

# Clinical Trials in Russia

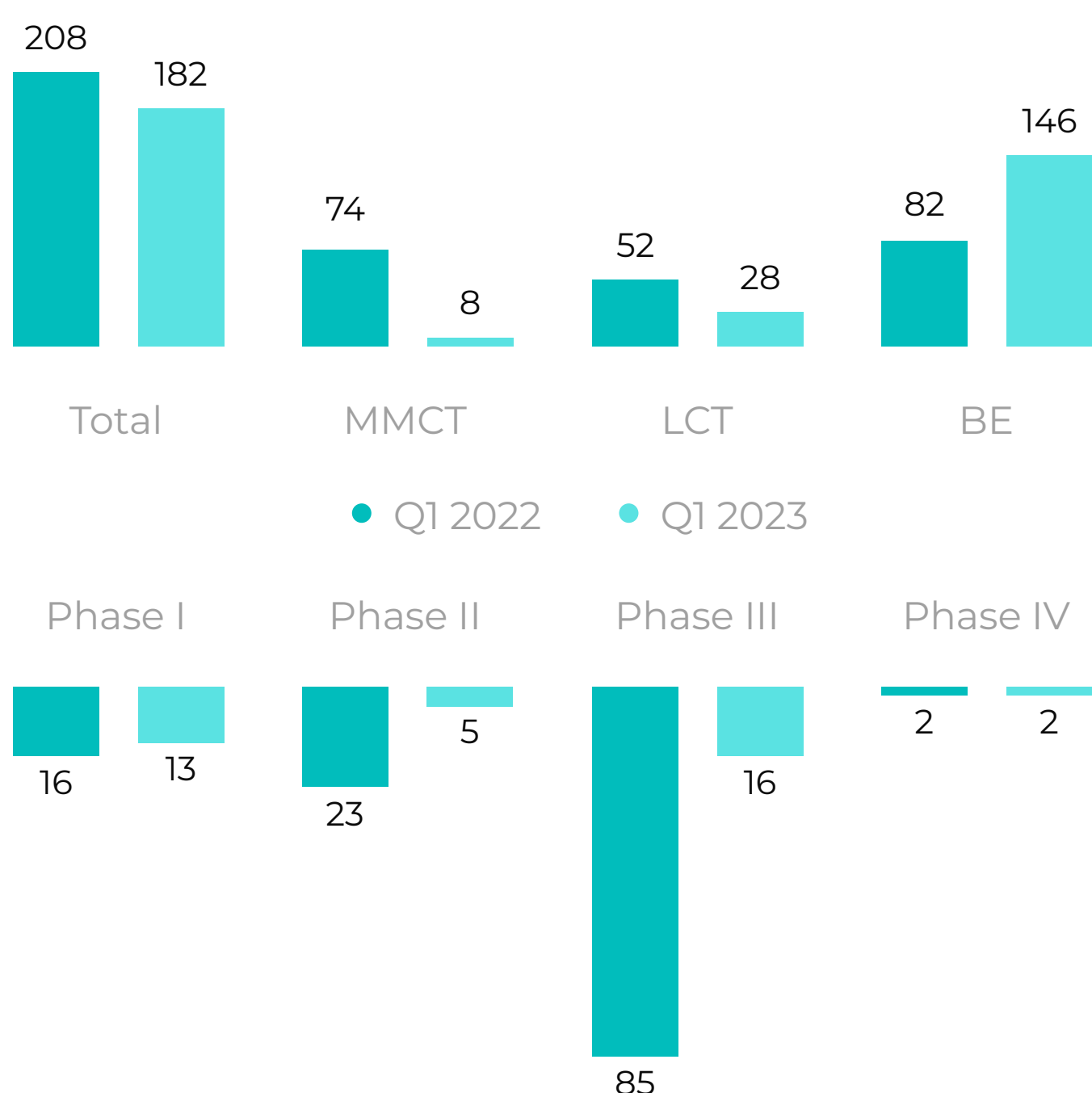
Q1 2023 Research report

## Trial Data

During Q1 2023 the Ministry of Health of the Russian Federation approved the start of 182 new clinical trials of all types, including local and bioequivalence studies. This represents a 13% year on year decline by the total number of studies.

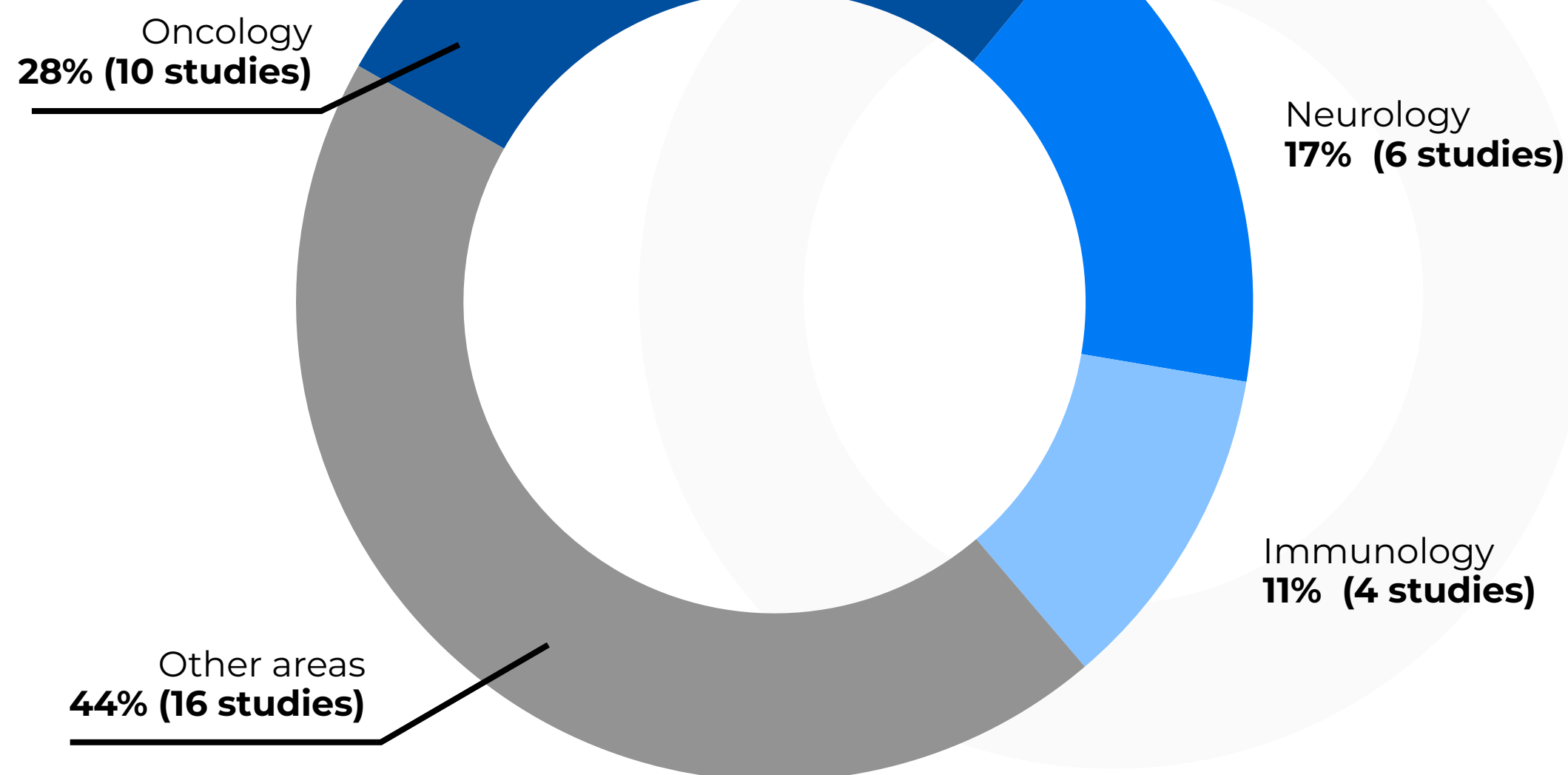
The dominant type of clinical trials conducted across Russian sites in Q1 2023 were BE (Bio-equivalent Clinical Trials). The market share of BE studies achieved the unprecedented rate of 80% and doubled from 39% in the previous year. The market share of MMCTs (Multinational Multi-center Clinical Trials) collapsed from 36% to 5% whilst Local Clinical Trials declined from 25% to 15%.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Q1 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.



## Sponsor Data

Clinical trials initiated in Russia during Q1 2023 were sponsored by pharmaceutical companies from Russia and 14 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 46% to 19% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q1 2023 was Phase III with 22% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q1 2023 were Russia (147 studies), Belarus (6 studies) and India (6 studies). Other prominent countries include the U.S. (5 studies), Croatia (3 studies) and Romania (3 studies).

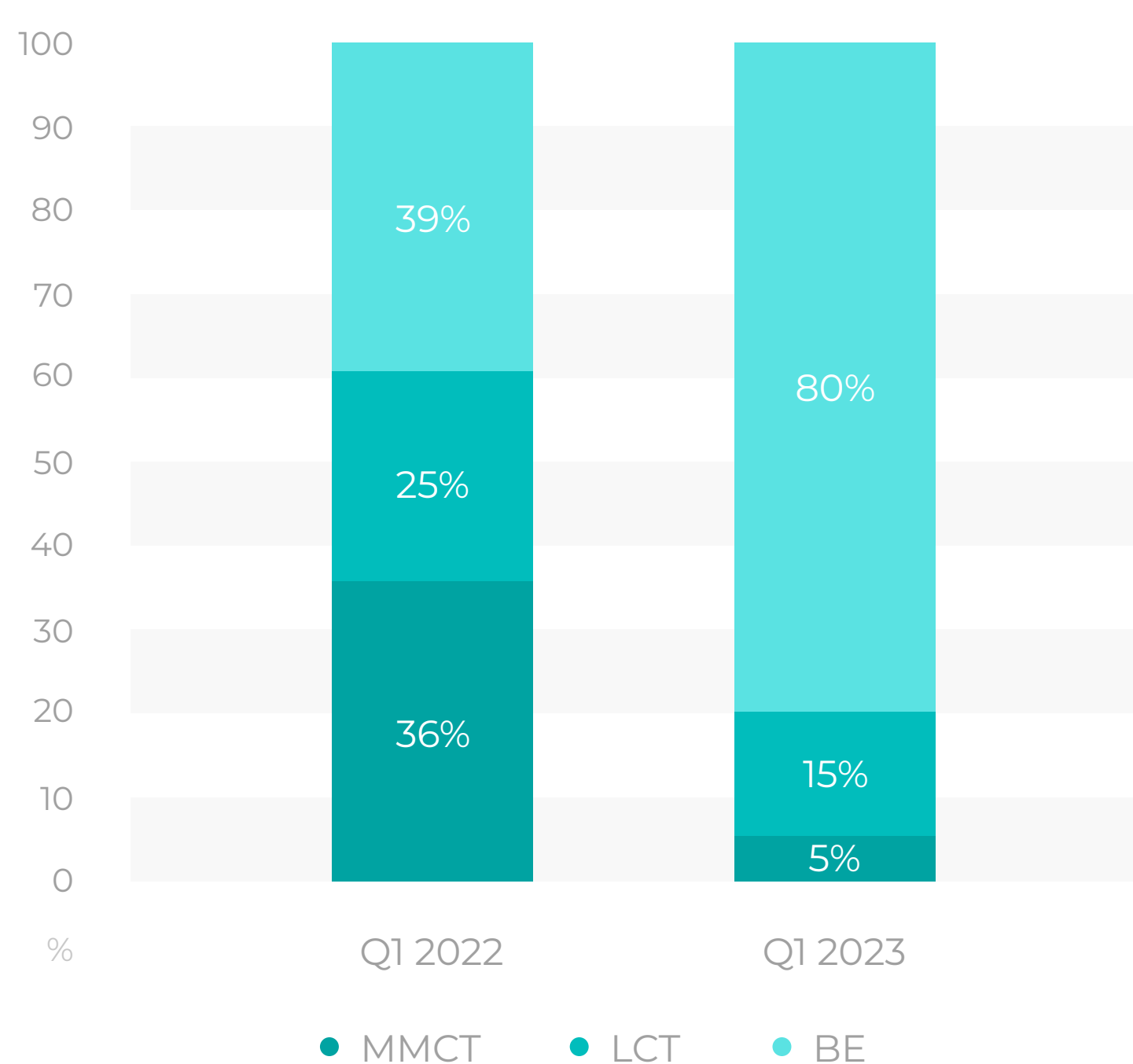
Observational trials and trials without FDA-defined phases (from I to IV) were not counted in the following ranking.

Top-10 International Trial Sponsors in Russia in Q1 2023

Nº	Company Name	Studies	Subjects
1	Agenus	2	170
2	Besins Healthcare	1	332
3	Rompharm	1	220
4	Daewon	1	200
5	Belupo	1	182
6	Hyperion	1	120
7	Serum Institute of India	1	80
8	Merck	1	39
9	Abbvie	1	10
10	Pfizer	1	3
Combined market share		31%	23%

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

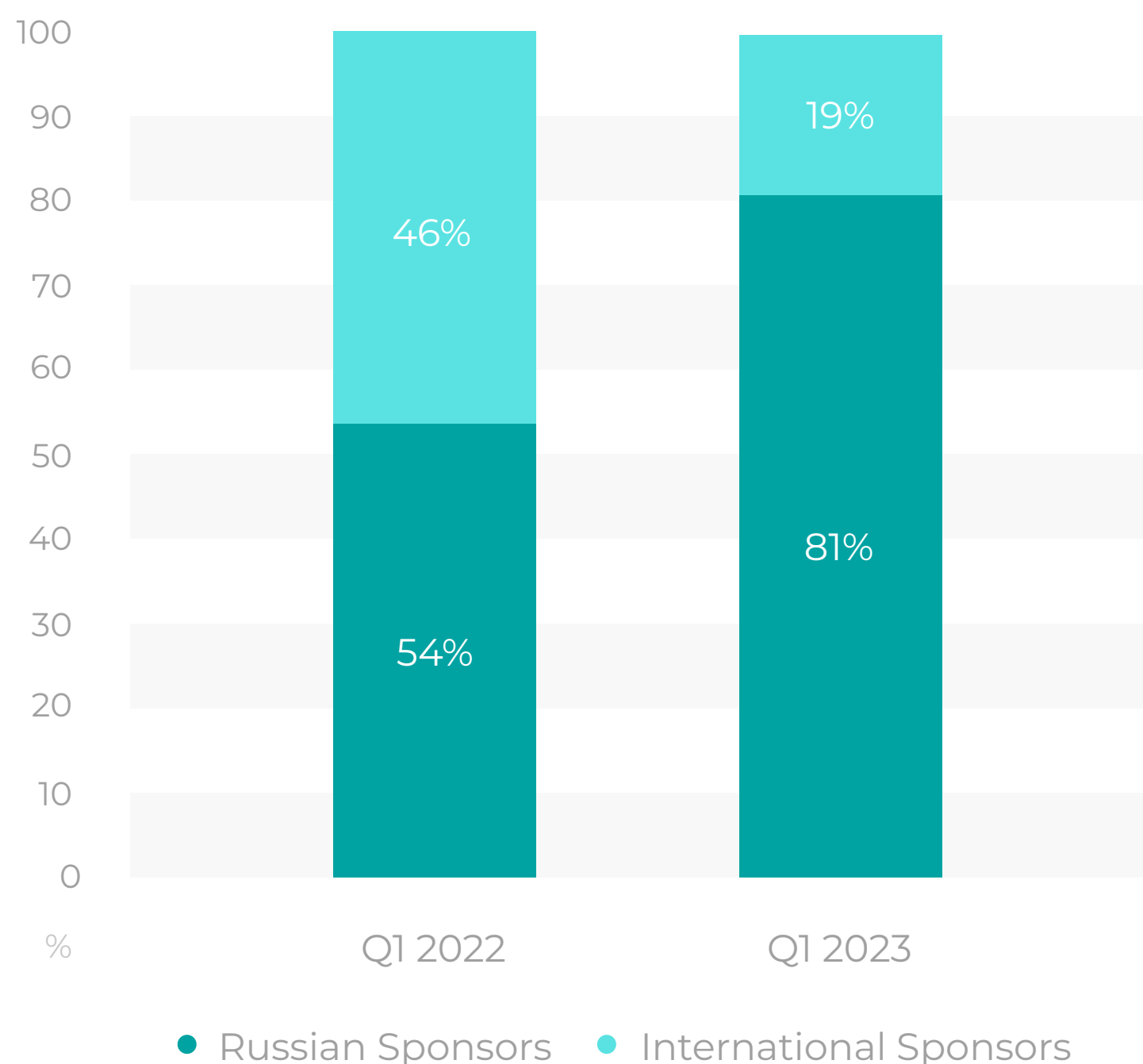
Percentage Breakdown of Clinical Trials by Type



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 crashed by 81% – from 85 trials in Q1 2022 to 16 trials in Q1 2023.

The largest number of clinical trials initiated in Russia during Q1 2023 were related to Oncology (10 studies), Neurology (6 studies) and Rheumatology (4 studies). Other dominant therapy areas include Hematology, Dermatology and Infectious diseases.

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 Russian Trial Sponsors in Russia in Q1 2023

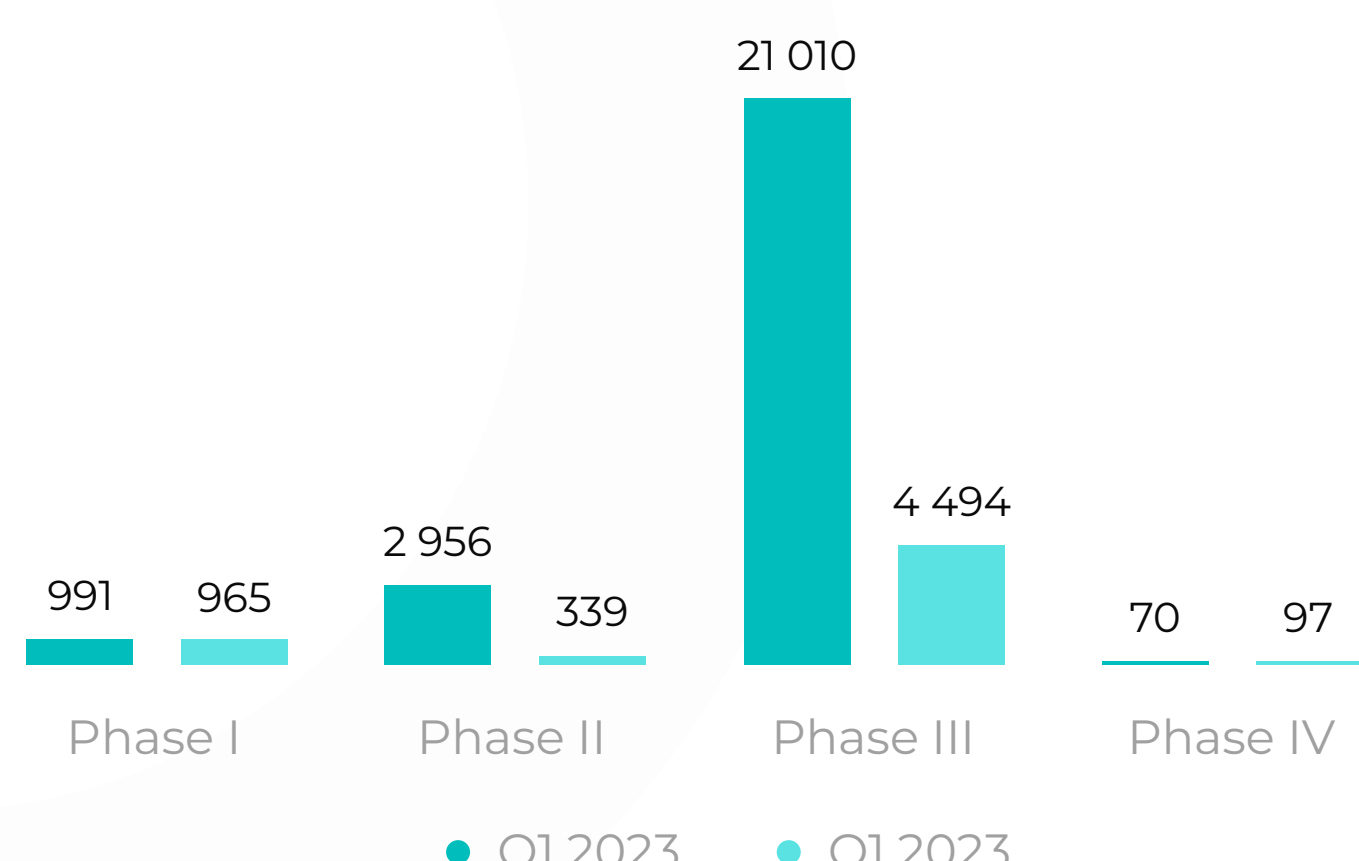
Nº	Company Name	Studies	Subjects
1	Generium	4	820
2	Promomed	4	740
3	BIOCAD	2	738
4	AVVA	2	60
5	Mabscale	1	884
6	Microgen	1	600
7	Polysan	1	120
8	Petrovax Pharm	1	105
9	Moscow Pharmaceutical Factory	1	96
10	Grand	1	90
Combined market share		50%	72%

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q1 2023 reached a total of 5,895 subjects – a 77% crash in comparison with the previous year when 25,027 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 76% 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





# Clinical Trials in Russia

Q1 2023 Research report

## Research Site Data

### Top-5 Russian research sites (all studies) in Q1 2023

Nº	Site Name	City	No. Studies
1	City Hospital Nº 3	Yaroslavl	17
2	City Hospital Nº 2	Yaroslavl	14
3	Ecosafety	Saint Petersburg	14
4	I.M. Sechenov First Moscow State Medical University	Moscow	12
5	Clinical Hospital Nº 9	Yaroslavl	11

Combined market share of these sites

37%

## CRO Data

### Top-10 CROs in Russia

in Q1 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	X7 Clinical Research	3	302
2	Atlant Clinical	2	170
3	Benerix	1	884
4	iPharma	1	120
5	Ecosafety	1	42
6	Accellena	1	32
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-

### Top-5 CROs in Russia

in Q1 2023 (BE studies)

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

Combined market share

25%

26%

Nº	Site Name	No. Studies	No. Subjects
1	Probiotec Medical Center	4	181
2	National Scientific Center for Research and Pharmacovigilance	4	155
3	ClinPharmDevelopment	2	100
4	Medical Development Agency	2	88
5	Accellena	2	64

Combined market share of these companies

10%

7%

## Regulatory Data

During Q1 2023 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 24 new drugs, including 10 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Five of these 24 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
20.01.2023	Brenzavynda (Bexagliflozin)	TheracosBio
27.01.2023	Jaypircanda (Pirtobrutinib)	Loxo Oncology
01.02.2023	Jesduvroqnda (Daprodustat)	GlaxoSmithKline
17.02.2023	Syfovrenda (Pegcetacoplan)	Apellis Pharms
16.03.2023	Mekinistnda (Trametinib Dimethyl Sulfoxide)	Novartis

In Q1 2023 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 27 new drugs including 5 generics, 2 biosimilar and 3 orphan medicines.

Eleven of these 27 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
26.01.2023	Tolvaptan Accord (Tolvaptan)	Accord Healthcare
26.01.2023	Sitagliptin / Metformin Hydrochloride Sun (Sitagliptin Fumarate; Metformin Hydrochloride)	Sun Pharma
23.02.2023	Tidhesco (Ivosidenib)	Servier
23.02.2023	Tibsovo (Ivosidenib)	Servier
23.02.2023	Libtayo (Cemiplimab)	Regeneron
23.02.2023	Akeega (Abiraterone Acetate; Niraparib Tosilate Monohydrate)	Janssen
30.03.2023	OmvoH (Mirikizumab)	Eli Lilly
30.03.2023	Wegovy (Semaglutide)	Novo Nordisk
30.03.2023	Entresto (Sacubitril; Valsartan)	Novartis
30.03.2023	Ultomiris (Ravulizumab)	Alexion
30.03.2023	Neparvis (Sacubitril; Valsartan)	Novartis

### FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q1 2023.

### Roszdrazvnadzor inspections

According to the Roszdrazvnadzor quarterly report, as of 26/04/2023 there were no Regulatory inspections conducted by Roszdrazvnadzor during Q1 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: 26/04/2023

## 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.