

Form 2: Follow up Report of a Suspected Serious Adverse (SAE)

Version 0.3, 15 June 2020

| Section Header | Num. | Question Text | Question Responses | Required |
|---------------------------------|------|---|---|----------|
| | | Instructions: To be completed daily by a supervisor for a minimum of 14 days from the first reporting of the suspected SAE. After 14 days and if applicable (issue unresolved), to be completed weekly. | | |
| | | Supervisor 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 SAE | | Suspected SAE type | Pre-filled | |
| | | Main symptoms | Pre-filled | |
| | | Treatment | Pre-filled | |
| Progression on the event | | Since <date of latest previous assessment> how have the child's symptoms and condition developed? | Free text | |
| | | Medical findings as of <today's date> | Free text | |
| | | Status of child's condition 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 | |
| | | Cause (s) of Death | Free text | |
| | | 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) | |
| | | Autopsy findings | Free text | |
| | | If applicable, current treatment of <name> | | |
| | | If applicable, planned treatment of <name> | | |