

LAKANA trial

**Data collection form: Adverse Events**

Version 1.0, 08 October 2020

Purpose: Active surveillance for the incidence of adverse events (AE) within 14 days of study drug administration, in the 60 villages selected for more detailed data collection on outcomes other than mortality.

Section Header	Num.	Question Text	Question Responses	Required
	[0]	Instructions: Complete this form for targeted age group children.		
	[1]	Interviewer ID		
	[2]	Child ID		
Visit information	[3]	Date:		
Symptoms	[4]	Check the symptoms experienced in the last 14 days:		
	[5]	Diarrhea	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[6]	On how many days did <name> experience diarrhea?	<i>integer</i>	Yes (if [5] != 0) <i>max=14</i>
	[7]	Loose stools	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[8]	On how many days did <name> experience loose stools?	<i>integer</i>	Yes (if [7] != 0) <i>max=14</i>
	[9]	Vomiting	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[10]	On how many days did <name> experience vomiting?	<i>integer</i>	Yes (if [9] != 0) <i>max=14</i>
	[11]	Rash-itching	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[12]	On how many days did <name> experience Rash-itching?	<i>integer</i>	Yes (if [11] != 0) <i>max=14</i>

	[13]	Swelling of the lips	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[14]	On how many days did <name> experience Swelling of the lips?	<i>integer</i>	Yes (if [13] != 0) <i>max=14</i>
	[15]	Difficulty breathing- wheeze	0, None   1, Mild   2, Moderate   3, Severe/Life threatening	Yes
	[16]	On how many days did <name> experience difficulty breathing- wheeze?	<i>integer</i>	Yes (if [15] != 0) <i>max=14</i>
	[17]	Crying more than usual	1, Yes   0, No	Yes
	[18]	Did the child experience other symptoms?	1, Yes   0, No	Yes
	[19]	If yes, describe symptoms		Yes (if [18] = 1)
	[20]	What was the outcome of the event (s) reported?	1, Child was hospitalized (Fill out Suspected SAE Form)   2, Child was seen as an outpatient and returned home   3, Other	
	[21]	Specify Other		