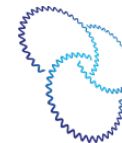


# Spotlight on New PrEP Tools and Data

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From R&D to Access

28 November 2023



medicines  
patent  
pool



# Welcome!

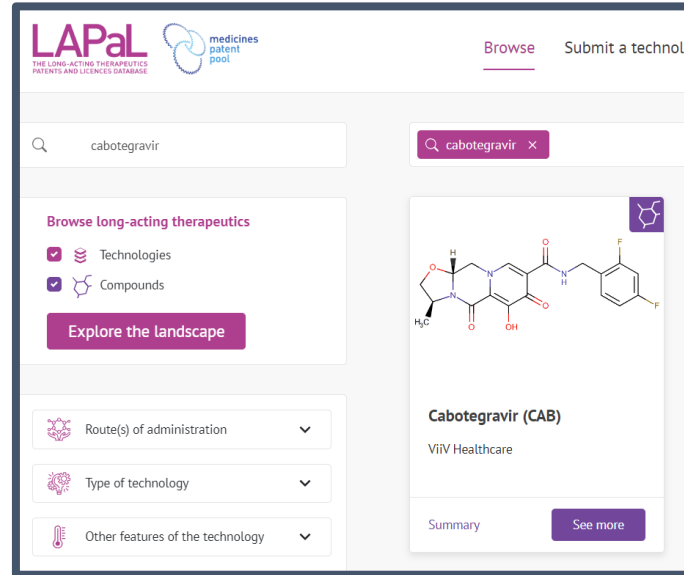


PrEPWatch An initiative of AVAC

PRODUCTS & PARTNERS STORIES

EXPLORE DATA AND INFORMATION ON PREP ACROSS THE GLOBE

LATEST NEWS: US Task Force recommends that healthcare professionals prescribe PrEP to people at increased risk for



LAPaL THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE medicines patent pool

Browse Submit a technology

cabotegravir

cabotegravir

Browse long-acting therapeutics

- Technologies
- Compounds

Explore the landscape

Route(s) of administration

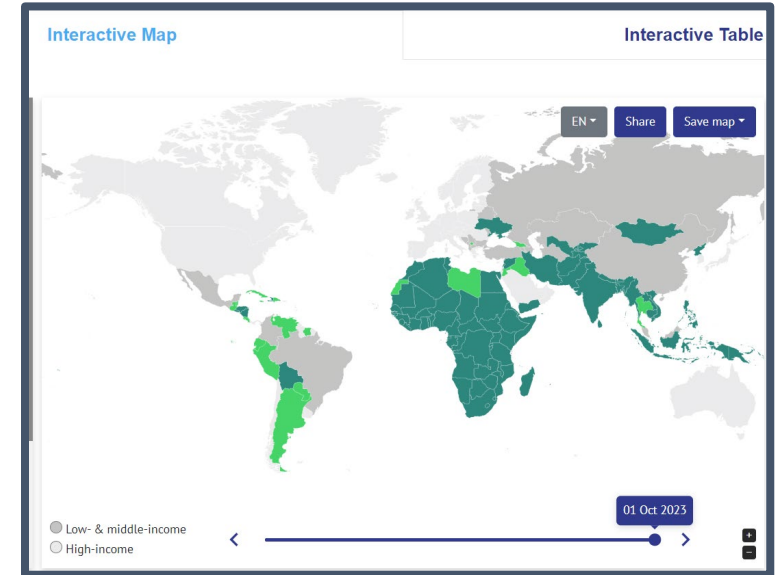
Type of technology

Other features of the technology

CN1C=NC2=C1C(=O)N(C(=O)Nc3ccc(F)c(F)c3)C2=O

Cabotegravir (CAB)  
Viiv Healthcare

Summary See more



Interactive Map Interactive Table

EN Share Save map

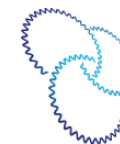
01 Oct 2023

Low- & middle-income High-income

PrEPWatch

LAPaL  
THE LONG-ACTING THERAPEUTICS  
PATENTS AND LICENCES DATABASE

ACCESS TO MEDICINES  
TRACKER



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patent  
pool



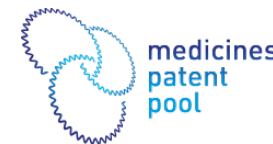
# Agenda

<b>Welcome</b>	Mitchell Warren, AVAC Cherise Scott, Unitaid
<b>The Current PrEP Landscape</b>	Catherine Verde Hashim, AVAC Sébastien Morin, MPP
<b>PrEPWatch</b>	Janki Tailor, AVAC Catherine Verde Hashim, AVAC
<b>The Long-Acting Therapeutics Patents and Licenses Database</b>	Lobna Gaayeb, MPP
<b>Access to Medicines Tracker</b>	Sébastien Morin, MPP
<b>When do I use each tool?</b>	Janki Tailor and Catherine Verde Hashim, AVAC Lobna Gaayeb, MPP
<b>Interactive Quiz</b>	Wawira Nyagah, AVAC Lobna Gaayeb, MPP
<b>Q&amp;A</b>	Anne-Isabelle Cameron, Unitaid



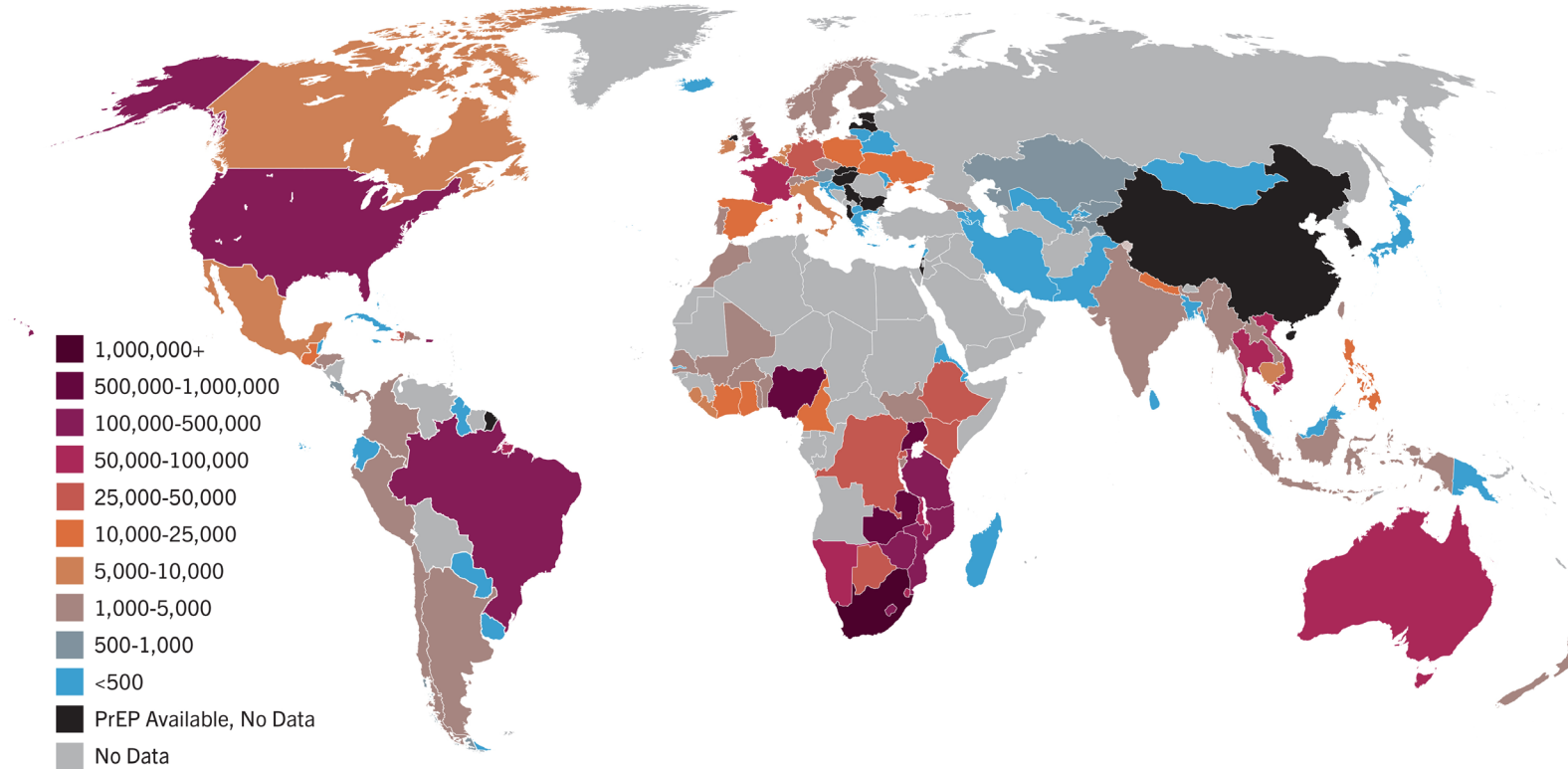
# The Current PrEP Landscape

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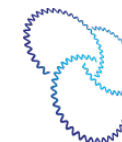
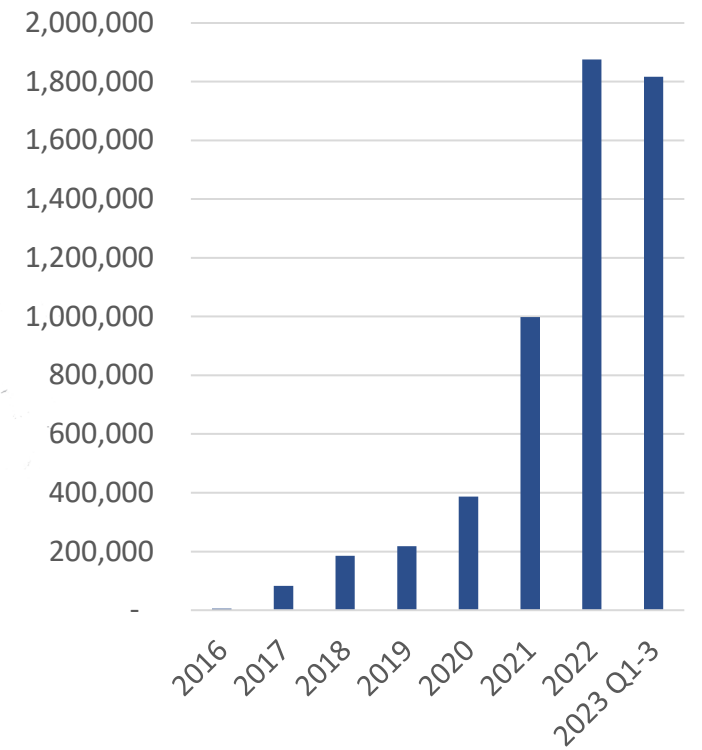


# The PrEP Landscape - Initiations



**5.7m** initiations to Sept 2023

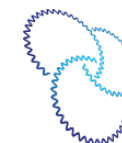
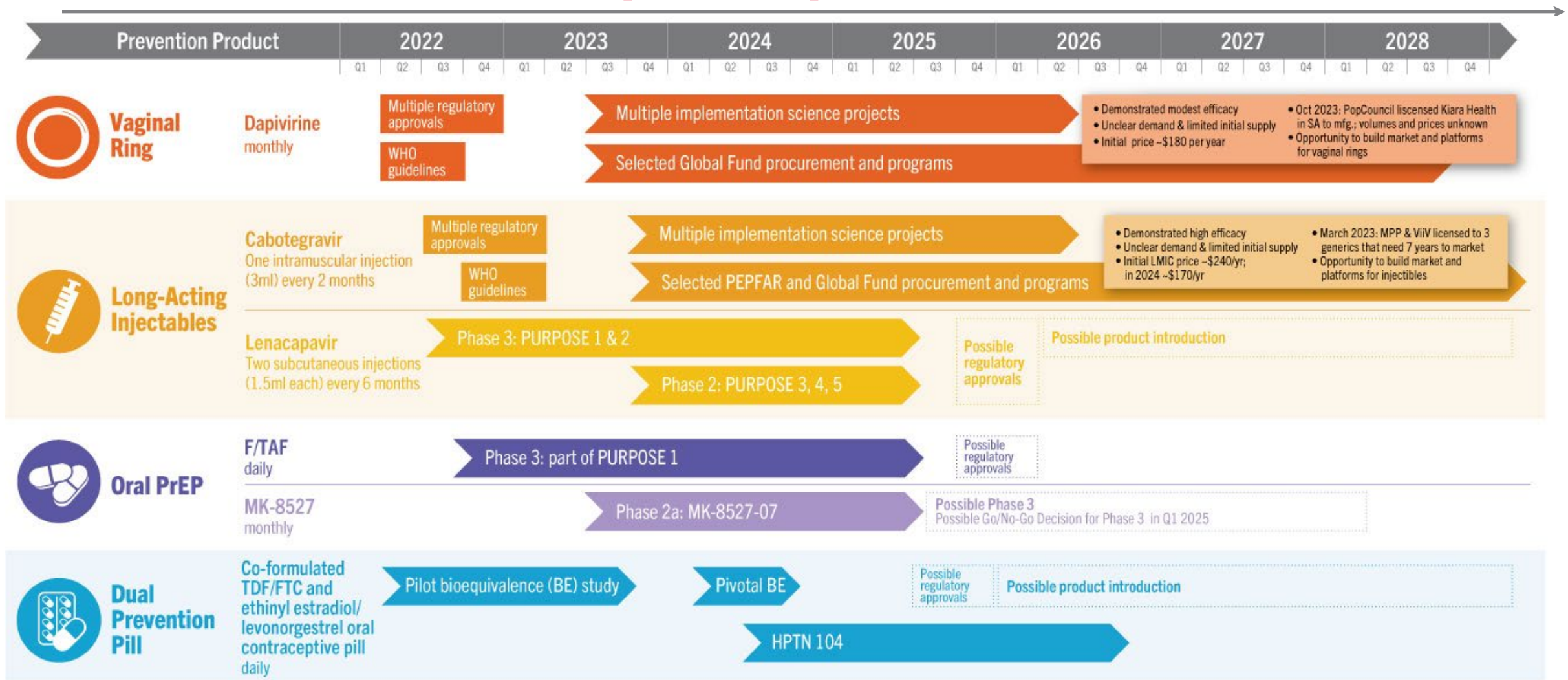
### PrEP Initiations Over Time



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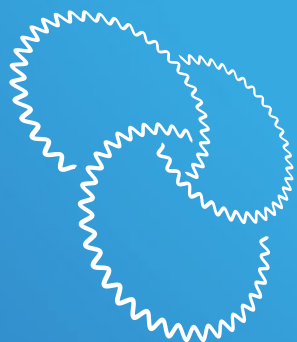
# The PrEP Landscape - Pipeline



medicines patent pool







medicines  
patent  
pool

# Access to generic CAB-LA for PrEP: Update on licensing and outlook for broad access

**Webinar – *Spotlight on new PrEP tools and data: From R&D to access***

Convened by AVAC, MPP, and Unitaid on 28 November 2023

Presented by Sébastien Morin (Medicines Patent Pool)

MEDICINESPATENTPOOL.ORG

Spotlight on New PrEP Tools  
and Data: **FROM R&D TO ACCESS**



**TUESDAY, NOVEMBER 28**

**8:30 TO 10:00 AM ET / 14:30 TO 16:00 PM CET**

Join us to learn about three important online PrEP resources and to understand how they can support and enhance your work.

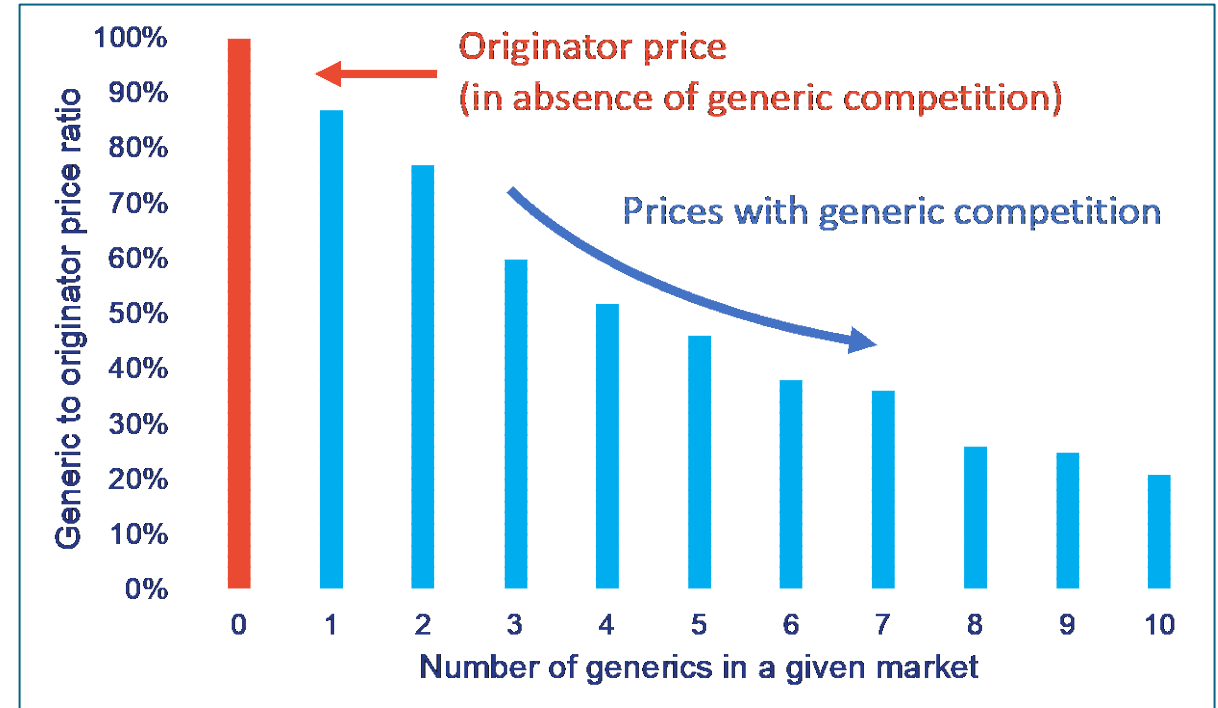
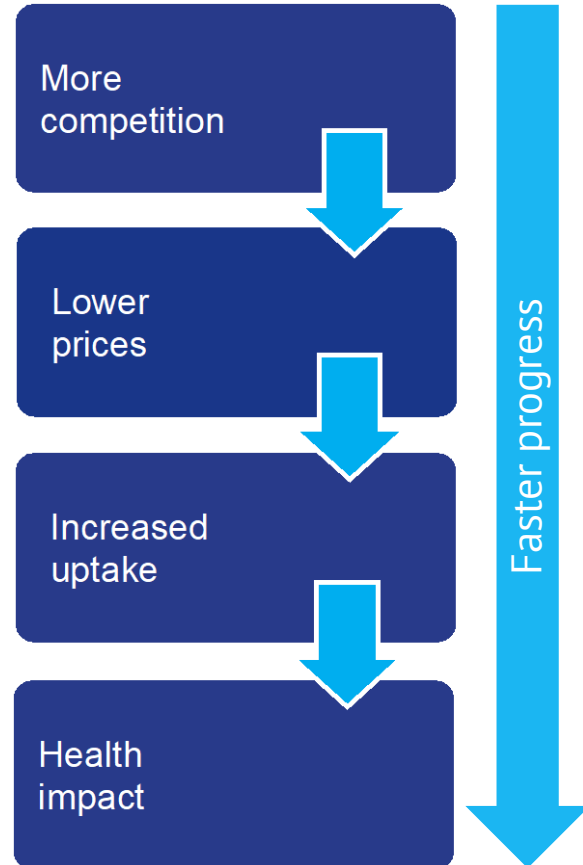
Register at [tinyurl.com/PrEPTools](https://tinyurl.com/PrEPTools)



# Accelerated access to generics and price reductions

## Overview of the voluntary licensing model

- Driving prices down through generic competition
- Accelerating timelines for generic product availability



Generic competition induced pricing benchmarks: Dave et al. (2017) *NEJM*

# Access to MPP-licensed medicines

We will present some of these tools today...

## Patent and licence information tools

- To support procurement agencies, national programmes, and treatment advocates
- Fully public quarterly-updated country-by-country information

**MedsPaL**  
THE MEDICINES PATENTS AND LICENCES DATABASE

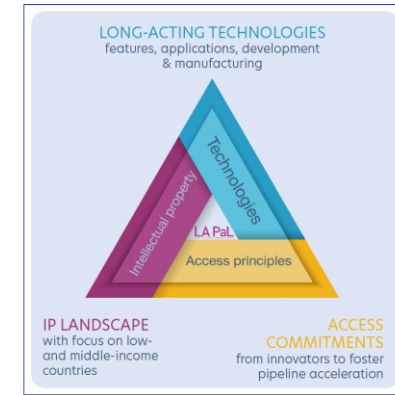
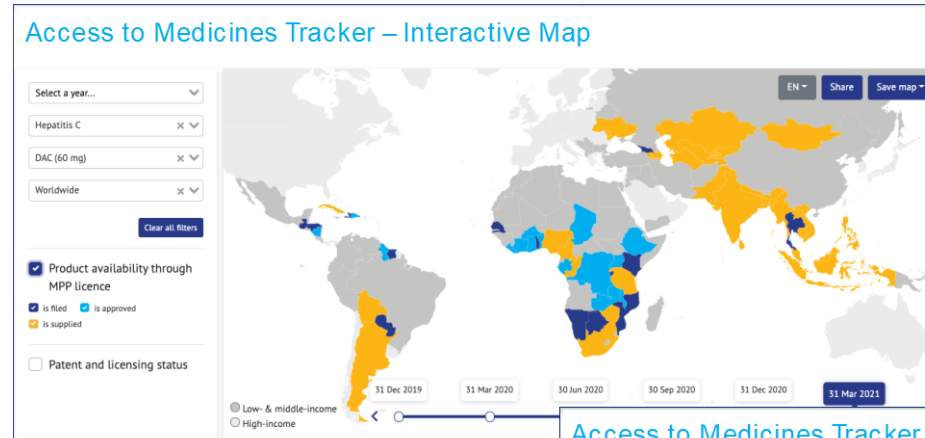
[www.medspal.org](http://www.medspal.org)

**VaxPaL**  
COVID-19 VACCINES PATENT LANDSCAPE

[www.vaxpal.org](http://www.vaxpal.org)

**LAPaL**  
THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

<https://lapal.medicinespatentpool.org>



## Access to Medicines Tracker – Interactive Table

Key: ■ HIV ■ Hepatitis C ■ Tuberculosis

Filter table rows by product Filter

PRODUCTS	COMPANIES DEVELOPING THE PRODUCT	PENDING APPROVAL			READY TO SUPPLY			COUNTRIES WHERE		
		WHO-PQ*	USFDA**	WHO-PQ* APPROVED	USFDA** APPROVED	ERP*** APPROVED	PRODUCT IS FILED	PRODUCT IS APPROVED	PRODUCT IS SUPPLIED	
DTG 50mg	12			Cipla DEBATE	JD ALPHAREDO Cipla		Benin, Bolivia (Plurinational)	Anguilla, Antigua and Barbuda.	Alghanistan, Albania, Anolis.	

More at: <https://medicinespatentpool.org/what-we-do/medspal>  
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

# To learn more about the work of MPP...

## MPP strategy for 2023-2025



*Greater access to medicines and health technologies for those who need them, 2023*  
<https://medicinespatentpool.org/what-we-do/strategy>

## Peer-reviewed publications

Articles

**The economic and public health impact of intellectual property licensing of medicines for low-income and middle-income countries: a modelling study**

Sébastien Morin, Hannah Barron Moak, Oliver Bubb-Hunfryes, Christian von Drehle, Jeffrey V. Lazarus, Esteban Burrone



*The Lancet Public Health, 2022*  
[https://doi.org/10.1016/S2468-2667\(21\)00202-4](https://doi.org/10.1016/S2468-2667(21)00202-4)

Review


**Expanding access to biotherapeutics in low-income and middle-income countries through public health non-exclusive voluntary intellectual property licensing: considerations, requirements, and opportunities**

Sébastien Morin\*, Giulia Segafredo\*, Manuele Piccolis\*, Aditi Das, Meghmala Das, Nicola Loffredi, Amina Larbi, Kim Mwamelo, Elena Villanueva, Sandra Nobre, Esteban Burrone



*The Lancet Global Health, 2023*  
[https://doi.org/10.1016/S2214-109X\(22\)00460-0](https://doi.org/10.1016/S2214-109X(22)00460-0)

Gaayeb L et al. Journal of the International AIDS Society 2023, 26(S2):e26092  
<http://onlinelibrary.wiley.com/doi/10.1002/jia2.26092> | <https://doi.org/10.1002/jia2.26092>



COMMENTARY

**Voluntary licensing of long-acting HIV prevention and treatment regimens: using a proven collaboration- and competition-based mechanism to rapidly expand at-scale, sustainable, quality-assured and affordable supplies in LMICs**

Lobna Gaayeb<sup>1</sup>, Aditi Das<sup>2</sup>, Ike James<sup>1</sup>, Rajesh Murthy<sup>2</sup>, Sandra Nobre<sup>1</sup>, Esteban Burrone<sup>1</sup> and Sébastien Morin<sup>1,4</sup>

<sup>4</sup>Corresponding author: Sébastien Morin, Rue de Varembe 7, CH-1202 Geneva, Switzerland. ([smorin@mppf.ch](mailto:smorin@mppf.ch))

*Journal of the International AIDS Society, 2023*  
<https://doi.org/10.1002/jia2.26092>  
<https://www.youtube.com/watch?v=h57gXs4aQtg>

*BMJ Global Health, 2023*  
<http://dx.doi.org/10.1136/bmjgh-2023-012964>



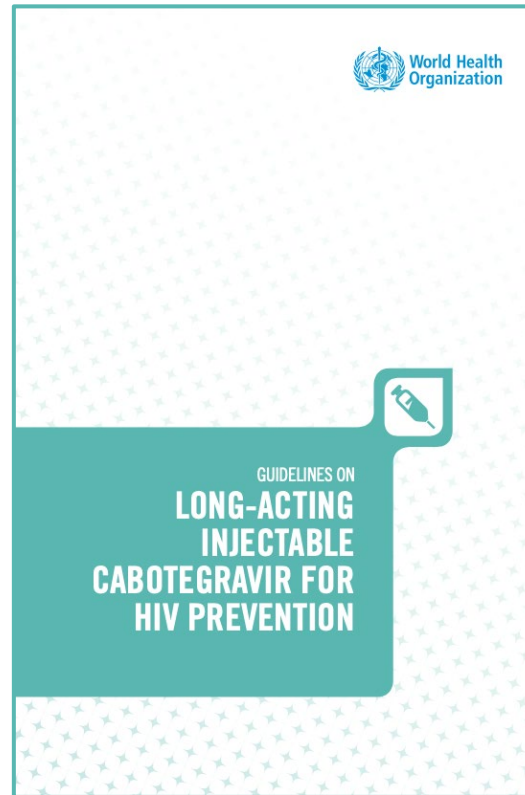


## CAB-LA as one more HIV prevention option

*“CAB-LA should be delivered as an additional choice alongside other PrEP options, including oral PrEP and the DVR, as part of a comprehensive HIV prevention approach.”*

CAB-LA for PrEP is

- ✓ Recommended by WHO
- ✓ Approved in several countries
- ✓ Effective, well tolerated, safe
- ✓ Taken as an injection every 2 months
- ✓ **Patented until 2031 but licensed to MPP – thanks in large parts to community advocacy efforts!**



### Prevention

- Oral PrEP (TDF/XTC)

*Patents expired*

- **CAB-LA**

*MPP licence*

- Dapivirine vaginal ring

*Population Council*

## MPP-ViiV licence for CAB-LA for PrEP

**The licence covers the patents on CAB-LA for PrEP**, enabling the development and supply of generic versions

The market for CAB-LA for PrEP is uncertain and investments from generic manufacturers might be significant; hence the decision to have **a maximum of three licensees** (this could be revised at a later stage)

Technical and financial support to manufacturers is being explored, such as **technology transfer from ViiV to licensees**

**Development and approval of generic versions will likely take 3-4 years from now**; meanwhile, the only source of CAB-LA will be the originator product from ViiV Healthcare

+ **Quality**: WHO PQ or SRA approval required

+ **Transparency**: the licence is published in full on the MPP website

### ViiV Healthcare and the Medicines Patent Pool sign new voluntary licensing agreement to expand access to innovative long-acting HIV prevention medicine

28 July 2022



### Medicines Patent Pool signs sublicences with Aurobindo, Cipla and Viatris to produce generic versions of ViiV Healthcare's innovative long-acting HIV prevention medicine

30 March 2023

- *Licences should enable potentially millions of people living in areas most impacted by HIV to access this innovative prevention medicine through low-cost generic manufacturers*
- *Announcement includes potential for large scale manufacturing on the continent of Africa*





## Partnering with generics

### Sub-licensee selection process

- MPP invites qualified product developers to **apply for licences** to manufacture and sell licensed medicines in LMICs; this is done **through an Expression of Interest (EOI) process**
- The assessment is rigorous and objective (with **blinded review** for short-listing), and responses are graded using a standardised tool and top-scoring applicants are selected
- The number of licences granted is informed by demand forecasts and other information

*By granting multiple sublicences, MPP aims to support adequate supply and competitive pricing*

**For CAB-LA, there was also an onsite audit of short-listed candidate's manufacturing plant**

### Sub-licensee selection criteria

- **Capacity, capabilities and track-record** for manufacturing quality-assured medicines (including experience developing, manufacturing and/or marketing other products)
- **R&D, financials, and regulatory compliance** (including around required quality standards)
- **Specific plans** for the licensed product (regarding development, manufacturing, regulatory plan, distribution, and projected investments – viability of those plans, especially in case of projects requiring specific capital expenditure or investments)
- **Readiness with needed formulation technologies** (e.g., FDCs, paediatrics)
- **Past experience and performance as MPP licensee**

# MPP licence for CAB-LA for PrEP

## – Understanding the effective territory

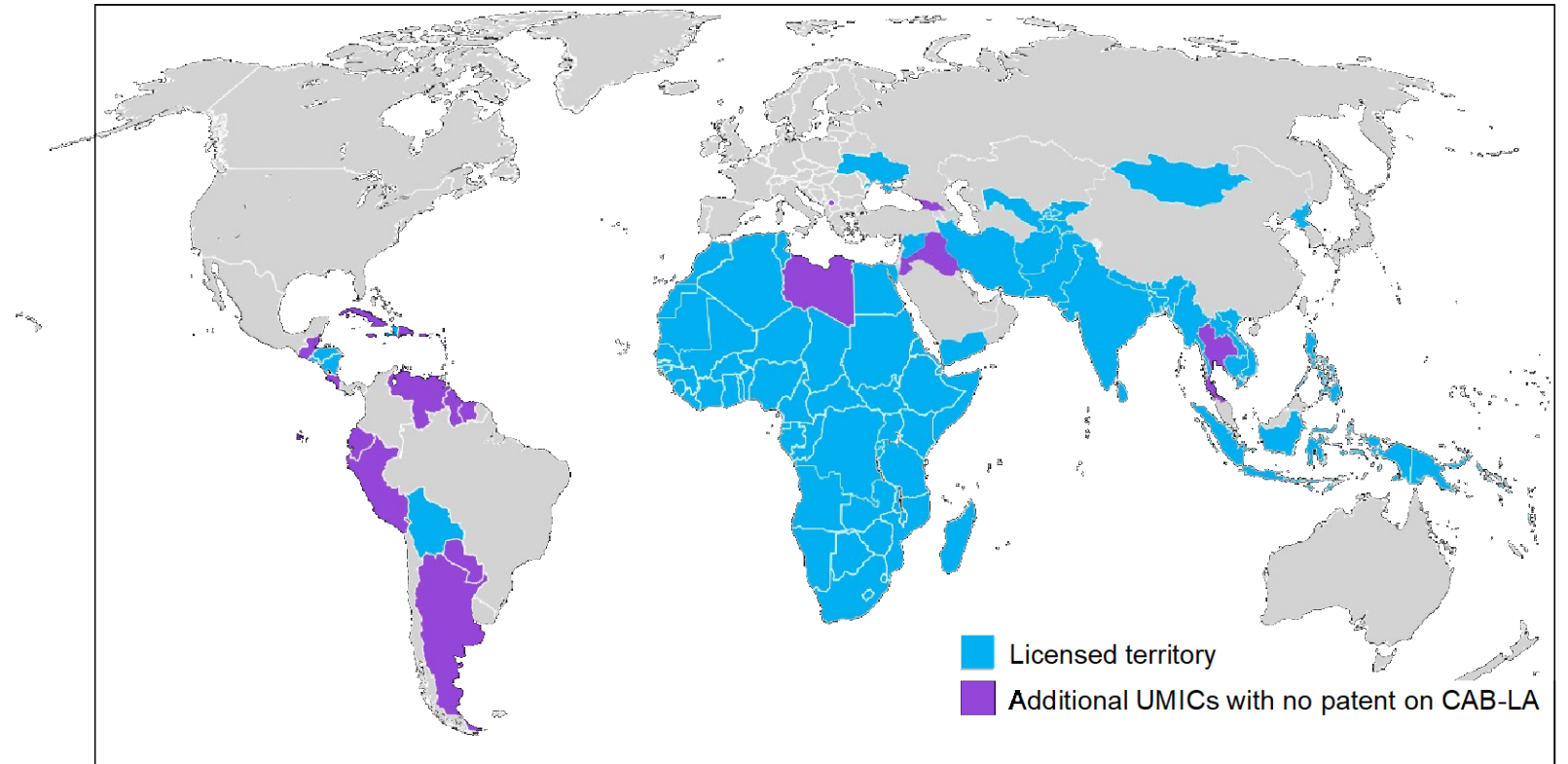
*The effective licence territory covers: all countries listed + countries without patents and where supply may be possible*

### Countries listed (90)

- All low-income countries
- All lower middle-income countries
- All sub-Saharan African countries
- All least-developed countries

### Countries without patents and where supply may be possible

- Based on data from MedsPaL ([www.medspal.org](http://www.medspal.org))



Source: Beatriz Grinsztejn, Long-acting PrEP implementation: Fostering access and equity, AIDS 2022

More at: <https://medicinespatentpool.org/licence-post/cabotegravir-long-acting-la-for-hiv-pre-exposure-prophylaxis-prep>  
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>

# MPP licence for CAB-LA for PrEP – Navigating the effective territory

CAB-LA has now been added to our interactive map!

## Interactive Map

2023 x v

HIV x v

CAB LAI x v

Worldwide x v

Clear all filters

Product availability through MPP licence

Patent and licensing status

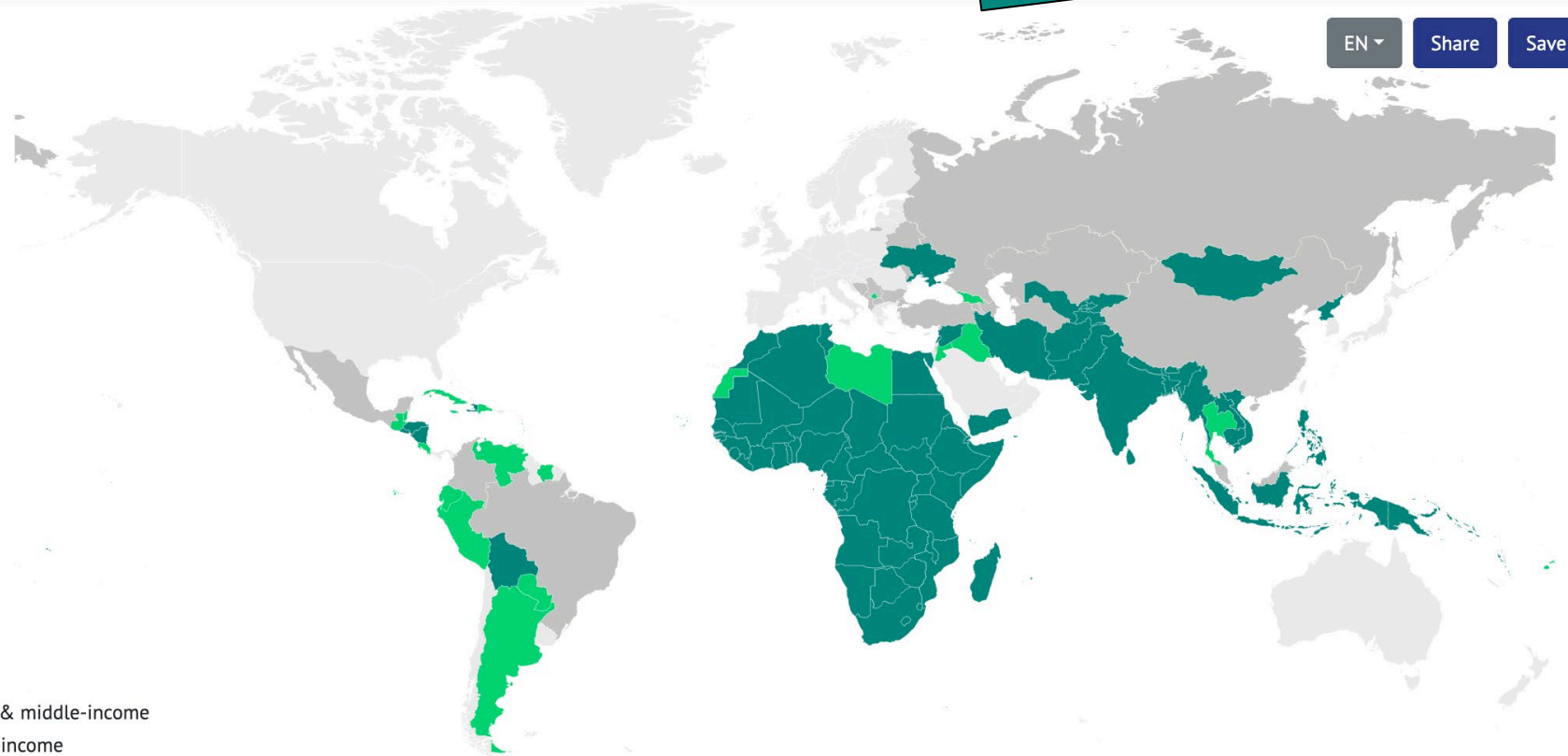
Included in MPP and other relevant licences

Outside of licences but no patents found (MPP sublicensees may be able to supply)

Outside of licences with compound patents

Other complex patent situations

Low- & middle-income  
 High-income



*MPP's interactive map focuses on low- and middle-income countries. Access in high-income countries is generally not included.*

# Closing message & ideas for future increased collaboration

Now is the time to **(1) continue expanding access to oral PrEP** and **(2) plan for the introduction of CAB-LA for PrEP** in anticipation of future availability of generic versions!



**We can share information about access to MPP-licensed medicines in your region or country and support you in many ways**

- Please tell us about your needs to increase generic competition for a given product
- Please notify us of stock-outs, quality issues, registration delays, or other challenges regarding MPP-licensed medicines

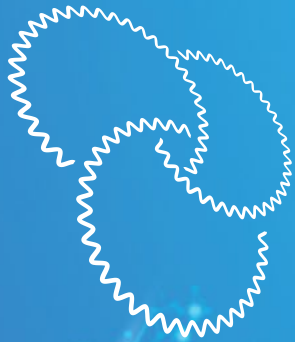
Do not hesitate to be in touch!

**Sébastien Morin, PhD**  
**Policy and Advocacy Manager**  
**Medicines Patent Pool**  
**Geneva, Switzerland**



[smorin@mppf.ch](mailto:smorin@mppf.ch)






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Thanks for your attention!

I will be happy to continue the discussion, including over emails ([smorin@mppf.ch](mailto:smorin@mppf.ch))



 Schweizerische Eidgenossenschaft  
Confédération suisse  
Confederazione Svizzera  
Confederaziun svizra

Swiss Agency for Development  
and Cooperation SDC

 **MINISTÈRE  
DE L'EUROPE  
ET DES AFFAIRES  
ÉTRANGÈRES**  
*Liberté  
Égalité  
Fraternité*



[MEDICINESPATENTPOOL.ORG](https://www.medicinespatentpool.org)



[YOUTUBE.COM/USER/MEDICINESPATENTPOOL](https://www.youtube.com/user/medicinespatentpool)



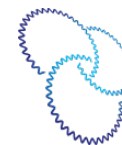
[WWW.LINKEDIN.COM/COMPANY/MEDICINES-PATENT-POOL/](https://www.linkedin.com/company/medicines-patent-pool/)



[YOUTUBE.COM/USER/MEDICINESPATENTPOOL](https://www.youtube.com/user/medicinespatentpool)

# Introducing PrEPWatch

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**Unitaid**  
SAVE LIVES FASTER



# Introducing PrEPWatch

## Country Data Resources



Global PrEP Use Landscape as of September 2023										PrEP Registration, Guidelines & Estimates											
Country	Year Initiated	Current Initiations	PrEP Reg. Initiations	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	PrEP Reg. Products	
Kenya	1	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	2021	2021	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	43	44	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	6302	6302	N/A	N/A	7	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	757	757	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	13	13	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	128	128	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kenya	206	206	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Raw Data

### Global PrEP Tracker

Use this dynamic tool to see global trends by geography, track factors such as use of different delivery models, and get key updates.

[Visit data.prepwatch.org](https://data.prepwatch.org)

### Global PrEP Tracker

AVAC has created this tool in order to highlight the full range of PrEP use across the globe. Through this tool, you can explore and understand the status of PrEP use in the USA and other countries. This tool provides a comprehensive database of all countries, and the status of PrEP use in each country. The tool is designed to be user-friendly and easy to use. This tool provides a comprehensive database of all countries, and the status of PrEP use in each country. The tool is designed to be user-friendly and easy to use.

### Explore the Data

This Excel document provides a sortable database with detailed information on the status of PrEP approval and delivery by product and by country.

[2023 Q2 Global PrEP Tracker Data](#)

### Snapshot: PrEP Initiations by Country

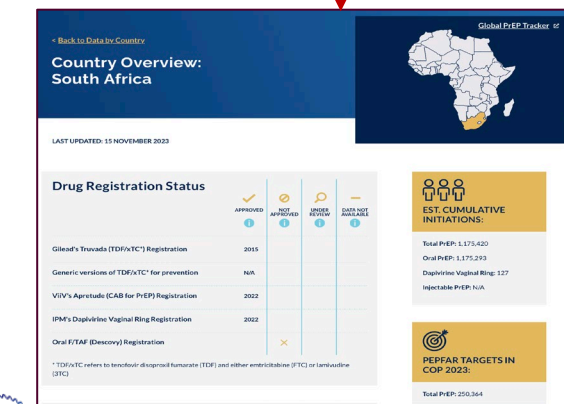
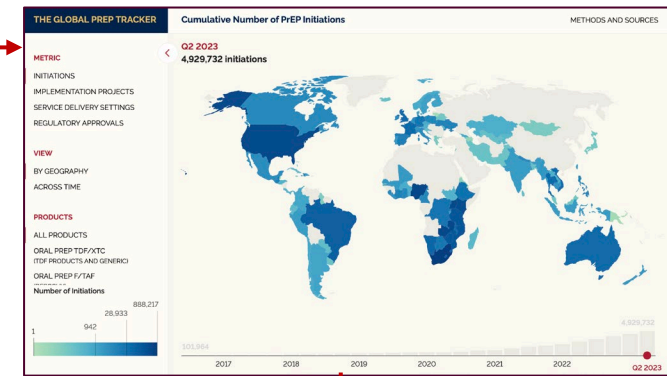
AVAC's quarterly surveys of ongoing oral PrEP demonstration and implementation projects, combined with data collected from manufacturers and government agencies inform this graphic on PrEP initiations around the globe.

[Visit AVAC.org to view this map](#)

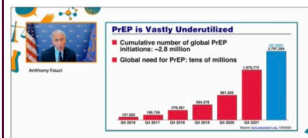
### Explore Publications

A library of publications and presentations featuring data from the PrEP Tracker.

[Click here for links to publications that are citing data from the PrEP Tracker.](#)



Global PrEP Tracker & Country Pages



# Introducing PrEPWatch

The Resource Library- 770+ Resources and Growing



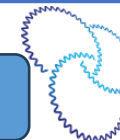
## Resource Library

The PrEPWatch Resource Database offers a wide range of material on the status of PrEP as an option for biomedical HIV prevention around the world. Search this database to find step-by-step guidance for rolling out PrEP, summaries of the research to date on safety, efficacy and implementation, tools to assist planning and roll out, country updates on PrEP policy and access, and lessons learned from those efforts.

- Tools for advocates
- Demand generation resources
- Costing guides
- M&E tools
- WHO guidelines
- National HIV strategies
- Published research
- Service delivery best practice
- *...and more*



Filter by topic, product, format, population, region, country, and/or language



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# Introducing PrEPWatch

## Delivering PrEP- Highlights from the Resource Library

PrEPWatch

An initiative of AVAC

PRODUCTS & PARTNERS

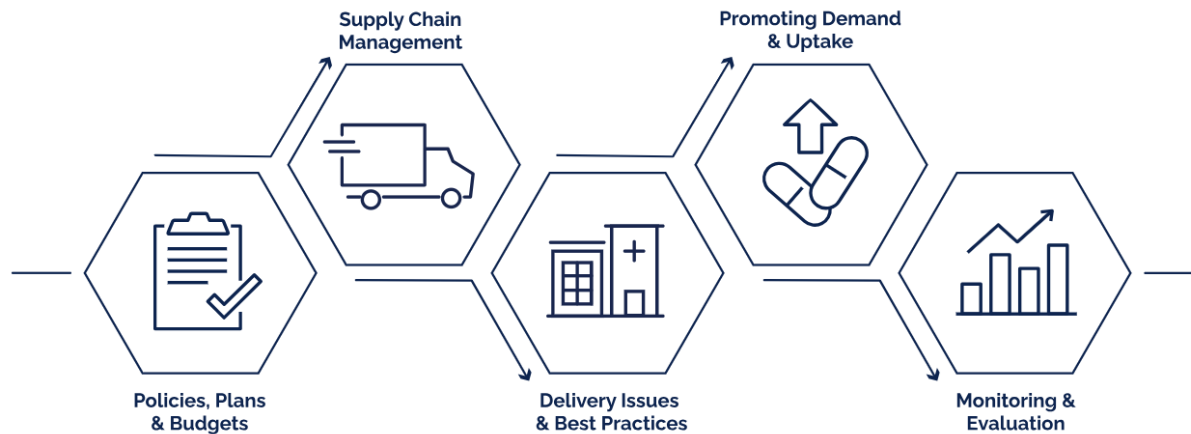
STORIES

EVENTS

COUNTRY DATA

DELIVERING PREP

RESOURCES



- The most important and widely-used resources, organised by stage of the rollout process
- Product-specific rollout toolkits:
  - Plan 4 Oral PrEP
  - Plan 4 Ring



# Introducing PrEPWatch

## Dashboards

**PrEPWatch** An initiative of **AVAC** PRODUCTS & PARTNERS STORIES EVENTS COUNTRY DATA DELIVERING PREP **RESOURCES** 🔍

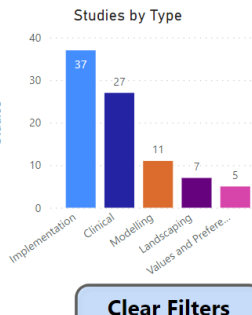
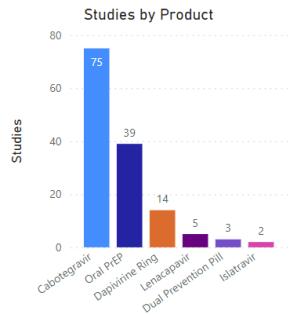
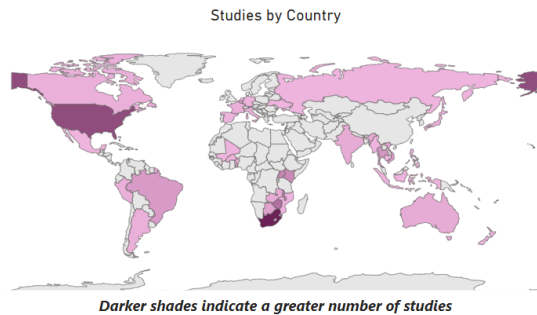
### Integrated Study Dashboard for New PrEP Options

This dashboard, produced under the [BioPIC](#) project, reflects all currently known activities relating to implementation research, modelling, clinical research, and landscaping for new late stage biomedical HIV PrEP options, including cabotegravir for PrEP and the dapivirine vaginal ring. To update or add any activities missing from the dashboard, or if you have questions on using the dashboard, please contact [Catherine Verde Hashin](#).

Click the buttons below to navigate to the dashboards, organised by study type, or click "Full Study Details" for a table of all studies. You can also navigate through the dashboards using the arrows at the bottom of the screen. The graphs below summarise all studies by location, product, and study type.

All graphs are interactive, and clicking on a graph element will filter all other graphs on the page accordingly. To clear a filter, either click on the graph element again, or click the "Clear Filters" button. For additional details on any of the studies, right click on the relevant graph element and select "Drill through > Full Study Details." For example, right click on South Africa on the map to get details of all studies taking place in South Africa. To expand any graph to full screen, hover over the top right corner and click "Focus mode."

Implementation Studies | Modelling Studies | Clinical Research | Landscaping and Values and Preferences | Full Study Details



**Integrated Study Tracker**

Clear Filters

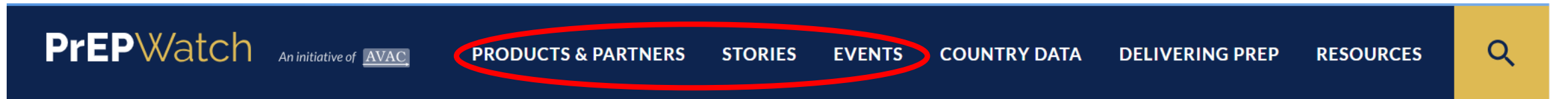
AVAC's **Country Planning for Product Introduction Matrix** tracks the regulatory status of cabotegravir for PrEP and the dapivirine vaginal ring, along with related late stage clinical trials and implementation research, procurement plans, and oral PrEP provision. Use the buttons on the left to filter by region. Right click on any number in the Implementation Studies columns and select "Drill through > Study Details" for full study details. Note that "N/A" indicates year of oral PrEP approval not available. [Click here to visit the PrEPTracker for full PrEP initiation data and click here to visit the study dashboard for full late-stage PrEP research data.](#)

Filter by Region	Country	CAB for PrEP Regulatory Status	DVR Regulatory Status	HPTN 083/084 Studies	Ring/ASPIRE Studies	PURPOSE 1/2 Studies	Year Oral PrEP approved	Oral PrEP Initiations in 2022	PEPFAR CAB Procurement 2023-2025 (# people)	Global PrEP Funding
Select all	Argentina						N/A			
East Asia & Pacific	Australia	Approved					2016	12,196		
	Austria	Approved					2016			
	Belgium	Approved					2016			
	Botswana	Approved	Approved				2016	10,214		
Eastern & Southern Africa	Brazil	Approved					2017	41,589		
	Bulgaria	Approved					2016			
Europe & Central Asia	Burkina Faso						N/A	391		
	Canada	Pending					2016			
	China	Pending					2020			
	Colombia	Pending					N/A			
	Cote D'Ivoire	Pending					N/A	7,080		
Latin America & Caribbean	Croatia	Approved					2016			
	Cyprus	Approved					2016			
	Czech Republic	Approved					2016			
	Denmark	Approved					2016			
North America	Estonia	Approved					2016			
	Eswatini	Via South Africa	Via South Africa				N/A	28,603	Starting 2024/25	
Western & Central Africa	Ethiopia		To file in 2023				N/A	15,141		
	Finland	Approved					2016	150		
	France	Approved					2016	4,547		
	Germany	Approved					2016			

**Product Introduction Matrix**

# Introducing PrEPWatch

Also on PrEPWatch...



[← Back to Products & Partners](#)

## The Dapivirine Vaginal Ring

The PrEP Vaginal Ring

LAST UPDATED: 1 NOVEMBER 2023

The first topical HIV prevention vaginal ring (DVR) is a silicone ring (IPM).

The ring is inserted in the vagina over the course of one month to prevent HIV. The drug is absorbed elsewhere in the body, not through the bloodstream and other tissues. The development of HIV resistance to ARV drug to which dapivirine is added.

Click here to access the PrEP ring, including basic information and user experience.

Click here to access the [PrEP ring research summary](#), which shares an overview of PrEP ring research in East and Southern Africa, including trial overviews and key findings.

### Evidence and Research for the Dapivirine Vaginal Ring

[Learn more →](#)

### Stories

For a look at real world challenges with PrEP delivery and innovative solutions, these stories showcase lessons from the field. To share your story on PrEPWatch, [click here](#).

Visit the [MOSAIC blog](#) for more stories from the field.

### 9 NOVEMBER 2023

#### Inclusion of Pregnant and Lactating People in HIV Research

People who are pregnant or lactating (PLP) have historically been excluded from research because of concerns for the developing fetus. But this has led to a dearth of data on new interventions against health threats for this population. In the case of HIV, pregnancy raises the risk of acquiring HIV by up to three times...

[Read the full story →](#)

### 9 OCTOBER 2023

#### PxWire Volume 13, Number 3: September 2023

The latest data from our Global PrEP Tracker and our HIV Prevention Resource Tracking Report shows progress in expanding access to oral PrEP and positive trends in research and development funding for PrEP. This is good news as we know that research alone will not end the epidemic. Effective products must be paired with robust...

[Read the full story →](#)

### 31 AUGUST 2023

#### Highlights from IAS 2023

IAS 2023 brought together civil society, advocates, policy makers, donors, and scientists to share the latest HIV scientific findings and discuss where advocacy is needed to both advance research and ensure equity informs every aspect of the development process, from basic science to delivering new interventions. Read on for highlights from the conference. [AVAC at...](#)

[Read the full story →](#)

### Events

Scroll down for a list of webinars, workshops, conferences, and other convenings where the field is coming together to learn, connect and ensure that PrEP reaches everyone who needs it!

For more events, visit the [Global PrEP Learning Network](#) and [The Choice Agenda](#).

Tuesday  
**28**  
November  
13:30 - 15:00 GMT

VIRTUAL

#### Spotlight on New Tools and Data: From R&D to Access >

Between the recent accelerated growth in global PrEP initiatives, and the introduction of new PrEP products like cabotegravir and the dapivirine vaginal ring, the field of PrEP data has never been more exciting or more complex. Staying on top of the latest advances is key for advocates, researchers, funders, and others working in HIV prevention...

Wednesday  
**29**  
November  
13:00 - 14:00 GMT

VIRTUAL

#### New Data, New Opportunities: The expanding evidence base for the PrEP ring >

Three MTN studies – REACH, DELIVER, and B-PROTECTED – recently published critical new data on PrEP ring use among adolescent girls and young women (AGYW), pregnant individuals, and breastfeeding individuals in Africa. All studies offer compelling evidence that the ring is safe for use among these populations. Moreover, the REACH study is the first to...

Detailed Product Overviews

Lessons from the Field

Webinars and Other Events







## The PrEPWatch Team

Please do be in touch with any questions at [prepwatch@avac.org](mailto:prepwatch@avac.org) or

---

**Catherine Verde Hashim**

[catherine@avac.org](mailto:catherine@avac.org)

**Janki Tailor**

[janki@avac.org](mailto:janki@avac.org)



# LAPaL

THE LONG-ACTING THERAPEUTICS  
PATENTS AND LICENCES DATABASE

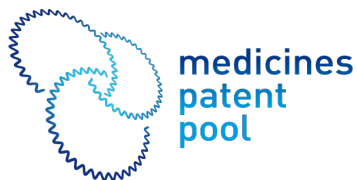


## THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE

A collaborative tool to support access to innovative long-acting therapeutics

LAPaL is a free online resource that provides innovation and access support on technical features, development status and intellectual property status of selected long-acting therapeutics that could have impact in low- and middle-income countries.

[www.lapal.ch](http://www.lapal.ch)





# WHAT ARE LAPaL'S MAIN COMPONENTS?

Long-acting technologies and compounds



# THE LONG-ACTING THERAPEUTICS ONE-STOP-SHOP



Long-acting therapeutics development landscape with technologies, compounds and their co-formulations



Visualisation dashboard:  
- Insights on clinical trials  
- Overview of regulatory status



Intellectual property landscape



Access commitments for pipeline acceleration

Technology name, API or developer

Clear

Browse long-acting therapeutics

- Technologies
- Compounds

Explore the landscape

Route(s) of administration

Type of technology

Other features of the technology

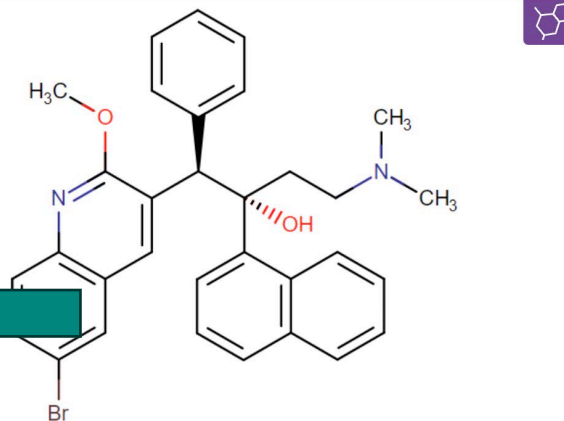
Development stage

Therapeutic area(s)

Targeted population

Ease of administration

Active Pharmaceutical Ingredient (API)



Bedaquiline

Janssen Pharmaceuticals

Summary

See more

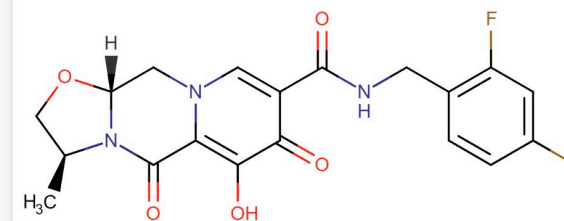


BEPO®

MEDINCELL

Summary

See more

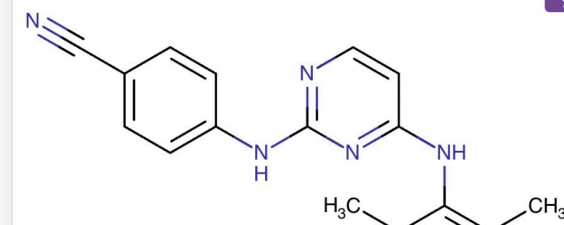
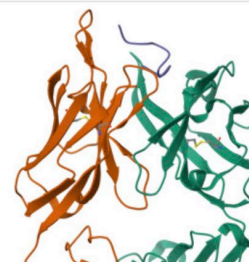
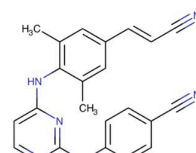
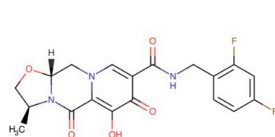


Cabotegravir (CAB)

Viiv Healthcare

Summary

See more



## Drug Combination Nanoparticles (DcNP)



Verified by the innovator, on Jul 2021

# W



### Active Pharmaceutical Ingredient

Tenofovir disoproxil fumarate (TDF),  
Lamivudine (3TC), Dolutegravir (DTG),  
Lopinavir and ritonavir (LPV/r),  
Tenofovir (TFV)



### Route(s) of administration

Subcutaneous



### Type of technology

Based on other organic particles,  
Aqueous drug particle suspension



### Other features of the technology

Biodegradable, Non-removable, Room  
temperature storage, At least 1 year  
shelf life



### Development stage

Pre-clinical



### Therapeutic area(s)

HIV



### Ease of administration

Administered by a community health  
worker, Administered by a nurse,  
Administered by a specialty health  
worker, Self-administered

Access principles



## Drug Combination Nanoparticles (DcNP)

Targeted & Long-acting drug Combination (TLC)  
Program, University of Washington

Summary

See more





## Drug Combination Nanoparticles (DcNP)

×

Verified by the innovator, on Jul 2021

# W



### Active Pharmaceutical Ingredient

Tenofovir disoproxil fumarate (TDF),  
Lamivudine (3TC), Dolutegravir (DTG),  
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### Route(s) of administration

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Based on other organic particles,  
Aqueous drug particle suspension



### Other features of the technology

Biodegradable, Non-removable, Room  
temperature storage, At least 1 year  
shelf life



### Development stage

Pre-clinical



### Therapeutic area(s)

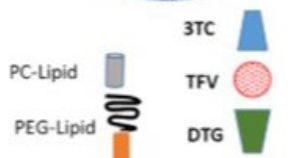
HIV



### Ease of administration

Administered by a community health  
worker, Administered by a nurse,  
Administered by a specialty health  
worker, Self-administered

### Access principles






## Drug Combination Nanoparticles (DcNP)

Targeted & Long-acting drug Combination (TLC)  
Program, University of Washington

Summary

See more



	<p><b>Technology name</b></p> <p>Drug Combination Nanoparticles (DcNP)</p>	<p><b>Main developer(s)</b></p> 	<p><b>Sponsor(s)</b></p> 
---	--	---	--

- Technology information
- Potential application(s)**
- Clinical trials
- Patent info
- Supporting material
- Access principles
- Partnerships & sponsors



**Therapeutic area(s)**

- HIV

**Use case(s)**

- Treatment



**Potential associated API(s)**

- Tenofovir disoproxil fumarate (TDF), Lamivudine (3TC), Dolutegravir (DTG)
- Lopinavir and ritonavir (LPV/r), Tenofovir (TFV)

**Use of technology**

<p><b>Ease of administration</b></p> <ul style="list-style-type: none"> <li>Administered by a community health worker</li> <li>Administered by a nurse</li> <li>Administered by a specialty health worker</li> <li>Self-administered</li> </ul>	<p><b>Frequency of administration</b></p> <p>Monthly, Once every 8 weeks</p>
---	--

**User acceptance**

Potentially good

**Targeted user groups**

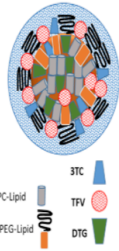
<p><b>Age Cohort</b></p> <ul style="list-style-type: none"> <li>Adults</li> </ul>	<p><b>Genders</b></p> <ul style="list-style-type: none"> <li>Male</li> <li>Female</li> <li>Cisgender female</li> <li>Cisgender male</li> <li>Transgender female</li> <li>Transgender male</li> <li>Intersex</li> <li>Gender non-binary</li> <li>All</li> </ul>
<p><b>Pregnant individuals</b></p> <p>Yes</p>	<p><b>Lactating individuals</b></p> <p>Yes</p>
<p><b>Healthy individuals</b></p> <p>No</p>	
<p><b>Comment</b></p> <p>Not provided</p>	

**Tenofovir disoproxil fumarate (TDF), Lamivudine (3TC), Dolutegravir (DTG)**

<p><b>Class(es)</b></p> <p>Antiviral</p>	<p><b>Foreseen user group</b></p> <p>People living with HIV (Chronic HIV positive patients)</p>
--	---

**Lopinavir and ritonavir (LPV/r), Tenofovir (TFV)**

<p><b>Class(es)</b></p> <p>antiviral</p>	<p><b>Foreseen user group</b></p> <p>People living with HIV</p>
--	---



Technology name

Drug Combination Nanoparticles (DcNP)

Main developer(s)

W

Sponsor(s)



Technology information

Potential application(s)

**Clinical trials**

Patent info

Supporting material

Access principles

Partnerships & sponsors

Clinical trials (1 result)

Use case

Use case ▾

Phase

Filter by Phase ▾

Status

Filter by Status ▾

Name

Identifier

Phase

Status

Purpose

Use case

Clinical trial detail

First in Human Clinical Trial of a Next Generation, Long-acting Injectable, Combination Antiretroviral Therapy Platform TLC-ART 101 (ACTU 2001)

NCT05850728

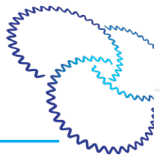
Phase I

Recruiting

Safety, tolerability and PK of single subcutaneous injection of TLC-ART 101 in healthy adults

Treatment





Global information

Trials dates

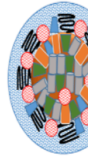
Studied population

Study design

Use of drug candidate

Key results

## Clinical trial general information



3TC  
PC-Lipid  
TFV  
PEG-Lipid  
DTG

### Name

First in Human Clinical Trial of a Next Generation, Long-acting Injectable, Combination Antiretroviral Therapy Platform TLC-ART 101 (ACTU 2001)

### Link

<https://clinicaltrials.gov/study/NCT05850728?intr=TLC-ART&rank=1>

### Sponsor

NIH

### Purpose

Safety, tolerability and PK of single subcutaneous injection of TLC-ART 101 in healthy adults

### Countries

United States

### Sites / Institutions

- Seattle, Washington

### Identifier

NCT05850728

### Phase

Phase I

### Status

Recruiting

### More details

This study is a prospective, open-label, single-site, first-in-human study of a long-acting, injectable combination antiretroviral therapy platform, with a pharmacologically-guided adaptive design for dose escalation, de-escalation, and study duration. The study is designed to learn whether the formulation can be used as a platform for other drugs for treatment of HIV. The formulation is a drug combination nanoparticle (DCNP). The study will be conducted by UW Positive Research. The sample size for this study is 12-16. The study population consists of healthy adults without HIV. The study duration is 57 days per participant at the start of the study.

### Interventions

- TLC-ART 101 containing lopinavir 15.6mg , ritonavir 4.2 mg, and tenofovir 9.15 mg in a combination nanoparticle suspension of 1.5 mL



Technology info

Clinical trials (

Name

First in Human Clinical Trial of a Next Generation, Long-acting Injectable, Combination Antiretroviral Therapy Platform

Close

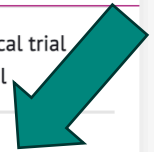
Status

Filter by Status

Case name

Clinical trial detail

Treatment



« < 1 > »



**Technology patent families**

Patent description	Representative patent	Categories	Patent holder	Abstract	Patent status	Licence with MPP	Licence details	Patent source
Drug Combination Nanoparticles for multiple drugs extended release <b>Expiry date:</b> 15 Jun 2036	<a href="#">WO2016205384</a>	Long-acting platform	The University Of Washington			✓		Company
Combination pharmaceutical compositions including a combination of hydrophilic and hydrophobic therapeutic agents <b>Expiry date:</b> 10 Jan 2040	<a href="#">WO2020146788</a>	Long-acting platform	University of Washington			✓		Company
Antiviral compositions that transform short-acting therapeutic agents into long-acting injectable forms that lasts for many weeks per administration <b>Expiry date:</b> 7 Jan 2041	<a href="#">WO2021142150</a>	Long-acting platform	University of Washington			✓		Company



**Technology patent families**

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Combination pharmaceutical compositions including a combination of hydrophilic and hydrophobic therapeutic agents, [WO2020146788](#), Long-acting platform, University of Washington, (10 Jan 2020)  
Source: Company

Patent status	Low, low-middle and upper-middle countries	High income countries
<b>Granted</b>	South Africa	
<b>Filed</b>	China, Brazil, India, Nigeria	United States of America
<b>Not in force</b>	World Intellectual Property Organization (WIPO)	World Intellectual Property Organization (WIPO)

Close



## Technology patent families

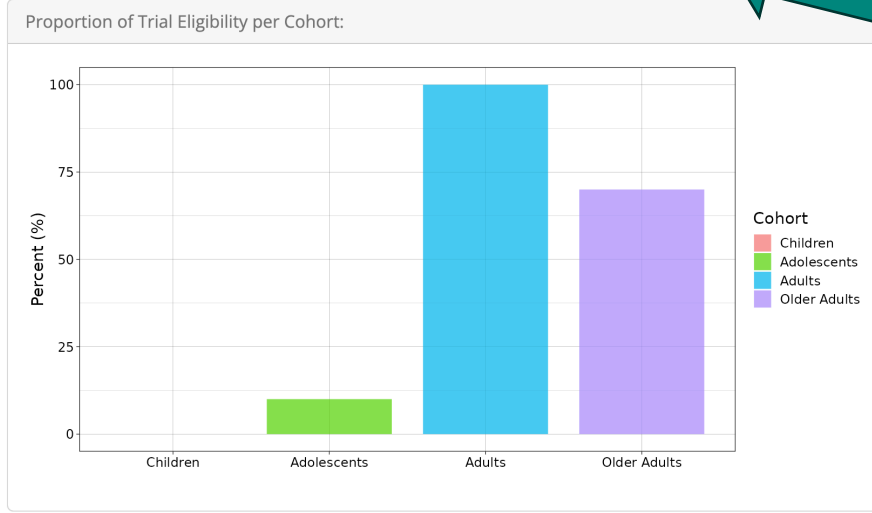
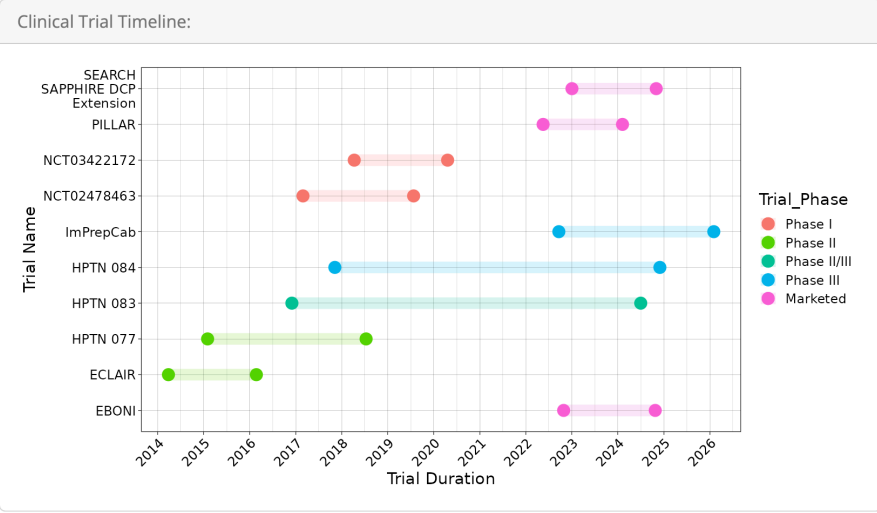
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**MPP/Uni Washington licence on Drug Combination Nanoparticles (DcNP) - HIV prevention/treatment****Type:** MPP Licence**Licensor:** University of Washington**Jurisdictions:** Afghanistan; Algeria; American Samoa; Angola; Argentina; Armenia; Azerbaijan; Bangladesh; Belarus; Belize; Benin; Bhutan; Bolivia (Plurinational State of); Bosnia and Herzegovina; Botswana; Brazil; Bulgaria; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Central African Republic; Chad; China; Colombia; Comoros; Congo; Congo, democratic Republic of the; Costa Rica; Côte d'Ivoire; Cuba; Djibouti; Dominica; Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Eritrea; Eswatini; Ethiopia; Fiji; Gabon; Gambia (the); Georgia; Ghana; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; India; Indonesia; Iran (Islamic Republic of); Iraq; Jamaica; Jordan; Kazakhstan; Kenya; Kiribati; Korea (Democratic People's Republic of); Kosovo; Kyrgyzstan; Lao People's Democratic Republic (the); Lebanon; Lesotho; Liberia; Libya; Madagascar; Malawi; Malaysia; Maldives; Mali; Marshall Islands; Mauritania; Mexico; Micronesia (Federated States of); Moldova, Republic of; Mongolia; Montenegro; Morocco; Mozambique; Myanmar; Namibia; Nepal; Nicaragua; Niger; Nigeria; North Macedonia; Pakistan; Papua New Guinea; Paraguay; Peru; Philippines; Russian Federation; Rwanda; Saint Lucia; Saint Vincent and the Grenadines; Samoa; Sao Tome and Principe; Senegal; Serbia; Sierra Leone; Solomon Islands; Somalia; South Africa; South Sudan; Sri Lanka; State of Palestine; Sudan; Suriname; Syrian Arab Republic; Tajikistan; Tanzania, United Republic of; Thailand; Timor-Leste; Togo; Tonga; Tunisia; Türkiye; Turkmenistan; Tuvalu; Uganda; Ukraine; Uzbekistan; Vanuatu; Venezuela (Bolivarian Republic of); Viet Nam; Yemen; Zambia; Zimbabwe**Licensee(s):****MPP licence:** <https://medicinespatentpool.org/licence-post/long-acting-injectable-drug-combination-for-hiv-treatment-prevention>

Close

Indication:  Drug Name:  Use Case:  Display Timeline By:



Clinical Trial Summary Table:

Drug Name	Trial Name	Trial ID	Trial Phase	Enrollment	Age Eligibility	Cohort	Current Status	Use Case
Cabotegravir	ECLAIR	NCT02076178	Phase II	127	18-65	Adults, Older Adults	Completed	PrEP
Cabotegravir	HPTN 077	NCT02178800	Phase II	199	18-65	Adults, Older Adults	Completed	PrEP
Cabotegravir	HPTN 083	NCT02720094	Phase II/III	4570	18+	Adults, Older Adults	Active Not Recruiting	PrEP
Cabotegravir	HPTN 084	NCT03164564	Phase III	3224	18-45	Adults	Active Not Recruiting	PrEP
Cabotegravir	EBONI	NCT05514509	Marketed	250	18+	Adults, Older Adults	Recruiting	PrEP

Showing 1 to 5 of 10 entries

Previous 1 2 Next



Regulatory Map Filters:

Drug Name:

Cabotegravir

Use Case:

PrEP

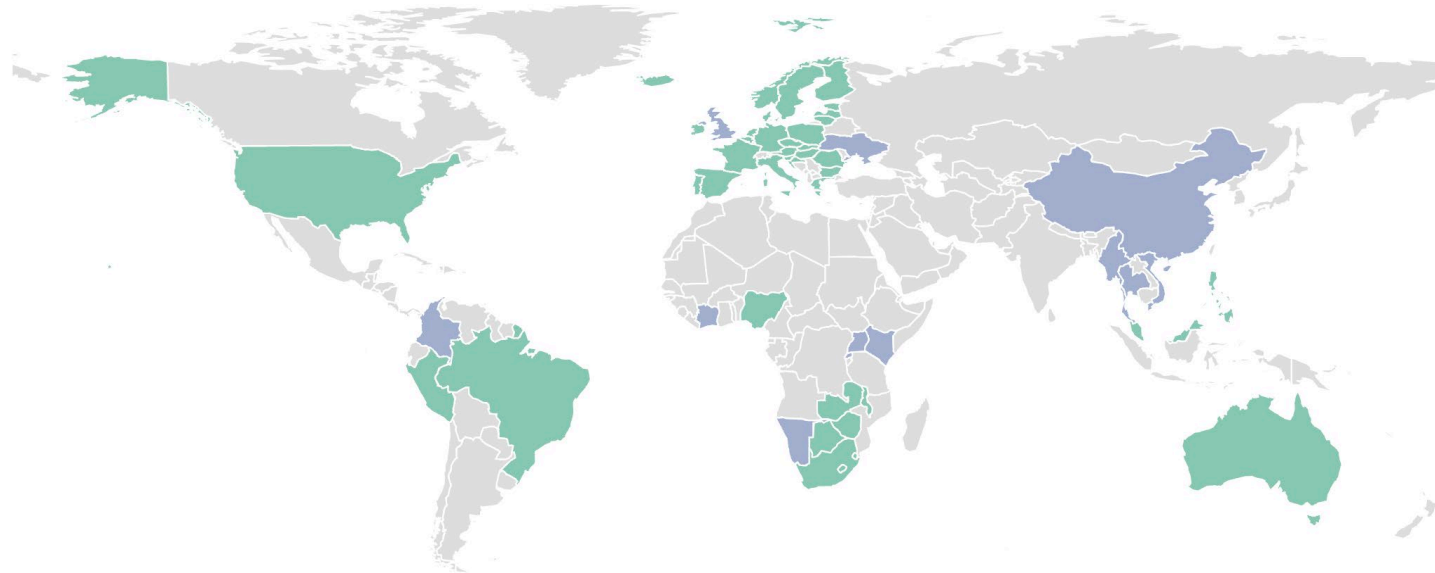
Regulatory Statistics:

Approved 44

Submitted 12

Date of Last Update:

1st Nov 2023



Approved Submitted

## THE LONG-ACTING THERAPEUTICS PATENTS AND LICENCES DATABASE



**Lobna Gaayeb**  
*Lgaayeb@mppf.ch*

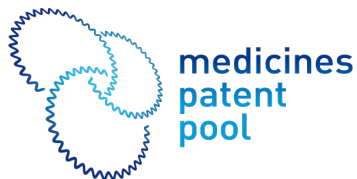


**Mark Ryan**  
*M.P.Ryan2@liverpool.ac.uk*

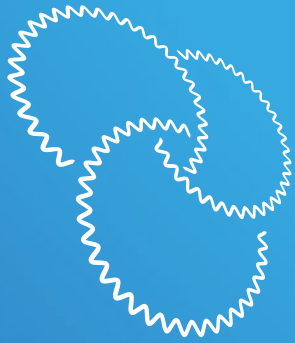
### Thanks for your attention!

Please reach out to us with questions, proposals for improvements or any comments

[www.lapal.ch](http://www.lapal.ch)







medicines  
patent  
pool

# Access to Medicines Tracker: Interactive Map (and Table)

**Webinar – *Spotlight on new PrEP tools and data: From R&D to access***

Convened by AVAC, MPP, and Unitaid on 28 November 2023

Presented by Sébastien Morin (Medicines Patent Pool)

MEDICINESPATENTPOOL.ORG

Spotlight on New PrEP Tools  
and Data: **FROM R&D TO ACCESS**



**TUESDAY, NOVEMBER 28**

**8:30 TO 10:00 AM ET / 14:30 TO 16:00 PM CET**

Join us to learn about three important online PrEP resources and to understand how they can support and enhance your work.

Register at [tinyurl.com/PrEPTools](https://tinyurl.com/PrEPTools)

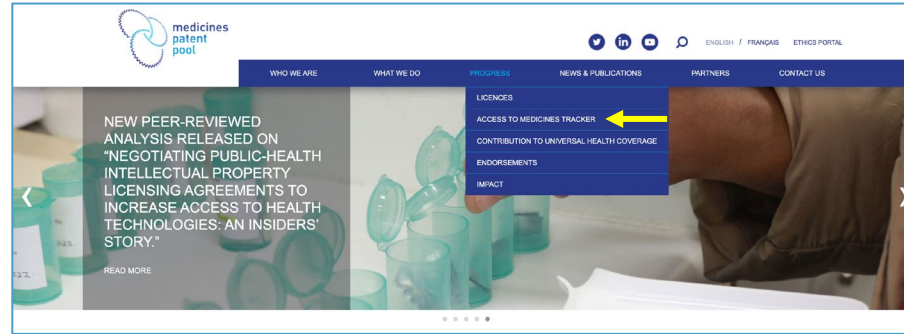




# Access to Medicines Tracker: *Interactive Map (and Table)*

## Step 1.

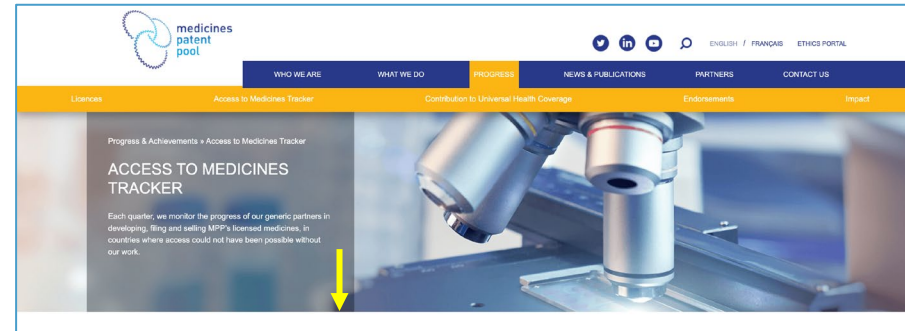
Navigate to the MPP website and select “Progress”/“Access to Medicines Tracker”



Now, let's do it!

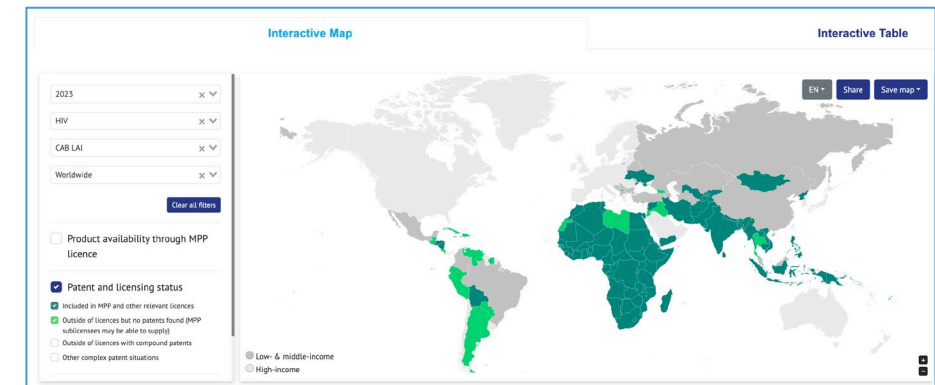
## Step 2.

On the “Access to Medicines Tracker” webpage, scroll down to the “Interactive Map”



## Step 3.

Explore country-level quarter-by-quarter data on access, filing, approval, and supply of MPP-licensed medicines

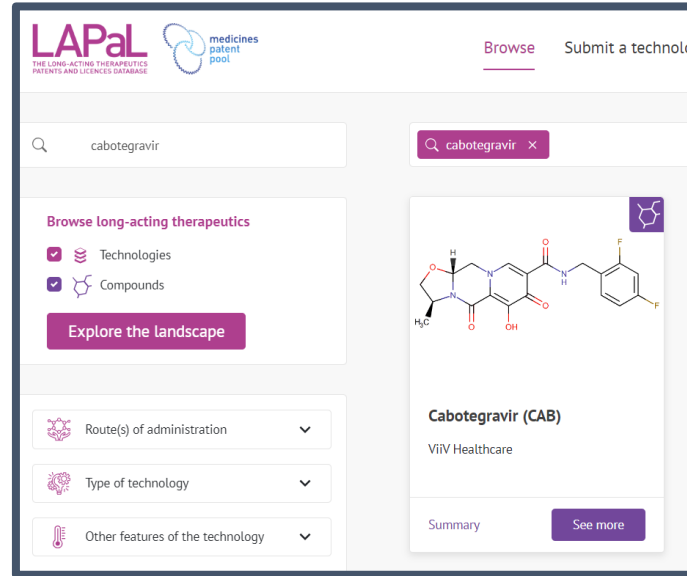


More at: <https://medicinespatentpool.org>  
<https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker>  
<https://map.medicinespatentpool.org> -> This is the link for direct access to the **map** in full window mode.  
<https://map.medicinespatentpool.org/table> -> This is the link for direct access to the **table** in full window mode.

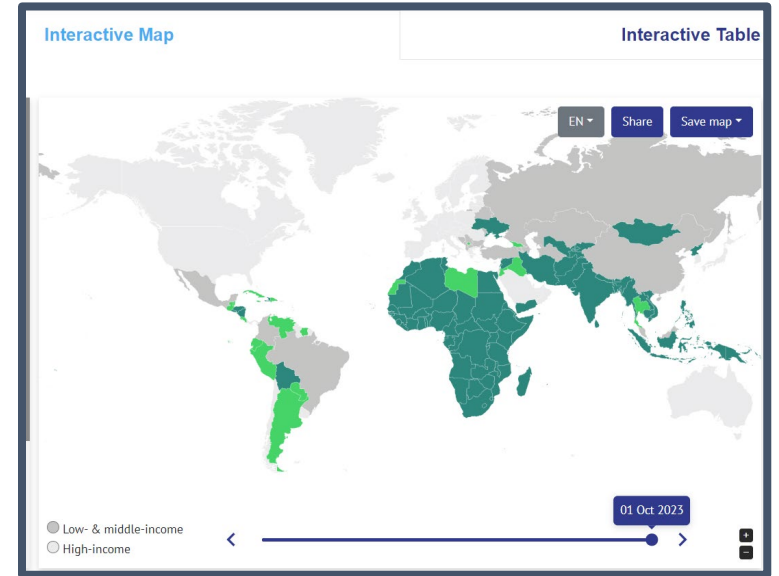
# When do I use each tool?



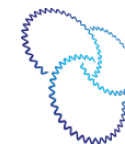
**PrEPWatch**



**LAPaL**  
THE LONG-ACTING THERAPEUTICS  
PATENTS AND LICENCES DATABASE



**ACCESS TO MEDICINES  
TRACKER**



medicines  
patent  
pool



# Cheat Sheet

Where do I go to find information on...?

**PrEP**Watch

**LAPaL**  
THE LONG-ACTING THERAPEUTICS  
PATENTS AND LICENCES DATABASE

ACCESS TO MEDICINES  
TRACKER

Technical info on PrEP- applicable LA platforms & compounds (incl. publications & documentation)

Scaled-up manufacturing information

Intellectual property information (patents and licences)

Intellectual property access information (patents & licences) for MPP-licensed products (such as CAB-LA)

PrEP research studies (incl. implementation studies, modelling studies)

Information on PrEP product approvals

Information on filings, approvals, supplies, & suppliers of MPP-licensed products (such as CAB-LA)

Country MoH & WHO PrEP guidelines

Innovators access commitments

Resources to support PrEP rollout process

PrEP initiations & PEPFAR targets

Quarter-by-quarter country-by-country data (with possibility to explore historical data points starting from 2019)

# Finding and Using Data

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# Mentimeter

[Click here to launch Mentimeter interactive quiz](#)

Find the answers here:

[PrEPWatch](#)

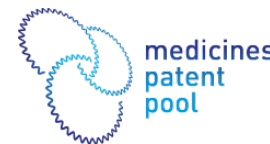
[The Long-Acting Therapeutics Patents and Licenses Database](#)

[Access to Medicines Tracker](#)



# Q&A

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# Thank you!

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## Further Resources

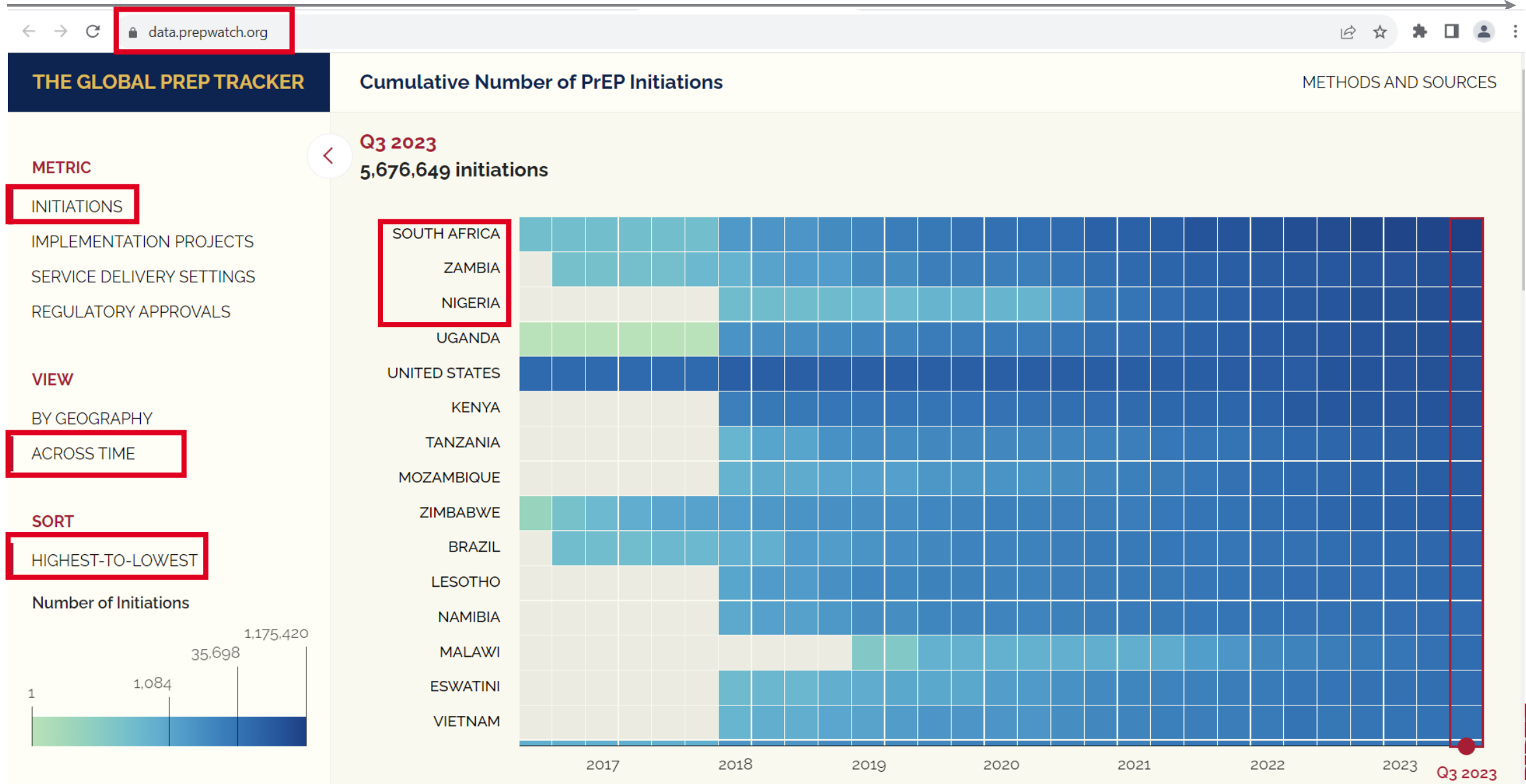
- [PrEPWatch](#)
- [PrEPTracker](#)
- [Integrated Study Dashboard](#)
- [Country Planning for Product Introduction Matrix](#)
- [The Long-Acting Therapeutics Patents and Licenses Database](#)
- [Access to Medicines Tracker](#)
- [MedsPaL](#)



# Quiz Questions and Answers

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# What are the top three countries for PrEP Initiations?



# Which policy frameworks are available for South Africa?


**PrEPWatch** An initiative of **AVAC**

PRODUCTS & PARTNERS   STORIES   EVENTS   **COUNTRY DATA**   DELIVERING PREP   RESOURCES

[< Back to Data by Country](#)

**Country Overview: South Africa**





[Global PrEP Tracker](#)

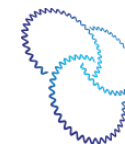


**Scroll down**



**Policy Frameworks**

-   
South African Guidelines for the Provision of Pre-exposure Prophylaxis (PrEP) to Persons at Substantial Risk of HIV Infection, 2020
-   
National Strategic Plan for HIV, TB and STIs, 2017-2022
-   
National Sex Worker HIV Plan, 2016-2019
-   
National Policy on HIV PrEP and Test and Treat, 2016



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# How many resources does the PrEPWatch library have on demand generation materials for CAB for PrEP aimed at adolescent girls and young women?

The screenshot displays the PrEPWatch website interface. At the top, the navigation bar includes the PrEPWatch logo, the text "An initiative of AVAC", and menu items: PRODUCTS & PARTNERS, STORIES, EVENTS, COUNTRY DATA, DELIVERING PREP, and RESOURCES (circled in red). A search icon is located on the right. Below the navigation bar, there are three filter columns: Topic, Product, and Populations. In the Topic column, "Demand Creation/Marketing" is selected. In the Product column, "Cabotegravir" is selected. In the Populations column, "Adolescent Girls and Young Women" is selected. A red arrow points from the selected filters to the search results. The search results show "Showing results 1 - 4 of 4" and list four documents: "HIV Prevention User Journey Tool" (1 FEBRUARY 2023), "HIV Prevention Ambassador Training Package and Toolkit" (17 JANUARY 2023), "MOSAIC Gender and Youth Strategy" (3 JANUARY 2023), and "Creating Demand for PrEP Among Adolescent Girls & Young Women" (1 NOVEMBER 2020).

**PrEPWatch** An initiative of AVAC

PRODUCTS & PARTNERS STORIES EVENTS COUNTRY DATA DELIVERING PREP **RESOURCES**

Showing results 1 - 4 of 4

**Topic**

- Community/Advocacy
- Demand Creation/Marketing
- Financing & Costing
- Monitoring & Evaluation
- Normative Guidance/Policies
- Research
- Service Delivery
- Supply Chain Management
- Testing

**Product**

- Cabotegravir
- Dapivirine Vaginal Ring
- Dual Prevention Pill
- Event-Driven PrEP
- F/TAF
- Implants
- Injectable Prep
- Lenacapavir
- Multipurpose Prevention Technologies
- Oral PrEP
- Post Exposure Prophylaxis
- TDF/xTC
- Trial Prep Options

**Populations**

- Adolescent Girls and Young Women
- Adolescents and Young People
- Cisgender Men
- Cisgender Women
- Gay and Bisexual Men Who Have Sex With Men
- Incarcerated People
- Nonbinary People
- People Who Use Drugs
- Pregnant and Lactating Populations
- Serodifferent Couples
- Sex Workers
- Trans Men
- Trans Women
- Young Men Who Have Sex with Men

**1 FEBRUARY 2023**  
**HIV Prevention User Journey Tool >**  
The HIV Prevention Journey Tool was developed to support adolescent girls and young women to explore methods that would align with their lifestyle, needs and personal preferences; and support healthcare providers to provide informed counseling based on client needs. The digital tool, which has been optimized for use on mobile devices, can be accessed here....  
Demand Creation/Marketing, Service Delivery  
DOCUMENT

**17 JANUARY 2023**  
**HIV Prevention Ambassador Training Package and Toolkit >**  
The HIV Prevention Ambassador Training Package and Toolkit is designed for community-based organizations and other groups to train HIV Prevention Ambassadors with the goal of promoting the meaningful engagement of communities and potential and current PrEP users in the rollout of oral PrEP for HIV prevention.  
Community/Advocacy, Demand Creation/Marketing  
DOCUMENT

**3 JANUARY 2023**  
**MOSAIC Gender and Youth Strategy >**  
This Gender and Youth Strategy, developed by the MOSAIC consortium, offers an analysis of the gender- and age-related barriers faced by – and the opportunities that could be leveraged in collaboration with – potential users of PrEP.  
Community/Advocacy, Demand Creation/Marketing, Service Delivery  
DOCUMENT

**1 NOVEMBER 2020**  
**Creating Demand for PrEP Among Adolescent Girls & Young Women >**  
Slide-deck Review of HIV, PrEP and Contraceptive Focused Projects in Sub-Saharan Africa  
Demand Creation/Marketing  
DOCUMENT



In LAPaL, how many long-acting technology platforms could potentially be associated with cabotegravir?

Five platform technologies listed on LAPaL could potentially be coupled with cabotegravir to extend its release


cabotegravir

**Browse long-acting therapeutics**

- Technologies
- Compounds

Explore the landscape

<https://lapal.medicinespatentpool.org/>



**DelSiTech Silica Matrix Drug Delivery**

DelSiTech

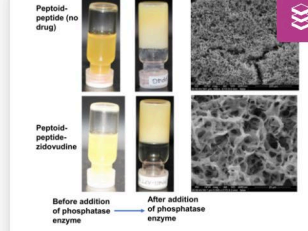
Summary [See more](#)



**Dissolving microarray patches**

Queen's University Belfast

Summary [See more](#)



**Peptide-like hydrogels as a long-acting injectable drug delivery platform**

Queen's University Belfast

Summary [See more](#)



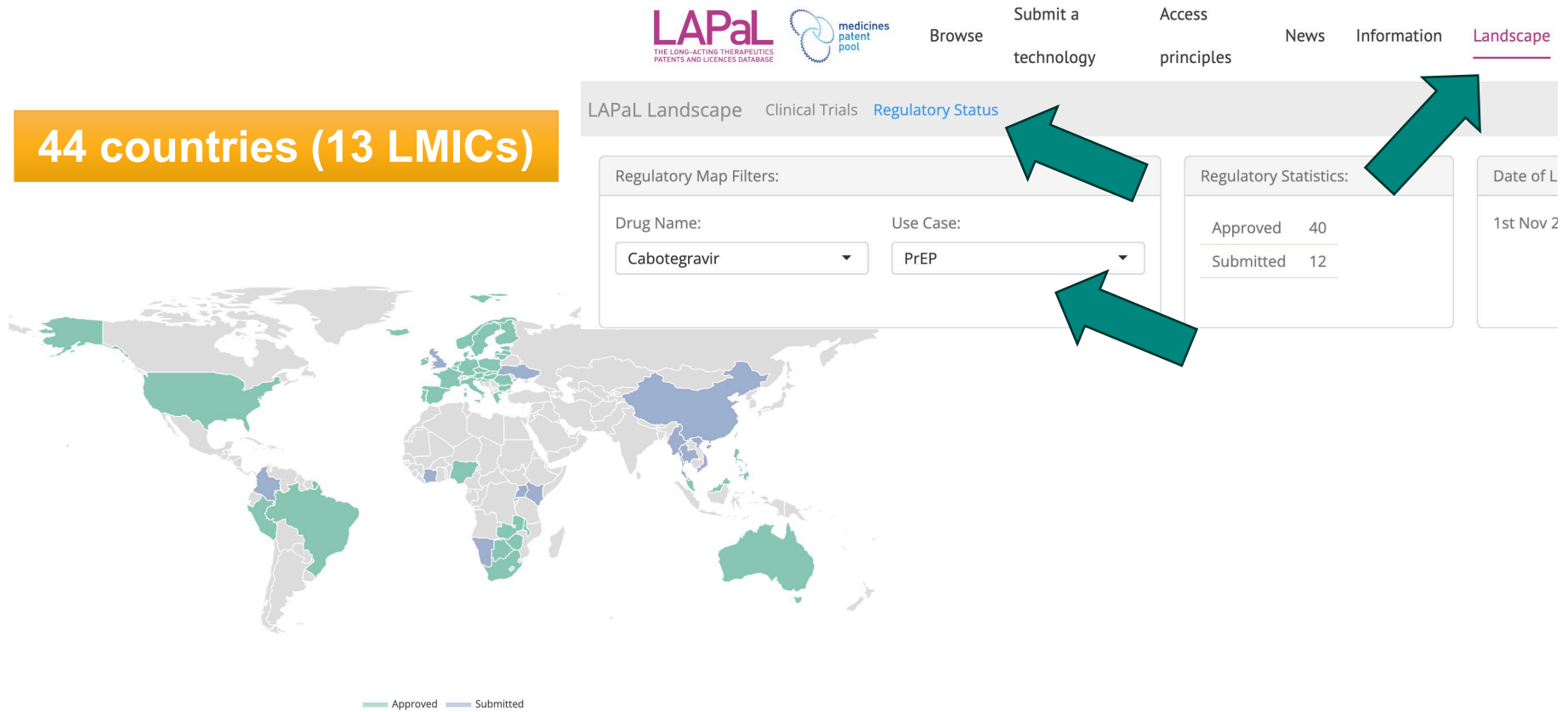
**Tunable Biodegradable Ultra-Long-Acting Polymeric Solid Implant**



**Ultra-Long-Acting Multi-Purpose In-situ Forming Implant (ISFI)**

# In how many countries has CAB-LA for PrEP received approval?







44 countries (13 LMICs)



<https://lapal.medicinespatentpool.org/landscape>. → Regulatory status → Cabotegravir + PrEP use case

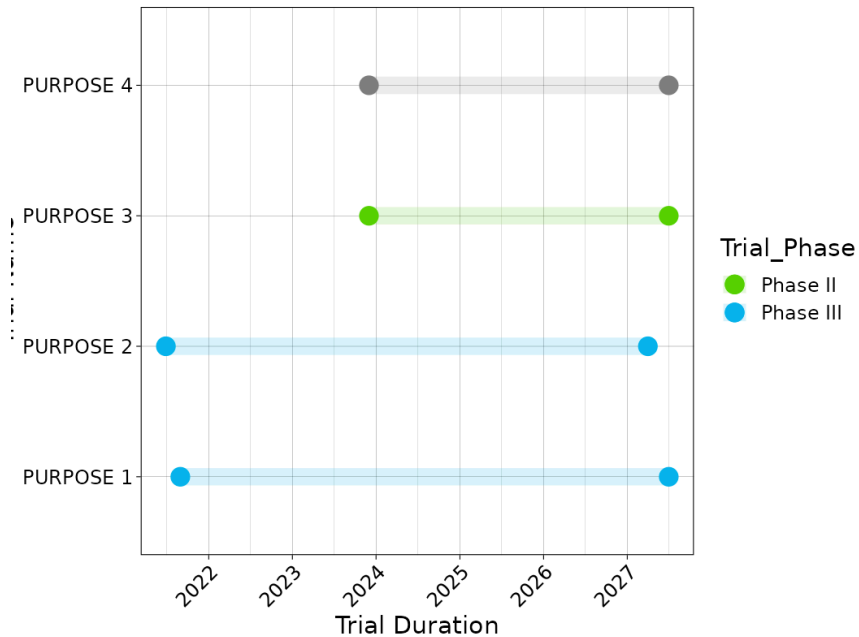
In the absence of a licence, when could generic quality assured versions of **lenacapavir** enter the market?

Not before 2034 or even 2037 in many LMICs

Compound patent families								
Patent description	Representative patent	Categories	Patent holder	Abstract	Patent status	Licence with MPP	Licence details	Patent source
Lenacapavir and analogues (Markush formula) and their use in HIV  <b>Expiry date:</b> 28 Feb 2034	<a href="#">WO2014134566</a>	Compound	Gilead Sciences, Inc					MPP Search, US FDA
Lenacapavir compound and its use in HIV (oral and parenteral)  <b>Expiry date:</b> 17 Aug 2037	<a href="#">WO2018035359</a>	Compound	Gilead Sciences, Inc					MPP Search, US FDA
Crystalline forms of Lenacapavir sodium salt  <b>Expiry date:</b> 16 Aug 2038	<a href="#">WO2019035904</a>	Polymorphs	Gilead Sciences, Inc					MPP Search, US FDA

## How many clinical trials are ongoing or planned for lenacapavir in the context of PrEP?

4 trials: PURPOSE 1 to 4



<https://lapal.medicinespatentpool.org/landscape>

### About PURPOSE 1

- Phase 3 study of an investigational drug, lenacapavir, for PrEP and emtricitabine/tenofovir alafenamide (F/TAF) for PrEP in Adolescent Girls and Young Women
- This study will be conducted in South Africa and Uganda

### About PURPOSE 2

- Phase 3 study of an investigational drug, lenacapavir, for PrEP for Cisgender Men, Transgender Women, Transgender Men, and Gender Non-Binary individuals Who Have Sex With Partners Assigned Male at Birth
- This study will be conducted in the United States, South Africa, Peru, Brazil, Argentina, Mexico, and Thailand

### PURPOSE 3

PK, Safety, and Acceptability of LEN for PrEP in Cisgender Women in the United States.

### PURPOSE 4

PK, Safety, and Acceptability of LEN for PrEP in People Who Inject Drugs.

## Which of these trials have the earliest primary completion date?

**PURPOSE 1: 2024-09-01**

Drug name: Lenacapavir (LEN) | Originator/manufacturer: GILEAD

Drug information | **Clinical trials** | Patent info | Supporting material

Clinical trials (4 results) | Use case: PrEP | Phase: Filter by Phase | Status: Filter by Status

Name	Identifier	Phase	Status	Purpose	Use case	Clinical trial detail
PURPOSE 1	NCT04994509	Phase III	Active, not recruiting	Evaluate the efficacy of Lenacapavir (LEN) and Emtricitabine/Tenofovir alafenamide (F/TAF) in preventing the risk of human immunodeficiency virus (HIV) infection	PrEP	
PURPOSE 2	NCT04925752	Phase III	Recruiting	Evaluate the efficacy of Lenacapavir (LEN) in preventing the risk of HIV-1 infection.	PrEP	
PURPOSE 3	NCT06101329	Phase II	Not yet recruiting	Evaluate the Pharmacokinetics, Safety, and Acceptability of Twice Yearly Long-acting Subcutaneous Lenacapavir for Pre-Exposure Prophylaxis in Cisgender Women in the United States.	PrEP	
PURPOSE 4	NCT06101342	Phase II	Not yet recruiting	Evaluate the Pharmacokinetics and Safety of Twice Yearly Long-Acting Subcutaneous Lenacapavir for Pre-Exposure Prophylaxis in People Who Inject Drugs.	PrEP	

PURPOSE 1

Global information | **Trials dates** | Status

### Trials dates

Anticipated Start Date

Unspecified

Actual Start Date

2021-08-30

Anticipated Date of Last Follow-up

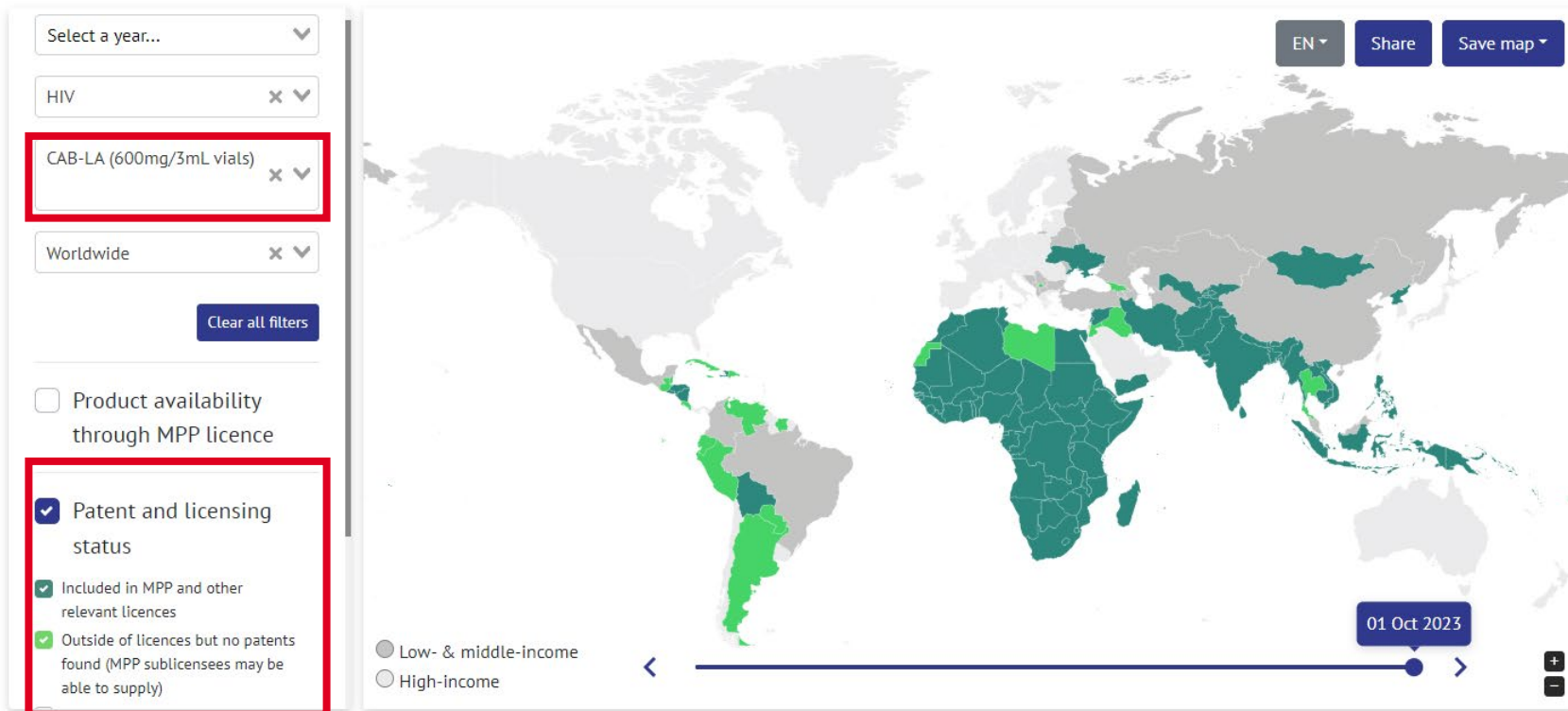
Unspecified

Estimated Primary Completion Date

2024-09-01



## List three countries included in the MPP-licensed territory for generic cabotegravir long-acting injectable, and three countries not included in the licensed territory, but where access may be possible as there are no patents



- Countries included MPP-licensed territory for generic cabotegravir long-acting injectable can be visualized on [this interactive map](#) and are also available from [MedsPaL](#) or on the [CAB-LA licence page](#)
- Countries not included in the licensed territory, but where access may be possible as there are no patents can be visualized on [this interactive map](#)
- The full, effective overall territory can be visualized on [this interactive map](#), it is also discussed in an [online post by Brook Baker](#)