Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Post-Market Drug Evaluation

Program Overview

November 2024

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Abbreviations

CDA-AMC	Canada's Drug Agency
CIHR	Canadian Institutes of Health Research
FPT	federal, provincial, and territorial
PMDE	Post-Market Drug Evaluation
RFP	request for proposal

1. Background

In September 2022, Canada's Drug Agency (CDA-AMC) launched the Post-Market Drug Evaluation (PMDE) program alongside the CoLab research network. The CoLab network comprises leading experts in applied research, drug evaluation methodology, and data analysis. Together, the PMDE program and the CoLab network work collaboratively to generate evidence on the safety and effectiveness of drugs used in real-world settings to meet the needs of federal, provincial, and territorial (FPT) decision-makers. As the pharmaceutical landscape continues to evolve rapidly, the PMDE program is building capacity for high-quality post-market research.

This Program Overview will provide an outline of the innovative and dynamic PMDE program and CoLab network.

The PMDE program is built upon the foundational work of the Drug and Safety Effectiveness Network (DSEN), which was funded by the Canadian Institutes of Health Research (CIHR). It leverages CDA-AMC's deep knowledge of the pharmaceutical life cycle and its long-standing relationships with FPT decision-makers.

1.1 Purpose

The PMDE program's purpose is to respond, with credible and timely evidence, to queries about post-market drug safety and effectiveness from senior policy decision-makers situated within the FPT governments.

With the evolving health care needs of Canada's population, an increasingly important goal for our health systems is to have ongoing, appropriate access to safe, effective, and clinically relevant drugs. In addition, the regulatory review system continues to be more agile, clinical development has been accelerated, and the resultant data and evidence provided are progressively more complex. In this changing landscape, products may be marketed with more uncertainty about long-term and real-world effectiveness. This new reality requires an ongoing and systematic approach to ensure the safety and effectiveness of drug products. These demands on current health systems in Canada illustrate the need for a robust, coordinated approach to post-market drug evaluation.

The PMDE program and CoLab network outlined in this overview are responsive and collaborative in their approach to post-market drug evaluation to address some of the many health care needs of Canada's population.

1.2 Goals

The goals of the PMDE program include:

- expanding on CDA-AMC's reputation as a trusted source for credible, objective evidence to include post-market drug evaluation
- fostering Canada's post-market drug evaluation capacity by investing in a dedicated network of experts and adopting a culture of innovation
- coordinating access to post-market drug data and evidence by facilitating collaboration between policy-makers, our network of researchers, data partners, patients, clinical experts, and pharmaceutical manufacturers
- enabling the uptake and utilization of post-market evidence to inform decision-making through knowledge mobilization
- partnering with international post-market drug evaluation bodies and experts to align on common strategic priorities, drive collaborative efforts, and share innovative approaches.

We acknowledge that meeting these goals requires a willingness to learn and adapt. Our commitment to being responsive and innovative ensures the PMDE program remains a trusted and relevant service.

1.3 Principles

The following are the principles upon which the program and the network will operate:

- customer focus (refer to section 2.1 on page 6 for a list of PMDE customers)
- timeliness
- relevance
- quality
- rigour
- collaboration
- innovation.

1.4 Priorities

As drug development continues to evolve and grow in complexity, the need for a more agile, informed, and integrated post-market drug evaluation program has become even greater. The PMDE program has become an integral part of the CDA-AMC suite of programs, delivering evidence across the drug life cycle. The PMDE program is well-informed through various channels (refer to Appendix 1 for more information) about the current health care climate and the evidence and information needs of the system. The PMDE program is designed to respond to rapidly shifting jurisdictional priorities, and ongoing unmet evidentiary needs. The PMDE Operations Centre acts as a coordination hub that constantly collects input from decision-makers and continuously adapts to the priorities of health systems in Canada.

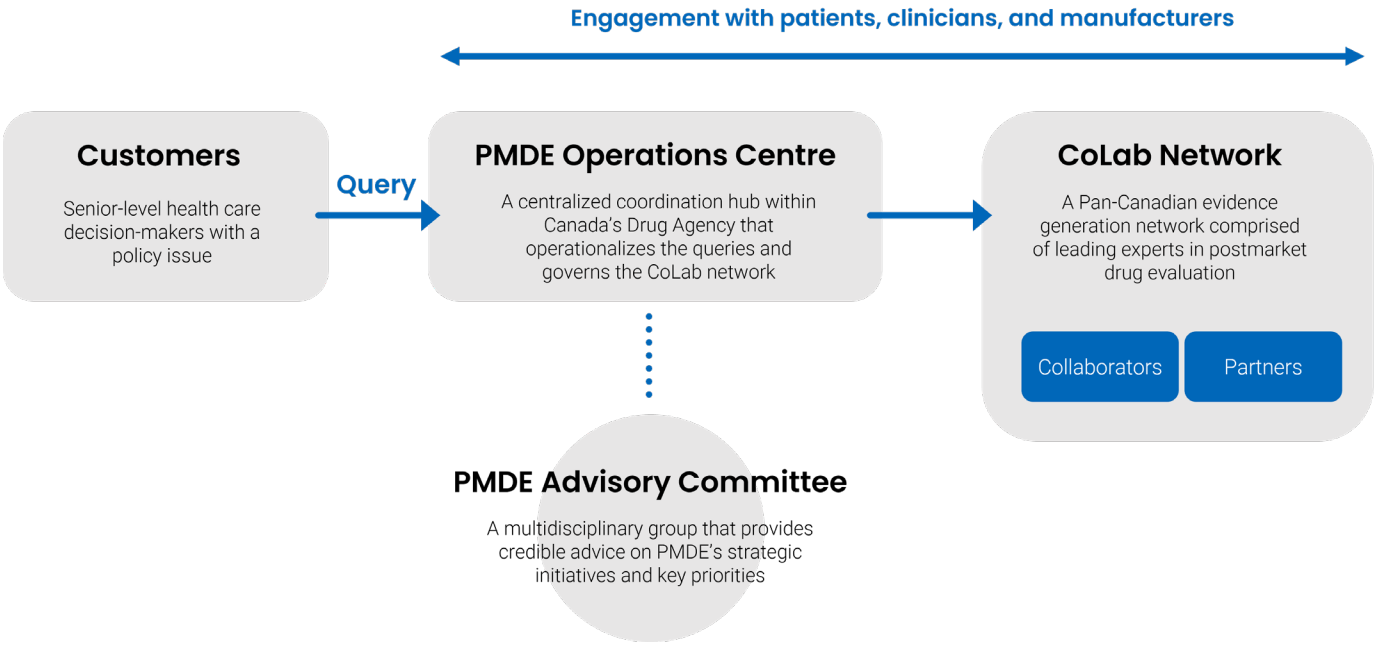
The PMDE program's priorities are informed through ongoing dialogue with a wide range of experts, health partners, and FPT decision-makers. Through these valued exchanges, the following have been identified as areas of importance:

- developing an easy-to-use, responsive, and timely query response process
- conducting targeted rapid analyses and evidence reviews to provide insight on the utilization and uptake of therapies by therapeutic area, indication, jurisdiction, and across the country
- supporting formulary management and harmonization across Canada, including guidance and insight from jurisdictions
- integrating and improving data accessibility to generate evidence to support decision-making
- performing observational studies to generate new evidence based on real-world data to inform decision-making
- improving, sustaining, and targeting knowledge translation and mobilization efforts to better use the evidence produced through the network and to expand its potential impact and benefit
- monitoring and reporting on the pharmaceutical pipeline and changes to the pharmaceutical landscape to better position jurisdictions to proactively address impending health system issues
- performing relevant appraisals of the evolving pharmaceutical landscape, including the emergence of new therapies and methods.

2. PMDE Program Overview

PMDE is a CDA-AMC program that offers query-based services to its customers, who are health care decision-makers situated within the FPT governments and select arm's-length organizations. The program is a core service offered by CDA-AMC and — like all other CDA-AMC activities — reports to the Conference of Deputy Ministers of Health through its Board of Directors.

Figure 1: PMDE Program Structure



PMDE = Post-Market Drug Evaluation

2.1 Customers

PMDE customers submit queries to the PMDE Operations Centre, which then engages its CoLab network of researchers and experts to provide evidence to support customers in their decision-making.

PMDE customers include:

- Health Canada
- federal drug programs
- Public Health Agency of Canada (PHAC)
- provincial and territorial decision-makers
- pan-Canadian Pharmaceutical Alliance (pCPA)
- Institut national d'excellence en santé et en services sociaux (INESSS).

Because of CDA-AMC's existing position in the drug review and approval system, it has knowledge of drug products being submitted for regulatory and health technology assessment. In some instances, we can anticipate evidence needs of FPT decision-makers, consult with them, and submit queries to the PMDE program on their behalf.

CDA-AMC regularly evaluates the PMDE program and may consider adding new customers who would also be eligible to submit queries to the program.

2.2 PMDE Operations Centre

The PMDE Operations Centre is a dedicated team at CDA-AMC. The responsibilities of the Operations Centre include:

- query intake and initial refinement with the customer
- further topic refinement, preliminary feasibility assessment, and additional information collection with the customer, followed by preparation of a topic brief in consultation with content experts and interested groups as needed
- identification and selection of the best-suited query response team and coordination of collaboration with partners and collaborators within the CoLab network
- oversight of the query response process and adjustments as required
- timely dissemination of query reports and all findings to submitters and other FPT decision-makers
- facilitation of connections to in-house expertise, such as the Engagement, Real-World Evidence, Scientific Advice, and Pharmaceutical Review teams, in addition to data partners and international counterparts
- knowledge mobilization
- monitoring and collection of metrics on the impact of the query work and feedback on the PMDE process.

The PMDE Operations Centre does not generate evidence itself to support queries, nor does it collect or hold data. It acts as a hub, connecting people and processes, and works collaboratively to maximize the efficiency of the CoLab network, including working with partners and impacted groups to identify and access relevant evidence.

2.2.1 PMDE Operations Team

The PMDE operations team is led by the director. Together, this team is responsible for the design and implementation of the program, managing the scope and refinement of incoming queries, providing oversight of the CoLab network, and reporting on performance and outputs. The team members are an important point of connection with many of the programs at CDA-AMC as well as the relationships with partners and impacted groups.

2.2.2 PMDE Advisory Committee

The PMDE Advisory Committee is a multidisciplinary group that provides credible, strategic post-market drug evaluation advice and expertise on strategic initiatives and key priority areas.

The membership of the Advisory Committee includes an independent chair, FPT decision-makers, academics, patients and/or caregivers, clinicians, industry representatives, CoLab representatives, and PMDE Operations Centre staff. Its size and composition reflect the program's commitment to be operationally responsive to changes in the pharmaceutical environment and position CDA-AMC to enable future-ready health care by responding to the evidence needs of decision-makers.

For more information on the Advisory Committee, refer to the PMDE Advisory Committee web page.

2.3 CoLab Network

The CoLab network consists of partners and collaborators. The current network was identified and selected through a request for proposal (RFP) to create a robust and complementary group of teams and experts who bring diverse methodological expertise, data management capabilities, and both a willingness and capacity to work within the parameters of the PMDE program. All CoLab teams were selected through a competitive process that included review of proposals by an ad hoc review panel. More information on eligibility and the process for submitting proposals to be a part of the CoLab network is available during active RFPs.

Applicants to the PMDE program may apply as either a partner or collaborator.

The methodological and content expertise required of the CoLab network may evolve over time. The PMDE Operations Centre continually monitors relevant therapeutic trends and innovative methods and seeks out experts in those fields.

Applied research teams are multidisciplinary, with resources and capacity to conduct rapid analyses and reviews across multiple data sources. Common query methodologies include environmental and horizon scanning, scoping reviews, rapid reviews, systematic reviews, health technology assessments, observational studies, utilization studies, and health economic studies.

The PMDE program is focused on both safety and effectiveness; therefore, capacity and expertise in both areas are required. Specifically, with respect to effectiveness, teams may be asked to evaluate and validate clinical end points and to assess and report on broader effectiveness topics. For example, if use of a drug is intended to reduce broader health care utilization and/or hospitalizations, teams may be asked to validate whether these system savings and patient experience improvements can be demonstrated in real-world settings. Additionally, drug utilization data could be used to identify patterns of use in specific populations, allowing payers to assess whether therapies are being prescribed appropriately according to guidelines and if outcomes align with expected benefits. This insight could inform policy decisions and optimize resource allocation within the health system.

No single team will have methodological expertise in all areas but, collectively, the network has broad skills and capabilities so both safety and effectiveness queries can be answered in a timely, robust, and scientifically rigorous manner.

2.3.1 Partners

Partners are teams of applied researchers, methodologists, and/or data analysts who are an established existing or a newly created team. Partners are awarded a 3-year grant with the potential for renewal. Granted partners make up the foundational component of the CoLab network. These teams work either individually or collaboratively with other CoLab teams to use the most appropriate methods and provide evidence to decision-makers. Appropriate teams are identified by the PMDE Operations Centre to respond to each query; at times, the Operations Centre staff may bring several CoLab teams together to discuss potential collaboration on a specific query. Partners are responsible for ensuring their teams have the capacity and the appropriate methodological expertise to respond to incoming queries throughout the granting period. The number of queries each partner responds to may vary from year to year; however, each grant agreement identifies the minimum requirements and the maximum number of queries.

2.3.2 Collaborators

Collaborators have specific technical, methodological, or related expertise and are awarded 1- or 2-year contracts with the potential for renewal. Collaborators are a part of the CoLab network, and they are kept appraised of incoming queries within their area of expertise by the PMDE Operations Centre. Collaborators embarking on query work will draw down from a retainer issued at the beginning of their contract. Once all these funds are used, additional funding will be available if the collaborator does query work beyond the value of the retainer.

2.3.3 Ad Hoc Contactors

If queries require niche expertise beyond the CoLab network's scope, the Operations Centre identifies and engages ad hoc contractors to meet the need.

2.4 Partnerships and Collaboration

With support from the PMDE Operations Centre, the network partners and collaborators are encouraged to leverage existing pan-Canadian and international relationships.

2.4.1 Data Partners

The program works with the CoLab network to identify data needs for queries and collaborate with groups that facilitate data access and those that hold data (e.g., Canadian Institute for Health Information [CIHI], research groups).

Data partners include:

- CIHI
- IQVIA
- provincially funded research groups
- international groups (e.g., MarketScan, Clinical Practice Research Datalink [CPRD]).

2.4.2 Strategic Partnerships

When possible, we collaborate with strategic partners for more coordinated generation and dissemination of post-market drug evidence and additional expertise to inform decision-making.

Strategic partnerships include:

- INESSS
- CIHR.

CoLab network partners and collaborators should also strive to engage with CIHR's Health Research Training Grant Program and its grantees to continue building capacity in post-market drug evaluation and developing early career researchers and analysts.

2.4.3 International Partnerships and Collaborations

To encourage sharing of methods, expertise, data, and strategic priorities, the PMDE program will look to form and leverage international partnerships.

International partners may include:

- European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) in France
- FDA's Sentinel Initiative in the US
- Data Analysis and Real World Interrogation Network (DARWIN EU) in the EU
- Observational Health Data Sciences and Informatics (OHDSI) in the US.

International partners are not eligible to receive funding from the PMDE program, and any collaborative activities will follow the terms and conditions outlined by Health Canada and CDA-AMC.

2.5 Engagement

We aim to foster trust, confidence, and connections in our work to help bring knowledge users closer to the research. Engagement helps ensure the research is more relevant and useful to the end user and increases the impact of PMDE's work.

2.5.1 Patient and Caregiver Engagement

We are dedicated to including patient-lived experience in our work. Patients might be involved in identifying patient-oriented research questions, outcomes of relevance, interpretation of findings, and reviewing reports. Query work may also incorporate existing evidence regarding the patient experience or consider patient priorities as identified by patient-facing organizations. For additional insights into our approach to patient engagement, please refer to the patient engagement framework. We also recommend integrating relevant guidance from other organizations — particularly CIHR's Strategy for Patient-Oriented Research.

The PMDE Operations Centre and the CDA-AMC engagement team are available to the CoLab network to support and facilitate patient engagement throughout the query process. The engagement plan will vary for each query depending on the needs, confidentiality, and timeliness of the query. Query engagement plans may be adapted for urgent requests to maintain flexibility and meet customer timelines.

The PMDE Advisory Committee membership includes patient and/or caregiver members who bring the patient perspective to the program. Patient involvement on the PMDE Advisory Committee supports public accountability and transparency. Patient members can champion patient-friendly research and grow PMDE program connections with patient communities.

2.5.2 Clinician Engagement

The PMDE Operations Centre and engagement team are available to the CoLab network to support and facilitate clinician engagement throughout the query process. CoLab members can also engage with clinicians directly to carry out query work.

The PMDE Advisory Committee membership also includes clinician members who bring the clinician perspective to the program. Clinician involvement on the PMDE Advisory Committee ensures clinical relevance of the selected queries and their outcomes. Clinician members can also assist the PMDE Operations Centre in identifying clinical experts for given queries.

2.5.3 Pharmaceutical Manufacturer Engagement

The PMDE Operations Centre facilitates engagement with pharmaceutical manufacturers throughout the query process, as appropriate, ensuring transparency and fair opportunity to provide feedback. Manufacturers are often a valuable source of real-world data and can assist PMDE in identifying additional evidence sources.

The PMDE Advisory Committee membership also includes industry members who bring the manufacturer perspective to the program. Pharmaceutical manufacturer involvement on the PMDE Advisory Committee ensures a balanced and transparent approach to the query response process. Industry members can also assist the PMDE Operations Centre in identifying relevant evidence or potential data sources for queries.

3. Queries

3.1 Prioritization

The Operations Centre prioritizes incoming queries by validating topics through FPT decision-makers using its various committees (refer to Appendix 1). Queries may be reprioritized to accommodate the evolving needs of our customers. Reprioritization is considered when the volume of queries is beyond the capacity of the CoLab network at any given time.

FPTs benefit from both reactive and proactive queries; the former are usually linked to urgent policy issues, and the latter to improving formulary management. Decision-makers, either individually or collectively, may benefit from a more rapid analysis to support reimbursement conditions and/or decisions, and may also look to longer-term queries as a potential source of evidence to support their decisions.

We use prioritization to effectively manage incoming queries and oversee the capacity of the CoLab network. Our aim is to balance the volume of rapid requests and larger systemic requests to ensure that the most relevant topics can be addressed.

We also strive for a balance between queries that are primarily focused on safety and those that are focused on effectiveness. Ultimately, the balance is dictated by the needs of decision-makers and may be adjusted in response to prioritized needs as they arise, particularly for safety issues that require timely action.

3.2 Process

The query process is summarized by the following steps (as displayed in Figure 2):

1. **Query submission or identification** — A decision-maker submits a query to the PMDE Operations Centre. Queries may also come through ongoing dialogue within CDA-AMC committees (PMDE customers are listed in section 2.1 on page 6)

   The PMDE Operations Centre acknowledges and confirms receipt of queries within 2 working days.

2. **Scoping and refinement** — The PMDE Operations Centre schedules an initial refinement call with the customer to seek clarification and gather any additional information. A topic brief is created and shared with the customer.

   The PMDE Operations Centre notifies the CoLab network of all incoming queries. Teams can express their interest based on previous work in the area, specific expertise, or data holdings.

   Deliverable 1: Topic brief

3. **Query response team engagement and feasibility assessment** — The Operations Centre identifies the best-suited query response team for the submitted query. The Operations Centre and the query response team meet in advance to discuss the query, assess feasibility, and determine next steps.

   The query response team may be made up of any combination of teams within the CoLab network. All deliverables and specific accountabilities are established at the preliminary meeting of the query response team.

   The query response team alongside the Operations Centre conducts a feasibility assessment, when needed. This assessment is done in advance of project kickoff to identify any potential data gaps or data access issues and discuss project timelines.

   When a query is deemed feasible, a query kickoff meeting is held with the customer, query response team, and members of the PMDE Operations Centre. Clinical experts may be invited to provide expertise on the therapeutic area. Once a query is initiated, it is added to the CoLab query dashboard.

4. **Delivery of draft protocols and plans** — The query response team drafts the protocol and statistical analysis plan to be reviewed by the PMDE Operations Centre and patients, clinicians, and manufacturers, when appropriate.

   Deliverable 2: Query protocol

   Deliverable 3: Statistical analysis plan

5. **Evidence generation and analysis** — The query response team generates evidence and analyzes existing evidence to support the decision-making process. The Operations Centre and the query response team meet regularly to discuss progress and any potential delays or challenges. We provide regular updates to query submitters throughout this step, including sharing of preliminary findings.

6. **Interpretation of evidence and findings** — The query response team interprets the results and writes a study report, which is submitted to the PMDE Operations Centre using PMDE product templates. The PMDE Operations Centre, customers, and other impacted groups review this report and submit feedback. Customers may request a presentation of the findings from the response team.

   The PMDE Operations Centre coordinates copy-editing, ensuring consistency in all PMDE reports and findings, and is responsible for publishing the final study reports on the CDA-AMC website.

   Deliverable 4: Scientific report

7. **Knowledge dissemination** — At the request of the customer, the PMDE Operations Centre and the query response team will create knowledge translation materials.

   Deliverable 5: Knowledge mobilization tools

8. **Follow up for impact** — The PMDE Operations Centre follows up with the customer to determine how the study report informed policy change or decision-making.

3.3 Data Management

The PMDE program is dedicated to building a collaborative network that focuses on ensuring decision-makers have access to appropriate information to make timely evidence-informed decisions.

CDA-AMC does not hold data but acknowledges that data access is a critical success factor to meet the PMDE program objectives. Therefore, the PMDE Operation Centre supports and facilitates the data access needs of the CoLab network by leveraging relationships with data partners.

Storage and management of external data (from a third party) is the responsibility of the network partners and collaborators. They must clearly describe their data management plans when responding to the RFP that also uphold any privacy requirements to which they must adhere.

Although we are not a data holder, and we do not envision becoming a data holder, we will continue to stay informed about data management and support the alignment work being undertaken toward a pan-Canadian health data strategy.

Figure 2: Post-Market Drug Evaluation Query Process

3.4 Further Dissemination of Findings

The PMDE program is focused on the needs of the decision-maker, and we prioritize query reports and disseminate query findings to decision-makers as quickly as possible. Reports are submitted by the agreed-upon deadline and are written with customer needs at the forefront. The Operations Centre provides query response teams with templates for query protocols, statistical analysis plans, and reports to present their findings. Although our intent is to always make both the query and query response publicly available, there may be a delay between sharing the information with decision-makers and making it publicly available. Intention to publish in an academic journal is not a sufficient justification to delay the public release of findings from a PMDE query.

When appropriate, the PMDE team leverages other CDA-AMC programs to offer products and services to support the needs of its customers (refer to Appendix 1).

Once customers have received a query report, a query response team that wants to publish or present their findings through academic channels may do so and may be supported in part by funding received by the PMDE program. Funding for these types of publications is established with the PMDE Operations Centre. Priority and emphasis are placed on publicly facing query reports; however, peer-reviewed publications and the sharing of knowledge at scientific conferences and other venues is also supported if appropriate. These publications need to follow the *PMDE Publication Policy*.

CoLab researchers may wish to publish in the CDA-AMC journal, the *Canadian Journal of Health Technologies*, to expedite dissemination and for a more integrated approach with CDA-AMC.

4. Funding Model

To ensure a solid network foundation that is both responsive and dynamic, funding for CoLab is allocated as follows:

- 80% to its partners through grants
- 10% to 15% to its collaborators and other contractors through contracts
- 5% to 10% for data access.

This allocation is based on the findings of an independent evaluation, which determined that contracts would allow the PMDE program to be more agile in accessing expertise outside of the partners, as needed, while also maintaining stability with partners. This model also allows for data access costs based on queries. This funding distribution is suggested and may be adjusted based on a future evaluation of the funding model, contingent on the number of proposals received during the RFP process.

All funds will be issued through CDA-AMC. For more information, please refer to the PMDE RFP documents.

4.1 Partner Funding

A significant portion (80%) of CoLab funds is distributed through multiyear grants to partners. This funding model ensures that partners can maintain a consistent team of analysts, methodologists, and applied researchers, which ensures their availability and readiness for ongoing and future work.

The process by which grants are awarded and grantees are selected will be made publicly available when PMDE issues an RFP.

4.2 Collaborator Funding

A portion (10% to 15%) of PMDE funds is distributed through contracts to its collaborators and contractors. PMDE offers 2 types of contracts: standing offer contracts to its collaborators and query-specific contracts to ad hoc contractors.

The process by which standing offer contracts are awarded and the collaborators are selected will be made publicly available when PMDE issues an RFP.

5. Network Management

5.1 Network Communication

The PMDE Operations Centre will keep the CoLab network informed of incoming and ongoing queries, new methodological needs, other initiatives in the pharmaceutical environment that may affect work, as well as new or evolving priorities. The PMDE team will facilitate a collaborative environment to catalyze and foster network collaboration and support innovation through the network. The PMDE Operations Centre will work to accomplish this through query alerts, a monthly newsletter, bimonthly network meetings, and ad hoc communications.

5.2 Knowledge Mobilization

The PMDE Operations Centre will lead with knowledge mobilization principles to communicate and disseminate query findings to customers and other health care decision-makers and impacted groups (patients, clinicians, pharmaceutical manufacturers). The network partners and collaborators will also use and lead with the knowledge mobilization expertise that they bring. The functionality of this knowledge mobilization approach will result in a more comprehensive and strategic dissemination of evidence generated through queries when needed and appropriate.

Knowledge mobilization strategies can be customized to specific queries based on audience identification, context assessment, and input from decision-makers (knowledge users). Knowledge mobilization tools can include plain language summaries, presentations, infographics, publications, and other custom products.

5.3 Reporting and Performance Measurement

The PMDE program is an integral part of overall work at CDA-AMC; as such, we ultimately report to the President and CEO of CDA-AMC. As with other areas of work at CDA-AMC, PMDE progress and performance measurement reports will be shared with the CDA-AMC Board of Directors and its funders, as appropriate. The program will be monitored on an ongoing basis, and the progress of the program will be included in the current CDA-AMC reporting system.

To ensure program performance, performance data from each query will be collected to demonstrate the impact of the overall program and to inform future iterations of the program.

The Operations Centre will, at minimum, collect the following quantitative data from its network:

- number of queries completed on time (as established at the time of scoping and refinement) as well as any variance between expected and actual completion timelines
- number of partnerships (names and affiliations of all collaborators to be provided)
- percentage of queries with patient input
- cost of accessing data external to the network
- number of queries submitted per fiscal year by customer type
- number of customers referencing a query for decision-making or policy change.

The following qualitative data will be collected through surveys, interviews, and other feedback:

- overall satisfaction of the customer (Did the output meet the customer's needs? Were the findings shared in time? Were the findings decision-grade and relevant to the needs of the decision-maker?)
- reports contributing to a policy change or decision-making (Was the report helpful?)
- feedback and qualitative data on using the PMDE program and network (Was it easy to use?)

- feedback and suggestions from the research teams
- success and impact stories.

CoLab partners and collaborators will be provided with regular feedback.

The program will undergo independent program evaluations at the end of the 3-year funding cycle and at regular intervals thereafter.

5.4 Equity, Diversity, and Inclusivity

CoLab partners and collaborators are expected to adhere to their institution's equity, diversity, and inclusion principles (or, if none exist, principles from an equivalent Canadian organization) for all aspects of their work — from hiring to designing query response protocols and reporting results.

5.4.1 Sex- and Gender-Based Analysis Plus

CDA-AMC is committed to undertaking Sex- and Gender-Based Analysis Plus (SGBA+) as part of its PMDE program.

Diversity in premarket research and clinical trials is a well-documented concern. Given the unequal representation of specific populations in research, there may be a considerable gap in the full understanding of the safety and effectiveness of new pharmaceutical products in the real world following market authorization.

Network partners and collaborators will be responsible for collecting and analyzing relevant information to contribute to the overall SGBA+ analysis of the network. Note that the CoLab network is required to adhere to any Indigenous Data Sovereignty protocols regarding data related to First Nations, Inuit, and Métis Peoples.

5.5 Transparency and Confidentiality

The PMDE program strives to be transparent and accessible to all its customers and impacted groups. Some data and evidence may be confidential in nature for a period of time; however, the intent is to ensure that all query outputs and reports are made publicly available as soon as possible. If a customer requests the response be kept confidential, it will be decided at the initiation phase and be conveyed to the responding team in advance of any work.

5.6 Conflicts of Interest

CDA-AMC is a trusted and credible source of evidence and strives to maintain this standard in all its work, including the PMDE program. Network partners and collaborators and impacted groups who contribute to query work are therefore expected to comply fully with our Conflict of Interest Guidelines.

Appendix 1: PMDE Channels to Decision-Makers

- Pharmaceutical Advisory Committee (PAC)
  - Provide strategic direction and identify system-level queries.
- Provincial Advisory Group (PAG), Formulary Working Group (FWG), and FWG–Health Technology Assessment (HTA)
  - Identify pharmaceuticals and therapeutic areas that would benefit from post-market drug evaluation.
  - Provide committee members with evidence generated from CoLab to allow for potential reimbursement change.
- Expert review committees — Canadian Drug Expert Committee (CDEC) and pan-Canadian Oncology Drug Review (pERC)
  - Identify actively reviewed pharmaceuticals that may benefit from proactive pharmaceutical queries.
  - Potentially trigger future evidence generation as it relates to conditional recommendations.
- Health Canada (Health Products and Food Branch [HPFB] and Marketed Health Products Directorate [MHPD])
  - Identify actively reviewed pharmaceuticals that may benefit from proactive pharmaceutical queries.
  - Potentially generate evidence as it relates to Notice of Compliance with conditions (NOC/c).
- Board of Directors
  - Input on system-level needs and evaluation of evolving PMDE program strategy.
- Engagement of patients, clinicians, and industry
  - Provide an opportunity to include patient voice in queries.
  - Identify relevant methodological trends and prioritized therapeutic areas within the clinical community and disseminate evidence generated through CoLab.
  - Inform and engage pharmaceutical manufacturers of current queries and explore potential for data sharing.