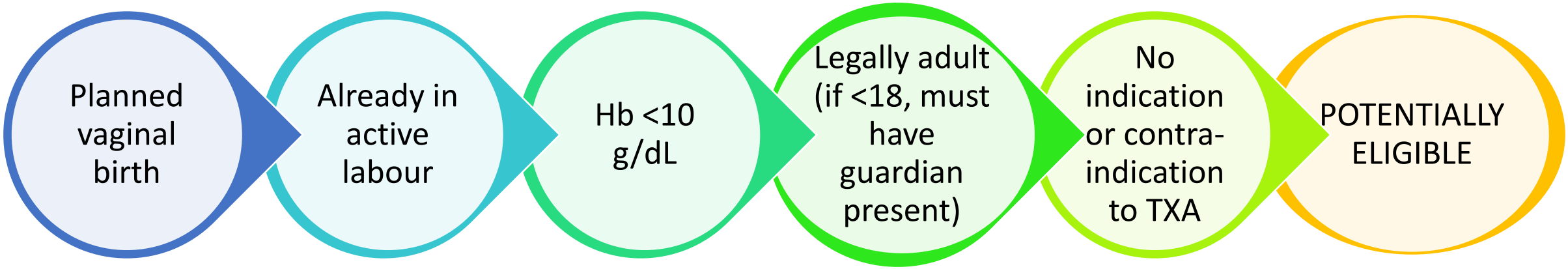
INITIAL ASSESSMENT OF ELIGIBILITY

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

INITIAL ASSESSMENT OF ELIGIBILITY (BEFORE DELIVERY)

After a women as been admitted, an **initial assessment of eligibility** should be carried out

Review woman's medical records and check the woman has/is:

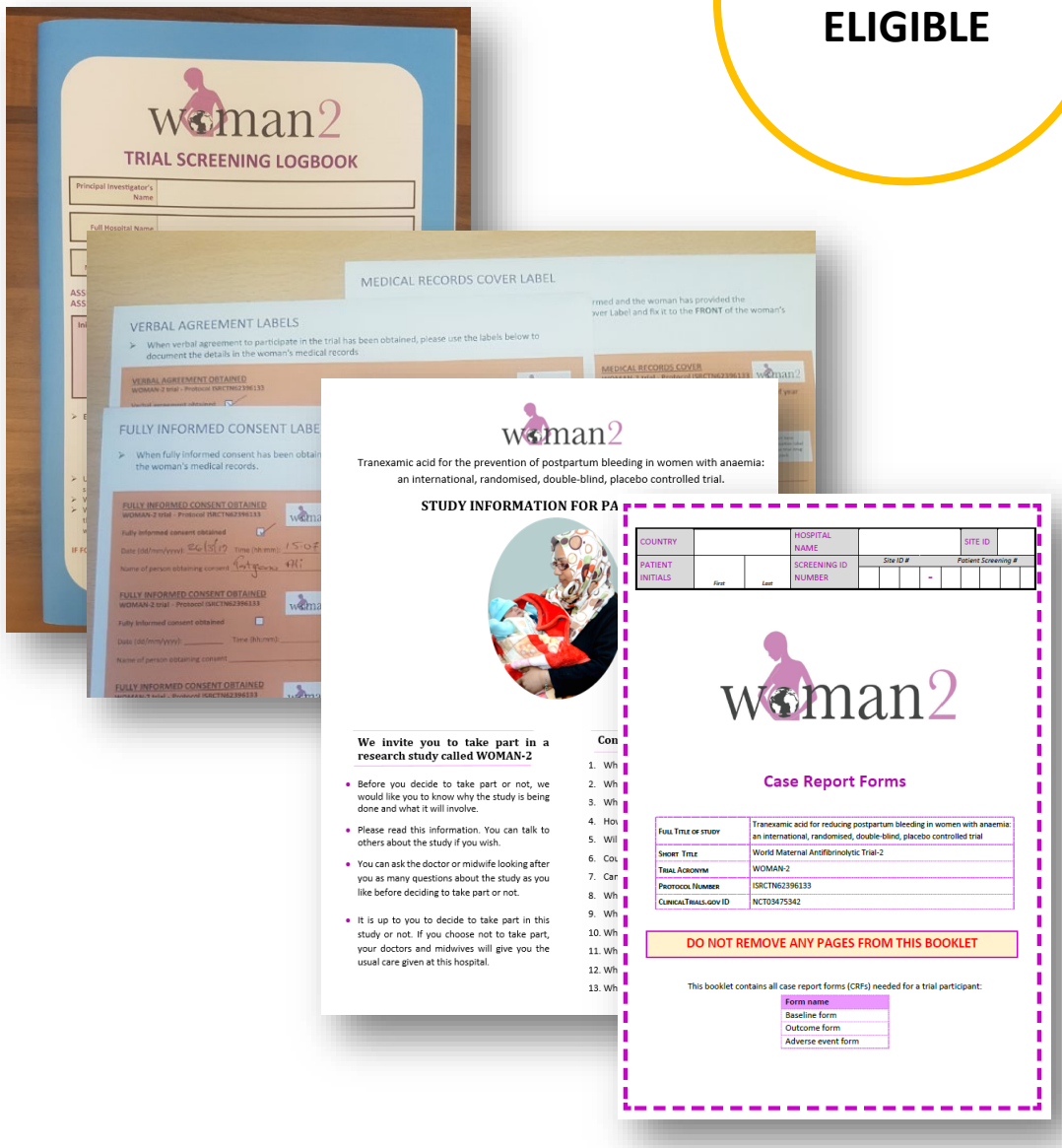


IF POTENTIALLY ELIGIBLE

POTENTIALLY ELIGIBLE

Assemble the following

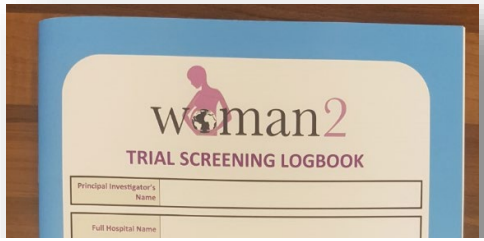
- Woman's medical records
- Trial Screening logbook
- Participant Information Sheet and Informed Consent Form
- WOMAN-2 Consent Labels
- WOMAN-2 Medical Records Labels
- Case Report Form (CRF) Booklet



OBTAIN AGREEMENT / CONSENT AS APPROPRIATE

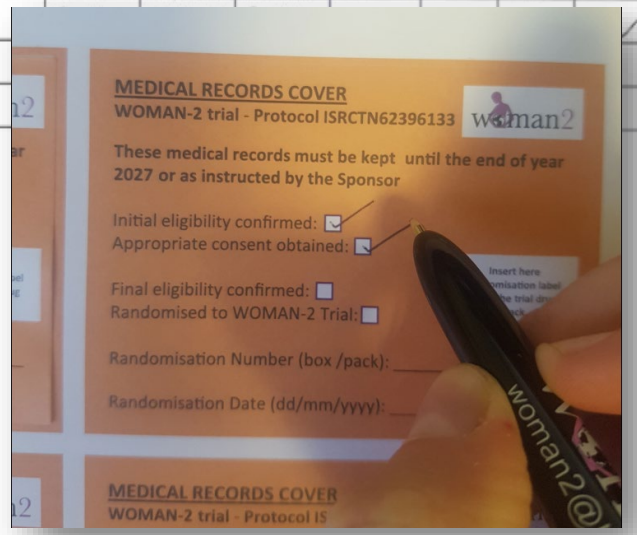
DOCUMENTING INITIAL ASSESSMENT OF ELIGIBILITY

- Complete trial screening logbook and assign a 5-digit participant screening number:
  - **Each woman will have a unique Screening ID Number in the format of: XXX - XXXXX**
    - The first three digits correspond to the Site ID Number
    - The following 5-digits correspond to the Participant Screening Number. This number should be allocated to women in SEQUENTIAL ORDER
    - **In the Trial Screening Logbook you only need to enter the 5-digit Participant Screening Number (column 1)**



PLEASE UPDATE THE PARTICIPANT'S RECORD AS THEY PROGRESS THROUGH THE TRIAL PATHWAY

1	2	3			4		5	
5-digit Participant Screening Number	Participant's Initials (first letter of name & surname only)	Haemoglobin (Hb) Test			Participant has met the Initial Assessment of Eligibility Criteria		*Participant has provided written informed consent or verbal agreement? (tick one)	
		Hb Value (g/dL)	Date (dd/mm/yy)	Time (hh:mm)	Yes (obtain appropriate consent)	No (do not continue)	Yes (complete Question 6 or 7**)	No (do not randomise)
00001	DE	9·8	07/12/18	11:22	✓		✓	
00002	CM	8·0	07/12/18	12:45	✓		✓	
00003	CD							
00004	PG							
00005	MP							



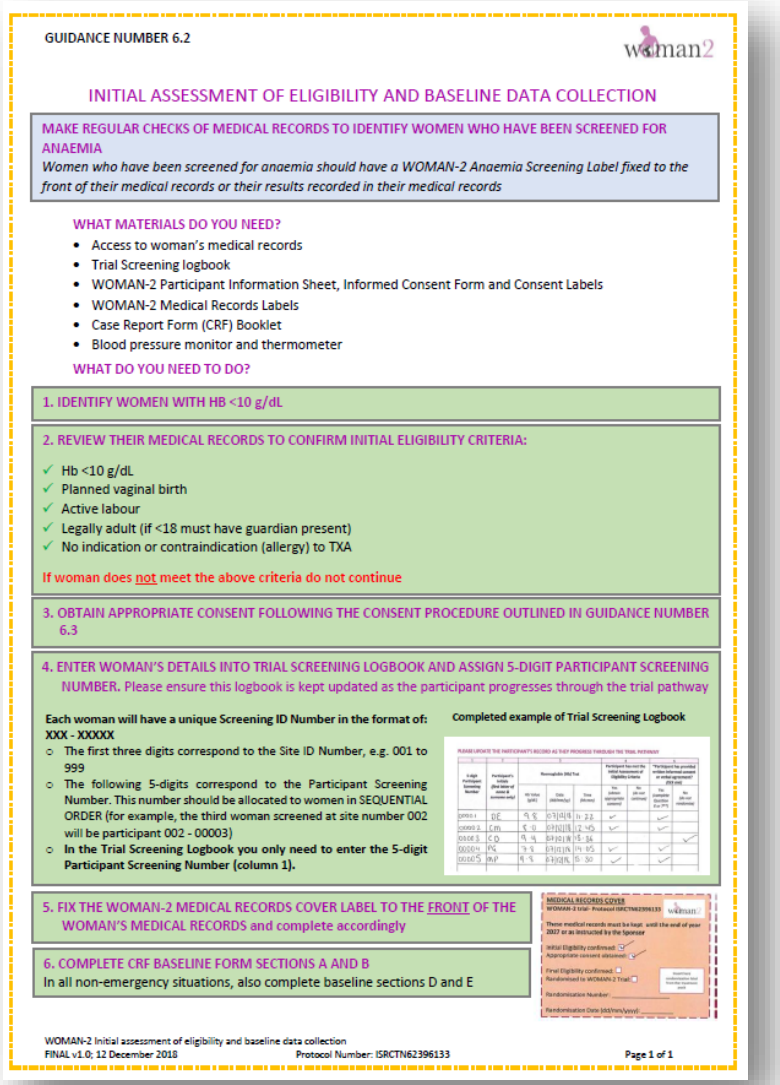
- Fix the WOMAN-2 medical records cover label to the **front** of the woman's medical records and complete

- Complete sections A-G of the Baseline Form in the participant's CRF booklet before randomisation

FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 6:

- Initial assessment of eligibility and baseline data collection, guidance number 6.2.



GUIDANCE NUMBER 6.2

woman2

INITIAL ASSESSMENT OF ELIGIBILITY AND BASELINE DATA COLLECTION

MAKE REGULAR CHECKS OF MEDICAL RECORDS TO IDENTIFY WOMEN WHO HAVE BEEN SCREENED FOR ANAEMIA

Women who have been screened for anaemia should have a WOMAN-2 Anaemia Screening Label fixed to the front of their medical records or their results recorded in their medical records

WHAT MATERIALS DO YOU NEED?

- Access to woman's medical records
- Trial Screening logbook
- WOMAN-2 Participant Information Sheet, Informed Consent Form and Consent Labels
- WOMAN-2 Medical Records Labels
- Case Report Form (CRF) Booklet
- Blood pressure monitor and thermometer

WHAT DO YOU NEED TO DO?

1. IDENTIFY WOMEN WITH HB <10 g/dL

2. REVIEW THEIR MEDICAL RECORDS TO CONFIRM INITIAL ELIGIBILITY CRITERIA:

- ✓ Hb <10 g/dL
- ✓ Planned vaginal birth
- ✓ Active labour
- ✓ Legally adult (if <18 must have guardian present)
- ✓ No indication or contraindication (allergy) to TXA

If woman does not meet the above criteria do not continue

3. OBTAIN APPROPRIATE CONSENT FOLLOWING THE CONSENT PROCEDURE OUTLINED IN GUIDANCE NUMBER 6.3

4. ENTER WOMAN'S DETAILS INTO TRIAL SCREENING LOGBOOK AND ASSIGN 5-DIGIT PARTICIPANT SCREENING NUMBER. Please ensure this logbook is kept updated as the participant progresses through the trial pathway

Each woman will have a unique Screening ID Number in the format of: XXX - XXXXX

- The first three digits correspond to the Site ID Number, e.g. 001 to 999
- The following 5-digits correspond to the Participant Screening Number. This number should be allocated to women in SEQUENTIAL ORDER (for example, the third woman screened at site number 002 will be participant 002 - 00003)
- In the Trial Screening Logbook you only need to enter the 5-digit Participant Screening Number (column 1).

Completed example of Trial Screening Logbook

5. FIX THE WOMAN-2 MEDICAL RECORDS COVER LABEL TO THE FRONT OF THE WOMAN'S MEDICAL RECORDS and complete accordingly

6. COMPLETE CRF BASELINE FORM SECTIONS A AND B
In all non-emergency situations, also complete baseline sections D and E

WOMAN-2 Initial assessment of eligibility and baseline data collection
FINAL v1.0; 12 December 2018 Protocol Number: ISRCTN62396133 Page 1 of 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