Updates on

Accelerating Access to Long-Acting PrEP

Oral PrEP Progress and Planning for the Future

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Making PrEP Accessible: Updates on Long-acting Injectable Options

30 March 2023

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Key Updates

- Zimbabwe, South Africa & Malawi approvals – with quite permissive labels in terms of age, oral lead-in, use in pregnancy and testing
- Eight implementation science projects approved
- PEPFAR procurement plans and COP agreements in 6 countries
- Global Fund and CIFF partnership in 6 countries
- Limited supplies available from ViiV thru 2023, pending additional mill approval from FDA to expand
- Three generic sub-licenses from MPP announced today
- Coalition to Accelerate Access to Long-Acting PrEP working with wide range of stakeholders

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Parallel Universes/Journeys

Providers & Health Systems

- Who is at risk?
- Where do I find them?
- When I can test them?
- What do I tell them?
- Where can I provide px info and products to them?
- What px options can I provide them?
- Oral, ring, injectable, condoms, DPP?

Users

- What do I want?
- Who do I want to talk with about sex and relationships?
- Do I want an HIV test?
- Where do I want to get an HIV test?
- Do I need and want HIV prevention?
- What kind of HIV px do I want?
- Oral, ring, injectable, condoms, DPP? — Choice
- Where and from whom do I want it? — Choice

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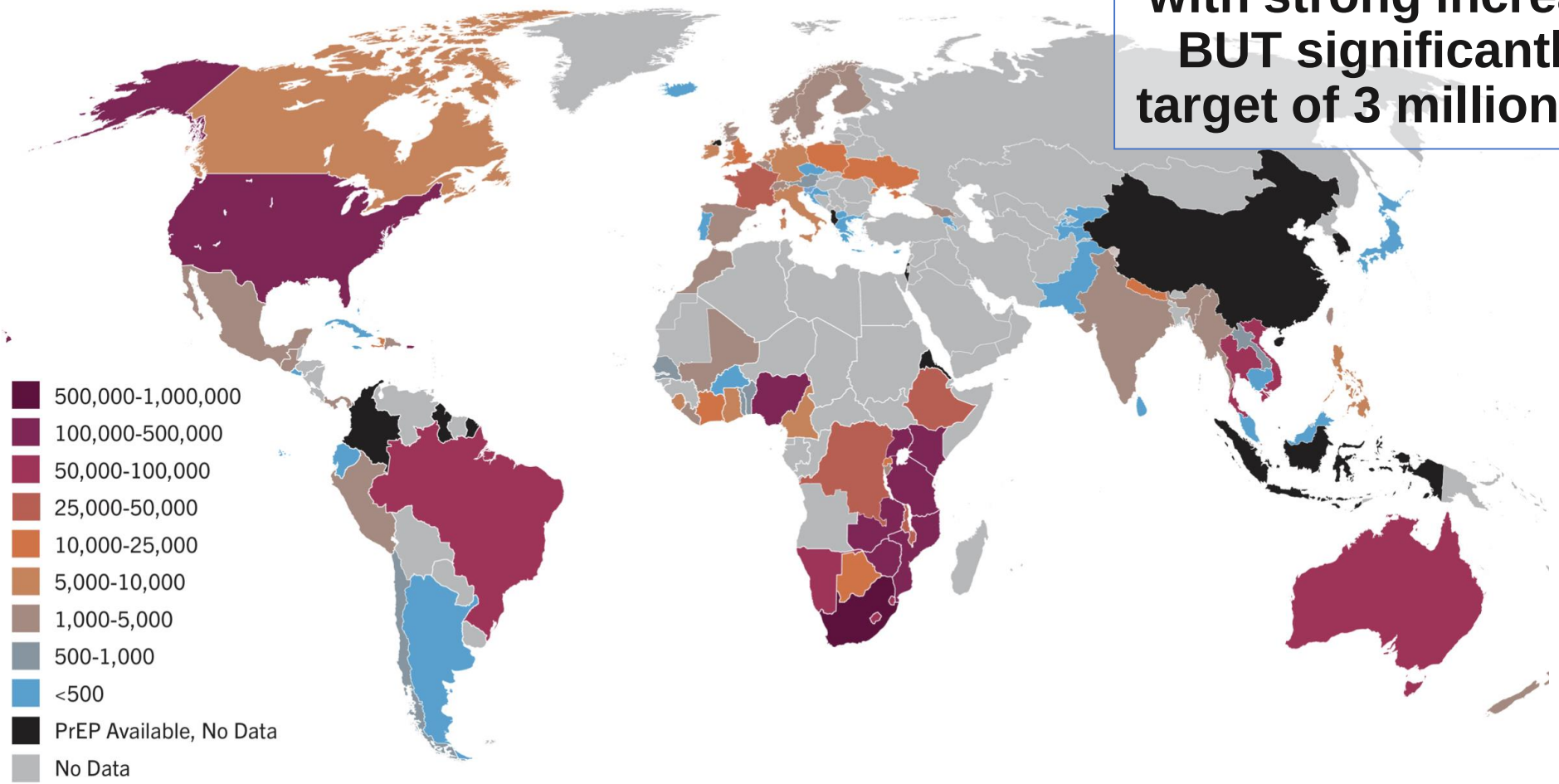
Global PrEP Uptake – 10+ years in

Approx. total PrEP initiations:
3.8 million
with strong increases in 2022 –
BUT significantly missed UN target of 3 million users by 2020



Source: AVAC Global PrEP Tracker, Q4 2022, https://www.prepwatch.org/data-by-country/

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Learning from and Building on Oral PrEP

Oral PrEP Implementation Studies

Post-approval studies and projects

131 Distinct post-approval oral PrEP implementation projects and studies; most were small-scale

Countries

68 Different countries conducted projects including multiple in the same country (e.g. 25 in one country)

Stakeholders

54 Different organizations involved in oral PrEP implementation research

Key Takeaways from early Oral PrEP rollout

Post-approval studies were not all designed to address decision-maker questions

Data from research was not well timed to inform decision making at global or country level

Complex, fragmented stakeholder landscape

Lessons Lessons From Oral PrEP Programs & Implications for Next Generation Prevention

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The Way Forward

Requirements of Collaboratively Planning for Successful Introduction:

- **Mapping decision-maker questions against studies**
- **Planning in parallel with clinical trials**
- **Shared strategy developed by diverse stakeholders**

Ideal Scenario for Future Px Products:

Post-approval studies are **well designed** to address decision-maker questions

Data from research is **well timed** to inform decision-making at global and country level

Coordinated stakeholder landscape with roles agreed upon in advance

[BioPIC CAB-LA initial Introduction Strategy]

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Translating Scientific Advance into Public Health Impact:
A Plan for Accelerating Access and Introduction of Injectable CAB for PrEP

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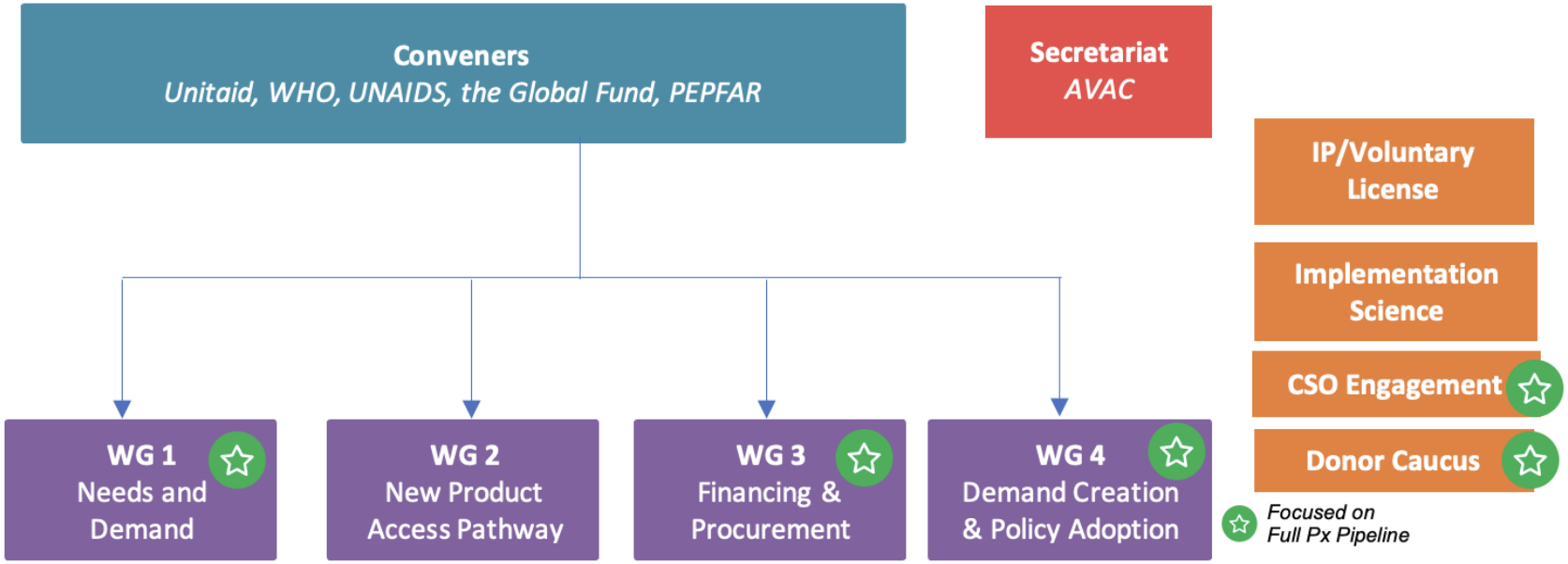
June 2022

Pathway	Immediate Priorities
Product	▶ **ViiV** to license injectable CAB to the Medicines Patent Pool (MPP). ▶ **The MPP and ViiV** to work with generic manufacturers and donors, including Africa-based manufacturers, to expedite technology transfer and ensure sustainable supplies of the product. ▶ **Generic manufactures, with MPP**, to identify capital expenditure needs and timeframe to be able to develop capacity. ▶ **Innovative donor(s)** to fund capital investments needed for generic manufacturing to reach scale. ▶ **ViiV** to confirm publicly, maximum quantity and minimum price for 2022-2025. ▶ **Donors** to negotiate this price/volume guarantee to ensure sustainable supply for initial introduction period, given the timeline for generic licensing agreements and manufacturing upgrades (likely 4-5 years).
Regulatory Approval & Normative Guidance	▶ **Eight regulators** currently reviewing injectable CAB for PrEP to ensure priority review. ▶ **ViiV** to pursue widespread registration of CAB in high-burden countries. ▶ **ViiV** to register with WHO Pre-Qualification (PQ) to allow expedited registration in countries participating in WHO's Collaborative Procedure for Accelerated Registration process.
Planning & Budgeting	▶ **Governments and donors** to set targets for supply and programs at scale – what is needed and possible in 2022-2023 in implementation science projects, and what is needed from 2024 to begin programs at scale.
Delivery / Supply Chain	▶ **Large, resourced and coordinated implementation studies** to begin immediately to answer critical questions about how CAB performs outside the clinic setting and across populations. ▶ **Provider training** materials and tools updated to incorporate CAB administration and implementation studies that assess the feasibility of task-shifting to expand the cadres of providers that are authorized and trained to administer injections and that offer choice (explaining efficacy, clinic visits, side effects, etc. of all methods available) and assist in shared decision-making. ▶ **Innovative demand creation** strategies (for injectable PrEP and for "choice" among options) developed with process to test and iterate, and share across projects.
Individual Uptake & Continued Use	
Delivery / Supply Chain	▶ **Testing requirements** should not become a barrier to CAB introduction. Testing strategies should be both robust and feasible and work with locally available tests and assays to, maximize the benefits of access to CAB while minimizing the risk of undetected cases.
Research	▶ **Data to be collected on the benefit of injectable CAB as PrEP for populations that were not part of efficacy trial**s, especially adolescents, pregnant and breast-feeding people, and transmasculine and gender non-conforming individuals. ▶ **Study alternate injection sites and frequency of injections**, recognizing that the impact of injectable CAB holds the potential to expand, if the injection schedule could align with injectable contraception.
Stakeholder Engagement	▶ **Integrate and engage civil society** in all decision-making relevant to planning and preparation for access to CAB, including designing, conducting and monitoring implementation studies and delivery programs.

Coalition to Accelerate Access to Long-Acting PrEP



- Build on lessons learned from oral PrEP and coordinate stakeholders activities
- Jointly develop strategies to identify and overcome access challenges for new PrEP options in near- to medium-term (*ViiV's injectable CAB, including generics, and dapivirine vaginal ring*) and medium- to long-term (*future PrEP products*)
- Ensure new, longer-acting PrEP options reaching the market will be available and equitably accessible to all who need them more quickly than ever before

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PrEParing for New Products

COUNTRY	CAB Regulatory Status	DVR Regulatory Status	HPTN 083/084 Studies	Ring/ ASPIRE Studies	Oral PrEP approved	Oral PrEP Initiations in 2022	Cumulative PrEP Initiations since launch	Global Fund PrEP Matching Funds	CAB & DVR Projects: Approved	CAB & DVR Projects: Planned	PEPFAR Procurement
Argentina	To file by Q2, 2023		●			—	129				
Botswana	Pending	Pending	●		2016	10,214	21,972				
Brazil	Pending		●		2017	41,589	89,410		●ImPrEP; ●PrEP 1519		
Colombia	To file by Q2, 2023					N/A	N/A				
Cote D'Ivoire	To file by Q2, 2023					7,080	10,138			●CohMSM (also in Burkina Faso, Mali, Togo)	
Eswatini	Via SA		●			28,603	57,340			● Ring Intro	
Kenya	Pending	Approved	●		2015	170,551	298,455	$3,000,000	●●Catalyst/ MOSAIC; ●SEARCH	●● PrEP-PP	
Lesotho	Via SA	Approved				27,235	82,147		●● Catalyst/ MOSAIC		
Malawi	Pending	Pending	●	●	2017	30,807	37,498			●MOH/BPS	
Malaysia	Pending					—	130				
Mozambique	To file by Q2, 2023	Pending				81,038	142,351	$3,750,000		●●MSF	
Myanmar	Pending					2,922	3,556				
Namibia	To file by Q2, 2023	Pending				20,187	68,762				
Nigeria	To file by Q2, 2023				2017	227,478	401,110	$6,500,000			
Peru	Pending		●		2021	—	2,931				
Philippines	Pending					6,763	8,494				
Rwanda	To file by Q2, 2023	Approved				7,430	21,239				
South Africa	Approved	Approved	●	●	2015	422,239	792,434	$5,750,000	●● Catalyst/ MOSAIC; ●● Project PrEP; ●Fast PrEP; ●Axis; ●Let's Talk	●PICASSO; ●CAB in Private Pharmacies; ●PrEP-PP; ●Mobile Men	
Tanzania	To file by Q2, 2023	Pending			2020	93,767	149,687				
Thailand	Pending		●		2016	11,764	51,072			●IHRI Key-Pop	
Uganda	Pending	Approved	●	●	2017	165,500	353,974	$3,000,000	●● Catalyst/ MOSAIC; ●SEARCH	●Mobile Men	
Ukraine	To file by Q2, 2023					5,690	11,065				
Vietnam	Pending		●		2015	21,238	50,265			●STEPS	
Zambia	To file by Q2, 2023	Approved			2017	148,503	351,207	$3,000,000			
Zimbabwe	Approved	Approved	●	●	2017	83,580	143,498		●● Catalyst/ MOSAIC; ● PSI Ring		

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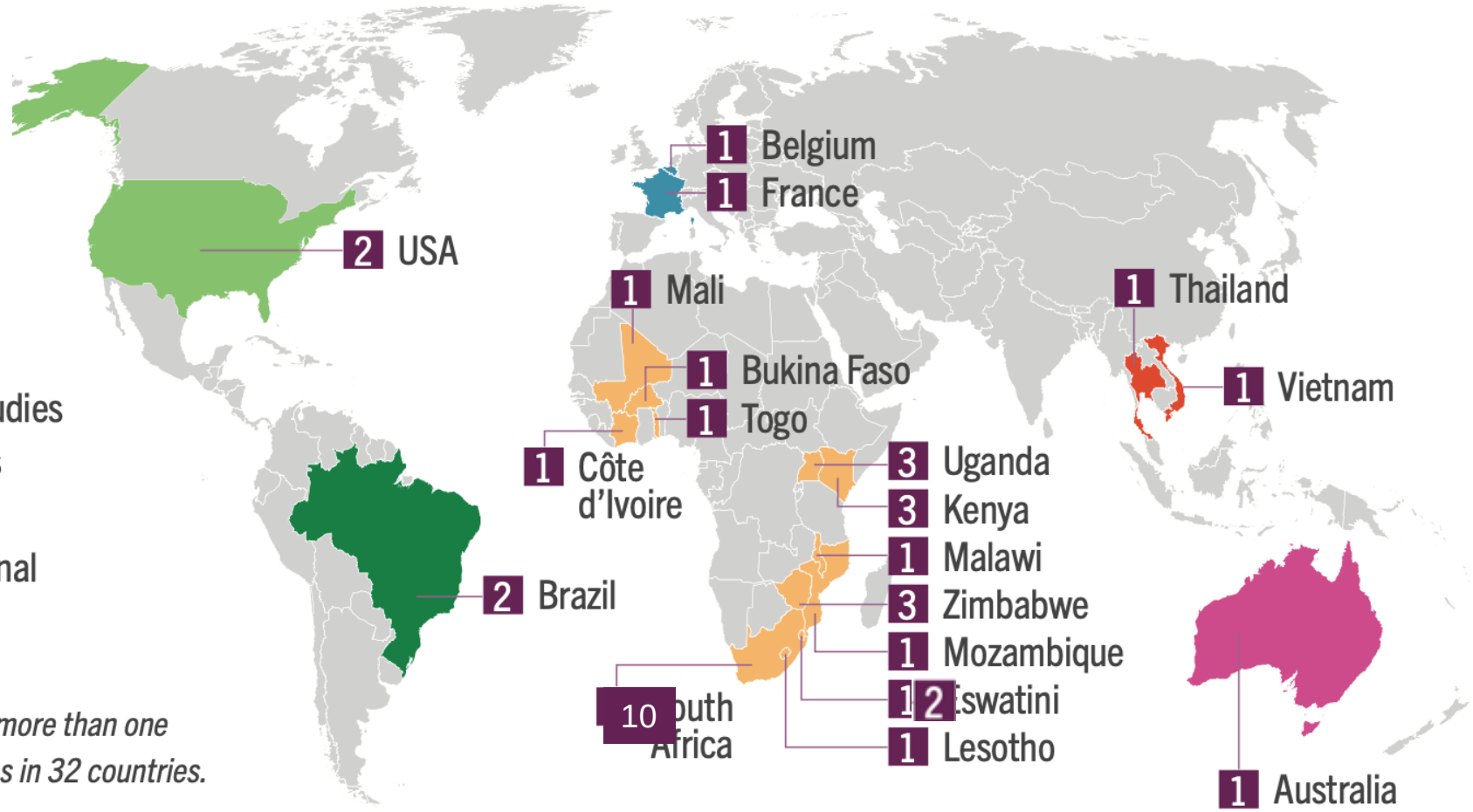
PrEParing for New Products – Geographically

27

implementation science studies are planned in 19 countries with cabotegravir (CAB) for PrEP and/or dapivirine vaginal ring (up

Some studies are happening in more than one county, with a total of 25 studies in 32 countries.



[BioPIC Implementation Study Tracker]

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PrEParing for New Products – Geographically

BUT, significant questions remain about timing:

- National regulatory approvals of product
- ViiV internal approvals of protocols
- Product supply – manufacturing capacity, timing, shipping
- Actual product delivery to participants
- Answers to critical questions to inform models, policies, program design, procurement, investment

[BioPIC Implementation Study Tracker]

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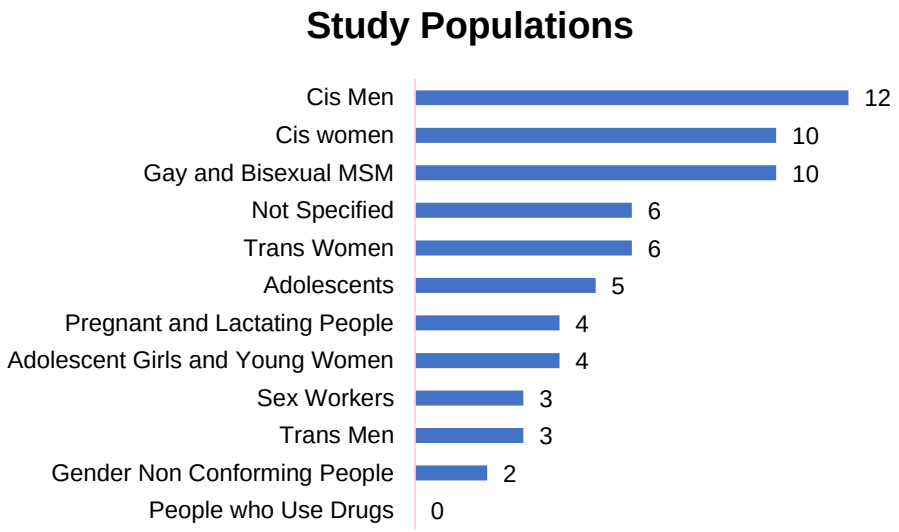
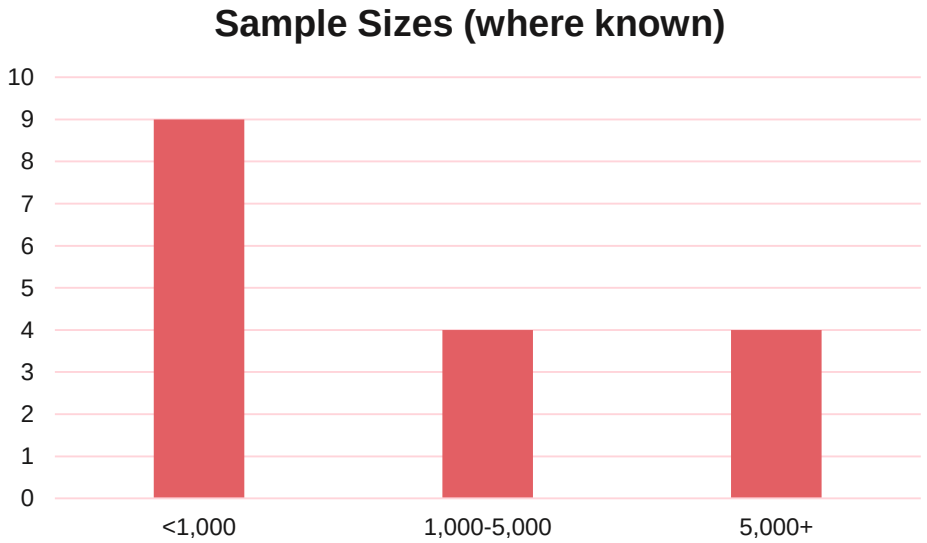
PrEParing for New Products – By Population





- Not all studies have established sample sizes
- Only four studies with over 5,000 participants: CATALYST (MOSAIC), Project PrEP (Wits RHI), FASTPrEP (DTHF), and Theta Nami Ngithethe Nawe (“Let’s Talk”) (AHRI)
- Most studies plan to run 2023- 2025, dependent on approvals and CAB supply

BioPIC Implementation Study Tracker

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Now What?

- Translate biomedical options into viable choices for users, providers and health systems
  - Intro new options as part of marketing and programming for choice
  - Identify (and differentiate) service delivery models that work for users
  - Ask and answer critical implementation science questions for each product, while building prevention platforms for the future
- Understand testing and initiation needs for PrEP
- Ensure robust civil society engagement in intro/implementation research and planning
- Procurement/commodity funding – for launch and ongoing
- Provider training – both clinical guidelines AND appropriate counseling, support, empathy
- Realistic targets for interventions, especially intro – and not just coverage targets
- Identify what products can "solve for" – and what they can't
- Ensure we do better, more equitable intro with ring and injectable than with oral PrEP and COVID-19 vaccines

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Resources

- Podcast: *New Products are Needed & a New Paradigm is Essential: A new era in prevention?*
- Summary slide decks:
  - Advocates Guide to CAB for PrEP
  - Advocates' Guide to Product Introduction
  - Advocates' Guide to HIV Testing and PrEP
- AVAC's Plan for Accelerating Access and Introduction of Injectable CAB for PrEP & summary document
- Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More
- Implementation Science Questions for CAB for PrEP
- Implementation Study Tracker
- Cost of Goods Sold (COGS) Analyses: FAQ Brief – AVAC & CHAI
- *A New Shot Guards Against HIV, but Access for Africans Is Uncertain* – New York Times
- Global PrEP Tracker (that includes DVR and CAB in addition to long-standing oral PrEP info)
- Lessons Lessons From Oral PrEP Programs & Implications for Next Generation Prevention
- BioPIC CAB-LA Initial Introduction Strategy
- BioPIC Adaptable Framework for Product Introduction
- Dual Prevention Pill Market Preparation and Introduction Strategy

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HIV Prevention Market Manager
Accelerating Product Introduction
Informing Product Development
Reducing Time to Impact

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BioPIC Biomedical Prevention Implementation Collaborative

Coalition to Accelerate and Support Prevention Research (CASPR)

Cooperative Agreement No. AID-OAA-A-16-00031
HIV Vaccine and Biomedical Prevention Research Project—Objective 3

CHILDREN'S INVESTMENT FUND FOUNDATION

BILL & MELINDA GATES foundation

COMPASS