Sebastian Schneeweiss, MD, ScD, is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology in the Department of Medicine, Brigham and Women’s Hospital.

His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision making around the globe. He is funded by NIH, PCORI, Burroughs Wellcome Fund, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions.

«From Real-World Data to Real-World Evidence: Some consideration for practitioners»

Regulatory agencies across the world increasingly consider real-world evidence (RWE) for effectiveness claims in medical product approval and coverage decisions. RWE complements RCT evidence to understand the effectiveness in clinical practice by analyzing large longitudinal healthcare data. In order to support decision makers we need 1) full transparency of study implementation, 2) fit-for-purpose data, 3) causal study designs and analyses, and 4) approaches that facilitate the review of RWE studies. This talk illustrates advances in these areas with empirical examples and recent regulatory developments.

Join the lecture on Thursday, 17 March 2022 at 4:00 pm online on zoom!

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