IBM	Clinical	Development -	Generated	on 21-JU	L-20 16	:17:20	P18-954
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Adverse Event

Adverse Events

[Revision: Initial revision of study]

(Visit ID = 100 / Visit Display Name = Adverse Event / Visit Abbrev = AE / PageID = 10 / Page Display Name = Adverse Events / Description = Adverse Events)

Please record all Adverse Events (serious and non-serio	us) f	rom the time of informed consent through infant follow-up.
* Any Adverse Events or Serious Adverse Events?	0	No
	0	Yes
If Yes, please record on the Adverse Event Details form.		
* Did the infant have any Serious Adverse Events after	0	No
birth?	0	Yes
	0	Not applicable
If Yes, please record on the Pediatric Serious Adverse E	vent	Details form.

Initial Design

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Adverse Events Details

[Revision: Initial revision of study]

(Visit ID = 100 / Visit Display Name = Adverse Event / Visit Abbrev = AE / PageID = 20 (*) / Page Display Name = Adverse Events Details / Description = Adverse Event Details)

AE Serial Number			
* Date of Contact			(DD-MMM-YYYY)
* Reporter of information	0 0 0 0	Patient Obstetrician Gynecologist Infant healthcare provider Other	
* Other, specify			
* Onset date			(UNK-UNK-UNK)
* Adverse Event			
* Ongoing?	0	No Yes	
* End Date			(UNK-UNK-UNK)
* Intermittent?	0	No Yes	
* Severity	0 0 0	Mild Moderate Severe	

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* Outcome	0	Recovered without sequelae
	0	Recovered with sequelae
	0	Ongoing
	0	Change in severity grade (worsening)
	0	Death
* Has the patient taken an AbbVie product during the	0	No
study?	0	Yes
If yes, please complete the Comorbidity Details form ar	d the	Concomitant Medications Details form.
* Was a product complaint associated with this	0	No
adverse event?	0	Yes
* Relationship to AbbVie product	0	Reasonable possibility
	0	No reasonable possibility
If no reasonable possibility, provide other cause of event		
* Action taken with AbbVie product	0	None
	0	Drug interrupted
	0	Drug withdrawn
	0	Not applicable
	0	Other
* Other, specify		
Other actions taken (Check all that apply)		
None		
Concomitant medication or therapy started		
Concomitant medication or therapy discontinued		
Other		
* Other, specify		

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* Is this Adverse Event serious?	0	No	
	0	Yes	
Please add the SAE folder and complete the associa	ated SAE	E related information.	
Serious criteria (select all that apply)			
Life-threatening			
Death			
Hospitalization or prolongation of hospitalization			
Other medically important serious event			
Persistent or significant disability/incapacity			
Congenital Anomaly			
* SAE awareness date			(UNK-UNK-UNK)
* Is this an AE of Special Interest?	0	No	
to this arrive or opposition for the	0	Yes	
Please add the AESI folder and complete the associ	ated AE		

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Pediatric Serious Adverse Events Details

[Revision: Initial revision of study]

(Visit ID = 100 / Visit Display Name = Adverse Event / Visit Abbrev = AE / PageID = 30 (*) / Page Display Name = Pediatric Serious Adverse Events Details / Description = Pediatric Serious Adverse Event Details)

Please do not enter hospitalizations related to the post b			
Please add the SAE folder and complete the associated	SAE	related information.	
Serial number			
* Date of Contact			(DD-MMM-YYYY)
* Reporter of information	0	Patient	
	0	Obstetrician	
	0	Gynecologist	
	0	Infant healthcare provider	
	0	Other	
* Other, specify			
* Birth Order	0	Birth order 1	
	0	Birth order 2	
	0	Birth order 3	
	0	Birth order 4	
	0	Birth order 5	
* Event			
* Start Date			(UNK-UNK-UNK)
* Ongoing?	0	No	
	0	Yes	
* End Date			(UNK-UNK-UNK)

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IBM Clinical Development -- Generated on 21-JUL-20 16:17:20 -- P18-954 * Intermittent? 0 No 0 Yes * Severity 0 Mild 0 Moderate 0 Severe * Outcome Recovered without sequelae Recovered with sequelae 0 Ongoing Change in severity grade (worsening) Death * What was the primary cause of death (DD-MMM-YYYY) * Date of Death * Has the patient taken an AbbVie product during the No study 0 Yes If yes, please complete the Comorbidity Details form and the Concomitant Medications Details form. * Was a product complaint associated with this No adverse event? 0 Yes * Relationship to AbbVie product Reasonable possibility No reasonable possibility * If no reasonable possibility, provide other cause of event * Action taken with AbbVie product 0 None Drug interrupted 0 Drug withdrawn Not applicable 0 Other

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* Other, specify

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Other actions taken (Check all that apply)		
None		
Concomitant medication or therapy started		
Concomitant medication or therapy discontinued		
Other		
* Other, specify		
Serious criteria (select all that apply)		
Life-threatening		
Death		
Hospitalization or prolongation of hospitalization		
Other medically important serious event		
Persistent or significant disability/incapacity		
Congenital Anomaly		
* SAE awareness date	(UNK-UNK-UNK)	

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