

Breach Report Form

Please report for:

1. any events that could have led to harm or could have been prevented by a change of process and not reported as a serious adverse event;

or

2. any breaches of trial protocol or Good Clinical Practice.

Chief Investigator:

Sponsor Reference:

EudraCT No:

REC Reference:

Date of incident

Site breach occurred:

Date reported to trial staff:

Name and contact details of person reporting breach to sponsor:

Detail of the breach (please specify if a patient safety/data integrity issue or both):

Corrective and Preventive Action Implemented (CAPA) by Trial Staff:

FOR OFFICE USE ONLY			
Date Breach Report received:		Date of Breach Assessment:	
Serious Breach:	<input type="checkbox"/>	Non-Serious Breach:	<input type="checkbox"/>
Date of notification to REC:		Reported by:	
Date of notification to MHRA: <i>(if applicable)</i>		Reported by: <i>(if applicable)</i>	
For Serious Breach CAPA, please refer to assessment report			