



# 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 #
				-	

  
**woman<sup>2</sup>**

**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?
<b>Sections A - B</b>	<ul style="list-style-type: none"><li>• Initial assessment</li><li>• Measurements</li></ul>	After completion of appropriate consent process and before randomisation
<b>Sections C</b>	<ul style="list-style-type: none"><li>• Eligibility, randomisation and trial drug administration</li></ul>	As soon as possible after final eligibility check
<b>Sections D – E</b>	<ul style="list-style-type: none"><li>• Medical history</li><li>• About this pregnancy</li></ul>	After completion of appropriate consent process and before randomisation. If insufficient time (e.g. the woman gives birth rapidly) complete immediately after randomisation.
<b>Sections F – G</b>	<ul style="list-style-type: none"><li>• About the birth</li><li>• About the baby/ies</li></ul>	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

SCREENING ID NUMBER

woman2

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 (circle one)	FULL WRITTEN CONSENT		VERBAL AGREEMENT	If verbal agreement, obtain written consent from the assessor at base or post-birth	
2. Age	20 years				
3. If <18 years old, accompanied by a guardian? (circle one)	NOT APPLICABLE		YES	NO	If over 18, circle 'not applicable'. If NO, patient not eligible for the trial
4. Date admitted to hospital	03	04	2019	5. Time admitted to hospital (24-hour clock)	12:30
6. Planned vaginal birth? (circle one)	YES	NO	If NO, patient not eligible for the trial		
7. Active stage of labour? (circle one)	YES	NO	If NO, not eligible for the trial now – reconsider at active stage		
B. Please provide haemoglobin level (Hb) OR packed cell volume (PCV) (only one field required):					
8a. Haemoglobin level	9.2 g/L		8b. Packed cell volume		
9. Date Hb or PCV tested	03	04	2019	10. Time Hb or PCV tested (24-hour clock)	12:25
11. Moderate or severe anaemia? (circle one)	YES	NO	Moderate or severe anaemia = Hb < 105 g/L or PCV < 33% (circle one)		
12. Intravenous cannula inserted? (circle one)	YES	NO	If NO, patient not eligible for the trial		

SECTION B – MEASUREMENTS

13. Date measurement started	03	04	2019	14. Time measurement started	
15. Temperature (°C)					
16. Blood pressure (mmHg)	16a. SYSTOLIC		16b. DIASTOLIC		
	120		80		
17. Heart rate	70 beats per minute				
18. Respiratory rate	15 breaths per minute				
19. Height	169 cm		19a (ACTUAL)	ESTIMATE	
20. Weight (current)	58 kg		20a (ACTUAL)	ESTIMATE	
21. Time since onset of labour	5 hours				

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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

**SECTION C - ELIGIBILITY, RANDOMISATION AND TRIAL DRUG ADMINISTRATION**  
ELIGIBILITY TO BE CONFIRMED AT DELIVERY OF BABY'S ANTERIOR SHOULDER AND UP TO WHEN THE CORD IS CLAMPED/CUT - ONLY RANDOMISE ONCE ELIGIBILITY IS CONFIRMED

22. Vaginal delivery? (circle one)	<input checked="" type="radio"/> YES	<input type="radio"/> NO	IF NO, not eligible for the trial - do not randomise
23. Known allergic response to TXA? (circle one)	<input type="radio"/> YES	<input checked="" type="radio"/> NO	IF YES, not eligible for the trial - do not randomise
24. Clinical indication/contraindication to TXA? (circle one)	<input type="radio"/> YES	<input checked="" type="radio"/> NO	IF YES, not eligible for the trial - do not randomise
25. Clinically diagnosed PPH? (circle one)	<input type="radio"/> YES	<input checked="" type="radio"/> NO	IF YES, not eligible for the trial - treat for postpartum haemorrhage (PPH) - do not randomise
26. Eligibility confirmed? (circle one)	<input checked="" type="radio"/> YES	<input type="radio"/> NO	Hb less than <math>< 100\text{g/L}</math> or PCV <math>< 30\%</math>, appropriate consent, vaginal delivery, no PPH, no clinical indication/contraindication/allergic response to TXA - IF NO, do not randomise
27. Date of delivery	03 day	04 month	2019 year
28. Time of delivery (24-hour clock)	14 hours	35 minutes	
29. Time umbilical cord clamped/cut (24-hour clock)	hours	minutes	For multiple births, record the time the cord was clamped/cut for the last baby
30. Trial drug number	BOX		Use next lowest numbered treatment pack
31. Date of randomisation			Randomisation is the start of administration of the trial drug - must be no more than 15 minutes after the time the umbilical cord is clamped/cut
32. Time of randomisation (24-hour clock)			
33. Name of person randomising (first name/last name)			
34. Trial drug fully administered? (circle one)			
34a. If trial drug not fully administered, give reason:			

**SECTION D - MEDICAL HISTORY**

35. Gravida	
36. Parity	
37. Number of previous caesarean sections	
38. Current infections? (circle all that apply)	
38a. If 'other' infection, specify	

**FINAL ELIGIBILITY AND RANDOMISATION DETAILS**  
WOMAN-2 trial - Protocol ISRCTN2396133

**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: Charlete Mangwaza  
Trial drug fully administered?  Yes /  No (please circle)  
If no, give reason:

WOMAN-2 Randomisation labels FINAL v.1.0, 06 December 2018 Protocol Number: ISRCTN2396133

# 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	APH = Antepartum haemorrhage			
43a. If yes, is APH still present? (circle one)	YES	NO				
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	<input checked="" type="radio"/> 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)	<input checked="" type="radio"/> 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)	<input checked="" type="radio"/> YES							
51.	Birth canal trauma? (circle all that apply)	<input checked="" type="radio"/> NONE							
51a.	If perineal, degree of tear (circle one)	1 <sup>st</sup> 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?  Both alive and stillborn

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

Baby number (order 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	<input checked="" type="radio"/> Alive	Died	3.5	YES	<input checked="" type="radio"/> 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) \_\_\_\_\_

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**’

COUNTRY	PAKISTAN	HOSPITAL NAME	WOMAN2 - HOSP	SITE ID	002
PATIENT IN TRIAL	C Site	F Site	SCREENING ID NUMBER	002-0145	PATIENT ID NUMBER

**woman2**  
**NOT RANDOMISED - SCREEN FAILURE.**  
Case Report Forms

Full Title of Study: Transcervical seal 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: ECT1262/01/13  
ClinicalTrials.gov ID: ECT1262/01/13

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

- Forms home
- Baseline form
- Outcome form
- Adverse event form



# GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- All data contained in the CRF booklet must 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

woman2

WOMAN-2: COMMUNICATION LOGBOOK

Principal Investigator's Name

Full Hospital Name

Site ID

This logbook consists of two sections:

**SECTION 1:** (pages 1 - 20) is to record key participant information.

**SECTION 2:** (pages 21 - 58) is to record general trial information.

Start a new Logbook when one section has been fully completed.  
File completed logbooks in the Investigator Site File.

IF FOUND, PLEASE RETURN TO: \_\_\_\_\_

Book Number: \_\_\_\_\_

woman2

SCREENING ID NUMBER

PRINCIPAL INVESTIGATOR CERTIFICATION

Please review CRF Booklet and complete below once all data has been entered

I certify, as Principal Investigator, that all information present in this CRF booklet accurately reflects the medical records, including the results of tests and evaluations performed on the dates specified

a) PI Full Name

b) PI Signature

c) Date

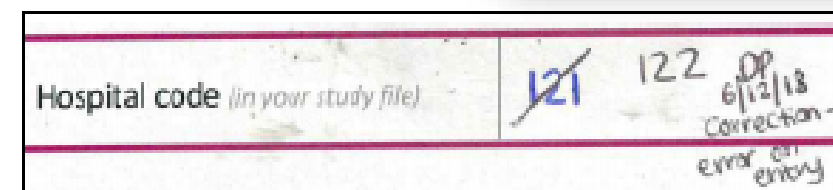
# GENERAL GUIDANCE ON COMPLETING THE CRF BOOKLET

- 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

The image shows a page from a CRF booklet. At the top right, there is a 'SCREENING ID NUMBER' field with a grid for entering digits. Below this, the page is divided into two main sections: 'BASELINE FORM' and 'GUIDANCE PAGE'. The 'GUIDANCE PAGE' contains instructions for completing questions 1-34 before randomisation and questions 35-60 after randomisation. Below the instructions, there are two conversion charts: 'Weight Conversion Chart' and 'Height Conversion Chart'. The 'Weight Conversion Chart' has columns for Imperial (lb, kg) and Metric (kg, lb) with values ranging from 10 to 200. The 'Height Conversion Chart' has columns for Imperial (in, cm) and Metric (cm, in) with values ranging from 4 to 7. Below the charts, there are instructions for recording height and weight, and a note about using conversion tables if needed. At the bottom of the page, there are instructions for recording height and weight, and a note about using conversion tables if needed.

## IF YOU ENTER AN INCORRECT VALUE ON THE FORM:

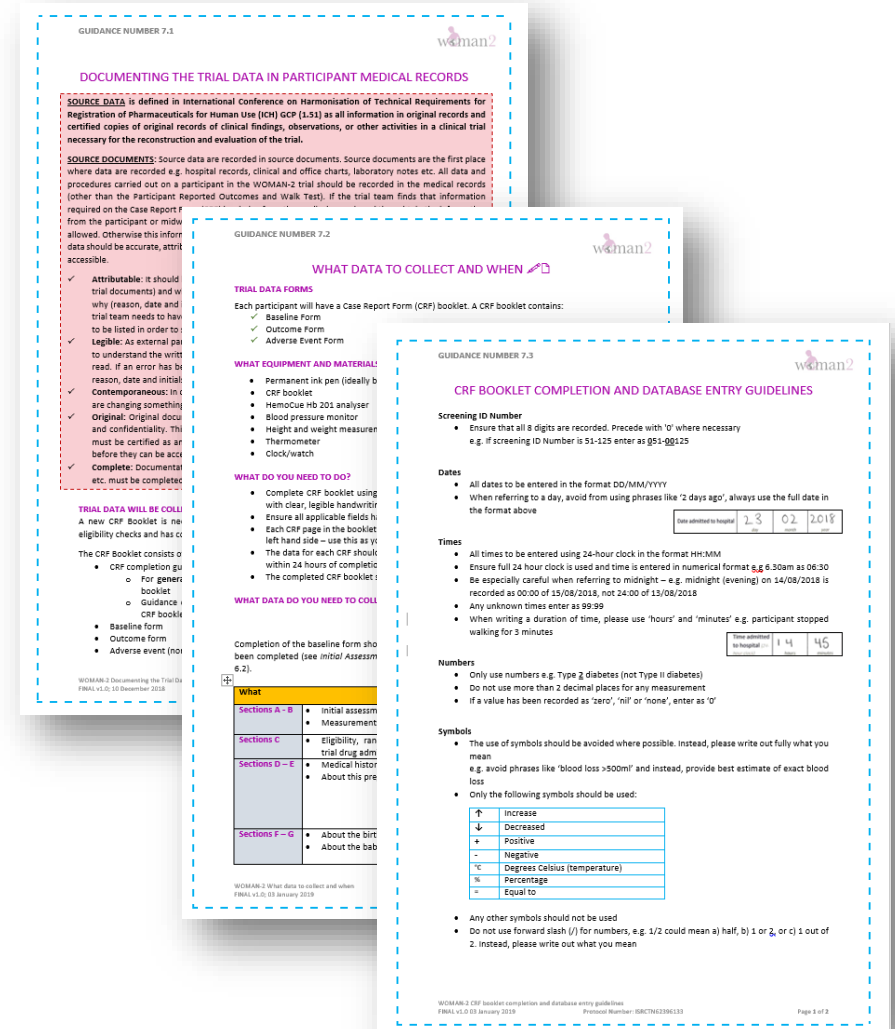
- Do NOT use correction fluid
- Cross out the incorrect value so it is still visible
- Enter the correct value alongside
- Date and initial and provide a reason for **each** change



# 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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