Submission of Comments
Draft guidance Decentralized Clinical Trials

Comments submitted by:

Full Name:	Ron Boch
Association Name: (if applicable)**:**	BIOTECanada
Telephone number:	613 230-5585
Address:	410-410 Nicholas Street, Ottawa Ontario K1R 1B7
E-mail Address:	ron.boch@biotech.ca
Date:	February 21, 2026

General Comments from BIOTECanada:

- Health Canada's draft guidance on decentralized clinical trials (DCT) represents an important step toward modernizing Canada's clinical research ecosystem. BIOTECanada is supportive of this effort and welcomes the opportunity for further engagement, especially as this guidance is interim being implemented during a period of transition for the Clinical Trial Regulations.
- Given the global nature of clinical trials, to ensure that Canada remains an attractive destination for clinical research investment, Health Canada should ensure alignment of the modernized clinical trial regulatory framework with approaches to decentralized trials by FDA and EMA. Unique Canadian specific requirements for decentralized clinical trials will increase burden and decrease efficiency for sponsors thereby deterring Canada as a key clinical research destination. BIOTECanada strongly encourages a global DCT model.
- Decentralized options have the potential to improve access; it is important to consider the intersectionality of participant populations. While the proposed guidance will likely encourage representation at urban centers additional considerations and clarifying text may be required to effectively support participation across rural and remote regions of Canada. With a large rural population in Canada, not all participants are able to engage with digital, wearable, or technology-enabled solutions, and decentralized models should avoid unintentionally creating new barriers to participation. Language barriers and culturally appropriate communication need to be considered when designing any decentralized solution. Without this, communities may reject decentralized options entirely and that defeats the purpose of representation and expanding access
- The guidance should also include some language, flexibility and provisions for inclusion of remote trial sites or smaller community hospitals that typically lack the resources/ infrastructure to conform to ICH/GCP requirements. Addition of this flexibility and clarity (and possibility tying it to the expanded access clinical program) will specifically be useful for the smaller companies and will allow for increasing research capacity and expanding access to new therapies (especially for development of drugs for use in emergency settings and for rare diseases).

Section	Comment and Rationale	Proposed Revised Text
Scope and Application (Lines 28-29): This guidance does **not** apply to: clinical trials involving medical devices	Medical devices / DHTs are often used in DCTs as discussed elsewhere in the guidance. The scope should be clarified to indicate that the guidance does not apply to clinical trials *evaluating* medical devices. Note: FDA DCT guidance is broader and extends to device trials – Can that not be considered by Health Canada?	This guidance does **not** apply to: clinical trials ~~involving~~ **evaluating** medical devices"

Section	Comment and Rationale	Proposed Revised Text
Policy Statements (Lines 49-51): 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"	Requiring sponsors to justify DCT elements positions DCT as exception requiring special approval rather than modern standard practice. Creates undefined evidentiary burden and will likely delay CTA preparation and submission for no clinical benefit Clarification should be provided regarding what documentation Health Canada would expect to be included in the CTA to demonstrate that decentralized elements have been assessed. Without specific guidance, the sponsors may face: ● Uncertainty regarding submission requirements ● Inconsistent regulatory expectations (FDA and EMA do not require similar justification) ● Potential delays in review and approval	Suggested revision: 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~~ **should ensure that the CTA includes supporting documentation that adequately describes how any decentralized elements or activities are consistent with participant safety and ensure that oversight, and ethical conduct of the trial are not compromised.**
Policy Statements (Lines 66-70): ● "…avoid unnecessary burden on participants, investigators and trial-related personnel or other third parties involved in decentralized elements…"	decentralized models should avoid unintentionally creating new barriers to participation	Suggest adding another bullet after Line 70: ● **offer support such as language interpretation and technology navigation**
Policy Statements (Lines 71-73): "Decentralization can involve a qualified investigator (QI) at a main location of a clinical trial site, who delegates trial-related activities to personnel or third parties in other physical locations."	Needs clarification because - Delegation can be to third parties but locations can be at the participant home or visits can be virtual conducted by a third party	Suggested revision: Decentralization can involve a qualified investigator (QI) at a main location of a clinical trial site, who delegates trial-related activities to personnel or third parties **not located at the main location of the clinical trial site (other physical location, remote)**
Background (Lines 83-93): Decentralized elements may involve using validated digital health technologies and community-based health care resources, such as: ● wearable sensors or medical devices to	Without ways to take the research to participants, many rural communities in Canada, especially indigenous communities could be left out. Moreover, cloud-based platforms, wearables, and remote monitoring	Suggest adding another bullet after Line 93: ● **mobile health units designed as a hybrid model to expand access to clinical trial participation in rural communities**

Section	Comment and Rationale	Proposed Revised Text
monitor and measure outcomes ● internet-based tools for collecting and managing electronic participant-reported outcomes ● telehealth platforms, such as online portals and videoconferences with investigators ● direct-to-home shipping of investigational drugs, including the use of local pharmacies for investigational drugs with specific storage and handling conditions ● at-home visits by trial personnel or follow-up visits with local health care providers who may be known to the participants ● testing and imaging, such as a blood test, at local clinical laboratories	can raise legitimate concerns, and communities often require clear information on: - where data are stored (including geographic considerations), - who has access to the data (e.g., sponsors, vendors, regulators), and - whether and how data may be reused or shared.	Also suggest including elements of a decentralized trial that could directly address the concerns on cloud-based platforms, wearables, and remote monitoring.
Background (Lines 91-92): "…at-home visits by trial personnel or follow-up visits with local health care providers who may be known to the participants"	Clarification on requirement of a 'local' health care provider for a follow-up visit'	Proposed revision: "…at-home visits by trial personnel or follow-up visits ~~with~~ local health care providers who may be known to the participants"
Background (Line 98-101): "..Decentralization is very important for clinical trials that face challenges with recruiting sufficiently large, geographically and culturally diverse participant group, such as rare disease trials. It can also improve the ability to recruit and retain a more representative participant group, which can lead to stronger and more general evidence or results."	Without ways to take the research to participants, many rural communities in Canada, especially indigenous communities could be left out. -	
Design considerations for decentralized clinical trials (Line 109)	This section describes both single-site and multi site and therefore the heading should be revised accordingly.	Please revise to "Design considerations for decentralized clinical trials **(single-site and multi-site)**

Section	Comment and Rationale	Proposed Revised Text
Design Considerations for Centralised Trials Table 1:	Table 1 and the comparison between decentralized trials and multi-site trials is difficult to interpret and should be clarified to avoid confusion. It is recommended that a short decision aid (e.g., examples) is added to clarify triggers for multi-site (and CTSI per site) vs. single-site delegation, Some additional suggestions to further clarify Table 1 are provided below	It is recommended that Health Canada revise the table title to: *Design considerations for decentralized clinical trials (**single-site and multi-site).*** In addition, the content of the table should be revised to provide greater clarity on Health Canada's expectations for decentralized trials. Some suggestions are provided below.
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials. Title of last column	It should be clarified whether the title of the last column also refers to studies with DCT elements	Please modify title of last column to: "Multi-site **with decentralized elements**"
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials Final column of Trial Suitability; multi site "Suited for complex trials, those needing large cohorts or where in-person site-specific interactions are required"	It should be clarified that the point of multi site decentralised trials is that the suitability would depend on a) need several sites (e.g. for recruitment reasons) b) that there are assessments/tests/visits/etc, that are amenable to be performed safely in a decentralised manner	Suited for ~~complex~~ trials~~, those needing~~ **recruiting** large cohorts ~~or~~ **and** where in-person ~~site-specific~~ interactions are required **(e.g. assessments/tests/visits/etc.) which are amenable to be performed safely in a decentralised manner**
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials Operational model, multi site "Distributed operations across multiple independent sites, under a single study protocol	Requires clarification	Distributed operations across multiple independent **central** sites, under a single study protocol**, with each site also having decentralised activities occurring in other locations'**
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials Administrative burden related to REBs, single site	Requires clarification	Suggest revising to: "Approval only needed from the REB related to the main location **as well as its decentralised activities occurring in other locations'**
Design Considerations for Centralised Trials	Requires clarification	Suggest revising to:

Section	Comment and Rationale	Proposed Revised Text
Table 1: Design items to consider for decentralized clinical trials Administrative burden related to REBs, multi site		REB approval is required for each ~~of the~~ **main location of each central** clinical trial site~~s,~~ **as well as its decentralised activities occurring in other locations'**
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials Patient reach, single site	Requires clarification	Below revisions are proposed: Broad**er** geographic reach **than a study without decentralised elements**, up to a point – **but still may be limited given a single central site (e.g. there may be elements which do require central site visit)** Participant-centric by reducing travel burden"
Design Considerations for Centralised Trials Table 1: Design items to consider for decentralized clinical trials Patient reach, multi-site	Requires clarification	Below revisions are proposed: Broad**est** geographic reach due to having **central** sites in different areas**, and also decentralised elements which reduce travel burden"**
Multi Site Trials (Lines 127-129): "When decentralizing activities in a multi-site trial, sponsors should ensure that trial-related activities delegated from each QI's main location are within the scope of that site's REB approval and supervised by the site-specific QI."	Unsure what this is referring to, if the site delegates any activities to another location, it would be on the site to ensure their REB has oversight.	HC is requested to add clarification
Research Ethics Board (Lines 138-139): "For multi-site trials where Health Canada requires each clinical trial site to obtain a REB approval, sponsors should consider using streamlined REB review systems	Requirement for each site to obtain separate REB approval perpetuates major barrier to Canadian trial participation. Multiple REBs create timeline delays, inconsistent protocol interpretations, and substantial administrative burden. Without single REB option, decentralization across Canada is administratively prohibitive. Note: FDA mandates single IRB for US multi-site trials	Suggested Revision: For multi-site trials where Health Canada requires each clinical trial site to obtain a REB approval, **use of a streamlined REB review systems is recommended**"
Considerations for coordinating decentralized clinical trials (Lines 178-188): Digital health technologies should be validated for their intended use and demonstrate compliance with ICH E6, for example, by: tracing any	Six-point validation list appears to exceed ICH E6(R2) requirements, particularly 'planning for future accessibility' which is vague and potentially requires indefinite technology support. Creates uncertainty about what documentation is sufficient. May	HC is requested revise the list to align the DHT validation requirement with ICH E6(R2)

Section	Comment and Rationale	Proposed Revised Text
changes and updates, such as source, date and content (audit trail); backing up at regular intervals; having security measures in place to protect against data corruption, whether through accidental deletion, equipment failures, material deterioration or other hardware and software problems; controlling access to appropriate individuals (such as through use of passwords); planning for future accessibility (in light of changes over time in technology, personnel or third-party contractors); allowing immediate access to records for inspection	limit availability of DHT vendors willing to support Canadian trials if requirements exceed global standards. ICH E6(R2) already establishes computer system validation requirements; additional Canadian expectations create divergence. Need clarity that global DHT platforms meeting ICH standards are acceptable without additional Canada-specific validation	
Considerations for coordinating decentralized clinical trials (Lines 212-213): "As per subsection C.05.012(4) of the regulations, records of contractual agreements must be maintained for 15 years."	Extending 15-year retention to all contractual agreements with third parties creates massive storage burden for DCT. Trials may have hundreds of local provider agreements (labs, pharmacies, home health agencies, imaging centers). 15-year retention for routine commercial service agreements is disproportionate and exceeds global norms. Need distinction between study-critical agreements (CRO, central services) requiring long retention and routine services. Without clarification, sponsors must retain every commercial service agreement indefinitely, creating cost and complexity disproportionate to risk.	HC is requested to add clarification
Sponsor's Obligation (Lines 259-266): "Sponsors must implement a quality system consisting of documented procedures (for example, standard operating procedures or SOPs, protocol procedures) to ensure quality of every aspect of the trial process and at all sites. Such a system should comply with the regulations and ICH E6." "Decentralization of clinical trial activities across third parties and locations could	Requirement for 'robust, comprehensive plans (or written procedures) for the decentralized elements' in addition to general quality systems creates potential for duplicative documentation. 'Robust, comprehensive' is undefined - what is sufficient? DCT is operational choice, not fundamentally different quality requirement. Existing ICH E6(R2) quality management systems should accommodate DCT as trial design variation.	HC is requested to confirm and clarify that existing quality systems apply to DCT and that appropriate integration of DCT into existing systems is and acceptable approach.

Section	Comment and Rationale	Proposed Revised Text
complicate oversight and monitoring of trial activities. Sponsors should develop and implement robust, comprehensive plans (or written procedures) for the decentralized elements"		
Oversight and Delegation Log (Lines 361-363; 374-376; 379-381): "QIs must maintain a delegation log, available at the main location of the clinical trial site (associated with the QI). The delegation log must clearly identify all persons to whom study-specific responsibilities have been delegated." "QIs do not need to include the following procedures in the delegation log. However, they should take appropriate measures to ensure that the individuals involved are qualified and that their planned involvement is clearly outlined in trial-related documentation: routine procedures (for example, a routine blood test or medical imaging) or non-study-related care provided ad hoc (such as emergency room procedures)" "For these types of procedures, Health Canada recognizes that, within reason, documentation on the qualifications of all third-parties may not be readily available to the QI."	Ambiguity between 'study-specific' requiring delegation and 'routine' excluded from delegation creates major compliance risk in DCT context. At scale (hundreds of local providers), individual delegation is administratively prohibitive. 'Within reason' is undefined - risk of inspection findings for inadequate documentation. Need bright-line rules, not judgment calls. Current ambiguity will drive sponsors to either over-document (massive burden) or risk inspection findings (compliance risk). This single issue could make large-scale DCT operationally infeasible in Canada	HC is requested to add clarification for the following: - list of procedures requiring delegation - threshold between 'routine' and 'study-specific' with examples across procedure types - define ‘within reason' standard for unavailable qualifications documentation - that using established network of qualified providers (e.g., home health agency) doesn't require individual delegation for each provider
Oversight and Delegation Log (Lines 367-368): “…tailored training requirements for persons or occupations involved in specific trial-related activities”	Needs Clarification because - Training plans should contain tailored training requirements and not the delegation log. Also should have flexibility for task-based training and not role-based training.	HC is requested to add clarification; remove/ clarify the requirement to contain tailored training requirements in the delegation log
Oversight and Delegation Log (Lines 387-389): “Note that this documentation includes any established contracts or agreements between the sponsor and other third parties, institutions or locations outlining specific	Is it expected that contracts between sponsors and third parties are included/filed with the delegation log at investigator main sites? Contracts between sponsors and third parties should only be filed at the sponsor/third party. A separate document outlining roles	HC is requested to confirm and clarify

Section	Comment and Rationale	Proposed Revised Text
roles, responsibilities, liabilities and indemnities”	and responsibilities should be made available and filed at the main site.	
Clinical Trial Inspections (Lines 457-465): “…….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”	Unreasonable ask for sponsor to assess potential risk or hazard to participant if trial activity occurs at home. How can sponsor establish this? Major privacy concerns as well. This will hinder Canada’s participation in a study The possibility of an inspection at a participants’ home will very likely deter participant from enrolling in a study and significantly impact recruitment. Also, will the REBs be open to accepting this?	It is suggested that this section be revised to indicate that any inspection activities would be initiated at the site, and that the QI should communicate directly with the patient, rather than an inspector arriving at a person’s home.