Form 3: Suspected Serious Adverse (SAE) conclusion

Version 1.0, 08 October 2020

Section Header	Num.	Question Text	Question Responses	Required
		Instructions: To be completed by a study physician (coordinator) for each suspected SAE.		
		Coordinator ID		
		Child ID	Pre-filled	
		Child age (months)		
		Date	Calculated automatically	
		Suspected SAE number	Pre-filled	
		Date of first reporting of this SAE	Pre-filled	
		Date of symptoms onset	Pre-filled	
Previous information on the suspected SAE		Suspected SAE type	Pre-filled	
		Description of the event (symptoms, clinical findings, lab & imaging data, diagnosis, treatment)	Pre-filled (from initial reporting and follow up information)	
Outcome of suspected SAE		How long did the symptoms last (in days)?	Number 99 if ongoing	
		Outcome of event as of <today's date>	1, Recovered | 2, Recovered with sequelae |3, Recovering|4, Not recovered/unchanged |5, Deteriorating | 6, Child died|7, Unknown	
		If recovered, date of recovery	Date	
		If child died, date of death	Date	

		Likely cause (s) of Death	Free text UKN is allowed	
		Methods for establishing cause (s) of death	1, Family opinion | 2, LAKANA Staff opinion-based on family interview |3, Verbal autopsy |4, Medical autopsy|5, Other|6, NA (cause of death unknown or child is alive) No	
		Autopsy findings	Free text	
Conclusions by the study physician		Should this event be considered a Serious Adverse Event?	1, Yes | 2, No	
		Categorization of the SAE	1, Resulted in death|2, Life threatening| 3, Hospitalization/prolongation of hospitalization|4, Persistent or significant disability or incapacity|5, Important medical event	
		Causality to the study	1, Not related| 2, Unlikely related | 3, Possibly related| 4, Probably related | 5, Definitely related| 4, Not assessable	
		Is there a reasonable possibility that the event is related to concomitant drug? (specify for each drug)	1, Yes|2, No Concomitant drugs = drugs recorded on the Initial report that the child was getting when the symptoms appear (within two weeks before event onset). Drugs used more than two weeks before the event onset or to treat the event or taken after the event onset are excluded.	
		Was the child withdrawn from the study?	1, Yes | 2, No | 3, NA (child died)	

		Can the child continue to receive the study drug medication?	1, Yes|2, No| 3, NA (child died)	
		Indicate whether breaking the randomization code for the participant is necessary	1, Yes- it is necessay|2, No-it is not necessary	
		If yes, specify reasons	Free text	
Follow-up of the SAE		Will the LAKANA staff continue the follow-up (weekly monitoring)?	1, Yes | 2, No | 3, NA (child died)	