Guidance for clinical trials with decentralized elements



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Publication date: October 2026

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Cat.: H169-14/2026E-PDF
ISBN: 978-1-100-01070-0

Foreword

Guidance documents provide assistance to industry, health care providers and sponsors on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a drug or clinical trial. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the accompanying notice, Part C, Division 5 of the Food and Drug Regulations, Food and Drugs Act and relevant sections of other applicable guidance documents

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Overview

Purpose

This guidance outlines regulatory considerations for conducting clinical trials with decentralized elements in Canada. These considerations are supported by Part C, Division 5 of the Food and Drug Regulations (FDR) and the International Council for Harmonisation's Guideline for Good Clinical Practice (ICH E6).

In clinical trials with decentralized elements, some or all trial-related activities occur outside traditional trial centres. These activities may be supported by digital health technologies and virtual tools. They may include in-person visits with health care providers or at treatment centres located closer to the participant than the clinical trial site. Activities conducted in a participant's home may also be offered.

Trials with decentralized elements are sometimes referred to as hybrid, remote or virtual clinical trials.

Health Canada is currently modernizing how clinical trials are regulated. This modernization initiative will better accommodate new trial types and designs. We have published an interim policy to advance targeted elements of this initiative until the proposed Clinical Trials Regulations come into force.

Learn more:

- Clinical trials modernization initiative
- Interim policy for the modernization of the clinical trial framework

This guidance reflects the interim policy. Once the modernized regulatory framework is in force, we will update the guidance to align with the new regulations.

Scope and application

This guidance applies to any party involved in conducting clinical trials in humans in Canada. This includes:

- sponsors
- investigators
- other third parties such as:
    - health care providers
    - clinical laboratories
    - academia
    - service providers such as contract research organizations and other vendors

This guidance concerns the following clinical trials involving drugs in Canada:

- phases I to IV
- clinical trials involving pharmaceuticals, biologics and radiopharmaceuticals for human use

Similar principles apply to the following products. However, because they're regulated under different regulations, this guidance does **not** apply to clinical trials or investigations that evaluate:

- medical devices
- natural health products
- foods for special dietary purposes

The considerations in this guidance focus on clinical trials with decentralized elements. For a complete understanding of the regulatory requirements for clinical trials, including those with decentralized elements, consult:

- Clinical trial sponsors: Clinical trial applications

- Good clinical practices (GCP) for drugs for clinical trials involving human subjects (GUI-0100)

Policy statements

A clinical trial with decentralized elements incorporates activities that are conducted outside traditional clinical trial centres. Including decentralized elements in a clinical trial can:

- reduce barriers to trial participation and increase accessibility
- improve access to potentially promising new therapies for a greater number of people
- improve and accelerate recruitment by broadening geographic reach and helping to connect a greater diversity of participants
- allow researchers and other health care providers to participate in pan-Canadian research without needing to be geographically co-located
- include more community-based practitioner and participant views in trial design, in line with participant-centred approaches in ICH E6

The regulatory requirements for a clinical trial with decentralized elements are the same as those for trials conducted in traditional settings. The regulatory obligations are the same, but planning and operational approaches may need to be adapted. As well, decentralized elements may involve additional considerations to ensure they comply with all applicable requirements.

Clinical trials with decentralized elements should:

- be operationally feasible
- be implemented with necessary safeguards and ethical considerations that are in proportion to the potential risks to participants

- avoid unnecessary burden on participants, investigators and trial-related personnel or other third parties involved in decentralized elements
    - for example, by offering flexible options where possible so participants may opt in or out of decentralized elements, based on their own needs, which may change over the course of the trial

Background

For people in Canada, clinical trials with decentralized elements can reduce the barriers to participating in trials conducted at traditional clinical trial sites. These barriers may include geography and travel, language, family and work responsibilities, health and care requirements or other circumstances. Providing options where people can access a clinical trial closer to home may reduce stress. It may also lead to higher enrolment and retention of participants, which in turn may result in better data.

Decentralized options may also make it easier for participants to more easily access and connect to research efforts, and may increase access to novel treatments. However, while clinical trials with decentralized elements may reduce some barriers to participation, other barriers may be created related to inequities in using technology and accessing reliable internet.

For community-based health care professionals, clinical trials with decentralized elements can make it possible to participate in broader research activities. It can also help their patients access a greater number of clinical trials and potentially beneficial novel treatments.

There is also an opportunity to incorporate community-based practitioner and participant considerations in the planning and design of trials. For example, study visits could be aligned with existing treatment schedules.

However, decentralized elements may create additional burdens for community-based health care professionals related to:

- training requirements
- appropriately implementing trial procedures
- operational complexities, such as requirements for different types of equipment, staffing and oversight, and related financial considerations

- logistics around shipping, handling and storing drugs involved in the trial in accordance with the trial protocol

- communications between trial personnel and participants who do not regularly visit a traditional trial site

For clinical trial sponsors and investigators, decentralized elements can help accelerate and address challenges with recruiting by reaching geographically and culturally diverse participant groups, such as for rare disease trials. They can improve the ability to recruit and retain a more representative participant population, which may lead to more generalizable and applicable trial results.

Conducting geographically dispersed trial activities under a single clinical trial site can increase logistical burden. But it can also help sponsors reduce other administrative or financial burdens associated with operating or coordinating participant visits across multiple clinical trial sites.

Designing the trial

Design considerations

A qualified investigator (QI) at a clinical trial site's main location may delegate trial-related activities to personnel or third parties in other remote locations.

Examples of decentralized elements include:

- wearable sensors or medical devices to monitor and measure outcomes
- tools for collecting and managing electronic participant-reported outcomes
- telehealth platforms, such as online portals and video conferencing
- local or direct-to-home shipping of investigational drugs, including using local pharmacies for investigational drugs with specific storage and handling conditions
    - The requirements for direct-to-home shipment and dispensing of investigational drugs may vary across Canadian jurisdictions. Sponsors should ensure they comply with applicable provincial and territorial requirements.
- follow-up visits with health care providers or regional treatment centres
- at-home visits by trial personnel or use of mobile clinics
- testing and imaging (for example, blood tests) at clinical laboratories closer to a participant's home

Sponsors should incorporate quality into the design of decentralized elements from the outset by:

- identifying potential critical to quality factors **and**
- designing trial procedures, operational processes, technologies and oversight mechanisms to avoid errors

When designing a clinical trial with decentralized elements, sponsors must demonstrate that:

- participant risk is minimized and safety will be appropriately monitored
- participants are made aware of the potential risks and benefits of participating in the trial
- decentralized elements will help achieve the study objectives

As well as protecting the rights, safety and well-being of each participant, sponsors should consider how decentralized trial activities may affect relationships with participating communities. Where appropriate, sponsors should take steps to promote cultural safety, foster trust and demonstrate accountability to communities involved in or affected by the trial. This is especially crucial when conducting research with Indigenous Peoples or populations in remote, rural or underserved settings.

When deciding to decentralize trial activities, sponsors and QIs have a number of considerations to make.

Product and specimen considerations:

- characteristics of the investigational drug and level of knowledge about the investigational drug's safety, including the extent to which its safety profile has been established
- route and complexity of administration of the investigational drug and the logistics for its administration in different clinical trial settings
- requirements for specialized preparation, administration and evaluation procedures or equipment
- transport and storage requirements for products or specimens, such as:
    - security and control of products, including for radioactive products or those classified as controlled substances
    - delivery logistics, including return of products and specimens
    - potential shipment delays and related impacts on the trial

- potential risks to the quality of trial data and extra burden on participants and others when handling, storing and tracking at-home products

Site, personnel and operational considerations:

- the logistical and financial capacity of decentralized locations, such as time, equipment and personnel, for supporting trial conduct in accordance with good clinical practices (GCP)
- any existing standards of care, standards for drug administration or institutional practices that may affect trial activities across locations
- potential for decentralized trial activities that cross provincial or territorial jurisdictions to introduce considerations around applicable legislation, regulatory requirements or professional practice requirements
- study-specific training needs for delegated third parties and linking this training with their own training requirements
- managing the increased logistical and operational coordination requirements associated with scheduling and conducting activities across multiple locations
- communicating between locations, trial-related personnel and participants, including providing information critical to participant safety such as test results
- approaches for consistently and appropriately record delegated third parties in trial-related documentation without creating unnecessary administrative burden

Data and technology considerations:

- implementing data management plans and cybersecurity protocols to effectively and safely manage, share and exchange digital information
- potential for technology to create digital accessibility barriers, thus unintentionally disadvantaging participants or contributing to inequities in trial participation

Participant and community considerations:

- language barriers and culturally appropriate communication

- effect of decentralized trial activities on participating communities, including cultural safety, trust, community engagement, accountability, continuity of care and potential impacts on local health care systems and resources
- integrating participant engagement, including input from patient advocacy groups, participants, caregivers and family members, into the trial design to help identify barriers and unintended participant burdens associated with decentralized elements
- using participant and stakeholder input during trial design to identify and prioritize factors that are critical to quality, including procedures that are essential to the safety and experience of participants and the reliability of trial results

Single- and multi-site clinical trials

Clinical trials can vary widely in structure, for example:

- fully decentralized models
- single-site studies led entirely from one trial site
- fully site-based trials with no decentralized elements
- multi-site trials coordinated across multiple clinical trial sites
- hybrid approach incorporating both site-based activities and decentralized elements

This flexibility allows sponsors to tailor their trial operations to meet participant needs and study objectives.

A clinical trial site refers collectively to the main location and the location of any decentralized elements associated with the site. While there can only be one QI at each clinical trial site, there may be other sub-investigators or co-investigators in the study under the supervision of a QI. All locations where trial-related activities (including decentralized elements) occur under the supervision of a single QI are considered part of that QI's clinical trial site.

In accordance with the interim policy for the modernization of the clinical trial framework (effective September 14, 2026)

Health Canada now allows a broader range of researchers to serve as QIs. Under this interim policy, a "qualified investigator" may be:

- a physician or dentist who is authorized under the Food and Drug Regulations (FDR) to act as a qualified investigator or
- an individual who has the education, training and experience required to conduct the clinical trial in accordance with applicable regulatory requirements despite not meeting the requirement to be a physician or dentist as outlined in the definition of “qualified investigator” in C.05.001

In clinical trials where the investigator is not a physician or dentist, medical decisions about the trial must be made by a qualified physician or dentist on the clinical trial team. This person:

- must be licensed to practise in the province or territory where the site is located
- is responsible for medical oversight and participant care, including medical decisions in respect of the trial

The considerations that sponsors should make for single- or multi-site clinical trials with decentralized elements are provided in Table 1.

Table 1: Considerations for single- or multi-site clinical trials with decentralized elements

Consideration	Single-site with decentralized elements	Multi-site with decentralized elements
Operational model	Main central location, with activities at other remote locations to facilitate trial activities (decentralized	Distributed operations across multiple independent clinical trial

Consideration	Single-site with decentralized elements	Multi-site with decentralized elements
	elements) under a single study protocol.	sites, under a single study protocol. Each site may have activities at other remote locations to facilitate trial activities (decentralized elements).
Trial suitability	For example, may be suited to investigational products with an established safety profile or where complex initial assessments can be done centrally with follow-ups at remote locations, including the participant's home. May be suited for trials aiming for centralized investigator oversight and managed through agreements with third parties or service providers.	For example, may be suited for trials needing larger cohorts, or specific participant populations requiring multiple sites, and site-specific in-person procedures or interactions. Certain follow-up activities may be conducted remotely, including in a participant's home. May be suited for trials aiming for oversight by several investigators (one for each site).
Interprovincial considerations	Decentralized elements that cross provincial jurisdictions may introduce additional considerations related to applicable	May allow individual inter-provincial sites to adapt to:

Consideration	Single-site with decentralized elements	Multi-site with decentralized elements
	provincial legislation and requirements.	• local applicable provincial laws and regulations • institutional capacity and requirements May add complexity to the coordination of a single study protocol across multiple sites.
Qualified investigator (QI) oversight	One QI. A single QI is responsible for overseeing and monitoring all trial activities, including at all locations associated with the site, and any decentralized elements. QIs must maintain a delegation log and documentation for their site, including relevant decentralized activities, to demonstrate compliance with Division 5 of the FDR and the applicable GCP requirements.	Multiple QIs. Each QI is responsible for overseeing and monitoring all trial activities associated with their specific clinical trial site, including all locations associated with their site and any decentralized elements. QIs must maintain a delegation log and documentation for their site, including relevant decentralized activities, to demonstrate compliance with Division 5 of the FDR and the applicable GCP requirements.

Consideration	Single-site with decentralized elements	Multi-site with decentralized elements
Research ethics boards (REBs)	REB approval is required for the trial site, including activities at all locations associated with the site and any decentralized elements.	REB approval is required for each clinical trial site, including activities at all locations associated with each site and any decentralized elements.
Participant reach	Broader geographic reach compared to a study without decentralized elements. Participant-centric by reducing unnecessary burden on participants.	Broadest geographic reach due to having trial sites in different locations and also having decentralized elements. Participant-centric by reducing unnecessary burden on participants.

For more information on multi-jurisdictional research, consult:

- TCPS 2 (2022) – Chapter 8: Multi-jurisdictional research

Managing risk

Managing the potential risks associated with decentralized elements requires well-coordinated trial monitoring and oversight by all parties involved in conducting the clinical trial. For decentralizing activities, sponsors and QIs should minimize the risk to participants and safeguard the integrity, accuracy, completeness and security of trial data.

When designing and conducting a trial with decentralized elements, sponsors should identify the potential risks that may have a meaningful impact on critical to quality factors. These factors are described by the International Council for Harmonisation's General Considerations for Clinical Studies guideline (ICH E8). They are a basic set of factors

relevant to ensuring study quality. Sponsors and QIs should then manage those risks according to the regulations and ICH E6.

In accordance with ICH E6, sponsors should establish and maintain quality management processes that are in proportion to the risks associated with the trial and focused on factors that are critical to quality. These processes should support the proactive identification, evaluation, control, communication and review of risks throughout the clinical trial lifecycle. Oversight activities, including monitoring, should be designed to help protect participants and generate reliable, fit-for-purpose data rather than relying solely on detecting errors.

For more information on critical to quality factors, consult:

- General considerations for clinical studies (ICH E8)

Where study activities are conducted across multiple decentralized locations or by multiple service providers, relevant critical to quality factors may include the following:

- **Participant safety oversight across decentralized settings**
    - Processes to ensure that clinically significant findings, adverse events, protocol-defined safety triggers and other information relevant to participant safety are communicated in a timely manner to the investigator and appropriately acted upon.
- **Consistency and comparability of endpoint assessments**
    - Measures to mitigate these risks, such as standardized procedures, training programs, centralized assessment manuals, predefined acceptance criteria and ongoing quality oversight.
- **Data integrity, traceability and integration**
    - Procedures to ensure data can be reliably attributed to the correct participant, reconstructed to their source when necessary and maintained in a manner that is fit-for-purpose to support the trial objectives, especially when multiple systems are used.
- **Training and oversight of third parties**
    - Risk-based oversight processes that define roles and responsibilities, communication pathways, performance indicators and corrective actions

where issues are identified. This is crucial where third parties are conducting activities that may affect participant safety or data quality.

- **Reliability and fit-for-purpose of digital technologies**
    - Appropriate controls and monitoring activities to detect and address device malfunction, software updates, connectivity issues, missing data or variability in device performance.
- **Participant capability and burden**
    - Measures to mitigate risks related to participant health status, age, language, digital literacy, accessibility needs, caregiver involvement and access to internet or communication technologies. These include training participants, providing technical support and using alternative methods for completing assessments or study procedures tailored to the needs of the target population.
- **Consistency of protocol implementation across distributed locations**
    - Consistency in procedures performed by multiple laboratories, health care providers, home-health personnel or other service providers to avoid variability that could affect participant safety or data reliability. Processes should promote consistent implementation of critical study procedures.

Based on an evaluation of relevant critical to quality factors, sponsors should implement proportionate risk controls for decentralized elements to support participant safety and generate reliable, fit-for-purpose data. Where relevant, sponsors should set pre-specified acceptable ranges (for example, quality tolerance limits at the trial level) to support the control of risks to critical to quality factors, in accordance with ICH E6.

Risk controls may include:

- limiting the type of trial-related activities performed remotely
- reducing risks associated with specific procedures
- ensuring products are safely stored and handled
- establishing protocols for remote oversight

- implementing safeguards to maintain data integrity, such as implementing an independent data and safety monitoring board
    - outlined in TCPS 2 – Chapter 11

- ensuring that third parties performing trial-related activities maintain appropriate quality management systems, including ongoing internal quality control processes that verify the consistent and accurate execution of laboratory procedures in routine practice

- implementing oversight mechanisms that assess both documented procedures and operational performance, especially where third party or laboratory testing is conducted across multiple clinical trial site locations

Proportionate risk mitigation strategies can be built into various aspects of the trial, such as protocol design, contractual agreements, informed consent process and standardized operating procedures. However, standard operating procedures may not be sufficient to ensure the quality of decentralized trial activities.

Sponsors and QIs should consider whether additional measures are needed to demonstrate that trial activities are conducted as intended and that resulting data are reliable and fit-for-purpose. Measures could include centralized training, ongoing quality control, competency assessments, targeted monitoring activities and review of protocol deviations or trends across service providers and locations.

Risk-based monitoring approaches should be tailored to the nature, complexity and risks of decentralized trial activities. They should form part of a broader risk-proportionate quality management approach focused on factors that are critical to quality, participant safety and reliable trial results. These approaches can also be outlined in trial-related documentation that defines and records the roles and responsibilities of everyone involved in the trial.

For information on quality risk management for the transportation and storage of drugs, consult:

- Guidelines for environmental control of drugs during storage and transportation (GUI-0069)

Computerized systems and digital health technology

Sponsors and QIs are responsible for ensuring that all computerized systems and digital health technology used to support decentralized elements are fit-for-purpose, reliable and appropriate for the trial design. This includes all systems used to create, process, transmit or store clinical trial data, including those that participants use in decentralized settings.

These technologies must be selected, implemented and maintained in a manner that protects participant safety, supports data integrity, demonstrates compliance with ICH E6 and GCP, and should enable equitable participation.

Implementation of decentralized elements may require sponsors and QIs to assess the:

- interoperability of systems, especially between the main trial site and other locations involved in trial activities
- adequacy of data transmission processes to support the required volume, security and timeliness of data flows

Additional safeguards may also be necessary to protect participants' personal information and align with applicable health privacy legislation.

Data management plans

Data management plans can describe the processes and controls used throughout the data lifecycle, such as collecting, handling, storing, transferring, retaining, sharing, securing, monitoring and reporting clinical trial data. These plans may be especially relevant for managing the collection of reliable data across multiple clinical trial site locations.

A plan should include measures to:

- protect participant confidentiality
- maintain data integrity, reliability, traceability and fit-for-purpose
- manage risks related to data manipulation, unauthorized access, data breaches and third-party service providers

The plan should also describe governance for electronic source data, access controls, data residency requirements and the exchange of data within and across trial sites. The

extent of these controls should be in proportion to the complexity of the clinical trial and the risks to participants and data integrity.

For trials incorporating digital technologies or decentralized elements, sponsors should consider how data collected through digital platforms, wearable devices and remote monitoring technologies will be managed. This includes where data is stored, who may access it and how to prevent unauthorized sharing or reuse.

Sponsors and investigators are responsible for protecting participants' personal information in accordance with applicable health privacy legislation and institutional practices. In some cases, institutions or jurisdictions may require additional data privacy reviews before a trial at a site may begin, which may cause additional delays. Other data sovereignty principles may also apply when conducting research in Indigenous communities or with Indigenous participants.

The data management plan should be reviewed and updated, as appropriate, throughout the clinical trial lifecycle.

Data standards

Incorporating data standards may improve data quality, transparency and interoperability across software systems, applications and devices. Their use can support faster trial activation, more efficient oversight and better participant outcomes.

Examples of data standards that may apply to clinical trials include the:

- Canadian Clinical Drug Data Set (CCDD)
- Pan-Canadian Health Data Content Framework (Canadian Institute for Health Information, or CIHI)

CIHI also has a library of health-related data standards and information on how these standards are used:

- Data standards library
- What are health data standards?

Equitable and participant-centred use of technology

Sponsors should take care to avoid introducing barriers and creating disadvantages when using digital tools. Participants may have unreliable internet access, or no access at all. They may also have limited digital literacy, be unfamiliar with digital tools such as wearable devices and virtual platforms or prefer not to use some or all digital tools.

Certain technologies may also bring confidentiality and trust-related concerns about privacy and data, including:

- where it's stored
- who can access it
- whether it can be reused or shared without their consent

Barriers and concerns that are not identified and addressed may affect a participant's ability and willingness to take part in the trial. There may also be ethical considerations around fairness and equity.

Sponsors and QIs can work collaboratively with participants to understand their needs, ensure they receive appropriate support and that informed consent is maintained. Support may include:

- alternative non-digital options
- technology navigation assistance
- information technology (IT) support
- other accommodations to make it easier to participate

Requirements and oversight for digital systems

Sponsors should ensure that computerized systems and digital health technologies used in decentralized elements are fit for their intended purpose and appropriately validated using a risk-based approach, in accordance with ICH E6. All technologies used to create, process, transfer, transmit, exchange, analyze or store clinical trial data should be

validated, secure and appropriately governed throughout their use in the clinical trial. They should also meet established requirements for completeness, accuracy, reliability and intended performance.

Where algorithmic tools, artificial intelligence (AI) or AI-enabled systems are used, sponsors should ensure that appropriate mechanisms are in place to validate their intended use and to monitor performance throughout the clinical trial. Accuracy, reliability, reproducibility, transparency, bias, version control, change management, the potential for algorithm drift and the system's continued fit-for-purpose should also be considered.

Digital technologies may perform differently in decentralized settings compared with controlled validation studies. For this reason, sponsors and QIs should continue to consider whether additional operational adjustments and safeguards are needed to maintain data quality and reliability. Any technology used should be fit for the operational realities and constraints of how these systems are used in decentralized settings.

Decentralized elements that increase the number of locations, devices, platforms and individuals involved in trial activities may introduce additional risks around cybersecurity, data privacy and data integrity. Participants should be given clear information on where data is stored, who has access to the data and whether and how data may be reused or shared. When applicable, this may also apply to their communities.

For decentralized elements, it may be very relevant to consider data transfer integrity, data security, interoperability between systems, audit trails and lifecycle management of participant-facing technologies. Sponsors should also implement appropriate cybersecurity, data protection and system security measures to prevent unauthorized access, data loss and breaches.

Documented procedures and appropriate training should be in place for developing, maintaining and using computerized systems.

Software as a medical device

Sponsors and QIs should assess whether any digital health technology used in a decentralized element of the trial meets the definition of software as a medical device (SaMD). Digital tools that perform a medical purpose such as diagnosing, treating, mitigating or monitoring a disease or condition may be regulated as medical devices. If so, they may be subject to additional requirements.

Sponsors should determine early in the trial planning phase whether any computerized systems or digital technologies qualify as SaMD. They should ensure that such technologies comply with the Medical Device Regulations in parallel with ICH E6 expectations. This may be especially important where decentralized elements rely on remote monitoring or participant-facing digital tools.

For information, consult:

- Guidance document: Software as a medical device (SaMD): Definition and classification

Obtaining regulatory and ethics approval, informed consent

Submitting a clinical trial application

Sponsors of Phase I, II or III clinical trials must file a clinical trial application (CTA) before a trial can begin.

As with all clinical trials, including those with decentralized elements, the CTA, protocol and supporting documentation should, if known at the time of submission, adequately describe how any decentralized elements and activities:

- were designed to minimize risk to participants
- supported appropriate oversight and monitoring throughout the trial
- helped achieve trial objectives

Sponsors must attest that the trial, including all decentralized elements, will be conducted according to good clinical practices (GCP).

With their CTA, sponsors are required to provide a copy of the informed consent forms (ICFs) to be used in the trial. These should include information on the potential risks and anticipated benefits to participating in the trial, including any planned decentralized elements of the clinical trial, if known at the time of submission.

Visit the section on informed consent process.

Depending on the decentralized elements and activities within the proposed trial, sponsors should, if known at the time of submission, describe in the CTA how participant visits and clinical trial activities will be conducted. For example, activities may be conducted:

- in person
- by telephone or telehealth platform
- through third parties or vendors

This information may be included in the CTA package, where appropriate. It doesn't have to be in a specific section or format (for example, could be included in an annex detailing planned Canadian implementation of a protocol).

For trials with decentralized elements, the CTA package doesn't have to refer to specific third-party services or vendors, or associated training and qualifications. In these cases, sponsors can adapt to changing circumstances over time (for example, a change in a vendor) without changing the protocol.

For information, consult:

- Guidance document for clinical trial sponsors: Clinical trial applications

Adding decentralized elements after trial is approved

In some clinical trials, sponsors may want to incorporate decentralized elements after the trial has been approved. Adding these elements can improve participant access and reduce trial-related burdens, helping participants remain in the study even when circumstances that affect their involvement change.

The need for such adaptations may arise for several reasons:

- new participants may be added
- the design of the trial may change
- a participant's ability to travel may change
- a participant's geographical location in relation to the closest trial site may change

In some cases, introducing decentralized elements to a clinical trial after approval may require the sponsor to submit a clinical trial application-amendment (CTA-A) or a clinical trial application-notification (CTA-N). Table 2 provides a high-level overview of the scenarios in which a CTA-A, CTA-N or neither is required.

For information on CTA-As and CTA-Ns, consult:

- Guidance document for clinical trial sponsors: Clinical trial applications

If a protocol is being changed to include an unplanned decentralized element, the requirement to submit a CTA-A or CTA-N may cause delays before the unplanned decentralized element can be undertaken.

Note: Changes that would fall under CTA-Ns may be implemented immediately and notification must be made in writing within 15 days after the date of the change.

To avoid these delays, sponsors may want to design their protocols (including any annexes related to Canadian or local implementation of a trial) to set out contingencies for adding decentralized elements.

Contingencies may include:

- pre-emptively outlining potential decentralization options within the protocol
- outlining critical to quality factors into the protocol in a way that reduces the likelihood of requiring a change to a protocol for unplanned decentralized elements
- not specifically identifying any delegated personnel, service providers or third-party organizations in the CTA
    - Not naming third parties may provide additional flexibility and avoid having to amend the protocol if there is a change.
    - Sponsors can instead rely on describing critical to quality factors for these activities and services.

Table 2: Regulatory submission requirements for adding decentralized elements post-approval

Scenario	Protocol change	Action to be taken
Adding decentralized elements requires a change to the protocol that **does affect** one or more of the following, under C.05.008(2): a. amendments to the protocol that affect the selection, monitoring or dismissal of a clinical trial subject	Yes	Under C.05.008(1), sponsor must submit a CTA-A.

Scenario	Protocol change	Action to be taken
b. amendments to the protocol that affect the evaluation of the clinical efficacy of the drug c. amendments to the protocol that alter the risk to the health of a clinical trial subject d. amendments to the protocol that affect the safety evaluation of the drug e. amendments to the protocol that extend the duration of the clinical trial and f. amendments to the chemistry and manufacturing information that may affect the safety or quality of the drug Note: These types of amendments may also lead to changes to other documentation, such as the informed consent form or other trial documents.		
Adding decentralized elements requires a change to the protocol that:	Yes	Under C.05.007, sponsor must submit a CTA-N.

Scenario	Protocol change	Action to be taken
• does not alter the risk to the health of a clinical trial subject and • does not require an amendment **according to the factors listed** under section C.05.008		
Adding decentralized elements does **not** require modifying the protocol, for example, decentralized elements not requiring a protocol change related to: • change in a laboratory • change in a delegated professional whose qualifications are consistent with those required by the protocol • change in a delegated service provider	No	Sponsor is **not** required to submit a CTA-A or CTA-N. **However**, any additional mitigation measures required to conduct the trial according to GCP must be implemented in compliance with the protocol, GCP and documented according to regulation.

Identifying clinical trial sites

Each clinical trial site is identified through its own Clinical Trial Site Information (CTSI) Form. Sponsors must submit the forms to Health Canada before trial activities can begin at a site.

The site's main location, associated with the qualified investigator (QI), must be listed on the CTSI form and have research ethics board (REB) approval before the trial can begin. A site's main location is usually the location from which the QI conducts the trial and oversees its conduct at each of the site's remote locations.

We do not require separate CTSI forms or REB approvals for other locations where decentralized activities occur, provided they are overseen by the QI and are conducted according to the approved protocol. Sponsors and QIs may need to obtain their own approvals to use institutional resources or gain access to specific locations or populations.

For information, consult:

- Instructions for completing the Clinical Trial Site Information Form

Research ethics board approval

REB approval must be obtained for each clinical trial site before a trial can begin at that site.

By decentralizing trial-related activities to trial personnel or third parties at remote locations, sponsors and QIs can conduct REB-approved trial activities across a wider geographic area, in more types of settings.

A single REB can approve activities at a clinical trial site as well as decentralized trial elements. However, sponsors and QIs may need to obtain their own additional provincial or institutional approvals or permissions, or meet community-specific requirements, to use institutional resources or gain access to specific locations or populations, such as Indigenous communities. Local REB processes can be important in verifying capacity and resources to undertake trial activities.

For multi-site trials, where each clinical trial site is required to obtain REB approval, sponsors should consider using a streamlined REB review systems. This is especially important where the REBs are recognized members of a streamlined ethics review network or have formalized cross-institutional agreements.

Several initiatives and organizations in Canada have developed streamlined ethics review systems, for example:

- BC Ethics Harmonization Initiative (BCEHI)

- Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER)
- CanReview, Canada's single research ethics review system
- CATALIS, Quebec's fast track evaluation service
- Clinical Trials Ontario's streamlined ethical review
- Maritime SPOR SUPPORT Unit (MSSU)
- Nova Scotia Health Research Ethics Board
- Ontario Cancer Research Ethics Board (OCREB)
- REB Exchange Alberta (REBX)
- Research improvements through harmonization in Manitoba (RITHIM)

For information on multi-jurisdictional research, consult:

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)

In accordance with the interim policy for the modernization of the clinical trial framework (effective September 14, 2026)

For trials using a streamlined REB process to approve multiple sites, CTSI forms now only need to include contact information for a research ethics board **once per trial**, as long as the:

- same board has been identified as having approved other sites in that trial
- board's contact information has been provided to Health Canada in the context of this clinical trial, and continues to be up to date

Accordingly, for a new site, the CTSI form section on research ethics board approval may only contain the name of the approving board and the date when approved.

Informed consent process

Informed consent must be obtained from each participant, in accordance with the applicable laws governing consent, before they participate in the clinical trial, including in any decentralized elements. Consent is a continuous process. It starts with first contact and finishes when the study ends or the participant withdraws.

Sponsors must inform participants of the potential risks and anticipated benefits of participating in the trial, including those associated with any decentralized elements.

Informed consent must comply with the applicable laws and regulations governing consent:

- ICH E6 requirements
- provincial and territorial rules and regulations
- REB approval of the informed consent process, including the informed consent form (ICF)

Sponsors and QIs should establish a process for how informed consent will be obtained in trials with decentralized elements, in accordance with ICH E6 requirements.

The process should give potential participants information on:

- the trial and decentralized trial activities that are relevant to their decision to participate
- who to contact if they have questions about the research
- how they will be informed about potential adverse events and who will communicate this information to them
- a 24-hour number or instructions for who to contact if they have a clinical trial-related emergency, adverse event or injury (for example, local health care provider, emergency services, QI)
- who will have access to their personal health information collected during the trial and how will it be securely stored and transferred
- potential third parties involved in trial activities with the participant

For clinical trials with decentralized elements, the informed consent process may involve the QI (or delegated persons) at a main location and participants at other remote locations. For a trial involving several remote locations, sponsors should ensure the informed consent process supports participation, builds trust, mitigates risks to participants and maintains appropriate records of participant consent.

In designing and implementing consent processes across locations, sponsors should consider whether the approach may introduce additional cognitive or emotional demands for participants. Reasonable steps should be taken to minimize unnecessary burden while supporting informed and voluntary decision-making.

Virtual meeting platforms and electronic signatures may make the informed consent process more efficient for those who live in remote areas. However, participants may face additional challenges in providing informed consent remotely. Sponsors and QIs should be careful not to create a disadvantage for those who:

- face barriers such as reliable private internet access, digital literacy, comfort with virtual tools **or**
- prefer not to use virtual platforms

Failing to address these barriers or not providing alternative options for obtaining informed consent may introduce ethical considerations around fairness and equity.

Consider:

- providing different methods of informed consent to those who request them, including in-person consent meetings and physical copies of the ICF
- using virtual meeting platforms that include both audio and video features so that QIs (or delegated persons) and participants can take part in the informed consent process and discussion in real time, and interact virtually with a real person if that's their preference

There must be a documented, retrievable and attributable record of the participant's informed consent. Trial-related documentation should support any proposed:

- delegation of duties related to the informed consent process to trial personnel or other third party

- virtual meeting (for example, at a health care provider's office or potential participant's home) to obtain informed consent

- medium of the documented record of participants providing their consent (for example, written, video, audio)

In accordance with the interim policy for the modernization of the clinical trial framework (effective September 14, 2026)

Informed consent is no longer limited to being “written.” Health Canada now permits consent processes that are appropriately documented, comply with good clinical practices and ICH E6 principles, and ensure consent is informed and given in accordance with applicable laws. New formats, including remote or electronic platforms may be used, as well as electronic signatures. Oral consent can be documented.

Conducting the trial, delegating activities

Introduction

Clinical trials that include decentralized elements may involve trial activities that take place away from the main clinical trial site, with the aid of digital health technologies and community-based health care resources. As per Division 5 of the Food and Drug Regulations (FDR), including sections C.05.010 to C.05.015, sponsors must ensure the trial is conducted in accordance with good clinical practices (GCP).

Access sections C.05.010 to C.05.015 of the FDR.

Quality management systems

Sponsors and qualified investigators (QIs) should work together with trial sites and service providers to implement a quality management system. Documented procedures (for example, standard operating procedures or SOPs and protocol procedures) help to ensure:

- quality at every stage of the trial process and at all sites
- that decentralized elements and activities have been appropriately integrated
- verifiable compliance with the regulations and the International Council for Harmonisation guideline ICH E6

From the outset, quality management activities should be reflected in the trial design and how it's conducted. The focus should be on critical to quality factors.

Sponsors and QIs should implement appropriate processes to identify, evaluate, control, communicate and review risks that may affect participant safety or the reliability of trial results, including risks introduced by decentralized elements. Quality management systems should ensure that decentralized elements are planned, put into operation and overseen with the same rigor as activities conducted at traditional trial sites. This includes clear documentation of roles, responsibilities, communication pathways and data flows.

Sponsors are responsible for systems and procedures that ensure the quality of every aspect of the clinical trial and the reliability of the results. This includes responsibility for:

- monitoring and overseeing trial conduct at all locations, including remote locations, to ensure compliance with the protocol, GCP and applicable legal and regulatory requirements
    - tailored to the identified potential safety risks, risks to data quality or reliability of the trial results and other risks related to decentralized elements
    - focus on aspects that are critical to quality
- including third parties or contracted services involved in decentralized activities under documented quality expectations
- monitoring participant compliance with the therapy
- managing data and maintaining records from the trial to support compliance with regulatory and GCP requirements
- identifying, documenting, escalating and reporting adverse events in a timely manner to protect participant safety and as specified by the regulations, to minimize communication delays between the locations where trial activities occur and the main site
- disseminating critical information (for example, for the timely review of test results and participant monitoring), including information from remote assessments, local health care providers or digital platforms
- verifying validation and calibration of technical instruments and measuring devices used across decentralized locations, such as those used in delegated activities or by participants
- ensuring the integrity of the products is maintained when transported and stored to safeguard the safety of participants and address any potential risk of diversion of any controlled substance used in a trial

For information on safety reporting, including criteria and process, consult the section on serious unexpected adverse drug reaction reporting:

- Drugs for clinical trials involving human participants (GUI-0100)

Agreements

Sponsors and QIs are responsible for ensuring that all agreements supporting decentralized trial activities clearly define the roles, responsibilities and oversight expectations of any delegated personnel, service providers or other third-party organizations. Trial-related documentation should distinguish between activities that require agreements and those that fall within routine clinical, imaging or laboratory practice where delegation documentation or agreements may not be necessary.

Any of the sponsor's or QI's trial-related activities that are delegated to and assumed by service providers should be documented in written agreements and the division of responsibilities defined. Clear, well-structured agreements help trial personnel, service providers and local health care providers comply with applicable laws, regulations and professional standards.

Agreements should establish how:

- trial-related tasks will be performed, supervised and documented
- investigational drugs and data will be managed
- compliance with regulations and GCP will be maintained

Sponsors and QIs must ensure that all parties understand and adhere to the approved protocol, applicable regulatory requirements and any procedures necessary to protect participant safety, data integrity and privacy.

Agreements help ensure that individuals and organizations conducting trial-related activities:

- understand their responsibilities and liabilities
- support participant safety by incorporating appropriate risk mitigation measures

Written agreements, such as contracts, can clearly set out:

- individual roles and responsibilities, including who performs specific activities and where
- required qualifications (education, training and experience) for personnel conducting trial activities

- how specific trial activities will be conducted and monitored for compliance to the protocol
- professional liability among sponsors, QIs, sub-investigators and delegated third parties, including local health care providers
- procedures for safety monitoring and timely reporting of adverse events
- indemnity coverage for participants
- any considerations relevant to specific groups, communities and Indigenous communities

Records of agreements and contracts (paper or electronic) must be available or accessible from the main location of the clinical trial site. This includes any established contracts or agreements between the sponsor or QI and other third parties, institutions or locations that outline roles, responsibilities, liabilities and indemnities.

Health Canada may review these documents during an inspection to ensure that all:

- relevant activities are covered
- relevant parties are mentioned and audited
- agreements are complete

As per subsection C.05.012(4) of the FDR, records including agreements and contracts must be maintained for 15 years. It's important to keep this documentation as it demonstrates who was responsible for specific trial activities, how oversight was maintained and how participant protection and data integrity were ensured.

We understand that clinical trials with decentralized elements may involve more service-provider agreements than traditional trial models. For this reason, we allow original paper documents to be converted into electronic copies for retention purposes (outlined in the GUI-0100 guidance).

For information on records access during inspection, consult:

- Policy on collection and retention of records related to health product compliance and enforcement (POL-0140)

For information on agreements, consult:

- Guidance document on drugs for clinical trials involving human participants (GUI-0100)

Other documents that may be relevant include:

- Tri-council policy statement: Ethical conduct for research involving humans
- Tri-agency research data management policy

Roles and responsibilities

Sponsors are responsible for the conduct of the clinical trial, while QIs are responsible for the conduct of the clinical trial at their site.

Both sponsors and QIs must ensure that all trial-related activities, including those in decentralized or remote locations, comply with applicable regulations, the approved protocol and ICH E6. This includes:

- appropriate oversight of all decentralized activities
- participant safety risks are managed
- drugs used in decentralized activities are transported, stored and handled according to good manufacturing practices (GMP) and the protocol
- all computerized systems and digital health technology supporting trial-related activities are validated, reliable and fit-for-purpose
- appropriate record-keeping and appropriate records retention for decentralized activities
- individuals and organizations performing trial-related activities are qualified by education, training and experience

Sponsor's obligations

Ultimately, sponsors are responsible for all trial-related activities, including any decentralized elements. This includes protecting participants' rights, safety and well-being and ensuring the integrity and reliability of the trial data, in accordance with GCP and applicable regulatory requirements.

In general, sponsors are responsible for:

- oversight of the trial and regulatory compliance
- systems and procedures that assure the quality of every aspect of the clinical trial are implemented
- data handling, including the integrity and confidentiality of data
- recording, handling and storing all information related to a clinical trial in a way that allows complete and accurate reporting, interpretation and verification
- maintenance of records of personnel, activities and essential documents
- appropriate reporting and record-keeping of adverse events, including:
    - suspected unexpected serious adverse reactions (SUSARs)
    - serious adverse drug reactions (SADRs)
    - serious unexpected adverse drug reactions (SUADRs)
- compliance with the approved protocol, investigational drug requirements and all applicable laws and regulatory requirements
    - includes provincial or territorial statutes governing informed consent, privacy and health records management

For information on federal and provincial privacy laws, consult:

- Privacy Commissioner of Canada's summary of privacy laws in Canada
- Provincial and territorial privacy laws and oversight

Qualified investigator responsibilities

In accordance with the interim policy for the modernization of the clinical trial framework (effective September 14, 2026)

Health Canada now allows a broader range of researchers to serve as QIs as long as medical decisions concerning the trial are made by a qualified physician or dentist on the clinical trial team.

The QI is responsible for the conduct of the trial at their site, any associated remote locations and any decentralized elements under their oversight. The QI must ensure the trial is conducted at their site in accordance with the approved protocol, applicable regulatory requirements and GCP, and that accurate and complete trial records are maintained.

In trials with decentralized elements, QIs may delegate trial-related activities to qualified personnel and third parties in accordance with applicable regulatory requirements and GCP.

While trial-related activities may be delegated, QIs are still accountable for participant safety, data reliability and compliance with applicable regulatory requirements.

Visit the section on delegating trial-related activities for other considerations related to delegation.

QIs should maintain appropriate oversight of trial conduct through a risk-based approach that is in proportion to the complexity of the activity and the associated risks to participant safety and data reliability. This includes ensuring appropriate operational and supervision plans are established and implemented for decentralized elements. Depending on the nature of the decentralized activities, QIs may also need to determine how to integrate those activities with local health care systems, telehealth platforms, institutional policies and training requirements.

Oversight responsibilities may include:

- ensuring timely access to trial-related medical care and medical decision-making, even in decentralized locations
- maintaining accountability for the investigational product, even in decentralized locations

- ensuring validation and calibration of technical instruments and measuring devices used at the trial site, associated locations, delegated activity locations or by participants
- monitoring data quality, reliability and fit-for purpose throughout the trial
- supporting monitoring, audits and inspections by maintaining access to essential documents and addressing identified issues or deviations

Delegating trial-related activities

Trial-related activities may be delegated to third parties, including service and local health care providers, when delegation supports the conduct of the clinical trial. These delegated activities may range from highly specialized procedures requiring specific equipment, expertise or training to tasks that fall within the standard scope of practice of local providers.

Sponsors may transfer or contract trial-related responsibilities and activities to qualified third parties, such as contract research organizations (CROs), laboratories and service providers. However, sponsors retain responsibility for ensuring appropriate oversight of trial-related activities that are transferred or contracted to third parties.

QIs may also delegate trial-related activities to qualified:

- trial personnel
- third parties, such as
    - health care providers
    - health centres or clinics
    - contracted service providers

When delegating activities, QIs must ensure that delegated activities are conducted in accordance with the approved protocol, applicable regulatory requirements and GCP. They must also ensure that delegated individuals and organizations have the necessary education, training, experience, qualifications and resources to perform their assigned responsibilities safely and in compliance with the protocol and regulatory requirements.

QIs are accountable for all trial-related activities conducted under their authority, including activities delegated to trial personnel or third parties. They should maintain appropriate oversight to protect the rights, safety and well-being of trial participants and ensure the reliability of trial data.

Regulations do not stipulate which clinical trial activities may or may not be delegated, or what specific training must be completed for each delegated activity. Rather, QIs are responsible for ensuring that delegated activities are performed competently and in compliance with the protocol, applicable regulations and GCP. Delegation should be clearly documented and consistent with the principles of ICH E6. Oversight should be in proportion to the complexity of the trial and the associated risks to participant safety, data reliability and other critical to quality factors.

As QIs oversee delegated activities throughout the trial, they should implement procedures to help them:

- identify and manage risks to critical to quality factors
- supervise delegated activities in accordance with documented operational and supervision plans
    - may include, for example, holding regularly scheduled supervision meetings or reviewing delegated activities
- ensure data security and integrity at a main site and related locations
- ensure appropriate record-keeping for trial-related documents (paper or electronic), including delegation logs, agreements and other relevant documentation
    - make all trial-related records available at the QI's main clinical trial site
    - ensure access to and management of essential records throughout the trial and their retention after the trial has ended

For information on documenting delegated activities, consult the section on good clinical practices:

- Drugs for clinical trials involving human subjects (GUI-0100)

Routine procedures

In general, routine clinical procedures (for example, routine blood tests or medical imaging, or standard-of-care procedures performed by local health providers) don't require specific trial-related training and delegation from a QI. However, where feasible, the QI should confirm that the individuals performing these procedures are qualified. This may mean verifying appropriate licensing or certification by applicable health authorities.

Trial-related documentation can be used to distinguish between activities that require delegation and trial-specific training, and those that fall within routine clinical practice, where such documentation or training may not be necessary. Documentation on the qualifications of third parties involved in routine procedures may not always be requested during an inspection.

Training and qualification

Any personnel or third parties involved in trial-related activities should have the necessary education, training, experience and resources to carry out their responsibilities in accordance with the protocol and regulatory requirements.

Sponsors and QIs should identify and document the specific training required for the activity to be conducted by delegated personnel or third parties.

For example, activities may include procedures that:

- require specific knowledge of the trial protocol, investigational drug, investigator's brochure or the specific disease area under study
- fall within the standard scope of practice of the applicable health care provider without additional training

For these activities, it may be crucial for delegated personnel or third parties to be aware of:

- participant safety (such as identifying possible adverse events)
- principles of ongoing consent
- protocol deviation reporting
- privacy breach reporting

- escalation pathways

Training requirements should be flexible to minimize unnecessary burden for participating health care providers while ensuring that delegated activities are conducted safely and according to the protocol, applicable regulations and GCP. Training should be appropriate to the delegated activity, as not everyone in the delegation log is required to have the exact same trial-specific training.

In general, training should include the relevant sections of trial protocol for which the person is responsible. If applicable to the duties being delegated, training could also be provided on relevant supporting guidance, including, for example, ICH E6, or on the specific medical condition under study.

For information on training, consult:

- Guidance document on drugs for clinical trials involving human participants (GUI-0100)

Delegation log

QIs should ensure a record is maintained of the persons and parties to whom the investigator has delegated trial-related activities (delegation log). Trial-specific tasks should not be conducted until the QI has documented the delegation and appropriate training has been completed.

The delegation log should be:

- completed before the trial begins and updated as necessary
- legible, adequately completed and clearly identify the names and signatures of key personnel, their key duties and the start and end dates of those duties
- signed and dated by the QI before a task has been delegated

Documentation of delegation should be in proportion to the significance of the trial-related activities. If activities are performed as part of standard-of-care clinical practice or by unplanned urgent care providers, delegation documentation or inclusion in the delegation log isn't usually required. As well, when tasks are delegated to a person in charge of other staff, further sub-delegation to individual staff doesn't need to be documented in the log, provided that evidence of their qualifications is available.

The delegation log and other relevant documentation to manage delegated activities must be available at the main location of a clinical trial site. We may request this information during an inspection.

For information on delegation logs, including examples of delegated duties to be captured, consult:

- Guidance document on drugs for clinical trials involving human participants (GUI-0100)

Health Canada inspections

Health Canada monitors clinical trials through inspections to verify that trial activities comply with legal and regulatory requirements, applicable standards and the approved protocol. Inspections may be conducted in person or remotely.

In clinical trials with decentralized elements, the main location of clinical trial site associated with the qualified investigator (QI) is the primary point of contact for an inspection.

Health Canada inspectors may request documentation from sponsors and QIs to demonstrate adequate coordination, oversight and monitoring of delegated parties, as well as the measures in place to protect participant safety.

For example, for an investigational drug that requires specific storage conditions, we may request documentation to help assess if the drug was stored appropriately when transported to remote locations, in accordance with the trial protocol. This may mean ensuring that shipping containers and configurations offer the required conditions for the maximum expected transport time, including any potential shipment delays.

We may also inspect other physical locations where study-specific activities took place. The selection of inspection locations is based on various criteria and uses a risk-based approach. Proper documentation at the main location of the clinical trial site can help us determine whether we need to inspect a decentralized location. For activities conducted remotely, all relevant information and records must be accessible for inspection at the main location of a site.

In general, routine or ad hoc procedures that don't involve protocol-specific elements or are performed in settings such as a medical imaging clinic or hospital emergency department are not subject to inspection.

We would not inspect a participant's home except in rare cases where we have serious and time-sensitive concerns around health or safety.

Clinical trial sites and QIs are the first point of contact for inspections. Sponsors and QIs should ensure that participants are informed about a potential visit from trial monitors who

may be working on behalf of sponsors or regulatory inspectors as part of the informed consent process.

Sponsors should consider inspection requirements early on when designing a clinical trial with decentralized elements, especially when trial-related activities may take place in a participant's home. Trial-specific procedures should be conducted in appropriate settings, as some trial activities may not be suitable for a home environment. Sponsors should ensure that trial-specific procedures are conducted in appropriate settings according to their level of risk.

We inspect clinical trials to assess adherence to good clinical practices (GCP).

For information on GCP, consult:

- Good clinical practices for drugs for clinical trials involving human subjects (GUI-0100)

For information on clinical trial inspections, consult:

- About inspections of clinical trials for human drugs
- Policy on accessing the premises of a regulated party remotely to verify compliance (POL-0138)
- Policy on individuals accompanying a health products inspector (POL-0141)

Definitions, resources, contact us

Definitions

The following definitions explain how terms are used in this guidance.

Most of the definitions are from the Food and Drugs Act or Food and Drugs Regulations. Other definitions are from Health Canada or International Council for Harmonisation (ICH) guidance documents. The ICH guidances are indicated as follows:

- General Considerations for Clinical Trials (ICH E8)
- Guideline for Good Clinical Practice: Harmonized Guideline (ICH E6)

If there's a conflict with how terms are defined in the legislation and a guidance document, the definition in the act or regulations prevails.

Adverse drug reaction (ADR): Any adverse and unintended occurrence in the health of a participant who is administered a drug in a clinical trial, where there are reasonable grounds to believe the occurrence could be a noxious response to a dose.

Adverse event (AE): Any adverse occurrence in the health of a participant who is administered a drug in a clinical trial that may or may not be caused by this drug. It includes an adverse drug reaction.

Agreement: A document (or set) detailing any arrangements on delegating, transferring, distributing or sharing activities and, if appropriate, on financial matters between 2 or more parties. The agreement could be in the form of a contract. The protocol may serve as the basis of an agreement. (ICH E6)

Clinical trial: An investigation related to a drug for use in humans that involves human subjects. The trial is held to:

- discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug
- identify any adverse events related to the drug

- study the absorption, distribution, metabolism and excretion of the drug **or**
- ascertain the safety or efficacy of the drug

This definition is consistent with the glossary in ICH E6.

Clinical trial site: Includes a main location, where the investigator conducts a clinical trial and oversees the conduct of the clinical trial at other locations, if any, that are remote from the main location.

Computerized systems: Digital systems used to create, process, store or manage clinical trial data, such as electronic data capture systems and trial databases.

Digital health technology: Participant-facing or remote data collection tools, such as wearables, sensors and mobile apps.

Drug: A drug for human use that's to be tested in a clinical trial.

For the purposes of this guidance, "drug" doesn't include natural health products within the meaning of the Natural Health Products Regulations.

Good clinical practices (GCP): Generally accepted clinical practices that are designed to help protect the rights, safety and well-being of clinical trial participants and other persons, and ensure the results are reliable. Outlined in the regulations and detailed in the ICH E6 guideline.

Participant: A person who participates in a clinical trial.

Protocol: A document describing the objectives, design, methodology, study population, statistical considerations and organization of a clinical trial.

Appendix B of the ICH E6 guideline describes the information found in a protocol.

Qualified investigator (QI): Person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site.

Under the 2026 interim policy, a "qualified investigator" may be:

- a physician or dentist who is authorized under the regulations to act as a qualified investigator
- an individual who has the education, training and experience required to conduct the clinical trial in accordance with regulatory requirements, despite not meeting the

requirement to be a physician or dentist as outlined in the definition of qualified investigator in C.05.001 of the regulations

In clinical trials where the investigator is not a physician or dentist, medical decisions about the trial that are outside the licensed scope of practice of the investigator must be made by a qualified physician or dentist on the clinical trial team. The physician or dentist is:

- licensed to practise in the province or territory where the site is located
- responsible for medical oversight and participant care, including medical decisions related to the trial

Research ethics board (REB): A body that isn't affiliated with the sponsor.

The REB's principal mandate is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects to ensure their rights, safety and well-being are protected.

The REB is to be composed as follows:

- at least 5 members (both men and women), most of whom are Canadian citizens or permanent residents under the Immigration and Refugee Protection Act
- includes at least:
    - 2 members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and 1 of whom is from a medical discipline or, if the clinical trial concerns a drug to be used for dental purposes only, is from a medical or dental discipline
    - 1 member with knowledge in ethics
    - 1 member with knowledge in Canadian laws relevant to the biomedical research to be approved
    - 1 member whose primary experience and expertise are in a non-scientific discipline
    - 1 member who is from the community or represents an organization interested in the areas of research to be approved and isn't affiliated with the sponsor or the site where the clinical trial is to be conducted

Serious adverse drug reaction (SADR): An adverse drug reaction that:

- requires in-patient hospitalization or a prolonged stay in hospital
- causes congenital malformation
- results in persistent or significant disability or incapacity
- is life-threatening
- results in death **or**
- requires medical intervention to prevent any of those outcomes

Serious unexpected adverse drug reaction (SUADR): A serious adverse drug reaction that's not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or equivalent document or on the product label.

Suspected unexpected serious adverse reaction (SUSAR): Term used to identify serious adverse reactions that require reporting to a regulatory authority.

Service provider: A person or organization (commercial, academic or other) providing a service used by either the sponsor or the investigator to fulfill trial-related activities.

Software as a medical device (SaMD): Software intended to be used for 1 or more medical purposes that perform these purposes without being part of a hardware medical device.

Sponsor: A person (would also include an organization) who:

- conducts a clinical trial solely or in combination with other persons **and**
- takes responsibility for the overall conduct of a clinical trial

Standard operating procedure (SOP): Detailed, documented instructions to achieve uniformity of the performance of a specific activity. (ICH E6, glossary).

Resources

Legislation

- Food and Drugs Act
- Food and Drug Regulations
- Clinical Trials Regulations (draft)

Health Canada

Branches:

- Health Canada
- Health Products and Food Branch
- Regulatory Operations and Enforcement Branch

Web pages:

- Drug products
- Health Canada publishes guidance on clinical trials with decentralized elements: Notice

Guidance documents:

- Guidance document for clinical trial sponsors: Clinical trial applications
- Drugs for clinical trials involving human subjects (GUI-0100)

Policies:

- Policy on individual(s) accompanying a health products inspector (POL-0141)
- Policy on accessing the premises of a regulated party remotely to verify compliance (POL-0138)
- Policy on collection and retention of records related to health product compliance and enforcement (POL-0140)

- Compliance and enforcement approach and inspection strategy for clinical trials of drugs involving human subjects (POL-0030)

Government of Canada agencies

- Tri-agency research data management policy
- Tri-council policy statement: Ethical conduct for research involving humans – TCPS 2 (2022)
- Canadian Core Data for Interoperability (CACDI) (Canadian Institute for Health Information, CIHI)

International Council for Harmonisation (ICH)

- International Council for Harmonisation
- Guideline for good clinical practice E6(R3)
- General considerations for clinical studies E8(R1)

Contact us

Pharmaceutical Drugs Directorate (PDD)
Office of Clinical Trials
Pharmaceutical Drugs Directorate
5th Fl, Holland Cross, Tower B
Address locator: 3105A
1600 Scott St
Ottawa ON K1A 0K9
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General enquiries: OCT_BEC_Enquiries@hc-sc.gc.ca
Clinical trial notifications: OCT_BEC_CTA-N-DEC@hc-sc.gc.ca
Clinical trial site information forms: clinical.trials.site@hc-sc.gc.ca

Biologic and Radiopharmaceutical Drugs Directorate (BRDD)
Office of Regulatory Affairs
Biologic and Radiopharmaceutical Drugs Directorate
100 Eglantine Dr
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Ottawa ON K1A 0K9
Fax: 613-946-9520

General enquiries: BRDD.ORA@hc-sc.gc.ca
Clinical trial notifications: brdd.ctan-ndec.dmbr@hc-sc.gc.ca
Clinical trial site information forms: brdd.ctsi-filec.dmbr@hc-sc.gc.ca

Regulatory Operations and Enforcement
Clinical Trial Compliance Program: GCP_BPC@hc-sc.gc.ca