Eastern Europe: A New Paradise for Clinical Trials?

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Ukraine has a population of about 50 million. There is an extensive network of health care facilities. Physicians are highly trained and experienced. Patient recruitment rates are outstandingly good. Large numbers of patients can be recruited for clinical trials within a short time. The participating patients are highly motivated since medical support within clinical trials is much better than standard health care. The drop-out rate is very low.
The Ukrainian health care system is centralized and well organized. It is to a great extent state-owned and financed by state budget. Private medical insurance and private hospitals play only a very small role. There are a relatively large number of physicians (more than 4 doctors per 1000 citizens) and a large number of public hospitals (over 3000) with about 450 000 hospital beds in total.
The National Health Service is in the process of being reformed. The role of the general practitioner / family doctor is being strengthened.

Clinical trials in Ukraine are conducted in accordance with the current ICH GCP requirements. Regulations for performing clinical trials of medicines are laid down in the Ukrainian Law on Medicines of 1996 (amended 1997 and 1999), Article 7.[20]

Regulatory requirements:

Clinical studies of medicinal products shall be performed in order to establish or prove the efficacy and safety of medicinal product. They may be performed at specified health care settings as determined by the Ministry of Health of Ukraine or by the body authorized by it. Before the start of clinical studies of medicinal products, the enterprises, institutions, organizations, or the citizens shall submit an appropriate application to the

Ministry of Health of Ukraine or to the body authorized by it. This application shall be annexed by materials containing general information on the medicine, the results of its pre-clinical examination, samples of the medicine, and the proposal for the clinical testing program.
The following are required before a decision may be taken on the clinical trial application for clinical testing: Positive opinions on the expert assessment of the pre-clinical data as to the safety and efficacy of the medicine.

Data supporting a positive benefit-risk ratio, such that any adverse drug reactions (ADRs) of the medicine shall be considerably lower than the expected positive effect.

The procedure for performing the expert assessment of the clinical data shall be specified by the Ministry of Health of Ukraine or by the body authorized by it.

The applicant for clinical trials shall have the right to receive information concerning the clinical testing of the medicine, to acquaint himself with the results of the clinical experts appraisal, and may request a substitution of specialized health care setting where the clinical trial is performed.
Clinical study of medicinal products shall be performed following obligatory appraisal of the ethical, moral, and legal aspects of the clinical testing program by Ethics Committees that are established and operate under health care settings where the clinical trials are conducted.[21]

(21) PHARMABIZ.COM, June 24, 2004 http://www.pharmabiz.com/article/detnews.asp?articleid=22504&sectionid=50

Canada, June 04, 2006