

Synergy **Orange** Paper / 2019 autumn / quarter 3



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: 01/10/2019



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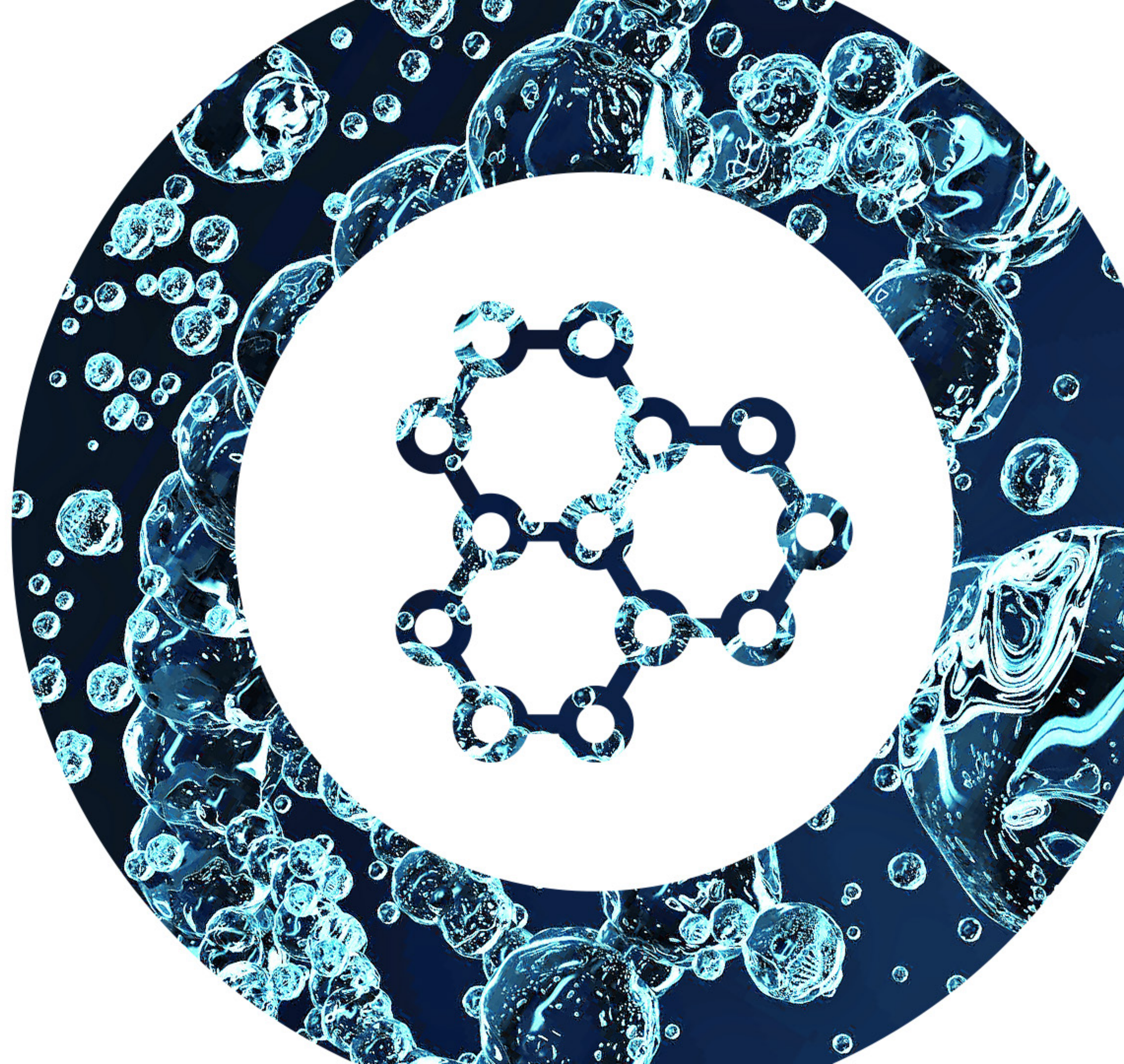


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Executive Summary

During Q3 2019 the Ministry of Health of the Russian Federation approved the start of 219 new clinical trials of all types, with an overall year on year growth of 10% by total number of studies.

The dominant type of clinical trials conducted in Russian sites in Q3 2019 were MMCT (Multinational Multi-center Clinical Trials) with 50% 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 29% of the total number of studies conducted, and for 17% of all subjects enrolled during the quarter. The top-10 Russian sponsors take up approximately 15% of the market by total number of trials conducted and have 33% of all subjects enrolled in these trials. The twenty largest pharmaceutical companies combined account for 44% of all clinical trials and for 50% of all subjects enrolled.

During Q3 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs, including 13 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers. Ten of these 29 drugs were tested (or being studied) in clinical trials involving Russian sites.

In Q3 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 24 new drugs. Fourteen of the approved drugs were tested (or being studied) in clinical trials involving Russian sites.

The top-5 domestic manufacturers in Russia during Q3 2019 were : [Biocad](#), [MedInvest](#), [Materia Medica Holding](#), [FSBI "N.F. Gamaleya NRCEM"](#) and [GeroPharm](#).

The top-5 international sponsors in Russia during Q3 2019 were: [Merck](#), [Novartis](#), [Bristol-Myers Squibb](#), [Amgen](#) and [Novo Nordisk](#).

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during Q3 2019.



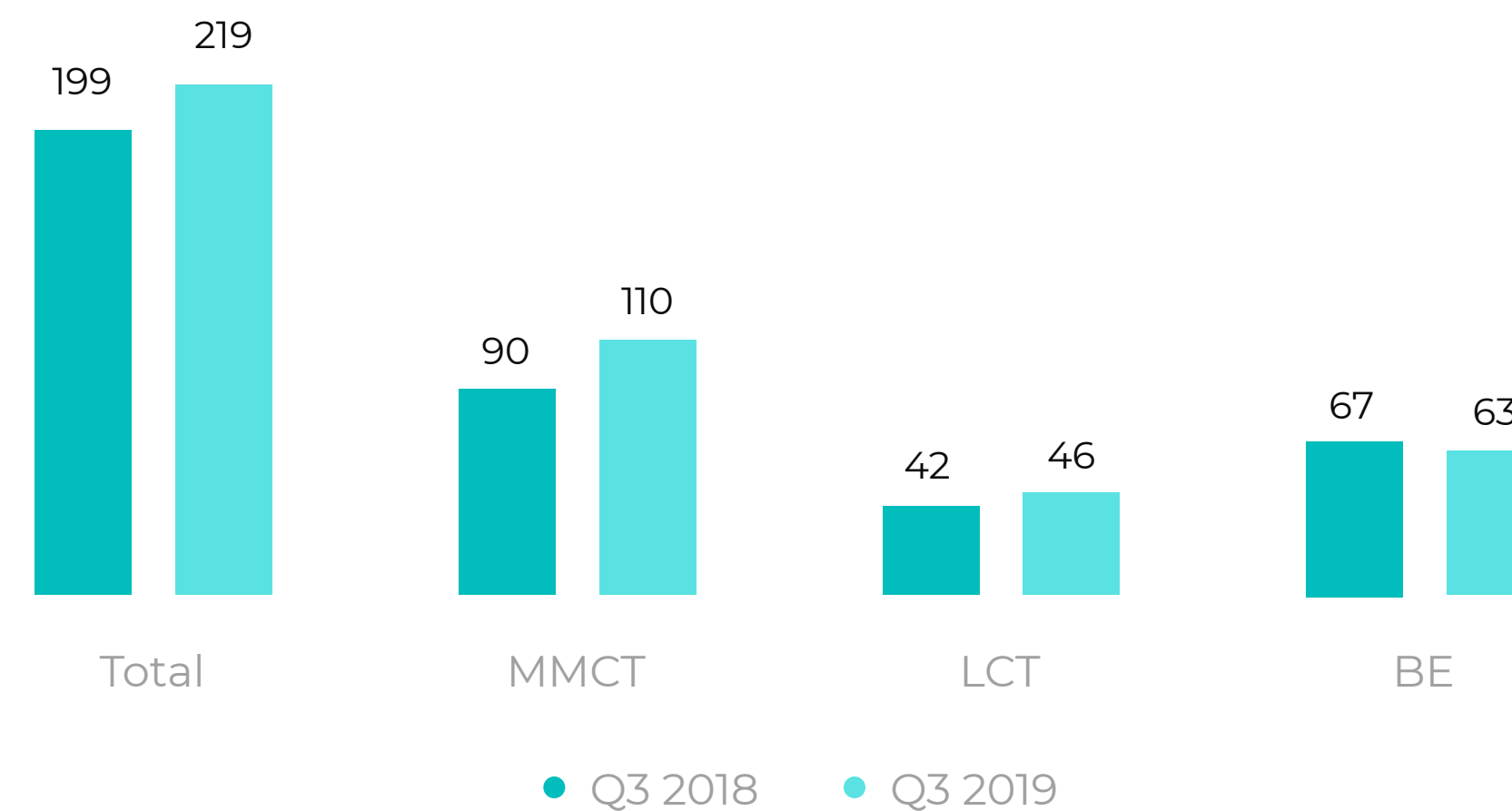
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Trial Data

During Q3 2019 the Ministry of Health of the Russian Federation approved the start of 219 new clinical trials of all types, including local and bioequivalence studies. This represents a 10% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q3 2019 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs increased from 45% to 50% of the total number of trials. The market share of Local Clinical Trials (LCTs) remains stable with 21% whilst the Bio-equivalent (BE') share dropped slightly from 34% to 29%.

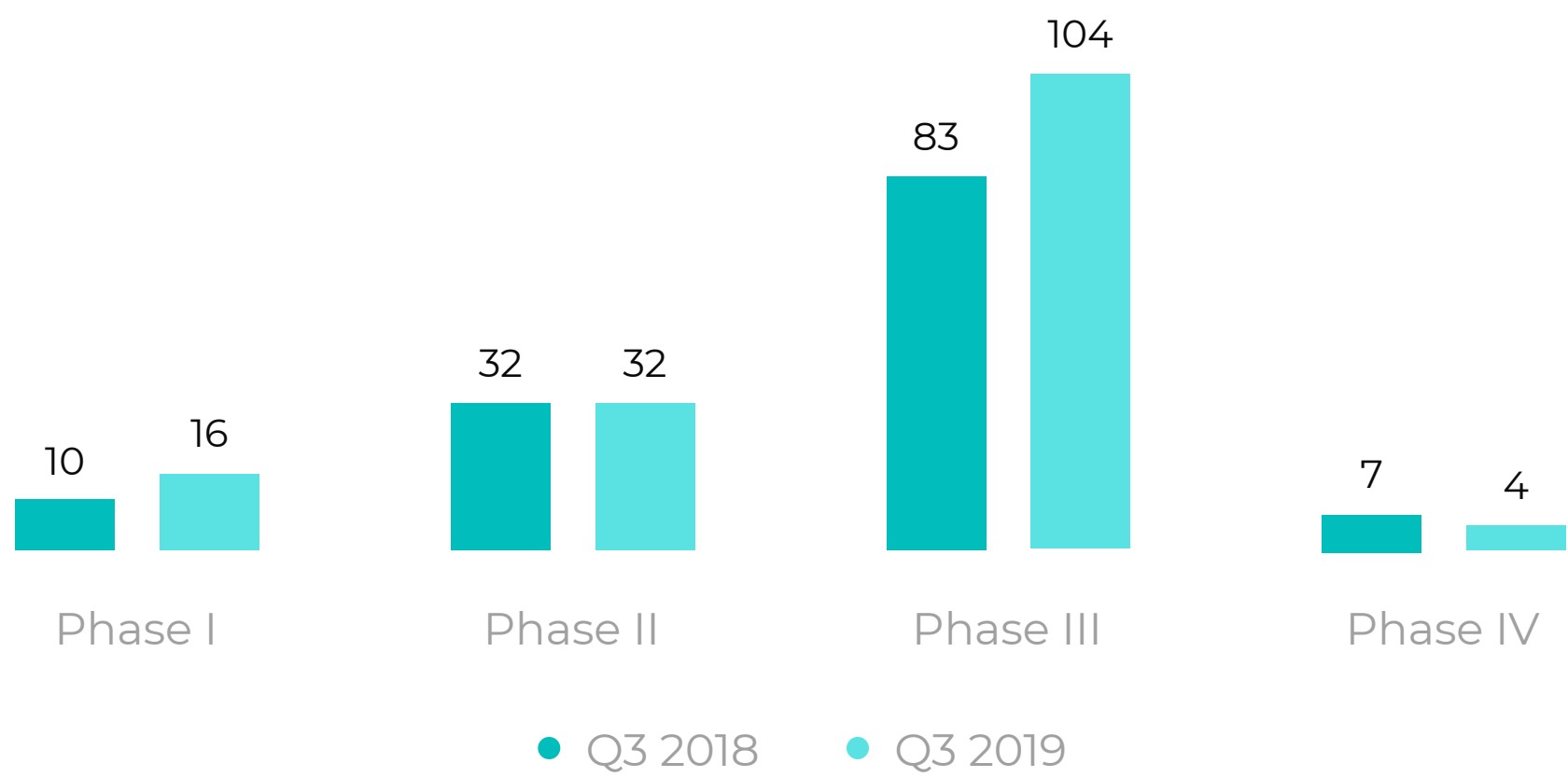
Breakdown of Clinical Trials in Q3 2019 by Type



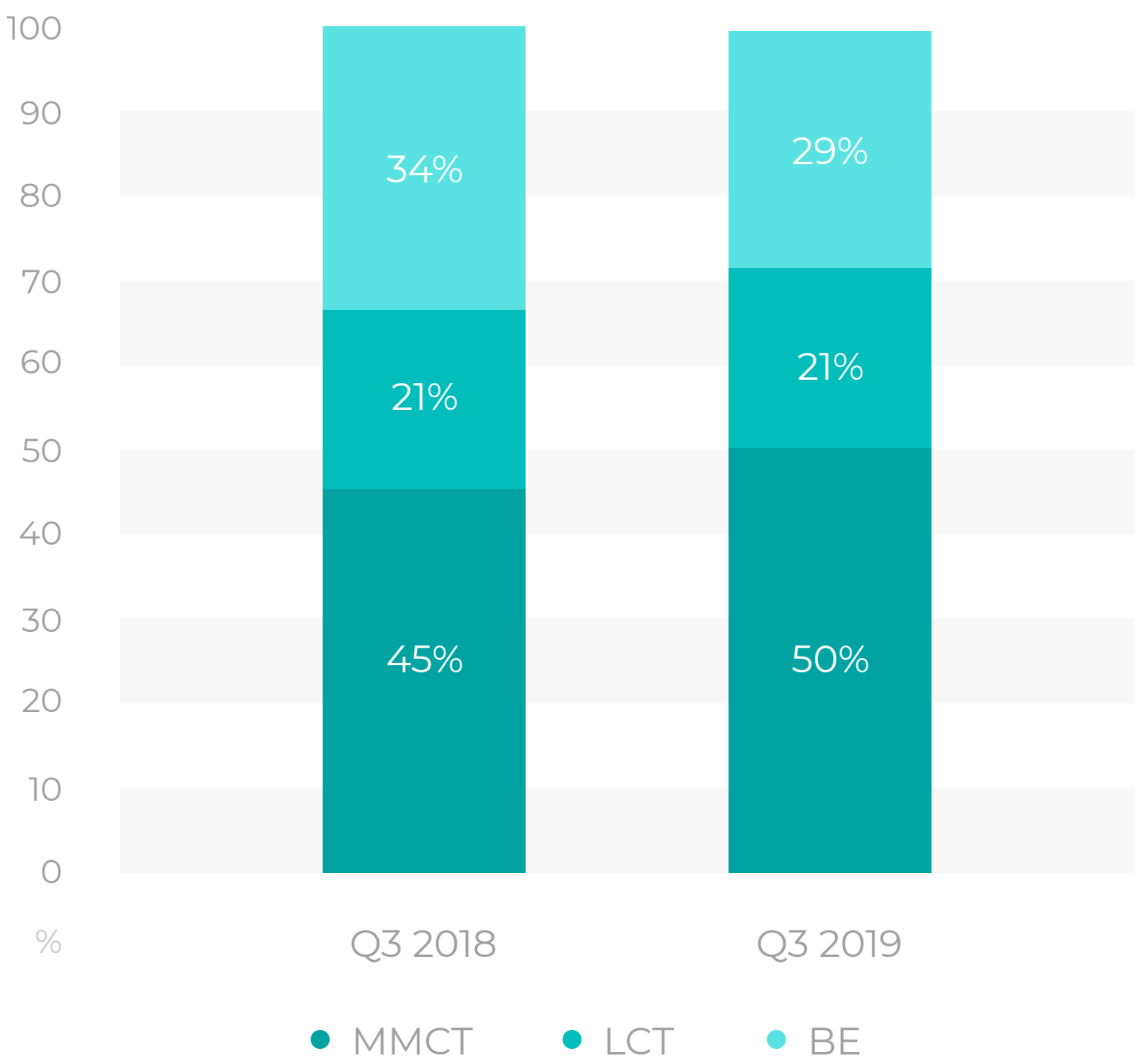
Trial Data

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 25% – from 83 trials in Q3 2018 to 104 trials in Q3 2019.

Breakdown of Clinical Trials by Phase



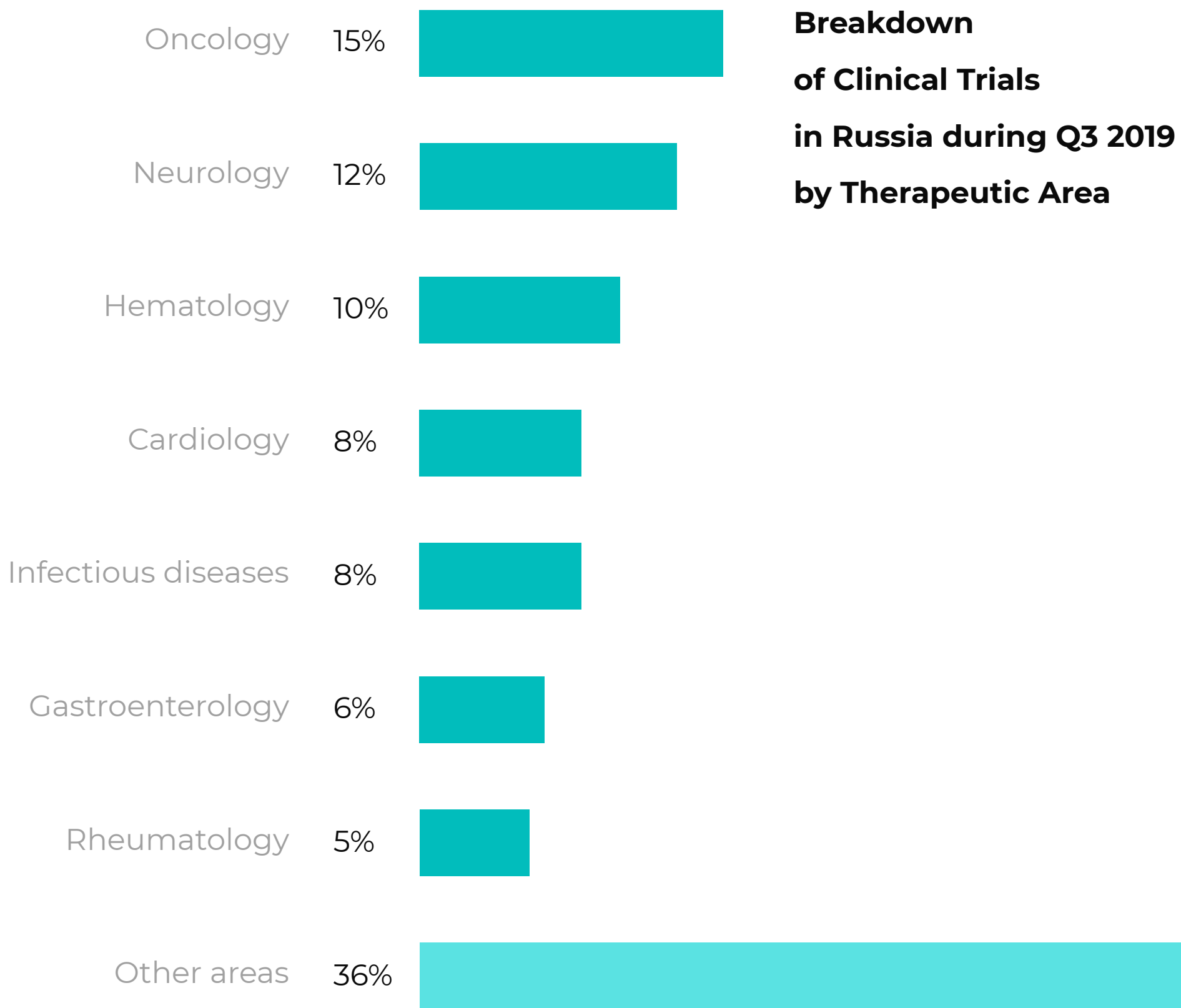
Percentage Breakdown of Clinical Trials by Type



Trial Data

The largest number of clinical trials initiated in Russia during Q3 2019 were related to Oncology, Neurology and Hematology. Other popular therapy areas include Infectious Diseases, Cardiology and Gastroenterology.

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

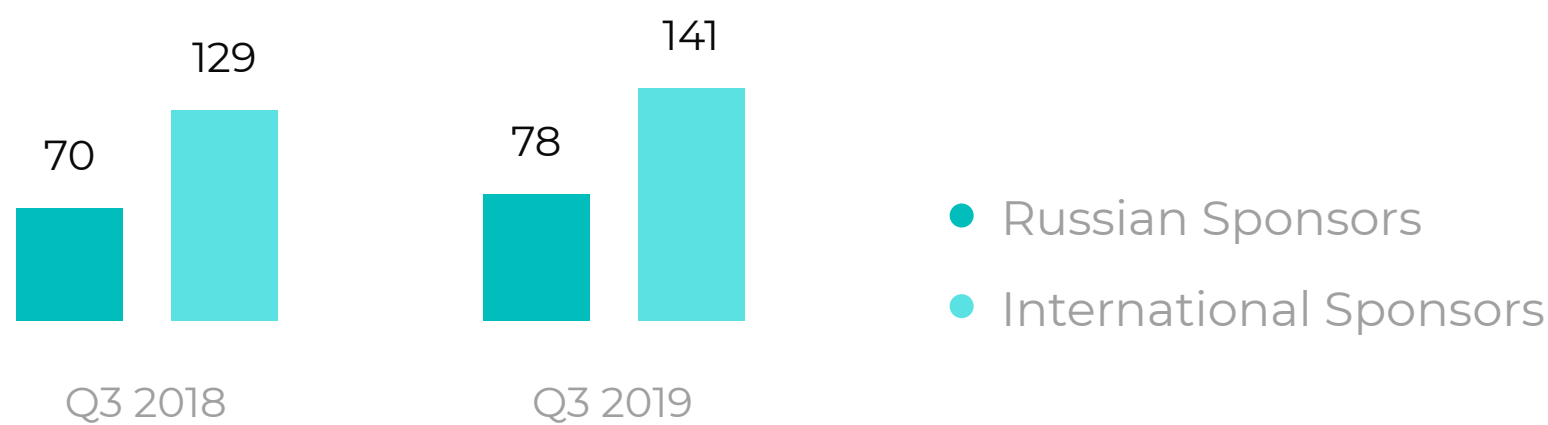


Sponsor Data

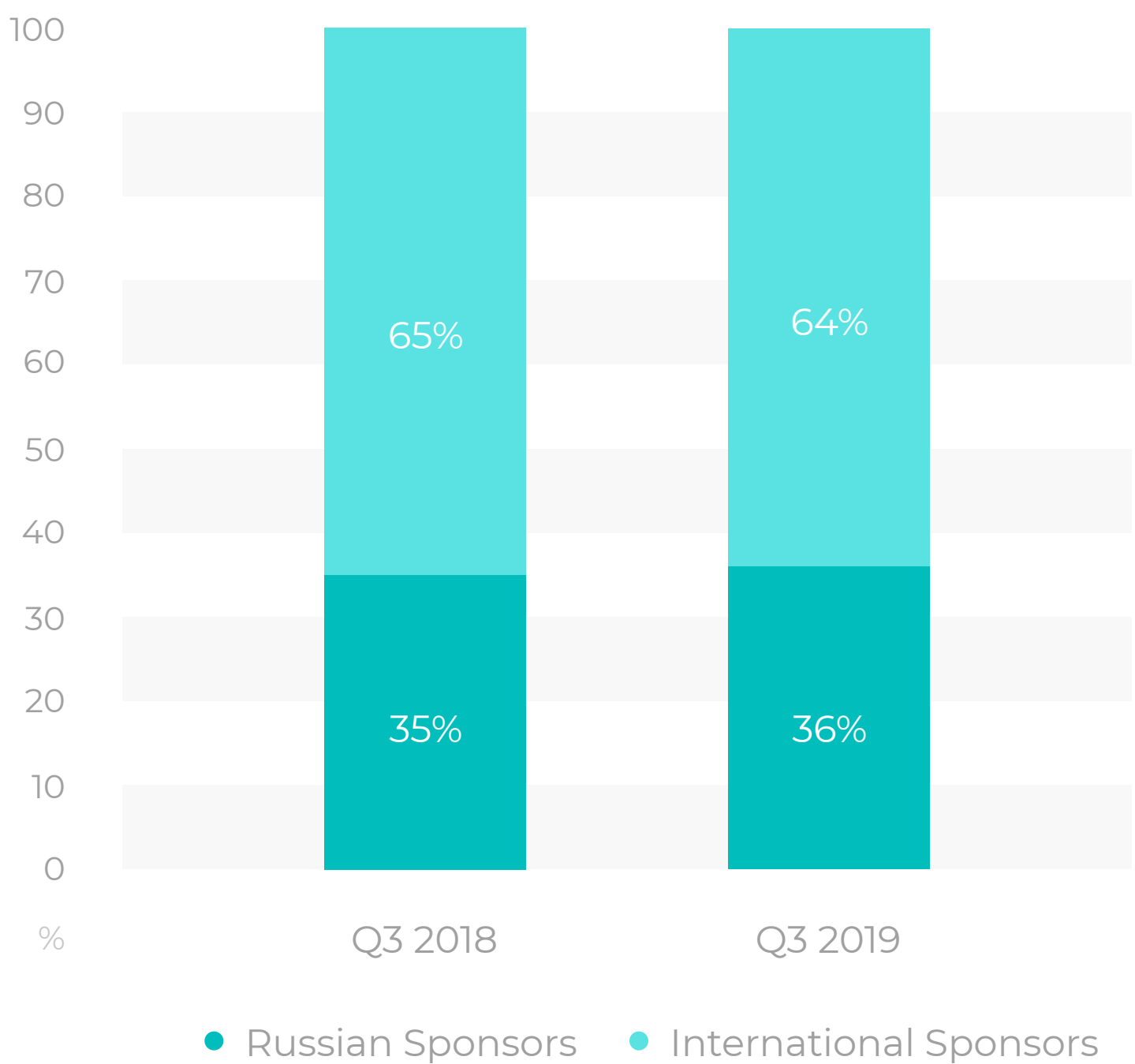
Clinical trials initiated in Russia in during Q3 2019 were sponsored by pharmaceutical companies from Russia and 29 foreign countries.

The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market remains stable with 64% of all studies.

Breakdown of Clinical Trials by Sponsor Origin



Percentage Breakdown of Trials by Sponsor Origin

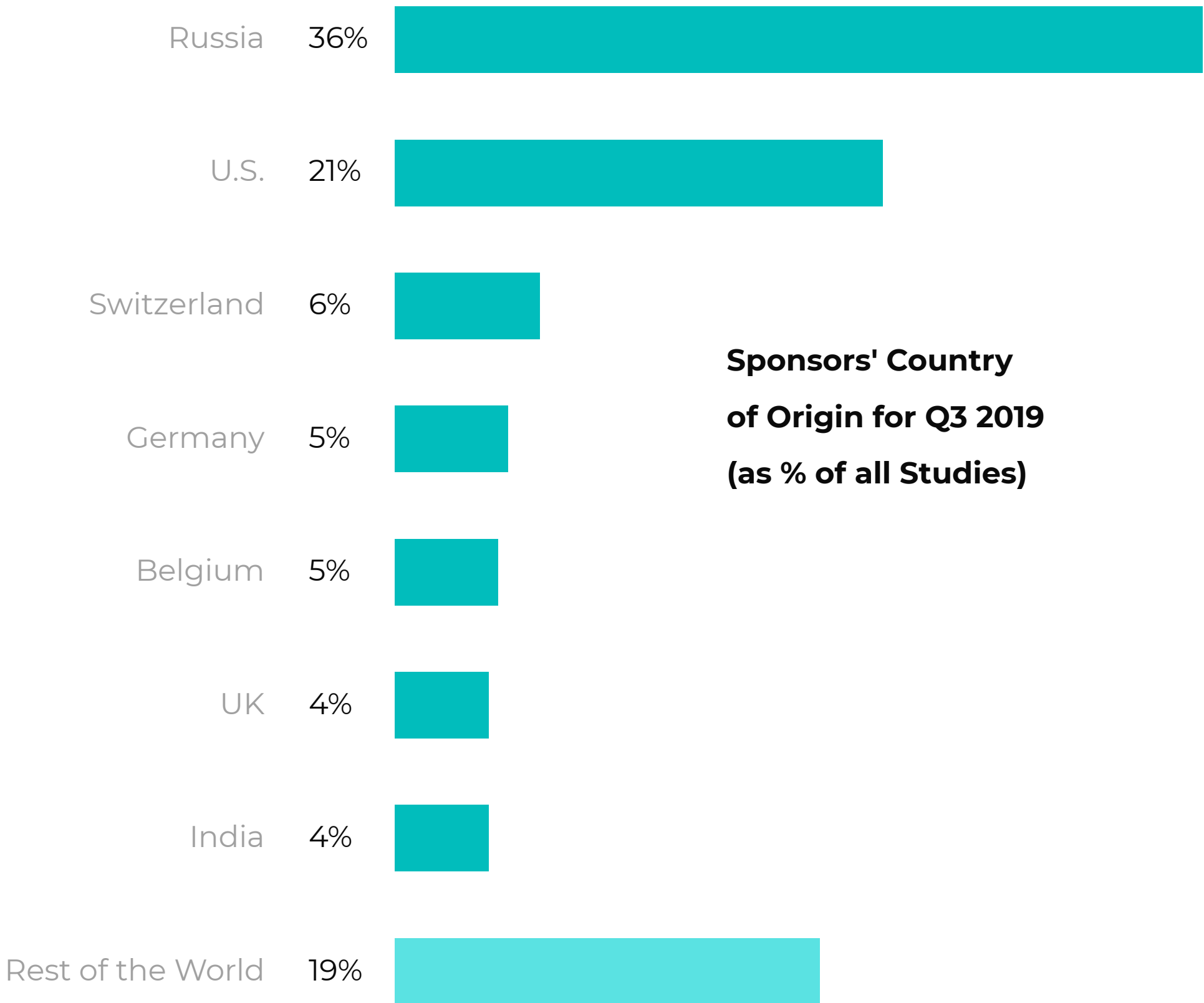
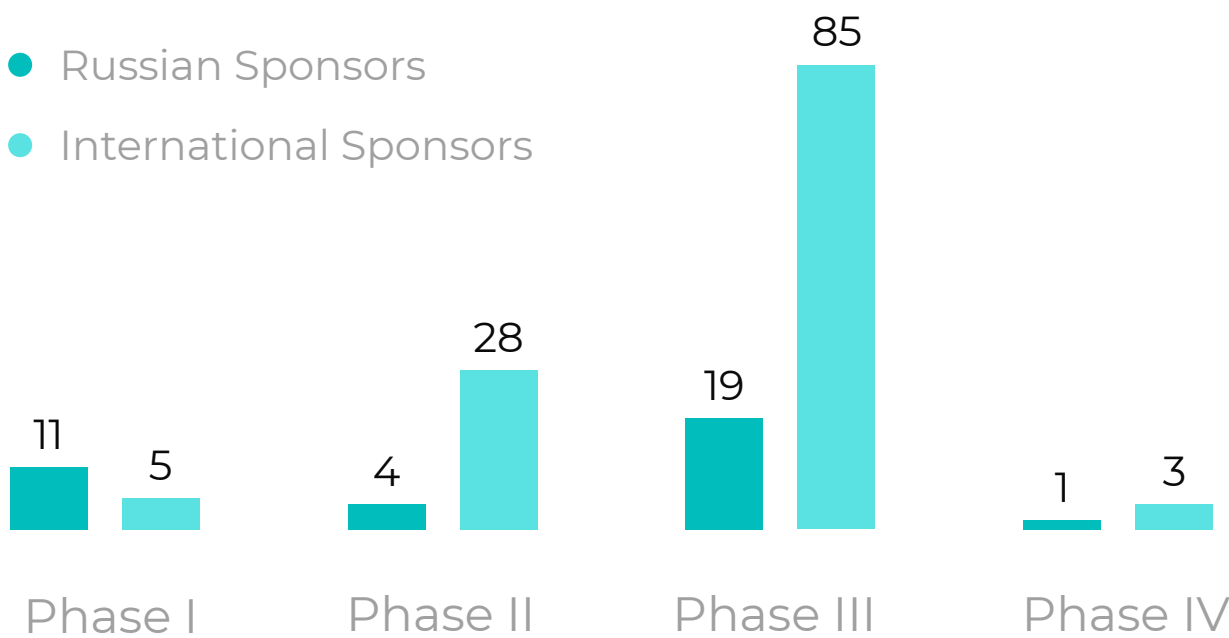


Sponsor Data

The most prevalent Sponsor's countries of origin in Q3 2019 were Russia (78 studies), U.S. (47 studies) and Switzerland (14 studies). Other prominent countries include Germany (11 studies), Belgium (10 studies) and UK (9 studies).

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2019 was Phase III with 67% share among Phase I – IV studies.

Breakdown of Clinical Trials by Sponsor's Origin and Phase



Sponsors' Country of Origin for Q3 2019 (as % of all Studies)



International Sponsor Ranking



Top-10 International
Trial Sponsors
in Russia in Q3 2019

Nº	Company Name	No. studies	No. subjects
1	Merck	7	427
2	Novartis	7	310
3	Bristol-Myers	6	203
4	Amgen	5	100
5	Novo Nordisk	4	709
6	Janssen	4	260
7	Hoffmann-La Roche	4	233
8	Sunovion	3	552
9	GlaxoSmithKline	3	410
10	Acadia Pharmaceuticals	3	195

Combined market share of these companies **29%** **17%**

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 Q3 2019

Nº	Company Name	No. studies	No. subjects
1	Biocad	5	1 857
2	MedInvest	4	246
3	Materia Medica Holding	3	800
4	FSBI “N.F.Gamaleya NRCEM”	3	785
5	GeroPharm	2	555
6	OTC Pharm	2	288
7	Moscow Endocrine Plant	2	260
8	Petrovax Pharma	1	750
9	Nearmedic Plus	1	540
10	PharmaSoft	1	350

Combined market share of these companies **15%** **33%**

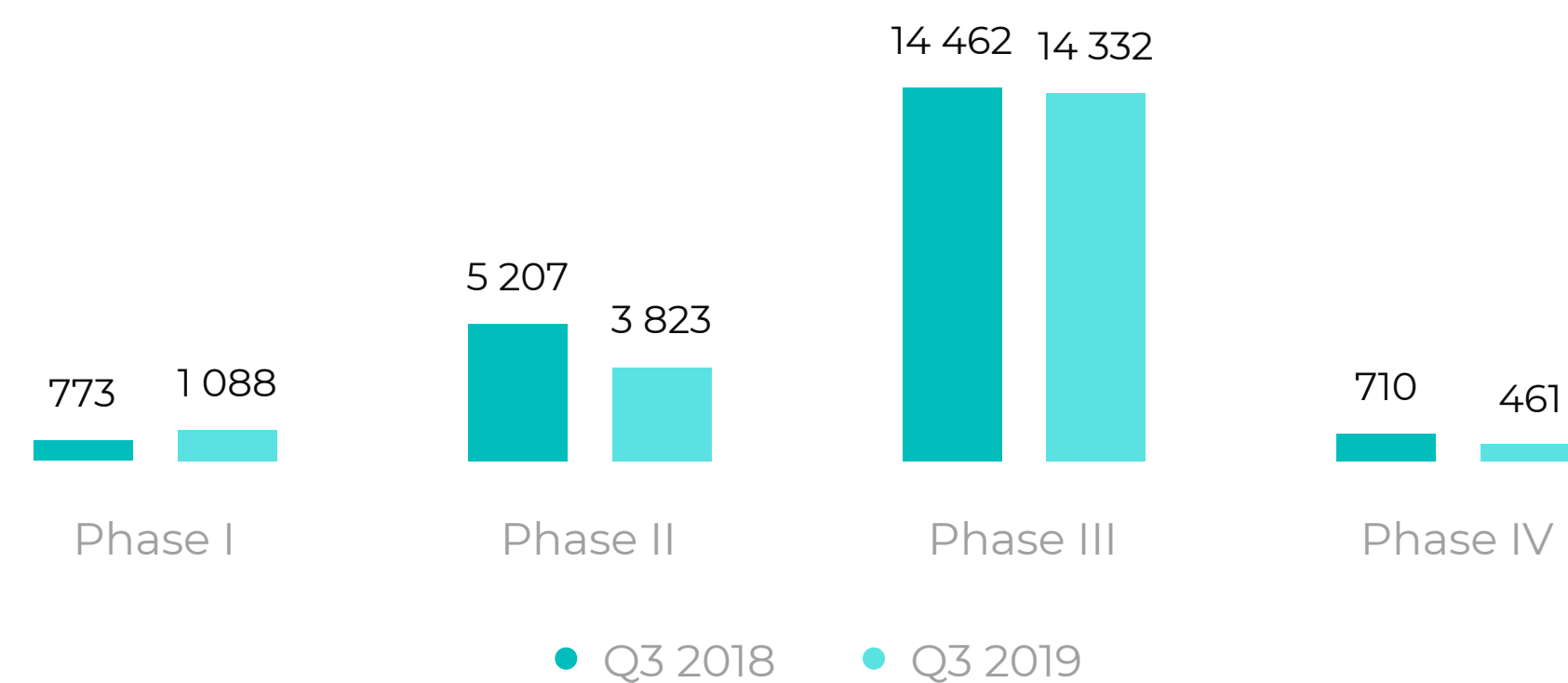
Combined market share shown as a percentage of both international and Russian sponsors.
Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

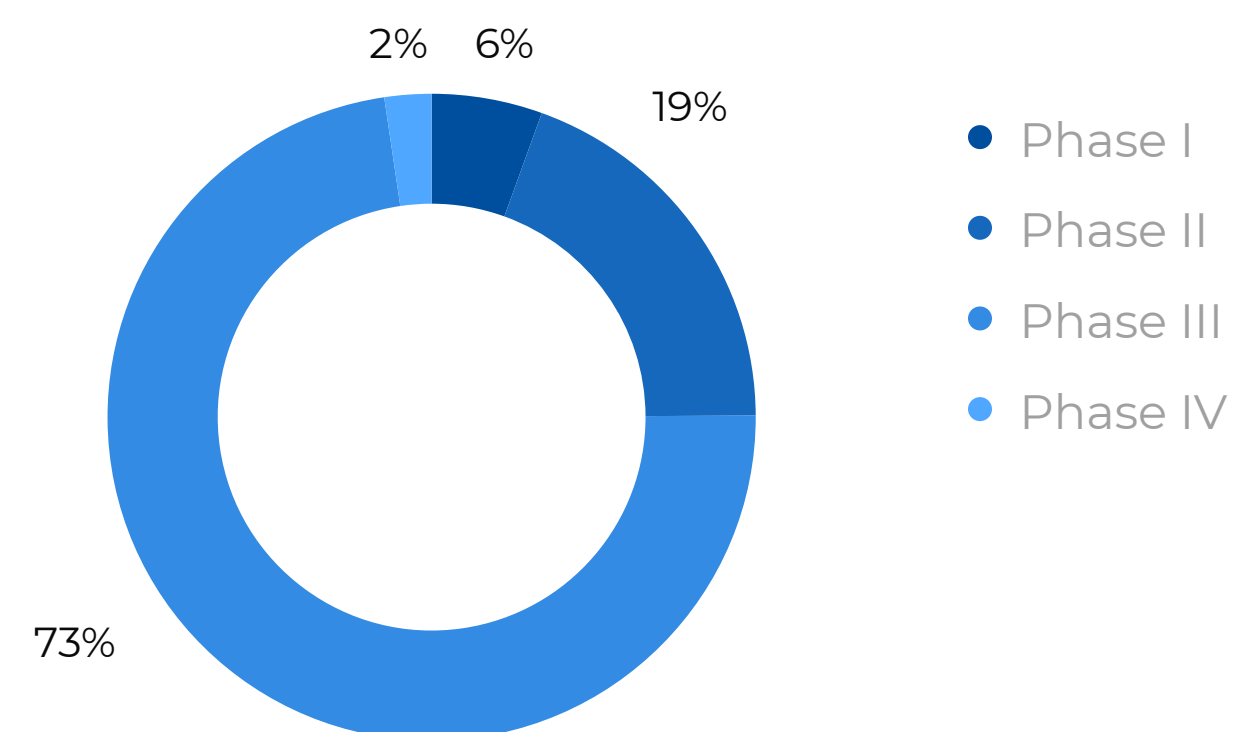
The overall number of subjects involved in clinical trials initiated in Russia in Q3 2019 reached a total of 19,704 subjects – a 7% decrease in comparison with Q3 2018, when 21,152 subjects were involved.

The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 73% 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	Clinical Hospital #2, Yaroslavl region	Yaroslavl	11
2	Human Brain Institute named after N.P. Bekhtereva	Saint-Petersburg	11
3	Ecosafety	Saint-Petersburg	6
4	Probiotec Medical Center	Moscow Region	5
5	Cardiology Dispensary	Ivanovo	5

Combined market share of these sites 17%

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	23
2	Kazan State Medical University	Kazan	22
3	St.Petersburg Psychoneurological Research Institute named after V.M. Bekhterev	Saint-Petersburg	19
4	Nizhny Novgorod Regional Clinical Hospital named after N.A. Semashko	Nizhny Novgorod	17
5	Siberian State Medical University	Tomsk	14

Combined market share of these sites 43%

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	23
2	Kazan State Medical University	Kazan	22
3	St.Petersburg Psychoneurological Research Institute named after V.M. Bekhterev	Saint-Petersburg	19
4	North-Western State Medical University named after I.I. Mechnikov	Saint-Petersburg	18
5	Nizhny Novgorod Regional Clinical Hospital named after N. A. Semashko	Nizhny Novgorod	17
6	Human Brain Institute named after N.P. Bekhtereva	Saint-Petersburg	16
7	First Moscow State Medical University named after I.M. Sechenov	Moscow	14
8	Clinical Oncological Dispensary	Omsk	14
9	Ecosafety	Saint-Petersburg	14
10	Siberian State Medical University	Tomsk	14
Combined market share of these sites			78%

CRO Data



CRO Rankings for Q3 2019 in Russia

Nº	Company Name	No. studies	No. subjects
1	IQVIA	18	1 509
2	Pharmaceutical Research Associates CIS	8	497
3	Syneos Health	7	558
4	PPD	6	296
5	ICON	5	340
6	Covance	4	690
7	Medical Development Agency	4	246
8	iPharma	3	509
9	Smooth Drug Development	3	490
10	Wordlwide Clinical Trials	3	219

Combined market share of these companies **39%** **27%**

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

Regulatory Data

During Q3 2019 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 29 new drugs; 13 of them are new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

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

In Q3 2019 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) evaluated 24 new drugs, including 3 generics, 1 biosimilar and 4 orphan medicines.

All of these 24 remedies received positive opinions and were approved for marketing. Fourteen of these 24 drugs were being studied in clinical trials that involved Russian sites.

Nº	Appr. date	Drug (active ingredient)	Company
1	07/03/2019	Xpovionda (Selinexor)	Karyopharm
2	07/16/2019	Recarbrionda (Cilastatin Sodium; Imipenem; Relebactam)	Merck
3	07/30/2019	Nubeqanda (Darolutamide)	Bayer
4	08/14/2019	Pretomanidnda (Pretomanid)	The Global Alliance for TB Drug Development
5	08/16/2019	Rinvoqnda (Upadacitinib)	Abbvie
6	08/16/2019	Inrebicnda (Fedratinib Hydrochloride)	Impact Biomedicines
7	08/19/2019	Xenletanda (Lefamulin Acetate)	Nabriva Therapeutics
8	08/28/2019	Harvoninda (Ledipasvir; Sofosbuvir)	Gilead Sciences
9	08/28/2019	Sovaldinda (Sofosbuvir)	Gilead Sciences
10	09/20/2019	Rybelsusnda (Semaglutide)	Novo Nordisk

Source: FDA



Inspection Data

FDA Inspections

According to the U.S. FDA data, there were no FDA inspections conducted in Russian investigative sites during Q3 2019.

Roszdruvnadzor Inspections

According to the Roszdruvnadzor quarterly report, as of 01/10/2019 there were no Regulatory inspections conducted by Roszdruvnadzor during Q3 2019.



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Drugs studied at
Russian sites
and approved by
EMA in Q3 2019

Nº	Appr. date	Drug (active ingredient)	Company
1	09/19/2019	Taxotere (Docetaxel)	Aventis Pharma
2	09/19/2019	Lucentis (Ranibizumab)	Novartis
3	09/19/2019	Xospata (Gilteritinib Fumarate)	Astellas Pharma
4	09/19/2019	Remsima (Infliximab)	Celltrion
5	09/19/2019	Dupixent (Dupilumab)	Sanofi-Aventis
6	09/19/2019	Benlysta (Belimumab)	GlaxoSmithKline
7	09/19/2019	Qtrilmet (Metformin Hydrochloride, Saxagliptin, Dapagliflozin)	AstraZeneca
8	09/19/2019	Bavencio (Avelumab)	Merck
9	09/19/2019	Trulicity (Dulaglutide)	Eli Lilly
10	07/25/2019	Zerbaxa (Ceftolozane Sulfate, Tazobactam Sodium)	Merck
11	07/25/2019	Keytruda (Pembrolizumab)	Merck
12	07/25/2019	Lonsurf (Trifluridine, Tipiracil Hydrochloride)	Les Laboratories Servier
13	07/25/2019	Soliris (Eculizumab)	Alexion
14	07/25/2019	Tecentriq (Atezolizumab)	Roche Holding

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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