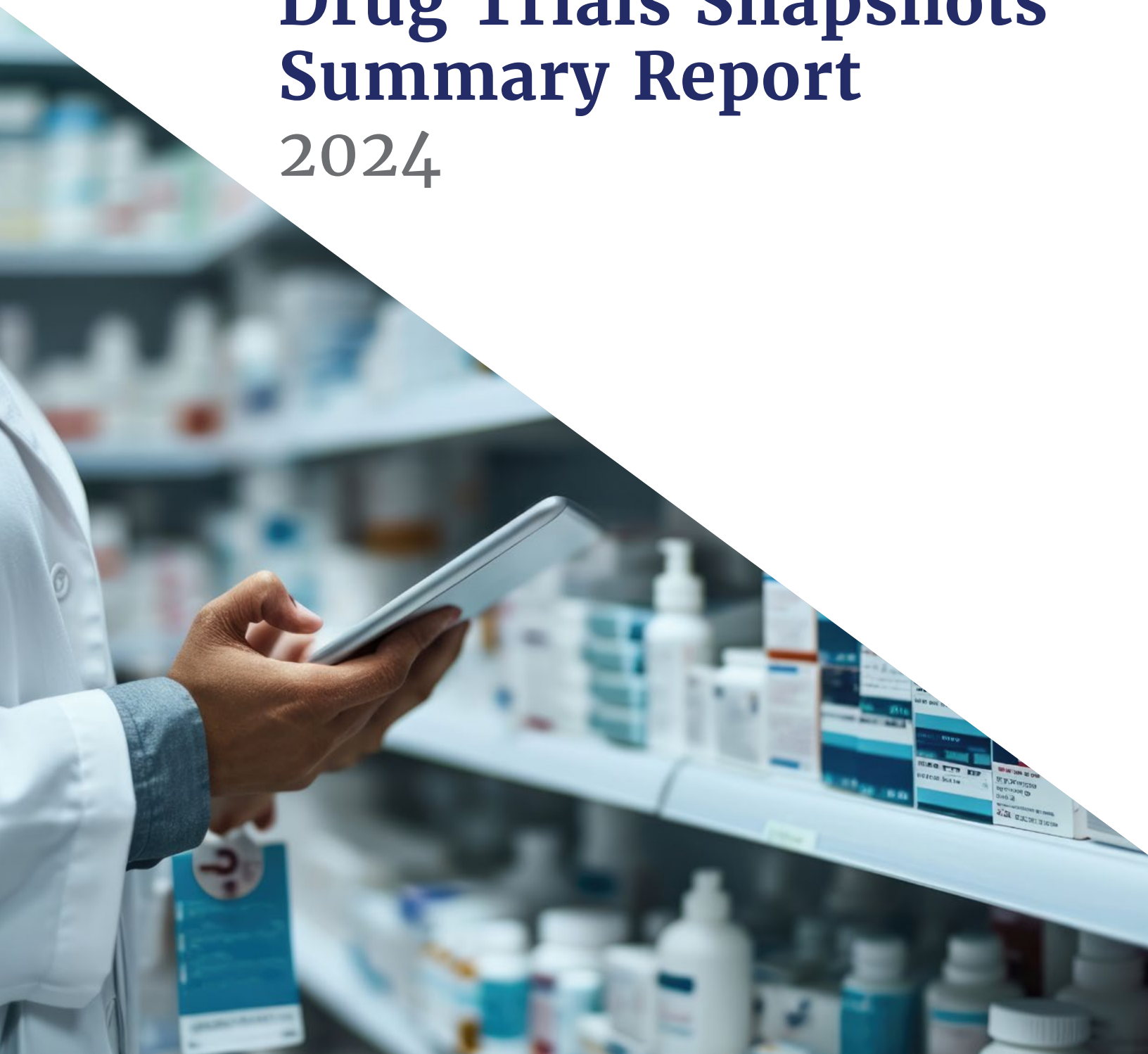
U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Drug Trials Snapshots Summary Report

2024



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Introduction

Welcome to the FDA's Center for Drug Evaluation and Research's (CDER's) Drug Trials Snapshots Summary Report

Since January 2015, CDER has shared information on the representation of participants in clinical trials through the transparency initiative called Drug Trials Snapshots (DTS). DTS provide consumers and healthcare professionals with concise information about who participated in the key clinical trials that supported the original FDA approval of new drugs by FDA's Center for Drug Evaluation and Research (CDER).

This year's annual report summarizes the 2024 DTS program, complementing CDER's annual report, "Advancing Health Through Innovation: New Drug Therapy Approvals 2024," published in January 2025, by providing information on the various demographic factors of participants in the clinical trials relied upon for approval of novel therapies. The approved therapies span a wide range of medical conditions, including ones that largely affect pediatric patients, diseases affecting only males or females, common diseases that affect a large proportion of the population in the United States, and rare (or orphan) diseases with a smaller number of patients in the United States and globally. Given the varied diseases being targeted, examining clinical trial populations by individual drug or therapeutic area provides the clearest insight into patient representation in clinical trials specific to a disease.

We hope this information is helpful to promote dialogue on the appropriate representation of different subgroups in clinical trials. We welcome your feedback on the DTS program and ideas you may have regarding how FDA can enhance the information provided in each snapshot. You can share your thoughts by sending an email to Snapshots@fda.hhs.gov.

2024 Summary Statistics (January 1, 2024 - December 31, 2024)

In 2024, CDER approved 50 novel drugs, either as new molecular entities (NMEs) under new drug applications (NDAs) or as new therapeutic biologics under biologics license applications (BLAs). Of these novel drugs, 24 out of 50 (48%) were first-in-class, meaning they have mechanisms of action different from those of existing therapies. In addition, 26 out of 50 (52%) of these approvals were for the treatment of rare or orphan diseases, or diseases that affect fewer than 200,000 people in the United States.

In this report, we summarized baseline demographic information from pivotal trials that support the approval of each novel drug. We presented the demographic percentages of sex, race, ethnicity, age group, and U.S. participants in the pivotal trials in tabular format, as well as summarized baseline demographic data by therapeutic area graphically. We presented data in pie chart format for therapeutic areas that include more than three drug programs for a more robust representation of participants in the clinical trials. We encourage readers to access the Drug Trials Snapshots database for updated summaries as well as the approved drug label for FDA reviews that support the novel drug approvals. Additionally, within the DTS summaries, you will find subgroup differences of the efficacy and safety of the drug. At Drugs@FDA you will find additional information on the disease or medical condition and the efficacy and safety information of the novel drug in the overall study population, appropriate to the approved condition.

Demographic data for each approved novel drug is organized by the following categories reflecting the organizational structure of CDER's Office of New Drugs (OND), which oversees these drug development programs. This report provides a summary of percent representation of sex, race, ethnicity, age group, and U.S. participants in the pivotal trials supporting these approvals by the respective therapeutic area:

- **Heart, Blood, Kidney, and Endocrine Diseases**
- **Autoimmune, Inflammatory, and Lung Diseases**
- **Infectious Diseases**

- **Neurological and Psychiatric Disorders**
- **Cancers**
- **Reproductive, Urologic, and Rare Metabolic Diseases**
- **Ophthalmologic and Imaging Therapies**

We hope information from this annual report will help promote further dialogue on how drug development can be enhanced to improve knowledge about the safety and effectiveness of therapies across the diverse patient community in the United States.

Heart, Blood, Kidney, and Endocrine Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
WINREVAIR* (sotatercept-csrk)	To treat pulmonary arterial hypertension in adults	323	79	89	2	2	18	17	27
VOYDEYA* (danicopan)	To treat extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria	63	59	44	2	40	6	25	14
PIASKY* (crovalimab-akkz)	To treat paroxysmal nocturnal hemoglobinuria in adults and children 13 years and older	204	45	30	2	67	12	11	0
TRYVIO (aprocitentan)	To treat hypertension in adults, in combination with other blood pressure-lowering medications	487	41	83	11	5	10	44	28
VAFSEO (vadadustat)	To treat anemia due to chronic kidney disease in adults on dialysis	3923	46	64	24	5	38	34	61
HYMPAVZI* (marstacimab-hncq)	To prevent or reduce bleeding episodes related to hemophilia A or B without factor inhibitors in adults and children 12 years of age and older	116	0	48	1	50	10	1	1
ATTRUBY* (acoramidis)	To treat cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis in adults	611	9	88	5	2	2	97	19
RAPIBLYK° (landiolol)	For short-term reduction of heart rate in adults with supraventricular tachycardia	1102	48	NA	NA	NA	NA	NA	NA

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
CRENESSITY* (crinecerfont)	To be used together with glucocorticoids to control androgen levels in adults and children 4 years of age and older with classic congenital adrenal hyperplasia	285	49	80	2	5	9	0	45
ALHEMO* (concizumab-mtci)	For routine prophylaxis to prevent or reduce bleeding episodes in adults and children 12 years of age and older with hemophilia A or B, and factor inhibitors	52	0	40	10	38	8	2	8
XOLREMDI* (mavorixafor)	To increase the number of circulating white blood cells in adults and children 12 years of age and older with WHIM (Warts, Hypogam-maglobulinemia, Infection, and Myelokathexis) syndrome	31	58	94	0	3	3	6	19
YORVIPATH* (palopegteri-paratide)	To treat hypopara-thyroidism in adults	82	78	93	0	6	9	2	37
TRYNGOLZA* (olezarsen)	As an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)	66	58	85	0	9	11	9	29

NA = not available.

* 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.

° Drug was approved based on literature review with limited information on subgroups

Participation by Sex, Age, and U.S. Participants for the Programs Evaluating Therapies to Treat Heart, Blood, Kidney, and Endocrine Diseases

Figure 1. Sex of Participants in the Programs* Evaluating Heart, Blood, Kidney, and Endocrine Diseases

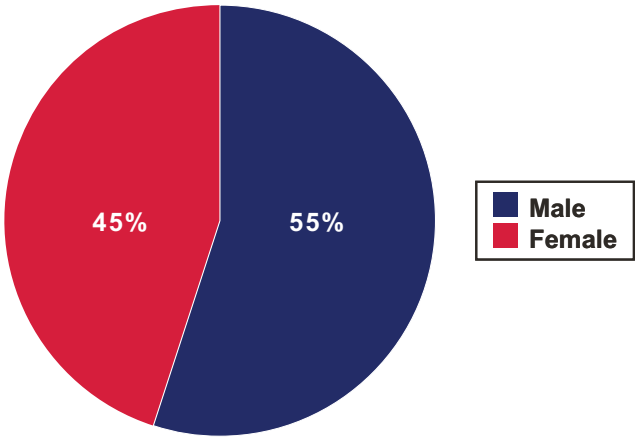


Figure 1 summarizes how many male and female participants were enrolled in the 11 drug programs evaluating therapies to treat heart, blood, kidney, and endocrine diseases that affect both males and females.

* Two sex-specific drug programs were excluded in the analysis

Figure 2. Age of Participants in the Programs* Evaluating Heart, Blood, Kidney, and Endocrine Diseases

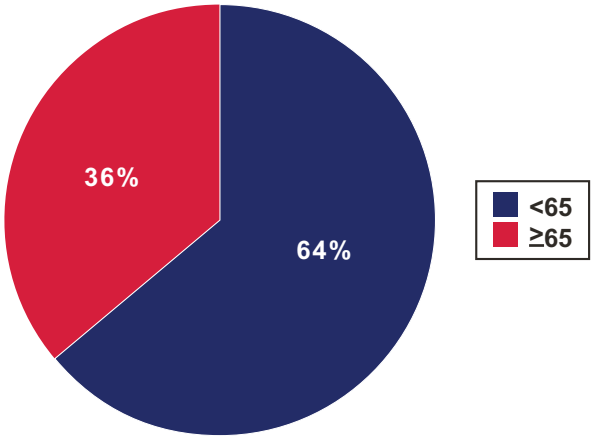


Figure 2 summarizes age of participants enrolled in the 12 drug programs evaluating therapies to treat heart, blood, kidney, and endocrine diseases.

* One pediatric drug program was excluded from analysis

Figure 3. U.S. Participants in the Programs Evaluating Heart, Blood, Kidney, and Endocrine Diseases

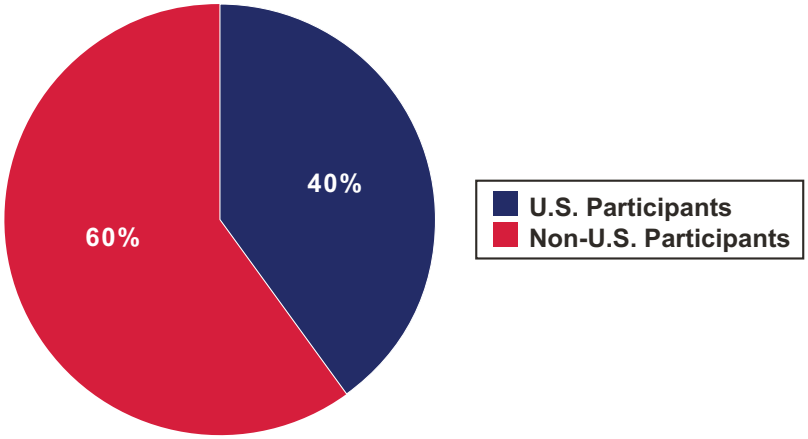
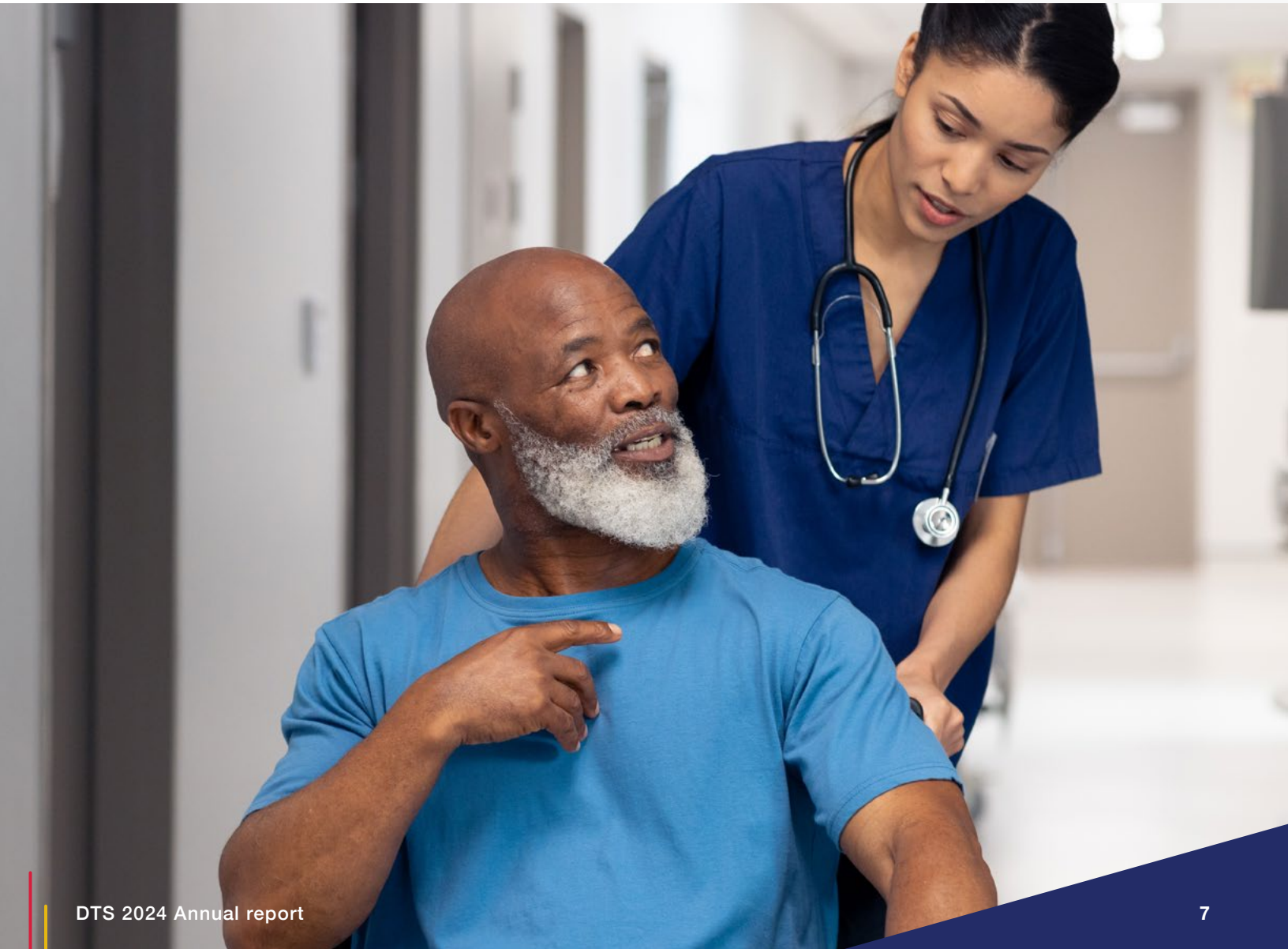


Figure 3 summarizes number of U.S. participants enrolled in the 13 drug programs evaluating therapies to treat heart, blood, kidney, and endocrine diseases.



Autoimmune, Inflammatory, and Lung Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
ZELSUVMI (berdazimer)	To treat molluscum contagiosum in adults and children 1 year of age and older	1598	49	88	6	1	21	0	100
LETYBO (letibotulinum-toxinA-wlbg)	To temporarily improve the appearance of moderate-to-severe glabellar lines in adults	1271	91	91	7	1	13	12	69
IQIRVO* †† (elafibranor)	To treat primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as a monotherapy in adults unable to tolerate UDCA	161	96	91	1	2	0	22	39
SOFDRA (sofpironium)	To treat primary axillary hyperhidrosis in adults and children 9 years of age and older	701	56	78	20	1	31	1	100
OHTUVAYRE (ensifentrine)	For the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults	1553	47	92	4	2	4	55	39
LEQSELVI (deuruxolitinib)	To treat adults with severe alopecia areata	1209	64	74	9	6	8	0	43
NEMLUVIO (nemolizumab-ilto)	To treat adults with prurigo nodularis	560	60	81	7	9	4	25	18

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
LIVDELZI*†† (seladelpar)	To treat primary biliary cholangitis (PBC) in adults in combination with ursodeoxycholic acid (UDCA) in patients who have an inadequate response to UDCA, or as a monotherapy in patients unable to tolerate UDCA	193	95	88	2	6	29	21	32
EBGLYSS (lebrikizumab-lbkz)	To treat moderate-to-severe atopic dermatitis in adults and children 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	1062	50	63	11	21	13	8	48
ALYFTREK* (vanzacaftor, tezacaftor, and deutivacaftor)	To treat cystic fibrosis in patients 6 years of age and older	971	46	95	1	0	3	0	38
REZDIFFRA†† (resmetirom)	As an adjunct to diet and exercise to treat non-cirrhotic MASH (metabolic dysfunction-associated steatohepatitis) with moderate-to-advanced liver scarring (fibrosis) in adults	888	56	89	2	3	21	26	66

* 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

†† This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Participation by Sex, Age, and U.S. Participants for the Programs Evaluating Therapies to Treat Autoimmune, Inflammatory, and Lung Diseases

Figure 4. Sex of Participants in the Programs Evaluating Therapies to Treat Autoimmune, Inflammatory, and Lung Diseases

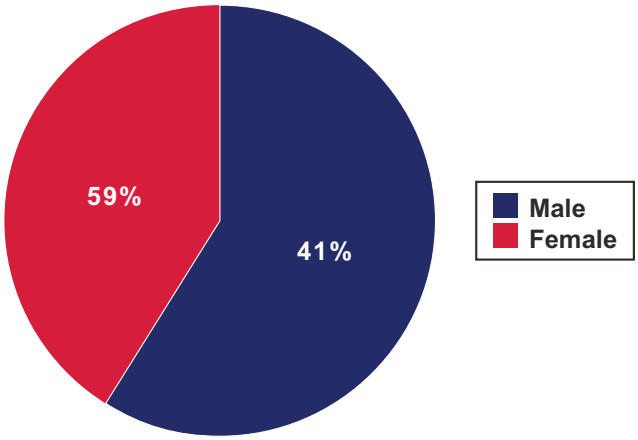


Figure 4 summarizes how many male and female participants were enrolled in the 11 drug programs evaluating therapies to treat autoimmune, inflammatory, and lung diseases that affect both males and females.

Figure 5. Age of Participants in the Programs Evaluating Autoimmune, Inflammatory, and Lung Diseases

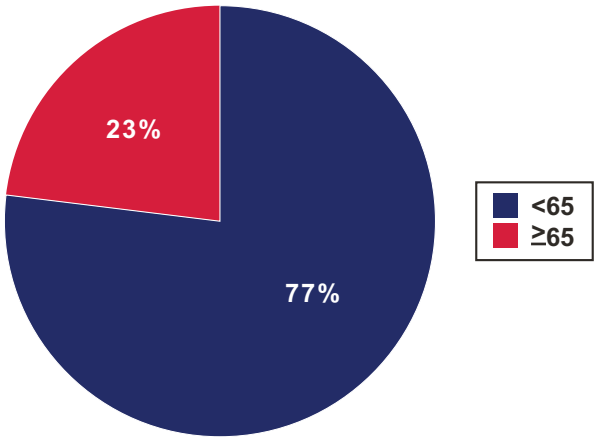


Figure 5 summarizes age of participants enrolled in the 11 drug programs evaluating therapies to treat autoimmune, inflammatory, and lung diseases.

Figure 6. U.S. Participation in the Programs Evaluating Autoimmune, Inflammatory, and Lung Diseases

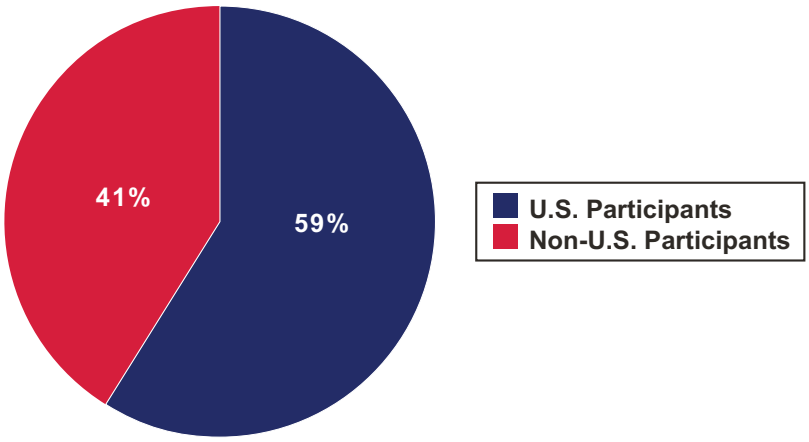


Figure 6 summarizes number of U.S. participants enrolled in the 11 drug programs evaluating therapies to treat autoimmune, inflammatory, and lung diseases.

Infectious Diseases

Trade Name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
ZEVTERA (ceftobiprole medocaril sodium)	To treat adult patients with *Staphylococcus aureus* bloodstream infections, including those with right-sided infective endocarditis, adult patients with acute bacterial skin and skin structure infections, and community-acquired bacterial pneumonia in adults and children 3 months and older	1842	40	84	3	8	22	24	28
ORLYNVAH (sulopenem etzadroxil and probenecid)	To treat uncomplicated urinary tract infections (uUTI) in adult women who have limited or no alternative oral antibacterial treatment options	2095	100	85	13	1	46	25	76
EXBLIFEP (cefepime and enmetazobactam)	To treat complicated urinary tract infections in patients 18 years and older	678	60	95	0	1	8	37	0

† 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.

Neurological and Psychiatric Disorders

Trade Name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
DUVYZAT* (givinostat)	To treat Duchenne muscular dystrophy in patients aged 6 years and older	120	0	92	0	3	8	0	23
KISUNLA (donanemab-azbt)	To treat Alzheimer's disease	1736	57	91	2	6	4	90	72
COBENFY (xanomeline and trospium chloride)	To treat schizophrenia in adults	470	25	31	68	1	11	52	90

* 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.

Cancers

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
TEVIMBRA* (tislelizumab-jsgr)	To treat unresectable or metastatic esophageal squamous cell carcinoma in adults who have undergone prior chemotherapy that did not include a PD-1 blocking antibody	513	16	19	0	80	1	38	0.3
ANKTIVA (nogapendekin alfa inbakicept-pmln)	Used in combination with Bacillus Calmette-Guerin (BCG) to treat carcinoma in situ (CIS) bladder cancer in adults	77	26	88	3	3	8	74	100
OJEMDA*†† (tovorafenib)	To treat relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement of BRAF V600 mutation in patients 6 months of age and older	76	47	53	3	7	4	0	33
IMDELLTRA*†† (tarlatamab-dlle)	To treat extensive stage small cell lung cancer in adults whose cancer has progressed after prior treatment with chemotherapy that contains platinum	99	28	58	0	41	1	59	3

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
VORANIGO* (vorasidenib)	To treat Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery in adult and children 12 years and older	331	44	78	1	4	5	1	53
LAZCLUZE (lazertinib)	To treat locally advanced or metastatic non-small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations in adults	858	61	38	1	58	12	45	1
VYLOY* (zolbetuximab-clzb)	In combination with fluoropyrimidine- and platinum-containing chemotherapy to treat gastric or gastroesophageal junction adenocarcinoma in adults whose tumors are CLDN18.2-positive and HER2-negative that cannot be removed by surgery	1072	38	43	1	47	8	36	7
REVUFORJ* (revumenib)	To treat relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene translocation in adults and children 1 year and older	104	64	72	8	10	22	13	94

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
ZIIHERA*†† (zanidatamab-hrii)	To treat previously treated, unresectable, or metastatic HER2-positive (IHC 3+) biliary tract cancer in adults	62	55	31	0	61	8	47	24
BIZENGRI*†† (zenocutuzumab-zbco)	To treat unresectable or metastatic NRG1-positive non-small cell lung cancer in adults and	64	64	33	0	56	0	47	42
	Unresectable or metastatic NRG1-positive pancreatic adenocarcinoma in adults	30	43	87	3.3	6.7	10	10	60
UNLOXCYT (cosibelimab-ipdl)	To treat metastatic or locally advanced cutaneous squamous cell carcinoma in adults who cannot have radiation or surgery	109	28	85	1	6	7	78	0
RYTELO* (imetelstat)	To treat low-to intermediate-1 risk myelodysplastic syndromes in adults with anemia	178	38	80	2	6	6	80	7
ENSACOVE (ensartinib)	To treat anaplastic lymphoma kinases-positive locally advanced or metastatic non-small cell lung cancer in adults who have not received and ALK-inhibitor	290	49	41	1	56	8	18	4

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
NIKTIMVO* (axatilimab-csfr)	To treat chronic graft-versus-host disease (cGVHD) in adults and children who have received at least two prior treatments	79	42	85	3	5	6	27	47
ITOVEBI (inavolisib)	In combination with palbociclib and fulvestrant to treat HR-positive, HER2-negative locally advanced or metastatic breast cancer in adults	325	98	59	1	38	6	16	5

* 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.

†† This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Participation by Sex, Age, and U.S. Participants for the 15 Programs Evaluating Therapies to Treat Cancers

Figure 7. Sex of Participants in the Programs Evaluating Therapies to Treat Cancers

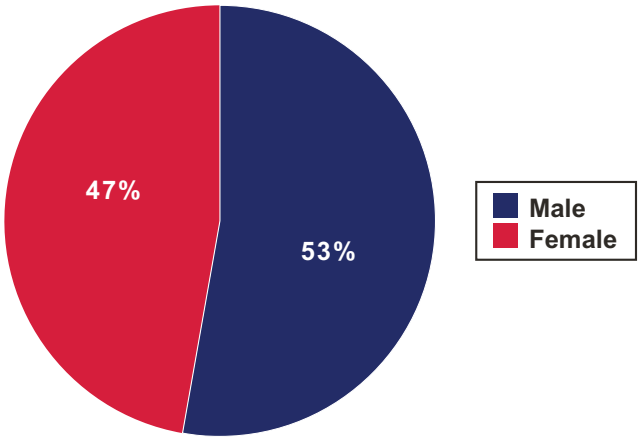


Figure 7 summarizes how many male and female participants were enrolled in the 15 drug programs evaluating therapies to treat cancers that affect both males and females.

Figure 8. Age of Participants in the Programs* Evaluating Therapies to Treat Cancers

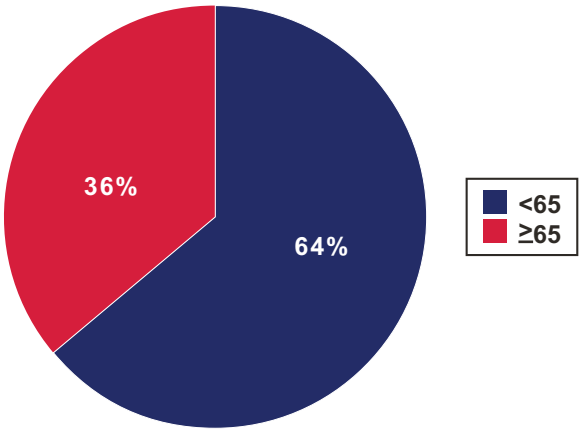


Figure 8 summarizes age of participants enrolled in the 14 drug programs evaluating therapies to treat cancers.

* One pediatric drug program was excluded from analysis

Figure 9. U.S. Participation in the Programs Evaluating Therapies to Treat Cancers

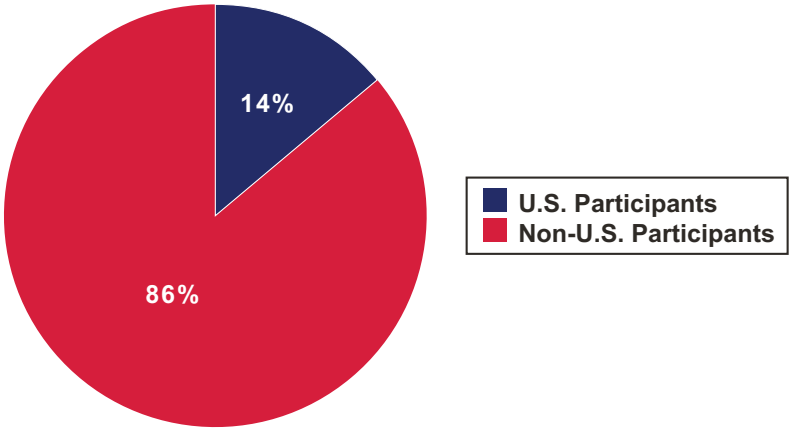


Figure 9 summarizes number of U.S. participants enrolled in the 15 drug programs evaluating therapies to treat cancers.

Reproductive, Urologic, and Rare Metabolic Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
MIPLYFFA* (arimoclomol)	In combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and children 2 years of age and older	39**	56	87	0	5	5	0	8
AQNEURSA* (levacetylleucine)	For the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and children who weigh 15 kg or more	60	45	90	NA††	3	NA‡‡	3	0

* Rare disease

** The data presented is only for the subgroup of clinical trial participants who also received miglustat

† 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

†† White, Asian, and "Other" were the only racial categories reported for this clinical trial.

‡‡ Ethnicity data was not available for 17% of clinical trial participants

Ophthalmologic and Imaging Therapies

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 Years	% U.S. Participants
LUMISIGHT (pegulicianine)	To use as an optical imaging agent for fluorescence imaging of breast cancer in adults	357	100	83	6	6	3	48	100
IOMERVU° (iomeprol)	For use as a radiographic contrast agent in adults and children	1105	NA	NA	NA	NA	NA	NA	NA
FLYRCADO (flurpiridaz F 18)	A radioactive diagnostic drug to evaluate for myocardial ischemia and infarction in adults with known or suspected coronary artery disease (CAD)	1333	32	82	10	1	9	46	76

NA = not available

° Drug was approved based on both clinical data and literature review, with the literature review having limited information on subgroups.

† 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.

Discussion

CDER approved 50 novel therapies for a range of diseases in 2024. About 31,000 study participants contributed to the pivotal trials supporting these approvals. Presenting demographic data by drug and therapeutic area in the annual summary report will: (1) facilitate tracking of trends in clinical trials representation by therapeutic area over time and (2) identify programs that have (or have not) generated clinical data in the population for which drugs are intended.

For the subgroup of sex, we summarized programs enrolling both males and females, excluding sex-specific indications as their inclusion would impact interpretability. The percentage of females participating across all individual drug programs ranged from 9% to 98%. The therapeutic area evaluating Autoimmune, Inflammatory, and Lung Diseases enrolled the highest percentage of females at 59%. Two drug programs that enrolled 100% females, *Lumisight* (an optical imaging agent for breast cancer) and *Orlynvah* (to treat UTI infections), and three drug programs that enrolled 0% females, *Duvyzat* (to treat Duchenne muscular dystrophy), *Alhemo* (for routine prophylaxis to prevent bleeding episodes in hemophilia A and B), and *Hymphazi* (to prevent bleeding episodes related to hemophilia A or B), were excluded in the analysis since they are sex-specific indications.

For race, the percentage of White participants enrolled in the drug programs ranged from 19% to 95% across therapeutic areas. White participants comprised more than 50% of the trial population enrolled for a majority of the drug programs. The second largest race category was Asian participants ranging from 0% to 80% across all therapeutic areas. The drug programs evaluating Cancers enrolled the highest percentage of Asian participants averaging 44%. Black or African American (herein referred to as Black) participants accounted for the lowest enrollment, ranging from 0% to 68% across all therapeutic areas. The drug programs evaluating Neurological and Psychiatric Disorders enrolled the highest percentage of Black participants. Since enrollment of American Indian or Alaskan Native race categories has historically been less than 1% to 2%, or not available, we did not include it in the table but encourage readers to look at the individual DTS summaries or FDA labels for the additional data. Finally, the percentage of Hispanic or Latino participants ranged from 0% to 46% of the overall study population across all therapeutic areas.

Age groups varied across therapeutic areas, with the percentage of participants ≥65 years of age ranging from 1% to 97%. The drug programs evaluating Neurological and Psychiatric Disease had the highest enrollment of participants ≥65 years of age, likely a result of the Alzheimer's drug *Kisunla* (90%) which had a larger number of participants than other drug trials in this therapeutic area. Notably, only 36% of the participants enrolled in the drug programs evaluating Cancers were 65 years of age or older.

All pivotal trials supporting each of the novel therapy approvals were conducted at multiple sites and the majority were multinational. Drugs evaluating Cancers (86%) and Reproductive, Urologic, and Rare Metabolic Diseases (97%) enrolled the highest number of participants outside the United States.

The goal of the DTS program is to make demographic data in key pivotal trials more available and transparent to the public. It is important to understand the enrollment of participants by sex, race, age, and ethnicity in drug development programs for highly prevalent diseases and compare these findings to the demographic makeup of patients with the disease in the United States. This will provide an opportunity to identify barriers to overcome and to leverage best practices that contribute towards improving representation in clinical trials. We hope the information obtained from Drug Trials Snapshots can contribute to this dialogue.

Acknowledgements

We acknowledge and appreciate the diligence of FDA review staff in providing additional analyses to support our transparency goals related to diversity and inclusion in clinical trials to support novel new drugs.

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