Masarykův onkologický ústav

CLINICAL RESEARCH AT MMCI

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BRINGING INNOVATIVE MEDICINE TO PATIENTS

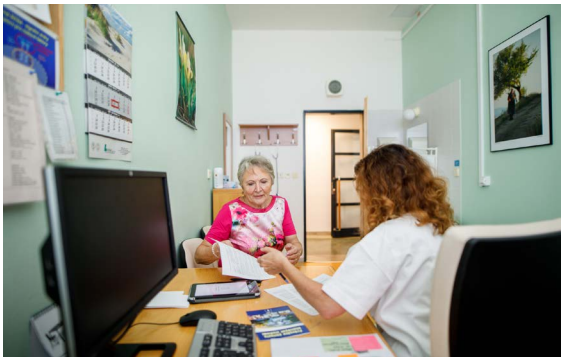
Clinical research is essential to test new medicines and to investigate existing ones, thus enabling significant advancement in the treatment.

Masaryk Memorial Cancer Institute has 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 to 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. The 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.

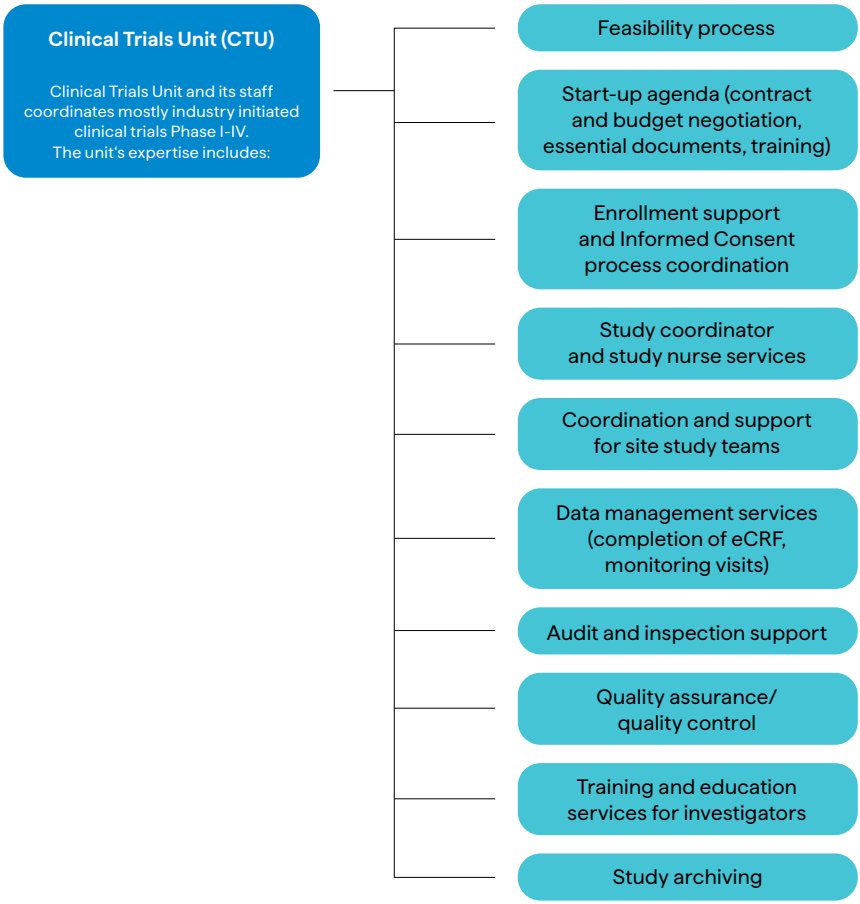
CLINICAL TRIALS IN NUMBERS AND FACTS

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:



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

EARLY PHASE TRIAL UNIT

The Early Phase Trial Unit was established at Masaryk Memorial Cancer Institute in 2012 and currently conducts Phase I clinical trials in solid tumor indications, including first-in-human trials.

The inpatient part of the Unit with 24/7 operation is located in the Clinic of Comprehensive Cancer Care and has 6 semi-intensive beds with telemetry.

The outpatient section is located in the Day Care Center and is equipped with 6 beds with telemetry.

Administrative facilities are provided by the Department of Clinical Trials.

Our Unit is capable of providing:

- Dose Escalation clinical trials
- Intensive sampling for pharmacokinetics, pharmacodynamics and other sampling and processing to a central laboratory
- Intensive monitoring of patients (telemetry, ECG, monitoring of vital signs)
- Active participation of investigators in safety and efficacy consultations
- Immediate availability of emergency medical care
- Source documentation management according to ALCOA principles and data entry into eCRF by qualified data managers
- Backing of the largest Department of Clinical Trials in the Czech Republic (monitoring area, experienced study team)
- Conducting clinical trials according to Good Clinical Practice (GCP) and local SOPs.

The Early Phase Trial Unit holds a certificate for first-in-human clinical trials issued in October 2022 by the Czech regulatory agency SUKL in accordance with the requirements of EU Regulation 536/2014.

The site is part of the Prime Site IQVIA network (2022) and a certified Novartis Translational Clinical Oncology Centre (2016).

Compliance with Good Clinical Practice has been verified by FDA inspections (2012) and SÚKL inspections (2020, 2021, 2022, 2023), as well as annual sponsor audits.

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 in cooperation with National Centre for Nursing Education and Health Care Professionals. Department of Clinical Trials also provides internships and trainings for study coordinators coming from other sites in the Czech Republic and holds the biggest annual conference for study nurses and coordinators.

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.

The 24/7 unit is equipped by telemetry and Intensive Care Unit (ICU) capacity is available if needed.

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, usually with minor findings.

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COLLABORATION AND CONTACTS

Our aim is to work in a collaborative way with a wide range of stake-holders – 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.

Contact:

Department of Clinical Trials
Email: studie@mou.cz
Tel.: +420 54313 6226, 6611, 6232
www.mou.cz

Notes:

Information and Education Centre
and Clinical Trials Unit
Proccesed by Mgr. Michaela Hanáková

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Masaryk Memorial Cancer Institute
Žlutý kopec 7, 656 53 Brno

www.mou.cz
+420 543 131111