Clinical Trials in Russia
Orange Paper
1st Quarter 2010

11, 4-Magistralnaya Ul., 123007 Moscow, Russia

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Contents

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Executive Summary

The Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (alias RosZdravNadzor, RZN) approved 134 new clinical trials of all types including local and bioequivalence studies during the first quarter of 2010 demonstrating an 18% increase over the corresponding period of last year.

The main contribution into the total number of studies is made by multinational multi-center clinical trials, the number of them also increased by 15% over Q1 2009 and stood at 83 new studies in Q1 2010.

The number of the local clinical trials conducted in Russia by domestic and foreign sponsors is also up from 27 to 36 clinical trials demonstrating a notable 33% increase over the same point in 2009.

Clinical trials in Russia in Q1 2010 were sponsored by companies from 20 countries. The maximum number of trials (44) were initiated by Russian sponsors, American sponsors with 30 studies took the runner-up place, they are followed by German sponsors with 10 trials, eight new studies were instigated by the UK and Swiss manufacturers, and the top six is concluded by French sponsors with seven new studies in Q1 2010.

Eleven new Phase I clinical trials were launched in the first quarter of 2010; seven trials up over the corresponding quarter of last year. The number of the Phase II trials increased by 27%, from 26 trials in the first quarter of 2009 to 33 studies in the first quarter of 2010. The number of Phase III trials demonstrated a 7% increase over last year number, up from 59 to 63 studies.

The number of patients which are planned to be enrolled in the Phase II-IV trials launched in the first quarter of 2010 stood at 13,016 patients, demonstrating a 25% increase over the last year number.

The Swiss *Novartis* sponsoring seven new studies is on the top of the heap in the first quarter of 2010. *GlaxoSmithKline* with six new trials in Q1 2010 took the runner-up place. It is followed by *Pfizer* also sponsoring six new studies, but with less number of patients, and French *Servier* with four new studies. The top five is concluded by *Merck & Co.* having three new studies in Q1 2010.

The Russian pharmaceutical company OAO *Sti-Med-Sorb* sponsoring four new clinical trials enrolling 290 patients in five sites, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the first quarter 2010. OOO *Geropharm* with three new trials and 480 subjects in 11 sites took the runner-up place. It is followed by ZAO *Infamed*, ZAO *Biocad* and AKO *Sintez* with two studies each differing only in the number of patients and sites.

Sixty nine per cent of the new studies in Q1 2010 were conducted in the six leading therapeutic areas. The maximum number of trials (28) were initiated in Oncology; 12 clinical trials in Respiratory diseases; nine new studies in Psychiatry; seven new studies in Cardiovascular, Infectious and Musculoskeletal diseases were initiated in Q1 2010.

The Center for Drug Evaluation and Research (CDER) of the FDA approved 26 new drugs during Q1 2010; four of them are new molecular entities (NME); others are the new dosages, manufacturers or indications of the already marketed drugs. Seven of the approved drugs were tested in clinical trials in Russia.

During the period from January 1 to March 31 2010 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMEA) reviewed 13 applications to market drugs in the EU. Three of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia.

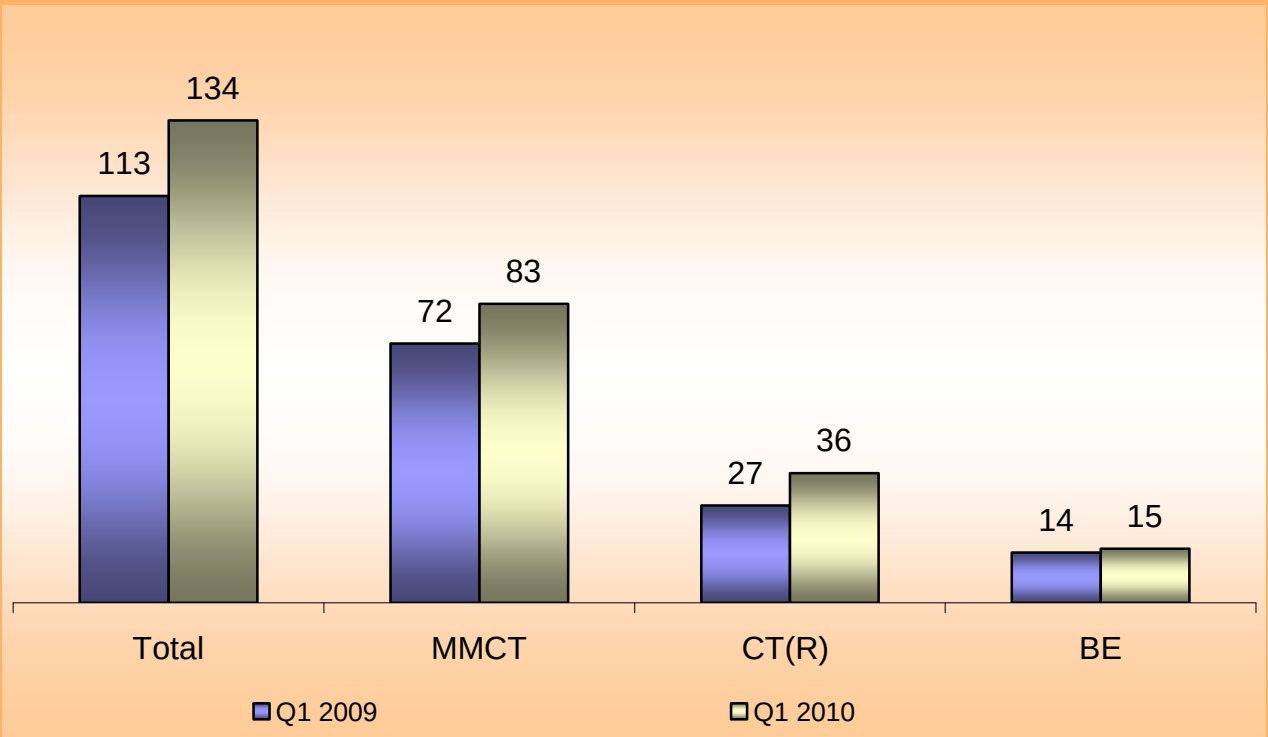
Clinical Trials by Type and Manufacturing Country

The RZN approved 134 new clinical trials of all types including local and bioequivalence studies during the first quarter of 2010; demonstrating a 18% increase comparing to the corresponding period of last year. As shown in the Figure 1, the main contribution into the total number of studies is made by multinational multi-center clinical trials (presented as MMCT in Figure 1), the number of these studies also increased by 15% over Q1 2009 and stood at 83 new studies in Q1 2010.

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 up from 27 to 36 clinical trials demonstrating a notable 33% increase over the same point in 2009.

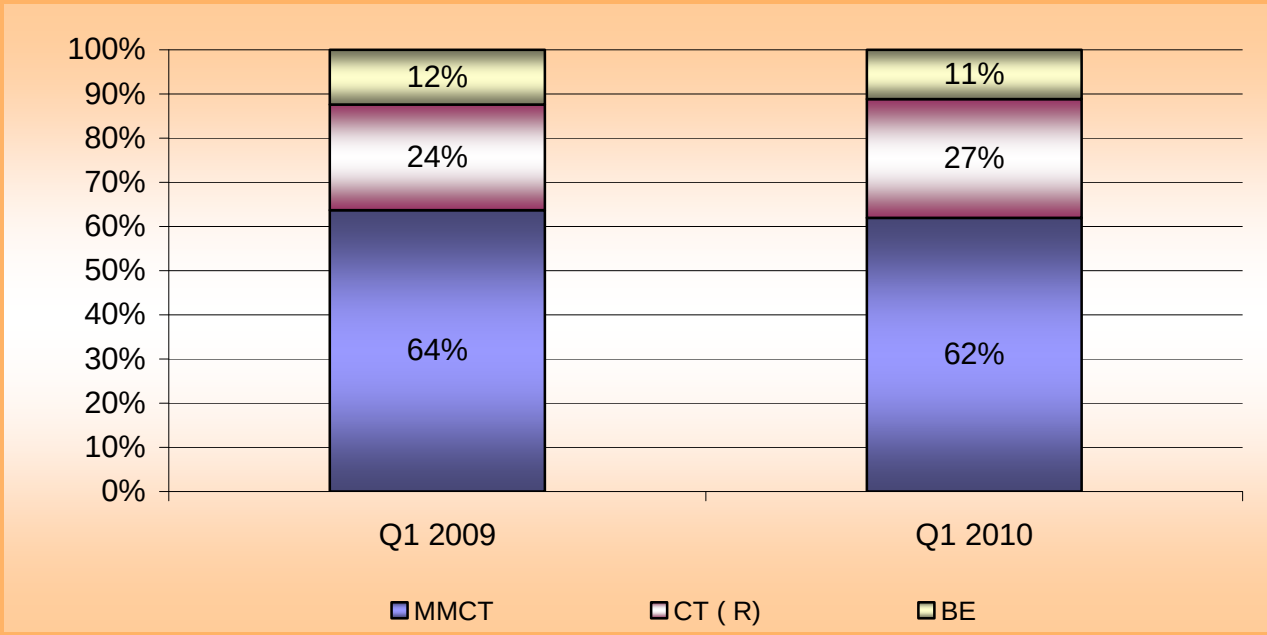
The number of bioequivalence studies (BE in Figure 1) in the first quarter of 2010 stood at 15 new trials, one study up over last year's figure.

Figure 1. Clinical trials approved by RZN in Q1 2010



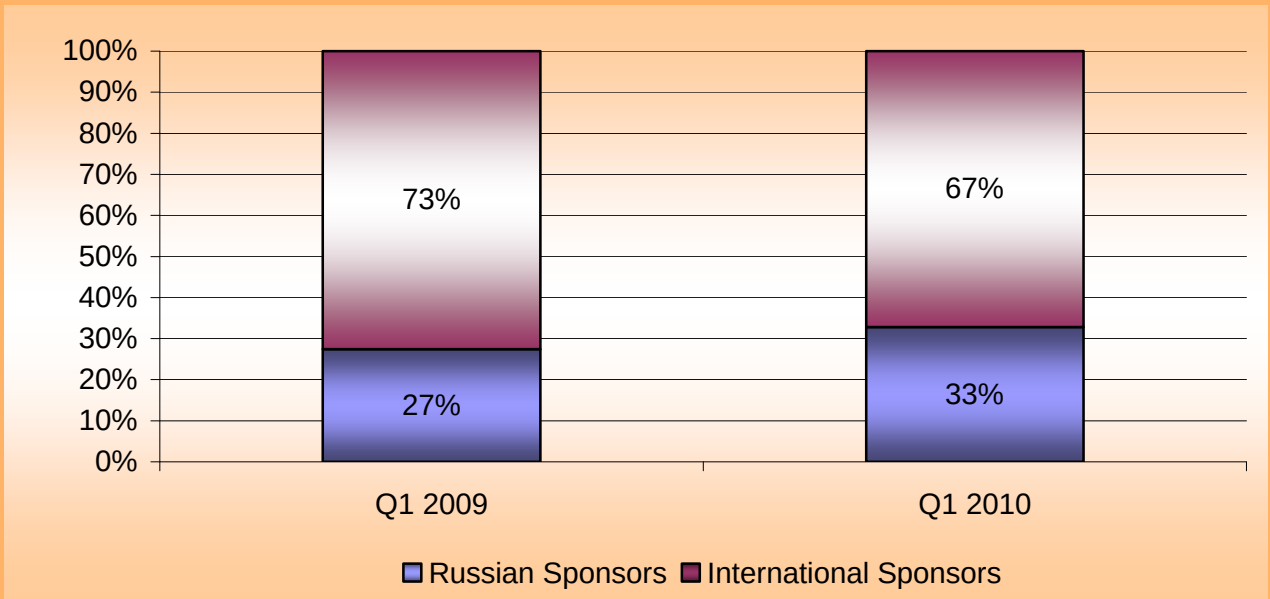
The proportions between different study types (multinational multi-center clinical trials, local studies and bioequivalence trials) did not change significantly over the same point in 2009 and will doubtfully change in the near future. Despite the increase in the number of studies, the share of multinational multi-center clinical trials slightly decreased from last year's figure and stood at 62% of the total number of clinical trials approved by RZN in the first quarter of 2010. The shares of the local trials and bioequivalence studies in Q1 2010 stood at 27% and 11% of the total number of studies, respectively, while they accounted to 24% and 12% in Q1 2009.

Figure 2. Clinical trials by type in Q1 2010



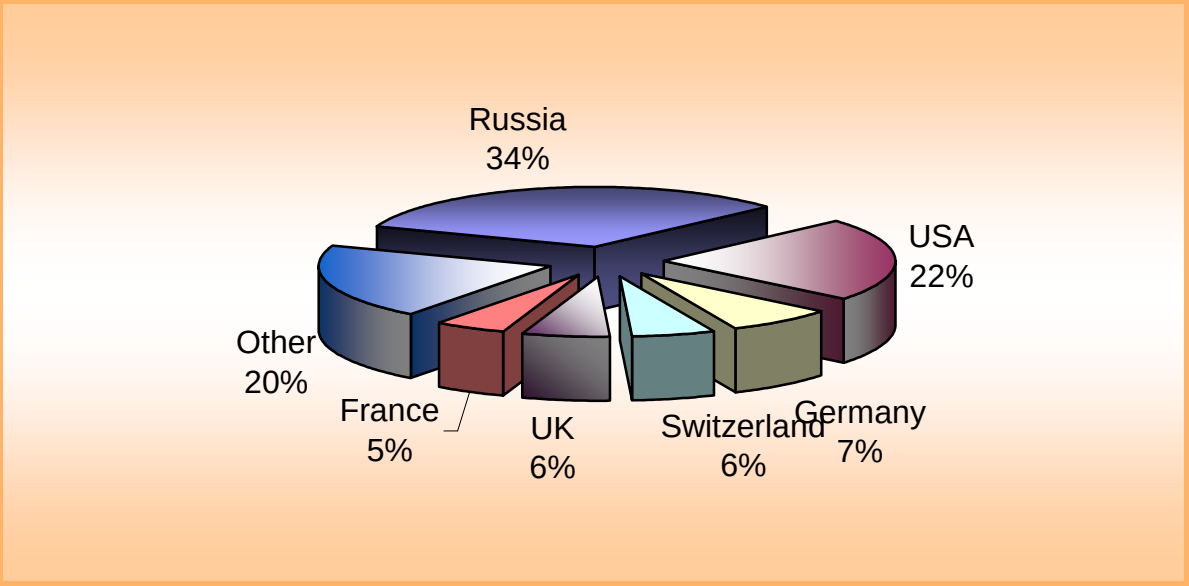
The lion's share of clinical trials in Russia is being sponsored by foreign companies - 67% of the total number of new studies in Q1 2009. The share of local sponsors increased by 5% over the last year figure and accounted up to the one third of the total number of studies.

Figure 3. Russian and International sponsors in Q1 2010



Clinical trials in Russia in Q1 2010 were sponsored by companies from 20 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 (44) were initiated by Russian sponsors, American sponsors with 30 studies took the runner-up place, they are followed by German sponsors with 10 trials, eight new studies were instigated by the UK and Swiss manufacturers, and the top six is concluded by French sponsors with seven new studies in Q1 2010.

Figure 4. Countries presented on the Russian clinical trials market in Q1 2010

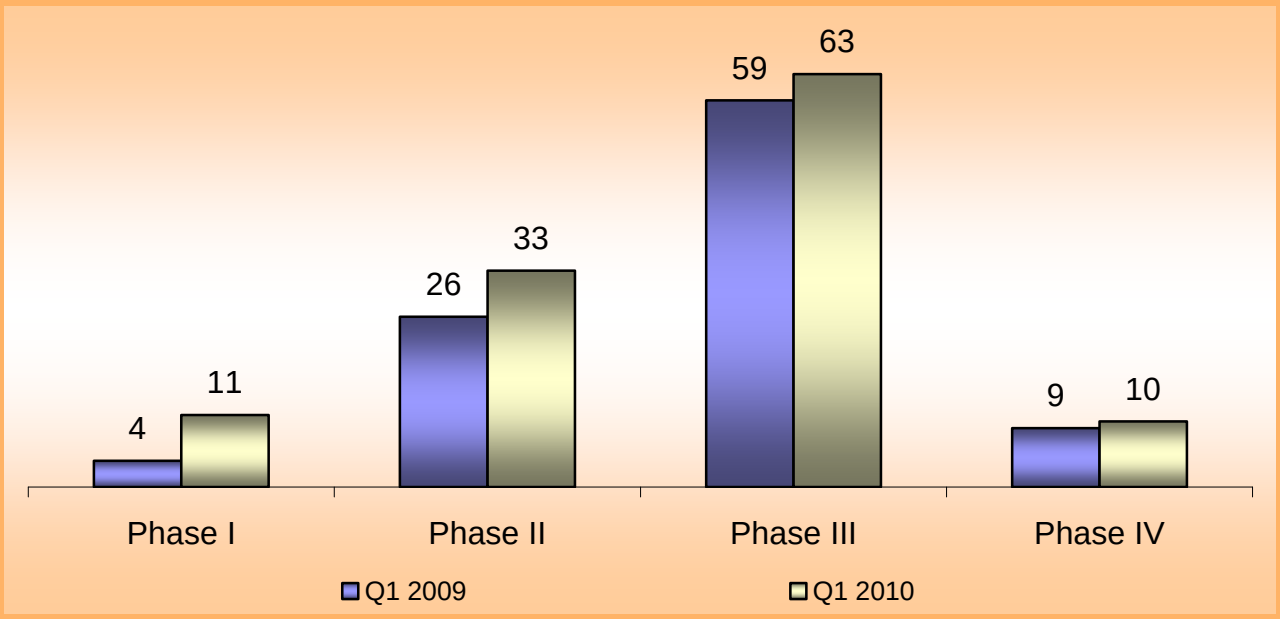


Belgium, Denmark, India, Ireland, Italy, Canada, Korea, the Netherlands, Norway, Finland and Sweden are represented among others.

Clinical trials by Phase

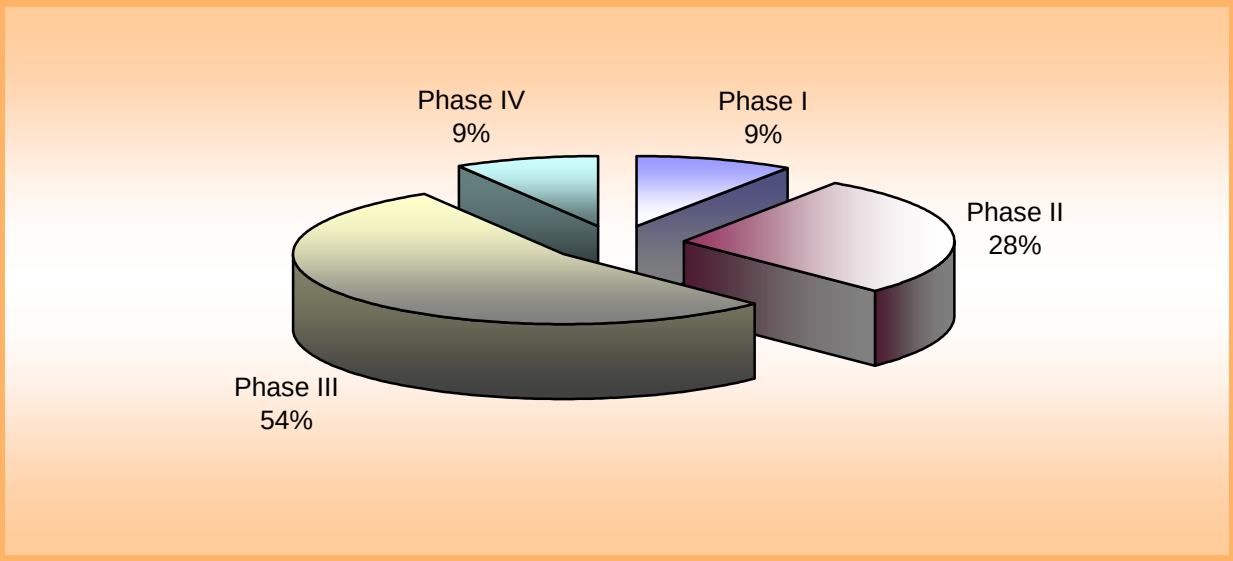
Eleven new Phase I clinical trials were launched in the first quarter of 2010; seven trials up over the corresponding quarter of last year. The number of the Phase II trials increased by 27%, from 26 trials in the first quarter of 2009 to 33 studies in the first quarter of 2010. The number of Phase III trials demonstrated a 7% increase over last year number, up from 59 to 63 studies. The number of Phase IV trials also slightly increased from 9 in Q1 2009 to 10 in Q1 2010.

Figure 5. Clinical trials in Russia in Q1 2010 by phase



As shown in Figure 6, the share of Phase III trials in Q1 2010 stood at almost 54% of the total number of studies, the share of Phase II trials accounted at 28%, Phase IV trials stood at nine per cent, the same as the share of Phase I studies.

Figure 6. The proportions between study phases in Russia in Q1 2010



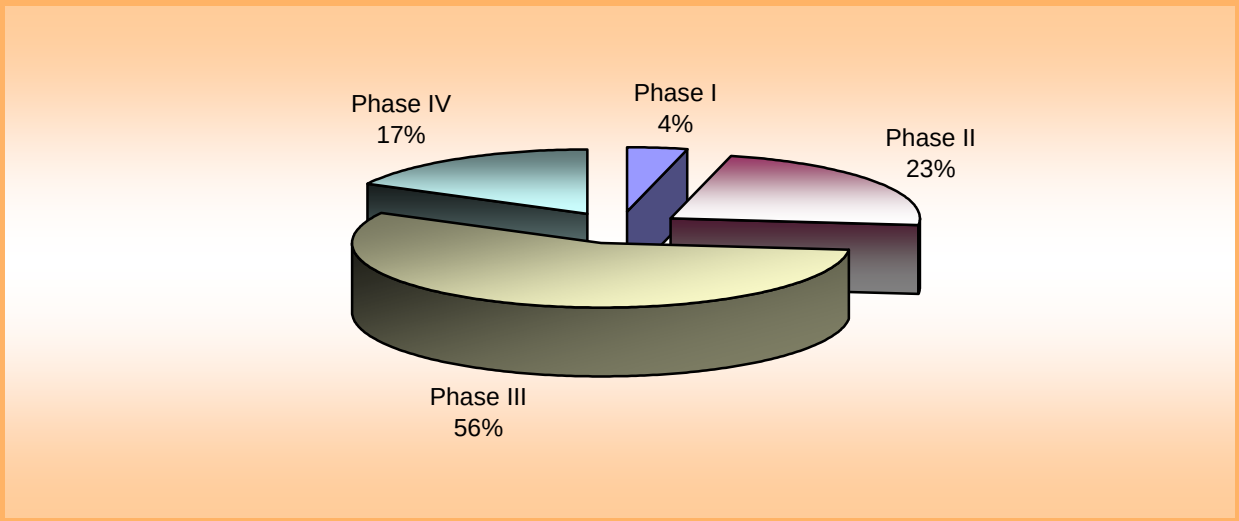
The number of patients which are planned to be enrolled in the Phase II-IV trials launched in the first quarter of 2010 stood at 13,016 patients, 2,232 patients up over the last year number of 9,784 patients.

Five hundred and eleven subjects will be recruited in Phase I trials; 2,945 patients – in Phase II trials; 7,315 subjects – in Phase III studies and 2,245 patients will be enrolled in Phase IV studies.

The minimal number of subjects in a single study is five, the maximum number is 1,125.

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

Figure 7. The number of patients in Q1 2010 by study phase



The duration of the shortest trial is three months, the longest one will take six years.

Rating of international sponsors

The Swiss *Novartis* sponsoring seven new studies is on the top of the heap in the first quarter of 2010. *GlaxoSmithKline* with six new trials in Q1 2010 took the runner-up place. It is followed by Pfizer also sponsoring six new studies, but with less number of patients, and French *Servier* with four new studies. The top five is concluded by *Merck & Co.* having three new studies in Q1 2010.

Top five international sponsors by the number of new studies in Q1 2010 are presented in Table 1.

Table 1. Top-5 international study sponsors in Q1 2010

№	Sponsor	No. of trials	No. of patients	No. of sites
1	Novartis	7	368	41
2	GlaxoSmithKline	6	2180	63
3	Pfizer	6	340	33
4	Servier	4	445	26
5	Merck & Co.	3	236	12

Rating of Russian sponsors

The Russian pharmaceutical company OAO *Sti-Med-Sorb* sponsoring four new clinical trials enrolling 290 patients in five sites, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in the first quarter 2010.

OOO *Geropharm* with three new trials and 480 subjects in 11 sites, took the runner-up place. It is followed by ZAO *Infamed*, ZAO *Biocad* and AKO *Sintez* with two studies each differing only in the number of patients and sites.

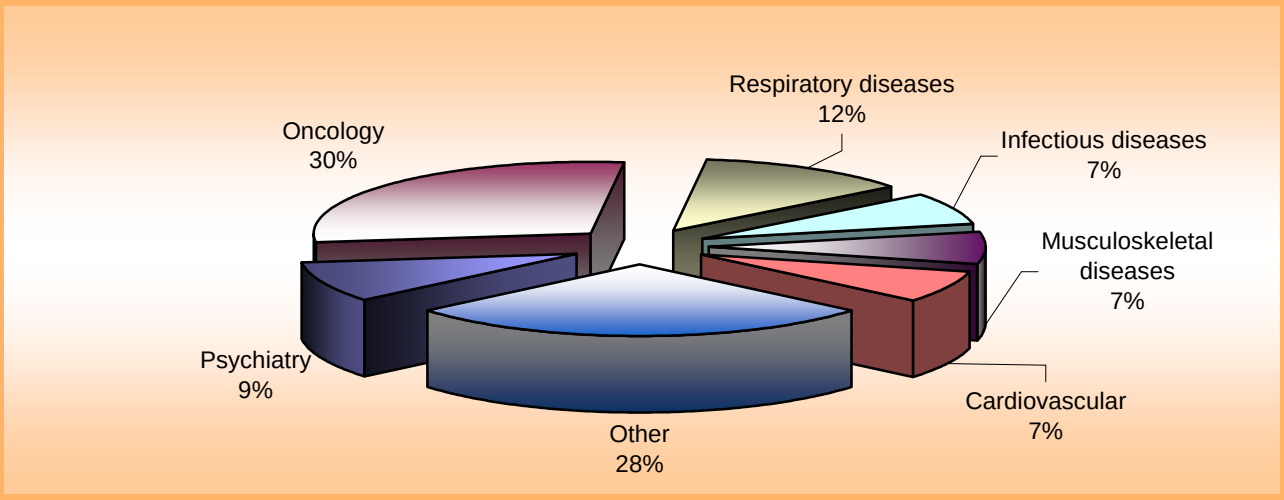
Table 2. Top-5 Russian study sponsors in Q1 2010

№	Sponsor	No. of trials	No. of patients	No. of sites
1	Sti-Med-Sorb	4	290	5
2	Geropharm	3	480	11
3	Infamed	2	160	4
4	Biocad	2	127	5
5	Sintez	2	110	3

Therapeutic areas of clinical trials in Russia in Q1 2010

Sixty nine per cent of the new studies in Q1 2010 were conducted in the six leading therapeutic areas. The maximum number of trials (28) were initiated in Oncology; 12 clinical trials in Respiratory diseases; nine new studies in Psychiatry; seven new studies in Cardiovascular, Infectious and Musculoskeletal diseases were initiated in Q1 2010. The proportions between different therapeutic areas are shown in Figure 8.

Figure 8. Clinical trials in Russia in Q1 2010 by therapeutic area



Clinical trials results

The Center for Drug Evaluation and Research (CDER) of the FDA approved 26[1] new drugs during Q1 2010; four of them are new molecular entities (NME); others are the new dosages, manufacturers or indications of the already marketed drugs. The Table 3 represents seven of the drugs which were tested in clinical trials in Russia.

Table 3. New Drugs approved by FDA in Q1 2010 and tested in Russian sites

Approval date	Drug	Manufacturer
01/04/2010	Lirica (Pregabalin)	**Pfizer**
01/08/2010	Actemra (Tocilizumab)	**Genentech**
01/20/2010	Dutasteride (Dutasterid, Tamsulosin hydrochloride)	**Smithkline Beecham**
02/10/2010	Ritonavir (Ritonavir)	**Abbott Labs**
02/19/2010	Mirapex ER (Pramipexole dihydrochloride)	**Boehringer Ingelheim**
02/26/2010	VPRIV (Velaglucerase alfa)	**Shire Human Genetic**
03/10/2010	Trelstar (Triptorelin pamoate)	**Watson Labs**
Source: CDER FDA http://www.fda.gov/cder		

During the period from January 1 to March 31 2010 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMEA) reviewed 13[2] applications to market drugs in the EU. No negative opinion was adopted for any of the drugs which had been approved earlier. Three 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 EMEA in Q1 2010 and tested in Russian sites

Approval date	Drug	Manufacturer
20/01/2010	Arzerra (Ofatumumab)	Glaxo Group Ltd
18/02/2010	Tyverb (Lapatinib)	Glaxo Group Ltd
18/03/2010	Tarceva (Erlotinib)	Roche Registration Limited

[1] CDER FDA http://www.fda.gov/cder
[2] CHMP EMEA http://www.emea.europa.eu/index/indexh1.htm

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 Q1 2010.