

Standard Operating Procedures for the LAKANA trial
SOP Admin-02: Writing and Managing a Standard Operating Procedures (SOPs)
Version 1.0 (2020-08-18)

1. Purpose and overview:

This document provides guidance in the preparation of an SOP¹.

2. Applicability to and responsibilities of various staff members

This SOP is aimed at all personnel who will be involved in SOP writing and review in the context of the LAKANA Trial activities.

Staff member	Responsibility
Members of the Project Steering Group (PSG)	Choose the processes that need to be standardized and described in SOPs Appoint SOP authors for each SOP Review the initial draft and consecutive amendments of the SOP Release and formally approve SOP versions
LAKANA TAU investigators	Coordinate SOP production Make SOP (e-version) available to intended users
SOP author	Draft initial version of SOP Amend SOP if required
LAKANA investigators	Review the initial draft and consecutive amendments of the SOP
External monitor	Ensure compliance of SOP by all intended users Ensure the SOP version used is the most recent one approved by PSG Report non-compliance to PI and PSG members

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, PSG=Project Steering Group, TAU = Tampere University, PI=Principal Investigator.

3. Required materials

Not applicable.

4. Definitions and general instructions

4.1. Definitions

4.1.1. Standard Operating Procedure (SOP): Standard Operating Procedures (SOPs) are detailed, written instructions to achieve uniformity of the performance of a specific function. Procedures can take the form of a narrative, a flow chart, a process map, computer screen printouts or combination of all or any other suitable form.

4.2. General instructions

4.2.1. The PSG appoints a person that is directly involved in the operation/procedure to describe as responsible for drafting a specific SOP.

4.2.2. The author of the SOP will write the procedures in short, clear and unambiguous sentences and preferably using active voice.

4.2.3. Each SOP will have a unique identifier number.

4.2.4. All SOPs will be typed using Microsoft Word application software and will have a standard common format (see *Appendix 1*). The author of the SOP will structure the body content of the SOP under standard subheadings as described in point 5.4.2.

4.2.5. The SOP will depict the sequence of activities logically. Wherever necessary, the author will incorporate some illustrations, drawings, flow charts or exhibits in the SOP, to provide better clarity and understanding.

4.2.6. English language will be used. For operational purposes, if any SOP is required to be translated in French, the same guidelines will apply.

4.2.7. TAU investigators will make LAKANA SOPs (e-version) available for all intended users.

5. Step-by-step procedures

5.1. Initiation and review process of SOP

5.1.1. For a new SOP, the author will prepare the first draft of the document in consultation with other directly concerned personnel.

5.1.2. The author of the SOP will send the draft to all concerned LAKANA investigators for review of its adequacy.

5.1.3. The author of the SOP will review the submitted comments, incorporate the requested edits, if any, in a revised version, and send it to his supervisor for approval.

5.1.4. After getting satisfactory correction and changes, the SOP will be sent for final approval by PSG members.

5.2. Numbering and naming system of SOP.

5.2.1. SOPs shall be uniquely enumerated with an alphanumeric designation.

5.2.2. The name of the SOPs will follow the naming convention 'LAKANA_Trial_SOP_No._Title_vNo._Date.

5.2.2.1. Version no. will be denoted in two numeric characters.

- New draft of SOP will carry version No. '0.1' denoted v0.1 and the subsequent revised versions will be denoted by 'v0.2', 'v0.3' and so on.
- Once approved by the PSG, the SOP will carry Version No. '1.0'.

5.2.2.2. The 'Date' will be written in YYYY-MM-DD format.

5.3. Formatting of SOP

5.3.1. All SOPs will be typed using Microsoft Word application software.

5.3.2. All SOPs will have a standard common format as per Appendix 1. The type of font for the contents in the SOP will be "Times New Roman". Orientation of page will be portrait. Landscape orientation will also be used in appendices.

5.3.3. All the points in the SOP will be numbered sequentially. Similarly the sub-paragraphs of each point will also be numbered sequentially, with an incremental number derived from the heading number. The system of numbering will be as follows: First level shall be 1, 2, and 3so on, Second level shall be 1.1, 1.2, 1.3.....so on, this shall continue up to 4th level and 4th level shall be 1.1.1.1., and after this level sub-numbering can be marked as 'i', 'ii' and so on. In case where numbering of sub-paragraphs are not necessary and listing is essential, bullets or other suitable identification marks may be used to illustrate the same.

5.4. Content of SOP

5.4.1. Content of header

5.4.1.1. 'LAKANA SOP No.' 'Title of SOP' and 'Page No.'

- SOP No. will be written as described in point no. 5.2.1.
- Page No. will be numbered in Page X of YY format, e.g. first page of SOP of total 05 pages shall be *Page 1 of 5*.

5.4.1.2. 'Standard Operating Procedures for the LAKANA trial'.

5.4.1.3. 'SOP No.': 'Title'.

5.4.1.4. 'Version No.' ('Date').

5.4.2. Contents of SOP body

- 5.4.2.1.Purpose and overview: as first point; an overview of the intention of preparation of the SOP Standard Operating Procedure will be briefly mentioned under this heading.
- 5.4.2.2.Applicability to and responsibilities of various staff members: as second point; this section will describe the personnel that will be responsible for implementation and compliance of the Standard Operating Procedure.
- 5.4.2.3.Required materials: as a third point; this section will list and specify, where necessary, equipment, materials needed to accomplish the procedures.
- 5.4.2.4.Definitions and general instructions: as a 4th point; this section will identify any words, phrases, or specialized terms used, and describe the detailed procedure to be followed in simple and clear sentences.
- 5.4.2.5.Step-by-step procedures: as a 5th point; this section will include the details of all operations, checks and special precautions to be taken, if any.
- 5.4.2.6.Occupational Safety Issues: as a 6th point; this section will indicate operations that could result in personal injury and explaining what will happen if the procedure is not followed or is followed incorrectly.
- 5.4.2.7.Quality Assurance / Quality Control: as a 7th point; this section will describe any control steps and provisions for review or oversight prior to acceptance of the product or deliverable.
- 5.4.2.8.Appendices and other related documents: as 8th point; this section will list all table, flow charts or any other attachment with the SOP.
- 5.4.2.9.Version history, authors and approvals: as 9th point; this section will contain a chronological record of significant changes / modifications in an SOP in brief. It will mention ‘Version Number’, and corresponding ‘Date’, ‘Author of the SOP’.

6. Occupational Safety Issues

None.

7. Quality Assurance / Quality Control

None.

8. Appendices and other related documents

Document number	Document content
Appendix 1	SOP Template.

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-08-18)	Original document (Author Laura Adubra, approved by the LAKANA PSG on August 19, 2020.)

Standard Operating Procedures for the LAKANA trial

SOP No.: Title

Version No. (Date)

1. Purpose and overview:

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility

3. Required materials

Item	Number	Specification

4. Definitions and general instructions

5. Step-by-step procedures

6. Occupational Safety Issues

7. Quality Assurance / Quality Control

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