

Clinical Trials in Russia
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Executive Summary

The Ministry of Health and Social Development of the Russian Federation (MoH) approved 114 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2011, demonstrating a 36% decrease compared to the same point last year.

The number of multinational multi-center clinical trials increased by 18% over 2010 and stood at 91 new studies in Q2 2011.

The share of multinational multi-center clinical trials stood at 80% of the total number of clinical trials in Q2 2011, while the local and bioequivalence studies amounted to 12% and 8%, respectively.

Clinical trials in Russia in Q2 2011 were sponsored by companies from 20 countries. The maximum number of trials (39) was initiated by American sponsors. Russian sponsors with 14 new studies took the runner-up place, followed by UK and Swiss sponsors with 13 trials each, and the top five is concluded by Austrian sponsors with five new studies in Q2 2011.

Three new Phase I studies were launched in Q2 2011, which is 10 trials less than in Q2 2010. The number of the Phase II trials fell by 20% and stood at 23 new studies in Q2 2011. The number of Phase III trials also decreased from 83 to 64 studies, almost 20% less than in Q2 2010. Phase IV trials stood at the same level of 14 new studies a quarter.

The number of patient planning to be enrolled in Phase I-IV trials launched in Q2 2011 stood at 11,203, a 27% drop from Q2 2010 figure, when 15,287 patients were planned to be enrolled.

British *GlaxoSmithKline* sponsoring seven new studies is on the top of the heap in Q2 2011. *Roche* with six new trials took the runner-up place, followed by *Lilly* and *Boehringer* each having five new trials differentiated by the number of patients. Top five is concluded by *Merck & Co.* with four new studies in Q2 2011.

Russian *Materia Medica* sponsoring two new studies was ranked number one among domestic pharmaceutical manufacturers by the number of new studies in Q2 2011. *The Russian Center of Cardiology* with two new trials and fewer patients took the runner-up place, followed by *Vifiteh*, *Microgen* and *Petrovax* each having one new trial and different number of patients in Q2 2011.

More than a half of new studies in Q2 2011 were instigated in seven leading therapeutic areas: the largest number of studies was initiated in Oncology (21); eight new studies in Cardiology and Infectious diseases; seven studies in Rheumatology; five new studies in Endocrinology and Pulmonology and four new clinical trials were instigated in Psychiatry.

The Center for Drug Evaluation and Research (CDER) of the FDA approved 31 new drugs during Q2 2011, and seven of them were studied in clinical trials conducted in Russia.

During the second quarter of 2011 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 11 new drug applications, four of which were tested in Russian sites.

Thirty-one inspections were conducted in the Russian sites by Roszdravnadzor during the second quarter 2011, and in fifteen cases violations of the clinical practice were found. No FDA inspections were conducted in Russia during Q2 2011.

Clinical Trials by Type and Manufacturing Country

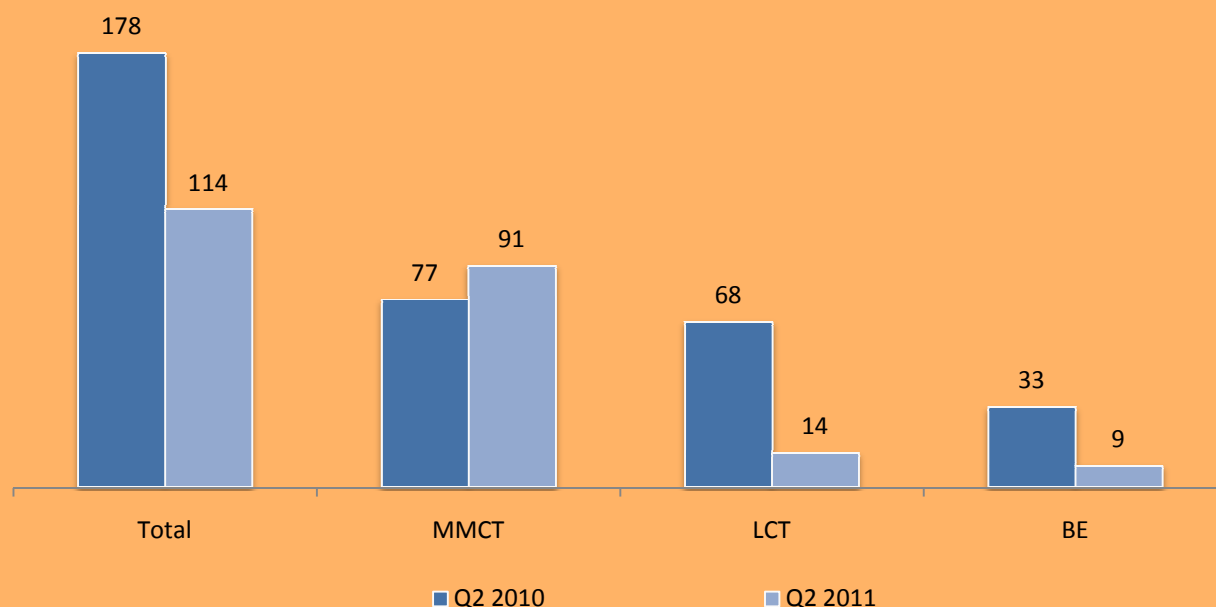
The Russian MoH approved 114 new clinical trials of all types including local and bioequivalence studies during the second quarter of 2011, demonstrating a 36% decrease compared to the same point last year.

As shown in Figure 1, the main contribution into the total number of studies is made by multinational multi-center clinical trials (MMCT), the number of these studies increased by 18% over 2010 and stood at 91 new studies in Q2 2011.

The number of the local clinical trials (LCT) conducted in Russia by domestic and foreign sponsors decreased from 68 to 14 clinical trials, almost 80% drop from last year's figure.

The number of bioequivalence studies (BE) in Q2 2011 stood at nine new trials, 73% less than in Q2 2010.

Figure 1. Clinical trials in Russia in Q2 2011

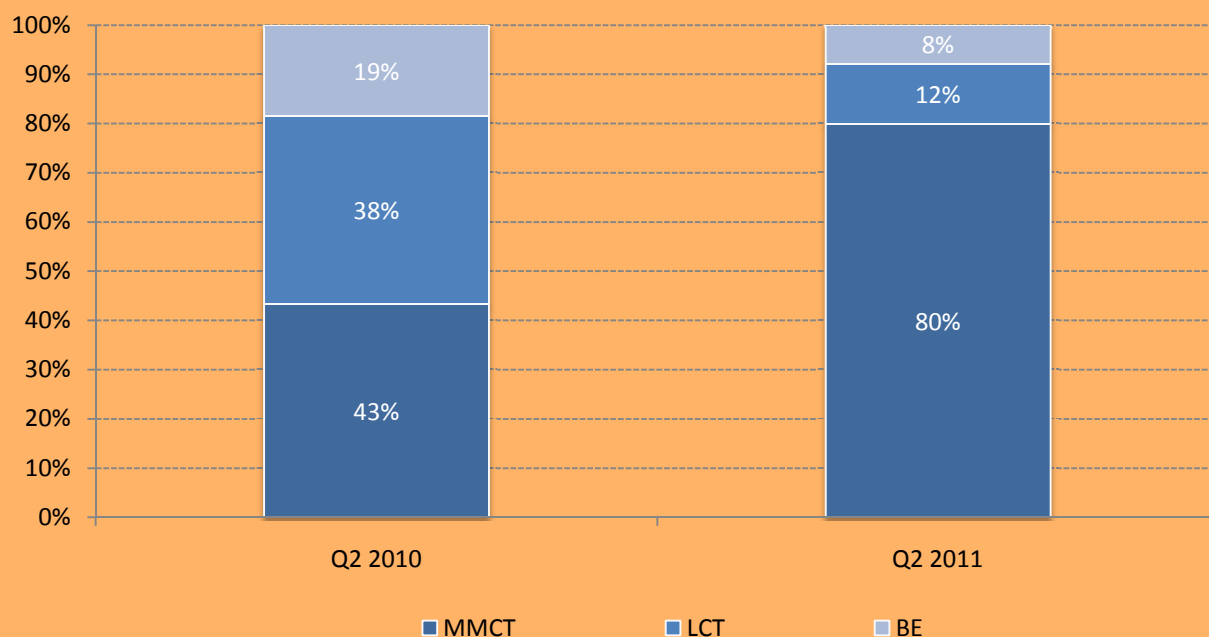


The proportions between different study types (multinational multi-center clinical trials, local studies and bioequivalence trials) notable changed since last year (see Figure 2).

The share of multinational multi-center clinical trials increased dramatically from 43% to 80% of the total number of clinical trials approved in Q2 2011.

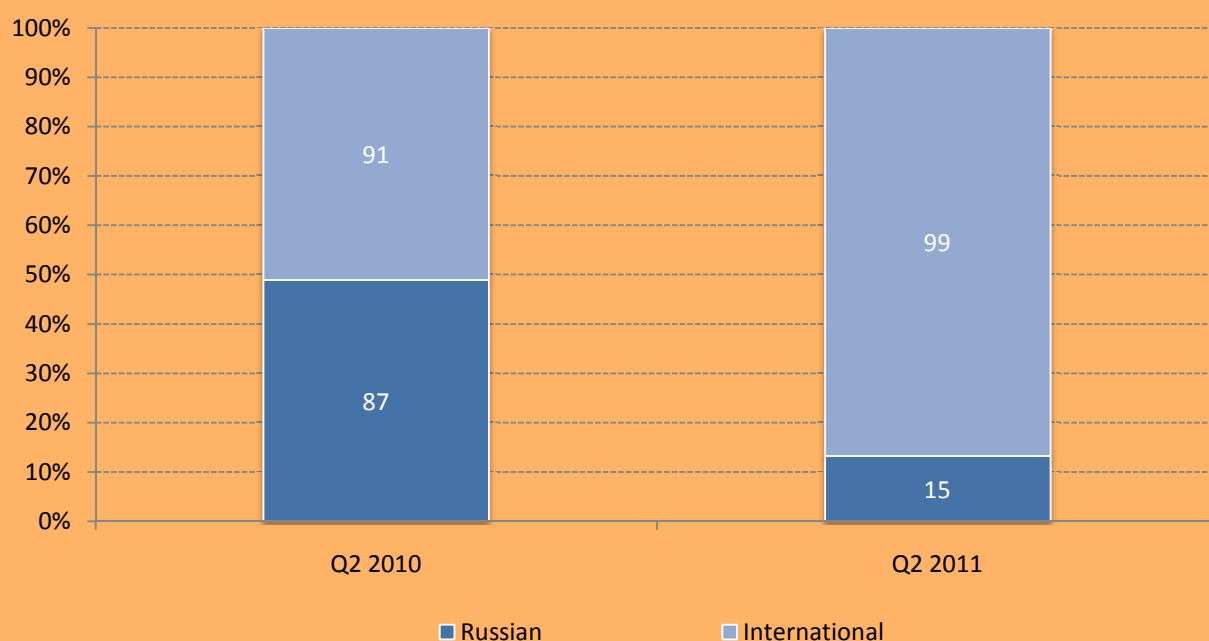
The share of the local trials decreased from 38% in Q2 2010 to 12% of the total number of studies in Q2 2011, and the share of bioequivalence studies also decreased from 19% to 8% of the total number of trials approved during the second quarter of 2011.

Figure 2. Clinical trials by type in Q2 2011



The major share of clinical trials in Russia is sponsored by foreign companies which received 99 study approvals, or 87% of the total number of new studies in Q2 2011. The share of studies of local manufacturers decreased from 49% in Q2 2010 to 13% in Q2 2011, from 87 to 15 studies, respectively.

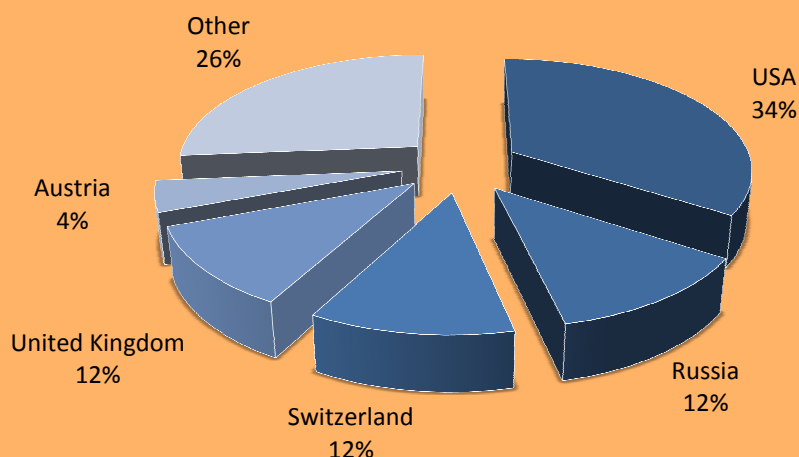
Figure 3. Russian and International sponsors in Q2 2011



Clinical trials in Russia in Q2 2011 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 (39) was initiated by American sponsors. Russian sponsors with 14 new studies took the runner-up place, they are followed by UK and Swiss sponsors with 13 trials each, and the group of leaders is concluded by Austrian sponsors with five new studies in Q2 2011.

Figure 4. Countries presented on the Russian clinical trials market in Q2 2011



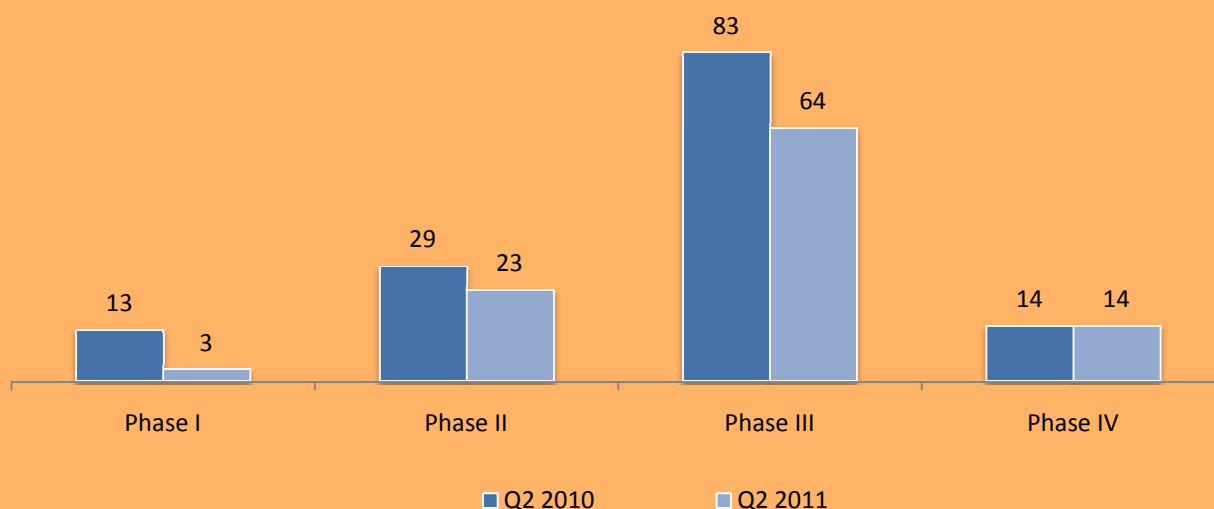
Among others are: Argentina, Belgium, Germany, Denmark, Ireland, India, Israel, Italy, Kazakhstan, Portugal, Slovenia, Sweden, France and Japan .

Clinical trials by Phase

Three new Phase I clinical trials were launched in Q2 2011, which is 10 trials less than in Q2 2010. The number of the Phase II trials fell by 20% and stood at 23 new studies in Q2 2011.

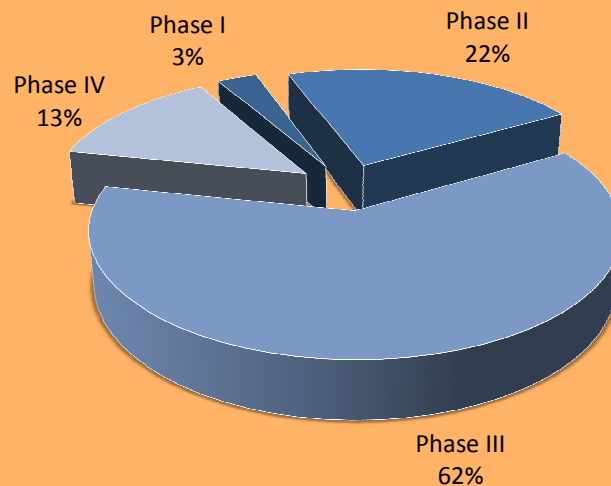
The number of Phase III trials also decreased from 83 to 64 studies, almost 20% less than in Q2 2010. Phase IV trials stood at the same level at 14 new studies a quarter.

Figure 5. Clinical trials in Russia in Q2 2011 by phase



As shown in Figure 6, the share of Phase III trials in 2010 stood at 62% of the total number of studies, the share of Phase II trials accounted at 22%, Phase IV trials stood at 13%, and the share of Phase I studies amounted to three per cent.

Figure 6. The proportions between study phases in Russia in Q2 2011



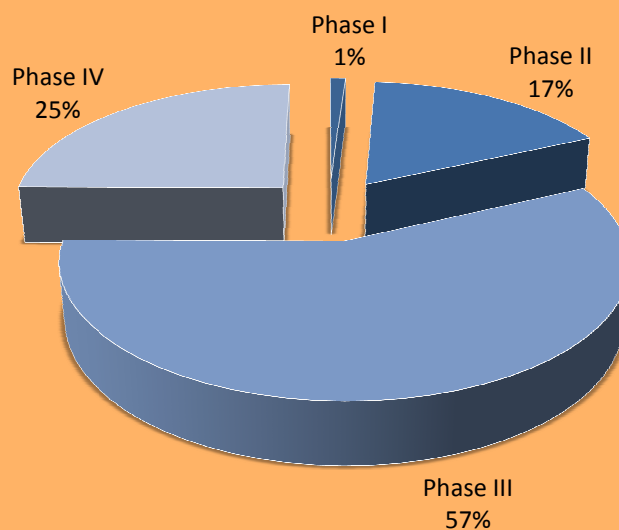
The number of patients which are planned to be enrolled in Phase I-IV trials launched in Q2 2011 stood at 11,203, a 27% drop from Q2 2010 figure, when 15,287 patients were planned to be enrolled.

One hundred and eight subjects will be recruited in Phase I trials; 1,924 patients – in Phase II trials; 6,386 subjects – in Phase III studies and 2,785 patients will be enrolled in Phase IV studies.

The minimal number of subjects in a single study is eight, the maximum number is 1,400.

The proportion of the number of patients between different Phases is shown on Figure 7. Only studies in which phase is specified were included.

Figure 7. The number of patients in Q2 2011 by study phase



Rating of international sponsors

GlaxoSmithKline sponsoring 7 new studies is on the top of the heap in Q2 2011. *Roche* with six new trials took the runner-up place; it is followed by *Lilly* and *Boehringer Ingelheim* each having five new trials and differentiating in the number of patients. Top five is concluded by *Merck & Co.* with four new studies in Q2 2011.

Top five international sponsors by the number of new studies in Q2 2011 are presented in Table 1.

Table 1. Top-5 international study sponsors in Q2 2011

<i>No</i>	<i>Company Name</i>	<i>No. studies</i>	<i>No. patients</i>
1	GlaxoSmithKline	7	883
2	Roche	6	518
3	Lilly	5	255
4	Boehringer Ingelheim	5	201
5	Merck & Co.	4	460

Rating of Russian sponsors

The Russian company *OOO "NPF Materia Medica"* sponsoring two new clinical trials, ranked number one among domestic pharmaceutical manufacturers by the number of new studies in Q2 2011. *FGU RKNPK (The Russian Center of Cardiology)* with two new trials and fewer patients took the runner-up place.

It is followed by *ZAO "Vifiteh"*, *FGUP "Microgen"* and *OOO "NPO Petrovax Pharm"* each having one new trial and different number of patients in Q2 2011.

Table 2. Top-5 Russian study sponsors in Q2 2011

<i>No</i>	<i>Company Name</i>	<i>No. studies¹</i>	<i>No. patients</i>
1	Materia Medica	2	350
2	RKNPK (Cardiocenter)	2	110
3	Vifiteh	1	120
4	Microgen	1	100
5	Petrovax	1	80

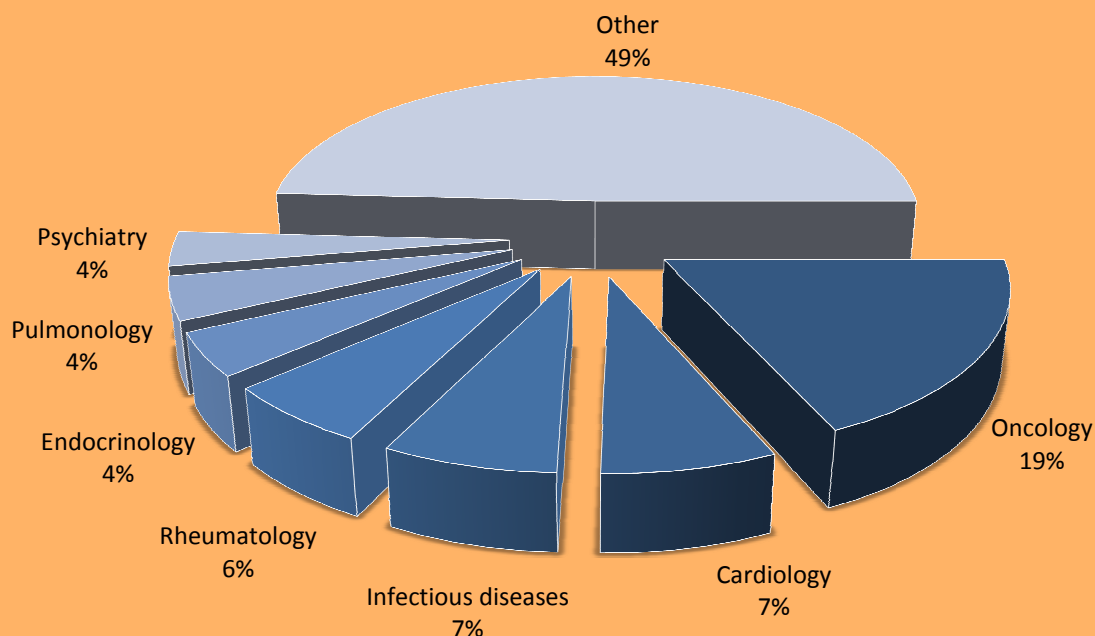
¹ Excluding BE studies

Therapeutic areas of clinical trials in Russia in 2010

More than a half of new studies in Q2 2011 were initiated in seven leading therapeutic areas: the largest number of studies has been initiated in Oncology (21); eight new studies were instigated in Cardiology and Infectious diseases; seven studies - in Rheumatology; five studies – in Endocrinology and Pulmonology and four new clinical trials were instigated in Psychiatry.

The proportions between different therapeutic areas are shown in Figure 8.

Figure 8. Clinical trials in Russia in Q2 2011 by therapeutic area



Clinical trials results

The Center for Drug Evaluation and Research (CDER) of the FDA approved 31 new drugs during Q2 2011; nine of them are new molecular entities (NME); others are new dosages, manufacturers or indications of the already marketed drugs. Seven drugs were studied in clinical trials conducted in Russia.

The Table 3 represents drugs which were approved by FDA and were being tested in clinical trials in Russia in Q2 2011.

Table 3. New drugs approved by FDA in Q2 2011 and tested in Russian sites

Appr.date	Drug (active ingredient)	Company	
06\04\2011	Horizant (Gabapentin Enacarbil)	GSK	
06\04\2011	Vandetanib (Vandetanib)	IPR Pharms	
29\04\2011	Androgel (Testosterone)	Abbott	
12\05\2011	Abacavir Sulfate; Lamivudine	Cipla	
08\06\2011	Docetaxel (Docetaxel)	Accord	
13\06\2011	Ceftazidime	B Braun	
29\06\2011	Docetaxel (Docetaxel)	Sandoz	
			Source: FDA

During the second quarter of 2011 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 11 new drug applications. Negative opinion was adopted for two drugs. Four of the drugs which received positive opinions were (or are being) tested in clinical trials in Russia (See Table 4).

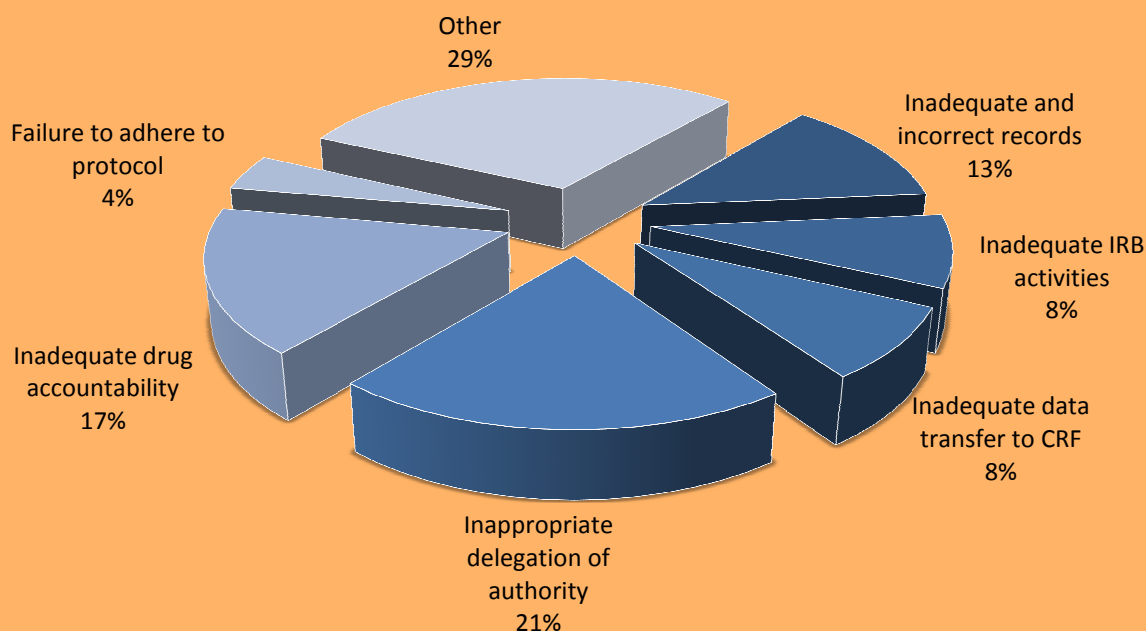
Table 4. New Drugs approved by EMA in Q2 2011 and tested in Russian sites

<i>Appr. date</i>	<i>Drug (active ingredient)</i>	<i>Manufacturer</i>
14/04/2011	Bydureon (exenatide)	Lilly
19/05/2011	Benlysta (belimumab)	GSK
19/05/2011	Xgeva (denosumab)	Amgen
19/05/2011	Yervoy (ipilimumab)	BMS
<i>Source: EMA</i>		

Roszdraznadzor inspections

According to the Roszdraznadzor, 31 inspections were conducted during the second quarter 2011. In fifteen cases violations of the clinical practice were found. The analysis of findings is shown in the Figure below.

Figure 9. Findings during Roszdraznadzor inspections in Q2 2011



FDA inspections

According to the FDA data, no FDA inspections were conducted in the Russian investigative sites during the second quarter of 2011.