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: (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 Cl'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) promotel 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: Email address:										
Is this a double blind study?											
	If Yes are the code brea										
Name of ALL IMPs and/or medical devices	IMP 1: Montelukas	st	IMP :	- -							
This section should be co	mpleted by the SITE	:									
Subject identification code:		Patient/init (first, last):									
DOB: (Day/Month/Year)	(//)	Sex:		M F							
Patient's Age:											
Principal Investigator:	Name: Phone No: Email address:										
Trial Co-ordinator local site:	Name: Phone No Email address:										
Name of reporting host institution:	Trust/ Institution name: Site number:										
Date of site becoming aware of the event	1 1	Onset date	e of SAE: Resolution date of S								
Event Description (e.g. body	Event*:	<u>I</u>	Severity:								
site, symptoms) (*please use separate form for each event)			Mild	Moderate Severe							
	Results in Death										
Type of SAE	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:										
				1,2,3,4 by the actual emplate to the sites.							
Is the SAE likely to be a	IMP 1 likely or possib		J tt	Unrelated							
reaction to one of the	IMP 2 likely or possibly Related Unrelated										

IMPs or medical device in	IMP 3 likely or possibly Related Unrelated										
the trial?	IMP 4 likely or possibly Related	Unrelated									
Is the SAE expected?	IMP 1 Expected Unexpected										
Expected reactions will be found in the Investigator Brochure,	IMP 2 Expected Unexpected										
SmPC(http://emc.medicines.org	IMP 3 Expected Unexpected										
.uk/) and/or protocol.	IMP 4 Expected Unexpected										
Is the SAE due to the	Yes No Is the SAE related to	Yes 🗆 No 🗆									
progression of an	the trial CONDUCT?	•									
underlying illness?											
Names of non IMPs											
concomitant medicines:											
Names of concomitant											
diseases:											
Is the event classified as a	Yes No										
SUSAR? (ie, RELATED	If Yes, please also complete CIOMS form										
to one of the IMPs and	http://www.jazmp.si/files/farmakovigilanca/ObrazecPoro%C4%8DanjeN										
UNEXPECTED)	UZ_CIOMS_angl.doc , also on page 4. If Yes, please give the batch										
,	number of each of the IMPs related to the Sa	AE:									
	IMP 1: Batch Num										
	IMP 2: Batch Num										
	IMP 3: Batch Num										
A (' 1 1 '(1 1 1	IMP 4: Batch Num										
Action taken with study	IMP 1 Continued Reduced	Increased									
treatment:	Temporary stop Permanen	t 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 Permaner	nt stop*									
Did the PI withdraw the	Yes No										
patient from the study?											
	Resolved Resolved with sequelae* *specify sequelae										
Outcome of SAE:											
	Improved Persisting	Worsened									
	Fatal (date of death /	/) Unknown									
	,	 ,									
	If fatal, copy of post-mortem available? Y	'es No									
Person completing the form if		res No ne No									
Person completing the form if not the PI											
	Name: Phor	ne No									
not the PI	Name: Phor Email address:	ne No									
not the PI Investigator's Name:	Name: Phor Email address: Signature: Date:	ne No									
not the PI	Name: Phor Email address: Signature: Date: Print :	ne No									
Investigator's Name: Investigator's Signature	Name: Phor Email address: Signature: Date: Print :	ne No									
not the PI Investigator's Name: Investigator's Signature Additional information rec	Name: Phore Email address: Signature: Date: Print: Date: Quested by the CI's team for this project:	ne No									
Investigator's Name: Investigator's Signature Additional information rec	Name: Phore Email address: Signature: Date: Print: Date:	ne No									
Investigator's Name: Investigator's Signature Additional information rec	Name: Phore Email address: Signature: Date: Print: Date: quested by the CI's team for this project: s team, please customise this table prior to sen	ne No									
Investigator's Name: Investigator's Signature Additional information recommendation recommendat	Name: Phore Email address: Signature: Date: Print: Date: quested by the CI's team for this project: s team, please customise this table prior to sen	ne No									
Investigator's Name: Investigator's Signature Additional information recommend CI Ple For Multi-site trials only	Name: Phore Email address: Signature: Date: Print: Date: Quested by the CI's team for this project: Steam, please customise this table prior to sente ease add as many rows as required.	ding the form to the sites.									
Investigator's Name: Investigator's Signature Additional information red CI Ple For Multi-site trials only Date form RECEIVED by CI's from external site: (/ / //	Name: Phore Email address: Signature: Date: Print: Date: Quested by the Cl's team for this project: s team, please customise this table prior to sene ease add as many rows as required. Reviewed by:	ne No									
Investigator's Name: Investigator's Signature Additional information recommend CI Ple For Multi-site trials only	Name: Phore Email address: Signature: Date: Print: Date: Quested by the Cl's team for this project: s team, please customise this table prior to sene ease add as many rows as required. Reviewed by:	ding the form to the sites.									
Investigator's Name: Investigator's Signature Additional information red CI Ple For Multi-site trials only Date form RECEIVED by CI's from external site: (/ / //	Name: Phore Email address: Signature: Date: Print: Date: Quested by the Cl's team for this project: s team, please customise this table prior to sene ease add as many rows as required. Reviewed by:	ding the form to the sites.									
Investigator's Name: Investigator's Signature Additional information red CI Ple For Multi-site trials only Date form RECEIVED by CI's from external site: (/ / //	Name: Phore Email address: Signature: Date: Print: Date: Quested by the Cl's team for this project: s team, please customise this table prior to sene ease add as many rows as required. Reviewed by:	ding the form to the sites.									

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

Date reported to the MHRA:

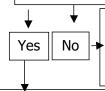
(___/____)
For SUSAR only:

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)?

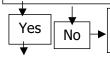
For guidance please see: www.ct-toolkit.ac.uk/route maps/stations.cfm?current station id=287&view type=map If ANY doubts please email your protocol to ctdhelpline@mhra.qsi.qov.uk and cc the JRO on that email.



- 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

Is it a serious adverse event (SAE)?

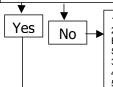
A SAE is defined as any untoward medical occurrence or effect that results in either death, is life threatening, requires hospitalisation or prolongation of hospitalisation, results in persistent or significant disability or incapacity or is a congenital anomaly or birth defect. Please note that all '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)?

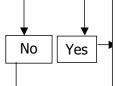
All AE judged by either the reporting investigator or the Sponsor as having a reasonable causal relationship to a medicinal product qualify as ADVERSE REACTION (AR).



- 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).
- The PI to complete sponsor SAE reporting form and CIOMS: http://www.cioms.ch/cioms.pdf
- The PI to scan & email/Fax (020 7882 7276) the <u>signed</u> 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.
- 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).
- 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.jaz	mp.si/file	s/farma	kovi	giland	ca/Ob	razecl	orc	%(24%	68	Da	nje	eΝl	JZ	CI	OM	IS_	angl	.do	oc_
SUSPECT ADV																				
			I. I	REAC	TION	INFO	RM	ΑTΙ	ON											
1. PATIENT INITIALS	1a. COU	INTRY	2.	DATE (2a. AGE			4-6	R	EACT) NC	ONS	SET	8-12 CHECK A			AL	.L
(first, last)			Day	Month	Year	Years			Day	Day Month				Yea	ar	ТО	APPROPRIATE TO ADVERSE REACTION			
7 + 13 DESCRIBE	REACTION	(S) (includ	ing re	elevant	tests/la	b data)	1	,								PRINFHO	INVOCATION OF THE PROPERTY OF THE PORT OF	TENI	ED D SAT ED T C T OR V	OR ION IR
					DRU	IG(S) I	NF	DRI	MA	ΤI	ΟN	I								
14. SUSPECT DRUG(S) (include generic name)							20. DID REACTION ABATE AFTER STOPPING DRUG? YES \(\) NO \(\)											ì?	NA	
15. DAILY DOSE(S)						ADMINISTRATION REA							REA	DID REACTION APPEAR ER REINTRO-						
17. INDICATION(S) FOR USE							DUCTION?										NO	_	NΔ	
18. THERAPY DATES (from/to)						19. TI	19. THERAPY DURATION													
1		III. CO	NC	MITA	ANT E	RUG	S) A	١N	ЭН	IS	тс	R'	Y				_			
22. CONCOMITAN	IT DRUG(S)	AND DAT	ESC	F ADM	IINISTF	RATION	(exclu	ıde t	hose	e u	ised	to 1	trea	t rea	actio	n)				
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 REPOF	RT NO.	24b. MFF	4b. MFR CONTROL NO.														_			
24c. DATE RECEI' BY MANUFACTUR	RER	24d. REF STUI LITE HEAI PROFES REG AUTHOR	DY RATU LTH SION ULAT	JRE IAL ORY OTI																
DATE OF THIS RE	FUNI	□ INITI			LOW-U	Р														

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.