

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 MTN LOC (Pitt) with respect to communications include the following:

- Ensuring communications preparedness of CTUs/CRSs by advising sites in the development of communications and stakeholder outreach plans, and providing relevant guidance and oversight

- Preparing news releases, fact sheets, backgrounders, web content and other materials about MTN studies and ensuring their timely dissemination to news media, advocacy groups, civil society and other key stakeholders.
- Maintaining MTN's presence and engagement on social media platforms as appropriate

8.2 Press Releases, Statements and Communications Materials

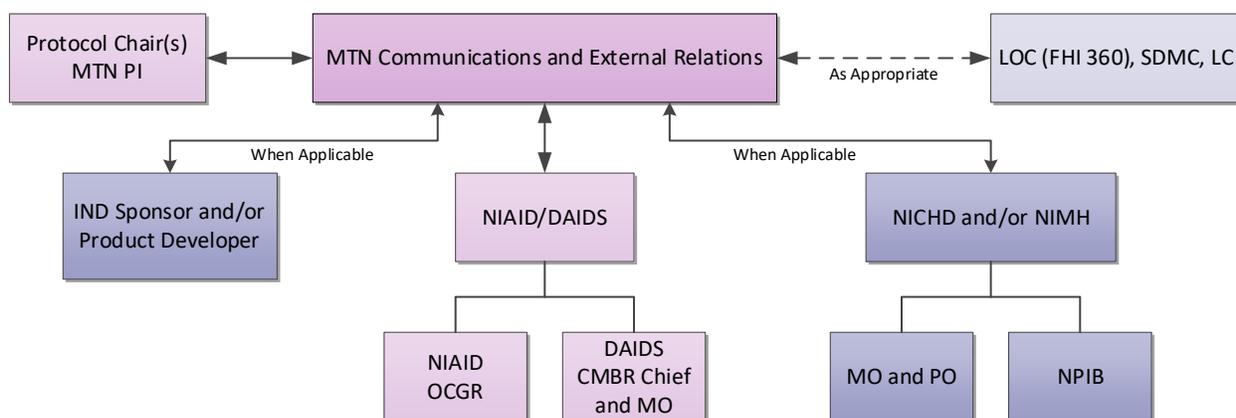
The development and review of press releases, statements and communications materials is coordinated by the MTN LOC (Pitt) or its designate to ensure compliance with expected communications standards and principles, U.S. National Institutes of Health (NIH) policies and agreements with IND Sponsors and 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) or its designate (formerly MTN Communications and External Relations) ;see Figure 8.1.

Figure 8.1 MTN Study-Related Press Releases and Statements

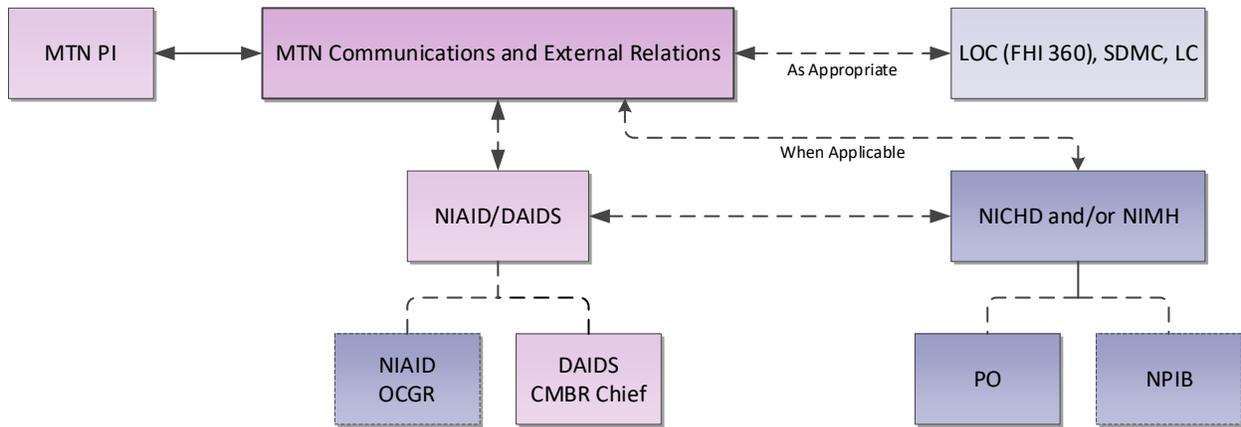


8.2.2 General MTN Press Releases and Statements

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 but MTN Communications and External Relations replaced by MTN LOC (Pitt)].

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) or its designate, such as 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

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 were or 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 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 the ring's approval in several countries 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) or its designate 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) or its designate 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 and Stakeholders Directory.

The MTN LOC (Pitt) or its designate 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.

8.4 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.

8.4.1 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.

8.4.2 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 LOC (Pitt) or its designate(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). 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) and MTN PI, 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.

8.4.3 Crisis Communications

In situations of crisis or breaking news involving an MTN study, the MTN LOC (Pitt) or its designate 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) and the MTN PI 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.

8.5 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 X (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 (<https://www.facebook.com/microbicidetrialsnetwork>) and a X (Twitter) account (@HIVMTN) to keep internal and external audiences up-to-date on relevant MTN-related news, including study results.