a. Strategies and messages that are socially and culturally appropriate, meet the needs of specific stakeholders in terms of language and literacy, and draw on a range of communication modes, including written, oral, and visual.

b. Procedures to anticipate, monitor, and mitigate trial-related stigma resulting from ineligibility to enrol or from enrolment itself.

c. Procedures for training and supervising trial site staff on creating respectful relationships with participants and fostering an environment that is nonjudgmental and welcoming.

d. Strategies to ensure the confidentiality of participants during trial visits, while following up participants outside of the trial clinic, and after trial exit.

e. Procedures for informing participants about trial results and trial product assignment, when available.

f. Procedures for transfer of care at the end of follow-up or trial closure, such as providing participants with referrals to HIV counselling and testing and to other supportive services.

2. Research teams provide relevant stakeholders with ongoing updates on trial accrual, follow-up, and trial exit.

3. Research teams seek advice from relevant stakeholders on how to improve accrual, follow-up and exit processes, and messages.

4. Research teams maintain clear written records of discussions and agreements, as well as ongoing discussions about ways to modify strategies.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support stakeholder engagement in the development of locally acceptable trial procedures.

## 3.15 Trial closure and results dissemination

### 3.15.A. Definition

Trial closure occurs when all participants have exited from the trial and all trial procedures are completed. Results dissemination

involves dissemination of trial results to participants, community stakeholders, and the public at large, as well as the unblinding of participants to trial group or arm assignment.

## 3.15.B. Relevance to good participatory practice

Effectively engaging relevant stakeholders about trial closure and results dissemination in a transparent process is essential for building trust and lays a positive foundation for future research. In the event that a trial is stopped early or unexpectedly, research team-initiated dialogue with relevant stakeholders will minimise the risk of misinformation.

## 3.15.C. Special considerations

1. Trials may run to completion per protocol or may be stopped early. Reasons for stopping early may be evidence of a clear protective effect, evidence of harm, or evidence of futility. Trials may also stop early due to other unforeseen circumstances, such as administrative or financial reasons, local objection, or sudden social unrest.
2. In multicountry or multisite trials, sites may complete participant follow-up at different times. Thus, while some sites might be closed for participant follow-up, research teams at other locations may continue to see participants.
3. Where trial product manufacturers are publicly traded companies, there may be legal requirements that affect the timing and methods for public announcement of a trial closure.
4. Ownership of data, issues of publication, and release of trial results vary by trial and may be strictly delineated in non-negotiable terms by sponsors or product manufacturers.

## 3.15.D. Good participatory practices for trial closure and results dissemination

1. Research teams consult with relevant stakeholders early in the research life-cycle to develop a trial closure plan. The plan addresses a range of possible closure scenarios, including:
   a. Trial closure as scheduled per protocol.

b. Early closure due to evidence of harm, futility, or clear protective benefit in interim analyses of trial data.

c. Early closure because of evidence of harm or of clear protective benefit from a different trial evaluating the same product.

d. Early closure due to unforeseen circumstances, such as administrative or financial reasons, stakeholder objection, or sudden social unrest.

2. Research teams ensure that trial participants are provided opportunities to learn trial results before they are announced publicly.

3. Research teams consult with relevant stakeholders to develop a results dissemination plan, detailing the following issues:

a. Strategies to manage expectations about trial results, including by preparing participants and relevant stakeholders for all possible outcomes.

b. Planned timelines for trial closure at the site and at other sites, completion of data analyses, and availability of results.

c. Procedures and timelines for those who will be informed of trial results in confidence prior to public release and how results will be disseminated publicly.

d. Development and piloting of key messages, how the messages will be finalised when the results are known, and the range of communication methods to be used.

e. How the messages will explain implications of the results for the area where the trial was conducted, limitations of the trial, and its ability to generalise findings for specific aspects, such as by sex, behaviours, or location.

f. How best to disseminate trial results that may be of a sensitive nature or that may put certain individuals or groups at risk of harm or stigmatisation.

g. Procedures for contacting and informing trial participants of research results before they are announced publicly.

h. Whether and how to disseminate additional findings that are not related to the primary trial question but may be of interest to some stakeholders, such as reported patterns

of sexual networks, rates of various infections, or demographic data.

i. How and when participants will be informed of their trial group assignment.

j. How community stakeholder responses to the results will be systematically collected and documented. Although community stakeholder agreement may not be a prerequisite for publishing or sharing research in a scientific forum, it is important that community stakeholder interpretations be noted, particularly if they differ from predominant scientific analyses.

k. Issues around ownership of the data, data access, and publication, including how the research team will facilitate community stakeholder access to published results of the trial.

4. Research teams maintain clear written records of discussions regarding trial closure and dissemination messages, as well as documentation of responses to the results.

5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure comprehensive dissemination of results for participants, community stakeholders and other relevant stakeholders.

## 3.16 Post-trial access to trial products or procedures

### 3.16.A. Definition

The term "post-trial access to trial products or procedures" refers to making the prevention product or procedure tested in the trial available to trial participants and local community stakeholders (1) should the new product or procedure be scientifically validated or approved by relevant authorities, and (2) in the form of follow-on, open label, or other such studies before product licensure or approval, should an efficacy or effectiveness trial have a compelling positive finding, with no safety concerns.

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

Research ethics call for maximising benefits to stakeholders who participate in research. Thus, local community stakeholders are to be among the first to gain access to new prevention products should they be found safe and effective. How trial sites communicate and interact with community stakeholders about issues of access to the prevention product or procedure studied is likely to have a significant influence on community stakeholder perceptions of a trial.

### 3.16.C. Special considerations

1. Availability of newly identified products or procedures to trial participants and other community stakeholders will depend on the biomedical HIV prevention strategy being tested.
2. After a trial is completed, other trials may be needed to corroborate findings.
3. After results from relevant trials are available, it may take time for normative agencies and appropriate regulatory authorities, including national governments, to approve the new product or procedure. Approval processes and timelines will differ by product or procedure and by country.
4. National regulatory authorities make the ultimate decision about whether a new product or procedure will be approved for use within a particular country.
5. Availability and pricing of new products or procedures may be affected by product-manufacturer parameters as well as by agreements with trial sponsors.

### 3.16.D. Good participatory practice practices for post-trial access to trial products or procedures

1. Research teams discuss with relevant stakeholders, early in the trial process, issues affecting future product or procedure availability, including the need for corroborated biomedical evidence, pursuit of licensure, production rights, and additional marketing and distribution research.

2. Trial funders, sponsors, and research teams conducting efficacy or effectiveness trials discuss with relevant stakeholders, early in the trial life-cycle, expectations about possible pre-licensure access, plans for follow-on, open label, or other such studies, and how such pre-licensure access will be funded, in the event that a compelling positive result, with no safety concerns, is observed.
3. Trial sponsors and research teams discuss, negotiate, and agree on responsibilities and funding requirements with national governments concerning licensure requirements and access issues, should the HIV prevention product or option under investigation be shown to be safe and effective.
4. Trial sponsors and research teams develop a clear strategy and funding mechanisms for how the HIV prevention product or procedure will be made available to participants (at a minimum) rapidly, affordably, and sustainably, should the HIV prevention product or procedure be shown to be safe and effective. Sponsors and research teams can collaborate with multiple stakeholders, such as UN organisations, development partners, local governments, and non-governmental organisations to design and support the overall access strategy.
5. Research teams inform community stakeholders of their rights, the access plan, and the factors that could postpone or prevent their gaining access to the new prevention product or procedure, such as the need to secure regulatory approvals or parameters related to the product manufacturer. Research teams give community stakeholders updates as they are available.

## 3.16.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 19, page 60, Availability of Outcomes).[1]
2. *Rethinking the Ethical Roadmap for Clinical Testing of Microbicides: Report on an International Consultation* (Chapter 10, After the trial: continued access and post-approval studies).[37]
3. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Recommendation 4.1).[38]