HIV Research & Development at Risk

Tracking the Impact of US Funding Cuts

May 2025



Introduction

Tracking the impact of US Government cuts on HIV R&D, with a focus on biomedical prevention

- This document analyzes of the impact of US Government funding cuts, terminated projects, and other policy changes on HIV research starting in January 2025
- Since January 2025, USAID funding has been abruptly halted across the agency; for HIV research, putting the future of vaccines, bNAbs, and new PrEP modalities at risk
- NIH research cuts have focused (initially) on diversity, equity, inclusion (DEI), gender ideology, vaccine hesitancy and climate with an increased emphasis on "America First" priorities, and pauses in international research, impacting funding for HIVfocused projects
- The President's proposed US Fiscal Year 2026 budget to begin Oct 1 includes even more sweeping rollbacks to R&D – and not clear how Congress will respond
- This report will be updated to track ongoing cuts and shifts to this work, and to highlight their implications on the HIV response



Tracking US funding Cuts for HIV R&D

Report outline

- NIH: Major retrenchment
- DAIDS Networks: In flux
- HIV Prevention Pipeline: People's Research Agenda in Crisis
- USAID: Dismantled
- Country-level collateral
- Potential impacts
- Now what?
- Resources



Research Under Assault

Trump plans \$18B NIH budget cut, wants 27 centers consolidated into 5

Trump Administration Slashes Research Into L.G.B.T.Q. Health

Nearly half of the N.I.H. grants canceled through early May together worth more than \$800 million — addressed the health of sexual and gender minority groups, The Times found.

Overseas grants could be 'closed down' by NIH under new policy, internal email suggests

Top agency official directs sweeping review of grants with a foreign component

'Borders on the insane': New NIH policy on funding foreign scientists stirs outrage

Agency will make researchers outside United States seek grants of their own rather than "subawards" from U.S. scientists



HIV Vaccine Research Decimated

Breaking News, May 30, 2025

Trump Administration Ends Program Critical to Search for an H.I.V. Vaccine

The termination is the latest in a series of cuts to H.I.V. research

and programs to prevent the disease.

'Devastating': NIH cancels future funding plans for HIV vaccine consortia

May 30, 2025

Researchers decry agency's decision just as new leads reinvigorate search for long-sought vaccine

The Trump administration has dealt a sharp blow to work on H.I.V.

vaccines, terminating a <u>\$258 million program</u> whose work was

instrumental to the search for a vaccine.

Trump administration ending multiple HIV vaccine studies, scientists and officials say



Research Under Assault

- "Pause"/ban on international research
- LGBTQ study terminations
- Cap on indirects
- Changes in review process
- Major staff reductions and forced reassignments
- May 30, 2025: NIH cuts the two Consortia for HIV/AIDS Vaccine Development (CHAVD) — the main drivers of upstream HIV vaccine design



HIV Prevention: People's Research Agenda

Launched in 2024 to amplify advocates' priorities for prevention research



- Provides a clear, concise and collaboratively developed set of priorities for how prevention research should be conducted and what products should be developed
- A living document and tool for communities to amplify priorities in real time, to hold those with most decision-making power accountable
- Reference for funders, product developers and policy leaders to use as crucial decisions are made about what to invest in, where and why
- USG cuts bring "People's Research Agenda in Crisis" outlined priorities are all under threat; potential for irrevocable damage to critical aspects of research, choice, access

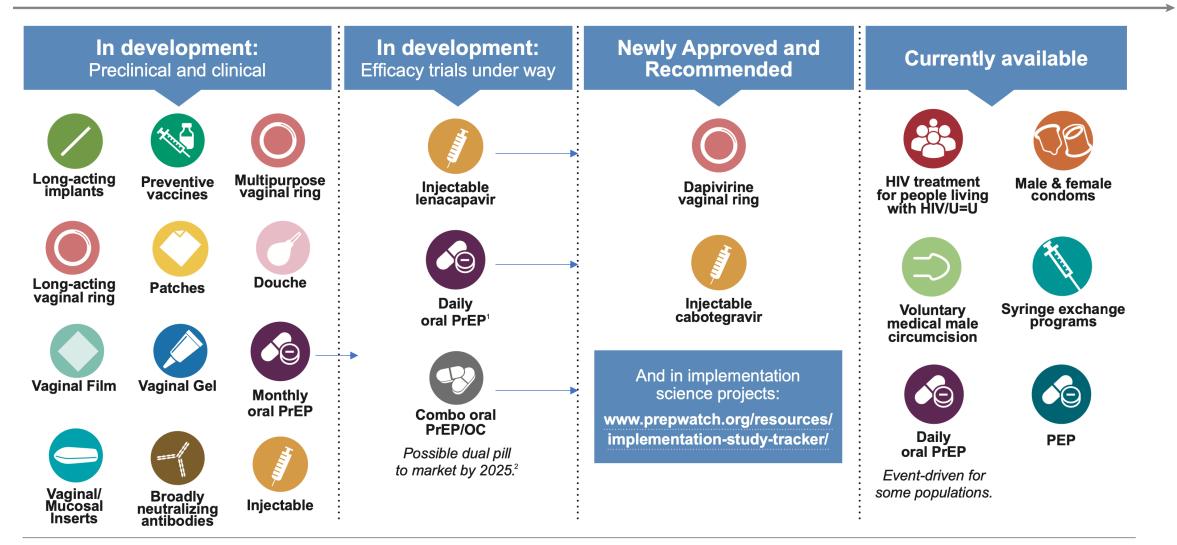
https://avac.org/peoples-research-agenda/

PRA: Key Messages at 2024 Launch

- Any product approaching efficacy trials cannot move forward without a clear access plan in place; trials must be conducted in parallel with considerations for access, pricing, and manufacturing
- New products should balance filling a gap in the toolbox with additions to existing products that make them more accessible and streamline uptake (e.g., both longer and shorter intervals of dosing; MPTs; novel formulations, mechanisms of action and/or delivery systems)
- Product development should move forward with greater focus and investment in social and behavioral science and being mindful of structural barriers such as stigma and discrimination
- Field needs realistic Target Product Profiles (TPPs) for all product categories
- There is excitement among advocates about the promise of MPTs, but regulatory pathway brings significant complexity
- Significant time and energy across stakeholders should rightfully continue to be placed into making newly efficacious products accessible



Overview of Biomedical Px Pipeline (pre-2025)





PRA in Crisis: Impact of USAID & NIH Cuts

In development: In development: Newly Approved and **Currently available** Efficacy & IS trials under way Recommended Preclinical and clinical USAID cancelled funding Introduction of Cuts to USAID's NIH and USAID Long-actfor pre-clinical and urpose promising new PEPFAR funding terminated HIV clinical trials, stunting for people living with H for-prevention products in implementation critical early progress on development and products and science and Long multiple upstream HIV newly approved is at programs may acceptability studies prevention products risk if USAID does not which could impact impact access to and ciravailable products, honor procurement product introduction Vaginal NIH terminated HIV they commitments and but the extent is vaccine research, not yet known fund prevention PrEP/OC including research on programs Daily Possible dual pill vaccine candidates and to market by 2025? Event-driven for **bNAbs**



NIH: Major Retrenchment

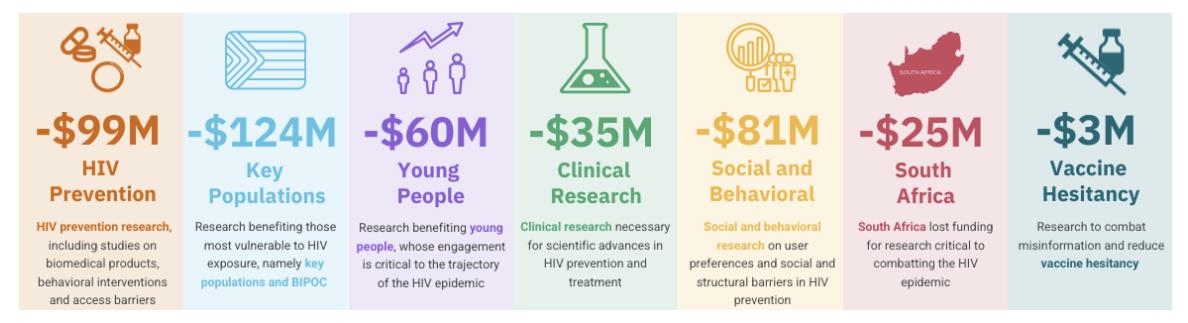
Top-line cuts

- Thousands of NIH grants terminated as of May 2025
 - 191 HIV-related grants terminated, worth over ~\$200M
 - Primary topics for NIH grant termination: DEI, "gender ideology", sexual minorities, vaccine hesitancy, mRNA vaccines, and South Africa
- No inclusion of subawards to ANY international partners and awards to be handled directly by NIH – new policy coming Sept 30
- NIH's workforce to be cut by 1,200-1,300 staffers
 - Including leaders of NIAID, NIAID's Division of Microbiology and Infectious Diseases, Fogarty International Center, chief bioethicist
- President's "skinny" budget for fiscal year 2026 would codify another 40% reduction, or \$18B in funding, plus \$3.6B for CDC and \$5.2B for NSF



The Cost of Cutting HIV Research

NIH terminated 191 HIV-specific grants in 2025, slashing over \$200 million from key HIV prevention research grants¹

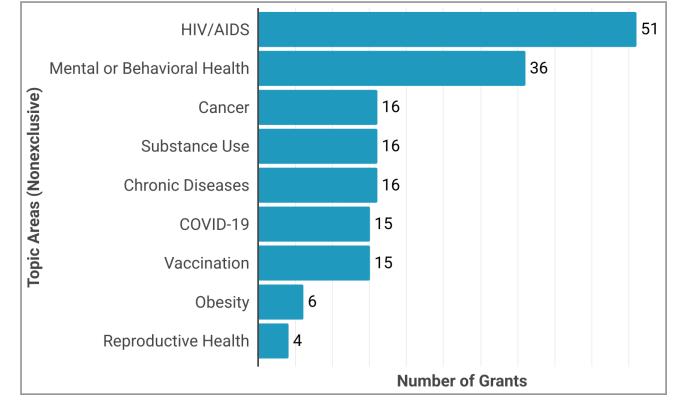


¹Grants may cover more than one research area, so total across categories shown here exceeds \$200 million in total funding lost



NIH: Cuts to Clinical Trials

- Total NIH termination of grants—unprecedented in history of agency
 - \$19B lost funding =777 terminated grants
 - \$643M = 113 active
 clinical trials
 terminated
 - 56% (\$~360M) of
 terminated clinical
 trials related to HIV



Terminated NIH Grants with Active Clinical Trials

Source: Association of American Medical Colleges



HIV/AIDS Clinical Trials Networks

Details on major clinical trials networks

- 30% of funding withheld from semi-annual Notice of Awards for NIAID's DAIDS-funded trial networks (HPTN, HVTN, ACTG, IMPAACT)
 - ~\$300M per year to networks = ~ \$90M cut for just six months
 - Restricts funding for international research activities
- NICHD-funded Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) was halted in March
 - \$18M cut with immediate effect
 - ATN led pioneering work on HIV prevention and treatment interventions for adolescents and young adults



USAID HIV Research Project Terminations

Tracking the impact of stop-work orders on HIV prevention R&D

- Since January 2025, withdrawal of USAID funding has halted HIV clinical trials, implementation science and the rollout of new prevention options
- Public records of projects receiving funding from USAID have been erased
- Terminations (details on next slide):
 - Promising preclinical HIV vaccine research, including mRNA-based candidates (ADVANCE project, ~\$32M/yr)
 - Early-stage, African-led HIV vaccine R&D (BRILLIANT consortium, ~\$9M/yr)
 - Next-generation, user-centered PrEP (MATRIX consortium, ~\$25M/yr)
 - Implementation science on delivering multiple PrEP options (MOSAIC project, ~\$17M/yr)



USAID HIV Research Project Terminations: Details

Project	Product(s)	Туре	Country(ries)	# of participants
Advancing R&D of Innovative HIV Prevention Products for Women	TAF/EVG Fast-dissolving insert	MATRIX-001 Phase 1 safety and acceptability	Kenya, South Africa, USA	60
	 One month dapivirine vaginal film 	MATRIX-002 Safety, acceptability, usability of placebo	Kenya, South Africa, USA, Zimbabwe	100
	Non-ARV nonhormonal contraceptive multipurpose vaginal ring	MATRIX-003 Safety, acceptability, usability of placebo	South Africa, USA, Zimbabwe	100
	Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	Cohort study of safety in mothers and babies exposed to ARV-based prevention	Kenya, Lesotho, Zimbabwe	500-800
	One-month dapivirine vaginal film plus levonorgestrel (LNG)	Preclinical study	USA	Preclinical
BRILLI PRI SU	BG505 GT1.1 and 426c.Mod. Core-C4b	B-001 Phase 1 clinical trial	Kenya, South Africa, Uganda	48
	Polyvalent HIV-SET saMRNA vaccine clinical program	Pre-clinical and clinical trials	Multiple African countries	Exploratory
	CAP 256 based mRNA vaccine candidates incl Africa-based mRNA manufacturing	Development program	Multiple African countries	Exploratory
	Multiple founder virus-based vaccines	Exploratory program	Multiple African countries	Exploratory
	Tech-transfer activities in Uganda with SOSIP trimers	Technology transfer	Uganda	Exploratory
ADVANCE	Mosaic Trimers: MOS1SIP, MOS2SIP, M3SIP8 and MPLA	Vaccine	Rwanda, Zambia	40
	Multisite Adolescent Girls and Young Women study	MAGY Epidemiological study	Uganda, Zambia, Kenya, South Africa	1,210
MOSAIC	 Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC 	CATALYST Implementation Science Study	Kenya, Lesotho, South Africa, Uganda, Zimbabwe	7,500
	Injectable CAB, Dapivirine	Policy and progammatic support, including user-centered research and technical assistance	Bostwana, Eswatini, Kenya, Lesotho, Namibia, South Africa, Uganda, Zambia, Zimbabwe	Community- based
	Dapivirine Vaginal Ring, Oral	Increasing PrEP Options for Women in Eswatini	Eswatini	400
CASPR COLITION TO ACCELERATE & SUPPORT PREVENTION RESEARCH	PrEP, vaccines and multipurpose technologies	Research translation and preparedness, policy support and advocacy to support prevention research	Kenya, Lesotho, Malawi, Nigeria, South Africa, Uganda, Zambia, Zimbabwe	Community- based



Potential Fallout from Cuts to HIV Prevention

Impacts on trials sponsored by non-USG funders

- USG funding is the scaffold on which pharma, philanthropies and other governments invest in transformative HIV & TB science
- Trials sponsored by other research funders build on top of core and other funding provided to clinical trials units and research sites through NIH awards
- USG cuts risk infrastructure, staff/talent, training the next generation of scientists, community engagement, data sharing, biorepositories, etc.
- If South African and other international study sites and participants are excluded from enrollment, follow-up, study completion, and data collection and analysis, ongoing and planned trials are likely underpowered to produce meaningful results, wasting years of work and tens or hundreds millions of dollars
- Trials no longer able to enroll internationally will face delays and increased costs as they seek new sites and study participants elsewhere

Treatment Action Group



Now what?

Action to prevent further harm and continue funding for HIV R&D

- Lawsuits against NIH & USAID
- Advocacy directed at US Congress
 - Monitor, advocate, and activate national and local political action around Fiscal Year 2026 US Budget
- Monitor DAIDS network funding and renewal after 2026
- Advocacy with national governments
 - Potential domestic resources to maintain scientific infrastructure
 - Ensure ethical follow-up with clinical trial participants
 - Adapt People's Research Agenda to develop national priorities and accountability mechanisms



Further resources

- People's Research Agenda, AVAC
- <u>Science in the Crosshairs: Research Advocacy in a Time of Crisis</u>, The Choice Agenda webinar recording, slides and resources
- The Best Investment You Didn't Know You Made: How NIH Funding Fuels Innovation and Economic Growth, amfAR
- Quick Take: HIV Research Matters for America, amfAR & O'Neill Institute
- Impact of NIH Grant Terminations, Association of American Medical Colleges
- Research Matters Advocacy Toolkit, AVAC, TAG, HIVMA
- <u>NIH halts more collaborations with South Africa on HIV/AIDS trials</u>, Science
- We do the sums: The NIH funds \$350-million (R6.65-billion) of research in SA, Bhekisisa
- Inside the Bloodbath at the NIH, The Nation
- Weekly <u>Global Health Watch</u>, AVAC

