

IMPs or medical device in the trial?	IMP 3 likely or possibly Related IMP 4 likely or possibly Related	Unrelated Unrelated
Is the SAE expected? <i>Expected reactions will be found in the Investigator Brochure, SmPC(http://emc.medicines.org.uk/) and/or protocol.</i>	IMP 1 Expected IMP 2 Expected IMP 3 Expected IMP 4 Expected	Unexpected Unexpected Unexpected Unexpected
Is the SAE due to the progression of an underlying illness?	Yes No	Is the SAE related to the trial CONDUCT? Yes <input type="checkbox"/> No <input type="checkbox"/>
Names of non IMPs concomitant medicines:		
Names of concomitant diseases:		
Is the event classified as a SUSAR? (ie, RELATED to one of the IMPs and UNEXPECTED)	Yes No If Yes, please also complete CIOMS form http://www.jazmp.si/files/farmakovigilanca/ObrazecPoro%C4%8DanjeN_UZ_CIOMS_angl.doc , also on page 4. If Yes, please give the batch number of each of the IMPs related to the SAE: IMP 1: Batch Number: IMP 2: Batch Number: IMP 3: Batch Number: IMP 4: Batch Number:	
Action taken with study treatment:	IMP 1 Continued Reduced Increased Temporary stop Permanent stop*	
	IMP 2 Continued Reduced Increased Temporary stop Permanent stop*	
	IMP 3 Continued Reduced Increased Temporary stop Permanent stop*	
	IMP4 Continued Reduced Increased Temporary stop Permanent stop*	
Did the PI withdraw the patient from the study?	Yes No	
Outcome of SAE:	Resolved Resolved with sequelae* *specify sequelae _____ <hr/> Improved Persisting Worsened Fatal (date of death ___ / ___ / ___) Unknown If fatal, copy of post-mortem available? Yes No	
Person completing the form if not the PI	Name: Phone No Email address: Signature: Date:	
Investigator's Name:	Print :	
Investigator's Signature		Date: _____

Additional information requested by the CI's team for this project:

	CI's team, please customise this table prior to sending the form to the sites.
	Please add as many rows as required.

For Multi-site trials only

Date form RECEIVED by CI's team from external site: (___ / ___ / ___) <i>(This date will be DAY 1 for SUSARs)</i>	Reviewed by: Date:
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For R&D Office use only

Date form RECEIVED by R&D team: (___ / ___ / ___)	Reviewed by: Date reviewed:
For SUSAR only:	Date reported to the MHRA:

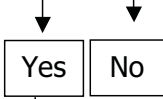
SAE reporting form V4, 22/12/08The CI cannot downgrade SUSARs reported by the treating PI at the site

Adverse Event (AE) Recording & Reporting

An AE occurs during a RESEARCH project, what do I do next?

Is the research project a Clinical Trial of an Investigational Medicinal Product (CTIMP)?

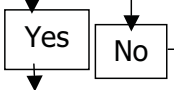
For guidance please see: www.ct-toolkit.ac.uk/route_maps/stations.cfm?current_station_id=287&view_type=map
 If ANY doubts please email your protocol to ctdhelpline@mhra.gsi.gov.uk and cc the JRO on that email.



1. Record AE in the study file and source documentation.
2. Follow up AE until resolved (if applicable).
3. SAEs in non CTIMPs that are related to the project and unexpected should be reported to the main ethics committee. "NRES report of serious adverse event form". [www.corec.org.uk/applicants/apply/docs/Safety_Report_Form_\(nonCTIMPs\)v2.0.doc](http://www.corec.org.uk/applicants/apply/docs/Safety_Report_Form_(nonCTIMPs)v2.0.doc)

Is it a serious adverse event (SAE)?

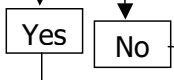
A SAE is defined as any untoward medical occurrence or effect that results in either death, is life threatening, requires hospitalisation or prolongation of hospitalisation, results in persistent or significant disability or incapacity or is a congenital anomaly or birth defect. Please note that all 'near misses' should also be reported via the Trust Incident form.



1. Record the AE in the study file (Case Report Form) and source documentation (patient's notes)
2. Follow up AE until it is resolved (if applicable)

Is the SAE likely to be a REACTION to the investigational medicinal product (IMP)?

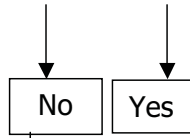
All AE judged by either the reporting investigator or the Sponsor as having a reasonable causal relationship to a medicinal product qualify as ADVERSE REACTION (AR).



1. RECORD SAE in study file (Case report form) and source documentation (patient's notes).
2. Inform the trial sponsor within the time line stated in the protocol (Unless agreed in the protocol that EXPECTED events do not need REPORTING). If BLT/ QMUL is the sponsor, scan and email the signed SAE form or fax it to the R&D Office on 020 7882 7276.
3. A template BLT/QMUL SAE form is provided for BLT/QM sponsored trials.
4. Follow up SAE until resolved (if applicable).
5. The SAE may need reporting to the ethics committee, www.nres.npsa.nhs.uk/applicants/guidance

Is the SAR expected?

Reactions are considered EXPECTED if they are listed in the Investigators Brochure (IB), summary of product characteristics (SmPC) or in the protocol.



1. RECORD SAE in study file (Case report form) and source documentation (patient's notes).
2. Inform the trial sponsor within the time line stated in the protocol (Unless agreed in the protocol that EXPECTED events do not need REPORTING). If BLT/ QMUL are the sponsor, scan and email the signed SAE form or fax it to the R&D Office on 020 7882 7276.
3. A template SAE form is provided for BLT/QM sponsored trials.
4. Follow up SAE until resolved (if applicable).
5. The SAE may need reporting to the ethics committee, see link for guidance www.nres.npsa.nhs.uk/applications/guidance

This event is a SUSAR (Suspected Unexpected Serious Adverse Reaction)

Actions to be taken

- 1 The PI to record the event in the study file (Case report form) and source documentation (patient's notes).
- 2 The PI to complete sponsor SAE reporting form and CIOMS: <http://www.cioms.ch/cioms.pdf>
- 3 The PI to scan & email/Fax (020 7882 7276) the **signed** SAE form to the sponsor, **as soon as possible and within a working day**. The PI to make contact with the sponsor and ensure that the SAE reporting form has been received if the event is a SUSAR.
- 4 The PI to inform the REC using cover sheet [safety report to main REC](#).
- 5 If the trial is multi-site, the CI has to inform the PIs on all sites.
- 6 The sponsor reports the SUSAR to the MHRA, within 7 days for death and life-threatening SUSARs and within 15 days for all other SUSARs
- 7 The sponsor to email to the PI an acknowledgment of receipt of this form (if the event is a SUSAR).
- 8 Follow up the SUSAR and record information in source documentation & compile annual safety report for sponsor. (Due date of the annual safety report is the anniversary date on the "notice of acceptance letter" from the MHRA.)

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL
(first, last)		Day	Month	Year	Years		Day	Month	Year	APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										<input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO- DUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)		19. THERAPY DURATION

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26-26a. NAME AND ADDRESS OF REPORTER (INCLUDE ZIP CODE)
ORIGINAL REPORT NO.	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> REGULATORY AUTHORITY <input type="checkbox"/> OTHER	
DATE OF THIS REPORT	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOW-UP	

Serious Adverse Event (SAE) Reporting Form, Guidance notes:

1. Please see the SAE flowchart (page 3) for assistance.

2. The BLT/ QMUL SAE reporting form detailed on page 1 of this document needs to be completed if a SAE occurs during a BLT/QM sponsored clinical trial. If BLT/QM is not the sponsor please contact the sponsor and follow the sponsor's SOP.

3. SUSAR's should be reported to the sponsor immediately as the sponsor has a legal obligation to report this to the MHRA within 7 days (for fatal or life-threatening SUSAR's) or 15 days for all other SUSAR's. The PI needs to fill in the CIOMS form which will also be forwarded to the MHRA.

4. SAE REPORTING IN MULTI-SITE STUDIES

In multi-site studies, the PI at each external site should fax this form to the CI at the BLT/QMUL site. The CI and study team should check that ALL fields have been completed and that the form has been signed by the PI at that site.

The CI should not down grade SAEs or SUSARs from the treating PI at the site. However the CI can upgrade an AE to a SAE or a SAE to a SUSAR. The CI should then scan, email or fax the completed form to the R&D office within a working day of becoming aware of the event.