Industry Pages

by OCT Clinical

2020

Annual Report on Clinical Trials
in Russia and Eastern Europe

OCT CLINICAL

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About Industry Pages

Industry Pages is released annually by OCT Clinical and gives thorough, accurate and useful information on the clinical trials environment in Russia and Eastern Europe, and how these clinical trials have performed in each respective year. The report is issued for industry experts, who are looking for new options to conduct clinical trials, and examining the ecosystem of Eastern Europe.

Russia remains one of the top destinations for clinical trials globally. High recruitment rates, modern infrastructure, competitive quotes and a solid regulatory framework make Russia a great option for companies seeking to optimize their clinical trials without compromising quality, and to avoid issues common to other regions. **Despite the pandemic-driven uncertainty in 2020, the overall clinical trial landscape in Russia has remained stable.**

The Industry Pages report will enable readers to understand and gain insights into the clinical research market in Russia and Eastern Europe, along with its landscape, key players and emerging trends. All of the data in this document is valid as of January 30, 2021.

Glossary

CIS	–	Commonwealth of Independent States
CRO	–	Contract Research Organization
EAEU	–	Eurasian Economic Union
FDA	–	Food and Drug Administration
GCP	–	Good Clinical Practice
ICH	–	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IMPD	–	Investigational Medicinal Product Dossier
LEC	–	Local Ethics Committee
LCT	–	Local Clinical Trials
MAA	–	Marketing Authorisation Application
MMCT	–	Multinational Multicenter Clinical Trials
WHO	–	World Health Organization

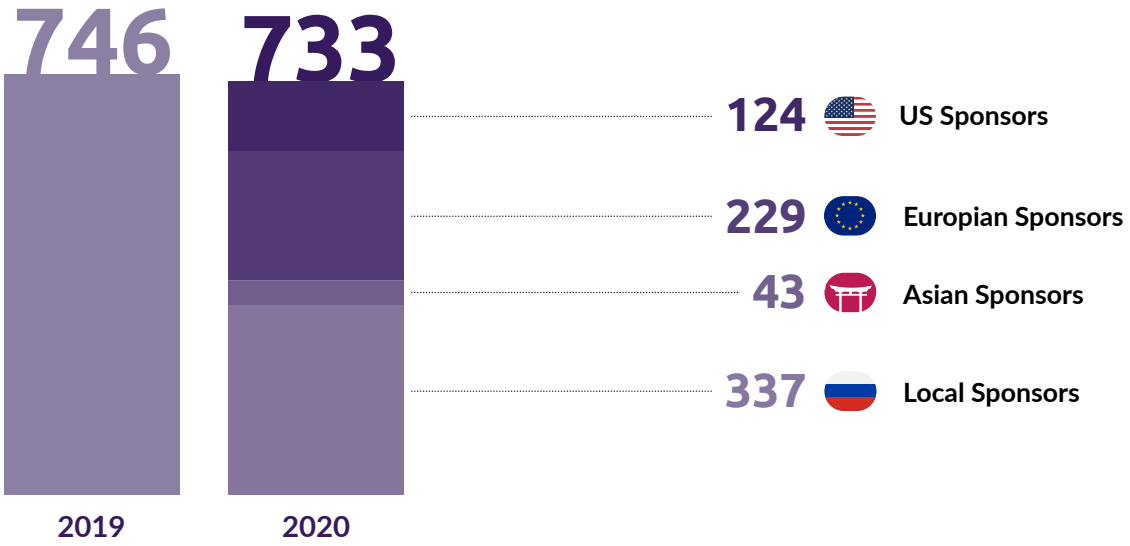
I. Clinical Trials Landscape: Market Size and Trends in 2020

In 2020 the Russian Ministry of Health issued 733 approvals for clinical trials, of which 396 studies were launched by foreign sponsors, with US companies leading the way with a total of 124 trials. European sponsors launched 229 trials in Russia last year, 55 of which were sponsored by Swiss companies, 28 by Swedish companies, 23 by Belgian companies, and 19 by Germany-based sponsors.

If we compare this with the 746 clinical trials initiated in 2019, it is evident that the overall picture remained relatively stable. Despite rather pessimistic forecasts in the aftermath of the pandemic outbreak, combined with lockdowns, there was no significant drop in the number of studies initiated in Russia.

The most active regions in terms of patient enrollment are still the cities of Moscow and St. Petersburg. The leading Russian research site in 2020 became the Pavlov First State Medical University of St. Petersburg.[1] According to data from the Russian Ministry of Health, 4,519 research sites were due to be involved in the clinical trials that were initiated in 2020 in Russia.

Number of clinical trials in Russia by Sponsor's Region of Origin, 2020 [1]

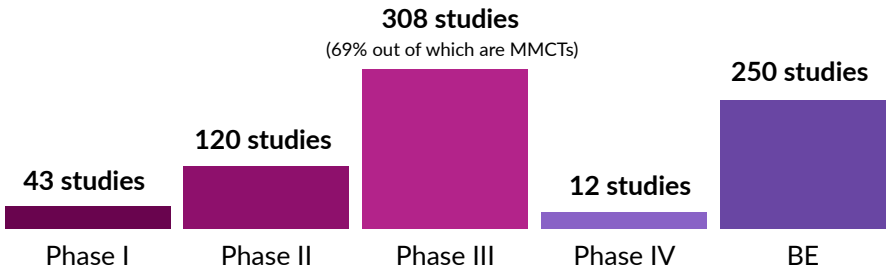


Multinational Multicenter Clinical Trials (MMCTs) accounted for the highest number of clinical trials conducted across Russian sites. In terms of total number of approved trials, the market share of MMCTs increased by 4% in comparison with the previous year, rising from 312 in 2019 to 326 in 2020. In addition, there was a jump in the number of bioequivalence studies of Russian-made generics (from 163 in 2019 to 192 in 2020). Finally, the number of local clinical trials of drugs developed by Russian sponsors (LCTs) decreased by 13.5% from 155 to 134, while LCTs of drugs developed by foreign sponsors also dropped by 34% from 35 to 23.

It is impossible to ignore the role of the COVID-19 pandemic in the clinical trial landscape in the past year. Following the outbreak, the Russian Ministry of Health issued 59 approvals for COVID-19 clinical trials in 2020, with 52 projects in COVID-19 treatment and 7 vaccine candidate studies. These account for 8% of all trials initiated in 2020.

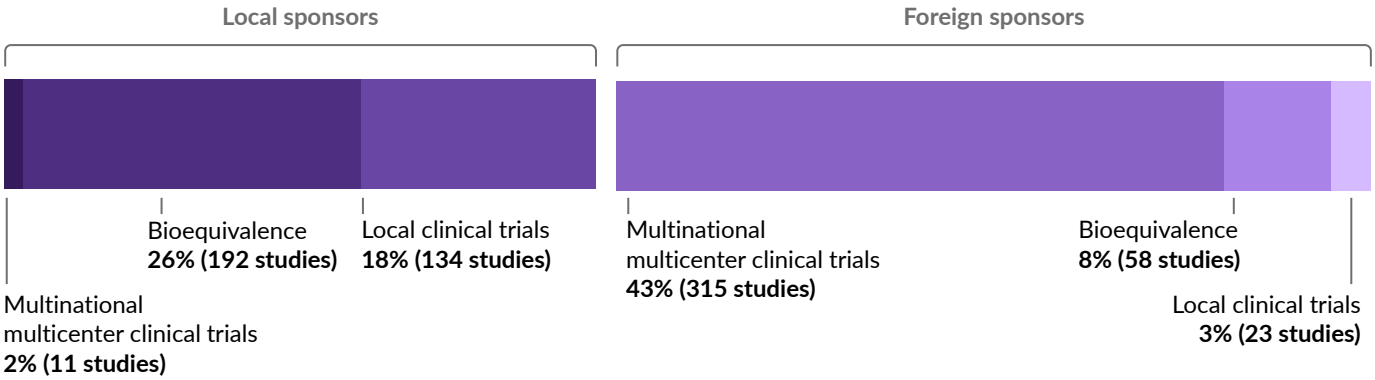
1 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/

Breakdown of Clinical Trials by Phase, 2020 [2]

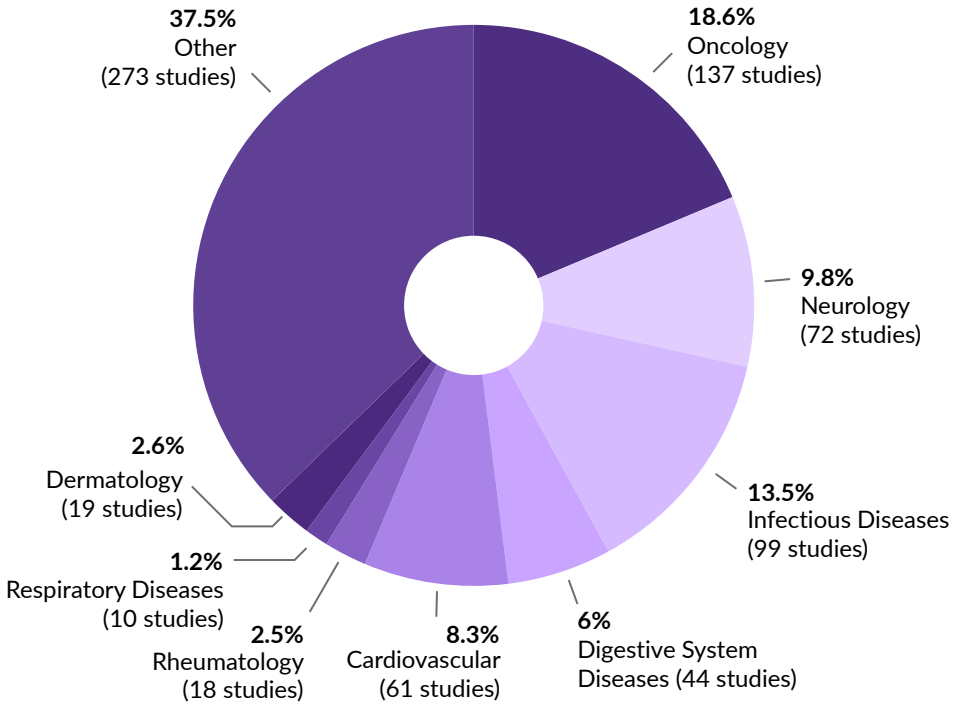


42% of the total number of studies initiated in 2020 were attributed to Phase III clinical trials.

Breakdown of Clinical Trials by Type, 2020 [2]



Breakdown of Clinical Trials by Therapeutic Area, 2020 [2]

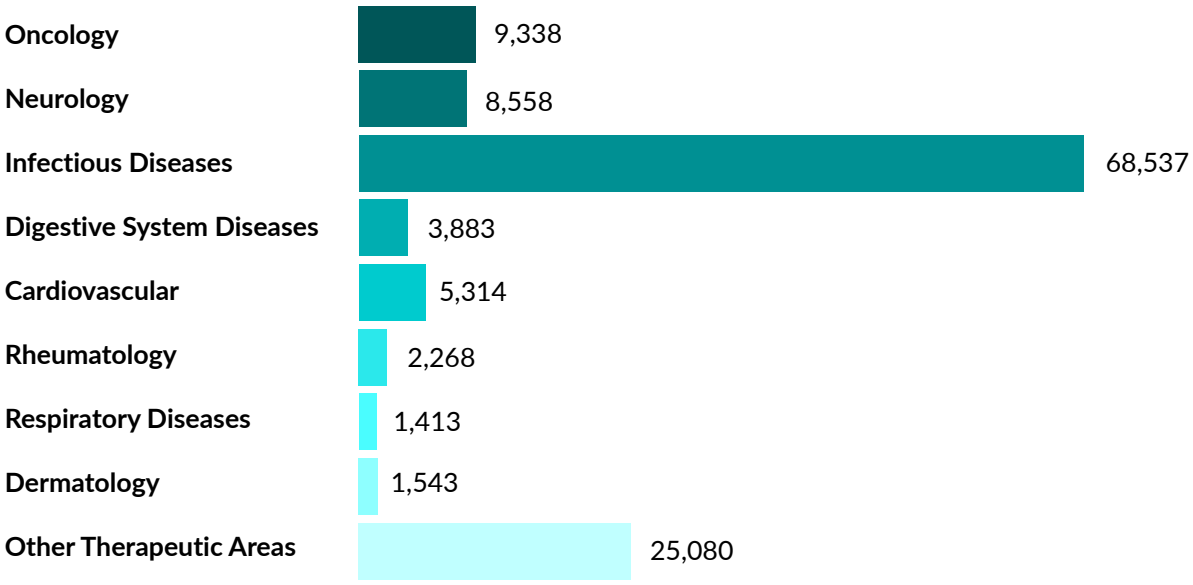


The prevailing therapeutic area among CTs launched in 2020 was oncology with 137 studies and a market share of 18.6% of the total number of CTA approvals. This was followed by 99 (13.5%) studies in infectious diseases, 72 (9.8%) approvals for neurology projects, 61 (8.3%) in cardiovascular diseases, 44 (6%) in digestive system diseases and 19 (2.6%) studies in dermatology.

2 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/

According to the Russian Ministry of Health Registry of Approved Clinical Trials[3], a record 68,537 patients and healthy volunteers were scheduled to be recruited for clinical studies in infectious diseases initiated in 2020.

Enrollment target for studies initiated in 2020 [3]



Top Sponsors in 2020

In 2020, more than 50% of approvals for clinical trials from the Ministry of Health were received by foreign sponsors (396 approvals). The list of foreign companies with the highest number of trials launched in 2020 is topped by Merck (USA), Roche (Switzerland), AstraZeneca (UK/Sweden) and Novartis (Switzerland).

Top-10 foreign pharmaceutical companies in Russia by number of studies approved by the MoH in 2020 [3]

#	Company Name	# of trials launched in 2020 in Russia
1	Merck (USA)	28
2	Roche (Switzerland)	26
3	AstraZeneca (UK/Sweden)	22
4	Novartis (Switzerland)	18
5	Janssen (Belgium)	12
6	Eli Lilly and Company (US)	11
7	Sanofi (France)	9
8	GlaxoSmithKline (UK)	8
9	Pfizer (USA)	8
10	Boehringer Ingelheim (Germany)	8

3 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/

The list of local companies with the highest number of trials launched in Russia in 2020 is topped by OZON Pharmaceutical, Promomed and Canonpharma Production.

Top-10 local pharmaceutical companies in Russia by number of studies approved by the MoH in 2020 [4]

#	Company Name	# of trials launched in 2020 in Russia
1	OZON Pharmaceutical	22
2	Promomed	19
3	Canonpharma production	16
4	Pharmasyntez	15
5	Renewal	11
6	RUS BioPharm	11
7	Severnaya Zvezda	10
8	Advanced Pharma	9
9	Pharmstandard	8
10	BIOCAD	6

Top CROs in 2020

It should be noted that 2020 was a record year for CRO activities - 38% of permitted research was carried out by contract research organizations (compared to 35% in 2019, 30% in 2018, 31% in 2017, 25% in 2016 and 29% in 2015) [5]

Top-10 global CROs in Russia by number of studies approved by the MoH in 2020 [4]

#	CRO Name	Total #
1	IQVIA	32
2	Parexel	19
3	PPD	14
4	Syneos Health	12
5	PSI	8
6	Biomapas	7
7	Covance	6
8	Medpace	6
9	Pharmaceutical Research Associates CIS	5
10	ICON	4

4 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/
5 - Association of Clinical Trials Organizations. http://acto-russia.org/files/bulletin_20.pdf

Top-10 local CROs in Russia by number of studies approved by the MoH in 2020 [6]

#	CRO Name	Total #
1	iPharma	14
2	OCT Clinical	10
3	ClinPharmInvest	9
4	Probiotech	8
5	ClinPharmDevelopment	6
6	RCT Global	4
7	Excellena Research and Development	4
8	Synergy Research	3
9	Ergomed Clinical research	3
10	East Site Management & Research	3

II. Russia: Destination of Choice for Global Pharmaceutical Companies

Russia, which joined the World Health Organization (WHO) international drug control program in 1998, has been actively involved in international clinical trials for about 20 years. Despite being a relative newcomer, the region demonstrated a lot of potential and increased significance over the past decade for sponsors looking for new clinical trial options.

Statistics from the State Registry of registered drugs in Russia demonstrate that U.S. sponsors lead the way among non-Russian companies (about ⅕ of the total number in 2020). Moreover, according to the Russian Ministry of Health's Registry of Approved Clinical Trials, every year about 10% of clinical research projects are initiated by Asian companies.

The overall attractiveness of the country in terms of clinical trials to international sponsors is shown in global statistics too, given the fact that it is one of the leading countries in terms of population size and diversity. Russia is the world's ninth-largest country by population with more than 146 million people, which provides access to a large potential pool of mostly treatment-naive clinical trial subjects. This leads to the advantage of fast patient recruitment. Among other advantages of the region is that there is a wide network of high-quality investigational sites with experienced physicians, the fact that ICH-GCP principles are incorporated into local legislation, and the attraction of a lower average cost per patient.

6 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/

Map of Trial Participants

According to the 2015-2019 FDA Report [7] and its Global Map of Trial Participants with a total of 292,766 clinical trial participants, Russia entered the top 10 and ranked second after the U.S. in terms of the number of subjects recruited for studies. According to the Russian Ministry of Health Registry of Approved Clinical Trials [8], the recruitment target of clinical trials initiated in 2020 in Russia is 125,934 patients and healthy volunteers.

Trial Participants by Country, 2015-2019 [7]

Percentage of Participants

35% United States

4% **Russian Federation**, Poland, Germany

3% Japan, Canada, Czech Republic

2% Ukraine, France, India, United Kingdom, Spain, Brazil, Argentina, Romania, Bulgaria

1% Republic of Korea, China, South Africa, Colombia, Australia, Mexico, Denmark, Belgium, Georgia, Israel, Netherlands, Taiwan, Austria, Slovakia, Sweden, Chile, Peru, Thailand

The countries that enrolled at least 1% of the total number of trial participants are represented on the graph. These countries account for 96% of all trial participants. The remaining 4% of participants were distributed across 59 countries. A total of 292,766 clinical trial participants were included in this analysis based on data collected between 2015 and 2019.

Enrollment Rate

It is well known that Russia is one of the world leaders in patient enrolment. Recruitment rates in the region in various indications can be significantly higher than in other countries.

Enrollment Rate Based on MMCTs conducted by a CRO [9]

Ph3 Ovarian Cancer

Ukraine	1 pt/site/month
Latvia	0.7 pt/site/month
Sweden	0.5 pt/site/month

Ph3 Erectile Dysfunction

Russia	3.9 pt/site/month
Hungary	2.1 pt/site/month
Slovakia	2 pt/site/month

Ph3 Breast Cancer

Russia	1.4 pt/site/month
USA	0.5 pt/site/month

Ph3 Ulcerative Proctitis

Russia	0.8 pt/site/month
Germany	0.4 pt/site/month

7 - FDA. https://www.fda.gov/media/143592/download
8 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/
9 - Based on MMCTs where OCT Clinical acted as a local CRO in Russia and CIS countries

Incidence in Russia

The following data has been collected according to a 2020 report by the Ministry of Health of Russia. The most prevalent therapeutic area in terms of the largest number of new cases was oncology with 640,391 new cases. The total number of oncology patients under observation was 3,928,338.[10]

New Cases in 2020 [10]

Oncology	
Breast Cancer	137,824
Lung Cancer	60,178
Prostate Cancer	45,473
Stomach Cancer	36,107
Intestine Cancer	31,850
Cervix Cancer	32,584
Other Indications	296,375
Total:	**640,391**

Digestive System Diseases	
Stomach and Duodenum Ulcer	101,680
Gastritis and Duodenitis	766,039
Non-infectious Enteritis and Colitis	143,844
Gallbladder, Biliary Tract Diseases	456,350
Pancreas Disease	221,692
Liver Disease	85,936
Other Indications	2,917,930
Total:	**4,693,471**

Neurology and Psychiatric Disorders	
Nervous System Disease	2,171,907
Inflammatory CNS Disease	20,702
Epilepsy	39,535
Multiple Sclerosis	6,496

Cardiology	
Chronic Rheumatic Heart Disease	7,674
Essential Hypertension	323,173
Other Heart Diseases	306,082
Cardiomyopathy	32,161
Cerebrovascular Diseases	1,161,960
Hypertensive Heart Disease	1,359,999
Acute Myocarditis	2,608

Infectious Diseases	
HIV	80,124
Tuberculosis	60,531

Respiratory	
Pneumonia	769,691
Allergic Rhinitis (Pollinosis)	92,495
Other Indications	51,415,461
Total:	**52,277,647**

Rheumatology	
Musculoskeletal System and Connective Tissue Disease	4,450,543
Rheumatoid Arthritis (Seropositive and Seronegative)	33,810

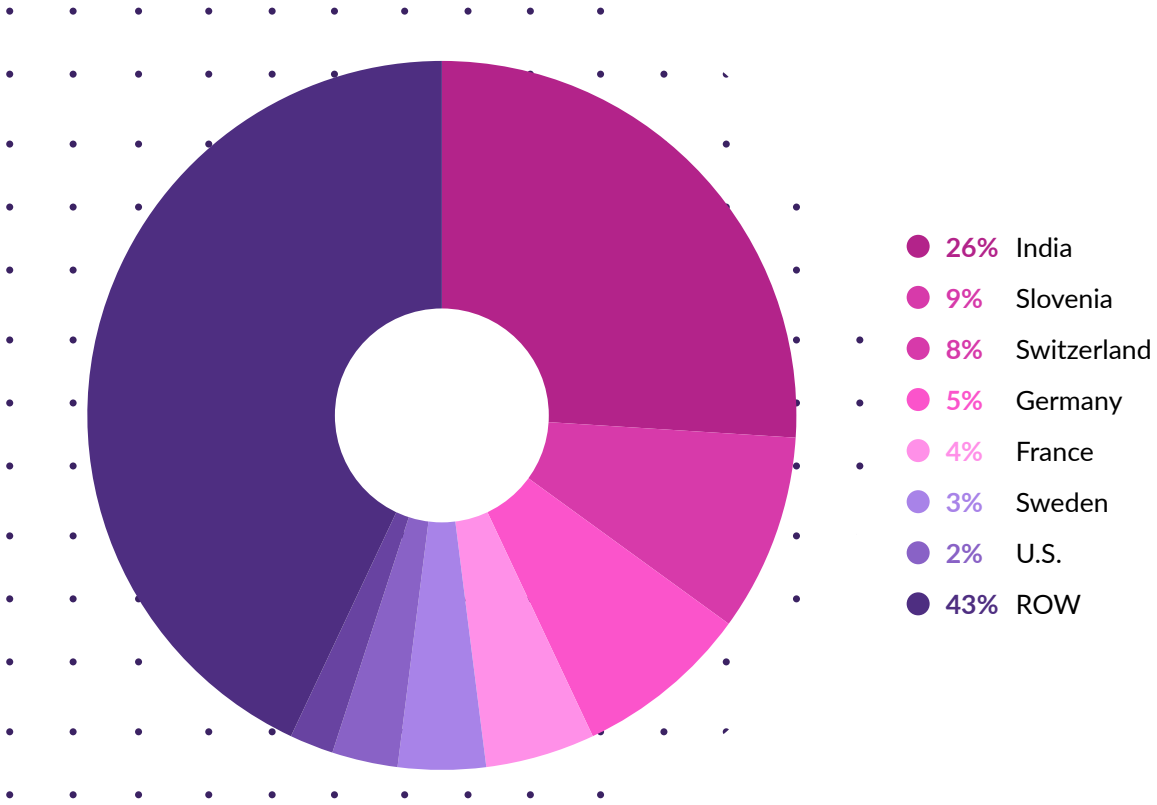
Dermatology	
Atopic Dermatitis	271,435
Psoriasis	95,821
Other Indications	5,610,075
Total:	**5,977,331**

Marketing Authorization

The Russian pharmaceutical market had reached USD 17.5 BLN[11] as of October 2020, having grown by 15% compared to the same period in 2019. Usually, more than 1,000 marketing authorizations are obtained by pharmaceutical companies annually in Russia. In 2020 more than half of approvals were secured by Russian manufacturers (684 approvals). The standout country among foreign manufacturers looking to export to Russia is India (51 approvals), followed by Slovenia (17), Switzerland (16), Germany (10), France (7), Sweden (6) and the USA (3).

The attractiveness of the region for marketing authorization and sales of drugs can be attributed to the fact that having obtained an approval for a drug in Russia, the drug is automatically registered in all member countries of the Eurasian Economic Union, since as of January 1, 2021, for a drug to be authorized for market in Russia it is necessary to follow the EAEU procedure[12].

Number of Marketing Authorizations received by foreign manufacturers in Russia in 2020 [13]



One of the attractions of product development in Russia is that we can carry out high-quality and efficient clinical development, taking European business into consideration, in a market where significant growth can be expected.[14]

Shigeru Koshimitsu, Head of Overseas Business Division, SENJU Pharmaceutical CO. LTD.

11 - Deloitte. https://www2.deloitte.com/content/dam/Deloitte/ru/Documents/life-sciences-health-care/russian/russian-pharmaceutical-market-trends-2020.pdf
12 - Eurasian Economic Union. http://www.eaeunion.org
13 - Russian Ministry of Health Registry of Approved Drugs. https://grls.rosminzdrav.ru/
14 - Russia: destination of choice for Asian pharmaceutical companies. https://oct-clinicaltrials.com/resources/articles/russia-destination-of-choise-for-asian-pharmaceutical-companies

III. Eurasian Economic Union

EAEU: What does it Mean for the Pharma World?

The unified market for medicines for the member states of the Eurasian Economic Union (EAEU) has been officially functioning since May 6 2017. It will, first of all, significantly improve the quality, safety and efficacy of drugs distributed within the territory of the member countries and will help them become more competitive in the global arena. The key takeaway for the pharmaceutical world is the opportunity to have a drug registered in one of the member states and obtain marketing authorization through a simplified procedure in the rest of the countries of the Union (Note: there are more than 20 cities with the population over 1 million people across the EAEU, while the total population of Union countries is 183.9 million).

The Member-States:

- the Republic of Armenia
- the Kyrgyz Republic
- the Russian Federation
- the Republic of Belarus
- the Republic of Kazakhstan

In addition, about 50 other countries have been expressing interest toward cooperating with the union.

> *This project without doubt represents a solid foundation with conditions for the circulation of safe, high-quality and effective medicines across the territory of the entire union. In turn, that essentially facilitates the overall access to high-quality medicines for almost two hundred million EAEU citizens.*
>
> **Eugenia Radkova, Medical Writer, OCT Clinical**

Market authorization through a simplified procedure within five member countries (Russia, Armenia, Belarus, Kazakhstan, Kyrgyzstan)

Registration in 1 country

=

Registration in 5 countries

126 entries on the EAEU Registry of Authorized Drugs

As of January 2021 there were 126 entries on the EAEU Registry of Authorized Drugs[15]. Among manufacturers there were pharmaceutical companies from Russia, the USA, Germany, Spain, the United Kingdom, Switzerland, Turkey, Slovenia, Belgium and India. Russian manufacturers lead the way with a total share of 49% (62 registrations), followed by Slovenian (13) and German (8) companies, while French and Belgian producers have 5 each. The first marketing authorization in compliance with EAEU standards was issued by the Ministry of Health of Russia in November 2019[16].

IV. FDA and Clinical Trials in Eastern Europe

FDA-approved New Drugs

The Center for Drug Evaluation and Research (CDER) plays a key role in helping to advance new drug development. In 2020 53 novel drugs and biologics have been approved by the CDER of the U.S. FDA. Overall, 32,000 patients participated in these trials. Seven of the 53 novel drugs underwent clinical trials involving Russian research sites.[17]

FDA-approved New Drugs Tested in Russia, 2020 [17]

Novel Drug Name	Company Name
Osilodrostat / Isturisa	Novartis
Rukobia / Fostemsavir	ViiV Healthcare
Vyepti / Eptinezumab-jjmr	Alder Biopharmaceuticals, Inc.
Sogroya / Somapacitan-beco	Novo Nordisk
Zeposia / Ozanimod	Celgene
Sarclisa / Isatuximab	Sanofi-Aventis U.S. LLC
Tabrecta / Capmatinib	Novartis

Among other therapies approved by the FDA in 2020 (inclusive of biosimilars, new formulations, manufacturers, combinations or dosage forms), the following five were also researched at Russian sites.

Other therapies approved by the FDA, 2020 [17]

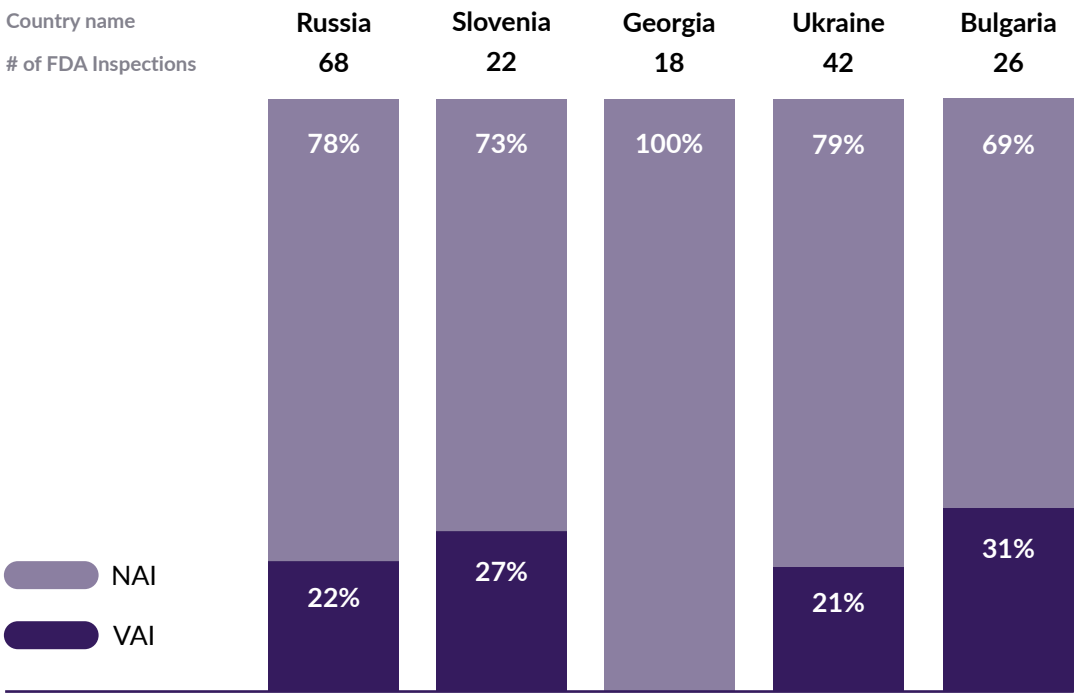
Drug Name	Active Ingridient	Company Name
Hulio	Adalimumab-FKJP	Mylan
Liumjev	Insulin Lispro	Eli Lilly
Xeljanz	Tofacitinib	Pfizer
Ozempic	Semaglutide	Novo Nordisk
Fetroja	Cefiderocol	Shionogi

15 - EAEU Registry of Approved Drugs. https://portal.eaeunion.org/sites/commonprocesses/ru-ru/Pages/DrugRegistrationDetails.aspx
16 - Pharmvestnik. https://pharmvestnik.ru/content/news/Minzdrav-Rossii-vydal-pervoe-registracionnoe-udostoverenie-po-pravilam-EAES.html
17 - FDA. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020

FDA Inspections and Findings

The FDA regularly performs inspections of clinical sites to determine their compliance with applicable regulations and laws. Publicly available statistics of FDA inspections results helps biotech and pharmaceutical companies choose the best options for assigning their future clinical studies. As shown in the table below, during the last 10 years Russia has had one of the highest NAI rates and is one of few countries with no OAI (Official Action Indicated: 0%).

FDA Inspections [18]



V. Stem Cell Research in Russia

2018 marked a key breakthrough for the Russian market and the global pharmaceutical arena, when the Russian government enacted a law involving amendments to biomedical cell product guidelines, which officially opened the door for Russia to enter the stem cell technologies industry.[19] This regulation stipulates and defines what a BCP is, specifying that both registered medical products and pharmaceuticals can be classified as BCPs. At the moment, 42 research centers in Russia are accredited to conduct clinical trials of biomedical cell products.[20]

In 2020 the Federal Service for Surveillance in Healthcare (Roszdravnadzor) issued the first Russian license for the production of biomedical cell products. To date, a domestic biotechnology company, JSC Generium,[21] is the sole production site in Russia.

18 - FDA. https://datadashboard.fda.gov/ora/cd/inspections.htm
19 - BioSpace. https://www.biospace.com/article/russia-opens-the-door-for-stem-cell-clinical-trials/
20 - Russian Ministry of Health Registry of Approved Clinical Trials. https://grls.rosminzdrav.ru/Default.aspx
21 - Generium Pharmaceutical. https://www.generium.ru/en/

> *With the stem cell industry on the rise there is an exponentially growing demand for trained professionals in the field, and therefore relevant courses are being included in university curriculums for students as well as professionals. There are also a few wide scale government programs which stimulate the emergence of new medical products and innovative technology in healthcare. One such program is aimed at developing stem cell technologies.*[22]
>
> **Alexey Martynov, Director of Stem Cell Products Manufacturer Association**

> *The Russian Federation government issued specific decrees which outlined the stem cell technologies development strategy for 2018-2020. This program undertook the development of knowledge sharing centers, both from product development and production points of view, as well as medical center accreditations, for them to be eligible for such studies.*[22]
>
> **Vadim Merkulov, Deputy Director of the Russian Ministry of Health Scientific Centre for Expert Evaluation of Medicinal Products**

VI. COVID-19 Implications for Clinical Trials

COVID-19 Treatment and Vaccine Trials in Russia

In 2020 the Ministry of Health of the Russian Federation issued 59 approvals for clinical trials on anti-coronavirus medical products, which made up 8% of all clinical trials launched in 2020.

Among the drug manufactures running research in COVID-19 treatment in 2020 were:
R-Pharm (Russia), Nearmedic (Russia), Alium (Russia), Innovation Pharmaceuticals (USA), AmGen (USA), Viriom (USA), Merck (USA), CTI Biopharma (USA), Octapharma (Austria), Chong Kun Dang Pharmaceutical (South Korea), Vicore Pharma Holding AB (Sweden), Apogenix AG (Germany), Sanofi (France), Pharmasyntez (Russia), Novartis (Switzerland), Biocad (Russia), Petrovax (Russia), Boehringer Ingelheim (Germany), and Fund S.A. (Belgium). Among the vaccine manufacturers were CanSinoBIO (China) and N.F. Gamaleya National Center of Epidemiology and Microbiology (Russia).

22 - BioSpace. https://www.biospace.com/article/russia-opens-the-door-for-stem-cell-clinical-trials/

COVID-19: Investigator Perspective

From April to May 2020, OCT Clinical ran a survey[23] among researchers from 61 sites in Russia to gain the perspective of investigators regarding clinical trials during the COVID-19 pandemic. According to the results, 22% sites reported being on a lockdown, while the remaining 78% were able to proceed with clinical research, adapting to the current situation. One of the key highlights of the survey results is the fact that only 3% of the sites had to transfer clinical trials and thus patients to other sites. In addition, more than 40% of respondents reported that new studies were being launched at their sites, including COVID-19 trials.

OCT Clinical All-Russia Investigator Survey, March-April, 2020 [23]

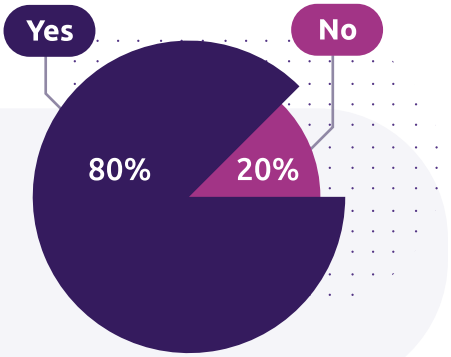
1. Is your site on a lockdown?

2. Did the communications with a sponsor get worse?

3. Did your site have to transfer a study to another site?

4. Do you participate in regular remote CRA visits?

5. Do you get any support from sponsors and CROs? *



* Frequent Responses

- Taxi for patients
- Home blood tests
- Arranging COVID-19 tests
- Remote patient visits
- Online trainings and meetings
- Personal protection equipment for patients and site personnel

6. Does your site initiate new studies?

7. Does your site participate in ongoing patient recruitment at the moment?

8. Do you employ home visits for patients?

9. Do you employ IP delivery to patients' homes?

10. Have you been working with eClinical platforms for clinical trials? (ePRO, EDC)

23 - OCT Clinical All-Russia Investigator Survey, 2020

> *We live in a time when, with the help of digital technologies, we are able to continue working as efficiently as possible. For instance, the role of e-questionnaires plays an important role in assessing the quality of life of a patient. Given the situation with the pandemic, this tool greatly simplifies the task of assessing a patient's condition and makes it possible to get a more detailed picture for the investigator.*
>
> **Karina Khidishyan, MD, Oncologist and Investigator at the Petrov Research Institute of Oncology of the Ministry of Health of Russia**

VII. Clinical Trials in Eastern Europe

The number of clinical trials conducted in Eastern Europe demonstrated a steady growth in 2020 despite COVID-19-imposed hurdles. Ukraine and Bulgaria are the next countries after Russia in terms of the number of initiated studies in 2020. Next come Lithuania (40), Estonia (38), Georgia (38), and Latvia (30).[24]

CTA Approval Timelines by Countries in Eastern Europe

Geography has a definite impact on the duration of clinical trial approval, and the CTA process and the cost of regulatory support services differ from country to country. Different countries and regions may have their own requirements for submission packages and sometimes it can be a challenge to put everything together.

CTA Approval Timelines [25]

42 days

- Georgia

60 days

- Baltic States
- Bulgaria
- Serbia
- The Netherlands

65-90 days

- Russia
- Ukraine
- Belarus
- Moldova

24 - ClinicalTrials.gov
25 - Directive 2001/20/EC; Local legislation for non-EU countries

Russia

The CTA approval procedure in Russia is independent from marketing authorization legislation. All drugs must be subject to clinical trials in Russia. While the application package must be submitted in Russian, it is otherwise relatively easy to put together, and includes the main documents required as per GCP (Protocol, Investigator Brochure and Informed Consent Form).
As soon as the MoH approval is obtained, it is mandatory to get approval from the Local Ethics Committees, which takes about 2 weeks. In parallel with that, an import license for the study drug must be obtained through a separate submission to the MoH. In the meantime, an IMPD is not required and information about the drug candidate and the manufacturer can be submitted in an abridged form.

Ukraine

In Ukraine, the CTA package is also easy to put together, similar to the EU CTA for initial submission, and to other EU requirements, such as completion of an IMPD. However, the local Ministry of Health requires multiple documents from investigators, and not only from principal investigators. Accreditation and certification of each medical institution involved in a trial have to be collected and reviewed for validity. Indeed, the preparation of such packages takes more time and is more expensive in terms of study budget. On the other hand, there is no need for a full translation of main study documents into Ukrainian.
The regulatory approval process takes 57-65 calendar days.

Georgia

An IMPD is not required in Georgia, but the package includes more documents compared to Russian requirements. Mostly these are documents provided by centers and researchers. Almost all documents require a notarized translation into Georgian.
Documents for a CT initiation are first submitted to the LEC, and once approved by the LEC, the package is submitted to the MoH. In terms of timelines, the review process usually takes a month if there are no additional inquiries. Also noteworthy is that the fee is quite small in comparison to other countries.

Belarus

Even though Belarus is not an EU member, local regulators urge applicants to include an IMPD in their CTA package. Otherwise, the same amount of information is required in the form of separate documents. Everything must be translated into Russian or Belarussian. Submission of CTAs is strictly consistent. First comes MoH approval, followed by LEC, import license, and afterwards the documents for export of biosamples can be submitted if required.

About OCT Clinical

OCT Clinical is a leading CRO in Russia, with operations in Central and Eastern Europe and the CIS region. With a team of over 150 professionals, the company provides a full range of high-quality clinical research services for phase I-IV and BE studies. With strong local expertise and focus on quality, OCT ensures seamless clinical trial conduct and drug registration on time and within budget. OCT's experienced team delivers both standalone services such as medical writing, consultancy, project management, monitoring, data management, biostatistics, regulatory support, logistics and turnkey service for clinical development. Since 2005, OCT Clinical Trials has worked on over 300 full-service and functional service projects in more than 20 therapeutic areas.

More information can be found at **oct-clinicaltrials.com**