Synthesizing adverse events data: challenges and approaches

Panel discussion (80 minutes)

Accurate information on harms is essential for understanding the benefit-risk profile of interventions. Systematic review and meta-analysis of adverse events (AEs) data is challenging because of fragmented data collection and suboptimal reporting in the primary studies, as well as statistical issues of analyzing rare events. We will convene a panel of four speakers to discuss challenges and approaches for synthesizing AE data.

Session chair: **Kay Dickersin, member**

Topics to be addressed include:

(1) How do the methods of AE data collection in the primary studies affect synthesis? Is it appropriate to combine systematically and non-systematically collected AEs in meta-analysis? What are the data sources for identifying AEs? How should inconsistent AE reporting between sources be reconciled? How should we best address under-reporting of AEs in the public sources? Does sharing of clinical trial data and clinical study reports help address these issues? **(Tianjing Li; member)**

(2) How will reporting thresholds (e.g., AEs are reported if they occur in 5% of participants in any intervention group) affect synthesis? How reliably can we assess the risk of bias of safety outcomes? **(Riaz Qureshi; guest)**

(3) What are the methodological challenges of using observational data for understanding safety of drugs? What are the roles of meta-analysis from a regulatory perspective, both before approval and after marketing (benefit risk assessment, individual patient data meta-analysis, FDA draft guidance on meta-analyses of randomized controlled trials)? **(Jesse Berlin; member)**

(4) What are the statistical considerations for analyzing adverse events (unit of analysis issue, implications of grouping AEs)? What is the performance of various models in handling rare events? **(Gary Rosner; guest)**

Each panel member will have 10 minutes for opening remarks, followed by a 40-minute open floor discussion.

Note that we will send an updated version of the abstracts before the program is finalized. We also kindly request the session to be scheduled on Monday, July 22 if possible, to accommodate travel schedules of speakers.