

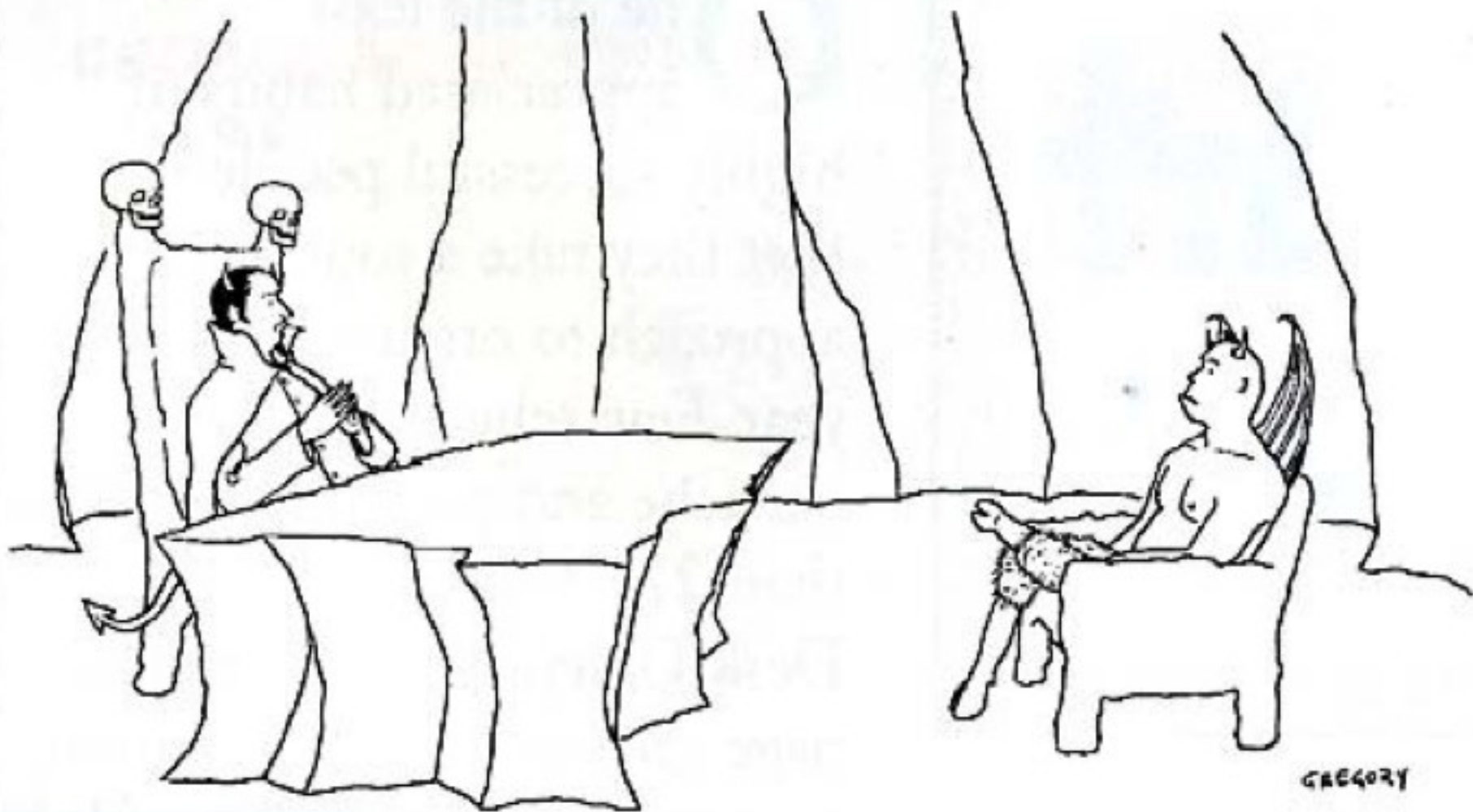
# Accrual & Retention Challenges in VOICE

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**Jeanne Marrazzo, MD, MPH**

**VOICE Meeting  
Cape Town, South Africa  
October 2010**





*"I need someone well versed in the art of torture—  
do you know PowerPoint?"*

# Topics

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

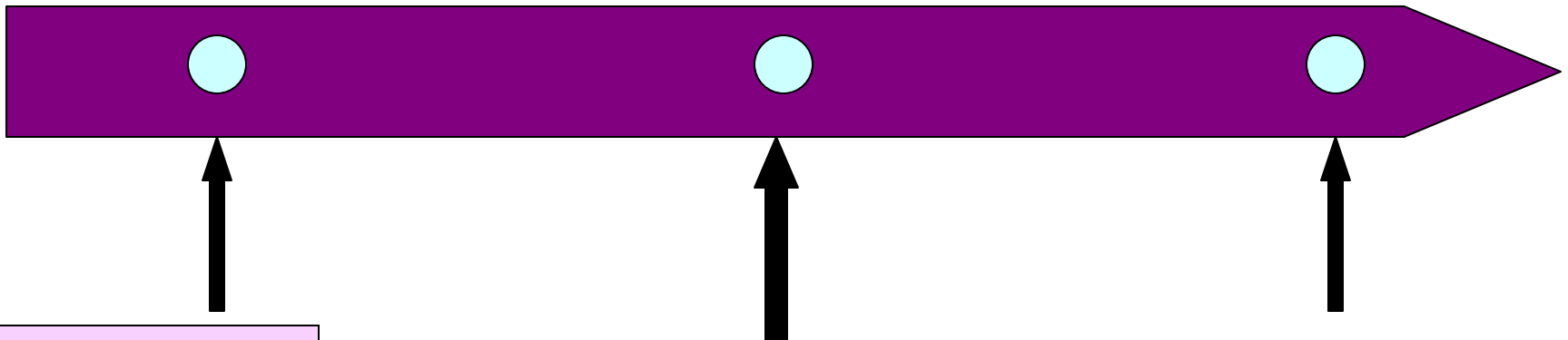
# VOICE - Progress

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Regional Meeting,  
October 2009

Annual Meeting,  
April 2010

**TODAY**



Spilhaus

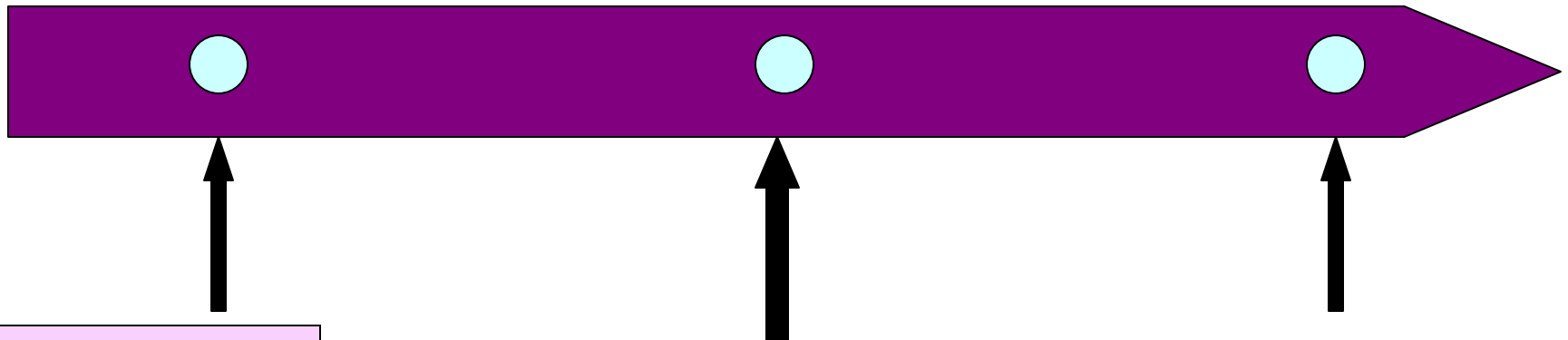
# VOICE - Progress

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**Regional Meeting,  
October 2009**

**Annual Meeting,  
April 2010**

**TODAY**



Spilhaus

Botha's Hill, Isipingo, Overport,  
Chatsworth, Tongaat,  
Umkomaas, Verulam, Uganda,  
Seke South, Zengeza

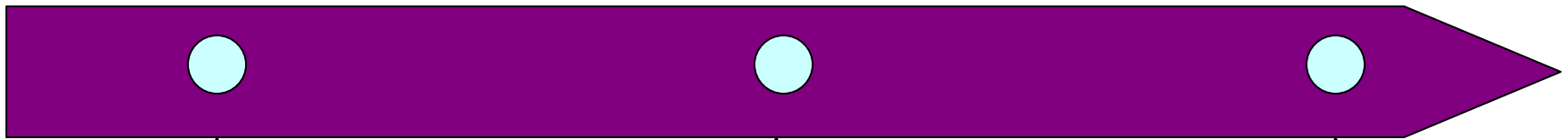
# VOICE - Progress

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**Regional Meeting,  
October 2009**

**Annual Meeting,  
April 2010**

**TODAY**



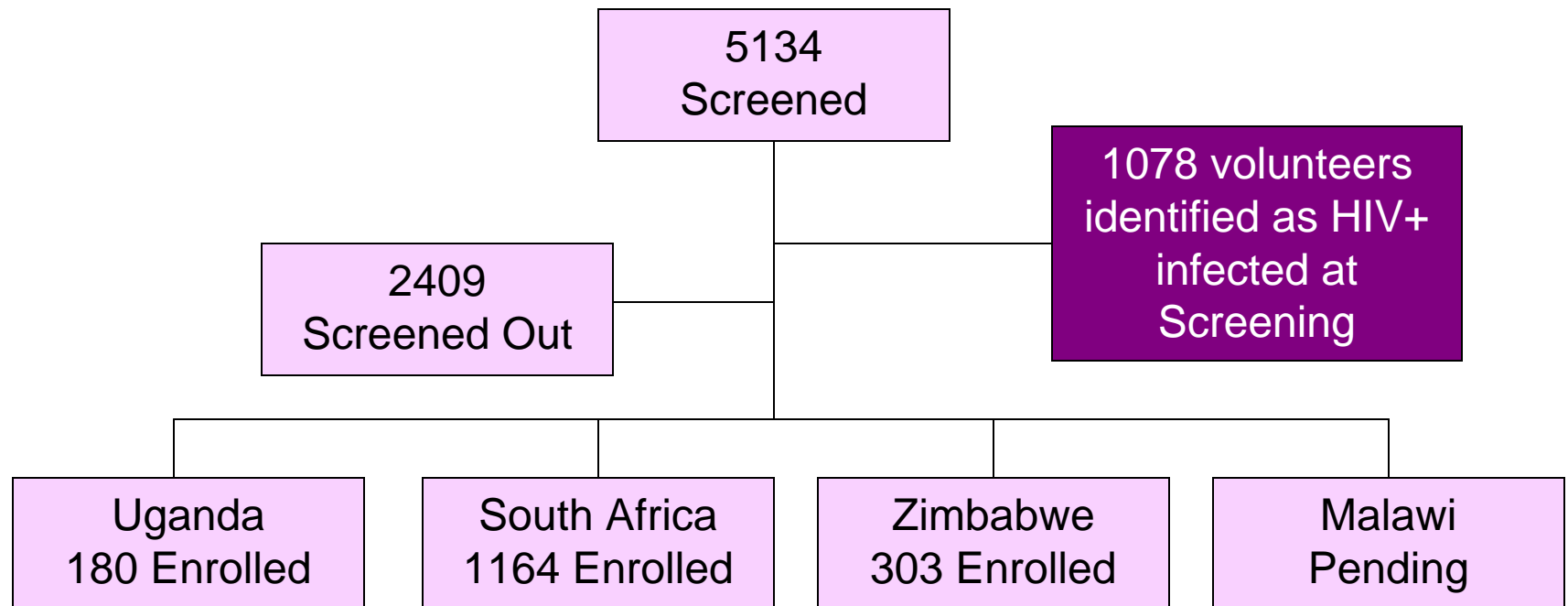
Spilhaus

Botha's Hill, Isipingo, Overport,  
Chatsworth, Tongaat,  
Umkomaas, Verulam, Uganda,  
Seke South, Zengeza

Aurum,  
RHRU,  
PHRU

# VOICE - Current Status

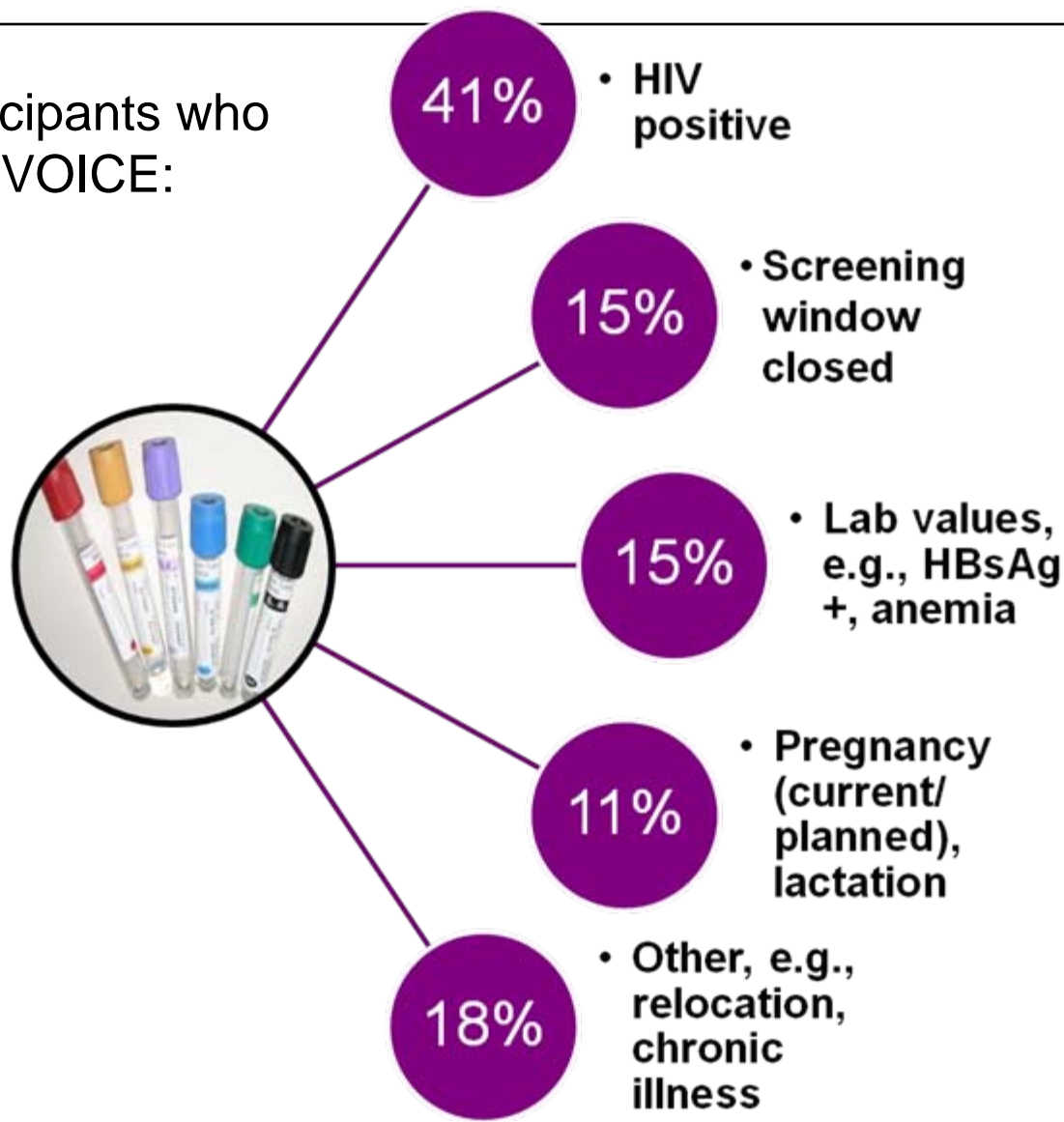
As of 24 September 2010



**Total Enrollment = 1647**  
**Overall Screen to Enroll Ratio = 2.7:1**

# Distribution of Screen-outs

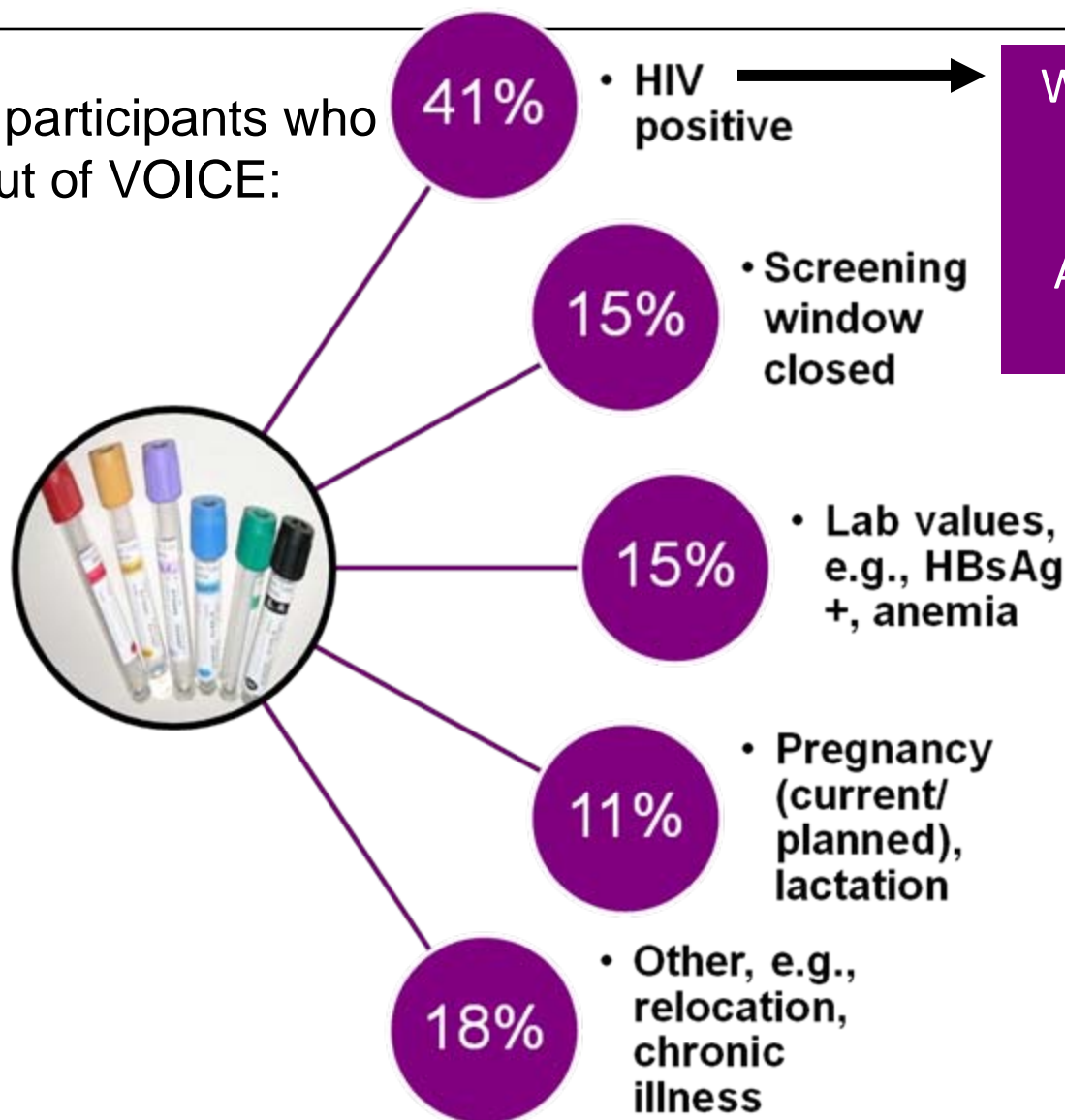
Of those participants who screen out of VOICE:





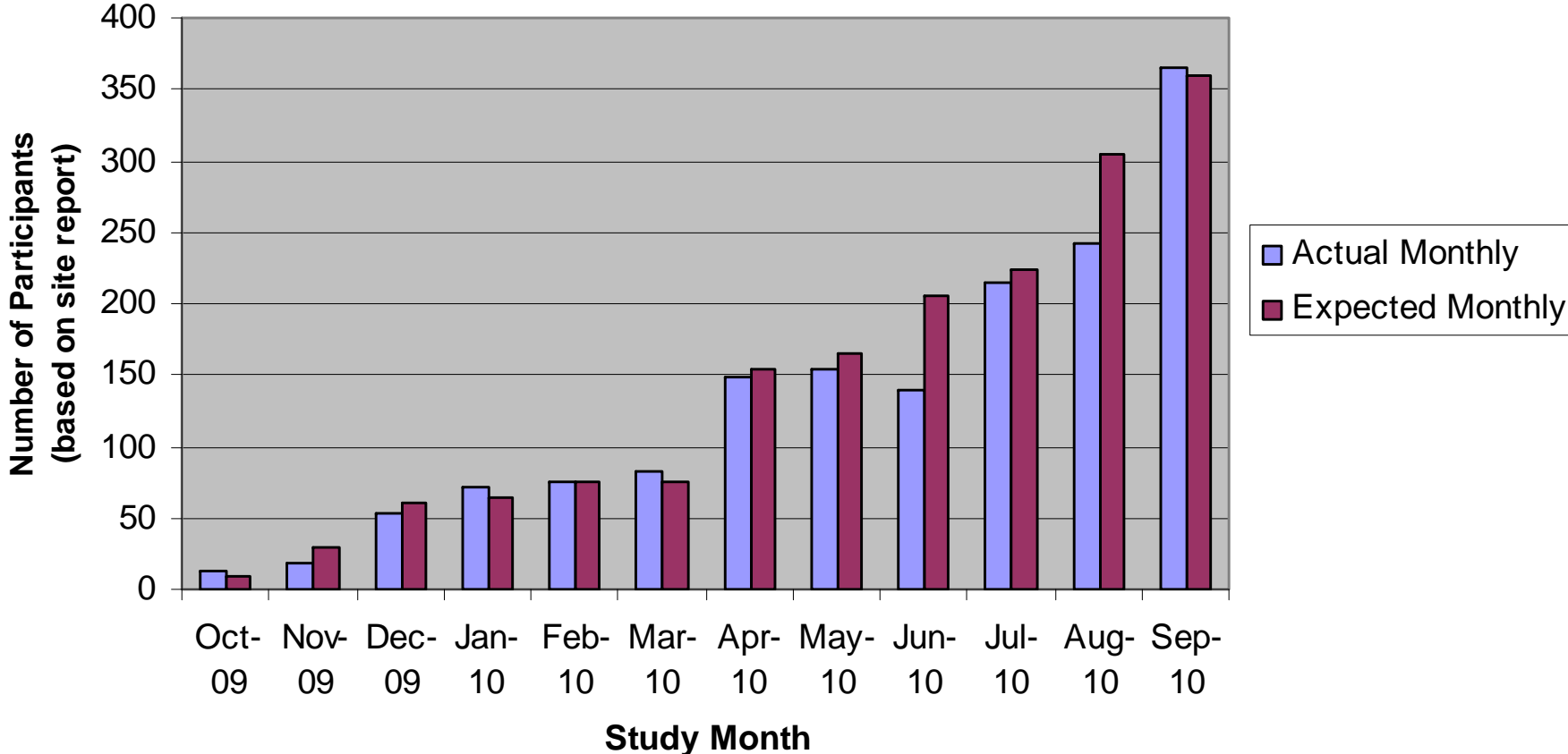
# Distribution of Screen-outs

Of those participants who screen out of VOICE:



With all MRC sites doing MTN-009, screen out due to HIV minimized. As of 10/1, 50 HIV+ pts enrolled in 009

### MTN003 Monthly Accrual- All Sites



Exceeded expected in September: Botha's Hill, Isipingo, Umkomaas, eThekwini, Aurum, RHRU, PHRU, Uganda

# Highlights for Month 12

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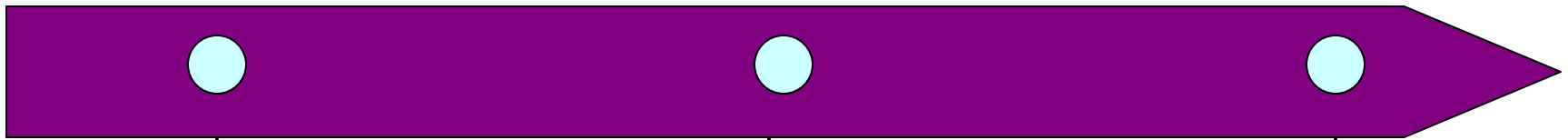
- VOICE sites enrolled 366 participants and EXCEEDED monthly target for the first time
  - Helps to close cumulative gap (151 participants behind schedule overall; 157 last month)
  - Botha's Hill did an outstanding job with 40 participants enrolled!
  - Isipingo and Umkomaas exceeded monthly targets; 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

# VOICE - Progress

Regional Meeting,  
October 2009

Annual Meeting,  
April 2010

TODAY

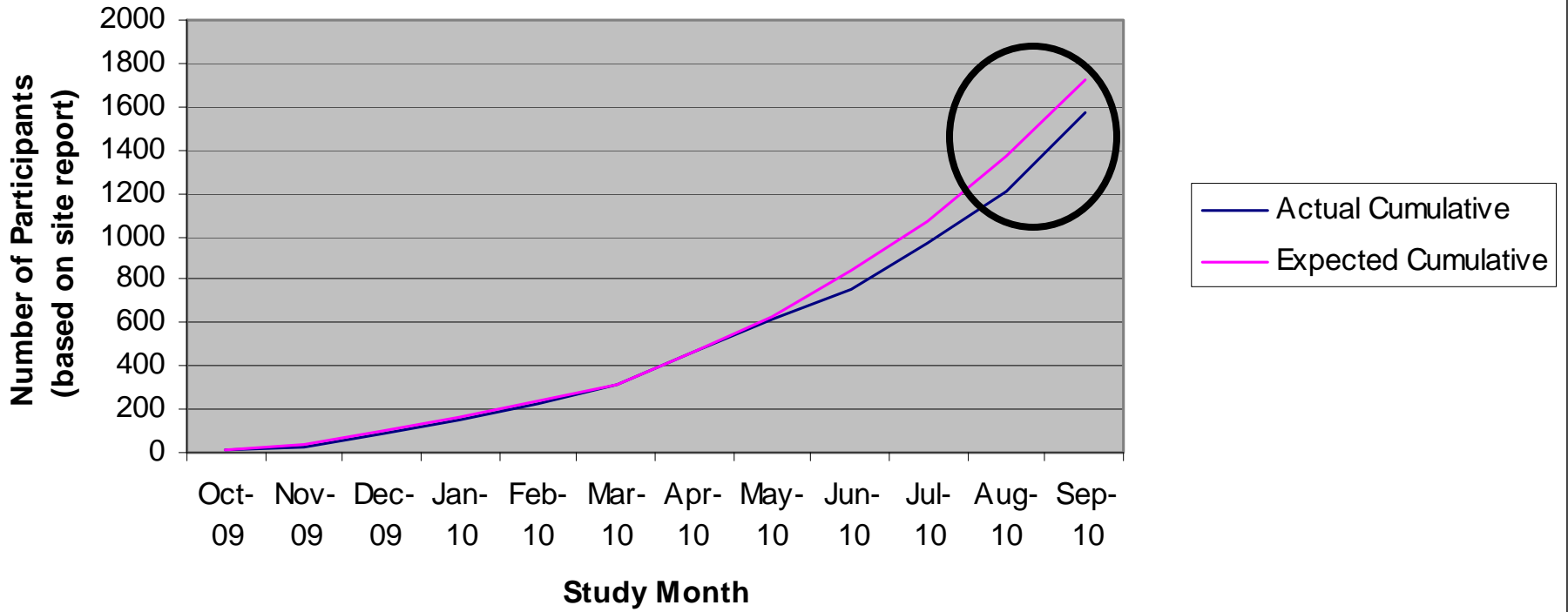


Spilhaus

Botha's Hill, **Isipingo**,  
Overport, Chatsworth,  
Tongaat, Umkomaas,  
Verulam, **Uganda**,  
**Seke South**, Zengeza

Aurum,  
RHRU,  
PHRU

### MTN003 Cumulative Accrual- All Sites



# Implementation Challenges

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- 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)

## Challenges

## Strategies

Women not presenting for Screening Part 1 appointments

Community education & sensitization; focus on male involvement

Concept of PrEP new; not well understood in community

Use CAPRISA 004 results to educate & increase awareness of clinical trials

Fear of taking ARVs, side effects

Community education; peer educators

Fear of HIV testing

Increase awareness of HIV & treatment options

## Challenges

## Strategies

Medical, lab screenouts

Encourage those screened out to refer ppts

Migrant populations

Expand recruitment areas

Transportation issues

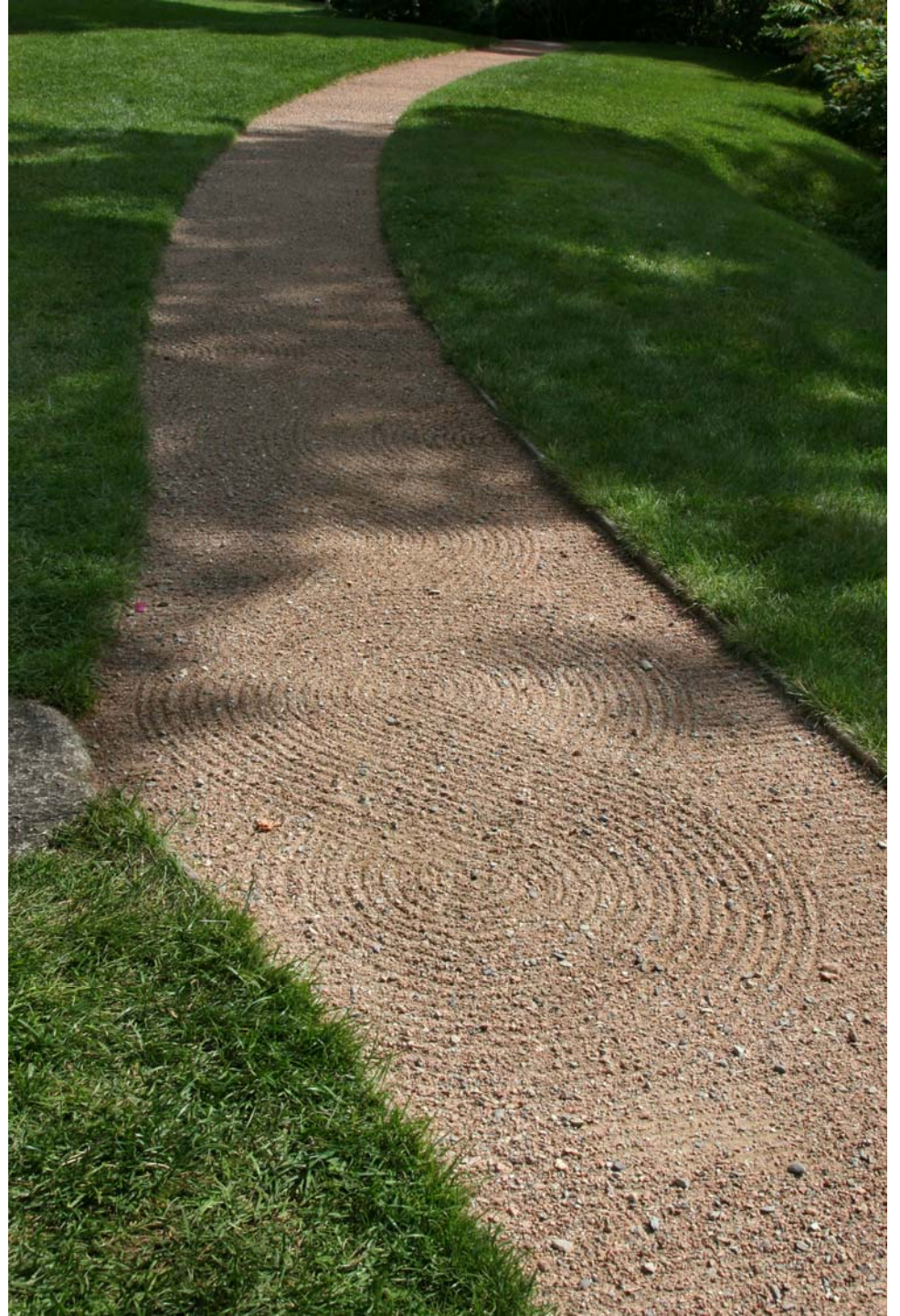
Increase field worker capacity/training; consider population-specific teams

Participants' work commitments

Daily AM education sessions



**THANK  
YOU!**





# Early Terminations

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- 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