Accrual & Retention Challenges in VOICE

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VOICE Meeting
Cape Town, South Africa
October 2010
"I need someone well versed in the art of torture—do you know PowerPoint?"
Topics

- Review current study status, recent trends (last month)
- Implementation challenges
- Discussion
VOICE - Progress

Regional Meeting, October 2009

Annual Meeting, April 2010

TODAY

Spilhaus
VOICE - Progress

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Botha’s Hill, Isipingo, Overport, Chatsworth, Tongaat, Umkomaas, Verulam, Uganda, Seke South, Zengeza
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TODAY
Aurum, RHRU, PHRU
VOICE - Current Status

As of 24 September 2010

5134 Screened

2409 Screened Out

1078 volunteers identified as HIV+ infected at Screening

Uganda 180 Enrolled

South Africa 1164 Enrolled

Zimbabwe 303 Enrolled

Malawi Pending

Total Enrollment = 1647
Overall Screen to Enroll Ratio = 2.7:1
Distribution of Screen-outs

Of those participants who screen out of VOICE:

- **41%** HIV positive
- **15%** Screening window closed
- **15%** Lab values, e.g., HBsAg +, anemia
- **11%** Pregnancy (current/planned), lactation
- **18%** Other, e.g., relocation, chronic illness
Distribution of Screen-outs

Of those participants who screen out of VOICE:

- 41% HIV positive
- 15% Screening window closed
- 15% Lab values, e.g., HBsAg +, anemia
- 11% Pregnancy (current/planned), lactation
- 18% Other, e.g., relocation, chronic illness

With all MRC sites doing MTN-009, screen out due to HIV minimized. As of 10/1, 50 HIV+ ppts enrolled in 009
Exceeded expected in September: Botha’s Hill, Isipingo, Umkomaas, eThekwini, Aurum, RHRU, PHRU, Uganda
Highlights for Month 12

- VOICE sites enrolled 366 participants and EXCEEDED monthly target for the first time
  - Helps to close cumulative gap (151 participants behind schedule overall; 157 last month)
  - Botha’s Hill did an outstanding job with 40 participants enrolled!
  - Isipingo and Umkomaas exceeded monthly targets; Chatsworth, Verulam, Overport better than prior month
  - eThekwini at 154% of their cumulative target
  - Aurum exceeded their cumulative target by 1
  - RHRU exceeded monthly target by 8, cumu target by 1
  - PHRU exceeded monthly target by 2
  - Uganda exceeding monthly target by 5!
  - Seke South on schedule with meeting monthly target this month and only down by 1 cumulatively
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TODAY
Aurum, RHRU, PHRU
MTN003 Cumulative Accrual - All Sites

Number of Participants (based on site report)

Study Month

- Actual Cumulative
- Expected Cumulative
Implementation Challenges

- Community concerns about ARV safety / stigma
  - Development of drug resistance

- Male partner issues
  - Participation might reflect on woman’s fidelity, loss of confidentiality for the couple

- Pregnancy and breastfeeding prohibition

- Right-sizing safety monitoring
  - Serum phosphate
  - Urine protein

- Length of study visits and complexity of protocol

- Regulatory issues (e.g., Zambia, Malawi)
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Strategies</th>
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<tbody>
<tr>
<td>Women not presenting for Screening Part 1 appointments</td>
<td>Community education &amp; sensitization; focus on male involvement</td>
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<td>Concept of PrEP new; not well understood in community</td>
<td>Use CAPRISA 004 results to educate &amp; increase awareness of clinical trials</td>
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<td>Fear of taking ARVs, side effects</td>
<td>Community education; peer educators</td>
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<tr>
<td>Fear of HIV testing</td>
<td>Increase awareness of HIV &amp; treatment options</td>
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<tr>
<td>Challenges</td>
<td>Strategies</td>
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<tr>
<td>Medical, lab screenouts</td>
<td>Encourage those screened out to refer ppts</td>
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<td>Migrant populations</td>
<td>Expand recruitment areas</td>
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<td>Transportation issues</td>
<td>Increase field worker capacity/training; consider population-specific teams</td>
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<tr>
<td>Participants’ work commitments</td>
<td>Daily AM education sessions</td>
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THANK YOU!
Early Terminations

- 20 to date
- 13 occurred within 3 months of enrollment
- 11 cited partner issues
  - An additional participant from the Uganda site had a social harm related to the partner and her participation in the study which may have led to the early termination as well