Preference Trials for HIV Prevention

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Presentation Highlights

1. What is the main issue or question the presentation addresses? **To introduce the concept of preference trials for HIV prevention research.**
2. What is the key finding or 'takeaway message'? **We can honor participants preferences and still obtain important, robust and unbiased evidence about the viability and effectiveness of novel interventions (biomedical or behavioral).**
3. How does the research advance HIV prevention efforts? **Allowing flexibility in trial design for investigating new interventions.**

What is a Preference Trial?

- A **pragmatic trial** that seeks to be *inclusive* of the population that would be targeted for the intervention in roll out.
  - Unwillingness to be randomized does not have to be an exclusion criteria.
- Seeks to understand how preferences and alignment of preference to the assigned intervention impact success of the intervention.
- Still seeks to estimate effectiveness of interventions
  - HIV prevention, adherence/use, persistence of use, etc.
  - Not limited to biomedical interventions

Two-Stage Preference Design

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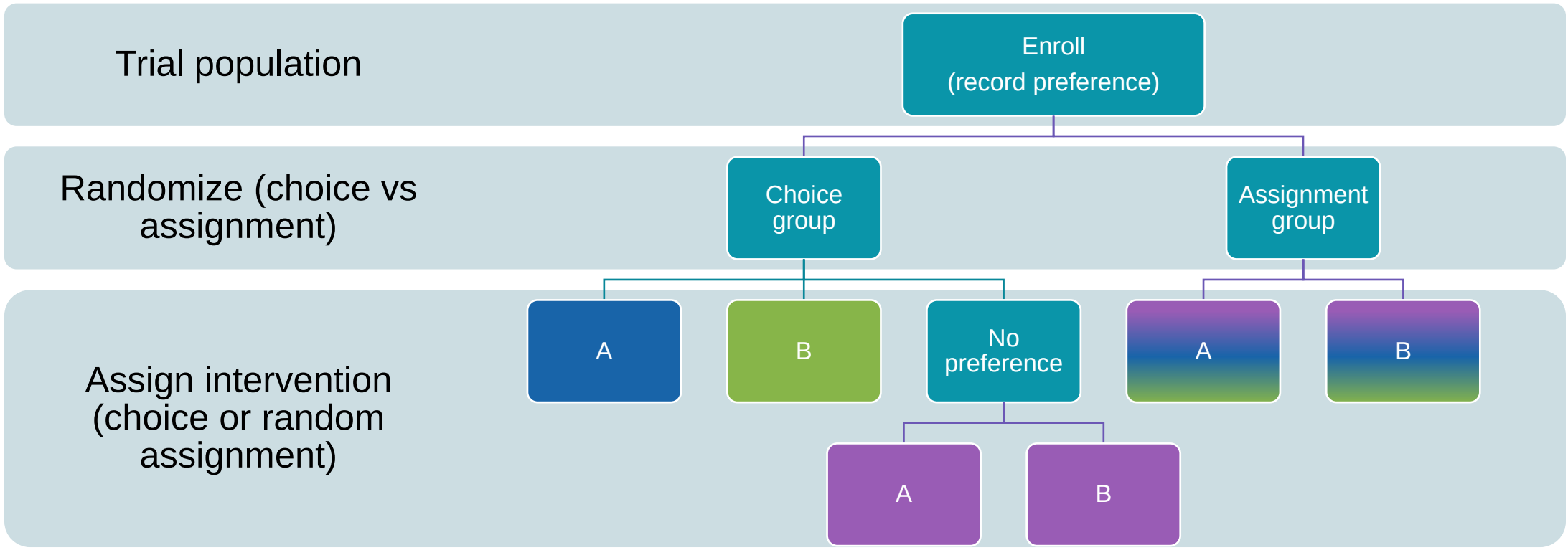
Two interventions: A and B



Effects of Interest

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Intervention effect

Effectiveness of A vs B (ITT)

- Estimated from the randomized group

Preference effect

Difference in effectiveness between those who would choose A and those who would choose B

- Is effectiveness of A vs B different in those who would choose A than those who would choose B?

Selection effect

Expected difference between participants who would choose A versus B

- Do people who would select A have different outcomes than those who select B, regardless of assignment?
- Not directly estimable but can be estimated under certain assumptions

Reimagining MTN-034/REACH as a Preference Trial

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Adherence, safety, and choice of the monthly dapivirine vaginal ring or oral emtricitabine plus tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis among African adolescent girls and young women: a randomised, open-label, crossover trial

Gonasagrie Nair, Connie Celum*, Daniel Szydlo, Elizabeth R Brown, Carolyne A Akello, Rita Nakalega, Pippa Macdonald, Gakiema Milan, Thesla Palanee-Phillips, Krishnaveni Reddy, Eunice Tahuringana, Felix Muhlanga, Clemensia Nakabiito, Linda-Gail Bekker, Bekezela Siziba, Sharon L Hillier, Jared M Baeten, Morgan Garcia, Sherri Johnson, Tara McClure, Lisa Levy, Edward Livant, Cindy Jacobson, Lydia Soto-Torres, Ariane van der Straten, Sybil Hosek, James F Rooney, John Steytler, Katherine Bunge, Urvi Parikh, Craig Hendrix, Peter Anderson, Kenneth Ngure, on behalf of the REACH Protocol Team*

Summary

Background Half of new HIV acquisitions in Africa occur in adolescent girls and young women. Pre-exposure prophylaxis (PrEP) with oral tenofovir disoproxil fumarate plus emtricitabine or the monthly dapivirine vaginal ring is efficacious but has lower adherence and effectiveness among adolescent girls and young women. We aimed to assess product adherence, safety, and choice of oral PrEP compared with the dapivirine ring among African adolescent girls and young women.

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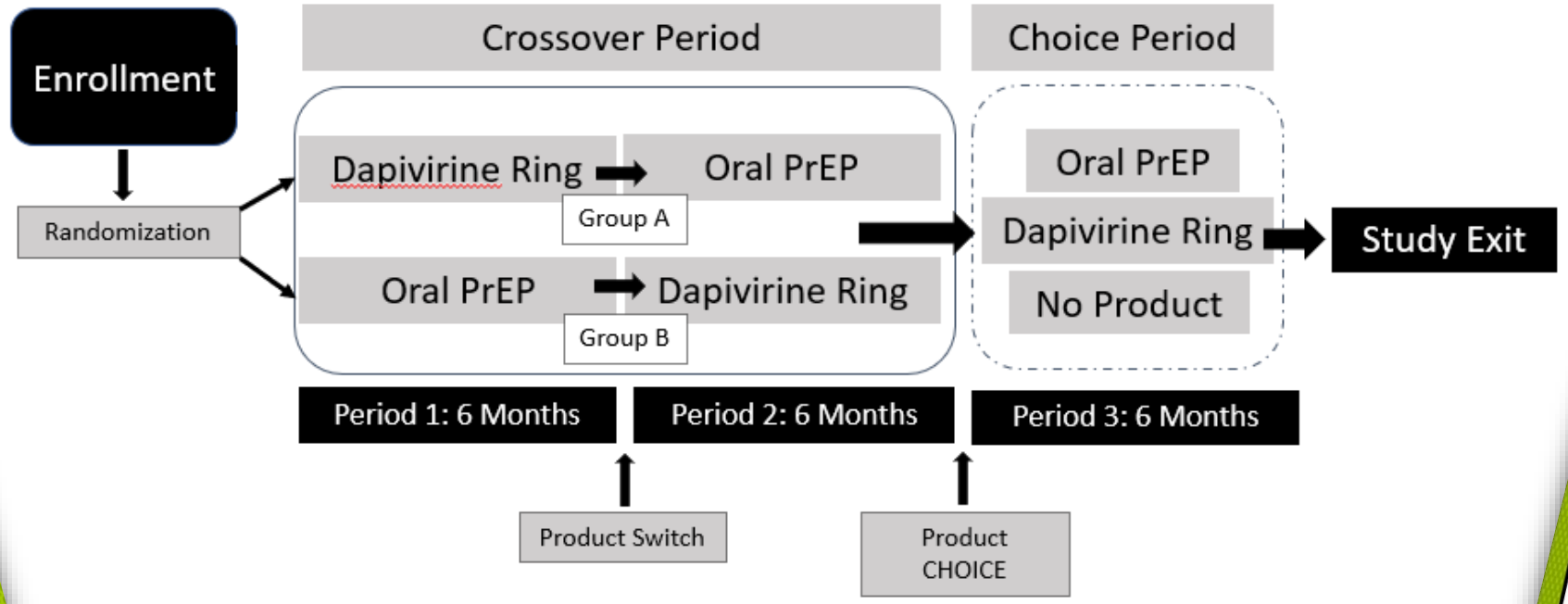
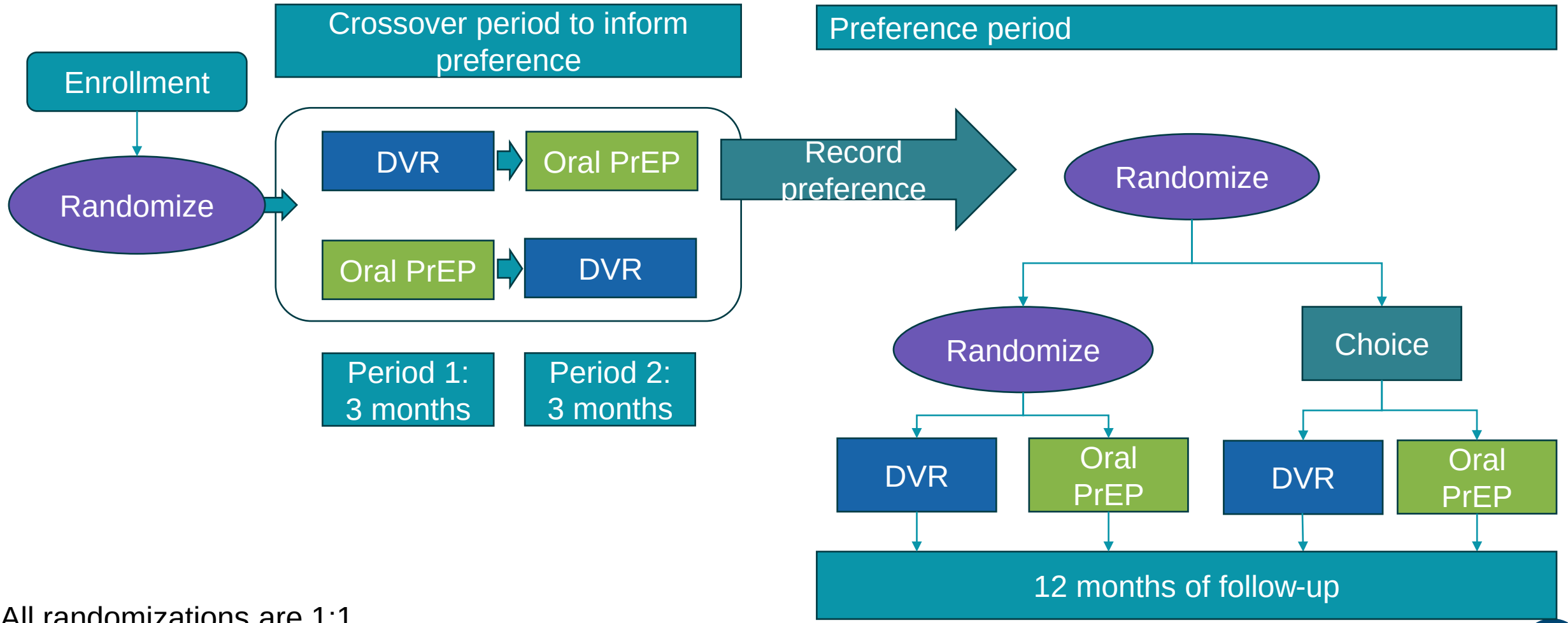
REACH Study Design



A randomized crossover study offering a diverse menu of adherence support options to all participants.

REACH Re-Imagined



All randomizations are 1:1

New design retains 6N person-months of randomized safety time

Summary

- Inclusion will be key as HIV prevention products diversify.
  - We should not limit trials to only those people interested in the control arm.
- Preference trials are an option for assessing new HIV prevention interventions.
- Now is the time for innovation!

Thank you

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