MOÚ MASARYKŮV ONKOLOGICKÝ ÚSTAV

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# Phase I Clinical Trials in Masaryk Memorial Cancer Institute

Česká společnost pro akreditaci ve zdravotnictví
CERTIFIKÁT KVALITY A BEZPEČÍ

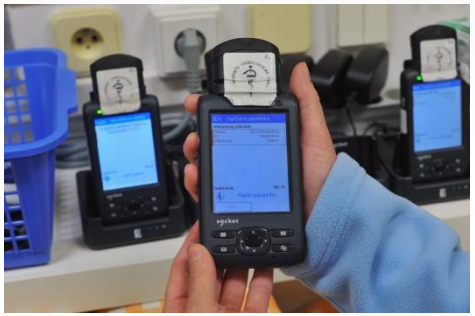
OECI CLINICAL Cancer Centre

# Phase I Unit

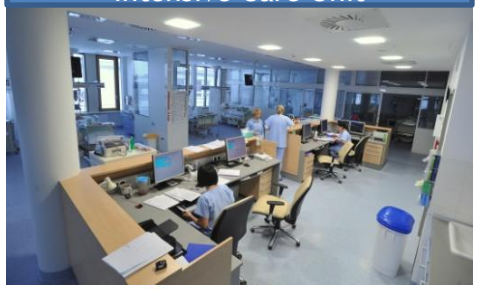
- Clinical unit established in 2012
- In-patient unit(4 beds)
- Out-patient unit
- Semi-intensive monitoring
- Background of Intensive Care Unit
- Telemetry since 2017
- Lab equipment
- ECG monitoring
- Possibility of PK/PD sampling
- Qualified Phase I team of investigators, study coordinators and study nurses


In-patient Unit


Out-patient Unit



Intensive Care Unit



Intensive Care Unit

Intensive Care Unit

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# Working Group/Study Team for Phase I trials

Head of Phase I Unit

Prof. Rostislav Vyzula, MD, PhD

Phase I Unit Head Physician

Radka Obermannova, MD, PhD

Phase I Unit Medical Affairs

Assoc.Prof. Igor Kiss, MD, PhD

Head of Clinical Trials Unit
Consultant in Clinical Pharmacology

Assoc.Prof. Regina Demlova, MD, PhD

Phase I Investigators

Phase I Study Nurses/Coordinators

Other dedicated study team members:
Pharmacist, Radiologist, Pathologist,
Lab Technician, Data manager

# Phase I Trials management

- Phase I trials feasibility process and start-up activities coordinated by Clinical Trials Unit (single point of contact at MMCI)
- Phase I Clinical Trial Working Group meets bi/monthly, with sessions opened for all concerned oncologists/SC/SN
- PI is chosen with respect to the diagnosis, all PI´s for Phase I are experienced (> 10 years), high qualified and GCP trained
- Priority approach in start-up activities, including Clinical Trial Agreement, with the effort to initiate the site as soon as possible

# What to expect at MMCI

- Professional support from **Clinical Trials Unit** (since 2000, the longest tradition and leading position in the Czech Republic) –
- **Fast Start-up activities**:
  - Local Ethic Commitee Approval up to 4 weeks
  - Clinical Trials Agreement (possibility to use the national template) – up to 6-8 weeks to execution for Phase I trials
  - Essential Documents up to 3 weeks
- More than 30 **SOP´s specific for clinical trials**
- Excellent results from Sponsor´s **GCP audits** (3-4 annually), no findings from FDA and SUKL **inspection**
- Experienced and **GCP trained investigators , study coordinators and data managers**
- **In-patient Phase I Unit**
- Reliable **enrollment rate**, globally top-enrollment in many trials
- Background of **experienced and well-equipped on-site departments** (Pharmacy, Radiology, Nuclear Medicine, Laboratory, Pathology)

# MMCI Phase I trials experience

*(update to AUG/2019)*

| Phase | Protocol number | site initiated | end of enrollment | patients screened | patients enrolled | indication |
|---|---|---|---|---|---|---|
| Ia | **CVPM087A2101** | 13.5.2019 | ongoing in 8/2019 | 2 | 1 | mCRC, 1.st or 2nd line of treatment |
| I/II | **TED14856** | 17.1.2019 | ongoing in 8/2019 | 4 | 4 | breast cancer, HER2-, ER+ |
| I/II | **ACT15377** | 17.8.2018 | ongoing in 8/2019 | 6 | 4 | head and neck, HCC |
| II | **CNIR178X2201** | 29.11.2017 | ongoing in 8/2019 | 24 | 22 | TCO study, solid tumors |
| Ib | **I5F-MC-JSCC** | 9.10.2017 | 30.7.2018 | 1 | 1 | NSCLC, ovarian |
| I | **CINC280A2105** | 28.7.2016 | 31.12.2016 | 24 | 0 | C-MET positive solid tumors |
| I | **D0816C00005** | 17.3.2016 | 22.12.2016 | 1 | 1 | hepatic impairment solid tumors |
| I | **CLDK378A2112** | 15.9.2015 | 23.10.2017 | 24 | 18 | NSCLC ALK+ |
| I/II | **D3610C00002** | 17.3.2015 | 22.2.2016 | 1 | 1 | breast cancer |
| I | **EMR 100070-001** | 9.6.2014 | 30.3.2017 | 6 | 3 | solid tumors, immunotherapy |
| I | **TPU-S1119** | 14.10.2013 | 15.8.2014 | 5 | 4 | gastric cancer, dose escalation |
| I | **BT-11C-2011** | 6.9.2012 | 20.3.2014 | 18 | 18 | academic diagnostic study with FDG PET |
| I | **EMR 62242-004** | 30.11.2009 | 1.10.2010 | 5 | 4 | mCRC, dose escalation |
| Ib | **LA-12 cps.** | 15.11.2004 | 2.1.2010 | 32 | 32 | solid tumors |
| I | **LA-12 cps.** | 3.9.2003 | 30.6.2010 | 27 | 27 | solid tumors |

# Support departments


Clinical Trials Unit Team


Department of Pathology


Department of Laboratory Medicine


Hospital Pharmacy


Hospital Pharmacy


Department of Laboratory Medicine


Department of Radiology

# MMCI – your partner in Phase I clinical trials


OECI accredited Clinical Cancer Center since 2017
TCO site accredited by Novartis in 2016

*History of clinical trials since 1990´s.*
*At least 20 new clinical trials phase I-III annualy initiated.*
*Around 250 patients annualy enrolled.*

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# Contacts

Assoc.Prof. Regina Demlova, MD, PhD
Head of Clinical Trials Unit (CTU)
demlova@mou.cz

Radka Obermannova, MD, PhD
Phase I Unit Head Physician
obermannova@mou.cz

Michaela Hanakova, MSc.
michaela.hanakova@mou.cz
Start-up and Feasibility Specialist, Deputy Head of CTU
Clinical Trials Unit

Email: studie@mou.cz
Tel.: +420 54313 6226
www.mou.cz