Clinical Trials in Russia

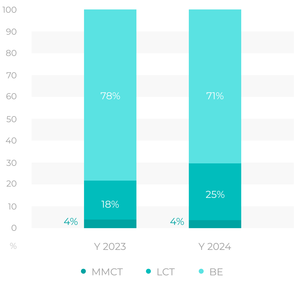
Y 2024 Research report

Trial Data

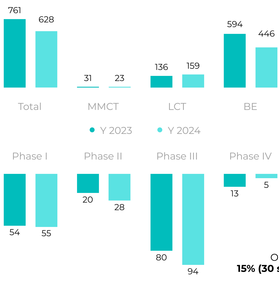
During the Year 2024 the Ministry of Health of the Russian Federation approved the start of 628 new clinical trials of all types, including local and bioequivalence studies. This represents a 17% year on year decrease by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in the Year 2024 were BE (Bio-equivalent). The market share of MMCTs (Multinational Multi-center) stayed at the same level as in 2023 and accounted for 4% of the total number of trials. The market share of Local Clinical Trials (LCTs) increased from 18% to 25% whilst the BE share decreased from 78% to 71%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

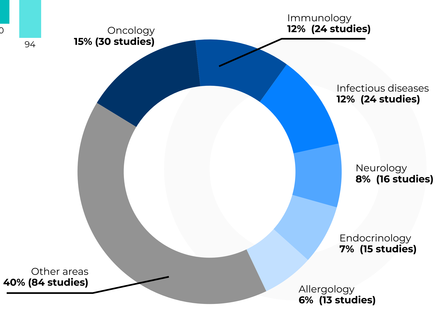


The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials increased by 18% – from 80 trials in the Year 2023 to 94 trials in the Year 2024.

The largest number of clinical trials initiated in Russia during the Year 2024 were related to Oncology (30 studies), Immunology (24), and Infectious diseases (24), Neurology (16), Endocrinology (15), Allergology (13), Dermatology (11), Pediatrics (11), Pulmonology (10), and Rheumatology (9 studies).

Breakdown of Clinical Trials in Russia in Y 2024 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

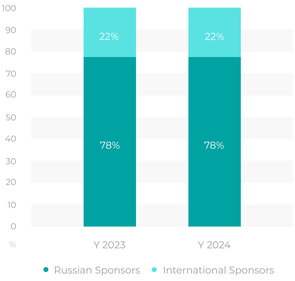
Clinical trials initiated in Russia during the Year 2024 were sponsored by pharmaceutical companies from Russia and 29 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market stayed at the same level as in the previous year – 22% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2024 was Phase III with 68% share among Phase I–IV studies.

The most prevalent Sponsor's countries of origin in the Year 2024 were Russia (488), India (51) and Belarus (17). Other prominent countries include Hungary (8 studies), Slovenia (7), Sweden (6), Iran, South Korea, and Turkey (4 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 2024

№	Company Name	Studies	Subjects
1	AstraZeneca	6	597
2	CinnaGen Co.	4	930
3	Dr. Reddy's	4	542
4	World Medicine	2	395
5	Lek	1	720
6	Belupo	1	688
7	Sandoz	1	600
8	GlaxoSmithKline	1	400
9	Cassiopea	1	365
10	Sun Pharmaceutical Industries Ltd.	1	364
	Combined market share	**12%**	**14%**

Top-10 Russian Trial Sponsors in Russia in Y 2024

№	Company Name	Studies	Subjects
1	Pharmasyntez	12	1,712
2	Generium	11	1,462
3	GeroPharm	9	1,252
4	R-Pharm	7	2,157
5	BIOCAD	7	1,965
6	Gamaleya Research Institute	6	4,014
7	Valenta	6	936
8	Grotex	4	786
9	Promomed Rus	4	774
10	Tula pharmaceutical factory	4	666
	Combined market share	**38%**	**39%**

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

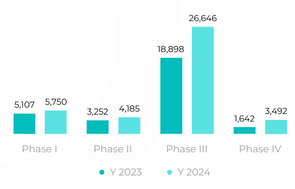
Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in Phase I-IV clinical trials initiated in Russia during the Year 2024 reached a total of 40,073 subjects – a 39% flourish in comparison with the previous year when 28,899 subjects were enrolled.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 66% of all subjects enrolled.

Number of subjects enrolled (or planned to be enrolled) in BE studies, accounted for 23,760 subjects – 23% decrease compared to the Year 2023.

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 2024

№	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	78
2	Clinical Hospital #9	Yaroslavl	47
3	Clinical Hospital #3	Yaroslavl	42
4	I.M. Sechenov First Moscow State Medical University	Moscow	40
5	Cardiology dispensary	Ivanovo	38
	Combined market share of these sites		**39%**

CRO Data

Top-10 CROs in Russia in Y 2024 (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	National Scientific Center for Research and Pharmacovigilance	6	905
2	OST Rus	5	559
3	Synergy Research Group	4	618
4	Medical Innovations and Technologies	3	810
5	Medical Development Agency	3	506
6	Benerix	3	480
7	Ligand Research	2	868
8	Accellena	2	640
9	Regana	2	395
10	iPharma	2	104
	Combined market share	**18%**	**15%**

Top-5 CROs in Russia in Y 2024 (BE studies)

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

№	Company Name	No. Studies	No. Subjects
1	Probiotech	18	825
2	AX Clinical Trials and Consulting	14	598
3	National Scientific Center for Research and Pharmacovigilance	13	637
4	Vita Aeterna	8	405
5	Synergy Research Group	6	404
	Combined market share of these companies	**13%**	**12%**

Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 38 new drugs during Q4 2024; 12 of them were new molecular entities (NME); other approvals concerned new dosages, formulations or manufacturers.

10 of these 38 drugs and 3 of 12 NMEs were tested in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
10.10.2024	Itovebi (inavolisib)	Genentech
11.10.2024	Hympavzi (marstacimab-hncq)	Pfizer
16.10.2024	Vyalev (foscarbidopa; foslevodopa)	Abbvie
25.10.2024	Orlynvah (probenecid; sulopenem etzadroxil)	Iterum Therap
20.11.2024	Ziihera (zanidatamab-hrii)	Jazz Pharms
13.12.2024	Unloxcyt (cosibelimab-ipdl)	Checkpoint Therapeutics
18.12.2024	Ensacove (ensartinib hydrochloride)	Xcovery
20.12.2024	Alhemo (concizumab-mtci)	Novo Nordisk
26.12.2024	Tevimbra (tislelizumab-jsgr)	Beigene
27.12.2024	Opdivo Qvantig (nivolumab; hyaluronidase-nvhy)	Bristol-Myers Squibb

In Q4 2024 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 35 new drugs including 4 generics/hybrids, 12 biosimilars and 6 orphan medicines.

7 drugs of approved 35 were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
17.10.2024	Alhemo (concizumab)	Novo Nordisk
14.11.2024	Lazcluze (lazertinib)	Janssen Cilag
12.12.2024	Andembry (garadacimab)	Behring
12.12.2024	Eydenzelt (aflibercept)	Celltrion
12.12.2024	Rytelo (imetelstat)	Geron
12.12.2024	Seladelpar Gilead (seladelpar lysine dihydrate)	CymaBay
12.12.2024	Welireg (belzutifan)	Merck Sharp & Dohme

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during the Year 2024.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 28/01/2025 there were no Regulatory inspections conducted by Roszdravnadzor during the Year 2024.

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: 28/01/2025

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.