Clinical Trials in Russia

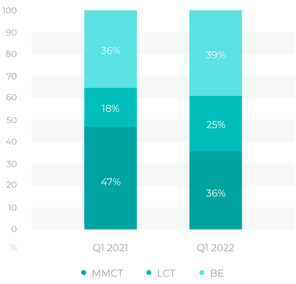
Q1 2022 Research report

Trial Data

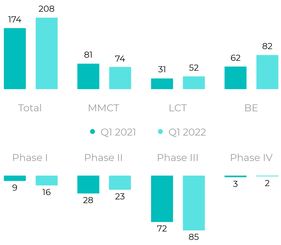
During Q1 2022 the Ministry of Health of the Russian Federation approved the start of 208 new clinical trials of all types, including local and bioequivalence studies. This represents a 20% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q1 2022 were BE (Bio-equivalent Clinical Trials). The market share of BE studies slightly increased from 36% to 39%. The market share of MMCTs (Multinational Multi-center Clinical Trials) dropped from 47% to 36% whilst the market share of Local Clinical Trials (LCTs) raised from 18% to 25%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

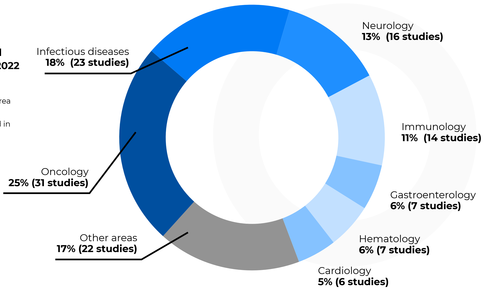


The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials increased by 18% – from 72 trials in Q1 2021 to 85 trials in Q1 2022.

The largest number of clinical trials initiated in Russia during Q1 2022 were related to Oncology (31 studies), Infectious diseases (23 studies), Neurology (16 studies) and Immunology (14 studies). Other dominant therapy areas include Gastroenterology, Hematology and Cardiology.

Breakdown of Clinical Trials in Russia in Q1 2022 by Therapeutic Area

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



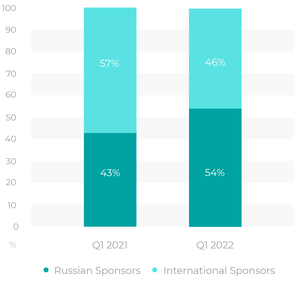
Sponsor Data

Clinical trials initiated in Russia during Q1 2022 were sponsored by pharmaceutical companies from Russia and 22 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market declined from 57% to 46% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q1 2022 was Phase III with 43% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q1 2022 were Russia (112 studies), U.S. (24 studies) and Switzerland (13 studies). Other prominent countries include Belarus (11 studies), Denmark (6 studies) and Germany (6 studies).

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



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

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

Top-10 International Trial Sponsors in Russia in Q1 2022

№	Company Name	Studies	Subjects
1	Merck	8	724
2	Hoffman-la Roche	7	1 625
3	Novartis	5	423
4	Janssen	4	230
5	AbbVie	4	147
6	GlaxoSmithKline	4	101
7	AstraZeneca	3	195
8	Novo Nordisk	3	180
9	Intra-Cellular Therapies	2	616
10	Immunic AG	2	346
	Combined market share	**33%**	**18%**

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.

Top-10 Russian Trial Sponsors in Russia in Q1 2022

№	Company Name	Studies	Subjects
1	Gamaleya Research *	4	3 181
2	Generium	4	456
3	Promomed	3	885
4	BIOCAD	3	792
5	R-Pharm	3	163
6	Radiology Research **	3	137
7	PharmaSynthez	2	540
8	Valenta Pharm	2	454
9	Vertex	2	170
10	Microgen	2	70
	Combined market share	**22%**	**27%**

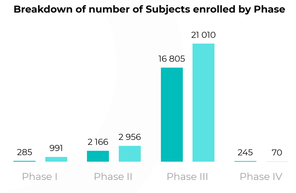
* Gamaleya Research Institute of Epidemiology and Microbiology
** National Medical Radiology Research Center

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q1 2022 reached a total of 25,027 subjects – a 28% jump in comparison with the previous year when 19,501 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 84% 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 Q1 2022

№	Site Name	City	No. Studies
1	Ecosafety	Saint Petersburg	16
2	I.M. Sechenov First Moscow State Medical University	Moscow	8
3	City Hospital №40 Kurortny District	Saint Petersburg	7
4	I.P. Pavlov Ryazan State Medical University	Ryazan	7
5	N.N. Blokhin Russian Cancer Research Center	Moscow	6
	Combined market share of these sites		**21%**

CRO Data

Top-10 CROs in Russia in Q1 2022 (Phase I - IV studies)

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

№	Site Name	No. Studies	No. Subjects
1	Syneos Health	5	223
2	IQVIA	4	239
3	PPD	4	101
4	K-Research	3	379
5	Pharmaceutical Research Associates CIS	3	296
6	OST Rus	2	2 520
7	Premier Research	2	616
8	Medical Development Agency	2	470
9	Atlant Clinical	1	630
10	Carpathian Research Group	1	460
	Combined market share	**21%**	**24%**

Top-5 CROs in Russia in Q1 2022 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	Probiotec Medical Center	7	382
2	X7 Clinical Research	3	196
3	Medical Development Agency	3	154
4	ClinPharmDevelopment	3	140
5	Accellena	3	119
	Combined market share of these companies	**23%**	**27%**

Regulatory Data

During Q1 2022 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 32 new drugs, including 6 new molecular entity (NME); other approvals concerned new dosages, combinations or manufacturers.

Five of these 32 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
13.01.2022	Ryaltrisnda (Mometasone Furoate; Olopatadine Hydrochloride)	Glenmark
14.01.2022	Cibinqonda (Abrocitinib)	Pfizer
18.03.2022	Ztalmynda (Ganaxolone)	Marinus Pharamceuticals
18.03.2022	Opdualagbla (Nivolumab; Relatlimab)	Bristol Myers Squibb
30.03.2022	Triumeq (Abacavir Sulfate; Dolutegravir Sodium; Lamivudine)	ViiV Healthcare

In Q1 2022 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 25 new drugs including 6 generics, 1 biosimilar and 3 orphan medicines.

Nine of these 25 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
27.01.2022	Vimpat (Lacosamide)	UCB Pharma
24.02.2022	Beovu (Brolucizumab)	Novartis
24.02.2022	Quviviq (Daridorexant Hydrochloride)	Idorsia Pharmaceuticals
24.02.2022	Truvelog Mix 30 (Insulin Aspart)	Sanofi
24.02.2022	Dimethyl Fumarate (Dimethyl Fumarate)	Mylan
24.03.2022	Polivy (Polatuzumab Vedotin)	Hoffmann-La Roche
24.03.2022	Keytruda (Pembrolizumab)	Merck
24.03.2022	Cabometyx (Cabozantinib (S)-Malate)	Ipsen
24.03.2022	Jakavi (Ruxolitinib (as Phosphate))	Novartis

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q1 2022.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 18/04/2022 there were no Regulatory inspections conducted by Roszdravnadzor during Q1 2022.

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: 18/04/2022

About Synergy Research Group

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 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 offer our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

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.

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.