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FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI

ANNUAL REPORT 2009

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2009

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TABLE OF CONTENTS

IN CONVERSATION WITH THE DIRECTOR PROF. DR. FRANK EMMRICH

Professor Emmrich, the past year was marked by several important and memorable anniversaries. The Fraunhofer-Gesellschaft celebrated its 60th anniversary, the University of Leipzig, where you hold a professorship, celebrated its 600th year of existence and the Federal Republic of Germany also turned 60 years old. What would you, as head of the institute, consider a particularly important event in 2009?

In addition to the events you mentioned, there was the 20th anniversary of the fall of the Berlin Wall, which has given the revitalized New Federal States of Germany the opportunity to catch up with the international scientific scene. To this end, all major non-university research organizations in Germany have determined and implemented plans for development and expansion. The Fraunhofer-Gesellschaft was particularly dedicated to this project, particularly in the Free State of Saxony. Many of the Saxonian Fraunhofer institutes were founded in the 1990s. Yet still, the foundation of our institute in 2005 and the fact that we are now witness to a rapid and successful development of our institute show that the interest of the Fraunhofer-Gesellschaft in the Saxonian research landscape persists. Only one year after moving into our new main building we will already start our next building project.

Laying the foundation stone of the first building expansion was a particularly significant event for the Fraunhofer IZI. How will the Fraunhofer IZI benefit from this new building and what are the institute's next goals?

The expansion facility of the Fraunhofer IZI bridges the gap in Zwickauer Street between our main building and the back wing of the BIO CITY. It primarily houses high-performance technical facilities and special laboratories for the development of biological and animal experimental model systems, right up to sophisticated imaging equipment for diagnostic and monitoring purposes. In this building we will also substantially extend our special GMP facilities for tissue and cell products. There will be a connection with the neighboring buildings via three self-supporting bridges, which will surely be an impressive sight to see. We estimate being able to move into the finished building by 2012.

In 2009, the global economic crisis was a topic that kept economy, politics and society in suspense – and it will not be overcome for a long time yet. How is the Fraunhofer IZI, one of whose tasks is the acquisition of industry contracts, dealing with the current economic situation?

Not all industrial sectors were equally affected by the economic crisis. In contrast to automobile and mechanical engineering industries, the health and pharmaceutical industries have experienced only a minimal loss in sales. Nevertheless, we also get a strong sense of general uncertainty here, which manifests itself, for instance, in a substantial decrease in testing new candidate drugs in clinical studies. Uncertainty and reluctance in the placing of orders are therefore also palpable. As we are a very young Fraunhofer institute, this particularly affects us because of the time it takes to establish relationships with industry in which repeat contracts are acquired on the basis of previously successful projects. We have reacted to this situation by streamlining our institutional organization, i. e. by establishing departments. The substantial goal here is to intensify our contacts with the industry. Luckily, there are no signs of the economic crisis showing in the field of public project procurement and we do hope it will remain this way.

In October 2009, the Fraunhofer IZI played an important role in the organization of the World Conference on Regenerative Medicine. More than 1000 participants made this international congress a great success. What is your assessment of the scientific and economic importance of regenerative medicine, in particular in Leipzig / Saxony?

Thank you for referring to this congress that was so important to us. It was a very special highlight from a scientific point of view and our institute was highly praised for its organizational oversight. The congress was not only an indicator for development on an international scale, but in light of the increasing number of exhibiting companies it also showed the industry's interest in regenerative technologies and regenerative medicine. The event also demonstrated the particular importance of this specialist field for research image creation in Saxony. The Center for Regenerative Therapies Dresden (CRTD) and the Translational Center for Regenerative Medicine (TRM) in Leipzig are two of the four large centers for regenerative medicine that have been established in our Free State. This is an excellent basis for the future and is probably only possible with very young specialist fields that allow for leaps of innovation by interdisciplinary pooling of experts. Within the framework of the "Verein für Gesundheitswirtschaft" (Health Management Association) in cooperation with the City of Leipzig, we have made regenerative medicine the central concept of our public scientific image in 2009.

In your capacity as head of institute, university professor and member of the German Ethics Council you spend a lot of time traveling in Germany and the rest of the world. What was the most exciting, most exceptional or most beautiful place you visited in 2009 and what did you do there?

This is an interesting and unexpected question which can be perceived and answered from different points of view. However, I should like to choose Xi'an – a city of more than a million people that is located in the heart of China and, in ancient times, had been the capital of China for almost 2000 years. It was there that the legendary Foundation of the Empire took place and the famous Terracotta Army can also be found in the vicinity of the city. The University of Xi'an is one of the ten elite universities in China. I hold a guest professorship there and with each visit I am impressed anew by the energy and determination with which my young Chinese colleagues are making progress in all fields and by the rapidly developing and improving infrastructure. Last year I was given my first opportunity to visit several spin-off companies from the university and are mainly active in the development of analysis equipment. I also met the excellently trained Chinese experts in regenerative medicine, who reported on the foundation of centers, for example, in Shanghai.

HIGHLIGHTS 2009

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THE FRAUNHOFER IZI ATTRACTS COMPANIES TO SAXONY

Two cooperations with companies from Canada and Italy, respectively, have borne fruit in the past year. Both Nuvo Research, Inc., and InnovaStem GmbH could be established in Leipzig and have contracted with Fraunhofer IZI to carry out applied research work.

The Canadian pharmaceutical and biotech company Nuvo Research Inc. is a cooperation partner of the Fraunhofer IZI in the field of drug development. The project is funded with revenue provided by the "Sächsische Aufbaubank SAB" (Saxon Development Bank) and promotes the pre-clinical and clinical development of the immunological drug WF10 in Leipzig. This agent is intended to be employed in the treatment of rheumatoid arthritis and allergic rhinitis. Nuvo Research Inc., a subsidiary of the Canadian company, was founded for the purpose of promoting the development of WF10, mainly in cooperation with local partners. Over the coming years, as many as 15 new staff members are intended to be employed in Leipzig. The project will run over three years and has a total volume of three million Euros. In August 2009, Thomas Jurk, then Saxon Minister for Economic Affairs, personally delivered the good news to the Fraunhofer IZI in form of the notification of acceptance issued by the SAB bank.

Also in August 2009, the company InnovaStem GmbH was founded. Its establishment in the BIO CITY Leipzig, assisted by the Fraunhofer IZI, is part of the Europe-wide expansion strategy of the Italian parent company I.M.S. (Innovative Medical Solutions). InnovaStem GmbH intends to establish a stem cell bank which focuses on storing adult stem cells derived from umbilical blood, umbilical tissue (Wharton's Jelly), placental tissue and menstrual fluid. A cooperation agreement between InnovaStem GmbH and the Fraunhofer IZI provides for the temporary use of pharmaceutical clean rooms in the Fraunhofer IZI by InnovaStem GmbH. Here, the Fraunhofer IZI monitors the process development according to GMP guidelines. As soon as the manufacturing license pursuant to the provisions of German Drug Law is granted and the manufacturing process is established InnovaStem GmbH will build its own production site in Leipzig in 2010 which requires an initial employment of ten staff members.

1 *From left to right: Thomas Jurk (former Saxon Minister for Economic Affairs), Dr. Wilhelm Gerdes (Fraunhofer IZI) and Dr. Henrich Guntermann (Nuvo Research Inc.).*


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WORLD CONFERENCE ON REGENERATIVE MEDICINE

In October 2009 researchers, clinicians and industry representatives held a three-day meeting in Leipzig on the trade fair grounds in the attractive Congress Center Leipzig (CCL) where they exchanged information with international top researchers and were able to experience and debate their latest research results.

The World Conference on Regenerative Medicine (WRM) hosted over 1100 participants from 37 countries, and encompassed 240 presentations in more than 60 sessions, with 227 posters and over 60 industry exhibitors.

The WRM, organized by the Fraunhofer IZI in cooperation with the Translational Center for Regenerative Medicine, was however not only a success in terms of quantity. Aside from a new attendance record, there was an impressive scientific program including presentations and posters by numerous internationally renowned researchers and medical scientists as well as aspiring young scientists. The issues presented and discussed represented the latest insights and results in the field of regenerative medicine, starting from stem cell therapies to organ replacement and tissue engineering right up to the framework conditions for the translation of therapeutic approaches into clinical practice. Moreover, biotech companies introduced their current equipment and developments as part of the comprehensive industry exhibition.

In the opening presentation of the World Conference, Ian Wilmut, "father" of clone sheep Dolly, spoke about the potential of induced pluripotent stem cells (iPS) and their application. Paolo Macchiarini, who had caused international stir with a tracheal transplantation in a 30-year-old patient in 2008, presented new research approaches in the field of tissue engineering *in vivo*. Moreover, recent developments of the legal framework conditions for cell research and cell products in the USA and in Europe were discussed. "The large number of scientific contributions has made clear that there was substantial progress in the field of regenerative medicine over the past years," Prof. Dr. Frank Emmrich, president of the congress, summed up. "Nevertheless, there is still a lot of work to be done for scientists, companies and regulatory authorities in order to safely and reliably bring this new knowledge to the patient."

1 *Saxon Minister for Social Affairs and Consumer Protection: Christine Clauß.*

2 *Chris Mason, Professor for Regenerative Medicine / Bioprocessing at the University College London, UK.*

3 *Industry Exhibition in the foyer of the CCL.*

4 *"Father" of clone sheep Dolly: Professor Ian Wilmut.*

LAYING THE FOUNDATION STONE OF THE FIRST EXTENSION BUILDING

The Fraunhofer IZI continues to grow. Almost exactly three years after laying the foundation stone of the cell-shaped main building and 17 months after its completion and occupation, the starting signal for building the first "daughter cell" was given.

In the anniversary year of the Fraunhofer-Gesellschaft, the Fraunhofer IZI in Leipzig also had a celebration – that of laying the foundation stone of the first extension building on September 23rd, 2009. The invited guests included the Saxon Prime Minister Stanislaw Tillich, Leipzig's Mayor for Economic Affairs Uwe Albrecht and Dr. Alfred Gossner, Chairman of the Fraunhofer-Gesellschaft. The planned building will be located between the main building of the Fraunhofer IZI and the BIO CITY. A total of three bridges will connect the buildings. The 3280 square meters will inlcude three stories and a basement which houses high-performance experimental medical laboratories and evaluation rooms as well as a GMP facility.

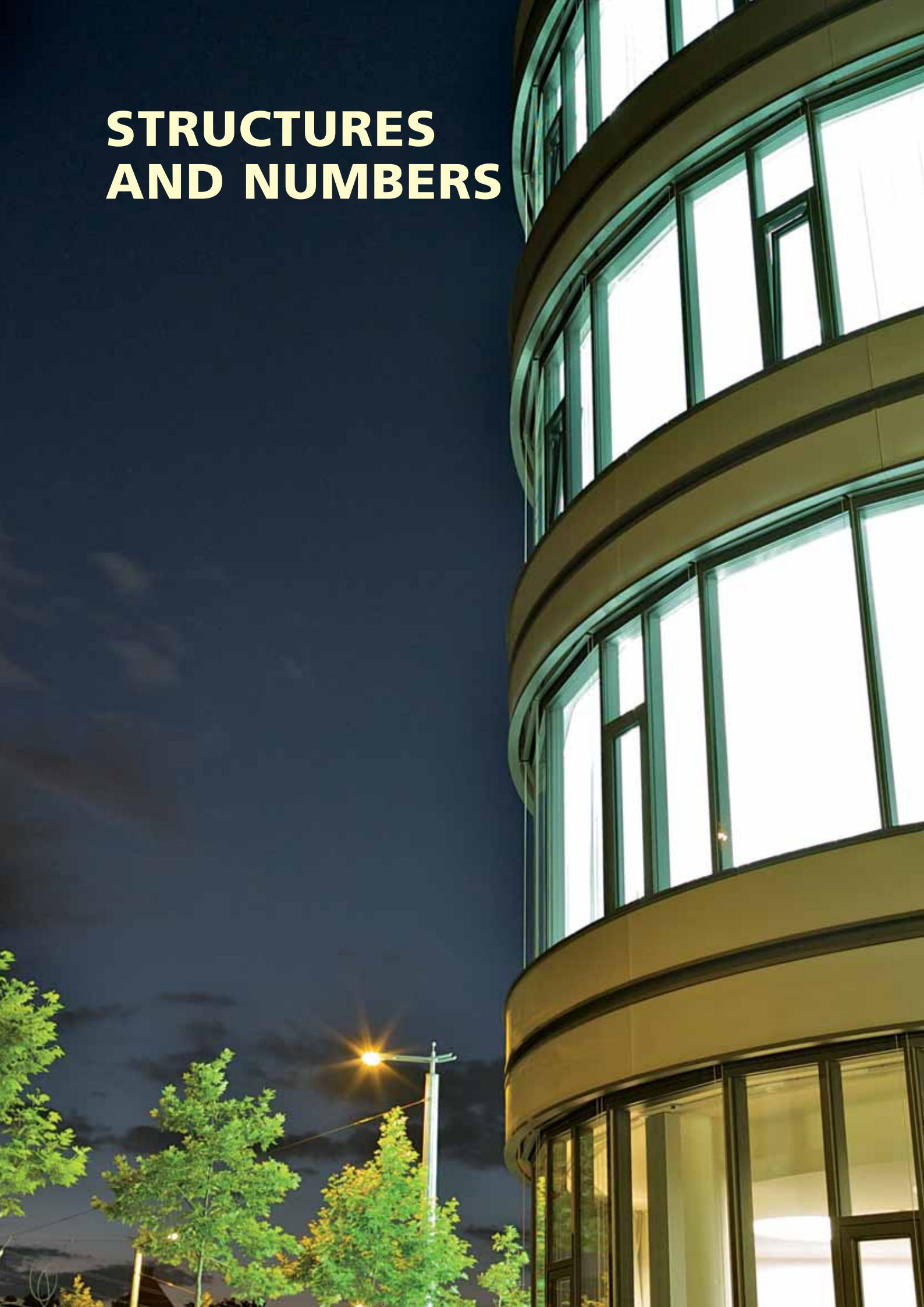
"The extension building allows our researchers to conduct very specific system biological trial and development work and provides us with the urgently required ultra clean rooms for manufacturing cell therapeutics and complex biomolecules. We hope that the construction work will be completed, as planned, by fall 2011 at the latest", as Professor Dr. Frank Emmrich, head of the institute, stated in his welcoming speech. The cost for the building including initial equipment amounts to a total of 10.8 million Euros, which is 60 percent financed by the European Union and 20 percent each by the Federal Ministry for Education and Research and the Free State of Saxony. In addition to the architectural office Heinle, Wischer & Partner, Stuttgart, the planners include the "Technische Gebäudeausrüstung DERU" (Technical Building Equipment) in Dresden, the support structure planners of the engineering office Wetzel & von Seht, Hamburg, as well as the landscape architectural office GFSL, Leipzig.

On the ceremonial occasion of laying the foundation stone, the Fraunhofer Truck stopped by at the Fraunhofer IZI and welcomed passers-by, visitors and other interested persons of the Fraunhofer IZI or neighboring institutes and companies to the exhibition that had been set up inside this impressive vehicle.

1 *Saxon Prime Minister Stanislaw Tillich.*

2 *An effective team: Mayor Albrecht, Prime Minister Tillich, Architect Schmidbauer, Chief Financial Officer of the Fraunhofer Society Dr. Gossner and Head of the Institute Prof. Dr. Emmrich (from left to right).*

STRUCTURES AND NUMBERS



PORTRAIT OF THE INSTITUTE

In light of an ageing society and an increasing number of chronic diseases, modern medicine is facing exceptional challenges. In order to meet the requirements with respect to health and quality of life, the Fraunhofer Institute for Cell Therapy and Immunology IZI has defined its role in finding new developments that can equally be employed in both young and very old patients.

Over the past years, biotechnology and regenerative medicine have taken on greater significance. Of these specialized fields the public expects new therapies for the treatment of diseases which lead to the irreversible damage of tissue and organs; these invariable include chronic, autoimmune and tumor diseases.

The goal is to systematically repair the damages caused by diseases associated with the destruction of cells or tissue and to correct dysfunctions by means of cell therapies, tissue engineering or targeted modulation of the immune system. This goal can be achieved by stimulating the body's own regeneration processes or by means of biological substitutes in form of extracorporeally cultivated tissues.

General topic: Cell therapy and immunology

In the narrow sense of the word, cell therapy denotes the transfer of cells that provide a substitute for lost functions however are also capable of taking over advanced active functions and additionally the term describes the repairing of defects by means of treatment with cells. Stem cells can be transferred in order to induce the formation or repair of tissue.

This builds a bridge to immunology, which is concerned with cellular defense and control mechanisms. It is expected that cell therapeutic methods for targeted enhancement, suppression or regeneration of the immune system will soon be available, e. g. for stimulating the defense mechanisms of degenerate cells or for suppressing undesired graft-versus-host reactions against grafted tissue. In addition, the further development of immunomodulatory techniques, e. g. vaccination, is of particular importance.

Our institute has four departments comprising a total of 17 units. The institute covers positions in the value chain which include research-intensive services for the biotechnology industry, medical technology suppliers and pharmaceutical companies, and offers intelligent, applied research services and development projects. The institute's offer comprises the conduct of market analyses, includes technical feasibility studies and extends further from prototype development using human and animal cells and tissues to the ultimate formulation of production and process technologies.

Organigram

Director
Prof. Dr. Frank Emmrich

Administrative Head
Patric Nitz

Project Service Team
Dr. Wilhelm Gerdes

Department of Cell Engineering
Dr. Gerno Schmiedeknecht

- Cell Engineering/GMP – Kati Kebbel
- Cell Engineering/GLP – Dr. Jörg Lehmann

Department of Immunology
Prof. Dr. Frank Emmrich

- Vaccine Development – Dr. Sebastian Ulbert
- Immune Tolerance – Dr. Stephan Fricke
- Virus-Host-Interaction – Dr. Sabine Breun, Dr. Jörg Baumann
- Immunological Models – Dr. Manja Kamprad
- Vascular Biology – Dr. Andreas Schubert
- Liganden-Entwicklung – Dr. Michael Szardenings

Department of Cell Therapy
Dr. Johannes Boltze

- Immunotherapy – Oncology – Dr. Christoph Schimmelpfennig
- Neuro-/Cardiorepair – Dr. Johannes Boltze
- Stem Cell Technology – Prof. Dr. Nicole zur Nieden
- Stem Cell Biology – Dr. Alexandra Stolzing

Department of Diagnostics and New Technologies
Dr. Wilhelm Gerdes

- RNomics – Dr. Jörg Hackermüller
- Molecular Diagnostics – Prof. Dr. Ulrich Sack
- Tumor Stem Cells – Dr. Peter Ruschpler
- Bio Nanofiber Scaffolds – Dr. Gyeong-Man Kim
- Nanotechnology – Dr. Christian Zilch

As of October 1st, 2009, the organization structure of the Fraunhofer IZI has been streamlined. The previous work units, which had concurrently been managed as organizational units, are now thematically combined in departments. Though the heads of the units are still responsible for their organizational unit and their projects scientifically speaking, they have been relieved of their responsibility for budget and staff, which allows them to give priority to their scientific work. Moreover, the project group Extracorporeal Immunomodulation (EXIM) will begin its work in the course of the current year 2010 in Rostock.

THE INSTITUTE IN FIGURES

In the past year the institute implemented a departmental structure. How does this new structure affect the workflows in the institute?

The departmental structure implemented starting October 1st, 2009, results in both improvement and acceleration of administrative processes. The relevant heads of department are authorized to take responsibility for and sign-off on defined processes, which facilitates a prompt and task-oriented inspection within the department and leaves only legal and formal aspects to the administration. This accelerates processes to the effect that queries from the administration team are reduced to a minimum and that, e. g., acquisition processes are monitored not only with respect to their economic but also to their scientific necessity.

When passing by the Fraunhofer IZI late in the evening, many of the office and laboratory windows are still lit. How do you motivate your employees to perform at an above-average level?

Its employees are a research institute's only source of long-term success. We operate with a concept of trust-based working time, which allows our employees to apply themselves as effectively as possible within the framework of their personal time management. This means that our employees can influence their attendance times upon consultation.

As compared to other institutes of the Fraunhofer-Gesellschaft, the Fraunhofer IZI has an above-average percentage of female employees. Does your institute follow a special strategy of equal opportunities promotion in this respect?

The promotion of equal opportunities is the stated aim of not only our institute, but of the entire Fraunhofer-Gesellschaft. Our recruiting measures are not specifically aimed at highly qualified female applicants, however. It is rather the case that our demands on potential employees as regards social and personal competence often result in employing a highly qualified woman.

What objectives do you bear in mind when thinking of the institute's future?

As already mentioned, the institute's future lies in the hands of its employees. The goal we wish to achieve, by all means available within the scope of public service law, is to gain and retain qualified employees.

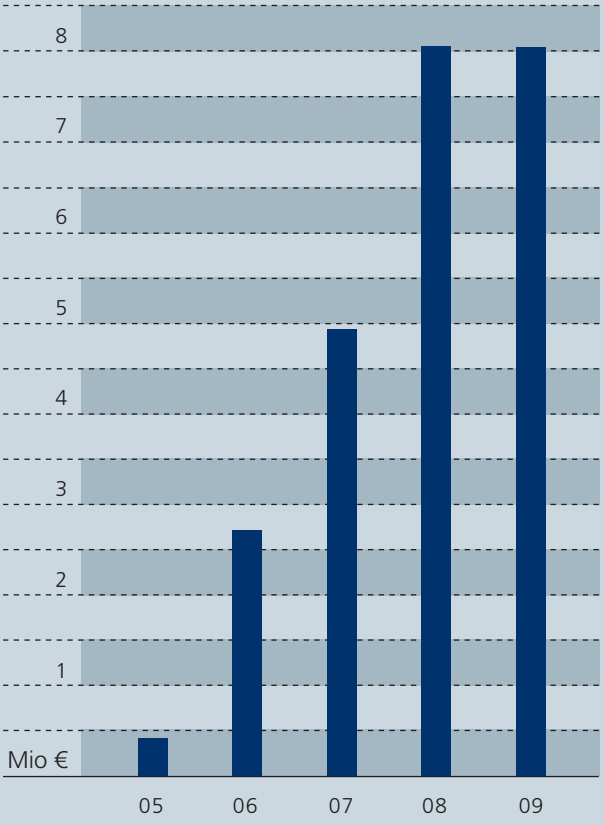
Budget

The rapid growth of the past few years has been consolidated in 2009. In the last year, pre-negotiations with our clients required much more time. Moreover, we are still waiting for the completion of our technology building, which unfortunately is substantially delayed. In answer to this we are planning to reduce our internal research projects and to gain new partners and clients. Since fall 2009 we are allowed to participate in several of the internal Fraunhofer programs.

Projects

The institute is breaking away from the concept of having a few major clients and is now addressing a broader range of clients. The proportion of industry projects could be increased despite the difficult economic situation, which also increases expectations for the years of economic recovery. The unassigned public funds, substantially those of the Free State of Saxony, that expire in 2010 are combined within the framework of special financing.

Budget of the institute



Overview of the projects

	Number 2008	Volume 2008
German national and regional government	8	5 417 954 €
EU	2	98 900 €
Industry projects	23	943 600 €
Other	10	1 571 800 €
Total	**43**	**8 032 254 €**

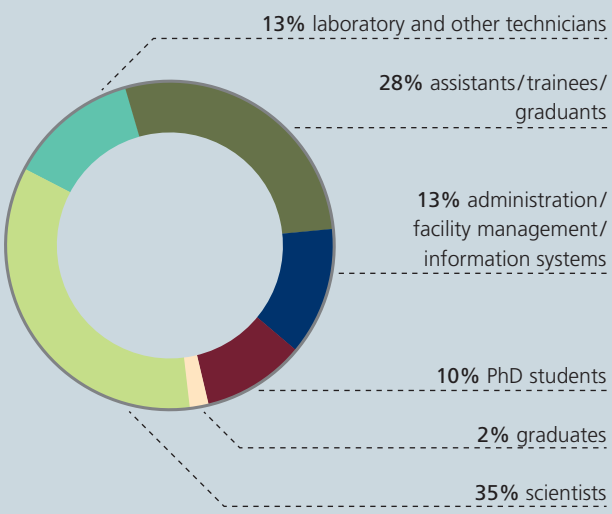
	Number 2009	Volume 2009
German national and regional government	16	2 690 700 €
EU	2	72 400 €
Industry projects	30	1 298 000 €
Other	18	1 443 700 €
Special financing	–	2 525 300 €
Total	**66**	**8 030 100 €**

Human resources

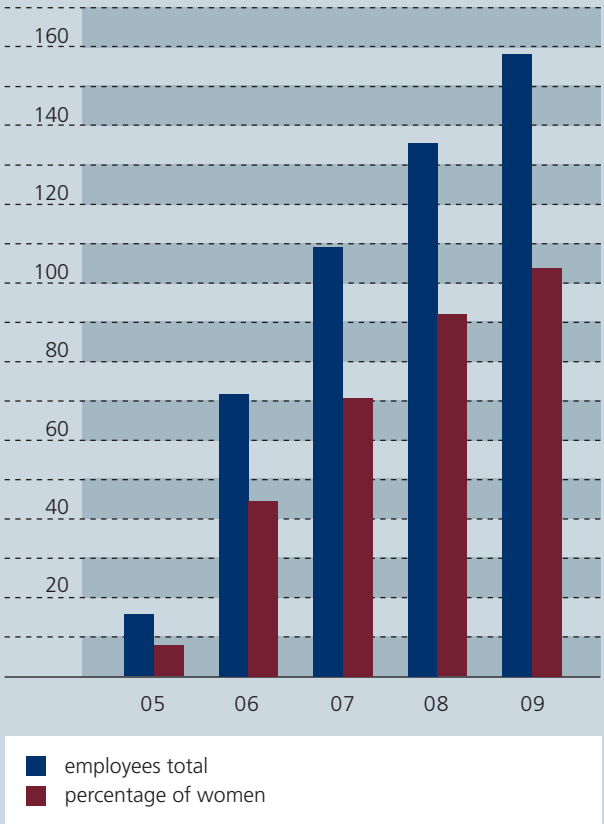
The increasing number of employees proves the Fraunhofer IZI to be an attractive employer. There has been a reduction in non-scientific employees in favor of scientists. In a focused and intensified manner, the Fraunhofer IZI now works with universities as cooperation and project partners. The proportion of female employees working at our institute amounts to 67 percent.

In the administrative department one vacant position was not reoccupied for reasons of process optimization, so that here too the consolidation process is completed.

Workforce composition



Employees



CELL ENGINEERING

IN CONVERSATION WITH DR. GERNO SCHMIEDEKNECHT

What are the central scientific priorities in the Department of Cell Engineering?

On the one hand, the central scientific priorities of the Department of Cell Engineering are in the field of GMP-compliant development and validation of manufacturing processes including quality control of tissue preparations and of so-called Advanced Therapy Medicinal Products (ATMP). This comprises, among others, tissue engineering products and somatic cell therapeutics, including all innovative drug developments based on adult stem cells. The second central issue is the GLP-compliant establishment and validation of immunotoxicological *in vitro* assays. Moreover, we are working on the extension of the GLP certification to include the specification "Immunotoxicology *in vivo",* which in particular encompasses testing for immunogenicity, tumorigenicity and biodistribution in the pre-clinical development of cell therapeutics and biopharmaceuticals.

In addition to scientific priorities, the department also comprises different areas of quality management. Why is expertise in the field of GLP and GMP so important to the Fraunhofer IZI?

An important objective of the Fraunhofer IZI is the transfer of therapeutic methods from research and development to the first clinical application. At the Fraunhofer IZI, this process, also referred to as translation, particularly pertains to Advanced Therapy Medicinal Products. After successful implementation of such therapeutic methods in the research and development laboratory, the aforementioned quality assurance systems are effective for further pharmaceutical development. Important pre-clinical investigations, e. g. of tumorigenicity or biodistribution, must be completed according to the guidelines of "Good Laboratory Practice". All manufacturing processes are subject to "Good Manufacturing Practice". Possessing these building blocks of pharmaceutical development, the Fraunhofer IZI is capable of completing its translational mission to the full extent.

This year the department obtained the GLP certificate for the conduct of immunotoxicological assays as well as a permit for the manufacture and quality control of autologous (the body's own) bone marrow stem cells. How will these milestones affect the future acquisition of industrial orders?

A GLP certificate or manufacturing authorization is issued only after having passed a comprehensive inspection conducted by the responsible regulatory authorities. These documents are a seal of quality and officially testify compliance with the regulations of "Good Laboratory Practice" and "Good Manufacturing Practice", respectively. Future project partners can therefore be assured that their projects are executed at a high level of quality and that the trial results/trial preparations are applicable within the scope of pharmaceutical development. Both the GLP certificate and the manufacturing authorization are deposited in public databases, thus enabling prospective project partners to identify and address the Fraunhofer IZI.

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CORE COMPETENCIES AND UNITS

Core competencies of the department

- GMP manufacture of investigational medicinal products for Advanced Therapy Medicinal Products
- Implementation and validation of GMP-compliant manufacturing processes
- Implementation and validation of GMP-compliant quality controls
- Quality assurance according to "Good Manufacturing Practice" and "Good Laboratory Practice"
- Conduct of GLP trials – Immunotoxicology *in vitro*
- Identification and validation of biomarkers
- Assay development *in vitro*
- Development of antibodies, e. g. by means of hybridoma technology
- Biobanking (model system of chronic inflammatory bowel diseases)

A selection of products and services offered by the department can be found on page 56.

Cell Engineering / GMP Unit

This unit operates a state-of-the-art clean room facility for the provision of investigational medicinal products according to "Good Manufacturing Practice" (GMP). Their expertise is in the field of Advanced Therapy Medicinal Products (e. g. tissue engineering products, somatic cell therapeutics). Here, the whole range from process development and validation to the manufacture of investigational medicinal products is covered.

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Cell Engineering / GLP Unit

This unit has established a GLP laboratory for the conduct of immunotoxicological trial studies *(in vitro)* and differential proteome analyses. The second thematic focus relates to the identification and validation of novel biomarkers for the detection and treatment of chronic inflammatory diseases and tumor diseases by means of immunological, cell biological and protein biochemical methods.

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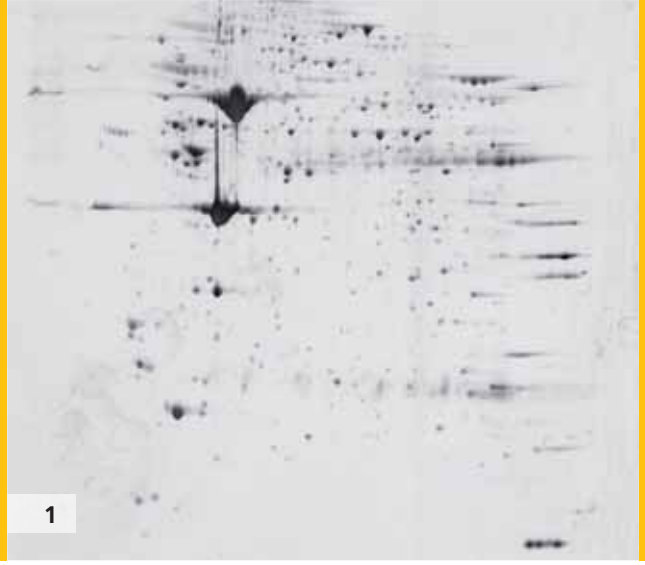

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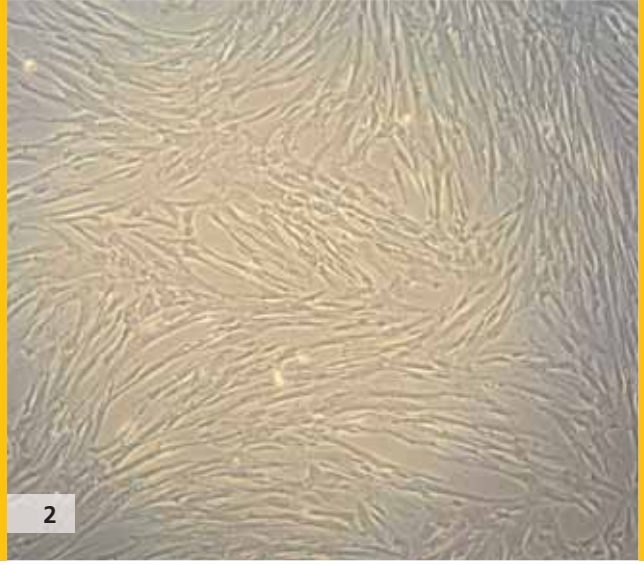

2

PROJECTS

Differential protein biochemical and serological study of UV-C-irradiated and non-irradiated canine thrombocyte concentrates

The "DRK-Blutspendedienst NSTOB gGmbH Springe" (German Red Cross Blood Donation Service, non-profit LLC Springe) has developed a novel method for pathogen inactivation of thrombocyte concentrates (TC) that is based on UV-C irradiation. This method was tested with respect to safety in a pre-clinical animal experimental GLP study within the scope of an R&D project. In this study, beagles were re-infused several times with UV-C-irradiated and non-irradiated (control) autologous TCs in order to investigate the extent to which the reinfusion yields ascertainable changes in the plasma and thrombocyte proteome and is capable of eliciting the generation of antibodies to neoantigens. Proteome changes were analyzed by means of high-resolution 2D gel electrophoresis of plasma and thrombocyte lysate samples. Immunogenicity was determined by means of 1D and 2D Western blot analysis using immune sera from treated dogs. In the evaluation of the study, no significant proteome changes or neoantigen formation upon UV-C treatment could be detected, which minimizes the immunotoxicological risk of a routine application of the method.

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Establishing an individual human cell bank consisting of umbilical vascular cells according to Good Manufacturing Practice (GMP)

In cooperation with the Laboratory for Tissue Engineering in the cardiac, thoracic and vascular surgery of the "Deutsches Herzzentrum Berlin (DHZB)" (German Heart Center Berlin), the Cell Engineering/GMP Unit is working on a development project relating to the establishment of an individual human cell bank consisting of umbilical vascular cells under Good Manufacturing Practice (GMP) conditions. These cells are intended to be used as a defined and safe starting material for tissue engineering of autologous blood vessels and heart valves that could, for example, be employed as living and growing grafts in children. Within the scope of the project, methods developed at the DHZB for the preparation, expansion and cryopreservation of different types of umbilical vascular cells are first optimized and then adapted to GMP-compliant conditions. It is a long-term goal of the project to obtain a manufacturing authorization pursuant to §13 of the "Arzneimittelgesetz" (German Drug Act) for the manufacture and storage of such autologous umbilical vascular cells. The project is sponsored by the Klaus Tschira Foundation.

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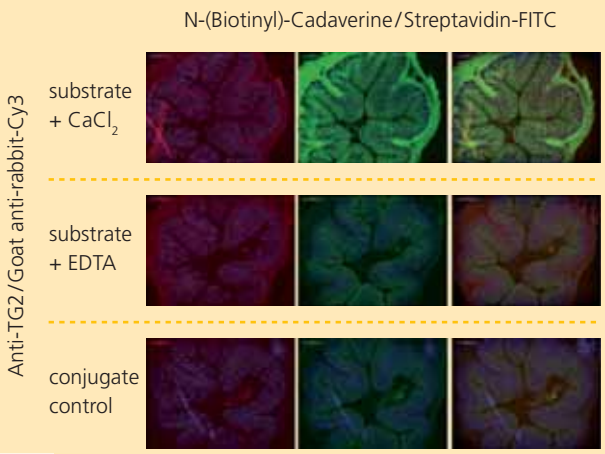
1 *Example of a 2D gel after UV-C-irradiation.*

2 *Primary myofibroblast culture obtained from umbilical vascular walls (50-times magnification).*



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Investigations of the efficacy of transglutaminase-2 inhibitors in the experimental therapy of celiac disease in a murine model of chronic inflammatory bowel diseases (DSS colitis)

This pilot study has the goal of establishing methods for the detection of transglutaminase-2 (TG2) by means of immunofluorescence and enzyme activity *in situ* using frozen murine bowel sections and subsequently utilizing the optimized methods in investigations of therapeutic applicability in the murine DSS colitis model.

Workable protocols for the combined detection of the enzyme and its activity have been developed for two different TG2 substrates (N-(biotinyl)-cadaverine and biotin-TVQQEL-OH). Using both methods, the enzyme could be detected reliably and reproducibly in sections obtained from mice with DSS colitis and also in healthy control mice. The structures Muscularis propria, Muscularis mucosae and Lamina propria of colon and small intestine exhibited enzyme activity.

The TG2 molecule as well as enzyme activity could be detected in all bowel sections and with both substrates. A dosage-dependent TG2 inhibitor-mediated reduction of enzyme activity could neither be detected in the colon nor in the small intestine.

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Supporting the establishment of a stem cell bank

In the summer of 2009, the company InnovaStem GmbH was founded. Part of the expansion strategy of the Italian parent company I.M.S. (Innovative Medical Solutions S.r.l.) includes the selection of the location of a spin-off, InnovaStem GmbH in the BIO CITY Leipzig, assisted by the Fraunhofer IZI. InnovaStem GmbH is involved in the establishment of a novel stem cell bank which stores adult stem cells derived from umbilical blood, umbilical tissue (Wharton's Jelly), placenta tissue and menstrual fluid. InnovaStem GmbH and the Fraunhofer IZI have signed a cooperation contract that provides the temporary use of pharmaceutical clean rooms at the Fraunhofer IZI by InnovaStem for establishing the stem cell preparation and cryopreservation processes. Within the framework of this cooperation, tasks of regulatory and scientific monitoring of process development and validation according to "Good Manufacturing Practice" (GMP) are taken over by Fraunhofer IZI personnel until the required manufacturing authorizations pursuant to the German Drug Act are obtained.

Contact

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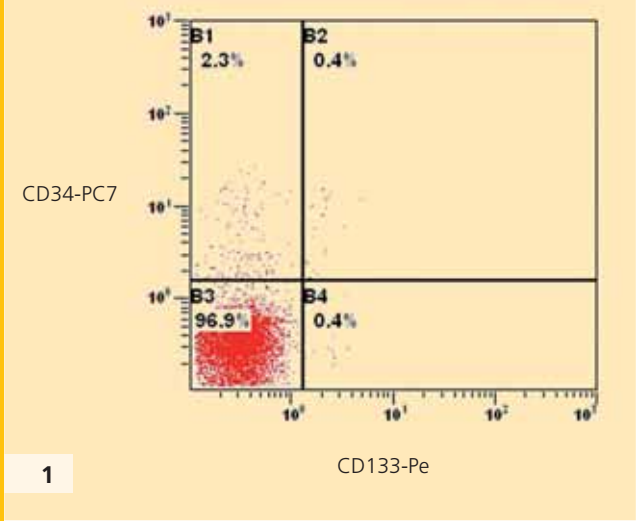
1 *Combined detection of the enzyme TG-2 based on immunofluorescence and enzyme activity.*

2 *Working in the clean room facility.*



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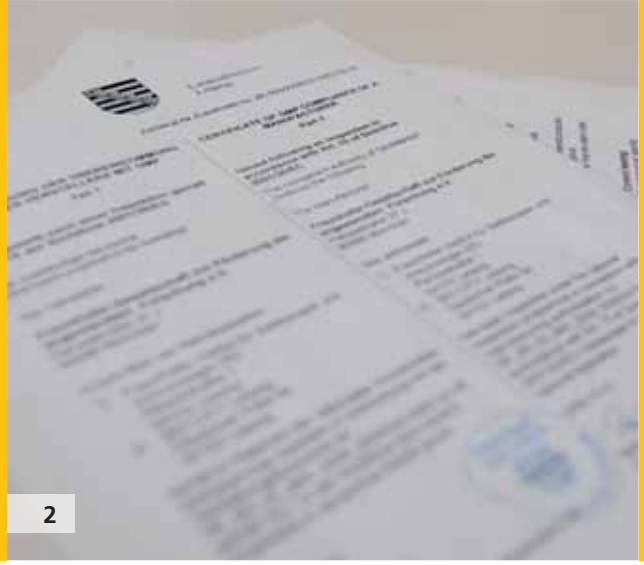

2

Obtaining a manufacturing authorization for autologous bone marrow stem cells

Background

One project that has been completed in 2009 is the setup of a GMP-compliant manufacturing process for a cell-based investigational medicinal products (BM-MNC = Bone Marrow Mononuclear Cells) for the treatment of ischemic stroke. This novel therapeutic approach, wherein stem cell populations isolated from the patient's own bone marrow are intended to be applied intravenously during the acute phase of stroke, has been developed over the last few years by the Neuro-/Cardiorepair Unit at the Fraunhofer IZI. Pre-clinical testing for efficacy and acceptability has already been conducted very successfully in small and large animal models (rat, sheep). In order to ensure the provision of these cell preparations for a planned clinical pilot study an application will be made for a manufacturing authorization pursuant to §13 of the "Arzneimittelgesetz AMG" (German Drug Act), as well as for a procurement permit for bone marrow pursuant to §20, section 2 of the AMG which is issued for a selected procurement clinic.

Approach to solution

Firstly, the standard protocol for the isolation of mononuclear cells using a Ficoll density gradient was optimized, which resulted in a 10-fold increased yield. After issuing all relevant documents (e. g. instructions/protocols for manufacturing, product specification, instructions /protocols for quality control tests, specifications of raw material) a process validation was conducted by manufacturing and testing three validation batches. The validation of the analytic methods, e. g. flow cytometry, testing for endotoxins, sterility, viability and cell count, was performed in parallel. The qualification of the procurement clinic was accomplished concurrently in order to guarantee the procurement of bone marrow pursuant to §20b AMG, §34 and 35 of the "Arzneimittel- und Wirkstoffherstellungsverordnung" (German Ordinance for the Production of Medicinal Products and Active Substances) and the "TPG-Gewebeverordnung" (Tissue regulation under the German Transplantation Law). Following the official inspection of the GMP manufacturing site and the procurement clinic, the manufacturing authorization pursuant to §13 of the AMG and the procurement permit pursuant to §20b, section 2 of the AMG were granted.

Potential

Initial investigational medicinal products can be carried out in cooperation with the clinical trial center as soon as the official permits from the pharmaceutical regulatory authority of the Free State of Saxony are issued. By successfully completing this internal development project the team of the Cell Engineering/GMP Unit of the Fraunhofer IZI will qualify as a competent partner for the GMP-compliant implementation of cell therapeutic projects, even beyond the scope of stem cell therapies based on bone marrow. In the near future such cell therapeutic projects will become more and more frequent due to the rapid development in the field of regenerative medicine and stem cell research.

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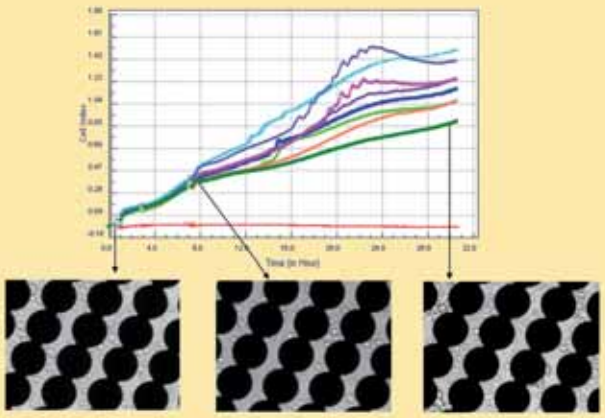
1 *Quality control measurement of CD133+ and CD34+ stem cells in a flow cytometer.*

2 *Manufacturing authorization.*

1



2

In vitro investigations into the mechanism of action of active substances obtained from colocynth and their immunotoxic and neurotoxic potential

Problem

Within the framework of a combined research project in cooperation with the Bombastus-Werke AG, Freital, and the Technical University of Dresden, the Fraunhofer IZI was given the task of researching the mechanism of action of the hypothesized immunostimulation effect of colocynth (Citrullus colocynthis L.). To this end the unit established, primarily under GLP conditions, a range of test systems and models for the conduct of immunopharmacological *in vitro* investigations.

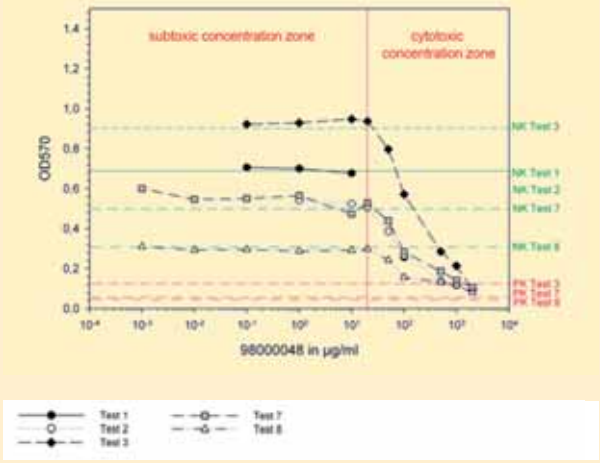
For ethical reasons, the contracting company insisted on strict requirements which excluded animal models and required the application of conclusive *in vitro* models. Comparative investigations of medicinal plants known to have an immunostimulating effect, such as Eastern purple coneflower (Echinacea purpurea L.) and mistletoe (Viscum album L.), which served as reference substances for colocynth, were the core of the Fraunhofer IZI subproject.

Objectives

Main objectives of the Fraunhofer IZI subproject:

- Characterization of the mechanisms of action of alcoholic colocynth/sage extracts and HPLC-purified colocynth ingredients using selected *in vitro* model systems
- Implementation and validation of specific *in vitro* methods and model systems for immunotoxicological and neurotoxicological trials of these substances

Neurotoxicity testing with IMR32 model cell line and MTT assay



1 *A reference medicinal plant: the coneflower.*

2 *Real-time cell analysis of Caco-2 cells by means of the xCELLigence RTCA system.*

1

Different cell lines were employed that mimic diverse cellular compartments in which the trial substances can be effective (e. g. intestinal barrier, endothelium, immune system). Using these model cell lines under normal conditions and under inflammatory conditions the substances were investigated in order to make predictions with respect to the effects of the colocynth ingredients in prophylactic or therapeutic applications.

The implementation and validation of GLP-compliant analysis methods, such as real-time PCR (RT-PCR), real-time cell analysis and flow cytometry, was a substantial objective of the subproject.

Potential applications

By implementing the two major objectives of the subproject the coordinating company is provided with important scientific data that play a substantial role in the clarification of the mechanisms of action of the traditional phytopharmaceutical product Arhama®-Tinktur N and which may also contribute to the development of novel phytopharmaceuticals based on colocynth.

The second objective resulted in the implementation of a test repertoire that can be sustainably employed by the Fraunhofer IZI for further immunotoxicological trials (e. g. phytopharmaceuticals, biologicals, nanoparticles). By December 31st, 2009, the project was completed successfully. Both objectives could be fully achieved.

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1 *Working in the GLP laboratory.*

IMMUNOLOGY

IN CONVERSATION WITH PROF. DR. FRANK EMMRICH AND DR. MICHAEL SZARDENINGS

What role does immunology play in the development and application of regenerative therapies?

The field of immunology encompasses not only defense against infectious agents but also the rejection of transplanted foreign (xenograft) tissues. Due to the so-called graft-versus-host reactions it is not yet possible to employ animal organs in human medicine. In this respect we have to outwit the immune system and induce it to selectively accept foreign tissue. This so-called specific immune tolerance enables the system to further fight infectious agents such as viruses or bacteria to the full extent. All modern stem cell therapies – unless they are based on the body's own cells – must deal with this immunological incompatibility. For this reason we are developing methods to avoid or suppress adverse immune reactions to cell and tissue transplants. This is of particular importance for example with cell transplants which in turn contain immune cells that could attack the recipient organism.

The Fraunhofer IZI wanted to "give birth" to a subsidiary group in Rostock in 2009. What results were achieved and what will be the group's objective?

In 2010 the project group Extracorporeal Immunomodulation (EXIM) will start its operative work in Rostock. In cooperation with the regional industry and the parent institute in Leipzig, the group will develop methods through which novel and highly complex procedures will be tested on organ models. However, it will be the group's central task to modulate the immune system via sites of intervention that are provided in extracorporeal blood circulation systems.

What synergies with the other departments of the institute arise from the various competencies of the Department of Immunology?

The competencies of the Department of Immunology are utilized for the development of novel detection and imaging methods and also as a service in the field of histology and histological analytics. In addition, the department's animal models are shared with other areas of activity dealing with the investigation of human cells in the natural environment of a complete organism. An intensified cooperation is planned in the area of ligand development for stem cell antigens and in standardized methods for GLP (Good Laboratory Practice) analytics. The Department of Cell Engineering implements novel therapeutic proteins in manufacturing processes compliant with GMP (Good Manufacturing Practice), i. e. in industry and approval standards.

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CORE COMPETENCIES AND UNITS

Core competencies of the department

- Vaccine development
- Tolerance induction
- Antibody development
- Immunological models
- Ligand development
- Rheologic models
- Antimicrobial peptides

A selection of products and services offered by the department can be found on page 56.

Immunological Models Unit

This unit is focused on the development and standardisation of *in vitro* and *in vivo* methods to test the immunological activity of newly designed compounds. A newly established mouse model characterised by functional human immuno-competent cells allows the development of experimental disease models and antibody-/ligand-based therapeutic strategies in cooperation with the University of Leipzig.

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Immune Tolerance Unit

The goal of this unit is the development of cell- and antibody-based therapeutic strategies to treat complications following hematopoietic stem cell transplantation. Novel concepts of immunological tolerance oriented towards immunologic and therapy associated complications (e. g. GVHD) are being tested in new, in-house developed animal models.

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Vaccine Development Unit

The unit is developing vaccines against a variety of infectious diseases in the veterinary sector. Primary activities include research on DNA vaccines, but also vector and subunit vaccines against viral infections in pigs and horses. In addition, diagnostic assays for the detection of veterinary infections are developed.

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Ligand Development Unit

The unit develops antibody and peptide ligands applying modern combinatorial and proprietary methods, which are under further development at the Fraunhofer Institute. Main areas of interest are the characterisation and modulation of proteins from the immune system, the identification of novel targets especially on stem cells and the development of peptide and antibody therapeutics.

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Vascular Biology Unit

The goal of this unit is the development of new therapies for the treatment of atherosclerosis. Using shear stress models, genes and promoters are identified that can be activated by biomechanical forces. Another focus of the unit is the establishment of a therapy against oral streptococcus species. Furthermore, antimicrobial peptides are being developed and tested for the food industry.

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Virus-Host-Interaction Unit

The unit studies the many aspects of the interaction of viruses with their hosts. Main focus is the development of new antiviral prevention and treatment strategies. To this end, the as yet poorly understood mechanisms of innate intracellular defence against viral infections, as parts of the species barrier, are being investigated. A second focus is aiming at a specific modulation of immune responses.

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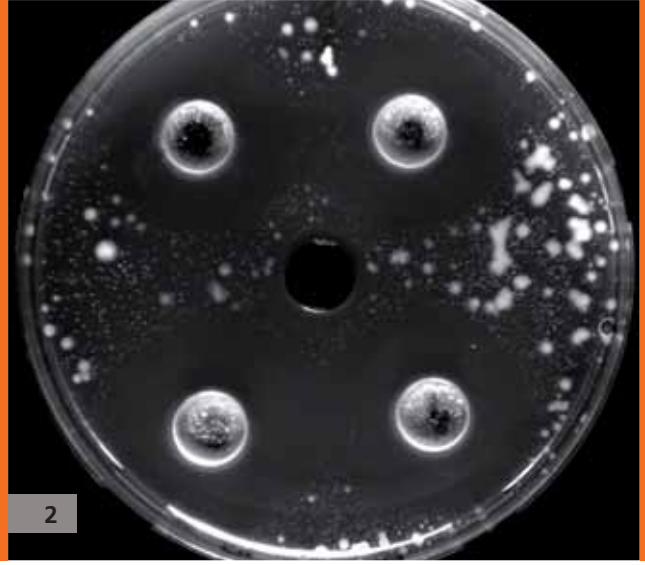

PROJECTS

HIV and co-infections in rural Ethiopia

In sub-Saharan Africa, co-infections with several pathogens are one major problem for the treatment of HIV infected patients. Among these pathogens are mycobacteria (causing tuberculosis), hepatitis C virus, plasmodium, and leishmania. The co-infection rates are largely unknown. However, at the same time these co-infections have a severe impact on the course of disease and treatment. In close cooperation with the University of Gondar, the Fraunhofer IZI has begun to determine co-infection rates in the rural areas of Northern Ethiopia. The Virus-Host-Interaction Unit headed by Dr. Baumann and Dr. Breun is coordinating the project. In cooperation with Prof. Dieter Reissig and Dr. Assegedech Bekele, together with colleagues on-site, blood samples are being taken and analysed for co-infections and possible drug resistance development of the HIV strains found. The German-Ethiopian Network was awarded with this year's Partec World AIDS Day Award. This prize supports the work in Gondar with necessary microscopes, a flow cytometer and consumables.

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Application of antimicrobial peptides in the food industry

The contamination of food results in annual losses of billions of Euro for food producers. In this project, the effect of antimicrobial peptides in the production process of fresh salad will be tested. Fresh salads are often contaminated with yeast and mould fungi. Previously identified antimicrobial peptides will be investigated. These are active against all putrefactive relevant microorganisms such as broad-spectrum antimycotica. The experiments will focus on short antimicrobial peptides with less than 20 amino acids to reduce allergic risks in their usage in processed food. Among others it will be investigated, whether the modification of the amino acid sequences results in more effective and more economic peptides. The development and testing of antimicrobial and oncologically active substances is a core competence of the unit.

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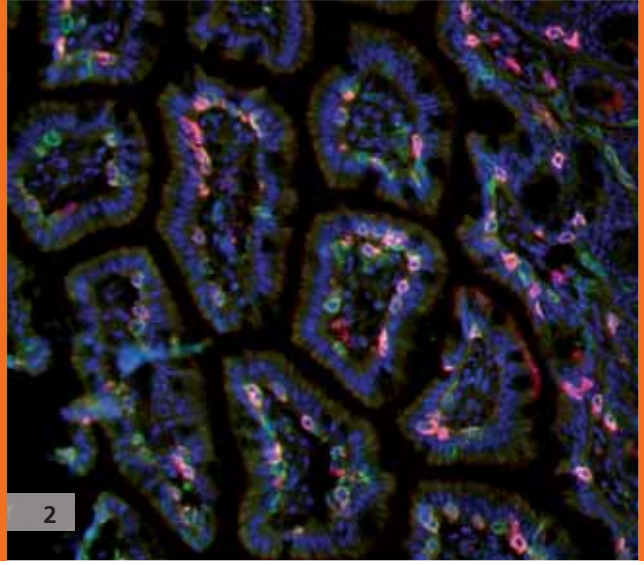
1 *Members of the German-Ethiopian network on-site in Gondar.*

2 *The effect of antimicrobial peptides on the growth of Candida albicans.*



Humane humoral and cellular immune response in an humanized mouse model

In cooperation with University of Leipzig, we developed a humanized mouse model which is characterized by stable and long-term engraftment of functional human immune cells. In the model, all NOD/SCID mice with transferred mononuclear cells from cord blood reconstituted human haematopoiesis. Human multi-lineage differentiation of blood cells in this model, which is observed in blood, spleen and bone marrow, includes B-cells, T helper cells, cytotoxic T cells, NK cells, monocytes, dendritic cells, granulocytes and CD34+ haematopoietic stem cells. Using our optimized transplantation protocol we showed a balanced engraftment of T and B lymphocytes. Functional analysis of human cells demonstrated that B cells underwent normal class switching and produced T-cell-dependent antigen-specific immunoglobulins, and dendritic cells secreted pro-inflammatory cytokines in response to acute inflammation using LPS (lipopolysaccharid) application. Therefore, this model is suitable for developing experimental disease models for pathogenesis research and development of new diagnostic and therapeutic strategies.

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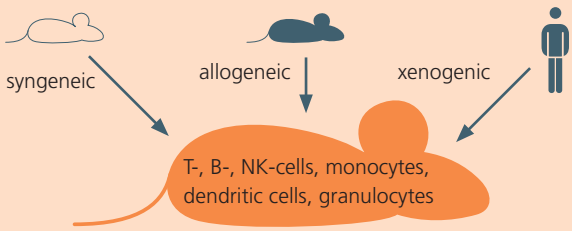
Mouse model with functional active immune cells after syngeneic, allogeneic or xenogenic stem cell transplantation



Murine GvHD model for testing of new developed drugs

Hematopoietic stem cell transplantations (HSCT) are the only curative treatment option for many hematological patients. Despite remarkable success with this therapy, patients still suffering from many treatment-associated complications. Graft-versus-Host Disease (GvHD) is still the most common complication. This also limits the use of HSCT for the treatment of other diseases (e. g. auto-immune diseases). To study GvHD *in vivo,* our unit has established a haploidentical murine model. Using this model the effect of drugs can be analyzed with regard to treatment or prevention of GvHD. Through the use of fully automated fluorescence microscopy to evaluate intraepithelial lymphocytes (IELs), the status of GvHD in this model can be quantified. Therefore, the efficiency of newly developed drugs could be determined more exactly. This model has been used to evaluate the therapeutic potential of antibodies (e. g. anti-CD4) and other experimental compounds.

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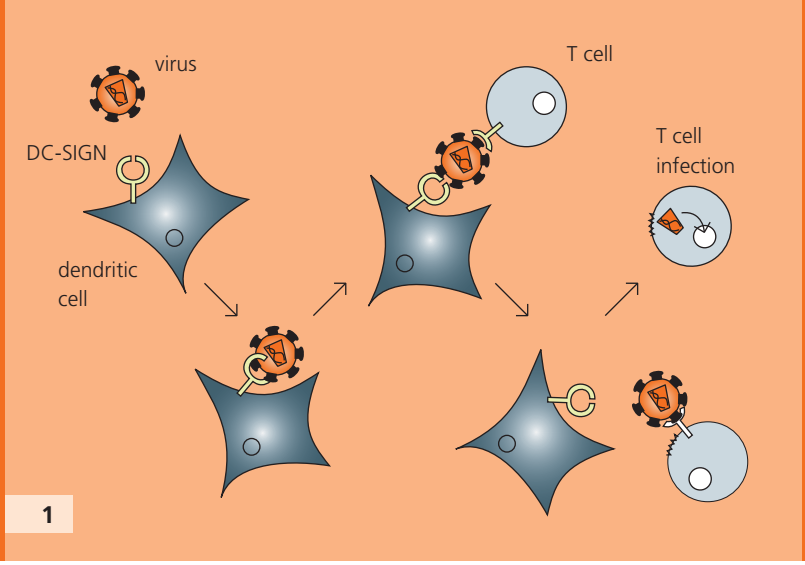
1 *Mouse after successful human stem cell transplantation.*

2 *Triple immunfluorescence staining for detection of intraepithelial lymphocytes of the intestine.*

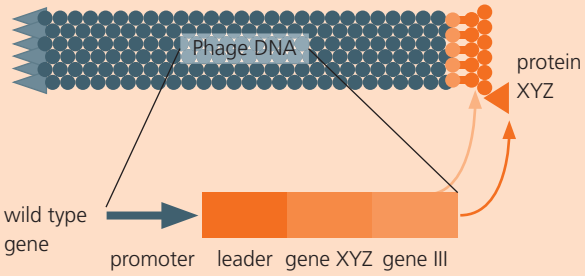


1

Evolution of ligands *in vitro*

The Ligand Development Unit is using selection from so called "phage display" libraries to identify peptides and antibodies that bind selected target molecules. Bacteriophages are viruses that infect bacteria. In this specific case these are modified to carry (display) a variant of a protein on the coat and the corresponding gene in its genome. A mixture of billions of gene/protein variants represents a library. In addition, special combinatorial procedures help us to overcome the general limitations of the phage display technology and to even exceed the variability of the human immune system. This allows us to generate ligands with higher affinity and specificity than those that would be accessible through standard methods. The technology is as well applicable for the discovery of unknown, therapeutic relevant proteins. Antibodies and peptides as ligand molecules are used as therapeutics, diagnostic tools and for the affinity purification of proteins or cells.

Construction of M13 libraries



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HIV, lectins, and immune modulation

DC-SIGN, a C-type lectin on the surface of dendritic cells, binds a large number of pathogens. Binding is accomplished through the detection of sugar residues on the pathogens. HIV uses this feature to its own advantage; the virus lets itself be caught by dendritic cells and is then transported to the lymph node, where it efficiently infects T cells. Using an array of specific mutations, the binding efficiencies of the lectin can be modified. Thus, the interaction of HIV with immune cells is prevented (Chung, Breun et al., in press). At the same time, HIV is also being used to obtain a different perspective on immunological processes, since this virus is exploiting several mechanisms of the human immune system. The knowledge obtained in these studies has culminated in an international patent application of a method to modulate the immune system in an antigen specific way.

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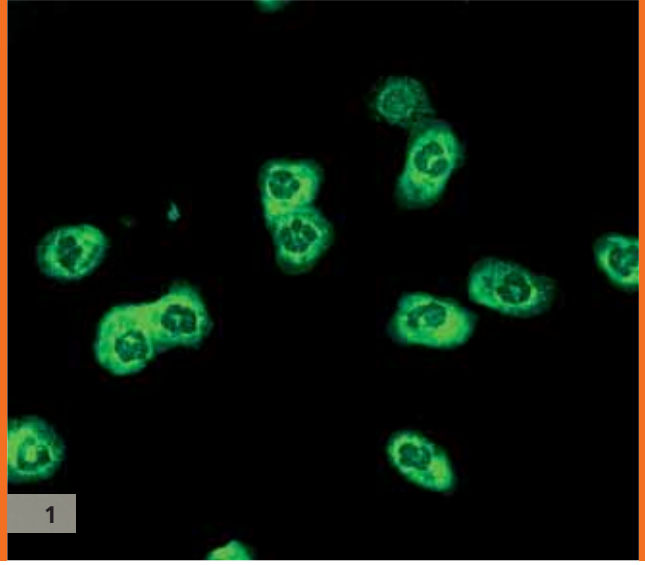
1 *Mucosal transmission pathway of HIV mediated by DC-SIGN on dendritic cells.*



1

2

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Proof of biocompatibility and risk analysis of products *(in vitro, in vivo)*

In the context of developing new therapeutic and regenerative strategies it is necessary to demonstrate the biocompatibility of products extensively and early-on using murine and human systems. This accelerates the development of products into pre-clinical and clinical application. The risk profiles of products based on various *in vitro* and *in vivo* analyses show the compatibility and potential adverse effects. The evaluation includes e. g. immunological compatibility, cytotoxic/proliferative/stimulating effects on primary, stem or tumour cells, thrombogenic, hemolytic or genotoxic activity. Specific mouse models complement the *in vitro* experiments. The certified diagnostic laboratory of the Institute for Clinical Immunology (University of Leipzig) is a competent partner to support clinical studies.

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Diagnosis and prevention of PRRSV

Porcine reproductive and respiratory syndrome virus (PRRSV) causes the economically most important viral swine disease worldwide. In the USA, it causes losses of hundreds of millions of dollars per year. To control the spread of PRRSV, serologic detection of infected animals is mandatory. However, PRRSV cannot always be detected by measuring antibodies against the virus. The basis for currently available serologic tests is the detection of antibodies against the major structural protein of PRRSV. Due to heterologous antibody responses of infected pigs this test principle is suboptimal, as false positive and false negative results are frequently observed. The Vaccine Development Unit has therefore developed a novel serologic PRRSV assay that uses a different antigen to detect PRRSV antibodies. By carefully screening viral proteins antigens were selected that show a greater diagnostic potential than available systems. Hence, this test is more sensitive, more specific and drastically reduces the numbers of false results. Some of these antigens also form the basis of a DNA vaccine to prevent PRRSV.

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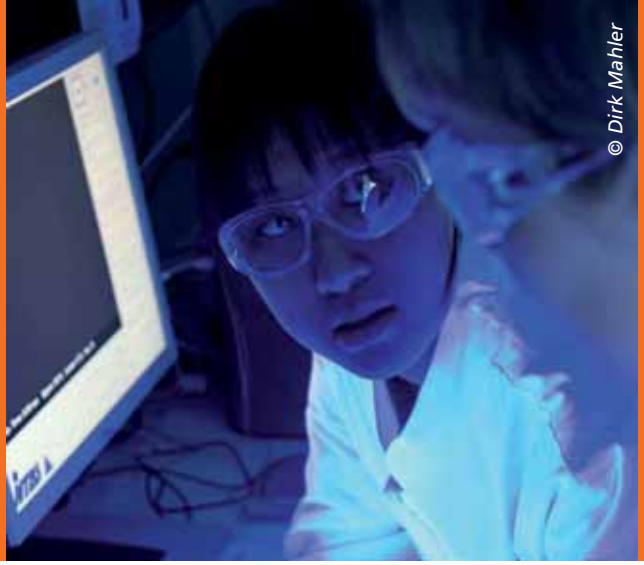
1 *Proof of biocompatibility and risk analysis of products include in vitro and in vivo analyses.*

2 *Piglets especially are affected by the symptoms caused by PRRSV.*



Intracellular defence mechanisms against HIV

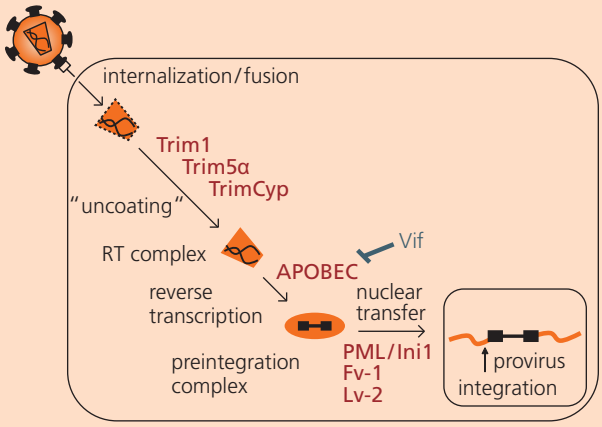
Background

Every year 2.7 Million people die because of the acquired immunodeficiency syndrome (AIDS). Despite of decades of intense research, there is still no cure for AIDS. Highly active antiretroviral therapy (HAART), a combination drug therapy, will keep the virus at bay for several years. However, with time resistant virus strains will appear due to the high mutation and replication rates of the virus. Up to now the drugs developed against HIV target the virus itself, for example through the targeted inactivation of the viral enzymes. An additional treatment option would be the use of innate defence mechanisms. Mammals have developed an arsenal of weapons against pathogenic intruders over millions of years of co-evolution with numerous pathogens. In addition to acquired immunity (which is mediated by antibodies and T cells), they have also developed an innate immune system that acts upon viruses on several levels.

Approach to solution

One level consists of the as yet poorly understood intracellular defence system. Mechanisms in this system attack the virus once it has entered a cell. Only a small number of restriction factors employed by this system have been identified over the past years. However, there are hints of numerous of such restriction systems. They provide a treasure trove of potential therapeutic drug targets to fight viral infections. Such factors have been shown to act in minute amounts and thus they are very efficient in inhibiting viral replication in a cell. The Virus-Host-Interaction Unit is applying a sophisticated screening system to identify these restriction factors in resistant tissues. In cooperation with the HIV Drug Resistance Program of the National Cancer Institute in Frederick, MD, USA, a further factor was recently identified and characterized. This factor was shown to be a very efficient inhibitor of HIV infection (Lee et al., in press).

Known intracellular restriction factors



Potential

The identification of further restriction factors is opening a new form of therapeutic intervention of HIV infections. It is targeting the host cell processes, not just the virus itself. Making use of a system that has been adjusted many times for many pathogens over millions of years may make it difficult for the virus to evade treatment – as it does right now – through single mutations. Thus the virus is fought from several sides at once, by applying a combination therapy aiming at restriction factors and in parallel using the currently available drugs. New forms of therapy are needed, for a cure to become a reality.

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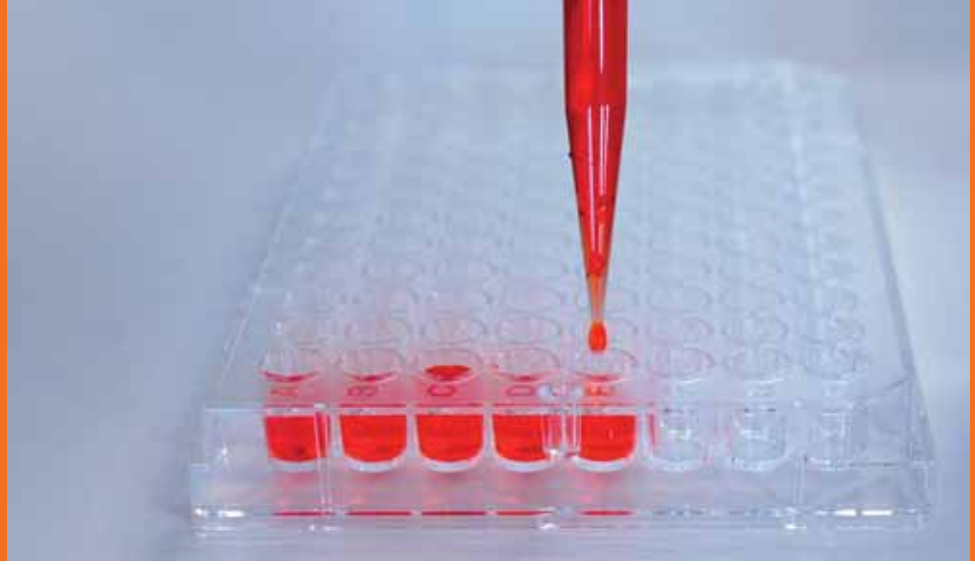
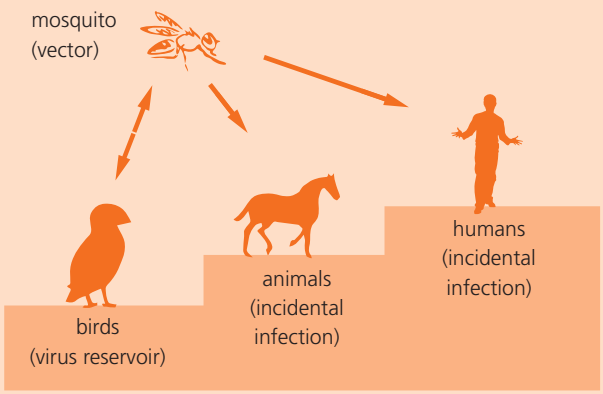


Development of a DNA vaccine against West Nile Virus

Problem

West Nile Virus (WNV) is a known zoonotic infectious virus affecting mainly birds but also humans and other mammals such as horses. The disease is primarily characterized by flu-like symptoms but rarely severe neurological cases, sometimes fatal, are observed. The virus is transmitted by many different mosquito species, several of which are endemic also in Germany. WNV was introduced in the USA in 1999 and has caused hundreds of fatal vases among humans. Also in Europe WNV recordings are increasing, although no epidemic as in the USA has occurred yet. Recently the virus was documented in Austria, France, Italy and Hungary. Until today, there is no human vaccine, and those present in the veterinary sector are not efficient enough as the protection only lasts for up to one year. Hence, further study of the virus and the development of a potent vaccine are mandatory.

WNV is transmitted by mosquitoes which, in addition to birds, can also infect mammals.



Approach to solution

The goal of the project is to develop a DNA vaccine against WNV. This vaccine is supposed to be first applied in horses but has the potential to be developed further for human use. DNA vaccines are a novel immunization strategy. They are very safe, efficient and can readily be adapted to the occurrence of novel antigenic variants (such as viral strains). At Fraunhofer IZI, several DNA plasmids were developed that can be used to immunize against WNV. The basis of these plasmids are DNA sequences which code for parts of WNV antigens. The plasmids were optimized in a way to stimulate a strong immune response. After application of the DNA vaccine the antigen is produced by the immunized individual itself and presented efficiently to the immune system. Several of the DNA plasmids developed at Fraunhofer IZI lead to a protective immune response against WNV in mice. First tests in horses were promising, as well.

Potential

Although WNV has not yet been found in Germany, it can be introduced here at any time. The virus has shown several times in the past that it can cause very severe outbreaks. Hence, it is necessary to develop tools to counteract this threat as long as a large epidemic has not occurred. The technologies delivered by this project build a basis for the development of a safe and efficient vaccine against WNV. The novel DNA-vaccine developed by Fraunhofer IZI is a perfect alternative to established immunization-strategies which until today failed to protect efficiently against WNV.

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CELL THERAPY

IN CONVERSATION WITH DR. JOHANNES BOLTZE

The Department of Cell Therapy combines different competencies in the field of stem cell technology. What are the potential applications of stem cells in medical practice?

Not only stem cells but all therapeutically relevant cell populations in general convey the hope for successful treatment of diseases that are to date considered untreatable. In particular, this applies to diseases that are associated with a loss of cells and therefore a loss of functionality. However, the possibilities of therapeutic application by far exceed a mere substitution of cells. Benefits could also be verified in the prevention or suppression of degenerative processes. For application in clinical practice, however, therapeutic cells must be evaluated extensively and according to strict quality criteria so that both, safety and efficacy of a planned application in patients, can be assessed with the highest possible accuracy. This is a core issue of the work in our department.

The road leading to the application of stem cell preparations in medical practice is long and winding. How does the Department of Cell Therapy support industry partners in translating research results into clinical applications?

In principle, we do not differentiate between industry partners and non-commercial partners. Rather, it is our concern to develop novel cell therapeutic strategies in cooperation with internationally renowned experts. This requires a basic scientific starting position of high quality. This is where we come in. Our passion is accompany the pre-clinical development until it interfaces with clinical practice. We have numerous cell culture and animal models at our disposal, some of them exclusive worldwide. However, our biggest concern is to maintain a very strict quality management – that is, for instance, to detect therapeutically ineffective cells as early as possible – in order to avoid failures that are dangerous for the patient and expensive for the developer. Aside from therapy evaluation, our model systems are incidentally also very well suited for the development of diagnostics.

How will your department develop over the coming year and which competencies will be strategically extended?

What is important is the best possible control over our model systems. In part, this substantially exceeds the internationally prevailing standards and is compliant with the strictest quality guidelines for pre-clinical research. In this area we make every conceivable effort to maintain and improve our standards. In addition to the development of therapies, we will also intensify our work in the development of diagnostic procedures. Our spectrum of model systems and imaging competence is also subject to a continuous development process. Moreover, it is important for us to remain academically competitive and to not exclusively concentrate on service-based research.

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CORE COMPETENCIES AND UNITS

Core competencies of the department

- Growth, expansion and differentiation of (stem) cells
- Infarction models (priorities: brain and heart)
- Models of osteo- and neurodegenerative diseases
- Behavioral phenotypic investigations
- Therapeutic monitoring and imaging (Ultrasound, CT, MRT, PET)
- Bioluminescence imaging
- Pre-clinical study design and quality assurance
- Histological investigations and cell diagnostics
- Evaluation of diagnostic and therapeutic procedures for cerebral and myocardial diseases

A selection of products and services offered by the department can be found on page 57.

Immunotherapy – Oncology Unit

The scientific focus of this unit is on the development and testing of novel therapeutic strategies for the treatment of patients with malignant tumor diseases. With the aid of innovative murine and tumor models (NOD/SCID; Luc-NFkB as sepsis model) it is possible to investigate novel active substances for the treatment of cancers.

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Neuro-/Cardiorepair Unit

This unit is focused on the development and testing of neuro- and cardioprotective therapies and diagnostics for the treatment of ischemic heart diseases and stroke. The pre-clinical evaluation of novel therapies using cell culture systems and small animal models is complemented by a large animal model and state-of-the-art imaging methods. The implementation of high quality standards ensures the translation of successful therapy concepts into clinical studies. The development of genetic tests for an early detection of dyslexia is another focal point of the unit.

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Stem Cell Biology Unit

This unit explores synergies between stem cell and ageing research with the aim of developing new strategies for tissue regeneration with a focus on the brain. Innovative approaches are investigated in order to "rejuvenate" adult stem cells so that these cells can again become a driving force in regenerative processes, in particular in elderly patients.

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Stem Cell Technology Unit

The application of embryonic and fetal stem cells offers unique potential for the formation of all known tissues and organs. Therefore, this unit concentrates on the development of cell culture techniques that facilitate a large-scale expansion of stem cells as well as an optimization of targeted differentiation into various adult cell types.

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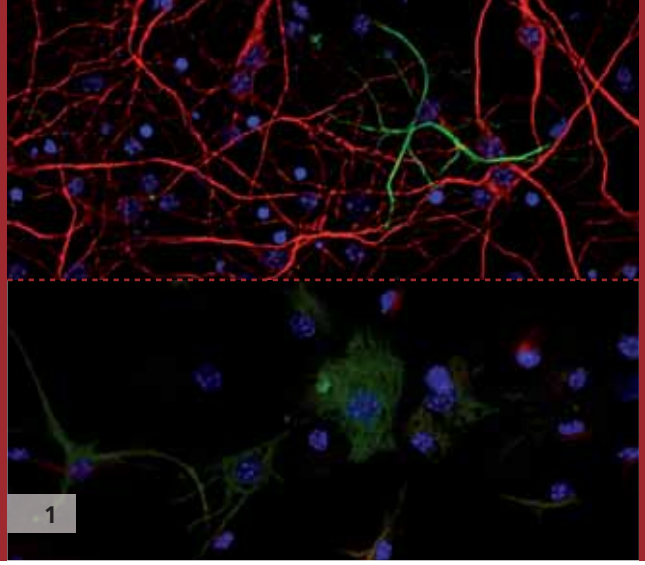

1

2

PROJECTS

Analysis of regenerative mechanisms upon oxygen / glucose deficiency *in vitro*
(Part of the ADUCELL joint research project)

This unit utilizes a model derived from isolated primary neuron and glia cultures which facilitates the analysis of cell populations upon oxygen/glucose deficiency at the cellular level. With the aid of these cultures it is possible to investigate the processes taking place during cerebral ischemia in a simplified model *in vitro*. For this purpose, the cells are cultivated for a defined period of time under oxygen/glucose deficient (OGD) conditions. The subsequent specific investigation of the cell populations facilitates a chronological classification of cellular processes at the molecular level which in turn allows for a systematic functional analysis of alternative regenerative substances that can be utilized for therapy development. Aside from this cell system, an organotypic tissue section model is also intended to be established that combines the advantages of a simplified cell culture system with the complexity of a cell-to-cell structure. In a first approach, the regenerative effects of adult stem-cell-containing cell populations derived from bone marrow on such tissue section cultures were investigated (ADUCELL).

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Development of products and methods for the cryopreservation of stem cells and tissues

This project targets the development of novel products for the process of cryopreservation. These innovative technologies can be employed in the long-term (biobanks), short-term (tissue engineering) and clinical (transplantation) application of cells. The use of hydroxyethyl starch for the cryopreservation of mesenchymal stem cells will be specifically investigated with a focus on the functional analysis of the stem cells and thus the adaptation for easy clinical application. The Serumwerk Bernburg AG is a medium-sized pharmaceuticals company and has comprehensive experience in the development and manufacture of colloidal and crystalloid infusion solutions. Hydroxyethyl starch (HES) is an active ingredient of colloidal volume replacements and harmless in patients and can therefore be used as a component in cryopreservation procedures.

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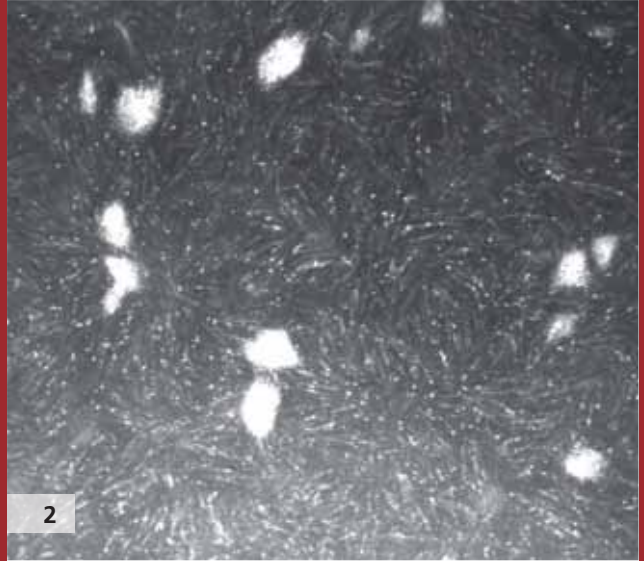
1 *Neuron culture before (control, above) and after OGD (below); neurons, red; astrocytes, green; nucleus, blue.*

2 *Cryopreservation of stem cells and tissues at -140 °C.*

1



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Genetics of dyslexia – Development of an early-detection test for diagnosis of reading and writing disorder

This project targets the developmental steps for a genetic screening test for dyslexia, a severe dysfunction in reading, writing and spelling abilities that affects more than 4 percent of all school children. The assay to be developed would detect affected children at a far earlier stage than current methods, thereby significantly increasing the chances for successful therapy and functional regeneration. The project will be conducted in cooperation with the Translational Centre for Regenerative Medicine (TRM). The genetic markers used in this test are identified from candidate genes and a screening based on micro arrays. They are validated following a multi-level strategy:

– Genotyping of an independent cohort
– Characterization of the markers by means of functional Magnetic Resonance Therapy (fMRT)
– Characterization of the markers with respect to their relevance regarding the expression levels of the respective genes

The screening test itself neither comprises fMRT nor expression analysis. The test serves to translate results from a genetic analysis into a clinical approach. This would facilitate an early identification of children at risk in order to enable a functional regeneration by means of early childhood intervention.

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Mass customized organ replicates – tissue engineering on demand

Tissue engineering is one of the most interesting research fields within regenerative medicine. There is, however, a lack of technologies for automating tissue manufacture in order to ensure adequate public supplies. The project's objective is the development of a production system for the automated manufacture of skin. Skin was chosen as an example as its cell biological processes are well understood and it can therefore be utilized as a test system for pharmaceuticals. The part taken over by the Fraunhofer IZI in this respect is the contribution of a cell source. As the use of human embryonic stem cells in tissue engineering is not allowed in Germany, human induced pluripotent stem cells (iPS) have been generated. These stem cells are theoretically immortal and can now be incorporated into the production system for skin manufacture. In addition, these cells can be employed in other forms of cell therapy. It would be possible, for instance, to generate dopaminergic neurons for the treatment of Parkinson's disease.

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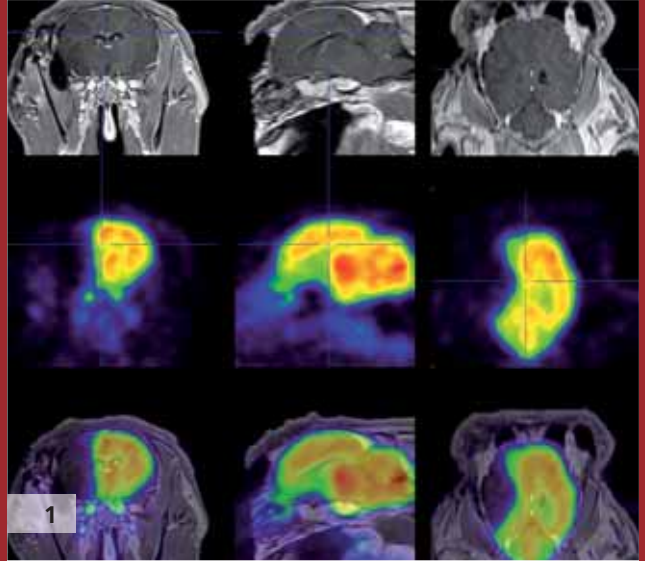
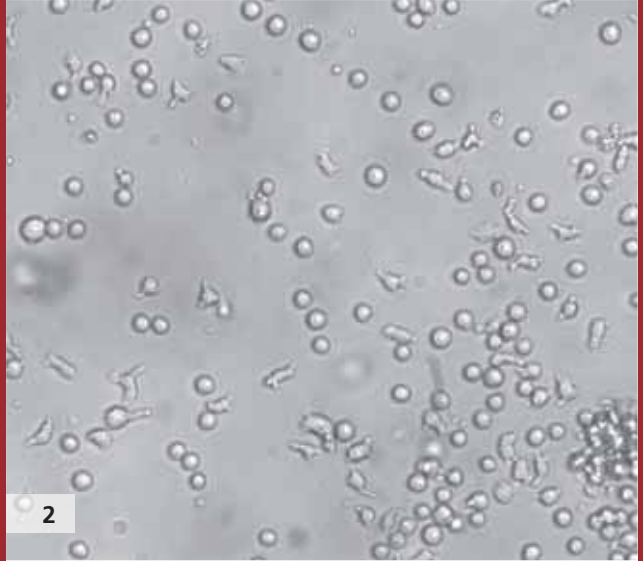
1 *Early detection of dyslexia increases the chances of success in therapy.*

2 *Human induced pluripotent stem cells (iPS).*





Neuroprotection upon acute ischemic stroke

Despite the establishment of specialized stroke units in hospitals, acute ischemic stroke is still the most frequent cause of permanent disability. There is a window of only a few hours for therapeutic intervention in order to save the remaining brain tissue. The cerebral damage can be reduced by means of a targeted increase of cerebral blood supply. To this end, an inhalative neuroprotector was tested under near-clinical conditions in a large animal model (sheep). A stroke was induced by permanently blocking the middle cerebral artery in adult animals. Using state-of-the-art imaging technology together with our cooperation partners a functional process analysis of the cerebral blood supply was conducted in a positron emission tomograph (PET) within 4.5 hours of acute stroke, either with or without an inhalative neuroprotector. The examination was completed by a magnetic resonance tomography (MRT) using sequences that are routinely applied in human medicine.

Cooperation partners: Prof. Hoffmann, Neuroradiology, University of Leipzig / Prof. Sabri, Nuclear Medicine, University of Leipzig / Prof. Plesnila, Royal College of Surgeons, Ireland.

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Tumor reduction by cytokine-induced killer cells

Metastasizing tumors are not curable at an advanced stage and are normally associated with only a short survival time. Curative treatments are not yet available. It is therefore necessary to develop novel therapeutic strategies. Immunological mechanisms can control malignant diseases and are therefore increasingly used to complement the hitherto established therapies. Cytokine-induced killer cells are suitable for an adoptive immune therapy in patients with metastasizing tumors. The cytotoxicity of *ex vivo* expanded cytokine-induced killer cells is investigated in murine tumor models (NOD/SCID colon carcinoma model) by means of bioluminescence imaging (BLI).

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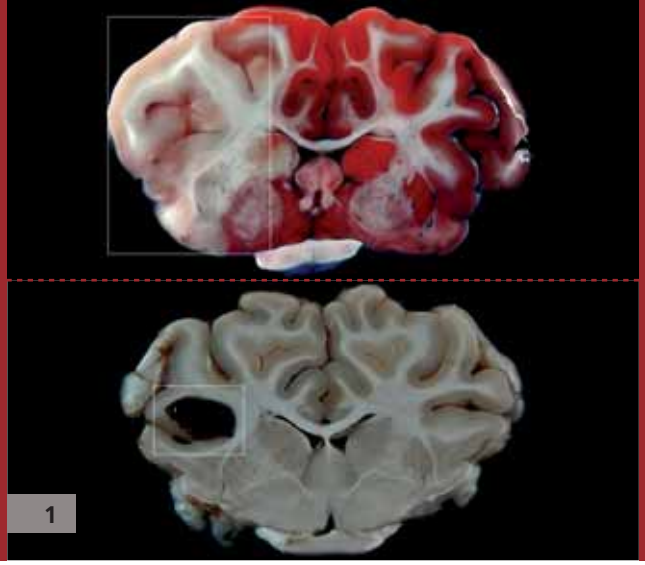
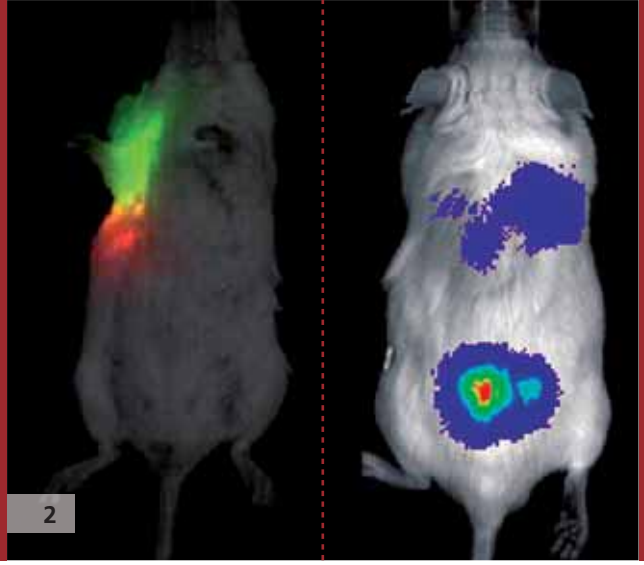
1 *Early stroke in MRT (above) and PET (center); overlay of both imaging methods (below).*

2 *Cytokine-induced killer cells.*





Model development for diagnostics in early and progressive stages of acute cerebral hemorrhage and ischemia (ECHO project)

The only established therapy for acute stroke is the medicamentous lysis of a vascular occlusion with a recombinant plasminogen activator. However, this can only be successful during the first 4.5 hours and moreover causes an inhibition of blood coagulation. It is therefore necessary to rule out cerebral hemorrhage by means of CT and MTR prior to the application of medication. In order to solve this problem, a mobile ultrasonic transmission system with high chronological and spatial resolution (by WITTENSTEIN AG) was tested in a large animal model (sheep) for its theoretical applicability. In addition to the previously established ischemic stroke model, the unit developed a new cerebral hemorrhage model for this purpose. Following an induced stroke or cerebral hemorrhage the system should distinguish between these two pathologies within the first 4.5 hours, with the diagnosis confirmed by MRT and pathology. The system was indeed capable of differentiating between the two disease patterns. It is possible that the project will be continued in a spin-off company.

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Bioluminescence imaging

Bioluminescence imaging (BLI) is a highly sensitive technology that allows monitoring the migration, expansion (tumor cells) and survival of effector cells or the activity of specific luciferase-coupled genes in a living animal. BLI is based on the measurement of photons emitting from a living animal through the action of the enzyme luciferase. As this examination is non-invasive, several examinations of the respective animal can be performed over a longer period of time and be complemented by histopathological examinations. It is possible to separately cleave various reporter genes, which are capable of emitting light of different wavelengths, so that a number of effector cells as well as their interactions can be monitored in a living animal.

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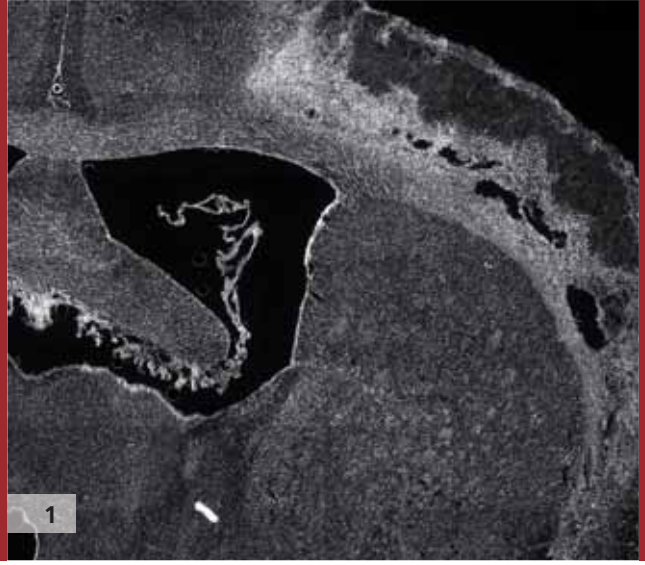
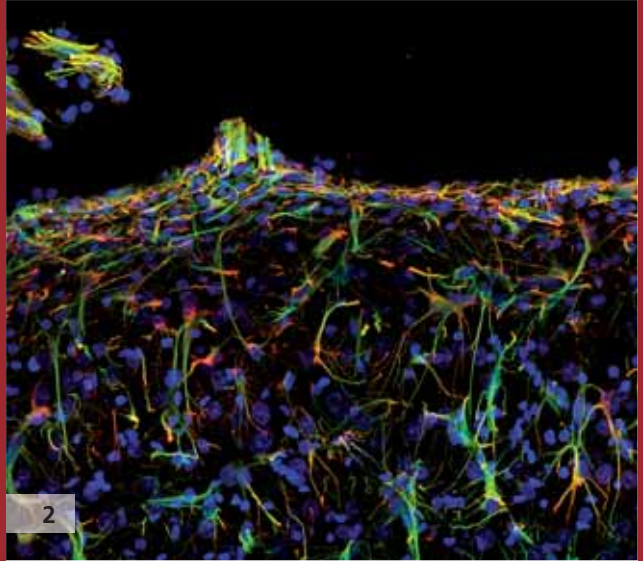
1 *Comparison of cerebral ischemia (above) and cerebral hemorrhage (below) after 4.5 hours.*

2 *Tumor growth examination by means of fluorescence imaging (left) and bioluminescence imaging (right).*





Evaluation of the therapeutic potential of placental cells in the treatment of stroke

Problem

Stroke is already referred to by experts as the epidemic of the 21st century. There are 5.7 million people deaths per year from the consequences of stroke and a further 10.6 million survive, however in some cases with severe disabilities. Stroke is a typical disease of old age and demographic changes will lead to a significant increase in stroke patients. Stroke burdens national health systems worldwide with an expense of up to 100 US Dollar per citizen.

Available options for a treatment of stroke are limited and researchers all over the world are intensively investigating alternative therapy options. Stroke cell therapy appears to be a promising approach, but there is still a lot of basic scientific work to be done in order to find suitable framework conditions for this experimental therapeutic option.

Approach to solution

The human placenta is a promising source of therapeutically active cell populations for the treatment of stroke. As a by-product of birth, the availability of this tissue is virtually unlimited and is not subject to ethical restrictions. Owing to the special characteristic of the placenta as an organ located at the interface between two different immune systems, placental cells exhibit an interesting immunological profile. These cells are ideal candidates for transplantation as they are only slightly rejected by the recipient immune system. On the other hand, they are capable of modulating the recipient's immune system – an effect that is associated with therapeutic success in the cell therapeutic treatment of stroke. It could furthermore be demonstrated in cell culture models that placental cells are able to deliver soluble substances that have a beneficial effect on stroke.

Potential applications

The experiments performed showed a significant improvement of the healing process caused by transplantation of placental cells. Experimental animals that were affected by stroke and treated with placental cells exhibited a significant improvement of neurological symptoms in association with a reduction in the extent of damage. It is assumed that the observed effects are brought on by a modulation of the immune system and a release of substances that reduce necrosis of nerve cells. A translation of this therapeutic concept into a clinical study is conceivable in case these results are confirmed in follow-up studies.

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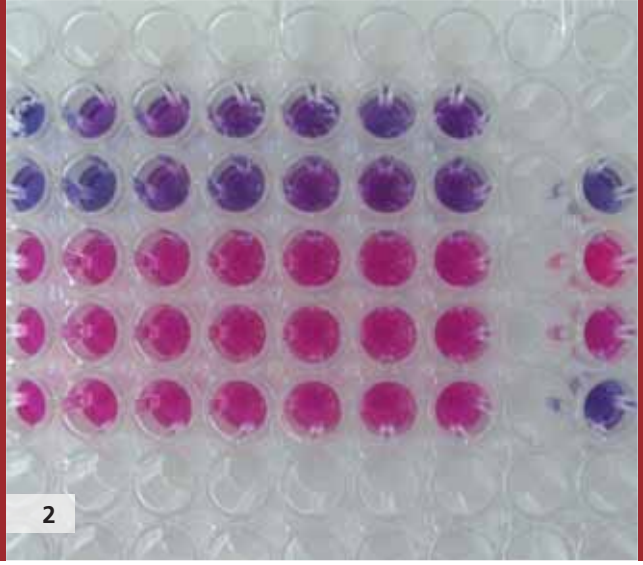
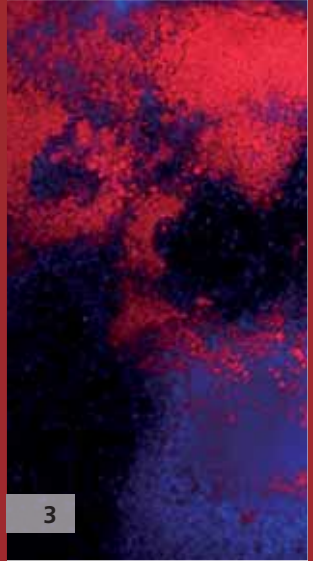
1 *The applied stroke model allows inducing a cortical ischemia without affecting the basal ganglia.*

2 *The peripheral region of the ischemic stroke is characterized by a distinct astroglial reaction.*





Pluripotent stem cells in the automated prediction of toxic influences on bone development

Background

The teratogenic potential of an agent can cause irreversible damage to the developing embryo. The pharmaceutical industry has been looking for years for a suitable *in vitro* embryo toxicity model as complete data records for most of the pharmaceutical agents and environmental chemicals are not yet available but already requested by law. The currently most promising *in vitro* embryo toxicity test, the embryonic stem cell test (EST), evaluates toxicity mainly in the endpoints heart, skeleton and nerves with the aid of murine embryonic stem cells. It is out of the question that this cell type passes through all stages of embryonic development from unspecialized cells right up to functional tissue-specific cells. Unfortunately, the Thalidomide Scandal of the late 1950s has dramatically illustrated that rodents are not invariably the best model systems for predicting toxic effects on human patients.

Approach to solution

It is the Stem Cell Technology Unit's objective to identify new endpoints for the EST that allow for predicting toxic effects on skeletal development and increasing the general predictivity of this assay. Therefore, we characterize the suitability of embryonic stem cells of the marmoset monkey (Callithrix jacchus) in the EST by comparative testing of chemicals in both primate and murine cells. To this end, the cells are incubated with different concentrations of test chemicals. In order to shine a light on prenatal toxicity two endpoints are measured, namely the effects of the chemical on growth (cytotoxicity) and bone differentiation. The latter endpoint is quantified by measuring matrix-incorporated calcium. However, by employing novel endpoint analyses, such as for instance image analysis, it will be possible to reduce the costs for testing in the long run.

Potential

The cytotoxicity data confirm that following exposure to toxic agents primate cells do indeed react differently than murine cells, although it is not possible to recognize a consistent pattern. Depending on the endpoint parameters, the primate cells exhibit higher or lower sensitivity to a toxic agent. The same tendency can be observed in differentiation tests. Our results confirm that the EST remains a promising *in vitro* model for developmental bone toxicity and illustrate the species-specific differences in toxic reactions to various chemicals. In the long run it will be inevitable to conduct such predictive assays using primate or even human cells.

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1 *Morphology of mineralized bone cells differentiated from embryonic Callithrix cells.*

2 *Calcium assay based on absorption change for evaluating successful differentiation.*

3 *Alizarin red S staining for visualizing the mineralized cells.*

DIAGNOSTICS AND NEW TECHNOLOGIES

IN CONVERSATION WITH DR. WILHELM GERDES

What topics is the department developing in particular?

Our developmental emphases are on the fields of ncRNA, i. e. non-coding RNA, and the development of nano-technological markers, so-called biomarkers. The department is thus involved in two novel technologies of the future that could have a significant impact on the biotechnology market. Molecular biological aspects are addressed as well as device-specific adaptations which are realized in cooperation with partners. Biomarkers are developed in particular for oncologic and inflammatory diseases, but we are also well-positioned in the field of infectious diseases. Moreover, we have succeeded in developing cell cultures from so-called tumor stem cells, which allow us to test the efficacy of pharmaceuticals already on the market as well as of novel substances that are still under development; these assays also allow us to pursue their further development where appropriate.

Your department integrates novel technologies as intersecting issues with connections to different fields of research. How do innovative technologies complement the service portfolio of the Fraunhofer IZI?

Let me mention only one of many examples. The development of complex biological tissues, which is a goal of other departments of our institute, can only be successfully implemented if there are complex scaffolds of various materials available that can be colonized with cells. With the aid of a patented system, our department develops novel scaffolds that are both biocompatible and biodegradable. What is crucial is the transfer of those technologies from material research to biology and vice versa. This is where we see the opportunity for the establishment of intersections (engineering/nanotechnology/biotechnology).

An early and reliable detection of diseases is often crucial for therapeutic success. How does your department contribute to a swift translation of novel diagnostic methods into clinical practice?

You are touching upon a pivotal issue here. Let us consider sepsis, i. e. blood poisoning, as an example. There are various diagnostic methods available at present all of which have one crucial disadvantage. An analysis procedure takes a minimum of eight hours, which is too long for patients with acute sepsis when considering the fact that with every hour there is a seven percent increase in patient mortality. Together with an industry partner we are developing a novel method that allows for a reliable therapeutic recommendation within one hour. As such systems must be validated before they can be routinely used in the clinic, we are additionally searching for approaches for accelerating the validation process.

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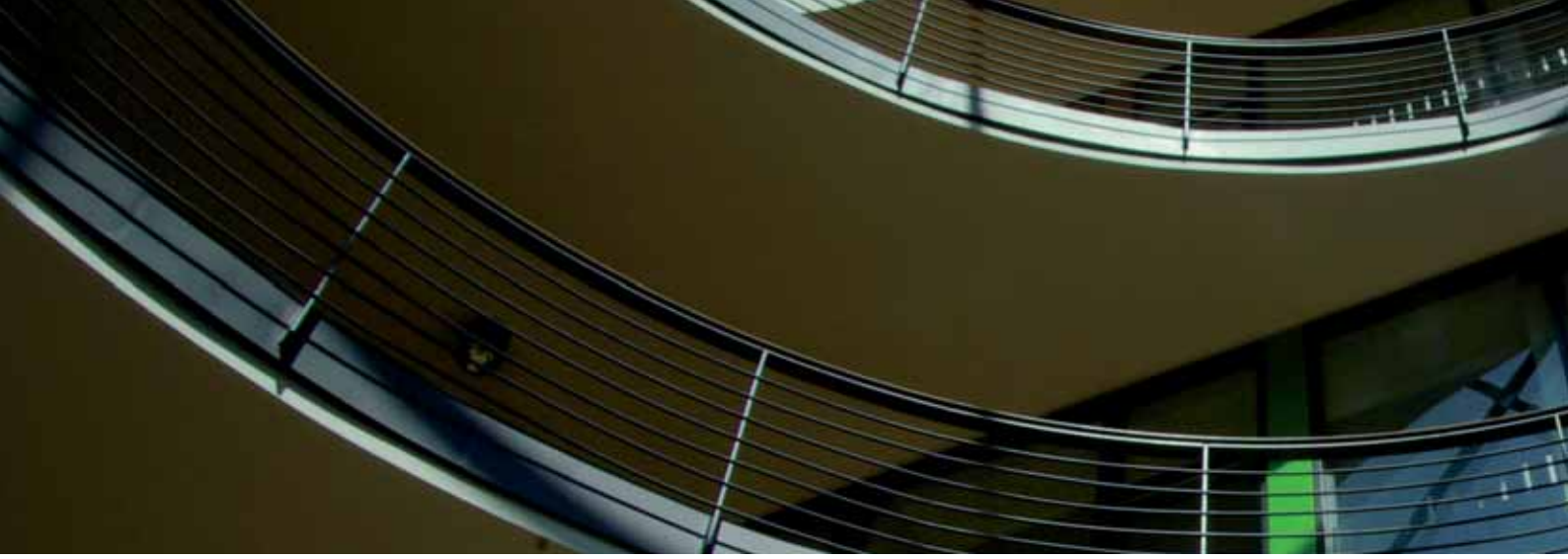

CORE COMPETENCIES AND UNITS

Core Competencies of the department

- Nanotechnology
- Electrospinning
- Tumor stem cells
- RNomics

A selection of products and services offered by the department can be found on page 57.

Bio Nanofiber Scaffolds Unit

Scaffolds consisting of polymeric nanofibers produced by an electrospinning method play a fascinating role in the field of nanotechnology. This unit concentrates on both the manufacture of high-performance scaffolds and the translation of therapeutic methods into clinical applications in the fields of tissue engineering and regenerative medicine.

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Molecular Diagnostics Unit

This unit develops rapid, easy-to-handle, immunological, cell biological and genetic analysis as well as model systems for the areas of graft-versus-host diseases, inflammation research and tumor biology, in particular for articular and pulmonary diseases. Innovative immunoassays, genetic analyses, complex cell culture models and animal experimental approaches are employed here.

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Nanotechnology Unit

This unit is occupied with the development of molecular diagnostic applications of microspheres and materials at nanometer scale. A novel point-of-care diagnostic platform is being developed on the basis of functionalized magnetic particles. Assays based on nucleic acids and proteins are transferred to this platform. In addition, the unit develops *in vitro* assays that contribute to the evaluation of the toxic potential of industrially applied nanomaterials.

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RNomics Unit

The RNomics Unit identifies and characterizes disease-associated non-protein-coding RNAs (ncRNAs) for the development of novel diagnostic markers and therapeutic targets. The methods and strategies required for this task are developed by this unit, wherein particular attention is directed to general disease- and system-independent applicability.

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Tumor Stem Cells Unit

This unit's objective is the development of therapeutic strategies based on cells and agents for the treatment of neoplastic diseases on the basis of the elimination or modification of tumor stem cells (TSCs) in the relevant malignant tumor. It is the intention of the concept to describe TSCs of further tumor entities and to facilitate therapeutic innovations in the field of internal oncology.

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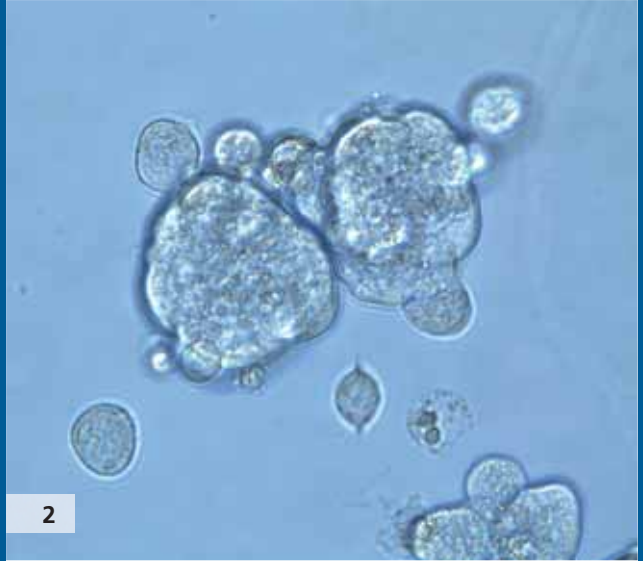

2

PROJECTS

In case of rheumatoid arthritis

Rheumatoid arthritis (RA) is the inflammatory joint disease with the highest incidence in western populations and is very painful for the patient. Primary therapy for RA currently consists of the treatment of inflammatory symptoms (e. g. using so-called TNF blockers). However, the pattern of the disease indicates autoimmunological causes, wherein inherent substances such as articular cartilage and cells of the immune system are attacked. It has not yet been clarified how this destruction of cartilage which define rheumatic diseases, can be stopped or even reversed; such a therapy would constitute a complete cure of RA. In addition to already existing animal models and respective investigative research, the Fraunhofer IZI can also offer *in vitro* models, wherein anti-destructive mechanisms of action and grades of activity of RA medications are observed in a test tube in direct interaction with human cells. In the medium term, this targeted screening of active agents promises the identification of optimized therapeutics.

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***In vitro* testing of cytostatics in tumor stem cells**

Tumor stem cells (TSCs) have been indicated to play an important role in the evolution of different types of cancer. They have the typical properties that are characteristic for stem cells, such as the potential for self-renewal and differentiation. It is currently assumed that this cell type is resistant to various forms of therapy which leads to both relapses and metastasis. A test platform was developed at the Fraunhofer IZI that allows for a rapid and application-oriented investigation of multiple candidate agents for intervening against tumor stem cell entities. Specific tumor stem cells are subjected to tests with respect to their sensitivity to novel candidate agents (e. g. cytostatics). In detail, this is about dosage-dependent kinetics in connection with specific irradiation regimes. In the first instance, this test platform provides growth curves of tumor stem cells upon drug exposure that could be complemented by a follow-up *in vivo* approach subsequently to tumorigenesis in a murine model.

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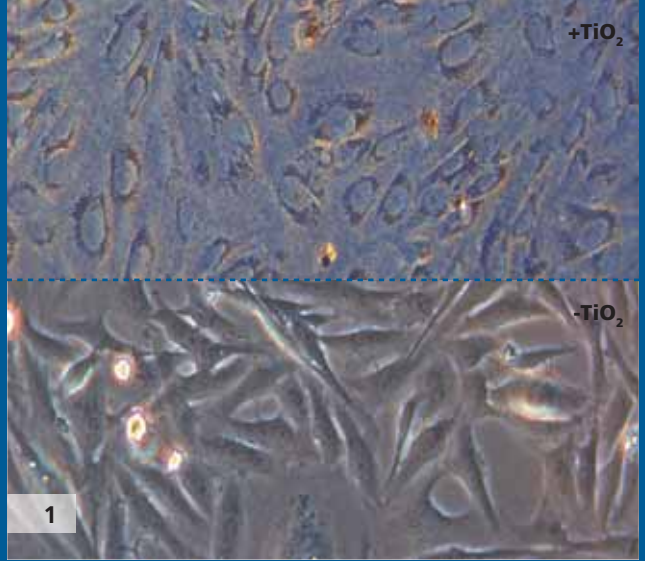
1 *Dense cellular infiltration of inflamed joints in collagen-induced arthritis in mice.*

2 *Spheroid formation of TSCs in mammary carcinoma.*



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Nanotoxicology

In order to estimate the potential risks of industrial nanomaterials a test system based on cell cultures has been established. It is the objective of this project to identify different cell biological parameters that specifically occur in the presence of nanomaterials.

On the basis of these defined parameters and by means of genetic engineering techniques cell lines are generated that serve as a test system for estimating the risk potential of nanomaterials.

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RNA interference-based *in vitro* models for the screening of agents

RNA interference is understood as a naturally occurring process in eukaryotic cells that regulates the expression of individual genes through the involvement of short RNA molecules. Due to the targeted downregulation of gene expression this method is suitable for a functional investigation of genes. Moreover, RNA interference is also employed in clarifying the mechanisms of action of novel agents and in the screening of agents.

With the aid of RNA interference, the Fraunhofer IZI generates stable knockdown cell lines that are particularly suitable for the screening of substance libraries owned by pharmaceutical companies. This specific suppression of gene expression and protein activity modulates the pharmacological inhibition of a target protein and is therefore an effective tool for the identification and validation of novel agents. Furthermore, the system serves for optimizing substances that are already known.

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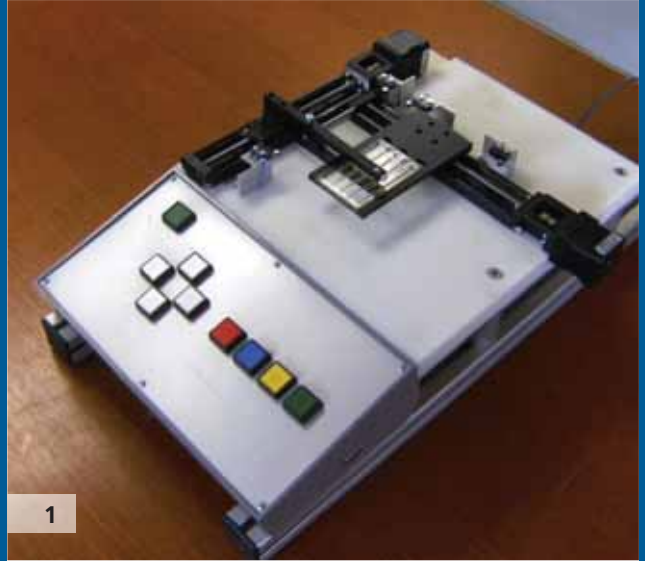
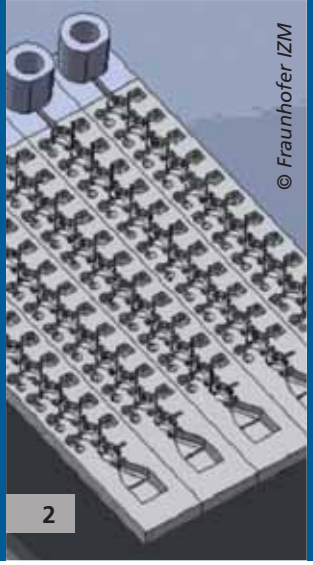
1 Attachment of titanium dioxide (TiO_2) particles to human bronchial epithelial cells BEAS-2B.





Rapid on-site diagnosis of infectious diseases based on a lab-on-a-chip system

Background

A reliable diagnosis of complex and life-threatening infectious diseases is currently only possible using elaborate and time-consuming methods involving an analysis laboratory and qualified specialists. In cooperation with the Leipzig company Magna Diagnostics GmbH, the Department of Diagnostics and New Technologies is developing an innovative system for rapid, easy-to-conduct and inexpensive on-site infection diagnostics.

Approach to solution

The system to be developed is based on magnetic particles that are only a few nanometers in size and can be functionalized according to application area as carriers for antibodies and disease-associated DNA sequences. These so-called magnetic beads are stored on a single-use cartridge in check card format. In the on-site examination a sample, e. g. blood, saliva or urine, is taken from the patient and is then applied onto this "check card". Upon lysis of the target cells, the magnetic beads bind to the respective target molecules contained in the sample and are transported in a fully automated manner through the individual reaction tubes via magnetic forces generated in a miniature device. At the end of the process chain, detection is conducted by means of highly sensitive magnetic sensor technology – the signals are digitalized and a fully electric read-out is performed.

Potential applications

Sepsis, i. e. blood poisoning, is one example for application. About half of the approximately 240,000 annual cases of sepsis in Germany must be treated in intensive care and still 43 percent of those cases treated result in the patient's death. Treatment is difficult due to the fact that sepsis can be caused by dozens of different pathogens. Moreover, individual classes of these pathogens have already developed a resistance to certain active agents. The time between blood sample collection and obtaining a diagnostic result still amounts to at least eight hours. By integrating the process steps from sample preparation to detection on the innovative diagnostic platform it is possible to detect pathogens and resistances in less than one hour. In addition to medical applications such as proteomic, genomic and microbiological tests, the future areas of application also comprise environmental analyses or civil protection measures.

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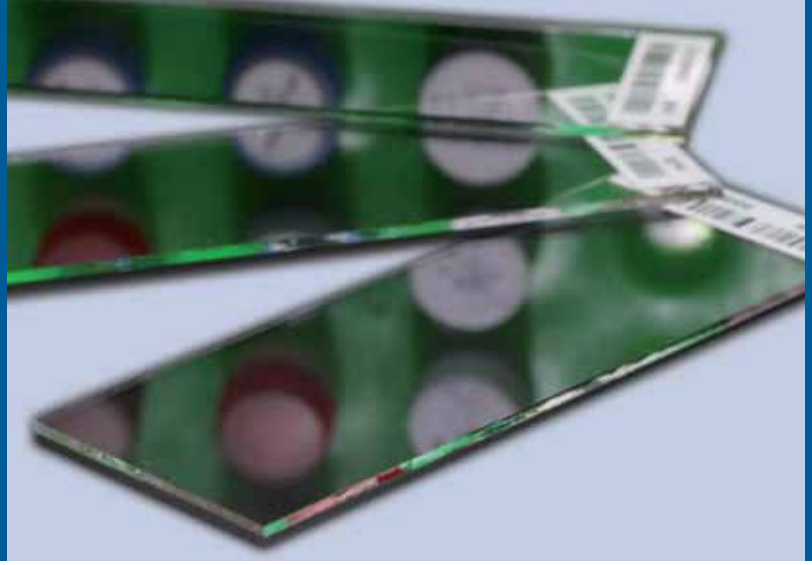
1 *First laboratory prototype of the diagnostic device with inserted micro fluidic card.*

2 *Micro fluidic card as CAD (Computer Aided Design) model.*

3 *Magnetic bead control by the micro fluidic card after manufacture in the Rapid Prototyping Method.*



Non-protein-coding RNA (ncRNA) biomarkers and therapeutic targets

Background

Early detection of oncologic and chronic inflammatory diseases and personalized therapy promise both increased therapeutic success and reduction of costs. Identification and validation of biomarkers play important parts in this strategy. To date primarily proteins and protein-coding RNAs have been utilized as biomarkers. The innovative approach of the RNomics Unit is to also include non-coding RNA (ncRNA) in the investigations. A large proportion of the human genome is translated into RNA while only a small proportion actually codes for proteins. In most cases, these non-coding RNAs play a regulatory role. Several ncRNAs could be proven to have a causal function in pathogenesis, which renders them attractive candidates for the identification of biomarkers and therapeutic target molecules. However, most of the ncRNAs have not yet been characterized.

Objective

The objective is to develop effective and efficient methods for the characterization and quantification of ncRNA for biomedical purposes. Within the framework of the ENCODE project and involvement of the RNomics Unit, new transcripts could be identified from tiling array and ultra-high-throughput sequencing data (ENCODE Project Consortium, Nature 2007). As these methods are very material- and time-consuming, the development of economic methods is another objective. For the establishment of ncRNA as therapeutic target molecules, model systems of prostate carcinoma and mammary carcinoma were developed. The goal was to identify ncRNAs that are formed in different amounts in healthy and tumorous tissues, respectively, and influence growth or programmed cell death (apoptosis) of the tumor cells.

Potential applications

With the nONCOchip a tool has been developed that allows for effective and efficient identification of ncRNA biomarkers for oncological diseases. The analysis of cell culture models of prostate carcinoma by means of tiling array studies was utilized to further develop the nONCOchip into a microarray that is specific for prostate carcinoma – the prONCOchip. In cell culture models and clinical samples of prostate carcinoma several ncRNAs could be identified that are lost in the tumor. Hereby it was possible to identify genes that are regulated by the identified ncRNAs. It has been shown in the cell culture model that a reinsertion of the lost ncRNAs into the tumor cells inhibits their growth and proliferation and also leads to programmed cell death (apoptosis). Studies of the application of these ncRNAs as therapeutic agents in a murine prostate carcinoma model are imminent. The RNomics Unit follows a platform concept for both the development of biomarkers and the identification of therapeutic targets on the basis of ncRNAs. Aside from the exemplarily pursued issue of finding, e. g., therapeutic targets for prostate carcinoma, the development of methods and strategies for general applicability is given priority. Important proofs-of-concept were achieved for those strategies in 2009, so that a transfer to other issues will be possible for our partners or clients.

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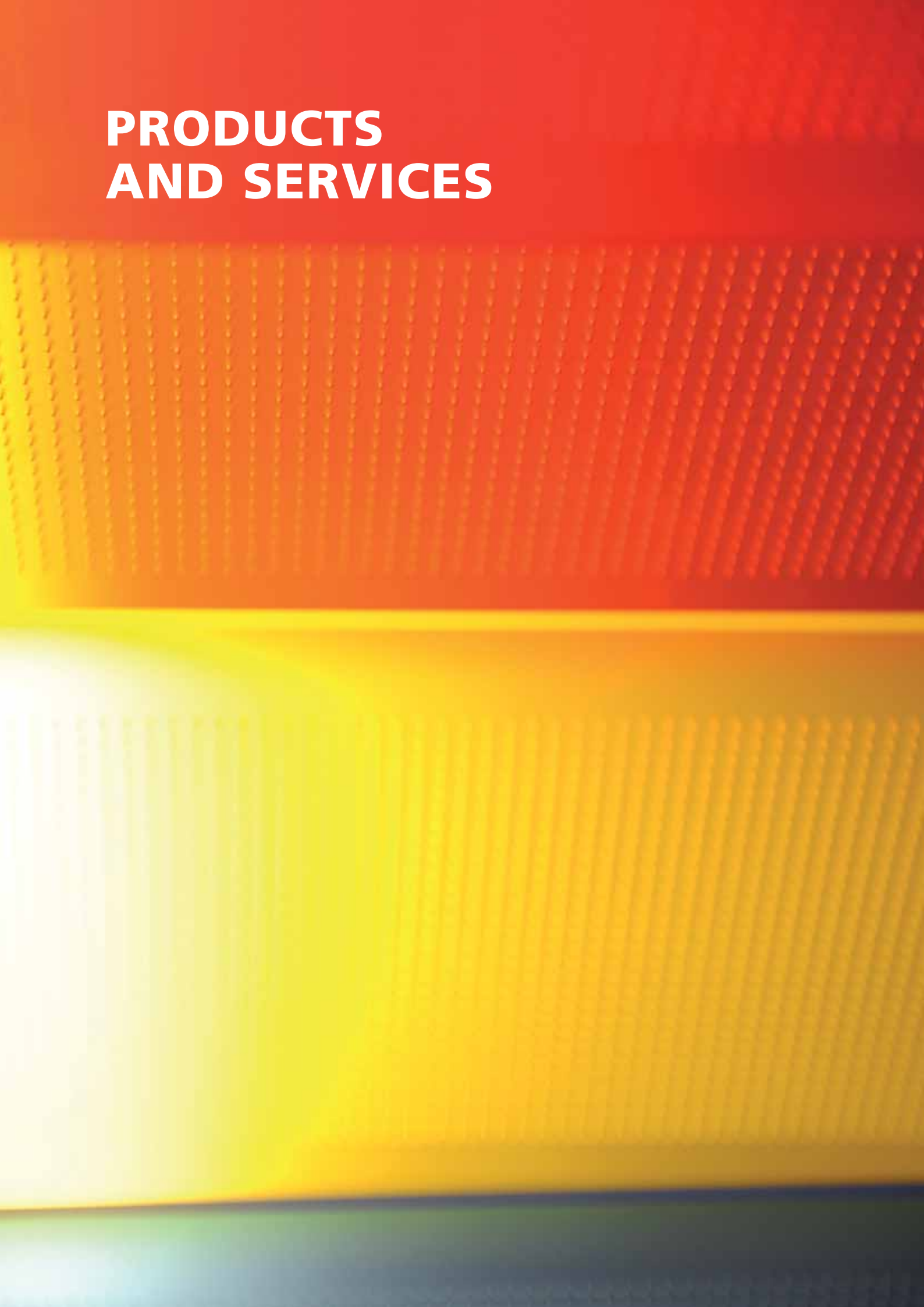
1 *The nONCOchip – an efficient and effective development of ncRNA biomarkers for the field of oncology.*

PRODUCTS AND SERVICES



NAVIGATION AID

The Fraunhofer IZI has an interdisciplinary structure and develops projects at different stages between research, industry and clinical practice. It is therefore important for us to communicate the services offered by our institute adequately to each of our target groups.

The following pages will give you a first impression of our services. In our service portfolio you can find the competencies of the departments in keywords as well as a general overview. For project examples please see pages 18 to 53, where our individual departments and units are introduced.

In addition, we would like to point out our institute's catalog of services which can be retrieved online via our homepage or ordered electronically.

www.izi.fraunhofer.de/izi_leistungsangebot.html?&L=1

In our catalog of services you find our service offers sorted according to target groups and different initial situations (e. g. indications or technologies). In addition to individual offers our institute also provides complete supply chains for different areas of service, such as antibody production or assay development..

Our Project Service Team offers comprehensive information on all our competencies and services, and their services are available to potential partners and clients. By identifying the adequate scientific contact person at our institute the Project Service Team assists our clients and partners in the preparation of business plans, funding application forms and project strategies. Furthermore, the heads of our departments and units are available to advise clients and partners in scientific and technical issues or to find the customized solution to their problem.

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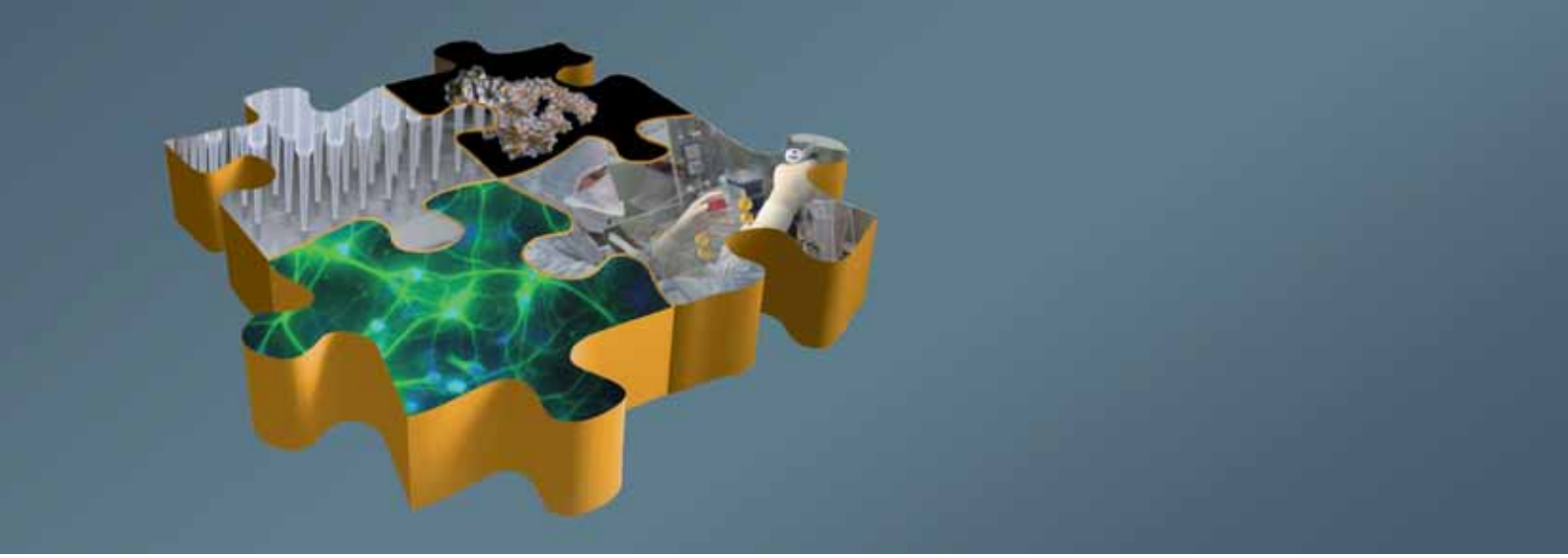

PRODUCTS AND SERVICES

Department of Cell Engineering

- Animal model (mice) for borreliosis (Borrelia burgdorferi)/ for diagnosis and therapy
- Animal model (mice) for chronic inflamed intestinal diseases/for therapy
- Animal model (mice) for salmonellosis (Salmonella enterica)/for diagnosis and therapy
- Conjugation and development of antibodies
- Custom made development and validation of immunological *in vitro* test systems
- GLP validation for differentiated proteomic analyses
- GMP conform production of cell- and tissue products
- Immunotoxic GLP validation *in vitro*
- Monoclonal antibodies – development
- Polyclonal antibodies – development
- Validation and beta evaluation of cell technological methods and equipment

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Department of Immunology

- Antigen specific tolerance induction
- Cell transduction for integrating genes in different kind of cells
- Conditioned humanized/non-humanized mice
- Defensins and anti microbial peptides
- Development of antiviral strategies
- Development of DNA vaccines for human medicine
- Development of DNA vaccines for veterinary medicine
- GvHD-mice (allogen induced)
- High complexity cDNA library
- Humanized, tripple transgenic mice
- Screening for antiviral active compounds
- Screening for the indentification of new cellular approaches (for diffenrent pathogenes)
- Testing biocompatibility in stem cell differentiation
- Therapy model for arteriosclerosis/plaque building
- Therapy model (mice) – testing pharmaceutical agents on the human immune system

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Department of Cell Therapy

- Animal model mice for solid and disseminated tumors (luciferase transgene)
- Cell culture models
- Clean room cell sorting (multi-parametric 11 dyes)
- Cryoconservation of cells
- Cytokine induced killer cells (CIK Cells) – production and clinical validation
- Experimental imaging
- *Ex vivo* expanded dendritic cells – production and clinical validation
- Histological analyses for mammal brain
- Imaging of biocompatibility *in vivo* (small animal) and material testing
- *In vivo* bioluminescent/fluorescent imaging in small animals
- Large animal model (sheep) for cerebral ischemia (stroke)
- Luciferase-transgenic mice
- Model systems myocardial ischemia – rat/mice
- Reproductive toxicology of additives and biomaterials
- Reprogramming of cells – iPS (induced pluripotent stem cells)
- SNP analyses of the human genome
- Stem cell analyses and stem cell manipulation
- (Stem cell) cytotoxicity of additives and biomaterial
- Stem cell medias
- Therapy model for tissue regeneration after fracture
- Therapy model (rat) for cerebral ischemia (stroke)
- Three dimensional stem cell cultures (bone/cartilage pressure training)

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Department of Diagnostics and New Technologies

- Arthritis model in mice
- Cartilage destruction model in mice
- Cellular functional testing for tissue destructive fibroblasts
- Microarray analytics
- MicroRNA analytics (expression, localization, targets)
- Non-coding RNA biomarker
- Non-coding RNA biomarker for oncology, nONCOchip
- Non-coding RNA – therapy targets
- Testing of cytostatics and cell therapeutics *in vivo* after TSC driven tumor induction in mice model
- Testing of cytostatics *in vitro* on tumor stem cells of different solid malignomas
- Transcriptomic analyses by tilling arrays and ultra high throughput sequencing
- Tumor stem cells (TSC) for therapy projects (production of TSC specific CD8+ CTL)

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EQUIPMENT

With a communicative infrastructure, state-of-the-art laboratory clusters and an extensive equipment pool at hand, the Fraunhofer IZI can offer a broad range of research activities and services.

Laboratories

Currently, the institute occupies a 2,300 m² laboratory area and a 1,400 m² office area. In 2012, the building extension will add another 1,200 m² for laboratories and the animal experimental area and an extra 140 m² office area.

The institute's modern laboratories are divided into seven clusters, each having standard equipment with different priorities. Besides cell biologically, molecular biologically and biochemically oriented laboratory units, the institute has an extensive immunohistochemistry laboratory, an isotope laboratory and a quality control laboratory with qualified analysis equipment. All laboratories at the Fraunhofer IZI are certified according to S2 standards and are therefore suited for work in the fields of genetic engineering and infection biology.

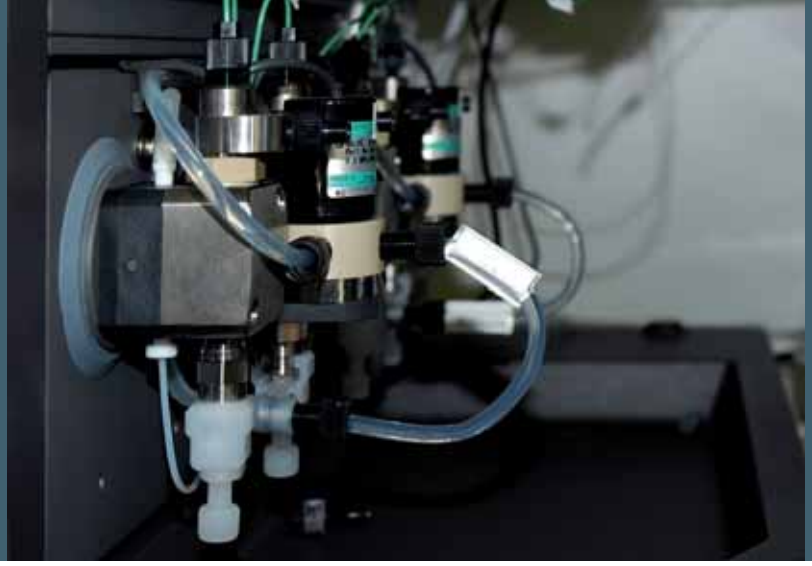
Clean room facility (GMP)

In the neighboring BIO CITY the Fraunhofer IZI maintains a GMP facility of 450 m² for the manufacture of biopharmaceutical products for early clinical studies. The GMP area is divided into different suites, where work under cleanliness class A can be performed in clean rooms. The suites are fitted with different types of equipment in order to meet different performance requirements. With the first building expansion the GMP facility will be extended by another 450 m².

Animal experimental area

Animal experiments are currently conducted in cooperation with the Faculty of Veterinary Medicine, the Medical Faculty and the Max Planck Institute for Evolutionary Anthropology. Further projects are conducted in cooperation with the Faculty of Biosciences, Pharmacy and Psychology in the animal experimental area.

From 2012 on, the Fraunhofer IZI will have its own animal experimental area in the extension building. In addition to various small animal models, the establishment and investigation of large animal models will also be possible there. An extensive equipment pool for various imaging methods completes this research unit.



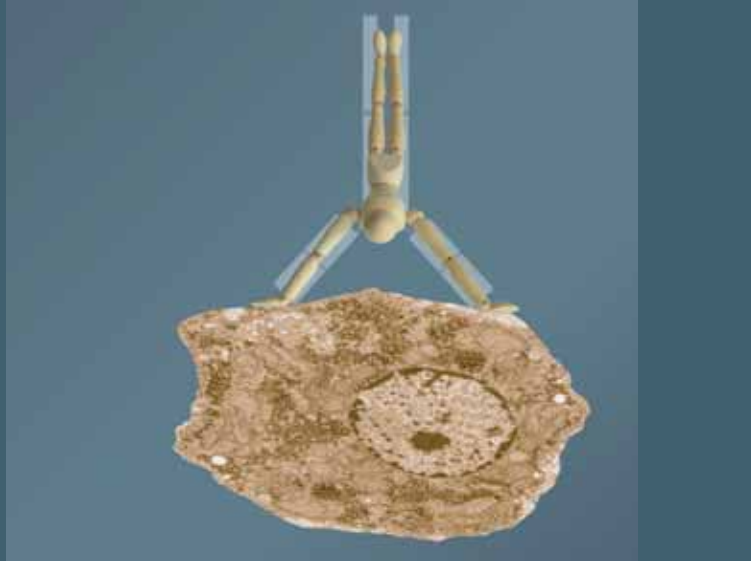
Excerpt of the equipment pool at the Fraunhofer IZI

Cell biological
- Bioreactors (partly automated, 8fold)
- Flow cytometry
- Cell sorting (e. g. FACS, high-speed)

Molecular biological
- Affinity measuring (Biacore)
- Expression analysis system
- High Pressure Liquid Chromatography (HPLC)
- Mass spectronomy
- Microarray scanner and hybridization stations
- PCR and electrophoresis park (e. g. real-time PCR)
- Proteom analytics
- Reporter gene measuring (Luminometer)

Imaging
- Bioluminescence imaging
- Fluorescence-/confocal microscopy
- Immunohistochemistry/histology

Others
- Bioinformatics
- BioTechFlow-System (simulation of vascular flow)
- DQ/IQ/OQ-qualified equipment for the production of cell therapeutics, therapeutical antibodies and for quality control
- Elektrospinning
- *in vivo* electroporation
- Cryopreservation technology
- Micro surgical instruments



TECHNOLOGY PLATFORMS

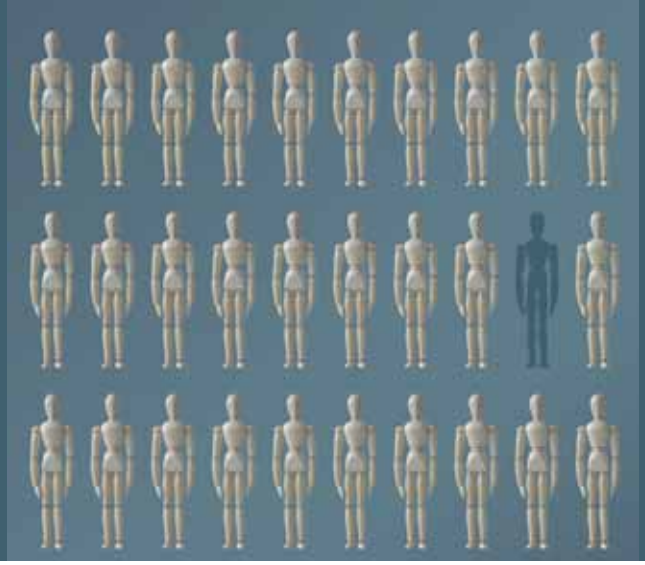
Antibodies
Antibodies identify antigens through a highly specific binding. This makes them interesting tools in biology, medical research and in both treatment and diagnostics.

The Fraunhofer IZI develops and produces antibodies for therapeutic and diagnostic use. Therapeutic antibodies have mainly been used for treatment of different kind of tumors and lymphomas, in treatment of rheumatoid arthritis, Crohn's disease, asthma and in prevention of rejection after organ transplantation.

Antibodies are an essential research tool used in test kits for the detection of soluble or cell-linked marker molecules. They can be modified to change their compatibility or biological characteristics.

For *in vivo* diagnostics as well as functional extension of therapeutic antibodies different linking methods can be used to link signal and effector molecules.

Research
Qualified research and market analysis of a specific field of application. Identification of competitor products, estimation of the size of a market, detection of market niches and the offering of targeted solutions.
Production
Production of polyclonal and monoclonal antibodies. Optimization through molecular biological methods and/or labelling.
Development
Identification of target molecules. Development corresponding epitopes. Testing of effectiveness in laboratory scale.
Documentation
GLP conform documentation, Development of protocols and SOPs.
Process
Development of a GMP conform production process. Production of clinical test samples conform with §13 of the German Pharmaceutical Act (AMG). Establishment of master- and working cell banks.
Clinical Trial
Design and performance of clinical trials (phase II und III) are supported by the institute.



Assay adaption and optimizing

Biotechnological and biomedical research as well as preclinical and clinical trials require valid high throughput analysing methods for detection of biomarkers, active agents and genes.

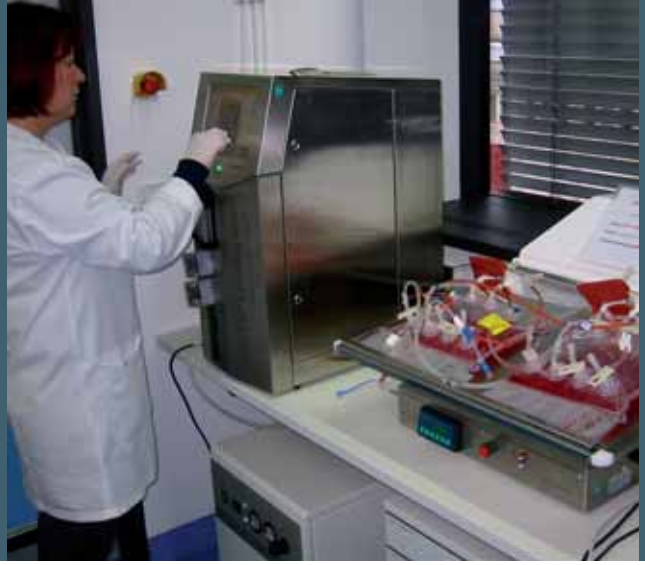
It is important to analyze samples of different origins as rapidly as possible with a high precision. Because customer demands varied widely, the development of a universal test is far away. The Fraunhofer IZI bundles competencies to offer a broad spectrum of analysis methods to its partners. Therefore existing technology platforms can be combined individually for the seperate requirements of each customer. New analysis methods are then developed for and together with the partner.

The modern, high level equipment and the broad competencies of the institute make it a strong partner in assay adaptation and development and screening,of pharmaceutical agents as well as in diagnostic and monitoring.

Therefore the complete value-added chain, from identification of target molecules to clinical validation of the assay, is represented by the institute.

A unique selling point is the special expertise of the Fraunhofer IZI in RNA technologies. Non-coding ncRNA has recently become more important as they can be used as significant biomarkers for either tumor detection or as a new therapeutic target.

Identification of target molecules
Identification of eligible target proteins or genes associated specifically with a disease.
Biomarker development
Design and synthesis of sensors with high affinity and specificity for a target.
Adaption analytical platforms
Adaptation of existing (proteomic or genomic) technology platforms for specific assay conditions.
Optimizing parameters
Optimization of the assay in regards to specific sensitivity, speed and costs.
Evaluation
Evaluation of the assay through patient samples in the laboratory according to the gold-standard.
Clinical Validation
Validation of the assay with patient samples in clinical environment.



QUALITY MANAGEMENT

GLP – "Good Laboratory Practice"

"Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."

This is the definition of Good Laboratory Practice in the GLP principles of the Organisation for Economic Co-operation and Development (OECD) that were devised following the EC-Directive, which were incorporated into German law and anchored in the chemical law ("Chemikaliengesetz").

Good Laboratory Practice, as almost no other quality system, has contributed to health, environmental and animal protection through its worldwide implementation and the consequent widely reciprocal recognition of study data.

Fraunhofer IZI possesses a separate GLP laboratory and trained personnel. These resources are fully equipped to provide integrated research and development solutions.

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GMP – "Good Manufacturing Practice"

Fraunhofer IZI operates a 450 m^2 GMP-compliant clean room facility. Through the flexible design, the facility is especially attractive for new biotechnology companies that seek to bring newly developed active ingredients and medicinal products into clinical application via clinical trials. The facility is divided into different independent suites. Each has its own grade C clean rooms (preparation), own air locks from grade C to B (personnel and materials transport) 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. Most of the available clean room suites are specialized for processes associated with manufacturing of human autologous or allogeneic cell-based therapeutics (e. g. tissue engineering products, stem cell preparations, cancer vaccines). One suite is designed for the manufacturing of therapeutic recombinant proteins and antibodies in small scale (for phase I to early phase II trials). In addition to the clean rooms and the technical and, respectively, regulatory infrastructure, the Fraunhofer IZI offers assistance for the set-up and validation of GMP-compliant manufacturing processes as well as for obtaining a manufacturing authorization according to §13 of the German Pharmaceutical Act (AMG).

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Why are GMP and GLP important?

The clinical trial of new drug candidates is an essential step on the way to approval. Since the 12th revision of the "Arzneimittelgesetz AMG" (German Drug Act) every clinical drug 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 Institute) and by the responsible ethics commission prior to the initiation of the clinical study. In order to obtain this authorization, the efficacy and safety of the investigational medicinal product must first be verified within the framework of GLP-compliant pre-clinical investigations (e. g. toxicological testing procedures). Furthermore, the quality of manufacture of the trial preparations must be verified by a GMP manufacturing authorization pursuant to §13 AMG, which ideally should already have been granted for the manufacture of preparations for selected pre-clinical investigations. 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.

GCP – "Good Clinical Practice"

GCP describes internationally accepted regulations which govern the execution of clinical trials. These regulations encompass ethical as well as scientific aspects. Clinical trials are divided into three phases.

- phase I: establishment of safety of the new medication/therapeutic
- phase II: establishment of the efficacy of the new medication/therapy (Phase IIa) and dose curve (Phase IIb)
- phase III: establishment of a significant proof of efficacy (also known as Pivotal-trial).

Only after successful completion of phase III can new substances register for marketing approval. All phases of clinical development must be carried out under the above described GCP-guidelines. The protection of the patient or volunteer must always remain in the foreground. Important aspects of this include the patient consent form, patient trial insurance as well as the exact documentation of the trial results. Additionally GCP regulates the roles of the essential entities involved in the trial including the sponsor, monitor, CRO, primary investigator and ethics committee or intuitional review board and also regulates quality management and adverse event reporting.

The Fraunhofer IZI carries out in cooperation with doctors and SMO's (site management organizations) clinical trials as requested by Sponsors. The focus here is primarily on trials with walk-in patients. The Fraunhofer IZI is a reliable partner in the area of clinical trial planning, composition of trial protocols and all other necessary documents required for submission to the regulatory authorities including the ethics committee. Private physicians and SMOs carry out on-site patient visits.

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CUSTOMER SERVICE

The Fraunhofer IZI has an administrative department that, aside from general press and public relations work, also conducts project acquisition and organizes advanced vocational training and events. This team provides a central interface for the institute and is in close contact with the relevant decision makers of the funding institutions. Our Project Service Team staff support the scientific units in the acquisition of projects and partners as well as in the preparation of applications for funding projects. The special focus is, however, on the establishment and cultivation of industry contacts.

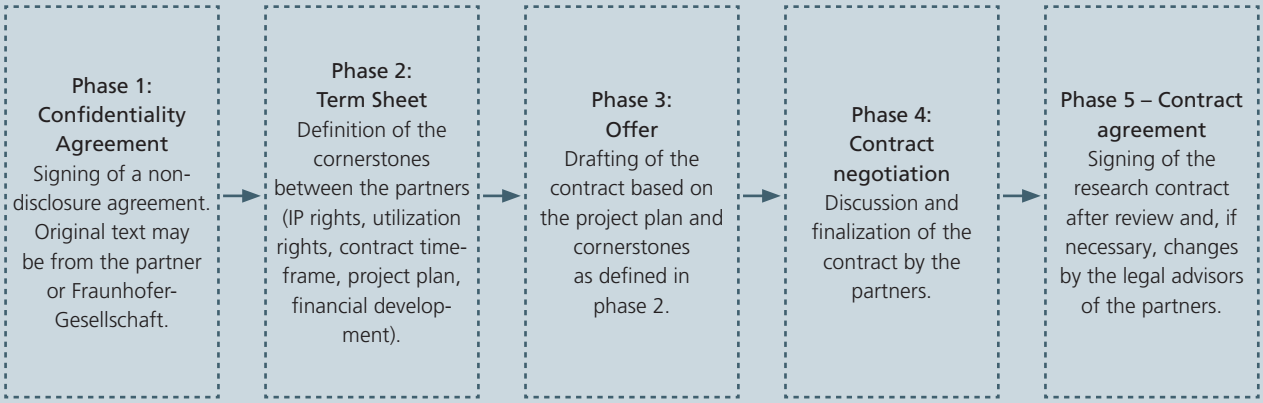
For potential clients and partners, our competent Project Service Team staff can provide an overview of all of the institute's competencies, technologies and service offers. Requests can therefore swiftly and purposefully be transferred to the relevant contact person at the institute. Moreover, the Project Service Team actively supports our partners and clients in the identification of and application for funds. Assisted by the Fraunhofer IZI, two spin-off projects of biotechnology companies could be realized and funded with support provided by the "Sächsische Aufbaubank" (Saxon Development Bank) in the reported year.

Another focus of the Project Service Team is the marketing of the institute's modern seminar rooms and the organization of internal and external advanced vocational training events. The team advises and assists partners in organizing and conducting annual conventions, contests, symposia and courses.

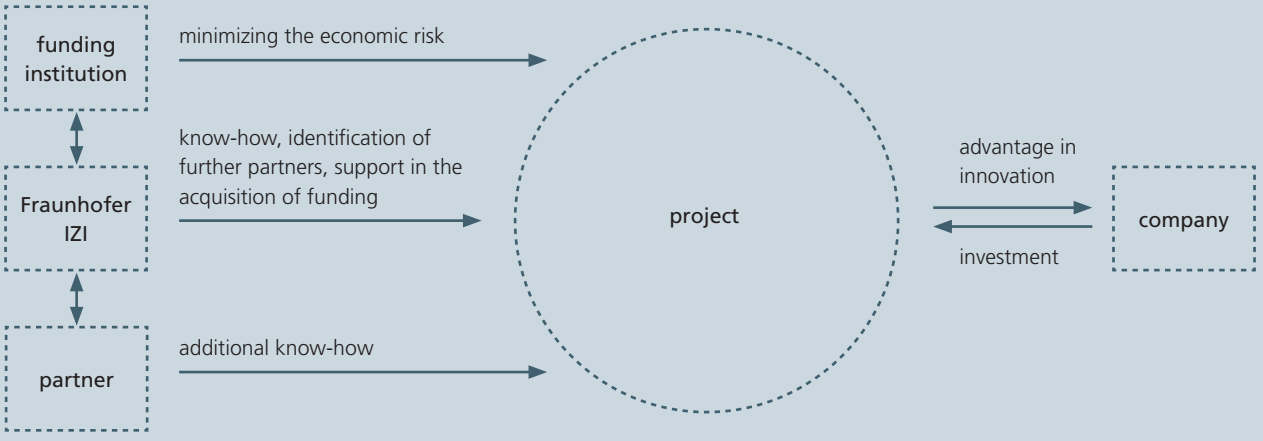
Service offers

- Project acquisition
- Planning and coordinating projects; controlling and marketing
- Support in the acquisition of third-party funding
- Public relations
- Business development
- Organizing and conducting scientific events
- Planning and conducting advanced vocational training measures

Phase model for signing research contracts



Project-related funding



As a special service for our business partners and clients we offer support in the acquisition of funding in order to launch innovative projects. Within the framework of cooperative or combined projects, innovative and high-risk projects can be funded and the amount to be invested can be raised. Beyond advice on funding options, our Service Project Team actively supports the preparation and submission of funding applications. Our close contact with the decision makers of local, regional and national funding institutions allows for an early identification of opportunities and risks during the application process and increases the probability of success.

ADVANCED VOCATIONAL TRAINING OFFERS

The Fraunhofer IZI puts strong emphasis on advanced vocational training and career developent of its employees. The Fraunhofer IZI has been maintaining a successful cooperation with the private academy WSR for quite some time. The space and modern ambience of the institute's new main building create ideal conditions for this very special symbiosis.

The combined services offered comprise the entire field of advanced corporate training with a focus on internal and external communication. The comprehensive advanced training offer is complemented by scientifically up-to-date seminars held by Fraunhofer researchers. Both the Fraunhofer IZI and WSR work with selected training staff who all have university degrees and several years of practical experience. The trainers are thus profoundly experienced and competent, particularly from educational and psychological points of view.

Each employee's commitment, motivation and self-dependent action are the most important factors for a company's success – and the team will be glad to assist in achieving these goals.

More detailed information on our seminars can be found in our Seminar Catalog at www.izi.fraunhofer.de/izi_seminare.html or via:

Our offers for advanced vocational training have been well received ever since they have become part of the Fraunhofer IZI's range of services. In particular, our offers in the context of project management, negotiation training, management training, presentation training and workshops for the successful acquisition of third-party funding and scientific writing enjoy great popularity. These offers have been appreciated by both our regional partners and scientific institutions throughout Germany.

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According to prior arrangement, the following seminars can of course also be offered as in-house seminars.

Instruments of scientific work

Good Clinical Practice (GCP)
Scientific writing

Management tasks in applied research and science

Successful acquisition of third-party funding
Marketing principles
Self- and time management
Project management (basics)
Project management (advanced)

For founders of scientific companies: Economic and legal principles

Business economic principles
Employment law
Corporate law
Contract law (basics)
Scientific patent law
Technology-oriented business start-up (basics)
Technology-oriented business start-up (advanced seminar)

Communication and leadership skills

Leadership seminar I
Leadership seminar II
Working in and with a team
Communication training
Negotiating successfully
Presentation training
Moderation training
Conflict training
Proper telephone etiquette
Sales training

LOCAL SITUATION

Location: Central for interface partners

The Fraunhofer Institute for Cell Therapy and Immunology IZI is located on the former trade fair grounds in the south-east of the city of Leipzig. The institute's premises are only about a ten minute drive away from the city center and can easily be reached with public transport. Moreover, many of our already established and potential future cooperation partners are located in the immediate vicinity. Among these are, for example, the BIO CITY Leipzig, the Max Planck Institute for Evolutionary Anthropology, the clinics and institutes of the Medical Faculty, the Chemistry Faculty, the Physics Faculty, the Veterinary Medicine Faculty, as well as the Faculty of Life Sciences, Pharmacy and Psychology.

BIO CITY Leipzig: a potent neighbor

The BIO CITY Leipzig unites university and industry-related research under one roof. It houses, for instance, the Biotechnological-Biomedical Center (BBZ) of the University of Leipzig and has available space for industrial settlements in the vicinity. More than 25 cell technology companies including VITA34, International AG, Haemabank AG and Curacyte AG are already located there. Cooperations with the Fraunhofer IZI have been established in the fields of cell engineering and applied stem cell biology, bioprocess engineering, protein structure analysis, mass spectroscopy, molecular cell therapy and molecular pathogenesis.

Integrated universities

The university landscape within Leipzig also benefits from cooperation with the Fraunhofer IZI: the University of Leipzig, the Leipzig University of Applied Science (HWTK) and the Graduate School of Management (HHL) have found in the Fraunhofer IZI a strong partner for research cooperations and the development of joint programs for teaching and advanced vocational training, which enhance local attractiveness from an economic and scientific point of view. Thus, for example, students of business administration from the HHL have already been successfully involved in practical scientific projects with their development of business plans or marketing concepts. A particularly intensive cooperation connects the Fraunhofer IZI and the Institute for Clinical Immunology and Transfusion Medicine (IKIT) of the University Leipzig.

Excellence partner: Translational Center for Regenerative Medicine

One of the most important partners of the Fraunhofer Institute for Cell Therapy and Immunology IZI is the Translational Center for Regenerative Medicine (TRM), which was founded within the framework of the Excellence Initiative 2006 by the German Federal Ministry of Education and Research and the Free State of Saxony. Under the auspices of the renowned immunologist Prof. Dr. Frank Emmrich, institutes from five faculties established the TRM in order to start conceptional, pre-clinical and clinical research projects focused on Tissue Engineering and Materials Sciences (TEMAT), Cell Therapies for Repair and Replacement (CELLT), Regulatory Molecules and Delivery Systems (REMOD), Imaging, Modeling, and Monitoring of Regeneration (IMONIT)

Established local partners: Almost a dozen

The neighboring partners of the University of Leipzig are, among others, the Interdisciplinary Center for Clinical Research (IZKF) and the University Hospital (special field of transplantation). Institutions relevant for cooperation are, among others, the Heart Center Leipzig GmbH, the Helmholtz Center for Environmental Research (UFZ), the Leibniz Institute for Surface Modification (IOM), the Interdisciplinary Center for Bioinformatics (IZBI), the Center for Clinical Trials Leipzig GmbH (ZKS) and the Center for Therapeutic Studies (ZET).

BIO CITY (I) with hired Fraunhofer IZI area (Ia), Faculty of Veterinary Medicine, institutes and hospitals (II), Max Planck Institute for Evolutionary Anthropology (III), German National Library (IV), Translational Centre for Regenerative Medicine (V), Fraunhofer IZI (VI), extension Fraunhofer IZI (VII).

Translational Centre for Regenerative Medicine (TRM)
Philipp-Rosenthal-Str. 55
04103 Leipzig
www.trm.uni-leipzig.de

Interdisciplinary Centre for Clinical Research (IZKF)
Liebigstr. 21
04103 Leipzig
www.izkf-leipzig.de

Center for Biotechnology and Biomedicine (BBZ)
University of Leipzig
Center for Biotechnology and Biomedicine
Deutscher Platz 5
04103 Leipzig
www.bbz.uni-leipzig.de

University Hospital Leipzig AöR
Liebigstr. 18
04103 Leipzig
www.uniklinik-leipzig.de

Heart Center Leipzig GmbH – University Hospital –
Strümpellstr. 39
04289 Leipzig
www.herzzentrum-leipzig.de

Coordination Center for Clinical Trials Leipzig (ZKS)
University of Leipzig
Härtelstr. 16-18
04107 Leipzig
www.kks.uni-leipzig.de


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LOCAL SITUATION

Interdisciplinary Center for Bioinformatics (IZBI)
University of Leipzig
Härtelstr. 16 - 18
04107 Leipzig
www.izbi.uni-leipzig.de

Max Planck Institutes (MPI)
Max Planck Institute for Human Congnitive and Brain Sciences
Post office box 500355
04303 Leipzig
www.cbs.mpg.de

Max Planck Institute for Mathematics in the Sciences
Inselstr. 22
04103 Leipzig
www.mis.mpg.de

Max Planck Institute for Evolutionary Anthropology
Deutscher Platz 6
04103 Leipzig
www.eva.mpg.de

Helmholtz Center for Environmental Research GmbH – UFZ
Permoserstr. 15
04318 Leipzig
www.ufz.de

Leibniz Institute for Surface Modification e.V.
Permoserstr. 15
04303 Leipzig
www.iom-leipzig.de

Association for the Advancement of the Health Economics of the Region Leipzig (VGF) e.V.
Deutscher Platz 5a
04103 Leipzig
www.med-in-leipzig.de

University of Leipzig
Ritterstr. 26
04109 Leipzig
www.uni-leipzig.de

Faculty of Medicine
Liebigstr. 27
04103 Leipzig
www.medizin.uni-leipzig.de

Faculty of Biosciences, Pharmacy and Psychology
Brüderstr. 32
04103 Leipzig
www.uni-leipzig.de/~biowiss

Leipzig University of Applied Sciences (HTWK)
Karl-Liebknecht-Str. 132
04277 Leipzig
www.htwk-leipzig.de

Graduate School of Management (HHL)
Jahnallee 59
04109 Leipzig
www.hhl.de

EVENTS

FRAUNHOFER LIFE SCIENCE SYMPOSIUM LEIPZIG

"Rapid Prototyping and Scaffolds – New Techniques for Tissue Engineering"

In 2009, the 4th Fraunhofer Life Science Symposium Leipzig was again organized on a large scale. Parallel to the World Conference on Regenerative Medicine in the Congress Center Leipzig, scientists and engineers applied themselves to the still minor but growing topic of "Rapid Prototyping and Scaffolds – New Techniques for Tissue Engineering".

Thus, the Fraunhofer IZI as organizer of the event has once more brought a specific topic from the field of regenerative medicine into focus. Rapid prototyping is a broad field of engineering sciences and only a small branch is occupied with technologies for regenerative medicine. Because of the disciplinary gap between medical sciences and engineering, the Fraunhofer IZI was supported in organizing the symposium by experts in the field of rapid prototyping. In cooperation with the Fraunhofer Additive Manufacturing Alliance and the Central Germany Rapid Prototyping Network ENFICOS a pooling of experienced material scientists, engineers and clinicians could successfully be achieved.

The symbiosis of research fields holds a great promise of possibilities for all partners. Parallel to the development of tissue engineering methods for the regeneration of tissues and organs, the need for scaffolds and adequate biocompatible materials is growing. In four conference sessions and a total of 16 presentations the 4th Fraunhofer Life Science Symposium not only presented techniques and materials but also current and future clinical applications of rapid prototyping.

This year's symposium will surely encourage cooperations and promote this new special field in order for this emerging scientific discipline to grow and to bear fruit some day.

1

THE FRAUNHOFER IZI AS HOST

7th Meeting of former chairpersons and heads of institute of the Fraunhofer-Gesellschaft (EVI)

In July, the Fraunhofer IZI was host to the former chairpersons and heads of institute of the Fraunhofer-Gesellschaft on the occasion of their 7th annual meeting. In addition, the extensive program lead the 40 participants from the Fraunhofer MOEZ in Leipzig, to the Fraunhofer IWM in Halle and then on to the pilot plant center of the Fraunhofer IAP in Schkopau.

At the Fraunhofer IZI, head of institute Prof. Dr. Frank Emmrich welcomed the "EVI" participants and Prof. Dr. Marion Schick, board member of the Fraunhofer-Gesellschaft, reported on recent developments at Fraunhofer. The visitors were then shown around the laboratories of the modern Fraunhofer IZI, which was very well received.

As the "EVI" meeting is more than just a business appointment, an appropriate cultural entertainment program was also provided. On a walking and driving tour around Leipzig the guests had the opportunity to discover the city together with former colleagues. The Stasi Museum and Auerbach's Cellar were further visit highlights and made the stay of the EVI participants in Leipzig complete.

Presentation of funding programs: Annual conference of the European Social Fund (ESF) and the European Fund for Regional Development (EFRE) at the Fraunhofer IZI

On September 13th, 2009, the Saxon State Ministry of Economy and Labor (SMWA) organized the annual conference of the ESF/EFRE in the premises of the Fraunhofer IZI and the BIO CITY. Sven Morlok (Saxon State Minister of Economic Affairs, Labor and Transport), Dirk Ahner (Director-General for Regional Politics of the European Commission) and Leina Samuel (Deputy Director-General of Employment, Social Affairs and Equal Opportunities of the European Commission) opened the event in the light-flooded atrium of the Fraunhofer IZI. Subsequently, various speakers illuminated the funding programs available in Saxony: reports were given on the effort of the EFRE in project funding for research and development (R&D) as well as on postgraduate perspectives such as funding of business foundations by the futureSax initiative. Further points for discussion were the development of the regional university and research infrastructure as well as the availability of specialists in Saxony. In the afternoon, the guests were given the opportunity to visit the laboratories of the Fraunhofer IZI and companies in the BIO CITY.

2

Annual convention of the Fraunhofer Group for Life Sciences (VLS)

On September 23rd, 2009, the 25th convention of the Fraunhofer Group for Life Sciences was held at the Fraunhofer IZI. The executive heads of institute, the head of the central office of the Fraunhofer VLS and the representative of the central administration congregated in order to discuss the Group's marketing strategy for the coming year 2010.

In addition to the discussion of suitable marketing instruments and media, the global media presence of the Fraunhofer VLS was also reviewed. In 2010, the Alliance will present itself and its institutes at the BIOTECHNICA (Hanover), the BIO USA (Chicago), the BIO Japan (Yokohama) and the AusBiotech (Melbourne). Further focal points of the convention were the venture capital strategy and the potential participation in structuring the 8th Framework Program for Research and Development of the European Union.

Dr. Claus-Dieter Kroggel, head of the central office of the Fraunhofer VLS, expressed his satisfaction with the highly constructive and positive convention. The ceremonial laying of the foundation stone of the first extension building at the Fraunhofer IZI brought the long convention day to an end for the participants.

1 *Sven Morlok, Saxon Minister of Economic Affairs.*

2 *Former Chairpersons and Heads of Institute of the Fraunhofer-Gesellschaft.*

Announcement of events at the Fraunhofer IZI in 2010

5th Anniversary of the Fraunhofer IZI/
Joint Science Day
April 28th - 29th, 2010

General Meeting of BIOSAXONY (registered association)
June 10th, 2010

Awards Ceremony – "Germany, Land of Ideas",
365 Locations, for the project: BIO CITY CAMPUS
August 5th, 2010

40th Annual convention of the German Society of Immunology (University of Leipzig/Campus Augustusplatz)
September 22nd - 25th, 2010

Researchers' Night
September 24th, 2010

Awards Ceremony – "Germany, Land of Ideas",
365 Locations, for the project: Magna Diagnostic
October 29th, 2010

Fraunhofer Life Science Symposium Leipzig
"Immunotherapy: The Cutting Edge of Stem Cell Applications"
October 29th - 30th, 2010

Visitors are always welcome.

Detailed information and further links can be found on www.izi.fraunhofer.de

SCIENTIFIC PRESENCE

CONVENTIONS AND CONFERENCES

17th Annual Meeting of the German Society for Pediatric Infectiology (DGPI) in cooperation with the Society for Child- and Youth Rheumatology (GKJR) (V)
April 2nd - 4th, 2009, Bremen, Germany

19th Annual Meeting of the German Society for Cytometry DGFZ (P/V)
October, 14th - 16th, 2009, Leipzig, Germany

19th Annual Meeting of the Society for Virology (P)
March 18th - 21st, 2009, Leipzig, Germany

2nd Science4Life Fair (S)
October 22nd, 2009, Frankfurt, Germany

2009 Keystone Symposia MicroRNA and Cancer (P)
June 10th - 15th, 2009, Keystone, CO, USA

4th X-ray Evening Leipzig (V)
December 9th, 2009, Leipzig, Germany

4th ESN Conference on Advances in Molecular Mechanisms of Neurological Disorders (P)
July 11th - 14th, 2009, Leipzig, Germany

52nd Annual Meeting of the Pathology Professional Group (V)
March 7th - 8th, 2009, Fulda, Germany

5th Annual International Imaging Genetics Conference (P)
January 19th - 20th, 2009, Irvine, USA

7th Workshop Sensors & MediTex (V)
October 28th, 2009, Greiz, Germany

8th Interdisciplinary Allergy Dicussion Leipzig (V)
May 27th, 2009, Leipzig, Germany

8th Saxonian Biotechnology Day (P)
May 26th, 2009, Leipzig, Germany

88th Annual Meeting of the Germany Physiological Society DPG (V)
March 23rd, 2009, Gießen, Germany

8th Researchfestival (P)
December 18th, 2009, Leipzig, Germany

American Anthropological Association Meeting (V)
June 2009, Phoenix, USA

Annual Congress of the Germany Society for Transfusion Medicine and Immunohematology (P)
September 15th - 18th, 2009, Rostock, Germany

Annual Meeting of the Germany Society for Hematology and Oncology DGHO (V/P)
October 2nd - 6th, 2009, Heidelberg, Germany

Annual Meeting of the Society for Neuroscience (P)
October 17th - 21st, 2009, Chicago, USA

Autumn Panel of the Germany Society of Regenerative Medicine e.V. (V)
November 13th, 2009, Berlin, Germany

Autumn Seminar Bioinformatics 2009 (V)
October 21st - 25th, 2009, Vysoka Lipa, Czech Republic

BIO International Convention (S)
May 18th - 21st, 2009, Atlanta, USA

Biotech meets Public (V)
May 6th, 2009, Leipzig, Germany

BioVaria (V)
May 8th, 2009, Munich, Germany

BIT's World Congress of Gene (WCG) (V)
December 1st - 7th, 2009, Foshan, China

BMBF Challenges BioFuture, GO-Bio/Funding Institution Jülich (P)
January 26th, 2009, Berlin, Germany

Computational Methods for RNA Analysis (V)
July 26th - August 8th, 2009, Benasque, Spain

Cooperation Forum Drug Development, Bavaria Innovative (P)
December 3rd, 2009, Würzburg, Germany

Course of Immunology (V)
November 12th, 2009, Leipzig, Germany

European Congress of Immunology (ECI) (P)
September 13th - 16th, 2009, Berlin, Germany

Functional Plant Ingredients – Food, Pharma, Cosmetics, Bavaria Innovative (P)
October 1st, 2009, Wolnzach, Germany

German Conference on Bioinformatics 2009 (P)
September 28th - 30th, 2009, Halle/Saale, Germany

German-Singapore Stem Cell Symposium (V)
April 2009, Singapur

Human Pluripotent Stem Cells Symposium (P)
April 22nd - 24th, 2009, Dublin, Ireland

Innovation Days of the Federal Agency for Agriculture and Food (BLE) (V)
November 25th - 26th, 2009, Bonn, Germany

ISSCR 7th Annual Meeting (P)
July 8th - 11th, 2007, Barcelona, Spain

Learning and Adjustment Disorders – with Special Reference to Disaster Affected Regions (V)
November 20th - 21st, 2009, Leipzig, Germany

Medical Physics and Biomedical Engineering World Congress 2009 (C)
September 7th - 12th, 2009, Munich, Germany

National Symposium for Zoonosis Research (V)
October 7th - 8th, 2009, Berlin, Germany

Neuroscience 2009 (P)
October 17th - 21st, 2009, Chicago, Il, USA

North German Gastroenterologist Congress (V)
January 2009, Hanover, Germany

Regulatory RNA in Prokarytes
June 3rd - 6th, 2009, Berlin, Germany

RNA 2009 (P)
May 26th - 30th, 2009, Madison, WI, USA

Scientific Seminar Texas A&M (V)
October 20th, 2009, College Station, Texas, USA

Scientific Seminar, Cleveland Clinic (V)
October 22nd, 2009, Cleveland, OH, USA

Scientific Seminar, Harvard Medical School (V)
October 23rd, 2009, Boston, MA, USA

Scientific Seminar, Medical School of University of Texas (V)
October 29th, 2009, Houston, Texas, USA

Seminar Series Newcastle University (V)
February 2009, Newcastle, UK

SENS III (V)
September 6th - 10th, 2009, Cambridge, UK

SMI Workshop (V)
February 2009, London, UK

TRM-Retreat (P)
October 19th - 20th, 2009, Wittenberg, Germany

UC System-Wide Technology Transfer Forum on Stem Cell Research and Regenerative Medicine (V)
April 15th, 2009, San Francisco, CA, USA

World Conference on Regenerative Medicine (P)
October 29th - 31st, 2009, Leipzig, Germany

World Health Summit – Future Challenges, Global Visions (S)
14. - 18.10.2009, Berlin, Germany

World Immune Regulation Meeeting
March 29th - April 1st, 2009, Davos, Switzerland

XXIVth International Symposium on Cerebral Blood Flow, Metabolism and Function (P)
June 29th - July 3rd, 2009, Chicago, USA

XXIVth International Symposium on Cerebral Blood Flow, Metabolism and Function and the IXth International Conference on Quantification of Brain Function with PET (V)
June 29th - July 3rd, 2009, Chicago, USA

XXXI. Congress of the German Society for Child and Youth Psychiatry DGKJP (V)
March 4th - 7th, 2009, Hamburg, Germany

V = Oral presentation
S = Stand
P = Poster

PARTNERS

Research partners

Arizona State University, School of Life Sciences, Arizona, USA

Association CARDIO-MONDE, Laboratory of Biosurgical Research, Paris, France

Baylor College of Medicine, Houston, Texas, USA

Biomedical Primate Centre, The Netherlands

Central Institute for Experimental Animals, Kawasaki, Kanagawa, Japan

Centre National de la Recherche Scientifique, Institut de Génétique Moléculaire de Montpellier, Montpellier, France

Centre of Molecular and Macromolecular Studies, Engineering of Polymeric Materials, Lodz, Poland

Charite – Campus Benjamin Franklin, Berlin, Germany

Frankfurt University, University Hospital, Frankfurt/Main, Germany

Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB, Stuttgart, Germany

Fraunhofer Institute for Manufacturing Engineering and Automation IPA, Stuttgart, Germany

Fraunhofer Institute for Mechanics of Materials IWM, Halle/Saale, Germany

Fraunhofer Institute for Production Technology IPT, Aachen, Germany

Freie Universität Berlin (Free University of Berlin), Veterinary Medicine, Berlin, Germany

German Heart Institute Berlin (DHZB), Berlin, Germany

Heart Center Leipzig, Leipzig, Germany

Helmholtz Center for Environmental Research UFZ, Department Proteomics | Department Environmental Immunology | Department Environmental Microbiology, Leipzig, Germany

Hospital "Rudolf-Elle", Chair for Orthopedy of the University Hospital, Faculty of Medicine, Friedrich Schiller University Jena, Jena, Germany

Imperial College, Department of Mathematics, London, UK

Institut de Recerca de l'Hospital Santa Creu i Sant Pau, Barcelona, Spain

Institute for Chemical-Physical Proc., C.N.R Pisa, Italy

Julius-Maximilians University of Würzburg, Medical Faculty, Institute for Virology and Immunobiology, Würzburg, Germany

Karolinska Institutet, Department of Medicine, Stockholm, Sweden

Ludwig-Maximilians-University Munich, Department Biology II | Faculty for Veterinary Medicine, Munich, Germany

Martin Luther University Halle-Wittenberg, Faculty of Natural Sciences I – Biomedical Sciences, Institute for Biology, Division of Genetics | Faculty of Natural Sciences II – Chemistry and Physics, Institute for Physics, Halle, Germany

Max Planck Institute for Evolutionary Anthropology, Department of Evolutionary Genetics, Leipzig, Germany

Max Planck Institute for Infection Biology, RNA Biology, Berlin, Germany

Monash University Melbourne, Australia

Municipal Hospital St. Georg Leipzig, Robert Koch Clinic, Leipzig, Germany

National Cancer Institute at Frederick, Center for Cancer Research | HIV Drug Resistance Program, Frederick, USA

National Insitutes of Health, Bethesda, USA

Newcastle University, Faculty of Medical Sciences, Newcastle, UK

Norwegian Radium Hospital Oslo, Dept. of Genetics, Oslo, Norway

Otto von Guericke University Magdeburg, Medical Faculty, Magdeburg, Germany

Radboud University Nijmegen Medical Centre, Experimental Urology, Nijmegen, The Netherlands

Royal College of Surgeons in Ireland RCSI, Neurodegeneration Physiology & Medical Physics, Dublin, Ireland

Saarland University Hospital and Faculty of Medicine of the Saarland University, Homburg/Saar, Germany

Salk Institute, San Diego, CA, USA

Shanghai Institutes for Biological Science, MPG-CAS Partner Institute, Shanghai, China

Southern Medical University China, South Genomics Research Center, Guangzhou, China

St. Elisabeth Hospital Leipzig, Breast Center | Urology, Leipzig, Germany

St. Georg Hospital, Academic Teaching Hospital of the University of Leipzig, Clinic for Internal Oncology and Hematology, Leipzig, Germany

Stanford University, Medical School, Stanford, CA, USA

Technical University Dresden, Dresden, Germany

Universidad Politécnica de Valencia, Valencia, Spain

Université Victor Segalen Bordeaux 2, Bordeaux Cedex, France

Universitat Pompeu Fabra, Complex Systems Lab, Barcelona, Spain

Universitat Ramon Llull Fundació Privada, Barcelona Bioengineering Center, Institut Quimic de Sarria, Barcelona, Spain

University Hospital Carl Gustav Carus, Clinic for Urology | Faculty of Medicine Carl Gustav Carus, Dresden, Germany

University Hospital Jena, Clinic for Child and Youth Psychiatry and Psychotherapy, Jena, Germany

University Hospital Leipzig, Clinic for Urology, Leipzig, Germany

University Hospital Schleswig-Holstein – Campus Kiel, Clinic for Applied Cell Therapy, Kiel, Germany

University of California Riverside, College for Natural and Agricultural Sciences, Riverside, CA, USA

University of Essen, Institute for Hygiene and Industrial Medicine, Essen, Germany

University of Freiburg, Faculty of Medicine, Freiburg, Germany

University of Ghent, Veterinary Medicine, Ghent, Belgium

University of Gießen, Department of Rheumatology and Clinical Immunology, Gießen, Germany

University of Gondar, Faculty of Medicine, Gondar, Ethiopia

University of Greifswald, Faculty of Medicine, Greifswald, Germany

University of Hamburg, Center for Bioinformatics, Hamburg, Germany

University of Leipzig, Faculty of Biosciences, Pharmacy and Psychology | Faculty of Chemistry and Mineralogy | Faculty of Mathematics and Informatics | Faculty of Veterinary Medicine | Translational Centre for Regenerative Medicine TRM | Centre of Biotechnology and Biomedicine | Interdisciplinary Center for Bioinformatics, Leipzig, Germany

University of Michigan, Medical School, Ann Arbor, MI, USA

University of Padova, Faculty of Medicine and Surgery, Padova, Italy

University of Pennsylvania, School of Medicine, Philadelphia, PA, USA

University of Queensland, Institute for Molecular Bioscience, St Lucia, Brisbane, Australia

University of Regensburg, Faculty of Medicine, Regensburg, Germany

University of Rostock, Faculty of Medicine, Rostock, Germany

University of Salzburg, Faculty of Biosciences, Salzburg, Austria

University of Zurich | VetSuisse Faculty, Zurich, Switzerland

Washington University in St. Louis, School of Medicine, Department of Medicine, Division of Infectious Diseases, Saint Louis, MO, USA

Weizmann Institute of Science, Department of Molecular Genetics, Rehovot, Israel

Westphalian Wilhelms University Münster, Faculty of Medicine, Münster, Germany

Industry partners

ACOMED Statistik

Affimed Therapeutics AG

AID GmbH

AIT Austrian Institute of Technology GmbH

Alcyomics Ltd.

Austrian Research Centers GmbH, Nano-Systemtechnologien

AVISO GmbH

BioE, Inc.

Biomedizinisches Forschungszentrum Rostock

Biotectid GmbH

blue-drugs GmbH

Bombastus Werke AG

Bundesministerium für Risikibewertung

Cellserve GmbH

Cleveland Clinic

CREASPINE

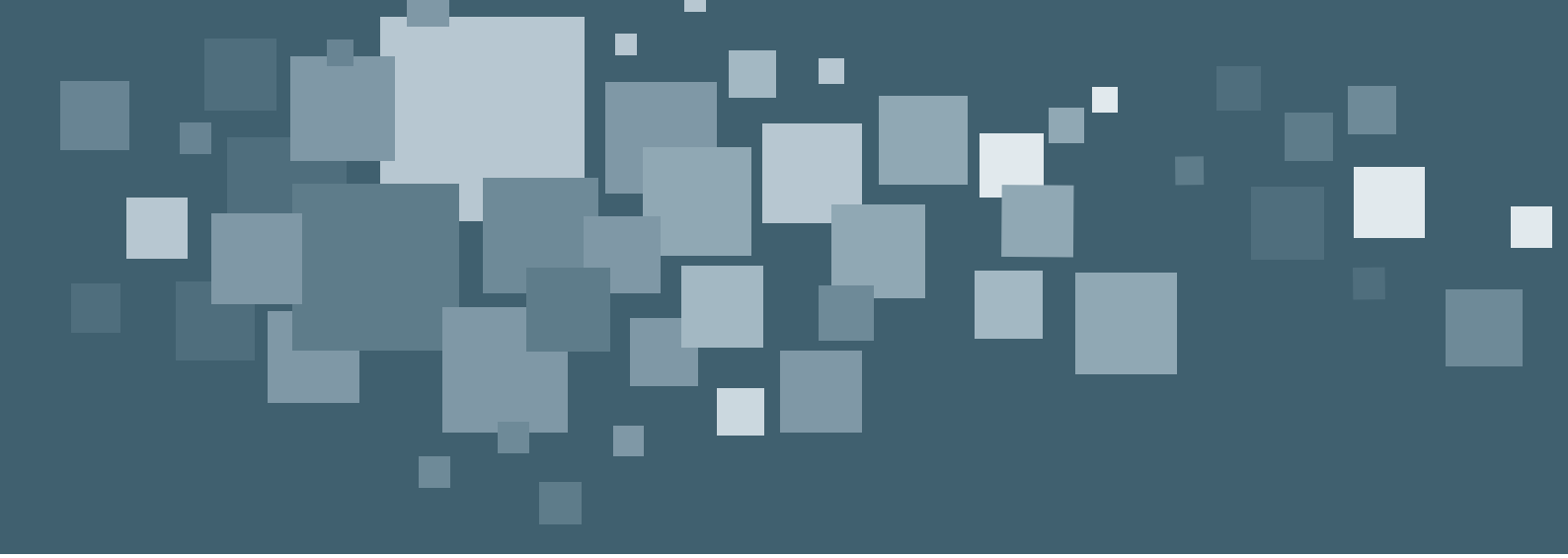
CREAVAC - Creative Vakuumbeschichtung GmbH

CSF Therapeutics

Cytori Therapeutics, Inc.

DASGIP AG

DMG Dental-Material Gesellschaft mbH



DRK-Blutspendedienst NSTOB

emergentec biodevelopment GmbH

euroderm GmbH

Forschungsinstitut Angewandte Neurowissenschaften GmbH (FAN)

Frankfurter Stiftung für krebskranke Kinder

Generic Assays GmbH

Genetic Immunity, Kft.

Geräte- und Vorrichtungsbau Spitzner OHG

GuangzhoGuangzhou Gendustry Inc.

Höft,Wessel & Dr. Dreßler GmbH

InnovaStem GmbH

Institut für Mikrotechnik Mainz GmbH

Institut für systemisch-integrative Lerntherapie

ISCONOVA A.B.

IXODES W5

Kapelan GmbH

KET GmbH

Labor Dr. Reising-Ackermann und Kollegen

Leibniz-Institut für Oberflächenmodifizierung

Merck KG

Mologen AG

Novartis Pharma GmbH

NUVO Research Inc.

ÖHMI Analytik GmbH

Partec GmbH

Planet ID GmbH

PlasmAcute AS

Pluristem Therapeutics Inc.

Praxis PD Dr. Hoheisel

RESprotect GmbH

Sanofi-Aventis Deutschland GmbH

Serumwerk Bernburg AG

Siemens AG

SOVICELL GmbH

Urologische Praxis Dr. Schulze, Markkleeberg

Vakzine Management GmbH

Vita 34 AG

WITTENSTEIN AG

ZEDIRA GmbH

QUALIFICATION

Internal Advanced Vocational Training

Application Training MoFlo XDP
Beckman Coulter GmbH, Krefeld, Germany

Application Training WAVE CultiBag RM
Sartorius AG, Göttingen, Germany

Acquisition of Third-Party Funds
WSR Seminare, Hamburg, Germany

Communication Training
WSR Seminare, Hamburg, Germany

Employee Assessment
Fraunhofer IZI, Leipzig, Germany

GLP Training
Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Hanover, Germany

Liability of Executive Directors and Partners in a GmbH (German LLC)
smile.medibiz, Leipzig, Germany

MoFLo XDP Training
Beckman Coulter GmbH, Krefeld, Germany

Negotiate Successfully
WSR Seminare, Hamburg, Germany

Preparation for and Experience in Government Inspections
Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Hanover, Germany

Presentation Training
Fraunhofer IZI, Leipzig, Germany

Project Management
WSR Seminare, Hamburg, Germany

Scientific Writing
Fraunhofer IZI, Leipzig, Germany

Statistics
Fraunhofer IZI, Leipzig, Germany

Team Management
smile.medibiz, Leipzig, Germany

External Advanced Vocational Training

4th Small Animal Imaging Workshop
Werner Siemens Foundation, Tübingen, Germany

Advanced Training "Neurology"
Timmendorfer Tierärzteseminare (Veterinary Seminars), Niendorf, Germany

Allergology/Infectiology
PD Dr. G. Hoheisel, Leipzig, Germany

Anthracycline-induced Extravasation Injury
TOPOTARGET A/S Copenhagen, Leipzig, Germany

Cell-based Assays – from Apoptosis to Cytotoxicity
Promega, Leipzig, Germany

Course for Animal Experiments
University of Leipzig, Medical Experimental Center MEZ, Leipzig, Germany

Course on Experimental Zoology
University of Leipzig, Medical Faculty, Leipzig, Germany

DRG Documentation
University of Leipzig, Training Center IMISE, Leipzig, Germany

FACS Course (FC 500 Training)
Beckman Coulter GmbH, Krefeld, Germany

FACS Stem Cell Diagnostics
Beckman Coulter Inc., Frankfurt/Main, Germany

Faculty Member Training
University of Leipzig, Medical Faculty, Leipzig, Germany

Gastric Seminar 2009/2010
Norgine GmbH, Leipzig, Germany

General and Internal Medicine
Evangelical Deaconess Hospital, Leipzig, Germany

Genetic Analysis with FAMHAP
University of Bonn, Bonn, Germany

GMP
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

Intracellular Proteins/Bead Technology
Becton Dickinson GmbH, Heidelberg, Germany

Laboratory Course Real-time PCR
EuroGene GmbH, Leipzig, Germany

Medical Specialist Training for Internal Medicine
PD Dr. Hoheisel Leipzig/University of Leipzig, Hematology/Oncology, Leipzig, Germany

Microsurgical Operations
berliner fortbildungen, Berlin, Germany

Munich Seminar on Veterinary Clinical Studies
KLIFOVET, Munich, Germany

New Concepts in Flow Cytometry
Beckman Coulter/University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

Pharmaceutical Chemistry
University of Leipzig, Leipzig, Germany

Pharmaceutical Technology
University of Leipzig, Leipzig, Germany

Pharmacology I
University of Leipzig, Leipzig, Germany

Preparation of GMP in the R&D Phase
BB Life Seminare, Berlin, Germany

Quality and Safety for Tissues and Tissue Preparations
Concept Heidelberg, Heidelberg, Germany

Section Seminar
German Society of Veterinary Medicine, Fulda, Germany

Spring School on Immunology
DGI, Ettal, Germany

Stem Cell Transplantation – Quality Control and Immuno-monitoring
Beckman Coulter, Frankfurt/Main, Germany

Steritest School Training
Millipore GmbH, Hanover, Germany

User Seminar Flow Cytometry
Becton Dickinson GmbH, Heidelberg, Germany

User Seminar Real-time Cell Analysis
Roche Applied Science GmbH, Fulda, Germany

Veterinary Medicine, Block Course I/II
Academy of Veterinary Advanced Training (ATF), Berlin, Germany

Veterinary Medicine, Block Course III/IV
Academy of Veterinary Advanced Training (ATF), Gießen, Germany

Teaching Activities

13th Workshop on Children's Immunology, Grimma-Höfgen, Germany
Biomarkers of Rheumatoid Arthritis and Chronic Inflammatory Bowel Diseases (C)

EuroGene GmbH, Leipzig, Germany
Academy for Advanced Vocational Training (Biochemistry) (L)

Merial Symposium: New Vaccination Strategies against Salmonellae, Hamburg, Germany
Immunity to Salmonellae – Principles, Vaccination Strategies, Diagnostics (C)

Roche Applied Science Marketing Meeting, Mannheim, Germany
Measurement and Kinetic Analysis of Real-time Cell Reactions (C)

Roche Symposium "Neue Wege in der Real-time Zellanalyse" (New Pathways in Real-time Cell Analysis), Berlin/Cologne/Hanover, Germany
Measurement and Kinetic Analysis of Real-time Cell Reactions (C)
Detection and Kinetic Analysis of Cell Reactions in Practice (C)

University of Leipzig
Acute Leukemia (S)
Autoimmune Diseases (C)
Development of Marker Vaccines (S)
Environmental Medicine, QSB (C)
Genetic Basis of Dyslexia (L)
Hybridoma Cell Culture Technique for the Production of Monoclonal Antibodies (L)
Immunological Lecture Series (L)
Immunology (PBL/P/L/C/S)
Introduction Clinical Medicine (C)
Lymphomas (S)
Medical Biotechnology (L)
New Concepts in the Development of Vaccines (L)
Pharmaceutical Biology: Basis of Immunology (L)
Practical Training: Main Focus Biomedicine (P)
Regenerative Medicine (L)
Regenerative Medicine/Medical Biotechnology (S)
Transfusion Medicine (S)

L = Lecture or student training and teaching
S = Seminar
P = Practical training
C = Course
PBL = Problem-based learning

EVALUATOR ACTIVITIES AND ASSOCIATION MEMBERSHIPS

Evaluator Activities

American Journal of Respiratory and Critical Care Medicine
Prof. Dr. Ulrich Sack

American Journal Physiology
Dr. Alexander Deten

Analytical Chemistry Insights
Prof. Dr. Ulrich Sack

Annals of Rheumatic Diseases
Prof. Dr. Ulrich Sack

Bioinformatics
Dr. Jörg Hackermüller

Biotechnology and Bioengineering
Prof. Dr. Nicole zur Nieden

BMC Medical Genetics
Holger Kirsten

Cardiovascular Drugs and Therapy
Dr. Alexander Deten

Cardiovascular Research
Dr. Alexander Deten

Cell Proliferation
Prof. Dr. Ulrich Sack

Cellular and Molecular Life Sciences
Prof. Dr. Frank Emmrich (Advisory Board)
Prof. Dr. Nicole zur Nieden

Circulation
Dr. Alexander Deten

Circulation Research
Dr. Alexander Deten

Clinical Chemistry
Prof. Dr. Ulrich Sack

Clinical Chemistry and Laboratory Medicine
Prof. Dr. Ulrich Sack

Current Stem Cell Research and Therapy
Prof. Dr. Nicole zur Nieden

Cytometry A
Prof. Dr. Ulrich Sack

Cytotherapy
Daniel-Christoph Wagner

Deutsche Medizinische Wochenschrift
Prof. Dr. Ulrich Sack

DFG
Dr. Alexander Deten

Disease Markers and Cancer Biomarkers
Prof. Dr. Ulrich Sack

Engineering in Life Sciences
Prof. Dr. Ulrich Sack

Europäische Forschungsinitiative – EUREKA (European Research Initiative)
Dr. Gerno Schmiedeknecht

European Journal Physiology
Dr. Alexander Deten

Future Drugs – Expert Reviews Vaccines
Dr. Jörg Lehmann

Future Virology
Dr. Jörg Baumann

German Medical Science
Prof. Dr. Ulrich Sack

Journal of Artificial Intelligence in Medicine
Prof. Dr. Ulrich Sack

Journal of Biological Chemistry
Dr. Jörg Baumann

Journal of Biophotonics
Prof. Dr. Ulrich Sack

Journal of Cellular and Molecular Life Sciences
Dr. Alexandra Stolzing

Journal of Molecular Medicine
Prof. Dr. Ulrich Sack

Journal of Neural Transmission
Dr. Alexandra Stolzing

Journal of Orthopedic Research
Prof. Dr. Ulrich Sack

Journal of Pharmacology and Experimental Therapeutics
Prof. Dr. Ulrich Sack

Journal of Rejuventation Research
Dr. Alexandra Stolzing

Journal of Rheumatology
Prof. Dr. Ulrich Sack

Lung Cancer
Prof. Dr. Ulrich Sack

Medical Research Council, UK, Funding Agency
Prof. Dr. Nicole zur Nieden

Neurobiology of Aging
Daniel-Christoph Wagner

Osteoarthritis and Cartilage
Prof. Dr. Ulrich Sack

Pathobiology
Prof. Dr. Ulrich Sack

Planta Medica
Dr. Alexander Deten

PLoS One
Dr. Jörg Baumann

PSB Pacific Symposeon on Biocomputing
Dr. Jörg Hackermüller

Respiratory Medicine
Prof. Dr. Ulrich Sack

Rheumatology International
Prof. Dr. Ulrich Sack

Stroke
Daniel-Christoph Wagner

Telethon
Dr. Alexander Deten

The Open Vaccine Journal
Dr. Jörg Lehmann (Editorial Board – Nominierung)

The Open Veterinary Science Journal
Dr. Jörg Lehmann (Editorial Board)

Transfusion Medicine and Hemotherapy
Prof. Dr. Ulrich Sack

Veterinary Immunology and Immunopathology
Dr. Jörg Lehmann

Virology
Dr. Jörg Baumann

Zeitschrift für Regenerative Medizin
(Journal of Regenerative Medicine)
Prof. Dr. Frank Emmrich

Association Memberships

American Heart Association
Dr. Alexander Deten

American Society of Hematology
Dr. Christoph Schimmelpfennig

Arbeitskreis Experimentelle Stammzelltransplantation
(Study-group Experimental Stem Cell Transplantation)
Dr. Stephan Fricke

BioSaxony e.V.
Dr. Christian Zilch

British Society of Research into Ageing
Dr. Alexandra Stolzing

CellNet
Prof. Dr. Nicole zur Nieden

Deutsche Gesellschaft für Alternsforschung
(German Society for Gerontology)
Dr. Alexandra Stolzing

Deutsche Gesellschaft für Geriatrie und Gerontologie
(German Society of Gerontology and Geriatrics)
Dr. Alexandra Stolzing

Deutsche Gesellschaft für Immunologie (DGfI)
(German Society for Immunology)
Dr. Jörg Lehmann
Dr. Nasr Hemdan
Dr. Stephan Fricke
Prof. Dr. Frank Emmrich
Prof. Dr. Ulrich Sack (Delegierter)

Deutsche Gesellschaft für Kardiologie
(German Cardiac Society)
Dr. Alexander Deten

Deutsche Gesellschaft für Zoologie
(German Society for Zoology)
Dr. Gustavo Rodrigues Makert dos Santos

Deutsche Physiologische Gesellschaft
(German Society of Physiology)
Dr. Alexander Deten

Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin (DGKL) (German Society for Clinical Chemistry and Laboratory Medicine)
Prof. Dr. Ulrich Sack

Deutscher Hochschulverband (German Association of University Professors and Lecturers)
Dr. Alexander Deten

European Autoimmunity Standardization Initiative (EASI)
Prof. Dr. Ulrich Sack (Vorstand)

European Molecular Biology Laboratory Alumni Association
Dr. Sebastian Ulbert

European Society for Clinical Call Analysis (ESCCA)
Prof. Dr. Ulrich Sack (Vorstand)

Forschungsplattform Zoonose (Research Platform Zoonosis)
Dr. Sebastian Ulbert

Freunde der Veterinärmedizinischen Fakultät der Universität Leipzig e.V. (Friends of Veterinary Medicine Faculty of the University of Leipzig)
Dr. Jörg Lehmann

Gesellschaft Deutscher Chemiker e.V. (GDCh) (German Chemical Society)
Dr. Michael Szardenings

Gesellschaft für Biochemie und Molekularbiologie (GBM) (Society for Biochemistry and Molecular Biology)
Dr. Michael Szardenings
Dr. Samiya Al-Robaiy

Gesellschaft für Regenerative Medizin (German Society for Regenerative Medicine)
Dr. Alexandra Stolzing (Wissenschaftler Beirat)
Dr. Stephan Fricke
Prof. Dr. Frank Emmrich

Gesellschaft für Versuchstierkunde (GV-SOLAS) (Society for Laboratory Animals)
Dr. Jörg Lehmann

Gesellschaft zur Förderung der Immundiagnostik (GfID) (Association for the Advancement of Immune Diagnostics)
Prof. Dr. Ulrich Sack (Vorstand)

International Society for Cellular Therapy
Dr. Alexandra Stolzing

International Society for Heart Research
Dr. Alexander Deten

International Society for Stem Cell Research (ISSCR)
Anke Dienelt
Prof. Dr. Nicole zur Nieden
Vuk Savkovic

International Society for Stem Cell Research
Dr. Alexandra Stolzing

International Study Group for Stem Cell Therapy
Prof. Dr. Nicole zur Nieden

Netzwerk Molekulare Bildgebung (Network Molecular Imaging)
Dr. Christian Zilch

REGENERATE, EEIG
Prof. Dr. Nicole zur Nieden

Society for Cryobiology
Dr. Alexandra Stolzing

Society for Neuroscience
Alexander Kranz
Björn Nitzsche
Daniel-Christoph Wagner
Teresa von Geymüller
Vilia Zeisig

The RNA Society
Dr. Jörg Hackermüller

Zentrale Tierschutzkommission der Landesdirektion Leipzig (Central Committee for Animal Protection, Directorate Leipzig)
Dr. Jörg Lehmann

PRIZES

Partec GmbH bestows World AIDS Day Award

In September 2009, the biotechnological company Partec GmbH, Görlitz/Germany, bestowed the "Partec World AIDS Day Award" for a cooperation project of the University of Gondar (Ethiopia), the University of Leipzig and the Fraunhofer IZI (Virus-Host-Interaction Unit). On the occasion of the World AIDS Day 2008, Partec had declared a worldwide competition in which research consortia that are committed to the fight against HIV/AIDS could participate. The international winning team convinced the judges with a sustainable project connecting patient care with the study of co-infections and the training of students and physicians. With the 52,000 Euros prize money the winning project will be supported for the period of one year with the required equipment and reagents for HIV/AIDS diagnostics.

IQ Innovation Award

A cooperation project of the Institute of Biochemistry, University of Leipzig (Prof. Dr. Gerd Birkenmeier) together with the Fraunhofer IZI (Dr. Wilhelm Gerdes) won the second place of the IQ Innovation Award 2009 in the cluster "Food Economy". The project comprised the development of a functional food – viz the spread "CurcuNat". To this end, the scientists investigated the mode of action of curcumin, a plant component of the spice curcuma, and found that it plays a role in the sugar metabolism of cells. Curcumin acts as a suppressor of inflammation and provide a basis for the treatment of many diseases including tumors, diabetes and Alzheimer's disease. Enriched with omega-3 fatty acids and vitamins, the spread could make a future contribution to a healthy daily nutrition.

Formula.1 research grant on the topic of
miRNAs in prostate carcinoma
for Kerstin Ullmann and Katharina Schutt from the RNomics Unit

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Poster Award – Research Festival Leipzig/Category: "Regenerative Medicine" for Antje Arnold from the Stem Cell Biology Unit
Development of an RNA-based reprogramming system for the derivation of human IPS cells.

Grant for the Promotion of Technical Assistants for Stephanie Tuche from the Immune Tolerance Unit
Stiftung Begabtenförderungswerk berufliche Bildung Gemeinnützige Gesellschaft mbH (Scholarship Foundation for Professional Training, non-profit LLC)

ZONTA Special Award (German Youth Science Competition "Jugend Forscht") for Anne Klose, who authored the scientific paper
"Das DC-SIGN Molekül – Ein neuer Ansatzpunkt im Kampf gegen AIDS" (The DC-SIGN molecule – A novel approach in the fight against AIDS)
in the context of a so-called BELL (BEsondere LernLeistung = an extraordinary learning achievement) in the Virus-Host-Interaction Unit

Magna Diagnostics wins business plan competition

In April, the diagnostics company Magna Diagnostics, Leipzig, a spin-off from the Fraunhofer IZI founded by Dr. Christian Zilch, Dr. Wilhelm Gerdes and Dr. Sonya Faber, was awarded the prize for the best business and marketing concept in the field of bio-/nanotechnology in the second phase of the Saxon business plan competition futureSax 2009. It is the company's objective to develop a fast, inexpensive and easy-to-operate diagnostic system that can be employed on the patient directly on site. This is achieved by using minute magnetic particles. A blood sample is sufficient for the particles to pass fully automatically through the system by means of magnetic forces. At the end of the process chain, detection is conducted by means of highly sensitive magnetic sensor technology.

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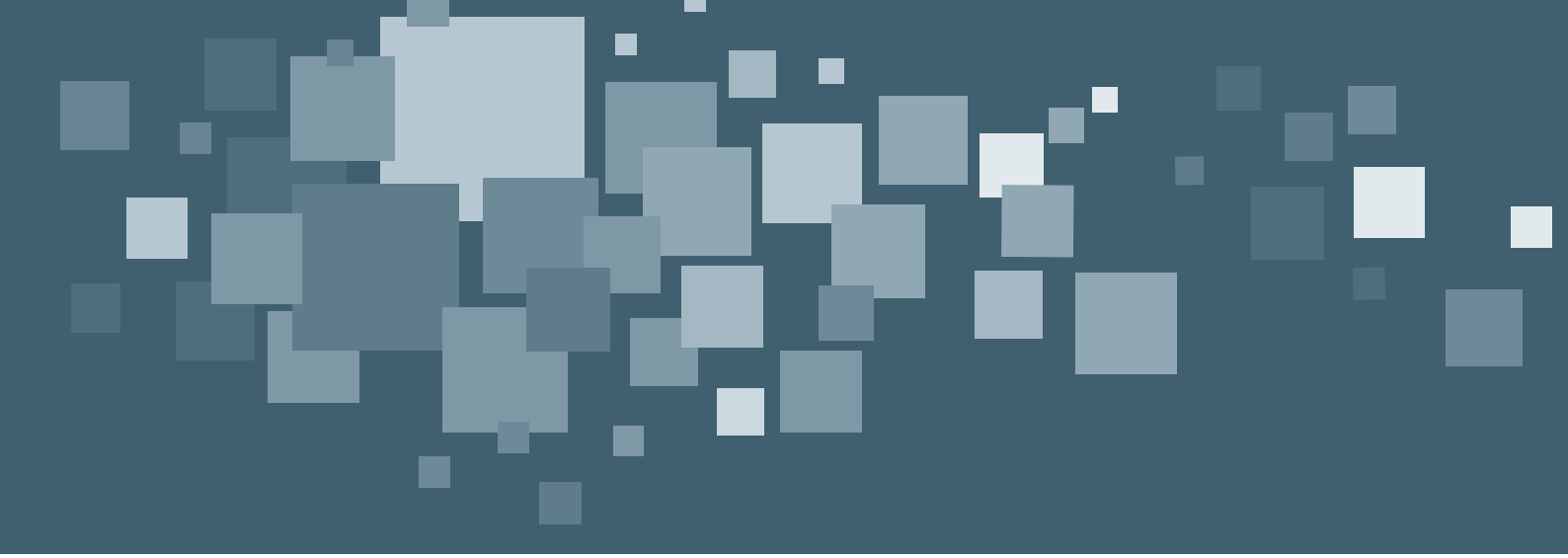

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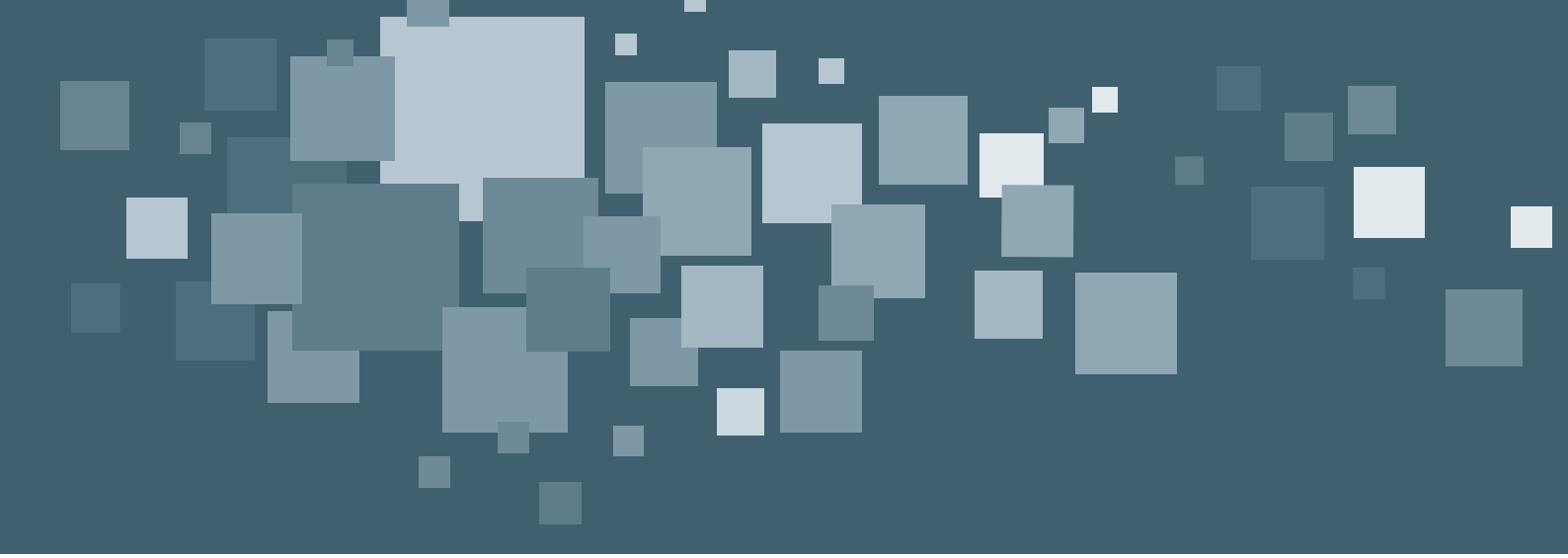

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Stem cells and their use in predictive assays.
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Graduation

Anett Käßner, Cell Engineering/GLP Unit
Etablierung einer spezifischen Diagnostik für Sensiblisierungen gegenüber Schimmelpilzallergenen.
University of Applied Sciences Jena, Diploma thesis

Anna-Maria Placht, Stem Cell Biology Unit
Etablierung eines Housekeeping-Gens für humane Fibroblasten.
University of Applied Sciences Jena, Bachelor thesis

Annekathrin Kränkel, Neuro-/Cardiorepair Unit
Modulation der Wachstumsfaktorexpression durch Zelltransplantation nach experimentellem Schlaganfall in der Ratte.
University of Applied Sciences Zittau/Görlitz, Bachelor thesis

Cathleen Pfefferkorn, Cell Engineering/GLP Unit
Etablierung von Differenzierungsprotokollen der murinen Stammzelllinie MuSC-E8 und Untersuchung des Einflusses. Molekular- und zellbiologische Evaluierung der murinen Zelllinie MuSC-E8 in Hinblick auf potenzielle Stammzelleigenschaften.
University of Leipzig, Diploma thesis

Doris Wolf, Cell Engineering/GLP Unit
Einsatz der Real-time Zellanalyse für die individuelle Qualitätskontrolle von permanenten Zelllinien, die für Bio-Assays genutzt werden.
Anhalt University of Applied Sciences, Köthen, Master´s thesis

Katharina Gwschandtner, Stem Cell Technology Unit
Influence of recombinant Wnt proteins on osteoblast differentiation of murine embryonic stem cells in serum free medium.
IMC University of Applied Sciences Krems, Diploma thesis

Kathleen Spier, Cell Engineering/GLP Unit
Vergleich des Einflusses der Antibiotika Mycoplasma Removal Agent und BM Cyclin auf das Proteom der myeloiden Leukämie-Zelllinie THP-1.
University of Applied Sciences Jena, Diploma thesis

Marek Staude, Stem Cell Biology Unit
Use of hydroxyethyl starch for the cryopreservation of rat mesenchymal stem cells.
TU Dresden, Master´s thesis

Silvana Schulz, Cell Engineering/GLP Unit
Qualitätsvergleich drei unterschiedlicher Verfahren zur Detektion von Mykoplasmen in Zellkulturen.
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Stefan Ishak, Stem Cell Biology Unit
Migration of mesenchymal stem cells.
IMC University of Applied Sciences Krems, Diploma thesis

Ulrike Fronz, Neuro-/Cardiorepair Unit
Multimodal evaluation of the neuroprotective potential of CSC in a rodent model of focal cerebral ischemia.
University of Leipzig, Diploma thesis

Patents

The employees of the Fraunhofer IZI submitted 5 invention disclosures and 15 patents in the past year. The patents were in the fields of active agents, (stem) cell technology, tissue manufacturing, diagnostics and analytics.

The following patents were granted or published in 2009:

Jörg Baumann, Sabine Breun
WO2009100928 (A1)
Antigen specific regulatory T-cell induction.
granted: August 20th, 2009

Ulrich Sack, Rainer Wurth, Angelika Bold
PCT/EP 06 00 9364.8
Method for quantifying a cell population of interest contained in a human blood sample.
granted: May 20th, 2009

Christian Zilch, Wilhelm Gerdes, Johann Bauer, Karl Holschuh
EP 08005370.5
Thermic guidance of biologic reactions using functionalized magnetic beads and alternating magnet fields.
granted: October 21st, 2009

SPONSORS AND ADVISORY BOARD

Sponsors

The Fraunhofer IZI would like to thank the European Union, the Federal Ministry for 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 throughout the current development phase.

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 for Education and Research and the Free State of Saxony. In the same manner, the expenses of about 11 million Euros for construction and equipment of the extension building are covered. The plot of land is provided by the City of Leipzig in hereditary leasehold and free of charge.

Financed by
European Union

Bundesministerium
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und Forschung

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Technologietransfer

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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.

Dr. jur. Dr. h.c. oec. publ. Albrecht Schmidt (Chair)
Bayerische Hypo- und Vereinsbank AG, emeritus Chairman of the Supervisory Board

Dr. Annerose Beck
Saxon State Ministry of Science and the Arts (SMWK), Deputy Head of National-Regional Research Centres Administration

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FRAUNHOFER-GESELLSCHAFT

Mission

The Fraunhofer-Gesellschaft is one of Germany's big four research organizations. It is currently the largest European organization conducting applied research, the outcome of which has direct benefits for business and society. Its clients and contract partners include industrial companies, the service sector and the public sector.

By developing state-of-the-art technology on behalf of its clients, the various Fraunhofer institutes help reinforce the competitive strength of the economy in their local region as well as throughout Germany and Europe. Ultimately, the Fraunhofer-Gesellschaft aims to promote the development of a society that is economically successful without losing sight of social welfare or environmental responsibility.

The Fraunhofer-Gesellschaft was founded in 1949 and is a recognized nonprofit organization. Its members include prestigious companies and private patrons, who help shape Fraunhofer's research policy and strategic development.

The organization was named after Joseph von Fraunhofer (1787–1826), an optician from Munich, who became a successful researcher, inventor and entrepreneur.

Organization

The Fraunhofer-Gesellschaft maintains 59 institutes with around 80 research units at more than 40 locations in Germany. The vast majority of the nearly 17,000 staff are qualified scientists and engineers. They work with an annual research budget of more than 1.6 billion euros, over 1.3 billion euros of which is generated through contract research. Roughly two thirds of the Fraunhofer-Gesellschaft's research revenue stems from industry contracts and publicly financed research. The remainder is contributed by national and regional governments, partly as a means of enabling the institutes to pursue fundamental research in areas that are first likely to become relevant to industry and society after five or ten years.

Affiliated research centers and branches in Europe, the USA and Asia facilitate contact to the main regions of current and future scientific progress and economic development.

As an employer, the Fraunhofer-Gesellschaft offers its staff the opportunity to develop the professional and personal skills they need to take up positions of responsibility within their institute, in other scientific domains and in business and society.

Executive board

Prof. Dr. Hans-Jörg Bullinger, President of the Fraunhofer-Gesellschaft, Corporate Management and Research

Prof. Dr. Ulrich Buller, Research Planning

Prof. Dr. Alfred Gossner, Finance and Controlling (including Business Management, Purchasing, Real Estate), IT

Head office

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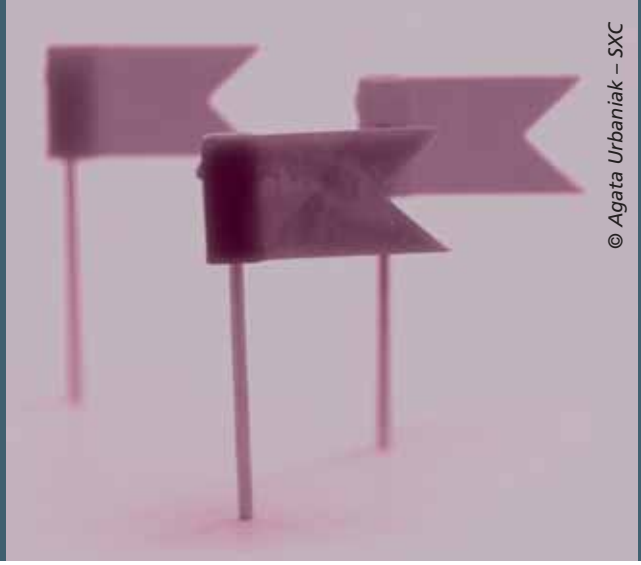

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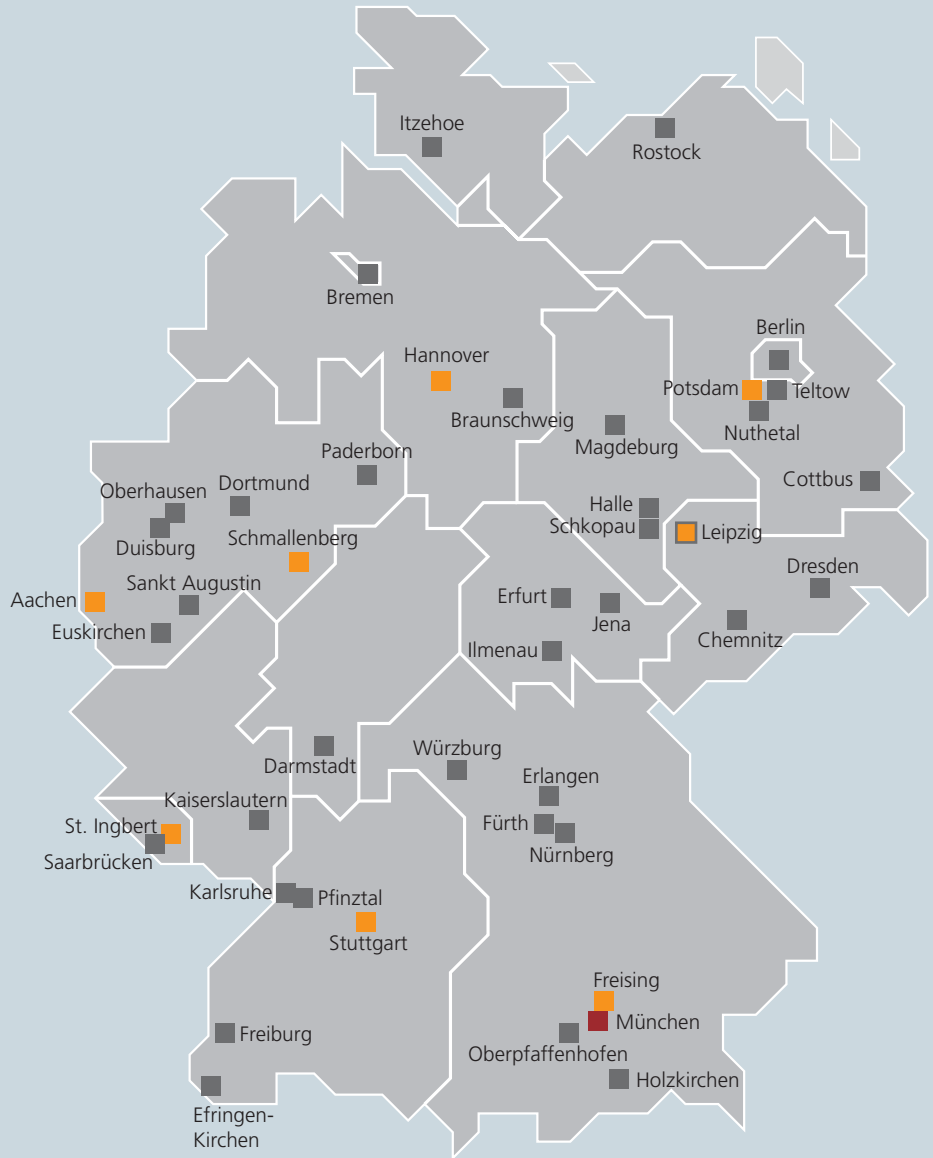
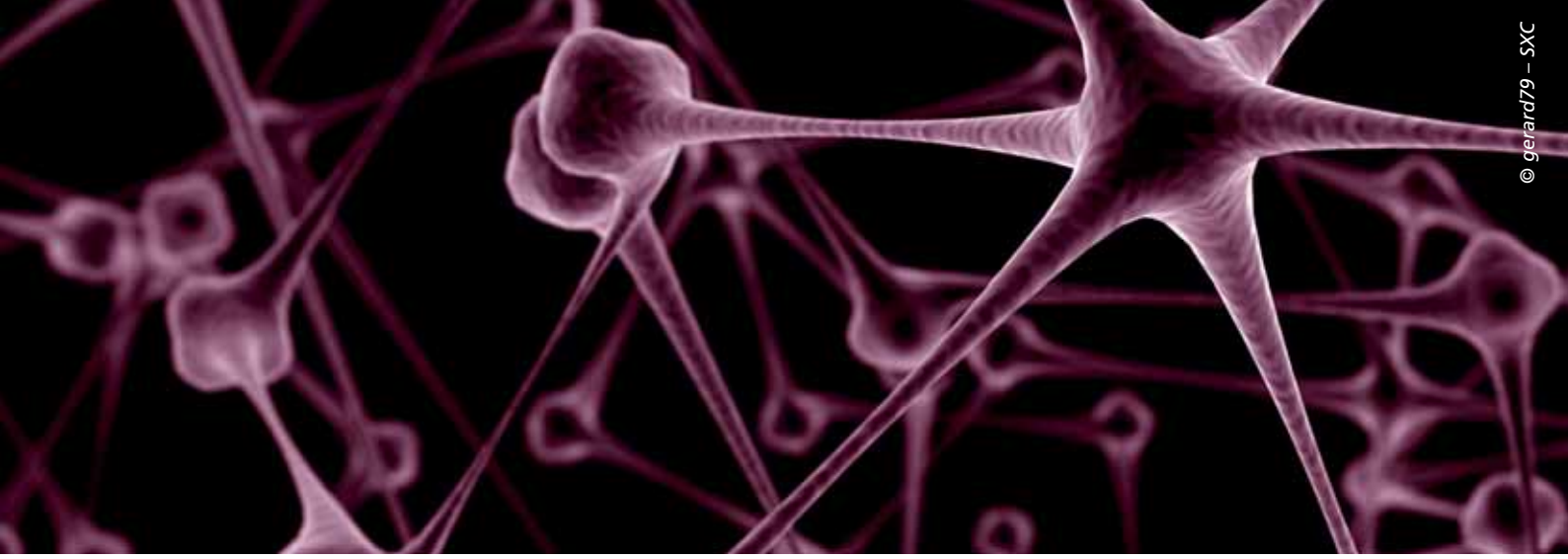
Locations



Fraunhofer Institute | Central office, Munich | Institutes of the Fraunhofer Group for Life Sciences | Fraunhofer IZI



FRAUNHOFER GROUP FOR LIFE SCIENCES

To strengthen the biosciences, biomedicine and biotechnology, in 2001 the Fraunhofer Group for Life Sciences was created. It currently comprises six institutes.

In terms of expanding research revenue as well as business spin-offs, the Fraunhofer Life Sciences Alliance is one of the Fraunhofer-Gesellschaft's most dynamic areas of research.

As far as its future development is concerned, the Fraunhofer Life Sciences Alliance focuses on four core competencies harboring excellent business prospects:

- accelerated drug development
- regenerative medicine
- production and safety of foods and animal feed
- biotechnical production, evaluation

The elected spokesman of the Fraunhofer Group for Life Sciences is Prof. Uwe Heinrich, who heads the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM in Hanover. Since 2008, Prof. Dr. Frank Emmrich (head of the Fraunhofer IZI) is deputy spokesman.

Institutes of the Fraunhofer VLS

- Fraunhofer Institute for Biomedical Engineering IBMT
- Fraunhofer Institute for Interfacial Engineering and Biotechnology IGB
- Fraunhofer Institute for Molecular Biology and Applied Ecology IME
- Fraunhofer Institute for Toxicology and Experimental Medicine ITEM
- Fraunhofer Institute for Cell Therapy and Immunology IZI
- Fraunhofer Institute for Process Engineering and Packaging IVV

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FRAUNHOFER IZI
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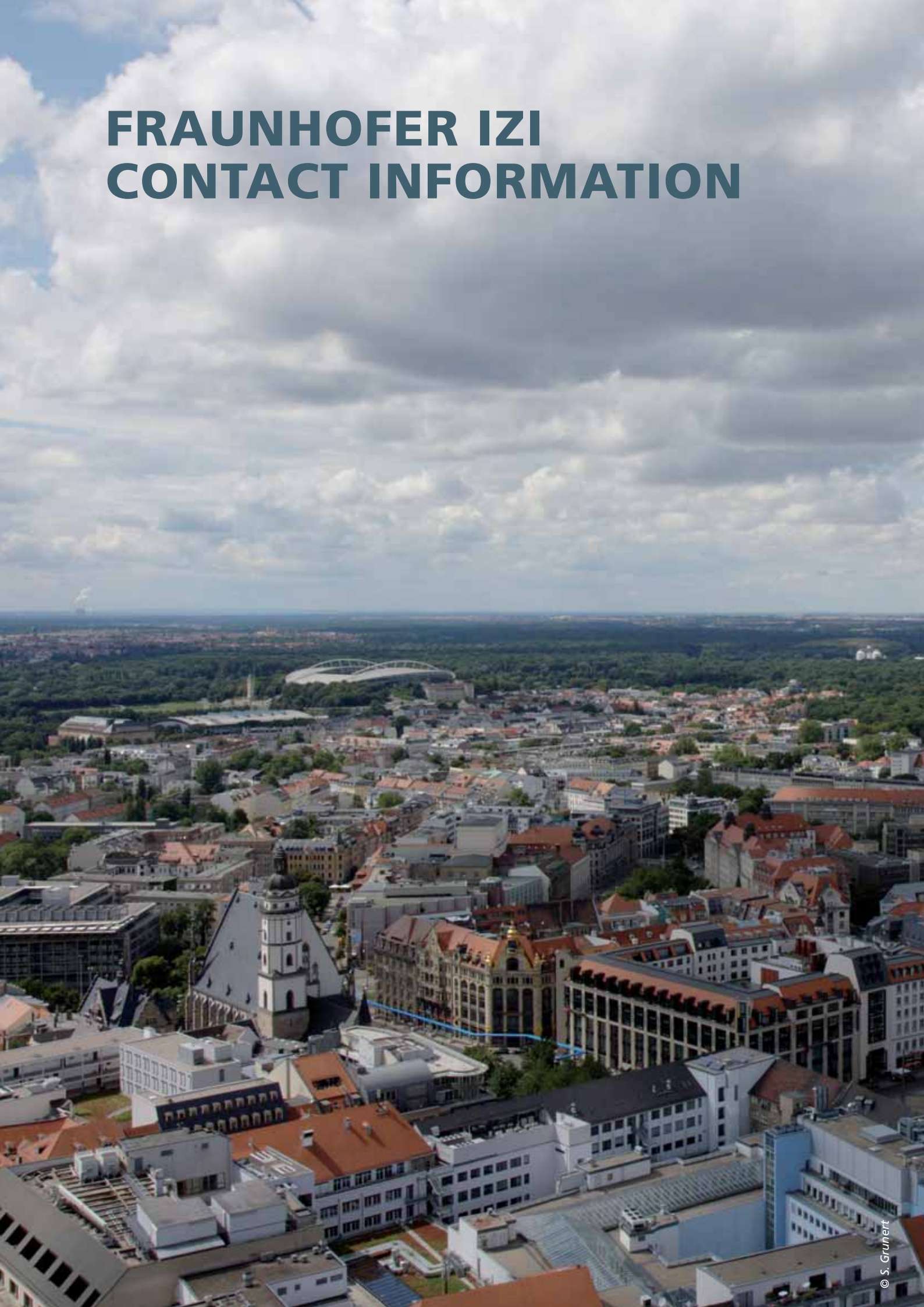

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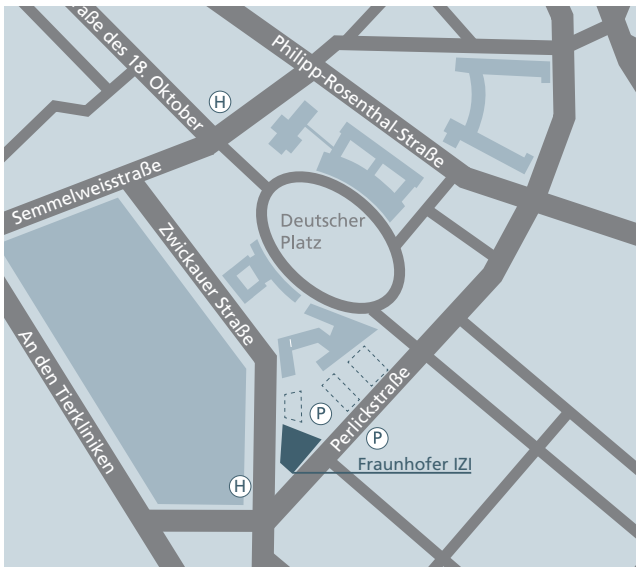
HOW TO REACH US



By car
Please note: Some navigation systems fail to find "Perlickstraße" as it is a private street belonging to the old trade fair grounds. We recommend that you enter "An den Tierkliniken" into your navigation system.

A9 – Exit Leipzig-West: Take the B181 in the direction of the city center ("Zentrum") and follow the B87 (Merseburger Straße, Lützner Str., Jahnallee). After passing the central station, turn right towards Augustusplatz (Leipzig Opera House). At Augustusplatz turn left and keep to the right, then follow Prager Straße. Turn right onto "Alte Messe" and after the second intersection turn right onto Puschstraße, at the end of which you turn left onto Perlickstraße.

A14 – Exit Leipzig-Mitte: Take the B2 (via Maximilianallee) in the direction of the city center ("Zentrum") and follow the B2 (via Gerichtsweg). Turn left onto Prager Straße (B2) in the direction of "Alte Messe", then turn right onto "Alte Messe" and after the second intersection turn right into Puschstraße, at the end of which you turn left onto Perlickstraße.

A38 – Exit Leipzig-Süd: Take the B2 in the direction of the city center ("Zentrum") and turn off at exit "Richard-Lehmann-Straße". Follow Richard-Lehmann-Straße and turn off before the BMW car dealership onto Zwickauer Straße in the direction of "Alte Messe", then turn right onto Perlickstraße.

The car park is accessible from Perlickstraße. You will find visitors' parking right in front of the façade of the institute.

By train and public transport
Take the train to Leipzig Central Station ("Leipziger Hauptbahnhof"), then transfer to the number 16 tram in the direction of Lößnig and get off at the stop "An den Tierkliniken".

From the airport
From the airport take the urban train ("S-Bahn") to Leipzig Central Station ("Leipziger Hauptbahnhof"), then transfer to the number 16 tram in the direction of Lößnig and get off at the stop "An den Tierkliniken".

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Project Service Team

The Project Service Team of the Fraunhofer IZI is responsible for project partners and interested parties who require an initial general contact or a reference for an appropriate scientific contact. The PST will be available and is pleased to be of service.

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INFORMATION SERVICE

Service Catalog

Our service catalog gives you a comprehensive insight into the products and services offered by the Fraunhofer IZI. On the basis of a target group-specific sorting according to fields of indication, technologies, competences or work units you will quickly find your appropriate contact person at our institute and gain insight into reference projects or applicabilities.

Seminar Catalog

Our seminar catalog gives you an overview of the advanced training program offered by the Fraunhofer IZI. Besides interdisciplinary seminars like project management, communication training and leadership coaching, we also offer scientific seminars and workshops to our partners.

Annual Report

In combination with past years' issues, our current annual report gives you an insight into the structure of the Fraunhofer IZI, our services, accomplishments and offers, as well as selected project examples.

Homepage

An overview of interesting events held at the Fraunhofer IZI as well as further information on our institute can be found on our homepage www.izi.fraunhofer.de.

All our brochures and publications as well as current announcements made by the Fraunhofer IZI can be found on our homepage **www.izi.fraunhofer.de** in the menu "Press and Publications" under "Downloads" (www.izi.fraunhofer.de/izi_downloads.html). You can also mail to **presse@izi.fraunhofer.de** and order our brochures as hard copies.