

CLINICAL TRIALS IN RUSSIA

DOKUMEDS – European Clinical Research Organization operating in Russia

With 140 million of population Russia represents an important market sector for Pharmaceutical companies.

European Clinical Research Organization DOKUMEDS is successfully operating in Russia almost 10 years. Since 2005 DOKUMEDS representative office is opened in Moscow, the capital of Russia. In 2009, understanding the increasing need of safe, time and cost effective local logistics chain for Clinical trials supplies, DOKUMEDS has opened its own warehouse in Moscow. During the years, DOKUMEDS has become proficient in management of Clinical trials and Regulatory procedures in Russia.

Why Russia is attractive for conducting of Clinical trials?

There are at least two substantial reasons why Russia remains attractive for conducting of international trials.

- High availability of study population and fast recruitment possibilities.
- Highly qualified medical personal and quality of performed Clinical trials.

Why foreign companies need to conduct Clinical trials in Russia?

New Federal Law of Russian Federation „On circulation of medicines” requires that starting from 01-Sep-2010 for registration of the medicinal product in Russia Clinical trials must be conducted in the territory of the Russian Federation.

What’s the challenge?

Implementation of new Federal Law has brought new challenges for Clinical trials in Russia. This Federal Law establishes the priority of the state control of safety, quality and efficacy of medicinal products in the process of their circulation. For this, more strict requirements have been formulated both for investigators and institutions/organizations conducting Clinical trials, as well as specific requirements concerning legal aspects of the contracting and payments, and study subjects insuring procedure were defined.

What is the impact of new legislation on Clinical trials in Russia?

Pharmaceutical companies continue to target Russia market despite the challenges it presents. The proportion of clinical trials conducted by foreign sponsors in the first quarter of 2011 has increased by 13% in comparison with the last year. In Jan-Mar 2011, 9 from 30 Clinical trials approved by FDA and 6 of 13 Clinical trials approved by EMEA were conducted also in Russia.

In total, 95 Clinical trials were approved in Russia from January to March 2011 which is by 29% less than within the same period last year. Experts recognize that the main reason for the drop in numbers of approved trials is the delay in reviewing of submissions and issuing of approvals shortly after the implementation of new Federal Law. However the situation has started to stabilize leading to gradual growth in figures of approved trials. Amendments of Federal Law issued in May 2011 makes less complicated some initially unfavorable aspects of study subjects insuring procedure.

How can DOKUMEDS help you with trials, product development and registration in Russia?

Considering recent challenging factors, experienced local based CRO can become a critical success factor for foreign Pharma companies looking for clinical development of their products and following authorization in Russia Federation.

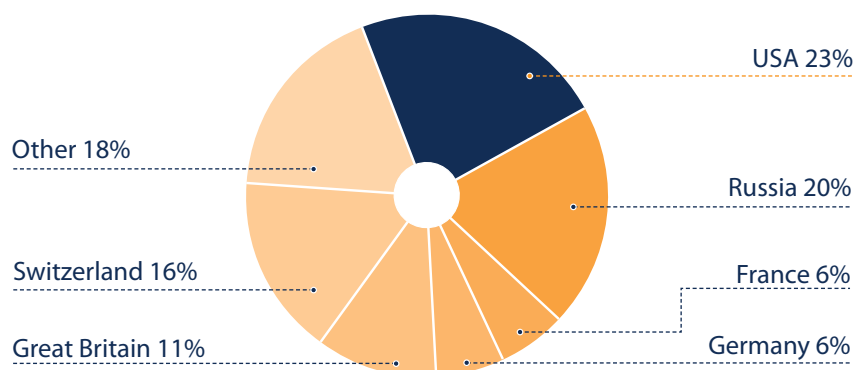
In the first quarter of 2011, DOKUMEDS has managed to keep the same level of successful submissions of Clinical trials in Russia as 2010, before the changes in local legislation were implemented.

DOKUMEDS know-how is based on substantial experience allowing the Company to evaluate the evolving regulatory landscape, to plan effective risk-management, and to provide dynamic solutions in rapidly changing local environment.

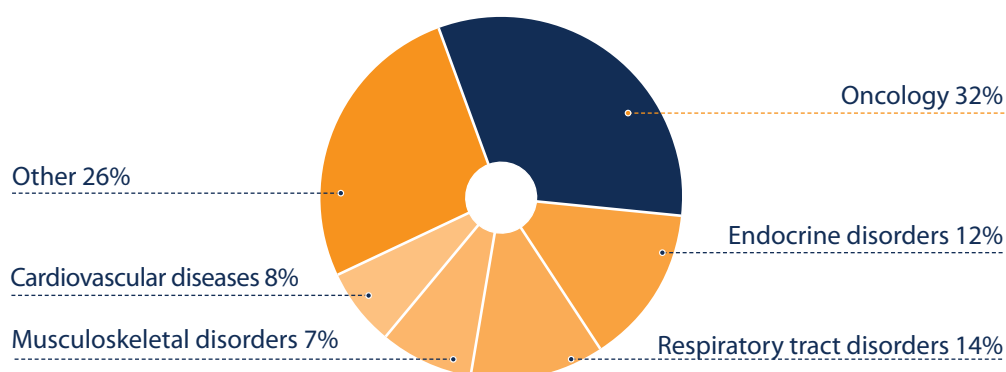
CLINICAL TRIALS IN RUSSIA – FACTS AND FIGURES

JAN-MAR 2011

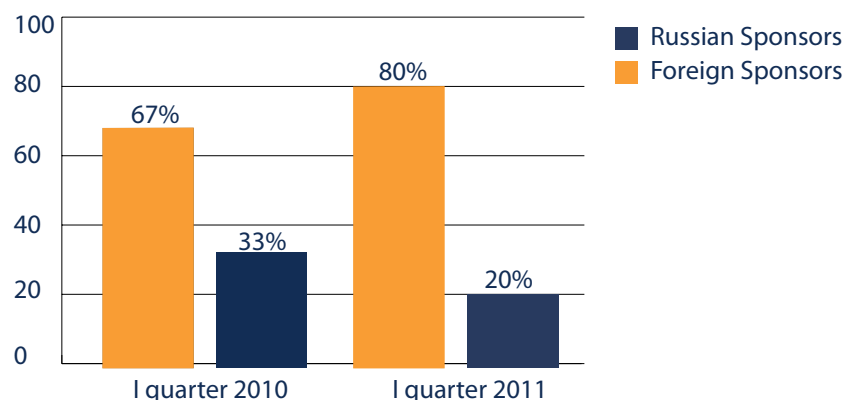
Structure of Clinical trials market (sponsors)



Therapeutic areas of initiated Clinical trials



Proportion of local and foreign sponsors



Data from Clinical trials conducted by leading local and foreign Pharmaceutical companies*

Company-Sponsor	Number of trials	Number of trial sites	Number of subjects
Local	9	39	1533
Foreign	28	242	3653

* 5 leading companies only; Jan-Mar 2011

Synergy Research Group www.synrg-pharm.ru