Clinical Trials in Russia

Y 2020 Research report

Trial Data

During the Year 2020 the Ministry of Health of the Russian Federation approved the start of 734 new clinical trials of all types, including local and bioequivalence studies. This represents a 2% year on year decrease by the total number of studies.

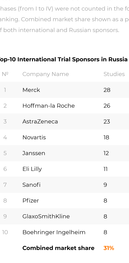
The dominant type of clinical trials conducted across Russian sites in the Year 2020 were MMCT. The market share of MMCTs slightly increased from 43% to 45% of the total number of trials. The market share of LCTs dipped from 25% to 22% whilst the BE share rose from 32% to 34%.

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 declined by 6% – from 327 trials in the Year 2019 to 306 trials in the Year 2020.

The largest number of clinical trials initiated in Russia during 2020 were related to Oncology (128 studies), Infectious diseases (79 studies) and Neurology (59 studies). Other dominant therapy areas include Hematology, Immunology, Gastroenterology and Cardiology.



Breakdown of Clinical Trials by Therapeutic Area

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

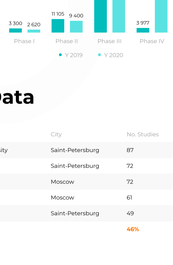
Sponsor Data

Clinical trials initiated in Russia during the Year 2020 were sponsored by pharmaceutical companies from Russia and 30 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market dropped from 58% to 54% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Year 2020 was Phase III with 67% share among Phase I – IV studies.

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.

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



Top-10 International Trial Sponsors in Russia in Y 2020

№	Company Name	Studies	Subjects
1	Merck	28	2 080
2	Hoffman-la Roche	26	2 027
3	AstraZeneca	23	2 579
4	Novartis	18	2 551
5	Janssen	12	935
6	Eli Lilly	11	1 564
7	Sanofi	9	582
8	Pfizer	8	824
9	GlaxoSmithKline	8	811
10	Boehringer Ingelheim	8	262
	Combined market share	**31%**	**12%**

Top-10 Russian Trial Sponsors in Russia in Y 2020

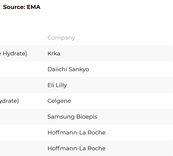
№	Company Name	Studies	Subjects
1	PharmStandard	7	1 830
2	PharmaSyntez	6	2 366
3	PROMOMED	6	990
4	BIOCAD	6	973
5	R-Pharm	6	920
6	GeroPharm	6	894
7	Gamaleya Research Institute	5	40 281
8	VECTOR State Research Center	5	5 659
9	Microgen	5	1 285
10	Sotex	5	748
	Combined market share	**12%**	**4.8%**

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during the Year 2020 reached a total of 115,675 subjects – a 75% jump in comparison with the previous year when only 66,024 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 48% 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



Research Site Data

Top-5 Russian Research Sites (all studies) in Y 2020

№	Site Name	City	No. Studies
1	I.P. Pavlov First Saint Petersburg State Medical University	Saint-Petersburg	87
2	Ecosafety	Saint-Petersburg	72
3	I.M. Sechenov First Moscow State Medical University	Moscow	72
4	N.N. Blokhin Russian Cancer Research Center	Moscow	61
5	V.A. Almazov National Medical Research Centre	Saint-Petersburg	49
	Combined market share of these sites		**46%**

CRO Data

Top-10 CROs in Russia in Y 2020 (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	33	2 781
2	Parexel	19	842
3	iPharma	14	2 885
4	PPD	14	1 113
5	Syneos Health	12	790
6	PSI	8	756
7	MedPace	6	474
8	Covance	6	400
9	Pharmaceutical Research Associates CIS	5	223
10	OST Rus	4	849
	Combined market share	**25%**	**10%**

Top-5 CROs in Russia in Y 2020 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	ClinPharmInvest	9	475
2	Probiotech	8	332
3	ClinPharmDevelopment	6	431
4	OST Rus	6	370
5	Biomapas	4	162
	Combined market share of these companies	**13%**	**15%**

Regulatory Data

During the Q4 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 26 new drugs; 10 of them were new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Two of these 26 drugs and two of these 10 NMEs were (or are being) studied in clinical trials involving Russian sites.

Source: FDA

Appr. Date	Drug (Active Ingredient)	Company
23/12/2020	Gemtesavnda (Vibegron)	Urovant Sciences
20/11/2020	Zokinvynda (Lonafarnib)	Eiger Biopharms

In Q4 2020 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 24 new drugs, including 3 generics, 3 biosimilar and 4 orphan medicines.

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

Source: EMA

Appr. Date	Drug (Active Ingredient)	Company
10/12/2020	Lenalidomide (Lenalidomide Hydrochloride Hydrate)	Krka
10/12/2020	Enhertu (Trastuzumab Deruxtecan)	Daiichi Sankyo
10/12/2020	Retsevmo (Selpercatinib)	Eli Lilly
10/12/2020	Innebic (Fedratinib Dihydrochloride Monohydrate)	Celgene
12/11/2020	Onbevzi (Bevacizumab)	Samsung Bioepis
12/11/2020	Xofluza (Baloxavir Marboxil)	Hoffmann-La Roche
12/11/2020	Phesgo (Pertuzumab, Trastuzumab)	Hoffmann-La Roche
15/10/2020	Vocabria (Cabotegavir Sodium, Cabotegravir)	ViiV Healthcare
15/10/2020	Trixeo Aerosphere (Budesonide, Glycopyrronium, Formoterol Fumarate Dihydrate)	AstraZeneca

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during the Year 2020.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 04/01/2021 there were no Regulatory inspections conducted by Roszdravnadzor during the Year 2020.

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: 04/01/2021

About Synergy Research Group

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

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

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 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.