

CADTH Post-Market Drug Evaluation Proposal
Core Network Partner
Competition: Proposal Guide



1. Background

The Post-Market Drug Evaluation (PMDE) Program is a new CADTH program that will leverage a network of applied researcher, data analysts, and methodologists to respond to federal, provincial, and territorial queries to assist in drug policy decision-making.

Core Network Partners are teams of applied researchers, methodologists, and/or data analysts who are an established or newly created team. Core Network Partners are awarded 3-year grants and will make up the foundational components of the PMDE network.

2. Guidelines for the Proposal

This guide is to be used by Core Network Partner applicants who have previously signalled their intention to submit a proposal through a Letter of Intent and should be used in conjunction with the Request for Proposals document, both available on the CADTH RFP webpage.

The proposal provides CADTH with detailed information on the team's suitability for the PMDE network, relevance of their work, methods and data access, quality and rigour of the work, and ability to work in accordance with the PMDE Program's process to deliver timely and relevant outputs to the program's customers. Core Network Partners will be critical in the success of the network and in achieving its goals. Through the proposal, applicants will be asked to describe various aspects of their ability to respond to queries from federal, provincial, and territorial decision-makers.

The proposal should be submitted on behalf of the proposed team by the team lead or principal investigator (the applicant).

2.1 Technical Proposal (Template, 12 Pages Maximum)

The PMDE Technical Proposal Form in Microsoft Word is provided on the <u>CADTH RFP webpage</u>. When filling out this form, applicants must adhere to the following format:

- Page size: letter size (21.59 cm x 27.94 cm)
- Margins: standard (1.45 cm on both sides; 2.54 cm on the top and bottom)
- Font: Arial, 11 pts (no condensed type)
- Numbering included in the bottom right corner of every page
- Graphs, tables, and illustrations may be included, but will count as part of the set page limits
- Any pages exceeding the page limits indicated will be removed
- Format must be a searchable PDF (prints, photocopies, scans, and faxes will NOT be accepted)

The following outlines the proposal sections that must be included, as well as the information to be provided in each section:

SECTION 1: Team Information

- Applicant and co-applicants' names, as indicated in the Letter of Intent
- · Host institution
- Team title and acronym (if applicable)

SECTION 2: Executive Summary

 A high-level summary of the Core Network Partner's ability to conduct work as part of the PMDE network, including a vision, goals, and objectives



SECTION 3: Overview of the Team

- A description of the individuals making up the team, including:
 - o the expertise they will provide to the PMDE work and the stage of their career; for example, student (undergraduate, master's, PhD), post-doctorate (including years of experience as a post-doctorate), research assistant
 - o their affiliation(s)
 - o the hours allocated weekly and the length of their current contract (if applicable)
 - o any links with relevant collaborators or partners
- The management and governance structure of the team (diagrams or images may be included)
- An explanation of intended project management practices, coordination of incoming queries, monitoring progress, and allocation of resources
- A demonstration of the efforts made to foster equity, diversity, and inclusivity (EDI) among the team.

SECTION 4: Work Plans

- A clear team focus that aligns with the goals of the PMDE Program (i.e., customer focus, timeliness, rigour)
- The nature and scope of the work being proposed and an explanation of how the focus of the work addresses a gap in the system
- A description of awareness of how outputs could inform regulatory and/or health technology assessment and reimbursement processes
- The strengths of the team as whole (this is separate from the individual expertise of the team described in Section 3)
- The minimum and maximum number of queries the team is willing to accept per year and any relevant possible factors that might influence the provided numbers
- When possible, a description of new, innovative, and/or emerging methodologies or trends in PMDE that may be beyond traditional approaches but may be of value in addressing some of the challenges in the PMDE space
- A description of demonstrated world-class capacity to address challenges in PMDE
- A description of knowledge of EDI and how an EDI lens will be applied to the work being carried out for the PMDE Program
- Clear plans to develop highly qualified personnel and how the team and the PMDE work will add value to existing traditional training opportunities

SECTION 5: Demonstrated Success

- Examples of relevant and successful PMDE work completed in the past 5 years
 - o Cohesive plans that are appropriate to the scope and type of work being proposed
 - o Work that leads to meaningful results for decision-makers
 - Work of international calibre
 - o Work that shows innovation in addressing safety and effectiveness needs now and into the future
- · A discussion of potential barriers and appropriate risk mitigation strategies

SECTION 6: Performance Measurement and Reporting

The applicant must include a plan to provide timely, quarterly performance metrics and data to the PMDE Operations Centre. Performance metrics should include the:

- number of partnerships for each query (including the names and affiliations of all collaborators external to the team)
- number of queries with patient input and name of patient organizations involved
- · cost of each query
- · cost of accessing data external to the network
- number of publications, presentations, and other disseminations.

In addition to providing the previously mentioned data, Core Network Partners must demonstrate dedicated time and resources to writing mid-annual and full annual reports to CADTH.



SECTION 7: Partner Funds or In-Kind Contributions

The PMDE Program recognizes both cash and in-kind support. Cash contributions provide the Core Network Partners with the flexibility to increase their research allocations, and generally expand the scope of the work. In-kind contributions also provide invaluable support and access to data or resources, equipment, salaries, and software are all examples of in-kind support recognized by the PMDE Program.

Both cash and in-kind contributions to the Core Network Partner are expected to evolve over the lifetime of the grant; however, the applicant must list any current partner funding or in-kind contributions.

Applicants must provide the:

• name of the partner organization or agency.

For cash contributions:

the dollar amounts.

For in-kind contributions:

- the type of contribution (e.g., salary, equipment, software, data source)
- the stipulations of the contributions (e.g., period of contract, terms of use)
- for data sources, applicants are asked to provide details on the type of data, geographical reach (provincial, national, international), estimated range of data points, date range of the data source, and level of accessibility of the data source (i.e., Who else can access this data?).

2.2 Financial Proposal (Excel Form)

The PMDE Core Network Partner Financial Proposal Form is also provided on the <u>CADTH RFP webpage</u>. The applicant's financial proposal will also be **submitted as a Microsoft Excel form**. Prints, photocopies, scans, and faxes will NOT be accepted.

SECTION 8: Budget

The proposed budget should demonstrate:

- feasibility, in that the proposed budget is within the available funds and the number of queries proposed per year is reflective of the proposed budget
- that the project team has access to appropriate facilities and resources to ensure project success (i.e., a host institution)
- that deliverables and milestones are attainable within the specified timeline given to the proposed team
- that project management is built in to ensure monitoring of progress against goals and objectives.

For additional information on eligible and ineligible expenses, refer to PMDE RFP - Appendix B.

Applicants may also include a budget justification as an attachment that provides detail and rationale for the items listed in the Financial Proposal Form (limit of 2 pages).

2.3 Attachments

In addition to the information provided in the proposal form, applicants must provide the following as attachments:

- a letter from the host institution (2-page maximum, free form) indicating agreement with the content of the proposal, willingness to provide the resources indicated in the proposal, and willingness to negotiate quickly given the timeline for the PMDE Program launch on September 1, 2022
- 2 to 3 reference letters (2-page maximum, free form) pertaining to similar work described within the proposal and having taken place in the last 5 years (references may include peers, customers, end-users, and so forth, but *References from current CADTH employees will not be accepted*); all listed references must be available for a reference check between April 11 and April 25, 2022
- a budget justification (2-page maximum, free form) providing detail and rationale for the items listed in the financial proposal.



3. Submitting Your Proposal

3.1 Submission

Applicants must submit their technical and financial proposals via email to contracts@cadth.ca.

3.2 Deadline

The deadline for electronic submission of the proposal to CADTH is March 31, 2022, at 2:00 p.m. EDT.

4. CADTH Support

4.1 Information Webinar

CADTH will be hosting an information session on February 8, 2022, from 1:15 p.m. to 2:00 p.m. EST. To register, please visit the CADTH website.

4.2 Bulletins

CADTH will be posting bulletins on the RFP webpage. Applicants are encouraged to check regularly for updates and responses to pertinent questions.

Please note: Bulletins may contain questions and answers, provide additional clarity to the content, revisions to the schedule, or other pertinent information.

4.3 Contact

For any additional information, please contact contracts@cadth.ca.