

MTN Manual of Operational Procedures (MOP)

Section 8: External Communications

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8 EXTERNAL COMMUNICATIONS

8.1 Overview, Roles and Responsibilities

Communications and media relations for the Microbicide Trials Network (MTN) are managed by the MTN Leadership and Operations Center [LOC (Pitt)] Director of Communications and External Relations, in conjunction with the U.S. National Institute of Allergy and Infectious Diseases (NIAID) Office of Communications and Government Relations (OCGR) News and Science Writing Branch (NSWB).

These activities are performed in collaboration with DAIDS Leadership, the MTN Principal Investigator (PI), Protocol Chair(s) and when applicable, the U.S. National Institute of Mental Health (NIMH) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), as well as with Product Developers.

The specific responsibilities of the MTN LOC (Pitt) Director of Communications and External Relations include the following:

- Developing and implementing study-related communications plans and ensuring accurate and timely dissemination of relevant information to news media, advocacy groups, civil society and other key stakeholders
- Ensuring communications preparedness of CTUs/CRSs by advising sites in the development of communications and stakeholder outreach plans, and providing relevant training, guidance and oversight
- Preparing news releases, fact sheets, backgrounders, web content and other materials intended for external audiences
- Planning and conducting consultations and meetings with in-country and international stakeholders about the MTN research agenda
- Maintaining MTN's active presence and engagement on social media platforms

8.2 Press Releases, Statements and Communications Materials

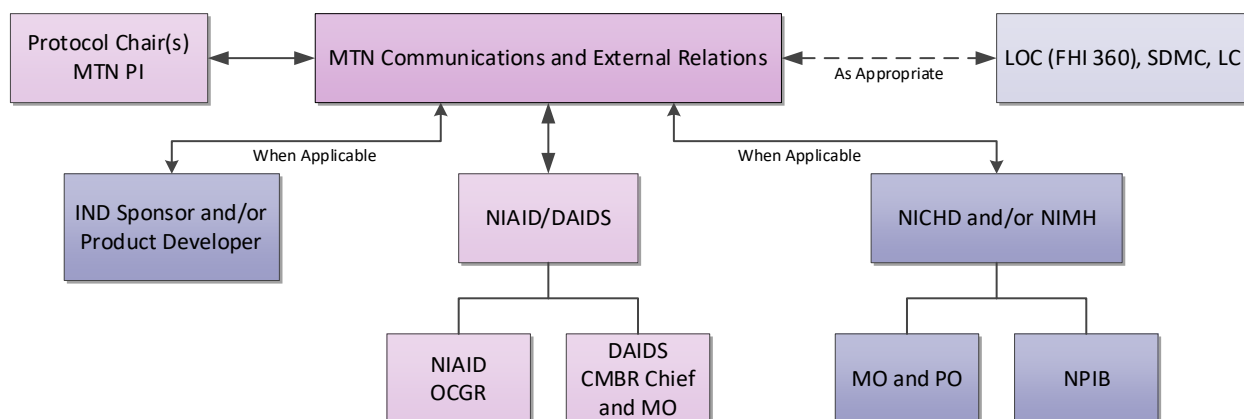
The development and review of press releases, statements and communications materials is coordinated by the MTN LOC (Pitt) Director of Communications and External Relations to ensure compliance with expected communications standards and principles, U.S. National Institutes of Health (NIH) policies and agreements with IND Sponsors and Product Developers. The review process for different types of press releases and communications materials is described below.

8.2.1 Press Releases and Statements on MTN Studies

Press releases and statements on MTN studies are reviewed by the DAIDS Prevention Sciences Program (PSP) Deputy Director, the DAIDS Medical Officer (MO) for the study, NIAID OCGR, and, when applicable, NIMH and NICHD program officers (POs) and their respective communications office or news and public information branch. When feasible, the Protocol Chair(s) and the MTN PI will approve study-related press releases and materials prior to DAIDS/NIAID review. In some circumstances, reviews occur simultaneously (see Figure 8.1).

MTN press releases and statements for studies that are conducted under a Clinical Trials Agreement (CTA), between DAIDS and the Product Developer(s), must also be reviewed by these parties in accordance with the terms of the CTA. NIAID/DAIDS is responsible for ensuring that specific terms of a CTA are met. The review process is coordinated by the MTN LOC (Pitt) Director of Communications and External Relations (see Figure 8.1).

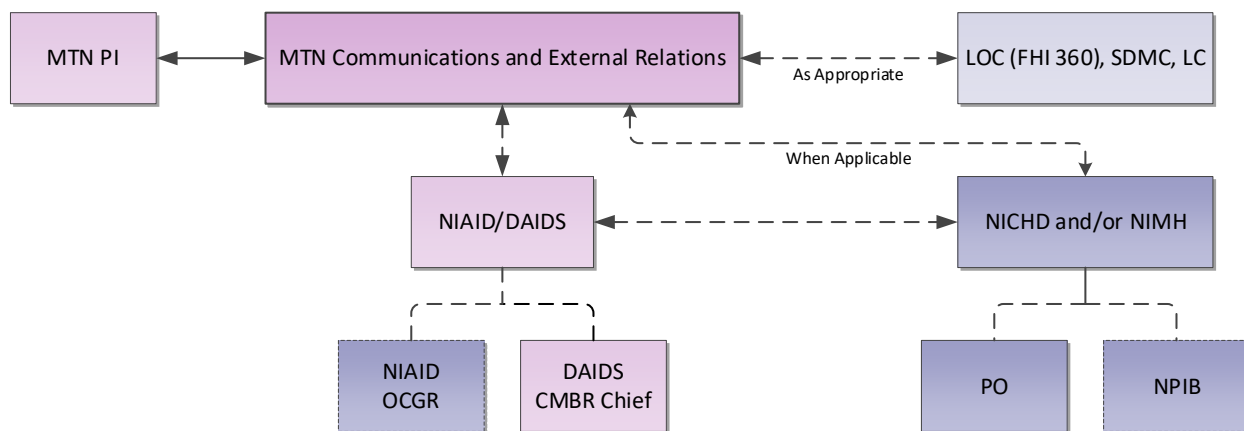
Figure 8.1 MTN Study-Related Press Releases and Statements



8.2.2 General MTN Press Releases and Statements

General (non-study specific) MTN press releases and statements are reviewed and approved by the MTN PI and may, as a courtesy, be reviewed by the DAIDS PSP Deputy Director, and as appropriate, by the NICHD and/or NIMH PO. Review by the NIAID OCGR is not necessarily required (see Figure 8.2).

Figure 8.2 General MTN Press Releases and Statements



8.2.3 Other MTN Communications Materials

In addition to press releases and statements, other communications materials developed by the MTN LOC (Pitt) Director of Communications and External Relations, such as fact sheets and Q&A documents, may be subject to review by NIAID, DAIDS and/or NIMH and NICHD. Table 8.1 summarizes the review process for both press releases and different types of communications materials.

Table 8.1 Communications Materials Review Process for U.S. NIH

	DAIDS PSP Deputy Director/MO Review	NIAID OCGR Review	NIMH/NICHD
MTN study press release	YES	YES	YES When applicable
MTN general release, statement	For information only	For information only	For information only When applicable
MTN study Q&A	YES	YES	YES When applicable
MTN study fact sheets and backgrounders	YES	For information only	YES When applicable
General topic and MTN fact sheets and backgrounders	For information only	NO	For information only When applicable
News release templates for sites	YES	For information only	YES When applicable
Scenarios and messages documents	For information only	For information only	YES When applicable
“Dear Colleague” letter	YES (MO only)	NO	YES When applicable

8.2.4 Press Releases, Statements and Materials Developed by CTUs/CRSs, MTN Organizational Units, MTN Affiliates or Outside Organizations

The MTN LOC (Pitt) Director of Communications and External Relations must review MTN-related press releases, statements and any other forms of public communication developed by CTUs/CRSs, MTN organizational units (LOC, Laboratory Center [LC], Statistical and Data Management Center [SDMC]), MTN affiliates and/or other outside organizations. This is to ensure accuracy of information, proper identification of MTN, NIAID and other funding sources, and compliance with any relevant CTA. As necessary or appropriate, the MTN LOC (Pitt) Director of Communications and External Relations will coordinate additional reviews by NIAID, and, when applicable, NIMH and NICHD and/or the Product Developer(s). NIAID/DAIDS and the NIAID OCGR must review materials that involve studies for which CTAs are in place.

8.2.5 Acknowledgment Requirements and Boilerplate Language

All press releases, statements and materials intended for public dissemination must properly acknowledge in the main text that MTN activities are funded by the US National Institutes of Health (NIH).

Press releases, statements and materials pertaining to completed studies should further acknowledge that, at the time they were conducted, the MTN was an HIV/AIDS clinical trials network funded by NIAID, with co-funding from NICHD and NIMH – all components of the US NIH.

Press releases, statements and materials pertaining to MTN's ongoing study, MTN-042 (DELIVER), should explain that the study is being conducted by the MTN, which from 2006 until November 30, 2021, was an HIV/AIDS clinical trials network funded by NIAID, with co-funding from NICHD and NIMH – all components of the US NIH.

The Award Number must also be included, although this information is not required to be in the actual text of a press release. DAIDS will provide the Award Numbers to be referenced prior to release or distribution.

News releases and other materials often include a boilerplate statement that appears after the document's main content, sometimes under the heading, "About the MTN".

The MTN's boilerplate statement, which is subject to approval by NIAID OCGR and DAIDS, follows:

The Microbicide Trials Network (MTN) works within a global community of research programs, investigators and partners that is committed to the development of a range of HIV prevention options that will meet the needs and preferences of people at different times of their lives. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN was from 2006 until November 30, 2021 an HIV/AIDS clinical trials network funded by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. MTN's mission was to conduct rigorous clinical trials designed specifically to support the potential licensure of promising microbicides – products applied inside the vagina or rectum to prevent the sexual transmission of HIV. MTN studies have provided important insight into what is needed in a rectal microbicide product, contributed to the World Health Organization's recommendation of the dapivirine vaginal ring as an additional HIV prevention option for women at risk of HIV and include among the first HIV prevention studies involving pregnant and breastfeeding women, a research agenda that still continues with NIAID support. More information about the MTN is available at www.mtnstopshiv.org.

8.3 Communications Planning for Public Release 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. Advance planning is essential, with an emphasis on the need for accurate, timely and well-controlled communication of results to different stakeholder groups.

NIAID (and NIMH and NICHD, when applicable) is responsible for determining the manner and timing in which results are shared with study participants and local communities, as well as publicly disseminated. NIAID also ensures that the process meets the terms of a study's specific CTA(s) with the Product Developer(s). Because primary results are typically reported in a peer-reviewed journal and/or at a scientific meeting, the specific timeline for public dissemination of study results must also consider the embargo policies of the journal and/or meeting.

The MTN LOC (Pitt) Director of Communications and External Relations works closely with the NIAID OCGR and Product Developer(s) in the development of coordinated communications

plans that meet CTA requirements and/or news embargo policies, should they exist, and with the study's Protocol Chair(s), the MTN PI, the MTN LOC (FHI 360) Clinical Research Manager (CRM) for the study and others as appropriate.

For large and/or high-profile trials, such as Phase IIb, Phase III and Phase IIIb studies, the MTN LOC (Pitt) Director of Communications and External Relations works directly with CTUs and CRSs on the development of site-specific plans and provides guidance and technical support throughout the planning and dissemination process. In preparation for results dissemination, CTUs/CRSs are required to complete and/or update specific communications planning documents, which may include a Results Dissemination Calendar, Communications Plan Template, Stakeholders Directory and Media Relations Standard Operating Procedures (SOP).

The MTN LOC (Pitt) Director of Communications and External Relations works to ensure that site communications plans allow for the timely dissemination of results so that study participants, Community Advisory Board (CAB) members, Institutional Review Boards/Institutional Ethics Committees (IRB/IECs), regulatory authorities and other key stakeholders are among the first to know.

At the discretion of MTN Leadership, NIAID/DAIDS and the Product Developer(s), select individuals or groups may be briefed about study results prior to public release, i.e., before the embargo lifts. Signed confidentiality disclosure agreements may be required.

For Phase I and Phase II studies and Ancillary and/or Sub-studies, the MTN LOC (Pitt) Communications and External Relations Team, Protocol Chair(s), and MTN Leadership will determine the most suitable process for disseminating results with input from NIAID OCGR, DAIDS PSP Deputy Director and MO, and as appropriate, NIMH and NICHD.

8.4 Communications Planning for Interim Reviews of Safety Data

MTN-042 (DELIVER) is a Phase 3b study designed to assess the safety of the dapivirine vaginal ring and Truvada (emtricitabine/tenofovir disoproxil fumarate, FTC/TDF) as oral pre-exposure prophylaxis (PrEP) when used by women during pregnancy. This trial is designed to enroll cohorts in a step-wise manner from later gestational age to earlier gestational age, pending acceptable safety evaluations after each cohort completes product use. As per the MTN-042 protocol, an Interim Review Panel (IRP) will advise whether enrollment into the next cohort should proceed after it reviews the primary outcome data of the just completed cohort. IRP reviews will take place approximately 4-6 weeks after the final pregnancy outcome. Based on its review, the IRP could recommend that the study:

- continue to enroll the next planned study cohort
- continue to enroll the next planned study cohort with specified modifications
- stop altogether.

The MTN LOC (Pitt) Director of Communications and External Relations is responsible for overall communications planning for interim safety reviews, in collaboration with NIAID and Product Developers. In turn, the MTN LOC (Pitt) Director of Communications and External Relations and MTN LOC (FHI 360) CRM of the study ensure that each study site and investigator is adequately prepared in advance of planned interim reviews to ensure the timely dissemination of the review outcome to study participants, community and stakeholders. How and when the outcome will be communicated to various stakeholders will depend on the whether the recommendation is to continue with the next cohort or to modify or stop the study.

As needed, the MTN LOC (FHI 360) CRM will assist the MTN LOC (Pitt) Director of Communications and External Relations and CTUs/CRSs in implementing communications strategies at the site level. The MTN LOC (FHI 360) Community Program Manager (CPM) helps to facilitate communication with the study-specific Community Working Group (CWG).

The general process and timelines for communications planning and dissemination of the review outcome are described in Table 8.2 below, though modifications can be expected depending on the specific circumstances, including external events of relevance to the study at the time of the review.

Table 8.2 General MTN Communications Process for MTN-042 Interim Safety Reviews

Timeframe	Procedure	Responsibility
Prior to Interim Safety Review		
Approximately 2-3 weeks prior to estimated due date (EDD) of last participant in cohort	Prepare Schedule of Events and Communications Tasks and Timelines Document	Pitt (LOC) Director of Communications and External Relations, FHI 360 CRM
Approximately 2-3 weeks prior to EDD of last participant in cohort	Inform clinical research sites (CRSs) of preparatory activities and provide relevant planning materials (e.g., communication plan template, stakeholders directory)	FHI 360 CRM, Pitt (LOC) Director of Communications and External Relations
Within 2 weeks prior to Interim Review Panel (IRP) meeting	Provide sites with scenarios/messages and other support materials	FHI 360 CRM, Pitt (LOC) Director of Communications and External Relations
Within 2-3 weeks prior to IRP meeting	Finalize overall communications plans for each scenario, including timing for and notification of key stakeholders, in collaboration with NIAID and Product Developers (International Partnership for Microbicides and Gilead Sciences)	Pitt (LOC) Director of Communications and External Relations
At least 1-2 week prior to IRP meeting	Finalize site-specific communications planning documents delineating processes for each scenario, including timing for and notification of Community Advisory Boards (CABs), study participants and Tier 1 and Tier 2 stakeholders.	Pitt (LOC) Director of Communications and External Relations, CRSs
Within 1 week prior to IRP meeting	In accordance with site-specific communications plans, inform select stakeholders (Tier 1) and CABs of the IRP meeting date, the potential review outcomes and the general plan for communicating the outcome	CRSs
Within 1 week prior to IRP meeting	In accordance with overall communications plan, inform select stakeholders (Tier 1) of the IRP meeting date, the potential review outcomes and the general plan for communicating the outcome	Pitt (LOC) Director of Communications and External Relations, Protocol Chairs/Co-Chair
Following Interim Safety Review		
As soon as possible once review outcome is known	Proceed with planned communications activities per actual IRP review outcome	Pitt (LOC) Director of Communications and External Relations, CRSs

Within 1-4 days of IRP meeting (depending on outcome)	Provide sites outcome-specific materials and documents for use in communicating the outcome, per site communications plans	FHI 360 CRM, Pitt (LOC) Director of Communications and External Relations
Within 1-5 days of IRP meeting (depending on outcome)	Communicate outcome to CABs, study participants, stakeholders, news media and other groups in accordance with site-specific and overall communications plans for the review outcome.	Pitt (LOC) Director of Communications and External Relations, CRSs

8.5 Media Relations

All sites must adhere to MTN-specific media relations policies and procedures in conjunction with any MTN study being conducted at the site.

8.5.1 Media Relations Standard Operating Procedures

Clinical research sites can expect to receive inquiries from news media about MTN studies or related research. Maintaining transparency with news media is extremely important, and investigators are encouraged to cultivate credible relationships with media representatives. In order to ensure appropriate, consistent messaging among study sites and across the MTN, CTUs/CRSs should have an SOP describing how media inquiries are to be managed at their site. This SOP should be updated regularly to reflect any changes in staffing or procedures at the study site.

Sites conducting large and/or high profile MTN studies may be asked to complete a template Media Relations SOP provided by MTN LOC (Pitt) Communications and External Relations Team. Completion of the MTN template is required even if the CTU or CRS already has an existing SOP or media relations policy.

8.5.2 Responding to Media Inquiries

Each site should designate a primary media point person to manage and triage MTN study-related media inquiries. A back-up contact should also be identified should the primary person not be available. While some organizations have a dedicated communications person on staff, this is not the case at many clinical trial sites. As such, sites may choose to designate a study coordinator, site coordinator or a community educator to serve as the point of contact for news media.

The media point person screens media inquiries and, when warranted, coordinates a response with the appropriate spokesperson. Under some circumstances, the point person(s) will notify the MTN Director of Communications and External Relations (see Crisis Communications, section 8.5.3).

Each site should designate two to three individuals to serve as spokespersons. Spokespersons may be the CRS Leader; study IoR or another key investigator. Designated spokespersons should be thoroughly familiar with relevant study background and materials, and should be able to speak articulately about MTN studies, oftentimes on short notice.

Media inquiries can be expected in conjunction with different events or study milestones, such as when study results are being reported for the first time. However, when inquiries occur outside these windows, particularly when results are under embargo, extreme caution is

advised. As such, investigators should refrain from providing comments to news media, community groups or other external audiences that relate to study outcomes, study participants or adverse events without first consulting the Protocol Chair(s) and the MTN LOC (Pitt) Director of Communications and External Relations. Investigators should not discuss or publicly release information about proprietary study products that have not yet been reviewed by or received approval from a drug regulatory authority for the indication being evaluated in the study without the explicit (written) permission of the IND Sponsor and/or Product Developer.

Press inquiries generally or specifically about the MTN should be referred to the MTN LOC (Pitt) Director of Communications and External Relations, who will coordinate an appropriate response with NIAID's OCGR, if necessary.

Requests by news media to interview or photograph study participants are handled according to the discretion of site investigators and in accordance with institutional policy and the site's IRB/IEC requirements and/or procedures. Sites that permit study participants (or former participants) to be interviewed or photographed should ensure the study participant is fully informed of the process and potential ramifications and social harms that may unwittingly occur. A specific media informed consent document is strongly advised.

The MTN provides guidance and training to individuals who have little or no prior experience dealing with the media.

8.5.3 Crisis Communications

In situations of crisis or breaking news involving an MTN study, the MTN LOC (Pitt) Director of Communications and External Relations is responsible for managing the response in consultation with the NIAID OCGR, DAIDS program leadership, MTN PI, Protocol Chair(s) and, as appropriate, the Product Developer(s) and NIMH and NICHD Program Leadership.

All CRSs should have a designated crisis communications team, which may include the CTU PI, CRS leader, site IoR, designated media contact and others, as per their MTN media relations SOP or other procedures already in place at the CTU.

The MTN LOC (Pitt) Director of Communications and External Relations must be notified about any urgent or potentially negative communications situation so that an appropriate response and course of action can be developed in coordination with site CTU and CRS leadership, NIAID/DAIDS and other partners as appropriate.

- Lisa Rossi (Director of Communications and External Relations), mobile: +1-412-916-3315; rossil@upmc.edu

8.5.4 Resource Information for News Media and External Audiences

The MTN LOC (Pitt) Director of Communications and External Relations develops materials about studies and general topic areas that are intended for lay audiences, including news media. These are publicly available in the News Room section of the MTN website (<http://www.mtnstopshiv.org/news>). As a matter of routine, the site media point person(s) should direct media representatives to the News Room to access background information, news releases and other materials.

8.5.5 Tracking Media Activities

Media inquiries and contacts should be documented to the extent possible by the CRS media point person(s) and the resulting media coverage shared with the MTN LOC (Pitt) Director of

Communications and External Relations in a timely fashion. MTN Communications aggregates media coverage and shares news stories and links with MTN leadership and other interested parties via periodic “MTN in the News” email distributions.

8.6 Social Media

The use of social media as a communications tool has changed the dynamics 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 may be used to create general awareness about HIV prevention, disseminate information about a study milestone and/or to aid (with IRB/IEC approval) in the recruitment of participants into a specific MTN study. Social media also includes blogs, listservs and bulk text messages.

The MTN hosts a Facebook page (MTNfacebook@mtnstopshiv.org) and a 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) Director of Communications and External Relations.

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 of Communications and External Relations should be immediately notified about any negative or potentially negative situation that involves the use of social media (see Crisis Communications, section 8.5.3).

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 is likely to be subject to IRB/IEC approval. Sites considering using social media in the context of an MTN study, including for recruitment purposes, should contact their IRB/IEC for guidance as well as the MTN LOC (FHI 360) CRM for that study.

8.7 Stakeholder Engagement

The MTN LOC (Pitt) Director of Communications and External Relations is responsible for planning and coordinating consultations and meetings with national in-country and international stakeholders to solicit their views and address their questions concerning the MTN research agenda. Stakeholder consultations and meetings help to establish new ties and strengthen existing relationships between researchers and key in-country stakeholders, concerned with HIV prevention, and create a framework for continued and broader engagement on issues of concern and/or relevance within each country or across large regions.

Whenever possible, the MTN partners work with key civil society groups and NGOs in planning and conducting consultations. They coordinate these activities in close collaboration with the MTN PI and Protocol Chair(s) as well as MTN trial site investigators.