

ACTO

ASSOCIATION OF CLINICAL
TRIALS ORGANIZATIONS

ACTO NEWSLETTER № 33

1st Half of 2026

MOSCOW 2026

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SUMMARY

In H1 2026, the clinical trials market in Russia reached a stable plateau, bringing a period of abrupt structural transformation to an end. During the reporting period, the Ministry of Health of the Russian Federation issued 285 clinical trial approvals, 2.5% more than in H1 2025 (278 approvals). However, over the longer term, the average number of approvals per half-year fell from 391.6 (in 2012–2021) to 305.8 (in 2024–2026).

The domestically sponsored bioequivalence study segment had a decisive impact on market dynamics, growing by 19.3%, from 140 to 167 protocols. It was the vigorous expansion of this sector, which accounted for an absolute majority of the market—58.6% of all approvals—that offset stagnation and declining performance in other segments. Only five new international multicentre clinical trials (IMCTs) were launched, an all-time low of 1.8% of the total market.

The foreign-sponsored local trial segment (eight projects) showed a sharp divide: half consisted of advanced innovative drug projects, while the other half involved mass-market generics from Indian manufacturers. In the foreign generic-drug segment, endocrinology (18.9%) and cardiology (17.0%) led the field, while oncology accounted for just 3.8%, underscoring foreign sponsors' shift towards outpatient and mass retail segments.

In the Russian generic and biosimilars portfolio, oncology is the main driver, accounting for a record 3,241 participants (23% of total enrolment in Russia). Biosimilars (22.4%) and original small-molecule drugs (19%) were the largest technology segments in local trials sponsored by domestic manufacturers. Russian sponsors obtained 27 approvals for local trials of original medicinal products.

A specific dualism has emerged in Russia's R&D sector: substantial resources are spent on marketing support for mature local brands, while innovative biotechnology products are being developed at the same time. Key fronts in patent wars were also identified: widespread development of triple amlodipine-based cardiology combinations, seven ivacaftor protocols, and a wave of empagliflozin bioequivalence studies, primarily by Indian companies.

An analysis of data from ClinicalTrials.gov as of July 2026 reveals a radical polarisation of the markets in the former Soviet republics. Against the backdrop of a four-year contraction in active trial portfolios in Russia (-52.7%) and Belarus (-46.7%), the markets of several countries in the South Caucasus and Central Asia are expanding and increasing their presence.

Estonia (98.6), Lithuania (75.5) and Latvia (75.0), as well as Georgia (64.6), remain the leaders in the number of active trials per million population. The largest four-year increases in active trial portfolios were recorded in Uzbekistan (+120%), Armenia (+75%) and Moldova (+33.3%), which reached an all-time high in 2025. In Central Asia (Kazakhstan—1.7 trials/million; Uzbekistan—0.6 trials/million), integration remains volatile and is still at the stage of unlocking its potential.

VOLUME AND DYNAMICS OF THE CLINICAL TRIALS MARKET

A review of approval data for H1 2026 demonstrates that the clinical trials market in the Russian Federation has reached a stable plateau. The period of abrupt structural transformation has ended with a definitive change in the composition of market participants: local developers and sponsors from friendly countries have consolidated their key role.

During the reporting period, the Ministry of Health of the Russian Federation issued 285 clinical trial approvals, 2.5% more than the 278 approvals issued in H1 2025.

Table 1 shows how the approvals were distributed by different types of trials.

Table 1

Approvals for Conduct Clinical Trials: H1 2026 vs H1 2025						
Year	Total	International Multicenter CTs	Local CTs (Foreign Sponsors)	Bioequivalence Studies (Foreign Sponsors)	Local CTs (Local Sponsors)	Bioequivalence Studies (Local Sponsors)
H1 2026	285	5	8	47	58	167
H1 2025	278	13	3	55	67	140
H1 2026 vs H1 2025, %	2.5%	-61.5%	166.7%	-14.5%	-13.4%	19.3%

Data from www.grls.rosminzdrav.ru

International multicentre clinical trials (IMCTs) accounted for the fewest new projects: five in H1 2026 vs 13 in the same period of 2025, a decrease of 61.5%. It should be recalled that our Newsletter statistics include as IMCTs only those protocols whose international status we were able to confirm through entries in international registries or national registries of other countries. As a result, our figures may differ from those in the Ministry of Health of the Russian Federation registry.

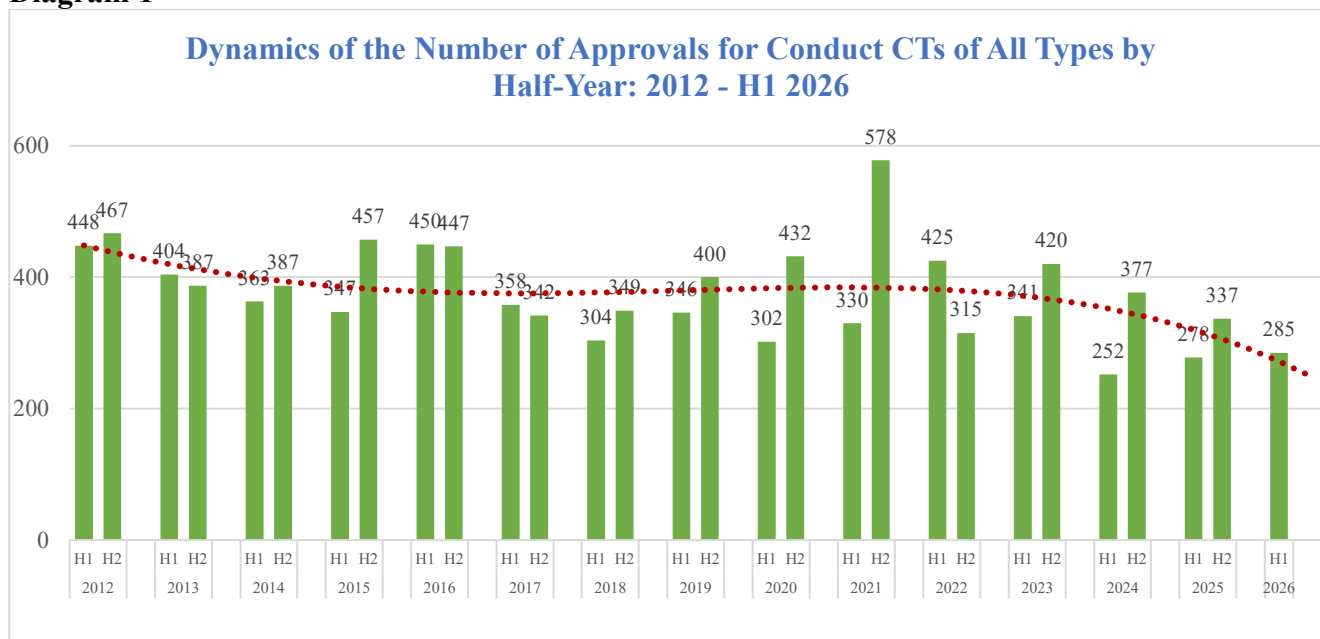
Another sector barely visible in the overall market is local protocols by foreign sponsors: there were eight, compared with three a year earlier. Foreign sponsors are more active in bioequivalence studies: 47 new projects in H1 2026 vs 55 in the same period of the previous year, a decrease of 14.5%.

As in recent years, Russian manufacturers remain the main driver of research activity in the country. They obtained 58 approvals for local trials, 13.4% below the result for the same period last year (67 protocols).

The domestically sponsored bioequivalence study segment had a decisive impact on overall market dynamics, growing by 19.3% (from 140 protocols in H1 2025 to 167 in the current reporting period). It was the vigorous expansion of this sector that offset stagnation and declining performance in other market segments, resulting in an overall 2.5% increase in the number of approvals.

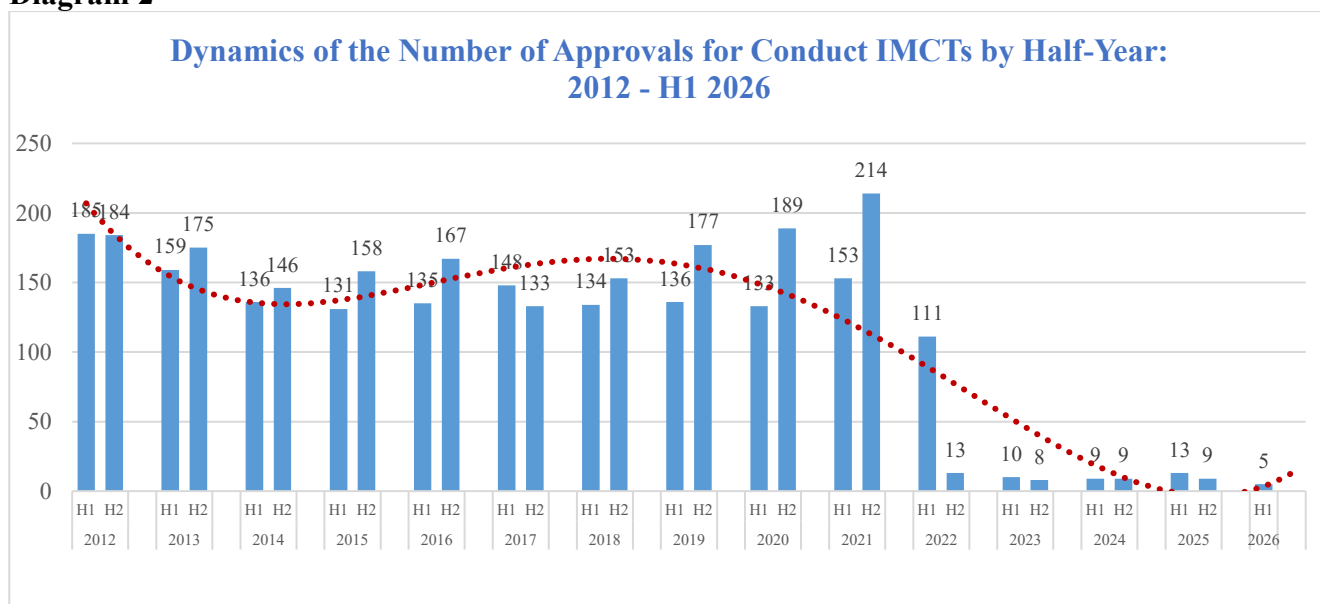
The series of diagrams below helps put the H1 2026 results into the context of previous years. Diagram 1 shows changes in the number of approvals per half-year from January 2012 to June 2026. Diagrams 2–6 present corresponding data for individual trial types.

As Diagram 1 shows, from 2012 through 2023 the Ministry of Health never issued fewer than 300 approvals in a half-year. The average over this period was 391.6 new trials every six months. From 2024 onwards, the figures began to decline: the average for a half-year from January 2024 through June 2026 was only 305.8. H1 2026 looks slightly better than the corresponding periods of the previous two years (285 approvals vs 278 and 252), but this does not warrant expectations that the year as a whole will necessarily outperform the previous one. Thus, the total number of approvals in 2025 was lower than in 2024 (615 vs 629), even though H1 2025 was better than the corresponding period of 2024 (278 approvals vs 252). A repetition of this scenario cannot be ruled out in the current year.

Diagram 1

Data from www.grls.rosminzdrav.ru

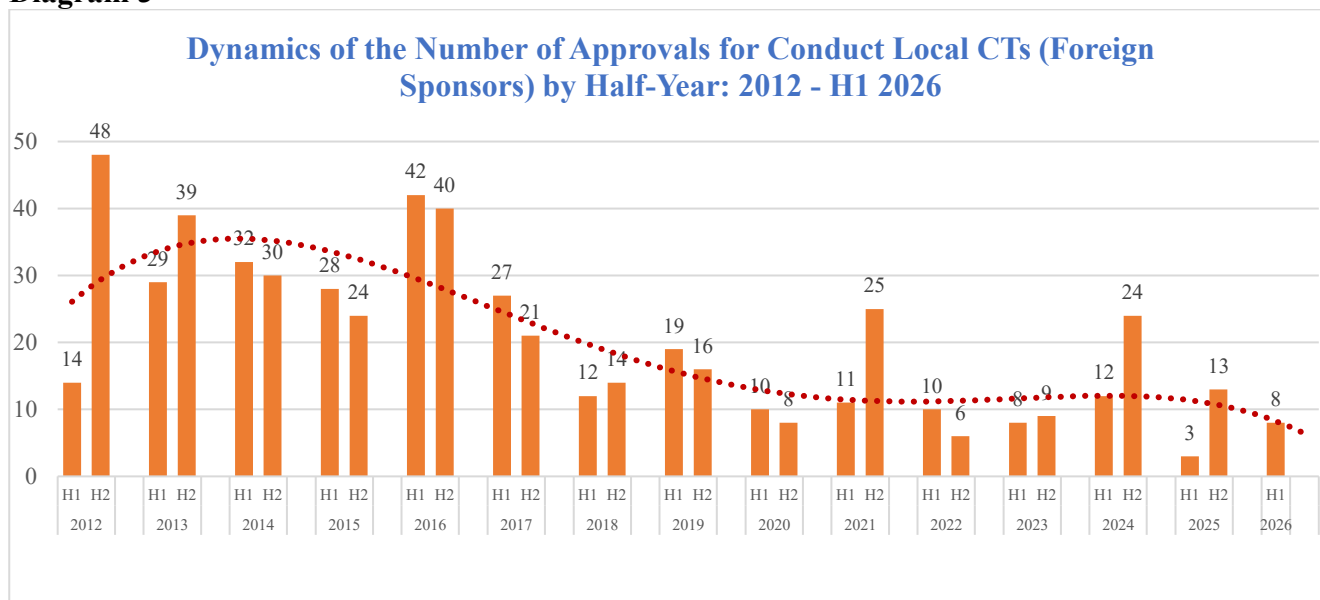
The trend in IMCT approvals is shown in Diagram 2. Since the start of the war, the average half-year figure for this market segment has fallen from 157.3 approvals in 2012–2021 to nine in 2023–H1 2026 (2022 is omitted as a transition year). Against this backdrop, and given the extremely low base, discussing the difference between H1 2026 (five approvals) and the corresponding period of 2025 (13 approvals) is statistically meaningless.

Diagram 2

Data from www.grls.rosminzdrav.ru

The average number of approvals for local trials by foreign sponsors also fell, although not as dramatically as for IMCTs: in 2012–2021, this category averaged 24.5 approvals per half-year, compared with just 11 in 2023–H1 2026 (Diagram 3). A noticeable decline in the number of trials in this sector has, however, been observed since 2017, when a requirement to submit manufacturing-site inspection results when launching a medicinal product on the Russian market came into force, which also affected foreign sponsors' interest.

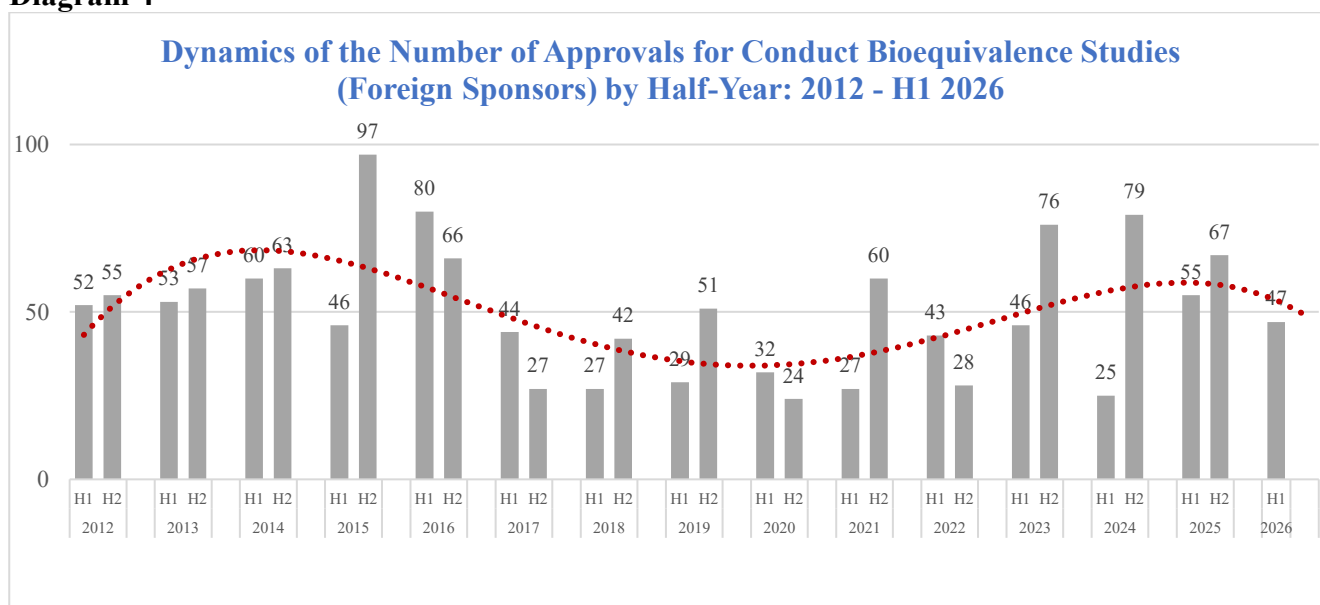
Diagram 3



Data from www.grls.rosminzdrav.ru

Unlike the trial types just discussed, the average half-year number of approvals issued to foreign sponsors for bioequivalence studies in 2023–H1 2026 actually exceeded the pre-war level: 56.4 vs 49.6 in 2012–2021. Diagram 4 shows that, despite fluctuations, this type of trial has not undergone any radical quantitative changes over the longer term.

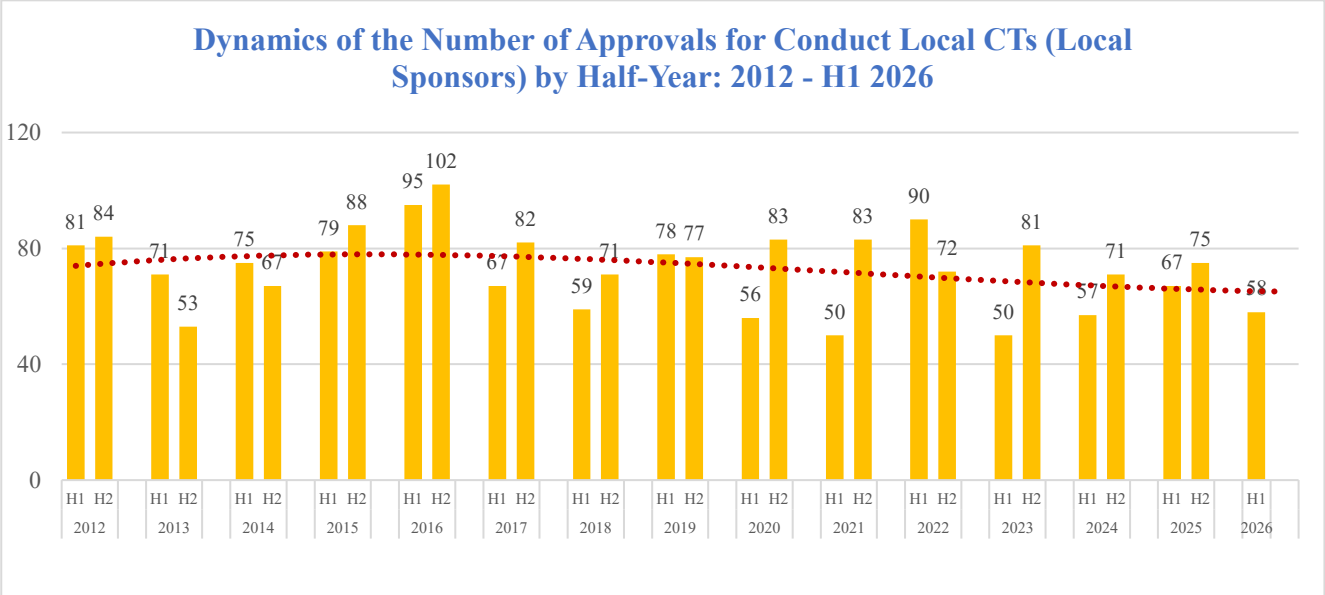
Diagram 4



Data from www.grls.rosminzdrav.ru

The number of approvals for local trials by domestic sponsors shows a steadier trend than the other trial types (Diagram 5), although a slight decline is still apparent here as well. In 2012–2021, an average of 75 projects per half-year were launched in this category, compared with 65.6 in 2023–H1 2026.

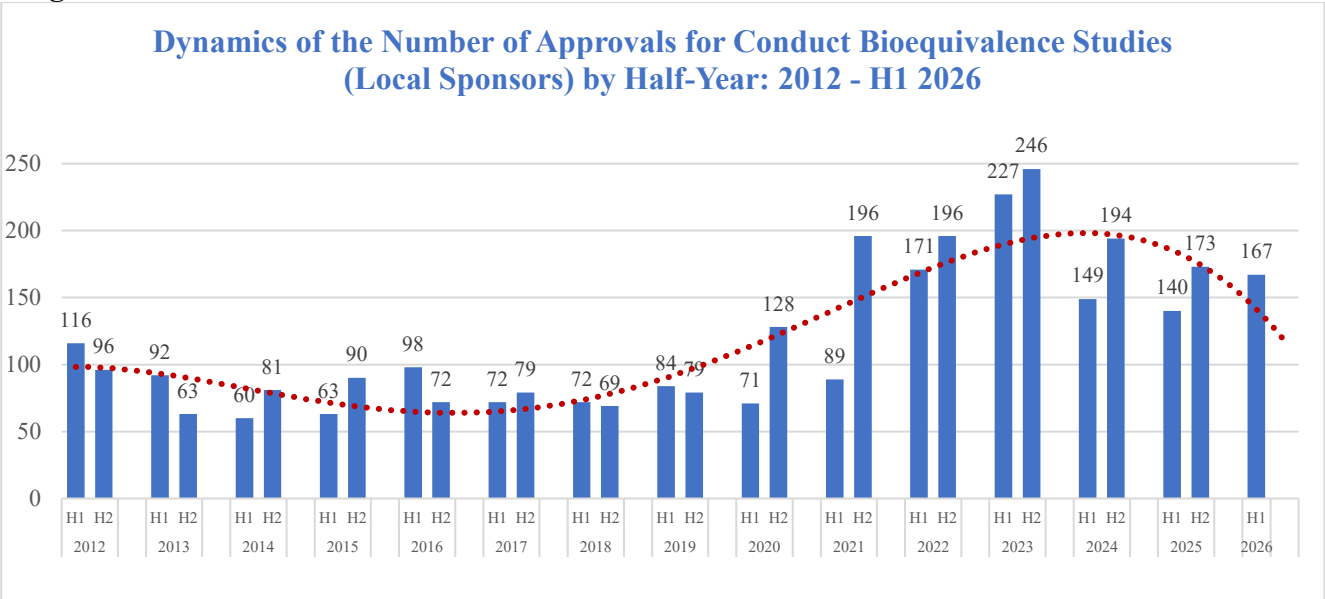
Diagram 5



Data from www.grls.rosminzdrav.ru

Russian companies' activity in bioequivalence studies (Diagram 6) was relatively low in 2012–2019 (80.4 approvals per half-year on average), then surged in 2020–2023, with the COVID-19 pandemic acting, in our view, as a catalyst (165.5 on average), before easing slightly, although it remains above the pre-pandemic level: in 2024–H1 2026, the average number of approvals per half-year was 164.6.

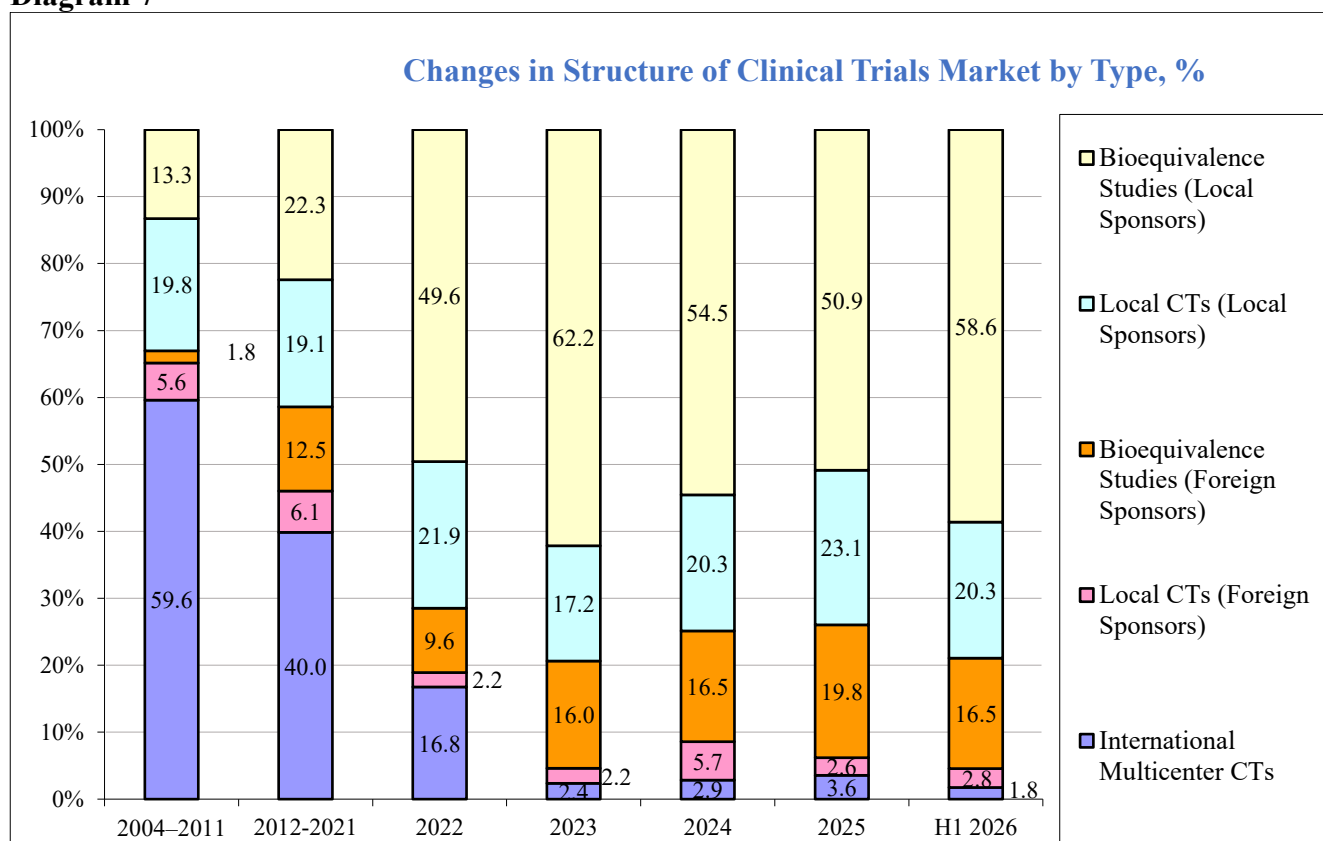
Diagram 6



Data from www.grls.rosminzdrav.ru

Diagram 7 shows how the landscape of the Russian clinical trials market changed across different periods. We have divided the timeline into intervals within which the figures for different trial types changed only marginally and can therefore be described well by average values.

Diagram 7



Data from www.grls.rosminzdrav.ru, www.roszdravnadzor.ru

In 2004–2011, when the previous industry legislation was in force, IMCTs dominated the market, accounting for an average 59.6% of all approvals per year. The second-largest sector was local trials by Russian sponsors, at 19.8%. Bioequivalence studies by Russian companies accounted for 13.3%, while another 5.6% came from local protocols by foreign sponsors. At the time, foreign companies received only 1.8% of all approvals on average for bioequivalence studies.

The period 2012–2021 was characterised by relatively stable rules of the game after the regulatory reform had been completed and before the start of the war. The share of IMCTs fell to 40%, as bioequivalence study protocols became much more numerous: their share rose to 22.3% for Russian sponsors and 12.5% for foreign sponsors. The situation with local trials changed little: 19.1% of approvals went to domestic sponsors, while a further 6.1% went to foreign sponsors.

The year 2022 was transitional for the market, but by 2023 a new landscape had broadly taken shape, dominated by Russian companies, particularly those conducting bioequivalence studies. Bioequivalence studies by local sponsors accounted for between 50.9% and 62.2% of approvals in 2023–2025; the H1 2026 result of 58.6% also falls within this range. The same is true of local trials by Russian companies: 17.2% to 23.1% in 2023–2025 and 20.3% in January–June 2026. The share of bioequivalence studies by foreign sponsors ranged from 16% to 19.8%, and stood at 16.5% in H1 2026. Local trials by foreign companies accounted for 2.2% to 5.7%, and stood at 2.8% of approvals in H1 2026. New IMCTs have accounted for 2.4% to 3.6% in recent years; in H1 2026 the figure was even lower, at just 1.8% of all approvals. This is the lowest figure recorded since ACTO records began.

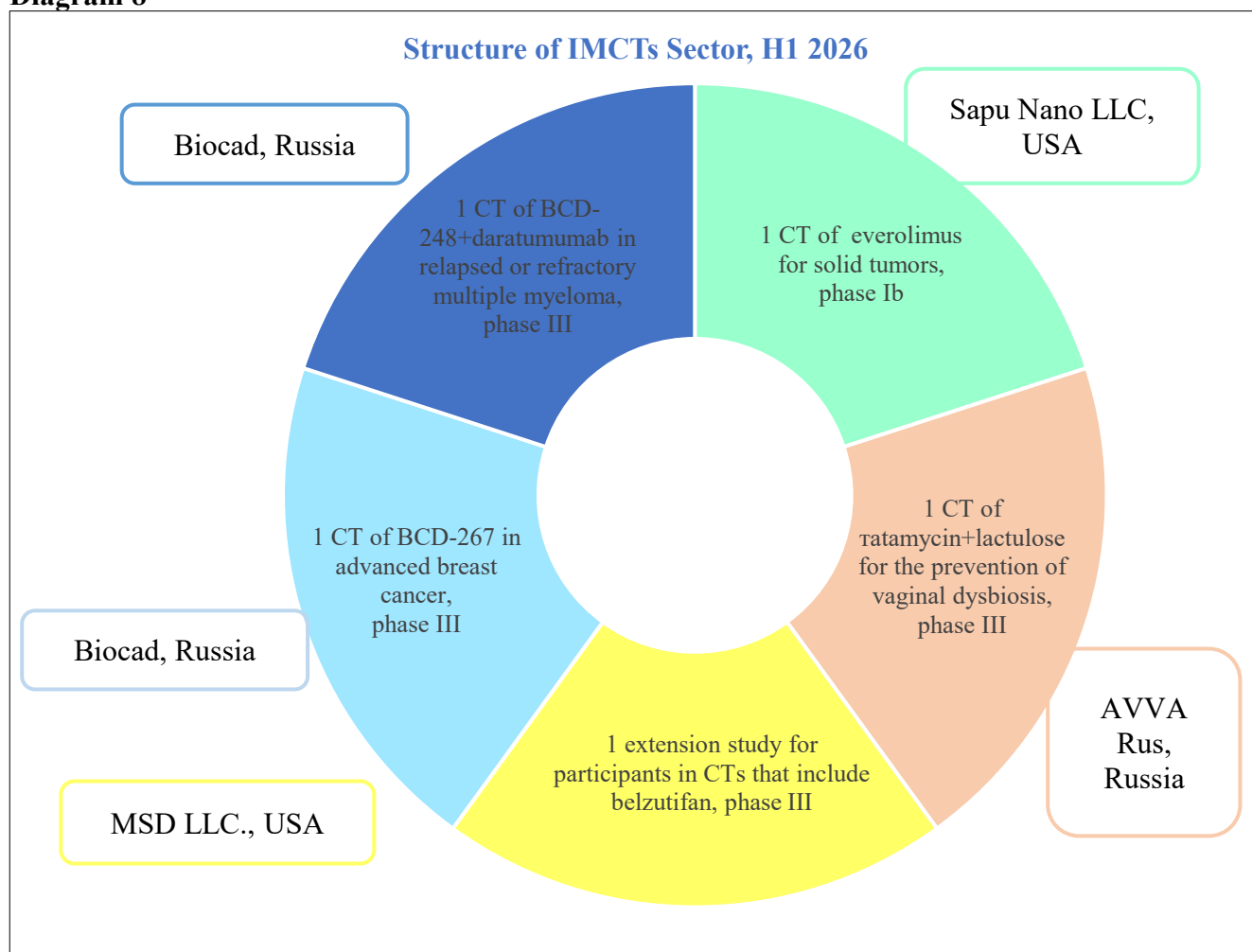
STRUCTURE OF THE CLINICAL TRIALS MARKET BY TYPE

Only five trials from the Ministry of Health of the Russian Federation registry in the first six months of 2026 were counted by us as international multicentre projects. Information on these trials is summarised in Diagram 8.

Three IMCTs were initiated by domestic sponsors. Biocad is studying its proprietary bispecific antibody BCD-248 in myeloma, as well as a trastuzumab deruxtecan biosimilar in advanced breast cancer. Both Phase III trials were initiated in Belarus as well as Russia. Another Phase III trial with a Russian sponsor has a similar geographical footprint¹: AVVA RUS is evaluating the efficacy and safety of Ecofucin Duo suppositories (a combination of the antifungal agent natamycin and lactulose) for the prevention of vaginal dysbiosis.

The other two IMCT approvals were issued to US companies. Merck Sharp & Dohme is conducting an additional Phase III study to evaluate the long-term efficacy and safety of belzutifan (an HIF-2 α inhibitor) in participants from ongoing oncology trials. Sapu Nano has launched a Phase Ib protocol to assess the safety, tolerability and pharmacokinetics of escalating doses of everolimus in patients with solid tumours.

Diagram 8



Data from www.grls.rosminzdrav.ru

It should also be noted that eight protocols in the Ministry of Health registry for H1 2026 are classified as IMCTs. However, we were unable to confirm this status for four of them and included them in the data for local trials instead. These were two Biocad protocols (seniprutug in patients with

¹ We have historically regarded AVVA RUS as a Russian company, albeit with Swiss participation, since it is part of the Swiss holding company AVVA Pharmaceutical AG.

spondyloarthritis and BCD-237 in breast cancer), a Generium protocol (GNR-107 in RAS wild-type colorectal cancer), and one Pharmasintez-Nord protocol (PZN-107 in Hodgkin lymphoma).

Conversely, the AVVA RUS protocol is not classified as international in the Ministry of Health registry. Nevertheless, we classified it as an IMCT after finding, as noted above, information on the trial in the national registry of the Republic of Belarus.

This approach may seem unduly strict. Why do we not simply rely on the State Register of Medicines (GRLS) and instead cross-check its information against external sources? Moreover, the state fee for an IMCT approval is RUB 75,000 higher than for a local trial, so this financial factor would seem to encourage sponsors to be precise. At first glance, domestic companies (whose protocols are most often the ones for which international status cannot be confirmed) might simply have failed to submit data to registries in other countries. However, according to our information, the registries in Kazakhstan and Belarus are maintained under the direct supervision of national regulators, and entries appear there in parallel with the issuance of approvals, just as they do in Russia. As for the leading global platform ClinicalTrials.gov, it is well known to the largest domestic sponsors: in recent years they have actively used it to register their clinical programmes, and by no means all of them international. As of August 2026, the platform listed 97 protocols for Biocad, 81 for R-Pharm, 31 for Generium and 23 for Geropharm. Even Materia Medica featured in this registry with 43 trials.

So why is the international status of domestic sponsors' trials so often not confirmed in practice? The trend is not new: in 2025, we verified as IMCTs only 22 of the 27 protocols declared as such in the Ministry of Health registry; in 2024, 18 of 23; and in 2023, 18 of 31. We approached a representative of one of Russia's leading developers for an explanation.

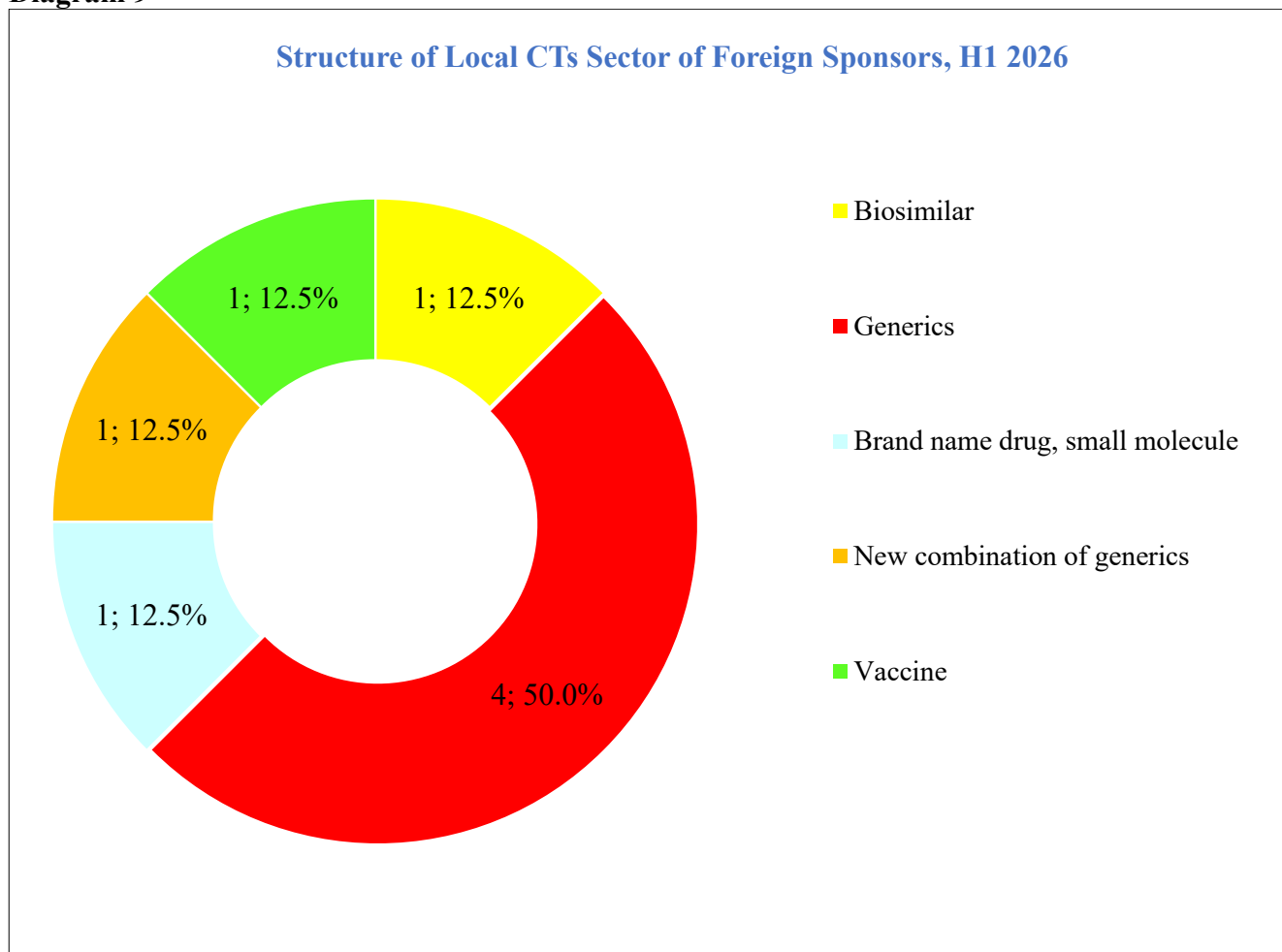
The reason turned out to be the complete inflexibility of the regulatory system. Changing the status of an already approved trial while it is under way is almost impossible from a bureaucratic standpoint. The regulator will not allow a sponsor to open an additional site in another EAEU country if the expert review was originally paid for at the "local" rate. The law provides no mechanism for paying an additional RUB 75,000 fee, while making amendments by submitting a new dossier means losing several months. As a result, major domestic players are forced to hedge their bets: they prefer to overpay at the submission stage and register a project as an IMCT "for future expansion", in case an opportunity arises later to broaden its geography abroad. The result is that companies' commercial risks and shortcomings in Ministry of Health procedures permanently distort the official statistics, presenting wishful thinking as reality.

The eight local trials approved by the Ministry of Health for foreign sponsors in H1 2026 (as usual, we exclude bioequivalence protocols here) show a striking polarisation of scientific interest. Half of the list consists of genuinely substantial, high-tech projects that merit close attention. These include elecoglipron, AstraZeneca's small-molecule GLP-1 receptor agonist (an ambitious oral competitor to injectable obesity blockbusters); a denosumab biosimilar from Germany's Hexal; and a Phase III trial of the bacterial vaccine BR-113 from China's CanSino Biologics. A separate regulatory precedent is the protocol by China's Beijing Feiruida for the ultrasound contrast agent FRD001 (perfluoropropane): the Chinese company is boldly attempting to enter Russia's unoccupied niche for gas-based liver contrast imaging.

The rest of this foreign research contingent is far more prosaic: seeking approvals for full-scale local trials from the Ministry of Health are generics for Strepsils-style sore-throat lozenges (Gepach International, India), anti-inflammatory ketorolac eye drops (Sentiss Pharma, India), psoriasis ointments (Glenmark, India) and adapalene gels for adolescent acne (Aristo Pharma, Germany).

Diagram 9 shows the shares of different product types in these eight trials.

Diagram 9



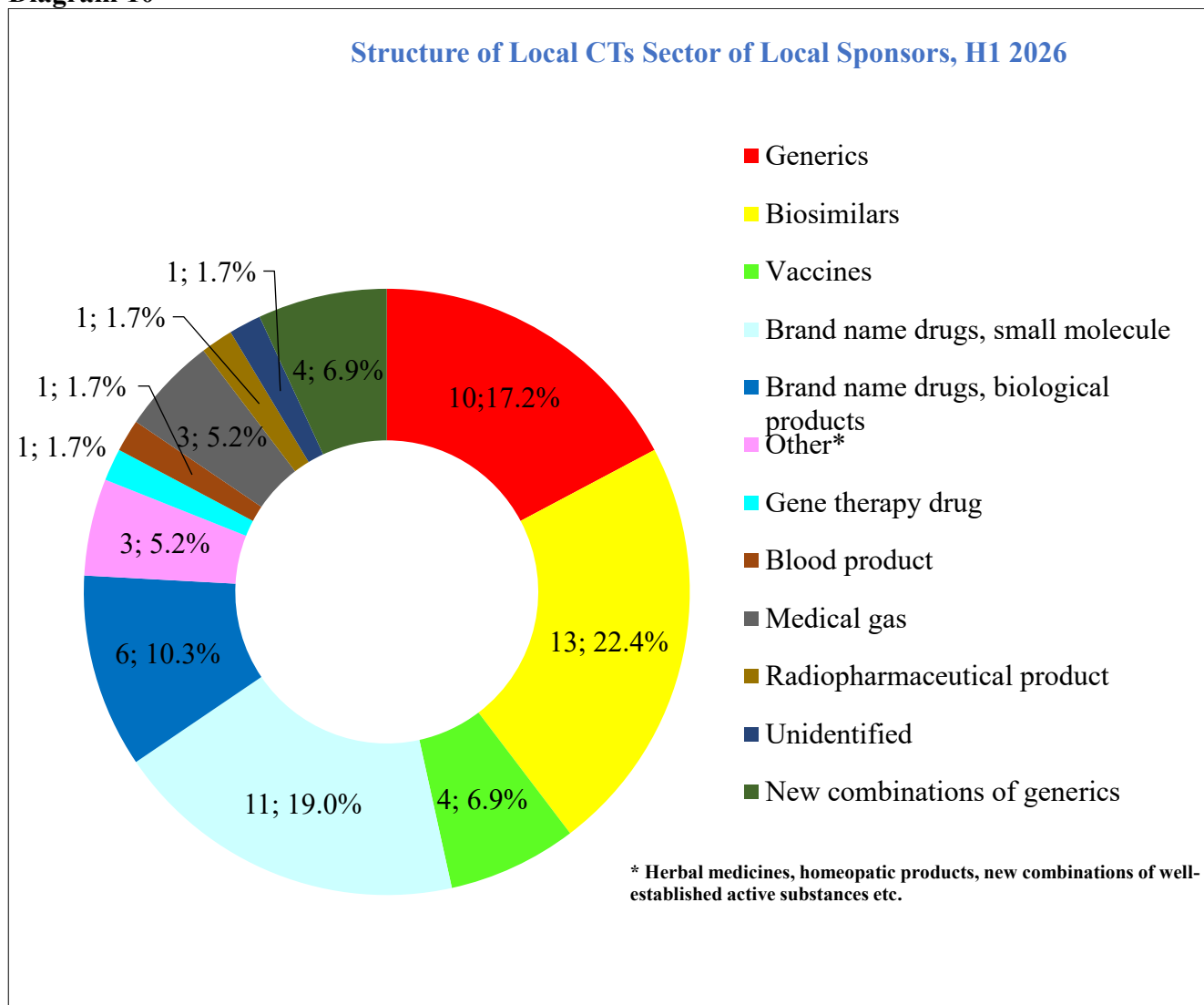
Data from www.grls.rosminzdrav.ru

The types of products in new local trials by domestic sponsors (excluding approvals for bioequivalence studies) are shown in Diagram 10.

Biosimilars account for the largest share of regulatory approvals in this segment, taking 22.4% of the market (13 protocols). This group reflects a large-scale expansion by domestic developers into expensive targeted and oncohaematology therapies. In the current period, the registry includes two trials, of denosumab and pertuzumab, by Mabscale; a trastuzumab emtansine (BCD-237) protocol by Biocad; panitumumab (GNR-107) and emicizumab (GMR-106) projects by Generium (which also has a dornase alfa protocol); and oncohaematology programmes involving nivolumab (PZN-105) and brentuximab vedotin (PZN-107) biosimilars by Pharmasintez-Nord. The monoclonal-antibody pipeline is supplemented by two parallel trials from Promomed (presumably of pembrolizumab LOFB07201 and nivolumab LOFB07801). Geropharm, meanwhile, has brought protocols involving a biphasic insulin product (GP40231) and basal insulin degludec (GP20091) into clinical development. The line-up is completed by recombinant human interferon alfa-2b from Firn M.

While preparing this review, we found no precise description of Biocad's BCD-285 in open sources, so the protocol was the sole entry in the "Unidentified" category (1.7%) in the final breakdown. The sponsor has announced a large Phase I study involving 360 healthy volunteers. The design and sample size could equally point to the development of an innovative original monoclonal antibody or to the creation of a complex biosimilar. Until the molecule's specifications are officially disclosed, the project remains outside the main groups.

Diagram 10



Data from www.grls.rosminzdrav.ru

Original small-molecule drugs—19% (11 trials)—and traditional generics—17.3% (ten protocols)—retain second and third place by number of approvals. A further 6.9% (four approvals) was recorded for new generic combinations.

The original small-molecule group included food-effect testing of 4-MUST by Valenta Pharmaceutica; a relative bioavailability study of the original anticoagulant Dimoleglin at 60 mg and 10 mg by Avexima Diol; and a two-stage safety and pharmacokinetics study of SN_9 (Gamaleya National Research Center for Epidemiology and Microbiology) for the treatment of coronavirus infection (SARS-CoV-2). The therapeutic segment was supplemented by a study of Maloben (Saint Petersburg State Chemical and Pharmaceutical University) in non-alcoholic fatty liver disease; two protocols by Pharmasoft on sequential use of Mexidol and Mexidol Forte 250 in ischaemic stroke; and an oncology protocol by the Russian Scientific Center of Roentgenoradiology involving intravesical administration of the peptide CDK4/6 inhibitor MM-D37K in bladder cancer. Early-phase trials in healthy volunteers also include the original tetrapeptide Ac-His-Ala-Glu-Glu-NH₂ (Pirogov University), Detoxen (Siberian State Medical University), the XC243 molecule (Valenta Pharmaceutica) and the OK1 infusion solution (Polysan NTFF).

Traditional generics and new combinations (14 approvals in total) are not included in the main part of the review, although several protocols deserve attention as markers of commercial displacement of retail-market leaders. In particular, AVVA RUS has taken Digestim Forte into comparative trials against the retail bestseller Creon (Abbott). OTC-FML-0125 from OTCPharm (0.1% fluorometholone eye drops) is aimed at filling a gap left by Western ophthalmology lines. In the high-margin gynaecology

segment, projects by Pharmproject JSC stand out: sertaconazole suppositories (an analogue of imported Zalain by Egis) and a combination of dexpanthenol and chlorhexidine intended to compete directly with the domestic product Depantol by Nizhpharm. The same group includes trials of vaginal tablets by the Tula Pharmaceutical Factory (vs the French product Tergynan) and a metronidazole/chlorhexidine gel from Renewal.

Original biological products accounted for 10.3% (six projects, five initiated by Biocad and one by R-Pharm). The domestic immunoprophylaxis sector accounted for 6.9% (four approvals). Medical gases and the “other” sector each accounted for 5.2% of the market (three approvals each). The latter group, which traditionally includes products of plant or animal origin as well as probiotics, comprised the following trials. Two involved safety assessments of cattle cerebral-cortex polypeptides and a cartilage-protein complex in healthy volunteers, both initiated by Geropharm. The third protocol, from the Kulakov National Medical Research Center for Obstetrics, Gynecology and Perinatology, studies a probiotic containing a combination of *Lactobacillus* and *Bifidobacterium* strains.

The scientific frontier is rounded out by single approvals (1.7% each) in highly specialised categories. The gene-therapy sector is represented by NextGen’s study of Neovascugen and Neovascugen Protect (supercoiled circular double-stranded plasmid DNA) for the treatment of Fontaine-Pokrovsky stage IIa–IIb chronic lower-limb ischaemia. Radiopharmaceuticals are represented by a study of ¹⁸F-borophenylalanine by the Blokhin National Medical Research Center of Oncology for PET imaging and planning of boron neutron capture therapy. Blood products are represented by a study protocol for human anti-Rho(D) immunoglobulin from the Chelyabinsk Regional Blood Transfusion Station.

Overall, the domestic market is clearly split between two poles: sponsors attempting to build highly sophisticated sovereign biotech capabilities (monoclonal antibodies, plasmid DNA, multivalent vaccines) coexist peacefully in the registry with manufacturers hedging their bets on proven pharmacy blockbusters, probiotics and cartilage extracts.

STRUCTURE OF THE CLINICAL TRIALS MARKET BY THERAPEUTIC AREA

This section provides information on the therapeutic areas of protocols approved for initiation in H1 2026.

At the beginning of the previous section, when discussing IMCTs, we already named the specific products and their areas of use. Here we will simply summarise: three of the five new IMCTs are in oncology, with one each in oncohaematology and gynaecology (Table 2).

Table 2

Distribution of International Multicenter CTs by Therapeutic Areas, H1 2026			
Therapeutic Area	Number of IMCTs	Share (%)	The number of planned participants
Oncology	3	60.0%	796
Oncohaematology	1	20.0%	780
Gynecology	1	20.0%	30
TOTAL	5	100.0%	1 606

Data from www.grls.rosminzdrav.ru

The therapeutic areas of local protocols by foreign sponsors, excluding trials of original medicinal products, are shown in Table 3.

Table 3

Distribution of Local CTs and Bioequivalence Studies (Generics and Biosimilars) of Foreign Sponsors, H1 2026			
Therapeutic Area	Number of CTs	Share (%)	Number of planned participants
Endocrinology	10	18.9%	545
Cardiology and CVD	9	17.0%	575
Gynecology	6	11.3%	682
Dermatology	5	9.4%	556
Urology	5	9.4%	282
Psychiatry	4	7.5%	270
Analgesic and NSAIDs	3	5.7%	136
Oncology	2	3.8%	160
Gastroenterology	2	3.8%	100
Other (contrast for diagnostics)	1	1.9%	250
Ophthalmology	1	1.9%	244
Haematology	1	1.9%	150
Rheumatology	1	1.9%	90
Otorhinolaryngology	1	1.9%	49
Neurology	1	1.9%	32
Phthisiology	1	1.9%	24
TOTAL	53	100.0%	4 145

Data from www.grls.rosminzdrav.ru

Endocrinology led the generics and biosimilars segment in H1 2026, with ten protocols (18.9% of all approvals). Cardiology and cardiovascular disease (CVD) ranked second with nine projects (17.0%). Gynaecology ranked third with six approvals (11.3%); these projects, however, led in total planned enrolment, at 682 participants.

Dermatology and urology each accounted for five new trials (9.4% each). Four protocols (7.5%) were in psychiatry, and three (5.7%) involved analgesics and NSAIDs. The oncology sector had a notably modest presence (just two trials, 3.8%), underscoring the shift in foreign sponsors' focus towards outpatient and mass retail segments. The same figures (two trials, 3.8%) were recorded in gastroenterology. The list is completed by single protocols in ophthalmology, haematology,

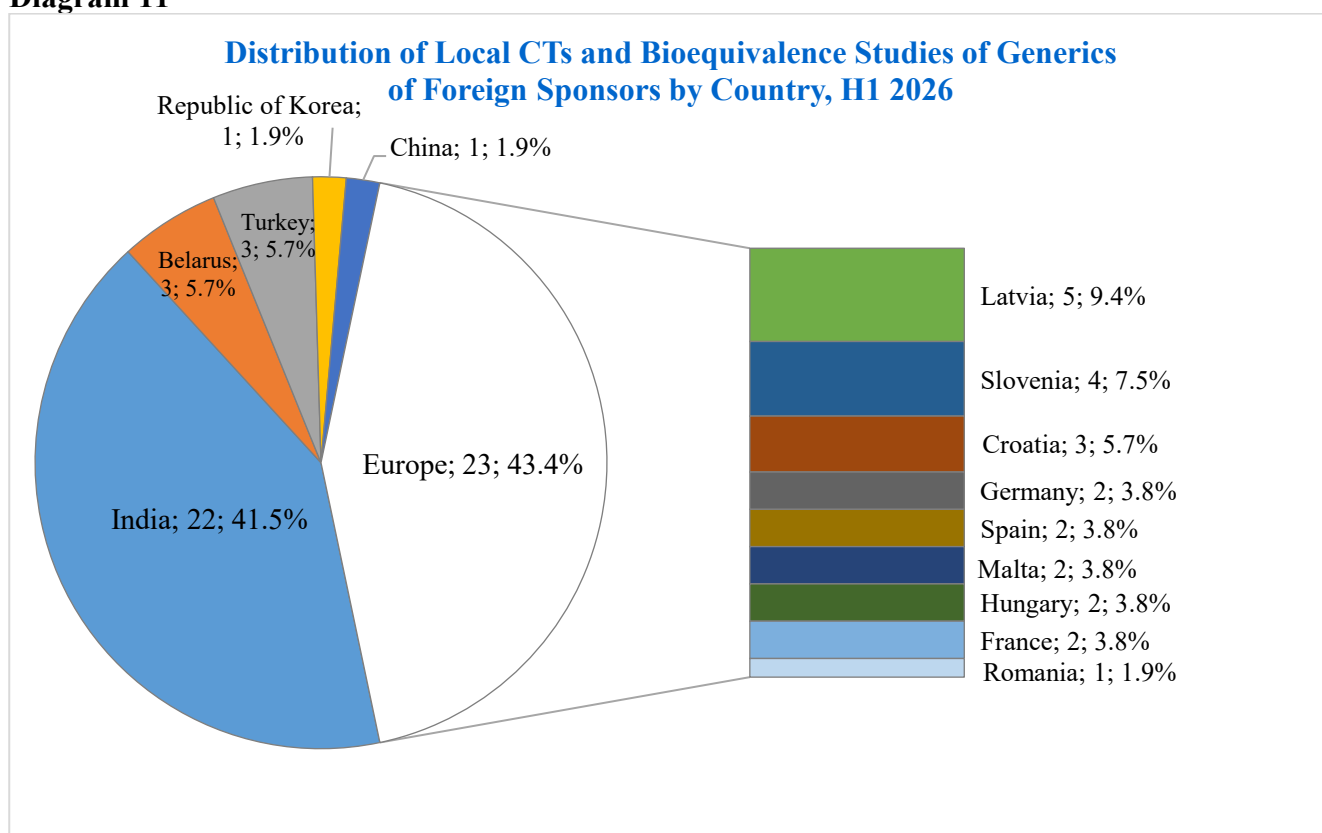
rheumatology, otorhinolaryngology, neurology and phthisiatry (1.9% for each therapeutic area). The “other” category includes a project studying an ultrasound contrast agent.

Diagram 11 shows the geographical distribution of foreign sponsors that obtained approvals for local trials of generics and biosimilars in the Russian Federation in H1 2026.

Twelve Indian companies initiated 22 projects, accounting for 41.5% of all approvals in this segment. Sponsors from Belarus had three protocols (5.7%)—two by Pharmtechnology and one by Rubicon—and sponsors from Türkiye also had three (5.7%), all by World Medicine Ilac San. Beijing Feiruida of China and Whan In Pharm of South Korea each had one approval (1.9%).

European sponsors initiated a total of 23 trials, including five by Latvia’s Olpha (formerly Olainfarm), four by Slovenia’s KRKA, three by Croatia’s Belupo, and two each by Malta’s Adalvo and Hungary’s Egis. German companies Aristo Pharma and Hexal, Spanish companies Seid and Chemo Research, and French companies UPSA and Sanofi each had one approval. One further trial is being launched by Romania’s Rompharm.

Diagram 11

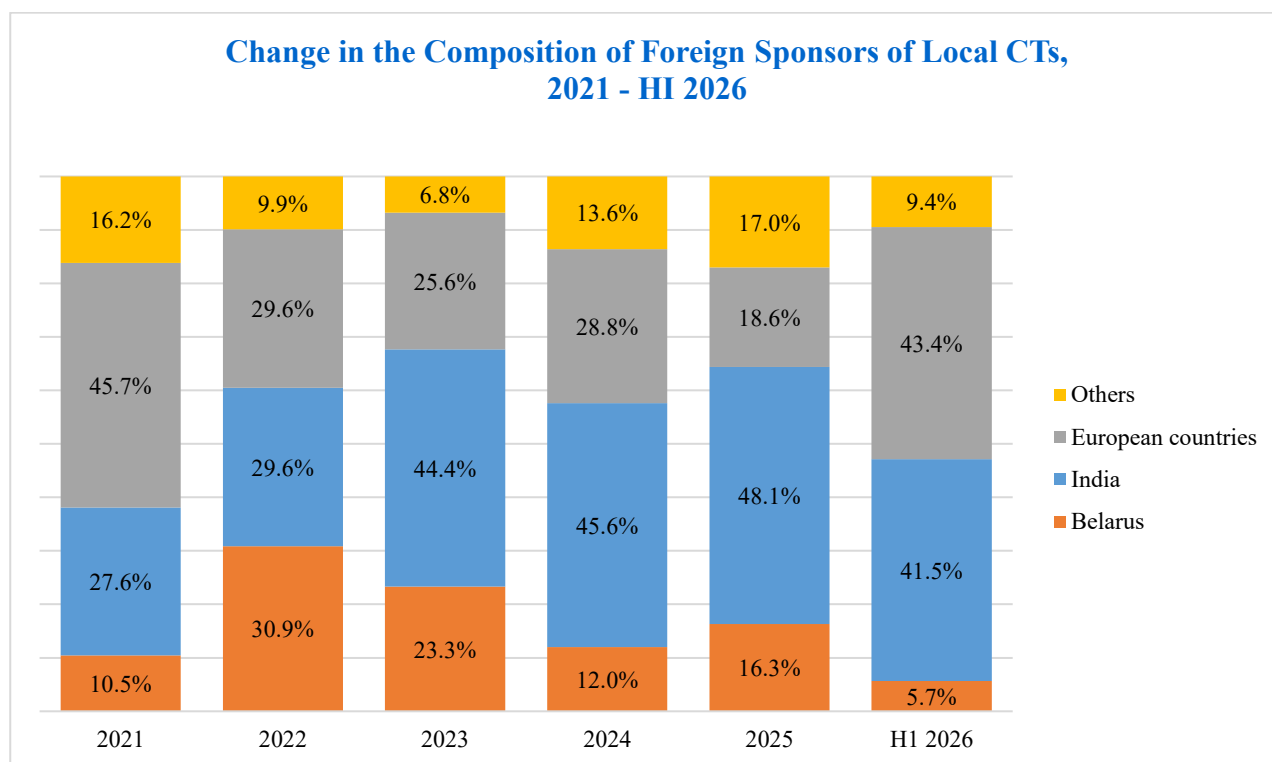


Data from www.grls.rosminzdrav.ru

Diagram 12 shows how the start of the war and changes in investment conditions affected the geography of foreign sponsors initiating local trials of generics and biosimilars in Russia. The initial breakdown of international ties benefited companies from Belarus: their share rose from 10.5% in 2021 to 30.9% in 2022. Over the longer term, however, Indian sponsors retained the largest share: from a pre-war level of 27.6%, it exceeded 40% as early as 2023 and has fluctuated between 41% and 48% in recent years.

European sponsors accounted for 45.7% of approvals in this market sector in 2021, after which their share fell markedly to 18.6% in 2025. Against this backdrop, the H1 2026 result for European companies looks unexpectedly positive, driven by strong registration activity among manufacturers from Eastern Europe and the Baltic states. However, statistics for H2 of the current year may yet alter both the final figures and the overall impression.

Diagram 12



Data from www.grls.rosminzdrav.ru

Table 4 shows the distribution by therapeutic area of approvals for local trials and bioequivalence studies obtained by Russian sponsors in H1 2026.

Cardiology and CVD (including vascular surgery) top the ranking with a 15.5% share (30 of 194 approvals). This high concentration of protocols despite a moderate sample size (1,460 participants) reflects the large-scale launch of standard generic programmes by domestic manufacturers in the retail segment.

Neurology and oncology each accounted for 11.9% (23 protocols each). The oncology sector is, however, the absolute market driver in terms of trial scale, accounting for a record 3,241 participants (almost 23% of total enrolment in Russia). Unlike the foreign generic-drug portfolio, where oncology was peripheral, local developers have shown unprecedented activity in bringing complex molecules in this segment into development.

Endocrinology and psychiatry each accounted for 8.2% (16 protocols each). A further 6.2% (12 new trials) were in pulmonology, while 5.2% (ten protocols) were in gastroenterology and coloproctology. Among the smaller segments (less than 5% of the market), the antiviral and antibacterial drug-development segment merits analytical attention: these are trials in HIV therapy (seven trials; 3.6%) and other infectious diseases (nine trials; 4.6%). Dermatology also stands out (six protocols; 3.1%), leading the second tier in terms of patient enrolment density (750 participants). The list is completed by single protocols in highly specialised areas, including dentistry, haematology and immunology.

Table 4

Distribution of Local CTs and Bioequivalence Studies (Generics and Biosimilars), Conducted by Local Sponsors, H1 2026			
Therapeutic Area	Number of CTs	Share (%)	Number of planned participants
Cardiology and CVD/Vascular surgery	30	15.5%	1 460
Oncology	23	11.9%	3 241
Neurology	23	11.9%	1 114
Endocrinology	16	8.2%	939
Psychiatry	16	8.2%	655
Pulmonology	12	6.2%	785
Gastroenterology/Coloproctology	10	5.2%	1 006
Obstetrics and gynecology	9	4.6%	954
Infectious Diseases (except HIV/HCV/tuberculosis, covid-19)	9	4.6%	685
Urology	8	4.1%	474
HIV	7	3.6%	455
Dermatology	6	3.1%	750
Unidentified	5	2.6%	223
Analgesic and NSAIDs	5	2.6%	178
Allergology	4	2.1%	360
Rheumatology	4	2.1%	340
Hepatology	2	1.0%	74
Oncohaematology	2	1.0%	140
Dentistry	1	0.5%	240
Haematology	1	0.5%	80
Immunology	1	0.5%	50
TOTAL	194	100.0%	14 203

Data from www.grls.rosminzdrav.ru

The substances most frequently featured in protocols testing generic medicinal products in H1 2026 are presented in Table 5.

Amlodipine, alone and in combinations, topped the cardiology ranking, with bioequivalence studies launched under seven protocols. Most of this activity is associated with the development of complex antihypertensive combinations. In particular, the combination of amlodipine with perindopril and indapamide (an analogue of Servier's triple-combination product Triplixam, launched on the European market in 2014) is being studied in four protocols by three sponsors: Croatia's Belupo, as well as AVVA RUS and Pharmstandard-Leksredstva. Two further Pharmstandard protocols target the fixed-dose dual combination of amlodipine and perindopril, an analogue of Servier's earlier two-component brand. The remaining protocol involves a single-agent amlodipine generic from Vertex. It is worth noting that the companion molecules in these combinations also generated a separate stream of studies: Belupo is testing the long-established indapamide/perindopril combination, while Slovenia's KRKA is testing its own fixed-dose combination of indapamide and telmisartan.

Table 5

Most Requested INN Used in Clinical Trials of Generics and Biosimilars in H1 2026				
Substance	Number of CTs of foreign generics	Number of CTs of local generics	All clinical trials to a given INN	Therapeutic Area
Amlodipin (separately and in fixed combinations)	1	6	7	Cardiology and CVD
Ivafactor (separately and in fixed combinations)	0	7	7	Pulmonology
Perindopril (in fixed combinations)	2	5	7	Cardiology and CVD
Empagliflozin (separately and in fixed combination)	5	2	7	Endocrinology
Indapamide (separately and in fixed combination)	3	3	6	Cardiology and CVD
Trazodone	0	6	6	Psychiatry
Isotretinoin	1	4	5	Dermatology
Ethinylestradiol (in fixed combinations)	3	2	5	Gynecology
Ibuprofen (separately and in fixed combinations)	1	3	4	Analgesic and NSAIDs
Carbamazepine	0	4	4	Neurology
Linagliptin	0	4	4	Endocrinology
Metformin (in fixed combinations)	4	0	4	Endocrinology
Mirabegron	0	4	4	Urology
Nitrofurantoin	4	0	4	Urology
Taptadol	0	4	4	Oncology, opioid analgesic
Valsartan (separately and in fixed combinations)	0	3	3	Cardiology and CVD
Vortioxetine	1	2	3	Psychiatry
Dapagliflozin (separately and in fixed combinations)	3	0	3	Endocrinology, Cardiology and CVD
Insulin aspart (separately and in fixed combinations)	0	3	3	Endocrinology
Paracetamol (in fixed combinations)	0	3	3	Analgesic and NSAIDs, Infectious Diseases
Perampanel	0	3	3	Neurology

Data from www.grls.rosminzdrav.ru

A striking trend in the half-year was domestic developers' move into the high-tech orphan-drug segment. The strong interest shown exclusively by Russian sponsors in ivacaftor and its combinations (also seven protocols) is linked to preparations for import substitution and efforts to identify regulatory gaps in the protection of the expensive cystic-fibrosis blockbusters Orkambi and Trikafta from US-based Vertex Pharmaceuticals. Foreign generic companies (notably Indian ones) have not yet entered this narrow, centrally funded public-procurement segment, apparently preferring not to compete with local players for the earmarked budget of the Circle of Kindness Foundation.

A similar patent situation is also driving bioequivalence studies of empagliflozin (the original product Jardiance by Boehringer Ingelheim, used for glycaemic control in type 2 diabetes and for the treatment of heart failure). Here, however, foreign sponsors are more active. International patent protection for empagliflozin is expiring, and in a number of markets, including India, patent barriers have already been removed. Against this backdrop, Indian sponsors Aurobindo Pharma and Ipca Laboratories are actively testing in Russia both single-agent empagliflozin and its combinations with metformin (an analogue of Boehringer Ingelheim's Synjardy, which was launched subsequently to Jardiance and has also already lost patent protection in India). Russian manufacturers also retain a share of this segment, having registered their own empagliflozin analogues and combinations since late 2023.

In psychiatry, the surge of interest in the antidepressant trazodone (six protocols) is noteworthy. Although the molecule itself has been used since the 1980s, for a long time Angelini Pharma's original product Trittico held a monopoly on the Russian market. Starting in 2023, Russian sponsors began

systematically testing its analogues, and in H1 2026 Velpharm-M and Akrikhin each obtained three approvals for bioequivalence studies of this product.

The list of the most popular molecules is rounded out by the systemic retinoid isotretinoin and combined hormonal contraceptives based on ethinylestradiol (five protocols each), generic versions of which are already widely available in the Russian retail market. All other active substances featured in fewer than five projects studying generics and biosimilars.

Table 6 lists the therapeutic areas of local trials of original medicinal products by foreign sponsors. Only two such approvals were issued in H1 2026.

Nevertheless, the project by UK-based AstraZeneca is of exceptional interest: despite the overall trend towards lower investment, the company initiated a Russian trial of the efficacy, safety and tolerability of eleoglipron. This molecule is a promising small-molecule GLP-1 receptor agonist for oral administration in adults with overweight or obesity. The launch of this protocol underscores the company's determination to maintain a presence in one of the most commercially significant therapeutic segments.

The second approval was issued to China's CanSino Biologics, which continues its systematic engagement with the Russian market. The company is evaluating the efficacy and safety of its new BR-113 vaccine, whose specific target the sponsor chose not to disclose in publicly available registry data.

Table 6

Distribution of Local CTs of Brand Name Drugs of Foreign Sponsors, H1 2026			
Therapeutic Area	Number of CTs	Number of planned participants	Developer's country
Infectious diseases (vaccine)	1	276	China, CanSino Biologics Inc.
Endocrinology	1	192	Great Britain, AstraZeneca
TOTAL	2	468	

Data from www.grls.rosminzdrav.ru

In H1 2026, Russian sponsors obtained 27 approvals for local trials of original products, including biological products. Their distribution by therapeutic area is shown in Table 7.

Four trials involve vaccines: vaccines to prevent meningococcal infections and dengue fever from the Saint Petersburg Scientific Research Institute of Vaccines and Sera, a hepatitis A vaccine from Vector-BiAgam, and the NLK-V423 project developed by Nanolek. COVID-19 also falls under infectious diseases, although since the pandemic we have tracked it separately in our statistics. The Gamaleya National Research Center for Epidemiology and Microbiology is conducting a Phase I–II study of the experimental antiviral agent SN_9. It is an ester derivative of NHC based on phenylpropionic acid; in essence, Russian researchers continue to systematically develop this concept, catching up with the already marketed molnupiravir, despite the global COVID agenda having receded.

In rheumatology, Biocad obtained three approvals to study two monoclonal antibodies with immunosuppressive effects (seniprutug and BCD-256). Another approval was issued to R-Pharm, which is studying its original interleukin-1 antagonist goflikicept in combination with the company's second original product, the interleukin-6 inhibitor olokizumab, in patients with Still disease.

Four neurology protocols clearly illustrate the specific dualism of Russia's R&D sector. On the one hand, substantial market resources continue to be spent on marketing support and line extensions for mature brands backed by local evidence, such as Pharmasoft's antioxidant Mexidol or a polypeptide hydrolysate of cattle cerebral cortex (Geropharm's Cortexin). On the other hand, against this

conservative backdrop stands an attempt to create a genuinely new molecule—an innovative tetrapeptide, Ac-His-Ala-Glu-Glu-NH₂, being developed by Pirogov University to combat neuroinflammation.

Table 7

Distribution of Local CTs of Brand Name Drugs (Including Biological Products) of Local Sponsors, H1 2026			
Therapeutic Area	Number of CTs	Share (%)	Number of planned participants
Infectious Diseases (except HIV/HCV/tuberculosis, covid-19), all – vaccines	4	14.8%	2 156
Rheumatology	4	14.8%	1 433
Neurology	4	14.8%	1 244
Surgery, orthopedics	3	11.1%	494
Oncology	3	11.1%	285
Hepatology	2	7.4%	282
Oncohaematology	1	3.7%	188
Neonatology	1	3.7%	180
Covid-19	1	3.7%	120
Anesthesiology	1	3.7%	52
Obstetrics	1	3.7%	46
Gastroenterology	1	3.7%	45
Urology	1	3.7%	32
TOTAL	27	100.0%	6 557

Data from www.grls.rosminzdrav.ru

As usual, we treat oncology and oncohaematology as two separate groups. If combined, however, a single antitumour therapeutic area would take the leading position alongside those already mentioned (also four protocols). Domestic biotech shows the highest concentration of science-intensive resources here. Biocad is studying the original antitumour agent larnependekin alfa in patients with bladder cancer and the neutrophil-precursor growth stimulator empegfilgrastim in healthy volunteers. In addition, the Russian Scientific Center of Roentgenoradiology (RSCRR) obtained approval for a safety study of MM-D37K (a peptide CDK4/6 inhibitor) in bladder cancer, while the Blokhin National Medical Research Center of Oncology obtained approval for a study of the radiopharmaceutical 18F-borophenylalanine for PET imaging of neoplasms.

In the “surgery, orthopaedics” category, Geropharm is evaluating the safety of the cartilage-protein complex GP20131, Avexima Diol is evaluating the pharmacokinetics and bioavailability of the anticoagulant Dimolegin, and NextGen is evaluating the efficacy and safety of supercoiled circular double-stranded plasmid DNA to stimulate vascular growth in lower-limb ischaemia of atherosclerotic origin.

The two hepatology protocols comprise an efficacy and safety study of Maloben from Saint Petersburg State Chemical and Pharmaceutical University, for which the developers claim antisteatotic activity, and a safety and tolerability assessment of Detoxen from Siberian State Medical University, intended to restore the liver’s detoxification function in chronic hepatitis.

As yet unmentioned are trials of 4-MUST (trimebutine for patients with chronic cholecystitis and biliary dyskinesia) and XC243 from Valenta Pharmaceutica; the latter molecule is being studied for potential anti-inflammatory and analgesic activity in cystitis. The list is completed by the “Anti-NEC-1” project (a probiotic for preterm infants) from the Kulakov National Medical Research Center for Obstetrics, Gynecology and Perinatology; human anti-Rho(D) immunoglobulin from the Chelyabinsk Regional Blood Transfusion Station (prevention of Rh incompatibility during pregnancy and childbirth); and Polysan’s OK1 infusion solution, about which nothing is known apart from the therapeutic areas declared by the sponsor: “anaesthesiology and intensive care, general therapy, internal medicine, other”.

CLINICAL TRIALS IN THE NEIGHBOUR COUNTRIES OF THE RUSSIAN FEDERATION

In this section, as has become customary, we analyse clinical trial market trends in former Soviet states using data from ClinicalTrials.gov.

An analysis of data as of 9 July 2026, compared with figures as of 2 February 2026, shows diverging trends (Table 8). Against the backdrop of a moderate global contraction in active interventional trials over the past five months and the continuing decline in volumes in the Russian Federation, most neighbouring countries show stability or pronounced growth in the number of active projects.

Table 8

The activity of clinical trial markets in the neighbouring countries of the Russian Federation as of 07/09/2026 (data for 02/02/2026 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	85 626 (87 316)			
Russia	662 (729)	0.77 (0.83)	146.1	4.5
Ukraine	317 (310)	0.37 (0.36)	28.7	11.0
Georgia	252* (245)	0.29 (0.28)	3.9	64.6
Lithuania	219 (220)	0.26 (0.25)	2.9	75.5
Estonia	138 (132)	0.16 (0.15)	1.4	98.6
Latvia	135 (131)	0.16 (0.15)	1.8	75.0
Moldova	92 (82)	0.11 (0.09)	2.4	38.3
Belarus	48 (47)	0.06 (0.05)	9.1	5.3
Kazakhstan	36 (34)	0.04 (0.04)	20.6	1.7
Armenia	28 (29)	0.03 (0.03)	3.1	9.0
Uzbekistan	22 (26)	0.03 (0.03)	38.4	0.6
Kyrgyzstan	9 (11)	0.011 (0.013)	7.4	1.2
Azerbaijan	6 (4)	0.007 (0.005)	10.3	0.6
Tadjikistan	2 (2)	0.002 (0.002)	10.7	0.2

Data from www.clinicaltrials.gov; data from official statistical agencies of the countries available at the beginning of July 2026

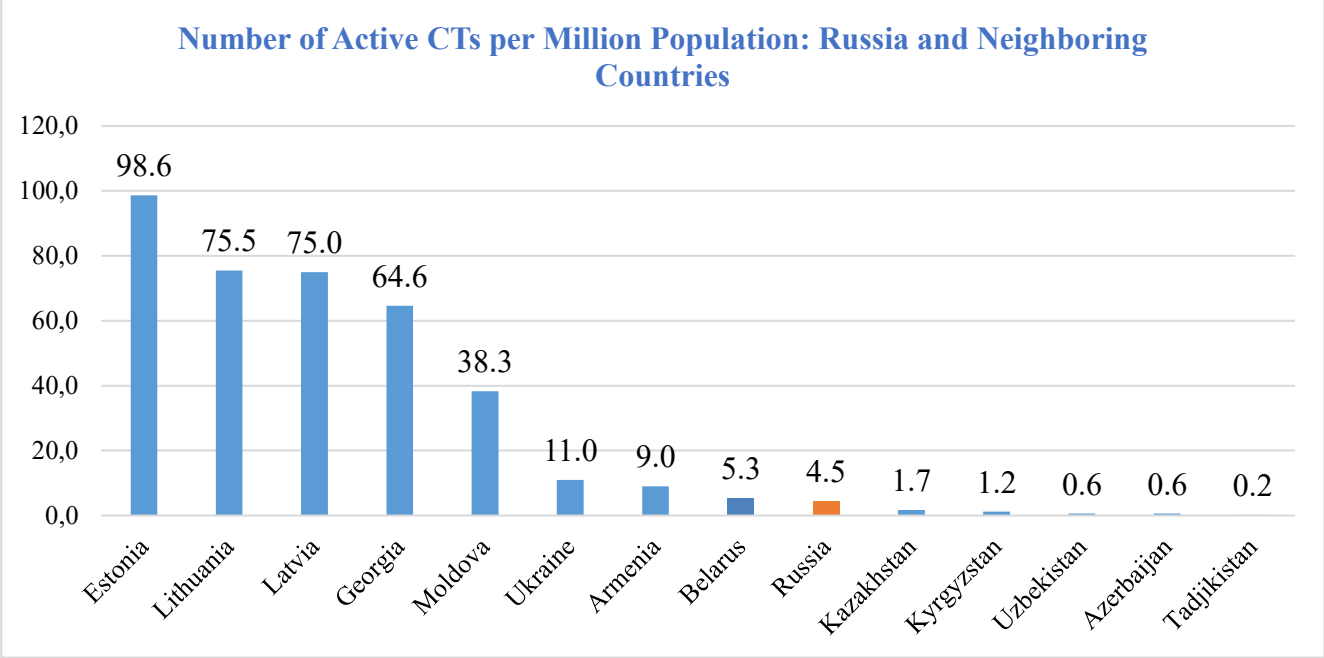
* In Georgia, only trials conducted in Tbilisi were taken into account, as changes in the search interface of the ClinicalTrials.gov database made it impossible to distinguish trials conducted in the country of Georgia from those conducted in the US state of Georgia. We could not find any trials conducted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

The number of active clinical trials per million population is a key indicator of investment attractiveness and the maturity of clinical research infrastructure within the healthcare system. The current distribution (Diagram 13) allows the countries of the region to be clearly divided into three tiers:

- Markets with a high density of trials. Estonia remains the clear leader at 98.6 trials per million population. Lithuania (75.5) and Latvia (75.0) follow closely behind. Georgia continues to post a remarkable result (64.6): thanks to its compact population and high concentration of sites, its trial density is tens of times higher than that of the largest post-Soviet countries.
- Markets with a moderate density of trials. This group includes Moldova (38.3), Ukraine (11.0) and Armenia (9.0). Belarus (5.3) and Russia (4.5) also fall into this group, albeit with a noticeable gap. Russia's position looks critical: despite having the largest population in the region, the country has effectively slipped into the lower part of the average tier by number of projects per capita.
- Markets with a low density of trials. Trial density remains minimal here for now. The figures for Kazakhstan (1.7), Kyrgyzstan (1.2), Uzbekistan (0.6), Azerbaijan (0.6) and Tajikistan (0.2) indicate that the potential of these markets for international sponsors using ClinicalTrials.gov as a reference is still only beginning to be realised. It should also be noted that Turkmenistan did not even enter this

category, as only one clinical trial has ever been recorded in the country since ClinicalTrials.gov records began, back in 2022.

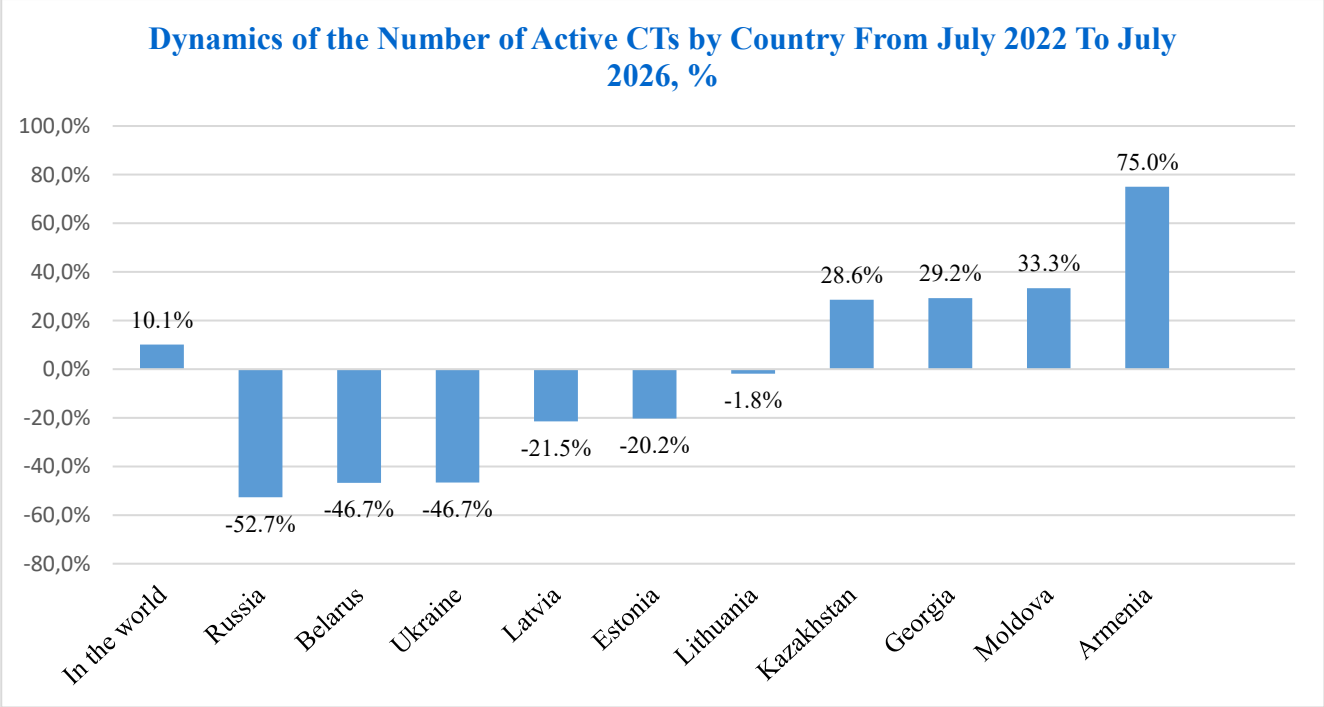
Diagram 13



Data from www.clinicaltrials.gov

The medium-term trend over the past four years (Diagram 14) clearly captures the structural reshaping of the macroregion. We intentionally excluded countries with a low trial density from the diagram so that the low-base effect would not distort the picture. While the global market grew by 10.1% over this period, individual countries in the post-Soviet region followed fundamentally different trajectories.

Diagram 14



Data from www.clinicaltrials.gov

1. Countries with negative trends

- Russia (-52.7%): according to ClinicalTrials.gov, the country lost more than half of its active trials, showing the steepest decline. This prolonged trend stems from the decision by the largest

international sponsors to suspend the initiation of new IMCTs in Russia from 2022. By mid-2026, the pool of older international projects had contracted substantially, while local trials had not yet made up the difference.

- Belarus (-46.7%): the development of the Belarusian market shows a direct parallel with the situation in Russia. As in Russia, the reduction in the number of trials here is due to stringent sanctions restrictions, disrupted logistics chains and a scaling-back of investment activity by global sponsors across the wider macroregion.

- Ukraine (-46.7%): despite an identical level of market contraction, the trend here is driven by fundamentally different factors—direct risks associated with hostilities in the country. This has created serious difficulties in maintaining continuity of trial procedures, made a number of study sites physically inaccessible and forced the evacuation of patients.

- Latvia (-21.5%) and Estonia (-20.2%): despite leading in the number of projects per million residents, the number of active trials in these two countries fell by about one-fifth over four years. Lithuania was the only stable market in the Baltic states, with its portfolio declining by just 1.8% over four years.

2. Countries with positive trends

The South Caucasus countries, Central Asian countries and Moldova recorded notable growth in the number of active trials over the four-year period:

- Armenia (+75.0%): became the clear leader in relative growth.
- Moldova (+33.3%): shows a sustained upward trend, including the addition of ten active trials in the most recent half-year alone (from 82 to 92 trials).

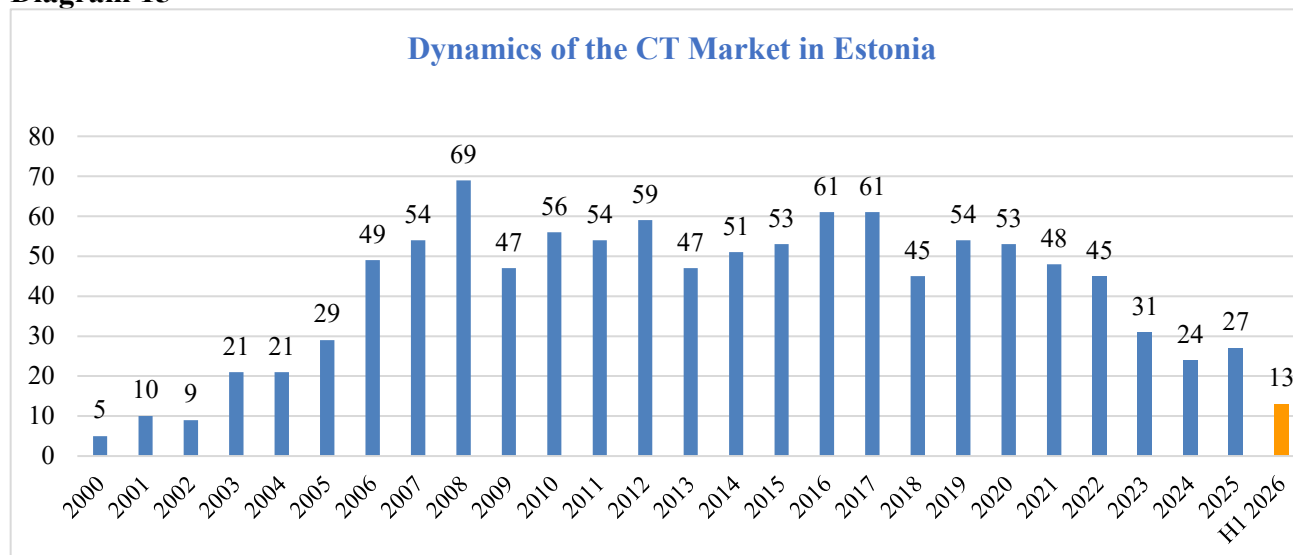
- Georgia (+29.2%): continues to steadily expand its project portfolio. Over the past five months (from February to July 2026), the number of active trials in Tbilisi increased from 245 to 252, raising the country's share of the global market to 0.29%.

- Kazakhstan (+28.6%): shows strong and steady medium-term growth; over four years, the country's active project portfolio in ClinicalTrials.gov increased from 28 to 36 trials. Although in absolute terms and in terms of per-capita trial density (1.7 trials/million) the potential of Central Asia's largest economy remains underused, the positive trend points to the gradual integration of local clinical research infrastructure into international projects.

- Kyrgyzstan (+50.0%), Azerbaijan (+100%), Tajikistan (+100%) and Uzbekistan (+120%) show high four-year percentage growth, although in absolute terms these countries' markets remain at an early stage of development (9, 6, 2 and 22 active trials, respectively, according to July 2026 data).

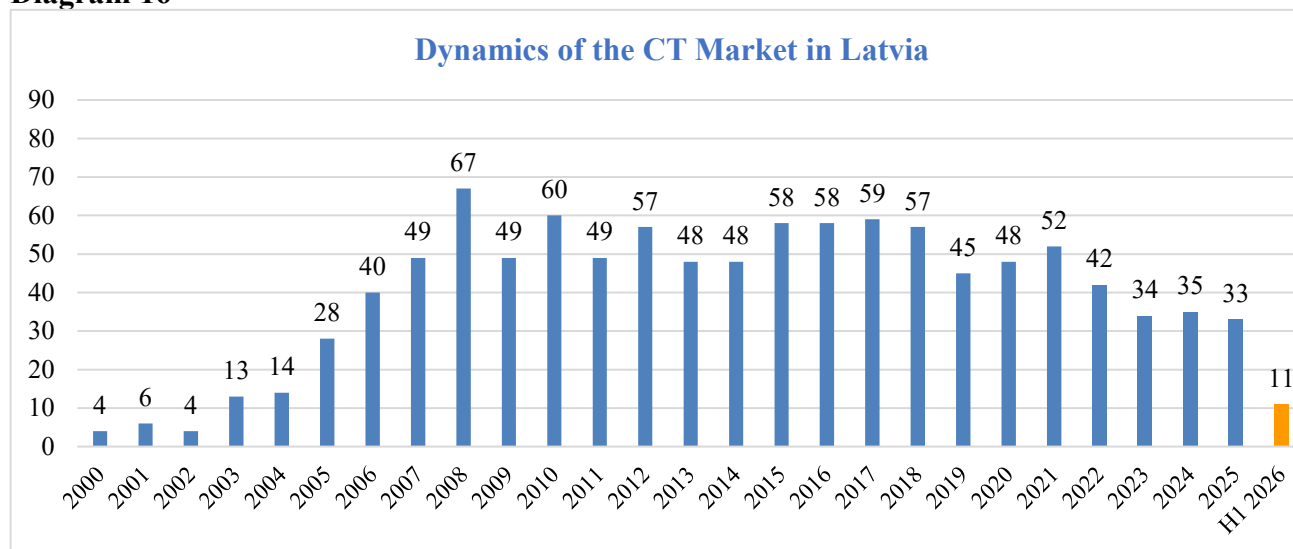
The diagrams below show trends in the annual initiation of new clinical trials by individual country from 2000 through H1 2026 (Diagrams 15–29). As usual, we invite readers to review them independently. However, an important caveat is necessary. The analysis must take into account a key methodological nuance of the ClinicalTrials.gov platform itself: the data in this database are not static and can change—that is, be supplemented—retrospectively over time. This phenomenon is particularly pronounced for the most recent years (2023–2025) and makes the current figures for H1 2026 provisional and the least representative at this point in time. We attribute this to the fact that an IMCT is often initiated by a sponsor in a limited group of countries, but during the project—especially if enrolment is insufficient—the company may decide to expand its geographical footprint and open additional study sites in other countries. When a new country is added to an ongoing project, ClinicalTrials.gov automatically assigns the trial to the protocol's original start date rather than to the date of actual approval by the local regulator. As a result, statistics for past years are supplemented over time with new entries that, in the current snapshot, are not yet physically linked to the maps of these countries.

Diagram 15



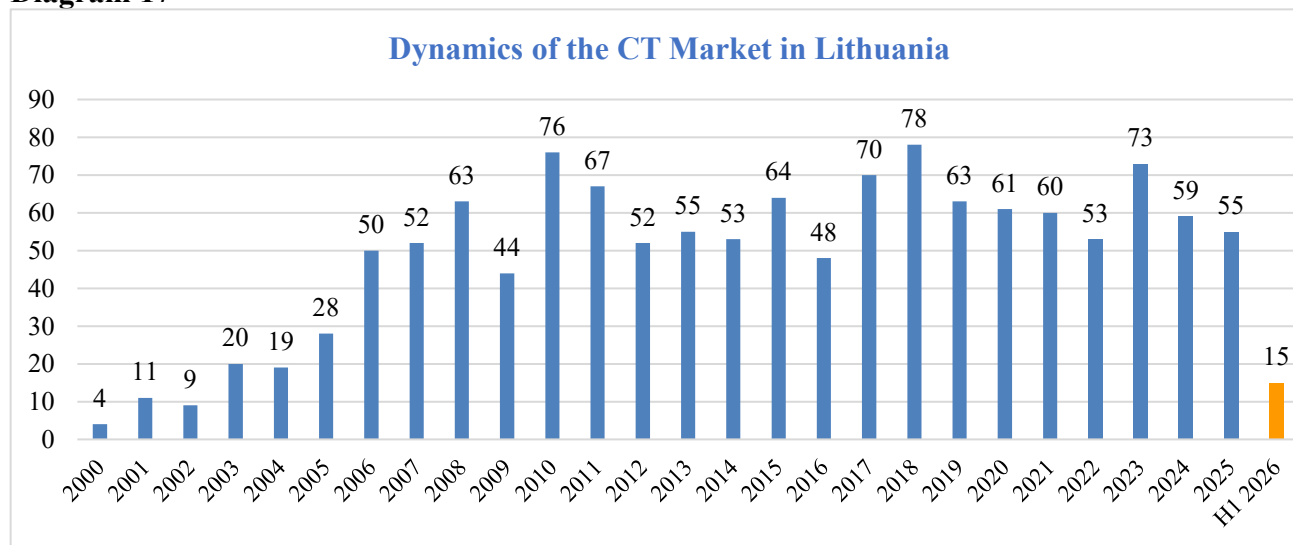
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Diagram 16



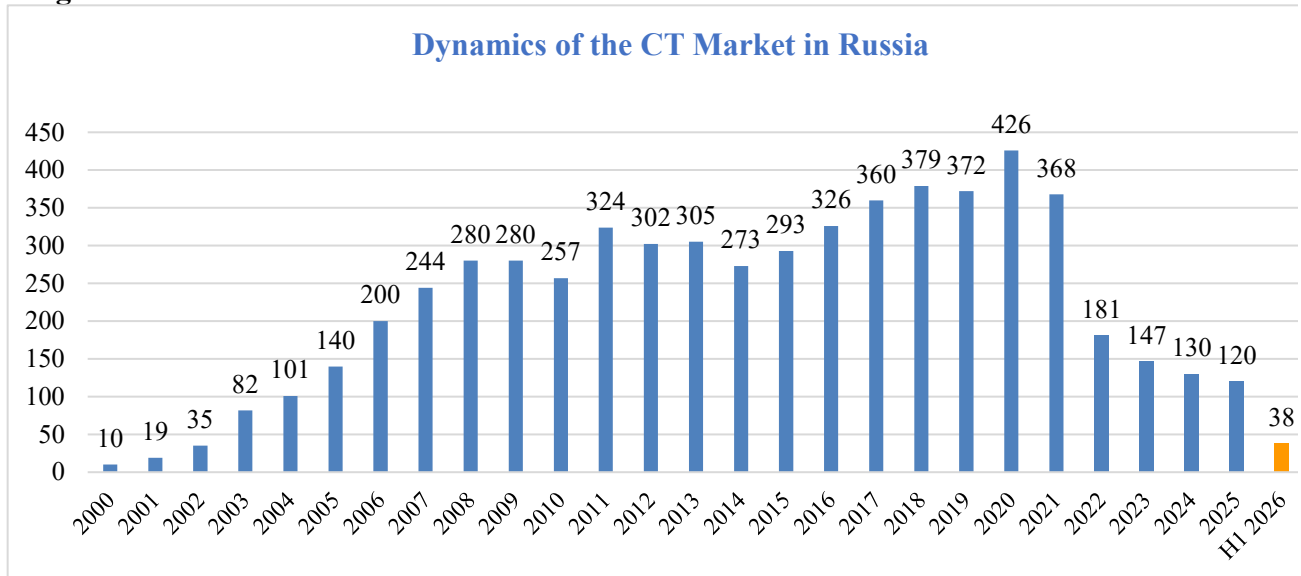
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Diagram 17



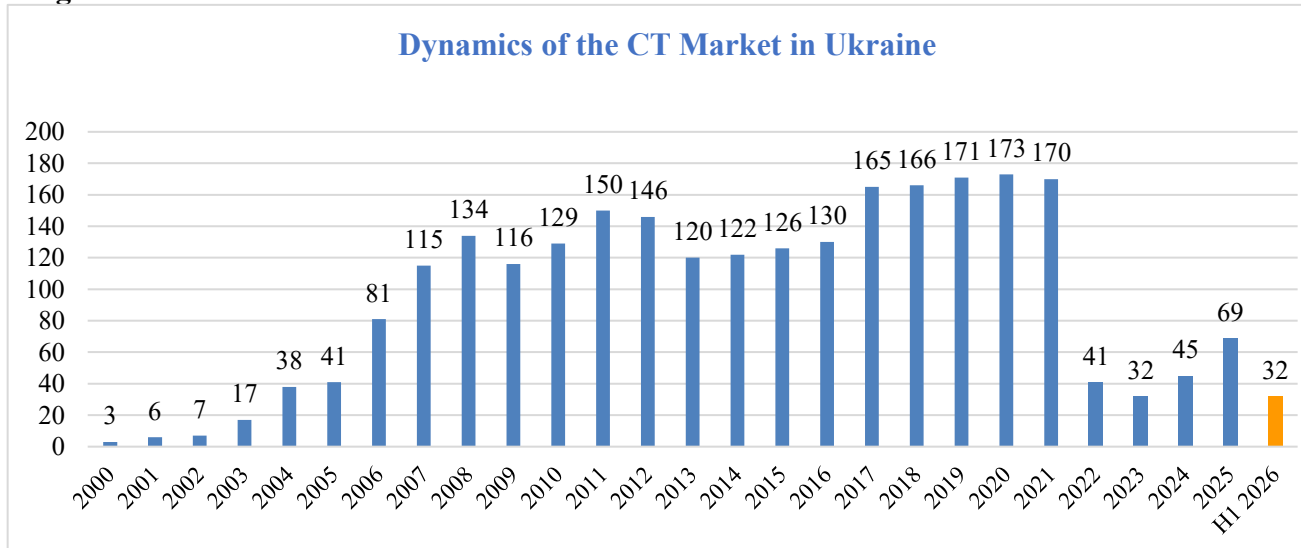
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Diagram 18



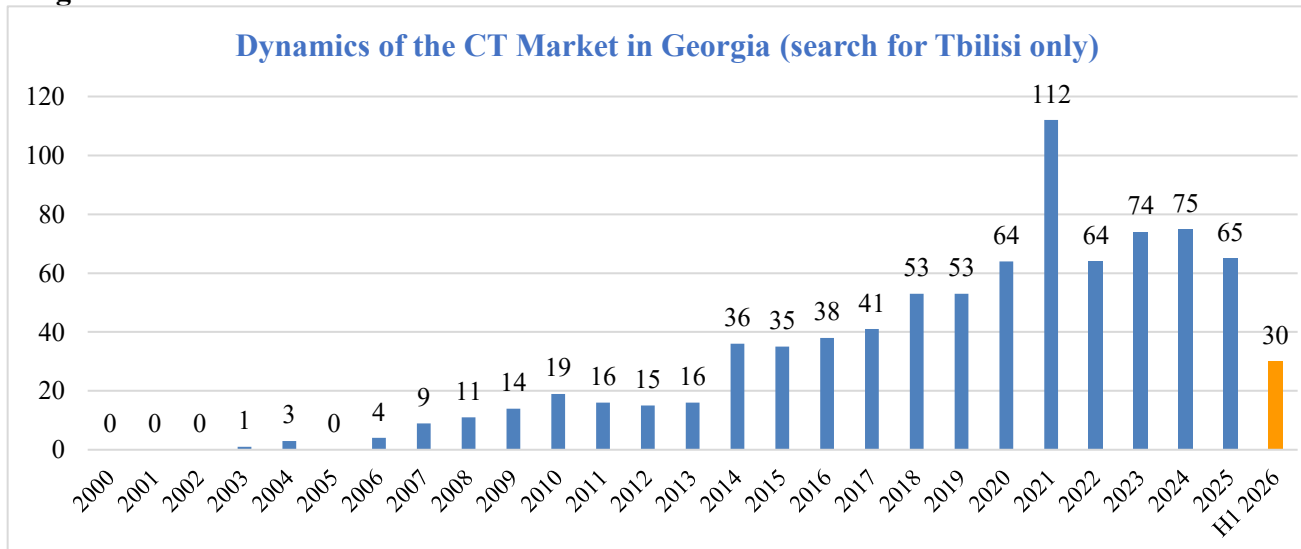
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Diagram 19



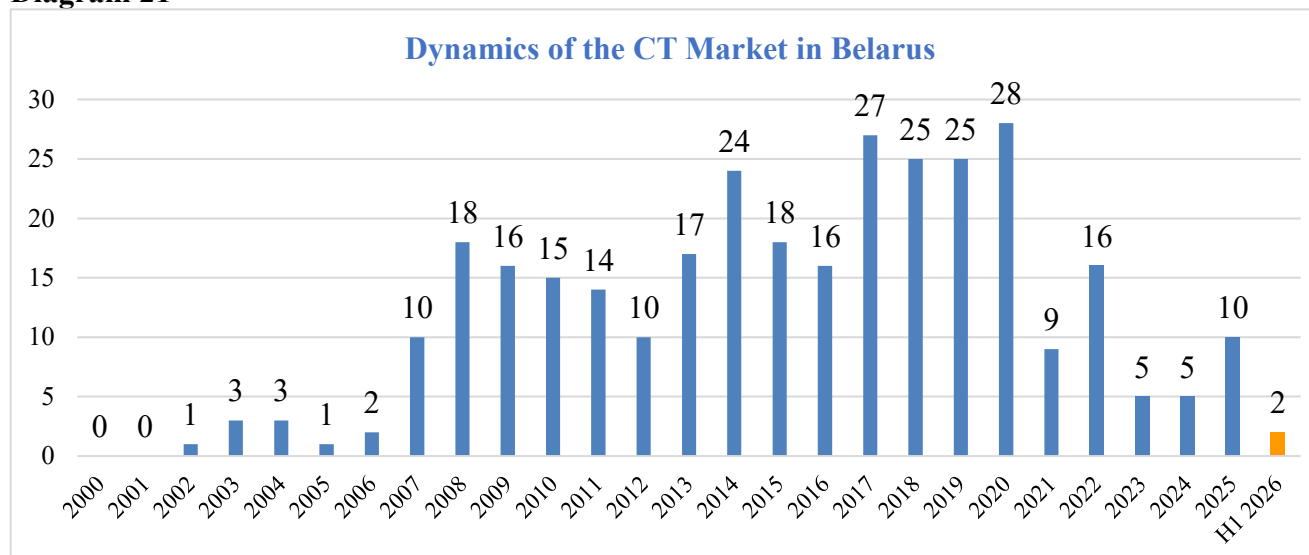
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Diagram 20



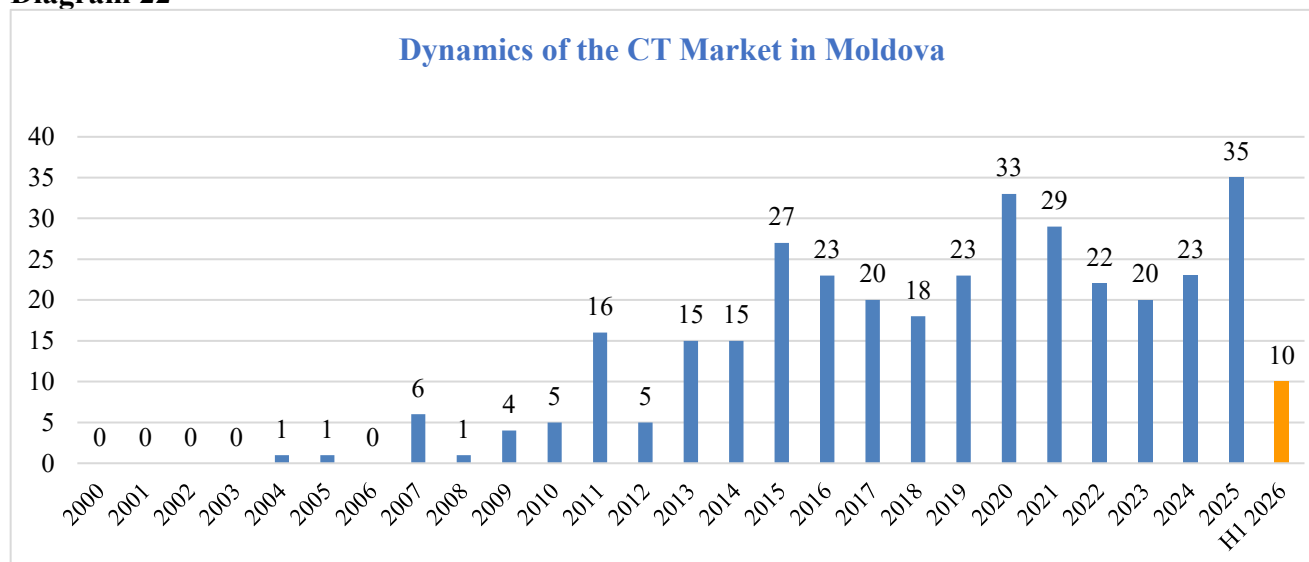
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Diagram 21



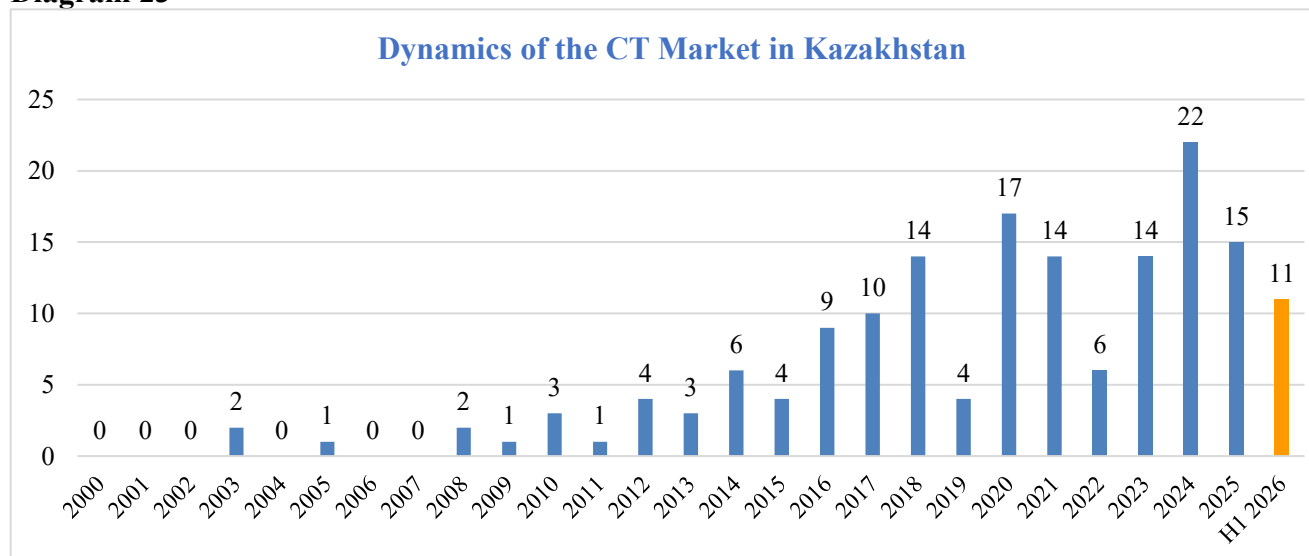
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Diagram 22



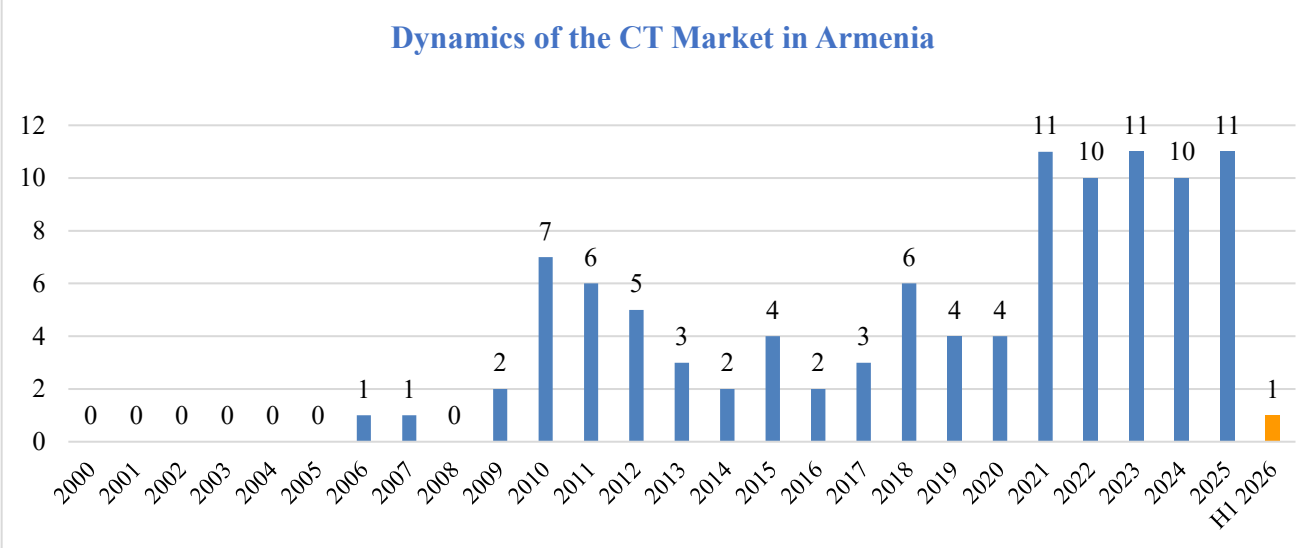
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Diagram 23



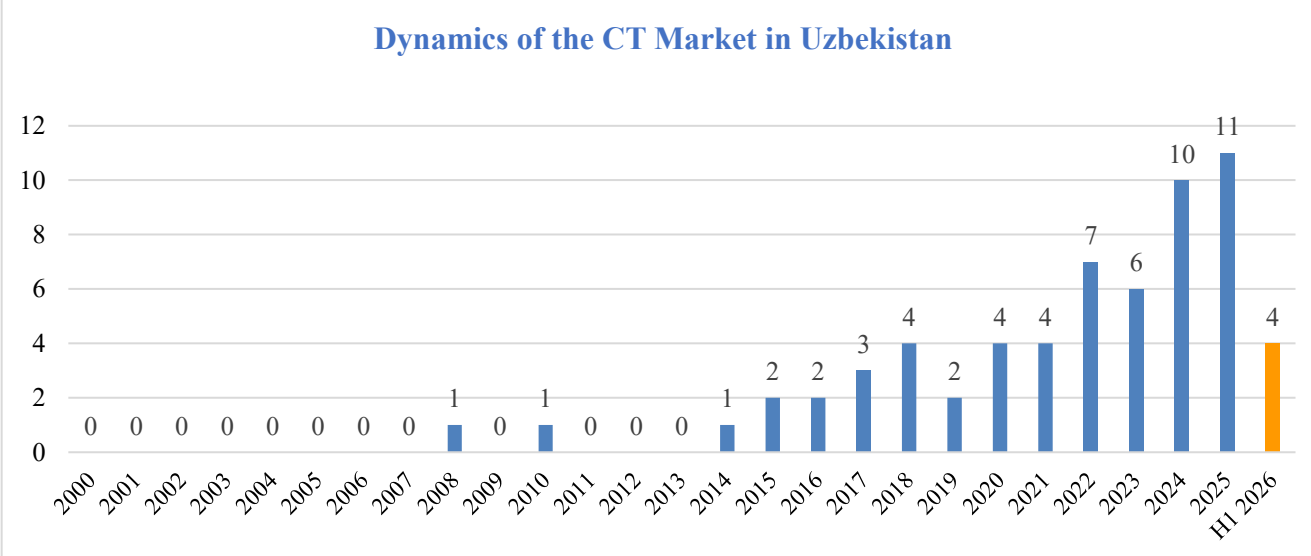
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Diagram 24



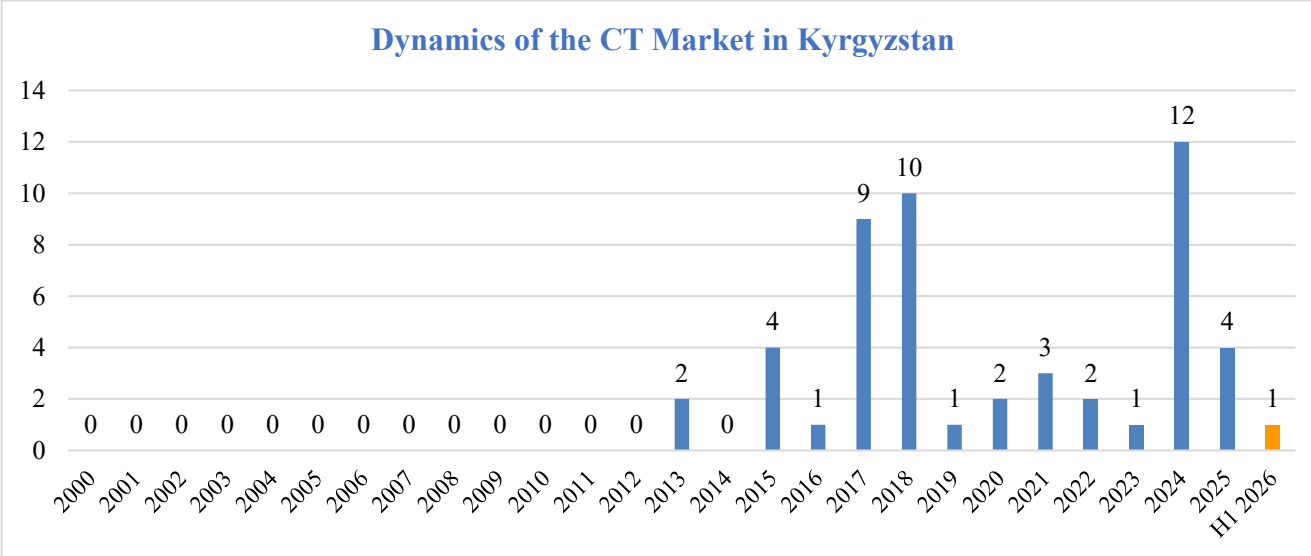
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Diagram 25



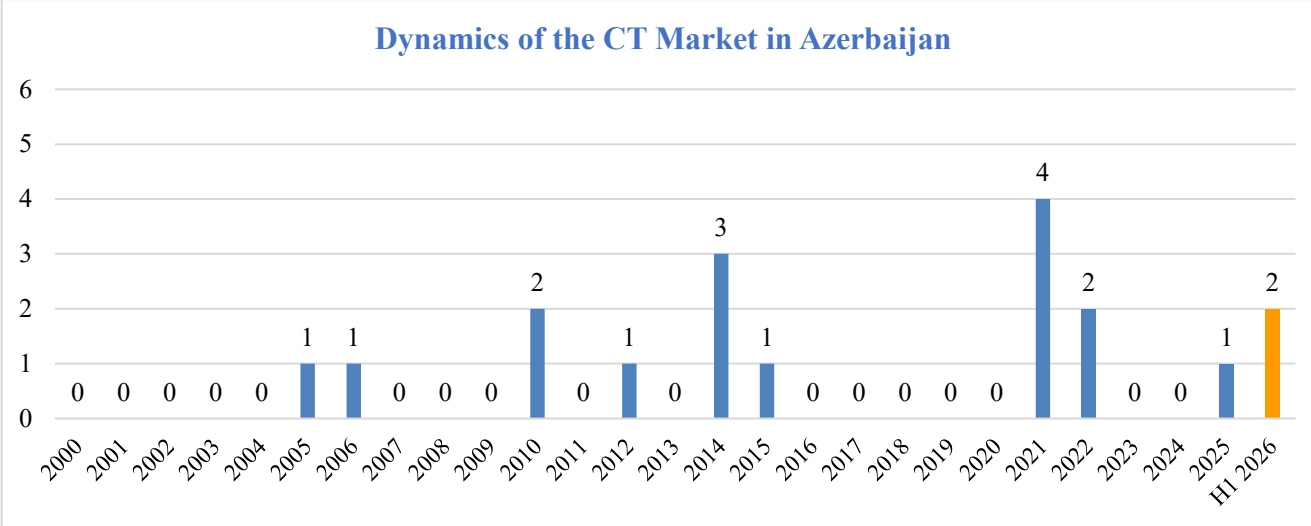
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Diagram 26



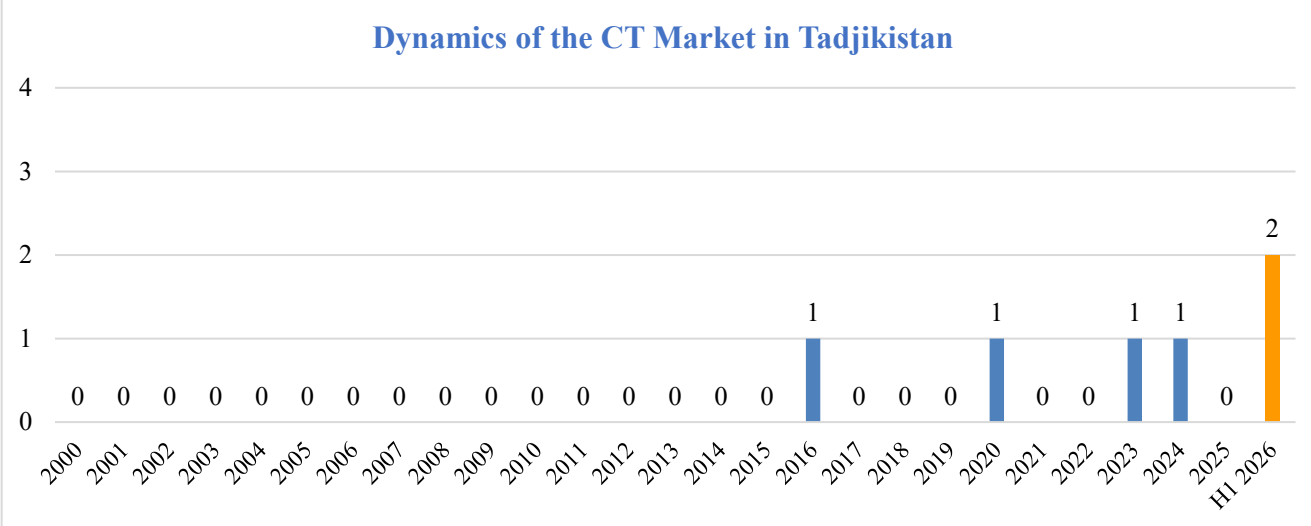
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Diagram 27



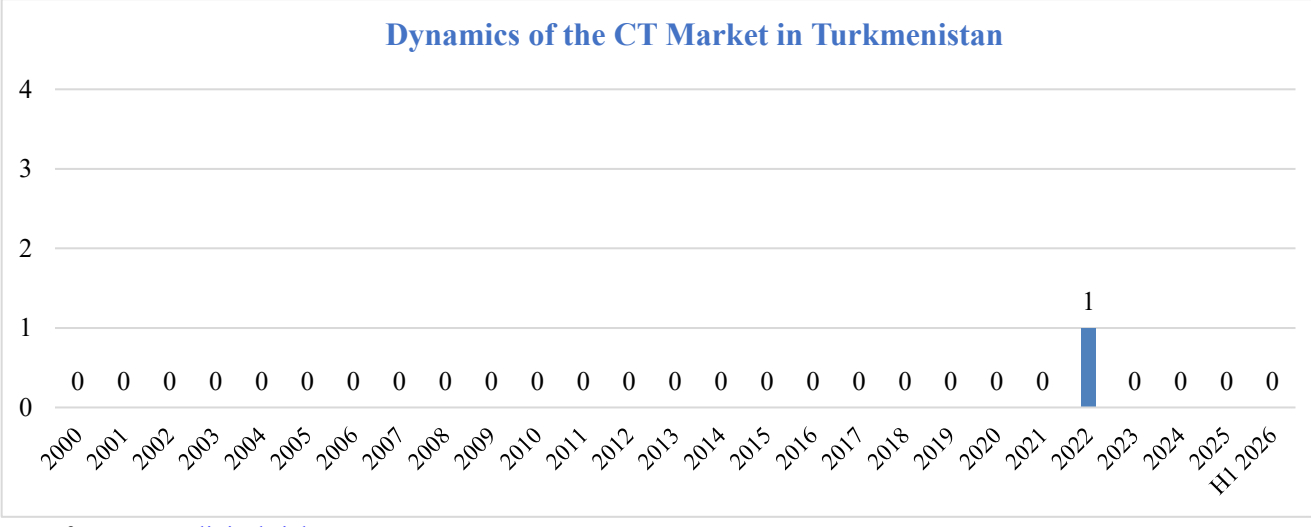
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Diagram 28



Data from www.clinicaltrials.gov

Diagram 29



Data from www.clinicaltrials.gov