

CADTH Post-Market Drug Evaluation

Request for Proposal – Standing Offer Competition

Competition File C-220440

March 15, 2022

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Issued: **March 15, 2022**

File #: **C-220440 Post-Market Drug Evaluation Standing Offer
Competition**

Proposal Due Date: **2:00 p.m. EDT on May 17, 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	March 15, 2022	Page 3
2	CADTH to Provide Proposal Templates	March 22, 2022	Section 2.3
3	RFP Information Session	March 22, 2022	Section 2.7
4	Advise CADTH of your intent to submit a proposal; send Letter of Intent to contracts@cadth.ca	April 8, 2022	Section 2.1
5	Enquiry Submission Deadline	2:00 p.m. EDT on April 22, 2022	Section 2.6
6	Responses to Enquiries	Within 2 business days	Section 2.6
7	Deadline for CADTH to Issue Bulletins*	April 26, 2022	Section 2.6
8	Proposal Submission Due Date	2:00 p.m. EDT on May 17, 2022	Section 2.1
9	Notification of Outcome of Proposal	June 7, 2022	Section 3.2
10	Work Commencement	September 1, 2022	Section 4.4
11	Work Completion	August 31, 2023	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 **Standing Offer Agreement** 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 should hold a Ph.D., M.D., or equivalent degree and experience in a field that specifically relates to the evaluation of drug safety and effectiveness and could be affiliated with a university, academic centre or institution, hospital research institute, research group, or independent not-for-profit organization based in Canada. Applicants cannot be affiliated with a for-profit entity or consulting group.

Applicants that were unsuccessful in retaining a grant from the Core Network Partner grant competition are eligible to apply.

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

Applicants are 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

Applicants interested in becoming a PMDE Standing Offer Contractor are expected to prepare a proposal that describes:

- a) Applicant(s) information 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, links with any relevant groups, committees, networks, or organizations.
- b) The nature and scope of the work being proposed, including description of the experience of the individual(s) and direct experience working to respond to decision-makers needs and timeliness; aims and objectives of the proposed work.
- c) The minimum and maximum number of queries that could reasonably be accommodated by the applicant within the requested budget in the span of one year, and the factors that might influence this range.
- d) 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.
- e) How diversity, equity, and inclusion (EDI) will or could be incorporated into the work including but not limited to how the work will be conducted and if applicable, 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. Contractors that are awarded are required to adhere to any Indigenous data sovereignty protocols, such as the First Nation's principles of OCAP.
- f) Hourly rate of work. 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 or agency 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 Standing Offer Contractors must be in place and ready to respond to queries as of that date (if applicable).
- b) 2 or 3 letters of reference from collaborators who can knowledgeably comment on the applicant's 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 the applicant to support decision-making.

2.4 Validity

Proposals **must** remain open for acceptance for a period of one hundred and twenty (120) 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 12:00-12:45 p.m. EDT on March 22, 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, March 25, 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 of 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 Appendix A.

3.2 Selection Methodology

Each Standing Offer Agreement award will be made based on 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

Standing Offers applicants are for individuals or teams of individuals who wish to take on PMDE work. 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(s) agrees to execute a CADTH 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 Standing Offer Agreement with the host institution or applicant, as required, that will cover payment terms; financial and performance management reporting requirements; conditions such as termination of the Agreement, evaluation of the PMDE program, audit, warranties, publication, among others. The Standing Offer 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.

- (a) Standing Offer Agreement: although CADTH intends to issue work to Standing Offer contractors, the agreement does not oblige CADTH to authorize or order any research services whatsoever or to spend the estimated expenditure or any monies whatsoever.
- (b) Call-up: A contractual obligation will come into force only if there is an authorized "Call-up" against a Standing Offer Agreement and only to the extent stipulated in the call up.
 - i. All Services will be requested in writing by the representative assigned by CADTH. Each agreed to service will be recorded in a supplemental Standing Offer Call-up and form a part of the Standing Offer Agreement.
 - ii. CADTH responsibilities include the selection of topics, product type, establishing the schedule and estimate level of effort for each research project.
- (c) CADTH does not guarantee the amount of work. Call-ups are based largely on the research requirements and may differ from year to year. CADTH intends to execute a number of standing offers agreements with different partners.

CADTH will provide applicants who were not selected for a PMDE Standing Offer Agreement with feedback about their proposal based on the Review Panel scoring and discussion. Unsuccessful applicants are entitled to submit a proposal to subsequent RFPs.

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 contractor's facilities, or as described in the contractor's proposal, in Canada.

4.4 Term

Applicant(s) selected for funding will be provided with a funding term of September 1, 2022, to August 31, 2023. Upon mutual agreement between CADTH and the contractor, the Standing Offer can be extended annually for up to two additional years.

4.5 Budget

The annual budget for Standing Offer Agreements is approximately \$1.6 million. The annual budget will not necessarily be distributed equally amongst all Standing Offer Agreements and will be reflective of the capacity and expertise of each applicant. CADTH reserves the right to negotiate technical and financial proposals to ensure an optimal balance of competencies in the PMDE network.

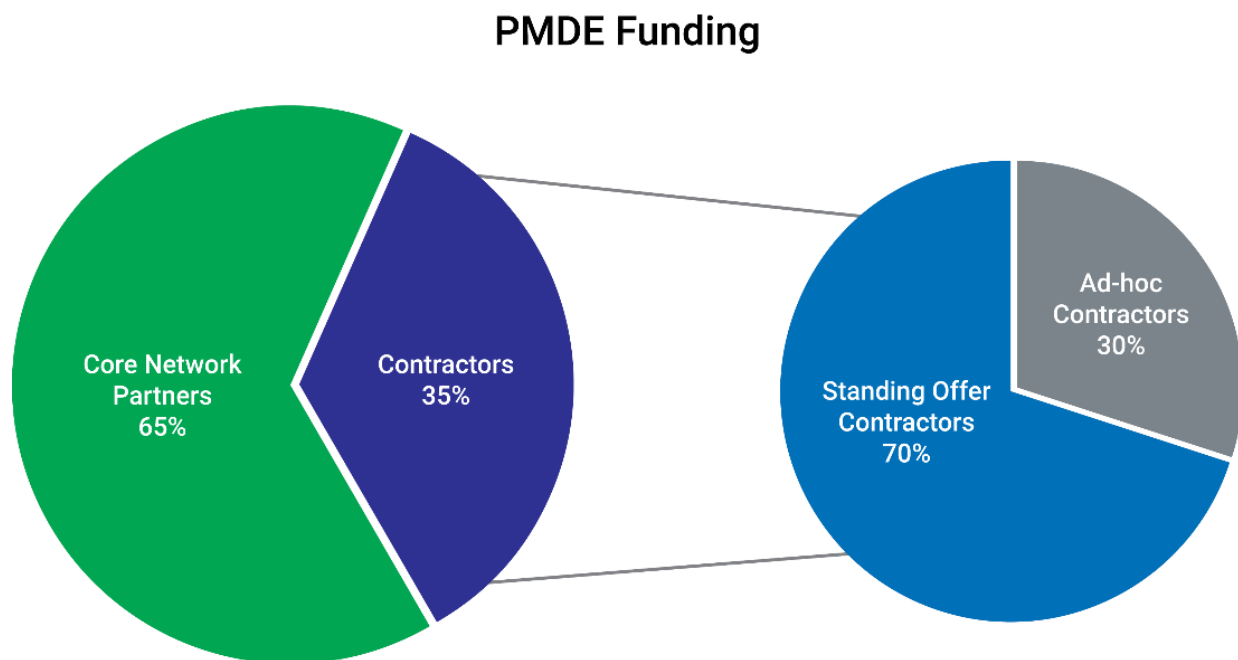
4.6 Fee Schedule

At CADTH's discretion, a retainer may be paid at the beginning of the agreement period and/or annually if extended for additional term(s), based on the applicants' expertise and number of individuals listed on the application. Payment thereafter shall made in accordance with the fees outlined in each Call-up.

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 Offer (SO) contracts for individuals or teams. 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 one-year Standing Offer Agreements.

4.8 Deliverables

The deliverables will be specified in the call-up. Deliverables may vary from call-up to call-up. Financial reports may be subject to audit by 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 75% of the overall evaluation.

TABLE 2: CRITERIA, WEIGHTING, DESCRIPTORS

Criteria	Weighting	Description: Applicant's proposal describes the following
1. Suitability and expertise of the applicant(s)	25%	<ul style="list-style-type: none"> • Nature and scope of expertise is clearly aligned with the goals of PMDE program • Description of methodology(ies) for post-market drug evaluation of the individual or team of individuals • Willingness to collaborate • Awareness of how applied research informs regulatory and/or HTA / reimbursement processes. • Ability to addresses specific priorities for PMDE • Current state of knowledge of identified priority areas
2. Historical work	25%	<ul style="list-style-type: none"> • Examples of relevant and successful PMDE work completed in the past 5-years • Historical work is of international calibre and shows innovation in addressing safety and effectiveness needs
3. Feasibility	20%	<ul style="list-style-type: none"> • Minimum and maximum number of queries / year possible and factors that might influence number • Proposal is feasible, within the term of the agreement, with potential for success • Applicants have access to appropriate facilities and resources to ensure project success
4. Additional	5%	<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 (if applicable) • 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 June 1-8, 2022. <i>References from current CADTH employees will not be accepted.</i>

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

TABLE 3: FINANCIAL PROPOSAL EVALUATION CRITERIA

Criteria	Weighting	Description
1. Fees	25%	Hourly rate of work for each individual on the proposal and if applicable, administrative fees of the host institution. A financial proposal template will be provided on CADTH's Request for Proposal webpage for interested applicants.