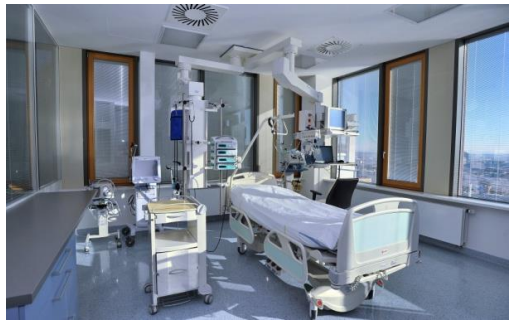
Masaryk Memorial Cancer Institute

Phase I Clinical Trials in Masaryk Memorial Cancer Institute



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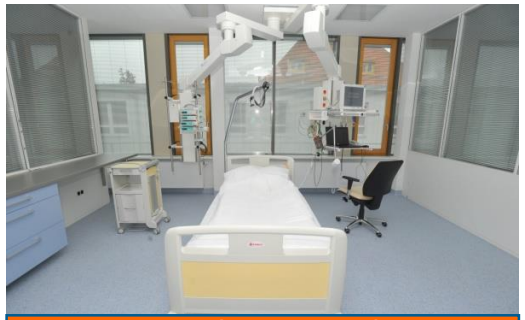
Phase I Unit

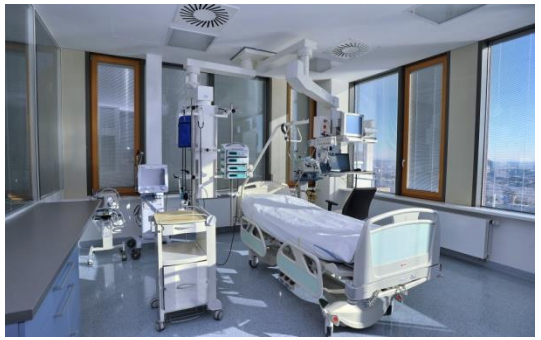
- Clinical unit established in 2012
- In-patient unit (4 beds)
- Out-patient unit
- Semi-intensive monitoring
- Background of Intensive Care Unit
- Telemetry since 2017
- Lab equipment
- ECG monitoring
- Possibility of PK/PD sampling
- Qualified Phase I team of investigators, study coordinators and study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

In-patient Unit



Intensive Care Unit

Out-patient Unit



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Working Group
Study Team for Phase I trials

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

6 Phase I Investigators

3 Phase I Study Nurses/Coordinators

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

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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 nominated 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

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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 **inspections**
- 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)

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MMCI Phase I trials experience

(update to FEB/2021)

Phase	Protocol number	site initiated	end of enrollment	patients screened	patients enrolled	indication
I	**SC103**	10.2.2021	ongoing	3	2	Solid tumors, dose escalation
II	**CNIS793B12201**	5.10.2020	ongoing	2	2	Pancreatic cancer, TCO study, dose escalation
Ia	**CVPM087A2101**	13.5.2019	ongoing	12	8	mCRC, 1.st or 2nd line of treatment
IIa	**VB C-02**	3.6.2020	ongoing	2	0	Cervical cancer
I/II	**TED14856**	17.1.2019	ongoing	11	9	breast cancer, HER2-, ER+
I/II	**ACT15377**	17.8.2018	ongoing	9	5	head and neck, HCC
II	**CNIR178X2201**	29.11.2017	ongoing	28	26	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

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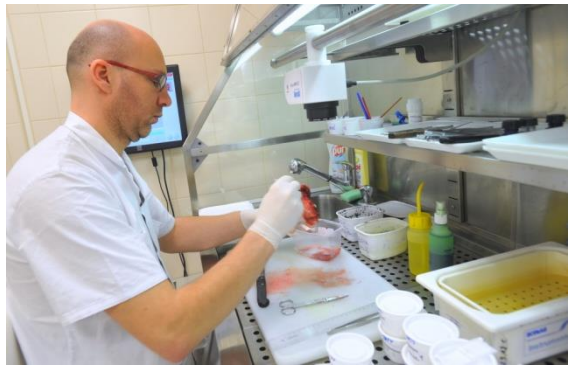
Support departments

Clinical Trials Unit Team



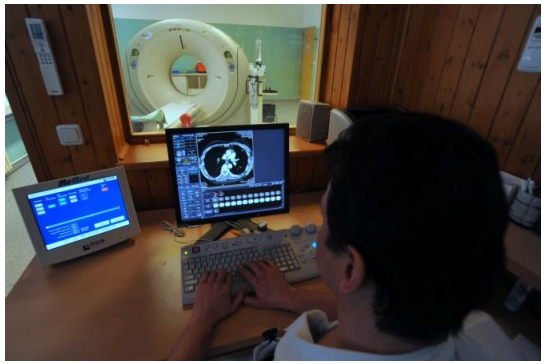
Department of Pathology

Department of Laboratory Medicine

Department of Laboratory Medicine

Hospital Pharmacy

Hospital Pharmacy



Department of Radiology

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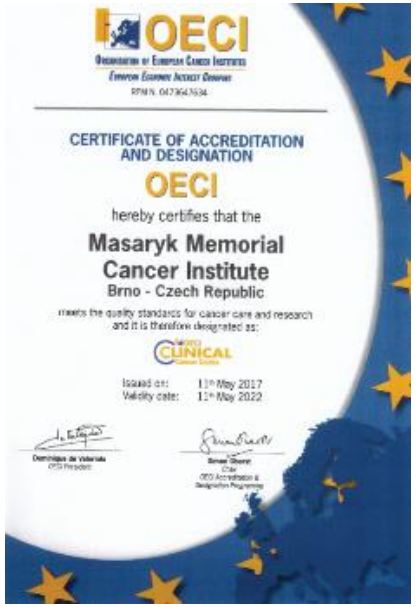
MMCI – your partner in Phase I clinical trials

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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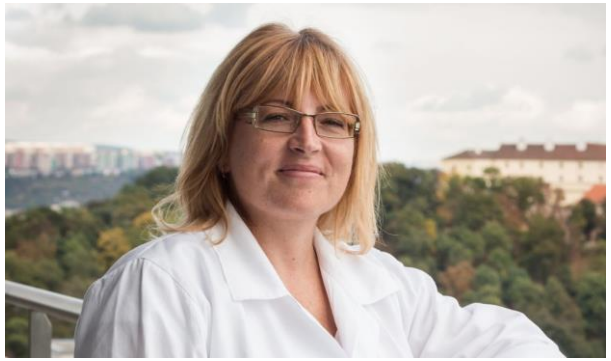
Contacts



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Clinical Trials Unit

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