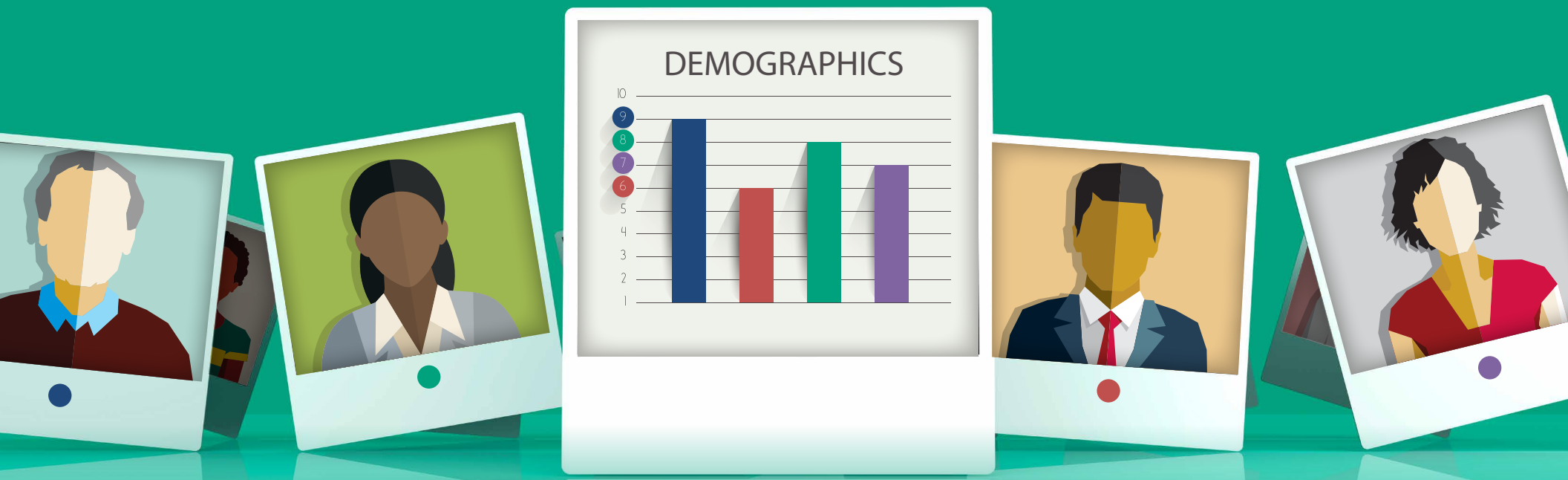
U.S. FOOD & DRUG ADMINISTRATION

2015-2016

# DRUG TRIALS SNAPSHOTS SUMMARY REPORT




January 2017

www.fda.gov

# Introduction

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

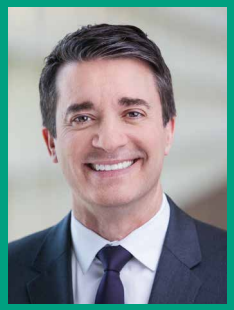
Every year, CDER approves a number of novel drugs based upon review of safety and efficiency measures from sponsor submitted clinical trial data. Participation in these clinical trials has varied greatly, with some trials having fewer than ten patients to others including several thousand. In recent years, the representation of certain subgroups such as women and people of racial minority groups, has become of greater interest to the general public. As part of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA 907), the U.S. Congress required the U.S. Food and Drug Administration (FDA) to report on the diversity of participants in clinical trials and the extent to which safety and effectiveness data is based on demographic factors such as sex, age, and race. Recognizing the lack of easily accessible information about participation in drug trials, CDER piloted a new transparency initiative called the Drug Trials Snapshots.

Snapshots are data posted online in a standardized format after approval of a novel drug that is either a New Molecular Entity (NME) or original biologic (BLA) product. They show who participated in the pivotal clinical trials used to approve the drug and stratify the data by sex, race, and age subgroups. Further, the Snapshots provide statements on whether there were any observed differences in safety and efficacy by demographic subgroups at the time of approval. Since January 2015, CDER has been publishing a Drug Trials Snapshot for each novel drug approved within a month of the official approval date.

Our Summary Reports are another commitment to enhancing transparency and better understanding of the drug development process. The report summarizes the first two years of the Drug Trials Snapshot program and is broken down by calendar years 2016 and 2015. Each calendar year provides an overall average of each demographic group followed by a more detailed summary table of the percent representation of sex, race, and age per clinical trial. Since the launch of the Drug Trials Snapshots, over a quarter million people have visited the website.

We hope this information is helpful to promote dialogue on the appropriate representation of different subgroups in clinical trials and welcome your feedback.

**Janet Woodcock, M.D.**
Director, Center for Drug Evaluation and Research (CDER)



**John Whyte, M.D., M.P.H.**
Director, Professional Affairs and Stakeholder Engagement (PASE)

## 2016 Summary Statistics

(Jan 1, 2016 - Dec 31, 2016)

In 2016, CDER approved **22**[1] novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs). Overall, **31,468** patients participated in these trials. Subpopulation demographics are presented below:

**Figure 1. Demographic Subgroups in 2016**

| DEMOGRAPHIC SUBGROUPS | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER* | AGE 65 and OLDER |
|---|---|---|---|---|---|---|
| PARTICIPANT AVERAGE | 48% | 7% | 11% | 76% | 7% | 21% |

* The percentages of the categories "American Indian or Alaska Native (AI/AN)," "Native Hawaiian or Other Pacific Islander (NH/OPI)," and "Unknown/Unreported" were small enough that we combined them into the "Other" category for the purposes of this report.

## Therapeutic Areas 2016

More insight into demographics for all 22 CDER-approved novel drugs are provided below in Table 1.

**Table 1. All Approvals (2016)**

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER |
|---|---|---|---|---|---|---|---|
| **ADLYXIN§** | Treatment of type 2 diabetes mellitus | **52%** | **3%** | **32%** | **64%** | **2%** | **19%** |
| **ADLYXIN§§** | Treatment of type 2 diabetes mellitus | **31%** | **4%** | **13%** | **75%** | **8%** | **34%** |
| **ANTHIM** | For the treatment of inhalational anthrax | **46%** | **28%** | **1%** | **69%** | **2%** | **9%** |

§ Clinical Trial of Type 2 DM patients
§§ Clinical Trial of Type 2 DM patients who recently had a heart attack

1. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm483775.htm

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER |
|---|---|---|---|---|---|---|---|
| **AXUMIN** | Detection of prostate cancer recurrence | **0%** | **4%** | **<1%** | **31%** | **64%** | **66%** |
| **BRIVIACT** | Treatment of partial-onset seizures | **49%** | **3%** | **12%** | **74%** | **11%** | **2%** |
| **CINQUAIR** | For the treatment of a specific type of severe asthma (called eosinophilic phenotype asthma) | **62%** | **12%** | **8%** | **73%** | **8%** | **6%** |
| **DEFITELIO** | Treatment of hepatic veno-occlusive disease (VOD) | **45%** | **6%** | **4%** | **71%** | **19%** | **0%** |
| **EPCLUSA** | Treatment of chronic Hepatitis C virus genotypes 1, 2, 3, 4, 5 or 6 infection. | **38%** | **6%** | **7%** | **85%** | **2%** | **11%** |
| **EUCRISA** | To treat mild to moderate eczema (atopic dermatitis) in patients two years of age and older | **56%** | **28%** | **5%** | **61%** | **6%** | **0%** |
| **EXONDYS 51#** | Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping | **0%** | **0%** | **8%** | **92%** | **0%** | **0%** |
| **EXONDYS 51##** | Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping | **0%** | **0%** | **0%** | **100%** | **0%** | **0%** |
| **LARTRUVO** | Treatment of soft tissue sarcoma | **56%** | **8%** | **3%** | **86%** | **2%** | **32%** |
| **NETSPOT** | For detection of a specific type of tumors called somatostatin receptor positive neuro-endocrine tumors (NETs) | **52%** | **N/A** | **N/A** | **N/A** | **100%** | **N/A** |
| **NUPLAZID** | Treatment of hallucinations and delusions in patients with Parkinson's disease | **36%** | **1%** | **5%** | **91%** | **3%** | **82%** |

# Baseline Demographics of Trials 1 and 2
## Baseline Demographics of Trial 3

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER |
|---|---|---|---|---|---|---|---|
| **OCALIVA** | Treatment of primary biliary cholangitis in adults | **91%** | **1%** | **1%** | **94%** | **3%** | **19%** |
| **RUBRACA** | Treatment of women with certain type of advanced ovarian cancer | **100%** | **2%** | **6%** | **80%** | **12%** | **42%** |
| **SPINRAZA** | Spinal muscular atrophy (SMA) | **55%** | **2%** | **6%** | **86%** | **6%** | **0%** |
| **TALTZ** | Treatment of moderate to severe plaque psoriasis in adults | **32%** | **2%** | **4%** | **93%** | **1%** | **7%** |
| **TECENTRIQ** | Treatment of a type of bladder cancer called urothelial carcinoma | **78%** | **2%** | **2%** | **91%** | **5%** | **59%** |
| **VENCLEXTA** | Treatment of chronic lymphocytic leukemia (CLL) | **31%** | **3%** | **<1%** | **94%** | **3%** | **58%** |
| **XIIDRA** | Treatment of the signs and symptoms of dry eye disease | **76%** | **9%** | **4%** | **85%** | **2%** | **37%** |
| **ZEPATIER** | Treatment of chronic Hepatis C genotypes 1 or 4 infection | **39%** | **15%** | **9%** | **75%** | **1%** | **11%** |
| **ZINBRYTA** | Treatment of relapsing forms of multiple sclerosis (MS) | **67%** | **1%** | **3%** | **91%** | **5%** | **0%** |
| **ZINPLAVA** | Decreasing the risk of Clostridium difficile infection recurrence | **57%** | **5%** | **8%** | **85%** | **2%** | **62%** |

## 2015 Summary Statistics

(Jan 1, 2015 - Dec 31, 2015)

In calendar year 2015, CDER approved **45**[2] novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs). Overall, **105,826** patients participated in these trials. Subpopulation demographics are presented below:

**Figure 2. Demographic Subgroups in 2015**

| DEMOGRAPHIC SUBGROUPS | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER* | AGE 65 and OLDER | AGE 75 and OLDER** | AGE 80 and OLDER** |
|---|---|---|---|---|---|---|---|---|
| PARTICIPANT AVERAGE | 40% | 5% | 12% | 79% | 4% | 37% | 15% | 6% |

* The percentages of the categories "American Indian or Alaska Native (AI/AN)," "Native Hawaiian or Other Pacific Islander (NH/OPI)," and "Unknown/Unreported" were small enough that we combined them into the " Other" category for the purposes of this report.
**These particular subgroups were calculated as part of a Geriatrics Report and are not a regular feature of the Drug Trials Snapshots

## All Approvals 2015

More insight into demographics for all 45 CDER-approved novel drugs are provided below in Table 2.

**Table 2. All Drug Approvals (2015)**

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **ADDYI** | Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women | **100%** | **8%** | **1%** | **89%** | **2%** | **0%** | **0%** | **0%** |

2. To be consistent with the 2015 CDER Novel Drugs Report, three Drug Trials Snapshots were removed: Stiolto Respimat, Ryzodeg and Vistogard. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm430302.htm

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| ALECENSA | For the treatment of metastatic non-small cell lung cancer | 55% | 2% | 18% | 74% | 7% | 14% | 4% | <1% |
| ARISTADA | Treatment of schizophrenia | 32% | 40% | 13% | 47% | <1% | 0% | 0% | 0% |
| AVYCAZ | Treatment of complicated intra-abdominal infection (abbreviated as cIAI) | 26% | <1% | 27% | 60% | 12% | 11% | 8% | 4% |
| AVYCAZ | Treatment of complicated urinary tract infection (abbreviated as cUTI) | 74% | 5% | 10% | 60% | 25% | 17% | 4% | 3% |
| BRIDION | For the reversal of the effects of certain neuromuscular blocking agents | 52% | 3% | 12% | 84% | <1% | 29% | <1% | <1% |
| CHOLBAM | For treatment of bile acid synthesis disorders due to single enzyme defects | 43% | 11% | 7% | 61% | 20% | N/A | N/A | N/A |
| CHOLBAM | For treatment of peroxisomal disorders, including Zellweger spectrum disorders | 33% | 0% | 0% | 83% | 17% | N/A | N/A | N/A |
| CORLANOR | To reduce hospitalization from worsening heart failure. | 24% | 1% | 8% | 89% | 2% | 38% | 11% | 3% |
| COSENTYX | Treatment of moderate to severe plaque psoriasis in adults who do not respond well to medication applied directly to the skin | 30% | 1% | 22% | 68% | 9% | 8% | 1% | <1% |
| COTELLIC | Part of combination treatment melanoma | 42% | N/A | N/A | 93% | 7% | 27% | 9% | 3% |
| CRESEMBA | Treatment of invasive aspergillosis | 40% | <1% | 21% | 78% | <1% | 24% | 5% | <1% |
| CRESEMBA | Treatment of invasive mucormycosis | 19% | 11% | 22% | 68% | 0% | 14% | 8% | 0% |

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **DAKLINZA** | Treatment of chronic Hepatitis C genotype 3 infection | **41%** | **4%** | **5%** | **90%** | **1%** | **7%** | **0%** | **0%** |
| **DARZALEX** | Treatment of multiple myeloma | **46%** | **10%** | **6%** | **76%** | **8%** | **45%** | **10%** | **3%** |
| **EMPLICITI** | Treatment of multiple myeloma | **40%** | **4%** | **10%** | **84%** | **2%** | **57%** | **20%** | **7%** |
| **ENTRESTO** | Treatment of heart failure | **22%** | **5%** | **18%** | **66%** | **11%** | **49%** | **19%** | **7%** |
| **FARYDAK** | Treatment of multiple myeloma | **48%** | **3%** | **33%** | **63%** | **1%** | **35%** | **5%** | **0%** |
| **GENVOYA†** | Complete regimen for the treatment of HIV-1 in adults and children 12 years of age and older. | **48%** | **83%** | **17%** | **0%** | **0%** | **0%** | **0%** | **0%** |
| **GENVOYA‡** | Complete regimen for the treatment of HIV-1 in adults and children 12 years of age and older. | **13%** | **23%** | **9%** | **61%** | **7%** | **3%** | **<1%** | **<1%** |
| **IBRANCE** | Treatment of a specific form of advanced breast cancer called ER-positive, HER2-negative (ER+/HER-) breast cancer in women who have gone through menopause (post-menopausal) | **100%** | **1%** | **6%** | **90%** | **3%** | **46%** | **9%** | **3%** |
| **KANUMA(i)** | Treatment of Lysosomal Acid Lipase (LAL) deficiency | **44%** | **11%** | **11%** | **44%** | **33%** | **0%** | **0%** | **0%** |
| **KANUMA(ii)** | Treatment of Lysosomal Acid Lipase (LAL) deficiency | **50%** | **2%** | **5%** | **83%** | **11%** | **0%** | **0%** | **0%** |
| **KENGREAL** | For prevention of coronary artery blood clot formation in patients undergoing PCI | **28%** | **3%** | **3%** | **94%** | **<1%** | **48%** | **18%** | **8%** |

† Clinical Trial of Children Only
‡ Clinical Trial of Adults Only
(i) Clinical Trial of Infants Only
(ii) Clinical Trial of Children and Adults

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **KYBELLA** | Treatment for double chin | **85%** | **8%** | **2%** | **87%** | **3%** | **1%** | **0%** | **0%** |
| **LENVIMA** | Treatment of progressive, differentiated thyroid cancer (DTC) that can no longer be treated with radioactive iodine | **49%** | **2%** | **18%** | **79%** | **<1%** | **40%** | **10%** | **4%** |
| **LONSURF** | Treatment of advanced colorectal cancer | **39%** | **1%** | **35%** | **58%** | **7%** | **44%** | **8%** | **1%** |
| **NATPARA** | For control of hypocalcemia along with calcium and vitamin D in adults with hypoparathyroidism | **79%** | **<1%** | **2%** | **96%** | **2%** | **6%** | **<1%** | **<1%** |
| **NINLARO** | Treatment of multiple myeloma | **43%** | **2%** | **9%** | **85%** | **5%** | **58%** | **2%** | **<1%** |
| **NUCALA** | For the treatment of a specific type of severe asthma (called eosinophilic phenotype asthma) | **59%** | **3%** | **11%** | **85%** | **<1%** | **9%** | **10%** | **3%** |
| **ODOMZO** | Treatment of locally advanced basal cell carcinoma | **37%** | **<1%** | **0%** | **94%** | **6%** | **54%** | **34%** | **23%** |
| **ORKAMBI** | Treatment of cystic fibrosis | **49%** | **0%** | **0%** | **99%** | **1%** | **0%** | **0%** | **0%** |
| **PORTRAZZA** | For the treatment of metastatic squamous non-small cell lung cancer | **17%** | **1%** | **8%** | **84%** | **8%** | **39%** | **4%** | **1%** |
| **PRALUENT** | Treatment of certain patients with high cholesterol | **40%** | **4%** | **3%** | **90%** | **3%** | **32%** | **6%** | **<1%** |
| **PRAXBIND** | Reversal of the anticoagulant effects of Pradaxa during emergency situations or when there is a need to reverse its blood-thinning effects. | **47%** | **<1%** | **7%** | **85%** | **7%** | **90%** | **60%** | **44%** |

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **REPATHA††** | Treatment of certain patients with high cholesterol | **50%** | **5%** | **9%** | **84%** | **2%** | **28%** | **3%** | **<1%** |
| **REPATHA‡‡** | Treatment of certain patients with high cholesterol | **49%** | **0%** | **4%** | **90%** | **6%** | **0%** | **0%** | **0%** |
| **REXULTI** | Treatment of schizophrenia | **37%** | **24%** | **7%** | **63%** | **6%** | **<1%** | **0%** | **0%** |
| **REXULTI** | Treatment of major depressive disorder | **69%** | **12%** | **<1%** | **85%** | **2%** | **<1%** | **0%** | **0%** |
| **SAVAYSA** | Reduction of risk of venous thromboembolism (VTE) in patients with previous VTE | **43%** | **4%** | **21%** | **70%** | **5%** | **33%** | **13%** | **6%** |
| **SAVAYSA** | Prevention of stroke in patients with atrial fibrillation | **38%** | **1%** | **14%** | **81%** | **4%** | **74%** | **40%** | **17%** |
| **STRENSIQ(^)** | Treatment of perinatal, infantile and juvenile-onset hypophosphatasia (HPP) | **52%** | **0%** | **9%** | **81%** | **10%** | **0%** | **0%** | **0%** |
| **STRENSIQ(^^)** | Treatment of perinatal, infantile and juvenile-onset hypophosphatasia (HPP) | **50%** | **0%** | **0%** | **95%** | **5%** | **0%** | **0%** | **0%** |
| **TAGRISSO** | Treatment of patients with advanced non-small cell lung cancer (NSCLC) | **68%** | **<1%** | **60%** | **36%** | **3%** | **45%** | **13%** | **4%** |
| **TRESIBA*** | To improve glucose control in adults with diabetes mellitus | **44%** | **1%** | **16%** | **80%** | **2%** | **7%** | **<1%** | **<1%** |
| **TRESIBA**** | To improve glucose control in adults with diabetes mellitus | **44%** | **7%** | **21%** | **70%** | **2%** | **24%** | **3%** | **<1%** |

†† Clinical Trial of heterozygous familial hypercholesterolemia (HeFH) Patients
‡‡ Clinical Trial of homozygous familial hypercholesterolemia (HoFH) Patients
(^) Clinical Trial of Perinatal/Infantile-Onset HPP patients only
(^^) Clinical Trial of Juvenile-Onset HPP patients only
*Clinical Trial of Type 1 DM patients only
**Clinical Trial of Type 2 DM patients only

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **UNITUXIN** | Treatment of children with high-risk neuroblastoma | **40%** | **7%** | **3%** | **82%** | **8%** | **N/A** | **N/A** | **N/A** |
| **UPTRAVI** | For the treatment of adults with pulmonary artery hypertension | **80%** | **2%** | **21%** | **75%** | **2%** | **18%** | **1%** | **<1%** |
| **VARUBI** | To prevent delayed phase chemotherapy-induced nausea and vomiting | **60%** | **2%** | **14%** | **75%** | **9%** | **26%** | **5%** | **1%** |
| **VELTASSA** | Treatment of hyperkalemia | **39%** | **<1%** | **<1%** | **99%** | **<1%** | **61%** | **21%** | **4%** |
| **VIBERZI** | Treatment of irritable bowel syndrome with diarrhea | **66%** | **12%** | **1%** | **86%** | **2%** | **10%** | **6%** | **<1%** |
| **VRAYLAR** | Treatment of schizophrenia | **28%** | **34%** | **17%** | **43%** | **6%** | **<1%** | **0%** | **0%** |
| **VRAYLAR** | Treatment of bipolar disorder | **41%** | **25%** | **24%** | **49%** | **2%** | **<1%** | **0%** | **0%** |
| **XURIDEN** | Treatment of patients with hereditary orotic aciduria | **25%** | **0%** | **0%** | **100%** | **0%** | **N/A** | **N/A** | **N/A** |
| **YONDELIS** | Treatment of certain types of advances tissue sarcoma | **70%** | **12%** | **4%** | **76%** | **8%** | **22%** | **3%** | **<1%** |
| **ZURAMPIC** | For lowering uric acid levels in the blood of adult patients with gout | **4%** | **12%** | **6%** | **78%** | **5%** | **13%** | **3%** | **<1%** |

## Therapeutic Areas 2015

For three groups of diseases (mental health, oncology, and cardiovascular health) there were multiple drugs approved in 2015. More insight in demographics for these approvals is provided below in Tables 3, 4, and 5.

**Table 3. Mental Health Drug Approvals (2015)**

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **ARISTADA** | Schizophrenia | **32%** | **40%** | **13%** | **47%** | **<1%** | **0%** | **0%** | **0%** |
| **REXULTI** | Schizophrenia | **37%** | **24%** | **7%** | **63%** | **6%** | **<1%** | **0%** | **0%** |
| **REXULTI** | Major Depressive Disorder | **69%** | **12%** | **<1%** | **85%** | **2%** | **<1%** | **0%** | **0%** |
| **VRAYLAR** | Schizophrenia | **28%** | **34%** | **17%** | **43%** | **6%** | **<1%** | **0%** | **0%** |
| **VRAYLAR** | Bipolar disorder | **41%** | **25%** | **24%** | **49%** | **2%** | **<1%** | **0%** | **0%** |

**Table 4. Oncology Drug Approvals (2015)**

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **IBRANCE** | Breast cancer | **100%** | **1%** | **6%** | **90%** | **3%** | **46%** | **9%** | **3%** |
| **YONDELIS** | Advanced soft tissue sarcoma | **70%** | **12%** | **4%** | **76%** | **8%** | **22%** | **3%** | **<1%** |

## Table 4. Oncology Drug Approvals (2015) *continued*

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **TAGRISSO** | Lung Cancer (T790M+, NSCLC) | **68%** | **<1%** | **60%** | **36%** | **3%** | **45%** | **13%** | **4%** |
| **ALECENSA** | Metastatic NSCLC | **55%** | **2%** | **18%** | **74%** | **7%** | **14%** | **4%** | **<1%** |
| **LENVIMA** | Thyroid cancer | **49%** | **2%** | **18%** | **79%** | **<1%** | **40%** | **10%** | **4%** |
| **FARYDAK** | Multiple Myeloma & other cancers | **48%** | **3%** | **33%** | **63%** | **1%** | **35%** | **5%** | **0%** |
| **DARZALEX** | Multiple Myeloma | **46%** | **10%** | **6%** | **76%** | **8%** | **45%** | **10%** | **3%** |
| **NINLARO** | Multiple Myeloma | **43%** | **2%** | **9%** | **85%** | **5%** | **58%** | **2%** | **<1%** |
| **COTELLIC** | Melanoma | **42%** | **N/A** | **N/A** | **93%** | **7%** | **27%** | **9%** | **3%** |
| **EMPLICITI** | Multiple Myeloma | **40%** | **4%** | **10%** | **84%** | **2%** | **57%** | **20%** | **7%** |
| **UNITUXIN** | Neuroblastoma | **40%** | **7%** | **3%** | **82%** | **8%** | **N/A** | **N/A** | **N/A** |
| **LONSURF** | Advanced metastatic colorectal cancer | **39%** | **1%** | **35%** | **58%** | **7%** | **44%** | **8%** | **1%** |
| **ODOMZO** | Advanced basal cell carcinoma (BCC) | **37%** | **<1%** | **0%** | **94%** | **6%** | **54%** | **34%** | **23%** |
| **PORTRAZZA** | Metastatic squamous non-small cell lung cancer (NSCLC) | **17%** | **1%** | **8%** | **84%** | **8%** | **39%** | **4%** | **1%** |

**Table 5. Cardiovascular Drug Approvals (2015)**

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER | AGE 75 and OLDER | AGE 80 and OLDER |
|---|---|---|---|---|---|---|---|---|---|
| **UPTRAVI** | Pulmonary arterial hypertension | **80%** | **2%** | **21%** | **75%** | **2%** | **18%** | **1%** | **<1%** |
| **REPATHA*** | Hypercholesterolemia | **50%** | **5%** | **9%** | **84%** | **2%** | **28%** | **3%** | **<1%** |
| **REPATHA**** | Hypercholesterolemia | **49%** | **0%** | **4%** | **90%** | **6%** | **0%** | **0%** | **0%** |
| **PRAXBIND** | Reversal of the anticoagulant effects of Pradaxa during emergency situations or when there is a need to reverse its blood-thinning effects. | **47%** | **<1%** | **7%** | **85%** | **7%** | **90%** | **60%** | **44%** |
| **SAVAYSA** | Reduce risk of pulmonary embolism in VTE patients | **43%** | **4%** | **21%** | **70%** | **5%** | **33%** | **13%** | **6%** |
| **PRALUENT** | Hyperlipidemia | **40%** | **4%** | **3%** | **90%** | **3%** | **32%** | **6%** | **<1%** |
| **SAVAYSA** | Reduce the risk of stroke in a Afib patients | **38%** | **1%** | **14%** | **81%** | **4%** | **74%** | **40%** | **17%** |
| **KENGREAL** | Blood thinner following heart procedure | **28%** | **3%** | **3%** | **94%** | **<1%** | **48%** | **18%** | **8%** |
| **CORLANOR** | Heart failure | **24%** | **1%** | **8%** | **89%** | **2%** | **38%** | **11%** | **3%** |
| **ENTRESTO** | Heart failure | **22%** | **5%** | **18%** | **66%** | **11%** | **49%** | **19%** | **7%** |

* Clinical Trial of HeFH Patients
** Clinical Trial of HoFH Patients

# DRUG TRIALS SNAPSHOTS


The data below were calculated from Google Analytics and highlights the total number of page views, unique visitors, and average time spent on all Drug Trials Snapshots pages.

### Snapshots Website Highlights:

- Over **235,946** people visited the site since launch of the website
- These people generated **277,555** visits to the site (some came more than once)
- Average of **10,000** visits per month
- The average visit lasted **2:13 minutes**
- The top 5 Snapshots visited were **Jublia, Lonsurf, Savaysa, Kybella, and Cosentyx**

### Visitors by Geographic Location:

The data below was calculated from Google Analytics, measuring Geographic Locations of visitors coming to the Drug Trials Snapshots.[3]

- Almost **70%** of visitors (115,407 sessions) are from the **United States**:
  - Top 5 Cities in the United States:
    - Silver Spring, MD (8%)
    - Seattle, WA (4%)
    - Denver, CO (2%)
    - Washington, DC (2%)
    - New York, NY (2%)

3. These data are based on a 0.15% subset of the entire traffic and reporting data of users coming to the Drug Trials Snapshots. It is measured in sessions, a group of interactions that take place on your website within a given time frame. For example a single session can contain multiple screen or page views, events, social interactions, and ecommerce transactions. By default, a session lasts until there's 30 minutes of inactivity.

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