Individuals and Organizations Completing Research in the IMEDS Lab
Rima Izem, PhD. Lead Mathematical Statistician, Office of Biostatistics/Division of Biometrics 7 in the office of Biostatistics at FDA/CDER

Scope of Research

Research Objectives and Aims: three objectives for training purposes (non-regulatory activity): (1) gain familiarity with the OMOP common data model (2) gain familiarity with different database sources in OMOP (3) gain familiarity with observational studies methods applied by OMOP to this database

Scope/Proposed Approach: To achieve these objectives, after we are familiar with the laboratory, we plan to conduct the following exercises:

(1) Reproduce results of the OMOP 2011/2012 experiment regarding Acute Myocardial Infarction endpoint.

(2) Apply same principles of OMOP 2011/2011 experiment for Major Cardiovascular Adverse Event endpoint.

Impact: Conducting this experiment will give safety reviewers practical experience that they can apply to writing statistical analysis plans and conducting statistical analyses to answer regulatory questions using observational studies.

Experience: We request that the 5 datasets in the lab be available to all members. All reviewers specialize in the review of safety of drugs in the pre-market or post-market setting. They each have a graduate degree in Statistics, Biostatistics, or Epidemiology. In the post-market setting, they write statistical analysis plans to answer safety questions using observational studies, and review the statistical results to support regulatory decisions on approval or labelling.

Working Group: From the **Office of Biostatistics/Division of Biometrics 7:** Mark Levenson, PhD; Rima Izem, PhD; John Yap, PhD; Thomas Ly, PhD; Ya-hui Hsueh, PhD; Rongmei Zhang, PhD; Joo-Yeon Lee, PhD. From the **Office of Biostatistics/Immediate Office**: Paul Schuette, PhD. From the **Office of Surveillance and Epidemiology**: Esther Zhou, PhD; Yulan Ding, MS; Simone Pinheiro, Sc.D.

Timeline: Beginning April 2014 for two years.

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