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MEDICAL WRITING IN RUSSIA: MORE THAN MEDICAL, MORE THAN WRITING

Eugenia Radkova[a]
[a]OCT Clinical Trials, Russia

The number of clinical trials has been actively growing in Russia since 2010 when the federal law on drug circulation was first published. For drug registration in Russia, the local registrational clinical trials (for products already marketed in other countries) as well as full program of phase I-III clinical trials (for innovative drugs) have become essential. This resulted in fast development of medical writing industry, since there was a growing demand for regulatory and trial-related documents. Specific conditions in which local pharmaceutical companies operate, such as little experience in planning and conducting of clinical trials, no possibility to liaise and get scientific advice from regulatory authorities, the deficiency of highly-qualified personnel in biostatistics, study design and methodology, have defined the special role of medical writers in Russia. In addition to basic professional skills, the medical writer should be ready to provide scientific advice on drug registration strategy and consult on all aspects of study design and methodology. The medical writer could also be involved in the statistical planning of the study, as well as final data statistical review and interpretation. This "Russian medical writer's mission" has its own pros and cons. The medical writers have the opportunity to develop wide range of professional skills, get deeper understanding of clinical trial "physiology" and obtain experience in both medical writing and medical advising in different therapeutic areas. On the other hand, the need for continuous self-education and the ability to daily work with huge amount of scientific information become critical for success.

Biography

Eugenia Radkova graduated with honors from the Mechnikov St. Petersburg State Medical Academy and is a holder of a scholarship from the Russian Government. She holds a PhD in Medicine and has a strong educational and research experience in pharmacology and preventive medicine. While working in the academic sphere she has published more than 50 scientific articles and was a co-author and co-investigator in research projects under the Russian Federal Targeted Programme. Research experience and knowledge gained in medicine and pharmacology allow her to successfully address the issues in the field of drug development and clinical trials.

ERadkova@oct-clinicaltrials.com

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