Fraunhofer
IZI

FRAUNHOFER INSTITUTE FOR CELL THERAPY AND IMMUNOLOGY IZI

ANNUAL REPORT 2010

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IN CONVERSATION WITH THE DIRECTOR PROF. DR. FRANK EMMRICH

On April 29, 2010, the Fraunhofer IZI celebrated its 5th anniversary. What are the institute's achievements so far and what is it that you are most pleased with? Normally, the development of a Fraunhofer Institute proceeds over several stages in which its power of innovation and reliability are verified. The Fraunhofer IZI, however, is an exception to this rule as it already had to stand up as a full-fledged institute after a quick start. Whether this was successful or not was evaluated within the scope of an expert assessment on behalf of the Executive Board. This evaluation yielded a very positive result, so that the German Federal States Commission was able to confirm for the Fraunhofer Institute for Cell Therapy and Immunology IZI the transfer to basic funding of the Fraunhofer-Gesellschaft. This is surely the most important of last year's issues and as it is the outcome of a collaborative effort of all employees we can now all share our pride and joy. Although our first laboratories were only available in 2006 and the newly constructed institute building only in 2008, we have already contracted research projects amounting to more than 28 million Euros and our annual turnover is approaching 10 million Euros.

What exactly is understood by "basic funding" and what does the Fraunhofer IZI subsist on? Basic funding is an operating grant the Fraunhofer Institutes receive as their share of the government funding given to the Fraunhofer-Gesellschaft. It is calculated on the basis of a formula according to which we, for instance in 2011, receive a little less than 20 percent of our operating costs from the Fraunhofer-Gesellschaft. The previously applicable special financing was granted by the Free State of Saxony on the one hand and by the Leipzig Foundation for Innovation and Technology Transfer on the other hand. With this developmental support they have helped us to stand on our own two feet within the Fraunhofer system. Usually, the Federal States bear a significant load with financing university and non-university institutions. Fraunhofer Institutes, however, allow the regional anchoring of jobs and innovative strength at far more cost-effective terms. We cover more than 80 percent of our personnel and material expenses by conducting contract research for public and private clients. This is done in more than 90 individual projects.

The Fraunhofer-Gesellschaft calls itself the largest European research organization for applied research. What exactly does this mean for the Fraunhofer IZI? Applied science in the field of biomedicine is always aimed at developing new diagnostic and therapeutic methods. This is the major concern forming the basis of all our projects. Moreover, we also wish to help the industry in developing new products and markets with the aid of innovative technology platforms. This is becoming increasingly difficult, especially for small and medium-sized enterprises working in the field of life sciences. As newcomers in the research market, our first industrial projects were comparatively small and although we have up to now contracted more than 40 research contracts from the industry the respective industrial portion of our project portfolio still amounts to only 15 to 20 percent in terms of financial volume.

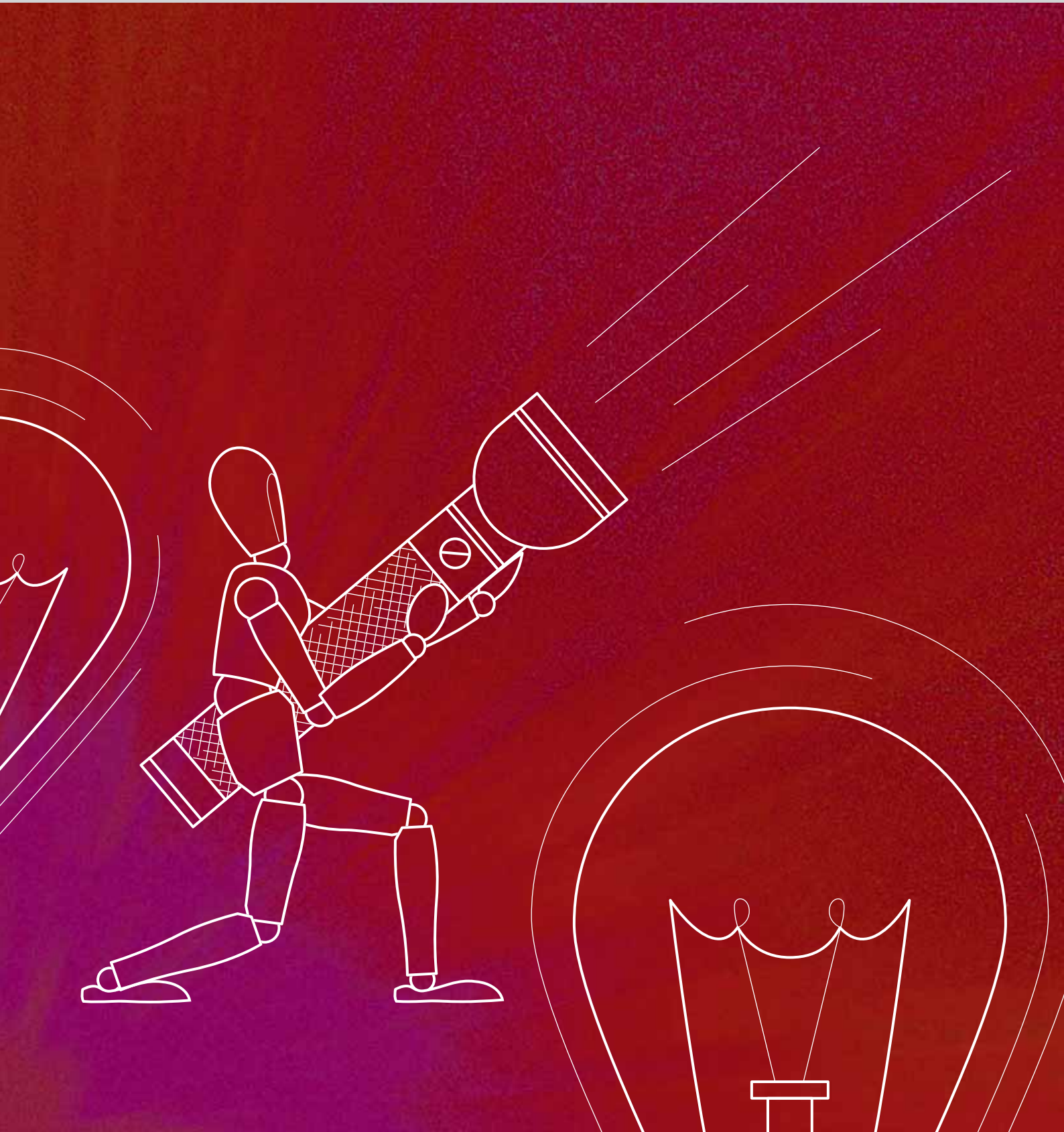
Which of the achievements attained by the Fraunhofer IZI in 2010 make you feel particularly proud? We have entered into our so far largest industrial contract worth more than 1 million Euros with an Australian company for which we will conduct the development of a most innovative cell therapy for the treatment of malignant tumors until a manufacturing authorization is granted. This is not only a challenge due to the great distance but also a special achievement by our employees in the Department of Cell Engineering, headed by Dr. Gerno Schmiedeknecht. Within the framework of Europe-wide competition, contracts of this magnitude are only assigned after critical and repeated inspections of the

corresponding on-site conditions. Moreover, we have also succeeded in leading our technology platform for biomarker development by means of non-coding (nc) RNA to the grant of funding in a multistage competitive process within the framework of a Fraunhofer Foundation Project ("Ribolution"). This is a joint project of several Fraunhofer Institutes under the coordinating leadership of the Fraunhofer IZI and Prof. Friedemann Horn. The project has a total worth of about 10 million Euros and aims at identifying new biomarkers, e. g. for prostate carcinoma and chronic inflammatory joint and lung diseases. A third significant milestone for us is the successful application for our first major EU project. In this WINGS project (West Nile Shield Project: Epidemiology, Diagnosis and Prevention of West Nile Virus in Europe), which is also of great importance in terms of research policy, a novel vaccine against the West Nile Virus is being developed under the direction of Dr. Sebastian Ulbert. We have already participated in several EU projects in the past, but this is the first project that we are to take responsibility for in terms of direction and coordination.

In 2010, the Fraunhofer IZI was selected as "Landmark in the Land of Ideas" not once but twice. How did this come about? We received this award within the scope of the nationwide contest "365 Landmarks in the Land of Ideas", which is substantially sponsored by the Deutsche Bank. One of the awards was for the concept "BioCity Campus" according to which an attractive research campus is supposed to be established on the former trade fair grounds in the southeast of Leipzig. Substantially, we owe this success to Dr. Wilhelm Gerdes, who has also contributed to another innovation award given for a novel miniaturized diagnostic platform. The issue here is the development of a highly sensitive measurement system for laboratory values that shall be available within a very short period of time right at the patient's bed. The device is supposed to be hardly larger than the small calculating and printing machines carried by the ticket inspectors of the German Railways. In order to develop and exploit this concept we supported an outsourcing project from the institute in the past year.

You mentioned the EU project "WINGS" for the development of a vaccine against the West Nile Virus. What is the role of the European Union in research funding of the Fraunhofer IZI? With its framework programs the European Union advances the networking of research groups all over Europe. Beforehand, the issues of highly comprehensive significance are determined in a very elaborate procedure. Subsequently, there is very fierce competition among different European consortia for the highly prestigious EU projects. The projects are based on international contracts and both drawing up these contracts and Europe-wide coordination are particular challenges for the project management. Besides, the European Union is also an important financer of our construction projects. Sixty percent of the financial resources for our main building as well as for the extension building, the latter still under construction, come from the European Fund for Regional Development (EFRE). In order to remain involved, the city of Leipzig and the Free State of Saxony invited EU commissioner Dr. Johannes Hahn to Saxony in 2010. In form of a reference project by the Free State of Saxony, we were given the pleasure of presenting to him how profitably the European funds had been invested. In this respect we are also pleased and satisfied to give credit to our region and the Free State of Saxony with our performance record.

HIGHLIGHTS 2010



FIVE YEARS OF FRAUNHOFER IZI

In 2010 the Fraunhofer IZI celebrated its fifth anniversary and looks back on a successful development. After the positive evaluation, the Institute is now a fully-fledged and permanent institution of the Fraunhofer-Gesellschaft as of January 1, 2011.

Positive evaluation of the Fraunhofer IZI

Following a 5-year development phase, the institute was evaluated and assessed in July 2010 by a commission of renowned experts in the fields of science, economy and politics. The result was eagerly awaited and turned out to be most positive. "With its research findings, the Fraunhofer IZI shows that it is well positioned amongst international competition. In a biomedically / biotechnologically and entrepreneurially strong environment, the Fraunhofer IZI has found a good basis for a sustainable development and for earning an international reputation", as Prof. Dr. Dr. Sabine von Schorlemer, Saxon State Minister for Science and the Arts, commented the result.

Hence, the institute has arrived at a significant milestone. The positive evaluation results in the institute's transfer to the Fraunhofer-Gesellschaft's regular mode of financing. While the start-up financing was substantially covered by the Free State of Saxony and EU funding, now 90 percent of the basic funding of the institute are covered by the Federal Government and the remaining 10 percent by the Free State of Saxony. The basic funding is calculated on the basis of the number of employees, the institute's turnover as well as attracted economic revenues and EU funding.

With the transfer to basic funding, the Fraunhofer IZI now also has the possibility to participate in internal support programs of the Fraunhofer-Gesellschaft, which in turn leaves the institute more opportunities for the implementation of innovative ideas. Moreover, the institute's flexibility with respect to development of research infrastructure, acquisition of equipment and building projects is increased as it can now establish its own investment budget.

The institute's development

On April 29, 2005, the Day of Immunology which was once established for all of Europe, the Fraunhofer IZI was founded in Leipzig. The first experimental work was carried out in the Max Bürger Research Center of the University of Leipzig. In the same year, the first laboratories in the Leipzig BIO CITY were rented and put into service. Renting, extending and equipping 1,500 m^2 of laboratory and office space was a logistical challenge for all parties involved, as was designing, planning and implementing the 450 m^2 clean room facility, which was put into operation as early as summer 2006. Finally, on September 22, 2006, the foundation stone for the institute building was laid. After only eight months of construction time the shell of the building was completed and the topping-out ceremony could be celebrated in May 2007. By spring 2008, the interior construction and equipping was completed and in April the migration from the BIO CITY to our new laboratories and offices ensued. On June 27, 2008, the new main building of the Fraunhofer IZI was ceremoniously opened and presented to the public. In parallel, the planning for the first extension building was already in progress, whose foundation stone was laid on September 23, 2009, and which is due to be put into service in spring 2012.

The institute's growth, however, is not only expressed in the construction of buildings. At the end of the foundation year 2005 the Fraunhofer IZI had 16 employees. Only one year later there were already 71 and in December 2007 as many as 109 employees. Even in the years of the economic crisis, 2008 and 2009, the number of employees could be increased to first 136 and eventually 158. With the annual closure 2010 the number of employees had increased tenfold in relation to the year of foundation. At the beginning of 2011 the institute now has 169 employees, with a tendency for further growth. The institute's operating budget has also been increased from 475,000 Euros to just under 9 million Euros within the five years since 2005. The Fraunhofer IZI looks back on a successful history of five years of development and, after the positive evaluation, we look to the future with high expectations.

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6TH INTERNATIONAL SYMPOSIUM ON NEUROPROTECTION AND NEUROREPAIR

With the International Symposium on Neuroprotection and Neurorepair the Fraunhofer IZI extends its spectrum of scientific events.

The Fraunhofer IZI is eager to provide an intense scientific exchange. Beside the annually held Fraunhofer Life Science Symposium and the biennially organized World Conference on Regenerative Medicine, the institute participated in an important neuroscience meeting, for the first time as the leading organizer. Thus, the sixth International Symposium on Neuroprotection and Neurorepair was substantially arranged by Dr. Johannes Boltze, Alexander Kranz and Daniel-Christoph Wagner of the Department of Cell Therapy. Together with Prof. Dr. Georg Reiser of the Otto-von-Guericke University in Magdeburg and Prof. Dr. Klaus Reymann of the Leibniz Institute for Neurobiology experts from all over the world were invited to Rostock-Warnemünde to discuss the latest findings on the protection and regeneration of the nervous system. Altogether, 250 scientists from 30 nations accepted this invitation. Thirty-five industry partners accompanied and supported the discussion on recent research results within the framework of 62 presentations and 124 poster contributions. In an animated podium discussion, approaches to the translation of fundamental research into clinical applications were debated as heatedly as the potential for improving quality management in the field of stroke research. From fundamental insights into molecular mechanisms right down to the development of neuroprotective agents the program offered a broad and exciting spectrum of topics around the protection of the nervous system.

From May 2 to 5, 2012, the successful event will be continued in Potsdam.

Further information is available at www.neurorepair-2012.de

1 *Podium (left to right): Prof. Wolf-Rüdiger Schäbitz, Prof. Ulrich Dirnagl, Prof. Olle Lindvall, Prof. Gary Steinberg, Prof. Frank Emmrich, Prof. Marc Fisher.*

2 *Congress Center of the Yacht Harbor Residence "Hohe Düne" (High Dune).*

COMPANY SETTLEMENT IN SAXONY

Thanks to the successful research cooperation with the Fraunhofer IZI another renowned company has been convinced to settle in Saxony in 2010.

The Australian company Prima BioMed Ltd. and the Fraunhofer IZI have already worked together for some time on the production of an immunotherapeutic for the therapy of ovarian carcinoma.

In this therapy, specific immune cells (monocytes) are obtained from a patient and differentiated into dendritic cells. By means of an antigen (MUC-1), which is present on the cancer cells, the body's own cells are directed against said cells. Subsequently, the immune cells are processed for intradermal application and the final product CVacTM can then be re-injected into the patient. The dendritic cells thus imprinted by the antigen support the body's own immune system by specifically attacking those cancer cells on which there is a particularly strong expression of the antigen (MUC-1). As compared to conventional chemotherapy, this method is significantly more tolerable and is supposed to be applied with other types of cancer later on. With the support of the Fraunhofer IZI, the cancer therapeutic developed by Prima BioMed Ltd. is supposed to be made ready for the market and produced for clinical trials in Europe.

Prima BioMed Ltd. is already the third international company that has come to identify Saxony as an attractive research location via its cooperation with the Fraunhofer IZI. In 2009 the Fraunhofer IZI accompanied two cooperating companies in establishing subsidiaries. The Italian biotech company I.M.S. Innovative Medical Solutions S.r.l. founded the stem cell bank InnovaStem GmbH. The Canadian pharmaceutical company Nuvo Research Inc. also founded a subsidiary and since then develops agents for the treatment of allergic rhinitis and rheumatoid arthritis in cooperation with the Fraunhofer IZI.

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. The Fraunhofer Institute for Cell Therapy and Immunology IZI is working on meeting the demands made on health and quality of life by developing new products for the regeneration or replacement of functioning organs, for monitoring the processes involved and for specifically controlling the immune system.

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.

The institute's tasks

The institute comprises the four departments of Cell Engineering, Immunology, Cell Therapy and Diagnostics and New Technologies. Assigned to these departments are a total of 15 units having a broad spectrum of competencies and qualifications.

The institute's spectrum of services is aimed at specific problem solutions at the interfaces of medicine, biosciences and engineering.

With this, the Fraunhofer IZI addresses not only the biomedical industry, including pharmaceutical and biotechnological companies and diagnostic laboratories, but also hospitals and research facilities.

Our core competencies are concentrated in the field of regenerative medicine, which in addition to the development and testing of new agents also specifically includes cell therapeutic approaches to the regeneration of dysfunctional tissues and organs through to biological replacement with tissues cultivated *in vitro* (tissue engineering). For an unproblematic engraftment of these tissues it is necessary to detect cellular and immunological mechanisms of defense and control and to integrate them into the development of methods and products. Around these core competencies a large variety of tasks for new products and methods arises. The institute is strongly oriented towards the hospitals and takes on quality testing, the production of clinical test samples according to GMP guidelines and contracted clinical trials. In addition, we support our partners in obtaining manufacturing and marketing authorizations.

IN CONVERSATION WITH ADMINISTRATION MANAGER PATRIC NITZ

Our employees' competence and creativity are the driving force and engine of our institute.

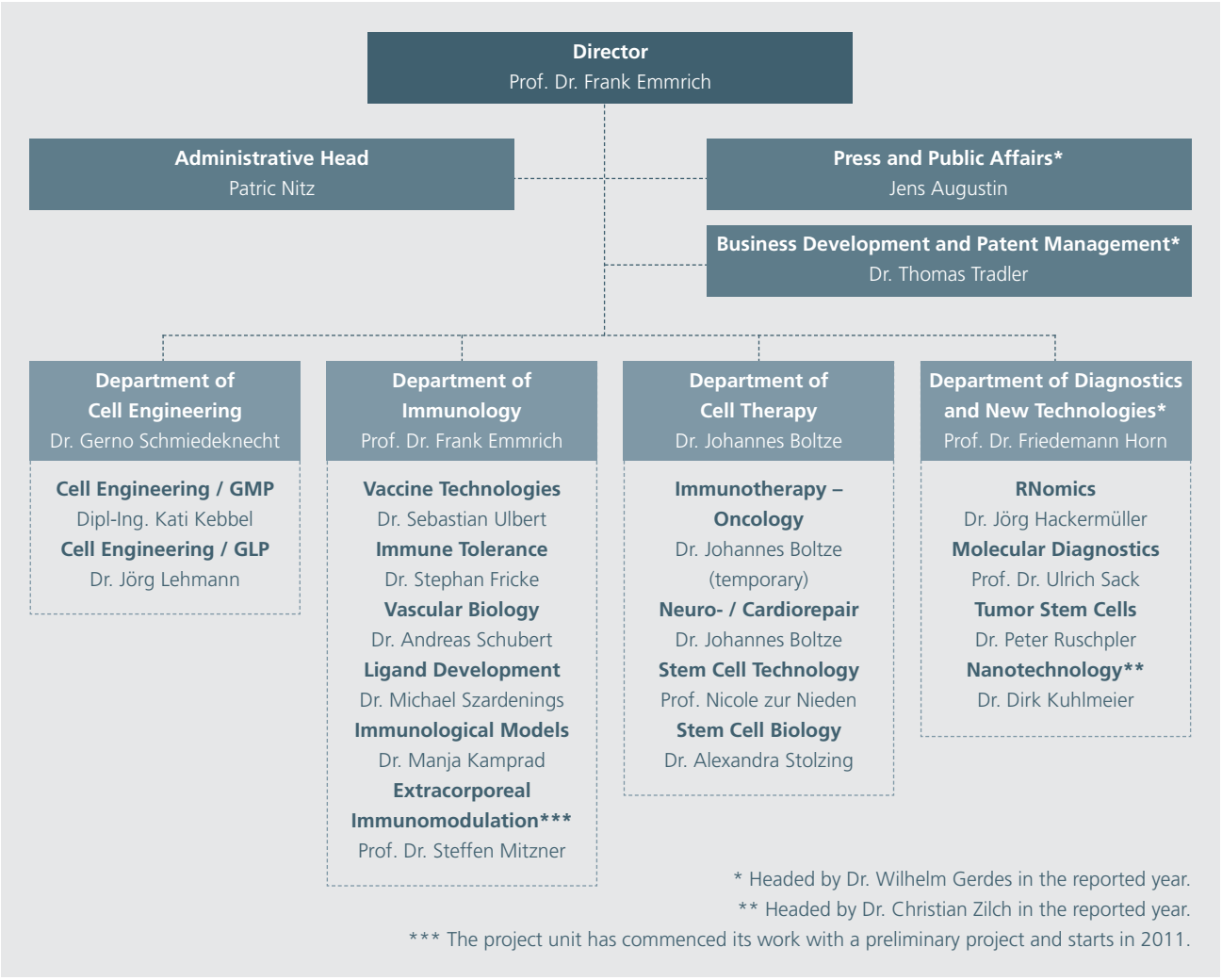
At present, the lack of skilled workers in Germany is intensely debated. In what respects is the Fraunhofer IZI affected? The lack of skilled workers, in particular of engineers and natural scientists, especially affects the developmentally and scientifically oriented sectors. As our personnel recruitment during the past year has shown we are also aware of the first signs of this development. It is one possibility to enhance the recruitment of skilled workers from foreign countries, even though the international market for highly skilled workers is most competitive. Further measures are the intensification of university marketing, the support of selected junior scientists by providing financial aid for tuition costs and the establishment of a dual career network in cooperation with other regional research facilities. Moreover, getting people interested in public research is not an easy task. We believe that this is due to the fact that the industry offers higher starting salaries than our pay scale allows. But the Fraunhofer-Gesellschaft is more flexible than some would think and offers substantial performance-oriented bonus systems as compensation.

From your point of view, what are the institute's administrative accomplishments? The administration has by now mostly optimized the internal and external interface processes and has stabilized its team structure, so that strategic projects like fund raising, university marketing, apprentice training and tutoring students of dual programs can be approached in 2011.

In 2010 the shell of the extension building was as good as completed. What does this extension of the institute mean to you? The extension building comprises urgently needed complementary infrastructure and technical equipment (e. g. further clean rooms) which are required for the acquisition and execution of major industrial contracts. The extension building rounds off our spectrum of services and substantially increases our marketability. If circumstances allow, we would like to retain the option of a further extension building. Our hitherto acquired industry contracts prove that we are capable of attracting the interest of the market leaders in the field of cell-based applications. It goes without saying that we also must have the required machinery and equipment at our disposal.

ORGANIZATION

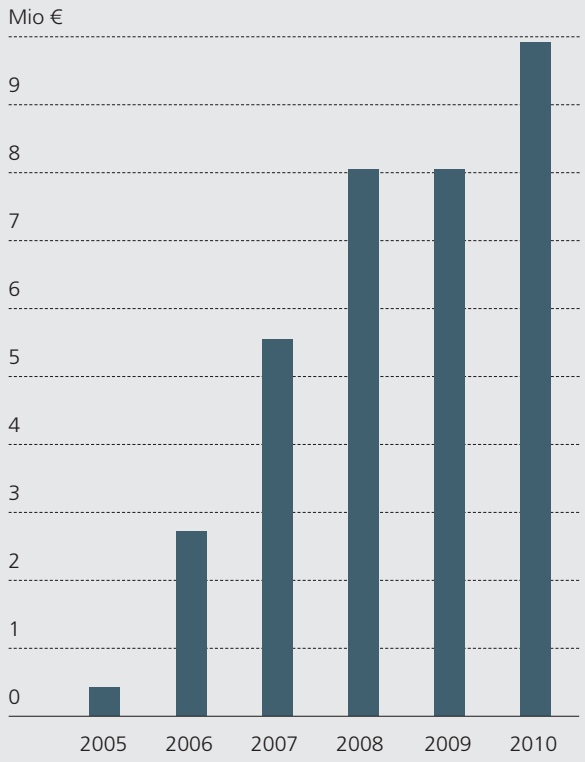
The institute comprises four departments which are in turn organized into different units. Our scientific employees are supported not only by the administration but also by the two executive departments "Press and Public Affairs" and "Business Development and Patent Management".



* Headed by Dr. Wilhelm Gerdes in the reported year.
** Headed by Dr. Christian Zilch in the reported year.
*** The project unit has commenced its work with a preliminary project and starts in 2011.

THE INSTITUTE IN NUMBERS

Financial volume

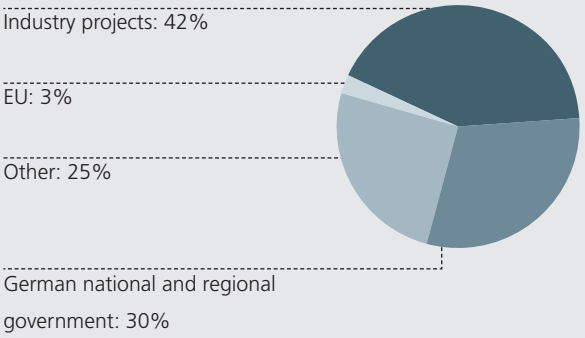


Overview of the projects

	number 2010	volume 2010
German national and regional government	25	4 558 000 €
EU	2	135 000 €
Industry projects	35	1 790 000 €
Other	21	1 304 000 €
Total	**83**	**7 787 000 €**

Overview of the projects

Number of projects



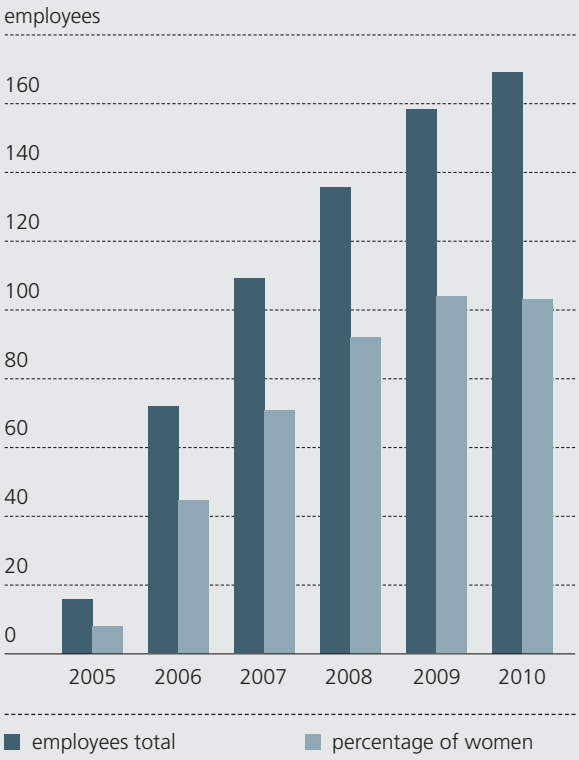
Budget

According to plan, the operating budget was reduced to the project volume this year, i. e. all internal research projects were terminated or continued through external projects, with the result that all of the special funding provided by the Free State of Saxony could be used for compensation measures. Thus, the institute reached a balanced budget at the end of 2010 and will be incorporated into the 90:10 funding by the federal and state authorities as a full-fledged institute as of January 1, 2011. The institute receives basic funding of about 15 to 20 percent of the operating budget, but also has to take over investments for equipment and machinery.

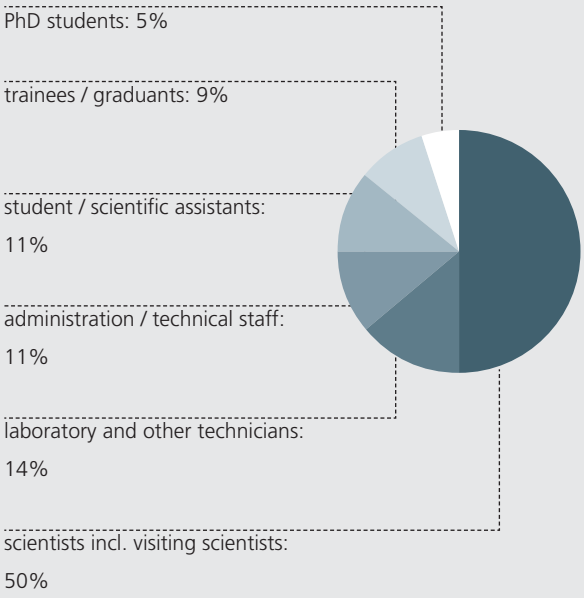
Projects

Meanwhile, the number of projects in the industrial sector distinctly outweighs that in the federal and state sector, but still does not express itself in project volume. The reason is that there are mainly small and medium-sized enterprises in the field of life sciences, with the result that the average project volume in this sector is about 50,000 Euros. One significant success, however, was the acquisition of a major project in the seven-figure range that is realized in cooperation with an international partner. Our visibility all over the world has thus increased and already led to follow-up requests and contract negotiations, which gives us reason to expect further major contracts from foreign countries.

Employees



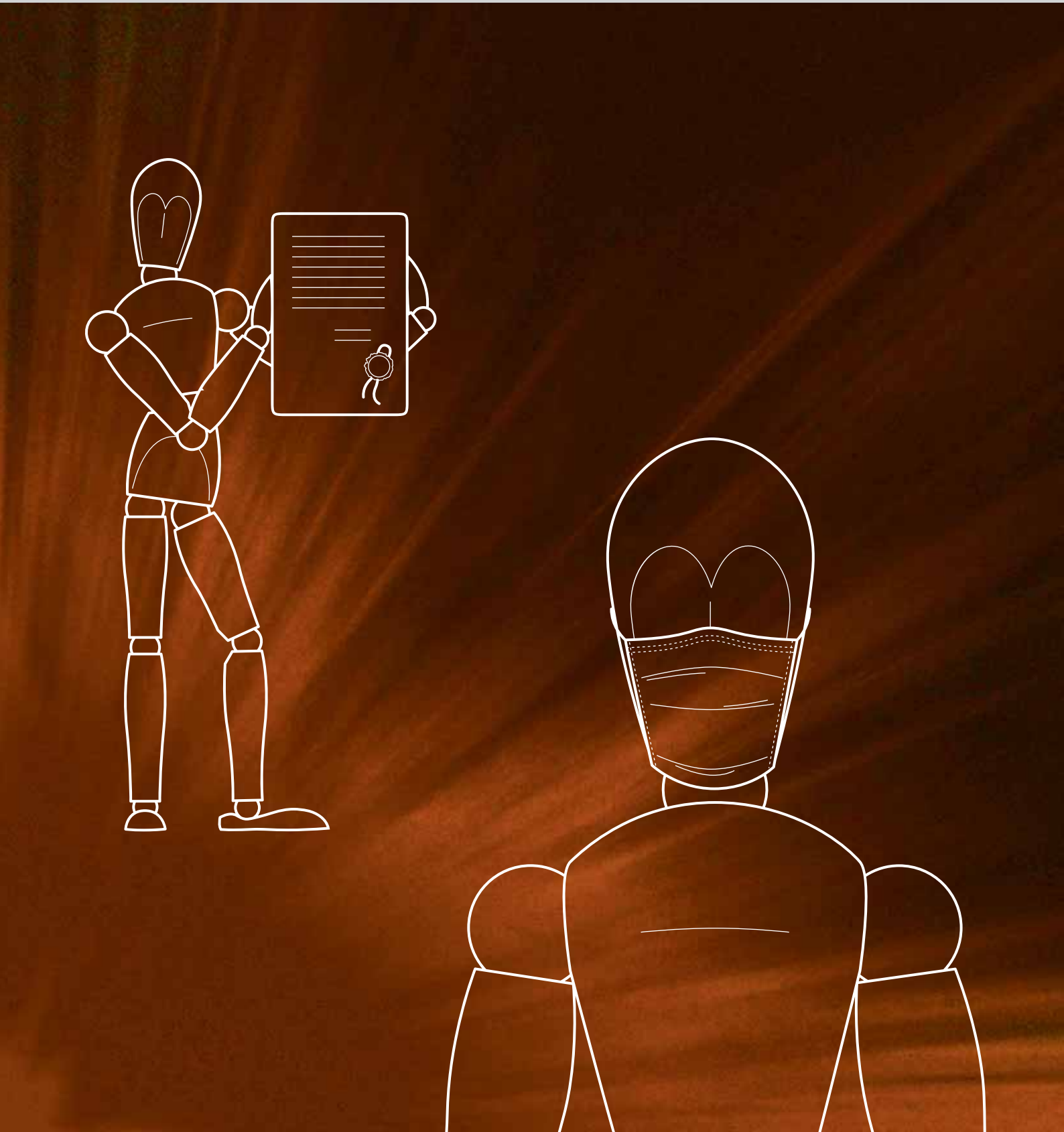
Workforce composition



Human resources

After 5 years of laying the groundwork the composition of our staff is now balanced and the proportion of scientists amounts to 50 percent (35 percent in 2009), including guest scientists from other research and education facilities working and researching in close cooperation with our institute. We can offer optimal support to doctoral students, constituting a proportion of 5 percent (10 percent among scientists), and our staff ratio for infrastructural tasks has arrived at a healthy balance of 11 percent (13 percent in 2009) in relation to the research sector. Our scientific non-professorial teaching staff was consolidated from 13 to 14 percent and the number of assistants / trainees / graduate students etc. was in turn reduced from 28 percent to 20 percent. Our work has become more professional, which complies with our demands made on the processing of clients' orders.

CELL ENGINEERING



IN CONVERSATION WITH DR. GERNO SCHMIEDEKNECHT

Which of the projects that you have managed in 2010 do you consider particularly important? In my opinion, the development project carried out with the Australian biotechnology company Prima BioMed Ltd. is of the utmost social relevance. The project aims at the production and clinical testing of the autologous cell-based immunotherapeutic Cvac™ for the therapy of ovarian carcinoma. The Cell Engineering GMP Unit takes over the transfer of the manufacturing process from Australia to Europe and the subsequent provision of the investigational medicinal products. As there are hardly any effective therapy options for ovarian carcinoma to date it is a great and very exciting challenge to be involved in the transfer of new therapeutic approaches to clinical practice and to contribute to alleviating the suffering of affected patients in the future.

Over the last months, stem cell research has hit the headlines with various promising stem cell applications: hair follicles were grown from stem cells, nerve cells were produced from skin cells for the first time ever, stem cells were to differentiate to retinal pigment epithelial cells to be injected into patients suffering from macular degeneration. What is in the focus of your attention? The main focus of the Department of Cell Engineering is not only in the field of stem cell research or the production of stem cell-based products for clinical testing. We rather consider it our hallmark to work on the broadest possible field of topics regarding cell-based products in our modern clean room facility and the associated quality control and development laboratories. Our service and project partner spectrum comprises various product developments including, for instance, autologous epidermal equivalents from hair root stem cells, autologous stem cell preparations from umbilical cord blood or bone marrow and autologous dendritic cells for cancer therapy.

One special feature of your department is the clean room facility. How much of its capacity was utilized in 2010? What would be your preferred project to be carried out with this facility? The clean room facility of the Fraunhofer IZI reached a capacity utilization rate of one hundred percent by the end of 2010. Until the new facility is completed in 2012, only minor new projects can be realized in the existing facility in a time-dependent manner. The facility is completely oriented towards the manufacture of investigational medicinal products for cell-based therapeutics, so-called advanced therapy medicinal products. In this sector, we are capable of projecting nearly all fields of topics in terms of available technology and cumulative expertise. I would be pleased if we could work on a project in the field of embryonic stem cells at some future point in time, provided that this technology will reach Europe and Germany after – hopefully successful – clinical trials in the USA, conducted by the Geron Corporation.

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From left to right:
Dr. Jens Knauer,
Dipl.-Ing. Kati Kebbel,
Dr. Jörg Lehmann,
Dr. Gerno Schmiedeknecht.

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
- 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 52.

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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, cancer vaccines). 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

The unit focuses on three main topics: 1) Planning and conduct of immunotoxicological and immunogenicity test studies under GLP *(in vitro)* and GLP-analogous *(in vivo)* conditions. This also includes the development, establishment and validation of new *in vitro* and *in vivo* models. 2) Identification and validation of new protein biomarkers for the diagnosis and therapy of chronic inflammatory diseases, tumor diseases and for the sector of veterinary medicine / animal breeding. 3.) Development and optimization of methods and techniques for the diagnostic detection of protein biomarkers and for the separation of cells. This includes the development, manufacture and modification of monoclonal antibodies as well as the participation in the development of analytical equipment and cell separation robots.

PROJECTS

Ultrasensitive detection of protein biomarkers in exhaled breath condensate for the non-invasive early diagnosis of bronchial carcinoma

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Problem: Every year, about 50,000 people in Germany develop lung cancer. Carcinomas of the lung are thus the third most frequent type of cancer in Germany. The Leipzig "WK-Potenzial Bronchialkarzinom" (Growth Center Potential, Bronchial Carcinoma) is therefore working on a technically innovative solution for the early diagnosis of lung cancer.

The early recognition of lung carcinomas, which is of crucial importance for optimal chances of cure, is regarded as very problematic as it is difficult to discern between chronic inflammatory and tumor-associated conditions at an early stage of the disease. In addition, the currently available examination methods are associated with substantial stress for the patients. This applies to X-ray methods with respect to radiation exposure as well as to inspections of the respiratory tract by means of a bronchoscopy, which is often associated with lung lavage or the removal of tissue samples from the lung.

Approach to solution: One alternative to these conventional diagnostic methods is the detection of specific protein biomarkers for bronchial carcinoma in exhaled breath condensate. Over the past years, this method was developed by scientists of the Leipzig University Hospital (units led by Prof. Dr. Hubert Wirtz and Prof. Dr. Ulrich Sack) and the Leipzig Fraunhofer Institute for Cell Therapy and Immunology IZI (unit led by Dr. Jörg Lehmann).

Applicabilities: Within the framework of the initiative "WK-Potenzial" (Growth Center Potential) an equipment platform for the routine laboratory diagnostic application of the method in cooperation with the regional companies Compart Umwelttechnik Weißenfels and GESA Automation Teuchern is now to be developed in order to produce a prototype.

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Support for the establishment of a stem cell bank

In the summer of 2009, the Italian-German company InnovaStem GmbH was founded in Leipzig. The InnovaStem GmbH pursues the establishment of a novel stem cell bank by depositing adult stem cells from different neonatal tissues like umbilical cord blood, umbilical cord (Wharton's Jelly) and placenta. With the support of the Fraunhofer IZI, a comprehensive quality assurance system according to the EU GMP guidelines was first arranged and all required process-specific documents were compiled, e. g. instructions / protocols for manufacture, product specification and test instructions / raw data test protocols. After successfully establishing all quality controls and processes for stem cell isolation and cryopreservation, a validation of the analytical methods and the entire manufacturing process was conducted. These working steps formed the basis for a successful inspection by the pharmaceutical supervisory authority and the subsequent grant of a first manufacturing authorization pursuant to section 13 of the German Drug Act for stem cells from umbilical cord blood.

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Development and validation of methods and application protocols for the practical application of the second generation cell separation robot CellCelectorTM

The directed separation of cells is of great importance in many sectors of cell biology. Owing to the enormous development in the field of cell therapy and regenerative medicine over the past decade the separation of specific cell populations from *in vitro* cultivated stem cells or other primary cells has attained great significance. Methodological and technical innovations in the field of cell separation are therefore very important. In the form of the first generation cell separation robot CellCelectorTM, the company AVISO Mechatronic Systems has developed a remarkable equipment system whose original configuration, however, was not optimal for many cell biological problems, e. g. for the harvest of hybridoma clones. Thus, two main objectives were pursued in this project:

– the definition and evaluation of features for quality assurance in the cell separation process in the form of specific standards for the technical realization in equipment development
– the development and pre-validation of specific application methods for the implementation of the CellCelector™.

1 *Isolation of stem cells from umbilical cord blood in the Sepax® cell separation system.*

2 *Alternative to manually harvesting hybridoma clones: the CellCelector™.*

Process transfer and manufacture of the immunotherapeutic Cvac™

Initial situation: The Australian biotechnology company Prima BioMed Ltd. is planning the conduct of a large-scale clinical trial for testing the safety and efficacy of their immunotherapeutic Cvac™. Cvac™ is a cell therapeutic based on autologous dendritic cells (advanced therapy medicinal product) for the treatment of ovarian carcinoma that has been and is still being employed in first clinical trials. As part of the project, the established GMP manufacturing process including quality controls shall initially be transferred from Australia to Leipzig, thereby adapting it to the basics of European law. The aim is the grant of a Cvac™-specific manufacturing authorization pursuant to section 13 of the German Drug Act issued by the responsible pharmaceutical supervisory authority. Following the grant of the manufacturing authorization, the focus shall be on manufacturing, quality control and provision of investigational medicinal products.

Approach to solution: The issuance of all documents required (e. g. instructions / protocols for manufacture, product specification, test instructions / raw data test protocols, specifications) was followed by the production and quality control of several test batches in order to establish the manufacturing process and the associated quality control procedures in the clean rooms and quality control laboratories of the Fraunhofer IZI. The subsequent step is process validation, comprising the production and quality control including complete documentation of three validation batches. Before the process validation, the validation of the analytical methods was carried out, in particular of flow cytometry in combination with absolute cell count, testing for bacterial endotoxins and sterility testing. Furthermore, the qualification of leukapheresate collection clinics is necessary in order to ensure high-quality procurement and testing of the cellular starting material.

Prospects: The application for a manufacturing authorization pursuant to section 13 of the German Drug Act, which was filed with the responsible pharmaceutical supervisory authority (Paul-Ehrlich-Institute, Landesdirektion Leipzig), is currently being examined. The examination of the application documents and the successfully completed validation of the manufacturing process and the analytical methods will be followed by two days of GMP acceptance inspection which in turn, if successful, will be followed by the grant of the requested manufacturing authorization. This official authorization is the basis for providing the cell-based investigational medicinal product for the planned clinical trial and therefore making a significant contribution to the transfer of this novel therapeutic approach to clinical practice. Moreover, the grant of the manufacturing authorization is an important prerequisite for the permission to conduct a clinical trial in various European countries, which has to be applied for by the sponsor.

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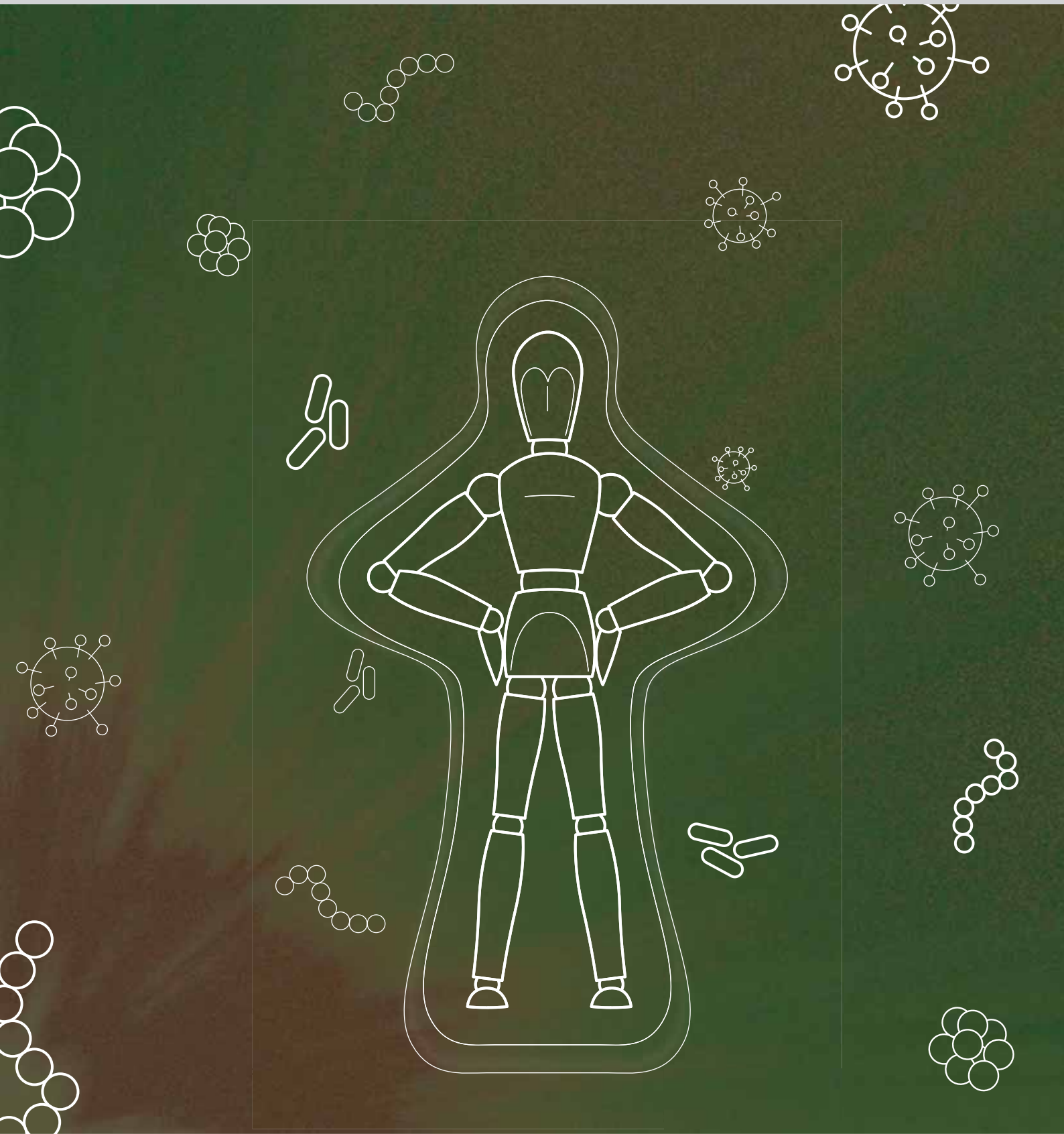
1 *Cell separation with the ELUTRA® cell separation system.*

IMMUNOLOGY



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

In 2010 Leipzig was the meeting place for the German Immunology Community. What is there to report? From September 22 to 24, 2010, more than 1,000 experts convened in the central lecture hall building of the University of Leipzig for the 40th annual meeting of the German Society for Immunology. The event connected three levels of work and discussion, namely conceptional and fundamental research, pathogenetic and clinical research as well as applied research for the development of new diagnostic and therapeutic methods. More than half of all novel agents that are currently undergoing clinical tests are monoclonal antibodies or messenger molecules of the immune system.

In autumn 2009, the Fraunhofer IZI introduced its departmental structure. In what respect has the Department of Immunology developed since then? The Department of Immunology was extensively restructured, competences were bundled and priorities in terms of research and development were defined. The structuring process was successfully completed in 2010. In the months and years to come the department shall be expanded in terms of personnel in order to meet the increasing staff requirements for handling major projects.

What are the department's scientific priorities since the reorganization? We concentrate on applied research in the field of developing peptide agents and inducing immunological tolerance to stem cell grafts. One essential aim is the development of therapeutic antibodies and cell-based strategies for the prevention and treatment of graft-versus-host reactions. Furthermore, we intend to expand our competencies in the field of developing vaccines and diagnostic technologies.

It is every Fraunhofer researcher's aim to transfer his / her own results to clinical application and economic successes. How is this process handled within your department? The individual units were able to file patent applications for numerous technologies and developments in 2010. This applies, in particular, to developments in the areas of vaccine technology, diagnostics and phage display. Following a basic idea and developmental work, patent applications are the first step towards the economic exploitability of a technology. We look forward with confidence to the coming year when the first patents will presumably be granted. One of our inventions that is soon to be out-licensed relates to an innovative immunological assay which is supposed to be fully developed and put on the market by an immunoassay manufacturer from 2011 on.

In retrospect, which project was particularly outstanding and should be mentioned in this place? There are a number of projects that are very valuable to us and, of course, all of them are handled with all due diligence. However, I should like to point out the EU project WINGS (see the following pages) in this context. It is the first major EU project to be coordinated by our institute. Of course, a project of this magnitude also promotes the international visibility of the entire institute and is therefore a significant milestone for us. For this reason, my special thanks go to Dr. Sebastian Ulbert, who is significantly responsible for this success and will coordinate the project over the coming years.

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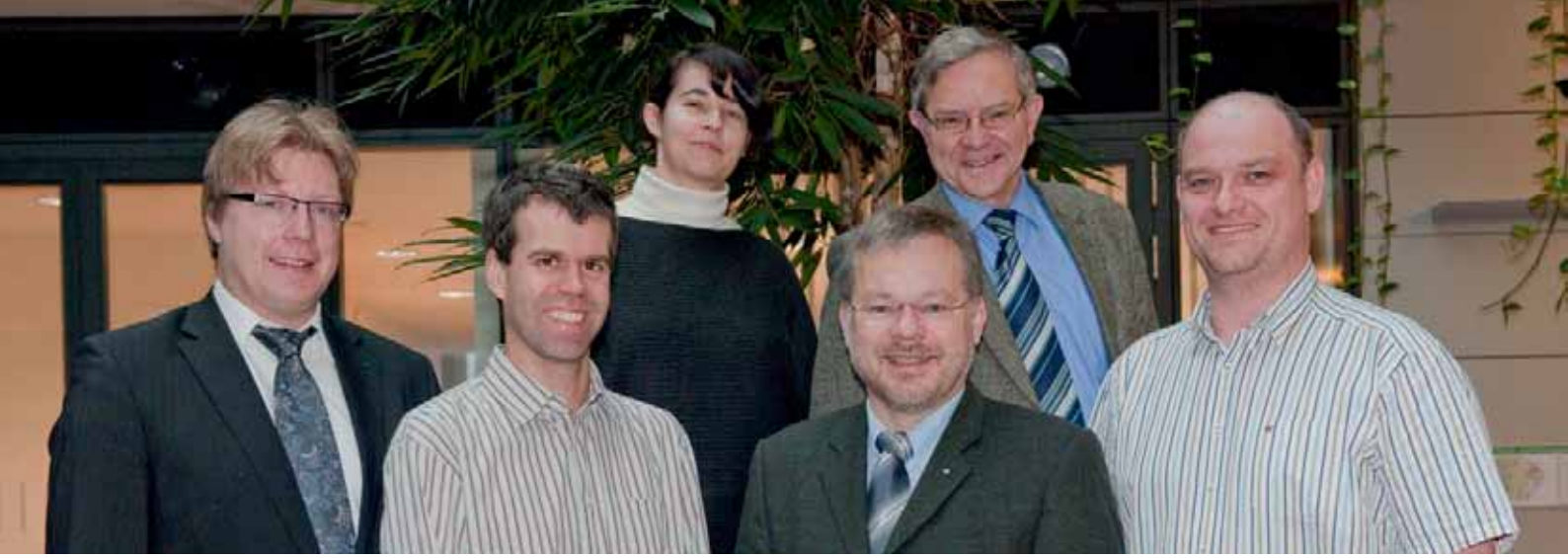

From left to right:
Dr. Stephan Fricke,
Dr. Sebastian Ulbert,
Dipl.-Biol. Nadja Hilger,
Dr. Michael Szardenings,
Prof. Frank Emmrich,
Dr. Andreas Schubert.

Core competencies of the dapartment

- Vaccine development
- Tolerance induction
- Antibody development
- Immunological models
- Phage display of peptides and antibodies
- Rheologic models
- Antimicrobial peptides

A selection of products and services offered by the department can be found on page 52.

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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 immunocompetent 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.

Vaccine Technologies 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

Modern therapeutic and diagnostic approaches demand novel highly specific biomolecules. We develop antibody and peptide ligands with modern combinatorial and proprietary methods, which are under development at the institute. Our goals are the modulation of the immune system, the identification of novel targets, especially on cell surfaces, and the development of potential 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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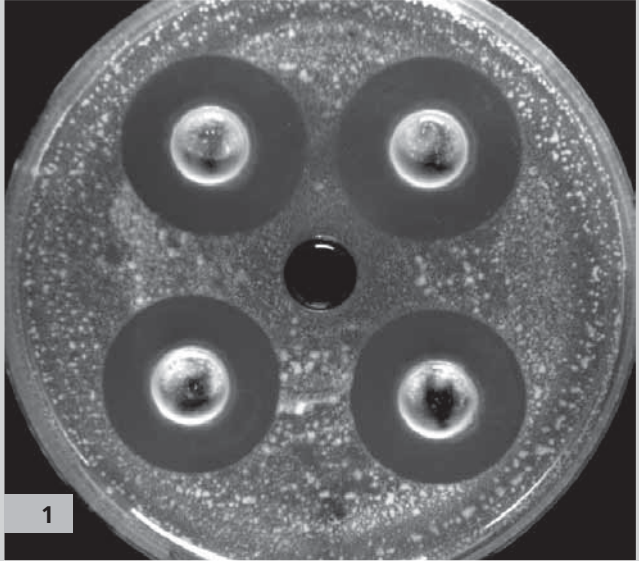

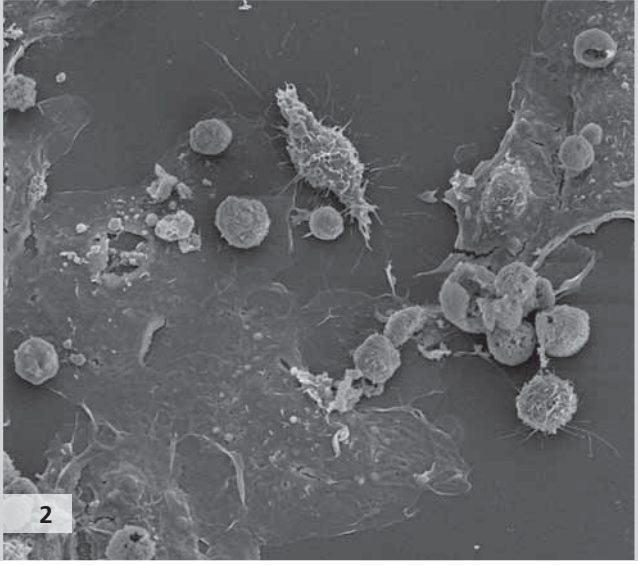

PROJECTS

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Application of antimicrobial peptides for increasing the shelf life of food products

Antimicrobial peptides (AMP) are an integral component of the defense systems of animals and plants. Their range of activity comprises bacteria, fungi and viruses. The intended project aims at the development of suitable peptides that effectively kill germs, in particular those associated with putrefaction, during production processes in the food industry. Thereby, for instance, the shelf life of fresh salads is intended to be increased by at least two days. On the basis of preliminary studies, sequence motifs have been produced from AMP having a known antimycotic / antibacterial activity and their effectiveness against yeasts, mildew and entero-cocci has been tested in an *in vitro* assay. We plan to concentrate, in particular, on short-chain antimicrobial peptides (<20 amino acids) as there are no immunological complications to be expected in case of a later application in association with food products. Five AMP could be identified that have a potent inhibitory effect on the growth of fungi and bacteria. No measurable toxicity to eukaryotic cells could be observed.

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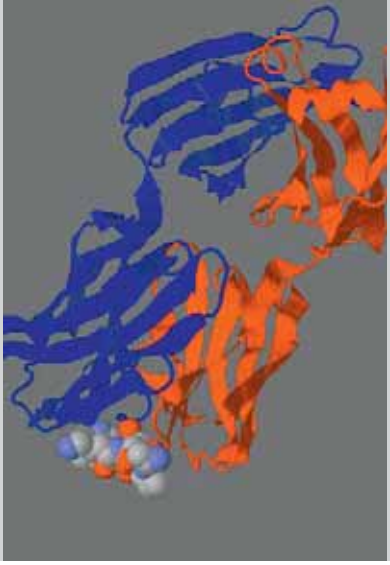
Analysis of new stem cell sources regarding their hematopoietic potential

In this project the emphasis lies on the investigation of new stem cell sources as therapy option for hematopoietic stem cell transplantations (HSCT). These are to be examined concerning their potential for the regeneration of hematopoiesis. The background is that fast hematopoiesis could decrease the risk of complications (e. g. infections, tumor relapse) in immunosuppressed and transplanted patients.

The research unit examined non-adherent bone marrow-derived stem cells (NA-BMC) and developed special competencies in cell culture models and immunological methods (e. g. CBA, ELISpot). By *in vitro* and *in vivo* experiments it could be shown that the mixed cell fraction of NA-BMCs possesses characteristics of hematopoietic and mesenchymal cells and supports hematopoiesis. Using humanized mice with a human CD4 and HLA-DR and a knock-out of the murine CD4 it can be exactly differentiated between donor and receptor cells. Thus, information on the therapeutic effectiveness of new cell stem cell sources can be determined.

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

2 *Analysis of non-adherent bone marrow cells (NA-BMC) by electron microscopy.*



1

Development of tumor therapeutics and antibiotics from plant extracts

About 80 percent of the tumor therapeutics currently in use originate from substances of the secondary plant metabolism. Many tumor diseases (e. g. brain tumors, pancreatic carcinoma) are still difficult or even impossible to cure despite the progress that has been made in developing new chemotherapeutic agents. In close cooperation with naturopathic scientists from Africa substances / extracts from about 20 plant species were prepared which, to some extent, have a potential as new anti-tumor drugs for a potential application in palliative care. First examinations on various cancer cell lines attest the selective effect of the plant ingredients on tumor cells. These data could be verified in experiments in a mouse model. This gives rise to new options for tumor therapy, in particular for brain tumors. Moreover, some plants hold highly effective antibiotic ingredients, in particular in bark and roots, which also have the potential for applications in human medicine.

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Ligand Development

The Ligand Development Unit is using the phage display technology to identify novel peptides and antibodies binding to selected target molecules. Bacteriophage are virus of bacteria which can be engineered to display peptides or antibodies on its surface, which a gene in the particle codes for. Using gene libraries comprising billions of variants we can select and amplify single phage particles with peptides / antibodies having special properties. In addition, 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. So we can claim to have one of the largest peptide libraries presently available worldwide. One of our important general goals is still to generate "Next Generation Libraries", which will exceed even our present peptide phage libraries in variability. This allows us to generate ligands with higher affinity and specificity than those that would be accessible through standard methods. Antibodies and peptides as ligand molecules are used as therapeutics, diagnostic tools and for the affinity purification of proteins or cells.

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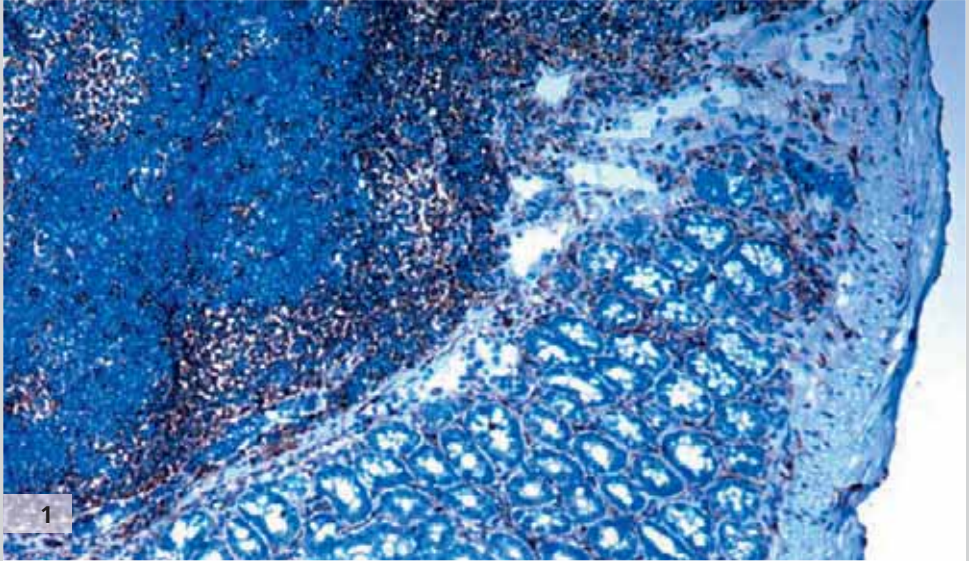
1 *Bark of an African plant from which ingredients were isolated.*



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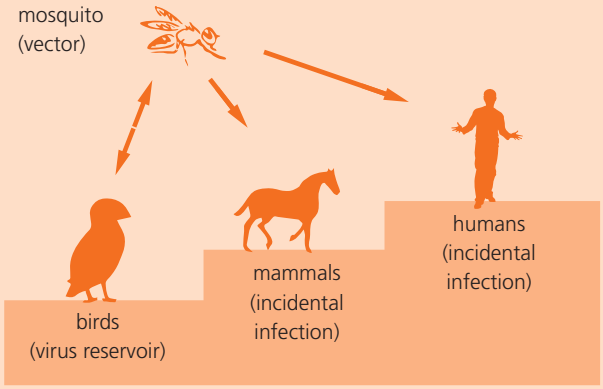
Induction of immune tolerance after transplantation by anti-human CD4 antibody therapy

Background: Hematopoietic stem cell transplantation (HSCT) is often the only curative regenerative treatment for diseases of the hematopoietic system (e. g. leukemia). HSCT is often accompanied by life-threatening complications (bacterial, viral and fungal infections). One of the main complications is the graft-versus-host disease (GVHD) which affects up to 80 percent of the patients. Donor T cells, which are located in the graft, recognize the recipient tissues as foreign and destroy them. Particularly the skin, intestine and liver are affected. Unfortunately, the current therapy options using immunosuppressive drugs (Cyclosporine) or monoclonal antibodies (OKT3®) are very limited, show many side effects and lead to a suppression of the entire immune system of the weakened patients.

Approach to solution: The focus of the project is the development of new therapeutic strategies using human CD4 antibodies. These antibodies should induce immune tolerance after transplantation, in particular hematopoietic stem cell transplantation, in patients and ensure their survival. For this purpose, a murine transplantation model was established in which humanized mice (huCD4+, muCD4-, HLA-DR3+) are used as donors and wild-type Balb/c mice as recipients. To investigate the tolerance-inducing effect, chimeric anti-human CD4 antibodies were investigated *in vitro* and *in vivo* and toxic effects were excluded. The use of human CD4 antibodies leads to a block of the human CD4 receptors on the T helper cells. In *in vivo* experiments this treatment led to a significant reduction of GVHD after HSCT and significantly increased the survival rate of recipient mice.

Potential: Although GVHD is considered as one of the orphan diseases it occurs in transplantations with a high incidence. Thus, it is all the more important to develop new therapies that are applicable in the clinical routine. The strategies outlined here could be a possible new therapeutic option in transplantation medicine. They are simple to perform and less expensive than the conventional treatment of GVHD. Also, the developed humanized murine animal model allows a direct testing of human drugs (e. g., antibodies, Fab fragments, TandAb, ligands) that interact with the human CD4 or HLA-DR3 in mice. The use of human anti-CD4 antibodies is an alternative to current treatment procedures. Perhaps this could also be an important option for patients who do not respond to conventional therapies.

1 *Immunohistology for human CD4 in the gut of humanized mice.*



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Development of a vaccine against West Nile Virus

Background: The West Nile Virus (WNV) infects birds and accidentally also mammals, including humans. The virus causes flu-like symptoms which can turn into severe neurological, even fatal, disease in rare cases. WNV is transmitted via several mosquito species some of which are endemic to Central Europe and Germany. Until 1999, the virus was spread over Africa, Australia and the Mediterranean; however, it was introduced to the USA in 1999. There, WNV has caused over a thousand fatalities among humans. Since 2008, an increasing number of WNV infections have been reported from Northern Italy and Hungary. In 2010, severe outbreaks occurred in Greece (about 40 fatal and 200 hospitalized cases) and around the Mediterranean. Current vaccines are in the veterinary sector. However, these are not yet optimal and there is no human vaccine available.

Approach to solution: Over the last three years a novel WNV vaccine has been developed at the Fraunhofer IZI (funding by the German Ministry for Nutrition, Agriculture and Consumer Protection). The basic principle is DNA vaccination which leads to safe and powerful vaccines. Upon application, the antigens are produced by the cells of the vaccinated individual itself and presented to the immune system. A DNA vaccine is easily modifiable to different antigenic variants (caused by newly emerging viral strains). This is of special importance for a virus such as WNV, which is able to mutate rapidly and to spread via migratory birds. At the Fraunhofer IZI, WNV antigens were cloned, modified and inserted into carrier DNA molecules. This vaccine candidate elicits a specific and strong immune response to the virus. A single injection is sufficient to completely protect animals from an infection with WNV.

Potential: A further spreading of WNV, especially over Europe, has to be expected. Therefore, countermeasures have to be taken in time. In this context, an EU-funded collaborative project, which is coordinated by the Vaccine Technologies Unit at the Fraunhofer IZI, is starting in 2011. Focus of this project is the development of WNV vaccine candidates and diagnostic systems ("West Nile Integrated Shield Project: Epidemiology, Diagnosis and Prevention of West Nile Virus in Europe"). Nine partners from all over Europe and the USA, including companies from the vaccine industry, will work together for 3 years in order to develop vaccine candidates until late-term pre-clinical studies. The DNA vaccine developed at the Fraunhofer IZI will be a core technology in this project. In addition, a diagnostic test will be established which can specifically diagnose a WNV infection, thus eliminating the risk of cross-reactivity with other related viruses.

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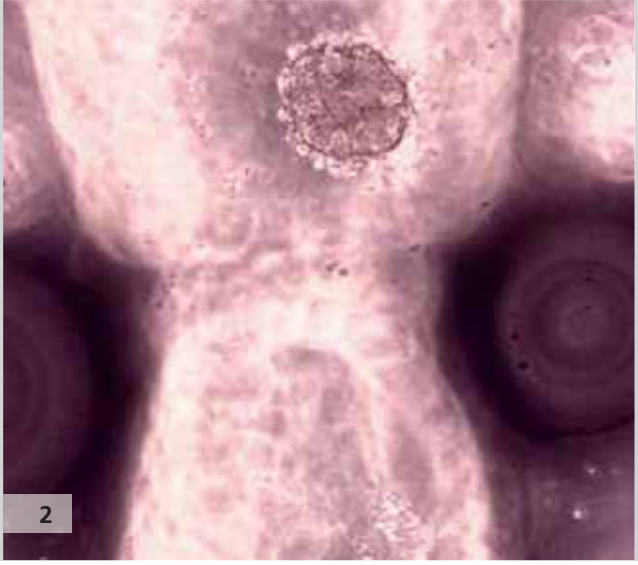
1 *WNV is transmitted by mosquitoes which, next to birds, can also infect mammals.*

1



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PRRSV Diagnostics

The Vaccine Technologies Unit at the Fraunhofer IZI has developed a test for the diagnosis of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in pigs. PRRSV is causing yearly losses in the range of several billions in pig industry worldwide. To control and limit the spreading of this aggressive virus a highly sensitive and accurate detection system is needed. The test developed at the Fraunhofer IZI detects antibodies that are produced in pigs upon infection with PRRSV. A critical advantage over existing tests is that different viral strains can be distinguished. This is of importance as available PRRSV vaccines are strain-specific. Using the test developed at the Fraunhofer IZI the veterinarian can quickly identify the viral strain causing the infection, which enables the use of the correct vaccine to protect healthy animals of the same or neighboring farms. A German diagnostic company plans to finish the development in cooperation with the Fraunhofer IZI and to bring this test to the market in 2011.

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Development of silicon surfaces for the directed differentiation of murine stem cells

In most cases, stem cells are located in tissue niches and exhibit a low metabolic activity. Their differentiation is only initiated by altered conditions (stimuli) in the microenvironment. The exact sequence of processes, however, is mostly unknown. Stem cell differentiation is significantly determined by intrinsic cellular signaling and extrinsic stimulators (cell-to-cell contact, contact between cell and extracellular matrix). Extrinsic signaling can be of a chemical (e. g. growth factors and cytokines) and also of a mechanical (expansion forces acting on cells due to interactions with micro- or nanostructured surfaces) nature. In the present project, a cell culture matrix prototype with a nanostructured surface (e. g. covalent peptide binding on cell culture basis, mechanical structuring patterns) shall be developed which is capable of inducing the differentiation behavior of stem cells in a directed manner.

1 *Infections with PRRSV are a threat to pigs worldwide.*

2 *Cultivation of murine stem cells on microstructured silicon surfaces with the aim of inducing directed differentiation.*

1

Peptide mapping and sera

With the form of phage display applied at the Fraunhofer IZI we are able to identify peptide sequences binding specifically to antibodies from up to 10^{15} peptides. From many slightly different sequences discovered in such experiments we do not only identify the part of a protein that is recognized by a monoclonal antibody but we also learn about the allowed variability of the original sequence. From so many binders it is easy to select those that are most suitable for different applications. In addition, the cross reactivity of antibodies as well as their suitability for the recognition of mutant proteins can be predicted.

Presently, we use this technology to investigate sera from patients with allergies. This may provide novel opportunities to diagnose allergies at a very early stage. This would allow, in particular for children, an early treatment to prevent the onset of severe allergic symptoms.

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1 *Allergies are excessive defense responses of the immune system to otherwise harmless environmental substances, e. g. pollen.*

CELL THERAPY

IN CONVERSATION WITH DR. JOHANNES BOLTZE

What were the most outstanding moments for the Department of Cell Therapy in 2010? For our department as well as for the entire institute the acknowledgement of our previous work in the form of a successful transfer to the Fraunhofer system was a very significant moment and a motivating appreciation of our last five years' work. Another special experience was the formation of a cooperation project together with the renowned Stanford University. In this project, special methods that are exclusively available at the Fraunhofer IZI are intended to help transferring a novel cell therapeutical method to clinical practice. Finally, a future-oriented cell work project, which has also spawned the patenting of a novel method for generating stem cells, could be successfully completed.

Your department organized the "6th International Symposium on Neuroprotection and Neurorepair 2010". Which of the presented developments would you consider as groundbreaking? The most interesting developments are not so much groundbreaking as they are fundamental. It was recognized that excessive expectations of success and hasty commercialization often led to the global failure of actually promising concepts in the past. With our work, the Fraunhofer IZI intend to steer in another direction. A diligent and free-of-assumptions validation of new concepts at an experimental stage allows for more appropriate conclusions on an eventual clinical impact and is helpful in preventing dangerous and costly failures at later stages. Further, exciting progress has been made in the field of clinical imaging. Moreover, numerous clinical studies on the application of stem cell after stroke have been launched, the results of which we will be eagerly expecting over the coming years.

With an eye toward medical industry, which developments is the Department of Cell Therapy going to focus on in the coming years? We are convinced that many costs could be saved and many risks could be minimized if preclinical studies would be designed to match clinical trials in terms of quality. Of course, this makes them more expensive, but it also serves to prevent even more expensive future failures in clinical practice. Therefore, we will not only offer the service of structuring and monitoring studies but also increasingly expand our portfolio of methods to be able to include further diseases in these studies. Moreover, we intend to enhance our imaging capacity as visual monitoring and the visualization of regeneration is becoming more and more important.

The first extension building strengthens the infrastructure of the entire institute. What are the tangible advantages for the work in your unit that arise from the extension? The extension building will finally put us in a position to utilize our own infrastructure. Projects can thus be processed faster, better and with higher quality. Over the last years our temporary accommodation in guest institutes has prevented the successful acquisition of numerous projects merely due to the fact that we as guests always had to stand back behind our hosts' plans. With the transfer to our own working area, this roadblock will be removed.

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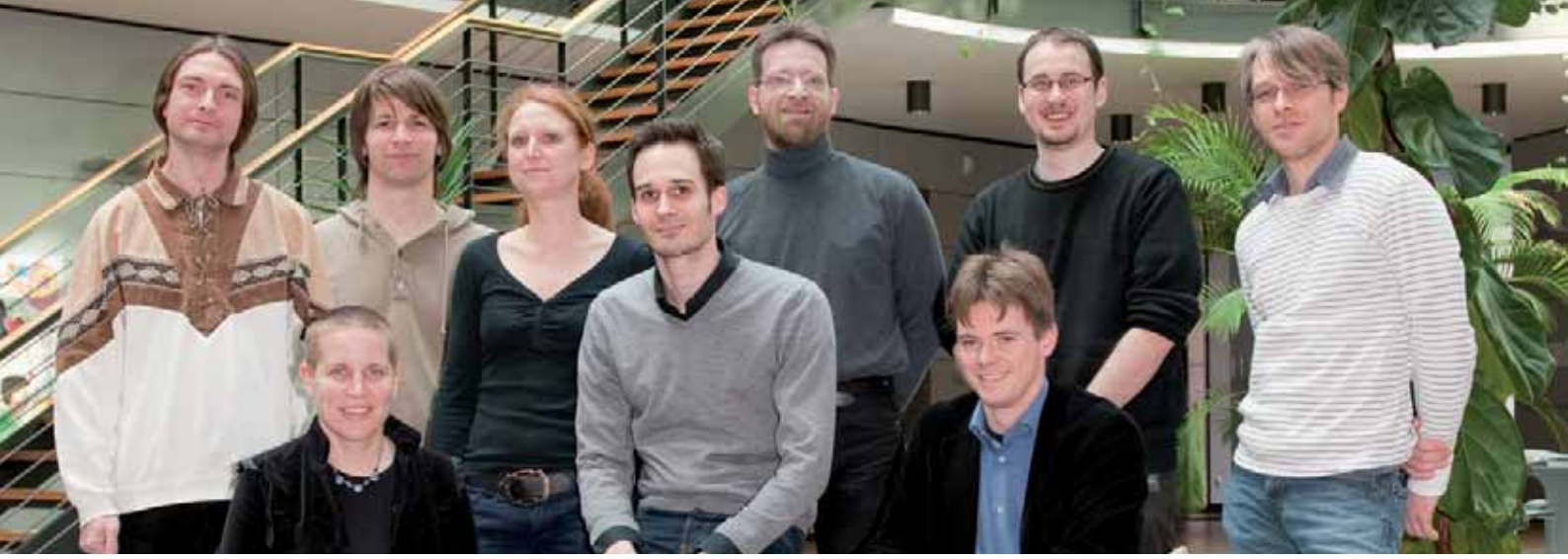

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Dr. Holger Kirsten,
Dr. Myriam Müller,
Daniel-Christoph Wagner M. D.,
Dr. Alexander Deten,
Dr. Johannes Boltze,
Christopher Oelkrug,
Björn Nitzsche D. V. M.

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)
- 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 53.

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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 a genetic test for an early detection of dyslexia is another focal point of the unit.

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Section Preclinical Trials: Our team uses different experimental models of neurological and cardiac disorders for the preclinical evaluation of novel therapeutic concepts. The implementation of rigorous quality criteria provides a successful translation of effective therapeutic concepts to clinical application.

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Section Translational Studies: Experts of the international STAIR committee recommend the additional testing of novel (cell) therapeutic and diagnostic approaches for stroke in a large animal model. The model of cerebral ischemia we established in sheep utilizes state-of-the-art imaging technology (like PET, MRI and CT), behavioral examinations and histological analyses in order to evaluate potential therapies and diagnostics before their application in human medicine.

Section *In Vitro* Studies: The main focus of the unit is on the development of primary cell culture systems. The aim is the development and use of an preclinical *in vitro* model system.

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Section Dyslexia Research: The unit primarily aims to develop an early genetic screening test to allow functional regeneration of dyslexia-related cellular neurological deficits.

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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) it is possible to investigate novel active substances for the treatment of cancers.

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Stem Cell Biology Unit

The unit combines insights from stem cell biology and biogerontology to develop novel strategies in regenerative medicine. We pursue different innovations to "rejuvenate" adult stem cells *in vitro* and *in vivo*, so that these cells can resume their function as promoters of regeneration, particularly in elderly patients.

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Stem Cell Technology Unit

The unit develops high-throughput culture methods for stem cells and optimizes strategies for the differentiation of these cells into diverse mature cell types. We further use these *in vitro* differentiated cells to screen new pharmaceutical compounds and environmental chemicals for their toxic potential.

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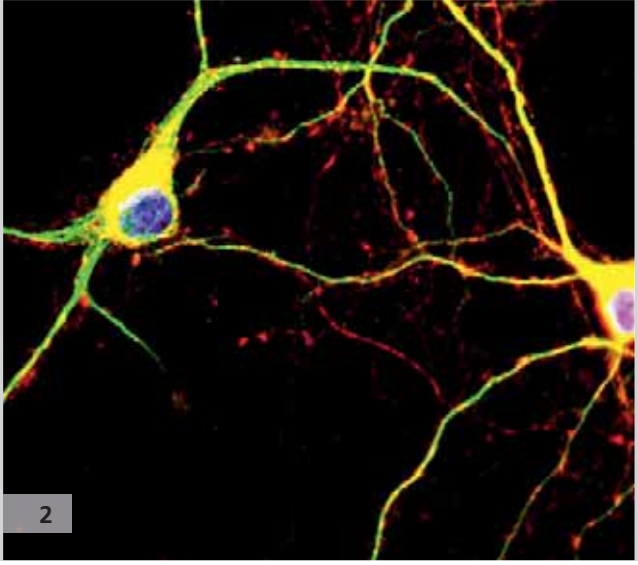

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PROJECTS

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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 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: A) genotyping of an independent cohort B) characterization of the markers by means of functional Magnetic Resonance Therapy (fMRT) and C) 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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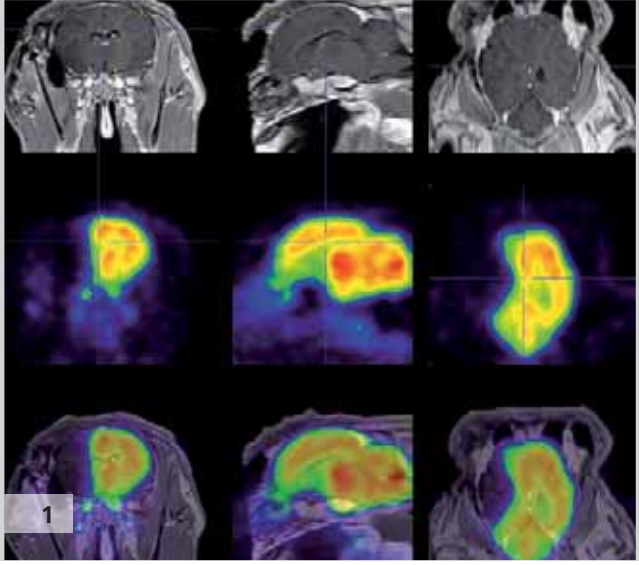
Analysis of neuroregenerative mechanisms using a complex *in vitro* stroke model

The *In Vitro* Studies Unit has developed a multiparametric approach for the quantification and characterization of primary cells within a complex *in vitro* stroke model. We use primary neurons, glia and mixed cultures as model systems which allow a quick, inexpensive and accurately quantifiable detection of vitality parameters. The *in vitro* models are used for the analysis of new therapeutically relevant intracellular processes and as a preclinical system for the analysis of potentially neuroprotective, -regenerative, or cytotoxic substances. Despite intensive research, stroke is still the most common cause of severe disability in this country. Therefore, the analysis of new molecular pathways is essential for the development of therapeutically relevant procedures. Focus of the unit is the analysis of glia cells and the role of mTOR as well as the SUMO / SENP pathway during the regeneration process after stroke.

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

2 *NMDA receptor (green). neurons 6 days in culture. Map2 (neuron, red), DAPI (nucleus, blue).*



Increased cerebral blood flow in a sheep model of stroke

Despite the establishment of specialized care units (stroke units), sufficient treatment of the remaining brain tissue (penumbra) after stroke is limited to only a few hours. Herein, we tested the hypothesis that a selective increase in cerebral blood flow could reduce the cerebral damage. Therefore, an inhaled neuroprotectant was tested under clinical-related conditions in a large animal model of stroke. Stroke was induced in adult sheep by occlusion of the middle cerebral artery. Serial imaging of cerebral blood flow with and without treatment was performed within the next 4.5 hours using highly sophisticated imaging procedures together with our partners (positron emission tomography and magnetic resonance imaging). Inhalative treatment results in a selective increase of cerebral blood flow within the penumbra while the proportion of potentially salvageable brain tissue may be increased.

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Human iPS – Alternative cell sources for producing skin preparations

Skin preparations produced by means of tissue engineering are a great hope for the medical treatment of severe wounds and burns. Moreover, laboratory-grown skin is suitable as a test system for new drugs and agents, which results in a decreasing number of animal experiments. However, to date there is a lack of cost-effective and automatable production systems to meet the increasing need for skin preparations.

In cooperation with its partners, the Fraunhofer IZI develops solutions to problems like limited availability of suitable cells as well as cryopreservation of these cells. This includes reprogramming of human fibroblasts to pluripotent stem cells (iPS) which in turn can be differentiated to skin cells (keratinocytes and melanocytes). These so-called induced pluripotent stem cells are examined for their stem cell characteristics (pluripotency) at the Fraunhofer IZI. Beside that, especially examinations on expandability and ageing processes are in the focus of research.

Another focus is placed on the cryopreservation of the cells. Innovative methods for gentle cell cryopreservation are supposed to ensure as high a flexibility for skin production as possible. Both research and development foci contribute to the production of a sufficient amount of skin preparations for medical application, pharmaceutical testing and research purposes in a manner independent of tissue donations.

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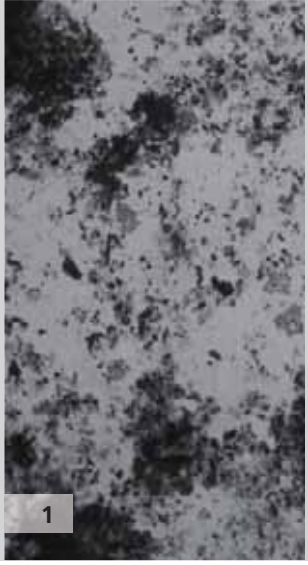
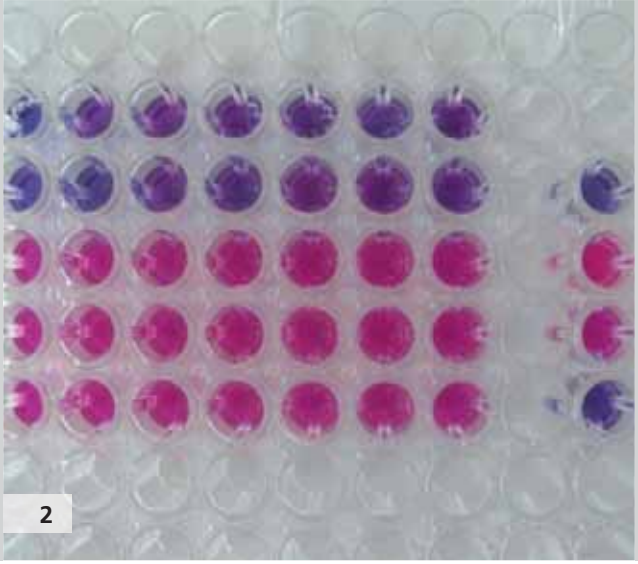
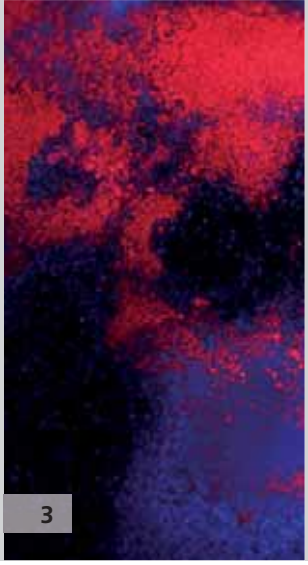
1 *MRI (top) and PET (middle) imaging of acute stroke in sheep; overlay (bottom).*







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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 the best model systems for predicting toxic effects on human patients.

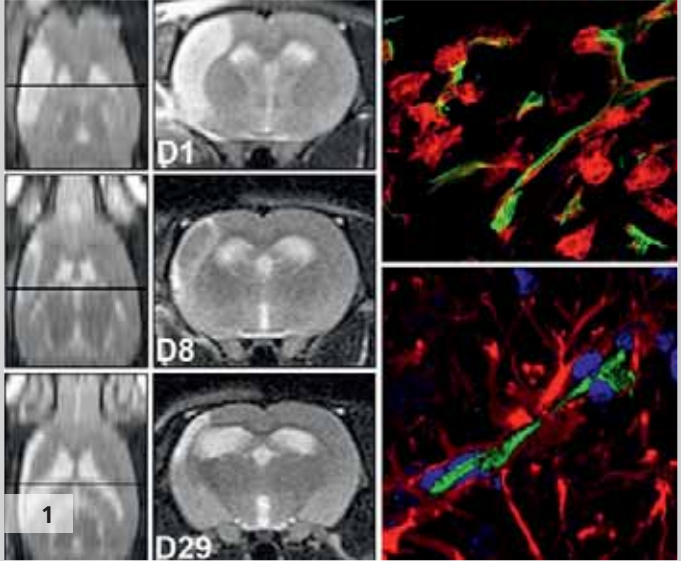
Approach to solution: The Stem Cell Technology Unit's objective is to identify new endpoints for the EST that allow for predicting toxic effects on skeletal development and increasing the general predictivity of this assay. Therefore, we characterize the suitability of embryonic stem cells of the marmoset 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.

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.*



Multimodal approach for regenerative stroke therapy

The aim of the joint research project is to establish a novel therapeutic concept for ischemic stroke. Transplantation of autologous bone marrow cells will be combined with the repeated administration of G-CSF. We hypothesize that transplanted exogenous as well as mobilized endogenous bone marrow cells migrate towards the ischemic brain injury. Hence, these cells might mediate neuroprotective and neurorestorative effects, thus supporting the damaged brain towards an improved recovery. However, the endogenous mobilization of bone marrow cells is delayed, whereas the efficacy of transplanted cells is potentially limited to a confined time window. An optimal temporal conjunction of both approaches is necessary to achieve a maximized synergistic effect.

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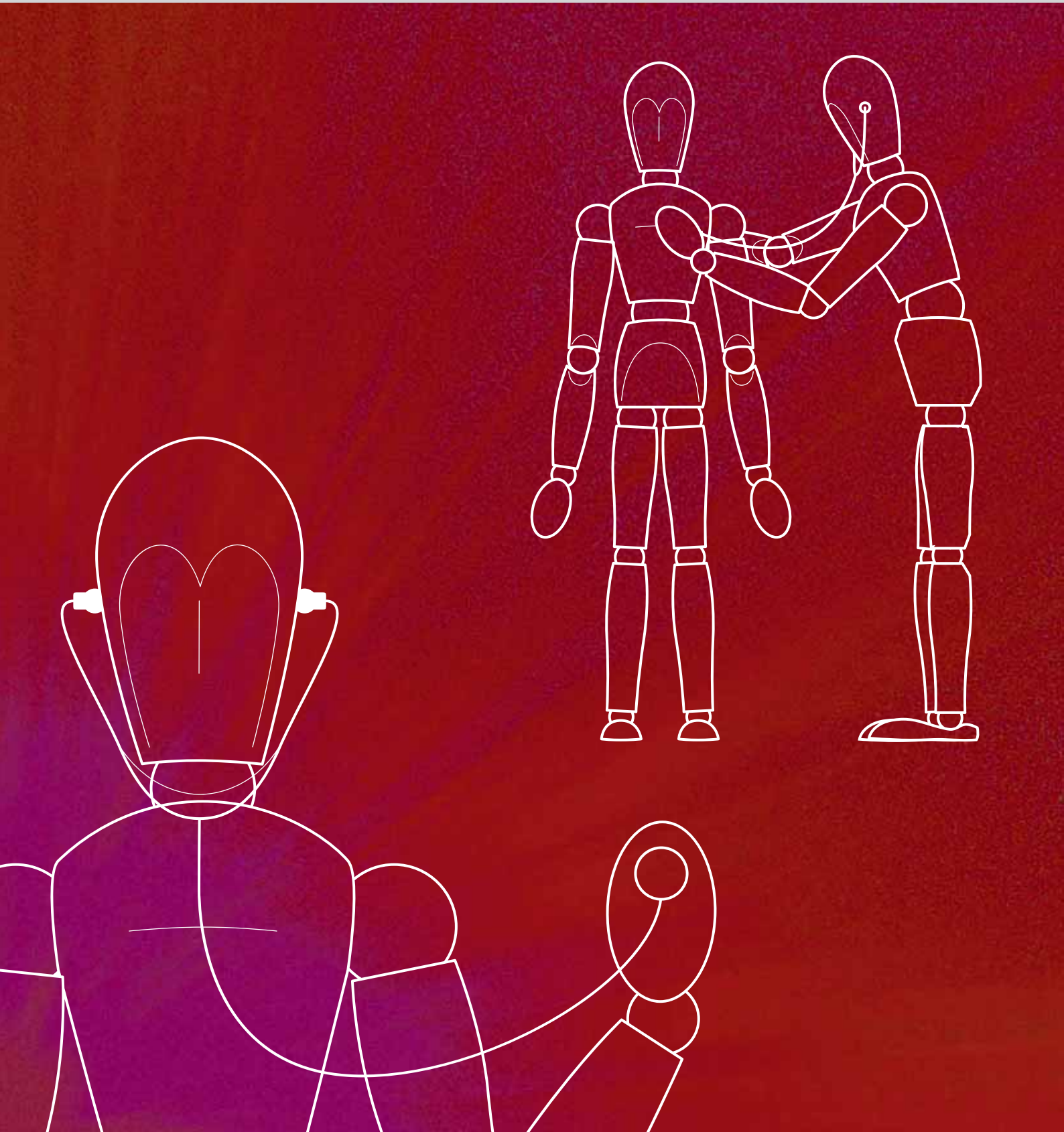
1 *Neuroimaging (left) and immunohistochemistry (right) after experimental brain ischemia.*

DIAGNOSTICS AND NEW TECHNOLOGIES



IN CONVERSATION WITH DR. WILHELM GERDES

Over the last one and a half years three company settlements in Leipzig have been initiated thanks to the Business Development Team, which is headed by you. What do you think are the location factors that distinguish Leipzig and make the city interesting for potential company settlements? My team supported the settlement of the companies Innovastem, Prima Biomed and Nuvo Research here in Leipzig. To some extent this was born out of necessity as Saxony, and in particular Leipzig, does not have many well-financed biotechnology companies that could conduct projects with us. In conjunction with the settlement of these three companies we were always successful in simultaneously acquiring projects for the Fraunhofer IZI. The location factors you referred to always play a significant role here. Besides the spatial conditions here at the BioCity Campus and the excellent funding environment in Saxony, the brilliant expertise of our partners is of prime importance. Soft factors like the city's offerings and favorable rents round off the picture.

There surely are many advantages Leipzig has to offer. What are the occasional disadvantages and which biotechnology clusters worldwide would you consider as ideal standards, respectively serious competitors? I think a comparison with other biotechnology clusters is very difficult. Each city has to find its own way in this respect. Of course, one can learn from the mistakes and correct approaches made at other locations, but in any case it is decisive to find the so-called unique selling points. These are not necessarily the same in each case; rather should they be customized for the respective companies. In that sense we have no immediate competitors but rather a competition for the best adapted conditions. We did not and will not have ideal standards as such; it is rather our intention, with the means we have at hand, to influence the development in a way to create as many jobs and as much value as possible in our region.

What were the scientific priorities of your department in 2010? It is one of our most important aims to create a patient-oriented diagnostic platform. Different units within the department are working on this issue. Our current development projects are biomarkers, e. g. like the ncRNAs, and, in cooperation with industrial partners, novel analysis devices for rapid and cost-effective measurement of such biomarkers, with the focus on providing the diagnostic market with new products as soon as possible. Moreover, our Tumor Stem Cells Unit is striking a new path with respect to monitoring the effectiveness of drugs. What is crucial to us is the close cooperation among the different scientific disciplines and in particular the benefits regarding improved patient care.

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From left to right:
Dr. Christian Zilch,
Prof. Ulrich Sack,
Dr. Jörg Hackermüller,
Dr. Wilhelm Gerdes,
Dr. Peter Ruschpler.

Core competencies of the department

- Nanotechnology
- Tumor stem cells
- RNomics

A selection of products and services offered by the department can be found on page 53.

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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.

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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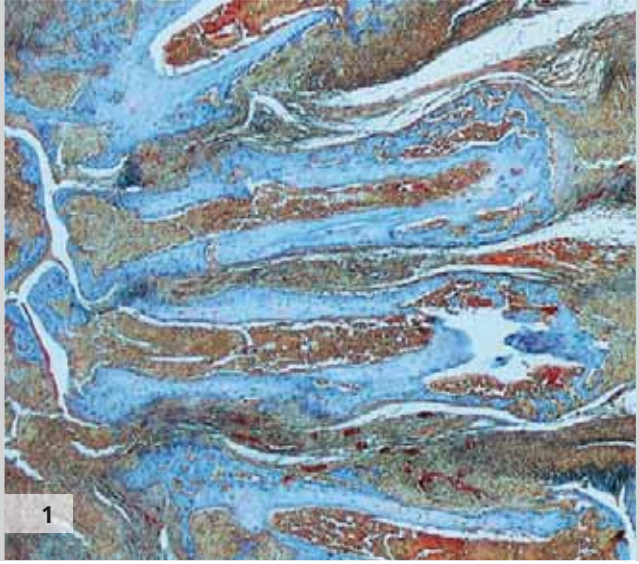

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PROJECTS

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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.

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

2 *Spheroid formation of TSCs in mammary carcinoma.*

1

2

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. The Nanotechnology Unit at the Fraunhofer IZI has received a positive funding decision from the VDI / VDE for the "MinoLab" project. Within the 3-year BMBF-funded project, which officially started in May 2010, a fully functional prototype of the diagnostic system is being developed together with the partners microfluidic ChipShop, Fraunhofer IZM, DICE, the Austrian Institute of Technology and Siemens. The project is coordinated by Magna Diagnostics GmbH, a Fraunhofer spin-off in Leipzig.

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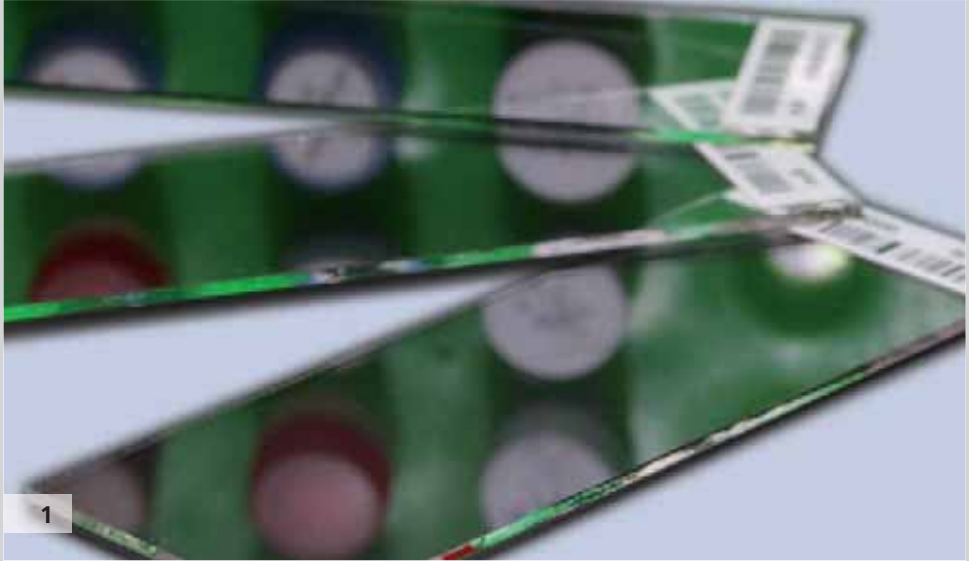
1 *Micro fluidic card as CAD (Computer Aided Design) model.*

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



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

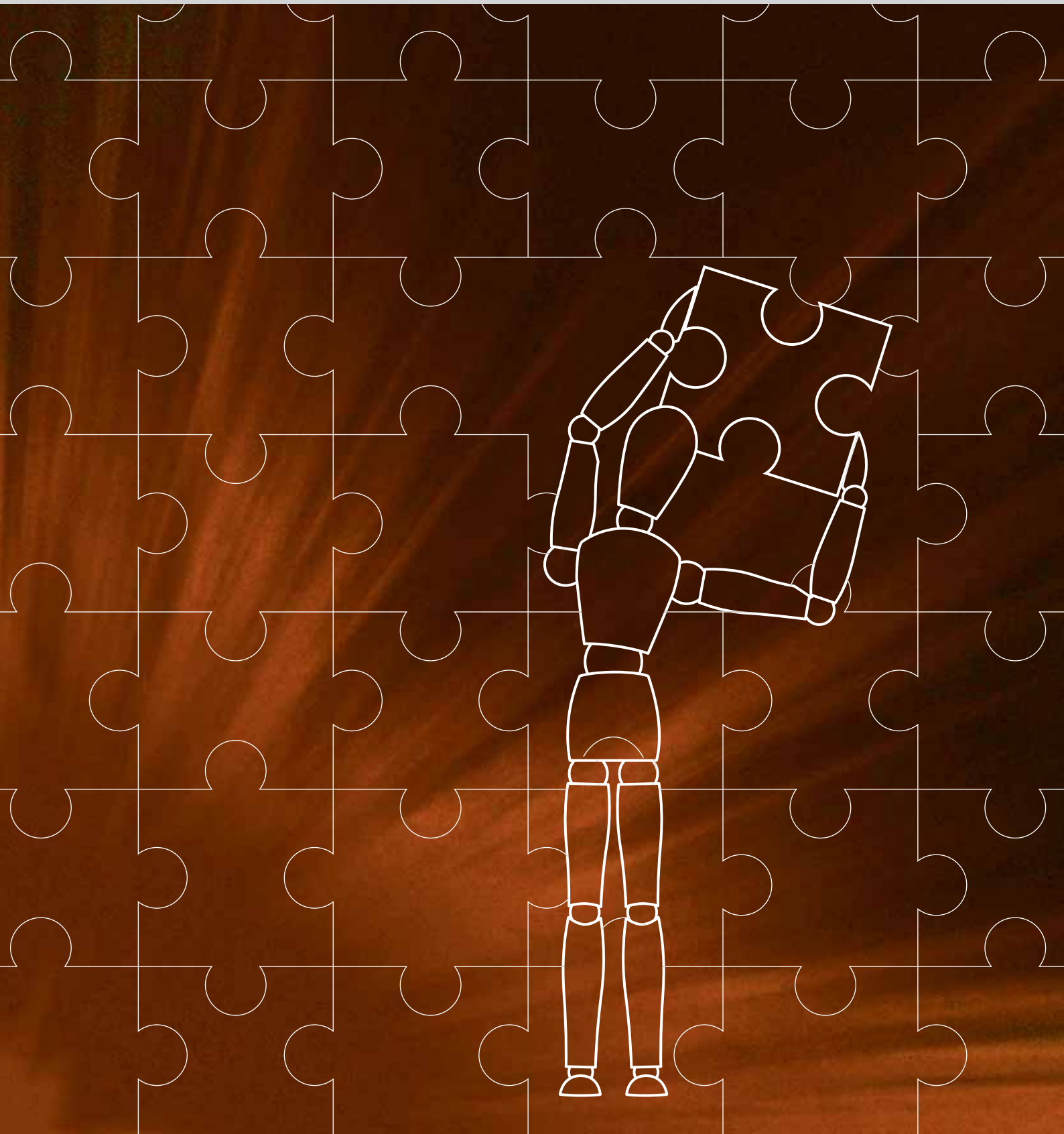
Background: Early detection of oncologic and chronic inflammatory diseases and personalized therapy promise both increased therapeutic success and reduction of costs. Identification and validation of biomarkers play important parts in this strategy. To date primarily proteins and protein-coding RNAs 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.

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

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.

PRODUCTS AND SERVICES



BUSINESS UNITS

The Fraunhofer Institute for Cell Therapy and Immunology IZI explores and develops solutions to specific problems at the interfaces of medicine, life sciences and engineering. To its clients and partners the institute offers complete solutions ranging from market studies right down to the development of a market-ready product and its marketing authorization. In the business units of agents, cell therapy, diagnostics / assays and biobanks the Fraunhofer IZI develops, optimizes and validates methods, materials and products for medical, biotechnological and pharmaceutical companies as well as for diagnostic laboratories, hospitals and research facilities. On the following pages please find a list of our special competencies, sorted by departments.

Business Unit "Agents"

The development of new therapeutic agents is a time- and cost-intensive process. In many cases there is a gap in the transfer of fundamental research results to clinical practice. The Fraunhofer IZI bridges this gap by means of its special know-how in the field of preclinical development. Our range of services already starts with development services and extends over characterization, optimization and preclinical studies right down to clinical trials. Particular priorities are the development of agents in the fields of oncology, infection biology, autoimmune and inflammatory diseases as well as ischemia.

Business Unit "Cell Therapy"

Cell therapy is the application of cells or cell suspensions. It is the aim of a cell therapy to induce regenerative processes and to replace dysfunctional or defective cells in the patient, respectively. In order to clinically apply cell therapeutics it is required to demonstrate their safety and effectiveness, which is done in extensive preclinical examinations and clinical trials. The Fraunhofer IZI conducts contract development and testing of cell therapeutic methods. The institute offers all developmental steps from one source, from the design of studies over preclinical development right down to the grant of a manufacturing authorization and the production of test preparations for clinical trials.

Business Unit "Diagnostics / Assays"

In order to promote the development of regenerative therapy strategies innovative diagnostic methods are required. From the characterization of individual cells to the imaging in living organisms, methods and processes must continuously be adapted and adjusted. The Fraunhofer IZI develops, tests and validates new and adapted diagnostic methods and accompanies its partners until a product has reached market maturity. With innovative methods and new classes of biomarkers (e. g. ncRNA) the institute seeks to develop more sensitive, rapid and cost-effective methods and to transfer them to clinical application.

Business Unit "Biobanks"

Biobanks are collections of biological material that are stored and optionally preserved in a special manner while providing additional information, e. g. about their origin. Biobanks are established for research and other purposes, e. g. as supply for diagnostic or therapeutic methods or, in the field of biology, for the conservation of biodiversity. As far as human materials are concerned, the donators' consent and specific handling regulations are required.

At the Fraunhofer IZI there are biobanks for various inflammatory and tumor tissues as well as for various types of stem cells, also including tumor stem cells, that serve for the processing of research contracts. The units at the Fraunhofer IZI also develop individual components themselves, like for example new cryoprotectors, and are very experienced in conceiving, establishing, documenting and operating biobanks, which are readily utilized within the scope of contracts.

PRODUCTS AND SERVICES

Department of Cell Engineering

- Diagnostic and therapeutic (mouse) model of borreliosis (Borrelia burgdorferi) and salmonellosis (Salmonella enterica) for preclinical studies under GLP-analogous conditions
- Development, validation and beta evaluation of cell technological methods and equipment
- GLP-analogous tests for immunotoxicology / immunogenicity, biodistribution and tumorigenicity of blood products, cell-based medicinal products, biologics, phytopharmaceuticals and nanoparticles *in vivo*
- GMP conform production of cell- and tissue products
- Identification and validation of protein biomarkers and development of methods and devices for their diagnostic detection
- Immunotoxic GLP validation *in vitro*
- Custom made development and validation of immunological *in vitro* test systems
- Monoclonal antibodies – Generation, production, purification and conjugation on a laboratory scale under GLP conditions
- Polyclonal antibodies – Generation, production, purification and conjugation on a laboratory scale under GLP conditions
- Therapeutic (mouse) model of chronic inflammatory bowel diseases for preclinical studies under GLP-analogous conditions
- Quality controls and their validation according to the European Pharmacopoeia (e. g. testing of mycoplasma, sterility and endotoxins; flow cytometry)

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Department of Immunology

- 3H-Thymidine proliferation assay
- Production and evaluation of histological preparations
- ELISPOT and automated cell separation
- Development of DNA vaccines
- Epitope mapping of antibodies and sera
- GvHD-mice (allogen induced)
- Contract library establishment
- Humanized, tripple transgenic mice
- Identification and testing of pathogenic antigens
- Conditioned humanized/non-humanized mice
- Model of the effects of flow parameters on vascular cells *in vitro*
- Phage Display
- Selection of ligands, antibodies and enzyme inhibitors for affinity chromatography
- Test systems for antibiotics, defensins and antimicrobial peptides
- Test systems for cytostatics based on tumor cell lines
- Therapy model for arteriosclerosis / plaque building
- Fully automated quantitative fluorescence microscopy
- Cell and tissue irradiations
- Cell transplantations (mouse)

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Department of Cell Therapy

- Three dimensional stem cell cultures (bone / cartilage pressure training)
- Imaging of biocompatibility *in vivo* (small animal) and material testing
- Developmental toxicity and cytotoxicity of additives, supplements and biomaterials
- Experimental imaging (CT, MRT, PET, bioluminescence / fluorescence imaging)
- Large animal model (sheep) for cerebral ischemia
- Histology: mammal brain, anatomical-pathological examinations
- Cryoconservation of cells
- Transgenic mice for bioluminescence imaging (BLI)
- Model systems myocardial ischemia – rat / mice
- Monitoring of preclinical studies and design consulting
- Center for preclinical studies for conducting highly predictive tests of therapies and agents
- Clean room cell sorting (multi-parametric 11 dyes)
- Reprogramming of cells – iPS (induced pluripotent stem cells)
- Senescence research
- SNP analyses of the human genome
- Stem cell analyses and stem cell manipulation
- Stem cell medias
- Therapy model (rat) for cerebral ischemia (stroke)
- Therapy model for tissue regeneration after fracture
- Animal model mice for solid and disseminated tumors (luciferase transgene)
- Behavioral phenotyping / neurofunctional testing in animal models
- Cell culture models of neuronal and glial ischemia
- Cytokine induced killer cells (CIK Cells) – production and clinical validation

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Department of Diagnostics and New Technologies

- Arthritis model in mice
- Transcriptomic analyses by tilling arrays and ultra high throughput sequencing
- Real-time monitoring of tumor initiation and remission by bioluminescence imaging (BLI) *in vivo*
- Development of molecular imaging methods
- Cartilage destruction model in mice
- Microarray analytics
- MicroRNA analytics (expression, localization, targets)
- Non-coding RNA biomarker
- Non-coding RNA biomarker for oncology, nONCOchip
- Non-coding RNA – therapy targets
- Optimization of pathogen isolation methods
- Optimization of molecular detection methods
- Testing of agents in tumor stem cells *(in vitro)*
- Tumor stem cells (TSC) for therapy projects (production of TSC specific CD8+ CTL)
- Investigation of nanoparticles
- Cellular functional testing for tissue destructive fibroblasts
- 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

Contact: Prof. Friedemann Horn | Head of Department of Diagnostics and New Technologies | Phone +49 341 9725-491 | friedemann.horn@izi.fraunhofer.de

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
- *in vivo* electroporation
- Cryopreservation technology
- Micro surgical instruments

TECHNOLOGY PLATFORMS

With extensive competencies and a state-of-the-art equipment pool the institute is able to offer research services along the entire value chain of a specific technology.

Antibody development

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
Target indentification
Identification of target molecules
Qualification of corresponding epitopes
Testing of effectiveness in laboratory scale.
Production
Production of polyclonal and monoclonal antibodies
Optimization through molecular biological methods and/or labelling.
Documentation
GLP conform documentation
Development of protocols and SOPs
Process development
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.

Biomarker tests

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

Vaccine development

Vaccines and diagnostic assays are elemental methods for combating infectious diseases, in both human and veterinary medicine.

The Fraunhofer IZI's activities in the development of vaccines range from the selection and optimization of suitable antigens right down to the conduct of proof-of-principle tests in various animal models. Pathogens from the fields of virology, bacteriology and parasitology can be processed. Models of ectoparasites (e. g. mites) are also established at the institute.

The Fraunhofer IZI's know-how comprises state-of-the-art vaccine technologies like DNA, recombinant subunit or vector vaccines. In veterinary medicine it is often decisive to distinguish between vaccinated animals and naturally infected animals (DIVA principle, differentiation of infected and vaccinated animal). This is ensured by the methods available at the Fraunhofer IZI.

For the testing of vaccine candidates we have at our disposal small and (due to a close cooperation with the Faculty of Veterinary Medicine at the University of Leipzig) large animal models.

For the serological detection of pathogens the Fraunhofer IZI recombinantly produces antigens which are then optimized for diagnosing by *in vitro* tests. On the one hand this allows for examining the effectiveness of our vaccine candidates. On the other hand this technology platform offers the possibility to develop novel serological assays (e. g. ELISAs).

Cultivation of pathogens

Display of antigens

Design of vaccine vectors / proteins

Small animal models for immunizations

Large animal models for veterinary vaccines

Characterization of the immune response

Fine mapping and optimization of epitopes

Design of accompanying serological assays

Ischemia models

Meaningful model systems are required for the development of therapeutic strategies and diagnostic methods in the field of cerebral and cardiac ischemia. Especially for the prevention of failures and costs in the technology transfer area it is crucial to minimize risks and sources of error already in the course of preclinical development.

The Fraunhofer IZI offers different model systems for addressing a variety of aspects within the development chain. Apart from various *in vitro* models this also applies to a number of *in vivo* models. As the transfer of research results from a small animal model to human applications led to a number of failures in the past, a large animal model that is much closer to the human physiology has been developed at the Fraunhofer IZI.

Comprehensive equipment and cooperations in the area of medical imaging have rendered the institute capable of evaluating both regenerative processes and diagnostic applications *in vivo.*

The institute is particularly specialized in, but not limited to, the development of cell therapeutic methods. Our service portfolio also comprises the testing of agents, surgical therapy methods and the development of new imaging methods.

Modular design of preclinical studies

Complete implementation of STAIR criteria

Adaptation and evaluation of models

Conduct of studies according to clinical standards

Monitoring of studies and data management

Concept assessment and evaluation

Model systems

in vitro models

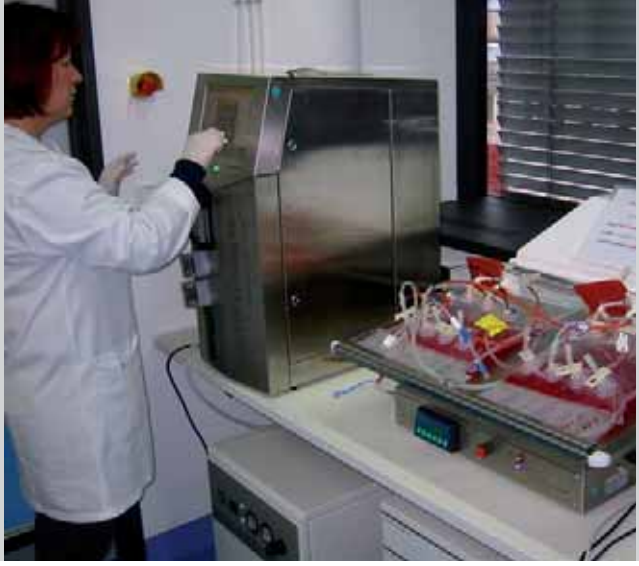
e. g. for the identification of neuroprotective effects

***in vivo* model (rodentia)**

e. g. cell transplantations, behavior analyses, magnetic resonance imaging, histology

***in vivo* model (ovine)**

e. g. long term studies, utilization of adult autologous stem cell populations, magnetic resonance imaging



QUALITITY MANAGEMENT

With a highly successful quality management the Fraunhofer IZI fulfills its clients' and partners' sophisticated demands and thus guarantees research services at the highest level.

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

In addition to research and development services, the Fraunhofer IZI offers to its clients and partners various services for the realization of innovative project ideas.

The Fraunhofer IZI has an administrative department that is responsible for the acquisition of new clients and projects and for technology transfer. Our administrative department "Business Development and Patent Management" is a central interface of the institute and keeps close contact with the relevant decision makers of the funding institutions, thereby supporting the scientific work units in the acquisition of projects and partners as well as in the preparation of applications for funding projects. Another focus is on the establishment and cultivation of industry contacts.

The team is a competent contact point for our potential clients and partners and offers a comprehensive overview of all the institute's competencies, technologies and service offers. Requests can therefore swiftly and purposefully be transferred to the relevant contact person at the institute. With the collaboration of the Fraunhofer IZI, a further foundation project of a biotechnology company could be realized and funded with means provided by the "Sächsische Aufbaubank" (Saxon Development Bank) in the reported year.

Another priority is the exploitation of the institute's patent portfolio and the implementation of scientists' patenting projects.

Service offers

- project acquisition
- planning and coordinating projects; controlling and marketing
- support in the acquisition of third-party funding
- business development

Phase model for signing research contracts

Phase 1: Confidentiality agreement
Signing of a non-disclosure agreement. Original text may be from the partner or Fraunhofer-Gesellschaft.

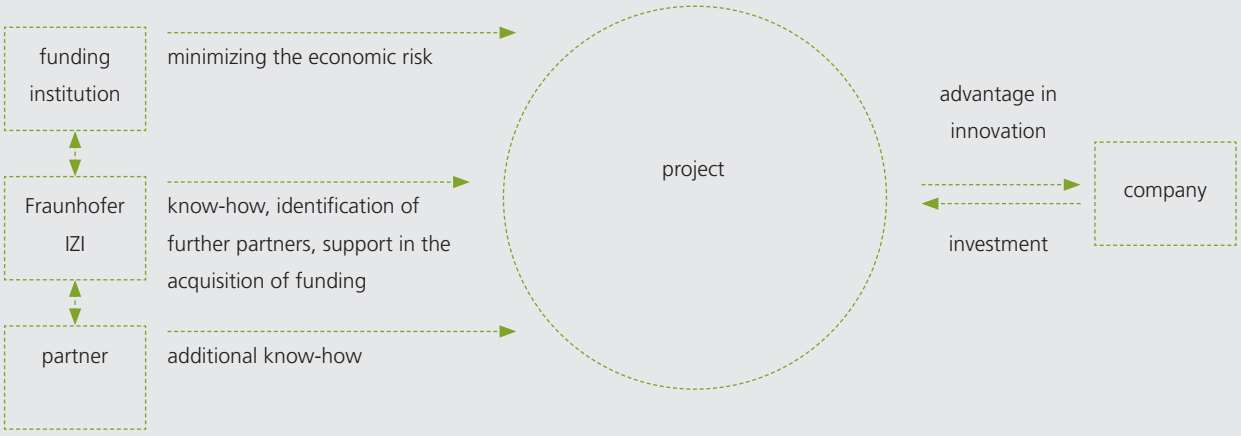
Phase 2: Term sheet
Definition of the cornerstones between the partners (IP rights, utilization rights, contract timeframe, project plan, financial development).

Phase 3: Offer
Drafting of the contract based on the project plan and cornerstones as defined in phase 2.

Phase 4: Contract negotiation
Discussion and finalization of the contract by the partners.

Phase 5: Contract agreement
Signing of the research contract after review and, if necessary, changes by the legal advisors of the partners.

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, partners and customers are actively supported in 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 WSR (˝Wirtschaft, Sprachen, Recht˝) 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:

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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.

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)

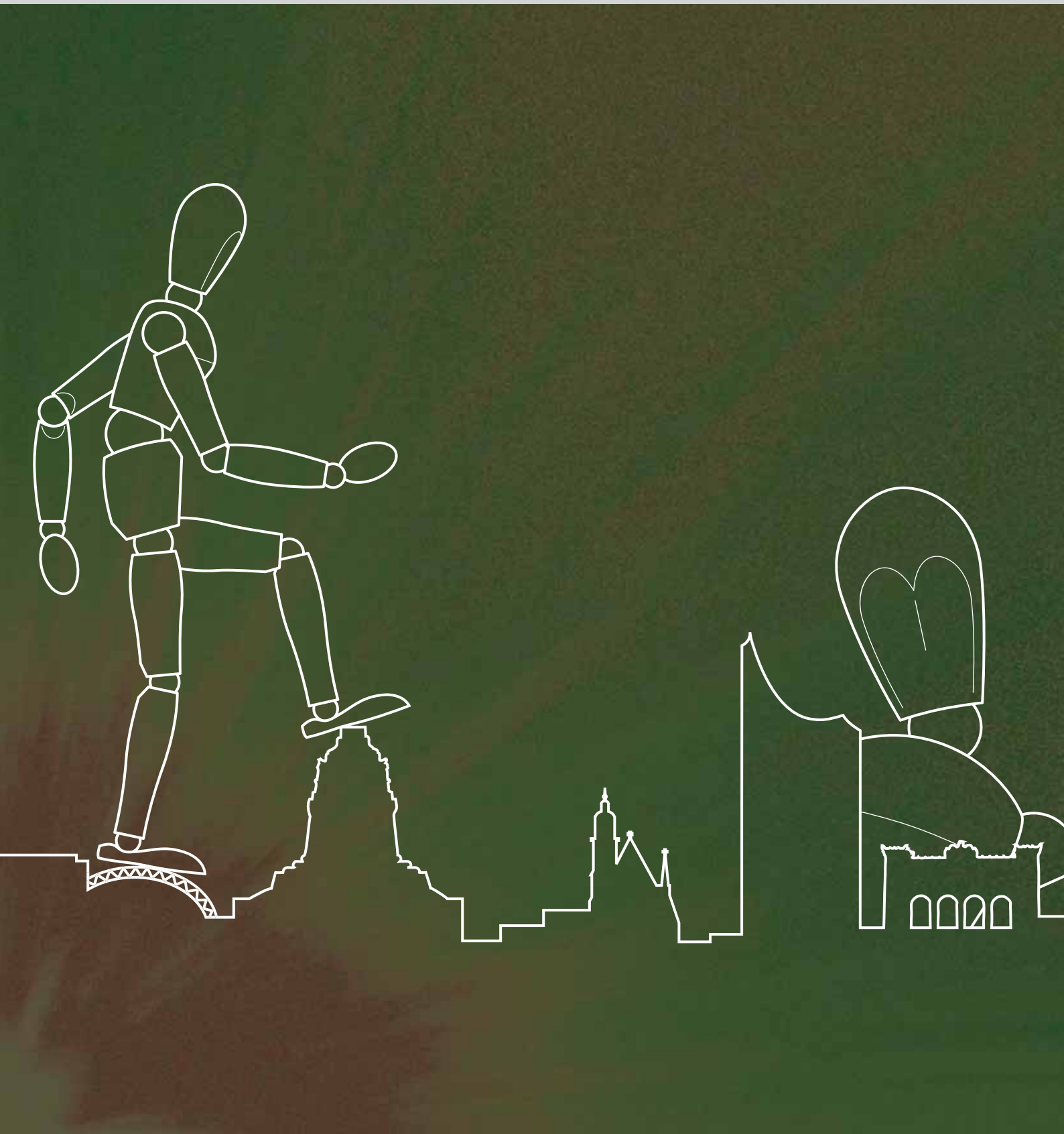
For founders of scientific companies: Economic and legal principles

- 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

SCIENCE LOCATION



LEIPZIG AND THE FORMER TRADE FAIR GROUNDS

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. Close cooperation with the nearby facilities of the University of Leipzig and the companies of the BIO CITY Leipzig is maintained.

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

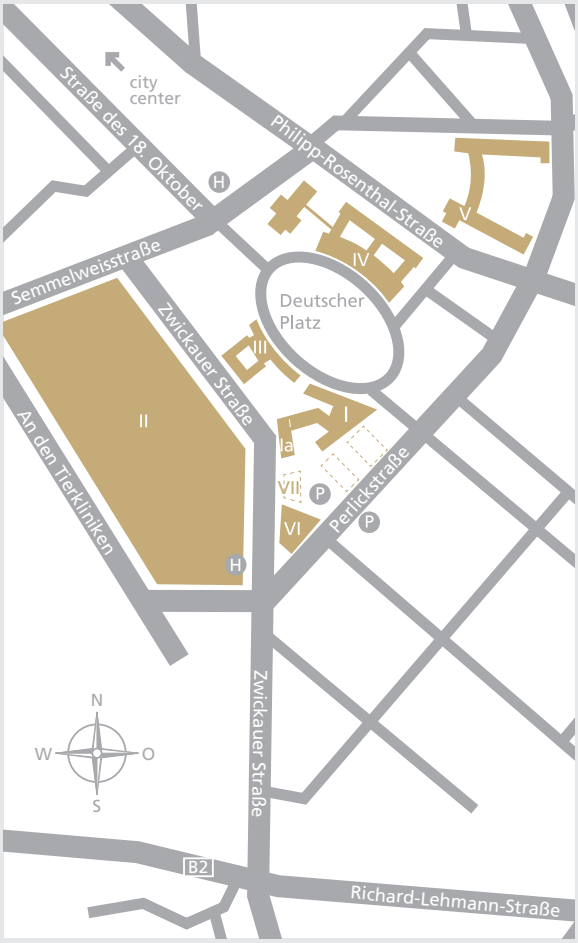
The university landscape within Leipzig also benefits from cooperation with the Fraunhofer IZI: the University of Leipzig, the Leipzig University of Applied Science (HWTK) and the Graduate School of Management (HHL) have found in the Fraunhofer IZI a strong partner for research cooperations and the development 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). In 2010, the TRM received a very positive evaluation by the consulting firm Capgemini Deutschland Holding GmbH and international consultants, so that funding was granted by the BMBF and Saxony for further support.

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), the Center for Therapeutic Studies (ZET) and the Leipzig Interdisciplinary Research Cluster of Genetic Factors, Clinical Phenotypes and Environment. Moreover, there are numerous interfaces with different special research areas and so-called Transregios (transregional research projects) that are located in Leipzig.



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).

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Interdisciplinary Centre for Clinical Research (IZKF)
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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
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Max Planck Institute for Human Congnitive and Brain Sciences
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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
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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 IZI AS HOST

In 2010, the Fraunhofer IZI's premises were once more a popular and frequently visited meeting place for the exchange between economy, science and politics.

5th anniversary Fraunhofer IZI / Joint Science Day

The Fraunhofer IZI was founded on April 29, 2005, on the occasion of the Day of Immunology. On the same day in 2010, the institute together with the University of Leipzig invited the protagonists of the Leipzig research and education landscape to enhance their networking and interchange activities. With the Joint Science Day a platform was created for interlinking local competencies more intensely and identifying synergies. This invitation was accepted by 80 guests from 20 institutes / work units who exchanged information about their research topics, infrastructure and strategies. Under the common vision of strengthening the science location Leipzig a discussion ensued within the framework of presentation series and workshops.

Annual convention of the German Society for Immunology (DGfI)

From September 24 to 26, 2010, Leipzig was the venue for the 40th annual convention of the German Society for Immunology (DGfI) under the leadership of Prof. Dr. med. Frank Emmrich as congress president. In symposia and workshops the members of the DGfI exchanged information on current areas of research in the field of immunology. Aspects of fundamental research and their clinical application were discussed.

365 Locations in the Land of Ideas

Since 2006, the initiative "Germany – Land of Ideas", under the patronage of the Federal President, annually honors 365 locations in the Land of Ideas for their future-oriented ideas.

In 2010, the Fraunhofer IZI was successful, with not one but two projects, against about 2,200 competitors and could score with innovative concepts. The first project, the BioCity Campus, was honored on August 5. The conceptual idea of a BioCity Campus Leipzig (BCC) takes the already existing scientific, research and development facilities at the location of the former trade fair grounds as a basis for creating a campus with international flair. With the extension of the existing research infrastructure, for instance with an internationally oriented kindergarten, a secondary school and a Center for Regenerative Therapy, it is further intended to attract the settlement of innovative companies and businesses.

On October 29, 2010, a second project was honored that will contribute to improving healthcare provision. The project "Magnetic Infection Diagnostics" aims at detecting life-threatening infections in a more rapid, reliable and cost-effective manner. As guest of honor, Prof. Dr. Dr. Sabine von Schorlemer, Saxonian State Minister for Science and the Arts, appreciated this idea as being a great service to patients and society. With the outsourcing of the MagnaDiagnostics GmbH, the implementation of this concept is now the primary focus of efforts.

EU Commissioner Dr. Johannes Hahn visits the Fraunhofer IZI

Within the framework of the debate on continuous structural funding by the European Union in Saxony from 2013 on, Dr. Johannes Hahn inspected the Fraunhofer IZI. Dr. Hahn, who has been responsible for regional politics as EU commissioner since February 2010, arrived on October 25, 2010, accompanied by Sven Morlok, Saxonian Minister of Economic Affairs.

Hahn and Morlok were both convinced that the European funding has been profitably invested. A total of 60 percent of the new institute building, about 14.8 Million Euros, were financed from the European fund for regional development (EFRE).

The former Federal Minister of Science and Research of Austria was convinced by the concept revolving around the issues of regenerative medicine and by the institute's positive development since its foundation.

By visiting the Fraunhofer IZI the Free State of Saxony demonstrates that, thanks to EU funding, significant impulses for the development of innovative technologies and their economic implementation are given and further funding is to be regarded as thoroughly sensible.

Long Night of the Sciences (Researchers' Night) in Leipzig

After the successful premiere in 2008, more than 40 scientific institutions in Leipzig were once again invited to the Long Night of the Sciences on September 24, 2010. A broad program with more than 200 events in over 40 institutions provided insight into places that are usually rarely accessible. The Fraunhofer IZI also actively participated in this EU-sponsored event. Beside Hamburg, Leipzig was the only German city to be granted funding within the scope of the EU Researchers' Night.

On the day, the institute's employees presented their research topics and projects. With guided tours, participatory events and experiments, the interested visitors were given an understanding of the research and development activities of the Fraunhofer scientists. The Fraunhofer Truck also stopped by for presenting the entire range of topics of the Fraunhofer-Gesellschaft.

In the run-up to the event the Fraunhofer IZI, together with the Carl Zeiss Group, organized a scientific photography contest. The best photographs were displayed within the framework of the Long Night of the Sciences and awarded by the audience. The winning photograph shows dorsal spinal ganglia and decorates the title page of this year's report.

Discourse of stem cell potentials: Fraunhofer Life Science Symposium

Under the heading of "Immunotherapy: The Cutting Edge of Stem Cell Applications" the fifth Fraunhofer Life Science Symposium was held in Leipzig from October 29 to 30, 2010. About 120 guests participated with 25 professional presentations and 30 poster contributions.

Discussed were, in particular, the therapeutic potentials in the field of inflammatory, oncological, hematological and autoimmune diseases. Beside the application of stem cells, immunotherapeutic strategies and approaches were also extensively dealt with. Professor Hans-Joachim Stauss of the UCL University College London, Great Britain, reported on treatment options for autoimmune diseases by means of genetically modified immune cells. Professor Joachim Schultze of the LIMES Institute in Bonn demonstrated the need for new biomarkers as a precondition for immuno-therapeutic strategies and Professor Ornella Parolini of the Centro di Ricerca E. Menni, Italy, reported on placental cells and their application in the treatment of inflammatory diseases. In addition to the scientific contributions the symposium was accompanied by an extensive industry exhibition in the spacious atrium of the Fraunhofer IZI.

As the interchange of both scientific and economic aspects and fields of interest is part of the guiding principle of the Fraunhofer-Gesellschaft, the event again successfully took up this concept.

Fraunhofer Innovation Forum "Demography and Health Resources"

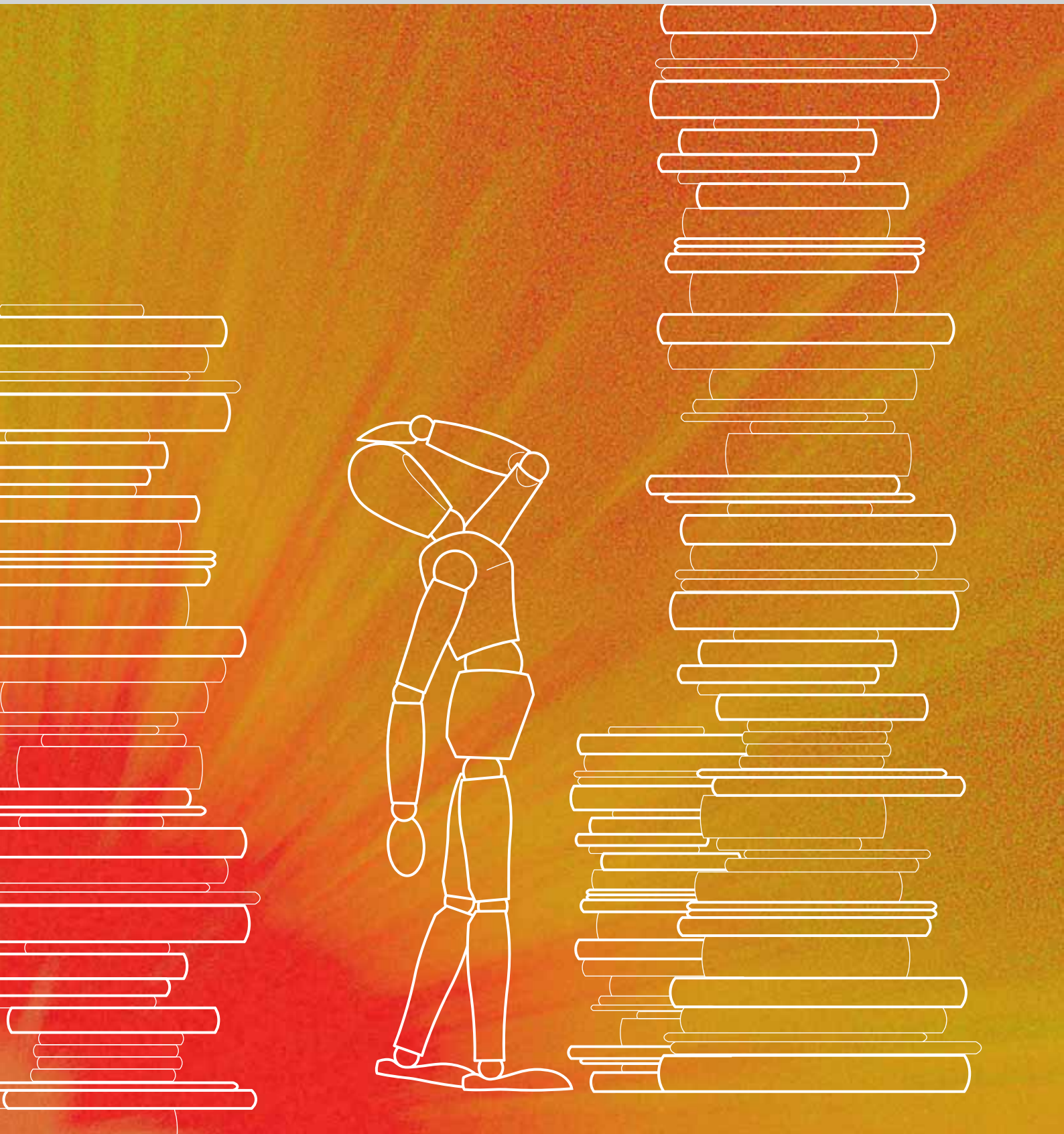
The demographic change and the associated employees' health situation bring about a number of economic and social challenges for the future.

Strategies and solutions for maintaining and restoring employees' health, vitality and productivity were discussed on November 4 and 5, 2010, within the framework of the Fraunhofer Innovation Forum "Demography and Health Resources". In a series of presentations and workshops there was an interchange between renowned experts in economy, science and politics on the aspects of health management. In his presentation, Professor Bert Rürup illustrated the value of health from an economic point of view. Professor Bernd Rebscher, executive board member of the DAK, elucidated the challenges in the field of health care. Beside current medical findings on all aspects of ageing there was a particular focus on the employers' responsibilities, not least because health is an essential economic factor.

This year's forum is already the second event of this kind held at the Fraunhofer IZI and was organized in cooperation with the European Association for Vitality and Active Ageing (registered association), the German Association for Fitness and Sports Therapy (registered association) and the DAK.

The highlight of the event was the ceremonial awarding of the Corporate Health Award to the PHOENIX CONTACT Deutschland GmbH for outstanding commitment to its employees' health.

SCIENTIFIC PRESENCE



CONVENTIONS AND CONFERENCES

103rd Annual Meeting of the German Society for Zoology (P)
September 17–20, 2010, Hamburg, Germany

15th Leipzig Workshop "Cytomics and Stem Cells" (P)
April 22–24, 2010, Leipzig, Germany

19th European Stroke Conference (P)
May 25–28, 2010, Barcelona, Spain

1st World Forum on Cerebral Blood Flow Metabolism and Function (P)
October 18–20, 2010, Kyoto, Japan

20th Annual Meeting of NECTAR (V)
November 25–27, 2010, Freiburg, Germany

20th Annual Meeting of the German Society for Cytometry (V)
October 13–15, 2010, Leipzig, Germany

21st Meeting of the European Association for Cancer Research (V)
June 26–29, 2010, Oslo, Norway

38th Annual Conference of the European Teratology Society (V)
September 5–8, 2010, Barcelona, Spain

3rd International Congress on Stem Cells and Tissue Formation (V)
June 11–14, 2010, Dresden, Germany

40th Annual Meeting of the German Society for Immunology (P/V/C)
September 22–25, 2010, Leipzig, Germany

49th Annual Meeting of the German Society for Experimental and Clinical Pharmacology and Toxicology (P)
March 11–13, 2010, Mainz, Germany

4th ESF Conference on Functional Genomics and Disease (P)
April 14–17, 2010, Dresden, Germany

4th European Congress of Virology (P)
April 7–11, 2010, Cernobbio, Lake Como, Italy

57th Annual Meeting of the Association of the German Bee Research Institutes (S)
March 23–25, 2010, Herne, Germany

6th Leipzig Veterinary Congress (S)
January 19–21, 2010, Leipzig, Germany

60th Annual Meeting of the American Society of Human Genetics (P)
November 2–6, 2010, Washington, D.C., USA

61st Annual Conference "Reading, Literacy and Learning" of the International Dyslexia Association (P)
October 27–30, 2010, Phoenix, AZ, USA

6th International Symposium on Neuroprotection and Neurorepair (P)
October 1–4, 2010, Rostock, Germany

7th World Stroke Congress (P)
October 13–16, 2010, Seoul, Korea

8th Annual Meeting of the International Society for Stem Cell Research (P)
June 16–19, 2010, San Francisco, CA, USA

8th World Congress on Trauma, Shock, Inflammation and Sepsis TSIS 2010 (V)
March 9–13, 2010, Munich, Germany

9th Leipzig Research Festival for Life Sciences 2010 (P)
December 17, 2010, Leipzig, Germany

Annual Meeting of the German, Austrian and Swiss Societies for Hematology and Oncology (V)
October 1–5, 2010, Berlin, Germany

Annual Meeting of the German Pharmaceutical Society (P)
October 4–7, 2010, Braunschweig, Germany

Annual Meeting of the German Society of Gerontology and Geriatrics (V)
September 15–16, 2010, Berlin, Germany

Annual Meeting of the German Society of Physiology, FEPS Young Investigator Award Competition (V)
March 27, 2010, Kopenhagen, Denmark

Autumn Panel of the German Society for Regenerative Medicine (V)
November 12, 2010, Berlin, Germany

Bavaria Innovative Cooperation Forum Biopharmaceuticals: Design – Optimization – Production (P)
May 18, 2010, Benediktbeuern, Germany

BIO International Convention (I)
May 3–6, 2010, Chicago, IL, USA

Biospine 3, 3rd International Congress Biotechnologies for Spinal Surgery (V)
September 1–4, 2010, Amsterdam, Netherlands

BIT's 3rd Annual Congress of Regenerative Medicine and Stem Cells 2010 (V)
December 5–7, 2010, Shanghai, China

BLE Innovation Days (P)
October 6–7, 2010, Berlin, Germany

BMBF Challenge BioFuture, GO-Bio / Funding Institution Jülich (P/V)
January 26–27, 2010, Berlin, Germany

EMBL Symposia "The non-coding Genome" (P)
October 13–16, 2010, Heidelberg, Germany

Fraunhofer Life Science Symposium 2010 (V/C/P)
October 29–30, 2010, Leipzig

III. All-European Dyslexia Conference of the European Dyslexia Association (V)
April 22–24, 2010, Brügge, Belgium

Koranet Workshop (V)
November 8–9, 2010, Berlin, Germany

National Symposium for Zoonoses Research (S)
October 7–8, 2010, Berlin, Germany

PEGS Europe (P)
October 5–7, 2010, Hanover, Germany

TRM-Retreat 2010 (V/P)
October 8–9, 2010, Wittenberg, Germany

UCR Symposium on Tobacco-Related Disease Research (V)
October 29, 2010, Riverside, CA, USA

Workshop on Cardiac Physiology and Experimental Cardiolgy (V)
September 16–18, 2010, Rauischholzhausen, Germany

World Immune Regulation Meeting WIRM IV (P)
March 29–April 1, 2010, Davos, Schwitzerland

V = oral presentation
P = poster
C = chair
I = stand
S = others

PARTNERS

Research partners

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

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

Biomedical Primate Centre, Rijswijk, Netherlands

Buck Institute for Research on Aging, Lunyak Lab, Novato, CA, USA

Central Institute for Experimental Animals, Kawasaki, Kanagawa, Japan

Charité – Campus Benjamin Franklin | Charité – Campus Mitte (Clinic 2), Berlin, Germany

Ernst Moritz Arndt University of Greifswald, Greifswald, Germany

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

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

Fraunhofer Institute for Manufacturing Technology and Advanced Materials – Adhesive Bonding Technology and Surfaces IFAM, Bremen, Germany

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

Fraunhofer Institute for Production Technology IPA, Aachen, Germany

Fraunhofer Institute for Reliability and Microintegration IZM, Berlin, Germany

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

Friedrich Schiller University Jena, Faculty of Biology and Pharmacy, Institute of Nutrition, Jena, Germany

German Heart Institute Berlin (DHZB), Berlin, Germany

Ghent University, Ghent, Belgium

Giessen University, Giessen, Germany

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

Helmholtz Centre for Infection Research, Non Earmarked Research Directed Evolution, Braunschweig, Germany

Helmholtz Zentrum München (Helmholtz Center Munich) – German Research Center for Environmental Health, Institute for Epidemiology, Munich, Germany

Heart Center Leipzig, Leipzig, Germany

Imperial College London, Faculty of Natural Sciences, Department of Mathematics, London, UK

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

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

Johann Wolfgang Goethe University, University Hospital, Frankfurt / Main, Germany

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

Karolinska Institutet, Department of Medicine, Solna, Sweden

Klinikum St. Georg gGmbH, akademisches Lehrkrankenhaus der Universität Leipzig (University Teaching Hospital St. Georg Leipzig) | Robert Koch Clinic, Leipzig, Germany

Ludwig Maximilians University Munich, Faculty for Veterinary Medicine, Munich, Germany

Maastricht University, Maastricht, Netherlands

Martin Luther University Halle-Wittenberg, Faculty of Natural Sciences I – Biomedical Sciences, Institute for Biology, Division of Genetics, Halle / Saale, Germany

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

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

Max Planck Institute of Psychiatry, RG Müller-Myhsok: Statistical Genetics, Munich, Germany

National Research Council (CNR), Institute for chemical and physical processes, Pisa, Italy

North East England Stem Cell Institute NESCI, Newcastle, UK

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

Otto-von-Guericke University Magdeburg, Magdeburg, Germany

Polish Academy of Sciences, Centre for Molecular and Macromolecular Studies, Department of Engineering of Polymer Materials, Łódź, Poland

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

Saarland University Hospital and Saarland University Faculty of Medcine, Homburg / Saar, Germany

Sabel-Schüler-Zentrum (Sabel Pupil Center), Markkleeberg, Germany

Sächsisches Landesamt für Umwelt, Landwirtschaft und Geologie (LfULG) (Saxon State Office for Environment, Agriculure and Geology), Dresden, Germany

Salk Institute for Biological Studies, 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 Krankenhaus Leipzig, Akademisches Lehrkrankenhaus der Universität Leipzig (St. Elisabeth University Teaching Hospital Leipzig), Leipzig, Germany

Stanford University, Stanfort, CA, USA

Technische Universität Braunschweig (Technical University Braunschweig), Department of Life Scineces, Institute for Biochemistry and Biotechnology, Braunschweig, Germany

The Royal College of Surgeons of England, London, UK

The University of Sheffield, Sheffield, UK

Universidad Politécnica de Valencia, Valencia, Spain

Universitat Pompeu Fabra, Complex Systems Lab, Barcelona, Spain

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

Universität Regensburg (University of Regensburg), Faculty of Medicine, Regensburg, Germany

Universitätsklinikum Bonn (University Hospital Bonn), Biomedical Center, Institute for Human Genetics, Bonn, Germany

Universitätsklinikum Freiburg (University Hospital Freiburg), Neuro Center, Stereotactic Neurosurgery, Freiburg, Germany

Universitätsklinikum Leipzig AöR (University Hospital Leipzig), Institute for Clinical Immunology and Transfusion Medicine | Institute for Medical Microbiology and Infection Epidemiology | Clinic for Radiation Therapy and Radio Onkology | Clinic for Urology | Medical Experimental Center | Independant Department for Hematology, Medical Onkology und Hemostaseology, Leipzig, Germany

Universitätsklinikum Rostock AÖR (University Hospital Rostock), Clinic for Radiation Therapy, Rostock, Germany

Université Victor Segalen Bordeaux 2, Bordeaux Cedex, France

University Hospital Carl Gustav Carus Dresden, Dresden, Germany

University Medical Center Schleswig-Holstein, Kiel / Lübeck, Germany

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

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

University of Freiburg, Freiburg, Germany

University of Gondar, Faculty of Medicine, Gondar, Ethiopia

University of Hamburg, Center for Bioinformatics, Hamburg, Germany

University of Leipzig | Center for Biotechnology and Biomedicine | Faculty of Biosciences, Pharmacy and Psychology, Institute for Pharmacy | Faculty of Mathematics and Informatics | Institute for Anatomy | Institute for Medical Informatics, Statistics and Epidemiology (IMISE) | Institute for Virology | Faculty of Medicine | Institute for Biochemistry | Institute for Pharmacy, Chair in Pharmaceutical Technology | Translational Center for Regenerative Medicine (TRM) | Faculty of Veterinary Medicine, Leipzig, Germany

University of Münster, Münster, Germany

University of Padova, Padova, Italy

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

University of Rostock, Faculty of Medicine, Rostock, Germany

University of Salzburg, Priority Programme BioScience and Health, Salzburg, Austria

University of Worcester, Worcester, UK

University of Zürich, Zürich, Switzerland

Waldkrankenhaus ″Rudolf-Elle″ GmbH (Hospital ″Rudolf-Elle″), Chair in Orthopedy of the University Hospital, Faculty of Medicine, Friedrich Schiller University Jena, Jena, Germany

Washington University, St. Louis, MO, USA

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

Industry partners

ACOMED Statistik, Leipzig, Germany

Affimed Therapeutics AG, Heidelberg, Germany

AID Diagnostika GmbH, Straßberg, Germany

AIT Austrian Institute of Technology GmbH, Vienna, Austria

AJ Roboscreen GmbH, Leipzig, Germany

Alcyomics Ltd., Newcastle, UK

AVISO GmbH, Jena, Germany

Biotectid GmbH, Leipzig, Germany

blue-drugs GmbH, Frankfurt / Main, Germany

Bombastus Werke AG, Freital, Germany

Bruker Daltonik Gmbh, Bremen, Germany

Bundesinstitut für Risikobewertung, Berlin, Germany

Cellserve GmbH, Berlin, Germany

Cleveland Clinic, Cleveland, OH, USA

Compart Umwelttechnik GmbH, Weißenfels, Germany

CREASPINE, Pessac, France

CREAVAC – Creative Vakuumbeschichtung GmbH, Dresden, Germany

CSF Therapeutics, Cleveland, OH, USA

Cytori Therapeutics Inc., San Diego, CA, USA

DASGIP AG, Jülich, Germany

DICE GmbH & Co KG, Linz, Austria

DMG Dental Material Gesellschaft mbH, Hamburg, Germany

Dr. med. Steffi Fricke, Facharztpraxis für Neurologie / Psychiatrie / Psychotherapeutische Medizin, Annaberg-Buchholz, Germany

emergentec biodevelopment GmbH, Vienna, Austria

Epiontis GmbH, Berlin, Germany

Euroderm AG, Baden-Dättwil, Germany

Forschungsinstitut Angewandte Neurowissenschaften FAN GmbH, Magdeburg, Germany

Frankfurter Stiftung für krebskranke Kinder, Frankfurt / Main, Germany

FrimTec GmbH, Oberostendorf / Lengenfeld, Germany

Generic Assays GmbH, Dahlewitz / Berlin, Germany

Genetic Immunity Kft., Budapest, Hungary

Geräte- und Vorrichtungsbau Spitzner OHG, Leipzig, Germany

GESA Automation GmbH, Teuchern, Germany

Guangzhou Gendustry Inc., Guangzhou, China

Höft, Wessel & Dr. Dreßler GmbH, Leipzig, Germany

InnovaStem GmbH, Leipzig, Germany

Institut für Mikrotechnik Mainz GmbH, Mainz, Germany

Institut für Systemisch-Integrative Lerntherapie, Leipzig, Germany

ISCONOVA A.B., Uppsala, Sweden

Kapelan Bio-Imaging GmbH, Leipzig, Germany

KET GmbH, Liegau-Augustusbad, Germany

Labor Dr. Reising-Ackermann und Kollegen, Leipzig, Germany

Leibniz-Institut für Oberflächenmodifizierung, Leipzig, Germany

Magna Diagnostics GmbH, Leipzig, Germany

Masterrind GmbH, Verden, Germany

Merck KGaA, Darmstadt, Germany

microfluidic ChipShop GmbH, Jena, Germany

Mologen AG, Berlin, Germany

North East England Stem Cell Institute NESCI, Newcastle, UK

Novartis International AG, Friedrich Miescher Institute for Biomedical Research (FMI), Basel, Switzerland

Novartis Pharma GmbH, Nuremberg, Germany

NUVO Research GmbH, Leipzig, Germany

ÖHMI Analytik GmbH, Magdeburg, Germany

pluriSelect GmbH, Leipzig, Germany

Pluristem Therapeutics Inc., Haifa, Israel

Praxis PD Dr. Gerhard Hoheisel, Leipzig, Germany

Prima BioMed Ltd., Melbourne, Australia

RESprotect GmbH, Dresden, Germany

Serumwerke Bernburg AG, Bernburg, Germany

Siemens AG Corporate Technologies, Munich, Germany

Urologische und Dermatologische Arztpraxis Dr. med. Matthias Schulze und Dr. med. Ina Schulze, Markkleeberg, Germany

Vakzine Projekt Management GmbH, Hanover, Germany

VITA 34 AG, Leipzig, Germany

WITTENSTEIN AG, Igersheim, Germany

ZEDIRA GmbH, Darmstadt, Germany

QUALIFICATION

Internal advanced vocational training

English course

Fundamentals of statistics

GLP training, QS / GLP testing facility

PhD seminar

QM for high-throughput genotyping

Systematic performance evaluation / target agreement

External advanced vocational training

Biomedical Basis of Disease
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

Compact seminar Tissue Law
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

Course Bone Marrow Cytology
University of Leipzig, Faculty of Medicine, Leipzig, Germany

Course Microsurgery
Berliner Kompaktkurse (Berlin Compact Courses), Berlin, Germany

Demands on risk management and biological safety of cell-based products
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

EMBO Practical Course on Computational RNA Biology
EMBO, University of Tübingen, Cargèse, Corsica

GLP Introduction
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

GMP for Beginners
European Compliance Acadamy, Berlin, Germany

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

Isolation of regulatory macrophages (TAIZ)
Clinic for Applied Cell Therapy, Kiel, Germany

Management training
Fraunhofer-Gesellschaft, Berlin, Germany

Mesenchymal stem cells – Application in Cell Therapy, Tissue Engineering and in situ Regeneration
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

OSHO Autumn Convention
University of Leipzig, Faculty of Medicine / OSHO, Wörlitz, Germany

OSHO Spring Convention
University of Leipzig, Faculty of Medicine / OSHO, Wörlitz, Germany

Residency Internal Medicine
Universitätsklinikum Leipzig AöR (University Hospital Leipzig), Independant Department for Hematology, Medical Onkology und Hemostaseology, Leipzig, Germany

Seminar "Cell-based Assays"
Promega GmbH, Leipzig, Germany

Transduction of hematopoietic cells
Julius-Maximilians University Würzburg, Institute for Virology and Immune Biology, Würzburg, Germany

Translation of scientific results
University of Leipzig, Translational Center for Regenerative Medicine TRM, Leipzig, Germany

University lecturer training
University of Leipzig, Faculty of Medicine, Leipzig, Germany

Work group seminar Neurobiology
University of Leipzig, Faculty of Biosciences, Pharmacy and Psychology, Institute for Biology II, Leipzig, Germany

Workshop Immunohistochemistry
DCS Innovative Diagnostik-Systeme, Fulda, Germany

Workshop Sequencing
EuroGene GmbH, Leipzig, Germany

Teaching activities

EuroGene GmbH, Leipzig, Germany:
Biochemistry (V)

University of Leipzig, Germany:
Acute Leukemias (K)
Ageing of stem cells derived from fat (V)
Bioinformatic analysis of high-throughput data (V)
Bioinformatics (P)
Biotechnology for Veterinarians (K/S/V)
Emergency medicine (POL)
Genetic basis of dyslexia (V)
Hybridoma cell culture technique for generating monoclonal antibodies (V)
Immunology (K/V/S/P)
Introduction Clinical Medicine (K)
Introduction Immunology (V)
Lymphomas (K)
Medical biotechnology (V)
Problem-oriented learning in medicine (POL)
Regenerative medicine (V)
Sequence analysis and genomics (V/S)

Telomeres and ageing (S)
Tissue typing (S)
Transfusion medicine (S)

University of California Riverside, CA, USA:
Cell Biology (V)
Stem Cell Biology (V)
Stem Cell Biology and Medicine (V)

BIO CITY LEIPZIG, Regular Meeting LifeScience, Leipzig, Germany:
Microfluidics and magnet sensor systems (S)

Flensburg University of Applied Sciences, Flensburg, Germany:
Lab-on-a-chip – Adoption in molecular diagnostics: Molecular diagnostics in mini format (V)

V = lecture or student trainng and teaching
S = seminar
P = practical training
K = course
POL = problem-based learning

EVALUATOR ACTIVITIES AND ASSOCIATION MEMBERSHIPS

Evaluator activities

American Journal of Physiology
Dr. Alexander Deten

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

Analytical Chemistry Insights
Prof. Ulrich Sack

Annals of Rheumatic Diseases
Prof. Ulrich Sack

Behavior Genetics
Arndt Wilcke

Bioinformatics
Dr. Jörg Hackermüller

BMC Bioinformatics
Dr. Jörg Hackermüller

BMC Cell Biology
Prof. Nicole zur Nieden

BMC Medical Genetics
Holger Kirsten

Canadian Institutes of Health Research
Dr. Alexandra Stolzing (Referee)

Cardiovascular Research
Dr. Alexander Deten

Cell Proliferation
Prof. Ulrich Sack

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

Circulation
Dr. Alexander Deten

Clinical and Experimantal Rheumatology
Prof. Nicole zur Nieden

Clinical Chemistry and Laboratory Medicine
Prof. Ulrich Sack

Clinical Chemistry
Prof. Ulrich Sack

Cytometry A
Prof. Ulrich Sack

Cytotherapy
Daniel-Christoph Wagner

Deutsche Akkreditierungsstelle (DAkkS) (German Accreditation Body)
Prof. Ulrich Sack

Deutsche Medizinische Wochenschrift (German Medical Weekly Paper)
Prof. Ulrich Sack

Disease Markers and Cancer Biomarkers
Prof. Ulrich Sack

Engineering in Life Sciences
Prof. Ulrich Sack

European Heart Journal
Dr. Alexander Deten

Experimental Neurology
Daniel-Christoph Wagner

Future Drugs – Expert Reviews Vaccines
Dr. Jörg Lehmann

German Medical Science
Prof. Ulrich Sack

Journal of Artificial Intelligence in Medicine
Prof. Ulrich Sack

Journal of Biophotonics
Prof. Ulrich Sack

Journal of Molecular Medicine
Prof. Ulrich Sack

Journal of Orthopedic Research
Prof. Ulrich Sack

Journal of Pharmacology and Experimental Therapeutics
Prof. Ulrich Sack

Journal of Rheumatology
Prof. Ulrich Sack

Life Sciences
Prof. Nicole zur Nieden

Lung Cancer
Prof. Ulrich Sack

Nature Protocols
Prof. Nicole zur Nieden

Neurobiology of Aging
Daniel-Christoph Wagner

Neurochemistry
Daniel-Christoph Wagner

Osteoarthritis and Cartilage
Prof. Ulrich Sack

Pathobiology
Prof. Ulrich Sack

PSB Pacific Symposeon on Biocomputing
Dr. Jörg Hackermüller

Respiratory Medicine
Prof. Ulrich Sack

Rheumatology International
Prof. Ulrich Sack

Rheumatology
Holger Kirsten

Stem Cells
Prof. Nicole zur Nieden

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

Tissue Antigens
Holger Kirsten

Tissue Engineering
Prof. Nicole zur Nieden

Transfusion Medicine and Hemotherapy
Prof. Ulrich Sack

Veterinary Immunology and Immunopathology
Dr. Jörg Lehmann

Zeitschrift für Regenerative Medizin (Magazine for Regenerative Medicine)
Prof. Frank Emmrich

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices)
Prof. Ulrich Sack

Association memberships

American Heart Assiciation
Dr. Alexander Deten

American Society for Cell Biology
Prof. Nicole zur Nieden

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

Association for the Advancement of Immune Diagnostics e. V. (GfID)
Prof. Ulrich Sack (Board of Directors)

BioSaxony e. V.
Dr. Christian Zilch

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

European Autoimmunity Standardization Initiative (EASI)
Prof. Ulrich Sack (Board of Directors)

European Molecular Biology Laboratory Alumni Association
Dr. Sebastian Ulbert

European Society for Clinical Call Analysis (ESCCA)
Prof. Ulrich Sack (Board of Directors)

European Society for Virology
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

German Association of University Professors and Lecturers
Dr. Alexander Deten

German Cardiac Society
Dr. Alexander Deten

German Society for Clinical Chemistry and Laboratory Medicine (DGKL)
Prof. Ulrich Sack

German Society for Immunology (DGfI)
Prof. Frank Emmrich
Dr. Stephan Fricke
Dipl.-Biol. Christiane Füldner
Franziska Lange
Dr. Jörg Lehmann
Prof. Ulrich Sack (Delegate)

German Society for Regenerative Medicine e. V.
Prof. Frank Emmrich
Dr. Stephan Fricke
Prof. Nicole zur Nieden
Dr. Alexandra Stolzing (Scientific Board)

German Society of Gerontology and Geriatrics
Dr. Alexandra Stolzing (Deputy Head of Section)

German Society of Physiology
Dr. Alexander Deten

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

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

Gesellschaft für Virologie e. V. (Society for Virology)
Dr. Sebastian Ulbert

GLP-Kommission (GLP Committee)
Prof. Ulrich Sack (Chairman)

International Society for Heart Research
Dr. Alexander Deten

International Society for Stem Cell Research (ISSCR)
Dorota Kaniowska
Prof. Nicole zur Nieden

National Research Platform for Zoonoses
Dr. Sebastian Ulbert

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

REGENERATE, EEIG
Prof. Nicole zur Nieden

Society for Biochemistry and Molecular Biology (GBM)
Dr. Michael Szardenings

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

The RNA Society
Dr. Jörg Hackermüller

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

PRIZES

3rd prize in the Stem Cell Imaging Contest of the University of California Riverside for Prof. Nicole zur Nieden of the Stem Cell Technology Unit on the topic "Neural differentiation of embryonic stem cells"

Award "Selected Location in the Land of Ideas" by the Federal Government for Dr. Wilhelm Gerdes of the Project Service Team on the topic "BioCity Campus"

Award "Selected Location in the Land of Ideas" by the Federal Government for Dr. Christian Zilch of the Nanotechnology Unit on the topic "Innovation with economic potential for Leipzig: Magnetic Infection Diagnostics"

Doctoral fellowship of the German National Academic Foundation (Studienstiftung des Deutschen Volkes) for Christiane Füldner of the Cell Engineering GLP Unit for professional excellence

Doctoral fellowship of the Manchot Foundation for Christiane Füldner of the Cell Technology GLP Unit for the outstanding topic and the concept of the doctoral thesis "Immune Modulation by Xenobiotics"

Doctoral fellowship of the University of Leipzig for Josefine Okoniewski of the Neuro- / Cardiorepair Unit for professional excellence

"EACR Presidential Session Research Award" by the European Association for Cancer Research for Dr. Kristin Reiche of the RNomics Unit on the topic "Long ncRNAs in mammacarcinoma"

Excellence bonus from the Fraunhofer Society for Dr. Sebastian Ulbert of the Vaccine Technologies Unit for the acquisition of the EU project "West Nile Integrated Shield Project"

"Formula 1 Fellowship" of the University of Leipzig for Katharina Schutt of the RNomics Unit for the project "Identification of cancer stem cell-associated biomarkers on the non-protein-coding RNA level"

Postdoctoral fellowship of the Translational Center for Regenerative Medicine TRM for Dorota Kaniowska of the Stem Cell Technology Unit on the topic "Osteogenic miRNAs"

Poster award from the German Society for Immunology (DGfI) for Dr. Stephan Fricke of the Immune Tolerance Unit on the topic "Scoring System, Immunotolerance / Anti-CD4"

Research bonus from the AVISO GmbH for Katharina Zoldan of the Cell Technology GLP Unit for her outstanding diploma thesis "Application Development CellCelector"

Top ten finalist in the Promega SwitchGear mini-grant competition was Prof. Nicole zur Nieden of the Stem Cell Technology Unit on the topic "Osteogenic miRNAs"

Travel Award for the best abstract of the International Society for Stem Cell Research for Dorota Kaniowska of the Stem Cell Technology Unit on the topic "Osteogenic miRNAs"

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Graduation

Andre Seidel, Stem Cell Biology Unit
Differenzierung von induzierten pluripotenten Stammzellen in Richtung Mikrogliazellen. (Differentiation of induced pluripotent stem cells in the direction of microglial cells.)
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Doreen Babin, Stem Cell Technology
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Engy Mohamed, Cell Engineering GLP Unit
Einfluss von Koloquinthen- und Salbeiblütenextrakten auf immunologische Entzündungsparameter humaner Zelllinien sowie primärer Immuneffektorzellen. (Influence of colocynth and sage extracts on the immunological inflammatory parameters of human cell lines and primary immune effector cells.)
University of Leipzig, Germany, diploma thesis

Franziska Nitzsche, Neuro- / Cardiorepair Unit
Analyse einer murinen Astrozytenkultur vor und nach Oxygen-Glucose-Deprivation. (Analysis of a murine astrocyte culture before and after oxygen/glucose deprivation.)
University of Leipzig, Germany, bachelor thesis

Katharina Zoldan, Cell Engineering GLP Unit
Entwicklung und Validierung von Methoden und Applikationsprotokollen zur praktischen Anwendung des Zellseparationsroboters CellCelector™ der zweiten Generation. (Development and validation of methods and application protocols for the practical application of the second generation cell separation robot CellCelectorTM.)
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Kerstin Boll, RNomics Unit
Three microRNAs synergistically repress androgen receptor signaling and are downregulated in prostate carcinoma.
University of Leipzig, Germany, dissertation

Michael Siebauer, RNomics Unit
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Stefan Chabierski, Vaccine Technologies Unit
Expression und Charakterisierung eines Proteins zur Bekämpfung von schädlichen Arthropoden. (Expression and characterization of a protein for combating harmful arthropods.)
University of Leipzig, Germany, master thesis

Patents

The employees of the Fraunhofer IZI submitted 5 patents in the past year.

Furthermore, the following patents were granted or published in 2010:

Johannes Boltze / Anrdt Wilcke / Holger Kirsten
WO 2010/007063 (granted: January 21, 2010)
Method of diagnosing dyslexia.

Johannes Boltze / Holger Kirsten
WO 2010/046454 (granted: April 29, 2010)
Quantitative determination of cDNA and genomic DNA comprised in a sample.

Johannes Boltze / Holger Kirsten
EP 2180065A1 (granted: April 28, 2010)
Method of reducing the molecular weight of at least one PCR product for its detection while maintaining its identity.

Stephan Fricke / Alexandra Stolzing
WO 2010/037826 (Veröffentlichung: September 30, 2010)
Method of enriching stem cells in culture.

Alexandra Stolzing / Fraunhofer IBG / Fraunhofer IPT / Fraunhofer IPA
WO 2010/130302 (granted: November 18, 2010)
DE 102009022351 (granted: November 25, 2010)
Modular system for the automatic production of three-dimensional tissue structures. GMP conform modular system.

Alexandra Stolzing
EP 2192174 (granted: June 2, 2010)
WO 2010/05614 (granted: May 27, 2010)
Reprogramming cells toward a pluripotent state.

Sebastian Ulbert
EP 2230246 (granted: September 22, 2010)
Arterivirus glycoprotein 5 virus-like particles.

FURTHERING

SPONSORS AND ADVISORY BOARD OF THE FRAUNHOFER IZI

The Fraunhofer IZI's successful development and continuous growth in the buildup phase was facilitated by the support and commitment of various institutions and persons.

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

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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.

The Fraunhofer-Gesellschaft and the Fraunhofer IZI extend their thanks to the former members of the advisory board (through 2010):

- Dr. Gabriele Hausdorf (Federal Ministry of Education and Research (BMBF), Head of the Section of Health Research within the Department of Life Sciences)
- Dr. Michael Herschel (GlaxoSmithKline GmbH & Co. KG, Head of Clinical Research)
- Dr. Eberhard Lampeter (VITA 34 AG, Chairman)
- Prof. Dr. med. Gustav Steinhoff (University of Rostock, Director of the Department of Cardiac Surgery)
- Prof. Dr. Hans Wolf (University of Regensburg, Director of the Institute for Medical Microbiology and Hygiene)

The advisory board from 2011 on:

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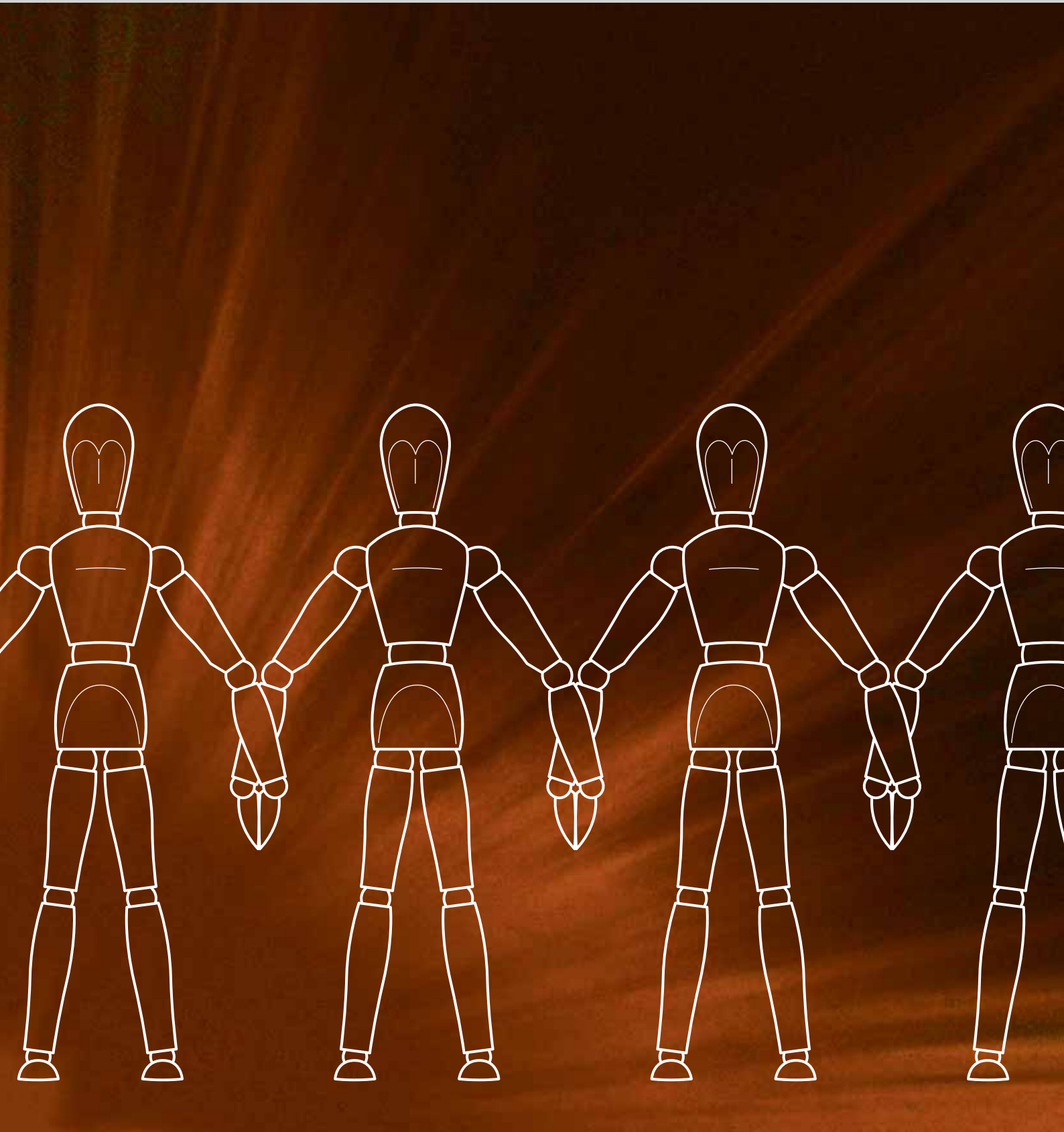
FRAUNHOFER-GESELLSCHAFT



FRAUNHOFER-GESELLSCHAFT IN PROFILE

Research of practical utility lies at the heart of all activities pursued by the Fraunhofer-Gesellschaft. Founded in 1949, the research organization undertakes applied research that drives economic development and serves the wider benefit of society. Its services are solicited by customers and contractual partners in industry, the service sector and public administration.

At present, the Fraunhofer-Gesellschaft maintains more than 80 research units in Germany, including 60 Fraunhofer Institutes. The majority of the more than 18,000 staff are qualified scientists and engineers, who work with an annual research budget of €1.65 billion. Of this sum, more than €1.40 billion is generated through contract research. More than 70 percent of the Fraunhofer-Gesellschaft's contract research revenue is derived from contracts with industry and from publicly financed research projects. Almost 30 percent is contributed by the German federal and Länder governments in the form of base funding, enabling the institutes to work ahead on solutions to problems that will not become acutely relevant to industry and society until five or ten years from now.

Affiliated international research centers and representative offices provide contact with the regions of greatest importance to present and future scientific progress and economic development.

With its clearly defined mission of application-oriented research and its focus on key technologies of relevance to the future, the Fraunhofer-Gesellschaft plays a prominent role in the German and European innovation process. Applied research has a knock-on effect that extends beyond the direct benefits perceived by the customer: Through their research and development work, the Fraunhofer Institutes help to reinforce the competitive strength of the economy in their local region, and throughout Germany and Europe. They do so by promoting innovation, strengthening the technological base, improving the acceptance of new technologies, and helping to train the urgently needed future generation of scientists and engineers.

As an employer, the Fraunhofer-Gesellschaft offers its staff the opportunity to develop the professional and personal skills that will allow them to take up positions of responsibility within their institute, at universities, in industry and in society. Students who choose to work on projects at the Fraunhofer Institutes have excellent prospects of starting and developing a career in industry by virtue of the practical training and experience they have acquired.

The Fraunhofer-Gesellschaft is a recognized non-profit organization that takes its name from Joseph von Fraunhofer (1787–1826), the illustrious Munich researcher, inventor and entrepreneur.

Executive board

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

Prof. Dr. Ulrich Buller, Research Planning

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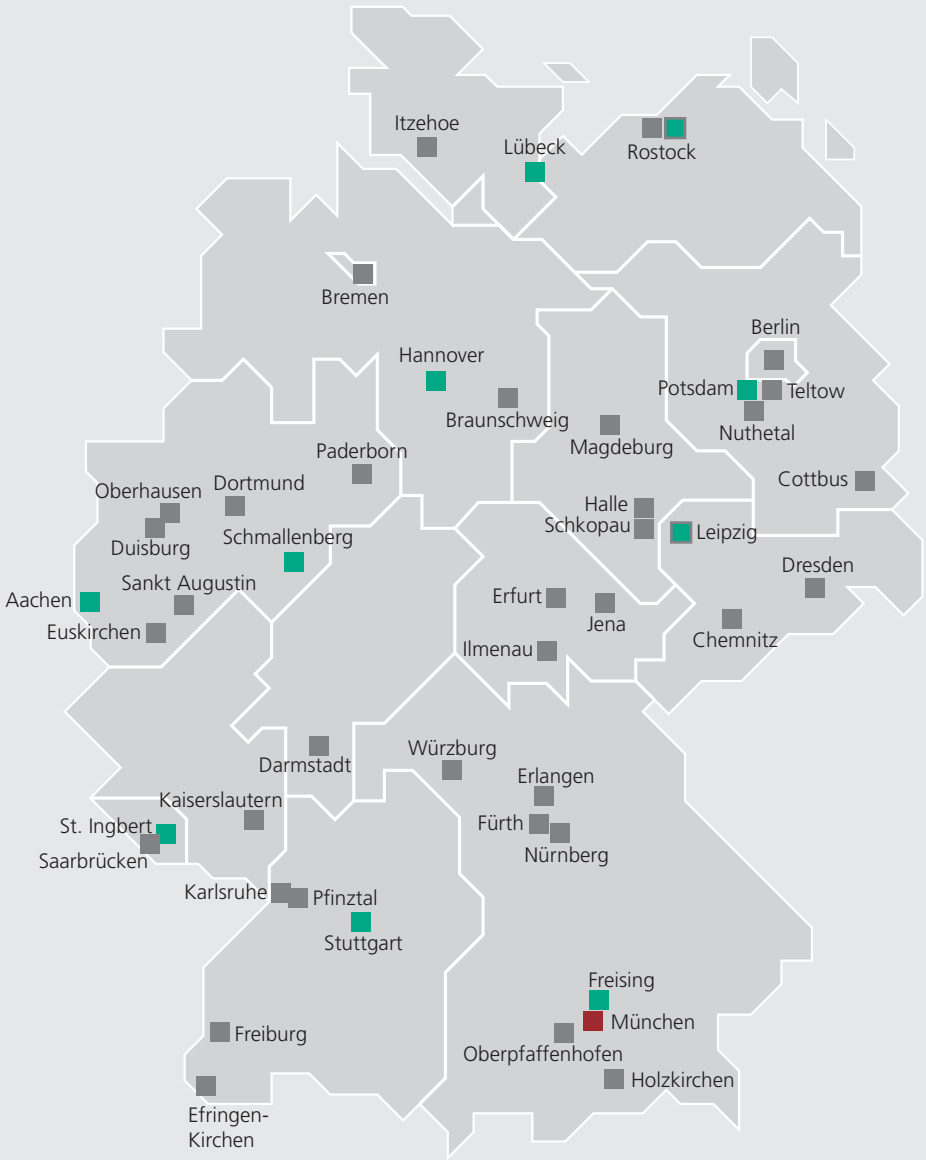

Fraunhofer Institute

Central office of the Fraunhofer-Gesellschaft, Munich

Location of institute 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 Group for Life Sciences is one of the Fraunhofer-Gesellschaft's most dynamic areas of research.

Business units of the Fraunhofer Group for Life Sciences:

- Medical translational research and biomedical technology: The challenge of innovative diagnostics and personalized therapy
- Regenerative medicine: The challenge of qualified biobanking and controlled self-healing
- Healthy foods: The challenge of high consumer acceptance and disease prevention
- The new potential of biotechnology: The challenge to learn from nature for industrial exploitation
- Process, chemical, and herbicide safety: The challenge of environmental and consumer protection

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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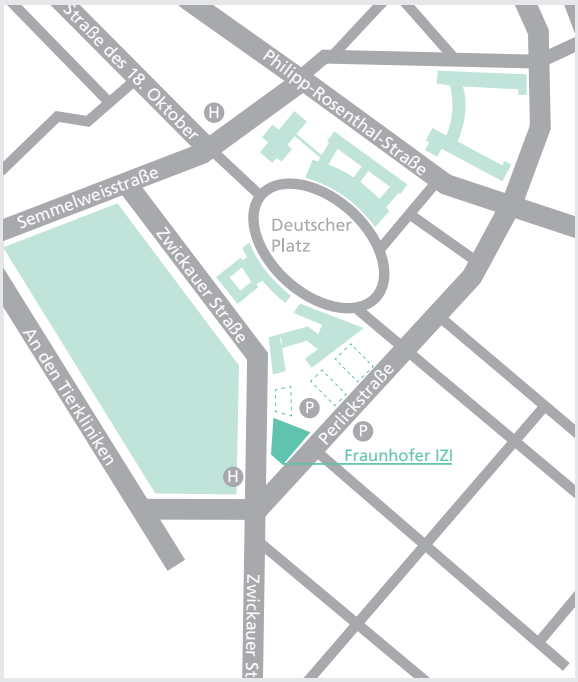

By car

Please note: Some navigation systems fail to find "Perlick-straße" 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 Haupt-bahnhof"), 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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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.

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Our seminar catalog gives you an overview of the advanced training program offered by the Fraunhofer IZI. Besides inter-disciplinary 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, important events and publications, 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.

Editorial notes

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Title page
Section of a dorsal spinal root ganglion (fluorescence microscopy). First prize in the photo competition "Fascinating Microcosm" (Faszination Mikrokosmos) within the framework of the Long Night of the Sciences / Researchers' Night (Lange Nacht der Wissenschaften): Verena te Kamp, University of Leipzig, Center of Biotechnology and Biomedicine (BBZ).

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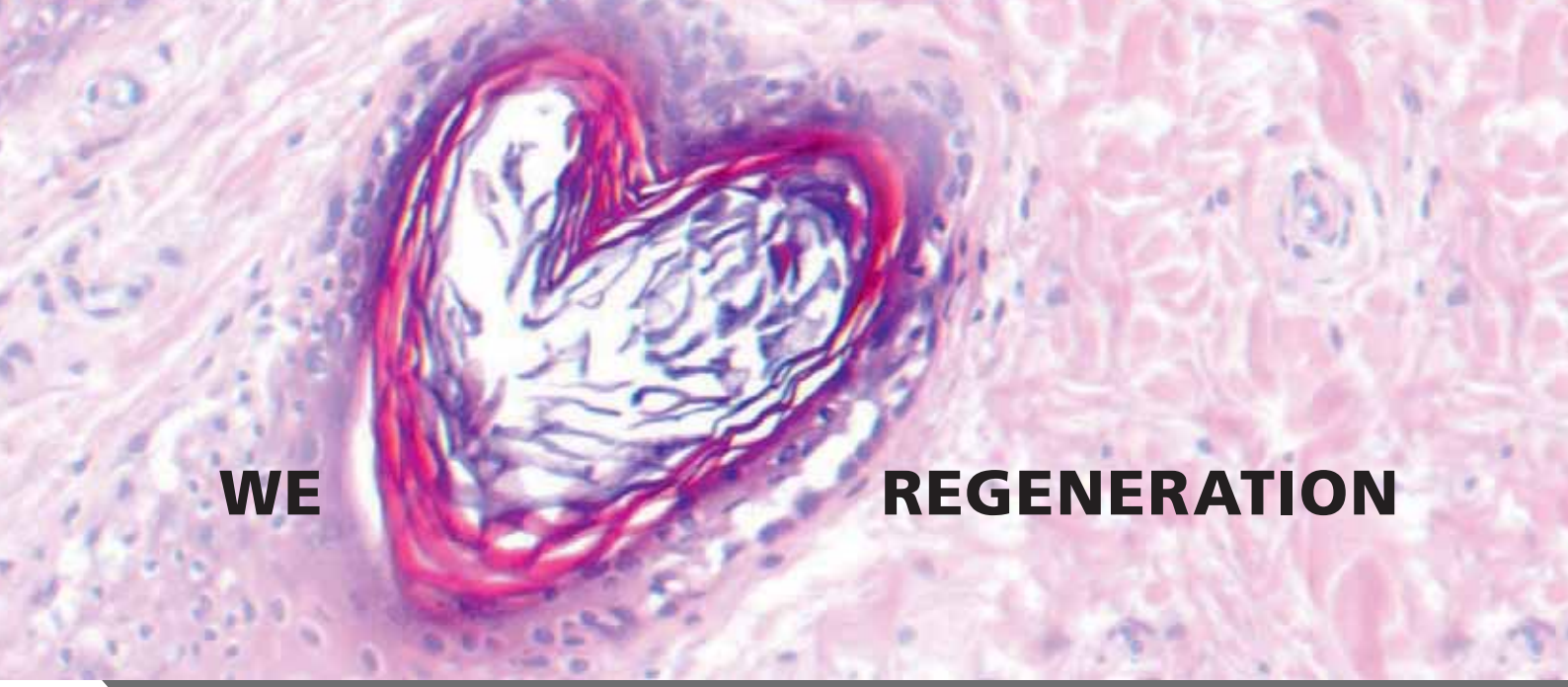

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