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9 DATA ACCESS, PUBLIC RELEASE AND COMMUNICATIONS

This section describes the policies and procedures regarding access to and release of data that is collected as part of a Microbicide Trials Network (MTN) study, and outlines the policies and procedures for the communication of study results, outcomes of interim study data and safety reviews and other study-related milestones.

9.1 Policy on Access to Study Data

The central database for the majority of the studies conducted by MTN resides at the Statistical and Data Management Center (SDMC). This database includes case report form (CRF) data, Audio/Computer Assisted Self-Interview (ACASI/CASI) data, the results of protocol-specified laboratory analyses, and ancillary study data.

9.1.1 Release of Data During a Study

9.1.1.1 Release of Site-Specific Study Data to Study Sites

The SDMC is responsible for releasing site-specific study data to Clinical Research Sites (CRS) participating in that study when appropriate and when resources are available. Publication and presentation at conferences of site-specific data is generally done in collaboration with the SDMC, as described in Section 6 of this manual. As part of each study’s Protocol Publications
Committee (PPC), the SDMC reviews all abstracts and manuscripts that contain or report on data collected by the SDMC.

9.1.1.2 Safety Studies
In Phase I, Phase II and Phase IIa studies, the primary objective is to provide an early assessment of participant safety. In these phases, a site can access most of the data that it submits during the study. For blinded studies, data are provided in a blinded fashion.

9.1.1.3 Clinical Effectiveness Studies and Comparative/Observational Studies
In Phase IIb, Phase III and Phase IIIb studies, the primary objectives are (i) to assess clinical effectiveness and (ii) to obtain greater insight about acceptability and safety. In such studies, most site-specific data collected from participants prior to randomization may be released to the site during the study, but data that are collected after randomization will not be released during the study.

A comparative or observational study with prospective data collection is handled in the same way as a Phase IIb or Phase III study.

9.1.1.4 Other Studies
For non-comparative cohort studies, natural history studies and comparative studies with retrospective data collection (for example, case-control), all data submitted from a site may be released to that site during the study.

9.1.1.5 Data Not Available During a Study (Regardless of Study Type)
Some categories of data will not be available to the protocol team (including study sites) during the study, regardless of study type. These data types include the following:

- Coding (for example, by MedDRA) of adverse events or concomitant medications
- Non-CRF laboratory data (that is, laboratory data that are sent directly to the SDMC from one of the laboratories that is affiliated with the MTN Laboratory Center [LC])
- Non-CRF data captured electronically (for example, ACASI/CASI)
- Non-CRF data with participant identifiers where the participant has an expectation of confidentiality (for example, in-depth interview data)
- For randomized studies, data that could potentially lead to unblinding unless approved by the MTN Protocol Chair(s) and Protocol Statistician

9.1.2 Release of Data after Completion of a Study
9.1.2.1 Release of Data to MTN Investigators
After completion of the last protocol-specified study visit, the SDMC may host a confidential meeting for the protocol, either in-person or via teleconference, to report the results of the primary analyses. The meeting may occur prior to locking the study database, but the relevant data should be clean; that is, stable enough that the results are not expected to change between the time of the meeting and the time of database lock. Ideally, and dependent upon SDMC recommendation, the meeting should occur prior to data being publicly presented at a scientific meeting and/or published. Participation in these confidential meetings is generally limited to the following:

- The study sponsor
• The MTN Principal Co-Investigators (Co-PIs)
• The MTN Protocol Chair(s)
• The Clinical Trials Unit (CTU) PIs and/or Investigators of Record (IoR) from participating CRSs
• The Protocol Statisticians
• Members of the study management team
• The protocol’s Community Working Group (CWG) representative

For Phase I, II, and IIa studies, the MTN Leadership and Operations Center (LOC) in consultation with the Protocol Chair(s) and the Protocol Statistician(s) will develop and make the final determination regarding who may participate in the meeting.

For Phase IIb or higher trials, the Protocol Chair(s), in conjunction with the MTN Network Co-PI(s), the Director of Communications and External Relations, and DAIDS will develop the list of meeting participants. The Protocol Chair(s) and Protocol Statistician, in consultation with the MTN SDMC PI (or designee), make the final determination regarding who may participate in the meeting.

All participants may be asked to sign a confidentiality agreement asking them not to disclose the results shared at the meeting until such time that the data are publicly presented at a scientific meeting and/or published. The SDMC PI (or designee) makes the final determination regarding whether a confidentiality agreement must be in place for the meeting.

Site-specific data sets, as well as the complete study data set, may be released to CTU and/or CRS investigators who contribute data to a study after the following:

• The study database has been cleaned and locked by the SDMC.
• All manuscripts reporting results of the protocol’s primary and secondary objectives have been accepted for publication.
• Resources have been identified to allow the SDMC to prepare the requested data.

To release the data to interested MTN CTU and/or CRS investigators, the Protocol Chair(s) or designee (MTN LOC [FHI] 360 Clinical Research Manager [CRM]) must confirm and communicate to the Protocol Statistician and MTN Co-PIs that the team has published all intended manuscripts of the protocol’s objectives.

9.1.2.2 Release of Data to Other Institutions

Generally, no study data or interim analysis reports may be released by the SDMC to other institutions during the conduct of the study. When applicable, release of data and/or data reports to the study’s Investigational New Drug (IND) Sponsor and/or Product Developer either during or after study completion, is governed by the terms set forth in the study-specific Clinical Trials Agreement (CTA). Exceptions noted in the protocol will be negotiated among National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS), the Protocol Chair(s) and the SDMC.

Any request to release data or data reports to other institutions or investigators during a study requires the approval of the protocol team in consultation with NIAID/DAIDS and, when applicable, the National Institute of Mental Health (NIMH) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). Please refer to Section 19.3, “Request for Datasets” for additional information.
9.1.3 Preparation and Release of Final Study Data Reports/Tables

The SDMC is responsible for preparing final study data tables that address the objectives of the protocol. For Phase I, Phase II and Phase IIa studies, the final study data tables will be provided in the form of a Final Study Data Report. This data report will include data tables as well as a data narrative to explain the tables (similar to a Study Monitoring Committee [SMC] Report).

For Phase IIb, Phase III or Phase IIIb studies, in which a closed results meeting may occur prior to public release of any study results, it may be that only final data tables are provided, with no accompanying data narrative. Regardless of whether a Final Study Data Report or final study data tables are generated, there is a specific review and approval process that must occur prior to the release of these documents (see Figure 9.1).

Figure 9.1 Review Process for Final Study Data Tables and Reports

Draft Study Data Report/Tables created by the SDMC

Draft reviewed by DAIDS, Protocol Chair(s) and, when applicable, NIMH and NICHD

Data Report/Tables finalized and provided to the Protocol Chair(s), DAIDS Medical Officer (MO), LOC (University of Pittsburgh [Pitt], and when applicable, the IND Sponsor and/or Product Developer

9.1.4 Reporting Gender, Race and Ethnicity

The MTN collects gender, race and ethnicity information of its study participants, in compliance with NIH requirements (1997 OMB Directive 15). This requirement applies to all new applications and proposals, annual progress reports, competing continuation applications, competing supplement applications for research grants and contracts, and intramural projects as of January 10, 2002.

9.1.5 Blinded Data

MTN’s randomized studies typically are double-blinded, which means neither study participants nor study-site staff have access to specific treatment assignments. Participants are blinded to reduce the chance that they may alter behaviors (such as those that could increase their HIV-exposure risk) based on knowledge of their treatment assignment. Study-site staff, including clinical and laboratory study staff members, are blinded to avoid bias in their clinical and laboratory assessments. Only the CTU/CRS Pharmacists, MTN Director of Pharmacy Affairs, DAIDS Protocol Pharmacist (if applicable), Protocol Statistician(s) and SDMC Project Manager(s) may have limited access to the randomization assignments. All SDMC MTN Statisticians may have access to unblinded treatment assignments for each MTN study. Typically, members of a study’s independent Data and Safety Monitoring Board (DSMB) have limited access to unblinded treatment assignments.
9.1.5.1 Formal Protocol Unblinding

Unblinding of participants and study-site staff occurs only after the Protocol Chair(s), NIAID, study co-sponsor and the SDMC have approved the decision to unblind the study. As a rule, unless otherwise requested by the DSMB, a study is not unblinded until after the study database has been locked. In a multicenter study with geographically separated study sites, unblinding may occur on a site-by-site basis after the study database has been locked.

Prior to formal unblinding, the SDMC notifies all parties of the intention to unblind the study. After approval, the SDMC provides each study site with a list of participants’ identification numbers and their respective treatment assignments.

Participants who complete the study prior to the formal unblinding must wait until the study is unblinded to be informed of their treatment assignments. This policy should be made clear to participants at the time of recruitment and when they exit the study. While the manner in which participants are unblinded is at the discretion of the site IoR, it is recommended that unblinding take place in person.

9.1.5.2 Emergency Unblinding

If the site IoR or designee determines that a participant has sustained an event that necessitates unblinding, the site IoR or designee may request that the SDMC reveal the participant’s study treatment assignment. Until unblinded product assignment information is received from the SDMC, the participant’s clinical management should proceed as if the participant were assigned to active study product. The need for emergency unblinding is expected to be rare.

To request unblinding for a specific participant, the following steps must be taken:

1. The site IoR or designee requesting the unblinded treatment assignment must contact the Protocol Safety Review Team (PSRT).
2. If the PSRT rules that unblinding is required, the PSRT will send the unblinding request to the Protocol Statistician and copy the site IoR or designee. The MTN Co-PIs should also be copied on this request.
3. The Protocol Statistician will provide the participant’s treatment assignment directly to the site IoR or designee.
4. In a separate email, the Protocol Statistician will notify the MTN Co-PIs, the DAIDS MO, the protocol management team and Protocol Chair(s) and the Fred Hutchinson Cancer Research Center’s (FHCRC) Institutional Review Board (IRB) responsible for the SDMC that the treatment information has been provided.
5. The site IoR or designee must notify – in an expedited manner – all responsible IRBs/Independent Ethics Committees (IEC) for the site that unblinding has occurred.

9.1.5.3 Accidental Unblinding

Should an accidental unblinding occur at a trial site by any mechanism, the site IoR must notify the SDMC Clinical Data Manager, the MTN Director of Pharmacy Affairs and the DAIDS Protocol Pharmacist, if applicable. The SDMC Clinical Data Manager notifies the Protocol Statistician, Protocol Chair(s), DAIDS MO, MTN Co-PIs, and the FHCRC IRB.
9.1.5.4 Protocol Extension and Unblinding

In the event that a study is extended, the MTN Executive Committee may decide to inform participants who do not participate in the extension of their treatment assignment after they have completed their study follow-up. In this situation, any participants who are not involved in the extension should be unblinded by a staff member who is not involved in the follow-up of participants in the extension.

9.1.5.5 Unblinding IND Sponsor/Product Developer

Once the decision is made to unblind study participants, the SDMC will, upon the IND Sponsors’ and/or Product Developers’ request, provide them with a list of the participants’ identification numbers and their respective treatment-arm assignments. If an IND Sponsors and/or Product Developer needs to know treatment-arm assignments earlier to interpret laboratory analysis of specimens, he or she should petition the SDMC PI and Protocol Chair(s) for release of that information.

9.2 Public Dissemination of Study Results

The public dissemination of study results provides an opportunity to share findings that could influence the standard of care in the communities served by MTN or the design and/or conduct of ongoing or future HIV-prevention studies. NIAID, and, when applicable, NIMH and NICHD, are responsible for determining the manner and timing in which results are shared with study participants and local communities as well as publicly disseminated. They also ensure that the process meets the terms of a study’s specific CTA. Planning is coordinated with the MTN LOC (Pitt) MTN Communications and External Relations Team, Protocol Chair(s), MTN Co-PIs, the MTN LOC (FHI 360) CRM for the study and others at the discretion of NIAID. For Phase IIb, Phase III and Phase IIIb trials in particular, the MTN LOC (Pitt) Communications and External Relations Team works with the CTUs and CRSs to develop site-specific results dissemination plans that are in keeping with the overall strategy and timelines set by NIAID, and provide guidance and technical support throughout the planning and dissemination process.

Scientific peer-review of results is an integral part of the research process. Results that are reported in a peer-reviewed journal or at a scientific meeting have more credibility. The MTN Publication Policy (described in Section 6 of this manual) is designed to be flexible and to facilitate the rapid and accurate dissemination of MTN study results.

When the results of a study are being reported in a peer-reviewed journal or at a scientific meeting, the specific timeline for public dissemination of the results is determined according to the embargo policies of the journal and/or meeting. For studies conducted under a CTA with an IND Sponsor and/or Product Developer, the publication guidelines and procedures described in the CTA must be followed. In case of specific points of discordance between CTA requirements and this policy, the CTA requirements should be followed.

Results should be accurately and comprehensively disseminated in a timely, well-controlled fashion. Results should be released first to study investigators, host-country officials, sponsoring-industry collaborators, study communities, key stakeholders and study participants; then to the news media and the general public, or simultaneously to all. In studies with non-U.S. sites, particular care is taken to coordinate the release of results with appropriate in-country officials and local communities.
The following section, and Section 9.3.4 in particular, provides additional information on planning for and the communication of study results.

9.3 Communications and Public Release of Information

The MTN LOC (Pitt) Communications and External Relations Team, in conjunction with the NIAID Office of Communications and Government Relations (OCGR) and DAIDS Workforce Operations, Communications and Reporting Branch (WOCRB), are responsible for planning and overseeing all MTN external communications. As such, the MTN LOC (Pitt) Communications and External Relations Team develops and coordinates network-wide communications strategies and media relations. The team supports the communications and media relations efforts of CTUs and CRSs by developing and providing relevant training, materials and related services. These activities are conducted cooperatively with NIAID, and, when applicable, NIMH and NICHD.

The MTN LOC (Pitt) Communications and External Relations Team’s specific responsibilities include the following:

- Developing communications plans and strategies for MTN studies and announcements
- Developing messages around studies and sensitive issues or events, often in collaboration with key partners
- Ensuring that CTUs/CRSs have up-to-date communications policies and adequate procedures for dealing with the news media
- Ensuring the accurate and timely dissemination of relevant information to news media, advocacy groups, civil society and other key stakeholders
- Working with DAIDS, OCGR and other stakeholders, as appropriate, to develop proactive plans for responding to communications crises or breaking news
- Preparing news releases, fact sheets, backgrounders, Web content and other materials intended for external audiences
- Advising and/or supporting regional and site-specific investigators, staff and community representatives in the development of press statements or talking points pertaining to potentially sensitive or problematic issues affecting the field
- Planning and conducting consultations with community stakeholders, civil society and advocates to address key questions related to the design and implementation of specific protocols and future research endeavors
- Cultivating relationships with and representing MTN’s interests to civil-society groups, HIV/AIDS-treatment activist organizations and HIV-prevention advocacy organizations
- Cultivating relationships with key journalists and keeping them abreast of MTN’s activities and other developments related to microbicides and HIV-prevention research
- Maintaining consistent communication through social media outlets to keep stakeholders up-to-date on MTN activities and study results

9.3.1 Disclosure of Study-Related Information to News Media and Other External Audiences

Protocol teams and CTU/CRS staff, as well as staff of the MTN LOC, LC, SDMC and members of MTN working groups and resource committees, may have access to proprietary and sensitive information as a result of their participation in MTN studies. The following guidelines relate to disclosure of product- and study-related information to the public and are in keeping with the policies and procedures of the DAIDS WOCRB and the NIAID OCGR.
Investigators may not provide comments to the press, community groups or other external audiences that relate to study outcomes, study participants or adverse events without first obtaining approval from the Protocol Chair(s) and the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations. Neither may investigators discuss or publicly release information about proprietary study products that are not yet FDA approved for the indications being evaluated in the study without the explicit (written) permission of the IND Sponsor and/or Product Developer.

Study investigators may address inquiries from the press, community representatives and public officials concerning general study issues in accordance with site-level communications policies and procedures developed in consultation with the MTN LOC (Pitt) Communications and External Relations Team. Press inquiries about MTN should be referred to the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations, who will coordinate an appropriate response with NIAID’s OCGR, if necessary.

Requests by news media to interview study participants are handled according to the discretion of site investigators. Separate informed consent is required, in keeping with site-level communications policies and procedures developed in consultation with the MTN Communications and External Relations Team.

9.3.2 Crisis Communications

The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations must be notified about any urgent situation that could significantly affect an MTN site or study. In the event of a real or potential crisis or breaking news, the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations is responsible for notifying all parties and managing the response in consultation with the MTN Co-PIs, DAIDS Program Leadership, WOCRB, OCGR and, as appropriate, NIMH and NICHD Program Leadership. If necessary, responses will be developed in collaboration with additional MTN LOC leadership and site and/or study investigators. All CRSs should have a designated crisis communications team, which may include the CTU PI, the CRS leader, the site IoR, the designated media contact and others.

9.3.3 Review and Approval of Press Releases and Related Materials

The development of all press releases, statements and materials is coordinated by the MTN LOC (Pitt) Communications and External Relations Team.

Press releases related to MTN studies are reviewed by the DAIDS Program Officer (PO); DAIDS MO; WOCRB; OCGR; and, when applicable, NIMH and NICHD program leadership and their respective communications office or news and public information branch. The Protocol Chair(s) and the MTN Co-PIs must approve study-related press releases and materials prior to NIH review (see Figure 9.2). In some circumstances, review will occur simultaneously.

MTN press releases for studies that are conducted under a CTA with an IND Sponsor and/or Product Developer (study co-sponsor[s]) must also be reviewed by the co-sponsor(s) in accordance with the terms of the CTA. NIAID/DAIDS is responsible for ensuring that the specific terms of a CTA are met; although, the review process may be coordinated by the DAIDS PO, DAIDS MO, NIAID’s OCGR or the MTN LOC (Pitt) Communications and External Relations team.
General (non-study specific) MTN press releases and materials are reviewed and approved by the MTN Co-PIs and the DAIDS PO and MO, as appropriate. A review by the NIAID OCGR NIH is not required (see Figure 9.3).

The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations must review press releases generated by MTN CTUs/CRSs, organizational units or study co-sponsors to ensure the accuracy of information and proper identification of MTN, NIAID and other funding sources. As necessary, the MTN LOC (Pitt) Communications and External Relations Team will coordinate additional reviews by NIAID, and, when applicable, NIMH and NICHD (see Figure 9.4). NIAID/DAIDS and the OCGR must review co-sponsor press releases that involve studies for which CTAs are in place.

All press releases, statements and public announcements must properly acknowledge that MTN activities are performed in cooperation with NIAID, and, when applicable, NIMH and NICHD. The appropriate Award Number must also be included, although this information is not required to be in the actual text of a press release.

Figure 9.2  MTN Study-Related Press Releases

Figure 9.3  General MTN Press Releases and MTN Statements
Table 9.1 shows the NIAID/DAIDS review process for different types of communications materials. The NIMH and/or NICHD leadership and communications offices review study-related materials, when applicable. The MTN LOC (Pitt) Director of Communications and External Relations ensures that these guidelines are followed.

Table 9.1 NIAID/DAIDS Communications Review Process

<table>
<thead>
<tr>
<th></th>
<th>DAIDS MO/PO Review</th>
<th>DAIDS WOCR Review</th>
<th>NIAID OCGR Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTN study press release (for example, launch or results)</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>MTN general release, statement (about another study)</td>
<td>YES</td>
<td>For information only</td>
<td>For information only</td>
</tr>
<tr>
<td>MTN study Questions and Answers (Q&amp;A)</td>
<td>YES</td>
<td>For information only</td>
<td>YES</td>
</tr>
<tr>
<td>MTN study fact sheets and backgrounders</td>
<td>YES</td>
<td>For information only</td>
<td>For information only</td>
</tr>
<tr>
<td>General topic and MTN fact sheets and backgrounders</td>
<td>For information only</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>News release templates for sites</td>
<td>YES</td>
<td>For information only</td>
<td>For information only</td>
</tr>
<tr>
<td>Internal Q&amp;A on MTN study or NIAID-funded study</td>
<td>YES</td>
<td>For information only</td>
<td>YES</td>
</tr>
<tr>
<td>Internal Q&amp;A on other studies</td>
<td>YES</td>
<td>For information only</td>
<td>For information only</td>
</tr>
<tr>
<td>Facts sheets on other studies</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Scenarios and messages documents</td>
<td>YES</td>
<td>For information only</td>
<td>YES</td>
</tr>
<tr>
<td>“Dear Colleague” letter</td>
<td>YES (MO only)</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>
9.3.4 Communications Planning for Release of Study Results

As indicated in Section 9.2, NIAID has overall authority for determining the manner and timing in which results are publicly disseminated. The MTN LOC (Pitt) Communications and External Relations Team in turn works closely with the NIAID OCGR and DAIDS WOCRB in the development of coordinated communications plans that meet requirements of CTAs and/or news embargo policies, should they exist. For large and/or high-profile trials, such as Phase IIb, Phase III and Phase IIIb studies, the MTN LOC (Pitt) Communications and External Relations Team works directly with CTUs and CRSs on the development of site-specific plans. As part of this process, CTUs/CRSs are required to complete a Communications Plan Template and make updates to their Stakeholders Directories and Media Relations Standard Operating Procedures. For other studies, protocol team leadership will consult with the MTN LOC (Pitt) Communications and External Team, the LOC (FHI 360) CRM, and as appropriate, others within the LOC, to determine the most suitable process for disseminating results.

For some studies, site communications plans must consider several different results scenarios so that trial sites are adequately prepared for the actual results. While the site’s IoR may have been unblinded to the study’s results (see Section 9.1.2.1), others at the site may not be unblinded until shortly before public release, even if they are intimately involved in communications planning and preparedness. Effort is made to provide ample notice to key site staff; although, how far in advance public release can occur depends on the CTA agreement, embargo restrictions and considerations specific to the situation. The MTN LOC (Pitt) Communications and External Relations Team works to ensure that site communications plans still allow for the timely dissemination of results so that study participants, CAB members; and key stakeholders, such as regulatory authorities, are among the first to know.

Subject to NIAID approval, communications plans may allow a small number of select individuals to be briefed in advance of the lifting of the embargo, provided they sign confidentiality disclosure agreements.

When study results are to be published or presented at a scientific meeting, the MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations will work with OCGR to coordinate press announcements with the authors and the peer-reviewed journal or scientific meeting organizer, in keeping with relevant embargo policies.

9.3.5 Communications Planning for Data and Safety Monitoring Board Reviews

The NIAID has overall responsibility for the public release of information following DSMB reviews of MTN studies. When a NIAID press release or public statement related to a DSMB review is required, DAIDS and NIAID communications staff develop these materials in consultation with the DAIDS PO and MO, the MTN LOC (Pitt) Director of Communications and External Relations Team, the MTN Co-PIs, the study Protocol Chair(s) and others. The MTN LOC (Pitt) Communications and External Relations Team and LOC (FHI 360) CRM of the study ensure that each study site and investigator is adequately prepared in advance of DSMB reviews. As needed, the LOC (FHI 360) CRM helps the MTN LOC (Pitt) Communications and External Relations Team coordinate the implementation of appropriate communications strategies, including dissemination of statements, at the site level. The LOC (FHI 360) Community Program Manager (CPM) helps to facilitate communication with the study-specific CWG.

At least eight weeks prior to a scheduled DSMB review, the LOC (FHI 360) CRM for the study, in consultation with the Protocol Chair(s), Protocol Statistician, DAIDS PO and MO, and the MTN LOC (Pitt) Director of Communications and External Relations prepares a draft Schedule
of Events, a timeline and planning document for DSMB’s review. Concurrent with this activity, the MTN LOC (Pitt) Director of Communications and External Relations prepares a Communications Plan Task List in coordination with the OCGR and WOCRB.

The MTN LOC (Pitt) Director of Communications and External Relations prepares a document with the most probable DSMB review-outcome scenarios with input from the DAIDS PO and MO, Protocol Chair(s), Protocol Statistician, LOC (FHI 360) CRM for the study and MTN Co-PIs. The scenarios document, draft messages and other supporting materials, such as背景ders or Q&A documents are provided to sites in advance of the DSMB review. The MTN LOC (Pitt) Director of Communications and External Relations prepares materials for the study in consultation with DAIDS leadership, WOCRB, OCGR, the Protocol Chair(s) and the LOC (FHI 360) CRM.

The OCGR, in consultation with the WOCRB, the DAIDS PO and MO and the MTN LOC (Pitt) Director of Communications and External Relations, prepares draft statements and Q&A documents for the press. Only the OCGR may issue an official statement or press release on behalf of NIAID concerning an NIAID DSMB review of an MTN study. All NIAID press releases and public statements must undergo standard review with clearance granted by the Office of the Director, NIAID; Office of the Director, NIH; and the U.S. Department of Health and Human Services (DHHS). NIAID is under no obligation to provide protocol team members with NIAID draft press releases/statements in advance of their official release, but confidential drafts may be provided in special circumstances. The process for reviewing MTN press releases or statements about DSMB outcomes is described in Table 9.2.

Immediately following each DSMB review, the Director of DAIDS communicates the DSMB’s recommendation to the Director of NIAID, who decides whether to adopt the recommendation. NIAID and MTN then proceed with the planned communications activities for the actual DSMB review outcome. The general communications process is described in Table 9.2.

Study sites and study co-sponsors may not issue their own press releases or public statements prior to NIAID’s press release or published statement. When a co-sponsor(s) is a publicly traded company on either a U.S. or foreign exchange, NIAID and the co-sponsor(s) will coordinate the release of statements in accordance with public disclosure requirements. The MTN LOC (Pitt) Director of Communications and External Relations must review and approve press releases or statements regarding a DSMB review outcome that are developed by a study site or study co-sponsor(s). (See Figure 9.4.) Review and approval of co-sponsor press releases is coordinated by the NIAID OCGR, in conjunction with the DAIDS PO and MO, the MTN LOC (Pitt) Director of Communications and External Relations, the Protocol Chair(s) and/or other designated protocol team members, as appropriate.

Certain situations require MTN and NIAID to coordinate DSMB planning activities with the co-sponsor(s) of the MTN study and/or another trial evaluating the same product. Coordinated communications planning is especially important when an MTN DSMB review is scheduled at or around the same time of a review of another study. On communications matters, the NIAID OCGR, in conjunction with the MTN LOC (Pitt) Director of Communications and External Relations, will determine the terms of engaging in joint or coordinated planning with the communications representative of the other study and/or co-sponsor.
Table 9.2 General MTN Communications Process for DSMB Reviews

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsible Party</th>
<th>Timeline</th>
</tr>
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<tbody>
<tr>
<td><strong>Prior to DSMB Review</strong></td>
<td></td>
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</tr>
<tr>
<td>Prepare draft “Schedule of Events”</td>
<td>LOC (FHI 360) CRM for the study, in consultation with Protocol Chair(s), Protocol Statistician and the MTN LOC (Pitt) Director of Communications and External Relations. Reviewed by the DAIDS MO and PO, MTN Co-PIs, NIAID OCGR, and DAIDS WOCRB</td>
<td>At least 8 weeks in advance</td>
</tr>
<tr>
<td>Prepare communications plan tasks list</td>
<td>The MTN LOC (Pitt) Director of Communications and External Relations, in consultation with the DAIDS WOCRB and NIAID OCGR. Reviewed by the study LOC (FHI 360) CRM, Protocol Chair(s) and the DAIDS MO and PO</td>
<td>At least 8 weeks in advance</td>
</tr>
<tr>
<td>Draft possible outcome scenarios and messages</td>
<td>The MTN LOC (Pitt) Director of Communications and External Relations, in consultation with the DAIDS PO and MO, Protocol Chair(s), the Protocol Statistician, the study LOC (FHI 360) CRM and the MTN Co-PIs. Reviewed by OCGR and WOCR.</td>
<td>At least 7 weeks in advance</td>
</tr>
<tr>
<td>Communicate with study sites about the general plan and timeline</td>
<td>The study LOC (FHI 360) CRM and MTN LOC (Pitt) Director of Communications and External Relations.</td>
<td>At least 6 weeks in advance</td>
</tr>
<tr>
<td>Distribute documents to study sites (for example, pre-review “Dear Colleague” letter for IRB/ECs and CABs; Study Q&amp;A, fact sheet, backgrounder; scenarios and messages)</td>
<td>The MTN LOC (Pitt) Director of Communications and External Relations and the study LOC (FHI 360) CRM.</td>
<td>At least 5 weeks in advance</td>
</tr>
<tr>
<td>Work with study sites to complete communication plans and “Stakeholders Directories”</td>
<td>MTN LOC (Pitt) Director of Communications and External Relations.</td>
<td>At least 3 to 5 weeks in advance</td>
</tr>
<tr>
<td>NIAID prepares and obtains approval of holding statements/press releases for each DSMB review outcome scenario</td>
<td>The OCGR, in consultation with WOCR, DAIDS PO and MO, and MTN LOC (Pitt) Director of Communications and External Relations.</td>
<td>At least 2 weeks in advance</td>
</tr>
<tr>
<td>Inform other investigators and stakeholders of upcoming DSMB review</td>
<td>Protocol Chair(s), in consultation with the MTN LOC (Pitt) Director of Communications and External Relations, DAIDS MO and PO and the NIAID OCGR Subject to NIAD and DAIDS leadership approval.</td>
<td>Within 1 week prior</td>
</tr>
</tbody>
</table>

**Following DSMB Review**

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsible Party</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proceed with planned communications activities according to actual DSMB review outcome</td>
<td>The NIAID OCGR and MTN LOC (Pitt) Director of Communications and External Relations</td>
<td>TBD per NIAD and schedule of events</td>
</tr>
<tr>
<td>Provide materials and documents to sites as appropriate for actual DSMB review outcome (for example, post-review “Dear Colleague” letter for IRBs/ECs and CABs;</td>
<td>The MTN LOC (Pitt) Director of Communications and External Relations, in consultation with the NIAID OCGR, WOCR, DAIDS MO and PO, Protocol</td>
<td>TBD per NIAD and schedule of events</td>
</tr>
</tbody>
</table>
9.3.6 Social Media

The emergence of social media as a communications tool has changed the dynamic of how information is shared and how researchers, study participants and communities can engage. For purposes of this manual, social media is defined as digital (mobile or web-based) technologies, such as Facebook, YouTube and Twitter, that can be used to disseminate general educational messages about HIV prevention and microbicides and/or to aid in the recruitment of participants into a specific MTN study. Social media also can include blogs, listservs and bulk text messages.

The MTN hosts a Facebook page (MTNfacebook@mtnstopshiv.org) and Twitter account (@HIVMTN) to keep internal and external audiences up-to-date on MTN activities and upcoming meetings, study launches and results, and more general HIV-related news. Content for both social media outlets is managed by the MTN LOC (Pitt) Communications and External Relations Team, who are responsible for constant monitoring of the sites.

With social media, information can be shared quickly. Although messages may be targeted to specific audiences, they can easily be shared more broadly and indiscriminately. Vigilant monitoring and managing of incoming messages and posts is necessary to prevent negative or inaccurate information from undermining the credibility and reputation of the site, MTN and NIAID. The MTN LOC (Pitt) Director (or Associate Director) of Communications and External Relations should be immediately notified about any negative or potentially negative situation that involves the use of social media. (See 9.3.2 Crisis Communications.)

The use of social media to recruit potential study participants for an MTN study or to communicate with participants already enrolled in an MTN study may be subject to IRB/IEC approval. Sites considering using social media in the context of an MTN study should contact their IRB/EC for guidance as well as the MTN LOC (Pitt) Communications and External Relations Team and/or the LOC (FHI 360) CRM for that study.

9.4 Acknowledgment Requirements of Publicly Accessed Materials

All scientific publications, audio-visual materials and/or public information materials, including but not limited to press releases, must properly acknowledge that MTN’s activities are performed in cooperation with NIAID, NIMH and NICHD. Boilerplate language is available from the MTN website (http://www.mtnstopshiv.org/resources) (also see Section 6.3.4.2 of this manual).