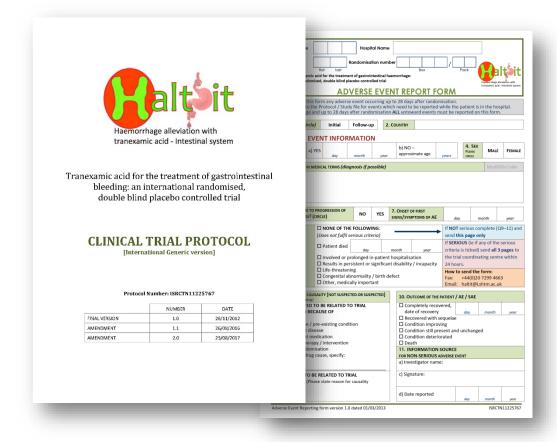


REPORTING ADVERSE EVENTS AND COMPLETING THE REPORT FORM

THIS PRESENTATION MUST BE USED WITH:

- 1. THE PROTOCOL (Section 2.9) and
- 2. The guidance for investigators: ADVERSE EVENT REPORTING AND COMPLETING THE REPORT FORM (in Investigator Study File section 7)



Definitions

	Any untoward modical accurrance offecting a trial participant				
Adverse event (AE)	Any untoward medical occurrence affecting a trial participant				
Adverse event (AL)	during the course of a clinical trial				
Serious Adverse Event	A serious adverse event (experience) is any untoward medical				
(SAE)	occurrence that at any dose				
(5.52)	results in death;				
	is life-threatening;				
	 requires in-patient hospitalisation or prolongation of 				
	existing hospitalisation;				
	 results in persistent or significant disability/incapacity; or 				
	is a congenital anomaly/birth defect.				
Advance Decetion (AD)	An adverse event when there is at least a possibility that it is				
Adverse Reaction (AR)	causally linked to a trial drug or intervention				
Serious Adverse	SAE that is thought to be causally linked to a trial drug or				
Reaction (SAR)	intervention				
Suspected Unexpected	An <i>unexpected</i> occurrence of a SAR; there need only be an				
Suspected Unexpected	index of suspicion that the event is a previously unreported				
Serious Adverse					
Reaction (SUSAR)	reaction to a trial drug or a previously reported but exaggerated				
Medicion (505AN)	or unexpectedly frequent adverse drug reaction.				

What should be reported as AE or SAE?

WHILE THE PATIENT IS IN HOSPITAL

➤ In hospital, any untoward medical event that occurs up to 28 days after randomisation and NOT collected on the outcome form, should be reported.



- ➤ Death and several life-threatening complications are already collected on the outcome form. They do not need to be reported also on the adverse event form.
- Events that are part of the natural history of GI bleeding or expected complications of this condition should not be reported as adverse events. (see Protocol section 2.10).

For example, events such as low blood pressure, increased heart rate, reduced urine output, altered level of consciousness due to blood loss, may be expected complications of GI bleeding and should not be reported as Adverse Events.

What should be reported as AE or SAE?

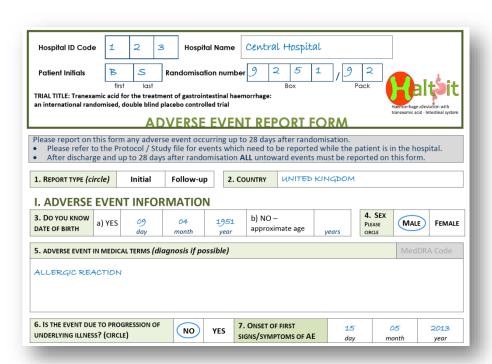
AFTER DISCHARGE

- ➤ If a patient is discharged or transferred to another hospital, they should be given an ALERT CARD which should contain information on who to contact if they develop any problems
- After discharge, report any untoward medical event, which develops up to 28 days after randomisation (including those listed on the outcome forms)



Reporting Adverse Events

- ➤ The Adverse Event Report form should be used to report all adverse events in line with the Protocol
- Adverse Event Report forms can be found in your Study File Section 7 and on the CD inside the front cover



Reporting Adverse Events

- ➤ The Adverse Event Report form must be completed by hand, in English, Spanish or French Please write clearly
- Adverse events that do NOT fulfil any of the seriousness criteria: only page 1 needs to be completed this should be sent to the TCC as soon as possible even if all the information is not available
- Adverse events that fulfil ANY of the seriousness criteria (Section 8 of the form): all 3 pages of the form must be completed and sent to the TCC WITHIN 24 HOURS of you becoming aware of the event.

If in doubt: Please report or call the 24-hour helpline for advice

Hospital ID Code	٠		Hosp	ital Name							
Patient Initials			Randomiso	ation num	ber		/				, <u>k</u> .
TRIAL TITLE: Tranexa	fir mic acid		ent of gastroi	intestinal h	aemorrhage:	Box		Pad	ck	Ha	Itə i
an international ran										Haemorrhage all tranexamic acid	
		AD	VERSI	E EVE	NT RE	PORT	FOR <i>N</i>	٨			
Please report on t											
 Please refer t After discharg 											
							5 111 disc 50	Tupo	100 01		
1. REPORT TYPE (ci	rcle)	Initial	Follow-u	лр 2.	COUNTRY						
I. ADVERSE	EVEN	IT INFOR	RMATIO	N							
3. Do you know	a) YES				b) NO				4. SEX	MALE	FEMA
DATE OF BIRTH	-,	day	month	year	approx	ximate age	years		CIRCLE		
5. ADVERSE EVENT I	N MEDIC	AL TERMS (dia	aanosis if p	ossible)						MedD	RA Code
6. IS THE EVENT DU			NO	VEC	7. ONSET	OF FIRST					
6. IS THE EVENT DUI UNDERLYING ILLNES			NO	YES		OF FIRST MPTOMS OF A	ιE	day	,	month	year
8. SERIOUSNESS	s? (circi	NONE OF TH	HE FOLLOW	/ING:			If No	OT ser	ious co	mplete (C	,
UNDERLYING ILLNES	s? (CIRCI	NONE OF TH	HE FOLLOW	/ING:			→ If No	OT ser	ious co	omplete (C nly	(9–11) a
8. SERIOUSNESS	s? (CIRCI	NONE OF TH	HE FOLLOW	/ING: teria)			If No	OT ser	ious co	omplete (C nly any of the	9–11) a
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to	s? (circi	NONE OF TH	HE FOLLOW serious crit	/ING: teria)	signs/syn	year	If No	OT ser	ious co page o S (ie if a ticked)	omplete (C nly	9–11) a serious pages t
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are	s? (circi	NONE OF THE Des not fulfil Patient died Involved or p Results in pe	day prolonged ersistent or	/ING: teria)	month hospitalisa	year ation	If No send If SE crite the	OT ser	ious co page o S (ie if a ticked)	omplete (C nly any of the send all 3	9–11) a serious pages t
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to	s? (circi	NONE OF TH pes not fulfil Patient died Involved or p Results in pe Life-threater	day prolonged ersistent or	/ING: teria) in-patient significar	month hospitalisat disability	year ation	If No send If SE crite the 24 h	OT ser d this partial is erial is erial colours.	ious copage of S (ie if sticked)	omplete (Conly any of the send all 3 ating centr	9–11) a serious pages t e withir
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to	s? (circi	NONE OF THE Des not fulfil Patient died Involved or p Results in pe	day prolonged ersistent or	/ING: teria) in-patient significar	month hospitalisat disability	year ation	If No send If SE crite the 24 h	OT serial is retrial cours.	ious copage of S (ie if sticked) pording	omplete (Conly any of the send all 3 ating centre form:	9–11) a serious pages t e withir
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to event)	s? (circi	NONE OF THe person of fulfill Patient died Involved or present in person of the person	day prolonged ersistent or ning abnormality impor	ving: teria) in-patient significar y / birth d	month thospitalise the disability efect	year ation	If No send If SE crite the 24 h	OT ser d this p RRIOUS eria is strial cours. / to se	ious co page o S (ie if ticked) poordina and the 14(0)20 altit@L	omplete (Conly any of the send all 3 ating centr	9–11) a serious pages t e withir
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of	s? (CIRCI	NONE OF THe person of fulfil Patient died Involved or properties in person of the congenital and the congenitation of the congenitation	day prolonged if ersistent or ning abnormality cally impor	ving: teria) in-patient significar y / birth d	month hospitalist t disability	year ation // incapacit	If No send If SE crites the the How Fax: Ema	OT ser d this p RRIOUS eria is strial cours. / to se	ious co page o S (ie if ticked) poordina and the 14(0)20 altit@L	omplete (Conly any of the send all 3 ating centre form:	9–11) a serious pages t e withir
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of INOT SUSPECT	S? (CIRCI	NONE OF TH pes not fulfil Patient died Involved or p Results in pe Life-threater Congenital a Other, medianty (NOT SUSPE BE RELATED TO	day prolonged if ersistent or ning abnormality cally impor	ving: teria) in-patient significar y / birth d	month hospitalisat disability efect 10.00	year ation // incapacit	If No sense the crite the the How Fax: Ema	OT ser d this p RIOUS eria is s trial cours. / to se +/4 iii: ha	ious copage of S (ie if sticked) poording and the 14(0)20 little L / SAE	omplete (Cinly any of the send all 3 ating centre form: 0 7299 466 shtm.ac.ul	19–11) a serious pages te within
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of	S? (CIRCI	NONE OF TH pes not fulfil Patient died Involved or p Results in pe Life-threater Congenital a Other, medianty (NOT SUSPE BE RELATED TO	day prolonged if ersistent or ning abnormality cally impor	ving: teria) in-patient significar y / birth d	month thospitalisation disability efect 10.00	year ation // incapacit	If No sense the crite the the How Fax: Ema	OT seried this partial cours. / to see // to see	ious co page o S (ie if ticked) poordina and the 14(0)20 altit@L	omplete (Conly any of the send all 3 ating centre form:	19–11) a serious pages te within
UNDERLYING ILLNES 8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Release) in the state of the st	CAUSALT	NONE OF THE DES NOT END TO SET THE DES NOT FUIFIL PATIENT OF THE DES NOT END T	HE FOLLOW serious critically day prolonged in the seristent or ning abnormality cally import	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10.00 Con dat Rec Co	year ation // incapacit	If NV send If SE crites the	OT serid this partial colours. / to see +4 iii: ha	ious copage of S (ie if sticked) poording the 44(0)20 altit@L	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages te within
8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of INTEREVENTION) INTEREVENTION INTEREVENTION Intercurrent	CAUSALITING CAUSALITING CAUSALITING COMMENT	NONE OF THE DESIGNATION OF THE D	HE FOLLOW serious critically day prolonged in the seristent or ning abnormality cally import	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10.00 Con dat Rec Con Con Con Con	year ation // incapacit	If NV send If SE crite to the Ey 24 h HOW Fax: Ema	OT serid this partial colours. / to see +4 iii: ha	ious copage of S (ie if sticked) poording the 44(0)20 altit@L	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
S. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of the control of th	CAUSALT (rug) CAUSALT (rug) ED TO E BECAU: e / pre-e disease t medic	NONE OF THE DES NOT GUISTIN THE DES NOT GUISTIN THE DES NOT GUISTIN THE DES NOT STATE OF THE	HE FOLLOW serious critically and serious critically important cally important to TRIAL dition	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10.00 Con dat Rec Con Con Con Con	year ation // incapacit urcome of r mpletely re te of recover covered wit ndition imp ndition still ndition det	If NV send If SE crite to the Ey 24 h HOW Fax: Ema	OT serid this partial colours. / to see +4 iii: ha	ious copage of S (ie if sticked) poording the 44(0)20 altit@L	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
8. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study of INTEREVENTION) INTEREVENTION INTEREVENTION Intercurrent	CAUSALITING CAUSA	NONE OF TH Des not fulfil Patient died Involved or I Results in pe Life-threater Congenital a Other, medi TY [NOT SUSPE EXERLATED 1 SE OF existing cond ation intervention	HE FOLLOW serious critically and serious critically important cally important to TRIAL dition	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10.00 Con dat Rete Con Con Don	year ation // incapacit urcome of r mpletely re te of recover covered wit ndition imp ndition still ndition det	If NI sense If SE crites the the Y 24 h How Fax: Ema	OT services of this part of thi	ious copage of S (ie if sticked) poording the 44(0)20 altit@L	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
S. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Medicionals) to study of INTEREVENTION Basic disease Intercurrent Concomitaan Non-drug th	CAUSALTIVAY	NONE OF THE DES NOT FURTHER THE DES NOT FURTHER THE DES NOT FURTHER THE DES NOT THE DES NO	HE FOLLOW serious critically and serious critically important cally important to TRIAL dition	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10. Ot	year ation year ation year ation y/ incapacit mpletely re- te of recovered with dition impudition still indition deta ath IFFORMATICO ON-SERIOU	If NI senior If SE crite the the the the the the the the the t	DT serial coordinates of the coo	ious co page o 5 (ie if iicked) 5 (ie if siticked) boordina 14(0)2(2) 14(0)2(2) 15(1) 16(1	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
S. SERIOUSNESS CRITERIA 1. (tick all that are appropriate to event) 9. ASSESSMENT OF (Medicinally to study of the control of	CAUSALTIVAY	NONE OF THE DES NOT FURTHER THE DES NOT FURTHER THE DES NOT FURTHER THE DES NOT THE DES NO	HE FOLLOW serious critically and serious critically important cally important to TRIAL dition	ving: teria) in-patient significar y / birth d	month hospitalist t disability efect 10. Ot	year ation y/ incapacit urcome of T mpletely rete of recove covered wit ndition inpl dition indition impl dition indition impl dition indition individual individ	If NI senior If SE crite the the the the the the the the the t	DT serial coordinates of the coo	ious co page o 5 (ie if iicked) 5 (ie if siticked) boordina 14(0)2(2) 14(0)2(2) 15(1) 16(1	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
9. ASSESSMENT OF (Relationship to study of the Control of the Cont	s? (circo	NONE OF TH pers not fulfil Patient died Involved or I Results in pe Life-threate Congenital a Other, medi TY [NOT SUSPE SE RELATED 15 SE OF ation intervention ion se, specify:	HE FOLLOW. serious crit day prolonged idersistent or ning shoormality cally impor	ving: teria) in-patient significar y / birth d	month h hospitalish t disability efect 10. Ou	year ation // incapacit UTCOME OF T mpletely re tee of recover tee of recover tee of the tee of the tee of the tee tee of the tee	If NI senior If SE crite the the the the the the the the the t	DT serial coordinates of the coo	ious co page o 5 (ie if iicked) 5 (ie if siticked) boordina 14(0)20 15 / SAE	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
S. SERIOUSNESS CRITERIA 1. (tick all that are appropriate to event) 9. ASSESSMENT OF (Medicinally to study of the control of	CAUSALT CAUSALT CONTROL CON	NONE OF These not fulfill Patient died Involved or patient died Involved or patient died Involved or patient died Congenital a Other, medi ry [NOT SUSPE SE RELATED 15 SE OF Existing conduction of the patient of the p	day prolonged is abnormality is all properties of the control of t	ving: teria) in-patient significar y / birth d	month h hospitalish t disability efect 10. Ou	year ation year ation year ation y/ incapacit mpletely rete of recovered with dition impudition still indition deta ath incommendation.	If NI senior If SE crite the the the the the the the the the t	DT serial coordinates of the coo	ious co page o 5 (ie if iicked) 5 (ie if siticked) boordina 14(0)20 15 / SAE	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	19–11) a serious pages t e withir
S. SERIOUSNESS CRITERIA (tick all that are appropriate to event) 9. ASSESSMENT OF (Relationship to study or Intercurrent Non-Touspect Basic disease Intercurrent Concomitan Non-drug th Prior to rane Other non-de	CAUSALT CAUSALT CONTROL CON	NONE OF These not fulfill Patient died Involved or patient died Involved or patient died Involved or patient died Congenital a Other, medi ry [NOT SUSPE SE RELATED 15 SE OF Existing conduction of the patient of the p	day prolonged is abnormality is all properties of the control of t	ving: teria) in-patient significar y / birth d	month h hospitalish t disability efect 10. Ou	year ation // incapacit UTCOME OF T mpletely re tee of recover tee of recover tee of the tee of the tee of the tee tee of the tee	If NI senior If SE crite the the the the the the the the the t	DT serial coordinates of the coo	ious co page o 5 (ie if iicked) 5 (ie if siticked) boordina 14(0)20 15 / SAE	omplete (C nly any of the send all 3 ating centr of form: 0 7299 466 shtm.ac.ul	9–11) a serious pages t e within

Reporting Adverse Events

- ➤ All fields must be completed do not leave blank fields. If the information is not known at the time of completing the form, write **NK** (not known) or **NA** (not applicable).
- ➤ The information supplied on the AE form must be consistent with the data recorded on the source data i.e. medical records and other data forms.
- ➤ The **Initial** adverse event report form should be submitted even if there is only limited information. Any clinical member of staff can complete the initial form. The P.I. will conduct the final overall review. When any additional or relevant information becomes available, it should be submitted on **follow-up** report forms there may be more than one follow-up form. If the event is serious, then follow-up data must be sent to the TCC within 24 hours.
- In the follow-up report form, you must complete the header information (to identify the patient), the diagnosis must be written in (to identify the event) and only new or corrected information must be reported. Please note that the information provided in the Follow-up AE Report Form supersedes the information previously reported.

Completed forms can be sent by FAX to +44(0)20 7299 4663 or as a scanned image/s attached to an email to haltit.data@Lshtm.ac.uk. If you would like access for the online data entry facility for Adverse Event reporting please email haltit.data@Lshtm.ac.uk.

IF YOU NEED URGENT ADVICE ABOUT REPORTING AN ADVERSE EVENT PLEASE CALL +44(0)7768 707500

How to complete the Adverse Events reporting form

Write in block capitals and try to describe the single diagnosis for the event (one even per form)

Patient Initials	B S	Randomisation nur	mber 9	/	9 2	n de en
RIAL TITLE: Tranexamic		•	-	Вох	Pack	altoit
n international random				ORT FOR	•	Haemorrhage alleviation with tranexamic acid - Intestinal system
lassa namant an this		VERSE EVI				
lease report on this Please refer to the		se event occurring i dy file for events w				n the hospital.
After discharge a	and up to 28 day	s after randomisation	on ALL untow	ard events must b	e reported on t	this form.
L. REPORT TYPE (circle	e) Initial	Follow-up	2. COUNTRY	UNITED KINGE	OM	
. ADVERSE E\	/ENT INFOR	RMATION			4. SEX	
ATE OF BIRTH	YES 9	04 195	annrovi	nate age	PLEASE	MALE FEMALE
ALCOFBIANT	day	month yea	г аррголи	years years	CIRCLE	
5. ADVERSE EVENT IN N	MEDICAL TERMS (di	agnosis if possible)				MedDRA Code
ALLERGIC REACT	TON S					
(000)(0)						
	`					
				The second second		

Header and Sections 1 to 5

first last	Hospital Name	Box	/	Pack Paltait	All field header		T be co	mplete	ed in the
TRIAL TITLE: Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial ADVERSE EVENT REPORT FORM Please report on this form any adverse event occurring up to 28 days after randomisation. Please refer to the Protocol / Study file for events which need to be reported while the patient is in the hospital. After discharge and up to 28 days after randomisation ALL untoward events must be reported on this form.									OUS, the be filled in.
1. REPORT TYPE (circle)	Initial	Follow-up	2	2. COUNTRY					
data being submit Circle <mark>FOLLOW-UP</mark> subsequent inforn	for any	nis AE.		here the ever					
3. DO YOU KNOW DATE OF BIRTH	day	month	year	b) NO – approximate age	years	4. SEX PLEASE CIRCLE	MALE	FEMALE	
If known enter the	exact da	ate of birth	۱.			Circle	either	male	
If not known put the estimated age in years.					OR fer	male			
Enter one field on	ly, NOT b	oth date	of bi	rth and age					
5. ADVERSE EVENT IN MEDIC	CAL TERMS (did	agnosis if possi	ble)				MedE	ORA Code	

Enter the diagnosis if known, otherwise the sign(s) / symptom(s) relating to the event

Sections 6 to 8

6. IS THE EVENT DUE TO PROGRESSION OF UNDERLYING ILLNESS? (CIRCLE)

NO
YES

Please indicate if this event is due to GI bleeding or any other pre-existing illness

7. ONSET OF FIRST
SIGNS/SYMPTOMS OF AE day month year

Insert the date when the first signs of the event were noted

- If the event does not fulfil any of the serious criteria tick box NONE OF THE FOLLOWING
- Complete sections 9 to 11 and send to the TCC as soon as possible (page 1)
- If the event fufils ANY of the serious criteria tick ALL that apply
- Date is only required if the patient died
- > If the event:
 - caused death
 - required in-patient hospitalisation, or prolonged existing hospitalisation
 - resulted in persistent or significant disability/incapacity
 - is life-threatening
 - is a congenital anomaly/birth defect
 - is medically important

then this is a **SERIOUS ADVERSE EVENT**

All serious adverse events must be reported to the TCC WITHIN 24 HOURS

	8. SERIOUSNESS	□ NONE OF THE FOLLOWING:						
	CRITERIA	(Does not fulfil serious criteria)						
	(tick all that are	☐ Patient died	day	month	year			
	appropriate to event)	☐ Involved or pr						
	evency	☐ Results in persistent or significant disability / incapacity						
☐ Life-threatening☐ Congenital abnormality / birth defect								
								☐ Other, medically important

Section 9

9. ASSESSMENT OF CAUSALITY [NOT SUSPECTED OR SUSPECTED] (Relationship to study drug) NOT SUSPECTED TO BE RELATED TO TRIAL INTEREVENTION BECAUSE OF Basic disease / pre-existing condition Intercurrent disease Concomitant medication Non-drug therapy / intervention Prior to randomisation Other non-drug cause, specify:	Please indicate whether or not you suspect the event is related to tranexamic acid or placebo
SUSPECTED TO BE RELATED TO TRIAL INTERVENTION: (Please state reason for causality assessment)	If you suspect the event is related to the trial intervention you must enter a reason for causality

NOT SUSPECTED: This is when a causal relationship between the event and administration of the trial treatment is considered unlikely. This may be because other drugs, therapeutic interventions or underlying conditions provide a sufficient explanation for the observed event.

SUSPECTED: The temporal relationship of the event to trial treatment administration makes a causal relationship possible – and other drugs, therapeutic interventions or underlying conditions do not provide a sufficient explanation for the observed event.

Sections 10 to 11

10. OUTCOME OF THE PATIENT / AE / SAE							
☐ Completely recovered,							
day	month	year					
9							
☐ Condition improving							
nd unchang	ed						
E							
EVENT							
c) Signature:							
day	month	year					
	day e and unchange E EVENT	day month e and unchanged E EVENT					

Tick as appropriate for the patient's current status

If the patient made a complete recovery please enter the date of recovery, **otherwise** do not enter a date

Complete this section ONLY if the event is not serious.

If the event is serious continue to page 2

Sections 12 to 13

12a. Start of trial treatment				12b. END OF TRIAL TREATMENT			
	day	month	year		day	month	year

Please insert the date (DD MM YYYY) when the trial treatment **started**

Please insert the date (DD MM YYYY) when the trial treatment **ended**

13. TIME ELAPSED BETWEEN LAST DRUG ADMINISTRATION AND					
ONSET OF FIRST SIGNS / SYMPTOMS OF SAE	minutes	hours	days	months	

Enter the time between last administration of the trial treatment and onset of the first signs or symptoms

Sections 14 to 17

14. ROUTE OF ADMINISTRATION	15. RANDOM CODE BROKEN (circle)	NO	YES		
Please state the route of	Please circle as appropriate – refer to the				
administration of the trial treatment	Protocol page 11 UNBLII	NDING			

16. HEIGHT		17. WEIGHT		Estimated if actual values not available
	cm		kg	

If the exact height and weight are not known, please enter an estimate

The exact height and weight may become available later and the estimates can be overwritten

Sections 18 to 20

18. PATIENT'S PAST MEDICAL HISTORY (eg co-existing medical conditions such as disease, allergies, similar experiences)

List here <u>IN BLOCK CAPITALS</u> any other medical conditions, allergies or similar experiences in the patient's past medical history

19. CONCOMITANT TREATMENT (list all below)

List <u>IN BLOCK CAPITALS</u> all concomitant drugs/medications If you need more space use a separate sheet

20. COMMENTS (if adverse event is considered to be caused by a concomitant treatment, please note it here)

Please make a note here if the AE is considered to be caused by any concomitant medication and state which medication is suspected

Sections 21 to 23

21. ACTION TAKEN (tick all that apply)	
 □ No action taken □ Trial drug dosage adjusted / temporarily interrupted* □ Trial drug permanently discontinued due to this adverse event □ Non-drug therapy given** □ Drug therapy taken** 	Please tick ALL that apply. Details about adjusted dosage and drug and non-drug therapies can be noted in field 23
☐ Hospitalisation / prolonged hospitalisation * if ticked, enter new dosage information in field 23 ** if ticked	d, provide therapeutic measure in field 23
22 Test / LARONATORY FINDINGS / value and for SAF discussions are description	

22. TEST / LABORATORY FINDINGS (relevant for SAE diagnosis or description)

List <u>IN BLOCK CAPITALS</u> all tests/laboratory findings relevant to the diagnosis of the SAE

23. ADDITIONAL INFORMATION:

Case description of the above SAE (include related signs/symptoms/lab results, treatment, outcome and suspected cause of the SAE)

In this section fully describe the nature, severity, cause and any other information that helps an understanding of the SAE. Describe therapeutic measures taken and, if available, outcome details. Please use precise medical terminology.

Sections 24 to 25

	a) Full Name	b) Telephone number	c) Signature
24. INVESTIGATOR DETAILS			

- Please state full name and provide a direct telephone number where you may be contacted urgently
- > Remember to sign the form (we cannot accept unsigned forms)
- ➤ If you are not the Principal Investigator, please make sure that s/he is informed of this SAE

25. DATE REPORTED			
	day	month	year

Please enter a full date of when this form was completed in format DD MM YYYY eg 25 | 06 | 2013

Corrections

If you enter an incorrect value on the form:

- a) Cross out the incorrect value so it is still visible
- b) Enter the correct value alongside
- c) Enter the date and your initials alongside each change

EXAMPLES

Name of A			GB11/06/2013
		06	
7. ONSET OF FIRST SIGNS/SYMPTOMS OF AE	I O day	05 month	2013 year

□ Completely recovered,			
date of recovery	day	month	year
Recovered with sequela	2		
Condition improving		16/2012	
- Condition improving	3 10 11 /	/ / / / /	
☐ Condition still present ar	nd unchang	ged	
☐ Condition still present ar ☐ Condition deteriorated	nd unchang	ged	

How to send the Adverse Events reporting form

The form must be

Faxed to +44(0)20 7299 4663

or emailed to haltit.data@Lshtm.ac.uk



PLEASE NOTE: if you would like access for the online data entry facility for Adverse Event reporting please email haltit.data@Lshtm.ac.uk

Please store original forms in Study file Section 7

JOIN THE GLOBAL COLLABORATION

haltit.Lshtm.ac.uk

Trial Coordinating Centre
London School of Hygiene & Tropical Medicine
Room 180, Keppel Street, London WC1E 7HT

Tel +44(0)20 7299 4684

Fax +44(0)20 7299 4663

Email: haltit@Lshtm.ac.uk



