Public Meeting on
Electronic Submissions and Data Standards

July 10, 2018
Great Hall South
Silver Spring Civic Building at Veterans Plaza

Eventbrite Registration website: Eventbrite PDUFA VI Public Meeting

Online WEBEX information:

Join WebEx Meeting

Meeting number (access code): 901 133 823

Meeting password: TvPm7ErG

Join by phone

+1-210-795-0506 US Toll

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Global call-in numbers | Toll-free calling restrictions

8:00 – 9:00 am	**Registration**
9:00 – 9:10 am	**Welcome and Opening Remarks** Ron Fitzmartin Senior Advisor Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA) David Donohue Head, Quality Data Analytics, Systems, Operations and Optimum GlaxoSmithKline

Session 1. Electronic Submissions Gateway and Electronic Common Technical Document

9:10 – 10:30 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
FDA

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

Mark Gray
Senior Project Manager, Bioinformatics Support Staff (BSS),
Office of the Director (OD)
Center for Biologics Evaluation and Research (CBER), FDA

Industry

David Donohue
Head, Quality Data Analytics, Systems, Operations and Optimum
GlaxoSmithKline

Boris Hawryluk
Business Change Leader, Regulatory Operations
GlaxoSmithKline

Goutham Kancharla
Regulatory Operations Manager
AstraZeneca

10:15 – 10:30 am Open Public Comment

10:30 – 10:45 am Break

10:45 – 12:00 pm Electronic Common Technical Document

This session will focus on the implementation of the electronic Common Technical Document (eCTD) guidance and the future implementation of eCTD v4.0. In

addition, the session will discuss an analysis and results of study data conformance based on the technical rejection criteria.

FDA

Ethan Chen
Director, DDMSS, OBI, OSP, CDER, FDA

Mark Gray
Senior Project Manager, BSS, OD, CBER, FDA

Industry

John Ferguson
Director, Regulatory Operations and Innovation
Novo Nordisk

Francis Quinn
Senior Manager, US Publishing Team Lead
Pfizer

Mike Stevens
Associate Director of Regulatory Information Management for Global Regulatory Affairs
Janssen Research & Development, LLC a Pharmaceutical company of Johnson & Johnson

11:45 – 12:00 pm **Open Public Comment**

12:00 – 1:00 pm **Lunch**

Session 2. Data Standards

1:00 – 2:30 pm **Identification of Medicinal Products (IDMP)**

This session will focus on the status of the implementation of International Organization for Standards (ISO) IDMP standards. IDMP standards can support a variety of regulatory activities related to pharmacovigilance and risk management, as well as development, registration and life cycle management of medicinal products. There are five standards in the IDMP group; these describe the substance (ISO 11238), dosage form and routes of administration (ISO 11239), units of measure (ISO 11240), medicinal product identifier (ISO 11615) and pharmaceutical product identifier (ISO 11616).

FDA

Mary Ann Slack
Acting Director, OSP, CDER, FDA

Virginia Hussong

Staff Chief (acting), Data Standards, OD, CBER, FDA

Ta-Jen (TJ) Chen
Program Lead, IDMP, OSP, CDER, FDA

Norman Schmuff
Associate Director, Office Pharmaceutical Quality,
Office of Process and Facilities
CDER, FDA

Industry

Robert Class
Director, RIM Data Standards, Governance and Operations for Global Regulatory Affairs
Janssen Research & Development, LLC a Pharmaceutical company of Johnson & Johnson

William Friggle
Senior Director
Sanofi

2:15 – 2:30 pm **Open Public Comment**

2:30 – 2:45 pm **Break**

2:45 – 3:30 pm **Individual Case Safety Reports (ICSR)**

This session will focus on the implementation International Council on Harmonization's E2B standard for ICSRs. ICSRs provide a consistent approach to the creation and review of drug and biologics safety information and pharmacovigilance activities.

FDA

Suranjan De
Deputy Director, Regulatory Science Staff, Office of Surveillance and Epidemiology, CDER, FDA

TJ Chen
Program Lead, IDMP, OSP, CDER, FDA

Industry

David Isom
Regulatory Policy and Intelligence Group, Worldwide Safety and Regulatory
Pfizer

William Gregory
Senior Director, Worldwide Safety and Regulatory
Pfizer

Raymond Kassekert
Senior Director & Global Head, Pharmacovigilance Systems
and Agreements
GlaxoSmithKline

3:30 – 3:45 pm **Open Public Comment**

3:45 – 4:00 pm **Closing Remarks**