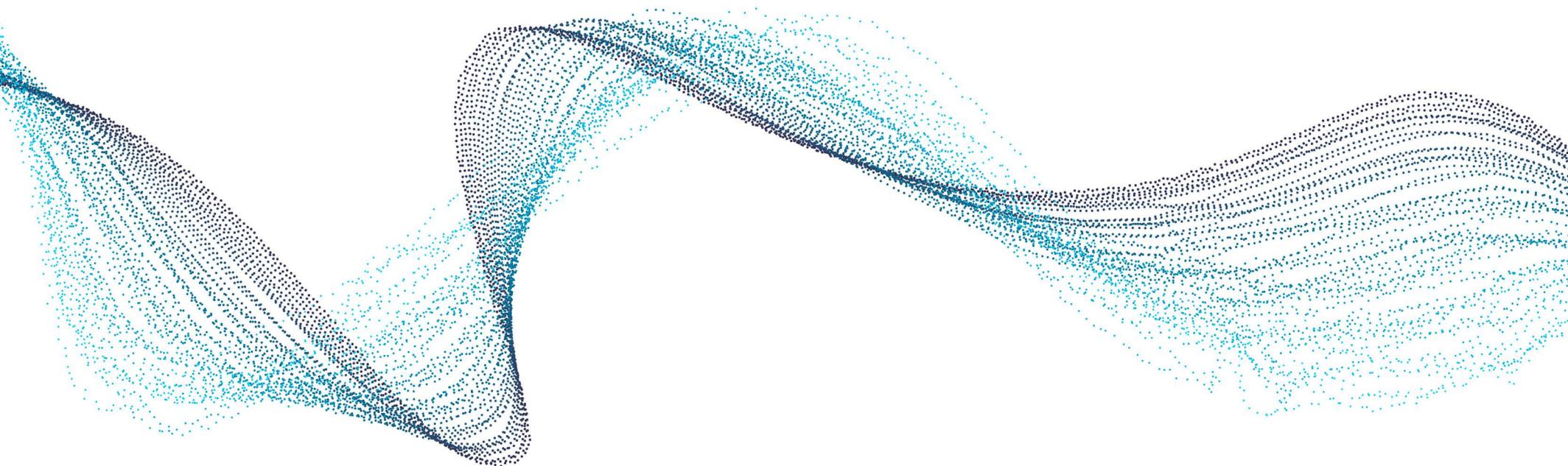




Infographic

# 505(b)(2) Products Global Market Overview



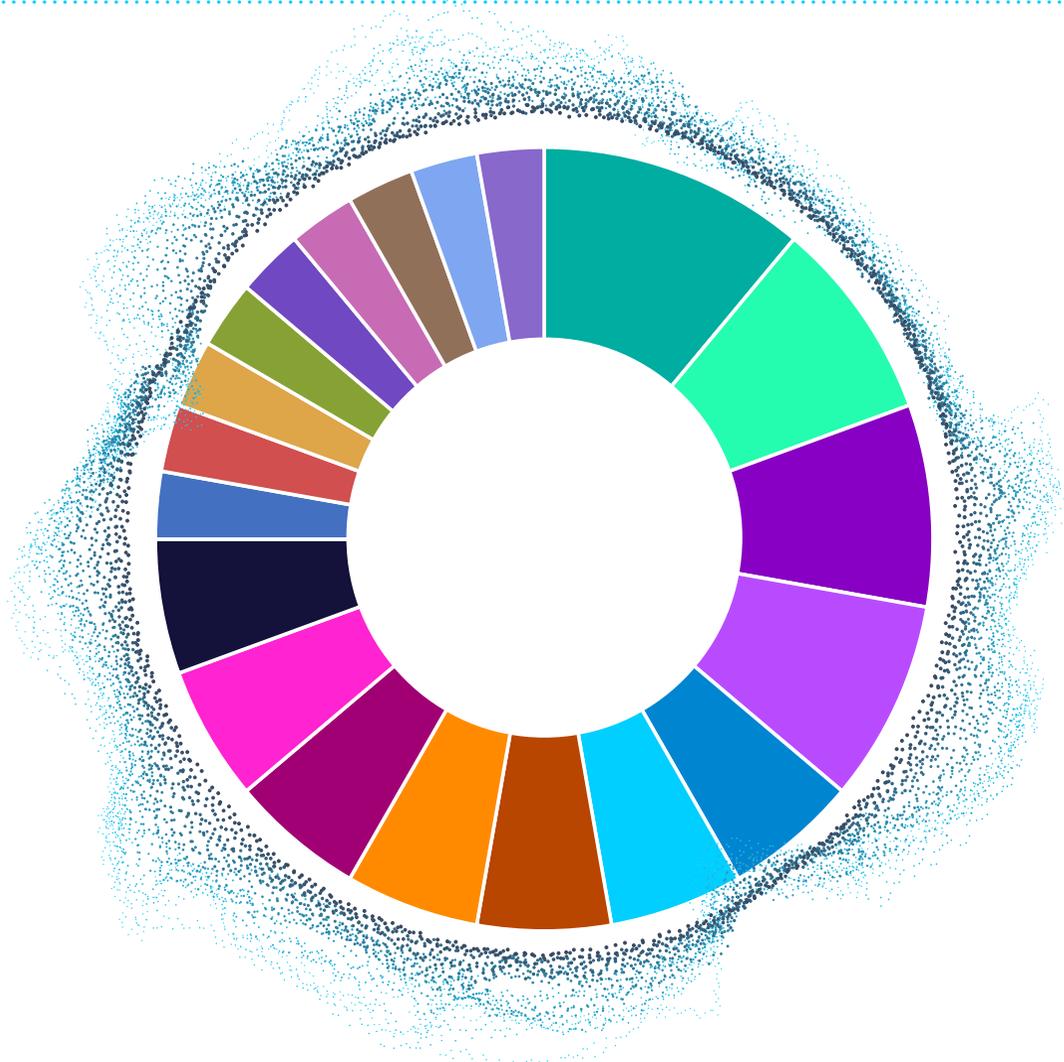
## 505b2

# Approved Data

- Drugs by Disease Names
- Drugs by Disease Group
- Drugs by Company
- Drugs by Country
- Trials by Phase
- Drugs by Therapeutic Class
- Trials by Therapeutic Area
- Trials by Disease
- Trials by Sponsor



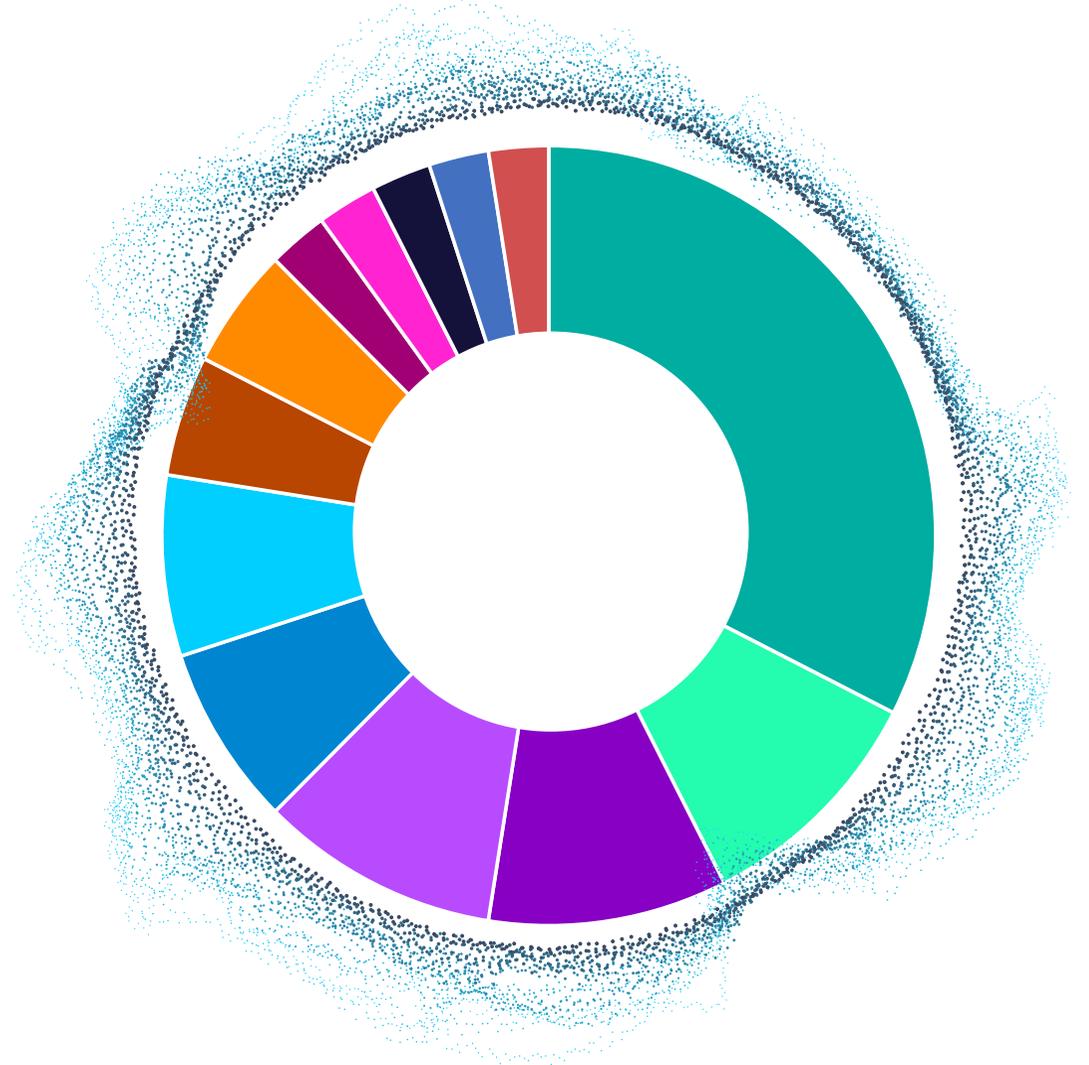
# Drugs by Disease Names (Showing top 20)



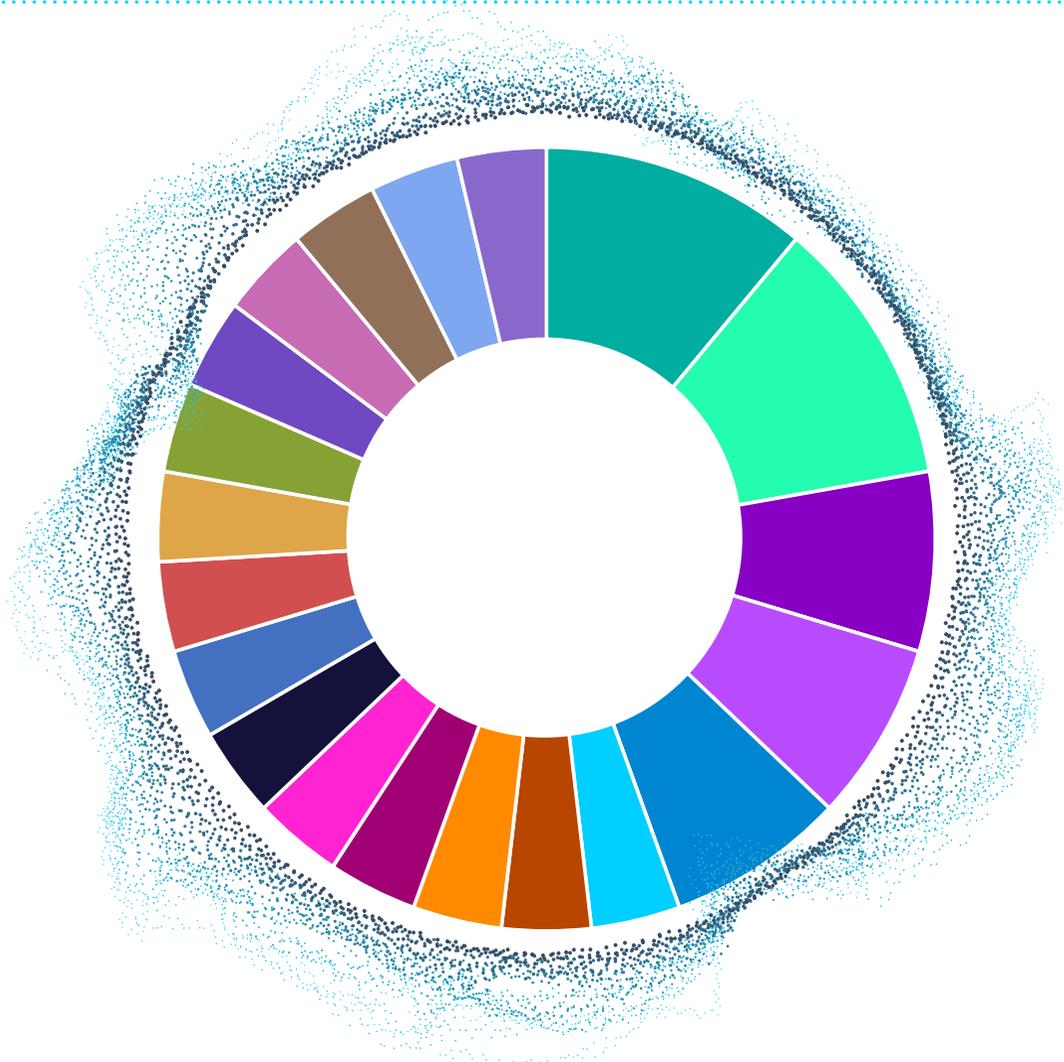
- 4 Hypertension, unspecified
- 3 Cancer, lung, non-small cell
- 3 Depression, major depressive disorder
- 3 Pain, nociceptive, general
- 2 Cancer, breast
- 2 Cancer, pancreatic
- 2 Not applicable
- 2 Pain, musculoskeletal, unspecified
- 2 Schizoaffective disorder
- 2 Schizophrenia
- 2 Spasticity
- 1 Acromegaly
- 1 Addiction, alcohol
- 1 Addiction, nicotine
- 1 Agitation, Alzheimer's disease
- 1 Alzheimer's disease
- 1 Anaesthesia, adjunct
- 1 Bipolar disorder
- 1 Cancer, biliary
- 1 Cancer, cervical

# Drugs by Disease Group

- 13 Neurological
- 4 Alimentary/Metabolic
- 4 Anticancer
- 4 Cardiovascular
- 3 Genitourinary (including sex hormones)
- 3 Musculoskeletal
- 2 Blood and Clotting
- 2 NA/Unspecified
- 1 Anti-infective
- 1 Antiparasitic
- 1 Hormonal (excluding sex hormones)
- 1 Respiratory
- 1 Sensory



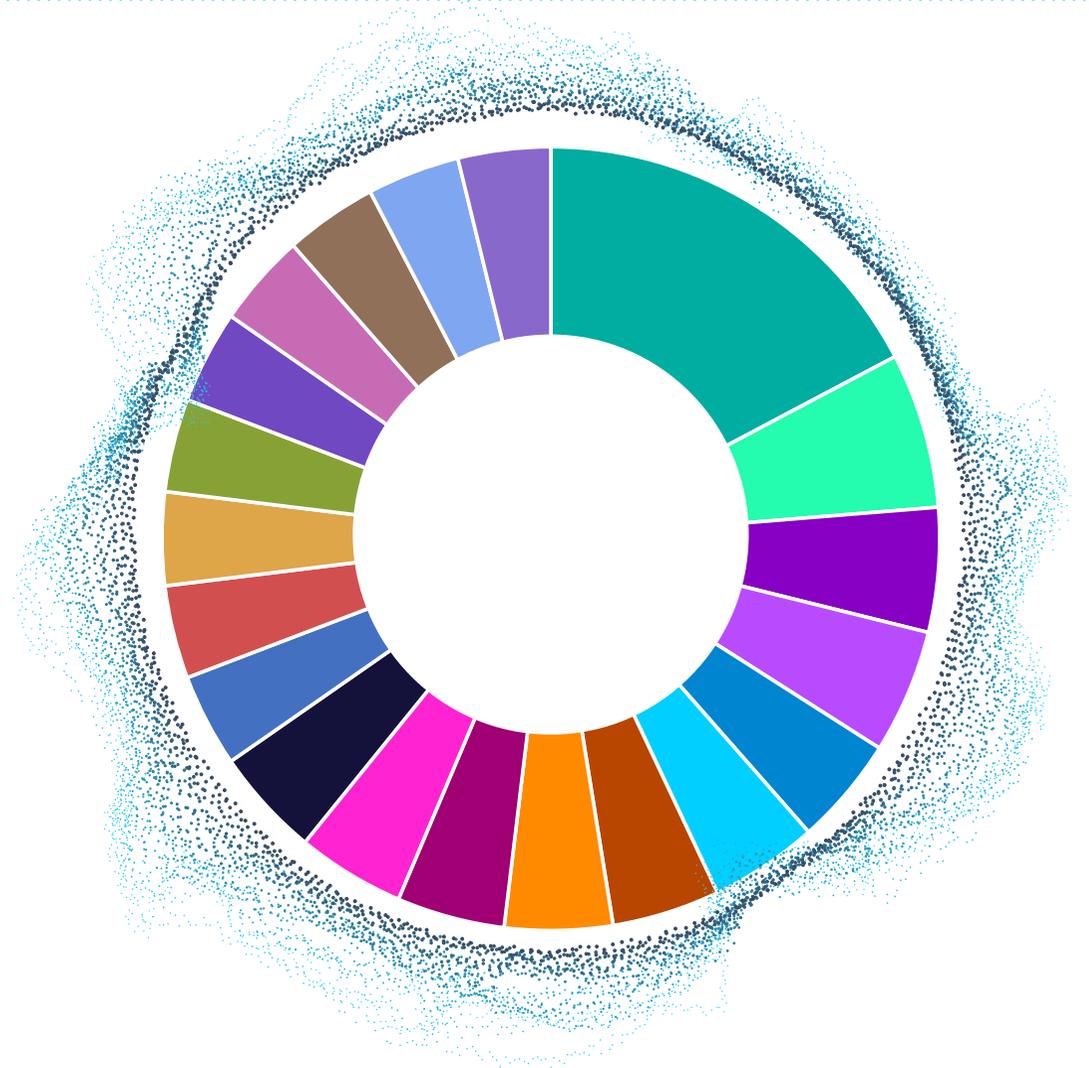
# Drugs by Company (Showing top 20)



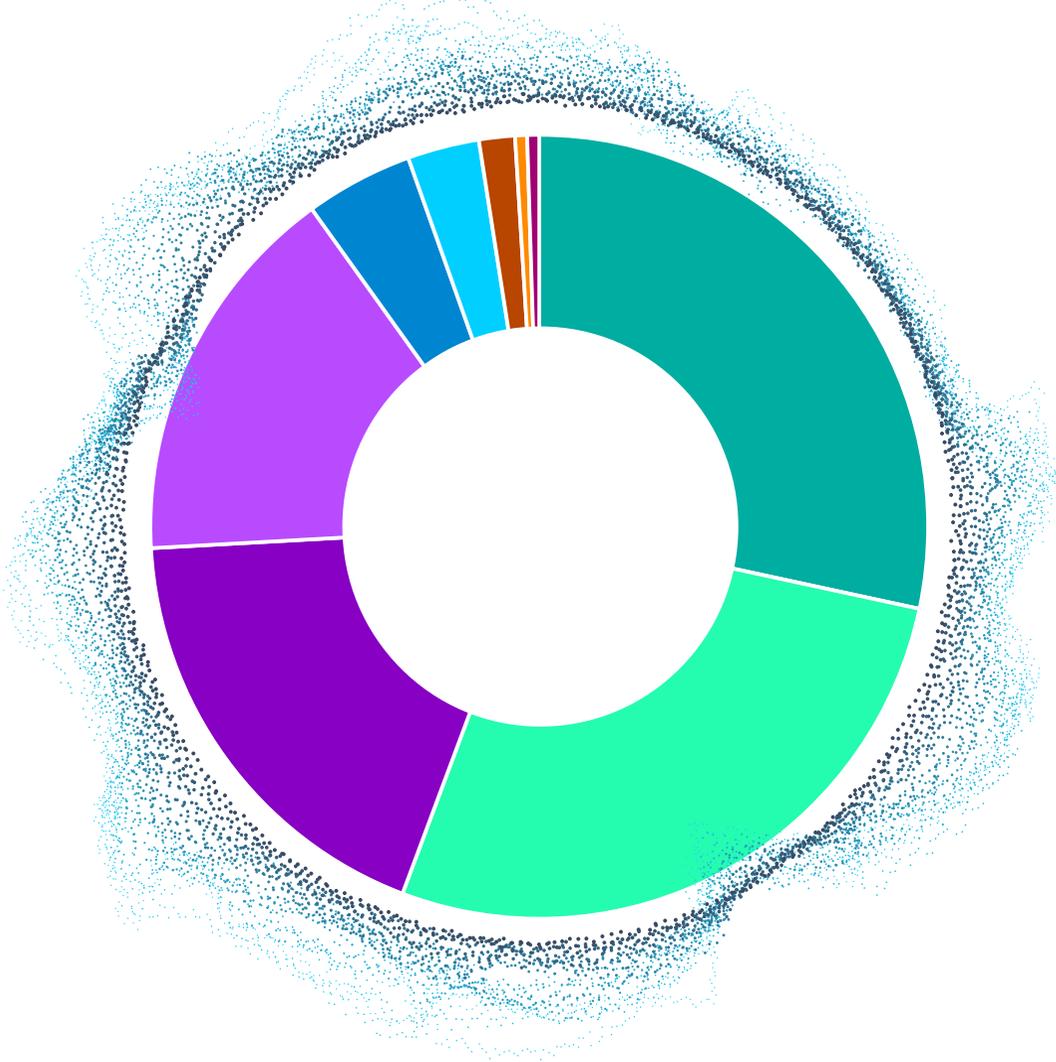
- 3 IntelGenx
- 3 Sun Pharma Advanced Research
- 2 Daewoong Pharmaceutical
- 2 Mallinckrodt
- 2 Relief Therapeutics Holding
- 1 AcelRx
- 1 Acer Therapeutics
- 1 Adare Pharma Solutions
- 1 Alembic Pharmaceuticals
- 1 Amryt Pharma
- 1 Asklepion Pharmaceuticals
- 1 Avenir Wellness Solutions
- 1 Axsome Therapeutics
- 1 Azurity Pharmaceuticals
- 1 Chiesi
- 1 China Medical System
- 1 Currax Pharmaceuticals
- 1 Daiichi Sankyo
- 1 Dr. Falk Pharma
- 1 Eagle Pharmaceuticals

# Drugs by Country (Showing top 20)

- 27 USA
- 10 Germany
- 8 Italy
- 8 Spain
- 7 Belgium
- 7 Croatia
- 7 Hungary
- 7 India
- 7 Luxembourg
- 7 Netherlands
- 7 Sweden
- 6 Austria
- 6 Bulgaria
- 6 Denmark
- 6 France
- 6 Greece
- 6 Ireland
- 6 Portugal
- 6 Romania
- 6 UK



# Trials by Phase



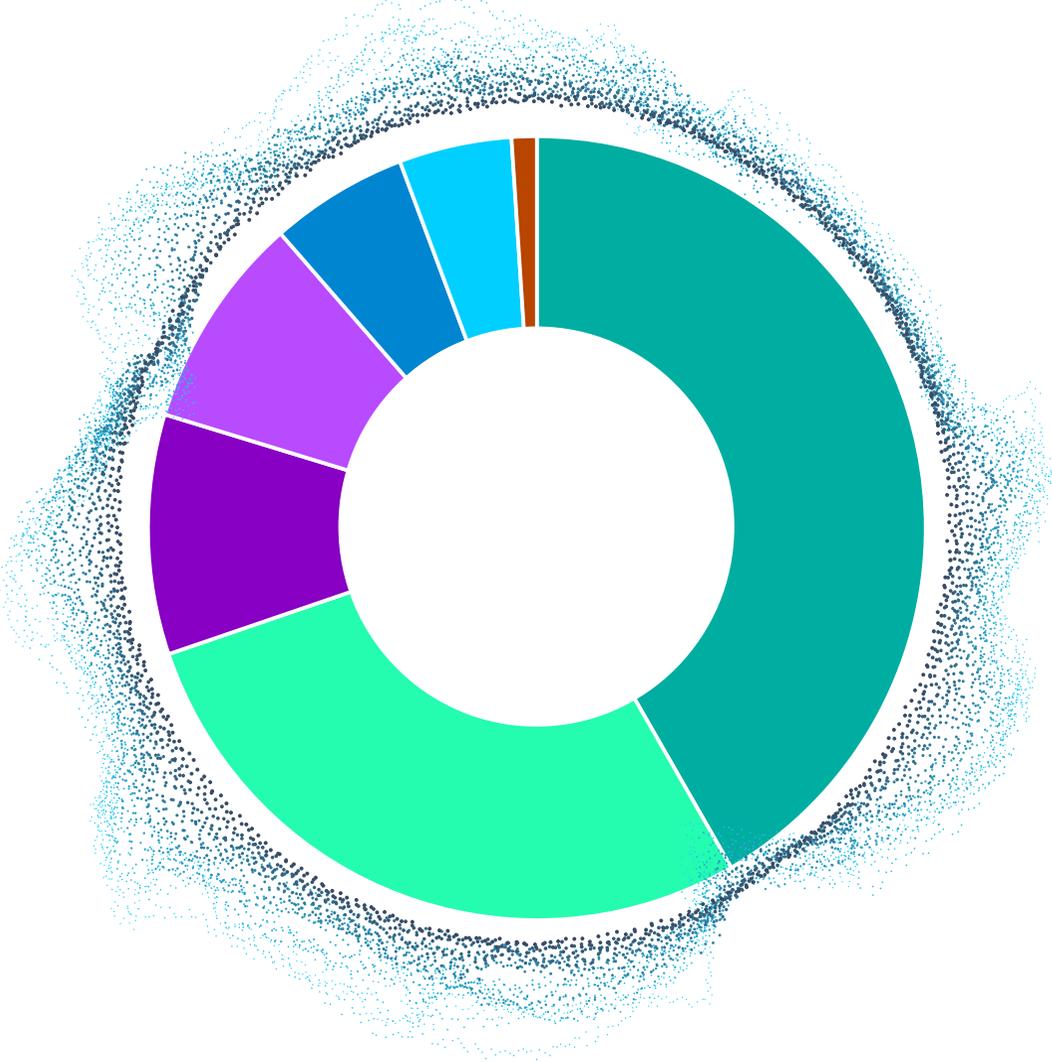
- 57 II
- 55 I
- 37 III
- 32 IV
- 9 II/III
- 6 I/II
- 3 Other
- 1 (N/A)
- 1 III/IV

# Drugs by Therapeutic Class (Showing top 20)

- 5 Reformulation, fixed-dose combinations
- 4 Antidepressant
- 4 Reformulation, oral, other
- 3 Analgesic, opioid
- 3 Anticancer, other
- 3 Antihypertensive, renin system
- 3 Muscle relaxant
- 3 Reformulation, modified-release, <=24hr
- 3 Reformulation, modified-release, immediate
- 3 Reformulation, other
- 2 Analgesic, other
- 2 Antihypertensive, other
- 2 Antipsychotic
- 2 Dependence treatment
- 2 Reformulation technology
- 2 Reformulation, modified-release, other
- 2 Reformulation, optimized, microencapsulate
- 2 Reformulation, optimized, nanoparticles
- 1 Analgesic, NSAID
- 1 Anti-inflammatory



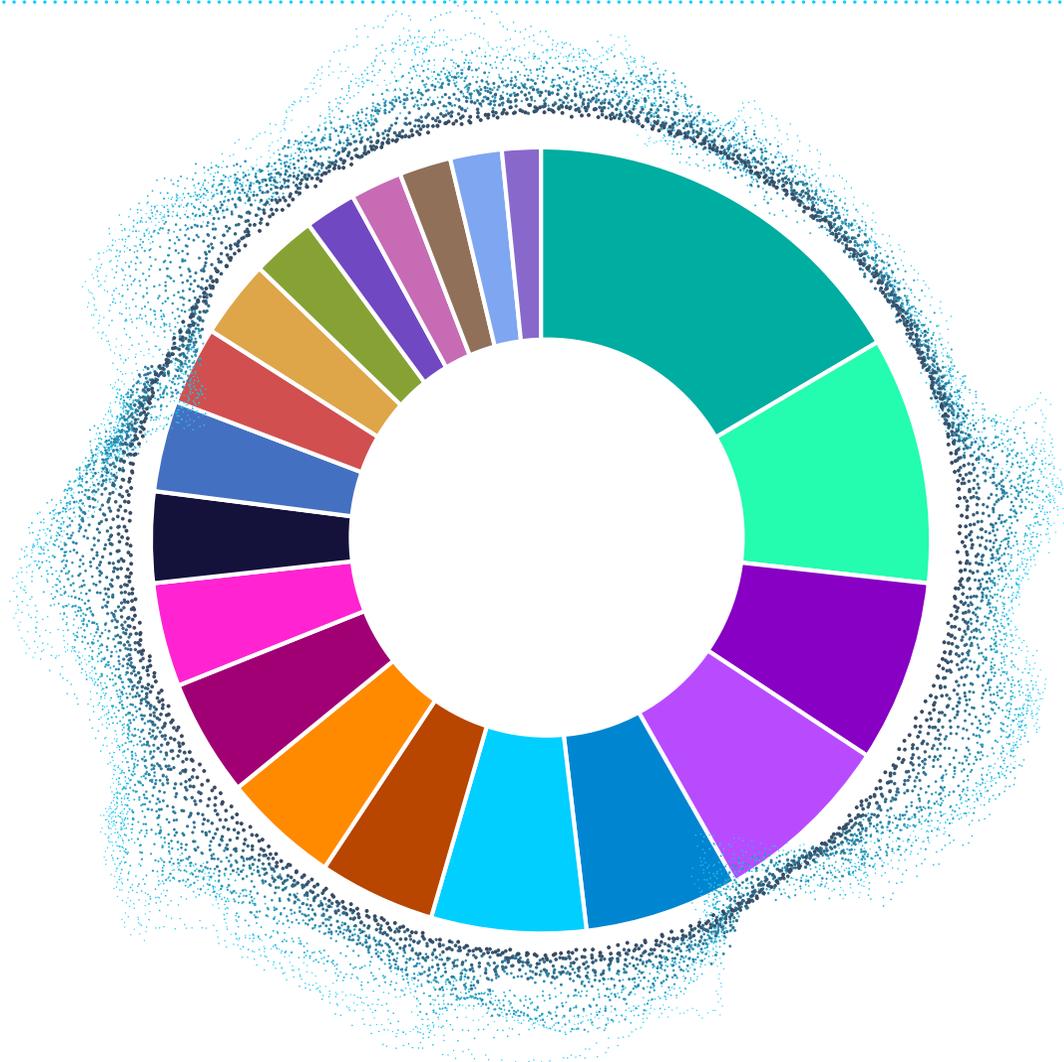
# Trials by Therapeutic Area



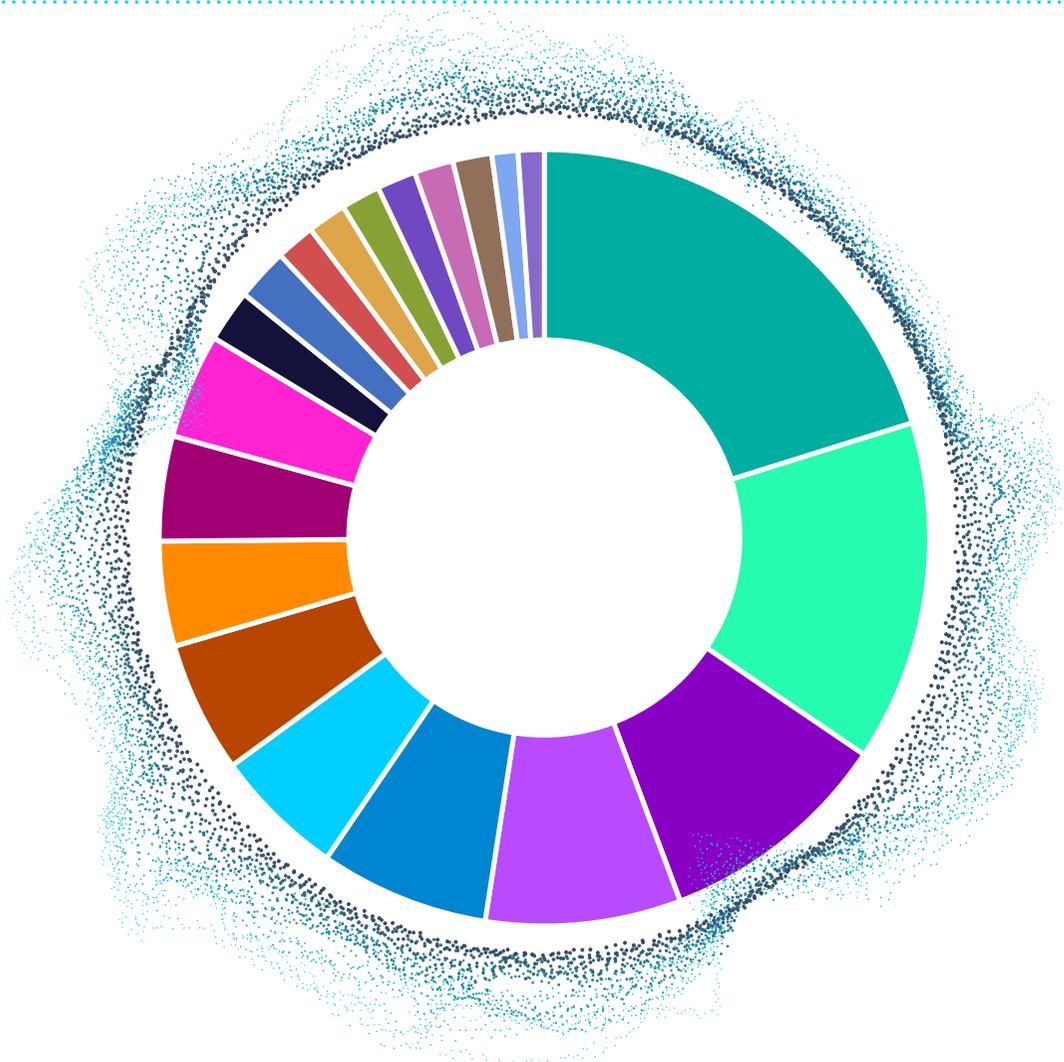
- 80 CNS
- 54 Oncology
- 19 Metabolic/Endocrinology
- 17 Infectious Disease
- 11 Cardiovascular
- 9 Autoimmune/Inflammation
- 2 Ophthalmology

# Trials by Disease (Showing top 20)

- 31 CNS: Pain (nociceptive)
- 19 Oncology: Breast
- 14 CNS: Schizophrenia
- 14 Infectious Disease: Onychomycosis
- 12 CNS: Depression
- 12 Oncology: Lung, Non-Small Cell
- 9 Cardiovascular: Hypertension
- 9 Metabolic/Endocrinology: Growth Disorders
- 9 Oncology: Ovarian
- 8 CNS: Movement Disorders
- 7 Autoimmune/Inflammation: Hepatic Fibrosis
- 7 Oncology: Pancreas
- 6 Cardiovascular: Dyslipidemia
- 6 Metabolic/Endocrinology: NAFLD
- 5 CNS: Alzheimer's Disease
- 4 CNS: Migraine
- 4 Oncology: Bladder
- 4 Oncology: Cervical
- 4 Oncology: Neuroendocrine
- 3 CNS: Alcohol Dependence



# Trials by Sponsor (Showing top 20)



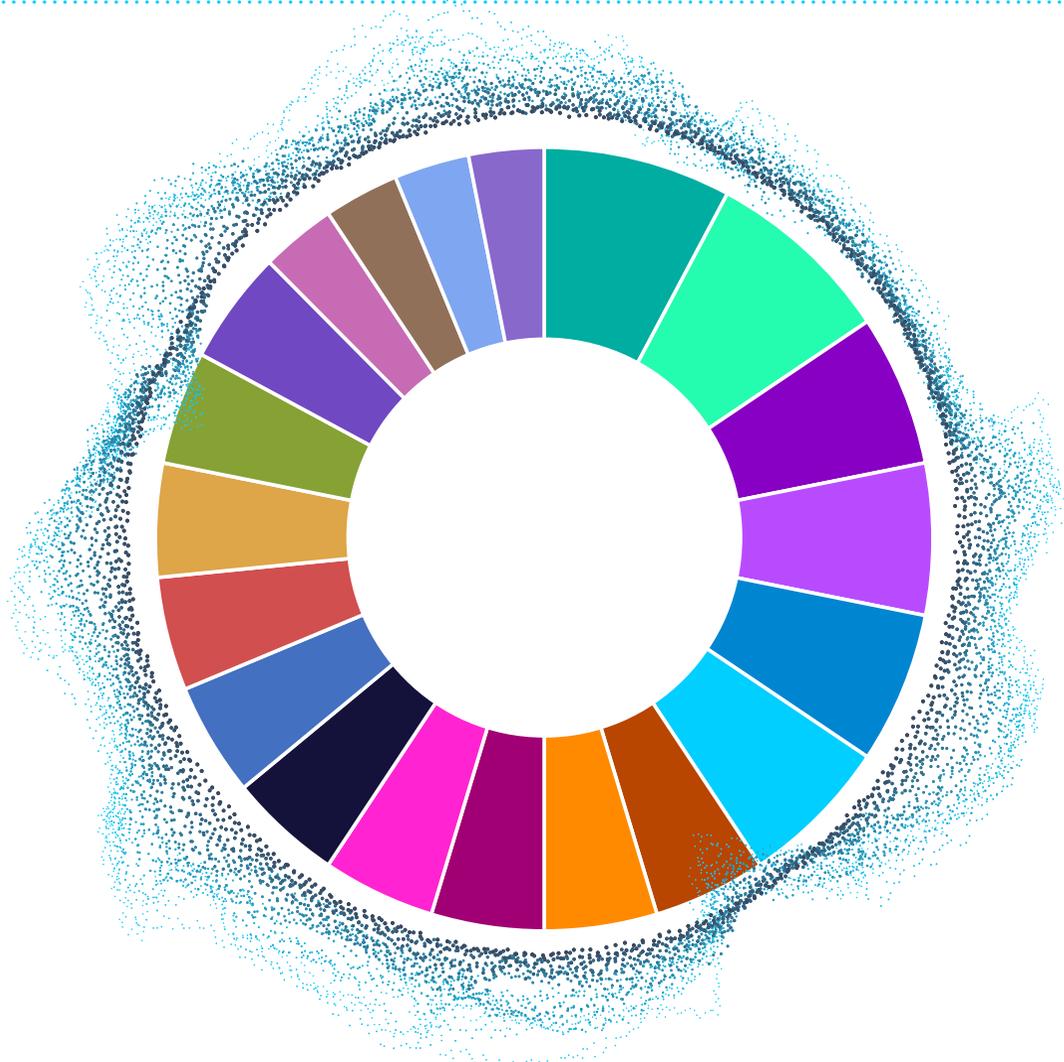
- 37 (Other Hospital/Academic/Medical Center)
- 26 Sun Pharma Advanced Research
- 18 Axsome Therapeutics
- 15 Samyang Holdings Corporation
- 13 AcelRx
- 10 Amryt Pharma
- 10 Mayne Pharma
- 8 Daewoong Pharmaceutical
- 8 Laboratorios Farmaceuticos Rovi
- 8 Luye Pharma Group
- 4 Dr. Falk Pharma
- 4 Lumosa Therapeutics
- 3 (Other Industry Sponsor)
- 3 Inhibitor Therapeutics
- 3 IntelGenx
- 3 Mayne Pharma International Pty Ltd
- 3 RedHill Biopharma
- 3 Sorrento Therapeutics
- 2 (Other Cooperative Group)
- 2 Asan Medical Center

## 505b2 Pipeline Data

- Drugs by Disease Names
- Drugs by Disease Group
- Drugs by Company
- Drugs by Country
- Trials by Phase
- Drugs by Therapeutic Class
- Trials by Therapeutic Area
- Trials by Disease
- Trials by Sponsor

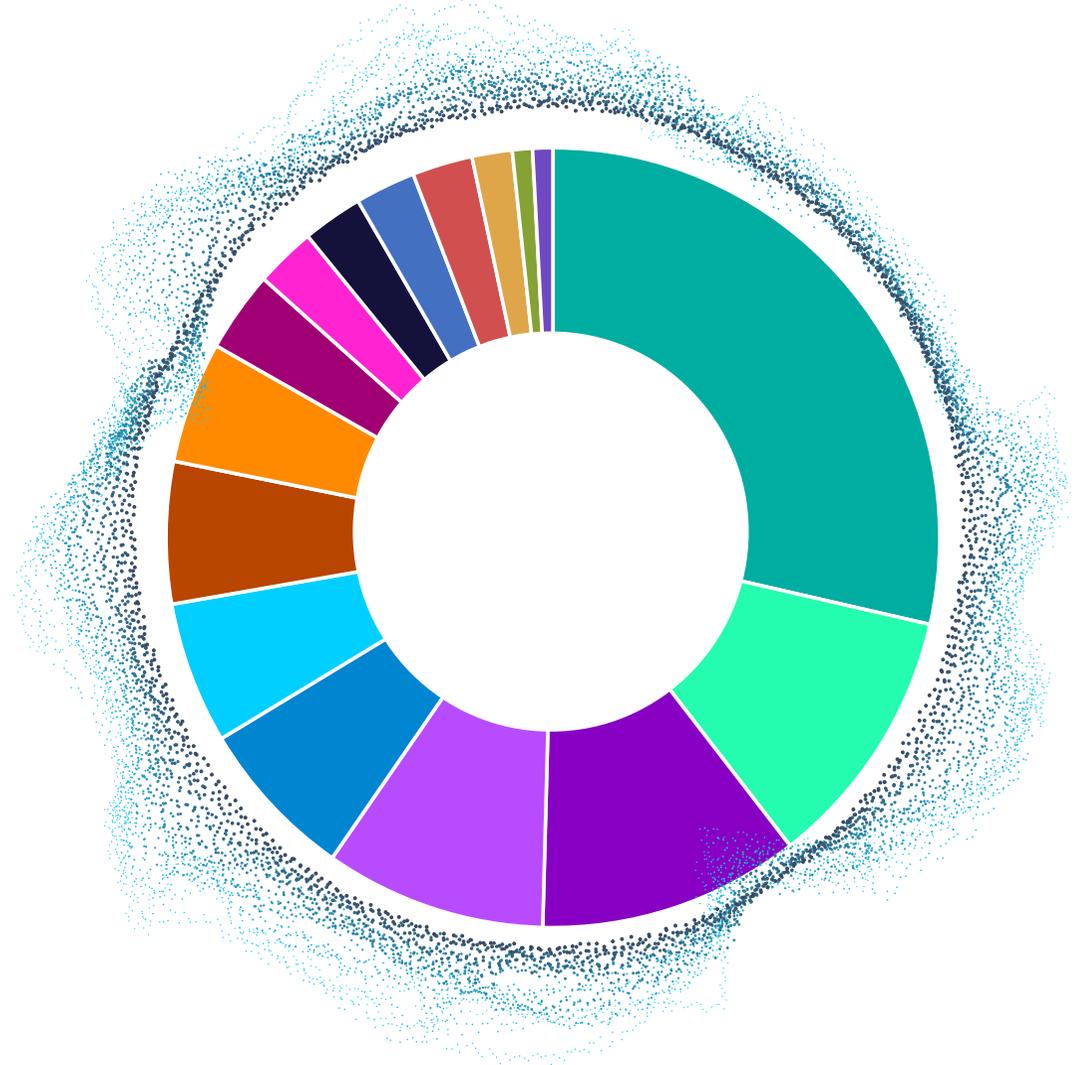


# Drugs by Disease Names (Showing top 20)

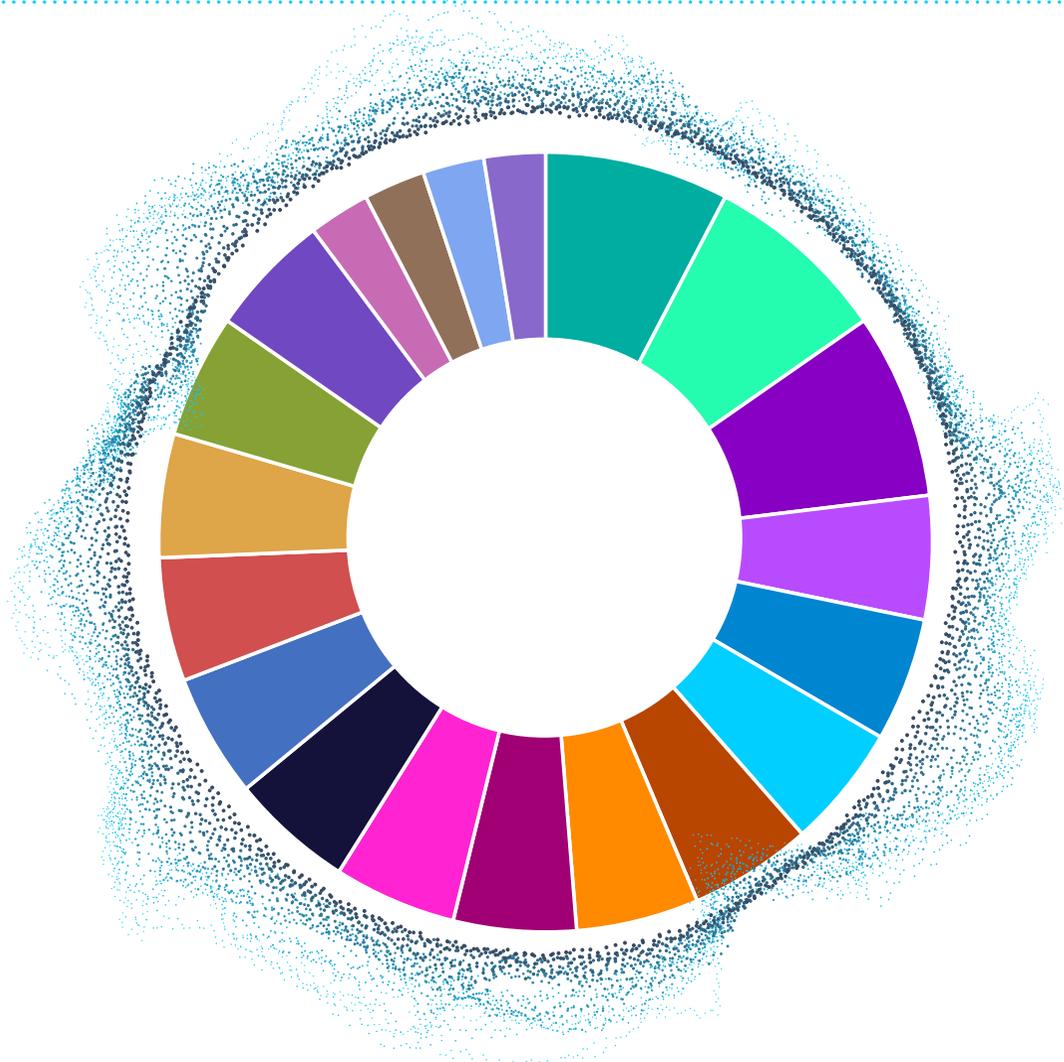


- 5 Pain, nociceptive, general
- 5 Parkinson's disease
- 4 Alzheimer's disease
- 4 Cancer, breast
- 4 Cancer, renal
- 4 Pain, post-operative
- 3 Addiction, alcohol
- 3 Addiction, narcotic/opiate
- 3 Cancer, bladder
- 3 Cancer, leukaemia, chronic myelogenous
- 3 Cancer, lung, non-small cell
- 3 Cancer, ovarian
- 3 Fibromyalgia
- 3 Inflammatory disease, unspecified
- 3 Non-alcoholic steatohepatitis
- 3 Pain, neuropathic, general
- 2 Acne
- 2 Agitation, Alzheimer's disease
- 2 Allergy, unspecified
- 2 Anaphylaxis

# Drugs by Disease Group

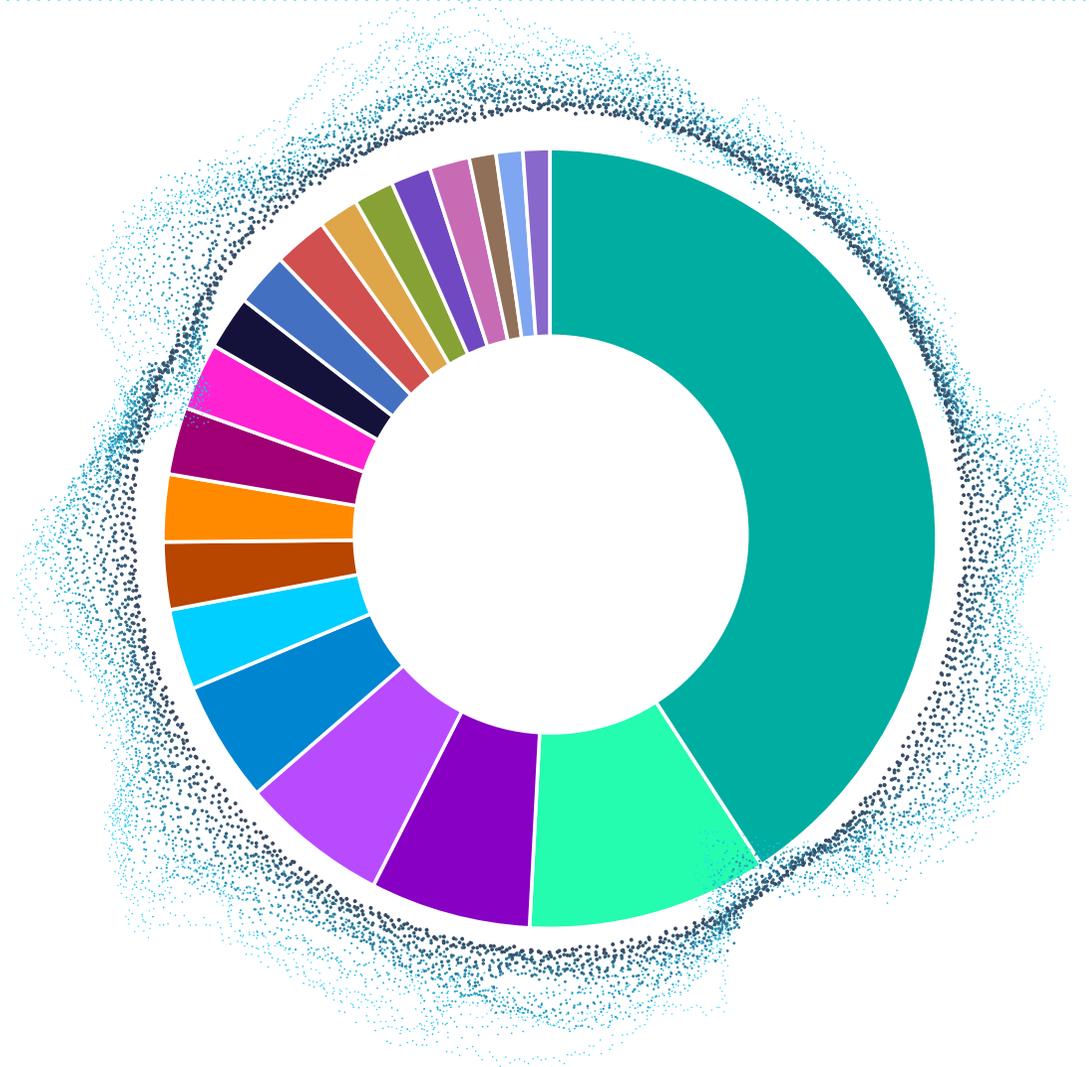


# Drugs by Company (Showing top 20)



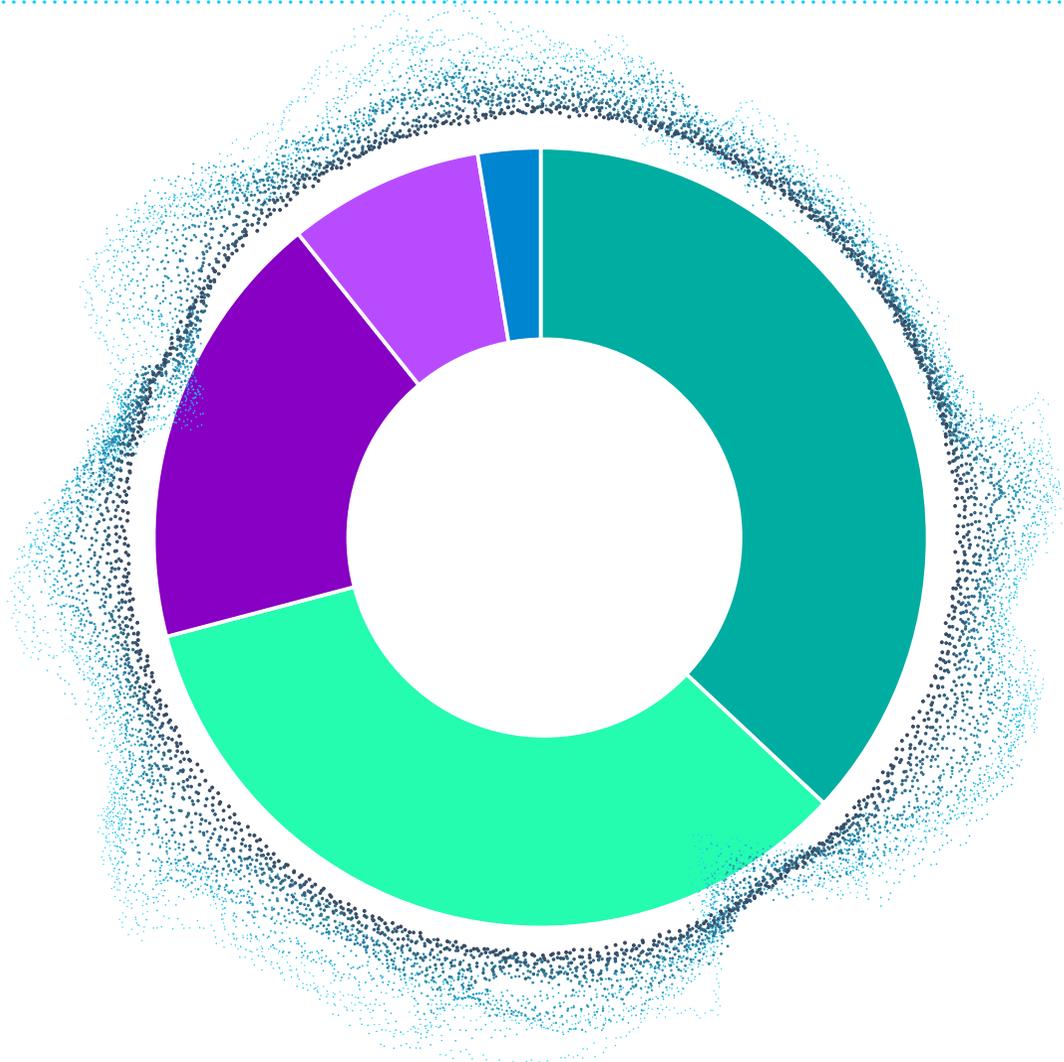
- 3 Aquestive Therapeutics
- 3 Daré Bioscience
- 3 XSpray
- 2 Acasti Pharma
- 2 Grand Pharmaceutical Group
- 2 IntelGenx
- 2 Intellipharma
- 2 Invea Therapeutics
- 2 Lipocine
- 2 Luye Pharma Group
- 2 MedinCell
- 2 Nanology
- 2 Surface Pharmaceuticals
- 2 Tetra Bio-Pharma
- 2 Timber Pharmaceuticals, Inc
- 2 Viatrix
- 1 10xBio
- 1 3SBio
- 1 Aldeyra Therapeutics
- 1 Alternavida

# Drugs by Country (Showing top 20)



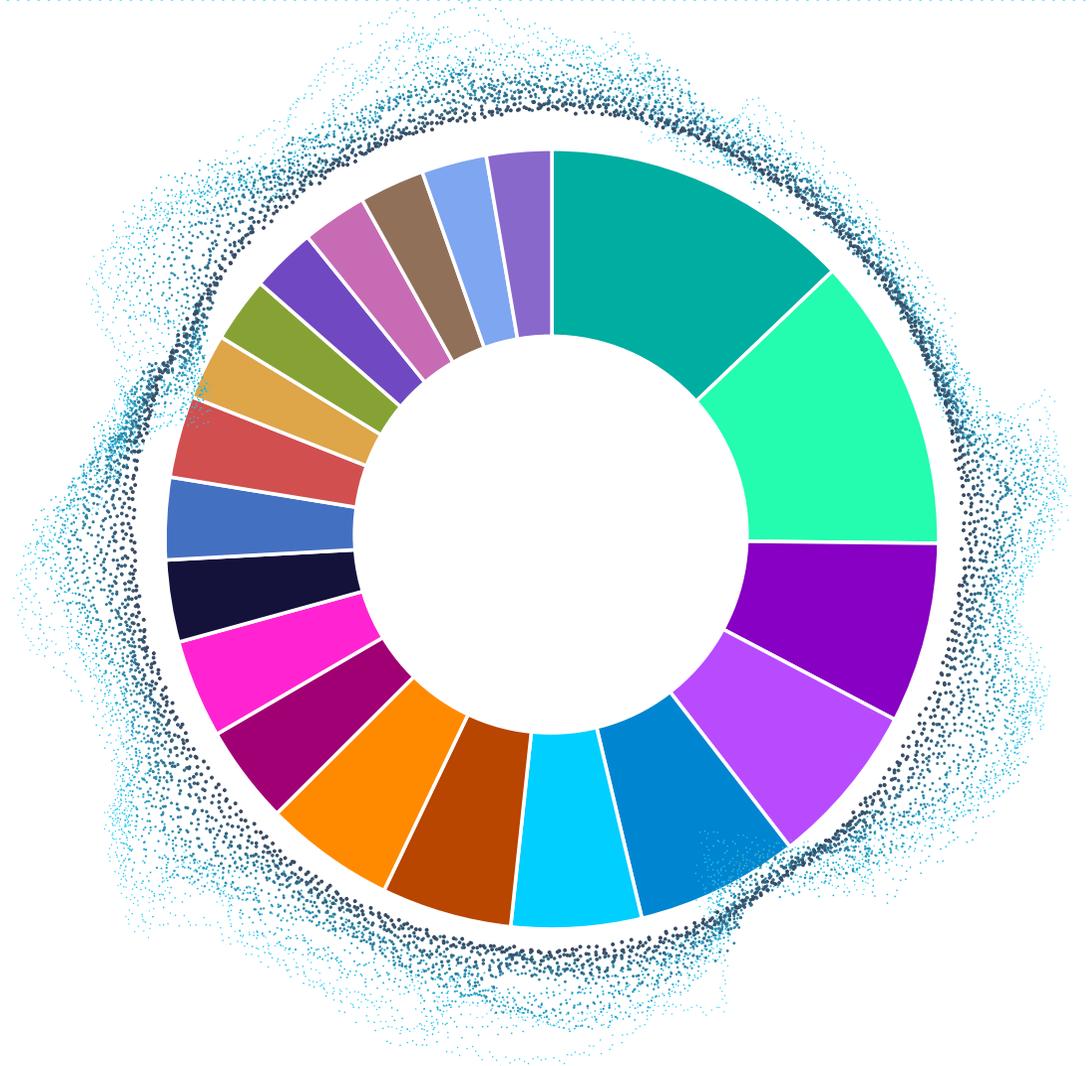
# Trials by Phase

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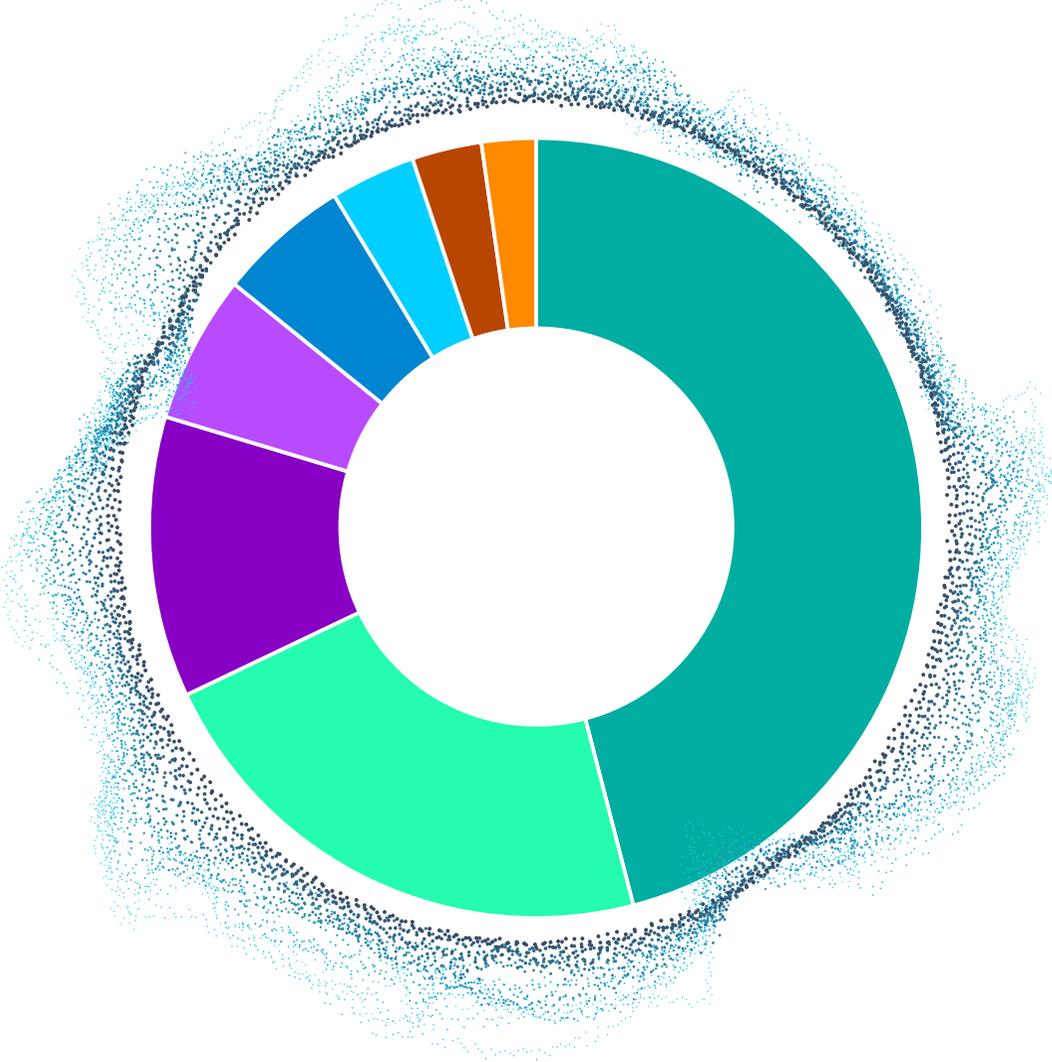


# Drugs by Therapeutic Class (Showing top 20)

- 19 Reformulation, other
- 18 Reformulation, oral, other
- 11 Analgesic, other
- 10 Anticancer, other
- 10 Ophthalmological, other
- 8 Neurological
- 8 Reformulation, fixed-dose combinations
- 8 Reformulation, modified-release, other
- 6 Antiparkinsonian
- 6 Reformulation, parenteral, other
- 5 Dependence treatment
- 5 GI inflammatory/bowel disorders
- 5 Musculoskeletal
- 4 Anti-inflammatory
- 4 Cognition enhancer
- 4 Hepatoprotective
- 4 Reformulation, dermal, topical
- 4 Reformulation, implant
- 4 Reformulation, modified-release, >24hr
- 4 Reformulation, optimized, nanoparticles



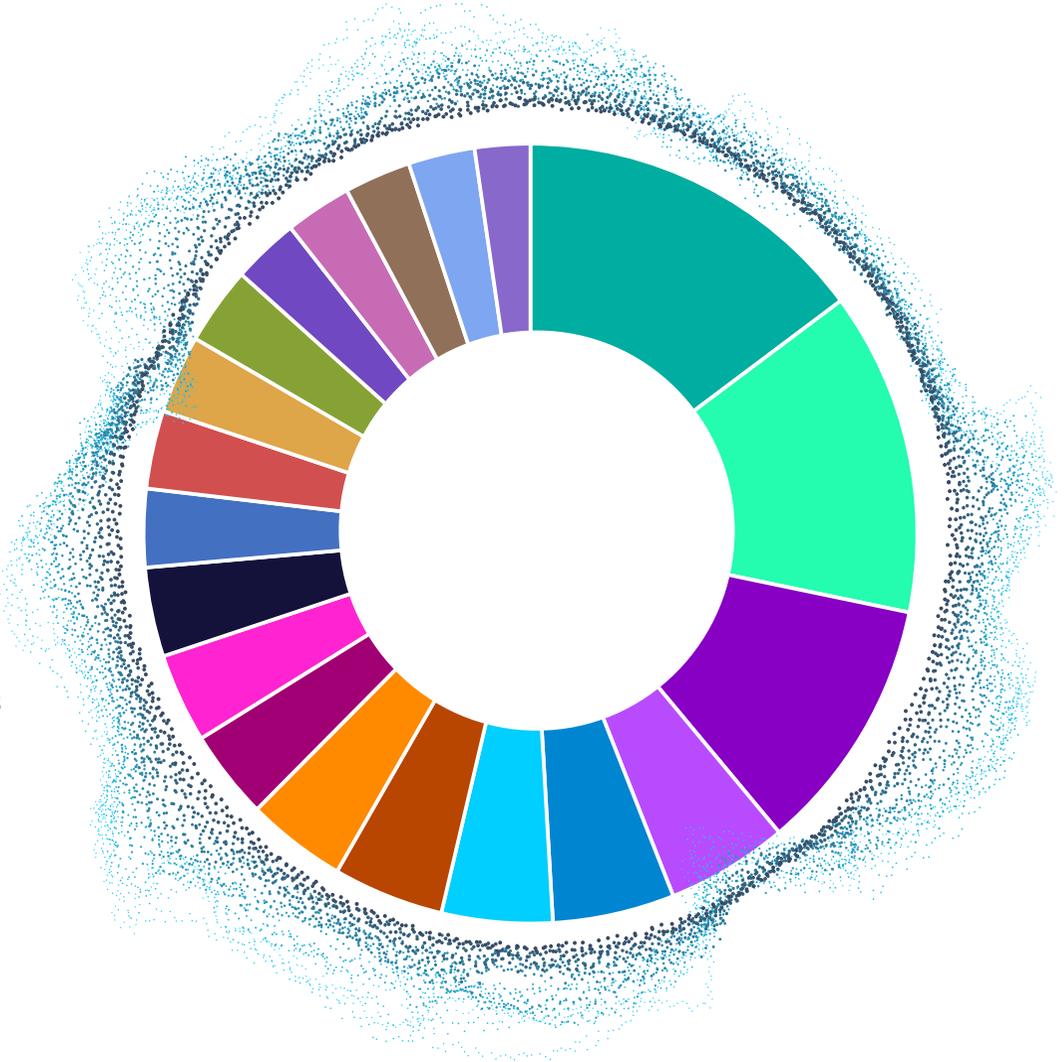
# Trials by Therapeutic Area



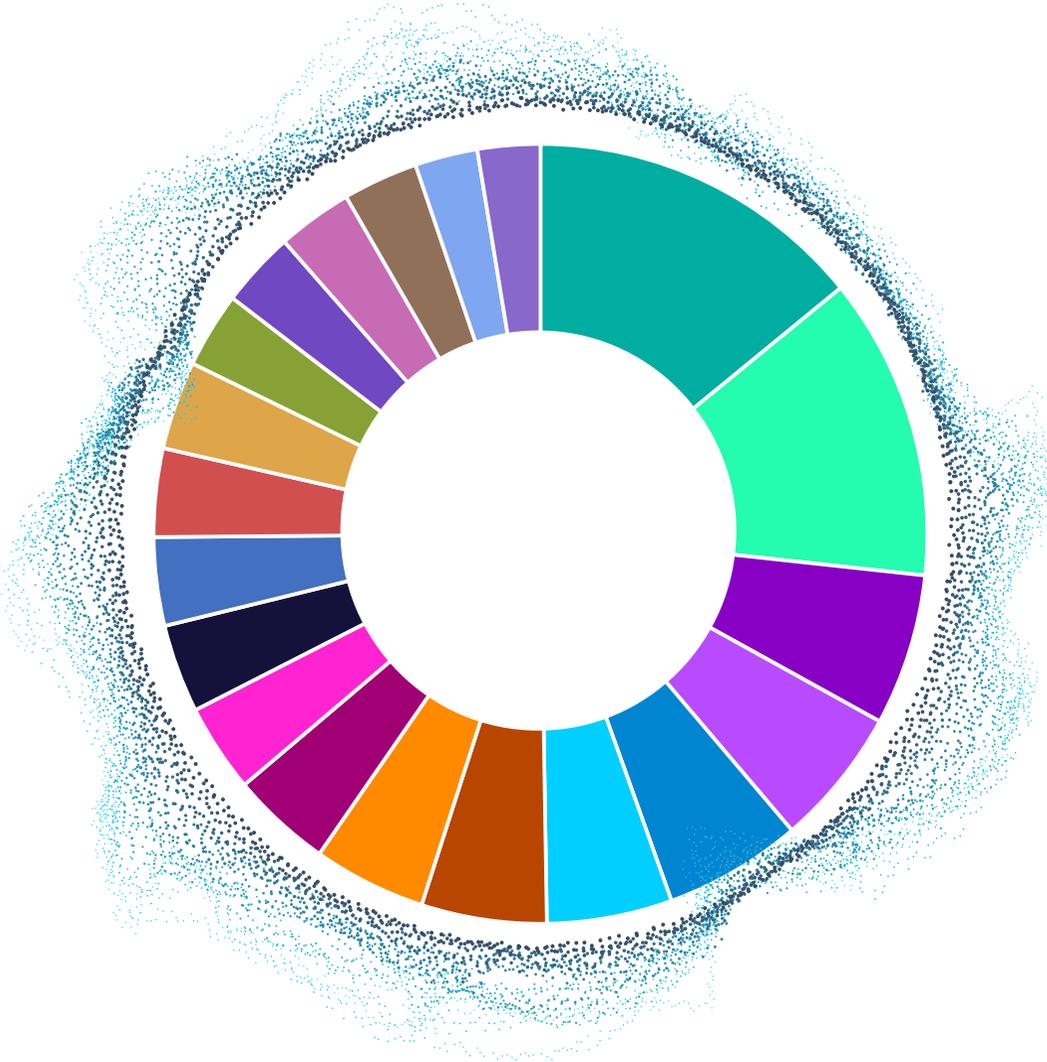
- 142 CNS
- 68 Oncology
- 36 Metabolic/Endocrinology
- 19 Autoimmune/Inflammation
- 17 Infectious Disease
- 11 Ophthalmology
- 9 Cardiovascular
- 7 Genitourinary

# Trials by Disease (Showing top 20)

- 32 CNS: Pain (neuropathic)
- 29 CNS: Pain (nociceptive)
- 23 CNS: Parkinson's Disease
- 11 Metabolic/Endocrinology: NAFLD
- 11 Oncology: Leukemia, Acute Myelogenous
- 10 CNS: Schizophrenia
- 10 Oncology: Bladder
- 9 Oncology: Soft Tissue Sarcoma
- 8 Autoimmune/Inflammation: Hepatic Fibrosis
- 8 CNS: Narcolepsy
- 8 Oncology: Pancreas
- 7 CNS: Post Traumatic Stress Disorder (PTSD)
- 7 Infectious Disease: Respiratory Infections
- 7 Metabolic/Endocrinology: Diabetic Complications
- 7 Oncology: Unspecified Cancer
- 6 Cardiovascular: Dyslipidemia
- 6 CNS: Alzheimer's Disease
- 6 CNS: Opioid Use Disorder (OUD)
- 6 Oncology: Breast
- 5 Autoimmune/Inflammation: Osteoarthritis



# Trials by Sponsor (Showing top 20)



- 27 TONIX Pharmaceuticals
- 24 Luye Pharma Group
- 12 Intellipharmaceuticals
- 11 Nanology
- 11 Race Oncology
- 10 NantWorks
- 10 Soleno Therapeutics
- 9 Xgene Pharmaceutical
- 8 (Other Hospital/Academic/Medical Center)
- 7 Entera Bio
- 7 LadRx
- 7 Lipocine
- 7 Pharmather
- 7 UroGen Pharma
- 6 BioSight
- 6 Nabriva Therapeutics
- 6 TaiwanJ Pharmaceuticals
- 6 XW Pharma
- 5 AZTherapies
- 5 Daré Bioscience



## 505b2 Deals Alliance from 2021

- Eton Pharmaceuticals Sells Its Hospital Products to Dr. Reddy's Laboratories
- BioDelivery Sciences Announces Agreement to Acquire U.S. and Canadian Rights to FDA-approved Elyxyb for the Acute Treatment of Migraine; Completes Rights Acquisition
- Journey Enters into a Definitive Agreement with Dr. Reddy's to Develop and Commercialize DFD-29 for Rosacea
- Nicox Partners with Laboratorios Grin to Bring Zerivate to Mexico
- Lupin Announces Partnership to Commercialize Endoceutics' Intrarosa in Canada

**Deal Date**

**Deal Title**



Eton Pharmaceuticals Sells Its Hospital Products to Dr. Reddy's Laboratories

**Deal Type**

**Deal Characteristics**

**Company Name**

Alliance

Includes Royalty or Profit Split Information|Marketing (Licensing)

Dr. Reddy's Laboratories Ltd.|Eton Pharmaceuticals, Inc.

**Lisensee**

**Lisenser**

**Product Name**

**Disease Group**

Dr. Reddy's Laboratories Ltd. | Dr. Reddy's Laboratories Ltd.|Dr. Reddy's Laboratories Ltd.

Eton Pharmaceuticals, Inc.|Eton Pharmaceuticals, Inc.|Eton Pharmaceuticals, Inc.

Biorphen|Rezipres

Cardiovascular|Gastroenterology (Non Inflammatory Bowel Disease)

**Indication**

**Phase At Time of Deal**

**Target**

**Molecule**

Hypotension/Shock|Hypotension/Shock|Liver Failure / Cirrhosis | Gastroenterologic Disorders

Approved|Approved|Approved

Alpha 1 Adrenergic Receptor |Beta Adrenergic Receptors|Norepinephrine (Noradrenaline)|Alpha Adrenergic Receptors

Small Molecule|Small Molecule

**Deal Date**

**Deal Title**



**BioDelivery Sciences Announces Agreement to Acquire U.S. and Canadian Rights to FDA-approved Elyxyb for the Acute Treatment of Migraine; Completes Rights Acquisition**

**Deal Type**

**Deal Characteristics**

**Company Name**

Alliance

Includes Royalty or Profit Split Information|Marketing (Licensing)

Dr. Reddy's Laboratories Ltd.|BioDelivery Sciences International, Inc.

**Lisensee**

**Lisenser**

**Product Name**

**Disease Group**

BioDelivery Sciences International, Inc.

Dr. Reddy's Laboratories Ltd.

Elyxyb

Neurology

**Indication**

**Phase At Time of Deal**

**Target**

**Molecule**

Migraine and Other Headaches

Approved

Cyclooxygenase 2 (COX2) / Prostaglandin-Endoperoxide Synthase 2 (PTGS2)

Small Molecule

Deal Date

Deal Title



Journey Enters into a Definitive Agreement with Dr. Reddy's to Develop and Commercialize DFD-29 for Rosacea

Deal Type

Deal Characteristics

Company Name

Alliance

R&D and Marketing (Licensing)

Dr. Reddy's Laboratories Ltd.|Journey Medical Corp.

Lisensee

Lisenser

Product Name

Disease Group

Journey Medical Corp.

Dr. Reddy's Laboratories Ltd.

Minolira

Dermatology

Indication

Phase At Time of Deal

Target

Molecule

Rosacea

II

Protein synthesis|Bacterial ribosome

Small Molecule

**Deal Date**

**Deal Title**



Nicox Partners with Laboratorios Grin to Bring Zerivate to Mexico

**Deal Type**

**Deal Characteristics**

**Company Name**

Alliance

Includes Royalty or Profit Split Information|Intra-Biotech Deal|R&D and Marketing (Licensing)

Nicox S.A.|Lupin Limited|Laboratorios Grin SA de CV

**Lisensee**

**Lisenser**

**Product Name**

**Disease Group**

Laboratorios Grin SA de CV

Nicox S.A.

Zerivate

Ophthalmology

**Indication**

**Phase At Time of Deal**

**Target**

**Molecule**

Allergic Conjunctivitis (Ophthalmology)

Approved

Histamine H1 Receptor (HRH1)

Small Molecule

**Deal Date**

**Deal Title**



Lupin Announces Partnership to Commercialize Endoceutics' Intrarosa in Canada

**Deal Type**

**Deal Characteristics**

**Company Name**

Alliance

Marketing (Licensing)

Endoceutics Inc.|Lupin Limited

**Lisensee**

**Lisenser**

**Product Name**

**Disease Group**

Lupin Limited

Endoceutics Inc.

Intrarosa

Endocrine|Obstetrics/  
Gynecology

**Indication**

**Phase At Time of Deal**

**Target**

**Molecule**

Female Sexual Arousal Disorder|  
Vaginal Atrophy

Approved

Androgen receptors|Estrogen

Small Molecule



Thank You



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