Clinical Trials in Russia

Q2 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.

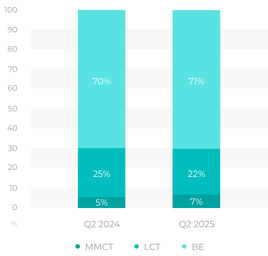
All data contained within this document is current as of 22 July 2025.

Trial Data

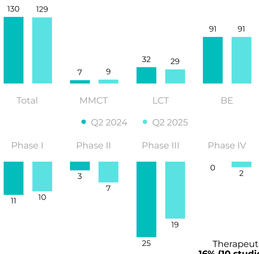
During Q2 2025, the Ministry of Health of the Russian Federation approved the start of 129 new clinical trials of all types, including local and bioequivalence (BE) studies. This number remained almost unchanged compared to Q2 2024, when the total number of studies was 130.

The dominant type of clinical trials conducted across Russian sites in Q2 2025 was BE studies. The market share of BE studies remained nearly stable at 71% (vs. 70% in Q2 2024). The market share of multinational multi-center clinical trials (MMCTs) increased slightly from 5% to 7%, while the market share of local clinical trials (LCTs) decreased from 25% to 22%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

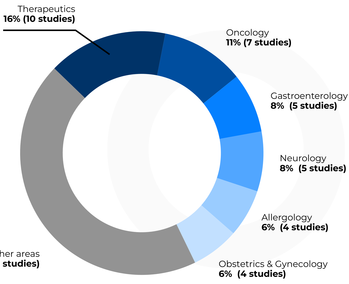


The most prevalent phase of clinical trials conducted at Russian sites by total number of studies was Phase III. However, the total number of Phase III trials decreased by 24% – from 25 trials in Q2 2024 to 19 trials in Q2 2025.

The largest number of clinical trials initiated in Russia during Q2 2025 was related to the following therapeutic areas: Therapeutics (10 studies), Oncology (7), Gastroenterology and Neurology (5 studies each), Allergology and Obstetrics & Gynecology (4 studies each). Cardiology, Dermatology, ENT, Hematology, and Immunology each had 3 studies.

Breakdown of Clinical Trials in Russia in Q2 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

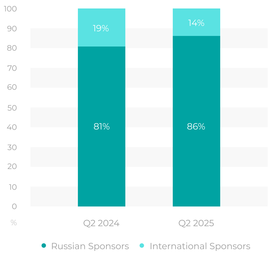
Clinical trials initiated in Russia during Q2 2025 were sponsored by pharmaceutical companies from Russia and 8 foreign countries. The combined market share of international pharmaceutical companies involved decreased from 19% in Q2 2024 to 14% in Q2 2025.

The dominant phases of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2025 were Phase I and Phase III (2 studies each).

The most prevalent sponsor countries of origin in Q2 2025 were Russia (111 studies) and India (9 studies).

Other countries represented were Australia and Belarus (2 studies each), and China, Croatia, Slovenia, Switzerland, and Turkey (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 Q2 2025

№	Company Name	Studies	Subjects
1	Eilean	2	60
2	Novartis	1	340
3	Bio-Thera	1	22
4	-	-	-
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
	Combined market share	**11%**	**6%**

Top-10 Russian Trial Sponsors in Russia in Q2 2025

№	Company Name	Studies	Subjects
1	BIOCAD	3	1,277
2	R-Pharm	3	730
3	Pharmstandard	3	700
4	Generium	2	306
5	Orphan-Bio	2	188
6	State Scientific Center for Virology and Biotechnology	1	405
7	Biomate	1	350
8	Alcea	1	320
9	Wertex	1	320
10	Art-pharm	1	290
	Combined market share	**47%**	**65%**

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

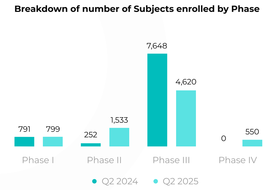
Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I–IV clinical trials initiated in Russia during Q2 2025 reached a total of 7,502 subjects – a 14% decrease compared to the previous year (8,691 subjects enrolled in Q2 2024).

The most prevalent phase by number of participating subjects was Phase III, accounting for 62% of all enrolled subjects.

The number of subjects enrolled (or planned to be enrolled) in BE studies, accounted for 4,609 subjects – nearly unchanged from to Q2 2024 (4,592 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 Q2 2025

№	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	17
2	Miramed	Maykop	12
3	I.M. Sechenov First Moscow State Medical University	Moscow	12
4	Cardiology dispensary	Ivanovo	8
5	Clinical Hospital №2	Yaroslavl	8
	Combined market share of these sites		44%

CRO Data

Top-10 CROs in Russia in Q2 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	2	60
2	M VED	1	350
3	ELC (Expert & Legal Center)	1	290
4	A-pharma	1	264
5	Medical Development Agency	1	250
6	X7 Clinical Research	1	80
7	Innovations LK	1	55
8	AX Clinical Trials and Consulting	1	40
9	-	-	-
10	-	-	-
	Combined market share	24%	19%

Top-5 CROs in Russia in Q2 2025 (BE studies)

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

№	Company Name	No. Studies	No. Subjects
1	X7 Clinical Research	4	166
2	ClinPharmDevelopment	3	197
3	National Scientific Center for Research and Pharmacovigilance	3	167
4	MDP-KIO	2	150
5	Probiotech	2	145
	Combined market share	15%	18%

Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 39 new drugs during Q2 2025, including 4 new molecular entities (NMEs). The remaining approvals concerned new active ingredients, dosages, formulations, or manufacturers.

Of these 39 drugs, 7 were tested in clinical trials involving Russian sites (none of the 4 NMEs were tested in Russia).
Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
17.04.2025	Eliquis (apixaban)	Bristol
17.04.2025	Eliquis Sprinkle (apixaban)	Bristol
29.04.2025	Datroway (datopotamab deruxtecan-dlnk)	Daiichi Sankyo
22.05.2025	Andembry (garadacimab-gxii)	Behring
12.06.2025	Zusduri (mitomycin)	Urogen Pharma
16.06.2025	Imaavy (nipocalimab-aahu)	Janssen
23.06.2025	Starjemza (ustekinumab-hmny)	Bio-Thera Solutions

In Q2 2025, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 39 new drugs including 4 generics/hybrids, 18 biosimilars, and 12 orphan drugs.

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

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
25.04.2025	Oczyesa (octreotide)	Camurus
22.05.2025	Blenrep (belantamab mafodotin)	GlaxoSmithKline
22.05.2025	Itovebi (inavolisib)	Roche
19.06.2025	Austedo (deutetrabenazine)	Teva

FDA inspections
According to U.S. FDA data, no inspections were conducted at Russian investigative sites during Q2 2025.

Roszdravnadzor inspections
According to the Roszdravnadzor data, as of 22 July 2025, no regulatory inspections were conducted by the agency during Q2 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.