The HIV Research Scorecard
for Trans and Gender-Diverse Inclusivity

This tool is intended for use by both advocates and researchers when envisioning, designing, and/or grading clinical trials for meaningful trans and gender-diverse inclusivity.

BACKGROUND

This Scorecard tool synthesizes the visions put forth in the *No Data No More: Manifesto to Align HIV Prevention Research with Trans and Gender-Diverse Realities* (https://www.avac.org/no-data-nomore) into scorable indicators to help realize trans-inclusivity in clinical trials.

A review of 41 milestone HIV clinical trials implemented since 1991 reveals that only about one percent of the 178,893 participants in these pivotal HIV studies were reported as trans or gender-diverse (TGD). While underreporting is likely at play, this means that TGD communities are represented by only 2,532 individuals who have participated in major HIV studies—and been counted as trans or gender-diverse— since the beginning of the epidemic. Within this one percent, the vast majority of these underrepresented participants were transgender women, with little representation of trans men and gender nonbinary people. Furthermore, reporting TGD status in HIV research is a relatively new practice; the first trans study participant was not reported until 2007 in the iPrEx PrEP study. Using the Scorecard's 14 indicators and available documents from these 41 milestone clinical trials, only two studies scored an A, three studies scored a B, seven studies scored a C, five studies scored a D, and 24 studies (59%) scored zero points for an F. A detailed analysis of TGD representation in these 41 milestone HIV studies is forthcoming, but preliminary findings are available on the AVAC website (https://www.avac.org/choice-agenda).

Recent efforts to include TGD people in research are evident, but there is still a dearth of guidance and information on how to specifically design, select, conduct, and report on such studies. This Scorecard serves as a starting point. Researchers and advocates are encouraged to use the Scorecard in the design and implementation of future HIV studies to more accurately and meaningfully represent TGD communities in HIV research.

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Study Design

		YES 1 pt	NO/Not Available 0 pt
1.	Eligibility criteria explicitly include gender nonbinary individuals.		
2.	Eligibility criteria explicitly include transgender men.		
3.	Eligibility criteria explicitly include transgender women.		
4.	If gender nonbinary individuals, trans men, or trans women are not included, their exclusion is explicitly justified.		
5.	Specific and measurable goals are set for the enrollment of TGD participants, either in absolute numbers or as a percentage of total participants.		
6.	Gender-affirming hormone use is accounted for as a variable (e.g. in eligibility criteria, safety monitoring, efficacy, drug-drug interactions, etc.).		

Study Implementation

7.	TGD status is ascertained in data collection using best practices (e.g. DAIDS TGD Working Group[1] or similar).		
8.	Outreach, marketing, and recruitment strategies and materials clearly exemplify TGD eligibility and inclusion.		
9.	TGD staff are included among the core study team and/or among research site staff.		
10.	Sites selected to recruit for the study have proven experience working with TGD communities.		
11.	The study includes a community engagement plan that involves partnerships with organizations serving TGD communities to foster engagement.		

Study Reporting

12.	Participant TGD status is readily ascertained in study publications, presentations, and reporting using best practices (e.g. DAIDS TGD Working Group[1] or similar).		
13.	TGD-specific safety and efficacy analyses are reported in study findings.		

Language

14.	All study-related documents, outreach materials, and study-led communications adhere to best practices in gender-inclusive language as outlined in the *NIAID HIV Language Guide*[2].		

SCORE   TOTAL = [YES] [NO] = [ ]

A. 11-13 points   B. 8-10 points   C. 4-7 points   D. 1-3 points   F. 0 points

REFERENCES

[1]NIAID Division of AIDS Cross-Network Transgender and Gender-Diverse Working Group. *Data Collection: Gender Identity, Sex Assigned at Birth, Intersex Status, and Sexual Orientation.* Office of HIV/AIDS Network Coordination website. 2023. https://www.hanc.info/resources/sops-guidelines-resources/community.html#trans. Accessed October 22, 2024.

[2]NIAID. *NIAID HIV Language Guide*. NIAID website. 2024. https://www.niaid.nih.gov/research/hiv-language-guide. Accessed October 22, 2024.