Clinical Trials Quebec™ | Sponsors

Process for Submitting Approval Applications to Health Canada for Clinical Trial Drugs

Introduction

Assess the need for a consultation meeting

Build the application package

Submission to Health Canada

Review by Health Canada

Step 1

- The sponsor must submit a Clinical Trial Application (CTA) before initiating any clinical trial. This requirement applies to Phase I to III trials as well as comparative bioavailability studies, including those involving marketed drugs when approved parameters (such as indications, populations, routes of administration, or dosages) are modified.
- Clinical trials conducted within approved parameters, such as Phase IV trials, do not require a CTA. However, all trials must comply with Good Clinical Practices (GCP), include appropriate labeling, and obtain approval from a Research Ethics Board (REB).
- Finally, sponsors must register their trials in a recognized public registry, such as ClinicalTrials.gov or Current Controlled Trials, to ensure transparency.
- The guidance provided hereafter is based on the Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications and the current electronic specifications for submission.

Note

Official Health Canada publications take precedence over the content presented here.

Step 2

Health Canada encourages sponsors to request a consultation meeting before submitting a Clinical Trial Application (CTA). This type of meeting can be particularly helpful for new active substances or applications involving complex issues that Health Canada may not have previously addressed.

For more information

See section 2.2 Pre-CTA Consultation Meeting of the Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications.

Step 3

- A CTA/CTA-A consists of three parts (modules) in accordance with the Common Technical Document (CTD) format. The CTA must be submitted electronically, accompanied by a paper cover letter, and organized according to the current electronic document specifications.
- The structure of the clinical trial application package and a summary of its content are described in section 2.3.2 of Health Canada's Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications.
- **A supporting document for preparing the application package, intended to be consulted alongside the guidance documents, is available to provide additional comments and tips.**

Step 4

- Combine all application components into a single ZIP file.
- Send this file by email to the Pharmaceutical Drugs Directorate (PDD) at: oct.smd-dgp.bec@hc-sc.gc.ca.
- For more details, please refer to the supporting document.

Step 5

- The review process for CTAs and CTA-As begins with a preliminary step to assess the completeness of submissions. If gaps are identified, a clarification request or a rejection letter may be issued.
- Sponsors must respond to clarification requests within 2 calendar days. Failure to respond within this timeframe may result in the submission being rejected or withdrawn. Once the submission is deemed complete, an acknowledgment letter is sent, confirming the start of the 30-day review period, or 7 days for comparative bioavailability studies. Additional clarification requests may be issued during this period.
- A Notice of Non-Satisfaction (NNS) may also be issued if major deficiencies are identified or if the sponsor does not respond promptly to a clarification request. In such cases, the submission must be resubmitted as a new application with a new control number.
- If the submission is deemed acceptable, a No Objection Letter (NOL) is issued. Throughout the process, it is the sponsor's responsibility to address issues raised by Health Canada.
- If, after 30 calendar days, no NOL is issued, the CTA is considered authorized.