Coverage with Evidence Development in Canada

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Why Consider Coverage with Evidence Development?

◆ Proof of Label Claim evidence for the Regulator is not always Proof of Value evidence needed by other decision-makers
  ◆ Limited external validity of the RCTs, absent active comparators, complex outcome measures
  ◆ Evidence needs for pharmacoeconomic analyses
The Patient Horizon
The “Benefit to Harm Profile”

- **RCT** (small, short, select)
- Labeled Use in the RW (large, long, liberal)
- Inappropriate Use (unregulated, unstudied, unsafe)

**Benefit-to-Harm**
- Positive
- Negative

**The Patient Horizon**

- Efficacy – Effectiveness Gap
- Poor External Validity

(Modified from T Lönngren 2010)
PRESENT DAY DSEN NETWORK

DSEN NATIONAL AND INTERNATIONAL REPRESENTATION

- National Organizations: 4%
- Outside Canada: 5%
- Atlantic Provinces: 7%
- Québec: 17%
- British Columbia: 17%
- Alberta: 7%
- Saskatchewan: 3%
- Manitoba: 7%
- Ontario: 33%
- Outside Canada: 5%
- National Organizations: 4%

NUMBER OF ACTIVE QUERIES BY METHODOLOGY

- Observational Studies
- Pharmacogenomics of AE
- Active Surveillance
- Comparative Effectiveness
- Network Meta-Analysis
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)