

# HOT INDICATIONS LIST

Top Indications  
for Global Pharma R&D  
Investment Intensity  
Published October 2016



# THE HOT INDICATIONS LIST

## 2016 UPDATE

### TOP 50 INDICATIONS

Over the last 50 years, innovation has become the pharmaceutical industry's defining characteristic. In 2015, the FDA's Center for Drug Evaluation and Research (CDER) gave the green light to 45 novel drugs, up from a record-breaking 41 approvals in 2014. The drive to innovate is evident, looking at both newly approved drugs (a third of which were granted Fast Track status by the FDA) and this year's Hot Indications in the global pipeline.

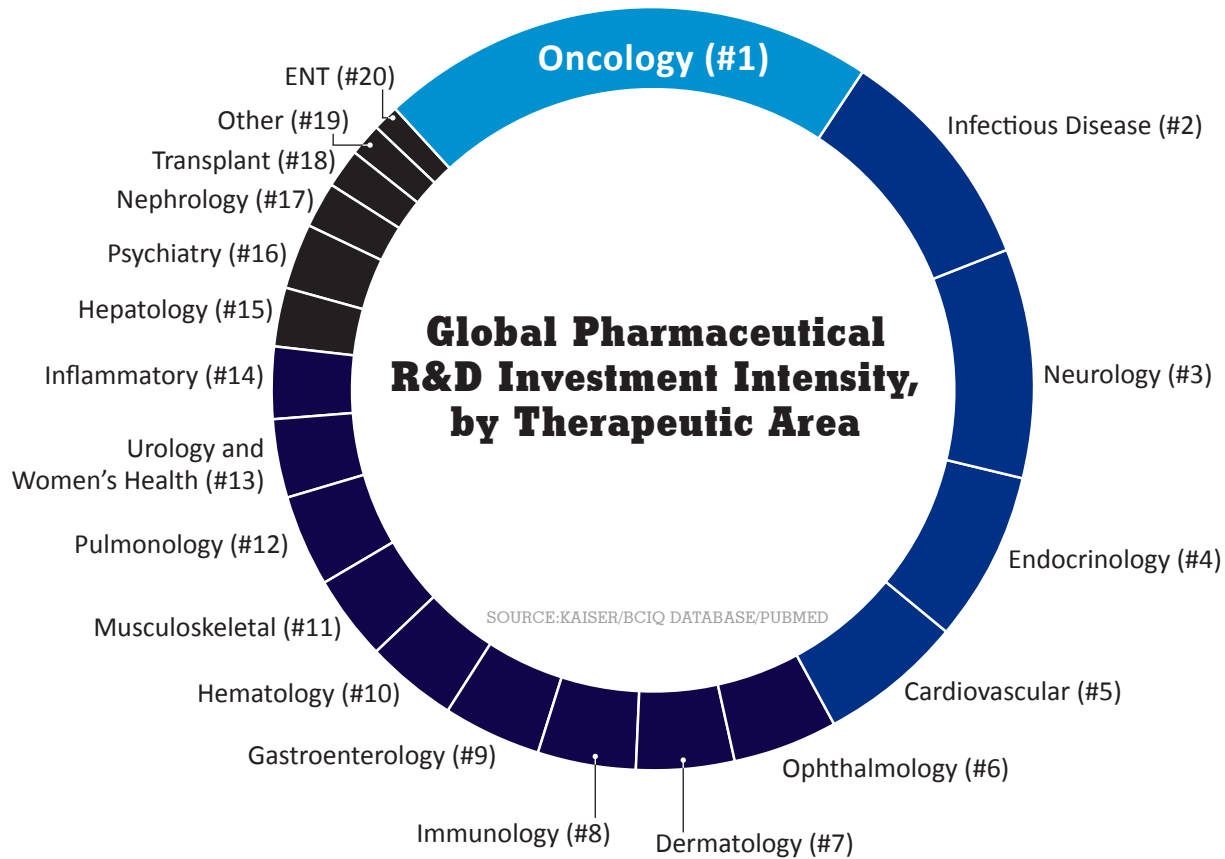
Climbing three positions from last year to be this year's top indication, **diabetes (#1)** is one of only two indications representing the Endocrinology therapeutic area in this year's Top 50. The market, and the pipeline, are both large and competitive, with big pharma such as Merck, Sanofi, and Novo Nordisk competing for top market share. The attraction to this indication reflects a stellar all-round scorecard performance. Diabetes captured nearly half of the financial allocation in a therapeutic area that includes a further 63 indications, attracting a striking combined IPO and VC investment of \$1.8 billion in 2015. This level of investment is not unexpected, considering in 2015 diabetes was able to support 10 blockbuster drugs and generate combined sales of close to \$30 billion [2]. The challenge in diabetes is to gain share in a mature and crowded market. Much of the late-stage pipeline is focused on improving current treatments in terms of outcomes and quality of life, such as insulin biosimilars, additions to the GLP1 class, and combinations of existing drugs. With the pipeline focused on competition rather than pure innovation, it is hard to see the next Jardiance (Eli Lilly), the SGLT2 inhibitor that was the first diabetes drug to demonstrate improved cardiovascular outcomes.

Oncology continues as the dominant therapeutic area, claiming 30% of indications in the Top 50 and 70% of indications in the Top 10. However, the reordering of indications illustrates a shift in focus this year. While **breast cancer (#2)** and **non-small cell lung cancer (#3)** retained their positions, Top 50 Oncology indications climbed 11 places on average, with **brain cancer (#6)**, **melanoma (#9)** and **B-cell lymphoma (#17)** averaging 18 places. These gains were chiefly based on strong IPO and VC funding contributions in 2015. For example, Immuncore's \$333 million venture financing was raised primarily to fund late-stage development of their lead immunotherapy, IMCgp100, for melanoma. Immuncore has partnerships with Eli Lilly (including trials combining Eli Lilly drugs with IMCgp100), AstraZeneca, GSK, and Roche, demonstrating the potential for big-small collaboration in Oncology. Overall, over a third of all therapy area funding was allocated to Oncology, with a staggering combined IPO and VC investment of more than \$8 billion in 2015. With the global Oncology market continuing to experience steady growth, and with global Oncology sales that surpassed the \$100 billion mark in 2014 [1], Oncology is the only therapeutic area that can command such levels of investment. It is not surprising that nearly a third of novel FDA approvals in 2015 were for Oncology indications, and this space will remain exciting for companies and investors as they continue to fuel innovation in oncology drug development. Further analysis of these Hot Indications is included in our Oncology Deep Dive, which goes beyond funding to address the question of innovation in Oncology drug development.

Oncology continues as the dominant therapeutic area, claiming 30% of indications in the Top 50 and **70% of indications in the Top 10.**

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While Oncology kept its stake in the top Therapeutic Areas (TAs) list, Neurology made a notable move into the top 5 TAs, based on truly Hot Indications that have jumped in the rankings. There were six Neurology indications among the Top 50 Indications this year, up from four in 2014. Among those, **pain (#4)** and **Alzheimer's disease (#5)** retained their Top 10 positions. Despite dropping three places and losing its #1 spot, pain remains one of the hottest indications dominating many of the scorecard categories. If not for a drop in venture capital and IPO investment, pain could have held its number one spot. As a physiological consequence of >70% of diseases associated with this year's Top 50 indications, pain will by default remain a Hot Indication into the foreseeable future.

Alzheimer's disease is currently one of the most challenging diseases to treat, and is also one of the most attractive opportunities; despite the high unmet needs for effective treatments, there remain no disease modifying therapies

(DMTs) for Alzheimer's. In spite of the dismal clinical trial success rate for DMTs to date, commitment to this indication remains strong. For example, earlier this year, Allergan, not long after backing away from a \$160 billion merger with Pfizer, made a licensing agreement with Heptares valued at \$3.3 billion for the global rights to a pipeline of novel subtype-selective muscarinic receptor agonists, including HTL9936 and HTL18318, designed to treat cognitive decline associated with Alzheimer's disease.

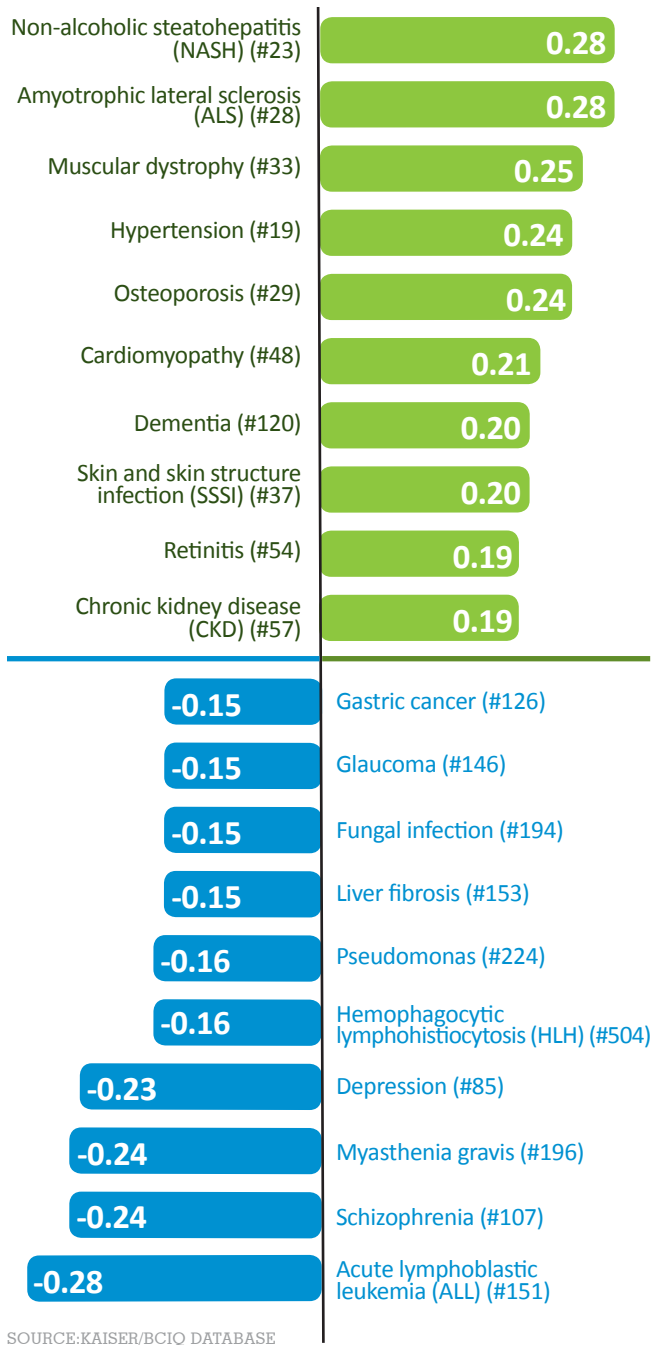
Also within Neurology, **amyotrophic lateral sclerosis (ALS) (#28)** was a big mover, climbing 96 positions to make the Top 50 in 2016. ALS has been a major focus for regulators. Of 46 candidates at any stage of development in 2015, four have received FDA Fast Track designation and five have received Orphan Drug designation, including promising preclinical and Phase I candidates from Maas BioLAB and Treeway. AB Science will be aiming for positive FDA and EMA opinions after gaining Or-

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## 2016 UPDATE

### Top 10 Movers and Losers

Net Change in Score



SOURCE:KAISER/BCIQ DATABASE

phan Drug Status for Phase III candidate Masiviera from both regulatory agencies. AB Science is running 18 clinical trials for its tyrosine kinase inhibitor in various cancers and immune and neurological diseases, but has courted controversy, with warnings from both US and French regulators. While Masiviera has been unsuccessful so far in Oncology, the FDA recently approved it for compassionate use in ALS patients, potentially forecasting future success in that disease. Finally, **epilepsy (#50)** also snuck into the Top 50, moving up two places from the year before.

Within Immunology, **rheumatoid arthritis (RA) (#12)**, **multiple sclerosis (MS) (#36)** and **lupus (#47)** were the only three indications on this year's Top 50. Despite the availability of highly efficient and hugely successful disease modifying therapeutics to treat RA, therapeutic newcomers are still making their way to the market. Celgene seems keen to come to the anti-rheumatics party, with the launch of Otezla (apremilast) approved for active psoriatic arthritis, and which analysts predict will reach sales of \$2 billion by 2020 [4]. Sanofi and Regeneron await FDA approval for sarilumab, a potential RA blockbuster with Phase III data showing superiority over AbbVie's blockbuster Humira (adalimumab), the top-selling product in 2015. The MS therapeutics market remains in an exciting phase, with an upsurge in promising products in the late-stage pipeline. Unfortunately, Biogen recently lost their MS gamble with their experimental drug opicinumab, which failed to meet the primary endpoint in their Phase III study. Hopefully Roche will have better success with Ocrevus (ocrelizumab), which in February was granted Breakthrough Therapy Designation for relapsing/remitting as well as primary progressive MS. If successful, Roche could well shake up the entire market.

Even based only on the large number of notable approvals and continued intense pipeline activity, 2015 was an eventful year for pharma. 2016 is continuing in the same direction, for example with Allergan's September deals, valued up to \$2 billion, to acquire Arkana and Tobira, both focused on **non-alcoholic steatohepatitis (NASH) (#23)**. Increased focus on newly Hot Indications, continuing M&A shakeups, and pricing scandals, indicate that 2016 will be another exciting year for pharma innovation.



# THE HOT INDICATIONS LIST

## TOP 200

Top 200 Hot Indications based on 2015 Investment Intensity: Pipeline Score, R&D Funding, and Academic Focus

2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
1	Endocrinology	Diabetes	4	3↑
2	Cancer	Breast cancer	2	0↔
3	Oncology	Non-small cell lung cancer (NSCLC)	3	0↔
4	Neurology	Pain	1	-3↓
5	Neurology	Alzheimer's disease (AD)	10	5↑
6	Oncology	Brain cancer	23	17↑
7	Oncology	Acute myelogenous leukemia (AML)	9	2↑
8	Oncology	Ovarian cancer	20	12↑
9	Oncology	Melanoma	26	17↑
10	Oncology	Prostate cancer	5	-5↓
11	Oncology	Pancreatic cancer	6	-5↓
12	Immunology	Rheumatoid arthritis (RA)	8	-4↓
13	Infectious Disease	HIV / AIDS	28	15↑
14	Oncology	Non-Hodgkin's lymphoma (NHL)	13	-1↓
15	Gastroenterology	Inflammatory bowel disease (IBD)	27	12↑
16	Oncology	Multiple myeloma (MM)	25	9↑
17	Oncology	B cell lymphoma	37	20↑
18	Neurology	Parkinson's disease (PD)	39	21↑
19	Cardiovascular	Hypertension	71	52↑
20	Pulmonology	Chronic obstructive pulmonary disease (COPD)	51	31↑
21	Oncology	Colorectal cancer	7	-14↓
22	Dermatology	Psoriasis	21	-1↓
23	Hepatology	Non-alcoholic steatohepatitis (NASH)	115	92↑
24	Infectious Disease	Bacterial infection	15	-9↓
25	Pulmonology	Cystic fibrosis (CF)	60	35↑

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
26	Oncology	Chronic lymphocytic leukemia (CLL)	24	-2↓
27	Dermatology	Acne	34	7↑
28	Neurology	Amyotrophic lateral sclerosis (ALS)	124	96↑
29	Musculoskeletal	Osteoporosis	95	66↑
30	Infectious Disease	Influenza virus	18	-12↓
31	Pulmonology	Pneumonia	56	25↑
32	Inflammation	Asthma	35	3↑
33	Musculoskeletal	Muscular dystrophy	117	84↑
34	Cardiovascular	Ischemia / reperfusion injury	49	15↑
35	Ophthalmology	Age-related macular degeneration (AMD)	14	-21↓
36	Immunology	Multiple sclerosis (MS)	17	-19↓
37	Dermatology	Skin and skin structure infection (SSSI)	92	55↑
38	Pulmonology	Pulmonary fibrosis	46	8↑
39	Oncology	Renal cancer	42	3↑
40	Hematology	Hemophilia	79	39↑
41	Transplant	Graft-versus-host disease (GvHD)	38	-3↓
42	Oncology	Head and neck cancer	41	-1↓
43	Psychiatry	Attention deficit hyperactivity disorder (ADHD)	75	32↑
44	Cardiovascular	Heart failure	47	3↑
45	Endocrinology	Glycosphingolipid storage disorders	86	41↑
46	Neurology	Ataxia	123	77↑
47	Immunology	Lupus	19	-28↓
48	Cardiovascular	Cardiomyopathy	199	151↑
49	Gastroenterology	Crohn's disease	43	-6↓
50	Neurology	Epilepsy	52	2↑

SOURCE: KAISER/BCIQ DATABASE/PUBMED

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
51	Endocrinology	Obesity	30	-21↓
52	Oncology	Bladder cancer	89	37↑
53	Endocrinology	Hypercholesterolemia	175	122↑
54	Ophthalmology	Retinitis	210	156↑
55	Oncology	Mesothelioma	153	98↑
56	Dermatology	Dermatitis	44	-12↓
57	Nephrology	Chronic kidney disease (CKD)	192	135↑
58	Hematology	Anemia	36	-22↓
59	Inflammatory	Allergy	33	-26↓
60	Neurology	Migraine	144	84↑
61	Oncology	Cervical cancer	99	38↑
62	Oncology	Sarcoma	125	63↑
63	Oncology	Neuroendocrine tumors	32	-31↓
64	Endocrinology	Dyslipidemia	129	65↑
65	Oncology	Small cell lung cancer	61	-4↓
66	Oncology	Epithelial cancer	275	209↑
67	Inflammatory	Shock / trauma	111	44↑
68	Musculoskeletal	Bone repair	164	96↑
69	Oncology	Gastrointestinal cancer	New indication	N/A
70	Neurology	Stroke	90	20↑
71	Nephrology	Polycystic kidney disease (PKD)	241	170↑
72	Infectious Disease	Clostridium	108	36↑
73	Oncology	Myelodysplastic syndrome (MDS)	137	64↑
74	Cardiovascular	Myocardial infarction (MI)	76	2↑
75	Cardiovascular	Peripheral vascular disease (PVD)	77	2↑

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
76	Urology & Women's Health	Urinary tract infection (UTI)	156	80↑
77	Immunology	Osteoarthritis	100	23↑
78	Immunology	Ankylosing spondylitis	217	139↑
79	Cardiovascular	Atherosclerosis	145	66↑
80	Oncology	Biliary cancer	176	96↑
81	Endocrinology	Mucopolysaccharidosis	124	43↑
82	Hematology	Sickle cell disease	93	11↑
83	Infectious Disease	Anthrax	73	-10↓
84	Hepatology	Hepatitis C virus (HCV)	29	-55↓
85	Psychiatry	Depression	12	-73↓
86	Urology & Women's Health	Human papillomavirus (HPV)	116	30↑
87	Neurology	Spinal muscular atrophy (SMA)	331	244↑
88	Infectious Disease	Dengue fever	63	-25↓
89	Psychiatry	Addiction	72	-17↓
90	Nephrology	Renal damage	109	19↑
91	Endocrinology	Pompe's disease	114	23↑
92	Infectious Disease	Rabies	281	189↑
93	Cardiovascular	Restenosis	260	167↑
94	Neurology	Neuropathy	206	112↑
95	Infectious Disease	Ebola	113	18↑
96	Infectious Disease	Viral infection	0	-96↓
97	Musculoskeletal	Muscular atrophy	221	124↑
98	Neurology	Huntington's disease (HD)	104	6↑
99	Oncology	Hodgkin's disease	146	47↑
100	Ophthalmology	Diabetic macular edema (DME)	31	-69↓



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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
101	Pulmonology	Respiratory distress syndrome (RDS)	224	123↑
102	Oncology	Esophageal cancer	187	85↑
103	Infectious Disease	Gram-negative bacterial infection	178	75↑
104	Endocrinology	Growth hormone deficiency	57	-47↓
105	Gastroenterology	Gastrointestinal infection	233	128↑
106	Urology & Women's Health	Incontinence	138	32↑
107	Psychiatry	Schizophrenia	16	-91↓
108	Cardiovascular	Acute coronary syndrome	165	57↑
109	Nephrology	Diabetic nephropathy	82	-27↓
110	Infectious Disease	Candida	133	23↑
111	Inflammatory	Angioedema	242	131↑
112	Hepatology	Cirrhosis	53	-59↓
113	Immunology	Scleroderma	152	39↑
114	Gastroenterology	Constipation	173	59↑
115	Endocrinology	Cachexia	198	83↑
116	Infectious Disease	Staphylococcus	81	-35↓
117	Hepatology	Hepatitis B virus (HBV)	67	-50↓
118	Nephrology	End-stage renal disease (ESRD)	406	288↑
119	Neurology	Spinal cord injury (SCI)	172	53↑
120	Neurology	Dementia	494	374↑
121	Endocrinology	Hypogonadism	130	9↑
122	Dermatology	Alopecia	340	218↑
123	Ophthalmology	Uveitis	126	3↑
124	Endocrinology	Hypoglycemia	377	253↑
125	Neurology	Intracerebral hemorrhage	300	175↑

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
126	Oncology	Gastric cancer	40	-86↓
127	Ophthalmology	Blindness	246	119↑
128	ENT	Rhinitis	147	19↑
129	Hematology	Paroxysmal nocturnal hemoglobinuria (PNH)	205	76↑
130	Infectious Disease	Tuberculosis	85	-45↓
131	Infectious Disease	Aspergillus	273	142↑
132	Infectious Disease	Respiratory syncytial virus (RSV)	163	31↑
133	Dermatology	Wounds	80	-53↓
134	Hepatology	Liver disease	45	-89↓
135	Oncology	Cutaneous T cell lymphoma (CTCL)	65	-70↓
136	Infectious Disease	Malaria	127	-9↓
137	Infectious Disease	Gram-positive bacterial infection	373	236↑
138	Endocrinology	Hyperuricemia / gout	168	30↑
139	Transplant	Renal transplant rejection	83	-56↓
140	Neurology	Excessive sleepiness	265	125↑
141	Musculoskeletal	Spasticity	383	242↑
142	Hematology	Myeloproliferative disorder	177	35↑
143	Cardiovascular	Fibrillation	180	37↑
144	Gastroenterology	Irritable bowel syndrome	97	-47↓
145	Psychiatry	Autism	58	-87↓
146	Ophthalmology	Glaucoma	50	-96↓
147	Neurology	Seizures	106	-41↓
148	Musculoskeletal	Arthritis	157	9↑
149	Ophthalmology	Dry eye	64	-85↓
150	Ophthalmology	Optic neuropathy	257	107↑

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
151	Oncology	Acute lymphoblastic leukemia (ALL)	22	-129↓
152	Endocrinology	Acromegaly	140	-12↓
153	Hepatology	Liver fibrosis	48	-105↓
154	Pulmonology	Cough	149	-5↓
155	Psychiatry	Anxiety	141	-14↓
156	ENT	Rhinosinusitis / nasal polyps	139	-17↓
157	Infectious Disease	Genital warts	404	247↑
158	Cardiovascular	Aneurysm	369	211↑
159	Cardiovascular	Blood clots	286	127↑
160	Endocrinology	Hyperoxaluria	87	-73↓
161	Musculoskeletal	Fibromyalgia syndrome	174	13↑
162	Endocrinology	Menopause	226	64↑
163	Dermatology	Seborrheic keratosis	477	314↑
164	Urology & Women's Health	Uterine fibroids	214	50↑
165	Other	Mucositis	179	14↑
166	Hematology	Neutropenia	121	-45↓
167	Urology & Women's Health	Polycystic ovary syndrome (PCOS)	250	83↑
168	Hematology	Hemolytic uremic syndrome	440	272↑
169	Infectious Disease	Sepsis	132	-37↓
170	Hepatology	Hepatitis D virus (HDV)	105	-65↓
171	Gastroenterology	Intra-abdominal infection	222	51↑
172	Other	Cushing's disease	251	79↑
173	Dermatology	Dermal ulcers	62	-111↓
174	Hematology	Thalassemia	385	211↑
175	Endocrinology	Hypertriglyceridemia	371	196↑

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2015 RANK	THERAPEUTIC AREA	INDICATION	2014 RANK	MOVEMENT
176	Hematology	Bleeding	91	-85↓
177	Neurology	Insomnia	161	-16↓
178	Oncology	Endometrial cancer	122	-56↓
179	Endocrinology	Urea cycle disorder (UCD)	400	221↑
180	Nephrology	Nephropathy	237	57↑
181	Endocrinology	Homocystinuria	512	331↑
182	Other	Poisoning	201	19↑
183	Cardiovascular	Congestive heart failure (CHF)	203	20↑
184	Infectious Disease	Cytomegalovirus (CMV)	68	-116↓
185	Endocrinology	Contraception	193	8↑
186	Cardiovascular	Coronary artery disease (CAD)	166	-20↓
187	Psychiatry	Post-traumatic stress disorder	227	40↑
188	ENT	Hearing loss	191	3↑
189	Cardiovascular	Tachycardia	529	340↑
190	Cardiovascular	Thrombosis	66	-124↓
191	Oncology	Mantle cell lymphoma (MCL)	195	4↑
192	Urology & Women's Health	Benign prostatic hyperplasia (BPH)	197	5↑
193	Endocrinology	Metabolic syndrome	360	167↑
194	Infectious Disease	Fungal infection	59	-135↓
195	Dermatology	Scars / wrinkles	182	-13↓
196	Immunology	Myasthenia gravis	269	73↑
197	Immunology	Psoriatic arthritis	136	-61↓
198	Oncology	Thyroid cancer	84	-114↓
199	Infectious Disease	Herpes simplex virus (HSV)	120	-79↓
200	Oncology	T cell lymphoma	131	-69↓

SOURCE: KAISER/BCIQ DATABASE/PUBMED

## METHODOLOGY

Kaiser Associates' methodology is designed to assess investment intensity of drug development for each indication through a comprehensive and balanced analysis of the key drivers and metrics.

Our Hot Indications analysis framework considers the volume of ongoing scientific investigation, as well as the types of companies and level of funding supporting these trials. Kaiser's analysis evaluated 13,182 drug programs ongoing in 2015, categorized them into 577 unique indications, and compared available data for these indications across three main criteria:

### 1. PIPELINE SCORE

The Pipeline Score measures the overall level of drug development activity for an indication. The score gives greater value to later-stage programs, higher volumes of programs overall, and indications with greater numbers of companies with programs.

### 2. R&D FUNDING

R&D Funding estimates the availability of financing to support the development of each drug program to its reasonable endpoint. For some programs, this endpoint will be FDA approval, while for others it will be discontinuation in preclinical or Phase I.

The score measures availability of funds and willingness to invest based on two main inputs for each indication. First, the R&D Funding Score quantifies the historical track record of sponsor companies, based on the number of drugs each company has successfully developed. Second, the score measures initial public offering and venture capital investment fundraising activity in 2014 for each indication, with the expectation that the financing from such events will be major contributors in supporting ongoing R&D programs.

### 3. ACADEMIC FOCUS

Academic Focus measures the overall publication activity for each indication, based on the absolute number and the one-year change in publications citing the indication for the evaluation period.

### Hot Indications Ranking

For each of the 582 indications, the overall ranking score is calculated by a weighted average of Pipeline Score (50%), R&D Funding (40%) and Academic Focus (10%). Throughout this analysis, the rank number from the final Hot Indications List is denoted in parentheses immediately following first mention of the indication in each section.

### Therapeutic Areas & Ranking

The Therapeutic Area Ranking is an index of R&D investment intensity that synthesizes and normalizes the Hot Indications Ranking scores for all indications within a Therapeutic Area.

Each indication is categorized into one of 21 TAs, which include 20 major fields of medicine and an "Other" group. The assignment of indications into TA plays a meaningful role in the Therapeutic Area Ranking. In general, indications are categorized based on the medical specialty most likely to treat patients with a disease or disorder.

Systemic diseases, such as autoimmune disorders, or TAs representing a variety of medical specialties, such as Musculoskeletal, are grouped on a case-by-case basis. For example, Crohn's disease and ulcerative colitis are included in Gastroenterology rather than Immunology, whereas Multiple Sclerosis is included in Immunology due to the variety of symptoms it presents.

### Sources

- [1] BCIQ database, accessed March 28, 2016.
- [2] IMS Institute for Healthcare Informatics, 5 May 2015.
- [3] FirstWord Lists: Blockbuster diabetes drugs 2014 and 2020, 10 May 2015.
- [4] Hurd MD, Martorell P, Delavande A, Mullen KJ, and Langa, KM. Monetary Costs of Dementia in the United States. *New England Journal of Medicine* 368: 126-1334 (2013).
- [5] EvaluatePharma, World Preview 2015, Outlook to 2020.

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## ABOUT KAISER ASSOCIATES

### ABOUT KAISER

Founded in 1981, Kaiser Associates is an international strategy consulting firm that serves as a key advisor to the world's leading companies. We provide our clients with the unique insight to drive critical decision-making and solve their most pressing problems.

Kaiser's Global Healthcare Practice engages with executives at leading Life Sciences companies, including pharmaceutical, medical device, clinical diagnostics, consumer health, and health IT. We work with our clients to identify new growth markets, develop long-term portfolio strategies, and maximize commercial success.

The foundation of Kaiser's service offering is its world-class "outside-in" methodology, which involves delivering critical facts and insights from the complex external environment to drive strategic decision making. Kaiser possesses the unique ability to generate insights across physicians, thought leaders, patients, competitors, partners, regulators, suppliers, and payers. Kaiser uses its deep industry experience and analytical tools to synthesize this diverse set of insights and develop high-impact solutions.

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