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Supplementary appendix

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MTN-043

Phase 3B, Randomized, Open-Label, Safety, and Drug Detection Study of Dapivirine Vaginal Ring and Oral TRUVADA® in Breastfeeding Mother-Infant Pairs

Microbicide Trials Network

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Gilead Sciences, Inc.
International Partnership for Microbicides

Protocol Chair:
Maxensia Owor, MBChB, MMed, MPH

Protocol Co-Chairs:
Lisa Noguchi, PhD, CNM
Jennifer Balkus, PhD, MPH

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LIST OF ABBREVIATIONS AND ACRONYMS

AAP	American Academy of Pediatrics
AE	adverse event
AIDS	acquired immune deficiency syndrome
ALT	alanine transaminase
ART	antiretroviral therapy
ARV	antiretroviral
ASCP	American Society of Clinical Pathology
ASPIRE	A Study to Prevent Infection with a Ring for Extended Use
AUC	area under the curve
BRWG	Behavioral Research Working Group
BSWG	Biomedical Science Working Group
BUN	blood urea nitrogen
BV	bacterial vaginosis
CAB	community advisory board
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CBC	complete blood count
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI	confidence interval
C_{max}	maximum concentrations
C_{min}	minimum concentrations
CMRB	Clinical Microbicide Research Branch
CRF	case report form
CRMS	Clinical Research Management System
CROI	Conference on Retroviruses and Opportunistic Infections
CRS	clinical research site
CT	*Chlamydia trachomatis*
CTI	clinical trial insurance
CTA	clinical trial agreement
CTU	clinical trials unit
CVF	cervicovaginal fluid
CWG	Community Working Group
DAERS	DAIDS Adverse Experience Reporting System
DAIDS	Division of Acquired Immunodeficiency Syndrome
DAPY	di-aminopyrimidine
DBS	dried blood spot
DLV	delavirdine
DNA	deoxyribonucleic acid
DOD	directly observed dosing
DOT	direct observed therapy
DPV	dapivirine
DREAM	Dapivirine Ring Extended Access and Monitoring
DSMB	Data and Safety Monitoring Board

EAE	expedited adverse event
EMA	European Medicines Agency
EC	ethics committee
EC_{50}	50% effective concentration
EFV	efavirenz
FDA	Food & Drug Administration (U.S.)
FHCRC	Fred Hutchinson Cancer Research Center
FTC	emtricitabine
FTC-TP	emtricitabine triphosphate
FTP	File Transfer Protocol
g	grams
GC	*Neisseria gonorrhoeae*
GCP	Good Clinical Practice
GEE	generalized estimating equations
GMP	Good Manufacturing Practices
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCP	health care provider
HEENT	head, eye, ear, nose and throat
HHS	Department of Health and Human Services (US)
HIV	Human immunodeficiency virus
HIV-1	human immunodeficiency virus type 1
HIV-2	human immunodeficiency virus type 2
HOPE	HIV Open-label Prevention Extension
HPTN	HIV Prevention Trials Network
HSV-2	herpes simplex virus 2
IATA	International Association of Air Transport
IB	Investigator's Brochure
ICF	informed consent form
ICH	International Council on Harmonization
ICRC	International Clinical Research Center
IDI	in-depth interview
IMPAACT	International Maternal, Pediatric, Adolescent AIDS Clinical Trials Group
IND	Investigational New Drug
IoR	Investigator of Record
IPM	International Partnership for Microbicides
iPrEX	Iniciativa Profilaxis Pre-Exposición
IQR	interquartile range
IRB	institutional review board
KOH	potassium hydroxide
3TC	lamivudine
LC	Laboratory Center
LDMS	Laboratory Data Management System
LOC	Leadership and Operations Center
LPVr	Lopinavir/Ritonavir
µg	microgram
µM	micromolar (10^{-3} mol/m^3)
mg	milligram
mL	milliliter
MO	Medical Officer
MSC	Mail Stop Code

MSM	men who have sex with men
MTCT	mother-to-child transmission
MTD	maximum tolerated dose
MTN	Microbicide Trials Network
MU-JHU	Makerere University – John Hopkins University Research Collaboration
NAAT	nucleic acid amplification test
NDA	New Drug Application
ng	nanogram
NGOs	non-governmental organizations
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
nM	nanomolar (10^{-6} mol/m^3)
NNRTI	non-nucleoside reverse transcriptase inhibitor
NOEL	No observed effect level
NOAEL	No observed adverse effect level
NRTI	nucleoside reverse transcriptase inhibitor
NVP	nevirapine
OHRP	Office for Human Research Protections
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief (US)
pg	picogram
PI	principal investigator
PID	pelvic inflammatory disease
PK	pharmacokinetic
PMTCT	prevention of mother-to-child transmission
PoR	Pharmacist of Record
PPD	Pharmaceutical Product Development, Inc.
PrEP	pre-exposure prophylaxis
PRO	Protocol Registration Office
PSP	Prevention Sciences Program
PSRT	Protocol Safety Review Team
PTID	participant identification
PUEV	Product Use End Visit
RE	regulatory entity
RHI	Reproductive Health and HIV Institute
RNA	ribonucleic acid
RSC	Regulatory Support Center
RT	reverse transcriptase
RTI	reproductive tract infection
SAE	serious adverse event
SAHPRA	South African Health Products Regulatory Authority
SCHARP	Statistical Center for HIV/AIDS Research & Prevention
SDMC	Statistical Data Management Center
SEV	Study Exit Visit
SOP	standard operating procedure
SSP	study specific procedure(s)
STI	sexually transmitted infection

SUSAR	suspected, unexpected serious adverse reaction
TDF	tenofovir disoproxil fumarate
TEAE	treatment emergent adverse event
TFV	tenofovir
TFV-DP	tenofovir diphosphate
TMC-120	dapivirine
TV	*Trichomonas vaginalis*
UA	urinalysis
UNICEF	United Nations Children's Fund
UPMC	University of Pittsburgh Medical Center
US	United States of America
UTI	urinary tract infection
VOICE	Vaginal and Oral Interventions to Control the Epidemic
VR	vaginal ring
WHO	World Health Organization
ZDV	zidovudine

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PROTOCOL TEAM ROSTER

Protocol Chair

Maxensia Owor, MBChB, MMed (Paed), MPH
Protocol Chair
Makerere University – Johns Hopkins University Research Collaboration
P.O. Box 23491
Kampala, Uganda
Phone: 256 414 541044
Email: maxowor@mujhu.org

Protocol Co-Chairs

Lisa Noguchi, PhD, CNM
Protocol Co-Chair
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, MD 21205 USA
Phone: 202-664-2721
Email: lnoguch1@jhu.edu

Jennifer Balkus, PhD, MPH
Protocol Co-Chair
Fred Hutchinson Cancer Research Center (FHCRC) – Statistical Center for HIV/AIDS Research and Prevention (SCHARP)
1100 Fairview Ave N, M2-C200
Seattle, WA 98109-1024 USA
Phone: 206-667-7149
Fax: 206-667-4812
Email: jbalkus@fredhutch.org

Site Investigators

Blantyre Clinical Research Site (CRS)

Taha E. Taha, PhD
Clinical Trials Unit (CTU) Principal Investigator (PI)
Johns Hopkins University Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, MD 21205 USA
Phone: 410-614-5255
Fax: 410-502-0688
Email: ttaha@jhsph.edu

Frank Taulo, MBBS, MPH, FCOG
Site Investigator of Record
Johns Hopkins Research Project/College of Medicine
Chipatala Avenue, P.O. Box 1131
Blantyre, Malawi
Phone: 265-99-125-0127
Fax: 265-1870-132
Email: ftaulo@yahoo.com

The University of Zimbabwe College of Health Sciences Clinical Trials Research Centre (UZCHS-CTRC) Clinical Trials Unit (CTU) – Zengeza CRS

Z. Mike Chirenje, MD, FRCOG
CTU PI
UZCHS-CTRC CTU
15 Phillips Avenue, Belgravia
Harare, Zimbabwe
Phone: 263-4-704-966
Fax: 263-4-704-897
Email: mchirenje@uzchs-ctrc.org

Felix G. Muhlanga, MBChB, MMed
Site Investigator of Record
UZCHS-CTRC CTU
15 Phillips Avenue, Belgravia
Harare, Zimbabwe
Phone: 263-4-704-920
Fax: 263-4-704-897
Email: fmhlanga@uzchs-ctrc.org

Makerere University - Johns Hopkins University (MU-JHU) Research Collaboration CRS

Mary Glenn Fowler, MD, MPH
CTU Co-PI
Johns Hopkins University School of Medicine
600 N. Wolfe Street
Baltimore, MD 21287 USA
Phone: 410-502-0683
Fax: 410-502-0688
Email: mfowler5@jhmi.edu

Clemensia Nakabiito, MBChB, MMed
Site Principal Investigator MTN MU-JHU Research Collaboration
Study Site Co-Investigator
P.O. Box 23491
Kampala, Uganda
Phone: 256-41-541044/256-772-405332
Fax: 256-41-541044/256-41-532091
Email: cnakabiito@mujhu.org

Brenda Gati Mirembe, MBChB, MSC Epidemiology
Site Investigator of Record
MU-JHU Research Collaboration
P.O. Box 23491
Kampala, Uganda
Phone: 256-414-541044/256-772-881922
Fax: 256-41-543002
Email: bgati@mujhu.org

Wits RHI Shandukani Research Centre CRS

Lee Fairlie, MBChB, FCPaeds
Site Investigator of Record
Wits Reproductive Health & HIV Institute (Wits RHI)
22 Esselen Street, Hillbrow
Johannesburg, South Africa 2001
Phone: 27-11-358-5317
Fax: 27-86-554-1093
Email: LFairlie@wrhi.ac.za

US National Institutes of Health (NIH)

Roberta Black, PhD
Chief, Clinical Microbicide Research Branch
National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS)
5601 Fishers Lane, Room 8B62, MSC 9831
Rockville, MD 20852 USA
Phone: 301-496-8199
Email: rblack@niaid.nih.gov

Nahida Chakhtoura, MD, MsGH
Maternal and Pediatric Infectious Disease Branch*, Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
National Institutes of Health (NIH)
6710B Rockledge Drive, Room 2140
Bethesda, MD 20817 USA
Phone: 301-435-6872
Fax: 301-480-3882
Email: nahida.chakhtoura@nih.gov

Naana Cleland, MHCA
Health Specialist, Clinical Microbicide Research Branch (CMRB)
Prevention Sciences Program (PSP) DAIDS, NIAID, NIH – U.S. Department of Health and Human Services (HHS)
5601 Fishers Lane, Room 8B27
Rockville, MD 20852 USA
Phone: 240-292-4779
Email: clelandn@niaid.nih.gov

Jeanna M. Piper, MD
DAIDS Senior Medical Officer
DAIDS/NIAID/NIH/HHS
5601 Fishers Lane, Room 8B68, MSC 9831
Rockville, MD 20852 USA
Phone: 240-292-4798
Email: piperj@niaid.nih.gov

Dianne M. Rausch, PhD
Director
Division of AIDS Research, National Institutes of Mental Health (NIMH)
5601 Fishers Lane Room 8D20, MSC 9831
Rockville, MD 20852 USA
Phone: 240-627-3874
Fax: 240-627-3467
Email: dianne.rausch@nih.gov

Teri Senn, PhD
Program Chief, Psychosocial Co-morbidities of HIV Prevention and Treatment
Division of AIDS Research, NIMH
5601 Fishers Lane Room 9G29
Rockville, MD 20852 USA
Phone: 301-761-7852
Email: teri.senn@nih.gov

MTN Leadership and Operations Center (LOC) – Pitt

Jared Baeten, MD, PhD
Co-Principal Investigator
University of Washington
325 Ninth Avenue, Box 359927
Seattle, WA 98104 USA
Phone: 206-520-3808
Fax: 206-520-3831
Email: jbaeten@uw.edu

Richard Beigi, MD, MSc
Protocol Physician
Magee-Womens Hospital of UPMC
300 Halket Street
Pittsburgh, PA 15213 USA
Phone: 412-641-3313
Fax: 412-641-1133
Email: rbeigi@mail.magee.edu

Katherine Bunge, MD
Protocol Safety Physician
Magee-Womens Hospital of UPMC
300 Halket Street
Pittsburgh, PA 15213 USA
Phone: 412-641-3464
Fax: 412-641-1133
Email: kbunge@mail.magee.edu

Luis Duran, DrPH, MPIA
Project Manager
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-8539
Fax: 412-641-6170
Email: duranl2@mwri.magee.edu

Sharon Hillier, PhD
MTN Principal Investigator
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-6435
Fax: 412-641-6170
Email: shillier@mail.magee.edu

Cindy Jacobson, PharmD
Director of Pharmacy Affairs
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-8913
Fax: 412-641-6170
Email: cjacobson@mail.magee.edu

Sharon A. Riddler, MD, MPH
Protocol Physician
UPMC, Keystone Building, Suite 510
3520 Fifth Avenue
Pittsburgh, PA 15213 USA
Phone: 412-383-1741 or 412-383-1675
Fax: 412-383-2900
Email: riddler@dom.pitt.edu

Devika Singh, MD, MPH
Protocol Safety Physician
19 Randall Drive
Jericho, VT 05465 USA
Phone: 206-920-0975
Email: devika@mtnstopshiv.org

Mei Song, PhD
Protocol Specialist
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-2282
Fax: 412-641-6170
Email: songm4@mwri.magee.edu

MTN Laboratory Center (LC)

Peter Anderson PharmD
LC Pharmacology Core
University of Colorado School of Pharmacy
Mail Stop C238
12850 E. Montview Blvd. V20-4101
Aurora, CO 80045 USA
Phone: 303-724-6128
Email: Peter.Anderson@ucdenver.edu

May Beamer, BS
Laboratory Manager/Supervisor
Microbicide Trials Network
204 Craft Avenue, Room A520
Pittsburgh, PA 15213 USA
Phone: 412-641-6042
Fax: 412-641-6170
Email: mbeamer@mwri.magee.edu

Craig Hendrix, MD
Pharmacology Core Principal Investigator/Protocol Pharmacologist
Johns Hopkins University
600 North Wolfe Street, Harvey 502
Baltimore, MD 21287 USA
Phone: 410-955-9707
Fax: 410-955-9708
Email: cwhendrix@jhmi.edu

Edward Livant, BSMT (ASCP), MPH
MTN LC Research Manager
Microbicide Trials Network
204 Craft Avenue
Pittsburgh, PA 15213 USA
Phone: 412-641-3772
Fax: 412-641-5290
Email: livantew@upmc.edu

Mark Marzinke, PhD, DABCC
LC Pharmacology Core Investigator
Johns Hopkins at Bayview
Clinical Pharmacology Analytical Laboratory (CPAL)/Marzinke Lab
4940 Eastern Avenue
Mason F. Lord (MFL) Center Tower Suite 6000, Room 621
Baltimore, Maryland 21224
Office: 443-287-7516
CPAL Office: 410-550-9703
Fax: 410-955-0767
Email: mmarzin1@jhmi.edu

MTN LOC – FHI 360

Cheryl Blanchette
Community Program Manager
FHI 360
359 Blackwell St., Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext 11359
Fax: 919 544-7261
Email: ccokley@fhi360.org

Abraham Johnson, MPH
Community Program Associate
FHI 360
359 Blackwell St., Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext. 11882
Fax: 919-544-0904
Email: ajohnson@fhi360.org

Ashley Mayo, MSPH
Sr. Clinical Research Manager
FHI 360
359 Blackwell St., Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext. 11164
Fax: 919-544-7261
Email: amayo@fhi360.org

Rachel Scheckter, MPH
Sr. Clinical Research Manager
FHI 360
359 Blackwell St., Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext. 11392
Fax: 919-544-7261
Email: rscheckter@fhi360.org

Jontraye Davis, MHA
Community Program Manager
FHI 360
359 Blackwell St., Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext 11715
Fax: 919 544-7261
Email: jodavis@fhi360.org

Tara McClure, MPH
Clinical Research Manager
FHI 360
359 Blackwell St, Suite 200
Durham, NC 27701 USA
Phone: 919-544-7040, Ext. 11012
Fax: 919-544-7261
Email: tmcclure@FHI360.org

MTN Statistical Data Management Center (SDMC)

Jennifer Berthiaume, MSW, MPH
Clinical Data Manager
FHCRC-SCHARP
1100 Fairview Ave. North, E3-129
PO Box 19024
Seattle, WA 98109-1024 USA
Phone: 206-667-1230
Email: jberthia@scharp.org

Barbra Richardson, PhD
Faculty Statistician
FHCRC-SCHARP
1100 Fairview Avenue North, M2-C200
PO Box 19024
Seattle, WA 98109-1024 USA
Phone: 206-667-7788
Fax: 206-667-4812
Email: barbrar@uw.org

Karen Patterson, MPH
Program & Portfolio Manager
FHCRC-SCHARP
1100 Fairview Avenue North, E3-129
PO Box 19024
Seattle, WA 98109-1024 USA
Phone: 206-667-7052
Fax: 206-667-4812
Email: karenp@scharp.org

MTN Working Group Representatives

Behavioral Research Working Group (BRWG) Representative

Elizabeth Montgomery, PhD
Women's Global Health Imperative, RTI International
351 California Street, Suite 500
San Francisco, CA 94104 USA
Phone: 310-694-7212
Fax: 310-841-2772
Email: emontgomery@rti.org

Community Working Group (CWG) Representatives

Esther Goliati
Community Educator
Johns Hopkins Research Project/College of Medicine
Chipatala Avenue, P.O. Box 1131
Blantyre, Malawi
Email: esthergoliati@gmail.com

Doreen Kemigisha
Community Educator
P.O. Box 23491
Kampala, Uganda
Phone: 256-782493311
Email: dkemigisha@mujhu.org

Biomedical Science Working Group (BSWG) Representative

Jenny Robinson, MD, MPH, FACOG
Johns Hopkins University
600 North Wolfe Street, Harvey 502
Baltimore, MD 21287 USA
Phone: 410-550-7202
Fax: 410-550-0196
Email: jrobin87@jhmi.edu