Russian Revolution

Igor Stefanov at Synergy Research Group analyses the facts and figures surrounding clinical trials in Russia in 2007

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Russia's clinical trials market has been enjoying significant growth since the early 1990s when the first trials were introduced. This growth has been especially notable since 1997, in which time the number of studies conducted in Russia has nearly tripled. It is also of interest that the share of international multi-centre studies has substantially increased during the last decade – from 35 per cent in 1997 to 66 per cent in 2007 – a very good indicator for an emerging clinical research market.

The data obtained from Russian investigator sites is now fully accepted by the US FDA and the European Agency for the Evaluation of Medicinal Products (EMEA). Indeed, six out of nineteen drugs approved by the FDA in 2007 had been developed with data coming collected during Russian studies (1). The high quality of Russian investigator sites is also confirmed by 36 FDA inspections conducted in Russia since 1995, with no major findings in 35 cases – the lowest deficiency rate among emerging markets (2).

Another factor behind the recent growth is that pharmaceutical manufacturers have begun to regard Russia as a potential new market for their drugs. According to the data provided by DSM Group, the total sales volume of the Russian pharmaceutical market in 2006 amounted to US $12.3 billion (3).

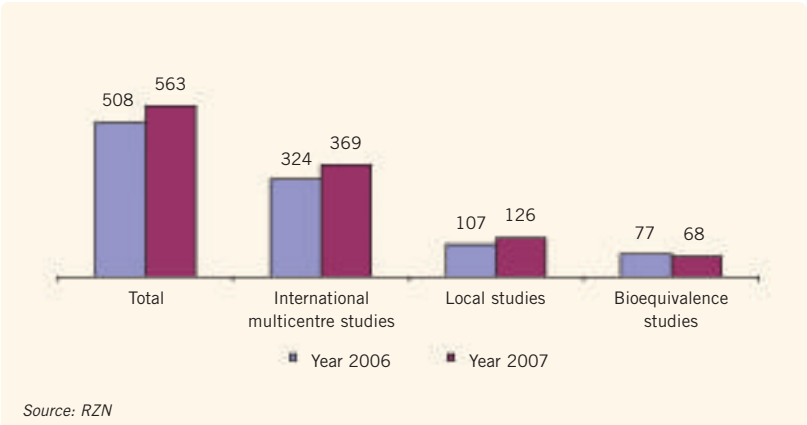
All of these factors – along with Russia's traditionally high patient recruitment rate, transparent regulatory system and stable political climate – make the Russia of today one of the most attractive clinical research markets in the world. The figures themselves aim to provide an accurate snapshot of the clinical trials market in Russia at the end of 2007.

THE 2007 MARKET

During 2007 the Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (alias RosZdravNadzor, or RZN) approved 563 new clinical trials in Russia showing an 11 per cent increase over the past year (4). Sixty-six per cent of trials are international multicentre studies conducted by foreign sponsors; 22 per cent are local clinical trials that are conducted only in Russia by local or international sponsors; and the remaining 12 per cent are bioequivalence studies mostly sponsored by Russian pharmaceutical manufacturers. The number of international multicentre studies grows even faster than the total number of clinical trials; thus in 2007 it stands at 369 – or 14 per cent – above the number in the previous year.

2007 experienced a big increase in the number of early phase studies: when compared to 2006, the number of Phase I

Figure 1: Clinical trials in Russia approved by RZN in 2007



Source: RZN

Figure 2: Clinical trials in Russia in 2007, by phase

Source: RZN

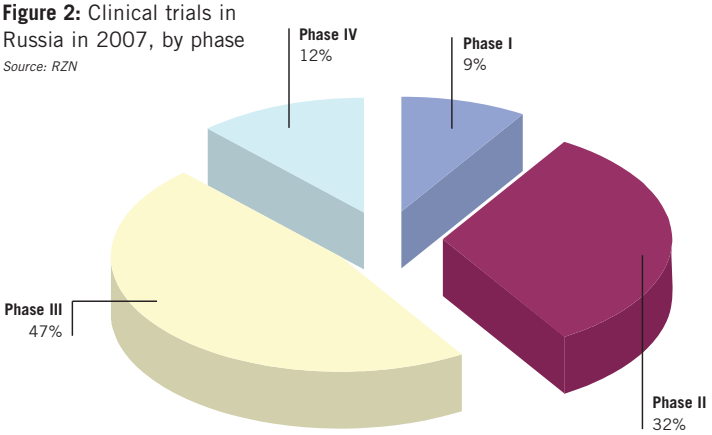


Figure 3: Clinical trials in Russia in 2007, by sponsor's country of origin

Source: RZN

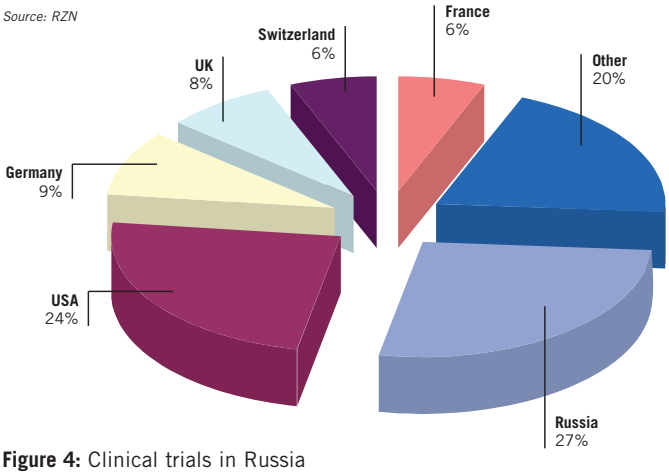
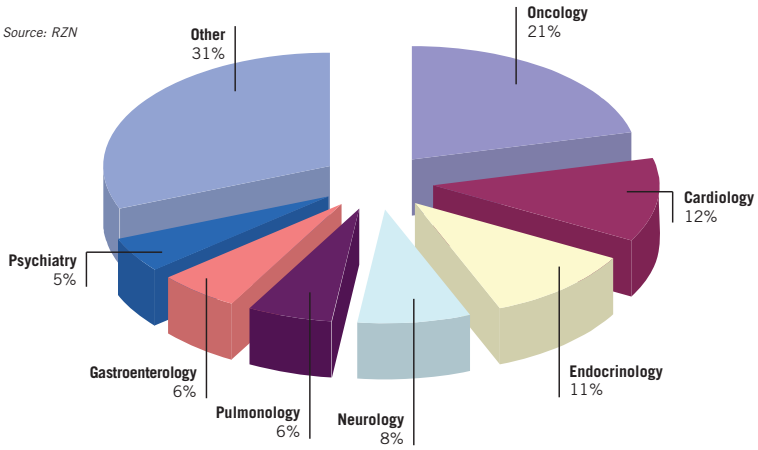


Figure 4: Clinical trials in Russia in 2007, by therapeutic area

Source: RZN



studies increased by 80 per cent – totaling 47 – and the number of Phase II studies rose to 160 studies, with a similarly remarkable 44 per cent increase. The number of Phase III trials slightly decreased over from 232 to 230, and the number of Phase IV trials increased by 35 per cent and amounted to 58 trials. Figure 2 illustrates the proportion of different study phases during 2007.

The number of patients planned for recruitment in clinical trials approved in 2007 amounted to 61,925 subjects. Compared to 2006, that figure grew by 34 per cent. The minimum number of patients is four, while the maximum is 5,000. The average study duration is 21 months, the longest trial will take 92 months, and the minimal study duration is two months.

SPONSORS

The studies were initiated by 54 Russian and 144 other companies from 29 different countries. These include: Japan, Sweden, Ireland, Portugal, Pakistan, China, Denmark, Spain, Hungary, Israel, India and even Puerto Rico. Eighty per cent of all studies were initiated by sponsors from the top six countries, shown in Figure 3.

Russian sponsors initiated 157 new clinical trials (including bioequivalence studies), followed by US sponsors with 133 studies, German manufacturers with 49 studies, then Swiss and French companies which started 33 and 31 new studies, respectively.

The ranking of sponsors in terms of the number of clinical trials initiated in 2007 shows that foreign companies remain the major 'players' in the clinical trials market in Russia. The French company sanofi-aventis is on top of the pile, with the highest number of 33 trials. Nevertheless, in terms of number of patients, the Russian Microgen with 5,960 subjects ranks number one. Tables 1 and 2 (see page 18) list the top five international and Russian sponsors, respectively.

THERAPEUTIC AREAS

The most popular therapeutic areas of the clinical trials in Russia in 2007 are presented in Figure 4. Oncology is still the number one area of interest for the industry, with the share increased from 17 per cent in 2006 to 21 per cent in 2007, and the number amounting to 106. The total number of patients to be recruited in oncology studies was 8,203 in 2007.

Source: Vlad Popov

Source: Ekaterina Kholodkova

Table 1: Top five foreign sponsors of clinical trials in Russia in 2007

Rating	Company name	Number of studies	Number of subjects
1	sanofi-aventis	33	3,131
2	GlaxoSmithKline	24	3,442
3	Novartis	19	1,418
4	Roche	18	1,790
5	Merck & Co	17	2,642

Table 2: Top five Russian sponsors of clinical trials in Russia in 2007

Rating	Company name	Number of studies	Number of subjects
1	Doctor N	7	420
2	Microgen	6	5,960
3	NIOPIK	6	360
4	Biocad	6	348
5	Nizhpharm	5	280

Sixty-one new studies recruiting 15,267 subjects were started in cardiology, and 53 new endocrinology studies will recruit 5,556 patients.

INVESTIGATOR SITES AND DATA QUALITY

During 2007 the RZN accredited 83 new investigator sites; the total number of sites in Russia currently stands at 833. The FDA conducted five inspections of Russian sites in 2007 with no major findings. In three cases no objectionable conditions or practices were found (no action indicated – NAI). Two inspections ended with a result of voluntary action indicated (VAI). In addition to the FDA inspections, there were 31 local RZN inspections in 2007. The purpose of RZN inspection is to make sure that the site conducts clinical trials in accordance with the current Russian legislation and good clinical practice (GCP).

Another mark of the quality of data collected from Russian sites is that six of 19 new molecular entities (NME) approved by the FDA in 2007 have been tested in clinical trials with high participation from Russian sites. These are: Tekturna (Novartis), Tykerb (GSK), Doribax (J&J), Ixempra (BMS), Tasigna (Novartis) and Mircera (Roche). The fact that the big pharmaceutical manufacturers have taken the risk of trialling new molecules in Russia is proof of their trust and commitment to the clinical trials market in Russia, and an important sign of its bright prospects. The growth statistics demonstrated in 2007 suggest that Russian trials will continue to exert a great force in the international market. ◆

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