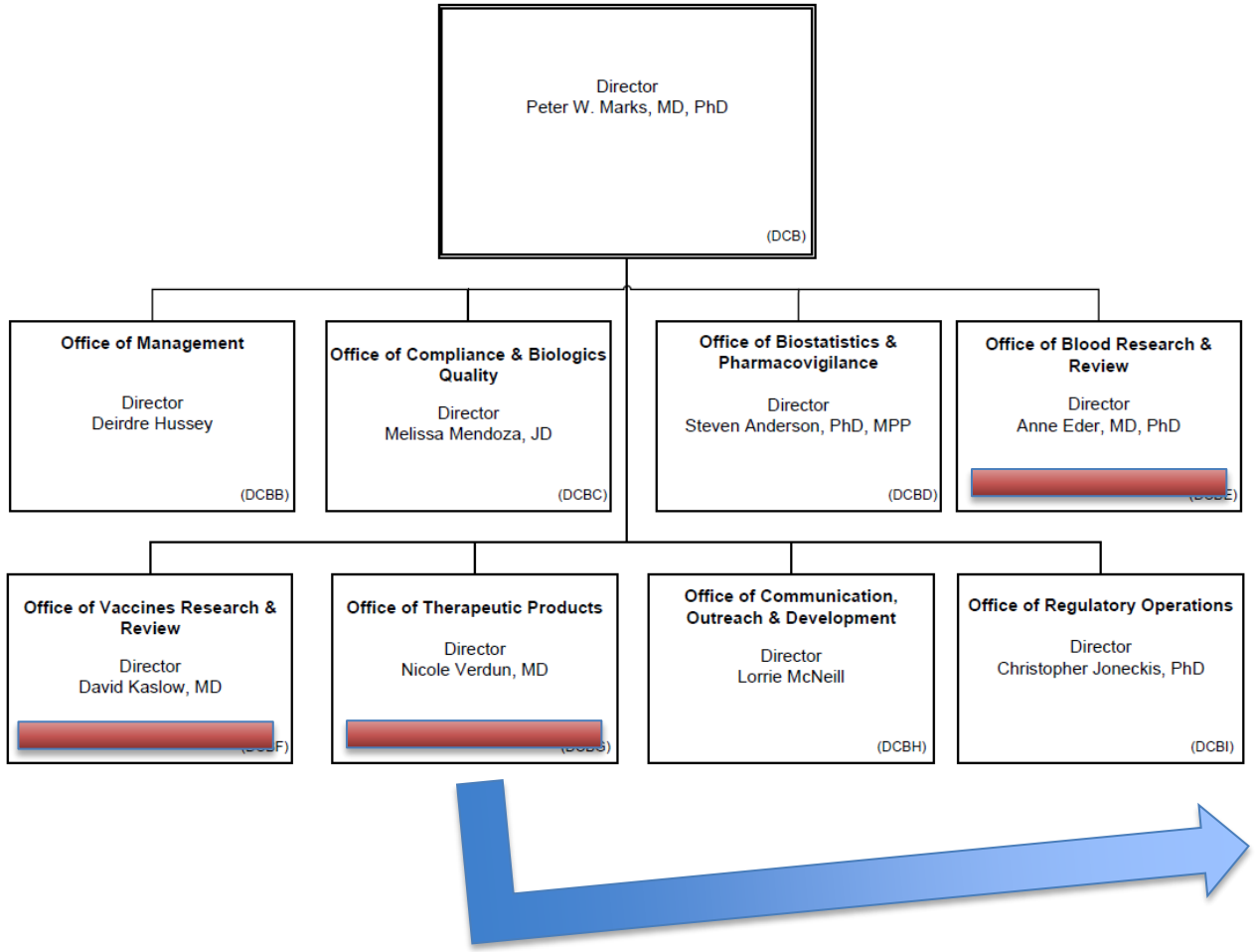
- Ensures efficient, effective, credible review and decisions based on sound science

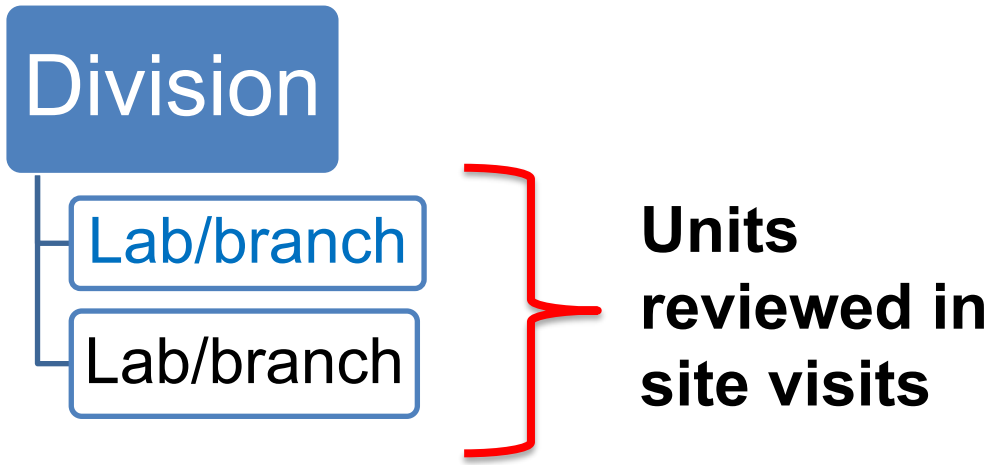
CBER Research Evaluation Framework



Evaluation	Frequency	By Whom
Project Review	Annually	Lab/Branch Chiefs, Division, and Office Management
Office Review of Projects	New projects	Office staff & Center RSC
Horizon Scanning	Every 4 years	Center, Office staff & Center RSC
Site Visits	*Every 4 years*	*External SME committee*

Overview of CBER Organization





CBER Research Evaluation Criteria

Science Quality & Impact:

Excellence and uptake by scientific community, regulated stakeholders

Dissemination:

Publications, presentations, technology transfer

Mission Relevance:

Align with CBER goals, support product development, and provide review capability

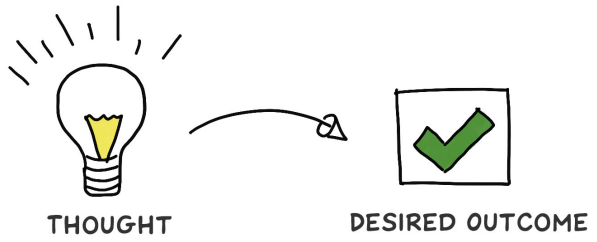
CBER Site Visits: Reviewers' Roles

For each principal investigator's research program, site visit reviewers are asked to comment on:

- Quality and relevance of science
- Progress and productivity since last SV, in the context of the work's nature, resources, and regulatory assignments
  - *CBER researchers are regulators too*
- Future research directions
- Laboratory organization, program management, mentoring

CBER Site Visits: Outcomes

- Draft report will be reviewed by the Advisory Committee to:
  - Accept report as is
  - Amend report
  - Reject report and send back to Site Visit committee
- Report is final upon the Advisory Committee's approval
- Final report is used in many ways:
  - Internal review of individual scientists' progress
  - By PIs and staff, to improve research program
  - By management, to respond and consider resource allocation decisions (pending resource availability)



Thank you!

Site visit input ensures CBER maintains high quality research programs

External review is critical to fulfilling CBER's regulatory mission

COVID-19 Pandemic Impact on Laboratories

- *On-site work voluntary; FDA set policies on building occupancy*