

The Current Landscape of HIV Cure-Related Research and Challenges

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HIV cure: Clinical research considerations and strategies
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HIV cure-related clinical research

- Since 2014, Treatment Action Group (TAG) has maintained a listing of HIV cure-related clinical trials and observational studies:

<https://www.treatmentactiongroup.org/cure/trials/>

- Information mainly drawn from clinical trial registries:

<https://clinicaltrials.gov/> and others internationally

(<https://trialsearch.who.int/>)

Research Toward a Cure July 16, 2025

Table 1. Current Clinical Trials

Trial	Trial Registry Identifier(s)	Country location(s)	Sponsor(s)	Phase	Estimated End Date/Interim Results
ADOPTIVE IMMUNOTHERAPY					
AutoRESIST: HIV antigen-specific T-cells targeting conserved epitopes for treatment of HIV-associated lymphoma	NCT04975698 (closed to enrollment)	United States	Catherine Bollard, Children's Research Institute	Phase II	June 2026
AlloRESIST: Evaluate the safety, immunologic, and virologic responses of donor derived HIV-specific T-cells in HIV+ individuals following allogeneic bone marrow transplantation	NCT04248192 (closed to enrollment)	United States	Catherine Bollard, Children's Research Institute	Phase I	April 2026
ANALYTICAL TREATMENT INTERRUPTION					
Assessment of HIV remission in early treated individuals with the MHC B35/53Bw4TTC2 genotype	NCT05482854	France	ANRS	N/A	July 2025
SCOPE-ATI	NCT04359186	United States	UCSF	N/A	June 2026 APCS, 2025 Feb 20 AIDS Behav. 2024 Sep 17 , CROI 2024, Abstracts 446 , 482 Strategies for an HIV Cure 2023, Abstract PP64
Imaging and biopsy of people with HIV undergoing ATI	NCT05419024	United States	National Cancer Institute (NCI)	Phase II	August 2026 CROI 2024, Abstract 502 Strategies for an HIV Cure 2023, Abstract PP41 Front Med. 2022 Aug 22;9:979756 .

Entries shaded in light grey include analytical treatment interruptions (ATIs); in some cases, ATIs are only initiated if certain outcomes are achieved.

For the most up-to-date version, visit: <http://www.treatmentactiongroup.org/cure/trials>. Please send updates, corrections, or suggestions to Richard Jefferys at richard.jefferys@treatmentactiongroup.org

Newly registered studies by year



HIV cure-related studies, July 2025

- **Interventional**

- 84 trials (80 adult, 4 pediatric)

- 34 phase I, 14 phase I/II, 23 phase II, 1 phase II/III (early infant ART in Botswana), 1 phase III (acute infection treatment)

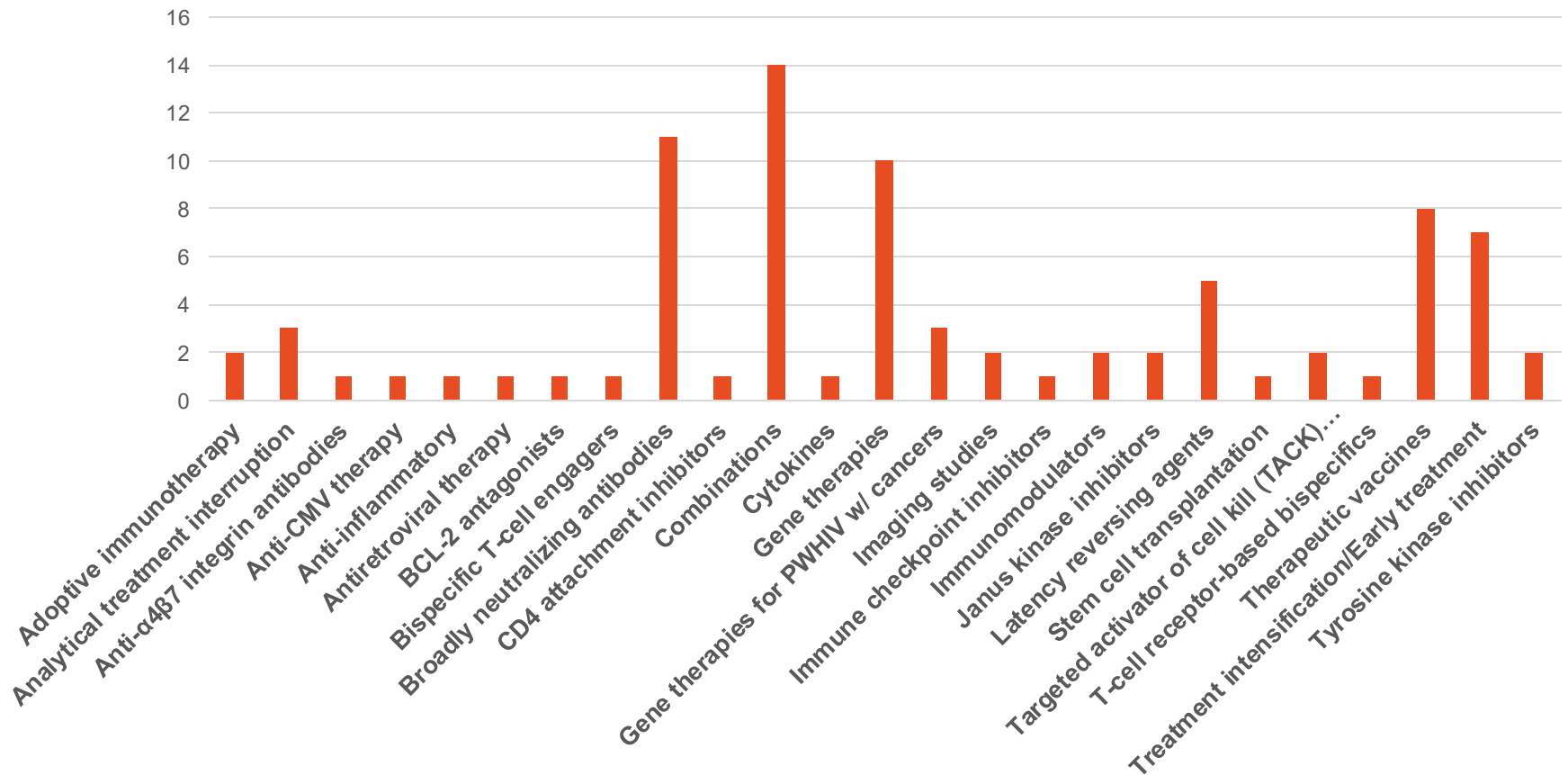
- **Observational**

- 41 studies (39 adult, 2 pediatric)

- **36 studies involve analytical treatment interruptions (ATIs)**

- In some cases, ATIs only initiated if certain parameters are met

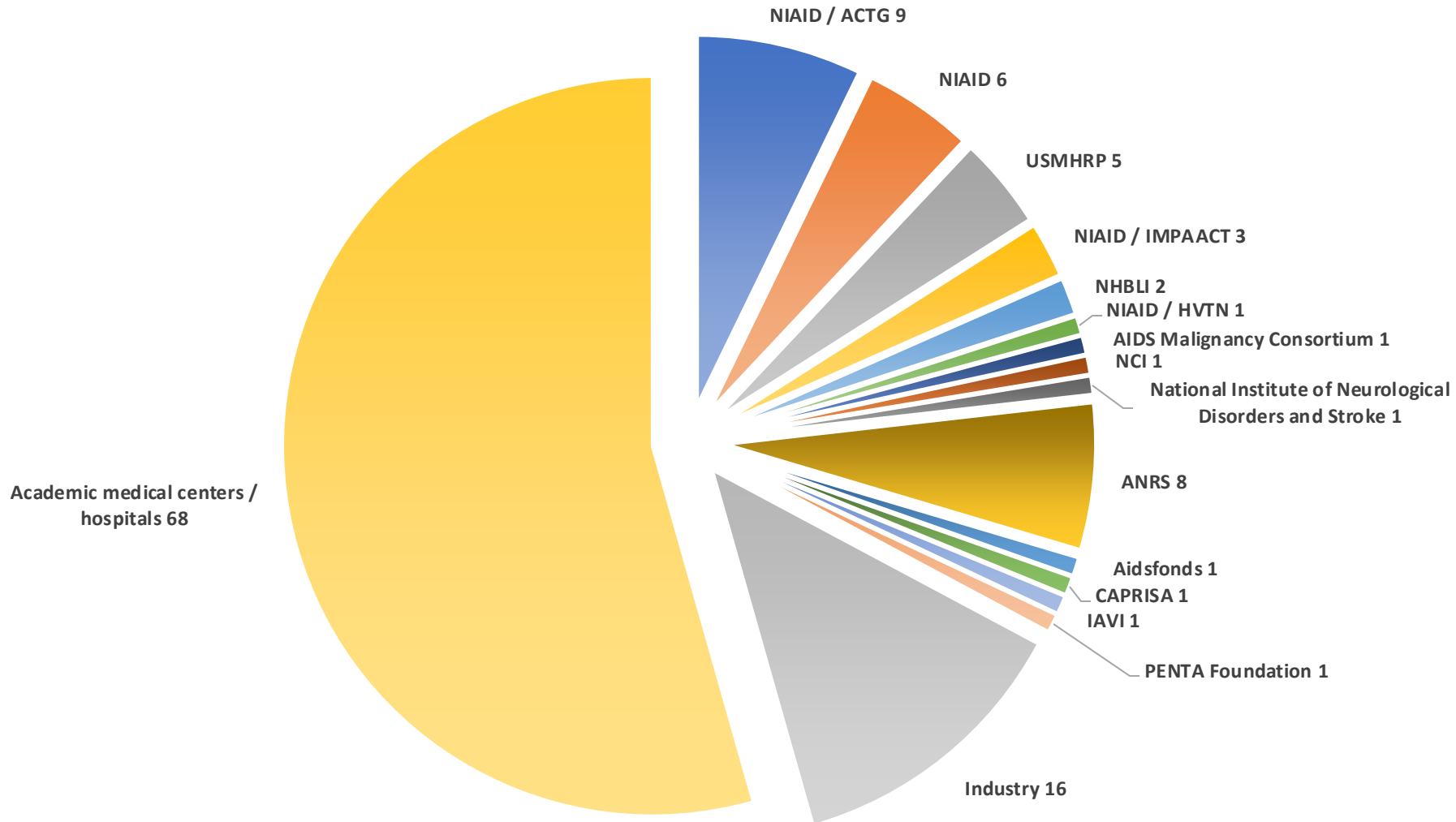
Types of interventions



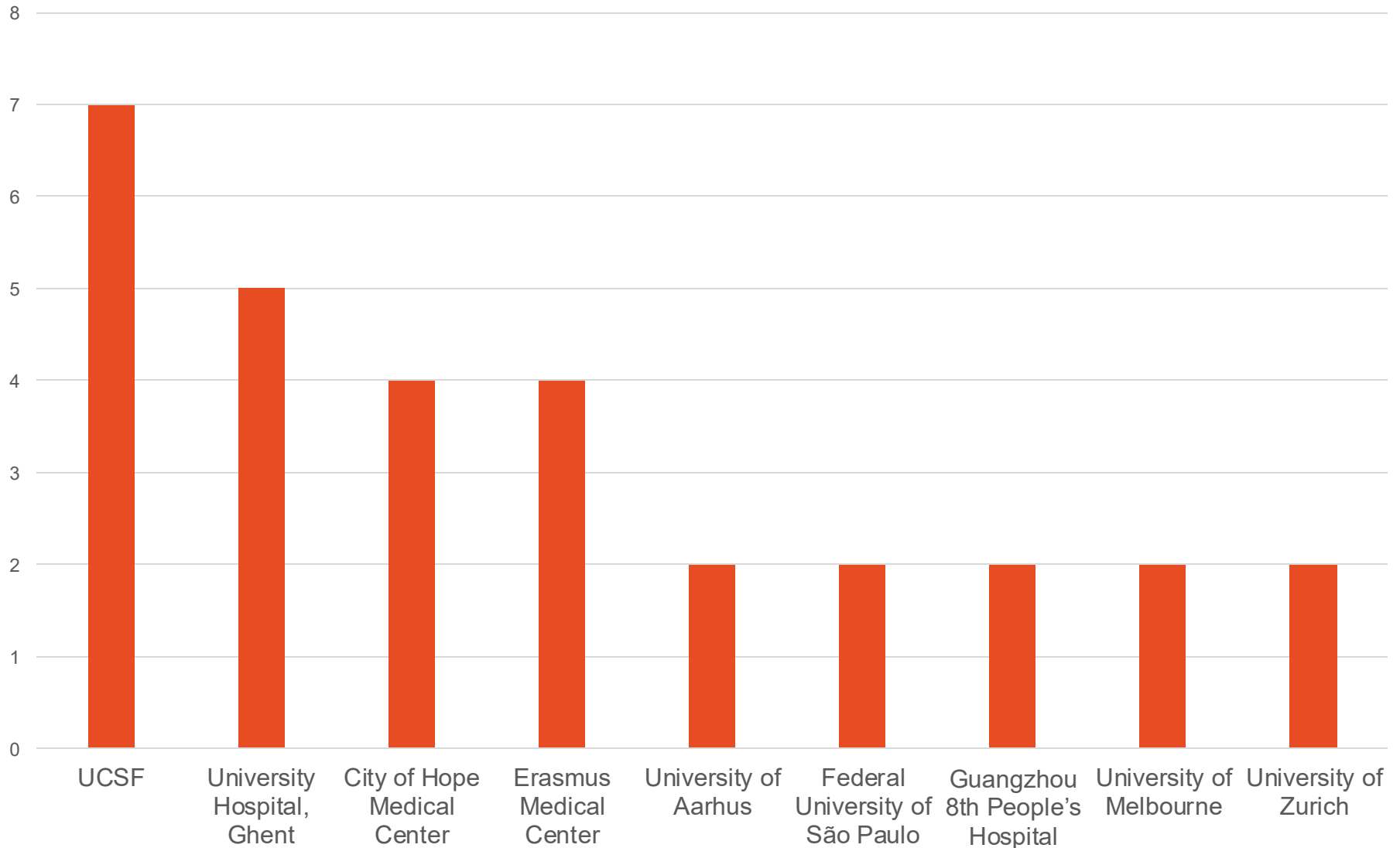
Types of interventions

- Adoptive immunotherapy – 2
- **Analytical treatment interruption – 3**
- **Anti- $\alpha 4\beta 7$ integrin antibodies – 1 (w/ATI)**
- Anti-CMV therapy – 1
- Anti-inflammatory – 1
- Antiretroviral therapy – 1
- Bcl-2 antagonists – 1
- Bispecific T-cell engagers - 1
- **Broadly neutralizing antibodies – 11 (8 w/ATI)**
- **Combinations – 14 (12 w/ATI)**
- CD4 attachment inhibitors - 1
- Cytokines – 1
- **Gene therapies – 10 (5 w/ATI)**
- **Gene therapies for PWHIV w/cancers – 3 (2 w/ATI)**
- Imaging studies – 2
- **Immune checkpoint inhibitors – 1 (w/ATI)**
- **Immunomodulators – 2 (1 w/ATI)**
- Janus kinase inhibitors – 2
- Latency-reversing agents – 5
- **Stem cell transplantation – 1 (w/ATI)**
- TACK molecules – 2
- **T-cell receptor-based bispecifics – 1 (w/ATI)**
- **Therapeutic vaccines – 8 (1 w/ATI)**
- Treatment intensification/early treatment – 7
- Tyrosine kinase inhibitors – 2

Primary sponsors (registry entries)



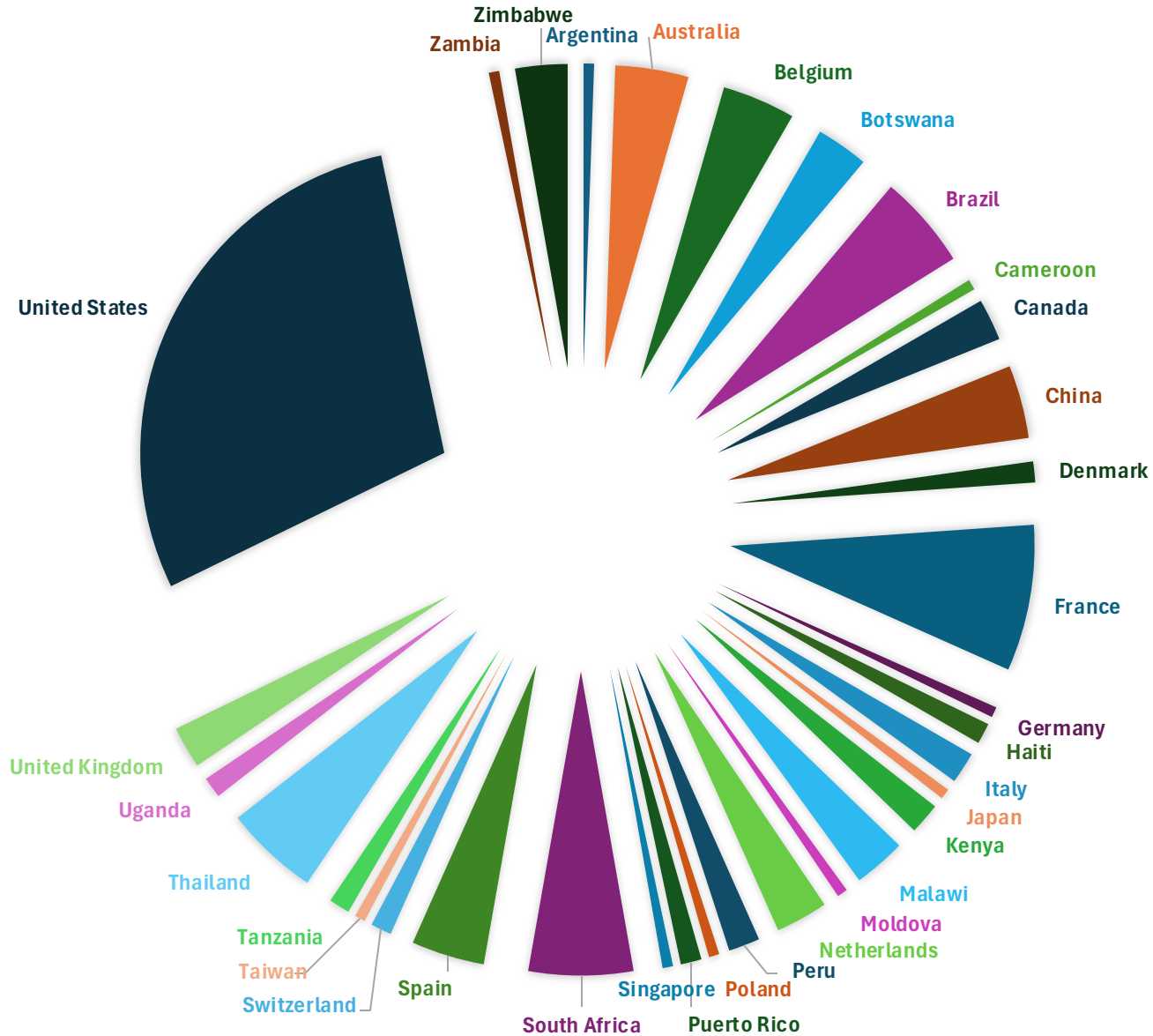
Academic centers (>1 study)



Industry sponsored

- AbbVie - 1
- American Gene Technologies International Inc. - 2
- Code Pharma - 1
- Excision BioTherapeutics - 1
- Gilead Sciences - 2
- Hookipa Biotech GmbH - 1
- Immunocore - 1
- Merck Sharp & Dohme LLC - 1
- Shenzhen Immuno Cure Biomedical Company Limited - 2
- UBP Greater China (Shanghai) Co., Ltd - 2
- ViiV Healthcare - 2

Study site locations



Study site locations, July 2025

- 179 country sites for the 125 studies
- 52 studies (41.6%) with sites in the US
- 47 (37.6%) Europe
- 34 (27.2%) African continent
- 26 (21%) Asia Pacific region
- 13 (10.4%) South America (9 Brazil)

Study participant demographics, 2018-February 2025

Total # of participants	7,792
Total from studies reporting sex and gender	7,682
Female	1,472 (19.2%)
Male	6,126 (79.7%)
Transgender women	35 (0.4%)
Transgender men	3 (0.04%)
Transgender (not identified)	3 (0.04%)*
Non-binary or gender non-conforming	12 (0.1%)**
Missing/not reported	36 (0.5%)
Total from studies reporting race/ethnicity	5,300
Asian	349 (6.6%)
Black	954 (18%)
Hispanic	388 (7.3%***)
White	3,262 (61.5%)
Native American/Native Hawaiian, American Indian/Alaskan Native	17 (0.3%)
Pacific Islander	2 (0.04%)
Indigenous Australian	1 (0.02%)
More than one race/ethnicity	168 (3.2%)
Other/unknown/not reported	331 (6.2%)

Early impacts of attack on science

- Funding for NIH-supported trial networks reduced and withheld
- Multiple ACTG HIV cure-related protocols paused
- Withholding of NIH funds to support research in South Africa and internationally
- Regression of research to US/Europe following a period of some geographic expansion

Effects on newly registered studies likely delayed

- # of additions to the TAG listing Feb-July 2024
 - Interventional: 10
 - Observational: 3
- # of additions to the TAG listing Feb-July 2025
 - Interventional: 11
 - Observational: 2

Acknowledgements

- Thanks to:
 - Treatment Action Group (TAG)
 - Support from the Foundation for AIDS & Immune Research (FAIR) and the Bill & Melinda Gates Foundation
 - Researchers and trial sponsors who take time to register their clinical studies in online registries, regardless of whether formally required
 - Researchers and trial sponsors who are diligent about reporting participant demographics