



Clinical trials in Russia

Tatiana Fedorova, MD, MPH, PhD, AP
Country Manager (General Director)



Russian Federation

Russia is the country with the largest territory and one of the highest population size – the seventh in the world.



Russian Federation

The population is highly centralized in large cities –
12 of them have more than one million
inhabitants.



Russia and clinical trials

Such demographic and geopolitical status makes Russia an attractive region for conducting large-scale trials involving hundreds or even *thousands of subjects*. At the same time there are many opportunities for clinical trials in *rare diseases and treatment-naïve patients*.



Russian health care system

- The health care system still remains centralized, preserving its Soviet structure - systems of emergency care, primary care, referral to specialists, hospital care, and return to the primary care.
- At present the health care reform in Russia aimed to turn into efficient, modern and widely available system has been announced.



A fundamental characteristic of the Russia

- concentration of both large patient populations and highly professional medical specialists at large hospitals/research centres.
- These centres play a pioneer role in implementation of western medical technologies in Russia (also via participation in multi-national clinical trials).



Russian health care system

- The Russian medical school traditionally provides a very high level of medical education with both practical and research oriented approach.
- There are more than 600,000 medical doctors and more than 50 medical universities, academies, institutions in Russia.



Russian health care system

- Patients are generally hospitalized more often and for a longer period than in Western Europe.
- Patients' attitude to doctors is traditionally characterized by a strong trust of patients in doctors thus in their opinions – the paternalistic model of health care system inherited from the Soviet time.



Clinical trials in RF

- All leading pharmaceutical companies are represented in Russia and other CIS countries, their number is still increasing. The recent tendency is that pharmaceutical companies register their medicines in Russia soon after obtaining the marketing authorisation in the USA or Western Europe.

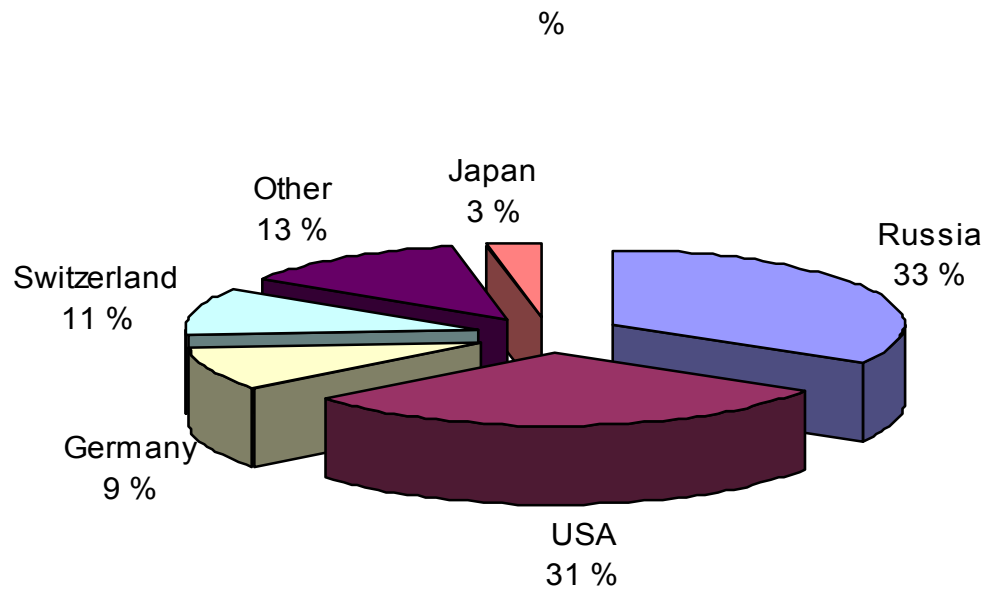


The clinical trials approved in Q2 2009 are sponsored by companies from 16 countries.

- 42 were initiated by Russian sponsors,
- American sponsors -37 studies,
- the Swiss sponsors with 13 trials,
- 12 new trials - the German manufacturers,
- UK sponsors - six new studies,
- Japan sponsors - four new studies.



Countries presented on the Russian clinical trials market in 2009



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



Clinical trials in the RF

- International clinical trials have been conducted in Russia for more than 15 years.
- Nowadays Russia has become a valuable partner in the drug development process: there has been a significant increase in the number of clinical trials with a parallel growth of portion of phase I and II trials that are science intensive and require involvement of the high-qualified medical staff and competent monitoring.



Why Russia?

- Investigators are well educated, experienced and highly motivated medical doctors
- There is a vast population of easily reachable patients interested in participating in clinical trials,
- Overall trial costs are comparable with those in Western Europe,
- Taxes are much lower than in Europe.



Russia – one of the world's remaining growth markets

- Where are the growth markets? Russia, China, India, Turkey, Iran, Brazil.
- Russia's advantage – huge potential and part of Europe.
- “Great potential when the rest of the world is down for acceptable risks,” says one industrial investor.
- “The tax and legal systems offer acceptable risks for us,” says Sir John Brown, Chairman of BP, about to put \$6bn into Russia.

Economist Corporate Network

The Economist

Positive trend in clinical trial approval processes

- They are becoming shorter and more similar to those existing in the US and Europe.
- There is an established infrastructure for successful conduct of the clinical trial: courier, customs and other supportive services, and CROs.



Today's clinical research environment in Russia

- Positive experience over the past years;
- Tremendous growth of the clinical research activity;
- Unsaturated clinical research market;
- High subjects recruitment rate;
- High level of motivation of the investigators and trial subjects;



Today's clinical research environment in R

- Compliance with the national and international standards;
- Strong State control on clinical research;
- Strong adherence to the ethical principles;
- Increase of the clinical research activity in regions.



75% of the new studies approved in Q2 2009 are 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 minimal number of subjects in a single study is five,
the maximum number is 2,300.



Phases of the new trials

- One 1078 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.



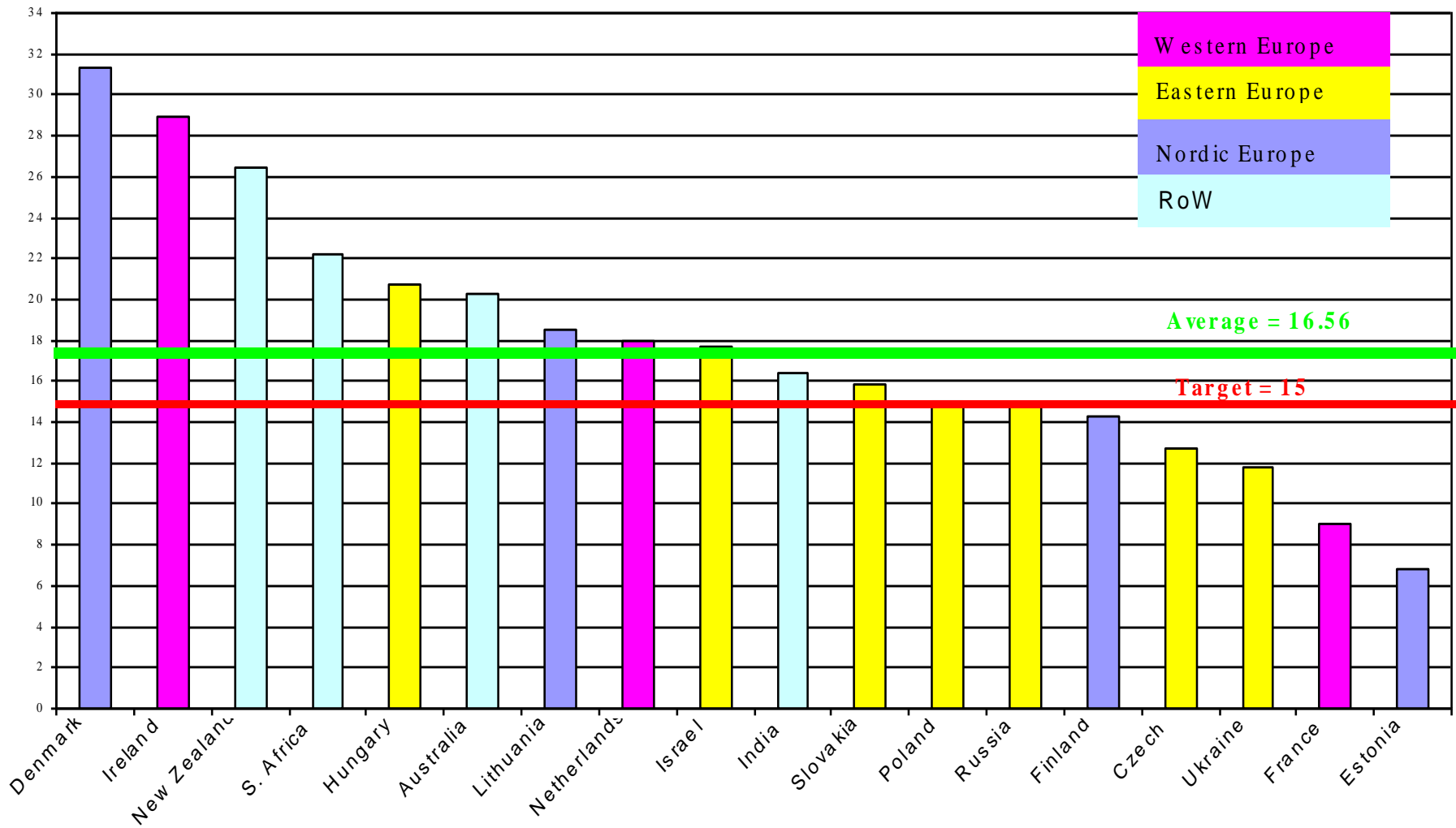
Quality of the clinical trials

High quality of the clinical trials data generated at investigational sites in Russia is a well-known fact that was proved by positive feedback of numerous audits and inspections (incl. FDA inspections).

A low number of queries addressed to the sites in Russia.



Query Rate per 100 Pages



The major competitive strengths will be concentration on the following target groups:

- Postmenopausal women (the Russian women can quit up working at age of 55, so they are more available as the patients)
- Rare diseases (new treatment schemes are more welcomed)
- Epidemiologically dangerous diseases (new treatment schemes are more welcomed)
- Diseases with higher risk of death and/or disability



Specific features of Russia

- Training and skills of the personnel: there is lack of trained scientists with monitoring skills and/or wish to work in clinical trials as monitors;
- Poor English in some medical doctors and in most of the experienced nurses.



Specific features of Russia

In Russia a CRO managing a clinical trial must obtain approvals from the Pharmacological Committee and the federal ethics committee of the Ministry of Health, from a national independent ethics committee, from the Narcotics Committee and the Customs Committee.



Specific features of Russia

- All documents submitted to ECs or RA should be translated into Russian.
- About half of all sites have local ethics committees.
- A Sponsor must obtain insurance from a Russian insurer for each study.



Specific features of Russia

The number of administrative staff in all the above mentioned committees is less than in the similar bodies in EU which slows down the approval processes. The paper flow may be pushed by personal contacts which is important in the Russian custom.



Specific features of Russia

Change in government regulations in Russia are surprisingly often and not always predictable, but in general there is a strong and visible tendency to switch the official processes towards EU standards which will make it easier for the European clients to promote clinical trials in the country. The new promising Minister of Health and Social Wellbeing (Tatiana Golikova) appointed in October 2007 and a new structure – Pharmacoinpectorate was established that time.



Specific features of Russia

Change in the economy of Russia may happen as in any other country involved into the global collaboration, but in Russia there is no strict dependency on the global economy due to the internal resources.



Conclusions

Russia offers excellent opportunities for sponsors to conduct clinical trial in compliance with GCP standards, international and local regulations, being attractive with fast subject recruitment for large-scale trials and trials in rare diseases, proved quality of the research data, and involvement of highly experienced and motivated investigators.

