# Clinical Trials in Russia

Q3 2025 Research report

## Foreword

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.

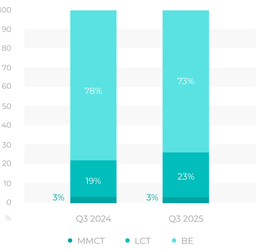
All data contained within this document is current as of 17 October 2025.

## Trial Data

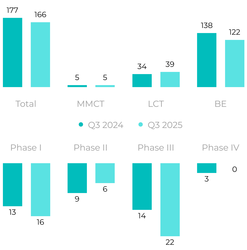
During Q3 2025, the Ministry of Health of the Russian Federation approved the start of 166 new clinical trials of all types, including local and bioequivalence (BE) studies. This number demonstrates a slight decrease of 6% compared to Q3 2024, when the total number of studies was 177.

The dominant type of clinical trials conducted across Russian sites in Q3 2025 was BE studies. The market share of BE studies decreased by 5% vs. Q3 2024 and accounted for 73%. The market share of multinational multi-center clinical trials (MMCTs) remained stable at 3%, while the market share of local clinical trials (LCTs) increased from 19% to 23%.

**Percentage Breakdown of Clinical Trials by Type**




**Breakdown of Clinical Trials by Type and Phase**





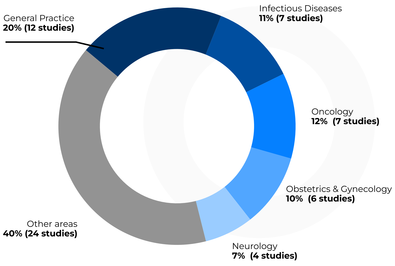


The most prevalent phase of clinical trials conducted at Russian sites by total number of studies was Phase III. The total number of Phase III trials showed growth of 57% – from 14 trials in Q3 2024 to 22 trials in Q3 2025.

The largest number of clinical trials initiated in Russia during Q3 2025 was related to the following therapeutic areas: General Practice (12 studies), Infectious Diseases and Oncology (7 studies each), Obstetrics & Gynecology (6), Neurology (4). Endocrinology, ENT, Hematology, and Surgery each had 3 studies.

**Breakdown of Clinical Trials in Russia in Q3 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

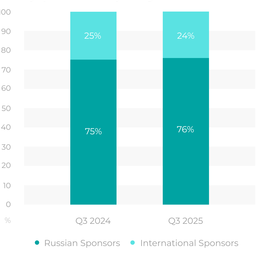
Clinical trials initiated in Russia during Q3 2025 were sponsored by pharmaceutical companies from Russia and 15 foreign countries. The combined market share of international pharmaceutical companies involved remained almost unchanged – 25% in Q3 2024 vs. 24% in Q3 2025.

The dominant phases for clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2025 were Phase III (5 studies) and Phase I (2 studies).

The most prevalent sponsor countries of origin in Q3 2025 were Russia (126 studies) and India (15 studies).

Other countries represented were Belarus and China (4 studies each), Bosnia and Herzegovina, Czech Republic, Hungary, Spain, and Turkey (2 studies each), Australia, France, North Macedonia, Romania, Serbia, South Korea, and Switzerland (1 study each).

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




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

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

**Top-10 International Trial Sponsors in Russia in Q3 2025**

| № | Company Name | Studies | Subjects |
|---|---|---|---|
| 1 | Laboratoires Boiron | 1 | 440 |
| 2 | F.Hoffmann-La Roche | 1 | 300 |
| 3 | Glenmark Pharm. | 1 | 258 |
| 4 | Rompharm | 1 | 216 |
| 5 | Sentiss Pharma | 1 | 176 |
| 6 | Buchang Pharm. | 1 | 30 |
| 7 | Lomond Therapeutics | 1 | 30 |
| 8 | - | - | - |
| 9 | - | - | - |
| 10 | - | - | - |
| | **Combined market share** | **16%** | **15%** |

**Top-10 Russian Trial Sponsors in Russia in Q3 2025**

| № | Company Name | Studies | Subjects |
|---|---|---|---|
| 1 | Pharmstandard | 5 | 930 |
| 2 | Generium | 4 | 476 |
| 3 | Valenta Pharm | 2 | 536 |
| 4 | Acrus BioMed | 2 | 200 |
| 5 | Gamaleya Research Institute | 2 | 190 |
| 6 | St. Petersburg Institute of Vaccines and Serums | 1 | 1,472 |
| 7 | GeroPharm | 1 | 780 |
| 8 | Dimebonet | 1 | 562 |
| 9 | Cytomed | 1 | 334 |
| 10 | Tula pharm. factory | 1 | 297 |
| | **Combined market share** | **45%** | **58%** |

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

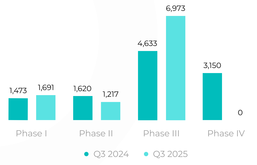
## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I–IV clinical trials initiated in Russia during Q3 2025 reached a total of 9,881 subjects – a 9% decrease compared to the previous year (10,876 subjects enrolled in Q3 2024).

The most prevalent phase by number of participating subjects was Phase III, accounting for 71% of all enrolled subjects.

The number of subjects enrolled (or planned to be enrolled) in BE studies, accounted for 6,450 subjects – an 11% decrease vs. Q3 2024 (7,252 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-7 Russian research sites (all studies) in Q3 2025**

| № | Site Name | City | No. Studies |
|---|---|---|---|
| 1 | Miramed | Maykop | 13 |
| 2 | I.M. Sechenov First Moscow State Medical University | Moscow | 13 |
| 3 | Ecosafety | Saint-Petersburg | 12 |
| 4 | AX Clinic | Yaroslavl | 11 |
| 5 | Cardiology Dispensary | Ivanovo | 11 |
| 6 | Rostov Central District Hospital | Rostov | 11 |
| 7 | Tomsk National Research Medical Center | Tomsk | 11 |
| | **Combined market share of these sites** | | **49%** |

Top-7 sites are listed instead of Top-5 due to the same number of studies conducted in 4 sites.

## CRO Data

**Top-10 CROs in Russia in Q3 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.

| № | Company Name | No. Studies | No. Subjects |
|---|---|---|---|
| 1 | iPharma | 4 | 792 |
| 2 | Vita Aeterna | 2 | 380 |
| 3 | Synergy Research Group | 1 | 440 |
| 4 | National Scientific Center for Research | 1 | 297 |
| 5 | and Pharmacovigilance | 1 | 230 |
| 6 | Smooth Drug Development | 1 | 100 |
| 7 | RIC-Pharma | 1 | 30 |
| 8 | OST | - | - |
| 9 | - | - | - |
| 10 | - | - | - |
| | **Combined market share** | **25%** | **23%** |

**Top-5 CROs in Russia in Q3 2025 (BE studies)**

Only BE (bioequivalence) studies were included in this ranking.

| № | Company Name | No. Studies | No. Subjects |
|---|---|---|---|
| 1 | Probiotech | 4 | 244 |
| 2 | Ligand Research | 4 | 190 |
| 3 | AX Clinical Trials and Consulting | 3 | 139 |
| 4 | ClinPharmDevelopment | 2 | 170 |
| 5 | OST | 2 | 124 |
| | **Combined market share** | **12%** | **13%** |

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 48 new drugs during Q3 2025, including 13 new molecular entities (NMEs). The remaining approvals concerned new active ingredients, dosages, formulations, or manufacturers.

10 of these 48 drugs, and 5 of the 13 NMEs were tested in clinical trials involving Russian sites.

**Source: FDA**

| Appr.Date | Drug (Active Ingredient) | Company |
|---|---|---|
| 23.07.2025 | Anzupgo (delgocitinib) | Leo Pharma |
| 31.07.2025 | Alhemo (concizumab) | Novo Nordisk |
| 12.08.2025 | Brinsupri (brensocatib) | Insmed |
| 29.08.2025 | Otezla (apremilast) | Amgen |
| 29.08.2025 | Wayrilz (rilzabrutinib) | Genzyme |
| 09.09.2025 | Zolymbus (bimatoprost) | Thea Pharma |
| 10.09.2025 | Koselugo (selumetinib) | AstraZeneca |
| 19.09.2025 | Keytruda Qlex (pembrolizumab; berahyaluronidase alfa-pmph) | Merck Sharp Dohme |
| 25.09.2025 | Inluriyo (imlunestrant tosylate) | Eli Lilly |
| 25.09.2025 | Palsonify (paltusotine hydrochloride) | Crinetics |

In Q3 2025, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 27 new drugs including 6 new (non-orfan) drugs, 3 generics/hybrids, 13 biosimilars, and 5 orphan drugs.

Five of the approved drugs were tested in clinical trials involving Russian sites.

**Source: EMA**

| Appr.Date | Drug (Active Ingredient) | Company |
|---|---|---|
| 24.07.2025 | Eyluxvi (aflibercept) | Biolitec |
| 18.09.2025 | Imaavy (nipocalimab) | Janssen |
| 18.09.2025 | Denosumab Intas (denosumab) | Intas |
| 18.09.2025 | Lynkuet (elinzanetant) | Bayer |
| 18.09.2025 | Ponlimsi (denosumab) | Teva |

**FDA inspections**

According to U.S. FDA data, no inspections were conducted at Russian investigative sites during Q3 2025.

**Roszdravnadzor inspections**

According to the Roszdravnadzor data, as of 17 October 2025, no regulatory inspections were conducted by the agency during Q3 2025.

## About Synergy Research Group

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

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

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.

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

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.