Clinical Trials in Russia

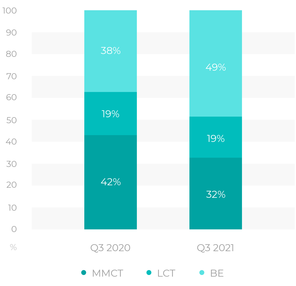
Q3 2021 Research report

Trial Data

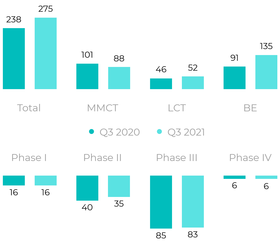
During Q3 2021 the Ministry of Health of the Russian Federation approved the start of 275 new clinical trials of all types, including local and bioequivalence studies. This represents a 16% year on year increase by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q3 2021 were BE (Bio-equivalent Clinical Trials). The market share of MMCTs (Multinational Multi-center Clinical Trials) dropped from 42% to 32% of the total number of trials. The market share of Local Clinical Trials (LCTs) remains the same with 19% whilst the Bio-equivalent (BE') share raised from 38% to 49%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

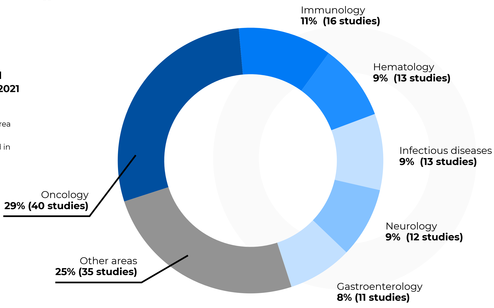


The most prevalent Phase of clinical trials conducted in Russian sites by total number of studies was Phase III. The total number of Phase III trials slightly dipped by 2%, from 85 trials in Q3 2020 to 83 trials in Q3 2021.

The largest number of clinical trials were related to Oncology (40 studies), Immunology (16 studies), Hematology (13 studies) and Infectious diseases (13 studies). Other dominant therapy areas include Neurology, Gastroenterology, Dermatology and Rheumatology.

Breakdown of Clinical Trials in Russia in Q3 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.



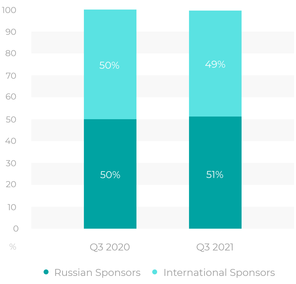
Sponsor Data

Clinical trials initiated in Russia during Q3 2021 were sponsored by pharmaceutical companies from Russia and 21 foreign country. The combined share of international pharmaceutical companies involved in the Russian Clinical trials market remains stable with 49% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2021 was Phase III with 47% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q3 2021 were Russia (140 studies), U.S. (43 studies) and India (16 studies). Other prominent countries include Sweden (14 studies) and Belarus (12 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 Q3 2021

№	Company Name	Studies	Subjects
1	AstraZeneca	14	1 258
2	Merck	10	600
3	Bristol Myers Squibb	5	707
4	Janssen	3	612
5	Allergan	3	413
6	Pfizer	3	202
7	Pharmland	3	36
8	Novo Nordisk	2	1 120
9	Rompharm	2	324
10	Hoffman-la Roche	2	80
	Combined market share	**34%**	**24%**

Top-10 Russian Trial Sponsors in Russia in Q3 2021

№	Company Name	Studies	Subjects
1	BIOCAD	3	723
2	Materia Medica Holding	2	4 280
3	Gamaleya Research *	2	1 000
4	St. Petersburg Institute of Vaccines and Serums **	2	840
5	NovaMedica	2	498
6	Peptek	2	488
7	Binergia	2	316
8	Generium	2	224
9	Pharmzashchita ***	2	216
10	Siberian Research Center for Pharmacology	1	850
	Combined market share	**14%**	**42%**

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.

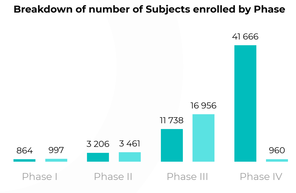
* Gamaleya Research Institute of Epidemiology and Microbiology
** Saint Petersburg Scientific Research Institute of Vaccines and Serums of the Federal Medical and Biological Agency
*** Pharmzashchita Research and Production Center of the Federal Medical and Biological Agency

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q3 2021 dropped by 61% – from 57,474 subjects in Q3 2020 to 22,374 subjects in Q3 2021. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 76% 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 Q3 2021

№	Site Name	City	No. Studies
1	Clinical Hospital "Russian Railways - Medicine"	Yaroslavl	22
2	I.M. Sechenov First Moscow State Medical University	Moscow	20
3	Clinical Hospital №2	Yaroslavl	18
4	Clinical Hospital №3	Yaroslavl	15
5	I.P. Pavlov First Saint Petersburg State Medical University	Saint-Petersburg	15
	Combined market share of these sites		**33%**

CRO Data

Top-10 CROs in Russia in Q3 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	Parexel	7	685
2	Pharmaceutical Research Associates CIS	7	427
3	IQVIA	7	303
4	Syneos Health	6	451
5	ICON	4	249
6	PPD	3	48
7	MedPace	3	40
8	Medici Pharma Group	2	498
9	PSI	2	369
10	Covance	2	90
	Combined market share	**31%**	**14%**

Top-5 CROs in Russia in Q3 2021 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	ClinPharmDevelopment	5	290
2	Medical Development Agency	3	134
3	ARS PharmRussia	2	72
4	Probiotech	2	64
5	OCT Clinical Trials	1	70
	Combined market share of these companies	**10%**	**9%**

Regulatory Data

During Q3 2021 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 27 new drugs, including 9 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Eight of these 27 drugs (and two of 9 NMEs) were (or are being) studied in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
09.07.2021	Kerendianda (Finerenone)	Bayer
29.07.2021	Uptravinda (Selexipag)	Actelion
30.07.2021	Saphnelobla (Anifrolumab)	AstraZeneca
13.08.2021	Weliregnda (Belzutifan)	Merck
25.08.2021	Skytrofabla (Lonapegsomatropin)	Ascendis Pharma
17.09.2021	Byoovizbla (Ranibizumab)	Samsung Bioepis
20.09.2021	Tivdakbla (Tisotumab Vedotin)	Seagen
21.09.2021	Opzeluranda (Ruxolitinib Phosphate)	Incyte

In Q3 2021 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 24 new drugs, including 2 generics, 2 biosimilar and 3 orphan medicines.

Fourteen of these 24 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
22.07.2021	Deltyba (Delamanid)	Otsuka
22.07.2021	Vosevi (Sofosbuvir, Velpatasvir, Voxilaprevi)	Gilead Sciences
22.07.2021	Ultomiris (Ravulizumab)	Alexion
16.09.2021	Steglatro (Ertugliflozin L-Pyroglutamic Acid)	Merck
16.09.2021	Opdivo (Nivolumab)	Bristol-Myers Squibb
16.09.2021	Segluromet (Ertugliflozin L-Pyroglutamic Acid, Metformin Hydrochloride)	Merck
16.09.2021	Jyseleca (Filgotinib Maleate)	Gilead Sciences
16.09.2021	Brukinsa (Zanubrutinib)	BeiGene
16.09.2021	Keytruda (Pembrolizumab)	Merck
16.09.2021	Noxafil (Posaconazole)	Merck
16.09.2021	Adempas (Riociguat)	Bayer
16.09.2021	Firmagon (Degarelix)	Ferring Pharmaceuticals
16.09.2021	Nucala (Mepolizumab)	GlaxoSmithKline
17.09.2021	Paliperidone (Paliperidone Palmitate)	Janssen

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative sites during Q3 2021.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 08/10/2021 there were no Regulatory inspections conducted by Roszdravnadzor during Q3 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: 08/10/2021

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.