LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

CLINICAL TRIALS UNIT

HOW TO COMPLETE THE CRF – BASELINE FORM

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

CONTENTS OF THE CRF BOOKLET

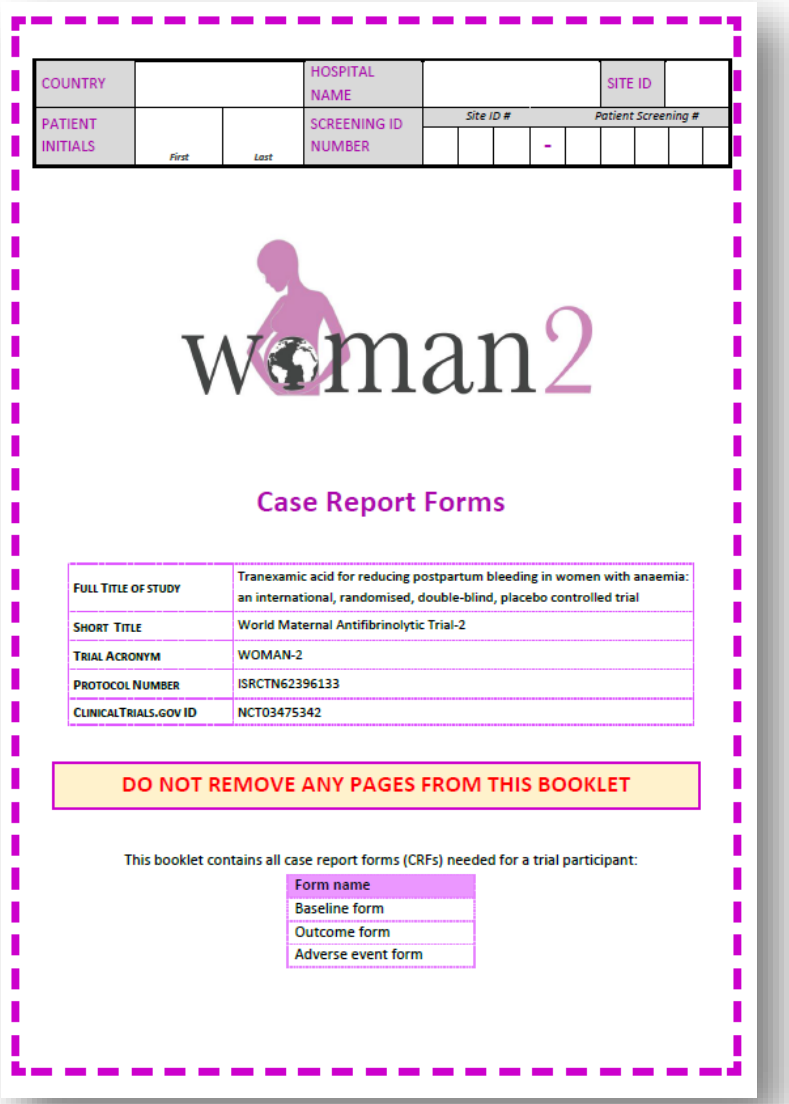
- Each participant will have a Case Report Form (CRF) booklet

- A CRF booklet contains:

  - Baseline Form
  - Outcome Form
  - Adverse Event Form

This presentation will focus on the **Baseline Form:**

- Completion should start as soon as the consent process has been completed



COUNTRY		HOSPITAL NAME		SITE ID	
PATIENT INITIALS	First / Last	SCREENING ID NUMBER	Site ID # - Patient Screening #		

woman2

Case Report Forms

FULL TITLE OF STUDY	Tranexamic acid for reducing postpartum bleeding in women with anaemia: an international, randomised, double-blind, placebo controlled trial
SHORT TITLE	World Maternal Antifibrinolytic Trial-2
TRIAL ACRONYM	WOMAN-2
PROTOCOL NUMBER	ISRCTN62396133
CLINICALTRIALS.GOV ID	NCT03475342

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

BASELINE DATA COLLECTION

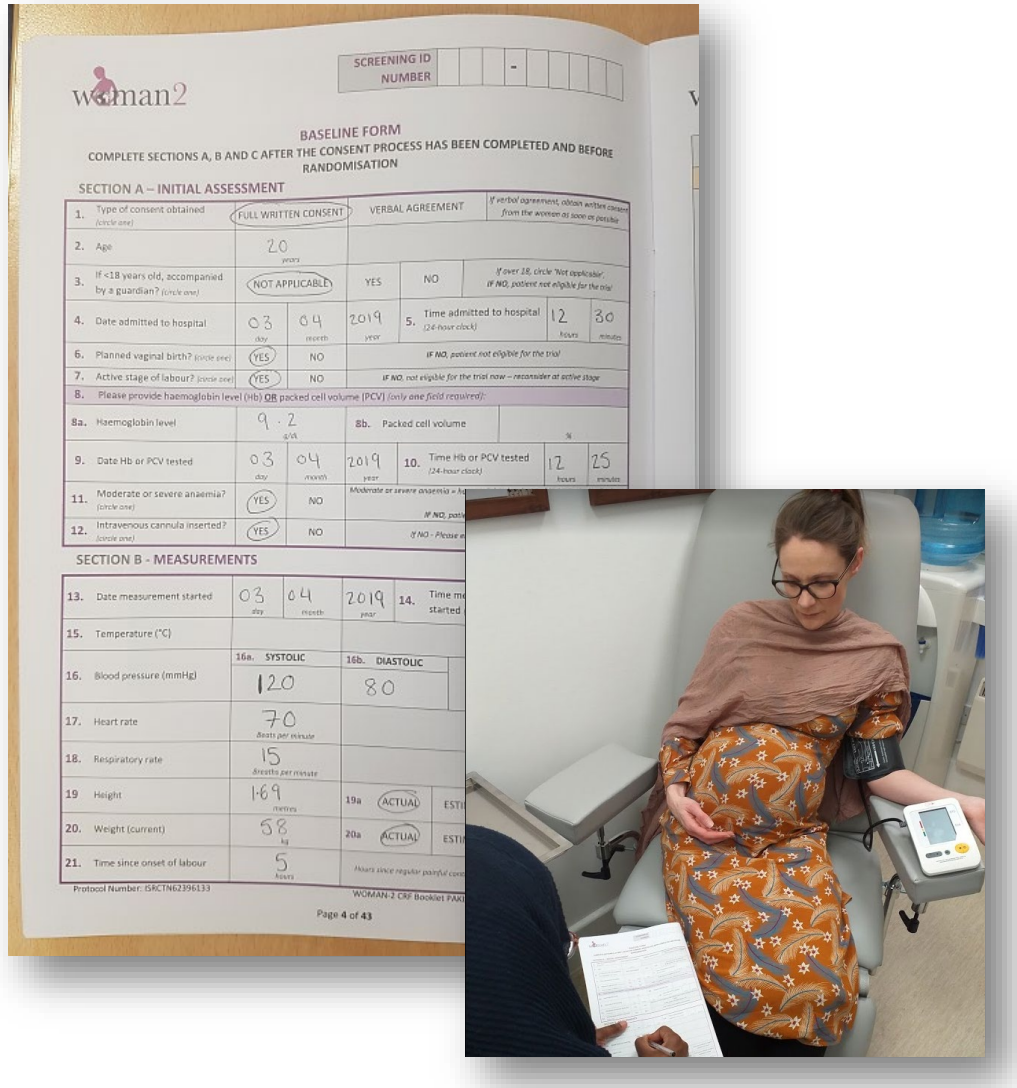
🕒 **WHEN?** **Completion of the baseline form should start for each participant as soon as agreement/consent has been obtained**

What?		When?
Sections A - B	• Initial assessment • Measurements	After completion of appropriate consent process and before randomisation
Sections C	• Eligibility, randomisation and trial drug administration	As soon as possible after final eligibility check
Sections D – E	• Medical history • About this pregnancy	After completion of appropriate consent process and before randomisation. If insufficient time (e.g. the woman gives birth rapidly) complete immediately after randomisation.
Sections F – G	• About the birth • About the baby/ies	Before randomisation but if insufficient time, immediately after randomisation. This must not delay randomisation.

BASELINE DATA COLLECTION: SECTIONS A & B

WHEN: After completion of appropriate consent process and before randomisation

- Complete **Section A:**
  - Enter details of initial assessment of eligibility
  - Check that an IV cannula is inserted
    - *If not, ensure this is inserted before delivery as this is how the trial drug will be administered*
- Complete **Section B:**
  - Take measurements including BP (BP monitor provide and available in research bag), HR, RR, height and weight



woman2

SCREENING ID NUMBER

BASELINE FORM

COMPLETE SECTIONS A, B AND C AFTER THE CONSENT PROCESS HAS BEEN COMPLETED AND BEFORE RANDOMISATION

SECTION A – INITIAL ASSESSMENT

1. Type of consent obtained	FULL WRITTEN CONSENT	VERBAL AGREEMENT	If verbal agreement, obtain written consent from the woman as soon as possible					
2. Age	20 years							
3. If <18 years old, accompanied by a guardian?	NOT APPLICABLE	YES	NO	If over 18, circle 'Not applicable'. IF NO, patient not eligible for the trial				
4. Date admitted to hospital	03 day	04 month	2019 year	5. Time admitted to hospital (24-hour clock)	12 hours	30 minutes		
6. Planned vaginal birth?	YES	NO	IF NO, patient not eligible for the trial					
7. Active stage of labour?	YES	NO	IF NO, not eligible for the trial now – reconsider at active stage					
8. Please provide haemoglobin level (Hb) OR packed cell volume (PCV) (only one field required):								
8a. Haemoglobin level	9.2 g/dl	8b. Packed cell volume	%					
9. Date Hb or PCV tested	03 day	04 month	2019 year	10. Time Hb or PCV tested (24-hour clock)	12 hours	25 minutes		
11. Moderate or severe anaemia?	YES	NO	Moderate or severe anaemia = Hb					
12. Intravenous cannula inserted?	YES	NO	If NO - Please					

SECTION B - MEASUREMENTS

13. Date measurement started	03 day	04 month	2019 year	14. Time m started				
15. Temperature (°C)								
16. Blood pressure (mmHg)	16a. SYSTOLIC 120	16b. DIASTOLIC 80						
17. Heart rate	70 Beats per minute							
18. Respiratory rate	15 Breaths per minute							
19. Height	1.69 metres	19a. ACTUAL	ESTI					
20. Weight (current)	58 kg	20a. ACTUAL	ESTI					
21. Time since onset of labour	5 hours	Hours since regular painful cont						

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BASELINE DATA COLLECTION: SECTION C

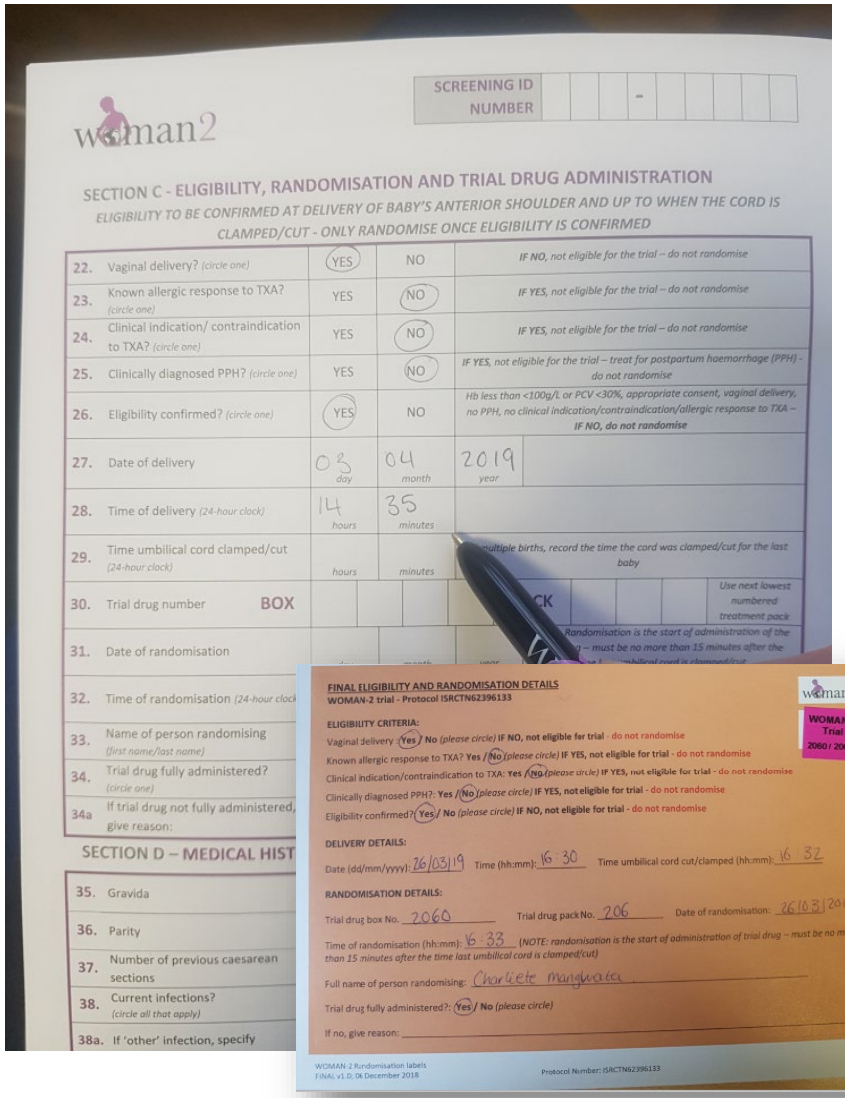
WHEN: As soon as possible after final eligibility check at birth

- Complete **Section C:**
  - Includes all details of final eligibility check, delivery and randomisation
  - WOMAN-2 Randomisation label can be used to capture this information and later transcribe into CRF

🕒 **Key times to note during delivery and randomisation:**

- 🕒 Time of delivery
- 🕒 Time of umbilical cord cut/clamped
- 🕒 Time of randomisation (start of administration of trial drug)

- All data entered into Section C must also be recorded in the participant's medical records. The WOMAN-2 randomisation labels can be used for this



BASELINE DATA COLLECTION: SECTIONS D - E

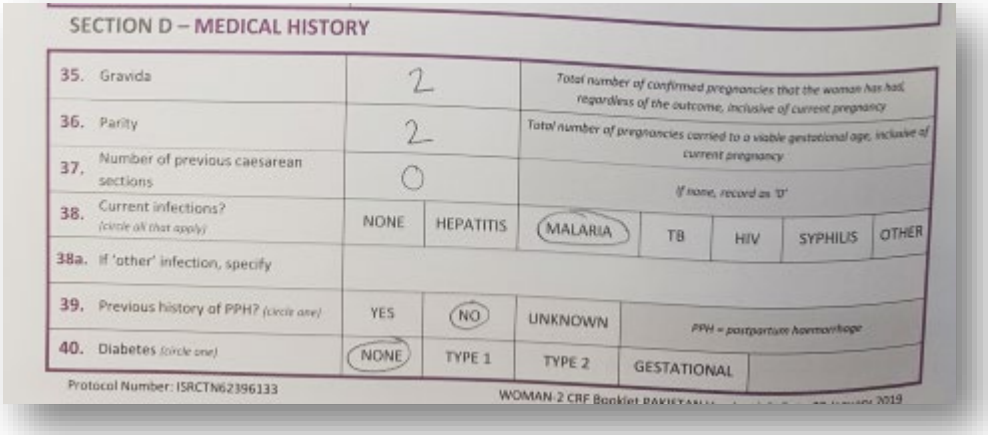
WHEN: After completion of appropriate consent process and before randomisation

If insufficient time (e.g. the woman gives birth rapidly) complete as soon as possible after randomisation.

- **Complete Section D:**
  - Includes history of previous pregnancies, previous post partum haemorrhage (PPH) diagnosis, current infections and diabetes

- **Complete Section E:**
  - Includes details of current pregnancy

- Obtain data from medical records



SECTION D – MEDICAL HISTORY

35. Gravida	2	Total number of confirmed pregnancies that the woman has had, regardless of the outcome, inclusive of current pregnancy					
36. Parity	2	Total number of pregnancies carried to a viable gestational age, inclusive of current pregnancy					
37. Number of previous caesarean sections	0	If none, record as '0'					
38. Current infections? (circle all that apply)	NONE	HEPATITIS	(MALARIA)	TB	HIV	SYPHILIS	OTHER
38a. If 'other' infection, specify							
39. Previous history of PPH? (circle one)	YES	(NO)	UNKNOWN	PPH = postpartum haemorrhage			
40. Diabetes (circle one)	(NONE)	TYPE 1	TYPE 2	GESTATIONAL			

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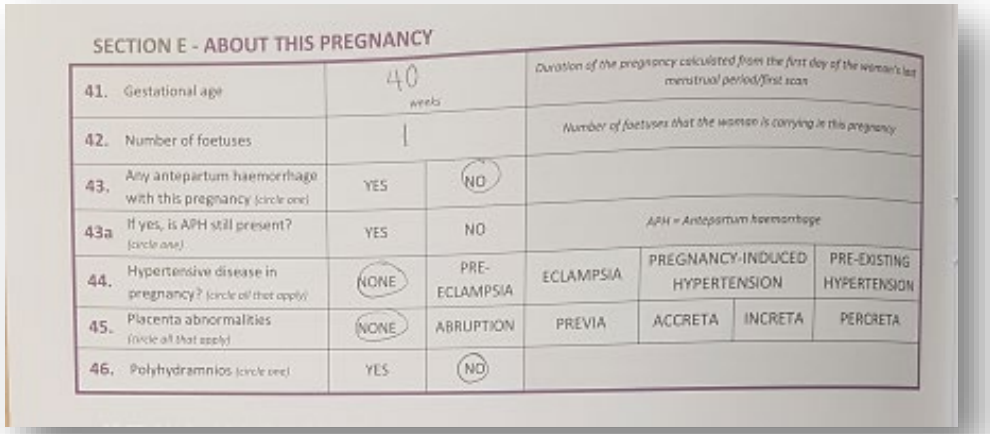


SECTION E - ABOUT THIS PREGNANCY

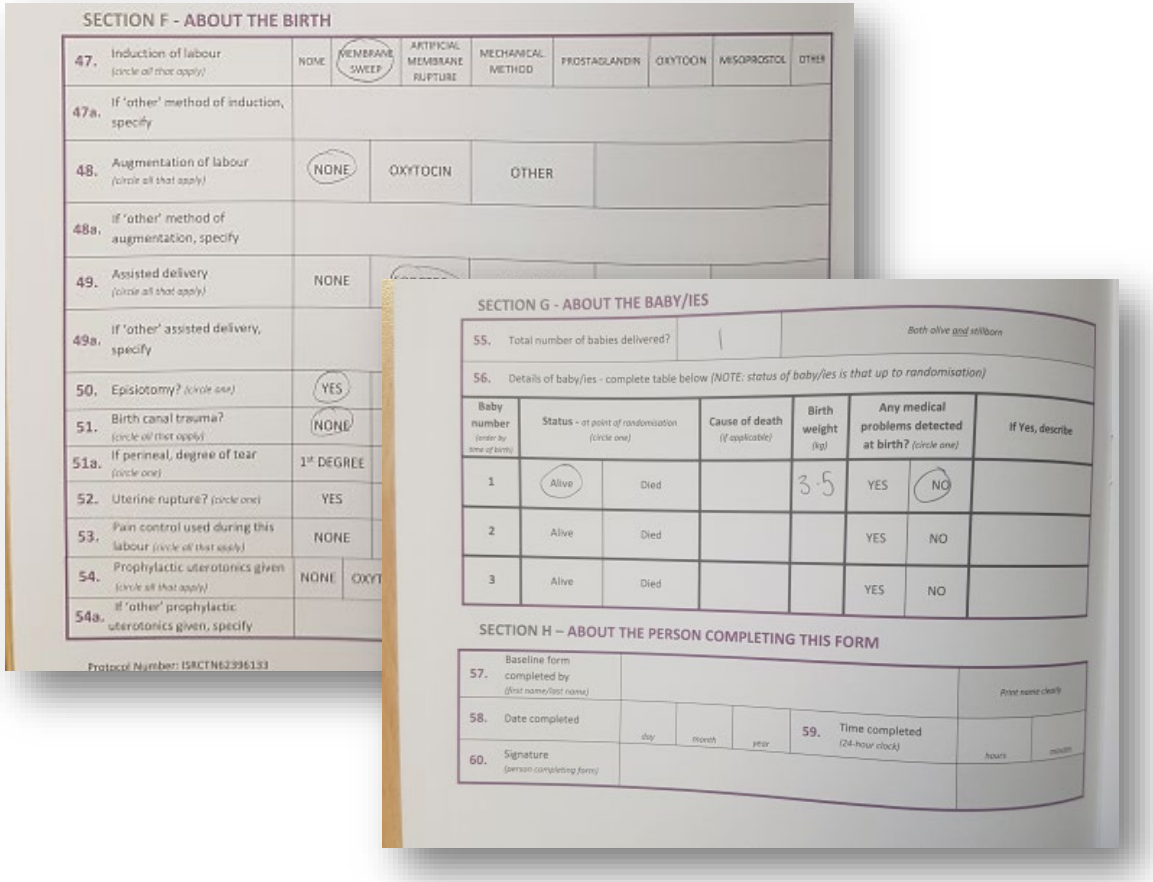
41. Gestational age	40 weeks	Duration of the pregnancy calculated from the first day of the woman's last menstrual period/first scan				
42. Number of foetuses	1	Number of foetuses that the woman is carrying in this pregnancy				
43. Any antepartum haemorrhage with this pregnancy (circle one)	YES	(NO)				
43a If yes, is APH still present? (circle one)	YES	NO	APH = Antepartum haemorrhage			
44. Hypertensive disease in pregnancy? (circle all that apply)	(NONE)	PRE-ECLAMPSIA	ECLAMPSIA	PREGNANCY-INDUCED HYPERTENSION		PRE-EXISTING HYPERTENSION
45. Placenta abnormalities (circle all that apply)	(NONE)	ABRUPTION	PREVIA	ACCRETA	INCRETA	PERCRETA
46. Polyhydramnios (circle one)	YES	(NO)				

BASELINE DATA COLLECTION: SECTIONS F - G

WHEN: Before randomisation

If insufficient time, immediately after randomisation. This must not delay randomisation

- **Complete Sections F:**
  - Includes details about the birth
- **Complete Section G:**
  - Includes details about the baby
- Obtain data from medical records or woman



SECTION F - ABOUT THE BIRTH

47.	Induction of labour (circle all that apply)	NONE	MEMBRANE SWEEP	ARTIFICIAL MEMBRANE RUPTURE	MECHANICAL METHOD	PROSTAGLANDIN	OXYTOCIN	MISOPROSTOL	OTHER
47a.	If 'other' method of induction, specify							
48.	Augmentation of labour (circle all that apply)	NONE	OXYTOCIN	OTHER				
48a.	If 'other' method of augmentation, specify							
49.	Assisted delivery (circle all that apply)	NONE						
49a.	If 'other' assisted delivery, specify							
50.	Episiotomy? (circle one)	YES						
51.	Birth canal trauma? (circle all that apply)	NONE						
51a.	If perineal, degree of tear (circle one)	1st DEGREE						
52.	Uterine rupture? (circle one)	YES						
53.	Pain control used during this labour (circle all that apply)	NONE						
54.	Prophylactic uterotonics given (circle all that apply)	NONE	OXYT					
54a.	If 'other' prophylactic uterotonics given, specify							

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SECTION G - ABOUT THE BABY/IES

55. Total number of babies delivered? 1 (Both alive and stillborn)

56. Details of baby/ies - complete table below (NOTE: status of baby/ies is that up to randomisation)

Baby number (enter by time of birth)	Status - at point of randomisation (circle one)		Cause of death (if applicable)	Birth weight (kg)	Any medical problems detected at birth? (circle one)		If Yes, describe
1	Alive	Died		3·5	YES	NO	
2	Alive	Died			YES	NO	
3	Alive	Died			YES	NO	

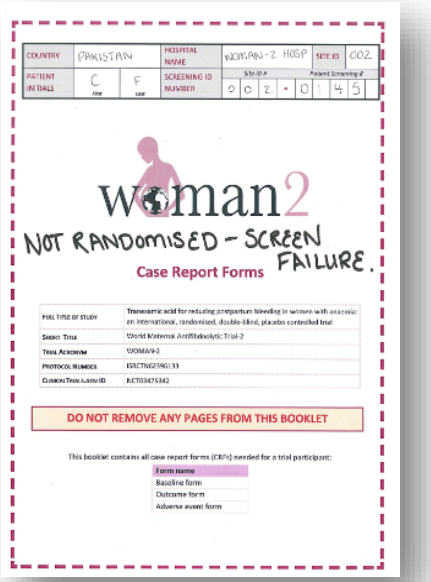
SECTION H – ABOUT THE PERSON COMPLETING THIS FORM

57.	Baseline form completed by (first name/last name)					Print name clearly
58.	Date completed	day	month	year	59. Time completed (24-hour clock)	hours / minutes
60.	Signature (person completing form)					

Once all sections are completed, sign and date **Section H** and enter baseline data into trial database **(must be entered within 24 hours of randomisation)**

BASELINE DATA COLLECTED BUT PARTICIPANT 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, should still be entered into the trial database**
- For screen failures, mark the front page of CRF booklets: **'Not randomised – screen failure'**

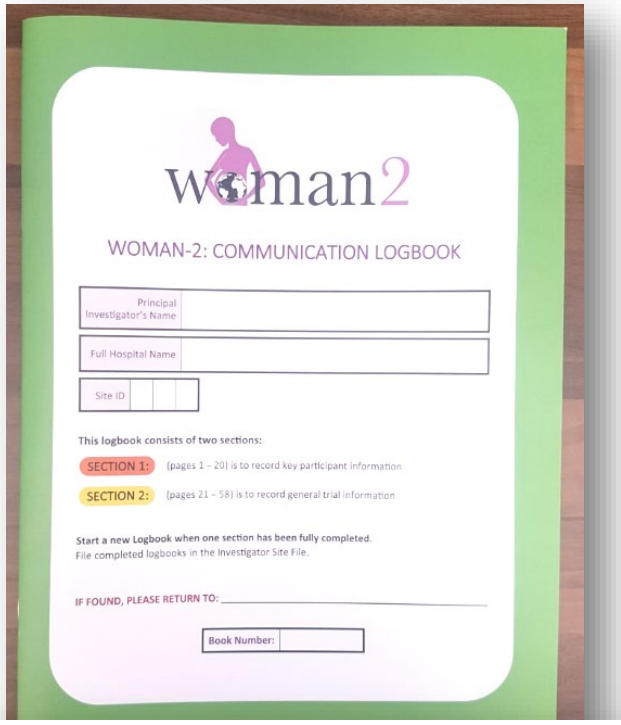


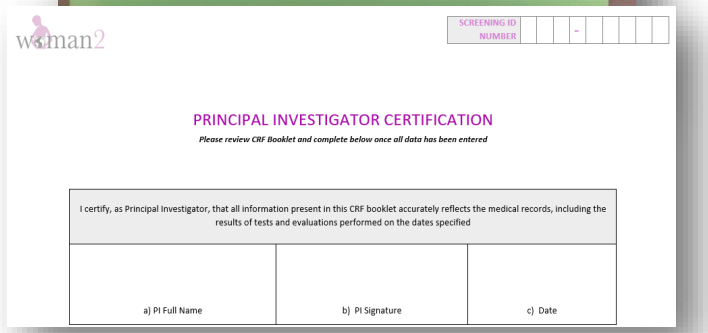
GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- **All data contained in the CRF booklet <u>must</u> be recorded in the medical records**
  - If trial data is *not* available in the medical records but has been obtained by speaking with the trial participant or the clinical team, record this in the medical records if allowed.
  - Otherwise, record this data in the WOMAN-2 communication logbook

- CRF completion and database entry can be delegated to a trained trial team member by the Principal Investigator (PI). The PI retains overall responsibility

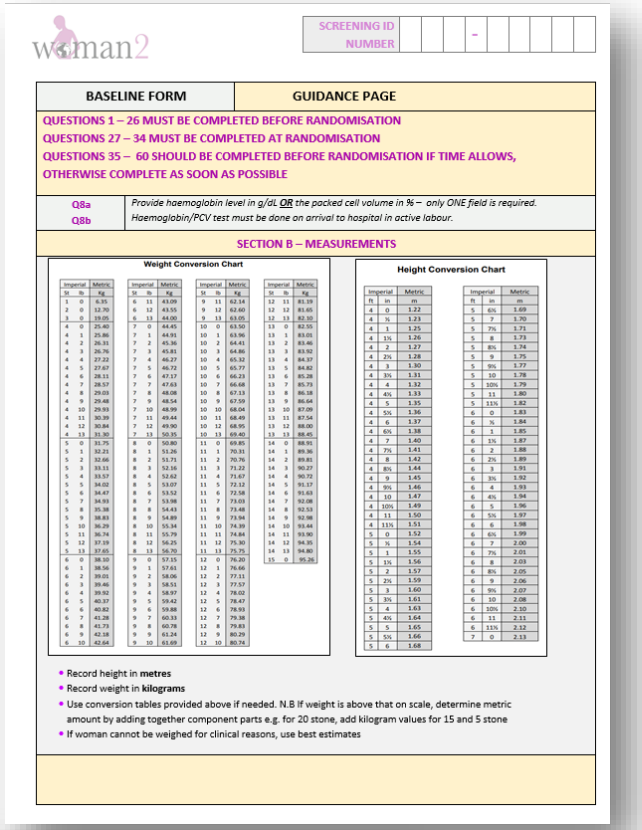
- The PI should review and sign each **completed** CRF booklet





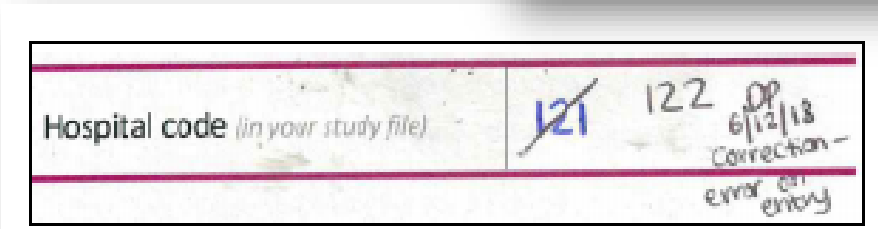
GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- Each page in the CRF booklet has guidance to help you complete the booklet correctly
- Use black or blue ink pen with clear, legible handwriting throughout
- Ensure all applicable fields have been completed



IF YOU ENTER AN INCORRECT VALUE ON THE FORM:

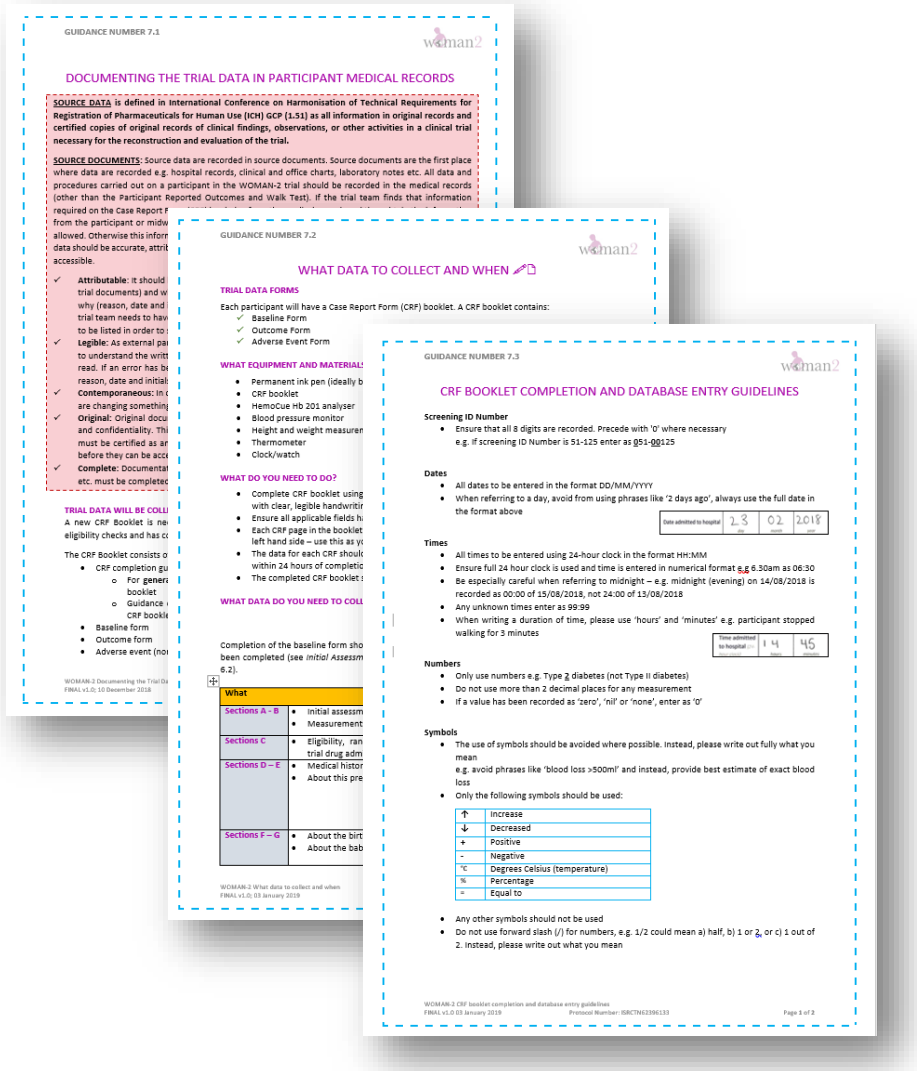
- Do NOT use correction fluid
- Cross out the incorrect value so it is still visible
- Enter the correct value alongside
- Date and initial and provide a reason for **each** change



FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 7:

- Documenting trial data in participant medical records, guidance number 7.1
- What data to collect and when, guidance number 7.2
- CRF completion and database entry guidelines, guidance number 7.3



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