

## 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:	
<input type="checkbox"/> Fatal or Life-Threatening Unexpected ADR	<input type="checkbox"/> All other serious and unexpected ADRs	Is there an ongoing clinical trial for this drug in Canada? Yes <input type="checkbox"/> No <input type="checkbox"/>	
<b>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</b>		Is this a followup to a previous report? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Reported ADR occurred in:  <input type="checkbox"/> Phase I - III study  <input type="checkbox"/> Phase IV study  <input type="checkbox"/> Spontaneous ADR		Has the drug been or is it currently marketed in Canada? If yes, provide DIN.	DIN:
ADR Country of Origin  <input type="checkbox"/> Canada  <input type="checkbox"/> Other		Has the drug ever been released under the Special Access Programme/ Emergency Drug Release?      Yes <input type="checkbox"/> No <input type="checkbox"/>	Is there a clinical trial application for this drug under review in Canada?      Yes <input type="checkbox"/> No <input type="checkbox"/>
Signature: _____		Date: _____	Is there a new drug submission for this drug under review in Canada?      Yes <input type="checkbox"/> No <input type="checkbox"/>
		<b>ADR Reports must be provided by the following deadlines:</b>  <b>Fatal and Life Threatening Unexpected ADRs</b> 1. Initial Report within 7 calendar days 2. Comprehensive Report within an additional 8 calendar days  <b>All Other Serious and Unexpected ADRs</b> 1. Comprehensive Report within 15 calendar days	

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

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