Health Canada Santé Canada

**Request for Information (RFI) Number: 1000219597**

**Health Canada**
Health Products and Food Branch/Therapeutic Products Directorate

**Project Title:** Describing the Impacts and Costs for Stakeholders Associated with the Potential Health Canada Implementation of a Unique Device Identification System for Medical Devices

**Purpose:**

The purpose of this Request for Information (RFI) enquiry is as follows:

Health Canada requires the services of a Contractor to develop a report describing the qualitative and quantitative impacts and costs to stakeholders that would be incurred with the potential implementation of a Unique Device Identification (UDI) system for medical devices in Canada. Health Canada is interested in the impacts and costs on the following stakeholder groups: hospitals, clinics, medical device manufacturers, and provincial/territorial governments.

Through the implementation of this Contract, Health Canada hopes to:

- Gain more information about the impacts and costs incurred by the various stakeholders when considering the potential implementation of UDI;
- Assess the readiness of the various stakeholders that could be impacted by UDI; and
- Help to determine the utility of UDI to the Canadian medical device landscape.

Health Canada is interested in knowing what the potential impact of implementing UDI will be on the various stakeholders and how UDI will be received by various stakeholders (particularly small medical device manufacturers and small clinics). This information will help Health Canada weigh the costs of UDI in comparison to the benefits, and thereby inform next steps, including whether Health Canada should continue to invest in UDI implementation in Canada.

In order to inform next steps with respect to the UDI initiative, Health Canada has determined that it needs additional information on the costs and impacts of UDI on a wider range of stakeholders, in addition to industry.

Given the current state of the pandemic and the uncertainty around it, Health Canada will take a phased-in approach:

**Phase-1:** This phase would cover interviews with medical devices stakeholders working outside the hospital setting.

**Phase-2 (Optional phase):** Pandemic permitting, this phase would cover on-site hospital, clinics visits. This could be done one year after all the deliverables described above are complete.

Health Canada is looking to this Contract to fill the gap in both qualitative and quantitative information. Health Canada expects the Contractor to address the relevant issues with the stakeholders in order to receive qualitative feedback, and further request quantitative information, as to how the introduction of UDI would impact either their business or their line of work.

Health Canada anticipates using the results of this report to inform their decisions about whether, when and how to introduce UDI into the Canadian regulations, and how to best work with stakeholders in order to mitigate potential negative impacts that the introduction of UDI would have on stakeholders. Health Canada also hopes to learn from this Contract about the positive impacts and potential success stories that might occur through the use of UDI, throughout the system. Health Canada is particularly interested in the impacts of UDI on small medical device manufacturers, small independent medical clinics and individual doctor's offices.

In phase 1, the Contractor would be responsible for the following:

1) Conducting background research to understand UDI and the potential impacts on stakeholders (background research may be incorporated into the report as context);

2) Developing a list of potential interviewees from the affected stakeholder groups;

3) Developing a list of questions to ask interviewees from the affected stakeholder groups;

4) Conducting stakeholder interviews to discuss the costs and impacts of UDI on stakeholders, as well as the positive and negative impacts of UDI on their business;

5) Analyzing and synthesizing the qualitative and quantitative data received from the interviewees, including validation of stakeholder responses as necessary;

6) Preparing a report, with both quantitative and qualitative elements, that describes the costs and impacts of UDI on stakeholders; and

7) Submitting the report to Health Canada and making themselves available to discuss the findings of the report.

In phase 2 (The Optional Phase): Pandemic permitting, the Contractor would be responsible for the following:

1) Travelling to up to three (3) on-site healthcare settings including, hospital, clinics sites to speak to interviewees and review how UDI is used in a healthcare setting.
2) These visits are to last (no more than 3 hours), and are allowed up to $5000 per visit for a planned 3 to 4 days per visit, that includes travel time to and forth the sites.
3) Submitting the report to Health Canada and making themselves available to discuss the findings of the report.

**Note to Potential Respondents:**

This is not a bid solicitation and a contract will not result.

Potential respondents are advised that any information submitted to the government in response to this Request for Information may be used by the government in the development of a subsequent Request for Proposal (RFP).

The issuance of this Request for Information does not create an obligation for Canada to issue a subsequent RFP.

It should also be noted that no agreement to do business with any respondent will result from this specific enquiry.

**Closing Date:**

Responses to this Request for Information will be accepted at any time until 12:00 pm EDT on July 3, 2021.

**Contracting Authority:**
All enquiries and responses related to this Request for Information shall be directed to the Contracting Authority:
*Shallee Doll*
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