

# Clinical Trials in Russia

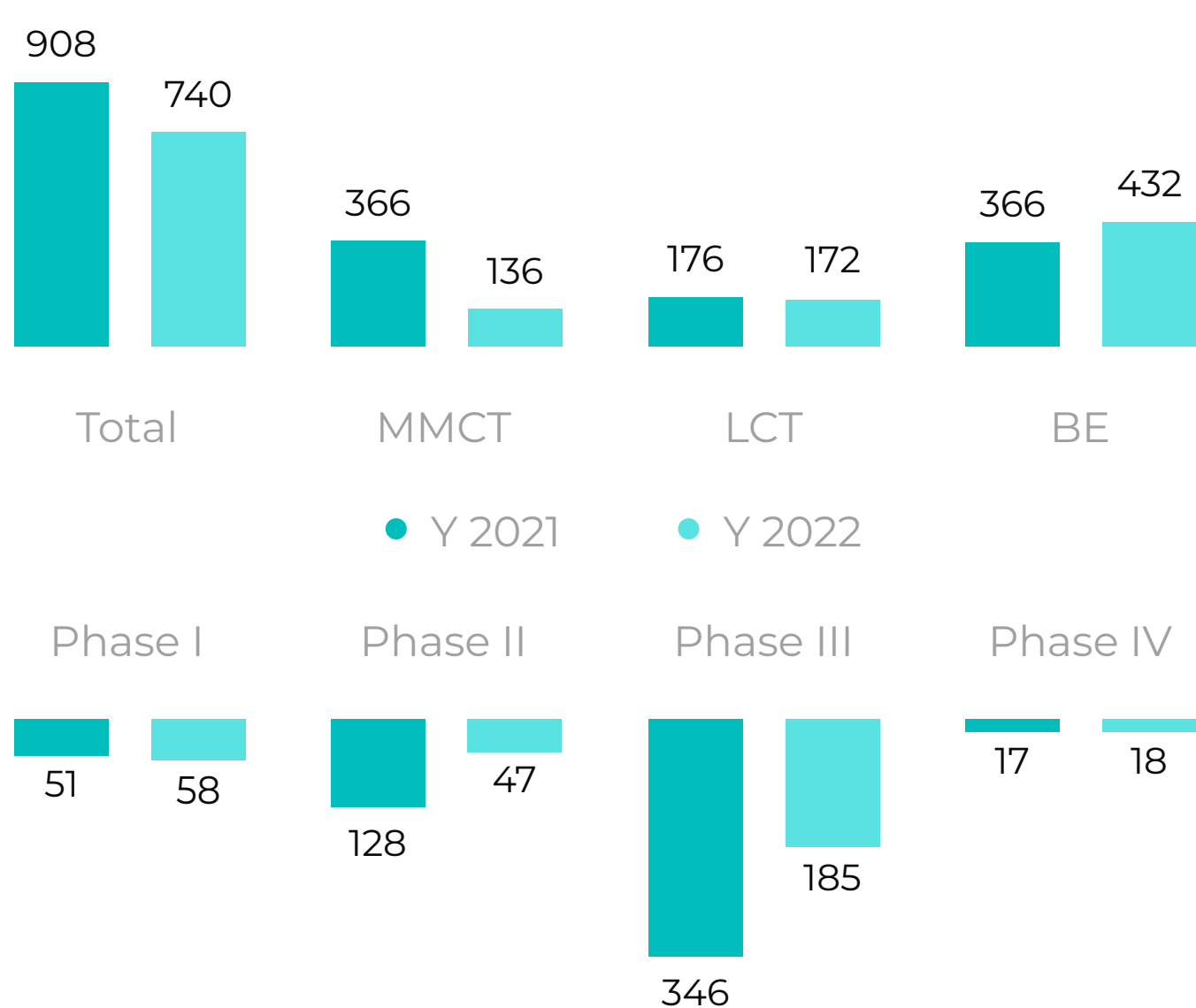
Y 2022 Research report

## Trial Data

During the Year 2022 the Ministry of Health of the Russian Federation approved the start of 740 new clinical trials of all types, including local and bioequivalence studies. This represents a 19% year on year drop by the total number of studies.

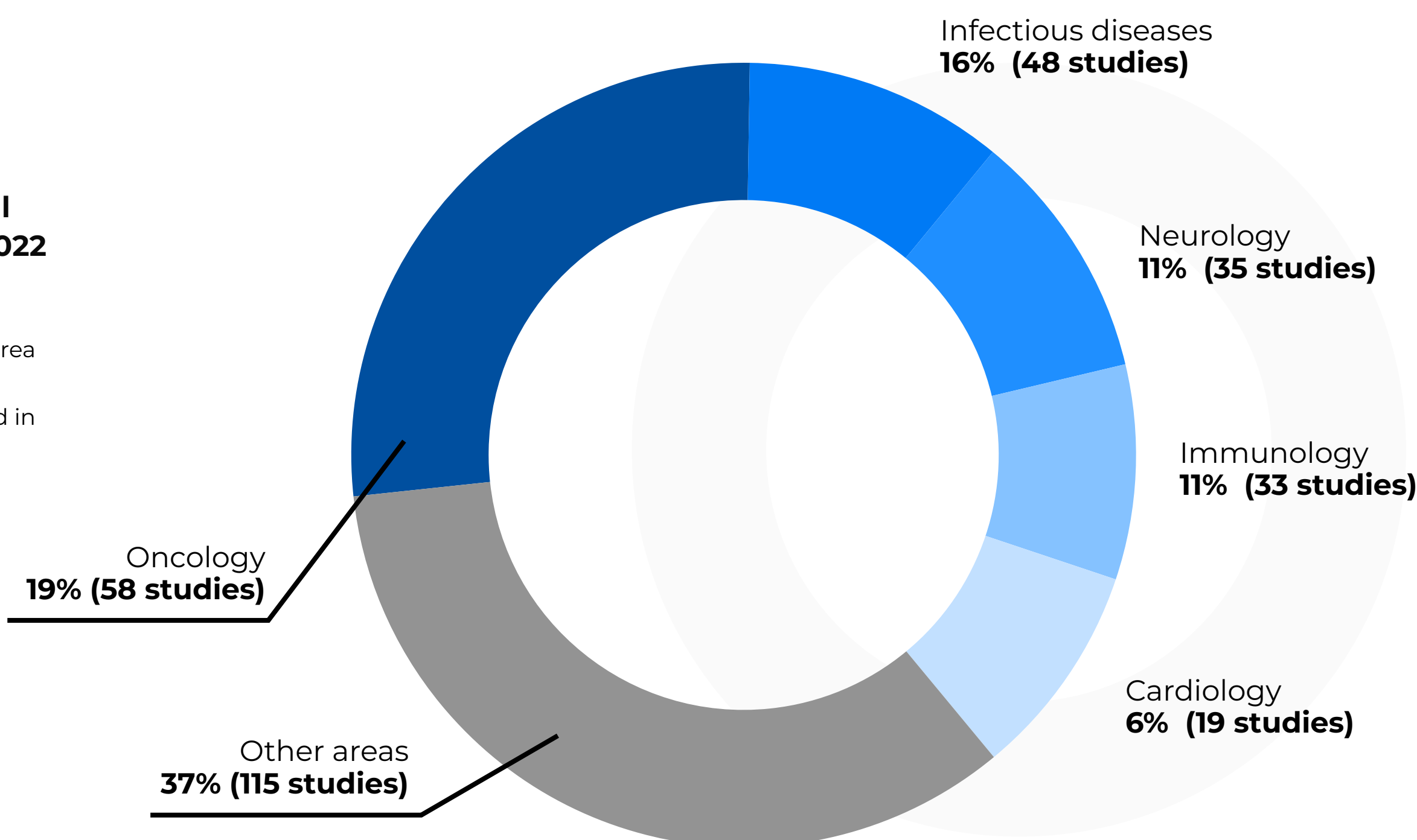
The dominant type of clinical trials conducted across Russian sites in the Year 2022 were BE (Bio-equivalent Clinical Trials). The market share of MMCTs (Multinational Multi-center Clinical Trials) dropped from 40% to 18% of the total number of trials. The market share of Local Clinical Trials (LCTs) increased from 19% to 23% whilst the Bio-equivalent (BE) share flourished from 40% to 58%.

### Breakdown of Clinical Trials by Type and Phase



### Breakdown of Clinical Trials in Russia in Y 2022 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 2022 were sponsored by pharmaceutical companies from Russia and 27 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 54% to 29% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2022 was Phase III with 33% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in the Year 2022 were Russia (526 studies), U.S. (42) and India (29). Other prominent countries include Switzerland (28), Belarus (25), Germany (10) and Slovenia (10).

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

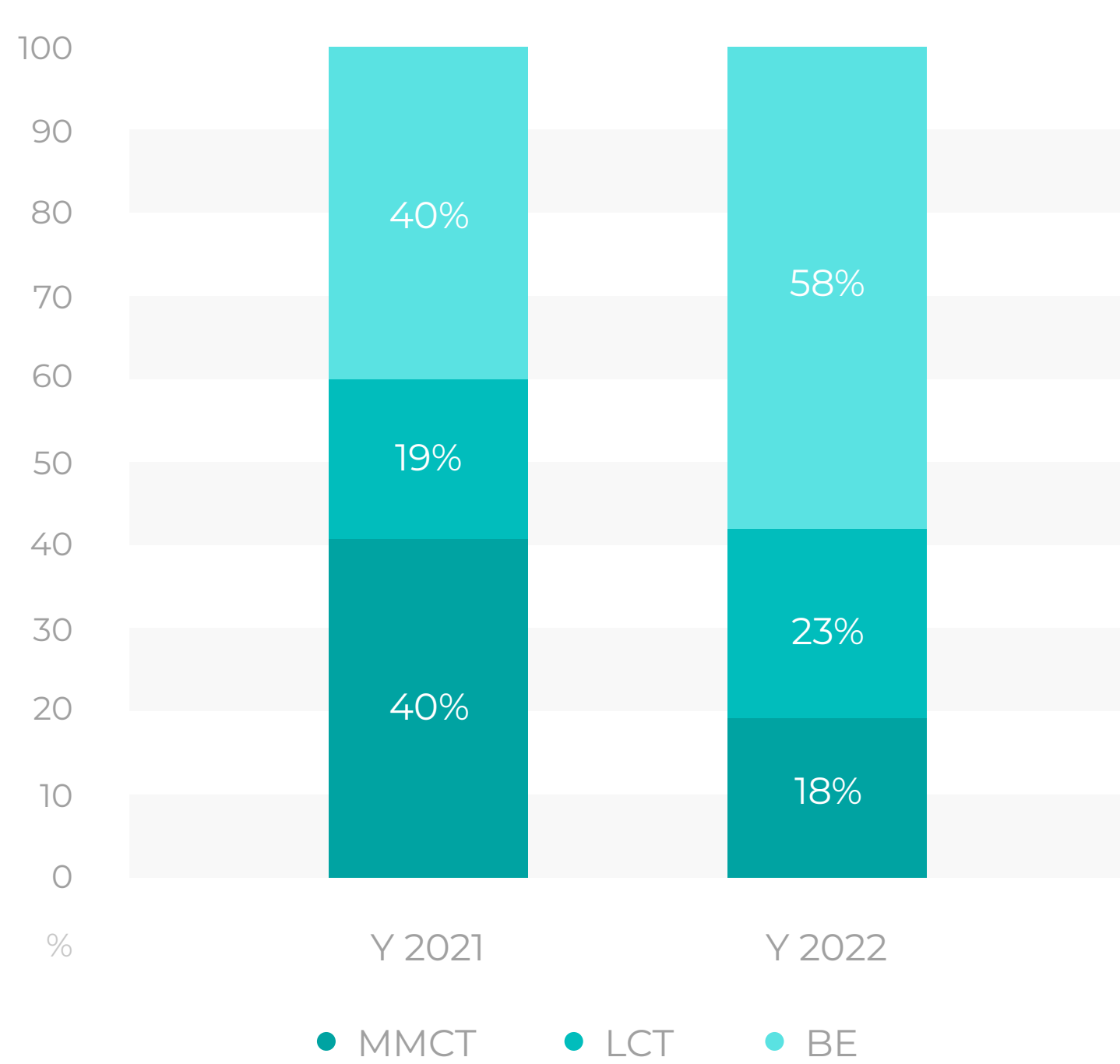
### Top-10 International Trial Sponsors in Russia in Y 2022

Nº	Company Name	Studies	Subjects
1	Merck	13	957
2	Novartis	13	534
3	Hoffmann-La Roche	10	1 805
4	GlaxoSmithKline	6	281
5	Janssen	5	330
6	AstraZeneca	5	306
7	AbbVie	5	247
8	Novo Nordisk	4	287
9	Boehringer Ingelheim	3	206
10	Intra-Cellular Therapies	2	616
Combined market share		21%	7%

Combined market share based on total studies conducted 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.

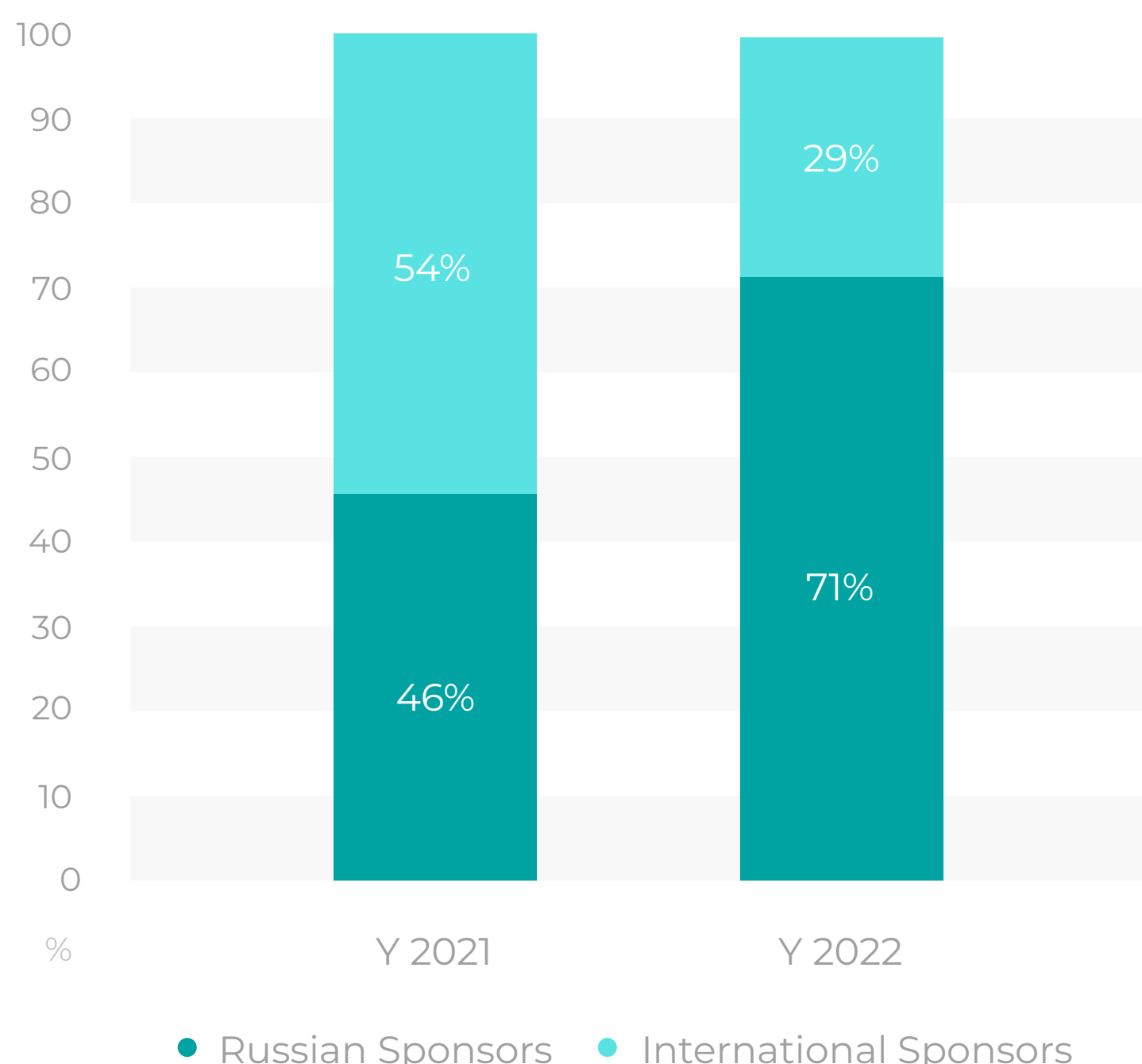
### Percentage Breakdown of Clinical Trials by Type



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 47% – from 346 trials in the Year 2021 to 185 trials in the Year 2022.

The largest number of clinical trials initiated in Russia during the Year 2022 were related to Oncology (58 studies), Infectious diseases (48 studies), Neurology (35 studies), Immunology (33 studies) and Cardiology (19 studies). Other dominant therapy areas include Hematology, Gastroenterology, Endocrinology and Dermatology.

### 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 2022

Nº	Company Name	Studies	Subjects
1	BIOCAD	14	3 682
2	Microgen	13	1 150
3	PROMOMED	12	2 625
4	Gamaleya Research *	9	3 989
5	Valenta Pharma	9	1 964
6	R-Pharm	8	915
7	Generium	7	1 197
8	GeroPharm	4	902
9	Vertex	4	426
10	Grotex	4	264
Combined market share		27%	22%

\* Gamaleya Research Institute of Epidemiology and Microbiology

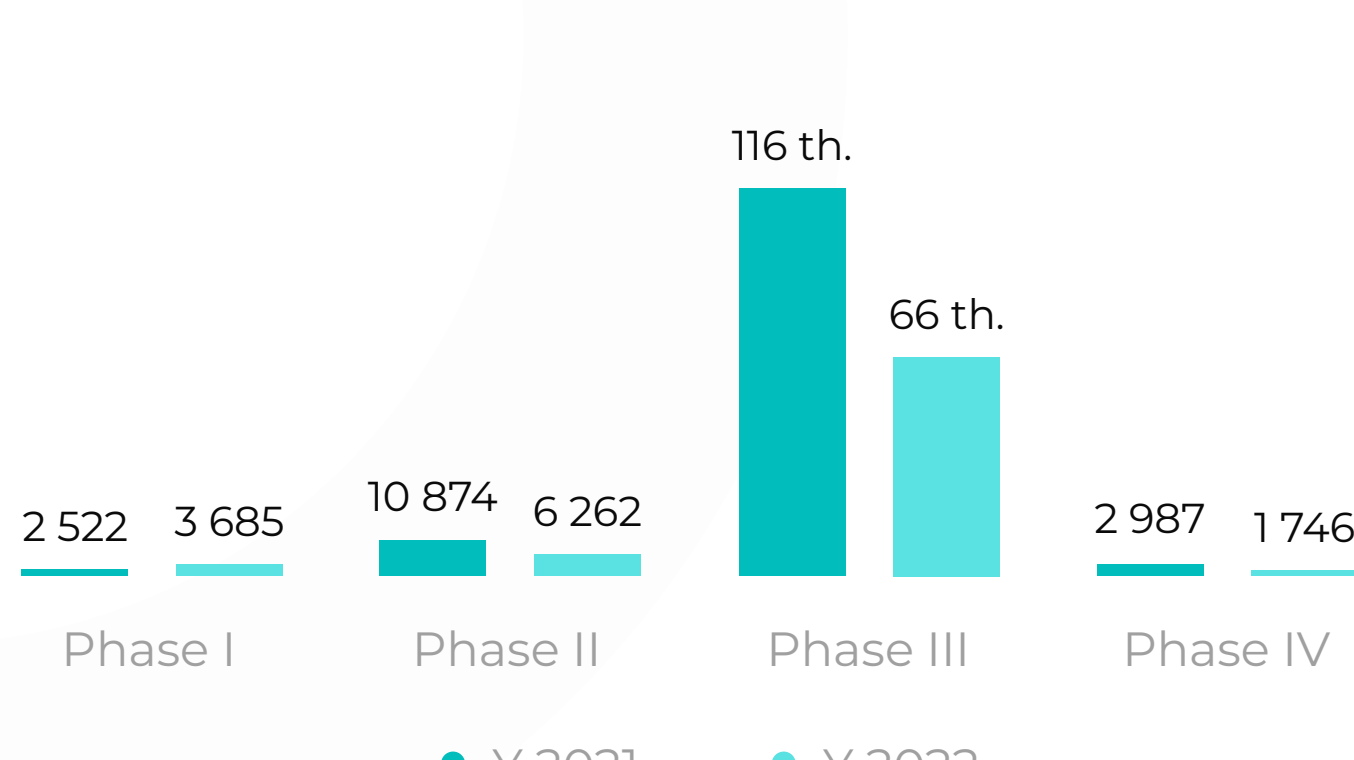
## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during the Year 2022 reached a total of 77,678 subjects – a 42% drop in comparison with the previous year when 132,843 subjects were enrolled.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 85% 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 2022

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	88
2	Clinical Hospital №3	Yaroslavl	72
3	I.M. Sechenov First Moscow State Medical University	Moscow	65
4	X7 Clinical Research	Saint-Petersburg	38
5	Yaroslavl Regional Clinical Narcology Hospital	Yaroslavl	33

Combined market share of these sites

40%

## CRO Data

### Top-10 CROs in Russia

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	IQVIA	13	907
2	Syneos Health	7	331
3	K-Research	6	615
4	Parexel	5	307
5	PPD	5	113
6	Medical Development Agency	4	851
7	Vita Aeterna	3	866
8	Synergy Research Group	3	444
9	Pharmaceutical Research Associates CIS	3	296
10	MB Quest	3	101

### Top-5 CROs in Russia

#### in Y 2022 (BE Studies)

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

Nº	Site Name	No. Studies	No. Subjects
1	Probiotech	26	1 247
2	Medical Development Agency	10	506
3	X7 Clinical Research	8	378
4	Smooth Drug Development	8	354
5	Ligand Research	5	400

Combined market share

17%

6%

Combined market share of these companies

13%

14%

## Regulatory Data

During Q4 2022 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 28 new drugs, including 5 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Five of these 28 drugs (and zero of 5 NMEs) were (or are being) studied in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
21.10.2022	Imjudobla (Tremelimumab)	AstraZeneca
25.10.2022	Tecvaylibla (Teclistamab)	Janssen
14.11.2022	Elaherebla (Mirvetuximab Soravtansine)	Immunogen
13.12.2022	Iyuzehnda (Latanoprost)	Thea Pharma
28.12.2022	Briumvibla (Ublituximab)	TG Therapeutics

In Q4 2022 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 33 new drugs, including 5 generics, 1 biosimilar and 4 orphan medicines.

Eighteen of these 33 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
13.10.2022	Spevigo (Spesolimab)	Boehringer Ingelheim
13.10.2022	Libtayo (Cemiplimab)	Regeneron
10.11.2022	Eylea (Aflibercept)	Bayer
10.11.2022	Ceprotin (Human Protein C)	Takeda
10.11.2022	Xofluza (Baloxavir Marboxil)	Hoffmann-La Roche
10.11.2022	Lynparza (Olaparib)	AstraZeneca
10.11.2022	Plavix (Clopidogrel Hydrogen Sulfate)	Sanofi
15.12.2022	Imfinzi (Durvalumab)	AstraZeneca
15.12.2022	Tremelimumab AstraZeneca (Tremelimumab)	AstraZeneca
15.12.2022	Dupixent (Dupilumab)	Sanofi
15.12.2022	Triumeq (Dolutegravir Sodium; Lamivudine; Abacavir)	ViiV Healthcare
15.12.2022	Hemlibra (Emicizumab)	Hoffmann-La Roche
15.12.2022	Kerendia (Finerenone)	Bayer
15.12.2022	Imjudo (Tremelimumab)	AstraZeneca
15.12.2022	Enhertu (Trastuzumab Deruxtecan)	Daiichi Sankyo
15.12.2022	Edistride (Dapagliflozin Propanediol Monohydrate)	AstraZeneca
15.12.2022	Forxiga (Dapagliflozin Propanediol Monohydrate)	AstraZeneca
16.12.2022	Adcirca (Tadalafil)	Eli Lilly

### FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative sites during the Year 2022.

### Roszdraznadvor inspections

According to the Roszdraznadvor quarterly report, as of 11/01/2023 there were no Regulatory inspections conducted by Roszdraznadvor during the Year 2022.

## 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: 11/01/2023

## About Synergy Research Group

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