Clinical Trials Ontario
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20 February 2026

Bureau of Policy, Science and International Programs
Pharmaceutical Drugs Directorate
Health Products and Food Branch
Health Canada
1600 Scott St.

To Whom It May Concern:

This letter is in response to Health Canada's request for input called "*Draft guidance on decentralized clinical trials.*" This submission has been put together by Clinical Trials Ontario (CTO) and on behalf of the thirty-two (32) health charities, patient organizations and research initiatives, that are named as signatories. This submission also includes specific patient and public input gathered from discussions with seven members of CTO's College of Lived Experience. The College of Lived Experience includes individuals from across Ontario who live with or are caregivers of individuals with a variety of different experiences related to diseases and conditions, healthcare, research, and clinical trials.

CTO is an independent not-for-profit organization established with support from the Government of Ontario. CTO's mandate is to work together with the clinical trials community, the public, and other partners to improve Ontario's clinical trials environment. One of CTO's three strategic pillars is patient and public engagement, hence our submission including input from organizations, initiatives, and individuals who bring perspectives from different parts of the trials space. We believe engaging patients and the public is critical to improving the environment for clinical trials in Ontario and Canada. This engagement will result in better: clinical trials, experiences for participants, and experiences of trial teams. Ultimately better trials and evidence also lead to an improved health care system.

To this letter, we attach our collective response for consideration. Of note, we have been working collaboratively with the clinical trials community for a number of years to support various efforts related to decentralized and hybrid clinical trials. Two explicit examples:

- The Participant Experience Toolkit which is a co-created effort with CTO's community and launched in 2021. This toolkit is a resource for anyone in the clinical trials community or interested in clinical trials. In 2025, we added a section dedicated to decentralized/hybrid trials that was co-created with the community. Health Canada's draft guidance on decentralized clinical trials is currently listed as a regulatory resource and the finalized guidance will replace this once available.

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- The peer-reviewed publication of a co-created research project to understand the perceptions of individuals in Canada relating to decentralized and hybrid clinical trials. This project was identified as a priority in conversations with CTO's College of Lived Experience and other members of the trials community early in the pandemic. Much of the Health Canada draft guidance document aligns with findings from this research.

In closing, we appreciate the opportunity Health Canada has provided us to submit this input and support for the Consultation: "Draft guidance on decentralized clinical trials." We look forward to seeing the finalized guidance document, in sharing it with our community, and in continuing to help the clinical trials community operationalize high quality clinical trials with decentralized and hybrid components.

Sincerely,

Susan Marlin, MSc
President and CEO

Dawn Richards, PhD
Director of Patient and Public Engagement

And on behalf of:

Asthma Canada
BioCanRx
Brain Tumour Foundation of Canada
Breakthrough T1D
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Cancer Survivor Network
Canadian CML Network
Canadian Council of the Blind
Canadian Lung Association
Canadian PKU & Allied Disorders
Canadian Skin Patient Alliance
Canadian Spondylitis Association
Colorectal Cancer Canada
Colorectal Cancer Resource & Action Network
Cystic Fibrosis Canada
Diabetes Canada
Fibromyalgia Association Canada
Fighting Blindness Canada
Huntington Society of Canada
Leukemia & Lymphoma Society of Canada
Melanoma Canada
Migraine Canada
Myeloma Canada
Obesity Matters
Ovarian Cancer Canada
Pain BC
Pancreatic Cancer North America
Psoriasis Canada
Save Your Skin Foundation
Sickle Cell Awareness Group of Ontario
WKG Foundation

/attachment follows

This feedback is provided with section headings that correspond to the guidance document along with specific line numbers and any context that we feel would be helpful to provide about our feedback..

Purpose

- Lines 6-8 - We're pleased to see the following sentence defining decentralized clinical trials, and recommend slightly changing language in this sentence as well as adding another sentence since some decentralized trials involve locations closer to home or even in one's home that are still in-person and do not rely on technology: "In decentralized clinical trials, some or all trial-related activities are conducted at locations other than traditional trial centres often with the help of digital health technologies and virtual methods. These types of clinical trials may also include in-person visits to centres closer to a participant's home (e.g., a lab) or even in a participant's home." We believe it would be helpful to also include some other names for trials that have some decentralized elements – i.e., hybrid or virtual trials, so after this statement, we suggest adding another sentence: "Clinical trials that have decentralized components may sometimes be referred to as hybrid, remote, or virtual clinical trials."
- Lines 8-9 - This statement "Decentralized elements can help reduce the travel burden for participants and also make clinical trials more accessible and diverse" is true, though it is not always travel that is the burden of participating in centralized clinical trials. We suggest changing the sentence to "Decentralized elements can help reduce a number of burdens related to participation and also make clinical trials more accessible and diverse."

Scope and application

- Lines 19-22 - We recognize that this document's audience is sponsors, investigators, and other third parties. With that said, we support and recommend adding a section near the start of the document which is a short summary of what the document is about and why it's important. This might be considered a plain language summary and this approach is aligned with many scientific journals (e.g., the BMJ) whose main audience is not the public/patients, but that might contain information of interest to these other audiences. This type of section not only helps other audiences understand the overall contents of the document, it also helps build trust with and demonstrates the transparency and accountability of Health Canada to the public.
- Lines 28-31 - We would appreciate explicit clarification in this section about whether or not the guidance applies to "dietary supplements."

Policy statements

- Lines 39-46 - We support the statements at the beginning of this section, which highlight how decentralized clinical trials are about equity for both participants and those who are conducting them: "Decentralized clinical trials consist of visits and activities that are conducted outside of traditional clinical trial centres, bringing research closer to participants. They can:
    - improve access to clinical trials and potentially promising new therapies for people across Canada
    - help connect a greater diversity of participants to research led from urban centres

They also allow researchers and other health care providers in remote areas to better connect to and participate in pan-Canadian research efforts, without requiring them to be co-located geographically."

- Line 49-51 - This is an awkwardly worded sentence that we suggest changing from: "As part of their clinical trial applications (CTA), sponsors must demonstrate in documentation that the inclusion of decentralized elements or activities are not against the best interest of participants." To: "As part of their clinical trial applications (CTA), sponsors must demonstrate in documentation that the inclusion of decentralized elements or activities are in the best interest of participants."
- Lines 52-54 - We appreciate the section on risks and suggest adding 'potential' to the following statement where it is highlighted in yellow:
  "Sponsors must also demonstrate that:
  - participants are told about the potential risks and benefits of participating in the trial"

Background

- Lines 83-108 - There are a number of important potential benefits listed here about decentralized clinical trials – some for participants, some for community-based health care professionals, some for sponsors and investigators. It might be more useful to create a table here that outlines potential benefits and who they may benefit and how, along with potential challenges to offer a balanced perspective. Some of the benefits and challenges impact more than one party- for example, being able to recruit 'sufficiently large, geographically, and culturally diverse participant group' benefits: participants who volunteer their time to participate, investigators who are doing the trial, sponsors/funders who are funding the trial, and the public in general because results are more generalizable. This type of nuance is currently lost in how the statements are listed as mostly benefiting one party. We provide a table here for consideration (note that the potential benefits are pulled from current language in this section, potential challenges are our own suggestions; these may not be exhaustive):

Table 1: Potential challenges and benefits of decentralized clinical trials and who these impact.

	Potential Challenges	**Potential Benefits**
Participants	• Create inequities: through the use of technology or for those who have no access to or unstable internet	• Save time with less travel • Allow opportunities to participate that might not otherwise be possible (e.g., if they cannot travel due to family, work, geography or other circumstances) • Provide opportunities to connect to research efforts, and potential to access to novel treatments • Decrease the stress of participating by doing so in a more comfortable, familiar setting (home or closer to home), which may also result in better data

	Potential Challenges	Potential Benefits
Members of Trials Teams	• Require (potentially) more planning, a budget for decentralized components, etc. • Offer operational complexity, for example, through logistical components that may require different types of infrastructure, staffing and oversight • Necessitate different approaches to communicating with participants who are not coming to a central site regularly	• Allow community-based health care professionals to participate in research activities • Provide community-based health care professionals the opportunity to gain access to more clinical trials and access to provide innovative treatments • Reduce logistical and administrative burdens for a single site via geographically dispersed activities (instead of needing to coordinate at multiple in person sites)
Overall	• Create inequities through requirement to use technology	• Reduce recruitment time, improve retention • Improve diversity of participants (i.e., increase representativeness of participants) • Reduce research waste • Increase generalizability of results

Design considerations for decentralized clinical trials

- Line 113 - In the opening statement, in the third bullet 'their' should be removed and the bullet should read: 'appropriately monitor safety'
- Line 118 - In Table 1, 'patient reach' should be replaced with 'participant reach.' While a number of participants are in fact patients, not all are, and these words should not be interchangeable. The item here that reads "Participant-centric by reducing travel burden" is an oversimplification. Instead, this might simply read: "Participant-centric by reducing burdens" as travel may not be the only burden to participation. Lastly, as part of this row, we suggest adding to both columns: "Increase the diversity of those who can participate."

Multi-site trials

- Lines 119-129 - It may be helpful to add in a statement about why there is not also a section on 'single-site with decentralized elements' and only those relating to 'multi-site'.

Research ethics boards

- Line 139 - We appreciate that there is a statement about 'sponsors should consider using streamlined REB review systems.' Many of the organizations involved in this submission support the CanReview initiative that is listed, and CTO's College of Lived Experience has written in Healthy Debate on the importance of research ethics review and their perceptions of it (including sentiments relating to equity, bureaucracy, and duplication).

- Lines 148-154 - We appreciate that the streamlined ethics review systems are listed here for easy access.

Considerations for coordinating decentralized clinical trials

- Lines 155-213 - We appreciate this section, especially how it begins around minimizing participant risk, and safeguarding the integrity and security of trial data.
- Lines 164-177 - Under the bulleted list that starts with "When deciding to decentralize trial activities, QIs and sponsors should consider:" we respectfully request three additional bullets be added that read (see highlighted yellow text; the text that follows it is for contextual purposes only for this submission):
    - "that the use of technology in decentralized elements does not unintentionally disadvantage or lead to inequities in participating in the trial." While many potential participants welcome technology as a means of easing participation burdens, trial teams need to be aware that some participants may need additional supports with technology or that they may be unintentionally excluding some potential participants altogether (for example, if these individuals do not have access to an internet or stable internet connection, etc.).
    - "how patients, caregivers, and family members representative of the intended participant population can be involved in supporting decentralized elements of the trial. These individuals' lived and living experience will be invaluable in helping consider how elements can be decentralized in ways that work best for their communities." We ask for this addition knowing that Health Canada is supportive of patients, caregivers, and family members being partners in clinical trials, given its support of International Council for Harmonization documents on this topic (e.g., the Reflection Paper on Patient-Focused Drug Development to which CTO has provided feedback during its consultation period).
    - "Cybersecurity protocols and procedures required to effectively and safely manage, share, and exchange digital information." While some of this information may be inferred in the other bullets in this list, we recommend being explicit about this given its importance and to minimize any assumptions being made by readers.
- Lines 191-213 - The section on written agreements here is important, and we recognize that these agreements can take a considerable amount of time and effort to execute and maintain.
- Line 190 - It would be helpful for Health Canada to explicitly state how it sees that agreements "…help protect the safety of trial participants."

Submitting a clinical trial application

- Lines 222-223 - We recommend adding the following highlighted information to this sentence: "Sponsors must also attest that the trial will be conducted according to good clinical practices, and that the decentralized components will not compromise the integrity of the trial."
- Lines 224-229 - While not currently a requirement in a clinical trial application, this would be another section where Health Canada could greatly benefit from knowing how patients, caregivers and family members have informed the trial design overall. An obvious place to include this is as a new bullet in the following section of text here which

is highlighted in yellow (i.e., after Line 229):
"Depending on the decentralized activities within the proposed trial, sponsors should describe in their CTA:

- how clinical trial activities and participant visits are expected to be conducted (for example, in person, by telephone or telehealth platform)
- how the proposed decentralized approach is in keeping with the risk posed by the trial to participants
- how patients, caregivers, or family members from the participant population have informed the clinical trial, including decentralized elements."

Conducting a clinical trial with decentralized elements

- Lines 249-304 – Under the Sponsor's obligations section, we recommend that a section relating to the Data Safety Monitoring Board (DSMB) and its role in this type of clinical trials be added. We can imagine that the DSMB will have an important role to play in these types of trials given the potential for additional parties and technologies to be involved with data collection, transfer, analysis, security, etc.. Including information about how trial teams take different approaches into consideration and with respect to the role the DSMB plays seems important to expand on in this document so as to ensure data is as of high quality as possible.

Training and qualification

- Lines 333-336 -We recommend being clear that there should be know-how and training related to the therapeutic area under investigation. While this may be implied in current wording, we suggest be explicit, for example by adding the following highlighted text to this section (after the first sentence in lines 333-334 ends): "In general, training should be relevant to the study-related duties and include the relevant sections of the trial protocol for which the person is responsible to carry out. Training may also include training about the specific disease area under study. For example, this may be especially important in the case of rare diseases, and for staff who are not at the main location of the clinical trial site."

Informed consent process

- Lines 390-439 - We are pleased with the information in this section, specifically that there are many options listed as possible ways to provide informed consent. The information shared here is very aligned with CTO's research findings co-produced with its College of Lived Experience members on decentralized and hybrid trials and perceptions of them in Canada, and which were published in a peer-reviewed publication, co-authored by a number of CTO's College of Lived Experience members. One of our key findings is that people generally want options relating to clinical trial participation, however they also want to be sure they can contact someone in case of emergencies or if they experience adverse events (i.e., the 24-hour number is especially important).
- Lines 407-418 - We recommend that an additional bullet highlighted in yellow be added at the end of this list (i.e., after line 418):
    - How they will be informed of what potential adverse events look like and who will communicate this information to them"

We suggest this addition because since participants may not be at a central site as much or at all, they may not have the same communications benefits about potential adverse events. As such, participants may not even consider adverse events to be adverse events, and knowing how this information about adverse events will be communicated and by whom will be helpful.

- Lines 420-423 - We appreciate the sentence "…sponsors should be careful not to create a disadvantage for those who do not have access to or who prefer not to use virtual platforms. Doing so may introduce ethical considerations related to fairness and equity."

Clinical trial inspections

- Lines 459-465 - We appreciate the information included here about the potential for Health Canada needing "…to enter a home if the clinical trial activity there poses a hazard to a participant. Recognizing that an inspection in a home may invade a participant's privacy, sponsors should ensure that trial-specific procedures are conducted in appropriate settings according to the risk or hazard posed to participants. If it's expected that study-related procedures will take place in a participant's home, the participant must be told that an inspection may take place as part of the informed consent process." We recommend that Health Canada change language here to make it clear that the inspection will not take place during the informed consent process, with changes highlighted here: ""…to enter a home if the clinical trial activity there poses a hazard to a participant. Recognizing that an inspection in a home may invade a participant's privacy, sponsors should ensure that trial-specific procedures are conducted in appropriate settings according to the risk or hazard posed to participants. If it's expected that study-related procedures will take place in a participant's home, the participant must be told as part of the informed consent process that an inspection at their home may be a possibility at some point during their participation in the trial." Additionally, Health Canada should include language here about the potential likelihood of this being an occurrence. While we appreciate this may mean some potential participants decide not to participate because of this, providing some information about the likelihood of this happening may be an important contributor for some people related to their making an informed decision about participation.
- Overall, in this section, we note that inspections for trials with these types of elements may become especially important given the additional parties that may be involved with conducting the trial, the various technologies and other approaches used with informed consent, data collection, etc., and the potential additional responsibilities on sponsors, PIs, and QIs.

General comments

- In addition to the comments above, we recommend that Health Canada have a summary section, a list of references, and a glossary at the end of document, much like other documents from Health Canada that are currently out for consultation.