

Clinical Trials in Russia
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Executive Summary

The Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (alias RosZdravNadzor, RZN) approved 129 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2009; demonstrating a 17% decrease over the corresponding period of last year.

Despite the decrease in the number of studies, the share of multinational multi-center clinical trials slightly increased from last year's figure and stood at 65% of the total number of clinical trials approved by RZN in the second quarter of 2009. The shares of the local trials and bioequivalence studies in Q2 2009 stood at 21% and 14% of the total number of studies, respectively, while they accounted to 24% and 15% in Q2 2008.

Clinical trials in Russia in Q2 2009 were sponsored by companies from 16 countries. The maximum number of trials (42) were initiated by Russian sponsors, American sponsors with 37 studies took the runner-up place, they are followed by the Swiss sponsors with 13 trials, 12 new trials was instigated by the German manufacturers, UK sponsors with six new studies, and the top six is concluded by the Japan sponsors with four new studies in Q2 2009.

Seven new Phase I clinical trials were launched in the second quarter of 2009; one trial less than in the corresponding quarter of last year. The number of the Phase II trials decreased by 27%, from 40 trials in the second quarter of 2008 to 29 in the second quarter of 2009. Following the overall trend, the number of Phase III trials demonstrated notable decrease over last year number, down from 83 to 64 studies. The number of Phase IV trials also decreased from 15 in Q2 2008 to 10 in Q2 2009.

The number of patients which are planned to be enrolled in the Phase II-IV trials launched in the second quarter of 2009 stood at 12,338 patients, nearly the same as the last year number (12,000).

The Swiss *Novartis* sponsoring 11 new studies is on the top of the heap in the second quarter of 2009. The American *Pfizer* with eight new trials in Q2 2009 took the runner-up place. It is followed by *Bristol-Myers Squibb* sponsoring six new studies. The top five is concluded by *Eli Lilly* and *Merck & Co.* both having five new studies in Q2 2009.

The Russian pharmaceutical company OAO *Valenta Pharmaceutica* sponsoring five new clinical trials enrolling 348 patients in 10 sites, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the second quarter 2009. OAO *Biokhimik* with three new trials and 54 subjects in three sites, took the runner-up place. It is followed by OOO *Lans-Pharm* and ZAO *Obolenskoe*. The top five is concluded by ZAO *Biocad*.

Seventy five per cent of the new studies in Q2 2009 were conducted in the six leading therapeutic areas. The maximum number of trials (29) were initiated in Cardiovascular diseases; 22 clinical trials in Oncology; 17 new studies in Endocrinology; 12 – in Respiratory diseases; 10 new studies in Infectious Diseases and six new Neurology studies were initiated in Q2 2009.

Clinical Trials by Type and Manufacturing Country

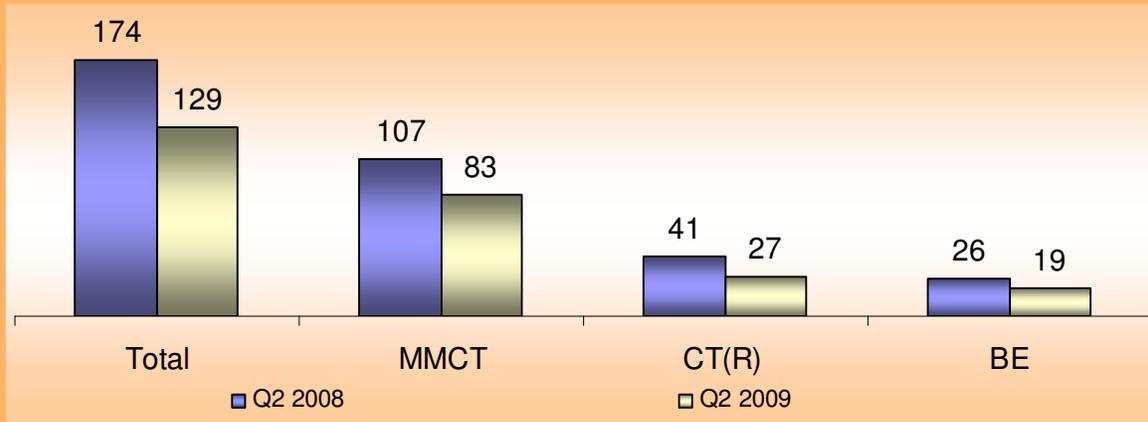
The RZN approved 129 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2009; demonstrating a 17% decrease over the corresponding period of last year. As shown in the Figure 1, the main contribution into the total number of studies is still made by multinational multi-center clinical trials (presented as MMCT in Figure 1), even though the number of these studies decreased by 22% over Q2 2008 and stood at 83 new studies in Q2 2009.

The number of the local clinical trials conducted in Russia by domestic and foreign sponsors (the CT(R) bar in the Figure 1) is also down from 41 to 27 clinical trials demonstrating a notable 27% fall over the same point in 2008.



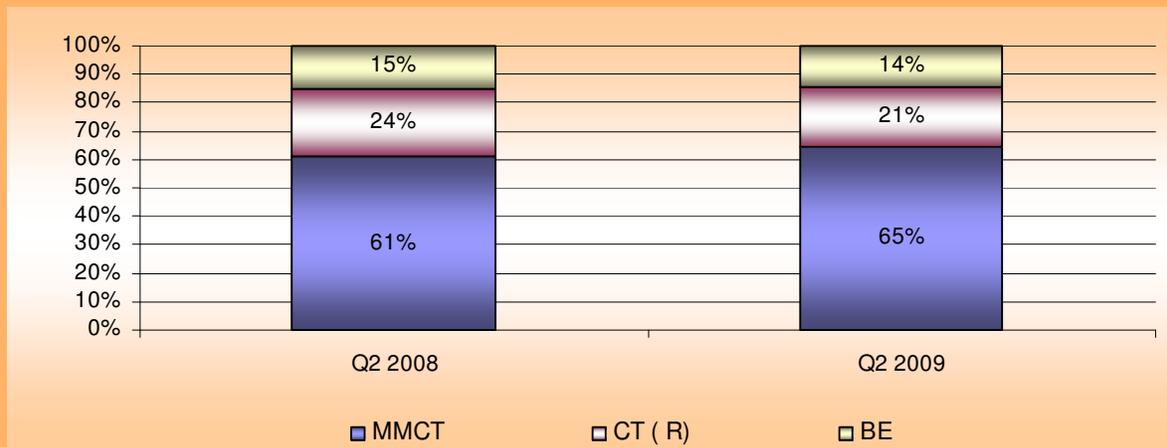
The number of bioequivalence studies (BE in Figure 1) in the second quarter of 2009 stood at 19 new trials, seven studies down over last year's figure.

Figure 1. Clinical trials approved by RZN in Q2 2009



The proportions between different study types (multinational multi-center clinical trials, local studies and bioequivalence trials) did not change significantly over the same point in 2008. Despite the decrease in the number of studies, the share of multinational multi-center clinical trials slightly increased from last year's figure and stood at 65% of the total number of clinical trials approved by RZN in the second quarter of 2009. The shares of the local trials and bioequivalence studies in Q2 2009 stood at 21% and 14% of the total number of studies, respectively, while they accounted to 24% and 15% in Q2 2008.

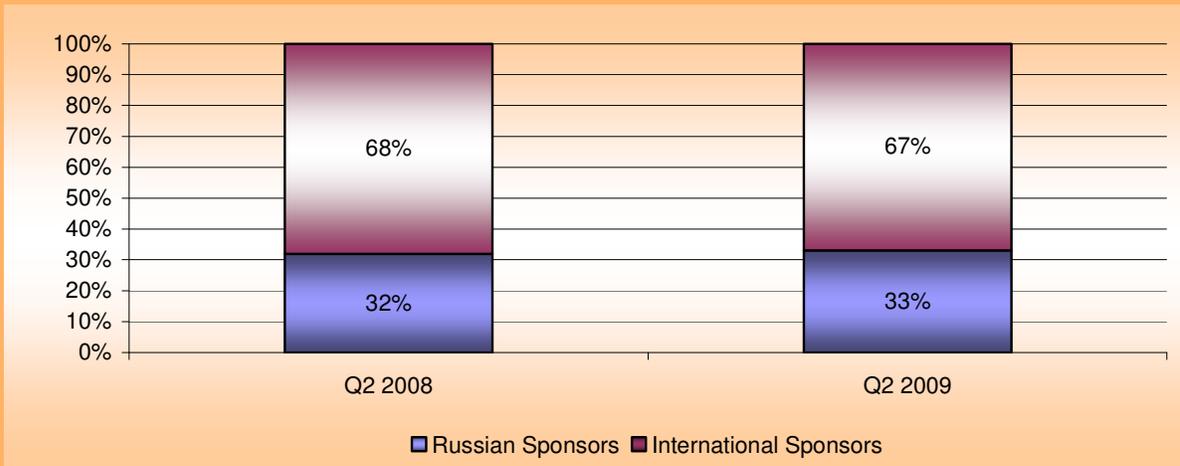
Figure 2. Clinical trials by type in Q2 2009



The lion's share of clinical trials in Russia is being sponsored by foreign companies, 67% of the total number of new studies in Q2 2009, almost the same as the last year figure.

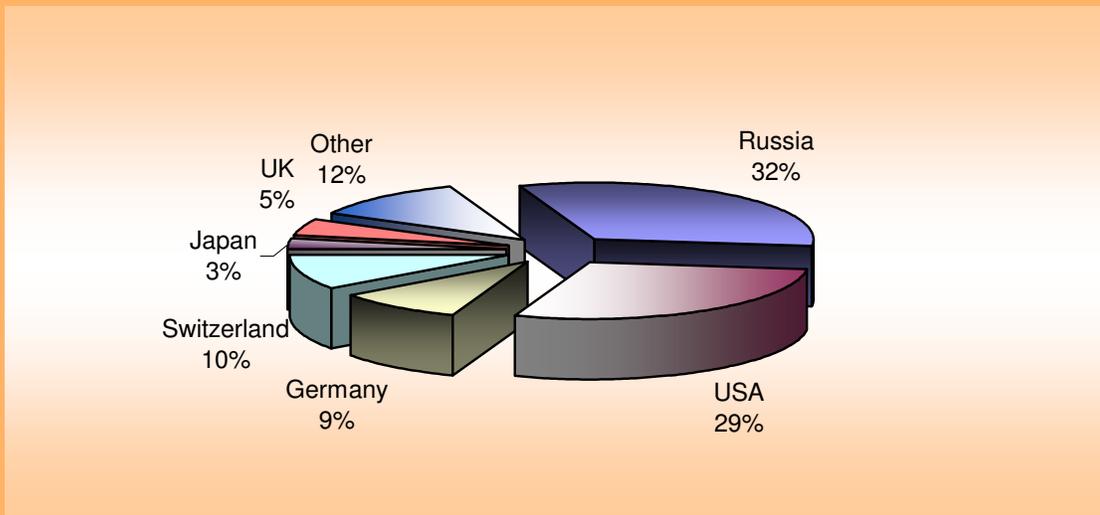


Figure 3. Russian and International sponsors in Q2 2009



Clinical trials in Russia in Q2 2009 were sponsored by companies from 16 countries. Figure 4 demonstrates the input of the leading countries of sponsor's origin into the total number of clinical trials. The maximum number of trials (42) were initiated by Russian sponsors, American sponsors with 37 studies took the runner-up place, they are followed by the Swiss sponsors with 13 trials, 12 new trials was instigated by the German manufacturers, UK sponsors with six new studies, and the top six is concluded by the Japan sponsors with four new studies in Q2 2009.

Figure 4. Countries presented on the Russian clinical trials market in Q2 2009



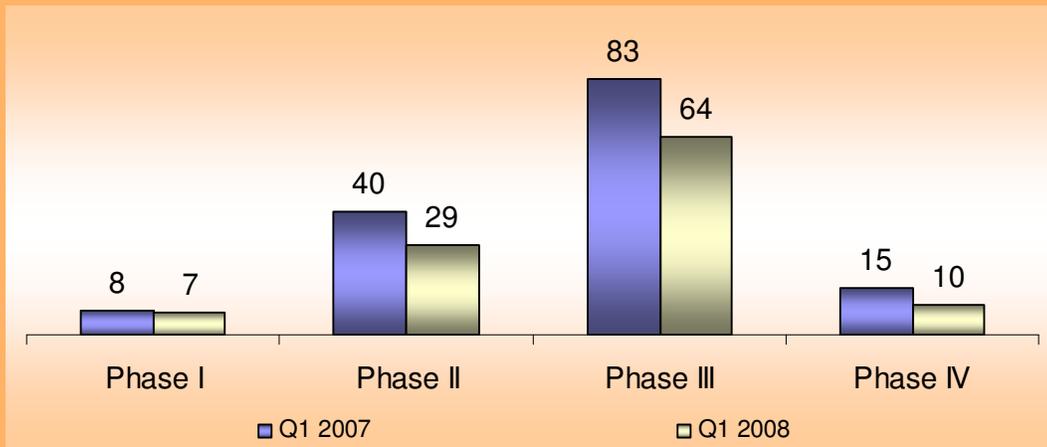
Belgium, India, Ireland, Canada, the Netherlands, Poland, Portugal and Sweden are represented among others.

Clinical trials by Phase

Seven new Phase I clinical trials were launched in the second quarter of 2009; one trial less than in the corresponding quarter of last year. The number of the Phase II trials decreased by 27%, from 40 trials in the second quarter of 2008 to 29 in the second quarter of 2009. Following the overall trend, the number of Phase III trials demonstrated notable decrease over last year number, down from 83 to 64 studies. The number of Phase IV trials also decreased from 15 in Q2 2008 to 10 in Q2 2009.

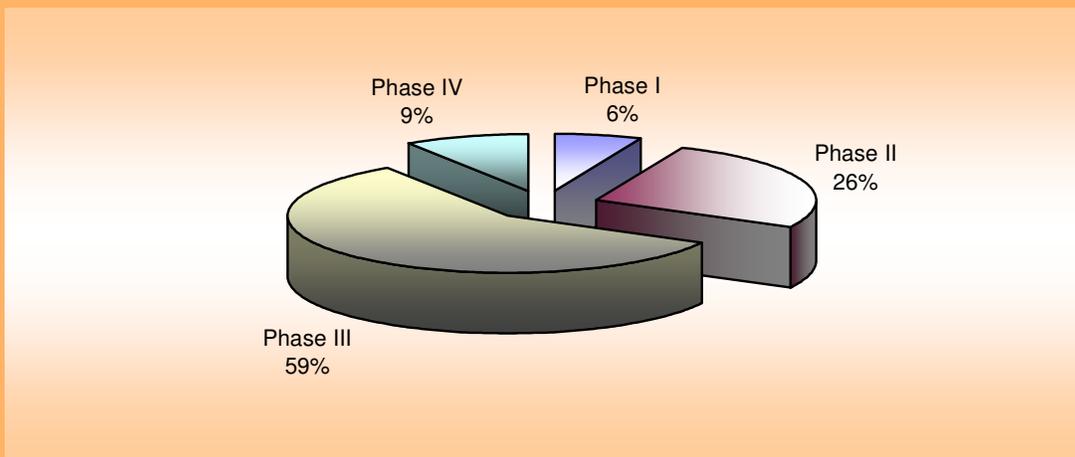


Figure 5. Clinical trials in Russia in Q2 2009 by phase



As shown in Figure 6, the share of Phase III trials in Q2 2009 stood at 60% of the total number of studies, the share of Phase II trials accounted at 26%, Phase IV trials stood at 9%, and the share of Phase I studies amounted to six per cent.

Figure 6. The proportions between study phases in Russia in Q2 2009



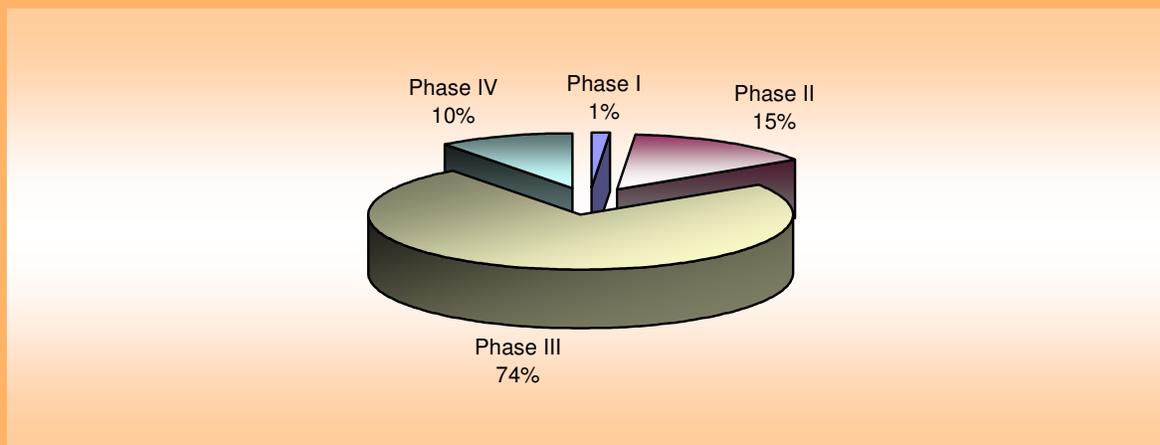
The number of patients which are planned to be enrolled in the Phase II-IV trials launched in the second quarter of 2009 stood at 12,338 patients, nearly the same as the last year number (12,000). It's worth mentioning that the number of Phase III subjects rose by 14% from last year's figure despite the overall fall.

One hundred and seventy eight subjects will be recruited in Phase I trials; 1,790 patients – in Phase II trials; 9,094 subjects – in Phase III studies and 1,276 patients will be enrolled in Phase IV studies.

The minimal number of subjects in a single study is five, the maximum number is 2,300.

The proportions of the number of patients between different Phases is shown on the Figure 7.

Figure 7. The number of patients in Q2 2009 by study phase



The duration of the shortest trial is two months, the longest one will last six and half years.

Rating of international sponsors

The Swiss *Novartis* sponsoring 11 new studies is on the top of the heap in the second quarter of 2009. The American *Pfizer* with eight new trials in Q2 2009 took the runner-up place. It is followed by *Bristol-Myers Squibb* sponsoring six new studies. The top five is concluded by *Eli Lilly* and *Merck & Co.* both having five new studies in Q2 2009.

Top five international sponsors by the number of new studies in Q2 2009 are presented in Table 1.

Table 1. Top-5 international study sponsors in Q2 2009

No	Sponsor	No. of trials	No. of patients	No. of sites
1	Novartis	11	544	117
2	Pfizer	8	605	44
3	Bristol-Myers Squibb	6	2755	130
4	Eli Lilly	5	492	34
5	Merck & Co.	5	110	19

Rating of Russian sponsors

The Russian pharmaceutical company *OAO Valenta Pharmaceutica* sponsoring five new clinical trials enrolling 348 patients in 10 sites, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the second quarter 2009.

OAO Biokhimik with three new trials and 54 subjects in three sites, took the runner-up place. It is followed by *OOO Lans-Pharm* and *ZAO Obolenskoe*. The top five is concluded by *ZAO Biocad*.

Table 2. Top-5 Russian study sponsors in Q2 2009

No	Sponsor	No. of trials	No. of patients	No. of sites
1	Valenta	5	348	10
2	Biokhimik	3	54	3
3	Lans-Pharm	2	75	7

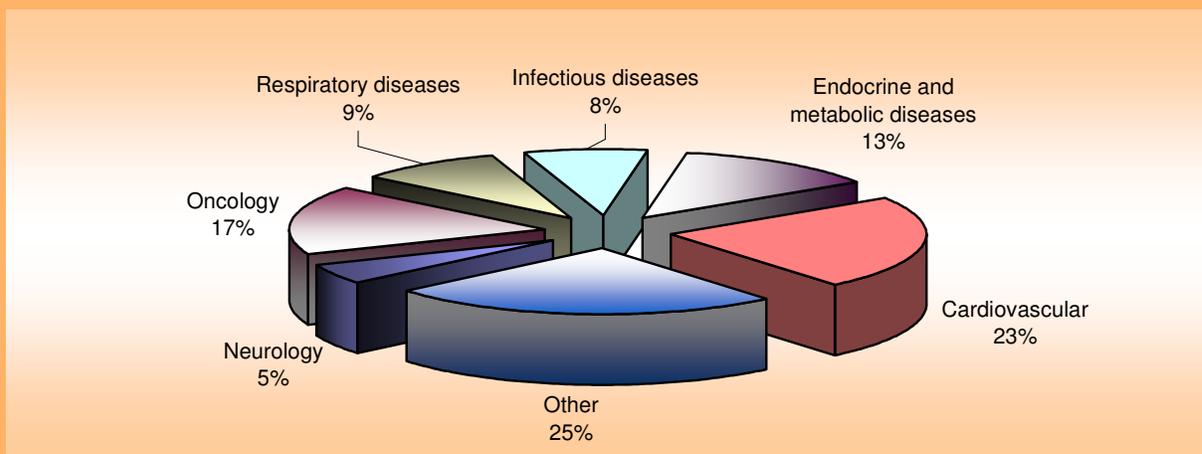


4	Obolenskoe	2	78	2
5	Biocad	2	220	7

Therapeutic areas of clinical trials in Russia in Q2 2009

Seventy five per cent of the new studies in Q2 2009 were conducted in the six leading therapeutic areas. The maximum number of trials (29) were initiated in Cardiovascular diseases; 22 clinical trials in Oncology; 17 new studies in Endocrinology; 12 – in Respiratory diseases; 10 new studies in Infectious Diseases and six new Neurology studies were initiated in Q2 2009. The proportions between different therapeutic areas are shown in Figure 8.

Figure 8. Clinical trials in Russia in Q2 2009 by therapeutic area



Clinical trials results

The Center for Drug Evaluation and Research (CDER) of the FDA approved 27¹ new drugs during Q2 2009; only five of them are new molecular entities; others are the new dosages, manufacturers or indications of the already marketed drugs. The Table 3 represents the one of them which was tested in clinical trials in Russia.

Table 3. New Drugs approved by FDA in Q2 2009 and tested in Russian sites

Approval date	Drug	Manufacturer
05/19/2009	TOLVAPTAN (Samsca)	Otsuka

Source: CDER FDA <http://www.fda.gov/cder>

During the period from April 1 to June 30 2009 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) reviewed 45² applications to market drugs in the EU. Negative opinion was adopted for one of the drugs which had been approved earlier. Ten of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia (see Table 4).

Table 4. New Drugs approved by EMA in Q2 2009 and tested in Russian sites

Approval date	Drug	Manufacturer
29.05.2009	Everolimus	Novartis europarm ltd

¹ CDER FDA <http://www.fda.gov/cder>

² CHMP EMA <http://www.emea.europa.eu/index/indexh1.htm>



29.05.2009	Pemetrexed	Eli Lilly
29.05.2009	Tolvaptan	Otsuka
29.05.2009	Sildenafil	Pfizer
25.06.2009	Golimumab	Centocor, Inc.
25.06.2009	Bevacizumab	Roche
25.06.2009	Saxagliptin	AstraZeneca/Bristol-Myers Squibb
25.06.2009	Sitagliptin	Merck
25.06.2009	Certolizumab Pegol	UCB Phatma
25.06.2009	Sifrol	Boehringer Ingelheim
Source: CHMP EMEA http://www.emea.europa.eu/index/indexh1.htm		

FDA inspections

According to the FDA data, there were no FDA inspections conducted in the Russian investigative sites during Q2 2009.