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
February 19, 2020

AGENDA

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

9:00 am	**Introduction**	Suranjan De, MS, MBA Deputy Director Regulatory Science Staff (RSS) Office of Surveillance & Epidemiology CDER, FDA
9:10 am	**FAERS II Update**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
9:30 am	**Review of E2B R3 Regional Data Elements** **- Premarket data elements** **- Combination product elements** **- Other regional elements**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
11:00 am	Break	
11:20 am	**Review FDA Specific Object Identifiers (OIDS)**	Ta-Jen Chen Project Manager, Office of Strategic Programs (OSP), FDA
11:45 am	Lunch	
1:00 pm	**Regional Forward Compatibility**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
1:30 pm	**Present submission paths for premarket and postmarket ICSRs**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
2:00 pm	Break	
2:20 pm	**Demonstration of E2B Validator**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
2:45 pm	**Next steps** **Open Discussion**	Suranjan De, MS, MBA Deputy Director, RSS, FDA
4:00 pm	**Adjourn**	