Clinical Trials in Russia

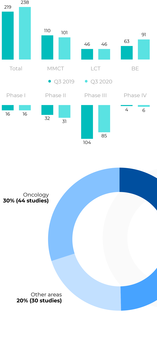
Q3 2020 Research report

Trial Data

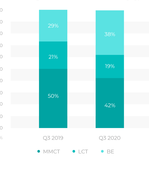
During Q3 2020 the MoH of the Russian Federation approved the start of 238 new clinical trials of all types, including local and bioequivalence studies. This represents a 9% year on year growth by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q3 2020 were MMCT. The market share of MMCTs decreased from 50% to 42% of the total number of trials. The market share of LCTs remained almost the same with 19% whilst the BE share rose from 29% to 38%.

Breakdown of Clinical Trials by Type and Phase

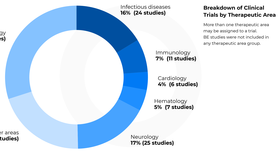


Percentage Breakdown of Clinical Trials by Type



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 collapsed by 18% – from 104 trials in Q3 2019 to 85 trials in Q3 2020.

The largest number of clinical trials initiated in Russia during Q3 2020 were related to Oncology (44 studies), Neurology (25 studies) and Infectious diseases (24 studies). Other dominant therapy areas include Immunology, Hematology 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.

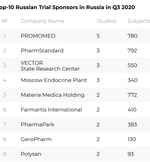
Sponsor Data

Clinical trials initiated in Russia during Q3 2020 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 dropped from 64% to 50% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in the Q3 2020 was Phase III with 51% share among Phase II – 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 Q3 2020

№	Company Name	Studies	Subjects
1	Hoffman-la Roche	13	844
2	AstraZeneca	8	914
3	Merck	7	376
4	GlaxoSmithKline	6	650
5	Janssen	5	450
6	Bayer	4	570
7	Genzyme	4	568
8	Eli Lilly	4	210
9	Boehringer Ingelheim	4	175
10	Novo Nordisk	2	230
	Combined share	**39%**	**9%**

Top-10 Russian Trial Sponsors in Russia in Q3 2020

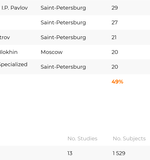
№	Company Name	Studies	Subjects
1	PROMOMED	5	780
2	PharmStandard	3	792
3	VECTOR State Research Center	3	550
4	Moscow Endocrine Plant	3	340
5	Materia Medica Holding	2	772
6	Farmartis International	2	410
7	PharmaPark	2	383
8	GeroPharm	2	130
9	Polysan	2	93
10	Gamaleya Research Institute	1	40 000
	Combined share	**17%**	**77%**

Subject Data

The overall number of subjects enrolled in clinical trials initiated in Russia during Q3 2020 reached a total of 57,474 subjects – a 19% jump in comparison with Q3 2019, when only 19,704 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase IV with 72% 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 Q3 2020

№	Site Name	City	No. Studies
1	First St. Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	29
2	Ecosafety	Saint-Petersburg	27
3	National Oncology Research Center named after N.N. Petrov	Saint-Petersburg	21
4	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	20
5	St. Petersburg Clinical Research and Practical Center of Specialized Types of Medical Care (Oncological)	Saint-Petersburg	20
	Combined market share of these sites		**4.9%**

CRO Data

Top-10 CROs in Russia in Q3 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	13	1 529
2	Parexel	7	330
3	iPharma	4	735
4	Covance	3	264
5	PSI	2	290
6	Medpace	2	218
7	PPD	2	150
8	Pharmaceutical Research Associates	2	108
9	Smooth Drug Development	1	420
10	OST Rus	1	212
	Combined market share	**25%**	**7%**

Top-5 CROs in Russia in Q3 2020 (BE studies)

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

№	Site Name	No. Studies	No. Subjects
1	ClinPharmInvest	4	190
2	OST Rus	3	152
3	ClinPharmDevelopment	2	90
4	ChorichPharm	2	66
5	Accellena	2	48
	Combined market share of these companies	**14%**	**14%**

Regulatory Data

During Q3 2020 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 36 new drugs; 10 of them were new molecular entities (NME), other approvals concerned new dosages, combinations or manufacturers.

Appr.Date	Drug (Active Ingredient)	Company
02/07/2020	Rukobiandа (Fostemsavir Tromethamine)	ViV Healthcare
06/07/2020	Huliodiа (Adalimumab-FKJP)	Mylan
23/07/2020	Brextri Aerosphereнда (Budesonide; Formoterol Fumarate; Glycopyrrolate)	AstraZeneca
04/08/2020	Xtandinda (Enzalutamide)	Astellas Pharma
05/08/2020	Blenreqbia (Belantamab Mafodotin-BLMF)	GlaxoSmithKline
12/08/2020	Vitepsondа (Vitolarsen)	Nippon Shinyaku
28/08/2020	Sogroyabia (Somapacitan-BECO)	Novo Nordisk
01/09/2020	Onureqnndа (Azacitidine)	Celgene
25/09/2020	Xelianzndа (Tofacitinib)	Pfizer

Nine of these 36 drugs and two of these 10 NMEs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

in Q3 2020 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 34 new drugs, including 3 generics, 1 biosimilar and 10 orphan medicines.

Appr.Date	Drug (Active Ingredient)	Company
23/07/2020	Equidacent (Bevacizumab)	Centus Biotherapeutics
23/07/2020	Crysvita (Burosumab)	Kyowa Kirin
23/07/2020	Calquence (Acalabrutinib)	AstraZeneca
17/09/2020	Yervoy (Ipilimumab)	Bristol-Myers Squibb
17/09/2020	MenQuadfi (Meningococcal Group A, C, W135 and Y Conjugate Vaccine)	Sanofi
17/09/2020	Lynparza (Olaparib)	AstraZeneca
17/09/2020	Olumiant (Baricitinib)	Eli Lilly
17/09/2020	Tecentriq (Atezolizumab)	Hoffmann-La Roche
17/09/2020	Deltyba (Delamanid)	Otsuka
17/09/2020	Zavicefta (Ceftazidime, Avibactam)	Pfizer
17/09/2020	Zejula (Niraparib)	GlaxoSmithKline
17/09/2020	Velphoro (Polynuclear Iron(III)-Oxyhydroxide, Sucrose and Starches)	Vifor Pharma
17/09/2020	Opdivo (Nivolumab)	Bristol-Myers Squibb

Thirteen of these 34 drugs were (or are being) studied in clinical trials involved Russian sites.

Source: EMA

FDA inspections

According to the U.S. FDA data, there was no FDA inspections conducted in a Russian investigative site during Q3 2020.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 01/10/2020 there were no Regulatory inspections conducted by Roszdravnadzor during Q3 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: 01/10/2020

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.