Background and Objective
- Uptake of gender diversity reporting remains limited, despite efforts to reduce sex and gender disparities in clinical trials.
- The U.S. Food and Drug Administration recognizes sex and gender as distinct terms; however, the recent guidelines for enhancing diversity of clinical trial populations require sex and gender to be consistent.
- In the United States, an estimated 240 million individuals identify themselves on electronic forms, and sex/gender remains a significant gap in inclusion of this underserved and underrepresented population in clinical trials.
- As a proxy to evaluating gender diversity in clinical trials, we analyzed trends surrounding 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.
- Sex and gender breakdown included in the “Study Results” tab of ClinicalTrials.gov was not identified by the search string applied.
- Because there was no standardized methodology for reporting on gender (definition), the study included specific terms, including trans-epidermal, etc.
- To explore recent trends in gender- vs sex-based eligibility in clinical trial records, we assessed eligibility criteria and gender-diversity reporting in clinical research.

Results

Study Selection
- A total of 2032 records were identified by searching the ClinicalTrials.gov database on May 10, 2021. A systematic search strategy was used to refine the results for relevance.

Trends in Studies With Gender-Based Eligibility Over Time
- After applying the exclusion filters (Figure 1, Approach 1), 152 records remained and were further analyzed.
- The number of records with gender-based eligibility has increased over the past 13 years.
- The highest number of studies with gender-based eligibility were recorded in 2020 (1024 records).

Eligibility Criteria
- Most studies related to HIV (41). Other therapeutic areas were also implemented, including hormone replacement therapy, social behavior, sex/gender diversity, and behavioral, sexual, and mental health, among others (Figure 3).
- This vast majority of studies was sponsored by academic and medical institutions (72%) but only very few industry-sponsored (3%).

Sex and Gender Reporting on ClinicalTrials.gov
- After applying the exclusion filters (Figure 1, Approach 1), 13 records remained and were further analyzed.
- Among the 13 records, 8 provided information on sex/gender diversity and 5 did not provide gender diversity information.
- Of the 8 studies reporting gender-based eligibility, only 3 reported gender-based eligibility criteria.
- One of the 3 studies reporting gender-based eligibility did not include a list of gender breakdowns.
- Gender Definitions Across Studies
- Gender definitions varied across studies, highlighting the need for more consistent terminology to classify gender diversity (Figure 4, Approach 1).

Eligible Studies by Funding Source
- The vast majority of studies were sponsored by academic and medical institutions (72%).
- The US Food and Drug Administration recognizes sex and gender as distinct terms; however, the recent guidelines for enhancing diversity of clinical trial populations require sex and gender to be consistent.

Eligible Studies by Funding Source
- The highest number of studies with gender-based eligibility were recorded in 2020 (1024 records).

Conclusion
- Although gender-based eligibility was applied, it was not consistently reported in the ClinicalTrials.gov records that were analyzed.
- There was a need for a 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.

Methods
- A second systematic search strategy was used to verify the findings from the clinical study.
- A comprehensive retrieval of search strategies used in this study was identified and published in the ClinicalTrials.gov database.

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References