

Synergy **Orange** Paper / 2020 Spring / Quarter 1



Clinical trials in Russia

Research report

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Foreword

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: 02/04/2020



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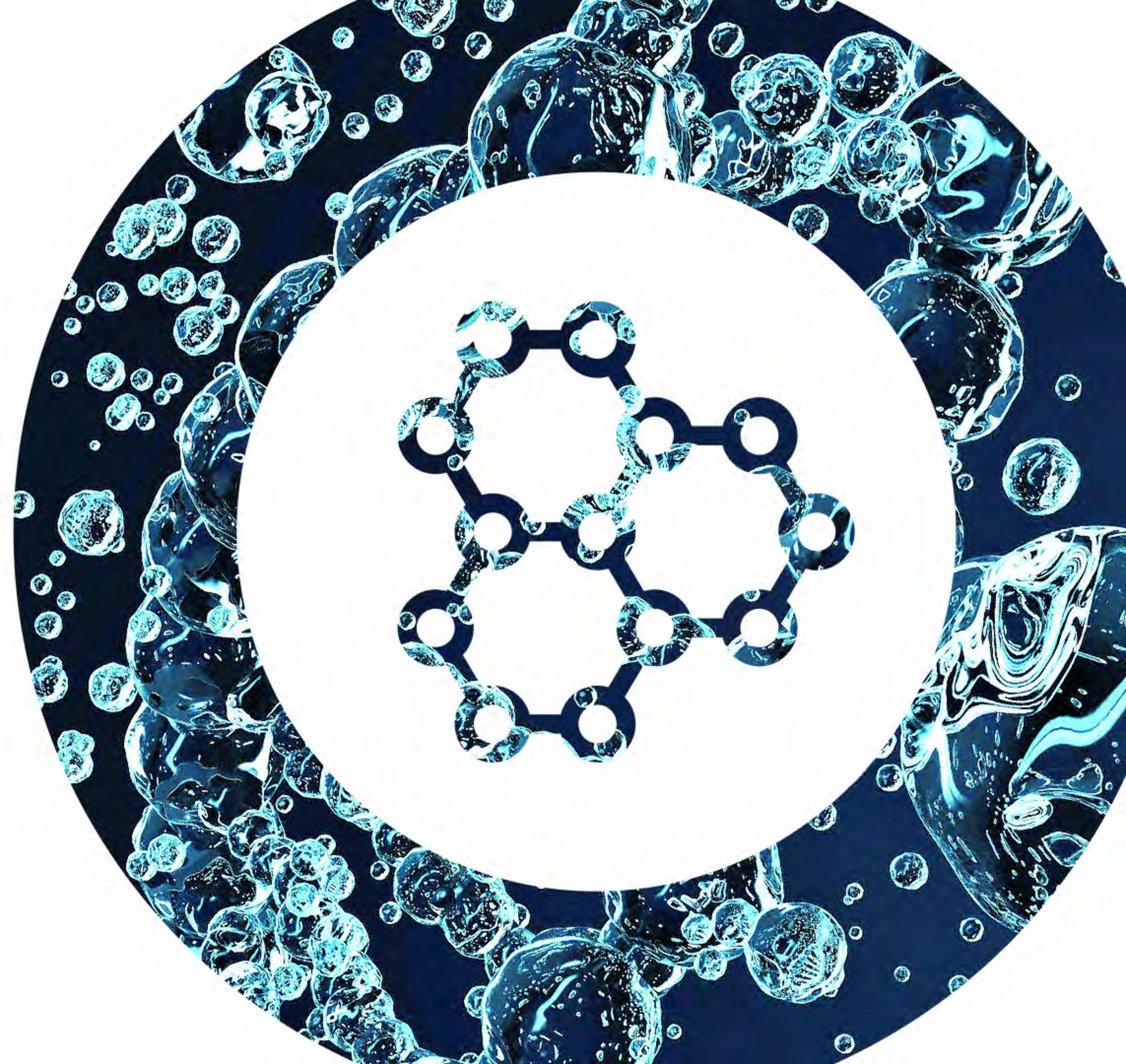


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Executive Summary

During Q1 2020 the Ministry of Health of the Russian Federation approved the start of 145 new clinical trials of all types, with an overall year on year decline of 5% by total number of studies.

The dominant type of clinical trials conducted in Russian sites in Q1 2020 were MMCT (Multinational Multi-center Clinical Trials) with 46% market share. The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III.

The top-10 International Sponsors account for 45% of the total number of studies conducted in Russia, and for 34% of all subjects enrolled during the year. The top-10 Russian sponsors take up approximately 15% of the market by total number of trials conducted in Russia and have 31% of all subjects enrolled in these trials.

The twenty largest pharmaceutical companies combined account for 60% of all clinical trials conducted in Russia and for 65% of all subjects enrolled.

During Q1 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs, including 8 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Seven of these 29 drugs were tested (or being studied) in clinical trials involving Russian sites.

In Q1 2020 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 23 new drugs. Nine of these drugs were tested (or being studied) in clinical trials involving Russian sites.

The top-5 domestic pharmaceutical manufacturers in Russia during Q1 2020 were: **Microgen**, **PSK Pharma**, **Polysan**, **FZ Immunoleks** and **SmartBioTech**.

The top-5 International Sponsors in Russia during Q1 2020 were: **Merck**, **Eli Lilly**, **Sanofi**, **Hoffmann-La-Roche** and **Pfizer**.

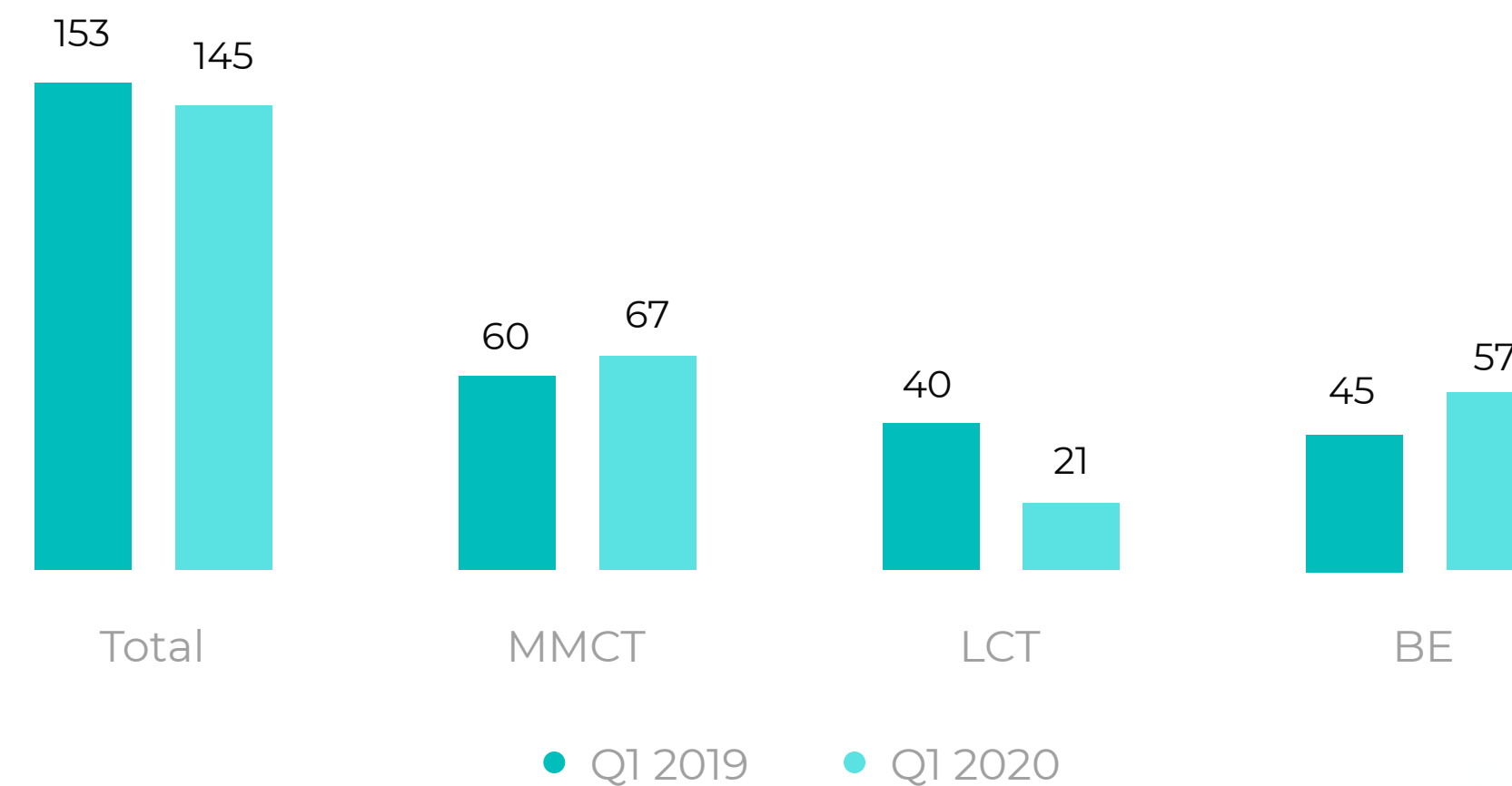
According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during Q1 2020.

Trial Data

During Q1 2020 the Ministry of Health of the Russian Federation approved the start of 145 new clinical trials of all types, including local and bioequivalence studies. This represents a 5% year on year decline by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q1 2020 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs increased from 39% to 46% of the total number of trials. The market share of Local Clinical Trials (LCTs) crashed more than twice from 31% to 14% whilst the Bio-equivalent (BE') share raised from 29% to 39%.

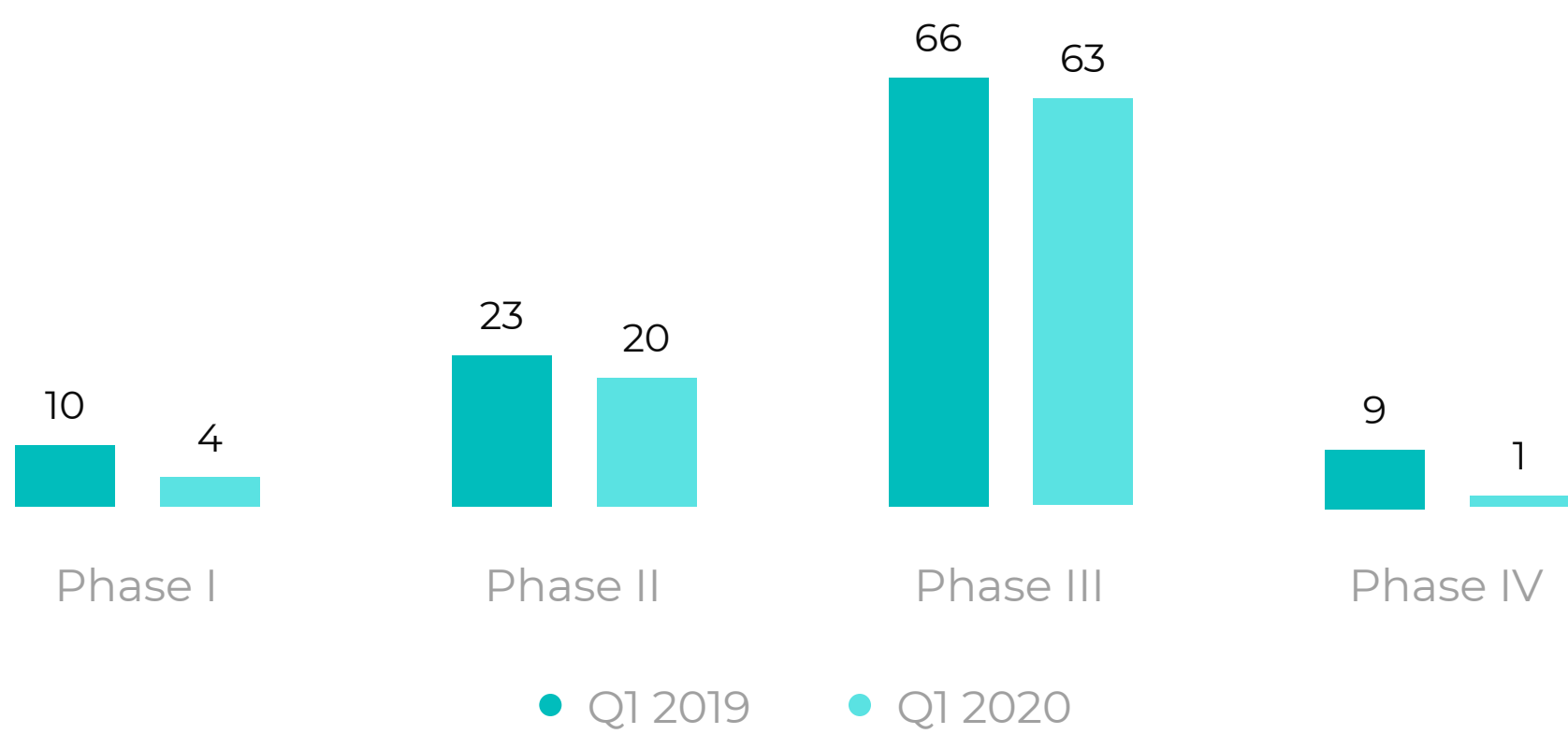
Breakdown of Clinical Trials in Q1 2020 by Type



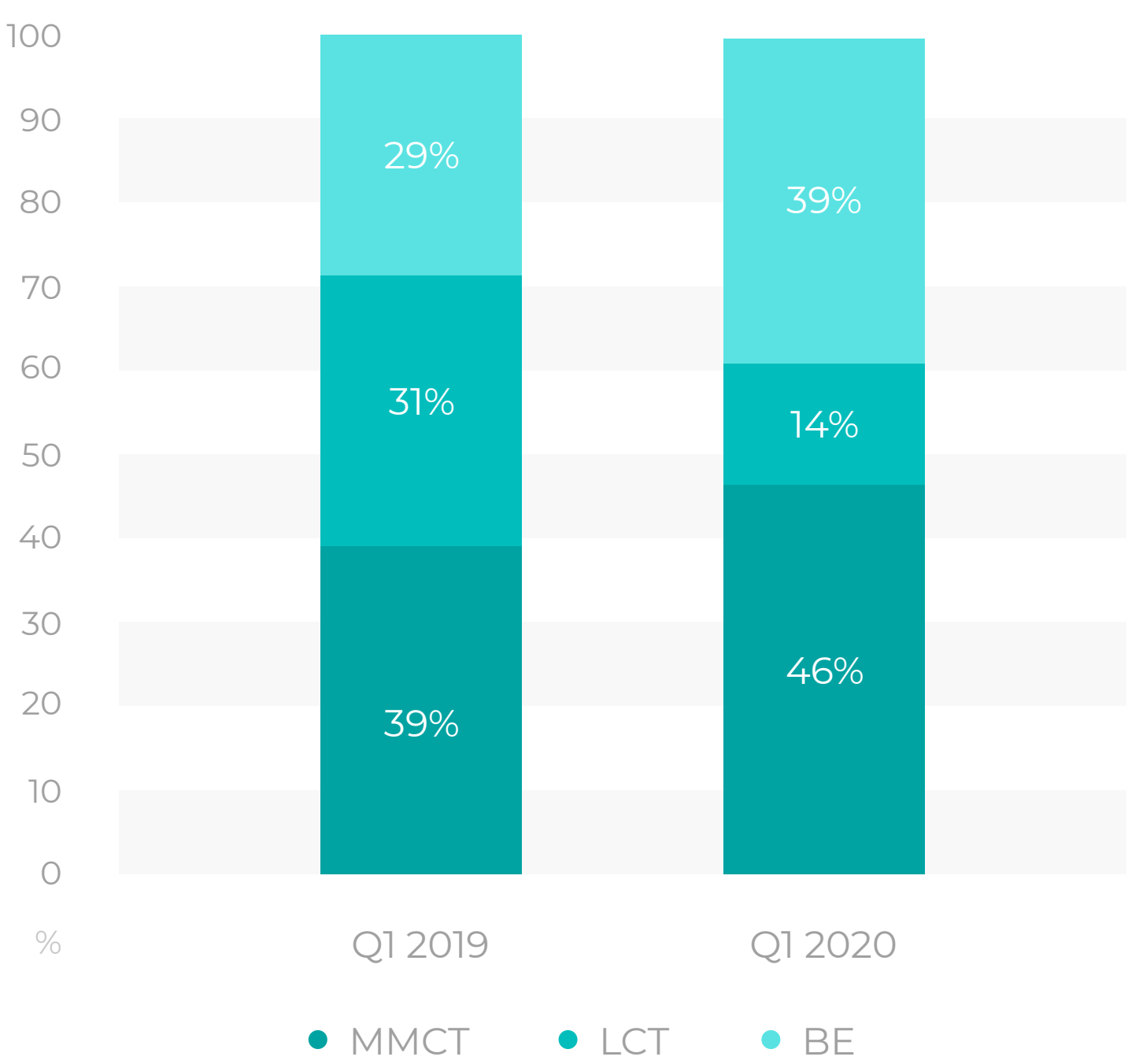
Trial Data

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 slightly by 5% – from 66 trials in Q1 2019 to 63 trials in Q1 2020.

Breakdown of Clinical Trials by Phase



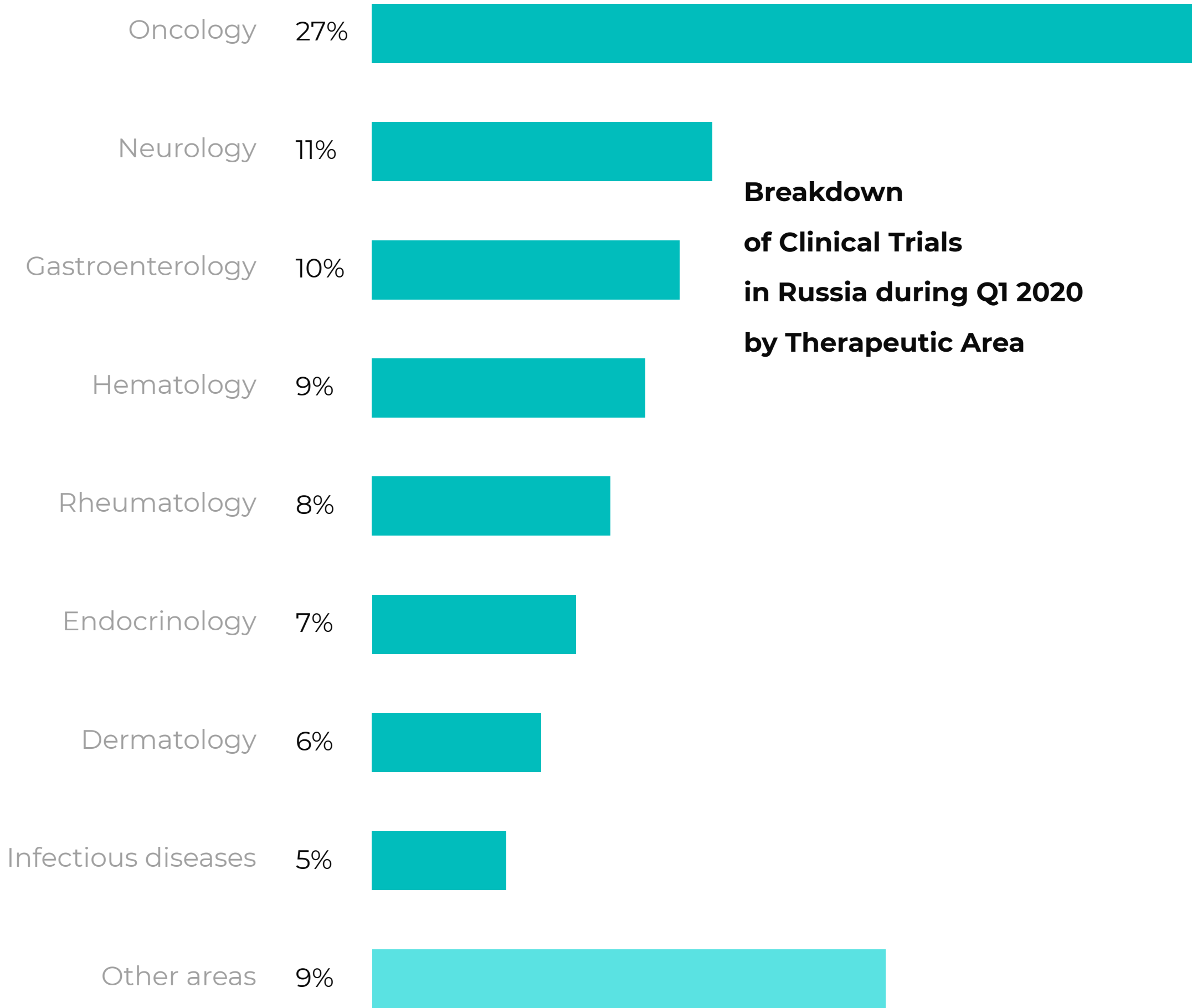
Percentage Breakdown of Clinical Trials by Type



Trial Data

The largest number of clinical trials initiated in Russia during Q1 2020 were related to Oncology (24 studies), Neurology (10 studies) and Gastroenterology (9 studies). Other dominant therapy areas include Hematology, Rheumatology and Endocrinology.

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

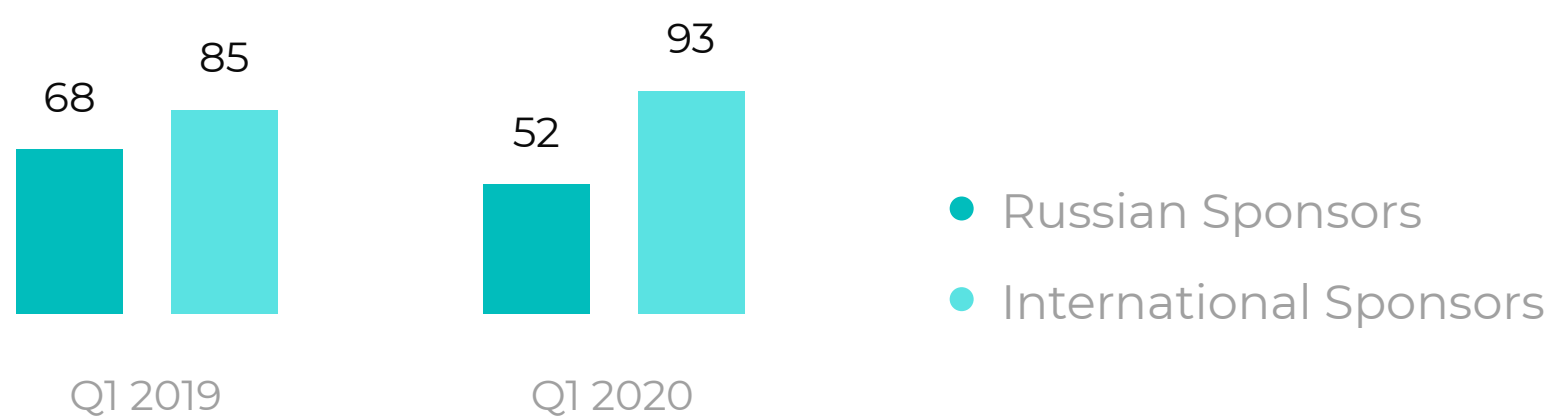


Sponsor Data

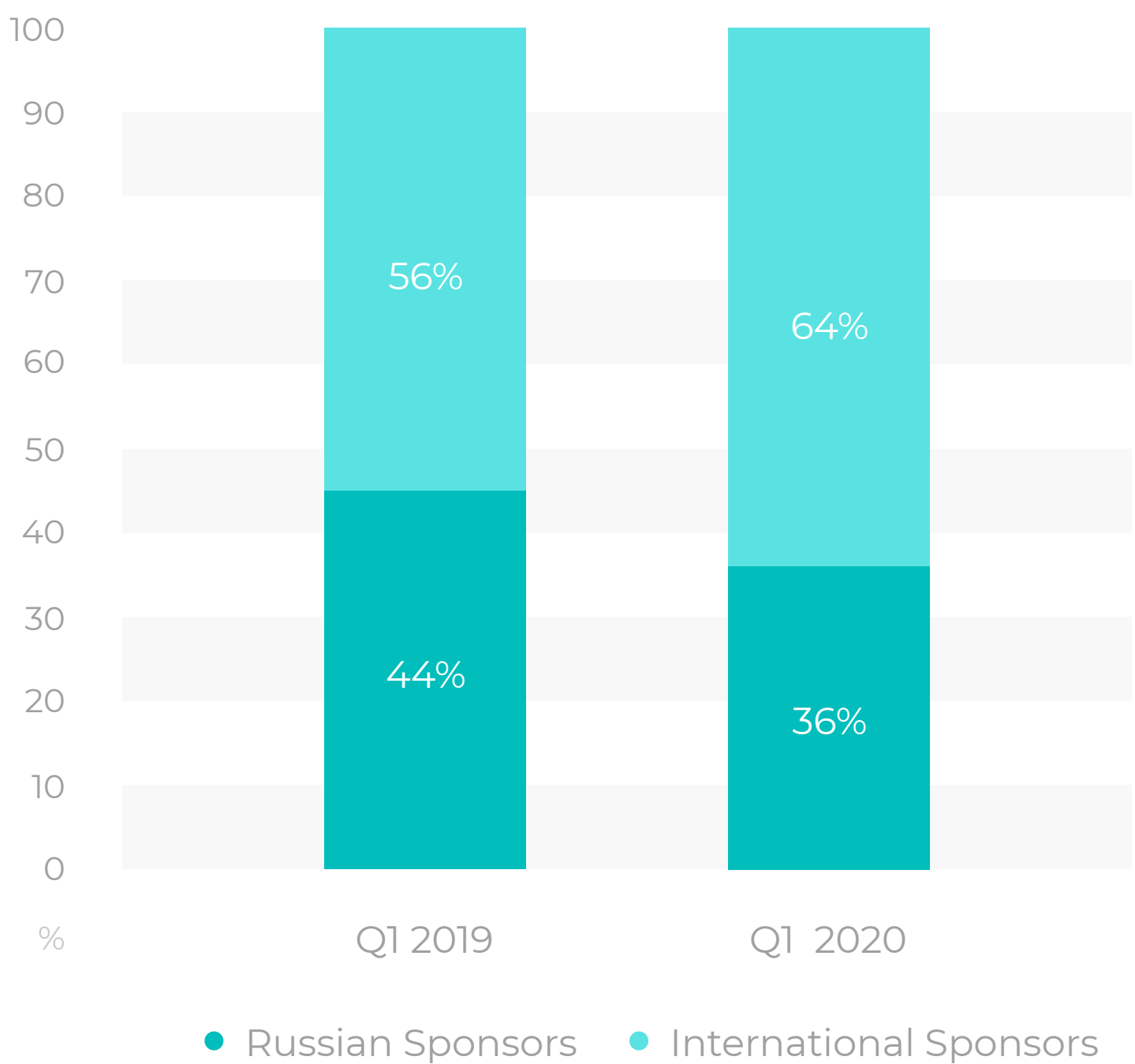
Clinical trials initiated in Russia during Q1 2020 were sponsored by pharmaceutical companies from Russia and 22 foreign countries.

The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market raised from 56% to 64% of all studies.

Breakdown of Clinical Trials by Sponsor Origin



Percentage Breakdown of Trials by Sponsor Origin

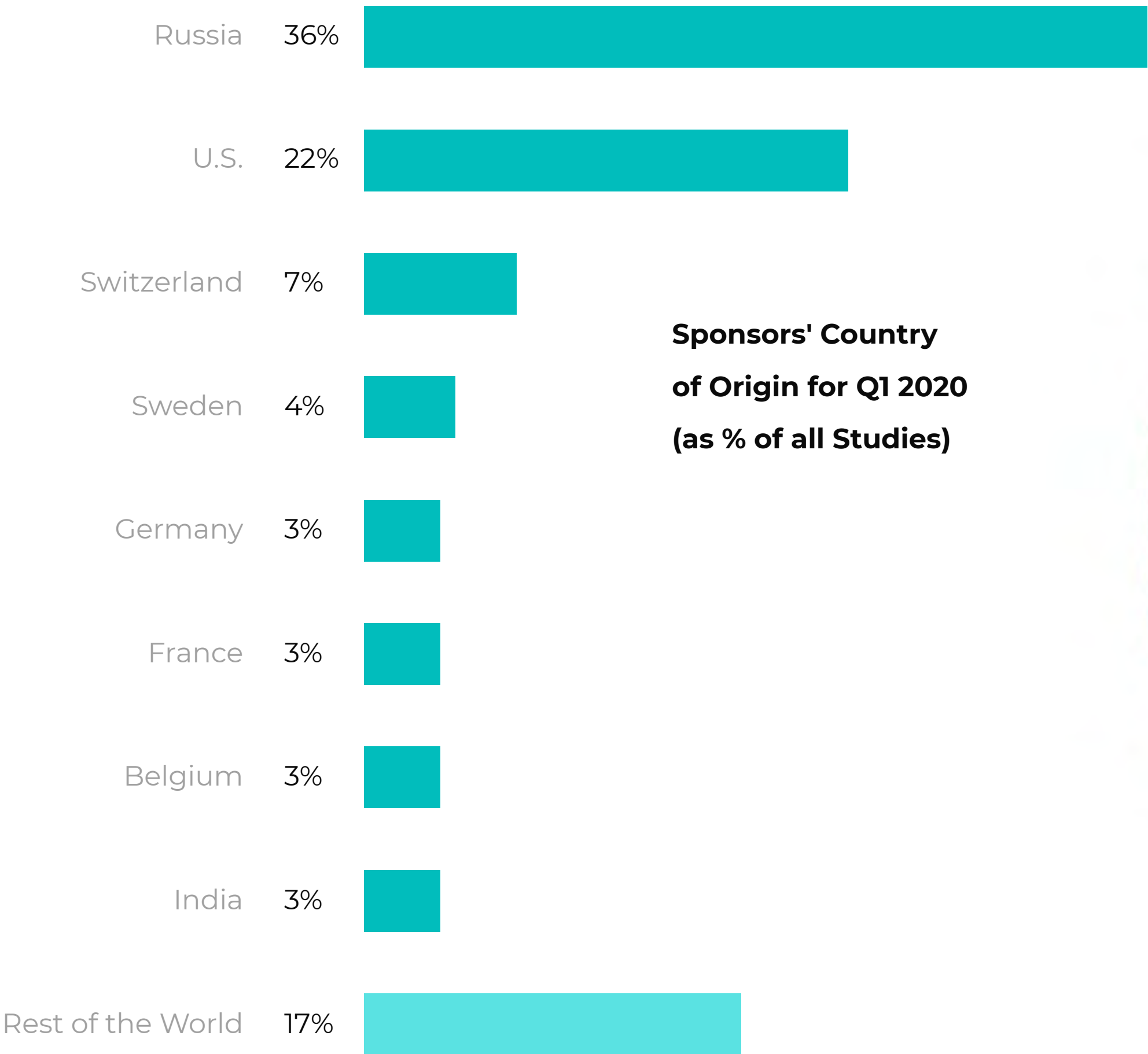
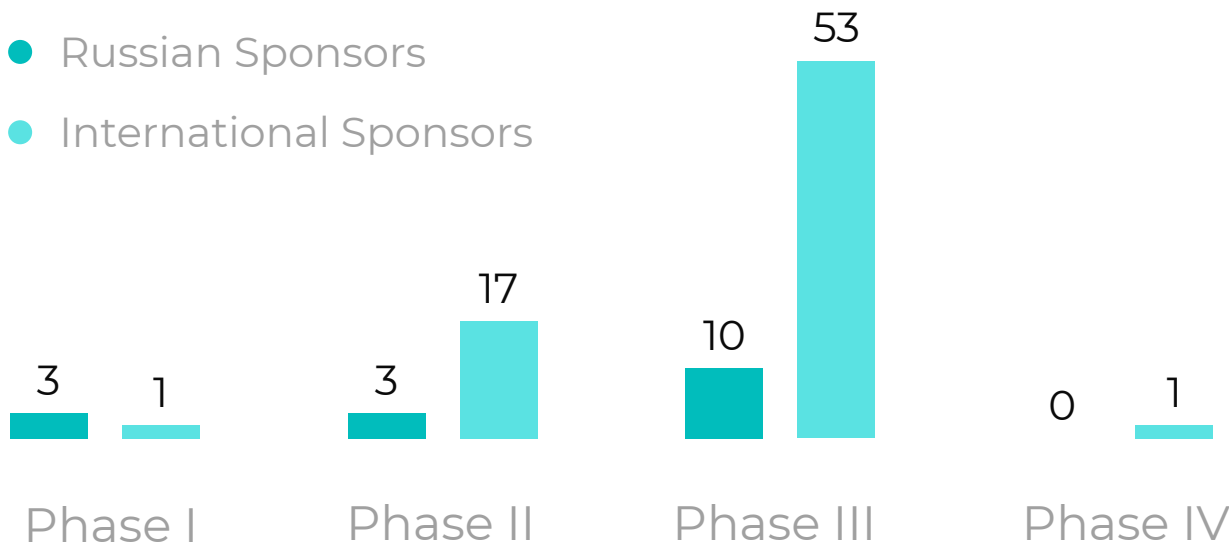


Sponsor Data

The most prevalent Sponsor's countries of origin in Q1 2020 were Russia (52 studies), U.S. (32 studies) and Switzerland (10 studies). Other prominent countries include Sweden (6 studies), Germany (5 studies) and France (5 studies).

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Q1 2020 was Phase III with 72% share among Phase I – IV studies.

Breakdown of Clinical Trials by Sponsor's Origin and Phase



Sponsors' Country
of Origin for Q1 2020
(as % of all Studies)

International Sponsor Ranking



Top-10 International Trial Sponsors in Russia in Q1 2020

Nº	Company Name	No. studies	No. subjects
1	Merck	7	480
2	Eli Lilly	5	1 098
3	Sanofi	5	297
4	Hoffmann-La Roche	5	229
5	Pfizer	4	217
6	AstraZeneca	4	200
7	Bristol-Myers	3	155
8	Novartis	3	111
9	Jadran-Galenski	2	268
10	Camurus	2	69

Combined market share of these companies **45%** **34%**

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

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

Russian Sponsor Ranking



Top-10 Russian Trial Sponsors in Russia in Q1 2020

Nº	Company Name	No. studies	No. subjects
1	Microgen	3	980
2	PSK Pharma	2	52
3	Polysan	1	432
4	FZ Immunoleks	1	414
5	SmartBioTech	1	300
6	Obnovlenie	1	220
7	OTC Pharm	1	140
8	NIzhPharm	1	130
9	SPBNIIVS	1	125
10	Generium	1	44

Combined market share of these companies **15%** **31%**

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

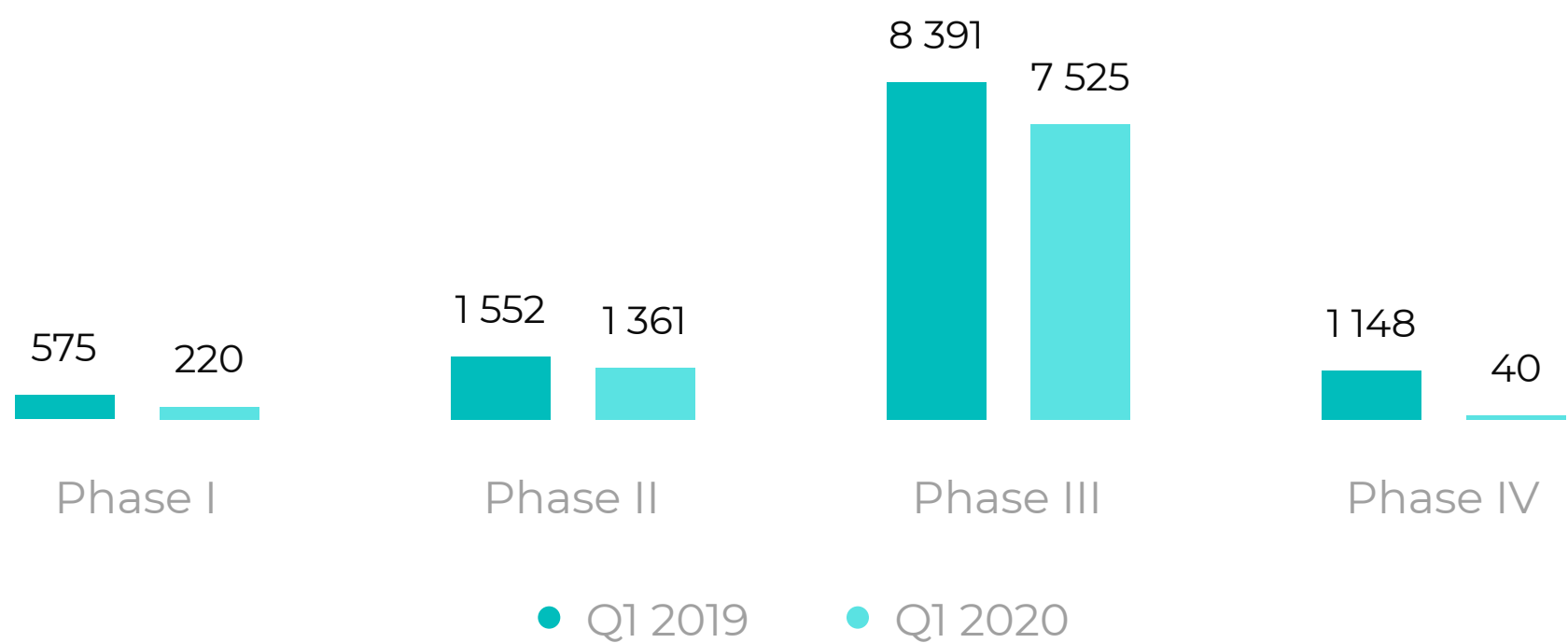
Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

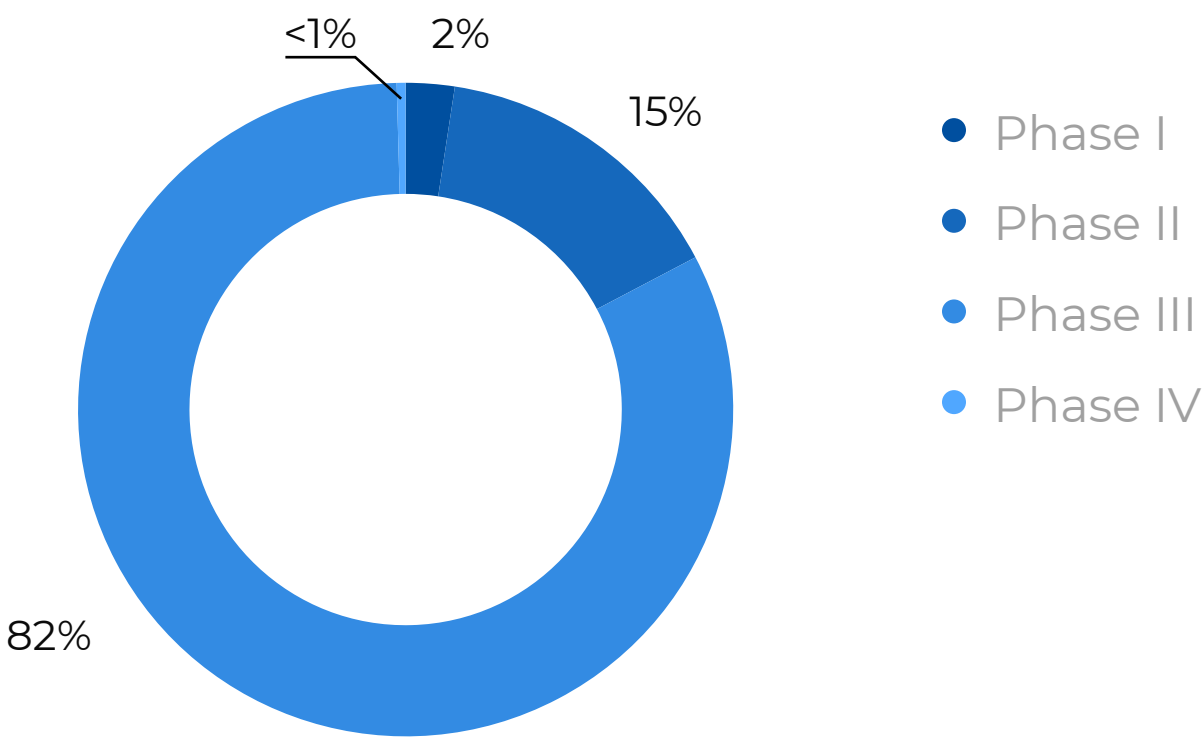
The overall number of subjects enrolled in clinical trials initiated in Russia during Q1 2020 reached a total of 9,146 subjects – a 22% decline in comparison with Q1 2019, when 11,666 subjects were enrolled.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 82% of all subjects enrolled.

Breakdown of Number of Subjects Enrolled by Phase



Percentage Breakdown of Number of Subjects by Phase



Studies indicated by sponsors as Phase I-II in the applications submitted to Ministry of Health, are shown in Phase II studies group; Phase II-III – in Phase III group, Phase III-IV –in Phase IV group.

Research Site Data



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Top-5 Russian Research Sites (BE and Phase I Studies)

Nº	Site Name	City	No. studies
1	Probiotec Medical Center	Moscow Region	9
2	Clinical Hospital #2, Yaroslavl region	Yaroslavl	8
3	Human Brain Institute named after N.P. Bekhtereva	Saint-Petersburg	7
4	Center for Physical and Chemical Medicine of the Federal Medical and Biological Agency	Moscow	4
5	Ecosafety	Saint-Petersburg	3

Combined market share of these sites **21%**

Top-5 Russian Research Sites (Phase II-IV Studies)

Nº	Site Name	City	No. studies
1	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	13
2	First Moscow State Medical University named after I.M. Sechenov	Moscow	12
3	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	10
4	National Medical Research Center for Radiology	Moscow	9
5	Rostov State Medical University	Rostov-on-Don	7

Combined market share of these sites **35%**

Research Site Data



Top-10 Russian Research Sites (all Studies)

Nº	Site Name	City	No. studies
1	Clinical Hospital #2, Yaroslavl region	Yaroslavl	14
2	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	13
3	First Moscow State Medical University named after I.M. Sechenov	Moscow	12
4	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	11
5	National Medical Research Center for Radiology	Moscow	9
6	St. Petersburg Clinical Scientific and Practical Center for Specialized Types of Medical Care	Saint-Petersburg	8
7	Human Brain Institute named after N.P. Bekhtereva	Saint-Petersburg	8
8	Rostov State Medical University	Rostov-on-Don	7
9	City Clinical Hospital #40	Saint-Petersburg	7
10	Ecosafety	Saint-Petersburg	6

Combined market share of these sites **66%**

CRO Data



CRO Rankings for Q1 2020 in Russia (Phase I - IV studies)

Nº	Company Name	No. studies	No. subjects
1	PPD	5	286
2	IQVIA	4	111
3	Syneos Health	3	110
4	ICON	2	245
5	Clinical Trials and Development	2	69
6	iPharma	1	432
7	OST Rus	1	264
8	PSI	1	70
9	Pharmaceutical Research Associates CIS	1	70
10	Parexel	1	68

Combined market share of these companies* 24% 19%

*Combined market share based on total studies conducted both sponsors and CROs.

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

CRO Data



CRO Rankings for Q1 2020 in Russia (BE studies)

Nº	Company Name	No. studies	No. subjects
1	ClinPharmDevelopment	4	341
2	Biomapas	4	144
3	X7 Clinical Research	2	130
4	ARS	2	64
5	OST Rus	1	110
6	ClinPharmInvest	1	80
7	Chorich Pharm	1	70
8	Probiotec Medical Center	1	60
9	IMTEC	1	50
10	Global Pharma	1	44

Combined market share of these companies* **32%** **36%**

*Combined market share based on total studies conducted both sponsors and CROs.

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

Regulatory Data

During Q1 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs; 8 of them were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Seven of these 29 drugs were (or are being) studied in clinical trials involving Russian sites.

In Q1 2020 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 23 new drugs, including 4 generics, 2 biosimilar and 1 orphan medicines. Nine of these 23 drugs were (or are being) studied in clinical trials involved Russian sites.

Drugs studied at Russian sites and approved by FDA in Q1 2020

Nº	Appr. date	Drug (active ingredient)	Company
1	16/01/2020	Monoferrienda (Ferric Derisomaltose)	PharmaCosmos
2	16/01/2020	Rybelsusenda (Semaglutide)	Novo Nordisk
3	27/01/2020	Trijardy (Empagliflozin; Linagliptin; Metformin Hydrochloride)	Boehringer Ingelheim
4	21/02/2020	Nexletolnda (Bempedoic Acid)	Esperion Theraps
5	02/03/2020	Sarclisabla (Isatuximab-IRFC)	Sanofi
6	04/03/2020	Durystanda (Bimatoprost)	Allergan
7	25/03/2020	Zeposianda (Ozanimod Hydrochloride)	Celgene

Source: FDA



Inspection Data

FDA Inspections

According to the U.S. FDA data, there was no FDA inspections conducted in a Russian investigative site during Q1 2020.

Roszdraznador Inspections

According to the Roszdraznador quarterly report, as of 04/02/2020 there were no Regulatory inspections conducted by Roszdraznador during Q1 2020.

Drugs studied at
Russian sites
and approved by
EMA in Q1 2020

Nº	Appr. date	Drug (active ingredient)	Company
1	31/01/2020	Ruxience (Rituximab)	Pfizer
2	31/01/2020	Budesonide/ Formoterol (Budesonide Formoterol Fumarate Dihydrate)	Teva
3	31/01/2020	Liumjev (Insulin Lispro)	Eli Lilly
4	31/01/2020	Rybelsus (Semaglutide)	Novo Nordisk
5	27/02/2020	Fetcroja (Cefiderocol Sulfate Tosilate)	Shionogi
6	26/03/2020	Atectura Breezhaler (Indacaterol Acetate; Mometasone Furoate)	Novartis
7	26/03/2020	Bemrist Breezhaler (Indacaterol Acetate; Mometasone Furoate)	Novartis
8	26/03/2020	Zeposia (Ozanimod Hydrochloride)	Celgene
9	26/03/2020	Sarclisa (Isatuximab)	Sanofi

Source: EMA

About Synergy

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

From year to year our company is consistently in the TOP-10 of market leaders by the numbers of conducted clinical studies and enrolled patients.

The high recruitment rates of the emerging markets combined with innovative technology allows Synergy to conduct faster, more cost-effective studies without sacrificing quality for our clients.

We ensure the highest level of quality of SOPs and of final study data for all clinical studies conducted by our company. We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – replacing outdated R&D strategies by novel, more efficient approaches to clinical research.



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