

Standard Operating Procedures for the LAKANA trial  
**SOP Prep 02: Scheduling village visits**  
 Version 2.0 (2023-05-31)

**1. Purpose and overview:**

This SOP provides step-by-step instructions for the scheduling of mass drug administration (MDA) visits to villages for the LAKANA trial and for the assignment of data collectors to each scheduled MDA. Scheduling is performed in two steps: first, on a district by district basis, each village is scheduled and second, data collectors are assigned to each village. All 9 MDAs for all villages within a district are assigned at the same time but the scheduling of later MDA can be adjusted over time. An electronic, tablet-based scheduling tool is used to generate the initial schedule and update it over time. The scheduling tool will identify scheduling conflicts, which the study coordinator can then resolve

**2. Applicability to and responsibilities of various staff members**

| Staff member        | Responsibility                                                                                                                                                                                                                                                                                                                                                      |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study coordinator   | Oversees all scheduling activities, manages master schedule of MDAs for all districts and villages, tracks completion of MDAs according to the master schedule and remediates issues.                                                                                                                                                                               |
| District supervisor | Reviews master MDA schedule and provides feedback to the schedule coordinator, adjusts schedule within agreed constraints to accommodate local scheduling issues and assigns data collector teams to each village MDA. Troubleshoots day-to-day staffing issues, seeking help from the study coordinator as needed. Tracks completion of MDAs at the village level. |
| Field supervisor    | Works with district supervisor to ensure village MDAs are staffed and completed appropriately.                                                                                                                                                                                                                                                                      |
| Data collector      | Conducts data collection according to the schedule defined by the schedule coordinator and district supervisor. Communicates work status and MDA completion status with the field supervisor.                                                                                                                                                                       |

**3. Required materials**

| Item               | Number    | Specification                                 |
|--------------------|-----------|-----------------------------------------------|
| Computer or tablet | As needed | To be used for accessing the master schedule. |

## 4. Definitions and general instructions

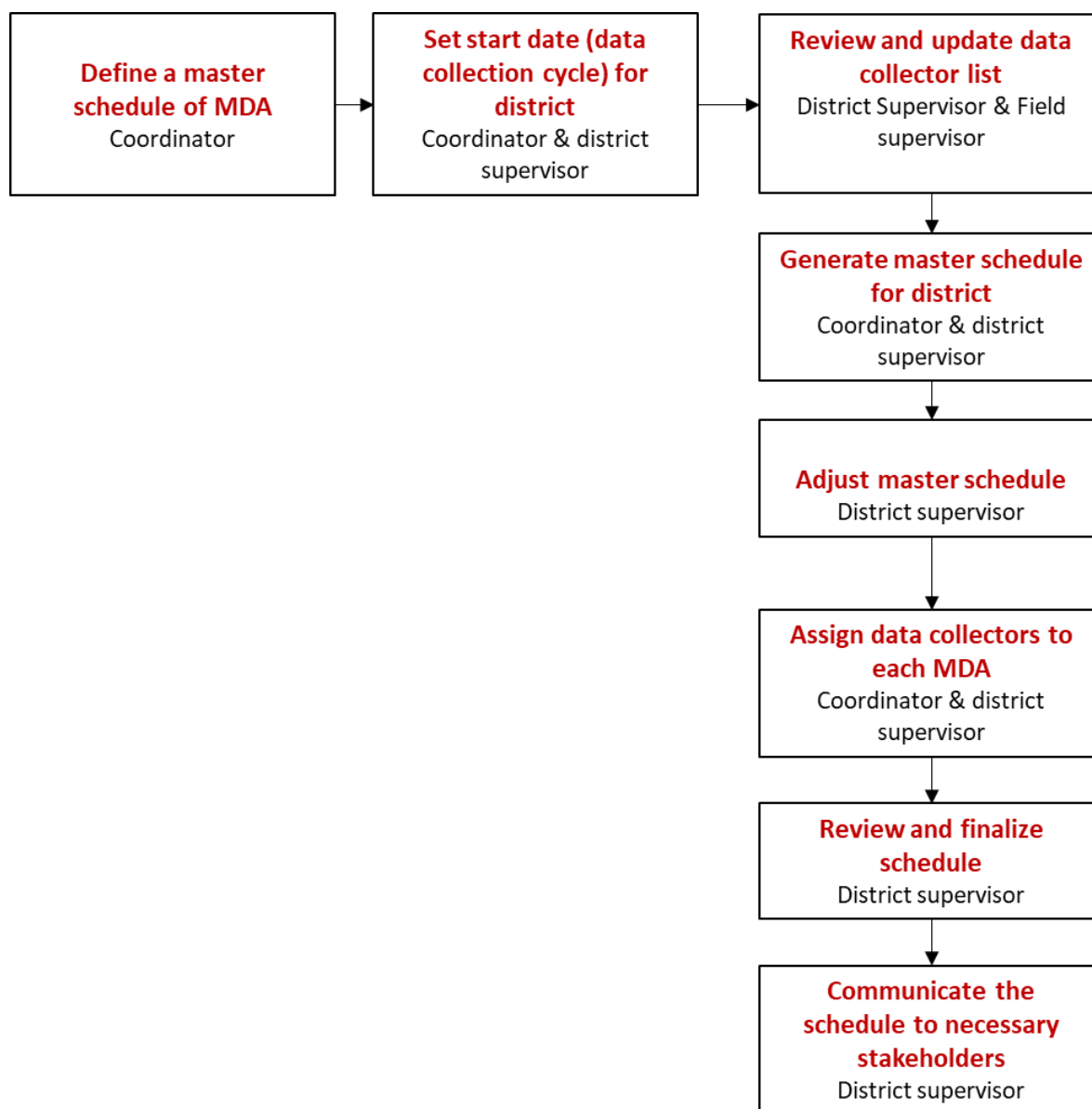
### 4.1. Definitions

- 4.1.1. Village MDA: one complete round of mass drug administration in a specific village by the LAKANA team, during which all households in the village will be visited and trial activities will be conducted. Each village will be entered 9 times over the course of the trial. The first round will take longer than the others due to the novelty of the procedures, the need to establish the team's credibility in the village, and extra baseline data collection. Subsequent rounds will be shorter, and the final round will be shortest due to the absence of study drug treatment. Villages may also be entered prior to the start of data collection in order to enumerate households.
- 4.1.2. Household enumeration exercise: if conducted, a small team of data collectors coupled with a team of census agent will visit each compound and household in the visit and collect based information to facilitate the smooth running of the subsequent village MDAs. This process will result in a complete list of households along with GPS coordinates, IDs and location descriptions.
- 4.1.3. Initial MDA: during the initial visit (village MDA #1), each household will be visited and given the opportunity to participate in the study. Baseline data collection will be conducted and, if consented, eligible children will be given the study drug.
- 4.1.4. Subsequent MDA: during the subsequent MDAs (village MDA #2-8) data will be updated and, if consented, eligible children will be given the study drug.
- 4.1.5. Final MDA: during the final MDA (village Visit #9) data will be updated but no study drug will be administered.
- 4.1.6. Master schedule: an overall study schedule that lists all villages and MDAs grouped by district, along with the scheduled dates for each MDAs. The master schedule is generated by TAU coordination team and managed by the study coordinator.
- 4.1.7. Scheduling cycle: a 13-week period (12 schedule weeks plus one overflow week) during which all villages within a district will complete an MDA.
- 4.1.8. Expected schedule: an automatically generated schedule calculated based on the start date for data collection in each district. The start dates for follow-up MDAs and Visit 9 are automatically generated based on the date of MDA 1.
- 4.1.9. Scheduling window: village MDAs must be conducted within the PSG-approved number of weeks of the expected date; the scheduling window is -4/+8 weeks.
- 4.1.10. Scheduling tool: an electronic tool that provides automatic scheduling capabilities and allows district supervisors to make adjustments.

- 4.1.11.** Scheduling constraints: rules used to generate the schedule, including: optimal duration (1 or 2 weeks), and the scheduling window.
- 4.1.12.** Study coordinator: a LAKANA staff member that supports, facilitates and coordinates the daily trial activities. The LAKANA study coordinator reports primarily to the Malian co-Principal Investigator.
- 4.1.13.** District supervisor: a LAKANA staff member coordinating trial activities at the district level. The district supervisor reports primarily to the study coordinator and will be stationed in a district office.
- 4.1.14.** Field supervisor: a LAKANA staff member coordinating trial activities at the CScCom level. He or she is under the supervision of the district supervisor.
- 4.1.15.** Data collector: a LAKANA staff member who will collect data and administer study drug. He or she is under the supervision of the field supervisor. Each data collector will be paired with one or more local relais.
- 4.1.16.** Data collection team: a group of data collectors and relais assigned to work in a village.

## **4.2. General instructions**

- 4.2.1.** There will be 8 separate phases for the scheduling of village MDAs as illustrated below. The detailed instructions for each phase are described in Section 5 Step-by-step procedures. NB: The master schedule is defined and generated in collaboration with the TAU coordination team.



## 5. Step-by-step procedures

**5.1.1.** Define study-level schedule, district and village characteristics: the study coordinator, in collaboration with the national district head, will discuss the general district schedule with supervisors. They will identify any large-scale events that would impact data collection and define a rough district-level schedule. In this schedule, the anticipated start dates of data collection for each village will be documented. The start will be staggered over time.

5.1.1.1. Define a high-level schedule that lists the start date for each district.

5.1.1.2. For each district, set the start dates of each 13-week cycle and ensure that all data collection can be completed within the overall study schedule. Make any needed adjustments.

**5.1.2.** Set start date for next district: the study coordinator will identify the next district that will start its first data collection cycle. In collaboration with the district

supervisor and field supervisor, they will verify that there are enough data collectors available between the proposed dates.

- 5.1.3.** Review and update data collector list: the district supervisor in collaboration with the field supervisor will review the list of data collectors available for data collection in the district. He will make any necessary adjustments (i.e., add new data collectors or remove data collectors who are no longer working).
- 5.1.4.** Generate master schedule for district: the district supervisor in collaboration with the study coordinator will use the scheduling tool to generate a master schedule for the district.
- 5.1.5.** Adjust master schedule: the district supervisor will adjust individual MDAs to accommodate any community events. Once dates have been agreed and meet scheduling and data collector availability constraints, lock the schedule.
  - 5.1.5.1.** Based on the information returned by the scheduling tool and any other available information, as needed, move the start date of data collection for each village.
- 5.1.6.** Assign data collectors to each MDA: prior to the next data collection cycle, the district supervisor in collaboration with study coordinator will assign data collectors to each village, balancing necessary constraints (duration, availability of data collectors, etc.).
- 5.1.7.** Review and finalize schedule: the district supervisor will review the schedule and data collector allocation. He will communicate the schedule to necessary stakeholders and make minor adjustments as needed.
- 5.1.8.** Repeat the above steps for each district.

## **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. Special considerations due to COVID-19 are presented in SOP-Safety 01 Hygiene and PPE.

## **7. Quality Assurance / Quality Control**

### **7.1. Automated Quality Control**

- 7.1.1.** The scheduling tool will use an optimization algorithm to generate an initial master schedule. Manual adjustments to the schedule will be assessed automatically to ensure that the schedule is still viable. Scheduling conflicts and other issues will be highlighted to the user in real time.

### **7.2. Review and Approval Process**

- 7.2.1.** The schedule produced by the scheduling tool will be viable based on the information available, however there are always intangible issues that can affect

on-the-ground logistics. As a result, the final schedule should be reviewed carefully by the study coordinator and other stakeholders at CVD-Mali.

## 8. Appendices and other related documents

None.

## 9. Version history, authors and approvals

| Version (date)              | Edits to the SOP text (author)                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version 2.0                 | <p>Updated by Laura Adubra in consultation with Juho Luoma.</p> <p>Main changes:</p> <p>Modified the authorized window for delays in conducting MDAs based on latest PSG recommendations.</p> <p>Clarified information that is used to generate the schedule with the scheduling tool (number of data collectors and size of villages are not used in the scheduling tool)</p> <p>Approved by LAKANA PSG.</p> |
| Version 1.0<br>(2020-08-18) | Original document (Author Kevin Wilson, approved by the LAKANA PSG on August 19, 2020.)                                                                                                                                                                                                                                                                                                                       |