SERIOUS ADVERSE EVENT REPORTING FORM

(BLT/QM sponsored trial)

Once you have become aware of a SAE or SUSAR, please scan & email/fax this signed form to the Research Governance & GCP Manager: [redacted] (or to the trial co-ordinator's fax number if multi site project) WITHIN a working day of learning of the event for SUSARs and within the time line outlined in the protocol approved by the MHRA and REC if expected SAEs. It is the CI's responsibility to inform the MREC of the SUSARs. If this event is a SUSAR, request an acknowledgment email of receipt of this form, from the JRO, print it and file it in your TMF.

Report type:	Initial Follow up		
If the project is multi-site, the section below should be completed by the Main site Trial coordinator prior to sending the template to the sites			
Full title of the study:	Parent-determined oral montelukast therapy for preschool wheeze with stratificatiobn for arachidonate-5-lipoxygenase (ALOX5) promoter genotype.		
Name of sponsor:	BLT QMUL		
Sponsor R&D Number:	EudraCT Number:2009-015626-11		
MREC Number:	09/H1102/110		
Chief Investigator:	Name: Prof J Grigg Phone No: [redacted] Email address: [redacted]		
Is this a double blind study?	Yes If Yes are the code break procedures in place with pharmacy? Yes		
Name of ALL IMPs and/or medical devices	IMP 1: Montelukast IMP 3: IMP 2: IMP 4:		
This section should be completed by the SITE:			
Subject identification code:		Patient/initials (first, last):	_____
DOB: (Day/Month/Year) (___/___/____) Patient's Age:		Sex:	M F
Principal Investigator: Trial Co-ordinator local site:	Name: Phone No: Email address: Name: Phone No Email address:		
Name of reporting host institution:	Trust/ Institution name: Site number:		
Date of site becoming aware of the event	___/___/____	Onset date of SAE:	Resolution date of SAE:
Event Description (e.g. body site, symptoms) (*please use separate form for each event)	Event*:	Severity: Mild Moderate Severe	
Type of SAE	Results in Death Life threatening Hospitalisation or prolongation of hospitalisation Persistent or significant disability or incapacity Congenital anomaly or birth defect "Other" important medical event If "Other", please describe: ……..		
	The co-ordinator needs to replace IMP 1,2,3,4 … by the actual name of the IMP prior to sending the template to the sites.		
Is the SAE **likely** to be a reaction to one of the	IMP 1 likely or possibly **Related** Unrelated IMP 2 likely or possibly **Related** Unrelated		

IMPs or medical device in the trial?	IMP 3 likely or possibly **Related** Unrelated IMP 4 likely or possibly **Related** Unrelated		
Is the SAE expected? *Expected reactions will be found in the Investigator Brochure, SmPC(http://emc.medicines.org.uk/) and/or protocol.*	IMP 1 **Expected** Unexpected IMP 2 **Expected** Unexpected IMP 3 **Expected** Unexpected IMP 4 **Expected** Unexpected		
Is the SAE due to the progression of an underlying illness?	Yes No	Is the SAE related to the trial CONDUCT?	Yes □ No □
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%8DanjeNUZ_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 _____ 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: (___ /___/_____) (*This date will be DAY 1 for SUSARs*)	Reviewed by:	Date:

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:	

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.

Yes / No →
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

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.

Yes / No →
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).

Yes / No →
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.

No / Yes →
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.)

CIOMS
http://www.jazmp.si/files/farmakovigilanca/ObrazecPoro%C4%8DanjeNUZ_CIOMS_angl.doc

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)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-
17. INDICATION(S) FOR USE		DUCTION? ☐ YES ☐ NO ☐ NA
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 ADRESS OF REPORTER (INCLUDE ZIP CODE)
ORIGINAL REPORT NO.	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ REGULATORY AUTHORITY ☐ OTHER	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ 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.