White Paper

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# The Annual Clinical Trials Roundup

## 2025 Edition: Innovation, Regulation, and Preservation

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# Contents

# Introduction: Total Trial Activities

Welcome to the 2025 edition of the Clinical Trials Roundup. In 2024, we saw the corrections to trial initiations based on the post-pandemic decrease of COVID-19 trials, the commencement of the Israel-Hamas war, the continued Ukraine-Russia conflict, and a new political regime in the US with different rules. Furthermore, trial designs were impacted with continued regulatory pressure globally to incorporate diversity, equity, and inclusion (DE&I) requirements and the demand for broader representation across race, sex, gender identity, and geography. Artificial intelligence (AI) and machine learning models also gained momentum as practical tools for trial recruitment, data review/sharing, and adaptive design.

Continuing with the same format we have published each year, this year's analysis provides an overview of Phase I–III clinical trials that initiated in 2024 compared to prior calendar years across therapeutic areas (TAs), diseases, sponsors, and geographies.

As of June 2025, Trialtrove analyzed 10,503 Phase I–III clinical trials (Table 1) investigating at least one drug with a disclosed start date within the 2024 calendar year.

As shown in Table 1, overall trial initiations increased from 2023 to 2024 by 5.5%, although not as grand as the 9.4% jump that occurred from 2022 to 2023. Industry-sponsored trials, consisting of 67% of all trials, mirrored the growth with a 3.6% increase in 2024, but down from the increase of 11% in 2023. This is a significant data point as these trials are a driving force in clinical research and indicative of a slight slowing of activity.

**Table 1:** Phase I–III clinical trial activity by volume and growth, 2017–24

| Year of trial initiation | 2024 | 2023 | 2022 | 2021 | 2020 | 2019 | 2018 | 2017 |
|---|---|---|---|---|---|---|---|---|
| Trial count | 10,503 | 9,959 | 9,104 | 10,410 | 9,819 | 7,765 | 7,606 | 6,794 |
| Year-on-year growth (%) | 5.50% | 9.40% | -12.5% | 6% | 26% | 2% | 12% | 12% |
| Industry sponsored trials | 7,048 | 6,801 | 6,151 | 6,646 | 6,542 | 6,211 | 6,127 | 5,684 |
| Year-on-year growth (%) | 3.6% | 11.0% | -7.0% | 1.6% | 5.3% | 1.4% | 8.0% | 12.0% |

Source: Trialtrove, June 2025

Over the last four editions of Clinical Trials Roundup, we have looked at the impact of COVID trials and the impact on other TAs. The decline occurred in 2020, with a resurgence in 2021, only to return to a decline in 2022. In 2023, there was an impressive non-COVID industry-sponsored trials growth at 14%, and this year shows a modest growth of 5.4%. Table 2 provides data inferring that COVID-19 trials have been declining in initiations from 2022 through 2024 with less than 100 trials initiated in 2024, signaling that the COVID-induced trial boom is over.

**Table 2:** Phase I–III industry-sponsored trials by volume and growth, 2017–24

| Year of trial initiation | 2024 | 2023 | 2022 | 2021 | 2020* | 2019* | 2018* | 2017* |
|---|---|---|---|---|---|---|---|---|
| Industry-sponsored trials | 7,048 | 6,801 | 6,151 | 6,646 | 6,542 | 6,211 | 6,127 | 5,684 |
| Year-on-year growth (%) | 3.6% | 11.0% | -7.0% | 1.6% | 5.3% | 1.4% | 8.0% | 12.0% |
| Industry-sponsored trials (excluding COVID-19 trials) | 6,970 | 6,611 | 5,807 | 6,027 | 5,709 | 6,202 | – | – |
| Year-on-year growth (excluding COVID-19 trials. %) | 5.4% | 14.0% | -4.0% | 5.6% | -8.0% | N/A | – | – |

*Data accessed August 2024

Source: Trialtrove, June 2025

To expand our investigation, let us dive into TAs, diseases, sponsors, and geographies to analyze any further trends.

# Clinical Trial Activity by Therapeutic Area

Growth was not homogenous across all TAs with the front-runners being oncology, CNS, and autoimmune/inflammation (A/I).

Figure 1 shows that oncology trials had the most initiations, solidifying that this is still a core area of research. Strides made in immunotherapy, T cell therapies, antibody-drug conjugates (ADCs), bispecific antibodies, and radiopharmaceuticals, among others, have enabled oncology to encompass 37.2% of all trial initiations. However, the growth rate has decreased from 9.5% in 2023, where it had an impressive bump in trials, to 5% in 2024.

CNS trials had a growth rate of 14.7% to claim the second most active area, comprising 15.7% of all trial initiations and indicating continued research and development into pain, depression, and Alzheimer's disease. According to the World Health Organization[1], neurological conditions are now the leading cause of ill health and disability worldwide. We believe this TA will continue to have a strong growth rate in the future.

The A/I TA had an impressive growth of 14.6% in 2024, capturing 14.8% of total development. Cell therapy, particularly CAR-T therapies, have expanded into autoimmune conditions and have shown the potential to be transformative in multiple areas, including lupus and multiple sclerosis.

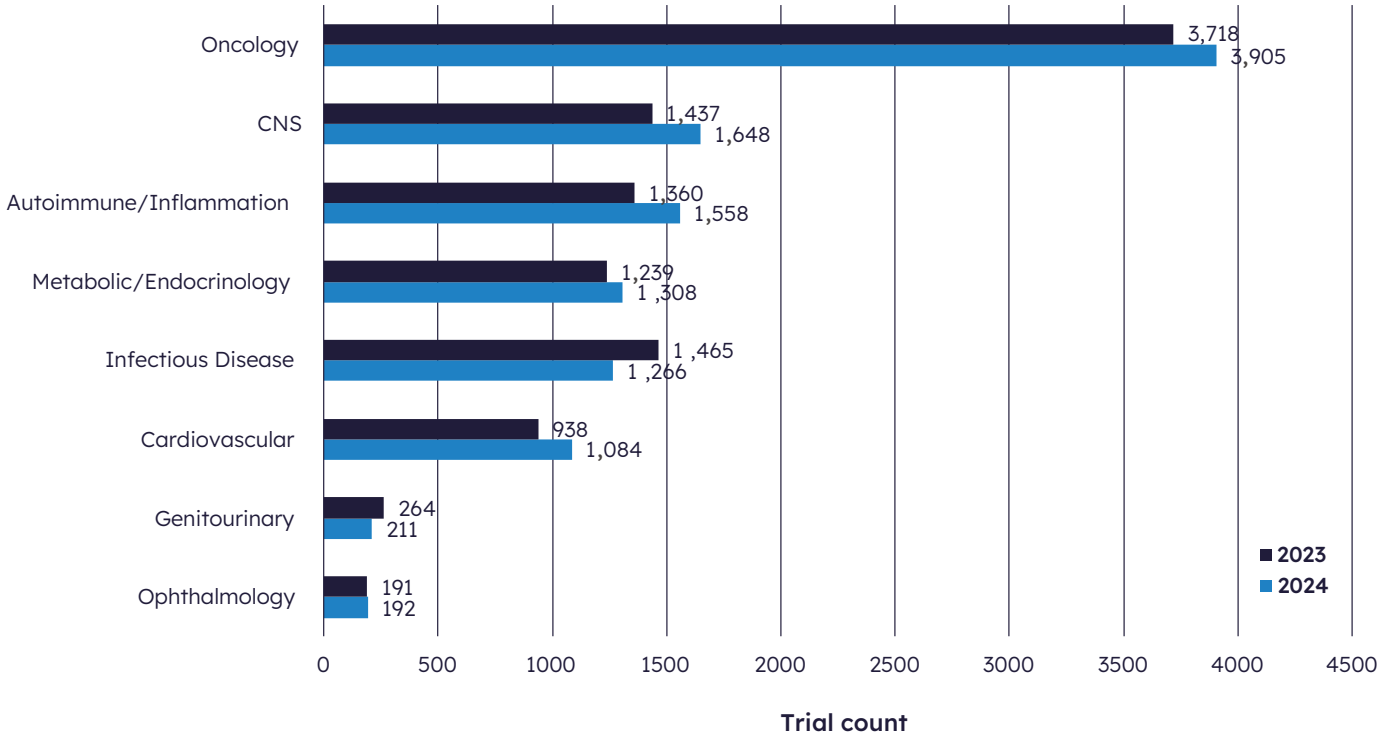
Cardiovascular trials experienced the highest growth rate of all TAs at 15.6%, significantly less than the prior growth rate of 29.7% in 2023. However, the development is still solid, capturing 10.3% of total development. This TA is prime for development with new gene therapies and drugs targeting the aging population.

Infectious disease (ID) trials moved from second place to fifth, receding in growth by 13.6% due to the decrease in COVID-19 trials. The need for transformative therapies to treat antimicrobial resistance will always be a concern, but there may be studies still affected in planning and initiating post-epidemic. Genitourinary diseases also had a decrease in development from 2023 to 2024.

Metabolic/endocrinology had a steady share of 12.5%, similar to the prior year, fueled by the successful GLP-1 drug class and future enhanced formulations in both obesity and type 2 diabetes (T2D). However, it achieved modest growth of 5.6% compared to the growth spurt of 20.4% in the prior year. Competition in this area is expected to intensify.

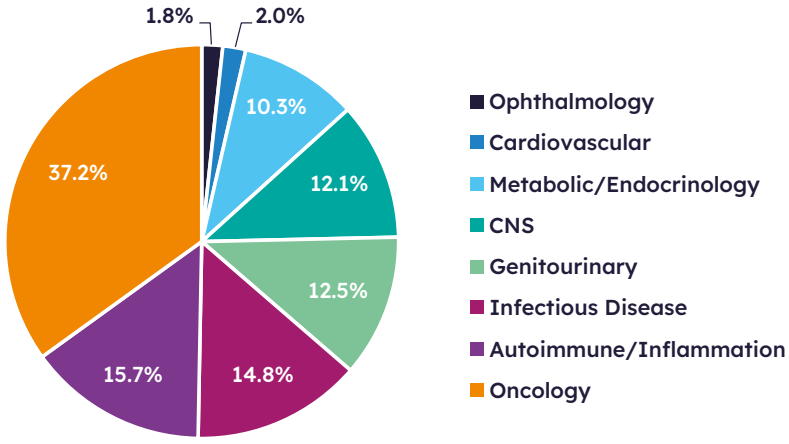
Holding steady in development in 2024 was the modest ophthalmology TA with only a 0.5% increase.

**Figure 1:** Phase I–III clinical trial initiations by therapeutic area, 2023–24[2]




Source: Trialtrove, June 2025

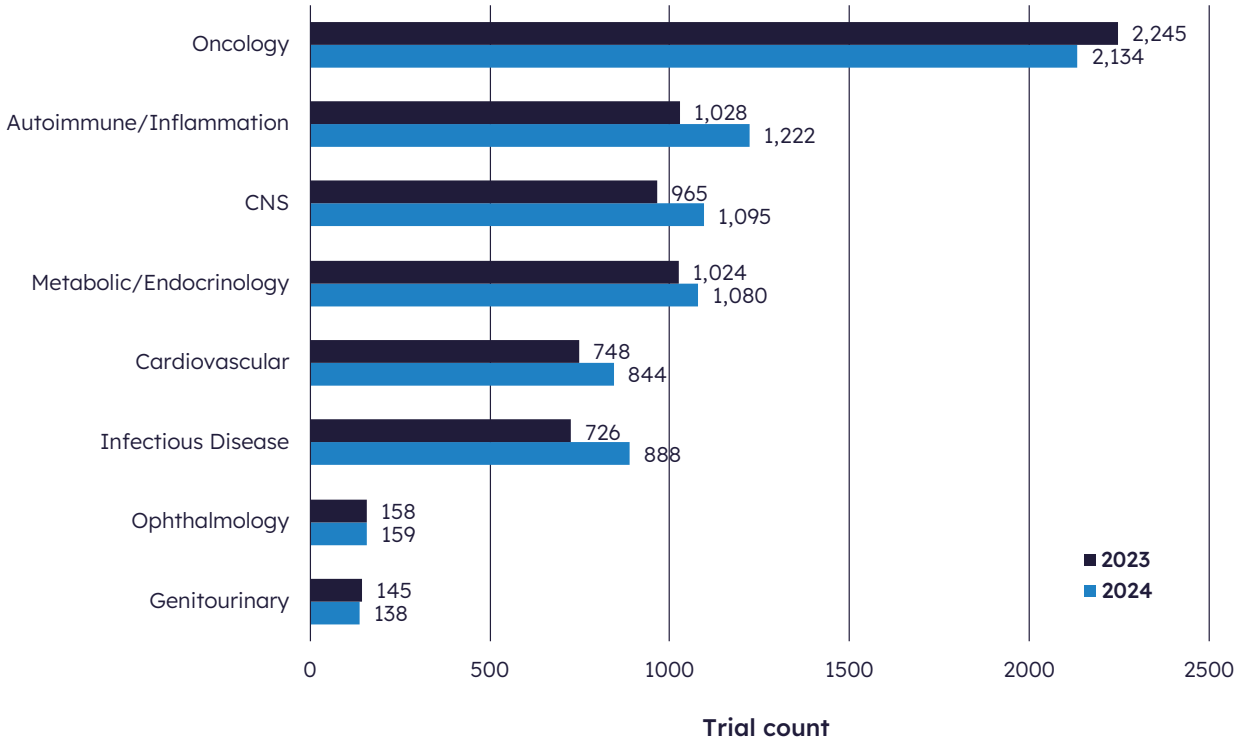
**Figure 2:** Therapeutic area share: 2024 trials




Source: Trialtrove, June 2025

Interestingly, if we look at only industry-sponsored trials in Figure 3, oncology was still the forerunner, but with a decline of 4.9%. However, the area still captured 30.3% of development. The A/I TA took the second-place spot for industry-sponsored trials with a 17.3% share of development, followed by CNS trials with a 15.5 % share.

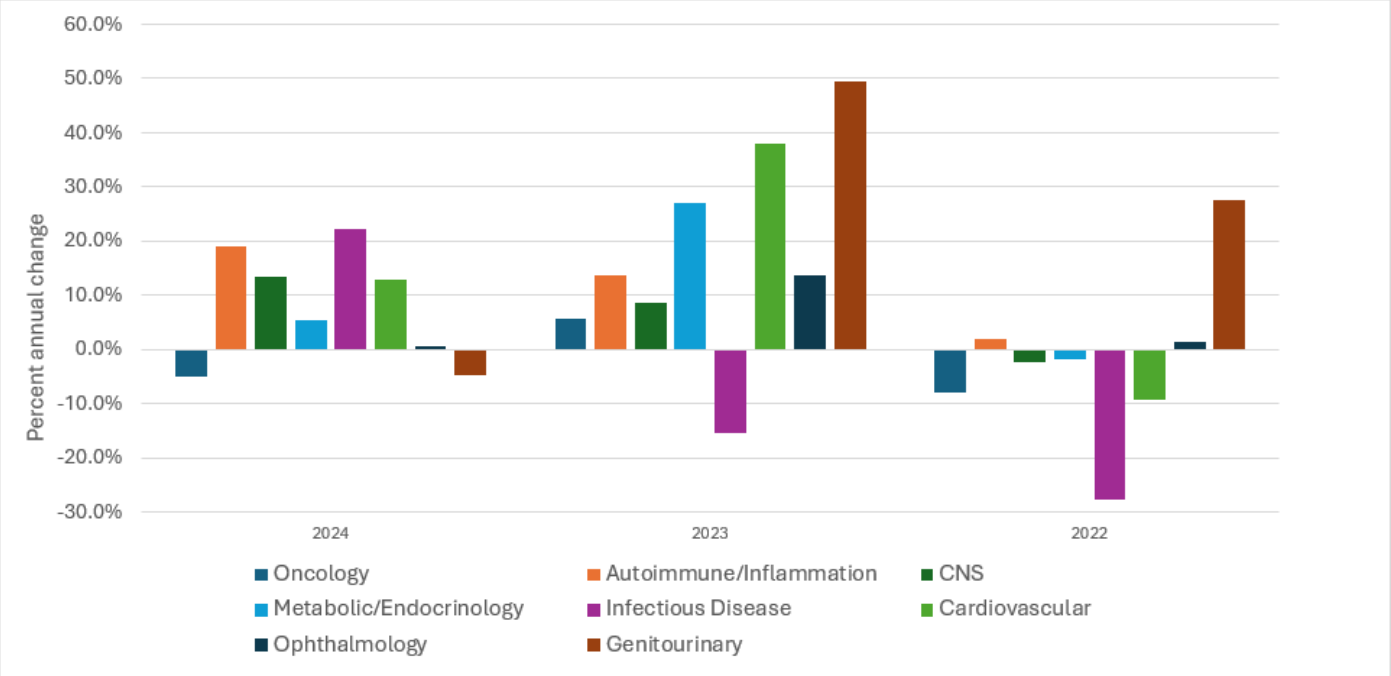
**Figure 3:** Phase I–III industry-sponsored clinical trial initiations by therapeutic area, 2023–24




Source: Trialtrove, June 2025

Figure 4 shows the annual change of each TA for trial initiations for industry-sponsored trials. Notable increases occurred in A/I (18.9%), CNS (13.5%), and cardiovascular (12.8%). The success of CAR-T cell therapy in oncology proved to be translatable to autoimmune diseases, thus opening new grounds in the A/I TA. The impressive upswing in cardiovascular since 2023 can be attributed to the rising prevalence in growing aging population and the focus shift towards preventative therapies. New technological advancement in RNA-targeted therapy like Leqvio (inclisiran) has shown great promise in addressing underlying biological conditions rather than just managing symptoms. The biggest declines are oncology (-4.9%) and genitourinary (-4.8%).

**Figure 4:** Industry-sponsored trial growth rates, 2022–24

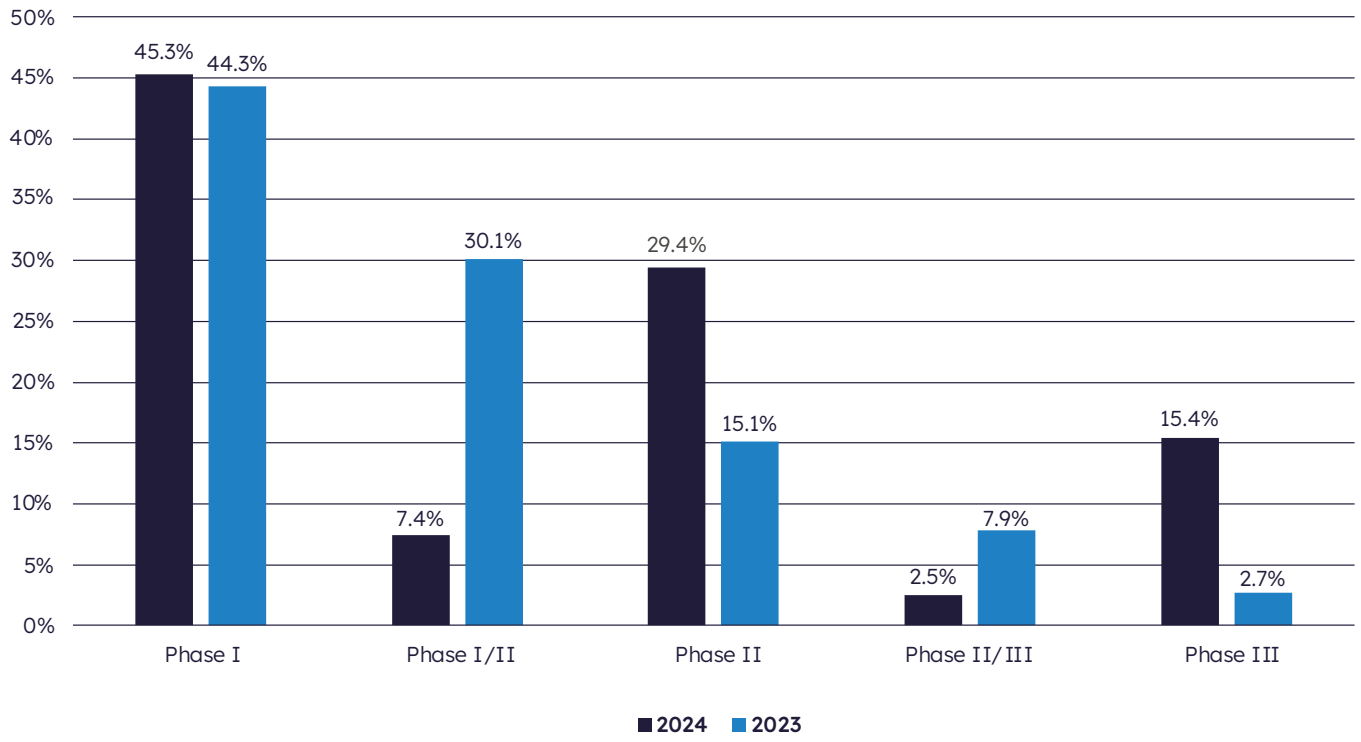



Source: Trialtrove, June 2025

# Phases of Trial Activities

Overall, 2024 revealed a healthy pipeline of trials across phases with increased development in Phase I, II, and III trials. Figure 5 shows a normalized view of the phase distributions, showing the percentage of each phase against the total trials in the respective years. Phase I trials appeared to experience little change, which may signify a stagnant early development pipeline. However, Phase II trials increased significantly by 14.3% and even more spectacular is that Phase III trials increased by 12.7%. This shows an amount of success with drugs moving past the crucial Phase I and II obstacles. Our annual edition of the Pharma R&D Review 2025 by Ian Lloyd reflected on the change and noted that "the more drugs making it through to Phase III will continue to feed the burst of new drugs hitting the market we've been seeing this decade, this is clearly a good thing."[3]

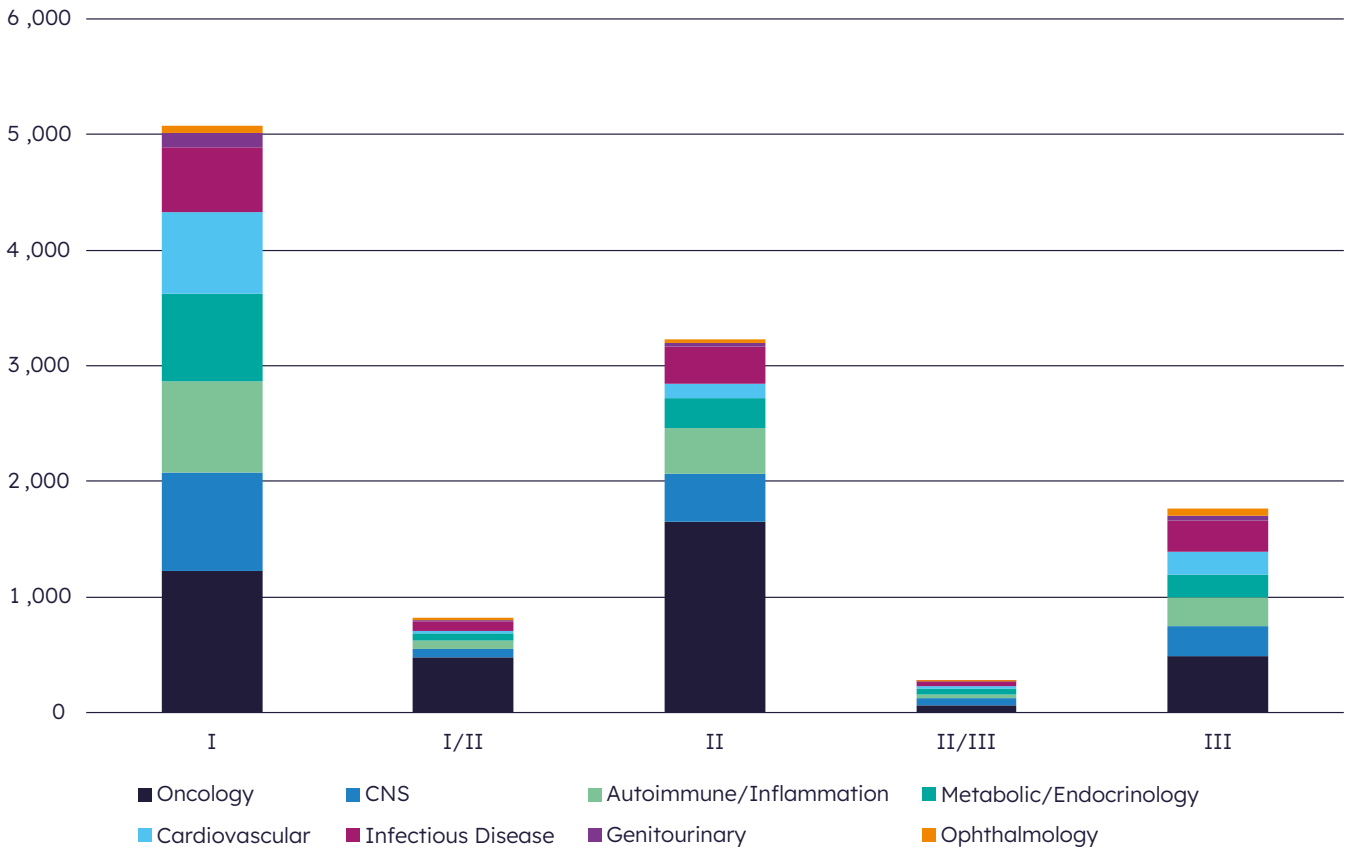
**Figure 5:** Distribution of Phase I–III clinical trials by trial phase, 2023–24




Source: Trialtrove, June 2025

Focusing on specific TA compositions by phase as shown in Figure 6, we can see a somewhat even distribution of Phase I and Phase III trials in each area. Interestingly, the CNS, ID, metabolic, and cardiovascular areas had twice as many trials in Phase I as II, suggesting an earlier stage pipeline, but also possible earlier attrition. Oncology had the most development occurring in Phase II (42%). The only TAs that had an increase from Phase II to III trials were cardiovascular, genitourinary, and ophthalmology.

**Figure 6:** 2024 trials by phase and TA




Source: Trialtrove, June 2025

# Top Disease Areas of 2024 Trial Initiations

Each year we analyze the top diseases for clinical trial activity to get a glimpse of where research efforts are taking place (Figure 7). Once again, non-small cell lung cancer (NSCLC) holds the top spot for clinical trial initiations in 2024, followed by breast cancer, which climbed from the third spot last year. Oncology diseases comprised five of the top 10 diseases.

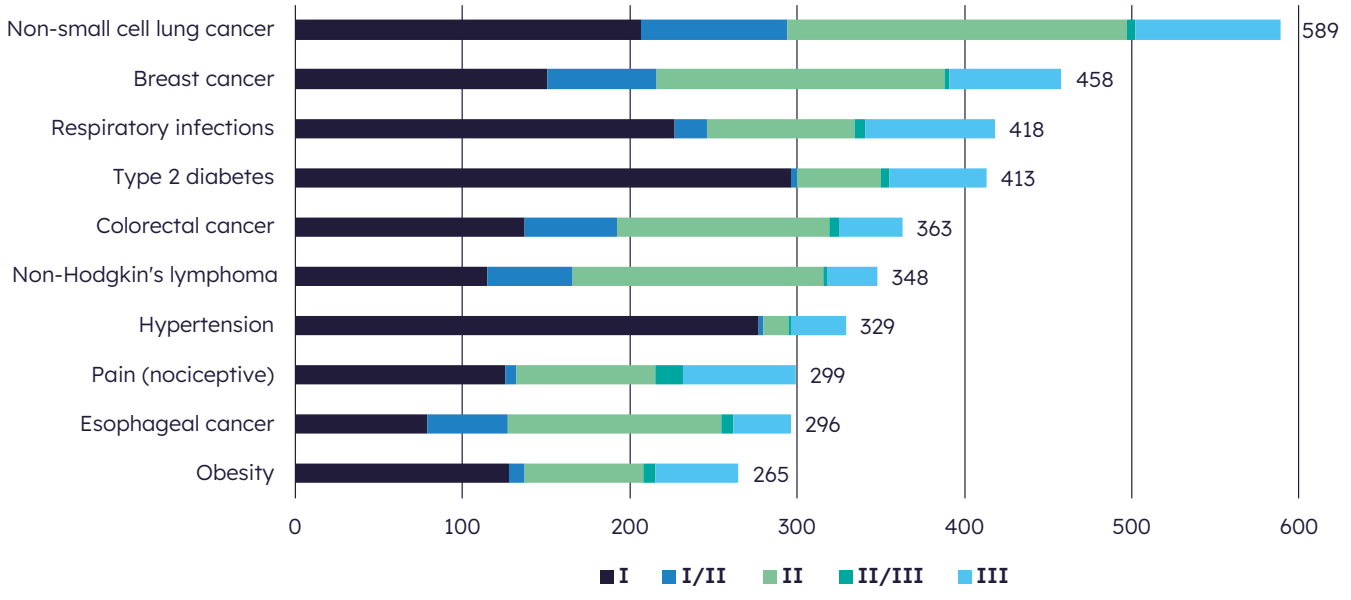
Overall, T2D fell in the ranking from #2 to #4 in initiations. However, the disease had the most Phase I trials that started, followed by hypertension and respiratory infections, alluding to the fact that new drugs have entered the pipeline in these areas.

Interestingly, esophageal cancer entered the top 10 diseases for trial initiations this year at the #9 spot (#12 in 2023). This shows the development and importance of rare disease drug development. Obesity was also absent from the list last year but made the most impressive ascent to #10 in 2024 from #24 in 2023, fueled by glucagon-like peptide-1s (GLP-1s). "Novo Nordisk's Ozempic/Wegovy (semaglutide) and Eli Lilly's Mounjaro (tirzepatide) are clearly fueling a boom in anti-obesity drug development."[3]

The principal diseases in Phase III development slightly changed with NSCLC capturing the blue ribbon at #1, showing progression from Phase II trials in 2023. Respiratory infections captured the #2 spot, with breast cancer and pain (nociceptive) tied for third place. T2D, which claimed the #1 spot in Phase III trials in 2023, fell into fourth place in 2024. However, T2D had the most trial initiations in Phase I for 2024, showing a commitment to new therapies/enhanced formulations.

Missing from the overall 2024 top 10 disease trial initiations were COVID-19 due to the end of the pandemic, and pancreatic cancer.

**Figure 7:** Top 10 diseases in Phase I–III clinical trial initiations, 2024




Source: Trialtrove, June 2025

**Table 3:** Top 10 diseases in 2024 and their ranking comparisons to 2023

| Disease | # of trials | Rank (2023 rank) |
|---|---|---|
| Non-small cell lung cancer | 589 | 1 (1) |
| Breast cancer | 458 | 2 (3) |
| Respiratory infections | 418 | 3 (4) |
| Type 2 diabetes | 413 | 4 (2) |
| Colorectal cancer | 363 | 5 (5) |
| Non-Hodgkin's lymphoma | 348 | 6 (6) |
| Hypertension | 329 | 7 (8) |
| Pain (nociceptive) | 299 | 8 (10) |
| Esophageal cancer | 296 | 9 (12) |
| Obesity | 265 | 10 (24) |

Source: Trialtrove, June 2025

Analyzing industry-sponsored trials, pancreatic cancer made the list at #10. Dyslipidemia also made this list at #8. The biggest leap was made in obesity trial initiations, jumping from #21 to #6.

**Table 4:** Top 10 industry-sponsored diseases in 2024 and their ranking comparisons to 2023

| Disease | # of trials | Rank (2023 rank) |
|---|---|---|
| Non-small cell lung cancer | 404 | 1 (1) |
| Type 2 diabetes | 362 | 2 (2) |
| Respiratory infections | 337 | 3 (3) |
| Hypertension | 304 | 4 (5) |
| Breast cancer | 287 | 5 (4) |
| Obesity | 222 | 6 (21) |
| Colorectal cancer | 216 | 7 (7) |
| Dyslipidemia | 193 | 8 (12) |
| Non-Hodgkin's lymphoma | 183 | 9 (6) |
| Pancreatic cancer | 173 | 10 (9) |

Source: Trialtrove, June 2025

# Rare Disease Trials

The steady upward trend of rare disease trial initiations demands attention. Rare diseases, as classified by Trialtrove, are diseases with a prevalence of 1 in 2,000 people in the EU, or affecting fewer than 200,000 people in the US (equivalent to around 1 in 1,600 people).

Rare disease trial initiations peaked in 2021 and then declined in the subsequent years. In 2024, the development increased once again, comprising 30% of the total trial activity. According to a report from Norstella (Breaking barriers in rare disease drug development), "artificial intelligence (AI) and data-sharing platforms are accelerating drug discovery and reducing uncertainty in rare disease research."[4] Furthermore, both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) are integrating real-world evidence (RWE), allowing rare disease drugs to be approved with smaller datasets.

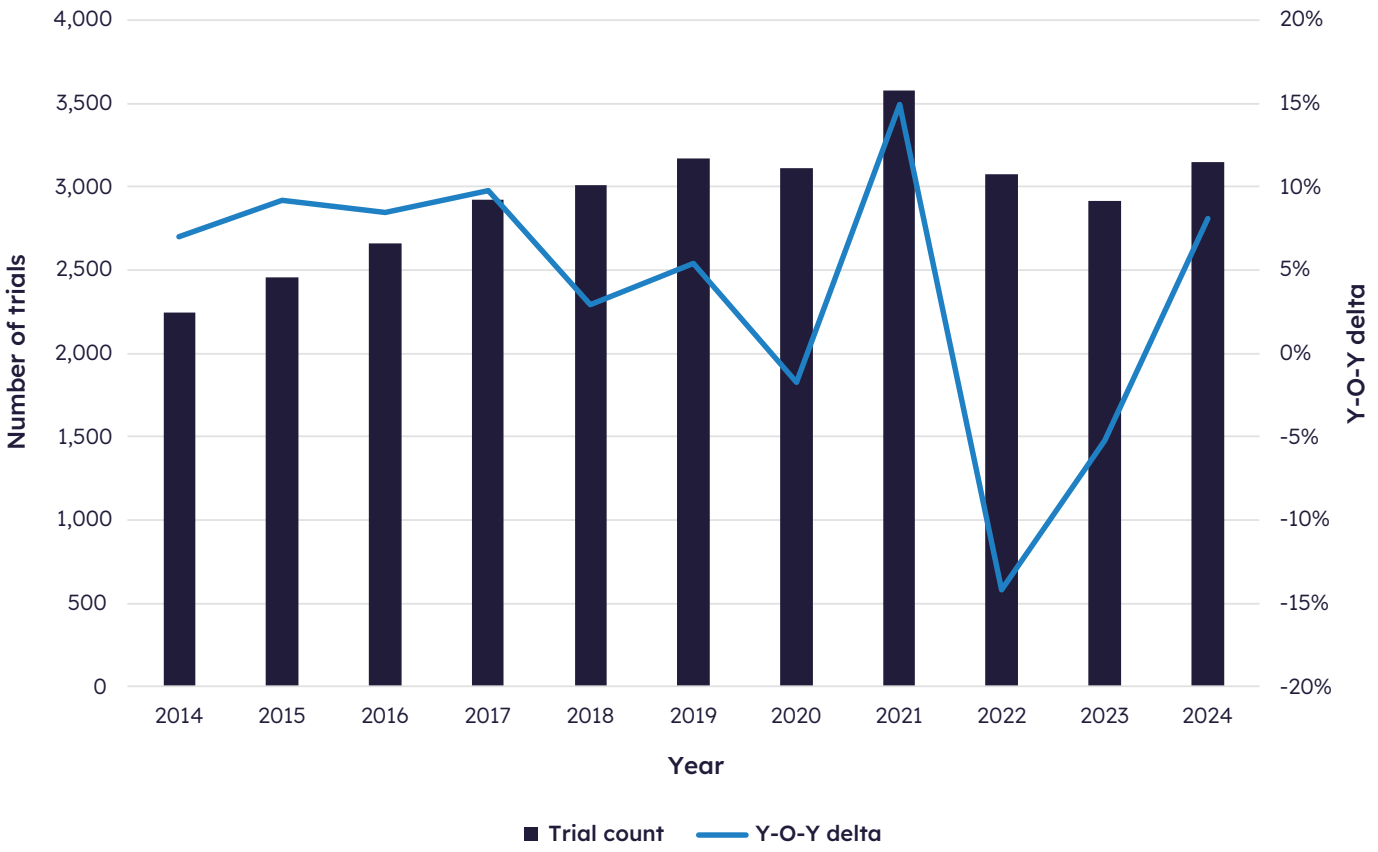
In 2024, The FDA Rare Disease Innovation Hub was created to improve collaboration and consistency between the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). In 2025, the first in a series of meetings on challenging areas in rare disease development called RISE (Rare disease Innovation, Science, and Exploration) was held.

In 2024, 52% of the novel drugs approved by the FDA were for treating rare diseases.[5] Along the same lines, our Pharma R&D Review 2025 reported that "drugs in development against rare diseases this year hit 7,721, up 7.4%, and accounting for 32.3% of the pipeline — almost a third, and up from 31.5% last year."[3]

The National Natural Science Foundation of China has launched a funding program for rare disease research, and the Ministry of Science and Technology has approved the creation of a national key laboratory for complex and rare diseases.

An interesting fact: Sponsorship for rare disease trials was essentially split between industry (48%) and academic entities (52%).

**Figure 8:** Rare disease trial initiations in Phase I–III, 2014–2024



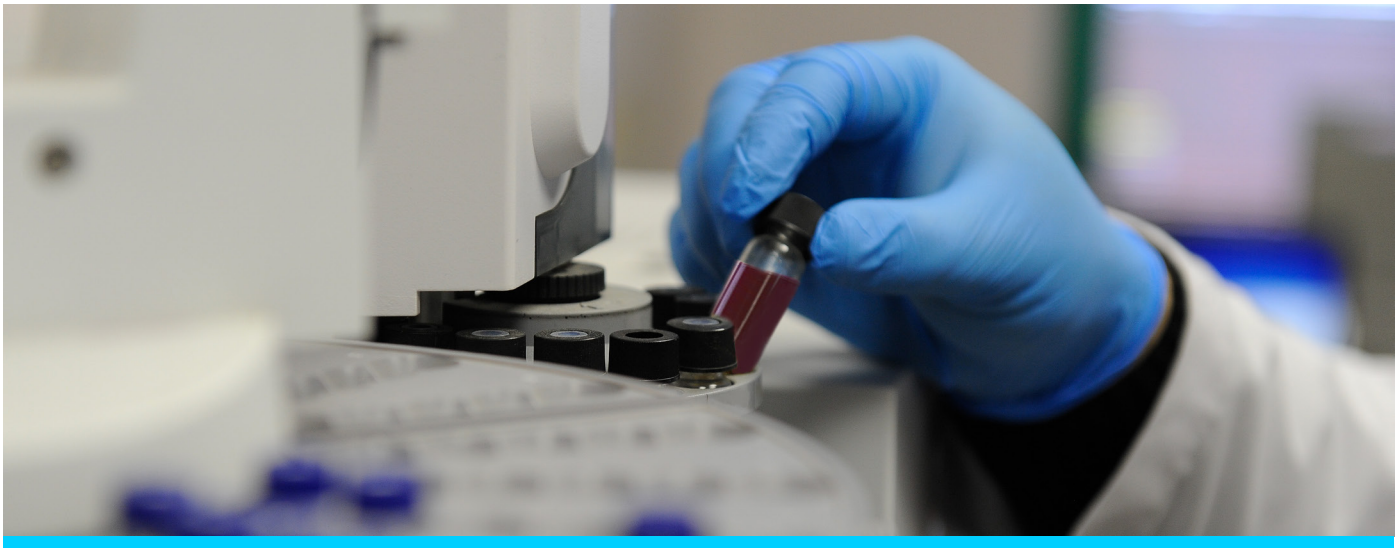

Source: Trialtrove, June 2025

As in past years, the majority of the development was in oncology, comprising the top 10 rare diseases. Non-Hodgkin's lymphoma (NHL) again had the highest number of trial initiations, followed by esophageal cancer as referenced in Table 5. Pancreatic cancer moved out of second place to third, with head/neck cancer and acute myelogenous leukemia (AML) rounding out the top 5. Liver cancer, which was #5 in 2023, moved to #7 with a decrease of initiations in 2024.

**Table 5:** Top 10 rare diseases in 2024 and their ranking comparisons to 2023

| Disease | Trials 2024 | Trials 2023 |
|---|---|---|
| NHL | 348 | 354 |
| Esophageal cancer | 296 | 247 |
| Pancreatic cancer | 259 | 271 |
| Head/neck cancer | 237 | 257 |
| AML | 211 | 173 |
| Ovarian cancer | 210 | 189 |
| Liver cancer | 198 | 228 |
| Neuroendocrine cancer | 156 | 143 |
| Bile duct cancer | 143 | 110 |
| Multiple myeloma | 140 | 155 |

Source: Trialtrove, June 2025



Looking at non-oncology rare disease indications in Table 6, the portfolio is more diverse with greater competition among diseases. Amyotrophic lateral sclerosis (ALS) had the most trials initiated and more than doubled the number of trials from 2023, although it is still less than half of oncology's #10 indication of multiple myeloma. Also notable is scleroderma, which had significantly more trial initiations from 2023 to 2024, moving it into the second spot from #10 in 2023.

Last year's top disease of immune thrombocytopenia (ITP) moved to #8 in 2024, decreasing 27%. Rounding out the bottom places, myasthenia gravis and prurigo nodularis were new contenders. Thalassemia and sickle cell disease, last year at #6 and #8 respectively, did not make the top 10 list for 2024.

**Table 6:** Top 10 rare diseases in non-oncology in 2024

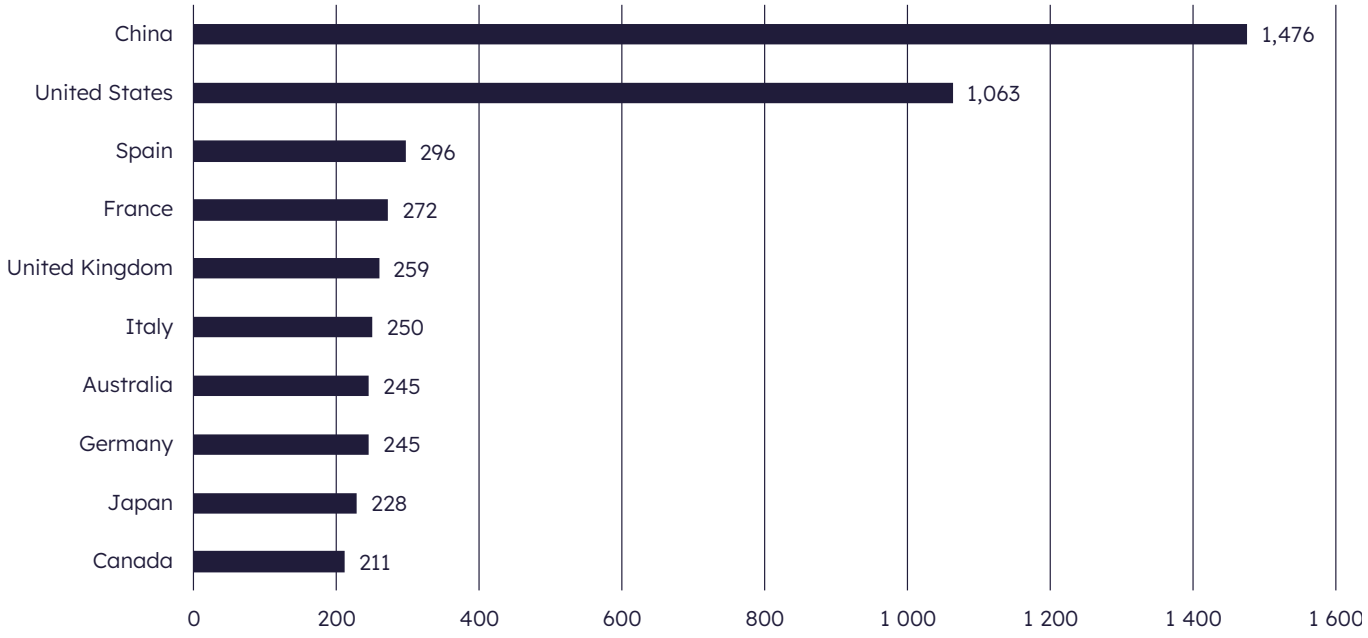
| Disease | Trials 2024 | Trials 2023 |
|---|---|---|
| Amyotrophic lateral sclerosis | 60 | 28 |
| Scleroderma | 44 | 16 |
| Tuberculosis (TB) | 41 | 43 |
| Pulmonary hypertension | 38 | 39 |
| Cystic fibrosis | 36 | 22 |
| Muscular dystrophy | 36 | 24 |
| Dermatomyositis/Polymyositis | 35 | 16 |
| Immune thrombocytopenia (ITP) | 33 | 45 |
| Myasthenia gravis | 30 | 12 |
| Prurigo nodularis | 27 | 8 |

Source: Trialtrove, June 2025

The geographical breakout in Figure 9 shows China once again dominating the area, with 1,476 trial initiations representing 47% of all rare disease development and 14% of all total trials. Relying on its quick development timelines and low costs, China is hoping to continue to be a leader in this area. The US came in at a distant second with 1,063 trials, representing 34% of rare development or 10% of the total market. Japan's Ministry of Health, Labour and Welfare (MHLW) has eased regulatory requirements for novel drugs targeting rare diseases, allowing approval filings without Japanese clinical trial data under specific conditions, which we imagine will boost their position in subsequent years. In 2024, Japan was #9 on the list, but we envision there will be positive movement in years to come.

Overall, the top 10 countries remained the same, with slight movements between Italy and Australia.

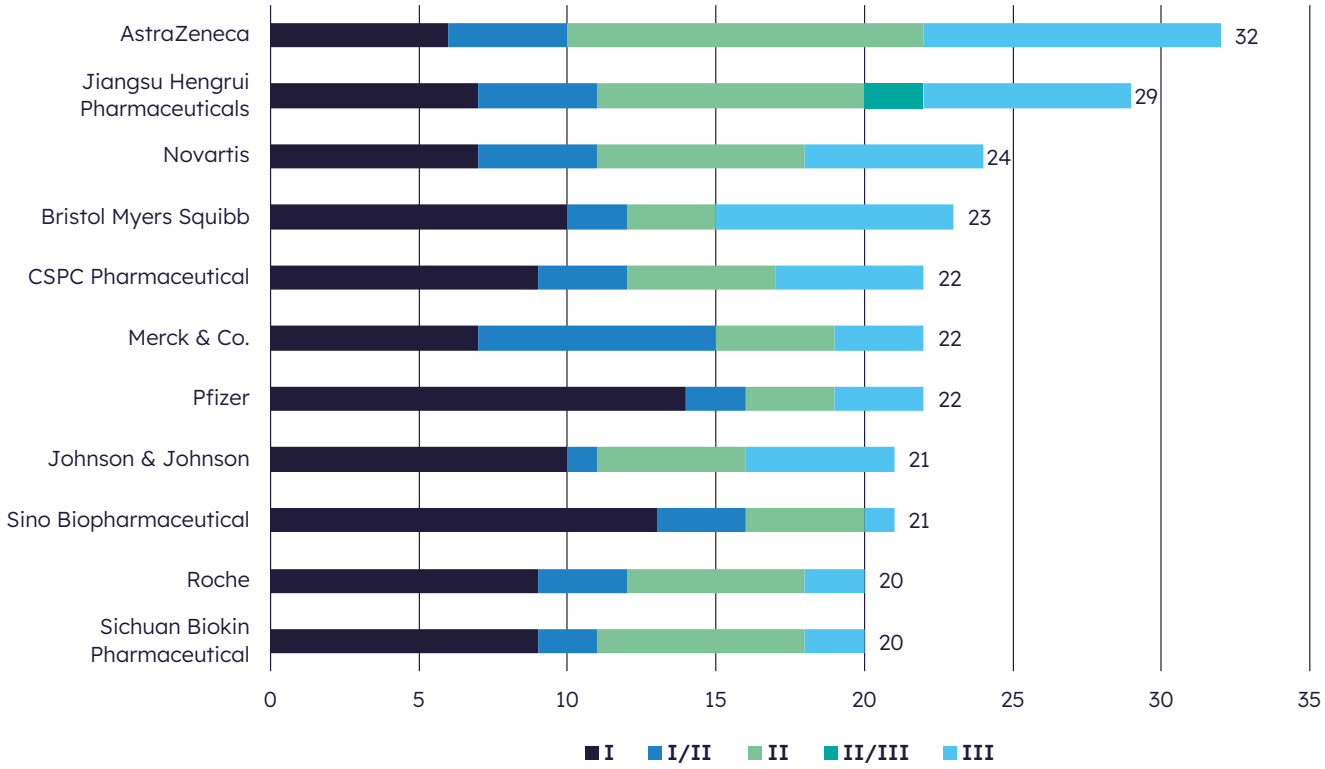
**Figure 9:** Top 10 countries of rare disease clinical trials in 2024




Source: Trialtrove, June 2025

AstraZeneca took the lead for sponsoring rare disease trials, ousting Roche from the #1 spot it held in 2023 (Figure 10). Chinese company Jiangsu Hengrui was a close second place. Echoing China's commitment to the rare disease space, CSPC Pharmaceutical entered the list at #5 and Sino Biopharmaceutical remained on the list, moving from #7 to #9. Chinese companies comprised four of the top 10 sponsors this year, with Sichuan Biokin Pharmaceutical tying with Roche for the #10 spot. The prolific investment of these Eastern companies nudged Sanofi off the list (11).

**Figure 10:** Top industry sponsors in rare disease clinical trials, 2024




Source: Trialtrove, June 2025

# Key Industry Sponsors in 2024 Trial Initiations

Table 7 shows the top 10 industry sponsors for trial initiations in 2024. The biggest surprise is that Jiangsu Hengrui, which was #5 last year, had the most in 2024 overall, replacing AstraZeneca in the first-place position. According to the Pharma R&D Review 2025, Jiangsu Hengrui Pharmaceuticals had a 19.1% increase in its R&D portfolio.[3]

Roche, previously tied for #3 with Merck & Co., fell off the top 10 list and landed at #12 this year with 54 trials. Also falling off the list were Bristol Myers Squibb (BMS), previously #6 and now #13, and Novartis, previously #9 and now #16. These top 10 sponsors contributed to 12% of all industry-sponsored trial initiations in 2024, with the majority of trials (55%) being Phase I or I/II (468 out of 847).

**Table 7:** Rankings of top 10 industry trial sponsors, 2024

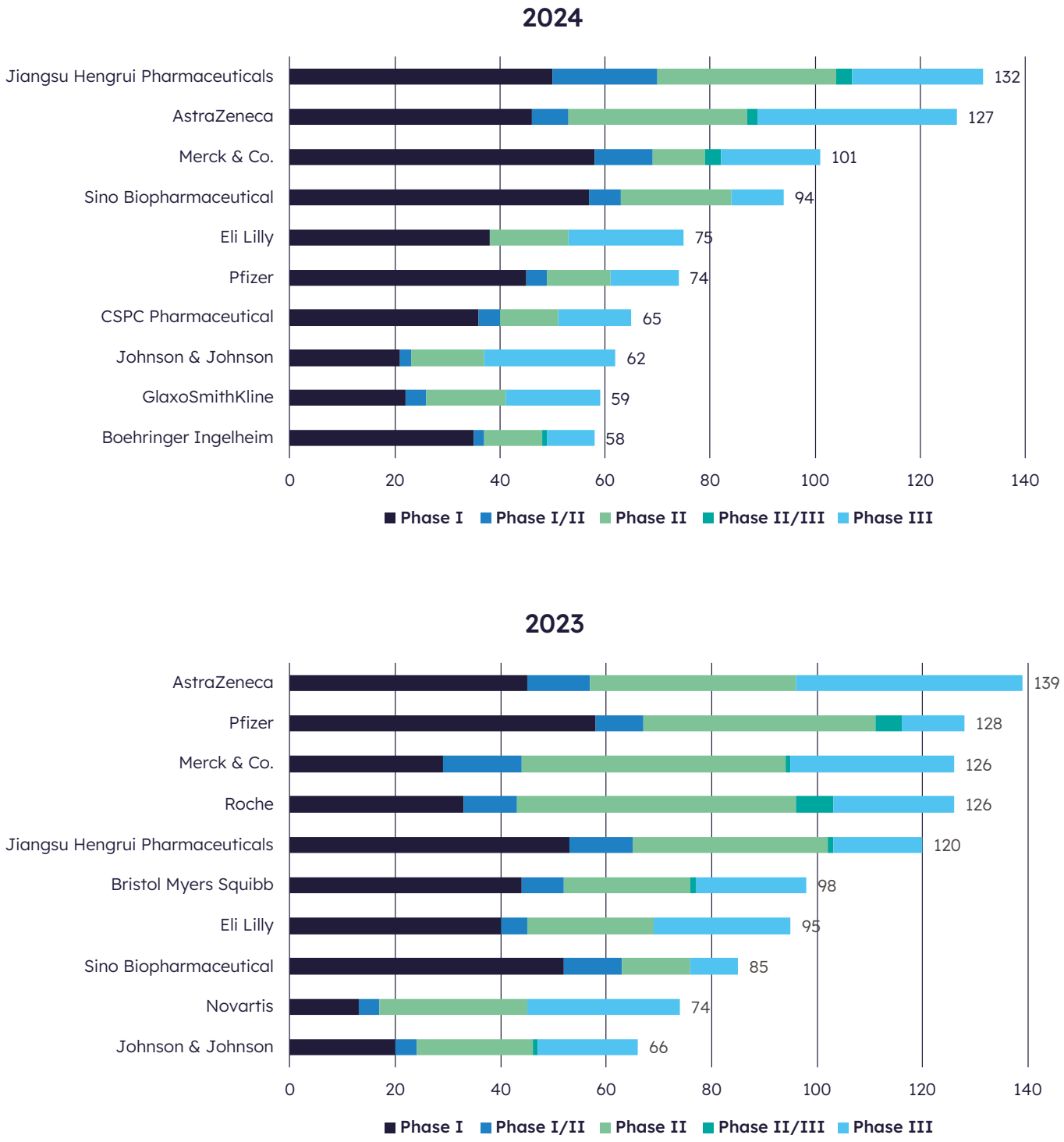
| Sponsor | Rank 2024 (2023) | Trials 2024 (2023) |
|---|---|---|
| Jiangsu Hengrui Pharmaceuticals | 1 (5) | 132 (120) |
| AstraZeneca | 2 (1) | 127 (139) |
| Merck & Co. | 3 (3) | 101 (126) |
| Sino Biopharmaceutical | 4 (8) | 94 (85) |
| Eli Lilly | 5 (7) | 75 (95) |
| Pfizer | 6 (2) | 74 (128) |
| CSPC Pharmaceutical | 7 (14) | 65 (56) |
| Johnson & Johnson | 8 (10) | 62 (66) |
| GlaxoSmithKline | 9 (12) | 59 (64) |
| Boehringer Ingelheim | 10 (16) | 58 (49) |

Source: Trialtrove, June 2025

Phase I–III trial distributions across these sponsors revealed that AstraZeneca had the most late-stage trials at 38, followed by Jiangsu Hengrui and Johnson & Johnson, both at 25 trials (Figure 11). Merck & Co. had the most Phase I trials at 58, signaling a commitment to new drug candidates and/or diseases. Sino Biopharmaceutical was a close second at 57 Phase I trials, and third runner-up was AstraZeneca at 46.

Surprisingly, even though overall industry-sponsored clinical development was up 3.6% for 2024, the number of trial initiations of the top 10 sponsors was down almost 20% from 1,057 trials to 847. This represents 12% of all industry-sponsored trials, suggesting that small-medium pharmaceutical and biotech companies initiated the other 88% of trials. Phase I trials were up 5%, but Phase II and Phase III decreased 47% and 16% respectively, alluding to early attrition in the pipelines.

**Figure 11:** Top 10 industry sponsors by trial distributions in Phase I–III, 2023–24




Source: Trialtrove, June 2025

# Top Disease Focus by 10 Most Active Sponsors

We now examine the disease focus of the top 10 industry sponsors, comparing primary diseases tested. Table 8 shows the top 3 diseases of each sponsor for both 2023 and 2024. The number of unique diseases increased from 16 in 2023 to 20 in 2024, including the additions of asthma, melanoma, and Alzheimer's disease.

Consistency was key as six of the 10 companies retained their top disease focus, including #1 Jiangsu Hengrui, continuing its commitment to T2D while also focusing on obesity. Eli Lilly also remained committed to obesity, with T2D its second focus. Its current pipeline lead and potential future blockbuster, orforglipan, is being tested in both indications.

CSPC (breast cancer), Johnson & Johnson (multiple myeloma), GSK (HIV), and Boehringer Ingelheim (pulmonary fibrosis) also kept the same top diseases.

Six out of the 10 companies maintained robust oncology pipelines, with at least one of the top 3 being NSCLC or breast cancer. AstraZeneca more than doubled down on the NSCLC area increasing trial initiations, including the popular bispecific antibodies and ADCs, from 12 in 2023 to 27 in 2024.

In fact, NSCLC was the highest priority disease among the top 10 sponsors, followed by obesity and respiratory infections. Although 2023 also saw NSCLC as the top disease, the 2023 second-place winner, breast cancer, moved to #5. The rise of obesity, fueled by the popular GLP-1 franchise and the development of next-generation drugs, is clearly an area to watch, with the potential to climb even further in 2025. New delivery/dosing technologies, combination formulations targeting comorbidities, and reduced side effects are all exciting innovations on the horizon.

Merck & Co. also appears to have redirected focus to dyslipidemia (14 trials) and melanoma (11 trials) yet still has a core focus in NSCLC (13 trials).

China's Sino Biopharmaceutical, which in 2023 had the most oncology trials, has three new indications taking the top spots: respiratory infections (9 trials), COPD (6 trials), and asthma (5 trials). However, we expect oncology trials to spike again after the recent acquisition of LaNova Medicines with bispecific/trispecific antibodies, monoclonal antibodies, and ADCs in the pipeline.

Pfizer focused on HIV (14 trials) fueled by the ViiV Healthcare joint venture including GSK and Shionogi, followed by NSCLC (12 trials), and respiratory infections (11 trials), which last year held the top spot with 22 trials.

**Table 8:** Top diseases by the most active sponsors, 2024 vs. 2023

| Top diseases by trial volume | | | | |
|---|---|---|---|---|
| **Company** | **Year** | **#1** | **#2** | **#3** |
| Jiangsu Hengrui Pharmaceuticals | 2024 | Type 2 diabetes (13) | Obesity (11) | NSCLC, Breast (8) |
| | 2023 | Type 2 diabetes (15) | Breast cancer (12) | Prostate cancer (7) |
| AstraZeneca | 2024 | NSCLC (27) | Asthma (14) | Breast cancer, Dyslipidemia (10) |
| | 2023 | Breast cancer (14) | NSCLC (12) | Bile duct cancer (9) |
| Merck & Co. | 2024 | Dyslipidemia (14) | NSCLC (13) | Melanoma (11) |
| | 2023 | NSCLC (19) | Renal cancer (12) | HIV (8) |
| Sino Biopharmaceutical | 2024 | Respiratory infections (9) | COPD (6) | Asthma (5) |
| | 2023 | Breast cancer (7) | NSCLC (6) | Liver cancer (4) |
| Eli Lilly | 2024 | Obesity (29) | Type 2 diabetes (10) | Alzheimer's disease (8) |
| | 2023 | Obesity (26) | Type 2 diabetes (26) | Dyslipidemia (10) |
| Pfizer | 2024 | HIV (14) | NSCLC (12) | Respiratory infections (11) |
| | 2023 | Respiratory infections (22) | Breast cancer (19) | COVID-19 (10) |
| CSPC Pharmaceutical | 2024 | Breast cancer (9) | NSCLC (8) | Colorectal cancer (7) |
| | 2023 | Breast cancer (8) | NHL (5) | GERD (4) |
| Johnson & Johnson | 2024 | Multiple myeloma (10) | Prostate cancer, Psoriasis (7) | NSCLC, Depression, Crohn's disease (6) |
| | 2023 | Multiple myeloma (13) | NSCLC, Prostate cancer (7) | Psoriasis (5) |
| GlaxoSmithKline | 2024 | HIV (16) | Respiratory infections (14) | Respiratory vaccines (11) |
| | 2023 | HIV (14) | Respiratory infections (7) | Asthma, Ovarian cancer (4) |
| Boehringer Ingelheim | 2024 | Pulmonary fibrosis (11) | Obesity (10) | NAFLD (6) |
| | 2023 | Pulmonary fibrosis (8) | Obesity (7) | Multiple diseases* (3) |

*Acute coronary syndromes; neuroendocrine; schizophrenia; Alzheimer's disease; dyslipidemia; respiratory infections
NSCLC = Non-small cell lung cancer
NHL = Non-Hodgkin's lymphoma

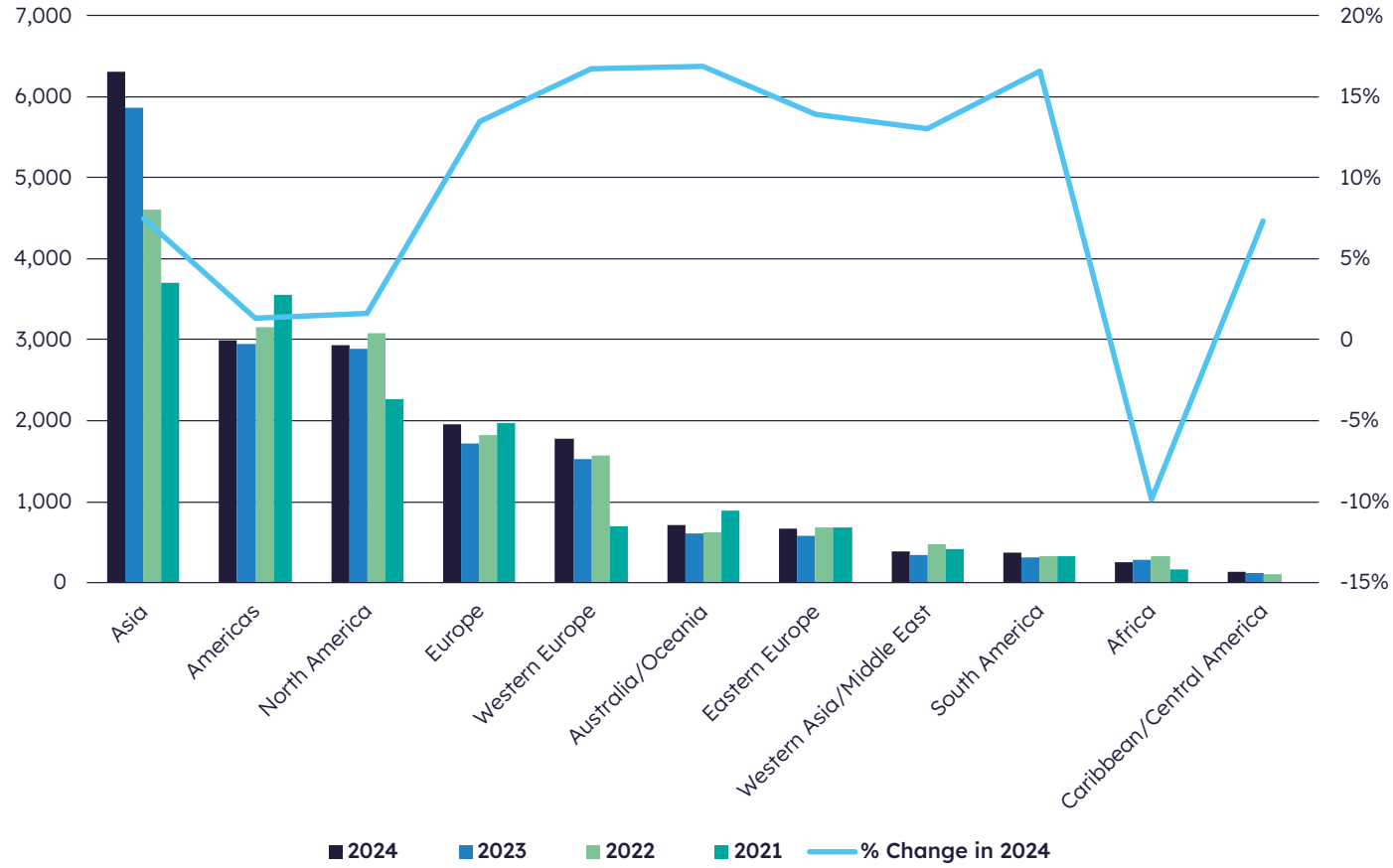
Source: Trialtrove, June 2025

# Geographical Survey of Trial Activity

We now look at the geographical breakout of clinical trial initiations. The past few years have shown that Asia, particularly China, has become a powerhouse for trials, followed by the Americas (including the US). This year is no different. It is obvious that COVID-19 trials were at their peak in 2021 as shown in Figure 12 and that at this time Asia and the Americas were somewhat similar in trial initiations. However, in 2023 a huge spurt in Asia propelled the region to the forefront of development.

Interestingly, every region, with the exception of Africa (-10%), had growth, albeit minimal in some areas. In 2024, the regions with the most prolific growth rates were Western Europe, Australia/Oceania, and South America, all with a 17% increase.

**Figure 12:** Trial distribution by region, 2021–24



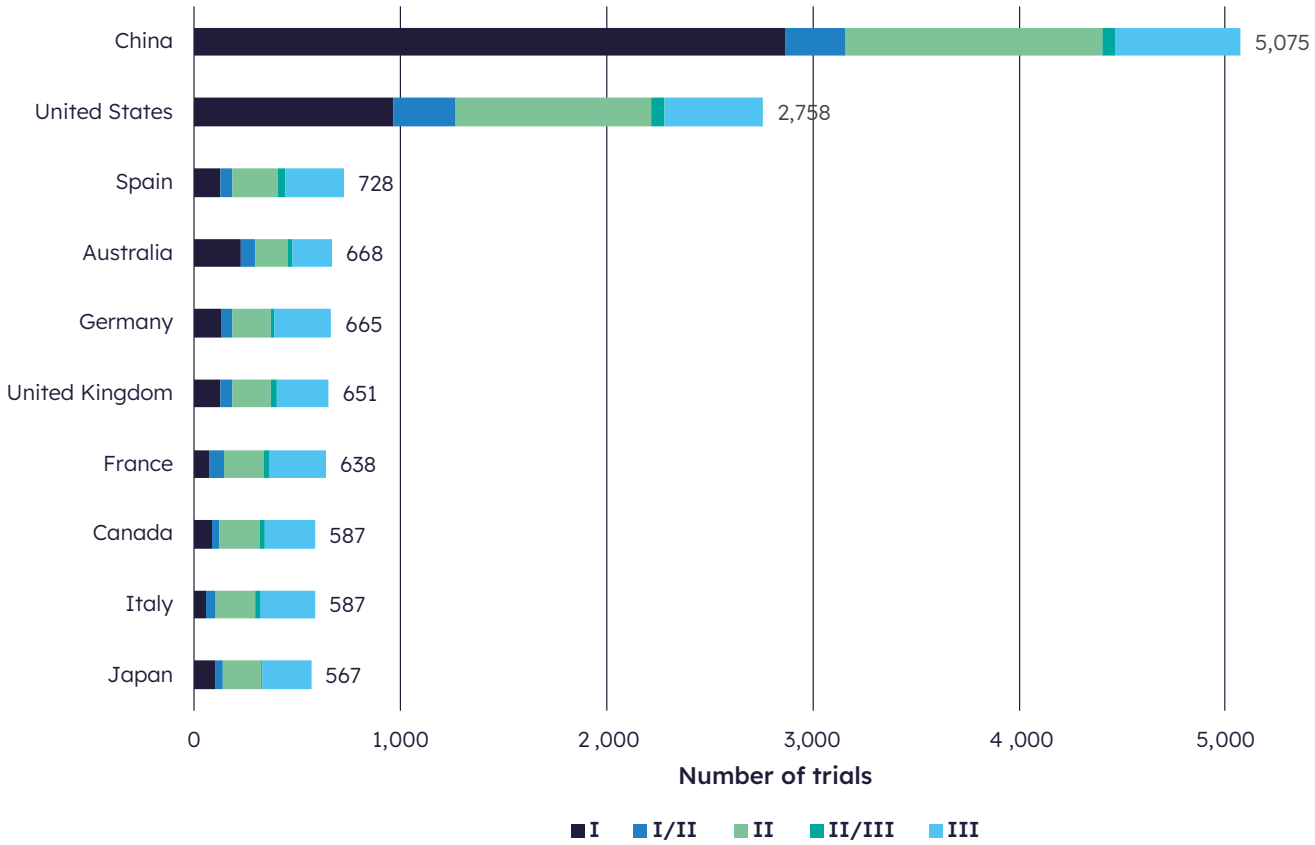

Source: Trialtrove, June 2025

Looking at specific country breakouts in Figure 13, China leads the trial initiations alone, encompassing over 80% of the Asia region. Fueled mainly by Phase I development (2,868 out of 5,075 trial initiations), China's regulatory reforms have sparked a surge in activity with a 10% increase in 2024.

However, it is again important to reiterate specific country requirements for the reporting of Phase I trials. For example, FDAAA 801 (Section 801 of the FDA's Amendments Act in the US) stipulates that Phase I trials are not subject to the mandatory reporting requirement, as all products are already regulated by the FDA. This contributes to a much smaller number of Phase I trials in the US compared to China, and the volume might be more in line if all Phase I trials were reported. The US is currently reporting only 963 Phase I trials.

The European hot spots of Spain, Germany, France, Italy, and the UK, as well as Japan, had the majority of development in Phase III. Australia concentrated on Phase I trials.

**Figure 13:** Top 10 countries by volume of clinical trial initiations, 2024

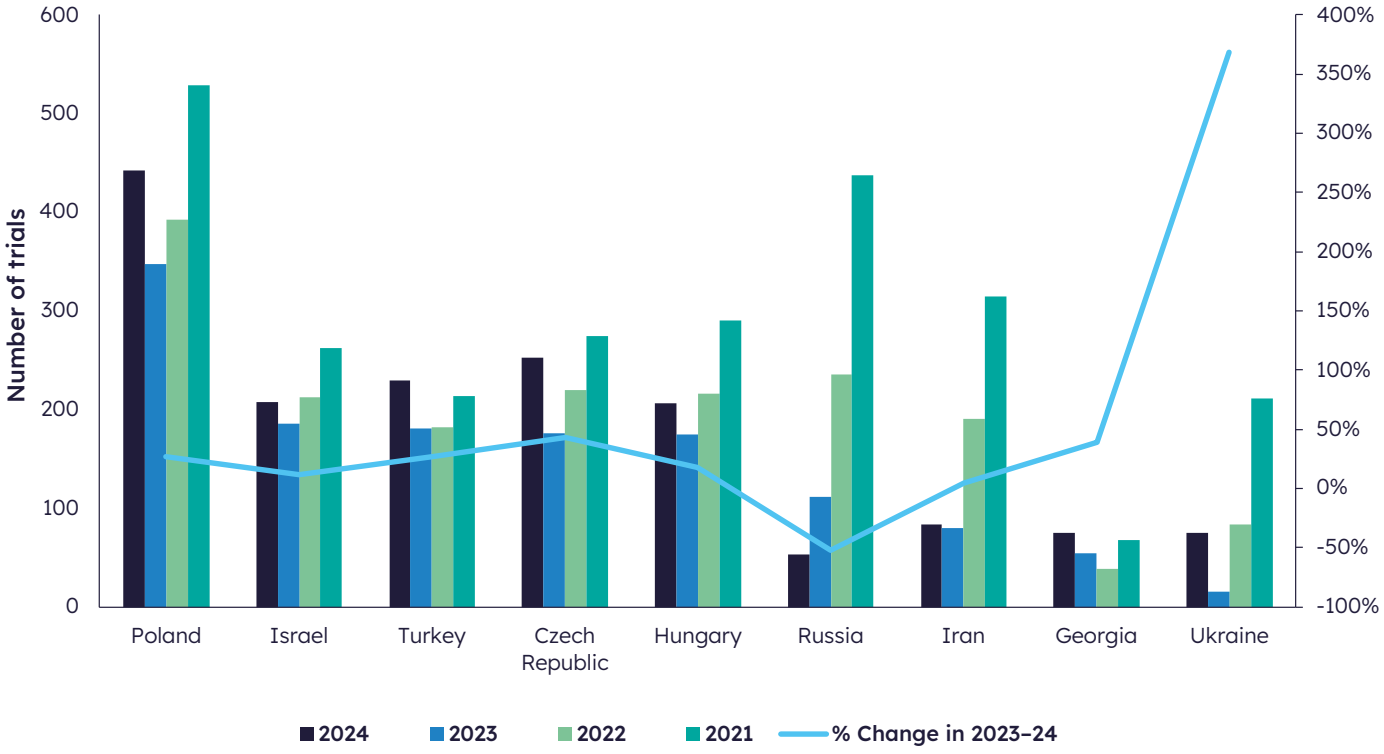



Source: Trialtrove, June 2025

Because geopolitical conflicts have occurred over the past few years, we began evaluating the landscape of those countries affected. The Israel-Hamas conflict, as well as the continued Ukraine-Russia war, have influenced research in these areas, as well as surrounding countries such as Poland, Hungary, the Czech Republic, Iran, Turkey, and Georgia.

We can see recovery in most of the countries, although not back to 2021 levels. Russia is the only country that continues to decline in research (-53%). On a percentage basis, Ukraine had the biggest increase in 2024 trial starts compared to 2023 (369%), followed by the Czech Republic (43%). On a volume basis, Poland had the largest rebound with 442 trials started in 2024, 95 more than 2023. This recovery across these countries is somewhat good news in terms of the future of pharmaceutical development and access to future lifesaving medications. However, in 2025, there will still be geopolitical tensions and risks that may continue to disrupt clinical research in terms of supply chains, new trade barriers, tariffs, and displacement of potential patient pools. This could affect the materials needed for drugs, and thus the future clinical trial landscape.

**Figure 14:** Country-level trial numbers for countries in and near geopolitical conflicts, 2021–24




Source: Trialtrove, June 2025

# Clinical Trials by Country and Therapeutic Areas

We now take a look at therapeutic area focus by the leading countries for 2024 (Table 9). There is no surprise here that China leads development in all areas, followed by the US, exceptions being genitourinary and ophthalmology. Overall, the top 10 country rankings for development are unchanged from 2023.

Oncology continues to be the largest volume area for clinical trials, with 83% of all trials taking place in China (51%) or the US (32%). South Korea which held the #8 spot last year moved to #10, Australia moved from #3 to #5, and Japan slid down the list from #6 to land at #8.

In A/I, Japan moved off the top 10 list after coming in at #8 in 2023, and Italy emerged as #10.

Similarly, Japan, previously #9, also did not make the 2024 list in CNS, and Italy entered at #9 this year. India fell from #3 to #8, and Australia increased its CNS trial starts by 50% to move into fourth place from eighth, focusing mainly on epilepsy, Alzheimer's disease, and depression.

Infectious disease, still normalizing after the COVID-19 pandemic, essentially had the same country ranking in 2024, with trials increasing slightly in all countries except China, which still retained the #1 spot.

In the cardiovascular TA, Canada and Italy rose in trial starts from #7 to #3 and #11 to #8, respectively. Unlike last year, Japan did not make the top 10 list.

Metabolic/endocrinology, fueled in part by the GLP-1 category in obesity and T2D, and the resurgence of the metabolic therapeutic area in general, had trial-start increases in half the countries listed in the top 10. China had the greatest increase, with 107 more trial starts in 2024. The top countries remained the same, with a bit of shuffling between Germany (seventh to fourth), Spain (10th to sixth), Canada (fifth to 10th), and South Korea (fourth to ninth).

**Table 9:** Ranking of top 10 countries by trial volume and TAs, 2024 vs. 2023

| Overall | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 5,075 (1) | 4,618 (1) |
| US | 2,758 (2) | 2,709 (2) |
| Spain | 728 (3) | 596 (3) |
| Australia | 668 (4) | 573 (4) |
| Germany | 665 (5) | 570 (5) |
| UK | 651 (6) | 540 (6) |
| France | 638 (7) | 533 (7) |
| Canada | 587 (8) | 523 (8) |
| Italy | 587 (8) | 502 (9) |
| Japan | 567 (10) | 428 (10) |

| Autoimmune/Inflammation | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 785 (1) | 635 (1) |
| US | 379 (2) | 383 (2) |
| Germany | 165 (3) | 140 (4) |
| UK | 151 (4) | 147 (3) |
| Spain | 146 (5) | 137 (6) |
| Canada | 140 (6) | 140 (4) |
| Poland | 138 (7) | 124 (7) |
| Australia | 137 (8) | 116 (9) |
| France | 135 (9) | 115 (10) |
| Italy | 131 (10) | 94 (11) |

| Oncology | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 2,008 (1) | 1,804 (1) |
| US | 1,257 (2) | 1,221 (2) |
| Spain | 331 (3) | 255 (4) |
| France | 302 (4) | 230 (5) |
| Australia | 259 (5) | 258 (3) |
| Italy | 255 (6) | 195 (7) |
| Germany | 250 (7) | 185 (9) |
| Japan | 238 (8) | 214 (6) |
| UK | 224 (9) | 169 (10) |
| S. Korea | 209 (10) | 190 (8) |

| CNS | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 641 (1) | 569 (1) |
| US | 480 (2) | 413 (2) |
| UK | 102 (3) | 75 (4) |
| Australia | 99 (4) | 66 (8) |
| Spain | 96 (5) | 70 (5) |
| Canada | 91 (6) | 70 (5) |
| Germany | 91 (6) | 69 (7) |
| India | 90 (8) | 86 (3) |
| Italy | 81 (9) | 43 (12) |
| France | 78 (10) | 58 (10) |

| Cardiovascular | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 642 (1) | 551 (1) |
| US | 172 (2) | 149 (2) |
| Canada | 68 (3) | 46 (7) |
| UK | 64 (4) | 49 (3) |
| Germany | 53 (5) | 47 (4) |
| Spain | 52 (6) | 47 (4) |
| Australia | 49 (7) | 43 (9) |
| Italy | 44 (8) | 41 (11) |
| France | 41 (9) | 42 (10) |
| S. Korea | 38 (10) | 43 (8) |

| Metabolic/Endocrinology | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 672 (1) | 565 (1) |
| US | 282 (2) | 284 (2) |
| India | 106 (3) | 91 (3) |
| Germany | 80 (4) | 64 (7) |
| Australia | 74 (5) | 58 (9) |
| Spain | 61 (6) | 55 (10) |
| Japan | 60 (7) | 72 (6) |
| UK | 60 (7) | 63 (8) |
| S. Korea | 59 (9) | 81 (4) |
| Canada | 56 (10) | 74 (5) |

| Infectious Disease | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 434 (1) | 469 (1) |
| US | 302 (2) | 264 (2) |
| Australia | 90 (3) | 52 (4) |
| Japan | 70 (4) | 56 (3) |
| India | 69 (5) | 52 (4) |
| UK | 67 (6) | 52 (4) |
| Canada | 50 (7) | 46 (7) |
| South Africa | 49 (8) | 45 (8) |
| Spain | 49 (9) | 44 (9) |
| France | 47 (10) | 38 (10) |

| Genitourinary | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| China | 111 (1) | 133 (1) |
| Iran | 18 (2) | 19 (2) |
| US | 18 (2) | 19 (2) |
| India | 12 (4) | 14 (4) |
| Denmark | 6 (5) | N/A |
| Japan | 6 (5) | 10 (6) |
| Spain | 6 (5) | 7 (7) |
| Australia | 5 (8) | 2 (20) |
| Egypt | 5 (8) | 14 (4) |
| Canada | 4 (10) | 3 (15) |

| Ophthalmology | | |
|---|---|---|
| Country | 2024 (rank) | 2023 (rank) |
| US | 76 (1) | 89 (1) |
| China | 53 (2) | 59 (2) |
| UK | 24 (3) | 8 (10) |
| Japan | 21 (4) | 11 (3) |
| Germany | 20 (5) | 10 (7) |
| Spain | 20 (5) | 10 (7) |
| Italy | 17 (7) | 6 (12) |
| Australia | 16 (8) | 11 (3) |
| Poland | 14 (9) | 5 (19) |
| India | 13 (10) | 11 (3) |

Source: Trialtrove, June 2025

# Clinical Trials Outlook: AI, Diversity, and Trial Design

The future of global pharmaceutical development is being reshaped by technology, demographics, and constantly changing regulations. Furthermore, there are new sophisticated therapies that could require a shift away from the typical randomized controlled trial (RCT) models requiring specific targeted patient populations.

Technology drivers including AI and machine learning may result in condensed development timelines and better outcomes for patients. Furthermore, digital health has been integrated with wearable devices and remote monitoring which ultimately will expand the use and validity of real-world data (RWD).

According to the *In Vivo* article "Enabling Precision Medicine at Scale Through Digital Innovation and AI," AI and machine learning are emerging as catalysts for clinical research, with nearly $10 billion in deals announced in 2024.[6]

At the same time, regulatory pressures from the FDA, EMA, and China's National Medical Products Administration (NMPA) have differing standards for patient diversity and AI use that may temporarily hinder global trials and slow approvals, even though AI offers the promise of more efficient and inclusive clinical trials. The reliance on decentralized and hybrid trial designs may help support broader geographic and socioeconomic participation.

RCTs are primarily designed for large, heterogeneous populations to detect average effects. However, newer gene/cell therapies or targeted drugs based on biomarkers or genetics can only be tested in the relevant patient population. Each patient's therapy is a custom-made biological product, making a large RCT extremely challenging. Smaller single-arm trials with historical controls and RWE gathered from registries and hospital records can help progress the development and help with long-term effectiveness and safety. Furthermore, rare diseases and orphan indication therapies are increasingly being developed with a very small patient pool.

Comparing modernization in clinical trials from 2023 to 2024, we can see a steady use in decentralized clinical trials (DCTs), innovative designs, and AI. In 2023, there were 603 trials initiated with an element of these designs and in 2024 there were 594.

Table 10 reveals that the top TAs with a DCT element in their trial design were CNS (33% of DCT trials), A/I (20%), and MET (17%). ID, which captured 22% of DCTs last year, did not make the top 3. In 2024, academic (49%) and industry sponsors (52%) almost equally employed these designs, most prevalent in North America (US and Canada), with China entering at #3. Similar to 2023, Phase II trials incorporated this design most frequently, although Phase III use has increased from 23% to 29%.

Innovative designs, including adaptive design, basket, umbrella, synthetic or historical control arms are emerging as approaches. Oncology again leads the charge with 70% of the innovative designs. Industry sponsorship is dominant, also with 70% of trials including one of these elements. Mirroring 2023, the US leads the charge in the area, with Spain and the UK rounding out the top 3.

Trials initiated in 2024 utilizing AI were mainly in the oncology area as well (68%). Industry sponsorship had the majority, but only by one trial. Following right behind were academic trials. Interestingly, government sponsorship made the top 3 in this category at #3. North America dominated (71%) with China following. Phase I trials included this element most prominently.

**Table 10:** Phase I–III clinical trials attributed with elements of modern trial designs, 2024*

| Total trials | DCT | 232 | Innovative designs | 324 | Artificial Intelligence (AI) | 38 |
|---|---|---|---|---|---|---|
| Top TAs | CNS | 76 | Oncology | 227 | Oncology | 26 |
| | A/I | 47 | CNS | 26 | CNS | 9 |
| | MET | 39 | A/I | 26 | A/I | 4 |
| Sponsor type | Academic | 114 | Industry, all other pharma | 148 | Industry, all other pharma | 24 |
| | Industry, all other pharma | 79 | Academic | 152 | Academic | 23 |
| | Industry, top 20 pharma | 42 | Industry, top 20 pharma | 78 | Government | 7 |
| Top countries | United States | 114 | United States | 202 | United States | 21 |
| | Canada | 41 | Spain | 65 | China | 10 |
| | China | 36 | UK | 63 | Canada | 6 |
| Phase | II | 100 | II | 115 | I | 15 |
| | III | 68 | I | 101 | II | 14 |
| | I | 44 | I/II | 61 | III | 11 |

*Trial designs above are based on text searches within the Trialtrove trial records and may exclude trials that do not explicitly mention the key terms searched.

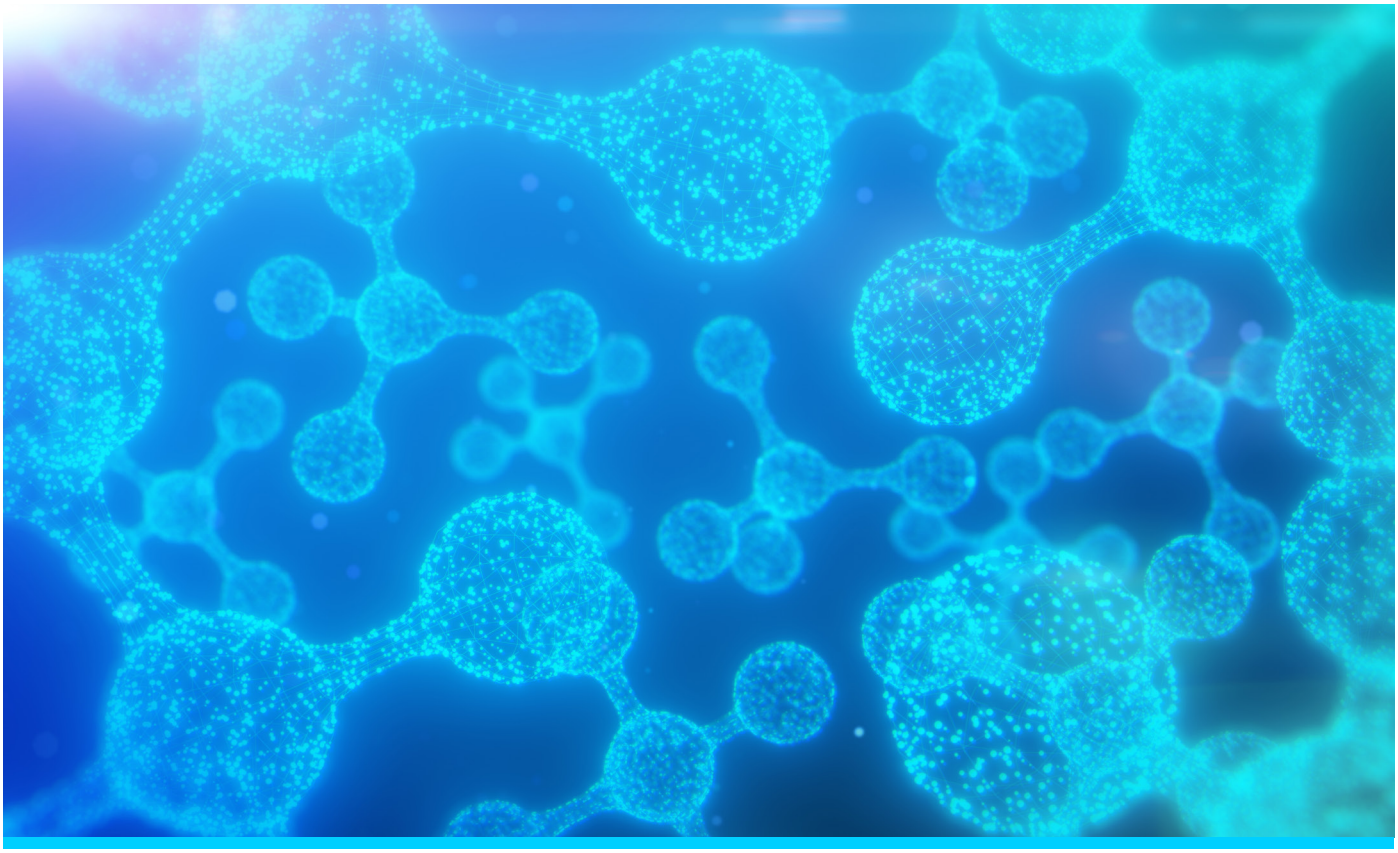
Source: Trialtrove, June 2025

# Concluding Thoughts

The continued growth of clinical trial initiations in 2024 is clearly a positive sign of the sustained rebound that began in 2023. Innovative trial design and the use of AI/machine learning should help the industry grow even more in the coming years. Furthermore, the shift toward niche drugs — more specialized, high-value therapies targeting rare conditions — has gained traction and is projected to continue this trajectory with the easing of clinical trial restrictions. In addition, drugs that are preventive and contribute to longevity are projected to grow with the aging population.

However, geopolitical risk and trade wars have emerged as serious risks for the pharmaceutical sector, potentially increasing the cost of drugs and slowing development. China, which manufactures a large amount of active pharmaceutical ingredients for Western companies, could be impacted by a trade tariff war, which will trickle down the pipeline and raise the cost of drugs. To combat this, some major pharmaceutical companies have announced increased investments in US manufacturing facilities.

With many political unknowns, changing regulatory standardization policies, and the evolution of trial designs, the next year is shaping up to be a very interesting one to watch.



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[1]World Health Organization (2024) Over 1 in 3 people affected by neurological conditions, the leading cause of illness and disability worldwide. Available from https://www.who.int/news/item/14-03-2024-over-1-in-3-people-affected-by-neurological-conditions--the-leading-cause-of-illness-and-disability-worldwide

[2]Trials that include multiple indications across different TAs will be counted for each targeted TA. As such, the sum of trial counts for the eight TAs will be higher than the total number of Phase I–III trials started in 2024. Trial counts for ID include activity from vaccines (infectious diseases), which is a separate TA module within Trialtrove. For the purposes of this analysis, all ID activity has been combined into a single TA.

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[6]Thompson C and Lisowska JA (2025) Enabling Precision Medicine At Scale Through Digital Innovation And AI. *In Vivo.* Available from https://insights.citeline.com/in-vivo/innovation/enabling-precision-medicine-at-scale-through-digital-innovation-and-ai-MB3A4XI26BAO3FSJ5VXJ42VGNY/

# Meet the Authors

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Shannon supports various areas of clinical trial intelligence, specifically in the oncology therapeutic area. Having decades of experience in the clinical trial and biopharmaceutical industry, she has a deep understanding of customer business needs as a past consultant for Citeline.

With extensive primary and secondary research experience, Shannon excels in conducting in-depth data analyses utilizing a variety of applications and applies these methods to construct detailed solutions that provide answers to various client clinical data requests.

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Associate Director, Research & Commercial Services

Heidi Chen supports client engagement with Citeline content through a deep understanding of customer business needs, seasoned expertise in proprietary platforms, market analysis, and commercial activities.

She oversees Citeline's production of customized Platinum Datapacks across hot topics facing the industry today. Heidi draws from her pharmaceutical industry experience as a drug discovery scientist and over two decades of therapy-area expertise in CNS, immunology, and ophthalmology.

Within this remit, she collaborates across various functional groups within Citeline, and contributes towards projects such as consulting engagements, webinars, and thought leadership white papers.

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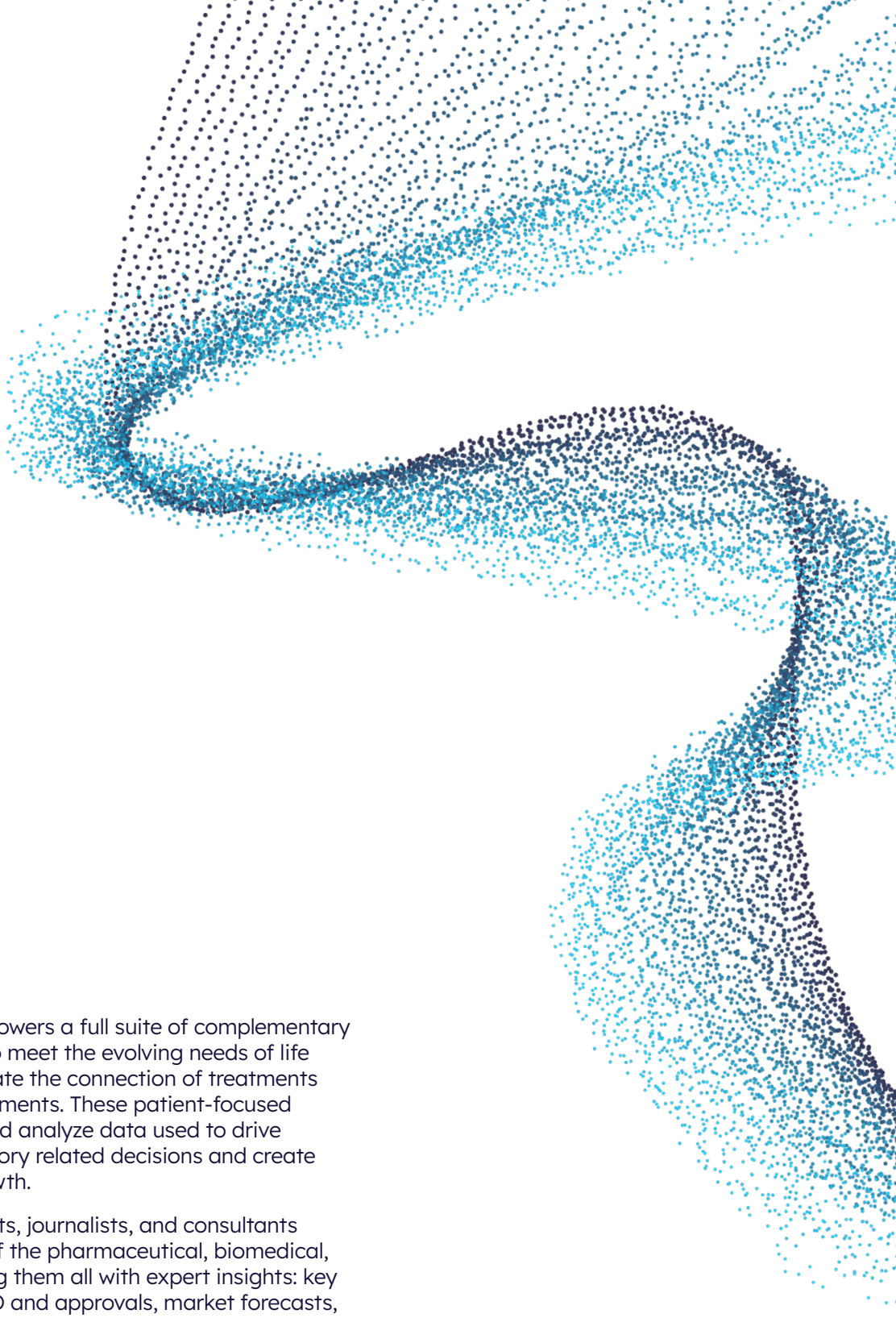

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Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory related decisions and create real-world opportunities for growth.

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