

Trial ID								Month of Birth				Visit Date	D	D	M	M	M	Y	Y	Y	Y
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Visit week:	4	8	12	16	24	36	48	72	Unscheduled
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THIS FORM SHOULD ONLY BE COMPLETED IF IT IS KNOWN THAT THE PARTICIPANT IS NO LONGER PREGNANT

MULTIPLE BIRTH

1a. Multiple birth? Yes ☐ No ☐ Unknown ☐ (Complete this form for each infant) **1b. If Yes, infant** ☐ **1c. of** ☐

FOETAL OUTCOME

2a. Date of outcome:

D	D	M	M	M	Y	Y	Y	Y
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 2b. Tick if unknown: ☐ (if Unknown go to question 2c)

2c. If date of outcome is unknown, provide expected delivery date:	D	D	M	M	M	Y	Y	Y	Y
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3. Specify outcome (*tick one only*)

- | | |
|--|--------------------------|
| a. Full term live birth (≥ 37 weeks) | ☐ |
| b. Premature live birth | ☐ |
| c. Therapeutic/elective abortion | ☐ |
| d. Ectopic Pregnancy (Complete Form 13: Child Adverse Event) | ☐ |
| e. Spontaneous abortion (< 20 weeks) (Complete Form 13 - Child Adverse Event) | ☐ |
| f. Spontaneous foetal death/ or still birth (> 20 weeks) (Complete Form 13 - Child Adverse Event) | ☐ |
| g. No information available | ☐ |

4. Were any foetal/infant congenital anomalies identified? Yes ☐ No ☐ Unknown ☐ (if yes complete Form 13 and Form 23)

5. Was the infant directly observed by a member of staff at this visit? Yes ☐ No ☐ N/A ☐

6. If the infant was born in a hospital, were they readmitted after leaving hospital or did they have a prolongation of their initial hospitalisation? Or if they were not born in a hospital, were they admitted to hospital following birth?

(only tick yes if within 28 days of birth) Yes ☐ No ☐ Unknown ☐ N/A ☐

7. Comments

[illegible]

Completed by: RA Code	Signature	Date:									
		D	D	M	M	M	Y	Y	Y	Y	
QC by: RA Code	Signature	Date:									
		D	D	M	M	M	Y	Y	Y	Y	
Database Entry 1: RA Code	Signature	Date:									
		D	D	M	M	M	Y	Y	Y	Y	
Database Entry 2: RA Code	Signature	Date:									
		D	D	M	M	M	Y	Y	Y	Y	