

Drug Safety and Effectiveness Network

The Canadian Association for Population Therapeutics

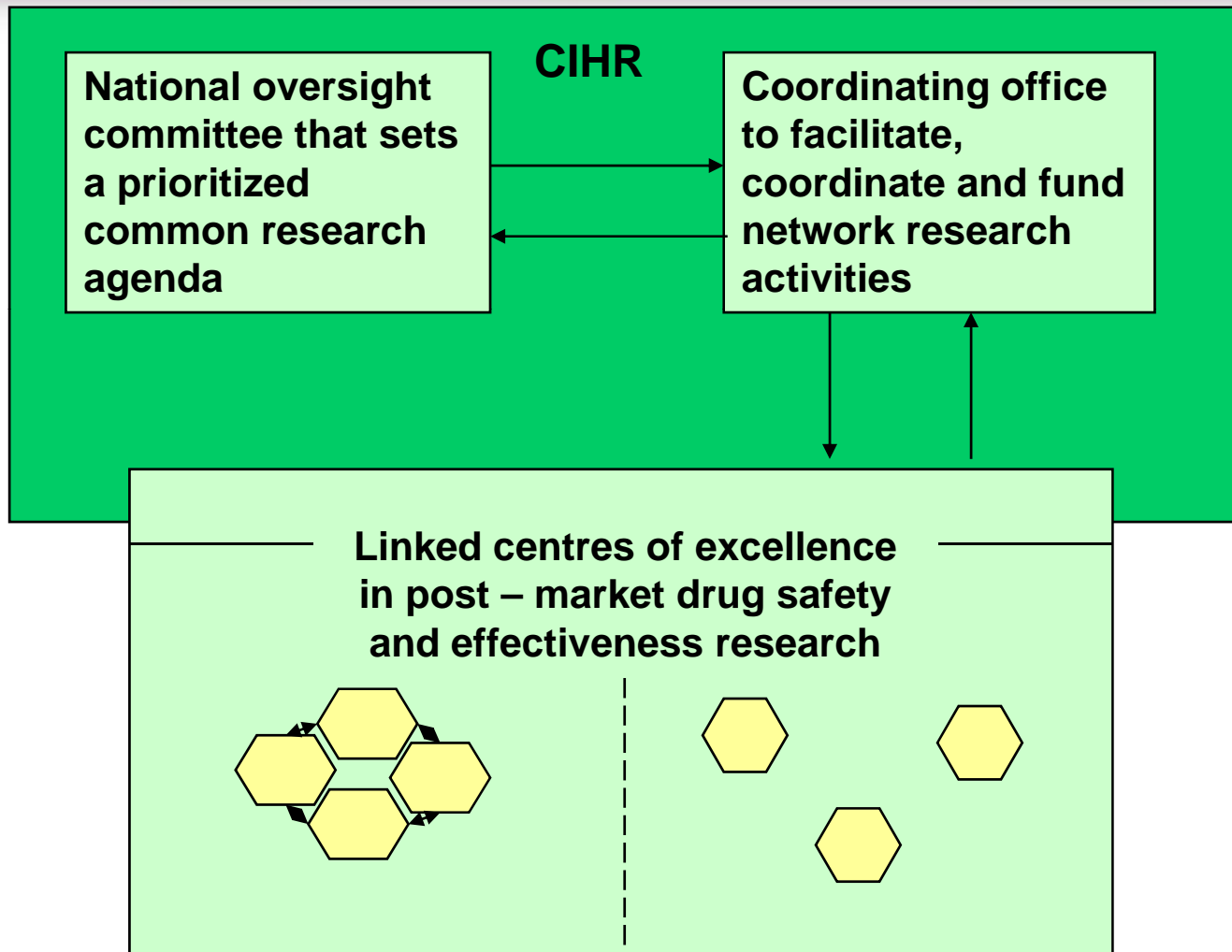
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Diane Forbes, Associate Director, DSEN
Canadian Institutes of Health Research

The DSEN at CIHR

- *Medicines that Work for Canadians: Business Plan for a Drug Effectiveness and Safety Network (2007)* outlined a conceptual framework
- DSEN has three fundamental components:
 - ✓ Linked centres of excellence
 - ✓ Oversight committee
 - ✓ Coordinating office
- As host, CIHR is implementing the DSEN within its existing governance framework

DSEN Components



National oversight committee

- Represents broad stakeholder groups (e.g., regulators, drug plan managers, health professionals, patients)
- Develops a DSEN common prioritized research agenda by identifying gaps in information needed to make decisions regarding safety and effectiveness of pharmaceuticals
- Identifies stakeholder priorities for consideration in creating the common prioritized research agenda
- Supports and promotes translation of research knowledge into actions aimed at improving the health and safety of Canadians
- Respects principles for addressing conflicts of interest

Office of the Executive Director

- Supports and enhances linkages among researchers, research organizations and data sources located across Canada
- Administers DSEN funding program to support conduct of research projects responding to the prioritize research agenda
 - ✓ Facilitates collaboration among network “nodes” to achieve DSEN program objectives
- Supports the national oversight committee in maintaining the prioritized research agenda
- Supports knowledge translation
- Facilitates existing and develops new national and international partnerships for both research and data

DSEN Funding

- Centre Funding:
 - ✓ Allocated to research centres to support capacity building and research activities allowing more rapid response to research questions.
- Project Funding:
 - ✓ Allocated more widely to support the conduct of studies addressing research questions which cannot be undertaken by dedicated centres alone (e.g., RCTs).

The Operational Process (1)

- Identify and Prioritize Research
 - ✓ Drug safety and effectiveness questions are identified by stakeholders and submitted via oversight committee to the DSEN Office of the Executive Director
 - Questions are prioritized (by oversight body) to create a rolling priority research agenda
 - Office of the Executive Director determines which studies can be funded and funding mechanism

The Operational Process (2)

- Conduct Research

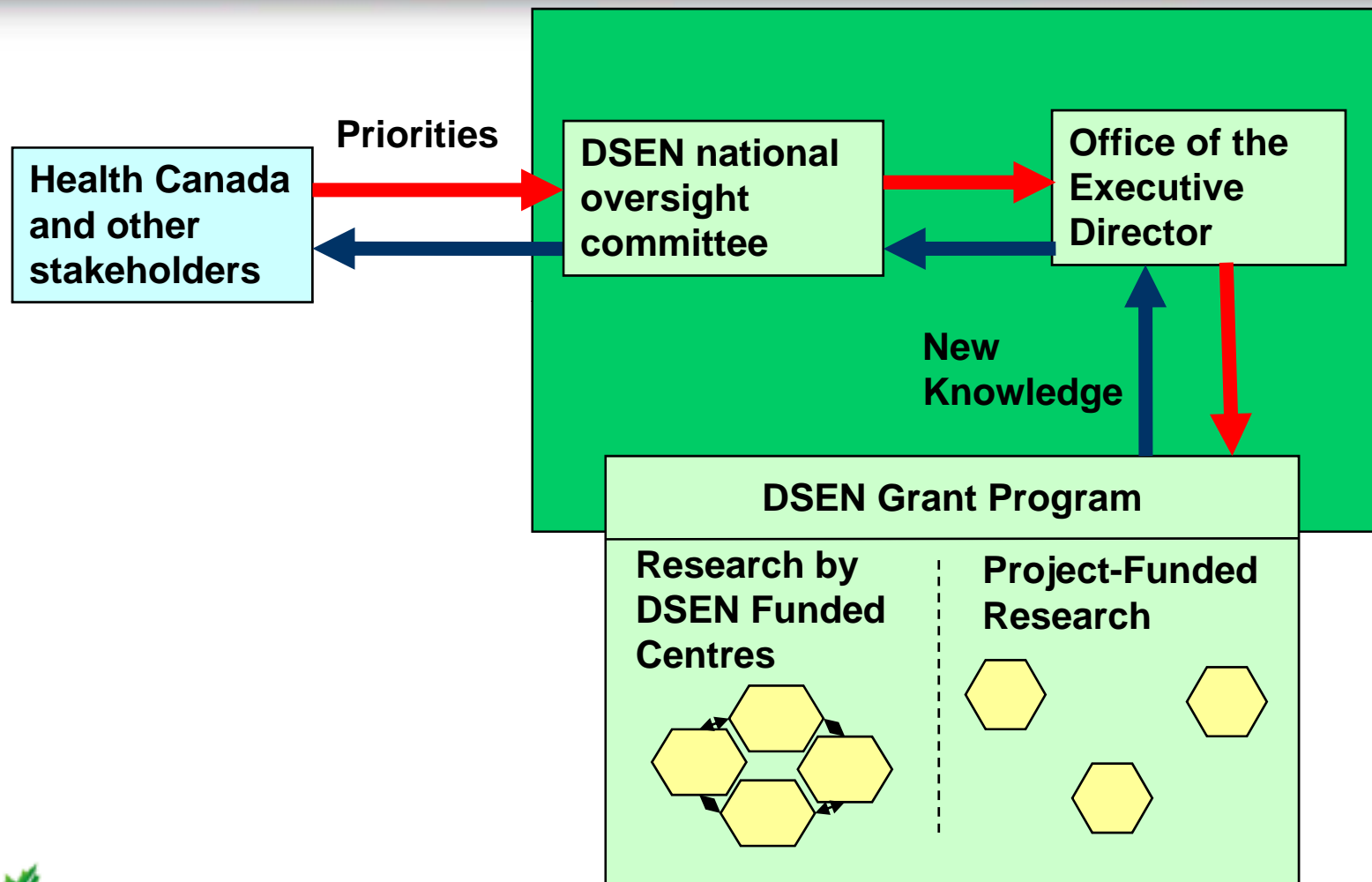
- ✓ DSEN researchers will propose research protocols responding to the prioritized research agenda
 - Research could be conducted by multiple centres, using Canada-wide or jurisdiction specific data
 - Research results will be shared with DSEN partners as the studies are conducted

The Operational Process (3)

- Use Results

- ✓ Decision makers will use new information in combination with existing evidence to make decisions within their responsibility areas

DSEN Program



Goals for the DSEN Program

- Support collaboration and networking among researchers, research organizations and data holders located across Canada
 - ✓ Generate new evidence to address a prioritized agenda of questions on the safety and effectiveness of drugs
 - ✓ Utilize existing and develop new national and international partnerships for both research and data
 - ✓ Maintain and grow research capacity across Canada dedicated to DSEN priorities

- Facilitate Knowledge Transfer between decision makers and researchers
 - ✓ Prioritization of research agenda
 - ✓ Utility of new knowledge generated

Current Status - Development in Parallel

- Planning and implementation are advancing together
 - ✓ Staffing the DSEN central coordinating office
 - ✓ Preparing grant opportunities for DSEN funding
 - ✓ Working with DSEN partners on processes to support:
 - data access
 - scientific advice to ensure priority research agenda contains researchable questions
 - priority setting mechanism
 - ✓ Developing plans for network growth

Priorities for DSEN Today

- Prepare funding opportunity for launch in Summer 2009
- Search for the Executive Director
- Stakeholder engagement for further input to the final DSEN architecture

Contact

Diane Forbes
Associate Director
Drug Safety and Effectiveness
Canadian Institutes of Health Research

diane.forbes@cihr-irsc.gc.ca
phone: 613-941-0796