

# VOICE

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## General Updates





# Outline

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- Accrual Status
- Protocol Version 2.0 Status
- Preparation for Upcoming DSMB Meeting



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# Accrual

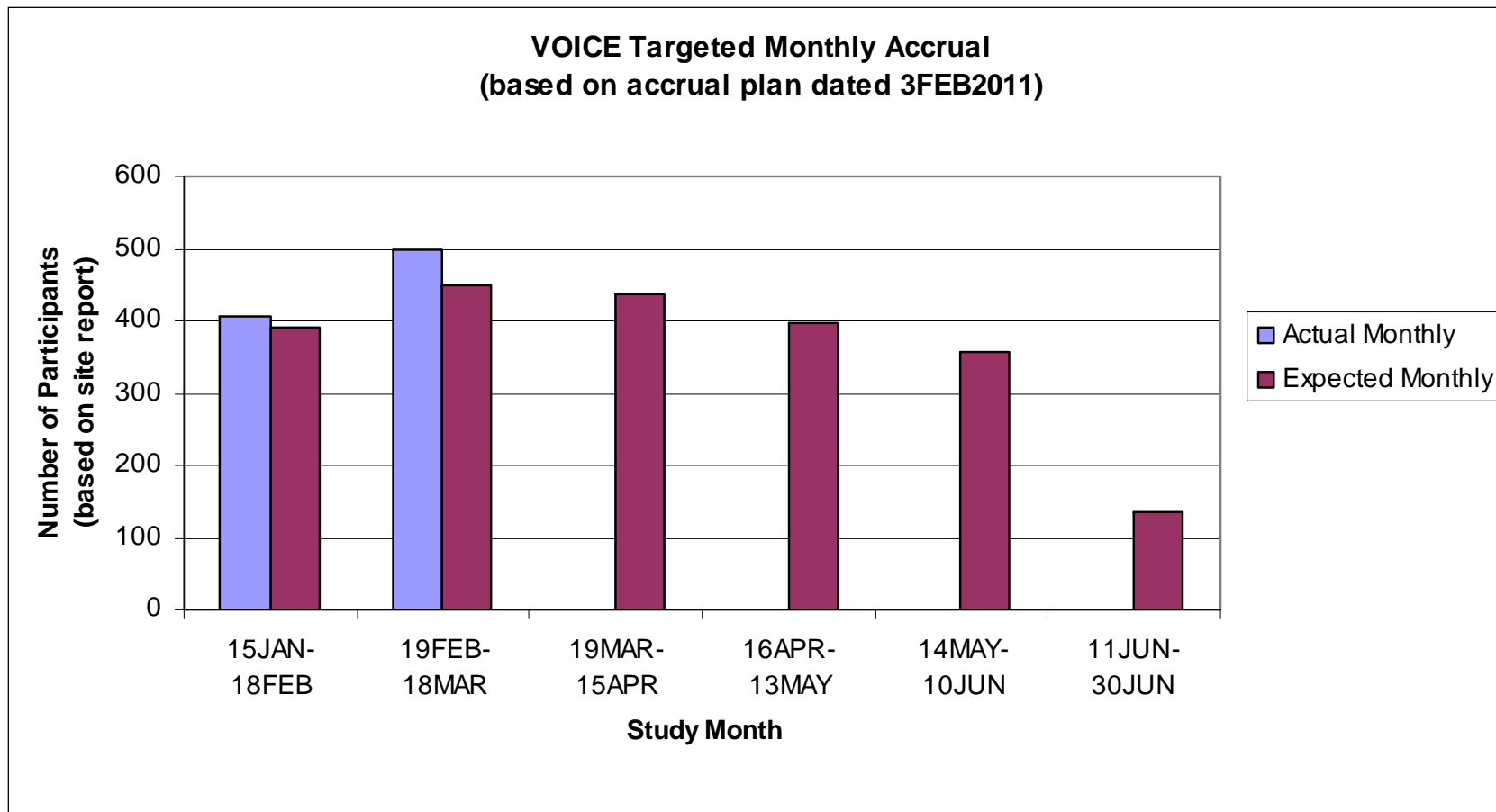


# Accrual Status

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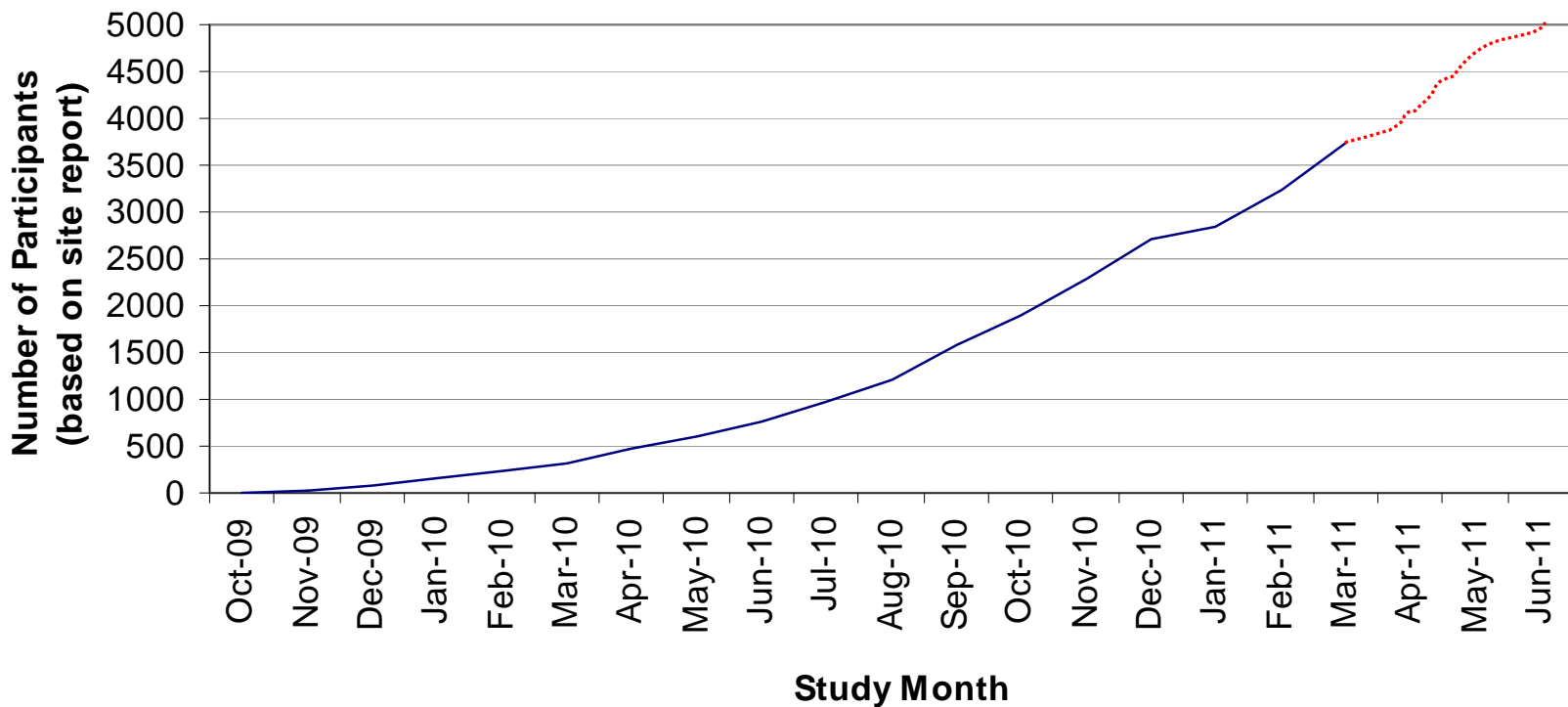
- As of Friday, 18 March:
  - 10,189 participants screened
  - 3,745 participants enrolled (74.9% enrolled)

# Accrual Status



# Accrual Status

**VOICE Cumulative Accrual**  
**Total Enrollment (18FEB) = 3745**  
**Target Enrollment = 5000**





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# Protocol Version 2.0

# Protocol Version 2.0 Status

Site	IRB/EC			RDA		
	Institution	Submission	Approval	Institution	Submission	Approval
eThekwini	BREC	4-Feb-11	Pending	MCC	15-Mar-11	Pending
Klerksdorp	UKZN IRB	3-Feb-11	Pending	MCC	Pending	
				North West DOH Notification	22-Feb-11	NA
MRC	MRC EC	27-Jan-11	Pending	MCC	27-Jan-11	Pending
PHRU	HREC	8-Feb-11	<b>24-Feb-11</b>	MCC	3-Mar-11	Pending
Uganda	NARC	7-Mar-11	Pending	UNCST	Pending*	
	JHU IRB	Pending*				
WHI	HREC	14-Mar-11	Pending	MCC	14-Mar-11	Pending
Zimbabwe	MRCZ	14-Feb-11	<b>11-Mar-11</b>	MCAZ	16-Feb-11	Pending
	UCSF IRB	16-Feb-11	<b>3-Mar-11</b>			

\* IRB approval required prior to submission





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# DSMB Meeting

# Preparation for upcoming DSMB meeting

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- On 9 May 2011 the VOICE Study DSMB will conduct a routine safety review and the first interim efficacy analysis.
- Because of the importance and confidentiality of DSMB deliberations and the potential impact for the VOICE study, the HIV prevention field and other active PrEP studies, communications must be orderly, timely and sensitive.

# Preparation for upcoming DSMB meeting

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- The protocol team, in conjunction with MTN leadership, and NIH is developing a communication plan
- The plan includes activities prior, during, and after the DSMB meeting to ensure proper communication among key team members and stakeholders

# Preparation for upcoming DSMB meeting

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## Draft Timeline

- 4-5 Weeks prior to DSMB meeting
  - Provide VOICE sites with relevant documents
    - Dear Colleague Letter (pre-review) for IRB/ECs and CABs
    - VOICE Q&A
    - VOICE Backgrounder
    - VOICE Factsheet
    - Scenarios and messages
  - Work with sites to update site-specific communication plans
    - Send sites communication plans template (to include expected timeline of activities)
    - Send sites Stakeholders Directories to be updated

# Preparation for upcoming DSMB meeting

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- 2-3 Weeks prior to DSMB meeting:
  - Site Communication Plan Templates and Stakeholders Directories due to Lisa Rossi
    - Lisa R will send feedback to sites within a week
  - Site to notify IRBs/ECs and CABs of upcoming DSMB meeting
- 1-2 Weeks prior to the DSMB meeting
  - Inform VOICE site's PI and leadership of *possible* call to take place following DSMB meeting
    - call will take place *ONLY* if immediate action is required



# DSMB meeting

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- On the day of the DSMB meeting
  - Key team members will participate in the open session of the meeting via conference call



# DSMB meeting

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- Following DSMB meeting
  - NIAID Director decides whether to accept DSMB recommendations. Timeframe for notification is generally within a few days.
  - Team discussion, action plan, and communication with other VOICE key team members will take place immediately after DSMB recommendations are received



# DSMB meeting follow-up

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- Possible Results:

- No Urgent Action Needed

- Inform sites of DSMB decision and cancel conference call with site PIs
- Communicate DSMB outcome to MTN stakeholders/partners
- Develop plan to incorporate DSMB recommendations into the protocol (if needed)
- Issue Dear Colleague letter and information sheet
- Distribute DSMB Meeting summary to sites





# DSMB meeting follow-up

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- Possible Results:

- Urgent Action Needed

- Based on DSMB Recommendations, team will determine next steps and action plan
    - Sites will receive e-mail confirming conference call and brief update of meeting outcome
    - Communication with other partners and stakeholders as appropriate
    - Sites will receive documents for communicating with participants, IRBs, CABs, and other stakeholders based on findings and action plan



# DSMB meeting

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- Next steps for sites:
  - Sites to quickly respond to request for updating Stakeholders Directories and Communications Plans and submission of Dear Colleague letter to IRBs and CABs
  - Become familiar with the relevant DSMB documents (e.g. VOICE Q&A, Backgrounder, Factsheet, Scenarios and messages)
  - Contact Lisa Rossi and Kaila Gomez if you have any questions



Thank you!

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Are there any questions?