

Standard Operating Procedures for the LAKANA trial
SOP Visit-09: Conducting the close-out visit for the LAKANA mortality trial
Version 1.0 (2023-01-31)

1. Purpose and overview:

This SOP provides instructions on how to conduct the close-out visit i.e., the 9th visit after the eight MDAs in villages participating in the LAKANA Mortality trial.

For villages participating in the AMR study, specific procedures will be followed at the 9th visit and are documented in a separate SOP.

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility
District Supervisor	<ul style="list-style-type: none">- Plans date of entry in villages- Reports on the close-out visits to the CVD-Mali coordinator and to the Implementation Working Group (IWG)
Field supervisor	<ul style="list-style-type: none">- Packs data collectors' rucksacks- Oversees data transmission to server- Reports on the close-out visit to the district supervisor
Data collector	<ul style="list-style-type: none">- Finds the compounds/households and requests permission to proceed for the final visit- Operates tablet computer- Records requests from community members and reports to field supervisor

3. Required materials

Same as MDA1-8 minus treatment-related material and stickers, *Refer to SOP Visit-01.*

4. Definitions and general instructions

4.1. Definitions

4.1.1. District Supervisor: a LAKANA staff member coordinating trial activities at the district level. The district supervisor reports primarily to the study coordinator.

4.1.2. Field Supervisor: a LAKANA staff member responsible for coordinating data collection teams' activities. He is under the supervision of the district supervisor.

4.1.3. Data collector (DC): a LAKANA staff member collecting data at the compound, household, and individual level.

4.2. General Instructions

- 4.2.1. At the close-out visit (visit 9) in a village, the DCs will first meet the village chief or his/her representatives and inform that the LAKANA staff will be conducting the study final visit.
- 4.2.2. At the close-out visit in a village, there will be no distribution of the investigational drugs. The DCs will only conduct interviews and record the vital status of household members and the Immunization and SMC-related information of eligible infants.

5. Step-by-step procedures

- 5.1. On the first day of the close-out visit in a village, the DCs will visit the chief or his/her representative and explain the close-out visit:
 - 5.1.1. The DCs will inform the representatives that no drugs will be distributed this time and that only interviews will be conducted.
 - 5.1.2. The DCs will thank the village representatives for their time and support to LAKANA staff throughout the 2-year follow-up, and for the village participation in the trial. The DC will inform the village representatives that they will later be called to a meeting in which information on trial findings will be distributed.
 - 5.1.2.1. At this encounter, the DC may also offer the village representatives a gift to acknowledge the village participation in LAKANA trial. The exact nature of the gift will be decided by the CVD-Mali coordination team, and it may vary during the LAKANA trial implementation.
 - 5.1.3. The DCs will record any questions or comments the village representatives may have regarding LAKANA and will share the information with their field supervisor.
- 5.2. Like the previous MDA visits in the village, the DCs will visit the compounds and households enrolled in the trial and collect:
 - **Vital status information of all members (DCF06)**
 - **Immunization and SMC data for eligible infants (DCF03)**The differences with the MDA visits are that at visit 9:
 - **No** drug will be distributed
 - **No** new compounds or households will be enrolled in the study
- 5.3. The DCs will thank the chiefs and members of compounds and households for their time and participation in the study. They will record any questions or comments the participants may have and report to the field supervisor.
- 5.4. At the end of the close-out visit in a village, the DCs will thank the Relais for their time and assistance with LAKANA study activities. The DCs will record any questions or comments the Relais may have and report to the field supervisor.

- 5.5.** The field supervisor will report to the district supervisor on the close-out visit and on any issues that needs to be addressed.

6. Occupational Safety Issues

In a non-epidemic situation, there are no specific occupational safety issues.

During COVID-19 epidemic, procedures for safe and proper work will be used to reduce the risk of exposure to a hazard and prevent transmission between the study team and the study participants. Special considerations due to COVID-19 are described in SOP-Safety 01.

7. Quality Assurance / Quality Control

8. Appendices and other related documents

Document number (Version)	Document content
DCF03	Immunization History
DCF06	Vital Status

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0	Laura Adubra, Per Ashorn, Ulla Ashorn. Reviewed by PSG. Approved by LAKANA PSG on 2023-01-31.