Consultation: Health Canada's Draft Guidance for Decentralized Clinical Trials Public Review

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Executive Summary: Health Canada released a draft guidance outlining regulatory expectations for decentralized clinical trials (DCTs), where activities occur outside traditional research sites using remote and digital approaches. The document clarifies that DCTs must comply with existing requirements, with no reduction in obligations related to participant safety, informed consent, oversight, and data integrity. Sponsors are expected to clearly describe decentralized elements, assess associated risks, and ensure appropriate monitoring and accountability, while Health Canada seeks stakeholder feedback as part of broader clinical trial modernization efforts.

CSHP provided the following feedback:

- CSHP supports efforts to modernize clinical trial conduct in Canada to improve accessibility, efficiency, and participant diversity while maintaining participant safety, data integrity, and regulatory compliance.
- CSHP is aligned to improve access to clinical trials and potentially promising new therapies for people across Canada to help connect a greater diversity of participants to research led from urban centres, while including participants in remote rural areas. Decentralization is very important for clinical trials that face challenges with recruiting sufficiently large, geographically and culturally diverse participant groups, such as rare disease trials, which can lead to stronger and more general evidence or results.
- CSHP supports that planning and conducting decentralized clinical trials may involve additional considerations, while ensuring regulatory requirements are the same as any other clinical trial to minimize patient risk, support patient safety through monitoring, and ensure study objectives can be achieved.
- CSHP also agrees that virtual meeting platforms and electronic signatures may make the informed consent process more efficient for those who live in remote areas. CSHP agrees that sponsors should be careful not to create a disadvantage for those who do not have access to or prefer not to use virtual platforms to ensure fairness and equity, while maintaining security measures to protect participants' personal information and safety.
- CSHP also suggests that since decentralized clinical trials likely require more parties involved in the study, Health Canada's guidance can emphasize the need to ensure all relevant parties receive appropriate training at all sites.
- CSHP is aligned that for investigational drugs that require specific storage conditions, Health Canada inspectors may request documentation so they can assess if the drug was stored appropriately when being transported to remote locations. This means ensuring that shipping containers and configurations offer the required conditions (for example, 2°C to 8°C, keep frozen, prevent from freezing) for the maximum expected transport time. CSHP also suggests inspectors include protocols where there may be shipment delays, especially for shipments being sent to highly remote areas.

38 promenade Auriga Drive, suite/bureau 200, Nepean, Ontario K2E 8A5
Tel./Tél.: 613.736.9733 | Fax/Télec.: 844.438.9397
cshp.ca