

# Enhancing Inclusion in Clinical Trials: A Scoping Review of Strategies for LGBTQIA+ People and People Living with HIV

Arwa Gulzar<sup>1</sup>, Kiersten Kelne<sup>2</sup>, Darwin Rodriguez<sup>3</sup>, and Casey D. Xavier Hall<sup>4, 5</sup>

<sup>1</sup> FSU College of Medicine; <sup>2</sup> FSU College of Nursing; <sup>3</sup> FSU College of Social Sciences and Public Policy; <sup>4</sup> Center of Population Sciences for Health Equity, FSU College of Nursing; <sup>5</sup> FSU College of Social Work

## Introduction

### Importance of Diversity in Clinical Trials:

- Addresses underrepresentation of marginalized groups in clinical trials, which reduces healthcare disparities and ensures more effective treatments for diverse populations.
- These communities suffer from mental health disorders, substance use, and intimate partner violence<sup>1,5</sup>.

### Impact of Limited LGBTQIA+ Representation:

- Negatively affects people living with HIV (PLWH) by obstructing proper healthcare, perpetuating discrimination in care, and overall poorer health<sup>2,4</sup>.
- Gay, bisexual, and men who have sex with men are at higher risk of contracting HIV, though anyone can contract it regardless of gender or sexuality<sup>3</sup>.

### Study Objectives:

- Identify barriers and strategies for better inclusion of lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+) individuals and PLWH through a scoping review.
- Conduct a comprehensive scoping review of existing research on inclusion and diversity in clinical trials, focusing on LGBTQIA+ communities and PLWH.

## Methodology

- Utilizes a scoping literature review approach.
- Covidence software is used to screen and analyze research abstracts.
- Focuses on inclusion and diversity in clinical trials for LGBTQIA+ populations and PLWH.

### Literature Search Details:

- Databases searched:
  - PubMed
  - Academic Search Complete
  - PsychNet
- Search terms included all possible combinations of clinical trial and population terms:
  - Clinical Trial Terms*: "Clinical Trial Inclusion," "Clinical Trial Diversity," "Clinical Trial Equity," "Inclusion in Clinical Trials," "Diversity in Clinical Trials," "Equity in Clinical Trials."
  - Population Terms*: "LGBT," "Sexual and Gender Minority," "HIV," "Transgender," "Nonbinary," "Lesbian," "Gay," and "Bisexual."

### Screening Process:

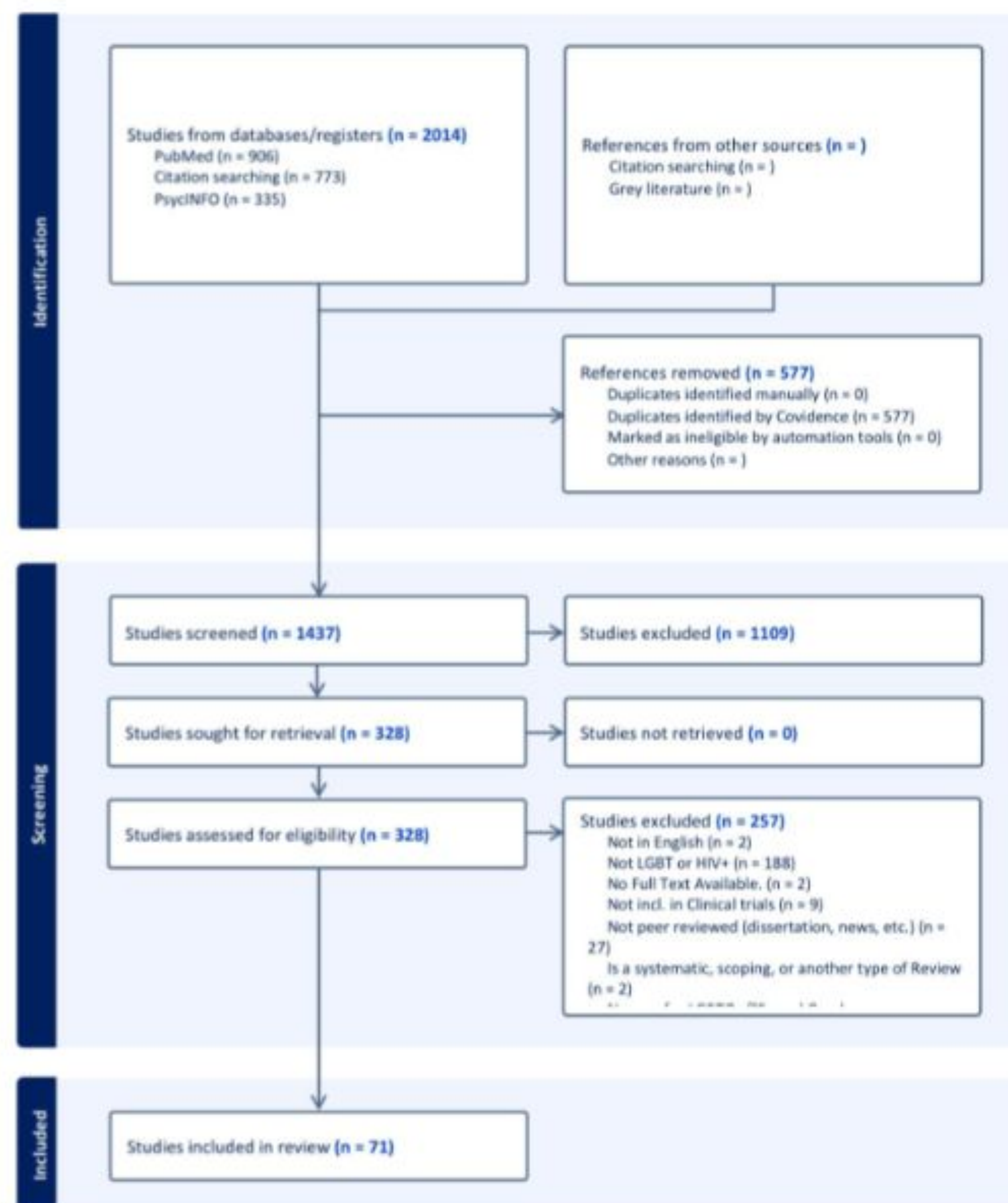
- Initial literature search yielded **n=2,014** results.
- Duplicates removed, leaving **n=1,437** abstracts for review.
- Each abstract reviewed by at least 2 of a team of 4 reviewers.

### Final Selection:

- n=323** abstracts selected for full-text review.
- n=71** texts selected for extraction

## Flow Diagram

Clinical Trial Diversity (UROP)



.This model crafted by Covidence demonstrates the path we took in order from top to bottom, starting with the identification process and ending at the studies included in the review.

## Inclusion and Exclusion Criteria

|                    | Abstract Review   | Full-Text Review   |
|--------------------|---|--|
| Inclusion Criteria | Abstracts must: <ol style="list-style-type: none"><li>Be in English.</li><li>Focus on clinical trials.</li><li>Address diversity, equity, or inclusion.</li><li>Be peer-reviewed and present original research, scientific commentary, or guidance.</li></ol> | Studies must: <ol style="list-style-type: none"><li>Studies must discuss recommendations to improve LGBTQIA+/Sexual and Gender Minority or PLWH diversity in clinical trials.</li><li>Include recommendations specifically for clinical trials or intervention studies.</li><li>Be written in English.</li></ol>   |
| Exclusion Criteria | Abstracts were excluded if they were: <ol style="list-style-type: none"><li>Systematic reviews.</li><li>Published research protocols.</li></ol>   | Studies were excluded if they: <ol style="list-style-type: none"><li>Are systematic Reviews</li><li>Not written in English.</li><li>-Not involving LGBT or HIV</li><li>-Not clinical trials/"trials"/intervention studies</li><li>-Is a clinical trial that doesn't test strategies for clinical trial diversity/inclusion/equity</li><li>-Not re: inclusion/diversity/recruitment/retention of LGBTQ+/Sexual Gender Minorities"/etc or HIV</li><li>Dissertation or not published.</li></ol> |

## Conclusions

- There are 71 studies that need to be subjected to text extraction.
- These studies seem to suggest possible solutions for including LGBTQIA+ individuals and PLWH in clinical trials, such as: transgender cultural responsiveness training<sup>6</sup>, revise binary sex reporting to consider all gender identities<sup>7</sup>, and even creating online platforms to allow members of these communities to have a clear way to get involved in clinical trials<sup>8</sup>.

### Future Steps/Recommendations for the Research:

- The rest of this project should consist of finalizing the included full-text pieces and extracting relevant and supportive information from them on the subject.
- Future research on this topic should be about prioritizing the inclusion of diverse populations to ensure that healthcare can be applied to all populations.
- Researchers should focus specifically on groups that have been excluded before by exclusionary practices in research.

## Results / Next Steps

### Current Progress:

- Final results have not yet been obtained.
- Focus remains on completing full-text screening and data extraction.

### Next Steps:

- Identify key strategies for enhancing representation in clinical research.
- Contribute to policies and practices that foster greater inclusion of LGBTQIA+ individuals and PLWH in clinical trials.
- Confirm the final full-text sample.
- Extract and summarize recommendations for improving clinical trial diversity for LGBTQIA+ populations and PLWH.

## References for Introduction & Included Texts QR

- National Institutes of Health. (n.d.). The importance of diversity in clinical trials. Retrieved March 3, 2025, from <https://www.nih.gov/health-information/importance-diversity-clinical-trials>
- Centers for Disease Control and Prevention. (n.d.). Health disparities among LGBTQ youth. Retrieved March 3, 2025, from <https://www.cdc.gov/healthy-youth/lgbtq-youth/health-disparities-among-lgbtq-youth.html>
- Harvard Medical School. (2021, June 29). Health disparities persist for LGB people. Retrieved March 3, 2025, from <https://hms.harvard.edu/news/health-disparities-persist-lgb-people>
- Kaiser Family Foundation. (n.d.). LGBT peoples health and access to care. Retrieved March 3, 2025, from <https://www.kff.org/report-section/lgbt-peoples-health-status-and-access-to-care-issue-brief/>
- U.S. Department of Health and Human Services. (n.d.). LGBTQ+ health objectives - Healthy People 2030. Retrieved March 3, 2025, from <https://health.gov/healthypeople/objectives-and-data/browse-objectives/lgbt>
- Andrasik, M., Yoon, R., Mooney, J., Broder, G., Bolton, M., Votto, T., & Davis-Vogel, A. (2014). Exploring barriers and facilitators to participation of male-to-female transgender persons in preventive HIV vaccine clinical trials. *Prevention Science*, 15(3), 268â€“276. <https://doi.org/10.1007/s11121-013-0371-0>
- Babu, T. M., Wald, A., & Restar, A. J. (2023). Health equity necessitates the inclusion of gender identity data in COVID-19 clinical trials. *Annals of Epidemiology*, 85, 3â€“5. <https://doi.org/10.1016/j.annepidem.2023.06.024>
- Cspedes, M., Das, M., Hojilla, J. C., Blumenthal, J., Mounzer, K., Ramgopal, M., Hodge, T., Torres, T. S., Peterson, C., Shibase, S., Elliott, A., Demidont, A. C., Callaghan, L., Watson, C. C., Carter, C., Kintu, A., Baeten, J. M., & Ogbuagu, O. (2022). Proactive strategies to optimize engagement of Black, Hispanic/Latinx, transgender, and nonbinary individuals in a trial of a novel agent for HIV pre-exposure prophylaxis (PrEP). *PLoS ONE*, 17(6), 1â€“12. <https://doi.org/10.1371/journal.pone.0267780>

ALL 71 INCLUDED TEXTS CAN BE FOUND AT:

[https://regroup-production.s3.amazonaws.com/reviews/509684/citation\\_exports/reviaw\\_509684\\_included\\_csv\\_20250306054723.csv?X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Credential=AKIAYSEKCAWYQ4DSIUHG%2F20250312%2FuS-east-1%2Fs3%2Faws4\\_request&X-Amz-Date=20250312T181628Z&X-Amz-Expires=604800&X-Amz-SignedHeaders=host&X-Amz-Signature=7fe9424434120b4bb17c0e9cdbe519c1d0ff5718ecf3cef8fad2d4425563398](https://regroup-production.s3.amazonaws.com/reviews/509684/citation_exports/reviaw_509684_included_csv_20250306054723.csv?X-Amz-Algorithm=AWS4-HMAC-SHA256&X-Amz-Credential=AKIAYSEKCAWYQ4DSIUHG%2F20250312%2FuS-east-1%2Fs3%2Faws4_request&X-Amz-Date=20250312T181628Z&X-Amz-Expires=604800&X-Amz-SignedHeaders=host&X-Amz-Signature=7fe9424434120b4bb17c0e9cdbe519c1d0ff5718ecf3cef8fad2d4425563398)