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Seqirus, a CSL Company

James A. Mansi joined Seqirus in 2016 following the acquisition of the Novartis Influenza Vaccines business by CSL, where he served as the Global Head, Medical Affairs for Novartis Influenza Vaccines. Over the course of his 23-year career in industry, James has supported the launch of several vaccines, including the human rotavirus vaccine, the human papillomavirus vaccine, the zoster vaccine, the invasive meningococcal vaccines, the MF59-adjuvanted seasonal influenza vaccine, and, most recently, the cell-derived influenza vaccine.

In his current role, James leads the Seqirus Centre for Outcomes Research & Evaluation (CORE) - a dynamic team responsible for the generation of Real World Evidence to help inform public health decisions on influenza vaccination programs.
James obtained his doctoral degree in Physiology and Endocrinology at Université Laval (Québec City, Canada).

Presentation title: Conducting Real World Evidence research: informing on quality measures of health networks and effectiveness of health care interventions

Short description: Despite the many advantages of randomized controlled trials, several important trade-offs between internal and external validity remain, which are potentially met by real-world evidence (RWE) studies.

We will begin by exploring the different sources of Real World Data (RWD) and the factors that define RWD data reliability and relevance. With an understanding of the RWD requirements to generate high quality evidence, we will review research parameters for the design and interpretation of robust observational studies. Using specific vaccines as case examples, we will travel across the spectrum of RWE that may be implemented within a health network starting with behavioral research to understand factors affecting acceptance and adherence to a given health intervention. Given the vast amount of data within such health network datasets, we will then discuss innovative RWE research designs ranging from retrospective to prospective pragmatic studies.

Outcomes: By the end of this session, participants will have an understanding for the importance of RWE generated from robust RWD and begin to explore how to apply different outcomes research designs to help inform public health on epidemiologic trends and effectiveness of specific health interventions.