



REQUEST FOR STANDING OFFERS (RFSO)

File #C-242500320

Post-Market Drug Evaluation (PMDE)

CADTH Confidentiality Statement:

This document and all attachments herein are intended solely for the use of the individual(s) and/or organization(s) to which it is directed. It may contain privileged, confidential or copyright-protected information. By accepting possession of this document, you agree to keep its contents in confidence and to not use, duplicate, or disclose the document to any other party for any purpose other than providing the services herein, unless otherwise to agreed in writing by CADTH.

Any unauthorized use, copying, review, or disclosure, including use other than by the intended recipient, is prohibited. If received in error, please delete this document and all copies immediately from your system, and notify the sender promptly by email that you have done so.

REQUEST FOR STANDING OFFERS

Issued: April 18, 2024

Project #: C-242500320 Post-Market Drug Evaluation (PMDE)

Proposal Due Date: 2:00 p.m. Ottawa EDT on May 2, 2024

Enquiries by Email: contracts@cadth.ca

REQUEST FOR STANDING OFFERS

Table of Contents

Table 1: Request for Standing Offers (RFSO) Schedule and Timelines..... 4

1.0 DESCRIPTION OF REQUIREMENT 5

 1.1 CADTH Overview 5

 1.2 PMDE Program Overview 5

2.0 ENQUIRIES, SUBMISSION OF PROPOSALS, and PROPOSAL PREPARATION INSTRUCTIONS..... 6

 2.1 Key Dates 6

 2.2 Point of Contact and Submission of Proposal 6

 2.3 RFSO Posting and Applicant Eligibility 7

 2.4 Proposal..... 7

 2.4.1 Technical Proposal..... 7

 2.4.2 Financial Proposal..... 8

 2.5 Proposal Preparation Instructions..... 8

 2.6 Validity 9

 2.7 Proposal and Pre-Award Costs 9

 2.8 Enquiries 10

 2.9 Acceptance of Proposal 10

3.0 PROPOSAL EVALUATION, CRITERIA and SELECTION 11

 3.1 Proposal Evaluation 11

 3.2 Selection Methodology 11

4.0 Statement of Work 12

 4.1 Working with CADTH 12

 4.2 Language of Work..... 13

 4.3 Location of Work 13

 4.4 Period of Contract 13

 4.5 Budget 13

 4.6 Fee Schedule..... 13

 4.7 Program Funding 13

 4.8 Deliverables 14

Appendix A Technical and Financial Proposal Evaluation..... 15

Table 1: Request for Standing Offers (RFSO) Schedule and Timelines

#	Description	Date	RFSO Reference
1	RFSO Release	April 18, 2024	Page 2
3	Advise CADTH of your intent to submit a proposal; send Letter of Intent to contracts@cadth.ca	April 26, 2024	Section 2.1
4	Enquiry Submission Deadline	April 26, 2024	Section 2.8
5	Responses to Enquiries	Within 2 business days	Section 2.8
6	Deadline for CADTH to Issue Bulletins*	April 30, 2024	Section 2.8
7	Proposal Submission Due Date	2:00 p.m. EDT on May 2, 2024	Section 2.1
8	Short-listed bidders may be requested to participate in a Question and Answer session via a video-conference meeting	May 23, 2024	Section 3.2
9	Notification of Outcome of Proposal	June 24, 2024	Section 3.2
10	Work Commencement	September 1, 2024	Section 4.4
11	Work Completion	August 31, 2026	Section 4.4

Note:

Applicants are advised to check the [Request for Standing Offers 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.

1.0 DESCRIPTION OF REQUIREMENT

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 Standing Offer (RFSO) for detailed technical requirements.

1.2 PMDE Program Overview

In September 2022, CADTH launched the new Post-Market Drug Evaluation program (PMDE). CADTH's PMDE program focuses solely on providing answers to decision-makers questions about the safety and effectiveness of drugs, whether they are existing or new products. Further, it leverages CADTH's extensive engagement with FPT decision-makers and other stakeholders including industry, clinicians, and patients, and 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,

Canadian Agency for Drugs and Technology in Health – Request for Standing Offers

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 needs 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. At this time the PMDE program is not conducting query work on medical devices.

2.0 ENQUIRIES, SUBMISSION OF PROPOSALS, and PROPOSAL PREPARATION INSTRUCTIONS

CADTH is issuing this request for proposal for interested Standing Offer Agreement applicants.

Interested bidders are required to submit their proposals in accordance with the instructions provided in this RFSO.

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 Standing Offers webpage](#) for the Letter of Intent Form.

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

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.

2.2 Point of Contact and Submission of Proposal

The point of contact for all Enquiries and Proposal Submissions is the following:

- By email to contracts@cadth.ca.

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

The deadline for submission outlined in Table 1. All Proposals will be date and time stamped upon receipt.

Proposals received after the submission deadline shall be rejected.

2.3 RFSO Posting and Applicant Eligibility

This RFSO 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 may apply as individuals or as groups.

Applicants that were unsuccessful in retaining a grant from the Core Network Partner grant competition are not eligible to apply. Applicants who are currently or intend to do contracted work for other CADTH programs 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.

2.4 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 2.2.

The applicant's signature indicates acceptance of the terms and conditions set out in the Statement of Work in Section 4 of this RFSO. 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.

2.4.1 Technical Proposal

Technical proposals will be assessed to determine their compliance with the proposal instructions provided in Section 2.5 and evaluation criteria detailed in this RFSO. 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 RFSO. 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 Standing Offers webpage](#) for more information.

2.4.2 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 2.5 and the evaluation criteria detailed in this RFSO.

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

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

2.5 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 RFSO, even though their involvement and engagement in the work of the proposed team and /or PMDE program is strongly encouraged.
- e) Access or ability to access Canadian data and experience in data analysis. Experience with provincial data, CIHI data, common data models such as TreeScan or OMOP, are all considered an asset.

Canadian Agency for Drugs and Technology in Health – Request for Standing Offers

- f) 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.
- g) Hourly rate of work. Note this information should be provided as part of the financial proposal, as described in Section 2.4.

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 Standing Offer Agreement must be signed by September 1, 2024. 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.

2.6 Validity

Proposals must remain open for acceptance for a period of one hundred and eighty (180) calendar days after the Proposal Submission Due Date as listed in Table 1.

2.7 Proposal and Pre-Award Costs

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

2.8 Enquiries

To ensure the integrity of the competitive bidding process, enquiries and other communications regarding the RFSO process up to the closing date, are to be directed ONLY to the Point of Contact identified in Section 2.2. All enquiries and responses to them will be provided to all organizations invited to respond to this RFSO.

Enquiry Schedule: Refer to Table 1.

2.9 Acceptance of Proposal

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 bidders. All decisions are final.

3.0 PROPOSAL EVALUATION, CRITERIA and SELECTION

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 RFSO. 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: As part of the selection process, short-listed bidders may be requested to present specific components of their proposal via a video conference meeting with a subset or full review panel. Refer to Table 1 for the schedule.

4.0 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.
 - iii. Budget will be negotiated between CADTH and the contractor, based on complexity and nature of the query.
- (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 RFSOs.

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. The location of meetings will be arranged between the successful bidder and CADTH.

4.4 Period of Contract

Applicant(s) selected for funding will be provided with a funding term of September 1, 2024, to August 31, 2026. Upon mutual agreement between CADTH and the contractor, the Standing Offer can be extended annually for up to two additional years.

Upon mutual agreement between CADTH and the Contractor, this work may be extended for up to 2 (two) additional years. The Bidder's Proposal Submission is to indicate acceptance of this possible extension.

4.5 Budget

The annual budget for Standing Offer Agreements is approximately \$1.3 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 be 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 renewable Standing Offer (SO) contracts for individuals or teams.

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.

Canadian Agency for Drugs and Technology in Health – Request for Standing Offers

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 RFSO is specific to the two-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 Proposal is to be submitted in two documents: Technical Proposal and Financial Proposal.

The technical and financial proposal templates can be found on CADTH’s [Request for Standing Offers webpage](#) for interested applicants.

The following tables provides the criteria, weighting and additional descriptors. Note the Technical proposal evaluation will represent 75% of the overall evaluation. Financial proposals will be opened for submissions with strong technical proposals, subsequently.

TABLE 2: TECHNICAL CRITERIA, WEIGHTING, DESCRIPTORS

Criteria	Weight	Description: Applicant’s proposal describes the following
1. Suitability and expertise of the applicant(s)	25%	<ul style="list-style-type: none"> i. Nature and scope of expertise is clearly aligned with the goals of PMDE program ii. Description of methodology(ies) for post-market drug evaluation of the individual or team of individuals iii. Willingness to collaborate iv. Awareness of how applied research informs regulatory and/or HTA / reimbursement processes. v. Ability to addresses specific priorities for PMDE vi. Current state of knowledge of identified priority areas
2. Historical work	25%	<ul style="list-style-type: none"> i. Examples of relevant and successful PMDE work completed in the past 5-years ii. Historical work is of international calibre and shows innovation in addressing safety and effectiveness needs
3. Feasibility	20%	<ul style="list-style-type: none"> i. Minimum and maximum number of queries / year possible and factors that might influence number ii. Proposal is feasible, within the term of the agreement, with potential for success iii. Applicants have access to appropriate facilities and resources to ensure project success
4. Additional	5%	<ul style="list-style-type: none"> i. 2-page maximum letter from host institution indicating agreement with the content of the application, as well as willingness to negotiate quickly given timeline to start on September 1, 2024 and willingness to provide the resources include in the proposal (if applicable) ii. References pertaining to similar work outlined in this RFSO and having taken place in the past 5 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. References from current CADTH employees will not be accepted. iii. Curriculum Vitae for applicant(s) may be included as an appendix (exclusive of the page count).

Canadian Agency for Drugs and Technology in Health – Request for Standing Offers

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.