

# Stakeholders Meeting: Day One Recap



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**Ensuring Safe HIV Prevention Methods for  
Pregnant and Breastfeeding Women**

Blantyre, Malawi – Thursday 21 March 2019



# Setting the stage

- Community voices-empowerment, PrEP experiences
- Pregnancy and breastfeeding are periods of high HIV risk acquisition, women are pregnant and/or breastfeeding for a considerable part of their life
- How do we know if a product or drug is safe to use during pregnancy and breastfeeding?
  - Drug development
  - process of clinical trials to drug approval
  - Learnt that pregnant and breastfeeding women often excluded, information comes after approval

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- Overview of PrEP and the dapivirine ring
  - PrEP status in Malawi
  - What we know and don't know about PrEP and the Dapivirine Ring in pregnant and breastfeeding women
    - Some information available about PrEP
    - Little on dapivirine
    - Need for more information
  - Overview of DELIVER and B-PROTECTED
  - Two studies that will evaluate the safety of PrEP and the ring in pregnant and breastfeeding women

# What is similar about the two studies?

- Women in both studies use either the monthly ring or daily PrEP during the time that they are in the study
  - Which product women use will be determined by chance (randomization) – like flipping a coin



*or*



# DELIVER: 4 Groups of Women

- Will enroll 750 pregnant women at different times during pregnancy
  - Group 1** – 36+ weeks pregnant (about 8-9 months)
  - Group 2** – 30-35 weeks pregnant (about 7-8 months)
  - Group 3** – 20-29 weeks pregnant (about 5-7 months)
  - Group 4** – 12-19 weeks pregnant (about 3-5 months)

- PrEP and the dapivirine vaginal ring are safe and can reduce the risk of HIV, but we need to know that they are safe to use by women during pregnancy and breastfeeding
  - PrEP and the ring are possible solutions, hence these two studies to collect data
- It is about ensuring that women can be protected against HIV with options they know are **safe**:
  - for themselves
  - their pregnancies
  - their babies