Standard Operating Procedures for the LAKANA trial
SOP Admin-03: Study documentation
Version 1.0. (2020-09-24)

1. Purpose and overview:

The purpose of this SOP[1] is to ensure that each trial site has approved versions of the trial documentation, so that people with a right to access and review such information can easily access it.

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility
Study PIs/study delegates	• Making sure the documentation is up to date, well organized, appropriately stored, and readily available • Informing study personnel and other stakeholders of the availability and location of the documentation

3. Required materials

Item	Number	Specification
Appropriate storage place for Study Documentation Folders.	1	None
Password protected database with documentation on informed consent for the main study.	1	None
Appropriate lockable place for storing paper copies of consent forms for the sub-study.	1	None
Folders or other document containers	As needed	None

4. Definitions and general instructions

4.1. Definitions:

[1] Abbreviations: SOP = standard operating procedure, LAKANA = Large-scale Assessment of the Key health-promoting Activities of two New mass drug administration regimens with Azithromycin, DSMB = Data Safety and Monitoring Board, SAE = Serious Adverse Events, PI= Principal Investigator, GCP = Good Clinical Practices.

4.1.1. LAKANA Study Documentation Folder: a folder or set of folders available in CVD-Mali Bamako office or district offices that contains trial documentation for the LAKANA research project. The content of the study documentation folder is specific to each level, see section 5 for detailed contents.

4.1.2. LAKANA Informed consent form: a document that participants/caregivers in the research project review and sign before being enrolled in the study. The form contains summarized information about the aims and procedures in the research project, implications of study participation or non-participation, and the rights of study participants.

4.2. General instructions

4.2.1. The corresponding LAKANA Study Documentation Folder will be placed at the facilities Bamako office, and district offices used for implementing the LAKANA trial. All study personnel will have access to the LAKANA Study Documentation Folders.

4.2.2. Access to informed consent forms will be restricted to dedicated study personnel and people who have the right to review the forms based on their affiliation (study monitors or auditors, regulatory authorities, other authorized personnel).

5. Contents of the Study documentation folder

		Available at	
Document number	**Document name / content**	CVD-Mali Bamako	District
1	Table of contents	x	
2	Approval documents from local IRB	x	
3	Approval documents from other national authorities	x	
4	Trial insurance documentation	x	
5	Recommendations from Data Safety and Monitoring Board (DSMB)	x	
6	Recommendations from other Advisory groups	x	
7	Trial protocol, latest version (that includes list of amendments)	x	x
8	French summary of the trial protocol, latest version	x	x
9	A data dictionary	x	
10	A copy of the participant information and informed consent form(s) used in the trial	x	x
11	A list of data collection forms used in the trial	x	
12	Copies of individual data collection forms used in the trial	x	

		Available at	
Document number	**Document name / content**	CVD-Mali Bamako	District
13	A list of standard operating procedures (SOPs) used in the trial	x	x
14	Copies of individual SOPs used in the trial	x	x
15	Staff organogram and list of staff members	x	x
16	Key staff CVs, Medical/Pharmacy licenses and recent Good Clinical Practices (GCP) trainings	x	
17	Authorized Person List (Delegation log)	x	
18	Staff training log	x	
19	Drug import permit	x	
20	Study drug receipts and transfer logs	x	x
21	Suspected serious adverse events (SAE) log	x	
22	Deviation from the planned study procedures log	x	
23	Material Transfer Agreement (if applicable)	x	
24	Summary of product characteristics (Azithromycin – chloroquine investigator's brochure, 2010)	x	

6. Occupational Safety Issues

None.

7. Quality Assurance / Quality Control

None.

8. Appendices and other related documents

None.

9. Version history, authors and approvals

Version (date)	**Edits to the SOP text (author)**
Version 1.0 (2020-09-24)	Authored by Laura Adubra in consultation with Per Ashorn and CVD_TroDa team. Approved by LAKANA PSG.