

## Clinical Trials in Russia – Report On 2017

The Russian MoH approved 700 new clinical trials of all types including local and bioequivalence studies during 2017, demonstrating a 22% decrease in comparison with the same point of the last year.

The main contribution into the total number of studies was made by multinational multi-centre clinical trials (MMCT); the number of these studies decreased from 319 studies in 2016 to 291 in 2017, a 9% decrease from the last year's figure. The number of bioequivalence studies (BE) decreased from 302 studies in 2016 to 215 in 2017, a 29% decrease from the last year's figure. The number of local clinical trials (LCT) has significantly decreased, from 276 in 2016 to 194 in 2017, a 30% decrease from the last year's figure. The proportions between different study types (multinational multi-centre clinical trials, local clinical trials and bioequivalence studies) changed since last year. The share of bioequivalence studies decreased from 34% to 31% of the total number of clinical trials approved in 2017.

The share of the local clinical trials decreased from 31% in 2016 to 28% in 2017, and the share of multinational multi-centre clinical trials was 42% of the total number of trials approved during 2017 (36% in 2016). The geographic origins of sponsors did not significantly change in comparison with last year. 57% of the total number of new studies in 2017 were sponsored by foreign companies, which received 402 study approvals (58% in 2016). The share of studies of local manufacturers increased from 42% in 2016 to 43% in 2017 and amounted to 298 studies.

Clinical trials in Russia in 2017 were sponsored by companies from 39 countries. The largest number of trials (298) were initiated by Russian sponsors. American sponsors with 116 new studies took the runner-up place; they are followed by Swiss sponsors with 55 new studies, then by Indian sponsors with 45 trials. The group of leaders is concluded by Germany with 24 trials, France with 20 studies, and Sweden and United Kingdom (19 studies each). Other sponsors include: Belgium (18 studies), Israel (eight studies), Denmark (seven studies), Netherlands and Austria (six studies each), Italy (five studies), Republic of Belarus, Japan, Poland, Spain, Turkey and Republic of Cyprus (four studies each), Republic of Korea and Republic of Macedonia (three studies each), Iran, Hungary, Croatia, Canada, Portugal, Slovenia and Malta (two studies each), and Republic of Bulgaria, Bosnia and Herzegovina, Czech Republic, Finland, Luxembourg, New Zealand, Republic of Kazakhstan, Ukraine, United Arab Emirates and Jordan, each started one new study in 2017.

### Clinical Trials by Phase

The number of Phase I clinical trials decreased by 45% compared to 2016: from 83 studies to 46 new studies in 2017. The number of Phase II trials increased by 1% compared to 2016, from 92 studies to 93 new studies. The number of Phase III trials decreased from 387 to 312 studies, 19% less than in 2016. The number of Phase IV trials increased in comparison with 2016 from 32 to 34 studies in 2017 (6% increase). The share of Phase III trials in 2017 is 64% of the total number of studies, the share of Phase I trials is 10%, Phase II trials is 19% and the share of Phase IV studies accounted for 7%.

The number of subjects planned to be enrolled in Phase I-IV trials launched in 2017 is 55,903, 17% less than the 2016 figure, when 67,385 subjects were planned to be enrolled. 2191 of these will be in Phase I trials; 6501 in Phase II trials; 42,230 in Phase III studies, and 4981 subjects will be enrolled in Phase IV studies. The lowest number of subjects in a single study is one, and the highest number is 1100.

### The Top Five: Sponsors, Sites and CROs

Nr	Company Name	No. studies <sup>1</sup>	No. patients
1	Novartis	25	2008
2	AstraZeneca	17	4664
3	Merck & Co.	17	1750
4	F. Hoffmann-La Roche	15	796
5	Dr. Reddy's	14	1663

<sup>1</sup> Excluding BE studies.

Table 1: Top-5 International Study Sponsors in 2017

Nr	Company Name	No. studies	No. patients
1	Biocad	18	2253
2	North Star	17	670
3	Microgen	14	945
4	Kanonpharma Production	13	480
5	Pharmasintez	11	1177

Table 2: Top 5 Russian Study Sponsors in 2017

Nr	Site Name	City	No. studies
1	Medical Center Probiotec	Serpukhov, Moscow region	33
2	Clinical Hospital N2, Yaroslavl region	Yaroslavl	25
3	Bioeq Ltd.	Saint-Petersburg	21
4	Ecosafety Ltd.	Saint-Petersburg	21
5	Road Clinical Hospital at the station Yaroslavl of Russian Railways	Yaroslavl	17

Table 3: Top 5 Russian Research Sites (BE and Phase I studies) in 2017

Nr	Site Name	City	No. studies
1	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	62
2	Kazan State Medical University	Kazan	54
3	First Moscow State Medical University named after I.M. Sechenov	Moscow	52
4	First St. Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	47
5	Kemerovo Regional Clinical Hospital named after S.V. Belyaev	Kemerovo	35
6	Regional Clinical Oncological Dispensary	Omsk	35

Table 4: Top 5 Russian Research Sites (Phase II-IV studies) in 2017

Nr	Site Name	City	No. studies
1	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	70
2	First Moscow State Medical University named after I.M. Sechenov	Moscow	61
3	Kazan State Medical University	Kazan	55
4	First St. Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	48
5	Ecosafety Ltd.	Saint-Petersburg	40

Table 5: Top 5 Russian Research Sites (all studies) in 2017

Nr	CRO Name	No. studies	No. patients
1	Quintiles	27	3008
2	PPD Development	15	1128
3	iPHARMA	14	1241
4	Pharmaceutical Research Associates CIS, LLC	14	872
5	Synergy Research Group	13	1389

Table 6: Top CROs in Russia in 2017

### Therapeutic Areas of Russian Clinical Trials in 2017

The largest number of studies were initiated in oncology (99 studies); this is followed by therapy (48 studies), haematology (47 studies), rheumatology and neurology (42 studies each), allergology and immunology (35 studies), infectious diseases (33 studies), gastroenterology (30 studies), endocrinology and pulmonology (24 studies each), and cardiology (23 studies).

## Clinical Trials Results

The Center for Drug Evaluation and Research (CDER) of the FDA approved 151 new drugs during 2017; 39 of them are new molecular entities (NME); other approvals concern new dosages, combinations or manufacturers. Thirty of 151 drugs were (or are being) studied in clinical trials involving Russian sites. Table 7 shows the drugs which were approved by FDA in Q4 2017 that were (or are being) tested in clinical trials in Russia.

Appr. date	Drug (active ingredient)	Company
10/11/2017	Lyrica CRNDA (pregabalin)	Pfizer Inc
10/20/2017	Bydureon Bcisenda (exenatide)	AstraZeneca AB
11/14/2017	Fasenraba (benralizumab)	AstraZeneca AB
11/21/2017	Julucanda (dolutegravir sodium/ rilpivirine hydrochloride)	ViV Healthcare
12/01/2017	Ogivibra (trastuzumab-dkst)	Mylan GmbH
12/05/2017	Ozempicnda (semaglutide)	Novo Nordisk Inc
12/11/2017	Admelognda (insulin lispro)	Sanofi Aventis US
12/13/2017	Ixifibra (infliximab-qbtx)	Pfizer Inc

Source: FDA

Table 7: New Drugs Approved by FDA in Q4 2017 and Tested in Russian Sites

During 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) gave positive recommendations on 94 new drug applications (1), 21 positive recommendations on new generic medicines, two for new hybrid medicines and 13 for new biosimilar medicines. A negative opinion was adopted for 12 drugs. Fifty-eight of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia. Table 8 represents those of them which were, or are being, tested in clinical trials in Russia in Q4 2017.

Appr. date	Drug (active ingredient)	Manufacturer
10.12.2017	Alecensa (alelectinib)	Roche Registration Limited
10.12.2017	Bydureon (exenatide)	AstraZeneca AB
10.12.2017	Faslodex (fulvestran)	AstraZeneca UK Ltd
10.12.2017	Pegasys (peginterferon alfa-2a)	Roche Registration Limited
11.09.2017	Fasenra (benralizumab)	AstraZeneca AB
11.09.2017	Ocrevus (ocrelizumab)	Roche Registration Limited
11.09.2017	Genvoya (elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide)	Gilead Sciences International Limited
11.09.2017	Nplate (romiplostim)	Amgen Europe B.V.
12/14/2017	Ozempic (semaglutide)	Novo Nordisk A/S
12/14/2017	Herzuma (trastuzumab)	Celltrion Healthcare Hungary Kft.
12/14/2017	Taltz (ixekizumab)	Eli Lilly Nederland B.V.

Source: EMA

Table 8: New Drugs Approved by EMA in Q4 2017 and Tested in Russian Sites

## Inspections

### FDA Inspections

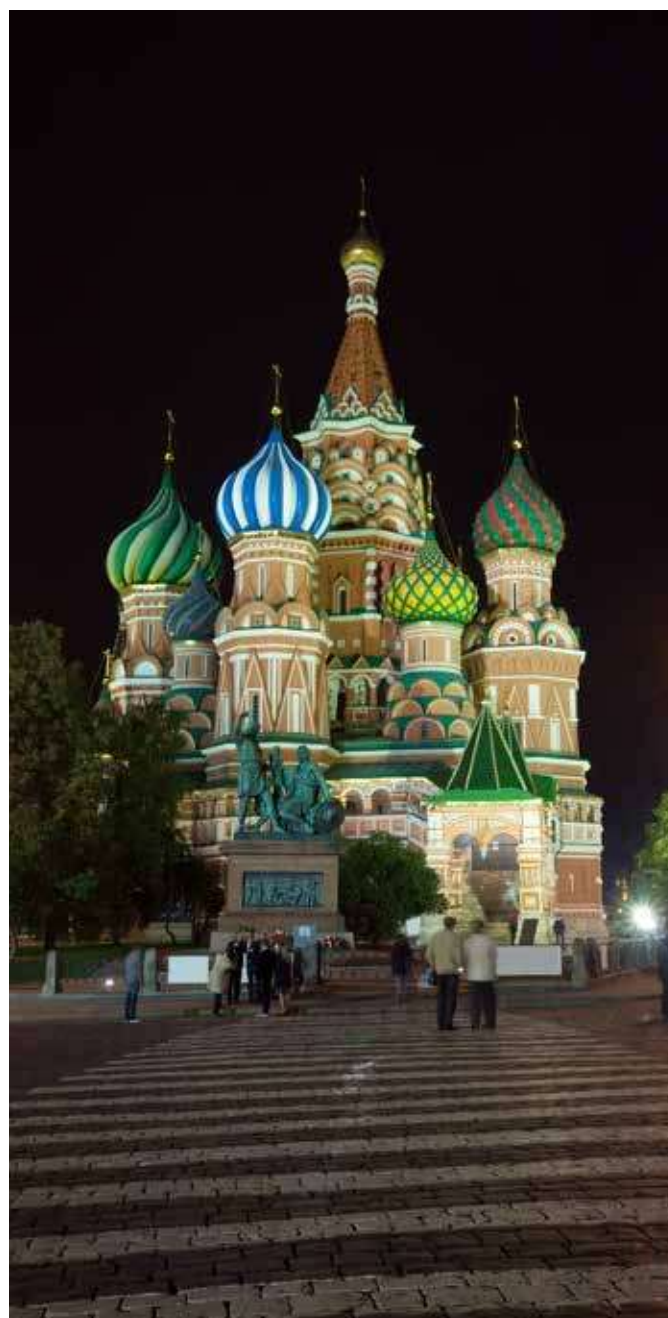
According to the FDA data, six FDA inspections were conducted in the Russian investigative sites during 2017: one in Ufa (on 06-Feb-2017), three in Saint Petersburg (on 20-Mar-2017, 24-Apr-2017 and 17-Jul-2017), one in Yaroslavl (on 17-Jul-2017), and one in Ryazan (on 30-Oct-2017). Five inspections ended with the result NAI – no action indicated, and one inspection ended with the result VAI – voluntary action indicated.

### Roszdraznadzor Inspections

According to the annual Roszdraznadzor report, 55 inspections were conducted in 36 institutions performing preclinical and clinical trials during 2017.

## REFERENCES

1. Positive opinions on new generic, hybrid and biosimilar medicines are not included.



## Igor Stefanov



Igor Stefanov graduated from the Moscow Aviation Institute in 1989. After the collapse of the Soviet Union, he received an MBA degree in economics at the Moscow International University in 1993 and went into the business consulting area, developing and implementing localisation strategies for the Fortune 500 companies in Russia, comprising big pharma representatives including Pfizer, J&J, GlaxoSmithKline, Roche and others. Prior to joining Synergy Research Group in January 2007 as CEO, Igor served as General Manager for SmartLock, the Russian hi-tech biometric company, and was recognised as an entrepreneur of the month by the Russian edition of Forbes magazine in 2005.

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