

## 3.5 Communications plan<sup>c</sup>

### 3.5.A. Definition

The communications plan describes policies and strategies that will increase broad awareness of the trial, facilitate dissemination and understanding of correct information about trial design, conduct, and results, and coordinate communication between the research team and relevant stakeholders.

### 3.5.B. Relevance to good participatory practice

Ongoing, transparent, and accurate communication with relevant stakeholders about proposed and ongoing research is essential for respectful, transparent relationships and builds trust among stakeholders. Additionally, consultation with relevant stakeholders will help research teams design communications strategies that are effective and help create a supportive and conducive environment for trial initiation and implementation.

### 3.5.C. Special considerations

The communications plan exclusively addresses external communication. However, effective internal communication, especially across multidisciplinary teams, is a prerequisite to attaining effective external communications.

### 3.5.D. Good participatory practices for communications planning

1. Research teams and relevant stakeholders comprehensively identify potential audiences within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams and relevant stakeholders discuss and negotiate a communications plan to support open channels

---

c Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

of communication about the trial throughout its life-cycle. The plan describes the following:

- a. The information needs of the different stakeholders at various stages of the research life-cycle, from early phases of stakeholder engagement to recruitment, enrolment, trial closure, and results dissemination.
  - b. The key messages to be communicated about the trial, such as the purpose, risks, benefits, ongoing progress, closure, and results dissemination.
  - c. The various communication methods that will be used for specific stakeholders, taking into account literacy levels and language needs.
  - d. Local stakeholders who could deliver or facilitate communications activities.
  - e. Specific training needs necessary to effectively deliver messages.
  - f. Procedures and timelines for disseminating information and procedures for actively addressing inquiries about the trial or HIV prevention research.
  - g. The frequency with which the communications plan will be reviewed.
  - h. The criteria by which to review the success of the communications plan.
3. Research teams develop communication materials in understandable language and translate them as needed, seeking input from relevant stakeholders.
  4. Research teams implement the plan and maintain clear written records of discussions, agreements, and communication activities. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues that require further follow-up.
  5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the communications plan.

### 3.5.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.<sup>28</sup>

## 3.6 Issues management plan<sup>d</sup>

### 3.6.A. Definition

The issues management plan describes how research teams intend to manage issues of concern or any unexpected developments that may emerge before, during, or after the trial, including those that could limit the support for, or success of, the specific trial or future biomedical HIV prevention trials.

Examples of the types of issues that may emerge are negative media coverage, rumours about the trial, socio-cultural taboos around certain trial procedures, developments in other HIV prevention trials, premature closure of a trial for reasons of harm, futility, or proven efficacy in interim analyses, recruitment challenges, or protocol issues.

### 3.6.B. Relevance to good participatory practice

The risk that unexpected developments will negatively affect a trial can be mitigated if research teams work closely with relevant stakeholders to identify and plan for such risks and if relevant stakeholders provide advice and direction on how to resolve issues when they do arise. By developing an issues management plan prior to trial implementation, research teams are better equipped to deal with issues or risks as they arise and are more likely to avert a crisis.

---

<sup>d</sup> Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

### 3.6.C. Special considerations

Research teams may find it helpful to participate in communications networks of biomedical HIV prevention trials to share and discuss emerging issues and their potential management.

### 3.6.D. Good participatory practices for issues management planning

1. Research teams identify and list all known issues that could emerge and undermine the success of the trial before, during, or after trial completion.
2. Research teams and relevant stakeholders discuss and negotiate an issues management plan to cover the life-cycle of the trial. The plan defines the following:
  - a. A site-level strategy to manage unexpected developments and emerging concerns.
  - b. Key trial site staff who are responsible for addressing emerging issues.
  - c. A chain of communication within the research team and with relevant stakeholders for emerging issues.
  - d. Relevant stakeholders who can act as advisers and help implement steps of the issues management plan.
  - e. Key messages created to address anticipated concerns.
  - f. Clear processes by which media reports and media requests will be addressed.
3. Research teams implement the plan and maintain clear written records of issues that emerge, how they are responded to, and their outcome.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the issues management plan.

### 3.6.E. Additional guidance

See *Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results*.<sup>28</sup>