Twelfth Annual Sentinel Initiative Public Workshop
Washington Plaza Hotel
10 Thomas Cir NW, Washington, DC 20005
April 21, 2020

Sentinel System Public Training Agenda

1:00 p.m.  Welcome and Overview  
Gerald Dal Pan, U.S. Food and Drug Administration

1:05 p.m.  Pre-Training Survey  
Noelle M. Cocoros, Harvard Medical School and Harvard Pilgrim Health Care Institute

1:15 p.m.  Introduction to the Sentinel System and Overview of Analytic Capabilities  
Objective: Provide an overview of the Sentinel System, including the distributed data network and Common Data Model. We will introduce Sentinel’s routine querying tools and describe current analytic capabilities. We will present a use case study for discussion: a real-world example of the antiepileptic drug topiramate exposure and risk of oral clefts in infants.

Speaker: Mayura Shinde, Harvard Medical School and Harvard Pilgrim Health Care Institute

2:00 p.m.  Creation of a Linked Mother-Infant Cohort and Descriptive Pregnancy Analysis  
Objective: Introduce how a pregnancy cohort is created in Sentinel, including the use of validated algorithms for identifying live birth deliveries, estimating gestational age, and methods for linking mothers to infants. We will discuss options for descriptive analyses that characterize medical product use during pregnancy and present descriptive results from the use case study of topiramate exposure during pregnancy.

Speaker: Elizabeth Suarez, Harvard Medical School and Harvard Pilgrim Health Care Institute

2:45 p.m.  Break

3:00 p.m.  Inferential Analyses for Perinatal Exposures  
Objective: This lecture will expand on the analytics capabilities for pregnancy studies presented in the previous section. We will describe the new tool available to conduct inferential analyses among pregnant women, enabling the assessment of infant and/or maternal outcomes using propensity score matching. We will share results from the topiramate use case study examining its association with oral clefts in infants.

Speaker: Jennifer Lyons, Harvard Medical School and Harvard Pilgrim Health Care Institute

3:45 p.m.  Post Training Survey and Adjournment  
Noelle M. Cocoros, Harvard Medical School and Harvard Pilgrim Health Care Institute

Join the conversation with #sentinelinitiative
Funding for this conference was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.