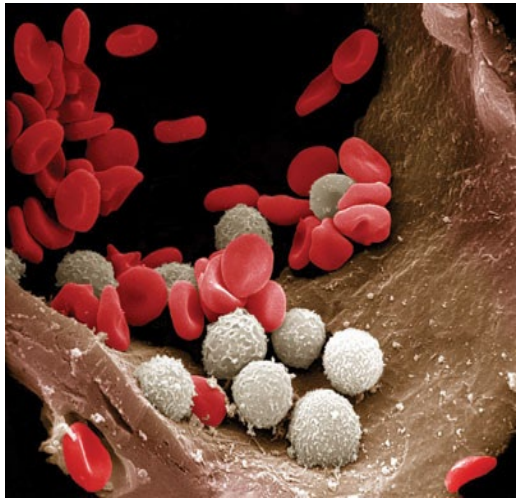
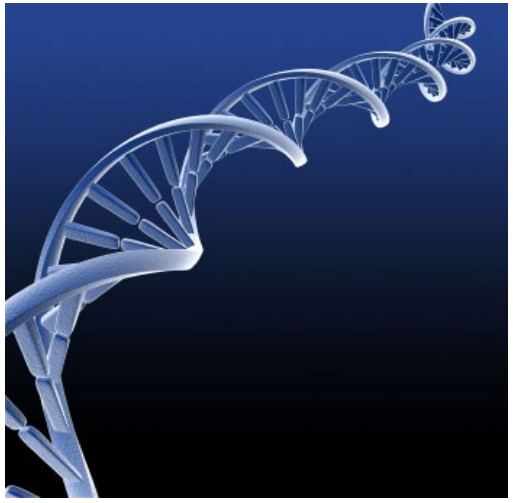
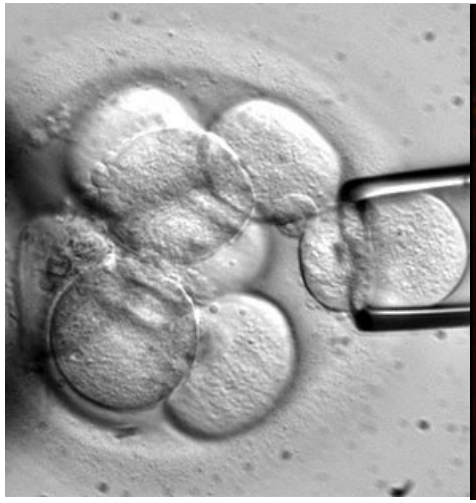
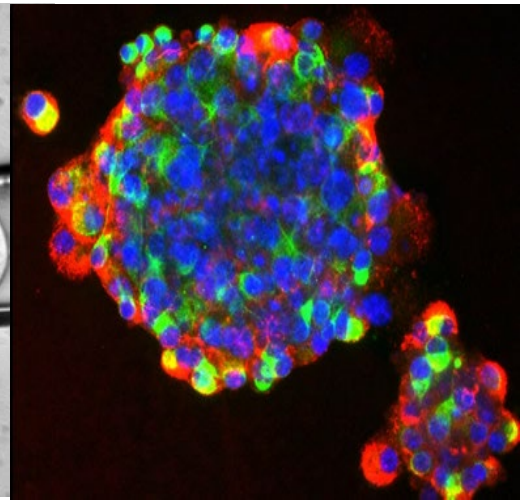
Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

U.S. FOOD & DRUG ADMINISTRATION

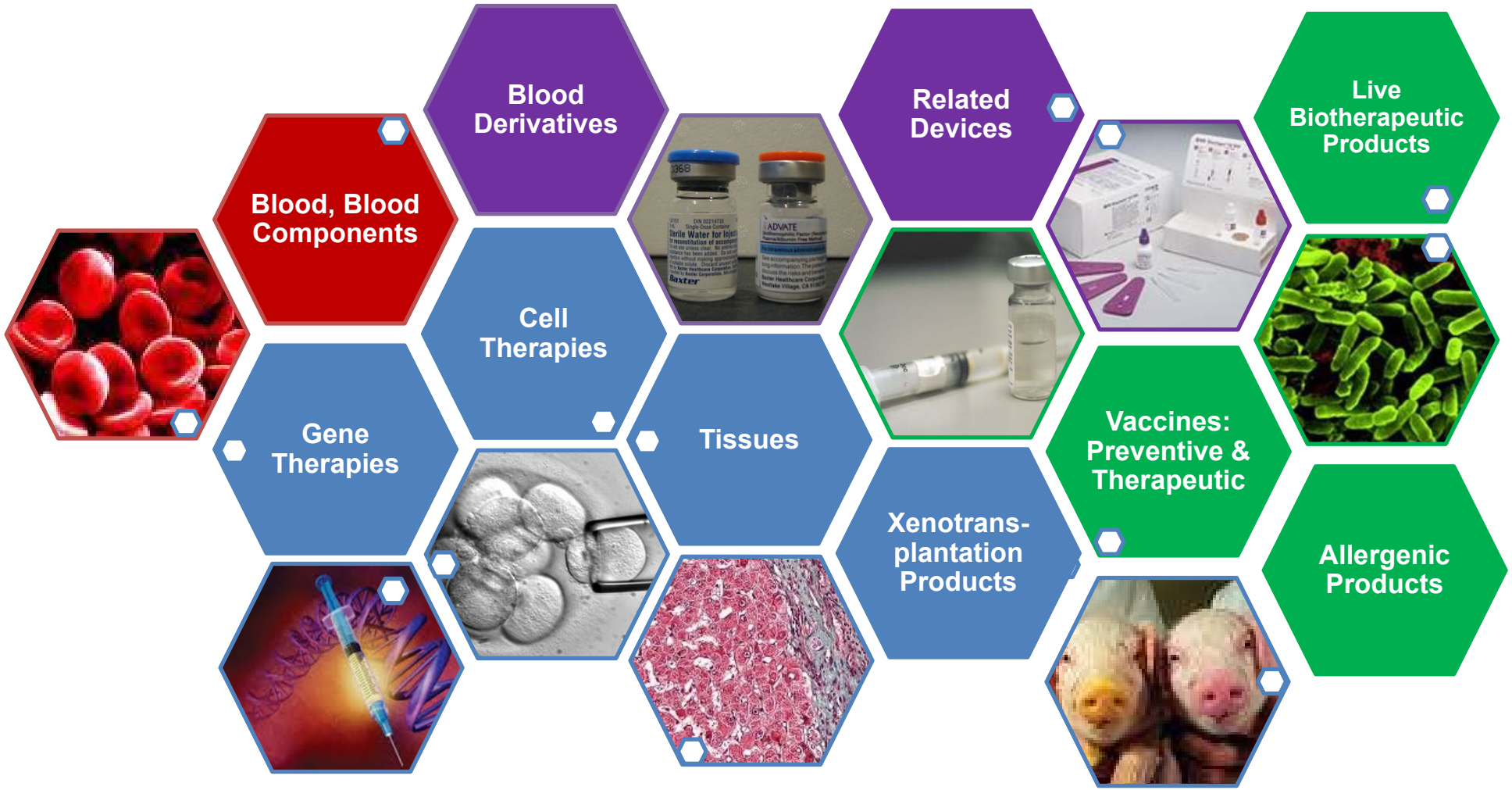
Center for Biologics Evaluation and Research, FDA

Overview of CBER Research and Site Visits

Karen Elkins, Ph.D.
Associate Director for Science

CBER Regulates Complex Biological Products



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

- CBER's research and review are integrated: Research staff conduct CMC regulatory reviews
- CBER's approach has been in place for > 75 years
- Investigator-initiated research, related to CBER's products
- Topics of research range from basic to targeted studies
  - Studies fill knowledge gaps that limit product development
  - Studies inform regulatory decision-making and policy development

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 ~ 65 PIs and 425 total 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: Role in Regulatory Review Teams

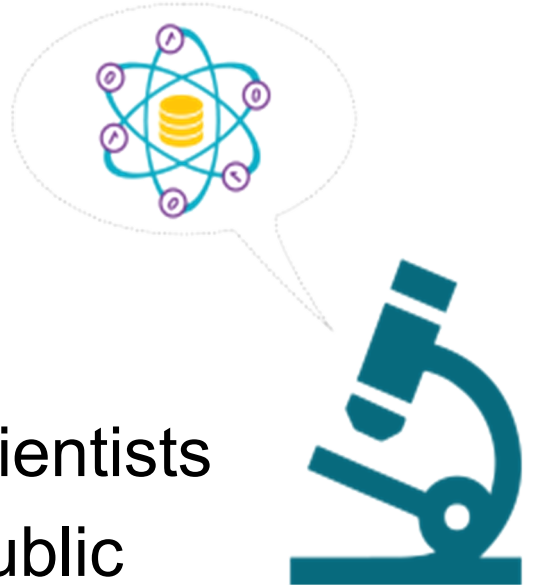
- Chemistry, manufacturing, and control (CMC) product reviewer:
  - Scientific rationale and data supporting proof-of-concept
  - Production approach, techniques, and facilities
  - Product quality control testing
  - Clinical assays

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 that support product development
- Develops a hands-on, state-of-the-art understanding of techniques that are the source of data in regulatory submissions
- Facilitates recruitment and retention of highly trained scientists
- Prepares for future review of 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*

CBER Research Evaluation Criteria

Science Quality & Impact:

Excellence and uptake by scientific community, regulated stakeholders

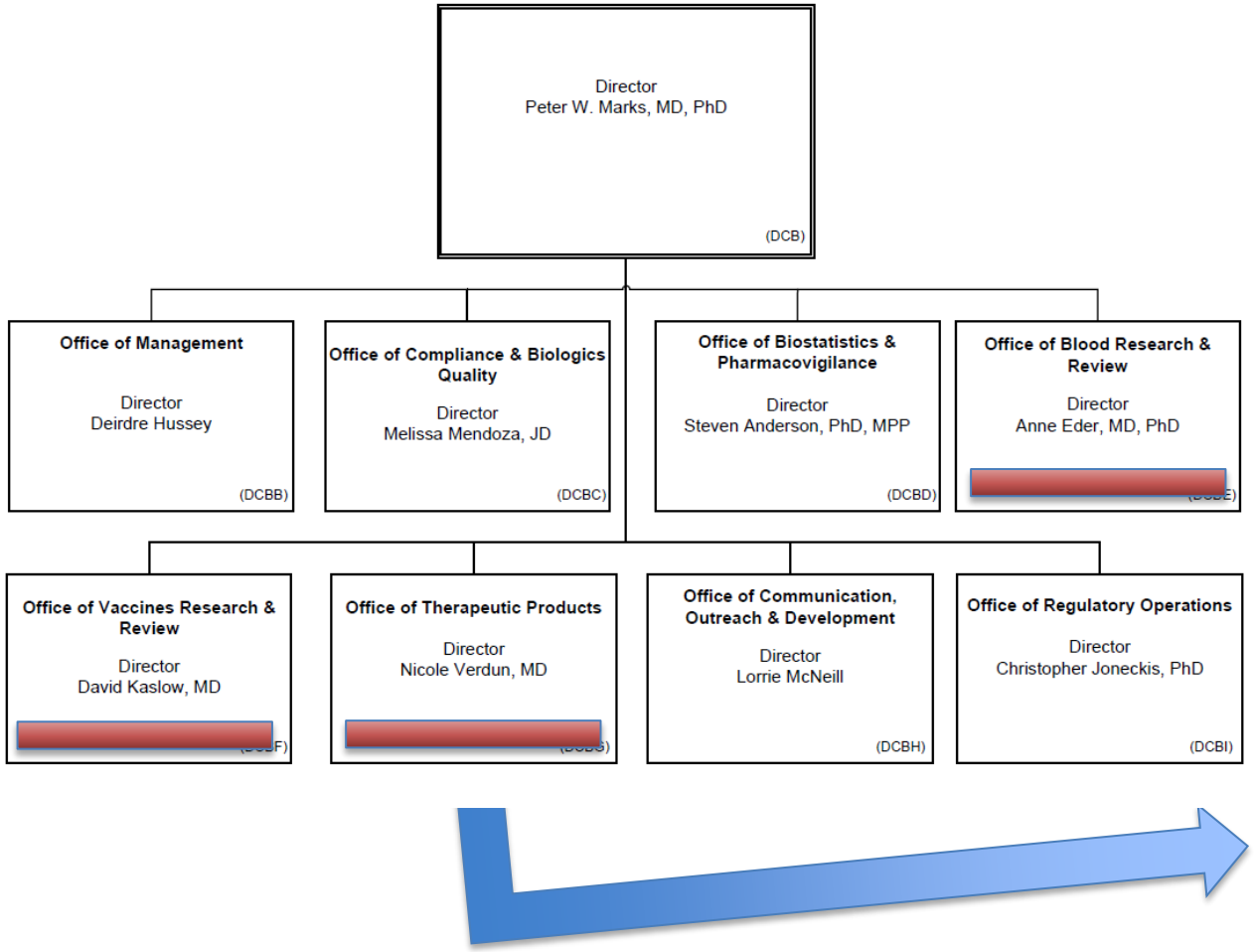
Dissemination:

Publications, presentations, technology transfer

Mission Relevance:

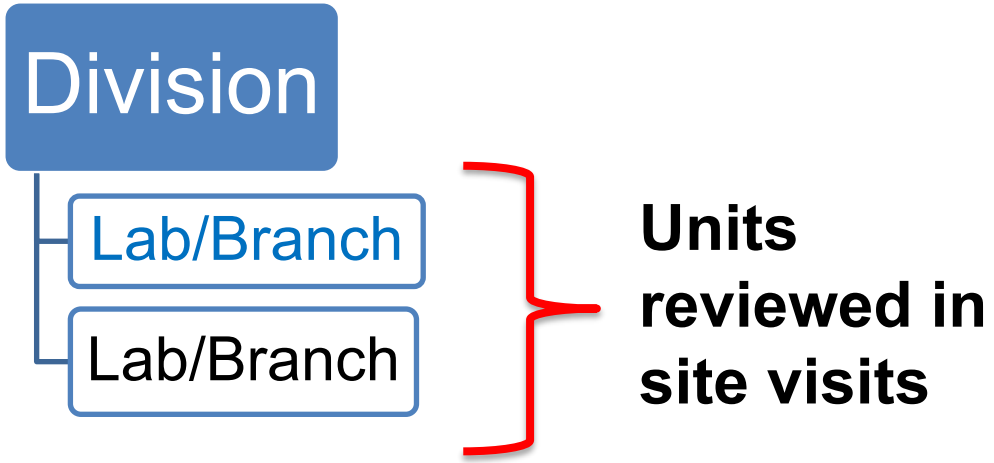
Align with CBER goals, support product development, and provide review capability

Overview of CBER Organization



Site visit format:

- PIs provide written reports of progress and plans
- Teams convenes for 1 – 2 days of presentations, discussions, and interviews
- Reviewers confer to critique strengths and weaknesses, then generate report



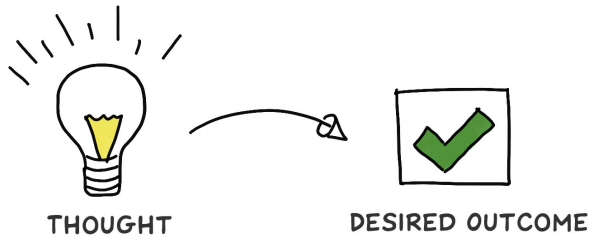
CBER Site Visits: Reviewers' Roles

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
- 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:
  - By PIs and staff, to improve research program
  - Internal review of individual scientists' progress
  - By management, to respond and consider program adjustments and resource allocation



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*