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SMi presents the 7th annual...

BioBanking

Focus on Ethics and Biosample Management

Holiday Inn Kensington Forum, London, UK

CONFERENCE:
14TH - 15TH
WORKSHOP: 13TH
JUNE
2017

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Dr Michael Luntang-Jensen,
Biobank Manager,
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Dr Brian Thomson,
Director and Clinical
Lead for 100K Genome
Project, **Nottingham
Health Science Biobank**

NEW FOR 2017:

- **Spotlight session** - The advantages of 'digital biobanks'
- The impact of the General Data Protection Regulation from **European Commission** and leading biorepositories
- **CASE STUDIES:** The use of biobank samples to progress research in Poverty Related Diseases and Cloud-based sample management of multi-centre clinical trial in corneal transplantation
- **Challenges and opportunities** in running a national, multicentre, disease-specific biobank
- Stay at the forefront of **Biobanking developments** in the 21st Century

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CHAIRS:

- **Dr Brian Thomson**, Director and Clinical Lead for 100K Genome Project, **Nottingham Health Science Biobank**
- **Heli Salminen-Mankonen**, Director, **Auria Biobank**
- **Dr Balwir Matharoo-Ball**, Deputy Director, **Nottingham Health Science Biobank**

KEY SPEAKERS INCLUDE:

- **Emanuele Barbarossa**, Legal Adviser / Policy Analyst, **European Commission**
- **Dr Arndt Schmitz**, Senior Translational Assay Technology Expert, Research Biobank, **Bayer AG**
- **Dr Kris Spreckley**, Business Development Director, **UK Biobank/ UK Biocentre**
- **Peadar Mac Gabhann**, Director, **Biostór Ireland**
- **Annemette Arndal-Lauritzen**, CEO, **European Sperm Bank**
- **Saakje Mulder**, CEO, **LifelinesNL**
- **Sarah Gilbert**, Principal Scientist, **NIBSC - MHRA**
- **Dr Laurent Dollé**, Operating Director, **Biotheque Wallonie-Bruxelles (BWB)**
- **Dr Vincent von Walcke-Wulffen**, CEO, **BioKryo GmbH**

PLUS AN INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOP
Tuesday 13th June 2017, Holiday Inn Kensington Forum, London, UK

Learn an original way in which biobanks can contribute to stratified medicines

1.30 - 5.30

Workshop Leader:
Dr Laurent Dollé, Operating Director, **Biotheque Wallonie-Bruxelles (BWB)**

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8.30 Registration & Coffee

9.00 Chairman's Morning Opening Remarks
Heli Salminen-Mankonen, Director, **Auria Biobank**

REGULATORY AND ETHICAL UPDATES

OPENING KEYNOTE SESSION

9.10 The impact of the General Data Protection Regulation (GDPR) on collaborative science in Europe

- Brief description of the GDPR:
 - Rationale
 - Objectives
 - Timeline
- Impact of the regulation on the R&I sector in Europe:
 - Why the GDPR is relevant
 - How it affects EU research
- The 'research exemption'
- The challenges ahead

Emanuele Barbarossa, Legal Adviser / Policy Analyst, **European Commission**

9.50 Ethical and regulatory considerations in Sperm Banking

Sperm banking is a topic that raises ethical issues abundantly. Hear one of the world's leading sperm banks thoughts on:

- Short and long term implications for the children, the mothers/parents and the donors
- Obligation and possibility to influence the public opinion as well as politicians
- The ethical issues of the future, when creating human life
- The upcoming EU data protection regulations

Annemette Arndal-Lauritzen, CEO, **European Sperm Bank**

10.30 Morning Coffee

11.00 The Baby Bio Bank: A legacy for researchers worldwide into common complications of pregnancy

- Setting up and coordinating a multi-site Biobank
- Recruiting additional family members and neonates
- Dealing with large data and sample sets
- Improving sustainability

Dr Nita Solanky, Manager, Genetics & Epigenetics in Health, **Institute of Child Health, UCL, Baby Bio Bank**

11.40 Ethics and biobanking practice

- Policies and practices governing relationships between biobanks, contributors and users
- Ethical dilemmas raised by developments in the linking and sharing of biobank data
- The changing nature of expectations and the need to promote greater trust

Dr Balwir Matharoo-Ball, Deputy Director, **Nottingham Health Science Biobank**

12.20 Networking Lunch

1.25 Chairman's Afternoon Opening Remarks
Dr Brian Thomson, Director and Clinical Lead for 100K Genome Project, **Nottingham Health Science Biobank**

1.30 CASE STUDY: Biosample access in academic setting

- Sustainability models in a funding-sparse era
- Tailoring prospective collections for possible future research
- Meeting and sustaining standards for collaboration with industry

Dr Joanna Baxter, Lead Scientist/Senior Research Associate, **Cambridge Blood and Stem Cell Biobank (CBSB)**



DATA MANAGEMENT

2.10 Mobile Biobanking in routine and emergency cases

- Need of organizing a back-up
- Transport solutions
- Conception of an emergency case insurance

Dr Vincent von Walcke-Wulffen, CEO, **BioKryo GmbH**

2.50 Afternoon Tea

3.20 Informed vs. standardised consent, the ethical implications

- Gaining broad consent
- Attaining clinical phenotype data
- Maintaining confidentiality
- Access to information

Dr Brian Thomson, Director and Clinical Lead for 100K Genome Project, **Nottingham Health Science Biobank**

4.00 PANEL DEBATE WITH SCIENTIFIC BOARD: Public engagement barriers: Obstacles to people donating tissue for biomedical research

- Developments in information technologies
- The ethics of passing on genomic data
- Are there barriers?
- Are the barriers due to processes or people?

Panelists:

Sarah Gilbert, Principal Scientist, **NIBSC – MHRA**

Dr Brian Thomson, Director and Clinical Lead for 100K Genome Project, **Nottingham Health Science Biobank**

Heli Salminen-Mankonen, Director, **Auria Biobank**

Dr Balwir Matharoo-Ball, Deputy Director, **Nottingham Health Science Biobank**

4.40 Chairman's Closing Remarks and Close of Day One

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8.30 Registration & Coffee

9.00 **Chairman's Morning Opening Remarks**
Dr Balwir Matharoo-Ball, Deputy Director, **Nottingham Health Science Biobank**

OPENING KEYNOTE SESSION

9.10 **Beyond biobanking towards digital future**

SPOTLIGHT SESSION

The biobanked samples and associated clinical and phenotypic data contained in the Finnish Biobanks and electronic health records (EHR) could provide opportunities for early recognition, successful targeted treatment, and effective preventive strategies to a variety of diseases and too many other indications. Creation of an unrivalled personalised medicine research tool has already raised major interest by the global pharma industry and is expected to provide a true competitive edge for Finnish health sector and greatly increase the interest for foreign investments

- Auria Biobank: Transforming today's data and samples into knowledge of tomorrow
- Creating an unrivalled personalised medicine tool both for pharmaceutical industry and academic investigators

Heli Salminen-Mankonen, Director, **Auria Biobank**
Samu Kurki, Senior Scientist, **Auria Biobank**

9.50 **The advantages of 'digital biobanks'**

- Bayer's Research Biobank concept and network and the special role Auria is playing here
- Discover how 'digital biobanks' can provide value for digital biomarker studies, trial feasibility analyses and HEOR
- The re-contact option allows to molecularly select cases for patient recruitment, realising translational medicine

Dr Arndt Schmitz, Senior Translational Assay Technology Expert, Research Biobank, **Bayer AG**

10.30 Morning Coffee

BIOSAMPLE MANAGEMENT

11.00 **Human biospecimen acquisition; risks, challenges and solutions**

Biopharma's define the acquisition of human biospecimens as a very high-risk activity. With thousands of global providers, it's become difficult for researchers to find high-quality samples that have been acquired in an ethically-compliant manner. This session looks at the risks and challenges, from an industry perspective, of acquiring samples and introduces the COMPLI™ to remove the barriers, administrative burden, and reduce the cost for both Biopharma's and providers of samples



- Risks and challenges of human biospecimen acquisition
- COMPLI™ - A New Standard for Procuring Human Biospecimens

Matthew McLoughlin, Senior Director, **Scientist.com**

11.40 **CASE STUDY: The use of biobank samples to progress research in Poverty Related Diseases.**



EURIPRED (European Research Infrastructures for Poverty Related Diseases) is a collaborative infrastructure programme with the objective to reinforce the knowledge infrastructure across diseases. The ultimate aim is to speed the development of new tools (vaccines, drugs, microbicides) to combat Tuberculosis, HIV, Malaria, Hepatitis B and Hepatitis C. One of the key activities is providing reference reagents, services and trainings for free

- Adding value to the biosample
- Challenges for sample sharing
- Forming networks
- Ensuring sustainability of the sample collections

Sarah Gilbert, Project Manager, **MHRA-NIBSC**

12.20 Networking Lunch

1.25 **CASE STUDY: Cloud-based Sample Management of multi-centre Clinical Trial in Corneal Transplantation**



With three out five years of operation, five diverse research hospitals and 4 specialised research laboratories throughout Europe were implemented under a Quality Management System

- Introduction of fully anonymised 2D Bar code sample ID to ease ethics concerns
- Automated sample scanning to an integrated Patient Database ensuring highly controlled sample collection & processing
- Fully configurable, easy to use, intelligent workflow to simplify project coordination and reporting

Peadar Mac Gabhann, Director, **Biosfor Ireland**

2.05 **Generating high quality biological samples for high quality research**

- Sample linkage: Establishing accurate linkage of patient and sample data
- Sample logistics: Maintaining sample integrity during transportation
- Sample processing: The importance of sample and data tracking during processing tasks
- Sample storage: Creating accurate sample traceability during storage and retrieval activities
- LIMS: A fundamental prerequisite to successful sample and data traceability

Dr Kris Spreckley, Business Development Director, **UK Biobank/ UK Biocentre**

2.45 Afternoon Tea

3.15 **Chairman's Afternoon Opening Remarks**

Dr Brian Thomson, Director and Clinical Lead for 100K Genome Project, **Nottingham Health Science Biobank**

ACCESS TO SAMPLES

3.20 **Lifelines' biomaterials collection and accessibility to researchers**

Lifelines is a three-generation cohort study and biobank including over 165,000 participants in the northern part of the Netherlands. The aim is to follow up this population during 30 years, and collect both subjective (questionnaires) and objective data (e.g. measurements in biomaterials) and biomaterials. Lifelines facilitates with these materials scientific research on healthy ageing

- Sample and data quality
- Implementation of comprehensive sample collection
- Population-level analysis of gut microbiome variation project

Saakje Mulder, CEO, **LifelinesNL**
Aafje Dotinga, Manager Research Office, **LifelinesNL**

4.00 **The changing world of drug development**

An academic research network's perspective on the implementation of biobanking in the future world of anticancer drug development

- Drug Development/design and their challenges
- The "seven wonders" for the future anticancer medicine world
- Emerging sample-related standards
- Standardised improved pre-analytical workflows
- The next generation of biobanking: The forgotten pillar
- Perspectives & conclusions

Dr Laurent Dollé, Operating Director, **Biotheque Wallonie-Bruxelles (BWB)**

4.40 **Chairman's Closing Remarks and Close of Day Two**

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TECHNOLOGY NETWORKS

HALF-DAY PRE-CONFERENCE WORKSHOP

Tuesday 13th June 2017

1.30 – 5.30

Holiday Inn Kensington Forum, London, UK

Learn an original way in which biobanks can contribute to stratified medicines

Workshop Leader: **Dr Laurent Dollé**, Operating Director,
Biotheque Wallonie-Bruxelles (BWB)

Overview of the workshop:

Within this workshop, we would like to introduce a real change in emphasis to using biobanks rather just how to set biobanks up. We would like to get you involved in this thinking process. We want to illustrate how important it is to apply business development strategies to summarize and creatively brainstorm any product idea in order to reinvigorate the biobanking in particular. We want to teach you how to draw business models to be adapted to the changing needs of the marketplace to reveal new possibilities and embrace success.

Why should you attend this workshop:

- Understand Strategic vision and business development as key features in biobanking
- Spotlight on how to think big, identify your apple, and propose smart plan
- Gain insight in the strategic business development principles
- Snapshot on the next-generation biobanking
- Gain insight in the challenges of sustaining biobanks
- Learn how to use global regulatory, legal and ethical compliance considerations to reinforce your biobank for better use of your sample collections
- Interactive dialogues and exchange experiences with and among participants

Programme

- 1.30 Registration & Coffee**
- 2.00 Opening remarks and introductions**
- 2.10 The changing world of drug development: opportunities and challenges**
- Biomarkers and imaging
 - Clinical trial methodology and quality assurance
 - Combined treatment, adaptive licensing and new forms of multi-stakeholder collaboration
 - Perspectives of the seven wonders for the future anticancer medicine world
- 2.50 Next-generation of biobanking**
- Critical issues on how to improve biobanking practices
 - Challenges and innovations
 - Regulations, standards updates
- 3.30 Afternoon Tea**
- 4.00 Strategic vision and business development tools**
- Understand business model thinking
 - Understand the value of things in the marketplace and define their purpose
 - Articulate a vision for change
 - Make new business models harmonized with that vision
- 4.40 Implement the next-generation of Biobanking for a real success in the changing world of drug development/design**
- Design a modern biobank
 - Sample preparation and acquisition to obtain high quality samples
 - New tools: TMA, digitalized tissues, digital pathology, machine learning, big data,
 - Integrated automated sample processing workflows
- 5.20 Closing remarks**
- 5.30 End of workshop**

About the workshop leader:



Laurent Dollé earned his PhD degree in Cell Biology and Life Sciences from the University of Science and Technologies of Lille (France) in 2003. Laurent joined then the group of Professor Marc Mareel from the University of Gent in Belgium to become specialist in breast cancer cell invasion and metastasis processes. After several positions at different Universities or Institutions of Belgium, Laurent has over 16 years of experience working in the Life Sciences field. In 2012, Laurent became Assistant Professor at the Free University of Brussels (VUB), and developed several skills in stem cells isolation, maintenance and differentiation and was the first to identify liver stem cells from healthy non-manipulated livers by playing with an innovative technique based on Aldehyde dehydrogenase. Laurent Dollé is currently the Operating Director of BWB (Biobanking Wallonia-Brussels; Belgium)

About the organisation:



BWB (Biotheque Wallonia-Bruxelles) regroups an impressive number of biobanks whose mission is to create and implement a virtual network to unify and make accessible human

materials and associated data managed by the biobanks of Wallonia-Brussels' territory. Our mission is to help you in identifying human samples that suit your queries; through a single-point of contact platform we facilitate the access to biological resources to public and private research teams exclusively for scientific research and not intended for human application. Our services benefit to Big Pharma, pharmaceutical, biotech, in vitro diagnostics and big data companies, and academia.

SCIENTIFIC ADVISORY BOARD FOR 2017



Sarah Gilbert,
Principal Scientist,
NIBSC - MHRA

Sarah is a principal scientist at the National Institute for Biological Standards and Control (NIBSC), a centre of the Medicines and Healthcare products Regulatory Agency (MHRA). After studying Microbiology and Virology at the University of Warwick, Sarah began working at NIBSC within the Centre for AIDS reagents, first as a scientist and later as project manager. Sarah has been the project manager for the repository for 16 years. Sarah is also the Project Manager for an EC grant funded project EURIPRED. This project aims to link biobanks worldwide for Poverty Related Disease research, using clinical isolates from biobank partners to create novel research reagents for use in research on Malaria, Tuberculosis, Hepatitis B and C and HIV. Sarah has significant expertise in the logistics of biological materials worldwide and an interest in facilitating research through the fostering of collaborations and material sharing.



Dr Michael Luntang-Jensen,
Biobank Manager,
H. Lundbeck A/S

Michael Luntang-Jensen, DVM, PhD, is leading the Global Biobank at H. Lundbeck A/S and accountable for all sample handling and processing activities, and for the development and global implementation of sample management and biobanking related processes.



Heli Johanna Salminen-Mankonen,
Head,
Auria Biobank

One of the founding member and head of the Auria Biobank (the first Finnish hospital biobank). Key player involved at the building phase of BBMRI-PP, BBMRI.fi activities and one of the founders at BBMRI-Nordic on 2008. During last few years more than 40 invited lectures on Biobanks and innovative medicine. Scientific coordination and management experience from several domestic and international projects. Co-organizers in various high level scientific meetings and events in national as well as global level. Selected in top ten among 100 most influential Finnish health care professionals 2014 by Medi-Uutiset weekly newspaper. More than 25 publications in the field of modern molecular biology.



Dr Brian Thomson,
Director and Clinical Lead for 100K
Genome Project,
Nottingham Health Science Biobank

Dr Brian Thomson qualified in medicine from the University of Edinburgh and trained in Edinburgh, London and Cambridge before becoming Associate Professor and Honorary Consultant in Nottingham. He has held MRC Training and Clinician Scientist Fellowships in London and Cambridge and was awarded a PhD in 1992. Dr Thomson is founder and Director of the Nottingham Health Science Biobank (NHSB). The NHSB is the only NHS led Biobank in England and brings together a centralised quality assured tissue resource and an innovative informatics strategy to provide a unique platform for research. Dr Thomson leads the NHSE 100,000 Genome Project in Nottingham and is co-investigator for the UKCRC Tissue Directory and Co-ordination Centre.

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BIOBANKING

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