The Trends and Opportunities in the International Multicenter Clinical Trials in Russia, ARS PharmRussia Comments

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Highlighted here are things potential foreign sponsors of the global clinical research programs should know about Russia.

Analysis of situation with the international clinical research projects in Russia:

Annually, the Russian Ministry of Health (MoH) approves approximately 300 international clinical studies financed by the Sponsors from abroad.

In 2017, about 100 overseas pharmaceutical and biotechnology companies initiated their multinational clinical trials in Russia to enroll 27,000 local patients in total. At least half of the projects involved the participation of contract research organizations (CROs).

Around thirty CROs were engaged into the global clinical research projects authorized in the country in 2017. The general trend in clinical trials outsourcing is that the sponsors prefer to conduct the international clinical projects mostly with global vendors, while the local, so called 'registration' clinical studies are carried out by local or regional CROs. Although, this approach is quite controversial, especially, if we talk about local expertise, costs, and flexibility.

In 2017, the leading therapeutic areas for the international clinical research programs launched in Russia were oncology (together with oncohematology, was a third of all projects), rheumatology, and neurology. Two thirds of all the multinational studies approved in the country referred to Phase III clinical research.

What opportunities do the foreign drug developers miss?

The statistical information indicates the high incidence and prevalence rates in respiratory disorders (like pneumonia, acute laryngitis, tracheitis, and bronchitis), trauma, and cardiovascular diseases that are not enough covered by the global clinical investigation programs in Russia.

Currently, around 1400 clinical centers and 3900 investigators with more than three years of experience in clinical research are accredited by the Russian authorities. However, only

around 500 local sites were claimed for the international clinical projects commenced in 2017.

In Russia, the clinical trial regulatory approval process takes three months on average that is heavily compensated by the following fast patient recruitment. Moreover, the clinical trial protocols controlled by the US FDA and EMA have a greater likelihood of the MoH approval.

By some estimates, currently about 1.5 million people in Russia are sick with hereditary rare diseases. Taking into account that orphan drugs are usually investigated in several countries to reach the necessary patient population size, Russia could be a great region to save in time and costs of clinical studies.

What is also very important, including Russia into global late-stage clinical projects, the foreign drug developers escape additional local clinical research for marketing authorization applications.

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