Guidelines for Safety Reporting Requirements to Health Canada

INTRODUCTION

When conducting Health Canada regulated clinical trials involving a drug, medical device or natural health product, investigators are required to report serious and unexpected adverse events / reactions to the study sponsor and appropriate Health Canada Directorates as applicable.

This document explains what needs to be reported to Health Canada, when to report it and how to report it.

WHAT NEEDS TO BE REPORTED AND WHEN?

For studies using pharmaceuticals, biologics, radiopharmaceuticals and/or natural health products:

During a clinical trial, the sponsor is required to inform Health Canada, in an expedited manner, of any Serious Unexpected Adverse Drug Reaction (SUADR), with respect of the drug that has occurred inside or outside Canada.

Contact ask.crs@sickkids.ca **immediately, to inform the Research Ethics and Regulatory Coordinator who will work with you to submit safety reports within the required timeframe to Health Canada.**

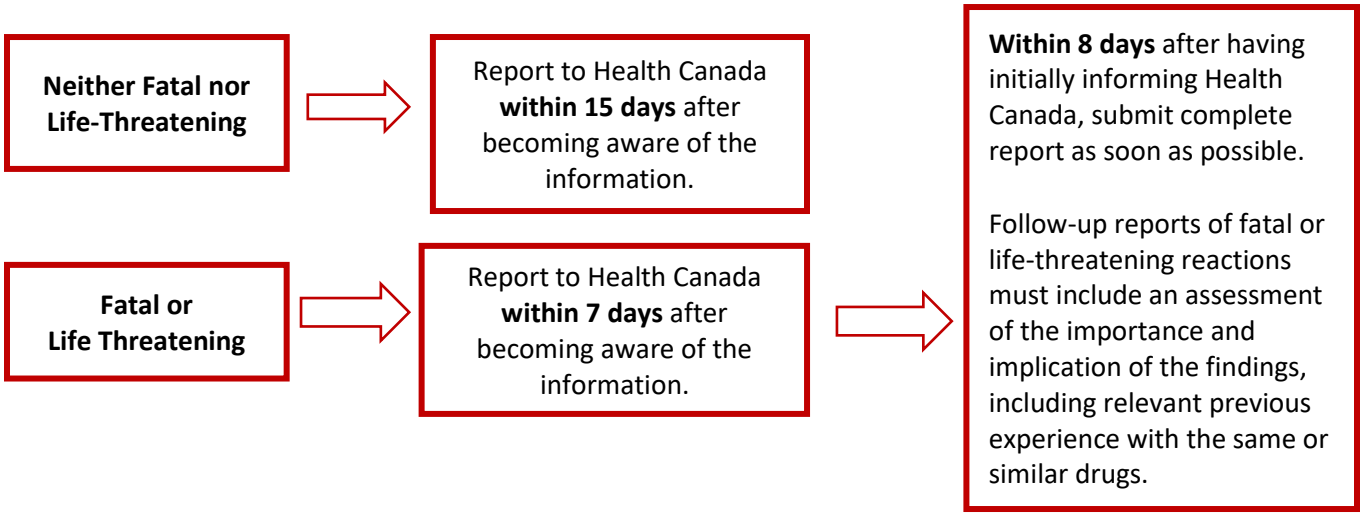
Expedited reports are required for events that meet all three of the following criteria:

Serious (if at any dose it)	• Results in death • Is life-threatening • Requires inpatient hospitalization or prolongation of existing hospitalization • Results in persistent or significant disability / incapacity • Is a congenital anomaly / birth defect
Unexpected	• The nature or severity is not consistent with information in the relevant source document(s), such as the IB or Product Monograph. Until source documents are amended, expedited reporting is required for additional occurrences of the reaction. • Reports which add significant information on specificity or severity of a known, already documented serious ADR (more specific or more severe than described in IB).

Suspected Causal Relationship	• All cases judged by either the reporting health care professional or the sponsor as having a reasonable suspected causal relationship to the medicinal product qualify as ADRs and should be reported. • Concomitantly, adverse reactions that are considered to be unrelated to the study drug by both the investigator and the sponsor should not be reported.

Timeline for Reporting To:

- Therapeutic Products Directorate (Pharmaceuticals)
- Biologics and Genetic Therapies Directorate (Biologics and Radiopharmaceuticals)
- Natural and Non-prescription Health Products Directorate (Natural Health Products)



Additional Reporting Requirements

Other situations may necessitate rapid communication to Health Canada, such as, information that might influence the risk-benefit assessment of a drug, or that would be sufficient to consider changes in drug administration, or in the overall conduct of a clinical trial; and appropriate scientific and medical judgment should be applied each time.

Examples include:

- For an "expected" serious ADR, an increase in the rate of occurrence which is judged clinically important;
- A significant hazard to the patient population, such as lack of efficacy with a drug used in treating a life-threatening disease; and
- A major safety finding from a newly completed animal study.

On becoming aware of such situations, if conducting a SickKids Investigator-Initiated Clinical Trial, please email ask.crs@sickkids.ca immediately and a Research Ethics and Regulatory Coordinator will help you submit the required forms.

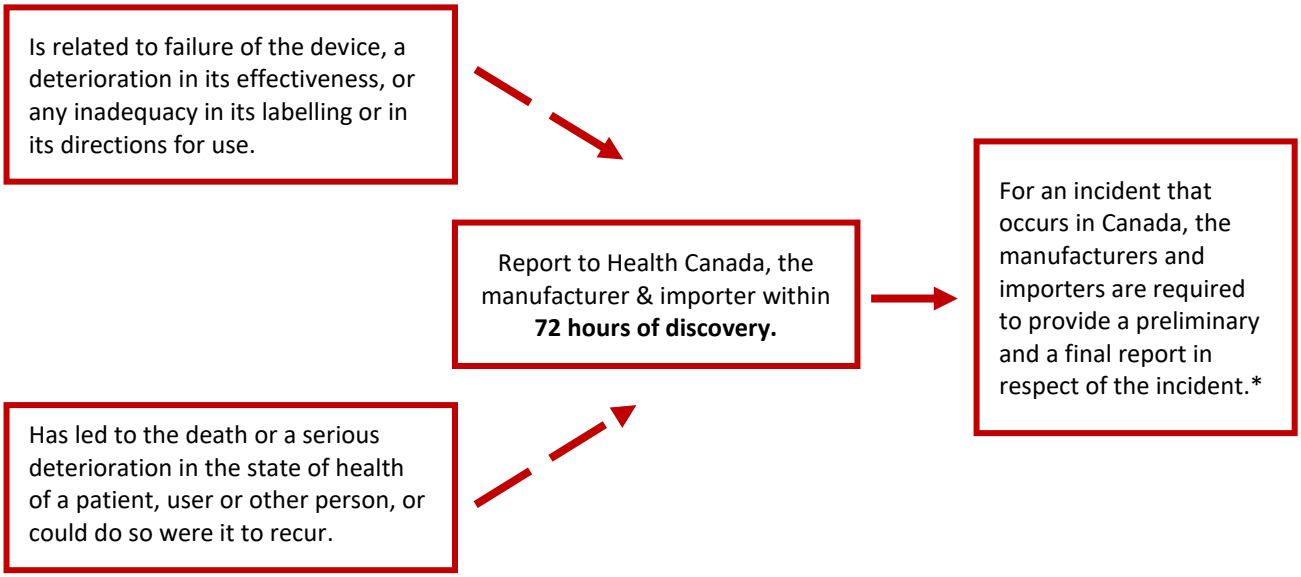
For studies using medical devices:

The Qualified Investigator is required to report **Serious Adverse Events** (SAEs) to Health Canada, the manufacturer and importer.

A **Serious Adverse Event** is defined as any untoward medical occurrence that includes one or more of:

- Results in death
- Is life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability / incapacity
- Results in a congenital anomaly / birth defect
- Based upon appropriate medical judgment, is an important medical event that may jeopardize the health of the research participant or may require medical intervention to prevent one of the outcomes listed above

This includes cases in which the incident:



***The preliminary report shall be submitted:**

- Within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person; or
- Within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur.

For SickKids Investigator-Initiated Clinical Trials, please email ask.crs@sickkids.ca immediately, on becoming aware of such situations.