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M	M	/	Y	Y	Y	Y
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Has the baby had any Adverse Reactions during this study (up to 36 weeks postmenstrual age)? Yes No (If yes, please list all Adverse Reactions below)

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AR	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely related 2 = Probably related 3 = Possibly related	1 = None 2 = Discontinued permanently 3 = Discontinued temporarily	1 = Resolved, no sequelae 2 = Resolved, with sequelae 3 = Ongoing 4 = Ongoing at final follow-up 5 = Fatal	1 = Yes 2 = No (If yes, complete SAE form)

Adverse Reaction	Start Date	Stop Date	Severity	Relationship to Study Treatment	Action Taken regarding study intervention	Outcome of AR	Serious Adverse Reaction?	Initials (PI or delegate)
1.	DD/MM/YYYY	DD/MM/YYYY						
2.	DD/MM/YYYY	DD/MM/YYYY						
3.	DD/MM/YYYY	DD/MM/YYYY						
4.	DD/MM/YYYY	DD/MM/YYYY						
5.	DD/MM/YYYY	DD/MM/YYYY						
6.	DD/MM/YYYY	DD/MM/YYYY						