Biobank Graz: Leader in Biobanking as Hub for Co-Opetitive Medical Research
DEAR READER,

thank you for your interest in the Biobank Graz.

The core asset of Biobank Graz is a large collection of clinical samples – actually one of the largest in Europe – comprising millions of well organised tissue, blood and DNA samples.

Moreover, Biobank Graz provides powerful logistics and infrastructure enabling prospective collection of samples and data designed according to the needs specified by our customers.

To ensure direct access to cutting edge technology and sustainable high quality research services, centralised core facilities operated by experienced technical and scientific staff are accessible at the Medical University Graz. It is our mission to efficiently support our partners at all steps of the research cooperation.

Yours sincerely,

Biobank Graz Team
WHAT IS A BIOBANK?

Biobanks are collections of biological samples and their associated data, organised in a structured, readily analysable format. Academic biobanks for medical research typically contain tissue samples, blood and other body fluids, as well as cells and DNA samples of human origin. As research data from these samples can be linked with data from medical records, environmental exposure, lifestyle information and other medically relevant information, biobanks are considered invaluable resources for medical research.

The samples stored in biobanks can be used by researchers for studying genetic and other molecular as well as environmental factors underlying diseases and influencing their outcome. The samples stored in biobanks can also be used for the identification and development of biomarkers and personalised therapies.

Biobanks lay the foundations for scientific research and development projects through the provision of biological material and the respective, anonymised data. The general public has a clear vested interest in this operational capability, since every sick person can potentially profit from medical progress.

Interoperability of biobanks is essential to facilitate international collaboration. In many cases industrial and academic scientists need to be able to pool and exchange relevant information held in other similar repositories. This is needed to reach the required statistical power or to compare research data generated from different populations.

**Biobanks and their infrastructures hold key resources to:**

- Understand gene-environmental/lifestyle interactions
- Unravel the molecular basis of disease subtypes and enable personalised medicine
- Develop biomarkers
- Identify new targets for therapy
- Boost development in drug discovery
The mission of the Biobank Graz, a central facility of the Medical University of Graz, is to support research on the cause of diseases and the development of improvements in disease diagnosis and treatment. Our goal is to contribute an improved and sustained healthcare for the general population.

The Biobank Graz is a publicly-owned non-profit organisation that is supported by public funds. It is committed to handle the available biological material in a responsible manner and protecting the personal rights of sample donors.

The Biobank Graz provides the logistics and infrastructure to offer optimal support for research teams at the Medical University of Graz in the collection, processing and storage of biological samples and their associated data. In the course of this, special attention is given to sample and data quality and to the protection of the individual rights of patients.

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**Biobank Graz: The goals**

- Integration of existing and future collection initiatives within a joint, interdisciplinary biobank for a competitive and efficient use of existing resources
- Support of academic and industrial research fostering the development of biomarkers and the improvement of diagnostics and treatments
- Ensure operation of the Biobank Graz database systems in accordance with data protection legislations protecting donor rights and reducing attrition in drug discovery and development
- Adjustment of the implemented Biobank Graz quality standards for sample/data collection according to the clinical procedures
- Integration of the Biobank Graz into the pan-European biobank network
Biobank Graz
The largest biobank in Europe

25 Biobanks with the highest number of samples.
Data source: www.bbmri.eu, April 2009
Samples from selected patients and donors at the LKH Univ.-Klinikum Graz (University Hospital), who have signed an informed consent declaration, are deposited in the Biobank Graz. This means that excess tissue and blood samples are collected and placed in storage. The samples are harvested in the course of routine interventions undertaken by the different departments and divisions of the University Hospital and approved for use in research projects only after the completion of all necessary laboratory and histopathological analyses. There are no associated drawbacks whatsoever for the patients/donors involved.

The Biobank Graz operates a quality management system according to ISO 9001:2008 and offers the following services for the processing and storage of biological samples and the handling of data:

- Consistently high sample quality through the processing of samples using standardised methods in accordance with written working instructions (SOPs)
- Efficient use of resources through the building of shared infrastructure and the development of optimised processes
- A high degree of reliability provided by the storage of samples in 24/7 monitored storage systems
- Processing and storage of all data in accordance with data protection legislations
The Biobank Graz currently contains more than 4.5 millions of samples representing a non-selected patient group characteristic of central Europe. Because the Institute of Pathology was, until 2003, the exclusive pathology service provider for major parts of the province of Styria, including its capital Graz, samples from all human diseases, treated by surgery or diagnosed by biopsy, are included in the collection at their natural frequency of occurrence and thus represent cancers and non-cancerous diseases from all organs and all age groups.

The scientific value of the existing tissue collection is, thus, not only determined by its size and technical homogeneity (all samples have been processed in a single institute under constant conditions for more than 20 years), but also by its population-based character.

These features provide ideal opportunities for epidemiological studies and allow the validation of biomarkers for the identification of specific diseases and determination of their response to treatment. Prospectively collected tissues, blood samples and clinical data comprise, on the one hand, randomly selected samples from all diseases and patient groups to provide sufficient numbers of samples for the evaluation of the disease-specificity of any gene or biomarker.

On the other hand, the Biobank Graz adopts a disease-focused approach for selected diseases (such as cancers of breast, colon and liver as well as some metabolic diseases) through the collection of a range of different human biological samples of highest quality and detailed clinical follow-up data.
The Biobank Graz includes:

- A cross-sectional biobank containing essentially unselected pathological samples and clinical data from the Styrian population, representing all detected diseases at their natural frequency of occurrence.

- A disease-focused clinical biobank providing different types of human biological samples of the highest quality and with detailed clinical follow-up data during the whole course of diseases, including long term observation for specifically selected diseases and targeted disease groups. Disease-focused collections are based on the major research interests of cooperating institutions.
Medical information generally associated with samples of the Biobank Graz:

- Disease diagnosis
- Full histopathological report, including classification, grading and staging of tumours
- State of the art immunohistochemical characterisation
- State of the art molecular genetic characterisation

Survival Data:

- Available from the University Hospital
- Detailed autopsy data are also available for > 6,000 of these patients.

Clinical Data:

- Full medical records in free text form are electronically available in follow up. It is planned to enter this information into a searchable database.
Tissue samples are stored as cryo material in the gas phase of liquid nitrogen (−120°C to −160°C) or are fixed and embedded in paraffin. Paraffin samples are stored at room temperature. Blood samples and other body fluids are stored at −80°C. The Biobank Graz is further developing its storage facilities and sets up (semi-)automated facilities for storage of paraffin samples as well as for blood samples at −80°C. After finishing the assembly of a study cohort and approval of their research project, medical doctors and scientists can have access to samples and their respective clinical data from the Biobank Graz. Prior to sending samples and data from the Biobank Graz to the project coordinator, the samples and data are encoded completely in order to disallow any backtracking of the donors.
**BioSample Pro** (developed by Joanneum Research) is a specially designed biobank software that is used for sample management. For data security reasons, the Biobank Graz holds all clinical data within the routine clinical databases (DB) and IT subsystems. These original sources of relevant information (clinical and scientific DB) are only accessed when assembling a study cohort. The locations of the various datasets and access instructions are stored in Biosample Pro. Definition of study cohorts, formulation of data queries and data set anonymisation/pseudonymisation are managed at the integration level.

A bundle of data mining programs that structure and clean up clinical data have been developed for the annotation of biospecimens in our repository with further clinical and other data. Existing pathological findings are converted into a searchable form and stored in a relational database.

**GENOPTIKUM** and GenView are interactive data exploration systems for the „visualisation of“ and „navigation in“ molecular and clinical data in the field of personalised medicine.
Efficient data and sample management is enabled by an IT-infrastructure that supports collection, administration and retrieval.

**IT-Infrastructure**

Anonymised sample inventory, in part statistically processed

Defined, individual projects with sample/data set inclusion/exclusion criteria

Anonymisation/Pseudoanonymisation

Sample management

Sample management

Results DBs (Genetic analysis)

Statistic Austria

Routine DBs

Research DBs

Open interface

Open MEDOCS

Archimed

BioSample Pro

Robotic systems

BioSample Pro

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Only because of the interdisciplinary cooperations with several different departments, clinics and institutes it is possible to collect large numbers of samples and their data on a high quality level.

The following institutions of the Medical University of Graz are engaged in the activities of the Biobank Graz based on written cooperation agreements:

- Department of Blood Group Serology and Transfusion Medicine
- Division of Cardiology
- Institute of Cytology (KAGes)
- Department of Dermatology and Venereology
- Division of Endocrinology and Metabolism
- Division of General Surgery
- LBI for Heart and Vessel Diseases
- Institute of Hygiene, Microbiology and Environmental Medicine
- LBI for Lung Vessel Research
- Clinical Institute of Medical and Chemical Laboratory Diagnostics
- Department of Neurosurgery
- Department of Obstetrics and Gynaecology
- Division of Oncology
- Department of Orthopaedic Surgery
- Institute of Pathology
- Division of Plastic, Esthetic and Reconstructive Surgery
- Division of Thoracic and Hyperbaric Surgery
- Department of Urology

More cooperation agreements are in preparation.
The use of data and samples is restricted to ethically and scientifically approved research. The Biobank Graz has been approved by the local ethics committee and by the official Austrian data regulatory board (DVR). A comprehensive data protection policy has been developed and implemented to protect the privacy of sample donors. A specific informed consent of the Biobank Graz has been established by an iterative process. The Biobank Graz is regularly reviewed by an International Evaluation and Advisory Board.

Informed Consent

The Biobank Graz has developed an informed consent procedure that covers all issues of modern medical research. All interested parties and the local ethics committee were involved in the developmental process. The informed consent is in line with the recommendations of existing international guidelines (e.g. OECD Guidelines for BRC) and approved by the Ethics Committee of the Medical University of Graz. Long established sample collections often face the problem that informed consent is not available for older samples. In a recent report from 2007 on biobanking the Austrian Bio-Ethics Committee recommended that existing human tissue collections, containing historical collected tissues during the years before biobanking was a big topic, can be used for scientific investigation without re-contact and/or specific informed consent, provided that the confidentiality of the sample donor is maintained and the specific research project is approved by the local ethics committee. This position, which accords with the emerging opinion in most European countries, was adopted by Biobank Graz and the procedure accepted by the local ethics committee.

Data Protection Policy

Protection of the privacy of sample donors is given top priority by the Biobank Graz. A series of data protection measures prevent the association of information generated from a given sample with the respective sample donor. All samples are automatically encoded when data are entered into the data base (BioSample Pro) and only the sample code is disclosed to researchers. Information on sample donor identity is only available in the hospital where the patient was treated. Research data are stored separately from all sample related information. It is planned to appoint an independent external data trustee to guarantee sample donor anonymity in the emerging field of sample use from biobanks.
The Biobank Graz has been specifically designed to support the needs of systems biology approaches to human diseases, drug discovery and public health. The advancement of modern biomedical research, aiming at improved therapeutic and diagnostic methods and strategies and culminating eventually in personalised medicine requires an integrated infrastructure which links biobanks with the required IT-infrastructure, analysis platforms, systems biology and other biological resources.

Research projects focusing on specific aspects of a disease, greatly benefit from extensive tissue collections. Biomarkers and potential therapeutic targets discovered by comparative analysis of normal and diseased tissues can be studied in detail in corresponding animal models. The results of this research can then be validated in human tissues.

Modern concepts for the elucidation of disease processes necessarily rely on the wealth of information contained in diseased tissues and on the comparison with healthy specimens. Technologies such as gene expression analysis, proteomics and metabolomics directly fuel systems biology which promises to understand the disease process at the organism level. Such efforts which are presently only just beginning will however be futile if the demands for biological data cannot be met. Biobanks are in a unique position to meet these demands.

Biobanks play a key role in the development of new drugs and diagnostic tools by the pharmaceutical industry by providing knowledge of the molecular basis of diseases. The trend towards personalised medicine and the increasingly global operation of companies will require biobanks to provide samples and data from populations of different ethnic origin, a task that can only reasonably be achieved by an international biobank network. These trends and developments have far-reaching social, ethical and political-legal implications that need to be considered to warrant smooth interaction between science and society on national and global levels.

Information about recent publications is available under www.medunigraz.at/12022
As a central service facility of the Medical University of Graz, the Biobank Graz supports basic, translational and industrial research. In recent years, a large number of research projects and clinical trials have been carried out using samples, data and/or logistics services of the Biobank Graz.

The Biobank Graz is involved as a scientific partner in a growing number of projects. Its main interests are ethical and social aspects of biobanking, standardisation of sample asservation and storage and the development of IT solutions for biobanking and mass data visualisation and interpretation. Some of the recently started projects include the GENAU-Programme, EU-FP7-projects such as DALI and EraSysBio, the COMET-Programme and Ludwig-Boltzmann Institute projects.
The Biobank Graz considers itself as a research partner and not a sample provider. It is the goal of the Biobank Graz to provide answers to our customers’ questions by combining:

- The well-established clinical experience of the University Hospital (Clinical Expertise)
- The unique technology platforms at the Centre for Medical Research (Technology Advantages)
- The largest biobank in Europe (Biobank Graz, Service Advantages)
Services provided by the Biobank Graz:

- Project development and project coordination
- Provision of samples and data
- Preparation of derivatives (e.g. nucleic acid extraction, etc.)
- Data pre-processing and clearing
- Quality assurance measures
- Prospective sample collection; planning and realisation of prospective study cohorts
- Contact to and networking with other biobanks
- Integration of pre-existing collections into the Biobank Graz
- Information for the respective personnel groups/advanced and continued education
- Consulting and training (legal, ethical, technical and organisational aspects of biobanking)
- Support at the installation of new biobanks

For further analysis:

The Biobank Graz prefers not to transfer samples outside the university. Instead we favour on-site analysis in the Core Facilities of the University of Graz to reach the following goals:

- Protection of sample quality and prevention of sample loss
- Minimal sample consumption
- Comparability and standardisation of analyses
- Use of analysis data in different studies
- Cost minimisation

The services of the following Core Facilities of the Organisational Unit for Research Infrastructure are available:

- Core Facility Flow Cytometry
- Core Facility Mass Spectrometry/Lipidomics
- Core Facility Mass Spectrometry/Proteomics
- Core Facility Microscopy
- Core Facility Molecular Biology
- Core Facility Ultrastructure Analysis
Scientists of the Medical University of Graz are pioneers with respect to the development and implementation of cutting edge ideas and strategies in the area of biobanking, both nationally and internationally. The Biobank Graz is an active and leading player in (inter-) national projects and activities aimed at improving interactions between and cooperation amongst biobanks.

A key goal of the 7th Framework programme of the European Union is the coordinated development of research infrastructures, an important goal for Europe as a whole. The roadmap for the development of the European infrastructure for the next 10–20 years was prepared by the “European Strategy Forum on Research Infrastructures (ESFRI)”. Of the six projects approved in the area of “Biological and Medical Sciences”, one targeted the establishment of a pan-European network of biobanks and biomolecular resource centres, their innovative further development and sustainable financing. The overall European coordination of this EU-infrastructure project with the name „Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)“ will be located in Graz. Furthermore, the K-Project BioPersMed opened a new study centre for the research of biomarkers.
Biobank Graz

THE KEY COMPONENTS

Healthy population/Patients

Ethical & legal issues

Informed consent

Healthy population/Patients

Human biological samples and data

Blood & derivates (eg. plasma)

DNA

RNA

FFPE tissues

Frozen tissues

Anamnesis, family history, lifestyle, labor parameter, treatment, data in follow up, outcome, study data (eg. biomarker)

Biobank infrastructure

High throughput sample storage in -80°C, -196°C and room temperature

Analysis platforms

CF Molecular Biology

CF Mass Spectrometry

CF Microscopy

CF Flow Cytometry

CF Ultrastructure Analysis

Application

Personalised medicine

Biomarker research

Targets for drug discovery

Basic research

Life sciences

Public health

Data storage

Biocomputing

Bioinformatics & Visualisation
A central medical and health-political challenge of the next centuries is handling of diseases adjusted to the needs and requirements of patients and economy. The Biobank Graz provides the scientific community with anonymised biological material to investigate the aetiology of diseases. This leads to a faster and target-oriented development of new and better diagnostics and therapies for a variety of syndromes and disease patterns.

**Benefits for Health Care Systems**

**Short term**
- Standardisation and international harmonisation
- Quality control and strategic planning
- Avoidance of redundancies

**Mid term**
- Biological samples and data as key resources for health care-related economies
- Health care as an economic value generator

**Long term**
- Better health care
- Personalised medicine

The medical innovations that will develop through the concept of the Biobank Graz can revolutionise the handling of human health. The Biobank Graz will thus considerably contribute to the long-term financing and distributive justice of the health system.
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