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-serious) from the time of informed consent through infant follow-up.

* Any Adverse Events or Serious Adverse Events?
- ○ No
- ○ Yes

If Yes, please record on the Adverse Event Details form.

* Did the infant have any Serious Adverse Events after birth?
- ○ No
- ○ Yes
- ○ Not applicable

If Yes, please record on the Pediatric Serious Adverse Event Details form.

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	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, specify		
* Onset date		(UNK-UNK-UNK)
* Adverse Event		
* Ongoing?	○ No ○ Yes	
* End Date		(UNK-UNK-UNK)
* Intermittent?	○ No ○ Yes	
* Severity	○ Mild ○ Moderate ○ Severe	

* Outcome	○ Recovered without sequelae ○ Recovered with sequelae ○ Ongoing ○ Change in severity grade (worsening) ○ Death
* Has the patient taken an AbbVie product during the study?	○ No ○ Yes

If yes, please complete the Comorbidity Details form and the Concomitant Medications Details form.

* Was a product complaint associated with this adverse event?	○ No ○ Yes
* Relationship to AbbVie product	○ Reasonable possibility ○ No reasonable possibility
If no reasonable possibility, provide other cause of event	
* Action taken with AbbVie product	○ None ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Other
* Other, specify	

Other actions taken (Check all that apply)

None	☐
Concomitant medication or therapy started	☐
Concomitant medication or therapy discontinued	☐
Other	☐
* Other, specify	

* Is this Adverse Event serious?	○	No
	○	Yes

Please add the SAE folder and complete the associated SAE 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?	○	No
	○	Yes

Please add the AESI folder and complete the associated AESI related information.

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 birth hospital stay.
Please add the SAE folder and complete the associated SAE related information.

Serial number		
* Date of Contact		(DD-MMM-YYYY)
* Reporter of information	○ Patient ○ Obstetrician ○ Gynecologist ○ Infant healthcare provider ○ Other	
* Other, specify		
* Birth Order	○ Birth order 1 ○ Birth order 2 ○ Birth order 3 ○ Birth order 4 ○ Birth order 5	
* Event		
* Start Date		(UNK-UNK-UNK)
* Ongoing?	○ No ○ Yes	
* End Date		(UNK-UNK-UNK)

* Intermittent?	○ No ○ Yes	
* Severity	○ Mild ○ Moderate ○ Severe	
* Outcome	○ Recovered without sequelae ○ Recovered with sequelae ○ Ongoing ○ Change in severity grade (worsening) ○ Death	
* What was the primary cause of death		
* Date of Death		(DD-MMM-YYYY)
* Has the patient taken an AbbVie product during the study	○ No ○ Yes	

If yes, please complete the Comorbidity Details form and the Concomitant Medications Details form.

* Was a product complaint associated with this adverse event?	○ No ○ Yes	
* Relationship to AbbVie product	○ Reasonable possibility ○ No reasonable possibility	
* If no reasonable possibility, provide other cause of event		
* Action taken with AbbVie product	○ None ○ Drug interrupted ○ Drug withdrawn ○ Not applicable ○ Other	
* Other, specify		

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)