



SITE FILES AND TRIAL MATERIALS

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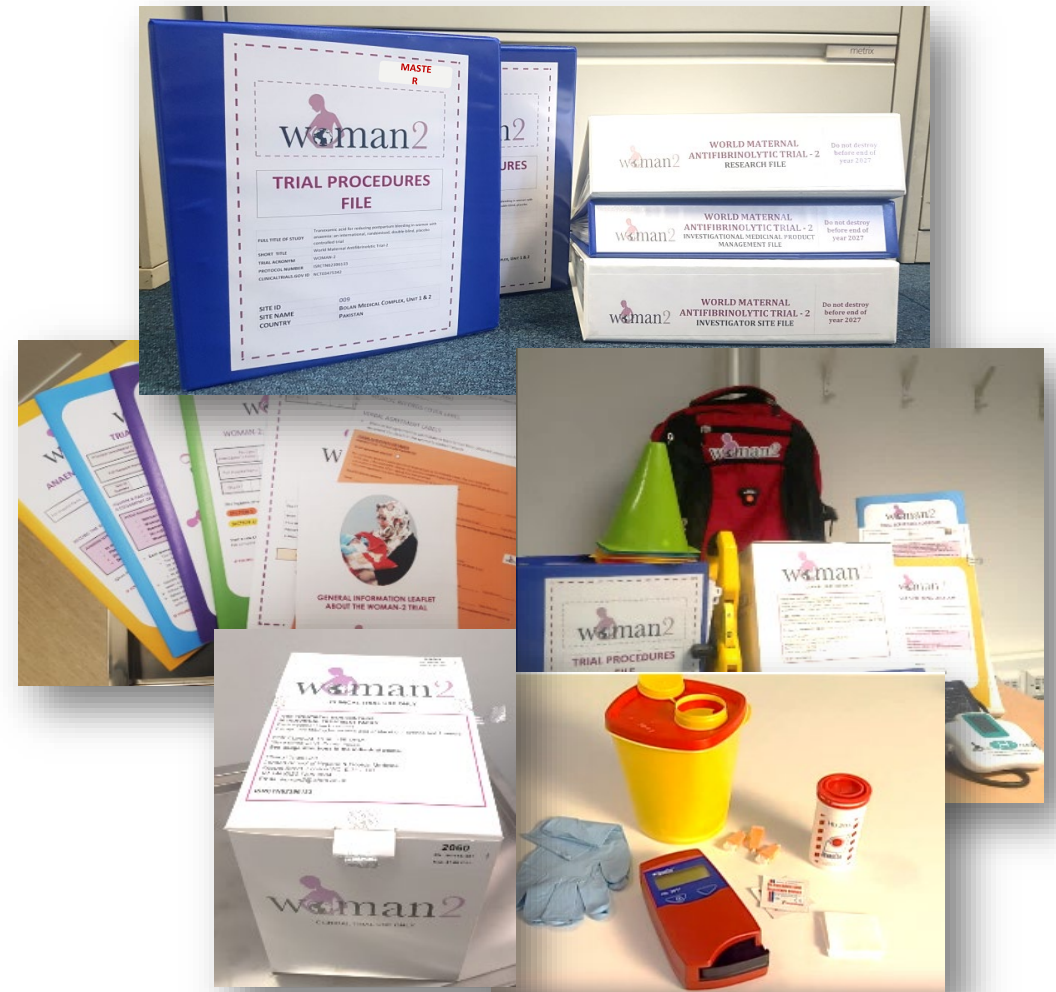
SITE FILES AND TRIAL MATERIALS

- **Before the trial starts at your site, you will be sent:**

- Five site files
- A supply of trial materials
- Equipment and consumables required for data collection
- A drug box

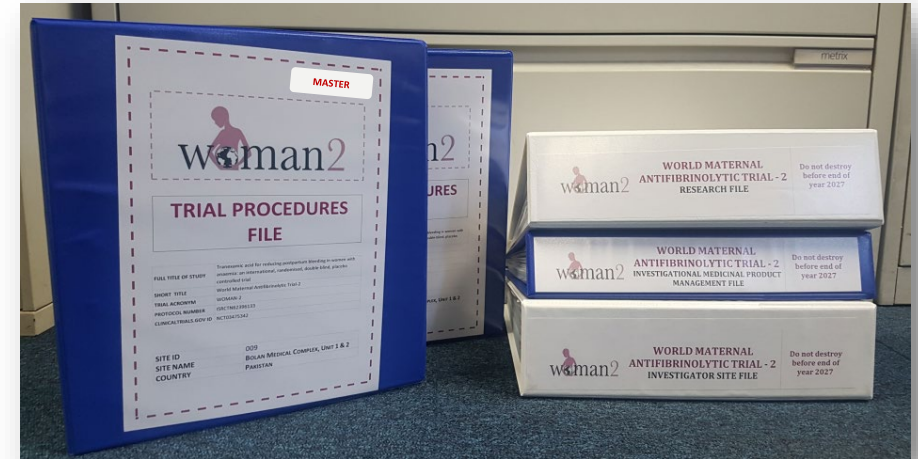
- As soon as you receive your site files, trial materials & equipment, **complete and return the receipt located inside the front cover of the ISF.** Keep a copy of the signed receipt in your ISF

- Any loss / damage of equipment will have severe consequences for the trial at your hospital. Notify your National Coordinating Centre / CTU immediately if items are lost or damaged (contact details in ISF, section 1)



SITE FILES

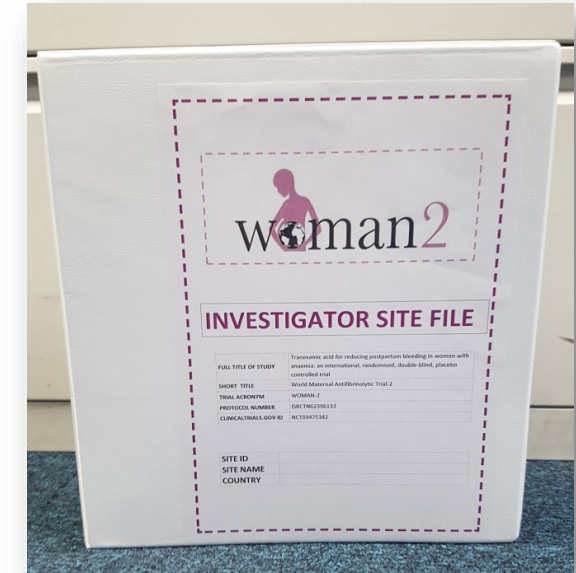
- **The WOMAN-2 site files consist of five folders:**
 - Investigator Site File
 - Investigational Medicinal Product Management File
 - Trial Procedures File (x2)
 - Research File



- **Familiarise yourself** with the contents of each file, so you know where to find information and materials when needed
- **The site files are your record of the trial at your hospital**
 - Ensure the site files are kept up to date by regularly filing trial documents and updating trial logs and logbooks
- **The site files will need to be available for monitoring visits** by the CTU and inspections by the relevant regulatory authorities

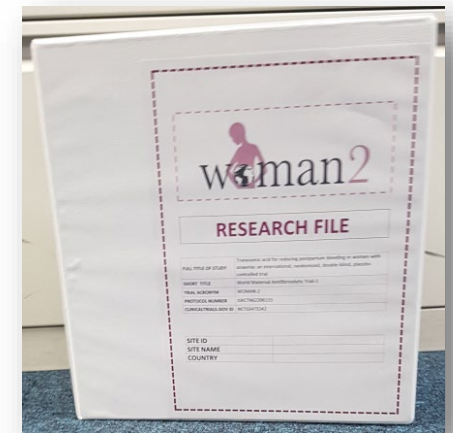
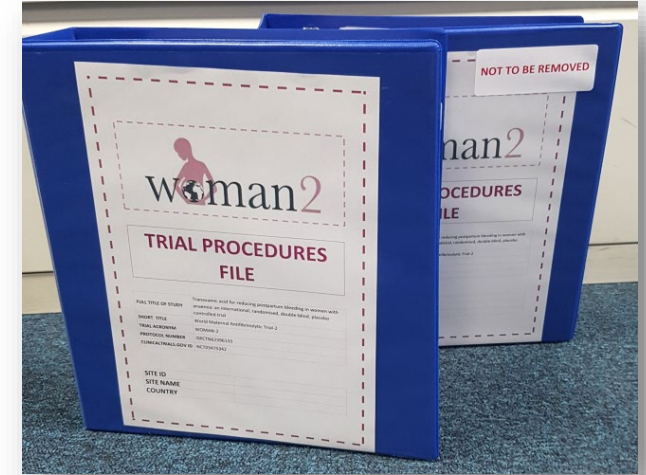
SITE FILES

- **The Investigator Site File contains:**
 - the trial protocol, master copies of the participant facing materials, blank trial forms, ethics and regulatory documents, investigator declarations, site agreements, completed reports, correspondence.
 - a USB which holds the training PowerPoint presentations and blank copies of all logs and forms, should you need to print additional copies.
- **The Investigational Medicinal Product Management File contains:**
 - IMP information, logs and forms for IMP accountability, guidance on unblinding and adverse event, IMP related correspondence.



SITE FILES

- **Trial Procedures File (TPF) (master copy) contains:**
 - Detailed guidance on all trial procedures.
 - No guidance documents should be removed from this file
- **Trial Procedures File (TPF) (second copy) contains:**
 - A duplicate of all trial procedures guidance documents.
 - This second copy can be used as appropriate for your team. You may decide to keep relevant sections of the file where it is most useful e.g. the guidance on randomisation can be stored in the labour room along with the drug box
- **The Research File contains:**
 - tips and guidance for Research Fellows and will have a supply of trial materials including: consent documents, trial labels, case report forms, alert cards and contact labels, the communications logbook currently in use and the trial screening logbook currently in use



STORAGE AND ARCHIVING OF SITE FILES

- Investigator Site File, Investigational Medicinal Product Management File and the master copy of the Trial Procedures File should be **stored in a secure place at your site that is accessible to the trial team.**
- The Research File should be kept in the researcher bag provided or easy access

At the end of the trial, all site files must be archived until the end of 2027



MAINTAINING THE SITE FILES

All logs and logbook must be kept up to date at all times. **This is a legal requirement and the logs will be required for monitoring and inspection:**

Investigator site file logs to update:

- Training log
- Site delegation of responsibilities log
- Anaemia screening logbook
- Trial screening logbook
- Communication logbook
- Randomisation log
- HemoCue Hb 201 liquid quality control log
- Final trial results request log

IMP management file logs to update:

- Drug Accountability Log
- IMP tracking log
- IMP monitoring log
- IMP storage temperature log

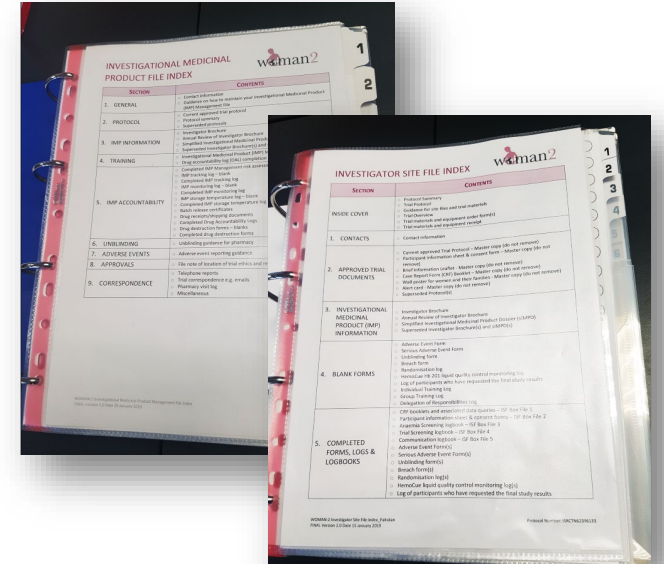
The image shows three overlapping forms from 'woman2'. The top form is the 'INVESTIGATOR MEDICINAL PRODUCT (IMP) STORAGE TEMPERATURE LOG' with fields for Site ID, Principal Investigator name, Hospital Name, and Clinical Trial Pharmacist name. The middle form is the 'DRUG ACCOUNTABILITY LOG' with fields for Site ID and Site name, and a list of instructions. The bottom form is the 'INVESTIGATIONAL MEDICINAL PRODUCT (IMP) MONITORING LOG' with a table for recording monitoring checks. Below it is the 'INVESTIGATIONAL MEDICINAL PRODUCT (IMP) TRACKING LOG' with a table for recording drug box details and signatures.

| DATE | NAME | SIGNATURE | LOCATION OF IMP | OUTCOME OF MONITORING CHECK |
|------|------|-----------|-----------------|-----------------------------|
| | | | | |
| | | | | |

| BOX DETAILS | | RECEIVED IN PHARMACY | | | RECEIVED IN PARTICIPATING DEPARTMENT | | |
|-------------|--------|----------------------|------|-----------|--------------------------------------|------|-----------|
| BOX NUMBER | EXPIRY | DATE | NAME | SIGNATURE | DATE | NAME | SIGNATURE |
| | | | | | | | |
| | | | | | | | |

MAINTAINING THE SITE FILES

- All completed forms, logbooks, logs, trial documents and key correspondence (with CTU, ethics committees, regulatory agencies) must be kept in the site files as per each Site File index
- For additional storage, box files have been sent to you. These are an extension of the Site Files and should be stored securely together with the ISF.
 - If you need additional box files, use the order form in the front of your ISF to request more.

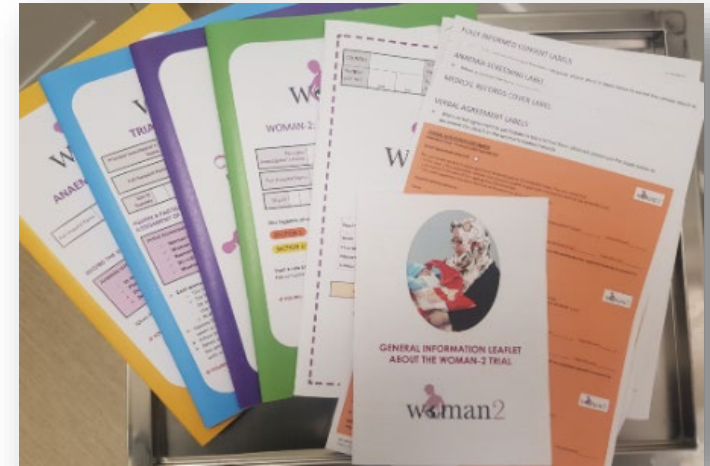


Monitoring/audits/inspections can occur at any time so it is important to ensure trial records are meticulously maintained

SUPPLY OF TRIAL MATERIALS

- **We will send you supplies of:**

- Case Report Form Booklets
- Participant Information Sheets and Informed Consent Forms
- Brief Information Leaflets
- Alert cards and contact labels
- Anaemia Screening Logbooks
- Trial Screening Logbooks,
- Communication Logbooks,
- Randomisation Logbook
- WOMAN-2 Labels



- These need to be stored where the trial team can access them when necessary.

All other blank forms that you will need are in Section 4 of the ISF

- **To request top up supplies of any trial materials or equipment, please use the Materials Order Form located in the front cover of the Investigator Site File**

MATERIALS ORDER FORM

Hospital _____
Country _____
Name _____
Email address _____ Date of Order _____

You may order additional materials at any point throughout the trial. Please provide details of the item(s) required below, any specific details to assist the Clinical Trials Unit (CTU) / National Coordinating Centre with your order, and the quantity of each item. Please ensure that you write clearly.

If you have lost any trial materials or equipment or data this must be reported to the CTU / National Coordinating Centre immediately.

| Item required <small>e.g. Trial protocol, CRF booklets, logbooks, poster, labels, SAE form, trial procedure guides, literature consumables etc.</small> | Provide details <small>e.g. language required, version</small> | Quantity |
|--|---|----------|
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Please return the completed form to the National Coordinating Centre (NCC) either by:
WhatsApp or email through: whatsapp@ncc.ctu.ac.uk +44 (0) 202 535 6048
Email as a scanned document: whatsapp@ncc.ctu.ac.uk +44 (0) 202 535 6048
Fax: +44 (0) 202 209 6033

If this is your last blank copy please to order immediately on pharmacy before van. Electronic copies are stored on the flash drive in the Site File.

WOMAN-2 Anaemia Screening Form
ISFMA Version 1.0 Date 18 January 2015
Protocol Number: 0877632386.010

FOR FURTHER GUIDANCE SEE:

The Investigator Site File:

- Guidance for site files and trial materials

The Investigational Medicinal Product Management File:

- Guidance of How to maintain you IMP Management File

Trial Procedures File:

- *Log and Logbooks to update*, in the Trial Procedures File, guidance number 5.1

SITE FILES AND TRIAL MATERIAL GUIDANCE

The wvman2 site files consist of five folders:

- Investigator Site File (ISF)
- Investigational Medicinal Product (IMP) Management File
- Trial Procedures File (TZ)
- Research File
- Site Files

As soon as you receive your site files, trial materials & equipment, please complete and return the receipt located inside the front.

INVESTIGATOR MEDICINAL PRODUCT (IMP) MANAGEMENT FILE GUIDANCE

Please review the IMP management file and familiarise yourself with its contents.

- It is important that the IMP management file is available to the trial team and stored in a safe place at your site.
- The IMP management file will need to be available for monitoring visits by the Clinical Trials Unit (CTU) and inspections by the relevant regulatory authorities.

MAINTAINING YOUR IMP MANAGEMENT FILE

Completed logs and forms, key IMP Management File as per the IMP Management File. Please ensure that all completed documents are filed.

The following logs must be kept up to date at all times. This is a legal requirement and the logs and logbooks will be required for monitoring.

The following logs must be kept up to date at all times. This is a legal requirement and the logs and logbooks will be required for monitoring.

MAINTAINING YOUR SITE FILE

The following logs must be kept up to date and updated, in the Trial Procedures File, guidance number 5.1. This is a legal requirement and the logs and logbooks will be required for monitoring and inspection:

INVESTIGATOR SITE FILE

- Training log
- Site delegation of responsibilities log
- Anaemia screening logbook
- Trial screening logbook
- Communication logbook
- Randomisation log
- HemoCue Hb 201 liquid quality control
- Final trial results request log

RESEARCH FILE

This file contains tips and guidance for Research conduct the trial including: consent material

IMP MANAGEMENT MATERIALS

Completed forms, logbooks, logs, document each Site File index – they will be required documents are filed in their appropriate file

IMP Management guidance

For full details on IMP accountability, storage, random trial drug packs, trial drug expiry and what to do if management guidance available in Section 4 of this file

Investigator's Brochure (IB)

The IB presents safety and efficacy data relevant to the LSHTM Clinical Trials Unit. It is important that the Principal Investigator (PI) is familiar with the IB.

Simplified Investigational Medicinal Product Dossier (SIMPD)

The SIMPD includes summaries of information related to the IMP.

LOGS AND LOGBOOKS TO UPDATE

The logs and logbooks listed below must be kept up to date at all times. This is a legal requirement and the logs and logbooks will be required for monitoring.

GROUP TRAINING LOG - Investigator Site File (ISF), section 4 (blank), section 6 (completed). A Training Log must be completed for all training activities for the trial. For group training, a Group Training Log should be completed and each attendee should sign the log to confirm their attendance.

INDIVIDUAL TRAINING LOG - Investigator Site File (ISF), section 4 (blank), section 6 (completed). Each trial team member should maintain an individual log of all training received for the trial.

SITE DELEGATION OF RESPONSIBILITY LOG - ISF, section 4 (blank), section 6 (completed). List all team members who have trial related responsibilities. Appropriate training must be completed before they can be delegated trial related responsibilities. Remember to i) record if a team member leaves the trial by completing the 'operations and dates' columns and ii) add new team members throughout the course of the trial. Please also file each team member's GCP certificate and CV in ISF, section 6 as soon as he/she joins the team.

SITE DELEGATION OF RESPONSIBILITY LOG

The persons named below are authorised by the Principal Investigator to carry out the specified duties for the wvman2 trial.

| Name | Job Title | Authorisation | Training | Operations | Dates | Signature | Phone | Mobile |
|------------|-----------|---------------|----------|------------|-------|-------------|---------|----------|
| Dr. [Name] | [Title] | Y | Y | Y | | [Signature] | [Phone] | [Mobile] |

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