CIHR IRSC

The Drug Safety and Effectiveness Network (DSEN)

Dr. Diane Forbes, Associate Director, DSEN

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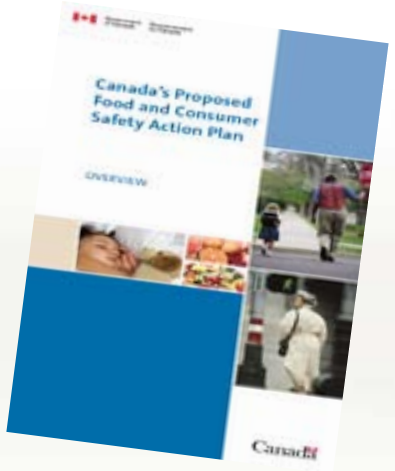
Canada

The Drug Safety and Effectiveness Network - Background

DSEN included in the Government of Canada's Food and Consumer Safety Action Plan (December 2007) to support a product life-cycle approach to drug regulation by providing additional evidence for use in ongoing risk-benefit assessment and an additional tool for surveillance.

Government investing a total of $32 million over 5 years (and $10 million per year ongoing) in the DSEN, through a partnership of CIHR and Health Canada:

- CIHR responsible for implementing, facilitating and coordinating DSEN operations and funding research
- HC providing policy leadership and coordination among DSEN program partners and integrating DSEN research findings into its existing drug regulatory and drug plan management activities



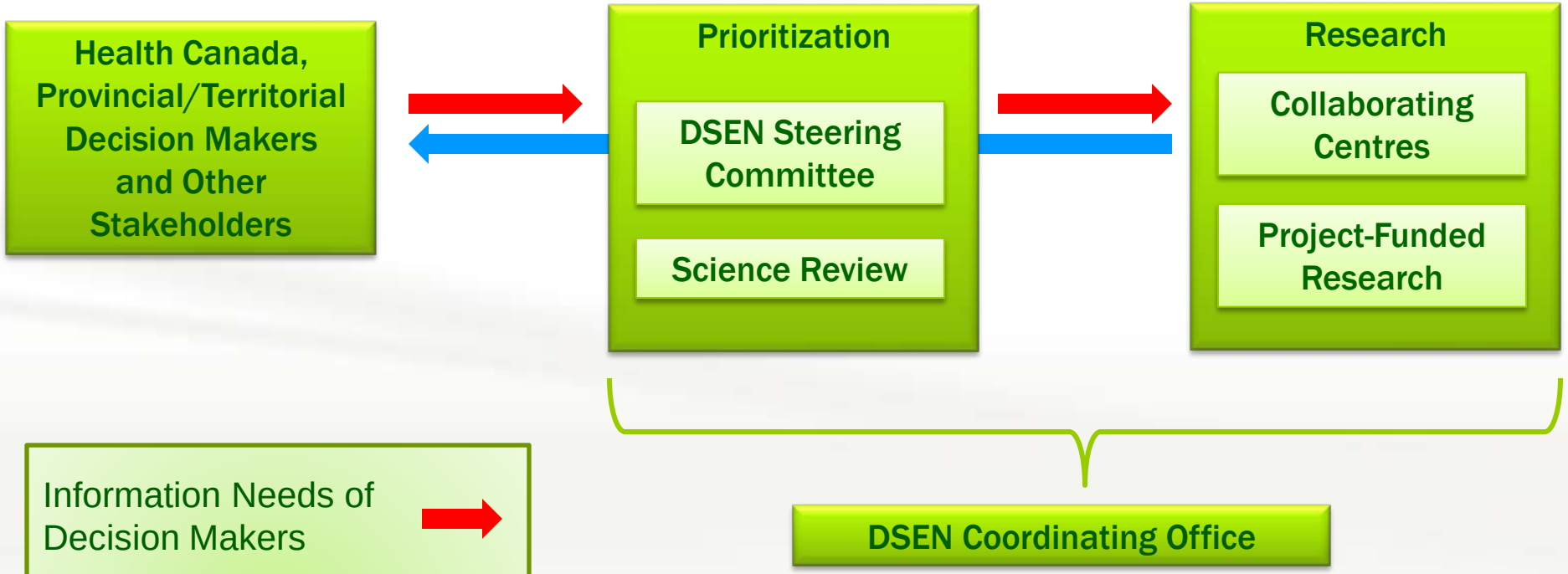
The Drug Safety and Effectiveness Network - Objectives

- Increase the evidence on the post-market safety and effectiveness of drugs available to public drug plan managers, policy-makers, health technology assessors, regulators and other end-users, to support their decision making

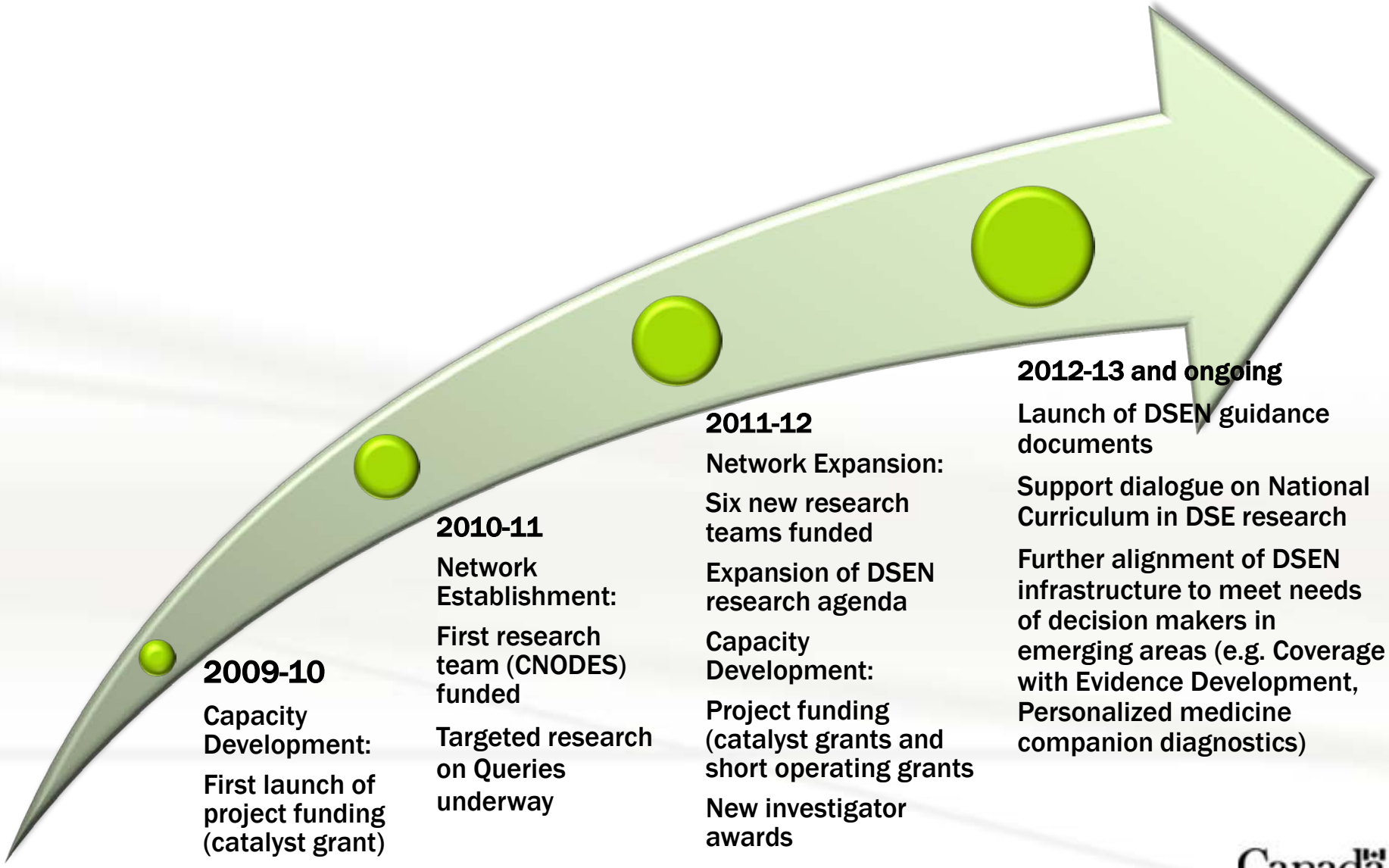
- Increase the capacity within Canada to undertake high-quality post-market research in this area

New evidence generated via DSEN to provide decision-makers with an important additional source of information about drug products' safety risks relative to their therapeutic benefits. DSEN evidence will support decision-making on public reimbursement, and safe and optimal prescribing and use of drugs within Canada.

DSEN Program Components



DSEN Trajectory



2009-10

Capacity Development:

First launch of project funding (catalyst grant)

2010-11

Network Establishment:

First research team (CNODES) funded

Targeted research on Queries underway

2011-12

Network Expansion:

Six new research teams funded

Expansion of DSEN research agenda

Capacity Development:

Project funding (catalyst grants and short operating grants

New investigator awards

2012-13 and ongoing

Launch of DSEN guidance documents

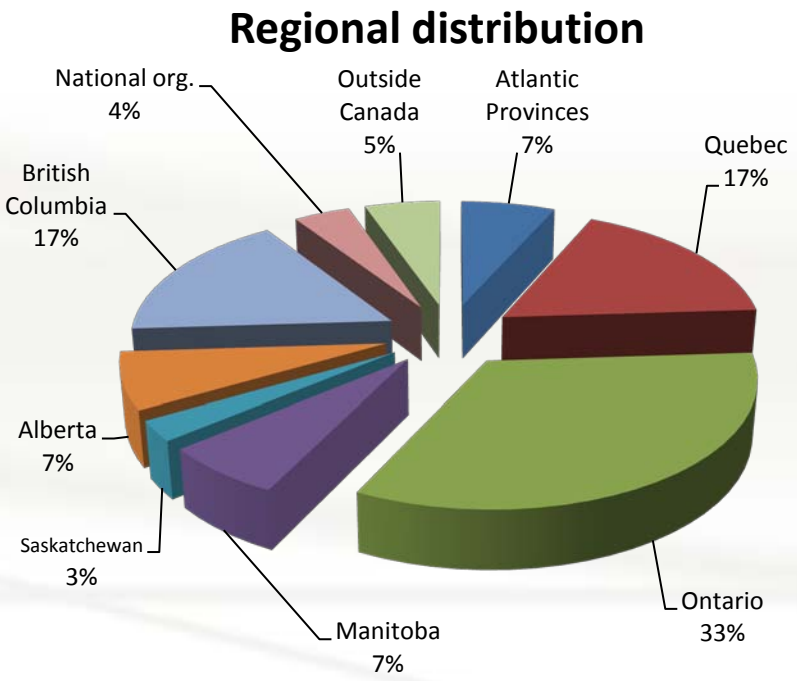
Support dialogue on National Curriculum in DSE research

Further alignment of DSEN infrastructure to meet needs of decision makers in emerging areas (e.g. Coverage with Evidence Development, Personalized medicine companion diagnostics)

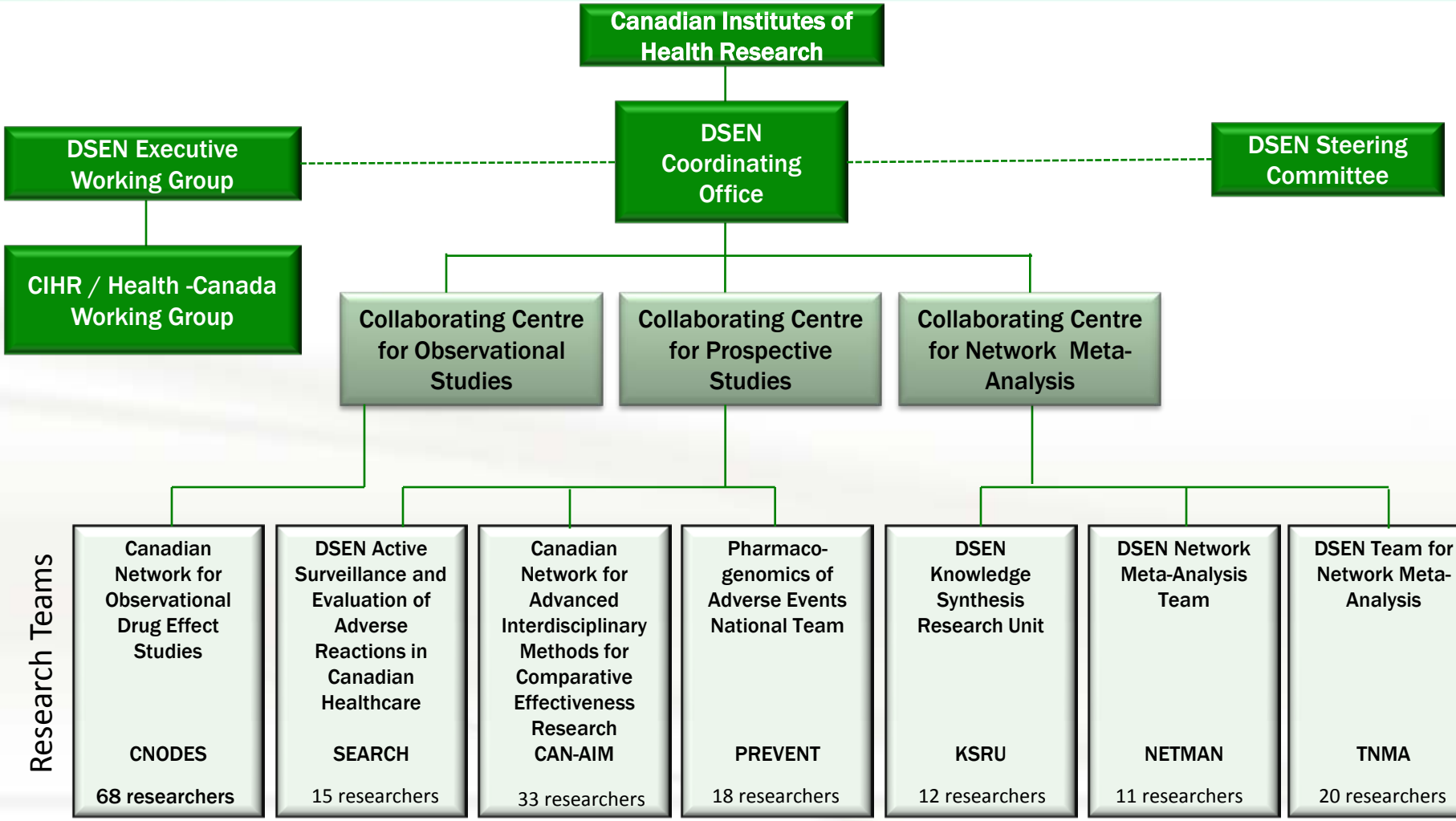
DSEN Collaborating Researchers

DSEN has built a functioning national network, comprised of 150 researchers across Canada focused on five distinct methodological areas, to support the development of new research evidence to fill knowledge gaps identified by decision makers within the Canadian health care system.

- Seven research teams established through three funding opportunities
- Researchers working in eight provinces (BC, AB, SK, MB, ON, QC, NS, NFL) with international collaborators (UK, USA, EU)



Drug Safety and Effectiveness Network Organizational Chart



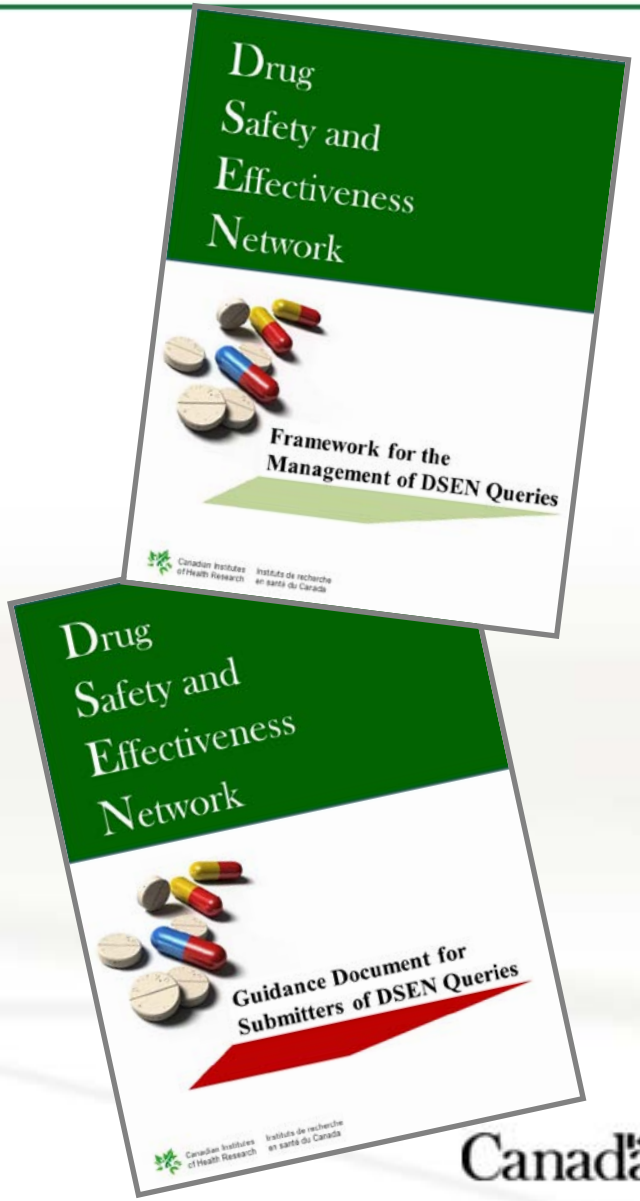
Publications Available

Framework for the Management of DSEN Queries

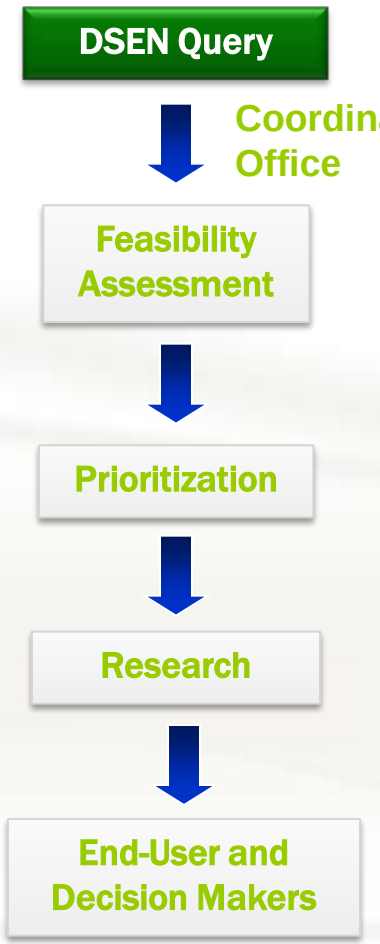
- Provides a clear and detailed description of the processes used for the management of Drug Safety and Effectiveness Network Queries (DSEN Queries)
- Identifies steps and elements for the identification and submission of the queries, as well as the feasibility assessment, prioritization, research and knowledge translation

Guidance Document for Submitters of DSEN Queries

- Assists stakeholders in submitting DSEN Queries for prioritization
- Provides an overview on the process and tools in the form of standardized procedures and templates



Component of the Query process: DSEN Query



A DSEN Query is defined as:

A focused, well defined question identified by healthcare decision-makers, as a gap in evidence on the safety and effectiveness of prescribed drugs on the Canadian market, that can be addressed through DSEN sponsored research and that could result in increased knowledge in ensuring the ongoing safety and effectiveness of these medicines in a "real world" environment.

Scope:

- DSEN's mandate regards potential DSEN Queries on the safety and/or effectiveness of prescription drugs on the **Canadian market**.
- Over-the-counter Drugs and Natural Health Products (including vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products such as amino acids and essential fatty acids) are presently not addressed under DSEN's mandate.

DSEN Research Capacity

Collaborating Centre for Observational Drug Effect Studies

- Perform drug safety and effectiveness research using epidemiological approaches and existing national healthcare databases
- Analyze, link, and develop electronic health data for research

Collaborating Center for Prospective Studies

- Active Surveillance
  - Active safety surveillance of post-market drugs using valid epidemiologic study designs
  - Working with established disease, or patient registries to assess the benefit to harm profile for drugs of interest in a "real world" context
  - Active surveillance by gender and/or in different patient subpopulations such as ethnic and racial minority population, children or seniors
- Pharmacogenomics of Adverse Drug Reactions
  - Assessments on the potential role of pharmacogenomics relating to the impact on reduction of incidence of ADRs
  - Validation of surrogate outcome measure and real world studies
  - Identification of predictive genomic biomarkers of drug risks
  - Compare incidence of ADRs by gender and/or in different patient subpopulations such as ethnic and racial minority populations, children or seniors
- Comparative Effectiveness
  - Performing studies comparing the clinical effectiveness, risk and benefits of treatment options in different patient subpopulations or circumstances
  - Developing strategy, best practices and methods for comparative effectiveness research in the "real world"

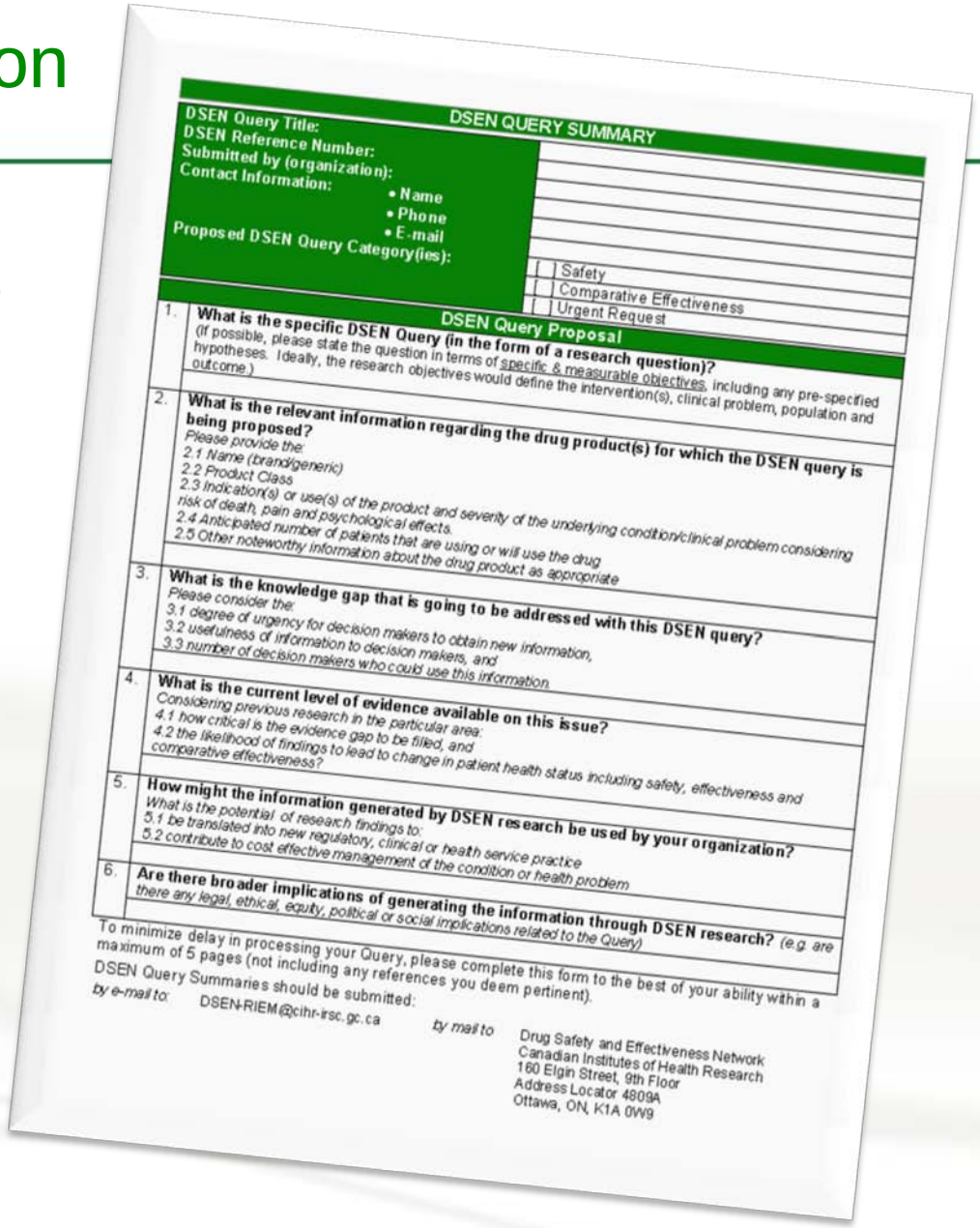
Collaborating Centre for Network Meta-Analysis

- Indirect comparisons (e.g. mixed treatment comparisons) of drugs of interest using data from previously completed RCTs
- Innovative methods for systematic reviews

Query Submission

Query Submitters complete the *DSEN Query Summary* template to summarize the various elements of the issue(s) relating to their query.

The template is a series of questions for capturing the relevant information on the DSEN Query that will be subsequently used in the prioritization process and ultimately as a reference source of information for the DSEN in conducting the research on the topic.



DSEN QUERY SUMMARY

DSEN Query Title:
DSEN Reference Number:
Submitted by (organization):
Contact Information:
- **Name**
- **Phone**
- **E-mail**

Proposed DSEN Query Category(ies):
- [ ] Safety
- [ ] Comparative Effectiveness
- [ ] Urgent Request

DSEN Query Proposal

1. **What is the specific DSEN Query (in the form of a research question)?** (if possible, please state the question in terms of specific & measurable objectives, including any pre-specified hypotheses. Ideally, the research objectives would define the intervention(s), clinical problem, population and outcome.)
2. **What is the relevant information regarding the drug product(s) for which the DSEN query is being proposed?**
   Please provide the:
   2.1 Name (brand/generic)
   2.2 Product Class
   2.3 Indication(s) or use(s) of the product and severity of the underlying condition/clinical problem considering risk of death, pain and psychological effects.
   2.4 Anticipated number of patients that are using or will use the drug
   2.5 Other noteworthy information about the drug product as appropriate
3. **What is the knowledge gap that is going to be addressed with this DSEN query?**
   Please consider the:
   3.1 degree of urgency for decision makers to obtain new information,
   3.2 usefulness of information to decision makers, and
   3.3 number of decision makers who could use this information.
4. **What is the current level of evidence available on this issue?**
   Considering previous research in the particular area:
   4.1 how critical is the evidence gap to be filled, and
   4.2 the likelihood of findings to lead to change in patient health status including safety, effectiveness and comparative effectiveness?
5. **How might the information generated by DSEN research be used by your organization?**
   What is the potential of research findings to:
   5.1 be translated into new regulatory, clinical or health service practice
   5.2 contribute to cost effective management of the condition or health problem
6. **Are there broader implications of generating the information through DSEN research?** *(e.g. are there any legal, ethical, equity, political or social implications related to the Query)*

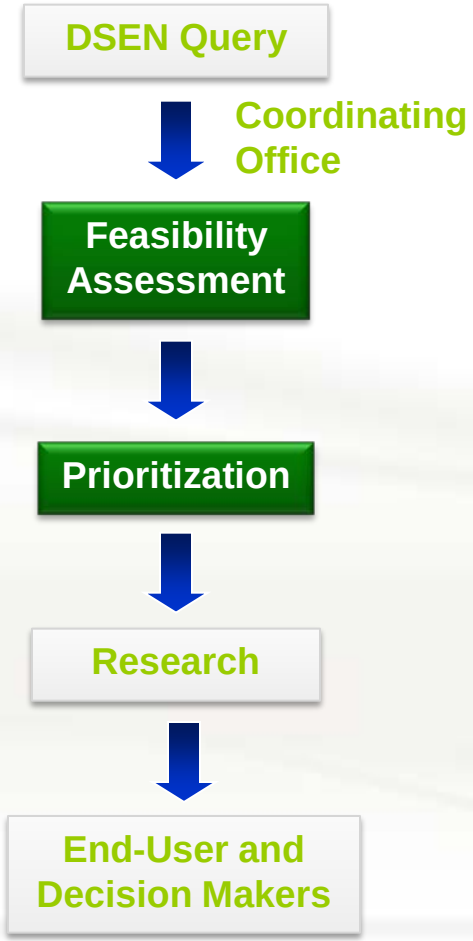
To minimize delay in processing your Query, please complete this form to the best of your ability within a maximum of 5 pages (not including any references you deem pertinent).

DSEN Query Summaries should be submitted:

by e-mail to: DSEN-RIEM@cihr-irsc.gc.ca

by mail to Drug Safety and Effectiveness Network
Canadian Institutes of Health Research
160 Elgin Street, 9th Floor
Address Locator 4809A
Ottawa, ON, K1A 0W9

DSEN Implementation Update: Validation Process



Each query will follow a two-step validation process:

- **Feasibility Assessment:**

  The first step is an assessment of the scientific feasibility of the project within the DSEN context (*e.g.* determine the best methodologies, project timeline, availability of data, cost)

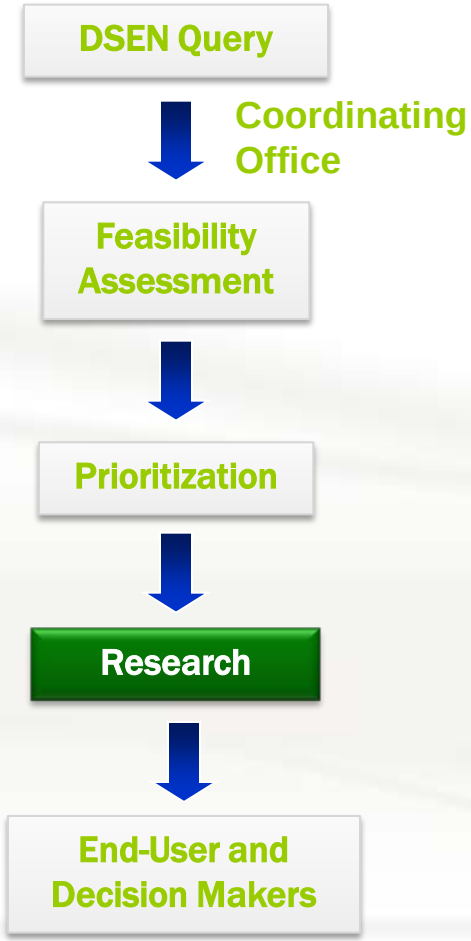
- **Prioritization:**

  The second step is the prioritization of the Queries by the DSEN Steering Committee (DSEN SC) based on the results derived by a multi-criteria decision analysis (MCDA) framework.

  A federal/provincial Working Group on Prioritization of DSEN Queries worked to refine the relevant criteria for weighting queries assessed as feasible.

  DSEN has prepared a document describing the criteria and process for prioritization by the DSEN Steering Committee for received DSEN Queries, the Framework for the Management of DSEN Queries.

Component of the Query Process: Research



Network of DSEN affiliated researchers:

Approximately 50 % of available DSEN funds for investment:

Includes platform funding for
- Networking
- Capacity Development (training)
- Knowledge Translation
- Research (initial project funds and in the case of CNODES ongoing research activities)

Project funded research

Approximately 50 % of available DSEN funds for investment: Supports additional projects responding directly to Queries identified on the DSEN prioritized research agenda, conducted by DSEN Collaborating Researchers and other Canadian researchers

Capacity Development

Investments in trainees and new investigators and developmental research that supports the DSEN mandate.

Contact Information

For questions on DSEN, contact:

DSEN-RIEM@cihr-irsc.gc.ca

DSEN's general website:
www.cihr-irsc.gc.ca/e/40269.html

Diane Forbes
Associate Director | Directrice associée
Drug Safety and Effectiveness Network (DSEN)|
Réseau sur l'innocuité et l'efficacité des médicaments (RIEM)

Canadian Institutes of Health Research
Instituts de recherche en santé du Canada
160 Elgin Street, 9th Floor | 160 Rue Elgin, 9e étage
Address Locator | Indice de l'addresse : 4809A
Ottawa, ON, K1A 0W9
Government of Canada | Gouvernement du Canada