The Clinical Trial Center (CTC Leipzig, German: Zentrum für Klinische Studien, ZKS Leipzig) is an institution of the Leipzig University (Universität Leipzig). It supports clinical research at the Medical Center Leipzig (MCL), which consists of the Faculty of Medicine and the University Hospital Leipzig. The CTC’s tasks are:

- administrative trial management
- quality management (QM) including sponsor QM
- IT/databases
- public relations

The Clinical Trial Center (CTC) consists of three divisions:

- **Coordinating Centre for Clinical Trials (KKS):** scientific coordination of Investigator Initiated Trials (IIT)
- **Academy at the CTC Leipzig:** basic and advanced trainings / Master of Science in Clinical Research and Translational Medicine
- **Site Management Organization (SMO):** central service - support and quality management for IITs and industrial trials at the Medical Center Leipzig. SMO-Partners at the University Hospital are 30 clinics and divisions active in clinical research in these areas:
  - Angiology
  - Anesthesiology
  - Dermatology
  - Endocrinology
  - Gastroenterology
  - Gynecology
  - Hepatology
  - ENT
  - Cardiology
  - Neurology
  - Neurosurgery
  - Oncology
  - Ophthalmology
  - Pneumology
  - Rheumatology
  - Urology

The SMO additionally cooperates with the Heinrich-Braun-Hospital Zwickau and the Heart Center Leipzig.
Clinical Trial Center Leipzig CTC – Site Management Organization SMO

The Site Management Organization (SMO) of the Clinical Trial Center (CTC, German: ZKS) offers comprehensive on-site support for clinical trials at the Medical Center Leipzig. We support the departments in establishing and expanding local study units and provide especially qualified staff, which supports the clinics in preparing and implementing the clinical trials according to the international quality standards. The work of the CTC Leipzig was funded by the Federal Ministry of Education and Research (BMBF) from 2007 to 2016.

Our partner organizations: University Hospital Leipzig (public institution), Heart Center Leipzig, Heinrich-Braun-Hospital Zwickau

Administrative study management

Central study management of all trials at the Medical Center Leipzig
Contract management
Cost calculation
Dunning processes

Our services

- central feasibility-management – inquiries please at: feasibility@zks.uni-leipzig.de
- administrative support in preparing and conducting clinical trials
- continuous training especially of study assistants and non-physician-staff (ICH-GCP, AMG)
- prompt communication due to the close network of all participating clinics and the administrative management
- establishing and continuous updating of a quality management system inter alia with SOPs, internal evaluation and audits in the trial sites
- mobile study nurse-support
- instruments for the selective patient recruitment

Major indications: angiology, anesthesiology, dermatology, endocrinology, gastroenterology, gynecology, hepatology, ENT, cardiology, neurology, neurosurgery, oncology, ophthalmology, pneumology, rheumatology, urology

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Infrastructure for Clinical Trials
at the University Hospital Leipzig and the Faculty of Medicine at the Leipzig University

The Medical Center Leipzig has an efficient infrastructure for the implementation of clinical trials. Apart from the Clinical Trials Center (CTC/ZKS) Leipzig and the tight interlinkage of all study active departments there are infrastructural facilities, which ensure, as service providers, an efficient and save (GCP- and GMP conform) implementation of clinical trials.

**Pharmacy**
- ordering, storing, distributing and documenting of trial medication
- shipping of study goods
- blinding and randomization
- disposal of expired or remaining investigational drugs
- optimal storage conditions
- continuous pharma monitoring
- ISO 9001:2008 certified
- manufacturing license for clinical investigational drugs according to §13 AMG

**Nuclear Medicine**
- PET/PET-CT/PET-MRT/SPECT/SPECT-CT
- drug occupancy and dose-finding trials
- incorporation dosimetry
- manufacturing of radio pharmaceuticals
- manufacturing license according to §13 AMG
- clinical testing/optimizing of imaging systems for nuclear medicine
- image data processing and modeling
- pre-clinical imaging
- EARL accredited center
- GMP and GCP conform service provision

**Pathology**
- reference pathology
- immuno-chemical analysis
- extraction of fresh tissue samples and cell culture analysis
- determination of the MGMT-promotor-status
- determination of the HPV-status
- molecular-pathological examinations
- shipping of tissue samples

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Clinic and Polyclinic for Ophthalmology

The Clinic for Ophthalmology in Leipzig provides all sub- and special fields of ophthalmology. There is a ward with 29 treatment units and functional areas for different purposes. In the division for functional diagnostics, special ophthalmological procedures are being conducted with the most modern devices. Additionally, clinic can perform all current laser therapies.

Major indications

- age-related macular degeneration
- retina and vitreous body surgery
- laser therapy in patients with retinal diseases, cataract, glaucoma and tumors
- glaucoma
- premature infant retinopathy
- neuroophthalmology
- functional diagnostic of the visual system

Clinical research

- processing of more than 70 phase II to IV trials since 2000
- outpatient study clinic with two study nurses and physicians
- EVICR.net certified institution for clinical trials

Equipment and services

- Heidelberger Retina Angiograph (HRA 2) + Spectralis OCT including anterior segment module, macular pigment density measurement, slit-lamp- and fundus photography, color test
- device for measuring the intraocular pressure via contact- and non-contact procedures
- perimetry Goldmann, oculus Twinfield, Heidelberg Edge perimeter (HEP)
- laser-polarization-measurement of the retinal nerval fiber layer
  - possible are furthermore electroretiongram (ERG), electrooculography (EOG) as well as visually evoked cortical potentials (VECP)

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Breast Center at the University Hospital Leipzig (public institution)

The Breast Center at the University Hospital has been for more than 10 years the central contact point for patients with breast cancer. Due to its position on the medical campus, it provides the most modern diagnostic and therapeutic opportunities. The interlocking of patient care, teaching and research leads to a high quality of patient care.

Equipment and services

- special study unit for conducting clinical trials in collaboration with the UCCL
- interdisciplinary network of specialists of all therapies for patients with breast cancer: gynecology, diagnostic radiology, radiation therapy, nuclear medicine, pathology, psycho-oncology and human genetics
- most modern diagnostic equipment: mammography | sonography | mamma-MRT | bone scintigraphy | computer tomography | PET-CT on-site

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Clinic and Polyclinic for Dermatology, Venereology and Allergology

The clinic for dermatology, venereology, and allergology builds on a long tradition of over 110 years of treating dermatological diseases. It provides a broad spectrum of all modern therapeutic procedures and has a strong clinical research unit with long-standing experience in phases I/II to IV trials.

Major indications
- psoriasis | malign melanoma / non-melanocytic neoplasia of the skin | allergies | autoimmunity | chronic wounds | laser / cosmetic | andrology

The clinic in numbers
- about 20 trials per year
- 2,246 stationary cases | 12,132 outpatient cases per year
- 3,140 procedures per year in- and outpatients
- 12 clinical investigators and 2 study nurses

Services and equipment
- spatially independent clinical research unit
- in-house mycological and dermal-histological laboratory
- scientific imaging and graphics
- ultrasound devices, ECP-devices
- several fully equipped operating-rooms (ORs)
- light therapy section (UVB311, UVA/UVB, UVA1, PDD/PDT)
- ECG, monitoring screens, emergency equipment

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Clinic and Polyclinic for Diagnostic and Interventional Radiology

The university radiology provides the complete radiologic-diagnostic spectrum. The clinic is a substantial part of the certified board for tumors of the gastrointestinal tract, mammae, prostate, lungs, as well as of bones and soft tissue. Since 1999, the clinic has a very active study unit at its disposal, which implements clinical trials and its own research projects.

Major indications
- tumor diagnostics and minimal invasive therapy
- thoracic diseases
- angiographic diagnostics and therapies
- illnesses of the abdominal and pelvic organs
- muscular-skeletal diseases

The clinic in numbers
- certified team of clinical investigators and comprehensive study coordination
- modern equipment on the highest technical level
- involvement in over 300 trials since 1999
- about 150,000 patients per year

Our Services
- most modern diagnostic procedures in imaging: X-ray examination | magnetic resonance tomography (MRT) | computer tomography (CT) | mammography/mamma sonography | angiography | ultrasound examinations | bone density measurement (osteodensitometry)
- worldwide cooperation with imaging companies
- digital imaging archiving and communication system (PACS)

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Echocardiographic Laboratories

The Echocardiographic Laboratories of the University Hospital Leipzig belong to the most modern facilities of their kind in Germany. The laboratory has been certified on a European level, and about 13,000 patients per year are being examined there. Since the year 2001, we have contributed to more than 20 clinical trials. The laboratory can perform all modern echocardiographic procedures (e.g. Deformation Imaging, multidimensional TTE and TEE as well as contrast- and stress-echocardiography).

Major indications

- diseases of heart valves and postoperative evaluation
- imaging of the coronary arteries and the coronary flux
- coronary heart diseases, LV-Deformation Imaging
- congenital heart defects in adulthood

Our services

- drafting of an illustrated, detailed and comprehensible study protocol
- conducting of a test run for correct digital documentation and transmission of the imaging data
- audits and visits at the participating trial centers to review the equipment standards, the examination qualification and the documentation standards
- for the statistic and biometric planning and analysis close collaboration with the Institute of Medical Informatics, Statistics and Epidemiology (IMISE) at the University of Leipzig
- consultation of industrial partners in planning of echocardiographic procedures
- high quality in imaging data, effective procedures in the CoreLab

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Clinic and Polyclinic for Gastroenterology and Rheumatology

Our clinic is a highly specialized division in the field of internal medicine, for gastroenterologist, hepatologist and rheumatologist diseases as well as geriatrics, infectiology, and tropical medicine. In close collaboration with the University Cancer Center Leipzig (UCCL) and in association with the tumor center at the University Hospital Leipzig the treatment and after care of cancer patients are on the highest level.

Major indications
- pancreatic diseases
- chronic inflammatory bowel diseases
- gastric and esophageal or diseases
- malignant diseases of the gastrointestinal tract (in cooperation with the UCCL)
- proctologic diseases
- neuroendocrine tumors of the gastrointestinal tract

Clinical research
- participation / management of prospective, randomized multicenter studies
- genome-wide association studies in pancreatic diseases
- clinical trials phase II – V
- “from bench to bedside”: co-operations with our own and DFG sponsored basic research projects
- 5 principal investigators, 1 study nurse

Equipment and services
- about 3000 inpatient and more than 500 outpatient treatments per year
- moleculargenetic diagnostics of pancreatic diseases
- comprehensive diagnostic and therapeutic procedures in the gastrointestinal endoscopy (e.g. ERCP, PTCD, TIPS, photodynamic laser therapy, neurectomy, mucosal ectomy, chromoendoscopy)
- sonography (e.g. new diagnostic procedures such as 3-D-sonography, ARFI, elastography), gastrointestinal functional diagnostics
- comprehensive laboratory diagnostics in co-operation with the respective institutes of the clinics

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Clinic and Polyclinic for Gastroenterology and Rheumatology – SECTION HEPATOLOGY

The main focus of our section, which exists since December 2009, is on the state-of-the-art and comprehensive differential diagnosis and treatment of patients with liver diseases, using the latest diagnostic and medical technology. The participation in numerous trials enables us to provide novel therapies.

**Major indications**
- acute and chronic viral hepatites (hepatitis B/D, C, E)
- hepatobiliary tumors (HCC, CCC)
- autoimmune disorders of the liver (PBC, PSC)
- fatty liver diseases (AFLD, NAFLD)
- fibrosis progression of the liver
- drug-induced liver disorders (DILI)
- interdisciplinary collaboration in liver transplantations

**Clinical research**
- over 1,000 outpatient treatments per year
- 9 clinical investigators | 2 study nurses
- clinical trials phase II - IV
- about 50 trial patients per year
- about 15 new clinical trials of the hepatological outpatient clinic per year
- participation of the hepatological research laboratory in 8 clinical trials
- case series and epidemiological trials

**Our services**
- analysis of genetic risk factors (e.g. IL28B, PNPLA3)
- specialized ultrasonic procedures (e.g. fibroscan, ARFI-ultrasound)
- ultrasound-controlled liver biopsy

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Clinic and Polyclinic for Gastroenterology and Rheumatology – SECTION RHEUMATOLOGY

For years, the rheumatological research outpatient clinic has performed clinical trials of the phases Ib to III. Presently, trials are being implemented with the help of a study coordinator, several part-time study nurses, as well as the specialist rheumatologists of the section as clinical investigators.

Major indications

- rheumatologist arthritis
- psoriatic arthritis
- Bechterew’s disease
- vasculitis
- collagenoses
- systemic lupus erythematosus (SLE)

The clinic in numbers

- about 1,000 inpatients and more than 1,500 outpatients per quarter
- implementation of about 13 clinical trials per year
- 3 clinical investigators | 2.5 study assistants
- 5 special outpatient clinics

Service and equipment

- Joint ultrasound and joint punctures, on-campus research laboratory, specialized diagnostics
- GCP-certified study personnel
- ultrasonic device for arthrosonography

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Clinic and Polyclinic for Otorhinolaryngology (ENT)

The University ENT-clinic is one of the oldest in Germany and looks back on a long tradition. Due to its continuous professional trainings and its international involvement in the development of new therapeutic approaches, the clinic has developed into a supra-regional center for ENT medicine.

Major indications
- head and neck tumors including salivary glands
- cochlea implantation and rehabilitation
- surgery of the middle and inner ear as well as the external ear
- operations on the larynx and the trachea
- aesthetic plastic surgery
- nose and paranasal sinus surgery
- allergic ENT diseases

The clinic in numbers
- over 20 phase I to III trials since 2008
- approximately 250 new cases of oncological illnesses
- over 50 free flap reconstructions
- approximately 2,800 cases per year
- 48 beds for inpatients

Our services
- interdisciplinary collaboration with the University Cancer Center Leipzig (UCCL)
- research laboratory for molecular characterization of ENT tumors
- training courses with the International Reference and Development Centre for Surgical Technology
- subunit of the ICCAS (Innovation Center Computer Assisted Surgery)
- established international training center for ENT surgeons and phoniatrists
- study unit with study assistant and study coordinator, experienced in trials according to Medicinal Products Act and Medicinal Devices Act
- Prof. Dietz is chairman of the working committee oncology of the German ENT Association

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Institute of Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics (ILM) at MCL

The accredited Institute for Laboratory Medicine has more than 10 years of experience in successful laboratory-diagnostics in national and international clinical trials on-site. The laboratory work is based on the GLP and the guidelines of the FDA and EMA.

**Main areas**
- pharmacokinetics / pharmacodynamics (method development, analysis)
- immunogenicity examinations of therapeutic proteins
- safety laboratory
- consultation about regulatory procedures
- medical-scientific consultation
- methodical-scientific consultation

**The services**
- full range of the clinical and molecular laboratory diagnostics
- electronical result reporting via data export, email, FTP
- international shipping management
- training of study centers
- drafting of laboratory manuals for clinical trials
- provision of laboratory materials/Kit design
- long-term storage of trial specimens at - 80 degrees Celsius

**About ILM**
- laboratory diagnostics based on GLP
- controlled specimen collection 24 hours /day, also on Sundays and holidays
- central European location with a very good traffic infrastructure (airport)
- offering of packet solutions for examinations of pharmacokinetics, pharmacodynamics, and immunogenicity (Ligand-bindings-, cellular based assays)
- accreditation according to guidelines 98/79/EG and DIN EN ISO/IEC 17025 as well as 93/42/EWG, 90/385/EWG and DIN EN ISO 15189

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Clinic and Polyclinic for Neurosurgery

The clinic provides the whole range of neurosurgery, including pediatric and functional surgery as well as the neurosurgical intensive therapy. Within clinical trials, the clinic participates directly in the implementation of new therapeutic approaches within the treatment of neuro-oncological and acute neurosurgical diseases after traumatic brain injury, subarachnoid hemorrhage, and stroke.

**Major indications**
- brain tumor surgery
- basal skull surgery
- aneurism and angioma surgery
- functional neurosurgery
- plexus and periphery nerve surgery
- spinal tumor surgery
- degenerative spine diseases
- dementia
- surgical therapy of strokes
- traumatic brain injury and subarachnoid hemorrhage
- experimental neuro-oncology
- experimental intracranial injury and neuro regeneration

**Our services**
- regular participation in national and international multi-center trials of phase II and III
- 4 especially qualified clinical investigators
- certified trans-regional stroke unit
- certified trans-regional trauma center
- interdisciplinary tumor board for malign CNS diseases
- own research laboratory as genetic engineering laboratory of the security level S1

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Clinic and Polyclinic for Neurology

The Clinic for Neurology covers the whole range of neurological diseases and our trained team of physicians makes for an intensive treatment of the patients. The implementation of clinical trials in various indications allows us to provide new and innovative therapies for many patients.

Major indications
- Parkinson’s disease and movement disorders
- neuro-immunological illnesses (multiple sclerosis, chronic neuritis)
- epilepsy
- stroke
- neuro-muscular diseases (e.g. myositis, myasthenia gravis, muscular dystrophy and amyotrophic lateral sclerosis, polyneuropathy)
- clinical neurophysiology

Our services
- special study units for the support of clinical trials with 4 study nurses
- 11 clinical investigators with experience in the implementation of clinical trials including certified knowledge on ICH-GCP and of the respective national regularities
- implementation of over 50 study projects of the phases I to IV since 2008
- special epilepsy monitoring unit
- intensive care unit and specialized stroke unit
- certified Neuromuscular Center of the German Association for Muscular Dystrophy (registered association)

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Division of Neuroradiology

The Division of Neuroradiology offers the complete spectrum of specialized diagnostics and minimal-invasive therapy of diseases of the brain, the spinal cord, the skull, and the spine. We cooperate with many clinics of the University Hospital and with external clinical and scientific institutions.

Scientific focus points
- cerebrovascular diseases
- pre- and post-operative diagnostics in case of brain tumors
- multimodal imaging with MRT-PET (molecular MR)
- regenerative therapy of the central nervous system (stroke)
- cerebral MR-elastography
- neuro-immunologic diseases

Clinical research
- participation in more than 40 clinical trials since 2000
- certified team of clinical investigators and comprehensive study coordination
- intensive collaboration with clinics of the University Hospital conducting trials and with other regional or national partners
- patient management of all participating study centers
- documentation/administration of the study results

Services and facilities
- comprehensive equipment on highest technical level: computer tomography (CT) | myelography/CT-myelography | magnet resonance tomography (MRT) | digital subtraction angiography (DSA)
- protocol implementation and protocol compliant/conformal test runs of the equipment/devices/instruments/machines
- digital filing of images and communications system (PACS)
- processing and transmitting of imaging data

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Division of Pneumology

The independent Division of Pneumology provides the whole spectrum of diagnostic procedures and therapeutic options, which are state of the art in pneumology. The division includes 42 clinical beds, a sleep laboratory, a specialized outpatient clinic, and a research laboratory.

**Major indications**

- pulmonary hypertension
- pneumological oncology
- lung transplantation
- mucoviscidosis
- interstitial lung disease
- COPD and pneumonia
- rare lung diseases, e.g. LAM

**Clinical research**

- participation in more than 35 pharmaceutical trials as well as investigator initiated trials in the last 14 years
- certified and skilled staff in the medical and coordinating field
- experience with interdisciplinary trials

**Services and equipment**

- endoscopy including all non-invasive and invasive diagnostics and therapeutic procedures (ultrasound/laser/cryo/stent/valves)
- right heart catheter measuring station, echocardiography
- complete lung function diagnostics
- ergo spirometry
- respiratory diagnostic procedures
- sleep laboratory (4 measuring stations)

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Section for Psychosocial Oncology / Division for Medical Psychology and Medical Sociology

The Section for Psychosocial Oncology has been established in October 2012. It is in charge of the psychosocial patient care, scientific issues, university teaching, and the professional training covering the various psychosocial aspects of patients with cancer and their relatives. The “Psychosocial Counselling Center for Tumor Patients and their Relatives” is affiliated with the division.

Major indications
- all malign tumor diseases in all phases of the illness and treatment
- the main focus in scientific research lies on:
  - hematological cancer diseases
  - breast cancer
  - colorectal cancer diseases
  - head and neck tumors

Clinical research
- quality of life
- evaluation of the outpatient cancer consultation
- psychotherapy in cancer patients
- psycho-oncological palliative patient care
- rehabilitation, prevention and survivorship

Our services
- collaboration with physicians and scientists in oncology, interdisciplinary work on regional, national, and international level
- implementation of psycho-oncological, scientific symposiums, and patient events
- psycho-oncological expertise and evaluation of patient care and its structures
- participation in tumor boards

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University Cancer Center Leipzig (UCCL)

The UCCL has been founded in 2012 as a central location for interdisciplinary, oncological diagnostics and treatment at the University Hospital Leipzig. Besides its management of central tasks in the field of oncological therapy, the UCCL is also developing a variety of activities in clinical and translational cancer research. The UCCL received in October 2015 the certification as an Oncological Center by the German Cancer Association.

**Major indications**
- tumors of the upper gastrointestinal tract:
  - stomach, esophagus, pancreas
- colorectal cancer
- breast cancer | ovarian cancer | sarcoma
- head and neck tumors
- psychosocially research and palliative care

**Clinical research**
- established study unit of the CTC Leipzig
- interdisciplinary team of investigators / physicians
- expertise for clinical phase I to III trials
- designated bio-imaging-facility (PET/CT, PET/MRT)
- laboratory expertise for additional scientific analyses

**Our services**
- core team of specialists (qualification: hematology, oncology)
- outpatient clinic with general tumor consultation | special consultation hours
- central chemotherapy unit with 12 treatment units
- close cooperation with all oncological disciplines
- tumor boards in all medical fields / departments
- networking in the region of Leipzig/Saxony/Central Germany
- close cooperation with the most important national and international research groups, especially AIO, EORTC and U.S. Intergroup

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Clinic and Polyclinic for Radiation Therapy

The clinic focuses on the optimal patient care, that is clinical treatment, consultation, and follow-up care of patients with malignant tumor diseases. The clinic also strives to participate in a broad range of clinical trials and to offer patients the possibility to take part in these.

Major indications

- breast cancer | prostate cancer | tumors of the CNS | gynecological tumors | lung tumors | gastrointestinal tumors | head and neck tumors | tumors in early childhood

The clinic in numbers

- treatment of 2,000 patients per year
- 40 inpatient beds
- 10 certified clinical investigators
- two especially qualified study nurses

Equipment and services

- 4 linear accelerators (6-10 MV) with imaging systems
- radiation systems (IMRT RapidArc technology)
- CT for radiation planning
- implementation of radio-chemotherapy
- stereotaxis with micro-multileaf collimator
- image-based HDR-brachytherapy
- reference center for brain tumor in childhood / implementation of respective trials
- own research laboratory
- extensive computer-based network for archiving the data

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Clinic and Polyclinic for Urology

In this clinic modern methods of diagnostics and treatment are utilized to treat benign as well as malign diseases of the urinary tract (kidneys, ureter, bladder, urethra) as well as the male sexual organs (penis, testicles, prostate). For many years, the clinic has engaged in the fields of basic and clinical research.

Major indications
- urological tumors (prostate, kidney-cell, bladder, testicle, penis carcinoma)
- lithiasis (kidney, ureter, bladder)
- benign prostate enlargement
- constrictions of the ureter and urethra
- neurogenic bladder dysfunction, incontinence
- erectile dysfunction

Clinical research
- certified team of principal investigators consisting of 8 physicians, study assistance and study coordination
- extensive study activity concerning medicinal tumor therapy
- development of new techniques for minimal-invasive urological surgery (endourology, laparoscopy and robot-assisted operations) for example endoscopic extra peritoneal radical prostatectomy (EERPE)
- basic and clinical research of interstitial cystitis and bladder-hyper function

Equipment and services
- certified center for prostate carcinoma and continence
- Center of Excellence for minimal-invasive urological surgery
- application of latest laser techniques | endoscopic department on highest technical level | x-ray devices | sonographic systems
- complete spectrum of robot-assisted surgery (daVinci)
- video-urodynamic measuring station | modern cell-biological research laboratory

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