

Update on the Drug Safety and Effectiveness Network

The Canadian Association for Population Therapeutics

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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

Background - CIHR

- ❑ 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:
 - *Medicines that Work for Canadians: Business Plan for a Drug Effectiveness and Safety Network (October 2007)*
 - Standing Committee on Health report on Post Market Surveillance of Pharmaceuticals (July 2008)

The Food And Consumer Safety Action Plan

- ❑ 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



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

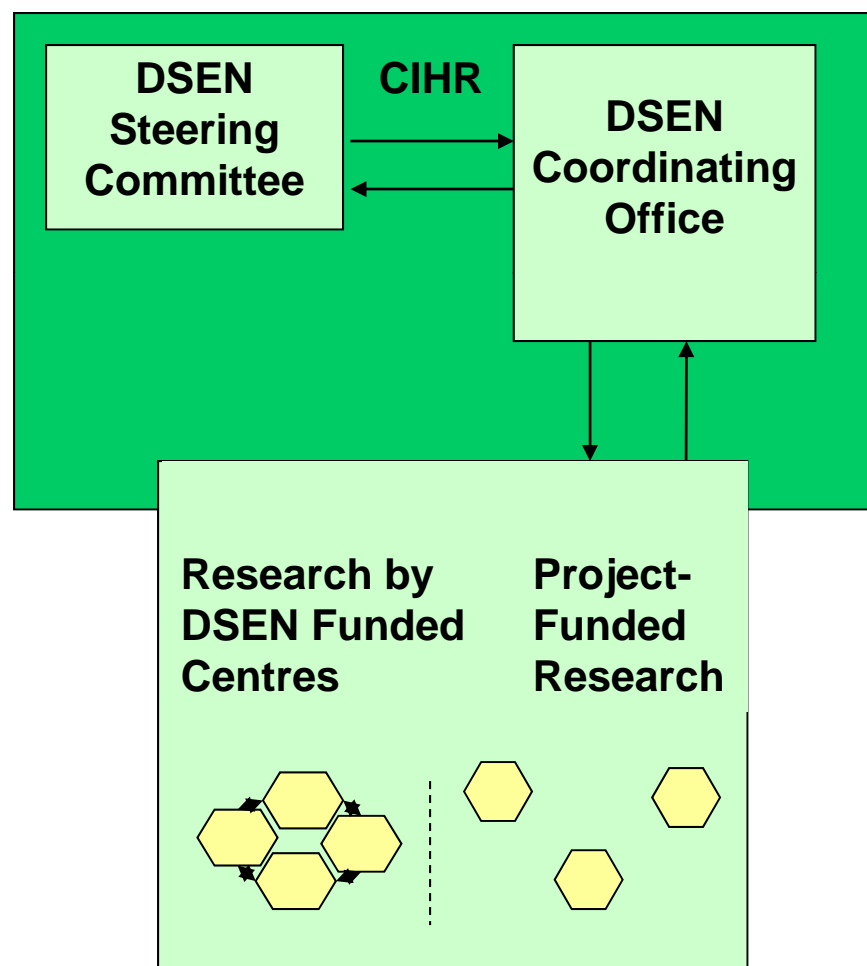
- Linkage of centres across Canada: retrospective observational or epidemiologic studies using administrative data shared through statistical query mechanisms
- Active surveillance, early detection, safety signals: prospective assessments through funded centres and projects

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

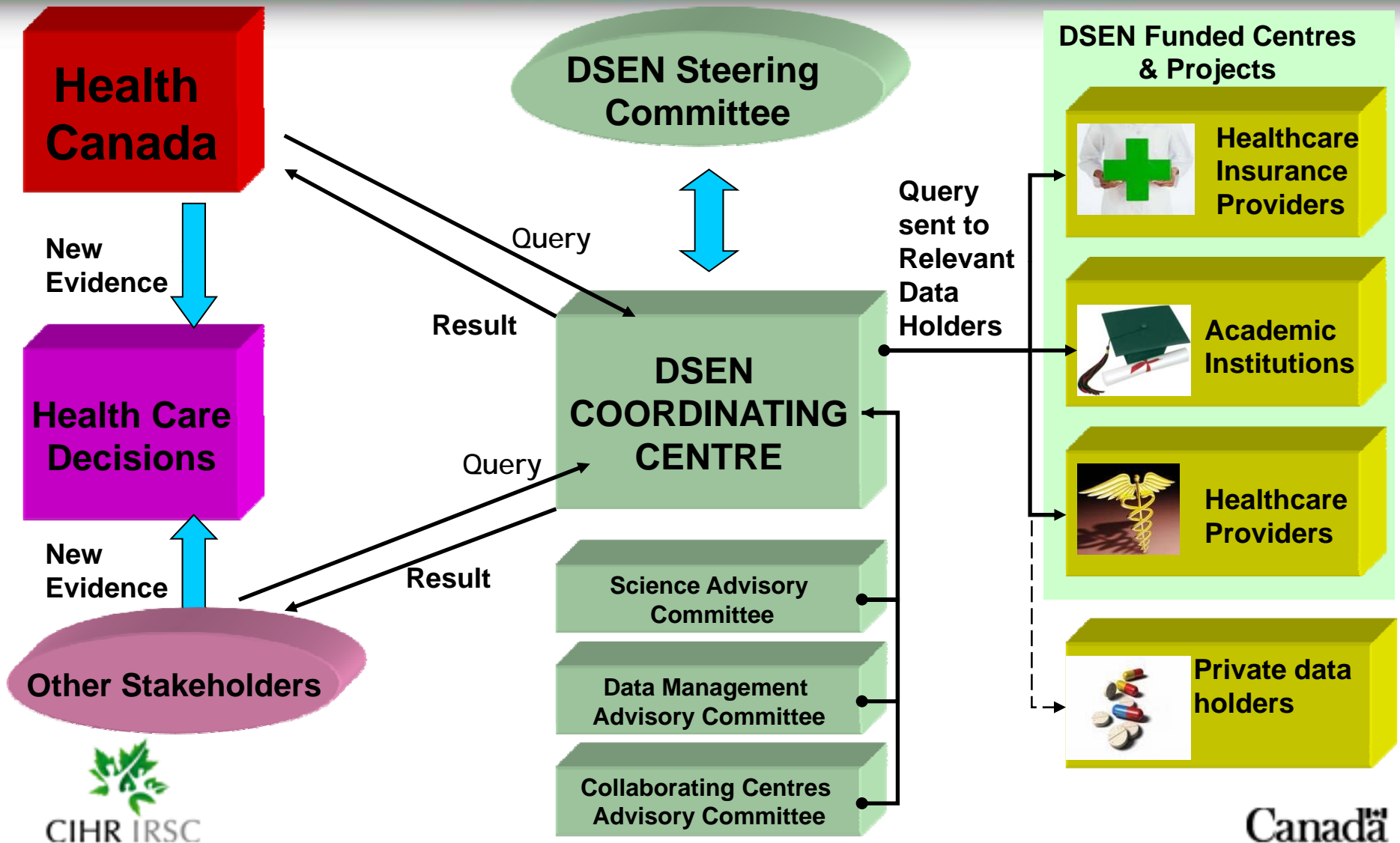
1. Steering Committee
 - Nominations closed
2. Coordinating office established under CIHR
 - Fully Staffed
3. Virtual network of linked centres of excellence in post-market pharmaceutical research
 - Development of the funding opportunity to establish the DSEN research network nearing completion
 - Future 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



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)

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>

<http://www.cihr-irsc.gc.ca/f/39389.html>

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