

Introduction



heath insurances under control.

Generics are getting more and more importance for a sufficient supply of medicinal products for all social classes of society. Especially in the European Union there is an increasing market for Generics as in most of the countries public health authorities favour the use of generics to keep expenses of public

Besides strong competition on the generic market, health authorities tend to limit costs for medicinal products which results in limited development budgets.

It could therefore be of great interest for pharmaceutical companies to perform the clinical trials outside of the European Union which are necessary to register new generics.

The clinical sites of **INNOPHAR Innovative Pharma Research Eastern Europe GmbH (PPN-EE)**, Pharm PlanNet – Ukraine Clinic Ltd. and **INNOPHAR Innovative Pharma Research Moldova Ltd.** can offer you services and solutions to perform clinical trials very cost effectively and time saving on a quality level which is accepted by European Union Health authorities.

PPN-UA, is the first private clinic in Ukraine, specialised exclusively in the conduction of clinical research and combines professional CRO skills with academic expertise in collaboration with members of the Bukovinian State Medical University.

IPR-MD is located at the National Institute of Cardiology and is operated in collaboration with members of the Medical University of Chisinau.

In both countries IPR-EE and the local sites have good connections to health authorities

Dr. Karl M. Eckl
Executive Director/Medical Director

Location of sites of IPR-EE

Currently IPR-EE operates tow clinical sites, one in Boyane close to Chernivtsi, Ukraine and one in Chisinau, Moldova.



Ukraine - Boyan:

The site at Boyan is currently equipped with up to 36 clinic beds.



Moldova - Chisinau:

The site in Chisinau is equipped with 24 clinic beds.

The site at Boyan can be reached by using the international airports in Lvov or Kiev. There are daily flights from Kiev to Chernivtsi and back. Chisinau has an international airport with flight connections to European cities.

The IPR-EE clinical teams



All trials are conducted by the same well trained clinical team consisting of physicians experienced in the treatment of emergency cases. The clinical teams of the IPR-EE sites are

continuously trained. The team has great experience in practical application of GCP and other international guidelines. Expertise is documented in training logs and CVs.

Medical responsibility is covered by academic experts like Prof. Semen Biletski, a well known



internal specialist and cardiologist in Ukraine and head of the department of general medicine at the Bukovinian State Medical University.

Ukrainian health authorities are currently adapting their legal framework for conduction of clinical trials to international standards. In

June 2005 a new law was released, on the conduction and reporting of bioequivalence studies, which follows the EMEA guideline^(*) The IPR-EE site in Ukraine is currently recommended by the Ukrainian Ministry of Health as the only clinical site in Ukraine where bioequivalence studies can be performed according to Western European standard.

^(*)Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98)

The standards of the IPR-EE clinical sites

All main procedures within IPR-EE clinical sites are standardised and documented in Standard Operating Procedures. The quality of data is guaranteed by an own quality control group.



The IPR-EE clinical sites are headed by Dr. Karl M. Eckl who has 20 years of experience in drug development on an international level. He was investigator or sub-investigator for more than 300 clinical trials in the past.



Laboratory staff members are trained in appropriate sample handling- and storage procedures. Sample handling is documented for each sample individually.

AAI Deutschland GmbH a GLP certified Analytical laboratory guarantees acceptance of analytical data by European Health Authorities.



How to contact IPR-EE?

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Your Partner for Bioequivalence Studies