Update on the Drug Safety and Effectiveness Network

Canadian Agency for Drugs And Technologies in Health

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Halifax

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Background

- Evolution of knowledge about medicines demands that governments and other decision-makers seek additional evidence about the balance of benefit and risk throughout the product life cycle
  - Strengthening evaluation of real-world drug safety and effectiveness (RWSE) included as a public policy priority
  - Recognition of significant gaps in post-market drug safety and effectiveness evidence – a clear barrier to effective, evidence-based decision making
  - Need for greater coordination of efforts to generate and transfer information necessary to fill evidence gaps and support decision makers in a timely manner
Collaborative work on RWSE includes:

- Invitational Workshop on Priority Research Projects for a Drug Safety and Effectiveness Network (May 2006)
- Workshop on Ethical Considerations for post-marketing evaluations of pharmaceuticals (March 2007)
- Project work with the National Pharmaceutical Strategy and Canadian Drug Policy Development Coalition (CDPDC)

Recommended as host agency for the DSEN:

- Standing Committee on Health report on Post Market Surveillance of Pharmaceuticals (July 2008)
DSEN included in the Government of Canada’s *Food and Consumer Safety Action Plan* (December 2007)

- Support product life-cycle approach to drug regulation by providing additional evidence to Health Canada for use in ongoing risk-benefit assessment of drug products
- Complement other pharmacosurveillance activities – provide additional tool

[http://www.healthycanadians.gc.ca/pr-rp/action-plan_e.html](http://www.healthycanadians.gc.ca/pr-rp/action-plan_e.html)
DSEN Policy Objectives

- Increase the evidence on drug safety and effectiveness available to regulators, policy-makers, health care providers and patients
  - Fill gaps in knowledge required to make evidence-based decisions about drugs

- Increase capacity within Canada to undertake high-quality post-market studies of drugs’ safety and effectiveness
  - Leverage greater value from existing investments in post-market research within Canada
Scope

Coordination and funding of two research directions: Drug Safety and Comparative Effectiveness (C.E.)

- **Safety**
  - Linkage of centres across Canada: retrospective observational or epidemiologic studies using administrative data shared through statistical query mechanisms
  - Active surveillance, early detection, safety signals: prospective assessments through funded centres and projects

- **C.E.**
  - Queries: arising from multiple sources (health technology assessments, clinical practice guideline development, funding decisions)
  - Methodologies: retrospective and prospective, direct and indirect comparisons, RCTs, meta-analysis
DSEN Program Components

1. Steering Committee
   - Nominations closed

2. Coordinating office established under CIHR
   - Fully Staffed

3. Virtual network of linked centres of excellence in post-market pharmaceutical research
   - Development of the funding opportunity to establish the DSEN research network nearing completion
   - Future research funding opportunities will be based on the priorities identified in the common research agenda
Implementation

- DSEN operations are being phased-in to full operations by 2012/2013

- CIHR is drawing on existing programs and processes to establish the DSEN

- New operational elements being identified to address the unique attributes of the DSEN program
DRAFT DSEN Query Process

Health Canada

New Evidence

Health Care Decisions

New Evidence

Other Stakeholders

Query sent to Relevant Data Holders

DSEN Steering Committee

Result

DSEN COORDINATING CENTRE

Query

Result

Science Advisory Committee

Data Management Advisory Committee

Collaborating Centres Advisory Committee

DSEN Funded Centres & Projects

Healthcare Insurance Providers

Academic Institutions

Healthcare Providers

Private data holders
Catalyst Grant: Drug Safety and Effectiveness

- Initial funding for 10 grants of up to $100 k
- Funding start date – March 15, 2010
- 26 relevant applications submitted to 7 research areas covering 18 different topics
- 14 fundable applications in 5 relevant research identified in peer review

- Through partnerships all funded
  Institute of Gender and Health (IGH)
  Institute of Human Development, Child and Youth Health (IHDCYH)
  Institute of Musculoskeletal Health and Arthritis (IMHA)
  Strategy on Patient-Oriented Research (SPoR)
  Institute of Cancer Research (ICR)

Total investment $1.35 million
Activities 2010/2011

FUNDING
- Next competition for Centres funding, followed by RFA’s for projects
- Centres funded – Winter, 2010-11
- Projects funding start date – 2011

STEERING COMMITTEE
- Finalize DSEN Steering Committee Membership – Spring, 2010

EVENTS
- First DSEN KT Forum on methodology – Late Spring, 2010
More information on the DSEN is available on the CIHR website

http://www.cihr-irsc.gc.ca/e/39389.html