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: November 7, 2023
Time: 9:00 am – 12:00 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 – 10:20 am	**Introduction and Housekeeping** **Recap from previous Public Meeting** **Implementation Plan and Progress** **External and Internal Testing Update**	Suranjan De, MS, MBA Deputy Director Regulatory Science Staff (RSS) Office of Surveillance & Epidemiology CDER, U.S. FDA
10:20 am – 10:35 am	**Break**	
10:35 am – 11:45 am	**Regional Extension Updates** **FDA Readiness** **Submitter Preparedness** **Summary**	Suranjan De, MS, MBA Deputy Director Regulatory Science Staff (RSS) Office of Surveillance & Epidemiology CDER, U.S. FDA
11:45 am – 12:00 pm	**Questions** **Adjourn**	