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Annual Completed Clinical Trials Report

Strong headwinds and winds of change

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Introduction

Trialtrove recorded 4,364 industry-sponsored clinical studies from Phase I through Phase III/IV that either reached completed status or attained primary endpoints during 2025. This is an 11% decrease from the previous year, which reported 4,903 completed trials. An additional 1,002 trials were noted as terminated in 2025, which is a 13% decrease from 2024 (1,153).[1]

After the last two years of consecutive gains seen for completed studies across every therapeutic area (TA), this year's results landed more flat-footed, recording minimal advancement and even mild to moderate regression for most TAs. However, there was a significant increase in the number of trials which meet their primary endpoints in 2025 and an increase in the number of positive, pivotal trials, making 2025 a year of quality over quantity. The average success rate increased for sponsors that completed at least 25 positive trials this year and for diseases associated with at least 25 positive trials. Additionally, all top 10 sponsors in the autoimmune/inflammation (A/I) therapeutic area had a higher success rate in A/I trials.

In comparison with the sponsor representation, the top 20 pharma companies again achieved a high degree of performance in several of the topline trial metrics and top TA coverage. The results displayed similarity in the measurements to those noted last year, with consideration to completed trials and positive results, but have accounted for lower overall numbers from those seen in 2024. All other pharma (AOP) also displayed a decrease in total activity but did amount to nearly twofold more trials than the top 20 pharma and definitively established presence in the pipeline status drugs for positive, pivotal results. Throughout the analysis, new trends become apparent, not only for how the industry fared in 2025, but also for new focus diseases, novel pharmaceuticals in the pipeline, key company contributions, wins, and more.

These results are pulled annually to reflect the landscape of the pharmaceutical industry. This assessment reflects a snapshot of the industry, and results change as the database is continually updated. As these results are extracted at the same point every year, we are also reliant upon the trial details to be publicly disclosed for our trial results prior to the analysis. These results are also subject to reporting bias or delays as trial completions are determined from a variety of public sources (trial registries, press releases, etc.). In 2025, the government shutdown reportedly delayed the processing and posting of clinical trial records to ClinicalTrials.gov.[2] These delays could have affected our data for the fourth quarter of 2025.

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Topline Trial Landscape Metrics

The completed trial result counts of 2025 for the represented TAs are evaluated within Table 1 and reflect the assigned TA rank value and corresponding trial totals. There is limited surprise that through this year's evaluation, oncology remains in the first-place ranking for completed trial activity. The oncology TA volumes have continued to maintain a high number of completed studies, despite marginal differences or even setbacks observed in the alternate TAs. To compare, the No. 2 TA (A/I) posted 702 fewer trials than oncology. Oncology displayed mild regression in the total number of trials (1,421 vs. 1,466). Alternatively, metabolic/endocrinology (met/endo) displayed a continuation in growth as it is captured in the top three TAs for the 2025 results.

Throughout the analysis of the respective TAs, minimal shuffling is found in the ranking of each TA. Comparing the results to that of 2024, there is a decisive decline in the overall count of trials in almost every TA. However, for the first time in the history of our completed trial evaluation, met/endo has stepped into the top three. Met/endo's third-rank placement can largely be attributed to the vast uptick in completed obesity and type 2 diabetes (T2D) trials. This valuation also comes off the back of the CNS TA facing a noteworthy drop in completed trial value, with some 123 fewer completed studies reported compared to the year before. Another TA that faced considerable opposition in the number of recorded trial completions was infectious diseases (ID). Through the course of last year, ID reported 182 fewer trials than in 2024. The number of ID trial completions had been on a steep, upward trajectory following the COVID-19 pandemic; however, in the most recent year's results, a disparity emerges where the results violently toppled to near pre-pandemic volumes.

Table 1: Trial counts and rankings for completed trials, by year

Therapeutic area	Ranking				Trial count*			
	2025	2024	2023	2022	2025	2024	2023	2022
Oncology	1	1	1	1	1,421	1,466	1,197	1,096
Autoimmune/Inflammation	2	2	2	2	719	828	758	669
Metabolic/Endocrinology	3	4	4	5	706	698	649	570
CNS	4	3	3	4	688	811	678	619
Cardiovascular	5	6	6	6	329	377	358	293
Infectious Diseases	6	5	5	3	304	672	648	643
Vaccines	7	7	7	7	208	288	286	255
Ophthalmology	8	8	8	8	111	146	136	121
Genitourinary	9	9	9	9	44	70	62	58

*Trials may span multiple therapeutic areas

Source: Trialtrove, February 2026

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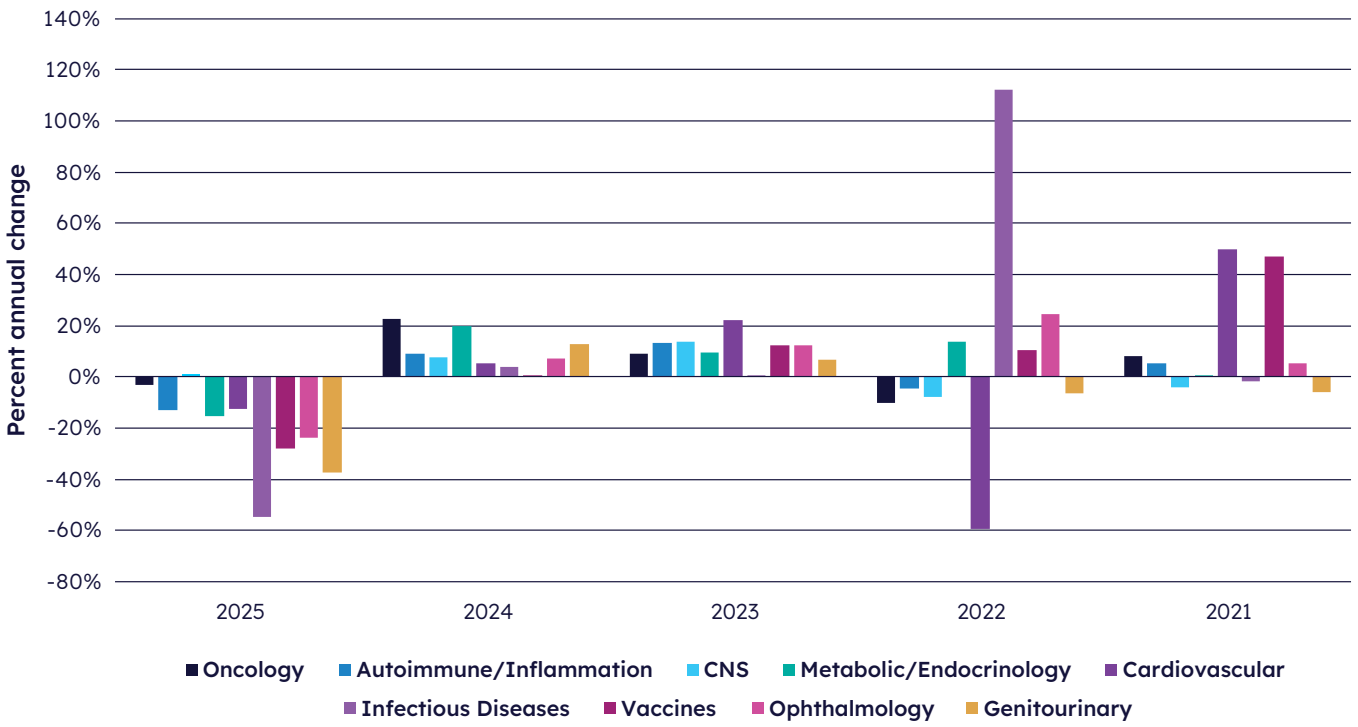
Unlike the past four years of successive growth, the relative annual changes in TA-specific trial activity had a resounding decline. Out of each TA, only met/endo exhibited advancement as the percentage change calculated to a meager 1.1% above last year's high. Throughout the remaining eight TAs, the average percentage drop accumulated to 20% less than 2024's results. Predominantly, the most significant declines were relegated to -55% in ID, -37% for genitourinary (GU), -28% in vaccines, and -24% for ophthalmology. Across the other TAs, less substantial drops were observed for CNS (-15%), cardiovascular and A/I (-13% each), and oncology (-3%). The percentage decline reflects the tangible impact driven by a range of factors, including regulatory changes, economic conditions, and geopolitical events. These include, but are not limited to, shifts in FDA disruptions, government shutdowns, funding cuts, and grant losses.

Figure 1: Relative annual changes in completed trial counts, by therapeutic area



Source: Trialtrove, February 2026

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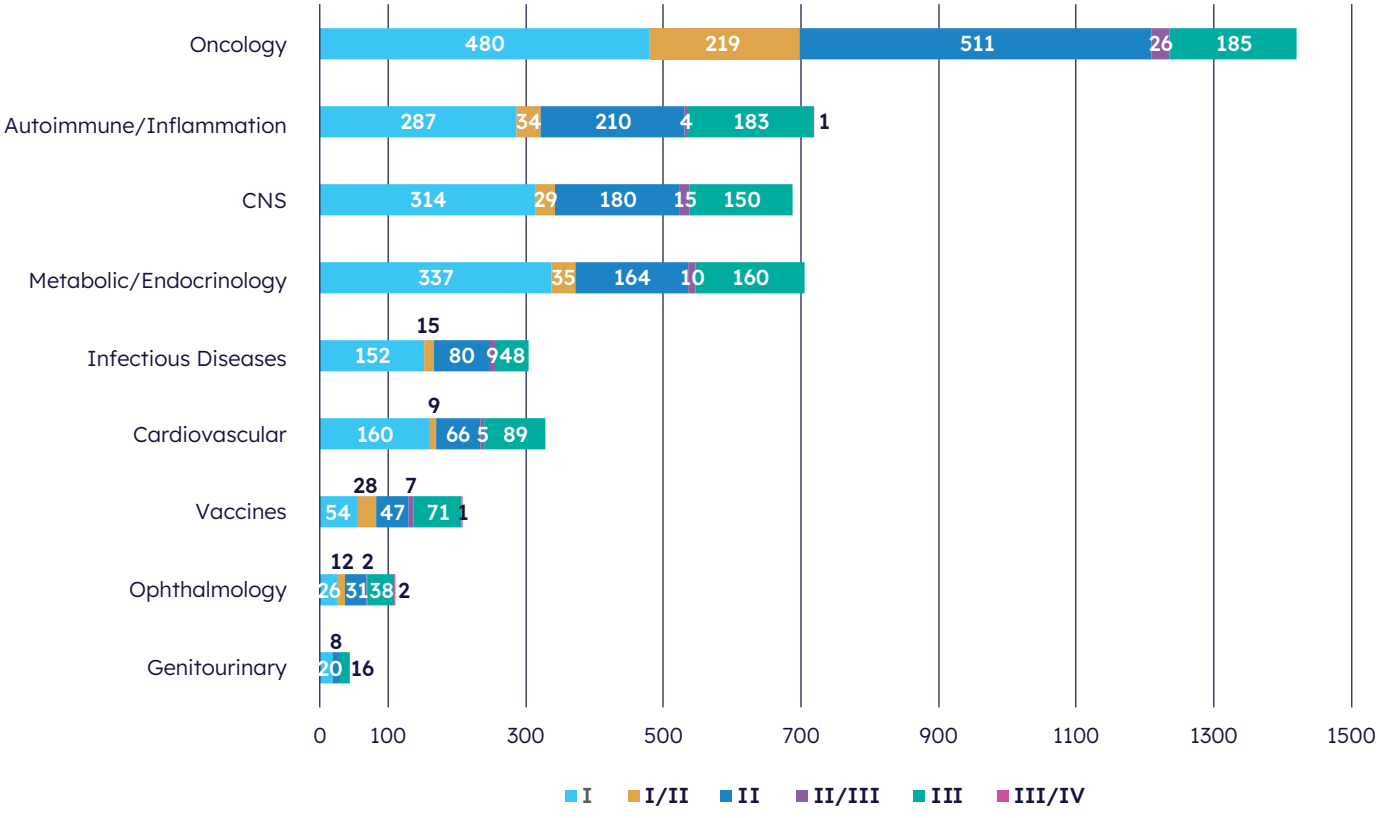
Distribution of 2025 completed trials by therapeutic area and phase

There were negligible changes in the distribution of trials between phases. Consistent with prior years' analysis, early phase trials (I, I/II, II) constitute the majority of completed trials. As has been the case since 2022, oncology has the highest proportion of Phase I–II trials (85%), and vaccines have the lowest proportion of Phase I–II trials (62%).

While the distribution of trials between phases did not change significantly, the number of completed trials decreased by an average of 23.3% for early phase trials and 14.5% for late-phase trials; the most marked difference was a 40% decrease in early stage GU trials (47 to 28). Only the met/endo and oncology therapeutic areas saw growth, both in late-stage trials, with met/endo rising by 15% (148 to 170) and oncology rising by 13% (186 to 211). This increase in late-stage met/endo clinical trial activity can largely be attributed to the increase in GLP-1 trials.

Figure 2: Distribution of industry-sponsored trials completed in 2025, by therapy area and phase



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Top reported trial diseases

Although several of the key diseases noted in 2024 returned in this year's trial evaluations, the top 10 diseases for trial completions in 2025 (Table 2) offered rearrangement of these indications. The top reported trial diseases are composed of both prevalent and rare cancers, high-impacting metabolic diseases, and a viral infection. In the course of a year, only three indications maintained their previously recorded ranking, which were non-small cell lung cancer (1), T2D (3), and colorectal cancer (5). Despite each of the diseases having similar ranking to the year before, only non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) increased their representation of completed studies. NSCLC follows last year's results and again reflects dominance in the top spot. CRC also continues to hold its own as it once again remains in the top five.

Jumping seven places into second, obesity displaced breast cancer. In 2025, obesity bolstered its trial volumes as it completed 59 more studies than in 2024. The rise in completed studies for this disease and the consistency of T2D's trial numbers largely influenced why met/endo TA is captured in the top three TAs. Upon further review of the disease area's experimental drug mechanisms of action, the largest proportion in each of these disease areas were represented by completed trials testing experimental glucagon-like peptide-1 receptor agonist (GLP-1 RA) drugs (73% in obesity and 59% in T2D). The studies displayed a renewed interest in expanding modalities for GLP-1 RA drugs from the upheaval of completed obesity trials.

Advances were also displayed for alternate indications, which not only increased trial volume but also laid new ground in ranking. Indications that experienced positive rank movement and gains in completed trials beyond obesity were non-Hodgkin's lymphoma (6) and head/neck cancer (7), both fall within the rare disease category. Other conditions that improved in rank but declined in trial volumes were pancreatic cancer (8), which listed three fewer trials completed, and ovarian cancer (10) which reported six fewer trials and reappeared in the top 10. Again, both indications are designated as rare, reflecting a rising commitment in rare disease research.

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Two indications declined in rank: breast cancer and novel coronavirus (COVID-19). Each disease displayed normalization in the number of completed trials, albeit for varying reasons. Breast cancer trial totals appear to have regressed to previous values observed (in 2022) for the disease as it lowered completed counts by 55. Even though breast cancer showed lower completed trials, several studies achieved primary endpoints and embodied a disposition of quality over quantity. Separately, COVID-19 continues a downward trend marking continuity in our assessments noted in our 2024 Annual Completed Clinical Trials Report[1] for further stabilization in the trial totals for this disease. The persistence of lower COVID-19 trials since the peak recorded in 2021 (354), in conjunction with stricter vaccine policy announced by the US Food and Drug Administration (FDA), tracks toward trends moving even lower in 2026.[3]

Among the companies that contributed to completed trial disease areas, we find prominent results noted from AstraZeneca (AZ) and Daiichi Sankyo, with products like Enhertu, for HER2-positive breast cancer. Additionally weighing in was Eli Lilly for the positive results outlined in their Phase III TRIUMPH trial of retatrutide.[4]

Table 2: Top 10 diseases for trials completed in 2025 and comparison to prior three years

Disease	2025	2024	2023	2022
Non-small cell lung cancer	254 (1)	242 (1)	202 (3)	160 (4)
Obesity	184 (2)	125 (9)	88 (12)	54 (30)
Type 2 diabetes	179 (3)	205 (3)	205 (2)	182 (2)
Breast cancer	176 (4)	231 (2)	155 (5)	174 (3)
Colorectal cancer	151 (5)	149 (5)	101 (7)	102 (7)
Non-Hodgkin's lymphoma*	147 (6)	134 (7)	119 (6)	115 (6)
Head/Neck cancer*	130 (7)	125 (8)	88 (11)	85 (12)
Pancreatic cancer*	121 (8)	124 (10)	71 (24)	54 (31)
Novel coronavirus (2019-nCoV, COVID-19)	117 (9)	196 (4)	255 (1)	304 (1)
Ovarian cancer*	110 (10)	116 (14)	85 (15)	82 (13)

*Rare disease

Source: Trialtrove, February 2026

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Trial success rates

Completed trials are assigned an outcome evaluation (positive, negative, unknown, or indeterminate) whether those studies publicly disclosed safety, efficacy, or biomarker/surrogate efficacy outcomes. The success rates of each disease were assessed and categorized based upon those that exhibited the greatest proportion of positive outcomes and were ranked based on the success of total completed trials in 2025 (Table 3).

Table 3: Diseases with ≥25 completed trials attaining primary endpoint

Disease	I	I/II	II	II/III	III	III/IV	Total	% of all trials	Rank #
Influenza vaccines	2	2	10	0	14	0	28	75.7%	1
Respiratory vaccines	10	8	12	8	28	0	66	64.7%	2
Novel coronavirus (2019-nCoV, COVID-19)	15	7	19	8	24	0	73	62.4%	3
Parkinson's disease	15	2	8	0	3	0	28	57.1%	4
Non-Hodgkin's lymphoma*	17	9	35	0	9	0	70	47.6%	5
Ulcerative colitis	15	0	8	0	6	0	29	47.5%	6
Psoriasis	13	1	4	0	19	0	37	45.1%	7
NAFLD	13	0	12	0	2	0	27	42.9%	8
Obesity	21	3	30	2	21	0	77	41.8%	9
Esophageal cancer*	13	11	13	3	4	0	44	41.5%	10
Rheumatoid arthritis	15	1	4	0	4	1	25	41.0%	11
Atopic dermatitis	14	0	9	0	13	0	36	40.9%	12
Acute myelogenous leukemia	6	11	5	0	3	0	25	40.3%	13
Neuroendocrine cancer*	4	14	10	0	4	0	32	40.0%	14
Gastric cancer	14	9	14	2	4	0	43	39.8%	15
Breast cancer	20	6	24	2	18	0	70	39.8%	16
Nociceptive pain	10	0	5	1	11	0	27	36.5%	17
Non-small cell lung cancer	25	18	31	0	16	0	90	35.4%	18
Bladder cancer	11	4	7	1	7	0	30	35.3%	19
Colorectal cancer	20	15	12	0	6	0	53	35.1%	20
Type 2 diabetes	15	1	17	0	29	0	62	34.6%	21
Prostate cancer	10	4	12	1	5	0	32	34.4%	22
Dyslipidemia	6	0	7	0	21	0	34	34.3%	23
Pancreatic cancer*	11	15	10	0	2	0	38	31.4%	24
Renal disease	9	3	11	1	4	0	28	30.8%	25
Ovarian cancer*	7	10	9	0	5	0	31	28.2%	26
Head/neck cancer*	16	5	10	1	4	0	36	27.7%	27

*Rare disease
Rank # based on percentage of trials attaining primary outcome per disease

Source: Trialtrove, February 2026

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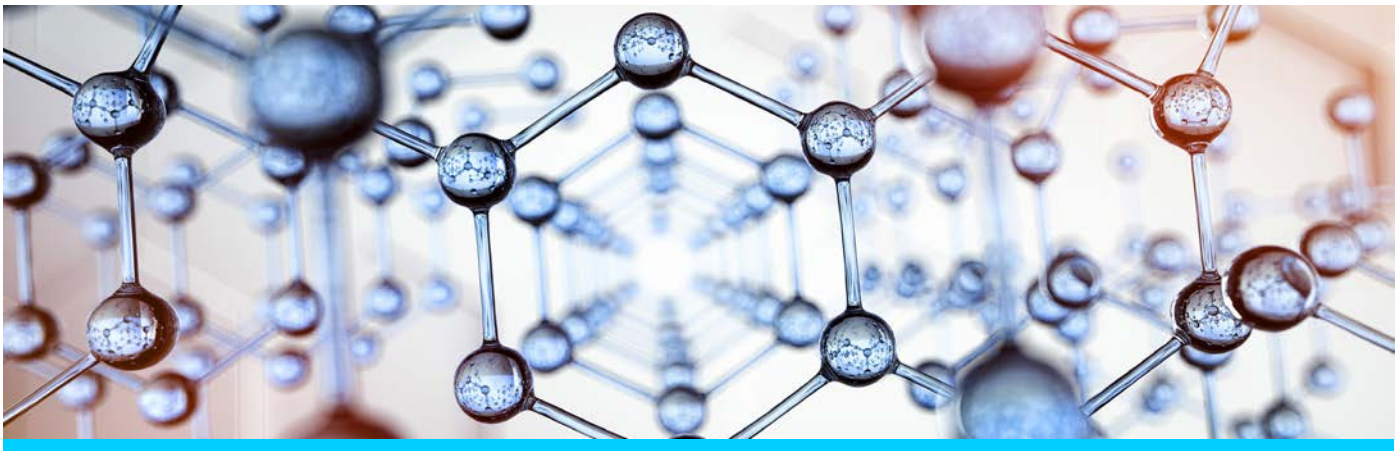
The number of diseases which meet primary endpoints in at least 25 trials essentially did not change from 2024 to 2025 (25 vs. 27), but the average success rate among diseases with at least 25 positive trials rose from 31% to 42%. Additionally, the average success rate for diseases ranked in the top 10 for positive trials was 53%, a substantial increase from 2024's average of 36%. This provides further evidence of a trend seen across multiple therapeutic areas and with multiple sponsors, where fewer trials were completed, but a greater proportion of completed trials had positive results.

All top 10 diseases by total completed trials counts in Table 2 achieved at least 25 successful trials in 2025. Novel coronavirus, non-Hodgkin's lymphoma, and obesity all rank among the top 10, both by completed trial counts as well as by success rate. As with last year, there are more oncological indications on this graph than any other therapeutic area and no GU, ophthalmology, or ID indications surpassed the 25-trial threshold to qualify them for this analysis. The industry's commitment to rare disease research is apparent this year as well, with five rare, oncological indications completing 25 or more positive trials.

Influenza vaccines, ulcerative colitis, NAFLD (non-alcoholic fatty liver disease), and Parkinson's disease did not meet primary endpoints in at least 25 trials in 2024, but in 2025 were in the top 10 diseases when ranked by success rate. Respiratory vaccines, novel coronavirus vaccines, non-Hodgkin's lymphoma and psoriasis remained in the top 10 by success rate this year, although non-Hodgkin's lymphoma rose from ninth to fifth place in 2025 and completed 26 more trials. Obesity fell from third to ninth place, but completed seven more trials, largely due to completing more than twice as many late-stage trials this year (10 vs. 23) and increasing research in GLP-1 medications. Parkinson's disease research has similarly expanded in recent years, with more than half of drugs in development aiming to slow disease progression and several alpha synuclein PET tracers being developed to enable us to more accurately track that progression in living patients.[5, 6]

Breast cancer, bladder cancer, renal disease, and dyslipidemia completed fewer successful trials this year, so they fell out of the top 10 when ranked by success rate. Breast cancer went from sixth to 16th place and completed 10 fewer positive trials in 2025 vs. 2024, although its success rate rose slightly from 35% to 40%. Dyslipidemia fell from eighth to 23rd place with an almost identical success rate (33% to 34%), bladder cancer fell from fifth to 19th place with an unchanged success rate, and renal disease fell from seventh to 25th (34% to 31%).



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Leading Trial Sponsors

Redirecting to assess sponsorship for the completed trials, each of the sponsoring company's trial results were aggregated and quantified for 2025. In this assessment, the company results are reflective of top 20 industry pharma, as determined by sales data in the annual In Vivo Outlook 2026 results, as well as additional AOP, excluding generics-only companies.[7] In the top five sponsors evaluation, for completed trials, these have historically been comprised of top 20 industry sponsors and continue to reflect this grouping (Table 4). For the second year in a row, Merck & Co. is listed as the top ranking sponsor for completed trial results. Merck & Co. nearly replicated their results in 2025 as there was only a difference of 18 trials (210 vs. 228). Moreover, the company consistently upheld notoriety in the oncology space as it saw 123 trials completed for the listed TA, a mere five completed trial differences from that recorded last year (data not shown). Returning to the second ranking, AZ demonstrated significant resolve as it was not only listed in the top five leading trial sponsors but also was among the top five sponsors recorded in each of the top three TAs. Roche distinguished itself through the completed results as it rose to third from fifth and added three completed trials over the previous count. Competition was observed for the fourth-place rank as Bristol Myers Squibb (BMS) and Eli Lilly reflected mirrored, completed study volumes in 2025. Following up the top five sponsors, Pfizer dropped three rank values as the company markedly went to fifth from second.

A granular analysis of the total number of completed trials for the top 20 industry sponsors displayed a count of 1,683 trials this year, a drop of 9% over the 1,853 individual trials recorded in 2024. Additionally, AOP sponsors tabulated a total of 2,872 completed studies in 2025, a nearly 12% decline from the 3,263 completed studies recorded in 2024. As the results are further compared, the shares of top 20 and AOP sponsor numbers last year presented a percentage evaluation of 38% (top 20) vs. 69% (AOP), wherein this year these observations continue as top 20 obtained a slight increase in share, raising an additional percentage point and AOP dropped three percentage points (39% vs. 66%).

Table 4: Top five sponsors* completing trials in 2021–2025

Sponsor	2025 (rank)	2024 (rank)	2023 (rank)	2022 (rank)	2021 (rank)
Merck & Co	210 (1)	228 (1)	152 (3)	116 (4)	140 (3)
AstraZeneca	174 (2)	192 (3)	170 (2)	159 (2)	175 (2)
Roche	155 (3)	152 (5)	118 (6)	116 (4)	115 (7)
Bristol Myers Squibb	133 (4)	184 (4)	147 (4)	142 (3)	177 (1)
Eli Lilly	133 (4)	111 (6)	110 (7)	90 (7)	121 (6)
Pfizer	118 (5)	218 (2)	174 (1)	165 (1)	134 (4)

*Trial count includes cosponsored trials

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Success of industry sponsors was measured by their overall counts of positive trials that attained primary endpoints and was dispersed by trial phase in Table 5. The number of sponsors demonstrating 25 or more positive trials returned to 11 after only 10 sponsors met these criteria in 2024. After last year's findings, Sanofi and AbbVie have each returned in the analysis noting more than 25 studies with positive results, while GSK was not included in the dataset after completing only 22 trials with positive results. Moreover, the list of companies matches those outlined in our 2023 report, sponsor-for-sponsor, although rearrangement was found.

Diving further into the positive results, AZ has achieved the top successful position in this analysis for the past three years. AZ has consistently reported successful positive trial results in excess of 60 (63 in 2025, 68 in 2024, and 64 in 2023), which has led to its top position in the table. Additionally, rising to the occasion, Roche found success in 13 more trials than in our previous coverage to now report 58 studies where primary endpoints were met. Merck & Co. also made strides to maintain its standing as it displayed a modest 52 trials. Looking at the totals between company results from 2025 and 2024, these values show that sponsors are improving on studies which meet their primary endpoints as this year 439 trials were noted for the sum of companies, vs. last year which listed 419 trials.

Table 5: Companies attaining primary endpoints in ≥25 trials, by phase (2025)

Sponsor	I	I/II	II	II/III	III	III/IV	Total
AstraZeneca	4	3	24	0	32	0	63
Roche	10	8	21	0	19	0	58
Merck & Co	4	2	30	1	15	0	52
Eli Lilly	6	3	15	0	17	0	41
Jiangsu Hengrui Pharmaceuticals	15	0	15	0	8	0	38
Sanofi	7	0	14	0	16	0	37
Novartis	8	3	7	0	17	0	35
Bristol Myers Squibb	7	5	14	1	6	0	33
Johnson & Johnson	6	2	7	0	14	0	29
Pfizer	9	2	10	0	6	0	27
AbbVie	4	3	4	0	14	1	26

Source: Trialtrove, February 2026

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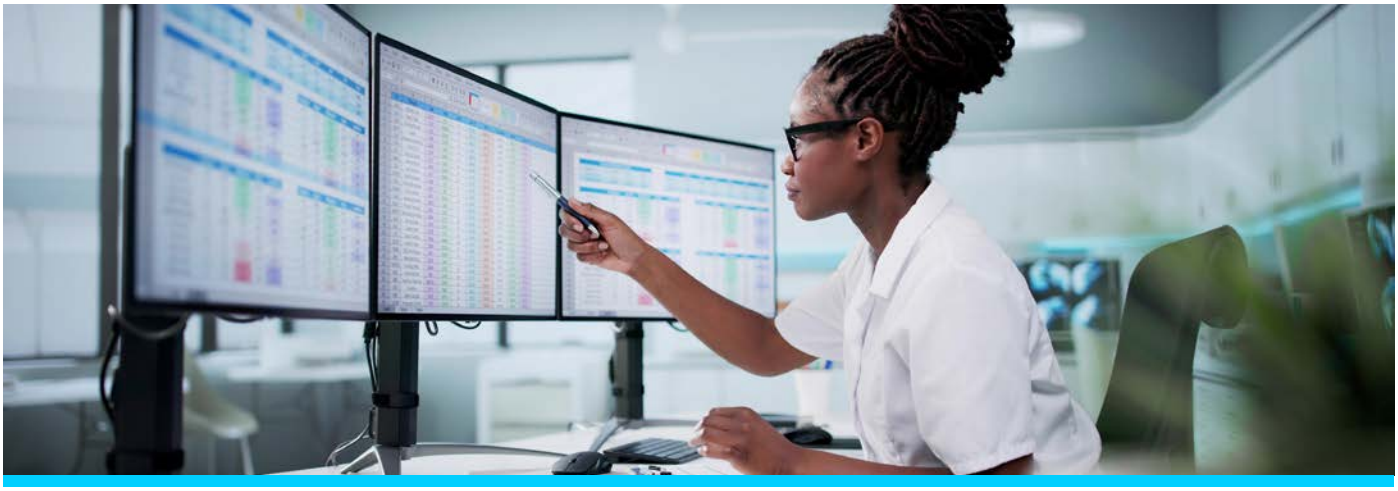
An alternate evaluation of sponsors completing a minimum of 40 trials was also completed and the success of corresponding trials was determined by the individual phase and total trial percentages (Table 6). Many of the companies captured within this section returned from preceding analyses and the top 20 sponsoring companies accounted for the main proportion of results (17 out of 20). The remaining AOP sponsors were Sino Biopharmaceutical, Jiangsu Hengrui Pharma, and Incyte Corporation. Each of the companies, displayed in the top five publicly reported attaining primary endpoints in 40% or more of their trials. Sino Biopharmaceutical again led with the most significant percentage of trials obtaining primary endpoints (44.4%); its trials primarily engaged the country of China. Jiangsu Hengrui Pharma, another AOP company acquiring a high degree of trial success (40.9%), also exclusively conducted trials in China. Numerous top 20 sponsors averaged higher percentages of trials obtaining primary endpoints in 2025, which consisted of Amgen, Sanofi, Novartis, Roche, AbbVie, Eli Lilly, Takeda, and Pfizer. Both Amgen and Sanofi elevated their primary endpoint percentages as they moved into the top five positions. Amgen recorded nearly double the percentage as it calculated 42.6% after noting 24.6% through their 2024 results. Likewise, Sanofi added countenance as it appraised 41.1% primary endpoints in their studies, which added 13.6% over their 2024 percentage (27.5%). Similarly positive but also less decisive mobility was observed for other key players, such as AstraZeneca, AbbVie, Eli Lilly, Takeda, and Pfizer. Each of these top 20 sponsors furthered their position in 2025 over 2024 results. BMS nearly replicated their results as they noted a 0.2% drop in percentage moving to 24.8% after finding 25.0% primary endpoints in their 2024 completed studies. Only one sponsor (Gilead Sciences) was added to the successful results and captured an average percentage of 31.7% throughout the completed trials. Each of the remaining sponsors revealed slightly lower percentages throughout the results, although each displayed meaningful success values to be captured within the results table.

The total successful trial percentages can also be utilized and compared year-over-year to track any changes in success for the sponsors captured. In contrast to last year's calculations, which revealed 28.8%, the average success percentage of sponsors attaining primary endpoints moved up to 31.3%. These results show a clear improvement in the industry's success, where greater than half the sponsors found in the results presented with higher success measurements in 2025.



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The rates of success demonstrated by sponsors are influenced by a variety of factors, including how trial outcomes are made publicly available and whether the outcomes established significant evidence of success. Significant evidence of success can be attributed to studies which met or exceeded primary endpoint(s). It is important to mention that Phase I trials that do not contain safety or efficacy/surrogate efficacy-related outcomes can further impact rates of success for respective sponsors, as the lack of endpoints can limit the determination of trial outcomes. As late-stage/late-phase trials are used to validate and corroborate a study drug's approval, the heightened level of success found for sponsors in such phases can manifest into new intervention approvals.

Table 6: Percentage of 2025 trials* attaining primary endpoint, by phase, for companies completing ≥40 trials

Sponsor	I	I/II	II	II/III	III	III/IV	Total percentage
Sino Biopharmaceutical	11%	100%	52%	0%	75%	0%	44.4%
Amgen	14%	100%	44%	0%	47%	0%	42.6%
Sanofi	32%	0%	40%	0%	62%	0%	41.1%
Jiangsu Hengrui Pharmaceuticals	28%	0%	68%	0%	47%	0%	40.9%
Novartis	47%	27%	23%	0%	63%	0%	40.7%
Roche	32%	42%	36%	0%	41%	0%	37.4%
AstraZeneca	6%	43%	43%	0%	67%	0%	36.2%
Bayer	24%	50%	39%	0%	36%	0%	34.5%
Johnson & Johnson	21%	33%	28%	0%	50%	0%	32.6%
Gilead Sciences	20%	0%	42%	33%	50%	0%	31.7%
AbbVie	17%	60%	19%	0%	44%	0%	31.0%
Eli Lilly	9%	38%	42%	0%	77%	0%	30.8%
Takeda	13%	25%	24%	0%	39%	0%	28.3%
Novo Nordisk	3%	50%	31%	0%	42%	0%	25.9%
Bristol Myers Squibb	19%	25%	30%	25%	24%	0%	24.8%
Merck & Co	5%	17%	37%	0%	41%	0%	24.8%
Pfizer	19%	25%	26%	0%	30%	0%	22.9%
GSK	25%	15%	19%	0%	26%	0%	21.3%
Incyte	7%	0%	23%	0%	67%	0%	20.0%
Boehringer Ingelheim	10%	0%	27%	0%	21%	0%	14.0%

*Trial count includes cosponsored trials

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Top 3 Therapeutic Areas: Assessment by Top Sponsors, Diseases with Positive Pivotal Trials, and Pipeline Therapeutics

A deeper analysis of the topline trial data focuses attention on three high-performing TAs. A subsequent examination of these areas delivers key characterizations of oncology, A/I, and met/endo landscapes. These TAs collectively accounted for 65% of the total number of clinical trial completions for the industry. Where dominance was shown by oncology and A/I, for their return involvement in the top three, met/endo arrives with a variety of fresh perspectives. Our granular evaluation of these TAs recognizes noteworthy sponsors, several high-burden and rare indications, and drugs in pipeline.

Oncology: Top sponsors, indications, and pipeline drugs in successful pivotal trials

Through this year's results, 11 individual sponsors were contained within the oncology top 10. These sponsors are ranked according to their total volume of completed trials, classified by calculated success rates from each sponsor's associated trials, regardless of phase, and denoted with the corresponding count of positive pivotal trials (Table 7). A breakdown of the top sponsors signifies that nine of the 11 sponsors are classified as top 20. The additional two sponsors, BeOne Medicines and Sino Biopharmaceutical, are AOP sponsors and maintain notoriety through our present oncology results after coming back with higher oncology trial completions. Juxtaposed to last year's returned sponsors, there are two fewer total sponsors captured within the assessment, but four sponsors that were not evaluated and two substitutes (Eli Lilly and GSK). After previously trailing in second, Merck & Co. separated itself in first place as the company brandished a completed trial count of 123. Measuring 17 trials fewer, Roche advanced its standing from third into second and boasted an uplift in trial values (106 vs. 95) and success rate (40.6% vs. 32.6%). BMS dropped two places after being recorded in first last year; however, it traded heightened trial totals for a higher success metric (24.8% vs. 23.4%). AZ (4) remained unchanged in ranking year-over-year and underscored a high degree of success as the company publicized positive results in more than 50% of their trials. Joining the oncology trial review, after noting only 24 completed oncology trials in 2024, Eli Lilly found themselves in fifth place, completing 42 more oncology studies for a total of 66, in 2025. Novartis continues to separate itself as it maintained rank but instead confirmed greater success (37.5% vs. 29.3%) in more trials (48 vs. 41). Pfizer prioritized higher success in their oncology studies which was reflected by slight declines in trial totals (46 vs. 81) but gains in success rates (32.6% vs. 27.2%). Johnson & Johnson (J&J) bolstered its trial counts (43 vs. 29) in the span of a year, but due to the increased trial volume from other sponsors the company fell one place moving from seventh to eighth in rank. Despite completing more trials with greater success, Sino Biopharmaceutical also was displaced from eighth to ninth rank. Rivalry over the 10th position was observed between BeOne Medicines and GSK, where each company completed 29 trials.

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Shifting perspective to the positive pivotal trial counts, pivotal trial totals were aggregated per sponsor and are reflected in the rightmost column of the table. Pivotal trials are defined as registrational studies, those which are being utilized to support initial marketing approval for related therapies or expanded indication programs, where previously approved drugs are being evaluated for the treatment of alternate indications. Ten sponsors, out of the 11, showed positive outcomes from respective pivotal studies. In review of the significant results, we find AZ reproduced the most substantial number of positive pivotal results and continued to add countenance to their oncology product development. The other key sponsors denoting positive pivotal results are listed in descending fashion and consisted of Roche, Eli Lilly, and Pfizer (five apiece); Merck & Co. (four); J&J (three); and BMS, Novartis, Sino Biopharmaceutical, and BeOne Medicines (two for each). It is worth noting that each of Sino Biopharmaceutical's positive pivotal studies were completed in the country of China and likely will be used to support local regulatory filings rather than global.

Deviating from 2024's results emphasizing growth with 777 oncology trials, 2025's even-keeled approach recognized a moderate sum totaling 694 trial completions for the top sponsors, marking a 10.7% decline in representation. The top sponsor trial range for completed oncology values also diverge from our prior assessment as we find a tighter grouping outlined by the current list of oncology sponsors (123–29). These details illustrate that although the total oncology trial completions (1,421) only deviated from last year by 3%, last year's top results had a wider range of trial totals per sponsor (145–26), which resulted in a broader set and higher sum of top oncology sponsor totals. However, the average trial success rates for the sponsors observed embodied a slight increase as the needle ticked up from 34.2% to 34.6%. These metrics signal a stronger focus on trial success and, because of this, translated to more oncology drugs in pipeline that were associated with positive pivotal trials.

Traversing to analyze key oncology diseases linked to the positive pivotal studies, 2025's findings match the values from our former report in the number of total diseases (33) and rare indications (22), but nevertheless featured new and return diseases. Trialtrove's "rare" designation is assigned to a disease based upon corresponding prevalence (diseases affecting one in 2,000 people in the EU or one in 1,600 people in the US). For the referenced results, trials that treat subjects with a broad range of diseases (e.g., basket trials) are parsed and calculated by individual disease in Figure 3. In all, the pivotal diseases were summarized from 80 unique oncology trials. These trial totals symbolize an annualized decrease of eight trials. By contrast, the sum of pivotal trials by disease (144), continues an ascending trajectory moving beyond the value ascertained from 2024 (127). The bulk of diseases remain consistent, where the main proportion is slanted

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toward registrational programs (101) and less are attributable to expanded indication (43). Homing in on the indication with the greatest positive pivotal results, non-Hodgkin's lymphoma pulls above the rest as the indication added six pivotal trials over last year's 10 to now yield 16 pivotal trials. This determination comes in stark contrast to the 2024 assessment and 2025's top 10 diseases as NSCLC, the predecessor of top pivotal oncology trials, did not maintain its elevated position and instead counted only 13 positive pivotal results. Breast cancer, which previously recovered success in 12 pivotal trials in 2024, also faced a minor setback as the disease had three fewer positive pivotal studies (nine).

Strong but unarguably more modest advancement was exhibited by a multitude of other indications across the oncology TA (colorectal cancer, AML, bladder, ALL, myeloproliferative neoplasms, ovarian cancer, esophageal cancer, gastric cancer, neuroendocrine tumor, head/neck cancer,

Table 7: Top 10 sponsors with completed oncology trials, by success rates and positive pivotal trial counts

Sponsor	Early positive outcome	Positive outcome/ primary endpoint(s) met	Outcome indeter-minate	Negative outcome/ primary endpoint(s) not met	Outcome unknown	N/A	Total trials (rank)	Success rate	Positive pivotal trials (count)
Merck & Co	0	33	34	13	40	3	123 (1)	26.8%	4
Roche	0	43	18	10	34	1	106 (2)	40.6%	5
Bristol Myers Squibb	0	25	23	7	41	5	101 (3)	24.8%	2
AstraZeneca	0	40	13	3	16	1	73 (4)	54.8%	8
Eli Lilly	0	16	23	6	15	6	66 (5)	24.2%	5
Novartis	1	17	13	3	13	1	48 (6)	37.5%	2
Pfizer	1	14	9	1	19	2	46 (7)	32.6%	5
Johnson & Johnson	0	14	4	1	22	2	43 (8)	32.6%	3
Sino Biopharma-ceutical	0	19	1	0	10	0	30 (9)	63.3%	2
BeOne Medicines	0	11	3	1	9	5	29 (10)	37.9%	2
GSK	0	6	11	2	10		29 (10)	20.7%	0

Note: Indeterminate designation is assigned to trials when the outcome is neither clearly positive nor negative. Unknown is assigned to trials that have yet to report full results for their primary endpoints. N/A indicates trials with no efficacy/safety outcomes to evaluate.

Source: Trialtrove, February 2026

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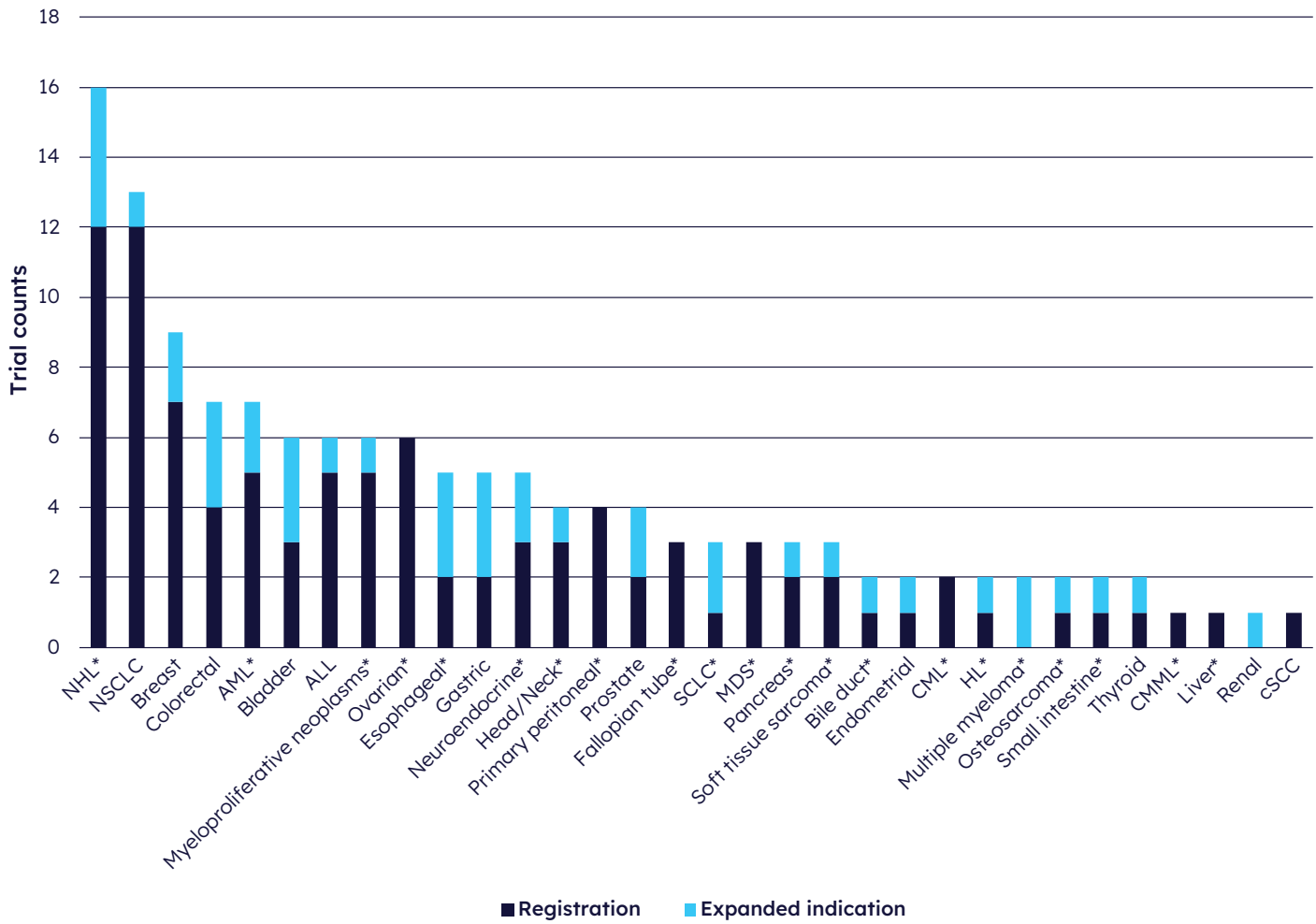
primary peritoneal cancer, fallopian tube cancer, SCLC, pancreatic cancer, and osteosarcoma). Results with no yearly change were localized to two indications for prostate cancer (four) and soft tissue sarcoma (three). Several additions were present in the standings for MDS, bile duct cancer, HL, small intestine cancer, thyroid cancer, CMML, and cSCC. Definitive progression was also found throughout the hematological malignancies, where these indications again rallied to increase share to 49 trials from 32 for the respective indications (NHL, AML, CLL, myeloproliferative neoplasms, MDS, CML, HL, multiple myeloma, and CMML). Outside of NSCLC and breast cancer, few drops were found, but were noteworthy for endometrial cancer, CML, multiple myeloma, liver cancer, and renal cancer. In examination of the sponsor categorizations, coupled with the pivotal oncology trial details, minimal change occurred in the sponsor representation, although reversion took place where the top 20 pharma sponsors were involved in 34 trials, mirroring 2023's totals and falling two trials behind 2024's evaluation (36).

Figure 3: Pivotal oncology trials achieving primary endpoints, by disease and filing type



*Rare disease

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After focusing attention on trials and disease areas, a detailed assessment of the oncology product pipeline is warranted. The investigational oncology drugs in pipeline status, which are affiliated with the positive pivotal trials, underwent examination to extract key information for the drug name, related developing companies, focus indication(s), mechanism of action (MOA), and MOA novelty (Table 8). Novelty in MOA is assigned to a given drug on the basis that the product has a previously unproven MOA. The determination of MOA novelty is assigned through publicly available sources and are validated within their Pharmaprojects profiles. A high-level overview reveals that six products are listed with novel MOAs and three of these therapeutics are targeted therapies for breast cancer. Additionally, three of the products were involved in global trials for breast cancer, soft tissue sarcoma, and colorectal cancer. AZ's camizestrant displayed significantly longer progression-free survival (PFS) through their Phase III trial treating subjects with ER-postitive, HER2-negative breast cancer. Moreover, two AOP sponsors, Immunome and Exelixis, also prevailed by attaining primary endpoints in their Phase III soft tissue sarcoma and Phase II/III colorectal trials, respectively.

Three products out of five total drugs are also found with novel MOAs and are further shaded in gray fill, to quickly identify those that are in development from companies that initiated trials exclusively engaging China. In their Phase II/III trial of anbenitamab, an anti-HER2 bispecific antibody, CSPC Pharmaceutical Group and Shanghai JMT-Bio found in second line plus patients with HER2-postive gastric and esophageal cancer the therapeutic lead met their primary endpoint of progression-free survival (PFS) during their interim analysis. Anvatabart opadotin, being developed by Zhejiang Medicine Co., and trastuzumab pamirtecan, in development by Duality Biologics and BioNTech, each reached their primary endpoint of PFS in subjects with HER2-positive breast cancer.

To shed light on the remaining 16 pipeline products, each of these therapies did not emphasize MOA novelty. As the company results are scanned, the ratio of AOP sponsors to top 20 pharma is 7:1, where the exceptions stood out from AbbVie/ImmunoGen's hematology therapy, pivekimab sunirine, and Pfizer's bladder cancer product, sasanlimab. Many of the products listed without key MOA novelty exhibited similarity to already existing or past approved drugs. Drugs sharing characteristics for any already approved, existing therapies are considered "me-too" products, which would be seeking to capitalize as alternative therapies to already marketed pharmaceuticals. These pivotal results will likely be utilized to support local regulatory filings, apart from global filings, and were observed for noteworthy Bruton tyrosine kinase (BTK) inhibitors, T cell stimulants, immune-oncology (IO) therapies, EGFR kinase inhibitors, EGFR antagonists, radioemitters, PD-1 antagonists, a glucocorticoid antagonist, hepcidin inhibitor/stimulant, and an ErbB-2 antagonist.

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Table 8: Pipeline status drugs in successful pivotal oncology trials, by sponsor, disease, MOA, and MOA novelty

Drug name	Sponsor	Disease	Mechanism of action	Novel
anbenitamab	CSPC Pharmaceutical Group Co/Shanghai JMT-Bio Technology Co	Esophageal*; Gastric	EGFR antagonist; ErbB antagonist; ErbB-2 antagonist; IO therapy	Yes
anvatabart opadotin	Zhejiang Medicine Co/NovoCodex Biopharmaceuticals Co	Breast	Tubulin inhibitor; ErbB-2 antagonist	Yes
camizestrant	AstraZeneca	Breast	Estrogen R antagonist; Selective estrogen R downregulator; Protein degrader	Yes
trastuzumab pamirtecan	Duality Biologics; BioNTech	Breast	DNA Topo I inhibitor	Yes
varegacestat	Immunome	Soft tissue sarcoma*	Secretase gamma inhibitor; Notch pathway inhibitor	Yes
zanzalintinib	Exelixis	Colorectal	Axl R TKI; VEGF R antagonist; Mer TKI; MET TKI; VEGF R TKI	Yes
anbalcabtagene-autoleucel	Curocell Inc	HL*; NHL*	IO therapy; TIGIT R antagonist; PD-L1 antagonist; T cell stimulant	No
cetuximab, R-Pharm	TRPharm {R-Pharm/ TRPharm}	Head/Neck*	EGFR antagonist	No
daznelimgene lisbac	OS Therapies	Osteosarcoma*	ErbB-2 antagonist; IO therapy; Immunostimulant	No
FHND-9041	Sino Biopharmaceutical/ Jiangsu Chia Tai Fenghai Pharmaceutical	NSCLC	EGFR kinase inhibitor	No
lacutamab	Innate Pharma	NHL*	ICI; IO therapy; KIR-mediated NK cell inhibition antagonist	No
Lu-177 PSMA I&T	Curium/Curium US	Prostate	GCP stimulant; Radioemitter	No
lutetium (177Lu) edotreotide	ITM Solucin	Neuroendocrine*	Radioemitter, beta	No
nofazinlimab	CStone Pharmaceuticals	Liver*	ICI; IO therapy; PD-1 antagonist	No
pivekimab sunirine	AbbVie/ImmunoGen	ALL; AML*; CML*; CMML*; MDS*; Myeloproliferative neoplasms*	DNA inhibitor; IO therapy; IL 3 R antagonist	No
relacorilant	Corcept Therapeutics	Fallopian tube*; Ovarian*; Primary peritoneal*	Glucocorticoid antagonist	No

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rocbrutinib	Guangzhou Lupeng Pharmaceutical Co	NHL*	BTK inhibitor; Kinase inhibitor	No
rusfertide	Protagonist Therapeutics	Myeloproliferative neoplasms*	Hepcidin inhibitor; Hepcidin stimulant	No
sasanlimab	Pfizer	Bladder	ICI; IO therapy; PD-1 antagonist	No
stem cell engraftment therapy, Orca Biosystems	Orca Biosystems	ALL; AML*; MDS*	IO therapy; T cell stimulant	No
zamtocabtagene autoleucel	Miltenyi Biomedicine	NHL*	IO therapy; T cell stimulant	No
zipalertinib	Otsuka Holdings/Taiho Pharmaceutical {Cullinan Oncology/Cullinan Pearl}	NSCLC	EGFR kinase inhibitor	No

*Rare disease
Gray fill: China-only trial

Source: Trialtrove and Pharmaprojects, February 2026

Autoimmune/inflammation: top sponsors, indications, and pipeline drugs in successful pivotal trials

For the fourth year in a row, the A/I therapeutic area had the second highest clinical trial activity of all TAs. There were 12 sponsors in the top 10 A/I diseases last year, but 22 in the top 10 this year. This is likely due to the overall decrease in completed clinical trials; the sponsors in fourth place in 2025 completed as many trials as the sponsors that were in 10th place in 2024 (17). Even though there were more than twice as many sponsors in the top 10 for A/I trials this year, as a result of their overall decline in completed trials, the total completed trials in this chart sums to 326 vs. 305 last year.

While the relative ranking for many sponsors changed significantly year over year, AstraZeneca retained first place. Despite completing fewer A/I trials (40 vs. 37), AZ had a higher success rate (25% vs. 32.4%). In fact, all but two sponsors in the top 10 completed fewer trials this year, and all sponsors had a higher success rate. On average, top 10 sponsors completed five fewer trials but increased their success rate by 12.8%.

GSK fell from third to 10th place this year, and completed 20 fewer A/I trials, although their success rate rose by 16.4%. Similarly, Eli Lilly fell from second to sixth place and completed 15 fewer A/I trials, with a 16.7% increase in their success rate. Three sponsors had a notable increase in both their ranking and success rate: Novartis (eighth to fifth, 35.7% increase), AbbVie (ninth to fourth, 24.5% increase), and Amgen (10th to sixth, 23.2% increase).

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Nineteen of the 22 top 10 sponsors completed zero or one positive, pivotal trial. When comparing the performance of A/I sponsors between 2024 and 2025 (2024 data not shown here), Sanofi was also one of only two sponsors that completed more A/I trials this year than in 2024, the other being Boehringer Ingelheim. While Boehringer Ingelheim completed one additional A/I trial, Sanofi completed an additional six, including four more positive, pivotal A/I trials. Sanofi also increased their success rate by 11.1%.

Table 9: Top sponsors with completed autoimmune/inflammation trials, by success rates and positive pivotal trial counts

Sponsor	Early positive outcome	Positive outcome/ primary endpoint(s) met	Outcome indeter-minate	Negative outcome/ primary endpoint(s) not met	Outcome unknown	N/A	Total trials (rank)	Success rate	Positive pivotal trials (count)
AstraZeneca	0	12	2	1	20	2	37 (1)	32.4%	0
Boehringer Ingelheim	0	5	7	1	7	8	28 (2)	17.9%	1
Sanofi	0	12	0	4	10	2	28 (2)	42.9%	7
Johnson & Johnson	1	8	3	2	6	0	20 (3)	45.0%	2
AbbVie	0	7	2	0	8	0	17 (4)	41.2%	0
Bristol Myers Squibb	0	5	1	0	7	4	17 (4)	29.4%	1
Sino Biopharmaceutical	0	4	0	0	10	3	17 (4)	23.5%	0
Novartis	0	8	2	1	3	2	16 (5)	50.0%	1
Pfizer	0	4	2	1	7	2	16 (5)	25.0%	0
Amgen	0	7	0	1	5	2	15 (6)	46.7%	0
Eli Lilly	0	6	2	1	6	0	15 (6)	40.0%	0
Incyte Corporation	0	5	0	1	7	2	15 (6)	33.3%	4
Takeda	0	3	1	2	4	3	13 (7)	23.1%	1
Jiangsu Hengrui Pharma	0	3	0	0	7	1	11 (8)	27.3%	0
Merck & Co	0	1	1	0	5	1	8 (9)	12.5%	0
PATH	0	4	1	0	3	0	8 (9)	50.0%	1
Regeneron	0	2	0	1	4	1	8 (9)	25.0%	1
Thermo Fisher Scientific/Patheon	0	4	1	0	3	0	8 (9)	50.0%	1
UCB	0	1	2	0	4	1	8 (9)	12.5%	0
GSK	0	4	0	1	2	0	7 (10)	57.1%	0
Haisco Pharmaceutical Group	0	1	0	0	5	1	7 (10)	14.3%	0
Kyowa Kirin	0	4	0	0	2	1	7 (10)	57.1%	0

Note: Indeterminate designation is assigned to trials when the outcome is neither clearly positive nor negative. Unknown is assigned to trials that have yet to report full results for their primary endpoints. N/A indicates trials with no efficacy/safety outcomes to evaluate.

Source: Trialtrove, February 2026

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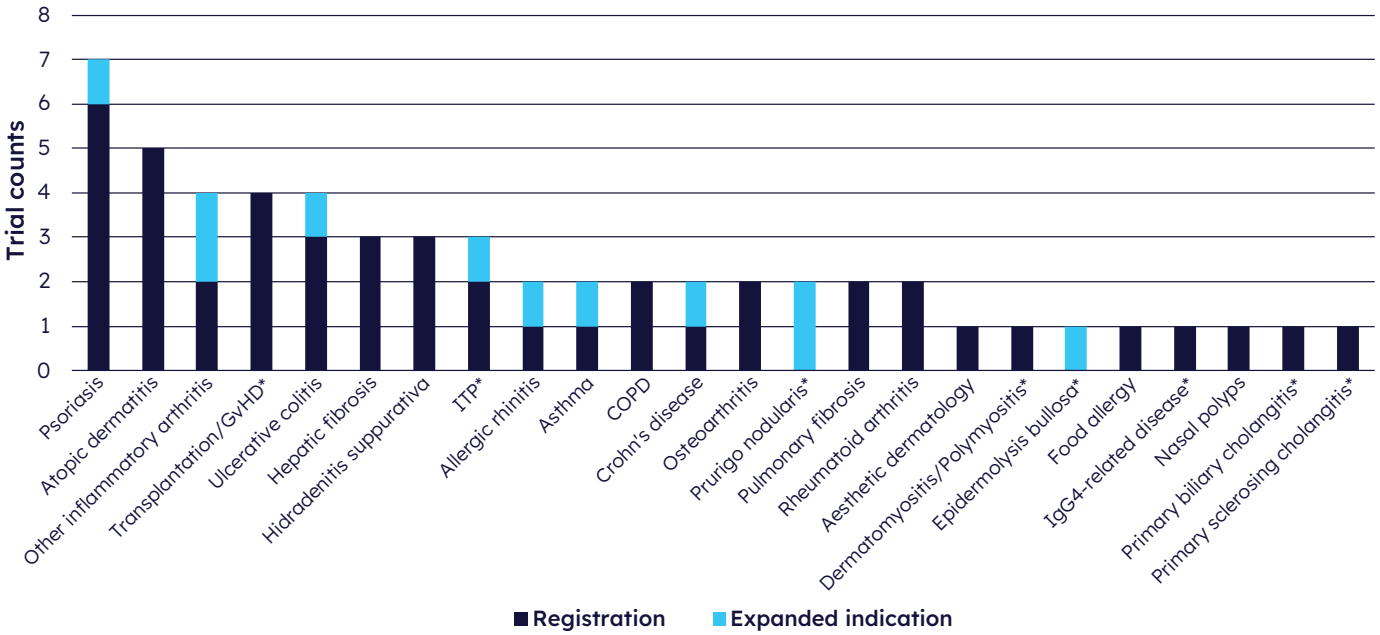
Twenty-five of the 49 A/I indications completed positive, pivotal trials in 2025. There were 53 positive pivotal trials, including 45 registrational and 11 expanded indications, as some trials were both registrational and expanded indication. This is a significant increase from the last two years (40 in 2024, 42 in 2023). The three A/I diseases which completed the highest number of positive pivotal trials remain psoriasis, atopic dermatitis and other inflammatory arthritis (including three axial spondyloarthritis trials and one psoriatic arthritis trial), with seven pivotal psoriasis trials. This year, transplantation/GvHD rose from one positive pivotal trial last year to four this year. Conversely, food allergy completed four trials last year, but one this year. Allergic rhinitis, osteoarthritis, prurigo nodularis, and rheumatoid arthritis all completed zero positive pivotal trials in 2024, but in 2025 completed two apiece.

As with last year, this figure includes nine rare indications, five of which (IgG4, dermatomyositis/polymyositis, epidermolysis bullosa, primary sclerosing cholangitis, Sjogren's syndrome) were not included in last year's analysis. However, IgG4 was added to our database after our 2024 Completed Trials paper was published, and retrospective analysis shows one positive, pivotal trial for this indication in 2024.

Dermatological indications were once again highly represented among pivotal trials, having 19 completed trials this year across six indications (psoriasis, atopic dermatitis, hidradenitis suppurativa, prurigo nodularis, aesthetic dermatology, and epidermolysis bullosa). Although in 2024 and 2025 there were 10 pivotal rheumatology trials, this year these trials were spread across a higher number of rheumatology indications, with six indications this year and four indications last year, if IgG4 diseases were retroactively included in 2024's analysis. In particular, the rheumatology indications were other inflammatory arthritis, osteoarthritis, rheumatoid arthritis, dermatomyositis/polymyositis, IgG4 related diseases, and Sjogren's syndrome in 2024 and other inflammatory arthritis, lupus, and polymyalgia rheumatica in 2025.

Figure 4: Pivotal autoimmune/inflammation trials achieving primary endpoints, by disease and filing type



*Rare disease

Source: Trialtrove, February 2026

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The pipeline status drugs included three top 20 pharma sponsors and 18 AOP sponsors. There were 22 drugs across 24 indications, as Upstream Bio's Verekitug completed positive trials in both asthma and nasal polyps and Dr. Falk Pharma's norursodeoxycholic acid completed positive trials in both hepatic fibrosis and primary sclerosing cholangitis. Two drugs with novel MOAs (manfidokimab and roconkibart) and two non-novel drugs (LZM-012 and hydronidone) were studied exclusively in China.

There were not only twice as many drugs with successful, pivotal A/I trials this year, but more than double the number of drugs with a novel MOA (three vs. eight). The remaining 14 drugs had non-novel MOAs and therefore are considered "me-too" drugs, or alternative therapies for drugs that have reached the market. Fifteen of these 22 drugs were biologicals, including 12 antibodies, and five of the drugs with a novel MOA were antibodies. For the most part, drug targets did not overlap, with the exception of four drugs targeting interleukin 17A.

An impressive number of these drugs may soon be providing relief to the patients suffering from autoimmune conditions. Since the beginning of 2025, brepocitinib, Maat 013, hydronidone, manfidokimab, povorcitinib, and roconkibart have filed for regulatory approval, and tocilizumab has been approved for the treatment of rheumatoid arthritis in Japan. The year 2025 was exceptional for A/I trials, with all A/I sponsors having a higher success rate than in 2024 and a significant increase in the number of positive, pivotal trials.

Table 10: Pipeline status drugs in successful pivotal autoimmune/inflammation trials, by sponsor, disease, MOA, and MOA novelty

Drug name	Sponsor	Disease	Mechanism of action	Novel
amlitelimab	Sanofi {Sanofi-Aventis}/ Sanofi Genzyme {Genzyme}	Atopic dermatitis	TNF ligand 4 antagonist	Yes
itepekimab	Regeneron	COPD	IL 33 antagonist	Yes
manfidokimab	Akeso Biopharma	Atopic dermatitis	IL 4 R antagonist	Yes
obefazimod	Abivax	Ulcerative colitis	HIV rev inhibitor; miRNA stimulant	Yes
povorcitinib	Incyte Corporation	Hidradenitis suppurativa	JAK 1 inhibitor	Yes
resiniferatoxin, Grunenthal	Grunenthal	Osteoarthritis	Vanilloid R 1 agonist	Yes
roconkibart	Shanghai Junshi Biosciences Co	Psoriasis	Immunostimulant; IL 17A antagonist	Yes
verekitug	Upstream Bio	Asthma; Nasal polyps	TSLP inhibitor	Yes

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LZM-012	Joincare Pharmaceutical Group Industry Co/ Zhuhai Livzon Monoclonal Antibody Biotechnology Pharmaceutical	Psoriasis	IL 17A antagonist; IL 17F antagonist	No
MaaT-013	MaaT Pharma	Transplantation/ GvHD*	Microbiome modulator, fecal	No
Viaskin peanut	DBV Technologies	Food allergy	Desensitizer; Ig E inhibitor; Immunostimulant; T cell stimulant; Th cell stimulant	No
brepocitinib	Priovant Therapeutics	Dermatomyositis/ Polymyositis*	JAK 1 inhibitor; TYK 2 inhibitor	No
efdoralprin alfa	Sanofi {Inhibrx}	COPD	AAT stimulant	No
envudeucitinib	Alumis	Psoriasis	TYK 2 inhibitor	No
hydronidone	GNI Group/Gyre Therapeutics/Gyre Pharmaceuticals Co {GNI Group/Beijing Continent Pharmaceutical Co}	Hepatic fibrosis	Unidentified pharmacological activity	No
ianalumab	Novartis	Sjogren's syndrome*	BAFF inhibitor; B-cell activator factor R antagonist; Ig inhibitor; TNF ligand antagonist	No
norursodeoxycholic acid	Dr Falk Pharma	Hepatic fibrosis; Primary sclerosing cholangitis*	Cholesterol inhibitor	No
obexelimab	Bristol Myers Squibb	IgG4-related disease*	CD19 antagonist; CD32 antagonist; CD23 antagonist; ICI	No
secukinumab, Bio-Thera Solutions	Bio-Thera Solutions	Psoriasis	IL 17A antagonist	No
sonelokimab	MoonLake Immunotherapeutics	Hidradenitis suppurativa	IL 17A antagonist; IL 17F antagonist	No
stem cell engraftment therapy, Orca Biosystems	Orca Biosystems	Transplantation/ GvHD*	IO therapy; T cell stimulant	No
tocilizumab, Mochida	Mochida	Rheumatoid arthritis	IL 6 R antagonist	No

*Rare disease
Gray fill: China-only trial

Source: Trialtrove and Pharmaprojects, February 2026

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Metabolic/endocrinology: top sponsors, indications, and pipeline drugs in successful pivotal trials

In terms of top sponsors' trial activity, these were similarly ranked for the corresponding TA and joined with success metrics to correlate trial volumes and success rate by respective sponsors (Table 11). Throughout our prior nine annual completed trial reports, met/endo has evaded the top three TA analysis after continually being hedged out by the CNS TA's higher trial numbers. However, for the first time, met/endo distinguished itself in such a way to join the top three TAs. In a deeper evaluation of met/endo, 12 total sponsors are reflected, 10 of which are classified as top 20, where the only two not categorized in this section and instead are denoted as AOP were Jiangsu Hengrui Pharma and Haisco Pharmaceutical Group Co.

As the details are further unpacked, we find the sponsor with the most completed studies for met/endo is Novo Nordisk (60), where the main number of these were studies assessing their amylin RA and GLP-1 RA product, cagrilintide + semaglutide, in subjects with obesity and/or T2D. Another key sponsor in the met/endo space, Eli Lilly, disclosed completion for 45 trials, where nearly one third (13) of the studies included its GLP-1 product, orforglipron. More than this, Eli Lilly almost exclusively completed met/endo trials for the indications of obesity and T2D (43) and only two of its studies were inclusive of other metabolic-related indications. Following in third place, and separate from the initial two sponsors, AZ grossed a total of 42 completed studies and had the highest number of completed studies evaluating treatment for non-alcoholic fatty liver disease (NAFLD; also known as MASLD) where they noted 16 completed trials for this disease. Exhibiting the greatest disease variation, displaying nine diseases in their trials, Jiangsu Hengrui Pharma completed 33 studies in anemia, C3 glomerulopathy, hyperuricemia/gout, IgA nephropathy, membranous nephropathy, renal disease (for secondary hyperparathyroidism and chronic kidney disease), paroxysmal nocturnal hemoglobinuria (PNH), obesity, and T2D. Boehringer Ingelheim rounded out the top five sponsors for met/endo and recognized completion of 25 trials for this TA in 2025. From a top-down view of the results, the top five ranked sponsors each completed nearly double that of the bottom ranked sponsors.

Prominence was further seen from the sponsor results and was demonstrated through the sponsor's corresponding success rates. Out of the 12 total sponsors, Sanofi promoted the highest success rate, where five out of their eight trials attained primary endpoints. Three of the positive completed results were also evaluating treatments for rare, Gaucher's disease. Other definitive success was noted for Jiangsu Hengrui Pharma (39.4%), Bayer (37.5%), Haisco Pharmaceutical Group Co. (36.4%), Eli Lilly (35.6%), and Roche (33.3%). Each of the above listed sponsors observed success in more than a third of their completed studies for the met/endo TA.

Annual insights were also present through a refined comparison of top sponsor trial totals and average success rates. The top sponsor assessment yielded a total of 276 individual trials, a 5.7% increase over the 261 trials noted from the top sponsors last year. Even though a minimal uplift in trial completions was seen, a decline of 6% in success was evident as this year reflected a success measurement of 25.4% over the previous value of 31.4%. When contrasting the details from 2025 to 2024, the rise in completions leaves room for growth in success for 2026.

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Table 11: Top sponsors with completed metabolic/endocrinology (met/endo) trials, by success rates and positive pivotal trial counts

Sponsor	Early positive outcome	Positive outcome/ primary endpoint(s) met	Outcome indeter-minate	Negative outcome/ primary endpoint(s) not met	Outcome unknown	N/A	Total trials (rank)	Success rate	Positive pivotal trials (count)
Novo Nordisk	0	14	3	1	25	17	60 (1)	23.3%	2
Eli Lilly	0	16	6	0	9	14	45 (2)	35.6%	7
AstraZeneca	0	4	4	2	24	8	42 (3)	9.5%	0
Jiangsu Hengrui Pharma	0	13	0	0	10	10	33 (4)	39.4%	2
Boehringer Ingelheim	0	3	1	0	6	15	25 (5)	12.0%	0
Roche	0	5	1	0	5	4	16 (6)	33.3%	0
Pfizer	0	0	3	1	4	4	15 (7)	0.0%	0
Haisco Pharmaceutical Group	0	4	0	0	5	2	11 (8)	36.4%	0
Merck & Co	0	2	2	0	4	1	9 (9)	22.2%	1
Novartis	0	1	0	1	4	2	8 (10)	12.5%	0
Bayer	0	3	3	0	2	0	8 (10)	37.5%	0
Sanofi	0	5	0	1	1	1	8 (10)	62.5%	0

Note: Indeterminate designation is assigned to trials when the outcome is neither clearly positive nor negative. Unknown is assigned to trials that have yet to report full results for their primary endpoints. N/A indicates trials with no efficacy/safety outcomes to evaluate.

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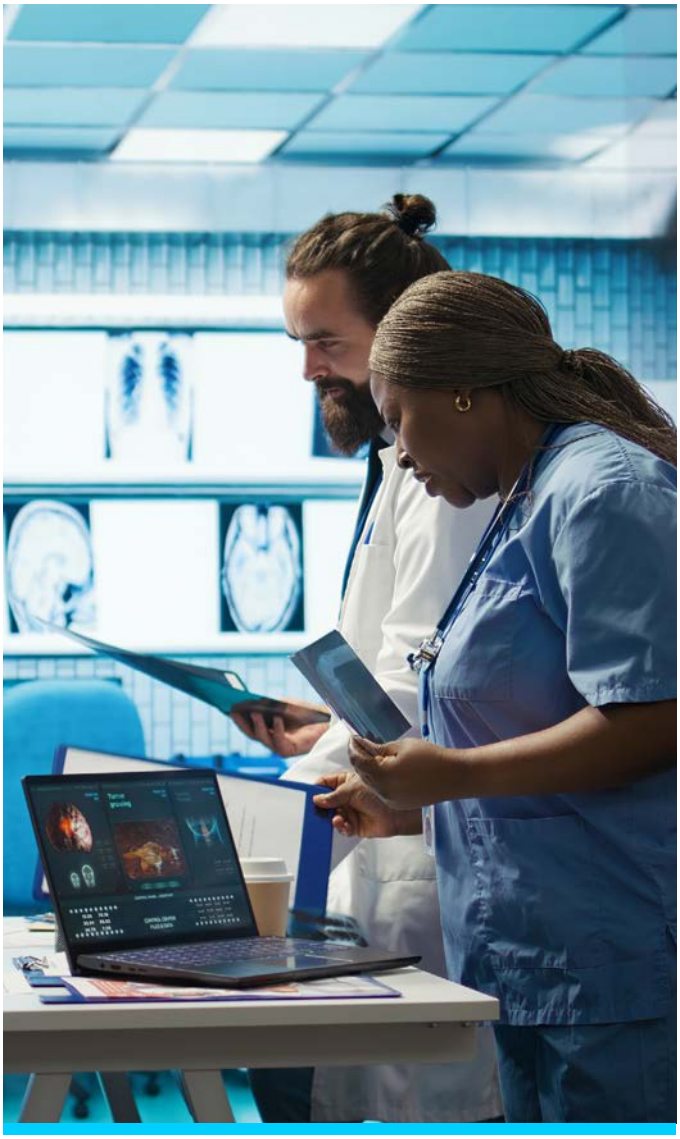
Furthermore, successful positive trial results were returned from 55 individual pivotal trials. Each of the respective studies emphasized intervention for the intention to treat 21 specific diseases and account for 34% of all diseases covered in Trialtrove's met/endo TA. The 66 total pivotal results are aggregated by sum per disease and detail that 57 were regarded as registrational and nine listed as expanded indication (Fig. 5). As sizeable contributions were made to T2D clinical development, as evaluated through the top 10 disease analysis, it is of little surprise that it captured the first spot being the disease collecting the most positive pivotal trial results. Through the graph, observations found three expanded indication studies and 11 registrational programs that added to T2D's advancement.

Also supplementing the analysis, obesity shared generously in the count of positive pivotal results, tallying one expanded indication and 11 registrational studies. Together, T2D and obesity amounted to almost 40% of the positive pivotal quantities for the related TA. These valuations are considered as many of the trials included similar experimental treatments for the patient populations and often enrolled subjects for both disease areas into select studies. Underneath the two highest-performing diseases, an abrupt decrease is found before encountering the disease with the third-most results (renal disease). In the metabolic space, renal disease trials are considered for patient segments that include treatment, progression, or prevention of acute kidney injury, chronic kidney disease (CKD), end-stage renal disease (ESRD), diabetic nephropathy, hypertensive nephropathy, hyperphosphatemia, secondary hyperparathyroidism (SHPT), or other renal diseases. The sum of successful pivotal trials with these patient segmentations resulted in five registrational trials being maintained. Below the three mentioned indications, the results were further composed of 18 less prominent diseases; proportionally, there are eight rare indications



and 10 non-rare diseases. Largely, the diseases were focused toward registrational programs, where 16 indications contained denotation of related information. However, cross-pollination was found for five indications that also mixed with or were solely noted as expanded indication studies. The diseases that contained expanded indication attributes, outside of the main three, were diabetic complications, progressive familial intrahepatic cholestasis (PFIC), hypoglycemia, and phenylalanine hydroxylase (PAH) deficiency. The aforementioned diseases were all found with one positive expanded indication trial each.

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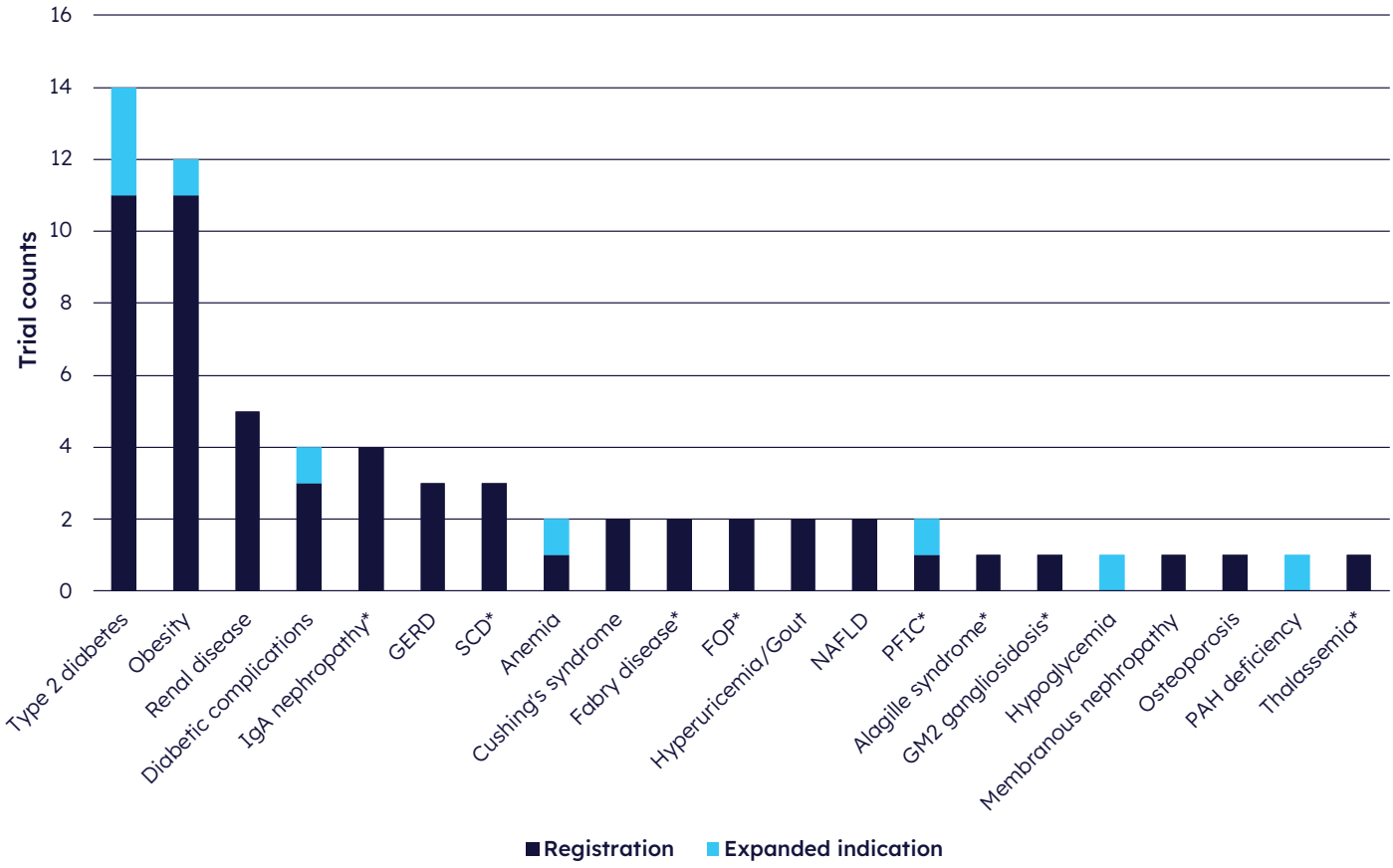
Figure 5: Pivotal met/endo trials achieving primary endpoints, by disease and filing type



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A breakdown of the met/endo pipeline for those involved in positive pivotal trials is supportive to investigating therapeutics which may be moving to market. Drugs designated with MOA novelty were captured and reflected accordingly, if they contained unique qualities, in Table 12. The pipeline status drugs were influenced by a conglomeration of both top 20 pharma (four) and AOP sponsors (10). In all, there were 16 drugs meeting the pivotal criteria to be housed within the table.

A top-down view of the therapeutics noted as the "primary tested drug" for each of the resultant positive pivotal trials finds that only two products are novel with distinguished MOAs. These two drugs were used in interventional trials, where Jiangsu Atom Bioscience & Pharmaceutical Co.'s product lingolinurad was utilized to treat subjects with hyperuricemia/gout in a global setting, and Jiangsu Hengrui Pharma and Kailera Therapeutic's drug ribupatide was included in an obesity trial that was solely engaging China. Significant recognition was found among these drugs as the MOAs were publicly disclosed as novel for lingolinurad, a URAT1 inhibitor, and ribupatide, a GLP-1 RA/GIP/incretin mimetic. The non-novel drugs summed 12 and are considered to be alternative therapies to drugs already in the market. Three of the "me-too" products are seeking approvals for rare indications, inclusive of fibrodysplasia ossificans progressiva (FOP), Fabry disease, and immunoglobulin A (IgA) nephropathy. Beyond those highlighted, two therapies were also used as experimental interventions for the treatment of diabetic complications for diabetic retinopathy, specifically diabetic macular edema. The treatments were evaluated through varying geographies, where RemeGen's RC-28 product was noted for China alone and UNITY Biotechnology's foselutoclax had been tested in their Phase IIb study in the United States. The pivotal drugs in pipeline disclose a robust portfolio of products for many prevalent diseases and fewer rare indications. Less common but also non-novel mechanisms were observed for each of the rare treating products and were found for an alpha-galactosidase stimulant, activin receptor-like kinase 2 inhibitor/inhibin beta A inhibitor, and an APRIL inhibitor/B-cell activating factor inhibitor/B-cell stimulant.

Table 12: Pipeline status drugs in successful pivotal met/endo trials, by sponsor, disease, MOA, and MOA novelty

Drug name	Sponsor	Disease	Mechanism of action	Novel
lingolinurad	Jiangsu Atom Bioscience & Pharmaceutical Co	Hyperuricemia/Gout	URAT1 inhibitor	Yes
ribupatide	Jiangsu Hengrui Pharma; Kailera Therapeutics	Obesity	GIP R agonist; GLP-1 R agonist; Incretin mimetic	Yes
orforglipron	Eli Lilly	Type 2 diabetes; Obesity	GLP-1 R agonist; Incretin mimetic	No
isaralgagene civaparvovec	Sangamo Therapeutics	Fabry disease*	Alpha-galactosidase stimulant	No

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relacorilant	Corcept Therapeutics	Cushing's syndrome	Glucocorticoid antagonist	No
garetosmab	Regeneron	FOP*	ALK 2 inhibitor; Inhibin, beta A inhibitor	No
cagrilintide + semaglutide	Novo Nordisk	Type 2 diabetes; Obesity	Amylin R agonist; GLP-1 R agonist; Incretin mimetic	No
SHR-4640	Jiangsu Hengrui Pharma	Hyperuricemia/Gout	URAT1 inhibitor	No
efpeglenatide	Hanmi Pharmaceutical	Obesity	GLP-1 R agonist; Incretin mimetic; Insulin secretagogue	No
atacicept	Merck & Co; Vera Therapeutics	IgA nephropathy; Renal disease	APRIL inhibitor; BAFF inhibitor; B-cell stimulant	No
VS-505	Alebund Pharmaceuticals	Renal disease	Phosphate antagonist	No
RC-28	RemeGen	Diabetic complications	FGF 2 antagonist; FGF antagonist; VEGF R antagonist	No
berberine ursodeoxycholate	HighTide Therapeutics	Type 2 diabetes	AMPK stimulant; NLR family pyrin domain containing 3 inhibitor	No
foselutoclax	UNITY Biotechnology	Diabetic complications	Bcl-XL inhibitor; Bcl2 inhibitor	No

*Rare disease
Gray fill: China-only

Source: Trialtrove and Pharmaprojects, February 2026

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Current Events in Clinical Trials and Related Impacts

The year 2025 saw significant regulatory changes aimed at streamlining the clinical trial approval process. The UK tested a program which would approve substantial, but low risk, changes to protocols within 14 days, and Portugal started a program which successfully reduced the time for clinical trial approval from an average of 71 to 32 days.[8, 9] The French Agency for Medicines and Health Products Safety announced that a new fast track program will begin in 2026 which will authorize eligible, early phase clinical trials within 14 days.[10] The ACCESS Consortium (Australia, Canada, Singapore, Switzerland, and the UK) are considering a "harmonized assessment process" where a trial's approval by one member of the consortium would expedite its approval by the other four members.[11] Finally, the European Union (EU) has proposed the EU Biotech Act, which could shorten the approval timeline for multinational trials from 106 days to 75 days and the approval timeline of substantial modifications to trial protocols from 96 to 47 days.[12] The EU Biotech Act also proposes to incentivize the manufacturing of drugs in the EU by granting 12 months of additional patent protection to drugs tested and manufactured in the EU.

The Trump administration has similarly tried to increase pharmaceutical manufacturing in the United States by enacting tariffs. These tariffs could increase the cost of running clinical trials in the United States and divert funding from research and development. These tariffs could also cause general market volatility and contribute to rising geopolitical tensions, in a year when 40% of 500 surveyed biopharmaceutical investors stated that geopolitics is their biggest concern.[13, 14] The significant NIH funding cuts by the current administration also led to the termination of hundreds of trials in 2025.[15] As breakthroughs in academic/government-sponsored research can impact industry-sponsored research, it's impossible to know the downstream effect of these terminated trials. There may also be a reduction in completed clinical trials next year now that the FDA requires only one positive, pivotal trial to approve a drug.[16] However, recent FDA rejections have requested additional evidence of drug efficacy, and the regulatory bodies of other countries still require multiple pivotal trials, so this policy change may not be very impactful.

Marking four years of continued conflict, the war in Ukraine endures and lower volumes of completed trials persist for the countries involved (Fig. 6). The regional disruptions have followed our previous analysis trends where lower annualized counts of trial completions ensue for both Russia and Ukraine. The yearly numbers dipped almost 3% more and now record 266 completed studies in 2025. Although the geopolitical tension remains for these countries, there are positive updates for Ukraine's pharmaceutical regulatory system. In recent news, Ukraine is at the critical juncture of gaining access to an advanced regulatory system, as it prepares for a path to accession into the EU and the EU's regulatory framework.[17, 18] Through the process of managing the Eastern European conflict, Ukraine has received support from the Lithuanian medicines regulator, Poland, and Germany to construct a new State Control Authority (SCA) that will better integrate with the EU network.[17] These changes will align the structure of Ukraine's regulatory process more closely to EU practices and allow for adaptation to the practices currently observed by other member states of the EU. The goal

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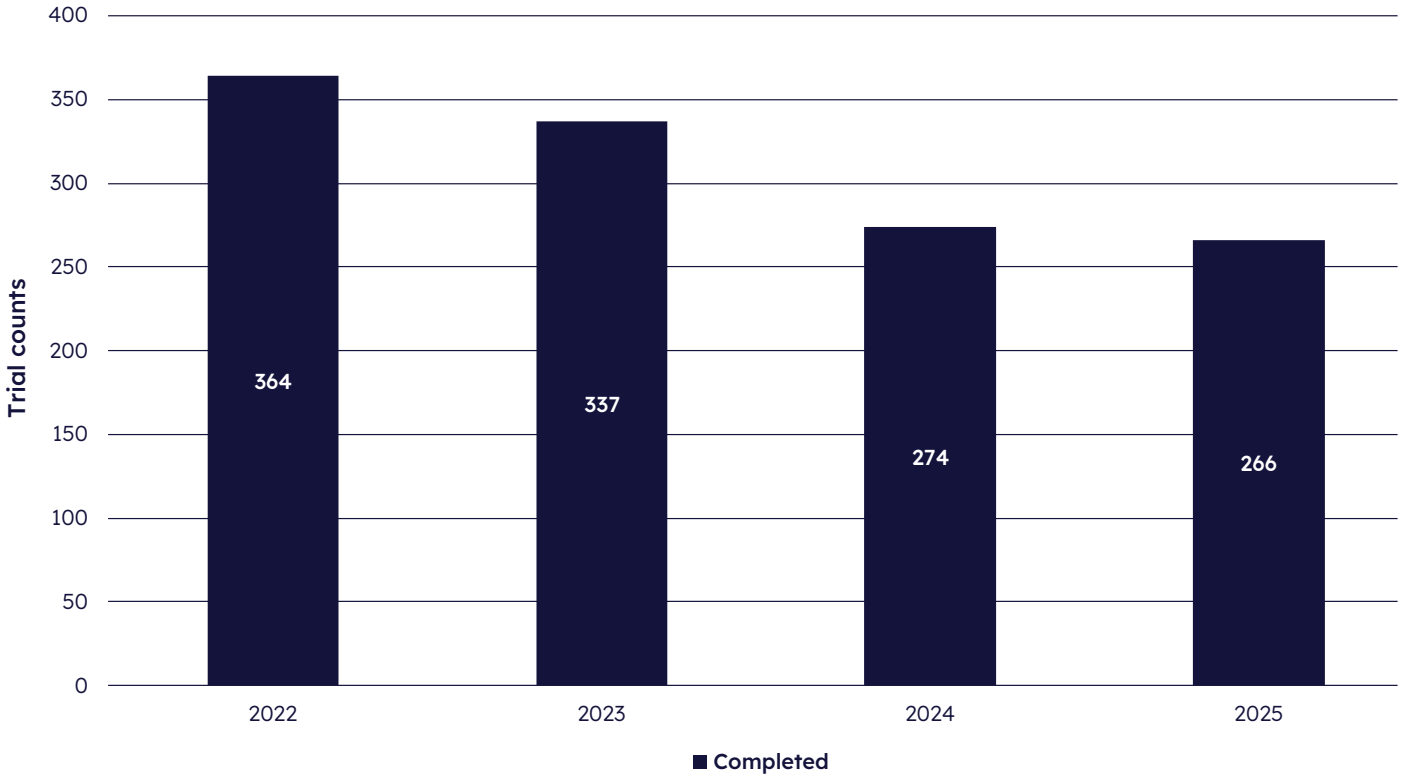
is to further support the country's adoption into the EU.[18] As the project is still in progress and the country responds to the ongoing war, these steps offer support to better position Ukraine's pharmaceutical development process and positively change the trial landscape in conjunction with the drug development for the country.

Figure 6: Trial counts for studies including the countries of Russia and/or Ukraine, 2022–2025



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Key Takeaways

The annual completed trials report continues to palpate the health of the clinical trial industry and define several key markers throughout 2025. In a season of unparalleled obstacles to the industry, solace was found through an increase of success measurements in lieu of 2025's completed trial results, albeit with 11% fewer trial completions yielded year-over-year (4,364). The results were also bolstered by the maintenance and minor progression of each of the top three TAs and compensated for many of the drops sustained by the less-prominent six TAs, as captured in Table 1. Although the dips were felt throughout the listed areas, oncology and met/endo recovered growth in late-stage completed programs, as seen in Figure 1. Additionally, key sponsor development unfolded as Merck & Co. remained in the top-ranked position, predominantly due to the definitive number of oncology trials completed but also reflected in each of the sponsor evaluations for the alternate top TAs. Furthermore, AstraZeneca, Eli Lilly, and Pfizer separated themselves and were also main contributors to the three top TAs.

Joining in the success of the completed trials, green shoots of growth were also present in the pipeline drug analyses, for those that were investigated in positive pivotal trials. A rise of 23.4% in the pipeline status drugs was reflected for the industry and highlights the potential for a multitude of new products to enter the market. Compared to the prior year's assessments, 2025 was underpinned by an advance in drugs with novel mechanisms for oncology, A/I, and met/endo (16 vs. 12). Moreover, the blended number of companies, present in the positive pivotal drug results, was driven by a substantial proportion of AOP sponsors. In total, 83% of the 58 total products are in development by AOP sponsors, and only nine top 20 sponsors with 10 individual products observed in the positive pivotal drug tables. Coupled with the tangible output of the pipeline drugs and in polar opposition to last year's results, higher success rates were also evident in two of the corresponding completed studies TAs (34.6%, oncology; 34.1%, A/I; 25.4%, met/endo). The aggregated calculations of success metrics for every TA further reflected a gain of 3% over our previous analysis, as the yearly percentages moved from 33% in 2024 to 36% in 2025, irrespective of top 20- or AOP-sponsored studies.

As attention is paid to remarkable impacts affecting the pharma sector, these key events curtail the annual completed trials report by emphasizing significant regulatory changes that contribute to reductions in time required for clinical trial approvals, effects from the Trump administration's initiation of tariffs, uncertainty in research funding shifts, and continued global and trial ambiguity amid the war in Ukraine. These multifactorial effects further share insights into how the industry's tectonic plates are shifting and any changes that can be seen on the horizon. Despite annual change, some optimistic transformation was evident from the Portuguese, French, and ACCESS consortiums' move toward streamlined clinical trial approval timelines. However, conflated with the initiation of tariffs and modifications noted in the FDA's approval process, the completed trial values may trend downward in 2026. As focus is drawn to the Eastern European conflict, support rallies to enhance Ukraine's regulatory framework while affected countries simultaneously manage the war. These influences share a generous mix of both encouraging and challenging forecasts; still, the industry shares formidable endurance as it adapts to these conditions.

The past year's unprecedented number of changes did translate to fewer clinical trial completions but were also replaced with higher success rates across the industry. The success of the industry reflects its durability during change and continues to display an aptitude to navigating strong headwinds.

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Appendix

Mechanisms of Action and Disease Terms Abbreviations

A/I	autoimmune/inflammation
AAT	alpha 1 antitrypsin
ALK	activin receptor-like kinase
ALL	acute lymphocytic leukemia
AML	acute myelogenous leukemia
AMPK	AMP-activated protein kinase
BAFF	B-cell activating factor
BTK	Bruton tyrosine kinase
CLL	chronic lymphocytic leukemia
CML	chronic myelogenous leukemia
CMML	chronic myelomonocytic leukemia
COPD	chronic obstructive pulmonary disease
cSCC	cutaneous squamous cell carcinoma
EGFR	epidermal growth factor receptor
FGF	fibroblast growth factor
FOP	fibrodysplasia ossificans progressiva
GCP	glutamate carboxypeptidase
GERD	gastroesophageal reflux disease
GIP	gastric inhibitory polypeptide
GLP-1	glucagon-like peptide 1
GU	genitourinary
GVHD	Graft-Versus-Host-Disease
HL	Hodgkin's lymphoma
ICI	Immune checkpoint inhibitor
ID	infectious disease
Ig	immunoglobulin
IL	interleukin
IO	immuno-oncology
ITP	immune thrombocytopenia
JAK	janus kinase
MASLD	metabolic dysfunction-associated steatotic liver disease
MDS	myelodysplastic syndrome
Met/Endo	metabolic/endocrinology
miRNA	microRNA
NAFLD	non-alcoholic fatty liver disease
NHL	non-Hodgkin's lymphoma
NK	natural killer
NSCLC	non-small cell lung cancer
PAH	phenylalanine hydroxylase
PFIC	progressive familial intrahepatic cholestasis
R	receptor
SCD	sickle cell disease
SCLC	small cell lung cancer
T2D	type 2 diabetes
Th cell	T helper Cell
TKI	tyrosine kinase inhibitor
TNF	tumor necrosis factor
Topo I	topoisomerase I
TSLP	thymic stromal lymphopoietin
TYK2	tyrosine kinase 2
VEGF	vascular endothelial growth factor

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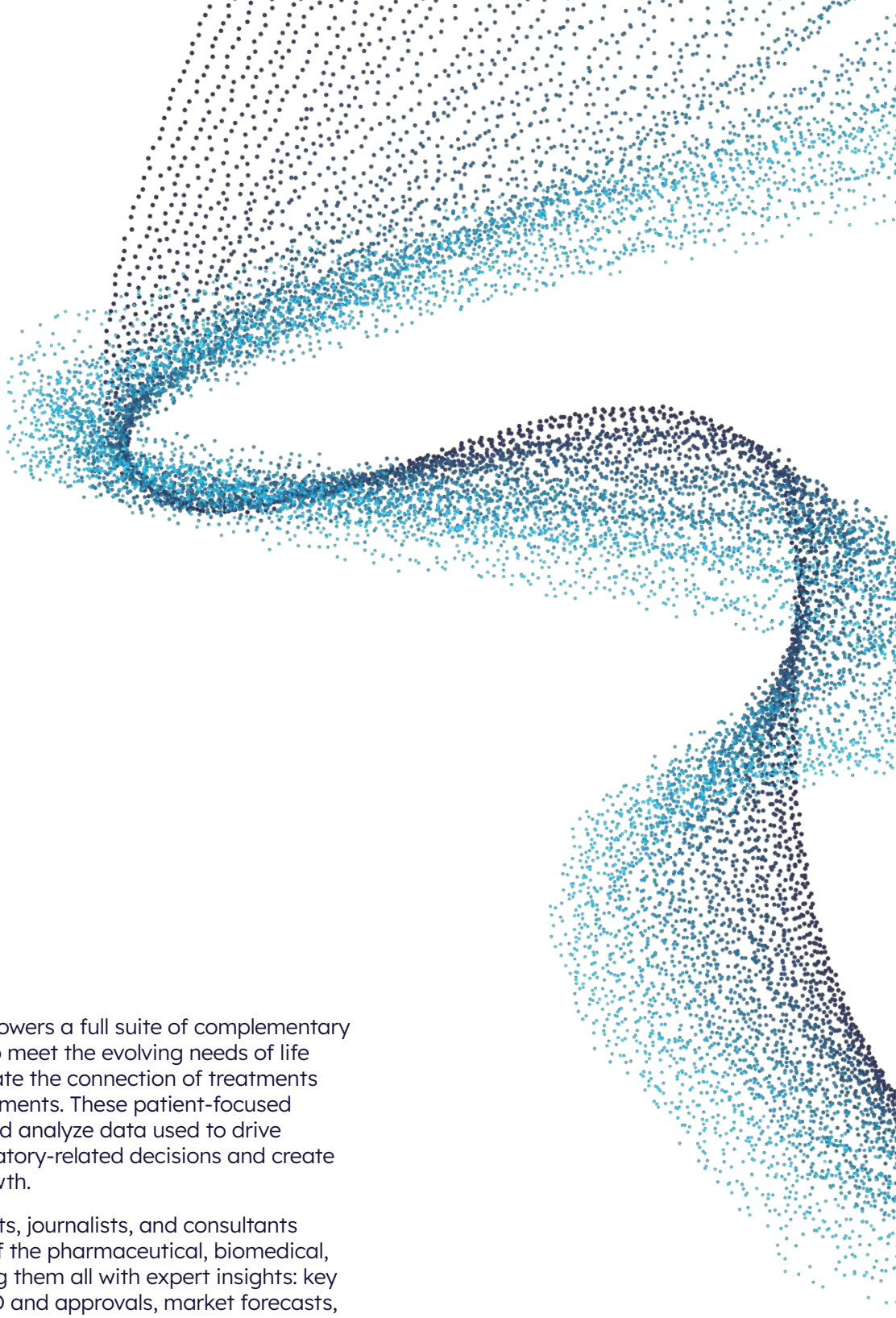

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