Sex and Gender Diversity Trends in Clinical Trials

Poster #18

Namita Satija,[1]* Jaclyn Mironov,[1]* Reem Berro,[1] Holly Crenca,[1] Courtney Laney,[1] Nik Sanyal,[1] Elizabeth Yannette,[1] Pauline Ng[1]

[1]Cadent Medical Communications, a Syneos Health™ group company, USA

*Equal contribution

Background and Objective

- Uptake of gender diversity reporting remains limited, despite efforts to reduce sex and gender disparities in clinical research[1,2]
- The US Food and Drug Administration recognizes sex and gender as distinct terms; however, the recent guidelines for enhancing diversity of clinical trial populations assume sex and gender to be concordant[3]
- In the United States, an estimated 390 adults in every 100,000 identify themselves as transgender. There remains a significant gap in inclusion of this underserved and understudied population in clinical trials[4,5]
- As a proxy to evaluating gender diversity in clinical trials, we analyzed trends around gender- and sex-based eligibility reporting in clinical trials registered in the ClinicalTrials.gov database

Methods

- The scope of this study included clinical studies conducted from 2005 to the present that are listed on ClinicalTrials.gov
- A 2-pronged comprehensive search strategy was used for identifying studies where gender-based selection was applied (**Figure 1**)
  - Approach I assessed trend distribution over time, therapeutic areas, types of intervention, and funding source (**Figure 1**)
  - Approach II evaluated records with study results available (n=13) to gather deeper insights into gender reporting trends and to understand associated challenges (**Figure 1**)

Results

Study Selection

- A total of 3210 records were identified by searching the ClinicalTrials.gov database for gender-based keywords (**Figure 1**). We excluded records with a start date before 2005 and manually screened the rest for relevance

Trends in Studies With Gender-Based Eligibility Over Time

- After applying the exclusion filters (**Figure 1, Approach I**), 102 records remained and were further analyzed
- The number of records with gender-based eligibility has increased over the past 10 years
  - The highest number of studies with gender-based eligibility were reported in 2020 (N=28) (**Figure 2**)
- Most studies were related to HIV (41%). Other therapeutic areas were also represented, including hormone replacement therapy, social behavior, sex reassignment, cardiometabolic conditions, human papillomavirus, and mental health, among others (**Figure 3**)
- The vast majority of studies were sponsored by academic and medical institutions (72%) but very few were industry sponsored (3%) (**Figure 4**)

Sex and Gender Reporting on ClinicalTrials.gov

- After applying the exclusion filters (**Figure 1, Approach II**), 13 records remained and were further analyzed
- In our analysis, we evaluated the following (**Figure 5**):
  - Sex- and gender-based eligibility listed under the "Study Details" tab
  - Detailed eligibility criteria reported under the "Tabular View" tab
  - Sex and gender breakdown included in the "Study Results" tab
- All 13 records analyzed reported sex-based eligibility but only 3 reported gender-based eligibility under study details
- Among records that did not specify gender eligibility (n=10), 4 provided details on gender-based eligibility and 8 provided gender breakdown information in the "Study Results" tab
- One of the 3 studies reporting gender-based eligibility did not include a gender-based breakdown in the study results

Gender Definitions Across Studies

- Gender definitions varied across studies, highlighting the need for more consistent terminology to classify gender categories (**Figure 6, Approach II**)

Figure 1. Methodology Flowchart

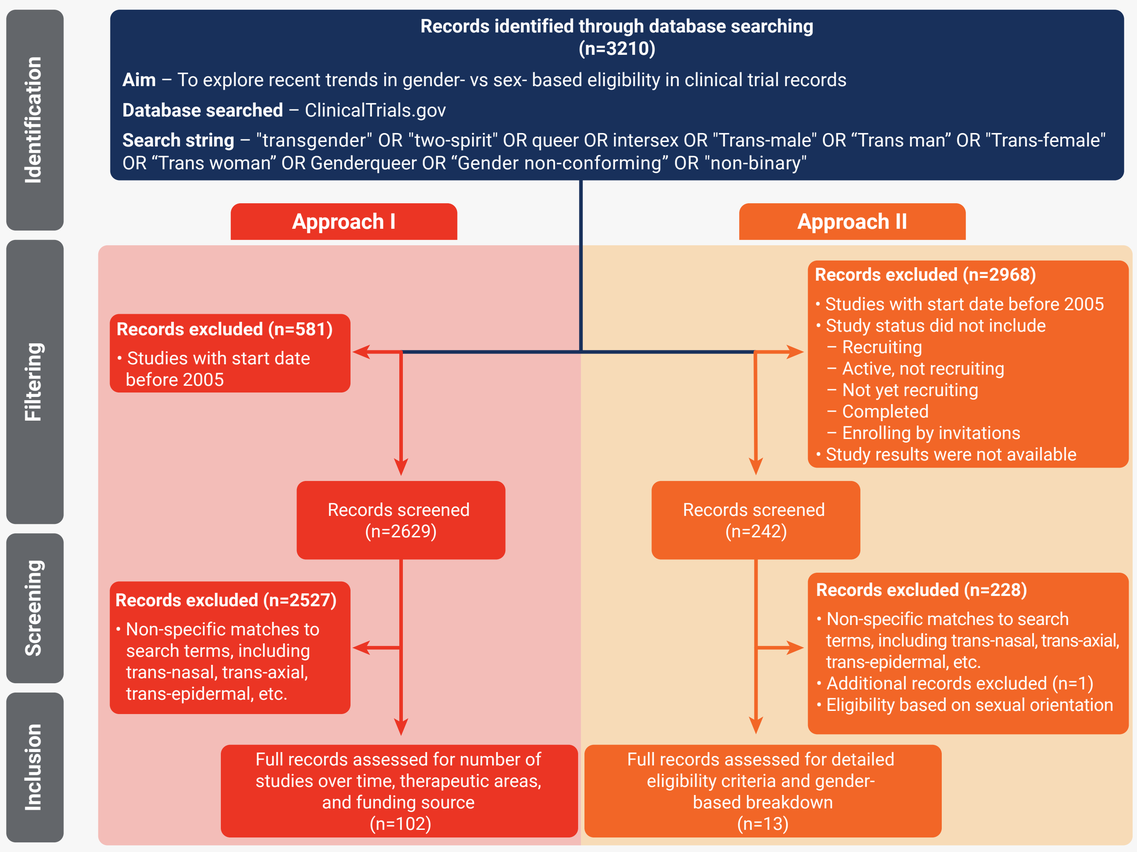


Figure 2. Eligible Studies Plotted Over Time Based on Start Dates

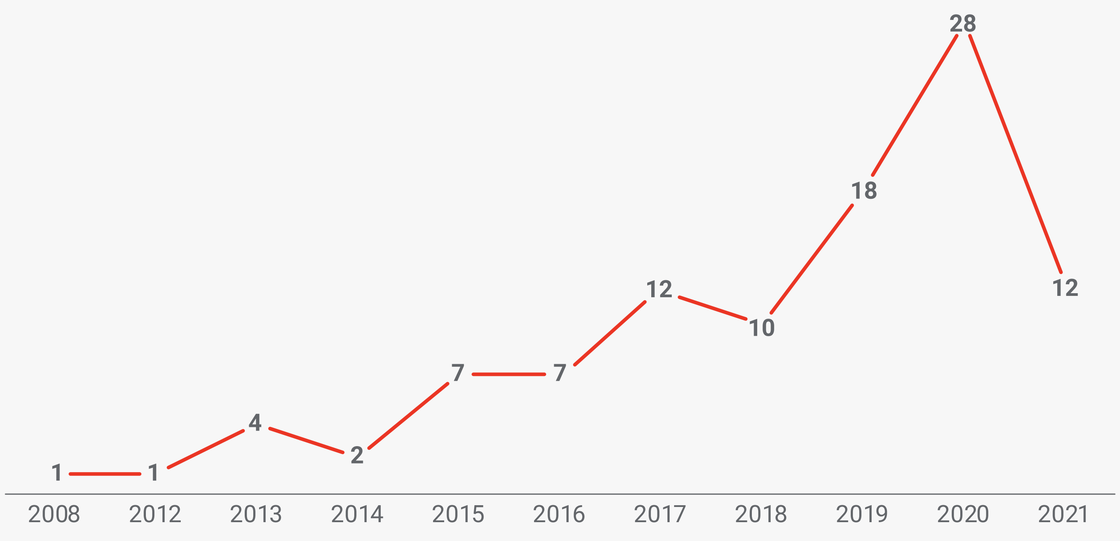
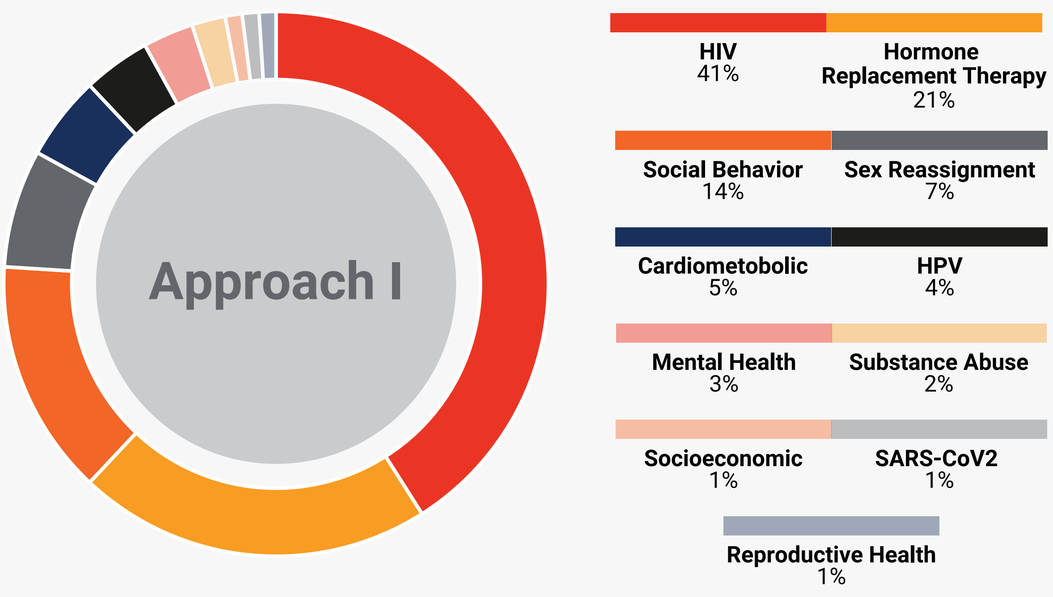
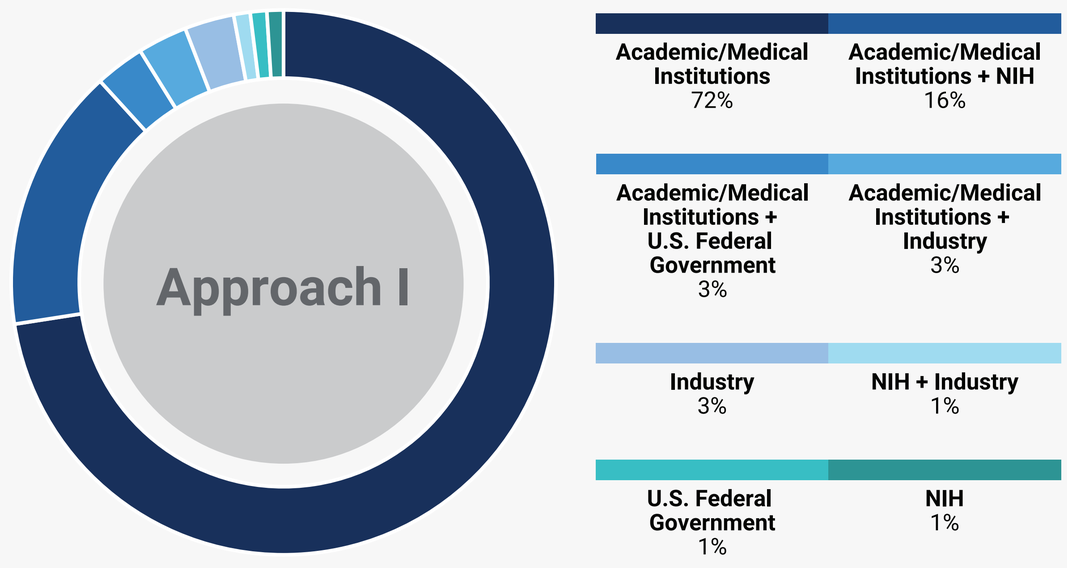


Figure 3. Eligible Studies by Therapeutic Category



HIV, human immunodeficiency virus; HPV, human papillomavirus; SARS-CoV2, severe acute respiratory syndrome-coronavirus 2.

Figure 4. Eligible Studies by Funding Source



NIH, National Institutes of Health.

Figure 5. Gender-Based Eligibility from ClinicalTrials.gov Shows Inconsistent Reporting of Gender-Based Data

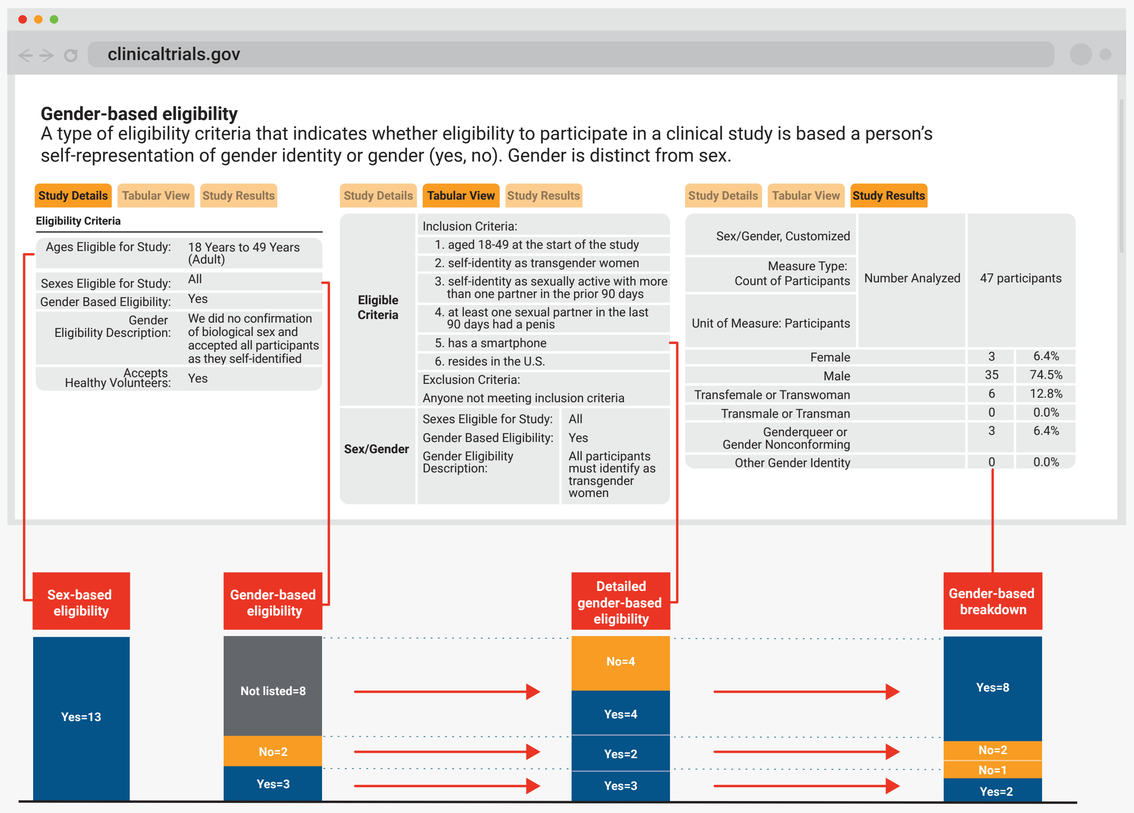
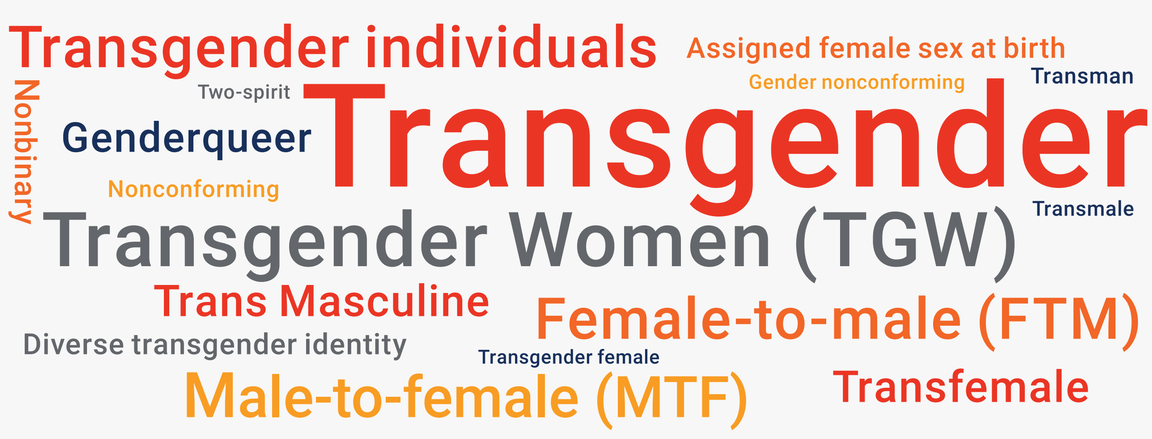


Figure 6. Gender Diversity Terms Used in the Eligibility Criteria of Studies Analyzed



Conclusions

- Although gender-based eligibility was applied, it was not consistently reported in the ClinicalTrials.gov records that were analyzed
- There was no standardized methodology for reporting on gender (definition)
- Study limitations:
  - The ClinicalTrials.gov search algorithm is not optimized for these searches
  - Gender breakdown in the "Study Results" tab of ClinicalTrials.gov was not identified by the search string applied

References

1. Chen B, Jin H, Yang Z, Qu Y, Weng H, Hao T. An approach for transgender population information extraction and summarization from clinical trial text. *BMC Med Inform Decis Mak*. 2019;19(Suppl 2):62. **2.** Chan PS. Invisible gender in medical research. *Circ Cardiovasc Qual Outcomes*. 2019;12(4):e005694. **3.** Enhancing the diversity of clinical trial populations — eligibility criteria, enrollment practices, and trial designs: Guidance for industry, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, and Center for Biological Evaluation and Research. November 2020. Accessed March 23, 2021. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial. **4.** Meerwijk EL, Sevelius JM. Transgender population size in the United States: a meta-regression of population-based probability samples. *Am J Public Health*. 2017;107(2):e1-e8. **5.** Jones NC, Otto AK, Ketcher DE, Permuth JB, Quinn GP, Schabath MB. Inclusion of transgender and gender diverse health data in cancer biorepositories. *Contemp Clin Trials Commun*. 2020;19:100597.

Acknowledgements

This study was supported by Cadent Medical Communications, a Syneos Health™ group company. The authors thank Nicholas Kenny, Chief Scientific Officer of Syneos Health™, for his insight and experience on clinical trial diversity.

Disclosures

All authors are employees of Cadent Medical Communications, a Syneos Health™ group company.

cadent® medical communications
a SYNEOS HEALTH company

Presented during the 17th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP), April 12-14, 2021, Virtual.