

# Clinical Trials in Russia

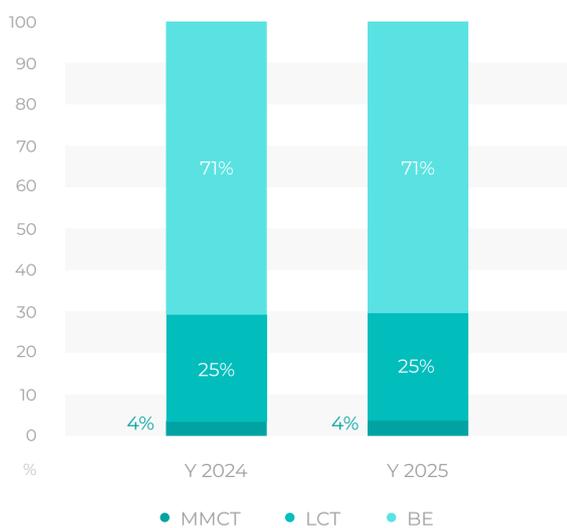
Y 2025 Research report

## Trial Data

During the Year 2025 (Y 2025), the Ministry of Health of the Russian Federation approved the start of 607 new clinical trials of all types, including local and bioequivalence (BE) studies. This number demonstrates a slight decrease of 3% compared to the Y 2024, when the total number of studies was 628.

The dominant type of clinical trials conducted across Russian sites in Y 2025 was BE studies. The market share of BE studies remained stable vs. 2024 and accounted for 71%. The market shares of multinational multi-center clinical trials (MMCTs) and local clinical trials (LCTs) also remained stable, at 4% and 25% accordingly.

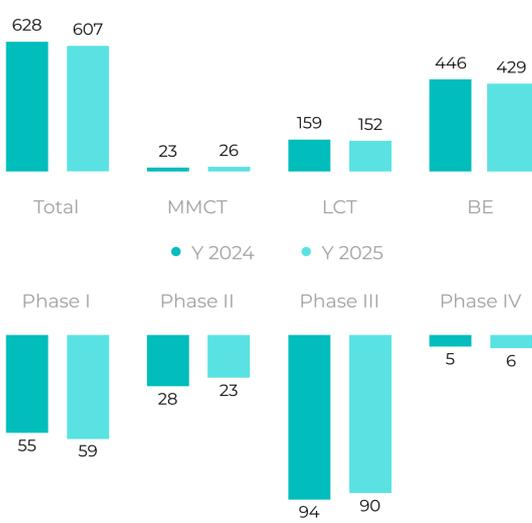
Percentage Breakdown of Clinical Trials by Type



The most prevalent phase of clinical trials conducted at Russian sites by total number of studies was Phase III. The total number of Phase III trials decreased slightly by 4% – from 94 trials in Y 2024 to 90 trials in Y 2025.

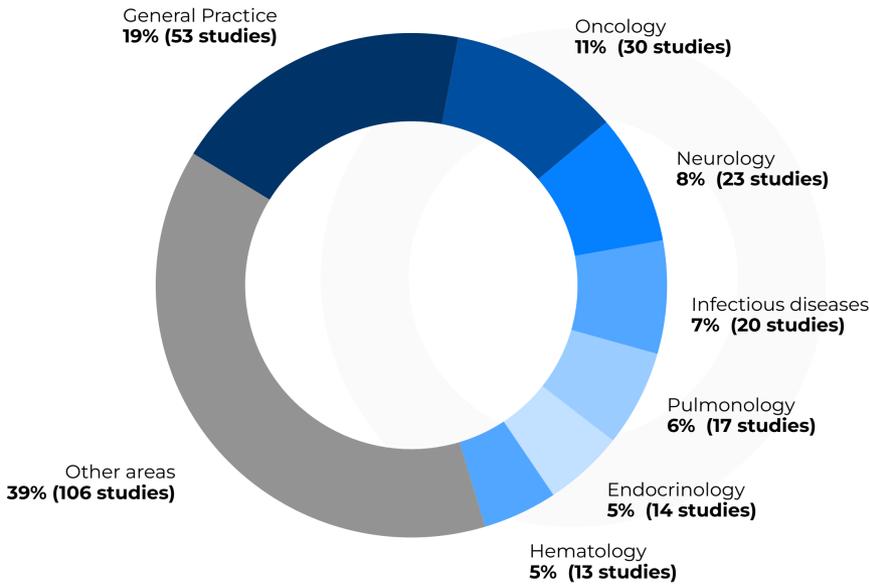
The largest number of clinical trials initiated in Russia during Y 2025 was related to the following therapeutic areas: General Practice (53 studies), Oncology (30), Neurology (23), Infectious Diseases (20), Pulmonology (17), Endocrinology (14), Hematology (13), Obstetrics & Gynecology (12), Allergology and Immunology (11 studies each). Dermatology, ENT, and Gastroenterology each had 8 studies, Cardiology and Pediatrics – 7.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Y 2025 by Therapeutic Area

More than one therapeutic area may be assigned to a trial. BE studies were not included in any therapeutic area group.



## Sponsor Data

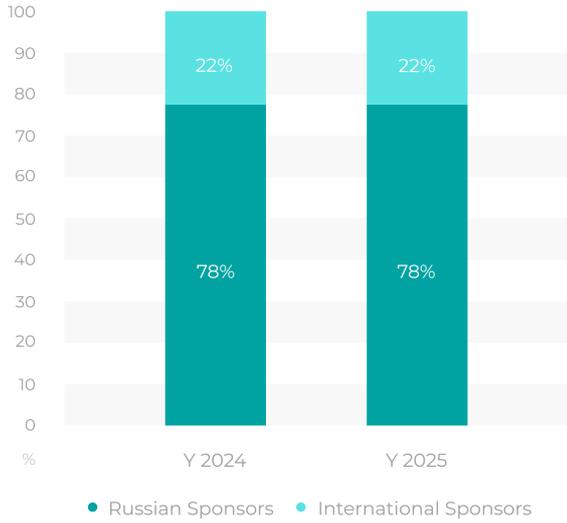
Clinical trials initiated in Russia during Y 2025 were sponsored by pharmaceutical companies from Russia and 25 foreign countries. The combined market share of international pharmaceutical companies involved remained unchanged vs. 2024 – 22%.

The dominant phases for clinical trials conducted across Russian sites by international pharmaceutical companies in 2025 were Phase III (52%, 13 studies) and Phase I (32%, 8 studies).

The most prevalent sponsor countries of origin in Y 2025 were Russia (471 studies) and India (51 studies). Other prominent countries represented were Belarus (21), China (10), Turkey (6), Hungary and Israel (4 studies each), Australia, Bangladesh, Iran, South Korea, Spain, Sweden, Switzerland (3 studies each).

Observational trials and trials without FDA-defined phases (from I to IV) were not counted in the following ranking.

Percentage Breakdown of Clinical Trials by Sponsor's Country of origin



Combined market share shown as a percentage of both international and Russian sponsors.

Top-10 International Trial Sponsors in Russia in Y 2025

Nº	Company Name	Studies	Subjects
1	AstraZeneca	3	697
2	Lomond Therapeutics	3	110
3	Ascentage	2	263
4	Jiangsu Hengrui Pharm.	2	72
5	Laboratoires Boiron	1	440
6	Zhifei	1	350
7	Novartis	1	340
8	F.Hoffmann-La Roche	1	300
9	Glenmark Pharm.	1	258
10	World Medicine	1	238
<b>Combined market share</b>		<b>9%</b>	<b>7%</b>

Combined market share shown as a percentage of both international and Russian sponsors. Bio-Equivalence (BE) studies were not included in this ranking.

Top-10 Russian Trial Sponsors in Russia in Y 2025

Nº	Company Name	Studies	Subjects
1	Generium	10	2,309
2	Pharmstandard	10	1,866
3	BIOCAD	9	3,109
4	R-Pharm	8	2,050
5	GeroPharm	8	2,470
6	PSK Pharma	7	915
7	Valenta Pharm	5	1,586
8	Pharmasyn tez	5	804
9	Materia Medica Holding	5	1,172
10	Grotex	4	592
<b>Combined market share</b>		<b>40%</b>	<b>41%</b>

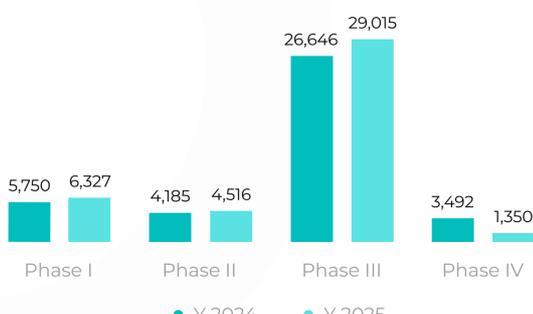
## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I-IV clinical trials initiated in Russia during Y 2025 reached a total of 41,208 subjects – a 3% increase compared to the previous year (40,073 subjects enrolled in 2024).

The most prevalent phase by number of participating subjects was Phase III, accounting for 70% of all enrolled subjects.

The number of subjects enrolled (or planned to be enrolled) in BE studies, accounted for 23,244 subjects – nearly unchanged vs. Y 2024 (23,760 subjects).

Breakdown of number of Subjects enrolled by Phase



Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

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## Research Site Data

### Top-5 Russian research sites (all studies) in Y 2025

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	56
2	AX Clinic	Yaroslavl	51
3	I.M. Sechenov First Moscow State Medical University	Moscow	50
4	Rostov Central District Hospital	Rostov	36
5	Miramed	Maykop	33

**Combined market share of these sites**

**37%**

## CRO Data

### Top-10 CROs in Russia in Y 2025 (Phase I-IV studies)

Observational Clinical trials and Clinical trials without FDA defined phases (from I to IV) were not included in this ranking.

Nº	Company Name	No. Studies	No. Subjects
1	iPharma	7	1,184
2	Benerix	3	1,183
3	Vita Aeterna	3	716
4	X7 Clinical Research	3	152
5	Medical Development Agency	2	500
6	Synergy Research Group	2	476
7	National Scientific Center for Research and Pharmacovigilance	2	394
8	Statandocs	2	338
9	Smooth Drug Development	2	270
10	K-Research	2	263

**Combined market share**

**16%**

**13%**

Nº	Company Name	No. Studies	No. Subjects
1	National Scientific Center for Research and Pharmacovigilance	21	832
2	Probiotech	14	955
3	AX Clinical Trials and Consulting	13	815
4	X7 Clinical Research	12	636
5	Ligand Research	10	605

**Combined market share of these companies**

**16%**

**17%**

In applications submitted to the MoH of Russia, the Sponsor may be listed as the organization conducting the clinical trial, whereas the practical execution of the trial is carried out by a CRO.

## Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 166 new drugs during Y 2025, including 34 new molecular entities (NME). The remaining approvals concerned new active ingredients, dosages, formulations, or manufacturers. 32 of these 166 drugs were tested in clinical trials involving Russian sites.

During Q4 2025, CDER of the FDA approved 40 new drugs, including 10 NMEs. 9 of these 40 drugs and 2 of 10 NMEs were tested in clinical trials involving Russian sites.

**Source: FDA**

Appr.Date	Drug (Active Ingredient)	Company
02.10.2025	Eydenzelt (afibercept-boav)	Celltrion
23.10.2025	Blenrep (belantamab mafodotin-blmf)	GlaxoSmithKline
24.10.2025	Lynkuet (elinzanetant)	Bayer
29.10.2025	Osvyrti (denosumab-desu)	Accord Biopharma
18.11.2025	Redemplo (plozasiran sodium)	Arrowhead
16.12.2025	Exdensur (depemokimab-ulaa)	GlaxoSmithKline
16.12.2025	Vybrique (sildenafil citrate)	Ibsa
18.12.2025	Nufymco (ranibizumab-leyk)	Formycon
22.12.2025	Wegovy (semaglutide)	Novo Nordisk

During Y 2025, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 104 new drugs including 21 new (non-orphan) drugs, 8 generics/hybrids, 41 biosimilars, and 23 orphan drugs. 16 of the approved drugs were tested in clinical trials involving Russian sites.

In Q4 2025, CHMP of EMA approved 19 new drugs including 10 new (non-orphan) drugs, 2 generics/hybrids, 4 biosimilars and 3 orphan drugs. 6 of the approved drugs were tested in clinical trials involving Russian sites.

**Source: EMA**

Appr.Date	Drug (Active Ingredient)	Company
16.10.2025	Inluriyo (imlunestrant)	Eli Lilly
13.11.2025	Gotenfia (golimumab)	STADA
13.11.2025	Wayrilz (rilzabrutinib)	Sanofi
11.12.2025	Brinsupri (brensocatic)	Insmmed
11.12.2025	Exdensur (depemokimab)	GlaxoSmithKline
11.12.2025	Ranluspec (ranibizumab)	Lupin

### FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during the Year 2025.

### Roszdraznavor inspections

According to the Roszdraznavor quarterly report, as of 13/01/2026 there were no Regulatory inspections conducted by Roszdraznavor during the Year 2025.

## About The Orange Paper

The Orange Paper is a free publication produced by Synergy Research Group for the pharmaceutical industry since 2007. It consolidates data from numerous public sources into a single concise document to aid decision-makers planning clinical trials.

The report is published quarterly, with an annual summary issued at the end of each year. All data contained within this document is current as of 13 January 2026.

## About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia and Kazakhstan since 2002.

For all clinical studies conducted by our company, we maintain the highest world-class quality standards, both in our SOPs and final study data.

Year after year, our company ranks among the market leaders in the number of conducted clinical studies and enrolled patients.

We continuously work to improve our SOPs, study risk management, and IT infrastructure – replacing outdated R&D strategies with novel, more efficient approaches to clinical research.

The high recruitment rates of emerging markets, combined with innovative technology, allow Synergy to conduct faster, more cost-effective studies for our clients without sacrificing quality.