



Health  
Canada

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## Notice

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### **Release of information about Medical Device Investigational Testing Applications authorized by Health Canada**

The purpose of this Notice is to communicate that, effective immediately, Health Canada will begin releasing certain information about authorized **Investigational Testing** (clinical trials) involving the use of medical devices in patients.

Improving public access to information about clinical trials is an important endeavor in Canada and abroad. Patients, prescribers, researchers, and regulators want greater transparency of information on trials to help them make informed health decisions. To this end, Health Canada will be sharing key information about investigational testing applications which were authorized under Part 3 of the *Medical Devices Regulations* after November 14, 2013.

Upon request, the following information about the investigational testing will be released:

- protocol title;
- device name;
- medical condition;
- study population;
- authorization date;
- end date of the study;
- name of the manufacturer or importer.

Information about investigational testing in healthy volunteers will not be released. For further information about a particular clinical investigation, such as patient enrolment criteria, potential investigational testing sites, and status of the investigation, enquirers will be directed to the manufacturer or importer of the device and their physician. This policy is consistent with the Department's commitment to enhanced transparency about regulatory decisions and with the recent launch of the Drug Clinical Trials Database (May 29, 2013).

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Since 2007, Health Canada has been encouraging registration and disclosure of clinical trial information for therapeutic products (including drugs and devices) in publically available registries. Manufacturers and importers of medical devices authorized for investigational testing are therefore reminded to register their investigational testing within 21 days of the start of the investigation, using a publicly available registry that conforms to international standards for registries such as: Clinicaltrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)); Current Controlled Trials ([www.controlled-trials.com](http://www.controlled-trials.com)).

Health Canada will continue to examine options for more proactive sharing of information about authorized clinical investigations with patients, prescribers, researchers, regulators and other interested parties.

Questions or concerns related to this Notice should be directed to the Investigational Testing Unit at [InvestigationalTesting@hc-sc.gc.ca](mailto:InvestigationalTesting@hc-sc.gc.ca).