Clinical Pharmacology Unit
Ist. Department of Internal Medicine
1083-BUDAPEST, HUNGARY
Korányi Sándor u. 2/a.

Department chair:

Szathmári Miklós  MD, PhD, DSc
Professor of Medicine, Director of the Ist Dept. of Internal Medicine, Semmelweis University, Faculty of Medicine.

Clinical Pharmacology Unit:

Head:  Judit Kapocsi MD, PhD
associate professor, specialist in internal medicine, clinical pharmacology and clinical hypertension.
At her previous workplace (St Imre Teaching Hospital such type of Clinical Pharmacology Unit was established in the early 1990s), between 1991 and 2003, 27 bioequivalence studies were performed with the staff headed by Judit Kapocsi. During the same period 53 phase II-IV studies were performed at the same department.

Deputy:  Zoltán Járai MD, PhD
assistant professor, specialist in internal medicine, clinical pharmacology, cardiology, clinical hypertension and clinical angiology

Chief research associate:

Mrs. Zibákné Soós Enikő

Staff:

István Takács MD, PhD: assistant professor, specialist in internal medicine, clinical pharmacology, endocrinology
András Tislér MD, PhD: assistant professor, specialist in internal medicine, clinical pharmacology, nephrology and clinical hypertension
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Brief unit history and experience:  
The 1st department of Internal Medicine was founded in 1909. Since 1946 there have been many clinical studies performed at the department, at the beginning mainly on the field of endocrinology with collaboration of the Richter Gedeon Pharmaceuticals Company. In 1968 the department joined to the national clinical pharmacology network. From 1980s dozens of clinical trials were done involving areas such as bone metabolism, diabetology, gastroenterology, hepatology, nephrology, and cardiology. In 2003 we have started to develop a Unit for Phase I clinical trials. At the beginning of 2005 the Phase I unit of the 1st Dept. of Internal Medicine, Semmelweis University, was accredited by National Institute of Pharmacy. The accreditation was renewed at 2008. 

The head of the Clinical Pharmacological Unit, Kapocsi Judit MD, PhD, At his previous affiliation at the St Imre Teaching Hospital such type of Clinical Pharmacology Unit was established in 1990, and between 1991 and 2003 27 bioequivalence studies were performed with the staff mentioned above. During the same period 53 phase II-IV studies were performed at the same department.  

Details of facilities:  

A separated Phase I Unit with 12 beds in 3 air-conditioned rooms, with 3 bathrooms.  
A room for social activities (television)  
Nurse base  
Office with telefon, fax, internet, copier  
Room for archiving documents  
Laboratory for processing and storing the samples  
The unit is with close connection to the Intensive Care Unit.  
The Central Laboratory is functioning in the same building. The Lab has official accreditation Bioanalytical Laboratory (cooperation with the Toxic Laboratory of the Semmelweis University, Department of Forensic Medicine, Kálmán Róna PhD, expert in bioanalytical methods)
More than 15 years experience in the managing Clinical Trial (Phase I-IV, bioequivalence, drug-drug interaction, drug-food interaction studies)
Well-trained and experienced staff (including study nurses) in Clinical Trial Management
SOP-s complying with the ICH-GCP
Quality assurance and control

**Outpatient Clinics**

Big outpatient system
Well-known experts in the field of cardiovascular diseases, angiology, diabetology, nephrology, gastroenterology, endocrinology, osteoporosis, hepatology, haematology
Cardiac ECHO
Exercise testing
24 h ABP Monitoring
BTB Monitoring
Cardiotens
Holter Monitoring
Duplex Doppler ultrasonography
Laser Doppler flowmetry
Panendoscopy (diagnostic and treatment)
ERCP
Bone Metabolism and Resorption laboratory testing
Dexa and Ultrasound Bone Densitometry
Isotop laboratory (in vivo and in vitro investigations)
Sleeping Laboratory (apnoe syndrome investigation)
General ultrasound investigation
Traditional X-ray investigations
Laboratory investigations (rutin, haematological, endocrinological, hormones, cytokines, virus markers, tumor markers)
Molecular biology investigations (PCR technic)
Biopsy (kidney, thyroid gland, liver, etc)

**Experts in the field of**

**Hypertonology:** Prof. Rudolf de Chatel, Dr István Barna, Dr Judit Kapocsi, Dr Zoltán Járai

**Nephrology:** Dr György Deák, Dr István Mucsi, Dr András Tislér, Dr Zsófia Németh
Cardiology: Dr Zoltán Járai, Dr Katalin Keresztes
Angiology: Dr Zoltán Járai
Diabetology: Prof. László Gerő, Prof Péter Kempler, Prof Gyula Tamás, Dr Ádám Tabák
Endocrinology: Dr Csaba Horváth, Prof. Péter Lakatos, Prof. Dr Miklós Szathmári, Dr István Takács, Dr Zsolt Nagy, Dr Szilvia Mészáros
Gastroenterology: Prof János Papp, Dr Henrik Horváth, Dr Péter László Lakatos
Hepatology: Dr Margit Abonyi, Prof Ferenc Szalay
Hematology: Prof Judit Demeter, Dr Zsolt Nagy

SERVICES

Management of Clinical Pharmacological Studies (Phase I-IV, bioequivalence, drug-drug interaction, drug-food interaction studies) in compliance with ICH-GCP
Bioanalytics-cooperation with audited GLP laboratory
Data Management- Biostatistics
Protocol, CRF writing
Final Report writing

Bioanalytical Laboratory

Semmelweis University, Faculty of Medicine
Department of Forensic Medicine
H-1091 Budapest, Üllői Street 93.

Head: Prof. Dr Kálmán Róna, scientific consultant
e-mail: rona@igaz.sote.hu
T/F:0036-1-215-7300/3474

The laboratory has GLP certification, well-skilled staff and excellent-quality equipments.
The staff has experienced in clinical pharmacological studies (Phase I-II, bioequivalence studies), in collecting and storing samples.

Services
Chemical analysis of animal and human samples
Forensic and clinical toxicological studies
Drug concentration analysis
Screening (drugs, genetics)
Analytical method development and validation
Biostatistics
Analytical report

Analytical techniques
FPIA
CC/FID, HS-GC/FID
GC/MS, HS-GC/MS, SPME-GC/MS
HPLC/UV, DAD, FD, EC
HPLC/MS