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

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

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

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Adverse Events

- Gastrointestinal – nausea, vomiting, diarrhoea
- Genitourinary
- Laboratory abnormalities – raised ALT/AST, hypophosphphataemia
- 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

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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

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Thank you!

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

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