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

Date: April 4, 2023
Time: 9:00 am – 3:00 pm

AGENDA
Meeting Website: Electronic Submission of Adverse Event Reports to FDA Adverse Event Reporting System (FAERS) using International Council for Harmonisation (ICH) E2B(R3) Standards - 04/04/2023 | FDA

Docket No. FDA–2018–N–4002

9:00 am – 10:15 am	**Introduction and Housekeeping** **E2B Background at FDA** **Regional Implementation of E2B(R3)** **Submission Methods & Mechanism**	Suranjan De, MS, MBA Deputy Director Regulatory Science Staff (RSS) Office of Surveillance & Epidemiology CDER, U.S. FDA
10:15 am – 10:30 am	**Break**	
10:30 am – 11:45 am	**E2B(R3) Implementation Package** **Common Regional Extensions**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
11:45 am – 12:30 pm	**Lunch Break**	
12:30 pm – 1:45 pm	**Postmarket Safety Reporting** **IND Safety Reporting** **BA/BE Study Safety Reporting for Generic Drugs** **Validation and Implementation**	Suranjan De, MS, MBA Deputy Director, RSS, FDA Y. Veronica Pei, MD, M.Ed, MPH Lieutenant Commander U.S. Public Health Service Associate Director of Biomedical Informatics, Office of New Drugs (OND) CDER, U.S. FDA Jung Lee, R.Ph, MPH Safety Officer Division of Clinical Safety and Surveillance, Office of Safety and Clinical Evaluation Office of Generic Drugs (OGD) CDER, U.S. FDA Suranjan De, MS, MBA Deputy Director, RSS, FDA
1:45 pm – 2:00 pm	**Break**	

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2:00 pm – 3:00 pm	**Rejection and Warning** **FDA Specific Object Identifiers (OIDs)** **R2 -> R3 Regional Forward Compatibility** **Summary** **Q&A**	Suranjan De, MS, MBA Deputy Director, RSS, FDA Y. Veronica Pei, MD, M.Ed, MPH Associate Director of Biomedical Informatics, OND, FDA Jung Lee, R.Ph, MPH Safety Officer, OGD, FDA Kelley Simms, PharmD, MS, BCPS Regulatory Policy Analyst Regulatory Affairs Staff (RAS) Office of Surveillance & Epidemiology CDER, U.S. FDA