FDA IN RUSSIA: CURRENT AND FUTURE TRENDS

This whitepaper is intended to provide you with the up-to-date information on the issues pertaining to FDA activities in Russia.

A pivotal meeting between FDA and Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation (RosZdravNadzor) took place on May 27, 2010 in Moscow. The head of FDA, Dr. Margaret Hamburg and the head of RosZdravNadzor, Dr. Elena Telnova have signed a letter of collaboration. This letter describes future steps in cooperation between the two agencies. During press conference Dr. Hamburg noted that FDA is very interested in building a strong relationship with Russia that will help advancing information exchange, harmonization, and joint efforts in curtailing diseases. There is a desire on both sides to press forward with the effort of global reinforcement of good clinical practices in the field of clinical trials.

The meeting and the signing of the document have highlighted a growing trend of collaboration between the two agencies. Within the last several years FDA's presence in Russia has become significantly more appreciable. In 2009 a first joined inspection of Russian clinical trial sites by the two agencies took place and plans are being made for such collaborative work to continue.

ICH/GCP in Russia: Brief Overview

While Russia is not a part of International Conference on Harmonization, its National Regulation (OCT 42-511-99) adopted in 1998 is a carbon copy of ICH/GCP guidelines. While the uptake was initially slow, with the increase in the number of clinical trials came better familiarization with the concepts of ICH/GCP. At present time an overwhelming majority of investigators and their support personnel have been through a number of training courses and have certificates of completion.

The new Russian law "Circulation of Medicinal Products" that has already been signed and that will be enabled in September of 2010 leaves the ICH/GCP provisions unchanged.

FDA Inspections

As the number of international clinical trials in Russia continues to grow, so does the frequency of FDA inspections. In table 1 you will find the main conclusions from the most recent inspections. Of interest, no notices of OAIs have been issued. When comparing these findings

with the ones from Western Europe and the US, the level of clinical trials conduct, as it is defined by the FDA, appears to be very high.

Table 1. Overview of FDA findings in Russia. 2006-2009

	NAI (No Action Indicated)	VAI (Voluntary Action Indicated)	OAI (Official Action Indicated)	Number of FDA-inspections
2008	7	6	**0**	13
2009	10	3	**0**	13
2006-2009	**28**	**12**	**0**	**40**

Source: www.fda.gov

Conclusion

There may exist a misconception about the quality of clinical trials and reproducibility of clinical trial data that comes out of Russia. The FDA audits speak to the contrary. We believe that the lack of serious findings by FDA is a product of two factors. Firstly, there is a vested interest on the part of investigators who are very involved in clinical trial conduct. In the vast majority of studies they are responsible for data entry and all trial-related communications. Secondly, the investigational sites that conduct the trials are super-specialized institutions that deal with a single area of clinical medicine (e.g. Oncology, Cardiology, etc.). Such specialization not only increases the recruitment rates but also improves the quality of clinical work.

Current trend of improved collaboration between FDA and the Russian regulatory agency is a welcome step that will ensure ongoing efforts of optimizing the quality of clinical trials conduct.