Masarykův onkologický ústav

Clinical Research at MMCI

Content

Bringing innovative medicine to patients

Clinical research is essential to test new medicines and to investigate existing ones, thus enabling the significant advancement in the treatment.

Masaryk Memorial Cancer Institute has a long-standing experience with clinical trials that have been carried out here already for decades. MMCI is proud to be in the family of top-rated and well recognized sites in Europe where new generation medicine is accessible for the patients.

Overview and structure

The agenda of clinical research, one of the long-term MMCI priorities, is well embedded in the institutional structure of MMCI and supervised by Director for Medical Care and Director for Science and Research. The clinical trials are being performed in compliance with the MMCI Internal Directive, Good Clinical Practice and all related legal standards and procedures.

Our experienced and qualified experts will ensure that the clinical research is conducted at a high global level. Department of Clinical Trials is in charge of clinical research operational management.

Our expert services and equipment

MMCI is the only comprehensive cancer centre in the Czech Republic that offers a significant advantage of performing clinical research. Having prevention, diagnostics, surgery and all types of cancer treatment under one roof, MMCI is able and well equipped to collaborate in clinical trials that require the involvement of:

- medical oncology
- radiology (including RECIST and other assessment)
- nuclear medicine
- radiotherapy
- cancer surgery
- pathology with a wide range of local testing
- local laboratory
- pharmacy - centralized preparation of medications including injections drugs (cytostatics, monoclonal antibodies, GMO), aseptic and fully certified processes
- Support clinical research staff (project managers, study coordinators, study nurses, data managers) and administrative back-office (legal, economic, funding etc.)

Trial Portfolio

MMCI participates in the international multicenter clinical trials. Apart from others, our research activities include also the design, conduct and analysis of academic and investigator initiated trials. We are launching about 25 new clinical trials Phase I-III each year, representing a major part of trials allocated in the Czech Republic. These trials cover all solid tumor indications that are being treated in MMCI. MMCI collaborates with leading global pharmaceutical companies. For most of the first studies in human oncology, MMCI is the only participating site in the Czech Republic.

Clinical trials in numbers and facts

Average number of recruiting interventional trials per year	40
Average number of patients enrolled in the interventional clinical trials per year	250
Average number of study visits per month	420
Average number of active trials	95

Department of Clinical Trials

Established in 2000 as the first specialized department in the Czech Republic. - Department of Clinical Trials (DCT) coordinates the clinical research at MMCI. The team consists of experienced; GCP trained study coordinators, study nurses, start-up managers and data managers, supervised and managed by the clinical pharmacologist and medical oncologist.

Two DCT units cover all clinical trials agenda:

Clinical Trials Unit (CTU)

Clinical Trials Unit and its staff coordinates mostly industry initiated clinical trials Phase I-IV.
Unit expertise includes:

- Feasibility process
- Start-up agenda (contract and budget negotiation, essential documents, training)
- Enrollment support and Informed Consent process coordination
- Study coordinator and study nurse services
- Coordination and support for site study teams
- Data management services (completion of eCRF, monitoring visits)
- Audit and inspection support
- Quality assurance/ quality control
- Training and education services for investigators
- Study archiving

Academic Trials Unit (ATU)

Academic Trials Unit and its project managers and research coordinators provide investigators with a broad range of services and expertise to assist in the launch and conduct of clinical trials initiated by investigators or academic institutions and academic networks, including:

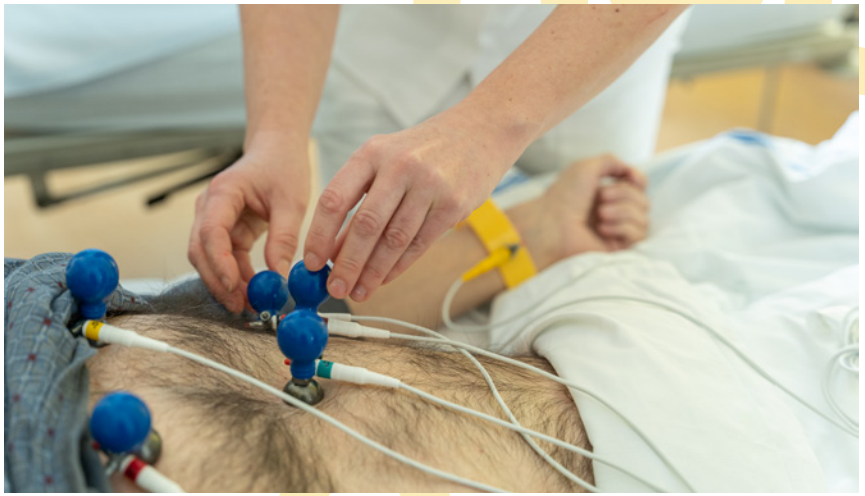
- Study design and formulating research questions
- Statistics
- Regulatory agenda
- Protocol development
- Trial management
- Data management
- Quality Assurance
- Enrollment support and Informed Consent process coordination
- Coordination of study visits
- Education for investigators and clinical trial staff

Phase I Unit

Since 2012, in-patient Phase I Unit supports development, implementation and conduct of Phase I and II clinical trials in order to assess and ensure safety, pharmacokinetics, and/or pharmacodynamics of therapeutic products that are subject to ongoing clinical study. Located within Department of Comprehensive Cancer Care, its current capacity of 6 semi-monitored beds enables enrolling and observing cancer patients, enrolled in first-in human clinical trials.

Phase I clinical trials are managed by the most experienced team of dedicated medical oncologists – investigators, study nurses, coordinators and data managers and other health-care professionals (radiologists, pharmacists, laboratory professionals, pathologists etc.). Phase I Unit Advisory Board meets on regular basis to discuss all relevant scientific, medical and operational issues.

The 24/7 unit is equipped by telemetry and Department of Anesthesiology and Intensive Care capacity is available if needed.



Training and Education

Good Clinical Practice (GCP) training is held on regular basis every second year. This training programme is designed for clinical investigators, study coordinators, study nurses and all other health care professionals, involved in clinical trials.

Department of Clinical Trials (DCT) provides also **internal training programmes** and consultations for new investigators and nurses. **The accredited three-day education programme** for study coordinators is annually provided by CRD in cooperation with National Centre for Nursing Education and Health Care Professionals. CRD also provides internships and trainings for study coordinators coming from other sites in the Czech Republic.

Patient and Public Involvement

To a large extent, clinical trials and interventions depend on patient participation. It is therefore essential that patient voice is reflected in all aspects of what we provide and patients are part of. We try to ensure easy and timely access to clinical trials for all our patients in MMCI, either newly diagnosed or those already being treated in our centre for a certain period of time. Our database of clinical trials covers all stages of the disease as well as solid tumor indications (diagnosis). Evaluation of patients' eligibility is a routine step in the overall concept of a decision process. The successful recruitment of patients in clinical trials is one of our priorities. We are proud to have a long track record of achieving target enrollment in almost every clinical trial, and in many of them we are among the best global or national recruitment sites. Patients not treated in MMCI, patient organizations as well as the public, they all are welcome and encouraged to contact us with any question related to clinical trials. List of active clinical trials are available on MMCI websites.

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Quality Assurance

Quality Assurance Scheme (QA) is the essential component of the clinical research credibility. Clinical trials follow MMCI Internal Directive since 2001 and dozens of in-depths SOP's, updated on regular basis. Quality Control Scheme (QC) is performed by internal or sponsor audits or by inspections of Regulatory Authority. The number of 3-5 sponsor audits is being carried out every year. Inspections were also realized by the FDA and SÚKL, the Czech regulatory authority, mostly with minor findings.

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Collaboration and contacts

Our aim is to work in a collaborative way with a wide range of stakeholders – investigators, sponsors, academic institutions, research networks, CRO and other partners – in order to ensure that all parties share their expertise in most effective and productive way.

We will be happy to provide you with any further information on the potential future cooperation in the field of clinical research.

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Notes

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V8/2022/1