Diversity in Clinical Trials: Drug Trials Snapshots Perspective

Aden S. Asefa, MPH

Drug Trials Snapshots Lead

Office of Drug Evaluation and Sciences (ODES)

CDER|US FDA

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Overview (or "Learning Objectives")

- Importance to Increase Diversity in Clinical Studies
- FDA's Initiative to Increase Diversity in Drug Development Program
- Drug Trials Snapshots Overview

Why it is important to Increase Diversity in Clinical Studies

- Generate data reflective of the diverse U.S. population in drug, biologic, and device development programs
- Potentially identify differences in safety or efficacy outcomes
- Incorporate diverse “patient voices”
- Build trust among patients
- Provide a more comprehensive understanding of the disease or condition
- **Improve Health Equity** in the access to clinical research and innovative treatments

Statutory Requirements to Increase Diversity in Drug Development

1998 Demographic Rule

-Revised the NDA content and format regulations to require effectiveness data be presented by gender, age, and racial subgroups…

2012 Section 907 of FDA Safety and Innovation Act (FDASIA)

-Directed FDA to investigate how efficacy/safety data by demographic subgroups are included in clinical trials…

- Implementation of **Drug Trials Snapshot Program** in 2015

2022 Clinical Trial Diversity and Modernization under Food and Drug Omnibus Reform Act (FDORA)

-Diversity Action Plans

FDA Guidance Documents Addressing Diversity and Inclusion in Clinical Studies

Collection, Evaluation, and Reporting of Data

Women and Sex-Specific Considerations

Age Group Considerations

Enhancing Clinical Trial Diversity

Collection, Evaluation, and Reporting of Data

- Collection of Race and Ethnicity Data in Clinical Trials (September 2016) Enrollment and Reporting of Age Trial Designs and Ethnicity Data in Medical Device Clinical Studies (October 2019)
- Collection of Race and Ethnicity Data in Clinical Trials (September 2016) Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs (November 2020)
- Collection of Race and Ethnic Data in Clinical Trials (September 2016) Diversity Plans to Improve Enrollment of Historically Underrepresented Racial and Ethnic Populations in Clinical Trials (April 2022)
- Evaluation of Sex-Specific Data in Medical Device Clinical Studies (July 2019) Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014) and Drug Administration Staff (August 2014)
- Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs (November 2020) Ethical Considerations for Clinical Investigations of Medical Products Involving Children (September 2022)

In 2016 the FDA issued new recommendations to industry as to the collection of race and ethnicity data in clinical trials

Drug Trials Snapshots (DTS)

In 2012, FDA Safety and Innovation Act (FDASIA 907) was enacted to require FDA to report on diversity of participants in clinical trials and the extent to which safety and effectiveness data are based on demographic factors such as sex, race, age, and ethnicity.

Drug Trials Snapshots Program– was implemented in 2015 as part of FDA's action plan in response to Section 907 of FDASIA.

Overall effort to make demographic data more available and transparent

- **Overarching Priorities:**
  - Improve the completeness and quality of demographic subgroup data collection, reporting and analysis
  - Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation.
  - Overall effort to make demographic subgroup data more available and transparent.

Drug Trials Snapshots (DTS)

What is Drug Trials Snapshot (DTS)?

- Provide consumers and healthcare professionals with information about who participated in Key Clinical Trials that support FDA approval of New Drugs.
- Only published for approved New Molecular Entities (NMEs) and Original Biologics (BLAs)

  - Demographic composition data and the resulting analysis by **age, gender, race and ethnicity** in pivotal clinical studies for FDA-approved medical products would be made available on FDA website
    - *Race categories defined from OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity**

  - The information also highlights the trials where the trials were conducted and whether there were any differences in benefits and side effects among different demographic groups (sex, race, age, and ethnicity).

- **(Federal Register, October 30, 1997)*

Drug Trials Snapshots (DTS)

Search: Export Excel Show 10 entries

Brand Name (Drug Trials Snapshot)	Drug Name	Original Date of FDA Approval	FDA Approved Use on Original Approval Date*	Brand Name (Prescribing Information)
ARISTADA	aripiprazole laurixil	October 5, 2015	Treatment of schizophrenia	Aristada
ARTESUNATE		May 26, 2020	Treatment on severe malaria	Artesunate
ASPARLAS	calaspargase pegol-mknl	December 20, 2018	Treatment of acute lymphoblastic leukemia (ALL)	Asparlas
AUGTYRO	repotrectinib	November 15, 2023	To treat ROS1-positive non-small cell lung cancer	Augtyro
AUSTEDO	deutetrabenazine	April 3, 2017	Treatment of chorea in patients with Huntington's disease.	Austedo
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated intra-abdominal infection (abbreviated as cIAI)	Avycaz
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated urinary tract infection (abbreviated as cUTI)	Avycaz
AXUMIN	fluciclovine F 18	May 27, 2016	Detection of prostate cancer recurrence	Axumin
AYVAKIT	avapritinib	January 9, 2020	Treatment of adults with certain gastrointestinal stromal tumors	Ayvakit
AZSTARYS	serdexmethylphenidate and dexmethylphenidate	May 7, 2021	To treat attention deficit hyperactivity disorder	Azstarys

Showing 21 to 30 of 401 entries

Previous 1 2 3 4 5 ... 41 Next

Link to website: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

What is in a Snapshot?

Consumer information

- **What is the Drug used for?**
- **How is the Drug used?**

Information about the Clinical Trials

- **Who participated in the clinical trials**
  - Includes number of participants, number of sites, and countries
- **Trial Design**
- **Demographic data – sex, age, race, and ethnicity**
  - Presented in table and/or pie charts.
- **Benefits and Side effects of the drug**
  - Adapted from FDA Review
- **Efficacy and Safety Subgroup analysis**
  - any differences in safety and efficacy among sex, race, age, and ethnicity

Link to website: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

MOUNJARO (tirzepatide)
mown-JAHR-OH
Eli Lilly and Company
Original Approval date: May 13, 2022

DRUG TRIALS SNAPSHOT SUMMARY:

What is the drug for?

MOUNJARO is a drug that that improves blood sugar control in adults with type 2 diabetes mellitus (DM) when used in addition to diet and exercise.

How is this drug used?

MOUNJARO is an injectable drug available in a prefilled pen. It is injected once weekly under the skin (subcutaneously) of the abdomen, thigh, or upper arm. MOUNJARO may be used alone or in combination with other FDA-approved diabetes medications such as metformin, sulfonylureas, sodium-glucose co-transporter 2 inhibitors, and insulin. In patients also using insulin injections, MOUNJARO and insulin should be injected separately and not mixed into the same syringe.

Who participated in the clinical trials?

The FDA approved MOUNJARO based on evidence from nine clinical trials of 7,769 patients with type 2 diabetes mellitus, of which 5,415 of these patients received MOUNJARO. The trials were conducted at 673 sites in 24 countries, including Argentina, Australia, Brazil, Canada, India, Israel, Japan, Mexico, Russian Federation, South Korea, Taiwan, multiple European countries, and the United States (including Puerto Rico). All nine trials were used to assess safety and five of these trials were used to assess the efficacy of MOUNJARO. The five trials used in the efficacy evaluation included 6,263 adult patients with type 2 diabetes mellitus. Four additional trials were included in the safety evaluation, for a total of 7,769 adult patients with type 2 diabetes; therefore, the number of patients representing efficacy findings may differ from the number of patients representing safety findings due to different pools of study participants analyzed for efficacy and safety.

What are the benefits of this drug?

In patients with type 2 diabetes, treatment with MOUNJARO can lower HbA1c (hemoglobin A1c), which is a measure of blood sugar control.

Who participated in the trials?

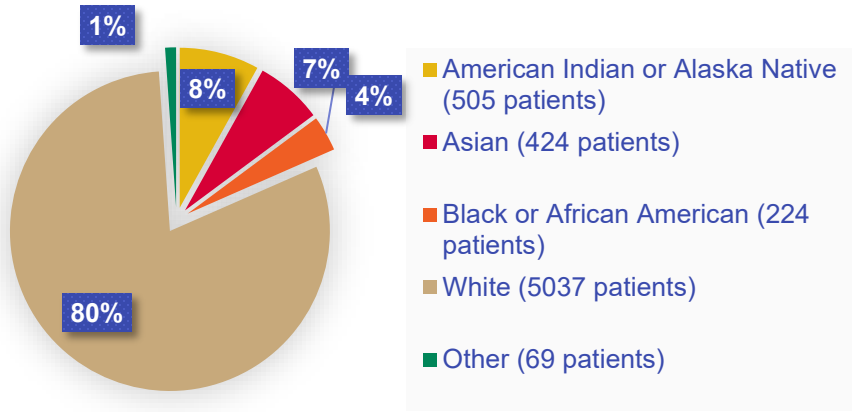
Table 7. Baseline Demographics - Efficacy Population

Demographic Parameter	Number of Patients N=6263	Percentage
Sex		
Female	2822	45
Male	3441	55
Race		
American Indian or Native Alaskan	505	8
Asian	424	7
Black or African American	224	4
White	5037	80
Other	69	1
Unknown	4	0
Ethnicity		
Hispanic or Latino	2917	47
Not Hispanic or Latino	3164	50
Unknown	182	3
Age category		
18 to 64 years	4181	67
≥65 years	2082	33

Source: Adapted from FDA Review

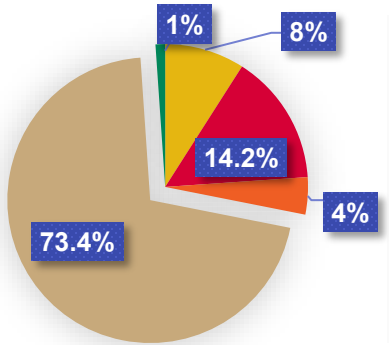
Drug Trials Snapshot - MOUNJARO

Baseline Demographics of Global Efficacy Trials by Sex, Race, and Age

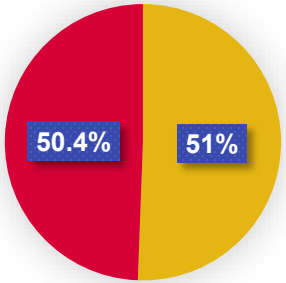


- **MOUNJARO** – approved on May 13, 2022
  - Improves blood sugar control in adults with type 2 diabetes mellitus (DM) when used in addition to diet and exercise.
  - 45% of patients enrolled were female, 80% white, 7% were Asian, 4% were Black; and 8% of patients were American Indian or Alaskan Native.

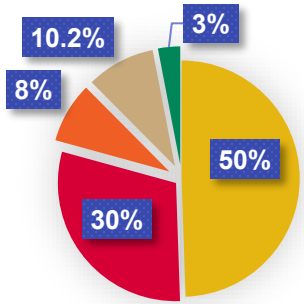
Drug Trials Snapshots - PAXLOVID



- American Indian or Alaska Native (191 patients)
- Asian (314 patients)
- Black or African American (89 patients)
- White (1496 patients)
- Other (23 patients)



- Male (1069 patients)
- Female (1044 patients)



- 18 to 44 (1045 patients)
- 45 to 59 (630 patients)
- 60 to 64 (175 patients)
- 65 to 74 (199 patients)

PAXLOVID (nirmatrelvir, ritonavir)– approved on May 25, 2023

- To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19

Baseline Demographics of Global Efficacy Trials by Sex, Race, and Age

- 50.4% of patients enrolled were female
- 73.4% white, 14.2% were Asian, 4% were Black, and 8% of patients were American Indian or Alaskan Native
- 45.4% of patients were of Hispanic ethnicity
- 10.2% enrolled 65 years of age and older

U.S. Population Enrollment

- 37.9% participants enrolled in U.S.

Drug Trials Snapshot: ZURZUVAE (zuranalone)

Efficacy Analysis

Were there any differences in how well the drug worked in clinical trials among sex, race, and age?

- **Sex:** All patients in the trials were female.
- **Race:** ZURZUVAE worked similarly in White and Black or African American patients. The number of patients in other races was limited; therefore, differences in how well ZURZUVAE worked in other races could not be determined.
- **Age:** Fewer patients younger than 25 years old were enrolled in the studies. Differences in how well ZURZUVAE worked in patients younger and older than 25 years of age could not be determined. All patients were younger than 65 years of age.

Table 4. Trial 1 Efficacy Results by Race and Age

Variable	N	Placebo LS Mean (SE) Change From Baseline	ZURZUVAE LS Mean (SE) Change From Baseline	Treatment Difference (95% CI)	P-value
Overall	183	-11.6 (0.82)	-15.6 (0.82)	-4 (-6.3, -1.7)	0.0007
Race					
Black or African American	36	-11.5 (2.18)	-17.5 (1.77)	-6 (-11.8, -0.2)	0.0424
White	132	-11.9 (0.94)	-15.4 (0.94)	-3.5 (-6.2, -0.9)	0.0089
Age, years					
18 to 24	31	-13.9 (2.25)	-18.8 (1.75)	-4.9 (-10.9, 1)	0.1023
25 to 45	152	-11.2 (0.89)	-14.9 (0.92)	-3.6 (-6.2, -1.1)	0.005

Source: Adapted from FDA Review
Abbreviations: CI, confidence interval; LS, least squares; SE, standard error

Drug Trials Snapshot: ZURZUVAE (zuranalone)

Safety Analysis

Were there any differences in side effects among sex, race and age?

- **Sex:** All patients in the trials were female.
- **Race:** In Trial 1, the occurrence of side effects was better in Black or African American patients. In Trial 2, the occurrence of side effects was better in White patients. Given these differences in Trials 1 and 2 and the limited number of patients in other races, differences in the occurrence of side effects among races could not be determined.
- **Age:** The occurrence of side effects was better in patients aged 25 years and older. However, the number of patients in the younger than 25-year-old age subgroup was limited; therefore, differences in the occurrence of side effects among age subgroups should be interpreted with caution.

Table 8. Trial 1 Overview of Adverse Events by Demographic Subgroup

Characteristic	ZURZUVAE N=98 n/Ns (%)	Placebo N=98 n/Ns (%)	Risk Difference % (95% CI)
Sex			
Female	60/98 (61.2)	44/98 (44.9)	16.3 (2.5, 30.1)1
Age group, years			
18 to 24	16/19 (84.2)	6/12 (50.0)	34.2 (1.5, 66.9)1
25 to 45	44/79 (55.7)	38/86 (44.2)	11.5 (-3.7, 26.7)
Race			
American Indian or Alaska Native	0/0 (N/A)	2/3 (66.7)	N/A
Asian	0/1 (0)	1/1 (100)	N/A
Black or African American	14/25 (56.0)	9/18 (50.0)	6.0 (-24.2, 36.2)
Multiple	1/3 (33.3)	0/2 (0)	33.3 (-20.0, 86.7)
Native Hawaiian or other Pacific Islander	0/0 (N/A)	0/0 (N/A)	N/A
Not reported	1/1 (100)	1/1 (100)	0 (0, 0)
Other	0/0 (N/A)	3/4 (75.0)	N/A
White	44/68 (64.7)	28/69 (40.6)	24.1 (7.9, 40.4)a
Ethnicity			
Hispanic or Latino	21/33 (63.6)	20/42 (47.6)	16.0 (-6.3, 38.3)
Not Hispanic or Latino	38/64 (59.4)	24/56 (42.9)	16.5 (-1.2, 34.2)
Not reported	1/1 (100)	0/0 (N/A)	N/A
Is in United States			
United States	60/98 (61.2)	44/98 (44.9)	16.3 (2.5, 30.1)1

Source: Adapted from FDA Review
a Indicates rows where the 95% confidence interval excludes zero.

Drug Trial Snapshot Summary Reports

- Complements CDER's New Drug Therapy Approvals Report
- Provides overall average of each demographic group followed by a detailed summary table of percent representation of sex, race, and age per Novel therapy
- Currently, publish Demographic data in Annual reports by categorized novel therapeutic area
- 2023 Annual Report included % participants in the %U.S. Participants

Drug Trial Snapshots Published Reports

- **2015-2016**

  *Drug Trials Snapshot Summary Report

  - In 2015 CDER approved 45 Novel Drugs, either as New Molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs).

  - In 2016, CDER approved 22 novel drugs

  * 2015-2016 Global Clinical Trials Report

  - Information on clinical trial participants by site location over the two-year time frame (2015-2016)

- **2017** -- 46 Novel Drugs approved
- **2018** -- 59 Novel Drugs approved
- **2019** -- 48 Novel Drugs Approved
- **2020** -- 53 Novel Drugs Approved
- **2021** -- 50 Novel Drugs Approved
- **2022** -- 37 Novel Drugs Approved

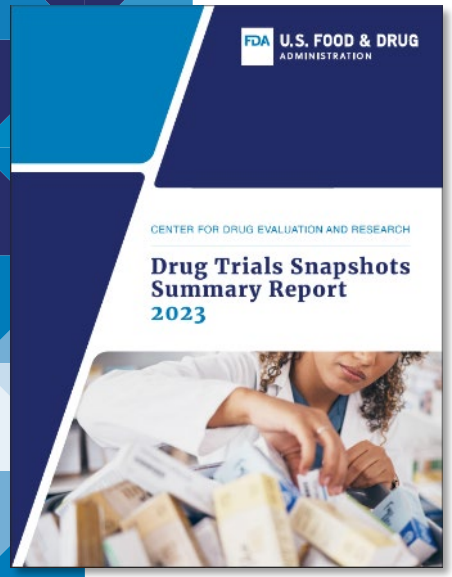
www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

2023 Drug Trials Snapshot Annual Report

- CDER approved **55 Novel Therapies for** a broad range of diseases in 2023 with more than half approved for rare diseases
- About **44,000 study participants** contributed through their participation in the pivotal studies supporting these approvals

2023 DTS Annual Report – Infectious Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Beyfortus (nirsevimab-alip)	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease	2943	48.0	62.7	23.0	2.3	15.9	12.1 (>6 months)	24.5
Defencath (taurolidine, heparin)	To reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter	806	41.9	63.3	29.5	4.1	45.4	41.1	100
Paxlovid (nirmatrelvir, ritonavir)	To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19	3188	50.4	73.4	4.0	14.2	41.8	10.2	37.9
Rezzayo* (rezafungin)	To treat candidemia and invasive candidiasis	199	38.2	60.8	4.5	29.1	5.5	40.7	25.6
Xacduro (sulbactam, durlobactam)	To treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex	177	26.0	49.2	0.6	43.5	13.6	55.4	0.6



Reproductive, Urologic, and Rare Metabolic Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Elfabrio* (pegunigalsidase alfa-iwxj)	To treat confirmed Fabry disease	93	39.8	90.3	6.5	2.2	5.4	48.4 (≥ 45 years)	67.7
Lamzede* (velmanase alfa-tycv)	To treat non-central nervous system manifestations of alpha-mannosidosis	30	43.3	96.7	0	0	NA	36.7 (≥ 18 and < 35 years)	0
Veozah (fezolinetant)	To treat moderate to severe hot flashes caused by menopause	1022	100	81.4	17.0	1.0	23.8	46.7% (≥ 55 years)	62.8

NA = not available. The reasons for data not being available are varied including study site in a region that prohibited collection of data on race and/or ethnicity or data not provided as part of submission.

*Rare disease

†The percentages of all other races combined (American Indian, Alaska Native, Native Hawaiian or Other Pacific Islander, Other, Unknown/Unreported) adds up to 100% of race category.

‡The percentage of Non-Hispanic and Unknown/Unreported ethnicity adds up to 100% of ethnicity category.

Figure 6. Participation by Sex for 2 Programs Evaluating Therapies to Treat Reproductive, Urologic, and Rare Metabolic Diseases

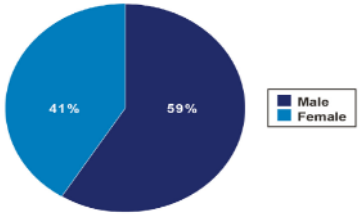
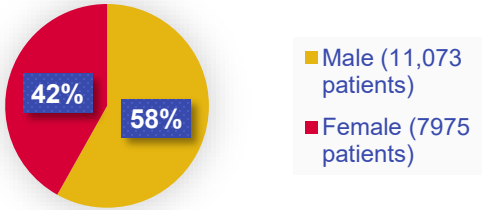


Figure 6 summarizes how many male and female participants were enrolled in the 2 drug programs evaluating therapies to treat reproductive, urologic, and rare metabolic diseases that affect both males and females. In total, 123 participants enrolled in clinical trials in the 2 disease programs, and 41% of the participants that enrolled were females.

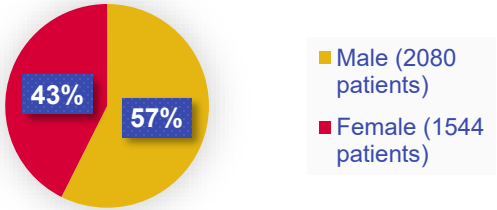
2023 DTS Annual Summary: Sex Statistics

- Percentage of females participating in the drug programs ranged from 41%-67% (median 48%)
- Drug Programs enrolling both males and females, excluding sex-specific indications (i.e., prostate cancer or post-partum depression)

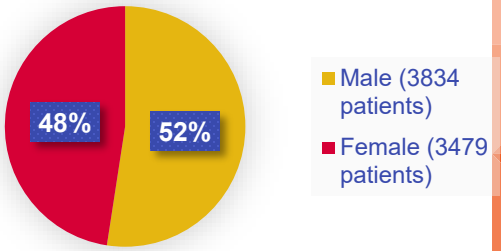
Heart, Blood, Kidney or Endocrine Diseases



Autoimmune, Inflammatory, and Lung Diseases

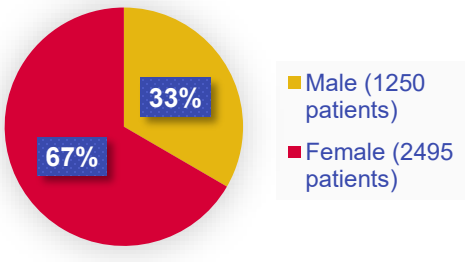


Infectious Diseases

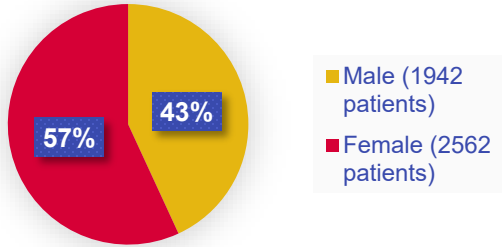


2023 DTS Annual Summary: Sex Statistics Continued

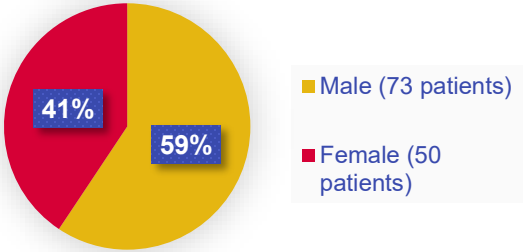
Neurological or Psychiatric Disorders



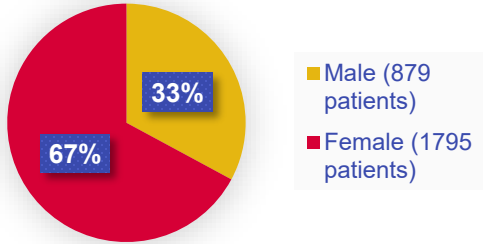
Cancers



Reproductive, Urologic, and Rare Metabolic Diseases



Ophthalmologic Therapies or Imaging Agents



2023 DTS Annual Summary: Race Statistics

Whites comprised more than 50% of trial population enrolled for all programs except three drug programs

Asians comprised the second largest race category; with six drug programs enrolled over 30% Asians: *FABHALTA (33.6.%), FILSPARI (34.5%), XACDURO (43.5%), AUGTYRO (59.1%), FRUZAGLA (43.1%), and LOQTORZI (100%)*

Two programs enrolled over 25% Blacks: *Defencath (29.5%) and Zurzuvae (30.1%)*

Five Drug Programs enrolled more than 30% Hispanics: *Inpefa (31.1%), Filsuvez (34.5%), Defencath (45.4%), Paxlovid (41.8%), and Zurzuvae (31.6%)*

Participants from the American Indian or Alaskan Native race categories was not reported in the 2023 DTS Annual Report, because participation has been historically been under 1-2 %.

U.S. Enrollment vs Outside U.S. Enrollment

- Majority were multinational
- % of participants within U.S. ranged from 0.4%-82%
- Five drug programs were conducted entirely in U.S.
  - DAYBUE, DEFENCATH, MIEBO, XDEMVY, and ZAVAPRET
- Two Drug programs enrolled participants entirely outside the U.S.
  - LAMZEDE and LOQTORZI

Drug Trials Snapshot

- From 2015-2020, DTS annual summaries provided aggregate data on demographics of study populations for all approved therapies within a calendar year
- In 2021 and 2022, DTS annual summaries provided demographic data of study population by individual drug program
- No prevalence information for the disease/medical condition targeted by the approved drug was provided as a benchmark

Medical Condition: Multiple Sclerosis

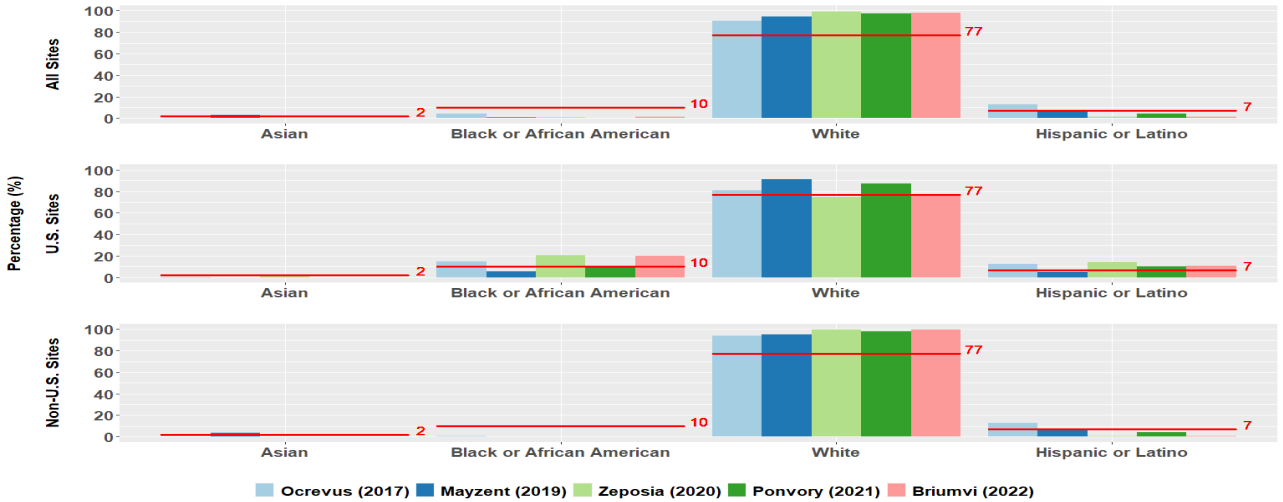
Enrolling a study population in a drug development program that is representative of the patient population in the U.S. requires an understanding of the epidemiology and demographic characteristics of that disease/medical condition

- **Multiple Sclerosis:** Is a chronic autoimmune inflammatory dymyelinating disease of the central nervous system that affects an estimated 744,781 adults in the U.S. and is a leading cause of disability in young adults.
  - Five Therapies were approved for MS between 2017 and 2023.
  - Baseline demographics by race and ethnicity are displayed graphically and compared to U.S. prevalence in the next slide.

Prevalence of U.S. Patients with Multiple Sclerosis by Sex, Race, Ethnicity and Age Group

Percentage (%)[1]							
Female	American Indian or Alaska Native	Asian	Black or AA	Native Hawaiian or Other Pacific Islander	White	Hispanic or Latino	e≥45
76	N/A[1,2]	1.7	10	N/A[1,2]	77	7	

Baseline demographics by race and ethnicity



Sex Statistics and MS

- Sex: Across all five programs, the percentage of female patients enrolled across all sites (60-67%) was similar between U.S. and non-U.S. sites and slightly below U.S. prevalence (76%).

Race Statistics and MS

Race

- Enrollment of Asian patients in MS programs was below U.S. prevalence (<2%), with exception of Mayzent at all sites and non-U.S. sites; three programs enrolled no Asian patients in the U.S.
- Enrollment of Black patients at U.S. sites (6%-21%) approximated or exceeded U.S. prevalence of MS whereas enrollment at non-U.S. sites (0%-0.5%) was lower when compared to U.S. prevalence (10%).
- Across MS programs, enrollment of White patients at all sites (91%-99%) exceeded U.S. prevalence for this race group (77%).
- Approximately 7% of MS patients in the U.S. are Hispanic or Latino. The percentage of Hispanic or Latino patients enrolled varied across programs. In general, U.S. sites enrolled a higher percentage of Hispanic or Latino patients (5%-15%) that approximated U.S. prevalence of MS in this ethnicity group.

Drug Trials Snapshot: Transparency

- Presenting demographic data by drug and therapeutic area in the annual summary help track trends in diversity in clinical trials over time.
- Identify programs that have achieved lower or greater enrollment of under-represented patient populations

Drug Trials Snapshot Closing Remarks

- Efforts across many years and by multiple stakeholders have led to improvements in enrolling diverse study population in some therapeutic areas
- Opportunities for improvement still need to be identified and addressed
- External engagement and open dialogue about knowledge gaps, under-representation, challenges, approaches, etc. important to ensure diversity in drug development programs

Summary

- It is important to generate data reflective of the diverse U.S. population in drug, biologic, and device development programs
- Drug Trials Snapshot Program is FDA's Overall effort to make demographic subgroup data more available and transparent.
- Interpretation of racial and ethnic composition of study populations across the novel therapies approved should consider the prevalence of the disease within each of these racial and ethnic subgroups
- Opportunities for improvement still need to be identified and addressed

Closing Quote

The way we work in Public Health is, we make the best recommendations and decisions based on the best available data

- Tom Frieden (former CDC Director)

Poll Question #1

Drug Trials Snapshots Program was in response to what FDA Statutory Requirement?

A. 1998 Demographic Rule

B. 2022 Clinical Trial Diversity and Modernization under Food and Drug Omnibus Reform Act (FDORA)

C. 2012 Section 907 of FDA Safety and Innovation Act (FDASIA)

D. All the Above

Poll Question #2

Drug Trials Snapshots are available for all drugs, devices, and biologics approved by FDA

- True
- False

Resources

Drug Trials Snapshots | FDA

Federal Register :: Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity

Clinical Trial Diversity | FDA

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- Mary Thanh Hai, MD, Deputy Director, OND, CDER
- Ariel Armstrong, PhD, Student Trainee, OND, CDER
- A'lexxuis Combs, PharmD, ORISE Fellow, OND, CDER
- Vaishali Jarral, Senior Science Policy Analyst, ODES, OND/CDER
- Alexander Williamson, Contractor/Medical Editor
- Mark Rothman, PhD, Director, Division of Biometrics II, Office of Biostatistics, OTS, CDER
- Robert Abugov, PhD, Senior Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, OTS, CDER
- Linda Jeng, Associate Director of Biomedical Informatics, Division of Biomedical Informatics, Research & Biomarker Development (DBIRBD), ODES, OND, CDER
- Rhonda Hearns-Stewart, MD, Associate Director of Implementation of the New Integrated Assessment of Marketing Applications (IAMA), CDER/OND/IO
- Jinzhong Liu, PhD, Director, OND Clinical Data Science Staff
  - +Clinical Data Science Staff, OND, CDER

Questions?

Aden S. Asefa, MPH

Drug Trials Snapshots Lead
Office of Drug Evaluation and Sciences (ODES)
CDER|US FDA
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Website: [Drug Trials Snapshots | FDA]
Email: Snapshots@fda.hhs.gov