



The Path Ahead

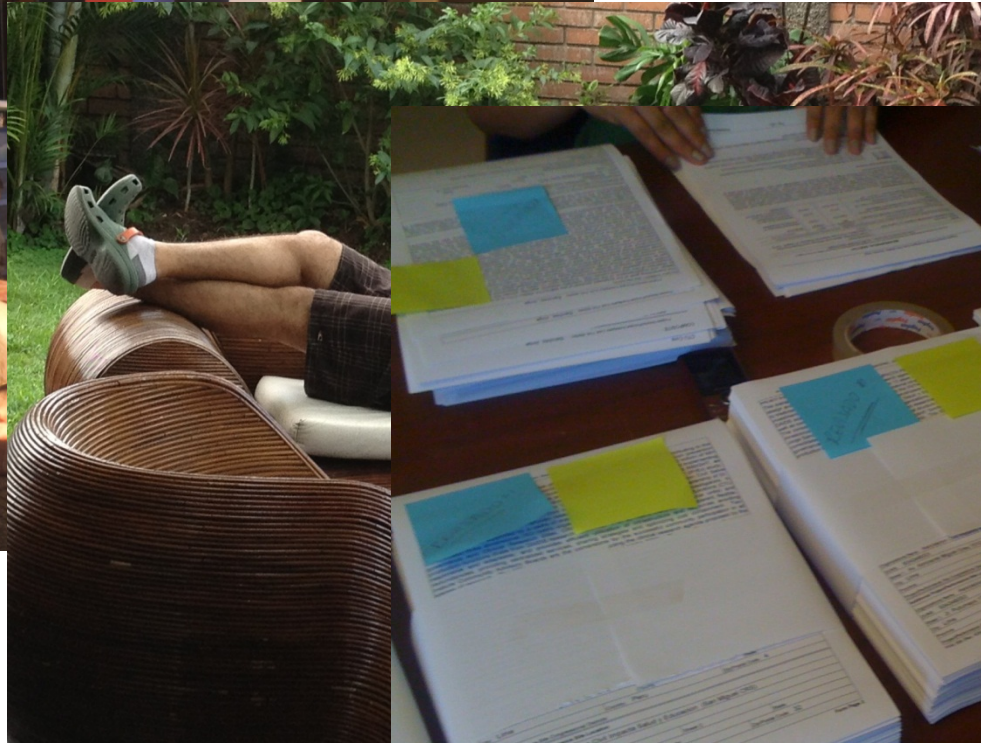
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Achievements Over the Last Year

The Recompetition



Study Updates

- Completed Studies
 - MTN-005
 - MTN-008
 - MTN-013
- Ongoing Studies
 - MTN-003D
 - MTN-011
 - MTN-015
 - MTN-016
 - MTN-020
- New Studies
 - MTN-017
- Studies in Development
 - MTN-023
 - MTN-024
 - MTN-025

Lessons Learned in Year 7

- Adherence, adherence, adherence
- Need to integrate objective measures of adherence into trial design
 - At a site level (MTN-020)
 - At an individual level (MTN-017)
- Altering contraceptive practices
 - Increasing the method mix
 - Reducing overall pregnancy rates

Mucosal Responses to ART

- Topical antiretroviral microbicides deliver 100 x concentration of ART compared to oral PrEP
 - MTN-001 (oral versus vaginal)
 - RMP-02 / MTN-006 oral versus rectal)
- Topical microbicides well tolerated BUT limited data on mucosal safety of ART microbicides

MTN Studies with Mucosal Assays

- Completed
 - RMP-02/MTN-006 & MTN-007
 - Flow, RT-PCR
 - MTN-008
 - Flow
- Ongoing
 - MTN-011
 - Flow
 - (HPTN-069)
 - Flow, explants
- Planned
 - MTN-017
 - Flow, explants
 - MTN-024
 - Flow

MTN-017

	8 weeks		8 weeks		8 weeks	
BL	TFV Gel Daily		TFV Gel With sex		Oral Truvada	
BL	TFV Gel With sex		TFV Gel Daily		Oral Truvada	
BL	Oral Truvada		TFV Gel With sex		TFV Gel Daily	



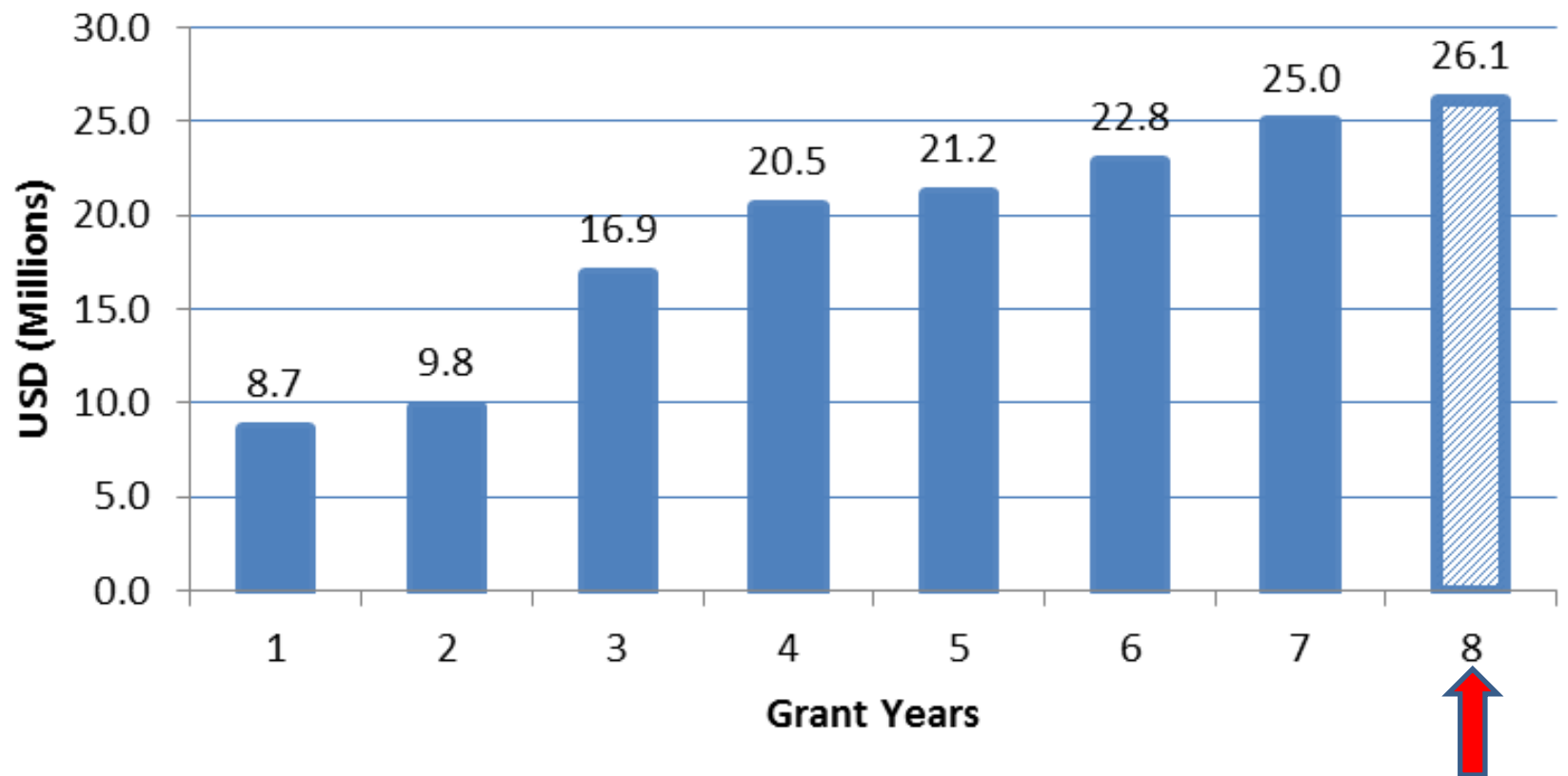
Mucosal substudy (N = 36 in Pittsburgh and Bangkok)



Network Challenges

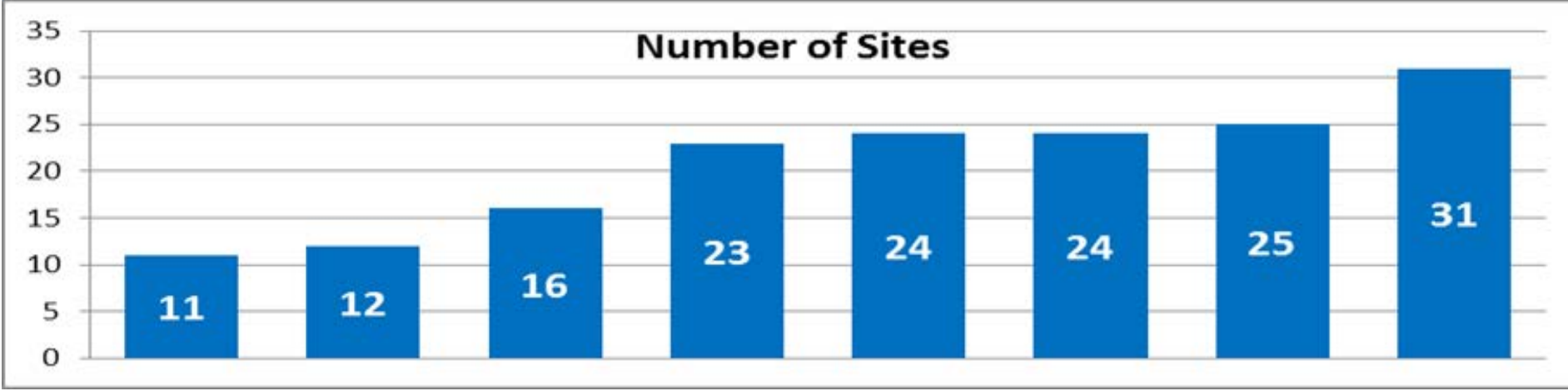
MTN Budget 2006-2013

Expenditures



Projected 2013-2014

	2006	2007	2008	2009	2010	2011	2012	2013	
Studies	HPTN 035	HPTN 035	HPTN 035	VOICE	MTN-001	VOICE	VOICE	VOICE-B	
	HPTN 059	HPTN 059	MTN-001	VOICE-B	MTN-002	VOICE-B	VOICE-B	MTN-003D	
			MTN-004	MTN-002	MTN-001	VOICE	VOICE-C	VOICE-C	MTN-008
			MTN-004	MTN-002	VOICE-B	MTN-	MTN-003D	MTN-011	
			MTN-015	MTN-004	VOICE-C	003D	MTN-005	MTN-014	
			MTN-006	MTN-006	MTN-005	MTN-008	MTN-015		
			MTN-015	MTN-007	MTN-007	MTN-009	MTN-016		
			MTN-016	MTN-009	MTN-008	MTN-011	MTN-017		
			MTN-015	MTN-009	MTN-013	ASPIRE			
			MTN-016	MTN-012	MTN-015	MTN-024			
			MTN-013	MTN-016	MTN-023				
			MTN-015	ASPIRE					





Strategic Goals for Year 8

Year 8 Priorities

- Complete VOICE-related activities
- MTN-020 (Dapivirine IVR)
 - Complete enrollment
 - Optimize adherence
- MTN-017 (Tenofovir Gel)
 - Initiate study at all sites
- MTN-015/MTN-016
 - Continue seroconverter / pregnancy cohorts
- MTN-023/MTN-024 (Dapivirine IVR)
 - Initiate studies
- Combination ART IVR
 - Initiate study

Priorities Beyond Year 8

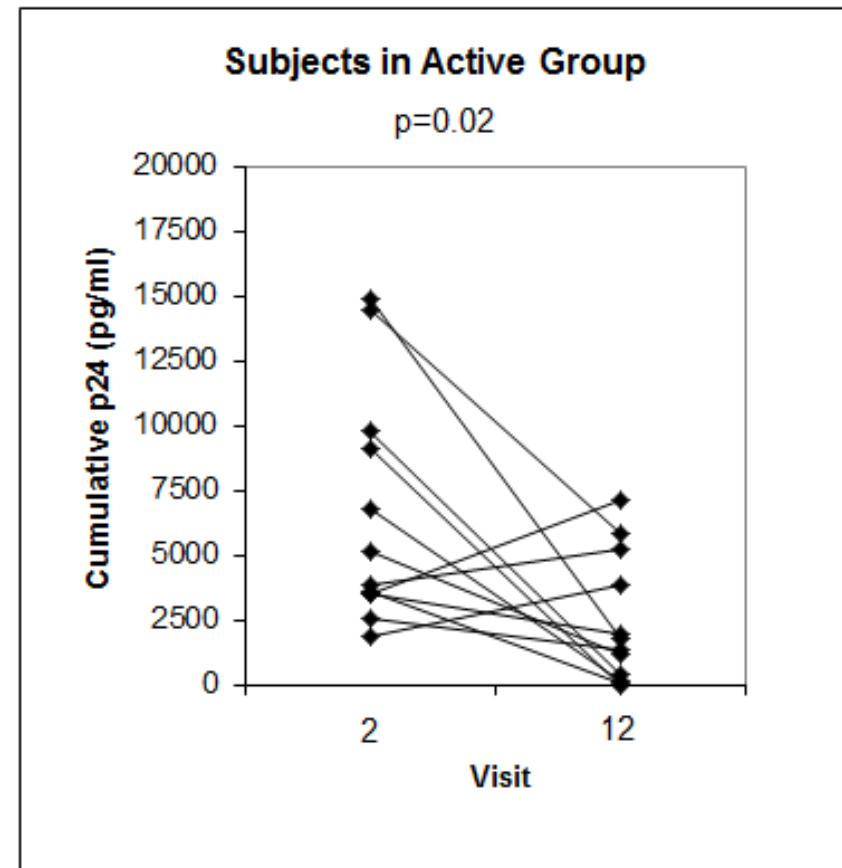
- Demonstrate effectiveness in MTN-020
- Expand the MTN pipeline
- 2nd generation rectal microbicide
- Multipurpose technology
 - Combination ART intravaginal rings
 - Combination ART/contraceptive rings

The MTN Pipeline

- MTN recompetition partners
 - IPM
 - CONRAD
 - Population Council
 - ImQuest
 - Intrucept
 - Merck
 - ViiV
 - Mintaka Foundation
- Potential products
 - TFV / TDF
 - Dapivirine
 - Griffithsin
 - 5P12 RANTEs
 - IQ-0528
 - Maraviroc
- Potential formulations
 - Vaginal gels
 - Rectal gels
 - Intravaginal rings

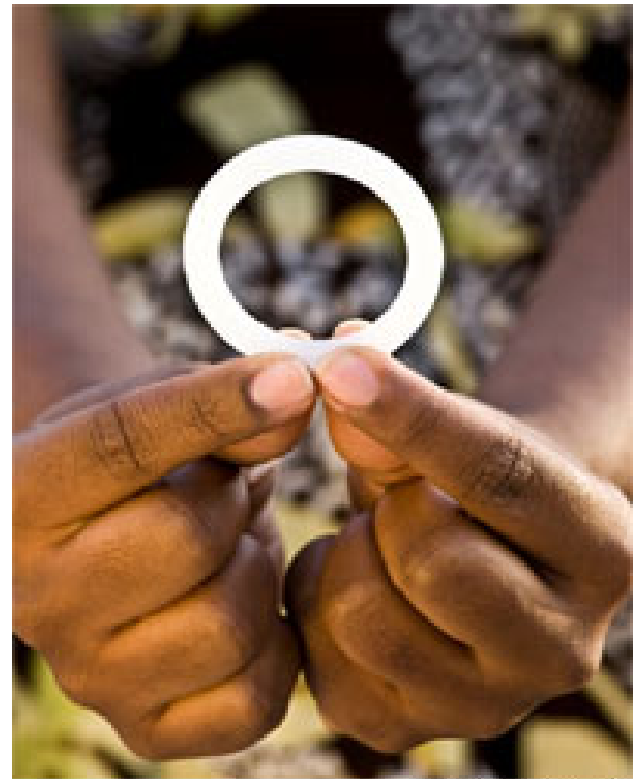
2nd Generation Rectal Microbicide

- TFV gel profile
 - Safety profile good but some GI signals
 - Efficacy seen in multiple models
 - MTN-007 gene expression changes may be API specific
- Dapivirine gel as a RM
 - Potent ART
 - Previous UC781 data



Multipurpose IVR

- Combination ART IVR
 - MTN-013 (DPV & Maraviroc)
 - Merck IVR ring
- Combination ART / Contraception IVR
 - CONRAD
 - Merck
 - IPM
- Need for selection process



Andrew Loxely

Summary

- The first MTN cycle has made several important contributions to the field of HIV prevention
- Focusing on strategic priorities will allow the MTN to continue to move the HIV prevention research agenda forward
- Future resources and success in MTN-020 will allow expansion into new products especially the MPT IVR research agenda



MTN Awards

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