

Standard Operating Procedures for the LAKANA trial
SOP Admin-01: Communication
Version 1.0 (2020-03-29)

1. Purpose and overview:

The purpose of this SOP¹ is to ensure effective communication among LAKANA project stakeholders.

2. Applicability to and responsibilities of various staff members

The SOP applies to all personnel engaged in the LAKANA Trial research activities. All members are responsible for making sure that the communication protocol as outlined in this SOP is adhered to.

3. Required materials

Not applicable

4. Definitions and general instructions

4.1. Definitions

- 4.1.1. Stakeholder:** A stakeholder is an individual or a group that is directly or indirectly involved in trial-related activities, in addition to those that may have interests in the study or be affected by the results.
- 4.1.2. Communication material:** A communication material is the deliverable produced with the information that will be used for communication.
- 4.1.3. Channel:** The channel is the general means of transmission for a given communication / message.
- 4.1.4. Responsible party:** The responsible party is an individual or a group who has overall responsibility and accountability for ensuring that a given communication happens.

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, TAU= Tampere University, BMGF=Bill and Melinda Gates Foundation, PSG=Project Steering Group, TAG= Technical Advisory Group, NAC= National Advisory Committee, DSMB= Data Safety and Monitoring Board, RTI= Research Triangle Park, CVD-Mali=Center for Vaccine Development Mali, UCL= University College London, WP=Working Package, PI=Principal Investigator.

4.2. General instructions

- 4.2.1. The communication plan for the LAKANA project identifies the project stakeholders, describes the purpose of communication, and identifies the channels, frequencies and products for a given communication.
- 4.2.2. Stakeholders include the funder, sponsor, regulatory agencies, investigators, research institutions and universities, study participants, local communities, their representatives, national or local government authorities, the scientific community or members of the public.
- 4.2.3. The communication purpose outlines the specific objective of the information that will be communicated to stakeholders in relation to their roles and responsibilities.
- 4.2.4. The medium for sharing information will include four main channels
 - 4.2.4.1. E-mail: The LAKANA project coordinator at TAU will set up lists of e-mail addresses for the different working groups for the sharing of documents and information. The rules for e-mail use are established to avoid overload of e-mails. It will be the responsibility of each partner to ensure that relevant personnel are included in the mailing lists and to communicate any changes to the project coordinator at TAU. Individual e-mails will be addressed to targeted stakeholder(s) as needed.
 - 4.2.4.2. Face-to-face/online meetings: An <http://www.zoom.com> virtual meeting room will be used for accommodating online meetings. Face-to-face meetings will be organized as needed.
 - 4.2.4.3. Microsoft Teams and dropbox: Microsoft Teams and dropbox are cloud-based collaboration softwares which allow members to collaborate and share information in real-time. The LAKANA project coordinator at TAU will set up distinct channels on the Teams platform and dropbox for the different working groups. All working groups will have dedicated files. Members can attach and send files, comment on documents and send direct messages to each other, and manage group schedules through Teams and dropbox.
 - 4.2.4.4. Website: A website for the LAKANA Trial will be set up to share news and information with the scientific community and members of the public. The project coordinator at TAU will be responsible for website management.
- 4.2.5. Communication material will include meeting agenda, meeting minutes, reports and any appropriate deliverables in relation to the communication purpose.
- 4.2.6. The responsible party will facilitate communication with stakeholders and ensure that products are filed and/or disseminated to appropriate target groups.
- 4.2.7. The communication plan for the LAKANA project is built on a project governance structure (Appendix 1) that presents the key stakeholders in the project, their roles and responsibilities.

- 4.2.7.1. White rectangles depict the funder, sponsor, project steering group, external monitor, regulatory agencies, study participants and Malian interest groups.
- 4.2.7.2. Green rectangles depict the research institutions involved in the LAKANA project, and ovals depict their main responsibility. Research activities will be coordinated at a working package (WP) level under the responsibility of one or two institutions acting as WP leader(s). They will coordinate the work within the individual WPs in close collaboration with the participating WP partners. They will report WP progress to the PSG.
- 4.2.7.3. Blue rectangles depict WPs. A WP is a group of research-related tasks within the LAKANA project.

5. Step-by-step procedures

- 5.1. The project communication matrix is presented in Appendix 2

6. Occupational Safety Issues

None

7. Quality Assurance / Quality Control

None

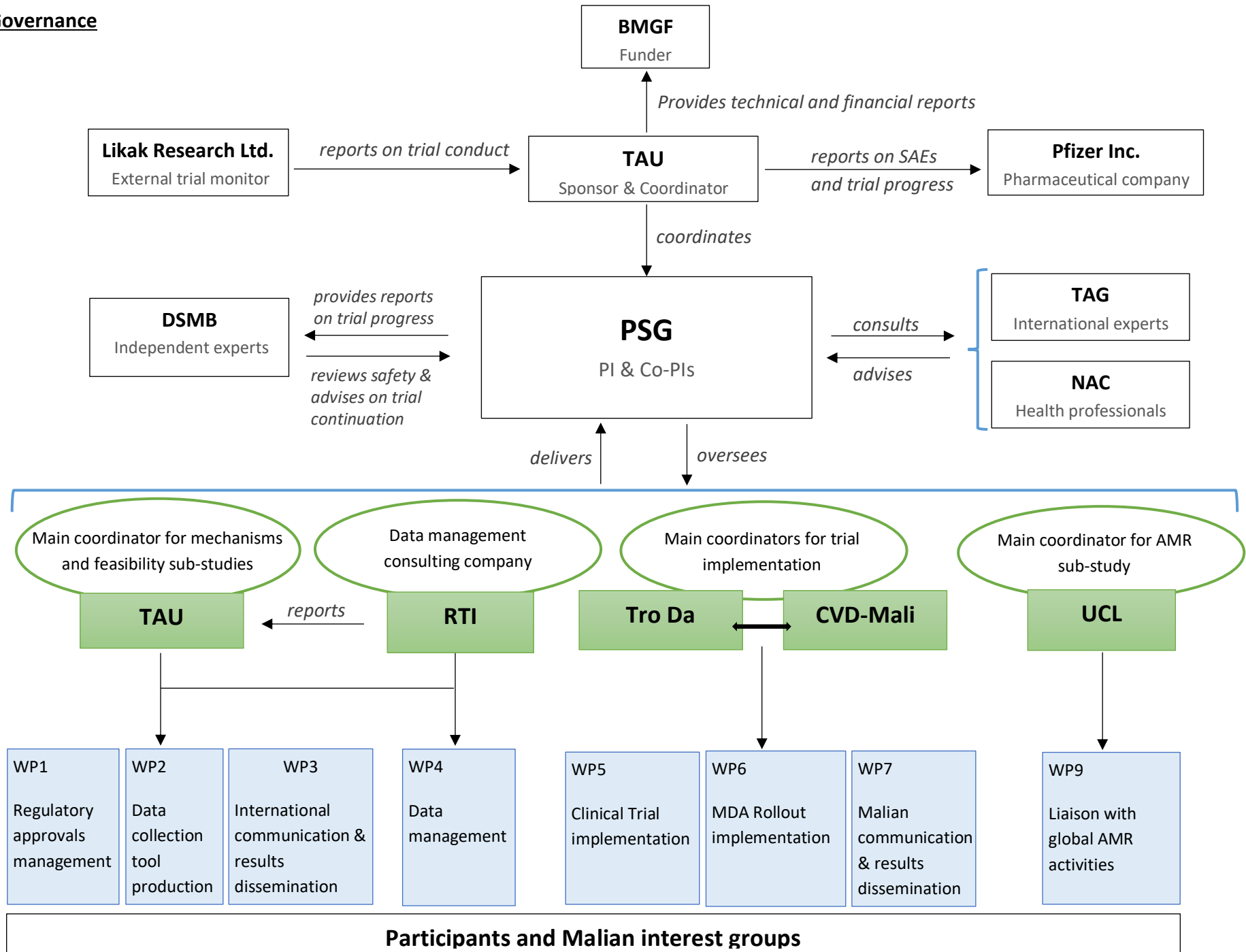
8. Appendices and other related documents

Document number	Document content
Appendix 1	Project Governance
Appendix 2	Communication matrix

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-03-29)	Original document (Author Laura Adubra, approved by the LAKANA PSG on April 1, 2020.)

Appendix 1: Project Governance



Appendix 2: Project Communication

Stakeholder	Communication purpose	Communication materials	Channels	Frequency	Responsible party
Bill & Melinda Gates Foundation	Updating program officer on trial progress	Statistical report on trial participant recruitment and success of follow-up	E-mail	Monthly	TAU
Bill & Melinda Gates Foundation	Official technical and financial reports to the funder	Technical and financial report on funder template	E-mail	Annual	TAU
Pfizer Inc	Report on study status: regulatory approvals, enrolment, publication plans, adjustments in study completion	Study status reports (<i>including copies of regulatory approvals</i>)	E-mail	Biannual	TAU
Pfizer Inc	Inform Pfizer of issues relating to imposition by Malian regulatory authority, and results of other Azithromycin-related trials	Reports	E-mail	As needed	TAU
Pfizer Inc	Enrolment update	Statistical report on trial participant recruitment and success of follow-up	E-mail	Monthly	TAU
Pfizer Inc	Serious adverse events (SAEs)	SAEs Reporting form	E-mail (Copied to Sponsor-PI)	Within 24 hours of Mali team becoming aware	CVD-Mali (Co-PI)
Pfizer Inc	Submit publication for Pfizer's review prior to submission or other public disclosure	Journal article/Abstract/Presentation/ Any type of public disclosure reporting study results	E-mail	As needed	TAU

Stakeholder	Communication purpose	Communication materials	Channels	Frequency	Responsible party
Pfizer Inc	Provide Study results to the donor of study drugs	Study report/Manuscript for publication	E-mail	Within six months of Study Completion	TAU
TAU (PI)	Discuss the reports of monitoring visits conducted on site	Agenda Meeting minutes	Online meeting	Monthly	Likak CEO
Members of the PSG	Discuss the project status including WP activities, progress, costs and issues	Agenda Meeting minutes	Online meeting	Weekly	TAU
Members of the DSMB	Discuss the protocol and the DSMB Charter including guidelines for monitoring the study	Meeting minutes	Online/Face-to-face meeting	Before trial onset	Members of the PSG
Members of the DSMB	Provide summary of trial progress, SAEs	Statistical report on trial participant recruitment, SAEs, and success of follow-up	E-mail	Monthly	TAU
Members of the DSMB	Facilitate interpretation of the interim analysis	Interim analysis results	E-mail	Once	TAU
Members of the PSG	Advice on trial continuation	DSMB meeting report and recommendation	Online meeting and Email	Bi-annual	Members of the DSMB
Members of the NAC	Discuss trial design, implementation strategy, trial conduct and progress, stakeholder interests and priorities	Meeting minutes	Face-to-face meeting	1-2 times a year	CVD-Mali - Tro Da
Members of local community	Share trial related information	Meeting minutes	Face-to-face meeting	Annual	CVD-Mali and Tro Da, with NAC

Stakeholder	Communication purpose	Communication materials	Channels	Frequency	Responsible party
Members of the TAG	Discuss trial design, implementation strategy, trial conduct and progress, DSMB reports and recommendations	Meeting minutes	Electronic or Face-to-face meeting	1-2 times a year	TAU and CVD-Mali
Members of the TAU team	Review WPs status and plan future activities	Agenda Meeting minutes Preparations file updated	Face-to-face meeting	Weekly	TAU
Members of the CVD-Mali - Tro Da team	Review WPs status and plan future activities	Agenda Meeting minutes Preparations file updated	Face-to-face meeting	Weekly	CVD-Mali - Tro Da
Members of the UCL team	Review WP status and plan future activities	Agenda Meeting minutes Preparations file updated	Face-to-face meeting	Weekly	UCL
RTI	Review Data management WP status and plan future activities	Agenda Meeting minutes	Online meeting	Weekly	TAU
Mali - District representatives	Launch the study	Agenda Meeting minutes	Face-to-face meeting	Once	CVD-Mali - Tro Da
Mali - CSCom representatives	Launch the study	Agenda Meeting minutes	Face-to-face meeting	Once	CVD-Mali - Tro Da
Mali - Village leaders	Launch the study	Agenda Meeting minutes	Face-to-face meeting	Once	CVD-Mali - Tro Da
Mali - Local communities	Launch the study	Agenda Meeting minutes	Face-to-face meeting	Once	CVD-Mali - Tro Da

Stakeholder	Communication purpose	Communication materials	Channels	Frequency	Responsible party
Mali - Local communities	Deal with rumours or any other community anxieties	Reports	Face-to-face meeting	As needed	CVD-Mali - Tro Da
Mali - Data collectors	Discuss trial activities, risks and feed back any issues to supervisors	Reports	Face-to-face meeting	Weekly	CVD-Mali - Tro Da
Mali - Data collection Supervisors	Discuss trial activities, risks and feed back any issues to central team in Bamako	Reports	Face-to-face meeting	Weekly	CVD-Mali - Tro Da
Members of CVD-Mali - Tro Da management working group	Meeting to review progress reports on enrolment and follow-up, discuss any problems encountered and plan activities for the subsequent week	Meeting minutes	Face-to-face meeting	Weekly	CVD-Mali - Tro Da
- Scientific community - Members of the Public	Share LAKANA trial information and news	Website content	Website		TAU
Mali local partners	Provide information about LAKANA Trial activities	Newsletter	E-mail	Bi-annually	CVD-Mali - Tro Da
Mali Ministry of health	Provide information about LAKANA Trial activities	Newsletter	E-mail	Bi-annually	CVD-Mali - Tro Da
Scientific community	Provide information about LAKANA Trial activities	Newsletter	E-mail	Bi-annually	TAU
Global AMR research community	Global AMR research community	As needed	As needed	As needed	UCL