



# Welcome to the 8<sup>th</sup> MTN Annual Meeting

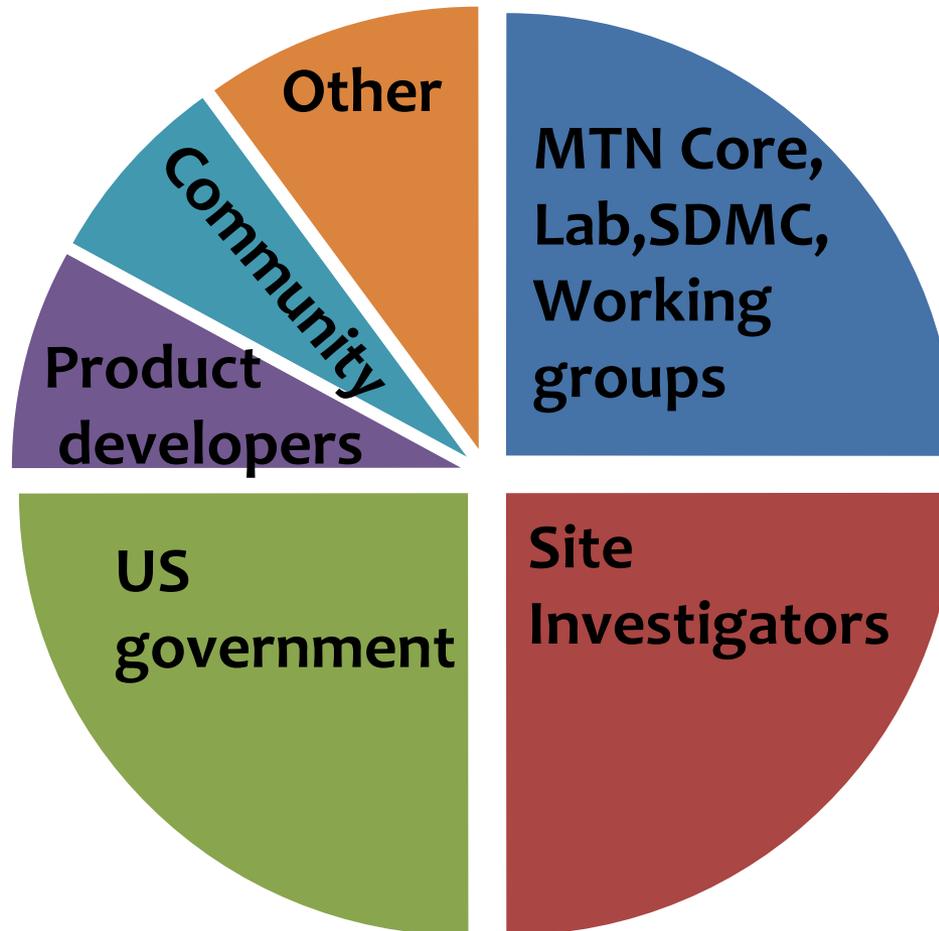
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University of Pittsburgh School of Medicine

February 24, 2014 Washington DC

# Who is Here Today?

## 320 Attendees



# What's New Since Last Year?

- Announcement of the VOICE results at CROI 2013
- Primary manuscript has been submitted
- Analyses ongoing & completed
  - World Congress on AIDS & STD (ISSTD) (July 2013)
    - Herpes simplex virus type-2 outcomes (Marrazzo)
  - CROI (March 2014)
    - Adherence measures: pK and self-report (A. van der Straten, oral)
    - Hormonal contraception and risk of HIV acquisition (L. Noguchi, poster)
    - Baseline predictors of HIV acquisition (G. Nair, poster)
    - Performance of rapid testing for incident HIV diagnosis (U. Parikh, poster)
    - HIV resistance in seroconverters (U. Parikh, poster)

# VOICE at Today's Meeting

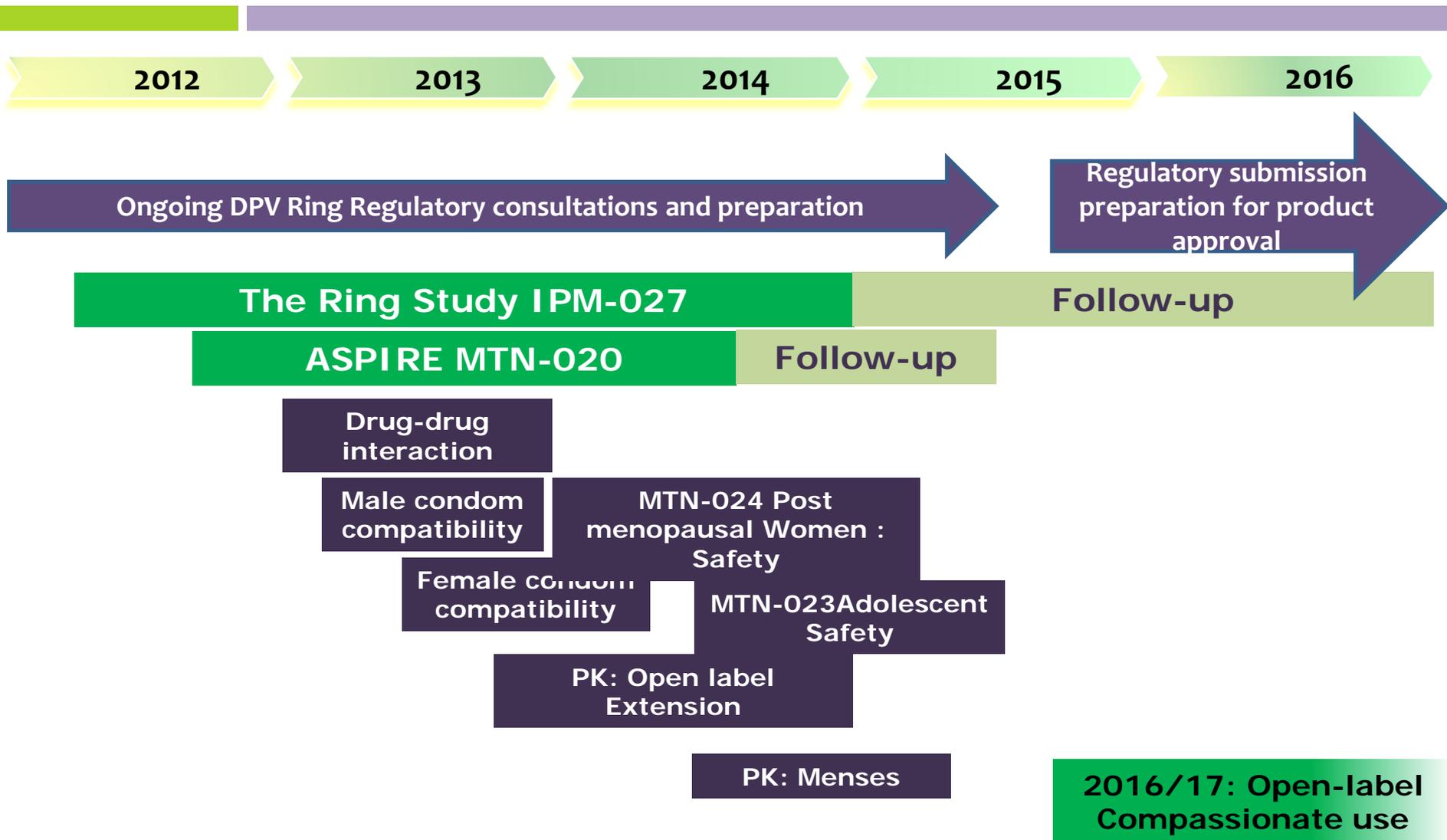
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- VOICE D: what women who participated in VOICE are telling us (van der Straten)
- What happened to the seroconverters: MTN-015 (Riddler)
- ARV resistance from women participating in PrEP and microbicide studies (Mellors)

# Dapivirine Ring Program: Progress Since Last Year

- ASPIRE: 2200 women now enrolled; outstanding retention; expanded contraceptive mix
- Launch of MTN-024: First study of dapivirine ring safety in *post-menopausal women*
- MTN-023: First study of dapivirine ring safety in adolescents
  - Collaboration between the MTN and the ATN
  - Study set to launch in April
- Planning underway for MTN-025, the open label extension of ASPIRE

# Dapivirine Ring Timeline





# The MTN Pipeline Prioritization Process

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Ian McGowan

# Current MTN Studies

| Study   | Product                    | Population          | Phase | Number | 2014  |    |    |    | 2015                     |    |    |    | 2016 |    |    |    | 2017 |    |    |    | 2018 |    |    |    | 2019 |    |    |    | 2020 |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---------|----------------------------|---------------------|-------|--------|---|----|----|----|--------------------------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|----|--|--|--|------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
|         |                            |                     |       |        | Q4  | Q1 | Q2 | Q3 | Q4                       | Q1 | Q2 | Q3 | Q4   | Q1 | Q2 | Q3 | Q4   | Q1 | Q2 | Q3 | Q4   | Q1 | Q2 | Q3 | Q4   | Q1 | Q2 | Q3 | Q4   | Q1 | Q2 | Q3 | Q4 |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-015 | N/A                        | Seroconverters      | N/A   | N/A    | [Green bar spanning all quarters from 2014 Q1 to 2020 Q4] |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-016 | N/A                        | Pregnancy           | N/A   | N/A    | [Green bar spanning all quarters from 2014 Q1 to 2020 Q4] |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-011 | TFV gel (vaginal)          | Women               | 1     | 40     | [Teal bar: 2014 Q1-Q2]                                    |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-014 | TFV gel (vaginal & rectal) | Women               | 1     | 14     | [Teal bar: 2014 Q2-Q3]                                    |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-020 | Dapivirine IVR             | Women               | 3     | 3003   | [Red bar: 2014 Q1-Q2]                                     |    |    |    | [Red bar: 2015 Q1-Q2]    |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-017 | TFV gel (rectal)           | MSM & TG            | 2     | 186    | [Teal bar: 2014 Q1-Q2]                                    |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-023 | Dapivirine IVR             | Adolescent women    | 2a    | 96     | [Orange bar: 2014 Q1-Q2]                                  |    |    |    | [Orange bar: 2015 Q1-Q2] |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-024 | Dapivirine IVR             | Menopausal women    | 2a    | 96     | [Orange bar: 2014 Q1-Q2]                                  |    |    |    | [Orange bar: 2015 Q1-Q2] |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  |                        |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-025 | Dapivirine IVR             | Open label extensio | 3b    | 2500   |   |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  | [Red bar: 2016 Q1-Q2]  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-026 | Dapivirine gel (rectal)    | Men and women       | 1     | 45     |   |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  | [Teal bar: 2015 Q3-Q4] |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| MTN-027 | Vicriviroc / MK-2048 IVR   | Women               | 1     | 48     |   |    |    |    |                          |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |    |  |  |  | [Teal bar: 2015 Q3-Q4] |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

# MTN Strategic Planning Process

- **September 2013:** Merck, ViiV, CONRAD, IPM, Population Council, Mintaka Foundation, and Intrucept asked to provide MTN with product development plans and requests for clinical trial support
- **October 2013:** Presentation of possible products and new protocol concepts to the MTN Executive Committee

# MTN Strategic Planning Process

- **December 2013:** 1.5 day meeting with Behavioral Research, Biomedical Science and Community Working Groups
  - Discussion of highest priority new products and concepts
- **January 2014:** Pipeline Prioritization Meeting Washington, DC
  - To create synergy and avoid unnecessary duplication across microbicide development groups and their sponsors

# Potential MTN Partners You Will Hear From Today

- Potential Collaborative Partners
  - IPM
  - CONRAD
  - Population Council
  - ImQuest
  - Intrucept
  - Merck
  - Mintaka Foundation
  - Albert Einstein College
- Potential products
  - TFV / TDF
  - Dapivirine
  - MK-2048 and Vicriviroc
  - Griffithsin
  - 5P12 RANTEs
  - IQ-0528
- Proposed formulations
  - Vaginal tablets and gels
  - Rectal gels
  - Intravaginal rings