

Cover Form for a Safety Report to the Research Ethics Committee on a Clinical Trial on a Medicinal Product for Human Use.

This cover form should be completed by the Sponsor and should be submitted with any safety reports.

Please indicate what type of safety report you wish to submit (tick as appropriate).	
Six monthly report	<input type="checkbox"/>
Annual Report	<input type="checkbox"/>

A. TRIAL IDENTIFICATION	
EudracCT No.:	
Title of clinical trial:	
Trial Reference No.:	
Title of Clinical Trial:	
Name of site:	
Name of REC:	
Submission date:	

B. APPLICANT IDENTIFICATION	
Name:	
Title:	
Position:	
Qualification:	
Address:	
Tel:	
Fax:	
E-mail:	

C. LIST OF ENCLOSED DOCUMENTATION	
Reporting Period	
Date of Report	