MTN-042 Publication Plan

1.0 MTN-042 Protocol Team Publication Goals

It is the goal of the MTN-042 Protocol Team to ensure trial data are cleaned, analyzed, and completed for publication as soon as possible; publications utilizing MTN-042 data are published in a timely fashion; and all site leadership and management team members are provided an opportunity to develop or participate in the development of MTN-042 manuscripts.

2.0 MTN-042 Publication Committee Membership and Responsibilities

The MTN-042 Protocol Publications Committee (PPC) will oversee the MTN-042 publication process. The Publications Committee will include the following individuals:

- Felix Mhlanga, Protocol Chair
- Katherine Bunge, Protocol Chair
- Lee Fairlie, Protocol Co-Chair
- Barbra Richardson, Protocol Statistician
- Jen Balkus, Protocol Epidemiologist
- Jeanna Piper, DAIDS Medical Officer
- Nahida Chakhtoura, NICHD Medical Officer

The following alias list includes the voting MTN-042 PPC members as well as supportive MTN LOC staff (FHI 360 and Pitt): mtn042pubcommittee@mtnstopshiv.org

Other members from the protocol team may be consulted and asked to review concepts (to ensure feasibility as well as scientific merit), abstracts, and manuscripts as needed, based on expertise. Notably, a representative from the MTN-042 behavioral team will be asked to review any concepts/abstracts/manuscripts that involve qualitative data (i.e., from in-depth interviews).

The responsibilities of the PPC are detailed in the MTN Manual of Operational Procedures (MTN MOP) Section 20: Network Publication Policy, available at: https://mtnstopshiv.org/manual-operational-procedures

3.0 MTN-042 Publication Plans and Concept Development Guidelines

Primary Publications: The availability of safety data for DPV VR use by pregnant women will be critical to inform product rollout. As such, the team aims to publish safety data from each cohort as soon as they are available (i.e., after cohorts 1 and 2, respectively). All publications that present primary endpoint safety data will be considered “primary” and as such will not require a concept as outlined in the MTN MOP Network Publication Policy. While these publications do not require a concept form, they still require all approvals (Coauthor, PPC, Product Developer, and MTN MRC) as outlined in the MTN Network Publication Policy.

Secondary/Other Publications: For all other manuscripts or conference abstracts, a publication concept is required. The MTN Publication Concept Proposal Form is available on the MTN website. It is the lead authors responsibility to develop the concept and send to the FHI 360 CRM who will facilitate PPC review and approval. Further details about concept development are available in the MTN Network Publication Policy.

The status of all MTN-042 Publications will be tracked in iEnvision.

4.0 MTN-042 Publication Review Process

Publication reviews will be conducted as outlined in the MTN Network Publication Policy. Outside of coauthor review, which is the responsibility of the lead author, all publication reviews will be documented in the iEnvision system and facilitated by the FHI 360 CRM and the MTN LOC (Pitt) Manuscript Coordinator. No MTN-042 publication should be submitted to the target venue (conference or journal) without all the required approvals.

5.0 MTN-042 Publication Authorship Guidelines

Authorship should be reflective of the multi-site nature of MTN-042, MTN publication policies, and generally accepted International Committee of Medical Journal Editors (ICMJE) suggested authorship guidelines. Authorship should be based on the collaborative contributions of all investigators; from conception and design, or acquisition of data, or analysis and interpretation of data; drafting the abstract or revising it critically for important intellectual content; and final approval of the version to be presented/published. For cross-site publications (i.e., publications that present study data from more than one site), representation from each site should be included in the coauthorship list whenever possible. Further information on authorship guidelines is outlined in the MTN Network Publication Policy.

It is the lead authors responsibility to seek interest in coauthorship from relevant team members. FHI 360 can provide contact information for MTN-042 site and/or study leadership as needed to facilitate these discussions. On request, the MTN-042 PPC can provide input on coauthorship.

6.0 MTN-042/DELIVER Specific Standards

To ensure consistency across publications, it is recommended that the following conventions be followed:

1. The first reference of the trial (in the title, as well as in the text body) should be MTN-042/DELIVER. Either MTN-042 or DELIVER may then be used later in the publication.
2. MTN-042/DELIVER should always be described for the benefit of readers unfamiliar with the protocol. A one-line explanation is often sufficient. For example: MTN-042/DELIVER was a phase 3b, randomized, open-label safety trial of the dapivirine vaginal ring and oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in pregnancy.

3. The ClinicalTrials.gov identifier for the study should be referenced: ClinicalTrials.gov number: NCT03965923
4. It is suggested that the locations (city, country) of the MTN-042 sites be provided in the abstract: Johannesburg, South Africa; Kampala, Uganda; Chitungwiza, Zimbabwe and Blantyre, Malawi
5. The study products should be referred to as: dapivirine vaginal ring (DVR) and oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) on initial reference and subsequently shortened to "the ring" and "oral PrEP".
6. All authorship lists for abstracts/manuscripts that include data from more than one site should include the wording "on behalf of the MTN-042/DELIVER Study Team" at the end of the authorship list. The study team and other acknowledgements are provided in Section 7.0 below.

7.0 Publication Acknowledgments

Acknowledgement of Participants and Study Communities: It is recommended that authors include a statement to thank the MTN-042 participants and study communities. The exact wording is left to the discretion of the lead author.

Acknowledgement of the Full MTN-042/DELIVER Study Team: The following listing should be included at the end of all multi-site MTN-042 manuscripts, as allowable by the journal formatting and other requirements.

> **Study Sites:** Bonus Makanani[±], MBBS, FCOG(SA) (Protocol Chair (PC), Investigator of Record (IoR)), Luis Gadama, MBBS, MMED UCT (IoR), Linly Seyama, Msc, RNM (Study Coordinator (SC)), Vitumbiko D. Mandiwa, MBBS (SC), Sufia Dadabhai, PhD (Clinical Research Site (CRS) Leader), and Taha E. Taha, PhD (Clinical Trials Unit Principal Investigator (CTU PI)), Johns Hopkins University (JHU) Research Project; Clemensia Nakabiito, MBChB, MMed (IoR), Phionah Bridget Kibalama Ssemambo, MBchB, MSc PH (SC), and Mary Glenn Fowler, MD, MPH (CTU PI), Makerere University - Johns Hopkins University (MU-JHU) Research Collaboration; Lee Fairlie, MBChB, FCPaeds (Protocol Co-Chair, IoR), Carlotta Mabuza, BS, PGDip, Dip (SC), Hermien Gous, PharmD (CRS Leader), and Ringson Ngozo, DipEd (Community Working Group (CWG) Representative), Wits RHI Shandukani Research Centre; Felix Mhlanga, MBChB, MMed (PC), Nyaradzo M. Mgodi, MBChB, Mmed, (IoR), Petina Musara, BSW (SC) and Z. Mike Chirenje, MD, FRCOG (CTU PI), University of Zimbabwe Clinical Trials Research Centre (UZ-CTRC)
>
> **Protocol Team:** Jeanna M. Piper, MD (DAIDS Senior Medical Officer (MO)), Naana Cleland, PhD, (Health Specialist Clinical Microbicide Research Branch (CMRB)), and Roberta Black, PhD (Chief, CMRB), National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS); Nahida Chakhtoura, MD, MsGH (NICHD MO), Maternal and Pediatric Infectious Disease Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institutes of Health (NIH); Dianne M. Rausch, PhD, (Director, DAIDS Research) and Teri Senn, PhD (Program Chief, Psychosocial Co-morbidities of HIV Prevention and Treatment),

National Institutes of Mental Health (NIMH); James F. Rooney, MD (Vice President Medical Affairs), Gilead Sciences; Zeda Rosenberg, ScD (Chief Executive Officer), International Partnership for Microbicides; Craig Hendrix, MD, (Biomedical Science Working Group (BSWG) Representative, Protocol Pharmacologist) and Mark Marzinke, PhD, DABCC (LC Pharmacology Core), Johns Hopkins University; Lisa Noguchi, PhD, CNM (Director, Pregnancy Research), Johns Hopkins Bloomberg School of Public Health; Peter Anderson, PharmD (LC Pharmacology Core), University of Colorado School of Pharmacy; Abraham Johnson, MPH (Community Program Associate), Ashley J. Mayo, MPH (Sr. Clinical Research Manager (CRM)), Cheryl Blanchette, MS(Sr. Community Program Manager (CPM), Jontraye Davis, MHA (CPM), Rachel Scheckter, MPH (Sr. CRM), Tara McClure, MPH (Sr. CRM), and Lisa Levy, MPH, MTN Associate Director, FHI 360; Katherine Bunge, MD, MPH (PC), Catherine A. Chappell, MD, MSc (Protocol Safety Physician (PSP)), Richard H. Beigi MD, MSc (Advisory), and Sharon A. Riddler, MD, MPH (Protocol Physician), Magee-Womens Hospital and the University of Pittsburg Medical Center (UPMC); Devika Singh, MD, MPH (PSP), Division of Infectious Diseases, University of Vermont; Cindy Jacobson, PharmD (Director of Pharmacy Affairs), Edward Livant, BSMT (ASCP), MPH (MTN LC Research Manager), Lisa Rossi, BA (MTN Director of Communications), Luis Duran, DrPH, MPIA, (Project Manager), Mei Song, PhD (Project Manager), and Sharon Hillier, PhD (MTN Principal Investigator), Magee-Womens Research Institute-UPMC; Ariana Katz, MPH (Behavioral Research Coordinator), Elizabeth Montgomery, PhD (BRWG Representative), Imogen Hawley, MA, MSc (Behavioral Research Coordinator), and Marie Stoner, PhD (Behavioral Co-Investigator), RTI International; Ariane van der Straten, PhD, MPH (Behavioral Research Working Group (BRWG) Representative), University of California San Francisco; Ivan Balan, PhD (BRWG Representative), Florida State University College of Medicine; Barbra Richardson, PhD (Statistician), Jennifer Balkus, PhD, MPH (Protocol Epidemiologist), Daniel Szydlo, MS, (Statistical Research Associate), Lena Kemel, Pharm.D. (Clinical Safety Associate), and Tanya Harrell, BS (Clinical Data Manager), Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchinson Cancer Research Center and the University of Washington

[±]Deceased

MTN-042 Interim Review Panel Members: We would like to thank the members of the MTN-042 Interim Review Panel who donated their time to review safety data between study cohorts: Deborah M. Money, MD, FRCSC; Annie Lyerly, MD, MA; Richard Adanu, PhD; Professor Ellen Chirwa, PhD MRNM; Paige Williams, PhD, MS; Charles Shey Wiysonge, MD, PhD; Dorothy Mbori-Ngacha, MBChB, MMed, MPH

Data Management: Data management was provided by The Statistical Center for HIV/AIDS Research & Prevention (Fred Hutchinson Cancer Research Center, Seattle, WA) and site laboratory oversight was provided by the Microbicide Trials Network Laboratory Center (Pittsburgh, PA). For qualitative data, management was provided by the Women's Global Health Imperative Program (RTI International, Berkley, CA). *[Include appropriate data management reference as needed]*

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Study Products: The dapivirine vaginal rings used in this study were developed and supplied by the International Partnership for Microbicides (IPM). Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) was donated by Gilead Sciences.

MTN-042/DELIVER Ethics approval *(include as needed if required by journal):* All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the following Institutional Review Boards/Ethics Committees and Drug Regulatory Authorities: Prevention Sciences Research Committee of the US National Institute of Allergy and Infectious Diseases; US Food and Drug Administration; College of Medicine Research and Ethics Committee; Johns Hopkins School of Public Health Institutional Review Board; Pharmacy, Medicines and Poisons Board of Malawi; Human Research Ethics Committee: (Medical), University of Witwatersrand, Johannesburg; South African Health Products Regulatory Authority; Joint Clinical Research Centre Institutional Review Board; Uganda National Council for Science and Technology; Johns Hopkins Medicine Office of Human Subjects Research Institutional Review Board; National Drug Authority of Uganda; Medical Research Council of Zimbabwe; Joint Research Ethics Committee for the University of Zimbabwe College of Health Sciences and Parirenyatwa Group of Hospitals; Research Council of Zimbabwe; Medicines Control Authority of Zimbabwe