



# MTN-003

## Lessons Learned from Zimbabwe

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# Outline

- Introduction – Statistics
- Study Product
- Adverse Events
- Laboratory abnormalities
- Pregnancies
- Conclusion



# Statistics as at 12 March 2010

	SPILHAUS	SEKE SOUTH	ZENGEZA
STARTED SCREENING	02 SEP 09	08 OCT 09	02 NOV 09
FIRST ENROLMENT	15 SEP 09	02 NOV 09	30 NOV 09
TOTAL SCREENED	176	157	139
HIV POSITIVE	22	20	18
TOTAL ENROLLED	54	62	44
TOTAL ENROLLED INTO BMD	17/29	29/32	16/28

HIV prevalence - 12.7%

HBV positivity at screening - 27%

Commonest STI - Chlamydia

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# Study Product

- Oral – no problems swallowing, grade 1 nausea, vomiting, GBW
- Vaginal – insertion reasonably easy, leaking, grade 1 vulvo-vaginal irritation, vaginal pain due to poor technique
- Adherence – variable, incongruent reports
- Gel cartons bulky
- Product hold, discontinuation



# Adverse Events

- Gastrointestinal – nausea, vomiting, diarrhoea
- Genitourinary
- Laboratory abnormalities – raised ALT/AST, hypophosphataemia
- 1 SAE
- No EAEs



# Laboratory Abnormalities

- Serum phosphate – reference range for Zim 1,90 – 5.30 mg/dl, obsolete? 5-7% with grade 1 and 2 reductions, 1% with higher grade
- Management of persistent grade 1/2 phosphate reductions, 4-5% have had oral supplements
- Management of persistent grade 1/2 raised AST/ALT – repeat LFTs, glycaemic index, hepatobiliary USS, ?HCV serology
- Pre-existing conditions



# Pregnancies

- Zimbabwe has highest contraceptive uptake in the region
- Enrolled participants – 39% injectable, 38% implants, 23% COCP
- **4 pregnancies so far**
- 3 on COCP, 2 forgot, 1 claims 100% adherence
- 1 on DMPA – supposedly had dose given by a CBD, next dose was due 10 days after enrolment, preg test negative, DMPA given, M1 – preg test positive!



# Conclusion

- Complex study with many minor details compared to 035
- Toxicities are a challenge
- Pregnancy and breastfeeding have not adversely affected accrual







# Thank you!

NIH, DAIDS, MTN CORE, FHI, NL, SCHARP, PAB,  
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