Data Collection

GUIDANCE SHEET 8

Overview of data collection:

Form Completed by women Completed by site staff	Format	When to complete
Screening log	Randomisation website (paper log available)	Complete monthly (entering data from paper log if required)
Consent form	As self-carbonating paper copy (in-person or remote)	As soon as a woman decides to take part (having had appropriate time to consider and ask questions) and **before any data is collected**
Randomisation	Randomisation website	When eligibility has been confirmed and woman has provided consent
Contact details form	Randomisation website	As soon as possible after randomisation – completion is essential for women to be able to access app and other important trial processes
Trial entry form	OpenClinica	As soon as possible after randomisation
Baseline form	Through email/SMS link sent to woman, onto OpenClinica OR if paper copy completed, entered onto OpenClinica by site staff or at MAMA Coordinating Centre	As soon as possible after randomisation
Monthly arthritis report	Using MAMA study app, **OR** through email/SMS link sent to woman, onto OpenClinica, **OR** if paper diary completed, entered onto OpenClinica at MAMA Coordinating Centre	Monthly during pregnancy
Outcomes form	OpenClinica	To be completed after the end of pregnancy and (if applicable) after the woman has been discharged from hospital following birth of their infant
Neonatal outcomes form	OpenClinica	To be completed if an infant is admitted to the neonatal unit, after they have been discharged home from neonatal care (or if they die prior to discharge home)
Wellbeing check	Entered on Contact details form	Before contact at 3, 6, 12, and 24 months
3 month arthritis report	Using MAMA study app, **OR** through email/SMS link sent to woman, onto OpenClinica, **OR** if paper diary completed, entered onto OpenClinica at MAMA Coordinating Centre	3 months after the end of pregnancy
6 month arthritis report		6 months after the end of pregnancy
12 month arthritis report		12 months after the end of pregnancy
Adhoc arthritis report	Using MAMA study app, **OR** if paper diary completed, entered onto OpenClinica at MAMA Coordinating Centre	At any time up to 12 months after the end of pregnancy
3-month questionnaire	Through email/SMS link sent to woman, onto OpenClinica OR if paper copy completed, entered onto OpenClinica at site	3 months after the end of pregnancy
6 month questionnaire		6 months after the end of pregnancy

12 month questionnaire	Through email/SMS link sent to woman, onto OpenClinica OR if paper copy completed, entered onto OpenClinica at site	12 months after the end of pregnancy
24 month questionnaire		24 months after the end of pregnancy
Child 24 month questionnaire		24 months after the end of pregnancy (in the case of multiple births, must be completed once per child)
Serious adverse event (SAE) form	OpenClinica	As soon as possible after site becomes aware of an SAE of special interest
Change of Consent form	OpenClinica	As soon as possible after a woman makes site staff aware that she would like to change her level of involvement in MAMA

OpenClinica access

Electronic CRFs are completed on OpenClinica. Each site staff member requires an individual account. Please contact the MAMA study team if you require an account (mama@npeu.ox.ac.uk)

- Data entry can only be completed by trained and delegated staff
- Online training to be completed
- Log in details will be sent to individuals

Randomisation Website access

The screening log and randomisation system is on the Randomisation Website.

Each site staff member requires an individual account. Please contact the MAMA study team if you require an account (mama@npeu.ox.ac.uk)

Randomisation can be completed by a member of staff who:
- has documented completion of MAMA randomisation training

AND
- has been authorised to undertake randomisation by the Principal Investigator (recorded on **MAMA Delegation Log**)

Please see **Guidance Sheet: Randomisation** for more details about the randomisation process

Screening Log

A record of all women screened should be maintained at site on the **MAMA Eligibility/ Screening Log**. Please include all women screened, even if the woman declines participation. Please see **Guidance Sheet: Screening and eligibility**

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Consent Form

Please see **Guidance Sheet: Informed Consent**.

Randomisation and Contact details form

Please see **Guidance sheet: Randomisation** Complete the contact details form as soon as possible after randomisation. If women wish to update their contact details, please update the contact details form on the randomisation system. **Do not send updated contact details via email.**

Once a woman has delivered her baby (or babies), please return to the contact details form and update it with the baby's name, NHS/CHI/healthcare number, and (if you have not already provided this via the Outcomes form) date of birth.

Trial Entry Form

Sections 1 and 2 of the Entry form on OpenClinica are completed automatically from the information entered during randomisation. Review information in section 1 on OpenClinica, then complete section 3. Section 2 can never be edited.

If any information was entered incorrectly at randomisation, it should be updated in Section 1 of the Entry form. If this has occurred and you are concerned that it may change the woman's eligibility for the trial, contact the MAMA Coordinating Centre.

Outcomes Form

To be completed after the end of pregnancy and (if applicable) after the woman has been discharged from hospital following birth of their infant. Please begin completing as soon as possible after you become aware of the outcome of a pregnancy.

If reporting **a stillbirth** via this form, please be aware that this **must also be reported via the SAE form.**

Do not enter infant names or NHS/CHI/healthcare numbers on this form. These should be added to the Contact Details form.

Neonatal Outcomes Form

To be completed if an infant is admitted to the neonatal unit, after they have been discharged home from neonatal care (or if they die prior to discharge home). If an infant is transferred to (an)other hospital(s) prior to discharge home, the data on the Neonatal Outcomes form should cover this entire period.

If reporting a **neonatal death** via this form, please be aware that this **must also be reported via the SAE form.**

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Wellbeing check

The woman will be asked to complete questionnaires at 3, 6, 12 and 24 months. Please confirm that the woman and/or her infant have not died before the Coordinating Centre makes contact the woman. Please inform the Coordinating Centre if you are aware of any hospital admissions for the infant. This is to ensure that we do not miss reporting of any SAEs.

Change of consent form

Please refer to **Guidance Sheet: Change of consent**.

Serious adverse event (SAE) form

Please refer to **Guidance Sheet: Safety and Incident Reporting**. SAEs must be reported to NPEU as soon as possible, even if you do not have all the information available yet.

Participant questionnaires and the app

We recommend that women use the MAMA app wherever possible, however, women who are unable or unwilling to use the app or electronic data capture can still take part in MAMA.

Alternative data collection methods listed below (recommended methods are highlighted in green:

	Baseline, 3-, 6-, 12-, 24-month questionnaire; Child 24-month questionnaire	**Arthritis questionnaires (monthly in pregnancy; at 3, 6 and 12 months post pregnancy)**	**Ad-hoc questionnaires about arthritis (completed whenever the woman wishes, up to 12 months post pregnancy)**
OpenClinica (through a direct link sent via SMS/email)	✓	✓	✗
MAMA App	✗	✓	✓
On paper	✓	✓	✓

The MAMA Coordinating Centre will send direct links and post paper questionnaires. We will also send reminders and make phone calls to women as required.

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