Government of Canada Gouvernement du Canada

Notice: Clinical trials for medical devices and drugs relating to COVID-19 regulations

The *Clinical Trials for Medical Devices and Drugs Relating to COVID-19 Regulations* (Regulations) were published on March 2, 2022. They came into effect on February 27, 2022, following the repeal of Interim Order No. 2 respecting clinical trials for medical devices and drugs relating to COVID-19 (IO No. 2). IO No. 2 was made on May 3, 2021.

The flexibilities under IO No. 2 will continue under the Regulations. This will ensure 2 things:

- sponsors may continue conducting clinical trials authorized under the interim order
- all authorizations, suspensions and exemptions for clinical trials issued under the interim order will remain in effect

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Overview

IO No. 2 provides a more flexible authorization and implementation pathway for the clinical trials of drugs and medical devices used to diagnose, treat, mitigate or prevent COVID-19 in people.

The provisions of IO No. 2 are set to expire on May 3, 2022. They will be replaced by the Regulations, which came into force on February 27, 2022.

The Regulations maintain the flexibilities set out by the interim order until the framework established through the Clinical Trials Modernization Initiative is in place.

By maintaining the pathway set out by the IO, the Regulations will continue to facilitate the authorization and implementation of COVID-19-related clinical trials. In addition to reducing administrative burden, they will continue to uphold the health and safety requirements for trial participants and ensure the validity of trial data.

Under the Regulations, all clinical trials applications (and amendments) for COVID-19-related drugs and medical devices will continue to be reviewed within 14 days. Research ethics boards are also prioritizing reviews and approvals for COVID-19 clinical trials.

Transition plan for clinical trial authorizations

A flexible pathway

Under the Regulations, all authorizations and suspensions for clinical trials issued under IO No. 2, including any terms and conditions, will remain in effect. Any applications and amendments made under IO No. 2 that are outstanding when it's repealed will be considered as applications and amendments made under the Regulations.

In addition, we have made minor changes to clarify the following:

- the classification framework for medical devices in the *Medical Devices Regulations* applies to the Regulations
- the type of information or material that, if changed significantly, would require an amendment to an authorization for clinical trials

involving COVID-19 medical devices

We have also improved the wording of the provisions related to amendments to authorizations (sections 8 and 24 of the Regulations). The improvements align with good drafting practices. They also more accurately describe the obligations of authorization holders in these situations.

Records retention

The Regulations include amendments to the records retention periods that were temporarily required under IO No. 2.

Under the Regulations, records for all clinical trials of COVID-19 drugs must be kept for 15 years.

For clinical trials of medical devices, clinical trial records must be kept for the entire authorization period. Distribution records for medical devices must be kept for whichever is longer:

- the projected useful life of the device or
- 2 years after the date the authorization holder first took possession, care or control of the device in Canada

At the same time, we have amended the *Food and Drugs Regulations* and the *Natural Health Products Regulations* to reduce the records retention period from 25 years to 15 years for clinical trials of drugs and natural health products.

Consequential amendment to the Certificate of Supplementary Protection Regulations

The Regulations include a consequential amendment to the *Certificate of Supplementary Protection Regulations* (CSPR) to exclude authorizations under section 21 and amendments under subsection 24(2) of the Regulations from the definition of 'authorization for sale' in the CSPR,

just as clinical trial authorizations and amendments under sections C.05.006 and C.05.008 of the FDR and sections 67 and 71 of the NHPR are currently excluded.

We also made a minor amendment to ensure consistency between the English and French and to avoid repetition.

Contact us

For more information about this notice, please contact Health Canada's Therapeutic Products Directorate at policy_bureau_enquiries@hc-sc.gc.ca.

Related links

- Interim Order No. 2 respecting clinical trials for medical devices and drugs relating to COVID-19
- Guidance on applications for COVID-19 drug clinical trials under the Regulations
- Guidance on applications for COVID-19 medical device clinical trials under the Regulations
- Applications for medical device investigational testing authorizations guidance document
- Guidance document for clinical trial sponsors: Clinical trial applications
- Clinical Trials Database
- Management of clinical trials during the COVID-19 pandemic: Notice to clinical trials sponsors
- Drugs and vaccines for COVID-19: List of authorized clinical trials
- Conducting a clinical trial for COVID-19 medical devices: List of authorized clinical trials
- Clinical trials for natural health products

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