

Clinical Trials in Russia

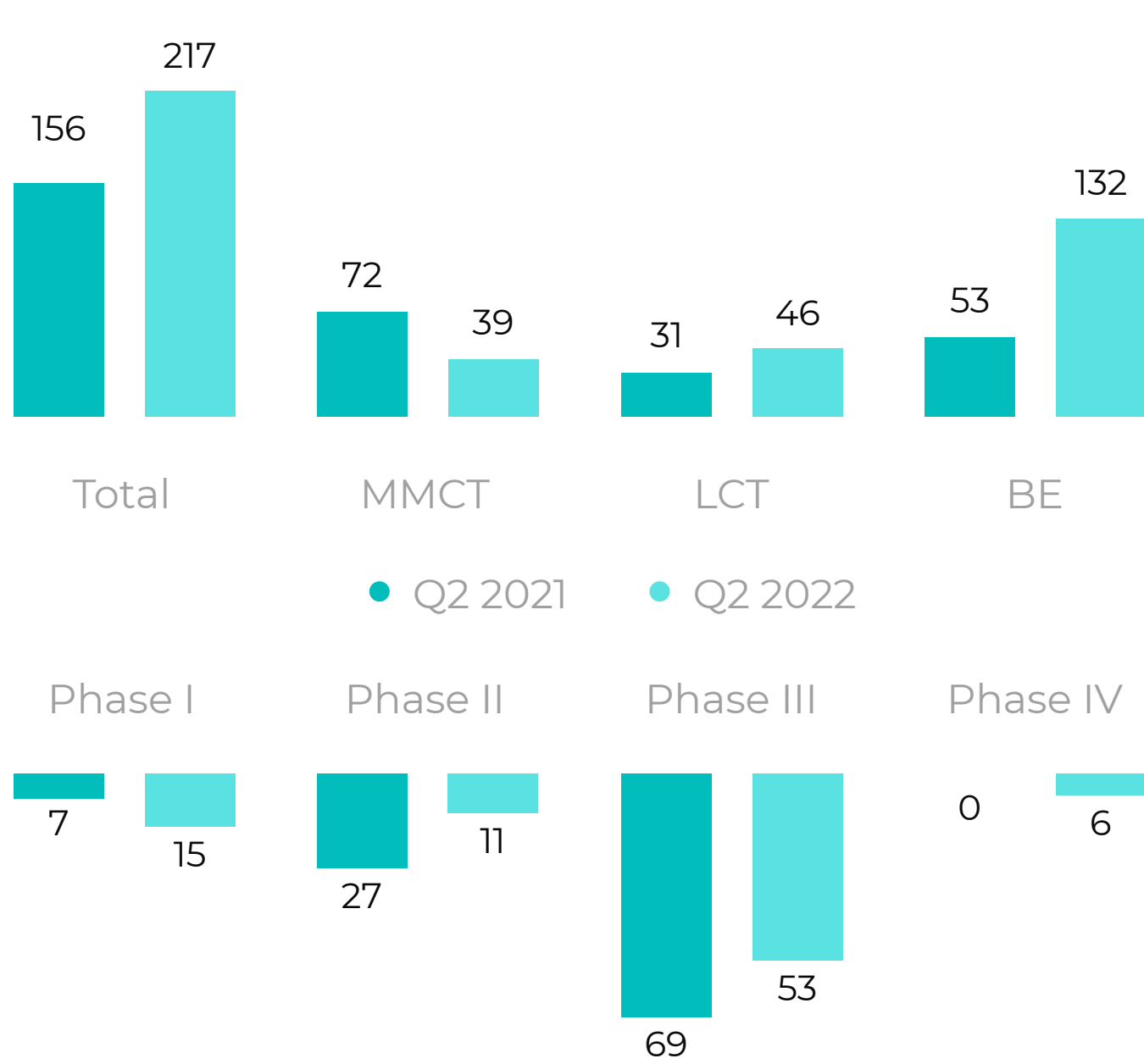
Q2 2022 Research report

Trial Data

During Q2 2022 the Ministry of Health of the Russian Federation approved the start of 217 new clinical trials of all types, including local and bioequivalence studies. This represents a 39% year on year growth by the total number of studies.

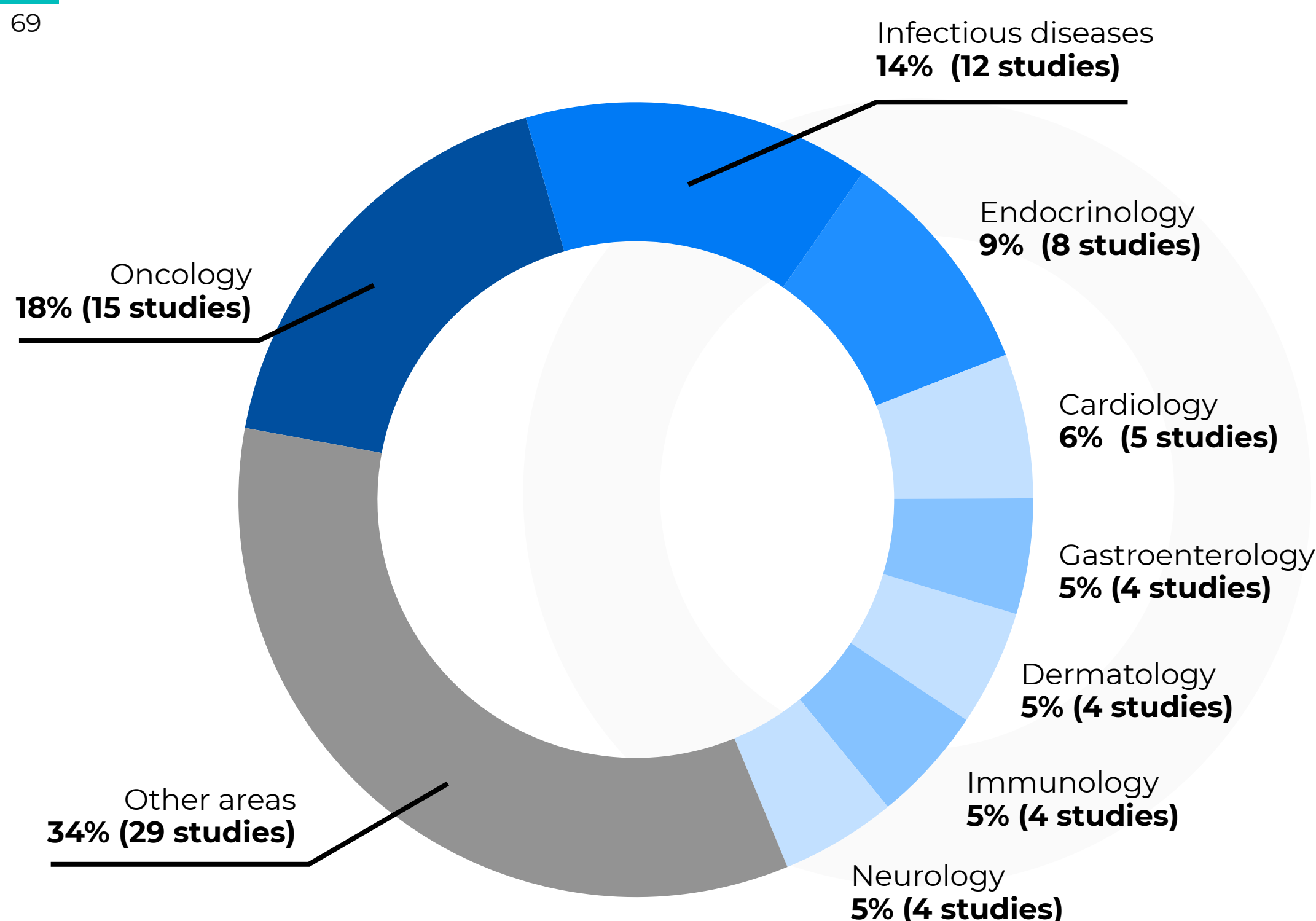
The dominant type of clinical trials conducted across Russian sites in Q2 2022 were BE (Bio-equivalent Clinical Trials). The market share of BE studies boomed from 34% to 61%. The market share of MMCTs (Multinational Multi-center Clinical Trials) crushed from 46% to 18% whilst the market share of Local Clinical Trials (LCTs) remains stable with 21%.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Q2 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 Q2 2022 were sponsored by pharmaceutical companies from Russia and 17 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 58% to 31% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2022 was Phase III with 39% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q2 2022 were Russia (149 studies), the U.S. (16 studies) and India (15 studies). Other prominent countries include Switzerland (7 studies), Belarus (4 studies) and Germany (4 studies).

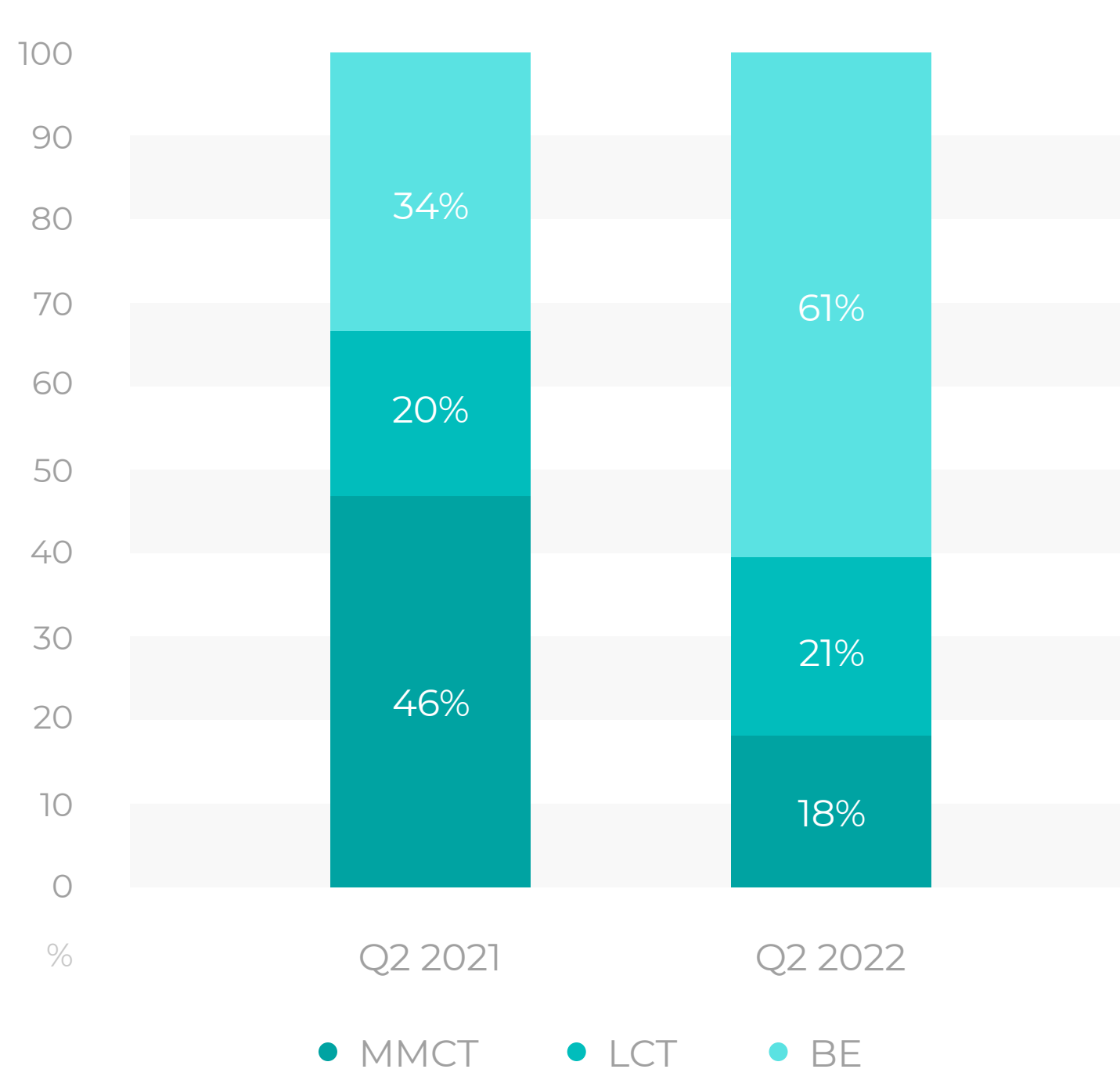
Observational trials and trials without FDA-defined phases (from I to IV) were not counted in the following ranking.

Top-10 International Trial Sponsors in Russia in Q2 2022

Nº	Company Name	Studies	Subjects
1	Merck	5	233
2	Sunovion	2	268
3	GlaxoSmithKline	2	180
4	Boehringer Ingelheim	2	171
5	Hoffman-la Roche	2	116
6	Novartis	2	38
7	Besins Healthcare	1	1 244
8	Sandoz	1	794
9	Viriom	1	505
10	Phytopharm Klenka	1	196
Combined market share		22%	26%

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

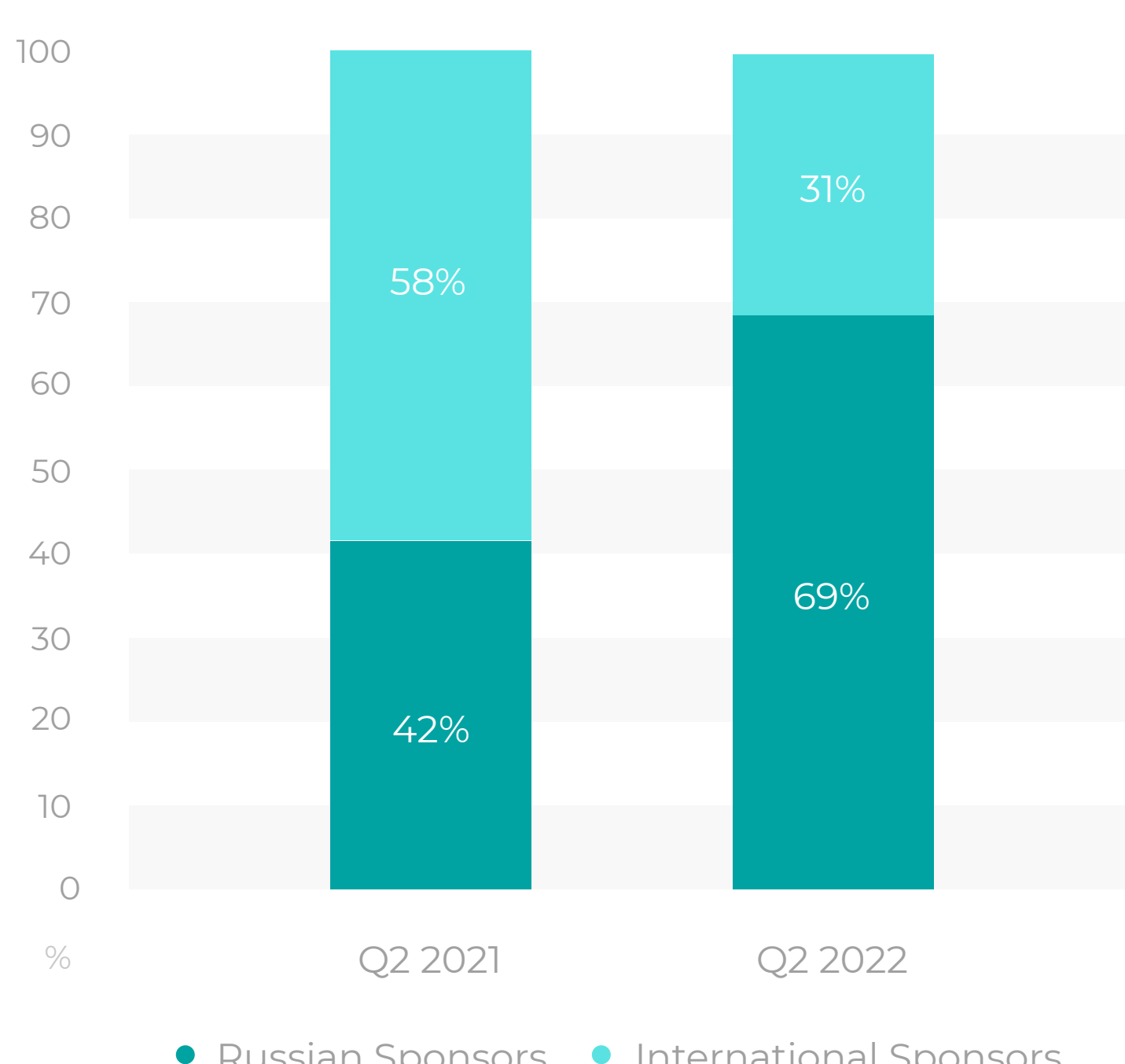
Percentage Breakdown of Clinical Trials by Type



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 decreased by 23% – from 69 trials in Q2 2021 to 53 trials in Q2 2022.

The largest number of clinical trials initiated in Russia during Q2 2022 were related to Oncology (15 studies), Infectious diseases (12 studies), Endocrinology (8 studies) and Cardiology (5 studies). Other dominant therapy areas include Gastroenterology, Dermatology, Immunology and Neurology.

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 Q2 2022

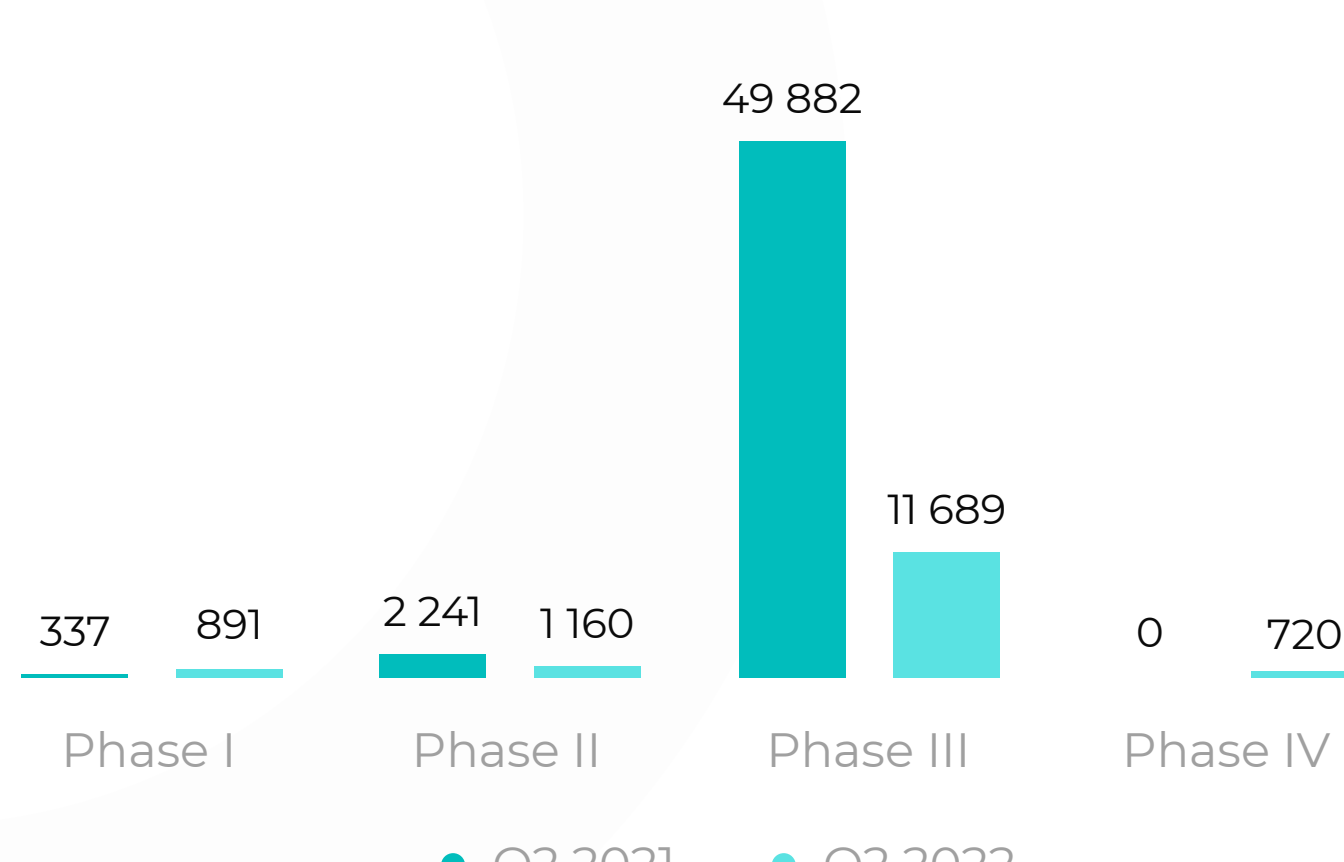
Nº	Company Name	Studies	Subjects
1	Promomed	3	1 220
2	Microgen	3	320
3	Grotex	3	232
4	MedSynthez	2	1045
5	PharmaSynthez	2	940
6	Sotex	2	500
7	Valenta Pharm	2	304
8	Saterex	2	300
9	GeroPharm	2	250
10	Pharminterprices	1	610
Combined market share		26%	40%

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q2 2022 reached a total of 14,460 subjects – a 72% crush in comparison with the previous year when 52,460 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 81% 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 2022

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint Petersburg	22
2	Clinical Hospital №3	Yaroslavl	19
3	N.P. Bekhtereva Institute of the Human Brain	Saint Petersburg	15
4	Cardiology Dispensary	Ivanovo	13
5	Yaroslavl Regional Clinical Narcology Hospital	Yaroslavl	12

Combined market share of these sites

37%

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	8	512
2	Parexel	4	298
3	MDP	2	1 045
4	iPharma	2	782
5	Syneos Health	2	108
6	MB Quest	2	78
7	Ligand Research	1	266
8	ARS Pharmrussia	1	196
9	MMC	1	175
10	Synergy Research Group	1	120

Top-5 CROs in Russia

in Q2 2022 (BE studies)

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

Combined market share		28%	25%
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Nº	Site Name	No. Studies	No. Subjects
1	Smooth Drug Development	8	354
2	Probiotec Medical Center	5	293
3	Ligand Research	3	270
4	Medical Development Agency	3	130
5	ARS Pharmrussia	2	192

Combined market share of these companies

16%

19%

Regulatory Data

During Q2 2022 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 32 new drugs, including 5 new molecular entity (NME); other approvals concerned new dosages, combinations or manufacturers.

Four of these 32 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
05.04.2022	Mijoicenda (Alpelisib)	Novartis
13.05.2022	Mounjaronda (Tirzepatide)	Eli Lilly
13.06.2022	Amvuttranda (Vutrisiran)	Alnylam Pharms
16.06.2022	Skyrizibla (Risankizumab-rzaa)	Abbvie

In Q2 2022 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 34 new drugs including 4 generics, 2 biosimilar and 10 orphan medicines.

Fourteen of these 34 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
22.04.2022	Bydureon (Exenatide)	AstraZeneca
22.04.2022	Tabrecta (Capmatinib Dihydrochloride Monohydrate)	Novartis
22.04.2022	Tecentriq (Atezolizumab)	Hoffmann-La Roche
22.04.2022	Retsevmo (Selpercatinib)	Eli Lilly
19.05.2022	Xeljanz (Tofacitinib)	Pfizer
19.05.2022	Zokinvy (Lonafarnib)	EigerBio
19.05.2022	Nexpovio (Selinexor)	Karyopharm
23.06.2022	Rinvoq (Upadacitinib)	AbbVie
23.06.2022	Lynparza (Olaparib)	AstraZeneca
23.06.2022	Scemblix (Asciminib Hydrochloride)	Novartis
23.06.2022	Vyvgart (Efgartigimod Alfa)	Argenx
23.06.2022	Enhertu (Trastuzumab Deruxtecan)	Daiichi Sankyo
23.06.2022	Vegzelma (Bevacizumab)	Celltrion
23.06.2022	Imbruvica (Ibrutinib)	Janssen

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q2 2022.

Roszdraznador inspections

According to the Roszdraznador quarterly report, as of 04/07/2022 there were no Regulatory inspections conducted by Roszdraznador during Q2 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: 04/07/2022

About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia, Kazakhstan, Ukraine and Canada 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.