

MAINTAINING THE INVESTIGATOR'S STUDY FILE

Protocol Code: ISRCTN11225767 Maintaining the investigator's study file – version 1.1 dated 04/03/2016

Investigator Study File

- Sent when all the necessary approvals / agreements are in place at your hospital
- Please return the receipt inside the front cover
- Familiarise yourself with the contents of all sections, so you know where to find the information when needed
- Contains all the information you need to conduct the trial, including training materials
- Keeps all study related documents together
- Documents will demonstrate your compliance with the protocol, GCP, regulatory requirements



Investigator Study File

- To be held in a secure location but accessible to the trial team
- It is a legal requirement to keep the study file up to date
- Must be available for monitoring visits by the TCC / National Coordinator / any relevant regulatory authorities



Maintaining the Study File

- Ensure all logs are up to date:
 - ✓ Site responsibility delegation log
 - ✓ Screening log
 - Randomisation log
 - Drug accountability log
 - ✓ Site visit log



- Documents i.e. data forms, reports, communication with the TCC, to be filed regularly
- Arrangements for archiving for at least five years after the end of the trial

Site responsibility delegation log

This log is contained in section 19 Site responsibilities

	SITE ID NUMBER	1	2	2	SITE	E NAME	Central	Hospital	arşıt		
÷	THE PERSONS NAMED B	ELOW ARE A	UTHORIS	ED BY TH	e Principal Investigat	OR TO CAR	RY OUT TH	e specified duties for the HALT-IT tria	L.		
	NAME	J	OB T ITLE	:	SPECIFIED DUTIES (please insert number codes as listed below)	COMPL	NING LETED? /N)	SIGNATURE	PI S IGNATURE & STAR	T DATE	END DATE
	DR JAMES REID				1,2,3	١	Y	James Reid	Sign: Dr James Reid date:01/05/2013		
	THOMAS MOORE	RESEAR	CH NUR	SE	1,4,5,6,7,8,9,10	١	Y	THOMAS MOORE	Sign: Dr James Reid date:01/05/2013		
									Sign: date:		

- List all members of staff involved in the conduct of the trial eg doctors, nurses, research coordinators and administrators
- Add new staff members when they join the trial team; note the end date for those who leave
- When a team member leaves the trial, ensure they are replaced with a new team member trained for their allocated tasks
- A brief CV (signed and dated) for each person listed on the log, to be filed in section 19

Screening log

This log is contained in 15 Patient Entry

PATIEN	I SCRE	ENING LO	JG					
Hospital IC) 1	2 3		Hospita	I name Cent	ral Hospítal		
							IE HALT-IT TRIAL	
Please keep ti	ne original E	ntry Form for th		n the Study File F	1		ndomised to the trial because:	
Date	Patient'	Date of		ith significant stinal bleeding	Patient did not	Patient/relative		Ciana tura
Date	s Initials (first & last)	Birth	YES	NO	meet eligibility criteria (tick if applies)	refused to take part (tick if applies)	Other reason (please document reason below)	Signature
01/05/2013	SH	13/12/1956						T. Doe

- Identify a potentially eligible patient and complete the relevant sections of the ENTRY FORM to determine if they can be randomised
- Screening log keeps a record of patients considered but not randomised. Reasons for not randomising may include ineligibility i.e. not adult
- Entry forms completed for patients considered but not randomised to be filed in Section 15 together with the Screening log.

Randomisation log

This log is contained in section 15 Patient Entry

RANDOMISATION	LOG					Haltoit
Hospital ID 1 2		tal name Cent	,			
PLEASE RECORD DETAILS OF	- ALL PATIENTS RANI	DOMISED TO T	HE HALT-IT TRI	AL		
PATIENT'S NAME	PATIENT'S HOSPITAL ID NUMBER	DATE OF BIRTH	DATE RANDOMISED	TREATMENT BOX NUMBER	PACK NUMBER	NAME OF PERSON WHO OBTAINED CONSENT
Joanne Smíth	12345678	21/12/1975	15/05/2013	9251	91	Dr Doe

- Keeps a record of patients randomised into the HALT-IT trial
- To be updated after every randomisation
- A patient is considered to be randomised at the point when the next treatment pack is removed from the box and found to be intact
- Number of treatment pack (box-pack number) is the 'randomisation number'
- Once a randomisation number has been allocated to a patient, the pack cannot be used again, even if the treatment is not given

Drug accountability log (DAL)

This log to be kept in section 13 Trial Drugs Documentation

BOX NUMBER

- Pre-printed form sent with every box
 Complete PART 1 to acknowledge receipt as soon as the box arrives and send a copy to TCC by fax or email
- File in Section 13 Trial Drugs Documentation

Hospital ID X X	×	Ho	spital name	e [HOSPIT	AL NAME	1		7	
Record the usage of all HALT-IT trial to Destroy any party used packs or any p PLEASE STORE THIS FORM IN STUDY F	acks that are	e damaged a			mistion			_	
PART 1: BOX RECEIPT	PART 2	DRUGA	COUNTAB	ILITY					
IMP Tranezamic Acid/placebo Expiry date: [date]	808	PACK	Date randomise	d used"?	MD ² used*?	Dumaged and destroyed**?	Lost and remaining ampoules destroyed**?	Der	
Batch number: (batch no) BOX NUMBER XXXX	XXXX	*1			_				
I CONFIRM THAT ALL PACKS LISTED ON	****	×2				2 12		-	
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Prigrature	3383	x4				WILL EMAIL			
Date	XXXX	×5				T FORM EAC			
	X80.X	×6		OLINE	100		· · · ·		
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COORDINATING CENTRE WHEN YOU HAVE CHECKED THAT ALL	200.2	84				-		-	
THE PACKS HAVE BEEN RECEIVED IN GOOD CONDITION.	Luntan			The Designation		a in			
			1	legated persor		Signature	Date		
	Comme	yes.							
	PLEASES	USN ANTIN	AND FAX OF Th	ALL A SCANNED		IS FORM TO THE OD ORDINATING	CENTRE WHITH ALL PACIFIC MARK	SEEN USED / DESTROYED, OR # REQ	URITED .

Complete PART 2 after each randomisation to account for when each treatment pack is used

FORM, WE WILL EMAIL YOU THE

Haltait

- When form is complete (all packs accounted for) send a signed copy to TCC by fax or email
- PI or delegate is responsible for accounting for every treatment pack sent to your hospital
- Usage of each pack to be recorded (randomisation, lost/damaged, destroyed due to withdrawal or expiry)

Trial treatment can only be used for patients randomised to the HALT-IT trial

Examples of how to use the DAL

RUG ACCOUNTABILITY LOG									
ospital National Abuja (Site #27), Nigeria								Fait	
return to supplies								Haemorrhage alleviation w	
							the second	tranexamic acid - Intestinal	
 Record the usage of all Hait It trial treatment packs Destroy any partly used packs or any packs that are damaged and cannot be used for ra 	ndomisation								
PLEASE STORE THIS FORM IN STUDY FILE FOLDER 2, SECTION 13, TRIAL DRI									
GN THIS PART WHEN YOU RECEIVE THE BOX AND FAX OR EMAIL TO TCC	SIGN THIS P	ART WHEN ALL	ACKS HAVE BEEN ACCOUNTED FOR, 1	HEN FAX OR EMAIL TO TCC	AGAIN				
PART 1: BOX RECEIPT	PART 2	: DRUG ACC	OUNTABILITY						When a pack is destroyed due to e.
IMP Tranexamic Acid/placebo	1000	Pack	Date randomized	LD ¹ used*	MD ²	Damaged and destroyed"*?	Lost and remaining ampoule	n Destroyed**?	expiry or if it is the end of the trial,
Expiry date: 30/10/2018	Box.	PIKR	Date Fandoossed	LD' used	used"?	Damaged and destroyed 7	destroyed"?		
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INTACT	1040	13				Data:	Deter LDr MDr	Oate: 30/11/2015 LD: 2 MD: 6	
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pack is destroyed due to e.g. or if it is the end of the trial, in stroyed' column, please the number of vials destroyed ich dose and date that they stroyed

Site visit log

This log is contained in section 12 Trial Monitoring

TO BE COMPI	SIT LOG Leted by all personnel conducting iational coordinators, trial moni		Halt
DATE	NAME OF PERSON CONDUCTING THE VISIT	INSTITUTION	REPORT RECEIVED AND FILED IN THE STUDY FILE — DATE

Should be updated every time there is a trial related visit to your site i.e. TCC representative, national coordinator, regulatory body

Final study results log

This log is contained in section 20 Reports

INAL STUD	OY RESULTS REQUEST	ED BY PATIENTS		
		Hospital name		
lospital ID		-		
PATIENT OR T	HEIR RELATIVES REQUEST A C available to the PI by the TCC after pu	COPY OF THE FINAL STUDY RESULTS, PLEA	SE RECORD THEIR DETAI	ILS HERE.

- Ask the patients you have considered for participation, or relatives, if they wish to receive a copy of the final trial results
- If so, record the contact details
- At the end of the trial TCC will send you copies of the final report
- PI to send to individuals listed on this log

Documents to be routinely filed

These documents must be systematically filed when they become available

Type of Document	Section number where this document to be filed
Completed Adverse Event reporting forms	17 – Completed forms
Correspondence with ethics committees	8 – Ethics
Correspondence with regulatory agencies	9 – Regulatory
Visit and monitoring reports (including consent monitoring)	12 – Trial Monitoring
Shipping Documents for the trial drugs	13 – Trial Drugs Documentation
Original Signed CONSENT FORMS	17 – Completed forms
Original Completed ENTRY FORMS	17 – Completed forms
Original Completed OUTCOME FORMS	17 – Completed forms
Data queries	18 – Correspondence
Correspondence with TCC (emails, letters etc)	18 – Correspondence
CVs of trial team	19 – Site Responsibilities
GCP training certificates of trial team	19 – Site Responsibilities

Additional training materials may be requested at any time

THE PROTOCOL

- The copy for you and your team to use is inside the front cover
- The copy in Section 2 is the version submitted for your ethics and regulatory approvals and must not be removed from the Study File

MANUAL OF OPERATING PROCEDURES (MOP)

- in section 3 Training Materials
- Detailed guidance on all aspects of the practical conduct of the trial

PRESENTATIONS

- PowerPoint presentations on various aspects of the trial on CD in the front cover of the Study File
- Film on Trial Procedures and the Scientific Rationale on DVD in section 3 Training Materials

INVESTIGATOR'S BROCHURE (IB) is contained in section 4 Trial drug guidance

- Relevant data on an Investigational Medicinal Product (IMP)
- Information on the protocol including dosing, route of administration and safety monitoring procedures
- PI should read and understand the IB before the trial starts. It will help in assessing eligibility in relation to the uncertainty principle.
- Includes Summary of Product Characteristics (SPC) for IMP – guidelines on the use of the trial treatment that have been approved by the UK regulatory agency
- Can be updated as new information accumulates. Updated numbered versions will be sent to you. When a new version is sent, clearly mark the previous version 'NOT IN USE' and file in the Investigator Study File.



PowerPoint presentations on CD

- Scientific background and HALT-IT introduction
- Conducting the trial at your hospital
- Maintaining your Investigator Study File
- GCP test guidance
- GI bleeding management
- How to assess eligibility
- How to complete the entry form
- How to obtain consent
- How to randomise an eligible patient
- How to manage and administer the trial treatment
- How to complete the outcome form
- How to send data electronically
- How to submit data online
- What to do if a patient develops an unexpected problem
- Reporting Adverse Events



- GCP training available on the trial website
- Email haltit@Lshtm.ac.uk for a username and password
- Email haltit@Lshtm.ac.uk for additional training materials



JOIN THE GLOBAL COLLABORATION

haltit.Lshtm.ac.uk

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