Fraunhofer IZI

Fraunhofer Institute for Cell Therapy and Immunology IZI

Fraunhofer IZI

Annual report 2023/2024

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»

Developing the medicine of the future together.«

Portrait of the institute

The Fraunhofer Institute for Cell Therapy and Immunology IZI investigates and develops solutions to specific problems at the interfaces of medicine, life sciences and engineering.
One of the institute's main tasks is to conduct contract research for companies, hospitals, diagnostic laboratories and research institutes operating in the field of biotechnology, pharmaceuticals and medical engineering.

The Fraunhofer IZI develops, optimizes and validates methods, materials and products within the business fields cell and gene therapy, drugs and vaccines, molecular diagnostics and immunodiagnostics, as well as extracorporeal therapies. Its areas of competence lie in cell biology, immunology, drug biochemistry, bioanalytics and bioproduction as well as process development and automation. Research in these areas is centered around developments in immuno-oncology and infectious disease pathology. The S3 safety laboratory allows research and development activities to be conducted and highly pathogenic agents investigated under biosafety level 3 conditions.

The institute works in close cooperation with hospital institutions and performs quality tests besides manufacturing investigational medicinal products in line with GMP requirements. Furthermore, it supports partners in developing processes for the pharmaceutical production of ATMPs and biologicals, for example by helping them to obtain manufacturing licenses.

Organization

You can find a detailed organization chart on our website.

Director

Administration

Executive departments and central facilities / officers

Department of GMP Cell and Gene Therapy

Department of Cell and Gene Therapy Development

Department of Preclinical Development and Validation

Department of Vaccines and Infection Models

Department of Diagnostics

Department of Extracorporeal Therapy Systems

Rostock

Department of Drug Design and Target Validation

Halle (Saale)

Department of Cellular Immunotherapy

Würzburg

Branch Bioanalytics and Bioprocesses

Potsdam-Golm

April 1, 2024

Business units and competencies

Cell and gene therapy | Drugs and vaccines | Molecular and immunodiagnostics | Extracorporeal therapies

Drugs & target discovery	Therapy & diagnosis concept	Preclinic & validation	Manufacturing	Clinical trials	Approval
▪ Biomarkers ▪ OMICS platforms (genome, RNA, proteome) ▪ Bioinformatics ▪ Cell analytics	▪ In vitro studies ▪ Bioanalytics ▪ Pharmacology ▪ Vaccines ▪ Antibodies ▪ ATMPs ▪ Small molecules	▪ In vivo studies ▪ GLP testing ▪ Toxicology	▪ Process development ▪ Process validation ▪ Manufacturing authorization	▪ Quality management ▪ Companion diagnostics	▪ Regulatory expertise from preclinic through to approval

▪ GMP manufacturing

Research area infectious disease pathology

Infectious diseases continue to pose a global threat to human and animal health. Understanding the spread, pathogenesis and possibilities of diagnosis, is essential for their effective control. With the research area infectious disease pathology, Fraunhofer IZI supports partners in the development and translation of technologies for research, diagnostics, prevention and therapy of infectious diseases.

R&D focus

- Preclinical development of active agents and vaccines (efficacy and safety analysis)
- Vaccine technologies
- Drug and material testing
- Assays and diagnostics

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Research area immuno-oncology

For a few years now, immuno-oncology has been complementing the classic methods of cancer therapy, radiotherapy, chemotherapy and surgery. Here, medicine makes use of the natural function of the immune system to eliminate foreign and degenerate cells via a wide variety of mechanisms. With the research area immuno-oncology, Fraunhofer IZI supports partners in the development and translation of innovative immunotherapies.

R&D focus

- ATMP development
- Preclinical development of cell and gene therapies (efficacy and safety analysis)
- Cell analysis, assay development and diagnostics
- GMP process development / process transfer
- Manufacturing of investigational medicinal products

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Research infrastructure at the Leipzig site

Isotope laboratory

GMP facilities

Animal husbandry incl. small and large animal OP and small animal MRI

Transparent prototyping laboratory

S3 laboratory

Seminar area and cafeteria

Buildings

Main building

- Usable area: 4 131 m²
- Lab space: 1 867 m²
- Offices: 1 615 m²
- Seminar area: 276 m²

First extension building

- Usable area: 1 568 m²
- Lab space: 470 m²
- Offices: 142 m²
- Clean rooms: 410 m²

Second extension building

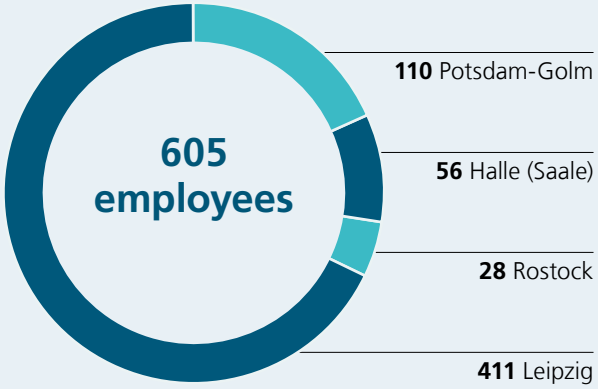
- Usable area: 3 050 m²
- Lab space: 1 171 m²
- Offices: 881 m²
- Clean rooms: 402 m²

Rental area at BIO CITY Leipzig

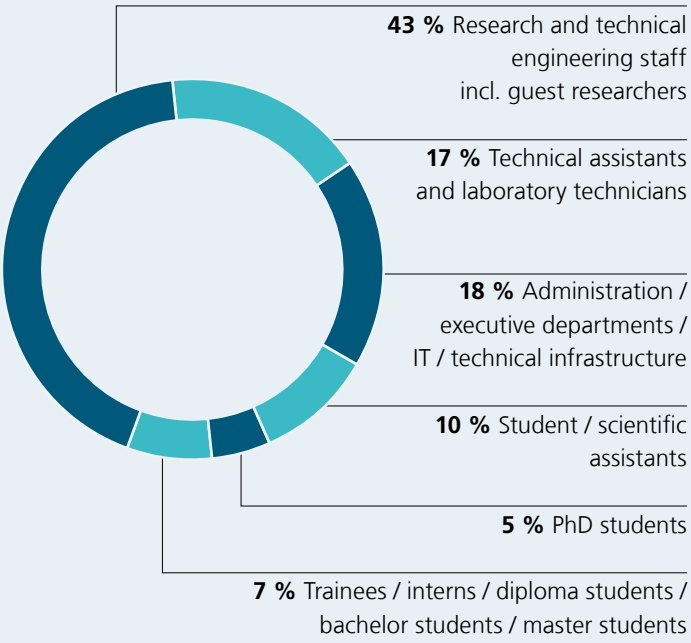
- Clean rooms: 334 m²

Key institute figures 2023

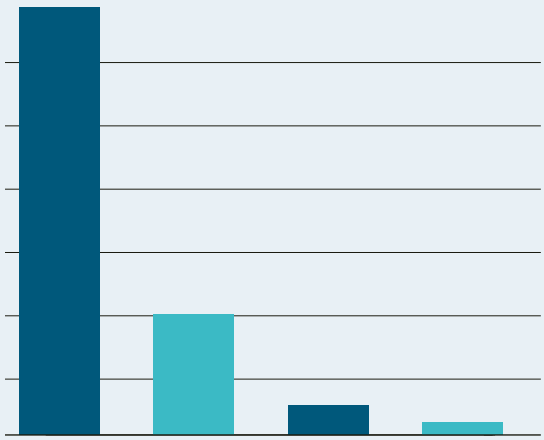
Employees
by location



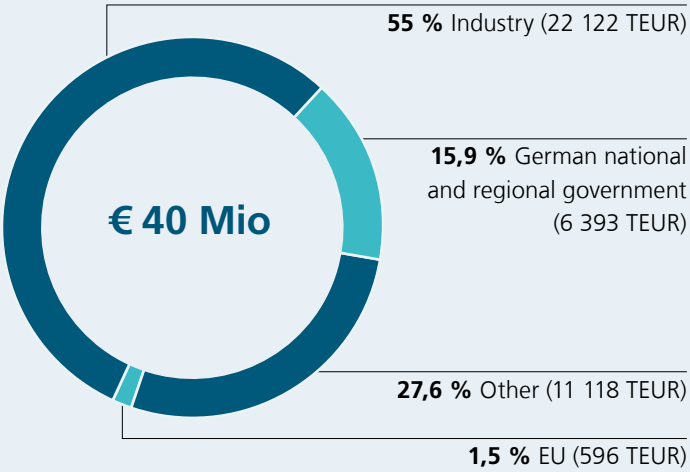
Employees
workforce composition



€ 40 Mio project revenue
by location in € mio



Project revenue
by funding agency

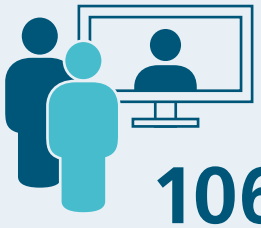


December 31, 2023

Scientific presence and network 2023

154 Industry partners

175 Research partners



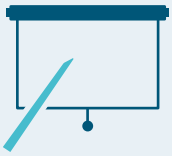
106 Conventions & conferences

64 Publications
2 Book articles
115 Abstracts

97 Association memberships in various expert associations

17 Graduation publications

(3 doctorates, 11 master theses, 3 bachelor theses)



87 Teaching activities

56 Patent families

with 284 patents & patent applications

Detailed information on the key figures and publications can be found on our website at **www.izi.fraunhofer.de/en/publications**

Locations and departments

Leipzig, Saxony, Germany

Headquarter

The main building boasts extensive laboratory capacities for conducting molecular and cell-biological work. An extensive immunohistochemistry laboratory, an isotope laboratory, a quality control laboratory with qualified equipment, as well as cyro-storage capacities also make up the institute's facilities.

The research infrastructure at the headquarters is complemented by various special facilities found in the extension buildings (e.g. imaging units, laboratories for experimental medicine, a S3 laboratory, and clean-room facilities).

All of the Fraunhofer IZI's laboratories are certified according to S2 standards and therefore suitable for carrying out work in the fields of genetic engineering and infection biology. A flexible cluster structure allows laboratory sections to be adapted and fitted out in line with the specific requirements of a broad range of projects.

The business units Cell and Gene Therapy, Drugs and Vaccines, and Diagnostics are primarily based in Leipzig. Biopharmaceutical products for clinical trials are manufactured in line with Good Manufacturing Practice (GMP) in the institute's clean-room facilities, which cover a total area of 1 200 m².

www.izi.fraunhofer.de/en

Management Prof. Dr. Dr. Ulrike Köhl | Director |
Tel. +49 341 35536-9110 | ulrike.koehl@izi.fraunhofer.de

Leipzig, Saxony, Germany

Department of GMP Cell and Gene Therapy

The Department of GMP Cell and Gene Therapy operates Fraunhofer IZI's two modern GMP facilities consisting of six separate clean room suites (altogether 13 clean room grade B manufacturing rooms) which have been specially optimized for manufacturing of cell and gene therapy products, so called Advanced Therapy Medicinal Products – ATMP. The particular specialty of the about 105 highly qualified staff members is the GMP-compliant manufacturing and quality control of investigational medicinal products.

GMP-compliant process and quality control development as well as the creation of Standard Operating Procedures (SOPs) are intensively discussed with the project partner before being implemented. The leading staff in charge has many years of experience in designing GMP-processes in the cell and gene therapy area.

Core competencies

- Manufacturing and quality control of ATMPs
- Update of the assortment list of the general manufacturing authorization according to § 13 AMG
- GMP process and method transfer
- Quality assurance in accordance with Good Manufacturing Practice (GMP)
- Operation of 632 m² clean rooms
- Support in preparing the Investigator Medicinal Product Dossier (IMPD)

Contact Dr. Gerno Schmiedeknecht | Tel. +49 341 35536-9705 | gerno.schmiedeknecht@izi.fraunhofer.de
Kati Kebbel | Tel. +49 341 35536-9712 | kati.kebbel@izi.fraunhofer.de

Leipzig, Saxony, Germany

Department of Cell and Gene Therapy Development

The Department of Cell and Gene Therapy Development researches and develops cell and gene therapy technologies and realizes the transfer of manufacturing processes from an experimental stage to GMP-compliant procedures.

The focus is on antigen-specific T cells, CAR T cells, CAR NK cells, dendritic cells, mesenchymal stromal cells and tissue engineering products.

The department's competencies, which build on each other, include research and development, preclinical evaluation and GMP process development for cell and gene therapies up to transfer into pharmaceutical manufacturing processes. Manufacturing parameters and quality controls can be tested and optimized flexibly and cost-efficiently.

New technologies (including digitalization, artificial intelligence, automation) as well as clinically relevant application aspects are considered at all stages of development.

In addition, biomolecules such as antibodies, proteins, enzymes and, in the future, viral vectors are produced in pharmaceutical quality in a separate GMP manufacturing unit.

After successful process optimization, investigational medicinal products can be produced by the Department of GMP Cell and Gene Therapy and further accompanied until approval.

Core competencies

- GMP process development and transfer for cell and gene therapy manufacturing
- mRNA technology
- Specialist expertise in hematology / oncology
- Process optimization and automation
- Good Manufacturing Practice (GMP) evaluation for cell and gene therapy manufacturing
- Quality assurance
- GMP-compliant equipment and processes
- Clinical trial planning
- CAR-T/NK cells and NK cell technologies
- Biomaterials research
- Non-clinical developments (in vitro and in vivo)
- Preparing GMP documents (SOPs, batch records, quality control records...)
- GMP process development for biopharmaceuticals
- GMP certification
- Manufacturing authorization for therapeutic antibodies pursuant to Section 13 (1) of the German Medicinal Products Act (AMG)

Contact PD Dr. Stephan Fricke | Tel. +49 341 35536-2205 | stephan.fricke@izi.fraunhofer.de

Leipzig, Saxony, Germany

Department of Preclinical Development and Validation

The main goal of the Department of Preclinical Development and Validation is the concentration of expertise for the preclinical validation of novel therapeutic approaches at Fraunhofer IZI, to maximize the efficiency in developing new in vitro or in vivo models and their application in preclinical studies. Since the department manages the GLP test facility of Fraunhofer IZI, preclinical studies (even those in other Fraunhofer IZI departments) can be performed under GLP.

The department covers the following topics

- Planning and execution of preclinical efficacy and safety studies for new drug candidates (especially ATMPs) and medical devices (ISO 10993) under GLP or GLP-analogous conditions. This includes the development and validation of suitable in vitro and in vivo models.
- Developing procedures for the diagnostic analysis of secretory and cellular protein biomarkers, including the development and production of specific monoclonal antibodies for their detection and finally the development and validation of the respective diagnostic assays (e.g. ELISA, Luminex®, lateral flow assays, flow cytometry).
- Identifying and validating new protein biomarkers for diagnosis and therapy (in particular using LC-MS-based proteomics) of chronic-inflammatory and tumor diseases, as well as for the sector of regenerative medicine.
- Developing human monoclonal antibodies to be directed against new therapeutic tumor targets (triple-negative breast cancer).

Kernkompetenzen

- Preclinical studies
- Good laboratory practice (GLP)
- Immunotoxicology (study design and implementation)
- Efficacy and safety studies for ATMPs and class-3 medical devices
- Protein biomarker (identification and validation)
- Antibody development (therapy)
- Antibody and immunoassay development (diagnostics)
- Histopathology, toxicopathology
- Chronic inflammatory bowel disease (therapy development)
- Triple-negative breast cancer (therapy development)
- LC-MS based proteomics

Contact Dr. Jörg Lehmann | Tel. +49 341 35536-1205 | joerg.lehmann@izi.fraunhofer.de

Leipzig, Saxony, Germany

Department of Vaccines and Infection Models

Procedures to stimulate or suppress the immune system in order to counter various infectious agents are developed in the Department of Vaccines and Infection Models. Innovative technology platforms are used for vaccine development, such as novel inactivation methods, mRNA, genetic vaccine technologies such as plasmid DNA or viral vectors. As such, efficient vaccines can be produced quickly and inexpensively. An S3 laboratory facilitates work with highly infectious pathogens. In vivo and in vitro model systems are also generated and used to develop diagnostic and therapeutic agents.

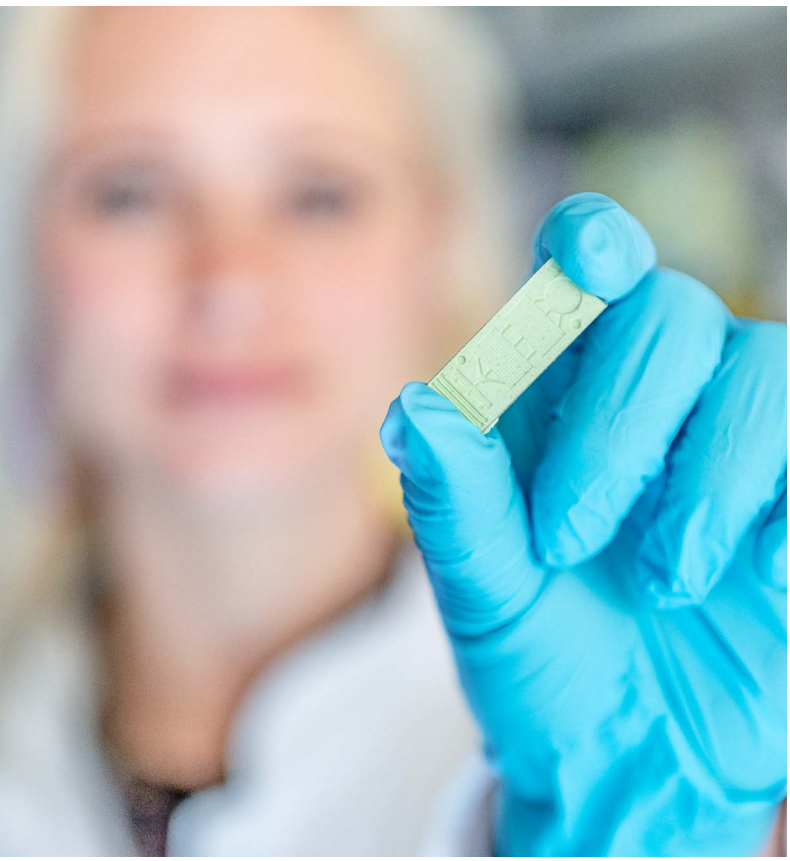
Core competencies

- Vaccine development
- Infection models
- Inactivation of pathogens
- Working with highly infectious pathogens
- Drug testing
- Antimicrobial therapies
- Serological test systems

Contact PD Dr. Sebastian Ulbert | Tel. +49 341 35536-2106 | sebastian.ulbert@izi.fraunhofer.de
PD Dr. Thomas Grunwald | Tel. +49 341 35536-5423 | thomas.grunwald@izi.fraunhofer.de

Leipzig, Saxony, Germany

Department of Diagnostics



The Department of Diagnostics offers a value chain that covers the identification and testing of new biomarkers, the bioinformatic analysis of complex transcriptomic and genomic data ("Big Data") as well as the development of prototypes for in vitro diagnostics and point-of-care platforms. Furthermore, it offers a broad range of analytical methods.

In the department's RIBOLUTION Biomarker Center new biomarkers are being systematically identified and validated using state-of-the-art techniques such as next-generation sequencing (NGS) and microarray analysis. A particular focus is on non-coding RNAs, which show high, so far mostly underestimated, biomarker potential. An experienced bioinformatics group provides efficient processing and (statistical) analysis of molecular biological data, particularly of NGS data obtained from large clinical cohorts. Competencies in study and data management enable our scientists to plan and conduct such cohorts. A quality management system has been implemented and certified according to ISO 9001:2015 with an eye to these processes.

A main focus of the department is to develop molecular and immunodiagnostic tests in the medical and food sector. This includes PCR and NGS analyses, lab-on-a-chip systems as well as peptide selection and epitope mapping technologies. Diagnostic needs are addressed e.g. for cancer, cardiological diseases and food allergies as well as pathogen tests for infectious diseases. Moreover, the department has a wide range of additional analytical methods at its disposal and develops novel biointeractive molecules on structural DNA-based scaffolds. New imaging procedures support the analysis of cell biological processes.

Core competencies

- Transcriptome and immunome analyses
- Next-generation-diagnostics
- Bioinformatics
- Nanotechnology
- Lab-on-chip
- Biomarker identification
- Tumor models
- Quality assurance according to DIN EN ISO 9001:2015
- Experimental imaging and image analysis
- Tumor tissue-specific peptides
- Epitope mapping in patient sera

Contact Dr. Dirk Kuhlmeier | Tel. +49 341 35536-9312 | dirk.kuhlmeier@izi.fraunhofer.de

Rostock, Mecklenburg-Western Pomerania, Germany

Department of Extracorporeal Therapy Systems

The Department of Extracorporeal Therapy Systems focuses on the development and evaluation of extracorporeal (outside the body), organ-supporting technologies with a particular emphasis on supporting the immune system. It offers the full range of preclinical and clinical analyses of extracorporeal technologies based on a broad spectrum of in vitro simulations, animal models, as well as a powerful clinical study network for in and out-patients. Moreover, the department offers self-developed unique analytic and diagnostic devices including an ex situ intestinal model, a cell sensor and novel protein assays.

Core competencies

- Cellular biosensors
- Medical devices for blood purification
- Dialysis procedure
- Organ-supporting technologies

Contact Prof. Dr. Steffen Mitzner | Tel. +49 381 494-2600 | exther-info@izi.fraunhofer.de

Halle (Saale), Saxony-Anhalt, Germany

Department of Drug Design and Target Validation

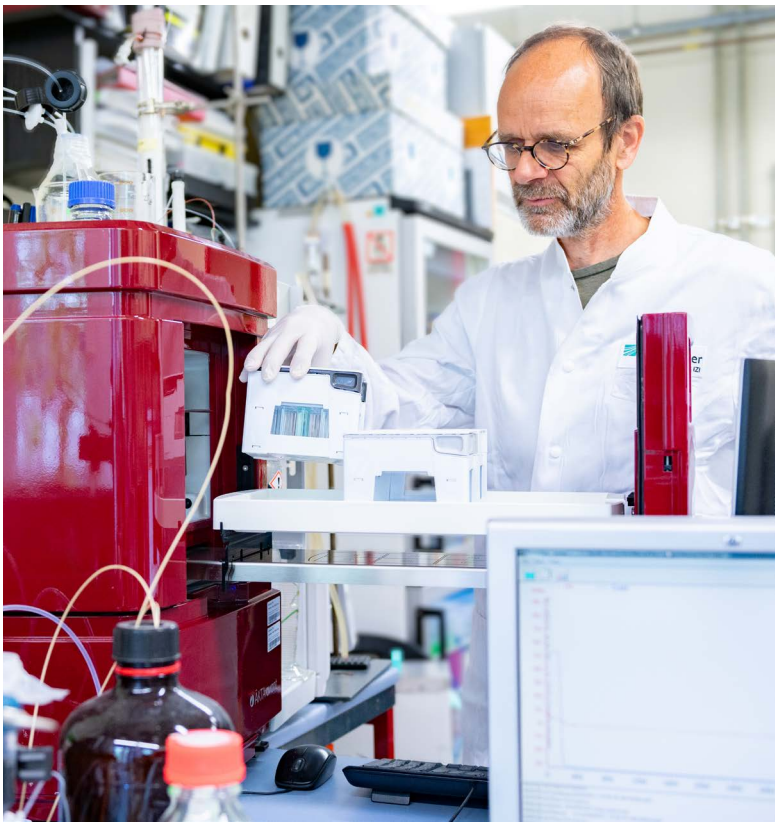
The Department of Drug Design and Target Validation in Halle (Saale) boasts considerable expertise in various areas of preclinical drug development, placing a special focus on neurodegenerative and inflammatory diseases. The department's work covers almost the entire range of activities associated with the early stages of drug development, from identifying and characterizing target proteins to identifying initial drug candidates right over to testing substances in the animal model. Members of staff at the Halle (Saale) branch are characterized by their extensive experience in industrial and pharma-relevant research. This allows scientific issues to be tackled on behalf of industry partners on the one hand, and new drugs and target proteins from the institute's own preliminary research to be identified, patented and subsequently form the basis of industry cooperations on the other.

Small molecules and biologicals will be developed and tested on the back of the department's new treatment concepts. Alongside this, testing procedures will be developed for the identification and diagnostic application of biomarkers, which allow the course of both the disease and therapy to be monitored. Furthermore, the department also houses the expertise required to create pharmacologically relevant in vitro and in vivo models.

Besides modern peptide synthesis and protein analytics methods (MALDI-TOF and LC-MS), the department has also developed a broad spectrum of biophysical methods for characterizing therapeutically relevant metabolic pathways, whose key proteins as well as cell-based and pharmacological models are used to characterize innovative chemical and biological agents.

Core competencies

- Medicinal chemistry
- Assay and model development
- Neurodegenerative diseases
- Pharmacology
- Drug development
- Drug design (in silico)
- Drug testing (preclinical)
- Synthesis



Contact Prof. Dr. Stephan Schilling | Tel. +49 345 131428-15 | stephan.schilling@izi.fraunhofer.de

Potsdam-Golm, Brandenburg, Germany

Branch Bioanalytics and Bioprocesses

The Bioanalytics and Bioprocesses Branch in Potsdam-Golm works on technological solutions for biomedicine and diagnostics as well as for biotechnology and bioproduction.

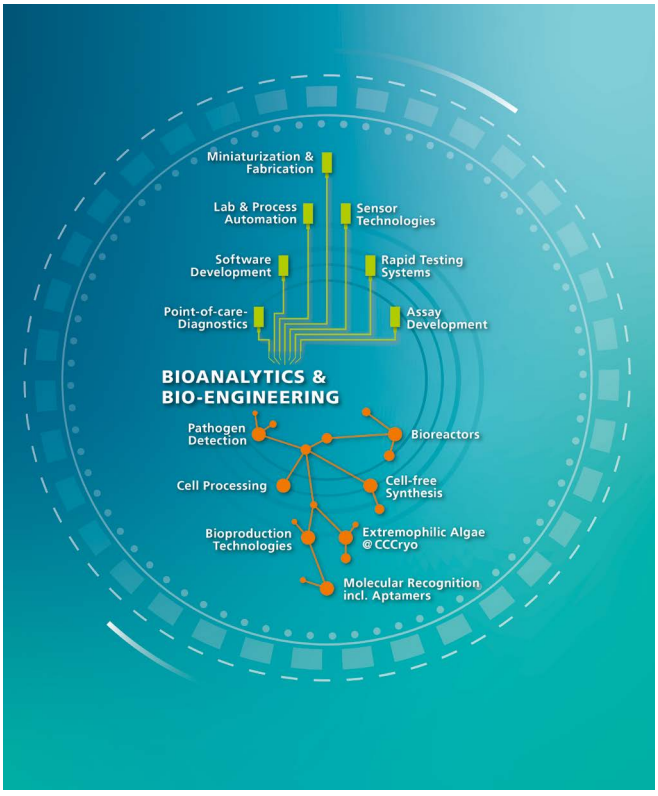
The interdisciplinary team comprising natural scientists, engineers and technicians develops powerful, analytical methods for the detection and validation of pathogens and biological markers besides processes to obtain, handle and manipulate cells and biomolecules. In this context, the team develops applications for personalized medicine, as well as biosensors and detection procedures for the areas of agriculture and the environment, for a broad spectrum of substance classes.

The site has the state-of-the-art infrastructure required for miniaturizing and automating biological processes. This includes various biosensor and biochip technologies, pipetting robots and micro and nano-dispensers, besides many different rapid-prototyping procedures.

A further special feature of the branch's facilities is the life culture collection of cryophilic algae (CCCryo), which serves as a resource for developing production processes for novel, industrial bioproducts.

www.izi-bb.fraunhofer.de/en.html

www.izi-bb.fraunhofer.de/en/media/annual-report.html



Management Prof. Dr. Antje Bäumner | Director |
Tel. +49 331 58187-0 | antje.baeumner@izi-bb.fraunhofer.de

Erfurt, Thuringia, Germany

Fraunhofer Center for Microelectronic and Optical Systems for Biomedicine

The Fraunhofer Center for Microelectronic and Optical Systems for Biomedicine in Erfurt brings together the core competencies of three Fraunhofer institutes to span the disciplines of biosciences, microelectronics, microsystems technology, optics and photonics. This combined expertise will be used to develop application-ready systems in the areas of medical engineering, analytics, diagnostics, biotechnology, biophotonics, pharma, health care, ageing and food economics which will then be transferred into industry. Fields of application here include improved medical imaging and visualization as well as technologies for biomarker analysis.

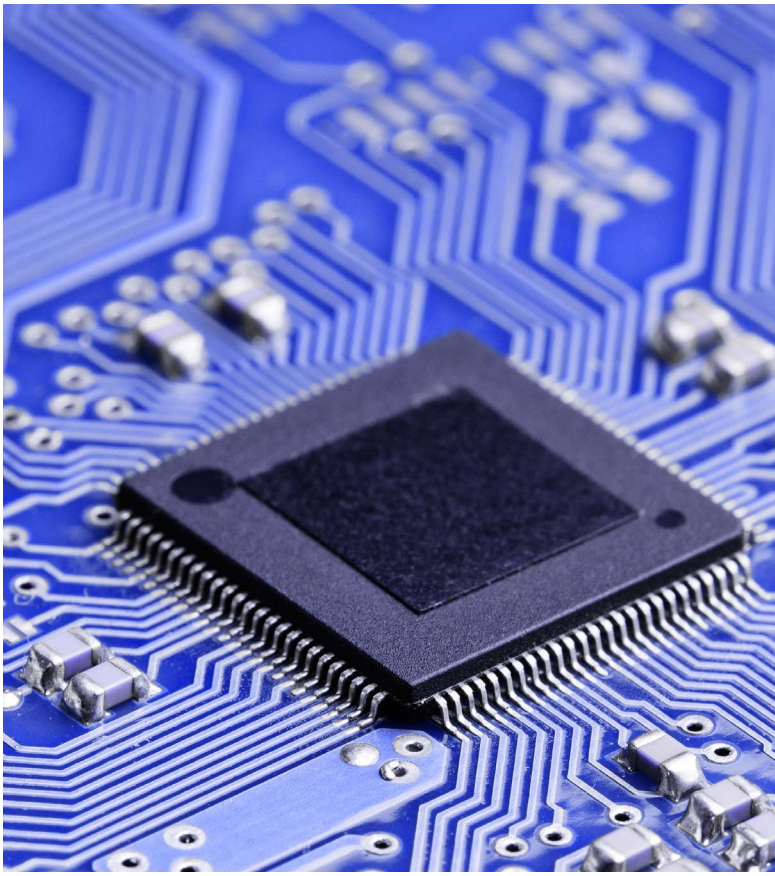
www.meos.fraunhofer.de/en

Involved Fraunhofer institutes

Fraunhofer Institute for Applied Optics and Precision Engineering IOF
www.iof.fraunhofer.de/en

Fraunhofer Institute for Photonic Microsystems IPMS
www.ipms.fraunhofer.de/en

Fraunhofer Institute for Cell Therapy and Immunology IZI
www.izi.fraunhofer.de/en



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Contact at Fraunhofer IZI Dr. Dirk Kuhlmeier |
Tel. +49 341 35536-9312 | dirk.kuhlmeier@izi.fraunhofer.de

Central facilities

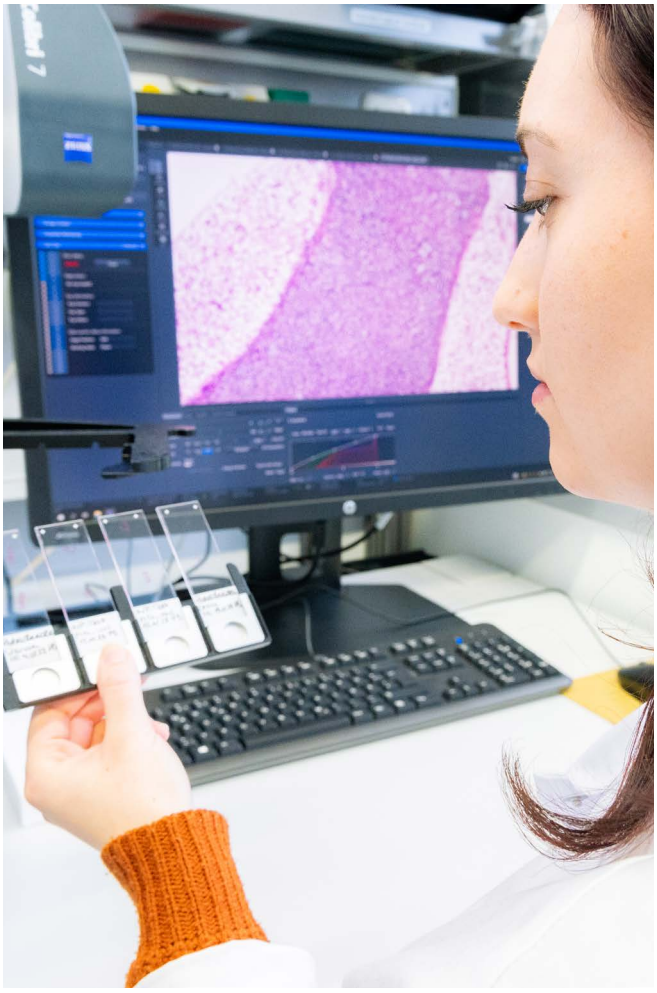
GLP test facility

Good Laboratory Practice (GLP) describes a quality assurance system for conducting safety tests on chemicals, drugs, pesticides and food additives. It regulates the implementation, documentation, archiving and reporting of respective tests.

Fraunhofer IZI has been certified as a GLP test facility for testing category 9 since 2009. Among other things, this includes safety tests for ATMP immunotoxicity / immunogenicity, biodistribution and tumorigenicity in vitro and in vivo. Testing category 2 was added to the portfolio in 2023, which includes tests to determine toxicological properties.

The facility plans and conducts preclinical efficacy and safety studies for new drug candidates (especially ATMPs) and medical devices (ISO 10993) under GLP and GLP-analogous conditions. This involves developing and validating suitable in vitro and in vivo models.The test facility boasts a state-of-the-art setup for keeping small animals as well as small and large animal operating rooms. Furthermore, a broad spectrum of validated SOPs are implemented here for equipment and methods.

Contact Dr. Jörg Lehmann | Head of GLP test facility |
Tel. +49 341 35536-1205 | joerg.lehmann@izi.fraunhofer.de



Why are GMP and GLP important?

A clinical trial of a new drug candidate is an essential step on the way to approval. Since the 12th revision of the "Arzneimittelgesetz AMG" (German Drug Act) every clinical trial must be approved of by the responsible higher federal authority ("Bundesinstitut für Arzneimittel und Medizinprodukte", Federal Institute for Drugs and Medical Devices, Paul-Ehrlich-Institut) and by the responsible ethics committee prior to the initiation of the clinical trial. In order to obtain this authorization, the efficacy and safety of the investigational medicinal product must

GMP manufacturing

GMP (Good Manufacturing Practice) describes a set of quality assurance guidelines for production and quality control processes and spaces with regard to drug manufacturing. It regulates, among other things, the requirements concerning hygiene, human resources, facilities, equipment, documentation and controls.

Fraunhofer IZI assumes the manufacture of investigational medicinal products for clinical trials.

Advanced Therapy Medicinal Products (ATMPs)

The Fraunhofer IZI maintains two GMP-compliant clean room facilities for the manufacturing of advanced therapy medicinal products (ATMPs). These include cell-based drugs such as gene therapeutics, somatic cell therapy medicinal products as well as tissue engineering products. Through the flexible design, the facilities are especially attractive for companies that seek to bring newly developed medicinal products into clinical application via clinical trials. The facilities are divided into different independent suites. Each has its own grade C clean room (preparation), own air locks from grade C to B (personnel and materials transfer) and two grade B rooms (aseptic manufacturing). The clean room grade A is provided via laminar airflow cabinets that are installed in the B-rooms. The available clean room suites are specialized in conducting processes for manufacturing human autologous and / or allogeneic cell and gene therapeutic products (advanced therapy medicinal products). In addition to the clean rooms and the technical infrastructure, the Fraunhofer IZI offers assistance for the set-up and validation of GMP-compliant manufacturing processes as well as for the update of the assortment list of the general official manufacturing authorization pursuant to section 13 of the German Drug Act (AMG).

first be verified within the framework of GLP-compliant preclinical investigations (e.g. toxicological testing procedures). Furthermore, the quality of manufacture of the investigational medicinal products must be verified by a GMP manufacturing authorization pursuant to § 13 AMG. Relevant trial results from GLP-certified trial institutions and a GMP manufacturing authorization are thus absolutely prerequisite when applying for the clinical trial of a new medication.

Contact Kati Kebbel | GMP manufacturing of ATMPs
Tel. +49 341 35536-9712 | kati.kebbel@izi.fraunhofer.de
Dr. Gerno Schmiedeknecht | GMP manufacturing of ATMPs | Tel. +49 341 35536-9705 | gerno.schmiedeknecht@izi.fraunhofer.de

Advanced Analytics Technology Platform

The Advanced Analytics technology platform bundles existing analytical competencies and technologies for data evaluation and interpretation at Fraunhofer IZI.

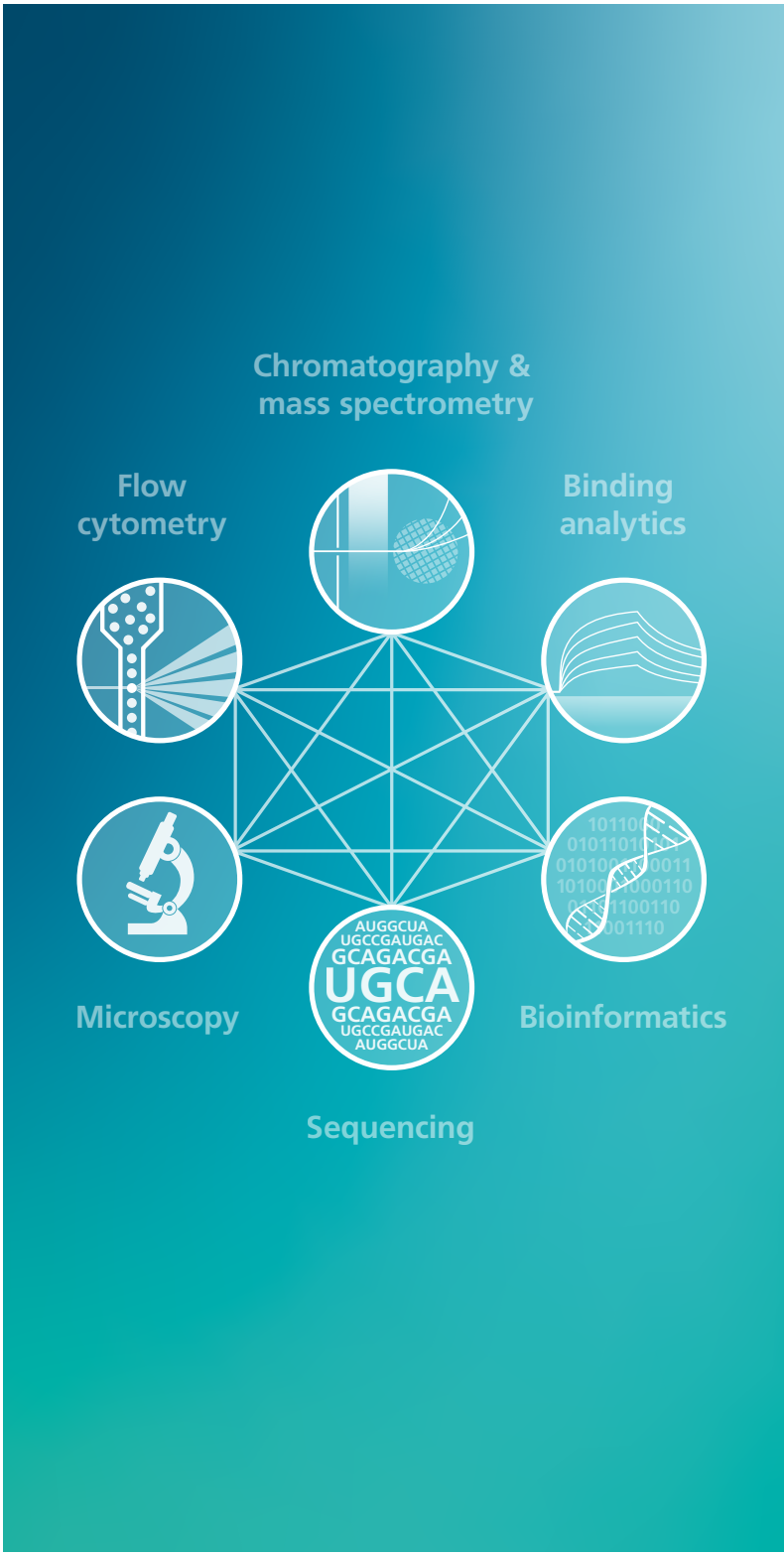
With a broad portfolio of state-of-the-art technologies and corresponding expertise, customers and partners are supported with comprehensive analyses in the development of a wide range of therapeutics and diagnostics.

Assays can be developed at different scales or complete proof-of-concept studies can be realized according to customer-specific requirements. The platform's subdivisions work together in an integrative manner, from study design and experiment execution to multi-modal data evaluation.

The Advanced Analytics technology platform bundles the following competencies:

Chromatography and mass spectrometry

- Preparative chromatographic separations (RP, SEC, IC) Identity determination of isolated proteins by peptide mass fingerprinting (PMF) and MS/MS analyses
- MS-based elucidation and detection of protein modifications and protein interactions
- Consulting, sample preparation, performance and evaluation of proteomics studies
- Determination of toxins and metabolites in biofluids by Multiple Reaction Monitoring (MRM)
- Analysis of active substances and their degradation products by MRM
- Characterization of ssDNA and ssDNA conjugates



Flow cytometry and FACS

- Cell-based assays (immunophenotyping, apoptosis, internalization, proliferation / cell cycle, migration, degranulation)
- Bacteria-binding assay
- Cell sorting

Microscopy / imaging

- Multimodal imaging for preclinical research
- Brightfield, live cell, fluorescence and confocal laser scanning microscopy
- Slide scanning services
- In vivo imaging via magnetic resonance imaging (MRI), computed tomography (CT) and optical imaging (BLI / FLI) for small animals
- Evaluation of various (also correlative) image data
- Microscopy training of users and technical support

Sequencing

- Classical next generation sequenzing (NGS) methods
  - Whole transcriptome sequencing (mRNA and total RNA)
  - Whole genome and exome sequencing
  - Small genome and 16S sequencing
- Advanced NGS methods
  - Single-cell multi-omics
  - Spatial transcriptomics

Bioinformatics and machine learning

- Machine learning & multi-omics: Machine learning & AI for deep molecular data; multi-modal data science; statistical learning; integrative bioinformatics; pipeline development
- Software components for IVDs: Development of algorithms and software components for medical devices in particular in vitro diagnostic devices (IVDs) and lab developed tests

Contact Dr. Christin Möser | Tel. +49 341 35536-9314 | christin.moeser@izi.fraunhofer.de

Center for Experimental Medicine

The development of new drugs entails testing using suitable animal models. Animal experiments are therefore an integral component in the development of new drugs, therapies and diagnostic procedures. The institute's Centre for Experimental Medicine (TEZ) is a central unit which facilitates important steps in translating research findings into a clinical application for human subjects.

Moreover, the institute has access to one of the most state-of-the-art animal houses in Germany. The TEZ is distinguished by its highly technical facilities, which are optimized to handle preclinical research projects. These facilities include modern rooms in which the animals are kept, featuring standardized hygiene levels and individually ventilated cage systems that are monitored via the building management system.

The health and care of the animals is of the highest priority. Highly qualified personnel support the scientific staff in daily care, health monitoring and breeding activities, and in administering treatments.

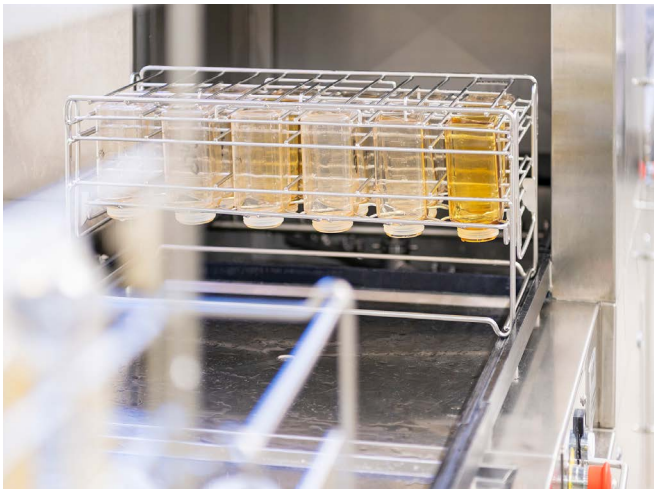
All experimental work can be carried out under practically sterile conditions. Several fully fitted operating suites allow small and large animals to be examined and treated. The comprehensive, state-of-the-art equipment guarantees correct anesthesia, analgesia and species-relevant blood analyses.

An expansive equipment pool for imaging technologies at the institute enables partly non-invasive analysis methods and also contributes towards reducing the need for animal experiments. This means, for example, that in vivo imaging analyses can be carried out using, for instance, 7 Tesla magnetic resonance imaging, bioluminescence imaging or small-animal CT.

In order to work on a range of issues, the TEZ has access to areas approved for genetic engineering safety levels S1 to S3; it may also conduct in vivo studies in line with GLP (Good Laboratory Practice).

The TEZ forms the central interface at the institute for processing preclinical development projects. Furthermore, cooperation projects with external clients and other research institutes are also carried out. At the same time, the TEZ acts as a training facility for animal care supervisors in a research and clinical setting, also offering advanced training courses for experimenters.

Adherence to the animal welfare guidelines is strictly monitored by the institute's animal welfare officers and regularly controlled by the regional animal welfare authority.



Equipment and services

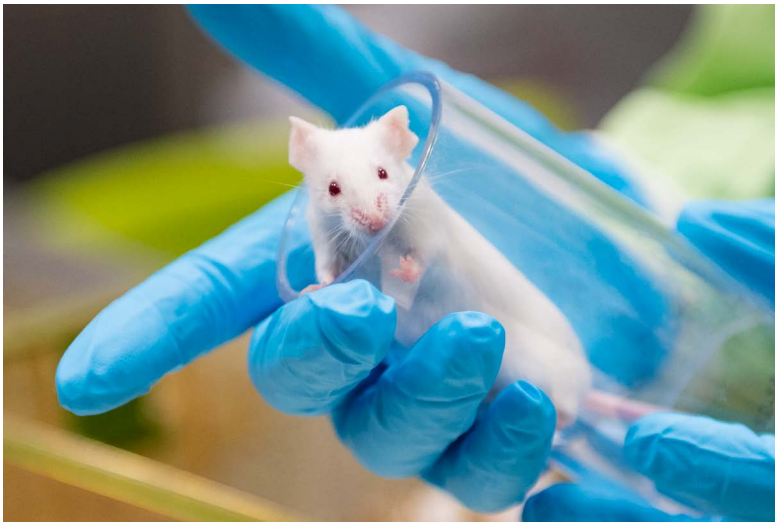
- Small animals are kept under state-of-the-art standards and permanently monitored
- Animal husbandry under GLP standards
- Animal husbandry with the option to use infecting agents for experimental infection

- Quarantine services
- Standard in-breeding and breeding transgenic lines
- Operation units in various areas including provision of inhalation anesthesia for small and large animals

- Large-animal OP area with intensive care capacity
- C-arm
- Option for individual stereotactic brain surgery
- Autopsy room for large animals
- Intraoperative blood gas analyses

- Small animal endoscope
- Blood cell meter
- Surgical microscope
- Stereotactic manipulation
- Temperature control during operations

- In vivo bioluminescence
- Small animal magnetic resonance imaging
- Small animal computer tomography
- X-ray unit for whole-body irradiation and pinpointed radiation therapy
- Large capacity autoclave
- Sterilization units using hydrogen peroxide fumigation
- Cryopreservation of spermatozoa and embryos
- Tissue bank



Contact Dr. Franziska Lange | Head of Center for Experimental Medicine | Tel. +49 341 35536-1401 | franziska.lange@izi.fraunhofer.de

RIBOLUTION Biomarker Center

In the Biomarker Center, new diagnostic and prognostic RNA biomarkers are systematically and comprehensively identified and validated using cutting-edge technologies such as next generation sequencing (NGS). Expertise in managing studies and data is essential when it comes to planning and arranging clinical cohorts as well as handling clinical and experimental data. The biomarker screening process is also being optimized and perfected with the aid of technical innovations. Since June 2020, the procedures involved here have been governed by a certified quality management system (ISO 9001:2015).

The TÜV certificate specifically covers: "Research and commissioned work in the field of molecular diagnostic analytics and the related bioinformatic evaluation, with emphasis on personalized medicine as well as optimizing and developing modern processes and applications for molecular diagnostics including next generation sequencing". The appraised quality management system ensures that internal operations, service quality, and partner and customer relationships are all overseen by a quantifiable system at the Biomarker Center. This means that processes are mapped precisely, their efficiency increased, and internal errors reduced. Process validation is another important aspect at the Biomarker Center. If a process is documented, evidence can always be provided to show that it fulfills the demands placed on a particular service and that it delivers reliable, transparent results. This enables competitive research and development projects to be driven forward together with clinical partners and interested research partners.

Zertifikat

Prüfungsnorm: ISO 9001:2015

Zertifikat-Registrier-Nr.: 01 100 2000010

Unternehmen:
Fraunhofer-Institut für Zelltherapie und Immunologie
RIBOLUTION Biomarker Center
Perlickstr. 1
04103 Leipzig
Deutschland

Geltungsbereich: Forschung und Auftragsarbeiten im Bereich molekulardiagnostischer Analytik und ihrer bioinformatischen Auswertung, mit Schwerpunkt auf personalisierter Medizin, sowie Optimierung und Entwicklung moderner Prozesse und Anwendungen für die Molekulardiagnostik inklusive Next-Generation Sequenzierung

Durch ein Audit wurde der Nachweis erbracht, dass die Forderungen der ISO 9001:2015 erfüllt sind.

Gültigkeit: Dieses Zertifikat ist gültig vom 23.07.2020 bis 22.07.2023.

10.08.2020

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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Contact Dr. Kristin Reiche | Contact RIBOLUTION Biomarker Center | Tel. +49 341 35536-5223 | kristin.reiche@izi.fraunhofer.de

S3 safety laboratory

Fraunhofer IZI operates a safety level 3 laboratory, making it possible to handle research and development projects under biosafety level 3 conditions and to investigate highly pathogenic agents. Genetic engineering work can also be undertaken. Adjacent premises for keeping animals permit the development of and work with infection models for corresponding types of pathogen.

Safety precautions taken in the S3 laboratory include an independent ventilation system with separate filters (H14 class HEPA filters) for all rooms incl. autoclave. The ventilation system guarantees eight air changes per hour with an air flow volume of up to 1500 m³/h air throughput.

Airlocks and pressure differences between areas prevent infectious particles from escaping into the air. Every room can also be aerated and ventilated separately to eliminate contamination.

Staff safety is ensured through specific training measures, special safety clothing and protective hoods with integrated air filter systems.

Facilities

The S3 laboratory is equipped with a safety cabinet, various centrifuges, an inverted microscope with phase contrast, a refrigerator, a -80°C ultra-low freezer, an incubator, a climate cabinet and a thermal cycler for cellular and molecular biology work.

Standard activities include using cell cultures for virus propagation, using assays to determine viral concentration (TCID50, plaque assay), and virus inactivation. Neutralization assays can also be carried out.

The laboratory is currently being used to examine viruses transferred by arthropods such as the dengue or West Nile viruses alongside SARS-CoV-2. Other pathogens that fall under biosafety level 3 can be added as required.

Achievements and contract research

- Testing and developing drugs in vitro and in vivo
- Testing and developing vaccines
- Immunology studies (e.g. analyzing protective antibodies from patients), also in cooperation with hospitals
- Material testing (e.g. antiviral coatings)
- Testing disinfectants
- Virus stability testing
- Establishing infection models on lab-on-a-chip technologies

Contact PD Dr. Sebastian Ulbert | Contact S3 safety laboratory | Tel. +49 341 35536-2106 | sebastian.ulbert@izi.fraunhofer.de

Selected projects

Immuno-oncology

Preclinical and clinical development of a novel CAR-T cell therapy for the treatment of multiple myeloma and clear cell renal cell carcinoma

CAR-T cell therapy is based on the principle of equipping immune cells (T cells) with an artificial chimeric antigen receptor (CAR) by genetic modification. This enables the immune cells to identify specific surface structures (antigens) on cancer or other target cells and to activate a corresponding immune response.

With the ROR2-CAR-T cell therapy, scientists at the University Hospital of Würzburg have developed an immunotherapy that differs from previously approved therapies both in the type of genetic modification and the target antigen addressed.

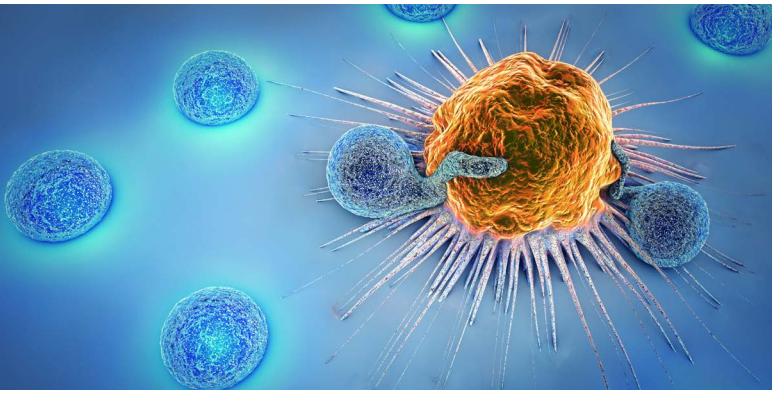
The ROR2 protein is a transmembrane receptor that plays an important role especially during embryonic development. It is normally not expressed, or only very slightly expressed, in adult, healthy cells. However, in some cancers, including multiple myeloma and clear cell renal cell carcinoma, it is highly expressed on the cancer cells in question. This makes the antigen a suitable target for appropriately targeted CAR-T cells.

In this project, a new method for the production of autologous CAR-T cells, which is still being tested, is used. The genetic modification of the patient's own T cells is carried out via a non-viral gene transfer, which, compared to viral gene transfer, will enable a simpler, more scalable and thus less expensive production process.

Fraunhofer IZI is responsible for two main areas within the project. On the one hand, the pre-clinical examination of the safety and effectiveness of the novel CAR-T cell product, including establishing the expression of the ROR2 target molecule in healthy tissues and identifying potentially cross-reacting epitopes (GLP study). On the other hand, the pharmaceutical manufacturing of the investigational medicinal products for the clinical trial, including the prior establishment and validation of the manufacturing process as well as the safety-relevant quality controls.

The project is funded by the Federal Ministry of Education and Research.

Partners
University Hospital Würzburg; T-CURX GmbH



Contact Claudia Müller | GLP study | Tel. +49 341 35536-1208 | claudia.mueller@izi.fraunhofer.de
Susann Schumann | GMP manufacturing | Tel. +49 341 35536-9747 | susann.schumann@izi.fraunhofer.de

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Immuno-oncology

TCR-modified NK cells for adoptive immunotherapy in cancer patients

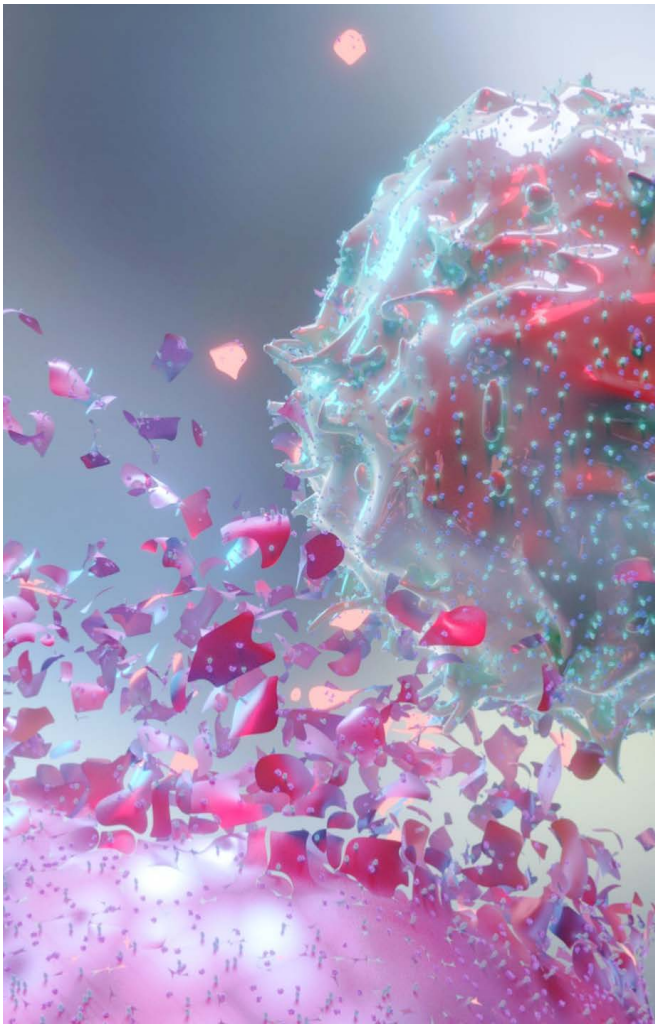
Building on the initial successes of T cell-based cancer immunotherapies and expanding both their scope and variety of applications, another type of immune cell is receiving increasing attention in biomedical research: Natural killer (NK) cells.

Unlike T cells, NK cells also lend themselves to allogeneic forms of therapy as they can be safely transferred between healthy donors and cancer patients. This facilitates standardizable and cost-effective stock production, which allows the products to be retrieved according to demand.

Before allogeneic NK cells can be employed as an efficient medicine, they first have to be genetically modified and equipped with new receptors that are able to recognize cancer cells. As part of a research collaboration between the Fraunhofer IZI and Oslo University Hospital, modified T-cell receptors (TCR) are being developed that are able to recognize fragments of intracellular tumor antigens on HLA-I complexes. Compared with CAR (chimeric antigen receptor) T cells, which can only recognize surface antigens, this makes for a much broader spectrum of potential target antigens.

In order to translate pertinent research findings into clinical application as quickly as possible, process solutions for pharmaceutical production are directly considered and factored in at every stage of development. Fraunhofer institutes IZI and IPA (Institute for Manufacturing Engineering and Automation) are also contributing their experience in the fields of GMP process development and the development of automation solutions for the manufacture of cell therapeutics.

Partners
Oslo University Hospital; Fraunhofer Institute for Manufacturing Engineering and Automation IPA



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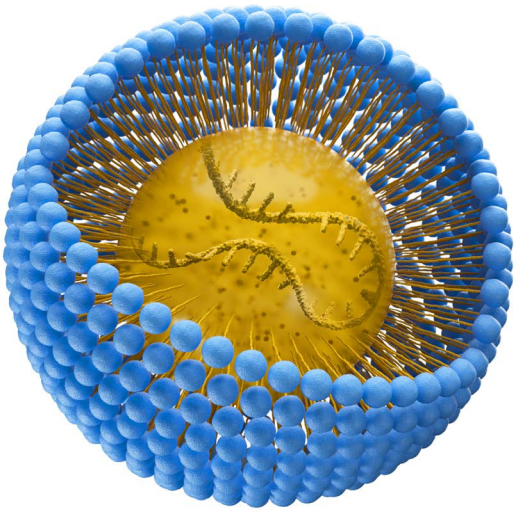
Contact Dr. Ulrich Blache | Tel. +49 341 35536-3220 | ulrich.blache@izi.fraunhofer.de

Immuno-oncology

Customized nano-carriers as mRNA transfection systems for immune cells (CONCENTRIC)



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Genetically engineered immune cells are revolutionizing cancer medicine. In recent years (from 2017 / 2018), the CAR-T cell treatment has established itself as an important treatment option for certain forms of leukemia and lymphoma.

In all CAR-T cell products which have been approved so far, the immune cells are genetically modified using modified viruses. These are then used as transport vehicles to permanently integrate the genes for the therapeutically relevant CAR receptor in the target cell's genome.

In order to further develop this technology, Fraunhofer IZI researchers are evaluating alternative methods for genetically engineering immune cells with the aim of enhancing the safety and efficiency of treatment and developing further fields of application, e.g. in autoimmune disorders.

The direct transfer of messenger RNA (mRNA) as a template for producing therapeutic protein molecules in target cells constitutes one of the most promising alternatives to viral gene modification. Under this approach, transporting mRNA to the target site in the body constitutes the biggest obstacle to clinical application. To overcome this challenge, the mRNA delivery via nano-carriers has been optimized to transport the "securely packed" mRNA safely and efficiently. The mRNA is then released in the interior of the cells and the production of the therapeutic molecules begins.

In addition to functionality and optimal composition, initial safety-relevant toxicity testing was carried out. The results obtained now form the basis for the next step of development – a proof-of-concept study and safety assessment in an animal model. The project is sponsored by the Federal Ministry of Education and Research.

Partner
Fraunhofer Center for Applied Nanotechnology CAN

Contact Dr. Sandy Tretbar | Tel. +49 341 35536-2240 | sandy.tretbar@izi.fraunhofer.de

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Immuno-oncology

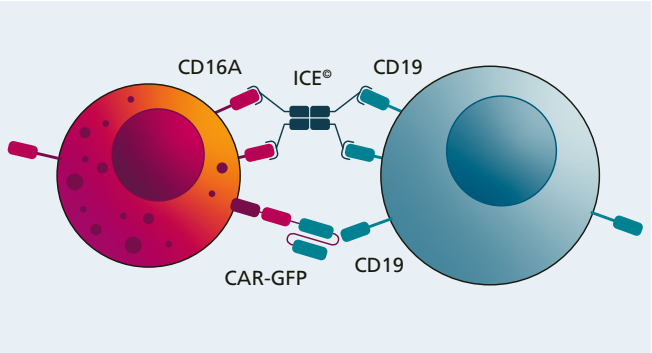
Combined cancer immunotherapy

The launch of CAR-T cell therapy to treat various cancers constitutes an important milestone for the use of cellular immunotherapy in oncology.

Apart from the high hopes that this promising treatment option will become available for various types of cancer as soon as possible, the increasing numbers of patients, in turn, are also connected with various challenges. One of these is that CAR-T cell products have to be tailored to the individual patient in a complex production process, resulting in limited availability and high treatment costs.

Therefore, international research efforts are focusing on alternative immunotherapies, in addition to optimized production processes.

Natural killer cells (NK cells) are considered a promising resource to optimize the cost-efficiency and availability of cancer immunotherapies. CAR-NK cells are genetically engineered according to the same principle as CAR-T cells to enable them to find and destroy tumor cells. Unlike T cells, NK cells are not immunogenic. This means, they can also be transferred from healthy donors to patients without triggering immunological rejection. As a result, NK and CAR-NK cell products can be produced more cost efficiently and on a larger scale.



A tumor cell is recognized and then destroyed by a CAR-positive NK Cell via the link using the ICE molecules.

Fraunhofer IZI has examined the potential of a combination treatment comprising NK cell products and so-called innate cell engagers (ICE) on behalf of Affimed GmbH (Mannheim).

These ICE molecules attach to both NK cells and tumor cells by binding to the CD16A receptor on the immune cells and a specific antigen (CD19) on the tumor cells. As soon as this bridge is created, the immune cell is activated and destroys the tumor cell.

In this project, the antitumor effectiveness of two combination treatments (NK cells and CAR-NK cells each combined with ICE) was examined in various in vitro experiments compared with the simple CAR-NK cell treatment. This showed that the cytotoxic potential of the combination treatment is superior to the simple version. Apart from this, a significant difference was not observed between the two combinations (NK cell + ICE vs. CAR-NK cell + ICE). The use of ICE in combination with an NK cell treatment has the potential for successful cancer immunotherapy. However, this potential now has to be examined in further pre-clinical and clinical studies.

Contact PD Dr. Thomas Grunwald | In vitro studies |
Tel. +49 341 35536-5423 | thomas.grunwald@izi.fraunhofer.de
Dr. Anna Dünkel | Process development |
Tel. +49 341 35536-3612 | anna.duenkel@izi.fraunhofer.de

Immuno-oncology | infectious disease pathology

Automated production technologies for mRNA-based drugs

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mRNA-based vaccines, along with gene and cell therapeutics, represent innovative drugs that can be used to prevent or treat infectious diseases, genetic disorders and cancer. Development of these drugs has been prodigious in recent years in terms of clinical research, translation and application. But advancement of the required production technologies has not yet managed to keep pace with the rapid biomedical progress made in these areas. Hence the need for automated and digitally supported production technologies that facilitate not only the rapid, safe and reliable development of mRNA-based drugs, but also their production in accordance with the high demands of pharmaceutical manufacturing.

Contact Dr. Claudia Kupfer | Tel. +49 341 35536-2279 | claudia.kupfer@izi.fraunhofer.de

The RNAuto lighthouse project focuses on developing bioprocessing methods and production technologies for the modular and automated manufacture of mRNAs, mRNA nanocarriers and mRNA-modified cells that can be scaled right up to industry level. For the automated manufacture of corresponding products to be successful, technical solutions will be developed in the areas of bioreactors, fluid dynamics, quality control and automated data analysis. Core elements of the Industry 4.0 concept are to be deployed to digitally map and monitor the production processes.

The primary objective is to develop automated manufacturing processes for mRNA molecules that will smooth the way for sustainable and cost-efficient health care. To this end, the project brings together the expertise of various Fraunhofer institutes from the fields of vaccine development, cell and gene therapy, bioprocess development, smart sensor technology, and the automation and digitalization of production processes.

Fraunhofer IZI is contributing its expertise in the development of innovative vaccine technologies and cell-based immune therapeutics. Alongside the development of GMP-compliant manufacturing processes, the project will also benefit from the institute's competences in the field of molecular drug design and the preclinical testing of novel drug candidates.

Partners
Fraunhofer Institute for Toxicology and Experimental Medicine ITEM; Fraunhofer Institute for Microengineering and Microsystems IMM; Fraunhofer Institute for Manufacturing Engineering and Automation IPA; Fraunhofer Institute for Production Technology IPT; Fraunhofer Institute for Experimental Software Engineering IESE; Fraunhofer Institute for Microelectronic Circuits and Systems IMS

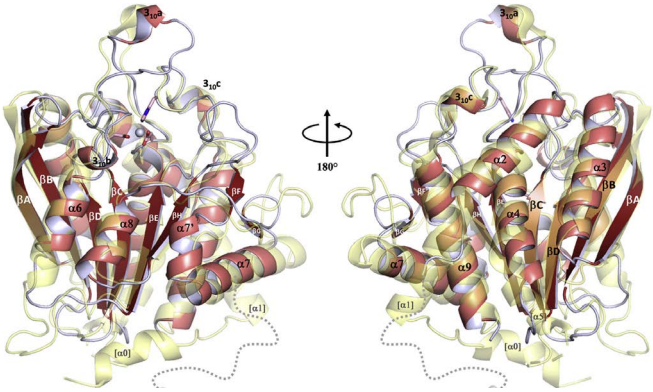
Infectious disease pathology

New strategies in the fight against the widespread disease periodontitis

Periodontitis is an inflammatory disease of the periodontium that can lead to destruction of tissue and bone around the teeth. The disease is caused by bacteria that settle in plaque and gum pockets and trigger an inflammatory response. If left untreated, this leads to damage to the entire periodontium and even tooth loss. Various studies also show a direct link between periodontitis and other diseases such as cardiovascular disease and diabetes, as well as an increased risk of stroke.

PerioTrap Pharmaceuticals GmbH, a Fraunhofer IZI spin-off, assumes the preclinical development of novel periodontitis treatments as part of the Paropaste project. The basis of the novel treatment concept is the inhibition of an enzyme that occurs almost exclusively in the bacteria that cause periodontitis and regulates the production of various virulence factors there. By selectively inhibiting these factors, the pathogenic germs can be specifically suppressed and the natural microbiome preserved. The use of classical antibiotics, on the other hand, leads to growth inhibition of all oral germs, which carries the risk of rapid and stronger recolonization by the pathogens.

The aim of the project is to test appropriate drug candidates for their efficacy and safety, thus creating the prerequisite for a clinical trial for initial testing in humans. The collaborative partners will address various regulatory aspects, including active ingredient formulation, tolerability, efficacy and toxicity.



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Fraunhofer IZI will contribute its expertise in the development and validation of bioanalytical methods for the comprehensive characterization of small molecule drugs. In addition, toxicity and safety are being investigated both in vitro and in animal models as part of a GLP study.

This project is sponsored by the German Federal Ministry of Education and Research as part of its "KMU-Innovativ Program" for small and medium-sized companies.

Partners
PerioTrap Pharmaceuticals GmbH; Skinomics GmbH; Fraunhofer IMWS

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Contact Dr. Martin Kleinschmidt | Bioanalytics | Tel. +49 345 1314 2827 | martin.kleinschmidt@izi.fraunhofer.de
Dr. Sina Riemschneider | GLP study | Tel. +49 341 35536-1260 | sina.riemschneider@izi.fraunhofer.de

Infectious disease pathology

Development of a vaccine candidate against the West Nile virus

The West Nile virus (WNV) is a zoonotic flavivirus spread by mosquitoes. The virus primarily circulates among birds, but can also be transmitted to mammals, like humans. Even though, in most cases, an infection only involves mild, cold-like symptoms, it can also cause severe neurological problems, in particular, in older or immunocompromised patients. So far, a human vaccine against the West Nile virus is not available.

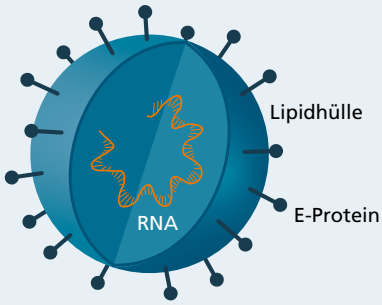
The envelope protein (E) is the most important target of neutralizing antibodies and, for this reason, it is of fundamental importance for vaccine development. It is located on the surface of the virus and has a central role at various points of the viral life cycle, especially, when the virus enters the host cells.

The close genetic relationship between WNV and other flaviviruses (such as the Zika virus or the Dengue virus) means that the E proteins are very similar in their sequence and structure and forms a particular challenge in the development of suitable vaccine candidates. In the case of an infection with other flaviviruses, the antibodies formed as a result of the immunization can lead to cross-reactions, which might amplify the infection and are associated with more severe courses of the disease. This is particularly difficult in regions in which several flaviviruses coexist.

Therefore, the aim is to develop improved protein- and mRNA-based vaccine candidates while avoiding cross-reactions with similar viruses.

Contact Dr. Jasmin Fertey | Tel. +49 341 35536-2160 | jasmin.fertey@izi.fraunhofer.de

Most cross-reactive antibodies bind the E protein in an area which is almost identical in most other flaviviruses, the so-called fusion loop. Therefore, a possible solution for immunization comprises the use of antigens in which this area has either been mutated or eliminated altogether. It was proven in an animal model that corresponding antigens induce a largely protective immune response. An analysis of the neutralizing antibodies showed a significantly reduced cross-reactivity with other flaviviruses, compared to the wild-type protein.



A large part of the work for this project was carried out in the S3 safety laboratory at Fraunhofer IZI. This enables us to carry out the research and development activities under the biological protection level 3 and study highly pathogenic agents. Moreover, it also permits genetic engineering work to be carried out. A connected animal-keeping sector permits the development of, and work with, infection models for the corresponding classes of pathogens. More information on this is available at: https://www.izi.fraunhofer.de/en/central-facilities/s3-safety-laboratory.html

Further selected projects

ASSESS-MED – on the way to becoming an accredited test laboratory for medical devices

For many patients diagnosed with chronic, irreparable kidney disease, dialysis is an important bridging technology that ensures survival up until kidney transplantation. However, it is more commonly becoming the final therapeutic procedure for those affected as there are simply not enough donor organs available for transplantation.

Consisting of several thousand hollow fibers with a semi-permeable membrane, dialyzers lie at the core of dialysis. In order to best adapt the therapy to each patient's individual requirements, the performance parameters (clearance, sieving coefficient and ultrafiltration coefficient) of a dialyzer have to be as precise as possible and comparably quantified.

Fraunhofer IZI's Rostock-based work group has been supporting customers and partners in the testing and characterization of dialyzers for several years now. The department has been working towards accreditation of its test laboratory since 2018. A key milestone was achieved with the introduction of a quality management system in accordance with ISO/IEC 17025. Moreover, through the test laboratory's continuously close involvement in the department's ongoing research projects, the various technical and quality-based processes are constantly being developed and optimized.

In the 2022 reporting year, the application for accreditation was able to be submitted to the German accreditation body.

This focuses primarily on the performance of clearance measurements, which are used to determine key filtering

properties of dialyzers. For a range of target molecules (such as urea, creatinine, phosphate and vitamin B12), clearance describes the cleaning performance of the semi-permeable hollow fiber membranes per unit time. The goal is to be able to carry out testing orders with legally binding deliverables in this field from next year onwards.

EUROPÄISCHE UNION
Europäischer Fonds für regionale Entwicklung

MV tut gut.

The ASSESS-MED project is being funded using means provided by the European Union, made available through the European Regional Development Fund (ERDF), as well as the Ministry for Economic Affairs, Labor and Health of Mecklenburg-West Pomerania.

Contact Dr. Reinhold Wasserkort | Tel. +49 381 494-2610 | reinhold.wasserkort@izi.fraunhofer.de

Further selected projects

Pathological blood-brain barrier model for the development of novel treatment strategies

The blood-brain barrier is one of the most impermeable protective barriers of the body. It protects the sensitive central nervous system against both cytotoxic influences and blood-borne pathogens. The barrier consists of microvascular endothelial cells, pericytes and astrocytes which form a neurovascular unit together with neurons and microglia.

In the event of a systemic disease, such as sepsis (blood poisoning), however, this barrier is weakened by the accumulation of harmful substances in the blood, which, in turn, can result in long-term neurological damage. For example, more than one half of patients affected by sepsis suffer from secondary cognitive and psychological conditions - even one year after the onset of the disease. Because of the high complexity of the pathophysiological processes in the body, specific neuroprotective treatment options for patients suffering from acute sepsis or organ failure have not yet been developed.

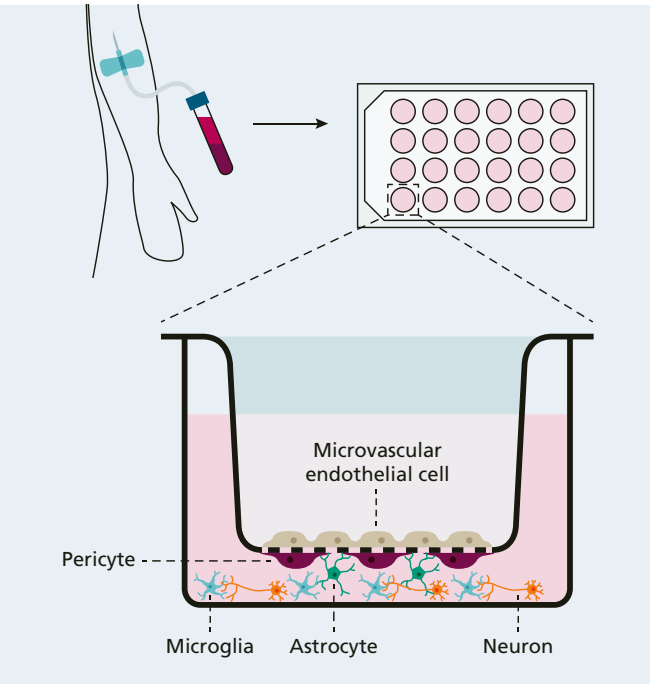
In cooperation with the University Medical Centre Rostock, Fraunhofer IZI is developing a human in vitro disease model of the blood-brain barrier based on induced pluripotent stem cells (iPS). As part of this, the cell types of the neurovascular unit – endothelial cells, pericytes, astrocytes, neurons and microglia – are created from stem cells by means of specific differentiations. These are brought together in physiological arrangement in a transwell system modelling the “healthy” blood-brain barrier. Pathological conditions under which the blood-brain barrier can possibly be damaged can then be simulated by incubating plasms from sepsis or organ-failure patients.

Contact Sophie-Charlotte Nelz | Tel. +49 381 494-2641 | sophie-charlotte.nelz@izi-extern.fraunhofer.de

Afterwards, the damage can be examined and characterized both at a cellular and molecular biological level. This project aims to establish a meaningful cell model for the development of protective agents and drugs.

The project is supported by the Damp-Stiftung.

Partner
University Medical Centre Rostock



The cell types of the neurovascular unit differentiated from stem cells are brought together in a transwell system. By using pathological plasm, this system develops a disease model of the blood-brain barrier.

Further selected projects

Bacteriophages as an alternative to antibiotics

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Increasing antibiotic resistance is a global health problem that is exacerbated by the overuse and inappropriate use of antibiotics. Bacteria are developing mechanisms to build resistance to these drugs, which impairs the effectiveness of conventional antibiotics. This leads to serious and difficult-to-treat bacterial infections, increased healthcare costs and a growing threat to public health. In addition to optimizing the use of antibiotics, there is a need to develop new classes of antibiotics and other antibacterial strategies.

Bacteriophages are an effective alternative for combating antibiotic-resistant bacteria.

These are viruses that infect and kill bacteria extremely specifically. Bacteriophages are almost ubiquitous in nature and play an essential role in the regulation of bacterial populations.

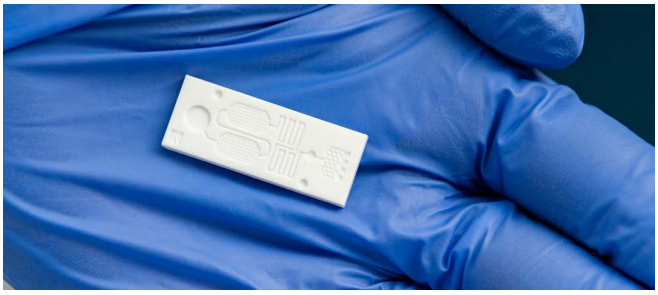
Phages consist of a nucleic acid core, either DNA or RNA, and surrounding coat proteins. They infect the bacterial cell by attaching to its surface and injecting their genome into the host cell. Within the bacterium, the bacteriophages multiply and produce enzymes that weaken the bacterial cell wall and finally destroy (lyse) the bacteria, releasing the newly formed phages to infect new bacteria.

Specificity and effectiveness make bacteriophages a potent alternative for the treatment of severe infections with antibiotic-resistant bacteria. At the Fraunhofer IZI, bacteriophages are systematically collected and examined for their medical potential. To this end, phages are isolated and characterized from a wide variety of environmental samples. In addition to the complete sequencing of the phage genome, it is examined, in particular, for resistance genes and potential virulence factors. The aim is to build a comprehensive therapeutic phage library, which will serve as a basis for the research and development of phage-based therapeutics.

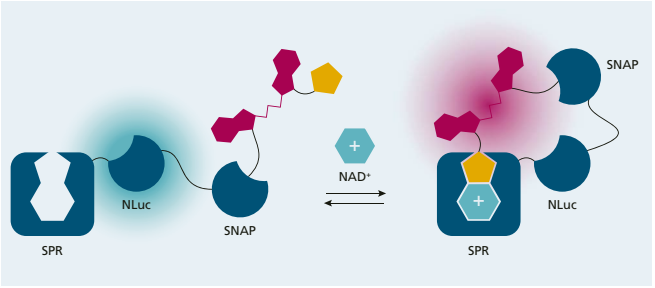
Contact Dr. Belinda Loh | Tel. +49 341 35536-2103 | belinda.loh@izi.fraunhofer.de

Further selected projects

Snifits4Health - Innovative platform technology for point-of-care analysis



Microfluidics chip.



NAD⁺ sensor and assay design.

The aim of the project is to develop an easy-to-use test system for the on-site analysis (point-of-care) of clinically relevant biomarkers in blood. Similar to a blood glucose measurement, the analysis should be fully automated and based on just a few drops of blood.

The detection approach is based on a class of bioluminescent synthetic sensor proteins which were developed by the Max Planck Institute for Medical Research and change the color of the emitted light in the presence of the analyte. This light can be captured by a powerful camera, as is already used in cell phones today, and quantified via the ratio of the emitted light colors.

One of the core tasks of the Fraunhofer IZI within the project was the development of a microfluidics-based test platform with automated sample processing. This should be designed to limit manual pipetting or dilution steps, making the process user-friendly, even for non-experts. In addition to the biosensors, the necessary reagents must also be provided in a chemically stable form within the test system by means of freeze-drying. The sample is transported exclusively by capillary forces, which minimizes the use of electronics and mechanics.

Contact Alina Menge | Tel. +49 341 35536-9325 | alina.menge@izi.fraunhofer.de

This reduces manufacturing costs and increases mobility as well as system stability.

To produce the microfluidic cartridges, three different methods were initially evaluated: 3D printing, flexographic printing and hot stamping, with the latter proving to be the most suitable method.

An assay for analyzing nicotinamide adenine dinucleotide (NAD+) was then implemented on this microfluidic test platform. NAD+ plays an essential role in various biochemical processes. A decrease in NAD+ levels has been associated with various pathologies and physiological ageing, while strategies to increase cellular NAD+ levels have been effective against age-related diseases in many animal models.

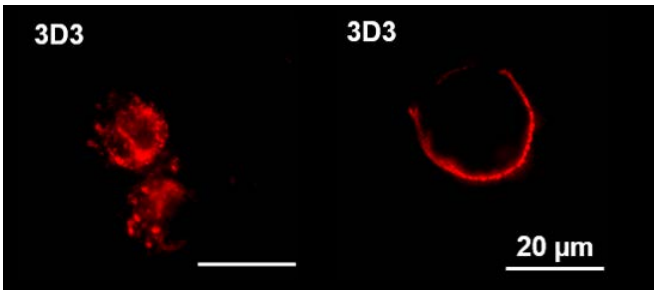
In the final phase of the project, the assay will be validated using patient samples.

The project is funded by the cooperation program between institutes of the Max Planck Society and the Fraunhofer-Gesellschaft..

Partners
Max Planck Institute for Medical Research; Fraunhofer Institute for Applied Optics and Precision Engineering IOF

Further selected projects

The impact of human endogenous retroviruses on autoimmune and tumor diseases



The fluorescence microscopy images of transfected HEK293F cells with HERV-Fc1 Env specific antibodies 3D3 (red) show the presence of the envelope protein in the cell interior in permeabilized cells (top) and on the cell surface in cells with an intact cell membrane.

Around 8 percent of the human genome consist of human endogenous retroviruses (HERV). These sequences come from infectious retroviruses that have become permanently integrated into the human genome as part of evolution. Most of these HERV are inactive or have mutated so that their ability to replicate is impaired. However, some HERV have retained functional elements and can, therefore, be involved in certain physiological and immunological processes. For example, HERV are connected to various autoimmune disorders, neurodegenerative diseases and cancers.

HERV (or proteins expressed by them) provide interesting target structures for treating autoimmune diseases and cancer. On the one hand, this is because certain proteins are directly involved in tumor biology. Others are exclusively produced by cancer cells and presented on its surface, making them specific targets for antibodies, active agents or immunotherapies.

At Fraunhofer IZI, envelope proteins of endogenous retroviruses of the HERV-K class, in particular, are tested for their suitability as tumor markers and therapeutic targets. To this end, monoclonal antibodies against HERV-K envelope proteins are being developed and various tumor entities are being tested for their expression. These research activities aim to evaluate antibodies for pre-clinical and clinical development and to render them usable for tumor-specific treatment.

Another focus of research examines immunomodulation in pathophysiological processes of multiple sclerosis (MS). Various HERV proteins are attributed as having immuno-stimulating and neurotoxic characteristics which can contribute to the development of MS.

This project is financed with support from the state of Saxony-Anhalt.

SACHSEN-ANHALT

EUROPÄISCHE UNION
EFRE
Europäischer Fonds für regionale Entwicklung

Contact Jun.-Prof. Dr. Holger Cynis | Tel. +49 345 13142835 | holger.cynis@izi.fraunhofer.de

Further selected projects

Precise analysis of cell-based medication

The MEOS Innovation Center for Precision Analysis of Cell Therapy Products (abbreviated: MIC-PreCell) is currently being established at the Fraunhofer Center for Microelectronic and Optical Systems for Biomedicine (MEOS) in Erfurt.

This involves developing new analysis methods for quality assurance and process control for the production of cell-based therapeutic products. As part of the project, infrastructure and know-how are combined to close the current gap between technologies which are available in principle to analyze cell-specific parameters and their broad application in the production of cell-based medication.

Usually, cell-based treatments are tailored to the specific patient and, due to the extremely complex production processes, they are often also very expensive. In addition, very rapid production is often essential for the survival of patients in a critical phase of the disease. Therefore, as part of the project, modern methods of integrated quality assurance are to be established to shorten production processes and identify potential production errors much earlier. In this context, the focus is on the broad use of innovative quality assurance methods in cell production, such as optomechanical profiling, with the help of which mechanical cell properties can be determined without labeling immediately. Moreover, VOCs (volatile organic compounds) which are emitted by cell cultures into the air are to be analyzed with the help of a gas chromatograph ion mobility spectrometer. In addition, equipment for the micromanipulation of cells and cell clusters or organoids will be used, permitting the acquisition of direct and real-time information on the state of therapeutic cell products.

Contact Dr. David M. Smith | Tel. +49 341 35536-9311 | david.smith@izi.fraunhofer.de

Freistaat Thüringen
REACT-EU - Als Teil der Reaktion der Union auf die COVID-19-Pandemie finanziert.
EFRE EUROPA FÜR THÜRINGEN
EUROPÄISCHER FONDS FÜR REGIONALE ENTWICKLUNG
EUROPÄISCHE UNION

Further selected projects

Early detection of diseases in bodily fluids using photonic bio-sensors

Many standard medical diagnostic methods are time consuming and, moreover, they do not take account of the individual differences between patients. This can lead to incorrect or incomplete diagnoses and sub-optimal treatment decisions.

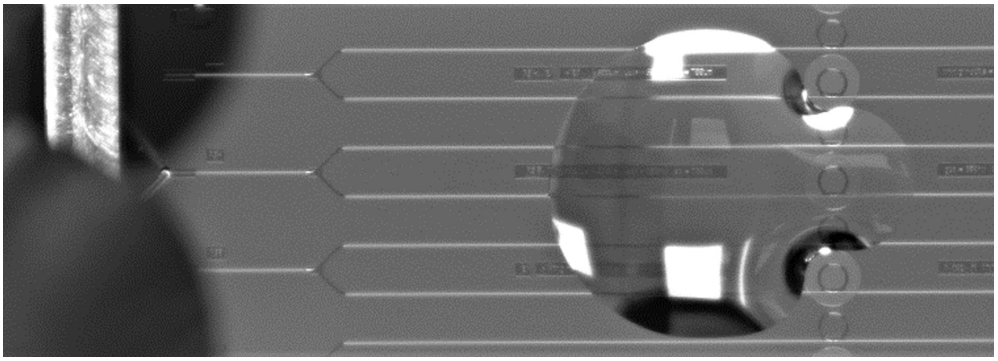
At the Fraunhofer Center for Microelectronic and Optical Systems for Biomedicine (MEOS), researchers of Fraunhofer IZI, IPMS and IOF are jointly developing disposable biosensors with the aim of improving the analysis speed, the number of measurement parameters and the precision of the results.

The photonic biosensor chips are developed on a silicon nitride waveguide platform at the Fraunhofer IPMS. These biosensors consist of specifically developed, scalable micro-ring resonators with several channels. The detection method is based on specialized bioassays developed at Fraunhofer IZI. In this process, specific catcher modules are bound to functionalized sensor layers whose transmission spectrums change as soon as corresponding analytes bind to the catcher molecules. These biosensors are highly sensitive and are suitable for detecting biomolecules in bodily fluids - which makes it valuable for the early detection of illnesses.

The research team has successfully developed a demonstrator based on a multi-channel silicon nitride micro-ring resonator biosensor system. This system permits the multiplex detection of specific miRNA biomarkers connected with neurodegenerative diseases. They are detected with the help of DNA-based catcher molecules immobilized on the sensor surface. The developed sensors and the integrated system are versatile and can be adapted to detect various biomarkers, viruses or bacteria in different fluids.

Partners
Fraunhofer Institute for Photonic Microsystems IPMS; Fraunhofer Institute for Applied Optics and Precision Engineering IOF

Contact Dr. David M. Smith | Tel. +49 341 35536-9311 | david.smith@izi.fraunhofer.de



Overview

EU and joint projects

AIDPATH
AI powered, Decentralized Production for Advanced Therapies in the Hospital

The AIDPATH EU project brings partners from industry and research together to develop an automated, smart system which can produce targeted and personalized cell therapy directly at the place of treatment, i.e. in the hospital. In addition, the project also looks into the integration of the system into the hospital environment under consideration of the logistics processes and of data management and security. Fraunhofer IZI is contributing its expertise, in particular, in the automation of production processes and plant networking, to the project.

- Coordination: Fraunhofer Institute for Production Technology IPT
- Project management at Fraunhofer IZI: Dr. Paul Franz
- Funding: EU / Horizon Europe

www.sciencrew.com/c/6499?title=AIDPATH

CERTAINTY
Cellular immunoTherapy Avatar for personalized cancer treatment

A team of 18 partners (led by Fraunhofer IZI) is planning to develop a virtual twin to improve treatment with personalized cancer immuno-therapies in future in the framework of the CERTAINTY project. As an example, the virtual twin will initially be implemented for multiple myeloma (MM), a malignant bone marrow disorder. It is designed to comprehensively represent the individual pathophysiology of patients who are candidates for cellular immune-therapies or are undergoing such. In this case, the Fraunhofer IZI team contributes its expertise in the field of personalized medicine and molecular diagnostics.

- Coordination: Fraunhofer IZI
- Project management at Fraunhofer IZI: Dr. Kristin Reiche
- Funding: EU / Horizon Europe

CREATIC
Central European Advanced Therapy and Immunotherapy Centre

In the framework of the CREATIC project, the EU supports the development of a new research and development center for novel treatments at the Masaryk University in Brno, Czech Republic. This project aims to develop research and innovation in the field of cell and gene therapy into clinical practice for the patients' benefit. The CREATIC research focuses on rare illnesses, including both rare hereditary diseases and various rare cancers. Fraunhofer IZI provides advice and training in the field of GMP process development and the production of advanced therapy medicinal products (ATMPs). Additionally, Fraunhofer IZI is also involved in shared pilot projects in which cells are to be developed for immuno-therapies (e.g., CAR-NK cells and CAR macrophages).

- Coordination: Masaryk University
- Project management at Fraunhofer IZI: Ilka Henze
- Funding: EU / Horizon Europe

www.creatic.muni.cz

ImSavar
Nonclinical mimicking of the immune system effects of immunomodulatory therapies

The EU consortium imSAVAR is designed to lay the foundation for new, Europe-wide standards in the development of medication. Its 28 international partners from eleven countries aim to improve existing model systems and to develop new ones to identify undesired side effects of new treatments on the immune system. As part of this, new bio-markers for diagnosing and assessing immune-mediated pharmacologies and toxicities are to be developed. In addition, research into toxicity mechanisms and the potential for reducing such through therapeutic measures is to be carried out.

- Coordination: Fraunhofer IZI / Novartis AG
- Project management at Fraunhofer IZI: Dr. Kristin Reiche
- Funding: EU / IMI

www.imsavar.eu

ISOS

Implantable Ecosystems of Genetically Modified Bacteria for the Personalized Treatment of Patients with Chronic Diseases

ISOS focuses its research on the treatment of chronic diseases requiring prolonged treatment. This project aims to develop a bio-medical product for the in-situ production and automatic administration of therapeutic agents into which a complex eco-system of probiotic, genetically engineered bacteria (GEB) is integrated for the first time. In this case, a bio-reactor based on biomaterials provides the GEB eco-system. The design and configuration of the GEB eco-system are customized for the specific patient with the help of in-silico tools and synthetic biology. As a result, ISOS is designed to establish the basis for a new generation of therapeutic products.

- Coordination: SILK BIOMED, S.L.
- Project management at Fraunhofer IZI: Prof. Dr. Stefan Kalkhof
- Funding: EIC Pathfinder open

JOIN4ATMP

Map, join and drive European activities for advanced therapy medicinal product development and implementation for patient and society benefit

JOIN4ATMP is to contribute to accelerating the development and broad availability of novel treatments in Europe. Since the standardized, conventional regulatory requirements for drug approval cannot be directly transferred to complex gene and cell therapies, obstacles in the application and development of advanced therapy medicinal products (ATMPs) are to be identified and, if possible, standardized solutions developed to overcome these. The European University Hospital Alliance, the T2EVOLVE consortium and the RESTORE initiative are involved in this project. They are supported by industrial partners and patient advocacy groups, in addition to other partners from ATMP development, production, application and regulation.

- Coordination: Charité – Universitätsmedizin Berlin
- Project management at Fraunhofer IZI: Dr. Ulrich Blache
- Funding: EU / Horizon Europe

https://join4atmp.eu

REANIMA

Prevent heart failure by reawakening the endogenous regenerative ability of the mammalian heart

REANIMA aims to provide new treatments for heart regeneration. It is the first project in Europe in this field to include results from basic research with the aim of transferring these into medical application. The knowledge obtained in animal models is to be analyzed comprehensively to develop new regenerative treatments of cardiac insufficiency. Twelve European partners are involved in the project.

- Coordination: Spanish National Center for Cardiovascular Research
- Project management at Fraunhofer IZI: Dr. Paul Franz
- Funding: EU / Horizon Europe

www.reanima2020.eu

REMEDI4ALL
European Platform for Medicines Repurposing

In the REMEDi4ALL research initiative, 24 project partners want to promote the repurposing of medication, i.e., the search for new therapeutic applications for existing medications, in fields with a high and unmet medical need. Fraunhofer IZI is evaluating known drug candidates identified as being interesting in the repurposing project in an in vivo animal model. As part of this, a technology platform is to be developed for evaluating approved medication from the identification of new fields of application through in vitro and in vivo testing as well as in clinical examinations in the future.

- Coordination: EATRIS ERIC
- Project management at Fraunhofer IZI: Dr. Thomas Grunwald
- Funding: EU / Horizon Europe

www.remedi4all.org

T2Evolve
Accelerating Development and increasing awareness and access of patients with cancer to immunothrapy

T2EVOLVE aims to accelerate the CAR-T cell treatment development within the EU, expand patient access to this treatment and, concurrently, provide guidelines for the sustainable introduction of this cancer treatment in the EU healthcare system. Additionally, the 27 partners from nine European countries want to reduce the financial burden which healthcare systems place on the economy and society. Also, by including patients, the project ensures that the focus in both research and treatment takes account of the perspective of cancer patients.

- Coordination: University Hospital Würzburg
- Project management at Fraunhofer IZI: Dr. Kristin Reiche & Dr. Paul Franz
- Funding: EU / IMI

www.t2evolve.com

ZOE
Zoonoses Emergence across Degraded and Restored Forest Ecosystems

In ZOE, 16 partners from seven European and four American countries examine the impact of changes in land use and loss of biological diversity on the transmission of pathogens between animals and humans. The project, as an example, includes detailed biodiversity mapping of forest areas with different levels of human intervention. For this, researchers in Guatemala, Costa Rica, Slovenia and Slovakia will study both virgin forests as well as deforested and renaturalized areas. Fraunhofer IZI is contributing its expertise in the fields of virology and assay development.

- Coordination: Charité – Universitätsmedizin Berlin
- Project management at Fraunhofer IZI: PD Dr. Sebastian Ulbert
- Funding: EU / Horizon Europe

RNAuto
Automated production of mRNA-based vaccines and gene therapeutics

In the RNAuto cooperative project, seven Fraunhofer institutes are working to develop automated production technologies for mRNA-based drugs.

mRNA-based vaccines as well as gene and cell therapeutics are innovative drugs with which infectious and genetic diseases and cancer can be prevented or treated. To ensure cost efficiency and availability in view of growing demand, automated and digitally supported production technologies are needed to ensure the fast, safe and reliable production of mRNA-based drugs.

The project focuses on the development of bioprocesses and production technologies for the modular and automated mRNA, mRNA nano carrier and mRNA-modified cell production, which can be ramped up to industrial scale.

This project brings together the expertise of different Fraunhofer institutes from the fields of vaccine development, cell and gene therapy, bioprocess development, smart sensor technology, automation and digitalization of production methods.

- Coordination: Fraunhofer IZI
- Funding: Fraunhofer

https://s.fhg.de/rnauto

SaxoCell
Precision medicine by cell and gene therapies

SaxoCell stands for the development of new fields of application and production methods for gene and cell therapeutics, so-called "living drugs". Here, the aim is to produce cells with precisely defined functions and a high safety profile for safe, clinical application on an industrial scale and at socially acceptable costs to permit a realistic and feasible business model with a high value creation potential for Saxony. In the SaxoCell cluster, Fraunhofer IZI is cooperating with TU Dresden, Leipzig University and the Chemnitz hospital. Fraunhofer IZI contributes its competences in the field of cell technology focusing, in particular, on the development and production of genetically engineered immune cells (e.g., CAR-NK cells and CAR-T cells). Moreover, pharmaceutical production processes are being developed and established, while cell and molecular biological datasets are collected and bio-statistically evaluated on the SaxoCellOmics technology platform.

- Coordination: Fraunhofer IZI / TU Dresden
- Funding: BMBF / Clusters for Future

www.saxocell.de

WIR! sind DIANA
Technologies for future point of care diagnostics

Since 2021, Fraunhofer IZI and the Fraunhofer Institute for Machine Tools and Forming Technology (IWU) have coordinated the "WIR! sind DIANA" alliance under the BMBF funding program "WIR! – Wandel durch Innovation in der Region". The alliance is pursuing the key task of developing the region in central and western Saxony as well as eastern Thuringia into an innovation and competence leader for point-of-care technologies in Germany. As a result, in the medium term, this regional and innovative initiative for the development of medical high-technology products is to also form the basis for new jobs in the region. Besides the coordinating Fraunhofer institutes, supra-regional partners are also part of the alliance. To put this project on a more permanent basis, DIANA – Point-of-Care-Technologien Mitteldeutschland e.V., a registered association, was set up in December 2023.

- Coordination: Fraunhofer IZI / Fraunhofer IWU
- Funding: BMBF

www.wirsinddiana.de

Federal Ministry
of Education
and Research

Sponsors and advisory board

The support and commitment of active institutions and individuals enable the Fraunhofer IZI to experience continuous and successful development as well as dynamic growth.

Sponsors

The Fraunhofer IZI would like to thank the European Union, the Federal Ministry of Education and Research, the Free State of Saxony and the City of Leipzig via the Leipzig Foundation for Innovation and Technology Transfer for their financial support.

The European Union sponsors through the programs EFRE and ESF. The building projects of the Fraunhofer IZI are sponsored 60 percent by the European Union and 20 percent each by the Federal Ministry of Education and Research and the Free State of Saxony. The plot of land is provided by the City of Leipzig in hereditary leasehold and free of charge. Furthermore, Fraunhofer IZI would like to thank the Leipzig Foundation for Innovation and Technology Transfer for its support during the institute's construction phase from 2005 to 2010.

Advisory Board

The advisory board functions as the external expert committee for strategic questions regarding the institutional direction and the Fraunhofer-Gesellschaft. Its members are invited and appointed by the president of the Fraunhofer-Gesellschaft. The advisory board includes representatives from industry and research as well as from authorities, ministries and foundations. The board meets once a year and evaluates the performance and image of the institute.

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- MR'in Dr. Annerose Beck, Saxon State Ministry of Science and the Arts (SMWK), Head of National-Regional Research Centers Administration
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The Fraunhofer-Gesellschaft

The Fraunhofer-Gesellschaft, based in Germany, is the world's leading applied research organization. Prioritizing key future-relevant technologies and commercializing its findings in business and industry, it plays a major role in the innovation process. A trailblazer and trendsetter in innovative developments and research excellence, the Fraunhofer-Gesellschaft supports science and industry with inspiring ideas and sustainable scientific and technological solutions and is helping shape our society and our future.

At the Fraunhofer-Gesellschaft, interdisciplinary research teams work with partners from industry and government to turn pioneering ideas into innovative technologies, coordinate and implement system-relevant research projects and strengthen the German and European economies with a commitment to value creation that is based on ethical values. International collaboration with outstanding research partners and companies from around the world brings the Fraunhofer-Gesellschaft into direct contact with the most prominent scientific communities and most influential economic regions.

Founded in 1949, the Fraunhofer-Gesellschaft currently operates 76 institutes and research units throughout Germany. Currently around 30,800 employees, predominantly scientists and engineers, work with an annual research budget of about 3.0 billion euros, 2.6 billion euros of which is designated as contract research. Around two thirds of Fraunhofer contract research revenue is generated from industry contracts and publicly funded research projects. The German federal and state governments contribute around another third as base funding, enabling the Fraunhofer institutes to develop solutions now to problems that will drastically impact industry and society in the near future.

The impact of applied research goes far beyond the direct benefits to the client. Fraunhofer institutes strengthen companies' performance and efficiency and promote the acceptance of new technologies within society while also training the future generation of scientists and engineers that the economy so urgently requires.

As a scientific organization, the key to our success is highly motivated employees engaged in cutting-edge research. Fraunhofer therefore offers its researchers the opportunity to undertake independent, creative and, at the same time, targeted work. We help our employees develop professional and personal skills that will enable them to take up positions of responsibility within Fraunhofer itself or at universities, within industry and in society at large. Students involved in projects at Fraunhofer institutes have excellent career prospects on account of the practical vocational training they enjoy and the opportunity to interact with contract partners at an early stage in their career.

The Fraunhofer-Gesellschaft is a recognized non-profit organization named after Joseph von Fraunhofer (1787–1826), an illustrious researcher, inventor and entrepreneur hailing from Munich.

Figures as of: March 2023

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Zentrale

Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e. V.
Hansastraße 27c
80686 München
Germany
Tel. +49 89 1205-0
Fax +49 89 1205-7531
info@fraunhofer.de

www.fraunhofer.de/en

Contacts and directions

Contacts

Prof. Dr. Dr. Ulrike Köhl | Director
Tel. +49 341 35536-9100 | ulrike.koehl@izi.fraunhofer.de

Anja Bochmann-Seidel | Administration
Tel. +49 341 35536-9250 | anja.bochmann-seidel@izi.fraunhofer.de

Jens Augustin | Corporate Communication
Tel. +49 341 35536-9320 | jens.augustin@izi.fraunhofer.de

Directions

Please visit our website for directions to the respective sites and for additional contact information
(www.izi.fraunhofer.de/en/contact.html)

Editorial notes

Editorial team | Jens Augustin, Britta Paasche
Typesetting & layout | Michaela Grunert
Translation | LSI Word of Languages GmbH

Editorial address | Fraunhofer Institute for Cell Therapy and Immunology | Perlickstraße 1 | 04103 Leipzig | Germany
www.izi.fraunhofer.de | info@izi.fraunhofer.de

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Contact

Fraunhofer Institute for Cell Therapy and Immunology IZI
Perlickstraße 1
04103 Leipzig
Germany
www.izi.fraunhofer.de

www.twitter.com/FraunhoferIZI

www.linkedin.com/company/fraunhofer-institute-for-cell-therapy-and-immunology