

HEALTH

Institute for Biomedical Research and Technologies





JOANNEUM RESEARCH Forschungsgesellschaft mbH

JOANNEUM RESEARCH develops solutions and technologies for business, industry and public authorities over a wide range of sectors and conducts applied cutting-edge research on an international level.

The company makes a significant contribution towards safeguarding the economic success of the region and assumes a key role in the transfer of technology and expertise into the economy.

State of Styria

80,75% 14,25%

BABEG Carinthian Agency for Investment Promotion and Public Shareholding

5%

Wirtschaftsagentur Burgenland

Certifications

ISO 9001

Requirements for quality management systems

ISO 14001

Environmental management systems

ISO 13485

Medical devices - Quality management systems -Requirements for regulatory purposes

ISO 14644

Cleanrooms and associated controlled environments

ISO 17025

Accredited test laboratory ROBOTICS Evaluation Lab

GLP

Good Laboratory Practice

Numbers - Data - Facts

around **500** employees (from over 25 nations)

7 research units

6 locations

around **50** million Euro of research services per year





MEDICINE. INNOVATION. TECHNOLOGY.

»Innovative ideas, products & solutions from HEALTH demonstrably contribute to an improved quality of life for people with medical needs. «

Prof. Dr Thomas Pieber (l.) and Dr Franz Feichtner (r.) *Directors*

HEALTH

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HEALTH sees itself as the link between medical research and industrial application and offers interdisciplinary solutions as R&D services to the pharmaceutical industry and medtech sector. We also work on continuous improvement in the healthcare sector and feel committed to contribute to overall societal interests.

The added value of our work arises from the combination of excellent scientific research with high industrial standards.



Our Focus Areas

We are working on innovative healthcare solutions with a focus on the following key areas:



Pharmacological Research in the Skin

We are investigating pharmacological principles of the skin to enable the development of effective and affordable therapies with minimal side effects for people with skin diseases.





Pharmacological Research in the Brain

We are doing pharmacological research in the healthy and the diseased brain to enable the development of effective therapies that can be tailored to each individual patient with a neurological disease.





Metabolic Research

We are applying our technologies to investigate the basic principles of metabolism and thus enable new treatments of widespread metabolic diseases such as diabetes and obesity, as well as an improvement in general aging processes.





Digital Healthcare

We contribute to a meaningful digitization of processes and decisions in healthcare to improve the quality of treatment while giving staff more time to work with people.



cons on the right: Flatico

Pharmacokinetics | Pharmacodynamics | Bioequivalence

We investigate pharmacokinetics (PK) and pharmacodynamics (PD) of new drugs and bioequivalence (BE) of new drug formulations for the pharmaceutical industry. We perform biomarker-based studies and metabolomics to identify causes of inflammatory diseases. We carry out tissue-specific preclinical ex-vivo and in-vivo studies and also clinical studies. In these studies, we use our patented open flow microperfusion (OFM) as well as microdialysis.

Open Flow

Our Competence

OFM is a minimally invasive, membrane free sampling method to continuously extract interstitial fluid directly from the tissue of interest.

OFM enables access to the entire biochemical information of the interstitium in-vivo and opens completely new perspectives in preclinical and clinical drug testing.



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Our Services

- Testing of Dermal Products We design customised test set-ups to generate reliable data as early as possible in the drug development process.
- Bioequivalence Testing of Topical Generics We plan and perform studies to assess the bioequivalence for topical generics directly in the dermis.
- Testing BBB Transport of Neuropharmaceuticals

 We take a look behind the blood-brain barrier (BBB) and investigate neuroactive substances in the brain.
- PK-PD Testing of Subcutaneous Drugs
 We monitor drug distribution and drug-tissue interaction after subcutaneous injection by providing direct access to the interstitial fluid.



Bioanalysis | Pharmaceutical Analysis

We support our clients with our expertise in the field of mass spectrometry and immunochemistry. We develop analytical methods and connect scientific competence with GLP (Good Laboratory Practice) / GCP (Good Clinical Practice) standards to answer scientific questions and to support the pharmaceutical approval process.

Our Competence

The combination of scientific expertise and professional project management enables us to offer individually tailored projects ranging from pilot to multicenter clinical studies. Many years of analytical experience enable us to react particularly flexible to client requirements.

Method validation according to the most current guidelinesAnalyses from a range of biological matrices (e.g. serum,

Our Services

 Analyses from a range of biological matrices (e.g. serum, plasma, interstitial fluid, tissue, cell cultures) as well as drug formulations

Development and optimisation of tailored, analytical methods

- Sample analysis, also with high sample throughput
- Established analysis panels for
 - pharmacodynamic parameters (e.g. small-molecule drugs, therapeutic antibodies)
 - pharmacodynamic parameters (e.g. cytokines, eicosanoids)
 - biomarkers (e.g. metabolites from energy metabolism (AcylCo) or polyamine)
 - isotope marked tracer
 - clinical parameters

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Metabolomics

We address the issue of how innovative, analytical procedures can be applied and optimised in order to investigate metabolic processes. We combine bioanalytical, statistical, medical, biological and biochemical expertise with highly developed information technology.

Our Competence

We combine highly specialised analyses with the highest certified quality standards (GLP — Good Laboratory Practice). Methods and analyses can be optimised for high sample throughput by using automated sample processing. This enables us to offer a wide spectrum of customeroriented services in the field of metabolomics and metabolic research.



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Our Services

Targeted Metabolomics

In our Biocrates-certified metabolomics lab, we can quantify over 5000 metabolites from one sample using the Biocrates method. We also offer specific analysis methods for biological metabolic pathways (e.g., tryptophan pathway, polyamines, CoA activated fatty acids, catecholamines).

Untargeted Metabolomics

Our "untargeted platform" offers optimised metabolic fingerprint acquisition that enables the recognition of new, unknown markers.

Data Analysis and Statistics

Include data conversion, peak detection, grouping, data filtering, drift correction, univariate and multivariate statistical methods, regression models and neural networks.



Data Management and Biostatistics

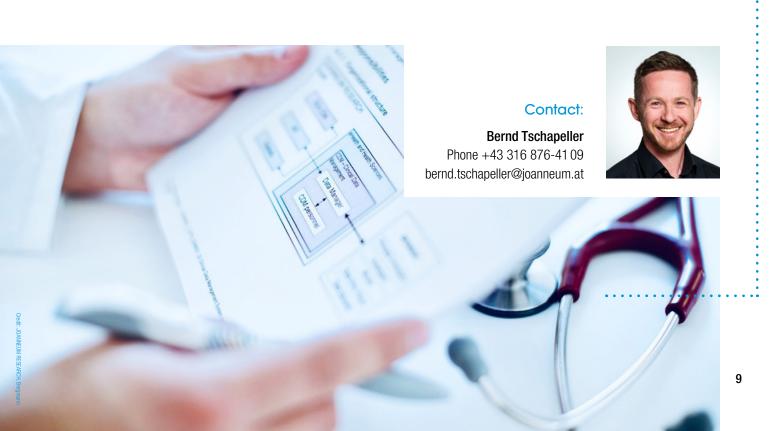
We offer tailored data management and biostatistical services where we assist our customers from protocol development to study reporting.

Clinical Data Management

- Data management plan
- CRFs and eCRFs (electronic Case Report Forms) including validation
- Validated electronic data capture (EDC) system
- EDC user training / user management
- Validated interfaces to external, electronic data
- Medical coding (MedDRA, ATC/DDD)
- Data validation plan (data plausibility)
- Data visualisation, transfer and archiving

Clinical Statistics

- Protocol development support
- Sample calculations
- Statistical analysis plan (SAP) including specifications for tables, listings, figures (TLFs)
- Selection and organisation of the randomisation process
- Data check including fault correction and imputation
- Intermediate analyses
- Statistical report with all statistical evaluations according to SAP
- Individual analyses for publications





Medical Writing

Our team of medical authors has long-standing scientific expertise, training and experience to generate the documents required to report and publish your results. We make sure that all documents meet the standards and that your results will attract the attention they deserve.

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Our Services

- Scientific publications
- Scientific abstracts and presentations
- Newsletters and press releases
- Documents for ethics and health authorities
- Study reports
- Clinical trials: trial documentation, safety reports, patient information, consent forms, trial summaries in everyday language for patients

Technology Development:

Digital Healthcare Solutions

Within our research activities, we provide information for healthcare planning and quality assurance and we digitize care processes that are integrated in eHealth systems.

Our Competences

We are specialized in the development and clinical validation of ICT-based systems for medical decision-making. An ISO 13485 quality management system is implemented and we meet the necessary requirements for quality-assured development (IEC 62304, ISO 14971, IEC 62366).

Process Digitization in Healthcare

- We digitize care processes with a focus on multiprofessional and integrated care.
- We are experts for integrating digital solutions into complex care processes and IT-integration in e.g. hospital information systems.



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Our Services

Real World Data in Healthcare

- We are providing services for quality assurance and research in healthcare systems.
- We support disease management programmes for audit and feedback purposes.
- We have a unique database of more than 500,000 patients in Austria and Germany in the fields of diabetes, cardiovascular diseases, hepatitis C, and geriatrics.
- We use structured real world data for the discovery of digital biomarkers and development of Al-based models for risk identification and risk stratification.

Development of Clinical Decision Support Systems (CDSS)

- We develop CDSS in co-creative processes with healthcare professionals and patients.
- We develop software as a medical device from product idea to market readiness.
- We develop Al-based clinical algorithms to support medical decision-making.



The Benefits of Partnering with Us

High quality standards, solution-oriented work style, excellent communication and teamwork make us an appreciated partner for universities, the pharmaceutical industry, medical product manufacturers and healthcare institutions.

Industry meets Science

Over 20 years of experience allow our experts to connect high scientific standards with professional project management resulting in more meaningful data.







GLP | GCP | GMI

Independent and Objective

Our team is a part of the publicly owned, non-profit JOAN-NEUM RESEARCH Forschungsgesellschaft mbH. As such, we are committed to independent and objective research.

Highest Quality Standards

We set ourselves high standards for the quality of our services and products, and we are certified according to the following standards:

- ISO 9001
- EN ISO 13485
- Good Laboratory Practice (GLP)



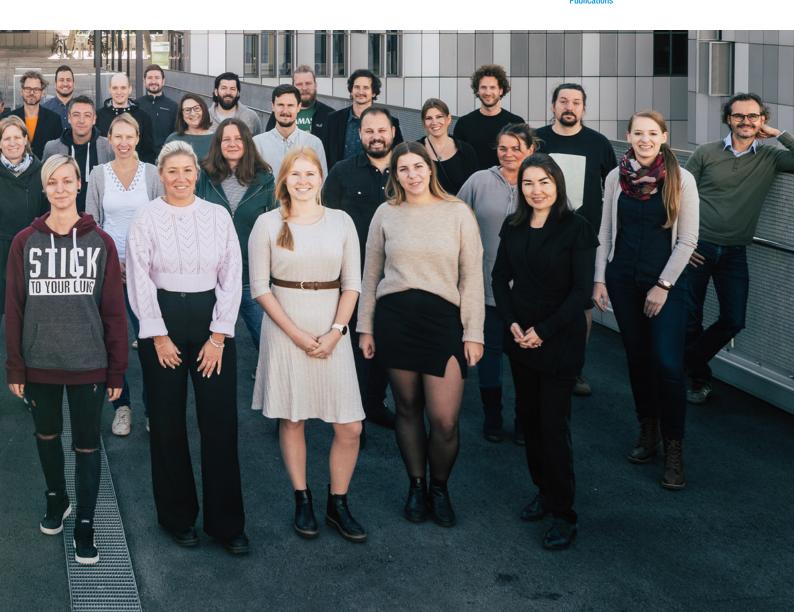
Scientific Excellence

The scientific excellence of HEALTH is largely evidenced by publications in high-ranking journals. We place great value in publishing the results of our research in high-impact and widely cited publications.

Publications in the Following Journals:

Nature Medicine, The Lancet, Nature Neuroscience, Nature Cell Biology, Molecular Systems Biology, Cell Metabolism, Molecular Cell, Autophagy, Annals of Internal Medicine, Gastroenterology, Journal of Internal Medicine, Diabetologia, Scientific Reports, Diabetes, Diabetes Care, Cell Reports, Obesity and Metabolism, Biosensors & Bioelectronics, Analytical Chemistry





Research Infrastructure

State-of-the-art laboratory infrastructure for (bio)analytical, pharmacological, and medical device studies.

360 m² of state-of-the-art laboratory infrastructure provide technologies, instruments, and processes to perform preclinical and clinical pharmacological studies and to analyze active pharmaceutical ingredients. Part of the laboratory is GLP certified for this purpose.

Sample entry, storage and processing

Quality-assured sample entry and storage in 24/7 temperature-monitored, fail-safe and alarm-protected freezers. Preparation of samples from different matrices (e.g., serum, plasma, interstitial fluid, urine, biopsies, tissue samples, smear sample) for analytical procedures

Automation

For sample processing in studies with a large number of samples (>1000), we rely on automation using a pipetting robot with integrated ELISA reader (UV, fluorescence) and washer from Hamilton.

Metabolomics

High-resolution mass spectrometers (HPLC-MS/MS from ThermoScientific®, Agilent®) for specific (targeted) and broad (untargeted) metabolomics analyses to determine and quantify metabolites from metabolic processes for biomarker research

OFM

Production and distribution of materials for the use of open flow microperfusion in preclinical and clinical studies

Studies

Conducting in-vitro release tests (IVRTs) and ex-vivo experiments using skin explants, artificial or cultured skin with continuous or single-point measurement methods (open flow microperfusion, microdialysis, biopsies, tape stripping)

We conduct clinical and preclinical studies with or at partner CROs. For clinical trials, we offer a fully validated online system for electronic data capture (EDC). This enables the efficient and traceable collection, transfer and validation of clinical trial data.









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