



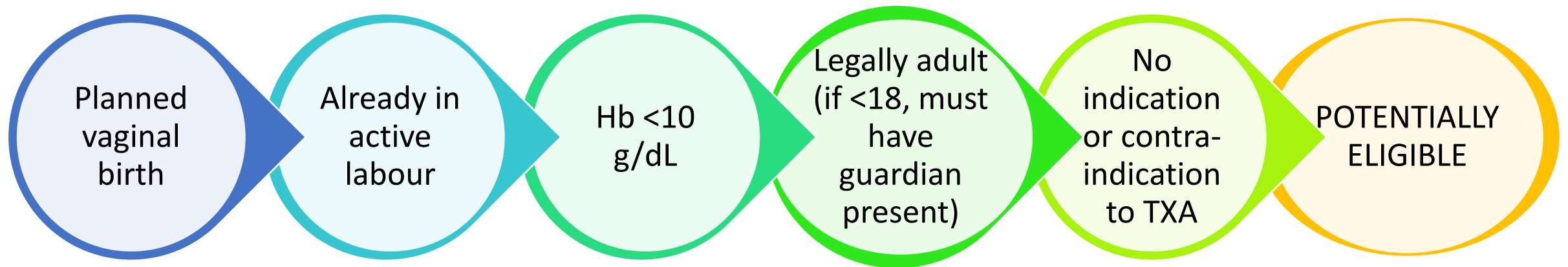
# INITIAL ASSESSMENT OF ELIGIBILITY

Protocol number: ISRCTN62396133  
Version 1.0; Date 05 April 2019

# INITIAL ASSESSMENT OF ELIGIBILITY (BEFORE DELIVERY)

After a woman has been admitted, an **initial assessment of eligibility** should be carried out

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



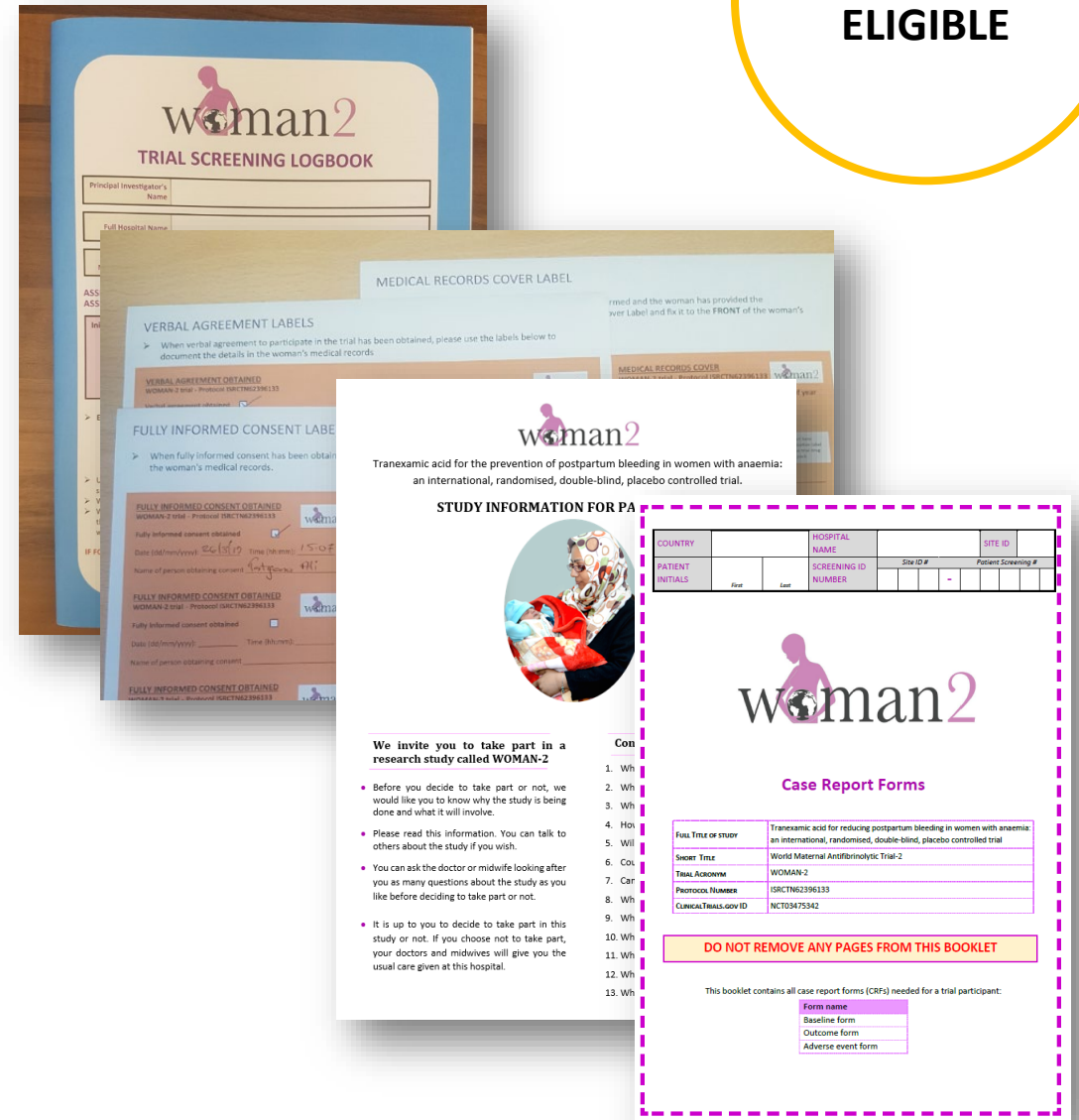
# IF POTENTIALLY ELIGIBLE

POTENTIALLY  
ELIGIBLE

## Assemble the following

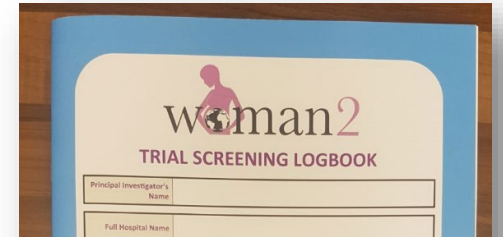
- Woman's medical records
- Trial Screening logbook
- Participant Information Sheet and Informed Consent Form
- WOMAN-2 Consent Labels
- WOMAN-2 Medical Records Labels
- Case Report Form (CRF) Booklet

OBTAIN AGREEMENT / CONSENT AS APPROPRIATE



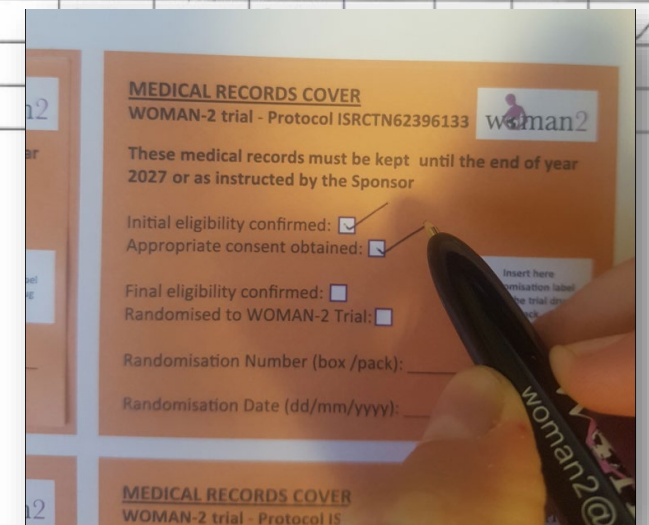
# DOCUMENTING INITIAL ASSESSMENT OF ELIGIBILITY

- 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)**
- 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



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


1 5-digit Participant Screening Number	2 Participant's initials (first letter of name & surname only)	3 Haemoglobin (Hb) Test			4 Participant has met the initial Assessment of Eligibility Criteria		5 *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							



# 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 

**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**

Age (years)	Parity (number of previous births)	Screening ID Number	Site ID	Participant Screening Number	Screening Date	Screening Time	Screening Location	Screening Method	Screening Result (g/dL)	Screening Status	Screening Notes
30	0	001	001	001	01/01/18	10:30	Site 001	Point of care	9.8	Not eligible	
28	1	002	002	001	01/01/18	11:00	Site 002	Point of care	10.2	Eligible	
32	0	003	003	002	01/01/18	12:00	Site 003	Point of care	10.5	Eligible	
29	2	004	004	003	01/01/18	13:00	Site 004	Point of care	10.1	Eligible	
31	1	005	005	004	01/01/18	14:00	Site 005	Point of care	10.3	Eligible	
27	0	006	006	005	01/01/18	15:00	Site 006	Point of care	10.4	Eligible	

**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

**MEDICAL RECORDS COVER**  
WOMAN-2 Trial Protocol ISRCTN62396133  
These medical records must be kept until the end of year 2027 or as instructed by the sponsor

Initial Eligibility confirmed:   
Participant consent obtained:   
Final Eligibility confirmed:   
Randomised to WOMAN-2 Trial:   
Randomisation Number: \_\_\_\_\_  
Randomisation Date (dd/mm/yyyy): \_\_\_\_\_

WOMAN-2 Initial assessment of eligibility and baseline data collection  
FINAL v1 0.12 December 2018 Protocol Number: ISRCTN62396133 Page 1 of 1



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