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Diversity in Clinical Trials: A Review of Drugs Approved By the FDA in 2024

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Introduction

- The ICER-developed Clinical trial Diversity Rating tool (CDR) provides an objective and transparent framework for evaluating the demographic diversity of clinical trial populations.
- Groups such as Health Technology Assessment bodies, clinical trial regulators, policymakers, journal editors, and researchers can use this tool to assess and improve diversity in clinical trials.

Research Objective

To report and discuss the clinical trial diversity in pivotal trials of drugs approved by the US FDA in 2024 using the ICER CDR tool.

Methods

We evaluated the pivotal trials **of 54 drugs** approved by CDER and CBER

We abstracted clinical trial demographic data from the **FDA drug trial snapshots**

We collected **disease-specific estimates**

We assessed clinical trial diversity using the **CDR tool**

PDRR: Participant to Disease-Prevalence Representation Ratio

$$\text{PDRR} = \frac{\text{Trial data}}{\text{Disease-specific estimates (or US Census)}}$$

Table 1. Summary of CDR Tool Framework

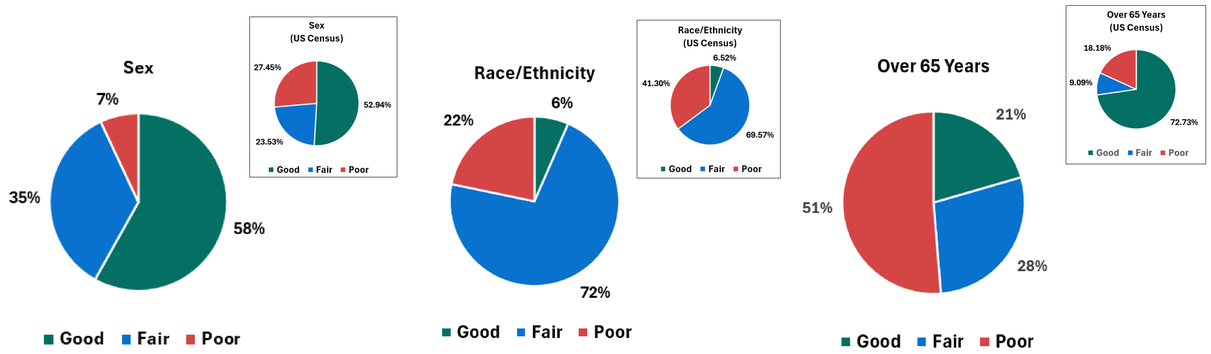
PDRR	Score
0	0
>0 to <0.5	1
0.5 to 0.8	2
≥0.8	3

Demographic Characteristics	Rating Categories (Total Score)
Race/Ethnicity	Good (11-12), Fair (7-10), Poor (≤6)
Sex	Good (6), Fair (5), Poor (≤4)
Age	Good (3), Fair (2), Poor (≤1)

PDRR: Participant to Disease-prevalence Representation Ratio

Results

Figure 1. Evaluation of Clinical Trial Diversity Using Disease-Specific Estimates vs. US Census Data



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Results

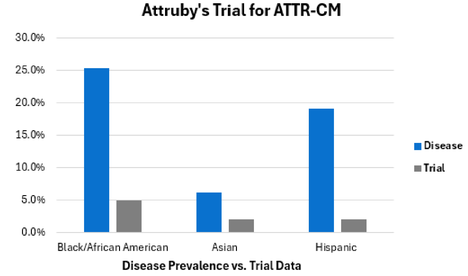
- **Sex**: Majority (58%) of the trials were rated as **good**. We excluded sex-specific diseases.
- **Race/Ethnicity:** Majority (72%) of the trials were rated as **fair**.
- **Age:** Over half of the trials (51%) were rated as **poor**.
- The results using general US population data and disease-specific estimates portray overlaps in the evaluation of clinical trials' diversity. However, disease specific estimates provide a closer comparison between the demographics of patients with a given condition and those enrolled in clinical trials.

How many trials had a PDRR of ≥0.8 for race/ethnicity, indicating good representation?

- Black/African American participants: **17%, 8**/46 trials
- Asian participants: **65%, 30**/46 trials
- Hispanic participants: **28%, 13**/46 trials
- White participants: **67%, 31**/46 trials

Diving Deeper into Poor Rated Trials

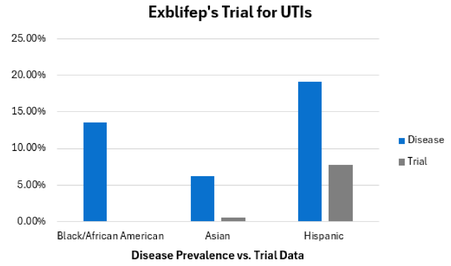
Figure 2. Racial/Ethnic Diversity for ATTR-CM



ATTR-CM: transthyretin amyloid cardiomyopathy
*White participants were excluded from this graph. White participants were adequately represented (88% of trial participants were White vs. 76% with ATTR-CM).

More Black Americans are affected by ATTR-CM and the prevalence in this group has increased over time.[1] Novel, effective therapies could improve health equity. Using the CDR tool shows that clinical trials must better reflect the demographics of patients with ATTR-CM.

Figure 3. Racial/Ethnic Diversity for UTIs



UTI: Urinary tract infection
*White participants were excluded from this graph to focus on racial/ethnic minorities. White participants were adequately represented (95% of trial participants were White vs. 76% with UTIs).

Black, Hispanic, and Asian patients experience a higher burden of UTIs[2], which may reflect underlying sociodemographic inequalities.[3] However, clinical trials of treatment for UTIs (Figure 3) continue to underrepresent these patients.

Key Takeaways

- The CDR tool objectively assesses clinical trial diversity across race/ethnicity, age, and sex using disease-specific prevalence estimates. Disease-specific estimates better illuminate the underrepresentation of groups, compared to general US population data.
- Most drugs approved in 2024 had good sex representation, but only fair representation for race/ethnicity and poor representation of older adults.
- Evaluating clinical trial diversity can ignite efforts to improve diversity in trials, consequently promoting equity in trials of new drugs, public trust and patient awareness of novel therapies.

Download the ICER Clinical Trial Diversity Rating Tool

References:
1. Wasfy JH, Nikitin D, Richardson M, Lee W, Rind, DM. Disease Modifying Therapies for the Treatment of Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Final Evidence Report ICER 10/21/2024
2. Advani SD, Luck ME, Chang R, et al. Assessing the burden of outpatient urinary tract infections in the United States: analysis of nationwide ambulatory data (2016-2019). Antimicrobial Stewardship & Healthcare Epidemiology. 2025;5(1):e143.
3. McAteer S, Wartko P, Hajat A, et al. Racial and Ethnic Disparities in the Incidence and Treatment of Urinary Tract Infection During Pregnancy. Journal of Women's Health. 2025;34(8):985-993.