Adverse Event and Serious Adverse Event log

Event no.	Site	Subject no.	Event type (please see final page for definitions)	Related to IMP? (Y/N)	Expected reaction to IMP? (Y/N)	AE/SAE/ SUSAR?	Date of onset	Body system	Event description	Outcome (please see final page for outcome options)	Resolved? (Y/N)
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											

Event types

An Adverse Event (AE) is defined (according to CPMP/ICH/377/95) as "*Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment*". Any adverse event which affects a participant from the time they give informed consent to 30 days after the last study related contact (as defined in the protocol) should be recorded.

An adverse event is defined as serious if it:

1) Results in death
2) Is life threatening
3) Requires inpatient hospitalisation or prolongation of existing hospitalisation
4) Results in persistent or significant disability/incapacity, or
5) Is a congenital anomaly/birth defect

Please indicate one of these 5 types in the "Event type" column for all SAEs and SUSARs.

An SAE is defined as a SUSAR if it may be related to, and is an unexpected reaction to, the study intervention.

Outcomes

For the "Outcome" column, please indicate one of the following outcomes of the event:

1) Resolved
2) Resolved with sequelae
3) Improved
4) Persisting
5) Worsened
6) Fatal
7) Unknown