

**PREVIEW**

A Year In Review

The journey of drug development in 2021

Last year we released our first year-in review report and received deep appreciation from around the globe. This encouraged us to produce a further version, which again draws from data and intelligence found in our AdisInsight database and aims to present an updated overview of drug development in 2021.

With the pandemic still lingering upon us, we appreciate the global efforts in the research and development of new therapies and the actions taken to advance these therapies to their possible approval, for the benefit of patients worldwide. Covid-19 is naturally still in the spotlight, but other conditions are not forgotten when it comes to conducting early, clinical and late-stage research, although faced with the obvious difficulties of our current times.

We present here a review of key drug development metrics that we were able to observe through the use of our AdisInsight database, providing analysis on the potential of new and existing medicines, clinical studies, safety data, and key events in the biopharmaceutical field of 2021.

Review
Report



Most Interesting Drugs in 2021

Top 10 AdisInsight Drug profiles viewed

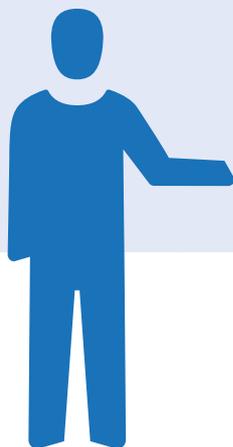
In 2021, Covid-19 continued to dominate drug development discussions. However, there was progress in other disease areas as well. The selection of drugs viewed by AdisInsight users included rare disease drug developments like Pegcetacoplan and Eculizumab. Additional profiles of high interest focused on cancer, atopic dermatitis and Covid-19 infections. It's interesting to note that the 2 most viewed profiles have remained unchanged in 2020 and 2021.

TABLE 1 - TOP DRUG PROFILES VIEWED GLOBALLY BY ALL USERS OF ADISINSIGHT

Drug name	Approved indication	Indications in development
1 Pembrolizumab - Merck & Co	Breast cancer ; Cervical cancer; Colorectal cancer; Diffuse large B cell lymphoma; Gastric cancer; Head and neck cancer; Hodgkin's disease; Liver cancer; Malignant melanoma; Non-small cell lung cancer; Oesophageal cancer; Pancreatic cancer; Solid tumours; Squamous cell cancer; Urogenital cancer	Acute myeloid leukaemia; Adenocarcinoma; Adenoid cystic carcinoma; Biliary cancer; Bladder cancer; Bone cancer; Brain metastases; Breast cancer; Cancer; Cervical cancer; Cholangiocarcinoma; Chronic lymphocytic leukaemia; Colorectal cancer; Diffuse large B cell lymphoma; Endometrial cancer; Fallopian tube cancer; Follicular lymphoma; Gastric cancer; Gastrointestinal cancer; Germ cell and embryonal neoplasms; Glioblastoma; Glioma; Gliosarcoma; Haematological malignancies; Head and neck cancer; Hodgkin's disease; Human papillomavirus infections; Inflammatory breast cancer; Leiomyosarcoma; Leucoplakia; Liver cancer; Liver metastases; Lymphoma; Malignant melanoma; Malignant thymoma; Mantle-cell lymphoma; Marginal zone B-cell lymphoma; Meningeal carcinomatosis; Meningioma; Merkel cell carcinoma; Mesothelioma; Multiple myeloma; Myelodysplastic syndromes; Nasopharyngeal cancer; Neuroendocrine tumours; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Oesophageal cancer; Osteosarcoma; Ovarian cancer; Pancreatic cancer; Penile cancer; Peritoneal cancer; Precursor cell lymphoblastic leukaemia-lymphoma; Prostate cancer; Rectal cancer; Recurrent respiratory papillomatosis; Renal cell carcinoma; Richter's syndrome; Sarcoma; Small cell lung cancer; Soft tissue sarcoma; Solid tumours; Squamous cell cancer; T-cell lymphoma; Thyroid cancer; Urogenital cancer; Uveal melanoma
2 Nivolumab - Bristol-Myers Squibb/Ono Pharmaceuticals	Colorectal cancer; Gastric cancer; Head and neck cancer; Hodgkin's disease; Liver cancer; Malignant melanoma; Mesothelioma; Non-small cell lung cancer; Renal cell carcinoma; Urogenital cancer	Acute myeloid leukaemia; Adrenocortical carcinoma; Alveolar soft part sarcoma; Autoimmune disorders; Biliary cancer; Bladder cancer; Brain metastases; Breast cancer; Bronchopulmonary dysplasia; CNS cancer; Cancer; Cervical cancer; Cholangiocarcinoma; Chronic lymphocytic leukaemia; Clear cell sarcoma; Colorectal cancer; Diffuse large B cell lymphoma; Fallopian tube cancer; Follicular lymphoma; Gastric cancer; Genitourinary disorders; Glioblastoma; Glioma; Haematological malignancies; Head and neck cancer; Hodgkin's disease; Leucoplakia; Liver cancer; Liver metastases; Lymphoma; Malignant melanoma; Meningeal carcinomatosis; Mesothelioma;

Drug name	Approved indication	Indications in development	
2		Multiple myeloma; Myelodysplastic syndromes; Nasopharyngeal cancer; Neurofibromatosis 1; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Oesophageal cancer; Ovarian cancer; Pancreatic cancer; Penile cancer; Peripheral T-cell lymphoma; Peritoneal cancer; Plexiform neurofibroma; Prostate cancer; Rectal cancer; Renal cell carcinoma; Small cell lung cancer; Soft tissue sarcoma; Solid tumours; Squamous cell cancer; Testicular cancer; Thyroid cancer; Urogenital cancer; Uterine cancer; Uveal melanoma	
3	Atezolizumab - Genentech	Breast cancer; Liver cancer; Malignant melanoma; Non-small cell lung cancer; Small cell lung cancer; Urogenital cancer	Acute myeloid leukaemia; Adrenocortical carcinoma; Anal cancer; Biliary cancer; Bladder cancer; Brain metastases; Breast cancer; Cervical cancer; Chronic lymphocytic leukaemia; Colorectal cancer; Cutaneous T-cell lymphoma; Diffuse large B cell lymphoma; Endometrial cancer; Fallopian tube cancer; Follicular lymphoma; Gastric cancer; Glioblastoma; Gynaecological cancer; Haematological malignancies; Head and neck cancer; Liver cancer; Malignant melanoma; Malignant thymoma; Mantle-cell lymphoma; Marginal zone B-cell lymphoma; Mesothelioma; Multiple myeloma; Neuroendocrine tumours; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Oesophageal cancer; Ovarian cancer; Pancreatic cancer; Peritoneal cancer; Pheochromocytoma; Prostate cancer; Renal cell carcinoma; Small cell lung cancer; Soft tissue sarcoma; Solid tumours; Squamous cell cancer; Thyroid cancer; Urogenital cancer; Waldenstrom's macroglobulinaemia
4	Dupilumab - Regeneron/Sanofi	Non-small cell lung cancer; Small cell lung cancer	Acute myeloid leukaemia; Biliary cancer; Bladder cancer; Brain metastases; Breast cancer; Cervical cancer; Cholangiocarcinoma; Chronic lymphocytic leukaemia; Colorectal cancer; Cutaneous T-cell lymphoma; Diffuse large B cell lymphoma; Endometrial cancer; Fallopian tube cancer; Gallbladder cancer; Gastric cancer; Gastrointestinal cancer; Germ cell and embryonal neoplasms; Glioblastoma; Haematological malignancies; Head and neck cancer; Liver cancer; Lung cancer; Lymphoma; Malignant melanoma; Mesothelioma; Multiple myeloma; Myelodysplastic syndromes; Neuroendocrine tumours; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Oesophageal cancer; Oropharyngeal cancer; Ovarian cancer; Pancreatic cancer; Peripheral T-cell lymphoma; Peritoneal cancer; Prostate cancer; Renal cancer; Renal cell carcinoma; Sarcoma; Small cell lung cancer; Soft tissue sarcoma; Solid tumours; Urogenital cancer; Uterine cancer; Vulvovaginal cancer
5	Dupilumab - Regeneron/Sanofi	Asthma; Atopic dermatitis; Nasal polyps	Asthma; Atopic dermatitis; Bullous pemphigoid; Chronic obstructive pulmonary disease; Chronic urticaria; Eosinophilic gastroenteritis; Eosinophilic oesophagitis; Milk hypersensitivity; Nasal polyps; Peanut hypersensitivity; Prostate cancer; Prurigo nodularis; Pruritus; Rhinosinusitis; Urticaria

	Drug name	Approved indication	Indications in development
6	Ruxolitinib - Incyte Corporation/Novartis	Atopic dermatitis; Graft-versus-host disease; Myelofibrosis; Polycythaemia vera	Acute myeloid leukaemia; Alopecia areata; Atopic dermatitis; Breast cancer; Breast disorders; Bronchiolitis obliterans; COVID-19 pneumonia; Cachexia; Chronic lymphocytic leukaemia; Chronic myeloid leukaemia; Chronic myelomonocytic leukaemia; Cytokine release syndrome; Essential thrombocythaemia; Graft-versus-host disease; Haematological malignancies; Head and neck cancer; Hodgkin's disease; Multiple myeloma; Myelodysplastic syndromes; Myelofibrosis; Polycythaemia vera; Precursor cell lymphoblastic leukaemia-lymphoma; SARS-CoV-2 acute respiratory disease; Thalassemia; Vitiligo
7	Eculizumab - Alexion AstraZeneca Rare Disease	Haemolytic uraemic syndrome; Myasthenia gravis; Neuromyelitis optica; Paroxysmal nocturnal haemoglobinuria	Antiphospholipid syndrome; Delayed graft function; Guillain-Barre syndrome; Heart transplant rejection; Myasthenia gravis; Neuromyelitis optica; Paroxysmal nocturnal haemoglobinuria; Preeclampsia; Renal transplant rejection
8	Venetoclax - AbbVie/ Genentech	Chronic lymphocytic leukaemia	Acute myeloid leukaemia; B-cell lymphoma; Blastic plasmacytoid dendritic cell neoplasm; Breast cancer; Cancer; Chronic lymphocytic leukaemia; Chronic myelomonocytic leukaemia; Diffuse large B cell lymphoma; Follicular lymphoma; Mantle-cell lymphoma; Marginal zone B-cell lymphoma; Multiple myeloma; Myelodysplastic syndromes; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Precursor cell lymphoblastic leukaemia-lymphoma; Prostate cancer; Small cell lung cancer; T-cell prolymphocytic leukaemia; Waldenstrom's macroglobulinaemia
9	Pegcetacoplan - Apellis Pharmaceuticals/Swedish Orphan Biovitrum	Paroxysmal nocturnal haemoglobinuria	Age-related macular degeneration; Amyotrophic lateral sclerosis; Autoimmune haemolytic anaemia; Glomerulonephritis; IgA nephropathy; Lupus nephritis; Membranous glomerulonephritis; Paroxysmal nocturnal haemoglobinuria; Thrombotic microangiopathy; Wet age-related macular degeneration
10	Selinexor - Karyopharm Therapeutics	Diffuse large B cell lymphoma; Multiple myeloma	Acute myeloid leukaemia; B-cell lymphoma; Breast cancer; COVID 2019 infections; Cervical cancer; Chronic lymphocytic leukaemia; Colorectal cancer; Diffuse large B cell lymphoma; Endometrial cancer; Extranodal NK-T-cell lymphoma; Gastrointestinal stromal tumours; Glioblastoma; Glioma; Liposarcoma; Malignant melanoma; Multiple myeloma; Myelodysplastic syndromes; Myelofibrosis; Neuroendocrine tumours; Non-Hodgkin's lymphoma; Non-small cell lung cancer; Osteosarcoma; Ovarian cancer; Peripheral T-cell lymphoma; Precursor cell lymphoblastic leukaemia-lymphoma; Sepsis; Soft tissue sarcoma; Solid tumours; Thymic epithelial tumour; Thymoma



Overview of 2021 drug launches**

In 2021, there were a total of 107 compounds that were approved for the first time. The majority of the compounds are indicated for cancer, kidney disorders, rheumatoid arthritis, and pain.

***Detailed information about the drugs that were first approved during the course of 2021 can be found in Table 2 at the end of this document. [Table 2]*

Overview

Summary of drug development programme failures

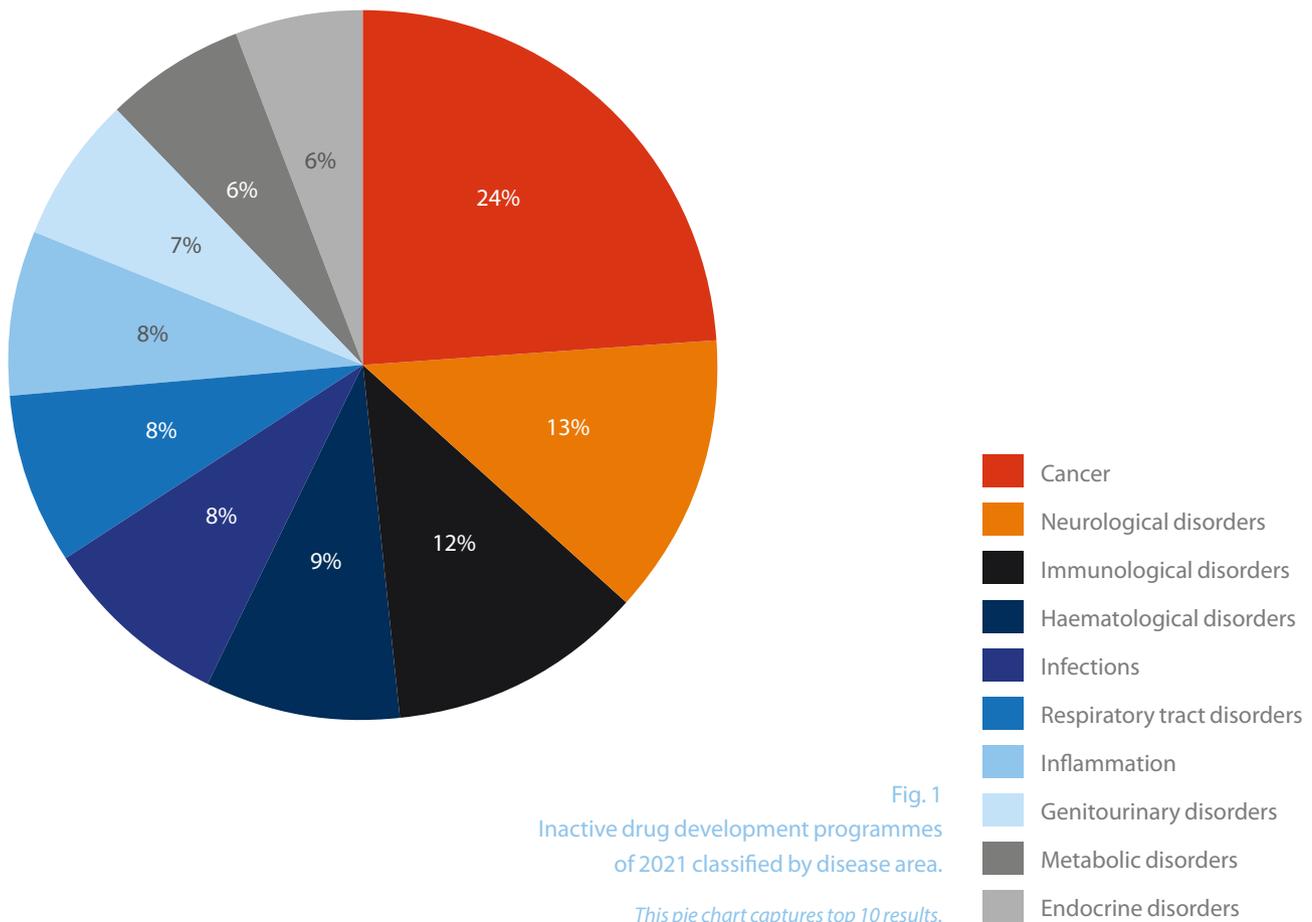
In 2021, 1,770 drug development profiles turned to 'inactive', while 1,277 saw a development line, e.g. an indication, being suspended while the relevant drug development programme remained active.

The leading area in terms of suspended and inactive programmes was cancer (which was also leading this chart in 2020), followed by neurological disorders, immunological disorders, haematological diseases, infections in the top 5. We observe here that the broad categories in this analysis are the same that were seen in 2020 but their relevant positions have shifted.

DRUG DEVELOPMENT PROFILES

1,770

were DISCONTINUED



More than
14,200
NEW TRIAL
RECORDS

Important research trends in 2021

Trials released by therapy area

More than 14,200 new trial records were added to AdisInsight in 2021. An analysis by disease area shows Tumours as the main area of focus, followed by Immunological disorders, Infections, which includes clinical development in coronavirus infections, Neurological disorders, and Respiratory tract disorders round out the top 5 categories.

- Tumours
- Immunological disorders
- Infections
- Neurological disorders
- Respiratory tract disorders
- Haematological disorders
- Lung disorders
- CNS disorders
- Genitourinary disorders
- Inflammation

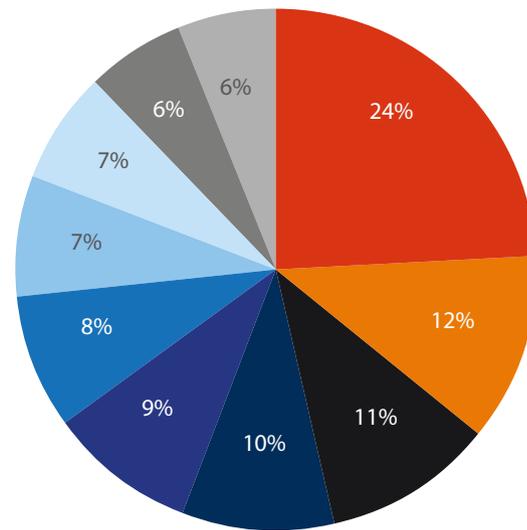


Fig. 2
Figure represents top 10 indications with most newly released trials in 2021.

Trial activity by region

Out of the more than 14,000 new trial records released to AdisInsight in 2021, a significant proportion of these were carried out in North America and Asia-Pacific, with the USA, China and Japan being prime locations, followed by Europe with Italy, Spain, UK, Germany and France, all showing comparable number of trials of around 800 each.

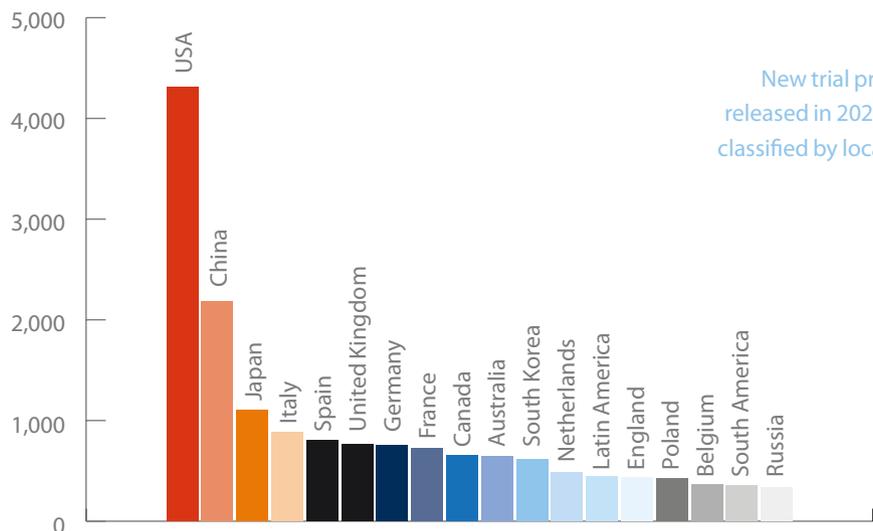
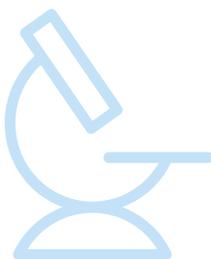


Fig. 3
New trial profiles released in 2021 and classified by location.

Outlook on clinical trials

In 2020, the number of suspended trials climbed 3 times the rate of trials suspended in the previous year. And while the correlation with the pandemic does not necessarily imply causation in all cases, we believe the trend points to the difficulties of recruiting and running clinical studies during a pandemic. In 2021, the number of suspended clinical trials was on par with pre-pandemic numbers.

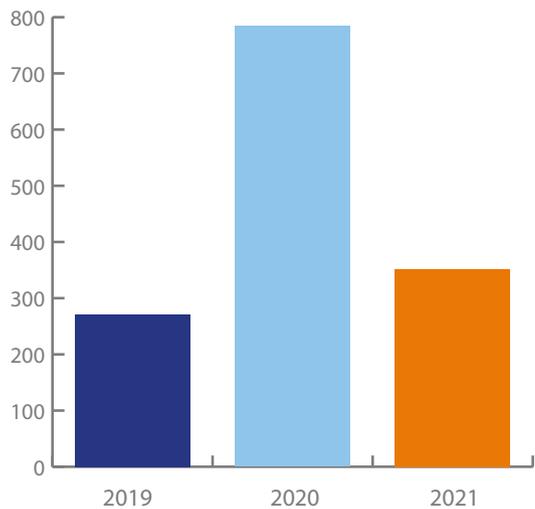


Fig. 4
Number of suspended trials from 2019 till 2021.

New profiles released in 2021 by Indication (top 10 indications)

In 2021, 4,713 new drug profiles were added to the AdisInsight database. When reviewing this list by Indication, cancer represented the largest increase in newly developed drugs, followed by neurological disorders, infections, CNS disorders and immunological disorders complete the top 5 indications with the most newly created drug programs. The Covid-19 drug development is classified within infections and helped propel this indication to the top 5 in 2021.

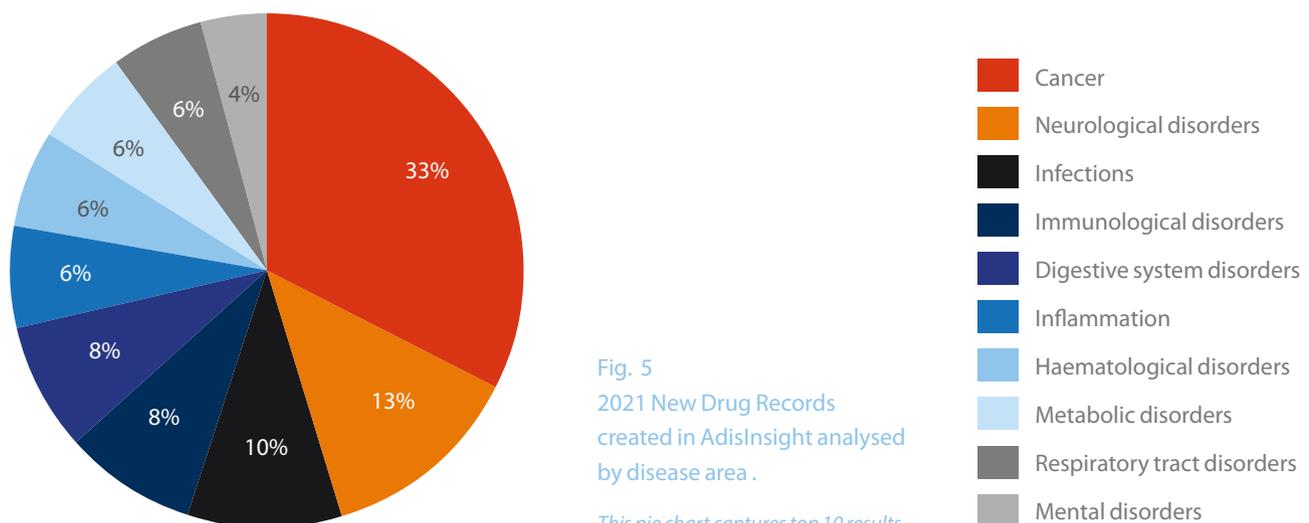


Fig. 5
2021 New Drug Records created in AdisInsight analysed by disease area .

This pie chart captures top 10 results.