

CADTH Post-Market Drug Evaluation

Request for Proposal – Grant Award

Competition File C-220350

February 1st, 2022

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Issued: **February 1, 2022**

File #: **C-220350 Post-Market Drug Evaluation Grant Award Competition**

Proposal Due Date: **2:00 p.m. EDT on March 31, 2022**

Enquiries by Email: contracts@cadth.ca

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Table 1: Request for Proposal (RFP) Schedule and Timelines

Item	Description	Date	Document location
1	RFP Release	February 1, 2022	Page 3
2	RFP Information Session	February 8, 2022	Section 2.7
2	CADTH to Provide Proposal Templates	February 7, 2022	Section 2.3
3	Advise CADTH of your intent to submit a proposal; send Letter of Intent to contracts@cadth.ca	February 22, 2022	Section 2.1
4	Enquiry Submission Deadline	2:00 p.m. EST on March 8, 2022	Section 2.6
5	Responses to Enquiries	Within 2 business days	Section 2.6
6	Deadline for CADTH to Issue Bulletins*	March 10, 2022	Section 2.6
7	Proposal Submission Due Date	2:00 p.m. EDT on March 31, 2022	Section 2.1
8	Notification of Outcome of Proposal	April 22, 2022	Section 3.2
9	Work Commencement	September 1, 2022	Section 4.4
10	Work Completion	August 31, 2025	Section 4.4

Applicants are advised to check the [Request for Proposal webpage](#) daily for update Bulletins.

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

1 Background

1.1 CADTH Overview

Canada's federal, provincial, and territorial (FPT) health care decision-makers (individuals responsible for implementing or supporting decisions about any part of the public drug programs) rely on CADTH to provide them with credible, impartial advice and evidence-based information about the safety and effectiveness of drugs and other health technologies. Our scope includes health technology assessment, the clinical and cost-effectiveness of new drugs, and best practices in drug prescribing and use in Canada. For more information on CADTH, visit <https://www.cadth.ca/>.

Refer to Section 4.0 Statement of Work of this Request for Proposal (RFP) for detailed technical requirements.

1.2 PMDE Program Overview

Building on the work of the Canadian Institute for Health Research (CIHR)'s Drug Safety and Effectiveness Network (DSEN), CADTH will be launching the new Post-Market Drug Evaluation program (PMDE) in September 2022. Consistent with the original mandate of DSEN, CADTH's PMDE program will focus solely on providing answers to decision-makers questions about the safety and effectiveness of drugs, whether they are existing or new products. Further, it will leverage CADTH's extensive engagement with FPT decision-makers and other stakeholders including industry, clinicians, and patients, and on the ground presence in jurisdictions across Canada to maximize how and where information generated by the PMDE program is shared across Canada.

The goals of the new PMDE program are to:

1. enhance the pan-Canadian, post-marketing query response capability and capacity by creating an efficient and responsive network of applied researchers, methodologists, and data analysts able to meet the needs of decision-makers using approaches that are appropriate and provide the right balance of methodological rigour and timeliness
2. coordinate access to post-market drug information and data by facilitating communication, awareness, and linkages between applied researchers, methodologists, data analysts, data holders, stakeholders, and decision-makers
3. enable the uptake and utilization (knowledge mobilization and implementation) of post-market evidence and information to inform decision-making through a centralized approach
4. create a culture of continuous quality improvement of the query process and timeliness
5. foster national and international PMDE partnerships to identify and streamline processes for improved post-market evaluation.

The program has been deliberately designed to maximize access to a wide range of applied researchers, data analysts and methodologists from across Canada and to ensure stability while balancing the need to pivot and be as responsive as possible to the needs of decision-makers. Given the drive to support rapid access to safe, effective, high-quality drugs, earlier and more agile regulatory approval, and changing face of clinical trials in Canada and internationally, the value of investing in post-market drug evaluation is higher now than perhaps ever before. To meet the needs of the future, the PMDE program will need access to individuals and teams who can: design, implement, and report on observational drug safety and effectiveness studies, as products move from clinical trial to more widespread use; stay abreast of and support effective use of novel methods and approaches that allow us to more accurately monitor and report on drug outcomes; and of course to seek, consolidate, analyze and report on the enormous wealth of data that is already being generated to avoid duplication, increase confidence and certainty among decision-makers, clinicians, and patients among others about the known and as yet unknown outcomes of specific drugs for specific indications or populations.

2 REQUEST FOR PROPOSALS

CADTH is issuing this request for proposal for interested **Core Network Partner** applicants.

2.1 Key Dates

Interested applicants are asked to provide CADTH with a **Letter of Intent** by the date outlined in Table 1. Refer to the [Request for Proposal webpage](#) for the Letter of Intent Form and Guide.

Applicants who wish to proceed to full proposal submission must do so in accordance with the instructions in this RFP.

The deadline for **proposal submission** is as outlined in Table 1. All Proposals will be date and time stamped upon receipt. Proposals received after the submission deadline shall be rejected.

All enquiries and submissions can be submitted via email to contracts@cadth.ca.

Please note that maximum email size is 20 MB inclusive of all attachments.

2.2 Applicant Eligibility

This RFP is being publicly tendered.

To be eligible, applicants must hold a Ph.D., M.D., or equivalent degree in a field that specifically relates to the evaluation of drug safety and effectiveness and be affiliated with a university, academic centre or institution, hospital research institute, or independent not-for-profit organization based on Canada.

All interested applicants are encouraged to submit their proposal and CADTH ensures that no advantage will be conceded to organizations that have worked with CADTH previously.

2.3 Proposal

The applicant is required to submit a technical proposal and a financial proposal as separate documents in searchable PDF format, electronically in one email, to the location specified in Section 2.1.

The applicant's signature indicates acceptance of the terms and conditions set out in the Statement of Work in Section 4 of this RFP. The signatory of the applicant must have the authority to commit the applicant's organization to the details contained in the proposal.

Applicants must provide their proposal in two (2) separate documents as follows below. Please note that maximum email size is 20 MB inclusive of all attachments.

2.3.1 Technical Proposal

Technical proposals will be assessed to determine their compliance with the proposal instructions provided in Section 2.3.3 and evaluation criteria detailed in this RFP. Applicants are instructed to address each requirement in sufficient depth to permit a complete analysis and assessment by the Review Panel.

The technical proposal shall be completed according to the specifications outlined in Section 4 of this RFP. Proposals will be evaluated based on scoring and criteria as outlined in Appendix A.

CADTH will provide a Proposal Guide and Technical Proposal Form to be used by the Applicant; refer to [Request for Proposal webpage](#) for more information.

2.3.2 Financial Proposal

The financial proposal will remain sealed until after the Technical Proposal receives a passing score. The financial proposal will be assessed to determine their compliance with the proposal instructions provided in Section 2.3.3 and the evaluation criteria detailed in this RFP.

CADTH will provide a Proposal Guide and Financial Proposal Form to be used by the Applicant; refer to [Request for Proposal webpage](#) for more information.

The financial proposal shall be completed according to the specifications outlined in Section 4 of this RFP. Financial proposals will be evaluated based on scoring and criteria as outlined in Appendix A.

2.3.3 Proposal Preparation Instructions

Each applicant interested in becoming a PMDE Core Network Partner is expected to prepare a proposal that describes:

- a) The nature and scope of the work being proposed, including description of the experience of individual team members and direct experience working to respond to decision-makers needs and timelines; aims and objectives of the proposed work; project management supporting capabilities; and barriers and risk mitigation strategies to conduct the type of work being proposed
- b) The minimum and maximum number of queries that could reasonably be accommodated by the proposed team within the requested budget on an annual basis, and the factors that might influence this range.
- c) Lead applicant/co-applicants including full name, position, department, institution, contact information, webpage (if any), list of relevant publications, grants or awards, number of hours to be allocated weekly and role in the proposed work, links with any relevant groups, committees, networks, or organizations.
- d) Information about proposed team members including full name, position, department, institution, list of relevant publications, grants or awards and number of hours to be allocated weekly and role in the proposed work. If some team members have not been chosen at the time the proposal is submitted -as might be the case for a trainee – information about the type of expertise these individual(s) would bring, and their role should be provided.
- e) How both early and later career scientists would be involved in the work of a dedicated team, given the high value CADTH places on supporting the next generation of applied researchers, data analysts and methodologists.
- f) How and where there may be opportunities for collaboration across Canada and with international applied researchers, data analysts and methodologists, given the high potential value of collaboration to create opportunities for synergy, spark innovation, and leverage the best available talent and learning. Applicants should note that neither teams nor individuals based outside of Canada are eligible to receive funding as part of this RFP, even though their involvement and engagement in the work of the proposed team and /or PMDE program is strongly encouraged.
- g) How diversity, equity and inclusion (EDI) will or could be incorporated into the work of the proposed team including but not limited to how the work will be conducted and how selection of team members will take place. This should be interpreted to include but not be limited to sex and gender analyses as well as how patient and caregiver voice will or could be integrated into the work (e.g., inclusion of evidence about impact on patients or families from the literature, to address one or more priorities of the James Lind Alliance, or potentially by having patients or caregivers directly involved in the proposed network or specific queries). Reference should be made to the applicant's host institution EDI principles or, if none exist, principles from an equivalent Canadian organization. Teams that are funded are required to adhere to any Indigenous data sovereignty protocols, such as the [First Nation's principles of OCAP](#).
- h) A detailed three-year budget, bearing in mind eligible and ineligible expenses as described in Appendix B. Applicants are expected to address in the three-year budget any changes to the budget that may be required to address, for instance, inflation or anticipated salary changes. Note this information should be provided as part of the financial proposal, as described in Section 2.3.2.

The proposal must also include:

- a) A letter from the host institution indicating a willingness to negotiate an Agreement with CADTH in a timely manner, with the understanding that the program launch date is set for September 1, 2022, and teams must be in place and ready to respond to queries as of that date.

- b) 2 or 3 letters of reference from researchers who can knowledgeably comment on the proposed team in terms of their ability to address post market drug evaluation OR from requestors who can comment on the proposed team's capabilities and/or the relevance, timeliness of work produced by some or all members of the team to support decision-making.

2.4 Validity

Proposals **must** remain open for acceptance for a period of one hundred and fifty-five (155) calendar days after the proposal submission due date as listed in Table 1.

2.5 Proposal and Pre-Award Costs

No costs incurred in the preparation and submission of the proposal will be paid by CADTH.

2.6 Enquiries

CADTH will host an **information session about this RFP from 1:15-2:00 p.m. EDT on February 8, 2022**. For more information and to register see the [Information Session](#). A recording of the information session will be available on the [PMDE webpage](#) by Friday, February 11, 2022.

For more information about the enquiry schedule, refer for Table 1.

To ensure the integrity of the competitive application process, enquiries, and other communications regarding the RFP process up to the closing date, are to be directed **ONLY** to the point of contact identified in Section 2.1. All enquiries and responses to them will be provided to all organizations invited to respond to this RFP.

3 PROPOSAL EVALUATION AND SELECTION

CADTH reserves the right to award in its best interest. Tenders with the lowest price, or any tender, need not necessarily be accepted. CADTH, at its sole discretion, reserves the right not to award this to any of the applicants. All decisions are final.

3.1 Proposal Evaluation

An administrative review will be completed by CADTH to assess the submission for conformity with the requirements described in section 4 in this RFP. Each application that is deemed to conform with the submission requirements will be reviewed by a multi-disciplinary Review panel comprised of internal and external stakeholders who have a range of expertise including in research methods and applied research.

The Review panel will receive applications approximately one week prior to the review meeting and will be tasked with providing scores for each technical criterion. Scores for each review will be tabulated and shared with the Review Panel prior to the panel meeting. For information on scoring and evaluation criteria, see Appendices A and B.

3.2 Selection Methodology

Each grant award will be made on the basis of the proposal evaluation. All decisions are final. The proposed criteria and point assessment are contained in Appendix A. Please note that these assessment criteria are subject to change. Note that as part of the selection process, short-listed applicants may be requested to present specific components of their proposal via a video conference meeting with a subset or full review panel.

4 Statement of Work

4.1 Working With CADTH

CADTH anticipates notifying successful applicants of the final decision to ensure sufficient time for negotiation of the Agreement prior to program launch.

The successful applicant agrees to execute a CADTH grant agreement for this work. The successful applicant agrees to follow CADTH procedures and use CADTH forms and templates provided by CADTH.

CADTH will establish a funding agreement with the host institution or applicant, as required, that will cover: payment terms; eligible expenses; financial and performance management reporting requirements; conditions such as termination of the agreement, evaluation of the PMDE program, audit, warranties, assignment of rights, payments or obligations of the funding agreement to a third-party; publication and publicity, including knowledge mobilization efforts; data management, retention, sharing and open access; among others. The funding agreement will also include the expectation for adherence to Open Access Principles, adherence with local or institutional ethics approval processes, adherence with generally accepted practices for research and for accounting and financial practices and reporting.

CADTH will provide applicants who were not selected for a PMDE grant with feedback about their proposal based on the Review Panel scoring and discussion. Unsuccessful applicants are entitled to submit a proposal to the PMDE RFP for Standing Offers that will be issued March 15, 2022, and that will close May 17, 2022.

4.2 Language of Work

Unless stated otherwise, all work and deliverables are to be done in the English language and CADTH will be responsible should any translation be required.

4.3 Location of Work

All work is expected to be performed at the grant awardees' facilities, or as described in the applicant's proposal, in Canada.

4.4 Term

Applicants selected for funding will be provided with a funding term of September 1, 2022, to August 31, 2025.

4.5 Budget

The annual budget for the grant award competition is approximately \$4.3 million. CADTH anticipates awarding 3 to 4 3-year grant awards. The annual budget will not necessarily be distributed equally amongst all grant awards. CADTH reserves the right to negotiate technical and financial proposals to ensure an optimal balance of competencies in the PMDE network.

4.6 Fee Schedule

Thirty percent of total per year Proposal Financial fees will be made at launch of the PMDE program on September 1 each year. Subsequent quarterly instalments will be paid within thirty (30) calendar days of submission and acceptance by CADTH of an appropriate invoice, quarterly financial and performance measurement reports. Submission of these documents must be made within thirty (30) days following the end of the previous quarter. CADTH acceptance must be provided within ten (10) calendar days.

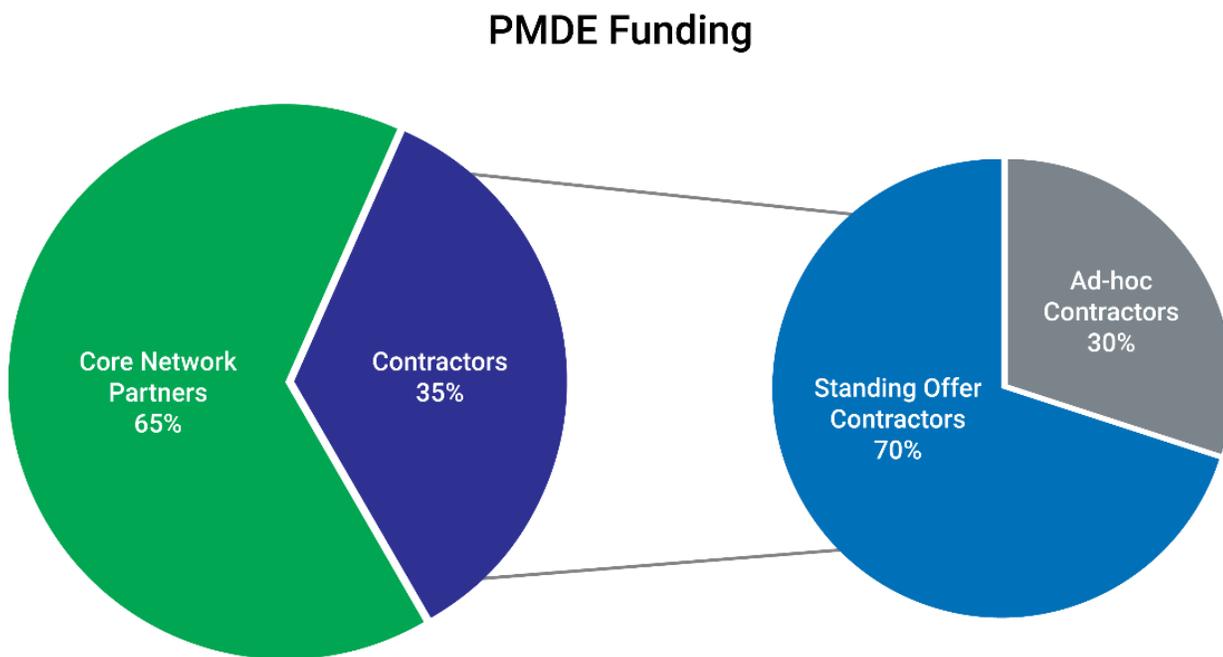
In the event of a grant award, the Proposal Financial fees amount shall constitute the full and complete amount which shall be paid to the applicant for the purpose of this RFP. Assuming the agreement between CADTH and the applicant or host is complete and duly signed and the proposed team is in place and fully ready to respond to decision-maker queries, a 30% of total per year Proposal Financial fees payment will be made at launch of the PMDE program on September 1st of 2022 and on this date for subsequent years. Thereafter, the remaining 70% of annual proposal financial fees will be paid retroactively on a quarterly basis following submission and CADTH acceptance of a performance and financial progress report.

Eligible expenses for this RFP are described in Appendix B.

4.7 Program Funding

The program will include Core Network Partners, comprised of a limited number of teams based on three-year grant awards and a similar number of one-year renewable standing offers (SO). Available funding will be broken down as follows: 65% allocated to grants, 35% to other of which 70% will be for standing offers and 30% for ad hoc contracts to fill time limited or topic specific needs that cannot be met by current grant or SO holders.

Figure 1: Post-Marketing Drug Evaluation Network Funding Model



The combined flexibility of longer-term funding with shorter-term renewable contracts maximizes CADTH's ability to position the PMDE network to respond to decision-makers queries quickly, with the right expertise, and to provide an even more expansive network of highly trained applied researchers, analysts and methodologists available to respond to decision-makers' queries.

Ad-Hoc Contracts will also be available when unique, uncommon, or highly specific skills are required that are not already available through one of the Network Partners or when workload of the Network is particularly intense, and a decision-maker query has been prioritized.

This RFP is specific to the three-year grant awards for the Core Network Partners. A second RFP specific to the one-year renewable Standing Offers will be released by CADTH on March 15, 2022.

4.8 Deliverables

In addition to specific project deliverables which would be agreed to in writing as each FPT decision-maker query is discussed and approval to proceed is granted, grant award holders are expected to submit quarterly performance and financial reporting updates and an end of grant update, within 30 days of the end of each quarter or grant end respectively. Financial reports may be subject to audit CADTH or CADTH appointed auditors.

Appendix A: Technical and Financial Proposal Evaluation

The following table provides the criteria, weighting and additional descriptors. Note the Technical proposal evaluation will represent 80% of the overall evaluation.

TABLE 2: CRITERIA, WEIGHTING, DESCRIPTORS

Criteria	Weighting	Description: Applicant’s proposal describes the following
1. Suitability of the team	24%	<ul style="list-style-type: none"> • Nature and scope of work being proposed • Min and max number of queries / yr. possible and factors that might influence number • Team including relevant work, hours allocate weekly and role on team, links with relevant groups • Early and late career involvement • Collaboration • Management and governance of the team • Project management capabilities • Equity, Diversity, Inclusivity
2. Relevance and Focus	20%	<ul style="list-style-type: none"> • Clear focus that aligns with the goals of the PMDE program (i.e., customer focus). • Awareness of how applied research could inform regulatory and/or HTA / reimbursement processes. • Description of methodologies for post-market drug evaluation • Understanding of the need for timeliness • Addresses specific, well-defined, priorities for post market drug evaluation • Current state of knowledge relative to the proposed work is included
3. Quality and Rigour	20%	<ul style="list-style-type: none"> • Examples of relevant and successful post-market drug evaluation work completed in the past 5-years • Cohesive plan, appropriate to the scope and type of work being proposed • Plan that will likely lead to meaningful results for decision-makers • Proposed work is of international calibre and shows innovation in addressing safety and effectiveness needs now and into the future • Potential barriers and risk mitigation strategies are addressed and appropriate
4. Feasibility	12%	<ul style="list-style-type: none"> • Proposal is feasible, within the term of the Agreement, with potential for success • Project team has access to appropriate facilities and resources to ensure project success • Deliverables and milestones are attainable within specified timeline. Appropriately defined to allow monitoring of progress against goals and objectives. • Demonstrated understanding and plan to provide quarterly performance metrics and data to the PMDE Operations Centre

Criteria	Weighting	Description: Applicant's proposal describes the following
5. Additional	4%	<ul style="list-style-type: none"> 2-page maximum letter from host institution indicating agreement with the content of the application, as well as willingness to negotiate quickly given timeline for PMDE program September 2022 and willingness to provide the resources include in the proposal. References pertaining to similar work outlined in this RFP and having taken place in the past 3 years. References may include peers, customers, or end-users, etc. All listed references should be notified they may be contacted and must agree to participate in a brief phone or video conference between April 11-25, 2022. <i>References from current CADTH employees will not be accepted.</i> Additional partner funds or in-kind contributions that may be leveraged for PMDE work

The following table provides the criteria and weighting of the financial proposal.

TABLE 3: FINANCIAL PROPOSAL EVALUATION CRITERIA

Criteria	Weighting	Description
1. Fees	20%	Include a detailed budget providing a breakdown of costs by level of staff and activity. Hourly rates for each team member must be included. A financial proposal template will be provided on CADTH's Request for Proposal webpage for interested applicants.
2. Fees: Reference Section 4.4 of this RFP	Mandatory 0% (pass or fail)	The applicant is to provide impact on budget for years 2 and 3.

Appendix B: Expenses

ELIGIBLE

1. Stipends, salaries and benefits.
2. Up to 15% of the principal investigator or co-investigators salary (for example to ensure the PI/co-PI is(are) available for a specified number of hours /weeks, to a maximum of \$40,000 for a PI or co-PI per year.
3. Costs to ensure open access of research results capped at costs to publish once per year on each distinct approved PMDE project (to a maximum of \$3,000 per publication). A 3-year project, for example, could include publication costs for up one publication per year to the maximum funding allowed in each of the three years.
4. Travel costs of up to \$4000 to present at up to one meeting in North America per year. Travel to present at international meetings must be pre-approved by CADTH. Note CADTH's agreement will preclude the use of grant funds to purchase alcohol.
5. General office and administration, including institution overhead to a proposed maximum of 15%. Note institution overhead above 15% must be justified in the proposal, will be considered during the proposal review process, and may be subject to negotiation as the Agreement is finalized. This expense category includes but is not limited to
 - 5.1. Equipment, IT, support services, data retention and software licenses beyond what is typically provided by the host institution.
 - 5.2. Costs for equipment maintenance and service contracts, training of staff operating equipment/software, and extended warranty for equipment limited to the life of the agreement.
 - 5.3. Knowledge mobilization/in team meetings for members of a specific network or members of more than one network where travel is required. Maximum allowed per year is \$8,000. Meetings must be in Canada and follow CADTH travel and any other relevant expense policy.
6. Limited funds for travel to annual PMDE program meeting.

INELIGIBLE

1. Discretionary severance or separation packages
2. Benefits for trainees
3. Any project costs that are funded, will be funded, or reimbursed by any third party, ministry agency, or organization of a FPT Government
4. Travel to international meeting other than on exception basis and with pre-approval by CADTH.