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

FDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A)
Silver Spring, MD, 20993

July 17, 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 (RSS) Office of Surveillance & Epidemiology CDER, FDA Gerald Dal Pan, MD, MHS Director Office of Surveillance & Epidemiology CDER, FDA
9:10 am	**Session 1: Synopsys from previous meeting**	Suranjan De, MS, MBA Deputy Director, RSS FDA
9:20 am	**Session 2: E2B R3 Regional Requirements for IND safety reporting**	Suranjan De, MS, MBA Deputy Director, RSS FDA
11:00 am	Break	
11:15 am	**Session 3: Generic Drugs – BA/BE trials safety reporting**	Karen Feibus, MD Acting Director Clinical Safety Surveillance Staff Office of Generic Drugs CDER, FDA
11:45 pm	Lunch	
1:00 pm	**Session 4: E2B R3 Regional Requirements for Combo Product safety reporting** Background	Melissa Burns, MS Senior Program Manager Office of Combination Products FDA
1:20 pm	Up versioning to ICH E2B R3 – Regional requirements	Suranjan De, MS, MBA Deputy Director, RSS FDA
2:00 pm	Break	

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AGENDA (cont.)

2:15 pm	**Session 5: CBER's Update on Electronic Safety reporting for Vaccine**	Craig Zinderman, MD, MPH Associate Director for Product Safety Division of Epidemiology Office of Biostatistics and Epidemiology CBER, FDA
3:00 pm	**Session 6: E2B R3 implementation – Industry experience with Regulators**	Dr. Hans-Jörg Römming Senior Director, Head of GPS PV Operations Merck KgaA, Darmstadt, Germany
3:50 pm	Summary and closing remarks	Suranjan De, MS, MBA Deputy Director, RSS FDA
4:00 pm	Adjourn	