Clinical Trials in Russia

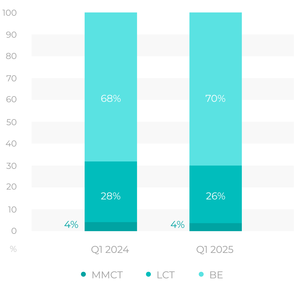
Q1 2025 Research report

Trial Data

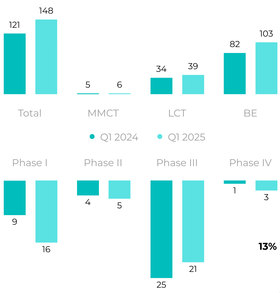
During Q1 2025 the Ministry of Health of the Russian Federation approved the start of 148 new clinical trials of all types, including local and bioequivalence studies. This represents a 22% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q1 2025 were BE (Bio-equivalent). The market share of BE studies achieved the rate of 70% and remained almost at the same level as in the previous year (68%). The market share of MMCTs (Multinational Multi-center) remained at the same level as in Q1 2024 and accounted for 4% whilst the market share of Local Clinical Trials (LCTs) slightly decreased from 28% to 26%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

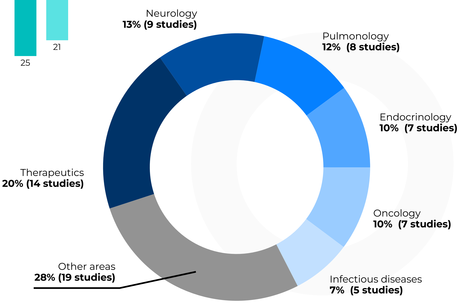


The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials decreased by 16% – from 25 trials in Q1 2024 to 21 trials in Q1 2025.

The largest number of clinical trials initiated in Russia during Q1 2025 were related to Therapeutics (14 studies), Neurology (9), Pulmonology (8), Endocrinology and Oncology (7 studies each), Infections diseases (5 studies).

Breakdown of Clinical Trials in Russia in Q1 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

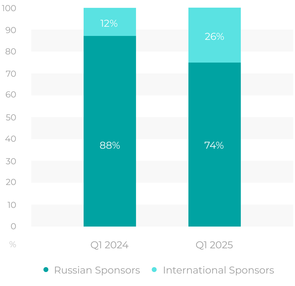
Clinical trials initiated in Russia during Q1 2025 were sponsored by pharmaceutical companies from Russia and 17 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market recovered from 12% in Q1 2024 to 26% of all studies in Q1 2025.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q1 2025 was Phase III (3 studies).

The most prevalent Sponsor's countries of origin in Q1 2025 were Russia (109 studies) and India (11 studies). Other countries include Belarus (6 studies), Bangladesh and Israel (3 studies each), Netherlands, Sweden, and USA (2 studies each), China, Greece, Hungary, Iran, Malta, Slovenia, South Korea, Spain, Switzerland, and Turkey (1 study 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 Q1 2025

№	Company Name	Studies	Subjects
1	AstraZeneca	2	532
2	Ascentage	1	57
3	Zhifei	1	350
4	CinnaGen Co.	1	80
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
	Combined market share	**13%**	**9%**

Top-10 Russian Trial Sponsors in Russia in Q1 2025

№	Company Name	Studies	Subjects
1	BIOCAD	4	968
2	GeroPharm	4	880
3	R-Pharm	4	680
4	Grotex	3	484
5	Valenta Pharm	2	650
6	Elpida	2	350
7	InertGas Medical	2	338
8	PSK Pharma	2	306
9	Saint Petersburg Institute of Vaccines and Serums	1	2610
10	Materia Medica Holding	1	552
	Combined market share	**56%**	**71%**

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

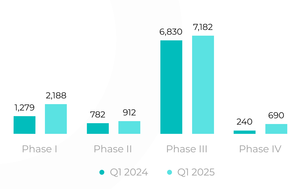
Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I–IV clinical trials initiated in Russia during Q1 2025 reached a total of 10,972 subjects – a 20% rise in comparison with the previous year when 9,131 subjects were enrolled.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 65% of all subjects enrolled.

Number of subjects enrolled (or planned to be enrolled) in BE studies, accounted for 5,781 subjects — a 42% shoot-up compared to Q1 2024.

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 Q1 2025

№	Site Name	City	No. Studies
1	AX Clinic	Yaroslavl	17
2	Eco-safety	Saint-Petersburg	12
3	Ligand Research	Moscow	12
4	I.M. Sechenov First Moscow State Medical University	Moscow	11
5	National Scientific Center for Research and Pharmacovigilance	Saransk	9
	Combined market share of these sites		41%

CRO Data

Top-10 CROs in Russia in Q1 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	Statandocs	2	338
2	K-Research	2	57
3	iPharma	1	312
4	Intelli	1	170
5	Medical Innovations and Technologies	1	80
6	Smooth Drug Development	1	26
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
	Combined market share	18%	9%

Top-5 CROs in Russia in Q1 2025 (BE studies)

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

№	Company Name	No. Studies	No. Subjects
1	National Scientific Center for Research and Pharmacovigilance	9	340
2	AX Clinical Trials and Consulting	5	279
3	Pharma Group	3	188
4	Ligand Research	3	175
5	Probiotech	3	154
	Combined market share	22%	20%

Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 39 new drugs during Q1 2025; 7 of them were new molecular entities (NME); other approvals concerned new active ingredients, new dosages, combinations, formulations, or manufacturers. 6 of these 39 drugs were tested (or are being tested) in clinical trials involving Russian sites. **Source: FDA**

Appr.Date	Drug (Active Ingredient)	Company
17.01.2025	Datroway (datopotamab deruxtecan-dlnk)	Daiichi Sankyo
07.02.2025	Emblaveo (avibactam sodium; aztreonam)	Abbvie
11.02.2025	Evrysdi (risdiplam)	Genentech
14.02.2025	Merilog (insulin aspart-szjj)	Sanofi-aventis
14.02.2025	Merilog solostar (insulin aspart-szjj)	Sanofi-aventis
28.03.2025	Qfitlia (fitusiran sodium)	Genzyme

In Q1 2025 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 17 new drugs including 3 generic/hybrid, 6 biosimilar and 1 orphan medicines. 1 of these 17 drugs were tested (or are being tested) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
30.01.2025	Datroway (datopotamab deruxtecan)	Daiichi Sankyo

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q1 2025.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 8/04/2025 there were no Regulatory inspections conducted by Roszdravnadzor during Q1 2025.

About The Orange Paper

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

It is produced quarterly, with an annual summary at the close of each year.

All of the data within this document are actual on date: 8/04/2025

About Synergy Research Group

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

From year to year our company is the one of market leaders by the numbers of conducted clinical studies and enrolled patients.

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

For all of clinical studies conducted by our company we've set up the highest level of world-class quality both for SOPs and for final study data.

We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – and replacing an outdated R&D strategies by novel, more efficient approaches to clinical research.