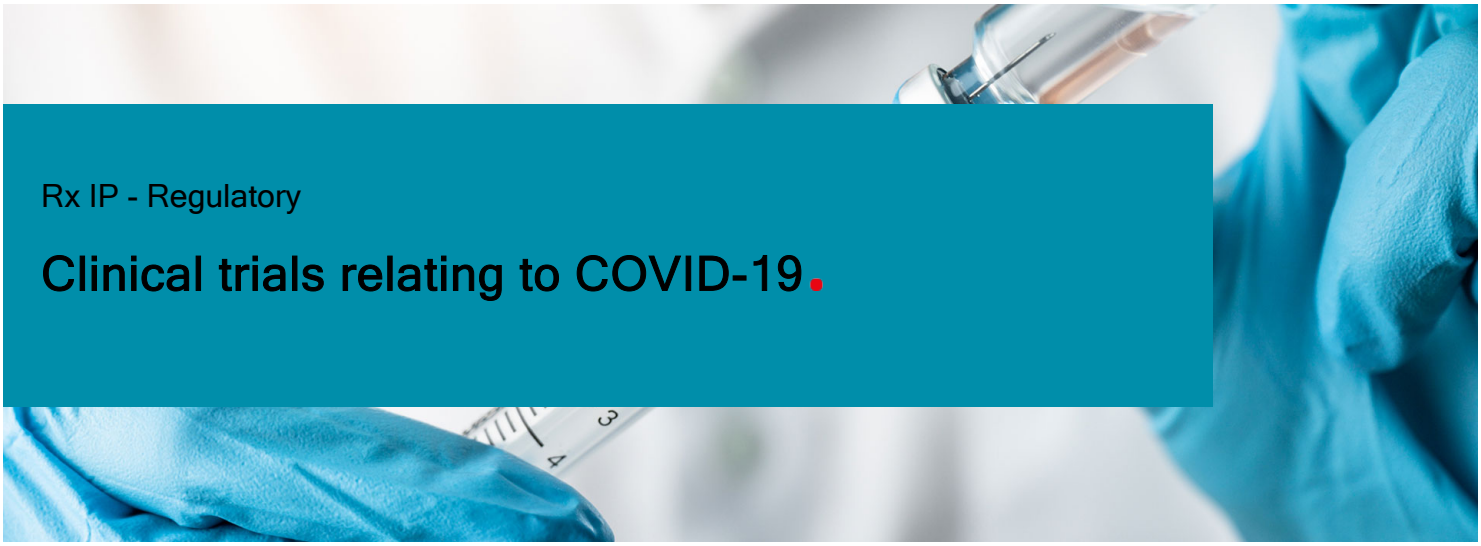

Rx IP - Regulatory

Clinical trials relating to COVID-19.

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Alice Tseng

This article was prepared with contribution from student Akiv Jhirad.

We discussed Health Canada's *Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors* (Notice) in a previous bulletin. While that Notice applies to all clinical trials *during* the pandemic, this article focuses only on clinical trials *for* COVID-19 related products.

More than 60 clinical trials for COVID-19 drugs (including vaccines) and medical devices have already been authorized by Health Canada:

- List of authorized clinical trials for COVID-19 drugs and vaccines
- List of authorized clinical trials for COVID-19 medical devices

The speed at which COVID-19 related clinical trials have been authorized has been assisted by Health Canada's commitment to prioritize the review of COVID-19 related applications generally as well as Health Canada's various measures to facilitate COVID-19 clinical trial applications specifically.

The *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19* (the Interim Order), released by the Minister of Health on May 23, 2020, creates a framework to increase the efficiency of COVID-19 clinical trials while upholding strong patient safety requirements, as further described below. The Interim Order encompasses pharmaceutical and biologic drugs and medical devices, but not radiopharmaceuticals, natural health products, class I medical devices or phase IV clinical trials.

Additional authorization and implementation pathways

The Interim Order develops an alternative regulatory pathway to the existing pathways under the *Food and Drug Regulations* (FDR) and *Medical Devices Regulations* for clinical trials for COVID-19 related drugs and medical devices. Applicants can opt to proceed through either the alternate or the regular pathway but once a clinical trial is authorized under the Interim Order, it must proceed with this pathway. Further, clinical trials which have already begun under the regular pathway cannot transition to the alternative pathway. The Interim Order uses the term "clinical trials" for both drugs and devices, rather than using the *Medical Devices Regulations* term "investigational testing" for devices.

Expanding the scope of individuals who can apply for and conduct clinical trials

The Interim Order also expands who may conduct clinical trials. For example, the definition of "qualified investigator" for clinical trials for drugs now includes additional licensed health care professionals, such as nurse practitioners, pharmacists and midwives, instead of just physicians and dentists. Further, independent researchers and clinicians can now also apply to sponsor a clinical trial for a medical device.

Increasing flexibility while streamlining administrative requirements

The Interim Order provides significantly more flexibility to the clinical trial process, such as permitting the partial suspension or revocation of a clinical trial, which means a single treatment group within a randomized trial can be suspended while the remainder of the trial proceeds.

Health Canada will also be able to use terms and conditions on clinical trial authorizations, to ensure appropriate oversight or to manage uncertainties or risks.

Alternative means of obtaining patient consent are permitted, such as allowing written informed consent to be provided remotely if it cannot be provided in person, or allowing non-written informed consent in cases where a patient cannot provide written consent.

The Interim Order reduces administrative requirements for trials for existing marketed drugs and medical devices involving new uses in the context of the COVID-19 pandemic in cases where the use of the drug aligns with standard medical practice.

Administrative requirements are also reduced for non-significant changes throughout the trial, with only significant changes requiring approval.

All these flexibilities are particularly beneficial for complex trials, such as:

- multi-site trials;
- multi-arm trials;
- remote trials; and
- trials for repurposing marketed drugs or medical devices for COVID-19 uses.

Other important details

For further guidance on the Interim Order, see the Applications for COVID-19 drug and medical device clinical trials under the Interim Order: Notice release of guidance documents.

Many of the requirements under the existing pathways for clinical trials under the FDA and *Medical Devices Regulations* continue to apply to trials conducted pursuant to the Interim Order, including reporting adverse events or medical device incidents to Health Canada and ensuring trials are conducted in accordance with good clinical practices.

Should you have any questions, please do not hesitate to contact a member of the Life Sciences Regulatory & Compliance group.

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