

Clinical research in Russia- Regulations and trends

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The Russian Federation adopted the international standards for biomedical research with intense development of the Russian legislation which regulates preclinical and clinical examination and market approval of drugs and devices. However, the law does not specify study types and efficacy and safety data evaluation criteria. As a result, market approval of the products is problematic despite available trial data. To examine trends in clinical research involving Russian subjects, we searched the World Health Organization portal of trial registries with key words "Russian federation" and identified 2,693 studies including 45 studies funded exclusively by Russian sponsors. The number of the studies reporting enrollment of Russian subjects increased in 2012 by 546% when compared to 2002. Most studies were sponsored by industry (92%), examined drugs (81%), were interventional (95%), and enrolled exclusively adults (86%) of both genders (89%). Half of the studies were completed while 6.5% were initiated but not completed. The results were posted for 16% of the studies that enrolled subjects in the Russian territory including 1 study funded exclusively by Russian sponsors. Medline search found 821 non registered randomized controlled clinical trials published in Russian language during the last 10 years and less than half of the registered multinational studies involving Russian subjects. Two studies sponsored exclusively by Russian sponsors were published in English in the journals indexed in Medline. Russian regulatory agencies should further revise existing policy to enhance high quality transparent clinical research in Russia, guarantee availability of the results and routine safety monitoring with approved treatments.

Biography

Anna Avanesova earned her law degree in Stavropol State University in Russia and her scientific degree in Moscow Humanitarian University. She has worked for the United Nations High Commissioner for Human Rights, in the International Children Foundation. She is a professor associate in Stavropol State University. Tatyana Shamliyan earned her medical degree in Russia and Master in Science in Clinical Research in the University of Minnesota. She works as a senior research associate in Minnesota Evidence Based Practice Center.

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