

# Clinical Trials in Russia – Report on Q3 of 2017

The Russian MoH approved 158 new clinical trials of all types including local and bioequivalence studies during Q3 2017, demonstrating a 34% decrease in comparison with the same period last year.

The main contribution to the total number of studies was made by multinational multi-centre clinical trials (MMCT); the number of these studies decreased from 89 studies in Q3 2016 to 65 in Q3 2017, representing a 27% decrease from last year's figure. The number of bioequivalence studies (BE) significantly decreased from 72 studies in Q3 2016 to 43 in Q3 2017, representing a 40% decrease from last year's figure. The number of local clinical trials (LCT) decreased from 80 in Q3 2016 to 50 in Q3 2017, representing a 38% decrease from last year's figure. The share of bioequivalence studies decreased from 30% to 27% of the total number of clinical trials approved in Q3 2017. The share of the local clinical trials was almost identical, 33% in Q3 2016, compared to 32% in Q3 2017, and the share of multinational multi-centre clinical trials was 41% of the total number of trials approved during Q3 2017 (37% in Q3 2016).

The geographic origins of sponsors changed in comparison with last year. 56% of the total number of new studies in Q3 2017 were sponsored by foreign companies, which received 89 study approvals (61% in Q3 2016). The share of studies of local manufacturers increased from 39% in Q3 2016 to 44% in Q3 2017, and amounted to 69 studies. Clinical trials in Russia in Q3 2017 were sponsored by companies from 22 countries. The largest number of trials (69) were initiated by Russian sponsors. American sponsors with 30 new studies secured the runner-up place; they were followed by Indian and Swiss sponsors with 11 studies each, then by French sponsors with six new studies. The group of leaders is concluded by German sponsors (five studies), Sweden and Belgium (each having four studies), and Spain (three studies). Other sponsors included: Macedonia and Portugal (two studies each), and Bosnia-Herzegovina, Croatia, Denmark, Japan, Jordan, Republic of Korea, New Zealand, Slovenia, Turkey, Ukraine and the United Kingdom each started one new study in Q3 2017.

## All Clinical Trials by Phase

The number of Phase I clinical trials decreased by 52% compared to Q3 2016: from 23 studies to 11 new studies in Q3 2017. The number of Phase II trials increased by 26% compared to Q3 2016 from 23 studies to 29 new studies. The number of Phase III trials decreased from 115 to 66 studies, 43% less than in Q3 2016. The number of Phase IV trials increased slightly in comparison with Q3 2016 from eight to nine studies in Q3 2017. If we look specifically at Russian clinical trials by phase, then the share of Phase III trials in Q3 2017 is 57% of the total number of studies, the share of Phase II trials is 25%, of Phase I trials is 10%, and the share of Phase IV studies accounted for 8%.

The number of subjects planned to be enrolled in Phase I–IV trials launched in Q3 2017 is 11,652, less than in Q3 2016, when 22,226 subjects were planned to be enrolled. 531 subjects are planned to be enrolled in Phase I trials; 1832 in Phase II trials; 7572 in Phase

III studies and 1717 subjects are planned to be enrolled in Phase IV studies. The minimal number of subjects in a single study is seven; the maximum number is 448.

## The Top Five: Sponsors, Sites and CRO

No	Company Name	No. studies (1)	No. patients
1	AbbVie Inc	7	264
2	Eli Lilly and Company	5	382
3	Novartis	5	286
4	Merck & Co.	4	280
5	AstraZeneca	4	373

Table 1. Top 5 International Study Sponsors in Q3 2017

No	Company Name	No. studies	No. patients
1	Biocad	6	789
2	North Star	6	300
3	Sotex	4	804
4	Pharmasyntez	4	561
5	Obnovlenie Pharmaceutical Company	3	105

Table 2. Top 5 Russian Study Sponsors in Q3 2017

No	Site Name	City	No. studies
1	Medical Center Probiotec	Serpukhov, Moscow region	7
2	Clinical Hospital N2, Yaroslavl	Yaroslavl	6
3	Ecosafety Ltd.	Saint-Petersburg	6
4	Bioeq Ltd.	Saint-Petersburg	5
5	Road Clinical Hospital at the station Yaroslavl of Russian Railways	Yaroslavl	3
6	Regional Clinical Cardiology Center, Ivanovo	Ivanovo	3
7	Federal North-West Medical Research Centre named after V.A. Almazov	Saint-Petersburg	3
8	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	3

Table 3. Top 5 Russian Research Sites (BE and Phase I studies) in Q3 2017

No	Site Name	City	No. studies
1	First Moscow State Medical University named after I.M. Sechenov	Moscow	13
2	First St. Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	11
3	Research Institute of Oncology named after N.N. Petrov	Saint-Petersburg	11
4	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	10
5	Moscow State University of Medicine and Dentistry	Moscow	9
6	Clinical emergency hospital named after N.V. Solovyov, Yaroslavl	Yaroslavl	9
7	Volgograd Regional Clinical Oncology Center	Volgograd	9

Table 4. Top 5 Russian Research Sites (Phase II–IV studies) in Q3 2017



No	Site Name	City	No. studies
1	First Moscow State Medical University named after I.M. Sechenov	Moscow	13
2	Russian Oncological Scientific Center named after N.N. Blokhin	Moscow	13
3	Research Institute of Oncology named after N.N. Petrov	Saint-Petersburg	12
4	Bioeq Ltd.	Saint-Petersburg	11
5	First St. Petersburg State Medical University named after I.P. Pavlov	Saint-Petersburg	11

Table 5. Top 5 Russian Research Sites (all studies) in Q3 2017

No	CRO Name	No. studies	No. patients
1	OST RUS	3	378
2	Quintiles	3	293
3	PSI	3	275
4	Synergy Research Group	3	164
5	iPharma	2	440

Table 6. Top CROs in Russia in Q3 2017

### Therapeutic Areas of Russian Clinical Trials in Q3 2017

The largest number of studies were initiated in therapy (22 new studies); and is followed by oncology (21 new studies), infectious diseases (17 new studies), rheumatology (12 new studies), haematology (12 new studies), neurology (eight studies), paediatrics (seven studies), traumatology and orthopedics, surgery and endocrinology (six studies each).

### Clinical Trials Results

The U.S. Center for Drug Evaluation and Research (CDER) of the FDA approved 41 new drugs during Q3 2017; nine of them are new molecular entities (NME); other approvals concern new dosages, combinations or manufacturers. Nine of 41 drugs were (or are being) studied in clinical trials involving Russian sites. Table 7 shows the drugs which were approved by the FDA in Q3 2017 that were (or are being) studied in clinical trials in Russia.

Appr.date	Drug (active ingredient)	Company
07/13/2017	Tremfya (guselkumab)	Janssen Biotech
07/20/2017	Benlysta (belimumab)	GlaxoSmithKline LLC
08/03/2017	Mavyret (glecaprevir/pibrentasvir)	Abbvie Inc
08/17/2017	Lynparza (olaparib)	Astrazeneca Pharms
09/05/2017	Tracleer (bosentan)	Actelion Pharmaceuticals Ltd
09/14/2017	Aliqopa (copanlisib)	Bayer Healthcare Pharms
09/18/2017	Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)	GlaxoSmithKline
09/28/2017	Verzenio (abemaciclib)	Eli Lilly and Co
09/29/2017	Fiasp (insulin aspart)	Novo Nordisk Inc

Table 7. New Drugs Approved by FDA in Q3 2017 and Tested in Russian Sites

During Q3 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) gave positive recommendations on 28 new drug applications (2), six positive recommendations on new generic medicines and two for new biosimilar medicines. A negative opinion was adopted for six drugs. 20 of the drugs which received positive opinions were (or are being) studied in clinical trials in Russia. Table 8 represents those drugs which were, or are being, studied in clinical trials in Russia in Q3 2017.

Appr.date	Drug (active ingredient)	Manufacturer
07/20/2017	Bavencio (avelumab)	Merck Serono Europe Ltd
07/20/2017	Dupixent (dupilumab)	Sanofi-Aventis groupe
07/20/2017	Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)	Janssen-Cilag International N.V.
07/20/2017	Tecentriq (atezolizumab)	Roche Registration Ltd
07/20/2017	Lacosamide Accord (lacosamide)	Accord Healthcare Ltd
07/20/2017	Bydureon (exenatide)	AstraZeneca AB
07/20/2017	Gazyvaro (obinutuzumab)	Roche Registration Ltd
07/20/2017	Humira (adalimumab)	AbbVie Ltd
07/20/2017	Keytruda (pembrolizumab)	Merck Sharp & Dohme Ltd
07/20/2017	RoActemra (tocilizumab)	Roche Registration Ltd
07/20/2017	Signifor (pasireotide)	Novartis Europharm Ltd
07/20/2017	Sovaldi (sofosbuvir)	Gilead Sciences International Ltd
07/20/2017	Vimpat (lacosamide)	UCB Pharma S.A.
09/14/2017	Elebrato Ellipta (fluticasone furoate/umeclidinium/vilanterol)	GlaxoSmithKline Trading Services
09/14/2017	Tremfya (guselkumab)	Janssen-Cilag International N.V.
09/14/2017	Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)	GlaxoSmithKline Trading Services
09/14/2017	Cyltezo (adalimumab)	Boehringer Ingelheim International GmbH
09/14/2017	Benlysta (belimumab)	Glaxo Group Ltd
09/14/2017	Tasigna (nilotinib)	Novartis Europharm Ltd
09/14/2017	Firazyr (icatibant)	Shire Orphan Therapies GmbH

Table 8. New Drugs Approved by EMA in Q3 2017 and Tested in Russian Sites

### REFERENCES

1. Excluding BE studies.
2. 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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