Clinical Trials in Russia

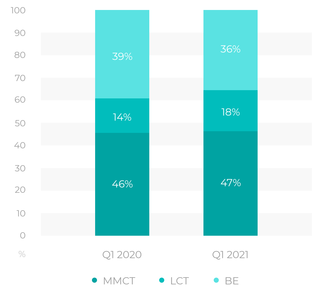
Q1 2021 Research report

Trial Data

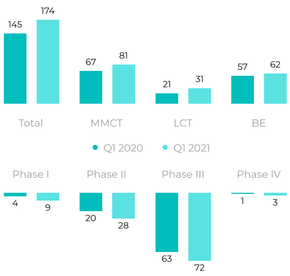
During Q1 2021 the Ministry of Health of the Russian Federation approved the start of 174 new clinical trials of all types, including local and bioequivalence studies. This represents a 20% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q1 2021 were MMCT (Multinational Multi-center Clinical Trials). The market share of MMCTs remains almost the same as in the previous year with 47% of the total number of trials. The market share of Local Clinical Trials (LCTs) increased from 14% to 18%, whilst the Bio-equivalent (BE') share slightly dipped from 39% to 36%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

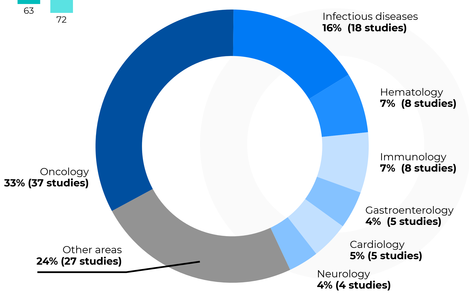


The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials increased by 14% – from 63 trials in Q1 2020 to 72 trials in Q1 2021.

The largest number of clinical trials initiated in Russia during Q1 2021 were related to Oncology (37 studies), Infectious diseases (18 studies), Hematology (8 studies) and Immunology (8 studies). Other dominant therapy areas include Gastroenterology, Cardiology and Neurology.

Breakdown of Clinical Trials in Russia in Q1 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.



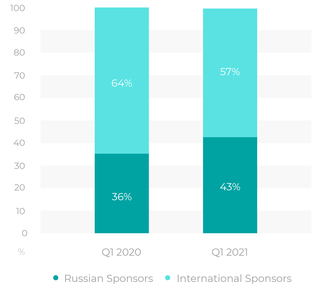
Sponsor Data

Clinical trials initiated in Russia during Q1 2021 were sponsored by pharmaceutical companies from Russia and 19 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market declined from 64% to 57% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q1 2021 was Phase III with 49% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q1 2021 were Russia (74 studies), U.S. (22 studies) and Switzerland (20 studies). Other prominent countries include Belgium (9 studies), Sweden (9 studies) and France (7 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 2021

№	Company Name	Studies	Subjects
1	Hoffman-la Roche	9	663
2	AstraZeneca	7	660
3	Janssen	5	752
4	Merck	5	535
5	Sanofi	4	310
6	Novartis	4	196
7	Argenx	4	120
8	Novo Nordisk	3	342
9	Bayer	3	159
10	GlaxoSmithKline	3	79
	Combined market share	**42%**	**20%**

Top-10 Russian Trial Sponsors in Russia in Q1 2021

№	Company Name	Studies	Subjects
1	Gamaleya Research Institute*	3	6 686
2	St. Petersburg Institute of the FMBA of Russia**	2	1 093
3	Valenta Pharm	2	430
4	Mabscale	1	600
5	BIOCAD	1	480
6	Materia Medica Holding	1	400
7	PharmaVAM	1	350
8	NovaMedica	1	348
9	RCV Therapeutics	1	304
10	Obnovlenie	1	274
	Combined market share	**13%**	**56%**

* Gamaleya Research Institute of Epidemiology and Microbiology

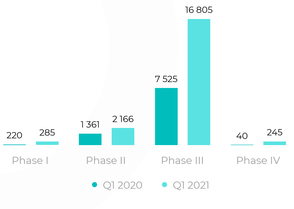
** The Saint Petersburg Scientific Research Institute of Vaccines and Serums of the FMBA of Russia

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q1 2021 reached a total of 19,501 subjects – a 113% jump in comparison with the previous year when only 9,146 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 86% 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 2021

№	Site Name	City	No. Studies
1	Clinical Hospital #2	Yaroslavl	14
2	I.P. Pavlov First Saint Petersburg State Medical University	Saint Petersburg	13
3	I.M. Sechenov First Moscow State Medical University	Moscow	12
4	N.N. Blokhin Russian Cancer Research Center	Moscow	11
5	Probiotec Medical Center	Moscow Region	9
	Combined market share of these sites		34%

CRO Data

Top-10 CROs in Russia in Q1 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.

№	Site Name	No. Studies	No. Subjects
1	IQVIA	5	649
2	Parexel	5	285
3	Medpace	4	163
4	Pharmaceutical Research Associates CIS	4	157
5	Covance	3	343
6	PSI	3	237
7	PPD	3	104
8	ClinPharmDevelopment	1	350
9	Medici Farma Group	1	348
10	Expert-Legal Center	1	314
	Combined market share	27%	15%

Top-5 CROs in Russia in Q1 2021 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	ARS PharmRussia	2	120
2	Medical Development Agency	2	76
3	Probiotec Medical Center	2	74
4	R&D Pharma	1	120
5	X7 Clinical Research	1	56
	Combined market share of these companies	13%	14%

Regulatory Data

During Q1 2021 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 26 new drugs, including 12 new molecular entity (NME); other approvals concerned new dosages, combinations or manufacturers.

Twelve of these 26 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
19.01.2021	Verquvonda (Vericiguat)	Merck
21.01.2021	Vocabrianda (Cabotegravir Sodium)	ViiV Healthcare
21.01.2021	Cabenuva (Cabotegravir; Rilpivirine)	ViiV Healthcare
22.01.2021	Lupkynisnda (Voclosporin)	Aurinia
03.02.2021	Tepmetkonda (Tepotinib Hydrochloride)	Merck Serono
11.02.2021	Evkeezabla (Evinacumab)	Regeneron Pharmaceuticals
25.02.2021	Amondys (Casimersen)	Sarepta Therapeutics
10.03.2021	Fotivdanda (Tivozanib Hydrochloride)	Aveo Pharms
12.03.2021	Kimyrsanda (Oritavancin Diphosphate)	Melinta Therapeutics
18.03.2021	Ponvorynda (Ponesimod)	Janssen
23.03.2021	Roszetnda (Rosuvastatin Calcium; Ezetimibe)	Althera Life Sciences
25.03.2021	Myrbetriqnda (Mirabegron)	Astellas Pharma

In Q1 2021 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 37 new drugs including 2 generics, 4 biosimilar and 7 orphan medicines.

Twenty-one of these drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
28.01.2021	Seffalair Spiromax (Salmeterol Xinafoate; Fluticasone Propionate)	Teva
28.01.2021	Sirturo (Bedaquiline Fumarate)	Janssen
28.01.2021	Vazkepa (Icosapent Ethyl)	Amarin Pharmaceuticals
28.01.2021	Kesimpta (Ofatumumab)	Novartis
28.01.2021	Sogroya (Somapacitan)	Novo Nordisk
28.01.2021	Nexpovio (Selinexor)	Karyopharm
28.01.2021	Alymsys (Bevacizumab)	Mabxience
28.01.2021	BroPair Spiromax (Salmeterol Xinafoate; Fluticasone Propionate)	Teva
28.01.2021	Tysabri (Natalizumab)	Biogen
25.02.2021	Abevmy (Bevacizumab)	Mylan
25.02.2021	Evrysdi (Risdiplam)	Hoffmann-La Roche
25.02.2021	Lextemy (Bevacizumab)	Mylan
25.02.2021	Sarclisa (Isatuximab)	Sanofi
25.02.2021	Opdivo (Nivolumab)	Bristol-Myers Squibb
25.03.2021	Xtandi (Enzalutamide)	Astellas Pharma
25.03.2021	Tecentriq (Atezolizumab)	Hoffmann-La Roche
25.03.2021	Copiktra (Duvelisib)	Verastem
25.03.2021	Ponvory (Ponesimod)	Janssen
25.03.2021	Lydisilka (Estetrol Monohydrate; Drospirenone)	Estetra
25.03.2021	Saxenda (Liraglutide)	Novo Nordisk
25.03.2021	Benlysta (Belimumab)	GlaxoSmithKline

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q1 2021.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 01/04/2021 there were no Regulatory inspections conducted by Roszdravnadzor during Q1 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: 01/04/2021

About Synergy Research Group

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

Synergy consistently ranks in the top-10 market leaders by number 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.

We set up the highest level of world-class quality both for SOPs and for final study data in every clinical trial we conduct.

We are continuously improving our SOPs, study risk management and IT infrastructure – and replacing outdated R&D strategies by novel, more efficient approaches to clinical research.