

## Partnership

### We maintain partnerships with

#### Interdisciplinary Center of Clinical Trials Mainz (Interdisziplinäres Zentrum Klinische Studien, IZKS)

Close cooperation in the realization of mono- and multicenter, investigator-initiated clinical trials (IITs)

#### Breast Center Mainz (Brustzentrum Mainz)

Realization of its phase I and II trials

#### Pharmacy

The pharmacy of the University Medical Center has its own study department for the GMP- and GCP compliant preparation of study medication

#### Radiology

Reservation of appointment quotas for clinical study related CT, PET and MRT examinations; close teamwork of radiation protection officer and principal investigators

## Memberships

- Joint research project "Early Clinical Trials" (earlyTrials.net)
- Center for Tumor Diseases at the University Medical Center Mainz (Universitäres Centrum für Tumorerkrankungen Mainz, UCT)

## Contact details

### Clinical Trials Center for Hematology, Oncology, Infectious Diseases, Hemostaseology, and Palliative Care of the Third Department of Medicine

Universitätsmedizin Mainz  
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55131 Mainz

You will find us on the 2nd floor of building 302.

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For more detailed information, please feel free to contact us at:

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#### Christina van Oordt

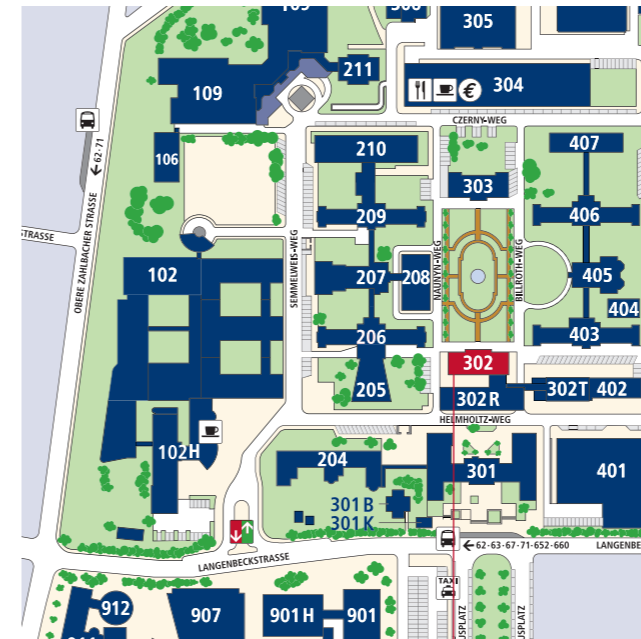
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#### For further information and currently active clinical studies, see:

<http://www.unimedizin-mainz.de/3-med/patienten/klinische-studien.html>

## Site map

### University Medical Center



Building 302, 2nd floor

#### University Medical Center

Third Department of Medicine  
Building 302, 2nd floor  
Langenbeckstraße 1, D-55131 Mainz  
[www.unimedizin-mainz.de](http://www.unimedizin-mainz.de)

You will also get all the directions, bus connections and other additional informations at the homepage of the university medical center Mainz.

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Third Department of Medicine

## CLINICAL TRIALS CENTER

### Hematology, Oncology, Infectious Diseases, Hemostaseology, and Palliative Care

Unser Wissen für Ihre Gesundheit



UNIVERSITÄTSmedizin.

MAINZ

# CLINICAL TRIALS CENTER

## About us

Our Clinical Trials Center at the Third Department of Medicine of the University Medical Center Mainz has already been established in 1986. The main purpose of the Clinical Trials Center is an integration of all study-related activities of patient-oriented research within the Third Department of Medicine. Thus, we coordinate and implement clinical trials while ensuring the application of international ethical and scientific standards as well as of effective laws and regulations (AMG, ICH-GCP).

We operate at the central interface between physicians, patients, scientists, academic study groups and research-ing companies and supervise sponsor-initiated as well as investigator-initiated single-site and multicenter clinical trials.

This information leaflet is to summarily introduce you to the services and clinical core areas of our Clinical Trials Center. If you need further information, please feel free to directly contact us. Our contact details can be found at the end of this leaflet.

We look forward to working with you.



PD Dr. med. G. Heß

## Core areas and recruitment network

### Our core areas of research

All our study projects are implemented under the direction of a disease-specific medical coordinator or a team featuring equivalent expertise. Thus, maximum coherence and competence as regards content are ensured, in addition to a highly professional standard of working structures.

Our clinical research focuses on:

- Solid tumors
  - Lung Cancer
  - Sarcoma
  - Breast Cancer
  - Urogenital Cancer
  - Advanced Cancer of unknown primary sites
- Hematologic neoplasias
  - Acute Leukemia
  - Multiple Myeloma
  - Malignant Lymphoma
  - Myeloproliferative Diseases
- Infectious diseases
- Hemostaseology
- Palliative Medicine

### Our recruitment network

We conduct clinical research projects in the outpatient and inpatient domains of the Third Department of Medicine and are beyond that able to rely on an extensive network of hospitals and practice-based physicians with contractually defined task structures.

## General information

### Our services

- Performance of phase I trials in a separate Phase I Unit
- Performance of clinical phase II and III trials
- Advice on the development and implementation of clinical phase I-III trials
- 24/7 service on demand

### Our interdisciplinary team

#### The team

Medical director, deputy medical director, and multi-disciplinary co-workers

#### Qualifications

Physicians, nurses with the additional qualification "study nurse", scientists, medical documentation assistants, administrative assistants and assisting students

#### Investigators

The investigators in charge are working closely with the team of the Clinical Trials Center

### Our premises and special facilities

- Separate offices for clinical trial management
- Separate rooms for visits of clinical research associates
- Dedicated rooms in inpatient and outpatient areas and the day-clinic of the Third Department of Medicine
- State-of-the-art Phase I Unit
- S2 laboratory for the production of genetically engineered medicine
- Safe, air-conditioned storage facilities for trial medication
- Safe, inhouse temperature-controlled storage facilities for study-related documents

## Quality and experience

### Quality assurance

- Training courses for the Clinical Trials Center team and the investigators on a regular basis
- Assessment of each study concept by a board of medical specialists
- Electronic system for data entry and central electronic filing system for all relevant documents and information
- Defined procedure instructions and SOPs
- Study documentation consistent with ICH-GCP and according to the sponsors' specifications
- Well-established contract and process management
- Training in transport of hazardous goods on a regular basis (IATA-certificate)

### Our operating experience

- Initiation of far more than 400 clinical trials since establishment of the center
- A quantity of more than 5.000 patients included in clinical trials
- Currently about 50 phase I-III trials activ
- Cooperation with numerous national and international academic study groups (AMLSG, GMALL, GMMG, GLSG, DCLLSG etc.)
- Cooperation with reputable sponsors (Bayer HealthCare, Boehringer Ingelheim Pharma GmbH & Co. KG, Novartis Pharma GmbH, Pfizer Pharma GmbH, Roche Deutschland Holding GmbH, etc.)
- Cooperation with various CROs (Covance Inc., Ergomed, Icon Clinical Research GmbH, Parexel International GmbH, Quintiles, PPD, etc.)