

# **MTN Annual Meeting**

## **Welcome and State of the Network**

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Sharon L. Hillier, Ph.D.  
Chair, Executive Committee



# Major Accomplishments of the MTN: completing the legacy studies

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- Completion of full enrollment of 3100 women on **HPTN-035** within 2 weeks of the timeline projected in May 2005
- Completion of **HPTN-059** and presentation of the final study outcome at the Microbicides 2008 meeting in Delhi, India

# Major Accomplishments of the MTN: moving new research forward

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- **MTN-001:** first crossover study of oral and vaginal tenofovir pharmacokinetics and acceptability
  
- **MTN-002:** first study of topical microbicides to be conducted among pregnant women
  
- **MTN-003:**
  - Approval of the concept by the Strategic Working Group of DAIDS,
  - Protocol development meeting in South Africa, including Community Working Group resulting in
  - Submission of the protocol for PSRC review in December 2007
  - Final PSRC approval of VOICE in April 2008

# Major Accomplishments of the MTN: safety of rings and rectal delivery

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- Development of a new collaboration with the International Partnership for Microbicides in evaluating the safety and acceptability of a vaginal ring for sustained delivery of microbicides (MTN-005, Version 1.0 April 2008)
- Approval of two protocol concepts for pharmacokinetic and safety studies of tenofovir gel used as a rectal microbicide (MTN-006 and MTN-007)

# Major Accomplishments of the MTN: developing long term follow-up

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- **MTN-015:** Implementation of a seroconverter protocol for women enrolled in MTN studies
- **MTN-016:** Development of a Pregnancy Registry protocol concept, with finalization of the protocol anticipated in this calendar year
- **Research Working Groups:** Expansion of behavioral and biomedical research initiatives, as well as enhanced community engagement

# Our Challenge: To Be Fast, Flexible and Efficient

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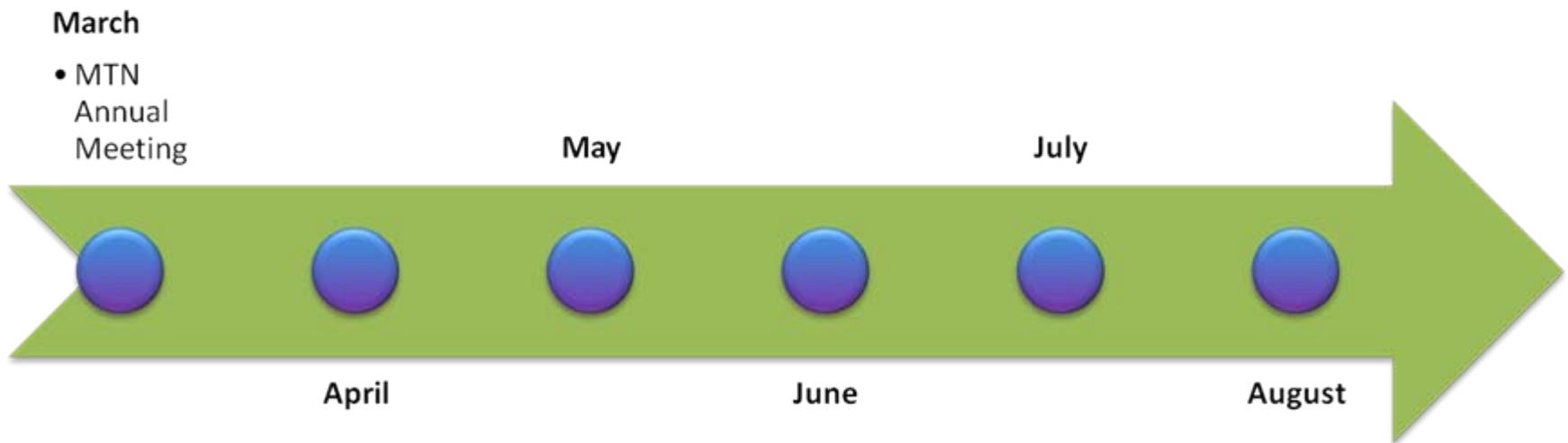
- Funders: NIAID, NICHD and NIMH
- Partners: IPM, Gates Foundation, CONRAD, Gilead, StarPharma
- Complex funding of sites and science through peer review
- Time zones and culture: sites and staff spread across 12 time zones, 3 continents and 7 countries
- Academic model of research versus drug development paradigm

# In Other Words.....

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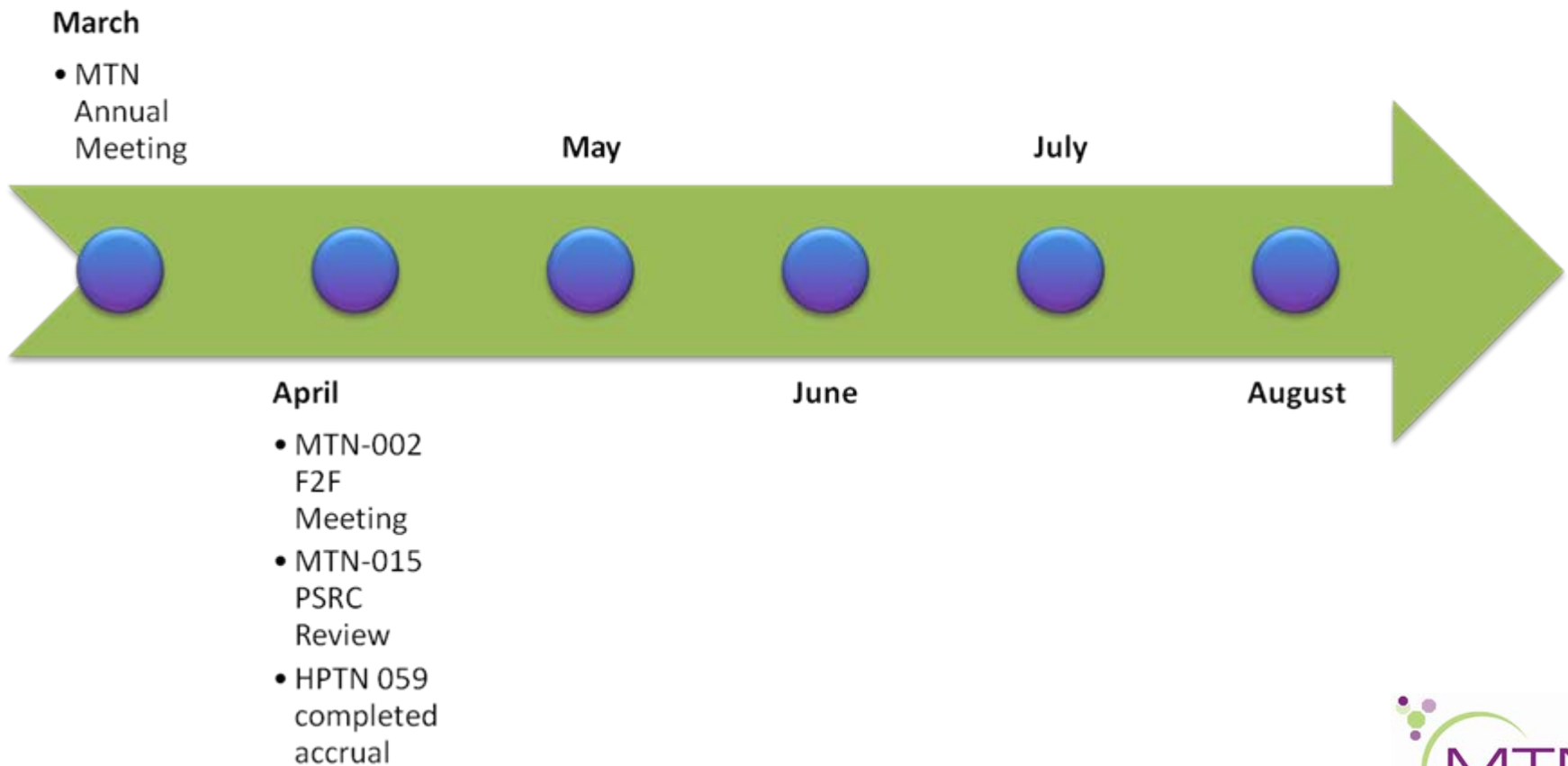
- There are a million reasons we could fail due to the sheer complexity of the work we are trying to do
- Our work takes place within the larger HIV prevention research world which has faced several setbacks
- Many question the wisdom of doing large scale clinical trial research at all because it seen as bloated, slow and expensive

# So What has the MTN been doing since the 2007 Annual Meeting?

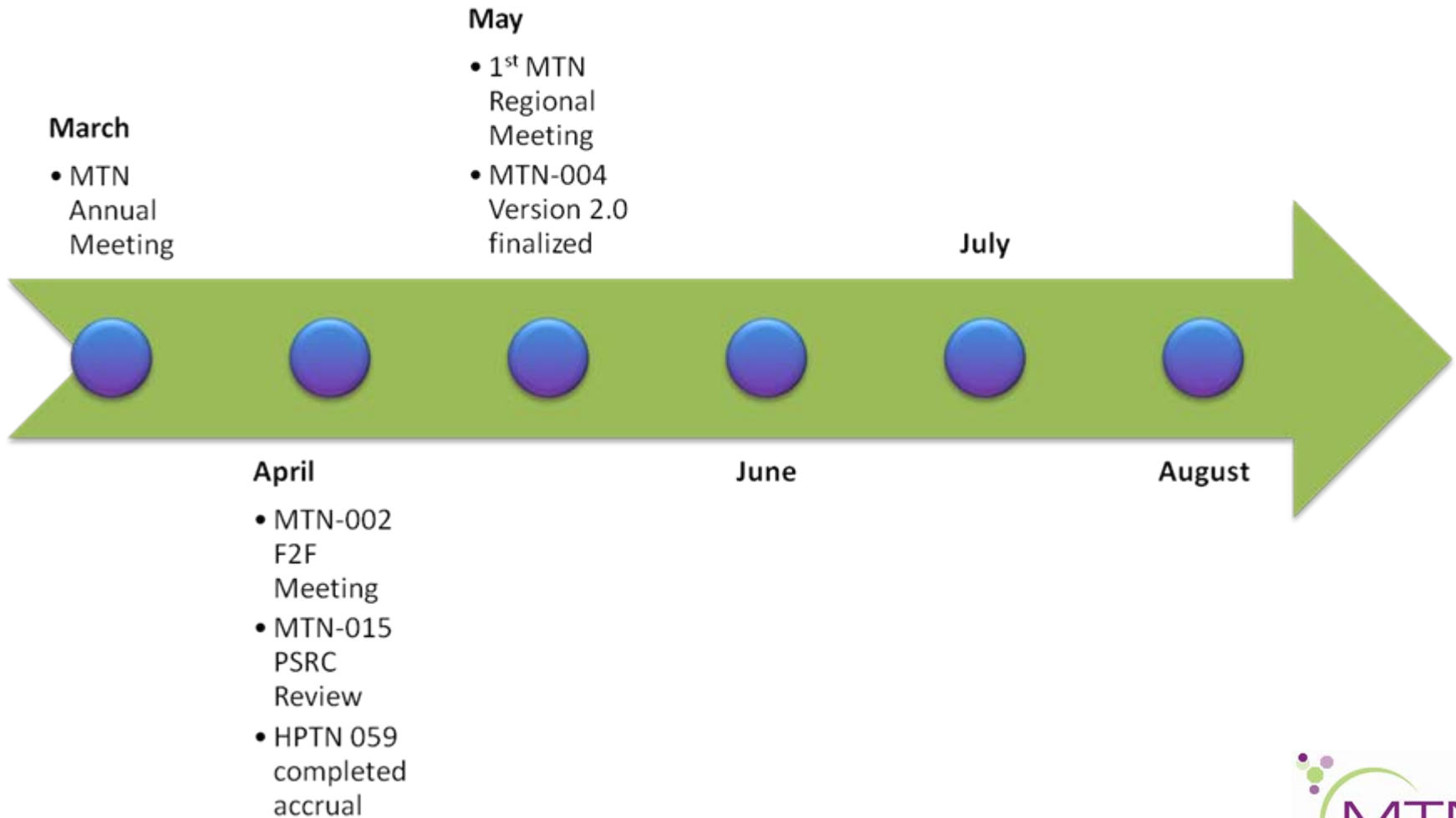




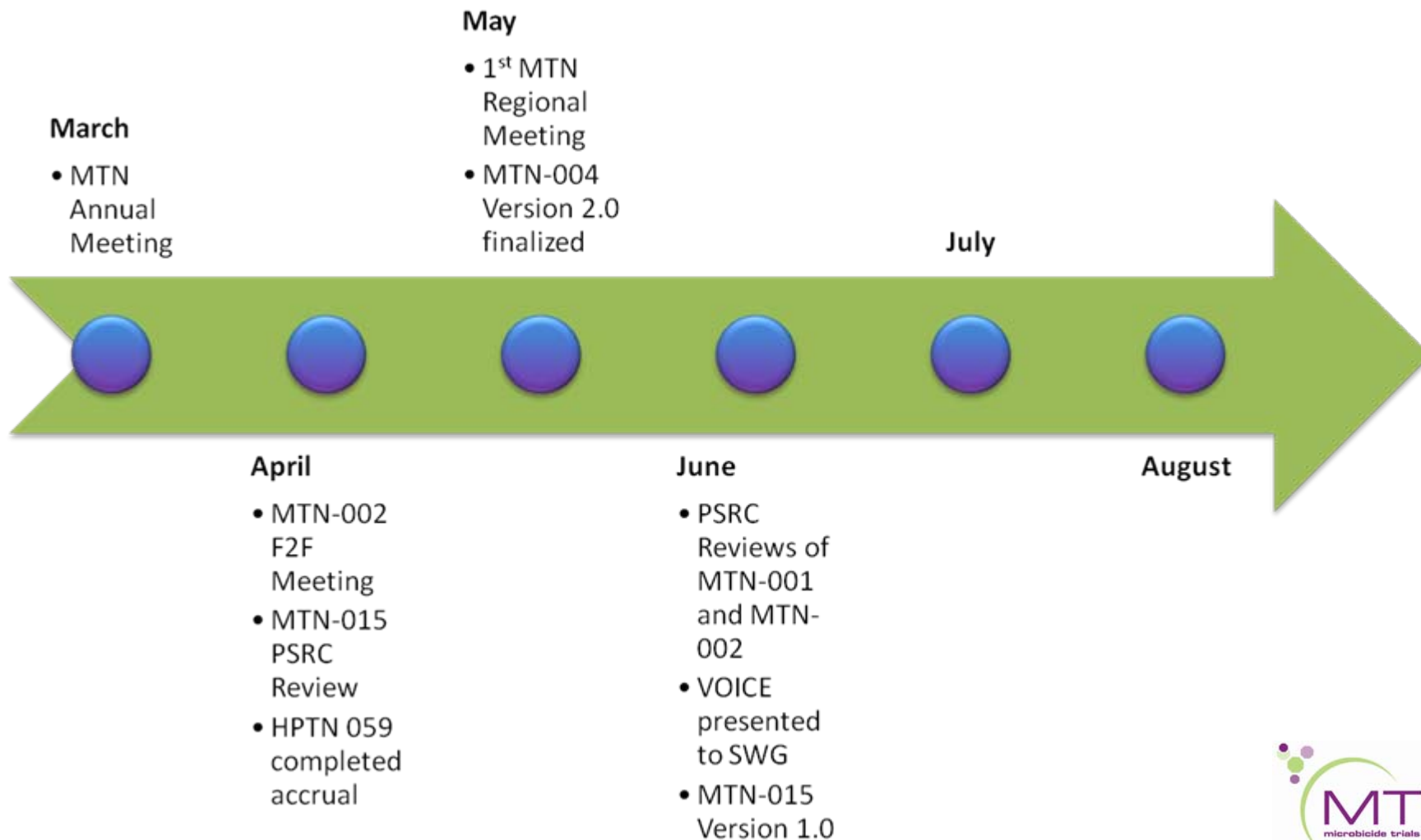
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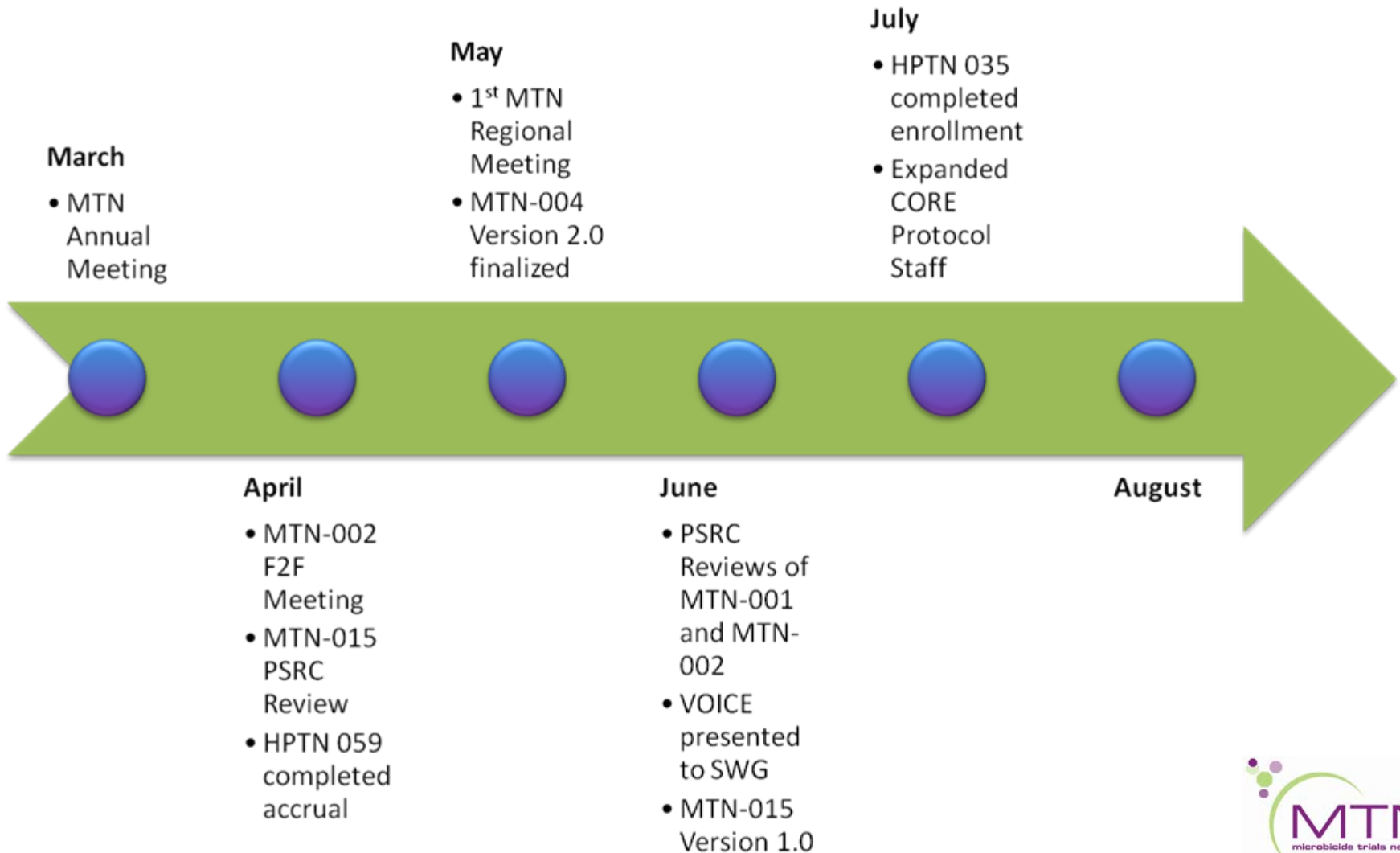
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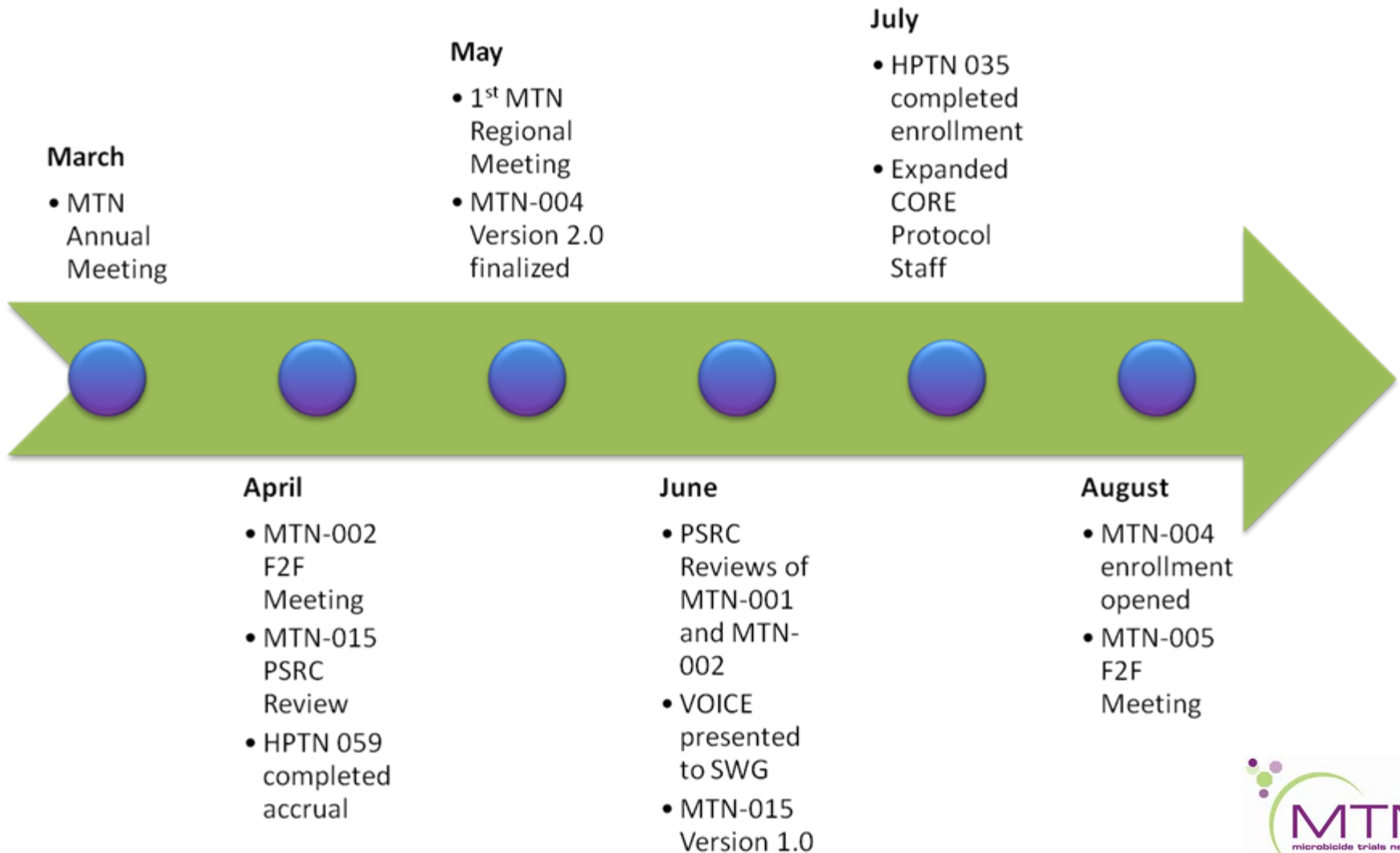
# 2007



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# 2007



# 2007

## September

- MTN-002 Version 1.0
- MTN-007 concept MTN EC approval

## November

October

December

# 2007

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## November

- VOICE protocol revised based on F2F meeting in Durban and CWG consultation
- HPTN 035 DSMB Review

## October

- HPTN 059 completed f/u
- VOICE Meeting Durban
- MTN CWG review of VOICE
- MTN-004 paused
- MTN-005 PSRC Review

# 2007

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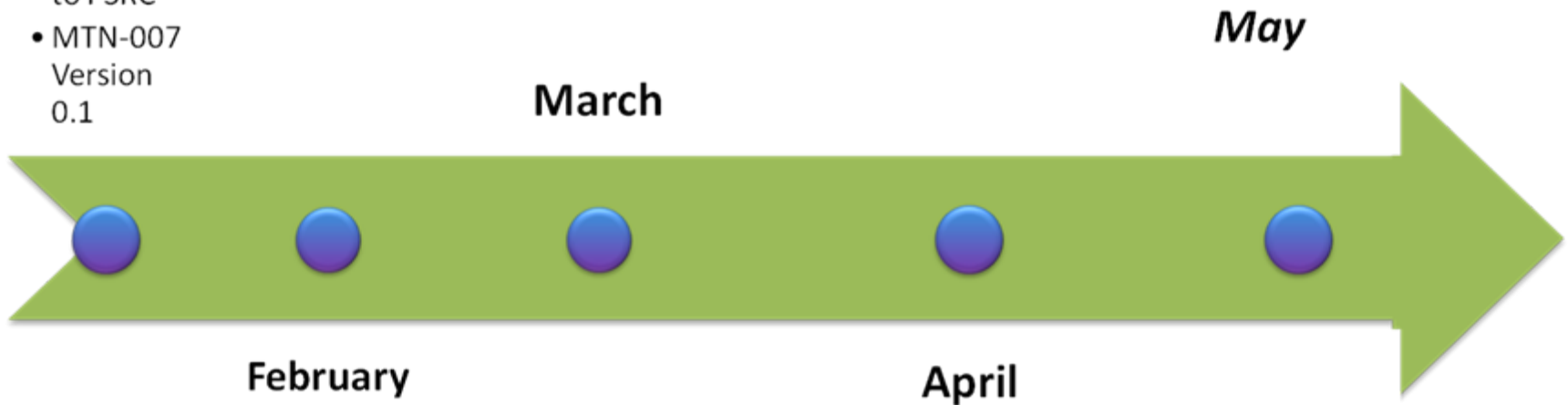
- MTN-001  
Version 1.0
- VOICE PSRC  
Review



# 2008

## January

- VOICE revised in response to PSRC
- MTN-007 Version 0.1



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- MTN-007 Version 0.1

March

May

## February

- HPTN 059 results reported at M2008 Meeting
- MTN EC Review of VOICE sites

April

# 2008

## January

- VOICE revised in response to PSRC
- MTN-007 Version 0.1

## March

- First MTN-001 IRB approval
- Nephrotoxicity consult for VOICE protocol

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## April

- MTN-002 IRB approval
- MTN-003 PSRC approval
- MTN-005 Version 1.0
- MTN-006 MTN EC approval of concept
- MTN-016 Version 0.1
- Expanded CORE protocol staff

# 2008

## January

- VOICE revised in response to PSRC
- MTN-007 Version 0.1

## March

- First MTN-001 IRB approval
- Nephrotoxicity consult for VOICE protocol

## May

- GOALS:
  - VOICE Version 1.0
  - Open MTN-001, MTN-002, and MTN-015

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# State of the MTN: Why Does it Work?

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- Because a **lot** of people have done everything possible to maintain the timelines
- Because we have valued efficiency over inclusiveness
- Because people have been willing to find common goals and shared values
- Because we really believe that we can make a difference in this epidemic, and treat every day of delay as a lost opportunity



# Today and Tomorrow You will Have a Chance to....

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- Hear about our studies and emerging scientific issues
- Meet the investigators
- Enjoy some excellent posters (and cocktails)
- Work hard and have some fun
- **And remember that only through a shared commitment to a common goal can we succeed!**