

CONDUCTING PRE-TRIAL SENSITISATION ACTIVITIES

1. PURPOSE

This document describes the process by which DeWorm3 Project staff will plan for and execute pre-trial sensitisation activities with relevant study stakeholders, including personnel from relevant Ministries, study partners or advocates (e.g. non-government or civil society organisations) as well as local community leaders (e.g. village elders). These activities should occur at baseline, before implementing any trial activities, to encourage maximum support and engagement from these stakeholders.

2. INTENDED USERS

Site Trial Coordinators and other DeWorm3 site study staff responsible for planning and executing pre-trial sensitisation activities.

3. RESPONSIBILITIES

All DeWorm3 study staff and individuals involved in the planning and implementation of pre-trial sensitisation activities should understand and follow this SOP. It is the responsibility of the site's Principal Investigator (PI) to ensure that all relevant staff comply with this SOP.

4. DEFINITIONS

- 4.1. **Pre-trial sensitisation:** The process by which relevant study stakeholders are made aware of the DeWorm3 Project before trial activities begin. The purpose of pre-trial sensitisation is to maximize goodwill, support, and engagement.
- 4.2. **DeWorm3 Research Brief:** A one-page document outlining the key objectives, procedures and outcomes of the DeWorm3 Project.
- 4.3. **DeWorm3 Pre-trial Sensitisation National-Level Presentation Deck:** A deck of PowerPoint slides for use in sensitisation meetings with National down to sub-national (district/county/commune) level stakeholders. This is a base deck of slides standardized across all sites and can be extended and adapted by each site.
- 4.4. **DeWorm3 Pre-trial Sensitisation Sub-National-Level Presentation Template:** A deck of PowerPoint slides with sample header for sites to develop and use in sensitisation meetings with the district-level stakeholders.
- 4.5. **Pre-trial sensitisation tracking form:** A form to capture location, duration, attendance of all pre-trial sensitisation meetings.

5. REQUIRED MATERIALS

- 5.1. Site-adapted DeWorm3 Research Brief
- 5.2. DeWorm3 Pre-Trial Sensitisation National-Level Presentation Deck
- 5.3. DeWorm3 Pre-Trial Sensitisation Sub-National-Level Presentation Template
- 5.4. Pre-trial Sensitisation Tracking Form
- 5.5. Information, Education, and Communication (IEC) materials for community members

6. PROCEDURE

6.1. Purpose

- a. The purpose of conducting pre-trial sensitisation is to
 - i. Inform relevant stakeholders about the DeWorm3 Project
 - ii. Foster support for trial and implementation science activities
 - iii. Build trust and ensure open and transparent communication between the study team and relevant stakeholders
 - iv. Establish roles and responsibilities in the management or coordination of any shared study activities.

- b. Pre-trial sensitisation is aimed at providing an overview of the five-year project. However, activity-specific sensitisation will be performed prior to each trial-related activity, including details of activity objectives and procedures, to allay any concerns. Pre-trial sensitisation also introduces the first activity – the site-wide census.

6.2. Groups to be sensitised during pre-trial sensitisation:

- a. Pre-trial sensitisation activities will be conducted with:
 - i. Multilateral organizations, such as World Health Organization (WHO) country office personnel
 - ii. Government officials at various Ministries and administrative levels
 - iii. Non-governmental organizations (NGOs)
 - iv. Community-based organizations (CBOs)
 - v. Local community leaders / religious leaders
 - vi. Community members

6.3. Planning for activities – identifying stakeholders

- a. Before conducting any sensitisation meetings or distributing any materials, the site study team, led by the Trial Coordinator, should identify and make a list of the relevant stakeholders that must be informed about DeWorm3, including:
 - i. Personnel from relevant Ministries (e.g. Ministries of Health, Education, and Development) at each administrative level who have authority to approve the implementation of the study, have roles and responsibilities regarding trial and implementation science activities, or can serve as study advocates.
 - ii. Personnel in NGOs or CBOs or from the WHO country office who implement relevant community-based programmes in the same location as study sites or those who can serve as study advocates within the community and support social mobilization activities.
 - iii. Local community leaders (e.g. village elders), as they are gatekeepers to community participation.
 - iv. The community members themselves, to introduce the project and activities that will be undertaken over the next five years and allay any fears surrounding participation.
- b. It is the responsibility of the Trial Coordinator to develop the list of potential attendees for each sensitisation activity. The site PI should approve the final list of attendees.
- c. The identification of stakeholders for pre-trial sensitisation is distinct from the day-long stakeholder mapping workshop that will be held; however this list may be brought to the workshop to help inform formal mapping activities
- d. The stakeholder mapping document, if completed, may assist in this process as it outlines all the key stakeholders involved in the DeWorm3 Project.

6.4. Schedule of activities

- a. Pre-trial sensitisation activities should start taking place within two months of the start of the baseline census.
- b. These activities should be scheduled to accommodate other pre-scheduled meetings at each level of sensitisation to maximize attendance from relevant stakeholders.

6.5. Stages of pre-trial sensitisation

- a. National-level stakeholder sensitisation: This will be the initial sensitisation, with a meeting conducted, to which the relevant Ministries, NGOs and multilateral

organizations are invited. The standardized DeWorm3 Research Brief and National-Level Presentation Deck are available for adaptation and expansion and subsequent use at this meeting.

- b. State-level sensitisation: To be conducted after the National-level sensitisation and will involve key members of the state Ministries and other organizations working in the state. The adapted DeWorm3 Research Brief and National-Level Presentation Deck can be used for this meeting.
- c. Sub-National-level sensitisation: This will include district/county/commune-level officers from all relevant Ministries, who will be instrumental in facilitating the delivery of both the trial and the interventions. This will be a more in-depth meeting likely involving planning of activities, schedules and recruitment. The standardized DeWorm3 Research Brief and Sub-National-Level Presentation Template can be expanded to cover the additional details required to plan for the activities.
- d. Community-level sensitisation: This may be conducted by the field officers at a village/community level or cascaded down from the district/county/commune sensitisation conducted previously. Materials prepared by the sites for use at the community-level, such as simple research briefs in the local language, sheets of “Frequently Asked Questions”, picture boards, videos etc. may be used by the teams delivering the key messages in the communities.

6.6. Planning for activities – preparing site study staff

- a. Site study staff who will be responsible for facilitating sensitisation meetings must be well-informed about the Deworm3 Project, including its purpose, design, schedule of activities, and personnel roles and responsibilities.
- b. These staff members should carefully review and internalize the research brief, DeWorm3 pre-trial sensitisation presentation deck, and any other relevant study materials. The Trial Coordinator should host mock sensitisation sessions to allow staff to prepare for actual sensitisation meetings.

6.7. Conducting pre-trial sensitisation meetings

- a. It is the responsibility of the Trial Coordinator to manage all planning activities, including sending and managing invites, setting a location for sensitisation meetings, and ensuring that all materials are ready prior to the meeting.
- b. The following topics should be discussed during all levels of sensitisation meetings:
 - i. Background and purpose of DeWorm3
 - ii. Detailed explanation of trial design, including study arms
 - iii. Rationale for site locations
 - iv. Overview of clinical trial and implementation science activities, including timelines and any roles and responsibilities of meeting participants
 - v. Communications plan for establishing a channel to relay concerns or issues that arise during the course of the study
- c. For meetings with government officials, DeWorm3 meeting facilitators should ensure that all participants understand that non-study related deworming activities cannot occur in any cluster during DeWorm3 surveillance years.
- d. It is recommended that the site PI and/or Trial Coordinator attend or facilitate each sensitisation meeting at the level of the district/county/commune or above to ensure quality control of messaging.
- e. There should also be an additional site study team member present at the meeting to take notes and capture any questions or issues for further follow-up.
- f. After all pre-trial sensitisation meetings, a final report detailing the dates, attendance, and any questions should be drafted and submitted to the site PI for review and approval

and subsequently shared with the core DeWorm3 study team.

6.8. Monitoring pre-trial sensitisation meetings

- a. Site study staff will use the Pre-trial Sensitisation Tracking Form to document location, duration and attendance and reimbursements at the meetings at all stakeholder levels.
- b. This process, as well as being useful to document the coverage of sensitisation messages in the lead-up to the trial, is also necessary for the implementation science and cost-effectiveness work.

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