ACTO

ASSOCIATION OF CLINICAL TRIALS ORGANIZATIONS

# ACTO NEWSLETTER № 32

## Summary of 2025 results

MOSCOW 2026

# CONTENTS

# SUMMARY

In 2025 the Ministry of Health of Russia issued 615 approvals for the initiation of new clinical trials, 2.2% less than in 2024 (629 approvals).

The largest contribution to the reduction of the overall figure was made by an 8.7% decrease in bioequivalence studies initiated by Russian sponsors: 313 in 2025 vs 343 the previous year. The increase in the number of local studies on the therapeutic efficacy and safety by domestic sponsors (142 compared to 128, a growth of 10.9%), as well as projects by foreign companies, mainly from India and Belarus, on bioequivalence studies (122 compared to 104, up by 17.3%), helped smooth out the overall decline. In comparison to 2024, the number of new local studies by foreign sponsors has more than halved: 16 in 2025 vs 36 a year earlier, but there are usually few records of this type, so fluctuations in their number hardly affect the market as a whole.

The number of approvals for international multicenter clinical trials (IMCTs) in 2025 amounted to 22 vs 18 the previous year. It is worth noting that 11 of them were initiated by Russian developers. It seems that the search for a new balance, provoked by the war and the crisis in international relations, has led to the fact that by the end of 2025 the Russian clinical trials market has acquired a relatively stable, but also, perhaps, not final form, the main characteristic feature of which is an abnormally small share of international trials.

In addition to general statistical information, the newsletter provides a detailed account of:

– types of drugs that were studied in local studies;

– distribution of various types of studies by therapeutic areas;

– the most popular molecules in research on generics and biosimilars;

– rapid growth in the number of comparative study protocols, in the titles of which sponsors do not indicate the reference drug;

– the geography of foreign sponsors who received in 2025 approvals to study their generics and biosimilars in Russia;

– medical organizations more often than others involved in conducting bioequivalence studies;

– sponsors and contract research organizations leading in the number of approvals in various types of studies.

In addition, the issue features a short note on the final results of the industry's fight against the Ministry of Health's attempt to make the electronic form of informed consent mandatory. Due to the sharp decline in activity in the IMCTs sector, it may seem that in recent years the industry has had nothing and no reason to fight for, but this is not true. Legislative initiatives regularly arise, the implementation of which is capable of seriously complicating the future of the clinical research market in the country. An attempt to introduce an electronic informed consent form as the only option is one of them.

The issue concludes with data on the dynamics of the number of clinical trials in the countries of the post-Soviet space. From mid-2022 to early 2026 the number of active interventional trials conducted with the involvement of centers from Russia, Ukraine, and Belarus decreased by half for each of the countries, which, of course, is related to the war. Among all neighboring countries, the most active market growth is observed in Georgia: 245 active interventional trials in the country in February 2026 vs 195 in June 2022 (25.6%).

# VOLUME AND DYNAMICS OF THE RUSSIAN CLINICAL TRIALS MARKET

The search for a new equilibrium, provoked by the war and the crisis in international relations, led to the fact that by the end of 2025 the Russian clinical trials market had acquired a relatively stable, but possibly not final, form, the main characteristic feature of which is an abnormally small share of international trials (IMCTs).

Table 1 presents the main data on approvals issued by the Ministry of Health of the Russian Federation in 2025 for various types of research. In total, for protocols of all types in 2025 615 approvals[1] were issued, which is 2.2% less than in 2024, when the corresponding figure was 629.

The greatest contribution to the overall decline was made by the contraction of the sector that, after 2022, became dominant in the Russian market – bioequivalence studies by domestic sponsors. The number of approvals of this type vs 2024 decreased by 8.7%: 313 in 2025 vs 343 the previous year. The growth in the number of approvals for new local studies by Russian sponsors (142 vs 128, an increase of 10.9%), as well as for projects of foreign companies, mainly from India and Belarus, to study bioequivalence (122 approvals vs 104, by 17.3%), helped to slightly smooth the overall decline. Compared to 2024, the number of new local studies by foreign sponsors decreased by more than half: 16 in 2025 vs 36 the previous year. But it should be taken into account that this type of research is traditionally the least numerous, and its fluctuations have a minimal impact on the market as a whole.

The number of approvals for IMCTs in 2025 amounted to 22 versus 18 a year earlier, that is, formally, an increase of 22.2% was recorded. At the same time, as will be shown in more detail in the following sections, a significant share of IMCTs approvals in 2025 is formed by studies of Russian sponsors with plans to open sites, in addition to Russia, also in one of the neighboring countries, for example, Belarus or Kazakhstan, which distinguishes such projects in scale from global international protocols. It is also worth reminding that we traditionally do not classify as IMCTs all studies that have the corresponding status in the register of approvals of the Ministry of Health of Russia. In our newsletters, only protocols that can also be found in other databases are taken into account, primarily in the international ClinicalTrials.gov and the EU Clinical Trials Register.

**Table 1**

| Approvals for Conduct Clinical Trials: 2025 vs 2024 | | | | | | |
|---|---|---|---|---|---|---|
| **Year** | **Total** | **International Multicenter CTs** | **Local CTs (Foreign Sponsors)** | **Bioequivalence Studies (Foreign Sponsors)** | **Local CTs (Local Sponsors)** | **Bioequivalence Studies (Local Sponsors)** |
| **2025** | 615 | 22 | 16 | 122 | 142 | 313 |
| **2024** | 629[2] | 18 | 36 | 104 | 128 | 343 |
| **2025 vs 2024, %** | -2,2% | 22,2% | -55,6% | 17,3% | 10,9% | -8,7% |

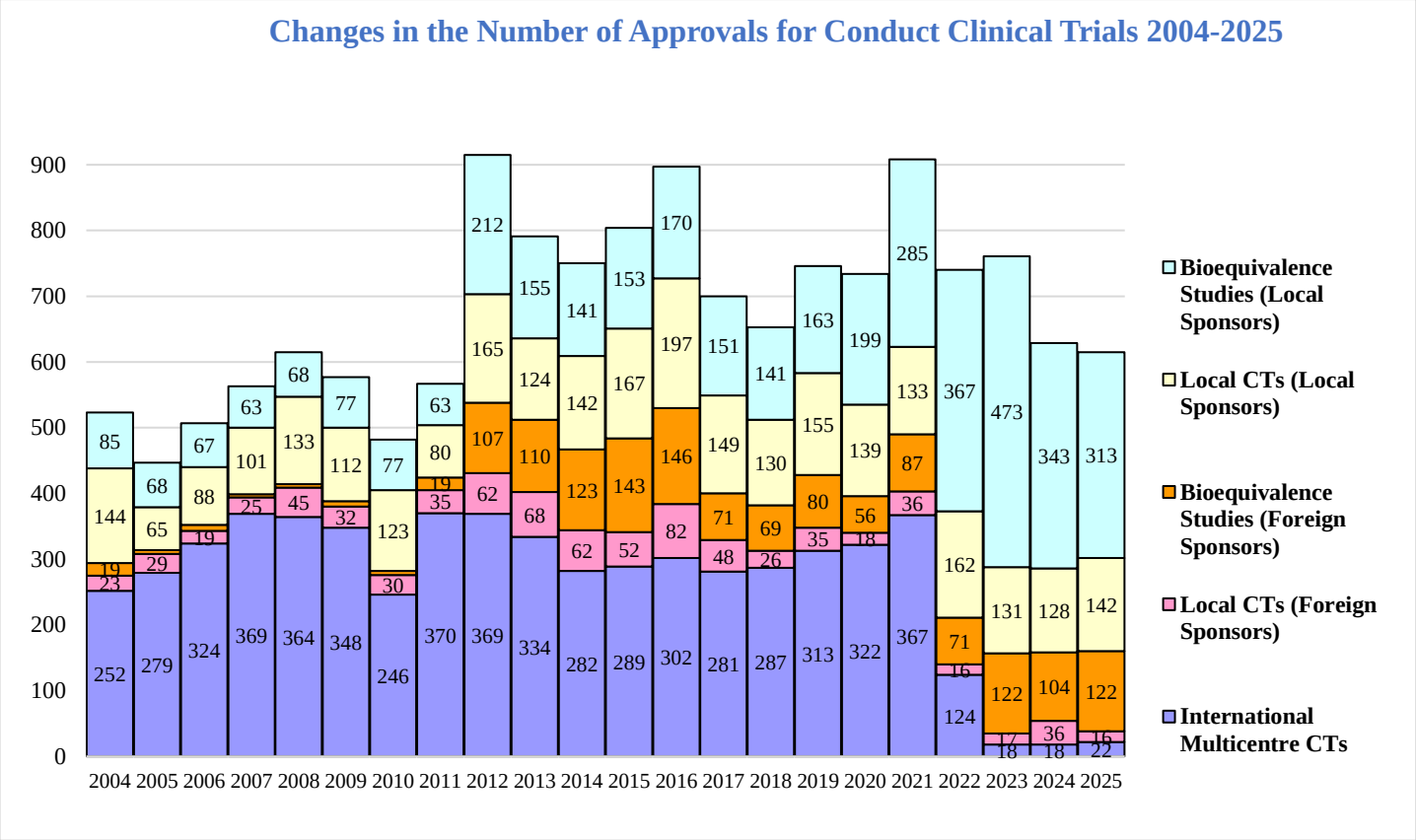
Data from www.grls.rosminzdrav.ru

Below, in diagrams 1–6, you can trace the dynamics of the number of issued approvals over a longer observation period. Diagram 1 presents indicators for all types of studies starting from 2004. Diagrams 2–6 contain data from 2012, i.e., after the final transition to the current industry regulation, separately for each type of studies, broken down by half-years.

[1] This is not a final figure, since we continue to record cases where the Ministry of Health enters records of issued approvals into its register retroactively. In the registry's continuous numbering, gaps appear that are filled not within one working day, as provided for by Order of the Ministry of Health of Russia dated August 26, 2010 No. 754n, but weeks, months, and even years (!) later. Thus, in February 2026 we discovered that, for the first time, the register included an approval to bioequivalence study, issued to a Russian sponsor back in December 2024.

[2] Taking into account the entries added to the register in 2025-2026, there are 632, but we did not consider it appropriate to recalculate all the statistics for 2024 after the fact, especially since there are still gaps in the register. At the time of publication of this newsletter, in the register for 2025 there remains a missing entry under number 577, for 2024 – under number 618.

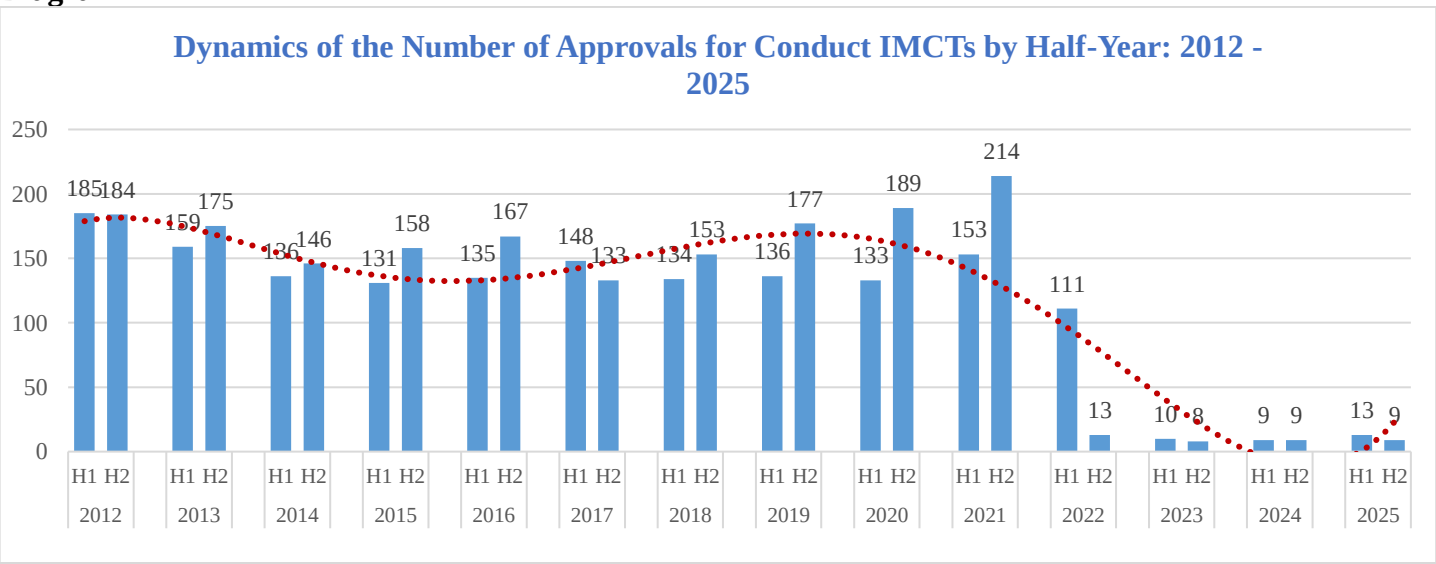
**Diagram 1**




Data from www.grls.rosminzdrav.ru

The number of new IMCTs after 2022 is less than 7% of the average value of the ten pre-war years and does not exceed 22 per year.

**Diagram 2**

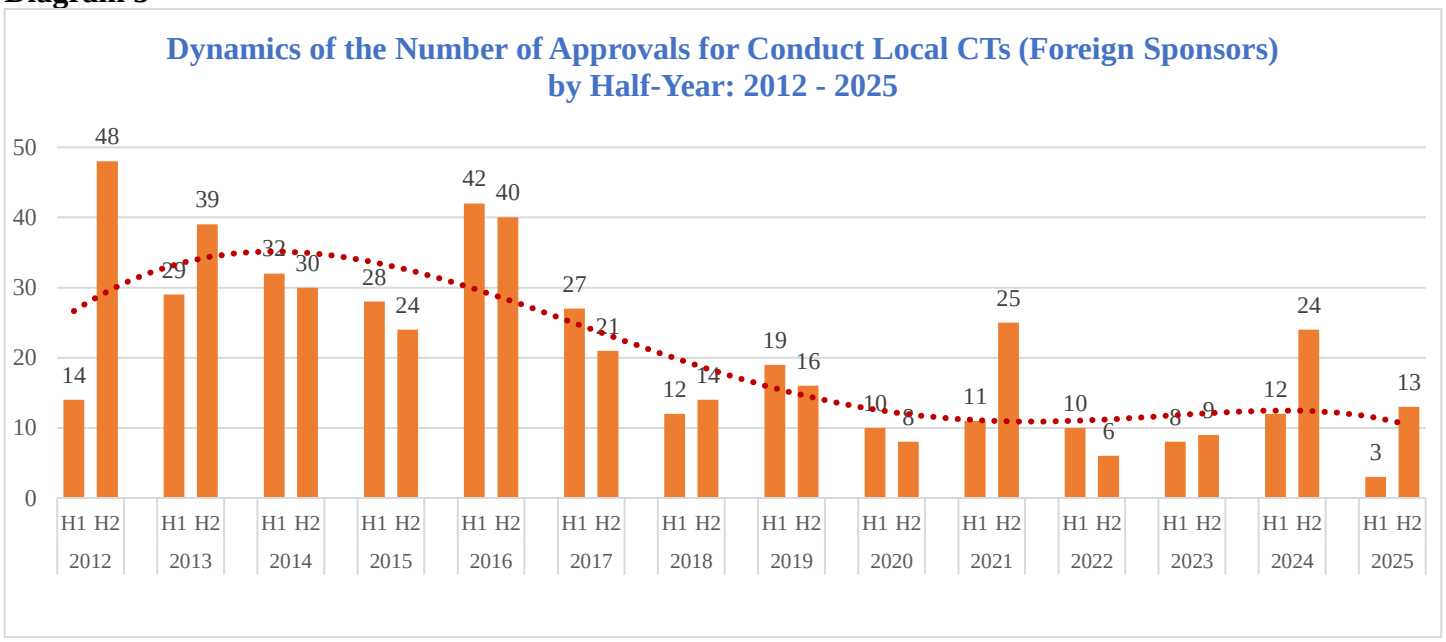



Data from www.grls.rosminzdrav.ru

The highest numbers of approvals for local trials of therapeutic efficacy and safety by foreign sponsors were observed in 2012–2016 years, when from 52 to 82 approvals of this type were issued per year. Since the beginning of 2016, the requirement has come into force to provide the results of an inspection of the manufacturing site when bringing a medicinal product to the Russian market. It predictably turned out to be burdensome for foreign sponsors, and starting in 2017 their interest in new local trials in Russia began to decline. Additional difficulties were brought by the pandemic in 2020 and the start of the war in 2022. As a result, the

average number of new studies of this type for 2017–2025 turned out to be slightly more than 40% of the average for 2012–2016. Despite small surges in activity in 2021 and 2024 (36 approvals each), the sector remains very small.

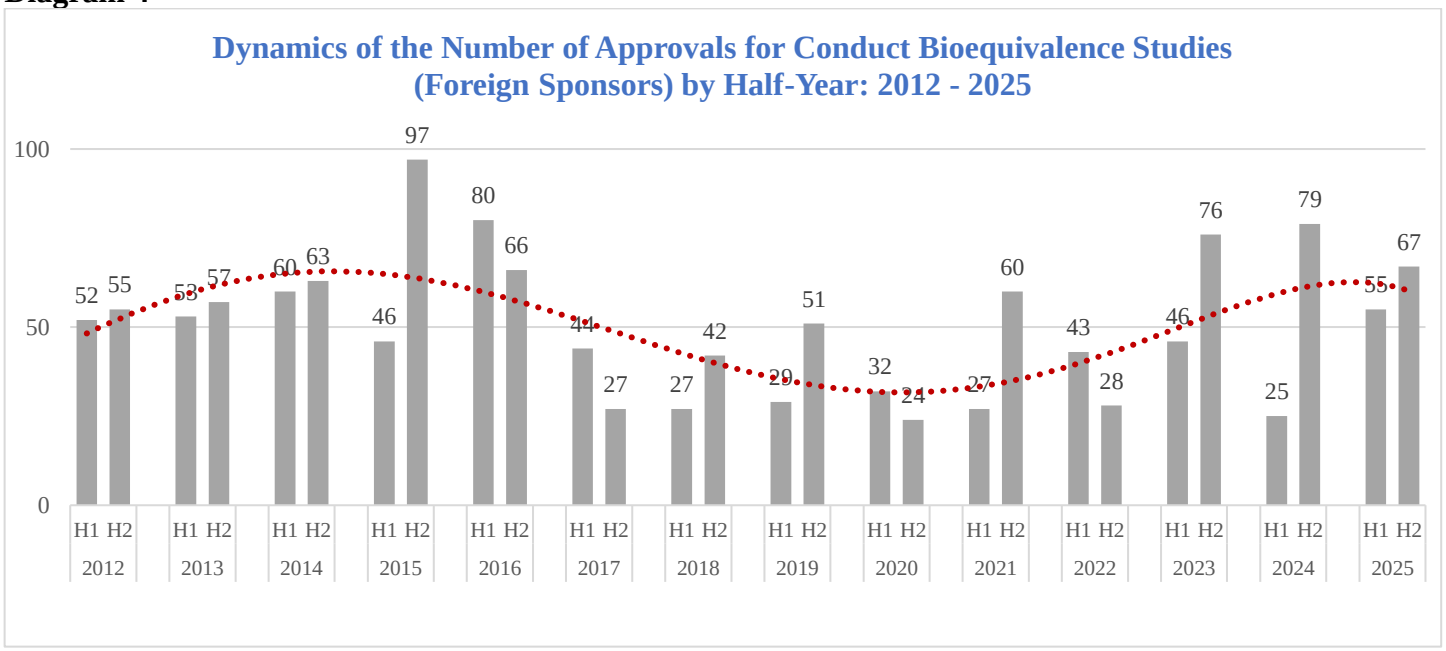
**Diagram 3**




Data from www.grls.rosminzdrav.ru

The number of bioequivalence study protocols initiated by foreign sponsors in 2012–2025 remained closer to its average values, unlike the previous category of studies. Sustainability is facilitated by the fact that bioequivalence testing requires fewer resources compared to a full development cycle and is available to a larger number of sponsors from a wider range of countries. In periods unfavorable for international cooperation, companies from other regions may replace sponsors from certain regions.

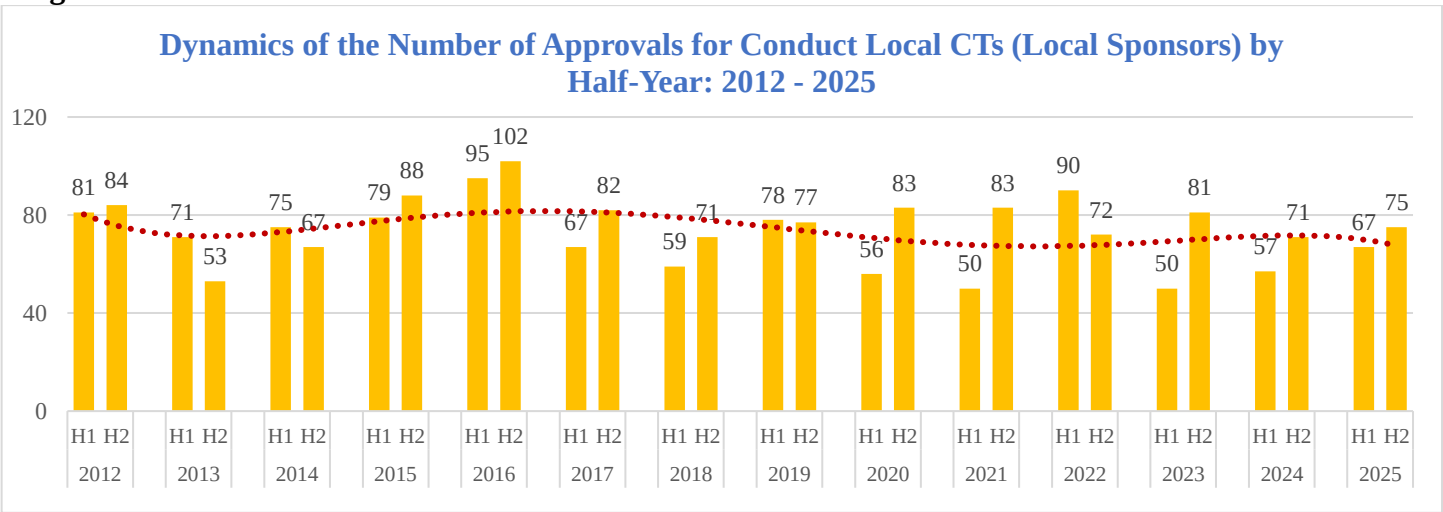
**Diagram 4**




Data from www.grls.rosminzdrav.ru

The dynamics of the number of approvals for local trials of domestic sponsors, shown in Diagram 5, is less subject to fluctuations than the others. The result for 2025 is less than 5% below the average for the previous ten years: 142 approvals vs 149.2.

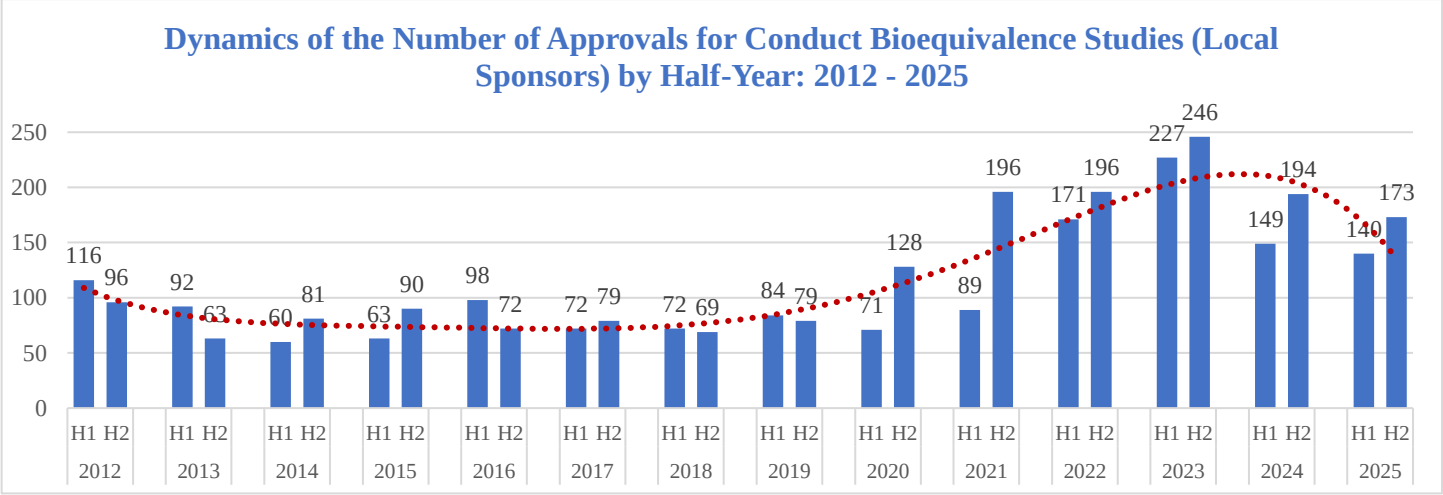
**Diagram 5**




Data from www.grls.rosminzdrav.ru

In a more dramatic and less obvious way, the number of approvals for bioequivalence studies obtained by Russian sponsors was changing (Diagram 6).

**Diagram 6**




Data from www.grls.rosminzdrav.ru

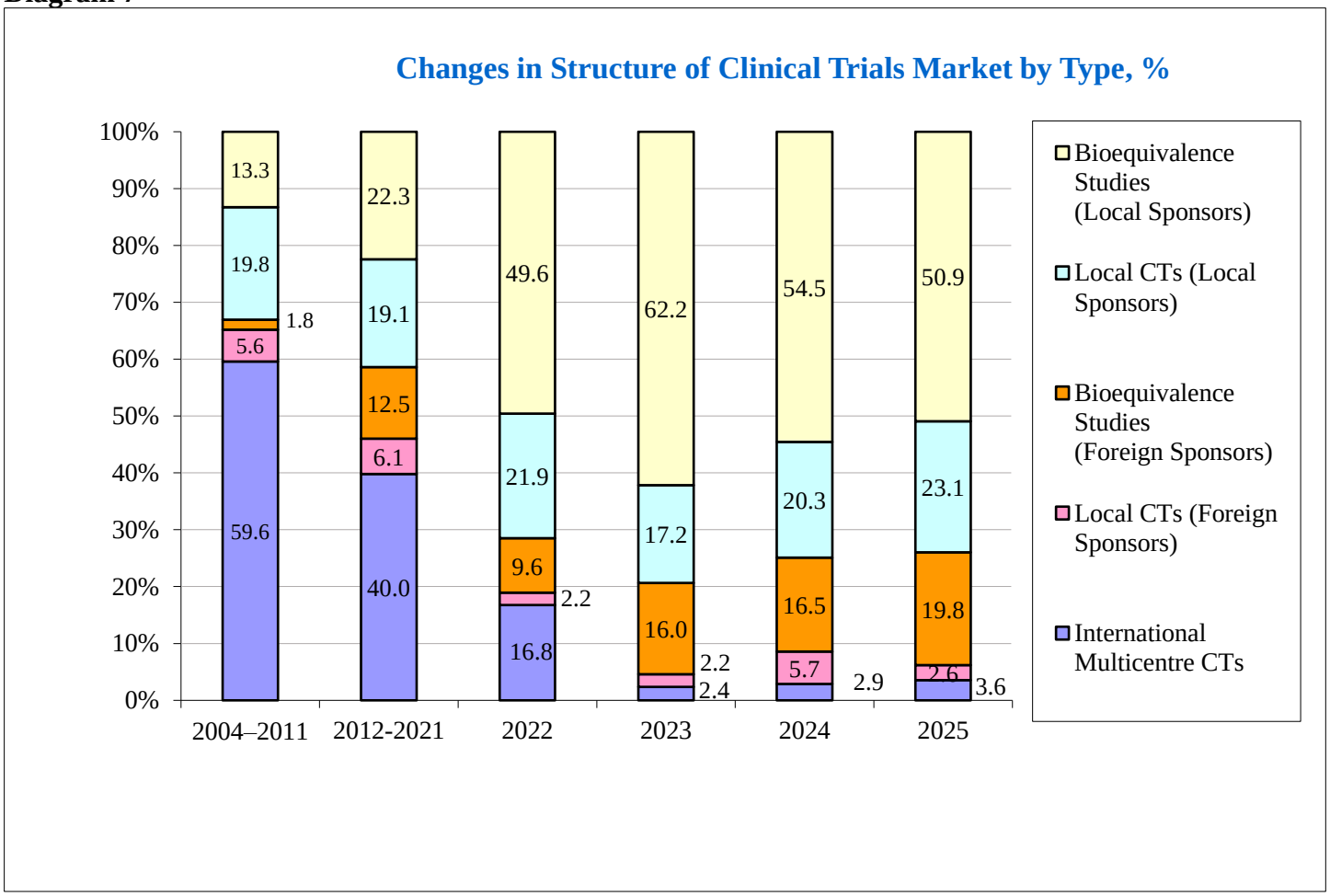
From the second half of 2020 this type of studies began to grow, and for several years nothing held back its rapid growth. However, in 2024 something still «happened»[3] and the indicators began to decline. If we take 2023, currently the most successful year for this type of clinical trials, as 100%, then the results of the two adjacent years will be about three quarters of this value (more precisely, 2024 will amount to 72.5%, and 2022 – 77.6%), and the indicators of the more distant neighboring years will be about two thirds (2025 – 66.2% and 2021 – 60.3%). That is, in a rough approximation, the decline is proceeding about as quickly as the growth did earlier. The market analysts we surveyed attribute this decline to the deterioration of the overall economic situation in Russia. In particular – with rising loan costs, increased expenses (incl. transaction costs), reduced profitability, etc. Apparently, now even generic drug manufacturers are forced to take a more careful approach to choosing the company's portfolio, trying to calculate future demand as accurately as possible. Another version put forward by experts against the backdrop of the obtained picture of a reduction in the number of bioequivalence studies is the use of a biowaiver, a procedure for assessing the bioequivalence of a generic drug in vitro without conducting clinical studies. However, the relevant rules that launched this mechanism were adopted in the EAEU back in late 2016, and, apparently, in recent years the practice has been gradually expanding. However, without

[3] In the Russian-speaking segment of the Internet, this expression has become a meme that serves to express irony toward those who are not interested (or pretend not to be interested) in politics and are not aware of the news.

dismissing the influence of this factor, we can hardly explain by it such a significant decline specifically in the last two years.

Diagram 7 illustrates the redistribution of the shares of various types of studies over three periods: before the reform of legislation on the circulation of medicinal products (average values for 2004–2011), after its implementation and before the start of the full-scale war in Ukraine (average values 2012–2021), as well as for the last four years separately.

**Diagram 7**




Data from www.grls.rosminzdrav.ru

Until 2022 the leading positions in the market were held by IMCTs: in 2004–2011 they accounted for an average of 60% of all approvals, and in 2012–2021, due to the growth in the number of other types of studies (see also Diagram 1) – 40.0%. The period 2012–2021 years differed from the previous one by a strengthening of the positions of bioequivalence research: the share of such projects by foreign sponsors increased in the total market volume from 1.8% to 12.6%, and by Russian sponsors—from 13.3% to 23.3%.

In 2022 international companies effectively stopped launching new studies in Russia. Although, due to the inertia of the bureaucratic system, documents continued to be issued for some time, the sponsors did not plan to start enrollment to many IMCTs after receiving permission. The scale of the losses was reflected in the approvals statistics only a year later: by the end of 2023 the share of IMCTs had shrunk to 2.4% (the lowest value for at least the 22 years over which we conducted observations) and changed little thereafter: 2.9% in 2024 and 3.6% in 2025.

IMCTs departure shifted the market balance toward Russian companies: in 2023–2025, their projects accounted for about three quarters of all approvals. Bioequivalence studies of domestic generics began to dominate: their share amounted to 49,6% in 2022, 62,2% in 2023, 54,5% in 2024 and 50,9% in 2025.

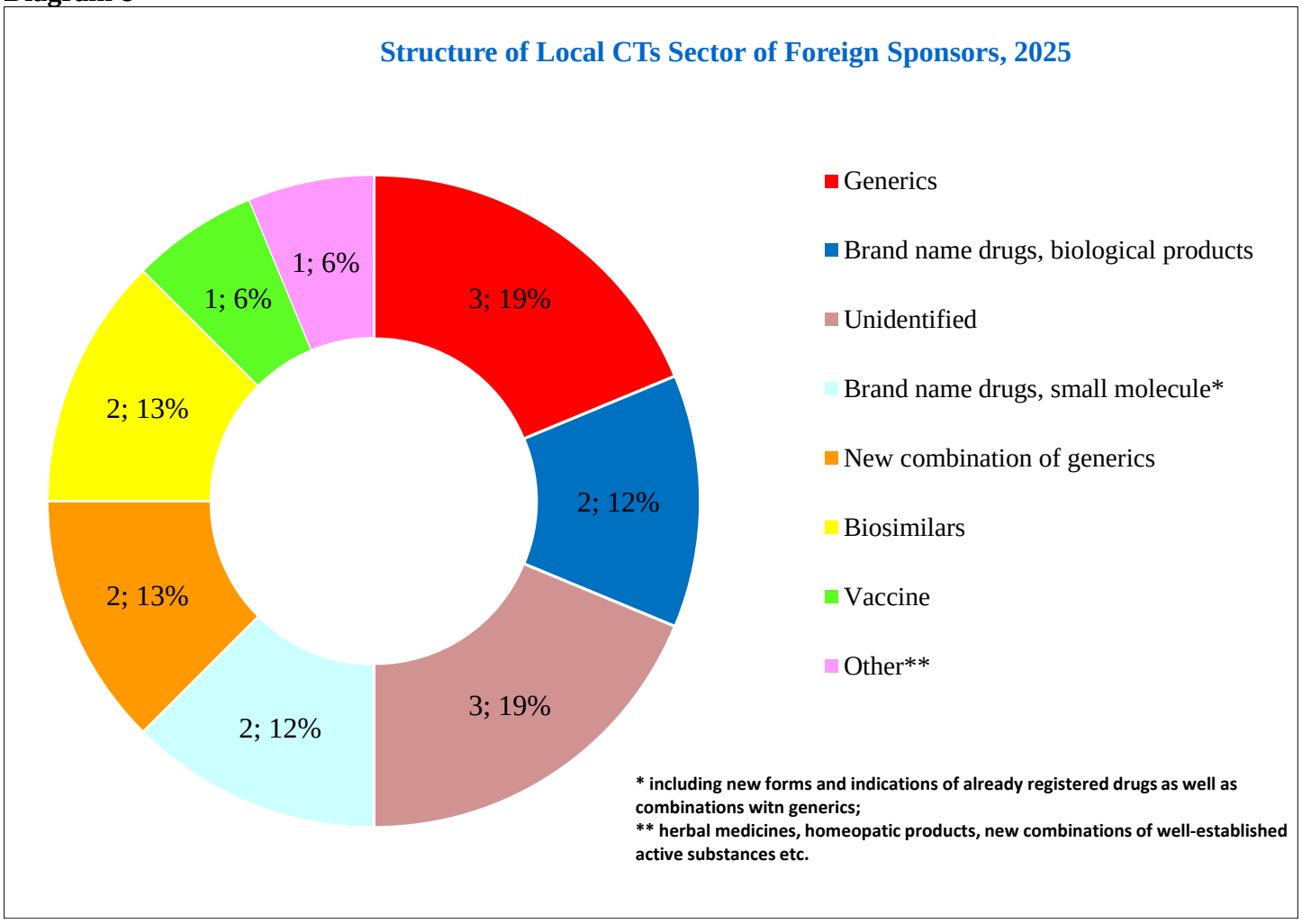
## STRUCTURE OF THE MARKET FOR LOCAL TRIALS

The diagrams below present the categories of medicinal products that were studied in local protocols of therapeutic efficacy and safety of foreign (Diagram 8) and Russian (Diagram 9) companies. Let us emphasize that, although generics appear in the statistics, we consider bioequivalence tests as a separate type of studies and do not take them into account in this section.

Foreign sponsors in 2025 received 16 approvals for local trials. They developed predominantly generic drugs: they account for three of the 16 protocols (18.8%), and in two more (12.5%) new combinations of generics were tested.

Two approvals were granted for originator biologics (AstraZeneca worked with tozorakimab in COPD, and the Serum Institute of India with a monoclonal antibody against human rabies), the same number for biosimilars (the Iranian CinnaGen indicated its version of ocrelizumab for multiple sclerosis in the application, and the Chinese company Sichuan Luzhou Buchang Biopharmaceutical a recombinant human monoclonal antibody to VEGFR2), and for originator small molecules (a post-registration study of pelubiprofen by the Korean developer Devon Pharma and a study of an oral PCSK9 inhibitor to regulate cholesterol levels from AstraZeneca) – 12.5% for each of the named categories. One approval (6.3%) was received by the Chinese Beijing Zhifei Lvzhu Biopharmaceutical to study a vaccine against pneumococcus, and another by the French Boiron for a homeopathic remedy (on the diagram indicated as «other»). Finally, we were unable to identify the drugs mentioned in three other protocols (18.8%).

**Diagram 8**



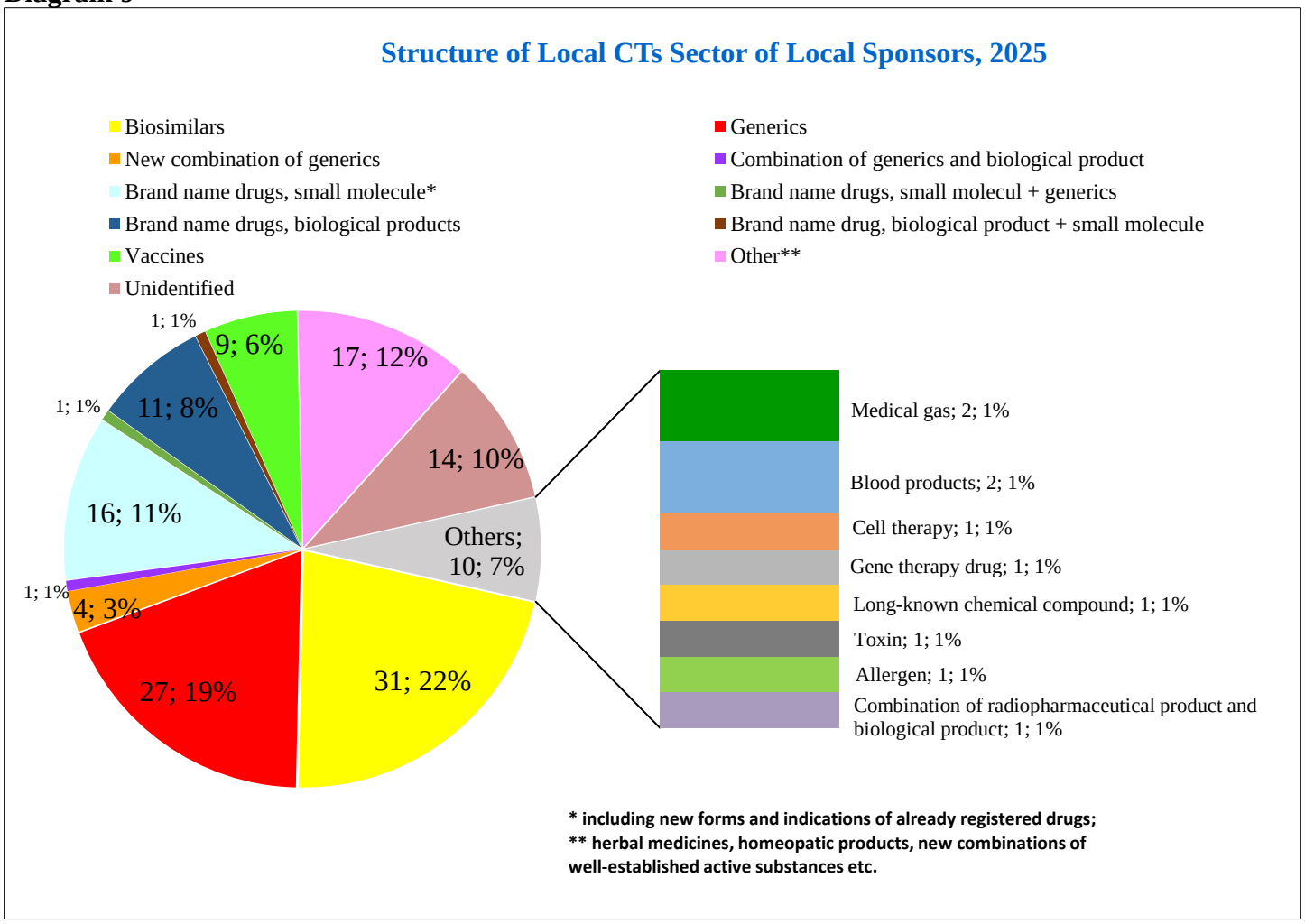

Data from www.grls.rosminzdrav.ru

Distribution by types of drugs of approvals obtained by Russian sponsors in 2025 for local trials of therapeutic efficacy and safety (let us remind again: excluding bioequivalence studies) is presented in Diagram 9. A total of 142 such approvals were issued over the year.

Formally, the largest share is for biosimilars – 31 protocols (21.8%). In recent years, as industry experts explained at our request, the reproduction of biological drugs has become less resource-intensive, which has made it possible to copy them more actively. This category first pulled ahead at the end of 2023 and has not relinquished its position since, pushing generic drugs into second place. In 2025 they accounted for 27 studies (19.0%). But since four protocols (2.8%) study new combinations of generics and one more (0.7%) — a combination of generics and recombinant alpha-fetoprotein, in total a parity has emerged between the two groups. The combined share of generics and biosimilars studies amounted to 44.4% of all local trials by domestic sponsors in 2025.

Originator products are presented in 29 trials (20.4%), of which 16 (11.3%) are small molecules and 11 (7.7%) are biologics. One more protocol (0.7%) for the combination of the original small molecule and generics, as well as for the combination of the original biologic with a small molecule.

**Diagram 9**




Data from www.grls.rosminzdrav.ru

Nine trials (6.3%) were on vaccines, two (1.4%) each on medical gases and on blood products. One protocol (0.7%) was for botulinum toxin, recombinant tuberculosis allergen, one well-known chemical compound (lithium chloride), for a combination of radiopharmaceutical and biological products («radiopharmaceutical with bispecific monoclonal antibodies to GITR and CTLA-4 and the radioisotope 177Lu» is listed in the application of the A. M. Granov Russian Research Center for Radiology and Surgical Technologies), as well as for cell and gene therapy. Cell therapy in this case is a study of allogeneic mesenchymal stem cells for neural tissue defects in patients with spinal column and spinal cord injury, initiated by the Federal Center of Brain Research and

Neurotechnologies of the FMBA. Gene therapy is a drug based on a non-viral plasmid construct encoding the target therapeutic genes FCU1, which was patented by the FMBA Center for Strategic Planning as a means to fight tumors. The latest examples show that among local trials of Russian sponsors there are also applications for modern, interesting, science-intensive developments, but since they are at early stages, it is still difficult to assess their chances of completing the entire cycle of research and entering the market.

This time, 17 protocols (12.0%) were assigned to the "other" category, which includes substances of plant or animal origin, homeopathic remedies, and other products that are difficult to classify. In 14 more trials (9.9%), the active substances could not be identified, since only its code was indicated in the protocol title. You can read more about the spread of the practice of concealing information about the drug being tested in the second half of the following section.

# STRUCTURE OF THE CLINICAL TRIALS MARKET BY THERAPEUTICS AREAS

## International multicentre clinical trials

Table 2 presents the distribution by therapeutic areas of IMCTs for which approvals were issued in 2025. Using international databases and direct inquiries to sponsors, we were able to confirm the international status of 22 projects. It is important to note that exactly half of them were initiated by Russian companies.

**Table 2**

| Distribution of International Multicenter CTs by Therapeutic Areas, 2025 | | | |
|---|---|---|---|
| **Therapeutic Area** | **Number of IMCTs** | **Share (%)** | **The number of planned participants** |
| Oncohaematology | 7 | 31.8% | 418 |
| Oncology | 3 | 13.6% | 639 |
| Neurology | 3 | 13.6% | 472 |
| Rheumatology | 2 | 9.1% | 340 |
| Gynecology | 2 | 9.1% | 45 |
| Endocrinology | 1 | 4.5% | 780 |
| Nephrology/endocrinology | 1 | 4.5% | 370 |
| Cardiology | 1 | 4.5% | 340 |
| Gastroenterology/coloproctology | 1 | 4.5% | 300 |
| Dermatology/immunology | 1 | 4.5% | 22 |
| TOTAL | 22 | 100.0% | 3 726 |

Data from www.grls.rosminzdrav.ru

Almost half of all IMCTs approved in 2025 are related to oncohematology and oncology (seven and three trials respectively, 45.4% in total). Three Phase I IMCTs for patients with certain types of leukemias and lymphomas were initiated by the Australian company Eilean Therapeutics (one of the approvals was issued to its subsidiary Lomond Therapeutics). American Ascentage Pharma Group launched two trials of a selective BCL-2 inhibitor called lisaftoclax. Chinese Dizal (Jiangsu) Pharmaceutical received an approval to assess the antitumor effect of birelentinib in leukemias and lymphomas, and another Chinese sponsor, Jiangsu Alphamab Biopharmaceuticals, to test the efficacy and safety of envafolimab in lung cancer. Among Russian companies, only Biocad is represented in these therapeutic areas. The company received three Phase I study approvals for its antibody-drug conjugates: brentuximab vedotin in patients with Hodgkin lymphoma, as well as trastuzumab emtansine and trastuzumab deruxtecan in breast cancer.

In neurology, three approvals have been issued. Swiss Hoffmann-La Roche continues to provide ocrelizumab to patients with multiple sclerosis who took part in the company's earlier studies. Russian Generium received an approval to compare with La Roche's original ocrelizumab its own version, as well as to launch a Phase I–II protocol of a gene-therapy drug for children with Duchenne muscular dystrophy.

Two IMCTs pertain to rheumatology, both were initiated by Russian R-Pharm, and both are testing olokizumab for polymyalgia rheumatica. In gynecology, there are also two approvals, and also with the same Russian sponsor, ABBA RUS. These two protocols are devoted to testing combinations of nifuratel and nystatin (in one case with the addition of lactulose) in candidal vulvovaginitis and bacterial vaginosis.

In the other therapeutic areas, one approval per each area has been issued. Novartis continues to study the long-term safety and tolerability of pelacarsen in participants of its previously completed cardiology protocols. AstraZeneca announced a Phase II study of the combination of zibotentan and dapagliflozin in patients with chronic kidney disease. Bio-Thera Solutions from China intends to compare the efficacy and safety of its drug with Novartis's original secukinumab in patients with psoriasis. Russian Geropharm is studying a semaglutide analogue in patients with type 2 diabetes mellitus; Generium — an ustekinumab analogue for ulcerative colitis.

## Local trials and bioequivalence studies, foreign generics and biosimilars

Table 3 presents the distribution by therapeutic areas of local trials and bioequivalence studies initiated by foreign sponsors.

**Table 3**

| Distribution of Local CTs and Bioequivalence Studies (Generics and Biosimilars) of Foreign Sponsors, 2025 | | | |
|---|---|---|---|
| **Therapeutic Area** | **Number of CTs** | **Share (%)** | **Number of planned participants** |
| Cardiology and CVD/Surgery/Intensive care | 36 | 27.9% | 2 083 |
| Endocrinology | 13 | 10.1% | 748 |
| Gastroenterology | 12 | 9.3% | 729 |
| Urology | 10 | 7.8% | 630 |
| Oncology | 10 | 7.8% | 614 |
| Gynecology | 9 | 7.0% | 881 |
| Otorhinolaryngology | 8 | 6.2% | 640 |
| Analgesic and NSAIDs | 7 | 5.4% | 268 |
| Neurology | 5 | 3.9% | 262 |
| Pulmonology | 3 | 2.3% | 342 |
| Allergology | 3 | 2.3% | 215 |
| Ophthalmology | 2 | 1.6% | 392 |
| Hepatology | 2 | 1.6% | 172 |
| Dermatology | 2 | 1.6% | 120 |
| Infectious Diseases (except HIV/HCV/tuberculosis) | 2 | 1.6% | 85 |
| Psychiatry | 2 | 1.6% | 64 |
| Haematology | 1 | 0.8% | 120 |
| Parasitology | 1 | 0.8% | 50 |
| Oncohaematology | 1 | 0.8% | 33 |
| TOTAL | 129 | 100.0% | 8 448 |

Data from www.grls.rosminzdrav.ru

A total of 129 approvals of this type were issued in 2025. Most relate to cardiology and cardiovascular diseases (CVD). Taking into account that this also included anticoagulants used in other fields (such as surgery, intensive care), in total this category was represented by 36 protocols (27.9% of the total number of approvals for this type of research), which made it the undisputed leader.

Second place is occupied by endocrinology with 13 protocols (10.1%). Gastroenterology is slightly behind it – 12 studies (9.3%). Next come urology and oncology – ten approvals each (7.8% each). Another nine protocols (7.0%) relate to gynecology, eight (6.2%) to otorhinolaryngology, seven (5.4%) to the group of analgesics and NSAIDs, and five (3.9%) to neurology.

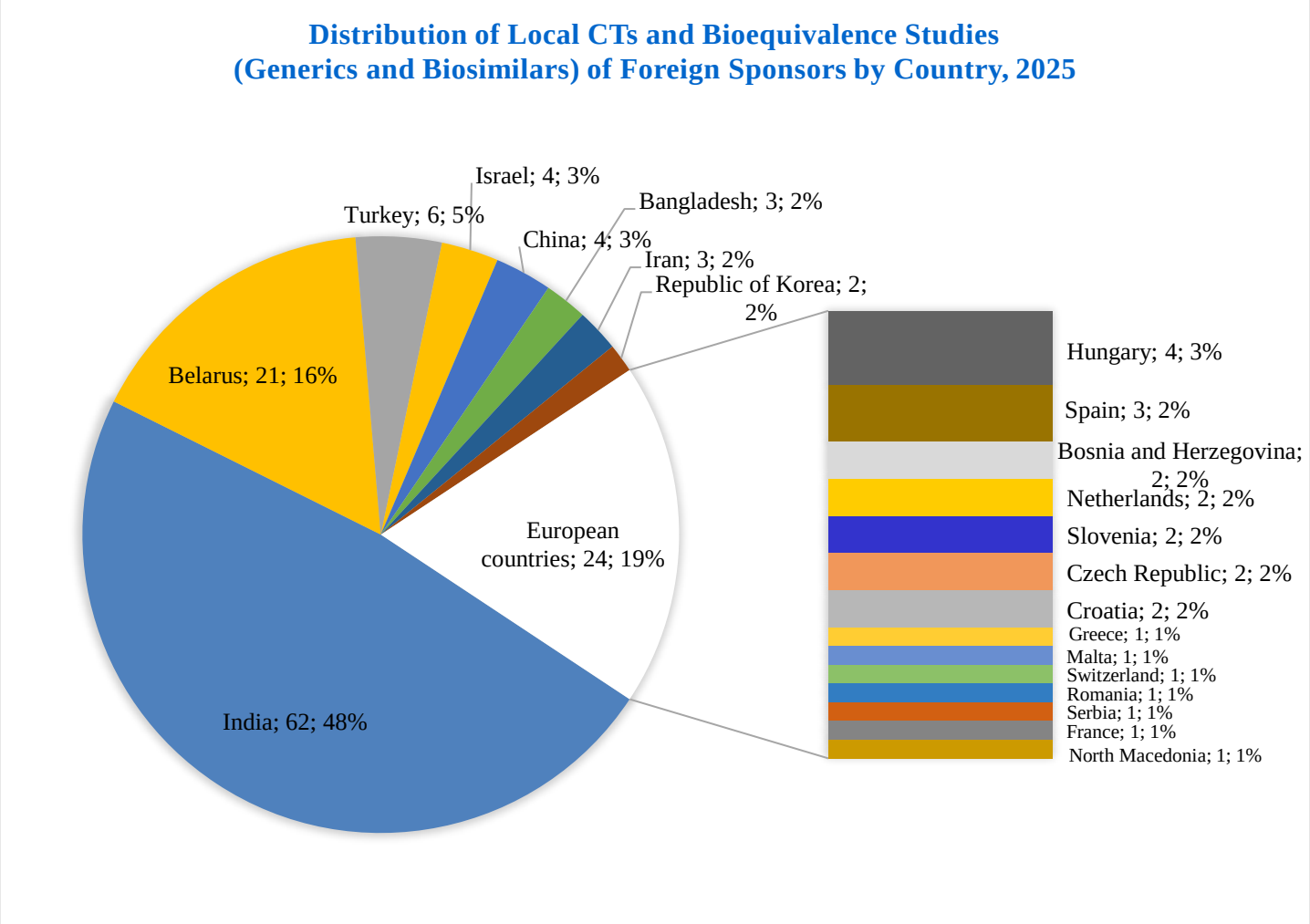
Three approvals were issued in pulmonology and allergology (2.3% each). Ophthalmology, hepatology, dermatology, infectious diseases (with the exception of HIV, hepatitis C, and tuberculosis), as well as psychiatry are represented by two studies each (1.6% each). In areas such as hematology, parasitology, and oncohematology, one approval was issued (0.8% each).

If we analyze similar tables for 2021–2024 years, we can make sure that among foreign manufacturers of generics, the most sustained interest is generated by medicines used in cardiology and CVD, as well as in endocrinology – they have been in the top 5 in all recent years. Infectious diseases were in the upper half of the table for four years out of five, in 2021–2024 years. Attention from sponsors to the other therapeutic areas is less stable.

## Geography of foreign sponsors of studies of generics and biosimilars

Starting in 2022, we describe the geography of foreign sponsors who have received approvals to conduct trials in Russia on their generics and biosimilars (Diagrams 10 and 11).

**Diagram 10**




Data from www.grls.rosminzdrav.ru

In 2025 almost half of all approvals were for India: 62 out of 129, or 48.1%. The share of Indian companies continues to gradually increase: in 2022 it was 29.6%, in 2023 – 44.4%, in 2024 – 45.6%. The most active companies were: Hetero Labs (11 approvals in 2025), Dr. Reddy's (seven) and Ipca Laboratories (six).

Second place at the end of 2025 is occupied by Belarus with 21 approvals (16.3%). After the indicator fell to 12.0% in 2024, the share of approvals issued to sponsors from this country rose slightly, although it remains lower than in 2022 and 2023 (30.9% and 23.3% respectively). In 2025 more than anything, the Borisov Plant of Medical Preparations and Rubikon received the most approvals (four each), only slightly behind them were Lekpharm, Pharmtechnology and Pharmland (they have three each).

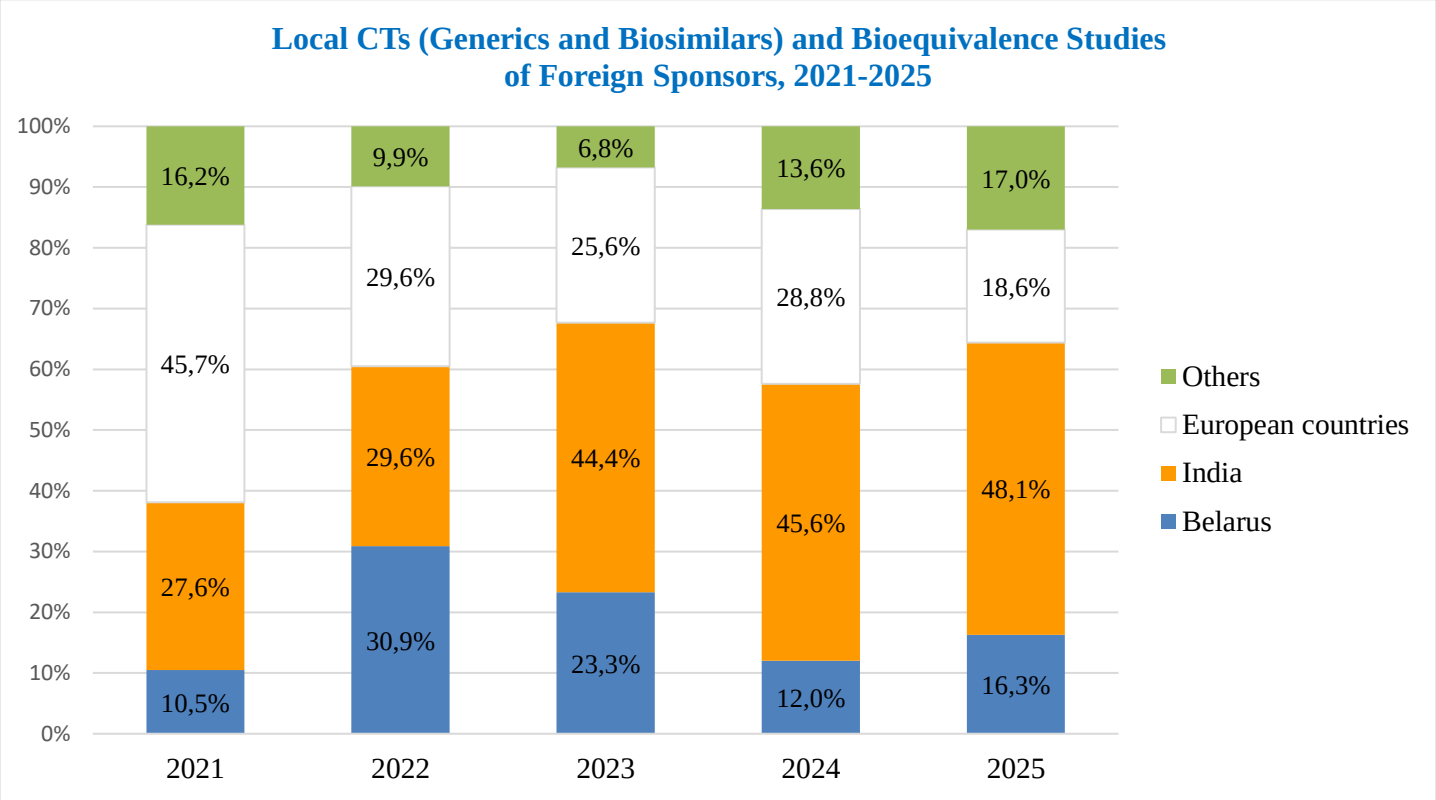
The combined share of European countries in 2025 decreased to 18.6% vs 28.8% a year earlier (24 versus 36 new studies). In this group there are no clear leaders among the sponsors: three approvals for Hungarian Gedeon Richter, two each for Bosnalijek from Bosnia and Herzegovina, Laboratorios León Pharma from Spain, Synthon from the Netherlands, KRKA from Slovenia, and PRO.MED.CS Praha from the Czech Republic.

In addition to sponsors from India, Belarus and Europe, companies from Turkey (six approvals, four of them held by World Medicine), Israel (four, all held by Teva), China (four, three of which are held by Zhejiang

Huahai), Bangladesh (three, all held by Renata Limited), Iran (three, all held by CinnaGen), South Korea (two, both held by Whan In Pharm) are represented on the Russian market.

Diagram 11 shows how the structure of the market sector we are interested in has changed over the last five years. And until 2022 more sponsors of generics and biosimilar studies came to Russia from India than from any other individual country, but previously about half of all new projects of these types were accounted for by companies from the European region. Now the dominance of Indian sponsors has become complete.

**Diagram 11**




Data from www.grls.rosminzdrav.ru

## Local trials and bioequivalence studies, domestic generics and biosimilars

In 2025, the Ministry of Health issued Russian sponsors 388 approvals for local trials and bioequivalence studies of generics and biosimilars, 5.8% fewer than in 2024 (412 protocols).

In first place remains the field of «cardiology and cardiovascular diseases» (including protocols with anticoagulants, also used in surgery and intensive care): 54 studies vs 71 the previous year. Next comes endocrinology with 37 protocols (48 in 2024). Neurology takes the third position in 2025 (33 studies), having increased compared to the previous year (there were 27). Psychiatry broke through to fourth place thanks to growth to 31 approvals (seven in 2024). Oncology rounds out the top five: 30 new studies vs 47 the previous year.

Compared to 2024 year, the most significant decrease was demonstrated by cardiology with CVD and oncology (17 fewer studies), as well as endocrinology (by 11). The most pronounced growth was shown by psychiatry (added 24 studies), pulmonology (seven more protocols) and urology (five more).

The number of unidentified protocols also doubled over the year (26 versus 13), but we will discuss this problem a little later, after reviewing the list of most popular molecules for generics and biosimilars studies approved in 2025.

**Table 4**

| Distribution of Local CTs and Bioequivalence Studies (Generics and Biosimilars), Conducted by Local Sponsors, 2025 | | | |
|---|---|---|---|
| **Therapeutic Area** | **Number of CTs** | **Share (%)** | **Number of planned participants** |
| Cardiology and CVD/Surgery/Intensive care | 54 | 13.9% | 2 600 |
| Endocrinology | 37 | 9.5% | 3 736 |
| Neurology | 33 | 8.5% | 2 226 |
| Psychiatry | 31 | 8.0% | 1 288 |
| Oncology | 30 | 7.7% | 2 535 |
| Unidentified | 26 | 6.7% | 2 079 |
| Infectious Diseases (except HIV/HCV/tuberculosis) | 26 | 6.7% | 1 630 |
| Analgesic and NSAIDs | 22 | 5.7% | 805 |
| Gastroenterology/Coloproctology | 20 | 5.2% | 2 467 |
| Rheumatology | 16 | 4.1% | 2 491 |
| Pulmonology | 15 | 3.9% | 1 506 |
| Obstetrics and gynecology | 12 | 3.1% | 1 330 |
| HIV/HCV/Tuberculosis | 11 | 2.8% | 570 |
| Urology | 10 | 2.6% | 437 |
| Allergology | 9 | 2.3% | 806 |
| Haematology | 7 | 1.8% | 709 |
| Oncohaematology | 6 | 1.5% | 712 |
| Dermatology | 5 | 1.3% | 889 |
| Hepatology | 4 | 1.0% | 269 |
| Otorhinolaryngology | 3 | 0.8% | 590 |
| Phlebology/vascular surgery | 3 | 0.8% | 200 |
| Other | 2 | 0.5% | 181 |
| Traumatology/surgery | 2 | 0.5% | 156 |
| Immunology | 2 | 0.5% | 150 |
| Parasitology | 2 | 0.5% | 100 |
| TOTAL | 388 | 100.0% | 30 462 |

Data from www.grls.rosminzdrav.ru

## Most popular molecules in clinical trials of generics and biosimilars

Table 5 presents a list of medicines most in demand in generics and biosimilars studies in 2025. The undisputed leader was combinations with amlodipine. With 14 protocols, this molecule took first place (in 2024 there were seven such projects). Last year's leader, ibuprofen, for the second year in a row appears in 12 protocols, but this time such a figure earned it only second place.

Overall, compared to 2024, in the list of the most popular substances for the study of which five or more approvals were issued, besides amlodipine and ibuprofen there remained another 12 INNs, although for many the number of protocols decreased, in particular for indapamide (from nine to seven), apixaban (from eight to seven), metformin (from eight to six), paracetamol and rivaroxaban (from nine to five in both cases), as well as empagliflozin (from six to five). The number of approved studies increased for valsartan (from nine to ten), semaglutide (from seven to eight), linagliptin (from five to six), dapagliflozin and nimesulide (from five to seven protocols each). In 2025, seven approvals were issued to evaluate generic versions of perindopril, the same number as in 2024.

Made it into fewer than five protocols and left the top of the rankings: estradiol (another 2024 leader, 12 studies), dydrogesterone (there were nine) and ademetionine (eight). Also dropped out of the list of the most popular were ticagrelor, fluticasone, pentoxifylline, raltegravir, tacrolimus, umifenovir, ezetimibe, esomeprazole and eltrombopag, which a year earlier had appeared in five to seven studies.

**Table 5**

| Most Requested INN Used in Clinical Trials of Generics and Biosimilars in 2025 | | | | |
|---|---|---|---|---|
| **Substance** | **Number of CTs of foreign generics** | **Number of CTs of local generics** | **All clinical trials to a given INN** | **Therapeutic Area** |
| Amlodipin (in fixed combinations) | 8 | 6 | 14 | Cardiology and CVD |
| Ibuprofen (separately and in fixed combinations) | 2 | 10 | 12 | Analgesic and NSAIDs |
| Valsartan (in fixed combinations) | 5 | 5 | 10 | Cardiology and CVD |
| Semaglutide | 2 | 6 | 8 | Endocrinology |
| Azilsartan medoxomil (separately and in fixed combinations) | 4 | 3 | 7 | Cardiology and CVD |
| Apixaban | 2 | 5 | 7 | Cardiology and CVD, perhaps covid-19 |
| Dapagliflozin (separately and in fixed combinations) | 3 | 4 | 7 | Endocrinology, Cardiology and CVD |
| Indapamide (separately and in fixed combinations) | 3 | 4 | 7 | Cardiology and CVD |
| Nimesulide | 1 | 6 | 7 | Analgesic and NSAIDs |
| Perindopril (separately and in fixed combinations) | 2 | 5 | 7 | Cardiology and CVD |
| Linagliptin | 3 | 3 | 6 | Endocrinology |
| Metformin (separately and in fixed combinations) | 3 | 3 | 6 | Endocrinology |
| Telmisartan (in fixed combinations) | 6 | 0 | 6 | Cardiology and CVD |
| Hydrochlorothiazide (in fixed combinations) | 2 | 3 | 5 | Cardiology and CVD |
| Candesartan (separately and in fixed combinations) | 4 | 1 | 5 | Cardiology and CVD |
| Paracetamol (separately and in fixed combinations) | 1 | 4 | 5 | Analgesic and NSAIDs, infectious diseases |
| Rivaroxaban | 4 | 1 | 5 | Cardiology and CVD, surgery, covid-19 |
| Tenofovir (in fixed combinations) | 0 | 5 | 5 | HIV |
| Flurbiprofen | 5 | 0 | 5 | Otorhinolaryngology |
| Chlorthalidone (in fixed combinations) | 2 | 3 | 5 | Cardiology and CVD |
| Empagliflozin (separately and in fixed combination) | 2 | 3 | 5 | Endocrinology |
| Emtricitabine (in fixed combinations) | 0 | 5 | 5 | HIV |

Data from www.grls.rosminzdrav.ru

They were replaced by azilsartan medoxomil (seven approvals versus three in 2024), telmisartan (six versus two), hydrochlorothiazide (five versus four), flurbiprofen (five versus three), tenofovir and emtricitabine (five versus two for both), candesartan (five versus one), and chlorthalidone (five in 2025 and none a year earlier).

The difference in the interests of foreign and Russian manufacturers of generics and biosimilars is most clearly manifested in the category «analgesics and nonsteroidal anti-inflammatory drugs»: ibuprofen preparations of the companies from Russia are tested in ten protocols, while sponsors from abroad – only in two, nimesulide is indicated in six approvals for Russian sponsors and only in one issued to a foreign company. Only drugs for HIV therapy attracted the attention of exclusively domestic pharmaceutical manufacturers: five studies with combinations of tenofovir and emtricitabine. The reverse situation, i.e., interest exclusively from foreign (mainly Indian) players, is observed when working with flurbiprofen (five protocols, otorhinolaryngology) and with combinations including telmisartan (six). Substances used in cardiology and CVD (valsartan, azilsartan medoxomil, indapamide, hydrochlorothiazide, and chlorthalidone) and in the treatment of metabolic disorders (linagliptin and metformin), as well as dapagliflozin, which is used in both of these therapeutic areas at once, were equally or almost equally popular among local and foreign sponsors.

We believe that the interest in specific substances is explained mainly by two factors: the recent or imminent expiration of patent protection on the one hand, and the high sales of the medicinal product on the other. A special buzz arises when both factors come together. Thus, in 2022–2023, Russia experienced a boom in testing generics of Xarelto® from Bayer (rivaroxaban[4]), protected from copying until December 2024 and ranking in 2019–2025 among the three best-selling in the country. After the registration in Russia of generics from 30 manufacturers at once, the number of new protocols with this INN dropped sharply. Similarly, strong sales and the expiration of patent protection in the 2020s for Eliquis® from BMS and Pfizer (apixaban), Edarbi® from Takeda (azilsartan medoxomil), and Forxiga® from AstraZeneca (dapagliflozin) are spurring active development of their generics. The same reasons also explain the interest in semaglutide, which in Russia was forcibly stripped of protection even before the expiration of the terms of the main patents in 2026.

A similar situation applies to valsartan. It is the active ingredient in such popular Novartis drugs as (in order of development) Diovan and Co-Diovan, Exforge and Co-Exforge, as well as Entresto/Uperio. Protection for the earliest of them expired in the 2010s; for Co-Exforge it expired partially, while for Entresto/Uperio the first patents cease to be in force precisely in 2025–2027 years. Of the ten valsartan protocols included in our table, four test analogues of Entresto/Uperio (a combination with sacubitril), three – Co-Exforge (with amlodipine and hydrochlorothiazide), two – Exforge (with amlodipine without hydrochlorothiazide), one – Co-Diovan (valsartan with hydrochlorothiazide), i.e., the number of studies correlates with the timing of the originals' entry to the market.

Relatively recently, only in the 2020s, generics began to appear for two more INNs presented in Table 5 – these are the antidiabetic drugs linagliptin and empagliflozin.

Attention to other medicinal products, long deprived of patent protection, is usually due to their wide demand. Thus, in second place by volume of ruble sales in Russia in 2024 were painkillers and antipyretics, which helps us understand the high interest in ibuprofen on the part of domestic companies.

In addition to the overall popularity rating, this time we decided to look separately at the biosimilar development of monoclonal antibodies, since their production is among the most complex and requires high competencies from the company. Table 6 lists biosimilars of monoclonal antibodies approved for studies in Russia in 2025, as well as the sponsors of these studies.

**Table 6**

| Monoclonal Antibodies Studied in Clinical Trials of Biosimilars in 2025 | | | | | |
|---|---|---|---|---|---|
| **Name** | **Number of CTs of foreign biosimilars** | **Number of CTs of local biosimilars** | **All clinical trials to a given monoclonal antibody** | **Therapeutic Area** | **Sponsors** |
| Ocrelizumab | 1 | 2 | 3 | Neurology | Generium, R-Pharm, CinnaGen |
| Adalimumab | – | 2 | 2 | Rheumatology, dermatology | Biocad, Biomate |
| Nivolumab | – | 2 | 2 | Oncology | R-Pharm, Orphan-Bio |
| Panitumumab | – | 2 | 2 | Oncology | R-Pharm, Pharmasyntez-Nord |
| Rituximab | – | 2 | 2 | Rheumatology | Mabscale (2 CTs) |
| Ustekinumab | – | 2 | 2 | Rheumatology, coloproctology, gastroenterology | Generium (2 CTs) |
| Brentuximab vedotin | – | 1 | 1 | Oncohaematology | Biocad |
| Durvalumab | – | 1 | 1 | Oncology | Solopharm |
| Ipilimumab | – | 1 | 1 | Oncology | Solopharm |
| Lanadelumab | – | 1 | 1 | Allergology | Orphan-Bio |

[4] The peak was in 2023 year, 31 studies, of which 24 had Russian sponsors. See the ACTO newsletter for 2023 year.

| | | | | | |
|---|---|---|---|---|---|
| Pertuzumab | – | 1 | 1 | Oncology | Pharmasyntez-Nord |
| Ravulizumab | – | 1 | 1 | Haematology | Generium |
| Ramucirumab | 1 | – | 1 | Oncology | Sichuan Luzhou Buchang Biopharmaceutical |
| Secukinumab | 1 | – | 1 | Dermatology, immunology | Bio-Thera Solutions |
| Trastuzumab deruxtecan | – | 1 | 1 | Oncology | Biocad |
| Trastuzumab emtansine | – | 1 | 1 | Oncology | Biocad |
| Emicizumab | – | 1 | 1 | Haematology | Orphan-Bio |

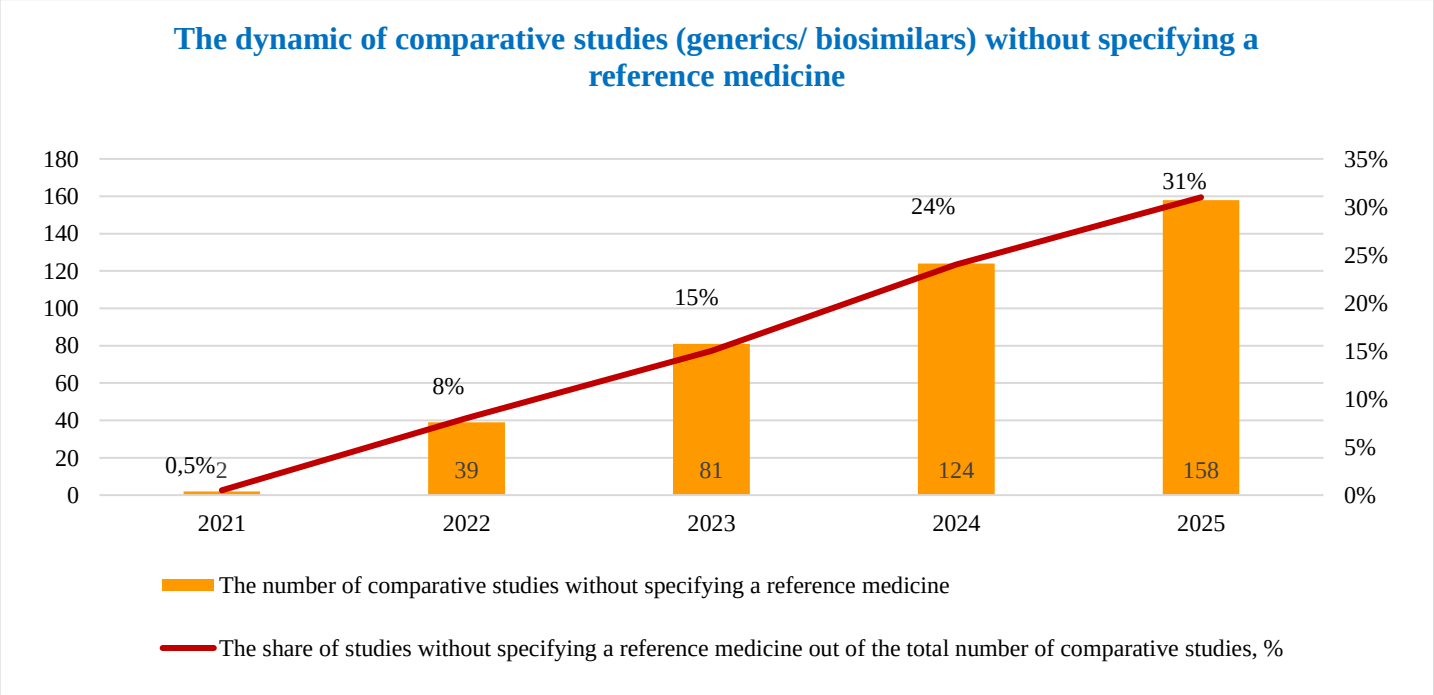
Data from www.grls.rosminzdrav.ru

## Absence of a reference drug in the titles of generics and biosimilars studies

In this issue, we once again want to draw readers' attention to the fact that among generics and biosimilars manufacturers, an alarming trend is gaining momentum: sponsors are ceasing to indicate the reference product in the titles of comparative study protocols. Instead of a specific name, general descriptive wordings are increasingly common («*in comparison with the reference drug*», «*bioequivalence study of drug N*»), and the object of comparison is not mentioned at all. We drew attention to this improper practice in the reports with the results of 2023 and 2024, however since then the situation has only worsened.

Diagram 12 illustrates the dynamics of the phenomenon's spread: the number of problematic protocols increased from two in 2021 to 158 in 2025. The share of studies without an indicated reference out of the total number of comparative studies is also increasing: from 0,5% in 2021 to 31% by the end of 2025. In other words, today, in almost every third new comparative study in Russia, the comparator drug remains unnamed. In a number of cases, it becomes impossible to independently verify even the pharmacological group of the substance under study and the therapeutic area to which the protocol pertains, so we are forced to rely on the information provided by the sponsor.

**Diagram 12**

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From the point of view of the law, everything remains in order in this case; the requirements for the name of the protocol are indeed not regulated by legislation. But, first of all, the very concept of «bioequivalence»

without specifying the reference loses its meaning. Secondly, by hiding the name of the reference, sponsors withhold information from the end consumer and other interested parties, and they do so in a public registry that was created precisely to ensure transparency. We consider such a practice unfair, and its widespread adoption a marker of the degradation of industry standards.

Table 7 lists the sponsors who in 2021–2025 years drew up protocols without specifying the reference drug. Companies are ranked by the total number of such cases over five years. Indicators for each specific year consist of data of two types: (1) the number of protocols without specifying the comparator drug and (2) the share of such studies among all comparative studies of generics and biosimilars initiated by this company per year. If the sponsor specified reference drugs in all of its comparative studies, its result for the year is zero. If, however, the company did not start any new comparative studies in a given year, the cell contains «n/a».

The list of companies hiding references is growing so rapidly that perhaps as early as next year we will have to publish the opposite ranking — those who still list references. The only worry is that the new list may turn out to be shorter than the current one. For now, let us simply name a few truly conscientious sponsors who over the past three years have received a total of 20 or more approvals for comparative studies and, at the same time, in all cases without exception named the reference drug in the protocol: LLC Amedart (86 approvals for comparative studies over three years), JSC Renewal (72 approvals), JSC R-Pharm (45), LLC Rif (36), JSC AVVA RUS (31), LLC Jodas Expoim (23), PJSC Ozon Pharmaceuticals (22), JSC Generium (21), Mylan Laboratories Limited (20).

**Table 7**

| Company | The number of comparative studies of generics/biosimilars without specifying a reference medicine (the share of such studies out of the total number of comparative studies of generics/biosimilars of a particular company for a given year is indicated in parentheses) | | | | | |
|---|---|---|---|---|---|---|
| | Total | 2025 | 2024 | 2023 | 2022 | 2021 |
| Promomed Rus (incl. Biokhimik), Russia | 79 | 8 (100%) | 14 (100%) | 25 (100%) | 32 (71,1%) | 0 |
| Pharmasyntez, Russia | 76 | 16 (84,2%) | 32 (88,9%) | 27 (71,1%) | 1 (3,1%) | 0 |
| PSK Pharma/ Rus Biopharm, Russia | 44 | 29 (100%) | 13 (86,7%) | 2 (40%) | 0 | 0 |
| Pharmstandard-Leksredstva, Russia | 37 | 15 (71%) | 10 (100%) | 9 (64,3%) | 3 (37,5%) | 0 |
| Advanced Pharma, Russia | 15 | 9 (100%) | 4 (100%) | 2 (20%) | 0 | 0 |
| Akrikhin, Russia | 14 | 7 (100%) | 7 (100%) | 0 | n/a | 0 |
| Izvarino Pharma (incl. Nanopharma Development), Russia | 13 | 8 (100%) | 5 (33,3%) | 0 | 0 | 0 |
| Binnopharm Group, Russia | 9 | 5 (100%) | 4 (40%) | 0 | 0 | n/a |
| Pharmproject, Russia | 8 | 7 (58%) | 0 | 1 (10%) | 0 | 0 |
| Biocad, Russia | 7 | 4 (80%) | 3 (100%) | 0 | 0 | 0 |
| Geropharm, Russia | 7 | 5 (71%) | 2 (33,3%) | 0 | 0 | 0 |
| ChemRar Pharma/CDRI (incl. AviPharma), Russia | 6 | 3 (100%) | 2 (100%) | 1 (33,3%) | 0 | 0 |
| OTC Pharm, Russia | 6 | 3 (75%) | 3 (75%) | n/a | 0 | n/a |
| Bright Way Group (incl. Velpharm, Velpharm-M), Russia | 6 | 5 (15%) | 1 (2,9%) | 0 | 0 | 0 |
| Tula Pharmaceutical Factory, Russia | 6 | n/a | 2 (33,3%) | 4 (33,3%) | 0 | n/a |
| Protek (incl. Rafarma, Sotex PharmFirm), Russia | 5 | 3 (100%) | 1 (100%) | 1 (9,1%) | 0 | 0 |
| CinnaGen, Iran | 4 | 3 (100%) | 1 (33,3%) | n/a | n/a | n/a |
| Solopharm, Russia | 4 | 4 (50%) | 0 | 0 | 0 | 0 |
| Emcure Pharmaceuticals, India | 4 | n/a | 2 (33,3%) | 1 (33,3%) | 1 (100%) | 0 |
| PIQ-Pharma, Russia | 4 | 0 | 1 (33,3%) | 1 (50%) | 2 (66,7%) | n/a |
| Akums Drugs, India | 3 | n/a | 3 (100%) | n/a | n/a | n/a |
| Pharm-syntez, Russia | 3 | 3 (100%) | 0 | 0 | 0 | 0 |
| Zhejiang Huayi Pharmaceutical, China | 3 | 3 (100%) | n/a | n/a | n/a | n/a |
| Endopharm (Moscow Endocrine Plant), Russia | 3 | 2 (25%) | 0 | 0 | 0 | 1 (5,9%) |
| Rubikon, Belarus | 3 | 1 (25%) | 2 (66,7%) | 0 | 0 | 0 |
| Polpharma, Poland | 3 | n/a | 3 (100%) | n/a | 0 | 0 |
| PRO.MED.CS Praha a.s., Czech Republic | 2 | 2 (100%) | 0 | n/a | 0 | n/a |
| Biomate, Russia | 2 | 2 (100%) | n/a | n/a | n/a | n/a |
| AryoGenPharmed, Iran | 2 | n/a | n/a | 2 (100%) | n/a | n/a |
| Concern MIR, Russia | 2 | n/a | 0 | 2 (25%) | n/a | n/a |
| Korea Arlico Pharm, Republic of Korea | 2 | n/a | 2 (100%) | n/a | n/a | n/a |

| | | | | | | |
|---|---|---|---|---|---|---|
| Adalvo Limited, Malta | 1 | 1 (100%) | 0 | n/a | n/a | n/a |
| Zydus Lifesciences Ltd., India | 1 | 1 (100%) | n/a | n/a | n/a | n/a |
| STPF POLYSAN, Russia | 1 | 1 (100%) | 0 | 0 | n/a | 0 |
| Rinpharm, Russia | 1 | 1 (100%) | 0 | 0 | n/a | 0 |
| Sentiss Pharma, India | 1 | 1 (100%) | 0 | n/a | n/a | 0 |
| Encube Ethicals, India | 1 | 1 (100%) | n/a | n/a | n/a | n/a |
| PharmEco, Russia | 1 | 1 (50%) | n/a | n/a | n/a | n/a |
| AlFarma, Russia | 1 | 1 (25%) | 0 | 0 | 0 | n/a |
| Dr. REDDY's Lab., India | 1 | 1 (14%) | 0 | 0 | 0 | 0 |
| Hetero Labs (incl. Hetero Biopharma), India | 1 | 1 (9%) | 0 | 0 | 0 | 0 |
| Atoll, Russia | 1 | 1 (6%) | 0 | 0 | 0 | 0 |
| Aizant (Basis-Metigrins), Russia | 1 | n/a | n/a | 1 (100%) | n/a | n/a |
| Vetprom, Bulgaria | 1 | n/a | n/a | 1 (100%) | n/a | n/a |
| Inteltreyd, Russia | 1 | n/a | n/a | 1 (100%) | n/a | n/a |
| Mabwell (Shanghai) Bioscience, China | 1 | n/a | 1 (100%) | n/a | n/a | n/a |
| Olainfarm, Latvia | 1 | n/a | 1 (100%) | n/a | n/a | n/a |
| RV Lifesciences, India | 1 | n/a | 1 (100%) | n/a | n/a | n/a |
| Ipca Laboratories, India | 1 | 0 | 1 (100%) | n/a | n/a | n/a |
| Synthon B.V., Netherlands | 1 | 0 | 1 (100%) | n/a | 0 | n/a |
| Belupo, Croatia | 1 | 0 | 1 (33,3%) | n/a | n/a | 0 |
| Intas Pharmaceuticals, India | 1 | n/a | 1 (25%) | n/a | n/a | n/a |

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## Local trials of originator products, foreign sponsors

Table 8 presents the distribution by therapeutic areas of approvals obtained by foreign sponsors to study their originator products in Russia. In 2025 there were five of them (11 a year earlier). A vaccine for the prevention of pneumococcal infections was indicated in the application by Beijing Zhifei Lvzhu Biopharmaceutical Chinese company. Monoclonal antibody against human rabies was provided by Serum Institute of India. AstraZeneca is studying the effect of AZD0780 on cholesterol levels, as well as the efficacy and safety of tozorakimab in COPD. Devon Pharma is studying the benefits of pelubiprofen in the symptomatic therapy of osteoarthritis.

**Table 8**

| Distribution of Local CTs of Brand Name Drugs of Foreign Sponsors, 2025 | | | |
|---|---|---|---|
| **Therapeutic Area** | **Number of CTs** | **Number of planned participants** | **Country of Sponsor** |
| Infectious Diseases (incl. vaccine) | 2 | 447 | India, China |
| Pulmonology | 1 | 162 | Great Britain |
| Cardiology and CVD | 1 | 127 | Great Britain |
| Rheumatology | 1 | 110 | Republic of Korea |
| TOTAL | 5 | 846 | |

Data from www.grls.rosminzdrav.ru

## Local trials of originator products, domestic sponsors

Distribution of local trials of originator products by domestic sponsors across therapeutic areas is presented in Table 9. In total for 2025, 66 such approvals were issued. In 2024 there were 51 of them, meaning the figure increased by 29.4%.

Most of the protocols, 15 out of 66, relate to infectious diseases. By tradition, we do not include HIV, hepatitis C, and tuberculosis in this category, but we decided not to single out Covid-19 anymore, since the period of heightened attention to the SARS-CoV-2 virus from the pharmaceutical industry has largely remained in the past: out of 15 trials, eight tested vaccines, but only one of them is intended to combat coronavirus infection

(organizer – N.F. Gamaleya NITSEM) and another is aimed simultaneously against Covid-19 and influenza (Nacimbio). Other vaccines are being developed for the prevention of smallpox (State Research Center of Virology and Biotechnology Vector), Marburg and Ebola fevers (also Vector), pneumococcus (R-Pharm and the St. Petersburg Research Institute of Vaccines and Serums), meningococcus (again the St. Petersburg Research Institute of Vaccines and Serums), as well as to prevent diphtheria, tetanus, and whooping cough (a combined vaccine by the company Microgen). In addition to vaccines, this therapeutic area includes the smallpox treatment drug NIOH-14 from Vector, as well as products intended for use for acute respiratory viral infections from Valenta Pharmaceutics (Ateriksen and Ingavirin forte), Cytomed (Citovir) and Materia Medica (Rengalin).

**Table 9**

| Distribution of Local CTs of Brand Name Drugs (Including Biological Products) of Local Sponsors, 2025 | | | |
|---|---|---|---|
| **Therapeutic Area** | **Number of CTs** | **Share (%)** | **Number of planned participants** |
| Infectious Diseases (except HIV/HCV/tuberculosis, incl. Covid-19) | 15 | 22.7% | 6 280 |
| Neurology | 8 | 12.1% | 2 348 |
| Oncology | 8 | 12.1% | 666 |
| Pulmonology | 4 | 6.1% | 666 |
| HIV/tuberculosis | 4 | 6.1% | 2 996 |
| Gastroenterology/Coloproctology | 3 | 4.5% | 409 |
| Obstetrics and gynecology | 3 | 4.5% | 240 |
| Urology | 2 | 3.0% | 1 005 |
| Surgery/neurosurgery/traumatology | 2 | 3.0% | 550 |
| Allergology | 2 | 3.0% | 1 602 |
| Otorhinolaryngology | 2 | 3.0% | 722 |
| Endocrinology and other metabolic disorders | 2 | 3.0% | 500 |
| Psychiatry | 2 | 3.0% | 350 |
| Cardiology and CVD | 2 | 3.0% | 340 |
| Rheumatology | 2 | 3.0% | 338 |
| Haematology | 2 | 3.0% | 90 |
| Cosmetology | 1 | 1.5% | 250 |
| Immunology | 1 | 1.5% | 50 |
| Other | 1 | 1.5% | 6 |
| TOTAL | 66 | 100.0% | 19 408 |

Data from www.grls.rosminzdrav.ru

In the category «HIV and tuberculosis» that we have separated from infectious diseases, four protocols were launched: two approvals were received by Elpida to study elsulfavirine and its combination with tenofovir and emtricitabine, one by Promomed for the drug with code JUFC11701, and one more – by the St. Petersburg Research Institute of Vaccines and Serums for a recombinant tuberculosis allergen.

Eight new trials relate to neurology. SupraGen is studying a recombinant protein containing the amino acid sequence of staphylokinase called Fortelysin. Tatkhimpharmpreparaty is a chemical compound with the trade name Dimephosphon. Both medicines are intended for patients with ischemic stroke, both have been developed since the mid-20th century, and both are already present on the Russian market. In addition, Geropharm is evaluating the efficacy and safety of bovine cerebral cortex polypeptides (Cortexin) in children aged two to five years with speech development disorders, and Art-Pharm is evaluating escin lysinate in the therapy of patients with radiculopathy. Dimebonet is recruiting patients with dementia in Alzheimer's disease to test dimebone synthesized back in the late 1960s. The Research Institute of Chemical Diversity initiated a Phase I study of the anxiolytic maritupirdine. Two more Phase I protocols for Tavit and Materia Medica: the first is working with the nootropic drug Ampasse (calcium hydroxynicotinoylglutamate), the second with something unidentified under the code MMH-450.

There are also eight protocols in oncology, among them the gene therapy of the FMBA Center for Strategic Planning already mentioned in the previous section and the «radiopharmaceutical with bispecific monoclonal antibodies to GITR and CTLA-4 and the radioisotope 177Lu» from the Russian Scientific Center of Radiology

and Surgical Technologies named after Academician A. M. Granov. In addition to them, in this group are the peptide inhibitor of Ras GTPase of the Russian Scientific Center of Roentgenoradiology, the monoclonal anti-FGFR1 antibody of the non-profit organization «Bureau for Cancer Research», a combination of sodium dichloroacetate with theophylline and recombinant alpha-fetoprotein of the company Adikom. Three more medicines are designated by codes from which it is impossible to understand what they are; two of them belong to Promomed and one to PSK Pharma.

Pulmonology is represented by four protocols, three of which also do not provide information about the candidate medicinal product under study: BCD-272 from Biocad and MMH-522 from Materia Medica are being tested with the participation of healthy volunteers, and the RB-0001 aerosol from PSK Pharma in patients with bronchial asthma. Some clarity in this group exists only with Rafamin – these are «affinity-purified antibodies to human gamma interferon» produced by Materia Medica, the sponsor wants to evaluate their efficacy and safety in the treatment of acute bronchitis in adults.

In urology, Pharmenterprises is studying HS243 in exacerbation of chronic cystitis, the Gamaleya Center – the safety and pharmacokinetics of fluorothiazinone in healthy volunteers, and Cytomed – rectal suppositories, which are a combination of bovine prostate extract and zinc arginyl glycinate for erectile dysfunction.

We classified three studies as surgery, neurosurgery, and traumatology. Akrus BioMed is testing a dermal skin equivalent for the treatment of venous trophic ulcers and a biological equivalent for thermal burns. The Federal Center of Brain Research and Neurotechnologies of the FMBA is studying the regenerative matrix «NeuroMat» based on allogeneic mesenchymal stem cells in patients with spinal cord injury.

In gastroenterology, Biocad has two protocols: the monoclonal antibody anti-TL1A is being studied in ulcerative colitis and in Crohn's disease. In gynecological protocols, Alcea indicated indolecarbinol for endometriosis and diindolylmethane for papillomavirus infection. Allergology is represented by Generium with a vaccine to prevent a reaction to birch pollen and the Tula pharmaceutical factory with a combination of fluticasone furoate and a substance under the code BM9 for seasonal allergic rhinitis. Otorhinolaryngology is two protocols of remedies for rhinitis from Homeopathic Pharmacy and Materia Medica. In endocrinology, there are also two studies: Polysan is testing meglumine sodium succinate for diabetic ketoacidosis, and NextGen is testing the pCMV-VEGF165 plasmid, which is presumed to stimulate tissue repair in diabetic foot syndrome. In psychiatry, Valenta Pharmaceuticals is studying Ranqvilon (GB-115) for anxiety conditions, and Valentek is selecting the dose of VLT-015 for patients with dementia. Both studies in cardiology and CVD are associated with dyslipidemia: The Gamaleya Center is studying a combination of sodium polyprenyl phosphate with phytosterol for this condition, and the Siberian State Medical University – its own development called Cholestan.

In rheumatology, Biocad is launching a Phase I protocol of a humanized monoclonal antibody (mAb) of class G, type 1 BCD-256 for systemic lupus erythematosus, and R-Pharm – of a humanized mAb against interleukin-6, olokizumab, with the participation of healthy volunteers. The hematology projects include a pilot study of the bioavailability of Generium's GNR-130 and Pharmstandard's protocol for studying blood coagulation factor VIII together with von Willebrand factor in children with the disease of the same name. In addition, Immuno-Gem received an approval to study human immunoglobulin, the Fijie Institute of Beauty – botulinum toxin type A, and Generium – a recombinant modified enzyme ID2S for mucopolysaccharidosis type II. We accounted for the latest protocol in the statistics as «other», since the nature of the disease is genetic, the mechanism is associated with a deficiency of the lysosomal enzyme ID2S, and the manifestations include cognitive impairments, bone deformities, pathologies of the respiratory and cardiovascular systems, as well as a whole range of other anomalies of a very different nature.

# PARTICIPATION OF MEDICAL ORGANIZATIONS IN BIOEQUIVALENCE STUDIES

The list of medical organizations presented in Table 10, which were mentioned more often than others in applications for bioequivalence studies approved in 2025, differs little from last year's: 12 clinics remained in the top-15. Dropped out were the Yaroslavl Regional Narcological Hospital, the RZD-Medicine hospital also from Yaroslavl, and the Moscow Serta Clinic, which in 2024 held 6th, 12th, and 13th-14th places with 29, 17, and 16 new projects respectively. Made it into the list of the 15 most active: those that were not there a year ago AX CLINIC (Yaroslavl again), the North-West Public Health Research Center (Saint Petersburg) and Sechenov University (Moscow). The last two organizations round out the top 15 of 2025 with 15 studies, while AX CLINIC not only broke into the ranking but also topped it with 43 protocols. Based on the results of 2024 this medical organization could boast of only five new projects, and in mid-2023 it had just opened. That is, we have a new ambitious player before us. Not as impressive, but also noticeably improved their positions over the year were Moscow Ligand Research (31 studies versus 16 a year earlier, third place versus 13-14) and the Tomsk National Research Medical Center of the Russian Academy of Sciences (19 versus 14, tenth versus 15th). Yaroslavl Clinical Hospital No. 9 fell in the rankings more than others: from first place in 2024 (56 new projects) down to 8-9 (only 20 studies) in 2025.

**Table 10**

| Top-15 medical organizations on the activity of participation in bioequivalence studies (approvals issued in 2025) | | | | | |
|---|---|---|---|---|---|
| **Place in ranking** | **Name of medical organization** | **Total number of bioequivalence studies** | **Number of bioequivalence studies conducted by local sponsors** | **Number of bioequivalence studies conducted by foreign sponsors** | **Number of bioequivalence studies and sites ranking on approvals issued in 2024** |
| 1 | AX Clinic, Yaroslavl | 43 | 27 | 16 | 5 (20-21) |
| 2 | Eco-Safety Research Center, St. Petersburg | 39 | 35 | 4 | 36 (2-3) |
| 3 | Ligand Research, Moscow | 31 | 8 | 23 | 16 (13-14) |
| 4 | Cardiology Dispensary, Ivanovo | 30 | 25 | 5 | 36 (2-3) |
| 5 | Miramed, Maykop | 29 | 27 | 2 | 32 (4) |
| 6 | National Scientific Center for Research and Pharmacovigilance, Saransk | 25 | 22 | 3 | 20 (8-9) |
| 7 | Rostov Central District Hospital, Yaroslavl region, Rostov | 22 | 17 | 5 | 24 (7) |
| 8-9 | Clinical Hospital No. 9, Yaroslavl | 20 | 16 | 4 | 56 (1) |
| 8-9 | Clinical Hospital No. 3, Yaroslavl | 20 | 17 | 3 | 30 (5) |
| 10 | Tomsk National Research Medical Center of the Russian Academy of Sciences, Tomsk | 19 | 17 | 2 | 14 (15) |
| 11–15 | Clinical Hospital No. 2, Yaroslavl | 15 | 10 | 4 | 18 (11) |
| 11–15 | Medical Technologies Malyj, St. Petersburg | 15 | 12 | 3 | 19 (10) |
| 11–15 | X7 Clinical Research, St. Petersburg | 15 | 5 | 10 | 20 (8-9) |
| 11–15 | North-West Public Health Research Center, St. Petersburg | 15 | 13 | 2 | 3 (22-23) |
| 11–15 | I. M. Sechenov First Moscow State Medical University, Russian Ministry of Health, Moscow | 15 | 13 | 2 | 5 (20-21) |

Data from www.grls.rosminzdrav.ru

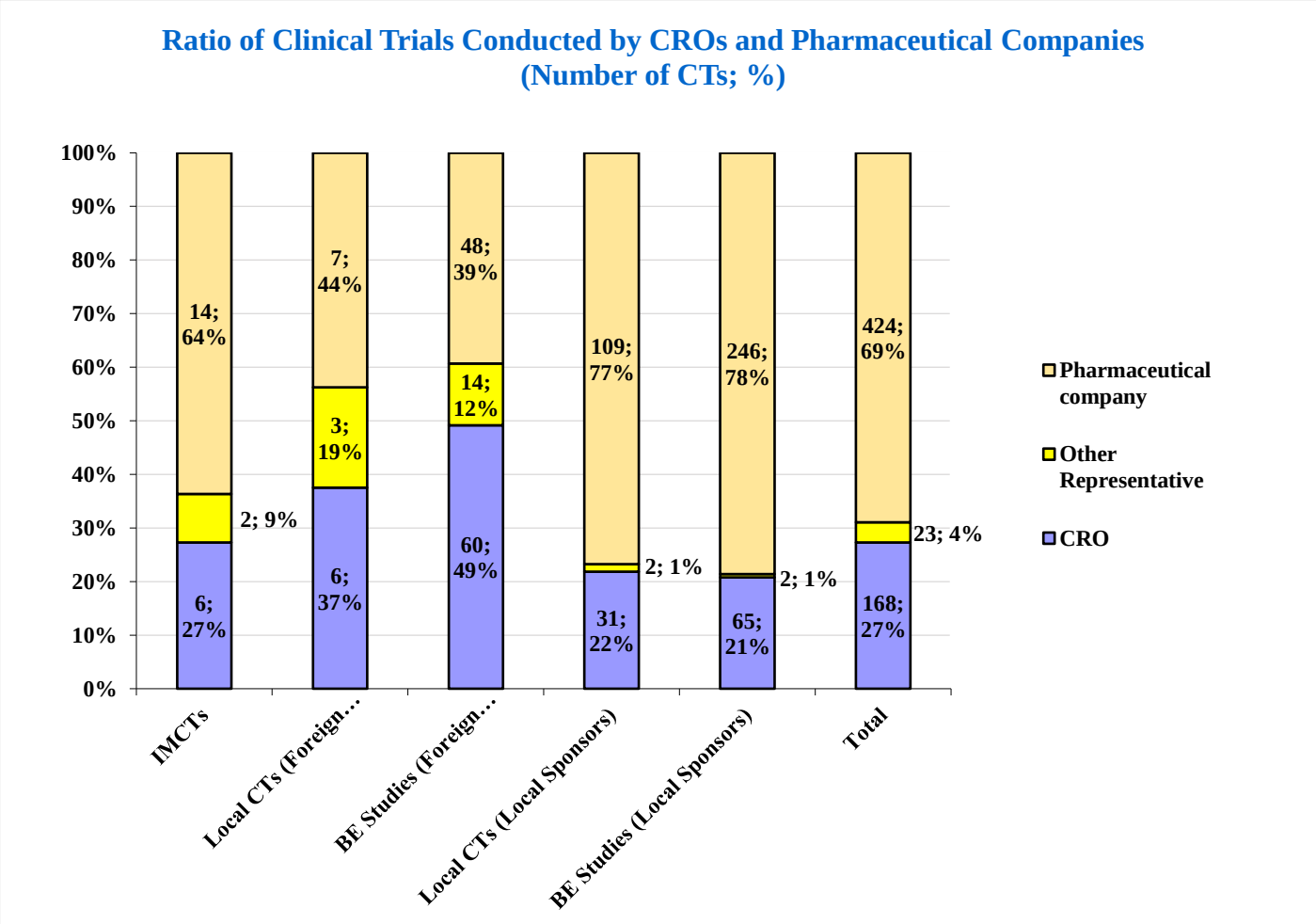
# MAIN PLAYERS OF THE RUSSIAN CLINICAL TRIALS MARKET – 2025

This section presents an overview of the key players in the Russian clinical trials market. These are mainly sponsors and contract research organizations (CRO). In addition to them, the statistics also include «other representatives» – companies that help bring drugs to the market but do not provide the full range of CRO services.

## Sponsors and CROs, general structural distribution

Diagram 13 presents information on sponsors' intentions to conduct research in-house or with the involvement of a CRO. Statistics are based on applications approved by the Ministry of Health, but the information we provide is knowingly incomplete, since the CRO may not be mentioned in the application, even if the sponsor has such plans or even agreements. Nevertheless, these data still remain useful for assessing the demand for CRO services and the overall situation on the market.

**Diagram 13**

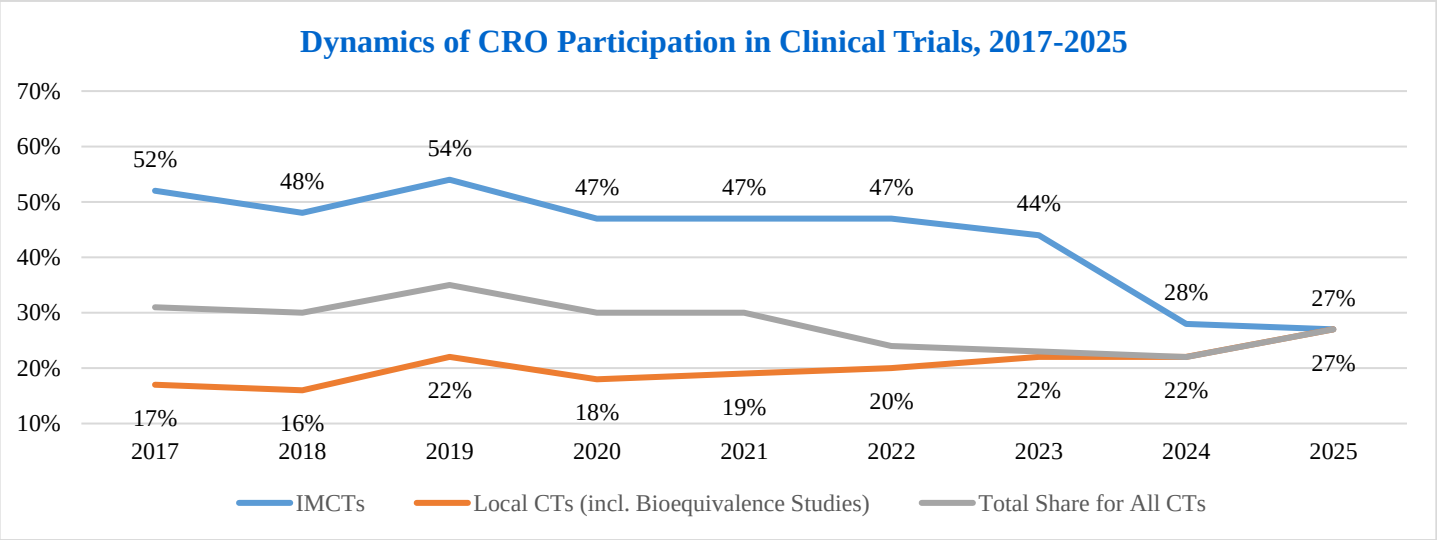



Data from www.grls.rosminzdrav.ru

The figures from Diagram 13 may seem more informative if considered dynamically. Diagram 14 illustrates the change in the share of studies involving contract research organizations from 2017 to 2025. Until 2022 in Russia, CROs were engaged to conduct approximately every third study, and in IMCT the corresponding share was about half. When local companies began to dominate the market, demand for CRO services declined: in 2023–2025 they were invited to only every fourth study. Moreover, demand fell within the IMCTs sector as well, since in it the ratio of foreign and Russian sponsors also began to change in favor of the latter. In 2025 the shares of studies involving contract research organizations in IMCTs and in other types of studies equalized and

amounted to 27%. Foreign companies more often expressed a desire to turn to CRO assistance, having obtained an approval to verify bioequivalence (in 49% of cases) and for a local study of therapeutic efficacy and safety (37%). Among Russian sponsors, this figure was only 21-22%.

**Diagram 14**




Data from www.grls.rosminzdrav.ru

## International multicentre clinical trials, sponsors

Table 11 lists the companies that received approvals to conduct IMCTs in 2025.

**Table 11**

| Pharmaceutical Companies on Approvals for International Multicenter CTs, 2025 | | | | | |
|---|---|---|---|---|---|
| **No.** | **Company (including separate companies, associated in group of companies, as well as independent divisions of the company)** | **Total** | **Conducted by themselves** | **Conducted by CRO** | **Number of IMCTs in 2023** |
| 1 | Biocad, Russia | 3 | 3 | - | 5 CTs |
| 2 | Generium, Russia | 3 | 3 | - | 3 CTs |
| 3 | Eilean Therapeutics (incl. Lomond Therapeutics), Australia | 3 | - | 3 | n/a |
| 4 | Ascentage Pharma Group, USA | 2 | - | 2 | 1 CT |
| 5 | AVVA Rus, Russia | 2 | 2 | - | n/a |
| 6 | R-Pharm International, Russia | 2 | 2 | - | 2 CTs |
| 7 | Novartis, Switzerland | 1 | 1 | - | n/a |
| 8 | AstraZeneca, Great Britain | 1 | 1 | - | 2 CTs |
| 9 | Bio-Thera Solutions, China | 1 | 1 | - | n/a |
| 10 | Dizal (Jiangsu) Pharmaceutical, China | 1 | - | 1 | n/a |
| 11 | F. Hoffmann-La Roche, Switzerland | 1 | 1 | - | n/a |
| 12 | Geropharm, Russia | 1 | 1 | - | n/a |
| 13 | Jiangsu Alphamab biopharmaceutical Co., China | 1 | 1 | - | n/a |

Data from www.grls.rosminzdrav.ru

Compared to 2024 there was a slight increase in both the total number of projects (from 18 to 22) and the number of sponsors (from ten to 14). Five of the 14 companies that initiated the IMCTs are Russian; together they received 11 of the 22 approvals (three each for Biocad and Generium, two each for AVVA Rus and R-Pharm, and one more for Geropharm). Among foreign ones, the Australian Eilean Therapeutics turned out to be the most active; it has three approvals (including one issued to its own division, Lomond Therapeutics). Two new studies from the American Ascentage Pharma Group, one each from AstraZeneca, Novartis, F. Hoffmann-La Roche and three Chinese companies.

## International multicentre clinical trials, CROs

In 2025 it was planned to involve only three contract research organizations in the new IMCTs, they are listed in Table 12. In a similar table for the results of 2023 there were five CROs with eight new projects in total; for the results of 2024 – four with five. In 2025 we see a further reduction in the list of CROs, but not in the number of studies; this time there are six. Three of them are being conducted by IPHARMA for Eilean Therapeutics and its subsidiary Lomond Therapeutics, two by K-Research (Cromos Pharma) for Ascentage Pharma Group from the USA, and the last by OCT for Dizal (Jiangsu) Pharmaceutical from China.

**Table 12**

| CROs on Approvals for International Multicenter CTs, 2025 | | | | |
|---|---|---|---|---|
| **No.** | **Company** | **Number of IMCTs** | **Number of Sponsors** | **Number of IMCTs in 2024** |
| 1 | IPHARMA | 3 | 1 | n/a |
| 2 | Cromos Pharma (K-Research) | 2 | 1 | 2 CTs |
| 3 | OCT | 1 | 1 | 1 CT |

Data from www.grls.rosminzdrav.ru

## Local trials and bioequivalence studies, foreign sponsors

Table 13 presents foreign sponsors who in 2025 initiated in Russia the largest number of local trials of therapeutic efficacy and safety, as well as bioequivalence studies.

**Table 13**

| Ranking of Foreign Sponsors on Approvals for Local CTs and Bioequivalence Studies, 2025 | | | | | |
|---|---|---|---|---|---|
| **Ranking in 2025** | **Company** | **Total** | **Conducted by themselves** | **Conducted by CROs/other representatives** | **Number of CTs; Ranking in 2024** |
| 1 | Hetero Labs, India | 11 | 11 | - | 8 CTs; 2-3 |
| 2 | Dr. REDDY's Lab., India | 7 | 7 | - | 6 CTs; 5-6 |
| 3 | Ipca Laboratories, India | 6 | - | 6 | 1 CT; 30-57 |
| 4-5 | Jodas Expoim, India | 5 | - | 5 | 8 CTs; 2-3 |
| 4-5 | Teva, Israel | 5 | 5 | - | 3 CTs; 12-20 |
| 6-11 | Aurobindo Pharma, India | 4 | - | 4 | n/a |
| 6-11 | BZMP, Belarus | 4 | - | 4 | n/a |
| 6-11 | Mapaex Consumer Healthcare, India | 4 | 4 | - | n/a |
| 6-11 | World Medicine, Turkey | 4 | - | 4 | 3 CTs; 12-20 |
| 6-11 | Pharmtechnology, Belarus | 4 | - | 4 | 4 CTs; 9-11 |
| 6-11 | SLS Pharma, India | 4 | 4 | - | n/a |

Data from www.grls.rosminzdrav.ru

Top 3 is entirely Indian. Hetero Labs became the leader with eleven approvals; its result last year was eight projects and a 2-3 place. Next comes Dr. REDDY's Lab. with seven studies; a year earlier the company held position 5-6 with six protocols. Ipca Laboratories rounds out the top three, it has six approvals, a year ago there was only one.

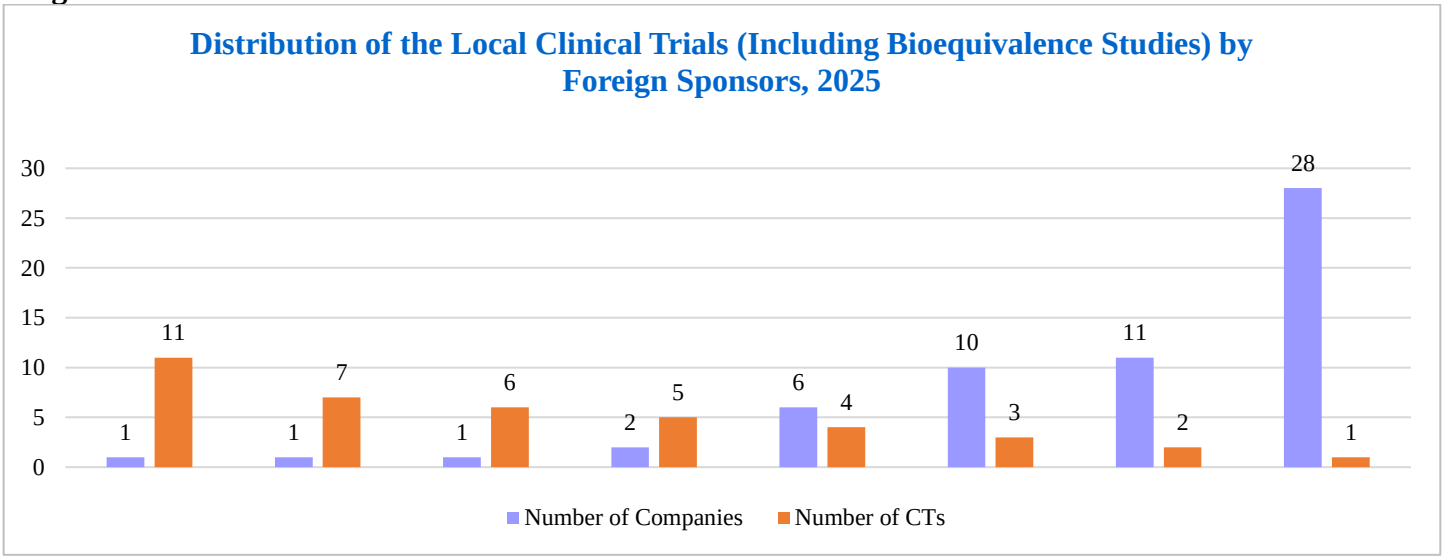
Places 4-5 were shared by Teva (Israel) and Jodas Expoim (India), which received five approvals each. Teva improved its result compared to 2024 by moving up from lines 12–20, which it shared with other sponsors with three new projects, while Jodas Expoim, on the contrary, moved down from the second line of the ranking (in 2024 the company had eight new studies).

Places 6–11 are shared by six companies at once, each with four approvals. Pharmtechnology from Belarus had the same result a year earlier, World Medicine from Turkey at the end of 2024 could boast only three. India's Aurobindo Pharma, Mapaex Consumer Healthcare and SLS Pharma, as well as the Borisov plant of medical preparations (BZMP) from Belarus, were not represented in the previous year's ranking.

Dropped out of the list of leaders were Mylan Laboratories (first place with ten approvals in 2024), Gedeon Richter (fourth with seven), as well as Emcure Pharmaceuticals, KRKA, Sun Pharma, AstraZeneca AB and Intas Pharmaceuticals (from six to four approvals, places in the second half of the top ten).

Diagram 15 shows how, in 2025, approvals for local trials of therapeutic efficacy and safety, as well as for bioequivalence studies, were distributed among foreign sponsors. The number of research organizers reached 60, slightly exceeding last year's figure (57). At the same time, the above-mentioned sponsors with four or more decisions account for 42% of the total number of new projects: 58 studies out of 138.

**Diagram 15**




Data from www.grls.rosminzdrav.ru

## Local trials and bioequivalence studies, domestic sponsors

Table 14 lists Russian pharmaceutical companies that received in 2025 the largest number of approvals to conduct local clinical trials, including bioequivalence studies.

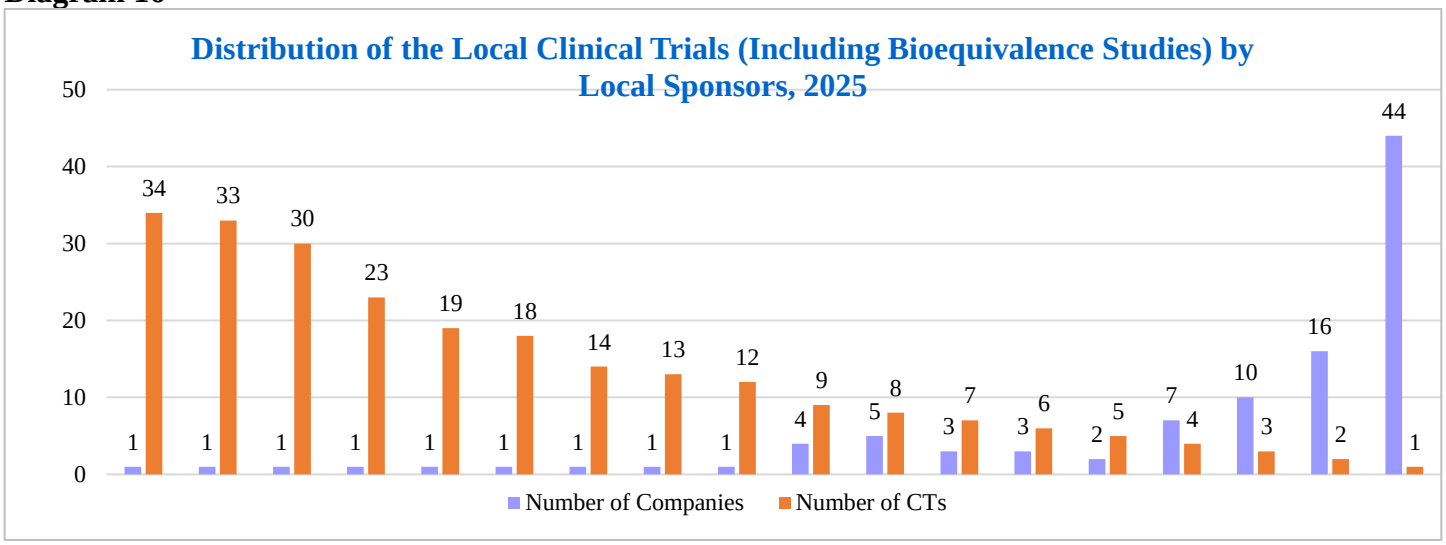
**Table 14**

| Ranking of Local Sponsors on Approvals for Local Clinical Trials and Bioequivalence Studies, 2025 | | | | | |
|---|---|---|---|---|---|
| **Ranking in 2025** | **Company** | **Total** | **Conducted by themselves** | **Conducted by CRO** | **Number of CTs; Ranking in 2024** |
| 1 | Amedart | 34 | 34 | - | 18 CTs; 4 |
| 2 | Bright Way Group (incl. Velpharm-M) | 33 | 33 | - | 35 CTs; 2 |
| 3 | PSK Pharma/ Rus Biopharm | 30 | 30 | - | 15 CTs; 6-7 |
| 4 | Pharmstandard (incl. Pharmstandard-UfaVita, Pharmstandard-Leksredstva, Lekko) | 23 | 23 | - | 11 CTs; 12-13 |
| 5 | Pharmasyntez (incl. Pharmasyntez-Tyumen, Pharmasyntez-Nord) | 19 | 19 | - | 43 CTs; 1 |
| 6 | Atoll | 18 | 18 | - | 13 CTs; 8-10 |
| 7 | Renewal | 14 | 14 | - | 13 CTs; 8-10 |
| 8 | Promomed Rus | 13 | 13 | - | 16 CTs; 5 |
| 9 | Pharmproject | 12 | - | 12 | 1 CT; 58-106 |
| 10-13 | Geropharm | 9 | 9 | - | 11 CTs; 12-13 |
| 10-13 | R-Pharm | 9 | 9 | - | 12 CTs; 11 |
| 10-13 | Advanced Pharma | 9 | 9 | - | 4 CTs; 28-34 |
| 10-13 | YuzhPharm | 9 | - | 9 | 5 CTs; 26-27 |

Data from www.grls.rosminzdrav.ru

The top lines of the ranking this time were taken by Amedart and Bright Way Group (including Velfarm-M). But if the first increased the result vs 2024 (34 vs 18 studies), then the latter, on the contrary, lost a little (35 vs 33). Third place goes to PSK Pharma/ Rus Biopharm with 30 approvals (15 the year before). Next come Pharmstandard and Pharmasyntez (including their divisions) with 23 and 19 protocols, respectively. Moreover, Pharmstandard increased its activity compared to 2024 (there were 11 projects), and Pharmasyntez showed the sharpest drop in the ranking (there were 43 approvals and first place). The most noticeable growth over the year was shown by Pharmproject: in 2024 it had only one approval and a position in the sixth ten, and in 2025 the number of approvals increased to 12, which allowed the company to take ninth place.

**Diagram 16**




Data from www.grls.rosminzdrav.ru

Diagram16 shows the distribution by Russian sponsors of approvals to conduct local trials, including bioequivalence studies. In total in 2025 such approvals were received by 103 companies, three fewer than a year earlier. The sponsors listed above in Table 14 with nine or more approvals initiated 50.1% (232 of 455) of all new studies of these species over the year.

## Local trials and bioequivalence studies, CROs

Table 15 contains the CROs mentioned in the largest number of approvals to conduct local trials, including bioequivalence studies, in 2025. This time we decided to expand the table and list the sponsors who planned to engage a specific CRO.

**Table 15**

| Ranking of CROs Involved in the Local CTs and Bioequivalence Studies (on Approvals Issued in 2025) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Ranking in 2025** | **Company** | **Total number of local CTs** | **Number of CTs of foreign sponsors** | **Number of CTs of local sponsors** | **Number of sponsors** | **Companies** | **Number of CTs; Ranking in 2024** |
| 1 | National Scientific Center for Research and Pharmacovigilance | 24 | 3 | 21 | 9 | Macleods Pharmaceuticals, MosFarma, Rusmed Exports, Serum Institute of India, CityPharm, Tech-Pharm, Tula Pharmaceutical Factory, Pharmproject, YuzhPharm | 19 CTs; 1 |
| 2 | X7 Research | 15 | 7 | 8 | 9 | AlFarma, VTF, Gerda, Ipca Laboratories, LekPharm, Rubikon, Pharmacor Production, World Medicine Ilac SAN. ve TIC. A.S., FSBI Russian Scientific Center of X-Ray Radiology | 6 CTs; 8-10 |
| 3-4 | AX Clinical Trials and Consulting | 14 | 12 | 2 | 7 | AmantisMed, BZMP (BoriMed), Med-interplast, Pharmland, Pharmtechnology, FSBI Federal Center of Brain Research and Neurotechnologies, Evalar | 14 CTs; 3 |

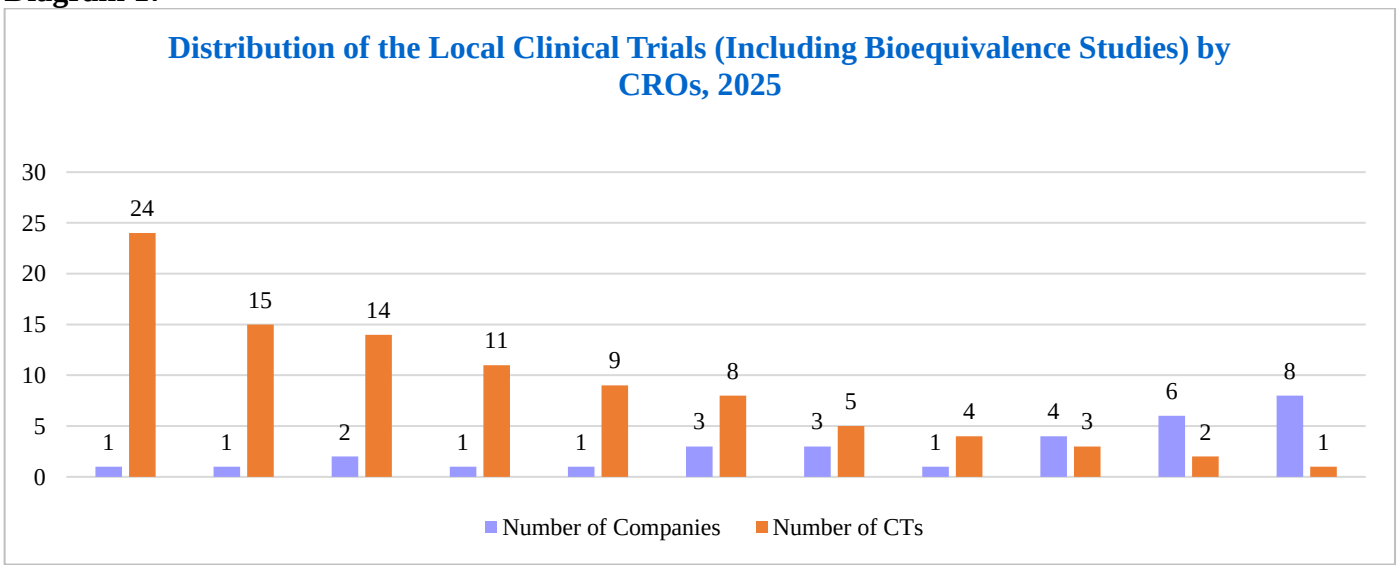
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3-4 | Probiotech | 14 | 2 | 12 | 3 | ALSI Pharma, Izvarino Pharma, LekPharm | 18 CTs; 2 |
| 5 | Ligand Research | 11 | 6 | 5 | 7 | Aurobindo Pharma, AFL, Bioferon, Hellespont, Sanofi, S Pharma, Evalar | 6 CTs; 8-10 |
| 6 | IPHARMA | 9 | - | 9 | 5 | IVFarma, Acrus Biomed, Dimebonet, ChemRar Pharma (incl. CDRI and AviPharma), STPF POLYSAN | 8 CTs; 5-6 |
| 7-9 | Vita Aeterna | 8 | 6 | 2 | 5 | Jodas Expoim, Medico-biological research and production complex "Cytomed", MosFarma, Rubikon, Signum Market Access | 8 CTs; 5-6 |
| 7-9 | ClinPharmDevelopment | 8 | 8 | - | 4 | Ipca Laboratories, Minskintercaps, PRO.MED.CS, Pharmtechnology | 3 CTs; 12-15 |
| 7-9 | Eco-Safety Research Center | 8 | 2 | 6 | 4 | Belupo, Rubikon, Pharmproject, Golikov Research Center of Toxicology | 6 CTs; 8-10 |
| 10-12 | Innovative Pharmacology Research (IPHAR) | 5 | 2 | 3 | 2 | Gen Ilac Ve Saglik Urunleri SAN. VE TIC. A. S., Uralbiopharm | 3 CTs; 12-15 |
| 10-12 | Medical Development Agency (MDA) | 5 | - | 5 | 3 | Fijie Beauty Institute, Life Sciences, Salutpharma | 5 CTs; 11 |
| 10-12 | OCT | 5 | 4 | 1 | 3 | Gedeon Richter, Sichuan Luzhou Buchang Biopharmaceutica, PharmEco | 7 CTs; 7 |

Data from www.grls.rosminzdrav.ru

As a year ago, the first line of the ranking is occupied by the National Scientific Center for Research and Pharmacovigilance, invited to 24 studies (19 in 2024). In second place is X7 Clinicals and Pharmaceutical Research with 15 approvals (this CRO has the biggest growth over the year, there were six protocols and a place 8–10). Positions 3-4 with 14 new studies are shared by AX Clinical Trials and Consulting (in 2024 there were the same number and third place) and Probiotech (there were 18, second place, this CRO has the largest decrease in activity compared to 2024). Fifth line for Ligand Research, 11 studies (six protocols and place 8–10 in 2024).

In Diagram 17, it is shown how approvals for local trials of therapeutic efficacy and safety and bioequivalence studies are distributed among contract research organizations. In 2025 it was planned to involve 31 CROs in carrying out such projects, two more than a year earlier. At the same time, the organizations named in Table 15 turn out to be engaged in ~78% (126 out of 162) of all new studies of these types.

**Diagram 17**




Data from www.grls.rosminzdrav.ru

## ELECTRONIC ICF IN THE SOVEREIGN INTERNET

The materials above show that against the backdrop of the military-political crisis continuing for the fifth year, the number of IMCTs in Russia has sharply decreased and the industry is in a kind of suspended animation. It may seem that in such conditions the industry has nothing to fight for. But no, in 2025 it had to face legislative initiatives that, if implemented, could seriously complicate the conduct of research when (and if) international cooperation nonetheless begins to be restored. One of them is an attempt to implement an electronic form of informed consent as having no alternative.

On January 18, 2024 the State Duma adopted, and on January 30 the President signed Federal Law No. 1-FZ, providing for amendments to the law «On the Circulation of Medicines». The document itself was prepared over several years, from 2020 to 2024, and was discussed many times, including with the participation of the industry. Initially, the industry as a whole perceived it neutrally or positively, since it included, among other things, useful innovations. In particular, it gave sponsors the opportunity to use the electronic ICF alongside the traditional paper one.

An unpleasant surprise was discovered at the second reading in December 2023. An amendment was introduced into the bill that made the ICF electronic signature the main and mandatory one, and not just one of the options, as provided for by an earlier version. It was proposed that the electronic signature on documents be either an enhanced qualified one or a simple one, but using the Unified identification and authentication system (ESIA)[5]. A signature on paper was becoming an optional add-on that the patient could use if desired. The new rules were supposed to come into force as of January 1, 2025.

Practical problems for research organizers were obvious. Not all patients have an account in the ESIA, not everyone knows how to use digital tools, including an electronic signature. Issues arise regarding personal data protection and compliance with Good Clinical Practice requirements. It will be necessary to update the standards for working with the ICF for the sponsor and the CRO, and to organize the processes at the sites in a new way. According to market participants' estimates, an attempt to introduce such a model in the current conditions could sharply complicate patient enrollment and effectively paralyze part of the projects. To avoid this, it was decided to initiate a broad discussion and try to find a solution jointly with the regulator.

In April, May, and June 2024, a number of discussions took place between industry representatives and specialists from the Ministry of Health and the Ministry of Digital Development, during which various aspects of the problem were considered: technical, organizational, legal, and ethical. The Ministry of Digital Development from the very beginning recognized the introduction of a mandatory electronic signature via the ESIA as premature, but the Ministry of Health continued to insist that in the time remaining until the end of the year it was still possible to find ways to implement the provision.

In September 2024, as many as five business associations, ARPM, AIPM, APM EAEU, Infarma and ACTO, sent a joint request to the Government of the Russian Federation, where they described the risks of introducing a new procedure for obtaining informed consent. The topic was discussed on various platforms: for example, in October 2024 it became one of the central ones at a meeting of the «Business Russia» committee for the development of the pharmaceutical industry. At the end of the year, when it became obvious that there was no way to avoid problems, the Ministry of Health had to postpone the introduction of the new requirements by a year, until January 1, 2026. This compromise opened up an opportunity for the industry to continue looking for ways to defend its interests.

In July 2025 the working group in the field of pharmaceuticals and medical devices under the Government Commission on the implementation of administrative reform attempted to resolve the issue by introducing amendments to the existing legislation. Wording enshrining the equality of paper and electronic forms of informed consent was proposed to be included in one of the major draft laws of the Ministry of Economic Development. There were no objections from the Ministry of Digital Development. Moreover, the text of the

[5] ESIA is a state identification and authentication system.

amendments was successfully agreed with the Ministry of Health. But, to our disappointment, the law drafter, the Ministry of Economic Development, ultimately did not include the proposals in the project for its own reasons.

Soon the industry was given a second chance. In mid-September 2025 the State Duma adopted in the first reading the bill of deputy Sergey Naumov, in which the possibility of obtaining informed consent in one of two alternative forms, paper and electronic, was explicitly described. In December, when once again the time came to make decisions quickly, Sergei Naumov's bill was considered and adopted immediately in the second and third readings, and on December 28, 2025 was signed by the President.

The industry can only be congratulated on preserving a realistic and flexible procedure for obtaining informed consent. The decision taken seems all the more relevant given the tightening restrictions on the Internet in Russia and the introduction of «white lists»[6] as the norm. It is quite likely that in the foreseeable future, the organizers of studies will have no alternative but to continue using the ICF in paper.

In conclusion, one would like to state – this time, thanks to the efforts of the industry (and first and foremost representatives of its domestic wing), trouble passed us by. Will it turn out the same way with other initiatives tirelessly generated by the Russian bureaucratic apparatus – the future will show.

[6] "White lists" is a list of websites that remain accessible even when the Internet is completely disconnected.

# CLINICAL TRIALS IN THE NEIGHBOR COUNTRIES OF THE RUSSIAN FEDERATION

Since 2022, after international pharmaceutical companies practically stopped launching new studies in Russia, we turned our attention to neighboring states and included a new section in the newsletter monitoring the situation in their markets. We were concerned with the question of whether the impact of the armed conflict would be limited to the territory of the direct participants (primarily Russia and Ukraine, and to a lesser extent Belarus) or would affect a wider range of countries in our region, and which of the neighboring states in particular would manage to attract those international projects that left Russia.

Table 16 contains information on the situation in the field of clinical trials in the countries of interest to us as of February 2026. Information on the number of active interventional trials is taken from the ClinicalTrials.gov registry. The ranking by the indicator «number of studies per million population» is given below separately in Diagram 18.

**Table 16**

| The activity of clinical trial markets in the neighboring countries of the Russian Federation as of 02.02.2026 (data for 02.17.2025 are also given in parentheses) | | | | |
|---|---|---|---|---|
| **Region** | **Number of active interventional CTs** | **Share in the global CT market** | **Population, mln** | **Number of CTs, per million population** |
| In the world | 87 316 (80 639) | | | |
| Russia | 729 (824) | 0.98 (0.98) | 146.1 | 5.0 |
| Ukraine | 310 (319) | 0.38 (0.38) | 28.7 | 10.8 |
| Georgia | 245* (235) | 0.28 (0.28) | 3.7 | 66.2 |
| Lithuania | 220 (215) | 0.26 (0.26) | 2.9 | 75.9 |
| Estonia | 132 (143) | 0.16 (0.16) | 1.4 | 94.3 |
| Latvia | 131 (137) | 0.16 (0.16) | 1.8 | 72.8 |
| Moldova | 82 (70) | 0.08 (0.08) | 2.4 | 34.2 |
| Belarus | 47 (49) | 0.06 (0.06) | 9.1 | 5.2 |
| Kazakhstan | 34 (30) | 0.04 (0.04) | 20.5 | 1.7 |
| Armenia | 29 (23) | 0.03 (0.03) | 3.1 | 9.4 |
| Uzbekistan | 26 (18) | 0.021 (0.021) | 38.2 | 0.7 |
| Kyrgyzstan | 11 (13) | 0.015 (0.015) | 7.4 | 1.5 |
| Azerbaijan | 4 (3) | 0.004 (0.004) | 10.3 | 0.4 |
| Tadjikistan | 2 (2) | 0.002 (0.002) | 10.7 | 0.2 |

Data from www.clinicaltrials.gov for 02.02.2026; data from official statistical agencies as of 01.01.2026.

* In Georgia, only trials conducted in Tbilisi were taken into account, as changes in the search interface of the ClinicalTrials.gov database made it impossible to distinguish trials conducted in Georgia from those conducted in the state of Georgia, USA. We could not find any trials conducted in Georgia that did not have centres in Tbilisi. Therefore, we considered this new search method sufficiently accurate.

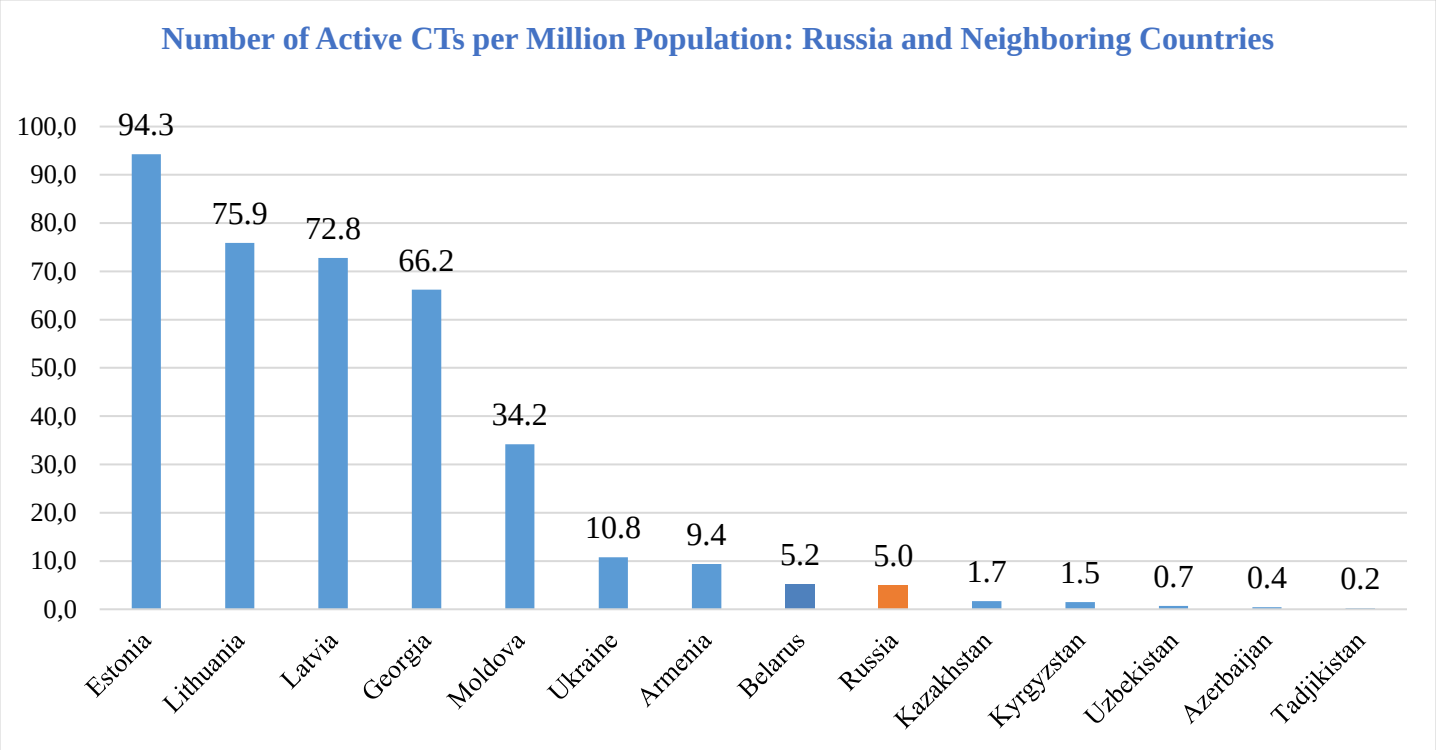
For the period from February 2025 to February 2026 the number of active interventional trials worldwide increased from 80 639 to 87 316, that is, by 8.3%.

In Russia, the decline continued: over the year, the number of studies decreased by 11.5% (729 active protocols at the beginning of 2026 versus 824 a year earlier). In Ukraine the decrease amounted to 2.8% (310 vs 319), in Belarus – 4.1% (47 vs 49). In the Baltic countries, the situation is uneven: in Estonia, the number of studies decreased by 7.7% (132 vs 143), in Latvia – by 4.4% (131 vs 137), and in Lithuania increased by 2.3% (220 vs 215).

In Moldova, the number of active trials over the year increased by 17%, from 70 to 82. Kazakhstan showed an increase of 13% (34 vs 30), and Armenia – of 26% (29 vs 23). In Uzbekistan, the increase amounted to 44% (26 vs 18), in Azerbaijan – 33% (four projects vs three). In Kyrgyzstan there is a slight reduction, from 13 to 11 protocols. Only Tajikistan remained unchanged, still two active trials.

In terms of the number of interventional trials per million population, the Baltic countries continue to lead, although their indicators have changed in different directions. In Estonia, the value decreased from 102,1 to 94,3, in Latvia it rose from 72,1 to 72,8, and in Lithuania – from 74,1 to 75,9. Fluctuations in the indicators did not affect the countries' positions in the ranking. Georgia continues to ramp up activity: 66.2 vs 63.5 a year earlier, and its lag behind the Baltic countries is shrinking every year. Moldova also improved its positions – 34.2 vs 29.2. Among other countries, an increase in the number of trials per million population is observed in Armenia (from 7.7 to 9.4), Ukraine (from 10.6 to 10.8), Kazakhstan (from 1.5 to 1.7), Uzbekistan (from 0.5 to 0.7), and Azerbaijan (from 0.3 to 0.4). Decline – in Russia (from 5.6 to 5.0) and Belarus (from 5.3 to 5.2), as well as in Kyrgyzstan (from 1.8 to 1.5). The latter even dropped in the rankings and let Kazakhstan move ahead. Finally, Tajikistan maintained the rate at the level of 0.2.

**Diagram 18**




Data from www.clinicaltrials.gov for 02.02.2026

Comparing the dynamics of clinical trials in different countries is complicated by the difference in the sizes of their markets. To smooth out this distortion, Table 17 presents for each country both the absolute and relative changes in the number of active clinical trials from July 2022 to February 2026. The color scale is intended to make the data easier to read. To further smooth out the difference in market sizes, the states in the table are divided into two groups: (1) with the number of trials greater than 20 in mid-2022 and (2) with a lower indicator.

In the first group, Russia, Ukraine, and Belarus, despite the fact that the number of trials in them differs noticeably, found themselves in a similar situation: all of them from mid-2022 to early 2026 lost half of their active projects, which, of course, is related to the war. During the observation period, the markets of the Baltic countries decreased: in Latvia by almost a quarter, and in Lithuania barely noticeably, by 1.3%. During this period, the indicators of Moldova (by 18.8%), Kazakhstan (21.4%) and especially – Georgia (25.6%) increased. In the second group of countries, in absolute terms, Uzbekistan and Armenia increased the most (growth from ten to 26 and from 16 to 29 active trials, respectively).

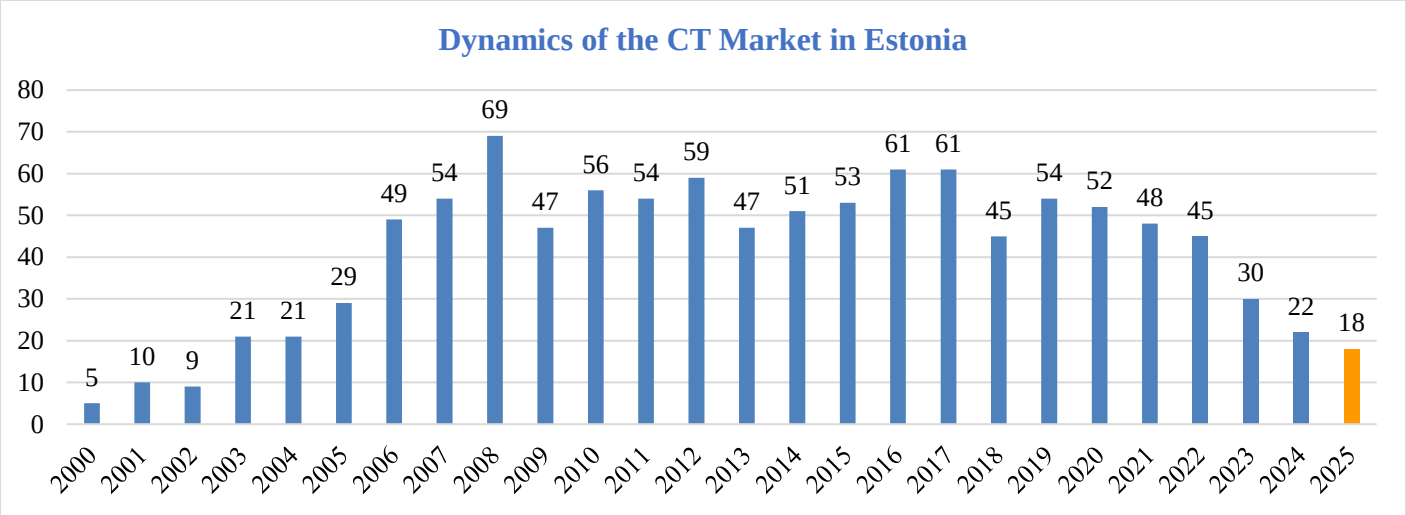
**Table 17**

| Dynamics of the Number of Active CTs by Country | | | | |
|---|---|---|---|---|
| **Region** | **Number of active interventional CTs for July 2022** | **Number of active interventional CTs for February 2026** | **Absolute change** | **Relative change** |
| In the world | 77 750 | 87 316 | 9 566 | 12,30% |
| *Group 1* | *Countries with more than 20 active CTs in mid-2022* | | | |
| Russia | 1 400 | 729 | -671 | -47.9% |
| Ukraine | 595 | 310 | -285 | -47.9% |
| Belarus | 90 | 47 | -43 | -47.8% |
| Latvia | 172 | 131 | -41 | -23.8% |
| Estonia | 173 | 143 | -30 | -17.3% |
| Lithuania | 223 | 220 | -3 | -1.3% |
| Moldova | 69 | 82 | 13 | 18.8% |
| Kazakhstan | 28 | 34 | 6 | 21.4% |
| Georgia | 195 | 245 | 50 | 25.6% |
| *Group 2* | *Countries with less than 20 active CTs in mid-2022* | | | |
| Azerbaijan | 3 | 4 | 1 | 33.3% |
| Armenia | 16 | 29 | 13 | 81.3% |
| Kyrgyzstan | 6 | 11 | 5 | 83.3% |
| Tadjikistan | 1 | 2 | 1 | 100.0% |
| Uzbekistan | 10 | 26 | 16 | 160.0% |

Data from www.clinicaltrials.gov for 02.02.2026

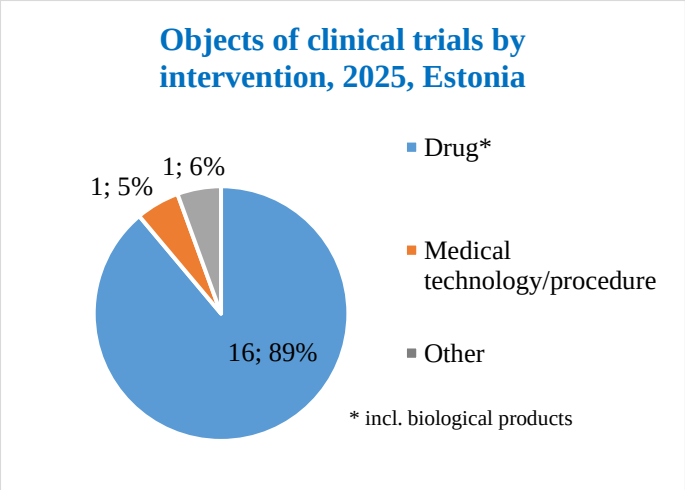
This section concludes with a selection of diagrams and tables prepared on the basis of data from the clinicaltrials.gov portal, with more detailed information on the situation with clinical trials in each of the countries. In addition, for additional data you can look into the registers of Belarus and Kazakhstan.

**Diagram 19**



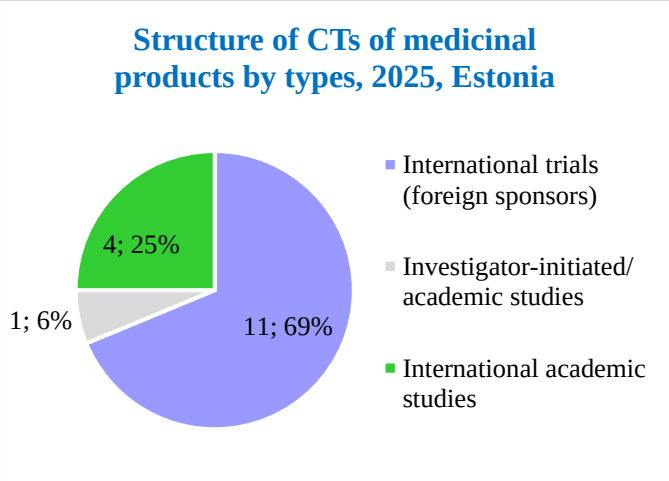

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 20**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 21**



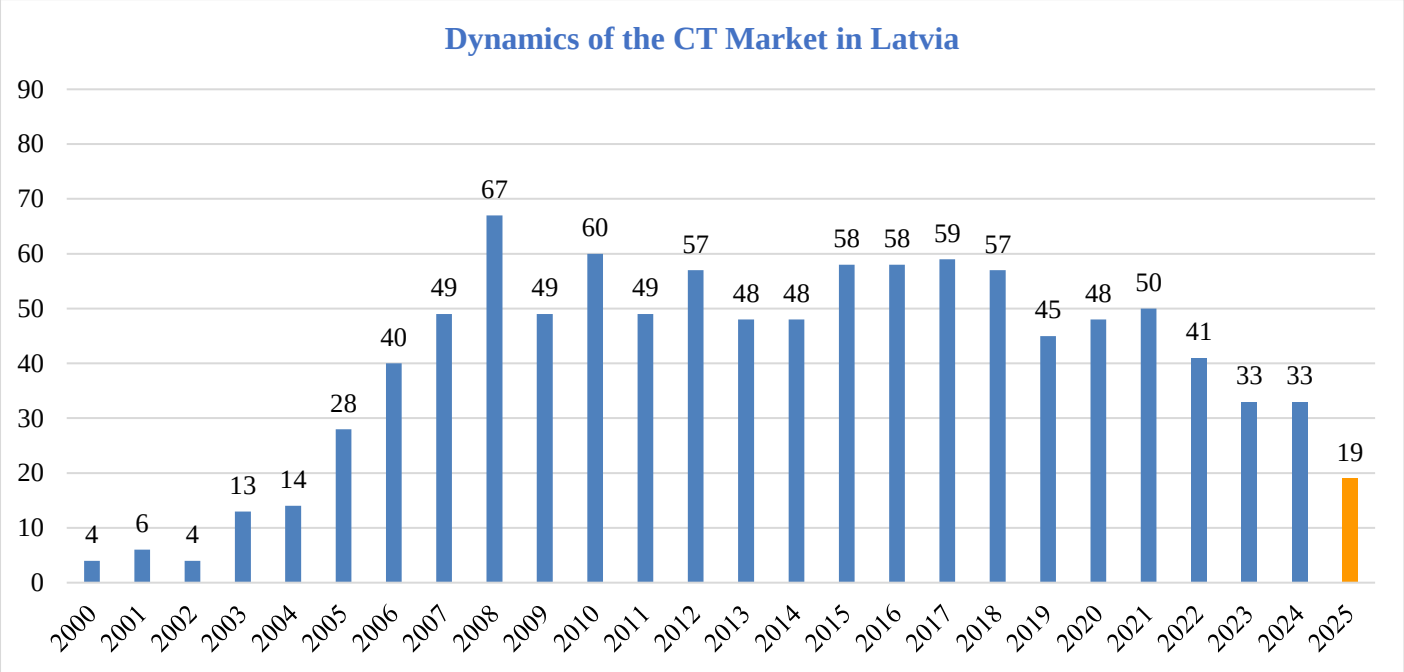

Data from www.clinicaltrials.gov for 02.02.2026

**Table 18**

| Sponsors, 2025, Estonia | Total | Number of IMCTs | Number of investigator-initiated/ academic studies | Number of international academic studies |
|---|---|---|---|---|
| Sanofi (incl. Sanofi Pasteur) | 2 | 2 | | |
| AbbVie | 1 | 1 | | |
| Alumis Inc | 1 | 1 | | |
| Argenx | 1 | 1 | | |
| Debiopharm International SA | 1 | 1 | | |
| Eli Lilly and Company | 1 | 1 | | |
| ETOP IBCSG Partners Foundation | 1 | | | 1 |
| European Myeloma Network B.V. | 1 | | | 1 |
| IDEAYA Biosciences | 1 | 1 | | |
| Immunovant Sciences GmbH | 1 | 1 | | |
| Mikk JÜRISSON | 1 | | 1 | |
| Neurocrine Biosciences | 1 | 1 | | |
| Stichting Hemato-Oncologie voor Volwassenen Nederland (foundation) | 1 | | | 1 |
| Takeda | 1 | 1 | | |
| Vejle Hospital | 1 | | | 1 |
| Total number of sponsors is 15 | 16 | 11 | 1 | 4 |

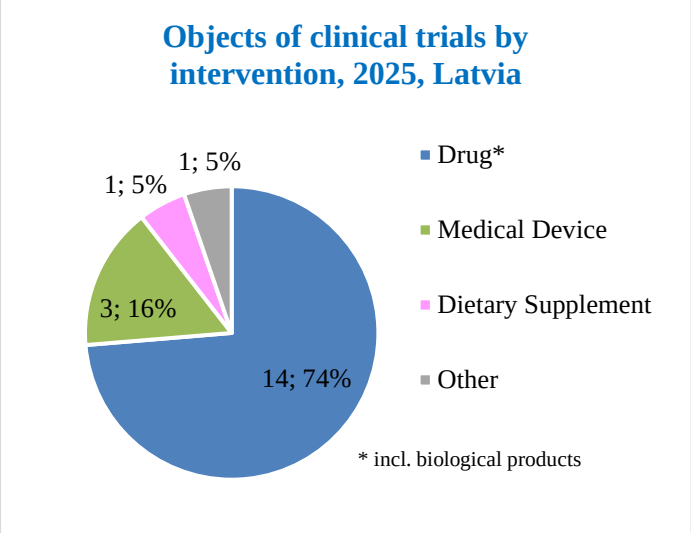
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 22**



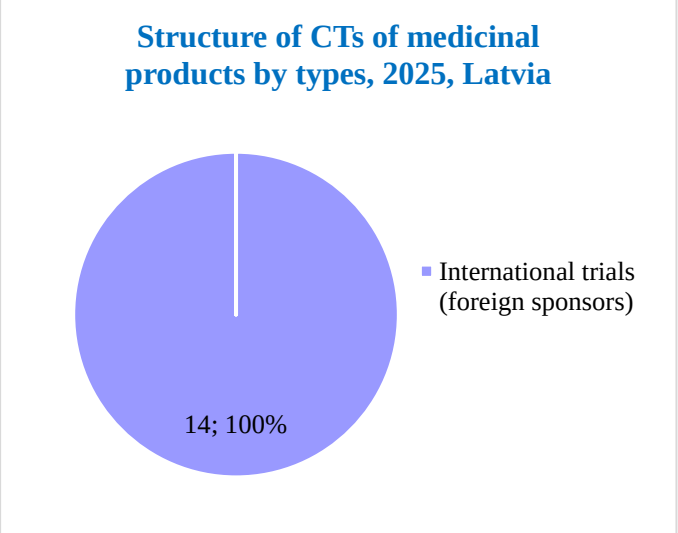

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 23**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 24**



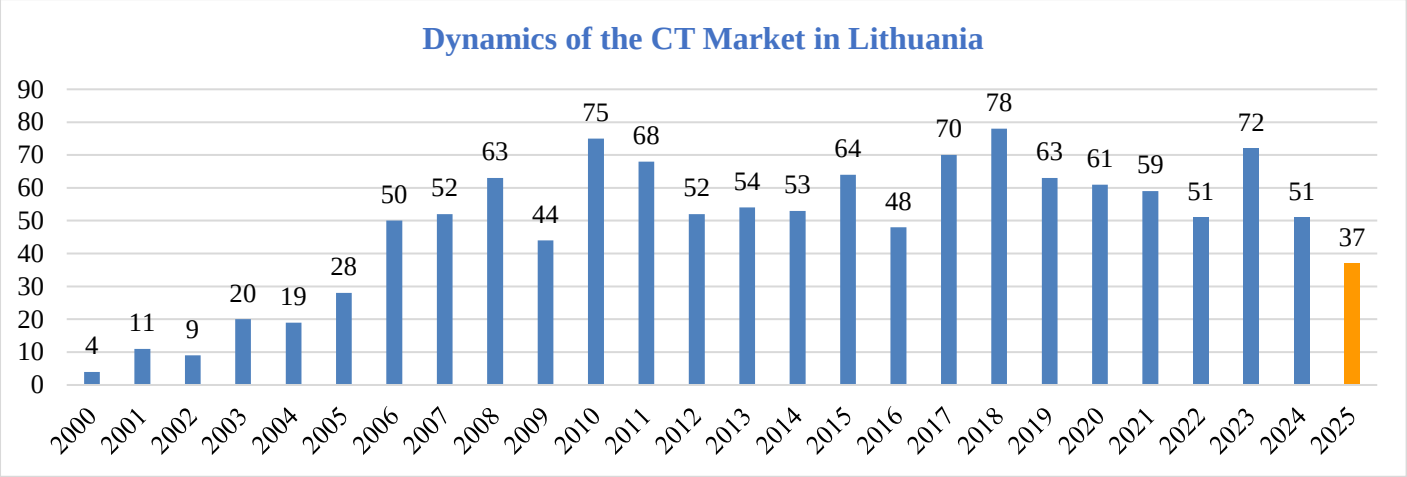

Data from www.clinicaltrials.gov for 02.02.2026

**Table 19**

| Sponsors, 2025, Latvia | Total | Number of IMCTs |
|---|---|---|
| Boehringer Ingelheim | 2 | 2 |
| Takeda | 2 | 2 |
| AbbVie | 1 | 1 |
| Alumis Inc | 1 | 1 |
| Debiopharm International SA | 1 | 1 |
| Dianthus Therapeutics | 1 | 1 |
| Immunovant Sciences GmbH | 1 | 1 |
| Immutep S.A.S. | 1 | 1 |
| Longboard Pharmaceuticals | 1 | 1 |
| Neurocrine Biosciences | 1 | 1 |
| Regeneron Pharmaceuticals | 1 | 1 |
| Upstream Bio Inc. | 1 | 1 |
| Total number of sponsors is 12 | 14 | 14 |

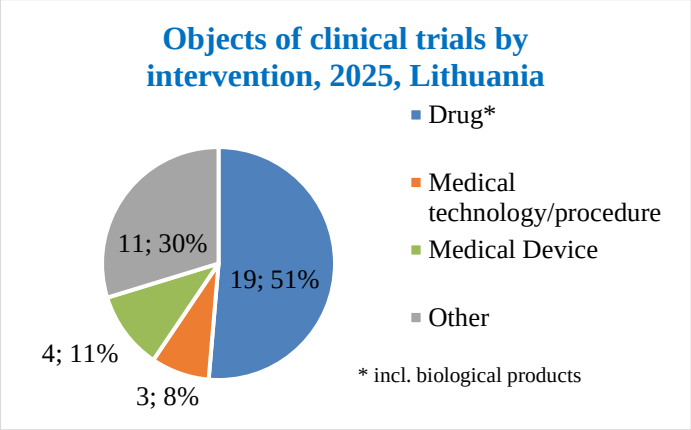
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 25**



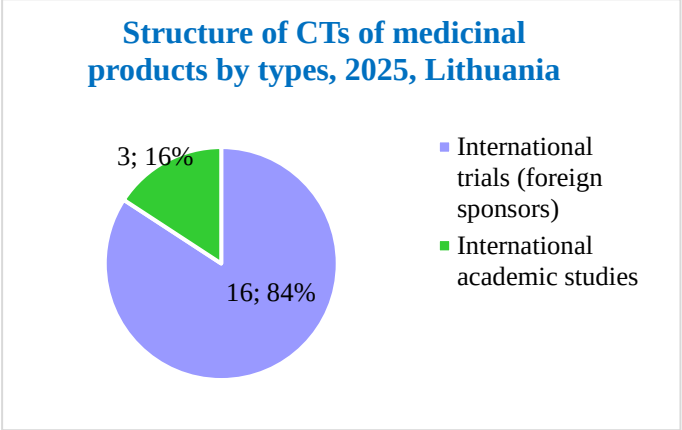

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 26**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 27**



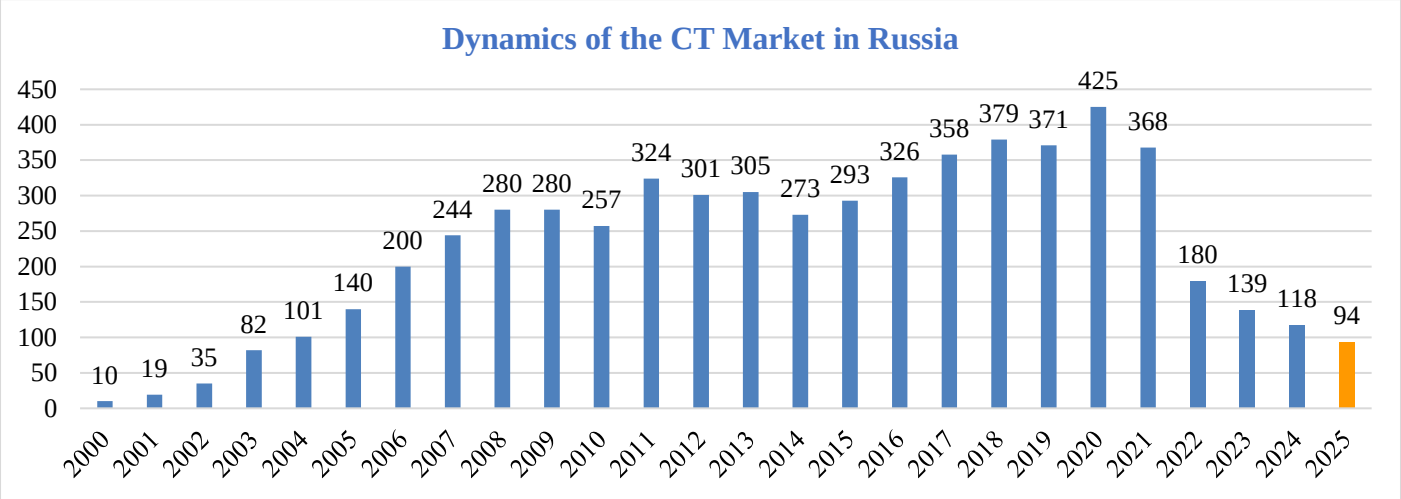

Data from www.clinicaltrials.gov for 02.02.2026

**Table 20**

| Sponsors, 2025, Lithuania | Total | Number of IMCTs | Number of international academic studies |
|---|---|---|---|
| Boehringer Ingelheim | 2 | 2 | |
| AbbVie | 1 | 1 | |
| Alexion Pharmaceuticals, Inc. | 1 | 1 | |
| Amgen | 1 | 1 | |
| Argenx | 1 | 1 | |
| Astellas Pharma Global Development, Inc. | 1 | 1 | |
| AstraZeneca | 1 | 1 | |
| Debiopharm International SA | 1 | 1 | |
| Eli Lilly and Company | 1 | 1 | |
| Immutep S.A.S. | 1 | 1 | |
| Istituto Romagnolo per lo Studio dei Tumori Dino Amadori IRST S.r.l. IRCCS | 1 | | 1 |
| Moleculin Biotech, Inc. | 1 | 1 | |
| Regeneron Pharmaceuticals | 1 | 1 | |
| SAb Biotherapeutics, Inc. | 1 | 1 | |
| Stichting Hemato-Oncologie voor Volwassenen Nederland | 1 | | 1 |
| Takeda | 1 | 1 | |
| Ukrainian Society of Clinical Oncology | 1 | | 1 |
| Upstream Bio Inc. | 1 | 1 | |
| Total number of sponsors is 18 | 19 | 16 | 3 |

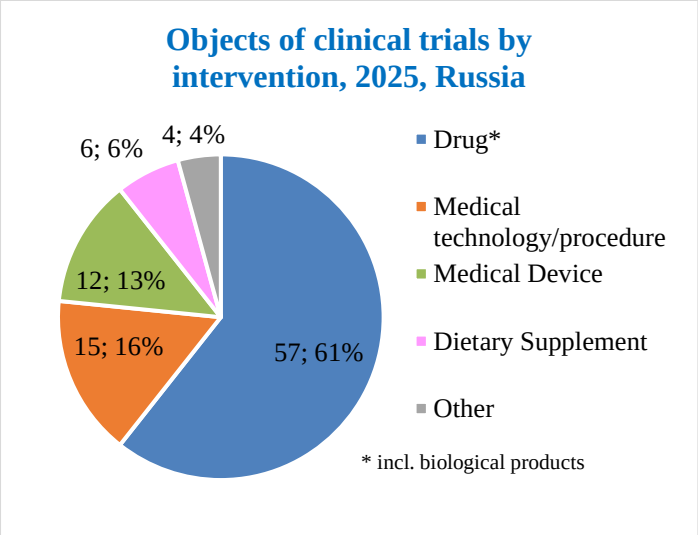
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 28**



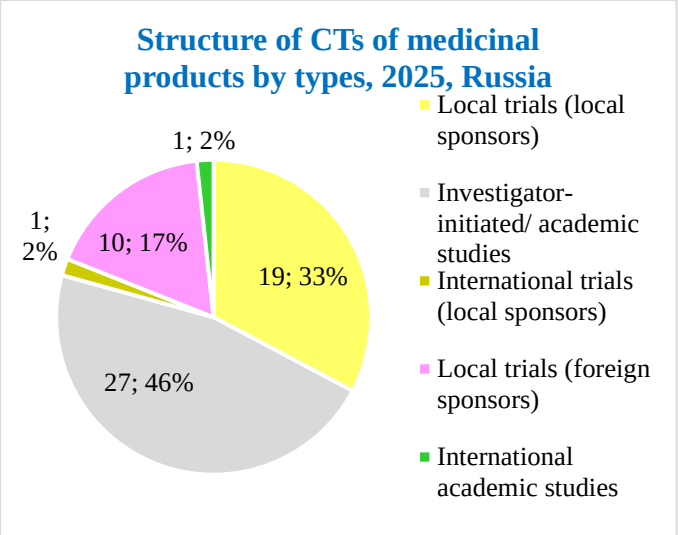

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 29**



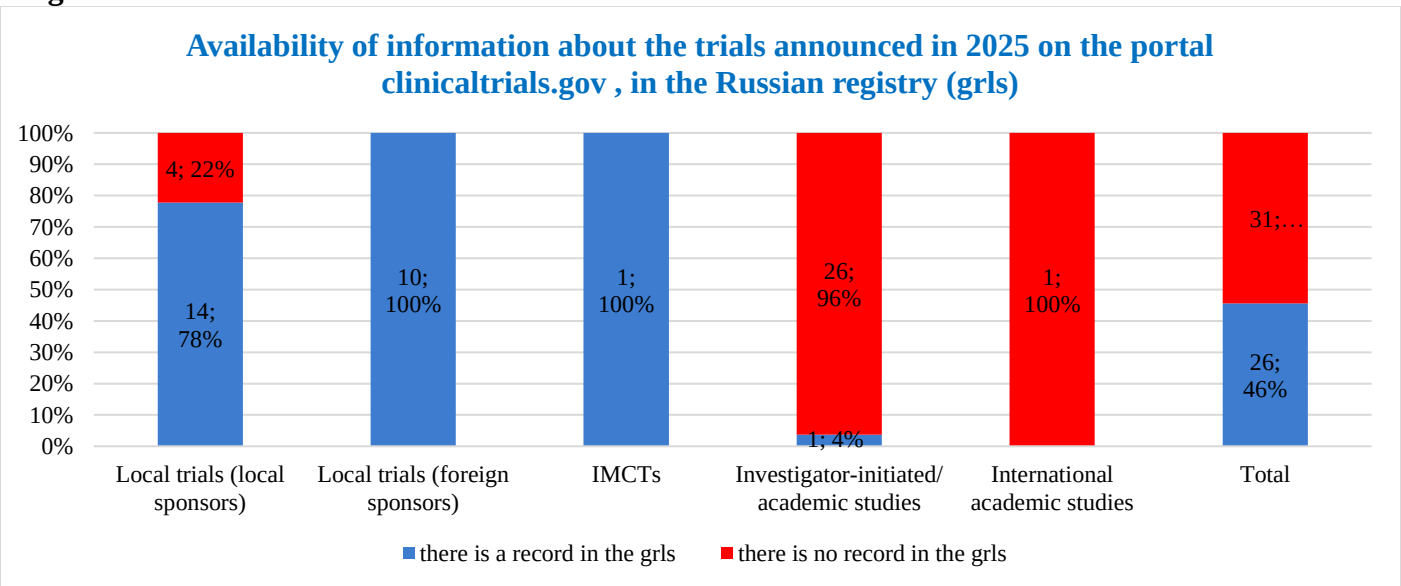

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 30**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 31**



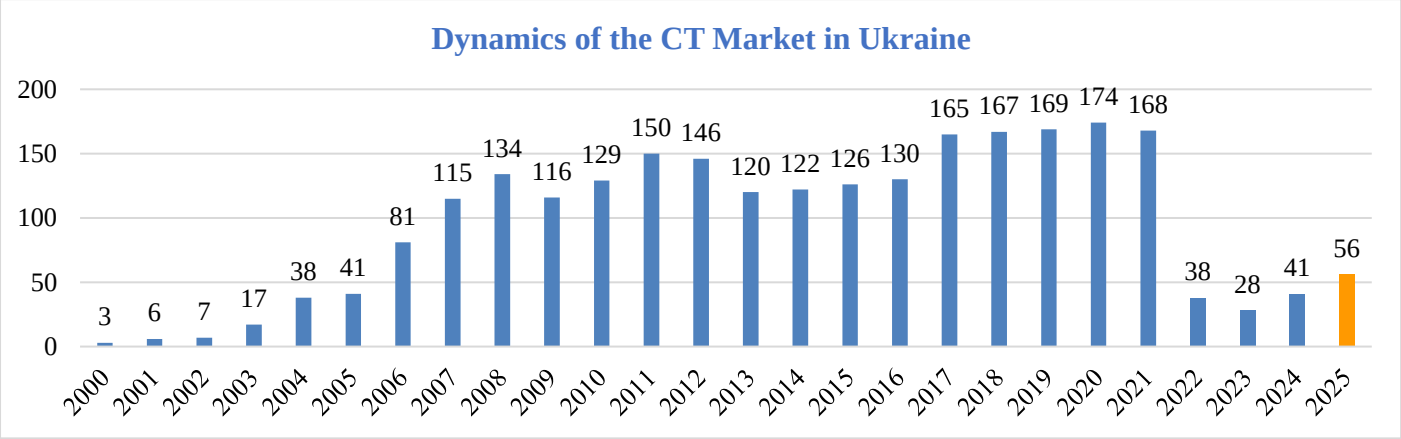

Data from www.clinicaltrials.gov for 02.02.2026, www.grls.rosminzdrav.ru

**Table 21**

| Sponsors, 2025, Russia | Total | Number of local trials | Number of IMCTs | Number of investigator-initiated/ academic studies | Number of international academic studies |
|---|---|---|---|---|---|
| Biocad | 6 | 5 | 1 | | |
| AstraZeneca | 5 | | | | 5 |
| Federal Research Institute of Pediatric Hematology, Oncology and Immunology | 4 | | | 4 | |
| Gedeon Richter Plc. | 4 | | | | 4 |
| S.LAB (SOLOWAYS) | 4 | 4 | | | |
| Blokhin's Russian Cancer Research Center | 3 | | | 3 | |
| Tomsk National Research Medical Center of the Russian Academy of Sciences | 3 | | | 3 | |
| Materia Medica Holding | 2 | 2 | | | |
| Saint Petersburg State University, Russia | 2 | | | 2 | |
| Valenta Pharm JSC | 2 | 2 | | | |
| Alcea | 1 | 1 | | | |
| Bigespas LTD | 1 | | | | 1 |
| Botkin Hospital | 1 | | | 1 | |
| EuroCityClinic LLC | 1 | | | 1 | |
| Federal Research and Clinical Centre of Intensive Care Medicine and Rehabilitology | 1 | | | 1 | |
| JSC NextGen | 1 | 1 | | | |
| Kidney Cancer Research Bureau | 1 | | | 1 | |
| National Medical Research Radiological Centre of the MoH of Russia | 1 | | | 1 | |
| National Research Center for Hematology | 1 | | | 1 | |
| Negovsky Reanimatology Research Institute | 1 | | | 1 | |
| Nizhny Novgorod Regional Clinical Oncology Center | 1 | | | 1 | |
| NPO Petrovax | 1 | 1 | | | |
| Pirogov Russian National Research Medical University | 1 | | | 1 | |
| POLYSAN Scientific & Technological Pharmaceutical Company | 1 | 1 | | | |
| Sergey Orlov, MD | 1 | | | 1 | |
| St. Petersburg State Pavlov Medical University | 1 | | | 1 | |
| State Budgetary Healthcare Institution, National Medical Surgical Center N.A. N.I. Pirogov, MoH of Russia | 1 | | | 1 | |
| Tatchempharmpreparaty, JSC | 1 | 1 | | | |
| Tomsk Cardiology Research Institute | 1 | | | 1 | |
| University Clinical Hospital na V.V.Vinogradov (branch of RUDN university na Patrice Lumumba) | 1 | | | 1 | |
| Vadim Kuznetsov | 1 | | | 1 | |
| Xijing Hospital | 1 | | 1 | | |
| Total number of sponsors is 32 | 57 | 18 | 2 | 27 | 10 |

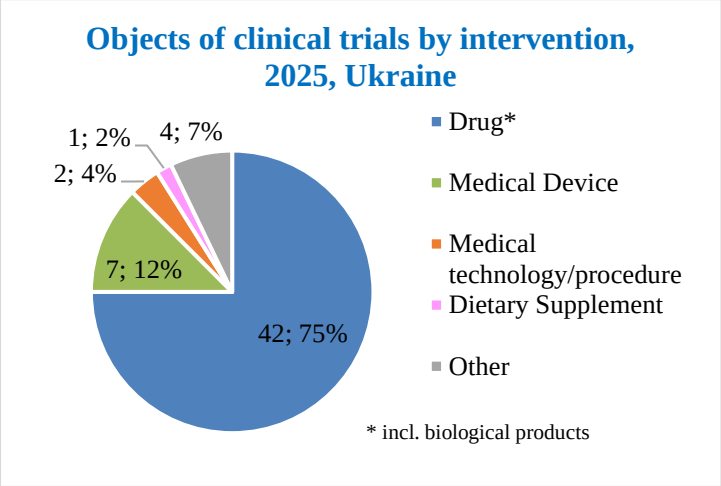
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 32**



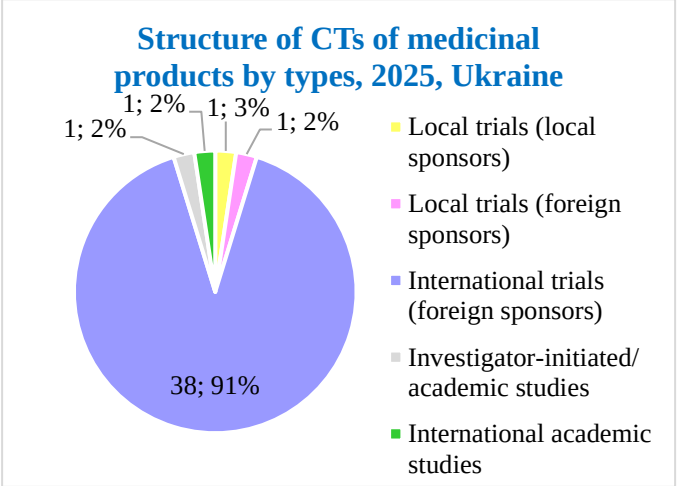

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 33**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 34**



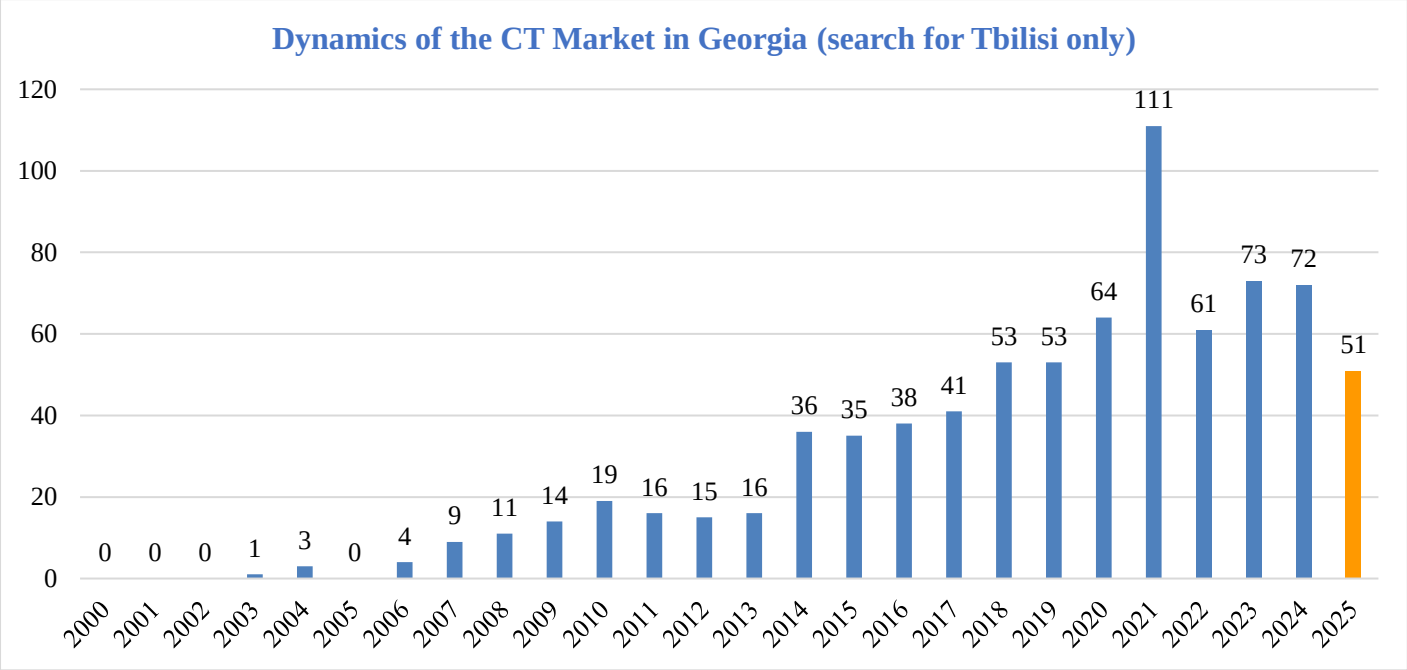

Data from www.clinicaltrials.gov for 02.02.2026

**Table 22**

| Sponsors, 2025, Ukraine | Total | Number of IMCTs | Number of local trials (local sponsors) | Number of local trials (foreign sponsors) | Number of investigator-initiated/ academic studies | Number of international academic studies |
|---|---|---|---|---|---|---|
| AstraZeneca | 8 | 8 | | | | |
| Merck Sharp & Dohme LLC | 8 | 8 | | | | |
| Bristol-Myers Squibb | 4 | 4 | | | | |
| Climb Bio, Inc. | 3 | 3 | | | | |
| Eli Lilly and Company | 2 | 2 | | | | |
| Hoffmann-La Roche | 2 | 2 | | | | |
| Vir Biotechnology, Inc. | 2 | 2 | | | | |
| Biopharma Plasma LLC | 1 | | 1 | | | |
| Bluejay Therapeutics, Inc. | 1 | 1 | | | | |
| Candid Therapeutics | 1 | 1 | | | | |
| Lifordi Immunotherapeutics, Inc. | 1 | 1 | | | | |
| mAbxience Research S.L. | 1 | 1 | | | | |
| Medice Arzneimittel Pütter GmbH&Co KG | 1 | | | 1 | | |
| Moleculin Biotech, Inc. | 1 | 1 | | | | |
| Spyre Therapeutics, Inc. | 1 | 1 | | | | |
| TG Therapeutics, Inc. | 1 | 1 | | | | |
| Triveni Bio | 1 | 1 | | | | |
| Ukrainian Society of Clinical Oncology | 2 | | | | 1 | 1 |
| Upstream Bio Inc. | 1 | 1 | | | | |
| Total number of sponsors is 19 | 42 | 38 | 1 | 1 | 1 | 1 |

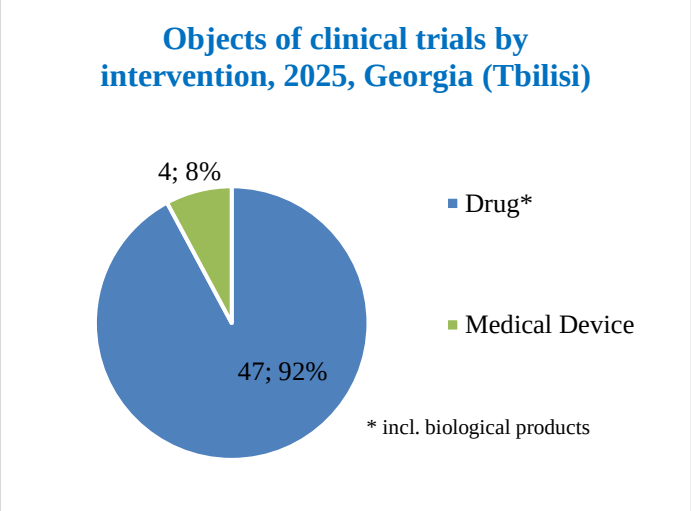
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 35**



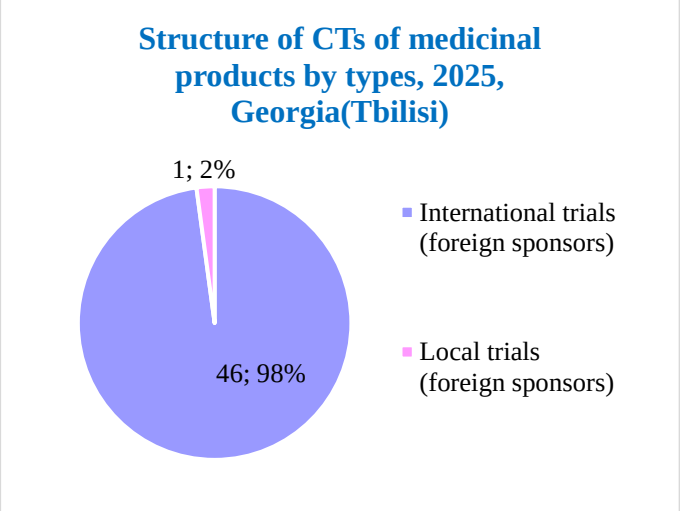

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 36**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 37**




Data from www.clinicaltrials.gov for 02.02.2026

**Table 23**

| Sponsors, 2025, Georgia | Total | Number of IMCTs | Number of local trials |
|---|---|---|---|
| AstraZeneca | 5 | 5 | |
| Immunovant Sciences GmbH | 4 | 4 | |
| Argenx | 2 | 2 | |
| Bluejay Therapeutics, Inc. | 2 | 2 | |
| Climb Bio, Inc. | 2 | 2 | |
| Connect Biopharm LLC | 2 | 2 | |
| Spyre Therapeutics, Inc. | 2 | 2 | |
| Amgen | 1 | 1 | |
| Aphaia Pharma US LLC | 1 | 1 | |
| BioNTech SE | 1 | 1 | |
| Boehringer Ingelheim | 1 | 1 | |
| Candid Therapeutics | 1 | 1 | |
| Celltrion | 1 | | 1 |
| Cinclus Pharma Holding AB | 1 | 1 | |
| Corteria Pharmaceuticals | 1 | 1 | |
| Cullinan Therapeutics Inc. | 1 | 1 | |
| Dianthus Therapeutics | 1 | 1 | |
| Galimedix Therapeutics Inc | 1 | 1 | |
| Genfit | 1 | 1 | |
| Gilead Sciences | 1 | 1 | |
| Immutep S.A.S. | 1 | 1 | |
| InflaRx GmbH | 1 | 1 | |
| Moleculin Biotech, Inc. | 1 | 1 | |
| Novartis Pharmaceuticals | 1 | 1 | |
| Otsuka Pharmaceutical Development & Commercialization, Inc. | 1 | 1 | |
| Rempex (a wholly owned subsidiary of Melinta Therapeutics, LLC) | 1 | 1 | |
| Sandoz | 1 | 1 | |
| Sanofi | 1 | 1 | |
| Sun Pharmaceutical Industries Limited | 1 | 1 | |
| Syndax Pharmaceuticals | 1 | 1 | |
| TG Therapeutics, Inc. | 1 | 1 | |
| Upstream Bio Inc. | 1 | 1 | |
| UroGen Pharma Ltd. | 1 | 1 | |
| Vir Biotechnology, Inc. | 1 | 1 | |
| Xencor, Inc. | 1 | 1 | |
| Total number of sponsors is 35 | 47 | 46 | 1 |

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 38**

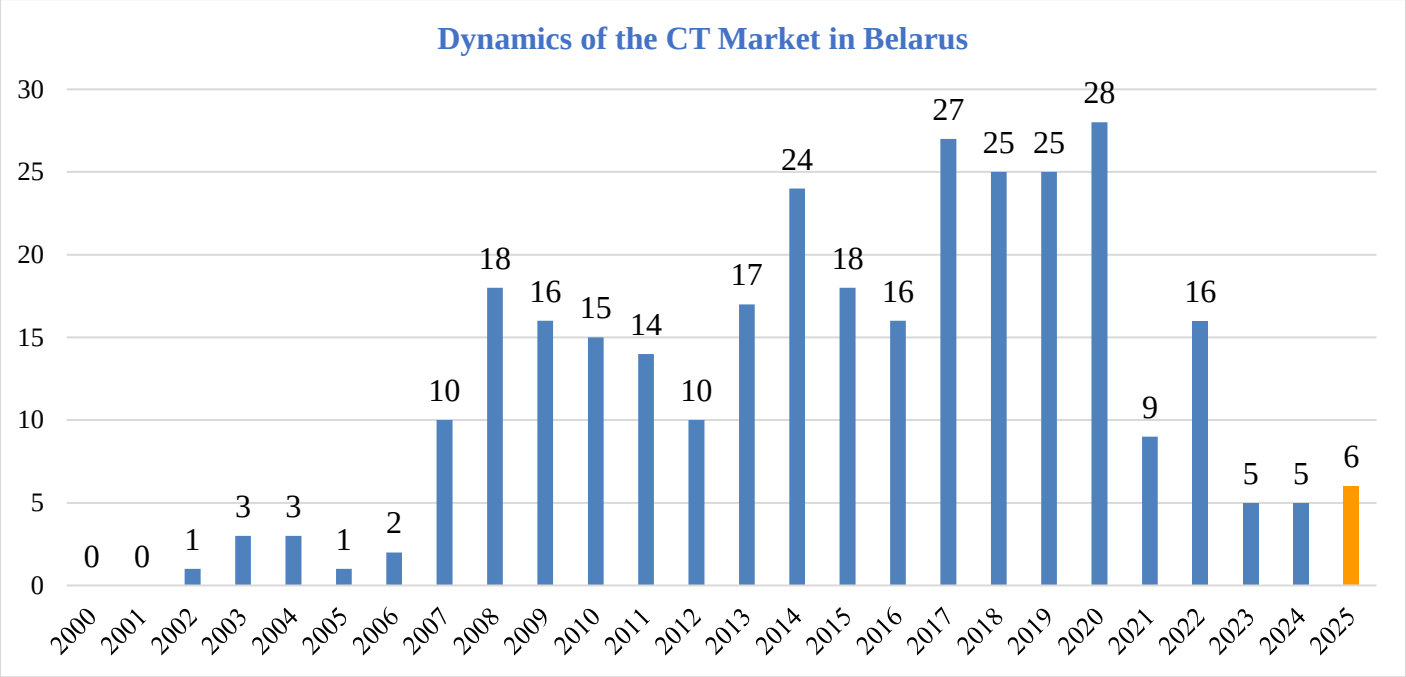
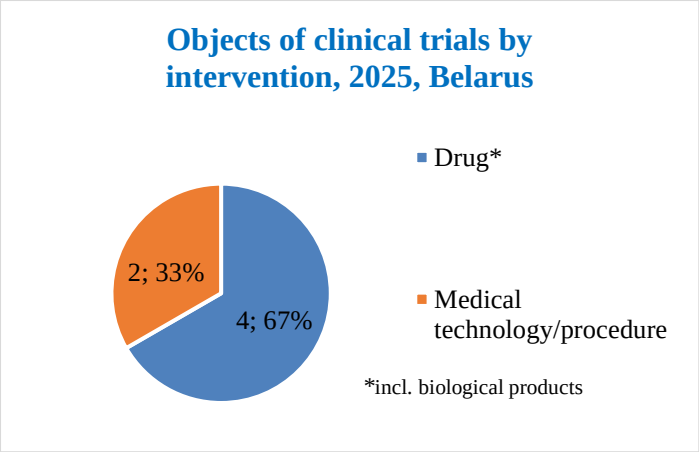
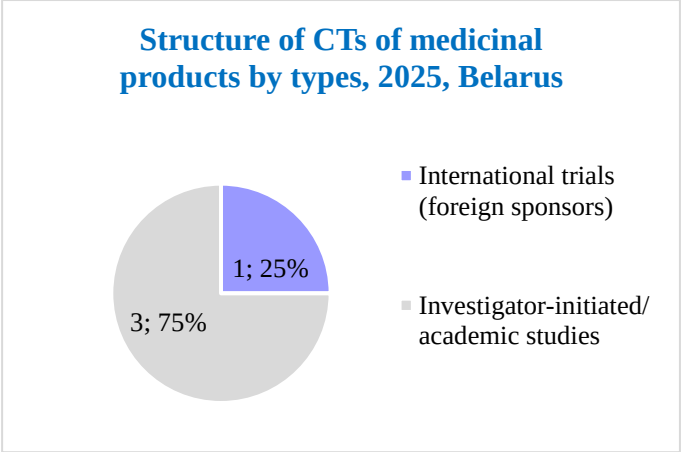



**Diagram 39**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 40**



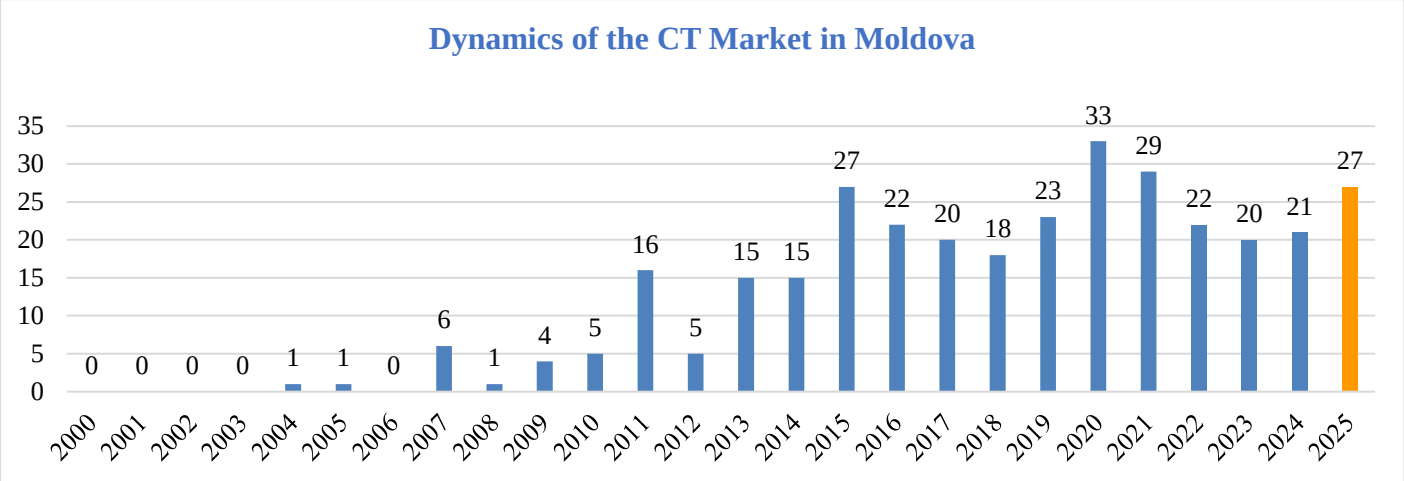

Data from www.clinicaltrials.gov for 02.02.2026

**Table 24**

| Sponsors, 2025, Belarus | Total | Number of IMCTs | Number of investigator-initiated/ academic studies |
|---|---|---|---|
| Research Institute for Physical Chemical Problems of the Belarusian State University | 3 | | 3 |
| Biocad | 1 | 1 | |
| Всего 2 спонсора | 4 | 1 | 3 |

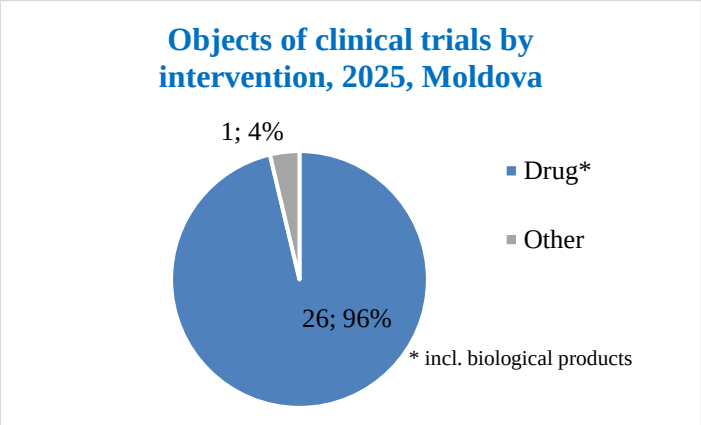
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 41**



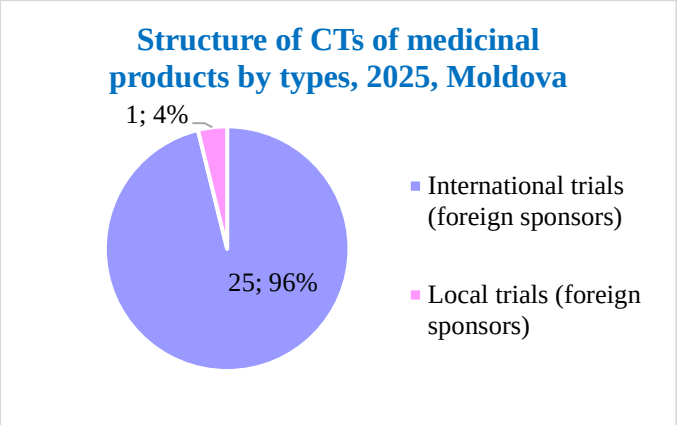

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 42**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 43**



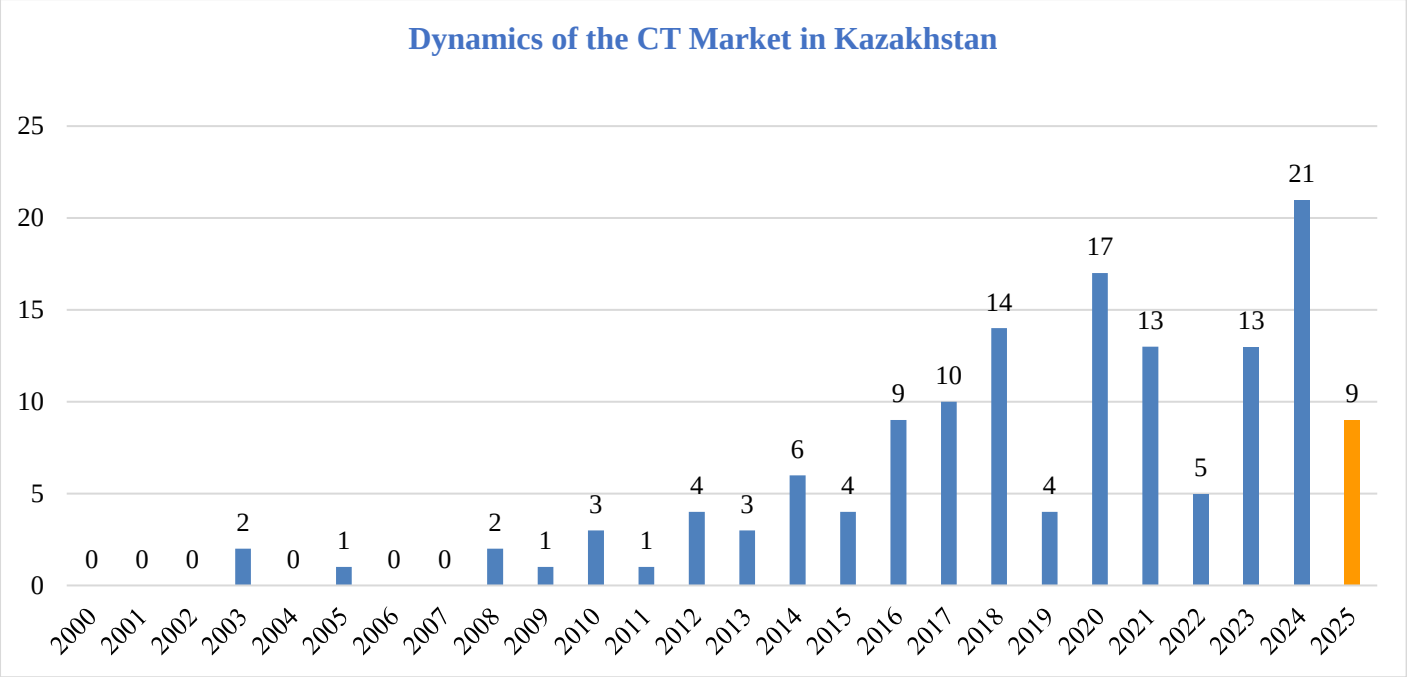

Data from www.clinicaltrials.gov for 02.02.2026

**Table 25**

| Sponsors, 2025, Moldova | Total | Number of IMCTs | Number of local trials (foreign sponsors) |
|---|---|---|---|
| AstraZeneca | 2 | 2 | |
| BioNTech SE | 2 | 2 | |
| Gilead Sciences | 2 | 2 | |
| Otsuka Pharmaceutical Development & Commercialization, Inc. | 2 | 2 | |
| Spyre Therapeutics, Inc. | 2 | 2 | |
| Vir Biotechnology, Inc. | 2 | 2 | |
| Aligos Therapeutics | 1 | 1 | |
| Atea Pharmaceuticals, Inc. | 1 | 1 | |
| Bluejay Therapeutics, Inc. | 1 | 1 | |
| Boehringer Ingelheim | 1 | 1 | |
| Candid Therapeutics | 1 | 1 | |
| Cullinan Therapeutics Inc. | 1 | 1 | |
| KeyBioscience AG | 1 | 1 | |
| Lifordi Immunotherapeutics, Inc. | 1 | 1 | |
| Merck Sharp & Dohme LLC | 1 | 1 | |
| Odyssey Therapeutics | 1 | 1 | |
| Regeneron Pharmaceuticals | 1 | | 1 |
| Sanofi | 1 | 1 | |
| Wave Life Sciences Ltd. | 1 | 1 | |
| Xencor, Inc. | 1 | 1 | |
| Total number of sponsors is 20 | 26 | 25 | 1 |

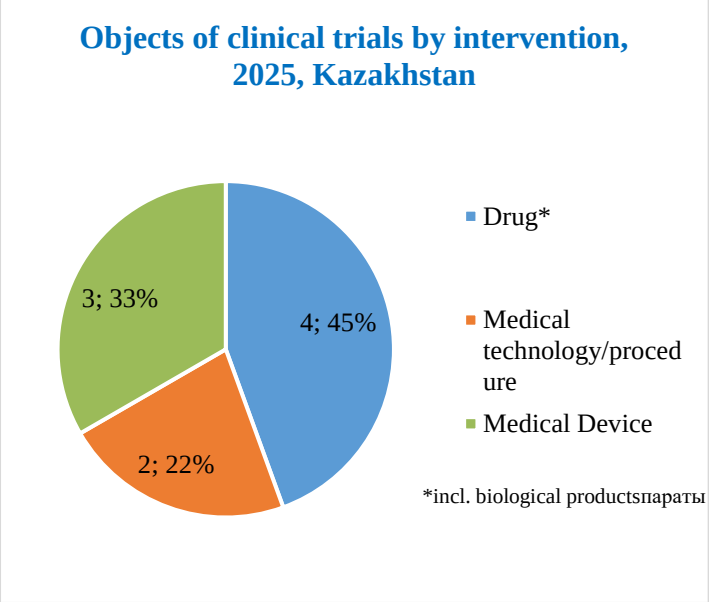
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 44**



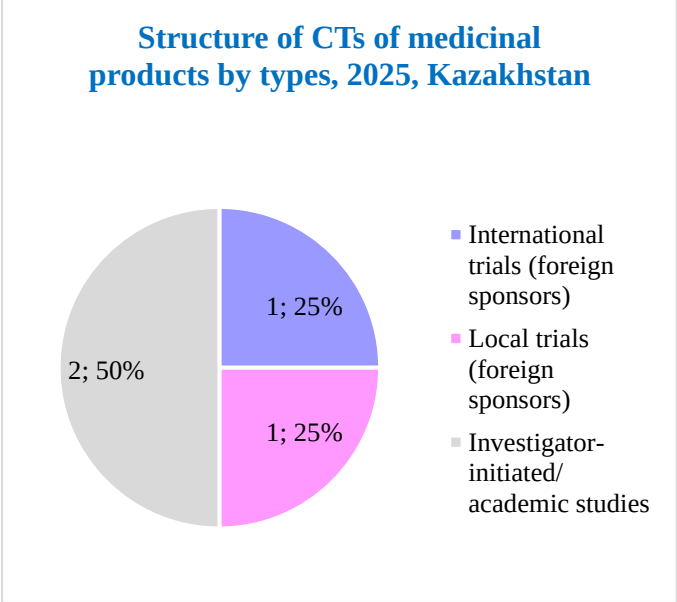

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 45**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 46**



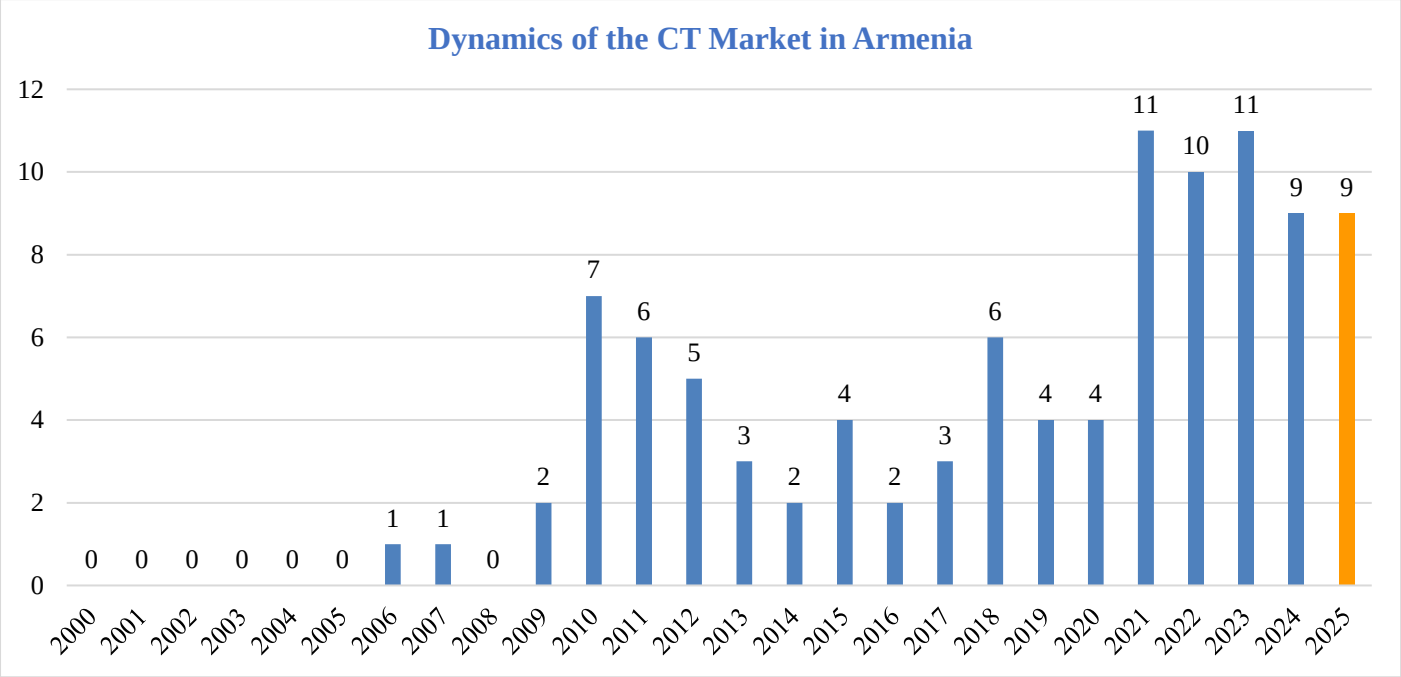

Data from www.clinicaltrials.gov for 02.02.2026

**Table 26**

| Sponsors, 2025, Kazakhstan | Total | Number of IMCTs | Number of local trials (foreign sponsors) | Number of investigator-initiated/ academic studies |
|---|---|---|---|---|
| Kazakh National Agrarian University | 1 | | | 1 |
| Scientific Center for Anti-infectious Drugs, Kazakhstan | 1 | | | 1 |
| Berlin-Chemie AG Menarini Group | 1 | | 1 | |
| Boehringer Ingelheim | 1 | 1 | | |
| Total number of sponsors is 4 | 4 | 1 | 1 | 2 |

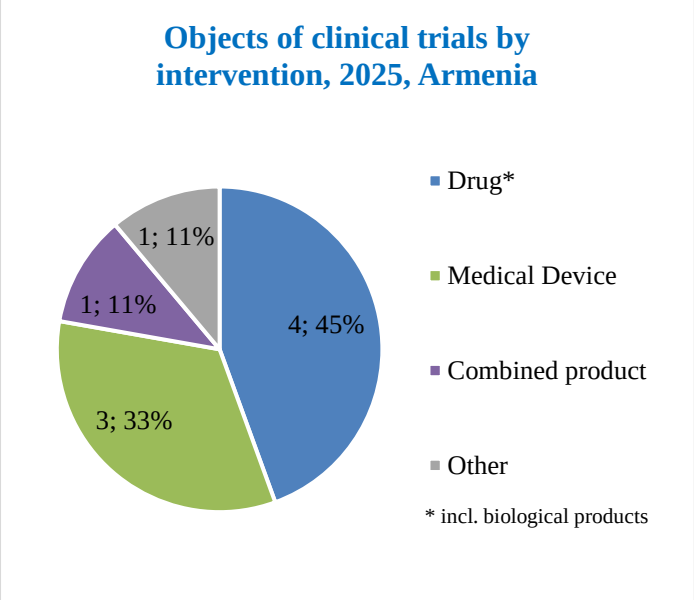
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 47**



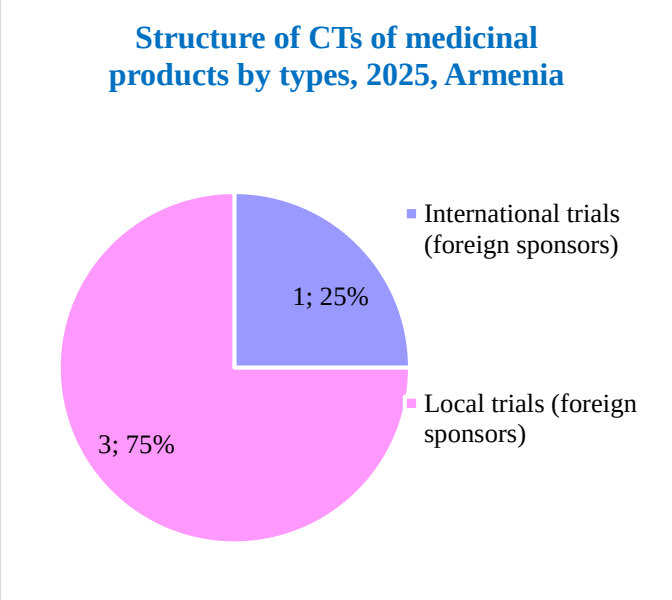

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 48**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 49**



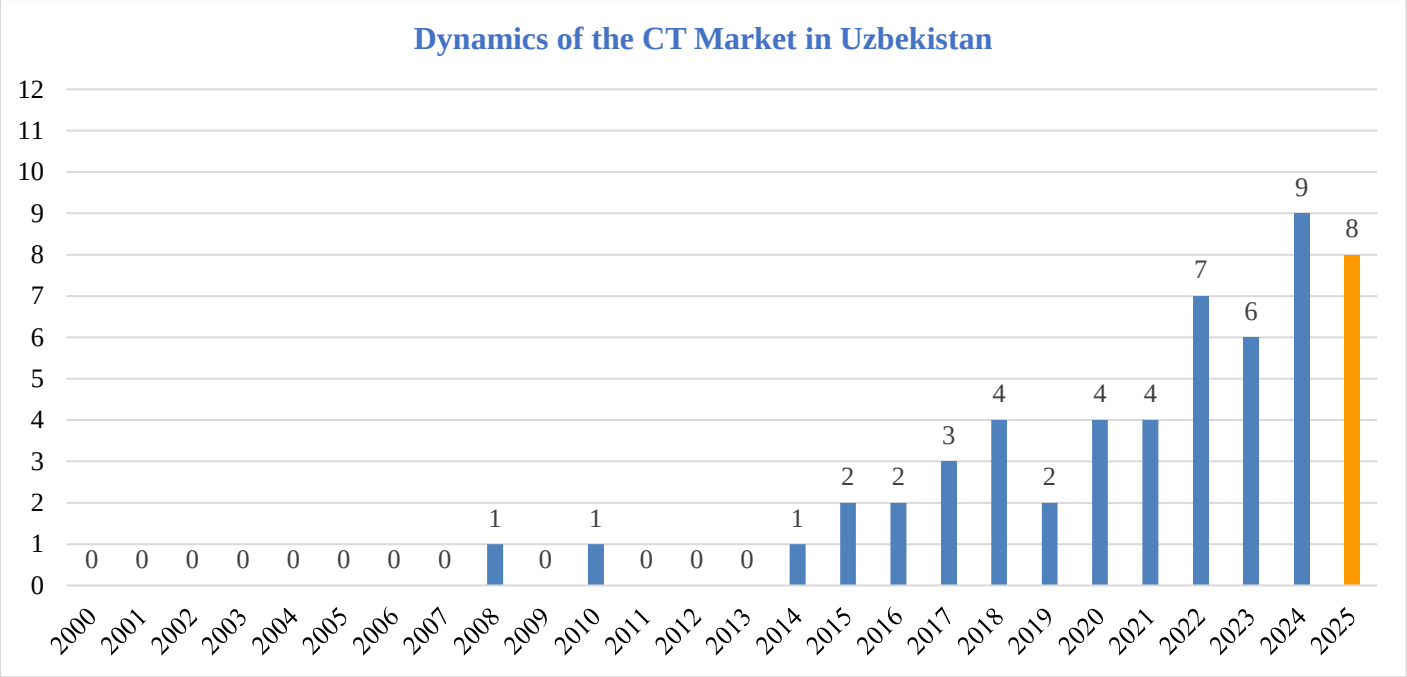

Data from www.clinicaltrials.gov for 02.02.2026

**Table 27**

| Sponsors, 2025, Armenia | Total | Number of IMCTs | Number of local trials (foreign sponsors) |
|---|---|---|---|
| Berlin-Chemie AG Menarini Group | 3 | | 3 |
| Galimedix Therapeutics Inc | 1 | 1 | |
| Total number of sponsors is 2 | 4 | 1 | 3 |

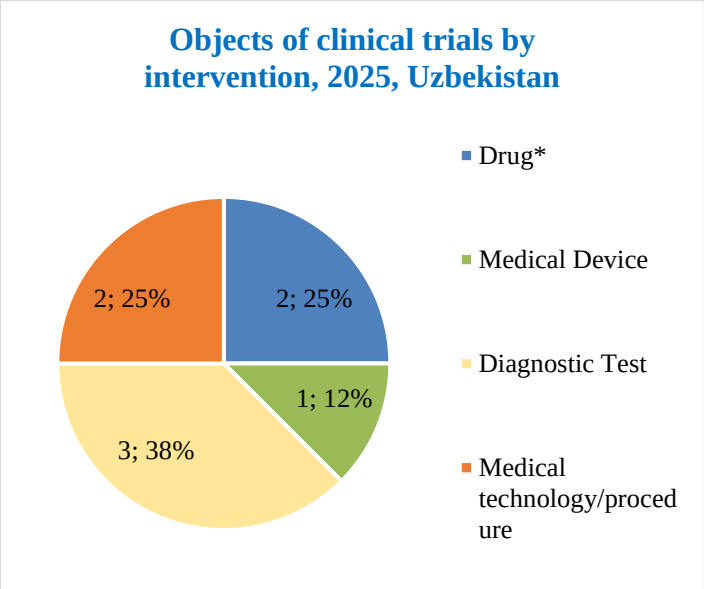
Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 50**



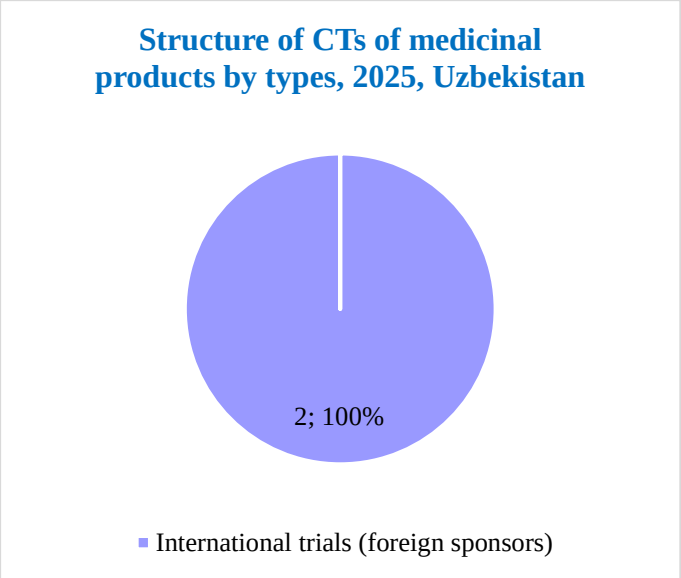

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 51**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 52**



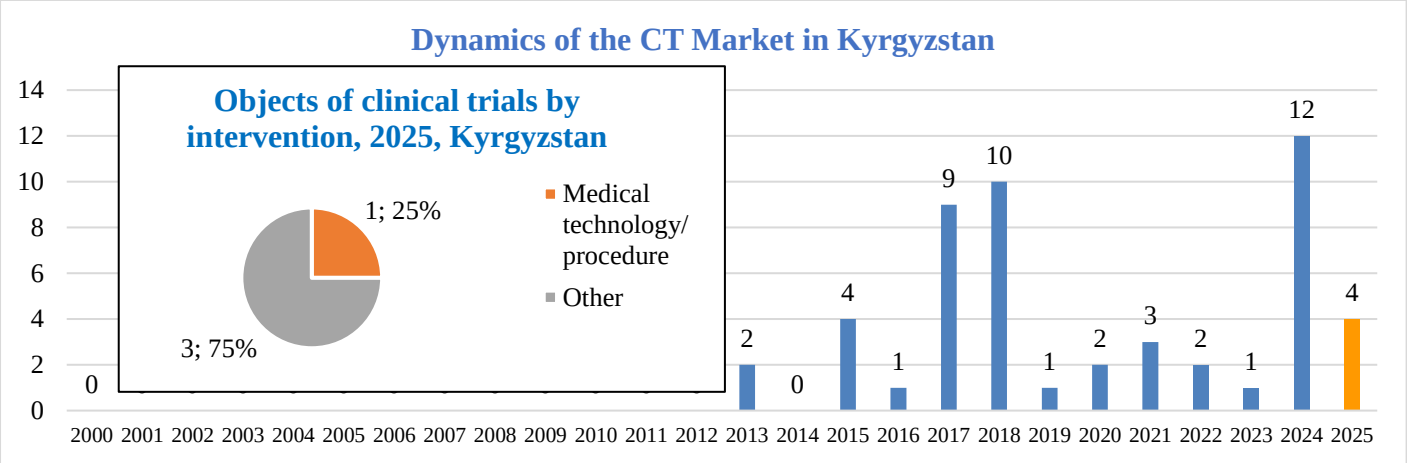

Data from www.clinicaltrials.gov for 02.02.2026

**Table 28**

| Sponsors, 2025, Uzbekistan | Total | Number of IMCTs |
|---|---|---|
| Eilean Therapeutics | 1 | 1 |
| Traws Pharma, Inc. | 1 | 1 |
| Total number of sponsors is 2 | 2 | 2 |

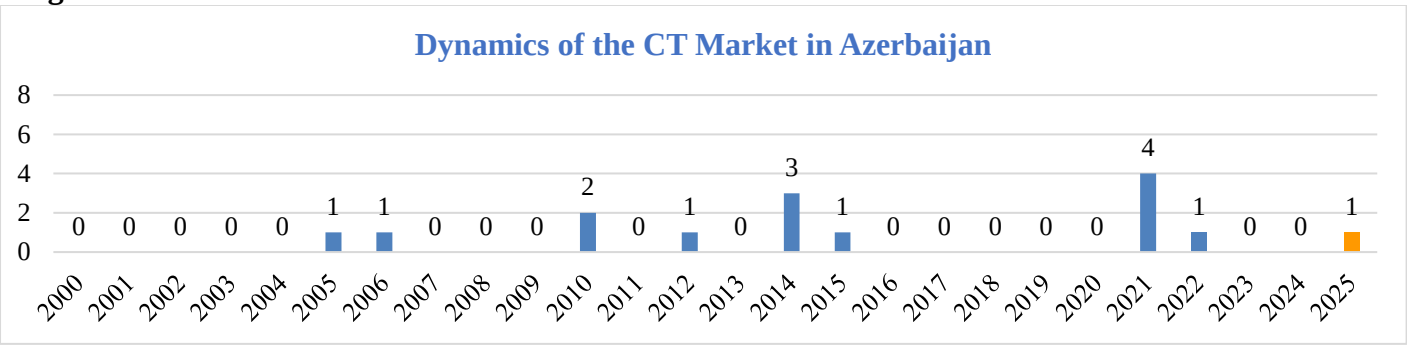
Data from www.clinicaltrials.gov for 02.02.2026

**Diagrams 53-54**



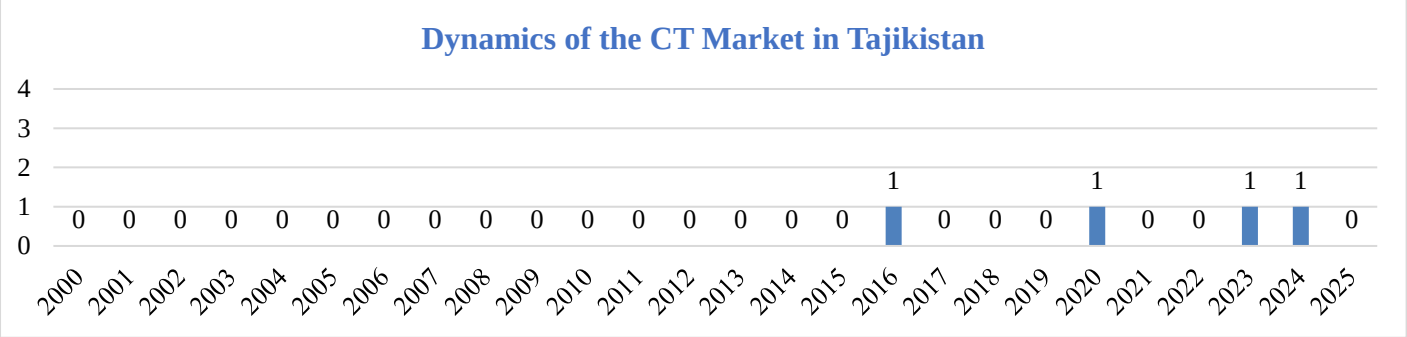

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 55**



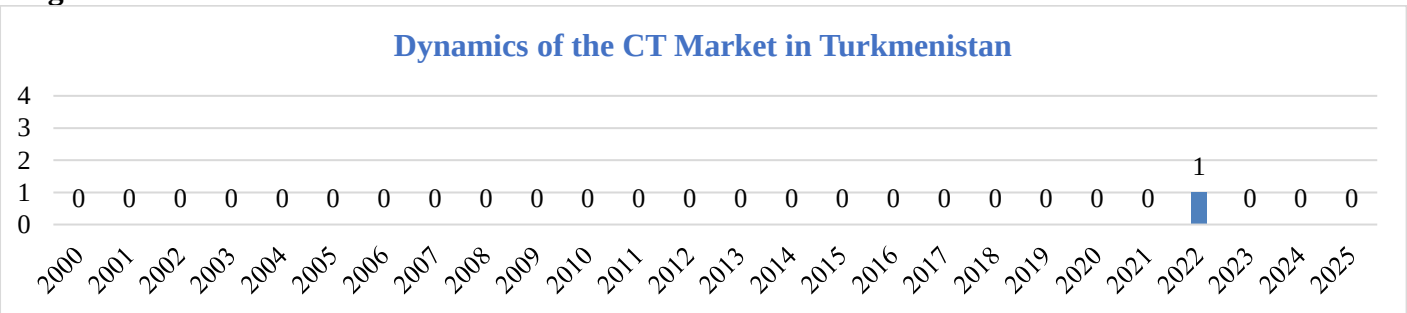

Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 56**




Data from www.clinicaltrials.gov for 02.02.2026

**Diagram 57**




Data from www.clinicaltrials.gov for 02.02.2026