

The logo for ASPIRE features the word "ASPIRE" in a purple, serif font. A green ring is positioned around the letter "A".

ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use

MTN-020: Study Start

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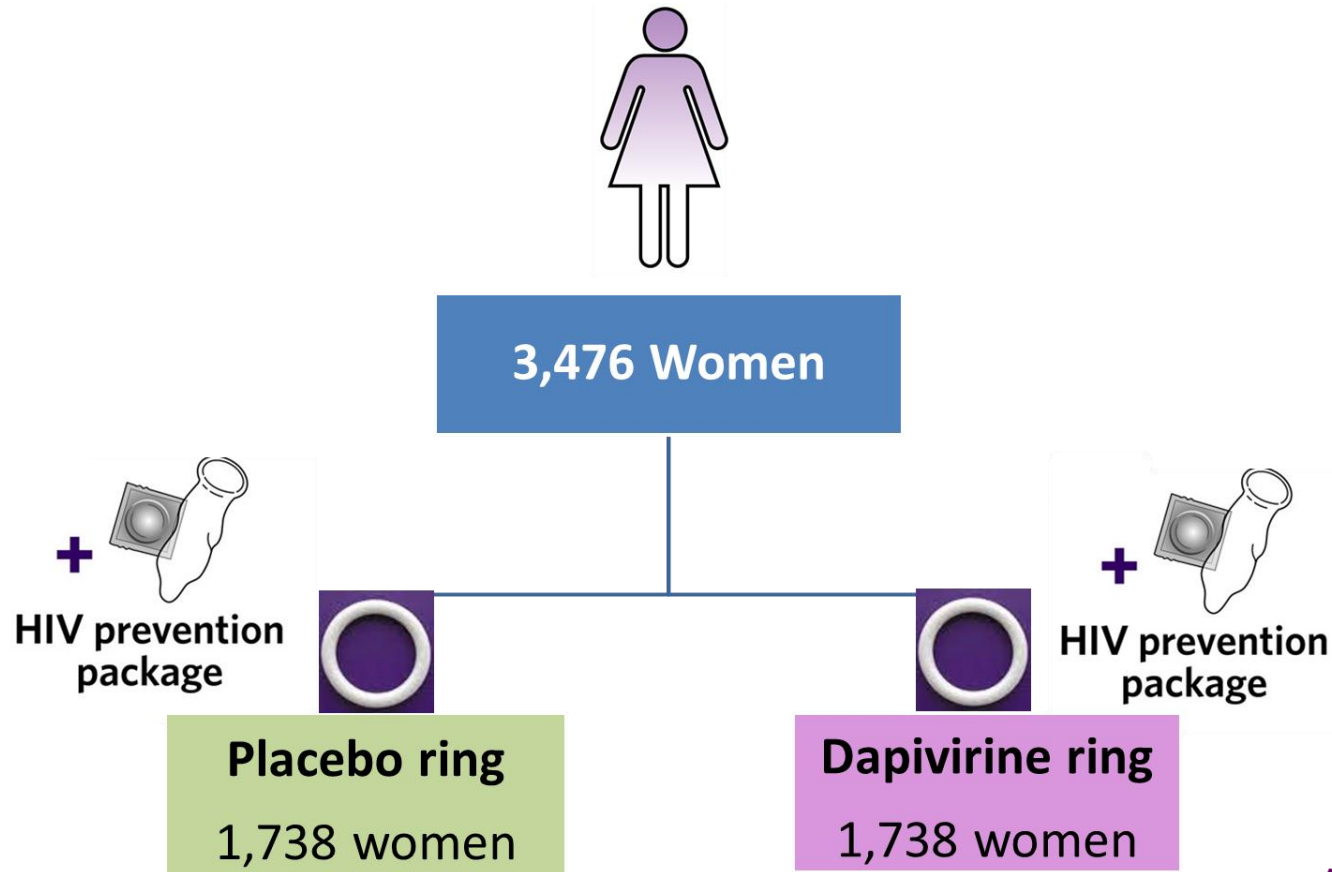
ASPIRE Protocol Team Meeting
22 February 2012



MTN-020 / ASPIRE

- **A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase III Safety and Effectiveness Trial of a Vaginal Matrix Ring Containing Dapivirine for the Prevention of HIV-1 Infection in Women**

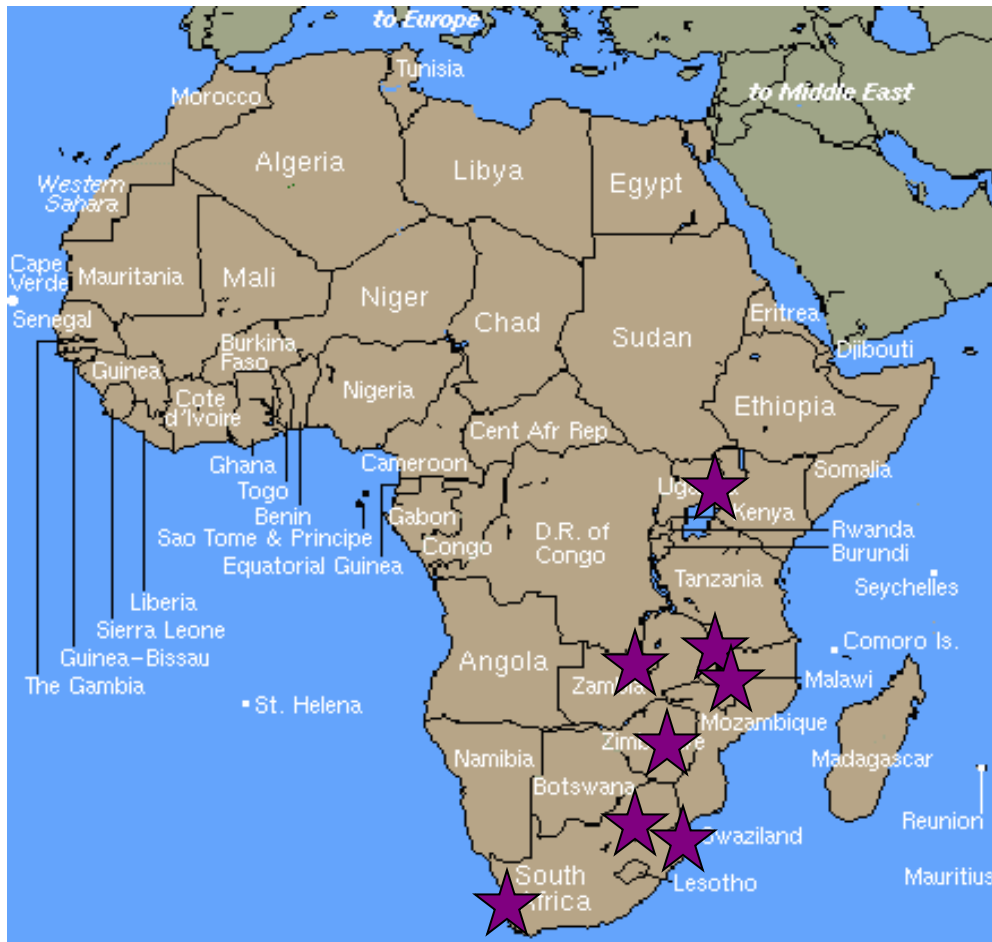
ASPIRE Study Design



Participants

- 3476 sexually active HIV-uninfected women who are non-pregnant, contracepting, and 18-45 years of age
- Accrual will require approximately 12 months, with total study duration approximately 24 months
 - Designed so that all participants will achieve 12 months on study product

Proposed sites – MTN-020



Blantyre
Lilongwe
Malawi

Cape Town
Durban (8 sites)
Klerksdorp
Johannesburg
South Africa

Kampala
Uganda

Lusaka
Zambia

Harare (3 sites)
Zimbabwe

Timeline

2011

- Initiate site IRB and regulatory approval process

2012

- IRB/regulatory approvals, trainings, enrollments begin Q3

2013

- Enrollments and follow-up continue

2014

- End of participant follow-up

2015

- Results

Numbers that matter

- 3476 = total number of women enrolled
- >95% = retention, product distribution
- 100% = attention to data quality, safety

Everything else flows from these

Getting to 3476

- To date, have defined site targets for start-up
 - These are clearly not set in stone and will flux depending on timing of site initiation
 - A portion of 3476 not currently assigned at all – pending early performance
- Period of accrual is about 12 months, driven by quality and appropriate pacing

Lessons I have learned...

- #1. Efficiency matters
 - *Efficient and focused start-up*
 - *Targeted participant visits*
 - *Attention to what is important for a quality study*

Lessons I have learned...

- #2. Adherence is key
 - *Products don't work if they aren't used*
 - *How will we set up a culture in ASPIRE so that women can accurately report non-use?*

Lessons I have learned...

- #3. Retention is adherence
 - *Missed visit = month of zero adherence*

Lessons I have learned...

- #4. We all work together – all parts of the study are all our business

Recruitment

Retention

Adherence

Sample collection

Staff morale

Community/outreach

Communications

Lab quality

QC/QA

Regulatory

Safety Monitoring

Space/facilities

Study drug/pharmacy

Contraception

Lab-clinic interface

Monitoring follow-up

Lessons I have learned...

- #5. Metrics and competition are healthy
 - *Retention #s*
 - *Data quality #s*



Lessons I have learned...

- #6. Bigger is not always better
 - *Smaller sites / new sites can be models of success*

Lessons I have learned...

- #7. No one knows how to do this perfectly
 - *Cross-site, cross-team sharing is important*
 - *Some of our ideas: job-specific list servs, biweekly calls with FHI360, regular protocol team meetings that focus on site-led presentations*
 - *Talk with each other...*



Lessons I have learned...

- #8. Talk with participants
 - *We have much to learn from them*

Lessons I have learned...

- #9. Stakeholder and community involvement is ongoing
 - *Continuous contact*



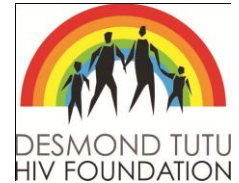
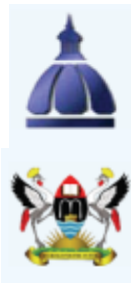
Lessons I have learned...

- #10. It takes a team
 - *We are all in this together*

It takes a team



Malawi College of
Medicine – JHU
Research Project



UNC Project -
Malawi



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PARTNERSHIP FOR
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