Government of Canada / Gouvernement du Canada

Notice: Update to Clinical Trial Site Information Form

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In an effort to improve efficiencies, and to support the submission of Clinical Trial Applications (CTAs) using the electronic Common Technical Document (eCTD) format, Health Canada has updated the Clinical Trial Site Information (CTSI) form.

The changes to the form are summarized as follows:

- Drug Product and Sponsor information sections removed, as they are already found with the Clinical Trial Application.
- Ability to use previous versions of a completed form to make revisions, along with the ability to identify exactly which sections of the form are revised.
- 'Submit' buttons on the form allow for direct electronic filing to Health Canada. An application control number is required prior to submitting a CTSI form, so that Health Canada can make the necessary link between the application and relevant CTSI form(s).

In accordance with section C.05.006 (1)(d) of the Food and Drug Regulations, completed CTSI forms must be provided to Health Canada prior to commencement of the trial.

The new Clinical Trial Site Information form may be used immediately, however, it must be used as of January 2, 2020. The old form will not be accepted as of that date. Information on how to complete and submit the form to Health Canada is outlined in the instructions.

For questions related to Pharmaceutical CTSI forms, please contact hc.oct.enquiries-requetes.bec.sc@canada.ca

For questions related to Biologic CTSI forms, please contact hc.bgtd.ora.sc@canada.ca

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