MTN-020: Study Start

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ASPIRE Protocol Team Meeting
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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

3,476 Women

+ HIV prevention package

Placebo ring
1,738 women

+ HIV prevention package

Dapivirine ring
1,738 women
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Events</th>
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<tr>
<td>2011</td>
<td>- Initiate site IRB and regulatory approval process</td>
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<tr>
<td>2012</td>
<td>- IRB/regulatory approvals, trainings, enrollments begin Q3</td>
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<tr>
<td>2013</td>
<td>- Enrollments and follow-up continue</td>
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<td>2014</td>
<td>- End of participant follow-up</td>
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<td>2015</td>
<td>- Results</td>
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Numbers that matter

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

Everything else flows from these
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