

CADTH Post-Market Drug Evaluation

Bulletin #02

RFP Questions and Answers from RFP Information Session on February 8, 2022

Competition File C-220350

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Notes by CADTH:

- 1. Questions may have been edited for clarity or to maintain confidentiality.**
- 2. All questions are from the CADTH Information Session held on February 8, 2022.**

Question #01

Reference: PMDE Program General Question.

Question: What is the role of steps like Research Ethics Board (REB) applications, how will that type of upfront work be handled between core network partners and the Operations Centre?

Answer: Core Network Partners will ultimately be conducting research and will have to follow their institutions REB protocol when necessary. The Operations Centre will not be conducting any research, but rather supporting the query process, the customer and the network.

Question #02

Reference: PMDE Program General Question.

Question: Can industry submit queries to the program? Will industry have a place in this program?

Answer: At the launch of this new program, the customers of the PMDE program will be the federal, provincial and territorial decision makers outlined in the PMDE program Overview, however CADTH may consider adding eligible customers to the program over time. Engaging with patients, clinicians, and industry is a cornerstone at CADTH and we will work to carry this on in the PMDE program. We are looking at opportunities to partner and collaborate with all stakeholders, including with industry.

Question #03

Reference: PMDE Program General Question.

Question: Will Core Network Partners and Standing Offer contractors be able to publish their work?

Answer: Yes – however the focus and priority will be getting evidence to the customers. Once customers have received their reports, the query response team may elect to publish. More details are available in the PMDE Program Overview, as well as the RFP Appendix B – Eligible and Ineligible expenses.

Question #04

Reference: PMDE Program General Question.

Question: How is the patient perspective being captured in this work?

Answer: There are a few ways in which the PMDE program hopes to engage with patients. The PMDE Advisory Panel will include the patient voice as part of its membership. Additionally, Core Network Partners and Standing Offer contractors are also being asked to provide plans in their proposal to outline how they will be including the patient voice when possible (depending on the nature of the query) and may also receive some support/guidance from CADTH's patient engagement team.

Question #05

Reference: PMDE Program General Question.

Question: How will CADTH ensure a consistent stream/volume of queries to the network?

Answer: The PMDE Team will work closely with the customers through various existing CADTH channels to promote the program and help identify potential queries. The intent is to ensure a consistent level of work across the network by identifying potential queries proactively based on CADTH's needs of the regulatory and reimbursement pharmaceutical landscape and decision-makers' needs, and balancing those against queries that are submitted from customers. CADTH will also leverage its visibility throughout the drug lifecycle (from early scientific advice up, to formulary review, to drug HTA) to create a pipeline of potential query topics.

Question #06

Reference: PMDE Program General Question.

Question: Will PMDE continue investing in capacity building and training of Highly Qualified Personnel (HQP)?

Answer: Although the DSEN program functions were largely transferred to CADTH, the investment in training and capacity building has been retained by CIHR given their history and strength in capacity building. CADTH and CIHR will work closely to ensure that the network continues building capacity and training in the post-market evaluation space. While direct investment in this function is not a goal of the PMDE program, the PMDE network is looking to continue to support established senior scientists while also involving early-career scientists.

Question #07

Reference: PMDE Program General Question.

Question: How will PMDE's work be integrated with CADTH's existing efforts in Real World Evidence (RWE)?

Answer: Prior to the transition of the DSEN functions to CADTH, CADTH had been working establishing an RWE function internally. RWE will be a pillar of the PMDE work and as such CADTH's PMDE team and RWE team are working hand in hand and meeting regularly to integrate these two initiatives.

Question #08

Reference: PMDE Program General Question.

Question: How will the PMDE enhance (or at least not add to) the timelines of the existing processes, some of which are still serial?

Answer: The PMDE network has introduced new processes with the intent to reduce the timelines seen with answering queries. Queries will be coming into dedicated staff that will work with requestors to better define the questions, conduct a feasibility assessment, and scope and refine the request. There will also be a project management process in place with clear timelines and deliverables expected for network partners. By centralizing the query process to identify the appropriate response teams within the network there should be reduced timelines to initiate a project.

Question #09

Reference: PMDE Program General Question.

Question: Is the intent of the PDME program to replace CADTH's Request for Advice (RFA) process (and broaden it), or is it a program that will supplement the existing RFA process?

Answer: The PMDE program will not replace any CADTH program. By adding PMDE to its suite of programs, CADTH will be engaged throughout the process, from pre-submission to post-market.

Question #10

Reference: PMDE Program General Question.

Question: Will PMDE take over responsibility of conducting class reviews?

Answer: The PMDE network is not intending to take over responsibility and be the sole producer of class reviews, but instead will be one of the options considered within CADTH if a federal, provincial or territorial decision-maker makes a request.

Question #11

Reference: PMDE Program General Question.

Question: Will evaluations follow the same framework as CDR?

Answer: The PMDE program will not be evaluating drugs for the purposes of an expert review and recommendations. The program will instead be considering post-marketing data for the purposes of safety and effectiveness evaluation. Queries will be submitted by decision makers, assessed, and evaluated and if approved sent to one of the Core Network Partners or Contractors to respond to. Note by CADTH: CDR (Common Drug Review) was renamed CRR (CADTH Reimbursement Review) in 2020.

Question #12

Reference: PMDE Program General Question.

Question: Can you provide examples of types of queries expected?

Answer: As the PMDE program will only launch in September 2022, CADTH has not yet received queries from customers. Interested applicants can refer to CIHR's DSEN webpage for a list of previous and ongoing queries to gain some insight into the types of queries asked by customers.

Question #13

Reference: PMDE Program General Question.

Question: What is an expected turn around time for work to be submitted for a typical query?

Answer: Turn around time will depend on the complexity of the query, available data, and various factors. The PMDE Operations Centre will work to develop process and templates for some queries, however queries can be quite complex in nature and may require customized work and reports. The PMDE program will be transparent and clear on the types of queries, and the expectations around the deliverables at the start of each request.

Question #14

Reference: PMDE Program General Question.

Question: As the core networks and contractors receive this funding, do they get ownership of the work produced (evidence) or ownership is shared?

Answer: The core network partners and contractors will have shared ownership of the work produced. Once the query report has been delivered to the customer, the network partner may use this evidence to publish or disseminate at conference, symposia, etc. The PMDE network should also have access to this evidence for follow-up aspects of the query, and for requests for appraisal and validation.

Question #15

Reference: PMDE Program General Question.

Question: How is conflict of interest (COI) being handled within the RFP process, core team applications and the eventual PMDE functions?

Answer: CADTH has a well-established COI process and will continue to apply the COI policy to the PMDE work and the PMDE network. CADTH intends to be transparent about all COIs.

Question #16

Reference: PMDE Program General Question.

Question: Will there be overlap in scope of PMDE program work and existing CADTH products and services?

Answer: The PMDE program is embedded in CADTH, and ongoing work is looking to dovetail its scope into the other HTA programs already in place. This synergy will allow CADTH to determine the most ideal resources to leverage in responding to a query based on capacity, most appropriate output, required expertise, and timelines. CADTH as an organization strives to produce evidence for decision-makers, and this goal will become more manageable and efficient with the introduction of the PMDE program.

Question #17

Reference: PMDE Program General Question.

Question: Is there an expectation that the volume of post market evaluations that CADTH is currently handling going to grow with the creation of the PMDE?

Answer: Although CADTH cannot predict the volume of queries submitted from customers, PMDE hopes to leverage CADTH's existing position in the health system and relationships with customers to support them in their post-market drug evaluation needs. This may result in a greater volume of evaluations and the program will adapt to best meet these needs.

Question #18

Reference: PMDE Program General Question.

Question: Will the research teams be required to go through CADTH to access data from variety of data partners?

Answer: No – research teams are not required to go through CADTH as some Core Network Partners and Contractors may have access or own data. However, CADTH will act as a facilitator and coordinator, when possible, to link the PMDE network to available data sources.

Question #19

Reference: PMDE Program General Question.

Question: Is the view of this work to be analysis/query reports conducted for health system planning or from an academic lens?

Answer: The focus of the program is to provide evidence to customers (federal, provincial, territorial decision-makers) to support their decision-making needs.

Question #20

Reference: PMDE General Question not related to the RFP for Core Network Partners. This question refers to the RFP for Standing Offers to be issued on March 15, 2022.

Question: What is the minimum number of queries required to work on by the Standing Offer contractors?

Answer: The minimum number of queries will be determined based on the applicant's proposal and further negotiation prior to being awarded a Standing Offer.

Question #21

Reference: RFP Section 1.2 PMDE Program Overview.

Question: Can you clarify who is driving the research question(s)?

Answer: The PMDE customers (federal, provincial and territorial decision-makers) will be submitting the queries to the PMDE program and thus driving the research agenda for the PMDE network.

Question #22

Reference: RFP Section 1.2 PMDE Program Overview goal 3.

Question: How will the new program improve knowledge dissemination?

Answer: CADTH is fortunate to have an exceptional implementation support and knowledge mobilization (ISKM) function which has Liaison Officers in most provinces, territories, and federal (FPT) government in our country. The PMDE program will be able to leverage this ISKM team to ensure queries are disseminated to all decision-makers and support their needs. Also, CADTH is also quite fortunate to have the ability to connect with the FPT decision-makers on a regular basis through our many committees and working groups. This will help with cross jurisdictional awareness and sharing of evidence once completed.

Question #23

Reference: RFP Section 2.3 Proposal. Also, in the PMDE Core Network Partner Proposal Guide 2022, Section 2.1 Technical Proposal.

Question: Will appendices be accepted as a separate document but complement to the technical report?

Answer: Additional documents can be added either as appendices to the technical proposal or as stand-alone documents. For more information about the format of these documents, please refer to the PMDE Core Network Partner RFP document and the PMDE Core Network Partner Proposal Guide.

Question #24

Reference: RFP 2.3.3 Proposal Preparation Instructions.

Question: Are you looking for expertise in areas of therapeutic subspecialty/ diseases-specific teams?

Answer: The PMDE program is looking to fund applied researchers, methodologists and data analysts that can respond to various queries submitted by the customers. As we cannot predict the incoming queries, the network will be built around methodological needs and not by therapeutic area.

Question #25

Reference: RFP Section 2.3.3 Proposal Preparation Instructions item g).

Question: Will the PMDE program conduct sex, gender, and health equity analysis?

Answer: Yes – the PMDE program plans to collect data on equity, diversity, and inclusivity from its network members (Core Network Partners and Standing Offer Contractors). All applicants are asked to provide plans to address sex, gender and health equity in their team selection process and project work. .

Question #26

Reference: RFP Section 3.1 Proposal Evaluation.

Question: Who will be reviewing the applications?

Answer: Applications submitted to CADTH will be reviewed by a selection panel consisting of external methodological experts, post-market evaluation experts, decision makers and internal senior CADTH staff.

Question #27

Reference: RFP Section 4.1 Working With CADTH.

Question: how will data that is proprietary or resides with a manufacturer be integrated in PDME, especially as it relates to confidentiality, manufacturer right to publish vs. PMDE/contractor desire to publish?

Answer: CADTH and its PMDE Operations Centre will not own, house, or collect data. The Core Network Partners and Contractors will be the data stewards for the data that they gather. As the focus of the PMDE work is to provide customers with evidence to meet their needs for decision-making, all Core Network Partners and Standing Offer Contractors funded through PMDE are welcome to publish, however the priority will be responding to the customer.

Question #28

Reference: RFP Section 4.1 Working with CADTH.

Question: If applicants are unsuccessful in securing a Core Network Partner grant, can they submit as individuals for a Standing Offer?

Answer: Yes – the RFP for standing offer Standing Offers will launch March 15, 2022 and will close May 17, 2022. Applicants will receive notice on the outcome of their grant applications by April 22, 2022, allowing them over 3 weeks to prepare a proposal for a standing offer.

Question #29

Reference: RFP Section 4.1 Working with CADTH.

Question: Can an investigator be both a member of a Core Network Partner and a Standing Offer Contractor

Answer: No – the new PMDE funding model is intended to broaden the pool of researchers, methodologists and analysts by expanding the network beyond granted teams with contracts.

Question #30

Reference: RFP Section 4.1 Working with CADTH.

Question: Is this RFP process only for core network partners? What about those who might be more suited as a Standing Offer Contractor?

Answer: This current RFP is for Core Network Partners only. The RFP for Standing Offers will be release March 15, 2022 and will close May 17, 2022.

Question #31

Reference: RFP Section 4.1 Working with CADTH.

Question: Is the RFP process only for core network partners? What about those who might be more suited as a Standing Offer Contractor?

Answer: Duplicate question. For answer, refer to Question 20 in this Bulletin.

Question #32

Reference: RFP Section 4.5 Budget.

Question: Is the budget \$4.3 million per team over 3-4 years?

Answer: No – the \$4.3 million is the total annual budget for all Core Network Partners. CADTH hopes to fund 3 or 4 Core Network Partners. Applicant's must submit a budget that is within this total budget.

Question #33

Reference: RFP Appendix A.

Question: Do applicants need to have access to data to be successful?

Answer: Although the technical proposal asks applicants to indicate what data they have access to; it is not a requirement. Emphasis will be on the capabilities and capacity of the applicant's team. Additionally, not all queries will require the need for real world data and may instead involve publicly available data.

Question #34

Reference: RFP Appendix A Table 2 Criteria 5. Also, in the Proposal Guide Section 2.3 Attachments.

Question: Can you provide more information on who should write a reference letter?

Answer: Reference letters should be written by references who have worked with your group in the past and can provide relevant insight into your team's work in the PMDE space. Perceived bias should be considered when selecting references. CADTH staff can not provide letters for applicants.

Question #35

Reference: Letter of Intent (LOI) Form.

Question: The LOI lists spots for 5 co-applicants. Is that the maximum? Can we include more investigators?

Answer: Although teams may be larger than 5, please only list the leads/PIs as co-applicants. If there are more than 5 leads/PIs, you may indicate this in the Technical Proposal.

Question #36

Reference: PMDE Core Network Partner Proposal Guide 2022, Section 2. Guidelines for the Proposal.

Question: Some data analysis may require using provincial administrative databases. How will these costs be covered? These questions cannot be pre-planned by the teams.

Answer: Access to provincial administrative databases will not be the sole responsibility of the network partners and may in part be partly coordinated by the PMDE Operations Center, through collaborative partnerships, and by the network partners where possible. Teams are not expected to have insight into potential queries and the data costs associated with those queries.

Question #37

Reference: PMDE Core Network Partner Proposal Guide 2022, Section 7. Partner Funds or In-Kind Contributions.

Question: Can you please provide information on partner and in-kind funding? What kind of partners (pharma, regulators, international or Canadian only)? If no partner funding is listed how does this affect chances of funding?

Answer: Additional partner funding is not required to be successful in securing PMDE grant funding. Any relevant partners should be listed (industry, patient advocates, clinicians, researchers, etc.) and can include domestic and international. This information is intended to provide the review panel with additional information on the applying team's network and reach in the PMDE space.

Question #38

Reference: PMDE Core Network Partner Proposal Guide 2022, Section 7. Partner Funds or In-Kind Contributions.

Question: Are applicants expected to link up with industry partners?

Answer: No – applicants are not expected to be linked to industry.

End of file.