

Clinical Trials in Russia

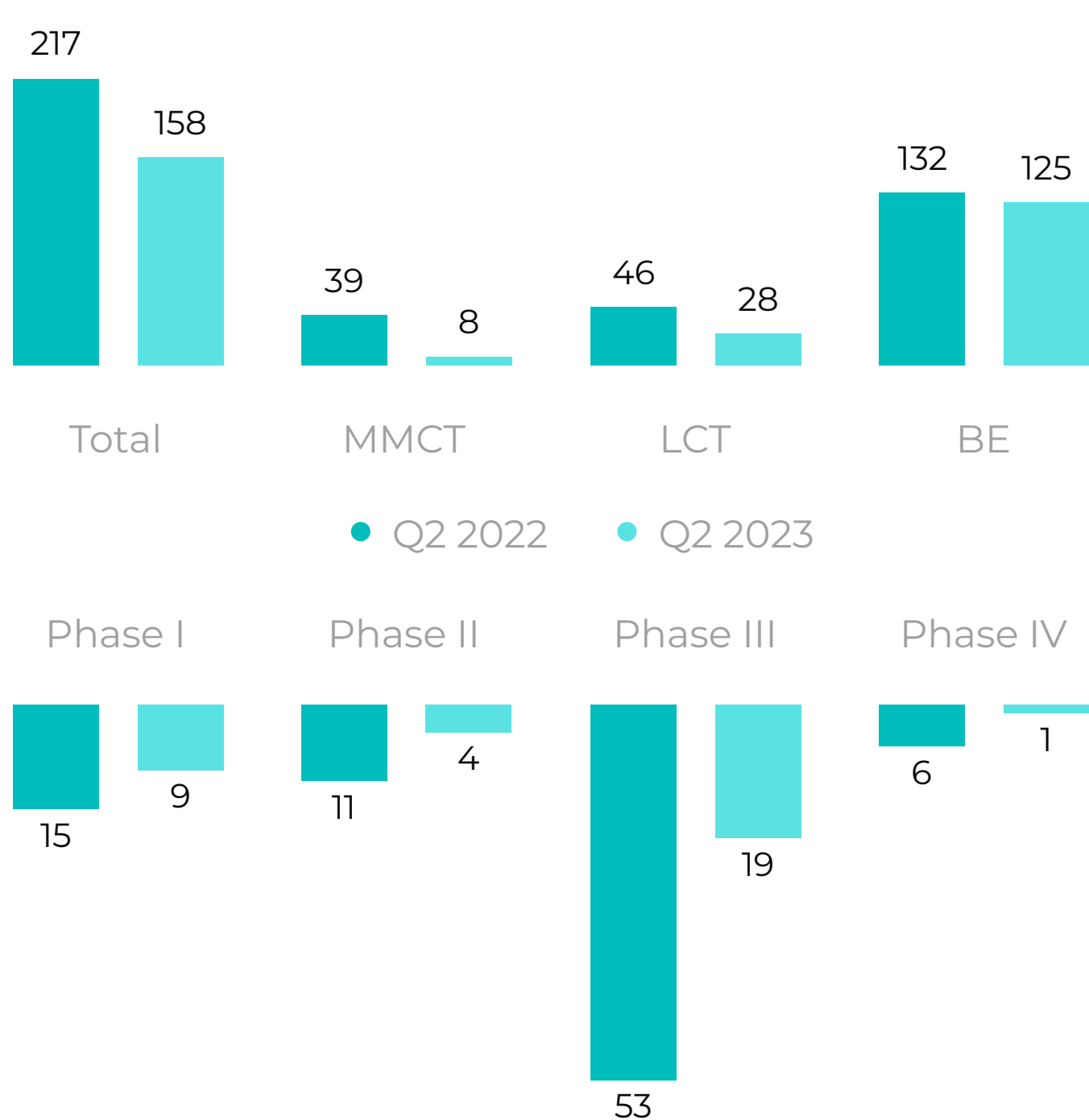
Q2 2023 Research report

Trial Data

During Q2 2023 the Ministry of Health of the Russian Federation approved the start of 158 new clinical trials of all types, including local and bioequivalence studies. This represents a 27% year on year decline by the total number of studies.

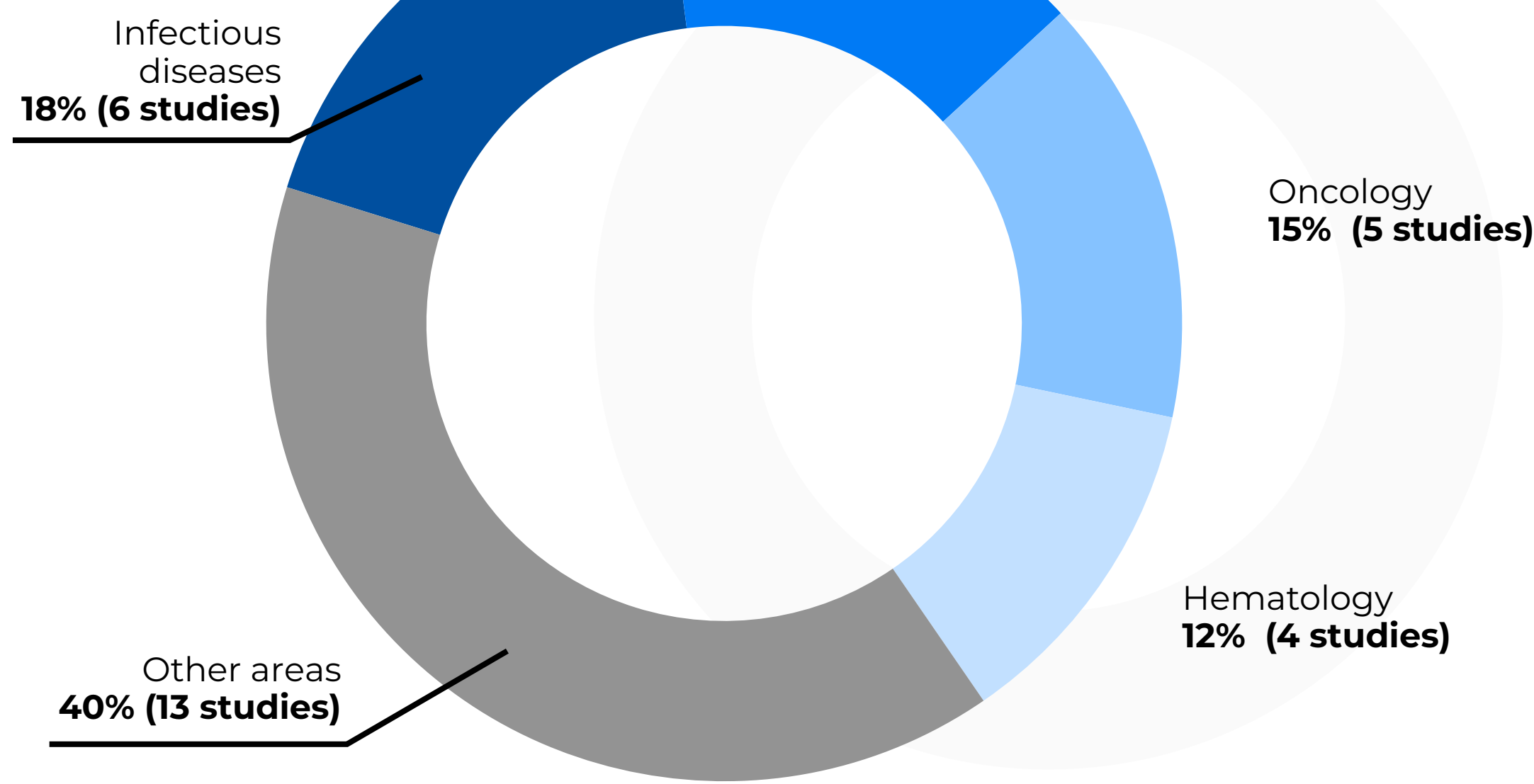
The dominant type of clinical trials conducted across Russian sites in Q2 2023 were BE (Bio-equivalent Clinical Trials). The market share of BE studies increased from 61% to 79%. The market share of MMCTs (Multinational Multi-center Clinical Trials) dropped from 18% to 5% whilst the market share of Local Clinical Trials (LCTs) shrank from 21% to 16%.

Breakdown of Clinical Trials by Type and Phase

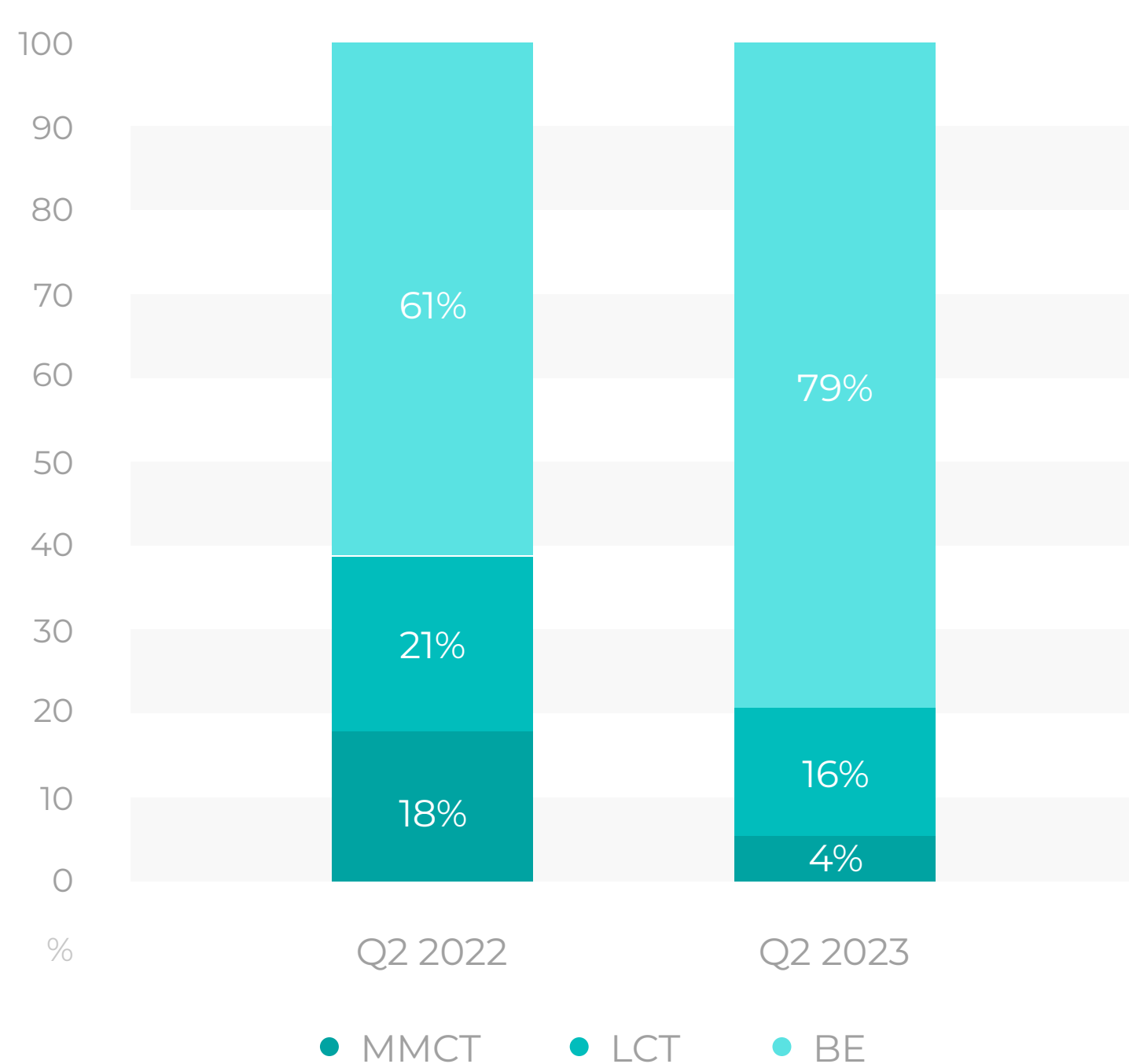


Breakdown of Clinical Trials in Russia in Q2 2023 by Therapeutic Area

More than one therapeutic area may be assigned to a trial. BE studies were not included in any therapeutic area group.



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 dropped by 64% – from 53 trials in Q2 2022 to 19 trials in Q2 2023.

The largest number of clinical trials initiated in Russia during Q2 2023 were related to Infectious Diseases (6 studies), Immunology (5 studies), Oncology (5 studies) and Hematology (4 studies). Other dominant therapy areas include Endocrinology, Gastroenterology and Urology.

Sponsor Data

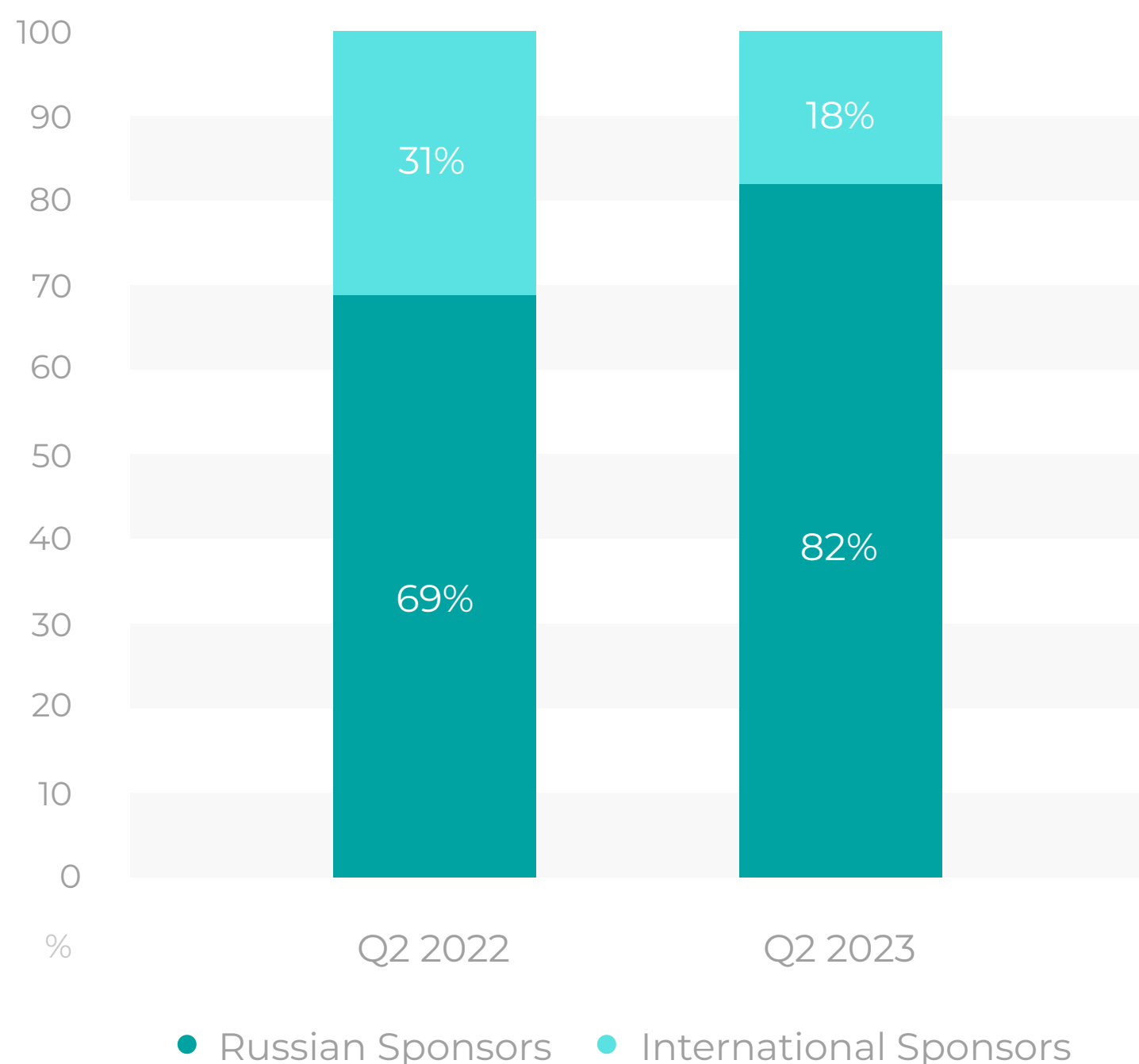
Clinical trials initiated in Russia during Q2 2023 were sponsored by pharmaceutical companies from Russia and 8 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 31% to 18% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2023 was Phase III with just 15% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q2 2023 were Russia (129 studies), India (14) and Belarus (4). Other prominent countries include Switzerland (3 studies), Turkey (2), Slovenia (2) and Austria (2).

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 2023

Nº	Company Name	Studies	Subjects
1	Dr. Reddy's Laboratories	2	140
2	Sun Pharma	1	122
3	Glenmark Pharm.	1	44
4	Hoffman-la Roche	1	5
5	-	-	-
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
Combined market share		15%	5%

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

Top-10 Russian Trial Sponsors in Russia in Q2 2023

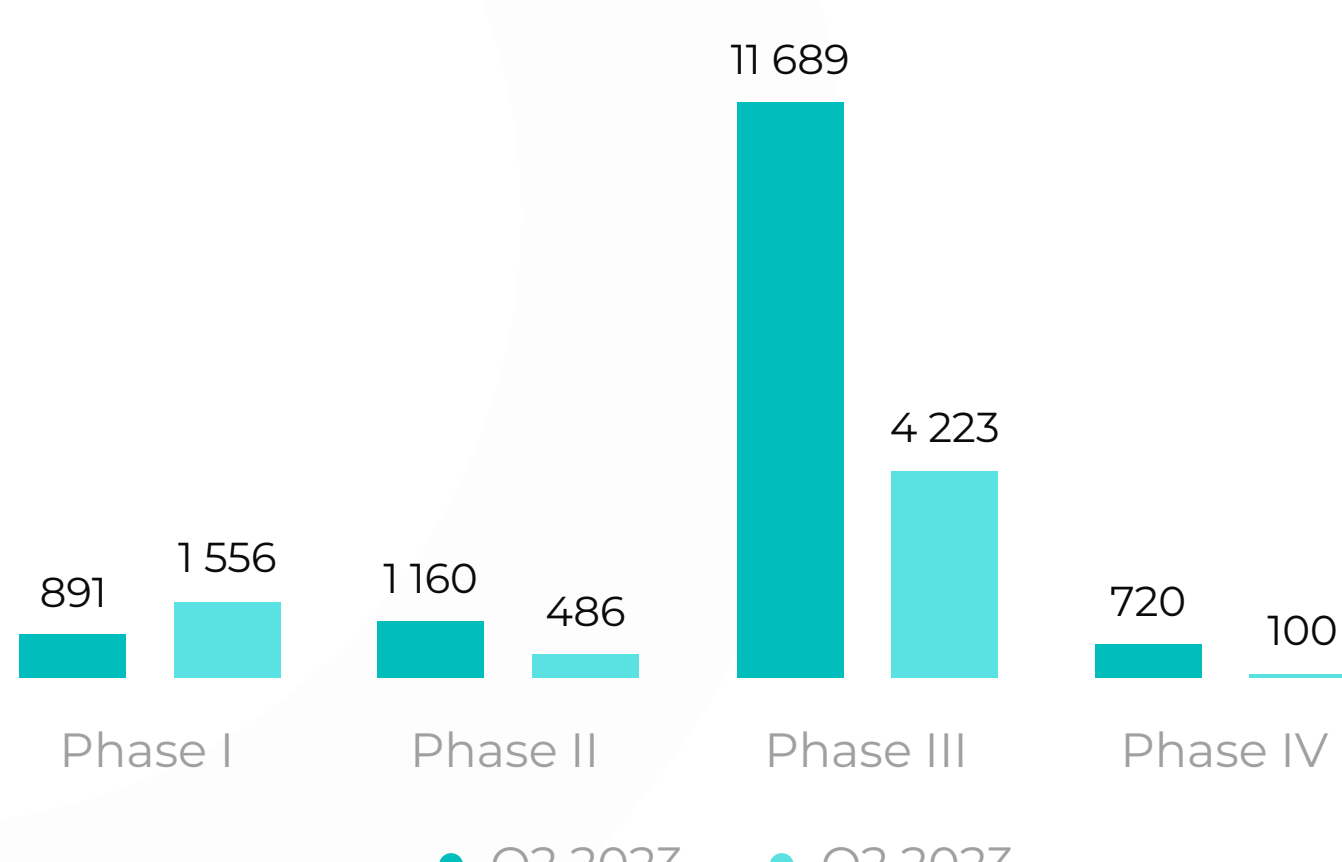
Nº	Company Name	Studies	Subjects
1	GeroPharm	4	650
2	BIOCAD	3	594
3	Mabscale	2	458
4	PeptidPRO	2	410
5	Gamaleya Research Institute	2	350
6	AFS Technologies	2	288
7	PharmaSynthet	2	26
8	Materia Medica Holding	1	632
9	Polysan	1	560
10	Pharm-Synthet	1	550
Combined market share		61%	71%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q2 2023 reached a total of 6,365 subjects – a 56% crush in comparison with the previous year when 14,460 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.

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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Research Site Data

Top-5 Russian research sites (all studies) in Q2 2023

Nº	Site Name	City	No. Studies
1	Clinical Hospital №3	Yaroslavl	17
2	Ligand Research	Moscow	13
3	Clinical Hospital №2	Yaroslavl	12
4	I.M. Sechenov First Moscow State Medical University	Moscow	12
5	Ecosafety	Saint-Petersburg	9

Combined market share of these sites

40%

CRO Data

Top-10 CROs in Russia in Q2 2023 (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	Medical Development Agency	3	530
2	Benerix	2	458
3	iPharma	1	560
4	MDP KIO	1	280
5	OST Rus	1	40
6	-	-	-
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-

Top-5 CROs in Russia in Q2 2023 (BE studies)

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

Nº	Site Name	No. Studies	No. Subjects
1	Probiotec Medical Center	4	199
2	Accellena	4	158
3	Ligand Research	3	190
4	X7 Clinical Research	2	96
5	ClinPharmInvest	1	80

Combined market share of these companies

11%

11%

Regulatory Data

During Q2 2023 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 40 new drugs, including 7 new molecular entity (NME); other approvals concerned new dosages, combinations or manufacturers.

Nine of these 40 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
25.04.2023	Qalsodynda (Tofersen)	Biogen
26.04.2023	Zejulanda (Niraparib Tosylate)	GlaxoSmithKline
27.04.2023	Abilify Asimtuftinda (Aripiprazole)	Otsuka
28.04.2023	Symbicort Aerospherenda (Budesonide; Formoterol Fumarate)	AstraZeneca
12.05.2023	Veozahnda (Fezolinetant)	Astellas Pharma
19.05.2023	Epkinlybla (Epcoritamab)	Genmab
26.05.2023	Inpefanda (Sotagliflozin)	Lexicon Pharms
20.06.2023	Vyvgart Hytrulobla (Afgartigimod Alfa; Yaluronidase)	Argenx
26.06.2023	Rystiggobla (Rozanolixizumab)	UCB BioPharma

In Q2 2023 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 20 new drugs including 0 generics, 1 biosimilar and 5 orphan medicines.

Thirteen of these 20 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
26.04.2023	Orkambi (Lumacaftor; Ivacaftor)	Vertex Pharmaceuticals
26.04.2023	Adempas (Riociguat)	Bayer
26.05.2023	Sogroya (Somapacitan)	Novo Nordisk
26.05.2023	Ztalmy (Ganaxolone)	Marinus Pharmaceuticals
22.06.2023	Refixia (Nonacog Beta Pegol)	Novo Nordisk
22.06.2023	Lonsurf (Trifluridine; Tipiracil Hydrochloride)	Servier
22.06.2023	Trodely (Sacituzumab Govitecan)	Gilead Sciences
22.06.2023	Jardiance (Empagliflozin)	Boehringer Ingelheim
22.06.2023	Soliris (Eculizumab)	Alexion
22.06.2023	Aquipta (Atogepant)	AbbVie
22.06.2023	Imjudo (Tremelimumab)	AstraZeneca
22.06.2023	Jesduvroq (Daprodustat)	GlaxoSmithKline
22.06.2023	Mircera (Methoxy Polyethylene Glycol-Epoetin Beta)	Hoffmann-La Roche

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q2 2023.

Roszdraznador inspections

According to the Roszdraznador quarterly report, as of 14/07/2023 there were no Regulatory inspections conducted by Roszdraznador during Q2 2023.

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: 14/07/2023

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 consistently in TOP-10 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.