

HEALTH

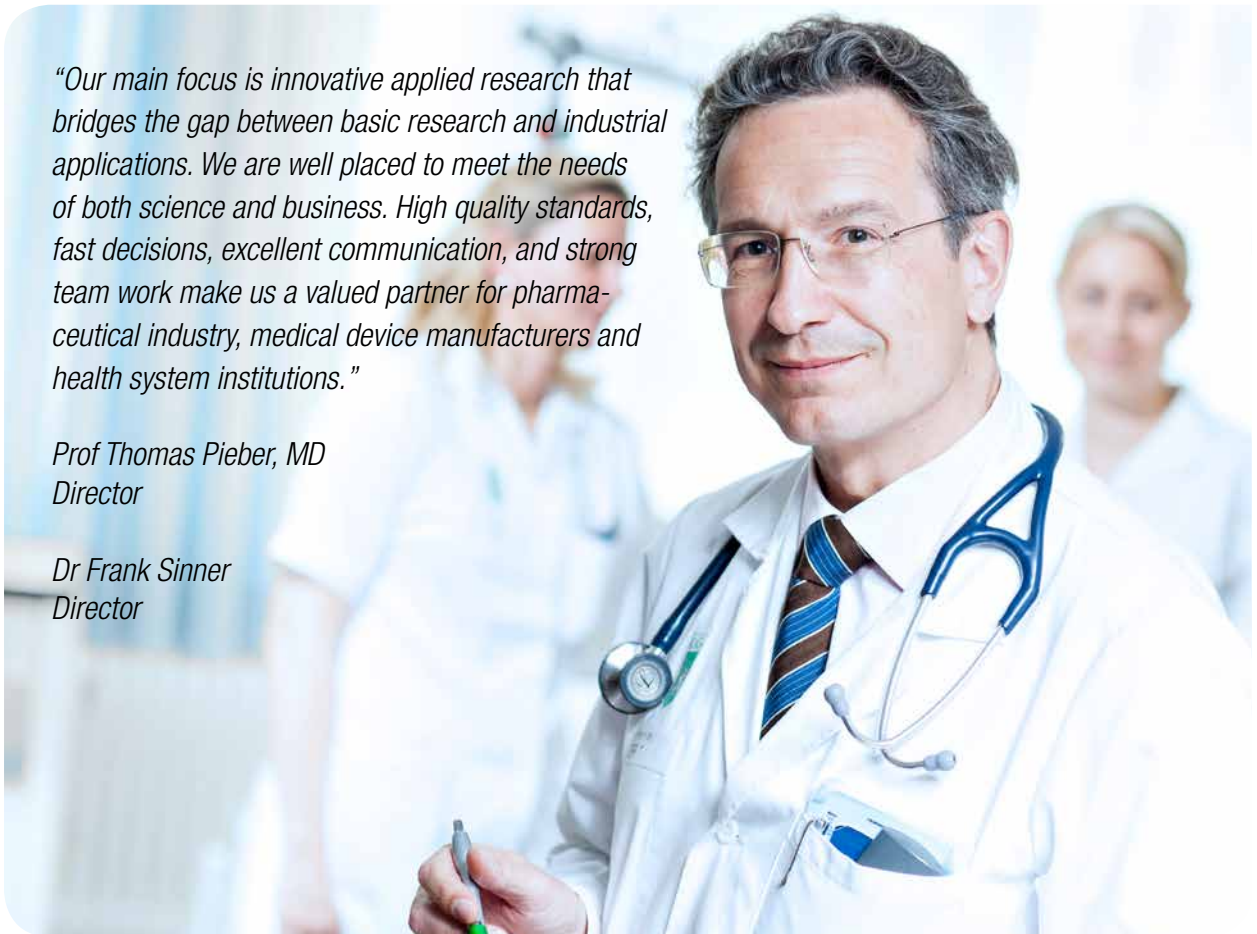
Institute for Biomedicine
and Health Sciences



“Our main focus is innovative applied research that bridges the gap between basic research and industrial applications. We are well placed to meet the needs of both science and business. High quality standards, fast decisions, excellent communication, and strong team work make us a valued partner for pharmaceutical industry, medical device manufacturers and health system institutions.”

*Prof Thomas Pieber, MD
Director*

*Dr Frank Sinner
Director*



Contact

JOANNEUM RESEARCH
Forschungsgesellschaft mbH

HEALTH

Institute for Biomedicine
and Health Sciences

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HEALTH – Institute for Biomedicine and Health Sciences

Bridging Boundaries

Successful medical research strongly depends on interdisciplinary collaboration to bring new ideas to market.

We work in a close strategic alliance with the Medical University of Graz. Our director, Prof. Thomas Pieber, MD, is also Chair of the Department of Internal Medicine and Chair of the Division of Endocrinology and Diabetology at the Medical University of Graz.

Our team consists of over 60 technical and scientific experts. We work closely with more than 100 medically oriented specialists from the Medical University of Graz.

Together, we translate ideas and technologies from medicine, pharmaceutical science and health services research into marketable products and services.

Research Services

- Pharmacokinetic, pharmacodynamic and bioequivalence studies
- Bio- and pharmaceutical analysis
- Metabolomics/Biomarker research

- Medical sensors
- Clinical decision support
- Health economics & outcomes research
- Planning of health care structures and processes



Quality

We set high quality standards for our services and products. We guarantee the application of international quality standards right from placing your order up to delivery of the final product/service. We operate according to the following guidelines:

- EN ISO 9001
- EN ISO 13485
- GLP

Our customers are welcome to assess our facilities and quality standards on-site at any time.



Pharmacokinetic, Pharmacodynamic and Bioequivalence Studies

We investigate pharmacokinetic (PK) and pharmacodynamic (PD) profiles of new drugs as well as the bioequivalence of new pharmaceutical formulations. We carry out biomarker-based studies and metabolomic trials to investigate the

causes of inflammatory diseases. We have the capacity to perform ex-vivo and in-vivo studies, using microdialysis and our patented Open Flow Microperfusion method.

Our services

- Study protocol preparation
- Submission of ethics applications
- Pre-clinical and clinical studies (GCP compliant)
- Development, validation and performance of bioanalytical procedures (GLP compliant)
- High quality data management
- Statistical data analysis

We focus on the target tissue level

- **Dermatology:** Transport routes and drug effects in the dermis after topical or systemic administration (e.g., topical glucocorticoids or systemic antibodies in the case of psoriasis)
- **Endocrinology:** Transport routes and drug effects in adipose tissue (e.g., insulin, glucagon, inulin, ...)
- **Neurology:** Transport across the blood-brain barrier (BBB), dose-response effects when the BBB is bypassed, monitoring of BBB function (e.g., highly lipophilic substances as well as psycho- and neuropharmaceuticals)



Open Flow Microperfusion (OFM)

- Direct in-vivo access to the interstitial fluid and to the interstitium's whole biochemical information
- Continuous sampling of diluted, unchanged tissue interstitial fluid
- No limitation in substance size (even cells), lipophilicity or protein binding effects
- Continuous multi-analyte sampling and PK-PD analysis

OFM material

CE-labeled OFM probes and small, wearable, multi-channel pumps for (pre-)clinical PK and PD studies.

GLP-certified laboratory

We specialize in microliter sample volumes and picomolar analyte concentrations by using state-of-the-art mass spectrometry.

Study planning, electronic data capture and management and statistics

Having a profound understanding of medical research, we combine electronic data capture and data management with long-term expertise in reliable statistical analysis – according to GCP and 21 CFR Part 11.

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Bioanalysis and Pharmaceutical Analysis

We develop, validate, optimize and automate innovative bioanalytical methods for high-throughput analyses that can be used by medical researchers and in the pharmaceutical industry. We can analyze sample volumes in the microliter range using the latest bioanalytical methods – GLP-compliant on request.

GLP certified

Our services

■ Bioanalysis

From innovative analytical methods to quality controlled analysis of human and animal blood and tissue samples.

■ Pharmaceutical analysis

Performed on pharmaceutical raw materials and formulations, e.g. drug analysis, cleaning validation, quantitative testing and impurity testing.

■ Cleaning validation

From optimizing sampling methods, the development of highly sensitive and selective analytical methods and validation according to international standards.

High-end metabolomics wetlab

- Metabolites including acyl-CoA enzymes, products of energy metabolism, isotope-labeled tracer molecules, etc.
- Drug analysis
- Polyamines





Metabolomics Biomarker Research

We are developing innovative and optimized analytical methods that can be used to investigate metabolic processes. We combine our bio-analytical, statistical, medical, biological and biochemical expertise with advanced information technology for a wide range of customer-oriented services in the field of metabolomics and metabolic research.

Our services

■ Targeted Metabolomics

Our GLP certified laboratory offers several targeted metabolomics platforms based on high resolution mass spectrometry (Orbitrap).

■ Untargeted Metabolomics

Our untargeted platform provides optimized metabolic fingerprinting for the detection of novel, unknown markers.

■ Data analysis

Includes data conversion, peak detection, alignment, grouping, data filtering.

■ Statistics

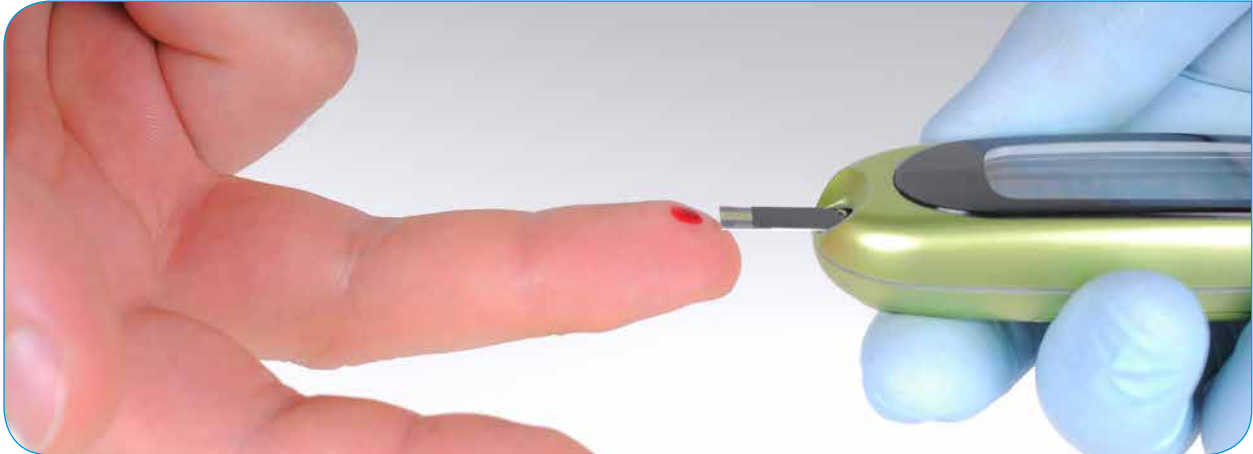
Includes multivariate statistical methods, regression models and neural networks.

■ Metabolite database

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Medical Sensors

We focus on the application of various sensor technologies for measurements in a clinical setting. We develop new optical and electrochemical sensor-based measurement methods and systems starting from ideas to prototypes that can be used in a clinical evaluation.

Our services

■ Sensors for online monitoring

- Continuous in-vivo monitoring of key substances in various tissues (e.g. glucose).
- Miniaturization of sensors (down to a few micrometers)
- Combination of sensors with different sampling techniques, and integration into microfluidic structures

■ In-vitro diagnostics

- Sensors for in-vitro point-of-care diagnostics
- Rapid and direct measurement of samples in their native state
- Devices must be simple to operate and safe to use

■ Bioimpedance measurement

- Using bioimpedance spectroscopy for indirect and non-invasive quantification of tissue properties or biological activity and motility in cell cultures.

■ Sensor development and evaluation

- Sensor design
- Exploration of calibration methods
- Workflow analysis
- Clinical and preclinical evaluation of sensor performance and system usability

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Clinical Decision Support

We optimize medical treatment processes by using modern eHealth and mHealth solutions. Our solutions digitize and connect intramural and extramural workflows. We develop software as a medical product from the idea to market maturity and, if necessary, take the regulatory responsibility as a manufacturer or EU authorized representative.

Services

■ Transferring clinical processes to electronic systems

- Evidence based and user friendly
- Modern ICT solutions directly at the point-of-care to support professional medical decision making and patient care
- Process analysis
- Development of demonstrators and mock ups

■ Development of clinical algorithms for decision support systems

- Evidence analysis and development of rule-based clinical processes
- Combination of clinical expertise and statistic modelling
- In-silico validation

■ Development of software as a medical product

- According to IEC 62304 in the ISO 13485 quality management system
- Technical documentation
- Conformity assessment

■ Software validation in clinical studies

- Clinical assessment according to MEDDEV 2.7/1 rev 4
- Data to assess clinical safety and effectiveness

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Health Economics and Outcomes Research

We support you by offering our unbiased, evidence- and science-based expertise in the areas of health care and pharmacoconomics, market analysis, horizon scanning, regulatory affairs and reimbursement, as well as in the scientific and economic evaluation of health care programs.

Our services

- Early assessment of new technologies and products
- Health economics and reimbursement
- Market analysis and horizon scanning
- Medical and economic evaluations of health care

Know-how

- Comprehensive analyses and solutions
- Interdisciplinary approaches
- Information about decision-making processes and requirements within the health care system
- In-depth knowledge of the health care system and services
- Expertise in specific diseases and indications
- Application of a wide range of scientific methods and study designs

Code of conduct

In our work, we place the highest value on the use of methods that have been scientifically established and supported, as well as on unbiased results derived by applying principles of both scientific rigor and objectivity.

We work toward the continuous improvement of health care in Austria and other countries and, for this reason, we feel that we are obliged to the interests of our society. We are particularly keen to represent the interests of patients insofar as possible, with the ultimate goal to benefit the whole of society with our concepts, expertise and analyses.



Integrated Health Care Concepts and Planning

We assist healthcare decision-makers and service providers in the development, implementation, monitoring and evaluation of integrated health care operations. We increase the visibility of your services in therapeutic, diagnostic and nursing settings and help you to unlock your full potential as a healthcare provider, support organization, hospital, insurance agency, association, clinic or doctor in a private practice.

Our services

- Structural planning
- Procedural planning
- Development of care management programs
- Medical and economic evaluations in the health care system

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