

Patient Populations available

Chernivtsi /Boyan, Ukraine

Renal impairment (450 patients):

- 300 different degrees of renal impairment
- 150 diabetes type II and renal impairment.

Hepatic impairment (460 patients):

- 400 Child Pugh A - B
- 60 Child Pugh C.

Chisinau, Moldova:

Renal impairment (850 patients):

- 350 patients with different degrees of renal impairment.
- 500 patients with diabetes II and renal impairment.

Hepatic impairment (750 patients):

- 650 patients Child Pugh A - B
- 100 Child Pugh C per year.

Experience with the last projects:

Clinical trial in severe renally impaired patients in comparison to age, gender and BMI matched healthy controls (N = 16) – recruitment and clinical phase were completed within 3 weeks.

Clinical trial in hepatic impaired patients (Child Pugh, A, B and C) versus age, gender and BMI matched healthy controls (N = 32) – recruitment and clinical phase were completed in less than four months.

The IPR-EE sites were submitted to several independent audits and two inspections from national health authorities without any major findings.

How to contact IPR-EE?

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INNOPHAR GmbH
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***Your Partner for Pharmacokinetic trials in
Renal- or Hepatic Impaired Patients***

Introduction



The conduction of pharmacokinetic trials in patients with renal- or hepatic impairment is one of the most difficult tasks in the course of the clinical development of a new compound. Both patient populations are difficult to recruit and to handle. Especially the clinical status in severe renal- or hepatic impaired patients may be instable and ethical considerations may limit recruitment. Problems in patient recruitment in both types of these clinical trials are frequently the reason for delayed clinical development especially in the case if authorities request those trials short before or after submission of the registration dossier.

INNOPHAR Innovative Pharma Research Eastern Europe GmbH (IPR-EE) and its two clinical sites Pharm PlanNet – Ukraine Clinic Ltd. (PPN-UA) and **INNOPHAR** Innovative Pharma Research Moldova Ltd. (IPR-MD) in Ukraine and Moldova can offer you tailored solutions for pharmacokinetic studies in special patient populations. All trials are conducted according to European and international standards and guidelines.

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 two 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 central health care system in both countries supports fast and as planned patient recruitment. The clinical teams in both centres are well trained in the conduction of clinical trials and are supervised by a quality control team. A project management group cares about time lines and submission of documents.

Recruitment strategy in the IPR-EE Sites

In cooperation with different public polyclinics PPN-EE and its local sites have established several recruitment centres. In these centres, experts in the therapeutic area of interest are recruiting patients according to the protocol and enable fast recruitment of the specified patient populations.

Suitable patients selected from different polyclinics are hospitalised at the IPR-EE sites. The trials are conducted always by the same well trained clinical team. The clinical team of the IPR-EE sites consists of physicians experienced in the treatment of emergency cases. Four out of six physicians of the PPN-UA clinical team are anaesthetists. The physicians of IPR-MD are cardiologists and trained in emergency care. The team is continuously trained in practical application of GCP and other international guidelines. Expertise is documented in training logs and CVs.

In addition to the permanent clinical team academic experts from the Bukovinian Medical State University and the University of Chisinau can be recruited as investigators or sub-investigators.

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