



MTN 003: Safety Trends

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Summary (as of Sept 9, 2010)

- Number of sites: 15
 - South Africa 11
 - Uganda 1
 - Zimbabwe 3
- Number of participants: 1403
- Number of product holds: 60 (55 ppts)
- Number of permanent holds: 2

Product Hold (All Sites)

Participants enrolled	All sites
Ppts with ≥ 1 product hold	55 (4%)
Number of product holds per ppt	
0	1330 (96%)
1	51 (4%)
2	3 (<1%)
3	1 (<1%)
Time on product prior to <u>first</u> hold (days)	
N	55
Mean (SD)	87.9 (66.1)
Min, Max	9, 271
Number of product holds	60

Hold and Reasons for Hold

Participants enrolled	All sites
Product permanently held	2 (3%)
Product temporarily held	58 (97%)
Product use resumed	26 (45%)
Product currently held	32 (55%)
Reasons for product hold	
Pregnancy	21 (35%)
Other AE (next slide)	28 (47%)
Other: serum Cr	5 (9%)
Other: enrollment violation	1 (2%)
Other: non-compliance with procedures	1 (2%)
Other: co-enrolled	1 (2%)
Other: ppt opting out of study	1 (2%)



'Other AE' Product Holds

□	Grade 3 Hypophosphatemia	x9	(2 ongoing)
□	Grade 2 Proteinuria	x8	(4 ongoing)
□	Grade 3 Unintentional Wt Loss	x2	
□	Grade 2 Increased ALT	x2	
□	Grade 3 Increased ALT		
□	Grade 2 Increased AST		(ongoing)
□	Grade 3 Global dementia		(ongoing)
□	Grade 3 PID		
□	Grade 3 HTN		(ongoing)
□	Grade 2 vaginal burning		
□	Grade 3 hyperemesis gravidarum		(ongoing)
□	Grade 4 parasuicide		

Duration of Product Hold

Participants enrolled	All sites
Duration of product hold (days)	
N	60
Mean (SD)	43.9 (58.5)
Min, max	1, 248
Duration of product hold due to pregnancy (days)	
N	21
Mean (SD)	82.0 (82.6)
Min, max	8, 248



Total Study Product Hold

Participants enrolled	All sites
Total person years of follow up	340.4
Person years of follow up on product hold	7.0
Percent of follow-up time on product hold	2.1%
Person years of follow up on product hold due to pregnancy	4.7
Percentage of follow up time on product hold due to pregnancy	1.4%



Social Harms

Partner doesn't want ppt to use contraception and doesn't want ppt to be in study. Ppt going to continue in study without partner knowing

Partner didn't want ppt to use tablet because he didn't understand what they were for. Her aunt believed the tablets will cause HIV and insisted that she stop the study

The **partner** had a problem with products that are inserted into the vagina. The ppt denied that there were products inserted into the vagina

Participant's **partner** was having a problem with ppt coming home late when she is visiting the clinic

Husband fought her because she participated in the study and she sustained a swollen right eye

I invited my **husband** to the MTN 003 launch on 30July2010. He arrived late and the proceedings of the launch were almost at the end. After the launch he went to my brother's place and told him that I was in the HIV treatment study. He misconstrued the information from the launch and assumed that I was HIV positive. He even went onto to tell our son who is 13 years old that I am HIV positive



Summary

- Low rates of product hold (4%)
- Most are due to a single AE, and almost half ppts resumed product (45%)
- One third of holds and 60% of time off product is due to pregnancy
- 9% of holds are for creatinine related AEs
- All 11 SAEs were deemed 'Not Related' to product by the IoR
- Social Harms AEs emphasize the importance of partner involvement



Thank you!