U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Drug Trials Snapshots Summary Report 2023

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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 diversity of participants in clinical trials through the transparency initiative called Drug Trials Snapshots.

This year's annual report summarizes the 2023 Drug Trials Snapshots program, complementing CDER's annual report, Advancing Health Through Innovation: New Drug Therapy Approvals 2023, published January 2024, by providing information on the diversity 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 (U.S.), and rare (or orphan) diseases with a smaller number of patients in the U.S. and around the world. Given the varied diseases being targeted, looking at patient populations by individual drug or therapeutic area gives the clearest insight into patient diversity 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 Drug Trials Snapshots 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.

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2023 Summary Statistics (January 1, 2023 - December 31, 2023)

In 2023, CDER approved 55 novel drugs, either as new molecular entities (NMEs) under new drug applications (NDAs) or as new therapeutic biologics under biologics license applications (BLAs). Twenty (36%) of these novel drugs were first-in-class, meaning they have mechanisms of action different from those of existing therapies. In addition, 29 (53%) of these approvals were for the treatment of rare or "orphan" diseases (diseases that affect fewer than 200,000 people in the U.S.).

In addition to summarizing baseline demographic data from pivotal studies supporting approval of each novel drug, unlike previous years, the 2023 annual report also provides information on the percentage of study participants from study sites within the U.S., and for programs that enrolled males and females, the overall percentage of participation by sex is displayed graphically. We encourage the reader to access the approved drug label and FDA reviews supporting a novel drug approval at Drugs@FDA to obtain more detailed information on the disease or medical condition and the efficacy and safety information of the novel drug in the overall study population and by demographic subgroups, appropriate to the approved indication.

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.

- **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 U.S.

Heart, Blood, Kidney, and Endocrine Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Aphexda* (motixafortide)	To use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma	122	35.2	86.1	8.2	1.6	9.8	44.3	63.9
Brenzavvy (bexagliflozin)	To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise	3346	35.3	73.2	5.8	16.0	16.7	43.6	36.1
Fabhalta* (iptacopan)	To treat adults with paroxysmal nocturnal hemoglobinuria	137	61.3	62.8	3.6	33.6	8.8	21.2	5.8
Filspari* (sparsentan)	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	281	31.0	61.6	1.4	34.5	6.8	55.2 (≥ 45 years)	16.4
Inpefa (sotagliflozin)	To treat heart failure	11806	43.8	83.4	3.5	5.9	31.1	69.6	10.5
Jesduvroq (daprodustat)	To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months	2964	42.7	66.7	15.6	12.0	24.9	33.0	28.5

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Ngenla* (somatrogon-ghla)	To treat growth failure due to inadequate secretion of endogenous growth hormone	224	28.1	74.6	0.9	20.1	10.7	59.8 (≥ 7 to < 12 years)	18.8
Rivfloza* (nedosiran)	To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function	29	55.2	69.0	0	17.2	6.9	62.1 (≥ 18 years)	10.3
Ryzneuta (efbemalenograstim alfa-vuxw)	To treat neutropenia	515	100	99.8	0.2	0	0.6	13.8	0.4
Sohonos*,§ (palovarotene)	To reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva (FOP)	139	49.6	76.3	1.4	5	15.8	44.6 (≥ 18 years)	51.1

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.

§ Based on safety subjects in the indicated population of ages 8 years and above for females and 10 years and above for males.

Figure 1. Participation by Sex for 9 Programs Evaluating Therapies to Treat Heart, Blood, Kidney, and Endocrine Diseases

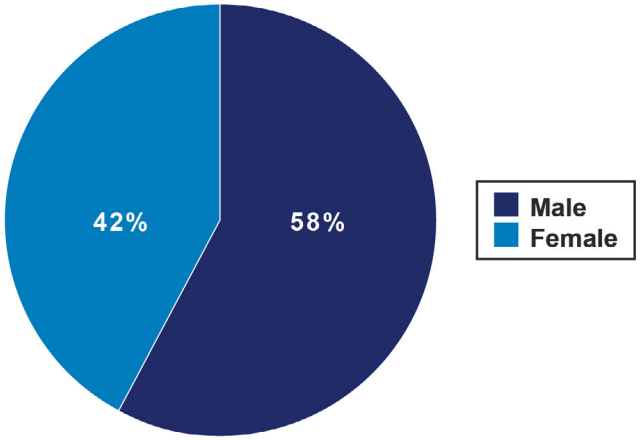

Figure 1 summarizes how many male and female participants were enrolled in the 9 drug programs evaluating therapies to treat Heart, Blood, Kidney or Endocrine Diseases that affect both males and females. In total, 19,048 participants enrolled in clinical trials in these 9 disease programs, and 42% of the participants that enrolled were females.

Autoimmune, Inflammatory, and Lung Diseases

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Bimzelx° (bimekizumab)	To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	839	28.2	83.8	1.8	13.0	4.8	8.2	19.9
Filsuvez* (birch triterpenes)	To treat wounds associated with dystrophic and junctional epidermolysis bullosa	223	39.9	83.4	1.3	4.9	34.5	31.4 (≥18 years)	6.3
Joenja* (leniolisib)	To treat activated phosphoinos-itide 3-kinase delta syndrome	31	51.6	80.6	6.5	6.5	3.2	61.3 (≥18 years)	51.6
Litfulo (ritlecitinib)	To treat severely patchy hair loss	718	62.1	68.0	3.8	25.9	12.1	86.4 (≥18 years)	27.2
Omvoh (mirikizumab-mrkz)	To treat ulcerative colitis	1062	40.2	71.3	1.0	25.3	3.3	7.6	12.8
Velsipity (etrasimod)	To treat moderately to severely active ulcerative colitis in adults	741	43.6	83.1	1.8	12.3	5.0	5.9	14.0

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Veopoz* (pozelimab-bbfg)	To treat patients ≥1 year old with CD55-deficient protein-losing enteropathy (PLE), also known as CHA-PLE disease	10	60.0	70.0	0	20.0	10.0	20.0 (≥12 years)	10.0

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

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

◦ Based on safety subjects who received the study drug

Figure 2. Participation by Sex for 7 Programs Evaluating Therapies to Treat Autoimmune, Inflammatory, and Lung Diseases

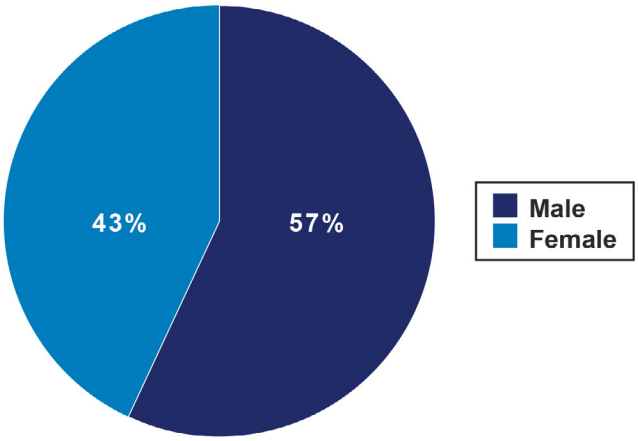

Figure 2 summarizes how many male and female participants were enrolled in the 7 drug programs evaluating therapies to treat autoimmune, inflammatory, and lung diseases that affect both males and female. In total 3,624 participants enrolled in clinical trials in the 7 disease programs, and 43% of the participants that enrolled were females.

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

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
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

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

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

Figure 3. Participation by Sex for 5 Programs Evaluating Therapies to Treat Infectious Diseases

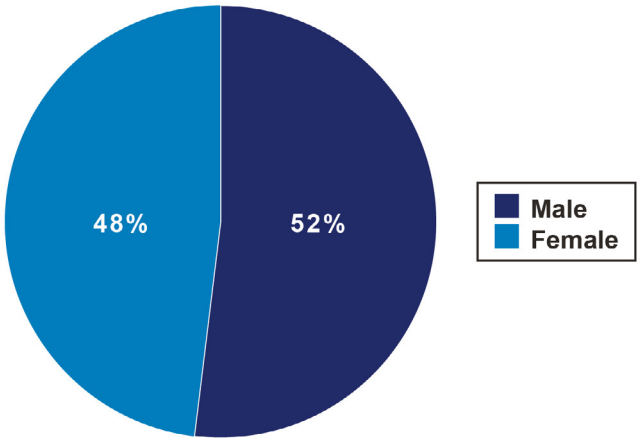

Figure 3 summarizes how many male and female participants were enrolled in the 5 drug programs evaluating therapies to treat infectious diseases that affect both males and females. In total, 7,313 participants enrolled in clinical trials in the 5 disease programs, and 48% of the participants that enrolled were females.

Neurological and Psychiatric Disorders

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Agamree*º (vamorolone)	To treat Duchenne muscular dystrophy	118	0	83.1	1.7	10.2	4.2	29.7 (= 6 years)	24.5
Daybue* (trofinetide)	To treat Rett syndrome	187	100	92.0	1.1	3.2	9.1	11.8 (≥ 18 years)	100
Exxua (gepirone)	To treat major depressive disorder	456	64.7	68.6	16.9	1.3	13.5	0.9	NA
Leqembi (lecanemab-irmb)	To treat Alzheimer's disease	856	49.5	90.5	2.5	6.2	0.0	80.0	80.1
Pombiliti* (cipaglucosidase alfa-atga)	To treat late-onset Pompe disease	123	54.5	84.6	0.8	3.3	NA	11.4	30.1
Qalsody* (tofersen)	To treat amyotrophic late ral sclerosis in adults who have a SOD1 gene mutation	108	42.6	63.9	0.9	8.3	4.6	13.0	50.9
Rystiggo* (rozanolixizumab-noli)	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positive	200	60.5	68.0	2.5	10.5	6.5	24.5	20.5
Skyclarys* (omaveloxolone)	To treat Friedrich's ataxia	103	46.6	97.1	NA	NA	4.9	76.7 (≥ 18 years)	68.9
Wainua* (eplontersen)	To treat polyneuropathy of hereditary transthyre-tin-mediated amyloidosis	144	30.6	77.8	3.5	15.3	15.3	30.6	13.2

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Zavzpret (zavegepant)	To treat migraine	1581	85.5	78.3	16.3	3.7	18.1	3.9	100
Zilbrysq* (zilucoplan)	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive	174	56.9	73.6	7.5	12.1	6.9	27.6	50.6
Zurzuvae (zuranolone)	To treat postpartum depression	345	100	64.1	30.1	1.2	31.6	78.8 (≥ 25 years)	55.1

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

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

° Based on safety subjects who received the study drug.

Figure 4. Participation by Sex for 9 Programs Evaluating Therapies to Treat Neurological and Psychiatric Disorders

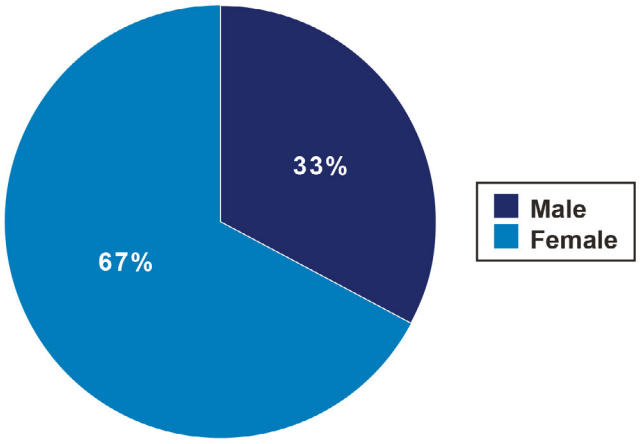

Figure 4 summarizes how many male and female participants were enrolled in the 9 drug programs evaluating therapies to treat neurological and psychiatric diseases that affect both males and females. In total, 3,745 participants enrolled in clinical trials in the 9 disease programs, and 67% of the participants that enrolled were females.

Cancers

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Augtyro* (repotrectinib)	To treat ROS1-positive non-small cell lung cancer	127	63.8	33.9	1.6	59.1	3.1	26.8	22.0
Columvi (glofitamab-gxbm)	To treat diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy	132	35.6	77.3	0.8	4.5	5.5	56.1	12.1
Elrexfio* (elranatamab-bcmm)	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy	97	40.2	59.8	5.2	13.4	7.2	67.0	38.1
Epkinly (epcoritamab-bysp)	To treat relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy	148	38.5	60.8	0.7	19.6	0.7	50	16.2
Fruzaqla (fruquintinib)	To treat refractory, metastatic colorectal cancer	1107	42.2	50.5	1.8	43.1	3.1	37.3	11.2

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Jaypirca* (pirtobrutinib)	To treat relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitor	120	20.8	77.5	1.7	14.2	2.5	77.5	60.8
Loqtorzi* (toripalimab-tpzi)	To treat recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies	289	17.0	0	0	100	0	4.8	0
Ogsiveo* (nirogacestat)	To treat adults with progress-ing desmoid tumors who require systemic treatment	142	64.8	83.1	6.3	2.8	7.0	26.1 (≥ 46 years)	63.4
Ojjaara* (momelotinib)	To treat intermediate or high-risk myelofibrosis in adults with anemia	376	38.8	80.6	1.6	8.8	3.7	73.4	13.3
Orserdu (elacestrant)	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutat-ed, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	467	98.5	70.4	2.8	6.6	7.7	45.6	28.3

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Talvey* (talquetamab-tgvs)	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior therapies	187	43.3	90.4	5.3	2.7	8.0	59.9	22.5
Truqap (capivasertib)	To treat breast cancer that meets certain disease criteria	708	99.0	57.5	1.1	26.7	8.8	30.6	6.2
Vanflyta* (quizartinib)	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria	539	54.5	59.7	1.3	29.3	4.1	25.0	3.9
Zynyz* (retifanlimab-dlwr)	To treat metastatic or recurrent locally advanced Merkel cell carcinoma	65	35.4	78.5	NA	1.5	NA	78.5	16.9

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

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

Figure 5. Participation by Sex for 14 Programs Evaluating Therapies to Treat Cancers

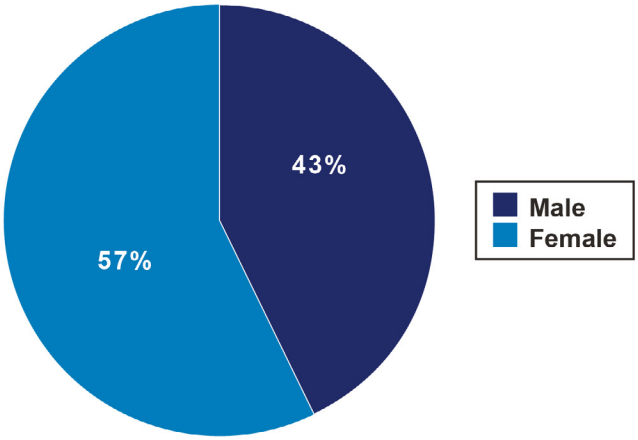

Figure 5 summarizes how many male and female participants were enrolled in the 14 drug programs evaluating therapies to treat cancers that affect both males and females. In total, 4,504 participants enrolled in clinical trials in the 14 disease programs, and 57% of the participants that enrolled were females.

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

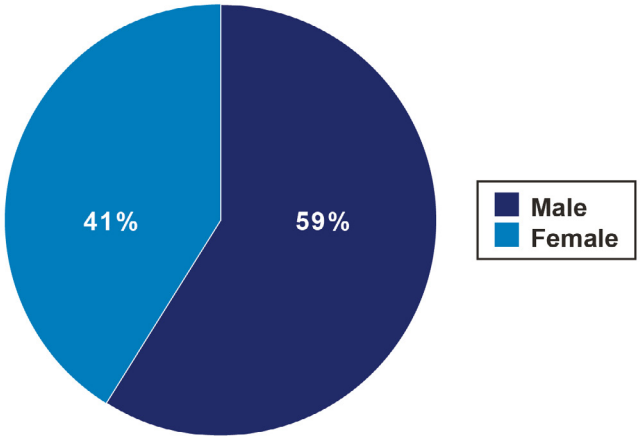

Figure 6 summarizes how many male and female participants were enrolled in the 2 drug programs evaluating therapies to treat reproductive, urologic, and rare metabolic diseases that affect both males and females. In total, 123 participants enrolled in clinical trials in the 2 disease programs, and 41%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

Ophthalmologic and Imaging Therapies

Trade name (active ingredient)	Indication	Total N	% Female	% White†	% Black†	% Asian†	% Hispanic‡	% ≥ 65 years unless otherwise denoted	% U.S. Participants
Izervay (avacincaptad pegol)	To treat geographic atrophy secondary to age-related macular degeneration	624	69.6	86.9	0.3	0.3	8.5	91.2	50.6
Miebo (perfluorhexyloctane)	To treat signs and symptoms of dry eye disease	1217	75.7	75.2	12.4	10.3	18.2	39.2	100
Posluma (flotufolastat F 18)	To use with positron emission tomography imaging in certain patients with prostate cancer	747	0	78.2	12.2	1.6	4.7	62.0	82.1
Xdemvy (lotilaner)	To treat Demodex blepharitis	833	52.8	89.4	7.4	1.3	7.1	62.2	100

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

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

Figure 7. Participation by Sex for 3 Programs Evaluating Ophthalmologic and Imaging Therapies

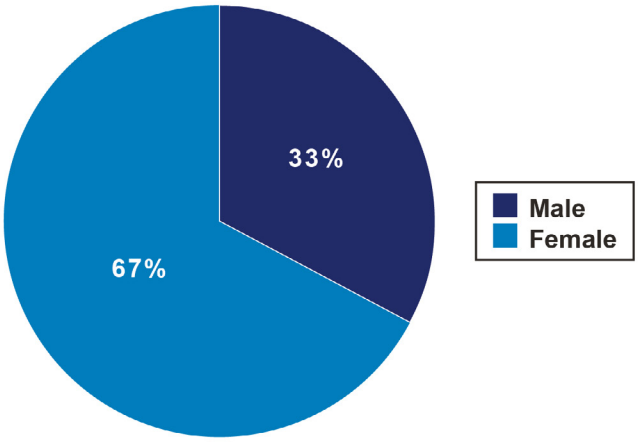

Figure 7 summarizes how many male and female participants were enrolled in the 3 drug programs evaluating therapies evaluating ophthalmologic and imaging therapies that affect both males and females. In total, 2,674 participants enrolled in clinical trials in the 3 disease programs, and 67% of the participants that enrolled were females.

Discussion

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 to the advancement of science and medicine through their participation in the pivotal studies supporting these approvals. This annual report summarizes the demographic information with respect to race, ethnicity, sex, and age across a range of populations studied, and unlike prior annual reports, the percentage of participants from the United States is also provided.

All the pivotal trials supporting each of the novel therapy approvals were conducted at multiple sites and the majority were multinational. Five programs were conducted entirely in the U.S. (Daybue, Defencath, Miebo, Xdemvy, and Zavapret) and two programs enrolled participants entirely outside the U.S. (Lamzede and Loqtorzi). For programs with enrollment both inside and outside the U.S., the percentage of participants from the U.S. ranged from 0.4 to 82% (median 24.5%). Interpretation of the percentage participation within the U.S. should consider the epidemiology and geographic distribution of the disease, particularly when considering aggregated data of multiple drug development programs.

For participation by sex, we summarized data for programs enrolling both males and females, excluding sex-specific indications (e.g., prostate cancer or post-partum depression) as their inclusion would impact interpretability of equitable participation by sex in trials for diseases impacting both sexes. Interpretation of these data should still consider the distribution of the targeted indication by sex. Across each of the clinical offices in OND, the percentage of females participating in these drug programs ranged from 41 to 67% (median 48%).

Whites comprised more than 50% of the trial population enrolled for all programs except Loqtorzi (0%), Augtyro (33.9%) and Xacduo (49.2%). Asians comprised the second largest race category enrolled in pivotal trials with 27 drug programs enrolling ≥ 10% Asians of the overall study population (range: 10.3% to 100%); six programs enrolled over 30% Asians, Fabhalta (33.6%), Filspari (34.5%), Xacduro (43.5%), Augtyro (59.1%), Fruzagla (43.1%), and Loqtorzi (100%). Nine drug programs enrolled ≥ 10% Blacks of the overall study population (range: 12.2% to 30.1%); two programs enrolled over 25% Black, Defencath (29.5%) and Zurzuvae (30.1%). Eighteen drug programs enrolled ≥ 10% Hispanics or Latinos

of the overall study population (range: 10% to 45.4%); five programs enrolled more than 30% Hispanics, Inpefa (31.1%), Filsuvez (34.5%), Defencath (45.4%), Paxlovid (41.8%), and Zurzuvae (31.6%). Participation in clinical trials of individuals from American Indian or Alaskan Native race categories has historically been under 1 to 2%. In 2023, there was one drug program (Paxlovid) that enrolled a notable percentage from the American Indian or Alaskan Native race category, (7.3%). 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.

Sections 3601 and 3602 of the Food and Drug Omnibus Reform Act (FDORA), included as part of the Consolidated Appropriations Act of 2023, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require, among other things, that sponsors of a phase III or another pivotal study of a drug submit a Diversity Action Plan in the form and manner specified by FDA in guidance. Specifically, under section 505(z) of the FD&C Act, as amended by FDORA, such plans must include 1) the sponsor's goals for enrollment, 2) the sponsor's rationale for such goals, and 3) an explanation of how the sponsor intends to meet such goals. Diversity Action Plans are required for applicable studies that commence enrollment after 180 days from FDA's publication of the final guidance outlining the content and format of such plans. We anticipate that Diversity Action Plans will reinforce the importance of diverse enrollment in clinical trials, including in rare disease programs.

Presenting demographic data by drug and therapeutic area in the annual summary report will facilitate tracking of trends in diversity in clinical trials by therapeutic area over time and identifying programs that have achieved lower or greater enrollment of under-represented patient populations. FDA is committed to working with sponsors to identify barriers to overcome and to leverage best practices that contribute towards improving diversity in clinical trials and hope the information obtained from Drug Trials Snapshots can contribute to this dialogue.

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