JOANNEUM RESEARCH HEALTH

HEALTH

Institute for Biomedicine and Health Sciences

THE INNOVATION COMPANY

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.

Corporate Film

Our 3 Thematic Areas

Information and Production Technologies

Human Technologies and Medicine

Society and Sustainability

JOANNEUM RESEARCH

Owners

80.75 %
State of Styria

14.25 %
BABEG Carinthian Agency for Investment Promotion and Public Shareholding

5 %
Landesholding Burgenland GmbH

Certifications

ISO 9001
Requirements for quality 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

ISO 14001
Environmental management systems

GLP
Good Laboratory Practice

Numbers – Data – Facts

around **500** employees (from over 20 nations)

3 overarching thematic areas

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

Institute for Biomedicine and Health Sciences

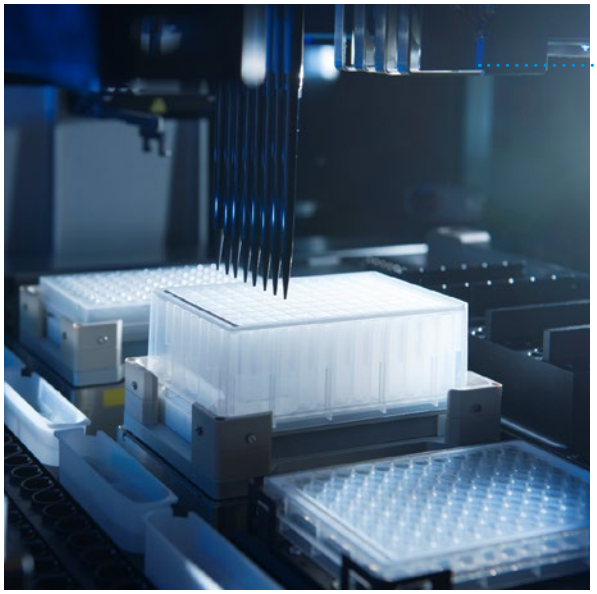
HEALTH sees itself as the link between medical research and industrial application and offers interdisciplinary solutions as R&D services to the pharmaceutical industry and MedTech sector. We also work on continuous improvement in the healthcare sector and feel committed to contribute to overall societal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

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

Translational Research

HEALTH is active in medical research and medically-related research disciplines and positions itself as a reliable link between engineering and medicine.

Our scientific expertise in the fields of medicine, pharmaceutical sciences and biotechnologies is grouped into the following, customer-oriented areas:

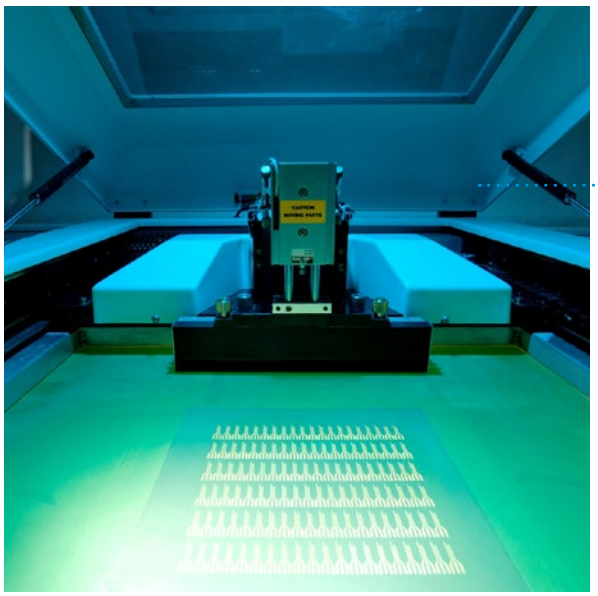


Clinical and Preclinical Research

JOANNEUM RESEARCH HEALTH acts as a dedicated boutique CRO for research projects and drug development programs. In the therapeutic areas of dermatology, neurology and metabolic research we cover the following fields:

- Pharmacokinetics | Pharmacodynamics | Bioequivalence
- Bioanalysis | Pharmaceutical Analysis
- Metabolomics
- Data management and Biostatistics
- Medical Writing

CRO Services
LinkedIn



Technology Development

Besides specialised research services, HEALTH develops technologies for future medical solutions.
We are particularly specialised in the following fields:

- Clinical Decision Support
- Medical Sensors

Clinical and Preclinical Research:

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 Microperfusion

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.

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.

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Clinical and Preclinical Research:

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.

Our Services

- Development and optimisation of tailored, analytical methods
- Method validation according to the most current guidelines
- Analyses from a range of biological matrices (e.g. serum, plasma, interstitial fluid, tissue, cell cultures) as well as drug formulations
- 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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Clinical and Preclinical Research:

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.

Metabolomics
Biomarker Research

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 customer-oriented services in the field of metabolomics and metabolic research.

Our Services

- **Targeted Metabolomics**
  High resolution mass spectroscopy based on Orbitrap technology coupled with LC enables the identification of metabolites via exact molecular mass and retention time.
- **Untargeted Metabolomics**
  Our “untargeted platform” offers optimised metabolic fingerprint acquisition that enables the recognition of new, unknown markers.
- **Data Analysis**
  includes data conversion, peak recognition, alignment, clustering and data filtering.
- **Statistics**
  includes multivariate statistical methods, regression models and neural networks.

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Clinical and Preclinical Research:

Data Management and Biostatistics

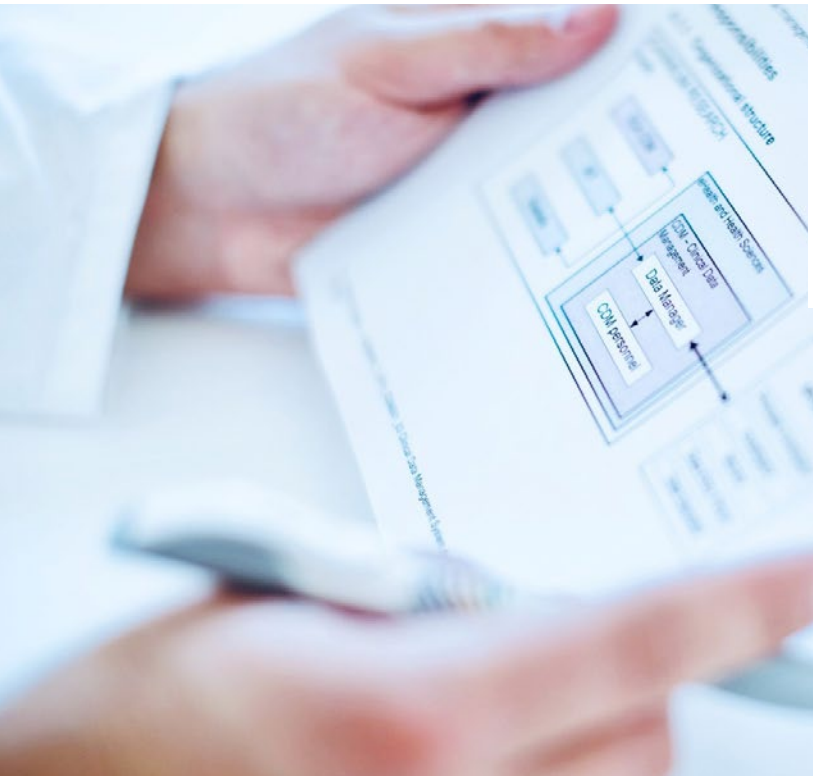
We offer tailored data management and biostatistical services where we assist our customers from protocol development to study reporting.

Clinical Data Management

- Data management plan
- CRFs and eCRFs (electronic Case Report Form) 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



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Clinical and Preclinical Research:

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.

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

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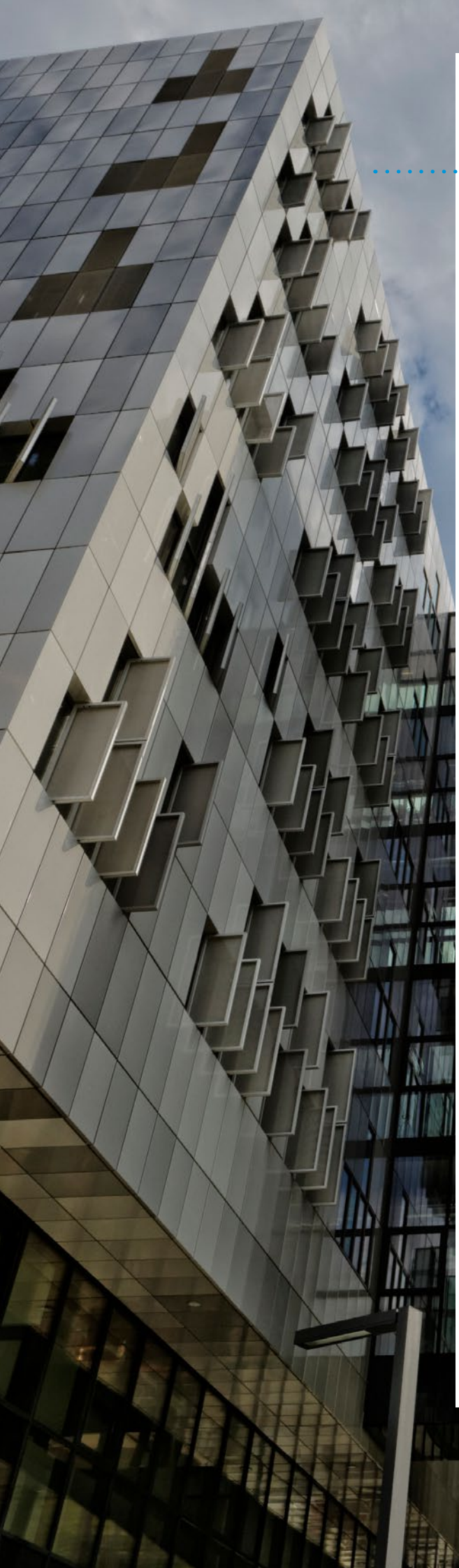

Research Infrastructure

Bioanalytics and Metabolomics

HPLC-MS (high resolution mass spectrometer)

- UHPLC-Q-Exactive (Thermo Scientific®)
- HPLC-LTQ Orbitrap XL (Thermo Scientific®)
- HPLC-Exactive (Thermo Scientific®)

HPLC-MS/MS (Triple-Quadrupol-mass spectrometer)

- 3 UHPLC-MS/MS (Thermo Scientific®, Agilent®, Shimadzu®)
- 1 HPLC -MS/MS (Thermo Scientific®)
- GC-MS/MS (Agilent®)

HPLC-UV

- 2 UHPLC DAD (Agilent®, Thermo Scientific®)

Robotic Liquid Handling Workstation

- Hamilton® Microlab STARlet liquid handling system

Reader

- Microplate reader Fluorescence, UV/VIS, (BioTek®)

Multiplexing Immunoassay

- MESO QuickPlex (Meso Scale Discovey®)

IVRT Testing

- Qualified 6-cell manual vertical diffusion cell system (Hanson Research Corporation)

Medical Sensors

Sensor production

- DEK 248 Semi-Automatic Screen Printer
- Performus™ III & IV Microdispensers
- Drying Cabinet FD 53
- UVACUBE – UV Curing Chamber
- ATTO Low Pressure Plasma System

Biosensor characterisation/analysis

- Gamry G300 potentiostats
- Palmsens4 multipotentiostat & multiplexer
- Spectrophotometer Genesys 10s UV
- Hitado Super GL compact analyzer
- Roche Reflotron Plus analyser
- G.E.M. Premier 3000 blood gas analyser
- Keyence VHX-5000 digital microscope
- Fluigent microfluidic automation tool
- Contactless conductivity instrument TraceDec

Visit our Laboratories in 360°

Technology Development:

Clinical Decision Support

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 (ISO 13485, IEC 62304, ISO 14971, IEC 62366).

Process Digitization in Healthcare

- We digitize care processes with a focus on multi-professional 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.

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 AI-based clinical algorithms to support medical decision-making.

Clinical Decision Support

Technology Development:

Medical Sensors

We focus on the application of various sensor technologies for measurements in clinical settings. We develop new sensor-based, optical and electrochemical measurement procedures and systems from the initial concept to a prototype that can be used in clinical evaluations.

Our Competence

We offer innovative sensor-based solutions for fast and more convenient monitoring of health-relevant parameters in home and clinical settings for diagnosis and prevention.

Our Tech Offers

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Our Services

Sensors for Online Monitoring

- Continuous in-vivo monitoring of key analytes in various tissues.
- Sensor miniaturisation (down to a few micrometres)
- Combination of sensors with a range of sampling techniques and integration in microfluidic structures

In-Vitro Diagnostics

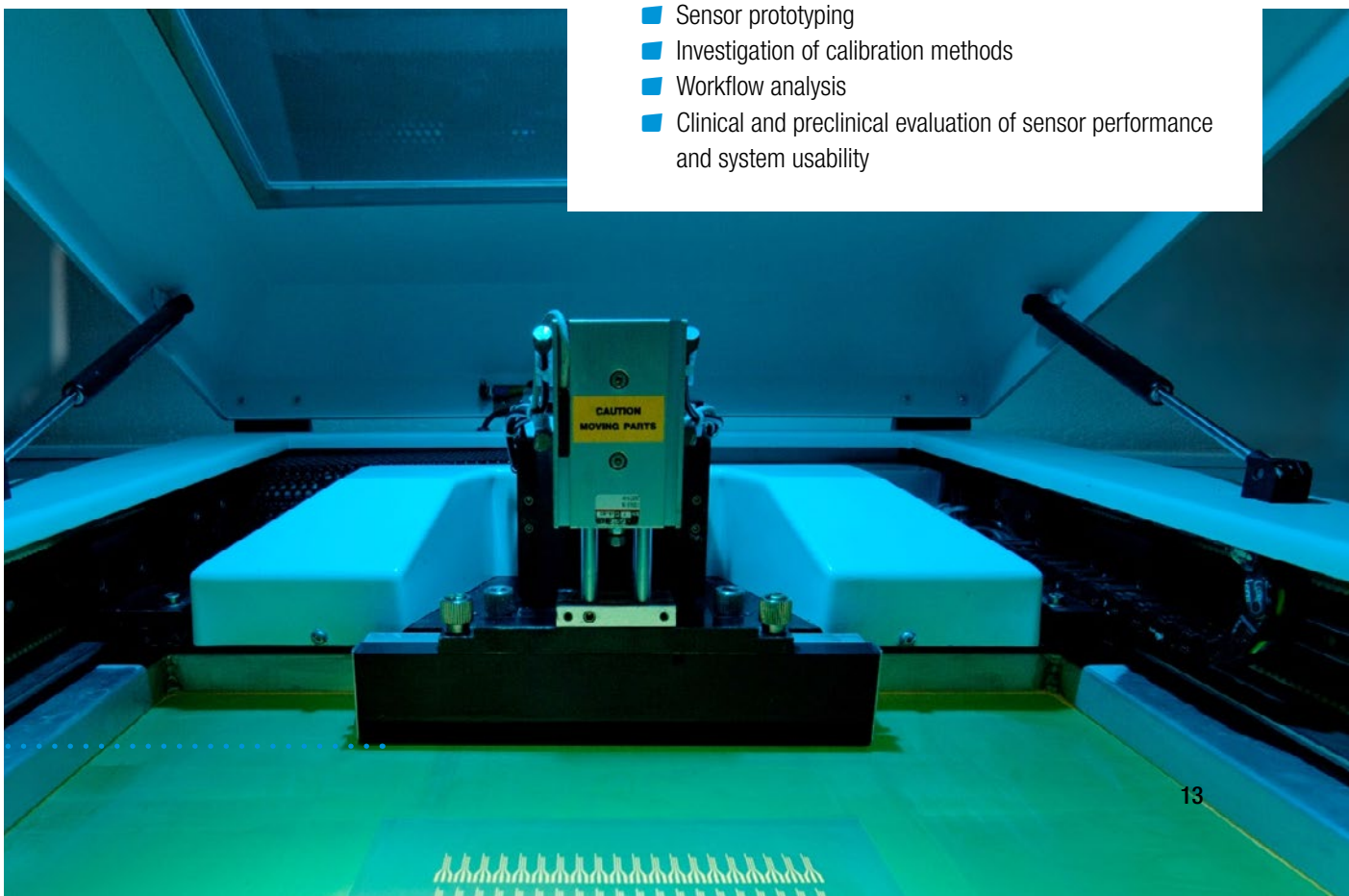
- Sensors for in-vitro point-of-care diagnostics
- Rapid and direct measurement of samples in their native state

Bioimpedance Measurement

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

Sensor Development and Evaluation

- Sensor prototyping
- Investigation of calibration methods
- Workflow analysis
- Clinical and preclinical evaluation of sensor performance and system usability



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.

Independent and Objective

Our team is a part of the publicly owned, non-profit JOANNEUM 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)

EN ISO 13485

GLP | GCP | GMP

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

Publications

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