Enhancing Patient Outcomes in Clinical Trials by Addressing Social Determinants of Health

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Introduction

Lack of diversity and inclusion in clinical trial participants has been a longstanding issue, with the underrepresentation of certain demographic groups, racial and ethnic minorities, women, and older adults. This poses significant challenges in ensuring the safety and effectiveness of medical interventions across diverse populations.

Historically, clinical trials have predominantly enrolled white, male participants, leading to a limited understanding of how different demographic groups may respond to treatments. This lack of diversity can result in disparities in healthcare outcomes, as certain populations may experience different side effects or treatment responses due to genetic, physiological, or socio-cultural factors. Moreover, the exclusion of diverse populations from clinical trials can hinder the identification of potential adverse effects or drug interactions specific to these groups, impacting the safety profile of medications and medical interventions. Having recognized the critical value of diversity and patients' socioeconomic status in clinical research, regulatory agencies, funding bodies, and advocacy groups have increasingly emphasized the need for inclusive trial enrollment strategies. Therefore, initiatives such as the FDA's Diversity in Clinical Trials Act aim to address disparities in clinical trial participation by promoting diversity in study populations and encouraging the inclusion of underrepresented groups.

By understanding the barriers to diversity in clinical trials, and designing and implementing strategies to improve representation, researchers can enhance the validity, applicability, and equity of medical research, leading to more effective healthcare for all populations.

Methods

Data Source

Data for this analysis was sourced from Drug Trial Snapshot Reports published by the U.S. Food and Drug Administration (FDA) between 2015 and 2023. These reports provide comprehensive summaries of the demographic characteristics of participants in clinical trials for approved drugs, including information on age, sex, race, and ethnicity. A total of 425,828 clinical trial participants from 415 drug trial snapshot reports were included in this analysis.

Statistical Analysis

Descriptive statistics such as percentages and proportions using Excel were utilized to summarize the demographic characteristics such as sex, race, age, and ethnicity of clinical trial participants. Trends over time were visually represented via graphs and charts created using Prism software to facilitate the interpretation of the data.

Data Collection and Analysis

Gender Representation Analysis

The percentage of male and female participants in clinical trials for all approved drugs was calculated for each year within the period (2015-2023). This involved extracting relevant data from the Drug Trial Snapshot Reports and computing the percentage of male and female participants each year.

Racial Participation Trend Analysis

Racial participation trends were assessed by examining the distribution of participants across racial categories (e.g., White, Black or African American, Asian & Others) for each year from 2015 to 2023. Data on racial demographics was obtained from the Drug Trial Snapshot Reports, allowing for the identification of any notable trends or disparities in racial representation over time.

Ethnicity Trend Analysis

Ethnicity trends were analyzed by investigating the representation of Hispanic and non-Hispanic participants in clinical trials over the study period. Similar to the approach for gender and racial analysis, data on ethnicity demographics was extracted from the Drug Trial Snapshot Reports, enabling the assessment of changes in ethnicity representation across the years.

Limitations

It is important to note that some data points of clinical trial participants were missing, either not reported or not available. These missing datasets were excluded from the analysis, which may have influenced the overall interpretation of the results. Additionally, variations in data collection and reporting methods across different trials and drug categories could impact the findings.

Results

A

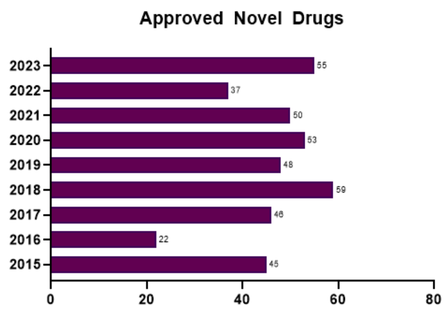

Figure A: The number of novel drugs approved by the FDA from 2015 to 2023

B

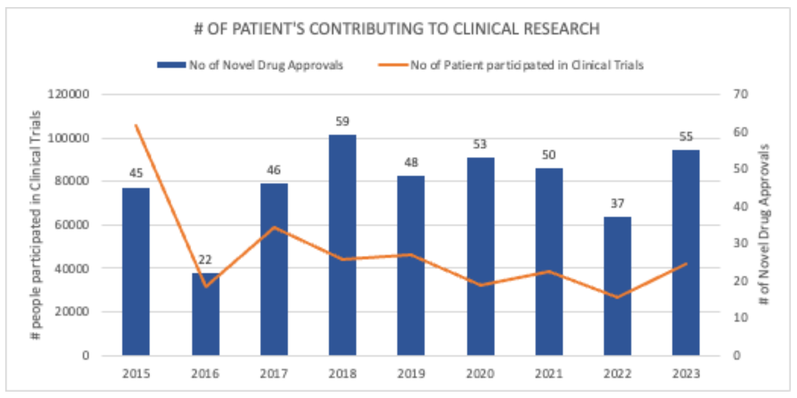

Figure B: The total number of patients who participated in clinical trials and a trend line showing the number of novel drugs approved by the FDA from 2015 to 2023

C

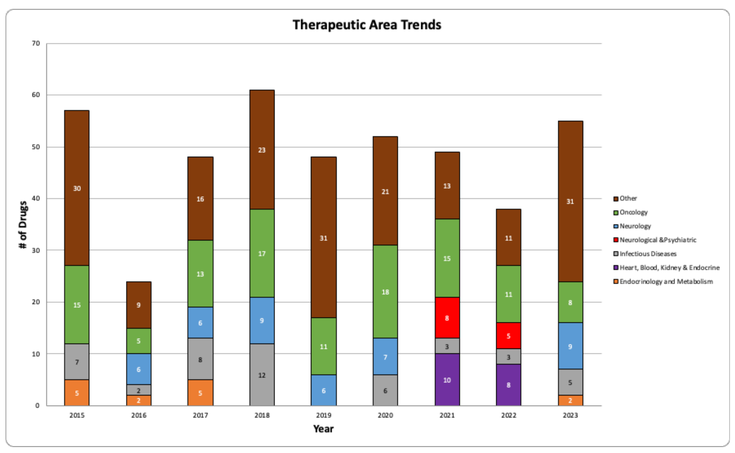

Figure C: The therapeutic groups with the highest number of novel drug approvals

D

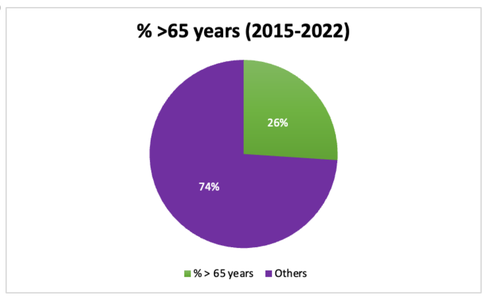

Figure D: Percentage of participants younger and older than 65 years in clinical trials for the years 2015 to 2022

Note: Data for the percentage of individuals older than 65 years in clinical trials for the year 2023 was not available at the time of analysis.

E

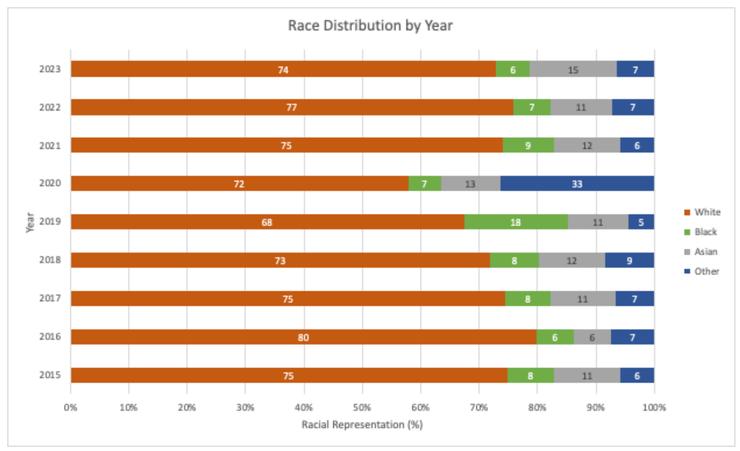

Figure E: Percentage of White, Black or African American, Asian, and other racial groups participants

F

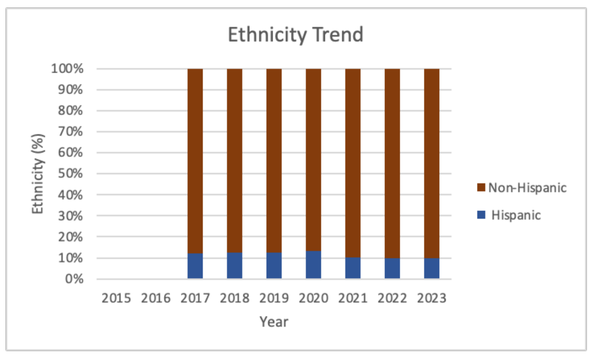

Figure F: Percentage of Hispanic and non-Hispanic participants in clinical trials

Note: Ethnicity data was not available for clinical trial participation for 2015 and 2016.

G

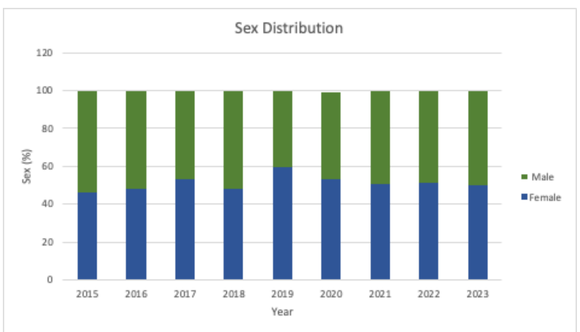

Figure G: Percentage of male and female participants in clinical trials

Discussion

Between 2015 and 2023, over 415 novel drugs were approved by the FDA, with specialties including Endocrinology & Metabolism, Neurology, and Oncology maintaining consistent approval rates. The number of patients participating in clinical trials fluctuated, ranging from 26,529 in 2022 to 105,826 in 2015. Notably, progress has been made in the representation of women in clinical trials, achieving balanced gender representation overall with a shift towards higher female representation in 2019.

However, disparities persist, particularly in the representation of racial and ethnic groups. White participants in comparison to other racial groups, consistently dominated clinical trial participation, highlighting the need for targeted efforts to enhance diversity and inclusion. Data from 2017 to 2023 showed that Hispanic individuals comprised 10% to 14% of participants, while non-Hispanic individuals ranged from 88% to 90%. These findings underscore the importance of addressing social determinants of health (SDOH) and implementing strategies to ensure clinical trials are applicable and beneficial to all populations. Efforts to promote diversity in research participation are imperative for advancing equitable healthcare outcomes. The disparities in clinical trial participation based on race and ethnicity reveal deeper societal and systemic issues affecting healthcare access and outcomes. Factors such as historical mistrust, limited access to resources, cultural barriers, and socioeconomic disparities contribute to these discrepancies. An evidence-based strategy will involve collecting SDOH or socioeconomic status (SES) data at the community level to better understand potential participants' lived experiences. By mainstreaming this information into trial design and recruitment strategies, companies can tailor their approaches to better serve diverse populations.

Policy Implications

⇒ Strategies aimed at building trust and engaging with communities are essential to raise awareness and address participation concerns.

⇒ Implement policies mandating the collection of social determinants of health (SDOH) and socioeconomic status (SES) data in clinical trials to better understand and address disparities in participation among underrepresented racial and ethnic groups.

⇒ Improve collaboration between key stakeholders including pharmaceutical companies, the FDA, policymakers, patient advocacy groups, patients in need, community leaders, and healthcare providers to develop comprehensive strategies aimed at increasing diversity and inclusion in clinical trials.

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