LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

CLINICAL TRIALS UNIT

HOW TO COMPLETE THE CRF – OUTCOME DATA

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

CONTENTS OF THE CRF BOOKLET

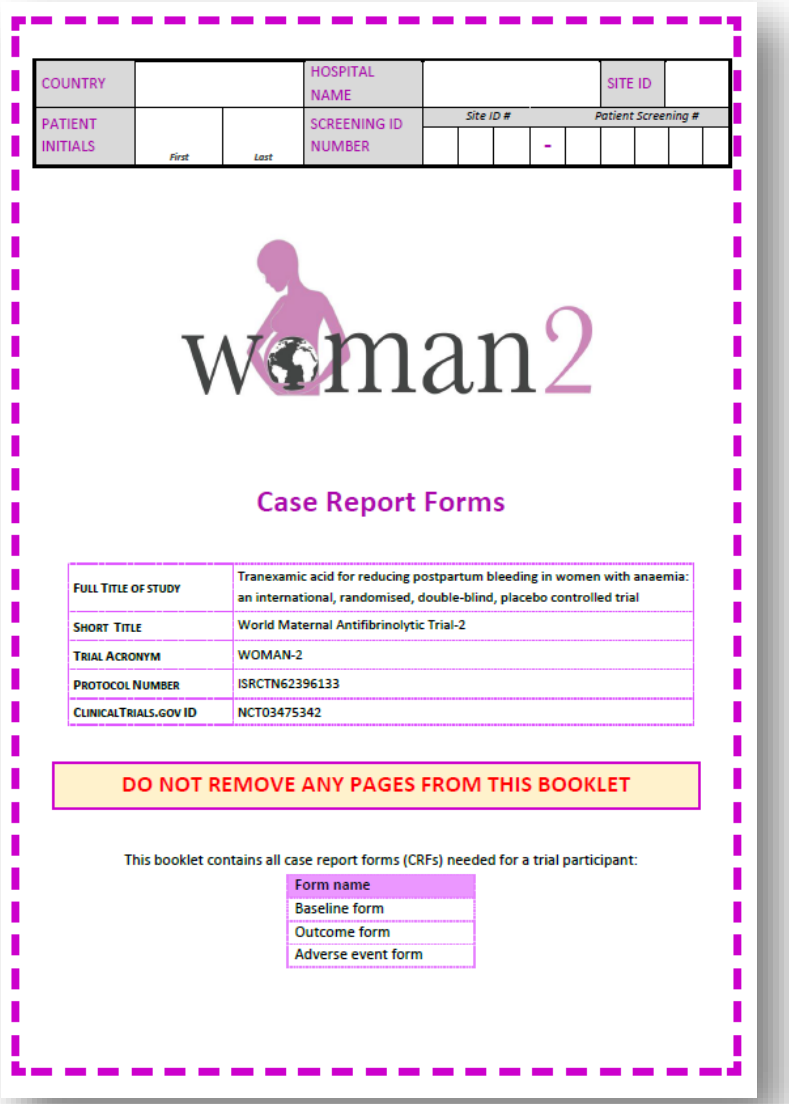
- Each participant will have a Case Report Form (CRF) booklet.

- A CRF booklet contains:

  - **Baseline Form**
  - **Outcome Form**
  - **Adverse Event Form**

This presentation will focus on the **Outcome Form** and the **Adverse Event Form:**

- Completion should start after the participant has been randomised.



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

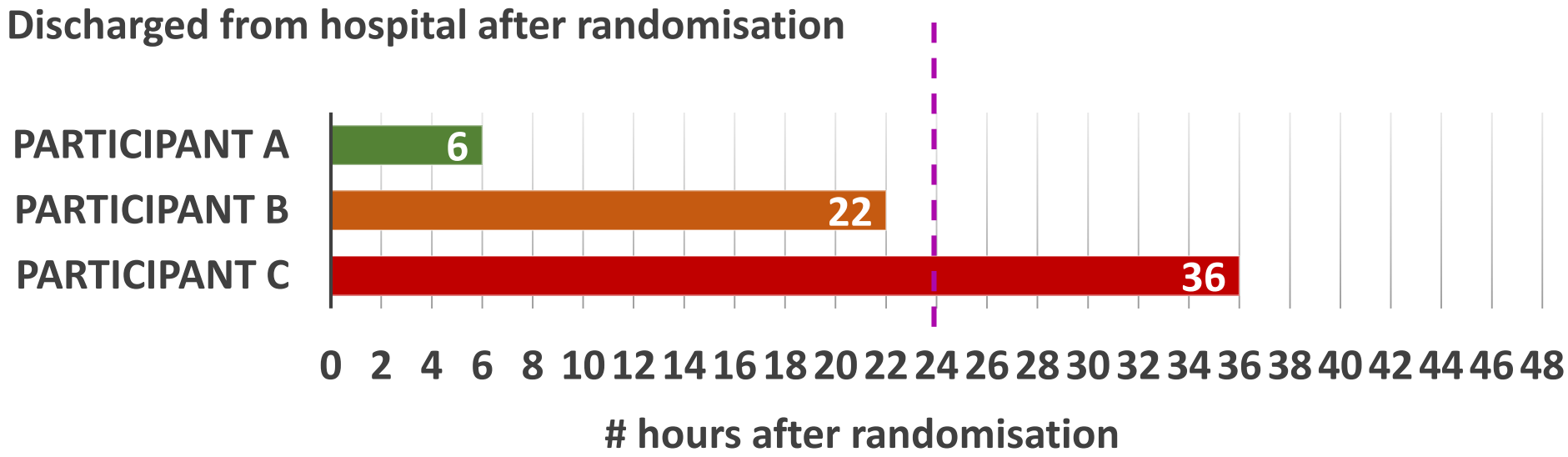
This booklet contains all case report forms (CRFs) needed for a trial participant:

Form name
Baseline form
Outcome form
Adverse event form

OUTCOME DATA COLLECTION

What?		When
Outcome form (Part 1): Sections A – C	• About the patient • Interventions given • Postpartum haemorrhage diagnosis	At 24 hours after randomisation, discharge from hospital or death – whichever occurs first
Outcome form (Part 2): Sections D – G	• Patient reported outcomes • Management • Complications • Status of baby/ies	At 42 days after randomisation, discharge from hospital or death – whichever occurs first
Adverse event form	• **If in hospital:** any <u>untoward</u> medical event that occurs up to 42 days after randomisation and is **NOT** collected on the outcome form • **If discharged from hospital**: any <u>untoward</u> medical event, which develops up to 42 days after randomisation **(including those listed on the outcome forms)**	Immediately any event that fulfils the Adverse Event definition as per the protocol, up to 42 days after randomisation

WHEN TO COMPLETE THE OUTCOME FORMS – example scenarios



- **Example 1: Participant A –** If a woman is discharged at 6 hours (or anytime before 24 hours) after randomisation complete **all** of the outcome form (Parts 1 and 2) at the point of discharge

- **Example 2: Participant B -** dies 22 hours (or anytime before 24 hours) after randomisation - complete **all** of the outcome form at the point of death. Questionnaire and walk test not applicable

- **Example 3: Participant C -** discharged 36 hours (or anytime after 24 hours and up to day 42) after randomisation - complete **Part 1** at 24 hours after randomisation. Complete **Part 2** at point of discharge

Enter all outcome data into the trial database within 24 hrs of <u>both</u> forms being completed

OUTCOME FORM (Part 1): SECTIONS A - C

WHEN: At 24 hours following randomisation, discharge or death – whichever comes **first**

- **Complete Section A:**
  - Using the HemoCue analyser provided, carry out a haemoglobin test:
    - Take a drop of blood from the participant's finger, fill the microcuvette, put it in the HemoCue holder, close and wait for 15 - 60 seconds for the results.

- **Complete Sections B:**
  - Includes information about interventions given during delivery.

- **Complete Section C:**
  - Includes information on postpartum haemorrhage (PPH) diagnosis.

- Obtain data from medical records where possible, otherwise speak to clinical team.

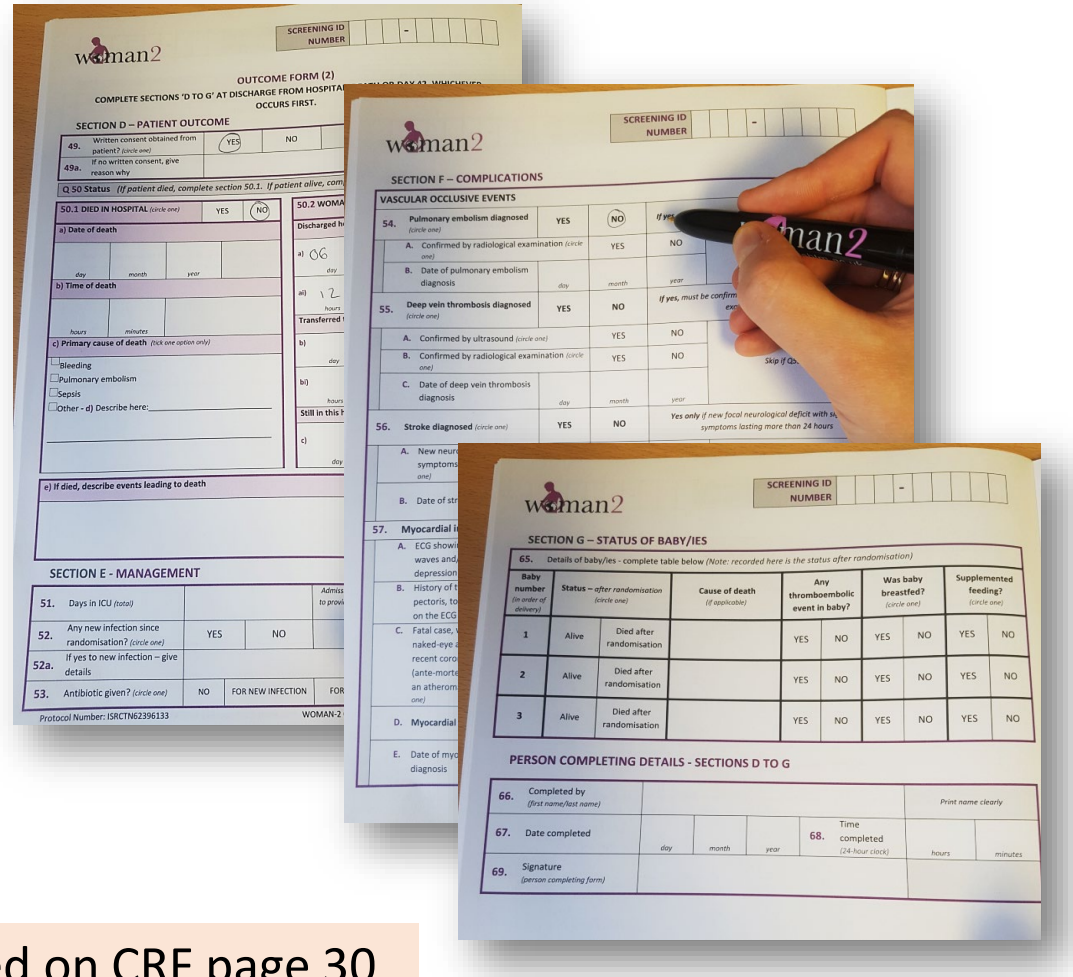
Once all sections are completed, sign and date where indicated on CRF page 20

OUTCOME FORM (Part 2): SECTIONS D – G

WHEN: At 42 days following randomisation, discharge or death – whichever comes **first**

- **Complete Sections D – G:**
  - Section D: Patient outcome
  - Section E: Patient Management
  - Section F: Complications
  - Section G: Status of baby/ies

- Obtain data from medical records.



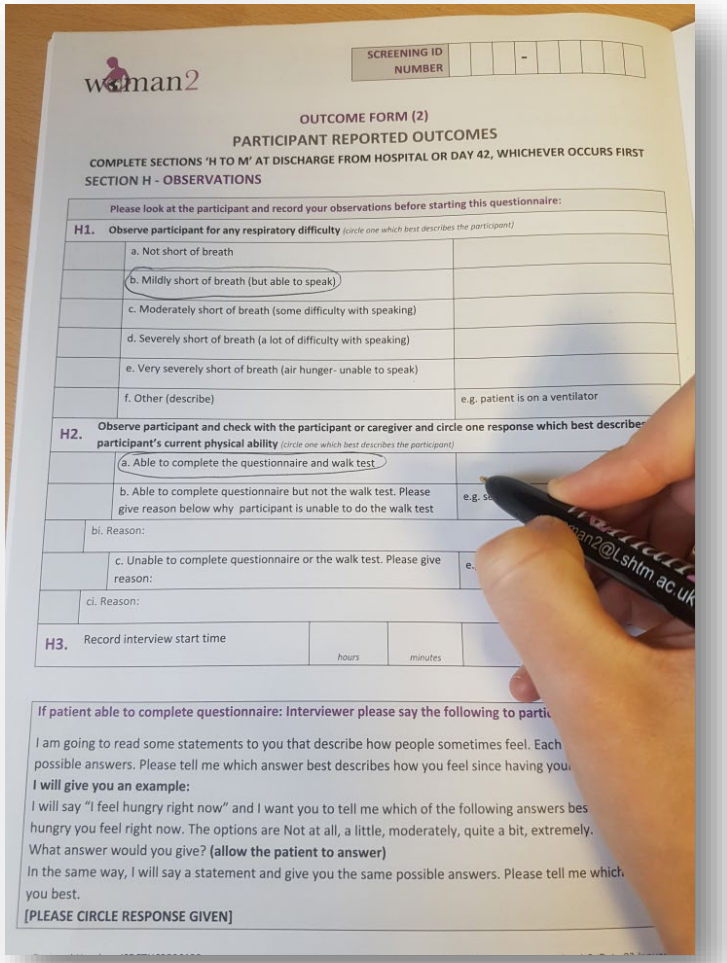
Once all sections are completed, sign and date where indicated on CRF page 30

OUTCOME FORM (Part 2): SECTION H

WHEN: At 42 days following randomisation, discharge or death – whichever comes **first**

Patient Reported Outcomes (PRO)

- **Complete Sections H:**
  - Observe the patient:
    - Are they short of breath?
    - Are they able to complete a questionnaire and/or 6 minute walk test?
  - If answer to **H2** is ‘a’ or ‘b’, begin the PRO questionnaire (sections I – K)



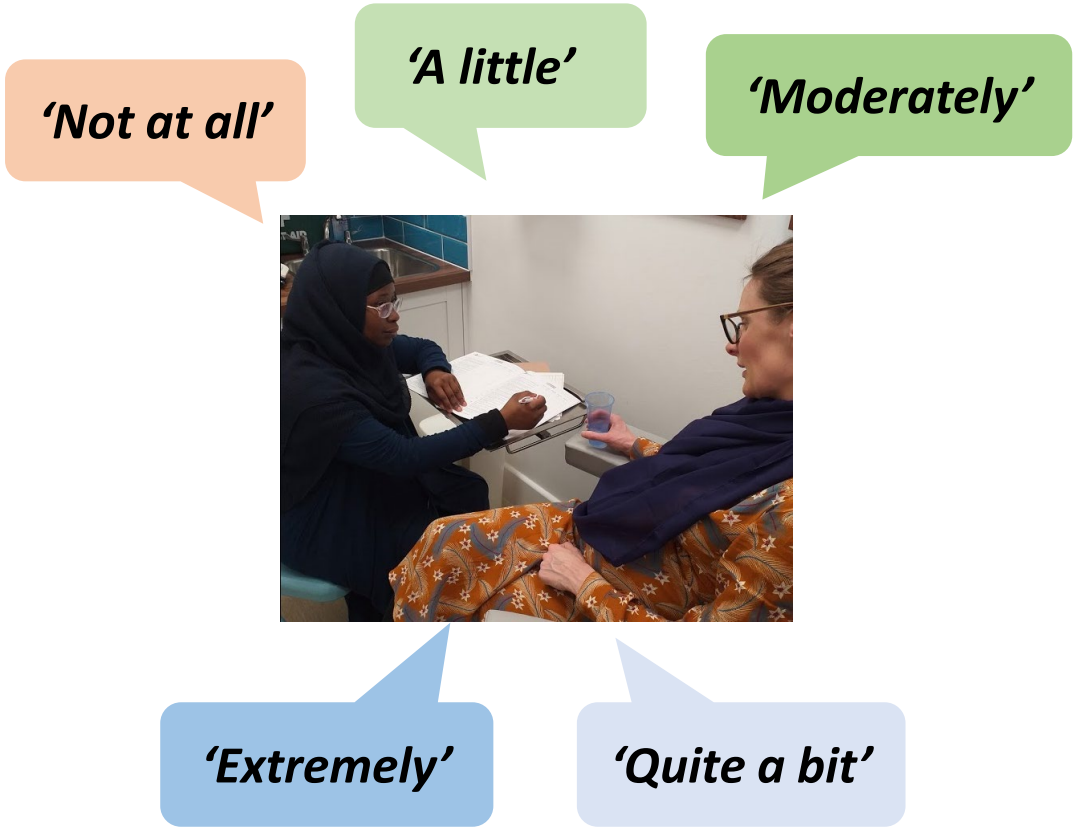
OUTCOME FORM (Part 2): SECTIONS I - K

WHEN: At 42 days following randomisation, discharge or death – whichever comes **first**

Patient Reported Outcomes (PRO): <u>questionnaire</u>

What is the PRO questionnaire?

- The PRO questionnaire is a quality of life assessment tool.
- Each statement describes how people sometimes feel.
    - For each statement, the participant should say which answer best describes how they feel since giving birth.
- There are five possible answers to each statement



OUTCOME FORM (Part 2): SECTIONS I - K

BEFORE STARTING THE QUESTIONNAIRE

- Check the participant's medical records:
  - *to determine whether question K8 is relevant (e.g.* baby could have been a stillbirth or is requiring hospitalisation)

- Complete question H1 (this has to be completed before disturbing woman) then complete question H2

- Find a suitable location to administer the questionnaire
  - E.g. Somewhere reasonably quiet and where the woman would be comfortable

- Give some background information on the PRO (guidance available on CRF pg 31 and 32)

OUTCOME FORM (Part 2): SECTIONS I - K

ADMINISTERING THE QUESTIONNAIRE

- Ask the questions exactly as they appear in the CRF

- Always ask questions in a sensitive manner

- Do not provide your own examples for questions.
  - If a participant finds it difficult to understand a question, try to explain the concept of the question being asked. If the participant has provided examples, you may use these examples to help elicit an answer to the question

- Do not change answers to previously asked questions

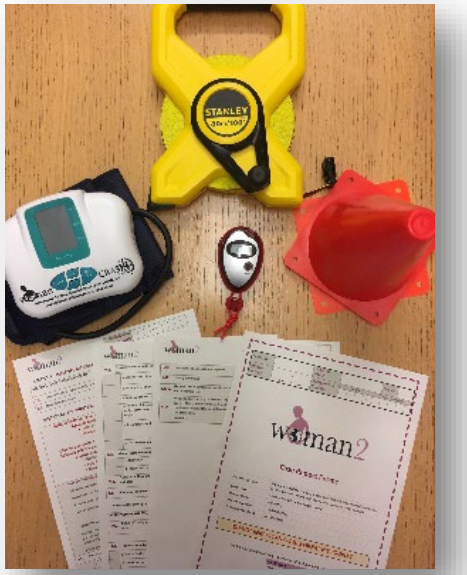
OUTCOME FORM (Part 2): SECTIONS L - M

WHEN: At 42 days following randomisation, discharge or death – whichever comes **first**

Patient Reported Outcomes (PRO): 6 minute walk test

What is the 6 minute walk-test?

- The 6 minute walk test is an assessment of exercise tolerance.
- Participants will be asked to walk between 2 cones, as many times as they can, for a period of 6 minutes.



Why the walk test for WOMAN-2?

- The walk test will show the impact of blood loss and give an indication of the woman's ability to carry out her daily physical activities after giving birth.

What will you need?

- 2 cones
- Tape Measure
- 1 or 2 chairs
- Blood Pressure Monitor
- Stopwatch

OUTCOME FORM (Part 2): SECTIONS L - M

WALK TEST - SET UP (1)

- Identify a **straight** area of walkway (e.g. a quiet corridor)
- Measure a distance between 10-30 metres and put the cones at either end as turning points
- The longer the distance the better to avoid participants having to make too many turns to minimise dizziness
- Have a chair (or 2) available to be given to the participant if she needs to stop and rest
- Ensure baby/(ies) is safely with family members, ward staff or in a cot where the mother can see him/her during the test
- Have water/other drinking fluid available
- Ensure help is available if needed during the walk test

OUTCOME FORM (Part 2): SECTIONS L - M

WALK TEST - SET UP (2)

- **Check the woman's medical records and confirm with her:**

Do not carry out the walk test if the woman has:

- A history of angina
- Had a myocardial infarction during the previous month

- Ensure appropriate pain relief has been given if required
- If participant uses walking aids (e.g. walking stick), have aid available
- If possible, use a wheelchair to bring the participant to the walk test area
- **Complete Section L** (*participants perceived breathlessness)*
- **Complete Section M1** (*blood pressure, heart rate and respiratory rate)*

A second person should be present during the walk test if the woman has a:

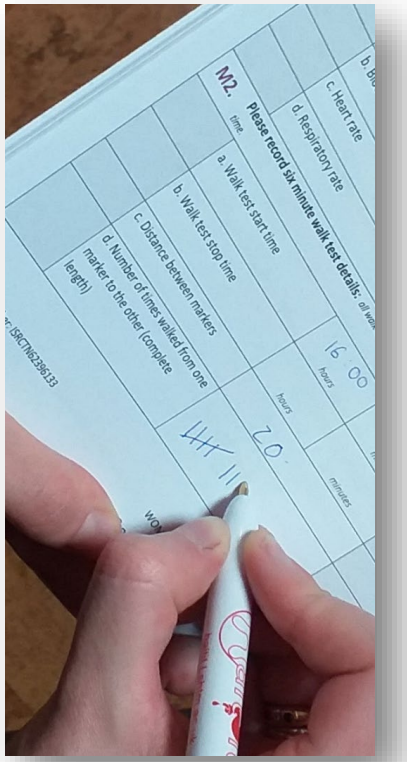
- Resting heart rate of greater than 120 bpm
- Systolic blood pressure of greater than 180 mmHg
- Diastolic blood pressure of greater than 100 mmHg

- **Read the script on page 36 of the CRF**
- **Provide a demonstration of the walk test**

OUTCOME FORM (Part 2): Section M

CARRYING OUT THE WALK TEST

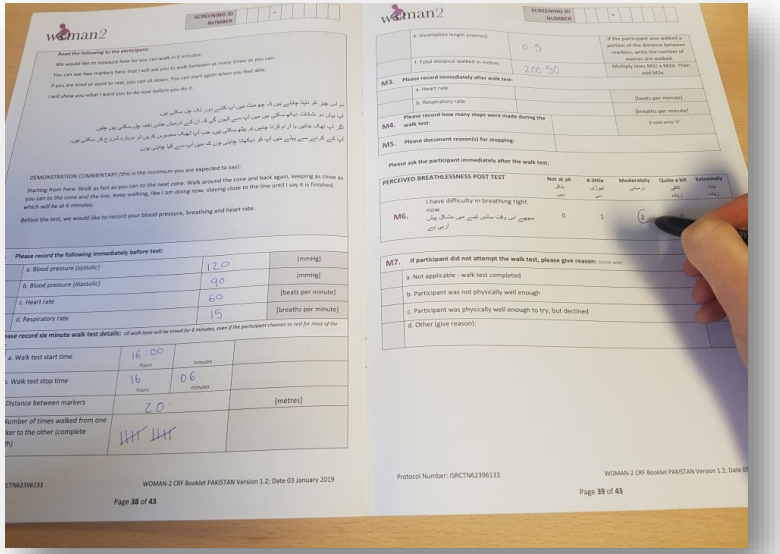
- Use the stop watch to time 6 minutes
- If a participant usually uses a walking aid, they should use it for the walk test
- To encourage the participant, after each minute, tell the participant the following:
  - After the first minute, *"You are doing well. You have 5 minutes to go."*
  - After two minutes, *"Keep up the good work. You have 4 minutes to go."*
  - After three minutes, *"You are doing well. You are halfway done."*
  - After four minutes, *"Keep up the good work. You have only 2 minutes left."*
  - After five minutes, *"You are doing well. You have only 1 minute to go."*
- Do not use any other words of encouragement (or body language, to speed the participant up)
- Keep a tally of :
  - the number of times walked from one marker to the other
  - the number of times the participant stops to rest
- The walk test is for 6 minutes in total, even if the participant rests for most of the time
- When a participant stops to rest, please remind them at 1 minute intervals to continue walking of they can



OUTCOME FORM (Part 2): Section M

IMMEDIATELY AT THE END OF 6 MINUTES

- Ask the participant to stop and stand still.
- Provide a chair if necessary
- If an incomplete length has been walked, mark where the participant stopped
- Complete **Sections M3 and M6** **immediately** after walk test (Bp, HR, RR and breathlessness score)
- Complete the remainder of **Section M**



If you have any concerns about the well-being of a participant, refer her back the treating clinician for further assessment and ongoing care

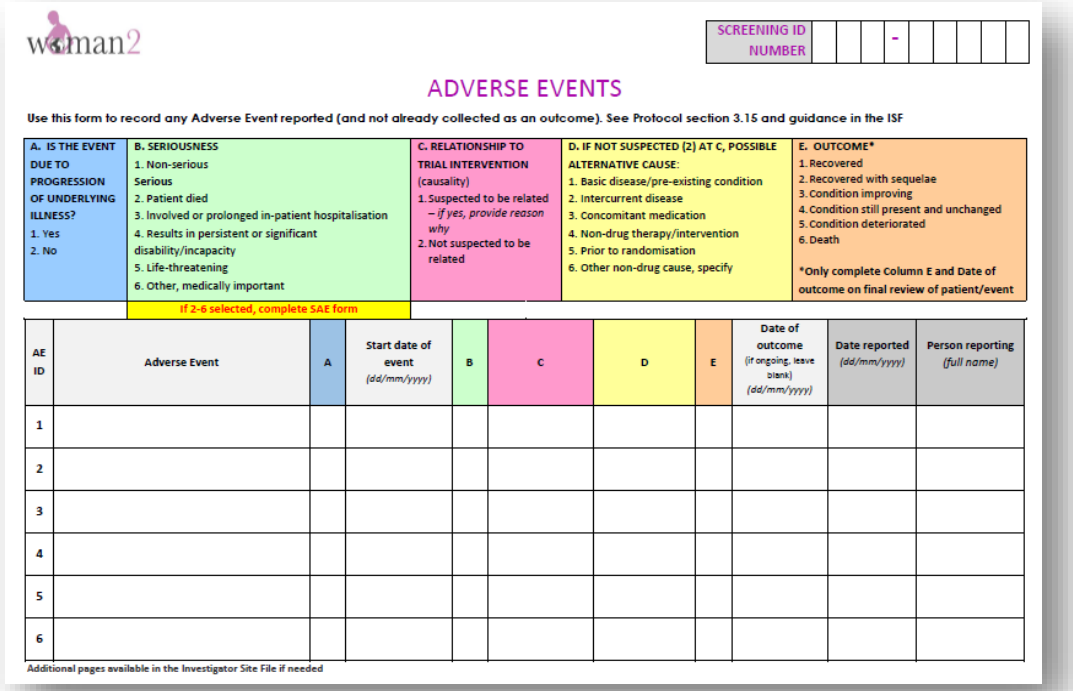
ADVERSE EVENT FORM

(1) While participant is in hospital: record any untoward medical event that occurs **up to 42 days** after randomisation and is **NOT** collected on the outcome form

(2) After participant has been discharged from hospital: record any untoward medical event, which **develops up to 42 days** after randomisation **(including those listed on the outcome forms)**

- Record any Adverse Event immediately when it occurs (see Protocol for definition) on the Adverse Event CRF
- Complete all columns of each row
- **Column B: SERIOUSNESS** - if any Adverse Event fulfils one or more of the 'seriousness' criteria, a Serious Adverse Event form (found in Investigator Study File, section 4) must also be completed

All adverse events must be uploaded to the trial database **within 24 hours of occurrence**



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SCREENING ID NUMBER | | | | - | | | | | |

ADVERSE EVENTS

Use this form to record any Adverse Event reported (and not already collected as an outcome). See Protocol section 3.15 and guidance in the ISF

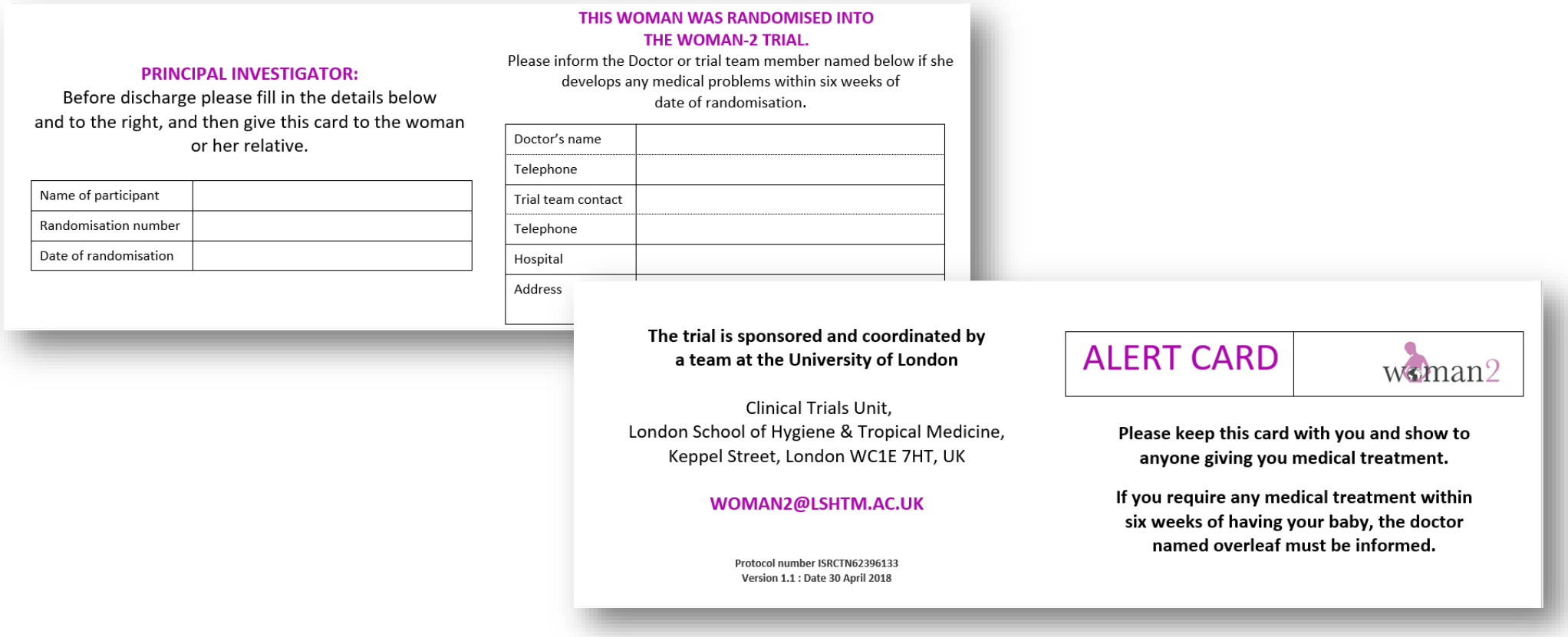
A. IS THE EVENT DUE TO PROGRESSION OF UNDERLYING ILLNESS? 1. Yes 2. No	B. SERIOUSNESS 1. Non-serious Serious 2. Patient died 3. Involved or prolonged in-patient hospitalisation 4. Results in persistent or significant disability/incapacity 5. Life-threatening 6. Other, medically important	C. RELATIONSHIP TO TRIAL INTERVENTION (causality) 1. Suspected to be related – *if yes, provide reason why* 2. Not suspected to be related	D. IF NOT SUSPECTED (2) AT C, POSSIBLE ALTERNATIVE CAUSE: 1. Basic disease/pre-existing condition 2. Intercurrent disease 3. Concomitant medication 4. Non-drug therapy/intervention 5. Prior to randomisation 6. Other non-drug cause, specify	E. OUTCOME* 1. Recovered 2. Recovered with sequelae 3. Condition improving 4. Condition still present and unchanged 5. Condition deteriorated 6. Death *Only complete Column E and Date of outcome on final review of patient/event
	If 2-6 selected, complete SAE form			

AE ID	Adverse Event	A	Start date of event (dd/mm/yyyy)	B	C	D	E	Date of outcome (if ongoing, leave blank) (dd/mm/yyyy)	Date reported (dd/mm/yyyy)	Person reporting (full name)
1										
2										
3										
4										
5										
6										

Additional pages available in the Investigator Site File if needed

ALERT CARD

- All participants should be given an **ALERT CARD at discharge** which contains information on who to contact if they develop any problems



PRINCIPAL INVESTIGATOR:
Before discharge please fill in the details below and to the right, and then give this card to the woman or her relative.

Name of participant	
Randomisation number	
Date of randomisation	

THIS WOMAN WAS RANDOMISED INTO THE WOMAN-2 TRIAL.
Please inform the Doctor or trial team member named below if she develops any medical problems within six weeks of date of randomisation.

Doctor's name	
Telephone	
Trial team contact	
Telephone	
Hospital	
Address	

The trial is sponsored and coordinated by a team at the University of London

Clinical Trials Unit,
London School of Hygiene & Tropical Medicine,
Keppel Street, London WC1E 7HT, UK

WOMAN2@LSHTM.AC.UK

Protocol number ISRCTN62396133
Version 1.1 : Date 30 April 2018

ALERT CARD

woman2

Please keep this card with you and show to anyone giving you medical treatment.

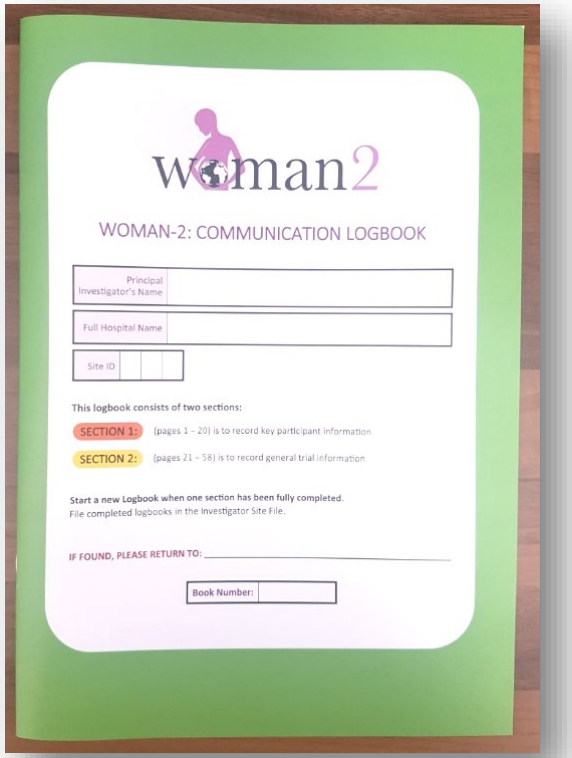
If you require any medical treatment within six weeks of having your baby, the doctor named overleaf must be informed.

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

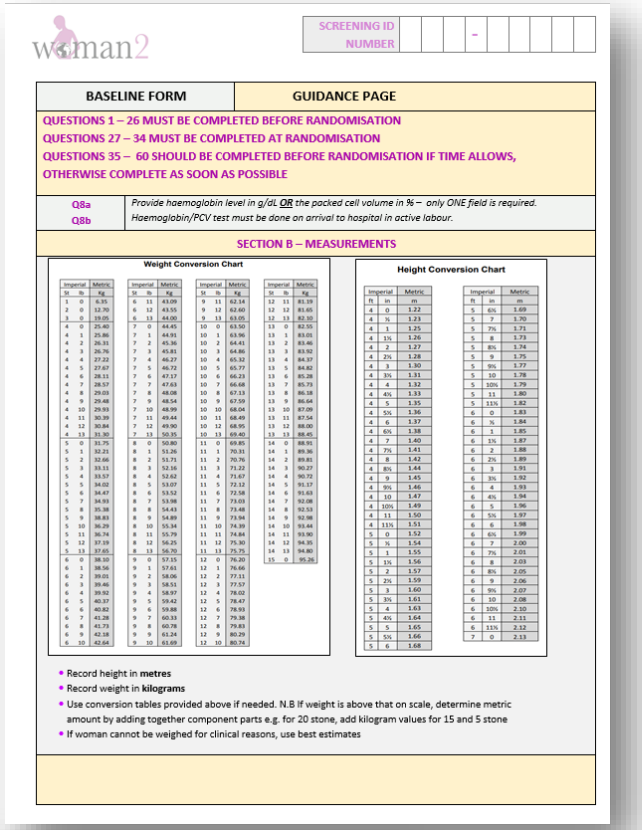
- CRF completion and database entry can be delegated to a trained trial team member by the Principal Investigator (PI). The PI retains overall responsibility

- 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 for completion. Review this guidance carefully
- Use black or blue ink pen with clear, legible handwriting throughout
- Ensure all applicable fields have been completed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SCREENING ID NUMBER

BASELINE FORM	GUIDANCE PAGE

QUESTIONS 1 – 26 MUST BE COMPLETED BEFORE RANDOMISATION
QUESTIONS 27 – 34 MUST BE COMPLETED AT RANDOMISATION
QUESTIONS 35 – 60 SHOULD BE COMPLETED BEFORE RANDOMISATION IF TIME ALLOWS, OTHERWISE COMPLETE AS SOON AS POSSIBLE

Q8a Q8b — *Provide haemoglobin level in g/dL **OR** the packed cell volume in % – only ONE field is required. Haemoglobin/PCV test must be done on arrival to hospital in active labour.*

SECTION B – MEASUREMENTS

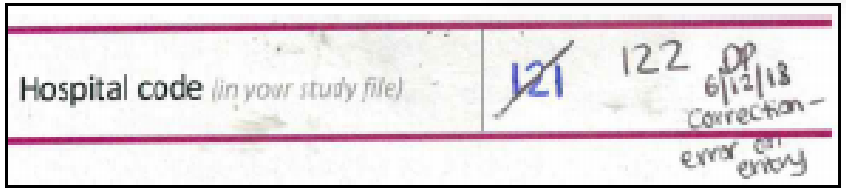
Weight Conversion Chart

Height Conversion Chart

- Record height in **metres**
- Record weight in **kilograms**
- Use conversion tables provided above if needed. N.B If weight is above that on scale, determine metric amount by adding together component parts e.g. for 20 stone, add kilogram values for 15 and 5 stone
- If woman cannot be weighed for clinical reasons, use best estimates

IF YOU ENTER AN INCORRECT VALUE ON THE FORM:

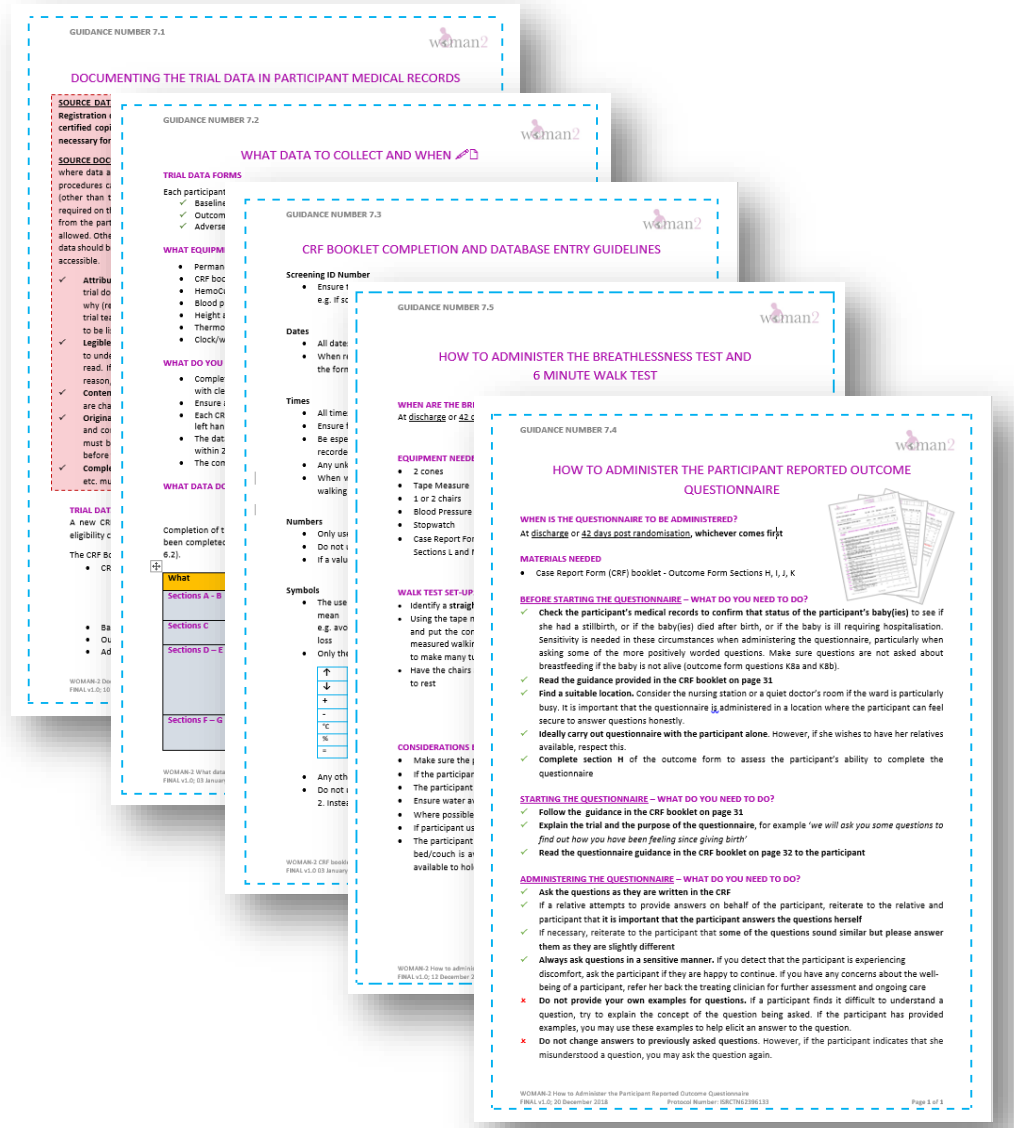
- Do NOT use correction fluid
- Cross out the incorrect value so it is still visible
- Enter the correct value alongside
- Date and initial and provide a reason for **each** change



FOR FURTHER GUIDANCE SEE:

The Trial Procedures File, section 7:

- 7.1 - Documenting trial data in participant medical records
- 7.2 - What data to collect and when
- 7.3 - CRF completion and database entry guidelines
- 7.4 - How to administer the Participant Reported Outcome Questionnaire
- 7.5 - How to administer the breathlessness test and 6 minute walk test



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