

# Clinical Trials in Russia

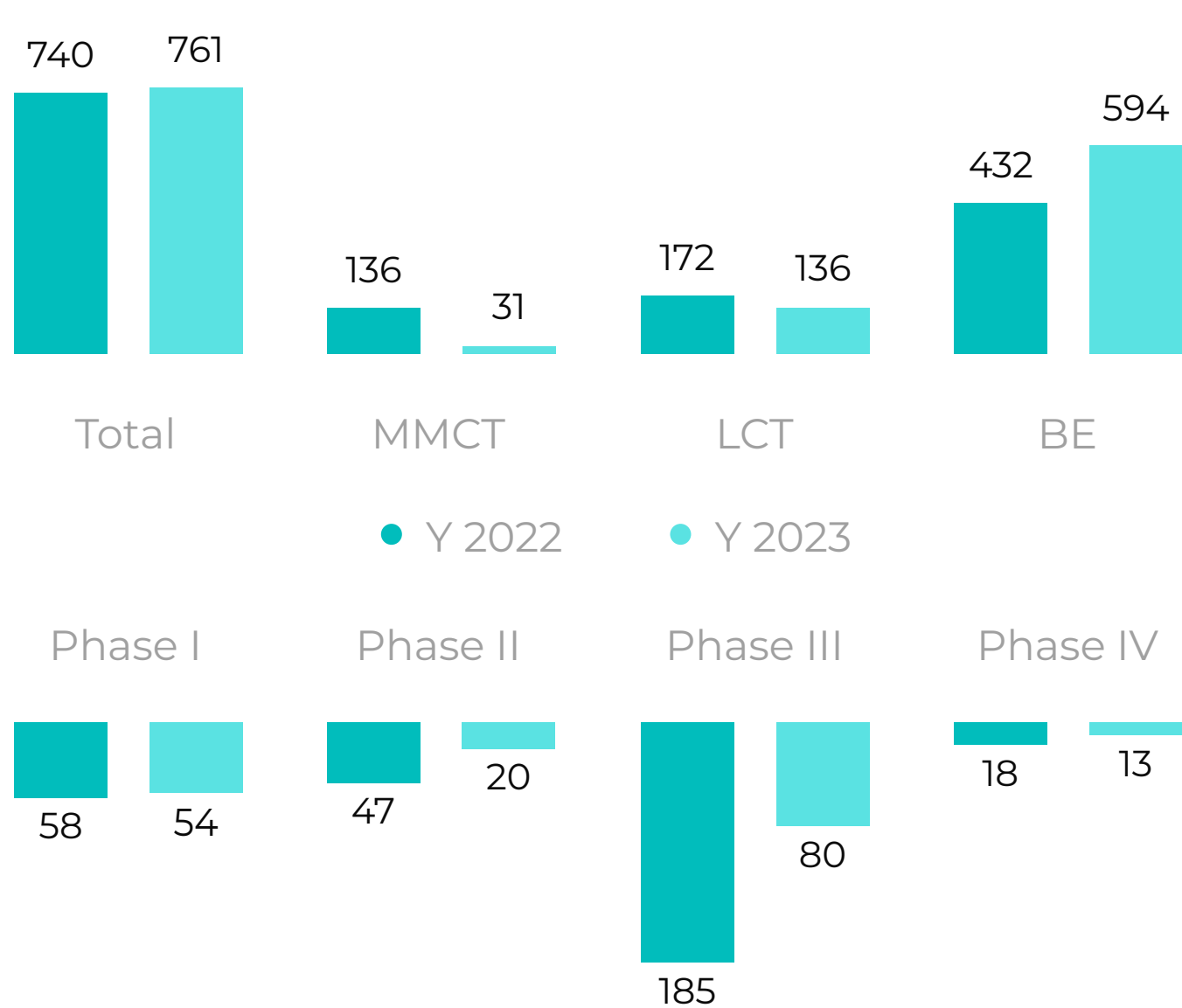
Y 2023 Research report

## Trial Data

During the Year 2023 the Ministry of Health of the Russian Federation approved the start of 761 new clinical trials of all types, including local and bioequivalence studies. This represents a 3% year on year increase by the total number of studies.

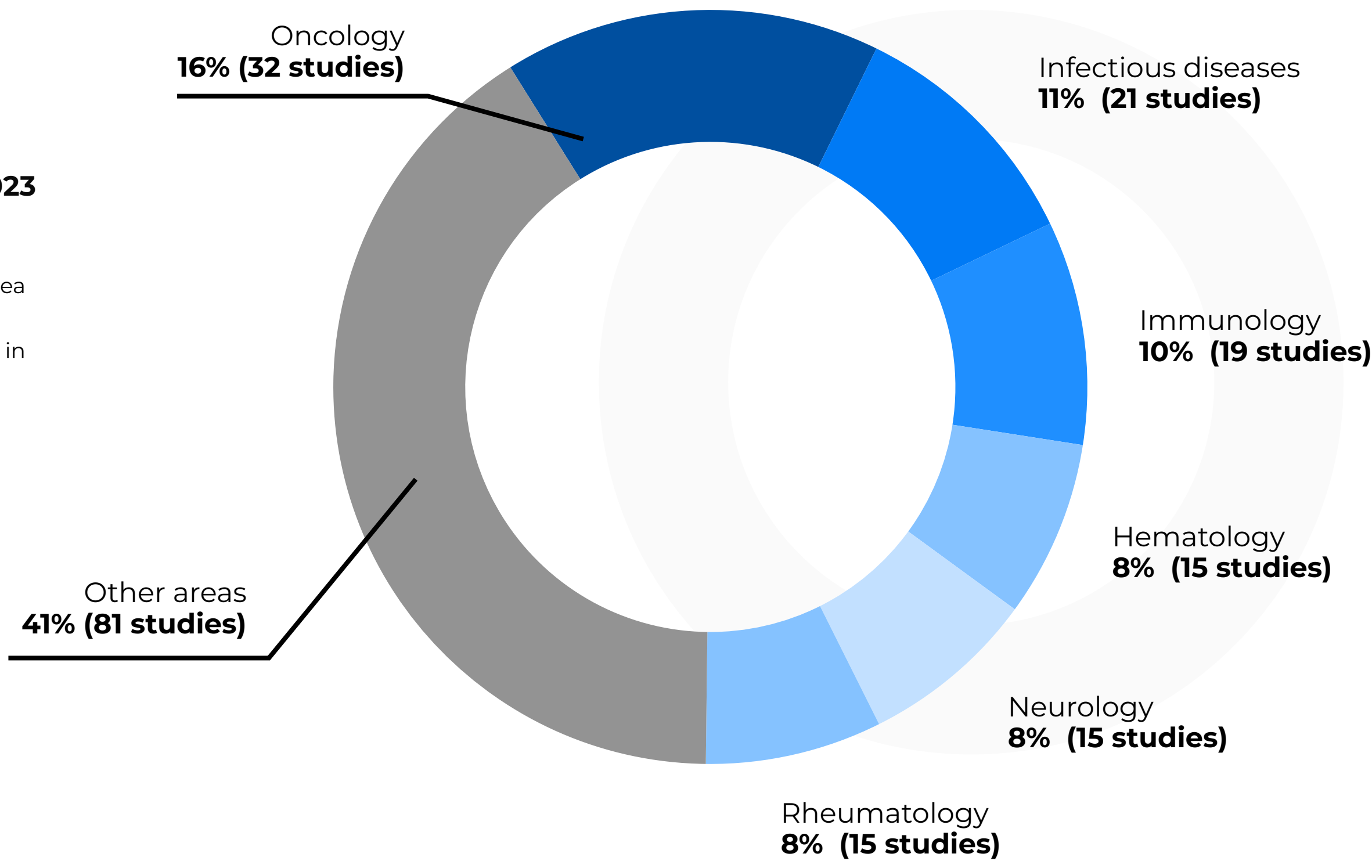
The dominant type of clinical trials conducted across Russian sites in the Year 2023 were BE (Bio-equivalent Clinical Trials). The market share of MMCTs (Multinational Multi-center Clinical Trials) dropped from 18% to 4% of the total number of trials. The market share of Local Clinical Trials (LCTs) decreased from 23% to 18% whilst the Bio-equivalent (BE) share flourished from 58% to 78%.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Y 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 the Year 2023 were sponsored by pharmaceutical companies from Russia and 24 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 29% to 22% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2023 was Phase III with 48% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in the Year 2023 were Russia (596), India (62) and Belarus (31). Other prominent countries include Slovenia (nine studies), Turkey (eight), USA and Switzerland (seven studies each).

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

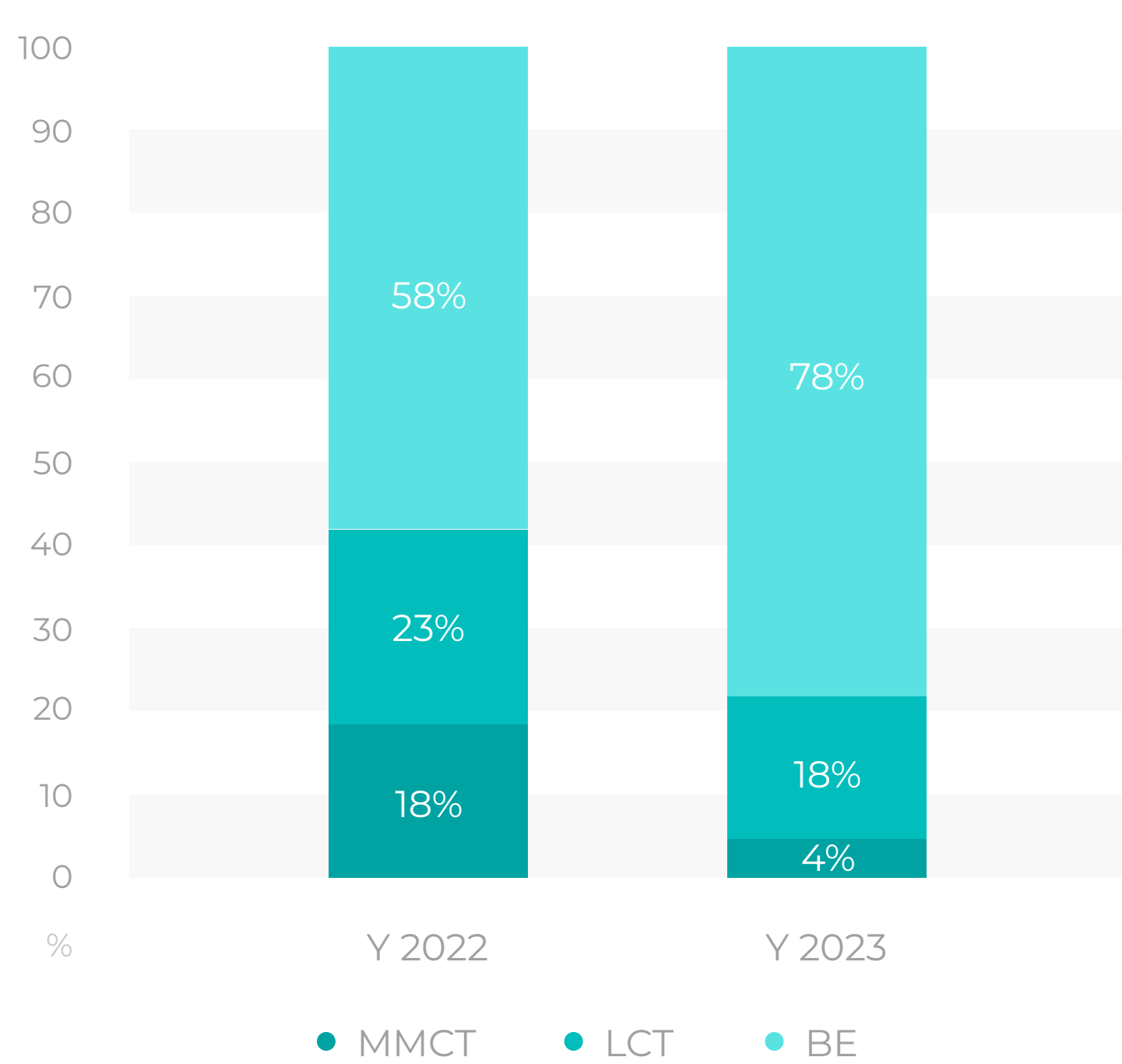
Top-10 International Trial Sponsors in Russia in Y 2023

Nº	Company Name	Studies	Subjects
1	AstraZeneca	4	308
2	Sun Pharmaceuticals	2	284
3	Agenus	2	170
4	Ascentage	2	145
5	Dr. Reddy's	2	140
6	Hoffmann-La Roche	2	7
7	Wockhardt	1	380
8	Besins Healthcare	1	332
9	Rompharm Company	1	220
10	Daewon Pharm	1	200
Combined market share		11%	8%

Combined market share based on total studies conducted by both sponsors and CROs.

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

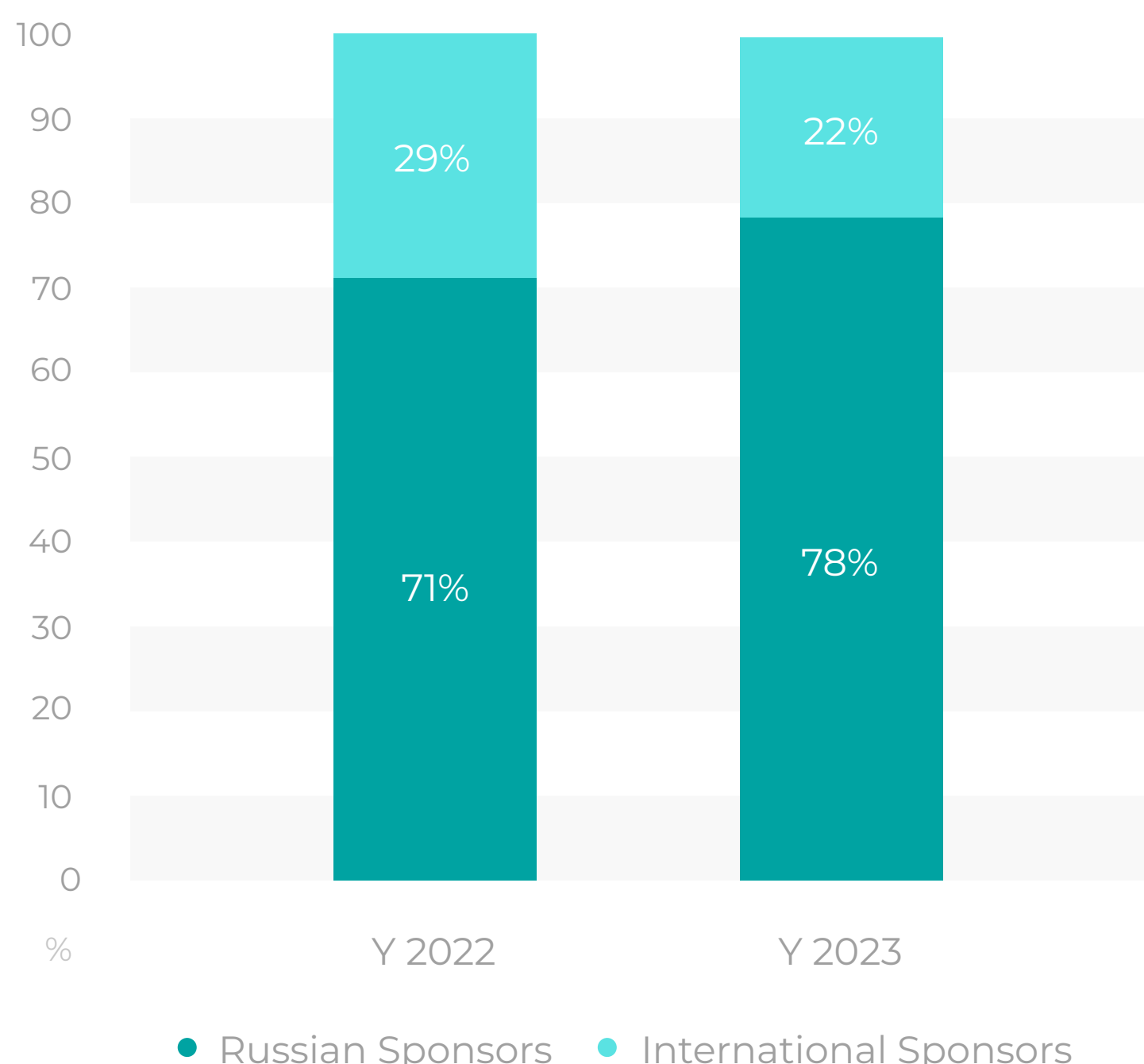
Percentage Breakdown of Clinical Trials by Type



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 dropped by 57% – from 185 trials in the Year 2022 to 80 trials in the Year 2023.

The largest number of clinical trials initiated in Russia during the Year 2023 were related to Oncology (32 studies), Infectious diseases (21 studies), Immunology (19 studies), Hematology, Neurology and Rheumatology (15 each). Other dominant therapy areas include Gastroenterology, Dermatology, Endocrinology and Pulmonology.

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 Y 2023

Nº	Company Name	Studies	Subjects
1	BIOCAD	11	2,925
2	Generium	9	1,862
3	Gamaleya Research *	9	1,073
4	PROMOMED	7	1,180
5	GeroPharm	7	916
6	Grotex	6	1,078
7	Binnopharm	5	1,031
8	Mabscale	4	1,836
9	POLISAN	4	1,561
10	PeptidPRO	4	810
Combined market share		40%	49%

\* Gamaleya Research Institute of Epidemiology and Microbiology

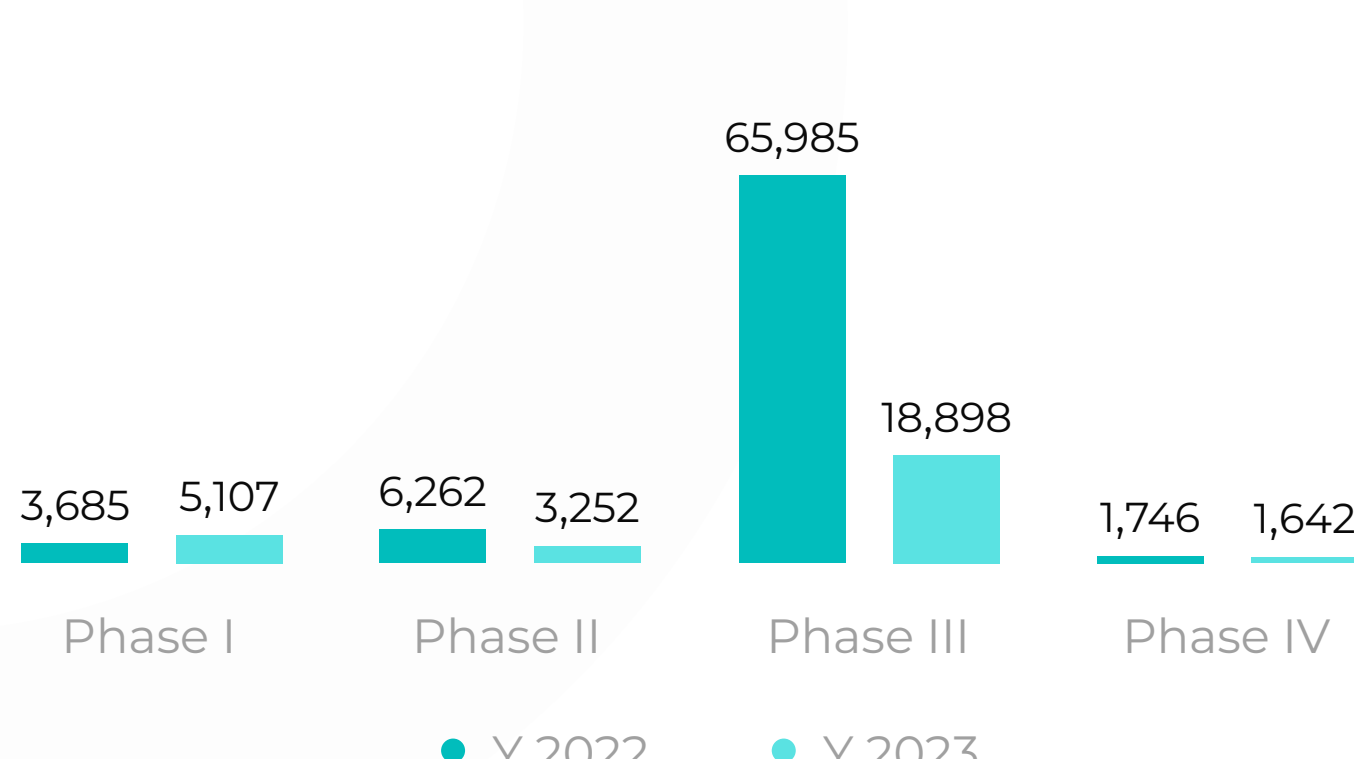
## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during the Year 2023 reached a total of 28,899 subjects – a 63% drop in comparison with the previous year when 77,678 subjects were enrolled.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 65% 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 Y 2023

Nº	Site Name	City	No. Studies
1	Clinical Hospital #9	Yaroslavl	68
2	Clinical Hospital #3	Yaroslavl	59
3	I.M. Sechenov First Moscow State Medical University	Moscow	54
4	Ecosafety	Saint-Petersburg	49
5	Yaroslavl Regional Clinical Narcology Hospital	Yaroslavl	42

Combined market share of these sites

36%

## CRO Data

### Top-10 CROs in Russia in Y 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	6	1,110
2	Benerix	4	1,836
3	X7 Clinical Research	3	302
4	Center of Clinical Research	3	102
5	iPharma	2	680
6	Accellena	2	678
7	OST Rus	2	352
8	MDP-KIO	2	352
9	LABMGMU	2	238
10	A.K.R. Service	2	204

### Top-5 CROs in Russia in Y 2023 (BE Studies)

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

Combined market share 17% 20%

Nº	Site Name	No. Studies	No. Subjects
1	Probiotech	30	1,336
2	National Scientific Center for Research and Pharmacovigilance	22	897
3	M VED	10	386
4	AX Clinical Trials and Consulting	9	482
5	X7 Clinical Research	7	379

Combined market share of these companies 13% 11%

## Regulatory Data

During Q4 2023 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 40 new drugs, including 11 new molecular entities (NMEs).

Other approvals concerned new active ingredients, new dosages, combinations, formulations or manufacturers.

11 of these 40 drugs (and four of 11 NMEs) were (or are being) studied in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
06.10.2023	Cosentyxbla (Secukinumab)	Novartis
12.10.2023	Velsipitynda (Etrasimod Arginine)	Pfizer
17.10.2023	Zilbrysqnda (Zilucoplan Sodium)	UCB
17.10.2023	Bimzelxbla (Bimekizumab-Bkzx)	UCB
20.10.2023	Rozlytreknda (Entrectinib)	Genentech
20.10.2023	Zymfentrabla (Infliximab-Dyyb)	Celltrion
26.10.2023	Omvothbla (Mirikizumab-Mrkz)	Eli Lilly
08.11.2023	Zepboundnda (Tirzepatide)	Eli Lilly
16.11.2023	Truqapnda (Capivasertib)	AstraZeneca
05.12.2023	Fabhaltanda (Iptacopan Hydrochloride)	Novartis
22.12.2023	Abacavir Sulfate And Lamivudinenda (Abacavir Sulfate; Lamivudine)	Mylan

In Q4 2023 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 16 new drugs, including six generics, two biosimilar and nine orphan medicines.

Six of these 16 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
12.10.2023	Elrex fio (elranatamab)	Pfizer
12.10.2023	Veoza (fezolinetant)	Astellas
09.11.2023	Omjjara (mometinib)	GlaxoSmithKline
09.11.2023	Rystiggo (rozanolixizumab)	UCB
09.11.2023	Spexotras (trametinib)	Novartis
14.12.2023	Velsipity (etrasimod)	Pfizer

### FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during the Year 2023.

### Roszdrazvnadzor inspections

According to the Roszdrazvnadzor quarterly report, as of 14/02/2024 there were no Regulatory inspections conducted by Roszdrazvnadzor during the Year 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: 27/02/2024

## About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia and 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.