

Clinical Trials in Russia

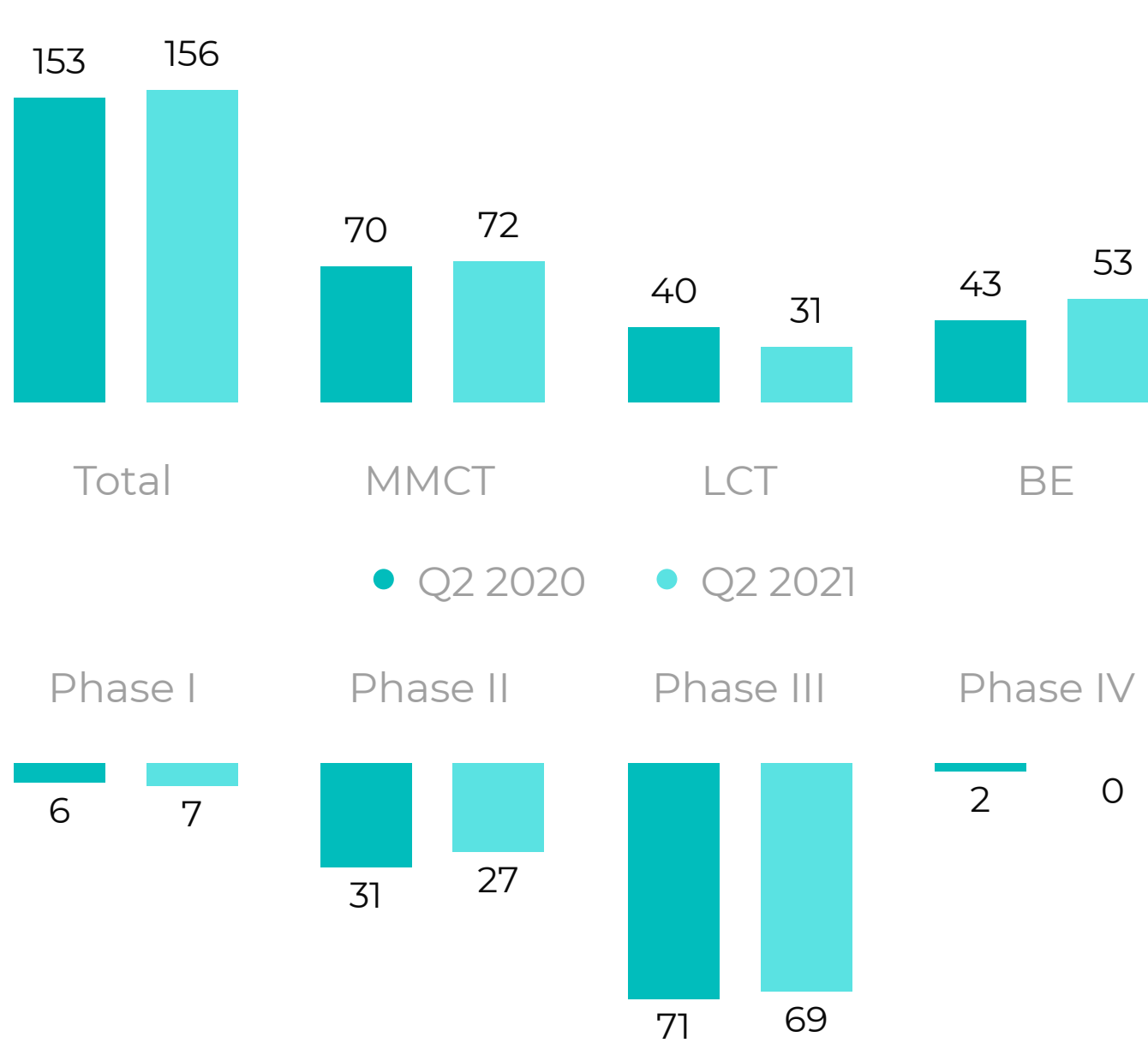
Q2 2021 Research report

Trial Data

During Q2 2021 the Ministry of Health of the Russian Federation approved the start of 156 new clinical trials of all types, including local and bioequivalence studies. This represents a 2% year on year increase by the total number of studies.

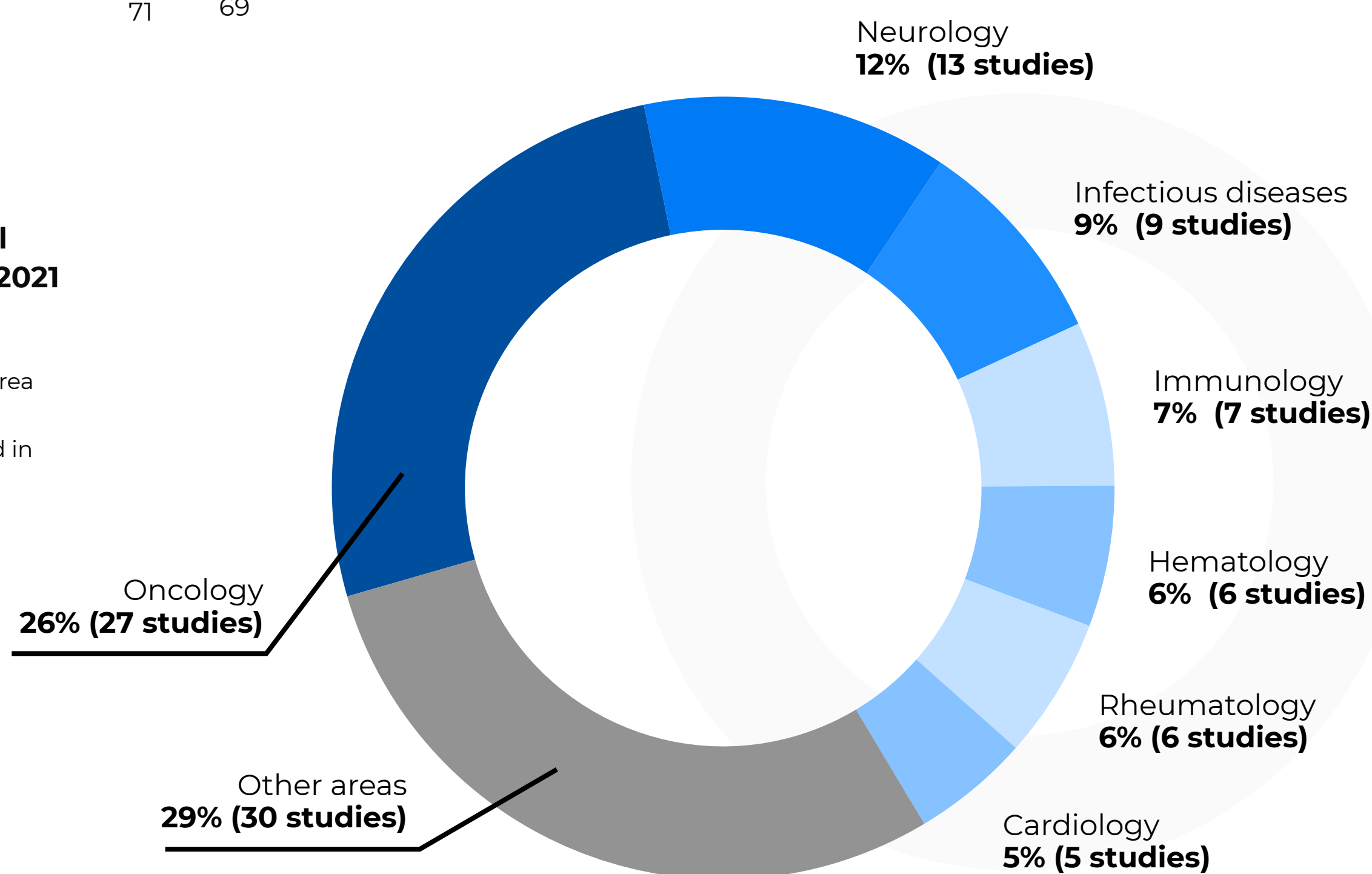
The dominant type of clinical trials conducted across Russian sites in Q2 2021 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs remains the same as in the previous year with 46% of the total number of trials. The market share of Local Clinical Trials (LCTs) dipped from 26% to 20% whilst the Bio-equivalent (BE) share increased from 28% to 34%.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Q2 2021 by Therapeutic Area

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



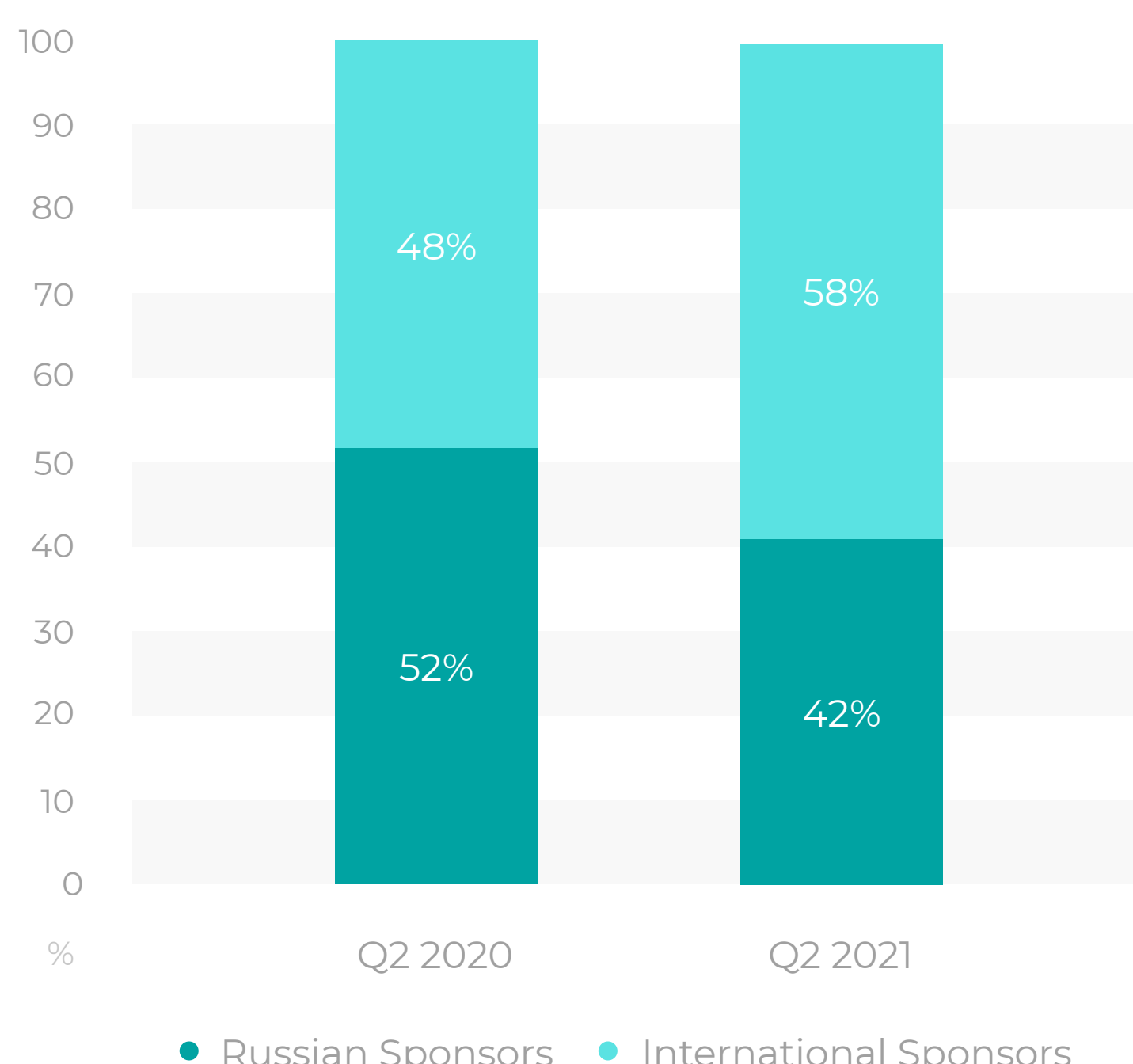
Sponsor Data

Clinical trials initiated in Russia during Q2 2021 were sponsored by pharmaceutical companies from Russia and 21 foreign country. The combined share of international pharmaceutical companies involved in the Russian Clinical trials market raised from 48% to 58% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2021 was Phase III with 54% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q2 2021 were Russia (65 studies), U.S. (29 studies) and Switzerland (12 studies). Other prominent countries include Austria and Sweden (5 studies each).

Percentage Breakdown of Clinical Trials by Sponsor's Country of origin



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

Combined market share shown as a percentage of both international and Russian sponsors.

Top-10 International Trial Sponsors in Russia in Q2 2021

Nº	Company Name	Studies	Subjects
1	Merck	8	545
2	Hoffman-la Roche	6	414
3	AstraZeneca	5	630
4	Boehringer Ingelheim	5	493
5	GlaxoSmithKline	4	569
6	Novartis	4	160
7	Novo Nordisk	3	750
8	Chiesi Farmaceutici	2	960
9	Pfizer	2	478
10	Bio-Thera Solutions	2	268
Combined market share		40%	10%

* Chumakov Federal Scientific Center for Research and Development of Immune and Biological Products of Russian Academy of Sciences

** Gamaleya Research Institute of Epidemiology and Microbiology

Top-10 Russian Trial Sponsors in Russia in Q2 2021

Nº	Company Name	Studies	Subjects
1	Valenta Pharma	6	1 684
2	Moscow Endocrine Plant	2	340
3	PROMOMED	2	60
4	Chumakov Research *	1	32 000
5	Gamaleya Research **	1	7 978
6	GeroPharm	1	784
7	Microgen	1	460
8	Alium Pharm	1	360
9	NRCI of Immunology ***	1	317
10	VECTOR ****	1	300
Combined market share		17%	84%

*** National Research Center Institute of Immunology Federal Medical-Biological Agency

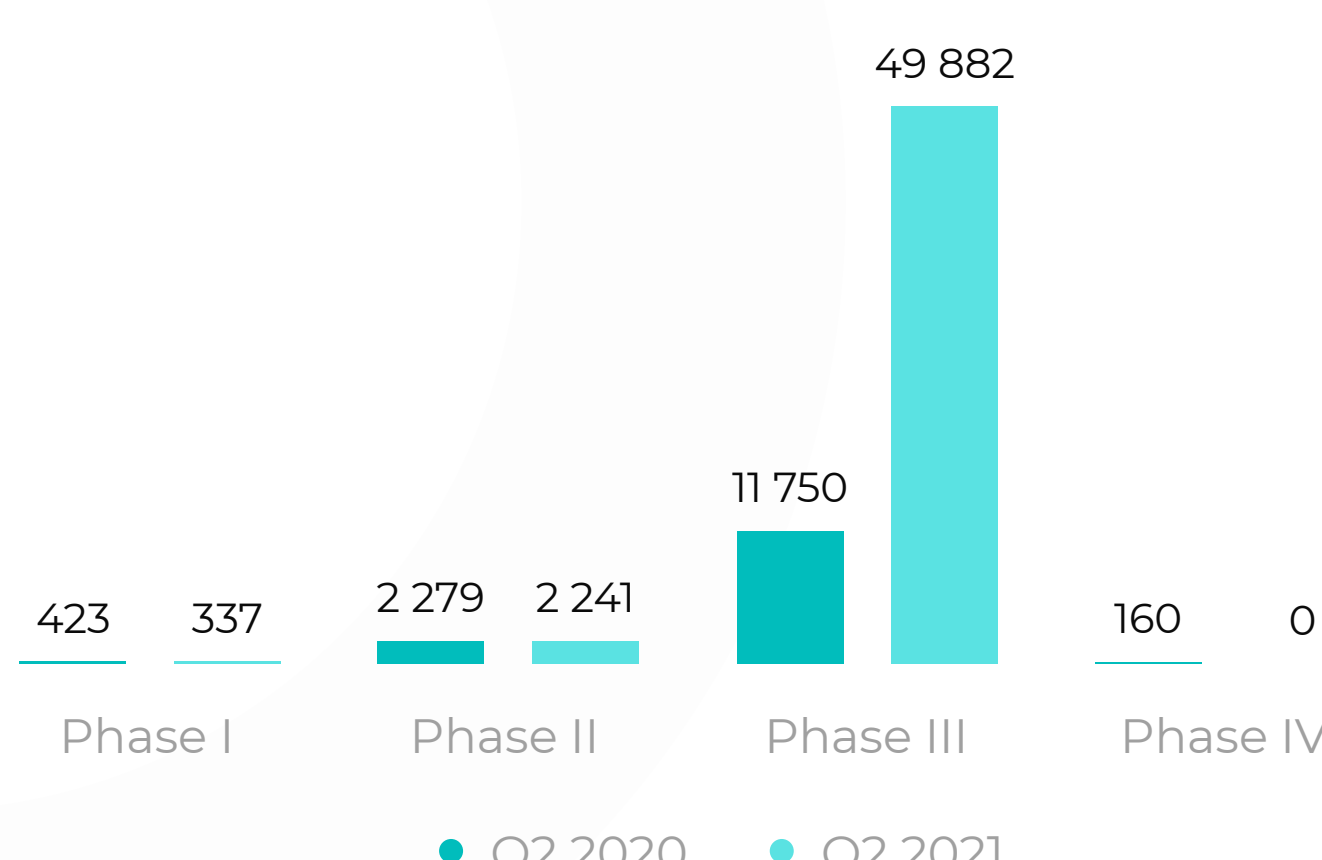
**** State Research Center of Virology and Biotechnology VECTOR

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q2 2021 reached a total of 52,460 subjects – a 260% jump in comparison with the previous year when only 14,612 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 95% 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 2021

Nº	Site Name	City	No. Studies
1	N.N. Blokhin Russian Cancer Research Center	Moscow	15
2	I.P. Pavlov First Saint Petersburg State Medical University	Saint-Petersburg	14
3	Ecosafety	Saint-Petersburg	14
4	V.A. Almazov National Medical Research Centre	Saint-Petersburg	13
5	Kazan State Medical University	Kazan	12

Combined market share of these sites

44%

CRO Data

Top-10 CROs in Russia

in Q2 2021 (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	Syneos Health	6	202
2	Parexel	5	384
3	PPD	5	130
4	MedPace	4	69
5	Covance	3	1 178
6	Pharmaceutical Research Associates CIS	3	218
7	Atlant Clinical	2	544
8	IQVIA	2	79

Top-5 CROs in Russia

in Q2 2021 (BE studies)

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

9	iPharma	1	7 978
10	X7 Clinical Research	1	158

Combined market share

31%

21%

Nº	Site Name	No. Studies	No. Subjects
1	Probiotech	3	114
2	X7 Clinical Research	2	154
3	ClinPharmInvest	2	140
4	ClinPharmDevelopment	1	55
5	Accellena	1	40

Combined market share of these companies

17%

19%

Regulatory Data

During Q2 2021 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 36 new drugs, including 7 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Ten of these 36 drugs (and two of 7 NMEs) were (or are being) studied in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
14.05.2021	Empavelinda (Pegcetacoplan)	Apellis Pharms
21.05.2021	Rybrevantbla (Amivantamab)	Janssen
28.05.2021	Lybalvinda (Olanzapine; Samidorphan l-malate)	Alkermes
31.05.2021	Noxafil Powdermix (Posaconazole)	Merck
01.06.2021	Brexafemmenda (Ibrexafungerp Citrate)	Scynexis
04.06.2021	Wegovynda (Semaglutide)	Novo Nordisk
10.06.2021	Epclusanda (Sofosbuvir; Velpatasvir)	Gilead Sciences
10.06.2021	Mavyretnda (Glecaprevir; Pibrentasvir)	Abbvie
21.06.2021	Pradaxanda (Dabigatran Etxilate Mesylate)	Boehringer Ingelheim
23.06.2021	Verkazianda (Cyclosporine)	Santen

In Q2 2021 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 32 new drugs, including 4 generics, 1 biosimilar and 10 orphan medicines.

Seventeen of these 32 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
22.04.2021	Maviret (Glecaprevir; Pibrentasvir)	AbbVie
22.04.2021	Koselugo (Selumetinib Sulfate)	AstraZeneca
20.05.2021	Jardiance (Empagliflozin)	Boehringer Ingelheim
20.05.2021	Keytruda (Pembrolizumab)	Merck
20.05.2021	Darzalex (Daratumumab)	Janssen
20.05.2021	Verquvo (Vericiguat)	Bayer
20.05.2021	Blincyto (Blinatumomab)	Amgen
20.05.2021	Xiliarx (Vildagliptin)	Novartis
21.05.2021	Zomarist (Vildagliptin; Metformin Hydrochloride)	Novartis
24.06.2021	Evrenzo (Roxadustat)	Astellas Pharma
24.06.2021	Edistride (Dapagliflozin; Propanediol Monohydrate)	AstraZeneca
24.06.2021	Rinvoq (Upadacitinib)	AbbVie
24.06.2021	Xeljanz (Tofacitinib Citrate)	Pfizer
24.06.2021	Opdivo (Nivolumab)	Bristol-Myers Squibb
24.06.2021	Minjuvi (Tafasitamab)	Incyte
24.06.2021	Byooviz (Ranibizumab)	Samsung Bioepis
24.06.2021	Bimzelx (Bimekizumab)	UCB Pharma

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative sites during Q2 2021.

Roszdraznador inspections

According to the Roszdraznador quarterly report, as of 12/07/2021 there were no Regulatory inspections conducted by Roszdraznador during Q2 2021.

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: 12/07/2021

About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia, Kazakhstan, Ukraine and Canada since 2002.

We set up the highest level of world-class quality both for SOPs and for final study data in every clinical trial we conduct.

Synergy consistently ranks in the top-10 market leaders by number 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.

We are continuously improving our SOPs, study risk management and IT infrastructure – and replacing outdated R&D strategies by novel, more efficient approaches to clinical research.