Public Meeting on
Electronic Submissions and Data Standards

April 7, 2021

9:00 – 9:10 am **Welcome and Opening Remarks***

Ron Fitzmartin
Sr. Informatics Advisor
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

Topic 1

9:10 – 10:10 am **Electronic Submissions Gateway**

Lowell Marshall
IT Program Manager, ESG
Office of Information Management and Technology (OIMT)
FDA

Srini Palle
ESG Program Manager Contractor
Assyst

Vishu Manegari
Senior Director, Regulatory Operations
Gilead Sciences

Peter Goodwin
Global Team Lead, Regulatory Submissions Group
Roche/Genentech

John Ferguson
Director, Regulatory Operations
Novo Nordisk Inc.

Open Public Comment

Topic 2

10:10 – 11:10 am **PQ/CMC Data Standards**

Norman Schmuff
Associate Director
Office of Pharmaceutical Manufacturing Assessment, Office of Pharmaceutical Quality

Clarice Hutchen
Senior Director, GCMC Advisory Office
Pfizer

David S. Ross
Director, Strategy and Continuous Improvement, Global Regulatory Excellence
AstraZeneca

Rodrigo Palacios
Associate Director, Global Regulatory Policy
Genentech

Open Public Comment

11:10 – 11:30 pm **Break**

Topic 3

11:30 – 12:30 pm **Identification of Medicinal Products (IDMP)**

TJ Chen
Program Lead, IDMP
Office of Strategic Programs
CDER, FDA

Larry Callahan
GSRS Program Lead
Office of Health Informatics
Office of the Commissioner, FDA

Vada Perkins
Executive Director, Regulatory Policy & Intelligence (Global)
Bayer Pharmaceuticals

Deanna Beckett
Director, Regulatory Lifecycle and RIM
AbbVie

Vanni Carapetian
Regulatory Data Capability Lead
Genentech

Open Public Comment

12:30-1:00 pm **Lunch / Break**

Topic 4

1:00 – 1:30 pm **IND Safety Reporting**

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

Virginia Hussong
Chief (acting), Data Standards
CBER, FDA

Nicole Cocuzza
Senior Manager, Regulatory Submissions
AbbVie

Teresa Martins
Senior Director, US Head Regulatory Submissions Management
Bayer Pharmaceuticals

Open Public Comment

Topic 5

1:30 – 2:30pm **eCTD**

Mark Gray
Senior Program Manager
Data Standards Staff, CBER, FDA

David Isom
Regulatory Policy and Intelligence, Global Regulatory Affairs
Pfizer

Arvind Ala
Regulatory Project Management, Global Regulatory Operations
EMD Serono

Teresa Eastwood-Kiefer
Regulatory Submission Group
Hoffmann-La Roche Ltd

Open Public Comment

2:30 – 2:45 pm **Break**

Topic 6

2:45 – 3:30 pm **Technical Rejection of Study Data**

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

Virginia Hussong
Chief (acting), Data Standards, CBER, FDA

Open Public Comment

3:30 pm **Meeting Adjourned**

*Please note that the meeting will progress to the next topic at the scheduled time or when the speakers have finished and there are no further comments.

*Due to the meeting platform limits, up to 500 attendees will have access.

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