U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

# CDISC Activities at the Center for Biologics Evaluation and Research (CBER)

CDISC International Interchange
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Review Management
Office of the Director

# Overview

- CBER Products
- Challenges
- Status Updates

# CBER Products

- Allergenics
- Blood
- Devices
- Gene Therapy
- Human Tissue and Cellular Products
- Vaccines
- Xenotransplantation

# Challenges

- SDTM
  - Standard modeling is drug specific, there are gaps as they apply to CBER products
  - Two vaccine pilot submissions received to date, no other product submissions have been piloted
  - Device Domain in draft for In vitro diagnostics (IVD's) which will help fill the gaps
  - Training and tools are not in place to allow reviewers to perform analysis on SDTM datasets

# CBER Status

- GENERAL
  - Training RFP with CDISC has been signed, planning for rollout is in progress.
  - Additional tool availability in progress
  - Developing a standard process by which any sponsor/application can submit pilot SDTM/ADaM/SEND datasets to CBER via the electronic gateway
  - *Request that industry send CBER voluntary pilot SDTM datasets for gap analysis and evaluation.*
    - Facilitated through Review Management
    - Contact Amy Malla

# CBER Status

- SDTM
  - Internal cross functional team is being developed
  - Participation in the CDISC pilot of v3.1.2
  - Clinical and statistical reviewer training for implementation/planning team members to facilitate gap analysis
  - Paper review gap analysis of release v3.1.2 for vaccines, biologics and devices
  - Third voluntary pilot submission to be received in the next quarter

# CBER Status

- ADaM
  - Participation in the ADaM working group
  - Participation in CDISC Pilot
  - Clinical and statistical reviewer training for implementation/planning team members to facilitate gap analysis
  - Paper review gap analysis of release v2.1 and IG v 1.0 for vaccines, biologics and devices
  - GAP analysis of guidance and procedural documents for implementation of data standards and the JANUS Initiative

# CBER Status

- SEND
  - Paper review gap analysis of release v2.3
  - Pharm/tox involvement in testing and implementation of the SEND standard via the Center for Veterinary Medicine pilot.
  - GAP analysis of guidance and procedural documents for implementation of this data standard

# THANK YOU

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