

The Drug Safety and Effectiveness Network – a perspective from Industry

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Perspectives

- DSEN is an important Canadian public policy initiative **BUT.....**
- Success will be determined by:
 - degree of inclusiveness
 - scientific rigor
 - integrity of processes, methods, results
- “Accountability” will make or break the initiative
 - the organization, its advisors, its processes, the researchers involved, the outputs, etc.
 - transparency of “everything” is key (policies, processes, etc.)



Opportunities

- Bringing safety into context with effectiveness data
 - balanced evaluation of safety AND effectiveness data
 - enable informed assessment, dialogue in the benefit-risk process
- Enhanced understanding of product performance in the real world
 - for the benefit of patients, prescribers, decision-makers, etc.
- Alignment and collaboration on multiple fronts
 - collaborative methods development approach
 - e.g., possible future CIHR/Rx&D Collaborative Research Program Theme Grant???



Challenges

- Help stakeholders to understand how they can make their views known
 - a “plague” on the NPS/RWSE/DSEN process since its inception
 - current stance continues to imply a desire to keep certain sectors out
 - undermines the transparency and credibility of the process from the outset
- Finding effective and genuine mechanisms for engaging groups with important inputs (e.g., industry, patients)
 - support high quality science
 - protect scientific integrity



Key Success Factors

- Multi-sectoral buy-in and support
 - “moral”, financial, other
- Long-term planning and commitments
- Decision-makers as key participants
 - developing the research question, assessing the value of the results (have we lost the lessons from CHSRF????)
- Get the right expertise at the table the first time
 - and then transparently manage real/perceived conflicts
 - focus on maximizing quality and integrity of research outputs
 - importance of access to international expertise
- At the end of the day.....
 - ensuring that focus is on executing the highest quality research in as transparent a manner as possible