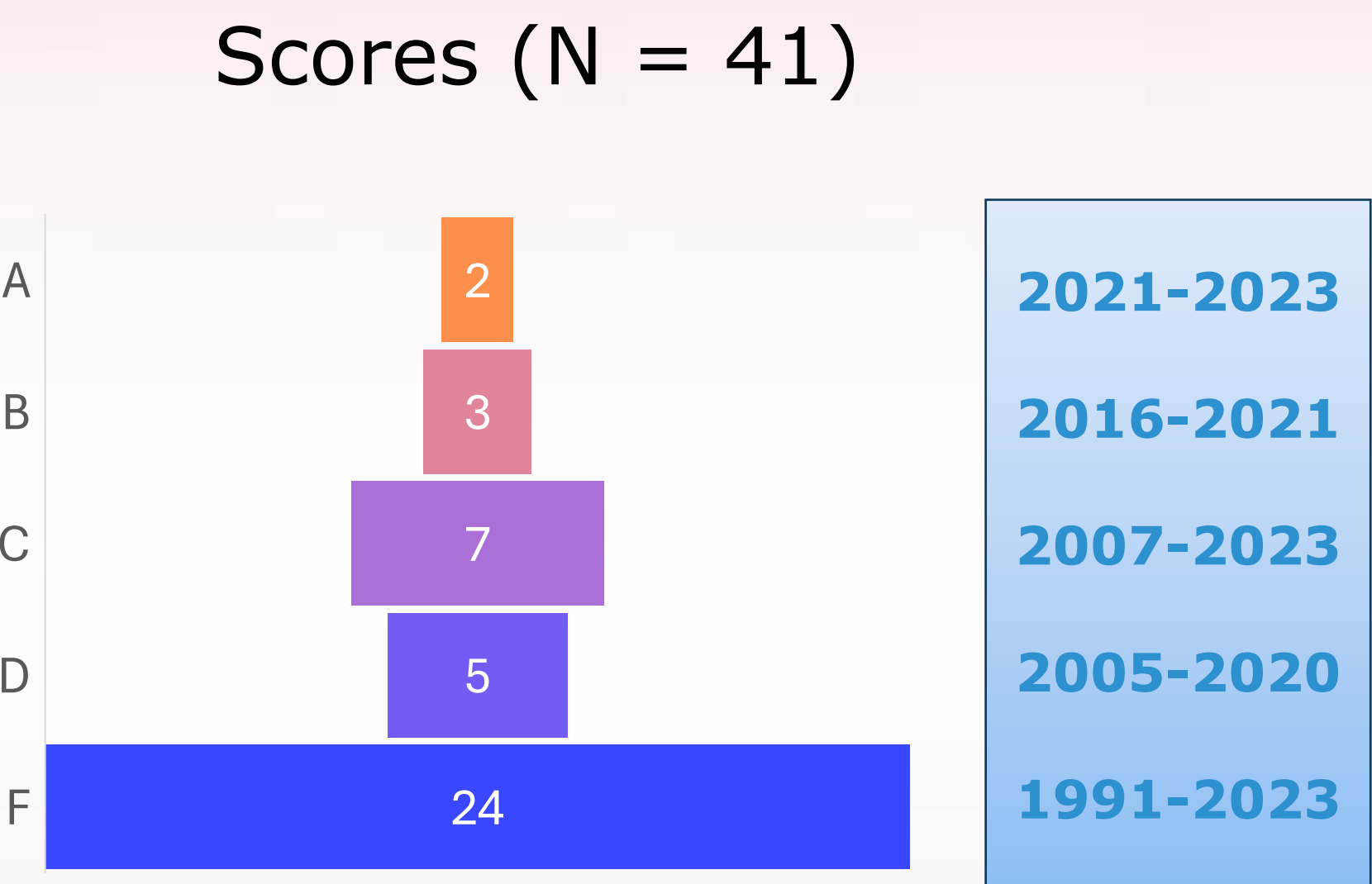


Background

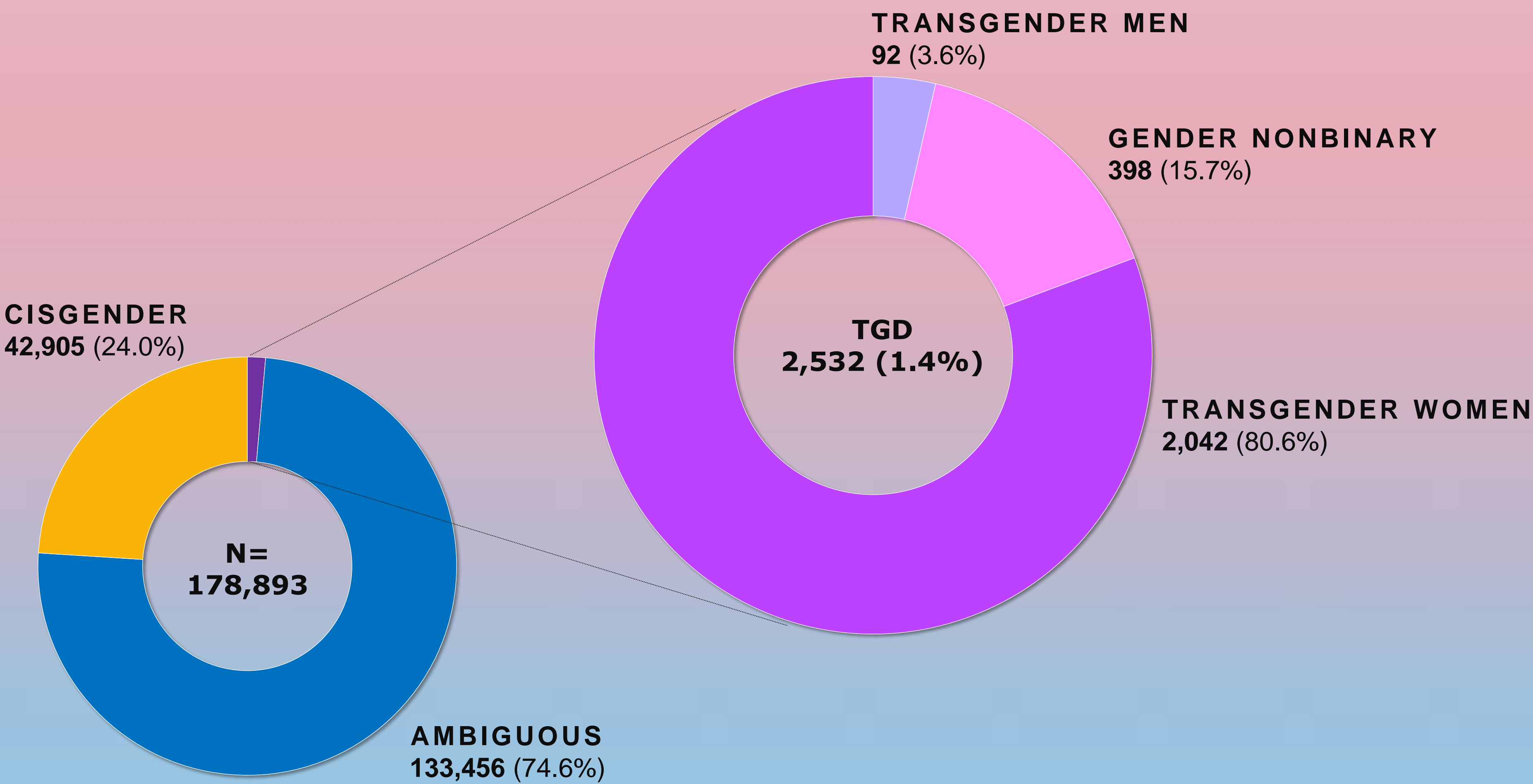
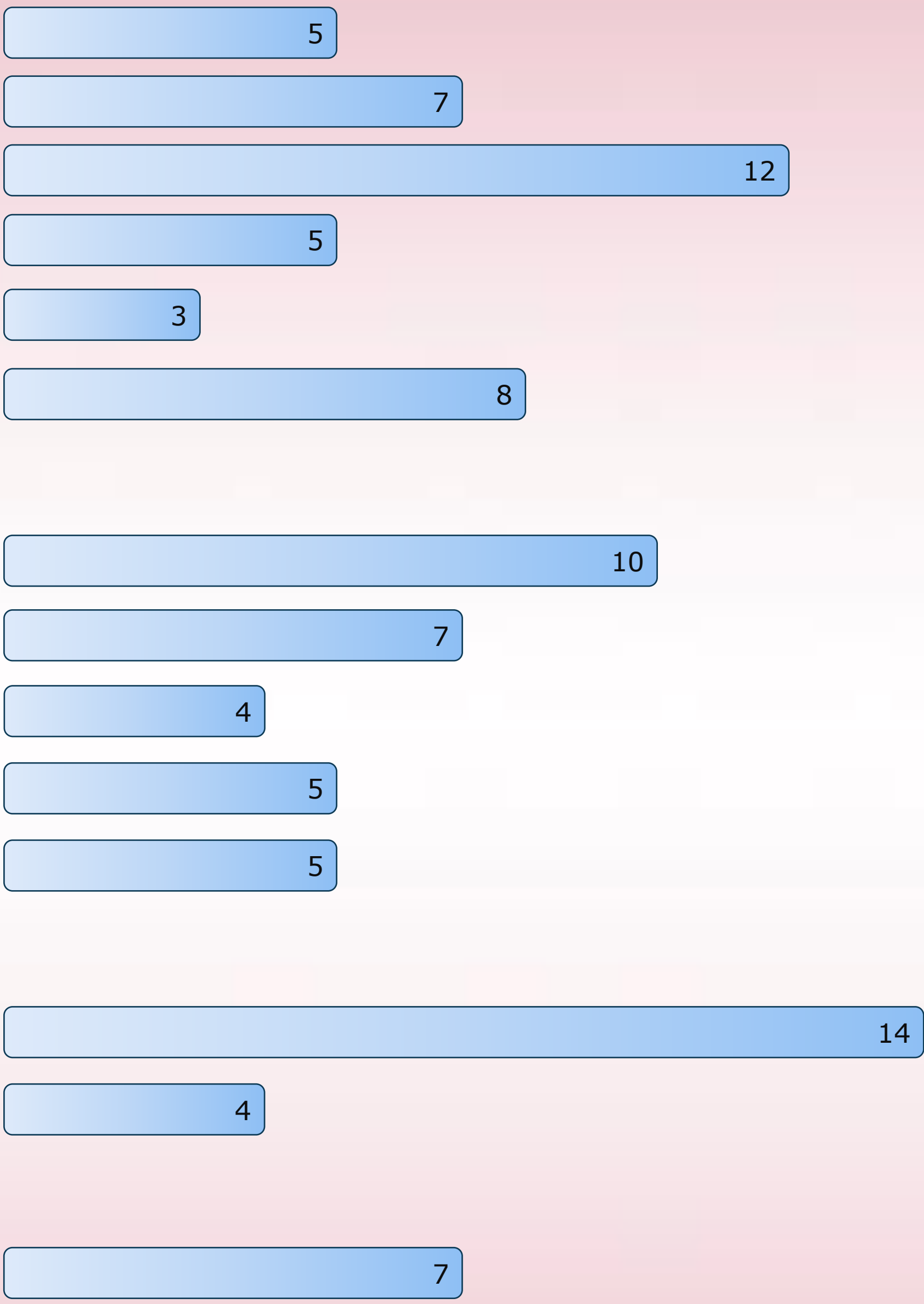
- Transgender and gender-diverse (TGD) people represent a key population in the HIV pandemic.
 - Incidence: up to 66x higher than overall population.
 - Prevalence: up to 58% in some locations.
- We sought to quantify and characterize TGD representation in pivotal HIV clinical trials.
 - Main question: Is HIV research inclusive of and responsive to the needs of TGD communities?
- We also sought to develop a structured framework for evaluating TGD inclusion with actionable criteria for trial design and conduct.

Methods

- With input from global TGD communities, we devised a tool (Scorecard) consisting of 14 scoreable indicators for TGD responsiveness in HIV clinical trials.
- We tested the Scorecard in a cross-sectional review of 41 biomedical trials enrolling from 1991-2023 with findings essential to the field of HIV (ART, U=U, vaccines, bnAbs, PrEP, etc.).
- Sources: study protocols, publications, AVAC database, ClinicalTrials.gov, conference presentations, correspondence with investigators from select trials.



HIV Research Scorecard for Trans and Gender-Diverse Inclusivity		
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 <i>NIAID HIV Language Guide</i> ² .		
SCORE		TOTAL = YES NO =
A. 11-13 points B. 8-10 points C. 4-7 points D. 1-3 points F. 0 points		



Results & Conclusions

- Since 1991, TGD representation is (mis)documented at only ~1% of participants in 41 of the most influential HIV clinical trials.
- Scorecard indicators reveal a dearth of HIV research that is responsive to TGD priorities.
- Trans erasure is an ethical violation that impedes TGD communities' right to benefit from science.
- The Scorecard should be implemented by researchers and advocates to help HIV research become more responsive to the needs of TGD communities.

