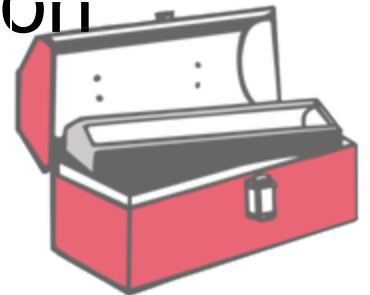


What Comes After VOICE: Thinking About MTN-018

Sharon Hillier, PhD
University of Pittsburgh
MTN CORE

Role of the MTN: the View from DAIDS

- Prove the concept
 - Show that a topically applied product can substantially reduce HIV transmission
- Maximize the effectiveness
 - Adherence
 - Route of administration
 - Safety
- Integrate into combination prevention strategies and programs





The VOICE Study Could..

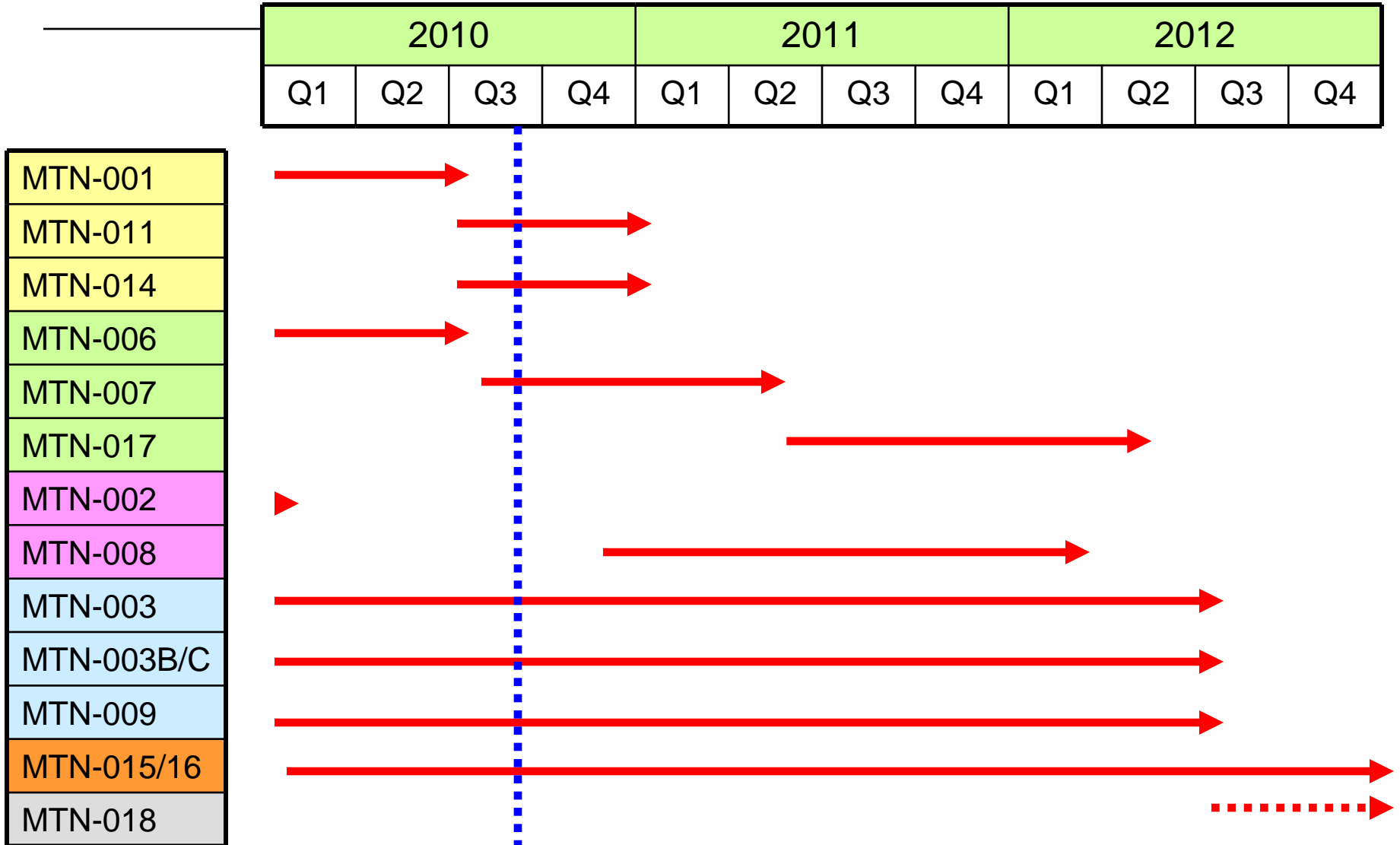
- Be stopped by the DSMB early because there has been a safety problem
- Could be stopped early because one or more arms has shown a high level of effectiveness
- Could be advised by the DSMB to stop just the oral arms or just the topical arms
- Could be allowed to continue to completion for all 5 arms in June 2012



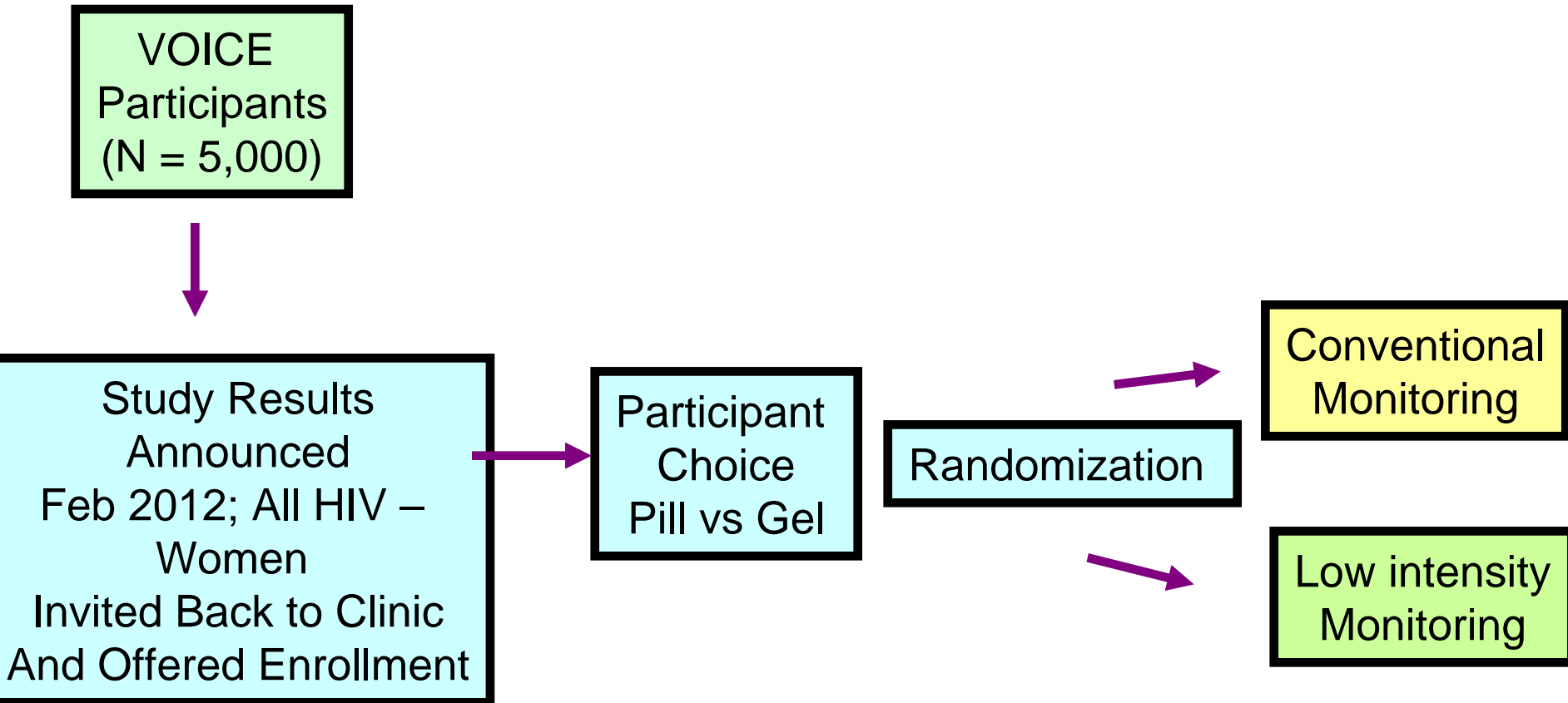
It is Hard to Plan for All of these Possibilities

- What happens in other studies could impact VOICE
- We cannot know for certain whether VOICE will be allowed to continue to completion of follow-up for all study arms
- We CAN plan for success: be ready to provide active drug to women after VOICE if one or more arms shows benefit

Tenofovir Gel Timelines



MTN-018 Design Concept





MTN-018 Objectives

- Nonscientific but important: to honor our commitment to study participants that they will be the first to have access to the products
- Scientific:
 - To evaluate frequent vs less frequent monitoring for HIV and drug toxicity
 - To assess women's preferences for oral vs topical product



MTN-018 Development

- Concept will be considered by the Executive Committee in November
- Protocol chair and co-chairs will need to volunteer to lead this effort (start thinking about this now)
- Meeting with advocates in January 2011
- Protocol development meeting January 19-21, 2011 in Durban, South Africa



Can We Do It?

“MTN is a masterful, powerful protocol-development machine filled with talented, competent and caring people.”

Comment from one of our partners at NIH



MTN-018

- Who will be writing the protocol?

Investigators (2 per site)

Site pharmacist


Site laboratory representative

Coordinator

CAB member

Community educator

Representatives from MTN CORE, FHI,
SCHARP, Network Lab, and NIH



“To me the MTN means HOPE. The innovative groundbreaking work undertaken by the MTN inspires hope for empowerment of women and raising the VOICES of women for social justice worldwide.”

NIH