MAMA Trial Pathway

Time points	Recruiting site trial activities	Participant trial activities	Oxford Vaccine Group activities
		All women and infants will be followed up to 12 months – a subset will be followed up to 24 months**	**Subset of infants with consent for contact and within geographical reach of Oxford**
Initial approach			
Eligibility check	**Screening log**	**Activities before 28 weeks gestation**	Women can consent (optional) to be contacted about the infant immunology element of the trial on the MAMA Consent Form.
Informed consent	**In person/ Remote Consent Form**		
Randomisation	**Online Randomisation Form** **Trial entry form** **Contact details form**	**Baseline Form (completed on OpenClinica via link sent by SMS/email)**	
	Women randomised to either: **CONTINUE** to take bDMARDs throughout pregnancy. OR **STOP** taking bDMARDs before the third trimester (**week 28**) of pregnancy and restarting no earlier than 2 weeks after the end of pregnancy.		
	Women randomised to **STOPPING** pathway to stop taking their biologic by 28 weeks gestation	Report Report Report Report Report Report **Monthly arthritis activity report (via app or alternative)** • From randomisation until the end of pregnancy • Women can also report arthritis activity at any time via app	
28 weeks' gestation			
End of pregnancy			Women who have consented will be contacted by Oxford Vaccine Group (OVG, part of the MAMA Coordinating Team) to arrange home visits when their baby has been born.
Postnatal discharge	**Outcomes Form**		
Neonatal discharge	**Neonatal Outcomes Form** • For infants admitted to neonatal unit		
Life status check	**Contact Details Form**		
2 months AEP*			**Home visit 1** • Written consent • Blood test • Nasal fluid sample • Data collection
3 months AEP*		**3 month arthritis app report** AND **3 month questionnaire** (OpenClinica)	
Life status check	**Contact Details Form**		
5 months AEP*			**Home visit 2** • Blood test • Nasal fluid sample • Data collection
6 months AEP*		**6 month arthritis app report** AND **6 month questionnaire** (OpenClinica)	
Life status check	**Contact Details Form**		
12 months AEP*		**12 month arthritis app report** AND **12 month questionnaire** (OpenClinica)	
13 months AEP*			**Home visit 3** • Blood test • Nasal fluid sample • Data collection
Life status check	**Contact Details Form**		
24 months AEP**		**24 month questionnaire**** (OpenClinica)	

*AEP = After End of Pregnancy

**For participants recruited within 24 months of the end of trial (guidance will be sent by MAMA Trial Team)