REGULATORY FOCUS

The Canadian application process and alternate pathway for COVID-19–related

By Mukesh Kumar and Melanie Oakley

This article offers an overview of the clinical trial application process and guidance on the regulatory obligations pursuant to Part C, Division 5, of the Food and Drug Regulations "Drugs for Clinical Trials Involving Human Subjects" in Canada. The authors focus on clinical trial applications only for biologics (schedule D) and pharmaceuticals (schedule F). They provide information on a range clinical trial submission requirements and communication with Health Canada's relevant directorates and offices.

Introduction

The Health Products and Food Branch (HPFB) of Health Canada is the scientific and regulatory authority for health products and food in Canada.[1] The investigational product classification for pharmaceuticals or biologics is designated by the directorate within HPFB, which will review and authorize the clinical trials.[2] Clinical trial inspections are overseen by the Regulatory Operations and Enforcement Branch (**Figure 1**).

Part C, Division 5, of the Food and Drug Regulations (FDR), which came into effect on 1 September 2001, provides the regulatory guide and framework for the conduct of clinical trials in humans. Health Canada issued the guidance document, which incorporates International Council for Harmonization (ICH)

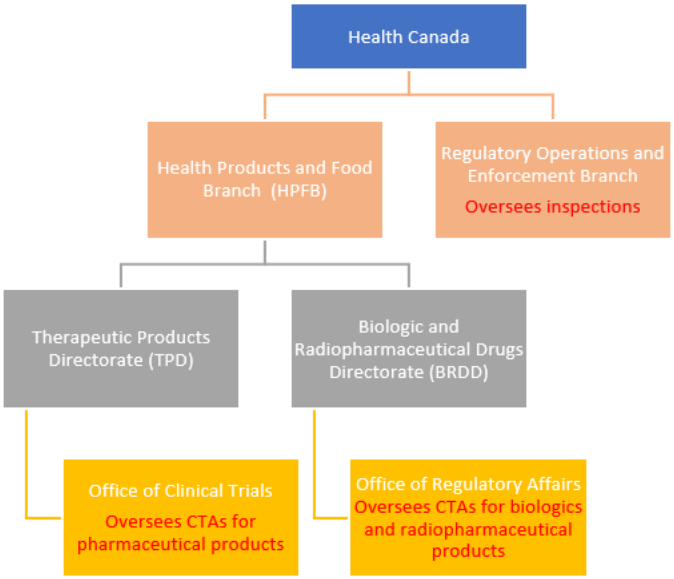


FIGURE 1 Schematic representation of Health Canada's branches, directorates, and offices involved with clinical trials, and their roles and responsibilities.

E6(R2) Addendum fundamentals on good clinical practice and ethical and scientific quality standards for trials with human participants.[3]

Except for phase 4 studies, clinical trial sponsors must submit a clinical trial application (CTA) to Health Canada for authorization to sell or import a drug for the purpose of a clinical trial. CTAs are required for trials using drugs that are not authorized for sale in Canada, as well as trials using marketed drugs in which the proposed use of the drug is considered "off label." This includes marketed drugs being used for a nonapproved indication or in a different target population than that for which it is approved, and/or if the route of administration or dosage regimens are outside the parameters of the notice of compliance (NoC) or drug identification number.

Health Canada must review the submission package and issue a no-objection letter (NOL) before initiation of a clinical trial or implementation of a CTA amendment (CTA-A). A CTA-A must be submitted after the initial CTA if any substantial changes are made to the initially approved protocol or quality (chemistry and manufacturing) information. Importation of investigational products may not occur until the sponsor has received the NOL.

CTAs should be sent to one of two review directorates within the HPFB of Health Canada. Pharmaceuticals are reviewed by the Office of Clinical Trials at the Therapeutic Products Directorate (TPD), and biologics and radiopharmaceuticals at the Biologic and Radiopharmaceutical Drugs Directorate (BRDD). For clinical trials involving both a pharmaceutical and a biologic, the lead directorate should be designated and the submission should be addressed accordingly. For clinical trials involving an investigational medical

device, including an ancillary-use device, an investigational testing authorization, ITA, may be required.

Regulations require clinical trial sponsors located outside of Canada to designate a senior medical or scientific officer who resides in Canada to represent them. The officer must sign a specific attestation related to the trial, for example Appendix 3 of the HC/SC 3011 Drug Submission Application Form, for every CTA/CTA-A submitted to Health Canada.[4]

Clinical trial application format

Health Canada has been accepting regulatory submissions in the electronic common technical document (eCTD) format since 2004. The eCTD format allows for an electronic method of exchange, review, and management of health product information, but it requires the Common Electronic Submission Gateway (CESG) to manage regulatory transactions securely. Electronic documents are uploaded into the Health Canada viewing tool upon receipt. For many stakeholders, access to the CESG is not an option, and they may submit in "non-eCTD, electronic-only" format. CTA submissions made in non-eCTD format are provided to Health Canada on a CD-ROM and sent via courier or email. Non-eCTD submissions must include a cover letter, in both electronic and paper format, to identify the content of the submission. Paper submissions are no longer accepted.

The CTA is composed of three parts, or modules, in accordance with the CTD format:[4]

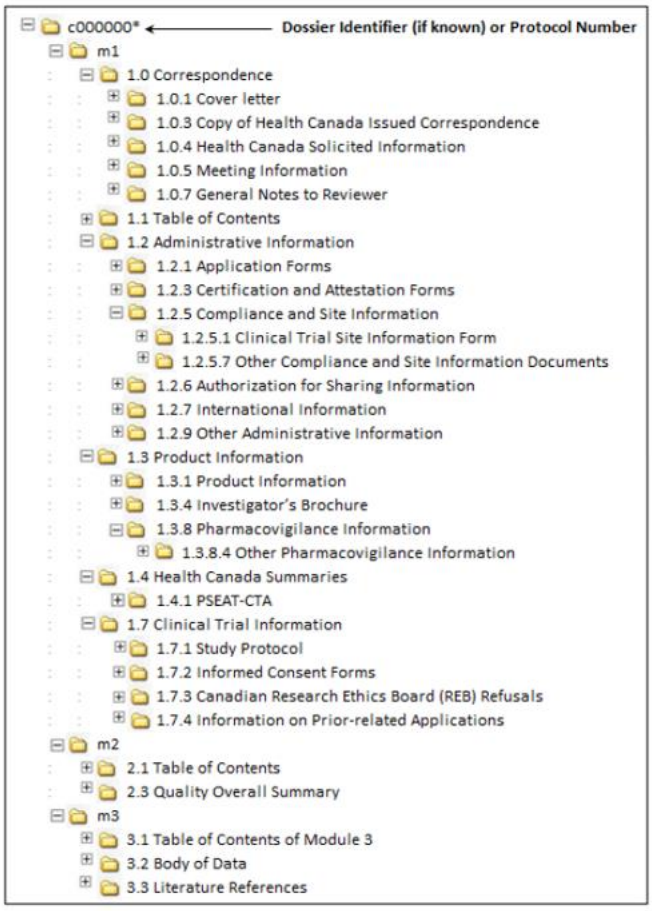
- **Module 1** contains the administrative and clinical information about the proposed trial.
- **Module 2** contains quality (chemistry and manufacturing) summaries about the drug products to be used in the clinical trial.
- **Module 3** contains any additional supporting quality information (if applicable)

Alternately, Health Canada accepts quality information in EU Investigational Medicinal Product Dossier (IMPD) format, which can be included in Module 2. For CTAs to the TPD, a quality overall summary with the introduction section should be submitted along with the IMPD.

Folder structure

The content of the electronic media should be organized into folders according to a set structure (**Figure 2**). There are no requirements for file-naming conventions. However, Health Canada recommends that the file names be kept as brief and as meaningful as possible. Files should not be password protected and the PDF is the recommended format for electronic documents. PDF files should also be properly bookmarked.

FIGURE 2 Health Canada CTA sample folder structure[5]



In line with Figure 2, the CTA includes two Canada-specific summaries:

- **Protocol Safety and Efficacy Assessment Template (PSEAT).** A protocol synopsis in the defined format of a PSEAT should be submitted. This requirement is for TPD only, and, although it is not a requirement for BRDD, it is recommended to submit a PSEAT to facilitate review. The PSEAT is required for the initial CTA only.6
- **Module 2 Quality Overall Summary.** Health Canada has made available three templates, one for each trial phase (1, 2, and 3). This is required for CTAs sent to TPD only.

Transmission of electronic data

CTAs and CTA-As can be submitted on electronic media in the form of a CD-R or a DVD, usually sent via courier. The submission must be organized in accordance with the current electronic specifications as outlined in the Health Canada issued guidance document for preparing submissions in the non-eCTD electronic-only format.[5]

By email

CTA notifications (CTA-Ns) should be provided to Health Canada via email, sent to the appropriate Directorate.

Regulatory transactions provided by email should meet the following requirements:

- The maximum email size accepted by the corporate mail server is 20 MB, anything larger should be sent on media.
- The regulatory transaction should be organized in folders and provided as a zipped file.
- The body of the email should contain only the zipped regulatory transaction. No other documents or related information should be included.
- Zipped files and documents contained in the email should not be password protected.

In general, CTA and CTA-As are to be submitted on electronic media, and CTA-Ns are sent via email.

Clinical trial application-review process

Pre-CTA meeting

Applicants have the option to apply for a pre-CTA consultation meeting with Health Canada to obtain guidance on complex issues that may arise during the application or review processes. Requests for pre-CTA meetings must be submitted in writing and should include a brief synopsis of the proposed study and a list of preliminary questions to be addressed by the appropriate directorate. Once the request is approved, the directorate will confirm the meeting date and the number of copies of the pre-CTA information package to be provided 30 days before the confirmed meeting date.

After the pre-CTA meeting, the sponsor must prepare a written summary of the discussions, which will be added to the central registry file for the drug. The CTA should include a copy of the meeting record.

Screening process

All CTAs are subject to the 30-day default period from the date of receipt of the completed application. The directorate will issue an acknowledgment letter, or acknowledgment of receipt (AoR), to indicate the start of the review period and that Health Canada is in receipt of a complete application. A control number will also be issued for the application on the AoR.

All CTAs and CTA-As will be screened for completeness. If deficiencies are identified at screening, these will be addressed through a screening clarification request (issued by the TPD) or a screening information letter or process hold (issued by the BRDD) sent via email or fax. There is no timeframe specified for the TPD, but the “review clock” will stop until a satisfactory response is received from the sponsor. Sponsors should respond to screening information letters issued during screening within 2 days for the BRDD and, if a process hold is used, the review clock is stopped, and a response is expected within 7 days.

A screening rejection letter may be issued if the required information has not been included in the CTA or CTA-A, or responses to requests for clarification have not been received in a timely manner. If the sponsor wishes to resubmit

the information later, the application may be withdrawn without prejudice and resubmitted as a new CTA or CTA-A.

Review process

During the review process, the sponsor is responsible for resolving issues identified by Health Canada. Sponsors must provide the requested information within 2 calendar days. A "not satisfactory notice", or NSN, may be issued if significant deficiencies are identified during review of the CTA or CTA-A, or if a timely response to the information requested has not been provided. If the applicant wishes to resubmit the information and material at a future time, it will be processed as a new CTA or CTA-A and assigned a new control number as per the guidance on management of drug submissions.4

If the CTA or CTA-A is deemed acceptable, an NOL will be issued within the 30-day review period (**Figure 3**).

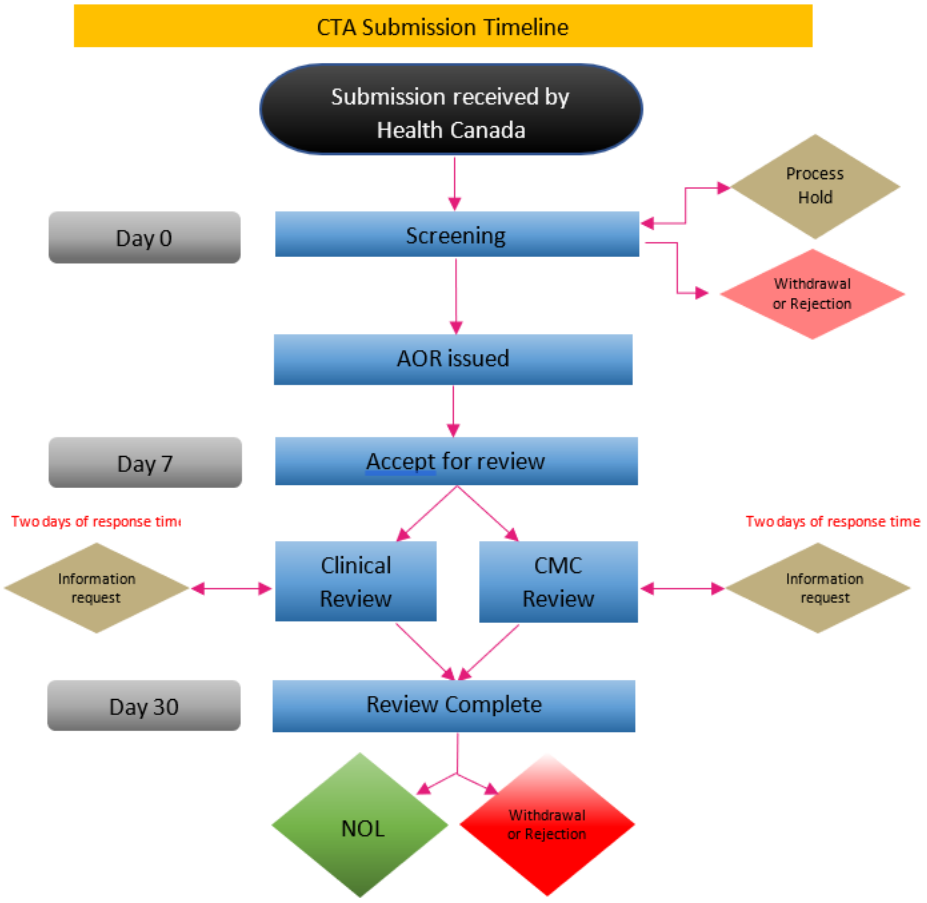


FIGURE 3 Clinical trial application review timeline[4]

CTA amendments

CTA-As are submitted to Health Canada when there is a change to the information in the previously authorized application. This includes changes to the protocol and/or the quality information, or changes that affect the quality

or the safety of the drug. CTA-As must be reviewed and approved by Health Canada before implementation unless there is imminent danger to the health or safety of clinical trial subjects. If the sponsor has to make an immediate change to the study protocol to protect patient safety, then Health Canada must be notified within 15 days after the date of implementation of the amendment and provide sufficient rationale and documentation to support the changes. A summary of changes to the protocol, as well as the rationale for each change, should be included.

A CTA-A must be filed when the proposed amendments to the protocol:

- Affect the selection, assessment, or dismissal of a clinical trial subject
- Affect the evaluation of the clinical efficacy of the drug
- Alter the risk to the health of a clinical trial subject
- Affect the safety evaluation of the drug or
- Extend the duration of the treatment

Protocol changes should also be reflected in the updated informed consent form (ICF), if applicable. Copies of the tracked changes to the ICF should be included with the CTA-A submission.

Quality amendments

Sponsors must file a CTA-A or CTA-N for changes to made to the quality summary of the drug in Module 2 or Module 3, if applicable. Examples may include, but are not limited to, the replacement or addition of a drug substance or product manufacturing site, changes to specifications for the drug substance or product, or shelf-life reductions owing to stability concerns.

Because submission requirements differ between the BRDD and TPD, the applicant should reference the Health Canada issued guidance document for clinical trial4 for detailed information.

Similar to CTAs, CTA-As should be organized and numbered as per the CTD format and submitted via electronic media with a hard copy cover letter as per the specifications in the Health Canada guidance document on preparing drug regulatory activities in the non-eCTD electronic-only format.5 The screening and review timelines for CTA-As are the same as those for CTAs. If the CTA-A is deemed acceptable, an NOL will be issued within the 30-day review period.

CTA notifications

Changes to an application not meeting the criteria for CTA-As should be submitted as notifications within 15 days of the change. Notifications should be submitted electronically and may be implemented immediately after submission.

Notifications may include, but are not limited to:

- Changes to administrative information
- Annual investigator brochure updates
- Updates to the ICF that do not require a protocol amendment

- Changes to the protocol that do not affect the study design or safety of the participants
- Changes to the quality information that do not affect the quality or safety of the drug
- Premature discontinuation of a trial

CTA-Ns can be sent via email to the appropriate directorate in a zipped file with an accompanying cover letter.

Additional post-authorization, pretrial requirements[4]

Research ethics board review

The proposed trial protocol/protocol amendment and the ICF must be reviewed and approved by a Research Ethics Board (REB) before initiation of a CTA or implementation of CTA-A. If the sponsor receives a refusal from another ministry of health (e.g., another country in a multinational trial) or ethics committee, then a notification should be submitted to Health Canada and the affiliated REB.

An REB attestation form, or a similar attestation, must be obtained and signed by the REB chair that approves the CTA/CTA-A at each site. The form should be retained at the sites and not submitted to Health Canada unless requested.

Qualified investigators

Only one qualified investigator (QI) is allowed per site. The QI must complete a qualified investigator undertaking form or develop similar documentation that meets the requirements of the regulations [C.05.012(3)(f)]3. The form should not be submitted to Health Canada unless requested.

CTSI form

A clinical trial site information (CTSI) form for each participating site should be submitted to the appropriate directorate before starting a clinical trial or implementing a CTA-A (applies to clinical amendments only). In addition, if there is a change in the site address, or if the REB with which the site is affiliated is changed, a new CTSI form should be submitted to Health Canada.

Lot release information (for biologics only)

Biologic lots intended for use in a clinical study are subject to a lot-release program requirement before the lot is used in a clinical study. Previously, all biologics lots used in a clinical study were subject to this requirement. However, as of 8 July 2020, this requirement is applicable only to:

biologics that contain human-derived excipients, such as human serum albumin clinical trials lots that are released outside of the approved specification.7

The “faxback form” should be signed by the sponsor or manufacturer and submitted to the BRDD, which will return the signed form to the sponsor within 48 hours. Once the sponsor has received the form, the specific lot can be used in the study.

Importation of clinical trials drugs
If the investigational product is imported, the importer should be authorized by the sponsor. The importer should be included in Appendix 1 of the application form (HC3011) and submitted to Health Canada. Importer information can be submitted with the initial CTA or later when determined.

Importation of additional drugs
For additional drugs (comparator, concomitant, and rescue medications) that have to be imported into Canada, a summary of additional drugs (SOAD) form must be submitted to Health Canada. A Health Canada official will sign the form and return it with the NOL. If the form was not submitted during the initial CTA, it should be submitted as a CTA-N before shipping the drugs to Canada. The signed SOAD form should accompany the shipment.

Labeling requirements
The investigation product should be labeled per section C.05.011 of the Food and Drug Regulations. The regulation applies to both inner and outer labels and commercially available products considered as investigational. Labels are not submitted to Health Canada unless requested.

Post-authorization, post-commencement requirements[4]
Changes to previously authorized CTA
Changes to any information submitted as a part of the initial CTA should be submitted to Health Canada. The changes can be submitted as a CTA-A or CTA-N, as discussed earlier in this article, based on the type of change and its impact.

Premature discontinuation of a trial
A CTA-N should be submitted as soon as possible, but no later than 15 calendar days after such decision.

Resumption of a trial after discontinuation
A CTA-N should be submitted with the proposed re-initiation date if there is no change to the authorized study documents. In the event a protocol or quality information is amended to facilitate the continuation of the trial, a CTA-A may be required, depending on the nature of the changes.

Study completion/site closures
A CTA-N to the relevant directorate should be submitted in the event of a site closure or completion of a study.

A study is considered to have been completed after the last subject has complete the end-of-study visit, as defined in the protocol. This does not include study suspension, cancellation, or closure of the trial in Canada. The end-of-study visit is the final visit for study-related tests and procedures, including the capture of any final potential study-related adverse events.

Safety reporting
Health Canada should be informed in an expedited manner of any serious, unexpected adverse drug reactions, as described in the timelines as below:

- neither fatal nor life-threatening, within 15 days after becoming aware of the information.
- fatal or life-threatening, within 7 days after becoming aware of the information. Submit as complete a report as possible within 8 days after initially informed Health Canada of the fatal or life-threatening adverse drug reaction.

Both investigators' and sponsors' causality assessment should be reported.

Updated investigator's brochure

An updated investigator's brochure, including all safety information and global status, should be submitted annually. If there is a determination that the brochure is not required, a CTA-N stating as much should be submitted.

Record retention

The sponsor is required to maintain complete and accurate records of all trial-related activities. The records are to be retained for 25 years. If any records are requested by the relevant directorate, they must be made available within 2 days.

An alternate pathway for COVID-19–specific trials[8]

On 23 May 2020, an Interim Order (IO) was issued regarding COVID-19–related clinical trials for medical devices and drugs in response to an urgent need for the diagnosis, treatment, mitigation, or prevention of COVID-19. The IO is a temporary measure that provides an alternate pathway to enable the initiation of clinical trials for potential drugs and medical devices for COVID-19 while upholding strong patient safety requirements and validity of trial data. The IO will be in effect for a year.

Health Canada issued two guidance documents to support the IO:

- For drugs: Applications for drug clinical trials under this Interim Order8
- For medical devices: Applications for medical device clinical trials under this Interim Order[8]

The guidance documents apply to COVID-19 clinical trials for pharmaceutical and biologic drugs (including blood and blood components) and medical devices, including combination products. Clinical trials are for phases 1 through 3 of medical device development. Radiopharmaceuticals (see Schedule C of the Food and Drugs Act), natural health products, Class I medical devices, and phase 4 clinical trials are not included in the IO.

The existing regulations and guidance for all clinical trials that are not COVID-19 related and are not in-scope would continue to apply.

Applicants for COVID-19 drug and medical device clinical trials can apply for authorization under one of the following:

- the IO pathway

- Part C, Division 5, of the Food and Drug Regulations (current regulation)[3]
- Part 3 of the Medical Devices Regulations[9]

The IO will reduce administrative requirements for assessing repurposed drugs for COVID-19, enable alternate means for consenting, and broaden criteria/definition of which health professionals are authorized to conduct clinical trials at remote sites.

It is important to note that COVID-19 trials that had commenced before 20 May 2020 cannot be transitioned to the new pathway under IO.

TABLE Comparison of current regulations and interim order[8, 10]

	Part C, Division 5 (current regulation)	Interim order (for COVID-19 trials)
Review period	30-day default authorization	Within 14 days, authorization for importation or sale of COVID-19 drug
Information request	Response within 2 calendar days	Response within 24 hours
Submission process	Mail CD-R/DVD to Health Canada	Via email, to: BRDD, hc.brdd.cta-dec.dmbr.sc@canada.ca TPD, hc.oct.smd-dgp.bec.sc@canada.ca
Minor changes to authorized information	Submitted as CTA-N	Changes qualifying as a CTA-N can be implemented without submitting a notification
Who can conduct research? *QI definition*	*The person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is (a) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case, a physician, and a member in good standing of a professional medical association.* Per the above definition, the QI must be a physician or a dentist.	*The person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care under their license in that province and who: (a) conducts the clinical trial; or (b) in the case of a clinical trial conducted by a team, who is the responsible leader of that team (chercheur compétent).* The definition is expanded to include other healthcare practitioners, such as nurses, pharmacists, and midwives.
Terms and conditions imposed on the authorization	Terms and conditions cannot be imposed or amended on the authorization.	Health Canada can at any point impose or amend terms and conditions on the authorization, e.g., requesting submission of periodic safety summary or of results of the first phase of a phase 1/2 study
Compliance and enforcement	Current regulations do not allow for discontinuation/cancellation of one arm of a study. The whole study should be cancelled or discontinued.	Enables suspension or cancellation of a part of or the entire study.
Labeling	Marketed product, if considered as investigational, should comply with labeling requirements under section C.05.011 of Division 5 of the FDR.	Commercial label acceptable.

BRDD, Biologic and Radiopharmaceutical Drugs Directorate; **CTA-N,** CTA-notification; **FDR,** Food and Drug Regulations; **QI,** qualified investigator; **TPD,** Therapeutic Products Directorate.

Modernization of clinical trials regulations

Clinical trial business models have evolved from the traditional linear clinical trial model (preclinical, clinical, and post-launch studies) as most of the innovative novel approaches are not suited under current regulations. For example, master protocols, such as basket trials and umbrella trials, are novel designs that facilitate evaluations of more than one investigational medicinal product and/or more than one type of indication within the same overall trial

structure. To facilitate such evaluations, the study includes a master protocol/study and sub-protocols/studies, as required. Currently, Health Canada reviews CTAs on a per-protocol basis. In case master protocol trial designs are utilized, a separate CTA should be submitted for each sub-protocol. This leads to an increased regulatory and financial burden. To address such issues, Health Canada is proposing to amend the current clinical trial regulations to introduce a coherent risk-based approach for oversight of conduct clinical trial and enable increased flexibility in the safe development of innovative therapies.[11-13] In addition, there are several other modernization initiatives Health Canada is proposing, including a reduced record retention proposal, from 25 years to 15 years, to better align with global regulators.[14]

Conclusion

Canada continues to be an attractive destination for the conduct of clinical trials. With shorter approval timelines and considerably more universal submission requirements, the Canadian framework will continue to be an appealing option for pharmaceutical companies and research institutions to make significant investments in Canadian clinical trial health research.

Abbreviations

BRDD, Biologic and Radiopharmaceutical Drugs Directorate; **CESG,** Common Electronic Submission Gateway; **CTA,** clinical trial application; **CTA-A,** CTA amendment**; CTA-N,** CTA-notification; **eCTD,** electronic common technical document; **EU,** European Union; **FDR,** Food and Drug Regulations; HPFB, Health Products and Food Branch; **ICH,** International Council for Harmonization; **IMPD,** Investigational Medicinal Product Dossier; **NoC,** notice of compliance; **NOL,** no-objection letter; **PSEAT,** Protocol Safety and Efficacy Assessment Template; **QI,** qualified investigator; **REB,** Research Ethics Board; **SOAD,** summary of additional drugs; **TPD,** Therapeutic Products Directorate.

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