

FIM Heidelberg

Background

[FIM Heidelberg](#) (First-in-Man) is a research association of highly specialized partners of the [Medical Faculty of Heidelberg University](#), the [University Medical Center](#), and the German Cancer Research Center ([DKFZ](#)) Heidelberg emphasizing the conduct of early clinical drug trials. FIM Heidelberg is specialized in the planning, the realization, and the evaluation of early clinical trials concerning hematological, oncological, rheumatological, metabolic, and immunological diseases.

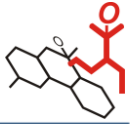
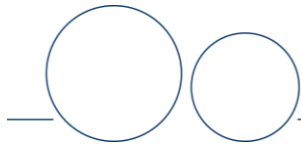
Mission

FIM Heidelberg efficiently conducts translational research projects and offers full service for the realization of first-time applications (First-in-Man: Phase 0 and Phase I) and proof-of-principle trials with innovative medicines in accordance with the highest safety and quality standards.

Structure

FIM Heidelberg comprises

- the Clinical Research Unit ([KliPS](#)) for the conduct of GCP-compliant studies. It is fully integrated into the Heidelberg University Hospital and has immediate access to all diagnostic (incl. PET) and therapeutic procedures (intensive care units, 24-hour access(ibility) to specialists) of one of Germany's largest high-capacity university hospitals
- a network of medical specialists, translational researchers
- an international catchment area of patients with hematological, adult and pediatric oncological, rheumatological, immunological, and other diseases
- a methodological and scientific study support for the planning, the realization, and the biometrical analysis of complex studies in accordance with international guidelines and local laws (Coordination Centre for Clinical Trials [KKS](#), Institute of Medical Biometrics and Informatics [IMBI](#), study center of the National Cancer Center Heidelberg [NCT](#))



FIM Heidelberg has access to

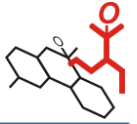
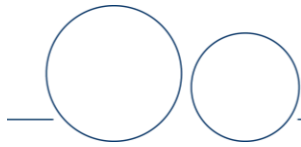
- an [accredited central laboratory](#)
- a certified (ISO 9001:2015) analytic-chemical [mass spectrometry facility](#) responsible for concentration measurements of drugs and metabolites in all biological matrices with validation according to EMA and FDA guidelines
- a large database of well characterized, genotyped probands
- all services and research facilities of the [DKFZ](#) Heidelberg, the largest German oncological research site
- a clinical cancer registry of all oncological patients of the [NCT](#)
- a standardized tumor tissue bank
- professional university hospital specialists and their patients

Setting

FIM Heidelberg is a joint venture consisting of the University Medical Center, the Medical Faculty of Heidelberg, and the DKFZ, and is located in the heart of the Heidelberg University Campus and the Rhine-Neckar area (catchment area of 5 million inhabitants).

KliPS: The Clinical Research Unit (KliPS) is integrated in the Department of Internal Medicine of the Heidelberg University Hospital and conducts all study types with healthy volunteers and adult and pediatric patients. KliPS consists of an ambulatory and a stationary area (11 beds), in which study participants can be accommodated for various time periods (shower facilities, dorm rooms and a lounge equipped with cable television, daily newspaper, and internet are available). Purpose-equipped rooms are dedicated to the preparation and storage of study medication and to the processing, storage, and shipment of study samples. All outpatient clinic rooms and all beds are equipped with an intensive care monitoring system (Mortara Surveyor S12) with invasive pressure measurement, continuous digital 12-lead ECG, telemetry etc.. All monitors are linked to a central monitoring room where study data is continuously supervised and stored. KliPS has a well-established quality management system and is certified according to ISO 9001:2015.

NCT: Similar to the model of American Comprehensive Cancer Centers, the Heidelberg National Center for Tumor Diseases consolidates patient care, cancer research, and cancer prevention. The NCT is a cooperation project of the Heidelberg University Medical Center, the German Cancer Research Center (DKFZ), the Heidelberg Thoracic Clinic ([Thoraxklinik](#)), the Heidelberg [Orthopedic University Hospital](#), and the German Cancer Aid. An interdisciplinary tumor outpatient clinic is the central gateway for all adult and pediatric oncological patients of the NCT. The NCT performs tumor diagnostics. All patients are treated according to international standards and to the recommendations of dedicated tumor boards consulted for every patient. New scientific information is transferred into diagnostics, therapy, and the prevention of cancer. A substantial fraction of all patients participates in clinical trials which are supported by a study center, a clinical cancer



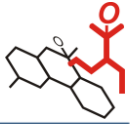
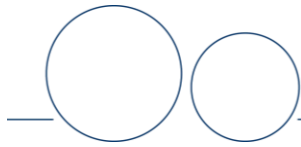
registry, and a tumor tissue bank. An extensive laboratory infrastructure supports the comprehensive laboratory research accompanying clinical studies.

KKS Heidelberg: The Coordination Center for Clinical Trials (KKS) was established by the Medical Faculty of the Heidelberg University to support clinical trials and efficiently improve the quality of clinical studies. The KKS ensures the compliance with applicable guidelines and laws during the entire study period thus guaranteeing an internationally competitive quality level. The KKS is divided into different areas of responsibility, such as (scientific) project coordination, clinical monitoring, and pharmacovigilance. Biometrics and data management processes are carried out in close cooperation with the Heidelberg Institute of Medical Biometrics and Informatics ([IMBI](#)). Data acquisition is supported by a validated RDE (remote data entry) system.

Services

FIM Heidelberg offers a comprehensive study service:

- ***Project management:***
 - ethical and regulatory consulting
 - feasibility and risk assessment of study plans, cost calculation, and budget supervision
 - continuous supervision of milestones
 - preparation and review of essential study documents (e.g., study protocol, patient's information, and informed consent)
 - Investigational Medicinal Product Dossier (IMPD)
 - ethical and authority contacts within the scope of the preparation and submission of documents
 - contract form and liquidation
 - insurance of study participants
 - development and implementation of recruitment strategies
 - quality assurance, organization of meetings and communication structures (involving study centers, labs and manufacturer of test preparations), logistics of study material and study medication, support in audits and inspections
- ***Clinical monitoring:*** Assurance of the study protocol and ICH-GCP compliance by regular site visits, source data validation and service of the essential documents for studies, including drug accountability and investigator study file (ISF)



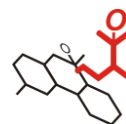
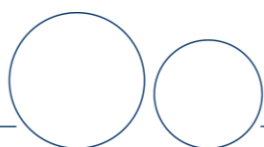
- *Data management:* Preparation and review of Case Report Forms (CRF), data management plan, construction and validation of study databases, also as a RDE solution, control of further inquiries (queries), encoding of data, e.g. use of MedDRA or ICD-10; coordination of data flow and electronic supervision of data management (Audit Trail), randomization lists, (graphic) processing of study results for reports, presentations, and study meetings
- *Biometry and data analysis:* Biometrical study planning (study design, population, terminator points, case number planning); concept of the biometrical part of the study protocol, preparation of the statistical analysis plan (SAP), planning and realization of evaluations (incl. interim analyses, case number adaptations, statistical report), pharmacokinetic analyses with validated software, supporting the interpretation of the study results; cooperation in preparing the final report
- *Pharmacovigilance:* Current and entire capture of events (incl. SAE, SUSAR), assessment, control of events and reporting to health authorities, sponsor, and ethical committees according to the legal obligations and timelines, development safety update report (DSUR)
- *Clinical conduct* with documentation of important endpoints (e.g. biomarker, surrogates, extensive possibilities of medical imaging): recruitment of study participants, screening and final examinations, execution of clinical studies under intensive care monitoring, (pre-analytical) standardization of sample preparation, and data collection
- *Accompanying laboratory research:* extensive, fully equipped laboratory and scientific competence to carry out accompanying translational molecular and cell-biological laboratory research

Directions

FIM Heidelberg is located in the center of the Rhine-Neckar triangle ([Metropolregion Rhein Neckar](#)).

By car: direct access via Autobahn A5 (60 minutes away from the Frankfurt International Airport)

By train: 30 min away from the main intercity express lines



Track record of first-in-man studies

Since 2008, the research association has successfully started and conducted the following first-in-human trials:

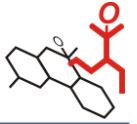
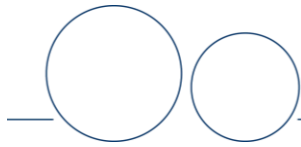
Compound class	Study population	Target indication
Phase 0 (FIM)		
monoclonal antibody	healthy volunteers	psoriasis
peptide	healthy volunteers	hepatitis B infection
Phase 1 (FIM)		
fusion protein	tumor patients	carcinoma
monoclonal antibody	tumor patients	carcinoma
small molecule	myeloma patients	multiple myeloma
monoclonal antibody	myeloma patients	multiple myeloma
monoclonal antibody	cancer patients	carcinoma
small molecule	patients	infection
bacterial tumor vaccine	tumor patients	pancreatic carcinoma
kinase inhibitor	tumor patients	CLL, Hodgkin, Non-Hodgkin
allosteric AKT 1/2 inhibitor	solid tumor patients	solid tumors
monoclonal antibody	psoriasis patients	psoriasis
RNA immunotherapy	tumor patients	triple-negative breast cancer
HDAC inhibitor	myeloma patients	multiple myeloma
antibody drug conjugate	myeloma patients	multiple myeloma
surface protein	healthy volunteers	malaria

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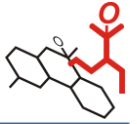
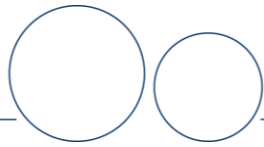
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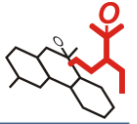
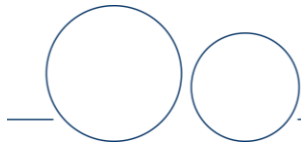
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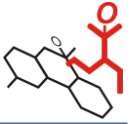
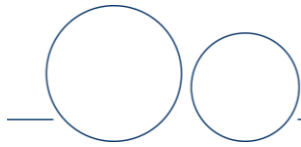
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