FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards

Silver Spring Civic Building at Veterans Plaza
The Buffalo Soldiers Great Hall
One Veterans Place
Silver Spring, MD, 20993

March 25, 2019

AGENDA

Meeting Website: https://www.fda.gov/Drugs/NewsEvents/ucm621215.htm
Docket No. FDA–2018–N–4002

9:00 am	**Introductions**	Suranjan De, MS, MBA Deputy Director Regulatory Science Staff Office of Surveillance & Epidemiology CDER, FDA Gerald Dal Pan, MD, MHS Director Office of Surveillance & Epidemiology CDER, FDA
9:20 am	**Session 1: FAERS II and E2B R3 Up Versioning Plans**	Suranjan De, MS, MBA Deputy Director, RSS FDA
9:50 am	**Session 2: Electronic submission of IND safety reporting** Background	Meredith Chuk, MD Acting Associate Director of Safety Office of Hematology and Oncology Products Office of New Drugs CDER, FDA
10:00 am	Implementation plans, Regional requirements using E2BR2, and Case examples	Meredith Chuk, MD Acting Associate Director of Safety, OHOP FDA
10:50 am	Questions	Meredith Chuk, MD Acting Associate Director of Safety, OHOP FDA
11:00 am	Break	
11:15 am	Up versioning to ICH E2B R3 – Regional requirements	Ta-Jen Chen, MS Project Manager Office of Strategic Programs CDER, FDA

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AGENDA (cont.)

11:45 am	Updates on electronic submission methods	Ta-Jen Chen, MS Project Manager, OSP FDA
12:00 pm	Lunch (on your own)	
1:00 pm	**Session 3: Electronic submission of Post-market safety reporting**	Suranjan De, MS, MBA Deputy Director, RSS FDA
1:10 pm	Up versioning to ICH E2B R3 – Regional requirements	Suranjan De, MS, MBA Deputy Director, RSS FDA
1:40 pm	Backward Forward Compatibility	Suranjan De, MS, MBA Deputy Director, RSS FDA
2:10 pm	Break	
2:20 pm	**Session 4: Updates on electronic submission routing mechanisms**	Suranjan De, MS, MBA Deputy Director, RSS FDA
2:50 pm	**Session 5: E2B R3 implementation – Industry experience with Regulators**	TBD
3:50 pm	Summary and closing remarks	Suranjan De, MS, MBA Deputy Director, RSS FDA
4:00 pm	Adjourn	

For more meeting information, visit the Meeting Website:
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