NO DATA NO MORE SCORECARD TOOL

for Trans- and Gender-Diverse Inclusivity in HIV Clinical Trials

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 advocacy 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-no-more*) into scorable indicators to help realize trans-inclusivity in research.

Based on the No Data No More Manifesto's indicators, an assessment of 41 milestone HIV clinical trials implemented since 1991 found that less than 1 percent of more than 170,000 participants were reported as trans or gender-diverse people. This means that transgender communities were represented by fewer than 2,000 participants in major HIV studies since the beginning of the epidemic. The vast majority of these underrepresented participants were transgender women, with very little representation of trans men and gender nonbinary people. The first trans enrollee was not reported until 2007 in the iPrEx PrEP study. A detailed analysis of trans and gender-diverse representation in these 41 milestone HIV studies is available on the AVAC website (*https://www.avac.org/choice-agenda*).

Recent efforts to include trans 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.

CLINICAL TRIAL SCORING TOOL ➡

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CLINICAL TRIAL SCORING TOOL

ELIGIBILITY

- Selection criteria include *trans women, trans men, and gender nonbinary participants, discretely. (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)*

REPORTING

- 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)*

LANGUAGE

- Adheres to best practices as outlined in NIAID's HIV Language Guide *(https://www.hptn.org/resources/HIVLanguageGuide)*. *(1 point)*

SCORING

- **A** **11-13** points
- **B** **8-10** points
- **C** **5-7** points
- **D** **2-4** points
- **F** **0-1** points

GENDER-AFFIRMING HORMONE THERAPY

- Accounted for as a variable (in eligibility criteria, safety monitoring, efficacy, and drug-drug interactions). *(1 point)*

SYSTEMS

- 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)*

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