



# Harnessing the Power of the Specimen Tsunami

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# History of the MTN

- Funded since 2006, the MTN had our first leadership meeting in Pittsburgh on Sept 16.
- The first protocol, MTN-004, started enrolling in July 2007.
- Over the past 8 years, 19 studies have been completed or are in the field!
  - <http://www.mtnstopshiv.org/studies>

# Our studies - safety/PK

- Safety/acceptability
  - MTN-004 (vaginal)
  - MTN-005 (vaginal)
  - MTN-007 (rectal)
  - MTN-012 (penile)
  - MTN-023 (vaginal)
  - MTN-024 (vaginal)
- Intensive pharmacokinetic
  - MTN-001 (oral/topical)
  - MTN-006/RMP-02 (rectal)
  - MTN-011 (coital)
  - MTN-013 (vag ring)
  - MTN-014 (vaginal/rectal)

# Our studies – special populations

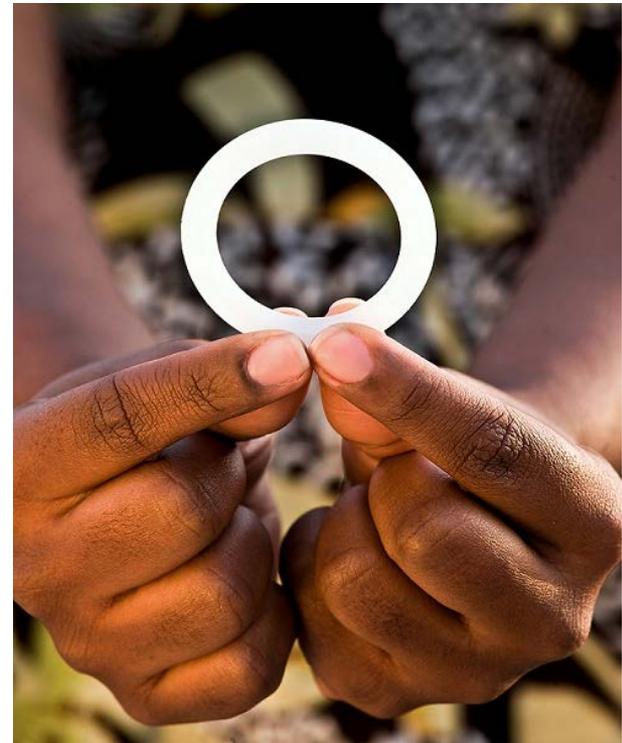
- Pregnancy
  - MTN-002
  - MTN-008
  - MTN-016
- Rectal (♀/♂/♀♂)
  - MTN-006
  - MTN-007
  - MTN-017
- HIV-infected ♀
  - MTN-015
- Adolescent ♀
  - MTN-023
- Post-menopausal
  - MTN-024
- HIV resistance ♀
  - MTN-009

# Our studies - effectiveness

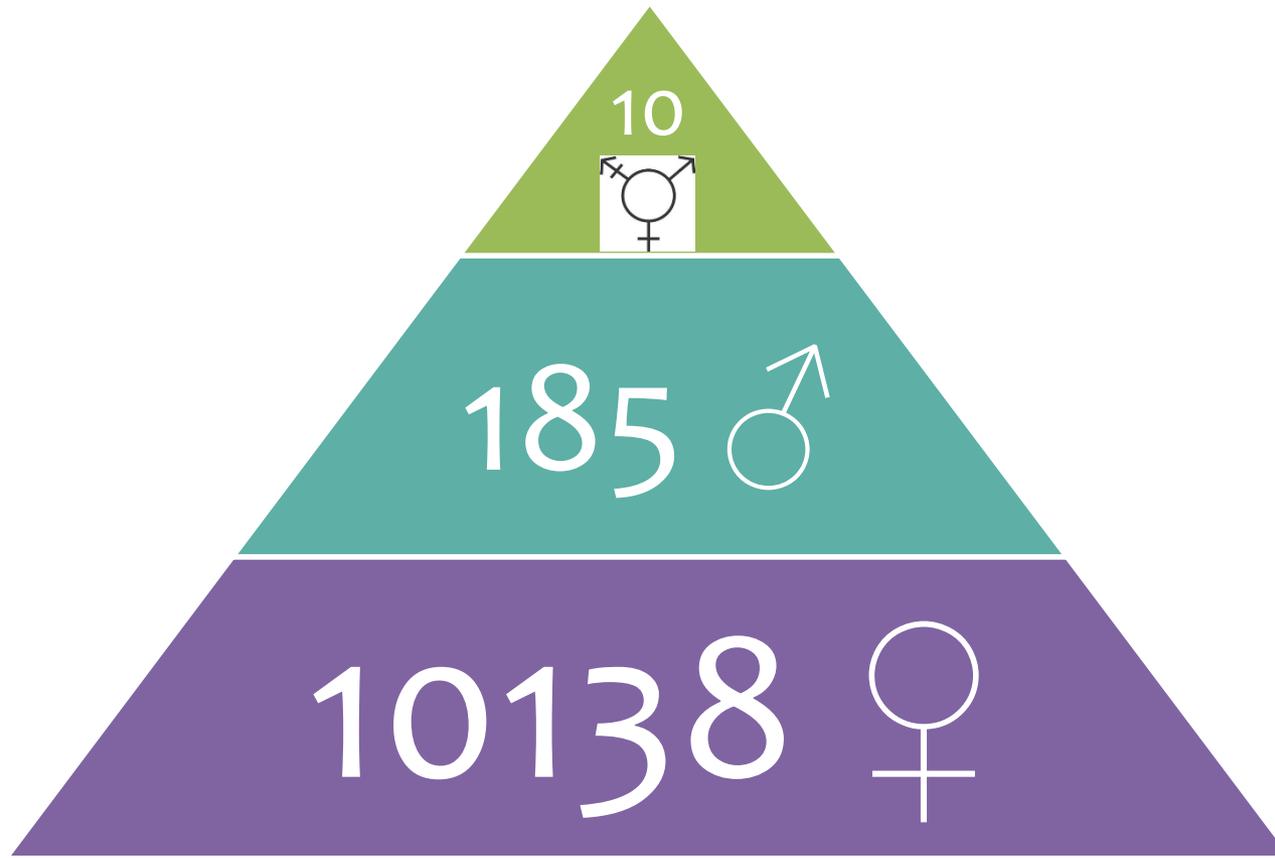
## MTN-003 (VOICE)



## MTN-020 (ASPIRE)



# Number of participants\* enrolled



\*excludes participants in MTN-015 and MTN-016

Number of specimens in storage from trials as of 1 July 2014

501,520

Specimen type	Aliquots*
Amniotic Fluid	28
Anal Swab	98
Blood Cell Pellet	247
Breast Milk	328
CVL Cell Pellet	336
Cervical Biopsy	360
Cervical Cytobrush	365
Cervical Swab	27482
Cervicovaginal Lavage	22428
Cord Blood	182
Cultured Explant	180
Cultured Tissue	276
Ear Swab	900
Endometrial Biopsy	32
Endometrial Swab	51084
Exfoliated Cervical Cells	5500
Feces	11380
Finger Swab	32
Genital Swab	298257
Rectal Biopsy	1736
Rectal Lavage Fluid	382
Rectal Sponge	1124
Rectal Swab	190
Semen	129
Serum	7398
Urine	160
Vaginal Biopsy	453
Vaginal Ring	10811
Vaginal Ring Swab	63
Vaginal Swab	58535
Vaginal Tear Strip	1044

\*Includes specimens from participants who have not consented to long-term storage.

# MTN-001

US/African sites cross-over design testing TFV PK after 6 weeks of oral, topical, or both.

Specimen	Aliquots
Cervical Cytobrush	212
Cervicovaginal Lavage	3615
PBMCs (lysate)	1568
Plasma	3209
Rectal Sponge	36
Serum	3154
Vaginal Biopsy	288

# MTN-003 (VOICE)

Placebo-controlled, 5 arm trial testing TFV gel, Viread, Truvada for safety and efficacy.

Specimen	Aliquots
Cervical Swab	19055
Gram Stain Slides	34202
PBMCs (lysate)	2393
Plasma	169011
Vaginal Swab	19076

# MTN-008

Safety and PK study in pregnant (34 to 39 weeks gestation) and lactating women applying 7 doses of TFV gel.

Specimen	Aliquots
Breast Milk	328
Cervical Swab	710
Cord Blood	149
Gram Stain Slides	727
PBMCs (lysate)	1405
Plasma	134
Serum	2687
Vaginal Swab	1084

# MTN-015

## Observational HIV seroconverter study.

Specimen	Aliquots
Blood Cell Pellet	109
CVL Cell Pellet	134
Cervicovaginal Lavage	17227
PBMCs (viable)	11380
Plasma	57510
Serum	1197
Vaginal Swab	4479

# Unique specimens

- Aside from blood, MTN has a unique collection of mucosal samples...
  - Amniotic fluid
  - Anal swabs
  - Breast milk
  - Cervical swabs
  - Cervicovaginal lavage
  - Rectal sponges
  - Vaginal swabs

# What to do?

Nothing?



Ride the wave?



# Have an idea?

The screenshot shows the homepage of the Microbicide Trials Network (MTN). At the top, there is a navigation bar with links for HOME, ABOUT, SITES, STUDIES, NEWS ROOM, NETWORK, MEETINGS & TRAVEL, PEOPLE, and RESOURCES. A search bar is located in the top right corner. Below the navigation bar, there is a main content area with several sections:

- The Latest...:** A purple header section containing two news items. The first is about the ASPIRE Phase III trial of a vaginal ring for HIV prevention, which has completed enrollment of 2,629 women. The second is about the 2014 MTN Manual of Operational Procedures being posted to the website.
- Welcome:** A section with a brief description of the Microbicide Trials Network as a U.S. National Institutes of Health-funded worldwide collaborative clinical trials network focused on preventing the sexual transmission of HIV.
- Network:** A section listing various study arms: LOC, LC, SDMC, BSWG, BRWG, CWG, and NEC.
- Enrolling Studies:** A section listing specific study IDs: MTN-014, MTN-015, MTN-016, MTN-017, MTN-023/IPM 030, and MTN-024/IPM 031.
- Research Sites:** A section featuring a world map with several countries highlighted in purple, indicating research sites. Below the map, it says "Nine Countries... 32 Sites... View All...".
- Meetings & Events:** A section with a photo of two women and text announcing registration for the MTN 2014 Regional Meeting.
- A Message From...:** A section with a photo of Sharon Hillier and Ian McGowan and text asking if the user has an idea for a study they would like to propose for the MTN. This section is highlighted with a red border and a red arrow points to it from the right.
- Resources & Links:** A section at the bottom left.
- Recent Documents:** A section at the bottom right.

The browser's address bar shows the URL <http://www.mtnstopshiv.org/>. The taskbar at the bottom of the screen shows various application icons and the system clock indicating 11:11 AM on 8/22/2014.

# Write it up!

- Ancillary study - investigations that are not described in the original protocol.
- Develop your hypothesis / study design and talk with the LC, SCHARP, and FHI360 folks familiar with that study.
- As you fill-in the ancillary concept application (<http://www.mtnstopshiv.org/node/5647>), please keep-in mind logistical considerations.

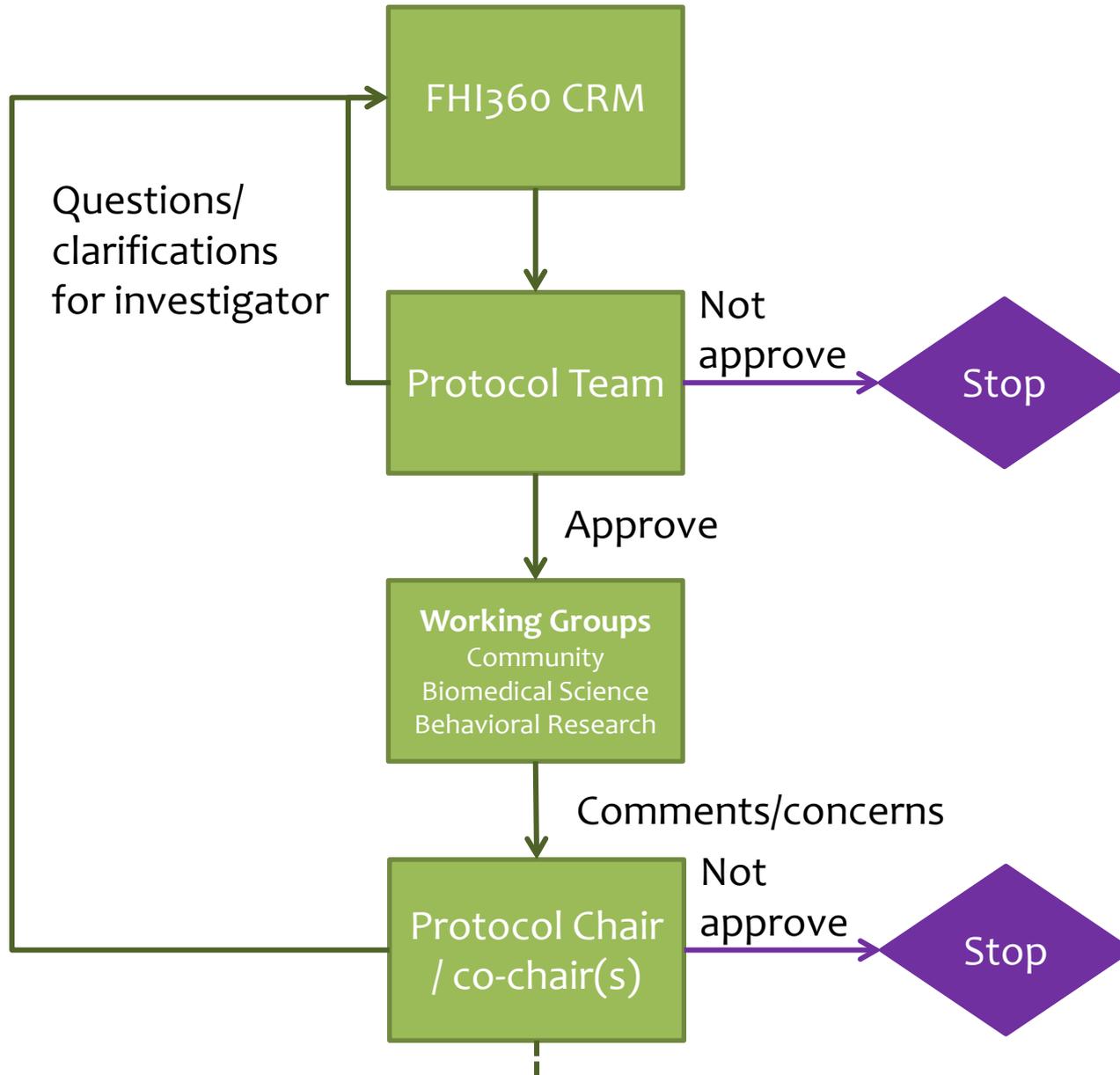
# Logistics

- Examples to consider:
  - What types of samples are available from which visits? Review Study protocol and SSP first.
  - Will I use samples only from my site or should I expand to include other sites?
  - Do your ethics committees need to approve your proposal?
  - How will I identify samples needed for my concept? Talk with SCHARP.
  - Will samples need to be shipped?
  - How will shipping, testing, and other aspects of my concept be funded?
  - How will the data be analyzed?

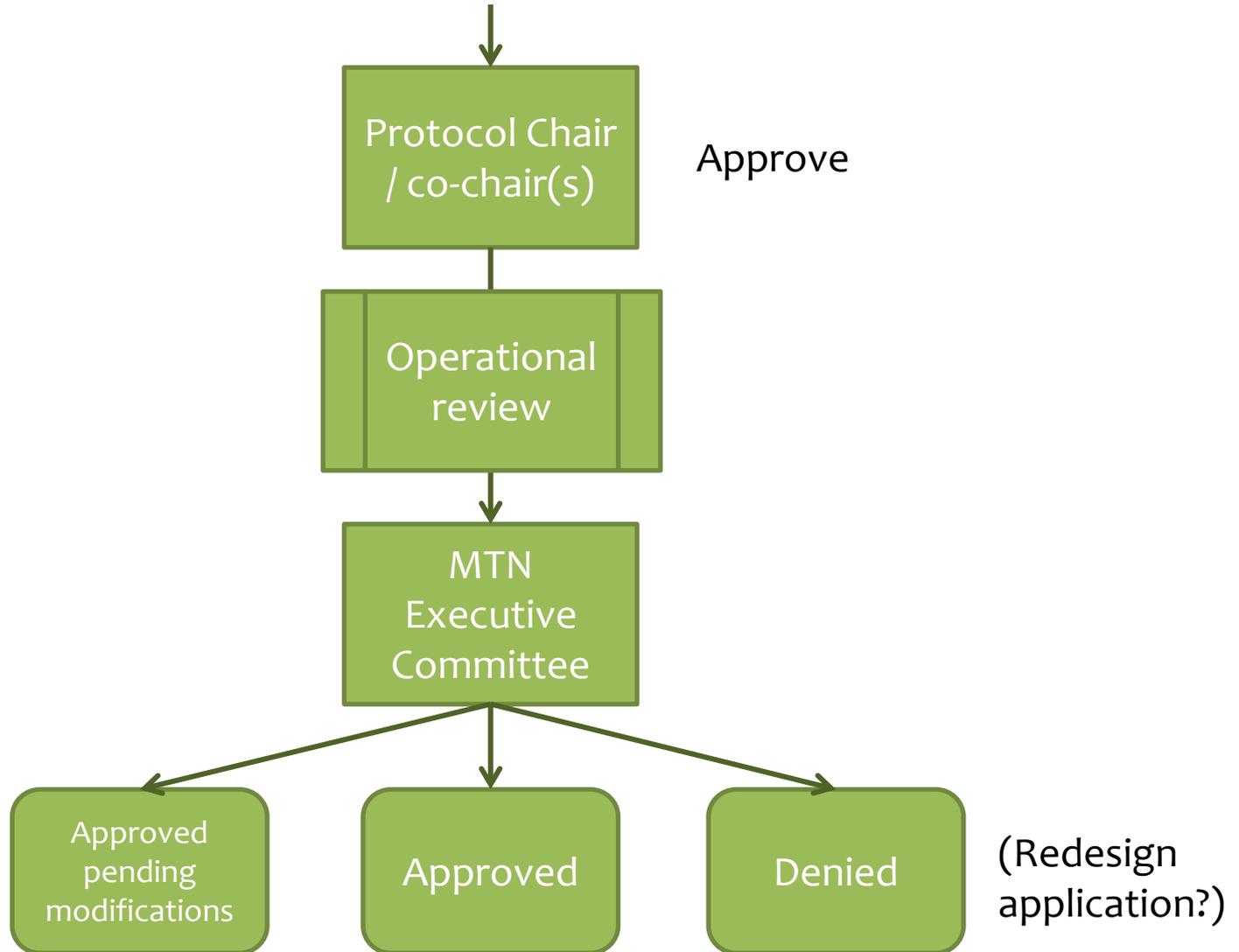
# Your concept

- Make sure your application addresses all elements and is clearly written.
- Once ready, send your form, and any additional information, to the FHI 360 Clinical Research Manager (CRM) for that study to start the approval process.

# Approval process



# Approval process



Investigator informed of the outcome.

# Surviving the Specimen Tsunami



- Your ideas are important!
- The MTN strives to have the best science.
- We want to optimally use these precious specimens.

# Big thanks to...

- The participants – for their dedication.
- The MTN family – for all your hard work.
- SCHARP: Jen Balkus, Marla Husnik, Karen Patterson, and Della Wilson
- Laboratory Center: Edward Livant, Pam Kunjara, Lorna Rabe, Wayne Hall, and Urvi Parikh



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