



**Meeting the HIV Prevention Needs of Adolescent Girls and Young Women:
Stakeholders consultation on the MTN-034/IPM 045 open-label safety and adherence study
of the dapivirine vaginal ring and oral PrEP**

29-30 September, 2016, Johannesburg, South Africa

THURSDAY 29 September 2016

Time	Session
6:00 pm	Registration
6:30-7:30	Meet and greet and buffet dinner (buffet will be open from 6:45 pm)
Program 7:30-9 p.m.	Welcome and Introductions – <i>Sharon Hillier, Manju Chatani</i> (15 min)
	Voices that Matter (15 min) <i>Loyce Maturu – Zimbabwe</i> <i>Helida Owuor – Kenya</i> <i>Sinazo Peter – South Africa</i>
	Setting the stage: Overview and status of the dapivirine ring (20 min) <ul style="list-style-type: none"> • Overview of ring results -what we know/don't know—especially in young women – and update on HOPE and DREAM open-label extension studies – <i>Sharon Hillier</i> • Ring regulatory process and timelines – Who might be able to use the ring? – <i>Leonard Solai</i>
	Setting the stage: Overview and status of oral PrEP in women (20 min) <ul style="list-style-type: none"> • Overview of PrEP studies - what we know/don't know, especially in young women – <i>Connie Celum</i> • WHO guidelines, approval status , and a snapshot of ongoing and planned PrEP demonstration projects – <i>Connie Celum</i>
	Questions and discussion (15 min)
	Overview of Friday's Agenda – <i>Sharon Hillier, Manju Chatani</i> (5 min)

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FRIDAY 30 September 2016

Time	Session
8 am	Registration
8:30 – 8:45 am	Welcome and Introductions – <i>Sharon Hillier, Manju Chatani, Lulu Nair and Partners</i> (15 min)
Session 1 8:45 – 9:35 am <i>Definate Nhamo</i> <i>Moderator</i>	Ring and PrEP: Recap and Reactions <ul style="list-style-type: none"> • Ring and PrEP - A Review – <i>Sharon Hillier, Connie Celum</i> (10 min) • Making it Real: Women’s Reactions and Responses – A moderated panel discussion (30 min) <i>Lucy Siphuma – South Africa</i> <i>Amanda Soza – Zimbabwe</i> <i>Winnie Wadera – Kenya</i> • Additional questions and discussion (10 min)
Session 2 9:35 – 10:30 am <i>Kawango Agot</i> <i>Moderator</i>	Prelude to MTN-034: What are women years, and why do they matter for girls under age 18? – <i>Leonard Solai</i> (5min) What is MTN-034, the REACH study? (40 min) <ul style="list-style-type: none"> • The basics and more: Rationale and study design overview, protocol development process and timeline, study sites, who may enroll; primary, secondary and exploratory objectives and how these will be measured – <i>Lulu Nair</i> • What will happen during the study: Study visits and procedures, safety monitoring, adherence measures, counseling and support – <i>Lulu Nair</i> • Qualitative aspects – tools for understanding acceptability and preferences – what questions are we asking? – <i>Kenneth Ngure</i> • Questions and discussion Now what? Overview of specific questions and issues we would like to discuss in this consultation – <i>Connie Celum</i> (5min)
10:30 - 10:45 am	Tea break
Session 3 10:45-11:15am <i>Imelda Makaha</i> <i>Moderator</i>	MTN-034 in Context: Understanding the ethical and legal framework within each trial-site country <i>Matters of consent, confidentiality and mandatory reporting</i> <i>Ambrose Rachier – Kenya</i> (5 min) <i>Paul Ndebele – Zimbabwe</i> (5 min) <i>Cathy Slack – South Africa</i> (5 min) Questions and discussion (15 min)

<p>Session 4 11:15 am -12:30 pm</p> <p><i>Manju Chatani and Megan Dunbar Moderators</i></p>	<p>MTN-034 in Context: What do young women think? Questions about product use, adherence monitoring and adherence support</p> <ul style="list-style-type: none"> • Panel discussion with young women –initial thoughts about the study (15 min) • What do you think? Questions about product use, adherence monitoring and adherence support: panel and group discussion (<i>Lulu Nair, Kenneth Ngure</i> – discussants) (60 mins) <p>Panelists:</p> <p><i>Analisa Madalene – South Africa</i> <i>Cleopatra Makura – Zimbabwe</i> <i>Lucy Masika – Kenya</i> <i>Sibongile Ndhlovu – South Africa</i> <i>Thulile Matebula – South Africa</i> <i>Thulisile Matebula – South Africa</i> <i>Sally Opado – Kenya</i></p>
<p>12:30-1:30 pm</p>	<p>Lunch</p>
<p>Session 5 1:30- 2:30 pm</p> <p><i>Lebo Ramofoko Moderator</i></p>	<p>Complicated Issues and sensitive topics: What are your views?</p> <ul style="list-style-type: none"> • Sexual activity, social harms and reimbursement of study participants: Overview of questions at hand – <i>Connie Celum</i> (10 min) • Small group discussions on specific issues and questions (30 min) • Reports back and full-group discussion (20 min)
<p>Session 6 2:30-3:30 pm</p> <p><i>Mitchell Warren Moderator</i></p>	<p>MTN-034 in Context: PrEP access and in-country considerations within a rapidly evolving landscape</p> <ul style="list-style-type: none"> • What’s happening where and when? – <i>Saiqa Mullick</i> (10 min) • Messaging about PrEP and PrEP access during REACH (MTN-034) and expectations for access to PrEP and ring after the study (25 min) • Views and perspectives on specific questions related to REACH (<i>Lulu Nair, Connie Celum</i> – discussants) (25 min) <p><i>In lieu of a break, tea service will be available in the room beginning at 3:30</i></p>
<p>Session 7 3:30–4:15 pm</p> <p><i>Ntombozuko Kraai and Manju Chatani Moderators</i></p>	<p>Unanswered questions and new ones: What do we need to do to succeed? Open discussion... (45 min)</p>
<p>Session 8 4:15-4:30 pm</p>	<p>What now? Study timelines, protocol reviews and next steps – <i>Sharon Hillier, Lulu Nair</i></p>
<p>4:30 pm</p>	<p>Close <i>Manju Chatani, Definate Nhamo, Kawango Agot and Ntombozuko Kraai on behalf of the partner organizations</i></p>