

Synergy orange paper / 2019 summer / quarter 2



# Clinical trials in Russia

Research report

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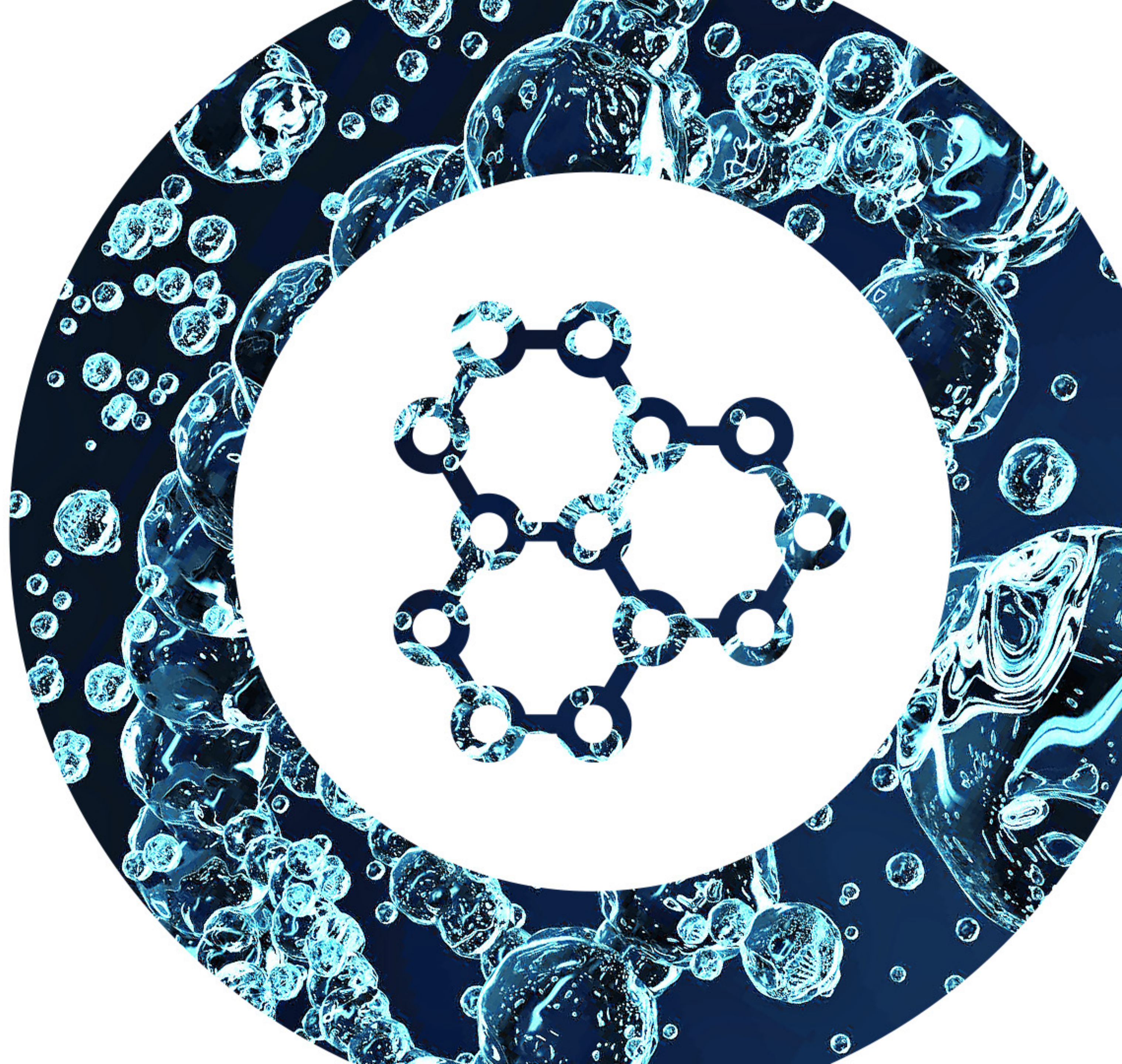
# Foreword

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: 01/07/2019



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# Executive Summary

During Q2 2019 the Ministry of Health of the Russian Federation approved the start of 193 new clinical trials of all types, with an overall year on year growth of 26% by total number of studies.

The dominant type of clinical trials conducted in Russian sites in Q2 2019 were MMCT (Multinational Multi-center Clinical Trials) with 41% 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 40% of the total number of studies conducted, and for 30% of all subjects enrolled during the quarter. The top-10 Russian sponsors take up approximately 16% of the market by total number of trials conducted and have 30% of all subjects enrolled in these trials. The twenty largest pharmaceutical companies combined account for 56% of all clinical trials and for 60% of all subjects enrolled.

During Q2 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. Eight of these 29 drugs were tested (or being studied) in clinical trials involving Russian sites.

In Q2 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 21 new drugs. Seven of the approved drugs were tested (or being studied) in clinical trials involving Russian sites.

The top-5 domestic manufacturers were: [Biocad](#), [Valenta Pharmaceuticals](#), [GeroPharm](#), [OTC Pharm](#) and [National Research Company](#).

The top-5 international sponsors were: [Merck](#), [Eli Lilly](#), [Novartis](#), [Sanofi](#) and [Hoffman-La-Roche](#).

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during Q2 2019.



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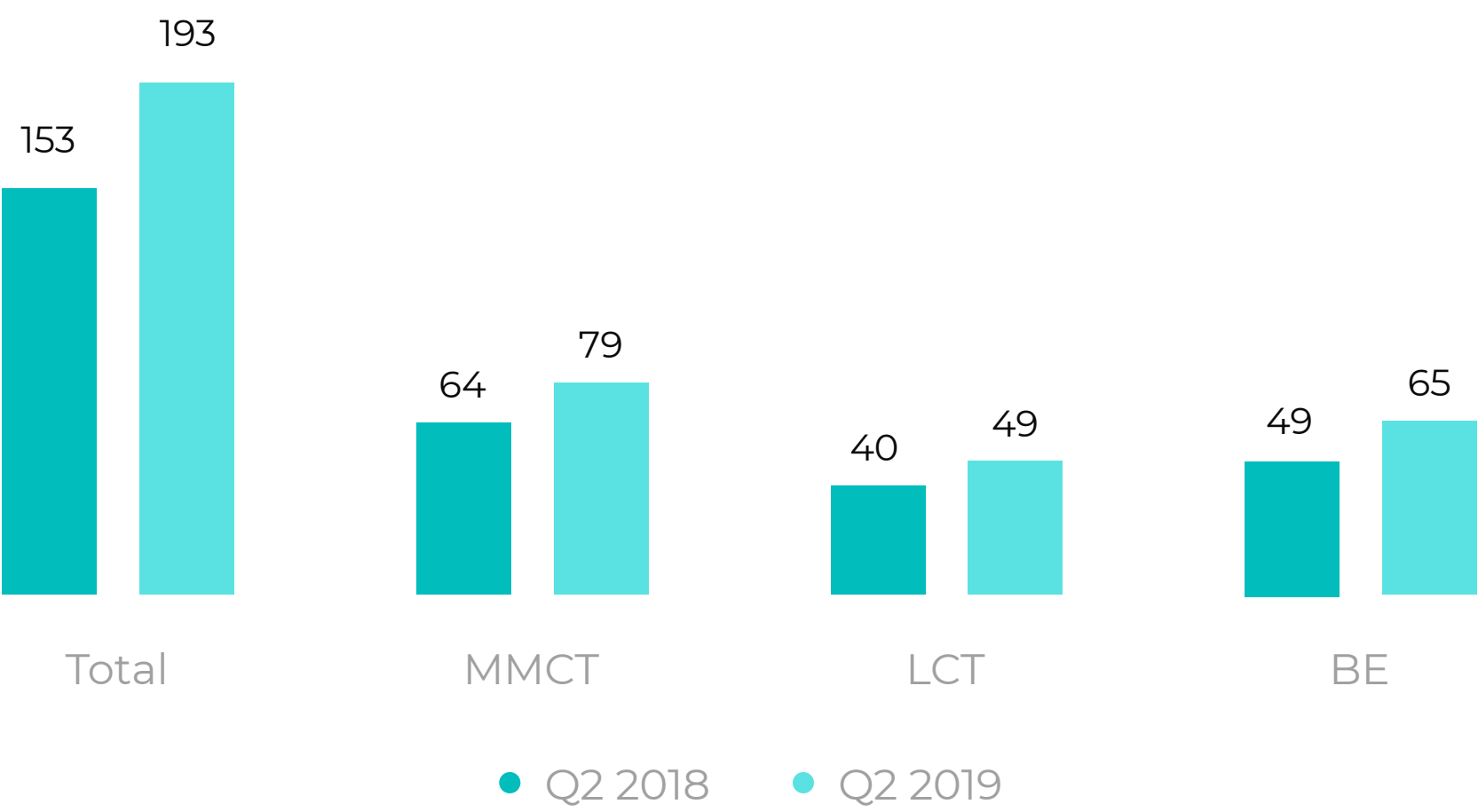
# Clinical Trials in Russia

## Trial Data

During Q2 2019 the Ministry of Health of the Russian Federation approved the start of 193 new clinical trials of all types, including local and bioequivalence studies. This represents a 26% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q2 2019 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs declined from 42% to 41% of the total number of trials. The market share of Local Clinical Trials (LCTs) dropped slightly from 26% to 25% whilst the Bio-equivalent (BE') share saw an increase from 32% to 34%.

Breakdown of Clinical Trials in Q2 2019 by Type



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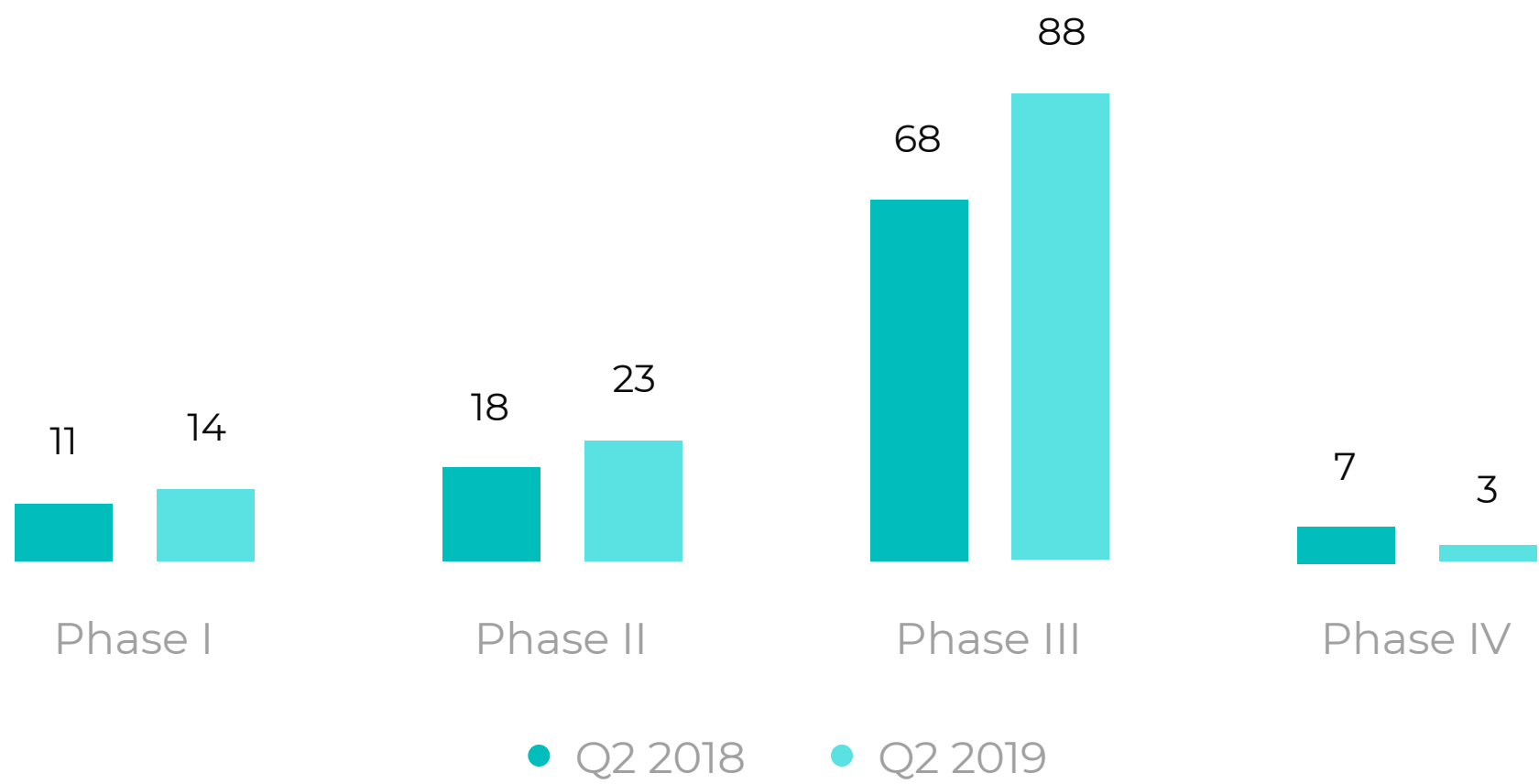




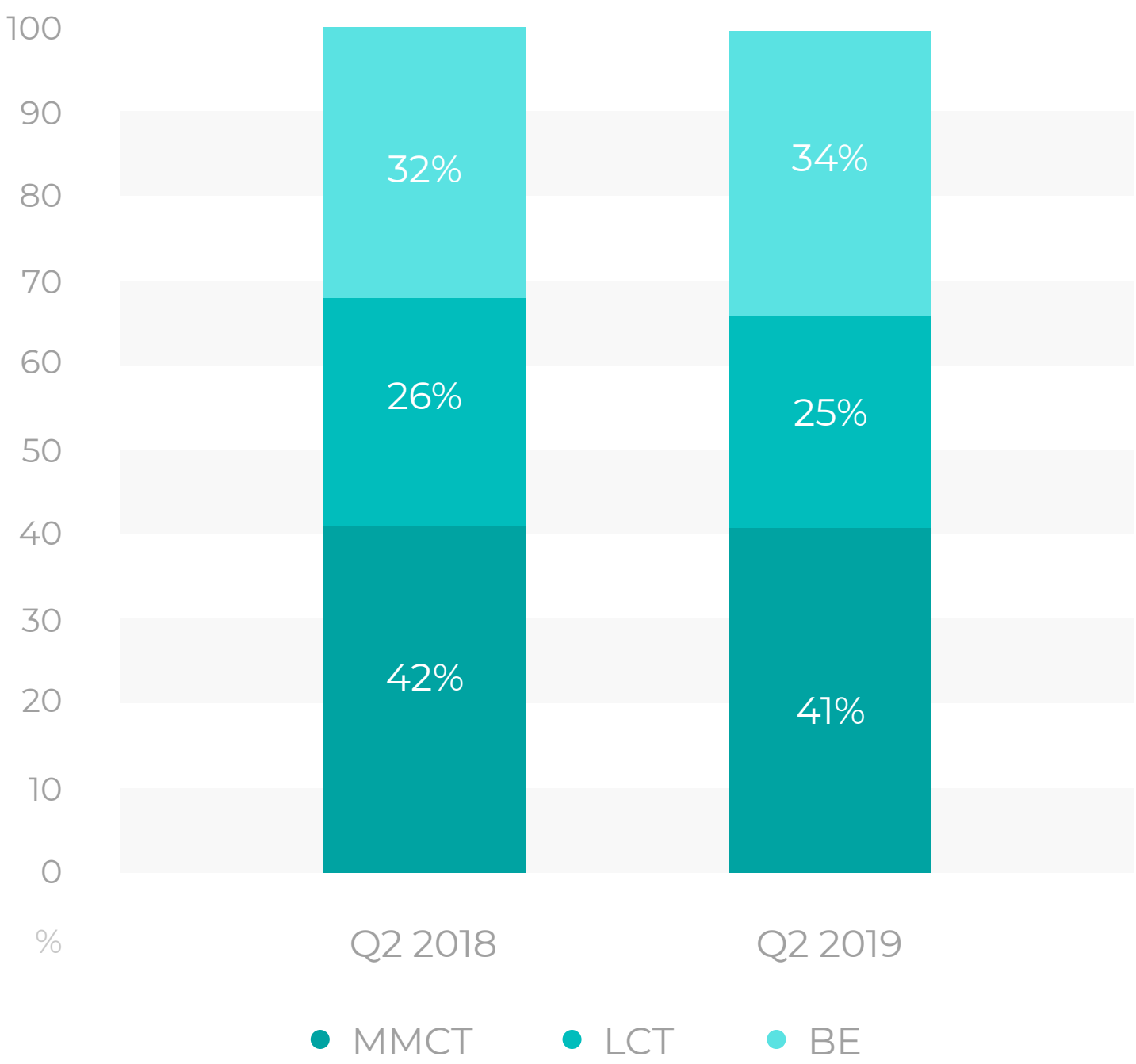
# Trial Data

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 29% – from 68 trials in Q2 2018 to 88 trials in Q2 2019.

Breakdown of Clinical Trials by Phase



Percentage Breakdown of Clinical Trials by Type

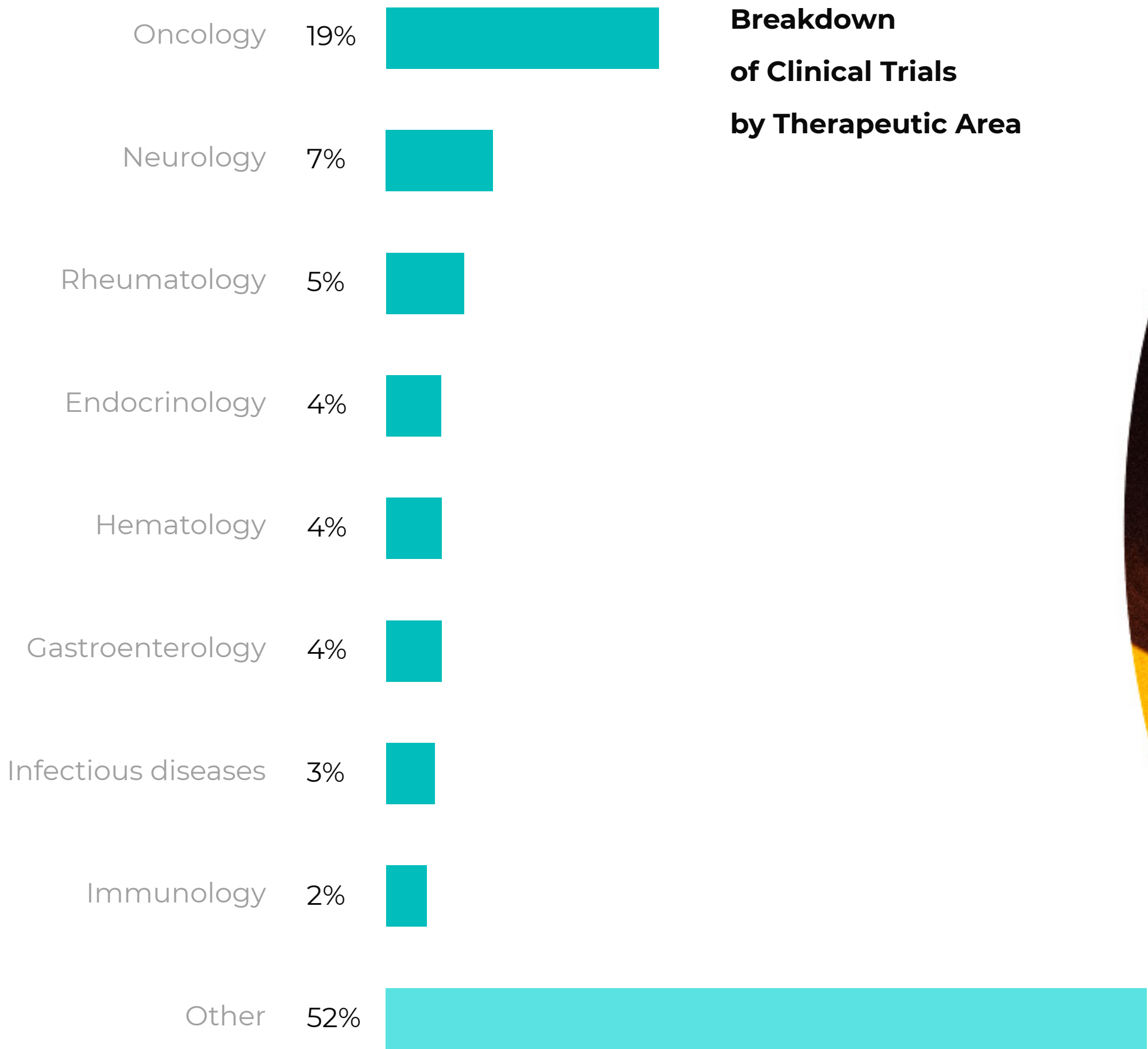




# Trial Data

The largest number of clinical trials initiated in Russia during Q2 2019 were related to Oncology, Neurology and Rheumatology. Other popular therapy areas include Endocrinology, Hematology and Gastroenterology.

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



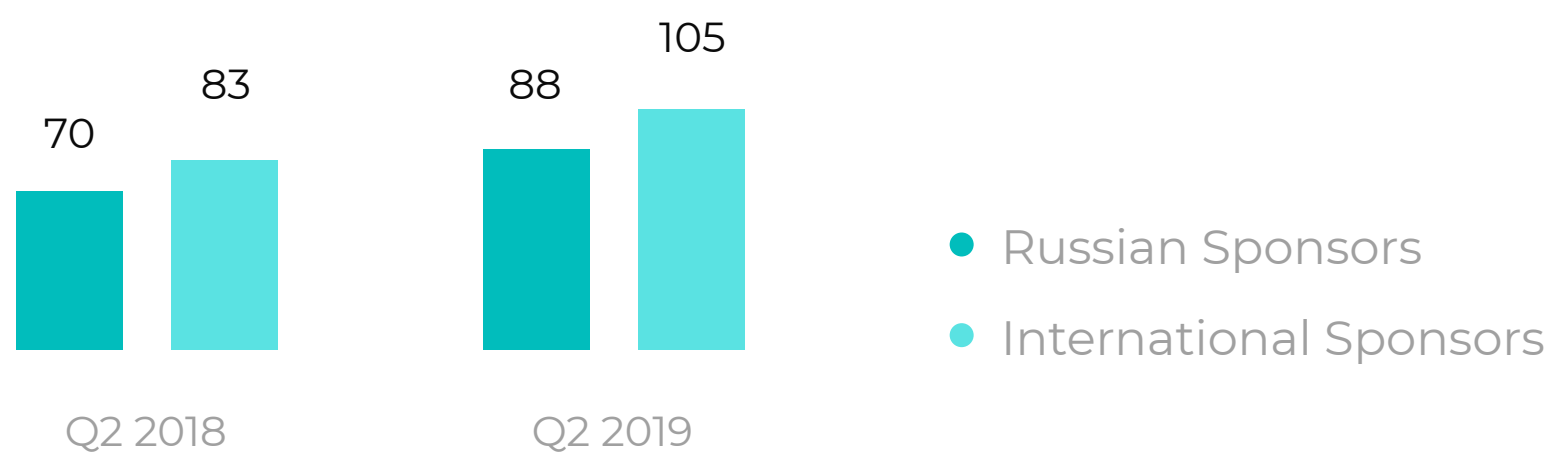


# Sponsor Data

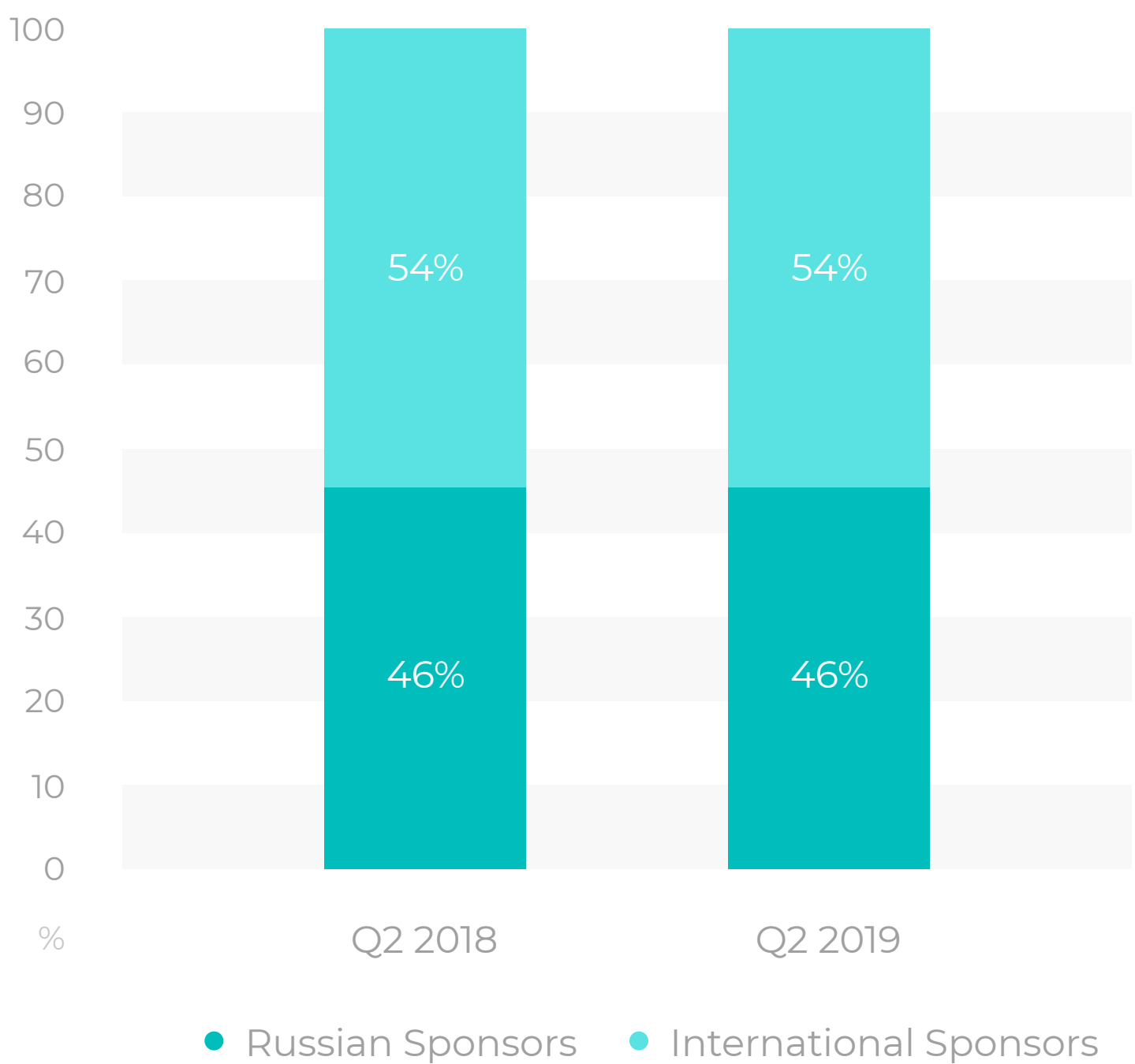
Clinical trials initiated in Russia in during Q2 2019 were sponsored by pharmaceutical companies from Russia and 24 foreign countries.

The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market remains stable with 54% of all studies.

Breakdown of Clinical Trials by Sponsor Origin



Percentage Breakdown of Trials by Sponsor Origin



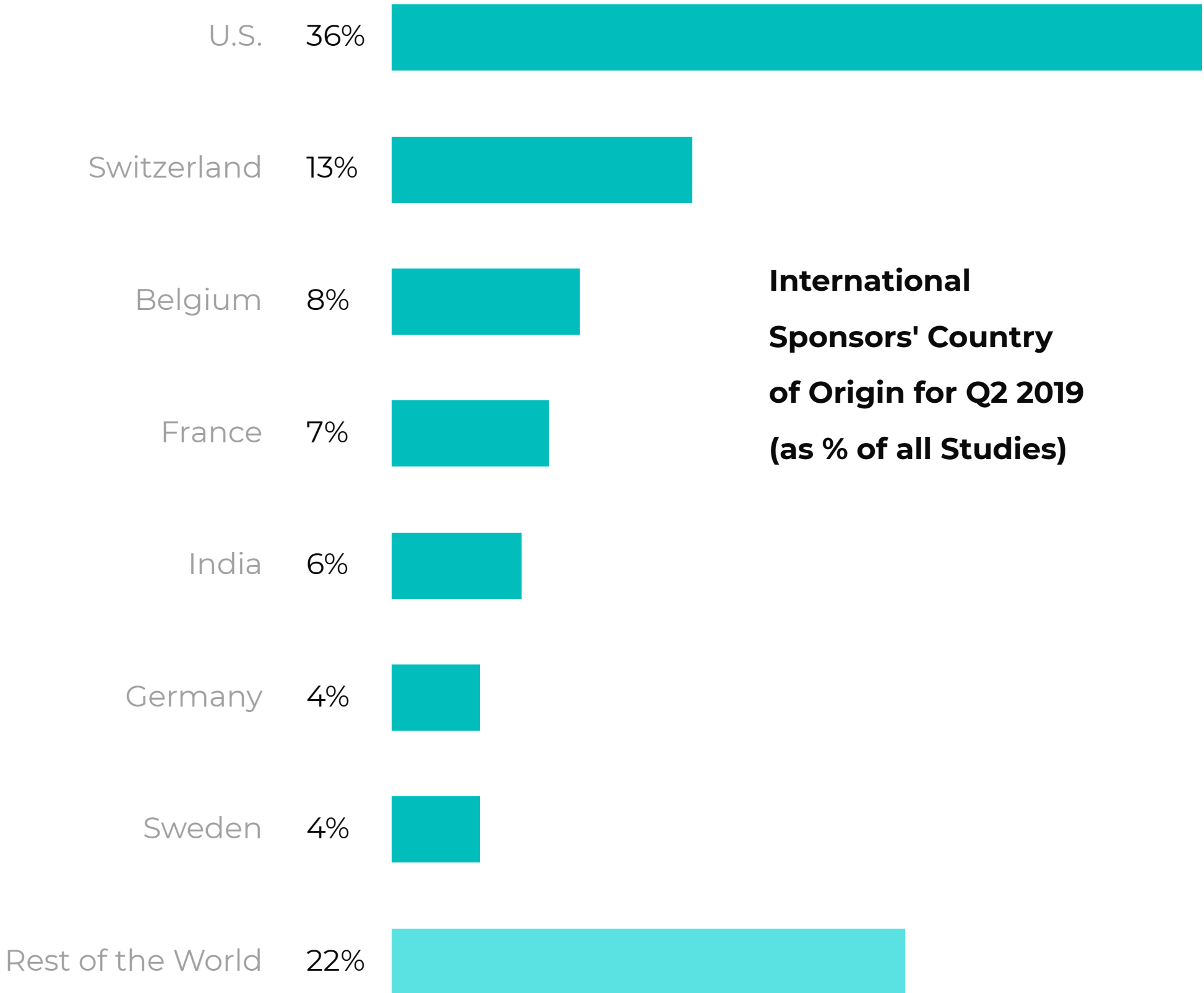
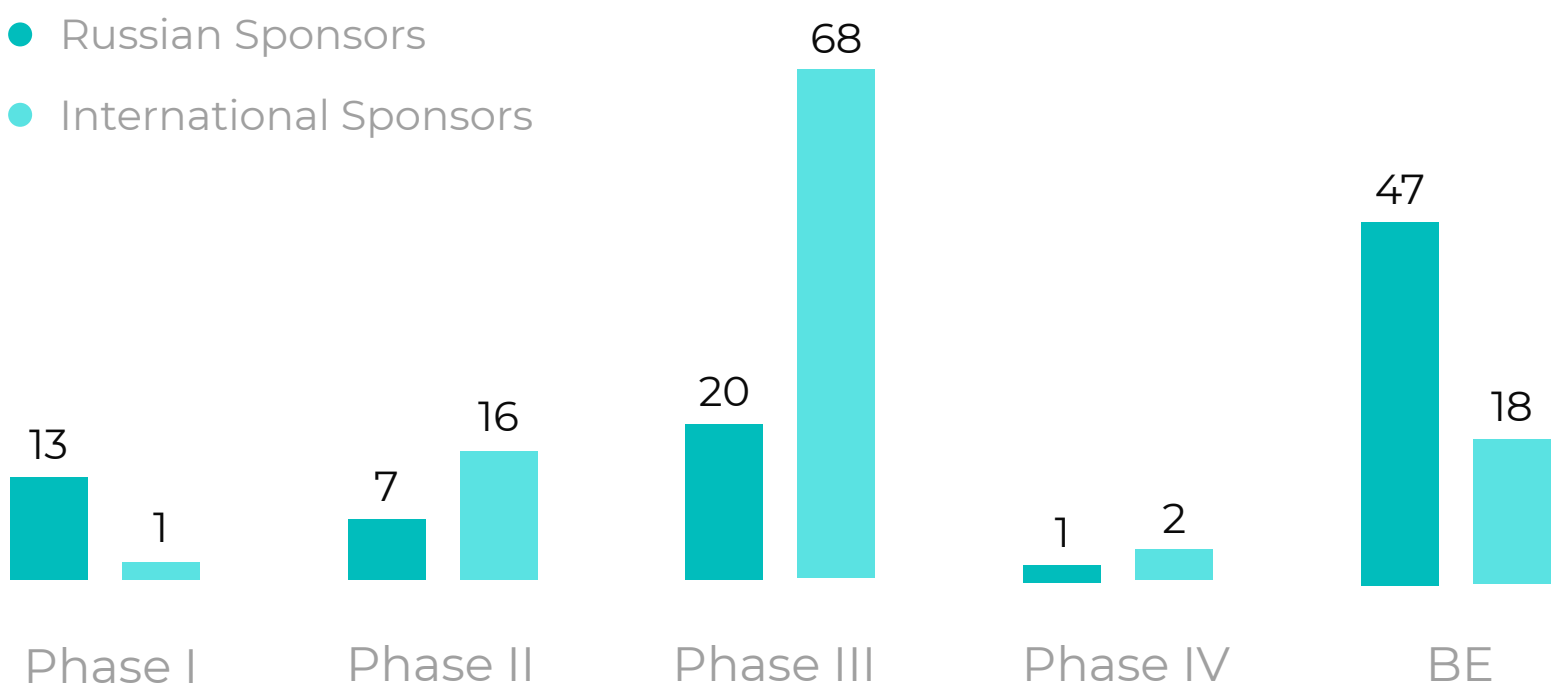


# Sponsor Data

The most prevalent Sponsor's countries of origin in Q2 2019 were Russia (88 studies), U.S. (38 studies) and Switzerland (14 studies). Other prominent countries include Belgium (8 studies), France (7 studies) and India (6 studies).

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q2 2019 was Phase III with 69% share among Phase I – IV studies.

## Breakdown of Clinical Trials by Sponsor's Origin and Phase



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# International Sponsor Ranking



Top-10 International  
Trial Sponsors  
in Russia in Q2 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	15	1 283
2	Eli Lilly	8	1 005
3	Novartis	6	666
4	Sanofi	5	977
5	Hoffmann-La Roche	4	187
6	Janssen	3	470
7	AstraZeneca	3	182
8	Bristol-Myers	3	44
9	UCB Biopharma	2	314
10	Novo Nordisk	2	270

Combined market share of these companies    **40%**                      **30%**

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 Q2 2019

Nº	Company Name	No. studies	No. subjects
1	Biocad	4	786
2	Valenta Pharmaceuticals	4	556
3	GeroPharm	3	1602
4	OTC Pharm	2	460
5	National Research Company	2	322
6	NovaMedica	2	139
7	PharmaDiall	1	440
8	FORT	1	401
9	Petrovax Pharma	1	394
10	Binnopharm	1	340

**Combined market share of these companies**    **16%**    **30%**

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

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

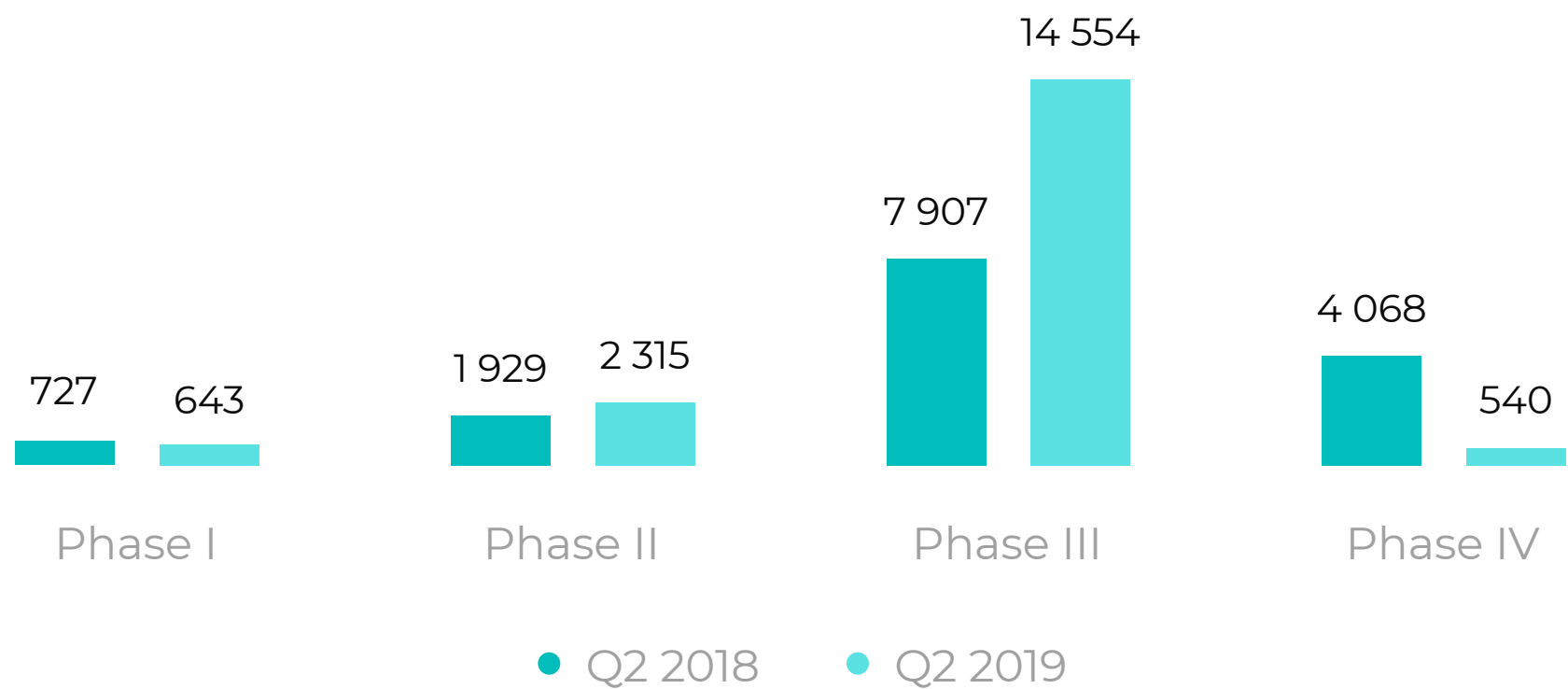


# Subject Data

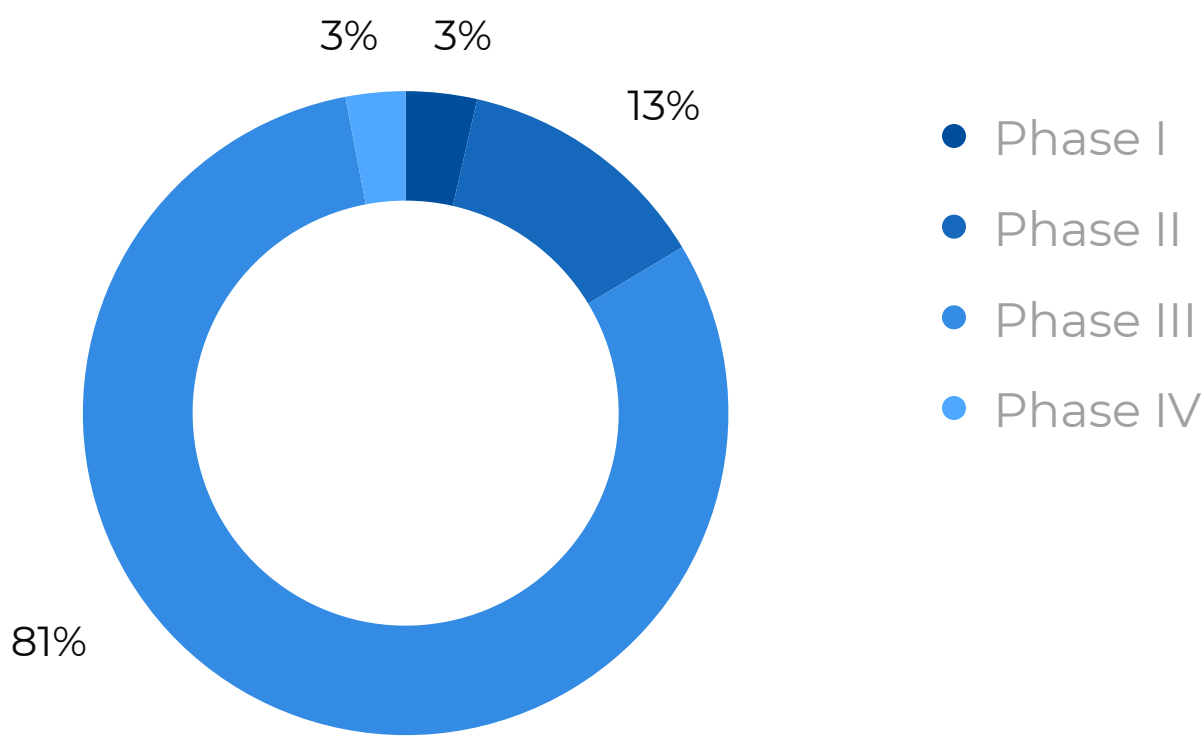
The overall number of subjects involved in clinical trials initiated in Russia in Q2 2019 reached a total of 18,052 subjects – a 23% jump in comparison with Q2 2018, when 14,631 subjects were involved.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 81% 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



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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	15
2	Clinical Hospital #2, Yaroslavl region	Yaroslavl	7
3	Road Clinical Hospital at the station Yaroslavl of Russian Railways	Yaroslavl	5
4	Clinical Hospital named after V.P. Demikhov	Moscow	5
5	Ecosafety	Saint-Petersburg	5

**Combined market share of these sites** **19%**

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

Nº	Site Name	City	No. studies
1	Clinical Oncological Dispensary	Omsk	20
2	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	17
3	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	15
4	First Moscow State Medical University named after I.M. Sechenov	Moscow	14
5	M.F. Vladimirsky Moscow Regional Research and Clinical Institute (MONIKI)	Moscow	13

**Combined market share of these sites** **41%**



# Research Site Data



## Top-10 Russian Research Sites (all Studies)

Nº	Site Name	City	No. studies
1	Clinical Oncological Dispensary	Omsk	21
2	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	19
3	First Moscow State Medical University named after I.M. Sechenov	Moscow	16
4	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	15
5	Probiotec Medical Center	Moscow Region	14
6	Russian National Oncology Medical Research Center named after N.N. Petrov	Saint-Petersburg	13
7	M.F. Vladimirsky Moscow Regional Research and Clinical Institute (MONIKI)	Moscow	12
8	Ecosafety	Saint-Petersburg	11
9	Road Clinical Hospital at the station Yaroslavl of Russian Railways	Yaroslavl	10
10	Clinical Hospital #2, Yaroslavl region	Yaroslavl	10

**Combined market share of these sites** **76%**



# CRO Data



## CRO Rankings for Q2 2019 in Russia

Nº	Company Name	No. studies	No. subjects
1	IQVIA	5	1 132
2	Syneos Health (incl. INC Research)	5	122
3	Parexel	4	598
4	Medical Development Agency	4	410
5	PPD	4	173
6	Ligand Research	2	245
7	PSI	2	220
8	Covance	2	152
9	ICON	2	100
10	Cromos	1	520

**Combined market share of these companies**    **24%**                      **20%**

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



# Regulatory Data

During Q2 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.

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

In Q2 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 21 new drugs, including 2 generics, 1 biosimilar and 1 orphan medicines.

Three drugs received negative opinions and as such 18 remedies received positive opinions and were approved for marketing. Seven of these 18 drugs were studied in clinical trials involving Russian sites.

Nº	Appr. date	Drug (active ingredient)	Company
1	04.08.2019	Dovatonda (Dolutegravir Sodium; Lamivudine)	ViiV Healthcare
2	04.09.2019	Evenitybla (Romosozumab-AQQG)	Amgen
3	04.12.2019	Balversanda (Erdafitinib)	Janssen
4	04.23.2019	Skyrizibla (Risankizumab-RZAA)	Abbvie
5	05.02.2019	Qternmet XRNDA (Dapagliflozin; Metformin Hydrochloride; Saxagliptin Hydrochloride)	AstraZeneca
6	05.24.2019	Piqraynda (Alpelisib)	Novartis
7	06.06.2019	Nucalabla (Mepolizumab)	GlaxoSmithKline
8	06.27.2019	Zirabevbla (Bevacizumab-BVZR)	Pfizer

Source: FDA



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# Inspection Data

## FDA Inspections

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during Q2 2019.

## Roszdravnadzor Inspections

According to the Roszdravnadzor quarterly report, during Q2 2019 there were 20 Regulatory inspections conducted at 20 Russian sites performing preclinical and clinical trials and located in 8 cities, with 9 violations found.

## Regulatory Data (EMA)

Nº	Appr. date	Drug (active ingredient)	Company
1	04.26.2019	Dovato (Dolutegravir Sodium; Lamivudine)	ViiV Healthcare
2	04.26.2019	Libtayo (Cemiplimab)	Regeneron
3	04.26.2019	Temybric Ellipta (Fluticasone Furoate; Umeclidinium Bromide)	GlaxoSmithKline
4	04.26.2019	Ultomiris (Ravulizumab)	Alexion
5	04.26.2019	Talzenna (Talazoparib)	Pfizer
6	06.27.2019	Lacosamide (Lacosamide)	UCB Pharma
7	06.27.2019	Azacitidine (Azacitidine)	Celgene

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 offer 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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