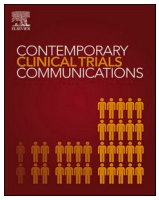
Contemporary Clinical Trials Communications 37 (2024) 101255

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Racial and ethnic diversity in global neuroscience clinical trials

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ARTICLE INFO

Keywords:
Clinical trials
Diversity
Inclusion
Race
CNS
Trial design

ABSTRACT

Background: Despite efforts to increase diversity in neuroscience trials, racial and ethnic minority groups remain underrepresented. Disparities in clinical trial participation could reflect unequal opportunities to participate and may contribute to decreased generalizability of findings and failure to identify important differences in efficacy and safety outcomes.

Methods: We retrospectively reviewed the F. Hoffmann-La Roche database for global, multicenter, neuroscience clinical trials from February 2016 to February 2021 and summarized and stratified race and ethnicity distributions by clinical trial therapeutic area and by country. These data were then compared to national population data for each study's targeted age group (available for studies conducted in the US, Canada, and the UK). The underrepresentation or overrepresentation of each racial and ethnic group was summarized.

Results: The analysis population included 8015 participants from 47 countries. Globally, 85.6 % of participants were White, 7.1 % were Asian, 1.6 % were Black, 1.3 % were American Indian or Alaska Native, less than 0.1 % were Native Hawaiian or other Pacific Islander, 0.7 % were of multiple races, and 3.6 % were of other/unknown race. White individuals predominated in all but one trial. Black individuals were underrepresented in all trials but one. Asian individuals were overrepresented in approximately 20 % of trials. In the US, 7.3 % of participants were of Hispanic or Latino ethnicity vs 16.4 % of the US population.

Conclusion: The findings and learnings from this summary and analysis demonstrate the need for continued awareness and new approaches in designing studies that reflect population diversity.

1. Background

Diversity of clinical trial participants helps ensure that trial populations represent those who will ultimately use medications and makes the results generalizable. Clinical studies in which minority groups are underrepresented may lead to decreased benefit from advances in medical and scientific knowledge due to lack of understanding of racial and ethnic differences in treatment responses [1]. Additionally, some neurological diseases or conditions may differ in prevalence or clinical course in different racial or ethnic groups. Many drugs exhibit racial and ethnic differences in pharmacokinetics (eg, exposure) or response, which may reflect factors such as genetic polymorphisms in metabolism or transport pathways or cultural differences in medical practices or diet [1,2]. Thus, the unnecessary underrepresentation of certain groups in clinical trials may result in limited understanding of efficacy or a failure to discover important safety information [3,4]. In addition, achieving racial and ethnic diversity in clinical trials also helps to ensure that the benefits of clinical research are allocated fairly across gender, racial, ethnic, and socioeconomic groups [3,5].

Despite efforts to increase diversity in neuroscience trials, racial and ethnic minority groups generally remain underrepresented [1,6–9]. In a previous systematic review examining diversity in 101 clinical trials for Alzheimer's disease (AD) [10], it was found that only 46 % of the trials reported data on the race and ethnicity of participants. Out of those 46

Abbreviations: AD, Alzheimer's disease; ASD, autism spectrum disorder; DMD, Duchenne muscular dystrophy; FDA, US Food and Drug Administration; HD, Huntington's disease; MS, multiple sclerosis; PD, Parkinson's disease; SMA, spinal muscular atrophy.

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https://doi.org/10.1016/j.conctc.2024.101255
Received 8 June 2023; Received in revised form 23 November 2023; Accepted 1 January 2024
Available online 4 January 2024

trials, 10 only provided the percentage of White participants without any breakdown of other racial categories. The majority of participants in the trials were White, with a median percentage of 94.7 %. There was no clear trend of increase or decrease in diversity over the period of 2001–2019. A similar systematic review was conducted for clinical trials of Multiple Sclerosis (MS) treatments [11]. This review analyzed 45 phase III studies, of which only 31 % reported the racial and ethnic breakdown of participants using two or more races or ethnicities. In the studies that did provide information on racial and ethnic representation, the median percentage of White participants was 93.8 %, 1.9 % for Black participants, and 0.5 % for Asian participants.

In this paper, we investigate the racial and ethnic distribution of recent F. Hoffmann-La Roche (hereafter Roche)-sponsored global neuroscience clinical trials and compare this distribution to available general population racial and ethnic distributions in the age ranges of the respective global trial populations. Previous publications on this subject primarily describe the lack of diversity in clinical trials in the US only; however, as advances in neuroscience increasingly require clinical trials to be conducted worldwide, a global approach to ethnic and racial diversity is warranted and reported here.

2. Methods

The data set for this analysis includes all Roche-sponsored neuroscience Phase 2 or 3 studies that completed enrollment over a 5-year period: February 2016 through February 2021 (Supplemental Table S1). These studies encompassed a broad range of therapeutic areas, including Alzheimer's disease (AD), autism spectrum disorder (ASD), Duchenne muscular dystrophy (DMD), Huntington's disease (HD), multiple sclerosis (MS), Parkinson's disease (PD), and spinal muscular atrophy (SMA). The analysis only included participants who met trial inclusion criteria and had at least baseline data; participants who failed screening were excluded.

Race and ethnicity were self-reported in all studies. For France, collection of such data is prohibited and therefore race and ethnicity of French participants was coded as "unknown." Racial categories were based on the US Office of Management and Budget classification, which is also applied in the US Census [12]. These categories reflect a social definition of race recognized in the US; they are not an attempt to define race biologically, anthropologically, or genetically. The racial categories included were White, Black or African American (referred to here as "Black," as it is used in a global context), American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Other Race, Multiple Races, and Unknown. Ethnicity categories included Hispanic or Latino, Not Hispanic or Latino, Not Reported, and Unknown.

Race and ethnicity distributions were summarized across the full data set and stratified by therapeutic area and country. Subsequently, race and ethnicity distributions of individual clinical trials were compared with national population data on demographic distribution when such data existed. As race and ethnicity information at the population level are not available in every country, we restricted this part of the analysis to data from participants in the US, Canada, and the UK. Additionally, because race and ethnicity distributions vary by age, we restricted the reference population to the age range of the respective trial population. Only clinical trials with at least 20 participants from the country of interest were included in this part of the analysis. US general population data were obtained from the US Census Bureau national population data sets [13]. Canadian general population data were obtained from 2016 Canadian Census data provided by Statistics Canada [14]. UK general population data were obtained from 2011 UK Census data provided by the UK Office for National Statistics [15].

Number and percentage were provided for each race and ethnicity category for both the trial populations and the reference data. To demonstrate the lack of data available in certain countries, unknown or not reported race or ethnicity was not included in percentage calculations (ie, total of all other race or ethnicity categories was considered 100 %). The underrepresentation or overrepresentation of each category was summarized by subtracting the percentage in the reference population from the percentage in the clinical trial population. Any negative difference was considered to be underrepresentation, whereas any positive difference was considered to be overrepresentation.

3. Results

3.1. Clinical trial participants by therapeutic area and top recruiting countries

The current analyses included 8015 participants from 47 countries who participated in 20 Roche-sponsored neuroscience Phase 2 or 3 trials that completed enrollment between 02/2016 and 02/2021. Ten were Phase 2; 10 were Phase 3. Seven were in AD, 4 in SMA, 3 in ASD, 2 in DMD, 2 in MS, 1 in HD, and 1 in PD. The top 10 recruiting countries were the US (n = 2729), Spain (n = 782), Italy (n = 489), Poland (n = 489), France (n = 386), Germany (n = 383), Canada (n = 290), Colombia (n = 252), Japan (n = 237), and the UK (n = 223).

3.2. Global clinical trial diversity overall and by therapeutic area

Across all trials, 85.6 % of all participants self-reported as being of White race, 7.1 % were Asian, 1.6 % were Black, 1.3 % were American Indian or Alaska Native, less than 0.1 % were Native Hawaiian or other Pacific Islander, 0.7 % were of multiple races, and 3.6 % were of other race. Race was unknown or not reported in 5.6 % of all participants—sometimes because collection of such data is prohibited in certain countries. Table 1 shows the race distribution across all trials, stratified by therapeutic area. Overall, 13.7 % of all participants self-reported as having Hispanic or Latino ethnicity; 84.2 %, non-Hispanic or non-Latino ethnicity; and 2.1 %, unreported ethnicity. Ethnicity was unknown or not reported for 1.9 % of all participants. Table 2 shows the ethnicity distribution across all trials, stratified by therapeutic area.

Fig. 1 shows race distribution for studies carried out in the top 10 recruiting countries (except France, where recording participant race is prohibited). Race distributions for all 47 countries are presented in Supplemental Table S2.

Comparison of racial diversity of clinical trial participants from the US, Canada and UK versus national population data.

Race distribution of study participants in the US, Canada, and the UK were compared with national population data of the respective country with a similar age distribution as the included trials, as comparator data are available for these countries (Table 3). White individuals predominated in all trials, except for 1 SMA trial in the UK. In contrast, Black individuals were underrepresented in all trials across the 3 countries, except for 1 AD trial in Canada. Asian individuals were overrepresented in 3 of 16 trials in the US, and in 1 of 5 trials in the UK.

Comparison of ethnic diversity of clinical trial participants from the US versus national population data.

Comparing ethnic distributions to reference populations was only possible for US trials. Ethnicity data were available for 2720 US participants; of these, 7.3 % self-reported as Hispanic or Latino. The US Census population describes an ethnic population of 16.4 % Hispanic or Latino individuals with similar age distribution (Table 4).

4. Discussion

This report describes the racial and ethnic composition of global Roche neuroscience clinical trials. Consistent with previous clinical trial diversity reports, the race distribution in Roche neuroscience trials did not fully reflect the diversity of the world at large or of participating countries (where such assessment was feasible) [10,11,16–18]. Reference population distribution is often difficult to estimate, as exact data are lacking in many countries. Nevertheless, our finding that White participants represented 85.6 % of all participants globally points to

Table 1
Global race distribution of 8015 participants in 20 Roche-sponsored studies, stratified by therapeutic area.[a]

	White		Black		Asian		American Indian or Alaska Native		Native Hawaiian or Other Pacific Islander		Other		Multiple		Unknown	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
AD	3629	82.2	43	1.0	389	8.8	90	2.0	1	0.0	252	5.7	10	0.2	153	–
ASD	726	86.4	47	5.6	29	3.5	3	0.4	1	0.1	9	1.1	25	3.0	12	–
HD	695	97.5	2	0.3	12	1.7	3	0.4	0	0.0	0	0.0	1	0.1	78	–
MS	592	91.5	25	3.9	8	1.2	3	0.5	1	0.2	0	0.0	18	2.8	35	–
SMA	432	85.7	4	0.8	66	13.1	0	0.0	0	0.0	0	0.0	2	0.4	94	–
PD	249	99.2	2	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	65	–
DMD	151	77.0	1	0.5	32	16.3	1	0.5	1	0.5	10	5.1	0	0.0	13	–
Total	6474	85.6	124	1.6	536	7.1	100	1.3	4	0.05	271	3.6	56	0.7	450	–

Abbreviations: AD, Alzheimer's disease; ASD, autism spectrum disorder; DMD, Duchenne muscular dystrophy; HD, Huntington's disease; MS, multiple sclerosis; PD, Parkinson's disease; SMA, spinal muscular atrophy.

[a] Percentages indicate the percent of the population for which race is known; people of unknown race were not included in these values.

Table 2
Global ethnicity distribution of 8015 participants in 20 Roche-sponsored studies, stratified by therapeutic area.[a]

	Hispanic or Latino		Not Hispanic or Latino		Not reported		Unknown	
	n	%	n	%	n	%	n	%
Alzheimer's disease	761	16.9	3665	81.6	66	1.5	75	–
Autism spectrum disorder	81	9.6	756	89.5	8	0.9	7	–
Huntington's disease	102	13.1	669	85.7	10	1.3	10	–
Multiple sclerosis	76	11.3	574	85.4	22	3.3	10	–
Spinal muscular atrophy	25	4.3	520	90.1	32	5.5	21	–
Parkinson's disease	14	4.5	275	89.3	19	6.2	8	–
Duchenne muscular dystrophy	22	11.7	161	85.6	5	2.7	21	–
Total	1081	13.7	6620	84.2	162	2.1	152	–

[a] Percentages indicate the percent of the population for which ethnicity was known or was classified as not reported. People of unknown ethnicity were not included in these values.

overrepresentation of this group. Although this degree of overrepresentation is lower than that of many other clinical studies, it is unsatisfactory [10,19]. Asian and Black participants only represented 7.1 % and 1.6 %, respectively, of all participants. Comparison of ethnic diversity between our clinical trial population and the reference population was limited to the US, as no national population-level data exist from other countries that use this classification. Although the proportion of Hispanic or Latino participants among participants in the US varied substantially across trials, the average inclusion of people of Hispanic or Latino ethnicity was underrepresented compared to the US Census data (7.3 % vs 16.4 %). Hispanic or Latino participants represented 13.5 % of all global trial participants, due to the inclusion of trial sites in several Hispanic countries. These findings on racial and ethnic distribution in Roche neuroscience trials provide a baseline for comparison of future efforts to promote greater diversity in clinical trial populations.

Achieving racial and ethnic diversity in clinical trials helps to ensure the generalizability of biomedical research to a broad range of patient populations [3,4]. It is also essential to address the ethical principle of justice in clinical research. In the US, ethical principles related to the conduct of clinical research are articulated in the Belmont Report, a publication of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [5]. In biomedical research, fair allocation of society's benefits and burdens requires that no single gender, racial, ethnic, or socioeconomic group receives disproportionate benefits or bears disproportionate burdens of research. Violations of distributive justice may occur when certain populations are unduly subjected to the risks of research (eg, prisoners, persons confined to institutions, racial and ethnic minority groups), or when the benefits of research are denied to certain groups of people [3].

Previous publications on clinical trial diversity have mainly focused on the US, and underrepresentation of minority groups in these trials have been demonstrated for many conditions, generally using the US Census data as a reference. [17,18,20–23] A previous report examined racial and ethnic distribution of US participants in trials of approved drugs that were presented in the US Food and Drug Administration's (FDA's) Drug Trials Snapshots between 2015 and 2019 [17]. Among trials in the field of neuroscience, on average, White patient participation was 81 %; Black patient participation, 14 %; Asian patient participation, 1 %; and Hispanic or Latino patient participation, 14 %. For neuroscience trials in the US, White and Black patient representation was above the census rate, whereas Asian, American Indian or Alaska Natives, and Hispanic or Latino patient participation were all below census rates [17].

Minority populations were also underrepresented in global trials, according to an analysis of global pivotal trials underlying FDA approvals of treatments for heart disease, cancer, and disorders of the central nervous system over 5 years studied (1997, 2004, 2009, 2012, and 2014). Of all participants of individual trials, Black participants constituted 1.8 %–3.5 %, and Asian participants constituted 0 %–7 %. The findings of that review were compared to the racial distribution in the US Census data, but the authors acknowledged that this comparison is limited given the variation in race and ethnicity distribution from country to country [9]. A systematic review of international randomized clinical trials conducted between 1996 and 2018 in participants with AD demonstrated that only 59 % of the 49 included studies reported information on the participants' race [24]. In that review, among participants with AD recruited in the considered trials with known race, 81.8 % were of White race, 13.6 % were of Asian race, 3.5 % of Hispanic race, and only 1.0 % constituted Black participants.

The FDA has released guidance for the determination of race and ethnicity in clinical data, and this classification has also been applied in the Roche clinical trials included in the current analysis. However, constructs of race may change over time, and European Union member countries have varying legal definitions of race and ethnic origin [2,25,26]. Laws in certain countries, such as France, even prohibit the collection of personal data that directly or indirectly reveals participants' racial or ethnic origin [26].

Despite the many challenges of evaluating the racial and ethnic composition of study populations, increasing diversity in clinical research, including global clinical trials, is necessary. However, some barriers exist to designing more diverse clinical trials. For a global trial, the optimal target distribution of race and ethnicity is unknown, as reference data are generally not available for each included country. Moreover, some racial or ethnic groups may be disproportionally affected by certain diseases, but only limited data exist globally on race and ethnic distribution within specific disease populations.

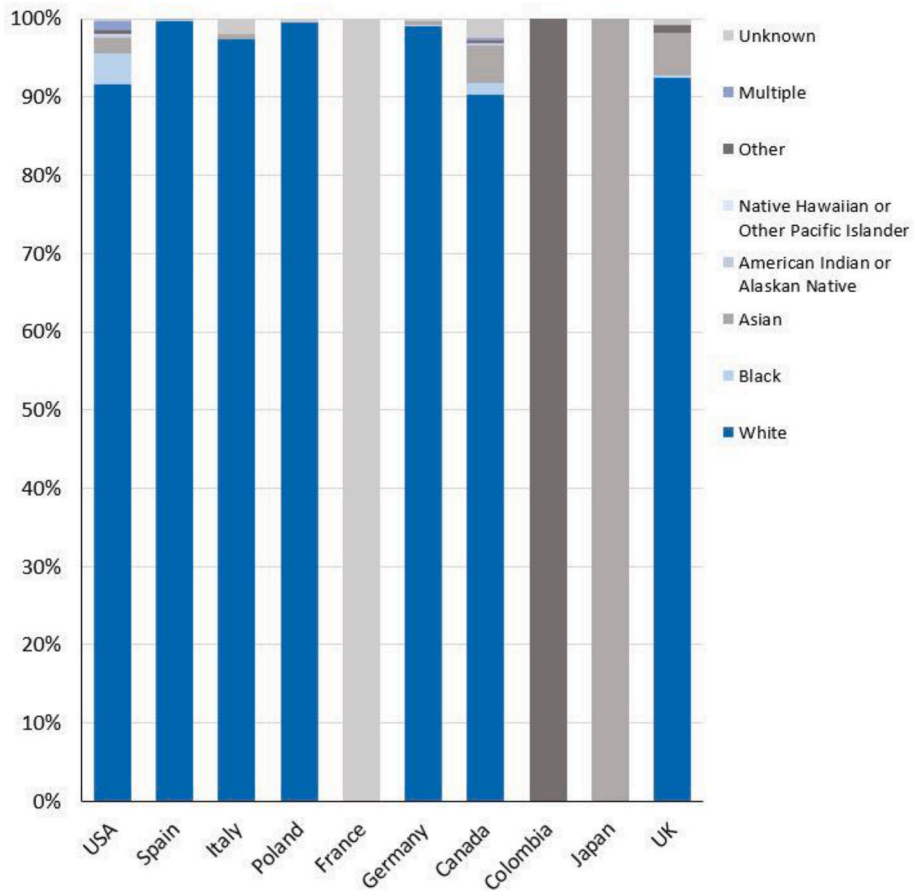

Fig. 1. Country-specific race distribution across studies carried out in the top 10 recruiting countries.*
*Race distributions for all 47 recruiting countries are presented in Supplemental Table S2.

Table 3a
Comparison of race distribution between the clinical trials and the general age-adjusted population in the United States.

Overrepresentation -30% -20% -10% 0% 10% 20% Underrepresentation

Trial age (years)	Study	n	Therapeutic area	White	Black	AI or AN	Asian	NH or PI	Two or more
50+	BN29552	254	Alzheimer's disease	14.5	-8.4	-0.9	-4.3	-0.2	-0.8
50+	BN29553	194	Alzheimer's disease	15.9	-9.6	-0.4	-4.6	-0.2	-1.2
50+	WN29922	201	Alzheimer's disease	15.5	-8.6	-0.9	-4.6	-0.2	-1.2
50+	WN39658	235	Alzheimer's disease	14.2	-7.7	-0.9	-4.2	-0.2	-1.2
50-79	GN39763	222	Alzheimer's disease	15.3	-9.7	-0.5	-4.7	0.3	-0.7
50+	GN40040	171	Alzheimer's disease	12.6	-5.9	-0.9	-4.5	-0.2	-1.2
20-44	BP28420	223	Autism spectrum disorder	16.5	-6.3	-1.4	-5.7	-0.3	-2.8
5-19	BP30153	308	Autism spectrum disorder	9.5	-10.5	-1.3	0.5	0.0	1.7
20-59	WN39434	241	Autism spectrum disorder	13.9	-8.2	-0.5	-4.2	-0.3	-0.7
25-64	BN40423	165	Huntington's disease	21.3	-13.6	0.0	-6.0	-0.3	-1.4
20-54	BN29739	82	Multiple sclerosis	19.3	-8.2	-1.4	-7.0	-0.3	-2.5
20-54	MA30143	137	Multiple sclerosis	8.3	-0.2	-1.4	-4.7	-0.3	-1.7
<60	BP39054	31	Spinal muscular atrophy	12.8	-11.2	-1.4	0.2	-0.3	-0.1
40-79	BP39529	160	Parkinson's disease	19.2	-10.8	-1.1	-5.7	-0.2	-1.4
5-9	WN40226	39	Duchenne muscular dystrophy	4.4	-12.5	1.0	13.1	-0.3	-5.8
5-9	WN40227	58	Duchenne muscular dystrophy	24.3	-15.1	-1.6	-3.4	1.6	-5.8

Abbreviations: AI, American Indian; AN, Alaska Native; n, number of participants; NH, Native Hawaiian; PI, Other Pacific Islander.

Inclusion of developing countries could potentially improve global trial diversity. Nonetheless, ethical and regulatory system obstacles, operational barriers, competing demands, and lack of financial resources, human capacity, and research environment may pose challenges to conducting global trials in developing countries [27].

Many actions have been taken by the overall clinical research community to increase diversity and to promote equity for underrepresented minority populations in clinical research, but unfortunately, these efforts have not always led to sufficient improvements. The FDA and the Revitalization Act of 1993 require that clinical trials funded by the National Institutes of Health include women and minority participants and assess outcomes by sex and race or ethnicity [28]. However, the diversity in clinical trials in the US and clinical trial reporting in the medical literature have not substantially improved since the Act was signed into law [1,6,28]. Another more recent initiative from the FDA was the 2020 publication of new guidance on eligibility and trial design to increase the diversity of clinical trial populations [4], but it will likely take time before any effects of this action are evident. Other efforts to increase diversity have been enacted at the study level. The Anti-Amyloid Treatment in Asymptomatic Alzheimer's study (the A4 Study) required that at least 20 % of people screened for enrollment at each recruitment site would be from racial and ethnic minority groups [29,30]. However, the study did not meet this goal; 88 % of population was non-Hispanic White, which suggests that despite the additional efforts, diversity was even less than previous neurology trials in the US [17] and the global Roche AD trials analyzed in this review. One explanation for the low inclusion of racial and ethnic minority groups in the A4 Study is that the minority population was more likely to meet exclusion criteria than the nonminority population [21,29].

Recognizing the continued underrepresentation of minority populations in clinical trials, Roche (Genentech) aims to embed diversity and inclusion as a key strategic component of research program planning. Roche is striving to take into account the needs of diverse populations for trial design; broadening eligibility criteria to increase diversity in enrollment, when scientifically and clinically appropriate; engaging in community outreach to build trust and understanding of the trial; offering language and cultural support to participants from diverse backgrounds; providing adequate support to participants to offset the time and resources they must invest in trial participation; and

Table 3b
Comparison of race distribution between the clinical trials and the age-adjusted general population in the United Kingdom.

Overrepresentation -30% -20% -10% 0% 10% 20% Underrepresentation

Trial age (years)	Study	n	Therapeutic area	White	Black	Asian	Two or more	Other
50+	BN29552	28	Alzheimer's disease	6.3	-1.6	-3.7	-0.5	-0.4
50+	BN29553	21	Alzheimer's disease	6.3	-1.6	-3.7	-0.5	-0.4
50+	WN39658	54	Alzheimer's disease	4.4	-1.6	-1.9	-0.5	-0.4
25-64	BN40423	46	Huntington's disease	13.5	-3.3	-7.7	-1.4	-1.1
<60	BP39054	20	Spinal muscular atrophy	-13.3	-3.9	21.1	-2.7	-1.2

Abbreviations: n, number of participants.

Table 3c
Comparison of race distribution between the clinical trials and the age-adjusted general population in Canada.

Overrepresentation -30% -20% -10% 0% 10% 20% Underrepresentation

Trial age (years)	Study	n	Therapeutic area	White	Black	Asian	Two or more	Other
50-85	BN29552	45	Alzheimer's disease	14.1	-2.1	-9.5	-0.4	-2.1
50-85	BN29553	32	Alzheimer's disease	13.2	1.0	-11.7	-0.4	-2.1
50-90	WN29922	65	Alzheimer's disease	10.1	-0.6	-8.7	-0.4	-2.1
50-81	GN39763	27	Alzheimer's disease	8.9	-2.1	-4.3	-0.4	-2.1
25-66	BN40423	48	Huntington's disease	19.9	-3.1	-12.9	-0.5	-3.3
21-55	BN29739	20	Multiple sclerosis	10.4	-3.8	-2.1	-0.7	-3.8

Abbreviations: n, number of participants.

implementing digital health technologies to address recruitment challenges and enrollment barriers due to site location, planned visit schedules, and travel and financial implications.

Other larger-scale initiatives prioritize understanding of racial and ethnic disparities in healthcare. The CHIMES study, which involves monoclonal antibody ocrelizumab developed by Roche (Genentech) for relapsing MS, seeks to provide insights to help improve the quality of care for underserved Black and Hispanic patients with MS [31]. Likewise, the ALUMNI AD study of the Roche (Genentech) gantenerumab molecule aimed to evaluate the treatment in historically underrepresented US populations with early symptomatic AD [32].

Clinical research is increasingly being conducted on a global scale; therefore, it is essential to establish global approaches to ensure that human diversity is reflected in such trials. Global trials may need to define and achieve diversity differently than has traditionally been done. For example, in addition to attempting to increase the proportion of Hispanic individuals in the US subpopulation of a global trial, one could also increase participation of Hispanic patients by including countries like Spain or Mexico. However, the infrastructure is not available everywhere for such trials. Africa is one example of a vast region that is notably underutilized presently. Ideally, a global trial should match the demographic distribution of the global population affected by the disease of interest rather than the distribution of the general population in any single country.

When designing a study, one of the starting points should be a careful consideration of why ethnic and racial diversity is important for the interpretation of that specific study's results. Ensuring the inclusion of subgroups large enough to allow for subgroup analysis has an enormous impact on cost and should therefore be weighed against the likelihood of the presence of diversity in health outcomes [33]. In the current paper, we provide an insight in the ethnic and racial diversity of Roche-sponsored global neuroscience Phase 2 or 3 studies that completed enrollment between February 2016 and February 2021. To conduct meaningful global clinical trials, we must develop an approach to achieving diversity that has been carefully balanced against the study population, design, objectives, and hypotheses.

Table 4
Comparison of ethnic distribution between Roche-sponsored clinical trials and the age-adjusted general population in the United States.

Overrepresentation -30% -20% -10% 0% 10% 20% Underrepresentation

				Hispanic or Latino		
Trial age (years)	Study	n	Therapeutic area	Clinical trial (%)	Census (%)	Difference
50+	BN29552	254	Alzheimer's disease	3.5	11.1	-7.6
50+	BN29553	194	Alzheimer's disease	2.1	11.1	-9.1
50+	WN29922	201	Alzheimer's disease	1.5	11.1	-9.6
50+	WN39658	235	Alzheimer's disease	17.5	11.1	6.4
50-79	GN39763	222	Alzheimer's disease	4.1	11.5	-7.5
50+	GN40040	171	Alzheimer's disease	0.6	11.1	-10.6
20-44	BP28420	223	Autism spectrum disorder	6.9	21.1	-14.2
5-19	BP30153	308	Autism spectrum disorder	12.5	25.2	-12.7
20-59	WN39434	241	Autism spectrum disorder	7.1	19.2	-12.1
25-64	BN40423	165	Huntington's disease	7.9	17.8	-9.9
20-54	BN29739	82	Multiple sclerosis	7.6	20.1	-12.5
20-54	MA30143	137	Multiple sclerosis	11.9	20.1	-8.1
<60	BP39054	31	Spinal muscular atrophy	16.1	21.2	-5.0
40-79	BP39529	160	Parkinson's disease	3.1	13.8	-10.7
5-9	WN40226	39	Duchenne muscular dystrophy	10.5	26.0	-15.4
5-9	WN40227	58	Duchenne muscular dystrophy	19.0	26.0	-7.0

Abbreviation: n, number of participants.

5. Limitations

Limitations of our study include self-reporting of both race and ethnicity, which relies on the participant's subjective interpretation of the race and ethnicity definition and its classifications. Moreover, some people may be only partly aware of their ancestry or may identify themselves with just one racial or ethnic group despite having a mixed background. Furthermore, the classification used in these trials may not be fitting for all countries and populations. The analyses were limited in that they used the general population as reference population, rather than the population affected by the disease. Some diseases may disproportionately affect certain racial and ethnic groups. Finally, analyses were limited by some unknown or not reported race and ethnicity both in the trials and in the reference populations, due to country-specific regulations.

6. Conclusions

Enrolling clinical trial participants from diverse ancestry, racial, ethnic, and socioeconomic groups is essential to improve health outcomes and address bioethical principles of justice in clinical research. Despite recent efforts to address inequities in clinical trial enrollment, underrepresentation of several racial and ethnic groups persists in neuroscience clinical trials. To help increase transparency in reporting of information about race and ethnicity as a first step toward diversifying clinical research, we report here the racial and ethnic distribution of recent Roche-sponsored global neuroscience clinical trials. Overall, 85.6 % of all participants in global Roche neuroscience clinical trials self-reported as being of White race, and 84.2 % self-reported as having

non-Hispanic or non-Latino ethnicity. Comparisons of study compositions with general population data from the US, Canada, and the UK where such information was available demonstrated substantial overrepresentation of White participants. These findings underscore the need for strategies to increase racial and ethnic diversity in global clinical research and provide a baseline for comparison of future efforts to promote greater diversity in clinical trial populations. The findings of this analysis have implications not only for Roche, but for the broader neurology research community. They underscore the work that remains to be done to improve representation of the entire population affected by a given disease, increase the generalizability of the findings, and ensure that the benefits of clinical research are truly reaped by all.

CRediT authorship contribution statement

Loes Rutten-Jacobs: Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Tammy McIver:** Data curation, Formal analysis, Methodology, Writing – review & editing. **Adriana Reyes:** Methodology, Writing – review & editing. **Marta Pereira:** Methodology, Writing – review & editing. **Rachel Rosenthal:** Writing – review & editing. **Christine T. Parusel:** Conceptualization, Writing – review & editing. **Kathryn R. Wagner:** Conceptualization, Writing – review & editing. **Rachelle Doody:** Conceptualization, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: LR-J, AR, MP, RR, CTP, and KRW are employees of and may own stock or stock options in F. Hoffmann-La Roche Ltd. TM is an employee of and may own stock or stock options in Roche Products Ltd. RD is an employee of and may own stock or stock options in F. Hoffmann-La Roche Ltd and Genentech, a Member of the Roche Group.

Acknowledgments

Medical writing and medical editorial support were provided by Mark Bowes, Yvonne Small, Clare Sonntag, and Katia Zalkind. These individuals are employees of Health & Wellness Partners, LLC; their support was funded by Genentech, A Member of the Roche Group, in accordance with Good Publication Practice guidelines (https://www.ismpp.org/gpp-2022).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2024.101255.

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