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

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SELECT AND PRESCRIBE

The trial drug pack at delivery of anterior shoulder

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PREPARE TRIAL DRUG

as cord is being cut or clamped

↓

RANDOMISE

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

↓

DOCUMENTING

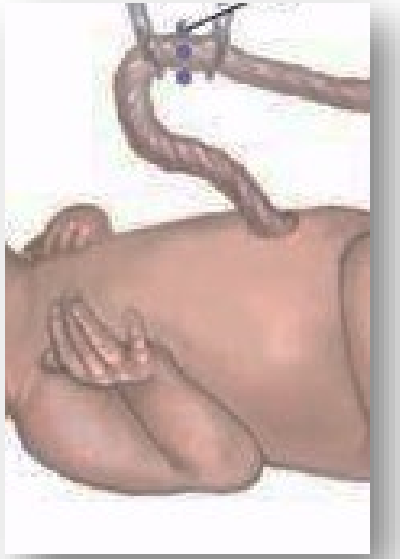
randomisation

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



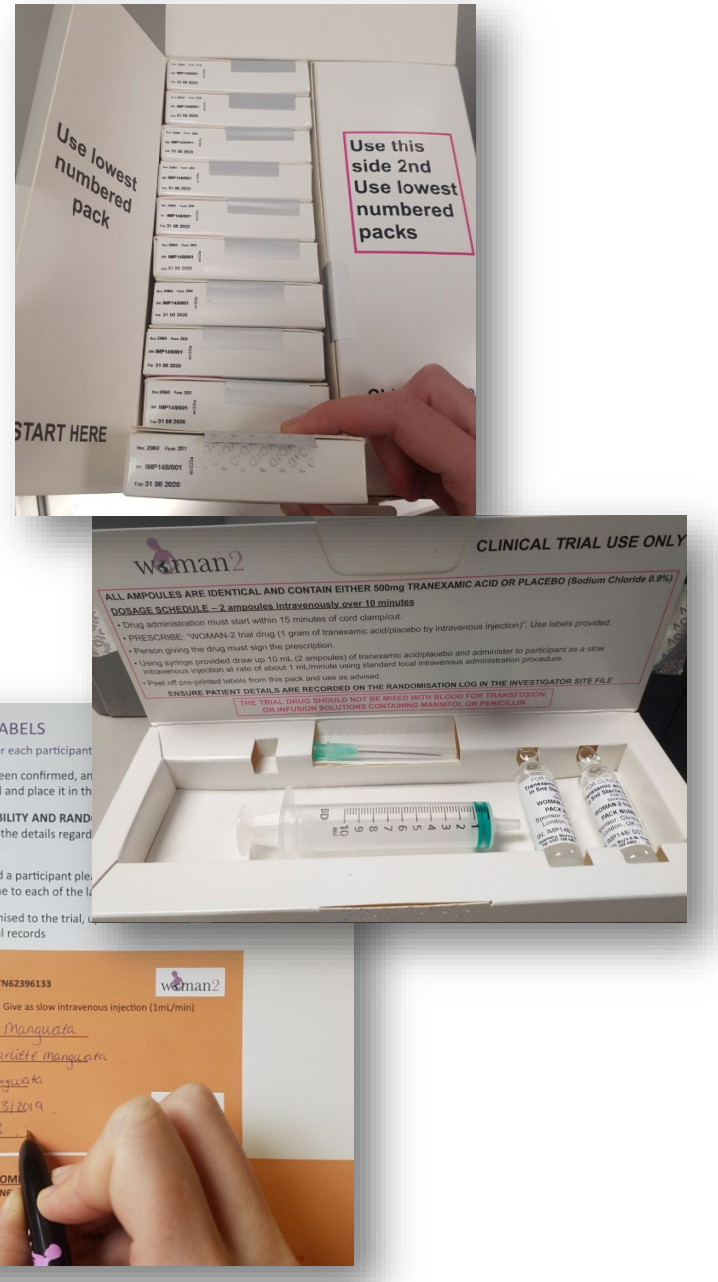
Final eligibility is confirmed at delivery of anterior as women may become ineligible because:

- 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)

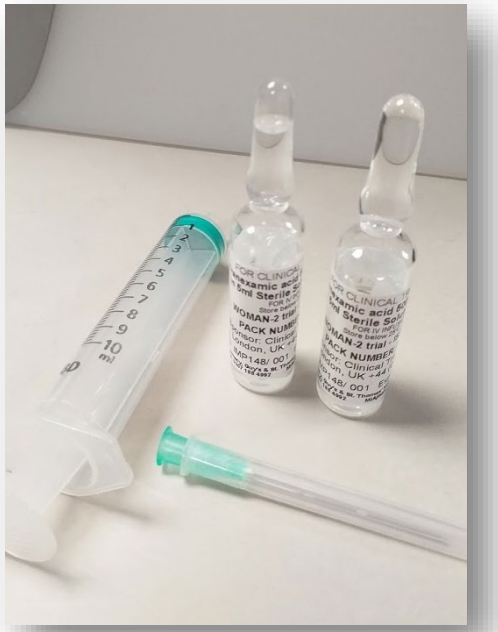


PREPARE TRIAL DRUG

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

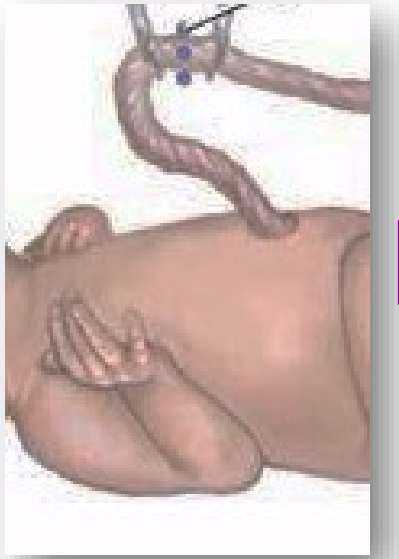


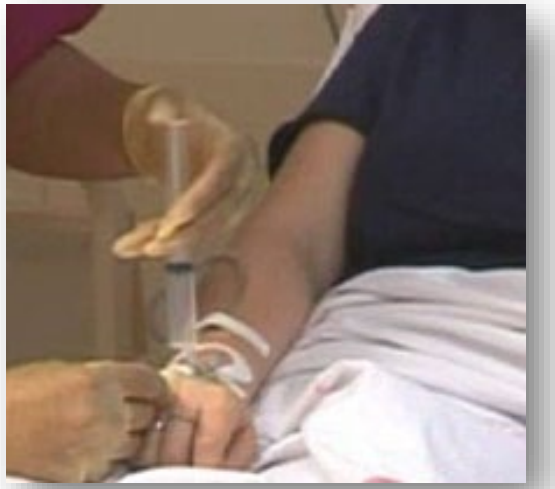
DO NOT mix the trial drug with blood for transfusion, or infusion solutions containing mannitol or penicillin

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

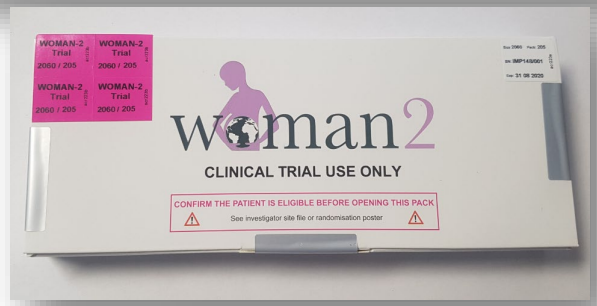
RANDOMISATION DETAILS

- 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

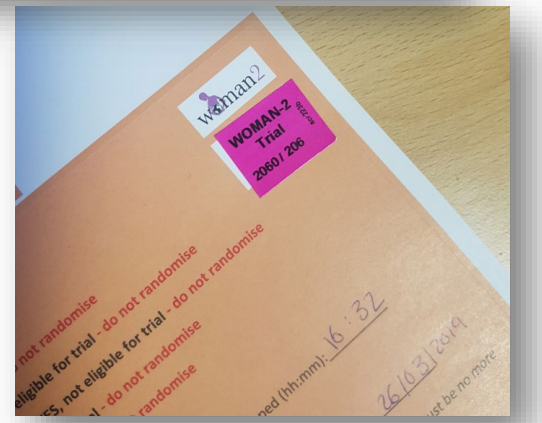
TRIAL DRUG PACK STICKERS

- Four pink stickers, pre-printed with the participant's randomisation number, are available on the trial drug pack lid



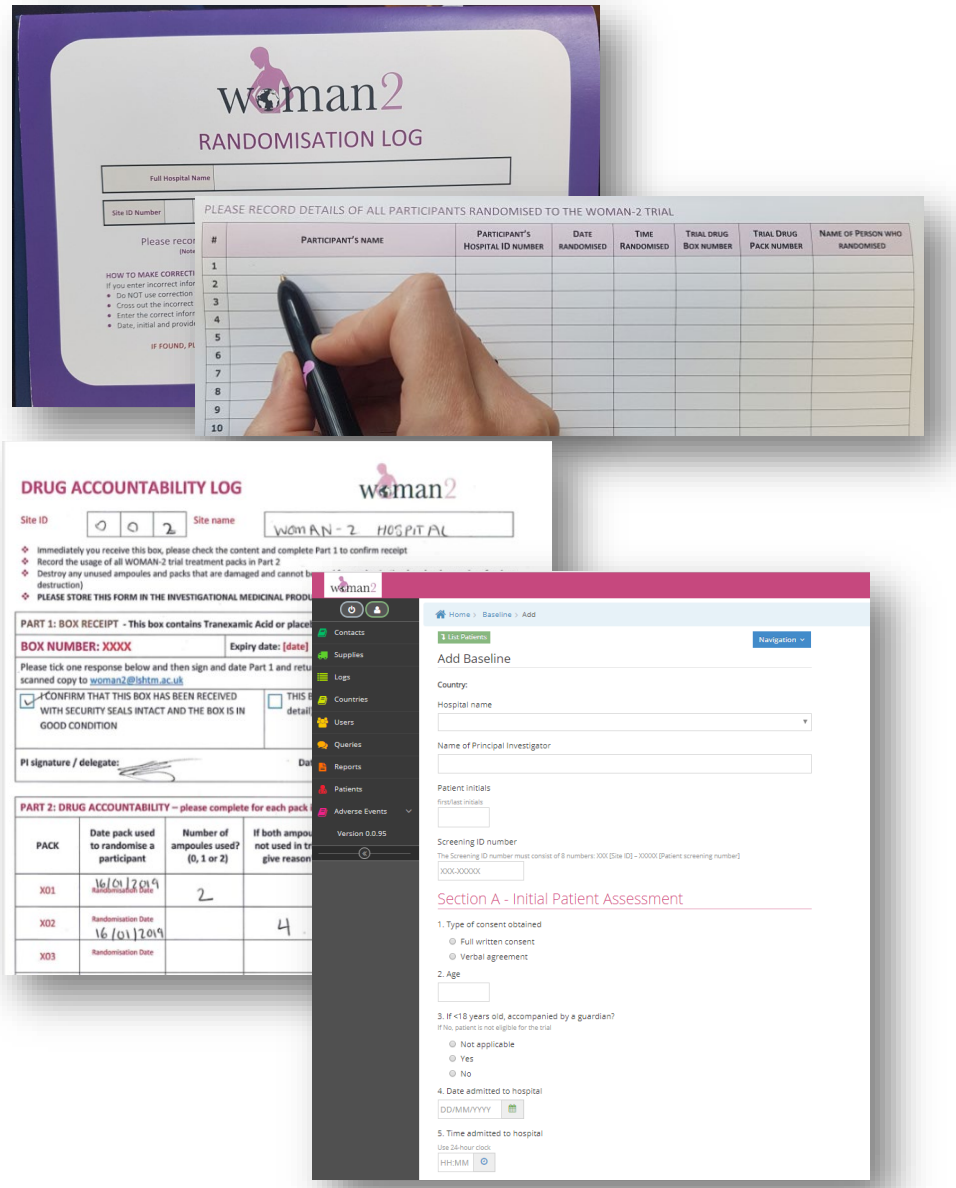
- If WOMAN-2 labels have been used, where indicated stick a pink sticker to each of the following (If pink stickers are not used, the drug pack number should be manually recorded):

  - Trial drug prescription Label
  - Final eligibility check and randomisation details label
  - Medical records cover label



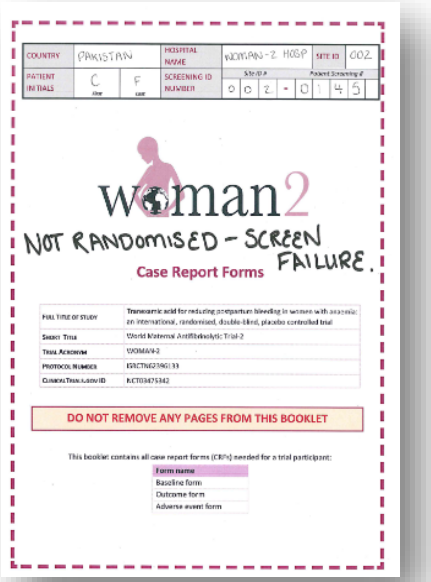
DOCUMENTING RANDOMISATION

- 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



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'**

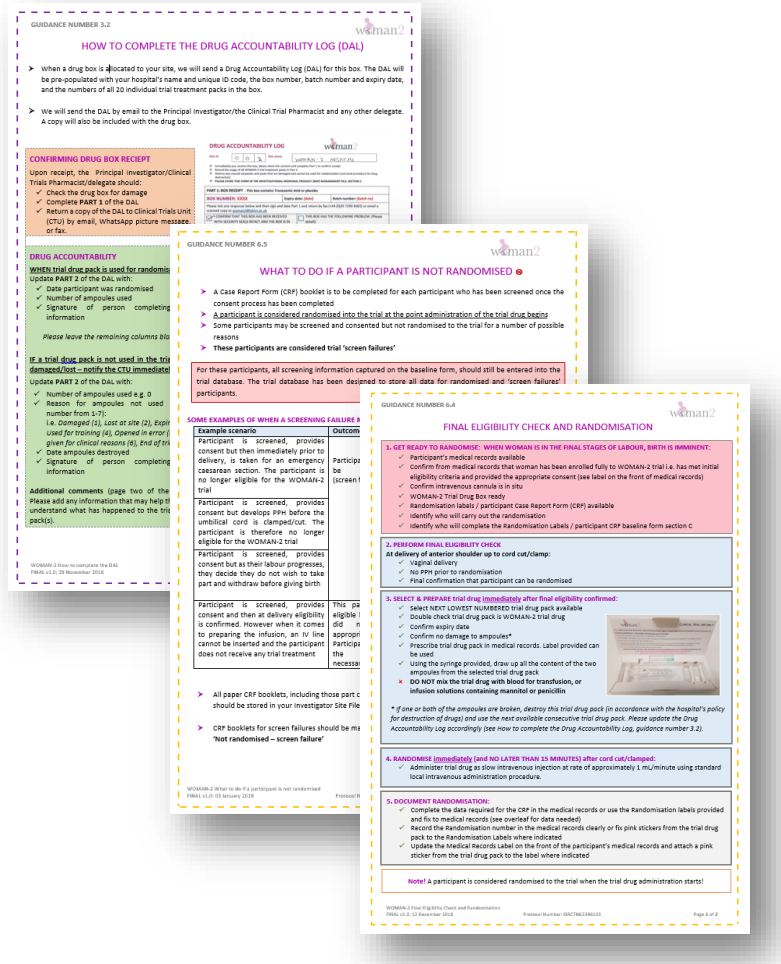
FOR FURTHER GUIDANCE SEE:

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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