

No Data No More: A Tool to End the Exclusion of Trans & Gender-Diverse People in HIV Research

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Background

✗ Transgender and gender-diverse (TGD) people face multiple forms of structural exclusion and neglect in the global HIV response.

📊 We sought to quantify the inclusion of TGD people in milestone HIV clinical trials over the course of the epidemic.

🔧 We also sought to devise a research and advocacy tool (Scorecard) to promote the meaningful inclusion of TGD people in future HIV research.

Methods

👥 Conducted consultations with global TGD stakeholders to create *No Data No More: Manifesto to Align HIV Prevention Research with TGD Realities*.

⚙️ Synthesized the Manifesto into 13 scoreable indicators to assess studies for TGD inclusivity.

🔍 Applied the Scorecard to 41 milestone HIV clinical trials conducted from 1991-2023 (protocols, clinicaltrials.gov, publications), including HIV treatment, ARV-based prevention, and vaccine/antibody studies.

An analysis of over 30 years of milestone HIV clinical trials confirms that **transgender and gender-diverse (TGD) people are severely underrepresented** in HIV research.

CLINICAL TRIAL SCORING TOOL

<h4>ELIGIBILITY</h4> <ul style="list-style-type: none"> Selection criteria include <i>trans women, trans men, and gender nonbinary participants, discretely</i>. (1 point) If no trans and gender-diverse participants are specified in the protocol, their exclusion is explicitly justified in the protocol and in the results reporting. (1 point) 	<h4>SYSTEMS</h4> <ul style="list-style-type: none"> Specified trans and gender-diverse enrollment goals—either in absolute numbers or percentage of participants. (1 point) Gender-identity status is assessed using a two-step method (Step 1: sex assigned at birth, Step 2: current gender identity). (1 point) Outreach, marketing, and recruitment strategies that clearly exemplify trans inclusion (or exclusion). (1 point) Trans and gender-diverse staff at research sites and/or as part of the core study team who reflect trial participants. (1 point) Trans-responsive site selection. Each study site has proven experience serving the population. (1 point) The core study team and/or study sites engage in partnerships to foster awareness and ownership with organizations serving trans and gender-diverse communities. (1 point)
<h4>REPORTING</h4> <ul style="list-style-type: none"> Participant characteristics are reported using the 2-step method such that sex assigned at birth and gender identity can be cross-referenced. (1 point) Trans-specific safety and efficacy results are reported (when possible). (1 point) If no trans and gender-diverse participants are reported in study results, their exclusion is explicitly acknowledged and, if possible, justified. (1 point) 	<h4>SCORING</h4> <ul style="list-style-type: none"> A 11-13 points B 8-10 points C 5-7 points D 2-4 points F 0-1 points
<h4>LANGUAGE</h4> <ul style="list-style-type: none"> Adheres to best practices as outlined in NIAID's <i>HIV Language Guide</i> (https://www.hptn.org/resources/HIVLanguageGuide). (1 point) 	<h4>GENDER-AFFIRMING HORMONE THERAPY</h4> <ul style="list-style-type: none"> Accounted for as a variable (in eligibility criteria, safety monitoring, efficacy, and drug-drug interactions). (1 point)

A clinical trial **Scorecard** developed by TGD people around the world may help to promote a future of HIV research that **meaningfully prioritizes TGD people** in ending the epidemic.

Results

Since 1991, TGD people have made up less than 1% of participants in 41 key HIV studies. The vast majority of the <1% were transgender women.

Next Steps

Promote the Scorecard as a research and advocacy tool to increase meaningful TGD inclusion in HIV clinical trials. Download the Scorecard below!

