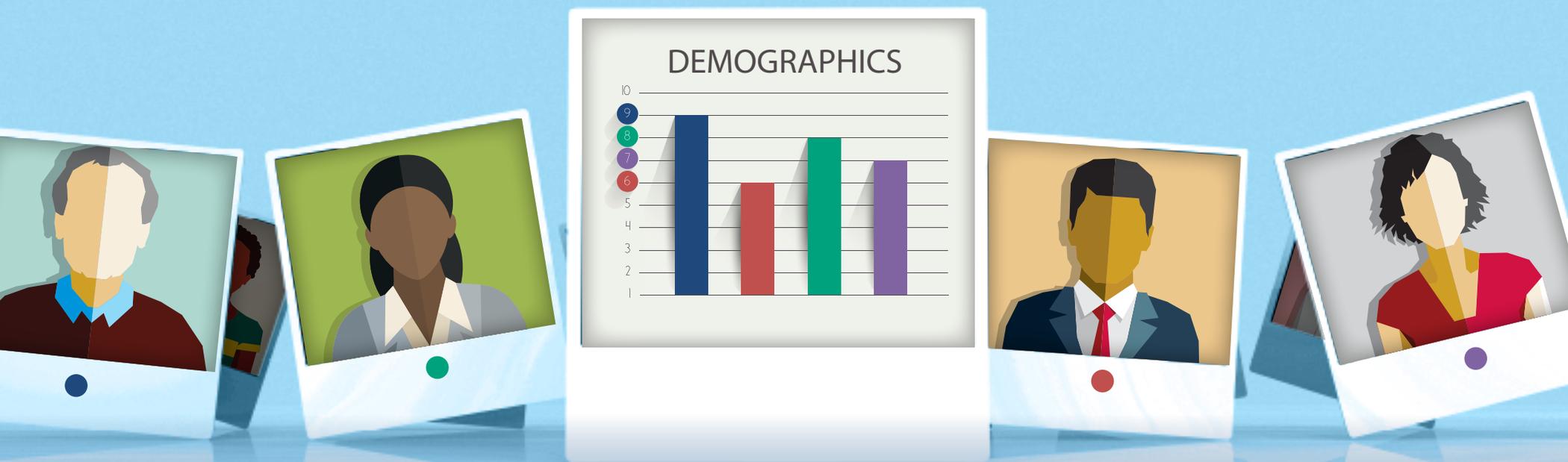


2020 DRUG TRIALS SNAPSHOTS SUMMARY REPORT



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. In addition to the individual snapshots and yearly summaries, we recently published the 2015–2019 Drug Trials Snapshots Summary Report, which aggregated demographic data from all snapshots published between 2015 and 2019.

This year's annual report summarizes the 2020 Drug Trials Snapshot program, highlighting 53 newly approved drugs and biologics. We provide an overall average of each demographic group, followed by a more detailed table of the percent representation of sex, race, age, and ethnicity participating in the clinical trials used to approve the drug. Demographics data from the top three therapeutic areas are presented at the end of the report.

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 Trial Snapshot 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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2020 Summary Statistics

(Jan 1, 2020 – Dec 31, 2020)

In 2020, CDER approved 53 novel drugs, either as new molecular entities (NMEs) under new drug applications (NDAs) or as new therapeutic biologics under biologics license applications (BLAs). Overall, 32,000 patients participated in these trials. Selected subpopulation demographics from these trials are presented below.

Table 1. Percent Participation in Clinical Trials by Subpopulation* for New Molecular Entities and Therapeutic Biologics Approved in 2020

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%

* The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific islander, Other, Unknown/Unreported) makes up to 100% of race category.

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

* The percentage of patients from anywhere else in the world makes up to 100% of geographic category.

More insight into demographics for all 53 CDER approved NMEs are provided below in Table 2.

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
ARTESUNATE	Treatment of malaria	26	NR	NR	NR	NR	3	0
AYVAKIT	Treatment of gastrointestinal stromal tumors	39	72	4	10	3	40	45

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020 *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
BARHEMSYS	Treatment of post-operative nausea and vomiting	88	79	9	1	10	14	63
BLENREP	Treatment of multiple myeloma	47	78	16	2	4	53	61
BYFAVO	Sedation for short procedures	52	78	17	4	8	31	100
CERIANNA	Detection of estrogen positive lesions in breast cancer	100	15	2	83	0	NR	17
DANYELZA	Treatment of neuroblastoma	37	69	3	18	6	0	84
DETECTNET	Detection of certain neuro-endocrine tumors	48	31	3	1	6	38	36
DOJOLVI	Source of calories for fatty acid oxidation disorder	48	87	5	4	9	0	91
EBANGA	Treatment of Ebola infection	54	NR	NR	NR	NR	3	0
ENSPRYNG	Treatment of neuromyelitis optica spectrum disorder	91	48	12	35	9	NR	29
EVRYSDI	Treatment of spinal muscular atrophy	53	69	1	19	3	0	3
Ga 68 PSMA-11	Detection of specific cancer lesions in men with prostate cancer	0	85	2	4	4	72	100

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020 *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
GAVRETO	Treatment of non-small cell lung cancer	52	50	0	41	4	37	26
GEMTESA	Treatment of symptoms of overactive bladder	85	79	15	5	73	44	90
IMCIVREE	Treatment of obesity in patients with certain rare disorder	52	67	0	4	7	0	4
INMAZEB	Treatment of Ebola infection	55	NR	NR	NR	NR	NR	0
INQOVI	Treatment of myelodysplastic syndromes	31	92	3	2	5	75	82
ISTURISA	Treatment of Cushing's disease	77	65	3	29	9	5	18
KLISYRI	Treatment of actinic keratosis	13	100	0	0	4	73	100
KOSELUGO	Treatment of neurofibroma	40	84	8	2	4	0	100
LAMPIT	Treatment of Chagas disease	54	71	0	0	99	0	0
MARGENZA	Treatment of metastatic HER2-positive breast cancer	99	80	5	6	9	21	33
MONJUVI	Treatment of diffuse large b-cell lymphoma	46	89	0	3	NR	69	7

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
NEXLETOL	Treatment of high LDL cholesterol	29	96	3	1	3	58	26
NURTEC ODT	Treatment of acute migraine	85	75	20	2	19	2	100
OLINVYK	Treatment of acute pain	79	72	23	2	19	18	100
ONGENTYS	Treatment of "off episodes" in Parkinson's disease	42	85	0	14	NR	48	0
ORGOVYX	Treatment of prostate cancer	0	68	5	21	9	81	24
ORLADEYO	Prevention of hereditary angioedema attacks	66	94	3	1	3	8	63
OXLUMO	Treatment of primary hyperoxaluria type 1	40	80	0	11	4	0	25
PEMAZYRE	Treatment of metastatic bile duct cancer	57	71	6	15	4	31	61
PIZENSY	Treatment of chronic idiopathic constipation	76	60	31	7	38	27	100
QINLOCK	Treatment of gastrointestinal stromal tumors	43	75	8	7	1	39	47

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
RETEVMO	Treatment of certain cancers caused by specific genes	48	69	3	22	5	34	61
RUKOBIA	Treatment of HIV-1 infection	26	68	22	1	29	4	32
SARCLISA	Treatment of multiple myeloma	48	80	1	12	2	60	2
SOGROYA	Replacement of growth hormone	52	67	2	29	6	14	26
TABRECTA	Treatment of non-small cell lung cancer	41	74	1	24	7	57	10
TAUVID	Detection of aggregated neurofibrillary tangles in Alzheimer's disease	50	86	5	6	5	80	77
TAZVERIK	Treatment of advanced epithelioid sarcoma	37	76	7	11	11	3	65
TEPEZZA	Treatment of thyroid eye disease	73	87	8	4	5	15	57
TRODELVY	Treatment of breast cancer	99	76	7	3	7	18	100
TUKYSA	Treatment of breast cancer	99	73	9	4	8	19	54

Table 2. Percent Participation in Clinical Trials by Subpopulation* and Brand Name of Product for New Molecular Entities Approved in 2020

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
UPLIZNA	Treatment of neuromyelitis optica spectrum disorder	94	52	9	21	19	5	18
VEKLURY	Treatment of COVID-19	37	57	18	14	21	35	65
VILTEPSO	Treatment of Duchenne muscular dystrophy	0	44	0	56	6	0	38
VYEPTI	Treatment of migraine	87	88	9	1	12	1	68
WINLEVI	Treatment of acne vulgaris	63	90	6	2	14	0	41
XEGLYZE	Treatment of head lice	84	97	1	0	66	0	100
ZEPOSIA	Treatment of multiple sclerosis	67	99	1	0	1	0	3
ZEPZELCA	Treatment of small cell lung cancer	40	75	1	1	NR	35	10
ZOKINVY	Treatment of rare conditions related to premature aging	48	NR	NR	NR	NR	0	19

*The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific islander, Other, Unknown/Unreported) makes up to 100% of race category.

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

The percentage of patients from anywhere else in the world makes up to 100% of geographic category.

NR=not reported

Therapeutic Areas in 2020

The main therapeutic areas for 2020 were: Oncology, Neurology and Infectious Diseases. Demographics for these approvals are provided in Tables 3, 4, and 5.

Oncology

A total of 4,922 patients participated in the trials that led to the approvals of 18 new drugs. Overall, 50% of all participants were women, 73% were White, 5% were Black or African American, 14% were Asian, 6% were Hispanic, 44% were 65 years and older, and 41% were from sites in the United States.

Demographics for individual approvals is provided in the Table 3.

Table 3. Percent Participation in Clinical Trials by Subpopulation for 2020 Oncology Approvals

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
AYVAKIT	Treatment of gastrointestinal stromal tumors	39	72	4	10	3	40	45
BLENREP	Treatment of multiple myeloma	47	78	16	2	4	53	61
DANYELZA	Treatment of neuroblastoma	37	69	3	18	6	0	84
GAVRETO	Treatment of non-small cell lung cancer	52	50	0	41	4	37	26
INQOVI	Treatment of myelodysplastic syndromes	31	92	3	2	5	75	82
KOSELUGO	Treatment of neurofibroma	40	84	8	2	4	0	100
MARGENZA	Treatment of metastatic HER2-positive breast cancer	99	80	5	6	9	21	33

Table 3. Percent Participation in Clinical Trials by Subpopulation for 2020 Oncology Approvals *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
MONJUVI	Treatment of diffuse large B-cell lymphoma	46	89	0	3	NR	69	7
ORGOVYX	Treatment of prostate cancer	0	68	5	21	9	81	24
PEMAZYRE	Treatment of metastatic bile duct cancer	57	71	6	15	4	31	61
QINLOCK	Treatment of gastrointestinal stromal tumors	43	75	8	7	1	39	47
RETEVMO	Treatment of certain cancers caused by specific genes	48	69	3	22	5	34	61
SARCLISA	Treatment of multiple myeloma	48	80	1	12	2	60	2
TABRECTA	Treatment of non-small cell lung cancer	41	74	1	24	7	57	10
TAZVERIK	Treatment of advanced epithelioid sarcoma	37	76	7	11	11	3	65
TRODELVY	Treatment of breast cancer	99	76	7	3	7	18	100
TUKYSA	Treatment of breast cancer	99	73	9	4	8	19	54

Table 3. Percent Participation in Clinical Trials by Subpopulation for 2020 Oncology Approvals *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
ZEPZELCA	Treatment of small cell lung cancer	40	75	1	1	NR	35	10

NR=not reported

Neurology

A total of 5,598 patients participated in the trials that led to the approvals of 6 new drugs. Overall, 74% of all participants were women, 87% were White, 3% were Asian, 8% were Black or African American, 9% were Hispanic, 5% were 65 years and older, and 46% were from sites in the United States.

Demographics for individual approvals is provided in the Table 4.

Table 4. Percent Participation in Clinical Trials by Subpopulation for 2020 Neurology Approvals

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
EVRYSDI	Treatment of spinal muscular atrophy	53	69	1	19	3	0	3
NURTEC ODT	Treatment of acute migraine	85	75	20	2	19	2	100
ONGENTYS	Treatment of "off episodes" in Parkinson's disease	42	85	0	14	NR	48	0
VILTEPSO	Treatment of Duchenne muscular dystrophy	0	44	0	56	6	0	38

Table 4. Percent Participation in Clinical Trials by Subpopulation for 2020 Neurology Approvals *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
VYEPTI	Treatment of migraine	87	88	9	1	12	1	68
ZEPOSIA	Treatment of multiple sclerosis	67	99	1	0	1	0	3

NR=not reported

Infectious Diseases

A total of 4,659 patients participated in the trials that led to the approvals of 6 new drugs. Overall, 36% of all participants were women, 32% were White, 6% were Asian, 9% were Black or African American, 16% were Hispanic, 16% were 65 years and older, and 30% were from sites in the United States.

Demographics for individual approvals is provided in the Table 5.

Table 5. Percent Participation in Clinical Trials by Subpopulation for 2020 Infectious Diseases Approvals

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
ARTESUNATE	Treatment of malaria	26	NR	NR	NR	NR	3	0
EBANGA	Treatment of Ebola infection	54	NR	NR	NR	NR	3	0
INMAZEB	Treatment of Ebola infection	55	NR	NR	NR	NR	NR	0
LAMPIT	Treatment of Chagas disease	54	71	0	0	99	0	0

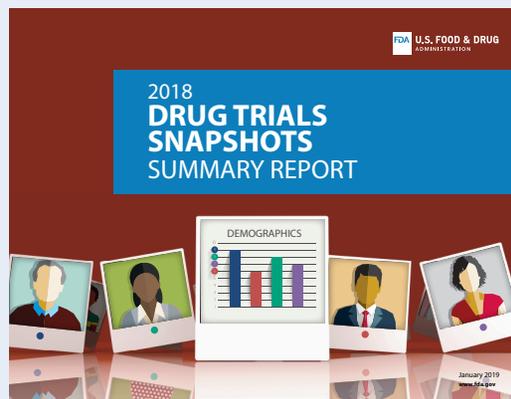
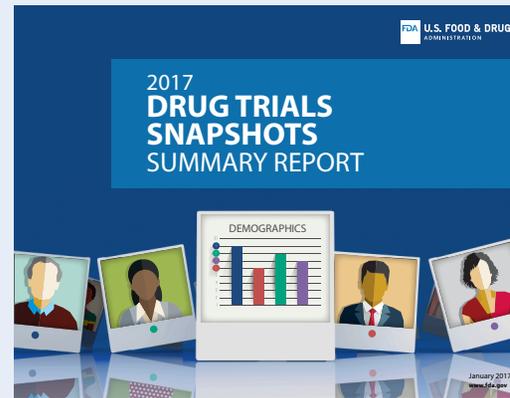
Table 5. Percent Participation in Clinical Trials by Subpopulation for 2020 Infectious Diseases Approvals *continued*

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
RUKOBIA	Treatment of HIV-1 infection	26	68	22	1	29	4	32
VEKLURY	Treatment of COVID-19	37	57	18	14	21	35	65

NR=not reported

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<https://www.fda.gov/Drugs/InformationOnDrugs/ucm412998.htm>





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