# Bulletin #06 Request for Proposal Questions and Answers

# File #C-2401280 Rare Disease Registry Funding

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### Canada's Drug Agency L'Agence des médicaments du Canada

## Questions may have been edited for clarity or to maintain confidentiality. Answers will be provided in the language of the original submission.

#### Question 1, Received April 24, 2024

Reference Request for Proposal (RFP) Section 3.1 (Proposal Components)

**Question:** Are "legal costs" specific costs paid out for legal services to a lawyer, or do they cover any work relating to the items given in the example (e.g., policies, consenting procedures), even if it is not carried out by a lawyer?

**Answer:** Legal costs are specific costs paid out for legal services to a lawyer. These costs are not for work related to legal matters, such as developing policies or consenting procedures, but rather the professional fees incurred when a lawyer is engaged to perform these tasks or provide legal guidance on them. If the work is done internally without engaging a lawyer, it would not typically be categorized as a "legal cost" but perhaps as an administrative or operational expense.

#### Question 2, Received April 24, 2024

Reference RFP Section 3.1 (Proposal Components)

**Question:** If we have an expense that is not necessarily hourly (e.g., work with a consultant billed at a flat fee), should we still input it with an approximate hourly rate in the template? Or is there an alternative place the team would like to see that?

**Answer:** If you have an expense that is not based on an hourly rate, such as a flat fee for consultant work, it would not be appropriate to approximate this with an hourly rate. The financial template is designed to standardize submissions, but it should also accommodate the reality of different billing structures. In this case, you can include a separate line item for flat-fee services and note the total cost as a lump sum. You can also provide a brief description of the service provided, for clarity.

#### Question 3, Received April 29, 2024

Reference RFP Section 3.1 (Proposal Components)

**Question:** The Excel sheet for the Financial Proposal Form contains a row specifically for administrative costs based on the total budget. Is this cell of the Excel sheet where you would like the overhead costs to be presented? Are there any sections of the Technical Proposal where the justification for the overhead costs should be presented?

**Answer:** Yes, the row for administrative costs in the Financial Proposal Form is where overhead costs should be presented. If there are other types of administrative expenses that differ from general overhead costs, please ensure these are detailed separately within the form to maintain clarity. Additionally, justifications for the overhead costs can be included in the Technical Proposal, where it should be clearly explained how these costs support the project objectives, ensuring that the justification aligns with the overall budget and project plan.

#### Question 4, Received April 29, 2024

Reference RFP Section 3.2.1 (Technical Proposal Preparation Instructions)

Question: Can you please provide clarification on the following?

- Important points to consider regarding CADTH assessments
- Data points or parameters to incorporate into a new or expanding registry to assist in the consideration of a new drug for a specific patient group.

**Answer:** When considering health technology assessments (HTAs) and determining necessary data points for a registry, the focus should be on the disease or condition being tracked and the specific treatment under evaluation. Due to the diversity and specific needs of different diseases, we do not provide a one-size-fits-all list of data points. We recommend that the developers of the registry determine the most relevant and critical data elements based on the disease characteristics, registry goals, clinical requirements, and clinical trials to ensure that the registry can provide valuable insights and support effective regulatory and HTA decision-making.

#### Question 5, Received April 30, 2024

**Question:** Are letters of support allowed to be included as supplementary materials? Is there a designated area for documentation related to the project to be shared with reviewers? Do all figures, tables, and any supplemental materials count as part of the 8-page limit?

**Answer:** Yes, letters of support from the host institution, if applicable, are encouraged and can be included with your application, and these do not count toward the 8-page limit. However, all figures, tables, and other types of supplementary materials will be included in the 8-page limit.

#### Question 6, Received May 3, 2024

**Question:** Does the 8-page proposal limit include the references section, and can we add appendices like data collection forms, diagrams, or our timeline?

**Answer:** The 8-page limit includes all sections, such as references, appendices, and supporting documents. Any diagrams, timelines, or data collection forms should be included within the page limit. Providing a web link for supplementary information is allowed; however, note that all key information must be presented and included within the first 8 pages of the submission.

#### Question 7, Received May 3, 2024

**Question:** Are CVs required for the submission, and is a specific format necessary (e.g., Canadian Common CV)?

Answer: CVs are not required for the submission.

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#### Question 8, Received April 30, 2024

**Question:** Would you be able to share example applications or similarly funded registry projects?

Answer: We are unable to share example applications or details of similarly funded projects.

#### Question 9, Received April 30, 2024

Question: Are the proposal documents to be submitted to contracts@cadth.ca?

Answer: Yes, all proposal documents need to be submitted to contracts@cadth.ca.

#### Question 10, Received May 1, 2024

**Question:** Should the Financial Proposal Form be submitted as part of the RFP or as a separate document, especially if it exceeds the 8-page updated limit?

**Answer:** The Financial Proposal Form in Excel should be submitted as a separate document. It is not included in the 8-page limit for the RFP.

#### Question 11, Received May 3, 2024

**Question:** Should we include a supporting Budget Justification? Could this be an appendix to the Technical Proposal? Is there a maximum page limit?

**Answer:** Yes, you can include a Budget Justification, but it must fit within the 8-page limit of the overall proposal.

End of file.