

Synergy **Orange** Paper / 2019 Winter / Annual Report



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: 01/01/2020



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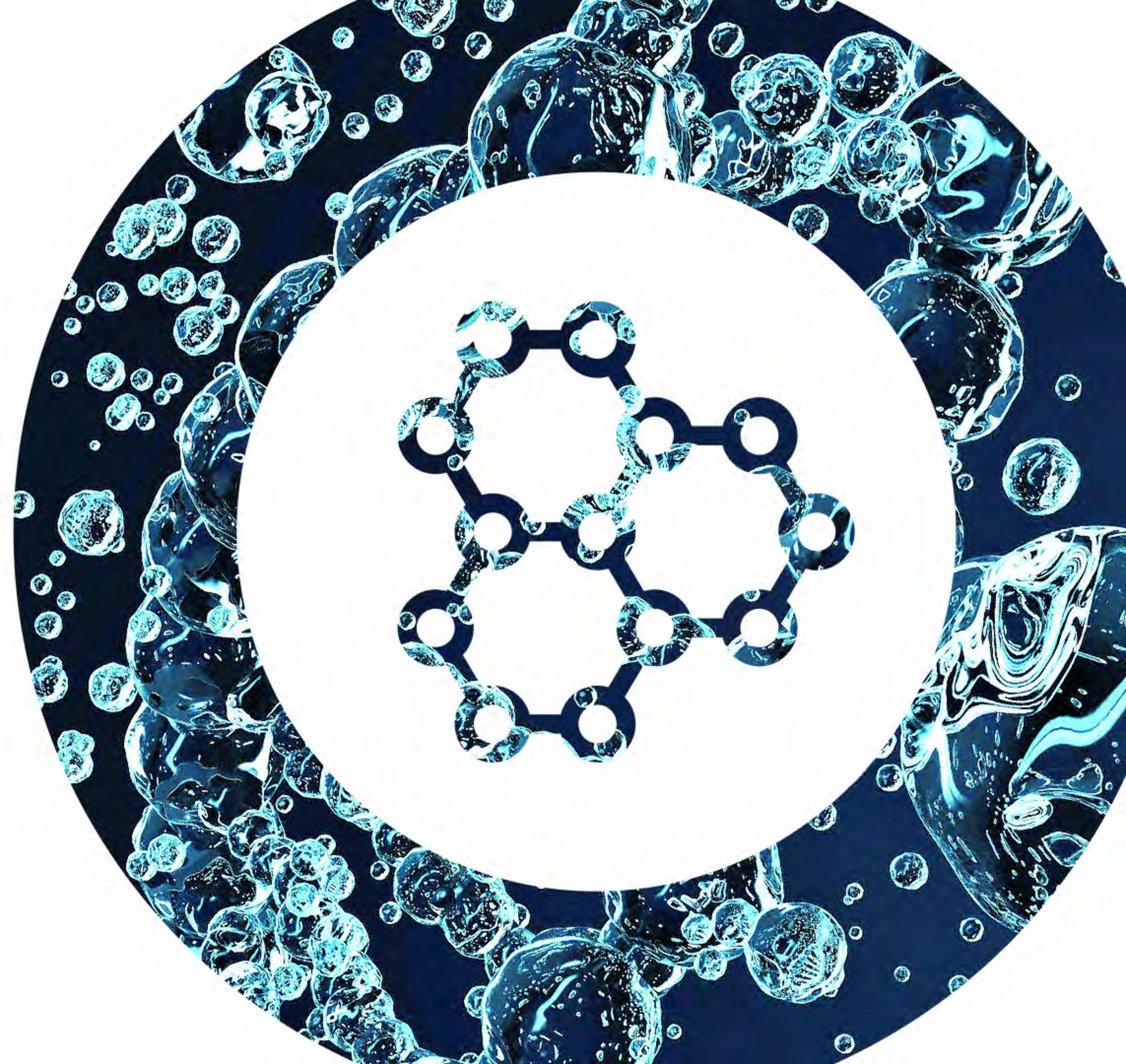


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Executive Summary

During the Year 2019 the Ministry of Health of the Russian Federation approved the start of 746 new clinical trials of all types, with an overall year on year growth of 14% by total number of studies.

The dominant type of clinical trials conducted in Russian sites in the Year 2019 were MMCT (Multinational Multi-center Clinical Trials) with 43% 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 28% of the total number of studies conducted in Russia, and for 20% of all subjects enrolled during the year. The top-10 Russian sponsors take up approximately 12% of the market by total number of trials conducted in Russia and have 20% of all subjects enrolled in these trials.

The twenty largest pharmaceutical companies combined account for 40% of all clinical trials conducted in Russia and for 40% of all subjects enrolled.

During the Year 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 132 new drugs, including 37 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Thirty-five of these 132 drugs were tested (or being studied) in clinical trials involving Russian sites.

In the Year 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 73 new drugs. Thirty-four of these drugs were tested (or being studied) in clinical trials involving Russian sites.

The top-5 domestic pharmaceutical manufacturers in Russia during the Year 2019 were: **Biocad**, **Generium**, **Medinvest**, **GeroPharm** and **OTC Pharm**.

The top-5 International Sponsors in Russia during the Year 2019 were: **Merck**, **Novartis**, **Eli Lilly**, **Janssen** and **Hoffmann-La Roche**.

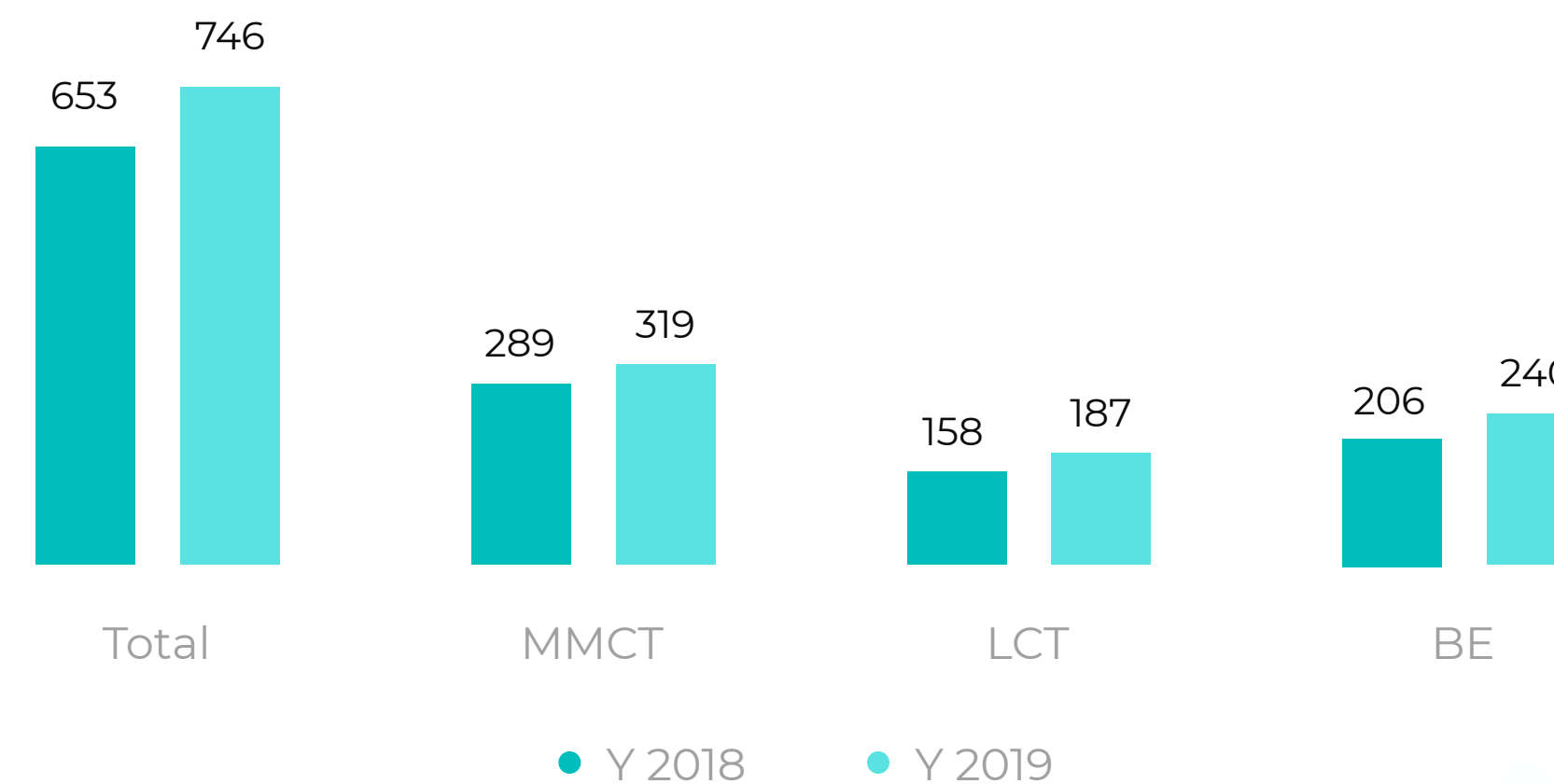
According to the U.S. FDA data, there was only one FDA inspection conducted in a Russian investigative site during the Year 2019. In March 2019 the FDA representatives inspected the clinical trial related activity of Dr. Yulia Karakulova, M.D. in Perm with a No Action Indicated (NAI) outcome.

Trial Data

During the Year 2019 the Ministry of Health of the Russian Federation approved the start of 746 new clinical trials of all types, including local and bioequivalence studies. This represents a 14% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in the Year 2019 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs dipped slightly from 44% to 43% of the total number of trials. The market share of Local Clinical Trials (LCTs) grew marginally by 1% whilst the Bio-equivalent (BE') share remained stable with 32%.

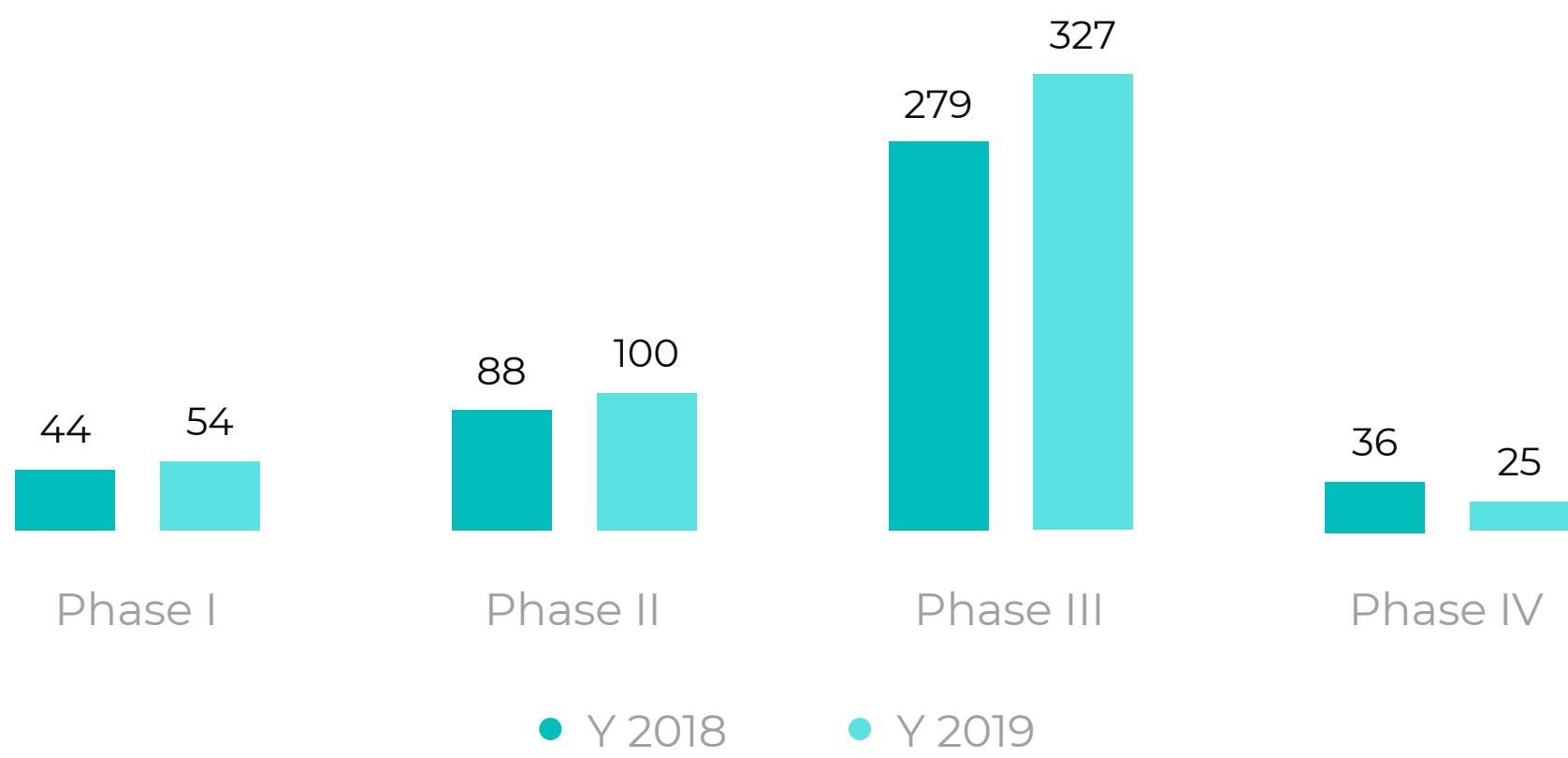
Breakdown of Clinical Trials in Y 2019 by Type



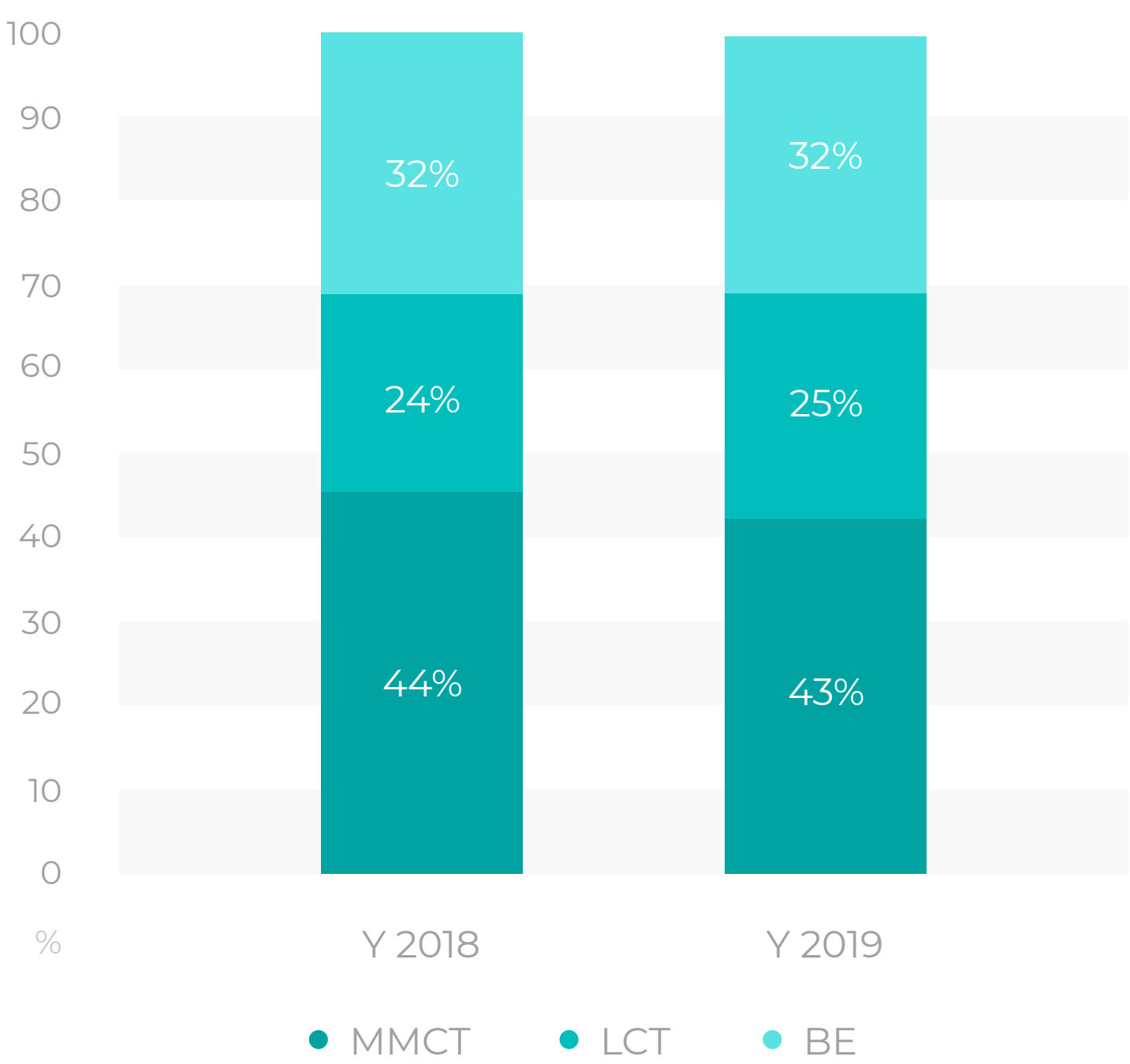
Trial Data

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 increased by 17% – from 279 trials in the Year 2018 to 327 trials in the Year 2019.

Breakdown of Clinical Trials by Phase



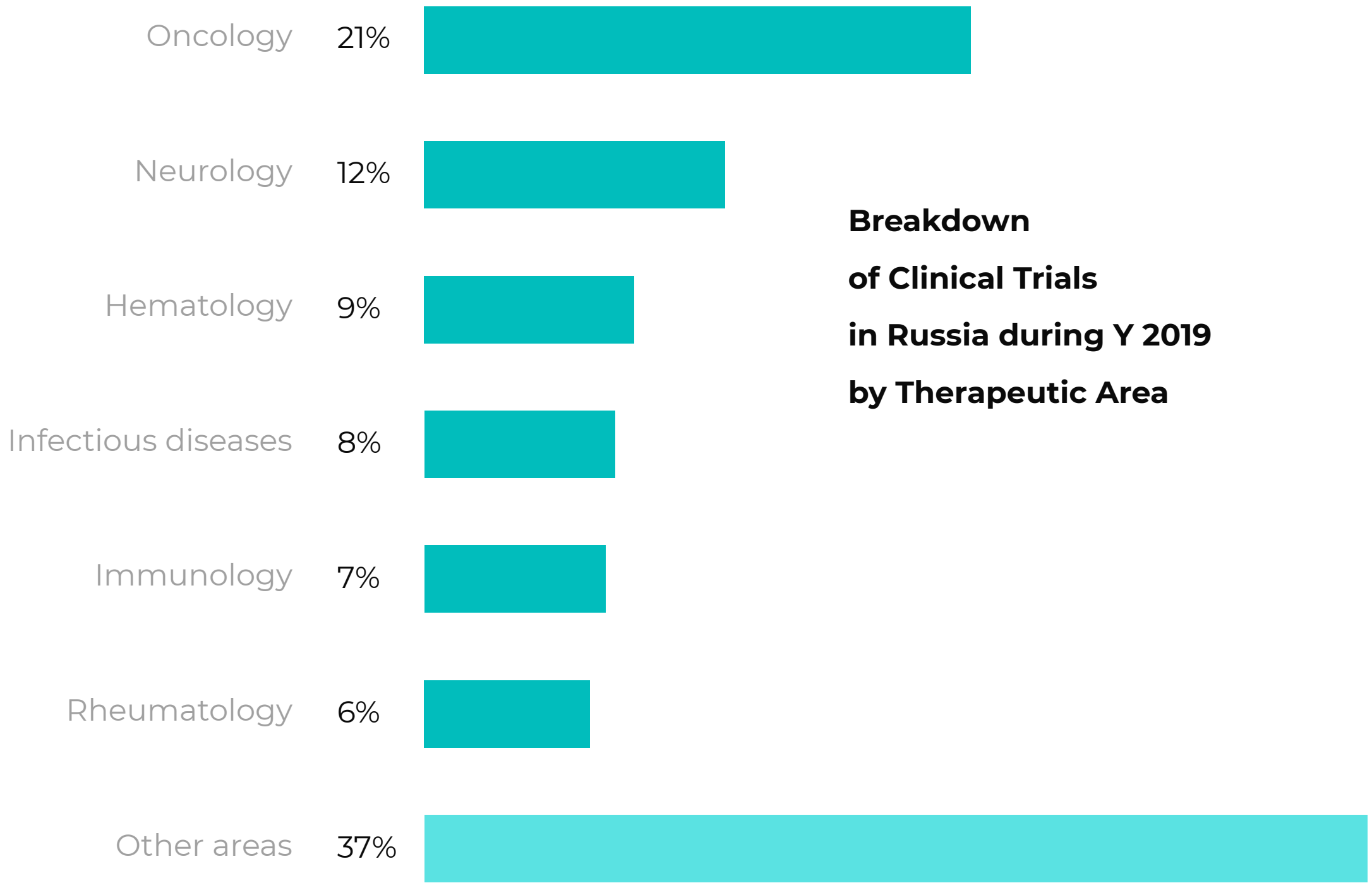
Percentage Breakdown of Clinical Trials by Type



Trial Data

The largest number of clinical trials initiated in Russia during the Year 2019 were related to Oncology (109 studies), Neurology (60 studies) and Hematology (42 studies). Other dominant therapy areas include Infectious Diseases, Immunology and Rheumatology.

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

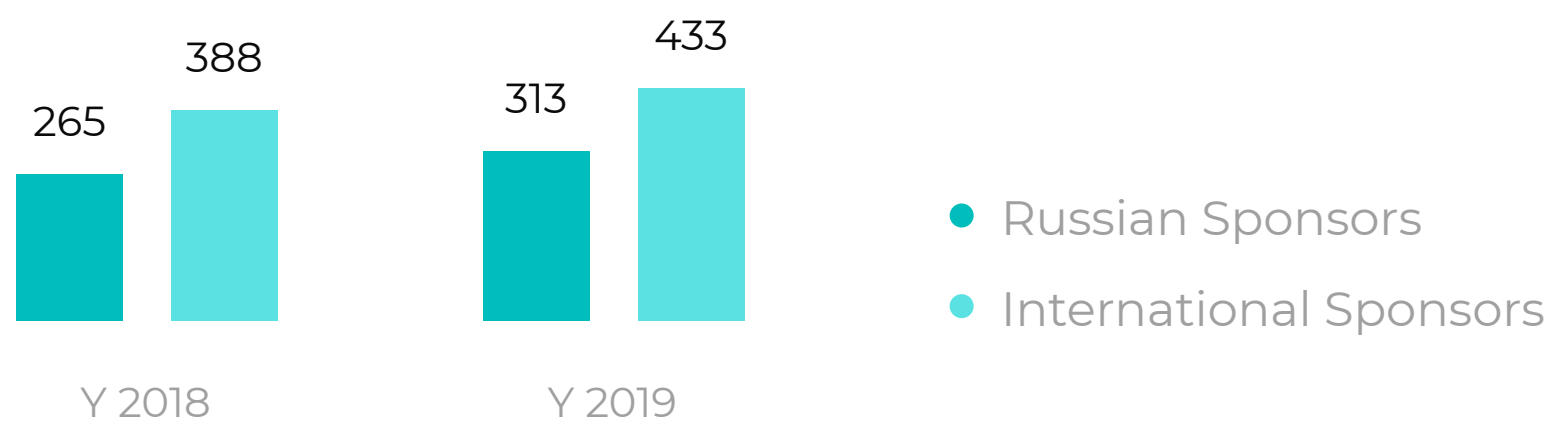


Sponsor Data

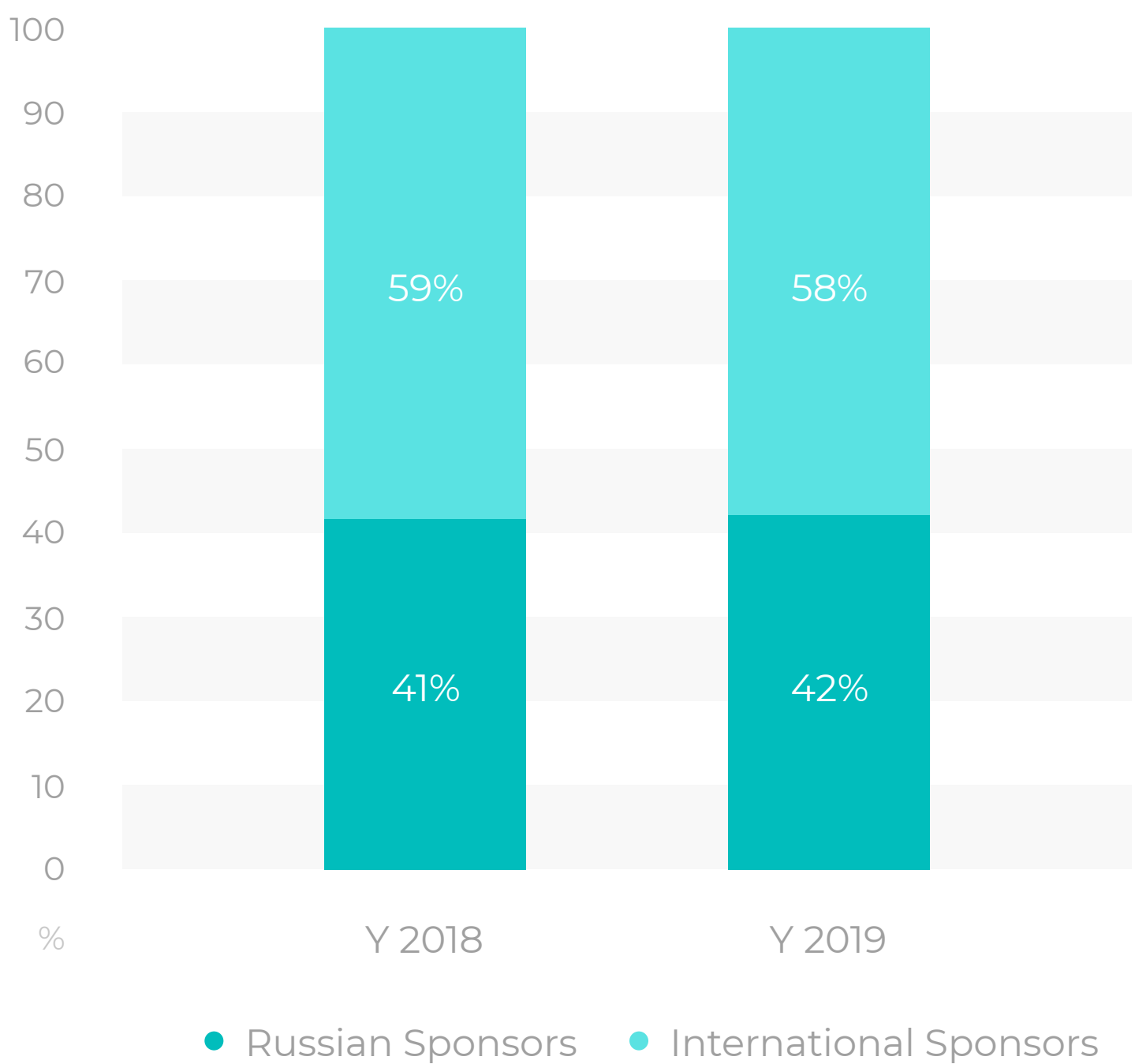
Clinical trials initiated in Russia during the Year 2019 were sponsored by pharmaceutical companies from Russia and 36 foreign countries.

The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dipped slightly by 1% to 58% of all studies.

Breakdown of Clinical Trials by Sponsor Origin



Percentage Breakdown of Trials by Sponsor Origin

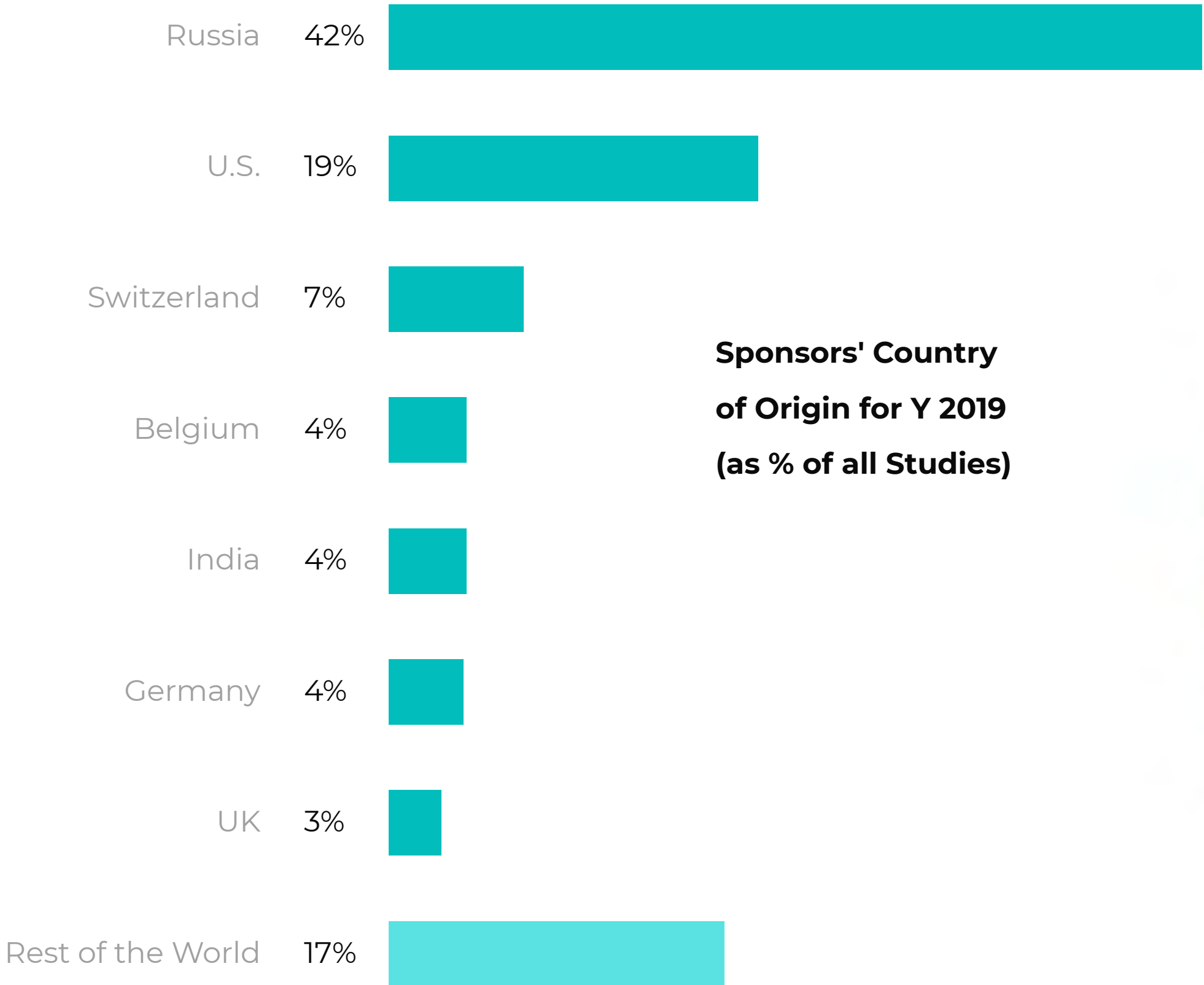
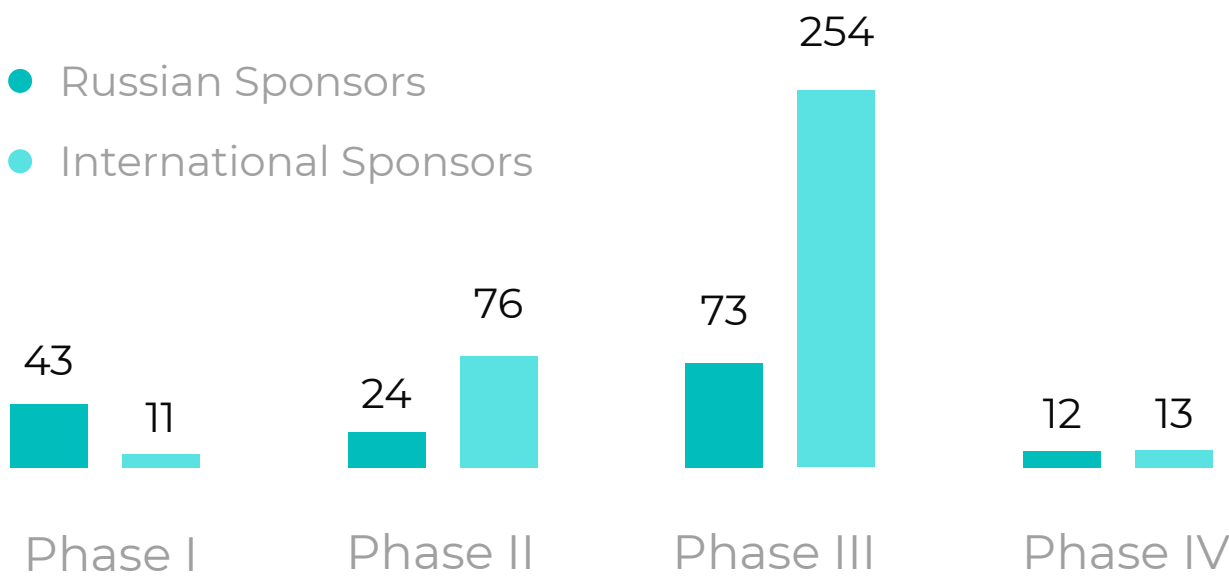


Sponsor Data

The most prevalent Sponsor's countries of origin in the Year 2019 were Russia (313 studies), U.S. (142 studies) and Switzerland (52 studies). Other prominent countries include Belgium (30 studies), India (30 studies) and Germany (29 studies).

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2019 was Phase III with 72% share among Phase I – IV studies.

Breakdown of Clinical Trials by Sponsor's Origin and Phase



International Sponsor Ranking



Top-10 International
Trial Sponsors
in Russia in Y 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	35	3 084
2	Novartis	24	1 648
3	Eli Lilly	13	1 474
4	Janssen	13	1 470
5	Hoffmann-La Roche	12	590
6	Bristol-Myers	11	511
7	Amgen	8	1 284
8	Sanofi	8	1 271
9	Novo Nordisk	8	1 138
10	Allergan	8	688

Combined market share of these companies **28%** **20%**

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 Y 2019

Nº	Company Name	No. studies	No. subjects
1	Biocad	12	3 417
2	Generium	9	614
3	MedInvest	8	826
4	GeroPharm	7	2 537
5	OTC Pharm	5	1 048
6	Valenta Pharm	5	756
7	Fort	4	1 801
8	Microgen	4	1 155
9	Sotex	4	579
10	R-Pharm	4	385

Combined market share of these companies **12%** **20%**

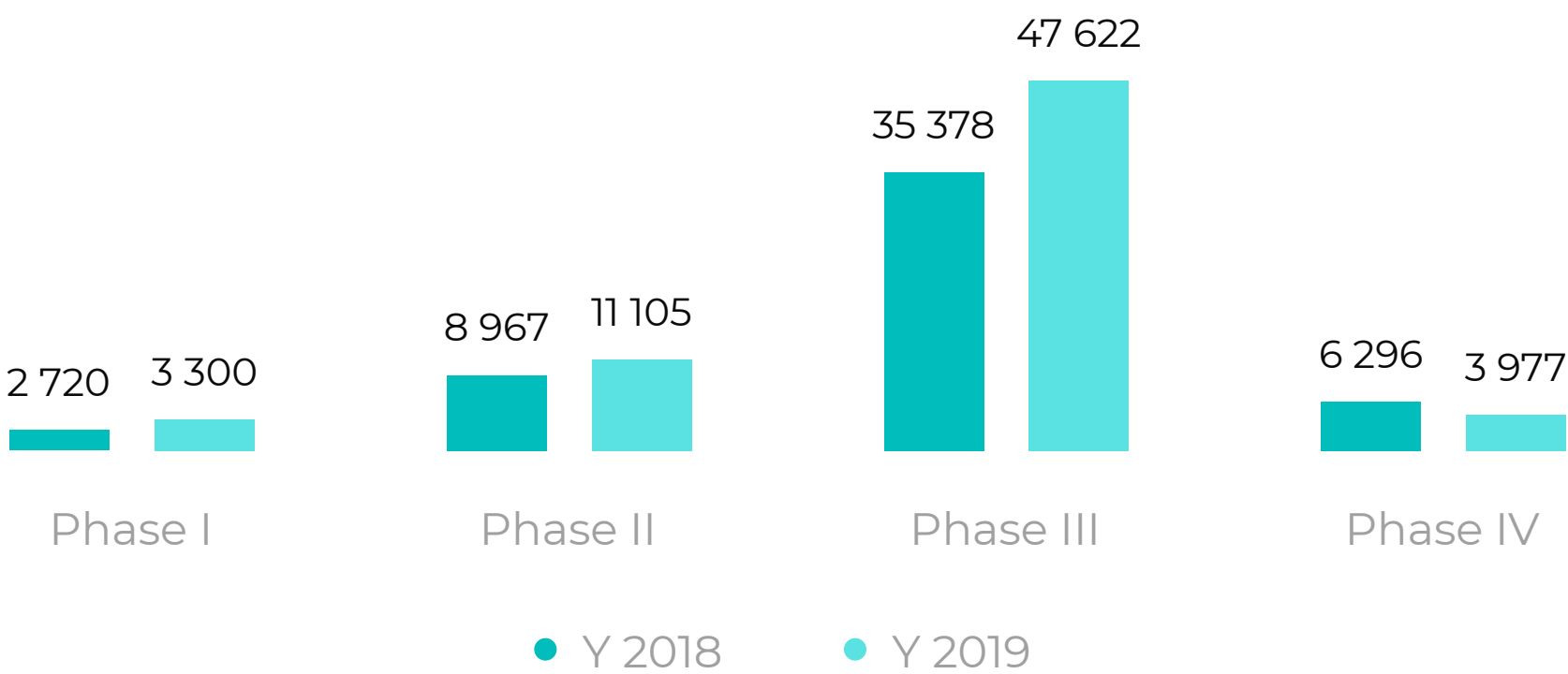
Combined market share shown as a percentage of both international and Russian sponsors.
Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

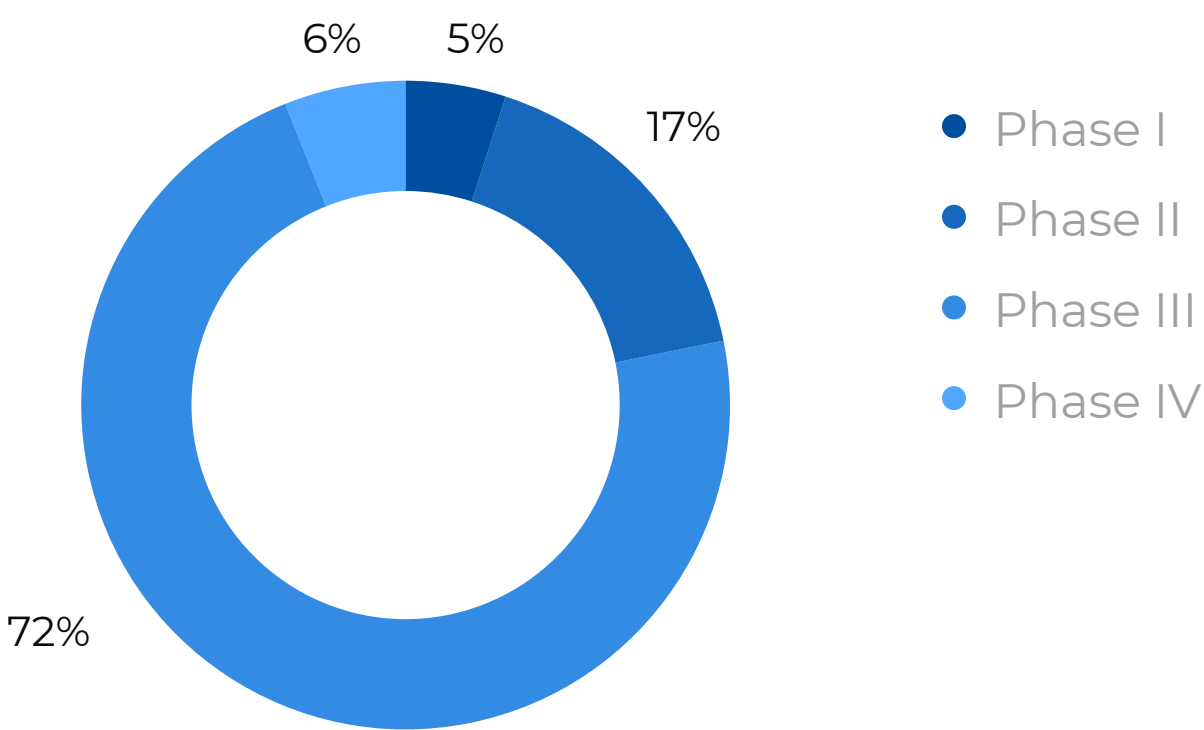
The overall number of subjects enrolled in clinical trials initiated in Russia in the Year 2019 reached a total of 66,024 subjects – a 23% increase in comparison with the Year 2018, when 53,361 subjects were enrolled.

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



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Research Site Data



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

Nº	Site Name	City	No. studies
1	Probiotec Medical Center	Moscow Region	28
2	Ecosafety	Saint-Petersburg	25
3	Clinical Hospital #2, Yaroslavl region	Yaroslavl	25
4	Human Brain Institute named after N.P. Bekhtereva	Saint-Petersburg	20
5	Clinical Narcology Hospital	Yaroslavl	16

Combined market share of these sites **15%**

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

Nº		City	No. studies
1	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	80
2	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	52
3	Clinical Oncological Dispensary	Omsk	46
4	Kazan State Medical University	Kazan	44
5	Siberian State Medical University	Tomsk	42

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

Research Site Data



Top-10 Russian Research Sites (all Studies)

Nº	Site Name	City	No. studies
1	First St.Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	81
2	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	60
3	Ecosafety	Saint-Petersburg	60
4	Clinical Oncological Dispensary	Omsk	51
5	First Moscow State Medical University named after I.M. Sechenov	Moscow	50
6	Kazan State Medical University	Kazan	44
7	Siberian State Medical University	Tomsk	43
8	Clinical Hospital #2, Yaroslavl region	Yaroslavl	43
9	Leningrad Regional Clinical Hospital	Saint-Petersburg	39
10	Medical Research Center for Psychiatry and Neurology named after V.M. Bekhterev	Saint-Petersburg	35
Combined market share of these sites			68%

CRO Data



CRO Rankings for Y 2019 in Russia (Phase I - IV studies)

Nº	Company Name	No. studies	No. subjects
1	IQVIA	34	4 154
2	Syneos Health	22	1 498
3	Pharmaceutical Research Associates CIS	16	967
4	PPD	15	1 014
5	Medical Development Agency	12	1 131
6	Parexel	12	1 051
7	ICON	10	796
8	PSI	8	1 761
9	Covance	8	942
10	Smooth Drug Development	6	956

Combined market share of these companies* **28%** **22%**

*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 Y 2019 in Russia (BE studies)

Nº	Company Name	No. studies	No. subjects
1	Probiotec Medical Center	21	898
2	Synergy Research Group	9	338
3	Biomapas	5	224
4	R&D Pharma	5	196
5	Euroservice	3	200
6	I Am Guide	2	56
7	Medical Development Agency	2	68
8	Chorich Pharm	2	110
9	Servier	1	70
10	ClinPharmInvest	1	40

Combined market share of these companies* **21%** **19%**

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

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

Regulatory Data

During the Year 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 132 new drugs; 37 of them were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Thirty-five of these 132 drugs were (or are being) studied in clinical trials involving Russian sites.

During the Q4 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 45 new drugs; 16 of them were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Eleven of these 45 drugs were (or are being) studied in clinical trials involving Russian sites.

In the Year 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 73 new drugs including 11 generics, 6 biosimilar and 9 orphan drugs. Thirty-four of these drugs were tested (or being studied) in clinical trials involving Russian sites.

In Q4 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 19 new drugs, including 4 generics, 2 biosimilar and 2 orphan medicines. Nine of these 19 drugs were (or are being) studied in clinical trials involved Russian sites.

Drugs studied at Russian sites and approved by FDA in Q4 2019

Nº	Aprr. date	Drug (active ingredient)	Company
1	10/04/2019	Akliefnda (Trifarotene)	Galderma
2	10/07/2019	Beovubla (Brolucizumab)	Novartis
3	10/11/2019	Reyvownda (Lasmiditan Succinate)	Eli Lilly
4	11/01/2019	Ibrancenda (Palbociclib)	Pfizer
5	11/08/2019	Reblozylbla (Luspatercept)	Celgene
6	11/14/2019	Brukinsanda (Zanubrutinib)	BeiGene
7	11/15/2019	Abriladabla (Adalimumab)	Pfizer
8	11/15/2019	Adakveobla (Crizanlizumab)	Novartis
9	12/12/2019	Vyondys 53nda (Golodirsen)	Sarepta Therapeutics
10	12/18/2019	Padcevbla (Enfortumab Vedotin)	Astellas Pharma
11	12/20/2019	Caplytanda (Lumateperone)	Intra-Cellular Therapies

Source: FDA



Inspection Data

FDA Inspections

According to the U.S. FDA data, there was only one FDA inspection conducted in a Russian investigative site during the Year 2019. In March 2019 the FDA representatives inspected the clinical trial related activity of Dr. Yulia Karakulova, M.D. in Perm with a No Action Indicated (NAI) outcome.

Roszdravnadzor Inspections

According to the Roszdravnadzor quarterly reports, as of 01/01/2020 there were 52 Regulatory inspections conducted by Roszdravnadzor during the Year 2019 with 24 violations found. No categorization (level) of the violations is made available.



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Drugs studied at
Russian sites
and approved by
EMA in Q4 2019

Nº	Appr. date	Drug (active ingredient)	Company
1	10/17/2019	Evenity (Romosozumab)	Amgen
2	11/14/2019	Isturisa (Osilodrostat)	Novartis
3	11/15/2019	Mayzent (Siponimod)	Novartis
4	11/15/2019	Polivy (Polatuzumab Vedotin)	Roche
5	11/15/2019	Tavlesse (Fostamatinib)	Rigel Pharmaceuticals
6	12/13/2019	Beovu (Brolucizumab)	Novartis
7	12/13/2019	Recarbrio (Imipenem; Cilastatin; Relebactam)	Merck
8	12/13/2019	Amsparity (Adalimumab)	Pfizer
9	12/15/2019	Rinvoq (Upadacitinib)	AbbVie

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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