



REQUEST FOR STANDING OFFER (RFSO) #C-190750

Scientific Advisor (Methodologist)

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REQUEST FOR STANDING OFFER

Issued: March 7, 2019

Title: C-190750 RFSO Scientific Advisor (Methodologist)

Proposal Due Date: 14:00 Ottawa Local Time on April 10, 2019

Enquiries by Email: contracts@cadth.ca

REQUEST FOR STANDING OFFER

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Table 1: RFSO Schedule and Timelines

#	Description	Date	RFSO Reference
1	RFSO Release	March 11, 2019	Page 2
2	Enquiry Submission Deadline	14:00 Ottawa Local Time on March 18, 2019	Section 2.6
3	Responses to Enquiry (ies)	2 business day(s)	Section 2.6
4	Deadline for Issuing Bulletins*	March 20, 2019	Section 2.6
5	Proposal Submission Due Date	14:00 Ottawa Local Time on March 29, 2019	Section 2.1
6	Notification of Outcome of Proposal	15 April 2019	Section 3.2
7	Work Commencement	June 3, 2019 **	Section 4.4

Notes:

Proponents are advised to check the CADTH website daily for update Bulletins.

<https://cadth.ca/careers/freelance-contractors/request-for-proposals>

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

** Work commencement date may change depending on CADTH's requirements and will be mutually agreed to between CADTH and the successful bidder(s).

1.0 DESCRIPTION OF REQUIREMENT

1.1 CADTH Overview

Canada's federal, provincial and territorial health care decision makers rely on CADTH to provide them with credible, impartial advice and evidence-based information about the 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://cadth.ca/about-cadth>.

Refer to Section 4.0 Statement of Work of this Request for Standing Offer (RFSO) for detailed technical requirements.

2.0 ENQUIRIES, SUBMISSION OF PROPOSALS, and PROPOSAL PREPARATION INSTRUCTIONS

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

2.1 Point of Contact and Submission of Proposal

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

Reference: C-190750 RFSO Scientific Advisor (Methodologist)

By email to: contracts@cadth.ca.

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

The deadline for submission is 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 RFSO Posting and Bidder Eligibility

This RFSO is being publicly tendered.

The current service providers are eligible to submit a response for this work.

2.3 Proposal Preparation Instructions

The bidder is required to submit a Cover Letter and Resume as separate documents in PDF format, electronically in one email, to the location specified in Section 2.1.

The bidder'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 bidding firm must have the authority to commit the bidding firm to the details contained in the proposal.

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

2.4 Validity

Proposals must remain open for acceptance for a period of sixty (60) calendar days after the closing date of the RFSO.

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

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 2.1. All enquiries and responses to them will be publicly posted.

Enquiry Schedule: Refer to Table 1

Proponents are advised to check the CADTH website daily for update Bulletins.

<https://cadth.ca/careers/freelance-contractors/request-for-proposals>

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

2.7 Acceptance of Proposal

CADTH reserves the right to award in its best interest. 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

Evaluation of the proposals will be based on the evaluation criteria outlined in Appendix “A”.

3.2 Selection Methodology

All proposals will be individually evaluated by a CADTH team. The results of these evaluations will be consolidated and the contract award will be made to the proposal that scores the highest combined total of the rated evaluation criteria, along with consideration of the overall cost proposed. 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.

Notes:

- As part of the selection process, Proponents may be requested to present their credentials via an in-person or video-conference meeting.
- Proponents may be required to participate in an appropriate CADTH issued test to assess the Proponent(s) skill(s).

4.0 Statement of Work

4.1 Working with CADTH

The successful bidder agrees to execute a CADTH Standing Offer Agreement for this work.

It is understood and agreed that:

- a) A contractual obligation will come into force only if there is an authorized “Call-up” against a Standing Offer and only to the extent stipulated in the Call-up;
- b) This RFSO does not oblige CADTH to authorize or order any services whatsoever or to spend the estimated expenditure or any monies whatsoever.

The successful bidder agrees to follow CADTH procedures and use CADTH forms and templates as required.

All properly submitted invoices will be paid thirty (30) calendar days after receipt.

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

The majority of the work is expected to be performed at the contractor's facilities. The location of meetings will be arranged between the successful bidder and CADTH.

4.4 Period of Contract

It is expected that the successful supplier selected from this process will commence work on this project on June 3, 2019. The work must be completed by June 2, 2020.

Work commencement date may change depending on CADTH's requirements and will be mutually agreed to between CADTH and the successful bidder(s).

Upon mutual agreement between CADTH and the Contractor, the Standing Offer may be extended for up to 2 (two) additional years. The bidder's Cover Letter is to indicate acceptance of this possible extension.

4.5 Services Overview and Requirements

CADTH is seeking contractors to provide Scientific Advisor (Methodologist) services.

The Scientific Advisor promotes methodological rigour and quality standards by supporting research staff and thorough reviews of CADTH reports. In addition, as a member of the Scientific Affairs team, you will support the Scientific Advice program which provides scientific and clinical advice to pharmaceutical manufacturers from a health technology assessment perspective on their proposed plans for early drug development.

a) Responsibilities Related to Scientific Affairs

- Conduct internal reviews of CADTH reports (e.g., formulary reviews, therapeutic reviews, and health technology assessments), ensuring adherence to all established internal processes, methodologies, and quality standards
- Provide leadership in the development and maintenance of CADTH methods
- Provide advice to research staff on methods including protocol development, data analysis, statistical analysis, and guidance in the interpretation of statistical analyses
- Develop and deliver technical education and training for internal research staff and external clients, including the supervision of students

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- Liaise with experts and representatives of academia and external organizations or agencies (local, provincial, and national) to promote and align CADTH's methods, processes, approaches, and tools with current best practices to ensure scientific credibility and continuous quality improvement, and to reduce duplication
- Develop and deliver key strategic initiative papers related to scientific and technical methods, processes, etc., including “white paper” briefs that are the foundation of future CADTH activities with CADTH stakeholders and partners in Canada and internationally
- Prepare CADTH methodology reports and peer-reviewed manuscripts, as required.

b) Responsibilities Related to the Scientific Advice Program

- Provide methodologic expertise and critical feedback on draft reports developed by the CADTH Scientific Advice team
- Lead Scientific Advice teams to provide high-quality scientific advice to pharmaceutical manufacturers on their early clinical development programs
- Critically appraise material related to the preparation of draft responses to questions posed by the manufacturer regarding drug development plans
- Gather, analyze, synthesize, and interpret relevant evidence, and evaluate the validity and relevance of complex and potentially conflicting data
- Assess the completeness of the evidence base, issues for discussion, identification of key issues, and suggestions to address gaps
- Determine the appropriate expertise required, identify appropriate experts to consult, and formulate key questions
- Lead high-level scientific advice meetings with pharmaceutical manufacturers and clinical and academic experts; attend CADTH Canadian Drug Expert Committee (CDEC) and CADTH pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) meetings
- Keep abreast of current issues in the CADTH Common Drug Review (CDR) and the CADTH pCODR
- Stay current on new developments in clinical trial design and analysis relevant to the Scientific Advice Program.

c) Core Requirements

- The minimum formal knowledge requirement is a PhD in a health-related research methods discipline (e.g., clinical epidemiology, health outcomes research, health research methods). A PharmD or an MD with an MSc in a health-related research methods discipline and a strong research background may be considered. A minimum of six (6) to eight (8) years of progressive experience in drug evaluation is also required.
- This position requires a broad knowledge of and experience in research methods used in the assessment of pharmaceuticals for formulary reimbursement and health technology assessments (e.g., quality assessment of clinical trials, network meta-analyses, observational study design methods).
- In-depth knowledge and expertise in traditional and complex clinical trial designs and related research methods combined with extensive experience with critical

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appraisals of clinical trials for pharmaceuticals, particularly with complex clinical trial designs (e.g., adaptive trial designs, sequential methods, enrichment designs)

- Extensive knowledge of key methodological guidance reports and guidelines related to the conduct of clinical trials, and the ability to apply that knowledge to the critical appraisal of individual clinical trials
- Experience in the peer-review process used for scientific reports and consulting with clinical and academic experts
- A demonstrated ability to guide staff in the development of protocols, the application of research methods, and in the writing of CADTH reports
- Strong communication skills including writing, negotiation, facilitation, and the ability to effectively present to and communicate with a large and diverse group of stakeholders
- The ability to build and maintain strong working relationships with a variety of internal and external audiences
- Exceptional analytical and problem-solving skills, with the ability to independently problem-solve and determine the best course of action using research, logic, and evaluative judgment
- Being organized, proactive, attentive to detail, and resilient in the context of tight deadlines, multiple tasks, and conflicting priorities
- A collaborative approach; tactful, respectful, and diplomatic
- An understanding of the Canadian health care system and knowledge of the health technology-related decision-making processes within the federal, provincial, and territorial bodies.

d) Assets

- A health professional degree (e.g., pharmacy, medicine, or nursing)
- Experience working with CDR, pCODR, CDEC, pERC, or other formulary review committees
- Clinical experience in a health care setting
- Expertise in biostatistics
- Knowledge of, and experience in, pharmacoeconomics.

e) References

Bidders that are short listed may be requested to provide references. Otherwise, there is no need to provide references with the bidder's submission.

f) Effort

It is estimated that up to 100 hours per month may be required. CADTH would allocate work by appropriately matching needs with the bidder's skill set. Some work will be related to specific projects and reports; other tasks will be more content development for training, or process-related work.

g) Fees

CADTH offers a rate of \$100 per hour for this service. The Contractor is to invoice for actual time only not to exceed the agreed to number of hours for each task. Any changes to tasks or hours are to be mutually agreed to in advance.

**Appendix “A”
Proposal Preparation Instructions and Evaluation Criteria**

The Bidder’s Submission is to be in two documents: Cover Letter and Resume.

The Submission will be evaluated on the following:

Criteria	Weighting	Description
<p>1. Errors and Omissions (E&O) Insurance</p> <p>Reference Section 4.1 of this RFSO: The successful bidder agrees to execute a CADTH Contract for this work.</p>	<p>Mandatory 0% (pass or fail)</p>	<p>In the CADTH Contract, E&O insurance of \$2,000,000 is required. Refer to Insurance FAQ in Appendix “B” for more details. The bidder’s Cover Letter is to indicate E&O insurance status.</p>
<p>2. Liability Insurance</p> <p>Reference Section 4.1 of this RFSO: The successful bidder agrees to execute a CADTH Contract for this work.</p>	<p>Mandatory 0% (pass or fail)</p>	<p>In the CADTH Contract, liability insurance of \$2,000,000 is required. Refer to Insurance FAQ in Appendix “B” for more details. The bidder’s Cover Letter is to indicate liability insurance status.</p>
<p>3. Conflict of Interest (COI)</p> <p>Reference Section 4.1 of this RFSO: The successful bidder agrees to execute a CADTH Contract for this work.</p>	<p>Mandatory 0% (pass or fail)</p>	<p>Contractors that receive funding from industry may not be eligible to work with CADTH. The bidder’s Cover Letter is to indicate COI status.</p> <p>More information and CADTH’s COI Guidelines can be found at the link below.</p> <p>https://cadth.ca/sites/default/files/corporate/CADTH-COI-Guidelines-Contractors-R1.1_e.pdf</p>

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Criteria	Weighting	Description
4. Reference Section 4.4 of this RFSO	Mandatory 0% (pass or fail)	Upon mutual agreement between CADTH and the then successful contractor, this work arrangement may be extended for up to 2 (two) additional years. The bidder's Cover Letter is to indicate acceptance of this possible extension.
5. Effort Reference Section 4.5f of this RFSO	Mandatory 0% (pass or fail)	The amount of work may vary from month to month. The bidder's Cover Letter is to indicate their availability to perform the services.
6. Fees Reference Section 4.5g of this RFSO	Mandatory 0% (pass or fail)	CADTH offers a rate of \$100 per hour for this service. The bidder's Cover Letter is to indicate their acceptance of this rate.
7. Experience and Qualifications Reference Section 4.5 of this RFSO	100%	The Bidder is to submit a resume that demonstrates the Bidder's: <ul style="list-style-type: none"> • ability to perform the Responsibilities • education and experience to meet the Core Requirements of the role or roles they are interested in • knowledge and experience related to the Assets

Appendix “B” Insurance Frequently Asked Questions (FAQ)

Follows on next page

FAQ

Insurance Requirements for CADTH Contractors

1. Q. Why does CADTH now require insurance coverage for contractors?

A. Recently, some of CADTH's Funders have requested that CADTH ensure contractors have adequate insurance. This was changed because of how our Funders view risk and how best to mitigate this risk.

2. Q. When does the change take effect?

A. At April 1st, 2016 this change takes effect. CADTH needs to consider insurance coverage that contractors have in place when completing any new contracts after this date

3. Q. What are CADTH's insurance requirements for Contractors?

A. CADTH's Contracts and Agreements have the insurance requirements listed below. These are essentially asking our contractors to have insurance that can cover liability and errors and omissions.

- a. At its own cost and expense, arrange for and keep enforced comprehensive liability insurance against all claims for damage or injury, including death, to any person or persons and for damage to any property or any loss for which the Contractor may become liable resulting from the performance, or non-performance of the Services or other services hereunder, with a policy limit of not less than \$2,000,000.
- b. At its own cost and expense, arrange for and keep Errors and Omissions (E &O) insurance in an amount not less than \$2,000,000 per claim insuring its liability resulting from errors and omissions in the performance of its professional services under this Contract. Such insurance is required to remain in place for a period of 12 months following the completion or termination of this Contract. Such insurance shall include bodily injury coverage.
- c. Deliver, upon request by CADTH, evidence that such policies of insurance have been obtained by the Contractor and are being maintained in good

standing.

4. **Q.** I'm a small business with no employees and it's financially difficult for me to afford this insurance. Are there any other options?

A. It is good business practice to understand your risks related to both E&O and Liability issues and to consider insurance that you may require for all business activities that you carry out. That being said, CADTH's E&O insurance does cover small independent contractors. If you are a sole proprietor or incorporated with very few employees, our insurance can cover you in this instance. Please let your contact know if this is the case.

CADTH's insurance does not cover you for Liability. In some instances, we can waive the requirement in the contract. Please let your contact know if this is the case and we can determine the best way forward.

5. **Q.** I would like this contract to be with the institution or business where I am employed. What impact does this have on the insurance requirements?

A. Insurance is still a requirement of the contract in this instance. Please check with the finance or contracting department at your institution or business to ensure that the insurance requirement can be met. CADTH insurance does not cover institutions or businesses.

6. **Q.** I'm a licensed Doctor and a paid member of the CMPA; does this cover me?

A. Please contact Member Services at CMPA and they can advise you on the coverage that you have. If you are not covered by CMPA, please note that CADTH can cover you as stated in question 4 above.