

# Clinical Trials in Russia

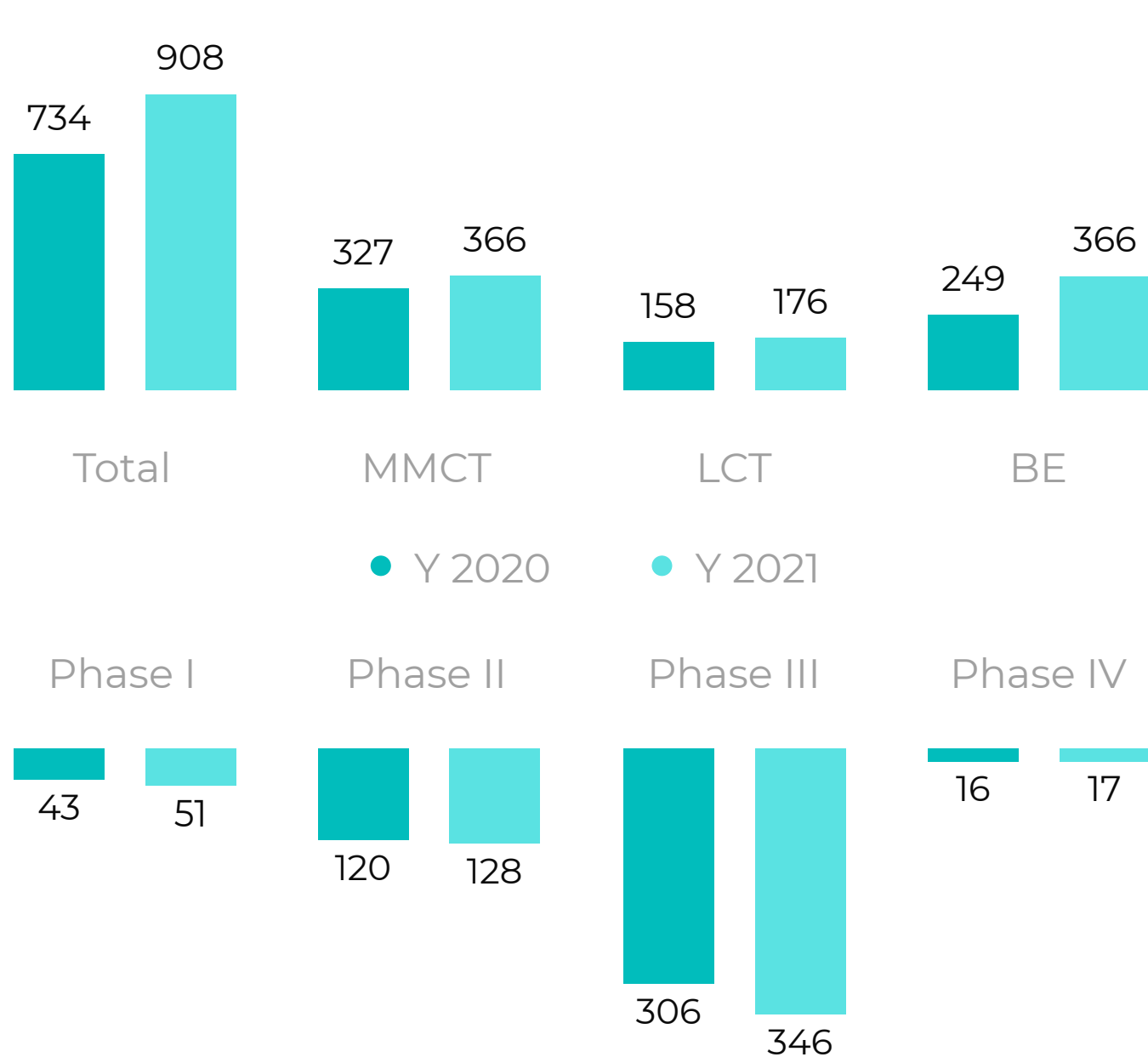
Y 2021 Research report

## Trial Data

During the Year 2021 the Ministry of Health of the Russian Federation approved the start of 908 new clinical trials of all types, including local and bioequivalence studies. This represents a 24% year on year increase by the total number of studies.

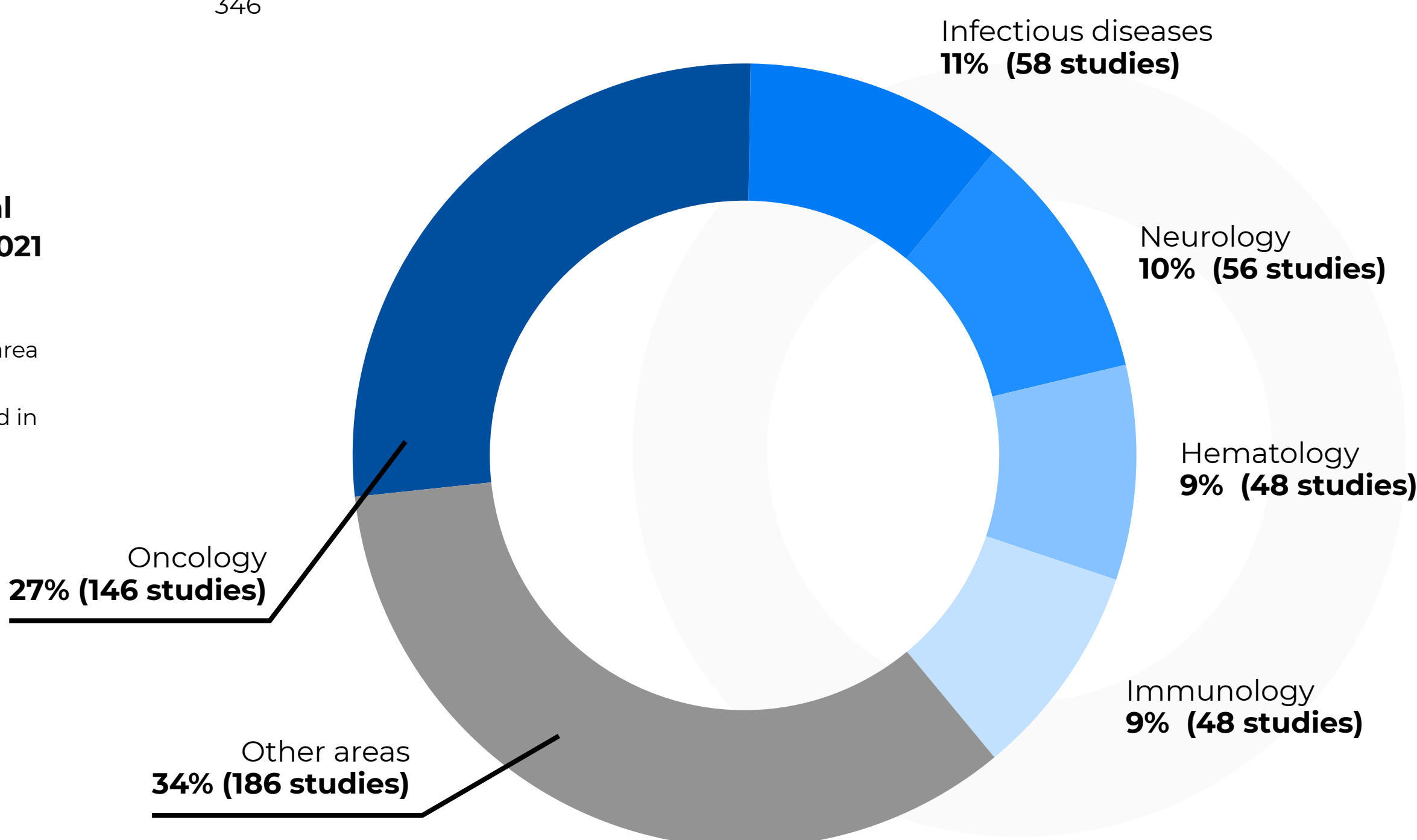
The dominant type of clinical trials conducted across Russian sites in the Year 2021 were both MMCT (Multinational Multi-center) and BE (Bio-equivalent). The market share of MMCTs dropped from 45% to 40% of the total number of trials. The market share of Local Clinical Trials (LCT) dipped from 22% to 19% whilst the BE share increased from 34% to 40%.

Breakdown of Clinical Trials by Type and Phase



Breakdown of Clinical Trials in Russia in Y 2021 by Therapeutic Area

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 2021 were sponsored by pharmaceutical companies from Russia and 35 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market remains stable with 54% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2021 was Phase III with 50% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in 2021 were Russia (415 studies), U.S. (139) and Switzerland (69). Other prominent countries include Sweden (40), India (32), Germany (27) and France (27).

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

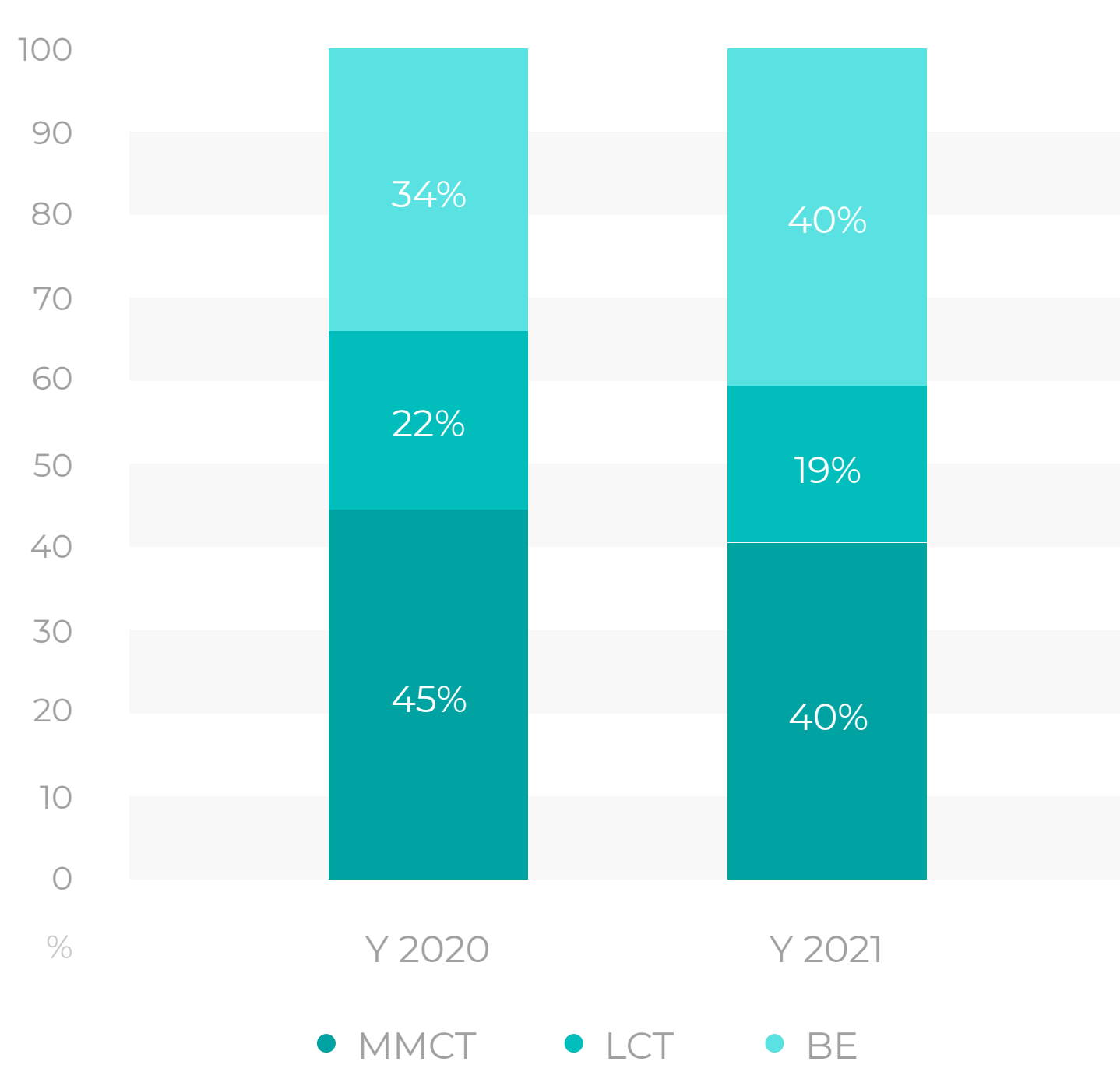
Top-10 International Trial Sponsors in Russia in Y 2021

Nº	Company Name	Studies	Subjects
1	AstraZeneca	33	3 325
2	Novartis	28	2 828
3	Merck	26	2 535
4	Hoffman-la Roche	24	3 504
5	Janssen	16	2 139
6	Sanofi	15	1 134
7	Pfizer	13	1 666
8	Novo Nordisk	12	2 832
9	GlaxoSmithKline	9	1 299
10	Bayer	7	555
Combined market share		34%	16%

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

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

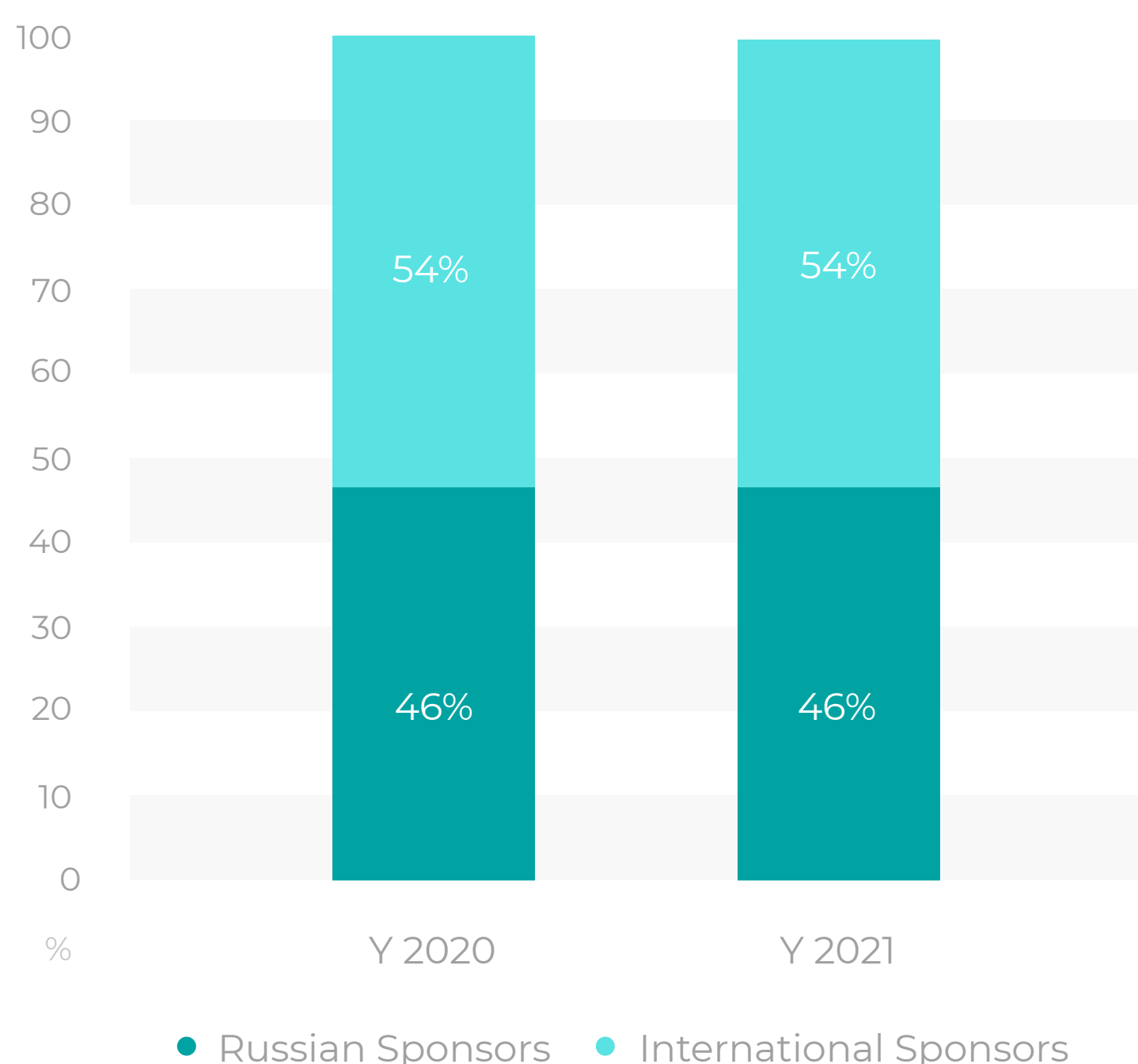
Percentage Breakdown of Clinical Trials by Type



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 13% – from 306 trials in the Year 2020 to 346 trials in the Year 2021.

The largest number of clinical trials initiated in Russia during the Year 2021 were related to Oncology (146 studies), Infectious diseases (58 studies), Neurology (56 studies), Hematology (48 studies) and Immunology (48 studies). Other dominant therapy areas include Gastroenterology, Cardiology, Dermatology and Endocrinology.

Percentage Breakdown of Clinical Trials by Sponsor's Country of Origin



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

Top-10 Russian Trial Sponsors in Russia in Y 2021

Nº	Company Name	Studies	Subjects
1	Valenta Pharma	14	2 670
2	Gamaleya Research *	9	21 134
3	PROMOMED	8	755
4	St. Petersburg Institute of Vaccines and Serums **	5	3 593
5	Generium	5	1 820
6	Microgen	5	1 160
7	GeroPharm	4	2 045
8	BIOCAD	4	1 203
9	Materia Medica Holding	3	4 680
10	Alium	3	1 086
Combined market share		11%	30%

\* Gamaleya Research Institute of Epidemiology and Microbiology

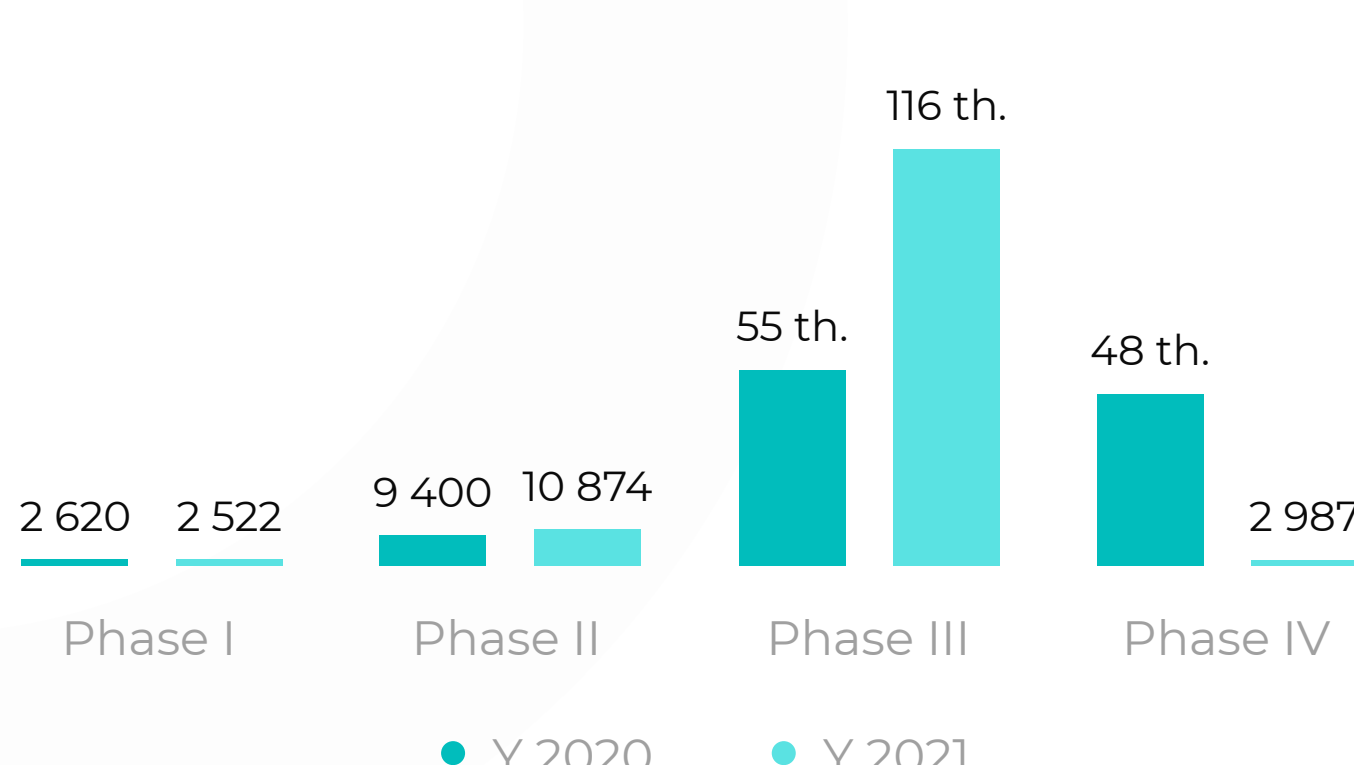
\*\* Saint Petersburg Scientific Research Institute of Vaccines and Serums of the Federal Medical and Biological Agency

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during the Year 2021 reached a total of 132,843 subjects – a 15% increase in comparison with the previous year when 115,675 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 88% of all subjects enrolled.

Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

Breakdown of Number of Subjects Enrolled by Phase





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## Research Site Data

### Top-5 Russian Research Sites (All Studies) in Y 2021

Nº	Site Name	City	No. Studies
1	Ecosafety	Saint-Petersburg	78
2	I.P. Pavlov First Saint Petersburg State Medical University	Saint-Petersburg	76
3	N.N. Blokhin Russian Cancer Research Center	Moscow	69
4	I.M. Sechenov First Moscow State Medical University	Moscow	65
5	N.N. Petrov National Medical Research Center of Oncology	Saint-Petersburg	53

**Combined market share of these sites** **38%**

## CRO Data

### Top-10 CROs in Russia

in Y 2021 (Phase I - IV Studies)

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

Nº	Site Name	No. Studies	No. Subjects
1	Pharmaceutical Research Associates CIS	22	1 266
2	IQVIA	22	1 252
3	Parexel	20	1 686
4	PPD	19	493
5	Syneos Health	17	919
6	Covance	11	1 818
7	MedPace	11	362
8	PSI	8	776
9	Atlant Clinical	6	938
10	ICON	6	325

### Top-5 CROs in Russia

in Y 2021 (BE Studies)

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

**Combined market share** **26%** **7%**

Nº	Site Name	No. Studies	No. Subjects
1	Probiotech	15	658
2	ClinPharmDevelopment	7	390
3	Medical Development Agency	7	306
4	ARS PharmRussia	6	384
5	Accellena	5	168

**Combined market share of these companies** **11%** **10%**

## Regulatory Data

During Q4 2021 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 42 new drugs, including 6 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Eight of these 42 drugs (and two of 6 NMEs) were (or are being) studied in clinical trials involving Russian sites.

**Source: FDA**

Appr.Date	Drug (Active Ingredient)	Company
29.10.2021	Scemblixnda (Asciminib Hydrochloride)	Novartis
17.12.2021	Vyvgartbla (Efgartigimod Alfa)	argenx
17.12.2021	Vusimrybla (Adalimumab)	Coherus Biosciences
17.12.2021	Tezspirebla (Tezepelumab Ekko)	Astrazeneca
20.12.2021	Apretudenda (Cabotegravir)	ViiV Healthcare
20.12.2021	Xareltonda (Rivaroxaban)	Janssen
22.12.2021	Leqvionda (Inclisiran)	Novartis
27.12.2021	Adbrybla (Tralokinumab)	Leo Pharma

In Q4 2021 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 23 new drugs, including 3 generics, 0 biosimilar and 6 orphan medicines.

Fifteen of these 23 drugs were (or are being) studied in clinical trials involved Russian sites.

**Source: EMA**

Appr.Date	Drug (Active Ingredient)	Company
14.10.2021	Rybrevent (Amivantamab)	Janssen
14.10.2021	Vaxneuvance (Pneumococcal Polysaccharide)	Merck
11.11.2021	Lonapegsomatropin (Lonapegsomatropin)	Ascendis Pharma
11.11.2021	Wegovy (Semaglutide)	Novo Nordisk
11.11.2021	Riltrava Aerosphere (Budesonide; Formoterol Fumarate Dihydrate; Glycopyrronium Bromide)	AstraZeneca
11.11.2021	Uplizna (Inebilizumab)	Viela Bio
16.12.2021	Sitagliptin (Metformin Hydrochloride; Sitagliptin Hydrochloride Monohydrate)	Mylan
16.12.2021	Sapropterin (Sapropterin Bihydrochloride)	Dipharma
16.12.2021	Saphnelo (Anifrolumab)	AstraZeneca
16.12.2021	Apexxnar (Pneumococcal Polysaccharides)	Pfizer
16.12.2021	Ontilyv (Opicapone)	Bial Portela & Companhia
16.12.2021	Okedi (Risiperidone)	Laboratorios Farmacéuticos Rovi
16.12.2021	Tepmetko (Tepotinib Hydrochloride Monohydrate)	Merck
16.12.2021	Padcev (Enfortumab Vedotin)	Astellas Pharma
16.12.2021	Kerendia (Finerenone)	Bayer

### FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative sites during Q4 2021.

### Roszdraznador inspections

According to the Roszdraznador quarterly report, as of 10/01/2022 there were no Regulatory inspections conducted by Roszdraznador during Q4 2021.

## About The Orange Paper

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: 10/01/2022

## About Synergy Research Group

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

For all of clinical studies conducted by our company we've set up the highest level of world-class quality both for SOPs and for final study data.

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

We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – and replacing an outdated R&D strategies by novel, more efficient approaches to clinical research.

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.