

Clinical Trials in Russia

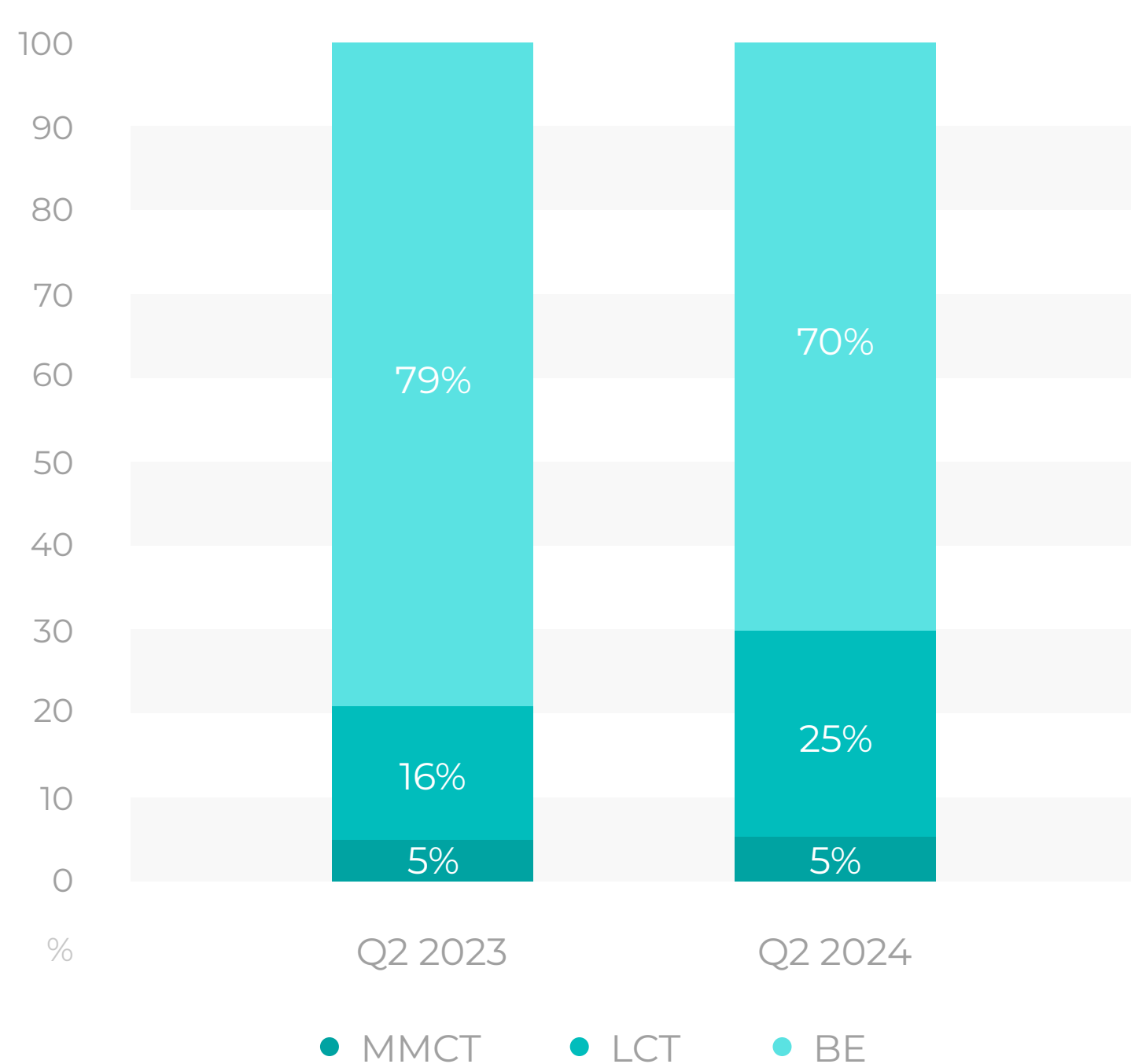
Q2 2024 Research report

Trial Data

During Q2 2024 the Ministry of Health of the Russian Federation approved the start of 130 new clinical trials of all types, including local and bioequivalence studies. This represents a 18% year on year decline by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q2 2024 were BE (Bio-equivalent Clinical Trials). The market share of BE studies slightly decreased from 79% to 70%. The market share of MMCTs (Multinational Multi-center Clinical Trials) remained at the same level of 5% whilst the market share of Local Clinical Trials (LCTs) increased from 16% to 25%.

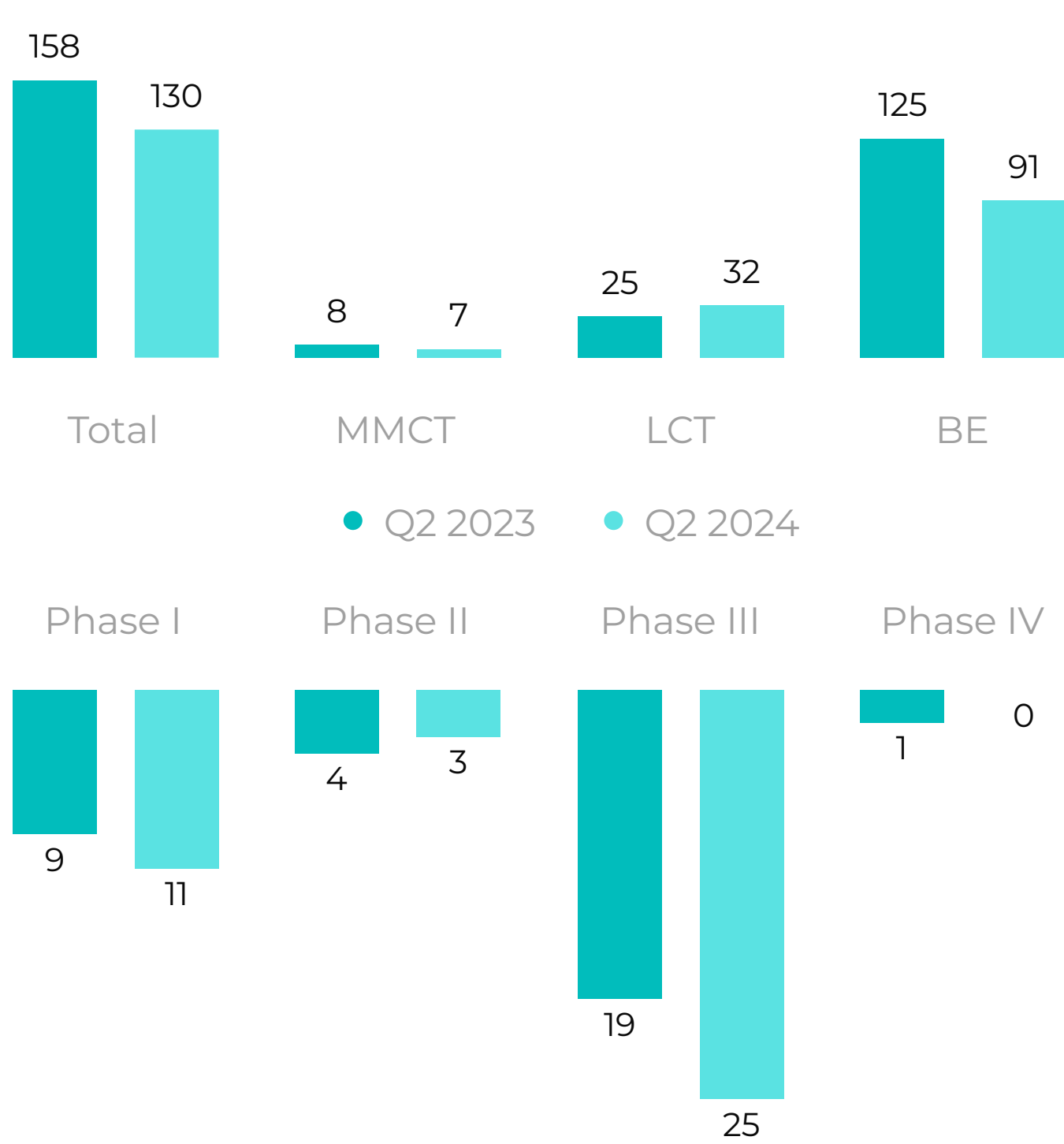
Percentage Breakdown of Clinical Trials by Type



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 32% – from 19 trials in Q2 2023 to 25 trials in Q2 2024.

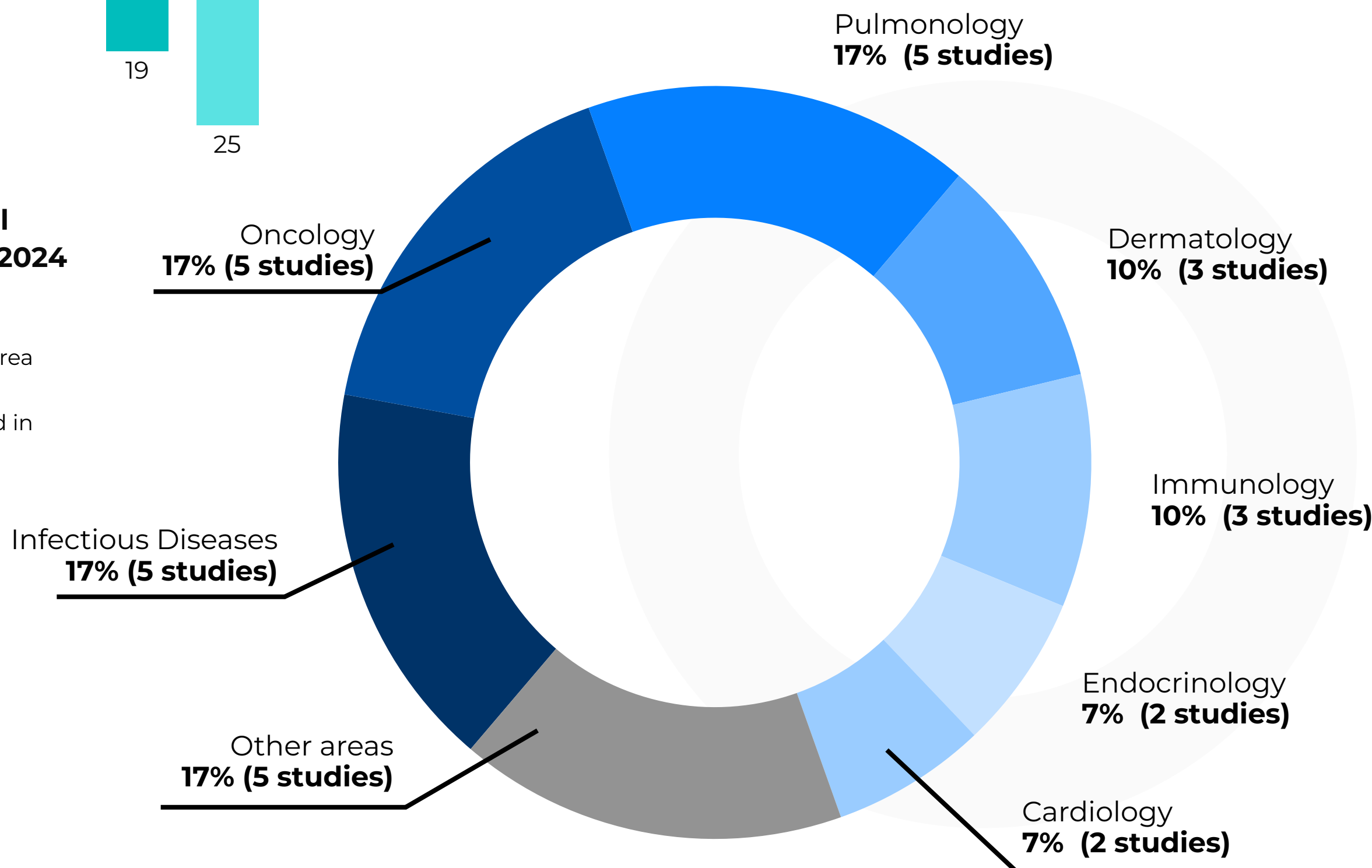
The largest number of clinical trials initiated in Russia during Q2 2024 were related to Infectious Diseases, Oncology and Pulmonology (5 studies each), Dermatology and Immunology (3 each). Other dominant therapy areas include Cardiology and Endocrinology.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Q2 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

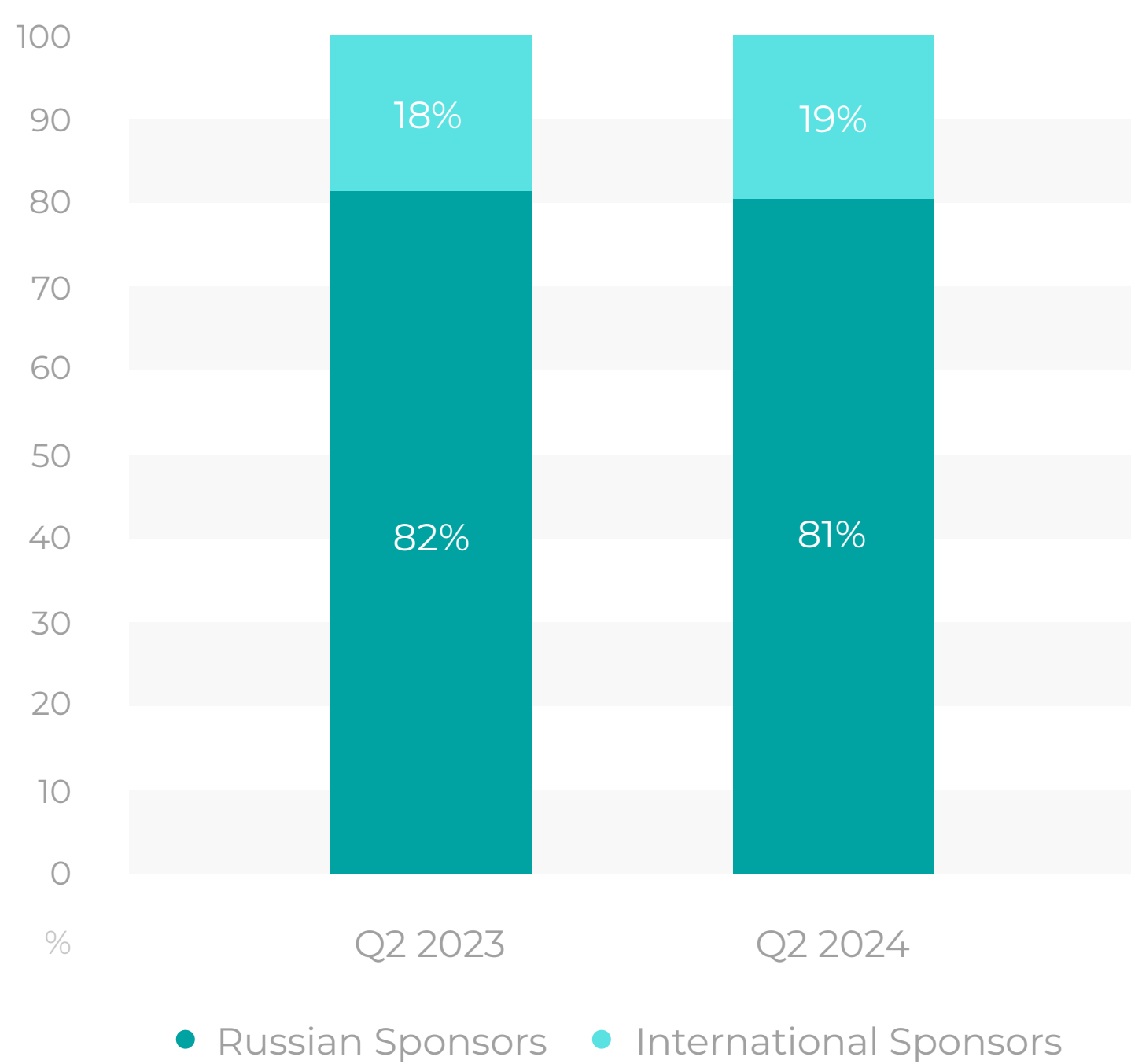
Clinical trials initiated in Russia during Q2 2024 were sponsored by pharmaceutical companies from Russia and 13 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market remained almost at the same level – 19% in Q2 2024 vs 18% in Q2 2023.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2024 was Phase III (9 studies).

The most prevalent Sponsor's countries of origin in Q2 2024 were Russia (105 studies) and India (9 studies). Other countries include Iran (3 studies), Belarus and Slovenia (2 studies each), Austria, Belgium, China, Israel, Latvia, Netherlands, Singapore, Sweden, USA (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 Q2 2024

Nº	Company Name	Studies	Subjects
1	CinnaGen Co.	3	730
2	Dr. Reddy's	2	262
3	Lek	1	720
4	GlaxoSmithKline	1	400
5	PVP Labs	1	344
6	AstraZeneca	1	267
7	Tonghua Anrate Biopharmaceutical	1	160
8	Hetero	1	30
9	Oncotelic	1	24
10	-	-	-
Combined market share		31%	34%

Top-10 Russian Trial Sponsors in Russia in Q2 2024

Nº	Company Name	Studies	Subjects
1	PharmaSynthet	3	630
2	BIOCAD	2	867
3	Gamaleya Research Institute	2	430
4	Yursfarm	2	52
5	Proton	1	1080
6	Gritvac	1	500
7	Avexima	1	480
8	R-Pharm	1	340
9	ALPharma	1	230
10	Petrovax Pharm	1	230
Combined market share		38%	56%

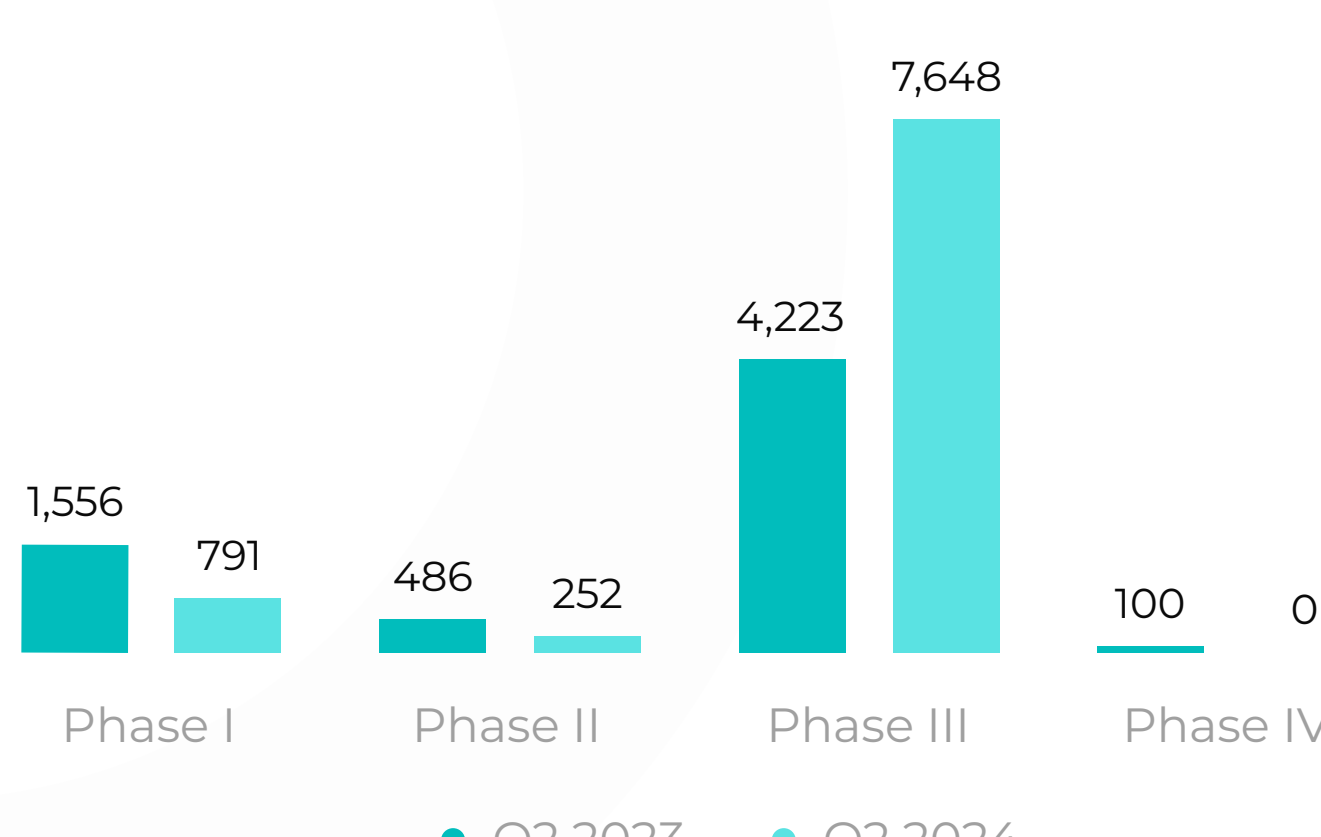
Combined market share shown as a percentage of both international and Russian sponsors. Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q2 2024 reached a total of 8,691 subjects – a 37% flourish in comparison with the previous year when 6,365 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 88% of all subjects enrolled.

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.

Breakdown of number of Subjects enrolled by Phase



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Q2 2024 Research report

Research Site Data

Top-5 Russian research sites (all studies) in Q2 2024

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	19
2	Clinical Hospital Nº9	Yaroslavl	15
3	N.P. Ogarev Mordovia State University	Saransk	9
4	Clinical Hospital Nº2	Yaroslavl	9
5	I.M. Sechenov First Moscow State Medical University	Moscow	9

Combined market share of these sites

47%

CRO Data

Top-10 CROs in Russia

in Q2 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.

Nº	Site Name	No. Studies	No. Subjects
1	National Scientific Center for Research and Pharmacovigilance	3	455
2	Medical Innovations and Technologies	2	610
3	Synergy Research Group	1	480
4	RusClinic	1	344
5	Medical Development Agency	1	230
6	M VED	1	120
7	Ecosafety	1	42
8	OST Rus	1	42
9	K-Research	1	24
10	-	-	-

Combined market share

31%

27%

Top-5 CROs in Russia

in Q2 2024 (BE studies)

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

Nº	Site Name	No. Studies	No. Subjects
1	National Scientific Center for Research and Pharmacovigilance	3	144
2	Vita Aeterna	2	127
3	Medical Development Agency	2	88
4	AX Clinical Trials and Consulting	2	78
5	Accellena	1	46

Combined market share of these companies

11%

11%

Regulatory Data

The Center for Drug Evaluation and Research (CDER) of the FDA approved 40 new drugs during Q2 2024; 9 of them were new molecular entities (NME); other approvals concerned new active ingredients, new dosages, formulations or manufacturers.

12 of these 40 drugs and 4 of 9 NMEs were tested in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
03.04.2024	Zevtera (Ceftobiprole Medocaril Sodium)	Basilea Pharm Allsch
10.04.2024	Retevmo (Selpercatinib)	Loxo Oncol Eli Lilly
12.04.2024	Entresto Sprinkle (Sacubitril; Valsartan)	Novartis
18.04.2024	Entyvio (Vedolizumab)	Takeda Pharms
24.04.2024	Vijoice (Alpelisib)	Novartis
26.04.2024	Xolremdi (Mavorixafor)	X4 Pharms
26.04.2024	Rinvoq (Upadacitinib)	Abbvie
26.04.2024	Rinvoq LQ (Upadacitinib)	Abbvie
30.04.2024	Ingrezza Sprinkle (Valbenazine Tosylate)	Neurocrine
20.05.2024	Opuviz (Aflibercept-Yszy)	Samsung Bioepis Co Ltd
06.06.2024	Rytelo (Imetelstat Sodium)	Geron
26.06.2024	Ohtuvayre (Ensifentrine)	Verona Pharma

In Q2 2024 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 32 new drugs including 8 generics, 4 biosimilars and 5 orphan drugs.

4 drugs from approved 32 were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
25.04.2024	Jeraygo (Aprocintentan)	Idorsia
25.04.2024	Truqap (Capiasertib)	AstraZeneca
27.06.2024	Balversa (Erdafitinib)	Janssen-Cilag
25.04.2024	Obgemsa (Vibegron)	Pierre Fabre

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q2 2024.

Roszdraznadzor inspections

According to the Roszdraznadzor quarterly report, as of 24/07/2024 there were no Regulatory inspections conducted by Roszdraznadzor during Q2 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: 24/07/2024

About Synergy Research Group

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

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.

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

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.

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.