Getting in closer touch with clinical research

The founding of the Phase I Unit builds on a long tradition of professional conducting clinical trials in the Masaryk Memorial Cancer Institute (MMCI). In the last ten years, the Institute has contributed to more than 250 clinical trials, in particular phase II and III.

However, since 2010 the spectrum of clinical trials has been moving towards the earlier phases of the development of a new drug. The trials of phase I and II, which are often “first in men”, have greater demands on the professional, technical and organizational aspects of its realization. For this reason, Phase I Unit was established in the Masaryk Memorial Cancer Institute in February 2012.

The unit provides complete implementation of the clinical trials of early phases in accordance with all legislative requirements, good clinical practice (ICH GCP) and international standards.

It is made up of two semi intensive triple rooms within the Department of Complex Oncology Care. The outpatient clinic and administrative and technical facilities are also a part of it.

Our ambition is to become a part of the European network of Phase I units and to participate in the phase I clinical trials conducted in Europe and overseas.
Prof. Rostislav Vyzula, MD

Originates from the Masaryk Memorial Cancer Institute (MMCI), Brno, which is the only Comprehensive Cancer Center in the Czech Republic. After gaining Board certification in Internal Medicine I and II, Dr. Vyzula started to focus on Medical Oncology. Between 1991 and 1995 he spent time as a postdoctoral fellow at the research laboratory in Albany, NY, USA, studying chronobiology, and completed a Graduate Medical Education fellowship in Medical Oncology at the Albany Medical Center. During his fellowship in the US he passed the ECFMG exams. He received his PhD in Internal Medicine for his thesis: „Circadian dependent toxicity of 5-fluorouracil“ from the Masaryk University in Brno in 1997.

He joined the MMCI in 2000 as the Head of Comprehensive Cancer Care Department, a position which he still retains, and was he director of the MMCI between 2001 and 2008. He received the title of Associate Professor in 1999 and Professor of Oncology in 2005 from the Masaryk University Brno. He primarily gives lectures on targeted therapy in Breast and Colon cancer, and is the founder of the National Clinical Registry for associated therapies such as trastuzumab, bevacizumab etc. in the Czech Republic.

He is a member of the board of the Czech oncology society. He has been the principal or co-investigator in many clinical trials over the last 15 years. His basic research interests include prognostic biomarkers of solid tumors, and genomic and proteomic profiling in multiple tumors. He has recently become a member of the Scientific Advisory Board of translational research at the Organization of European Cancer Institutes (OECI).
Igor Kiss, MD PhD

Igor Kiss, MD, PhD is a Deputy Director for Curative and Preventive Care in the Masaryk Memorial Cancer Institute (MMCI) in Brno, Czech Republic. After gaining Board I certification in Internal Medicine and Board II certification in Medical Oncology he focused on chemoresistence and sensitivity of anticancer treatment, clinical pharmacokinetic and pharmacodynamic studies of anticancer drugs. From 1992 – 1993 he participated in cancer research as a Postdoctoral Scholar in the School of Pharmacy and Medicine, University of Kansas, U.S.A. In 1993 he began working in the University Hospital Brno, at first in the Department of Internal Medicine (1993 – 1997), then as an Assistant Professor, Specialist in Oncology (1997 – 2000) and finally as a Head of the Department of Medical Oncology (2000 – 2008).

Regina Demlova, MD PhD

Regina Demlova, MD PhD is Head of the Clinical Research Unit in the Masaryk Memorial Cancer Institute (MMCI) in Brno. After gaining Board I certification in Internal Medicine and Board II certification in Clinical Pharmacology she started to focus on clinical pharmacology including clinical trials. From 1993 - 1996 she worked at the Department of Pharmacology, Faculty of Medicine, Masaryk University, Brno, Czech republic in an assistant lecturer position working on scientific projects in preclinical pharmacology including psycho-neuro-immunological areas, behavioral pharmacology and teaching activities. Since 1997 Dr. Demlova has been working in the Masaryk Memorial Cancer Institute as the Head of the Clinical Research Unit. In 1998 she received the ESMO certificate in Good Clinical Practice in Medical Oncology. She spent her time at the Karolinska Hospital, Clinical Research Unit, Stockholm during year 2000 and received her PhD in Clinical Oncology for her thesis „Interindividual Variability of Metabolizing enzymes - Pharmacogenetic perspective in anti-cancer therapy“ from the Masaryk University in Brno in 2009. At that time she became active in the field of clinical trials, becoming responsible for all clinical trials conducted in the MMCI, and is experienced in phase I-III trials. She is also involved in designing trial protocols. She is certified by the DIA in pharmacovigilance and cooperated with Eudravigilance. Since 2008 she has been cooperating with the Institute of Biostatistics and Analysis of the Masaryk University in the area of Pharmaco-economy and Heath Technology Assessment. Dr. Demlova gives lectures at Masaryk University on the Clinical Trials theme. She is a member of the Czech Pharmacological Society, Czech Pharmacoeconomic Society and a member of Clinical Trials Association in the Czech republic.
Radka Obermannova, MD

Dr. Obermannova graduated from Faculty of Medicine, Masaryk University Brno, in 1995. She gained the Board I certification in Internal Medicine in 1998 and Board II certification in Clinical Oncology in 2003. Dr. Obermannova started her postgraduate oncology studies in 2010 and she is an assistant professor at the Faculty of Medicine, Masaryk University. In 2009 she passed the ESO (European School of Oncology) MasterClass in Clinical Oncology. Dr. Obermannova has already been working at the Masaryk Memorial Cancer Institute already for 16 years. Since 1997 she has worked as the Head of the Inpatient Division A of the Department of Complex Oncology Care. As a clinical oncologist she focuses on gastrointestinal and breast cancer. Dr. Obermannova has participated in many clinical trials since 2001 and is currently the principal investigator of four clinical trials phases IIa – III and co-investigator of many others. She is trained in GCP. Dr. Obermannova is a member of the Czech oncology society.

---

In addition to the most advanced treatments, including biological treatment, MMCI also offers its patients participation in international clinical trials, phases I-III.

The tradition of conducting clinical trials in the MMCI dates back to the 1970s, when the institute was an important research partner of the pharmaceutical company Lachema in the area of the development of new cytostatics. However, since the last decade of the 20th century the possibility of clinical research and the number of clinical trials have significantly increased which led to the establishment of the new Clinical Research Unit (CRU) in 2000.

In 2010, there were 19 new clinical trials initiated in the MMCI and 246 patients enrolled. However, the total number of patients undergoing the treatment in the clinical trials was 877 that year. In some clinical trials we have achieved a leading global position in the number of enrolled subjects.

For more statistics please see the diagrams below.

The most common sponsors of the clinical trials in the MMCI are pharmaceutical companies, as well as European research organizations (EORTC, CEECOG) and increasingly more often also academic institutions (investigator initiated trials).

The preparation of a new clinical trial and pre-study procedures, i.e. the approvals of the State Institute for Drug Control (SIDC) as well as Ethics Committees and the contract signature, takes approximately 3 months.
Since 2000, already for more than a decade, the Clinical Research Unit (CRU) has provided unique professional and administrative support to clinical research in the MMCI.

The department is led by an experienced clinical pharmacologist. The team consists of 9 study coordinators/nurses, a data manager and an administrative coordinator.

The unit provides complete pre-study procedures and after the initiation of a clinical trial coordinates its implementation under the protocol. It also provides data management and communication with the sponsor.

The CRU is the main partner of the principal investigator (PI). The team dedicated to every clinical trial consists of the PI, co-investigators, study coordinator/nurse, radiologist, pharmacist and a pharmaceutical assistant.

Positive responses from sponsors and cooperators, as well as colleagues from other institutions, confirm that the CRU represents a step in the right direction. The CRU is pleased to cooperate with these MMCI departments:

- **MMCI Pharmacy** is responsible for the proper receipt, storage and recording of study medication.

- **Department of radiology** successfully meets the increasingly demanding requirements for radiological assessments according to RECIST criteria and study protocol.

- **Department of laboratory medicine** provides complex and accredited laboratory support for all patients, treated in both the inpatient and the outpatient setting. According to the study protocols it provides pharmacokinetics and pharmacodynamics assessments.

- **Department of nuclear medicine/PET center**
The Department of Surgical Oncology provides sampling of biological material that is subsequently being examined at the Department of Oncological and Experimental Pathology (DOEP) and its Division of Molecular and Experimental Pathology and also Bank of Biological Material. The department is engaged in the translation of primary molecular biology research into clinical oncology. The primary research is focused on the role of chaperones in malignant transformation, on tumor suppressor p53 and on protein family AGR (Anterior gradient). The results of basic research are applicable for individual tumor characterization thanks to their close relation with the department of pathology. The tissue bank and the department of pathology allow us to provide proteomic or genomic studies focused on the discovery of new biomarkers.

**Methodological approaches of DOEP:**

- Analysis of gene expression at the level of mRNA and protein.
- Study of protein-protein interactions.
- Analysis of posttranslational modifications of chaperones.
- Development of new monoclonal antibodies.
- Immunohistochemical analysis of chaperones in tumor samples.
- Proteomic analysis and mass spectrometry
- Production and purification of recombinant proteins

**Masaryk Memorial Cancer Institute**

The MMCI is a leading Czech oncological center, founded in 1935. It provides the most comprehensive care for patients with solid tumors: prevention, diagnosis and vaccine therapy.

In 2010 the MMCI had 279 beds, 9,043 inpatients, 190,779 outpatients. It currently maintains 830 employees.

The MMCI is the only health care provider in the Czech Republic carrying two quality approvals: by the Joint Commission International and by the independent Czech Republic Joint Accreditation Commission (SAK).

The MMCI is a member of the Organisation of European Cancer Institutes (OECI).

In 2010 the MMCI was voted by patients as the best hospital in a survey conducted by the Ministry of Health of the Czech Republic.

More at: [www.mou.cz](http://www.mou.cz)
Contact:
Masaryk Memorial Cancer Institute
Clinic of Complex Oncology Care, Phase I Unit
Žlutý kopec 7
Brno 656 53, Czech republic
Email: demlova@mou.cz
Telefon: +420 54313 6611