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

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Global Advocacy for HIV Prevention

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1. Background

In 2020, two large-scale efficacy trials found that a long-acting injectable form of pre-exposure prophylaxis (PrEP) provided high levels of protection among people at risk of HIV. Injectable cabotegravir (CAB) showed a substantial prevention benefit in gay men and other men who have sex with men, transgender women who have sex with men, and cisgender women. ViiV Healthcare, the developer of CAB, received FDA approval in late 2021 and has filed for regulatory approval for injectable CAB for PrEP in eight additional priority countries, with decisions anticipated in 2022. WHO convened its Guidelines Development Group in March 2022 and is expected to finalize and release guidelines by mid-2022.

Since FDA approval, there has been increasing momentum and discussion – and concern – around what is and isn't happening to ensure the introduction of injectable cabotegravir for PrEP is optimized to answer critical questions and deliver the potent prevention that the trials imply it might. The experiences of the first decade of oral PrEP implementation show the impact of delays in delivery and inequity in access.

Oral PrEP was first shown to be safe and effective in 2010 and first approved in 2012, but the field moved too slowly – and now 10 years later, only approximately two million people have initiated use of this option, far short of the 2020 target of three million and a tiny fraction of the estimated number of people who need it and could benefit from it. There are significant questions about how to deliver injectable cabotegravir for PrEP, but the world cannot afford to squander another decade navigating these questions without bold actions, global urgency, and coordinated partnerships.

ViiV, policy makers, normative agencies, donors, program implementers, researchers, generic manufacturers, civil society, advocates and communities each have critical roles to play in the coming months. This document attempts to provide a **comprehensive view of all the moving parts and identify specific priority actions and actors** responsible for ensuring time is not wasted and opportunity not squandered.

Top-line Summary

- Despite progress, HIV infection rates remain high.
- PrEP options have an important role to play in ending the epidemic, and no one option will address the needs of all.
- Injectable cabotegravir offers an additional option with high efficacy.
- It has been approved by the US FDA, submitted to other regulators, and WHO guidelines are expected in mid-2022.
- Answering operational questions around distribution, HIV testing, delivery and demand is critical.
- So, too, is securing an affordable, cost-effective price for injectable CAB.
- Voluntary licensing to generic manufacturers, along with capital investments, will be necessary to secure a low-cost, sustainable and diversify product supply – and this process will likely take at least 4-5 years.
- ViiV Healthcare, the developer of injectable CAB for PrEP, will be the sole supplier in this initial period. Current capacity and price are uncertain, and ViiV and donors must urgently identify an appropriate price-volume commitment during this initial 4-5 year period to answer critical questions and build the market.

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2. Guiding Principles

The overarching goal and focus must be to move faster, **more strategically, more coordinated and with an acceleration towards impact** with injectable CAB for PrEP than the field did with oral PrEP in the first decade. To do so, the following principles must drive all parties:

- **Lead with Equity**: Products don't end pandemics if they aren't delivered with equity and urgency; COVID vaccine delivery is yet another harsh reminder.
- **Center the Community and User**: It is critical to center the community in design and implementation of programs and center users in actual product delivery. We have learned from the Good Participatory Practice Guidelines that effective community engagement builds mutually beneficial, sustainable relationships and strengthens programs.
- **Accelerate Scale and Speed**: We need to break the sequential nature of traditional approaches to scale and speed up introduction. Part of accelerating speed is moving toward a parallel approach where research, implementation science, and scale programs are designed, funded and implemented in parallel.
- **Deliver Impact**: Priorities and targets for the next 12 months must focus on building a pathway to public health impact. Wildly ambitious coverage targets on the one hand, and small-scale thinking related to initial projects on the other, provide the extremes, as seen in the oral PrEP experience. Coverage-based targets can add to confusion when there's so much that needs to be understood about delivery for impact. Instead, it makes sense to assess and set a deadline for analyzing current operational studies and another deadline for when a coverage target towards impact could be in place.
- **Work With What We Know, While Continually Adding To The Evidence-Base**. There is still much we don't know about injectable cabotegravir, but there is also a lot we do know. We have consistently failed at prevention and let the perfect be the enemy of the good. But we can learn from past mistakes and missteps, and CAB for PrEP is a chance to reorient, reimagine and re-energize HIV prevention programs.

3. Top Priorities

Introducing a new product depends on multiple actions from a diverse array of stakeholders. Global health is filled with examples of these activities happening too slowly, without rigorous coordination and accountability, and in a sequential manner. But COVID-19 has shown us that the global community can compress timelines and new technologies can be developed, tested and distributed quickly and with urgency, at least for wealthier nations. The challenges now are:

- whether the lessons of urgency and working in parallel instead of sequentially can be applied to injectable CAB for PrEP, AND
- if access and impact can be done with equity, so those most affected and disproportionately impacted by HIV will benefit from the promise of injectable PrEP.

To address these challenges, these are top priorities that are critical in the next five years (2022-2026) to getting injectable CAB for PrEP to those who need it most, categorized into what needs to happen with the product and with the programs that facilitate access:

	Priority	Target Time
Product-specific	■ WHO guidelines include injectable CAB for PrEP.	Q3 2022
	■ Cost-effective, affordable and transparent CAB price and volume commitment from ViiV to support early launch and roll-out.	Q3 2022
	■ Sufficient ViiV capacity to meet initial, near-term order forecast (covering implementation studies and initial demand from national programs and implementing organizations).	2023-2026
	■ CAB for PrEP demand and supply monitored and coordinated by the ARV Procurement Working Group.	2022-2023
	■ Donors negotiate price/volume guarantee with ViiV to ensure sustainable supply for initial introduction period until generics registered and readily available, given the 4-5 year timeline for generic licensing agreements and manufacturing upgrades.	2022-2023
	■ Voluntary licensing and sub-licensing from ViiV to select generic manufacturer(s), including technology transfer as required.	2022-2023
	■ Donor investment identified to fund generic manufacturing capacity.	2022-2023
	■ Generic manufacturer(s) develop product and high-volume sterile fill/finish capacity, undertake bioequivalence (BE) studies and file with regulatory authorities.	2023-2026
	■ Regulators define BE pathway, paving the way for approval of a generic product.	2023
Programmatic	■ National Programs in priority countries complete CAB registration (or secure relevant waivers); revise PrEP guidelines/adapt WHO CAB guidance; design provider trainings and introduction efforts.	2022-2023
	■ Operational research/implementation science studies identify successful, scalable delivery channels, including primary care facilities and integration with family planning services, ANC/PNC and key population drop-in sites, etc.; a testing algorithm that balances resistance risk with the needs of users and providers; ongoing engagement with communities and civil society; and an independent coordination mechanism.	2022-2024
	■ Market assessments and demand forecasts updated with data from initial projects to inform manufacturing, volume and cost.	2022-2025

4. Pathway to Access and Impact, with Immediate Priorities

This table outlines the immediate priorities across the pathway to access and impact and includes key actors responsible for them, while ***Annex 1: Detailed Status and Action Table*** provides a more detailed description of Status and Key Questions/Priorities/Next Steps for each issue area.

The Pathway to Access and Impact

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.

Pathway	Immediate Priorities
Delivery / Supply Chain Individual Uptake & Continued Use	■ **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.
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 trials**, 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

5. Who's Who in the Zoo

Organization	Opportunities for Injectable PrEP
Centers for Disease Control and Prevention (CDC)	■ Potential integration into current PEPFAR-supported PrEP programs ■ CDC-funded PrEP project in Thailand to be leveraged for critical implementation science questions.
Children's Investment Fund Foundation (CIFF)	■ Currently investing in Dual Px Pill Consortium that is working towards future product introduction and interested in possible investments in other HIV prevention and PrEP activities ■ Historically invested in various market shaping efforts, including advanced purchase commitments, manufacturing, etc.
Foreign, Commonwealth & Development Office (FCDO in the UK)	■ Bilateral funder that has not invested in PrEP directly but watching this space
Gates Foundation	■ Co-funded HPTN 084 ■ Considering implementation science projects in Kenya and South Africa ■ Possible additional investments in research on dosing regimen; volume purchases; generic manufacturing
Global Fund to Fight AIDS, TB and Malaria	■ Potential integration into new NFM4 ■ Created new Advisor position to focus on HIV Prevention Product Introduction and support Country Teams in four TBD countries to "implement objective of scaling up evidence-based and innovative HIV prevention interventions (products and service delivery innovations) as part of comprehensive HIV prevention and SRH packages for people at high risk of HIV infection"
Kenyan NASCOP	■ Early oral PrEP adopter and actively updating national guidelines to incorporate CAB (and dapivirine vaginal ring (DVR))
MedAccess	■ Social finance company that looks at market shaping and innovative financing to accelerate product access ■ Could include advanced purchase commitments, manufacturing support, etc.
Medicines Patent Pool	■ Manage licensing and IP to engage generic manufactures ■ In May, launched the Coalition for Preparing for Access to CAB-LA Together via Voluntary Licensing (PrEP-ACT VL Coalition), but specific terms of reference, roles and responsibilities are not yet clear.
NIAID, NIH	■ Co-funded both HPTN 083 and 084, sub-studies and OLEs ■ Possible support to SEARCH study to integrate CAB into ongoing intervention
OGAC/PEPFAR	■ Integrated CAB and DVR into COP 2022
South African National Dept of Health	■ Early oral PrEP adopter and actively updating national guidelines to incorporate CAB (and DVR)

Organization	Opportunities for Injectable PrEP
UNAIDS	■ Considering new campaigns on HIV prevention and PrEP
UNITAID	■ Added CAB into three existing PrEP programs – two in Brazil; one in South Africa (which also includes DVR)
USAID	■ Research division supporting MOSAIC and the CATALYST implementation science study that includes CAB and DVR in five countries – Kenya, Lesotho, South Africa, Uganda, Zimbabwe ■ Program division looking at potential integration of CAB into current PEPFAR-supported PrEP programs
WHO	■ Guidelines Development Group met in March; guidelines expected mid-2022 ■ Support national governments with adaptations and training ■ Pre-Qualification (PQ) to support with guidance for BE requirements

Mechanism/Project	Plans or Possibilities for Injectable PrEP
African Women Community Prevention Accountability Board	■ Serve as an ongoing, independent mechanism for stakeholder engagement, consisting of key national and regional advocates and civil society representatives to provide input into CAB planning and implementation
AfroCAB	■ Mobilize advocates to engage in planning for CAB planning ■ Establishing two working groups to focus on demand generation and engaging policymakers, stakeholders and technical experts
Biomedical Prevention Implementation Collaborative (BioPIC)	■ Gates-funded, AVAC-led product introduction clearinghouse and coordination mechanism ■ Published both CAB introduction strategy and adaptable framework for future product introduction ■ Tracking global implementation science projects ■ With WHO, convene think tanks on critical introduction issues – design of implementation projects; testing and resistance; marketing prevention and choice
Coalition to Accelerate and Support Prevention Research (CASPR)	■ USAID-funded prevention research advocacy project ■ Linking civil society partners to introduction project planning ■ Support to ongoing and independent CS advisory groups on CAB for PrEP providing input into ongoing research and introduction. ■ Developing materials related to CAB, testing and product introduction to support civil society advocates. ■ Engagement with journalists and media to translate key messages
Key Population Advisory Group	■ Following initial engagement with ViiV in 2020, developing terms of reference and links to the African Women Prevention Accountability Community Board, and collaborating with Global Black Gay Men Connect (GBGMC)

Mechanism/Project	Plans or Possibilities for Injectable PrEP
Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC)	■ USAID-funded product introduction and implementation science project focused in East and Southern Africa, focused on AGYW ■ Applying a user-centered approach to product introduction with meaningful youth engagement and gender integration ■ Conducting product introduction research, including 5-country CATALYST study to introduce both DVR and CAB ■ Facilitating integration of new products into national policies and programs, including demand generation, provider training, monitoring and evaluation ■ Supporting research utilization and rapid knowledge exchange ■ Strengthening local partner capacity in product introduction

6. Advocacy Priorities

- **Talk to your community**. Understanding specific questions and concerns will help frame advocacy priorities. Help communities understand the results of HPTN 083 and 084, the potential role of injectable PrEP that is delivered every eight weeks, the regulatory process and the importance of scaling up oral PrEP and the dapivirine vaginal ring in the meantime.
- **Demand funding, targets and innovation to support prevention programs that translate options into real choices**. This includes designing programs with the communities that need prevention most and gathering robust data on user preferences. It also includes advocacy for investments in large, well-designed, and coordinated implementation studies to begin immediately to answer critical questions about how CAB-LA performs outside the clinic setting and across populations.
- **Advocate for investments that will lead to impact**. Donors, national ministries of health, and ViiV need to urgently negotiate a price/volume guarantee that ensures a sustainable supply within high-quality programs for the initial introduction period until generics are registered and readily available, given the 4-5 year timeline for generic licensing agreements and manufacturing upgrades.
- **Call for program innovation and equitable access to the proven options that exist today**. The best understood, already proven strategy, oral PrEP, is still not available to all who need it. Multi-month prescriptions, self-testing and user-centered services are essential.
- **Hold decision-makers on CAB for PrEP — and on prevention generally — accountable**. Is there clarity about next steps? Are there targets and milestones in place? Is there adequate funding to support rollout? How might decisions be made about who would get the product first, if it's licensed and introduced through phased rollout?
- **Work locally with research sites**. Bring your advocacy know-how to sites where clinical and implementation research is planned or ongoing to ensure that communication, access and continued work reflect your needs and priorities. And ensure that research continues on next-generation prevention options, as no one option will be the right choice for every person or for any one person and different times in their lives.

7. Recent Resources and Statements

Resources

- Injectable CAB for PrEP Introduction Project Planning Clearinghouse, April 2022
- Modelling Impact of Injectable Cabotegravir for PrEP on Drug Resistance, April 2022
- Vaccine equity: The rollout that needs a booster shot, April 2022
- Px Pulse Podcast: Getting Rollout Right for Ring and Injectable PrEP, March 2022
- Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More, AVAC, May 2021; updated February 2022
- Product Introduction Project Planning for Next-Generation PrEP Think Tank Report, CASPR/AVAC,WHO, Sept 2021
- Getting Rollout Right: Lessons from Oral PrEP Lessons from Oral PrEP Programs and their Implications for Next Generation Prevention, AVAC/PrEP Watch, October 2021
- Implementation Research Questions for CAB for PrEP, BioPIC/AVAC, Dec 2021
- HIV Testing and Injectable Cabotegravir for PrEP Think Tank Report, BioPIC/AVAC/WHO, Dec 2021

Statements

- Communities demand ViiV/GSK accelerate access to CAB-LA in LMICs AfroCAB, 1 March 2022
- Statement by Southern African Women Advocates in Advance of ViiV Convening, Advocates at ViiV meeting South Africa, 9 March 2022
- ViiV continues to not meet our demands to ensure CAB-LA is accessible for our communities, AfroCAB, 17 March 2022
- ViiV Healthcare is working with Medicines Patent Pool to progress voluntary licensing for cabotegravir long-acting for PrEP, ViiV, 4 April 2022
- ViiV Healthcare commits to grant voluntary license for patents relating to cabotegravir long-acting for PrEP to Medicines Patent Pool, ViiV, 27 May 2022

8. AVAC'S Role

AVAC was founded in 1995 to advocate for the ethical development and global delivery of HIV vaccines. A decade later, AVAC was still committed to that cause, but in our first PrEP report in March 2005 (*Will a Pill a Day Prevent HIV?*), we wrote: "We are also not blind to the fact that other new prevention technologies are likely to arrive sooner than a vaccine. And we think many of the issues we work on – accelerated research, community involvement and education, research ethics, global access, and policy analysis – are highly relevant with PrEP. In the coming years, AVAC will continue to work in partnership with other advocates to advance ethical prevention research and ensure that the benefits are shared globally."

Since that first report, AVAC has worked on PrEP advocacy, stakeholder engagement and introduction and access since 2004, when the earliest oral PrEP efficacy studies were being designed – and dogged in controversy. Out of that controversy, AVAC developed with UNAIDS the Good Participatory Practice Guidelines to guide PrEP and other HIV prevention research; and launched the PrEP Watch web clearinghouse, first to track the trials and subsequently to track the rollout, as well serve as an online hub of information. With a range of partners, AVAC has helped link communities with PrEP programs to ensure GPP also guided introduction; push UNAIDS and PEPFAR to develop PrEP targets – and resource the programs to achieve them; reviewed the early oral PrEP demonstration projects to distill lessons for introduction of next-generation products; and established a Production Introduction and Access team to serve as a catalyst for better, faster implementation. AVAC's current activities include a range of efforts to influence and accelerate access to injectable CAB for PrEP, including:

- **Advocacy**: Through the USAID-funded CASPR and Gates-funded COMPASS projects, AVAC and a range of civil society partners have pushed for implementation of the GPP Guidelines throughout the injectable PrEP efficacy trials; developed materials to understand the results and advocate for applying them; pushed PEPFAR, Global Fund and national governments to integrate injectable PrEP into guidelines, targets and programs.
- **Stakeholder Engagement**: CASPR partners engaged directly with the HPTN in trial conduct and results dissemination. More recently, AVAC has worked with these and other partners to ensure civil society is actively engaged with planners and funders of implementation science projects, and provided technical assistance in the creation of the African Women Prevention Accountability Community Board and the Key Population Advisory Group. As a partner in the USAID-funded MOSAIC project, AVAC is working with civil society partners to ensure ongoing stakeholder engagement in the five-country CATALYST study.
- **Production Introduction and Access**: In addition to its role within MOSAIC, AVAC continues to lead the Biomedical Prevention Implementation Collaborative (BioPIC) which serves as a clearinghouse to monitor and track HIV prevention product introduction activities; as a convener of stakeholders brought together as part of ongoing think tanks to address roadblocks to product introduction and scale-up; and as a catalyst for investments towards the HIV prevention product introduction strategy which was developed under a previous project.

Annex 1: Detailed Status and Action Table:

This table provides a more detailed description of Status and Key Questions/Priorities/Next Steps for each issue area:

Issue	Status	Key Questions/Priorities/Next Steps
Product Safety	Done in clinical trials	Monitor on ongoing basis in robust post-marketing surveillance
Product Efficacy	Done overall for range of populations	Need to understand additional populations and approaches: ■ Populations: adolescents, PBFP, people who inject drugs, trans men ■ Approaches: alternate injection sites, revisions in frequency of injections
Regulatory Approval & Normative Guidance Regulatory	Approved in US (Dec 2021); applications pending in Australia, Botswana, Brazil, Kenya, Malawi, South Africa, Uganda, Zimbabwe	■ Accelerate actions in countries where applications are pending. ■ ViiV needs to file in at least the other high burden countries (as identified in Global Prevention Coalition roadmap and PEPFAR prioritization) within next six months. ■ Targeted technical assistance to NMRAs to rapidly review CAB and understand the requirements across regulatory authorities to secure efficient reviews of both innovator and generic products.
Product Product availability and pricing	ViiV announced in March they anticipate that they will be sole supplier of cabotegravir for PrEP "at least during the initial years of introduction"; then in April that they are working with MPP to "progress voluntary licensing"; and then in May that they were "committing to grant voluntary license for patents relating to cabotegravir long-acting for PrEP to MPP" Price not public, and cost of goods analyses present disparate estimates	■ What volume can ViiV supply under current manufacturing and at what price? ■ How much and how fast can this respond to increased demand? Is it only in one production site/line or is there some backup in case of production problems? ■ Identify the price/volume ratio for initial 4-year supply: how low can price go with significant volume (and how quickly), and then secure with donors a volume guarantee – and map this to mfg capacity over time (from both ViiV and from potential generics). ■ ViiV to grant MPP a license to encourage and engage generic manufactures ■ Work with MPP and generics to map out what is possible for generic manufacturing and accelerate voluntary license to MPP ■ Generics explicitly share what they need for capital expenditure needs (e.g. what it will cost to be able to mfg CAB) and how long it will take before a generic is available in the market ■ Identify those funders who work in these kinds of de-risking efforts to provide CapEx grant/loan for generic companies. ■ Ensure appropriate technical support throughout the technology transfer process, product development, and bioequivalence studies.

Issue	Status	Key Questions/Priorities/Next Steps
Regulatory Approval & Normative Guidance Guidelines	WHO committee meeting on 9-10 March; due for release mid-2022	■ Development of practical implementation tools and guidance following the WHO CAB guideline recommendation, and coordination to inform later-stage revisions of normative guidance based on early evidence generation. ■ National Technical Working Groups to begin process of adapting/adopting/nationalizing guidelines over next three months – for intro of both CAB and DVR.
Delivery / Supply Chain Individual Uptake & Continued Use Implementation science/operational research	Draft agenda created; BioPIC mapping of potential projects to assess initial volumes Unitaid and MOSAIC studies have confirmed funding and protocols in development	■ Need a discrete number of coordinated, implementation science projects to answer specific questions, but not in lieu of planning the scaled programs. These may only begin in 2023/4, but how they are designed, delivered, etc. need to be defined over the next 9 months and informed by IS but not waiting for it. ■ Additional operational research needed across other geographies and priority populations (beyond Unitaid's operational projects among TG and MSM in Brazil [~1,500 participants] and AGYW in South Africa [~2,600 participants] and USAID-funded MOSAIC project [~4,225 AGYW in five sub-Saharan African countries) ■ Ongoing coordination between donors, implementers, civil society and governments to ensure highest-priority evidence gaps are addressed. ■ Need clear paths from IS to planning for scale up of programs, clarity about testing algorithm needed that ensures the mitigation of risks related to resistance and initiating people with HIV onto PrEP, but not creating a barrier to program design and operation. Need to think big and beyond implementation science/demo projects – need to get to scale to answer critical questions; drive price down; and deliver impact
Delivery / Supply Chain HIV testing – for initiation and ongoing	HPTN 083 provided initial data related to the risk of INSTI resistance; HIV Modeling Consortium conducting modelling the potential effects of CAB introduction on integrase inhibitor drug resistance	■ MUST not let RNA testing issue get in the way of implementation science, implementation proper, and scale-up. ■ Plan for potential breakthrough and/or resistant infections and ensure appropriate treatment options are available. ■ Leverage the most sensitive scalable assay there is available locally – and continue to advocate for advances in sensitive, inexpensive, POC HIV testing.

Issue	Status	Key Questions/Priorities/Next Steps
 Research	Safety and efficacy demonstrated; sub-studies and open-label extensions ongoing	■ 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 (every three-months). ■ Need data for populations that were not part of efficacy trials, especially adolescents, pregnant and breast-feeding people, transgender individuals and people who use drugs. ■ Study interactions between gender-affirming hormones and CAB, and operational research needed on how to integrate CAB with gender-affirming care services.
 Civil society engagement	Ad hoc engagements with ViiV led to establishment of African Women Prevention Accountability Community Board as well as Key Population Advisory Group, and collaborating via CASPR network; AfroCAB actively engaging	■ Ongoing advocacy and community engagement to drive access-focused decision-making from ViiV and inform national product adoption and introduction approaches. ■ Targeted investments to support effective demand generation and develop platforms to facilitate community-led rollout.

About AVAC: Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of HIV prevention options as part of a comprehensive response to the pandemic. Follow AVAC on Twitter @HIVpxresearch and find more at www.avac.org and www.prepwatch.org.