

Percentage of Non-Caucasians in Clinical Trials from 2000 to 2009

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INTRODUCTION

According to medical terms race is ethnic stock or division of humans. The Office of Management and Budget (OMB) suggested the classification of races for record keeping, presentation and collection of the data (Office of Management and Budget, 1995). They even mentioned that these should not be considered as being scientific or anthropologic in nature and these were just developed for federal statistics and program administrative. Race and ethnic categories are defined by the OMB (Office of Management and Budget, 1997) as:

- 1) American Indian or Alaska Native: A person who has origin in any of the original peoples of North, south or Central America and who maintains community or tribal attachment.
- 2) Asian: A person who has origins in any of the original peoples of the Far east or south east Asia or the Indian subcontinent including like Pakistan, Philippines, China ,India, Japan, Korea etc.
- 3) African-American: A person who has origins in any of the black racial groups of Africa
- 4) White: A person who has origins in any of the original people of middle east, north Africa or Europe
- 5) Hispanic or Latino: A person who has origins in Cuba, Mexico, south or central American or Spanish origin regardless of race.
- 6) Native Hawaiian or Pacific Islander: A person who has origins in any of original people of Hawaii, Guam, Samoa or other pacific islands.

The respondents should be offered the option of selecting one or more races according to the OMB (Office of Management and Budget, 1997). FDA also recommends using the same classification as this will help in comparing the results of clinical trial data between other agencies and FDA. Using the standard categories would also help the FDA in identifying and analyzing the differences in response (Food and Drug Administration, 2003).

The differences in the responses to drugs had already been observed between different races. These differences may be because of many factors like pharmacokinetics, environmental exposure. For example, gefitinib, a lung cancer drug prolonged life on medication for 9.5 months for Asians, nearly double the 5.5 month average for the general population (Zamisak N, 2005). Similarly Bidil (hydralazine hydrochloride and isosorbide di-nitrate), a drug intended to treat congestive heart failure worked far better in African-Americans than in whites (Duster, 2007). The serum creatine kinase levels were found to be higher in black people when compared to white people (Brewster, Coronel, Sluiter, Clark, & Van Montfrans, 2012). An important enzyme that metabolizes drugs belonging to the beta blocker class and antipsychotic class was found to be abnormally low in Caucasians when compared to Asians and African origin (Xie, Kim, wood, & Stein, 2001).

BACKGROUND

To assure the safety and efficacy of the drugs in the larger population of intended use FDA has given great deal of attention to the racial and ethnic differences in response to drugs during NDA development. In 1988 “The Guideline for The Format and Content of The Clinical and Statistical Sections of An Application” notes the importance of the inclusion of the demographic data like age, sex, race in the New Drug Applications (Food and Drug Administration, 1988). To increase the participation of minority racial groups, FDA has developed guidelines and regulations which improve the collection of data on racial differences during the research. In 1997 the “Food and Drug Administration Modernization Act (FDAMA)” required inclusion of minorities and women into the clinical trials (Food and Drug Administration, 1997). Section 115 of the Act required a guidance to help increase the inclusion of women and minorities in clinical trials. To develop the guidance a working group was established by FDA which released a report on July 1998 stating that no additional guidance was required but that agency would increase its competency in collecting and evaluating demographic data and then determine about the additional guidance in the future.. The demographic rule of “Final Rule on Investigational New Drug Applications 1998” mandates that enrollment of subjects be tabulated by demographic subgroups (Food and Drug Administration, 1998). Effectiveness and safety data should be analyzed for demographic subgroups such as race and should be reported in the Investigational new drug annual reports. The guidance for industry on population pharmacokinetics (Food and Drug Administration, 1999) explained clearly how to gather information about differences in pharmacokinetics, how the analysis should be done and how to represent the data when a population model parameter was included in label. “Content and Format of The Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics” was developed (Food and Drug Administration, 2006) provides guidance to report the adverse reactions for specific

demographic subgroups. In the guidance specific consideration was given about the clinically important differences between subgroups. It also mentioned that the presenter should discuss the differences, and even if there is no information about differences they should explain why that information was not available. The guidance “Clinical Studies Section of Labeling for Prescription Drugs and Biologics- Content and Format” suggests that a summary statement should be given about the results of required studies and effects in different age, sex, racial sub groups and the summary statement should mention clearly about the differences (Food and Drug Administration, 2006).

According to Crawley (Crawley & Lavera, 2001) mistrust was a significant barrier in inclusion of minorities into clinical trials. The USPHS syphilis study (Gamble, 1997) had greater influence on African-Americans regarding the participation of clinical trials but according to the data from focus group research with African-American groups showed that some of the participants, even though they had the information about the syphilis study, stated it did not influence their decision on participation in a trial. The Office of Special Health Issues (OSHI) conducted three projects which collected and analyzed demographic data. The first study “Special populations: Testing and Labeling of New Drugs” (Evelyn, Togio, Banks, Gray, Robins, & Ernat, 2001) collected demographic data on new molecular entities (NME’S) approved in 1995-1996. The results from this study indicate that all clinical studies had African American participants but representation of the other minority racial groups was low. The second study “Race Age and Gender: A Review of Demographic Subgroups in Clinical Trials of FDA Regulated Drugs and Biologics” (Evelyn, Togio, Banks, Gray, Robins, & Ernat, 2001) reviewed INDs to check whether the sponsors adhered to the requirements of 1998 demographic rule. The results showed that 85% of the INDs did not have all the required information according to the demographic rule. And from the INDs where race was mentioned, of the total percentage of study participants, 9 percent were found

to be African-Americans, 3 percent each for the Latinos, Asians, pacific islanders, native Hawaiians. Three percent were reported as non-whites and American Indian and Alaska natives were found to be less than 1 percent. The third study “Participation of Racial/Ethnic Groups in Clinical Trials and Race Related Labeling: A Review of New Molecular Entities Approved 1995-1999” (Evelyn, Togio, Banks, Gray, Robins, & Ernat, 2001) collected data from FDA Medical Officers’ reviews of 185 new molecular entities approved by the Center for Drug Evaluation and Response (CDER) 1995-1999. In this study the medical reviews were examined for data related to race of participants and were analyzed by year of product approval and therapeutic class. The results from the study show 53 percent of participants race could be identified from the Medical Officer’s reviews. Of these participants, whites were 88 percent, Africans Americans were 8 percentage, Asian or pacific islander were 1 percent, Hispanic were 3 percent and American Indian or Alaska native were less than 1 percent. When the results were analyzed by year these percentages varied for every racial group. The percentage of African-American participants decreased from 12 percent in 1995 to 6 percentage in 1999 and had been declining over the period. Among the trials conducted only in USA, the percentage varied from 18 percent in 1995 to 10 percent in 1996. And according to Gifford and colleagues (Gifford, Cunningham, Heslin, & al., 2002) in a clinical study conducted for human immunodeficiency virus infection in USA in 1996-1998, only 25 percent of the total African-Americans who enrolled at start of the study were enrolled in follow-up clinical trials. This percentage was low when compared to whites whose percentage was 53. From the above information presented, there has been a decrease in the percentage of the non-Caucasian race participation in the clinical trials.

Research questions:

The number of drugs which show a difference in response in different race has been increasing as more clinical trials are conducted. During the clinical trials it is important that

Comparison of Caucasian and non-Caucasian race participation in clinical trials from 2000-09

participants from different racial groups are included that represent the whole targeted patient population. By this method the differences in responses can be determined during the initial stages of drug development. This information would be useful in product labeling and minimize unwanted effects in the patients who will be using the drug. The main purpose of this research is to answer following questions:

- 1) Has the percentage of the non-whites increased or decreased during 2000-2009 period?
- 2) What is the percentage of the different racial groups' participation in clinical trials during 2000-2009 period?
- 3) Has the percent of participation increased or decreased within each racial subgroup?

METHODOLOGY

For this project, the findings of Evelyn et al (ref year?) were extended to next 10 year period and followed the same methodology. The data was collected from the FDA website where drug approvals by month are listed. For each new molecular entity approved, a medical officer review was available. From those reviews data related to description of races and information about the total number of participants in trial and their division by race was collected. This information was collected from all the NMEs approved during 2000-2009. All the data collected was analyzed by individual racial subgroups and compared the percent of participation by year for individual racial subgroups and also between racial subgroups. From these data a chart was developed that include percentage of non-Caucasians, percentage of different racial participation in clinical trials on x axis and year on y axis and the chart will show whether the percent has increased or decreased. And the present trends were compared to 1995-1999 trends.

Data Analysis:

From the clinical trials mentioned in the 218 new molecular entities Medical Officers' reviews, racial data were collected for analysis. Data were collected for each race mentioned in each NME approved in each year. The same data was gathered for all the 218 NMEs. The total participants by race per year were calculated. The total number of participants by race over the period 2000-09 was calculated by adding the number of participants in each race per year. The percentages were calculated for each year and over the period 2000-09 by adding the total participants. The percentages have been calculated by using the following formula:

Percentage of a specific race participation = Total number of participants in a specific race in clinical trials from NDAs approved in the specific year divided by the total number of participants in clinical trials from NDAs approved that year times 100.

RESULTS

Table 1 provides the total number of NDAs approved and NMEs approved by year.

YEAR	NDA'S APPROVED	NEW MOLECULAR ENTITIES APPROVED
2000	98	27
2001	66	24
2002	78	17
2003	72	21
2004*	119	36
2005	80	20
2006	101	22
2007	78	18
2008	89	24
2009	90	26
Total	871	235

Table 1. Total number of NDA'S and NME'S approved by year. *The number of approvals after 2004 includes both new molecular entities and biological license applications transferred from the Centre for Biological Evaluation and Research (CBER) to the CDER.

From the clinical trials mentioned in the 218 new molecular entities, most of the Medical Officers' reviews did not have clinical trials participants' race and ethnicity mentioned clearly. From the 218 NMEs for which the race and ethnicity could be determined, 81.9% of the participants were Caucasians, 6.8% were African-American, 3.5% were Hispanic, 0.1% were American Indians, 4% Asian and 3.7% mentioned race as "other." Table 2 provides the percentages of the different racial subgroups' participation by year from 2000-09.

Comparison of Caucasian and non-Caucasian race participation in clinical trials from 2000-09

Year	Caucasian	African American	Hispanic	Asian	Other
2000	87.1	7.3	2.6	0.64	2.4
2001	73.8	10	6.9	4.8	4.4
2002	79.8	4.3	6.8	2.6	6.5
2003	87.3	6.6	0.4	1.7	3.6
2004	76.2	7	6.8	2.5	7.33
2005	76.5	6.8	4.2	7.3	5.2
2006	79.7	6.3	4.3	4.2	5.2
2007	82.5	8.3	3.4	0.1	4.7
2008	85.4	7.1	2.6	4.8	3.6
2009	75	5.5	5.3	9	5.7

Table 2. Clinical Trial Participation of Different Races per Year. Total number includes only for those whose race and ethnicity was mentioned in medical officer’s reviews of approved NME’s over the period of 2000-09.

The average percentage of the participation by race over the period 2000-09 has been calculated by adding up the total participants by each racial subgroup. The percentages are depicted in Figure 1.

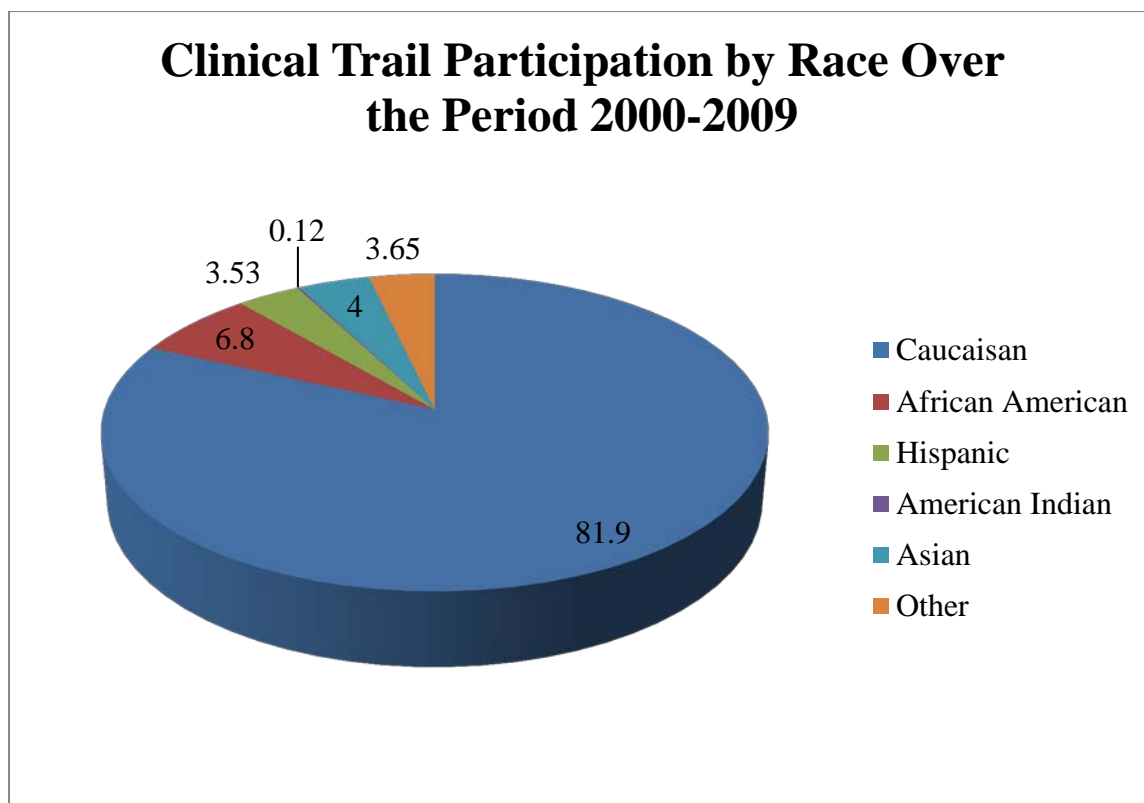


Figure 1. Clinical Trial Participation by Race Over the period 2000-09. Total number includes only those whose race and ethnicity were mentioned in Medical Officers' reviews of approved NMEs over the period of 2000-09.

Participation of Different Races in Clinical Trials by Year

For each racial group, the percentage of participation varies from year to year. Overall, the Caucasian race participation has decreased from 87.1% in 2000 to 75% in 2009. For African-Americans, participation varied from 7.3% in 2000 to 5.5% in 2009. For Asian and Hispanic races the percentage increased from 0.6% in 2000 to 9% in 2009 and 2.6% in 2000 to 5.3% in 2009, respectively. Figures through 2 to 7 display the different racial participation by year.

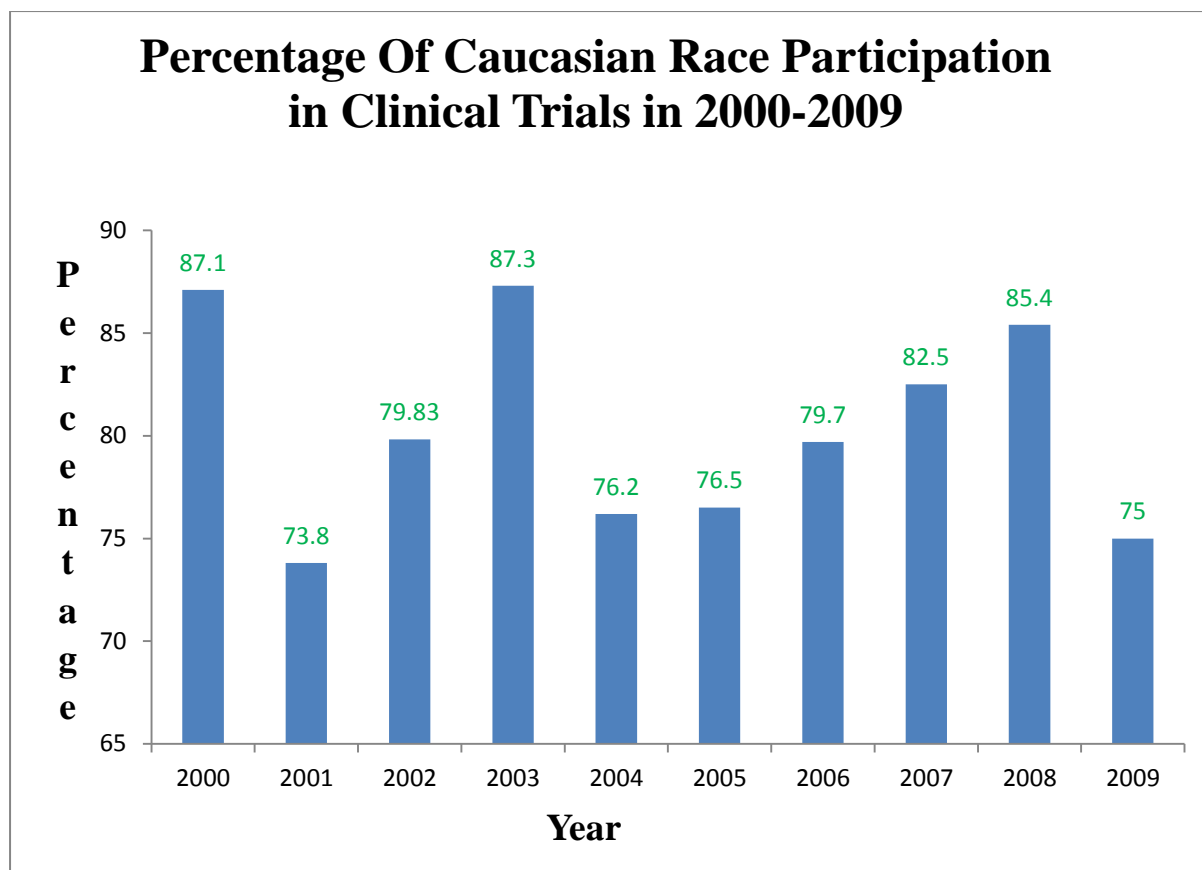


Figure 2. The Percentage of Caucasian Participation in Clinical Trials in 2000-09. Caucasian participation has decreased from 87.1% to 75% by 2009. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers' reviews of approved NMEs over the period of 2000-09.

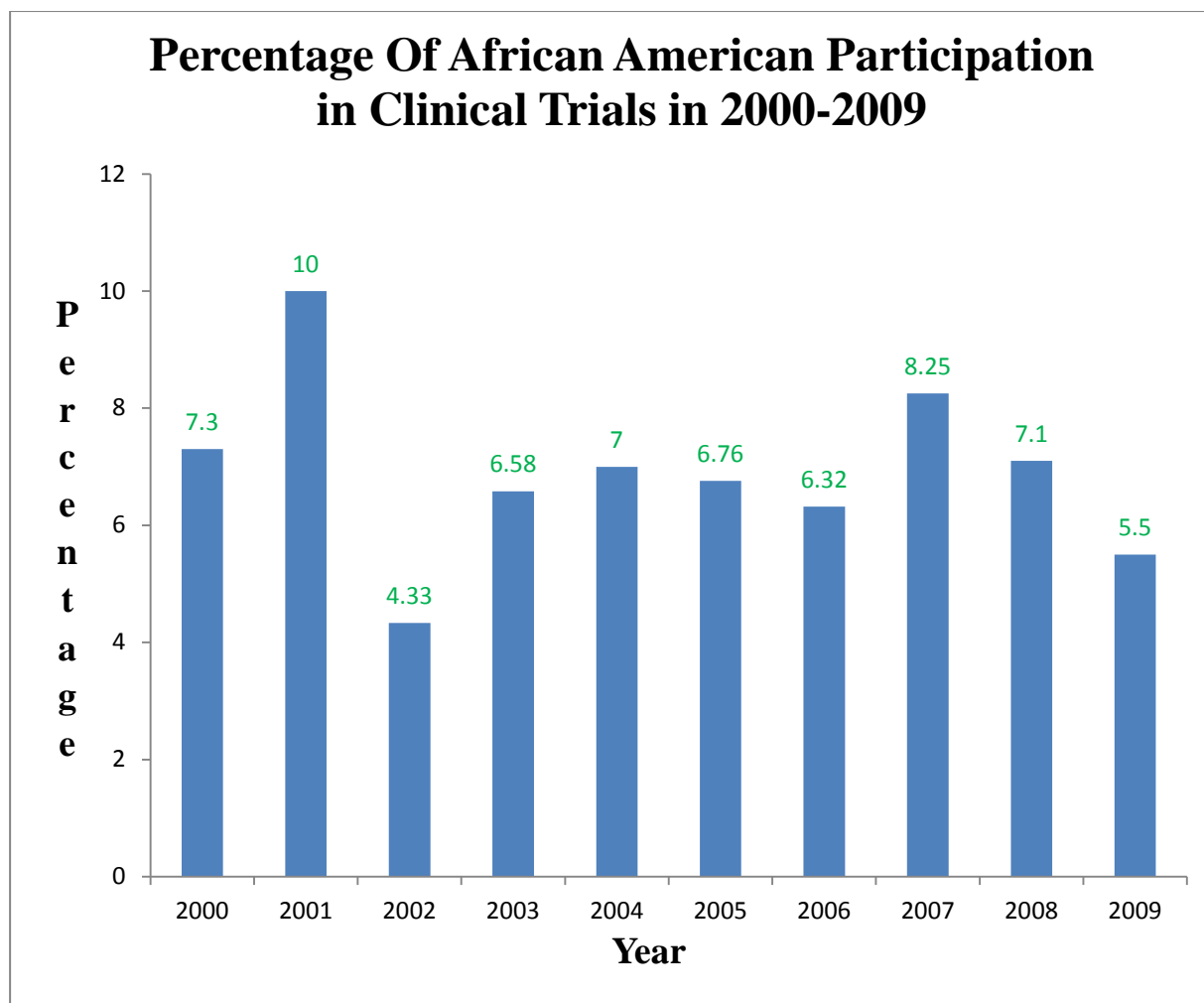


Figure 3. The Percentage of African American Participation in clinical trials in 2000-09. African American participation has been on an average of 6.8% over the 10 year span. The highest being 10% in 2001 and lowest being 4.33 in 2002. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers' reviews of approved NME's over the period of 2000-09.

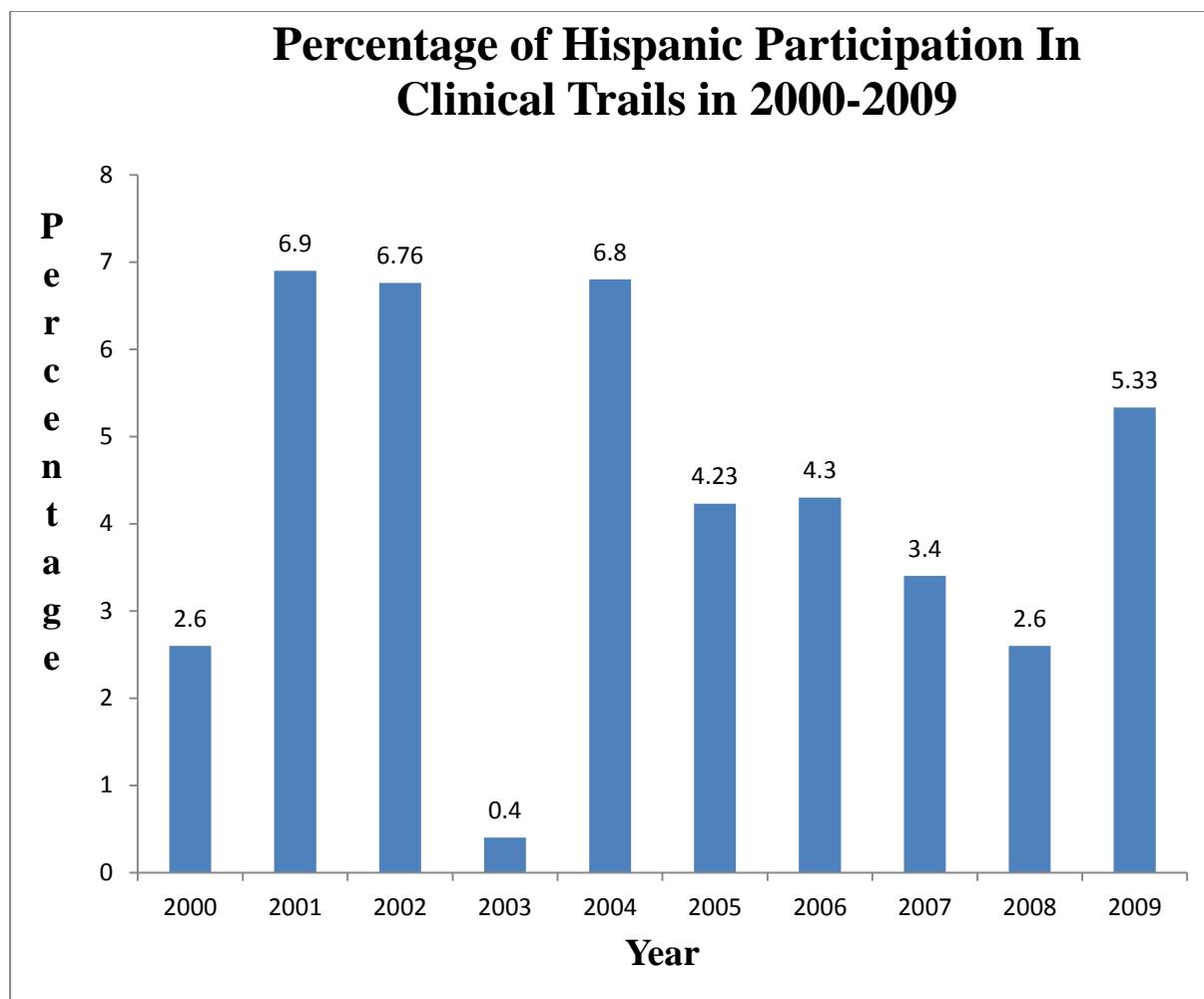


Figure 4. The Percentage of Hispanic Participation in Clinical Trials in 2000-09. Hispanic population participation has varied from 2.6% in 2000 to 5.33% in 2009 with 6.9% being the highest in 2001 and 0.4% being lowest in 2003. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers' reviews of approved NME's over the period of 2000-09.

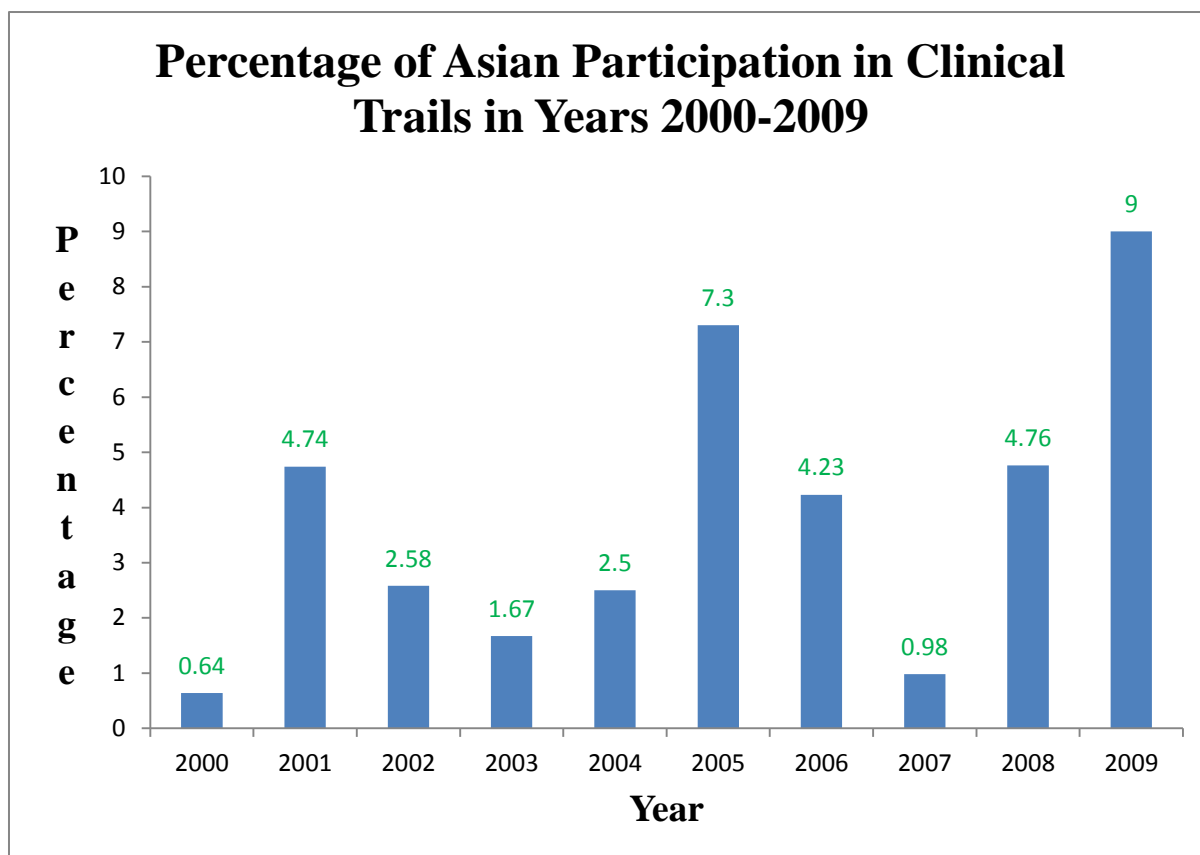


Figure 5. The Percentage of Asian Race Participation in Clinical Trials in 2000-09. Asian participation in clinical trials has increased from 0.64% in 2000 which lowest in the 10 year span to 9 % in 2009 which is the highest in the 10 year span. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers' reviews of approved NME's over the period of 2000-09.

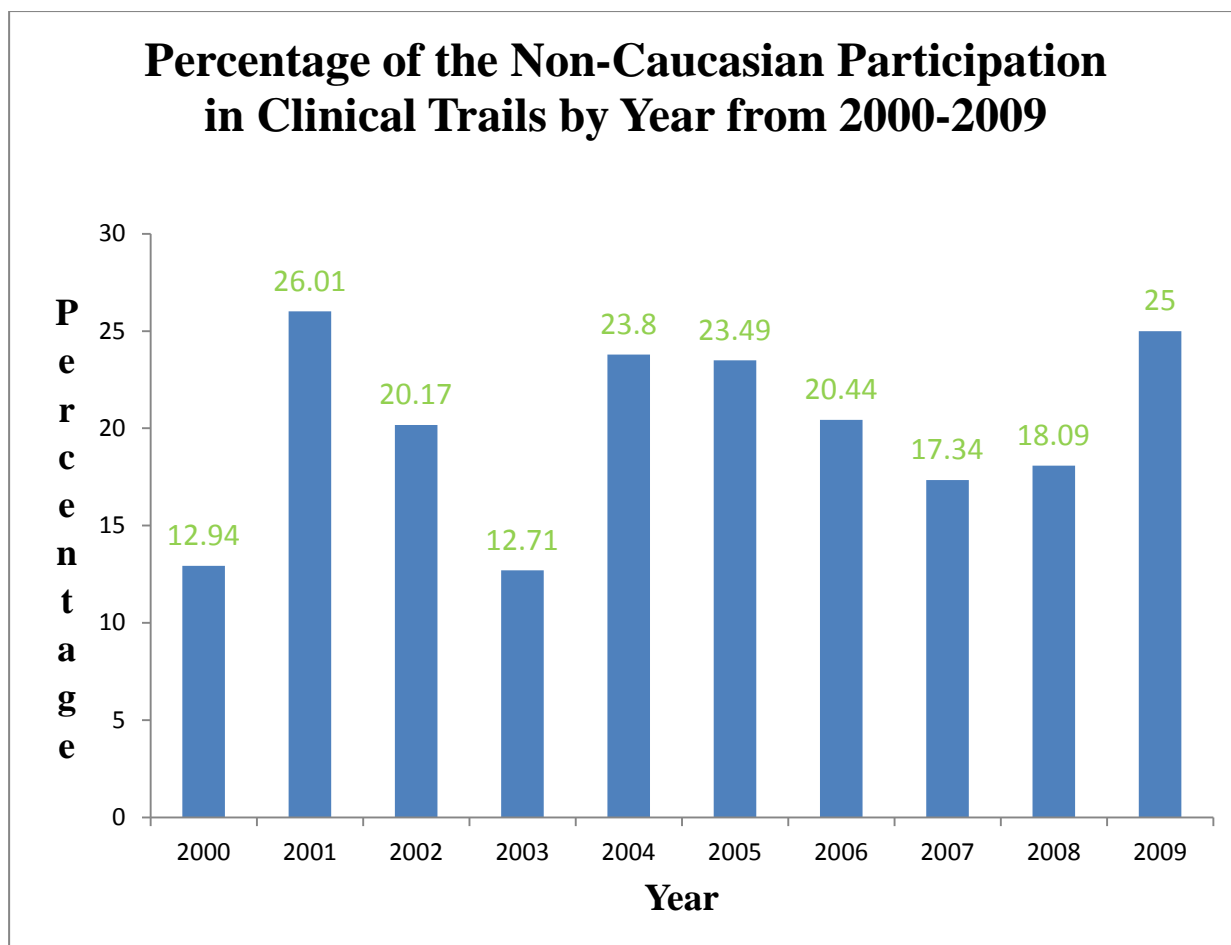


Figure 6. The Percentage of Non-Caucasian Participation by Year from 2000 to 2009 which has an increase from 12.94% in 2000 to 25% in 2009. The highest being 26.01% in 2001 and lowest being 12.71 % in 2003. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers' reviews of approved NME's over the period of 2000-09.

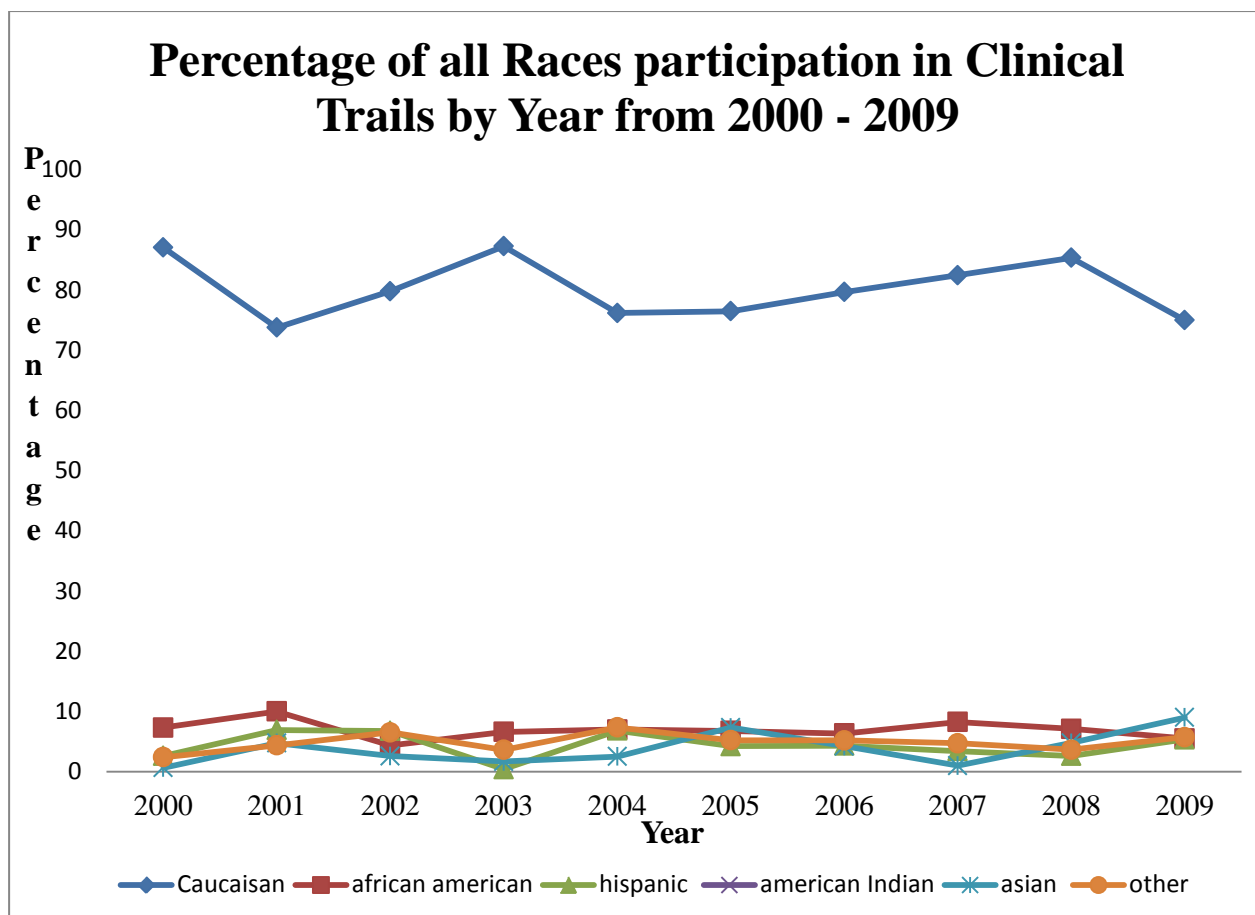


Figure 7. The Percentages of All the Racial Subgroups Participation in Clinical Trials for 2000-09. Total number includes only for those whose race and ethnicity was mentioned in Medical Officers’ reviews of approved NME’s over the period of 2000-09.

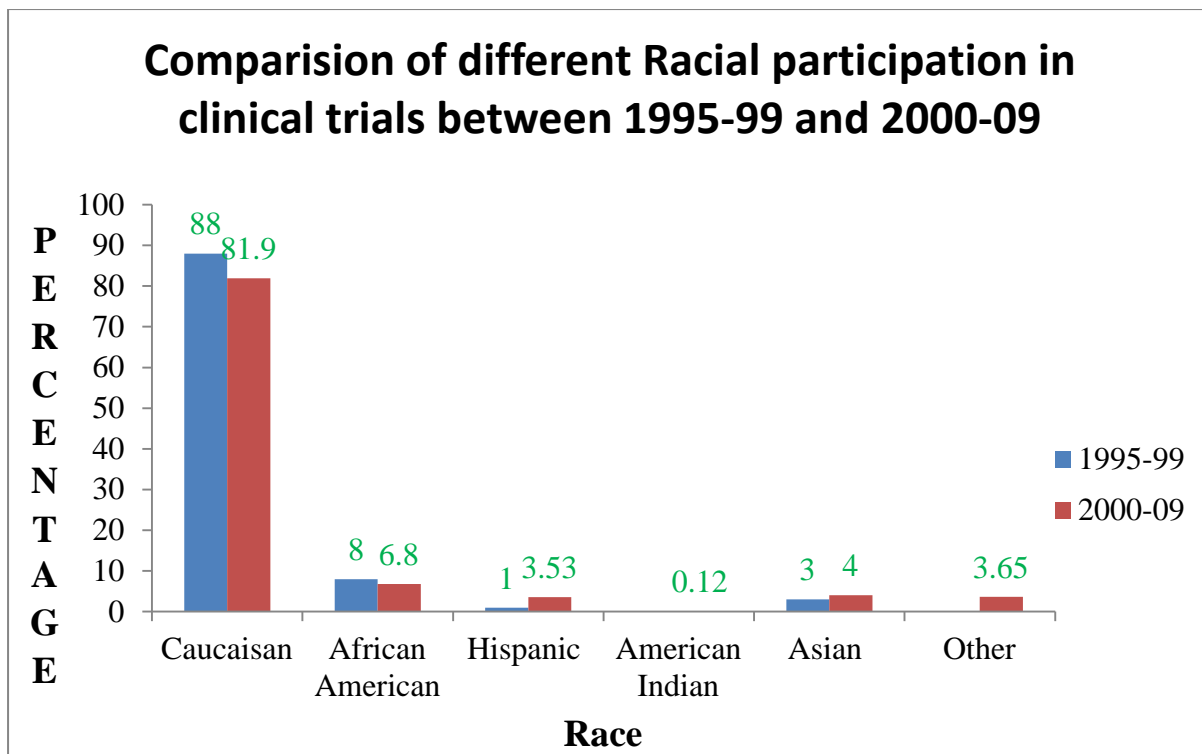
DISCUSSION

Participation of Racial/Ethnic Groups

In clinical trials during the 10 year period 2000-09 observed, the percentage of participation of Caucasian and non Caucasian race varied. Caucasian participation decreased over the period where as the African-American participation did not see a rise. African-Americans had an overall average of 6.8%. On the other hand, the highest rise in terms of participation was seen in Asians which rose from 0.64% in 2000 to 9% in 2009. To determine year-to-year differences, no differences were seen in product approvals which could provide insight to these differences. No comparisons were done to determine whether the approvals of different drug classes, such as cardiology products, anti-infective products, metabolic or endocrine products, which have higher percentage of minorities, had any effect on the total percentages by year.

Comparison of data from 1995-99 with 2000-09

The data of different racial participation in clinical trials for 1995-99 was obtained from “Participation of racial/ethnic groups in clinical trials and race related labeling: A review of new molecular entities approved 1995-1999” (Evelyn, Toglio, Banks, Gray, Robins, & Ernat, 2001): During this 5-year period Caucasian race participation was 88%, African-American participation was 8%, Asian participation was 1%, and 3% Hispanic/Latino and less than 1% were American Indians. These years are compared to the next 10 years in Figure 8.



- Figure 8.** Comparison of the Percentages of Different Races’ Participation in Clinical Trials for Years 1995-99 and 2000-09. The data include only of those whose race was mentioned in the Medical Officers’ reviews of the NMEs approved during those years.

Based on these data, the following observations may be made:

- The percentage of Caucasian race has been decreased from 88% to 81.9%.
- African American participation also decreased, from 8 % to 6.8%
- Hispanic participation saw small increase from 3 % to 3.5%
- Asian participation saw highest rise from 1% to 4%
- American Indian race representation was less than 1% for both of the periods

There was no description of the option “OTHER” in the races during the 1995-99 periods where as during 2000-09 period there was 3.7% of participants mentioned their race as other.

From the percentages of participation of various races in clinical trials mentioned in the Figures 1 – 9 it is evident that the non-Caucasian racial participation has increased over

the period even though the percentages varied from year to year. There might be various reasons behind the increase of the non-Caucasian participation but the major would be the globalization of clinical trials, change in the attitude of the minorities, planning and implementing effective recruitment strategies. Still there is under representation of minorities in randomized clinical trials and cancer trials (Shark, et al., 2002) . There were different studies that were conducted to identify the motive of the racial/ ethnic minority group's participation in clinical trials. Walter JK, Bruke JF, Davis MM, conducted a study "Research participation by low income and race/ethnic minority groups: how payments may change the balance" to find the effect of payments on the participation among the minority racial groups (Walter, Burke, & Davis, 2013). The results from their study suggested that higher payments yielded a proportional representation of minority racial groups. These authors also found that Hispanics were requesting higher payments for participation which might be the cause for their underrepresentation in clinical trials. In contrast, the study conducted by Wendler D et al. to find out the willingness of the racial/ethnic minorities to participate in clinical trials yielded different results (Wendler, et al., 2006). From their study they found out that African American and Hispanics in US have very small differences in willingness to participate in clinical trials when compared to non-Hispanic whites. Further investigation should be carried out to verify the reasons for minorities' participation in clinical trials. Identification of the reason for under representation in the clinical trials is the first step to solving this problem.

During the conference for "Increasing Participation of Minorities in Clinical Trials: Summary of The Moving Beyond The Boundaries" by Nancy Shark et al. some steps to increase the participation of minorities in cancer clinical trials were presented (Shark, et al., 2002).In the conference, the steps to reduce physician-based barriers were given as educating the physicians regarding the importance of minority race/ethnicity participation in clinical trials, reducing the physician time in recruiting the patients, educating the nurse and ancillary

staff about the importance all racial/ethnic participation and to answer questions of patients.

To reduce the economic barriers the steps mentioned were (1) legislation which would mandate medical insurance and managed care coverage of experimental therapies, (2) coverage of other financial costs raised during the trial period, and (3) stipends for participation should be approved. To reduce personal and cultural barriers, the steps mentioned were:

- Assure the subjects understand the consent form
- Build the community trust by linkage with community leaders
- Develop and maintain relationships within the community and involve the community in research
- To develop trust with minority community, try to understand and answer the cultural beliefs that might be causing the concerns among the minority community concerning participation in clinical trials and hire staff from the community.
- Develop flexible scheduling
- Use community based services to improve access and transportation to clinic.

These steps would be helpful for increasing the participation as well as developing the trust and confidence of minority population. Improved trust should increase minority participation in clinical trials as well as provide the alternate care which might help the community health care.

LIMITATIONS

There are several limitations to the study. The study was based on the Medical Officers' reviews and the participant racial data were collected from these reviews. Race could not be determined for all the participants in clinical trials from the reviews. The race representation and analysis does not represent the complete analysis of sponsors or the FDA as only the approved NMEs, but not the NME's submitted for approval and not approved. The study did not determine the racial sub-groups participation in clinical trials was comparable to prevalence of the specific disease for which the clinical trials were conducted. In some clinical trials Hispanic was mentioned as race and in other as ethnicity, the percentage of Hispanics may be underrated. As the data collected and used for analysis does not represent the total participants in clinical trials, it is not possible to say whether we can generalize the results obtained for this study to total population who participated in clinical trials during the period 2000-09.

CONCLUSION

Non-Caucasian racial participation increased during the period 2000-09 when compared to the period 1995-99 on an average percentage basis. Asian race participation saw the highest increase. There is a slight decrease in African-American participation over the period. Attention to race in Medical Officer's reviews of NMEs was not consistent. Even though clinical review standard template has been implemented with a section of special population which was intended to record the various racial/ethnic participation or exposure of the drug to them, the representation of the total population was not consistent. Even though there is an increase in the participation of non-Caucasian races, there is still there underrepresentation of certain racial. To increase the minority participation, steps should be followed which will decrease the racial and personal barrier between the participants and physician. Further studies should be conducted to identify the potential barriers which are effecting the minority subgroups participation in clinical trials and also to find out if their participation in specific diseases differs from the overall participation rate.

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