

Synergy orange paper / 2019 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: 04/04/2019



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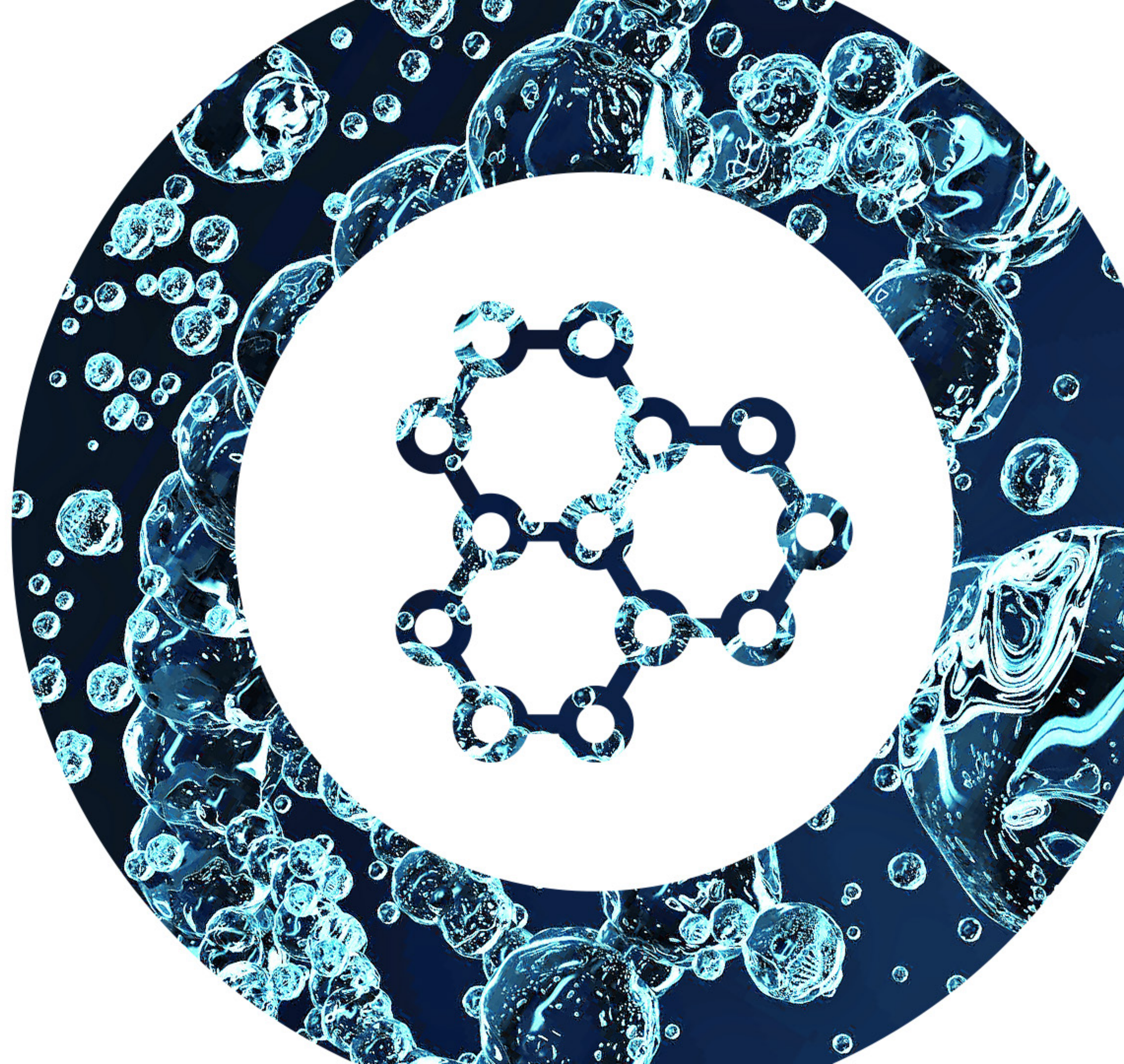


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Executive Summary

During Q1 2019 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 growth of 1,3% by total number of studies.

The dominant type of clinical trials conducted in Russian sites in Q1 2019 were MMCT (Multinational Multi-center Clinical Trials) with 39% 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 24% of the total number of studies conducted, and for 22% of all subjects enrolled during the quarter. The top-10 Russian sponsors take up approximately 14% of the market by total number of trials conducted and have 28% of all subjects enrolled in these trials.

The twenty largest pharmaceutical companies combined account for 38% of all clinical trials and for 50% of all subjects enrolled.

During Q1 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs, including four new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Six of these 29 drugs were tested (or being studied) in clinical trials involving Russian sites.

In Q1 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 17 new drugs. Four of the approved drugs were tested (or being studied) in clinical trials involving Russian sites.

Top domestic pharmaceutical manufacturers are **Sotex, Biocad, MedInvest, OBL Pharm and Generium.**

The top-5 International Sponsors in Russia are: **Merck, Novartis, Iterum Therapeutics, ACADIA Pharmaceuticals and Minerva Pharmaceutical.**

According to the U.S. FDA data, there was one FDA inspection conducted in Russian investigative sites during Q1 2019. The FDA representative inspected activity of Dr. Yulia Karakulova, M.D. in Perm with a No Action Indicated (NAI) outcome.

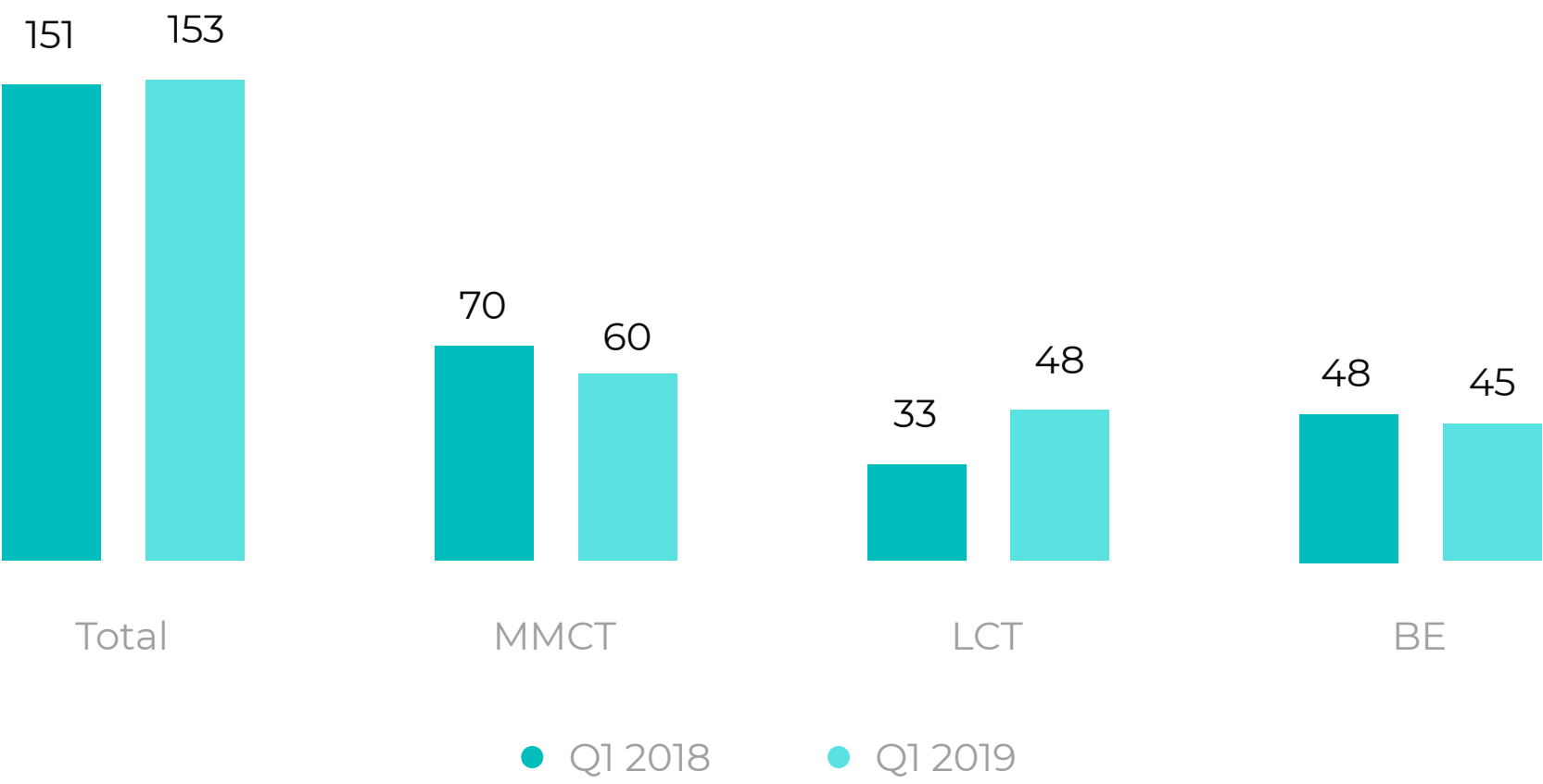
Clinical Trials in Russia

Trial Data

During Q1 2019 the Ministry of Health of the Russian Federation approved the start of 153 new clinical trials of all types, including local and bioequivalence studies. This represents a 1,3% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q1 2019 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs declined from 46% to 39% of the total number of trials. The market share of Local Clinical Trials (LCTs) flourished with an increase from 22% to 31% whilst the Bio-equivalent (BE') share dropped slightly from 32% to 29%.

Breakdown of Clinical Trials in Q1 2019 by Type



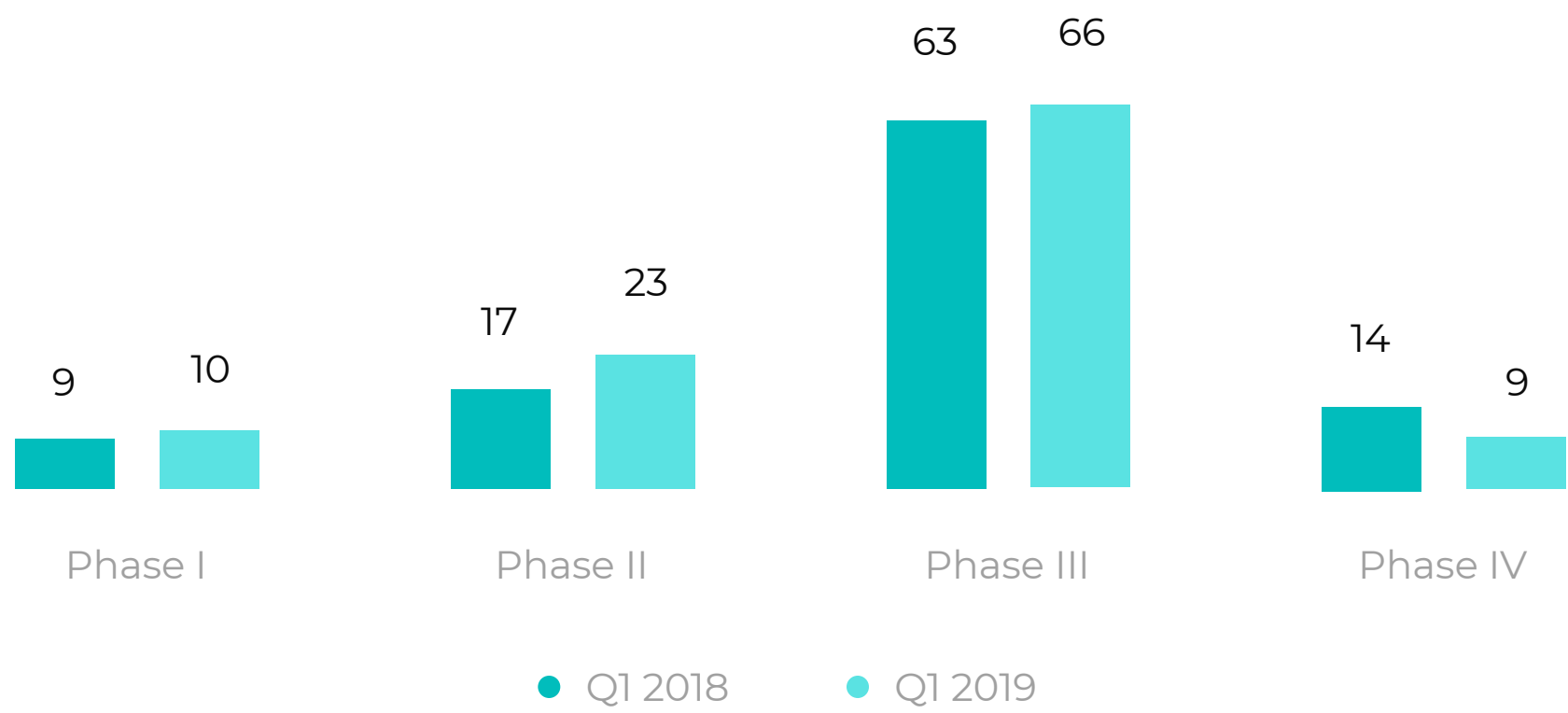
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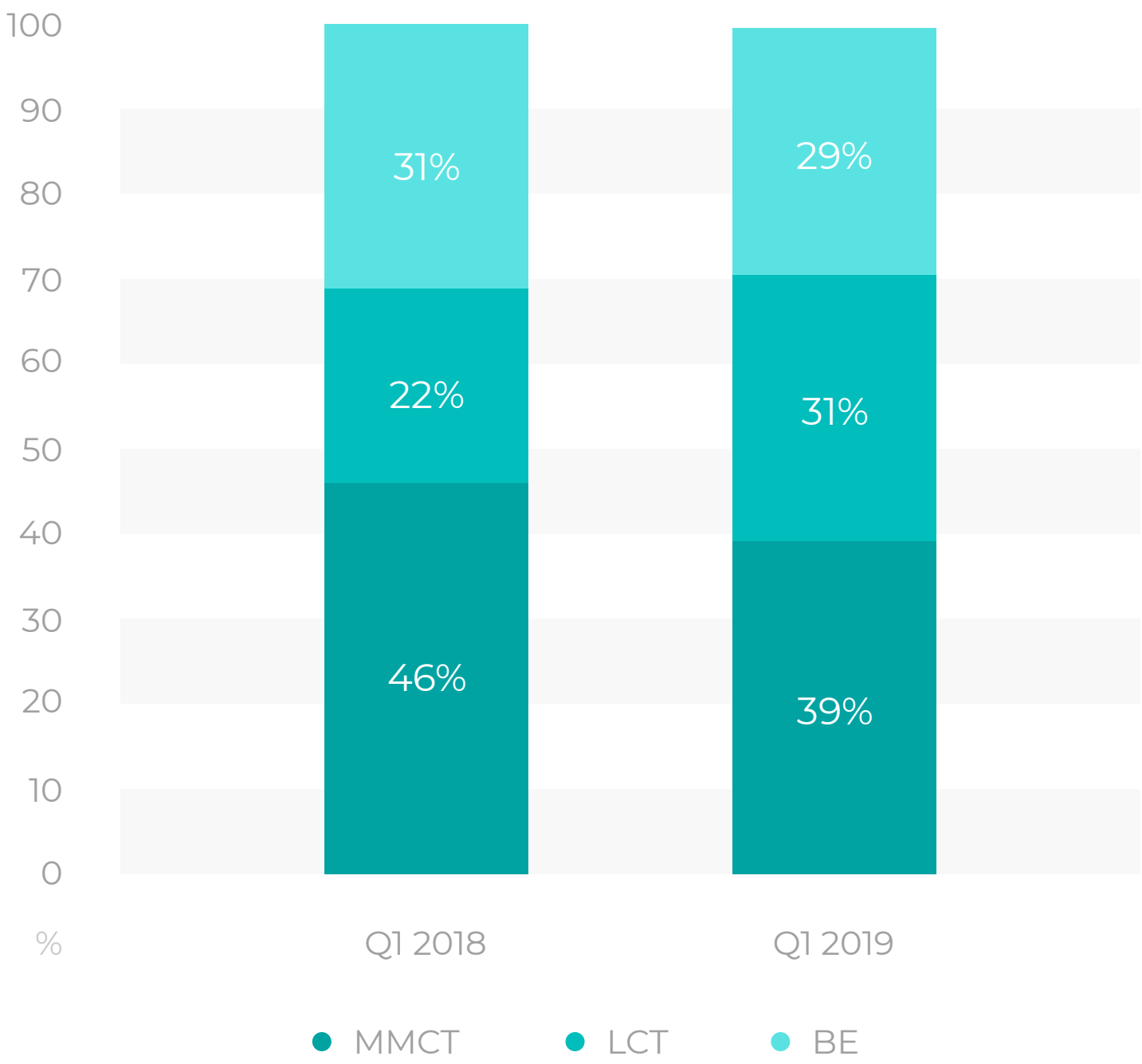
Trial Data

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 increased by 5% – from 63 trials in Q1 2018 to 66 trials in Q1 2019.

Breakdown of Clinical Trials by Phase



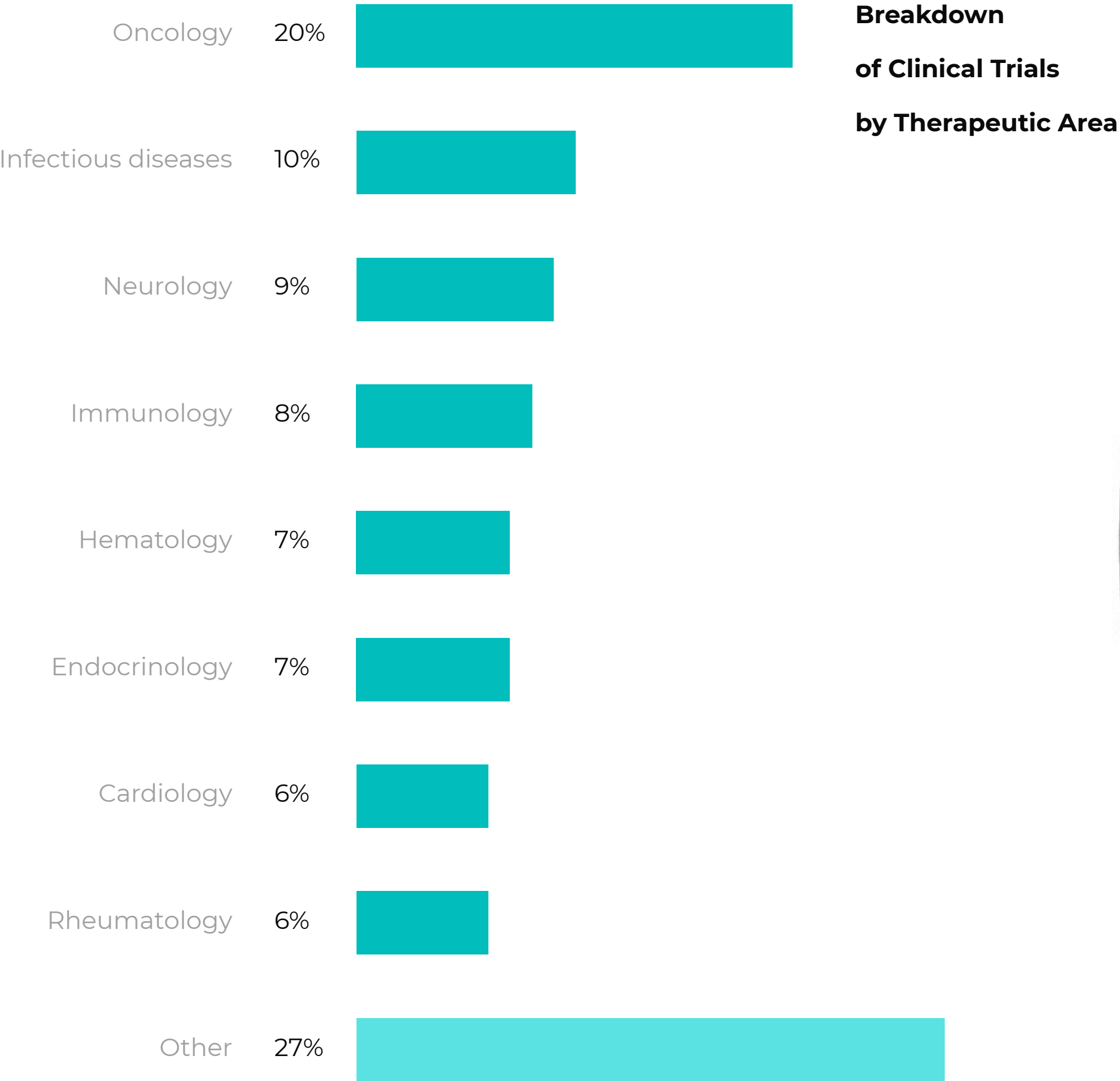
Percentage Breakdown of Clinical Trials by Type



Trial Data

The largest number of clinical trials initiated in Russia during Q1 2019 were related to Oncology, Infectious Diseases, Neurology and Immunology. Other popular therapy areas include Hematology, Cardiology and Endocrinology.

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

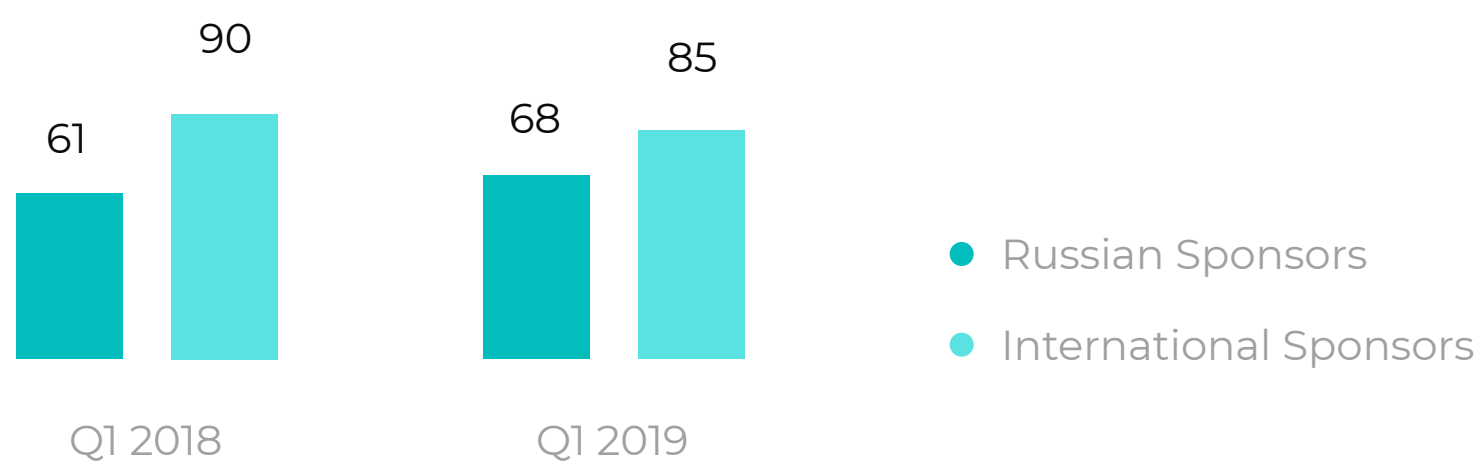


Sponsor Data

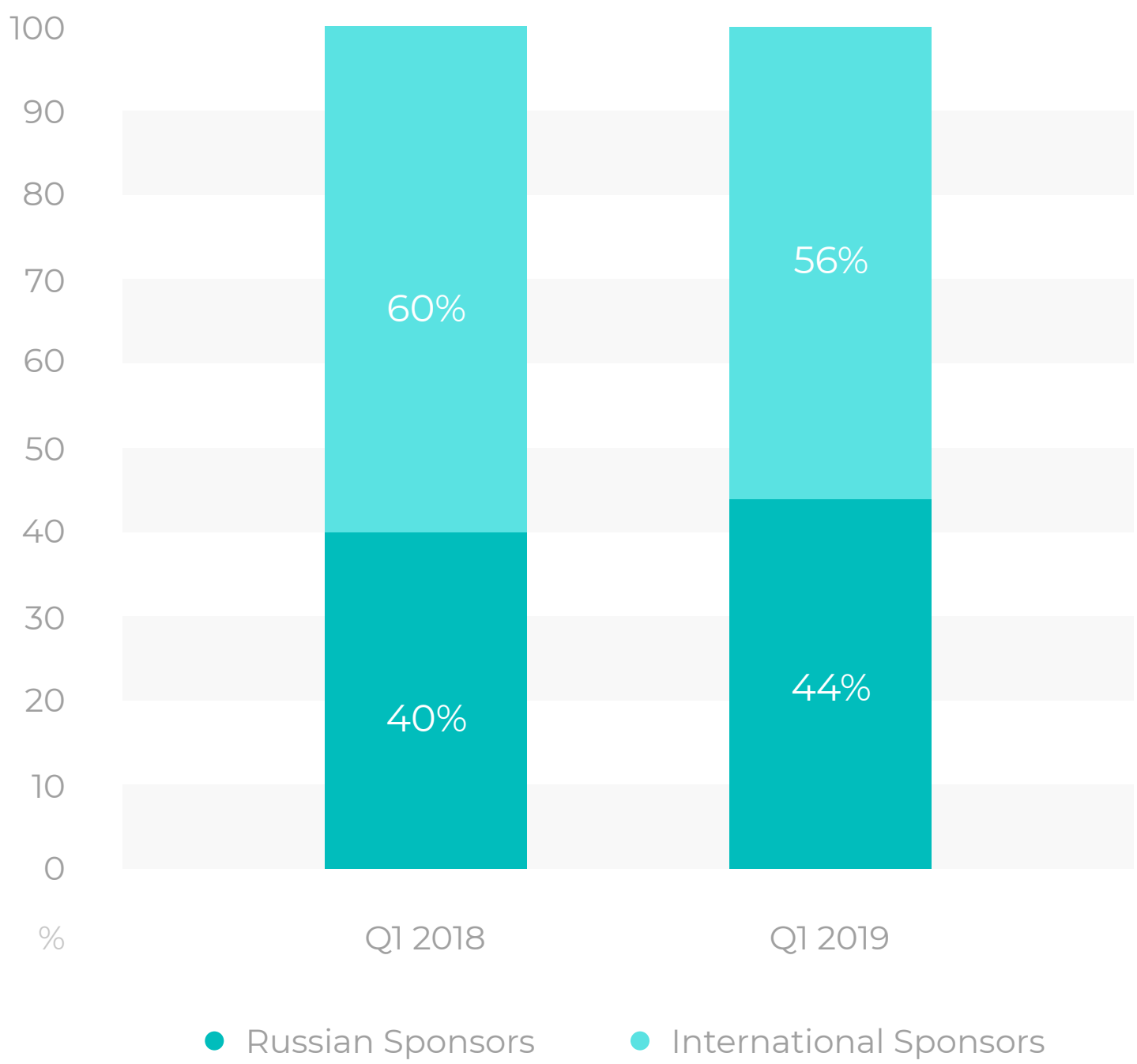
Clinical trials initiated in Russia in during Q1 2019 were sponsored by pharmaceutical companies from 23 countries.

The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market shrank by 4% from 60% to 56%.

Breakdown of Clinical Trials by Sponsor Origin



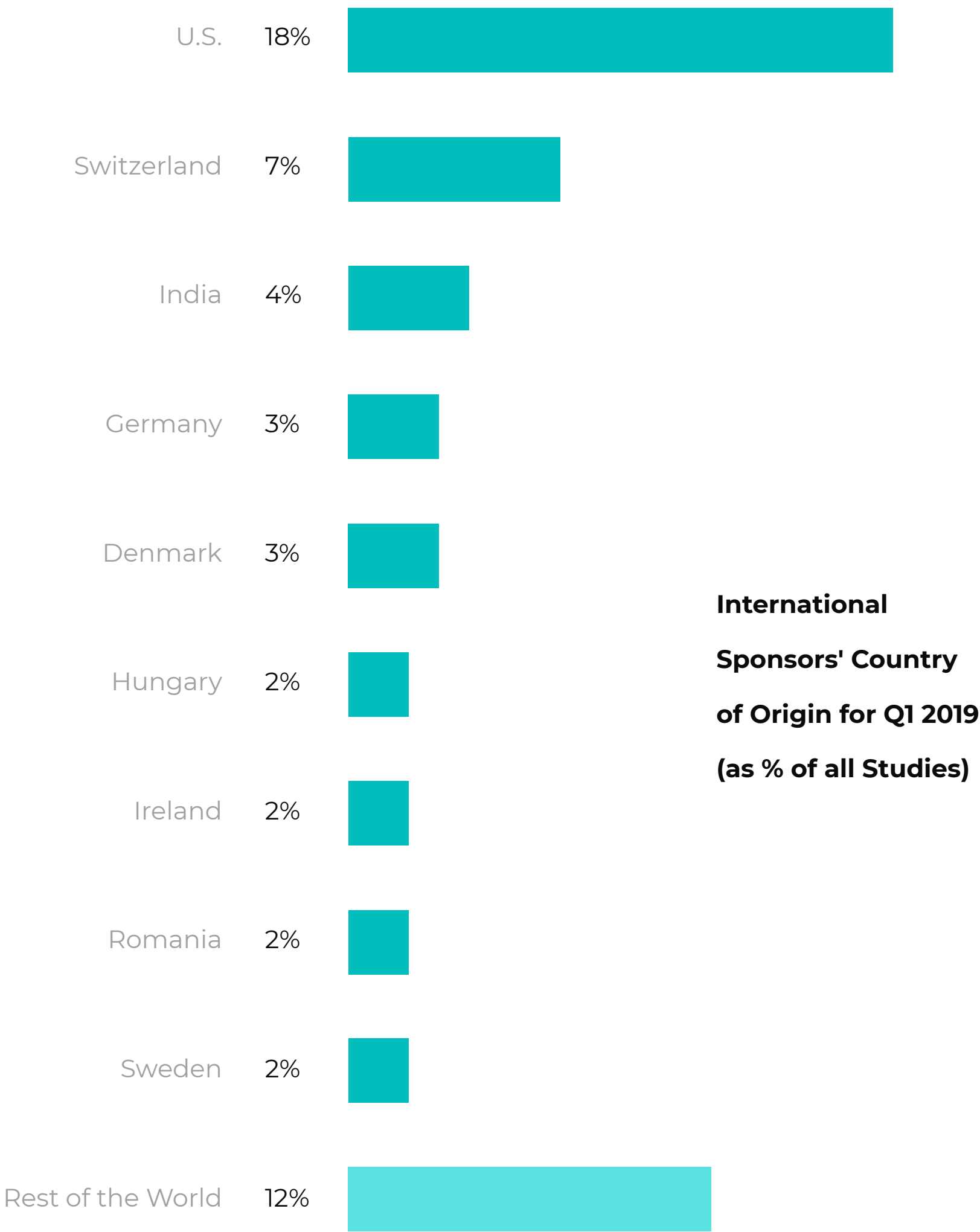
Percentage Breakdown of Clinical Trials by Sponsor Origin



Sponsor Data

The most prevalent Sponsor’s countries of origin in Q1 2019 were Russia (68 studies), U.S. (28 studies) and Switzerland (11 studies). Other countries include India (6 studies), Germany (5 studies) and Denmark (4 studies).

The dominant Phase of Clinical trials across Russian sites by international pharmaceutical companies in Q1 2019 was Phase III with 68% share among Phase I – IV studies.



International Sponsor Ranking



Top-10 International
Trial Sponsors
in Russia in Q1 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	4	500
2	Novartis	4	77
3	Iterum Therapeutics	3	464
4	ACADIA Pharmaceuticals	3	158
5	Minerva Pharmaceutical	2	380
6	Rompharm	2	330
7	Sentiss Pharma	2	264
8	Janssen	2	160
9	AstraZeneca	2	128
10	Novo Nordisk	2	118

Combined market share of these companies **24%** **22%**

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 2019

Nº	Company Name	No. studies	No. subjects
1	Sotex	2	324
2	Biocad	2	282
3	MedInvest	2	280
4	OBL Pharm	2	230
5	Generium	2	178
6	Chumakov Federal Scientific Center	1	600
7	Pharmasoft	1	417
8	Pharm-Sintez	1	333
9	SupraGen	1	310
10	OTC Pharm	1	300

Combined market share of these companies 14% 28%

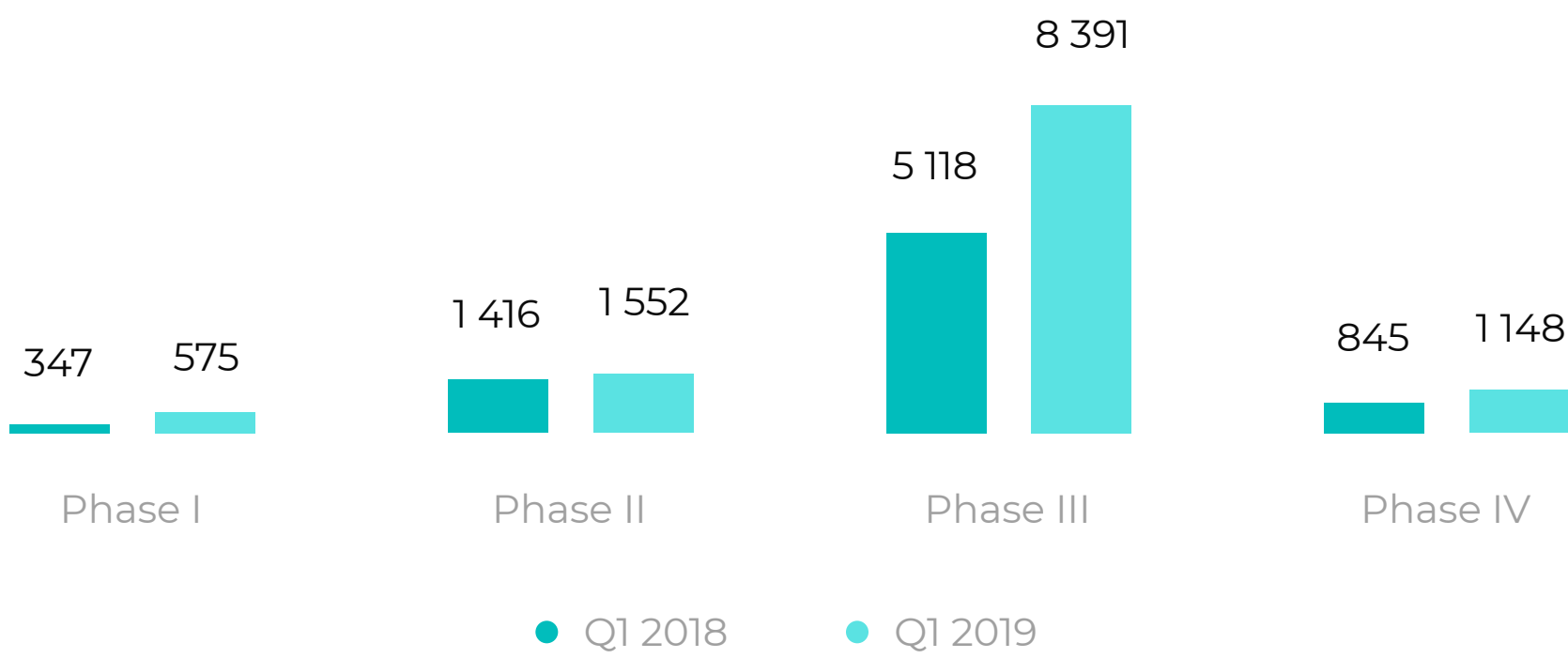
Combined market share shown as a percentage of both international and Russian sponsors.
Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

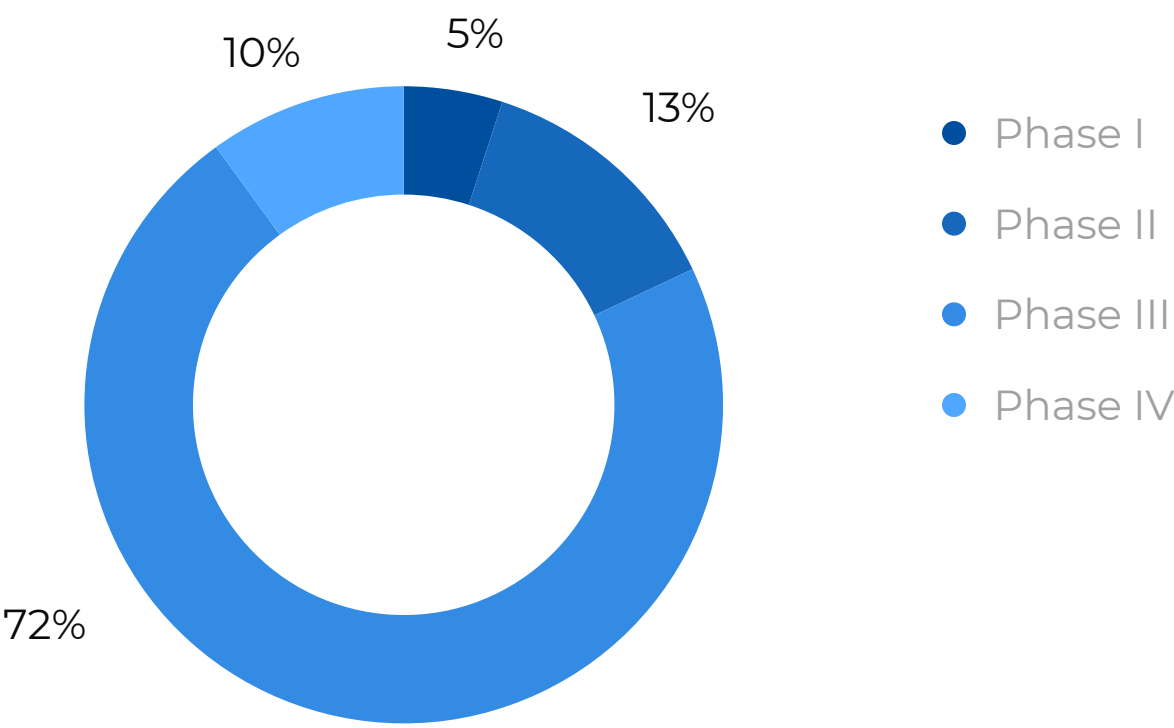
The overall number of subjects involved in clinical trials initiated in Russia in Q1 2019 reached a total of 11,666 subjects – a 51% jump in comparison with Q1 2018, when 7,726 subjects were involved.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 72% of all subjects involved.

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



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

Nº	Site Name	City	No. studies
1	Ecosafety Ltd.	Saint-Petersburg	10
2	Probiotec Medical Center	Moscow Region	6
3	Clinical Hospital #2, Yaroslavl region	Yaroslavl	5
4	Kazan State Federal Medical University	Kazan	4
5	X7 Clinical Research	Saint-Petersburg	3

Combined market share of these sites 18%

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

Nº	Site Name	City	No. studies
1	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	12
2	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	11
3	Clinical Hospital #8	Yaroslavl	9
4	Moscow City Clinical Hospital named after S.P. Botkin	Moscow	8
5	Clinical Oncological Dispensary	Omsk	8

Combined market share of these sites 31%

Research Site Data



Top-10 Russian
Research Sites
(all Studies)

Nº	Site Name	City	No. studies
1	Ecosafety Ltd.	Saint-Petersburg	16
2	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	12
3	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	12
4	Clinical Hospital #8	Yaroslavl	9
5	Clinical Hospital #2, Yaroslavl region	Yaroslavl	9
6	Kazan State Federal Medical University	Kazan	9
7	Moscow City Clinical Hospital named after S.P. Botkin	Moscow	8
8	Clinical Oncological Dispensary	Omsk	8
9	First Moscow State Medical University named after I.M. Sechenov	Moscow	8
10	Ivanovo Regional Clinical Hospital	Ivanovo	7
Combined market share of these sites			64%

CRO Data



CRO Rankings for Q1 2019 in Russia

Nº	Company Name	No. studies	No. subjects
1	Pharmaceutical Research Associates	5	285
2	PSI	4	479
3	IQVIA	4	216
4	Medical Development Agency, LLC	3	305
5	Worldwide Clinical Trials, Inc	3	158
6	PPD	3	155
7	ICON	2	298
8	Smooth Drug Development	2	112
9	MB Quest	2	105
10	INC Research (Syneos Health)	2	21

Combined market share of these companies **28%** **18%**

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

Regulatory Data

During Q1 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs; four of them are new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Six of 29 drugs were (or are being) studied in clinical trials involving Russian sites.

In Q1 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 17 new drugs, including 2 generics, 2 biosimilar and 3 orphan medicines.

Five drugs received negative opinions and as such 12 remedies received positive opinions and were approved for marketing. Four of these 12 drugs were being studied in clinical trials involved Russian sites.

Nº	Aprr. date	Drug (active ingredient)	Company
1	01.18.2019	Ontruzantbla (Trastuzumab)	Samsung Bioepics
2	02.28.2019	Herceptin Hylectabla (Trastuzumab; Hyaluronidase)	Genentech
3	03.11.2019	Trazimerabla (Trastuzumab)	Pfizer
4	03.18.2019	Zykadianda (Ceritinib)	Novartis
5	03.26.2019	Mayzentnda (Siponimod)	Novartis
6	03.29.2019	Duaklir Pressairnda (Aclidinum Bromide; Formoterol Fumarate Dihydrate)	AstraZeneca
Source: FDA			



Inspection Data

FDA Inspections

According to U.S. FDA data, there was one FDA inspection conducted in Russian investigative sites during Q1 2019. The FDA representative inspected activity of Dr. Yulia Karakulova, M.D. in Perm with a No Action Indicated (NAI) outcome.

Roszdrazhnadzor Inspections

According to the Roszdrazhnadzor quarterly report, 17 Russian sites performing preclinical and clinical trials were a subject of Regulatory inspection by Roszdrazhnadzor during Q1 2019. Deviations were reported at 9 sites.

Regulatory Data (EMA)

Nº	Appr. date	Drug (active ingredient)	Company
1	01.31.2019	Atazanavir (Atazanavir)	KRKA
2	02.28.2019	Dectova (Zanamivir)	GlaxoSmithKline
3	02.28.2019	Zynquista (Sotagliflozin)	Sanofi
4	03.01.2019	Lorviqua (Lorlatinib)	Pfizer
Source: EMA			

About Synergy

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

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

We have replaced outdated R&D strategies by novel, more efficient approaches to clinical research.



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