Supporting Document

Guidance Document for Clinical Trial Sponsors
Clinical Trial Applications

The reference document is available here. The instructions below reflect those recommended by Health Canada, in addition to the guidance provided in the official guidelines. Only the points requiring further explanation are addressed in this document.

Note: Depending on the stage of drug development, the information available for a CTA may be limited. In such cases, the sponsor must provide all available data at the time of submission.

Compilation of the CTA Dossier

MODULE 1 – INFORMATION ON ADMINISTRATION AND THE PRODUCT

1.0 Correspondence

1.2 Administrative Information

1.2.1 Application Forms

The form can be found on the main templates page. We strongly recommend completing it in MS Word format rather than using the online Smart Form, as the latter may occasionally cause issues for the sponsor. Please refer to the following instructions to complete it correctly.

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Some tips:

- Box 11: Confirm the sponsor* of the proposed clinical trial, meaning the person or entity assuming legal responsibility. If you are acting independently, your name must appear in this box, and you must complete and sign boxes 89 to 92 as well as 93 to 96. If you are acting under the authority of a university, hospital, or institution as a qualified investigator, you must complete and sign boxes 89 to 92, while boxes 93 to 96 must be completed and signed by the appropriate department head.
- Box 82: If no protocol number has yet been assigned, please create one. It should be an arbitrary combination of numbers and letters chosen by you, used for tracking purposes.
- Appendix 1: To be completed only if the clinical trial sponsor has authorized one or more third parties to import drugs for the clinical trial in Canada. Each authorized importer must be listed. As additional importers are identified, extra copies of Appendix 1 must be submitted to Health Canada. If the importer remains the same for an amendment request, it is not necessary to resubmit Appendix 1.
- Appendix 2: To be completed only if the signatory of form HC/SC 3011 is a third party acting on behalf of the manufacturer/sponsor of the company indicated in section 11. A separate authorization is required for each application.

*The **sponsor** is the individual, corporation, institution, or organization that conducts a clinical trial. The sponsor is solely responsible for complying with all regulatory requirements related to the conduct of the trial in Canada. When a third party, such as a contract research organization (CRO) or a site management organization (SMO), is delegated part or all of the sponsor's responsibilities through a written agreement, that party must also demonstrate compliance with the applicable regulatory requirements. If a physician is designated as the sponsor in the Clinical Trial Application (CTA), they must assume the responsibilities of both the sponsor and the qualified investigator. They are therefore responsible for ensuring compliance with the obligations set out in section C.05.010 of Division 5, Part C, and any other applicable sections of Division 5, Part C, at all clinical trial sites. Division 5, Part C does not distinguish between commercial and non-commercial sponsors.

1.2.5 Compliance and Site Information

1.2.5.1 Clinical Trial Site Information Forms (CTSI)

The form can be found on the main templates page.

Note: If the specific clinical trial sites, the date of Research Ethics Board (REB) approval (box 47), or the trial start date (box 35) are not known at the time of application, the form may be submitted for each site after the review is complete and before the study begins. Submit by email to mailto:clinical.trials.site-lieu.essai.clinique@hc-sc.gc.ca.

1.3 Product Information

1.3.1 Product Monograph

A copy of the current product monograph must be submitted (https://health-products.canada.ca/dpd-bdpp/?lang=eng).

1.3.4 Investigator's Brochure

The Investigator's Brochure contains preclinical and clinical data on the drug(s) responsible for/used in the study. It must include the information required under paragraph C.05.005(e) of the Food and Drug Regulations.

For guidance on its preparation, refer to the document: Good Clinical Practices: Integration of Addenda to ICH E6(R1) Topic E6(R2), Section 7. The regulation will change on April 1, 2026, but is already available: ICH Harmonised Guideline for Good Clinical Practice E6(R3).

Note: Please also consult the Notice to Stakeholders – Clarification of Requirements under the *Food and Drug Regulations* and the *Controlled Drugs and Substances Act* regarding clinical research with Psilocybin for additional considerations.

1.4 Health Canada Summaries

1.4.1 Protocol Safety and Efficacy Assessment Template-Clinical Trial Application (PSEAT- CTA)

Please refer to these guidelines for details on how to complete the form.
Note: This application must be submitted in MS Word format.

1.7 Clinical Trial Information

1.7.1 Study Protocol

A copy of the *final* version of the study protocol must be submitted. The information contained in the protocol must comply with the ICH guideline adopted by Health Canada entitled Guideline for Good Clinical Practice E6(R2). We encourage you to pay particular attention to Section 6 – Clinical Trial Protocol and Protocol Amendments, which addresses the essential aspects of clinical trial protocols.

Note: The protocol number must appear on the first page of the document and match the number indicated on Form 3011.

1.7.2 Informed Consent Form

Section 4.8, entitled Informed Consent of Trial Subjects, of the Guideline for Good Clinical Practice E6(R2) sets out the requirements for the content of the informed consent form. The regulation will change on April 1, 2026, but is already available: ICH Harmonised Guideline for Good Clinical Practice E6(R3) (see section 2.8).

The Health Canada Research Ethics Board has also published a document specifying the requirements for informed consent documents.

It is also recommended to review Chapter 3 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, which describes the ethical requirements applicable to consent in human research.

MODULE 2 – SUMMARIES OF THE COMMON TECHNICAL DOCUMENT

2.3 Quality Overall Summary (QOS)

PHARMACEUTICAL PRODUCTS

You must provide one of the following documents:

- A letter from the manufacturer confirming that the quality is identical to that of the marketed version, including the drug formulation, manufacturing process (same site), controls, specifications, and container closure systems, or explaining the differences between the investigational product and the marketed version;
- A letter of authorization from the manufacturer granting access to a previously approved CTA, confirming that no changes have been made to the quality information;

- A complete set of quality information in accordance with Health Canada guidelines. For reference, consult the following documents:
  - Notice and Guidance Document - Quality (Chemistry and Manufacturing)
  - Quality Overall Summary Template – Phase I
  - Quality Overall Summary Template – Phase II
  - Quality Overall Summary Template – Phase III

In accordance with section C.05.010(j) of the Food and Drug Regulations, the sponsor must ensure that the drug is manufactured, handled, and stored in compliance with **Good Manufacturing Practices (GMP)**.

STUDIES WITH PLACEBO

For studies involving a placebo, information on the placebo must be provided, including a description of the manufacturing process, the qualitative and quantitative list of ingredients, specifications, batches, as well as stability and establishment information.

BIOLOGICAL AND RADIOPHARMACEUTICAL PRODUCTS

For the section related to the quality of submissions concerning biological or radiopharmaceutical products, several documents describe the applicable summaries depending on the product type and context, notably the Quality Overall Summary (QOS) and the Quality Information Summary (QIS).

For more information:

- Quality Overall Summary – Biological Products (QOS-B)
- Guidance for industry on the preparation of the quality information for drug submissions in the CTD format: Biotherapeutic and blood products
- Draft Guidance for Industry, Preparation of the Quality Information for Radiopharmaceuticals (Schedule C Drugs) using the Quality Information Summary-Radiopharmaceuticals (QIS-R) and Certified Product Information Document

Sponsors should also refer to Health Canada's quality guidelines (chemistry and manufacturing), as well as notification updates, to obtain the most recent additional information.

Submission of the CTA File

Gather the documents into a ZIP file

Before submitting your file, you must organize the documents according to the current electronic specifications and place them in a ZIP file.

For convenience, the file PRODUCT NAME.zip contains the appropriate folder structure. Once the templates have been completed, the relevant documents must be placed in the corresponding folders of your electronic CTA.

Send the ZIP file

As an interim measure, your submissions may be sent to the Pharmaceutical Drugs Directorate (PDD) by email: oct.smd-dgp.bec@hc-sc.gc.ca. Sponsors may use this email address until further notice from the PDD.

Restrictions applicable to email submissions:

- The maximum email size accepted by the mail server is 20 megabytes (MB). Any file exceeding this size must be sent by courier. Please consult the Guidance Document: Non-eCTD Electronic Format for instructions regarding documents submitted by courier or mail. Your submission may also be divided and sent in multiple separate emails (for example, one email for Module 1 and another for Modules 2 and 3). The subject line of each email must clearly indicate the link between the submissions (for example, “Email 1 of 2: CTA or CTA-A, [product name], [protocol number]”).
- The subject line of the email must include the statement: “CTA or CTA-A, [product name], [protocol number]”.
- Emails received after 3:00 p.m. (EST) will be considered as received on the following business day.