



HOW TO RANDOMISE ELIGIBLE WOMEN

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

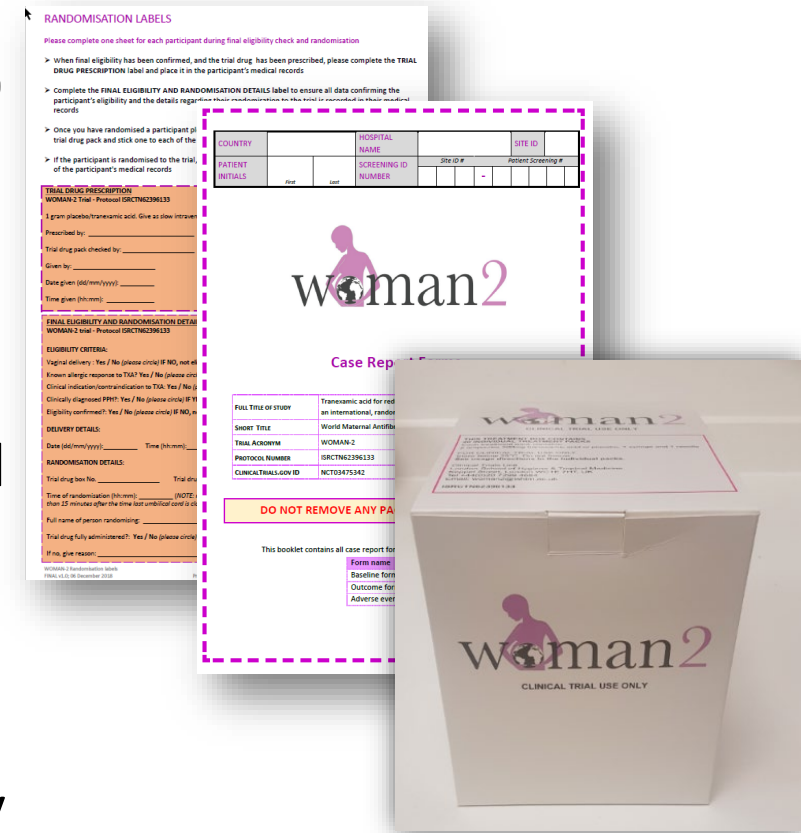
PREPARING FOR RANDOMISATION

What do you need?

- Access to women's medical records
- Randomisation labels / participant Case Report Form (CRF)
- WOMAN-2 trial drug box

What do you need to do?

- Check her medical records to confirm she has met initial eligibility criteria and provided the appropriate consent
- Confirm intravenous cannula is in situ
- Identify who will administer the trial drug
- Identify who will complete the Randomisation Labels / participant CRF baseline form section C



RANDOMISATION

FINAL ELIGIBILITY CHECK



SELECT AND PRESCRIBE

The trial drug pack at delivery of anterior shoulder



PREPARE TRIAL DRUG

as cord is being cut or clamped



RANDOMISE

immediately (no later than 15 minutes)
after cord is cut/clamped



DOCUMENTING

randomisation

FINAL ELIGIBILITY CHECK

To be confirmed at **delivery of anterior shoulder up to when cord is cut or clamped.**

Final eligibility criteria:

- Vaginal delivery
- No diagnosis of PPH before cord is cut or clamped
- No known allergy to TXA

Final eligibility is confirmed at delivery of anterior as women may become ineligible because:

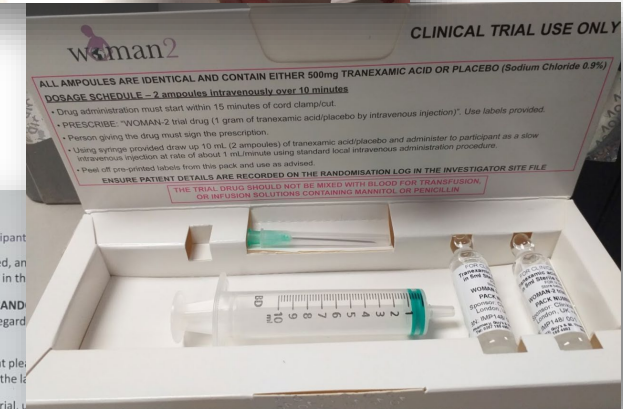
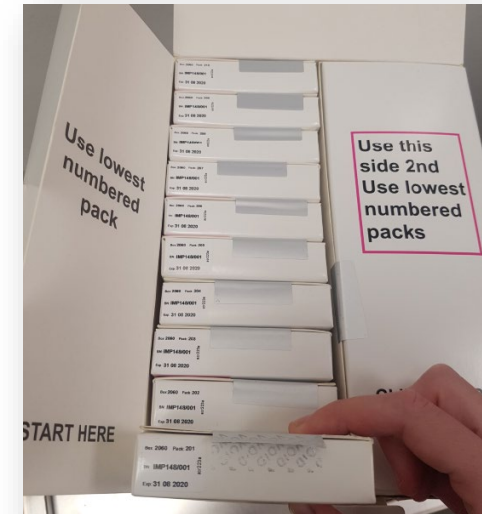
- some women may require a caesarean section
- some women may develop PPH before randomisation



SELECT AND PRESCRIBE TRIAL DRUG

Immediately at delivery of the baby's anterior shoulder (i.e. vaginal delivery confirmed):

- Take the **next lowest numbered** trial drug pack from the drug box
 - **DO NOT SKIP numbers!**
- Open the pack, check expiry date, check both ampoules are intact:
 - If damaged, destroy (as per hospital policy) and use the next lowest numbered pack
- Prescribe trial drug and **note time of delivery** in medical records (WOMAN-2 label can be used)



RANDOMISATION LABELS
Please complete one sheet for each participant

- > When final eligibility has been confirmed, an **DRUG PRESCRIPTION** label and place it in the
- > Complete the **FINAL ELIGIBILITY AND RANDOMISATION** label and place it in the
- > Once you have randomised a participant please stick one to each of the
- > If the participant is randomised to the trial, stick one to the participant's medical records

TRIAL DRUG PRESCRIPTION
WOMAN-2 Trial - Protocol ISRCTN62396133

1 gram placebo/tranexamic acid. Give as slow intravenous injection (1ml/min)

Prescribed by: *Charlotte Mangueta*

Trial drug pack checked by: *Charlotte Mangueta*

Given by: *Charlotte Mangueta*

Date given (dd/mm/yyyy): *26/03/2019*

Time given (hh:mm): *16:33*

FINAL ELIGIBILITY AND RANDOMISATION
WOMAN-2 trial - Protocol ISRCTN62396133

ELIGIBILITY CRITERIA:

Vaginal delivery (Yes) No ()

Known allergic response

PREPARE TRIAL DRUG

Prepare trial drug as cord is being cut or clamped:

- Use the syringe provided to draw up all the contents of both ampoules

Note time of
cord clamp



DO NOT mix the trial drug with blood for transfusion, or infusion solutions containing mannitol or penicillin

RANDOMISE

Immediately after cord is cut or clamped:

- Administer trial drug as slow intravenous injection at rate of approximately 1 mL/minute
- **NO LATER THAN 15 MINUTES AFTER CORD CUT/CLAMPED**



Note time of
randomisation

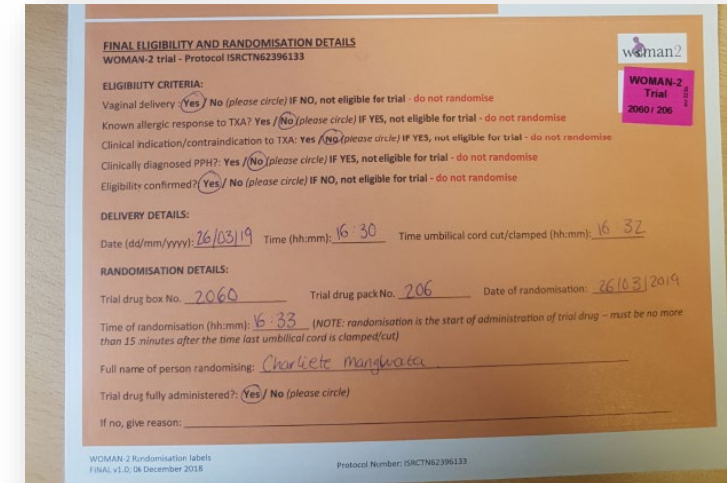
DOCUMENTING RANDOMISATION

RANDOMISATION DETAILS

- Details of randomisation must be documented in the participants medical records.
 - i.e. the details needed for CRF Section C (e.g. confirming final eligibility, details of delivery and randomization)
- You can use the WOMAN-2 randomisation label for this

TRIAL DRUG PACK STICKERS

- Four pink stickers, pre-printed with the participant's randomisation number, are available on the trial drug pack lid
- If WOMAN-2 labels have been used, where indicated stick a pink sticker to each of the following (If pink stickers are not used, the drug pack number should be manually recorded):
 - Trial drug prescription Label
 - Final eligibility check and randomisation details label
 - Medical records cover label



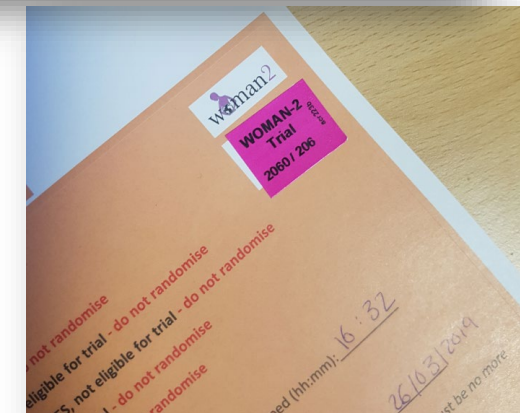
FINAL ELIGIBILITY AND RANDOMISATION DETAILS
WOMAN-2 trial - Protocol ISRCTN62396133

ELIGIBILITY CRITERIA:
Vaginal delivery: Yes / No (please circle) IF NO, not eligible for trial - do not randomise
Known allergic response to TXA? Yes / No (please circle) IF YES, not eligible for trial - do not randomise
Clinical indication/contraindication to TXA: Yes / No (please circle) IF YES, not eligible for trial - do not randomise
Clinically diagnosed PPH? Yes / No (please circle) IF YES, not eligible for trial - do not randomise
Eligibility confirmed? Yes / No (please circle) IF NO, not eligible for trial - do not randomise

DELIVERY DETAILS:
Date (dd/mm/yyyy): 26/03/19 Time (hh:mm): 16:30 Time umbilical cord cut/clamped (hh:mm): 16:32

RANDOMISATION DETAILS:
Trial drug box No. 2060 Trial drug pack No. 206 Date of randomisation: 26/03/2019
Time of randomisation (hh:mm): 16:33 (NOTE: randomisation is the start of administration of trial drug - must be no more than 15 minutes after the time last umbilical cord is clamped/cut)
Full name of person randomising: Charlotte Mangwate
Trial drug fully administered? Yes / No (please circle)
If no, give reason:

WOMAN-2 Randomisation labels
FINAL v1.0, 06 December 2018 Protocol Number: ISRCTN62396133

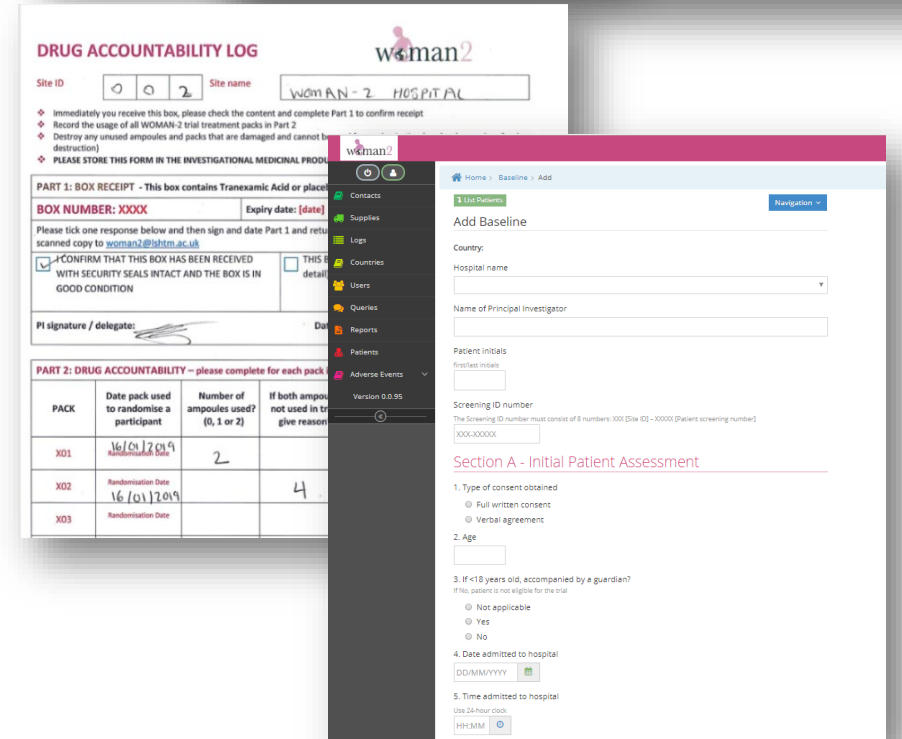


DOCUMENTING RANDOMISATION

- Record the participant on the **Randomisation Log**
- Update the part 2 of the **Drug Accountability Log**
- Upload the participant's baseline data to the trial database **within 24 hours of randomisation**



The image shows a 'WOMAN2 RANDOMISATION LOG' form. It includes fields for 'Full Hospital Name' and 'Site ID Number'. Below these is a table with columns: '#', 'PARTICIPANT'S NAME', 'PARTICIPANT'S HOSPITAL ID NUMBER', 'DATE RANDOMISED', 'TIME RANDOMISED', 'TRIAL DRUG BOX NUMBER', 'TRIAL DRUG PACK NUMBER', and 'NAME OF PERSON WHO RANDOMISED'. A hand is shown writing in the table. To the left of the table, there are instructions: 'Please record (N/A)', 'HOW TO MAKE CORRECT: If you enter incorrect: inform, Do NOT use correction, Cross out the incorrect, Enter the correct inform, Date, initial and provide', and 'IF FOUND, PL'.



The image shows two overlapping forms from the WOMAN2 trial. The top form is the 'DRUG ACCOUNTABILITY LOG' with fields for 'Site ID' and 'Site name' (WOMAN-2 HOSPITAL). It contains instructions and a table for 'PART 2: DRUG ACCOUNTABILITY - please complete for each pack'. The bottom form is the 'Add Baseline' screen, showing fields for 'Country', 'Hospital name', 'Name of Principal Investigator', 'Patient initials', 'Screening ID number', and 'Section A - Initial Patient Assessment' with numbered questions.

PACK	Date pack used to randomise a participant	Number of ampoules used? (0, 1 or 2)	If both ampoules not used in trial give reason
X01	16/01/2019	2	
X02	16/01/2019		4
X03	Randomisation Date		

WHAT TO DO IF A PARTICIPANT IS NOT RANDOMISED

- Some participants may be screened and consented but **not** randomised to the trial if they, for example,
 - *Require an emergency caesarean*
 - *Develop PPH before the umbilical cord is cut or clamped*
 - *Decide they would like to withdraw from the trial before giving birth*
- These participants are considered trial **'screen failures'**
- **For these participants, all data captured on the CRF baseline form up to that point, should still be entered into the trial database.**
- For screen failures, mark the front page of CRF booklets: **'Not randomised – screen failure'**

COUNTRY	PAKISTAN	HOSPITAL NAME	WOMAN-2 HOSP	SITE ID	002
PATIENT IN TRIAL	C Site	F Site	SCREENING ID RANDOMISED	STUDY 0 2 - 0 4 5	SCREENING ID RANDOMISED

woman²
NOT RANDOMISED - SCREEN FAILURE.
Case Report Forms

Full Title of Study: Transcervical acid for reducing operative bleeding in women with anaemia: an international, randomised, double-blind, placebo-controlled trial
Sponsor Title: World Maternal Antifibrinolytic Trial 2
Trial Acronym: WOMAN-2
Protocol Number: ECT102/06/13
ClinicalTrials.gov ID: ECT102/06/13

DO NOT REMOVE ANY PAGES FROM THIS BOOKLET

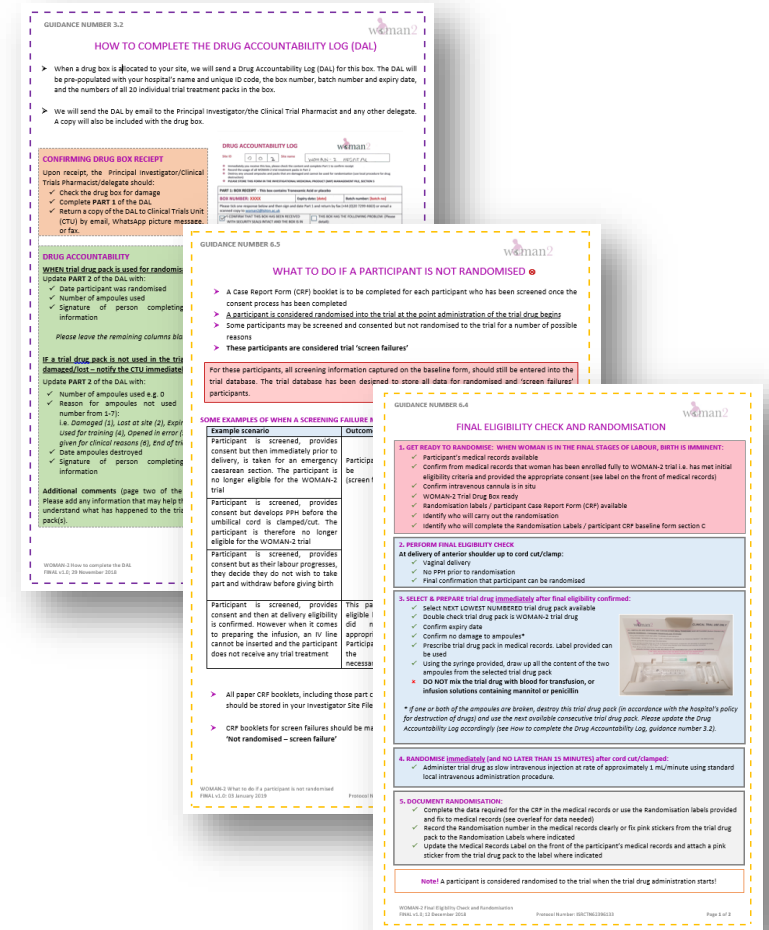
This booklet contains all case report forms (CRFs) needed for a trial participant:

- **Form name**
- Baseline form
- Outcome form
- Adverse event form

FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 3 and 6:

1. How to Complete the Drug Accountability Log, guidance number 3.2.
2. Final eligibility check and randomisation, guidance number 6.4.
3. What to do if a participant is not randomised, guidance number 6.5.





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