



Notice

Our file number: 12-118429-25

Update: Registration and Disclosure of Clinical Trial Information

This Notice serves to provide an update on Health Canada's activities related to the registration and disclosure of clinical trial information.

Health Canada is planning to publish on its website an administrative list of clinical trials authorized by Health Canada. The list is aimed to include administrative information about each trial for which a No Objection Letter (NOL) is issued pursuant to a Clinical Trial Application (CTA) for the study of a drug in patients, and will provide information to patients, healthcare providers, and the public about clinical trials that have been authorized by Health Canada. Further information on this initiative, including the opportunity for consultation, will follow shortly.

As part of the modernization of the *Food and Drug Regulations*, Health Canada is also continuing to pursue the development of mandatory requirements for the registration of clinical trials. This initiative has been incorporated into the regulatory roadmap for the modernization of the regulatory framework for drugs, and updates will be communicated to stakeholders as progress is made.

Health Canada continues to support the registration of clinical trials, as well as the comprehensive reporting of clinical outcomes, in two publicly accessible registries of the World Health Organization's (WHO's) Register Network. Since November 2011, the NOL issued by Health Canada when a CTA or CTA-Amendment is deemed acceptable, reiterates to sponsors the importance of registration within 21 days of the trial's onset. To date, these registries contain over 130,000 clinical trials.

Sponsors can access the two designated third party registries accepting international clinical trial information as follows:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- Current Controlled Trials International Standard Randomised Controlled Trials Number Register (www.controlled-trials.com/isrctn).

.../2

In addition to these registries, Health Canada is providing the link to the WHO's search portal, a central database for trial registration data, which can bridge multiple records pertaining to one trial:

- International Clinical Trials Registry Platform Search Portal
(<http://apps.who.int/trialsearch/Default.aspx>)

Questions or concerns related to this Notice should be directed to:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
Holland Cross, Tower B, 2nd Floor
Address Locator 3102C3
1600 Scott Street
Ottawa, Ontario
K1A 0K9

Telephone: 613-948-4623
Fax: 613-941-1812
E-mail: Policy_Bureau_Enquiries@hc-sc.gc.ca