Public Meeting on
Electronic Submissions and Data Standards

April 10, 2019
Food and Drug Administration
Building 31, Great Room 1503A
10903 New Hampshire Avenue
Silver Spring, MD 20993

Adobe Connect link for online access: https://collaboration.fda.gov/pdufavi/

Eventbrite Registration website: https://www.eventbrite.com/e/pdufa-vi-public-meeting-on-electronic-submissions-and-data-standards-tickets-49895060469

****Please note the times for each session has change*****

8:00 – 9:00 am **Registration**

9:00 – 9:10 am **Welcome and Opening Remarks**
Ron Fitzmartin
Senior Project Manager
Office of the Director (OD)
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

Session 1. Electronic Submissions Gateway and Electronic Common Technical Document

9:10 – 9:30 am **Electronic Submissions Gateway (ESG)**
This session will focus on the electronic submission process, including key electronic submission milestones and associated sponsor notifications from the completion of its upload to the ESG through the time the submission is made available to the review team.

FDA
La Misha Fields
Program Manager, ESG
Office of Information Management and Technology (OIMT)

9:30 – 9:45 am **Electronic Common Technical Document (eCTD)**

This session will provide an update on eCTD, including the transition to the new eCTD viewer and validator software.

FDA

Mark Gray
Senior Project Manager
OD, CBER

9:45 – 10:00 am **Session 1: Open Public Comment**

Session 2. Digital Investigational New Drug (IND): Safety Reporting Program

This session will focus on the Digital Investigational New Drug (IND) Safety Reporting Program which will implement a digital framework for the electronic submission, review, and tracking of certain IND safety reports required under 21 CFR 312.32.

10:00 – 10:30 am **Program Overview, Implementation and Guidance to Industry**

FDA

Meredith Chuk
Acting Associate Director of Safety,
Office of Hematology and Oncology Products (OHOP)
Office of New Drugs (OND), CDER

Ta-Jen (TJ) Chen
Project Manager
Office of Strategic Programs (OSP), CDER

Virginia Hussong
Chief, Data Standards Staff
OD, CBER

10:30 – 10:45 am **Session 2: Open Public Comment**

10:45 – 11:00 am **BREAK**

Session 3. Pharmaceutical Quality and Chemistry, Manufacturing, and Controls (PQ/CMC) Project

The goal of the PQ/ CMC project is to establish electronic standards for submitting Pharmaceutical Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data in regulatory applications and to develop and implement a data exchange standard for submission of the data.

11:00 – 11:15 am **Project Overview**

FDA

Scott Gordon
Senior Health Informatics Officer
OSP, CDER

11:15 – 11:30 am **Structured PQ/ CMC Data**

FDA

Norman Schmuff
Associate Director, Office of Process and Facilities (OPF),
Office of Pharmaceutical Quality (OPQ), CDER

11:30 – 11:45 am **Session 3: Open Public Comment**

Session 4. Data Exchange Standards Projects

This session will focus on projects to assess Fast Healthcare Interoperability Resources (FHIR) for regulatory applications.

11:45 – 12:00 pm **Overview**

FDA

Boris Brodsky
Project Management Officer
OSP, CDER

12:00 – 12:15 pm **Session 4: Open Public Comment**

12:15 – 12:25 pm **Break**

Session 5. Clinical and Nonclinical Study Data

This session will focus on the study data standards listed in the FDA Data Standards Catalog are required for clinical and nonclinical studies that started after December 17, 2016. Technical rejection criteria have been developed and added to the existing eCTD validation criteria to enforce compliance to the required study standards.

12:25 – 12:45 pm **Update on Technical Rejection Criteria for Study Data**

FDA

Ethan Chen
Director, Division of Data Management Services and Solutions (DDMSS),
Office of Business Informatics (OBI),
OSP, CDER

Virginia Hussong
Chief, Data Standards Staff
OD, CBER

12:45 – 1:00 pm **Session 5: Open Public Comment**

1:00 pm **ADJOURNED**