Show Us The Money
Tracking HIV Vaccine R&D Funding & Trends

Mitchell Warren, Executive Director
Stacey Hannah, Director of Research Engagement
Global HIV Vaccine Enterprise Annual Stakeholders’ Meeting
28 November 2023
For this system to work, it must address several challenges. Funders and major stakeholders of HIV vaccine development must agree to a common vision so that they can coordinate their activities with other components of the enterprise. There must be considerable sharing of information among vaccine developers regarding preclinical investigation and trial results, with the ultimate goal of advancing to clinical trials. Solving problems of access to reagents, platforms, and technologies of potential commercial interest will be required. Finally, this must be a global effort. The research and development enterprise described here must build and include full participation of the developing world where this pandemic is raging. Tens of millions of lives are dependent on the development of a safe and effective HIV vaccine. It is essential that we aggressively explore all mechanisms that might expedite this process. While comparable vaccine access initiatives will also be required to ensure that HIV vaccines are made available to populations in need throughout the world, the expanded global AIDS vaccine effort proposed here hopefully would be a major step towards accelerating successful HIV vaccine development.
Established in 2004, the Resource Tracking for HIV Prevention Research & Development Working Group comprises AVAC, IAVI & UNAIDS

Collaboration has yielded two decades of estimates, providing important trend data – and links with G-FINDER data across all global health R&D

Relies on public information and direct appeals to public, industry & philanthropic funders, using definitions developed by the NIH’s Office of AIDS Research

Some funders decline to provide info, and some do not provide grant-specific detail

Every year the data gets richer
The Money Overall


Preventive vaccines: 794.6 US$ million
Microbicides: 112.6 US$ million
Prevention of vertical transmission: 14.3 US$ million
Pre-exposure prophylaxis: 269.8 US$ million
Treatment as prevention: 49 US$ million
Voluntary medical male circumcision: 8.6 US$ million
Female Condoms: 0.2 US$ million
The Money Overall in 2021

HIV Prevention R&D Funding by Sector in 2021

(US$ Million(s))

$1,020.9
$150.8
$82.9

Public
Philanthropic
Private

HIV Prevention R&D funding by Country in 2021

(US$ millions)

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HIV Vaccine Funding Trends Over Time

2000-2021 in US$ millions
HIV Vaccine "League Table"
2021 in US$ millions, excluding commercial investments

Top HIV Vaccine Funders
2021 (US$ millions)

- $573,700,000
  National Institute of Health
- $65,500,000
  Bill & Melinda Gates Foundation
- $33,800,000
  US Military HIV Research Program
- $28,700,000
  USAID
- $12,900,000
  DLR Project Management Agency – Germany
- $4,900,000
  South African Medical Research Council
- $3,900,000
  Danish Ministry of Foreign Affairs
- $3,100,000
  EDCTP
- $2,400,000
  UKMRC
- $2,300,000
  Research Council of Norway
- $2,200,000
  DST South Africa
- $2,100,000
  Serum Institute of India

$735,500,000
TOTAL FUNDING
2021
HIV Vaccine Investments 2021
By Research Stage

2021 FUNDING

- Preclinical: 43.4%
- Clinical: 37.1%
- Basic: 18.9%
- Policy and advocacy: 0.5%
- Implementation: 0.1%
But Context Matters

Two Positive Efficacy Signals Over Twenty Years

<table>
<thead>
<tr>
<th>YR END</th>
<th>TRIAL NAME/PRODUCT/CLADE</th>
<th>LOCATION</th>
<th>#</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>VAX004, AIDSVAX B/B</td>
<td>Canada, Netherlands, Puerto Rico, US</td>
<td>5,417</td>
<td>No effect</td>
</tr>
<tr>
<td>2003</td>
<td>VAX003, AIDSVAX, B/E</td>
<td>Thailand</td>
<td>2,546</td>
<td>No effect</td>
</tr>
<tr>
<td>2007</td>
<td>STEP, MRK-Ad5, B</td>
<td>Australia, Brazil, Canada, Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico, US</td>
<td>3,000</td>
<td>Immunizations halted early for futility; subsequent data analysis found potential for increased HIV risk among Ad5-seropositive, uncircumcised men</td>
</tr>
<tr>
<td>2007</td>
<td>Phambili, MRK-Ad5, B</td>
<td>South Africa</td>
<td>801</td>
<td>Immunizations halted based on Step result</td>
</tr>
<tr>
<td>2009</td>
<td>Thai Prime-Boost/RV 144, ALVAC-AIDSVAX, B/E</td>
<td>Thailand</td>
<td>16,402</td>
<td>Modest effect (31.2%)</td>
</tr>
<tr>
<td>2013</td>
<td>HVTN 505, DNA+Ad5, A/B/C</td>
<td>US</td>
<td>2,500</td>
<td>Stopped early for futility; vaccine regimen did not prevent HIV infection nor reduce viral load</td>
</tr>
<tr>
<td>2020</td>
<td>Uhambo/HVTN 702, ALVAC/gp120 MF59 boost</td>
<td>South Africa</td>
<td>5,400</td>
<td>Stopped early for futility</td>
</tr>
<tr>
<td>2021</td>
<td>Imbokodo/HVTN705, Ad26 Mosaic/gp140 clade C boost</td>
<td>Malawi, Mozambique, South Africa, Zambia, Zimbabwe</td>
<td>2,600</td>
<td>No efficacy</td>
</tr>
<tr>
<td>2021</td>
<td>AMP Studies, VRC01 monoclonal antibody</td>
<td>Botswana, Kenya, Malawi, Mozambique, Republic of South Africa, Tanzania, Zimbabwe, US, Brazil, Peru, Switzerland</td>
<td>1,924</td>
<td>Did not reduce risk overall, but VRC01 did reduce risk of acquisition in small subset of HIV strains classified as “highly sensitive” to VRC01</td>
</tr>
<tr>
<td>2023</td>
<td>Mosaic/HVTN706, Ad26 Mosaic/gp140 mosaic boost</td>
<td>Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain and US</td>
<td>3,900</td>
<td>No efficacy</td>
</tr>
</tbody>
</table>
## But Context Matters

### A shifting pipeline – all upstream

<table>
<thead>
<tr>
<th>Prevention Product</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
<th>2028</th>
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<tbody>
<tr>
<td><strong>Vaginal Ring</strong></td>
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<tr>
<td>Dapivirine</td>
<td></td>
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<tr>
<td>Multiple regulatory approvals</td>
<td>Multiple implementation science projects</td>
<td>Selected Global Fund procurement and programs</td>
<td></td>
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<tr>
<td>WHO guidelines</td>
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</tbody>
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**Cabotegravir**
- Intra-muscular injection (IM) every 2 months
- Multiple regulatory approvals
- WHO guidelines
- Multiple implementation science projects
- Selected PEPFAR and Global Fund procurement and programs
- Demonstrated high efficacy
- Unclear demand & limited initial supply
- Initial LMIC price: $240/yr; in 2024: $170/yr
- March 2023: MPP & VIV licensed to 3 generics that need 2 years to market
- Opportunity to build market and platforms for injectables

**Lenacapvir**
- Two subcutaneous injections (1.5mg each) every 6 months
- Phase 3: PURPOSE 1 & 2
- Phase 2: PURPOSE 3, 4, 5
- Possible regulatory approvals
- Possible product introduction

**F/TAF**
- Oral PrEP
- Phase 3: part of PURPOSE 1
- Possible regulatory approval
- Possible Phase 3
- Possible Go/No-Go Decision for Phase 3 in Q1 2025

**Dual Prevention Pill**
- Co-formulated TDF/FTC and ethinyl estradiol/levonorgestrel oral contraceptive pill daily
- Pilot bioequivalence (BE) study
- Pivotal BE
- Possible regulatory approval
- Possible product introduction
- Acceptability Study: HPTN 194

**CASPR**
- Coalition to Accelerate & Support Prevention Research

**AVAC**
- Advocacy, Access & Equity
But Context Matters

A shifting pipeline – all upstream

<table>
<thead>
<tr>
<th>In development: Preclinical and clinical</th>
<th>In development: Efficacy trials under way</th>
<th>Newly Approved and Recommended</th>
<th>Currently available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-acting implants</td>
<td>Long-acting injectable</td>
<td>Dapivirine vaginal ring</td>
<td>HIV treatment for people living with HIV/U=U</td>
</tr>
<tr>
<td>Long-acting vaginal ring</td>
<td>Preventive vaccines</td>
<td></td>
<td>Male &amp; female condoms</td>
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<tr>
<td>Patches</td>
<td>Multipurpose vaginal ring</td>
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<tr>
<td>Vaginal Film</td>
<td>Douches</td>
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<tr>
<td>Vaginal Gel</td>
<td>Monthly oral PrEP</td>
<td></td>
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<tr>
<td>Vaginal/ Mucosal Inserts</td>
<td>Broadly neutralizing antibodies</td>
<td></td>
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</tr>
<tr>
<td>And in implementation science projects: <a href="http://www.prepwatch.org/resources/implementation-study-tracker/">www.prepwatch.org/resources/implementation-study-tracker/</a></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Daily oral PrEP</td>
<td>Daily oral PrEP</td>
<td></td>
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<tr>
<td>Combo oral PrEP/OC</td>
<td>Syringe exchange programs</td>
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<tr>
<td>Possible dual pill to market by 2025:</td>
<td>Voluntary medical male circumcision</td>
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</table>

Event-driven for some populations.
But Context Matters

Different pandemics; different vaccine developments

- SARS-CoV-2 virus sequenced
- WHO declares Public Health Emergency
- 2 mRNA efficacy trials begin
- 2 mRNA vaccines get EUA
- Plus multiple other vaccines AND antibodies studied and authorized

Jan 2020 | July 2020 | Jan 2021 | July 2021 | Jan 2022 | July 2022
---|---|---|---|---|---
Uhambo Results
AMP Results
HPTN 083 Results
HPTN 084 Results
WHO Guidance on Dapivirine Vaginal Ring
Imbokodo Results
Mosaico Results
US FDA approval of CAB for PrEP
WHO Guidance of CAB for PrEP

Research Results | Regulatory approvals/ normative guidance
Return on Investment

Leveraging HIV Vax for COVID R&D

Five “P”s to Watch: Platforms, Process, Partnerships, Payers and Participatory Practices that Drive Vaccine Development
Key Developments & Takeaways

- Sustaining current investment levels in the midst of a pipeline that is currently focused primarily upstream
- Diversifying investments and investors beyond US government and Gates
- When the next efficacy trial for a vaccine or bNAb does begin, it will take place in a very different context:
  - Where to conduct it – geographically and by population
  - How to design it in the context of PrEP choice, including possibly two ARV injectables in the market
  - What will we be testing, and why – and how does the TPP evolve
  - How much will it cost and who will pay
- Will industry come back to the funding table? And, if not, who will make the products we need in the future?
Key Advocacy – Then & Now

HIV Vaccine Research: Building on Lessons from COVID-19

1. Sufficient and diversified research funding
2. Enhanced global coordination and collaboration
3. Support for research innovation and novel trial designs
4. Strengthened political commitment and urgency
5. Placing communities at the center of vaccine research
6. Planning early for success and equitable access
Key Advocacy – Then & Now

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HIV Vaccines in 2022: Where to from here?

HIV vaccines in 2022: where to from here?

Stacey Hannah¹, Kundai Chinyenze²,³, Robin Shatlock³,³, Ntando Yola⁴,⁵ and Mitchell Warren³,³

While almost four decades of research have yet to deliver a licensed HIV vaccine, they have been an engine of discovery, providing vaccine know-how, technology, clinical trial network and site infrastructure, researchers and advocates that galvanized the development of multiple COVID-19 vaccines in record time. SARS-CoV-2 proved to be a far easier vaccine target than HIV, but even so, the response to COVID-19 has shown that timelines can be compressed and new technologies can be developed, tested and distributed quickly—at least for wealthier nations. The field must face the challenges ahead with honest reflection, innovation, speed and clarity. The field must confront what it has learned—and not learned—from the science to-date, and generate new hypotheses, fresh ideas and novel strategies to what is tested, and how. And when an HIV vaccine is finally licensed, the most important work begins—delivering it with equity, confidence and trust.

FROM THE LAB TO THE JAB

A series of advocate’s guides

Vaccine Research and Development: Key Lessons and Ways Forward

Vaccine Access: What’s Working and What’s Next

mRNA Technology: What It Might Mean for Future Vaccines

Local Vaccine Production: Harnessing Its Potential for Equity

All four briefs can be found at avac.org/FromLabToJab
Thank You!

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https://www.hivresourcetracking.org/