

ViiV'S COMMUNITY STAKEHOLDER ENGAGEMENT STRATEGY FOR LOW- AND MIDDLE-INCOME COUNTRIES

2022-2024

Working through Collaborative Partnerships to Inform
and Enable Sustainable Access to Cabotegravir Long-
Acting for PrEP

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1. Introduction and Purpose

ViiV Healthcare's approach to access, outlined in our [Access to Medicines](#) policy, aims to support and enable the sustainable scale-up of access to our medicines and care for people living with HIV (PLHIV) and affected populations. We are the only pharmaceutical company solely focused on combating, preventing, and ultimately curing HIV and AIDS. We have developed Cabotegravir long-acting for PrEP (CAB LA for PrEP), the first and currently the only long-acting injectable pre-exposure prophylaxis (PrEP) option to reduce the risk of sexually acquired HIV. The medicine was studied in men who have sex with men (MSM), women and transgender women who have sex with men who were at increased risk of sexually acquiring HIV. We recognize that CAB LA for PrEP is one, among other HIV prevention options. Our access strategy for CAB LA for PrEP in low- and middle-income countries (L&MIC's), is to maximize rapid access and uptake of CAB LA for PrEP as a prevention choice for populations with highest unmet needs, in a sustainable way, centered on partnership and integration into existing healthcare services and HIV prevention programmes. In line with this, we are dedicated to ensuring community stakeholder engagement and participation throughout all aspects of the product access pathway to bring CAB LA for PrEP to market in L&MICs.

Our *Community Stakeholder Engagement Strategy for CAB LA for PrEP in L&MICs* guides our engagement with key community stakeholders committed to HIV prevention, to enable people affected by HIV to exercise choice when it comes to HIV prevention options, including the use of CAB LA for PrEP. We want to **facilitate meaningful community-led and community-driven engagement opportunities for community stakeholders throughout the product access pathway**. As part of this strategy, we will consult with community stakeholders to identify and prioritise concrete and actionable initiatives that improve access to CAB LA for PrEP in line with each aspect of the access pathway (see Figure 1). For example, we recognize that there are a number of issues in relation to access that have been already raised by community stakeholders, including affordability and pricing, availability of the product for all populations with an increased likelihood of acquiring HIV including rural and stigmatized populations, voluntary licensing and manufacturing by generics, and the availability of appropriate HIV testing services to support initiation and continuation of CAB LA for PrEP. In this strategy, we seek to articulate our commitments and objectives for engagement with community stakeholders in the implementation and achievement of our access plan, which includes addressing these existing concerns. A summary of the Access Plan for CAB LA for PrEP in L&MIC's and our commitments to support various aspects of the pathway in partnership with other stakeholders are included in Annex 1.

Figure 1: Access Plan for L&MIC's

Workstreams



Stakeholder Groups*

Global Multilaterals	National Programmes & Governments	Professional Associations	Civil Society & User Advocacy Group	Implementers	Donors	Key Opinion Leaders	Key External Experts
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**ViiV will engage these stakeholder groups across all workstream areas*

Importantly, while we seek to ensure that the strategy clearly articulates our commitments, we also seek to remain nimble, flexible, and open to adapting our approach as we continue to receive feedback to shape our engagements with communities to optimize impact.

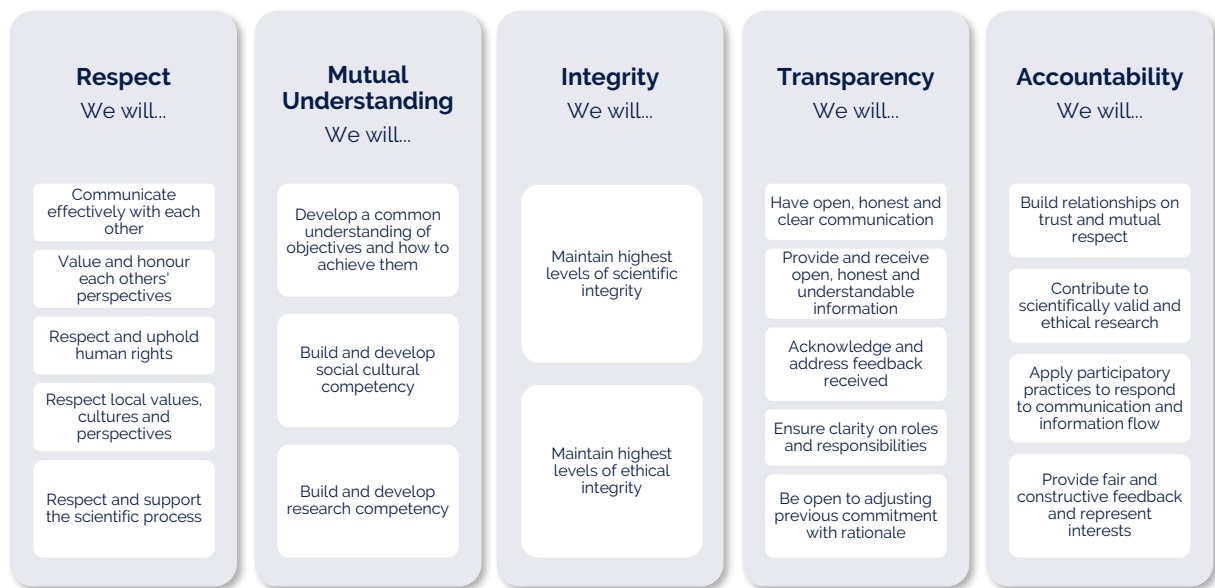
2. ViiV's Commitment to Good Participatory Practice (GPP) Guidelines

We are committed to engaging with community stakeholders in a positive, collaborative and mutually beneficial manner. Our engagement is informed by the Greater Involvement of People with HIV (GIPA) principles and grounded within the Good Participatory Practice Guidelines (GPP).¹ These guidelines, jointly developed by UNAIDS and AVAC with a range of research and community stakeholders, are well known by communities and provide a strong basis for strengthened partnerships and collaboration when they are meaningfully embedded. Values drawn from the GPP principles have long since been a solid foundation to ViiV's work, including during our research and clinical trial phase with the HIV Prevention and Trials Network

¹ [Good Participatory Practice \(GPP\) Guidelines | AVAC](#)

(HPTN). The GPP principles will continue to be the backbone of our community stakeholder engagement strategy, demonstrating our commitment to ensuring open and meaningful dialogue with community stakeholders (see Figure 2). We recognise and support community stakeholder autonomy and welcome diverse perspectives and authentic voices based on experience and lived reality including their right to refuse or support proposals related to research. We also commit to recognizing power dynamics in relation to race, gender, age, HIV status or other factors that could cause inequities, and to work towards addressing them through our engagement with community stakeholders. Finally, we recognize that partners are working towards adapting the GPP principles to be better suited towards community engagement across the product access pathway. We look forward to contributing to this and ensuring that our strategy remains grounded in these evolving GPP principles, with the ultimate goal of ensuring meaningful and sustained engagement with community stakeholders.

Figure 2 Good Participatory Principles Guiding Principles²



ViiV is committed to upholding these GPP principles and will ensure that we operationalize these principles in our day-to-day work and in our engagement with community stakeholders.

3. Vision and Objectives of Engagement Strategy

Meaningful partnerships are critical to every step of our access plan – from CAB LA for PrEP trials and Open Label Extension (OLE) to product registration and eventual scale-up. We are deeply thankful for the individuals and communities who have accompanied us on this journey so far. **Our vision of community stakeholder engagement is that the voices of individuals and communities are understood and integrated into access strategies to enable personal choice and increase their HIV prevention options, regardless of income or where they live.** We believe that informed and educated community stakeholders are the best drivers for access for PrEP, and key partners in designing and implementing effective programs to increase access to PrEP. We will actively invest in community stakeholder groups to support their efforts to increase access to HIV prevention options, including CAB LA for PrEP, putting these stakeholders, communities, and users of the product at the center of our strategy.

Our strategy has a **priority focus** on countries where the HPTN 084 and HPTN 083 clinical trials were conducted but will also serve other L&MICs (see Table 1).³

² Adapted from Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials. 2011. UNAIDS. AVAC.

³ A secondary focus will be on other L&MICs where there is an unmet need and a degree of political and systemic PrEP readiness.

Table 1: ViiV L&MIC focus populations and priority countries

Trial	Focus Populations	Priority Countries
HPTN 084	Women of reproductive age (WRA) including adolescent girls and young women (AGYW)	Botswana, eSwatini, Kenya, Malawi, South Africa, Uganda and Zimbabwe
HPTN 083	Gay men and other men who have sex with men (MSM), and transgender women who have sex with men	Argentina, Brazil, Peru, South Africa, Thailand, Vietnam and USA ⁴
Non-trial countries	Populations who will benefit from PrEP (include populations described above)	Other L&MICs not included in 084 or 083 listing

Over the next two years, the **objectives of our community stakeholder engagement strategy** are to:

- 1) Actively create and harness opportunities for ongoing dialogue and conversation with communities and the stakeholders that represent them to understand their experiences and respond, ensuring that these interactions shape our access strategy**
- 2) Collaborate with community stakeholders to identify and co-create tools and provide all stakeholders, including ViiV, with the information needed to collectively fulfil our respective roles effectively and contribute to increased access to HIV prevention options**
- 3) Strengthen and expand sustainable relationships via existing community stakeholder groups and co-create new strategic partnerships as needed to support the accelerated introduction of CAB LA for PrEP and pathways for future HIV prevention options**

3.1 Objective 1: Actively create and harness opportunities for ongoing dialogue and conversation with communities and the stakeholders that represent them to understand their experiences and respond, ensuring that these interactions shape our access strategy

Communities most affected by HIV have played a pivotal role in shaping the HIV response since the early 1980s, with activists calling for inclusion in decisions that affect them, and trial participants being key to ensuring the success of clinical trials related to treatment and prevention. ViiV has a long history of engaging community stakeholders on critical issues for HIV treatment. Through our Positive Action programmes, for example, we have created strategic partnerships with community stakeholders who help to identify gaps in service provision for paediatric AIDS. When it comes to expanding access to CAB LA for PrEP and HIV prevention options more broadly, we seek to deepen our work with community stakeholders to enable us to listen, respond and engage on an ongoing basis, to ensure there is continuing dialogue around community stakeholder experiences and needs so we can improve our understanding, and respond to specific barriers to access within national and local contexts.

We recognise that there are pressing issues which need to be resolved; through this strategy, we seek to work with community stakeholders to better understand issues from their point of view, learn from their experience, and co-create solutions. To this end, we plan to create several opportunities for ongoing interactive dialogue, and collaborative action planning, ranging from physical tours to virtual Zoom calls and other opportunities created at events, webinars, or conferences, and via existing community stakeholder engagement structures.

We acknowledge that we will not always be able to agree or land on common ground, but we are committed to intentionally achieving a mutual understanding.

Objective 1 Success Indicators:

- / 90% of community stakeholder groups/partners surveyed feel that ViiV has:
 - Actively engaged them, solicited their inputs, and listened to their perspectives
 - Satisfactorily acted on and responded to these inputs (including providing clear explanations for areas where they have not acted or responded) ⁵

⁴ United States of America is not included in this strategy.

⁵ The denominator for all success indicators in the strategy will include a full list of community stakeholder partnerships that ViiV identifies and prioritizes as the focus/target stakeholders for this strategy. A list of current partnerships is included in Table 3, but we **actively seek to include more partnerships** that will be added to the list.

3.2 Objective 2: Collaborate with community stakeholders to identify and co-create tools and provide all stakeholders, including ViiV, with the information needed to collectively fulfil our respective roles effectively and contribute to increased access to HIV prevention options

We have heard through our existing community stakeholder engagement that increasing awareness around HIV prevention and product knowledge of CAB LA for PrEP is critical. We also see improving product literacy as an important aspect of supporting community stakeholders and advocates to actively participate in discussions and decisions related to the rollout of CAB LA for PrEP. We have started this process and will continue to collaborate with our stakeholders to share existing resources, co-create relevant tools, and provide additional information, and learning opportunities so that diverse and representative groups can collectively engage and participate in discussions influencing access and achieving our shared goals. Where possible, we intend to **invest in strengthening existing community stakeholder systems** and mechanisms, supporting them to develop and share tools and information in formats that can most effectively reach a wide range of community audiences.

Community stakeholders have identified possible future learning opportunities, and **we will continue to seek further inputs and iterate** on what would be most useful in supporting community stakeholders to pursue their advocacy goals (see Table 2). In addition to providing product specific knowledge, we will leverage and support our partners and broader networks to fill any gaps in knowledge or information identified by community stakeholders.

Table 2: Potential topics/content areas for informational sessions in line with the product access plan

Potential Topics	Potential Content Areas
Product and Clinical Development	<ul style="list-style-type: none"> / Data gaps / Clinical trial updates/emerging evidence / Implementation science and demonstration projects / Other areas as needed
Regulatory and normative guidance	<ul style="list-style-type: none"> / Clinical guideline inclusions / Regulatory submissions / Other areas as needed
Supply chain and service delivery	<ul style="list-style-type: none"> / Procurement processes and supply chain issues / Voluntary licensing / Task shifting and community-level delivery/use / Other areas as needed
User demand	<ul style="list-style-type: none"> / Pathways to user uptake and continuation for those with the most likelihood of acquiring HIV / Promising approaches to demand generation and social marketing / Challenges with stigma / Barriers to continued adherence / Other areas as needed
Other	<ul style="list-style-type: none"> / Indicators to measure success / Monitoring and evaluation of programme outcomes / Other areas as needed

In addition to providing medical content, and always subject to local laws and regulations that govern the promotion of prescription medicines, ViiV will work with community stakeholders to contribute to the co-creation of engaging tools such as infographics, memes, learning videos, including for TikTok and interviews, and FAQ pamphlets to ensure communication about medical content is more accessible and digestible across a variety of audiences.

We commit to providing and receiving as transparent information as possible on key topics as they arise. We will consider all feedback and revert with more information or suggestions where possible. Where commercial factors and confidentiality inhibit our ability to share detailed information, we will clearly state what information we can provide, and what is confidential.

Objective 2 Success Indicators:

- / 90% of community stakeholder groups/partners surveyed:
 - Feel confident about discussing CAB LA for PrEP and product features as an HIV prevention option
 - Feel requests for information have been responded to in a timely manner
 - Provide positive feedback on the utility of opportunities for co-creation of tools, and interactive information sharing
- / 90% of attendees of discrete opportunities for dialogue, conversation and information sharing report positive feedback on the utility of attending and participating.

3.3 Objective 3: Strengthen and expand sustainable relationships via existing community stakeholder groups and co-create new strategic partnerships as needed to support the accelerated introduction of CAB LA for PrEP and pathways for future HIV prevention options

ViiV deeply respects and supports the role that community stakeholders have in driving the access agenda. We intend to work closely with community stakeholders to ensure that the diverse issues and needs of community stakeholders are reflected and adequately represented in our work. We will primarily focus on strengthening existing partnerships at global, regional, and national levels that represent the interests of people who can benefit from CAB LA for PrEP, and where needed will co-create new partnerships with community stakeholders. These partnerships will be the platforms through which we will be able to effectively achieve the first two objectives of the strategy. Importantly, these partnerships will be community-led, placing community stakeholders, communities, and the potential users of CAB LA for PrEP as leaders and conveners of stakeholder engagement. Our long-term goal will be to ensure that these partnerships can be sustained over time, to support the introduction of future HIV prevention options.

Figure 3 outlines the diversity of ViiV Stakeholders supporting our common goal for access. Our **focus** will centre on existing regional community stakeholder groups, structures and partners that can cascade to the country and community levels. We will also work closely with global stakeholders to align and amplify messages and collaborate with structures in their networks where possible.

Figure 3: Circle of ViiV Community Stakeholders



Meaningful and sustainable partnerships will help us understand the roles of community stakeholders and ensure that research and interventions meet the needs of diverse communities most affected by HIV. The aim will be to be as inclusive as possible, while still targeting efforts to reach communities and populations that are at highest risk for HIV without unintentionally stigmatising them.

While this **list is not exhaustive**, it is meant to provide a summary overview of some of the key community stakeholder structures that ViiV currently partners with to execute our L&MIC access strategy (see Table 3). We will **expand this list** and create additional partnerships as necessary to support our community stakeholder engagement goals.

Table 3: Illustrative list of existing ViiV community stakeholder partnerships

Category	Organisation	Purpose
Global	AVAC	AVAC's mission is to accelerate the ethical development of effective HIV prevention options and ensure access to those options for everyone who needs them as part of comprehensive and integrated path to global health equity.
	HIV Prevention Trials Network Community Working Group (HPTN CWG)	The CWG is responsible for ensuring that the principles of community involvement are the foundation of all community engagement activities at each site and for facilitating community participation throughout the research process.
	Key Population Advisory Group on HIV Prevention (hosted by GBGMC & GATE, with support from AVAC)	A standing group for the purpose of offering recommendations, input, skills, and knowledge in support of a comprehensive HIV prevention tools for key populations across the globe.
	Coalition to Accelerate and Support Prevention Research (CASPR)	A set of partnerships and activities focused on accelerating biomedical HIV prevention research, toward the goal of HIV epidemic control.
	International Treatment Preparedness Coalition World Community Accountability Board (CAB) (ITPC)	A global network of people living with HIV, community activists and their supporters working to achieve universal access to HIV treatment and other life-saving medicine through education, monitoring and advocacy.
	MPACT Global Action for Gay Men's Health and Rights	Advocate for equitable access to effective HIV prevention, care, treatment, and support services for gay men and bisexual men, including those living with HIV, while promoting their health and human rights worldwide.
Regional ⁶	African Women's Community Prevention Accountability Board	Serve as an ongoing, independent mechanism for stakeholder engagement on prevention, consisting of key national and regional advocates and civil society representatives.
	AfroCAB	AfroCAB is a network for community HIV treatment (and prevention) advocates across Africa.
	MSM and transgender women's CAB (Southeast Asia)	The community advisory board is in the process of being set up, and its purpose is still being defined.
	APCOM	Working to improve the health and rights of gay men and other men who have sex with men and sexual orientation, gender identity, gender expression and sex characteristics. (SOGIESC) diverse people across Asia and the Pacific.
	European AIDS Treatment Group (EATG)	A patient-led NGO that advocates for the rights and interests of people living with or affected by HIV/ AIDS and related co-infections within the WHO Europe region.
	AIDS Action Europe (AAE)	Brings together civil society to work towards a more effective response to the HIV epidemic in Europe and Central Asia.

⁶ In addition to other organizations, regional community stakeholder organizations representing Latin America and the Caribbean are being identified and will be added to this list

Timely, regular, and transparent communication is key to developing and maintaining trust with community stakeholders and is a strong foundation of the engagement strategy. Our communication approach will provide opportunity for interaction and engagement throughout the product introduction process and beyond. Communication channels include but are not limited to the list below (see Table 4).

Table 4: Illustrative communication channels/platforms to facilitate stakeholder engagement

Communication Channel/Platform	Purpose	Group	Frequency
Stakeholder Engagement Calls	<ul style="list-style-type: none"> / Address issues, co-create tools, and implement ongoing work with specific structures and organisations (e.g., CABs, AVAC, HPTN etc.) 	<ul style="list-style-type: none"> / Stakeholder Advisory Groups 	<ul style="list-style-type: none"> / As agreed with relevant group
	<ul style="list-style-type: none"> / Calls to update and engage with stakeholders on specific issues 	<ul style="list-style-type: none"> / National, regional, and global stakeholders 	<ul style="list-style-type: none"> / As required
Quarterly Updates (electronic)	<ul style="list-style-type: none"> / Share updated progress with and obtain input from community stakeholders on progress related to the Product Access Pathway 	<ul style="list-style-type: none"> / Stakeholder Advisory Groups 	<ul style="list-style-type: none"> / Quarterly
	<ul style="list-style-type: none"> / External facing dashboard with KPIs of strategies 	<ul style="list-style-type: none"> / National, regional and global stakeholders 	<ul style="list-style-type: none"> / As required
Education workshops	<ul style="list-style-type: none"> / Provide education on, and engage in iterative dialogue on issues related to product introduction and access 	<ul style="list-style-type: none"> / Stakeholder Advisory Groups 	<ul style="list-style-type: none"> / As agreed with relevant group/s
Webinars	<ul style="list-style-type: none"> / Provide listen to and provide relevant updates and/or information on a particular issue or topic 	<ul style="list-style-type: none"> / Stakeholder Advisory Groups / National, regional and global stakeholders 	<ul style="list-style-type: none"> / As required
Conferences and workshops	<ul style="list-style-type: none"> / Specific sessions or topics to be covered through discussion related to product introduction and access and/or community engagement 	<ul style="list-style-type: none"> / Stakeholder Advisory Groups / National, regional and global stakeholders 	<ul style="list-style-type: none"> / As scheduled
Engaged Social Media	<ul style="list-style-type: none"> / Continuous, responsive ongoing engagement to support all elements of the strategy 	<ul style="list-style-type: none"> / All 	<ul style="list-style-type: none"> / Continuous

Given our limited footprint on the ground in all the L&MIC countries where CAB LA for PrEP will be made available, we intend to prioritise engagement with regional structures. We believe these regional partners will be best placed to cascade information and communication to ViiV, and to both the global and national levels, where information will flow quickly and widely to reach all types of community stakeholders. While we will not be able to engage with every type of stakeholder at every level, we are confident that our cascade approach will allow us to share effectively and critically, to receive timely feedback from other stakeholders we are not engaging directly.

Objective 3 Success Indicators:

- / 90% of community stakeholder partners surveyed reporting:
 - Strong, meaningful, mutually respectful, and sustainable engagement and partnership with ViiV or with a regional stakeholder mechanism/partnership that is engaging with ViiV
 - Being reached via appropriate and timely communication channels

4. Accountability, Monitoring & Evaluation

Accountability is a key principle on which the community engagement strategy is developed and implemented. We see accountability as a two-way process whereby ViiV and our community stakeholders commit to ensuring that:

- / Relationships are built on mutual trust and respect

- / Communication and information sharing will be regular, transparent, and participatory
- / Feedback and input will be timely and constructive

We will regularly monitor and evaluate our progress against our success indicators, and solicit feedback through community stakeholders by:

- / **Surveying our partners' level of satisfaction** with ViiV's engagement and opportunities for ongoing dialogue and conversation on an annual basis (specific success indicators are outlined under Objectives 1, 2 and 3 in Section 3 above)
- / Regularly soliciting **feedback on discrete opportunities** for training, ongoing dialogue and conversation, collaborative planning, co-creation of tools, or information-sharing activities, including how community stakeholders have been able to use the knowledge and tools we have co-created towards their advocacy efforts (specific indicator is included under Objective 2 in Section 3 above)
- / Conducting an annual evaluation of the **community stakeholder engagement strategy** exploring:
 - How community stakeholder engagement has influenced and impacted the implementation and achievement of our access plan
 - How well community stakeholders have been able to pursue their advocacy objectives in policy and practice change, amplifying messages, etc.

Specific cross-cutting indicators in relation to measuring overarching impact of the strategy are outlined below.

Cross-Cutting Access Success Indicators:

- / # of L&MIC's with CAB LA for PrEP registration ongoing and/or registrations completed
- / # of implementation science studies in L&MIC's approved and/or completed
- / # of enrolments/initiations of CAB LA for PrEP in L&MIC's (disaggregated by country)
- / Pace of product roll-out of CAB LA for PrEP (disaggregated by countries)

5. Illustrative Workplan

Table 5: ViiV's Community Stakeholder Engagement Illustrative Workplan Plan for 2022-23

Objectives	Engagement Activities	Countries/Platforms	Timeline
Objective 1: <i>Actively create and harness opportunities for ongoing dialogue and conversation with communities and the stakeholders that represent them to understand their experiences and respond, ensuring that these interactions shape our access strategy</i>	/ Ongoing opportunities for dialogue/conversations	/ 084 countries: Botswana, eSwatini, Kenya, Malawi, South Africa, Uganda and Zimbabwe	Q3-Q4 2022
	/ Regular communication calls set up with community stakeholder structures	/ 083 countries: Argentina, Brazil, Peru, South Africa, Thailand, Vietnam and USA	Q3- Q4 2022
	/ Participatory process with various stakeholders established and functioning	/ International AIDS Conference—AIDS 2022 in Montreal	Q3 2022
		/Adherence 2022 Conference in Washington DC	Q3 2023
		/ International AIDS Conference—AIDS 2023 in Brisbane	Q4 2022
		/ Virtual	Q3-Q4 2022

<p>Objective 2: <i>Collaborate with community stakeholders to identify and co-create tools and provide all stakeholders, including ViiV, with the information needed to collectively fulfil our respective roles effectively and contribute to increased access to HIV prevention options</i></p>	<ul style="list-style-type: none"> / At least 3 opportunities for co-creation and information sharing on priority topics requested by community stakeholders (subject to the licensing status of CAB LA for PrEP in that country) 	<ul style="list-style-type: none"> / 084 & 083 countries / Virtual 	
<p>Objective 3: <i>Strengthen and expand sustainable relationships via existing community stakeholder groups and co-create new strategic partnerships as needed to support the accelerated introduction of CAB LA for PrEP and pathways for future HIV prevention options</i></p>	<ul style="list-style-type: none"> / Mapping of community stakeholder groups/ partners / Key community stakeholder groups/partners prioritized for active engagement / African Women's HIV Prevention CAB set up and functional / Virtual consultation calls with MSM and transgender CAB / African Women's HIV Prevention CAB meeting / MSM and transgender women CAB meeting / Structured input with community stakeholders based on need and engagement with broader CAB LA for PrEP team / Structured input with focal points at the priority community stakeholder groups/partners 	<ul style="list-style-type: none"> / 084 countries / Vietnam and Thailand / Other L&MIC's not included in 084 or 083 listing 	<ul style="list-style-type: none"> Q3 2022 Q3 2022 Q2 2022 Q3 2022 Q4 2022 Q4 2022 2023 2023

ANNEX 1: ACCESS PLAN

LONG-ACTING CABOTEGRAVIR FOR PREP

ViiV's Access Plan to guide the rollout of CAB LA for PrEP in L&MICs

The Access Plan below helps to map and understand the major activities ViiV is leading, catalysing, and collaborating on to achieve sustainable access to CAB LA for PrEP. This work builds on the BioPIC Adaptable Product Introduction Framework which was informed by the work of more than 80 organisations across 20 countries.⁷

Product & Clinical Development	Regulatory, Normative Guidance, Policy	Planning, Coordination & Financing	Supply Chain & Service Delivery	User Demand & Continued Use	Monitoring & Evaluation
ACCESS PLAN WORKSTREAMS					
Engagement with key stakeholders on product	Approval by stringent regulatory authority	Develop pricing strategy	Manufacturing strategy (including voluntary licensing strategy)	Demand generation (including broad awareness of PrEP and stigma & discrimination mitigation)	Impact monitoring and evaluation of product introduction activities
End-user research to inform product formulations	WHO pre-qualification	Demand forecasting and modelling	Country introduction plan development	Adherence information and support	Design and implement research to address emergent, specific implementation challenges
Completion of clinical trials (including support for OLEs and adolescents)	L&MIC country registrations	Inclusion in national HIV operation planning	Support provider training (including provider specific initiatives, materials & approaches)	Ongoing HIV/other testing	Surveillance data insight gathering
	Inclusion in WHO, global and country HIV prevention guidance and health agendas	Inclusion in government and donor budgets and quantification	Map out procurement strategy		Key: ViiV Lead/Own Catalyse/Collaborate Support Monitor
		Alignment to global and regional coordinating mechanisms	Delivery channel expansion and service delivery optimisation		

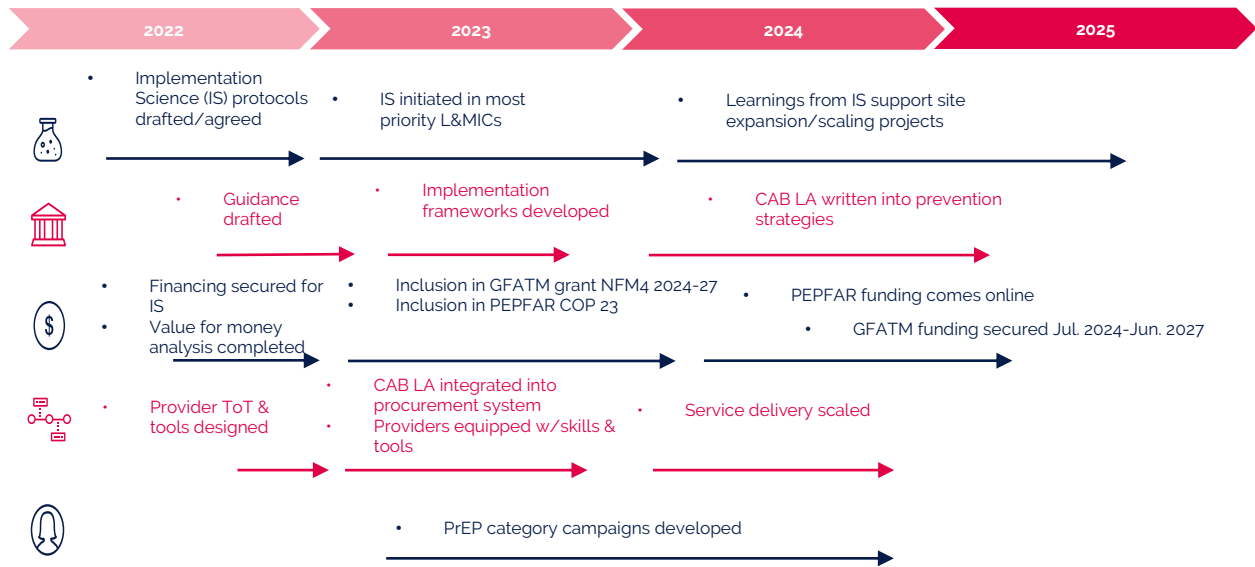
Partnerships, Advocacy & Community Engagement						
CROSSCUTTING WORKSTREAM						
<ul style="list-style-type: none"> Outreach and engagement with civil society and the user community, national programmes, normative bodies, implementers, donors and stakeholders Develop partnership models to support and lead efforts in L&MICs 						
<i>Global Multilaterals</i>	<i>National Programmes & Governments</i>	<i>Professional Associations</i>	<i>Civil Society & User Advocacy groups</i>	<i>Implementers</i>	<i>Donors</i>	<i>Key Opinion Leaders</i>

Abbreviations – AIDS: Acquired immunodeficiency syndrome; BioPIC: Biomedical Prevention Implementation Collaborative; BMGF: Bill and Melinda Gates Foundation; GFATM: The Global Fund to Fight AIDS, Tuberculosis and Malaria; GNI: Gross National Income; HIV: Human immunodeficiency virus; HPTN: HIV Prevention Trials Network; L&MIC: Low-and middle-income countries; M&E: Monitoring and Evaluation; MOSAIC: Maximizing Options to Advance Informed Choice for HIV Prevention; MPP: Medical Patent Pool; MSM: Men who have sex with men; OLE: Open-label extension; PEPFAR: The U.S. President’s Emergency Plan for AIDS Relief; PrEP: Pre-exposure prophylaxis; USAID: United States Agency for International Development; WHO: World Health Organization

⁷ The BioPIC Adaptable Product Introduction Framework can be found here: https://www.avac.org/sites/default/files/resource-files/BioPIC_Adaptable_Framework_March2021.pdf

Timelines and Critical Milestones for Product Introduction of CAB LA for PrEP in L&MIC's

The timelines and critical milestones for product introduction outlined below are broadly representative of what is expected across L&MIC's but were developed based on landscaping efforts in a selection of HPTN L&MIC countries.



ViiV Commitments

ViiV has made several commitments around access to CAB LA for PrEP, as outlined below (as of July 2022):

Negotiating a voluntary licence with the Medicines Patent Pool. Five months after the first regulatory approval of CAB LA for PrEP in the world, by the US Food and Drug Administration (US FDA), we announced that we were negotiating a voluntary license with the Medicines Patent Pool for patent rights relating to CAB LA for PrEP.⁸

Constructive engagement with generic manufacturers. Once the voluntary license with MPP is agreed and generic manufacturers are selected, we will engage with those generic manufacturers with the aim of offering them appropriate support to bring forward viable generic versions of CAB LA for PrEP at greater scale and at hopefully lower cost than ViiV can produce in our factories (which are based in the UK). Until that day, we are committed to supplying the medicine at a non-profit price in low-income, least developed and all sub-Saharan countries for use in public programmes.

Collaborating around implementation. We believe that the collaboration of multiple partners could be instrumental in enabling broader access to CAB LA for PrEP in L&MICs. We are supporting requests from countries and international donors for implementation studies on CAB LA for PrEP to inform public health guidelines and policies and ultimately support wider-scale adoption and roll-out of CAB LA for PrEP. We have already committed to donate product to several studies and are in discussions with several other partners on additional projects.

Continued access to CAB LA for PrEP for trial participants. ViiV continues to support the provision of CAB LA for PrEP for participants involved in the HPTN-083 & 084 studies, regardless of which medicine they received during the study, in the form of open-label extensions (OLEs). These OLEs will continue for a maximum of 96 weeks, after which ViiV will continue to provide supply of CAB LA for PrEP for study participants who choose to continue on this therapy and still get benefit from doing so if in-country approvals or access are delayed. The mechanisms for this continued supply will depend on a variety of factors, including country specific laws, supply routes, and infrastructure.

Non-profit price. Consistent with our [Access to Medicines](#) policy and as we have done with all of our medicines, we will offer a non-profit price for CAB LA for PrEP in public and international donor agency programmes in all low-income, least-developed and Sub-Saharan African countries.⁹

Registrations. ViiV makes publicly available our registration submission and approvals for CAB LA for PrEP.¹⁰

⁸ ViiV's commitment to voluntary licensing with the MPP can be found here: <https://viiVhealthcare.com/hiv-news-and-media/news/press-releases/2022/may/viiV-healthcare-commits-to-grant-voluntary-licence-for-patents/>

⁹ ViiV's Access to Medicines Policy can be found here: https://assets.gskstatic.com/viiV/VHC/GB/pdf_files/ViiV_Access-to-medicine-policy_FINAL_25June2020.pdf

¹⁰ Updates on worldwide registrations of Cab La for PrEP can be found here: <https://viiVhealthcare.com/ending-hiv/viiV-improve-access-to-hiv-medicines/>