SITE FILES AND TRIAL MATERIALS

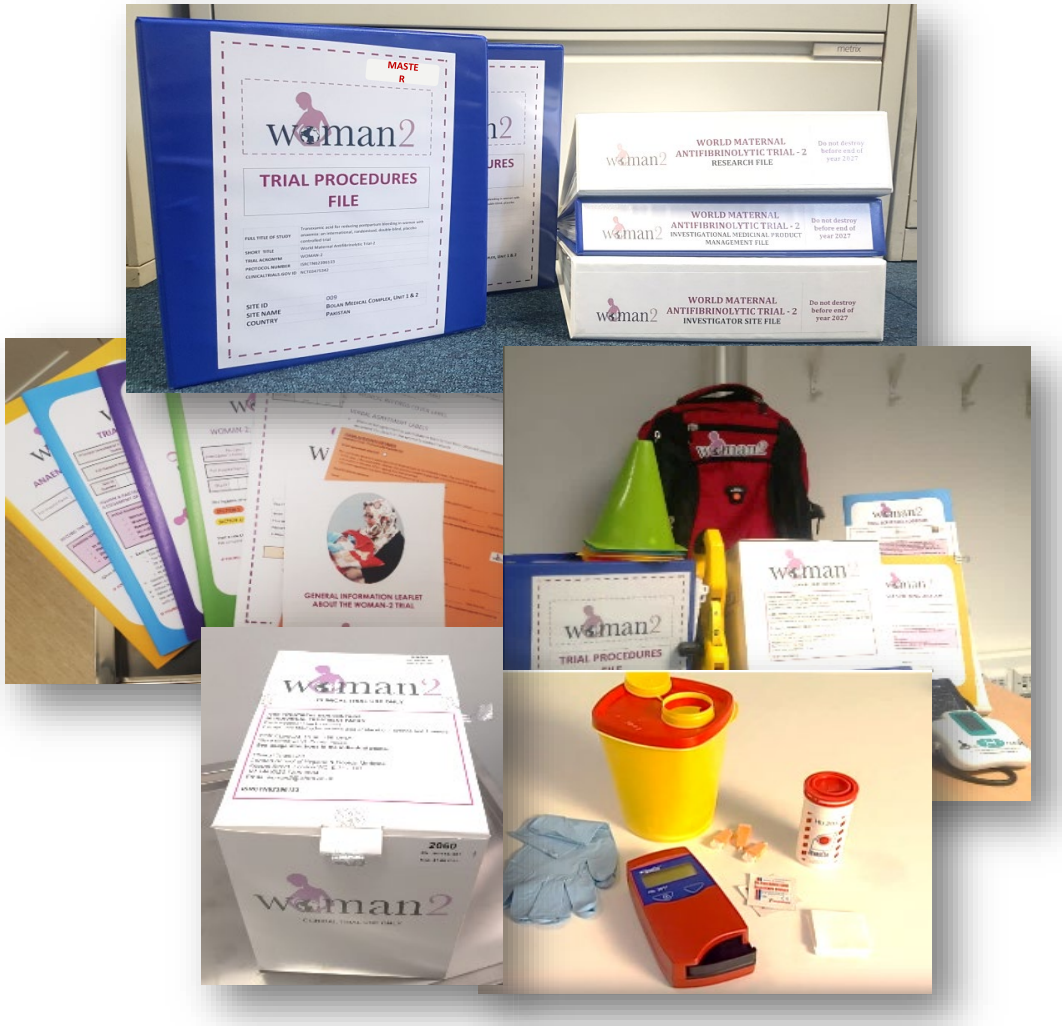
Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

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

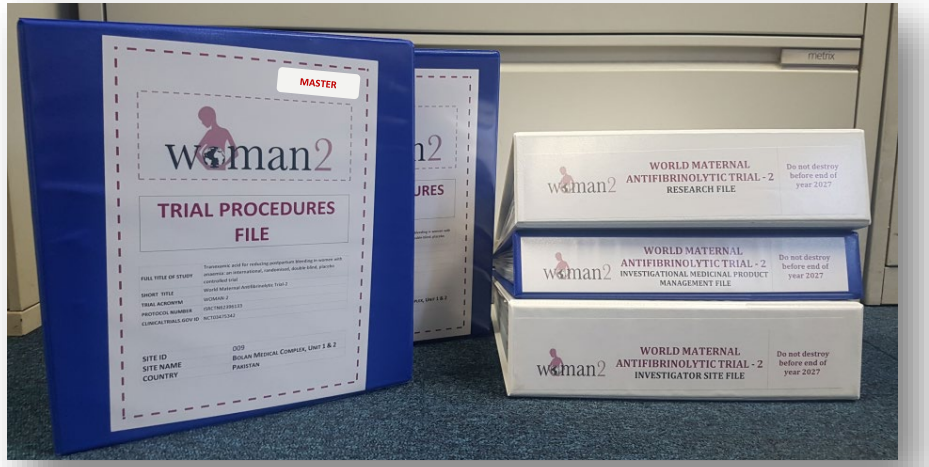
- As soon as you receive your site files, trial materials & equipment, **complete and return the receipt located inside the front cover of the ISF.** Keep a copy of the signed receipt in your ISF

- 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

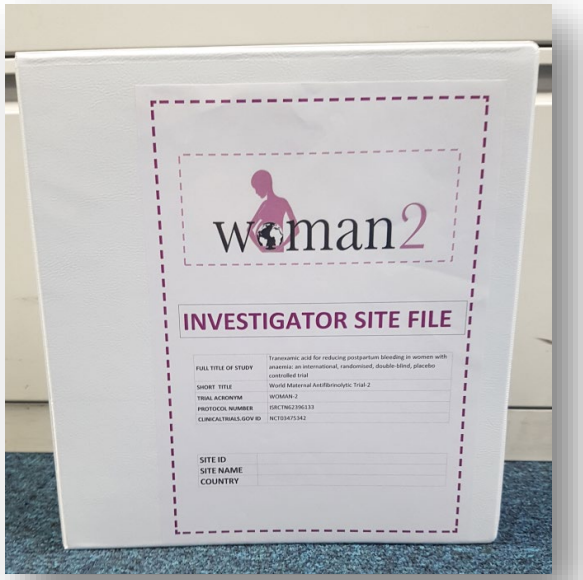
- **The site files will need to be available for monitoring visits** by the CTU and inspections by the relevant regulatory authorities

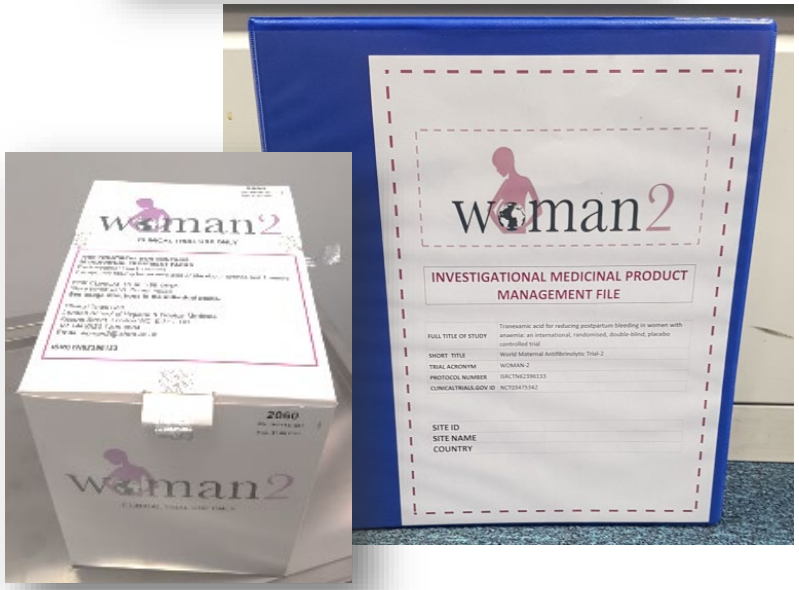
SITE FILES

- **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.



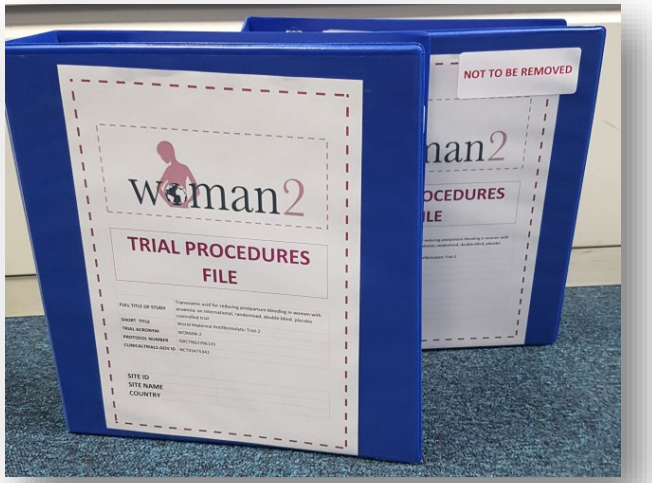


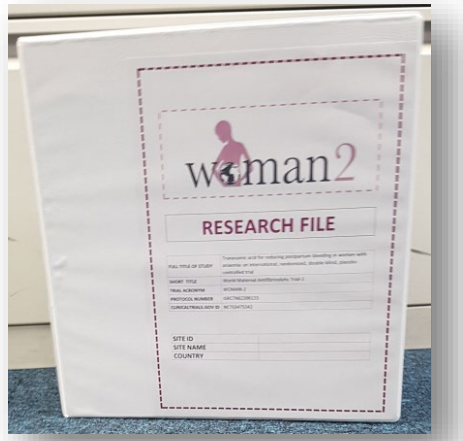
SITE FILES

- **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



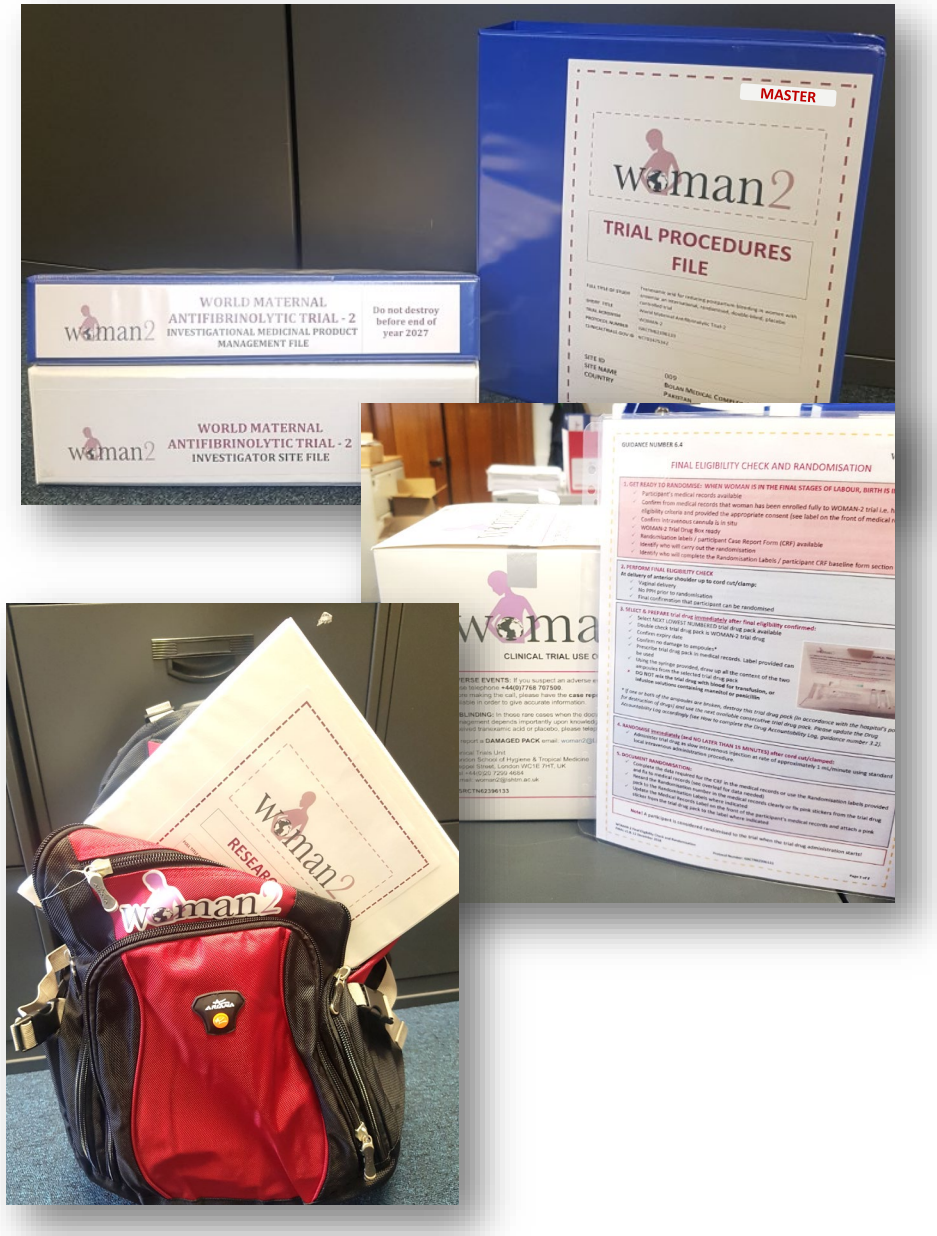


STORAGE AND ARCHIVING OF SITE FILES

- 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

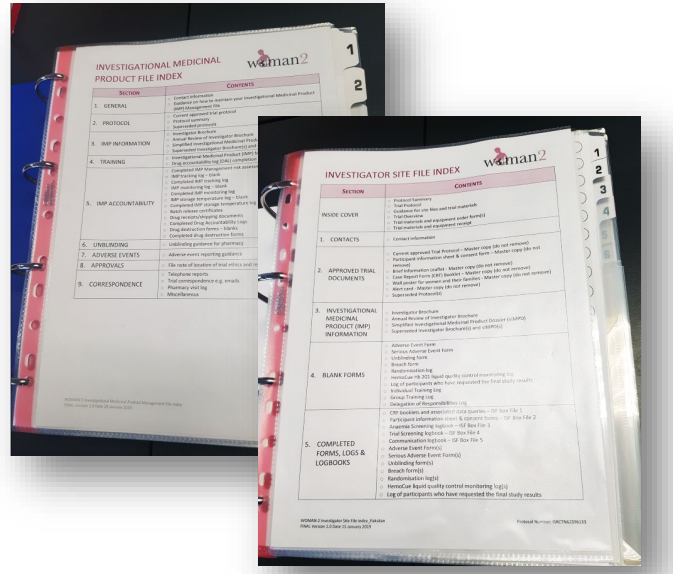
IMP management file logs to update:

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

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

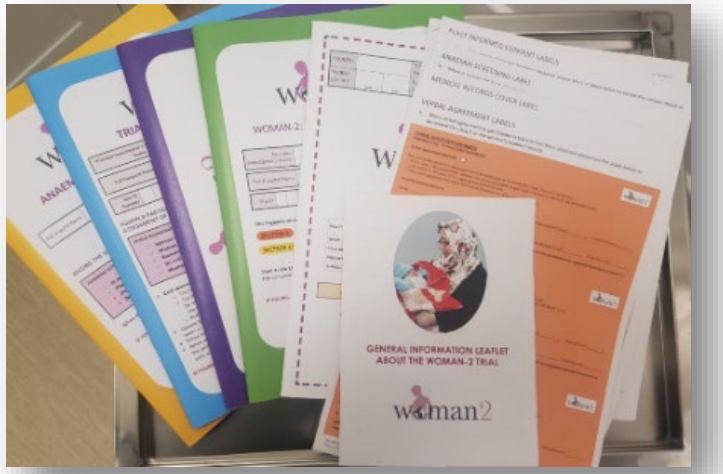
- For additional storage, box files have been sent to you. These are an extension of the Site Files and should be stored securely together with the ISF.
  - If you need additional box files, use the order form in the front of your ISF to request more.



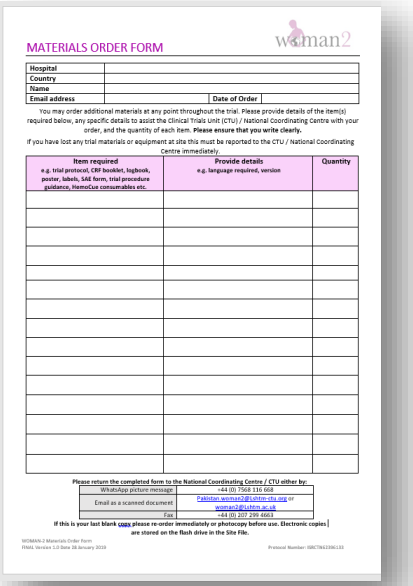
Monitoring/audits/inspections can occur at any time so it is important to ensure trial records are meticulously maintained

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


MATERIALS ORDER FORM

woman2

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 at site this must be reported to the CTU / National Coordinating Centre immediately.

Item required e.g. trial protocol, CRF booklet, logbook, poster, labels, SAE form, trial procedure guidance, HemoCue consumables etc.	Provide details e.g. language required, version	Quantity

Please return the completed form to the National Coordinating Centre / CTU either by:

WhatsApp picture message	+44 (0) 7568 116 068
Email as a scanned document	Pakistan.woman2@lshtm.ac.uk or woman2@lshtm.ac.uk
Fax	+44 (0) 207 299 4663

If this is your last blank copy please re-order immediately or photocopy before use. Electronic copies are stored on the flash drive in the Site File.

WOMAN-2 Materials Order Form
FINAL Version 1.0 Date 28 January 2019

Protocol Number: ISRCTN42396133

- **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**

FOR FURTHER GUIDANCE SEE:

The Investigator Site File:

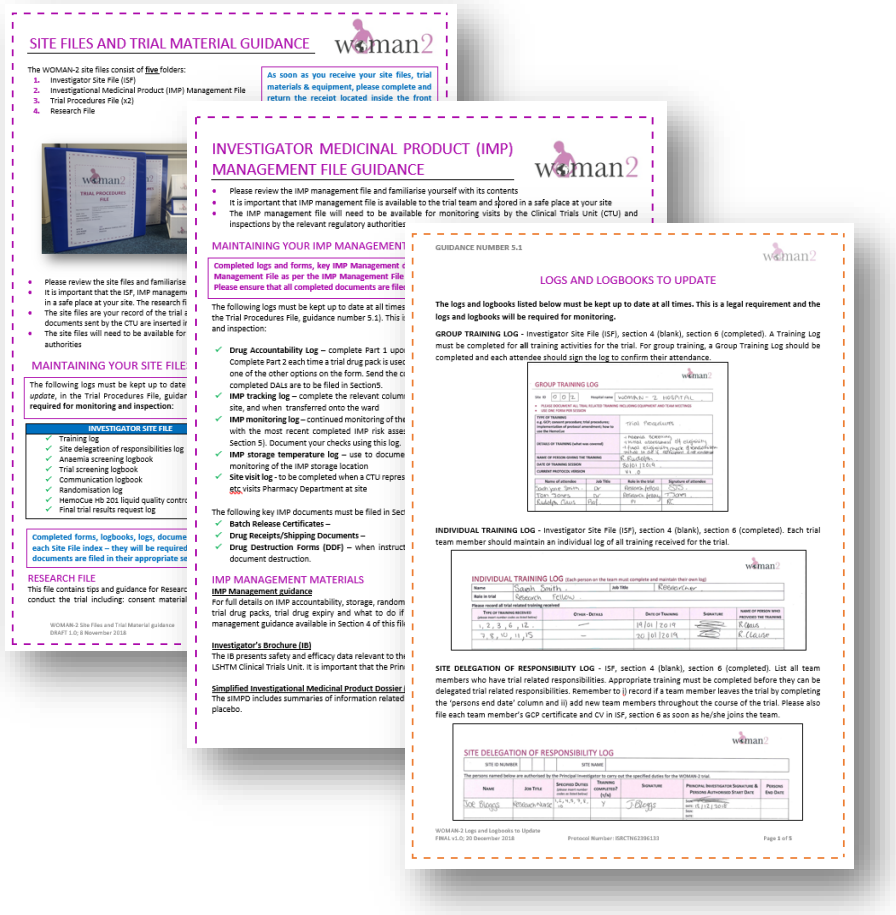
- Guidance for site files and trial materials

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



Clinical Trials Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

Tel: +44(0)20 7299 4684
Email: woman2@Lshtm.ac.uk
Website: woman2.Lshtm.ac.uk