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

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Happy Anniversary

POLICY FORUM

MEDICINE

27 JUNE 2003

The Need for a Global HIV Vaccine Enterprise

Richard D. Klausner, Anthony S. Fauci, Lawrence Corey, Gary J. Nabel, Helene Gayle, Seth Berkley, Barton F. Haynes, David Baltimore, Chris Collins, R. Gordon Douglas, Jose Esparza, Donald P. Francis, N. K. Ganguly, Julie Louise Gerberding, Margaret I. Johnston, Michel D. Kazatchkine, Andrew J. McMichael, Malegapuru W. Makgoba, Giuseppe Pantaleo, Peter Piot, Yiming Shao, Edmund Tramont, Harold Varmus, Judith N. Wasserheit

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.

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Resource Tracking

- 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

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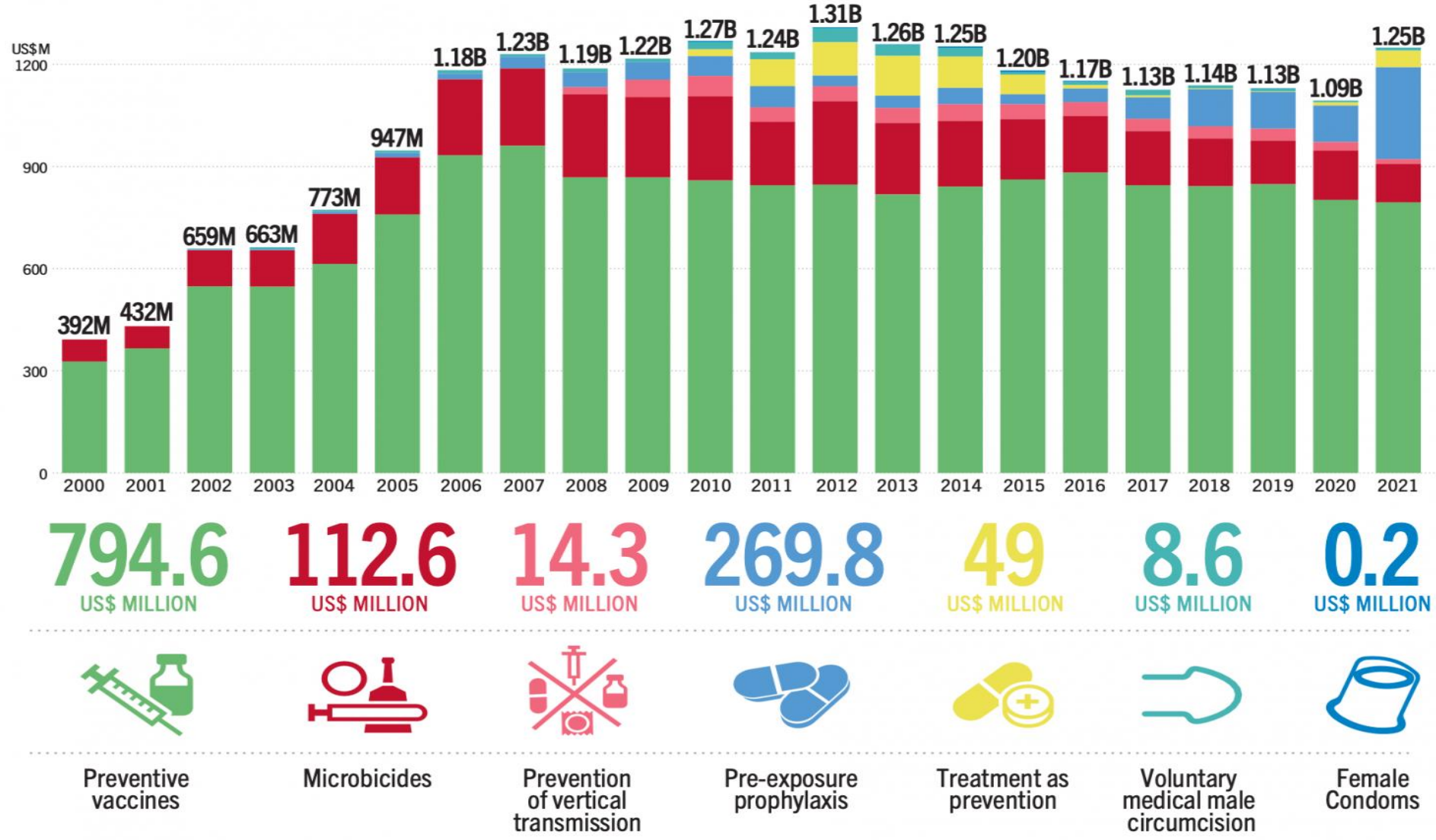
The Money Overall

Global HIV Px R&D Investment by Tech: 2000-2021 in US$ millions



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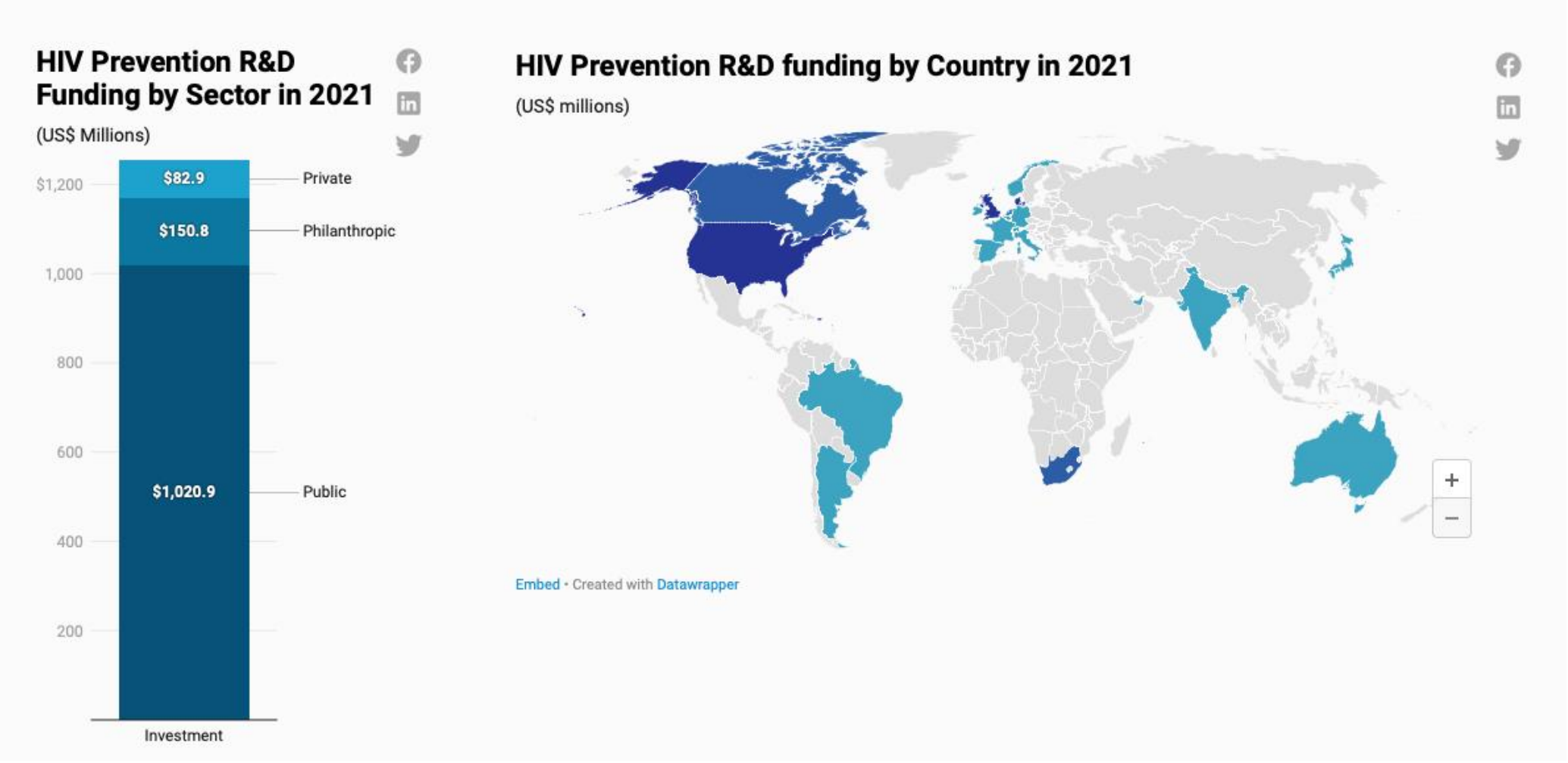
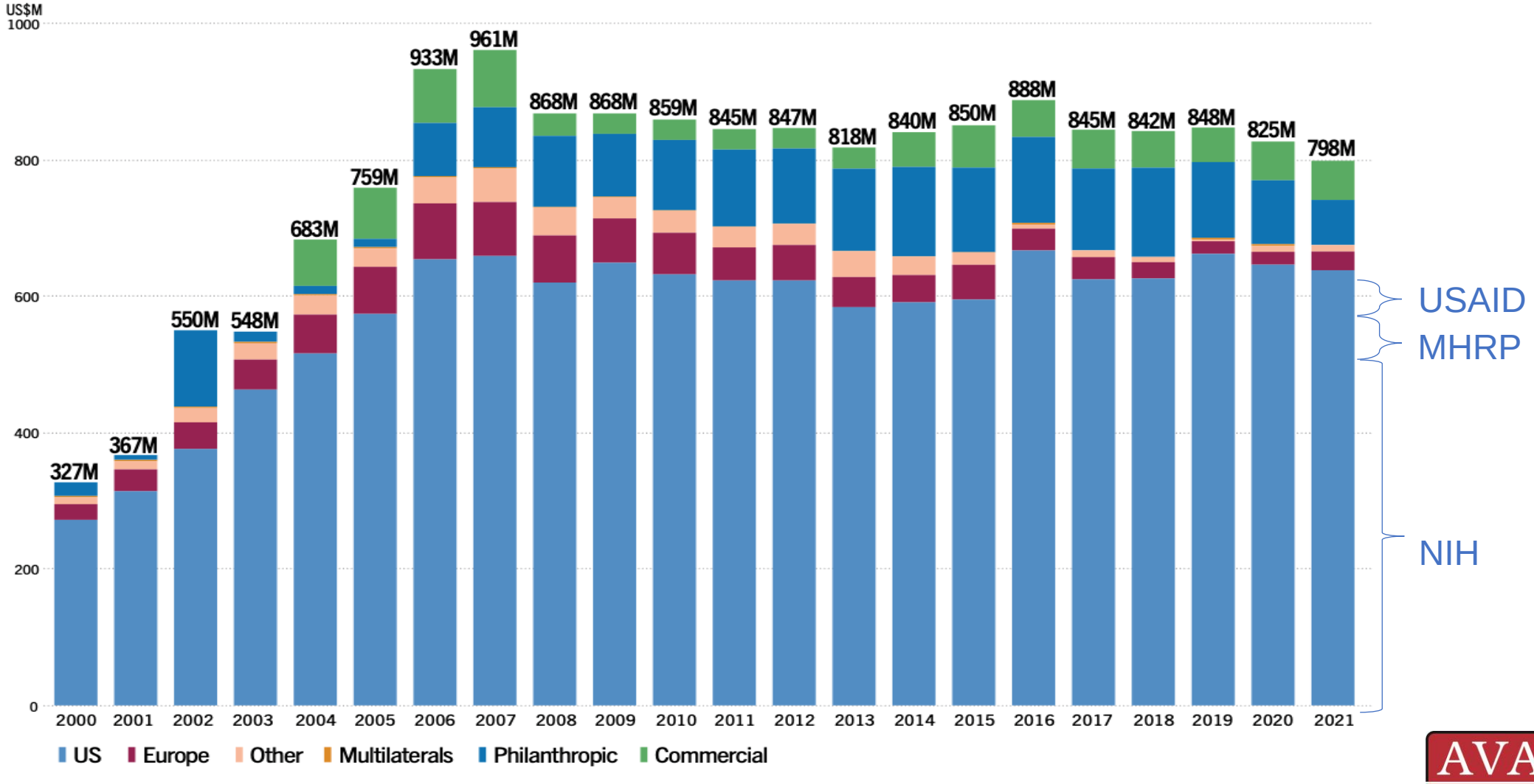
The Money Overall in 2021



HIV Vaccine Funding Trends Over Time

2000-2021 in US$ millions



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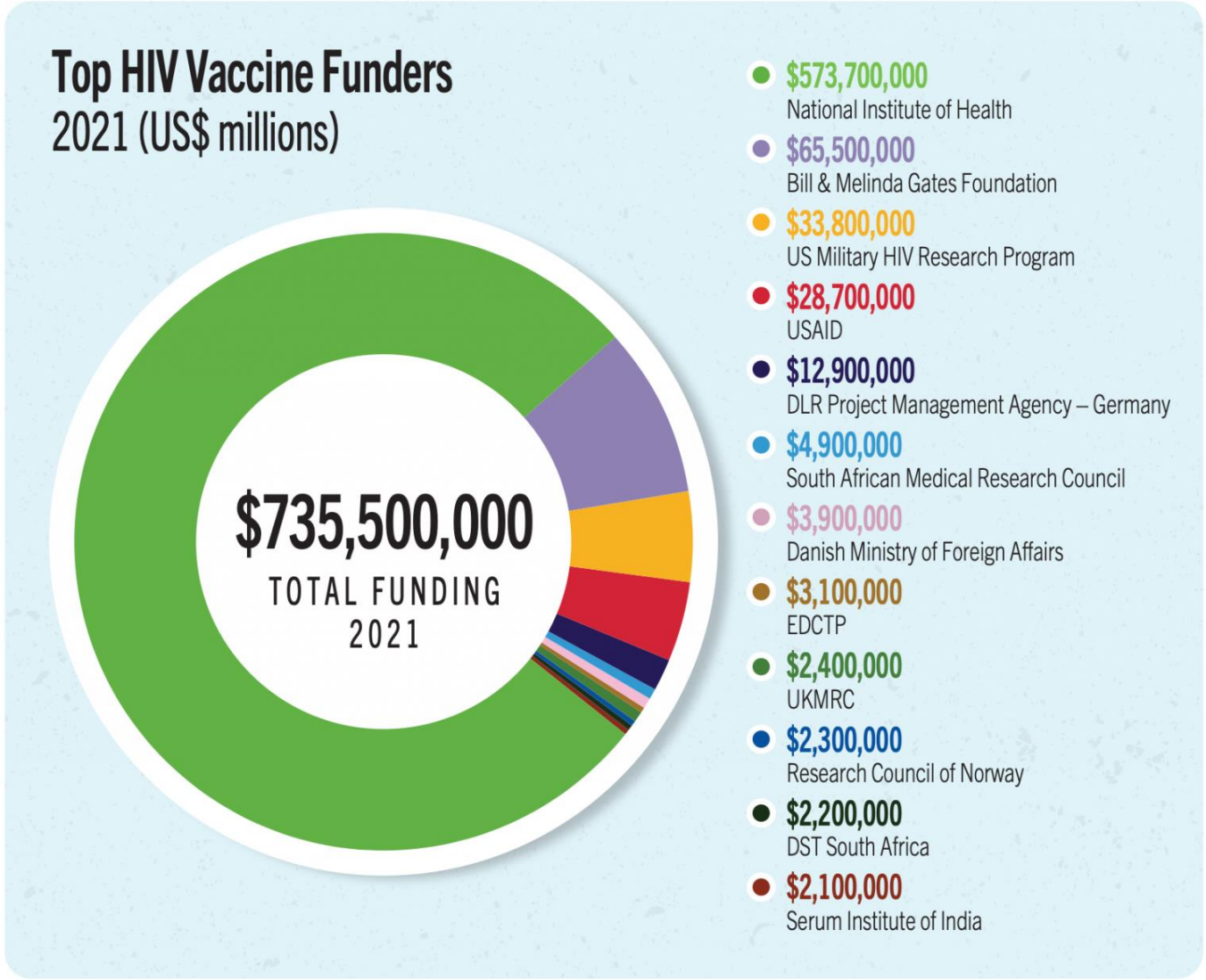
HIV Vaccine ”League Table”

2021 in US$ millions, excluding commercial investments



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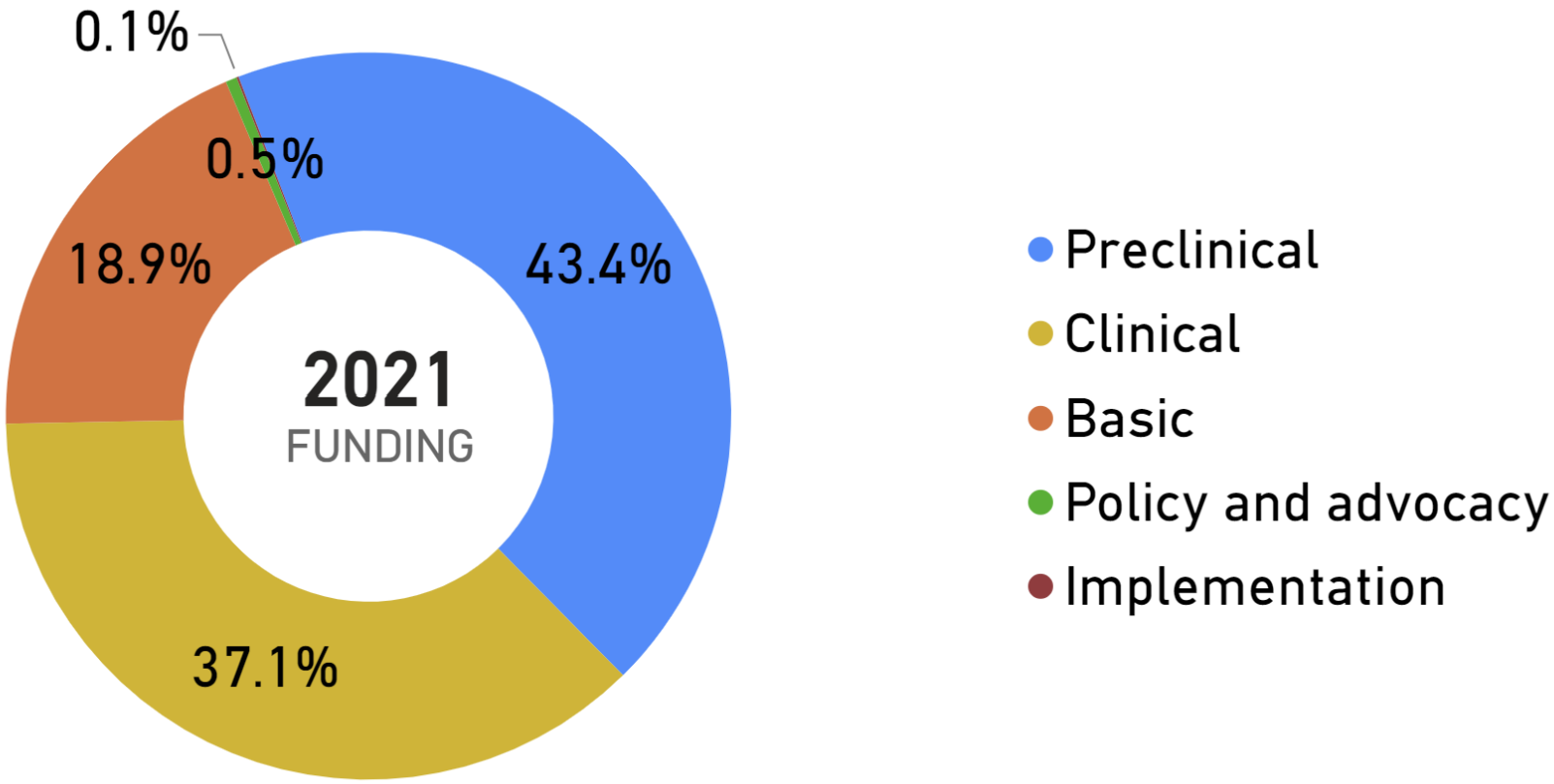
HIV Vaccine Investments 2021

By Research Stage



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But Context Matters

Two Positive Efficacy Signals Over Twenty Years

Yr End	Trial Name Product/Clade	Location	#	Result
2003	**VAX004,** AIDSVAX B/B	Canada, Netherlands, Puerto Rico, US	5,417	No effect
2003	**VAX003,** AIDSVAX, B/E	Thailand	2,546	No effect
2007	**STEP,** MRK-Ad5, B	Australia, Brazil, Canada, Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico, US	3,000	Immunizations halted early for futility; subsequent data analysis found potential for increased HIV risk among Ad5-seropositive, uncircumcised men
2007	**Phambili,** MRK-Ad5, B	South Africa	801	Immunizations halted based on Step result
2009	**Thai Prime-Boost/RV 144,** ALVAC-AIDSVAX, B/E	Thailand	16,402	Modest effect (31.2%)
2013	**HVTN 505,** DNA+Ad5, A/B/C	US	2,500	Stopped early for futility; vaccine regimen did not prevent HIV infection nor reduce viral load
2020	**Uhambo/HVTN 702,** ALVAC/gp120 MF59 boost	South Africa	5,400	Stopped early for futility
2021	**Imbokodo/HVTN705,** Ad26 Mosaic/gp140 clade C boost	Malawi, Mozambique, South Africa, Zambia, Zimbabwe	2,600	No efficacy
2021	**AMP Studies**, VRC01 monoclonal antibody	Botswana, Kenya, Malawi, Mozambique, Republic of South Africa, Tanzania, Zimbabwe US, Brazil, Peru, Switzerland	1,924 2,699	Did not reduce risk overall, but VRC01 did reduce risk of acquisition in small subset of HIV strains classified as “highly sensitive” to VRC01
2023	**Mosaico/HVTN706,** Ad26 Mosaic/gp140 mosaic boost	Argentina, Brazil, Italy, Mexico, Peru, Poland, Puerto Rico, Spain and US	3,900	No efficacy

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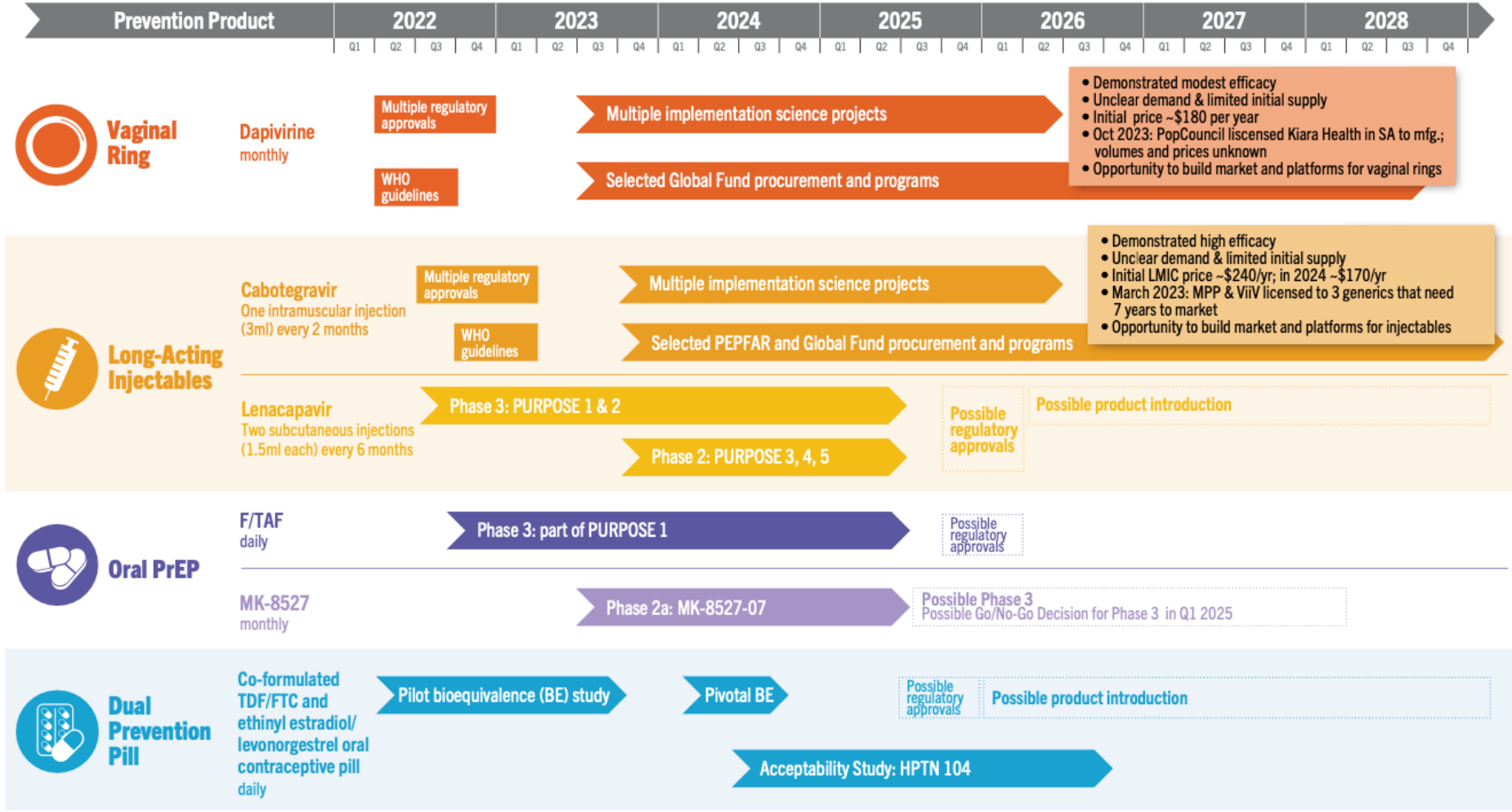
But Context Matters

A shifting pipeline – all upstream



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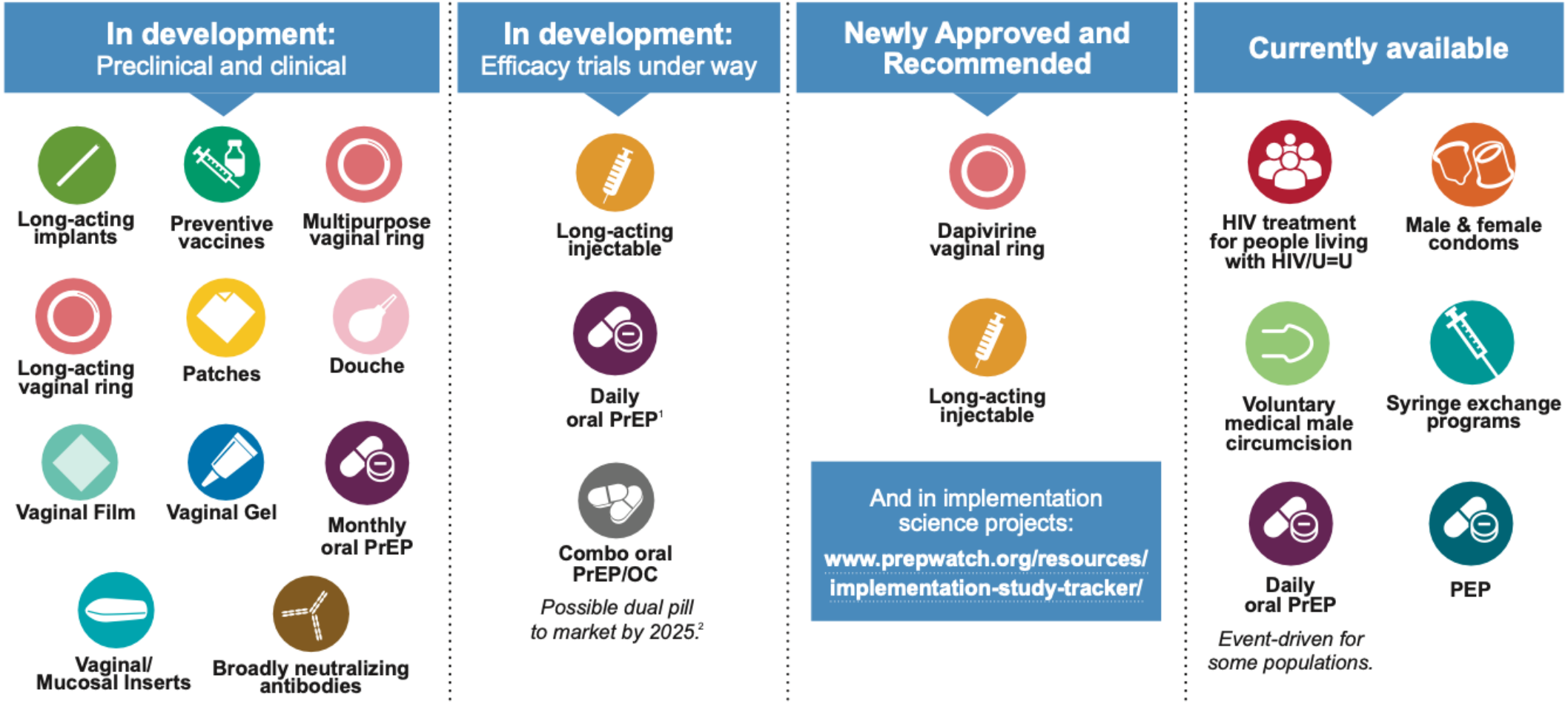

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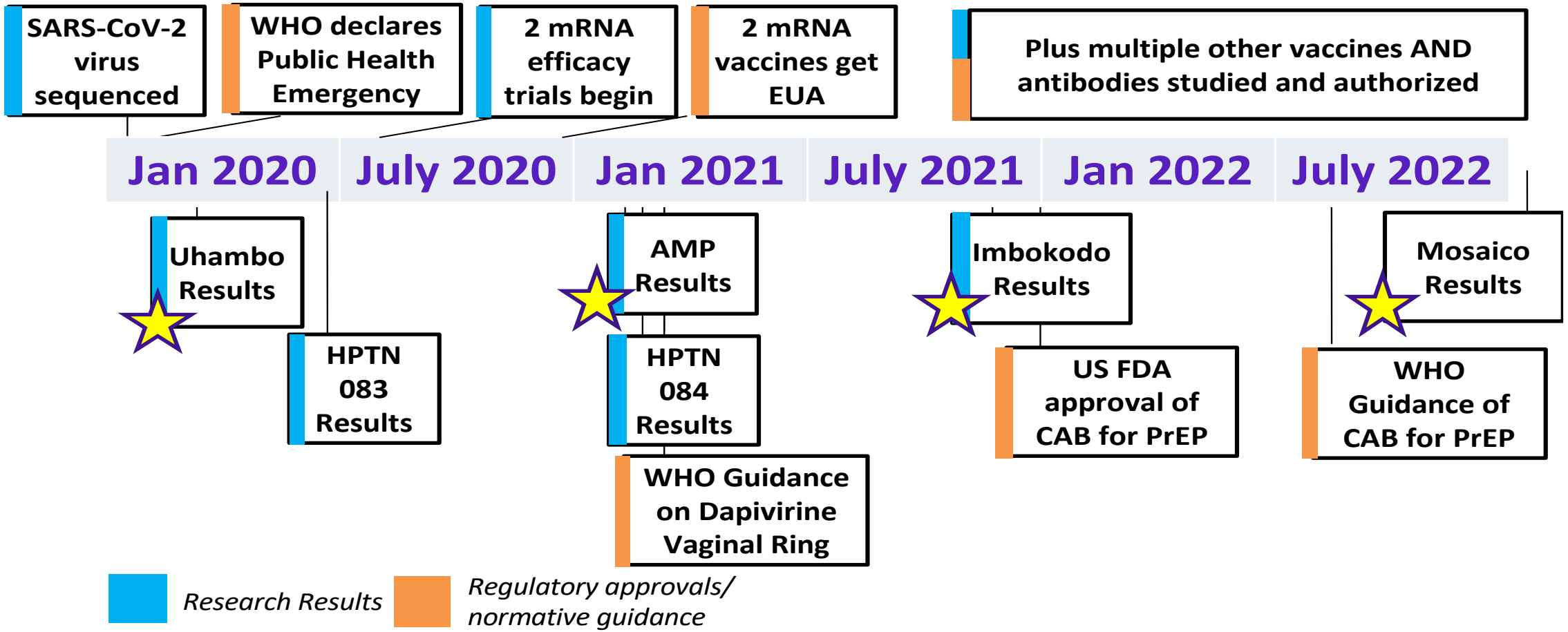
Different pandemics; different vaccine developments



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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

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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?

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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

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HIV Vaccine Research: Building on Lessons from COVID-19 – and from 20 Years of the Enterprise

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HIV Vaccines in 2022: Where to from here?

Hannah S et al. *Journal of the International AIDS Society* 2022, **25**:e25923
http://onlinelibrary.wiley.com/doi/10.1002/jia2.25923/full | https://doi.org/10.1002/jia2.25923

JIAS
JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

VIEWPOINT

HIV vaccines in 2022: where to from here?

Stacey Hannah[1,#], Kundai Chinyenze[2,#], Robin Shattock[3,#], Ntando Yola[4,#] and Mitchell Warren[1,§]

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.

https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25923

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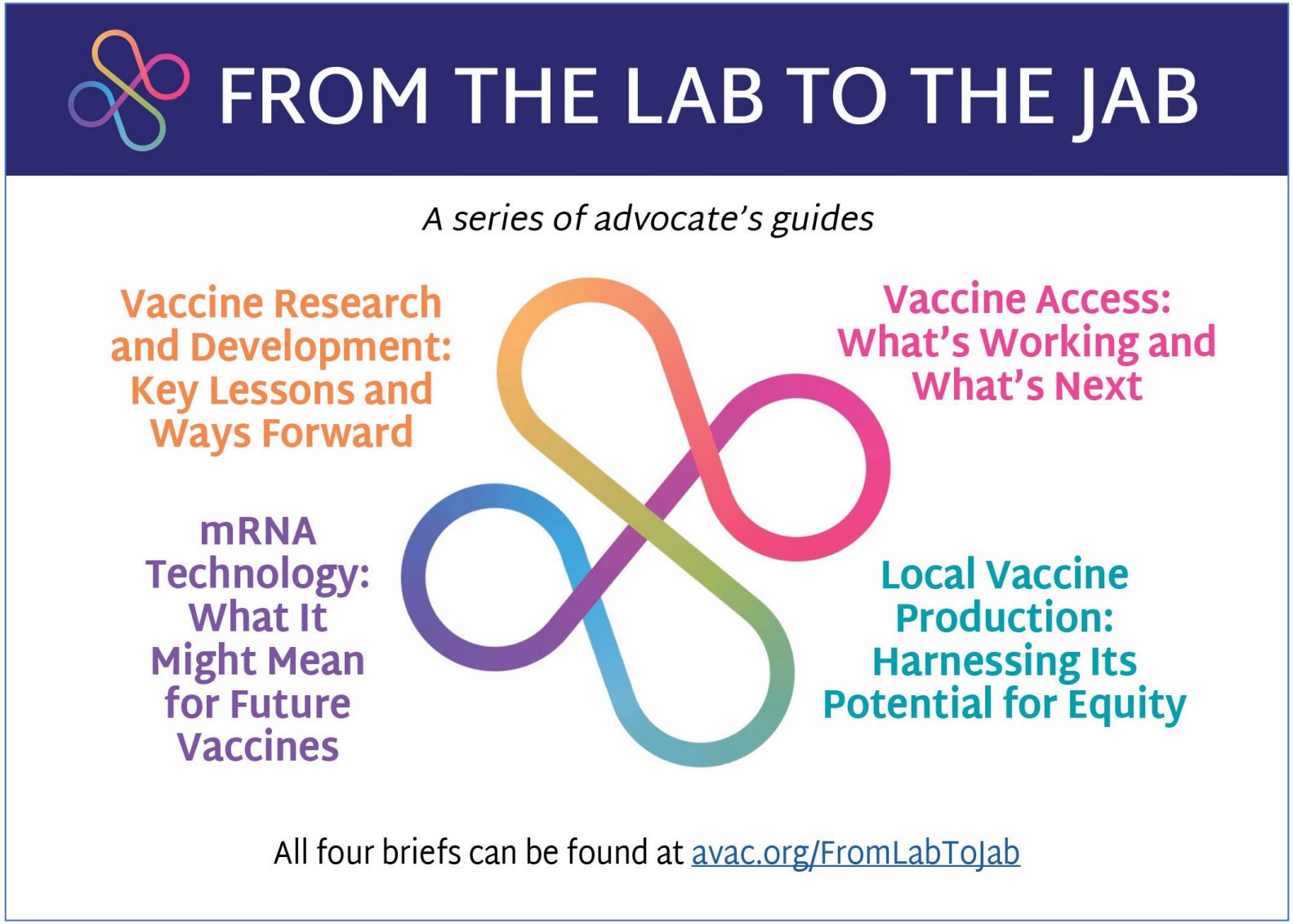
From the Lab to the Jab



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Thank You!

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https://www.hivresourcetracking.org/

Coalition to Accelerate and Support Prevention Research (CASPR)

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