Global Biobank Week Abstracts Book 2017

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Session 2A

Keynote Plenary 2

Keynote Speaker: Jan-Eric Litton, Professor at Karolinska Institutet, Former Director General of BBMRI-ERIC, Sweden

Future Biobanks?

The evolution of healthcare, regulatory and medical practice – and lately precision medicine – is not an arbitrary choice of the academic and industrial researchers or policy and decision makers. It is driven by science and availability of new tools and knowledge originating from different sectors.
BBMRI-ERIC is proud to announce the availability of new tools that aim at improving quality, findability and accessibility of biobanking resources.
Among them, the BBMRI-ERIC Negotiator, which is a brand new service tool that provides an efficient communication platform between biobankers and researchers requesting samples and/or data in the Directory 3.0. The Directory today contains more than 100 million samples, and keeps counting.
That said, BBMRI-ERIC is dedicated to work hard in order to facilitate better quality of samples and data. For this, we have set up 5 different Quality Expert Working Groups to develop a Self-Assessment Survey based on the pre-examination processes (CEN/TS norms, and at a later stage the upcoming ISO norms). These working groups currently involve 106 experts and researchers in 18 different Member States. Life sciences, however, generally suffer from fragmentation, while health research in particular suffers from substantial reproducibility issues. Increasing dependence of research domains on data led to the FAIR data principles: While the FAIR principles are a good starting point, they are not specific enough to deal with the major challenges of the health research, namely reproducibility and privacy protection. Therefore we have suggested the FAIR-Health principles. These principles include: (i) quality and traceability, (ii) incentive schemes, and (iii) privacy regulations compliance.

Especially critical is Europe's new General Data Protection Regulation, which will enter into force in May 2018 and in which medical research is not addressed in a way it should have been done to allow clarity for transnational research for the benefit of citizens and researchers alike. Therefore, we have started the process for a Code of Conduct, which aims to specify the requirements General Data Protection Regulation in non-legalistic terms to researchers and is supported by more than 80 organisations worldwide. The Commission next year should approve the code.

Session 2B

Insights and Experiences of Healthcare Integrated Biobanking for Rapid Progress in the Development of New Diagnostic Markers and Tools for Personalised Medicine – A Swedish Perspective

Biobank Sweden: A Joint Biobank Infrastructure for Healthcare Providers and Academic Research

Tobias Sjoblom

Biobank Sweden, the new national biobank infrastructure, joins healthcare authorities and research universities with the intent to facilitate the use of biobanked samples. Key areas are establishment of a well-functioning national collaboration, harmonization of regional research services to customers, facilitation of sample linking with data, and healthcare integrated biobanking. Two large ongoing efforts in cancer, U-CAN and SCAN-B, together encompass tumor tissues, longitudinal blood samples and clinical data from more than 20 000 patients. These efforts will be discussed in the context of distributed healthcare integrated sample collection in Sweden.

Scapis: The New Swedish Cohort for Cardiovascular Health and COPD

Margaretha Persson

I will present the SCAPIS study and the challenges in collecting and storage of samples at six different local biobanks.

The Swedish CArdioPulmonary BioImage Study (SCAPIS) was initiated as a major joint national effort in Sweden at six University and University hospitals to reduce mortality and morbidity from cardiovascular disease and chronic obstructive pulmonary disease. Its main goal is to characterize phenotypic, environmental and socio-economic influences in a Swedish cohort of 30 000 men and women aged 50–64 years to obtain novel information that is relevant in today's environment. SCAPIS capitalizes on the latest developments in imaging that enable direct investigation of sub-clinical disease in multiple organs and vascular tissues. In addition, innovative use of large-scale genotyping, metabolomics and proteomics will facilitate the identification of new biomarkers and mechanisms for disease.

SCAPIS is designed as a prospective observational study of a randomly selected sample from the general population.

Protocols for collecting and processing of venous blood and spot urine samples was defined and tested in collaboration with the Swedish Biobanking and Biomolecular Resources Research Infrastructure (BBMRI.se) and the National Netwok of healthcare integrated biobank services at the university hospitals in Sweden ensuring uniform and standardized handling of all samples in SCAPIS Biobank.

Session 3A

The Measure of Success – Metrics Used to Describe the Utilisation of Biobanked Samples

Lessons Learned: Challenges Experienced by the NHLS/Stellenbosch University Biobank (NSB), A South African Perspective

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The National Health Laboratory Services (NHLS)/ Stellenbosch Biobank (NSB), situated in Cape Town, South Africa, as well as H3Africa, B3Africa, BCNET and international societies such as ISBER and ESBB have made great stride in promoting biobanking science in Africa.

This has accelerated the opportunity for international collaborative efforts to engage in multicenter research with the aim of conducting as much primary research in Africa, thereby building capacity and reducing the fear of bio-piracy that retards research and discovery on the continent. This has also led to implementation of best practices through benchmarking exercises rapidly increasing standardization and harmonization of biobanking practices to make these African collections more valuable.

NSB has gained extensive biobanking experience over the years and serve as a tool/link that aid in the collection, validation, and storage of human biopspecimens. NSB helps to ensure tight application of standardized protocols, quality control (QC), and address the effects of pre-analytical and storage variation on a broad range of biospecimen types and advises researchers accordingly. An overview of the NSB established in 2012 and registered with Stellenbosch University is given as well as challenges faced and lessons learned over the years. NSB follows standardized ethical, social, and legal policies, procedures and frameworks governed under both an external and internal governing structure. Thus important fundamental issues such as governance, ethics, infrastructure and bioinformatics that are important foundational prerequisite for the establishment of a successful human biobank are covered along with services that NSB can provide to the outside research community.

Business Plan Overview of the LPCE Hospital Biobank (Nice, France): Establishment of a Permanent Dynamic Strategy for Sustainability

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A biobank is a long-term investment that requires a sound business plan with its financial sustainability as a top priority. The increase in the number of biobanks generates strong competition. This fact encourages these structures to establish a robust economic model aiming to have an overview of the functioning and then to regulate the processes in order to optimize their efficiency. In this context, we established the state of the economic model of the Nice Hospital Biobank by evaluating the parameters that can influence its productivity over the time. These parameters mainly include the notoriety of the biobank as well as the "recipes/expenses" balance which led to a quantified assessment. The notoriety aspect was evaluated through several indicators (such as the level of the scientific publications associated with the biobank activity). The assessment of the expenses demonstrated that staff costing is the most important item of expenditure. This study allowed us to find new paths of optimization and to keep a permanent dynamic strategy aiming to obtain a better profitability of the system. Recognizing that the human resource is an important cost, it's mandatory to remedy the demotivation of staff by assessing them new inter-service responsibilities linked to the biobank. The Nice Biobank is financed by the French Ministry of Health and the Nice Hospital, but also by recurrent grants obtained with public and private partnerships. Finally the valorization and communication linked to the collections represent a major action for the Nice Biobank contributing to its sustainability.

Current Condition and Issues of Clinical Biobanks in Japan: A Point of View from Laboratory Medicine

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The final goal or aim of clinical biobanks is sharing sample data and feedback their results to public for better commonwealth. So far, clinical biobanks are considered as an infrastructure that is advantageous or valuable for checking developing reagents, searching companion biomarkers for diseases, cohort research, and constructing medical big data, so on. However, the easy-to-approach systems to access clinical samples between academia and commercial companies have not been established yet in Japan. The major bottleneck reasons are ethical, legal, and social issues (ELSI), lacking the simple evaluating procedures of stored samples, and the burden of expense among concerned participants. Additionally, cultivation/training of human resources of related fields is also required. Recently, next generation DNA sequencer (NGS) has begun to be used in clinics, called clinical sequences based on the samples of clinical biobanks. Clinical biobanks that preserves standardized and/or high-quality clinical samples are required. Further, to accomplish the “precision medicine” or “individualized medicine”, the clinical sequences/genetic testing by high-quality DNA samples is required.

Together, the authors discussed about problem lists to overcome these situations to establish commercially available clinical biobanks networks in this country. Since so-called “medical big-data” based on personal data surely develops future medicine, the rules or consensus in clinical biobanks for treating and/or sharing of personal clinical data is also discussed. Further, the concept of clinical biobanks and clinical sequencing are argued to accelerate better clinical biomarker research in this manuscript.

Samples and/or Service Requests in Principado de Asturias Biobank

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INTRODUCTION

The main objective of biobanks is provide researchers with high quality samples and clinical data. But it is also important to make deliveries as soon as possible. In order to control and improve these delivery times, the BPA registers quality indicators that allow to act on possible deviations from the established limits. Until December 2015, BPA had established a maximum delivery time of 60 days for all requests, which were processed in rigorous order of reception. This indicator reflected significant deviations in these terms and generated low customer satisfaction.

OBJETIVE

To design an algorithm to classify the sample requests. By means of this algorithm we valued different factors, such as the number of samples requested, what type of processing is needed, clinical data gathering, etc. to be able to establish three types of requests, based on their complexity and each of them associated with a maximum delivery time (mdt).

MATERIAL & METHODS

Throughout 2016, 83 samples and services requests were registered at the BPA. They were classified using the new algorithm into three types;

- A: 1-49 points. mdt: 10 days
- B: 50-99 points. mdt: 30 days
- C: >100 points. mdt: 60 days

RESULTS & CONCLUSION

As a result of using this algorithm to classify the samples requests, we have obtained 46 requests type A, 14 type B and 23 type C.

All delivery time indicators are above the established lower level (70%).

The new method using to classify the requests help us to increase our customers satisfaction.

Session 3B

Regulating Across the World – Re-Using and Sharing Resources, Data, and Samples

Re-Using & Sharing Resources, Data and Samples: Asian Perspectives

Yali Cong

The need for re-using and sharing of specimens and data is raising dramatically among the biomedical researchers. However, how about the public attitude towards this, and what implication of the national level survey can provide? There are still not sufficient information. Take an example of China, multi-level biobanks have been there, and national biomedical big data sharing platform is being set up according to the National Precision Medicine Research Plan, the guideline of data sharing is the urgent work task. Comparing to the United States and EU, a sort of ethical and legal regulation is on going. The presentation will take references about the regulations among several Asian countries, including China, Japan, Korea, Singapore, India and Taiwan, to summarize the current situation of governance, and try to propose some strategies to contribute to the global trend of bio-specimen research.

Challenges and Strategies for Biobank Regulation in Transnational and Global Research: An African Perspective

Keymanthri Moodley

Biobanks are located at the intersection of science, genetics, genomics, society, ethics, the law and politics. This multi-disciplinarity has given rise to a new discourse in health research involving diverse stakeholders. African genetic diversity lies at the core of the controversy that surrounds data and sample mining. African samples are highly sought after internationally and the unidirectional flow of samples out of Africa over the past several decades has raised concerns about exploitation. These concerns were voiced as recently as the Ebola outbreak in West Africa over the past 2 years where samples left the continent in the absence of adequate consent or material transfer agreements. Such events have impacted negatively on the relationships of trust that ought to exist between researchers and communities. Superimposed on the general concerns about exploitation on the continent are complex heterogenous cultural contexts and indigenous belief systems that create unique views with respect to ownership, storage and export of biospecimens. This talk will reflect such perspectives from research participants, researchers and Community Advisory Board (CAB) members gleaned from empirical research conducted in South Africa.

Clearly, strategies must be developed to address both existing and emergent concerns. In Africa, strategies include community engagement and robust governance processes. Community engagement is key to the biobanking enterprise yet remains challenging where complex science translation is necessary in low and middle income countries. Innovative efforts must be applied to accelerate science translation to ensure that consent processes are authentic and trust is maintained. Governance includes oversight by Research Ethics Committees (RECs), Data and Sample Access Committees, guidelines, policies and regulations. A robust legal framework as well as capacity development of all stakeholders including REC members will enhance expeditious and efficient review of biobanking protocols and research. This, in turn, will reinforce trust in the researcher-donor relationship.

The EU GDPR and a Code of Conduct in the Area of Health

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The EU General Data Protection Regulation (GDPR) is not easily accessible to non- lawyers. In addition, it leaves room for interpretation on areas relevant for research. By developing codes of conduct under Art. 40 of the GDPR, we can help guide researchers and administrative staff, reduce unnecessary fear about compliance and enhance data sharing for the sake of progress in research. If successful, the code could provide some clarity for the field of health research and suggest a lead way also for member States in the interpretation of the GDPR with regard to research.

Building on a strong participatory approach and including in the drafting process Research Infrastructures, patient advocacy groups and industry representatives, the Code of Conduct on Processing of Personal Data for Purposes of Scientific Research in the Area of Health, is developed under the leadership of BBMRI-ERIC.

The code is directed to data controllers who process personal data for purposes of scientific research in the area of health, e.g., researchers and research institutions, biobanks, health databases and registries. The aim is to contribute to the proper application of the regulation, taking into account the specific features of processing personal data in the area of health; to clarify and specify certain rules of the GDPR for controllers who process personal data for purposes of scientific research; to help demonstrate compliance by controllers and processors with the regulation; to help foster transparency and trust in the use of personal data in the area of health research.

Broad Consent for Future Research: International Perspectives

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In the United States, final amendments to the Federal Policy for the Protection of Human Subjects ("the Common Rule") were published on January 19, 2017. The new research regulations, effective January 19, 2018, for the first time authorize the use of broad consent for future, unspecified research on individually-identifiable specimens and associated data. The final amendments state that research uses of specimens and data obtained with broad consent are subject to "limited IRB review," but this important phrase is not further defined. The U.S. Department of Health and Human Services will issue guidance and broad consent templates before the effective data of the amendments. This presentation will review the prospect of broad consent in the U.S. as well as describe how broad consent works in five other countries: Canada (Quebec), Israel, Nigeria, Taiwan, and the United Kingdom.

Supporting Responsible Samples and Data Sharing: When Regulation Comes into Play

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In October 2016 was adopted the "Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks" by the World Medical Association (WMA), revising its previous Washington Declaration (2002). It intends to be the main soft law instrument specifically dedicated to Biobanks and Health Data bases to be cautiously interpreted as a complement of the Helsinki Declaration (2013). Recalling basic principles for biobanking research, the Declaration goes beyond emphasizing on Public Health objectives and, thus, on the need for sharing human samples and attached data in a responsible manner. This Declaration offers a unique framework to foster trustworthiness for sharing based on stratified principles and procedures for informed consent (unique protocol, future usage) and more importantly describes the internal and external governance mechanisms to be adopted in order to complement the process of responsible sharing. In this presentation, we will assess the relevance of the Taipei Declaration principles with regards to similar European legal frameworks from the Council of Europe (Oviedo Convention, Protocol on Biomedical Research) and the European Union (General Data Protection Regulation). We will then present and analyse the contributions of this Declaration for supporting responsible data and samples sharing insisting on its relevance for cohorts and long term biobank activities.

Session 3C

Quality Management for Biobanking

Biobanking for Next Generation Transcriptome Wide Analysis in Situ

Joakim Lundeberg

Analysis of the histology and the expression profiles of molecular biomarkers in tissues is a corner stone in diagnostics. Different staining techniques of histological samples have long been used to establish the basic structural organization of healthy organs and the changes that take place in common pathologies. The study of the distribution and relative levels of specific proteins by immunohistochemistry is routine today in basic research and clinical pathology.

There has been a revolution in the molecular understanding of many diseases in the post-genomic era, and a very large number of biomarkers associated with staging, sub-classification and prognosis have been identified. The use of molecular markers are increasingly making their way into routine clinical pathology, and it appears safe to predict that we are only seeing the beginning of this. Further molecular characterization of tumors promises to allow much more precise diagnoses, in turn allowing better-tailored treatment.

The molecular signature of cells, tissues and tumors are today frequently captured by genome-wide transcriptome analysis, which allows precise characterization of the global gene expression pattern. The revolution this has brought has led to a dissociation of the analysis of histology and molecular markers, as there has not been any feasible method available for global transcriptome analysis with spatial resolution.

In this presentation a new approach will be demonstrated that combines histology and RNA sequencing denoted Spatial Transcriptomics that paves the way for a new generation of diagnostics. This allows for visualization and quantitative analysis of the transcriptome with spatial resolution in individual tissue sections obatianed from biobanks. The presentation will cover some basic methodological concepts and provide a set of applications.

Raising Quality by the Introduction of a Biobank Certification Program for Australia

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Surveys within Australia demonstrate diversity of practices and Biobank types, from single research projects to large multi-site, multi-user operations. It follows that there is a diversity in quality, and there is evidence of this in the uptake of SOPs; participation in quality assurance programmes and similar quality parameters.

One of the cornerstones of developing a statewide Biobanking strategy by New South Wales Health Pathology was to introduce a Biobank Certification Program, available to all NSW biobanks. This was achieved in collaboration with the Canadian Office of Biobank Education and Research, the product being an adaptation of the existing Canadian scheme. Currently voluntary, the program raises standards through provision of education and document templates. The content encompasses Australian laws and guidelines.

Certification requires the completion of pertinent education modules. New to the program is that each module now includes a short test, developed with NSW Health's education and training provider. Another new initiative is that leaders register as either a biobank or a pathology department. A specific education module based on biobanking within pathology has been developed for this latter scenario.

We are confident the program should improve quality and provide a foundation for if any accreditation program is subsequently introduced.

During the socialisation of the program across hospitals, universities and research centres it was observed that in addition to Biobanks, there was perceived value by ethics committees, clinical trials, and governance offices. It is hoped that Certification will become a pre-requisite for ethics approval for the undertaking of biobanking activities.

Working Towards ISO 9001 Quality Standards: Building a Quality Management System (QMS) for a Biobank

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Hospital integrated biobanking is a multidisciplinary undertaking involving review board, outpatient departments, several laboratories and researchers. The Radboud Biobank has a dedicated team of 11 part-time employees scattered across various departments at a large Dutch University Medical Center. This poses a great challenge in maintaining high quality, professional service.

To assist with establishing a QMS we engaged an external consultant and internal quality assurance officer. The QMS was developed aligned with the requirements of the NEN-EN-ISO 9001:2015 standards, Dutch and international laws and codes of conduct and the demands of our clientele. We applied a so-called inside-out approach, involving people in sessions to increase knowledge and awareness about quality management. First we described the context and scope of the QMS and identified stake-holders. We developed the QMS framework by creating necessary documents and evaluation and improvement processes. Then the real work began; effecting change, adjusting work practices and establishing Service Level Agreements for outsourced processes.

Implementation addressed issues such as a planning and review cycle and a data management system, a web based SharePoint system allowing easy sharing of documents plus automatic version management. Internal and external communication improved with regular meetings, information sharing via OneNote, contact forms on the website and a quarterly newsletter. A monitoring and measurement cycle was installed including audits and performance registration. The whole process lead to an increased awareness of quality issues within the team.

The next step is NEN-EN-ISO 9001:2015 certification. Despite the challenges we are well underway to attaining the desired standards.

Biobanking Quality Control from the Shanghai Clinical Research Center Perspective

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The top priority of biobanking is to ensure the high quality of biospecimens and associated data. Chinese biobankers have focused on evidence-based practices to assess pre-analytical variables that can affect the quality of samples. Shanghai, Beijing, and Shenzhen are the leading locations for the development of Chinese biobanks. The Shanghai Clinical Research Center (SCRC), as the only Engineering Research Center of Biobank in China, is playing a leading role in developing the China Biobanking Network.

Many biomedical research centers are equipped with high-quality technologies for sample processing, storage, and utilization, giving long-term support to large cohort studies launched recently in China. SCRC has developed a sampling program for quality management, which will be necessary for new biobank construction and coordination. The quality management system (QMS) is comprised of quality assurance and quality control. Biobanking terminology for data quality control and interconnection is under development, which is a systematically organized computer processable collection of biobanking terms and definitions used in documenting and reporting the whole lifecycle of biospecimens.

Using the Brain Health Cohort in Shanghai as an example, pre-analytical variables have been tracked and method validation has been optimized. SCRC has focused on the validation of DNA quantitation by spectrophotometry. This validation model for DNA quantitation has been part of the sampling program for biospecimen quality control in the China Biobanking Network. Indicative of its leadership in Chinese biobanking, SCRC also served to develop a special issue on Biobanking in China for Biopreservation and Biobanking in 2015.

Session 4A

Digital Pathology Meets Biobanking

Diagnostic Telepathology and Digital Tissue Repositories in Africa: Implications for Teaching, Training, and Research

Dan Milner

The American Society for Clinical Pathology initiated the Partners for Cancer Diagnosis and Treatment in Africa program with the intention of providing 100% access to diagnosis and treatment to patients across the continent. Bringing together a large number of partners including NIH, CDC, WHO, Partners in Health, the American Cancer Society, the Clinton Health Access Initiative, Pfizer, Sakura, GE, Philips, and a host of others, ASCP sought to assess current pathology services, create implementation plans tailored to a given health system, and provide diagnostic assistance through telepathology and connection to ASCP members. In the first site deployed in Butaro Rwanda, within one year, almost 7000 digital whole slide images were created. As the program expands to Uganda, Tanzania, Malawi, and Haiti this year and beyond to DRC, Ghana, Liberia, and Kenya in 2018, what will be the value of these digital repositories of cases for teaching, training and research? Quality control and improvement, telementoring, and onsite technical assistance to maximize histology and immunohistochemistry capabilities will be discussed in addition to the role of digital pathology in the future of African cancer care.

Helsinki Biobank's Digital Pathology Solutions in Tissue Sample Pathway

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Digital pathology is a dynamic, image-based environment that enables viewing, management and analysis of histological samples in the form of digitized slide. It has been widely used in teaching and training medical students and residents as well as in clinical pathology including diagnostics and remote consultation. One growing application area is clinical research and biobanks.

Currently, Helsinki Biobank repository contains tissue samples of over one million patients. The majority of the total of 4 million samples are paraffin embedded and formalin fixed (FFPE). To maximize the value of this collection, digital pathology solutions are widely used when obtaining new, prospective tissues samples or when processing archived FFPE samples.

Prospectively biobanked tissues are processed in a way that a digital H&E staining image is available from each fresh frozen sample. This allows researchers to select most suitable samples for their studies and serves also as a quality control for tissue biobanking.

In Helsinki Biobank, tissue microarray (TMA) is the main technology for delivering FFPE material. Every possible step in the TMA process in digitized. Stained slides of donor blocks are scanned and areas for TMA punching are annotated on these images. Annotated areas are then overlayed on donor blocks. Each staining made on a TMA slide is digitized and image analysis tools are utilized in interpreting the staining. Digital pathology is also used for archiving and sharing the slides.

Helsinki Biobank's experiences in digital pathology have been very positive: it saves working hours and increases accuracy especially in TMA processing.

Comparison of Immunohistochemistry Antibodies Across and Within Tissue Microarrays Using Digital Image Analysis: The Basis for Objective Antibody Validation

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We report here the development of methodology for using digital images to compare the staining quality of antibodies used for immunohistochemistry. By undertaking a comparative study on the performance of antibodies using a tissue microarrays (TMA) we limited batch to batch variation and other technical confounders. To ensure that comparable immunohistochemistry conditions were used, the TMA slides were stained using an automated stainer (Leica-BOND MAX). The staining of all whole cores, were analysed using the Optimised Positive Pixel Counting Algorithms within the ImageScope software (Aperio/Leica). An IHC Index, based on the weighted sum of intensity of each pixel in the spot image, was determined to gauge the total signal intensity for each individual tissue spot. To demonstrate the merits of our approach we will discuss three experiments. (i) Comparison of anti-Synaptophysin antibodies used as a diagnostic positive marker for neuroblastoma. The monoclonal antibody Bond™ Ready-To-Use Primary anti-Synaptophysin (clone 27G12) and polyclonal antibody Zymed's Rabbit anti-Synaptophysin (Z66) were compared on TMAs containing 120 neuroblastoma and 40 control tissue cores. Subtle but quantifiable difference in signal intensity were observed. (ii) Comparison of two markers of muscle differentiation, MyoD1 and Myogenin, across TMAs containing the embryonal and alveolar rhabdomyosarcoma tumours. (iii) Establishing the expected levels of signal from Dicer1 antibody TMAs containing Wilms tumours. In summary, our results suggest that use of tissue microarray, automated immunohistochemistry staining and quantifiable image analysis of stained tissue will provide the basis for the objective optimization and validation of antibodies used in diagnostic and research applications.

Biobanking Incorporating Digital Pathology to Accomplish Large-Scale Clinicopathological Projects: The PARADIGM Experience

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The PARADIGM project (PAtients with bReAst cancer DIaGnosed preMenopausally) was initiated in 2011 as part of the Netherlands Breast Cancer Project. PARADIGM aims to reduce the overtreatment of women diagnosed with breast cancer aged ≤40 years, by linking clinical information from the Netherlands Cancer Registry (NCR) with pathological and molecular data from tissue samples of the same patients.

The NCR has registered all cancer patients diagnosed from 1989 onwards. Records on patients of interest, identified through the NCR, were linked to the Dutch nationwide pathology registry PALGA1 by a trusted third party. Using this approach we were able to obtain clinical information and ~16,000 tissue samples on 2,777 patients. New haematoxylin and eosin stained (H&E) slides were cut from all blocks to perform pathological tumour reassessment. Faced with such a tremendous workload we recognized that collaboration between many pathologists was needed. Therefore a workflow, incorporating digital-pathology, was established to secure project feasibility. All H&E slides were digitalized and placed on an online image-platform linked to the clinical database. Pathologists could access the secured platform for image reassessment and data entry at any time. Immunohistochemistry was performed for standard breast cancer markers and tumor DNA and RNA were isolated. All information was placed in the PARADIGM biobank for future study.

This presentation will focus on the advantages and disadvantages of incorporating digital pathology in your biobank workflow, using the PARADIGM workgroup experience as an example. In addition, future possibilities like teaching purposes; deep learning applications and data sharing will be discussed.

Imaging Biomarker Infrastructure

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In the Imaging work package of BBMRI-NL2.0 we focus on supporting the extraction of quantitative imaging biomarkers from population imaging to relate them to other data in biobank repositories. In order to achieve this, we have built an image analysis infrastructure which runs standardized automated image-analysis pipelines on large medical imaging datasets. The infrastructure is currently used to process population imaging studies with either clinical or healthy cohorts, and processed data will be linked to other data, creating more comprehensive biobank repositories.

The infrastructure consist of three main components:

* Medical imaging data storage using XNAT (provided by CTMM TraIT)

* Compute infrastructure built in the HPC Cloud of SurfSara (Dutch national high performance compute facility for research).

* Fastr workflow platform for managing the execution of automated analysis pipelines, interfacing with the data storage, and the compute infrastructure in a reproducible and consolidated way.

Additionally, we are investigating the use of a Science Portal as a front-end to increase the accessibility to researchers in all linked domains. All of these components are developed in the Imaging work package of BBMRI-NL2.0 in conjunction with the IT service work package.

Our infrastructure can greatly benefit personalized medicine by making pipelines for imaging biomarker extraction available to researchers and clinicians. Additionally, we create a reference database for different imaging biomarkers, which can be used to compare biomarker values of individuals against those of a healthy population with matching covariates. This will enable improved re-use of imaging data for diagnostics and prognostics.

Session 4B

Utilisation & Valuation and Public Trust

Building partnerships with patients and other stakeholders: Collaboration as a model for stakeholder engagement

Francesco Florindi

Consider, for example, the oncology community that firmly endorses multidisciplinarity as the standard for the organisation of cancer care. 'Placing the patient at the centre' is one of the key assumptions of multidisciplinarity, but while there are plenty of examples and methods on how to set up and manage multidisciplinary tumour boards, no method currently exists to formally start and run partnerships between patient organizations and cancer centres willing to promote patient involvement and multidisciplinarity. In 2017, the largest umbrella associations representing cancer patients (European Cancer Patient Coalition-ECPC) and cancer institutes (Organisation of European Cancer Institutes-OECI) produced "Solving problems together" a conceptual framework to guide patients, their associations and cancer institutes to establish and consolidate their relationship. The conceptual framework was recently implemented as a pilot within the Institut Jules Bordet in Brussels.

The experience of this framework can be beneficial also to biobanks in their effort to better connect with different stakeholders. Generating concepts how an infrastructure or a network can support researchers and biobanks in their stakeholder activities is thus key. Yet, who are the key stakeholders in the first place? Which experiences in stakeholder engagement already exists? How can best practices be shared?

Broad Consent for Healthcare-Embedded Biobanking: Understanding and Reasons to Donate in a Large Patient Sample

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'Healthcare-embedded biobanking' (HERB) - collection and storage of samples left over from clinical routine differs from project-oriented biobanking in that donors are not recruited among healthy volunteers or outside the clinic, but get involved because they seek diagnosis or treatment.

Since most scientific questions that can potentially be addressed by 'HERB' are unknown at time of collection, broad consent was recommended as an ethical option. To ensure that 'HERB' with broad consent is ethically acceptable and practically successful, patients' acceptance and motivation need to be explored, including the relation to the level of comprehension.

We set out to examine decision-relevant aspects of comprehension and motivation in a large cohort involved in a pilot implementation of broad-consent-based 'HERB' in Germany (n=760).

To the best of our knowledge, our study is the first to appraise these aspects in a large sample and at the time of consenting within a regular healthcare setting, thereby filling an important gap in the scientific literature.

There is great willingness to give broad consent to the collection of leftover biomaterial and the use of routine data for research. Moreover, the better the understanding, the higher is the willingness to get involved. Pro-social reasons appear to play a major role: Altruism, reciprocity, solidarity, gratitude were found to be more relevant for decision-making than objective or subjective knowledge, or objection to non-reporting of findings. Therefore, future efforts to improve information material used in 'HERB' should emphasise pro-social motivation, instead of focussing on the amount and precision of information conveyed.

Participants Generating Their Own Data for Biobanks: Utility of Self-Measurements

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The number of devices and apps to collect data on health and lifestyle is growing explosively. Besides offering many opportunities for personal health monitoring and healthcare, such data could also be interesting for research. We investigated opportunities and challenges of data collection by participants as (cost) efficient contribution for biobank research.

We interviewed researchers that use self-measurements and explored whether and how they secure useful and usable results. We learned that biobank- and cohort studies are particularly suited for self-measurement data, as expertise and prerequisites are already in place to address issues such as privacy, data protection, data management and participant interaction. Biobank research could benefit from the use of self-measurements, especially for repeated measurements producing multiple data points. If, in addition, suitable portals or mobile interfaces are used, that offer dynamic functionalities for consent and information, participants can have more control over their health data; As the use of these devices and interfaces creates opportunities for engagement and interaction, this form of self-measurement indirectly also contributes to sustainable biobanking.

However, to be useful and usable for research, data from self-measurements should be collected responsibly under the direction of (biobank) organisations. In this way it can be secured that the device/app and interface are subject to proper standards as for privacy protection, data management and ownership. This requires additional efforts that challenge the balance between costs and benefits of self-measurements for biobank research.

Your DNA Your Say: An International Multilingual Survey on Public Views of Donating and Sharing Genetic and Medical Data

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The online survey "Your DNA Your Say" aims to obtain the attitudes of different publics regarding the donation and sharing of medical and genetic data. More specifically, the survey queries respondents regarding, among others, their views on the following: Is there a difference between the sharing of medical, genetic and other online data? What are the potential benefits and harms of sharing such data? Would they feel differently about donating their genetic information to medical doctors or laboratory researchers? Would it make a difference if the researchers worked at for-profit or non-profit institutions? Beyond these salient questions, the survey is unique in that it is presented along with short educational and entertaining films that explain the practical and ethical issues of genetic and medical data sharing. In addition, the survey is being translated into different languages to ensure that different lay publics, including those who do not speak English, can also participate. It has already been translated into French, Polish, Portuguese, and Russian while the Swedish translation is underway. We will present the survey and preliminary data from the English language version as well as discuss how such a survey can be used for multiple purposes, including academic research, public education and a form of engagement. In the era of Big data and Biobanks, such multipurpose tools may prove invaluable to ensure a proper exchange with different publics and as such should be given consideration and resources to develop and test them.

Opt Out for Residual Materials Preferred Over Signed Informed Consent (WMA Declaration of Taipei)

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The opt-out system for residual materials in medical research has been adopted in the Netherlands since the FEDERA publication of the Dutch Code of Conduct. The acceptance in other countries however has been far from ideal. Every change in legislation this method needs to be defended, even during the aftermath of the GDPR. This was also true for the drafts of the WMA Declaration of Taipei on ethical considerations in Health Databases and Biobanks. Through counter arguments the declaration now accepts other consent methods then signed informed consent for residual materials in democratic countries.

Arguments used:

Where signed informed consent is the norm, it is common practice that in case of secondary use a waiver is given, which allows all requested materials can be used despite the fact the donor could not make a choice. An active opt-out system, collects the objections from the patients even over decades.

The waiver is actually violating the integrity of the person in its freedom of choice, whereas an opt-out system supports that particular point.

In countries where health care is accessible to all, without major differences between rich or poor, a more liberal standpoint is possible due to higher trust between patients, medical staff and government. In fact the draft text would inhibit such countries in their more positive medical research development, where actually medical research should become a well-accepted integrated part of the diagnostic process. For optimal exploitation of the “4P” opportunities, this is a must.

Recalling research participants based on their genotype: ethical and legal challenges.

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The unprecedented amount of human genomic data that can now be generated by Next Generation Sequencing in different research contexts, including population biobank projects is a huge resource to advance research. Researchers are now identifying genetically interesting variants (based on their location and/or their potential impact on human biology) in a number of human genome sequences from different individuals with partial or no knowledge of related phenotypes. In such cases, researchers may have good reasons to try to maximize the full potential of the data set by inviting such research participants or "recall" them for additional phenotyping (e.g. physiological testing) to find the common thread, if any, between them. We define this approach of re-inviting or re- recruiting research participants, stratified based on their genetic variants to allow further phenotyping "recall by genotype".

While this process of recalling or re-inviting individuals who are already research participants may sound benign, it is in fact challenging the established ethical, legal and practical research frameworks and need careful assessment. For example, some of the challenges of this approach are similar to those faced with the return of secondary findings from whole genome sequencing, including uncertainties and unknowns regarding what to tell participants. In order to implement recall by genotype in a responsible way, we must carefully reconsider the following: the informed consent process, the information provided about future research and return of results (including participants' right not to know) and the ongoing discussion about researchers' duties (or lack thereof) to return results.

Session 4C

Academic-Industrial Collaborations and Partnerships

Creating Innovative Collaborative Relationships Between Industry and Academia

Larson Hicks

Academic-Industrial Collaborations and Partnerships are advancing the mission of research universities and accelerating discoveries that save lives. Too many academic institutions are overly-protective of their biorepository samples to the detriment of the biorepository, academic researchers, and ultimately, patients.

Conversant Bio has collaborated with more than a dozen academic institutions in mutually-beneficial partnerships. A myriad of creative collaboration opportunities can be explored if both parties are open and honest about their objectives. Even strict fee-for-service prospective collection projects can enable a biorepository to expand their capabilities and offset costs.

Survey on the Perception of Academic Biobankers on the Collaboration Between Academic Biobanks and the Biomedical Industry

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Background: Academic biobanks play a critical role in the discovery and development of and new diagnostic, prognostic and predictive biomarkers. We carried out a survey on the views of industry when interacting with academic biobanks for accessing human biospecimens. Publications and communications from academic biobanks and related organizations suggest that there is often a limited understanding of the requirements and needs from either side. Industry has certain expectations regarding time scales, accompanying data, freedom to work with the samples, among others, and academic biobanks have governance regulations they are required to follow. In the current survey we collected the data about biobanks' perceptions and practices when collaborating with the pharmaceutical and diagnostic industry.

Methods: Persons managing academic biobanks or any collection of academic biospecimens were invited to participate in a survey about their perceptions and practices when collaborating with the pharmaceutical and diagnostic industry. A total of 51 questions were asked. They were grouped in type, organization, structure of the biobank and the disease areas they were in as well as projects and collaboration with industry.

Results: The survey was conducted in April / May, 2017. We received 183 responses until mid of May, 2017.

Conclusion: Our aim is to build a better understanding of the challenges both academia and industry face when working in this particular area. It is clear that industry needs access to human biospecimens for R&D and that academic researchers and biobanks are in a prime position to aid in the process.

ESBB Translate: Providing a Solution for Fostering Partnership and Collaboration with Industry and Pharma

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Biobank resources are fundamental in their vital role in drug development and personalised medicine and it is the pharmaceutical industry that will lead the development of these treatments. Companies in the pharma industry often face difficulties accessing a sufficient number of high quality biospecimens and they therefore need to access suitable samples in large public biobanks. Realising this issue, the European, Middle Eastern and African Society for Biobanking and Biopreservation (ESBB) set up the ESBBtranslate Working Group. The ESBBtranslate Working Group which brings together ESBB members and pharma/ biotech industry representatives in order to identify, elaborate and launch common research projects. The first mission of this group is to develop a directory allowing industry to not only identify but access relevant biobanks for envisioned collaboration quick and easy, whilst allowing ESBB member biobanks to showcase their specific services, strengths and assets.

To make the Directory a reality we first obtained feedback from members of ESBBtranslate, ESBB and future users in industry. We collected test data on from eight volunteering ESBB member biobanks (biobank1 – biobank8) over a web-based questionnaire developed by the ESBBtranslate Working Group. Based on this test data, Fraunhofer IZI-BB has set up a mock-up version which we will present. ESBB has approved the Directory v 1.0, which is foreseen to provide the full-fledged dynamic biobank locator in its final version. This shall be made available as a regular web-based ESBB service for biobanks to promote their specific services, thus fostering collaboration with industry.

Preparing for Commercialization: Preparing a Historical Clinical Research Biobank for Cooperation with the Pharma Industry

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Cooperation and partnerships between the Pharma Industry and Clinical Research Biobanks can contribute to valuable knowledge to improve diagnostics and patient treatment.

The Pharma industry has strict requirements to quality and information associated with samples in a biobank. In addition detailed information about the donor is often a necessity.

A clinical biobank can be an especially valuable industry partner due to the availability of donors undergoing a specific disease and treatment that allows for repeated sampling, long follow-up time and detailed clinical information.

When preparing a sample collection for cooperation with Pharma industries, there are some challenges to considerate such as legal issues, ethics, consent and quality documentation. When working with a historical biobank, some of these issues and requirements can be challenging to satisfy.

In this poster we will discuss some possible solutions for practical implementation of modernization and systematization based on preparing a Multiple Myeloma biobank for commercialization.

Session 6A

Sustainability in Biobanking – Past, Present, and Future?

Biobank Sustainability: Considering New Dimensions

Peter Watson

We have previously proposed a framework for considering biobank sustainability (Watson et al, Biopreservation & Biobanking, 2014) in terms of three dimensions (Financial, Operational, and Social). This framework has helped to guide the discussion and consideration of the key factors influencing sustainability and a growing literature on a range of strategies and their applicability to different types of biobank. However, beyond the context of the Financial, Operational, and Social dimensions that can be influenced by the biobank itself, it is important to recognize additional dimensions. Research dimensions of Time and Space are also relevant to biobank sustainability but perhaps more so to the entire landscape of biobanking in support of research, and are primarily determined by the broader arena of the research market. This presentation will discuss these research dimensions as well as factors such as biobank size and numbers and biospecimen complexity and how they impinge on the life of a biobank.

Business Planning as Basis for Biobank Sustainability and Professionalism

Daniel Simeon-Dubach

The scientific communities have acknowledged that the need for sustainable resources to support long-term research and development is paramount to guarantee access to high-quality specimens. However biobanks are expensive organizations and there is a strong need for smart and mature business planning to support sustainability for such an infrastructure.

Over the past few years, we have seen an increasing number of scientific papers focusing on the many aspects of biobank sustainability. Most experts recommend that biobanks be set up and run in a similar manner to small- and medium sized business enterprises. As a consequence biobank governance and management become more and more professionalized.

There is not a one-size-fits-all concept of sustainability in biobanking. It is therefore even more important to have a sound business plan unique to the biobank that takes into account the downstream goals of the resource. A quality infrastructure with valuable, quality biospecimens must be planned, implemented and maintained to fit the intended purpose(s). However, this end purpose should be documented in writing in a business plan and must be revised periodically to ensure continued relevance. This holds true for any size of a biobank and in every sector.

Financial Sustainability of Biobanks

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Despite substantial support from public funding bodies and the development of multinational research infrastructures, concerns remain about the long-term sustainability of public biobanks. Here, we focus on return-on-investment models for biobanks and discuss strategies that may improve their long-term sustainability.

Using a literature review, we examined the financial activities of 53 biobanks and 11 networks of biobanks. We also analysed the results of a questionnaire part of the Pan-European Biobanking and BioMolecular Resources Infrastructure (BBMRI) preparatory phase that was sent to 23 centres located in France and 22 centres in the Netherlands. Data collected included operational costs and funding streams.

Results from this survey revealed that three funding streams of comparable size contributed to the budget of biobanks: public funding (32%), funding by research institutions (27%) and funding by research grants (25%). Cost recovery for biological samples contributed just 1% of the budget. We found that most biobanks relied on short-term institutional sources or project-related research income and often struggled to secure long-term financial support. Our study also demonstrated that financial sustainability will unlikely be achieved with a sole cost-recovery policy or with commercialisation of research results or derived products. Long-term sustainability may however be improved by sharing samples and consolidating biobanks (to reduce unit costs), embedding public biobanks in healthcare systems and working to implement global funding mechanisms.

Bimetra Biobank: Achieving Sustainability Through Rationalised Change of Service at Our 5-Year Anniversary

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The last 5 years Bimetra Biobank – the central biobank of the CRC of Ghent University Hospital and Ghent University - has focused upon the biobank needs of local researchers and balance those out towards a realistic cost model, striving to expand our services to demand. Hence, Bimetra Biobank was gradually able to build upon trust, exemplified by an increase in service requests and collaborations, leveraging towards more high-quality collections and prospective collaborations. Establishing a sustainable biobank is challenging in times with scarce (governmental) funding. We aim to set forth to evaluate our reliability on three levels: operational, social and financial in order to guarantee sustainability and accommodation of the needs of researchers.

The operational sustainability was evaluated through efficiency analysis of our yearly daily operations (sample flows), including our data management. This entailed an extensive management review linked to a customer satisfaction survey, resulting in the calculation of the biobank Net Promotor Score (NPS), a marker indicating loyalty and likelihood to recommend.

Social sustainability was investigated through initiatives engaging the major stakeholders. Information has been given out to the public at scientific research days and reverse science cafés are being organised to capture opinions.

Finally, financial sustainability was analysed by assessing the yearly expenses and investments with the ultimate goal to eliminate/improve inefficient operational processes on the basis of cost. Subsequently, new cost models related to renewed business strategies arose to accommodate a maximum of researchers. This rationalised improvement of service will allow our sustainability.

Calculation of Biobank Total Cost and Setting Up of a Fee for Service Scheme

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Financial sustainability is a major challenge for biobanks, though often disregarded. Efforts in setting up a financial plan frequently already fail on the attempt in identifying the total costs of biobank operations. Yet, reliable estimation of the real costs of all biobank services is crucial for adequate planning.

Depending on the organizational structure a biobank may follow different strategies to secure adequate funding. The ibdw is an independent organization jointly supported by the University and the University Hospital of Wuerzburg. The ibdw was installed in 2011 in the framework of the BMBF national biobank initiative. The foreseeable cessation of the initial funding by the BMBF prompted the ibdw to assess the total cost and develop a scheme for cost recovery.

First an analysis of all relevant figures for biobank costs was carried out, followed by a review of the biobank workflows (sample transport, processing, storage and retrieval) with regard to cost and performance. The results were compiled, analyzed and a multi-tier scheme of cost recovery was derived.

Biobank customers are charged a fee for services depending on the kind of service requested, the funding and where the project is located. Costs for sample collections based on the ibdw broad are covered by the faculty while project specific sample collections are charged to the account of the respective project. Supported by the ibdw-IT team the costs for sample storage are invoiced on a monthly basis. The scheme has been adopted by the ibdw steering committee and came into effect in 2016.

Biobanking for the Public, by the Public: Reducing Costs and Increasing Participation

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Finding ways to increase financial sustainability is an ongoing challenge for biobanks and innovative methodologies are sought to increase biobank participation whilst reducing keeping costs.

In 2016, the Wales Cancer Bank introduced lay, volunteer consenters to consent patients to donate tissue and blood samples to the biobank for cancer related research. This was initiated as a response to a review of biobank activity and related costs, and was based on a program run by the Nottingham Health Science Biobank.

Members of the public are trained, following a recruitment process, to discuss biobanking with cancer patients and gain consent. The volunteers are focussed in a tertiary cancer centre in Velindre hospital and commit to attending one clinic per week.

A mixed consenting model is now in place in Velindre with nurses and clinicians consenting as well as the volunteers. One volunteer consented during 2016 and increased the annual consent figures by 27%. The program was expanded in 2017, with a further two volunteers undergoing training. In their first two months, they have increased the percentage of patients consented in Velindre by 34.5%

This presentation will show some background data from the activity review that prompted the introduction of the volunteers, give highlights of the training program, feedback from the volunteers and show updated data detailing the impact on the biobank.

Session 6B

Biobanks and Electronic Health Records

Biobanks and EMRs - a Perfect Marriage

Olli Carpen

The success of personalised medicine critically depends on the ability to collect and analyse large comprehensive datasets of human diseases. However, longitudinal “real life” datasets linked to biological specimens are rare and their use may require substantial investments. Yet, such infrastructures could provide a unique opportunity to create a powerful toolkit to address opportunities for early recognition, successful targeted treatments, and effective preventive strategies to a variety of diseases and to many other indications. The prerequisites for building high quality infrastructures serving both research and clinical medicine include the presence of accessible Electronic Medical Records (EMRs) and registries, a close collaboration between biobanks and data providers and supportive legislation. Under a modern Biobank Act, Finnish hospital biobanks have for several years served as a testbed for creating novel personalised medicine infrastructures. I will provide examples of the achievements, possibilities and challenges along the road towards personalised medicine ecosystem, with a vision to create individual profiles (digital phenotypes) within various disease entities.

Curation of Large Scale EHR Data for Use with Biobank Samples

Henrik Edgren

In large scale biobanks that collect samples without predefined research use cases, the future value of the samples is significantly dependent on the wealth of data available on them. For samples collected in a healthcare setting, Electronic Health Records (EHR) represent one such rich source of data, but the challenge is how to use this data, originally collected for clinical and billing use, in biobank research.

For this presentation, curation of EHR data will broadly be categorized into dealing with two types of data: discrete entities and narrative text. Discrete entities are usually recorded in specific fields, often using public or organization internal codes and, even when coding is not used, the number of name variations for a concept is usually limited. Narrative text, in turn, contains much of the wealth of clinical observation, as well as provides nuance not captured in discrete entity encodings, but is difficult to handle computationally. As sample numbers increase, manual searching of EHR data rapidly becomes unfeasible, necessitating automated data curation methods.

This presentation will describe efficient approaches to curating large volumes of EHR data, with the aim of comprehensively encoding the data using ontologies and other structured controlled vocabularies. We will start with automation of clean-up and ontology mapping of discrete data items, and proceed to machine learning based methods for analysis of narrative text. These in turn open up EHR data for efficient searching and analysis in a biobank context, both through standardizing data representation as well as allowing it to be used at varying levels of abstraction through the ontology hierarchies.

Health-RI: Empowering Personalised Medicine and Health Research in the Netherlands

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Personalized medicine and health research focuses on identifying which interventions will be effective for citizens and patients based on genetic, environmental, and lifestyle factors. The development of novel personalized healthcare solutions requires integration of highly diverse collections of longitudinal phenotype, biological and imaging data, generated at different health and research centers. In Health-RI, the common goal is to interconnect these biomedical resources, empowering researchers to develop better personalized medicine & health solutions.

Launched in 2015, Health-RI is the interconnected infrastructure for personalized medicine & health research in the Netherlands. The Dutch national nodes of the European Infrastructure initiatives, BBMRI, ELIXIR and EATRIS, together with national initiatives like DTL, NFU Data4lifesciences, Eurobioimaging and TraIT joined forces and worked out a shared roadmap on how the Netherlands can set course for a collective biomedical research infrastructure that ultimately will result in better and more targeted treatments. Health-RI will bring a much higher level of synergy in the fragmented landscape of infrastructure initiatives by offering the next-generation linked-data & workflow infrastructure tuned for high-end FAIR data and information sharing, as well as analytics across distributed data resources, all within one single platform. With Health-RI, researchers will have the tools at their fingertips to generate new research models, data and hypothesis, ultimately improving and accelerating the development of personalized health and medicine solutions for patients and citizens.

Secondary Use of Clinical Routine Data for Enhanced Phenotyping of Biobank Sample Data

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Electronic health records (EHRs) constitute an interesting data treasure for primary and secondary use scenarios. The Austrian Center for Biomarker Research in Medicine (CBmed GmbH) investigates methods and develops technologies within the project IICCAB - Innovative Use of Information for Clinical Care and Biomarker Research for the management of clinical and research data in order to facilitate re-use of EHRs which contain highly heterogeneous information. IICCAB is leveraging data semantics, natural language processing and data analytics technologies as well as terminology resources.

The core of the IICCAB system is a clinical data warehouse based on the SAP Connected Health platform and its analytic services. A natural language processing pipeline analyses clinical texts and annotates them with a standardized vocabulary. The resulting semantically standardized patient profiles are used for a broad range of clinical and research application scenarios.

One scenario supports the context-based delineation of patient cohorts for research projects. A retrieval and information extraction process, defined by Biobank Graz, is feeding semantically explicit data extracts into the clinical data warehouse, most of which were extracted from pseudonymized discharge summaries. These extracts are used to characterize biobank samples in terms of the clinical history of the donor. The formulation of use cases will be driven by Biobank Graz, for which the retrieval of clinical information is fundamental for a precise selection of suitable biosamples according to the phenotypic characteristics of the needed patient cohort. Patients suitable for a planned research project can thus be selected according to phenotypic and genotypic information.

GCAT | Genomes for Life. Cohort study of the Genomes of Catalonia

Anna Carreras Nolla [(1)]

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GCAT is 50.000 people participating in the same biomedical project to help researchers answer questions about our health and the treatment of illnesses.

The prevalence of chronic diseases is increasing worldwide, and it is estimated that before 2030, they will be responsible for 80% of deaths across the world. The GCAT study is designed to assess the role of epidemiologic, genomic and epigenomic factors in the development of cancer and other major chronic diseases.

The GCAT project is a prospective cohort study that was designed to recruit general population from the northeast region of Spain, Catalonia, with a population of 7.522.596 inhabitants. The study covers a middle-age population corresponding to 30% of the Catalonian population. Participants complete a self-administered computer-driven questionnaire that collects data on a large number of lifestyle and health factors that are of interest in epidemiological and genetic studies. Blood derived samples are collected according to standardized procedures. Participants will be biannually followed-up, and follow up for multiple and simultaneous endpoints through personal consented access to the Electronic Health Records (EHR) of the Catalan Public Health Care. GCAT will analyze genomic and metabolite data of 6K individuals at the end of 2017.

GCAT is a very ambitious biomedical project with scientific, medical and social implications. A summary of the current state of the project will be presented as well as its societal dimension.

www.genomesforlife.com

Session 6C

International Biobanking Harmonisation, Standardisation, and Globalisation

International Standards for Biobanking

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The availability of high quality biological resources is essential for the advancement of biotechnology, human health and R&D in life sciences at a global level. An appropriate quality of samples relies on three pillars: A) The control of pre-analytical variables, B) quality management of the biobanks and C) quality control of samples and associated data. Several international and initiatives were set up to define the requirements of these three pillars.

Pre-analytical variables can affect the quality of samples, their control is a major issue in particular in the development of precision medicine. To address this issue, a Technical committee at the ISO level (TC 212) is developing a set of 20 norms to ensure the quality and safety of in vitro diagnostic (IVD) examinations performed on human specimens.

On the other hand, more than 80 guidelines and best practices aim to improve the access to qualified samples and data. Considering this large number, an ISO standard is needed in order to harmonize approaches in quality management of biobanks and stem the multiplication of these guidelines by becoming the reference for biobanks BRCs and biorepositories. A technical committee at the ISO level (TC 276) drafted an International Standard for biobanking which is currently the topic of a public consultation. In addition to management criteria, this standard relies on three major chapters: i) competence of personnel, ii) validation of methods, iii) quality control tests and can be considered as the synthesis of the different guidelines in this field.

In addition to this standard, the technical committee is developing other standards that could be useful for biobanking among these standards for i) validation of methods; ii) cell culture; iii) collection and transport of animal and human germ cells; iv) database for microorganisms.

By implementing these complementary approaches, biobanks would guarantee an appropriate quality of samples and data, and reinforce trust between partners globally.

The College of American Pathologists Biorepository Accreditation Program

Nilsa Ramirez

The speaker will introduce the audience to the College of American Pathologists Biorepository Accreditation Program (CAP BAP). This program is based on the principles of the CAP clinical Laboratory Accreditation Program and introduces multiple, scalable tools specifically designed to improve and validate the quality of biospecimens and biorepositories. The BAP ensures consistent, industry-wide verification of biospecimen quality and the proper implementation of regulatory efforts to protect the privacy and confidentiality of those individuals from whom the biospecimens and data were obtained.

Standardising Data for Biobanking: ISO Standards Defined by ISO/TC 276/WG5

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The complexity and interdisciplinarity of modern biotechnology and life sciences require a high degree of standardisation of processes, as well as standardised formats for data, computer models and their descriptions. It is crucial to standardise the acquisition and description of data and the documentation of its origin and context. This comprises the standardised description of the applied methods and biological material stored in biobanks, as well as workflows for data processing, analysis, exchange, integration and for the incorporation of the data into computational models. To this end many grassroots community standards for formatting and exchanging data, models and metadata (data describing the data) have been defined by different scientific communities in the field. However, it often is confusing and cumbersome for the potential users to find the appropriate standards for their tasks and apply them in their workflows.

In light of the rapid growth and market relevance of biotechnology, the International Organization for Standardization (ISO) has established the technical committee for biotechnology standards (ISO/TC 276). In the working group for data processing and integration (WG5) of ISO/TC 276 we define new ISO standards in close collaboration with initiatives like BBMRI-ERIC and WFCC (World Federation for Culture Collections), among other things, for:

- Data management and publication in microbial biological resource centers

- Requirements for data formatting and description in the life sciences for downstream data processing and integration workflows

- Data element and metadata specification to describe production management of human isolated cells

- Data publication

- Provenance Information Management

Results of an ISBER/AABB Survey to Assess Biorepository Community Readiness for Standards and an Accreditation Program for Biorepositories/Biobanks

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Background: ISBER is a professional society of organizations and individuals who share an interest in promoting consistent, high quality industry best practices, ethical principles, and innovation in biospecimen biobanking by uniting the global community.

Methods: ISBER, in cooperation with the American Association of Blood Banks (AABB), created a 21 question survey to determine how prepared the biorepository and biobank community is for the development of ISBER best practices-based standards and a standards-based accreditation program.

Results: The survey was conducted from March 22 to April 26, 2017. 1,568 survey invitations were sent out, 241 (15.4%) responded. 82.3% had a Quality Management System in place. 20.1% were ISO certified and 11.5% were in the process of seeking ISO certification. 17.2% were CAP accredited and 16.7% in the process of seeking CAP accreditation. The participants strongly agreed / agreed that the biorepository field would be ready to adopt ISBER standards for specimen collection (66.1%), processing (67.8%), storage (64.5%), and distribution (62.7%). Most of the respondents also strongly agreed / agreed that they were likely to seek ISBER accreditation based on ISBER standards if developed.

Conclusion: In a selected group of biobankers with a high focus on quality processes a large majority of responders would be willing to follow ISBER standards and a standards-based accreditation program, if offered, for specimen collection, processing, storing and distribution. The results of this survey will help shape future ISBER policy regarding an accreditation program.

Innovative Technology and Its Contribution to Biobanking

Guiding Principles for Dynamic Consent

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Increasingly, the possibilities of using Dynamic Consent, a personalised interactive digital interface for citizens, are being explored for biobanks. Dynamic consent allows participants to access a record of their consent decisions, to review what they have agreed to, to change their mind if they wish to, to receive updates on how research is progressing, and are recognised as partners in biobank governance. This system allows real-time updating of consent decisions, easy re-contact of participants, and improved tracking of interactions with participants, which could ultimately lead to cost-savings across the research process, particularly on large-scale studies. As this trend becomes more widespread, there is a need to have principles that can guide the people who are building software and implementing Dynamic Consent within biobanks. This paper outlines the principles that apply to Dynamic Consent to assist implementation and proposes an accreditation scheme to improve biobanking practice as it moves to digital platforms for consenting and actively engaging individuals in scientific research. An exemplar pilot project in this area is the development of a personal locker which enables individuals to participate in research projects with their own personal health data.

Innovative Technology and its Contribution to Biobanking

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Innovation in biobanking has been driven by a variety of factors ranging from medical needs to new analytical methods and advancement of biobanking-related technologies and products. In this context, major game changers have been the marked increase in and cost reduction of nucleic acid sequencing and, more recently, progress in metabolomics and proteomics technologies. Furthermore, new diagnostically important analytes, such as free circulating nucleic acids or the microbiome have a major impact on the design of biobanks. New CEN Technical Specifications, ISO standards as well as regulatory and legal requirements (e.g., the European General Data Protection Regulation and the Regulation on In vitro Diagnostic Medical Devices) are impacting on quality management and data management solutions as well as governance models.

One of the latest components that will have a major impact on biobanks is the increasing impact of imaging data. Imaging data is a central application field of big data science in medicine, the relevance of which has been highlighted in radiology by establishing so called imaging biobanks, which should provide access to biological samples, molecular and imaging data to obtain further insight into disease mechanism and to generate new imaging biomarkers. Recently, developments in digital pathology boosted the relevance of imaging data for biobanks. Histological slides for microscopic evaluation are highly information rich and only a minor part of this information is currently used in medical research and diagnostics. Using the power of computers and machine learning approaches has great promise to make this information accessible and to translate it to better health care. Another aspect is that digital image information will allow content-based searches for tissue samples in biobanks, making tissue banks better accessible for users. Scanning technology is continuously increasing capacities to digitize histological slides. This shifts bottle necks from data generation to data hosting and analytics. A specific challenge in this context is the massive information contained in a digital histological slide which is in the range of more than 1 GB per slide. Considering that biobanks host millions of slides they will become a several PB data resource for health-related big data science.

The Netherlands Donor Feces Bank: It Takes Stool to Get Better

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Background: Fecal Microbiota Transplantation (FMT) is becoming increasingly popular as treatment for several diseases. Standardized protocols for donor screening, fecal preparation, and transfer of the fecal suspension, however, have not yet been established. The Netherlands Donor Feces Bank (NDFB) was founded to provide a standardized FMT product primarily for the treatment of patients with recurrent Clostridium difficile infections (rCDI).

Material/Methods: Standardized operation procedures were developed for donor recruitment, selection, and screening tests, and for the production of frozen fecal suspensions. All treated patients and voluntary donors also provide informed consent to obtain clinical data and to deliver fecal samples for follow-up analysis.

Results: Based on scrutinized selection criteria 21 of 165 registered voluntary donors had laboratory screening tests of which only 10 passed. Six of these donors were discarded after re-screening two months later. Finally, 4 (2.4%) volunteers were enrolled as qualified feces donors. Up to now 30 rCDI patients were treated with FMT of which 26 (87%) were cured, 4 patients (13%) suffered from a relapse. One serious adverse event (SAE) was reported from a patient vomiting part of the FMT feces suspension three hours after nasal tube duodenal installation, no aspiration occurred and the rCDI was cured. One patient died one week after FMT due to pneumonia without a clear cause.

Conclusion: The NDFB is a national organization to support FMT. Only 2.4% of the volunteers qualified as FMT donor. The FMT success rate for rCDI was 87%. Protocols are now also operative for other putative microbiota-associated disorders.

Biomarker Profiling by NMR Metabolomics: Using Biobank Partnerships to Build the Evidence-Base for Clinical Use

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Blood biomarker measurements by metabolomics are increasingly used in biobank studies to aid biomedical research. Nightingale Health Ltd has developed a high-throughput NMR-based metabolomics platform that quantifies >200 metabolic measures per blood sample at costs comparable to routine lipid testing. The biomarkers cover multiple metabolic pathways, including standard lipid measures, lipoprotein subclasses, fatty acids and amino acids. This biomarker screening technology is already widely used in biobanks and clinical trials, with close to 500,000 blood samples analysed thus far. Scientific publications using the detailed metabolic biomarkers indicate numerous medical applications for cardiovascular disease and diabetes prevention; however, further evidence is needed to clarify the specfic clinical use cases and the cost-effectiveness.

To increase the evidence base for using NMR metabolomics in clinical settings, Nightingale is now partnering with multiple large biobanks. During 2017 alone, over 50,000 biobanked blood samples from Finnish research cohorts and hospital settings are measured by Nightingale and the resulting biomarker data made available for the medical research community. In return, the biobank-enterprise collaboration provides Nightingale access to clinical data on disease events and possibilities for validating intriguing results from research cohorts in hospital biobanks. Similar partnerships will be sealed with global biobanks, with the aim to validate personalised risk prediction scores enhanced by the NMR-based metabolic biomarkers. The talk will outline how the metabolomic biomarker enrichment in large biobanks helps to accelerate clinical uptake: it requires metabolic profiling at population scale to translate the medical benefits meaningfully back to individual patients.

Exploring Novel Ways to Promote the Interaction Between Biobanks and Innovative Product Development for Active and Healthy Ageing: Introducing the Pointlab Program

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Innovative products focused on healthy and active ageing can improve public health prevention programs and lead to better therapies for patients. The better these products align with end-user demands, the greater their societal and economic impact. Whereas larger companies can perform wide-ranging market analyses, for SMEs it is far more difficult to acquire valid information on their end-user's needs.

The newly launched Population Intelligence lab program (Pointlab) has identified the great potential of data and biomaterials from large population- and patient-based biobanks for innovative product development. These biobanks however were created using public funding to serve primarily academic purposes, which makes them inaccessible for business purposes in general.

Pointlab aims to collect and develop tools and procedures needed to promote interactions between SMEs and biobanks to enhance their societal and economic impact.

In co-creation with academic partners, healthy ageing biobanks and innovative entrepreneurs a procedure book is being developed which includes:

- inventory of diverse business intelligence needs in the development of innovative products for active and healthy ageing;
- overview of organizational challenges in data acquisition, analysis and dissemination to facilitate collaboration between biobanks and entrepreneurs;
- enabling tools and templates for biobanks to engage in projects with entrepreneurs;
- analytical tools transforming medical and lifestyle data into applicable business intelligence;
- strategies for education and result dissemination by biobanks.

The Pointlab approach aims to become a transferrable European blueprint for promoting public private partnerships in biobanking. Pointlab was co-funded by the European Institute for Innovation and Technology (EIT) Health framework.

Building Isaacus: One Stop Shop for Finnish Data Reserves

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Finnish social and health registries as well as the biobanks are currently undergoing a unique national level organisational and regulatory reform. This restructuring aims at achieving a high level of integration between the various information providers with the ultimate goal of providing a single point of customer access for social and health research in Finland. A reform in the legal framework governing data use and access is due in 2018. The focus will be on privacy protection and data security reflecting the Act on Safe Use of Health and Social Data, and preparing for the General Data Protection Regulation (GDPR). Following this, a new national organisation will be tasked with the work of establishing the single point of access and central permit authority. ISAACUS – A Digital Health Hub is a joint project of Sitra, the Finnish Innovation Fund and The Ministry of Social Affairs and Health that coordinates work for defining legal, procedural, administrative, and technical requirements for establishing this new organization. These requirements are identified in several interlinked ISAACUS sub-projects that simulate different aspects in the access process. The sub-projects deal with various aspects of health research pipeline. One national process starting from preliminary queries and applying permits, following with a remotely and securely accessible set of samples from several biobanks combined, containing harmonized data from a range of national registries, all available on a safe analytics platform.

Enabling Novel Clinical Trial & Biobanking Workflows: Advances in Cell Free Nucleic Acid Collection & Processing

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Emerging analytical technologies have resulted in the development of sample type specific collection and processing workflows. One example of an increasingly important biosample from a diagnostics development perspective is cell free nucleic acid. Whole blood contains cell free DNA and RNA that are a source of important genetic information on both the genetic status of a fetus in a pregnant woman, as well as important information from nucleic acid shed by a variety of cancers. These degraded and limiting populations of nucleic acid potentially hold the key to a variety of non-invasive diagnostic strategies as well as the ability to follow minimal residual disease post treatment in cancer patients. As analytical technologies continue to develop to assess the genetic relevance of this unique class of nucleic acid, so do the technologies and workflows required to collect, protect and process cell free nucleic acids for molecular analyses. This presentation will review both novel technologies in the collection and preservation of cell free nucleic acid, as well as emerging technologies for sample separation and nucleic acid purification. Lastly, the development of novel quality control approaches that focus on the purity, fidelity and enrichment of cell free nucleic acids will be discussed. The incorporation of these approaches will be illustrated in the context of large and global clinical trials using these novel workflows in active trials.

Personalizing Surgical Options for Advanced Heart Failure: Reliance on Cardiac Biorepositories

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Unlike heart transplant surgery, the use of left ventricular devices (LVADs) as a treatment for advanced heart failure has accelerated over the past decade. Stroke is the most debilitating adverse event following LVAD implantation and it is clinically valuable to identify at-risk patients to adjust management and prevent this complication. We hypothesized that targeted genetic panels may be able to predict the development of stroke in these at-risk patients.

Three LVAD centers in the US participated in this study. DNA was extracted from a core of left ventricle removed from the patient at the time of surgery. DNA was genotyped using real-time PCR for a variety of SNPs previously identified as associated with the development of stroke in non-LVAD patients. A chart review was conducted to identify clinical factors and adverse events. Stroke and survival outcomes were matched with each SNP individually and in combination for associations. The distribution of each SNP was compared between the LVAD patients and the general population.

Thus far, we have found one SNP associated with the development of stroke in LVAD patients. Since few LVADs have been implanted worldwide, there is a need for enhanced collaborations among implant centers to address adverse events and must include a detailed data harmonization plan for clinical data and biobanking protocols for specimen collections. An understanding of the genetic variability associated with increased adverse events rates will help risk stratify and modify patient management. This will be increasingly important as the number of LVAD patients exponentially increase.

The iSpecimen Marketplace: Instantly Connecting Your Biobank to Thousands of Researchers –

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The iSpecimen Marketplace provides researchers with the specimens they need from the patients they want. By connecting biorepositories and their samples with the scientists who need them, it solves one of the research industry's biggest challenges – how to more efficiently and more quickly obtain specimens. Researchers gain instant access to millions of specimens anytime, anywhere, while participating contribute compliantly to medical research as well as their bottom line.

At the heart of the iSpecimen Marketplace is technology. The platform receives de-identified data from EMRs, LIMS, LIS, and other healthcare data sources about available specimens, and harmonizes the data across all participating partner sites in our network. This data is then easily searchable by researchers using our intuitive, web-based interface. Researchers instantly find the specific specimens they need for their studies, request quotes, place orders, and track and manage their specimens and associated data across projects.

In addition to streamlining the search process for researchers, the iSpecimen Marketplace simplifies administrative tasks associated with specimen procurement. iSpecimen contracts once with each participating supplier, once with each research organization, and instantly all are connected. The platform handles all compliance management (e.g. supplier qualification, researchers qualification, consent and IRB tracking) and financial transactions on behalf of both suppliers and researchers.

Biorepositories that participate in the iSpecimen Marketplace gain broad access to researchers, earn new revenue for enhanced sustainability, and fulfill their research mission and the wishes of patient donors. The iSpecimen Marketplace represents an unparalleled opportunity for researchers and specimen providers alike.

To Automate or Not to Automate: That is the Question…..or is It?

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For biorepository managers the question of whether to automate sample storage is often a difficult one, balancing the benefits against cost. A better question is "what to automate?" Rather than considering whole scale automation versus manual storage, repository managers should consider which processes could benefit the most from automation in terms of efficiency savings, sample security and sample integrity. A case study of the MRC Epidemiology Unit at the University of Cambridge will be presented. This will outline how the intelligent combination of automated and manual storage systems has provided an affordable solution with significant efficiency savings, whilst providing high quality samples for downstream research.

Standardised Quality Control of Nucleic Acids: The New Agilent 4200 Tape Station as Ideal Tool for the Analysis of Biobanked RNA and DNA Samples

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With its unique ScreenTape technology, the 4200 TapeStation meets the needs of biobankers for a standardized analysis of nucleic acids. The system allows the automatic electrophoretic separation, fluorescence detection and analysis of samples from a variety of different sources, e.g. RNA and genomic DNA from FFPE blocks, blood, fresh frozen tissue or circulating free DNA (cfDNA). The TapeStation analysis software automatically provides the RNA Integrity Number (RIN) for total RNA samples as well as the DNA Integrity Number (DIN) for genomic DNA samples which enables a standardized quality control as well as ensures experimental reproducibility. The 4200 TapeStation applications only requires a minimal sample input (1-2ul) which is valuable when working with precious sample material. The ready-to-use ScreenTape technology enables easy and fast system setup. This ensures experimental results as it takes out variability caused by manual handling steps. A wide range of different ScreenTape assays cover different sizing and sensitivity ranges. Partially used ScreenTapes can be reused at a later point of time .This keeps cost per sample independent of the throughput. The sample throughput is flexible and can be any number between 1 and 96. Due to the 96 well plate compatibility, sample preparation can be automated which is important for studies with higher sample numbers.

Session 8A

Establishing Hospital-Based Biobanks as a Foundation for Clinical Trials and Precision Medicine

Hospital-Based Biobanking as Basis for High-Quality Validation of New Biomarkers in Clinical Trials and Precision Medicine

Stefan Holdenrieder

The concept of precision medicine has gained great importance during recent years to stratify patients for specific therapies by biomarker profiles. Particularly in oncology, molecular tissue characterization is the precondition for application of targeted antibody or small molecule therapies that address defined genetic changes or for immune checkpoint-inhibitor approaches that reactive the endogeneous immune system.

Recently, highly sensitive technologies have enabled the tumor-specific profiling also on cell-free DNA (cfDNA) and tumor cells (CTC) circulating in the blood and opened the door for individualized disease monitoring and patient guidance. In addition to genetic testing, profiling on the epigenetic, protein or metabolic levels provides meaningful diagnostic, predictive and prognostic insights that can be used for patient characterization and therapy stratification. However, the advent of novel diagnostic technologies, parameters and algorithms has created new challenges for laboratories dedicated to patient care to assure their methodical quality, control biological and preanalytical variations and define clearly their diagnostic and predictive power. This applies also to biomarkers that are to be implemented in cardiology, immunology, neurology and other clinical areas.

If biomarker evaluations are performed in our lab center, first, we thoroughfully test novel assays on their methodical quality and robustness. Subsequently, we investigate all factors in the preanalytical phase from blood drawing until analysis that could affect the biomarker results. Finally, we do a comprehensive evaluation of diagnostic, predictive and prognostic power including not only the disease at focus and healthy controls but also all other clinical conditions that also could lead to non-intentional marker changes that are relevant for the interpretation of the results.

For the clinical evaluation, we use large numbers of serum or plasma samples stored in a high-quality biobank that were collected in diverse institutions of the hospital or as part of multicentric clinical trials. Standardized sample collection and handling have to be implemented in all participating centers to ensure good comparability of the results. Several biomarker classes are assessed on the same sample set and compared with currently established lab biomarkers in order to identify the most meaningful pattern for specific clinical indications.

Surfing the Electronic Medical Records: A Biobank Challenge

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One of the greatest Biobank difficulties in sample selection with pre-set criteria is to have a tool that allows navigating through the electronic medical record (EMR) exploring clinical course, analytical tests, diagnostic images, and free-text reported during the clinical care process.

Furthermore, attaining legal aspects, these searches should be done only in those patients with an available Biobank informed consent.

Under these premises, our biobank, with the hospital healthcare management approval, and assisted with our in house EMR developers and the Clinical Documentation Department, has developed a search system to navigate through the EMR for selecting biospecimens and their associated data.

It offers the possibility to chain different searches in all EMR fields: first of all for the availability of the informed consent and then for a set of combined searches. In each step the results could be exported or chained again.

It allows browsing the EMR contents, the clinical course and all reports generated during the clinical care process (analytical tests and results); it's able to search for coded data or free-text and to access to data not otherwise available.

Once finished, a coded patients list for the selected criteria is returned, preserving personal data.

This search engine, more efficient, universal and confidential than all systems used before is totally adapted to the EMR format. And benefits are not only for the biobank and researchers, but also for healthcare personnel, tumour register service, clinical epidemiology department and the clinical documentation department, building bridges between biobank and patient care.

How Can Hospital Integrated Biobanks Support Clinical Trials and Precision Medicine? Experiences of the Interdisciplinary Center for Biobanking-Lübeck (ICB-L)

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Hospital-integrated biobanks are increasingly recognized as supporting infrastructures for clinical trials and precision medicine by closing a structural gap between clinical routine and translational research. However, such scenario brings along several challenges such as ethics, data protection, and IT-implementation among others. Against this background, the Interdisciplinary Center for Biobanking-Lübeck (ICB-L) and the IT Center for Clinical Research-Lübeck (ITCR-L) have setup and applied the software system CentraXX (Kairos GmbH) as a central tool to support i) biobanking, ii) automated patient recruitment based on electronic interfaces between hospital and biobank IT systems, iii) study registries and trial management including eCRFs, iv) wet-lab projects, and v) molecular tumor boards for therapy guidance based on research data linked back to individual patient courses. This concept has been achieved by a full integration of the CentraXX system into the clinical context, a three-stage broad consent procedure starting at the central patient admission, a harmonized ontology of clinical and research items, a quality management system certified according to DIN EN ISO 9001 since 2011, and data protection clearances by all responsible authorities since July 2015. This presentation will demonstrate potentials and challenges of using one central IT system for biobanking, clinical trials, and supporting molecular tumor boards.

Transfer Management of Health Care Archive Samples for Oncological Clinical Trial by the Biobank Platform

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Clinical trials are the last phase of an investigation study usually performed by pharmaceuticals, so they can test drugs, diagnosis techniques or products in humans. That is why special trained staff is needed; they need to know about ethical and legal use of the information and samples, and how to process them at the laboratory, ensuring the correct management of the sample as it is indicated at the Royal Decree 1090/2015 which these trials are regulated. To this effect the Biobank Platform action is essential, because it guarantee the patients privacy, the correct process of the samples if it will be needed and it traceability since it is obtained until the delivery manager send it to the pertinent laboratory (study coordinator). In this way, is reflected the exit of the material in case someone need it again, so we can go back and know where it is.

The objective of this study was to open an effective circuit to transfer and/or processing the healthcare archive samples from the Pathological Anatomy centres in Málaga Hospitals, to the oncological clinical trials that are being undertaking in this province.

The results of the implementation of this circuit show a good coordination between the different professionals involved in this process (oncologist, study coordinator, pathologist and Biobank), ensuring the tracking of the sample following the guidelines of the current legislation.

Challenges of Biobanking in Primary Care: Policies and Harmonisation

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Less than 1% of the population is seen in university based hospitals while most of the population seeking medical care are seen in a primary healthcare setting. Primary care (PC) fills a huge gap between the general healthy population and the university teaching hospital in provision of healthcare services. With standardized governance planning,sharing and access policies specific for biobanks, the roadblock to samples/ data have been lifted, leading to increased usage of specimens/data. Patients seeking medical care in a primary setting present with symptoms that do not always render towards diagnosis. However,having a biobank in PC is key in studying trends,susceptibilities to disease and obtaining population data. Nonetheless, it can provide some reliable assessment of lifestyle, environmental and genetic factors as determinants of chronic disease. But, the challenges we face in a PC biobank in Quebec are of multiple facets. The first facet relates to the nature and organizational aspect such as patient sampling (population), governance and the type of collections (data and biospecimen) in a PC setting. The other facet relates to the current Canadian and provincial regulatory landscape around biobanks and its application in the context of PC. How do we tackle these challenges to ensure use and sharing of data/biospecimen that will benefit the patient and researchers? The population in PC is diverse and sampling is challenging. What type of data/biospecimen do we collect with different populations? We begin by providing an overview of the Canadian and provincial regulatory landscapes and the difficulties associated with our challenges.

Session 8B

Big Data and Large Population Research – From Cohorts to Healthcare

Building a 1 Million Cohort: All of Us Research Program Precision Medicine Initiative

Mine Cicek

In U.S., a federal effort has launched in 2015 with a mission to enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care. The mission of the *All of Us* Research Program is simple. We want to speed up health research and medical breakthroughs. To do this, we're asking one million people to partner with us and lead the way to provide the types of information that can help us create individualized prevention, treatment, and care for all of us. We are creating a research community of one million people with very diverse backgrounds who will share their unique health data. This will include answering survey questions about health, environment, and lifestyle. Some participants may also be asked to have their physical measurements taken, and/or give blood and urine samples. The health data we gather from our community of one million people will be added to a database. Researchers can then access this data to further understand how different factors, like environment, lifestyle, and genes, can impact health. This may help develop new medical treatments that are unique to individuals, and enable a future of precision medicine for all of us. The data we collect can be used by any researcher in the U.S. and around the world under defined rules. What we're doing with the All of Us Research Program is intersecting with other fundamental changes in medicine and research to empower healthier lives.

Taiwan Biobank for the Health of Future Generations

Chen-Yang Shen

The Taiwan Biobank is a scientific infrastructure accessible to biomedical researchers aimed at furthering understanding of the relationships between environmental exposure, diet, genetics, and the aetiology and progression of chronic disease. Through the recruitment and follow-up of a cohort of 200,000 individuals from the general population with no history of cancer and a cohort of 100,000 patients with chronic diseases of public health importance from medical centres, the Taiwan Biobank aims to improve the health of future generations and facilitate genomic/epigenomic research in the post-genomic era. Currently, more than 84,000 participants from different regions of Taiwan have been recruited, 14,000 participants have completed their first follow-up, and more than 1,900,000 biospecimens, including blood, urine, and DNA, have been collected. Electronic, structured questionnaires have been administrated to collect comprehensive information on risk factors, dietary patterns, lifestyle, and family history of diseases. Physical examinations and biochemical measurements have been performed. Whole-genome genotyping of more than 20,000 individuals using a chip designed by the Taiwan Biobank, which contains 653,291 single-nucleotide polymorphisms, has been performed, and whole-genome sequencing of 1,500 individuals has been completed in May 2017. Two examples of the use of the valuable information contained in the Taiwan Biobank will be presented. These include the identification of specific HLA allele that derived at the time when ancient Han Chinese migrated to southern China and a Mendelian randomization analysis to explore causal relation between triglyceride and HBA1c. The information and specimens contained in the Taiwan Biobank have been made publicly available. The goal is to develop personalised and precision medicine in which progressive elucidation of risk factors and molecular pathogenesis of disease will improve disease prevention and facilitate therapy development for individuals and generations to come.

The Kaiser Permanente Research Bank: A Resource for Precision Medicine Research

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The Kaiser Permanente Research Bank (KPRB) is among one of the largest biobank in the US with 270,000 participants enrolled. The mission of KPRB is to improve health and healthcare by advancing precision medicine research as well population and discovery research. The goal of the KPRB is to attain 500,000 participants through its 3 current recruitment areas - general cohort (440,000), incident cancer (30,000), and pregnancy (30,000). The KPRB collection comprises biospecimens (saliva, whole blood, serum and DNA) and data which includes longitudinal electronic medical record (EMR) and an extensive self-administered health survey.

All active adult Kaiser Permanente (KP) members across 7 KP regions nationwide are eligible to participate in the KPRB. Recruitment methods include email and mail invitations and in-clinic enrollment. KPRB participants consent via an electronic consent platform or through a paper-based consent. Members participate by consenting to provide their biospecimens, EMR and health survey for research and providing permission to be recontacted for future research.

This presentation will describe the KPRB infrastructure with the KP-central office working with each of the 7 KP regional areas and advisory boards in the areas of bioethics, science and community engagement. The functional units within KPRB includes recruitment, biorepository, data coordinating core, access review committee and translational research core. The activities within each of the functional units including work being planned in the area of return of research results will be presented. The KPRB is an excellent resource for precision medicine research with extensive genotyping data available for over 103,000 individuals.

The Generation and Sharing of Omics Data Sets Augmenting Scientific Collaboration

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BBMRI-NL has generated multi-level omics data in more than 24 Dutch cohorts under the constraint that the generated data will be centrally stored and publically shared (BBMRI-Omics). BBMRI-Omics (http://www.bbmri.nl/omics/) generated DNA sequencing data (N=694), DNA methylation data (N=6,309), RNA sequencing data (N=4,533), and Nightingale Health (formerly Brainshake) metabolomics data (N=23,729). BBMRI-Omics is building an infrastructure consisting of three main pillars 1) data analysis platform, 2) tools, 3) genomic atlases. The data analysis platform consists of a data warehouse taken into account FAIR data principles, and the availability of computational resources. For the pre-processing and analysis of data tools have been developed and made available, and the results of GenomeWASes, EpigenomeWASes, TranscriptomeWASses and MetabolomeWASes for numerous phenotypic traits will be made available in a browsable genomic atlas. To serve the community, workshops and symposia will be organised how to obtain access and use the available data.

A direct result out of the BBMRI-NL efforts are the collaborative scientific outputs in the sense of contributions to GWAS and EWAS consortia, identification of eQTLs and meQTLs, and contributions to national and international multi-omics initiatives. The cohorts with metabolomics data jointly search for biomarkers for several complex traits including among others dementia, osteoarthritis, and mortality. The BBMRI mortality initiative expanded into an international collaboration where prospective mortality could be predicted by a metabolomics signature of 14 metabolites improving the previously identified signature of only 4 metabolites. In addition, a clock based on the metabolome is developed predicting biological age.

Pipeline Inspection and Monitoring

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Modern biobanking includes digital data (e.g. genetic, imaging data) thus affording the opportunity to apply complex processing pipelines for the automated extraction of biomarkers. The extraction of biomarkers is modeled by a processing pipeline, which typically demands a substantial amount of computing- and storage resources. To shorten the execution time, pipeline execution engines usually split up the workload into computing jobs which are distributed over a High Performing Computing Cluster. Despite this optimization, pipelines kan take days to complete. Ideally, a researcher with little or no programming experience can accurately track the progress of a pipeline and in case of failure pinpoint why and where it fails.

As part of the BBMRI-NL2.0 project, we have developed a Pipeline Inspection and Monitoring (PIM) web service that provides an intuitive and user friendly visual representation of a processing pipeline, including detailed progress information. We exploit the concept of 'details on demand' to provide a rich experience where high level overview is combined with fine grained information (e.g. succeeded or failed jobs). The researcher does not need a technical background to monitor progress and to inspect (intermediate) results. PIM only requires a modern browser.

Even though we demonstrate PIM in the context of image processing, it is pipeline execution engine agnostic. Other fields that use processing pipelines such as genetics and metabolomics can benefit from PIM due to it's loose coupling. Ultimately, we aim to integrate PIM in a self-service portal where researchers can autonomously run biomarker extraction pipelines.

Connecting Northern Finland Birth Cohorts with Borealis and THL Biobanks (CoCoBi)

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The CoCoBi project, which started in January 2017, aims to support the study of healthy aging by integrating data from birth cohorts, population-based cohorts and hospitals. It is collaboration between 3 different research infrastructures: Biobank Borealis from Oulu, Northern Finland Birth Cohorts of Oulu University, and FINRISK and Health 2000 population cohorts of THL Biobank.

CoCoBi focuses on harmonizing and compiling data from several Finnish birth cohorts and population studies and complementing it with hospital data. Cohorts contain both questionnaire and clinical data, together with genetic, epigenetic, metabolomics, and registry follow-up data. Genome-wide data is available for more than 40 000 individuals in these cohorts. In hospital biobanks there is a myriad of clinical data available, however, it is in silos within different patient record systems and it has never systematically been integrated with the population health studies. For data integration, we will use existing tools such as BiobankUniverse and also develop in-house data mining tools. In order to integrate the data, legal and ethical aspects concerning individuals' data protection will be handled.

The integrated database of hospital, biobank and cohort data created in CoCoBi will be invaluable for scientific and innovative outputs, and it will provide means for wide variety of research. It will form a unique database which will be an essential tool for research aiming to promote life-long health. The long term goal of the project is to propagate the Northern Finland integration model (hospital –cohort data) and data-derived mining and analysis tools to the national level.

Session 8C

Reproducibility of Data from Specimens – Quality and Heterogeneity from Original Pathology to Derived Source

Circulatory miRNA Biomarkers as "Liquid Biopsy" in Diseases: Hope or Hype?

Too Heng Phon

MicroRNAs (miRNAs) are short single-stranded RNA (~22 nt), belonging to a class of small noncoding RNAs. Recently, the number of publications has escalated exponentially on the presence and functions of miRNAs, impacting on almost all fields of research in medical and basic sciences. Considering the wide involvement in gene control, aberrant miRNA expression is strongly associated with the development and progression of diseases. Hence, it is not a surprise that miRNAs may serve as biomarkers for the diagnosis and prognosis of human disorders including cancers, cardiovascular and others. The majority of miRNAs are intracellular, but recently they have been reported in numerous bodily fluids at low levels, posing a significant challenge to measuring circulatory miRNA accurately. Here we demonstrate the use of qPCR/dPCR and the design of discovery workflows with extensive quality control system to measure miRNA expressions, mitigating pre-analytical and analytical variables. The robust quantitative determinations of expression levels have enabled the rapid identification of panels of useful biomarkers for early detection of diseases and stratification of patients in many disorders. This presentation will discuss the value of circulating miRNAs as liquid biopsy and discuss the challenges which we have faced, from preanalytics to clinical utility.

IPGB: Biobank for Development of Personalised Medicine in Incontinentia Pigmenti

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Incontinentia Pigmenti Genetic Biobank (IPGB, http://www.igb.cnr.it/ipgb) is the first disease-oriented biobank dedicated to Incontinentia pigmenti (IP, OMIM#308300), an X-linked dominant neuroectodermal rare disease, caused by NF-kB-Essential-MOdulator (NEMO) gene mutation. IPGB collects DNA samples, harmonised clinical and biological data of IP-TRIOS families from worldwide. IPGB biobank arises from innovative combination of three complementary expertises of our group: genetic expertise on the X-linked gene-disease, molecular expertise on the NF-kB pathway, and the availability of a large collection of DNA samples and clinical data from the historical IP families due to a long-time and consolidated collaborations with clinical international groups on skin disease. The principal aim of IPGB is to build a powerful research infrastructure for the identification of biomarkers related to severe forms of IP, and for the investigations on drug response for personalized medicine. Indeed, although the IP phenotype is always associated with skin defects each patient requires a personalized approach for the molecular diagnosis and clinical description that has revealed in 30% of cases, an unpredicted severity. Here we present the preliminary results of the first genome-wide association analysis to identify genetic modifiers of IP with neurological and/or ocular defects, the worst forms of IP. We have sequenced by HaloPlex-panel focused on metabolic gene pathway 80 IP cases belonging to two subtypes, severe and not-severe, and we identified specific differences in genetic susceptibility to severe forms of IP. This is the first study in IP where the biobank by providing highly characterized biological specimens accelerates the pace of discovery.

With Well Characterised Biobank Samples the Secret of Aggressive Prostate Cancer is Unlocked

Heather Thorne [(1)]

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Using well characterized tumour samples collected by the kConFab bio-bank, our first study provided novel insight to the clinic-pathological implications of Intraductal carcinoma of the prostate (IDCP) in BRCA2 mutation carriers diagnosed with prostate cancer (PCa) using patient derived xenografting (PDXs)1. PDX's of BRCA2 carrier patient tumours generated PIN and adenocarcinoma, but IDCP lesions were the most prominent pathology. In contrast, IDCP was rarely detected in PDX's of sporadic PCa. A retrospective analysis was conducted on 52 PCa patients from the kConFab bio-bank. Comparison of the incidence of IDCP in BRCA2 mutational carriers showed that BRCA2 carriers with IDCP have a worse (survival) outcome than BRCA2 carriers without IDCP. Therefore, the presence of IDCP represents one of the underlying causes of aggressive tumours in patients with BRCA2 mutation carriers. This work was expanded upon and demonstrated that BRCA2 mutation carriers with PCa harbour increased genomic instability and a mutational profile that more closely resembles metastatic than localized disease2. Our studies high-lights the importance of high quality samples linked to clinical and mutation data in gaining clinical significant results.

1. Patient-derived xenografts reveal that intraductal carcinoma of the prostate is a prominent pathology in BRCA2 mutation carriers with prostate cancer and correlates with poor prognosis. Risbridger GP, Taylor RA, Thorne H et al. Eur Urol. 2015 Mar;67[(3)]

2. Germline BRCA2 mutations drive prostate cancers with distinct evolutionary trajectories. Taylor RA, Fraser M, Livingstone J, Espiritu SM, Thorne H, et al. Nat Commun. 2017 Jan 9;8

Heterogeneity of Cancer and its Effects on Xenografts as Corresponding Tissue Models

Rita Teresa Lawlor

Background: The lack of cancer tissue for research requires the creation of reproducible cancer models to provide sufficient analogous cancer tissue for research and testing of potential drug therapies, particularly for cancers such as pancreas ductal adenocarcinoma (PDAC) where low cancer cellularity impedes research for certain technologies. It is thus vital to evaluate the correspondence of patient derived xenografts (PDX) to their primary cancer tissue.

Methods: 100 PDAC and matched PDXs were molecularly characterized using targeted next generation sequencing using the Ion Torrent PGM system to investigate variants in the genes commonly altered in PDAC and in other pathways identified from whole genome sequencing. These were also then treated with standard of care therapies for PDAC.

Results: We verified that the PDX retain the morphology of the patient tumour for all samples. 96% of PDX correctly replicated variants in the primary. 4% of cases did not have complete concordance, as mutations found in human tissue were not in PDX. 3% of these were germline mutations whose loss was most likely due to homozygous deletion, while 1% lost a somatic mutation, potentially due to clonal selection pressure. Response to therapy corresponded to that of the patient. Interestingly, one case produced two morphologically different PDX with different therapy responses.

Conclusion: PDX represent a valuable model that faithfully recapitulates the main genetic features of primary tumours and may be used as in-vivo avatars to predict drug responses as well as enable co-clinical trials using models as prime time treatment for patients.

Session 9A

Biobank Catalogues – Technical Operations

Directories: Build Them and They Will Come?

Philip Quinlan

There is a proliferation of directories/catalogues/locators that all seek to make it easier for researchers to find suitable samples. The BBMRI-ERIC directory has an estimated 100 million samples available, yet, we witness almost daily statements from researchers that the ability to find and access samples is still a big constraint on their work. Therefore, are we on the right path? How do we know what we are providing gives benefit? And when will the job be done? In the UK we do not have all the answers, but we have been tackling this problem in a slightly different way that opens up questions about where we should be moving towards as a community and what can realistically be achieved by any Directory.

Harmonizing Biobanks within Regional and National Level Directories: Lessons Learned

Horst Pichler

The Austrian Biobanking and Biomolecular Resources Infrastructure node (BBMRI.at) implemented a national biobank directory providing searchable information about Austrian biobanks and sample collections, hosted by different partner institutions.

European biobank directories provide an insight into biobanks and sample collections within and across regional boundaries.

Our objective is to facilitate the establishment of future data integration infrastructures in the biobanking domain, sharing the lessons learnt during the establishment of the Austrian biobank integration framework.

We will address the major organizational, semantic and technical challenges faced during harmonization and electronic data interchange (EDI) between the national biobank directory and regional BBMRI.at partner biobank data sources or directories.

Organizational challenges include for instance the definition of a clear notion of the research questions and target users (i.e. what information must be delivered by biobank directories to which audience?).

On semantical level, developers have to deal with different understandings of biobank concepts (e.g., what is a sample collection, material group or an aliquot?), heterogeneous data models and data granularities.

On a technical level, electronic data interchange (EDI) between local biobank information systems and directories is limited due to missing or different technical implementations of local biobank information systems and interfaces.

Our aim is to show how we dealt with these challenges and which problems can be avoided, will probably re-emerge in future projects or will be solved by next level biobank information systems providing common APIs or data representation standards (e.g. MIABIS) for EDI.

Key Factors in Developing The National Cancer Institute’s Specimen Resource Locator – Joanne Demchok

Satellite Group on Biobanks: EBE-EFPIA Personalised Medicine Working Group

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The Satellite Group on Biobanks has been formed to represent Biobanking aspects under the umbrella of the EBE-EFPIA (European Biopharmaceutical Enterprises – European Federation of Pharmaceutical Industries and Associations) Personalised Medicine Working Group. For pharmaceutical companies, biobanks play a pivotal role to ensure access to high quality biosamples allowing broad assessment of stratifying biomarkers across diseases, which enables development of precision medicines and novel diagnostics.

The aim of the Satellite Group on Biobanks is to ensure that the needs of biopharmaceutical companies in biosamples are met. The group is therefore collaborating and aligning with relevant experts and initiatives across Europe and internationally, such as BBMRI-ERIC, ISBER Pharma working group, TransCelerate, in order to fulfill the following objectives:

- Drive and contribute to relevant IMI (Innovative Medicine Initiative) projects, e.g. BD4BO, DO-IT.
- Foster dialogue with academic Biobanks
- Map current environment and identify opportunities, e.g. harmonization of sample reuse
- Develop industry position on biobanking
- Advocate the industry position towards key stakeholders.

The development of new therapies in precision medicine and companion diagnostics requires the exchange or reuse of precious biomaterials collected in clinical studies. However, due to the global footprint of clinical study conduct, documentation of sample collection, accompanying sample annotation as well as structured retrieval of patient consent and local regulations remains challenging. The EBE-EFPIA biobanks group is working towards harmonization of biosample practices, particularly with a focus on:

- Compliance to legislations
- Consent and transparency to patients regarding biosample usage
- Respect of patient confidentiality
- Quality control of collection and storage
- Data annotation

Lessons Learned from the BCNet Catalogue Pilot Phase

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The Low- and Middle-Income Countries Biobank and Cohort Building Network (BCNet) catalogue has been developed to contribute to the visibility of LMIC biobanks and promote collaboration between BCNet members and scientists worldwide. It has been designed in compliance with biobank standard MIABIS 2.0.

A pilot phase was conducted with a group of BCNet members (n=5) whose biobanks are at different levels of development and biobank management. The pilot phase was implemented with established Guidelines. Biobanks that participated in the pilot, shared their experiences and provided feedback with an emphasis on operations in terms of data and IT management, which are key elements for the progress and improvement of the BCNet catalogue.

Further development and updates of the appropriate templates for uploading data in the BCNet catalogue are part of the implementation process. This resulted in the overall improvement of the data collection and integration processes in order to increase the quality of the data provided by the respective BCNet members' biobanks.

The adaptation of the templates and processes will enhance the interoperability of the BCNet platform and provide a gateway to the BBMRI-ERIC Directory which is developed using a similar strategy. This therefore strengthens the visibility of BCNet members' bio-resources. The challenges and benefits of development and participation in the BCNet catalogue will be presented.

Session 9B

Linking Human Biomonitoring and Population-Based Health Studies

Biomonitoring and the United States National Health and Nutrition Examination Survey (NHANES)

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People in modern societies are potentially exposed to thousands of environmental chemicals. Some of these chemicals are toxic in animal studies and replacement chemicals are entering consumer markets. Understanding the extent of exposures to both original and replacement chemicals is of public health interest. Biomonitoring measurements (i.e., amounts of a given chemical in the body) are increasingly used to quantify exposures within populations. Biomonitoring programs are particularly useful for assessing human exposures to environmental chemicals. In the United States, the National Health and Nutrition Examination Survey (NHANES) is conducted annually since 1999 by the Centers for Disease Control and Prevention. NHANES participants undergo a physical examination, answer comprehensive questionnaires on demographics and health behaviors (including diet), and provide detailed medical history, as well as biological specimens (i.e., blood and urine)—some of which are used to assess exposure to select chemicals. NHANES biomonitoring data have important uses in public health. NHANES data show that exposure to some chemicals is prevalent and may reflect lifestyle differences. NHANES biomonitoring data are also used to establish reference ranges, to provide exposure information for risk assessment (e.g., set intervention and research priorities, evaluate effectiveness of public health measures), and to monitor exposure trends.

Science and Policy for a Healthy Future: HBM4EU, the European Human Biomonitoring Initiative

Marike Kolossa-Gehring

HBM4EU follows an innovative approach to generate the knowledge policy makers need to improve policy in the field of environment and health. The overarching goal of HBM4EU is to generate new knowledge, to inform the safe management of chemicals, and consequently protect human health in Europe. Human Biomonitoring (HBM) data supply information on the aggregate exposure from all sources and by all pathways. They will serve as the basis to assess the risks from human exposure to chemicals. Intensive communication with policy makers from the state of planning on will ensure that HBM4EU results are used in the further development and design of new chemicals policies as well as the evaluation of existing measures

HBM4EU consists of 107 partner organisations from 26 countries and is organised around 16 work packages led by key players of national HBM studies and research programmes. Major fields of activities are the science policy transfer, HBM studies, and research to elucidate the impact of exposure on health. HBM reveals extent and quality of multiple chemicals exposures. Therefore, one work package investigates solely mixtures. This data also demonstrates the need to develop concepts for health risk assessment beyond traditional single substance evaluation methods.

Key objectives of HBM4EU are:
1. Harmonizing procedures for HBM , to provide policy makers with comparable data on human internal exposure to chemicals and mixtures of chemicals in Europe
2. Linking data on internal exposure to chemicals to aggregate external exposure and identifying exposure pathways and upstream sources. Information on exposure pathways is vital for targeted policy measures aiming for exposure reduction.
3. Generating scientific evidence on the causal links between human exposure to chemicals and negative health outcomes and
4. Adapting chemical risk assessment methodologies to use HBM data and account for the contribution of multiple external exposure pathways to the total body burden of various chemicals.

We will achieve these objectives by harmonizing national HBM initiatives, drawing on existing expertise and building new capacities. We will create a robust HBM Platform at the European level by establishing National Hubs in each country to coordinate national and European activities.

This initiative contributes directly to the improvement of health and well-being for all age groups, by investigating how exposure to chemicals affects the health of different population sub-groups, such as, children, pregnant women, foetuses and workers. We will also investigate how factors such as behavior, lifestyle and socio-economic status influence internal exposure to chemicals across Europe.

The HBM4EU project has received funding from the European Union’s Horizon2020 research and innovation programme under grant agreement No 733032.

Diabetes-Specific Biobanking Requires Interdisciplinary Alliances

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Aim: Many institutions and specified skills are required for a diabetes-specific biobank. As surgical interventions are primarily not demanded to treat diabetes, patients have operations rarely and mostly due to other medical conditions. Consequently, biomaterial is limited. Moreover, diabetes affects diverse organs which are provided by different surgical wards. However, the expertise on diabetes is located at the department of endocrinology. As such interdisciplinary collaborations are required to preserve biomaterial of diabetic and control patients along with relevant clinical parameters and information on existing comorbidities.

Methods: The interdisciplinary alliance of the diabetes-specific biobank involves surgeons who provide biomaterial associated with diabetic complications and pathologists who describe diabetes-associated morphological alterations. Endocrinologists assemble the liquid biobank with samples of a 10-year long-term study and quantify diabetes-relevant information such as nerve velocity measurements and kidney sonography. The information collected within this process and all patient-associated ICD-coded diagnoses are gathered in a laboratory information management system.

Results: The interdisciplinary cooperation results in high-quality preservation of specimens from well characterized patients and guarantees a purposeful assembly of pseudonymized patient cohorts. Using this material it has been shown that results obtained in diabetic model organisms can be translated to diabetic patients.

Conclusion: The diabetes-oriented biobank demonstrates that interdisciplinary cooperation is essential for the conservation of biomaterial along with disease-specific clinical parameters. As a consequence of this alliance the biobank is able to provide research with patient material and clinical data, needed to investigate innovative drug targets for the prevention of diabetic complications.

Breaking New Ground in Human Biomonitoring Research: Considerations in Triangulation of Methods for the Review of Existing Evidence

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Human biomonitoring (HBM) is a well-established field of research. Although in the last decades numerous studies have been published, there is an evident lack of integrated information required for the production of adequate knowledge in this area. This emphasizes the need to develop suitable methods for systematic mapping of available evidence and identification of existing research gaps. This is a cross-sectional problem in different realms of research, eventually more striking when considering interdisciplinary fields, such as the one of environmental health, an overarching concept in which HBM is included. A strong majority of available synthesizing strategies are based on narrative and systematic reviews. However, this research designs cover only primary sources –literature available via publication–, with over-representation of traditional academic research (e.g., ignoring documents created by other agents of knowledge production). Moreover, the 'non-significant result' bias is well recognized, impairing the quality of systematic reviews or meta-analysis. This paper discusses the use of a triangulation of methods, including innovative processes of literature review, to continuously map and expand an inventory of HBM studies that will help to inform further research needs in this realm. Moreover, general considerations concerning the specificity of some contexts for data collection and analysis (namely, in cases of international projects involving a collaborative effort), and the necessity to continuously update the information in this realm to assure the sustainability of these initiatives, are made. Finally, implications of the proposed methodological approach for the environmental health practice, research and policy are envisioned.

The Norwegian Human Environmental Biobank: MoBa Etox

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Environmentally hazardous chemicals are considered to be one of the greatest threats to the health of future generations, but little is known about body levels in Norwegians and their impact on health. Therefore, the Norwegian Institute of Public Health has established a biobank where blood and urine samples have been collected for research and for monitoring environmental contaminants in humans. The Norwegian human environmental biobank (MoBa Etox) can contribute to assess known and, till now, unknown environmental contaminants, including changes over time, identify population groups at higher risk, assess exposure pathways, among others.

MoBa Etox consists of two parts. Part I is based on retrieval and analysis of whole blood, plasma and urine samples from 3000 pregnant women in the Norwegian Mother and Child Cohort Study. Part II consists of a new collection of biological material where the same 3000 women have been invited to participate together with their child and the child's father. The adult participants also fill out a questionnaire regarding diet and lifestyle.

In the part II biobank, whole blood in Tempus tubes for RNA isolation, whole blood (EDTA), EDTA plasma, blood cells, serum and urine are stored. 658 mothers, 500 fathers and 668 children have participated and donated biological material. Some analysis will be done shortly after the collection period is finished, but the bulk of the samples will be stored for future studies, both to allow for analysis of until now unknown contaminants and for the purpose of studying trends in exposure.

Session 9C

Biospecimen Evidence-Based Practices for Collecting and Utilizing FFPE Tissues

RNA and miRNA Expression Profiles in FFPE Tissues Subjected to Extended Ischemic and Formalin-Fixation Times

Fay Betsou

BACKGROUND
Potentially there are thousands of formalin-fixed paraffin-embedded (FFPE) tissue blocks available for scientific research. However many are of unreliable quality, partly due to unknown preanalytical variables. As part of the NCI BVPV program, we analysed FFPE tissue biospecimens identifing mRNA markers denoting cold ischemic time and miRNA markers denoting fixation time.

MATERIALS and METHODS
miRNA, extracted from kidney and ovary tumor FFPE blocks (19 patients, cold ischemia ≤ 2 hr), using fixation times of 6, 12, 24 and 72 hr, were analysed using WaferGen SmartChip platform (1036 miRNAs). mRNA was extracted from colon, kidney and ovary cancer FFPE blocks (40 patients, 10-12 hr fixation time), with 1, 2, 3 and 12 hr cold ischemic times. These samples were analysed using qRT-PCR for 23 genes selected based on a literature search.

RESULTS
Fixation times of 72 hr and 6-24 hr could be distinguished using principal component analysis of miRNA expression. Four targets were identified that best determine fixation time. These results were validated using a second cohort of samples. Thetargets can be used together to determine a "snoRNA score" to distinguish fixation times of ≤ 24hrs and 72 hrs in FFEP tissues, with 79% sensitivity and 80% specificity. No genes tested could determine short ischemic times (1-3 hrs). However, a combination of three unstable genes normalized to a more stable gene could generate a "Cold Ischemia Score" able to distinguish 1-3 hr cold ischemia from 12 hr cold ischemia with 62% sensitivity and 84% specificity.

CONCLUSION
Fixation times of ≤ 24 hr do not affect miRNA expression. They become significant for miRNA at a fixation time point between 24 hr and 72 hr. Cold ischemia times of ≤ 3 hr do not affect mRNA expression levels of the 23 genes tested in the FFPE tissue-types used. However cold ischemia becomes significant at a time point between 3 hr and 12 hr. Additional samples are being collected to confirm the results.

Development of a Correction Index to Estimate the Necessary Tissue Block Sections for Nucleic Acids in Isolation

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Background/information: To preserve morphology and molecules from human tissue biospecimens for downstream applications, chemical fixation or freezing methods are widely used. Specifically, the SSPA Biobank isolates DNA and RNA from both frozen tissues in optimal cutting temperature (OCT) and formalin-fixed paraffin-embedded (FFPE) tissue samples. For this purpose, a pre-defined number of tissue block sections are prepared resulting in surplus or deficient nucleic acids yields. To optimize the amount of tissue employed and to improve the effectiveness of the DNA and RNA extractions respectively, we performed an analytical process based on the hematoxylin-eosin staining evaluation to estimate the necessary number of tissue sections.

Methods: Firstly, by using information from 55 RNA extractions from frozen tissues in OCT, we developed an analytical tool containing the area occupied by the tissue, the percentage of this area composed by cells and the corresponding RNA yield. In a second phase, we implemented the previous tool for 20 new RNA isolations from frozen tissues in OCT to calculate the necessary number of sections. Finally, we checked this approximation for DNA and FFPE tissues with 12 isolations in each case.

Results and conclusions: We obtained a correction index from the hematoxylin-eosin staining evaluation of tissues to estimate the necessary number of tissue blocks sections for RNA and DNA isolations. We achieved a standardized tool to calculate the number of sections to be prepared in order of obtaining the necessary nucleic acids yield.

A Collaborative Academic Research Network's View on the Implementation of the Next-Generation of TMA Technology in Biomarkers Discovery and Validation

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Reliable detection of tissue molecular targets is important for using their expression as a biomarker in medical diagnostics (a.k.a. companion diagnostics). Yet some issues hinder their extensive use, i.e. the inherent biological complexity underlying diseases heterogeneity, inconsistent responses to treatment, and the lack of standardization in the sampling, processing and storage of biospecimen. Tissue microarray (TMA) still represents a powerful method for undertaking large-scale tissue-based biomarker studies but required revisions. To address these issues, BWB (Biobank Wallonia Brussels network) and Auria Biobank join forces to present the next-generation TMA (ngTMA) technology as a powerful tool to improve the robustness and reproducibility of TMA-based studies in biomarker discovery. The ngTMA platforms combine histopathological skills with (semi)-automated tissue microarraying and cutting-edge digital pathology by using image analysis and high performance computing to acquire histological accuracy, enhance the precision of punching, and speed of construction. Further steps to ngTMA manufacturing and processing, as well as validation steps to assess quality assurance and quality control would be developed to support the TMA excellence. Furthermore, the standardization of specimen handling, the best practice of centralized optimized IHC-staining protocols (Proficiency Testing), the full-automatic advanced IHC apparatus and the digital image analysis would be jointly used to complete the ngTMA technology and to strengthen their quality. The merge of all these methodologies could constitute a genuine high-throughput analysis platform for TMA biomarker discovery significantly enhancing the reliability for biomarker research to the benefit of both individuals and the healthcare system as a whole.

Session 10A

Biobank Catalogues – Metrics and Quality

The Belgian Virtual Tumourbank (BVT) Project: Data Quality Control on Primary Breast Tumour Tissue Samples

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The Belgen Virtual Tumourbank (BVT) project consists of a network of eleven Belgian university hospitals. To facilitate the search for tumour samples scattered among different institutions, one central database collects data from residual material of human tumours. The coded data are available for researchers in a catalogue module (BVTc) after extensive quality control analysis. The first step of data quality analysis involves an automated quality control of uploaded data in which format and contents of each field are checked by the BVT application. Next, successfully uploaded registrations in the central database of the BVT are checked manually for inconsistencies between different fields by BVT experienced data analysts. After these initial controls, the data is published in the BVT catalogue and made available for researchers in a coded form. When tumour samples are requested by researchers, a comparison can be made with the BCR cancer registry database between is further contrasted, that contains overlapping information. In a pilot study, more than 200 breast tumour samples and collected during the year 2014 and registered in the BVT were compared to the data available at the BCR cancer registry database. Results on data quality control for this pilot study will be shown.

King's Health Partners Prostate Cancer Biobank (KHP PCaBB): A Unique Biobank Capturing the Ethnic Diversity of London

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The KHP PCaBB was established in 2013 and recruits donors from the Urology or Oncology Department at Guy's Hospital in London (UK). Between 2013 and 2015, 549 prostate cancer patients gave their consent to the biobank and the tissue repository collected 489 blood samples, 120 frozen prostate tissue samples and 1064 formalin fixed paraffin embedded diagnostic blocks.

A recent audit of the KHP PCaBB revealed that between 2013 and 2015, 1,796 patients were diagnosed with prostate cancer at King's Health Partners (KHP) and 549 (30.6%) gave their consent to KHP PCaBB. Comparisons between demographic and clinical characteristics of patients who had given consent compared to the total patient population revealed that the KHP PCaBB is demographically representative of the total prostate cancer patient population seen in Guy's and St Thomas' NHS Foundation Trust. We observed no differences in distribution of ethnicity ($p=0.507$) and socioeconomic status ($p=0.097$). Some differences were observed in clinical characteristics, specifically with treatment type differing significantly between the patients who had given consent and total patient population.

The KHP PCaBB has thereby amassed a rich data and tissue repository that is largely reflective of the demographic and clinical diversity within the total prostate cancer patient population seen at KHP, making it an ideal platform for prostate cancer research. Furthermore, the clinical diversity of our repository facilitates investigations in different areas of research as evidenced from current ongoing studies investigating the clinical use of Lymphoid Stress-Surveillance or Duffy antigen receptor as prognostic markers.

Session 10B

The Power of Connections – New Biobanking Networks

Mexico's Biobank Laboratory: Consolidation and Expansion into a National Network

Hugo Alberto Barrera Saldana

Introduction: To better support translational research and innovation in medicine, we have been introducing in Mexico good biobanking practices. We started the project at the School of Medicine and University Hospital of the Autonomous University of Nuevo Leon in the city of Monterrey (NE Mexico), where we established the first official biobank of biomedical and clinical biospecimens of Mexico.
Objective: To achieve the greatest profit from clinical samples to improve diagnosis and treatment through the Mexico´s National Biobank Laboratory Network.
Methods: The project aims were, firstly, to raise the rank of our Biobank to a National Biobank; thus, we first convinced the National Medical Research and Nutrition Institute to join us and subsequently other three national health institutes and three major universities joined us. We have received valuable help from colleagues, and important funds from CONACyT and donors.
Results: This network is composed of the resources and expertise of ten plus research institutions. This has allowed us to renew the infrastructure, migrate to a more efficient and secure way of managing the biospecimens, better handling of the biospecimens related to information through the implementation of a LIMS and to participate in the preparation of the National Decalogue for the Ethical treatment of BioSpecimens and the Genetic Information derived from their analyses.
Conclusions: We are now able to safeguard, process and analyze biomolecules and relevant information from the valuable biospecimens of users from all over the country who trust them to us.

Malignant Melanoma Biobanking: A Cancer Moonshot Lund Program

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The National Cancer Institute (NCI), a part of the National Institute of Health (NIH) identified research opportunities that align with the Cancer Moonshot that is the biggest Cancer initiative ever, as a US & Global Cancer program. These opportunities, which may be supported with existing funds or with funds from the 21st Century Cures Act, mark the beginning of a Cancer Moonshot portfolio that will be expanded on with a 7 year project period and a substantially resourced budget. Ultimately, the aim of the "Moonshot" is to win the war on cancer and to get to a point in the very near future when we are managing cancer the same way we might manage any chronic disease, such as diabetes or asthma. Additional objectives involving drug treatments and therapies are to finally stop the toxic therapies, such as chemotherapy and radiation that decimate the immune system.

In Lund, Sweden, we have partnered with the Cancer Moonshot activities and will work on Melanoma Cancer. Malignant Melanoma is the type of cancer that has the fastest increase in the number of patients in Sweden (3% per year). In 2012, 2800 new malignant Melanoma cases were reported in Sweden. Taking all cancers into consideration, every fifth cancer patient will die in malignant melanoma. The 5-year survival rate is 5%–10% and the median survival is 6–10 months.

The most imporant risk factors are type-, and number- of pigments, nevi, sun exposure, as well as geneteic factors. Melanoma is also a disease that features a cancer type where currently no biomarker or diagnostics is available to safely identify the disease staging, or responders to Personalized Medicine treatment within this patient group.

An outline and status report will be given on the Cancer Moonshot LUND activities.

Building a Biobank Network in Indonesia

Jajah Fachiroh

Biopsecimen collection for research is common in Indonesia. They are mostly managed by research principle investigator with variety of collection and storage methods. The term “biobank” or “biorepository” was mostly translated as biospecimen storage system, rather than its complex aspects. Faculty of Medicine UGM has been coordinating biobank workshops and networking for the last 2 years in Indonesia, in collaboration with BCnet WHO-IARC France and Lifeliness cohort biobank The Netherlands. The need for national networking was identified on the 1st workshop in 2015. National network was established in the 2nd workshop (2016) through the formation of four working groups, including infrastructure (7 participants), standard operating procedures (12 participants), ethic and legal (6 participants), education and training (7 participants). Participants came from 8 institutions. Further communication was done per working group through Whatsapp, led by working group. We, as network coordinator has suggested specific program for each working group, including identification of infrastructure and their specific needs in each institution, evaluation of common practice and best practice in biobank, drafting recommendation to the ministry of health and research and technology for regulation on biobank for research, and identification of training requirement for biobank in Indonesia based on the needs and expectation. Preliminary results should be reported during network meeting on the 3rd national workshop that will be held in November 2017. This network is an exercise for different institution to collaborate and reaching the same understanding and experience in the development of biobank.

US NCI'S Center for Global Health Regional Center's for Research Excellence Program to Support Research Infrastructure on Non-Communicable Diseases, Mental Health and Injuries (NCDS)

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Cancer researchers have begun to unravel the complex relationship between genes, the environment, cancer diagnosis, and survival. Through this process, it has become clear that working in populations outside the US is essential to their success. Forward-looking teams of meritorious investigators from the US and institutions across the world have come together to create Regional Centers of Research Excellence (RCREs). These centers are based at top-tier institutions in low- and middle income countries. They have galvanized investigators to work in multidisciplinary teams to tackle cancer and other non-communicable diseases (NCD) to improve the health of the US and LMIC populations.

Investigators recognize that reproducing basic, clinical, and population-based NCD research relies on high-quality biospecimens that are curated so that the integrity of the biomarkers is preserved. The analytes contained in these specimens become the direct source material from which targets for therapy, detection, and prevention are identified. The lack of available standardized, high-quality biospecimens is widely recognized as a significant roadblock to conducting NCD research in these settings.

In order to quickly and effectively increase high-quality research from LMICs, investigators are building local biobanks. Many biobanks are part of a larger research network, such as the NCI's RCRE Program, and have support from the local research institutions. Participating in a network brings together like-minded investigators focusing on using resource-appropriate biobanking practices that yield reliable, reproducible results.

This presentation will detail the strengths of a network of global biobanks used by investigators as they investigate cancer and other non-communicable diseases worldwide.

The Partnership for Research on Ebola VACcination (PREVAC): A Phase II Clinical Trial that is Creating the Opportunity for a Sustainable Biobank Model in Guinea Conakry

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In the aftermath of the last Ebola outbreak, Ebola-related samples were located across the sub-region in laboratories lacking appropriate infrastructures. To prevent the uncoordinated storage of specimens in case of future outbreaks the need of developing in-country capacity became clear.

Guinea is investing concrete resources and creating networks for the stockage of the Ebola samples. Biobank initiatives associated to specific studies are being implemented. The conversion of these discrete initiatives into sustainable centers for the systematic collection and storage of specimens will fuel innovation leapfrogging the country into the future.

PREVAC is a multi-centric phase II clinical trial studying the immunogenicity and durability of two vaccines against Ebola. Laboratory tests will be performed both in-country and abroad.

In Guinea the trial has two sites, one urban and one rural. In both sites a biobank has been established consisting of a set of -80°C freezers connected to a cold chain monitoring system and in which specimens are archived through the support of a Laboratory Information System (LIS). During the implementation phase different constraints have been met, mainly related to logistics: stabilization of power supply, backup for freezers, implementation of the LIS, shipment plan for the specimens.

The PREVAC biobank represents a concrete model of biobank responding to high quality standards implemented in Guinea. All the implementation phase has been developed in collaboration with local authorities. The PREVAC model could serve as starting point for the development of the biobank system planned by the Guinean authorities.

Establishing a Pediatric Biobank Model and Expert Centre Within the Polish Biobanking Network (BBMRI.pl)

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Polish Biobanking Network (BBMRI.pl) has engaged the efforts to identify Polish institutions which deal with banking of biological material, also those that collect samples from children. The aim is to introduce common standards for sampling, storage and sharing of samples and medical data with outside parties, including research centers, diagnostic and pharmaceutical companies. Specific ethical and legal problems arise in pediatric research, including pediatric biobanking, such as informed parental consent and child assent.

BBMRI.pl has identified a broad store of biological samples in Centre of Postgraduate Medical Education (CMKP), in the Department of Pediatrics, which deals with treatment of children, research and postgraduate education. The samples of blood, serum and cerebrospinal fluid from healthy and unhealthy children, including neonates, were until now collected in form of a human subject bank. A large part of the samples come from children with lifestyle diseases. As soon as the samples are no longer needed for individual patient, they are used for research, after each approval by the bioethics committee.

It was proposed to create a Pediatric Biobank model and expert centre based on that specific collection of pediatric samples and the expertise of CMKP employees. The aim is to create standards for sampling, storage, sharing and IT solutions, which would serve to create other pediatric biobanks. Guidelines that will be developed during the BBMRI.pl project will serve to solve specific ethical and legal problems of the Pediatric Biobank.

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ELP Consortium Biobank: A New Strategic Model for Harmony to Bank Research Resources for Cohort Study

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Biobanking is still a young discipline. It has experienced several developing stages with gradual realization of the critical factors hallmarked with quality, associated data and utilization of banked biospecimens. Biobanking in China is basically motivated to collect samples to meet the needs of funded projects or keep up to follow the generic trends and developments in the field of translational and precision medicine. Regardless, biobanking faces the challenges in resource heterogeneity due to poor interoperability, restriction utilization due to lacking design thinking ahead.

ELP (short for Early Life Plan) is such a longitudinal initiative by Xinhua hospital in Shanghai, to explore the early life programming and developmental disease susceptibility for diagnosis, genetic counseling and clinical decision-making, improve the quality of birth population. With this research theme, we have formed a team by cross-disciplinary experts from clinicians to epidemiologists, and the team is motivated by building a generic resource for the broad scope of research. We have developed a new strategic model and approach to emphasize design thinking with the collective experts in the very beginning and apply "refactoring" to any new twists of thinking to fit the research theme. The key is to rethink the way of biobanking, to shift from one model to another. We aim to have such a resource for sufficient scope to lead to full-length research theme.. We expand the model to consortium member hospitals that act in full compliance. Therefore, we can sidestep the major challenges by increasing interoperability to reduce heterogeneity for sharing.

Session 10C

Quality Assessment – A Key Factor for Successful Biobanks and Reproducible Science

SPIDIA4P – New International and European Standards for Biobanking in the Making

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International and European standardization with ISO (International Standardization Organization) and CEN (European Standardization organization) in general intends to provide a reference framework and universal language for suppliers and customers, facilitate trade and technology transfer, ensure technical compatibility, provide a scientific basis for legislation in the health, safety and environment sectors, ensure that trade agreements can be successfully implemented, and to develop Standards as a source of technical know-how.

SPIDIA4P aims to improve pre-analytic workflows of biological material for the analysis of specific analytes. These workflows can enhance the quality of biobanking including sample collection, handling, processing, quality control and storage procedures, and thus a biobank's market acceptance.

This session will provide an overview about the standardization activities currently ongoing in CEN/TC 140 "In vitro diagnostic medical devices" and additional project that are planned for ISO and CEN during the term of SPIDIA4P.

Also, an overview of why standardization is relevant to every biobank and why an early involvement in the ongoing standards' development holds numerous advantages and benefits in comparison to competitors in the market.

Quality Assessment and Successful Biobanking in Japan

Tohru Masui

Japanese biomedical sciences have been depending on and appreciated quality of biological materials and information. However the development of technologies and the moves of interests in biomedical sciences have pushed the requirements of biological resources onto a different phase. The quality is revisited, and biobanks now have been paying much attention on the quality issues.

In this talk, I will present Japanese cases of the pursuit of the best quality in biological resources, i.e. muscle tissue bank and cerebrospinal fluid bank in NCNP. I also will present cases of use of established quality management activity in combination with ordinary research activities. In these cases the established activities helped and assured a better management of good quality sciences.

Now in the development of ISO/DIS20387, Japanese research community and biobanks are preparing the next phase in biological resources in biomedical sciences. I will present research activity in my research project on biobank networking.

German Biobank Alliance: Quality Management for Biobanks

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The German Biobank Alliance (GBA) follows up and builds upon the achievements of the German Biobank Node (GBN) project which comprise the development of a quality management system (QMS) for the German Biobanking community. Quality is made up of 3 main objectives: i) establishment of a QMS compliant with international standards, ii) development of a quality assurance concept by identification of quality relevant biomarkers and iii) development of a ring-trial and audit program. The implementation of a QMS to all relevant parts of the biobank will substantially contribute to its success.

A collection of template SOPs made through GBN is already available. This collection was complemented and connected to a questionnaire covering the fulfilment of applicable standards. This also includes the recently published technical specifications (CEN/TS) for molecular in-vitro diagnostic procedures and specifications for pre-analytics thereby ensuring the compliance with specific demands of the IVD directive.

As a result, a self-assessment tool for biobanks including template documents and specific proposals for their respective implementation is available with the GBA QM manual. An audit program for the participating GBA biobanks according to ISO 19011 and a survey for the evaluation of user satisfaction will complement the project goals. Our quality project closely corresponds to the activities of BBMRI-ERIC, e.g. in terms of a joint audit program and the CEN/TS compliance of biobanks.

Technical Specifications for Collecting Diagnostic Samples: The Tool to Increase the Reproducibility of Results

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Biobanking forms one of the major pillars in the realization of precision medicine. Especially where discovery of biomarkers/targets are involved for the development for new methods and therapies. Currently however, the reproducibility of research findings is a major issue. The development of new methods, tests and therapies need validation for intended use. The validation is based on samples collected in the routine diagnostic process. The lack of standardization during the pre-analytical phase introduces unwanted variations in the samples. This way only robust tests survive the selection process. The downside of this is that many useful tests, sensitive to the variations, do not survive through irreproducible results, leading to scientific and financial waste.

Published CEN Technical Specifications, which were accepted at ISO level for development to ISO Standards, could change this. Standardization becomes obligatory where it can be applied and if not, documentation is required. Documentation is the tool to get a handle on the introduced variations. In the form of sample metadata it could give the insight, if samples are or were fit for purpose. This knowledge can be used for sample selection and for identifying those critical steps in the collection procedure introducing major variations, which can then be re-evaluated to be standardized or avoided.

The diagnostic standard specifications need to be taken over in the biobanks for health care research to avoid incompatibility of sample quality. This way the reproducibility increases and allow implementation of more sensitive tests for 4P medicine saving waste due to sample variation.

Implementation of Self-Assessment Surveys Based on the CEN/TS for Pre-Examination Processes

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The reproducibility of biomedical research strongly relies on biosample quality. Quality controlled sample handling throughout the pre-analytical process is essential for high-quality samples. Therefore, the European Committee for Standardization (CEN) released Technical Specifications (CEN/TS) for pre-examination processes for ensuring sample quality.

The Medical University of Innsbruck developed in cooperation with BBMRI-ERIC a tool to assess the conformity with requirements defined by the CEN/TS on sample collection level. The development of the Self-Assessment surveys (SAS) started with a detailed analysis of the CEN/TS and extraction of relevant criteria by the Quality Management (QM) working groups. An initial usability study was conducted among the QM working group members based on a spread-sheet list of criteria. Then, a web-based prototype of the SAS was implemented by the Medical University of Innsbruck by using the REDCap framework. This prototype provided the possibility to customize the surveys and offered a reporting functionality by using the REDCap Application Programming Interface (API). The users received pdf reports of their given answers which provides the possibility of improving processes to fulfil all requirements. The prototype surveys were evaluated regarding content, usability and functionality by the prototype users. The feedback was integrated, the SAS migrated from the test server to the productive environment running on a BBMRI-ERIC server and Version 1 of the SAS was launched.

The SAS supports users in assessing the conformity of their sample handling processes with the CEN/TS. For the next version, improvements regarding content and usability will be incorporated based on user feedback.

Tissue Preservation, Aliquoting Methods and Quality Controls in Biobanking

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CRO-Biobank (CRO Aviano NCI, Italy) is a structured facility integrated in a clinical setting aimed at collecting human biological samples for cancear research. We collect frozen and FFPE tissue samples with associated biomaterials (e.g. serum, plasma, buffy-coat, and nucleic acid). Frozen tissue samples are OCT-embedded, flash frozen in liquid nitrogen and stored at -80°C. For clinical diagnosis, molecular analysis and biobanking of PE tissues, we are evaluating different histological fixatives, alternative to formalin, which is toxic and carcinogenic.

We use well-defined methods to control tissue quality: histocytology (frozen sections, FFPE mirrored samples and cytological imprint), molecular pathology and molecular analyses for DNA, RNA and protein extracts.

Based on the model of “Expert Centers”, a specific activity of biological characterization of solid and hematological tumors has been planned in our Institution, using aliquots of samples stored in our biobank. NGS, proteomic and immunohistochemical preliminary analyses provide selected series of highly informative biosamples to the researchers.

In order to optimize the use of biological samples we have elaborated an “aliquoting system” that allows to select the appropriate quantity of material delivered for a single project and may warrant appropriate selection of cells for research purposes.

Moreover, we are implementing quality processes and procedures to guarantee the safety and privacy of the providers and to ensure both the traceability and the quality of samples. We also consider ELSI and IT topics, taking into account indications from the Common Service ELSI established in 2015, as a key asset of BBMRI-ERIC.