



TRAVEL DIRECTIONS (BUILDING 4)

Public Transport:

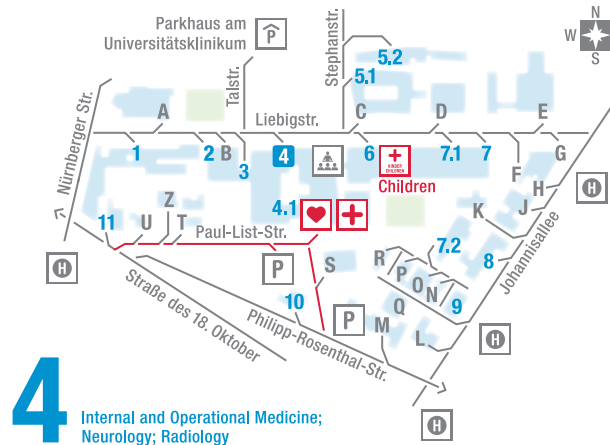
- 🚉 (Station ÖPNV):
 - Bayerischer Bahnhof: Tram 2, 9, 16; Bus 60; Train S1-S5X
 - Johannisallee: Tram 2, 16; Bus 60
 - Ostplatz: Tram 12, 15; Bus 60

by Car:

- via Ostplatz / Johannisallee
- via Nürnberger Straße or Stephanstraße
- via Bayrischen Platz / Nürnberger Straße

Car Parking:

- 🚗 Car Park, Brüderstraße 59
- 🅇 Parking Area beside the building 7, Liebigstraße



The University Hospital of Leipzig is distinguished by the highest standards of quality, the human touch, highly qualified staff, state-of-the-art technology and outstanding cost-effectiveness. All areas of medicine are represented. Our Early Clinical Trials Unit Leipzig (ECTUL) is embedded in a network of specialized institutions with a long standing record in all aspects of cancer related research:

- Leipzig University is one of the highly ranked German universities and offers access to a diverse cluster of basic and translational research, including preclinical cancer and stem cell fields
- The University Hospital Leipzig belongs to the top 10 German hospitals in the 2021 national „Focus“ health-care ranking with top scoring in various pathologies including leukemia, colon cancer, nuclear medicine, and radiotherapy
- Our hospital comprises over 1400 hospital beds and over 4600 employees, treating 400.000 patients per year
- The ECTUL is an interdisciplinary center enabling patients with various malignant and non-malignant conditions to benefit from optimal treatment in an environment of ground-breaking clinical research.

in collaboration with:



UNIVERSITY OF LEIPZIG
MEDICAL CENTER

DEPARTMENT OF HEMATOLOGY, CELL
THERAPY AND HEMOSTASEOLOGY

EARLY CLINICAL
TRIALS UNIT LEIPZIG

Setting

The ECTUL is a central early clinical trial unit for the conduct of phase-I/II clinical trials, including First-in-Human clinical trials.

Our primary goal is to evaluate the safety, tolerability and efficacy of investigational therapies and thus to contribute significantly to the advancement of new, innovative treatment approaches. The ECTUL is open to all medical departments of the University Hospital Leipzig and their collaborators and offers innovative therapeutic options for patients while multiplying translational research opportunities.

The ECTUL consists of an outpatient center as well as inpatient area, equipped as an intermediate care unit with two double rooms (four beds in total). The ECTUL is set to expand up to four rooms (eight beds in total). We use an electronic data management system for documentation and organization of appointments for all patients, enabling an optimal link between in- and outpatient treatment.

Further rooms equipped with computer, WLAN and printers are available for study monitoring.

Success Factors

The ECTUL is based on the established management organization of our Clinical Trials Unit, including:

- Our dedicated quality management system (with provision of appropriate standard operating procedures), embedded in the university quality and risk management structure
- Clear delineation of the responsibilities of all involved parties - both internally (including laboratory, pathology, radiology, judicial office) and externally (ethics committee, authorities)
- Effective patient recruitment through established networks and collaborations in the professional environment
- Active awareness-raising and public relations work in various media
- Our long lasting record of commitment within early clinical trials:

Year	No. of phase I/II trials	No. of enrolled patients
2017	61	114
2018	55	123
2019	56	124
2020	79	123

Collaboration + Network

The ECTUL is a nationally and internationally collaborating facility. We have strong and successful collaborations with:

- An accredited central laboratory (certified according to DIN EN ISO/IEC 17025:2018, DIN EN 13612 and directive 98/79/EG) offering comprehensive services 24 hours / 7 days
- A GMP pharmacy, regularly certified according to DIN EN ISO 9001:2015, licensed for German Drug Law (AMG) for production, blinding, randomization, (re-) packaging and distribution of investigational medicinal products
- Specialized R&D scientists at the Fraunhofer Institute for Cell Therapy and Immunology (IZI)
- Several companion study groups, such as Study Alliance Leukemia, East-German Study Group for Hematology, German Myelodysplastic Syndrome Group, and European Myelodysplastic Syndromes Cooperative Group
- Large network of oncologists and hematologists in private practice
- A range of university departments and with the Leipzig University Cancer Center (UCCL)
- On-site GMP and apheresis laboratories with genetic engineering facility to safety level 2.

Team

The ECTUL is led by PD Dr. med. Sabine Kayser together with Professor Dr. med. Uwe Platzbecker, director of the Department of Hematology, Cell Therapy and Hemostaseology. Our interdisciplinary team is specialized and trained for the individual demands of early clinical protocols to national and international standards of good clinical practice. In addition, the medical professionals receive regular training in advanced life support. The effective conduct of clinical trials within the ECTUL is guaranteed by a dedicated team of physicians, study nurses, study coordinators and documentarists.

Our Services

- In- and outpatient intermediate care unit
- 24 / 7 on-site physician/nurse attendance
- Patient care by highly qualified site staff
- Localization next to the intensive care unit to assure immediate emergency measures if required
- Networking and outreach management for patient recruitment
- Electronic data management system enabling an optimal link between in- and outpatient treatment

- State of the art equipment, security and surveillance technology - to comply with regulatory guidelines of European and German authorities for First-in-Human trials
- Central monitoring and documented qualification of medical, analytical and research equipment

Contract Management

- To smooth the path to study initiation, we organize and coordinate contract processing in German and/or English with all involved parties

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