Health Canada / Santé Canada

Adverse Drug Reactions (ADRs) for Clinical Trials
Expedited Reporting Summary Form

Drug Code, Generic, or Brand Name:

Sponsor of Clinical Trial:

(CR) File Number:

Report Submitted By:

Contact Name and Telephone Number:

Protocol Title / Protocol Number (if applicable):

Sponsor's Identification Number for the case:

Date of ADR Onset:

☐ **Fatal or Life-Threatening Unexpected ADR**

☐ **All other serious and unexpected ADRs**

Is there an ongoing clinical trial for this drug in Canada?

Yes ☐ **No** ☐

FOR DETAILED INFORMATION ON ADVERSE DRUG REACTIONS SUBJECT TO EXPEDITED REPORTING REFER TO PART C DIVISION 5 OF THE FOOD AND DRUG REGULATIONS AND E2A 'CLINICAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING' HC / ICH GUIDELINES, 1995

Is this a followup to a previous report?

Yes ☐ **No** ☐

If yes , date of previous report (s):

Reported ADR occured in:

☐ **Phase I - III study**

☐ **Phase IV study**

☐ **Spontaneous ADR**

ADR Country of Origin

☐ **Canada**

☐ **Other**

Has the drug been or is it currently marketed in Canada? If yes, provide DIN.

DIN:

Has the drug ever been released under the Special Access Programme/ Emergency Drug Release? **Yes** ☐ **No** ☐

Is there a clinical trial application for this drug under review in Canada? **Yes** ☐ **No** ☐

Is there a new drug submission for this drug under review in Canada? **Yes** ☐ **No** ☐

ADR Reports must be provided by the following deadlines:

Fatal and Life Threatening Unexpected ADRs

1. Initial Report within 7 calendar days
2. Comprehensive Report within an additional 8 calendar days

All Other Serious and Unexpected ADRs

1. Comprehensive Report within 15 calendar days

Signature:

Date:

For **Pharmaceutical Drugs: Please fax to: (613) 941-2121:**

For **Biologics and Radiopharmaceuticals: Please fax to: (613) 957-0364**