Canada's
Drug and Health
Technology Agency

Introducing CADTH's New Post-Market Drug Evaluation (PMDE) Program

Dr. Tarry Ahuja, PhD
Director, PMDE

What is Post-Market Drug Evaluation?

What is PMDE?

- Post-market drug evaluation (PMDE) focuses on drugs that have proceeded through the approval process and are broadly available to patients and consumers
- PMDE integrates health data and real-world evidence to inform decisions on drug safety and effectiveness
- Provides evidence to decision-makers as they work to manage formularies

Information Session

Information Session

Scientific Advice | Reimbursement Reviews | Real World Evidence | **Post-Market Drug Evaluation**

Background

- The Drug Safety and Effectiveness Network (DSEN) was established by the Canadian Institutes of Health Research (CIHR) and Health Canada in 2009
- established for federal, provincial, and territorial (FPT) decision-makers to fill gaps in information on the safety and effectiveness of drugs used in real-world settings
- and to increase the capacity of Canada to undertake high-quality post-market drug evaluation

Background

The DSEN Program Was Evaluated in 2019

- highlighted the ongoing importance of post market research in the "current, rapidly evolving drug environment”
- found an increasing need for expedited drug evaluation (ie. NOCc)
- DSEN's strength in building capacity

Background

- intent to transition Drug Safety and Effectiveness Network (DSEN) functions from CIHR to CADTH communicated mid-August 2021
- Health Canada, CIHR and CADTH working collaboratively to ensure a smooth transition
- launch date of new program within CADTH scheduled for **September 2022**

PMDE Program Overview

PMDE Program Overview

Goals

1. Enhance the pan-Canadian, post-marketing query response capability by creating an **efficient and responsive network** of applied researchers, methodologists, and data analysts able to meet the needs of decision-makers.
2. Leverage access to post-market drug information by facilitating **communication, awareness, and linkages** between applied researchers, methodologists, data analysts, stakeholders, and decision-makers.

PMDE Program Overview

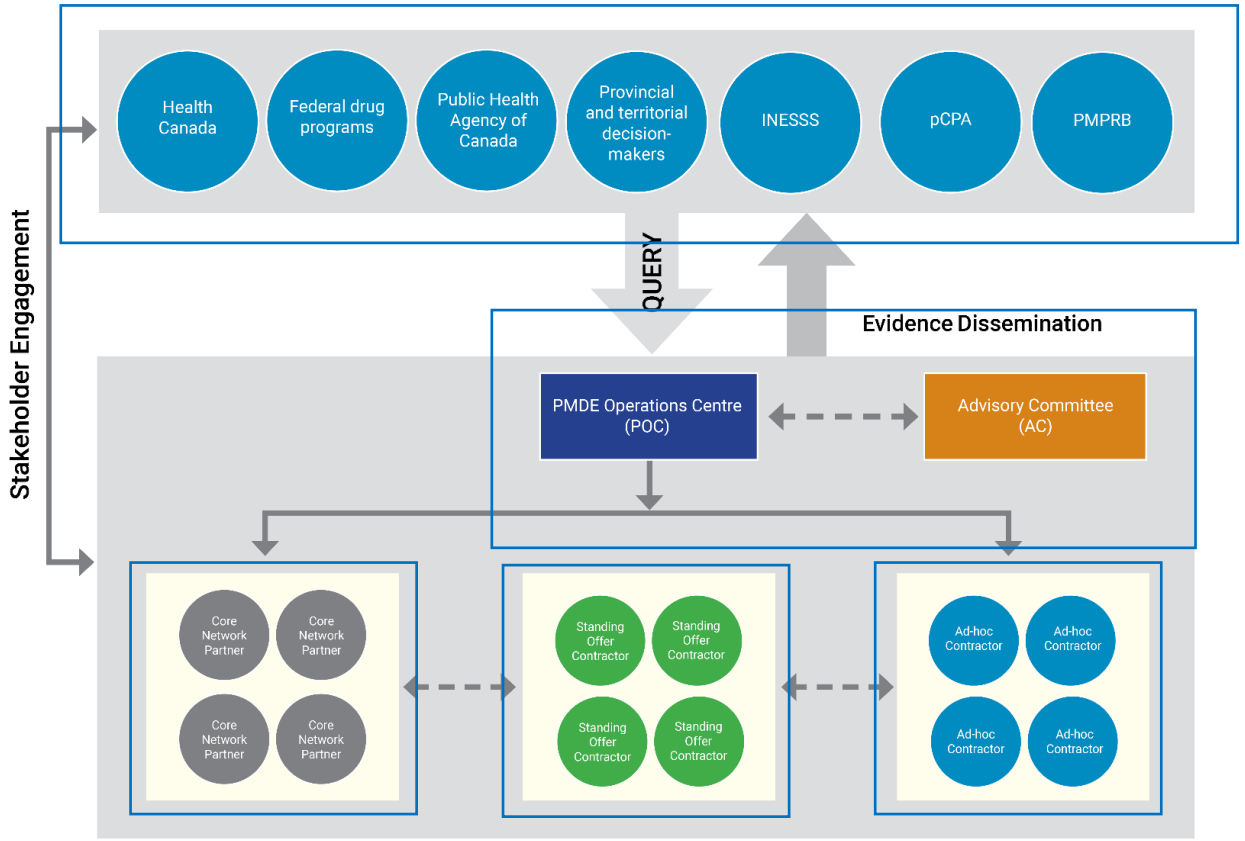
Goals

3. Enable the **uptake and utilization** (knowledge mobilization and implementation) of post-market evidence and information to inform decision-making.
4. Create a culture of continuous **quality improvement**.
5. Foster national and international PMDE **partnerships** to identify and streamline processes for improved post-market evaluation.

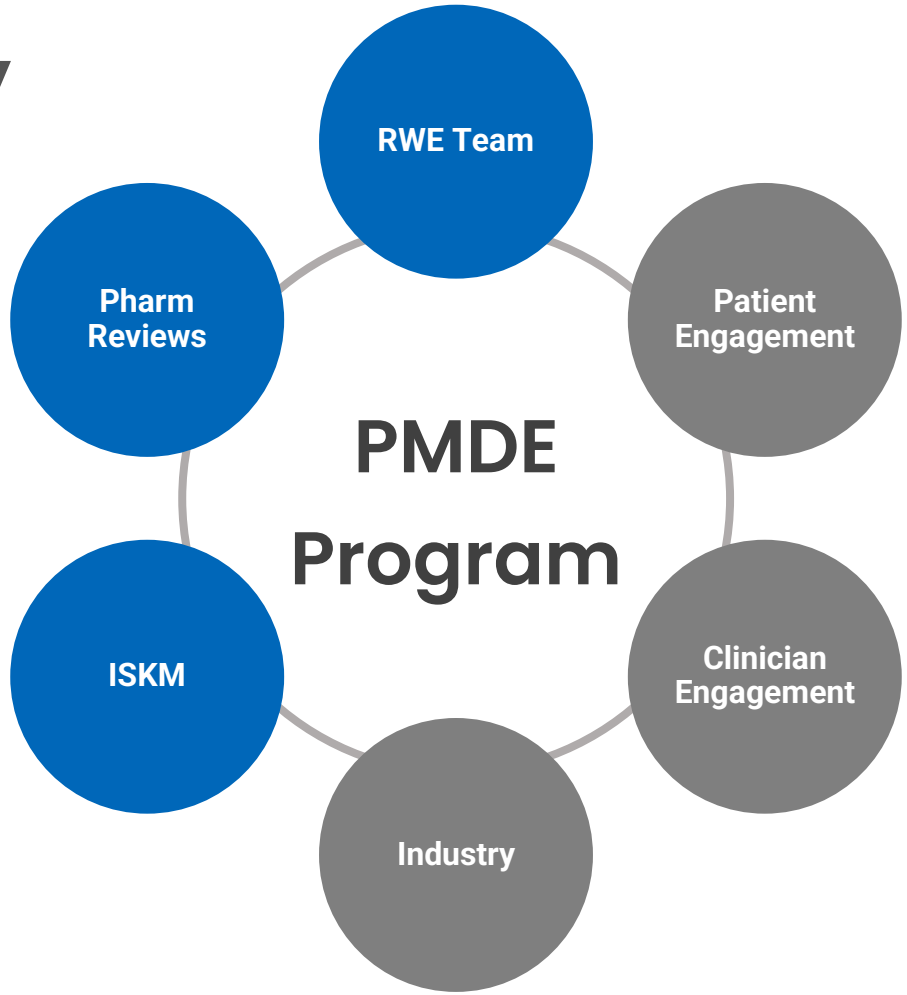
PMDE Program Goals

Work with FPT decision makers and regulator to anticipate future evidentiary needs.

PMDE Program Overview – By Component



PMDE Connectivity



PMDE Advisory Committee

PMDE Advisory Committee

Objective

Multi-disciplinary group that provides credible, strategic PMDE advice and expertise to CADTH on complex queries, strategic initiatives, and key priority areas.

Membership

- FPT decision-makers
- Experts: applied researchers, methodologists, data analysts
- Clinicians, patients, industry

Progress Update: On Track to Launch

PMDE Program Resources

- PMDE Program Overview document is available on CADTH website **www.cadth.ca/post-market-drug-evaluation-pmde-program**
- check the FAQs on the site which are updated regularly
- Request for Proposal (RFP) is available online with guidance docs and forms **www.cadth.ca/request-proposals**
- RFP questions may be directed to **contracts@cadth.ca** and program questions to **InfoPMDE@cadth.ca**
- recording of previous PMDE information session is available online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