

Form 1- Part A: Initial Report of a Suspected Serious Adverse (SAE)

Version 1.0, 08 October 2020

Section Header	Num.	Question Text	Question Responses	Required
	0	Instructions: Complete this form for each suspected serious adverse event (SAE).		
	1	Interviewer ID		
	2	Child ID		
	3	Child age (months)		
	4	Date	Calculated automatically	
Event information	5	Suspected SAE number	Generated automatically?	
	6	Date study staff notified	Date	
	7	Date of symptom onset	Date	
	8	Date when latest dose of study drug was given	Date	
	9	Description of the event (symptoms, sites and dates of care seeking)	Free text	
	10	Medical exam findings:	Free text	
	11	Laboratory findings:	Free text	
	12	Imaging findings:	Free text	
	13	Identified diagnosis:	Free text	
	14	Treatment offered:	1, Yes 2, No	
	15	If yes, specify treatment (list all drugs or surgical procedures)	Free text	

	16	Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form	Free text	
Medication history	17	Besides study drug, list all other drugs that the child was getting when the symptoms appear (Include drugs taken up to two weeks before event onset. Do not include drugs used to treat the event or taken after the event onset)		
	18	Drug 1 name		Repeat field for Drug 2 etc...
	19	Reason for use		
	20	Route		
	21	Start date	Date	
	22	End date	Date	
Patient history	23	List illnesses present at time of symptoms or pre-existing medical conditions		
	24	Illness or Condition 1		
	25	Onset date		
	26	Stop date		
	27	Ongoing	1, Yes 2, No	
Infant's outcome to date	28	Infant's outcome as of <today's date>	1, Recovered 2, Still ill but ambulatory 3, Hospitalized 4, Death	
	29	If death, date of death	Date	
	30	Cause (s) of Death		
	31	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)	
	32	Autopsy findings	Free text	
Action taken	33	Was study drug discontinued (children withdrawn from the study)?	1, Yes 2, No NA	