

SAFETY REPORT TO MAIN RESEARCH ETHICS COMMITTEE

Indicate which type(s) of safety report you wish to notify with this cover sheet (tick all that apply). Use a separate sheet for notifications relating to different trials. Send only to the main REC.

- 1. **Expedited report(s) of SUSAR**
(Suspected Unexpected Serious Adverse Reaction)
- 2. **Quarterly safety report with global list of SUSARs**
- 3. **Annual safety report with global list of SSARs**
(Suspected Serious Adverse Reaction)
- 4. **Other**

Full title of study:	
EudraCT number:	
Research sponsor:	
Name of Chief Investigator:	
Name of main REC:	
Main REC reference number:	

Contact details for person making this notification

Name:	
Address:	
Telephone:	
Fax:	
E-mail:	
Date of this notification:	

List of enclosed documents

Please list each report submitted with this notification (please insert additional rows in table as required).

1. **Expedited SUSARs**

Sponsor's report no./reference	Trial site	Date SUSAR first reported to sponsor	Is this a 7 or 15 day report?

2. Other reports

Type of report	Date of report

Acknowledgement of receipt by main REC (please insert name):

The [] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

*Signed original to be sent back to sponsor (or other person submitting the report)
Copy to be kept for information by main REC.*