

Clinical Trials in Russia

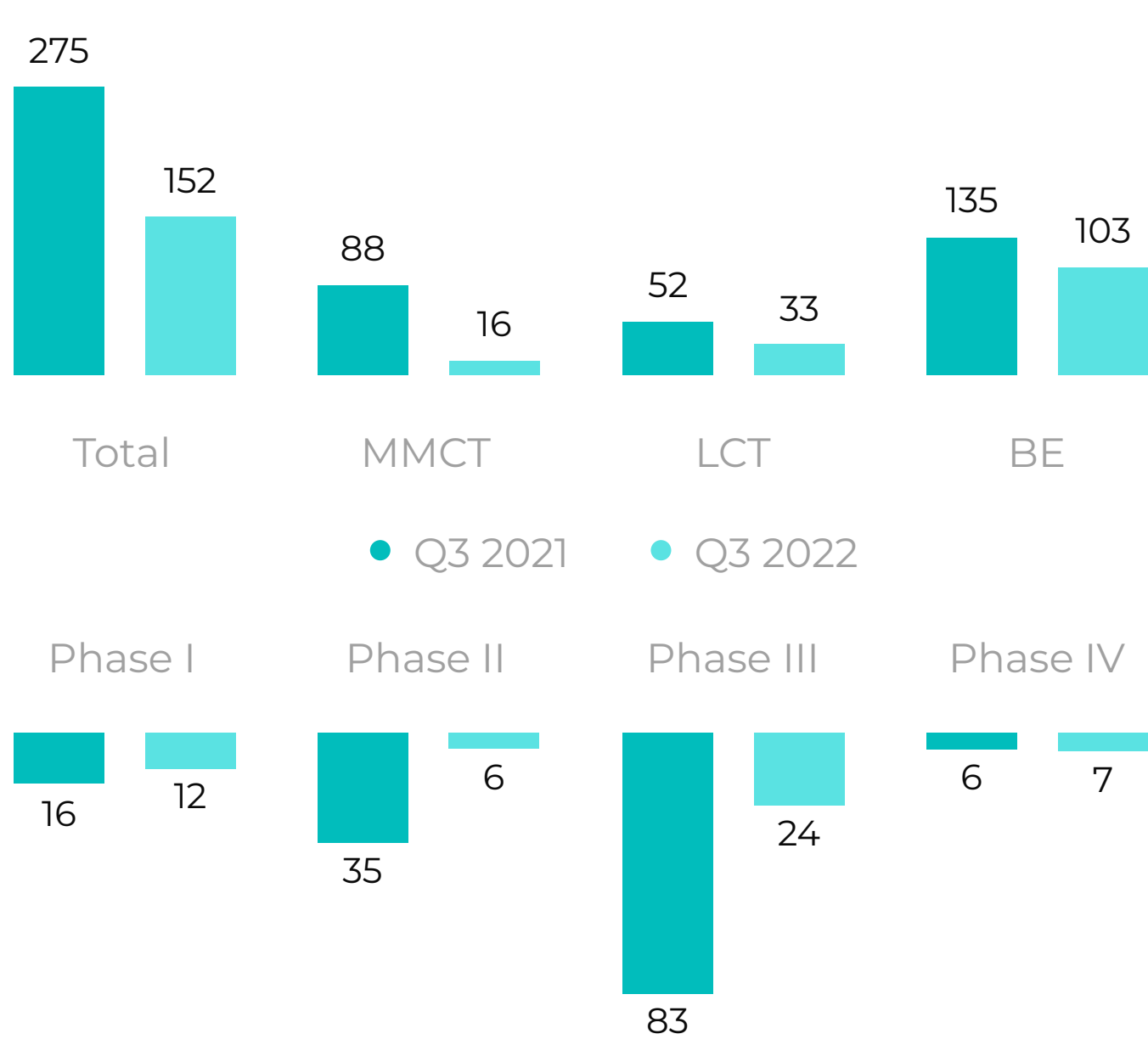
Q3 2022 Research report

Trial Data

During Q3 2022 the Ministry of Health of the Russian Federation approved the start of 152 new clinical trials of all types, including local and bioequivalence studies. This represents a 45% year on year collapse by the total number of studies.

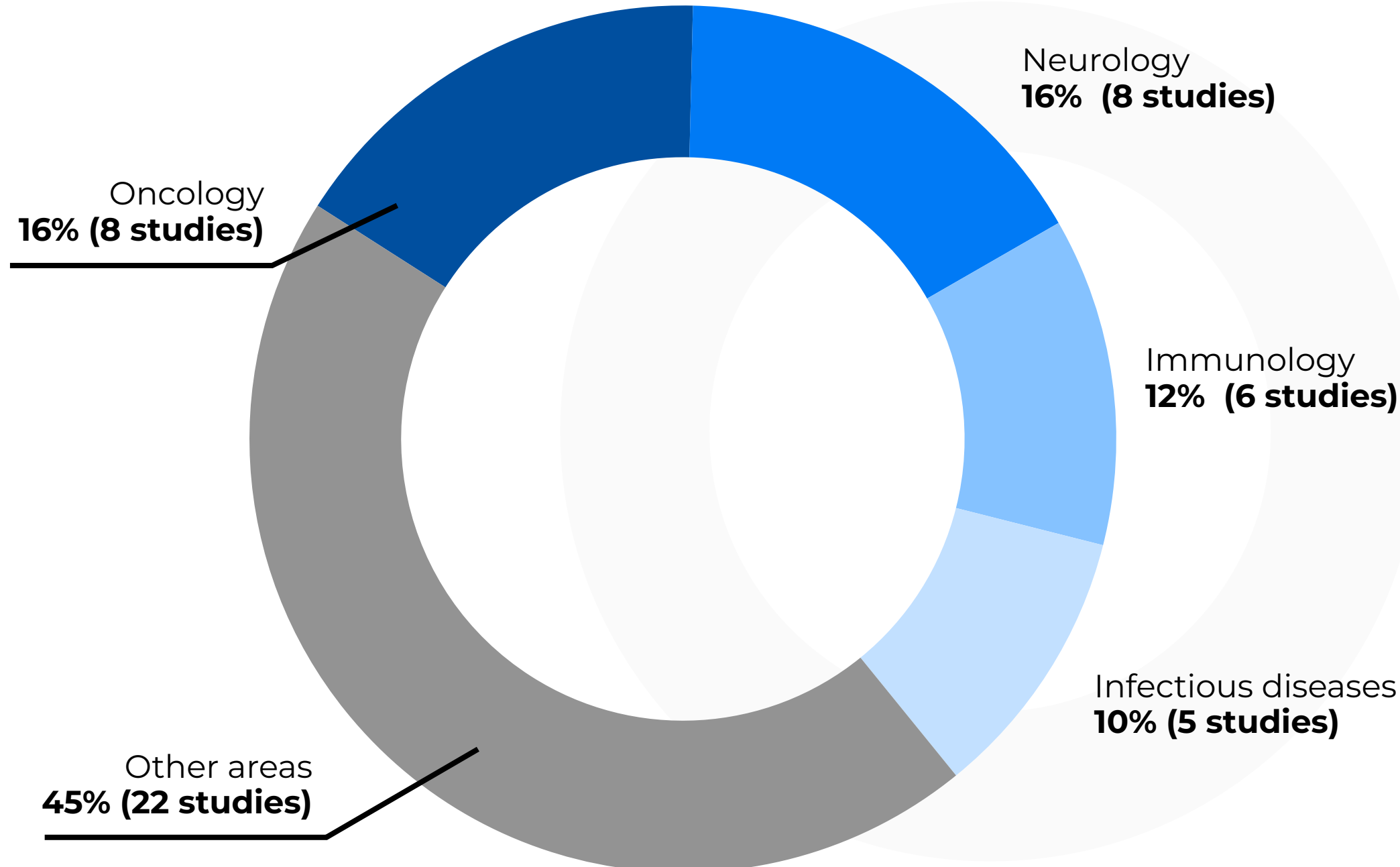
The dominant type of clinical trials conducted across Russian sites in Q3 2022 were BE (Bio-equivalent Clinical Trials). The market share of BE studies raised from 49% to 68%. The market share of MMCTs (Multinational Multi-center Clinical Trials) crushed from 32% to 11% whilst the market share of Local Clinical Trials (LCTs) remains almost stable with 22%.

Breakdown of Clinical Trials by Type and Phase

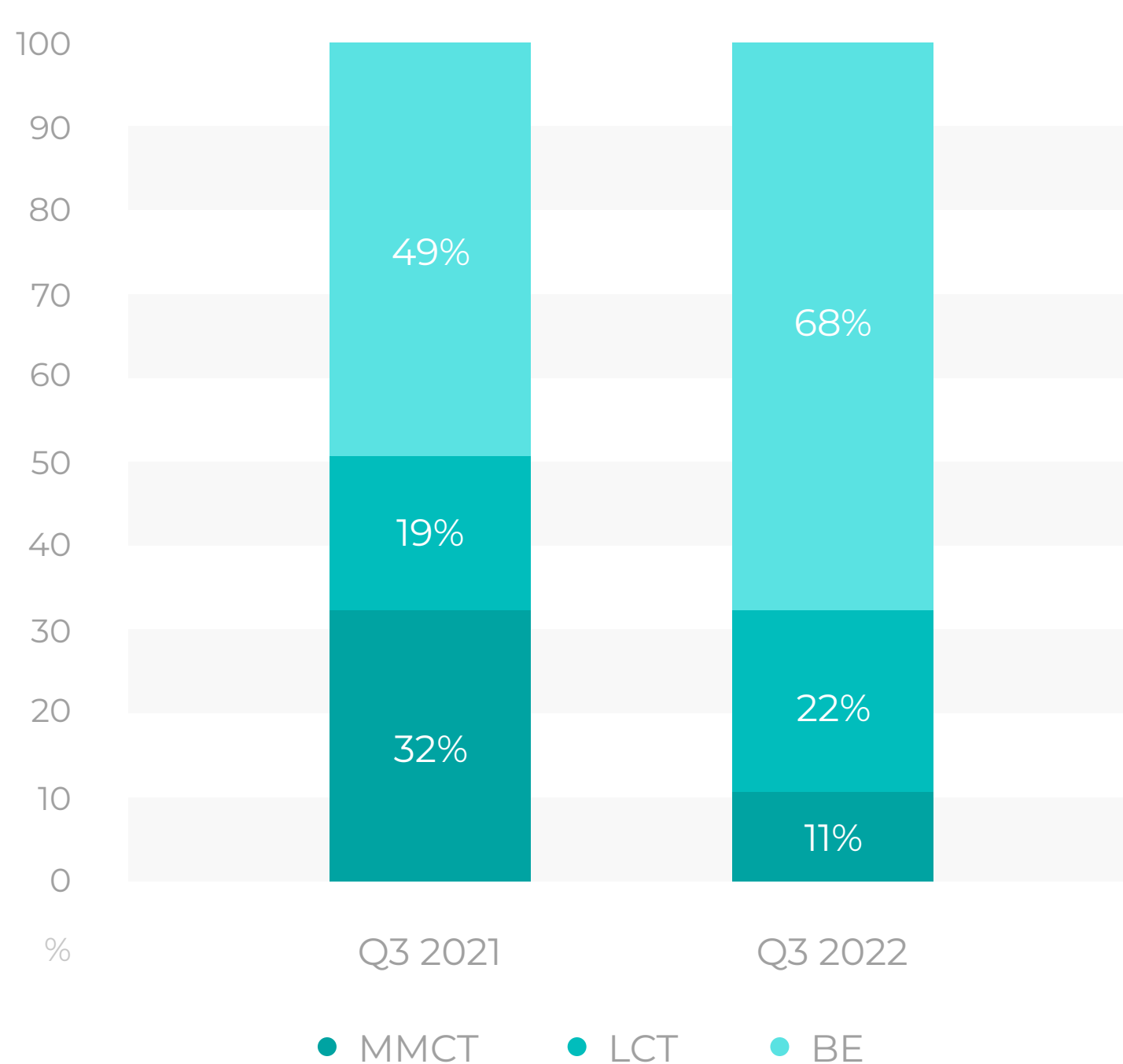


Breakdown of Clinical Trials in Russia in Q3 2022 by Therapeutic Area

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



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 collapsed by 71% – from 83 trials in Q3 2021 to 24 trials in Q3 2022.

The largest number of clinical trials initiated in Russia during Q3 2022 were related to Oncology (8 studies), Neurology (8 studies), Immunology (6 studies) and Infectious diseases (5 studies). Other prominent therapy areas include Hematology, Dermatology, Cardiology and Endocrinology.

Sponsor Data

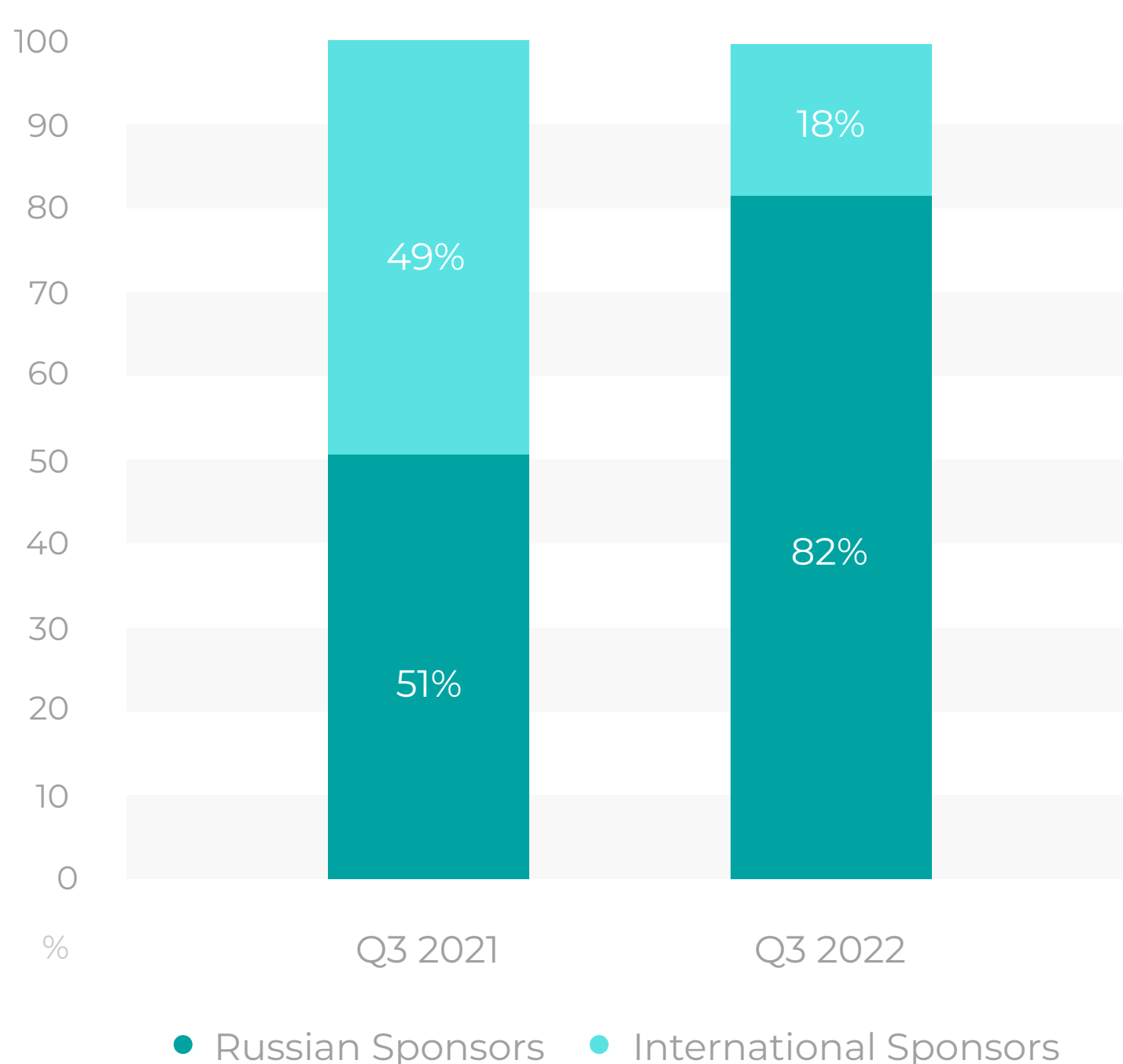
Clinical trials initiated in Russia during Q3 2022 were sponsored by pharmaceutical companies from Russia and 10 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 49% to 18% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2022 was Phase III with 20% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q3 2022 were Russia (124 studies), Switzerland (6 studies), Slovenia (6 studies) and India (6 studies). Other prominent countries include Belarus (3 studies) and the U.S. (2 studies).

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 Q3 2022

Nº	Company Name	Studies	Subjects
1	Novartis	4	57
2	Dr. Reddy's Laboratories	2	522
3	Lek	1	590
4	Teva	1	180
5	Bosnalijek	1	150
6	Alvotech	1	150
7	Intas Pharmaceuticals	1	150
8	AstraZeneca	1	65
9	Hoffman-la Roche	1	64
10	Solstice Neurosciences	1	50
Combined market share		29%	19%

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 Q3 2022

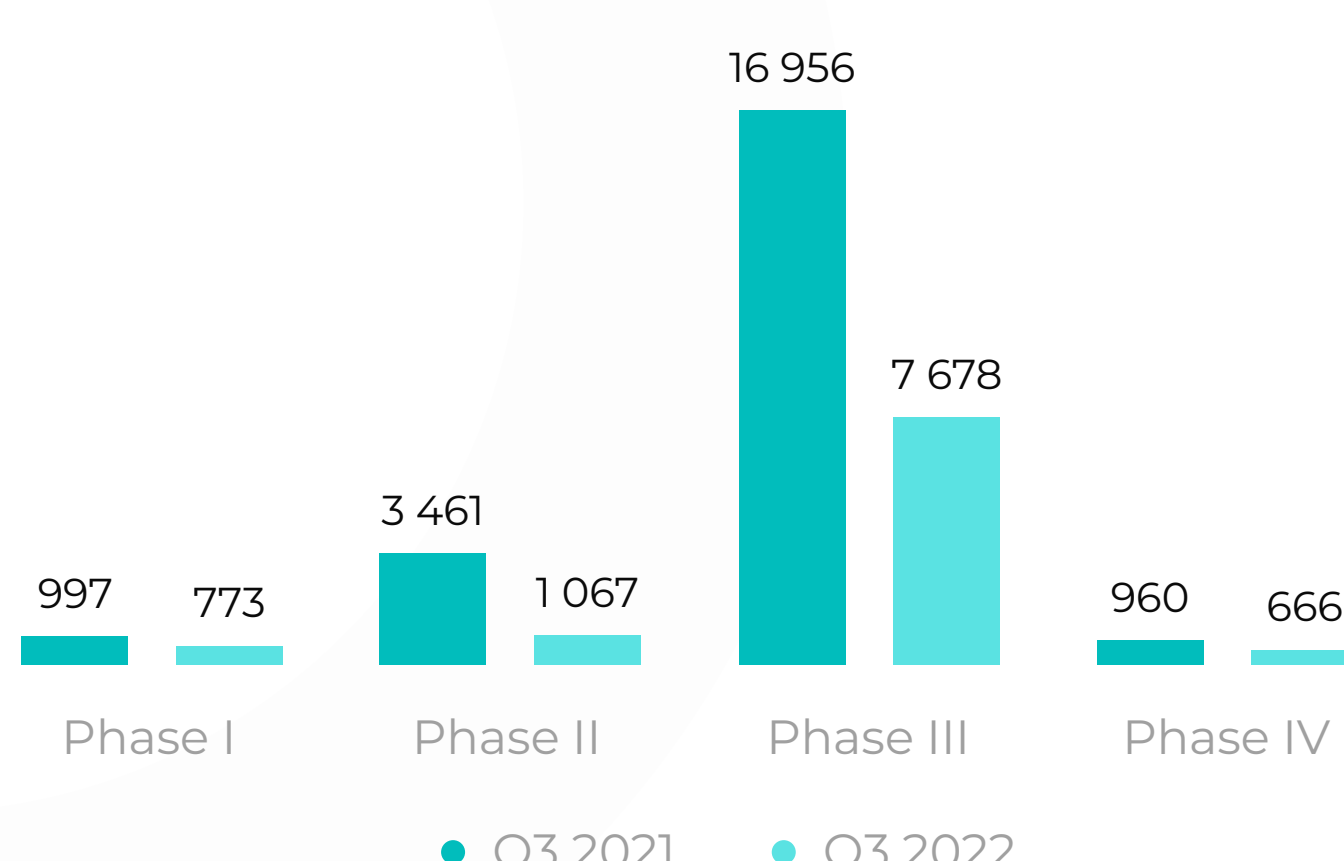
Nº	Company Name	Studies	Subjects
1	BIOCAD	5	1 259
2	Microgen	5	620
3	Valenta Pharm	4	906
4	Petrovax Pharm	2	1 862
5	Gamaleya Research Institute	2	645
6	Promomed	2	92
7	Drugs Formulation	1	1 160
8	Obninsk Chemical and Pharmaceutical Company	1	335
9	ImmunoHelp	1	272
10	Smorodintsev Research Institute of Influenza	1	250
Combined market share		49%	73%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q3 2022 reached a total of 10,184 subjects – a 54% drop in comparison with the previous year when 22,374 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 75% 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 Q3 2022

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint Petersburg	16
2	Clinical Hospital №3	Yaroslavl	14
3	X7 Clinical Research	Saint Petersburg	9
4	I.M. Sechenov First Moscow State Medical University	Moscow	7
5	Bessalar Clinic	Moscow	7

Combined market share of these sites

35%

CRO Data

Top-10 CROs in Russia in Q3 2022 (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	K-Research	2	170
2	Medical Development Agency	1	335
3	Vita Aeterna	1	272
4	IQVIA	1	150
5	Probiotec Medical Center	1	150
6	Atlant Clinical	1	60
7	Ligand Research	1	50
8	Synteract HCR	1	50
9	PPD	1	12
10	-	-	-

Top-5 CROs in Russia in Q3 2022 (BE studies)

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

Nº	Site Name	No. Studies	No. Subjects
1	Probiotec Medical Center	8	330
2	X7 Clinical Research	3	102
3	Medical Development Agency	2	112
4	ARS Pharmrussia	1	50
5	FarmInnovations	1	34

Combined market share of these companies

20%

12%

Regulatory Data

During Q3 2022 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 37 new drugs, including 5 new molecular entity (NME); other approvals concerned new dosages, combinations or manufacturers.

Five of these 37 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
03.08.2022	Calquencenda (Acalabrutinib Maleate)	AstraZeneca
24.08.2022	Imbruvicanda (Ibrutinib)	Pharmacyclics
01.09.2022	Spevigobla (Spesolimab)	Boehringer Ingelheim
09.09.2022	Sotyktunda (Deucravacitinib)	Bristol
27.09.2022	Vegzelmabla (Bevacizumab)	Celltrion

In Q3 2022 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 26 new drugs including 3 generics, 1 biosimilar and 7 orphan medicines.

Eleven of these 26 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
21.07.2022	Mounjaro (Tirzepatide)	Eli Lilly
21.07.2022	Retsevmo (Selpercatinib)	Eli Lilly
21.07.2022	Ultomiris (Ravulizumab)	Alexion
15.09.2022	Xalkori (Crizotinib)	Pfizer
15.09.2022	Adtralza (Tlalokinumab)	LEO Pharma
15.09.2022	Brukinsa (Zanubrutinib)	BeiGene
15.09.2022	Zynlonta (Loncastuximab Tesirine)	ADC Therapeutics
15.09.2022	Skyrizi (Risankizumab)	AbbVie
15.09.2022	Biktarvy (Bictegravir; Emtricitabine; Tenofovir Alafenamide; Fumarate)	Gilead Sciences
15.09.2022	Livtency (Maribavir)	Takeda
15.09.2022	Revolade (Eltrombopag)	Novartis

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q3 2022.

Roszdraznador inspections

According to the Roszdraznador quarterly report, as of 01/11/2022 there were no Regulatory inspections conducted by Roszdraznador during Q3 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: 01/11/2022

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.