

Biobanking & Biorepositories

THE ONLY EUROPEAN EVENT
where you can hear from the
European Commission on the new
guidelines for the use of cells and DNA in research

Biobanking for discovery and development – Over 20 expert sessions bringing you the latest in sample collection and management, bioinformatics and international regulatory harmonisation

NEW
Tailored
workshops for
2010

27-28 October 2010 • Holiday Inn • Munich • Germany

www.informa-ls.com/biobanking

Benchmark your protocols with practical advice from leading experts:

Maurizio Salvi, Head of EGE Secretariat, **European Commission**, Belgium

David J. Pulford, PhD, Genetics Sample Acquisition, **GlaxoSmithKline**, UK

Steve Kelly, Capability Leader - Sample & Data Management, **AstraZeneca**, UK

Michael Stumm, Head of Translational Medicine, Oncology, **F. Hoffmann La Roche**, Switzerland

Jane Rogan, Business Manager, **Manchester Cancer Research Centre Biobank**, UK

Christer Ericsson, Senior Research Scientist, **Karolinska Institute**, Sweden

Louise Goodwin, Research Nurse Biobanker, **Royal Hallamshire Hospital, University of Sheffield**, UK

Maria Krestyaninova, Biomedical Informatics Coordinator, **European Bioinformatics Institute EMBL-EBI**, UK

Alex Denoon, Partner, **Lawford Davies Danoon**, UK

Rohan Massey, Partner, **McDermott Will & Emery UK LLP**

- Regulatory update from the European Commission on the different ethical and regulatory frameworks covering the use of cells and genetic materials in Europe
- Are your samples fit for purpose? Optimise your sample collection and sample validation techniques for tissue, liquid and cell samples
- SOPs to overcome common human errors in sample collection
- Ensure a smooth implementation of your LIMS system with practical experiences from industry peers
- Manage the lifecycle of your samples with candid industry feedback on different LIMS packages
- Learn what the data privacy requirements are in Europe, the US and Asia Pacific
- Understand how different cultural concerns in different regions can impact the biobanking process with our international panel of experts

Pre-conference workshop

Tuesday 26 October 2010

Building and Developing your Biobank

Learn tried and tested strategies for establishing a biobank in both China and Europe

Evening seminar

Tuesday 26 October 2010

Funding and Managing Actions for Biobanking

Share experiences and discuss collaborative and novel approaches for funding your biobank

Evening seminar

Wednesday 27 October 2010

Biobanking and the Drug Discovery Process

Learn how your peers ensure the quality of samples to allow for the testing of clinically relevant biomarkers

Post-conference half day workshop

Friday 29 October 2010 – International Informed Consent

Overcome the problems of obtaining informed consent internationally

Confirmed Exhibitor



“An excellently well organised cutting edge conference, with ample networking opportunity!” (Ericsson, Karolinska Institutet, Biobanking and Biorepositories Delegate 2009)

Pre-conference workshop: Tuesday 26 October 2010

Building and Developing your Biobank

09.00 Registration • 09.30 Workshop start
17.00 End of workshop

Software management and documentation of sample collections is a key process in the growth and development of any biobank, small or large. However without a thoughtful implementation strategy this can act as a key bottleneck often preventing growth in industry, public healthcare and university biobanks.

This interactive full day workshop has been designed for all those who are setting up a new biobank, looking to collaborate with a biobank or research institute, growing a biobank or trying to overcome the challenges of maintaining the records for a large biobank.

This workshop day will take the format of a mixture of presentations and discussion sessions allowing you to learn from the expert advice of the leaders and the specific experiences of your peers. Bring your questions with you for discussion.

The day will be split into 2 sessions addressing the challenges of setting up a biobank in different regions:

- 1 – Building and developing a biobank Europe
- 2 – Building and developing a biobank in China

The following topics will be discussed:

- Case studies on the setting up of different biobanks
 - National
 - Pharma run
 - Virtual biobanks and biobank networks
- How to characterise the samples contained in the biobank. What kind of data you will need?
- What information will be made available to those wanting to use the biobank?
- Coding
- Tracking of samples
- Quality assurance

Your workshop leaders:

Dr. Karine Sargsyan, *Director, Biobank Graz*, Austria
Professor Neil Thomas, *The University of Birmingham*, UK

Evening seminar: Tuesday 26 October 2010

Funding and Managing Actions for Biobanking

17.30 Registration • 17.45 Seminar start
19.45 End of seminar and networking dinner

Refreshments and seminar materials will be provided. The seminar is followed by a networking dinner.

Through presentations, small group exercises and discussion this interactive evening seminar will guide you through the complex area of funding and managing actions for biobanking.

Throughout the evening the following topics will be addressed:

- Who to collaborate with?
- How to get involved with the organisation of national biobanks?
- What are the rules to obtain access to samples from biobanks for research?
- What is best practice for collaboration with biobanks?
 - Different opportunities
 - Regulatory requirements for sharing data and samples
 - How they are managed in scientific terms
 - How samples are treated before storage
 - What are the protocols to following when working with existing samples or cell lines?
 - How are they managed? How to conform with regulations

Seminar leader: **Dr. Karine Sargsyan**, *Director, Biobank Graz*, Austria

Conference Day 1: Wednesday 27 October 2010

08.30 Registration

08.55 Opening remarks from the Chairperson

UPDATE FROM THE COMMISSION - GLOBAL BIOBANKING LEGISLATION

09.00 **Different ethical and regulatory frameworks covering the procurement and use in research of cells and genetic material in Europe**

KEY NOTE

While a robust regulatory system exists in the EU (2004/23/EC, 98/44/EC, 2001/83/EC Regulation 726/2004/EC, FP7 legal text etc.) and internationally (e.g. the Council of Europe, OECD and UNESCO), the degree of similarity between legal systems in different EU countries varies according to the respective field of jurisdiction. Additionally, current changes in the EU regulatory framework, such as the entering into force of the Lisbon Treaty, or adopted EU policy strategies (such as “Delivering an area of freedom, security and justice for Europe’s citizens - Action Plan Implementing the Stockholm Programme”) may affect the use of biobanking in the future.

A debate on an ethically sound establishment of biobanks in the EU and internationally is therefore needed to ensure a responsible use of such technologies.

The debate should cover, inter alia, issues related to: informed consent (further use than the consented one of material from donors), protection of privacy, accessibility of material to third parties; benefit sharing and patenting, cross border transfer, forensic use –including security and police measures.

In this speech the main ethical, legal and social issues related to biobanks will be summarised, with specific references to opinions adopted by the European Group on Ethics of science and new technologies (EGE) and current EC actions in this specific field.



Maurizio Salvi, *Head of EGE Secretariat*, European Commission, Belgium

OPTIMISING SAMPLE COLLECTION AND VALIDATION TECHNIQUES TO ENSURE SAMPLE INTEGRITY

09.35 **Industry experiences and relevance of tissue collection in clinical trials**



For further details of this presentation please go to the event website www.informa-ls.com/biobanking

Michael Stumm, *Head of Translational Medicine, Oncology*, **F. Hoffmann La Roche**, Switzerland (awaiting final confirmation)

10.10 **University hospital human tissue collection for urology research**

This presentation will address the following topics:

- Variety of the collection
- Sourcing
- Processing
- Characterisation
- Aims for the future

Louise Goodwin, *Research Nurse Biobanker*, **Royal Hallamshire Hospital, University of Sheffield**, UK

10.45 Morning coffee and exhibition viewing time

11.20 **Quality management and accreditation of tissue banks**



- Quality management
- Accreditation
- Translational research

Dr. Esther Herpel, *Head of Tissue Bank*, **National Centre for Tumour Diseases (NCT) Heidelberg**, Germany

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“A broad-range conference covering relevant aspects of biobank management. A great arena for networking” (Gregusson, BioBank AS Norway, Biobanking and Biorepositories Delegate 2009)

11.55 **Spotlight session**

Hosted by a leading company operating in the field of biobanking, this presentation slot offers an opportunity for delegates to learn about your product and or services. If you would like to host a spotlight session please contact

Martin Cheung at martin.cheung@informa.com
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12.30 Lunch

13.40 **Prenalytical sample preparation for liquid based cytology**

- Contaminated or diluted samples may yield useless or erroneous analytic results
- Appropriate sample preparation can remove contaminating cells, particles and molecules
- The pros and cons of the currently available sample preparation techniques
- The unmet needs of liquid based cytology sample preparation
- A novel technique to purify and concentrate tumour cell samples for cytology

Christer Ericsson, *Senior Research Scientist, Karolinska Institute, Sweden*

14.15 **Out of industry case study - The Millennium Seed Bank Partnership: maintaining high quality seed collections for conservation and use**



- Introduction - Kew and the Millennium Seed Bank Partnership
- The role of seed banks in plant conservation
- Long term seed storage - principles and practice
- Monitoring seed quality
- Challenges & next steps

Dr. John Dickie, *Head of Botanical Information Section Seed Conservation Department, Royal Botanic Gardens, Kew, UK*

14.50 Afternoon tea

GLOBAL ETHICAL CONSIDERATIONS FOR THE COLLECTION AND USE OF HUMAN SAMPLES IN R&D

15.25 **Local guidance and ethical considerations in the collection and potential use of pharmacogenetics samples in clinical studies run in Asia**

An increasing number of clinical studies are being conducted on a worldwide scale. Yet, not all populations respond similarly to drugs, suggesting the presence of genetic factors underlying inter-individual response in drug response.

The major goal of pharmacogenetics research is to identify genetic factors that contribute to variable drug response. Thus, the collection of pharmacogenetics samples from diverse patient groups involved in clinical trials is an essential component of the research. Local regulatory and ethical guidelines in several Asia-Pacific countries impact sample collection and in some cases influence how future pharmacogenetics research is conducted. We will review aspects of the local regulatory and ethical framework in these countries and how these local guidelines impact international pharmaceutical companies' ability to collect and utilize samples for pharmacogenetics research.

David J. Pulford, *PhD, Genetics Sample Acquisition, GlaxoSmithKline, UK*

16.00 **The changing role of ethics in European biobanking**

- Why is ethics important in the context of biobanking?
- Ethics as a regulatory device or a moral obligation
- The changing approach to ethics
- The advantages of professionalised ethics strategies in biobanking

Dr Nils Hoppe, *Partner, Scholz Hoppe & Associates LLP; Senior Research Fellow, University of Hannover, Germany*

16.35 Closing remarks from the Chairperson

16.40 End of conference day one

Evening seminar: Wednesday 27 October 2010

Biobanking for Drug Discovery

**17.30 Registration • 17.45 Seminar start
19.45 End of seminar and networking dinner**

Refreshments and seminar materials will be provided. The seminar is followed by a networking dinner.

Isolation of circulating tumour cells (CTC) from blood samples - a paradigm shift in biobanking, biomarkers and cancer care?
Following an introductory presentation, the delegates will split into discussion groups to define further the current unmet needs, roadblocks, ways forward and potential of CTC analysis. The conclusions of the discussion groups are presented as part of a moderated formative discussion. There will then be an inclusive networking dinner where the discussions can continue.

- Metastases are what cause most of the sickness and death, not the original tumour!
- The relationship between circulating tumour cells and blood-borne metastases
- Current methods to isolate and analyse CTCs - opportunities and shortcomings
- How to address the unmet needs for isolating and analysing CTCs?
- The clinical potential of using CTC analysis to direct treatment of metastasising cancers - how realistic is it?

Seminar leader: **Christer Ericsson**, *Senior Research Scientist, Karolinska Institute, Sweden*

Conference Day 2: Thursday 28 October 2010

09.00 Opening remarks from the Chairperson

INFORMATICS FOR BIOBANKING

09.05 **The challenges of implementing informatics in a multi-centre biobank**

- Introduction to MCRC Biobank
- What we do and our progress so far
- Sample labelling & bar-coding
- Sample tracking - problems and solutions
- Choosing a commercial LIMS system
- Future plans for Biobank informatics

Jane Rogan, *Business Manager, Manchester Cancer Research Centre Biobank, UK*

09.40 **Using a biorepository management system to support a variety of research scenarios at Erlangen University Hospital**



- A federated architectural framework comprising primary data sources for clinical annotations, a pseudonymisation service, a clinical data warehouse with a flexible and user-friendly query interface and a biorepository management system.
- Supporting multiple project configurations and multi-tenancy
- Support for varying monocentric and multicentric research scenarios and multiple medical clients
- Tracking sample transportation logistics and storage conditions
- Interfacing with clinical information systems, liquid handling platforms for aliquotation and storage robots

Prof. Dr. Hans-Ulrich Prokosch, *Chair of Medical Informatics, University of Erlangen, CIO, Erlangen University Hospital, Germany*

10.15 **Using laboratory information management systems effectively for clinical studies**



For full details of this presentation please go to the event website www.informa-ls.com/biobanking

Steve Kelly, *Capability Leader - Sample & Data Management, AstraZeneca, UK*

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Building and Developing your Biobank • Improving Sample Collection and Management Informatics for Biobanking • Global Regulatory, Legal and Ethical Compliance

10.50 Morning coffee and exhibition viewing time

11.20 Spotlight session

Hosted by a leading company operating in the field of biobanking, this presentation slot offers an opportunity for delegates to learn about your product and/or services. If you would like to host a spotlight session please contact **Martin Cheung** at martin.cheung@informa.com tel: +44 (0) 207 017 4938

11.55 Using laboratory information management systems effectively for clinical studies

- EU Directives and Legal Requirements for recording information from Clinical Studies
- Designing workflows for study processes and the information to be recorded
- Testing, troubleshooting, training, backup
- Audit trails and levels of access
- Validation

Dr Maria Maguire, *Quality Assurance Manager*, **Liverpool Cancer Research UK Centre**, UK

12.30 Data management and data harmonisation platforms for large collaborative biobank-based studies

- Communications and data exchange in collaborative discovery
- Biobank-controlled data access and data transparency
- Fast and secure internet-based access to data and metadata
- Data harmonisations and semantic enrichment in the context of meta-studies

Maria Krestyaninova, *Biomedical Informatics Coordinator*, **European Bioinformatics Institute EMBL-EBI**, UK

13.05 Lunch

CLASSIFICATION

14.10 Legally, what is a biobank?

- Lack of legislative clarity over defining a biobank – what samples in the biobank can be used for? (very different for academic, governmental or private biobanks)
- Some are regulated by legislation alone, others by legislation and ethical codes
- Navigating the complex and dynamic legal and regulatory hurdles including Data Protection, Clinical Trials, Tissues and Cells Directive and IP
- The need for harmonisation and legislative action
- German and UK perspectives

Alex Denoon, *Partner*, **Lawford Davies Denoon**, UK
Mathias Klümper, *Partner*, **Lützelner und Partner Rechtsanwälte**, Germany

GLOBAL DATA PRIVACY REQUIREMENTS

14.45 Data privacy issues - European update

- Provide an overview of the legal issues and commercial concerns linked to the use of personal data in Biobanks, including the problems of ownership of the data, and the scope of personal data use
- Provide an overview of the key issues arising from the EU data privacy regime, including Directive 54/45/EC, and its application to Biobanks
- Discuss the differences in the legal regimes on data privacy within the EU
- Overview of data privacy developments, trends and attitudes in Europe as they impact on Biobanking
- Overview and impact of the new OECD guidance for data privacy for biobanks
-High level discussion of non-EU data privacy issues concerning biobanks and personal data transfer and processing outside the EU and EEA

Rohan Massey, *Partner*, **McDermott Will & Emery UK LLP**

15.20 Afternoon tea and networking break

15.50 Biobanks - ownership and access

- Property rights in tissues and cells
- Interpretation of the rules in the EU and the US
- The trust model of guardianship
- Rights of access by the donor, family members and police

Brian Kelly, *Regulatory Lawyer*, **Covington & Burling LLP**, UK

16.25 A data protection and intellectual property framework in clinical trial research - Finding the best equilibrium between the main stakeholders

- Data protection issues
- Intellectual property rights
- Ownership of biological data
- Patient rights

Marcelo Corrales, *Institute for Legal Informatics*, **University of Hannover**, Germany

17.00 Closing remarks from the Chairperson

17.05 End of the main conference

Half day post-conference workshop

Friday 29 October 2010

Obtaining Informed Consent in Different European Countries

08.45 Registration • 09.00 Workshop start
12.30 End of workshop and networking lunch

This interactive workshop, incorporating presentations and discussion sessions will address the following topics:

- National biobanks vs international biobanks – can you get one single informed consent for inclusion on both?
- What are the key concerns?
- How do concerns differ in different European countries? (case studies, different regions and countries)
- How must you go about getting informed consent? (direct to patient or via investigator)
- Is there a blanket approach that can be used to ensure that your informed consent is valid in all countries?
- The need for EU harmonisation
- Are there any standard forms and/or recommendations for the right wording from national regulatory bodies?
- Policy issues with regards to withdrawing from a study, how do you ensure that sample is destroyed?

If you're involved with biobanking this workshop will be invaluable for your continued learning and discovering new contacts to help you to realise the solutions you are seeking.

Your workshop leaders:

Mathias Klümper, *Partner*, **Lützelner und Partner Rechtsanwälte**, Germany

Alex Denoon, *Partner*, **Lawford Davies Denoon**, UK

Confirmed Exhibitor



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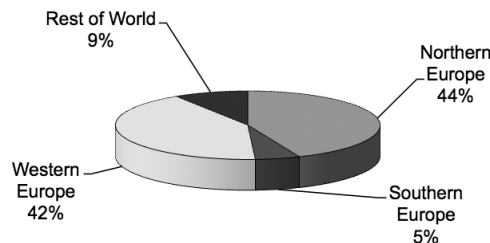
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2009 Delegate Breakdown by Geographical Region



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- Pre Conference Workshop W - Building and Developing your Biobank
- Evening Seminar S - Funding and Managing Actions for Biobanking
- Post Conference Workshop X - International Informed Consent
- Evening Seminar T - Biobanking and the Drug Discovery Process

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