

# HPTN: Priority Focus Areas

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# Scientific Aims

Identifying	Novel antiretroviral (ARV)-based methods and delivery systems for HIV prevention
Developing	Multi-purpose technologies for HIV prevention as well as for contraception, prevention of other sexually transmitted infections or opioid dependence
Evaluating	Broadly neutralizing antibodies alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network
Designing and conducting	Population-specific integrated strategy studies that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness



1

## STI and HIV

**Gap:** Study of STI prevention interventions that will reduce risk of HIV transmission/acquisition: inflammatory STI, including gonorrhea, HSV-2, vaginal dysbiosis



2

## Broadly neutralizing monoclonal antibodies (bnAbs) for HIV Prevention

**Gap:** Optimizing design of combined bnAbs -selection of bNAbs, dose and combination



3

## Choice

**Gap:** Interventions and tools to choose the best method with the goal of improving PrEP persistence (e.g for adolescents and young participants and in pregnant women)



4

## Treatment as Prevention: (Status Neutral Approach)

**Gap:** Status-neutral approach in populations with the highest prevalence. For e.g. PWID (follow-up of HPTN 074), general population (follow-up of HPTN 071) MSM (follow-up of HPTN 075) etc.



5

## Implementation: Scale-up of PrEP in real world

**Gap:** How to get PrEP out of clinics for healthy, uncomplicated cases – delivery out of clinic could improve persistence



6

## People who use Drugs (PWUD): Outside the US

**Gap:** Studies determining the best combinations of MOUD and PrEP formulations (including long acting MOUD, oral PrEP, CAB-LA and lenacapavir) to reduce HIV incidence among PWUD. Studies in other substance users.



# Focus Areas

7

Studies in Pregnant Women



8

Follow-up of HPTN 075 and 091: Status-neutral approach in MSM and transgender persons in Africa



# Strategy for prioritization

- **Identified based on:**
  - Recurring themes across committees/groups
  - Alignment with scope of HPTN
- **Rejected ideas based on:**
  - Concepts addressing significant societal issues
  - Unfocused ideas
  - Same idea in different populations (unclear of prevalence or why outcome will be different)
  - Topical agents beyond 106 (until results are available)
  - Early FIH trials that are being done in MATRIX

# Status of Biomedical Agents

- Current HPTN studies evaluating biomedical agents
- Timelines for drug availability for integrated strategies
- Planning for what comes next



## Injectable CAB LA

- HPTN 083-OLE
- HPTN 084-OLE

## Multi-purpose Prevention Technology (MPT)

- HPTN 104

## Injectable Lenacapavir

- HPTN 102
- HPTN 103

## Rectal Microbicide

- HPTN 106



# CAB-LA : Approvals and Roll-out

- **Approvals:** US, Australia, Zimbabwe, South Africa, Malawi, Botswana, Brazil
- **Submissions:** Kenya, Uganda, Vietnam, Malaysia, Myanmar Philippines, Peru, China, European Medicines Agency (EMA), Thailand, Ukraine, Zambia
- Direct discussions with many donors and procurers and with the Global PrEP Coalition with respect to affordability and availability.
- Timelines for programmatic roll out are part of those discussions
- For generic manufacturing, the Medicines Patent Pool announced licensing agreements with 3 generic manufacturers, timelines to be determined
- **Speculation: Programmatic rollout: Q2 2024?**  
**Generic version: Q 4 2025?**



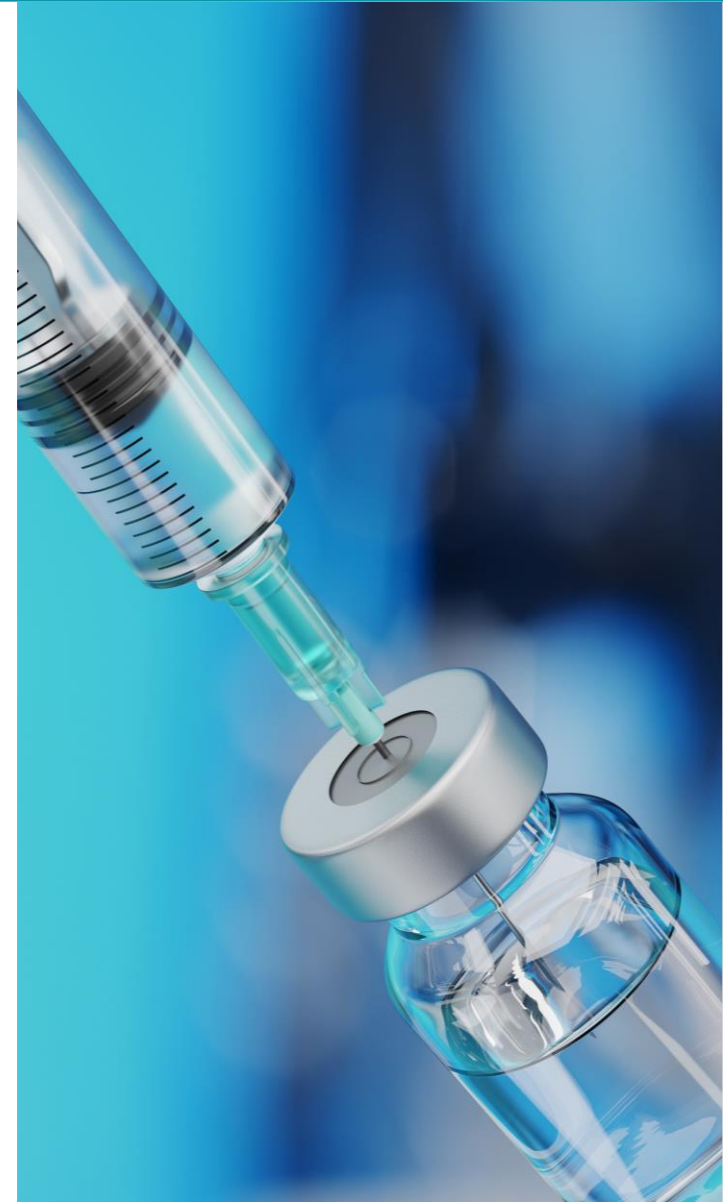
# Lenacapavir Development

Injectable lenacapavir, q 6months (LEN) Efficacy and Safety Studies:

- **Purpose 1:** cis-gender Women
- **Purpose 2:** MSM and transgender women having sex with men

Data available in 2025

**Speculation: Approvals in late 2026?**

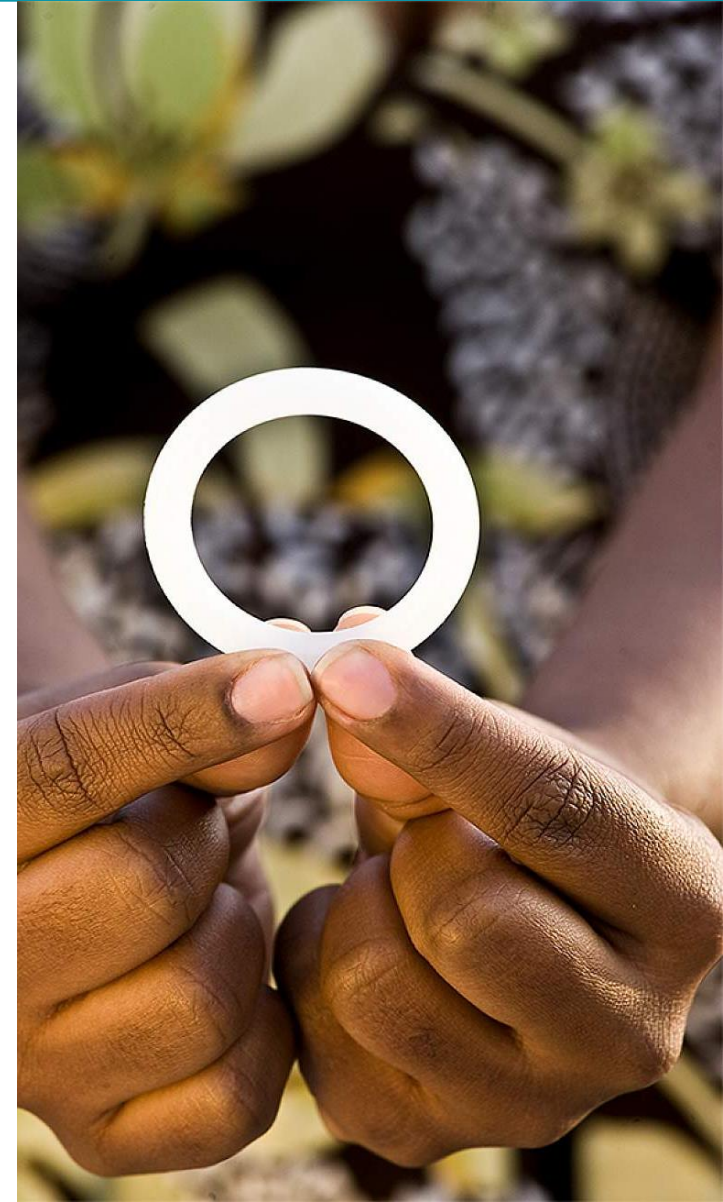


# Dapivirine Vaginal Ring

- Reduced HIV risk in trials: 27% (ASPIRE)–35% (The Ring Study)
- Open-label extension studies: increased adherence

## Current regulatory and procurement status

- US FDA application voluntarily withdrawn Approved by multiple regulatory bodies in Africa
- 2021 WHO recommendation for cis-gender women  $\geq 18$  yrs unable to take oral PrEP
- 2022 PEPFAR guidance supports procurement for research only.
- The Global Fund will support procurement of PrEP ring for program delivery.
- **Speculation: available for Integrated Strategy in 2024?**



# Multi-Purpose Technology

## **DPP (co-formulated TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill (OCP))**

Manufacturer: Viatrix

- Approval of DPP is through 503B pathway (bioequivalence data is sufficient)
- BE 4 pilot completed Aug 2023. Bioequivalence demonstrated!
- Pivotal BE: Results expected Q3 2024

*Speculation: submissions (Q4 2024). Approval ; Q 4 2025?*

## **F/TAF-MPT DPP**

Manufacturer: Medicines 360 in partnership with Pop Council (prototype)

- Needs to find a GMP manufacturer

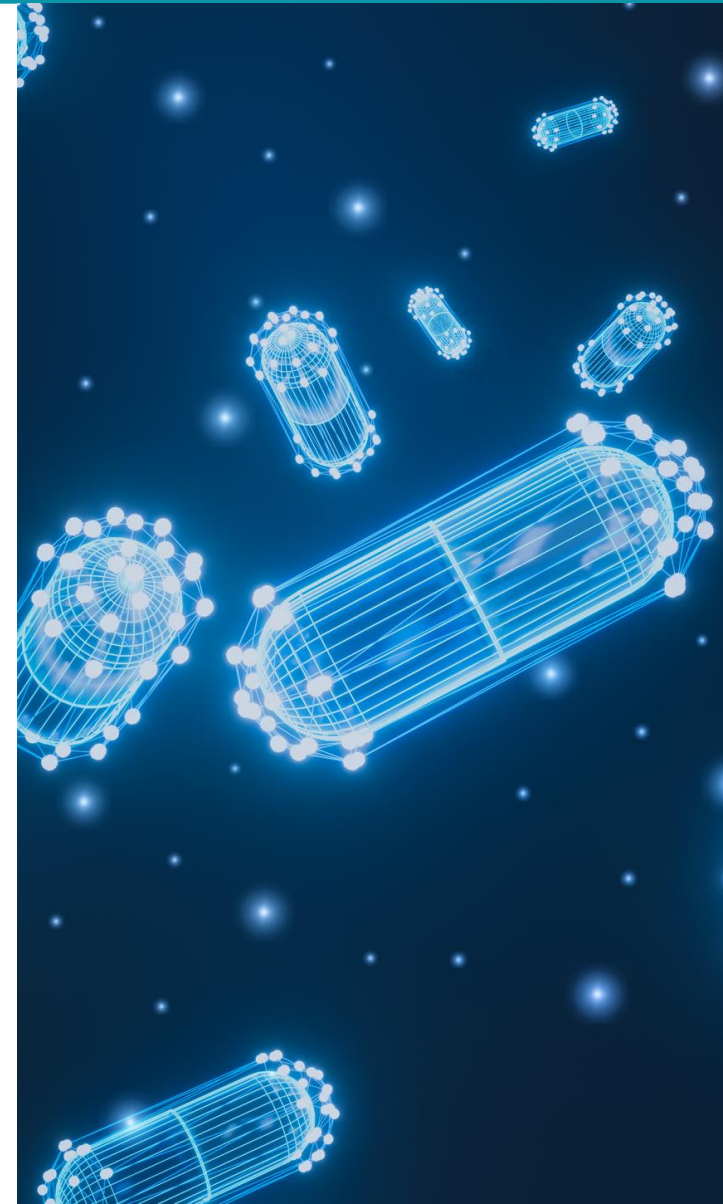
*Possibly available for phase 1 in 2024?*

## **Injectable CAB-LA-levonorgestrol**

Manufacturer: Conrad

- FIH phase 1: 2025

*Speculation: Phase 2 Q 4 2026 – Q1 2027 with HPTN?*



## **Are there research gaps for any agent for PrEP/TasP?**

- Use in special populations (e.g. pregnant women, Latino MSM, adolescents)
- Are there other new agents?

## **What is needed for integrated strategies?**

- Regulatory approval in the region? Availability of agents? Need for generics?
- Engaging diverse populations
- Providing options for the needs/realities of different communities



# Acknowledgements

- Sinead Delany-Moretlwe
- Myron Cohen
- Wafaa El-Sadr
- Katie Schwarz
- Ayana Moore
- Marybeth McCauley

# Acknowledgments

- Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center).
- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.





# Thank you



- EXTRA