EXAMPLES FROM ICPE 2017 in Montreal

Keynote: Typically a single, highly visible and accomplished speaker, who can draw a large audience.

Keynote Address
Robert Califf, Vice Chancellor for Health Data Science, Duke Health
Benefits and Risks of Medical Products: A Systematic Approach to Continuous Evidence Generation
A system in which the point of market entry for medical products could be carefully calibrated to assure patients and providers that the benefits of using the products as intended were likely to outweigh its risks would fairly balance the need for safety with the desire for access to effective technologies. Given the documented risk tolerance differences in different patient populations, an evidence generation system is needed that could be used to develop rational policies that would be specific for each clinical situation. In order for this system to work, a comprehensive post-market environment is needed to constantly provide reliable surveillance for safety while also fostering the generation of new evidence about the risks and benefits for intended use; the comparative effectiveness relative to alternative approaches to therapy; and the cost effectiveness and value of the product. The past disaggregated approach in the US has left major holes in the information needed for rational policy and created a system that cannot generate information that is needed for a reasonable cost.
Major changes in computation, analysis and policy are putting the elements of a comprehensive system into place. Critically for our national philosophy, the system is federated, not entralized, and it is subject to controls at the individual, local and regional levels. The FDA's Sentinel System for drugs and biologics, PRISM for vaccines and the NeST for devices use various combinations of claims data, EHR data and registries to produce a tapestry of information. This is now bolstered by PCORI's PCORnet and the Clinical and Translational Science Awards to bring in the capability of prospective trials and observational studies linking these data sources to health systems and providers.

Plenary: Typically 3-4 speakers for a topic of broad interest.

Plenary Session: *Medical Product and Performance Evaluation Programs Using Distributed Data Sources*

Analyses of distributed data have played a significant role in a wide range of scientific disciplines. These developments in data science and in biostatistics, along with the need for rapid evaluation of safety and effectiveness, have led to real-world studies that have far

greater power than individual center studies to detect unintended drug safety signals, by combining data from multiple repositories. Two existing networks – the Canadian Network of Observational Drug Effect Studies (CNODES) and the US Sentinel System – analyze distributed data to respond to queries about drugs generated by Health Canada and the US Food and Drug Administration, respectively. In this Plenary Session, CNODES and Sentinel System investigators will compare and contrast the methods for distributed analyses of CNODES and the Sentinel System, and, regulators from Canada and the US will describe barriers and facilitators for generating queries and applying the study results to regulatory decision making. Canadian CNODES and US FDA Sentinel System teams and representatives of the regulatory authorities will discuss the uses of distributed administrative, claims, and electronic health record data to support medical product performance evaluation involving large segments of a nation's population. They will focus on systems that leverage routinely collected administrative, claims, and electronic health record data from separate private organizations and/or government agencies. The experience of both countries will be used to illustrate the strengths and limitations of distributed systems, the pros and cons of standardizing on a common data model, the potential for developing reusable tools to analyze data, the efficiencies that reusable tools can enable, and opportunities for coordination between systems in different countries. Throughout the session, studies conducted by both teams will serve as illustrative examples.

Moderator: **Samy Suissa**, McGill University

Speakers:
Richard Platt, Harvard Medical School and Harvard Pilgrim Health Care Institute
Robert Platt, McGill University
Robert Ball, Deputy Director, Office of Surveillance and Epidemiology, CDER/FDA
Megan Beetle, Health Canada

Hot Topic: Typically 3-4 speakers for a particularly timely or controversial topic.

Hot Topic Session: *A Bitter Pill to Swallow, Snort or Inject: What have we learned about the impact of our opioid policies in North America?*

The increasing prevalence of opioid use and addiction is one of the largest public health issues currently facing North America. Over the past two decades, regulators and clinicians have been attempting to develop evidence-based policies and guidelines that adequately balance access to these drugs for pain management against a growing epidemic of opioid addiction.
This has been met with varied success due to the complexity of this issue as it spans the fields of prescription drug regulation, access to pain management alternatives and addiction services, and illicit drug trafficking. Furthermore, many jurisdictions have been criticized for poor data collection and ability to actively monitor this issue as it evolves. This hot topic presentation will include a panel of speakers from the US, Canada and Europe that will present various perspectives on the value and impact of different policies that have been introduced to address

this problem. This will provide a forum for discussion and debate of past successes and failures in drug policy, and potential consequences as this problem extends globally.

Moderator:

Yola Moride, FISPE. Professor, Faculty of Pharmacy, Université de Montréal; Moderator Speakers:

Judy A. Staffa, Associate Director for Public Health Initiatives, Office of Surveillance & Epidemiology, CDER/FDA

Tara Gomes, Ontario Drug Policy Research Network; Institute for Clinical Evaluative Sciences. St. Michael's Hospital

Richard C Dart, Director of the Rocky Mountain Poison and Drug Center; Executive Director of Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS. System); and Chairman, Denver Health Authority Pharmacy and Therapeutics Committee

Maryse Lapeyre-Mestre, Associate Professor of Clinical Pharmacology, Toulouse University Hospital, Head of the Addictovigilance Center of Toulouse