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Synergy Orange Paper / 2020 summer / quarter 2
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Clinical Trials in Russia

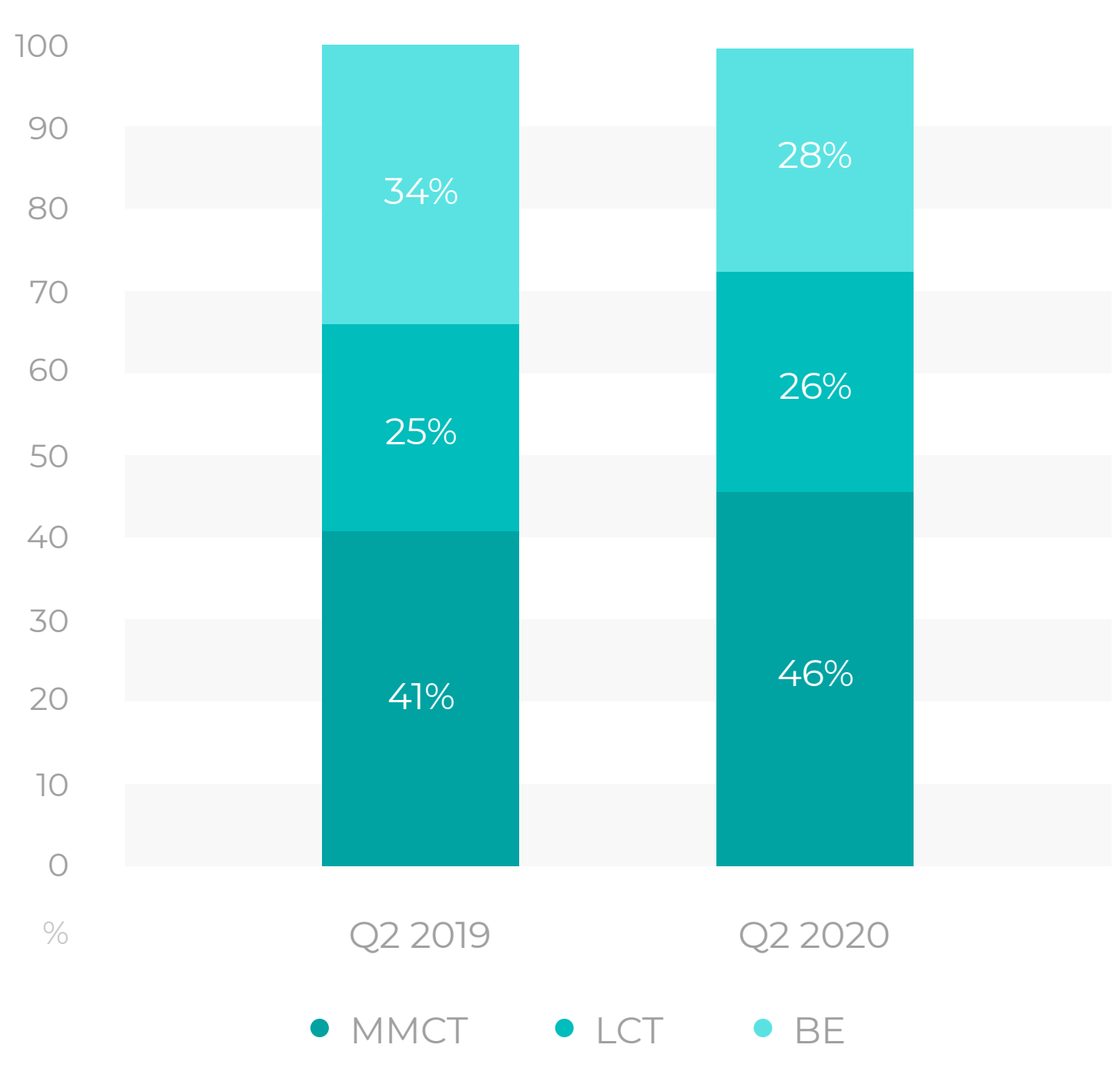
Q2 2020 Research report

Trial Data

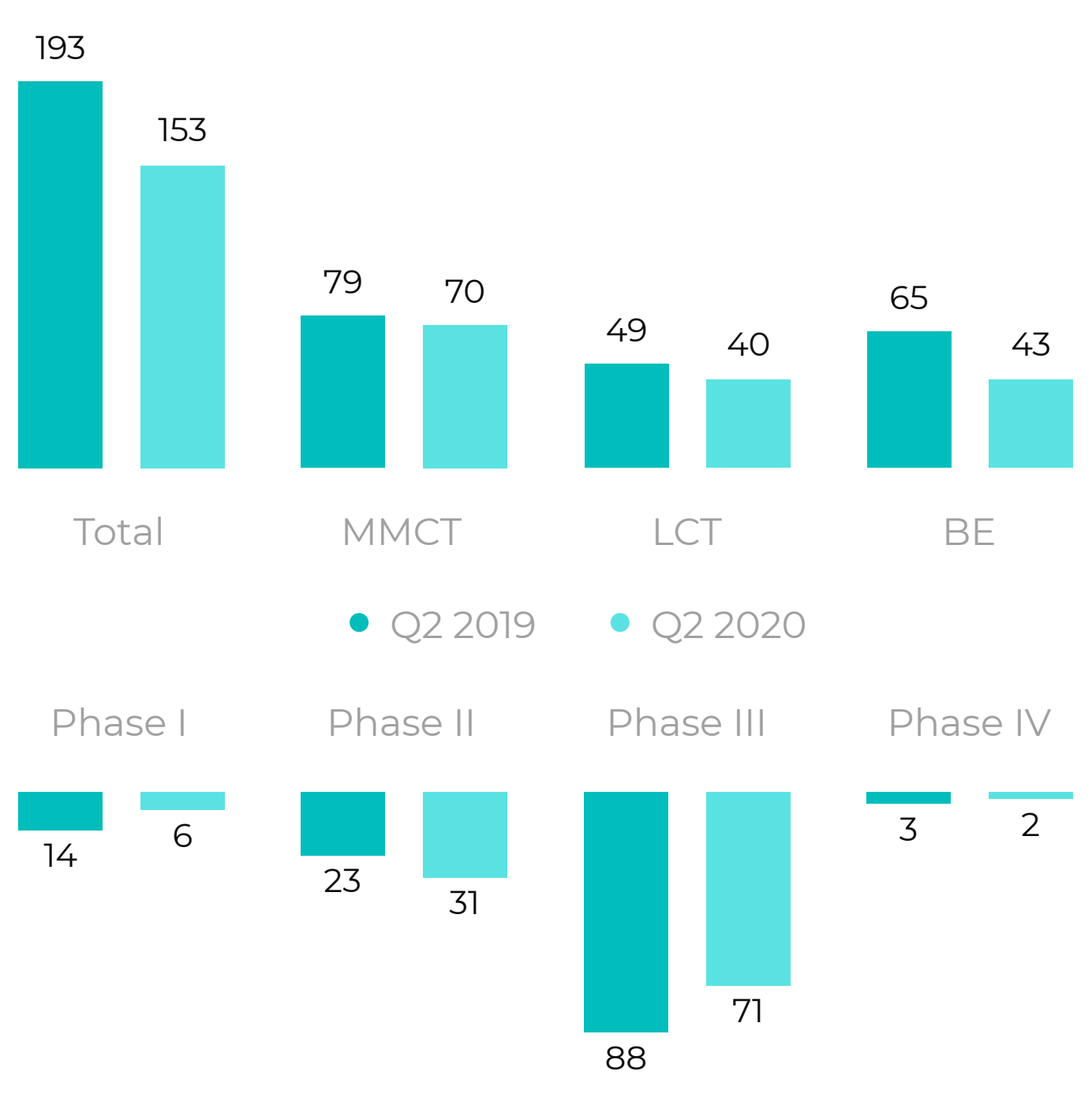
During Q2 2020 the Ministry of Health of the Russian Federation approved the start of 153 new clinical trials of all types, with an overall year on year decline of 21% by total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q2 2020 were MMCT. MMCT market share increased from 41% to 46% of the total number of trials. LCT market share remained almost the same with 26% whilst the BE share dipped slightly from 34% to 28%.

Percentage Breakdown of Clinical Trials by Type

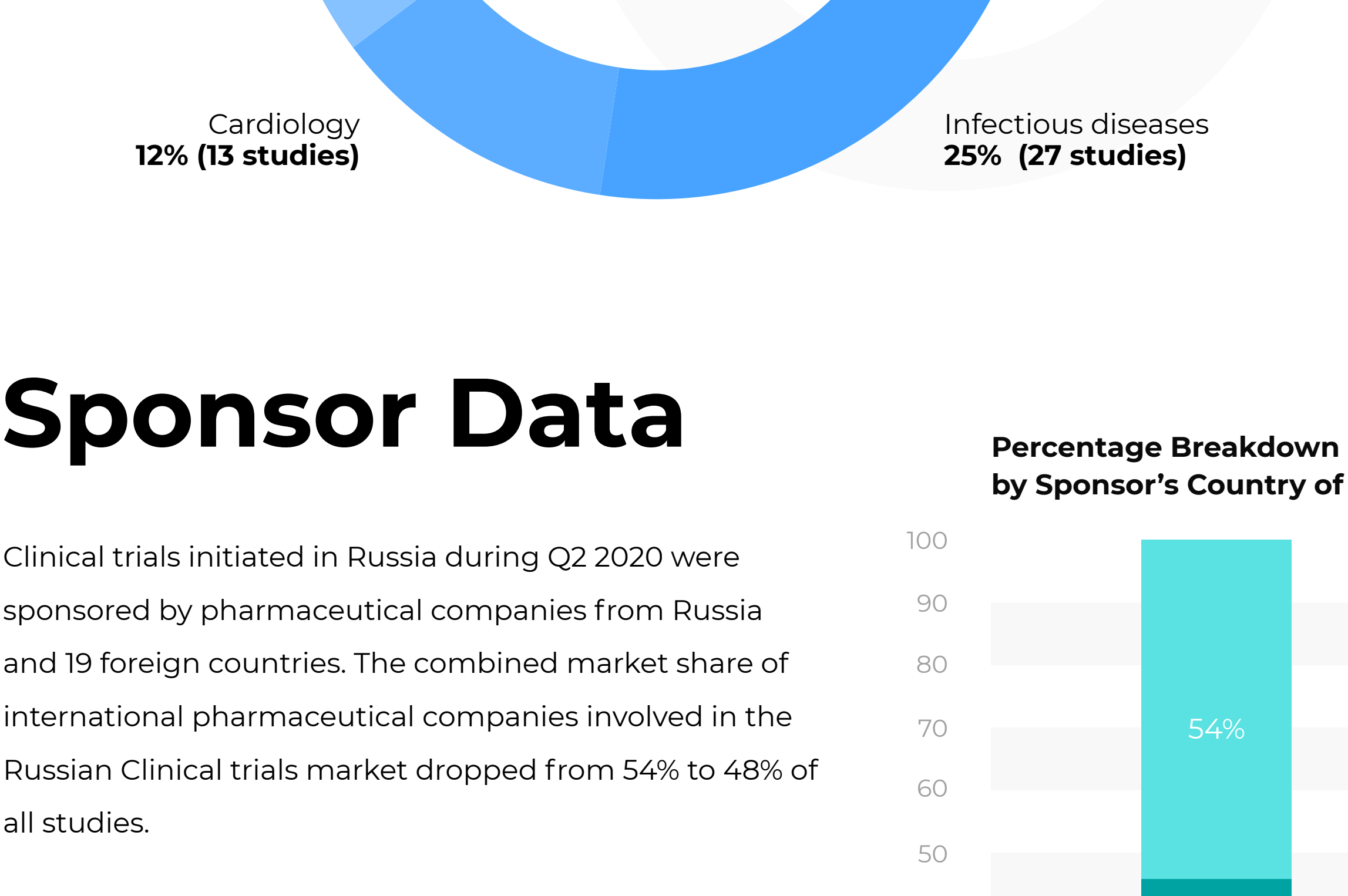


Breakdown of Clinical Trials by Type and Phase



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 19% – from 88 trials in Q2 2019 to 71 trials in Q2 2020.

The largest number of clinical trials initiated in Russia during Q2 2020 were related to Infectious diseases (27 studies), Oncology (26 studies) and Cardiology (13 studies). Other dominant therapy areas include Neurology, Gastroenterology and Hematology



Breakdown of Clinical Trials by Therapeutic Area

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

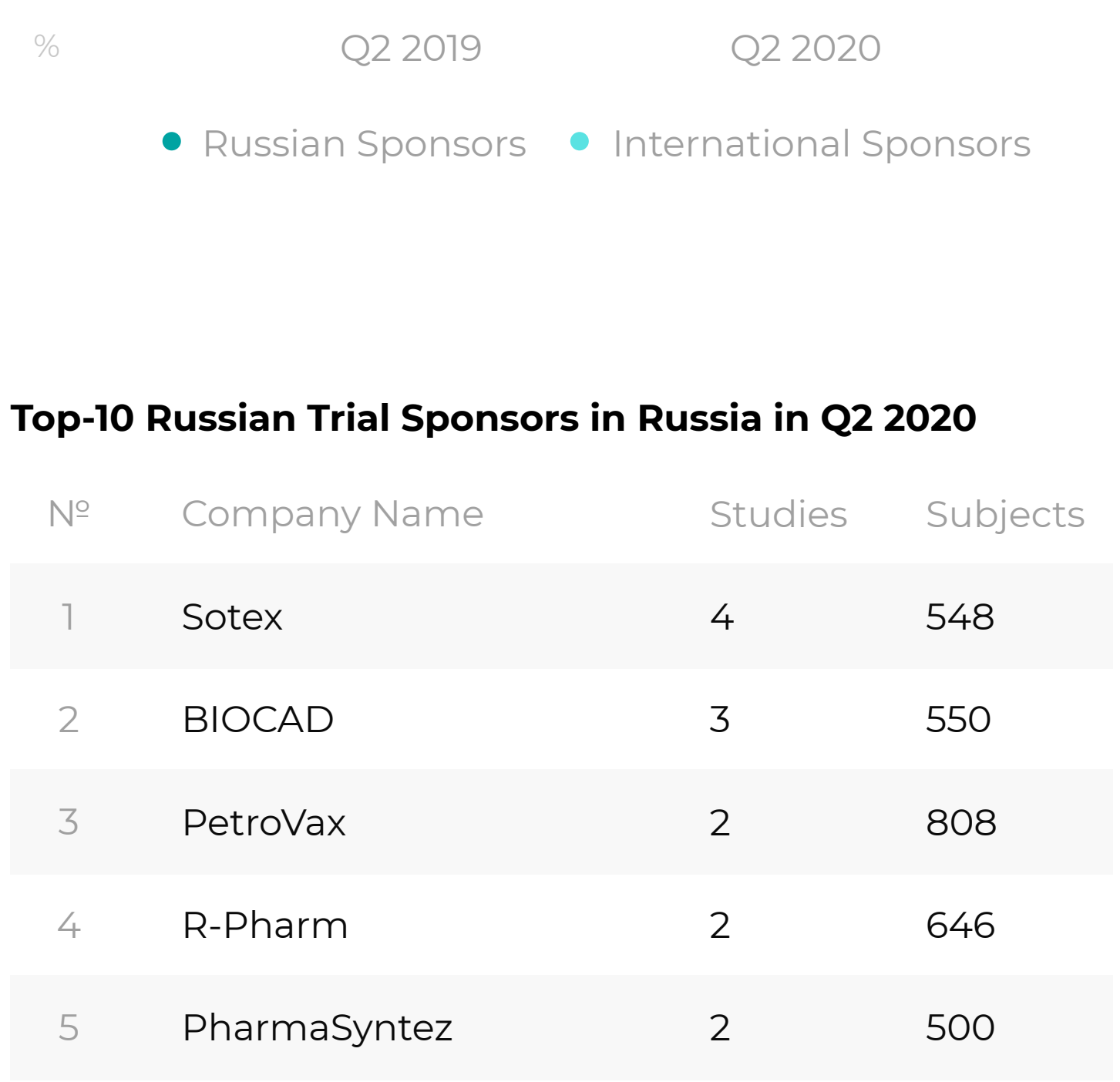
Sponsor Data

Clinical trials initiated in Russia during Q2 2020 were sponsored by pharmaceutical companies from Russia and 19 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 54% to 48% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Q2 2020 was Phase III with 65% share among Phase I – IV studies.

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.

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



Top-10 International Trial Sponsors in Russia in Q2 2020

№	Company Name	Studies	Subjects
1	Novartis	10	1 785
2	AstraZeneca	6	515
3	Allergan	3	326
4	Merck	3	200
5	Hoffman-la Roche	2	190
6	Pfizer	2	168
7	Eli Lilly	2	158
8	Argenx	2	112
9	Actelion	2	40
10	UCB BioPharma	2	32
	Combined share	**31%**	**24%**

Top-10 Russian Trial Sponsors in Russia in Q2 2020

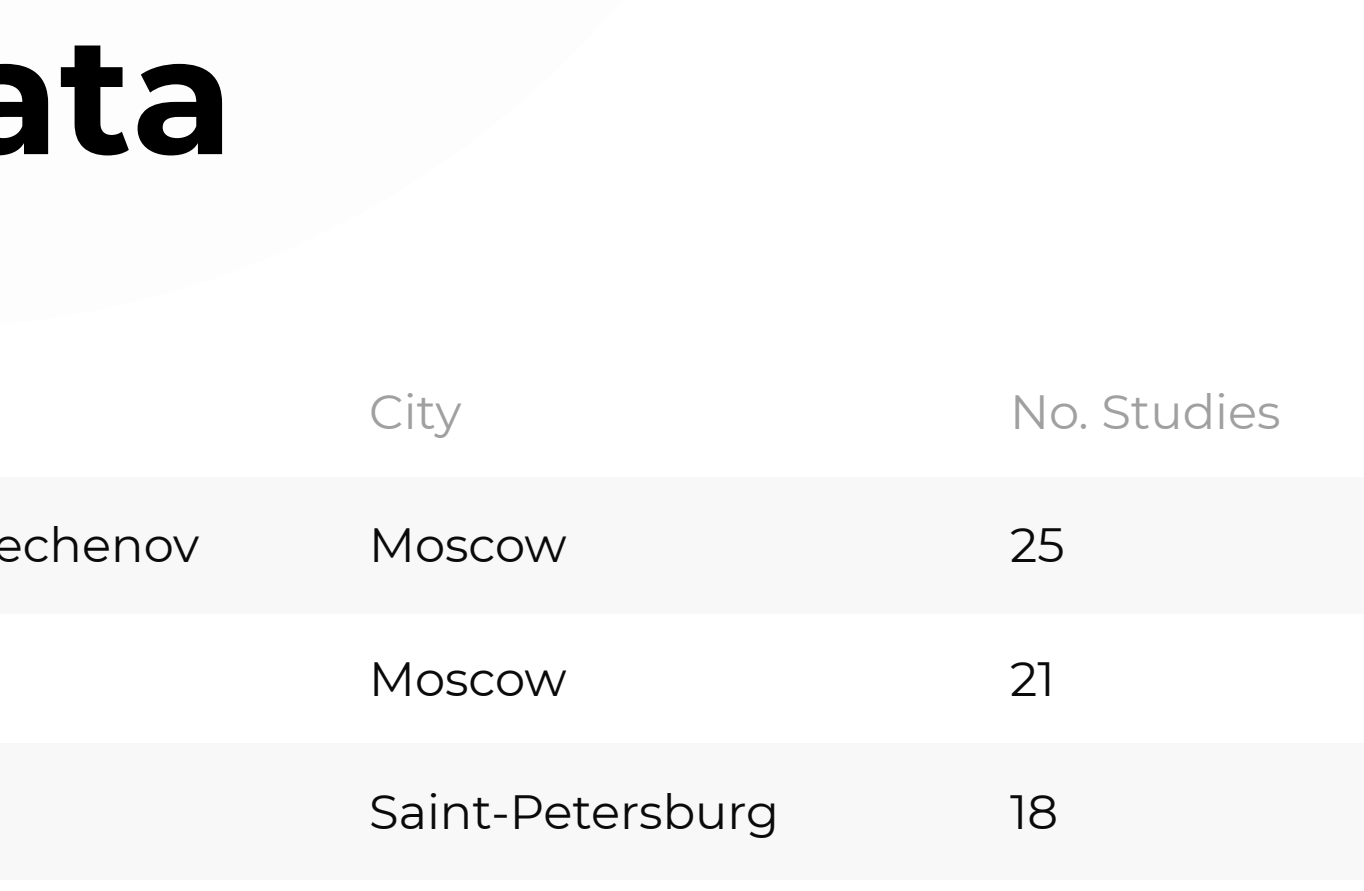
№	Company Name	Studies	Subjects
1	Sotex	4	548
2	BIOCAD	3	550
3	PetroVax	2	808
4	R-Pharm	2	646
5	PharmaSyntez	2	500
6	MedInvest	2	360
7	GeroPharm	2	320
8	Generium	2	300
9	NovaMedica	2	174
10	Gamaleya Research Institute	2	86
	Combined share	**21%**	**29%**

Subject Data

The overall number of subjects enrolled in clinical trials initiated in Russia during Q2 2020 reached a total of 14,612 subjects – a 19% decline in comparison with Q2 2019, when 18,052 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 80% 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



Research Site Data

Top-5 Russian research sites (all studies) in Q2 2020

№	Site Name	City	No. Studies
1	First Moscow State Medical University named after I.M. Sechenov	Moscow	25
2	City Clinical Hospital #52	Moscow	21
3	Almazov National Medical Research Centre	Saint-Petersburg	18
4	City Hospital #40 of the Kurortny District	Saint-Petersburg	18
5	City Clinical Hospital #15 named after O.M. Filatov	Moscow	17
	Combined market share of these sites		**65%**

CRO Data

Top-10 CROs in Russia in Q2 2020 (Phase I - IV studies)

Observational Clinical trials and Clinical trials without FDA defined phases (from I to IV) were not included in this ranking.

№	Site Name	No. Studies	No. Subjects
1	Parexel	5	164
2	Syneos Health	4	377
3	PPD	4	312
4	iPharma	3	532
5	IQVIA	3	151
6	OST Rus	2	373
7	Medical Development Agency	2	360
8	East Site Management & Research	2	328
9	Medpace	2	239
10	Synergy Research Group	2	200
	Combined market share	**26%**	**21%**

Top-5 CROs in Russia in Q2 2020 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	Probiotec	6	244
2	MAMI Health for You	1	58
3	ClinPharmInvest	1	50
4	Accellena Research and Development	1	44
5	Medical Development Agency	1	36
	Combined market share of these companies	**23%**	**22%**

Regulatory Data

During Q2 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 33 new drugs; 13 of them were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Five of these 33 drugs and two of these 13 NMEs were tested (or are currently being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
10/04/2020	Koselugonda (Selumetinib Sulfate)	AstraZeneca
06/05/2020	Tabrectanda (Capmatinib Hydrochloride)	Novartis
26/05/2020	Vesicare (Solifenacin Succinate)	Astellas
12/06/2020	Tivicay (Dolutegravir Sodium)	ViiV Healthcare
26/06/2020	Mycapssanda (Octreotide)	Chiasma

In Q2 2020 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 23 new drugs, including 2 generics, 2 biosimilar and 1 orphan medicines.

Ten of these 23 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
30/04/2020	Daurismo (Glasdegib Maleate)	Pfizer
30/04/2020	Paliperidone (Paliperidone Palmitate)	Janssen
30/04/2020	Zimbus Breezhaler (Glycopyrronium Bromide, Indacaterol Acetate, Mometasone Furoate)	Novartis
30/04/2020	Insulin Aspart (Insulin Aspart)	Sanofi
30/04/2020	Reblozyl (Luspatercept)	Celgene
28/05/2020	Xenleta (Lefamulin Acetate)	Nabriva Therapeutics
28/05/2020	Hepcludex (Bulevirtide Acetate)	MYR
28/05/2020	Rozlytrek (Entrectinib)	Hoffmann-La Roche
28/05/2020	Piqray (Alpelisib)	Novartis
25/06/2020	Aybintio (Bevacizumab)	Samsung Bioepis

FDA inspections

According to the U.S. FDA data, there was no FDA inspections conducted in a Russian investigative site during Q2 2020.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 01/07/2020 there were no Regulatory inspections conducted by Roszdravnadzor during Q2 2020.

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: 01/07/2020

About Synergy Research Group

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

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

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.