Biobank Management 6
Towards a Dutch National Tissuebank Portal 6
European Virus Archive: research and preparedness to emerging diseases 7
Perspectives of Community and opinion Leaders in Nigeria on the Role of Biobanks in Research 8
The Swedish Cervical Cytology Biobank: Sample Handling and Storage Process 9
Highlights from 12,5 year Erasmus MC Tissue Bank 10
Applying biological samples in genomics - Cohort studies 11
Alignment of a Research Biobank with Pharma Biomarker Validation 12
Biobank Profile of Uppsala Biobank 13
Status of former biobanks in Uppsala 14
Application and Review Procedures for Access to the Tumorbank@UZA 15
CSR 3.0 and the gaps with truly sustainable biobanking 16
ISENET dedicated stem cell bank 17
Process cost analysis - a tool for planning and financing of Biobank projects 18
Quality Management in Biobanking 19
The Fluidigm® SNPtrace panel sensitively identifies gender contamination, sample degradation and low quality samples. 20
Israeli Tumor Biorepository Networking - Roadblocks & Segways 21
Development of a cost recovery tool at Biobank Graz 22
From sample collection to cancer research - perspectives from a prospective cancer biobank 23
Incorporation of SPREC code into Bio-e-Bank (Laboratory Information Management System) 24
Incorporation of SPREC code into Bio-e-Bank (Laboratory Information Management System) 25
Collection of control samples from subjects blood donors generated by Biobank staff 26
Adjustment of quality management system of biobank to a global certification including all certified services of Hospital Universitario Ramón Y Cajal 27
Novartis Biotracker: No Sample Left Behind 28
Biorepository to BioBanking at Novartis 29
GERMETHEQUE, a Bio Banking network dedicated to Human Reproduction 30
Quality management system on a multicenter biobank: challenges and opportunities. 31
Effective Governance Tools for a Functional Biorepository Service Provider Partnership 33
Understanding the Need for Business Continuity and Disaster Recovery Planning for Research Samples 34
Implementation Of A Quality Assurance Policy In A Biobank Network: Andalusian Public Health System Biobank (BB SSPA) 35
Suggesting a ticketing system for biobank service and quality assurance 36
Analysis of semantic resources in biobank databases. Approaches to harmonization of standards. 37
The Belgian Virtual Tumourbank (BVT) Project: Data Quality Control 38
ONCO-i2b2 system: clinical, genetic and biospecimens data integration for traslational research in oncology 39
Managing The Secure Transport Of Cryostorage Tanks 40
The Northern Ireland Biobank: the story so far. 41
Providing Human Diagnostic Tissue for Research - Experiences with an Administrative Quality Assurance System 42
Newborn Screening Dried Blood Spots and Biobanking 43
Basque Biobank in the way to become a Hospital integrated biobank 44

CryoStem: establishment of a national thematic collection of biological samples pre- and post-Allogeneic Hematologic Stem Cell Transplantation for the study of Graft-versus-Host Disease 45
Starting Up And Operating Of The IdiPAZ Biobank: Our Child Has Gotten Older 46
Biobankers and Pathologists: MARBiobanc as an example of collaboration 47
From small departmental biosamples collection to an institutional biorepository 48
A modular, integrated storage solution to facilitate the biobanking workflow . 49
IceTrack: a biobank information management system maximizing flexibility and usability 50
IT-Solution for Feasible Data Protected Multicentric Clinical Biobanking. 51
Definition of nonconforming products based on standardized quality indicators in the biobank's samples distribution service. 53
Management of Forensic Biospecimen in South Africa. 54
Biobanking for research in surgery: are surgeons in charge for advancing translational research or mere assistants in biomaterial and data preservation? 55
Bimetra biobank: bringing together different initiatives for high quality biobanking 56
Ensuring Quality within the EU-FP7 IMPROvED Biobank 57
Aragon Biobank: a Biobank to foster traslational research 58
The CNESPS Biobank: a population based resource for epidemiological research in Italy 59
Consent for biobanking - a partnership approach 60
The Regulation of Biobanks in South Africa 61

Biospecimen Research 62
DNA fingerprinting: Sherlock Holmes in the biobank. A case study. 62
Microbial Translocation in HIV-1 infected patients. 63
Marine mammal tissue banking and cell cultures: extending efforts for protecting endangered species 64
A standardized technique for excision and storage of high quality human retinal tissues 65
Metabolomics Technology Validated Quality Markers for Biobank Plasma Samples 66
Preservation of biological material derived from OSNA assay: beyond its diagnostic use 67
Automated biobanking workflow for room temperature collection, transport and storage of human blood samples for molecular RNA and DNA diagnostics. 68
Sample Quality Assessment of the Oncological Serumbank@UZA 69
Biospecimen Science in the Janus Serumbank 70
Histological Quality Control (QC) Of Frozen Samples Using Matching Formalin-Fixed Paraffin-Embedded (FFPE) Tissue – Preliminary Results Of Our Institutional Biobank 71
Biobanking for Dermatological Disorders 72
Samples preservation: which for what? 73
Glioblastoma stem like cells in the BestaCriobank for Brain tumors, an important source for biological and clinical studies on glioblastoma 74
Biobanco-IMM: an overview 75
Prolonged Cell Viability for Mouse Implantation of Human Tumor Tissues 76
Paraffin Embedded Tissues Use For Next-Generation Histopathologic Diagnosis: A Lesson From a Hepatic Carcinosarcoma 77

Maximalizing the use of clinical samples: development of limited hands-on time DNA extraction method from frozen blood clots....78
Genetic Mutations As Prognostic Biomarkers In Patients With Early Stage Lung Cancer....79
Quick And Donor-Saving Method For Mesenchymal Stem Cell Extraction For Biobanking And Clinical Use....80

Education & Standards 81
Improved Utilization Of Fresh-Frozen Tissue Specimens Using A Novel Frozen Tissue Aliquotter....81
Standard Operating Procedures for a Biorepository Network....82
Biobank Graz: Training and Coaching....83
Munich Biobank Alliance: Implementation of improved standards for collecting biospecimens in the era of personalized medicine 84
Optimization of Tissue Microarray construction and processing for breast cancer research....85
The Establishment of an ISO Compliant Cancer Biobank for Jordan and its Neighbouring Countries Through Knowledge Transfer & Training....86

ELSI 87
How much factual information is necessary for an optimal informed consent in the field of biobanking?....87
Development of an open informed consent for biobanking....88
Challenge: implementation of an open consent for donors of a disease-oriented biobank at one of the National German Biobanks - the ibdw experience....89
Sharing and Making Use of Digitalized Slides Obtained from Biobanked Human Tissue Samples for BIOPOOL: Legal and Ethical Issues....90
A Specific Biobanks' Ethics Committee: The "CEBCI" Of Hospital La Fe....91
The Brazilian Regulatory Framework on Biobanking for Health Research compared with other International Regulations: some (but not total) consensus 92
Personalized assent for pediatric biobanks....93
Biobanking for genetic research: ethical legal and social issues beyond traditional bounds 94
Balancing the rights and obligations of stakeholders in relation to access to biobanks....95
Biobanking Challenges in Illiterate and Low Resources Context: Case of Mali...96
Easy! Requesting and sharing reagents, biospecimens and data through the new Technology Agreement Dashboard at the US National Institutes of Health....97
Biobanking towards a participatory agreement among scientists and society as innovative standard of quality 98

New Technology 99
Network based biobanking for biomarker discovery....99
eagle.trace - Software for Biological Sample Tracking in a Biobank 100
Biobank Graz: Automated pipetting with direct freezing 101
Biobank Graz: Semi-automated FFPE sample storage 102
Case Study: Creating a successful facility for large-scale extraction of DNA 103
BIOPOOL PROJECT: A new approach to look for samples across worldwide biobanks 104
Exploring Sample Preparation Techniques that Optimize Biospecimen Collections for Prospective and Retrospective Research 105
New Instrumentation for Sustainable and Cost Efficient Long-Term Storage of Biospecimens at Ambient Temperature 106
A novel technology for stabilizing eukaryotic cells dry at room temperature 107

Interconnecting biobanks to their partners, collaborators and contributors using an open science platform 108
New phenol-free technology for simultaneous DNA/ RNA/miRNA extraction from difficult-to-lyse and FFPE tissue 109
DNAQual: an index of human DNA quality validated in different degradation models 110
Development of cell-based arrays to characterize stem cells and their derivatives 111
Improved storage system for liquid nitrogen tanks 112
The Impact of Preanalytical Variables in Blood: Enabling High Quality Protein Analysis 113

Other Topics 114
Radboud Biobank: a central facility for prospective clinical biobanking in the Radboud University Medical Centre, Nijmegen 114
The Australasian Biospecimen Network Association – Building links for biobanking across Australia and New Zealand 115
CIBERER Biobank: A support platform for research into rare diseases. 116
Pathology lab accreditation stimulates tissue research support, leading to better research results. 117
Analysis of Yeast and Mould Species Commonly Found in High Risk Units of C.H.U. Oran, Algeria 118
Italian Network of Genetic Isolates Biobank: a good instrument to study complex diseases. 119
Circuit Stablishment For Quality Biological Samples Retrieval In A Third Level Hospital Biobank 120
The Frozen Ark Project 121

Resource Development 122
Developing an Electronic Standard Operating Procedure Management Information System to Facilitate High Quality Research Within Biobank Networks and Collaborations 122
LifeLines Cohort and Biobank 123
Australian Breast Cancer Tissue Bank (ABCTB): Clinical Data Standardisation & Normalisation for Streamlining Data Retrieval Methods 124
GCAT Genomes for life. Cohort Study of the genomes of Catalonia. Validation of the use of White cells Residue from a blood donation for biobanking purposes. 125
Biobanking Networks: Why now? 126
Development of biobanking in Central and East European Countries 127
Governing an academic biobank: What are the challenges? 128
Pioneer in biobanking – hard work leading to success 129
The Janus Serum Bank of Norway- a prospective cancer biobank 130
Telethon Network Of Genetic Biobanks (TNGB) 131
Workflow for controlled collection and processing of patient samples 132
The Biological Library of the Université catholique de Louvain 133
Free reliable digital signatures 134
Biobanking data platform for translation research 135
TMF Represents an Interdisciplinary Platform for the Advancement of Biobanking in Germany 136
Integration of biobanks into fully established molecular pathology programmes. 137
Services for the harmonization of the Italian biobank network 138
Validating The Use Of Under Vacuum Fresh Tissue Sealing And Cooling For Molecular Analyses 139

The Value Of External Technical Support And Benchmarking To Evolving Centralised Biobanks In Africa 140
Developing a state-of-the-art Biorepository in Uganda – The BioReMU 141
Biobanco-IMM tumour collection: from the bedside to the bench 142
Multidisciplinary working groups around the Virtual Biobank stimulates the Translational Biomedical Research Collaboration in Flanders, Belgium – a focused approach 143
RNA stability in the human liver tissue and the ileum mucosa 144
Bimetra: integrative model for translational research 145
Bimetra biobank: bringing together different initiatives for high quality biobanking 146
QBB: The First QATAR Public Biobank , Participant Feedback and Observations. 147
QBB: Milestones in building a successful biobank 148
Development of a pilot project of data sharing between partners of the Italian Hub of Population Biobanks (HIBP) 149
Qatar Biobank, a valuable resource for future healthcare initiatives 150
Biobanking in Financial Crisis 151
Biobank and everything around 152
DNA extraction for long-term storage: our experience 153
Piccolipiù biobank: an Italian resource for children's health 154
CASCADE: A CAncer tiSsue Collection After DEath programme to improve our understanding of the progression from primary stage cancer to metastatic, treatment resistant disease. 155

Biobank Management

ID number: 001

Towards a Dutch National Tissuebank Portal

C.Steegers, F. van Kemenade, A. Hoffman

VUmc, De Boelelaan 1117 1007 MB Amsterdam, The Netherlands

OBJECTIVE: Good clinical governance requires pathology laboratories to store tissue samples and their data in the event of delayed diagnostic use for the patient. Yet, researchers increasingly expect pathology laboratories to make these samples and data accessible for research purposes. The DNTP (Dutch National Tissuebank Portal) project will make all Dutch pathology reports and archives better accessible for research without infringement on the good clinical governance task of pathology laboratories and in accordance with the ethical, legal and social issues involved.

DELIVERABLES: - Engagement of the Dutch pathology and research community by establishing partnerships and contracts with DNTP.
- DNTP pilot study for another project that will request large amounts of samples in several pathology laboratories
- Streamlining ethical and legal procedures for secondary use of pathology samples such as requested by the new Code of Conduct for Responsible Use.
- Organize logistic, administrative and technical support for pathology laboratories and researchers through one portal.

RESULTS AND CONCLUSION: In a few years the Netherlands will have a professional resource that will provide virtual and physical access to pathology data, samples and derivatives for research. This will benefit researchers, pathology laboratories, patients and, ultimately, public health.

ID number: 002

European Virus Archive: research and preparedness to emerging diseases

Jean-Louis Romette, Nora Ghandour

IRD, Unité des virus Emergents UMR 190 & Protisvalor, Université de la Mediterannée, MARSEILLE

The European Virus Archive (EVA) was conceived as a direct response to the need for a coordinated and readily accessible collection of viruses that could be made available to academia, public health organisations and industry, initially within Europe, but ultimately throughout the world. Although scientists worldwide have accumulated virus collections since the early twentieth century, the quality of the collections and the viruses collected may vary according to the personal interests and agenda of the scientists. In 2009, funding under the FP7–EU infrastructure programme enabled the initiation of the EVA. Within three years, it has developed from a consortium of nine European laboratories to encompass associated partners in Africa, Russia, China, Turkey, Germany and Italy. Today 27 partners and associated partners are members of the consortium. The ultimate objective of EVA was to make it a permanent archive that can provide access to viruses and reagents globally. This has included, forming partnerships and alliances with Health organizations including GOARN/WHO, ENIVD/European–CDC and China–CDC and soon US-CDC. The concept of EVA is unique, no other collection provides the accessibility, reagent backup, sequence data, provenance, quality control, and capacity to inform, through the web. Around 2000 products have been distributed worldwide very often for free of charge. The reputations, high quality, experience and knowledge of the EVA partners, provide end-users with opportunities to approach new fields of research in structural viral genomics, evolutionary biology, control of infectious diseases, antiviral drugs design, and a wide variety of associated disciplines

ID number: 003

Perspectives of Community and opinion Leaders in Nigeria on the Role of Biobanks in Research

Michael A. Igbe, Clement A. Adebamowo and Emilomo Ogbe

Department of Surgery, Faculty of Clinical Sciences, University of Ibadan, Ibadan, Nigeria

Background: Biobanking has become an important tool for research. Given its increasing use and the ethical challenges associated with it, we studied the attitudes and willingness of community leaders to use of biobanking in research in Nigeria.

Methods: We conducted Key Informant Interviews (KII) to elicit perspectives on biobanking among participants selected using purposive sampling method to represent a broad range of views and experiences in Nigeria.

Results: None of the participants knew about biobanking but they were willing to donate their specimens for the research. Most were not aware of risks associated with donating their specimen to biobanks, supported use of broad consent, would permit their specimens to be shared with commercial and non commercial entities, and would like a feedback of such collaborations. Only a few participants would want the biobank to specify the future uses of their specimens.

Conclusions: Given the limited knowledge of biobanking and the positive attitude of the population towards it, scientists should incorporate significant population engagement into research that includes long term storage of biospecimens. It is of utmost importance to maintain a trusting relationship with participants and ensure confidentiality through adherence to ethical principles and guidelines.

ID number: 006

The Swedish Cervical Cytology Biobank: Sample Handling and Storage Process

Nasrin Perskvist,1,2,4 Ingrid Norman,2 Carina Eklund,3 Jan-Eric Litton,4 and Joakim Dillner4,5

Karolinska Institute and Karolinska University Hospital, Clinical Cytology Biobank, Stockholm

The Swedish Cervical Cytology Biobank (SCCB) is the first national initiative of a prospective repository for liquid-based gynecological cell samples (LBC) from women participating in organized cervical cancer screening programs. Development and implementation of a nationally standardized method for the handling and long-term storage of cervical cell samples has been a primary goal for the Swedish hub of The Biobanking and Molecular Resource Infrastructure (BBMRI.se, www.bbmri.se). The sample handling protocol was developed through i) review of the literature on biobanking processes, ii) wide consultation within the academic community, and iii) various verification assays in collaboration with the clinical cytology laboratories. A general quality management system, covering all aspects of sample handling and storage, has been established. BBMRI.se financed the development and implementation of SCCB. The protocol established in the pilot project in Stockholm is now being implemented in other counties in Sweden, and during this year, more than 120,000 LBC samples will be processed for biobanking nationwide. SCCB is embedded in a comprehensive cytology diagnostic registry and will be linked with the national cancer registry to constitute a nearly inexhaustible resource for performance of fundamental and applied biologic research.

ID number: 008

Highlights from 12,5 year Erasmus MC Tissue Bank

Monique Oomen, Bas de Jong, Peter Riegman

Pathology Erasmus MC Rotterdam

In 2002 the Erasmus MC Tissue Bank (EMCTB) started participation within the Tubafrost Project, a European project aiming to unite frozen tumor tissue banks into a network. A standardization plan was developed and implemented in order to obtain tissue samples of equal and high quality, from the developed SOP's and QA consisting of choices and recommendations. The coded and bar coded vials are registered in a database. In 2001 the registration started with an access database where each sample is directly administrated with the following items: Pathology number, vial number, Tissue type, Tissue condition, FFPE block and comments, allowing double coding for issued samples. In 2013 registration is done in the optimized database, Ocimum Biotracker.

The EMCTB collected in 12,5 year about 60.000 samples, also for prospective studies. From the year 2006 the EMCTB issued 6000 samples to researchers. All samples are collected and issued according to the Dutch Code of Conduct (adapted in May 2011).
For QA 2% of all new samples need to be checked yearly on correct storage and RNA quality. These results are documented in a year report along with the research projects that were supported.
For medical research on tissue samples we started the Tissue Research Support Unit.

Biobanks can opt for accreditation of specific procedures such as quality and/or security management systems. The EMCTB is an integral part of the Erasmus MC Pathology department , which recently was accredited for ISO 15189:2007, which specifically requires quality and competence particular to medical laboratories. Therefore all Tissue Bank procedures that touch base or share facilities with the diagnostic pathway must also apply to the accreditation requirements.

The EMCTB now ensures high quality samples and data to be used by researchers and for sharing in biobank network platforms. A timeline including these and more important events in our tissue bank development will be presented.

ID number: 010

Applying biological samples in genomics - Cohort studies

Joris Parmentier

LGC Genomics, Units 1 & 2 Trident Industrial Estate, Pindar Road, Hoddesdon, Herts, EN11 0WZ, UK

This talk covers DNA Extraction and other genomics technologies in the framework of one of the most typical applications of biological samples from Biobanks; Human cohort studies. Biobanks and Biorepositories are linked with Cohort studies in a variety of ways. These studies may provide a source of biological samples or be the destination you send your samples to. Regardless, one of the primary applications of samples will include genomics analysis such as sequencing and genotyping. This talk covers pragmatic solutions and applications of these technologies in the framework of cohort studies. Additionally the talk will focus on DNA extraction technologies, exemplified with pictures and movies from the Lab.

ID number: 012

Alignment of a Research Biobank with Pharma Biomarker Validation

Janine Swifka, Thomas Krahn, Ulrich Zuegel, and Arndt Schmitz

Research Biobank, Global Biomarker , Bayer Pharma AG, D - 13342 Berlin, Germany

Background Information - The understanding and treatment of many diseases is severely handicapped by the absence of biomarkers that can be measured in body fluids like blood or urine. To identify and validate biomarkers in pharma research especially in translational medicine excellent clinical material is indispensably needed (e. g. for molecular analyses at mRNA level). To support and empower research, there is a high demand to create utmost 'value' from scarce samples. Compliance to legal requirements is a must, with additional emphasis on socioethical values.

Methods - We analyzed the legal situation in Germany. We then developed a concept for and established a research biobank including both human and animal specimens.

Results - The Research Biobank of Bayer Schering Pharma AG leverages the clinical network driven by the research projects by providing human samples and their clinical data for bioanalytics under strict compliance with legal, ethical, biosafety, biotechnology, data privacy and information technology guidelines.

Conclusions - We favour a collaborative approach to biobanking where both clinicians and researchers contribute their strengths. By combining our respective experiences and accepting mutual cultural differences during partnering as well as clinical realities during the operations phase in order to minimise risks in clinical sample and data collection we were able to accelerate setting up prospective collections as a reliable, convenient, robust and affordable solution. Experiences gained in the build up of a pharma research biobank can be instrumental in further developing best practices. We will present case studies from our indications which include Oncology, Cardiology, and Gynecology.

ID number: 015

Biobank Profile of Uppsala Biobank

Malin Engelmark

Uppsala Biobank, Dag Hammarskjölds väg 14B, 1tr, MTC-huset, Science Park, 751 85 Uppsala

Uppsala Biobank is a centre of competence for biobanking and a collaboration between Uppsala County Council and Uppsala University. Uppsala Biobank includes sample collections for both research and healthcare. The mission of Uppsala Biobank is to (1) administrate Uppsala Biobank towards the National Board of Health and Welfare, (2) establish, support and maintain a stable biobank structure and organisation, (3) obtain and supply high competence and tools in order to fulfil the laws and regulations that govern biobank activities and (4) perform services in relation to management and processing of samples.

In January 2013 Uppsala Biobank comprised millions of samples distributed on 137 sample collections, 131 research sample collections and 6 healthcare sample collections. Uppsala Biobank sample collections covers basically all human diseases and research such as basic, translational, epidemiological and clinical. The date range of cases is from 1930s to present. There are thousands of samples from cases associated with both fresh-frozen tumour and blood biospecimens in the collection of clinical pathology. In the hospital integrated biobank service, samples are collected prospectively for 8 different cancer diagnoses, myocardial infarction, psychiatric disease and several others are starting up. Uppsala Biobank administrates around 100 studies per year connected to ethical approval. About 40% of the studies apply and get tumour samples from the biobank.

Uppsala Biobank is an example of how research and healthcare principals with common interest in biobanking can collaborate in a successful manner. The biobank profile of Uppsala Biobank was published in Biopreservation and Biobanking, April 2013.

ID number: 016

Status of former biobanks in Uppsala

Malin Engelmark

Uppsala Biobank, Dag Hammarskjölds väg 14B, 1tr, MTC-huset, Science Park, 751 85 Uppsala

Uppsala Biobank was founded in 2008 as the joint and only biobank of the two principals Uppsala County Council and Uppsala University. The head of Uppsala Biobank became the biobank custodian of all biobank samples. Previously registered biobanks consequently needed to be investigated and get new status. In total there were 138 former biobanks, 132 research sample collections and 6 healthcare sample collections. New status could be: (1) Ended, (2) Released to other biobank, (3) Converted into sample collection in Uppsala Biobank or (4) Unknown due to absence of reply.

Individual meetings were held and information and status were collected about the former biobanks. All the information was gathered in a registry. Research collections were formally converted to Uppsala Biobank though signed contracts between the biobank custodian and sample collection responsible person. The contract clarifies responsibilities and gives the researcher responsible for the sample collection sole right to dispose the samples. Samples can only be used for ethically approved research in line with informed donor consent. Director of clinics with healthcare collections were appointed responsible for those sample collections through a decision by the hospital director.

Of 138 former biobanks, 52 (37.7%) were ended, 69 (50%) were converted to sample collections, 2 (1.4%) were released and 15 (10.9%) remained unknown.

In January 2013, 89.1% of former biobanks was known and given new status which is a major success. The reorganisation points to the need of having updated biobank registries and the importance to discuss and formalise rights and responsibilities.

ID number: 020

Application and Review Procedures for Access to the Tumorbank@UZA

Britt Peeters, Elke Smits, Els Meulemans, Kin Jip Cheung, Katrien Lesage, Annemieke De Wilde, Véronique De Vroey, Léon Luyten, Philippe Jorens, Geert Smits, Tim Van den Bulcke, Patrick Pauwels, Marc Peeters

Antwerp University Hospital, Wilrijkstraat 10, 2650 Edegem, Belgium

Introduction: Tumorbank@UZA at the Antwerp University Hospital (UZA) has systematically collected over 16.286 residual tissue and serum samples from oncological subjects by an opting-out legislative system. Nowadays, the high-qualitative stored samples are available for academic scientific research. Aim(s): Setting-up a hospital-integrated Access Policy for the usage of the tumour bank samples.

Material & Methods: A Standard Access Policy (SAP) procedure was established consisting of a Material Request Form, a multidisciplinary advisory board (i.e. surgeons, clinicians and scientists) and a Human Material Transfer Agreement (HMTA). Requests are reviewed in terms of study design, sample availability, project funding and scientific relevance. Samples and associated coded data are released following approval by the local ethical committee and the HMTA. According to the terms of the HMTA, researchers are committed to give feedback on all results obtained with the Tumorbank@UZA samples and to acknowledge the Tumorbank@UZA in any scientific communication, when appropriate.

Results: Eight requests have been revised according to the SAP procedure since its approval in the early 2013. An approval-rate of 75% was obtained and 95 oncological samples were released. Samples were primarily requested by researchers from the dual affiliation Antwerp University and Antwerp University Hospital. The requested sample types were predominantly from breast, lung and gastrointestinal origin.

Conclusion: The use of the SAP enables a good and structured management of the sample outflow. However, further optimization of the SAP procedure is required for automation and better quality assurance of the Tumorbank@UZA, aiming at a balance between sample input and sample outflow.

ID number: 022

CSR 3.0 and the gaps with truly sustainable biobanking

Erik Steinfelder, Andre Nijhof

Thermo Fisher Scientific, Takkebijsters 1, 4817 BL Breda, Nyenrode Bussines University, Straatweg 25, 3621 BG, Netherlands

Some generic companies have a Corporate Sustainability and Responsibility strategy simply in their DNA according to Wetzels/Nijhof (Nyenrode Business University) and is fully in line with its mission. These companies who are in the phase of CSR 2.0 have full strategies for example in place to:

- Make the current business activities as sustainable as possible
- Shorten the supply chain
- Participate and be active in Round Table Initiatives
- Product or process redesign to lengthen the lifetime

The majority of the biobanks around the globe are not in that stage yet but seem still to be influenced from a sustainability point of view by actions and results, a product centric approach and only publish broadly what went well. Using the 4 typologies of Wetzels/Nijhof a call to action can be defined to make the leading biobanks embracers of CSR 3.0 and centralize their strategy around People, Planet and Profit which is in most case also already part of the academia or research centers' mission.

ID number: 026

ISENET dedicated stem cell bank

Aikaterini Ntai 1, Jacopo Turri 3, Alessandra Storaci 2, Miriam Aresi 2, Maria Vittoria Rinaldi 3, Alberto La Spada 1, Simona Baronchelli 3, Monica Cattaneo 3, Andrea De Blasio 1, Pasquale De Blasio 1, Ida Biunno 2,3

1 Integrated Systems Engineering srl, Via Fantoli, 16/15, 20138 Milan, Italy; 2 Institute for Genetic and Biomedical Research, Via Fantoli, 16/15, 20138 Milan, Italy, 3 IRCCS Multimedica, Via Fantoli 16/15, 20138 Milan, Italy

There is a growing demand for human stem cell lines of varying origin (eg embryonic, induced pluripotent and somatic) and grades (eg research and clinical) in response to the expectation that the scientific knowledge gained from their use, will radically improve our ability to understand and treat diseases, enhance drug development, and generate new clinical therapies. A Stem Cell Biobank effort is to harmonize important parameters starting from the technology and conditions used for their isolation, derivation and culturing, long term viability and stability. These parameters may vary according to the stem cell source and the type of technology used for their establishment. Isenet (www.isenet.it) by participating in a number of European and National Research Projects and by joining stem cell biology academic laboratories, has established a cell bank, in Milano-Italy, in order to cryopreserve human and animal stem cells. Isenet applies "high quality management system" to assure long-term cell storage and preservation of the cells original features. Isenet ultimate goal is to make available, to the scientific community and in a timely manner, high quality stem cells able to answer specific experimental questions regarding their biology and safety, regardless of the original source.

ID number: 027

Process cost analysis - a tool for planning and financing of Biobank projects

Elfriede Elstner, Natalie Giese, Ralf J. Rieker, Arndt Hartmann, Tilman T. Rau

CCC Biobank, Institute of Pathology, Friedrich Alexander Universität Erlangen-Nürnberg, CCC Erlangen-EMN Nuremberg

Aims: Sustainable financing of Biobanks is still an unsolved problem. Several proposals for financing have been made, e.g. all-inclusive calculations for political claims, classical full costing methods, stock exchange methods addressing different values of samples, etc.. We want to present process cost analysis as an easy tool adjustable to local requirements, which outlines project immanent personal and material costs.

Methods: Due to the ongoing accreditation process of the biobank of the Comprehensive Cancer Center Erlangen - Eurpean Metropolitan region Nuremberg (CCC-EMN), processes were well defined and fixed in standard operation procedures (SOPs). These defined processes served as backbone for calculations of time consumption for different biobank-workers like technicians, documentation officers, medical doctors etc. Additional material costs were assessed. To enable easy calculation for upcoming projects we defined two reference points, once-only costs per project or costs per treated sample.

Results: As expected high-tech services like immunohistochemistries or nucleic acid extractions are the most expensive regarding materials. However, there are also techniques, which are cost-intensive due to hands on time like tissue microarray generation. Hidden extras sometimes forgotten during project generation are working times in archives and storage facilities, assembling of collectives and sorting it back or special documentations for study purposes. Biobanking could benefit from process cost analysis along its project management. If the biobank offers services to the collaborating researchers two parameters could easily be assessed, the material costs and the factor time in which the personal might be engaged.

Conclusion: In general process cost analysis gives a good overview about time consumption and costs for biobank projects, which might be useful for funding applications and time schedules. However, it doesn't consider the added value to biomaterials treated under qualitiy guidelines or addressed with additional information. Process cost analysis shows the minimum costs, which should be pursued from the collaboration partner as a compensation. As an economic model, it might be suitable for non-profit biobanking in academic hospital integrated biobanks, but still needs institutional basic fundings for maintenance and collecting of biomaterials, or not project-based workloads e.g. for quality assurance. Hence Biobank funding still is based on multiple columns, but one could be process cost analysis.

ID number: 031

Quality Management in Biobanking

Neumann M, Geiger J, Lohmueller R, Boetsch A, Jahns R

Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw), Straubmühlweg 2a - A9, 97078 Würzburg, Germany

The Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw) is one of five German National Biobanks and has implemented a comprehensive Quality Management System (QMS) based on OECD Guidelines, ISBER Recommendations, and International standards such as SPREC. The QMS is the basis for all current and future organizational and technical procedures and addresses process safety, document management, environmental protection, crisis management and action planning.
A cornerstone of process safety is the thorough analysis and documentation of all processes within the ibdw. The aim of this work is to gain control on the processes, to make the process transparent to both internal and external observers, and to be able to eventually optimize the processes. This is accomplished by workshops utilizing the Event-driven Process Chain (EPC) modeling method. The result of this systematic process modeling and reflection is a process map as well as the corresponding rules and materials needed at each critical control point are the foundation for the resulting Standard Operating Procedures (SOP).
This systematic approach is complemented by the use of a document management system which encompasses functionalities for high-quality document handling, such as versioning, approval workflow, and full audit trail.
Protecting the ibdw environment is done by means of access control for ibdw locations (offices, laboratories, storage), intrusion detection system, building control, temperature monitoring and alerting, emergency power support, UPS support, and facilities for remote technical service.
Crisis management and action planning are precautions taken to prevent samples and their associated data from being harmed, destroyed, or lost.

ID number: 035

The Fluidigm® SNPtrace panel sensitively identifies gender contamination, sample degradation and low quality samples.

Marie M. Lee1 and Nico Tuason1*

1Fluidigm Corporation, 7000 Shoreline Court, Suite 100, South San Francisco, CA

The lack of standardization and high quality samples from biorepositories can impede the progress of disease and basic research exposing a need for quality control and assessment methods to determine sample utility. The Fluidigm biobanking panel facilitates quality control and assurance studies on DNA samples. The panel consists of 96 assays selected by Dr. Andrew Brooks of Rutgers University to provide critical information regarding sample identity, integrity and quality. In this set of experiments, we will determine the limit of detection for gender contamination, assess DNA degradation detection and evaluate the performance of low quality samples assayed by the Fluidigm biobanking panel on the 96.96 genotyping integrated fluidic circuit in the BioMark™ HD system.

ID number: 037

Israeli Tumor Biorepository Networking - Roadblocks & Segways

Ayelet Itzhaki-Alfia 1, Yehudit Cohen 2, Ronit Almog 3, Karen Meir 4

1 Institutional Biorepository, Department of Pathology, Division of Research & Development, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel
2 Institutional Tissue Banks, Chaim Sheba Medical Center, Ramat-Gan and Tel Aviv University, Tel-Aviv, Israel
3 Hospital integrated biobank, Rambam Health Care Campus, Haifa, Israel
4 Department of Pathology, Hadassah - Hebrew University Medical Center, Jerusalem, Israel

Background:In 2012 Israel's Ministry of Health decided to form a national biorepository network, contributing approximately $10M over 5 years. The network will serve as a platform for medical research, providing academia and industry access to biological samples, to enable researchers to develop new diagnostic methods for personalized medicine for the benefit of cancer patients. Four central and six peripheral medical centers won bids to form the network. All collecting centers will be required to meet yearly collection quotas to maintain funding.
Roadblocks:Slow progress in establishing the network has been due to:

1. Delayed government funding
2. Lack of a uniform informed consent form
3. Disagreement among the partners in seeking to ensure:
   Collaboration of surgeons collecting the specimens
   Provision of adequate material to researchers
   Fair distribution of biosamples
   Appointment of a general manager
   An agreed-upon location for the administration

In process:Four independent, institutional biorepositories have been established, each with a local IRB approval. Efforts have been made by the managers to set up network regulations and SOPs. All institutional biorepositories are funded by research grants and donations. So far we have preserved biosamples from ~6000 donors in all branches, and provided samples for at least 20 projects. A uniform biobanking-specific informed consent form is in the final stages of approval by Israel's Ministry of Health.
Summary:This biorepository network is a critical platform for cancer research in Israel. We hope to receive governmental funding in order to establish the national network by the end of 2013.

ID number: 040

Development of a cost recovery tool at Biobank Graz

Gabriele Granitz, Berthold Huppertz, Karine Sargsyan

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The infrastructure of a biobank is quite expensive; high costs are incurred by automated storage systems for different kinds of samples and naturally for personnel. The difficulty is that such expenses are not easily borne by research funding bodies since they mostly fund costs directly related to basic or applied research. This was the reason why a cost recovery tool for sample collection and sample distribution was developed, which allows calculation of direct costs for projects.

Methods: We aimed to develop a practical and efficient tool for the calculation of our projects. Only real expenses were considered including infrastructure and expenditure of time. An important aspect during development was to plan for which services or products costs can be defined, including costs only for sample handling, only for storage, only for using consumables or altogether.

Results: The result of our considerations is a flexible instrument in MS Excel which can be used to calculate costs for:
1. Sample collection taking into account (a) infrastructure investments, (b) personnel for sample handling, (c) personnel for storage, and (d) consumables for every kind of sample.
2. Sample allocation and project handling where working time for each step is taken into account.

Conclusion: With this new cost recovery tool established at Biobank Graz, the respective project managers are able to calculate projects promptly. The tool offers a convenient solution to calculate costs for projects and can easily be integrated into the work flow of the project managers.

ID number: 053

From sample collection to cancer research - perspectives from a prospective cancer biobank

Hilde Langseth and Randi Gislefoss

Cancer Registry of Norway, Institute of Population-based Cancer Research, Department of Research, P.O. box 5313 Majorstuen, N-0304 Oslo, Norway

Background: The Janus Serum Bank was established in 1973 as a prospective cancer biobank, and has since 2004 been fully integrated within the Cancer Registry of Norway. The repository consist of prediagnostic serum samples from 317 000 individuals of whom more than 56 000 have developed cancer at a later point in life. The research activity is high and a large number of papers have been published based on samples from Janus. The present abstract communicate the management of a biorepository with more than 40 years of operation.

Biobank management: To optimize the use of the archived material in cancer research, all research protocols to Janus are evaluated by an independent scientific board. Priorities are made to ensure that future research possibilities are not impaired, including stringent assessment to minimize sample consumption. Most studies in Janus are using a nested case-control design. We have developed and implemented standard procedures for the selection of cases and controls, matching, data handling and long-term storage of research files. Laboratory analyses are always carried out blinded and a code-keeping system ensure a high degree of confidentiality: participant's identities are never disclosed. In the long run, results from laboratory analysis will be conserved as data for re-use in future research projects.

Remarks and future perspectives: A valuable approach in future biobank-based research is to perform high-throughput analyses on a significant number of biospecimens. This will generate large amounts of data that, in combination with clinical patient data, can be utilized in a large number of studies.

ID number: 055

Incorporation of SPREC code into Bio-e-Bank (Laboratory Information Management System)

Ana Mª Torres, Esperanza Martín, Sonia Camaño, Paloma Mariscal, Bárbara Luna, Fernando Liaño

Biobanco. Hospital Universitario Ramón y Cajal - IRYCIS. Madrid. Spain

Hospital Universitario Ramón y Cajal-IRYCIS Biobank has been certified ISO 9001:2008, after carrying out the process of implementing a quality management system (QMS). This process was provided and performed under the supervision of the Quality Unit of our hospital. We describe our experience in the implementation of the QMS trying to be helpful to others biobanks.

This implementation process is reflected in a program of activities to be performed in an estimated period of one year. It is divided into 3 phases:
1) Organization of Biobank on the QMS.
-Constitution of the Quality Committee
-Designation of the Quality Manager
-Defining the Scope of Certification
-Identification of the processes and stages
-Preparation of Process Map
-Training on ISO 9001:2008
-Elaboration of the organizational structure
-Identification of Operational Procedures
-Definition of documentation structure
-Preparation of Equipment List
2) Preparation of documentation
-Training in flowcharting
-Development of Operational Procedures and adaptation of associated documentation
-Identification of external documentation
-Implementation of the Quality Manual and General Procedures
3) Continual Improvement
-Design and measurement of performance indicators
-Customer satisfaction surveys

Another important aspect is to plan the maintenance of equipment and perform the verifications or calibrations required.

Once everything is working according to the QMS, we proceed to perform the certification, comprising:
- Internal audit of our QMS
- Management review
- External audit of our QMS

ID number: 056

Incorporation of SPREC code into Bio-e-Bank (Laboratory Information Management System)

Bárbara Luna, Paloma Mariscal, Sonia Camaño, Ana Mª Torres, Fernando Liaño

Biobanco. Hospital Universitario Ramón y Cajal - IRYCIS. Madrid. Spain

Although there are free software tools available for the exploitation of SPREC, we have chosen to incorporate it into our preexisting Laboratory Information Management System (Bio-e-Bank, VITROSOFT). We created a questionnaire that includes only the types of samples and preanalytical conditions that apply to us among all the proposed options for SPREC code. It is possible to easily incorporate new options for answers in case of appearing a condition that was not initially envisaged.

In our Biobank is not possible to extract preanalytical information from our Laboratory Information Management System so that you can not set the code SPREC directly. Adoption of this standard preanalytical coding system compels the gathering of the required information during the sample collection phase, and to fill in the questionnaire generated in the LIMS all data collected.

The SPREC code populates the same record and is linked to all aliquots of the parent sample and to all other data. Thus, the SPREC can be considered as a new data point attached to the sample and entered as a new parameter into our biorepository database systems.

Adopting SPREC is useful both for internal purposes (such as finding the samples having some given preanalytical features, detect preanalytical phase points potentially for improvement…), and for exchanging the preanalytical information associated to biological samples between Laboratory Information Systems.

This approach will validate and record permanently all sample treatment from primary specimen procurement through simple processing and sample storage, thereby contributing to quality standards.

ID number: 057

Collection of control samples from subjects blood donors generated by Biobank staff

Paloma Mariscal, Bárbara Luna, Ana Mª Torres, Sonia Camaño, Fernando Liaño

Biobanco. Hospital Universitario Ramón y Cajal - IRYCIS. Madrid. Spain

Knowing the importance of control samples for research, the Hospital Universitario Ramón y Cajal-IRYCIS Biobank decided to create a collection of healthy donors in collaboration with the Blood Bank of the same hospital.

The donor recruitment is carried out by biobank staff in subjects that go to the Blood Bank to donate. It is a noninvasive situation as own donation is exploited to obtain samples for Biobank.

In addition to satisfy the criteria set by the Bank to donate blood, to check their health status the Biobank gets a blood sample, which is carried to biochemistry service to analyze. The data resulting from the analysis are recorded in Biobank as information associated with the samples.

Biobank staff enlists donors explaining the procedure and requesting informed consent. Once they are suitable by the Blood Bank, if they have signed the informed consent, nurses draw blood for biobanking during the donation. After donation, a questionnaire is complete to collect anthropometric and demographic data, dietary habits and pathologies of both the donors and their families, among others.

With the aim of increasing the quality, samples are processed and stored in Biobank in less than two hours, recording preanalytical conditions using SPREC code.

All samples and data associated are stored in the Laboratory Information Management System (Bio-e-Bank, VITROSOFT), which complies with the requirements of the Ley Orgánica 15/1999 de 13 de diciembre, de Protección de Datos de Carácter Personal.

ID number: 058

Adjustment of quality management system of biobank to a global certification including all certified services of Hospital Universitario Ramón Y Cajal

Sonia Camaño, Esperanza Martín, Ana Mª Torres, Bárbara Luna, Paloma Mariscal, Fernando Liaño

Biobanco. Hospital Universitario Ramón y Cajal - IRYCIS. Madrid. Spain

Hospital Universitario Ramón y Cajal, like other hospitals in the Community of Madrid (Spain), has certified Services and Units according to the UNE-EN ISO 9001:2008, among which is the Biobank. Following the directions of the Directorate General Patient Care and Quality Directorate General of the Ministry of Health of the Community of Madrid, Community Hospitals with at least two certifications will have to initiate a process of unification of the certifications up to now, on a global certification Hospital.

This global certification required to have a system of quality management common and homogeneous for all Hospital and implies the need to integrate and adapt existing systems so far, to the new designed. This requires, implement common documentation, modify some specific documentation certified service, the sharing of results and data for the preparation of common internal audit reports, perform a Directorate review of the overall quality management system, plan a common external audit and obtaining a Global certificate with subcerticates for every services.

This new system provides a significant reduction in the costs of obtaining certification by reducing considerably the days used in the external audit, aspect of great importance in the current economic situation. Also facilitate in the future, the addition of new Services and Units, with a simple extension of the scope of certification.

ID number: 061

Novartis Biotracker: No Sample Left Behind

Xavier Briand, Craig Isaacson & Bjoern Dallhoef

Novartis Institute for Biomedical Research, Basel, Switzerland

To ensure compliance with all biosamples management regulations and trends for the pharmaceutical industry, IT applications play a pivotal role. The paradigm is to improve the harmonization (introduction of ontologies) and to provide functionalities to be able to track biosamples from more diverse sources. In addition, the ability to integrate with others databases remains a key factor (e.g. ICF status tracking).

This poster will give an overview of the new biotracker which has been developed and deployed by Novartis to manage their biomarker samples for research and clinical activities. Several key functionalities have been incorporated to improve flexibility, to reinforce compliance and to facilitate the chain-of-custody for each sample will be preserved.
For instance:
- The implementation for clinical samples to be electronic flagged to ensure each specimen is aligned with their own IRB/EC outcome from multicentric trials.
- The ability to provide access to contract research organizations to the Novartis biotracker, thus enabling real-time chain-of-custody.

The main challenge faced with implementing such an application as our biotracker in a large "Pharma", Novartis, has been to anticipate future needs. Scientists want to know, in real time, the samples life cycle from it's collection to their lab, even if several partners have been involved.

ID number: 062

Biorepository to BioBanking at Novartis

Craig Isaacson, Xavier Briand, Dmitri Mikhailov**, Georges Imbert* and Bjoern Dahlloef**

Novartis Institute for Biomedical Research, East Hanover, New Jersey
*Novartis Institute for Biomedical Research, Basle, Switzerland **
*Novartis Institute for Biomedical Research, Cambridge, Massachusetts ***

Biorepositories have become a key asset for pharmaceutical companies over the last two decades. These strategic initiatives are providing avenues to answers those questions that arise during drug development, from regulatory agencies to answering why unexpected clinical findings were observed during a trial.

Every large facility worldwide is faced with employing elaborate infrastructure to support the increasing demand with having large relevant sample collections. Increasing sample numbers are required to support the evolution of high-throughput assays for genomics, proteomics and metabolomics. A robust sample tracking application must be employed to track the physical locations of every sample in their custody and ensure the chain-of custody is preserved. The storage conditions for every sample must be monitored and document to ensure sample integrity has not been compromised and where possible automation should be considered. However, most important, patient information must be kept confidential and unassociated with their samples and all samples must be analyzed only to the terms of the informed consent.

In order to evolve further, Novartis has started to expand the scope of their repositories to becoming true biobanks. Knowing the value of tissue derived from animal models to predict efficacy in human disease is limited, Novartis has expanded their facilities to collect disease relevant human samples. This collection will assist the scientists in understanding disease mechanisms and pathways to further escalate and drive discovery and the development of novel therapeutics.

ID number: 064

GERMETHEQUE, a Bio Banking network dedicated to Human Reproduction

Louis Bujan

GERMETHEQUE, Hôtel Dieu St Jacques, 2 rue de Viguerie 31059 Toulouse Cedex 9 , FRANCE

The Germethèque Biological Resources Center is a multi-site Biobank witch was developed in order to facilitate research and technology development in the field of human fertility. The French territory is covered entirely by differents centers.

Biological resources integrated in the Biobank all have a relation with human fertility. We can find gametes, germinal tissues, seminal plasma, DNA, and other biological resources in relation with fertility.

Since 2009, the year of its creation, Germethèque has steadily improved.
In 2010, the Biobank purchased a management software for Biological Resources. Data are entered into the software, and regularly, an inventory of available biological resources is extracted from the software, called the catalog.
The Biobank enrolled in a quality approach with obtaining ISO 9001 certification in accordance with standard NF S 96-900 which is a specific standard for Biobanks.
One of major developments of 2013 concerns the extension of the activity. Indeed, Germethèque intend to extend this network from 5 to 11 French sites during the year 2013.

This approach will allow us to enhance the strengths of the Biobank:

- A multi-site network, so access to diverse and scarce biological resources.
- A level of quality corresponding to a specific standard for Biobanks
- A computerized management of biological resources
- Access to a catalog through the website

The characteristics of the Germethèque Biological Resources Center make an original Biobank with a strong development potential already demonstrated. The user demand has been demonstrated and continues to increase in the field of human fertility.

ID number: 067

Quality management system on a multicenter biobank: challenges and opportunities.

Villena C1,2, Giménez P1, 2, Pozo-Rodríguez F1,3, Gámez AP1,3, Rodriguez-Peralto JL3, Maroto A3, Enguita AB3, Arias EM3, Marrón C3, Meneses JC3, Barberà JA1,4, Molins L4, Ramírez J1,4, Peinado VI1, 4, Esteban A1,5, Jiménez L5, de Olaiz B5, Camarero E5, Aramburu JA5, Casares M5, Sánchez I5, Rosell A1,6, Moya J6, Condom E6, Molina M1, 6, Estany S6, Montserrate DR6, Gea J1,7, Minguella J7, Pijuan L7, Casadevall C1, 7, Pedreny R7, Cortijo J1,8, Guijarro R8, Martorell M8, Juan G1,8, Lluch J1, 8, Peces-Barba G1,9, Fernandez-Arias J9, Escribano M9, Zapatero J9, Muguruza I9, Fernández MJ9, Rodríguez-Nieto MJ1,9, Monsó E1,10, López de Castro P1,10, Martínez C1,10, Fernández MT10, Marín A1,10, Pedrosa E10, García-Nuñez M1,10, Sirvent JJ11, Canalís E1,11, Garcia JF11, Bodí MA1,11, Gallart LL11, Carvajal A2, Torrecilla A2, Perna V2, Gigirey O2, Gómez C2, Sauleda J1, 2, Cosio B1,2, Agusti A1,4 on behalf of Pulmonary Biobank Consortium

1 Centro de Investigación Biomédica en Red de Enfermedades Respiratorias (CIBERES), Instituto de Salud Carlos III, Spain.
2 Hospital Universitario Son Espases, Mallorca, Spain
3 Hospital Universitario Doce de Octubre, Madrid, Spain
4 Hospital Clinic, Barcelona, Spain
5 Hospital Universitario de Getafe, Madrid, Spain
6 Hospital Universitario de Bellvitge, Barcelona, Spain
7 Hospital Universitario del Mar-IMIM, Barcelona, Spain
8 Consorcio Hospital General Universitario, Valencia, Spain
9 Fundación Jiménez Díaz Capio, Madrid, Spain
10 Hospital Universitario Germans Trias i Pujol, Badalona, Spain
11 Hospital Universitario Joan XXIII, Tarragona, Spain

Pulmonary Biobank Consortium CIBERES (PBP) is a non-profit network of 10 hospital biorepositories to promote biomedical research by collecting and distribution samples to national and international researchers, essentially lung tissue and blood derivates. Focusing on research requirements, the Quality Management System of PBP has been established according to International Organization for Standardization, and since January 2012, all its activity has been certified according ISO 9001:2008.

Mainly the lung tissue samples are collected from lung cancer surgeries, lung explants from transplants and organ healthy donors. In all cases, samples are obtained and processed following consensus standard operation protocols (SOP) and monitoring the cold ischemia time (CIT). Several methods have been validated to control and register the CIT according to the local hospital casuistry. The formation of the personnel involved and the adaptation of the current technology available to accomplish this objective has been the most important challenge.

Since 2012 has been registered the CIT in 84% of the surgeries (n=384), being less of 30 minutes in 87% of cases. In addition, the warm ischemia time is also controlled in some hospitals. All sample information is registered on a common database with relevant respiratory clinical data and CT scans. This strategy allows a real-time coordinated management of the activity, biospecimen research development and responding effectively to the researcher requests.

Working under a quality management system allows a real standardization of the procedures performed in several hospitals. And a well-established infrastructure with a robust management system allows facing complex challenges.

ID number: 074

Effective Governance Tools for a Functional Biorepository Service Provider Partnership

Kai-Alexander Wiemer

BioStorage Technologies, Im Leuschnerpark 1B, 64347 Griesheim Germany

Objective: The objective of this presentation is to provide best practices for designing and implementing a governance process and tools utilizing a functional service provider model that support internal decision making and enable the success of an outsourced partnership to be measured, evaluated and modified based on outcomes.

Summary: At the core of implementing an effective strategic partnership is the establishment of an appropriate governance structure with an experienced team, supportive processes and smart tools, which enable the success of the relationship to be measured. This presentation, which will use real-world case studies, will illustrate good practices for design, implementation and evaluation of assessing governance of outsourced partnerships. The presenter will provide in-depth information on smart tool methodologies, data analysis tools and reporting dashboards that can assist in the decision making processes and outcomes will be presented as a model for future governance projects within the organization.

Key Takeaways: Attendees of this presentation will receive in-depth information on a biopharmaceutical company and functional service provider case study model and will learn:

- Best practices for establishing governance processes and tools, including project charters that support decision-making processes and favorably guide project outcomes.
- How to evaluate and design governance processes that support performance targets and enable monitoring of performance trends over the course of a partnership.
- How to leverage planning tools to effectively manage and communicate the status of contracted deliverables and enable fast decision making.

ID number: 075

Understanding the Need for Business Continuity and Disaster Recovery Planning for Research Samples

Kai-Alexander Wiemer

BioStorage Technologies, Im Leuschnerpark 1B, 64347 Griesheim Germany

Purpose: Despite best efforts and precautions, disasters of all kind can eventually strike an organization, unanticipated and unannounced. Natural disasters like hurricanes and earthquakes and other events such as building fires and equipment failure can threaten the very existence of a research organization. To mitigate these risks, well prepared organizations establish plans, procedures and protocols to alleviate the effects any form of disaster may have on their sample inventories and research operations. As drug discovery and development become increasingly reliant on properly preserved samples, protecting these materials and providing for their continuity and recovery has become an even greater priority.

Methods: Using real-world case studies (i.e. Super Storm Sandy), the speaker will detail the various components of a business continuity and disaster recovery plan for research samples. Specific topics that will be addressed include: readiness assessment, action plan development, crisis management and disaster recovery.

Results: A comprehensive business continuity and disaster recovery plan begins with evaluating how samples and corresponding equipment are currently managed, transported, tracked and stored via internal and external resources. From that point, it must be decided what are the most efficient and effective redundancies that can be put in place. With these redundancies employed, one can mitigate the exposure and cost of lost or degraded research samples.

Conclusion: An organization's business continuity and disaster recovery plan should be discussed early in the planning stage and developed in a way that it runs on autopilot, minimizing the need for decision-making and strategic planning activities during these critical times.

ID number: 078

Implementation Of A Quality Assurance Policy In A Biobank Network: Andalusian Public Health System Biobank (BB SSPA)

Verónica Valdivieso Gómez, Rocío Aguilar Quesada, Tatiana Díaz Córdoba, Ángela Hens Pérez, Mª Isabel García Sánchez, Mª Inés Aroca Siendones, Carmen Ventura Gómez, Virginia Ruíz de Azúa García, Mª José Robles Frías, Rodrigo López Castro, Gracia Mª García Gemar, Mª Luisa Hortas Nieto, Ana Mª Sánchez López, Ana Isabel Sáez Castillo, Blanca Miranda Serrano

Biobanco del Sistema Sanitario Público de Andalucía. CIBM, Avda. del Conocimiento s/n, 18100 Armilla, Granada.

The new technological advances in research have resulted in the need of quality biological material. This need, promotes the development of a model of biological resources in which the biobanks are, in addition to samples banks, service providers. On occasions, to effectively meet the biobanking requirements, they have to organize into Biobanks in network, structures that establish their sampling protocols, share management experiences, comply with all ethical, legal, and privacy guidelines and generate value added to the BioBank itself and the network as a whole making the service they provide more competitive and better quality. The quality assurance policy that is implanted in these types of organizations in network, must take into account the grouping of all biological banks and must ensure an exquisite quality service for its users.
The BioBank network in Andalusia is a clear example of a BioBank network (consisting of 26 centres), in which the introduction of a quality assurance policy has been carried out through days of staff awareness training; design and implementation of a quality Commission; search for the users satisfaction. The quality management system is developed in the Commission and is a system based on the management of processes. The identification of the processes, as well as their sequence and interaction, is documented through the process map that is common to all the centres. In addition, the processes are described in documented procedures, general procedures and specific procedures common to all, with minimal differences described in instruction techniques, showing the way to run processes properly, depending on the complexity of the process or of the methods used. All of this is being achieved thanks to the high involvement of staff and a good dissemination system established between centres.

ID number: 079

Suggesting a ticketing system for biobank service and quality assurance

Matthias Quade 1,2 and Sara Y. Nussbeck 2,3

1 German Center for Cardiovascular Research, Göttingen, Germany
2 Department of Medical Informatics, University Medical Center Göttingen, Göttingen, Germany
3 UMG Biobank, Göttingen, Germany

The purpose of biobanks is the provision of high-quality and well documented annotated biomaterial to requesting persons and institutions. In the last few years, the processing of biomaterial and the storage workflows in biobanks have been given increased attention and by now are well supported through IT. Much less attention has been given to the processes of requests for biomaterial and the subsequent serving of them. In fact, IT-support in this area of biobank-workflows is mainly limited to generating shipping lists. Thus, important aspects in sales and distribution are neglected by IT so far: Questions regarding customer relationship management, involved staff, billing, quality assurance and statistics are not being addressed.

Ticketing or issue-tracking-systems (ITS) are used for such purposes in many commercial areas. ITS allow the tracking of requests received via telephone or email by means of standardized tickets which can be created, confirmed, categorised, prioritised, updated, or retrieved throughout the whole process. This provides the involved personnel on each administrative level with a detailed view of the process; from the standard operating procedures to documentation (technical assistant) and on to business intelligence (biobank manager), who is provided with significant statistics.
We assume that using ITS in biobanks would have many advantages and could fundamentally support all processes in sales and distribution.

Regarding the implementation of an ITS in a biobank, we have to collect requirements of key stakeholders through a standardised investigation. Furthermore, options for the interface between the ITS and existing biobank management software must be analysed.

ID number: 085

Analysis of semantic resources in biobank databases. Approaches to harmonization of standards.

Abril-Tormo C.(1,3), Sifres-Servà L. (1,3), Ahicart-Momplet A. (1,3), Martínez-Santamaría J. (1,3), López-Guerrero JA. (2,3)

(1) Biobanco FISABIO- CSISP (2) Fundación Instituto Valenciano de Oncología (3) Red Valenciana de Biobancos

Nowadays, biobanks have a large number of biological samples made available to the scientific community. Most of these samples have associated information of great interest that would have their impact in the results of the studies. However, in the real context most of this information is not easily accessible or available in a friendly format. SNOMED Clinical Terms is the most comprehensive, multilingual clinical healthcare terminology in the world and could be used to represent clinically relevant information consistently, reliably and comprehensively as an integral part of Information Management Systems (IMS) of biobanks.
The aim of this study was to analyze the IMS of biobanks integrating the Spanish Network of Biobanks (SNBB) in order to infer the best strategy for an effective semantic harmonization of the different IMS that allows integration in a common and centralized database. To reach this proposes, we first developed a questionnaire in order to know how, which and in which format biobanks are reporting the information associated to the samples. Secondly, we proposed an internal analysis of each of the different IMS with regard the Biospecimen Reporting for Improved Study Quality (BRISQ) variables.
The analysis of these surveys showed that all Biobanks have information regarding diagnosis and topography, but only in few cases this information is coded, the ICD-9, ICD-10 and SNOMED-CT being the systems used for codification. A high proportion of biobanks still use a self-coding system or free-text. Regarding implementation of BRISQ elements within the different IMS the framework is very heterogeneous.
In conclusion, our analysis confirms the need to establish a strategy to implement standards for harmonization articulated through the definition of SNOMED-CT based archetypes to allow semantic interoperability between IMS of the SNBB.

ID number: 091

The Belgian Virtual Tumourbank (BVT) Project: Data Quality Control

Araceli Diez-Fraile1, Eva Van der Stock1, Karen Vos1, Mia Slabbaert1, Liesbet Van Eycken1, Vincent Grégoire2 on behalf of the Steering Committee of the Belgian Virtual Tumourbank

1 Belgian Cancer Registry, Koningsstraat 215 bus 7, 1210 Brussels, Belgium
2 Radiation Oncology Dept & Center for Molecular Imaging and Radiotherapy and Oncology (MIRO), Université Catholique de Louvain, St-Luc University Hospital, 10 Ave Hippocrate, 1200 Brussels, Belgium

Background: The BVT is a tissue-banking web application for biospecimen annotation and localization among eleven Belgian university hospitals. BVT data provided to scientists working in translational research in oncology, undergo extensive quality control analysis to ensure that they meet stringent accuracy standards.

Methods: 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. Inaccurate or missing data are not registered in the BVT database and generate an error alert message to the local biobank partner where the information originated from. Next, successfully uploaded registrations in the central database of the BVT are checked manually for inconsistencies between different fields by BVT experienced data analysts. For each inconsistency or unlikelihood, the suspect data are sent back to the local biobank for verification. After these initial controls, the data is published in the BVT catalogue and made available for researchers in a coded form. When biospecimens are requested, corresponding data is further contrasted with the BCR cancer registry database, that contains overlapping information. In a pilot study, the renal tumours collected during the year 2010 and registered in the BVT were contrasted with the BCR cancer registry database.

Results and conclusions: Results on data quality control for this pilot study will be shown. By following a strict quality control of the data on biospecimens the usage of incorrect data, that could crucially impact the research output, can be avoided.

ID number: 095

ONCO-i2b2 system: clinical, genetic and biospecimens data integration for traslational research in oncology

Daniele Segagni MSc1; Valentina Tibollo MSc1,2; Arianna Dagliati MSc2; Alberto Zambello MD1; Riccardo Bellazzi PhD1,2

1) IRCCS Fondazione Salvatore Maugeri, Via Salvatore Maugeri 10, 27100, Pavia; 2) University of Pavia, Dipartimento di Ingegneria Industriale e dell'Informazione, Via Ferrata 1, 27100, Pavia

The University of Pavia and the IRCCS Fondazione Salvatore Maugeri of Pavia (FSM), thanks to a grant of the Lombardia region, has started in 2010 an IT initiative to support clinical research in oncology called ONCO-i2b2.
This project aims to support translational research in oncology and exploits the software solutions implemented by the Informatics for Integrating Biology and the Bedside (i2b2) research centre, an initiative funded by the NIH Roadmap National Centres for Biomedical Computing and headed by Partners HealthCare Center in Boston.
The ONCO-i2b2 software is designed to integrate the i2b2 infrastructure with the FSM hospital information system and with a cancer biobank that manages both plasma and cancer samples, taken with the informed consent of healthy individuals and oncologic patients.
The developed infrastructure, provides a web-based access to all the electronic medical records of cancer patients and allow researchers querying and analyzing the vast amount of information coming from the clinical practice.
Up to the present days, the i2b2 instance contains data of 28.838 patients (923 of them have at least one biological sample in the cancer biobank), 142.464 visits and 2.341.771 medical observations.
Recently we empowered the system implemented to far with a web-service that allows communication between i2b2 and the a NoSQL database capable of storing the vast amount of data derived from Next Generation Sequencing (NGS) experiments. Relying on such module, we will develop a set of ONCO-i2b2 dedicated plug-in to perform further relevant analysis, based on patient's genotype data, too.

ID number: 097

Managing The Secure Transport Of Cryostorage Tanks

*Müller, T. *, Schmidt, T. **, Schön, U. **, v. Walcke-Wulffen, V. **

** BioKryo GmbH, Industriestr. 5, Sulzbach, 66280, Germany*
*** Fraunhofer IBMT, Ensheimer Str. 48, St. Ingbert, 66386, Germany*

BACKGROUND: The safe transport of entire cryopreserved sample collections is logistically and technologically challenging.
For this purpose, we evaluate the relocation of entire cryostorage tanks containing cryopreserved sample collections. The samples were stored in the gas phase of liquid nitrogen within the tanks and were shipped using improved state-of-the-art transport systems and surveillance technology. Our intention was, to establish a secure relocation system of entire cryostorage tanks containing cryopreserved sample collections.

METHODS: To evaluate the shipment of entire cryopreserved sample collections we redesigned the whole transport process. Technologically optimized cryostorage vessels were equipped with sensors recording the temperature within the vessels and the vibrations affecting the tanks.
In practice, modified cryostorage tanks with air cushion systems for transport and vacuum isolation stabilization systems were equipped with control devices to measure and log the temperature and the vibrations.

RESULTS: Analysis of the temperatures appearing during the transport indicate, that the samples were constantly stored below -150°C within the gas phase of liquid nitrogen, which is clearly in the range of save cryostorage temperatures.
Analyses of the vibrations during the transport indicate that there was no significant external impact on the samples. Thus adverse effects on the cryopreserved samples induced by vibrations can be almost certainly excluded.

SUMMARY: The relocation system of whole cryostorage tanks established by the BioKryo GmbH and the Fraunhofer IBMT is an optimal way to guarantee a secure transport of cryopreserved samples including closed cooling chain and minimized external impacts.

ID number: 098

The Northern Ireland Biobank: the story so far.

Christine Sterrett, Edwina O'Doherty, Stephen McQuaid, Jacqueline James, NI Biobank.

Northern Ireland Biobank, Molecular Pathology Programme, CCRCB, Queen's University Belfast

Access to high quality human bio-samples is a pre-requisite for the discovery and development of novel approaches to cancer prediction, treatment and response. Biobanking has subsequently emerged as a mechanism for the standardised collection of quality assured samples for use in basic and clinical research studies.
The Northern Ireland Biobank (NIB) was established as a joint initiative between Queen's University Belfast (QUB) and Belfast Health and Social Care Trust (BHSCT) to support local cancer research. The NIB was awarded full ethical approval in August 2011 for the prospective collection of tumour and non-tumour control tissues and match blood samples, from consented patients undergoing cancer treatment. Since collection commenced in November 2011, the NIB have consented 263 patients undergoing surgery for colorectal, breast, prostate, gynae and lung cancers in BHSCT. From these cases, 409 fresh tumour and non-tumour control samples, 865 formalin fixed, paraffin embedded tissue blocks and 1136 blood samples have been collected. Sample collection, processing, storage and distribution is governed by a rigorous set of Standard Operating Procedures based on best practice guidelines and/or best evidence available to ensure maximum sample quality. Additionally, researchers also have access to linked clinical and pathological data from consented cases via the NIB's secure information management system.
The NIB is the first of its kind in Northern Ireland, offering a unique collection of high quality tissues and associated bio-samples to underpin local cancer research. Such a collection is vital to deliver on the promise of stratified medicine for cancer patients in Northern Ireland.

ID number: 103

Providing Human Diagnostic Tissue for Research - Experiences with an Administrative Quality Assurance System

Bettina Casati and Roger Bjugn

Bettina Casati, Department of Pathology, Akershus University Hospital, 1478 Lørenskog, Norway; Roger Bjugn, Department of Research Administration and Biobanking, Oslo University Hospital, 0407 Oslo, Norway

Introduction: In July 2009, a new law on medical research was enacted in Norway. The act requires organizations to establish a quality assurance (QA) system for research. Being a provider of diagnostic tissue to research projects, the Department of Pathology at Akershus University Hospital accordingly wanted to establish a QA-system for this.

Process: The Deming/Shewhart cycle ("Plan-Do-Study-Act") was used as a model for the work. Tasks for a biobank coordinator and a research committee was first defined, and then formally approved by the Head of Department. All applications for tissue have since September 2010 been evaluated by two formal criteria:
- Does the project have all necessary approvals?
- Can tissue be provided without compromising current and/or future diagnostic work?

Experiences: From September 2010 to December 2012, the department received 17 applications, whereby five with insufficient documentation. In six other cases, significant errors regarding institutions/participants/material to be included in the studies and participants' rights were found. None of the study protocols described the management of possible diagnostic discrepancies. Following an evaluation in March 2011, the Department now requires all recipients to sign a Material Transfer Agreement with a clause on feedback of results on findings of possible clinical significance (1). One formal complaint was filed with a regional ethics committee, but the department's views were upheld.

Discussion: The QA-system has caused some conflicts with researchers as they oppose being "controlled". Despite this, we believe the system has increased the quality of the department's routines and also provided researchers with valuable feedback.

References
1. Bjugn R, Casati B. J Clin Pathol 2012;65:1043-4.

ID number: 104

Newborn Screening Dried Blood Spots and Biobanking

Diaz, T.; Martín, I.; Mayorga, L.

Biobanco Hospital Regional universitario de Málaga. Plaza del Hospital civil s/n,Pabellón 5, sotáno.29009 Málaga, SPAIN

The Hospital Regional Universitario de Malaga (HRUM) is a referent center carrying out early diagnosis of metabolic disorders for the whole Eastern Andalusia, Spain. This means that about 40000 samples are analysed per year. The HRUM biobank has been integrating this welfare sample collection given to the enormous scientific and clinical interest and to fill the legal gap for storage and use of samples for research.

After several conversations, the signing of the collaboration agreement between the sample collection manager and the scientific director of the biobank took place. This document details precisely the terms of use of the samples and the commitment and responsibilities for both parties.
Then, we request to the local Ethics committee for approval of the sample incorporation into the biobank. This approval was achieved by means of the presentation of a report which details the importance of the samples and the advantages of their incorporation to the biobank.
After that, when samples are requested for use in research, the biobank has to perform different quality controls, that include DNA tests.

Samples from the newborn screening are, besides it's diagnostic use, a valuable tool for research. Numerous epidemiological studies focused on epigenetics are demanding this type of sample due to its non-slanted nature. Besides, they are used for the validation of new screening diagnostic tests for the detection and prevention of severe diseases, which need a large population size. The storage of these samples in institutional biobanks, after their welfare use, would ensure total compliance of the current laws. This scenario would generate trust from society for the integrity and ethics of research. The Hospital Regional Universitario de Malaga biobank, under the BBSSPA framework has this peculiar collection integrated in its facilities favouring greatly the accessibility of these samples for the scientific community as it strictly maintains a compromise to protect the donors rights.

ID number: 105

Basque Biobank in the way to become a Hospital integrated biobank

Amaia Del Villar(1), Oihana Belar (1), Leire Sanchez(1), Silvia Fernandez(1), Maribel Gomez(2) , Raquel Coya(3), Clara Rodríguez(4), Edurne Arrieta(5), Kerman Zorroza(6), Miren Carrera(7), Ainara Egia(6), Maialen Martin(2), Gontzal Yañez(8), Ikerne Vicente(5), Jennifer Mediavilla(5), Laura Marín(3), Roberto Bilbao(1)

(1)Basque Biobank for Research - O+EHUN
Plaza Asua, 1. 48150 Sondika. Bizkaia. Spain, (2) Donostia Universitary Hospital, (3) Cruces Universitary Hospital, (4) Basque Centre for Transfusions and Human Tissues, (5) Araba Universitary Hospital, (6) Basurto Universitary Hospital, (7) Onkologikoa, (8) Galdakao Hospital

The Basque Biobank forms a network of 8 biorepositories distributed in the main hospitals of the Public Health System of the Basque Country at the north of Spain. It can be classified as a disease-oriented and population based biobank with more than half million samples organized in 372 collections. The operation of the Basque Biobank takes place under a strict quality management and bio-safety plan that includes optimal conditions for the transportation of biological material and procedures to guarantee traceability of samples and data, among other precautions.

The number of sample requests and sample transfer is increasing every year, reaching approximately a turnover of the 24% of its production. Nevertheless, to obtain the necessary sustainability, the Basque Biobank has made a firm commitment to R&D by leading 2 projects to increase the added value of the sample collections deposited in the biobank: 1)BIOPOOL project, to enable biobanks to build a network that links collections of histological digital images and associated information, and 2)BIGBANK, in which a system of big data sharing and intelligent search on medical information in clinical records will be developed.

The Basque Biobank is also working on 3 strategies aiming to guarantee the sustainability of the Biobank:

- Introduction of new services: sample management for clinical trials and validation activities of new medical devices.
- R&D activities to give added value to samples
- Transformation into a hospital integrated biobank: turning the biobank into a structural component of a healthcare system that will include it in its funding

ID number: 106

CryoStem: establishment of a national thematic collection of biological samples pre- and post-Allogeneic Hematologic Stem Cell Transplantation for the study of Graft-versus-Host Disease

Boris Calmels, Claire Fontenille, and Régis Peffault de Latour

CryoStem consortium
Societe Française de Greffe de Moelle
Service d'Hématologie - Pavillon Marcel Bérard
Centre Hospitalier Lyon Sud
165, Chemin du Grand Revoyet
69495 Pierre-Bénite

Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) is the only curative treatment for many patients with hematologic disease. Unfortunately, the transplanted immune system can reacts against the patient, inducing Graft-versus-Host Disease (GvHD). GvHD is the leading cause of treatment related mortality and morbidity following HSCT, and is expected to increase in the forthcoming years. Pathophysiology and long-term determinants of GvHD are still largely unknown.
CryoStem brings together 24 French HSCT Units and 18 Biological Resources Centers that contribute to a networked, prospective and standardized HSCT samples collection with concomitant extensive clinical data. CryoStem has been selected and funded to the extent of 5,5 millions € by the French Government's "Investissements d'Avenir" program.
Patients sampling is scheduled before and after HSCT, depending on the occurrence or not of acute and/or chronic GvHD. Three types of pre-analytical products are processed and stored, according to standardized techniques: viable cells in DMSO, dried cell pellets and plasma. Samples and clinical data are anonymized and centralized in CryoStem-dedicated web-based database application.
The first center is including patients since July 2012, and the others will be progressively opened until the end of 2013. Currently, more than four hundred patients and about two hundred related donors have been included within twenty centers. An ISO9001 certification of the network is in progress.
CryoStem is a crucial step toward progress in GvHD research: it will allow collaborative studies between leading French and international research organizations and foster technology transfer with potential industrial players.

ID number: 107

Starting Up And Operating Of The IdiPAZ Biobank: Our Child Has Gotten Older

Mónica Barriuso-Iglesias (1), Ana Torrecilla Rodriguez (1), Elisabeth Moreno Lorenzo (1), and Fco. Javier Alves Ferreira (1,2).

(1) IdiPAZ Biobank. IdiPAZ Institute for Health Research of La Paz University Hospital. Maternity Hospital,1st floor. (2) Department of Pathology. Paseo de la Castellana nº 261, 28046, Madrid. Spain. e-mail: biobanco.hulp@salud.madrid.org

The IdiPAZ Biobank was established in October 2009 and began its scientific work in May 2010. The current Biobank stems from the La Paz Hospital´s Tumour Bank, launched in 2000.

At present, the organizational structure is based on the idea of a network-designed biobank: being a unique entity, made up of researcher groups and hospital departments with a centralized repository.

The aim has changed since 2000, while at the beginning it was meant to acquire neoplastic and non-neoplastic material taken from malignancies (FFPE and frozen tissue) found in different organs, its current aim is to promote the collection of qualitatively varied sample sets (all kinds of human biological samples), together with related data.

The IdiPAZ Biobank has a double-collection strategy: a) Project-driven collections with comprehensive related data, and b) Basic collections for already un-known retrospective projects where basic related data would be complemented, if it is necessary for the project. The Biobank currently handles 13 collections: around 22.000 samples.

The old tumour bank took part in 58 research projects during 2000-2009, whereas during the 2010-2012 period has been involved in 49 research projects, with 84 sample request attended, and the average impact factor of the 18 supported published projects was around 6.5. In 2013, so far we have taken part in 14 projects, which clearly shows that the annual project rate is steadily increasing.

Due to the increasing demands of the systems biology, the biobanking landscape is changing rapidly. Therefore our biggest challenges for the near future are networking with other biobanks, both academic and industry based, and trying to keep up with new proteomic and genomic technologies.

ID number: 110

Biobankers and Pathologists: MARBiobanc as an example of collaboration

**^M. Torà, *N. Somoza, *X. Palazón, *R. Ruiz, *E. Torres, *M. Mitjà, *G. Navarro, *S. Serrano, *B. Bellosillo*

**IMIM (Hospital del Mar Medical Research Institute). MARBiobanc. Dr. Aiguader 88. 08003 Barcelona. Spain*
^Universitat Autonoma de Barcelona

The main source of tissues for research purposes is the left over material from biopsies once the diagnostic or therapeutic process of patients is finished. These tissues are obtained at the hospital and are traditionally stored at the Pathology Department.
In our research center (IMIM- Hospital del Mar Medical Research Institute, Barcelona) we have designed a Biobank management system that takes into account the singularities of the Pathology Department and those of the Research Institute to optimize research without interfering in their daily routine.
Here we present our model of organization as a good example of well understanding in biobanking. This model consists on one biobank with two facilities and one technical staff responsible for each area (Hospital area and Research Institute area). Each responsible staff should be well integrated in the workflow of each area. In addition they must know all biobank ethical and legal constraints and must be aware of their responsibility in biobanking. Once consolidated this model, the biobank has been working in integrating these two facilities with a common secretary that manages all sample requests and delivery, and integrating common databases, freezers control, a quality management system, etc.

CONCLUSIONS: The establishment of a tight collaboration between Pathologists and Biobankers has resulted in a better control over the use of left-over tissues for research purposes.

ID number: 113

From small departmental biosamples collection to an institutional biorepository

Ayelet Itzhaki-Alfia, Gilad Gitstein, Asaf Aizic, Eli Brazowski, Avi Eisenthal

Institutional Biorepository, Department of Pathology, Division of Research & Development, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel

Background: In 2012, Israel's Ministry of Health decided to form and fund a national biorepository network. Four central and six peripheral medical centers won bids to form the network, the Tel Aviv Sourasky Medical Center (TSMAC) is one of them. In this year, we establish the institutional biorepository.

Implications: The institutional biorepository will serves as a platform for medical research providing access to tissues and biological samples to academia researchers. This networking will enable researchers to develop new diagnostic methods for personalized medicine for the benefit of cancer patients.

Challenges: We have several challenges ahead of us for a successful creation of institutional biorepository. First, in order to achieve maximal prospective collection of biopsies and tumor, a full cooperation from all surgical departments is required. Secondly, the transition from departmental biorepository (or single researcher bio-samples reservoir) to an institutional biorepository, is not trivial and the benefits must be explained to all researchers. Thirdly, assimilation of SOPs and protocols is required, including IRB approval for identifying samples collection from all departments. Finally, we have to map all departmental bio-repositories (contains mainly blood and DNA collections), arrange and organize them with a uniform database.

Summary: The institutional biorepository is an important and necessary platform for cancer research and will support researchers within and outside the hospital.

ID number: 115

A modular, integrated storage solution to facilitate the biobanking workflow

James Craven, Wayne Bennett, Chloe Carter

TTP Labtech Ltd, Melbourn Science Park, Melbourn, Royston, Herts, SG8 6EE, UK

In a large number of academic research centres, small pharmaceutical and biotech companies today, biological sample storage remains a manual process. There is a growing demand within smaller research groups and companies for a low cost, compact, automated secure biobanking solution which can grow as their sample library increases.
The introduction of compact, automated, high density storage modules such as TTP Labtech's comPOUND or arktic significantly alleviates the tedium and potential error associated with storage and retrieval of large sample numbers. These stores are also capable of holding up to three times the number of samples of a standard laboratory sized -80°C freezer
TTP Labtech's proprietary pneumatic transport technology removes the need for moving parts within the cold zone providing robust storage, longevity of each module and minimal down time. The ability to retrieve only the samples required eliminates any potential threat of partial thawing of samples.
This pneumatic transport technology has the additional advantage that it can be adapted to a fully automated transport system, lab2lab. This can connect biobanking modules from remote storage units directly to laboratories for integration with further instrumentation for assay set up and analysis.

ID number: 118

IceTrack: a biobank information management system maximizing flexibility and usability

Davide Capozzi [1,2]; Valentina Tibollo [2]; Germana Ginardi [2]; Veronica Valentini [3]; Francesca Lavatelli [3]; Giampaolo Merlini [3]; Nicola Barbarini [1]; Riccardo Bellazzi [2]

[1] Biomeris srl, Pavia, Italy;
[2] Dipartimento di Ingegneria Industriale e dell'Informazione, Universita' degli Studi di Pavia, Pavia, Italy;
[3] Amyloidosis Research and Treatment Center, IRCCS Policlinico San Matteo, Pavia, Italy;

A biobank is a critical source of information in diagnostics and therapeutics research. The use of dedicated software for biobank management is essential to properly deal with such kind of information. Many tools have been developed for sample management; however, two problems hamper the effective deployment of biobank software systems: research laboratories have a wide variety of needs and researchers are often overwhelmed by their day-by-day activities.
IceTrack has been designed to overcome these issues by maximizing both flexibility and usability. IceTrack is fully configurable: user can easily define models and templates for handling tubes, barcodes, boxes, fridges, middle layers and optional fields. IceTrack is a Rich Internet Application (RIA), which adds to the advantages of a Web-based application, the usability of a desktop application, providing accessible interactive controls such as drag and drop and interactive trees. This allows to significantly improve the user experience, saving time in the most frequent tasks.
The basic functionalities have been implemented with a simple interface: they comprise chain of custody, patient/cohorts management, sample traceability, tube shipment, informed consent management, short term storage, interoperability with printers and barcode readers, quick search and tube labelling. This makes IceTrack fully compliant with ISBER-2012 Best Practices for Repositories. IceTrack has been designed to be easily integrated with the i2b2 data-warehouse system in order to join biobank information to demographics, clinical and molecular research data.
IceTrack was tested at the Amyloidosis Research and Treatment Center (IRCCS San Matteo, Pavia), the Italian reference center for Amyloidosis.

ID number: 120

IT-Solution for Feasible Data Protected Multicentric Clinical Biobanking.

Michael Hackmann 1, Martina Oberländer 1, Josef Ingenerf 2, Heinz Handels 2, Jan Christoph 3, Sebastian Mate 3, Hans-Ulrich Prokosch 3, Jens K. Habermann 1
>on behalf of the North German Tumorbank Colorectal Cancer (ColoNet)<

1 Section for Translational Surgical Oncology and Biobanking, Department of Surgery, University of Lübeck and University Medical Center Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; 2 Institute of Medical Informatics, University of Lübeck, Lübeck, Germany; 3 Institute of Medical Informatics, University of Erlangen-Nürnberg, Erlangen, Germany

Introduction: For data analysis in multicentre clinical biobanking studies, ontological, data protection and technical problems have to be solved. "ColoNet" [1], a biobank network supported by the German Cancer Aid Foundation (Deutsche Krebshilfe e.V.), focuses on colorectal carcinomas and comprises University clinical centres, private oncology practices and non-university medical centres. For those numerous, partially small co-operational partners it is necessary to develop an economically priced and practicable software solution.

Methods and Results: For resolving those ontological problems a minimal data set (MDS) with default vocabulary was developed. All co-operative partners enter their patient-oriented data (using MDS) into their databases and export these patient-centred pseudonymized data in CSV-Format. A coordinator receives these data, consolidates, pseudonymizes again and exports the data into a project-specific configured i2b2-based [2] data warehouse. Certified researchers and the co-operational partners use i2b2 [3] query tool to analyse biobank data by creating SQL-inquiries with drag-and-drop-operations.

Conclusion: The developed MDS enables even small partners to participate in the biobank network "ColoNet". Hands-on experience shows that data quality is high although not every single clinical parameter can be taken into account. Usage of multiple patient-centred pseudonymization ensures patient-data protection and allows researchers to monitor courses of disease.

[1] ColoNet-Projekt, see http://www.northgermantumorbank-crc.de, see also http://www.biobanken.de
[2] Murphy SN, Weber G, Mendis M, Gainer V, et al. Serving the enterprise and beyond with informatics for integrating biology and the bedside (i2b2). J Am Med InformAssoc. 2010; 17(2):124-130.
[3] Prokosch HU, Mate S, Christoph J, Beck A, Köpcke F, Stephan S, Beckmann M, Rau T, Hartmann A, Wullich B, Eckardt KU, Titze S, Habermann J, Ingenerf J, Hackmann M, Bürkle T, Ganslandt T, Breil B. Designing and implementing a biobanking IT framework for multiple

research scenarios. Accepted for MIE 2012 in Pisa.

ID number: 131

Definition of nonconforming products based on standardized quality indicators in the biobank's samples distribution service.

guilar-Quesada R, Valdivieso-Gómez V, Díaz-Córdoba T, Aroca-Siendones I, García-Sánchez MI, Ruiz de Azua-García V, Barbero-Garces MA, Sánchez-López A, Sáez AI, Miranda B.

Biobanco del Sistema Sanitario Público de Andalucía; Avda. del Conocimiento, s/n, 18100-Armilla (Granada)

Biobanks act as a support service for research by providing high-quality biological samples. During samples preparation, the biobanks must use standardized methods to ensure their quality. Through quality indicators it is possible to determine the level of samples integrity and their long-term usefulness; but it is necessary for each type of sample normalize criteria for acceptance and rejection of these final products. This is specially important in a network of biobanks where derivatives production is decentralized.

Based on ISO 9001 quality management system, we defined as many nonconforming products as different types of samples are offered by our Biobank. For this purpose, we established limits in the different quality indicators that implied the rejection of samples. The threshold for each quality indicator had its origin in the functionality of samples, following the international recommendations and disposable literature. Furthermore, it was assumed that in specific cases, nonconforming products could be accepted again following a reclassification process. The newly classified samples could be used for other purposes, or for the same ones if these samples are additionally treated. The previously normalized criteria were summarized in our procedures.

ID number: 134

Management of Forensic Biospecimen in South Africa.

B. Duma

National Health Laboratory Services,National Biobank, Johannesburg, South Africa

The increase in the number of DNA samples collected for Forensic analysis has resulted in cooperation between National Health Laboratory Service(NHLS)National Biobank and the South African Police Services(SAPS) to work together in securing,storage and managemen of 10 million forensic biospecimen within the National Biobank in South Africa.The DNA samples and their data will be stored in the four storey building. The building will have limited access,high security,high technology building. Highly sensitive health and safety equipment installed .This includes smoke detectors,sprinkler system and fire escape routes and backup generator system.DNA is degraded by water, oxygen and unsuitable environmental conditions. This has resulted in the creating of temperature controlled rooms.Personnel will be trained on operations.The samples will be stored for long term until a sample is analysed and a case is closed.They will be yearly DNA quality control schemes to enusre the integrity of the stored DNA biospecimen.SAPS Forensic personnel will be trained on the storage and access of data on the biobank software system.This results in NHLS National Biobank managing all forensic biospecimen and establishing forensic biobank branches in other provinces within South Africa.

ID number: 136

Biobanking for research in surgery: are surgeons in charge for advancing translational research or mere assistants in biomaterial and data preservation?

Thasler WE, Thasler R, Schelcher C, Jauch KWJ

Department of General, Visceral, Transplantation, Vascular and Thoracic Surgery, Ludwig Maximilians University, Marchioninistr. 15, 81377 Munich, Germany

BACKGROUND: High-quality biospecimens of human origin with annotated clinical and procedural data are an important tool for biomedical research, not only to map physiology, pathophysiology and aetiology but also to go beyond in translational research. This has opened a new special field of research known as 'biobanking', which focuses on how to collect, store and provide these specimens and data, and which is substantially supported by national and European funding.

PURPOSE: An overview on biobanking is given, with a closer look on a clinical setting, concerning a necessary distinction from clinical trials and studies as well as a comparison of prospective sample collection with secondary use of archived samples from diagnostics. Based on a summary of possible use and scientific impact of human tissue in research, it is shown how surgical expertise boosts the scientific value of specimens and data. Finally, an assessment of legal and ethical issues especially from a surgical perspective is given, followed by a model of interdisciplinary biobanking within a joint 'centre' that as synergistic structure merges essential input from surgery as well as laboratory medicine, pathology and biometry.

CONCLUSION: Within the domain of biobanking, surgeons have to develop a better awareness of their role within translational research, not only on the level of medical faculties but also as nationally and internationally funded initiatives. Therefore, the authors suggest a platform for biobanking within the German association of surgeons in analogy to the existing special interest group for clinical trials.

ID number: 143

Bimetra biobank: bringing together different initiatives for high quality biobanking

V. T'Joen, M. Praet, S. Bekaert

Bimetra biobank, De Pintelaan 185 -1P8, 9000 Gent (BELGIUM)

In 2012, a central high-quality biobank facility was initiated at the Ghent University Hospital (UZGent), under the coördination of Bimetra, the Clinical Research Center of UZGent and Ghent University (UGent). The Bimetra biobank wants to facilitate and stimulate translational biomedical research by providing a high quality fully monitored preparation/storage facility with elaborate quality management procedures, a clear ethic-legal framework and powerfull datamanagement solutions.

Different biobanks have been centralized in this facility, funded by regional and national initiatives. The tumour biobank of the Pathology Department of UZGent , which was started in 2001, was one of the first biobanks to become integrated into the Bimetra biobank. In the tumour biobank, formalin fixed parafin embedded (FFPE) and snap-frozen tumor material is stored, together with corresponding normal tissue. The tumour biobank is a federal initiative (National Cancer Plan 27 - NKP27) and through the joint Belgian Tumour Biobank network, is connected with the "Virtual Belgian Tumour Biobank".

Our local biobank will also host specific biobanks within predefined disease focus areas in the context of a regional Flemisch initiative, the Center For Medical Innovation (CMI). The final purpose of the CMI is building inter-university/hospital translational research networks for which the collaborative biobank collections are only a means to that end. Bimetra, the Clinical Research Center Gent, is coordinating the focus biobank regarding "hepatotropic pathogens".

The bimetra biobank brings together these initiatives and is building out a strong quality managed and controlled facility for sample storage.

ID number: 150

Ensuring Quality within the EU-FP7 IMPROvED Biobank

Emma Snapes & Louise Kenny

EU-FP7 IMPROvED, University College Cork: INFANT Centre, Department Obs &Gyn, Cork University Maternity Hospital, Wilton, Cork, Ireland

Despite pre-eclampsia being the leading cause of maternal death in Europe, no clinically useful screening test exists and clinicians are unable to offer targeted surveillance or preventative strategies. Consortium members of the EU-FP7 funded project "Personalised medicine for pregnant women: novel metabolomic and proteomic biomarkers to detect pre-eclampsia and improve outcome (IMproved Pregnancy Outcomes by Early Detection)" http://www.fp7-improved.eu will use a personalised medicine approach to identify biomarkers through mapping of blood proteome and metabolome. A review of an existing collection system for a pre-existing pregnancy biobank (SCOPE, http://www.scopestudy.net/) was undertaken along with the establishment of a Quality Team within the consortium. To develop a sensitive, specific and economically viable early pregnancy screening test for pre-eclampsia, a multicentre, phase IIa clinical study will assess and refine novel and innovative prototype tests based on emerging metabolomic and proteomic technologies developed by SMEs within the consortium. With this aim, the study will recruit 5000 nulliparous pregnant women in centres throughout Europe to establish a high calibre biobank, augmented by accurate clinical metadata. To enhance the usefulness and longevity of the IMPROvED biobank, multiple 250 µl aliquots of blood serum, EDTA plasma, whole blood for DNA extraction, urine and hair are being collected for proteomic, metabolomic, genomic and adductomic analyses at four gestational time points. Uniformity of collection across all recruitment sites is paramount to ensure a high calibre biobank. Full details of the Quality Management System will be presented.

ID number: 163

Aragon Biobank: a Biobank to foster traslational research

Izaskun Arenaz Villalba, Ana Buesa Palacios, Dámaris Tamayo Alonso, Diego Serrano-Gómez.

Biobanco de Aragón. Instituto Aragonés de Ciencias de la Salud. IIS Aragon. Avda San Juan Bosco, 13, planta 1ª. Zaragoza.

Introduction: Actual biomedical research demands enormous series of samples and data to perform multidisciplinary and multicenter studies that allow the development of early diagnosis kits, drug discovery or advances in personalized medicine.
Biobanks are supposed to respond to this demand by sheltering collections of biological samples and personal and clinical data under strict ethical and scientific supervision, with the highest quality criteria and always warranting the fulfilment of law and the respect of donors' rights.
In this line, Aragon Biobank was created as a translational research infrastructure that integrates and gives visibility to the collections of samples and data with great scientific interest localized in Aragon Health Service.

Structure: Aragon Biobank is a Network Biobank, managed by the Instituto Aragonés de Ciencias de la Salud and organized in nodes, that are centers of the Aragon Health Service that lodge one or more collections of biological samples. Aragon Biobank currently consists of 4 nodes (3 Hospitals and the Tissue & Blood Bank). Each node has a responsible, which acts as an interface between hospital services and biobank.

Activity: - Sample collection: Aragon Biobank samples are organized in collections, according to their pathological interest. Each collection has a promoter in charge of the proper collection of biological samples and associated data.
- Samples are collected, processed and stored following common SOPs.
- Samples and data are registered in a unique Biobank Information Management System.
- There are also established procedures to provide unprocessed samples to researchers
- Sample distribution: sample requests are evaluated by unique scientific and ethics committees.
- More than 28.000 samples have been used in 54 research projects (30 external and 24 internal)
- Provided samples have contributed to more than 30 publications (and some patents).

Conclusion: Aragon Biobank is supporting and accelerating biomedical translational research, fostering collaboration between clinicians and basic researchers by making available human biological samples and clinical data with all guarantees ethical, legal and quality to the scientific community (public and private). It is becoming the benchmark for biological sample management for research in Aragon.

ID number: 164

The CNESPS Biobank: a population based resource for epidemiological research in Italy

S Giampaoli, MA Stazi, E Scafato, L Nisticò, L Palmieri, C Donfrancesco, MC Rota, V Toccaceli, C Lo Noce, L Galluzzo, R Scipione

Istituto Superiore di Sanità, National Centre of Epidemiology, Surveillance, Health Promotion, via Giano della Bella 34, 00162 Rome, Italy

The storage and maintenance of biological specimens is a fundamental component of population based cohort studies of the National Centre of Epidemiology Surveillance and Health Promotion (CNESPS) at the Istituto Superiore di Sanità in Rome, Italy. The CNESPS Biobank stores serum, plasma, buffy coat, packed red cells, urine, saliva, umbilical cord, DNA from the following national studies:
- MATISS, FINE, OEC/HES Projects aim at assessing the causal role of classical and new risk factors in the development of cardiovascular and chronic diseases; samples of 30,000 individuals are available;
- IPREA aims at evaluating the frequency of cognitive impairment, Alzheimer's Disease and dementia in the Italian population and studying the association of risk factors with cognitive decline; samples of 2,900 individuals;
- Italian Twin Register (ITR) aims at assessing the environmental and genetic role in the aetiology of multifactorial diseases; samples of 1,250 twins;
- ESEN Project, aims at valuating immunity toward vaccine preventable diseases; samples of 3,500 individuals;
- Piccolipiù aims at assessing the genetic and environmental role in the development of multifactorial diseases; samples of 2000 newborns and their mothers.
The strength of CNESPS Biobank is the availability of repeated measurements of lifestyles, risk factors, high risk conditions and the follow-up of morbidity and mortality from major chronic diseases in order to guarantee sound information for etiological questions on new risk factors. The biological specimen bank is available for public health research purposes, under the provision of international ethical guide-lines and the national legal norms.

ID number: 176

Consent for biobanking - a partnership approach

Balwir Matharoo-Ball, Sam Taylor, Tracy Locke, Jodie Elliott, Caroline Woolston, Brian Thomson

Nottingham Health Science Biobank, Nottingham Unversity Hospitals NHS Trust, The David Evans Medical Research Centre, Hucknall Road, Nottingham, NG5 1PB.

Background: Consent to donate is an expression of partnership and goodwill between the Biobank and potential donors. The process of taking this consent should be sensitive, user friendly and inclusive of both patients and donors. We here describe a pilot study in which patients were involved in leading the consent process in partnership with the Nottingham Health Science Biobank (NHSB).

Methods: Following consultation with our PPI group, a comprehensive person specification for patient led consent was produced which outlined:
1. experience
2. special attributes
3. communication skills

Results: We have recruited 5 PPI members who are now responsible for consent in 5 out-patient breast clinics.
The PPI members:
1. received full mandatory training and induction by the hospital Trust including the required governance issues
2. were given an Honorary Trust contract
We produced a fully comprehensive PPI training package, including presentations outlining the consent process followed by role plays. This package was then reinforced by 'hand-holding' in clinic for a minimum of 6 weeks, followed by shadowing, direct observation and a final competencies sign-off.

Conclusion: To the best of our knowledge, this is the first description of this novel and broadly applicable approach to consent for biobanking. The new role has had excellent feedback from both patient and the PPI members and has led to increases in the rates of consent. The involvement of PPI members is cost-effective and embeds the patient perspective at the core of the biobanking process.

ID number: 177

The Regulation of Biobanks in South Africa

Safia Mahomed

University of Witwatersrand

As we are all aware, biobanks play a crucial role in the development of research. However, in order for a biobank to be successful and ethically acceptable, it is imperative that a suitable review and management process must lay the foundation of biobank establishment and management. In the developing world, establishing a biobank has a pivotal impact on the community as a whole, as well as researchers. Currently the interest surrounding biobanks and the rate at which they are being established in the developing world is staggering. Without a satisfactory regulatory system in place, the developing world opens its biobanks up to misapplication. It is to this end that the University of the Witwatersrand's Subcommittee on Biobanking recognised the real need for regulatory management of this area and developed policy for the review and approval of biobank applications to the University. This policy was accepted by the National Health Research Ethics Council and will be incorporated into South Africa's national guidelines "Ethics in Health Research: Principles, Structures and Processes".

The policy outlines critical responsibilities that a public and private biobank must adhere to, in the context of a developing country. Some of the key aspects that the policy outlines are:

1. Stakeholder Consultation and Ongoing Information Sharing;
2. Informed Consent and Withdrawal;
3. Privacy and Risk;
4. Benefits, Structure and Governance;
5. Closure of a Biobank (i.e. what happens to samples should a biobank close down/ dissolve) and;
6. Regulatory Compliance in accordance with South African law.

All these aspects will form part of my oral presentation. I will also discuss law reforms that I believe are necessary in the South African context, as well as the proposed establishment of an international network of biobanks that could facilitate the progress at which research is made.

Biospecimen Research

ID number: 007

DNA fingerprinting: Sherlock Holmes in the biobank. A case study.

Olga A. Kofanova (1), William Mathieson (2), Gerry A. Thomas (2), Fay Betsou (1)

(1) Integrated Biobank of Luxembourg (IBBL), 6 rue Nicolas Ernest Barblé, 1210 Luxembourg, Luxembourg;
(2) Human Cancer Studies Group, Department of Surgery and Cancer, Imperial College London, Room 11L05, Charing Cross Hospital, Fulham Palace Road, London W6 8RF, United Kingdom.

A researcher using extracted nucleic acid samples supplied by a tissue bank, for an "omics" technology, reported that there appeared to be a mismatch between samples from 3 different cases. All the cases were collected in a single Institute (A) and extracted by a second Institute (B) in 2009 and 2011. There were three possible scenarios: mislabelling at the collection centre, mislabelling at the researcher's institute or contamination of tubes during the research analysis.

The Integrated Biobank of Luxembourg (IBBL) agreed to act as an independent assessor and provided DNA fingerprinting on the samples. IBBL was blinded to the sample identities. Using the IBBL biospecimen quality control (QC) assay for authentication of biospecimen identity, all samples were tested for different single- and multi-locus variable numbers of tandem repeats (VNTRs) based on polymerase chain reaction (PCR) amplification of highly polymorphic minisatellite VNTR loci with generation of banding patterns.

In this study, the DNA fingerprinting showed that there had been no mismatch of samples between individuals neither in Institute A nor during the extraction at Institute B. The researcher was finally provided with an extra aliquot of RNA and DNA from tumour and normal tissue blocks in order to re-run their analyses. This scenario emphasises the need for detailed and accurate record keeping during processing of biological samples, and the value of independent third-party assessment to resolve identification issues in biospecimens from tissue banks.

This actual case study illustrates the usefulness of the DNA fingerprinting method in biobank QC procedures.

ID number: 013

Microbial Translocation in HIV-1 infected patients.

Zisis Kozlakidis, Betsy Arefaine, Sylvie Clarefond and John Cason

Infectious Diseases Biobank, Division of Immunology, Infection and Inflammatory Diseases, School of Medicine, King's College London and NIHR Biomedical Centre at Guy's and St. Thomas' NHS Foundation Trust

Microbial translocation – as indicated by detectable plasma Lipopolysaccharides (LPS) - is increased in patients infected with HIV. However, it is not clear whether, or not, levels of plasma LPS are prognostic for HIV associated disease progression. To examine the association between plasma LPS and disease progression we examined 267 banked plasmas from untreated HIV patients. Our results show that LPS concentrations were unassociated with circulating CD4+ T-cell numbers or plasma HIV viral loads. LPS was significantly negatively associated with the time of sampling after diagnosis. We were able to demonstrate that LPS concentrations significantly increase in HIV patients in the first six months after diagnosis to levels which exceed those observed amongst patients in the chronic phase. Amongst patients, those with chronic disease or who were viral controllers had lower levels of plasma LPS and those with AIDS had higher levels.

ID number: 017

Marine mammal tissue banking and cell cultures: extending efforts for protecting endangered species

Panin Mattia, Giurisato Maristella, Martinello Tiziana, Montelli Stefano, Peruffo Antonella, Patruno Marco, Cozzi Bruno

University of Padova, V.le dell'Università 16, 35020 Legnaro (PD), Italy

The Mediterranean Marine Mammal Tissue Bank, established in 2002 at the University of Padova, stores more than 3400 tissue samples from more than 280 specimens, belonging to 15 species. Following its main mission, samples are provided for free to all institutions interested in marine mammals research, under motivated request. We recently added a new provisional division of the tissue bank, dedicated to tissue cultures. Primary cell cultures allow a wide range of reliable in vitro experiments with controlled settings and are of special interest in cetacean research. We already obtained and characterized tissue cultures from the skin of a bottlenose dolphin (Tursiops truncatus). We now decided to harvest samples of the m. longissimus dorsi from Grampus griseus and isolate satellite cells, that are in fact the myogenic precursors in postnatal and adult muscles. We observed the differentiation of satellite cells in culture. After 5 days the myoblasts in culture appear with typical elongated shape and after 15 days they begin to migrate and to align. The fusion of myoblasts yielded multi-nucleated myotubes, clearly identifiable in vitro. Standardized protocols for the isolation and culture of satellite cells are key tools for understanding autonomous and extrinsic factors that regulate the cell performance.

ID number: 029

A standardized technique for excision and storage of high quality human retinal tissues

Adriano Fasolo, Davide Camposampiero, Stefano Ferrari, Mohit Parekh, Gianni Salvalaio, Diego Ponzin

Fondazione Banca degli Occhi del Veneto (The Veneto Eye Bank Foundation), Via Paccagnella, 11 - 30174 Zelarino Venezia, Italia

The availability of retinal tissue is of utmost importance for research scientist and information on evisceration of retinal tissues from animal models is widely available.
We provide a standardized method for the isolation of retinal tissue from human eye of cadaveric donors and believe that if human ocular globe dissection is carried out as defined, research scientists would be able to have tissues of good quality to be used for their research projects. In fact, many eye banks around the world are likely to receive eye globes not suitable for transplantation that could still be used for research purposes.
Our technique does allow to preserve the quality of retinal tissue, suitable for histological studies, and - most important - that of retinal RNA, measured as RNA integrity number (RIN value).
We believe the same technique could be used to isolate the retinal tissues for many other different purposes such as (i) for retinal transcriptome studies, (ii) to study and advance the use of human induced pluripotent stem cells in regenerative medicine, (iii) to develop RNA expression atlas of human retinal diseases genes, (iv) to identify retinal stem cell to regenerate retinal tissues, etc.
This technique will be beneficial for those who need to perform such excisions or experiments, but have limited information on the method to deal with with human retinas.

ID number: 033

Metabolomics Technology Validated Quality Markers for Biobank Plasma Samples

Beate Kamlage (1), Oliver Schmitz (1) and Philipp Schatz (2)

(1) metanomics GmbH, Tegeler Weg 33, 10589 Berlin, Germany; (2) Metanomics Health GmbH, Tegeler Weg 33, 10589 Berlin

Background: Research in the healthcare area such as identification and validation of diagnostic biomarker candidates or new drug targets often starts with the analysis of existing biobank samples. The quality of these biospecimens can be impaired by various pre-analytical sample processing steps that will confound the analytical results and decrease the value of research if not identified and addressed properly. Metabolite profiling is a well-suited technology to support the identification of biomarkers for the quality control of biobank samples due to its high sensitivity plus the broad coverage of physiological and chemical processes.

Materials and methods: Human EDTA plasma samples obtained after applying defined pre-analytical confounding factors were subjected to mass-spectrometry based metabolomics including selected targeted platforms MxP™ Broad Profiling, MxP™ Eicosanoids, MxP™ Catecholamines and MxP™ Lipids.

Results: Metabolomics data sets were analyzed by simple and mixed-effect linear models. Various pre-analytical processes resulted in significant and reproducible changes of the human plasma metabolome. Several metabolites suited as Quality Markers were identified and validated in independent data sets after Bonferroni-Holm correction of the false-positive rate with p-values being $<<0.001$.

Conclusions: The plasma metabolome is influenced by the pre-analytical phase. Reproducible and meaningful biomarker research demands standardized protocols for sample handling (quality assurance) as well as a quality control of samples. High-level result interpretation of metabolomics studies requires framework studies to understand the impact of the pre-analytical phase on the results and to elucidate the underlying physiological and chemical mechanisms. A quality control service for EDTA plasma is currently being developed.

ID number: 034

Preservation of biological material derived from OSNA assay: beyond its diagnostic use

Peiró-Chova L (1), Bahamonde O (1), España MC (2), Caballero A (3), Ferrández-Izquierdo A (1,2), Burgués O (2)

1. *Biobank, INCLIVA Biomedical Research Institute, Valencia (Spain)*
2. *Department of Pathology, Hospital Clínico Universitario de Valencia, Valencia (Spain)*
3. *Department of Surgery, Hospital Clínico Universitario de Valencia, Valencia (Spain)*

Introduction & Objectives: The one-step nucleic acid amplification (OSNA) method is a highly sensitive and specific tool for intraoperative analysis of sentinel lymph node (SLN) status in breast cancer patients. Although OSNA is an increasingly used procedure in diagnostics, little is known about long-term preservation and integrity of the material derived from this assay. Our purpose was to assess its quality in order to evaluate its usefulness in molecular studies.

Materials & Methods: Thirty-six positive OSNA cases collected from 2010 to mid-2013 at our institution were analyzed. Total DNA and RNA (including miRNAs) from SLN samples homogenized with an mRNA-stabilizing solution (Lynorhag, pH 3.5 Sysmex®) and stored at -80ºC were isolated using commercial kits. Nucleic acids amounts and purity were determined using Nanodrop 2000 spectrophotometer. DNA integrity was assessed by agarose gel electrophoresis and PicoGreen® assay, and in the case of RNA, Agilent 2100 Bioanalyzer was used. The total amount of proteins in the SLN lysates was quantified by Lowry method and visualized in acrylamide gel.

Results: Great amounts of total DNA, RNA, and proteins were recovered. DNA and RNA purity obtained was high (mean A260/A280nm value was 1.85 for DNA and 2.01 for RNA). Nucleic acids integrity was optimal in almost all cases, irrespective of the age of the sample.

Conclusions: We conclude that SLN lysates derived from OSNA assay and stored at -80ºC are well preserved, thus being a valuable source of biomaterial suitable for research. A quality assessment of the excessive samples derived from diagnostic collections is recommended to take full advantage of this material in biomedical research.

ID number: 036

Automated biobanking workflow for room temperature collection, transport and storage of human blood samples for molecular RNA and DNA diagnostics.

Vasco Liberal, Angela Stassinopoulos, Scott Whitney, Steven Wilkinson, Winnie Huang, Rolf Muller and Judy Muller-Cohn

Biomatrica, Inc., 5627 Oberlin Drive, Suite 120, San Diego, CA 92121

Diagnosis and monitoring of disease based on gene expression profiles from blood requires reliable nucleic acid preservation during sample collection and shipment. Transcription profiles can change rapidly after sample collection, potentially affecting interpretation of gene expression and ultimately dictating inadequate treatment. Biomatrica's RNAgard® Blood Tube is a collection device for whole blood, which stabilizes the RNA in blood cells and allows for room temperature sample handling and storage. Coupled with a robust RNA purification method, it provides a complete solution for blood collection, storage and high yield RNA purification. RNA isolation can be performed with multiple automated platforms, allowing ease and flexibility in the workflow, and excellent results for low to high throughput sample processing.

Moreover, the RNAgard Blood Tube is a convenient solution for studies that require isolating and testing both DNA and RNA from the same patient. The logistics of such studies can be very complex, especially when large sample sets are required. Isolation of RNA and DNA from the same sample is ideal, since the use of separate samples could introduce operation errors and variation of results. To accommodate the need for RNA and DNA isolations from the same blood sample stabilized in RNAgard Blood Tubes, we have developed an automated workflow for sequential RNA and DNA purification, using the MagNA Pure System (Roche).

Biomatrica's room temperature nucleic acid preservation technology, coupled with automated purification, can provide accurate gene expression profiles, proving highly valuable for improved biomedical research and patient treatment.

ID number: 048

Sample Quality Assessment of the Oncological Serumbank@UZA

Cheung KJ, Wouters K, De Vroey V, Van Hoof V, Peeters B, De Wilde A, Lesage K, Smits E, Meulemans E, Van den Bulcke T, Luyten L, Jorens P, Smits G, Pauwels P, Peeters M

TumorBank@UZA, Antwerp University Hospital, Wilrijkstraat 20, B-2650 Edegem, Belgium

Introduction: Serumbank@UZA was initiated as a side-project of the tumour bank initiative of the Antwerp University Hospital for the storage of residual oncological sera at -80 °C. The serumbank has a collection of over 6719 samples from the department of Oncology (February 2012 – May 2013).

Aim: To assess the quality of the residual sera based on several routine parameters at different time-intervals.
Material & Methods: Residual sera were selected and defrosted after 2 (n = 30), 4 (n = 30), 6 (n 7. Posters 30) and 12 months (n = 31) of storage for reanalyses. Difference with the baseline values before freezing, was expressed in percentage change and analyzed by T-test with 95% confidence interval (CI) and compared with the total allowable error (TEa = allowable bias + 1.65 x allowable imprecision) for albumin (0.04), total bilirubin (0.31), creatinine (0.09), potassium (0.06), urea (0.16), alkaline phosphatase (ALP) (0.12) and aspartate aminotransferase (AST) (0.15) (www.westgard.com).

Results: Albumin (CI) (0.06; 0.08), creatinine (0.04; 0.06), urea (0.01; 0.03) and AST (0.05; 0.11) and ALP (0.02; 0.05) were statistically significantly increased, while bilirubin (-0.15; -0.12) was statistically significantly decreased ($p < 0.05$). Urea (0.00; 0.01) remained unchanged. However, percentage changes of all parameters, apart from albumin, remained within their predefined TEa's over time.

Conclusion: In general, the observed serum parameters were well preserved after storage at -80 °C according to the changes within the total allowable error range. Further characterization and quality measurements are required prior to usage of residual sera in clinical oncological research.

ID number: 052

Biospecimen Science in the Janus Serumbank

Randi Gislefoss

Cancer Registry of Norway, Institute of Population-based Cancer Research, Postbox 5313, 0304 Oslo, Norway

Background: The potential value of a biobank depends on the quality of the samples, i.e. to what extent they may reflects the biological, or biochemical situation in the individual at the time of sample collection. The sample quality is essential to obtain reliable measurements of archival samples, and lack of component stability may invalidate scientific results.
The Janus Serum Bank was established in 1973 and holds pre-diagnostic samples from 317.000 donors of whom 56.000 (2010) have developed cancer. Janus Serum Bank is integrated with the Cancer Registry of Norway.
The aim of this presentation is to communicate results from stability studies

Methods: Several serum components (i.e. proteins, hormones, amino acids, vitamins) have been investigated by a repeated cross-sectional design. Group comparisons were done by ANOVA and Student Newman Keul's.
Evaluation of central tendency and dispersion was done by median with quartiles and mean with 95% confidence interval for each component.
Microarray platform has been used to analyze miRNAs.

Results: The studies demonstrated non-significant or numerically small group differences in the levels of Albumin, Methyl malonic acid, Aspartate amino transferase, Cystatin C, Immunoglobulin E/G, Sex hormone binding globuline, Transferrin, Homocystein, Vitamin B12 and 6 vitamin B-related biomarkers. Large difference was demonstrated for Alanin amino transferase, Creatinine kinase, Insulin C-peptide, Ferritin and Folate. Selected miRNAs were stable in long-term stored serum.

Conclusion: Biospecimen science has demonstrated stability for a large number of serum components. The knowledge of sample stability is essential when using archival specimens in research.

ID number: 070

Histological Quality Control (QC) Of Frozen Samples Using Matching Formalin-Fixed Paraffin-Embedded (FFPE) Tissue – Preliminary Results Of Our Institutional Biobank

E. Mattioli, E. Foglia Manzillo, V. Rubini, F. Palma, A. Paradiso, G. Simone

National Cancer Research Centre, Istituto Tumori "Giovanni Paolo II", Viale Orazio Flacco 65, 70124 - Bari, ITALY

We performed histological QC by evaluating the reproducibility of immunomorphological features on frozen biobank samples and corresponding FFPE material.
60 cases from our Institutional Biobank were enrolled, including both primary (29 breast, 9 colorectal, 5 gastric and 5 endometrial) and metastatic tumors (6 lymphnodes and 6 liver metastases). At collection, each tissue sample was cut into two "mirror-matching" halves: one was reduced into aliquotes and frozen, while the other was prepared as a "specular" FFPE block. For each case tumor cellularity and MIB-1 immunostaining were evaluated on sections from both frozen and FFPE tissue.
Concordance of tumor cellularity varied from 55% (33/60) to 71.7% (43/60) of cases, depending on the tolerated discrepancy. Endometrial carcinoma and liver metastases showed the highest concordance fractions.
Concordance of Ki-67 immunostaining ranged from 52.1% (25/48) to 81.2% (39/48) of cases, depending on the allowed deviation. Metastatic tumors showed the highest concordance. 20% of cases (12/60) resulted non-assessable because of technical artefacts.
Our data indicate that immunomorphological features are not as reproducible between matching frozen and FFPE tissue as expected, because of the inherent heterogeneity of tumor tissue. Concordance appears to be influenced by anatomic site, histotype and cytoarchitectural features. The occurrence of marked staining artefacts in a significant fraction of cases suggests a higher lability of molecular components compared to morphological characteristics. Therefore, mirror-matching FFPE blocks can play a role in biobanking QC procedures; however, collection and storage procedures need to be optimized to minimize sample heterogeneity and to improve the preservation of molecular components.

ID number: 088

Biobanking for Dermatological Disorders

Ay e Yüzba ıo lu 1, Ay en Karaduman 2, Serap Dökmeci 3

1 Hacettepe University DNA/Cell Bank for Rare Diseases
2 Hacettepe University Faculty of Medicine Department of Dermatology
3 Hacettepe University Faculty of Medicine Department of Medical Biology

Hacettepe Medical Center Dermatology Department serves a referral point for all geographic regions of Anatolia . The outpatient capacity per year is about 4000. We wanted to combine the advantage of biobanking and the high consanguinity rate in the population (21%) for homozygosity mapping for new gene discovery and developing genetic tests for early diagnosis and stratification of patients for future personalized approach to treatment. Sampling is done for keratinizing group of dermatological disorders (ichthyoses) and psoriasis.

The registry consists of a total of 482 individuals from 84 families. There are 58 families with diagnosis of ichthyosis with a total of 99 affecteds and all families are consanguinous. Psoriasis group consists of 26 families with 53 affecteds and there is parental consanguinity in 8 families.

The AR ichthyosis cases were instrumental in identifying new genes in studies with international collaborations. ABHD5 (MIM: 604780) and PNPLA1 (MIM: 612121) gene mutations are screened for molecular diagnosis and genotype phenotype correlations are assessed to derive further insight into the pathogenesis of genodermatosis. Skin biopsy sampling has been initiated for ultrastructural studies and further work is being planed for deriving pluripotent cells to create a biobank for further investigations .

This study is a good example of the facilitating capacity of biobanks for research in genetic diseases where the priorities are in finding new disease genes and developing means to stratify patients for individualized modalities of treatment.

ID number: 112

Samples preservation: which for what?

Diaz-Cordoba, T; Ventura, C; Muñoz, C; Garcia-Martin, M.L*; Gallego, E°; Hierro, I°; Vicioso, L°.*

Andalusian Public Health System Biobank, Hospital de Málaga, 29010 Málaga.
° Pathology Department, Hospital Universitario Virgen de la Victoria, 29010 Málaga
** Nano-Imaging Facility, Bionand, P.T.A., Campanillas, 29590 Málaga*

The non existence of the perfect method to preserve the samples is already our reality. Here we reviewed our experience and the valuable found in the bibliography, in the solid tumor field, to describe the most suitable method in order to maximize the number of techniques accesible.

ID number: 116

Glioblastoma stem like cells in the BestaCriobank for Brain tumors, an important source for biological and clinical studies on glioblastoma

*Pellegatta S, Porrati P, *Tieni P, Bottega E, Eoli M, Anghileri E, Farinotti M, Ferroli P, Franzini A, Di Meco F and Finocchiaro G.*

*Department of Neuro-Oncology; *Cryomanagement service SOL; Fondazione IRCCS, Istituto Neurologico Besta, 20133 Milano, Italy.*

The BestaCriobank for Brain tumors (BCB) has been established with the collaboration of the GLP
cryomanagement service provides by SOL Group Spa, Italy. As of January 2010 specimens, blood and/or serum
were available from more than 4000 tumors. Glioblastomas (GB) are the most represented tumors (30%).Tumor
specimens have been used in different studies involving GB, low-grade gliomas, medulloblastomas and
meningiomas and focused on LOH analysis, mutations, and identification of genetic markers of clinical
relevance. Since 2004 more than 500 glioblastoma stem-like cells (GSCs) derived from GB specimens have
been stored in the BCB and used for a number of collaborative studies (Orzan et al, 2011; Ortensi et al, 2012;
De Rosa et al 2012; De Bacco et al, 2012; Singh et al, 2012). On a series of primary GB we obtained GSC in
52% of the cases, using tumor fragments and combining a mechanical and enzymatic disaggregation. The use
of tumor fragments obtained by CUSA (cavitron ultrasound sonic aspirator) increased the percentage of GB
forming GSCs to 70%.
BCB plays an important role in several national and international collaborations. An approach of next generation
sequencing is ongoing to characterize the evolution of GB mutations in collaboration with Columbia University.
Our Institution is also involved in the TCGA program for GB, thus emphasizing the role that BCB is playing in
basic and translational cancer studies.

ID number: 124

Biobanco-IMM: an overview

Afonso A.;Caetano-Lopes J.;Cascao R.;Pires R.;Polido-Pereira J.; Zhao A.; Fonseca JE

Instituto de Medicina Molecular, Faculdade de Medicina da Universidade de Lisboa

Biobanco-IMM, Lisbon Academic Medical Centre, is a structure created by the Instituto de Medicina Molecular (IMM) to promote and facilitate biomedical research. Biobanco-IMM vision is to position itself as a major member of the European Network of Biobanks within the next 5 years, offering excellent opportunities for translational and clinical research. Our main goal is to collect a wide variety of high quality human biological samples associated with detailed relevant clinical information and to promote their use for research purposes based on scientific and ethical criteria. The 2 year operational phase of the Biobanco-IMM development project started in May 2011, aiming at finishing the preparatory activities. In January 2012 we have started receiving samples.
In October 2012 we organized a formal opening event, which together with meetings in all medical departments of the Lisbon Academic Medical Centre, gave the needed visibility for achieving until now more than 5 thousand donors across 16 collections. Today, nearly 1500 samples have left the Biobanco-IMM, mostly through collaboration with research institutions in Spain, Brasil, Finland and Portugal.
Our expectation is that Biobanco-IMM will contribute to health promotion and society welfare, as well as have the potential to act as a promoter of new national and international cooperations between researchers, research institutions and pharmaceutical industry.

ID number: 125

Prolonged Cell Viability for Mouse Implantation of Human Tumor Tissues

Rita T. Lawlor, Dea Filippini , Nicola Sperandio, Nadia Mori, Vincenza Favuzzi, Irene Dalai, Aldo Scarpa

ARC-NET APPLIED RESEARCH ON CANCER, POLICLINICO G.B. ROSSI, PIAZZALE L.A. SCURO 10 37134 VERONA

Background: Prolonged transport time and processing delays of tissue specimens are known to affect cell vitality.

Aims: In this study we aimed to test the impact of vaccum storage of fresh tissue samples prior to use for mouse implantation and short term cultures.

Materials and Methods: Fresh pancreas surgical specimens were vacuum packed and refrigerated for 12 and 24 hours before being checked for cell viability using the Muse Cell Analyzer and processed for cell cultures. Fresh pancreas tumor tissue was sampled immediatley upon excision and dissected into three aliquots. One was processed immediately (T0) and the other two were placed in a vacuum pack and stored refrigerated for 24 and 48 hours respectively (T24, T48) before being processed. Each T0, T24 and T48 sample was fragmented into four pieces which were implanted in two immunodefficient mice from the strain of nude mice Swiss-nu/nu (one fragment in the nape and one fragment in the right flank of each).

Results: The tissue stored for 12 and 24 hours and then processed for cell cultures revealed a high level of viable cells. All tumor fragments implanted in the right flank of each mouse grew within 17 days of implantation showing the viability of tumor tissue stored vacuum refrigerated for up 48 hours.

Conclusion: The short term storage of vacuum packed refrigerated whole or sample tissue prolongs cell viability. Samples can be maintained fresh for up to 48 hours and still guarantee cell culture and xenograft production permitting longer periods and long distant transport of fresh tissue with less stringent transport.

ID number: 127

Paraffin Embedded Tissues Use For Next-Generation Histopathologic Diagnosis: A Lesson From a Hepatic Carcinosarcoma

Claudio Luchini, Paola Capelli, Matteo Fassan, Michele Simbolo, Andrea Mafficini, Andrea Ruzzenente, Alfredo Guglielmi, Rita T. Lawlor, Vincenzo Corbo, Aldo Scarpa

ARC-NET APPLIED RESEARCH ON CANCER, POLICLINICO G.B. ROSSI, PIAZZALE L.A. SCURO 10 37134 VERONA

Background and Aim. Application of molecular genetic screenings on paraffin embedded tissues is a mandatory step to apply results of basic sciences to routine diagnostics. Here we report the application of next-generation targetted sequencing to a case of hepatic carcinosarcoma. This neoplasm is a deadly neoplasia characterized by the mixture of carcinomatous and sarcomatous elements, whose biphasic nature render histogenetic classifications unsure and therapeutic approaches subjective.

Patient and methods. The diverse histologic components of a hepatic carcinosarcoma were microdissected and subjected to simultaneous sequencing of 46 cancer-associated genes using Ion Torrent PGM.

Results. The carcinosarcoma had a hepatocarcinoma and a sarcomatous component showing areas of rhabdomyosarcomatous differentiation. An intra-hepatic satellite hepatocarcinoma was also present. The primary and satellite hepatocarcinomas and both sarcomatous components disclosed the same TP53 mutation (F109C). The primary and satellite hepatocarcinomas had different PIK3CA mutations, H1047R and E545D, respectively; the satellite hepatocarcinoma also had two FGFR2 (C383R and M391T) mutations. The sarcoma showed two distinct FGFR3 mutations, S400fs in the poorly differentiated and G405fs in the rabhdomyosarcoma portion. A germline VEGFR2 variant (Q472H) was also found.

Conclusions. The case presented is an example of a "next generation histopathological diagnosis". Our morphology-driven geographical mutational analysis of 46 genes using routinely processed formalin-fixed paraffin-embedded tissues: (i) supports the monoclonal origin of carcinosarcoma, as all the components shared the same TP53 mutation; (ii) is able to trace the clonal evolution of the neoplasm, thus permitting the description of cancer heterogeneity in a diagnostic report; and (iii) identifies potential therapeutical targets, where agents currently in clinical trials for different tumor types, such as those blocking PIK3CA, FGFRs and VEGFR2 mutated gene products, could be of use.

ID number: 130

Maximalizing the use of clinical samples: development of limited hands-on time DNA extraction method from frozen blood clots

Loes Linsen (1,2), Tine Vanbinst (1), Merle Meus (1), Caroline Motmans (1), Jean-Luc Rummens (1,2)

1. Clinical Biobank, Jessa Hospital - campus Virga Jesse, Stadsomvaart 11, B3500 Hasselt, Belgium;
2. University Biobank Limburg, pa Stadsomvaart 11, B3500 Hasselt, Belgium

Background: Hospital integrated biobanks often only obtain restricted volumes of blood for storage and subsequent research. Previously we have shown the white blood cell pellet as the optimal storage type for downstream applications. In order to further maximalize the limited amount of material available per clinical donor, we assessed the usefulness of frozen blood clots as additional source of DNA.

Methods: Left-over blood clots were sampled from routine diagnostics and stored at -80°C till DNA extraction. DNA yield, integrity and PCR performance were determined.

Results: We tested different frozen clot homogenization protocols, (GentleMACS C- and M-tubes). Two optimal protocols for the C-tube and M-tube were selected. Homogenization was then tested in presence (+) and absence (-) of PBS, to minimize sample dilution and allow for other applications. The QiaAmp DNA mini kit, blood protocol, was used for DNA extraction of homogenized samples. The yield of the C-tube +PBS homogenized samples was higher than C-tube -PBS. The yield of DNA from M-tube homogenized samples was comparable +/-PBS and intermediate to C-tube extraction results. Integrity was similar for all conditions (size > 24 Kbp). Purity of the extracted DNA was good for all M-tube conditions and upon extraction from C-tube -PBS, but OD260/280 was above the acceptable range for C-tube +PBS. Performance by PCR needs to be confirmed.
Conclusion: We are on route to develop an easy to use, automation friendly, method to obtain qualitative DNA from frozen blood clots, to augment the amount of material from patients in a hospital setting.

ID number: 165

Genetic Mutations As Prognostic Biomarkers In Patients With Early Stage Lung Cancer

Cohen Yehudit^, Cohen Ruthie^, Hout Siloni Goni^, Khermesh Khens, Damianovich Maya^, Dar Erel^, Levanon Erez*, Barshack Iris^, Onn Amir^*

^ Sheba Medical Center, and Tel Aviv University, Israel
**Bar-Ilan University, Israel*

Non-small-cell lung cancer (NSCLC) is recognized as a collection of diseases (e.g. SCC, AC, LCC). The spectrum of mutations is very different according to smoking status, age and gender. In 2004, the first personalized treatment took place with EGFR tyrosine kinase inhibitor (TKI), gefitinib. BUT, only some patients responded; of these, many acquired resistance to TKIs.

Goals:
Address prognostic biomarkers for cancer recurrence in early stagers;
Develop an accessible and reliable mutations panel as a recurrence-predictive tool for these patients.

The cohort is divided to 3 groups:
Patients with recurrence within 2 years;
Recurrence within 2-5 years;
No recurence within 5 years.

Purified DNA from primary tumor, taken from both formalin fixed (FFPE) and fresh (FF) tissues provided by Sheba's biorepository, was sequenced on the Access_ArrayTM_Amplicon Sequencing on the PGMTM_Sequencer (Fluidigm). This new system is high quality, low cost, flexible, sensitive and simple. 48 samples can be scanned simultaneously for tens of mutations with 48 primer pairs.

Preliminary results on the Sequenom's_MassARRAY, where only FFPE samples were tested, showed that indeed mutations in EGFR have prognostic and predictive value of survival and recurrence. We have calibrated the work on the new Fluidigm system, so we could work with different sources of DNA (FF and FFPE) and expanded our genes scope, associated with cancer disease recurrence.

The first array reveals high quality and sensitivity with 30 mutations in 11 genes in FFPE and correlated FF samples. Correlation to recurrence (and smoking, gender, type_of_disease) will be addressed next. Following this analysis, a recommended panel of genes to test, will be published.

ID number: 169

Quick And Donor-Saving Method For Mesenchymal Stem Cell Extraction For Biobanking And Clinical Use

Gudleviciene Zivile, Kundrotas Gabrielis, Liudkeviciene Regina

Institute of Oncology, Vilnius University (Vilnius, Lithuania)

Introduction. Mesenchymal stem cells (MSC) are currently exploited in numerous clinical trials to investigate their potential in immune regulation, hematopoiesis, and tissue regeneration. The most common source of MSCs for clinical use is human bone marrow. To generate clinically relevant numbers of cells, usually high volumes (50-60 ml) of bone marrow aspirates are taken. The aim of our study was to compare the effectiveness of two MSC isolation from bone marrow and cultivation methods.

Materials and methods. 60 mL of bone marrow was aseptically aspirated from the iliac crest of 4 patients and 6 ml from over 4 patiets. For MSC extraction using centrifugation through ficoll gradien method 60 ml of bone marrow (10 vacutainers of 6 ml) was used. For MSC extraction using red blood cell lysis method 6 ml of bone marrow (1 vacutainer of 6 ml) was used. MSC were cultivated until 3th passage, until the named “therapeutical dose” was reached.

Results. In this study we have shown that using of red blood cell lysis the efficient amount of human MSCs can be isolated from 10 times less bone marrow volume (6 ml) and "therapeutical dose" could be achieved during similar period of time (3-4 weeks).

Conclusions. Small amount of bone marrow lysis is the quick and easier method reduces the patient inconveniences and should be promoted.

Education & Standards

ID number: 011

Improved Utilization Of Fresh-Frozen Tissue Specimens Using A Novel Frozen Tissue Aliquotter

Diane McGarvey, Theresa Kokkat, Larry Chin, Todd Basque*, Joseph Fraone**

*CHTN Eastern Division and *CryoXtract Instruments, 5 Constitution Way, Woburn, MA 01801 USA*

Frozen human biospecimens are invaluable resources that advance translational research, molecular medicine, and biomarker discovery. Multiple freeze-thaw cycles, can alter protein conformation and activity. It is pivotal that the tissue be maintained at an ultralow temperature and that the number of freeze/thaw cycles is minimized.

The novel Frozen Tissue Aliquotter addresses the above issue by maintaining the tissue at an ultralow temperature and thereby extending the usability of the banked tissues. This proprietary instrument allows for a mounting of the specimen to a frozen (e.g. -80 C) fixture, cutting of frozen slides from the frozen sample, and the ability to repeatedly access and remove frozen aliquots from specific regions (e.g. normal, tumor, margin) of the primary tissue without exposing it to unnecessary freeze/thaw cycles.

This presentation describes the materials, methods, and data obtained in a comparative study using human tissues. The study compares the preparation, use, and analysis of the tissue in four conditions, 1) Fresh, 2) Frozen-aliquotted simultaneously, 3) Frozen-aliquotted over time, and 4) Thawed/aliquotted/refrozen over time. Each sample will be analyzed to determine its RNA score (RQI) and purity to determine the effectiveness of frozen aliquotting.

ID number: 021

Standard Operating Procedures for a Biorepository Network

Brent Schacter, Rebecca Barnes, Jean de Sousa-Hitzler, Sambasivarao Damaraju, Monique Albert, Sugy Kodeeswaran, Peter Watson, Anne-Marie Mes-Masson

Canadian Tumour Repository Network, ON6022 – 675 McDermot Avenue, Winnipeg, Manitoba, Canada R3E 0V9

Despite the integral role of biorepositories in fueling translational research and the advancement of medicine, there are significant gaps in harmonization of biobanking practices resulting in variable biospecimen collection, storage and processing. This significantly impacts accurate downstream analysis and in particular creates a problem for biorepository networks or consortia. The Canadian Tumour Repository Network (CTRNet; www.ctrnet.ca) is a consortium of Canadian tumour biorepositories that aims to enhance biobanking capacity and quality through standardization. To minimize the issue of variable biobanking practices throughout its network, CTRNet has developed and maintained a comprehensive set of 45 Standard Operating Procedures (SOPs) for biobanks.

There were four key elements to the CTRNet SOP development process: 1) an SOP Development Team was formed from members across CTRNet to co-produce each SOP; 2) a principal author was appointed with responsibility for overall coordination of the SOP development process; 3) the CTRNet Management Committee (composed of Principal Investigators for each member biorepository) reviewed/revised each SOP completed by the Development Team; and 4) external expert reviewers were asked to provide feedback and recommendations on each SOP. Once final Management Committee approval was obtained, the ratified SOP was published on the CTRNet website for public access.

Since the SOPs were first published on the CTRNet website (June 2008), there have been approximately 15,000 downloads of one or more CTRNet SOPs/Policies by users from over 60 countries. In accordance with biobanking best practices CTRNet performs an exhaustive review of its SOPs at set intervals, to coincide with each granting cycle.

ID number: 046

Biobank Graz: Training and Coaching

Karine Sargsyan1, Bettina Amtmann2, Berthold Huppertz1

1 Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria; 2 Department of Obstetrics and Gynecology, Medical University of Graz, Austria

Background: The DALI project on "Vitamin D and Lifestyle Intervention for Gestational Diabetes Mellitus Prevention" is an FP7 funded project with 13 partners, coordinated by Medical University of Graz (MUG). As a core research facility of MUG, Biobank Graz does not only provide biobanking storage capacities but also know-how and standard operating procedures (SOP) for projects. Here training was specifically designed to support the needs of DALI.

Approach: First an inventory with a specifically developed questionnaire was performed to exactly recognize the local conditions at each participating partner institution. Then harmonized SOPs for each biospecimen type planned to be collected in this project were developed and validated at Biobank Graz.
A training course for biobanking personnel was held in Graz with the following topics:
- Overview on biobanking
- International development
- Ethical issues
- Quality management of biobanking process
- Critical points of quality management
- Impact of biobank standards on study results
- SOP DALI "Collection of Maternal and Cord blood"
- SOP DALI " Collection of Placenta Cryo Samples"
- Practical training
- Visit of Biobank Graz
- Questions and answers

During practical training, participants were divided into two groups, which were trained in parallel. This enabled the inventive communication and know-how transfer frame. Also special movies were recorded during training and provided to participants to ensure reproducible results of training.

The training was evaluated by the trainees with standard evaluation sheets and DALI moved into the next step of performance.

ID number: 063

Munich Biobank Alliance: Implementation of improved standards for collecting biospecimens in the era of personalized medicine

F. Schmalfuß, J. Slotta-Huspenina, R. Langer,I. Esposito, K.-F. Becker, M. Straub, F. Bader, U. Nitsche, C. Späth, K. Janssen, R. Blaser, K. Kuhn, J. Kleeff, H. Höfler, and the Munich Biobank Alliance investigators.

Gewebebank Klinikum Rechts der Isar, Technical University of Munich, Munich, Germany, www.m4.de

Biobanks and biospecimens are critical components for clinical and basic research and are fundamental for the development of personalized medicine and improvement in the quality of human health care. However, quality of biospecimens and associated data is critical and must be collected according to standardized procedures. A major aim of the Munich Biobank Alliance (www.m4.de) is to establish a sustainable infrastructure for state of the art biobanking in the era of personalized medicine. Moreover, a comprehensive ethical and legal concept in line with current national and international guidelines has been developed and implemented in cooperating institutions in the Munich area. As a member of the Munich Biobank Alliance the "Gewebebank of the Klinikum Rechts der Isar der medizinischen Fakultät TU München" aimed to improve standard operation procedures for collecting, processing and storing of tissue samples, as well as to expand and substantiate annotation, in consideration of personalized medicine. For data management, an in-house biobanking information system has been developed that interfaces clinical (PKIS) and pathological information systems. Parameters recorded for each samples include expanded clinical data, quality and processing-related data, biospecimen related data and pathological data. We believe that a high quality biospecimen collection together with a highly standardised clinicopathological annotation will advance the field of translational research and is critical for discovery, validation and implementation of biomarkers in clinical practice as well as the identification of new targets for personalized cancer therapy.

ID number: 082

Optimization of Tissue Microarray construction and processing for breast cancer research.

Martina Oberländer 1, Hendrik Alkemade 1, Felix Ernst 1, Stefanie Bünger 1, Christoph Thorns 2, Till Braunschweig 3, Jens K. Habermann 1
>on behalf of the Interdisciplinary Center for Biobanking-Lübeck (ICB-L)<

1 Section for Translational Surgical Oncology and Biobanking, Department of Surgery, University of Lübeck and University Medical Center Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; 2 Institute of Pathology, University Medical Center Schleswig-Holstein, Campus Lübeck, Lübeck, Germany; 3 Institute of Pathology, RWTH Aachen University, Aachen, Germany

Introduction: Apart from liquid samples, most archived patient material is collected as formalin-fixed paraffin-embedded (FFPE) tissue blocks in many biobanks. FFPE tissue blocks offer the opportunity of creating tissue microarrays (TMAs) for protein-based high-throughput validation of biomarkers, that are essential for early diagnosis, prognosis and therapy prediction in cancer research. In particular, the validation of target proteins on clinical samples is of high importance since the proteom reflects possible gene alterations of tumor cells. Furthermore, TMAs provide an excellent tool to economically and efficiently deal with patient samples. However, technical limitations like the loss of tissue cores during sectioning and staining exist. To overcome these problems, we introduced a water-driven transfer system in combination with specific protocol adaptions for immunohistochemistry and immunofluorescence staining methods. Methods and Results: 406 breast tissue cores from FFPE blocks from 245 patients representing breast cancer tissue, ductal carcinoma in situ (DCIS), benign lesions and normal tissue were distributed on three TMA blocks. TMA sections were cut using a rotary microtome in combination with a cooling clamb and a water-driven section transfer system. To further avoid tissue loss, TMA slides were baked at 60°C and dried at room temperature for two days before staining. Even after heat-induced antigen retrieval and staining processes, the range of cores suitable for further analysis ranged from 92.4% to 99.2%. Conclusion: The use of a water-driven transfer system combined with specific protocol modifications provides a robust method for manufacturing high density TMAs for protein-based high-throughput validation of biomarkers for breast cancer research.

ID number: 119

The Establishment of an ISO Compliant Cancer Biobank for Jordan and its Neighbouring Countries Through Knowledge Transfer & Training

1Martin Barr, 2Lina Souan, 3Peadar MacGabhann, 4Jeanette Müller, 2Maxim Ashhab, 2Sallam Alhassoon, 3Uwe Kuhn, 3Daniela Infante, 2Mohammed Mustafa, 2Khetam Mahmoud,
1Kathy Gately, 1Denise Lawlor, 1Kenneth O'Byrne, 2Maher A. Sughayer.

1Thoracic Oncology Research Group, Institute of Molecular Medicine, St James's Hospital & Trinity College Dublin, Ireland, 2Department of Pathology & Laboratory Medicine,
King Hussein Cancer Center, Amman, Jordan, 3Biostór Ireland, Wexford, Ireland,
4accelopment AG, Zürich, Switzerland.

The King Hussein Cancer Center (KHCC) is a specialized cancer centre in the Middle East where over 3,500 new cancer patients present annually from Jordan and its neighbouring countries. A cancer biobank (KHCCBIO) was established in November 2011 with the support of Seventh Framework Programme (FP7) funding from the European Union (INCO.2011.6.2), making it the first cancer biobank of its kind in Jordan.

A state-of-the-art, standardised biospecimen repository of matched normal and tumour tissue, in addition to blood components, was established by KHCCBIO through the support and experience of its partners, Trinity College Dublin and two European SMEs, Biostór Ireland, a licensed tissue establishment and accelopment AG (ACCEL), a Swiss company expert in EU project management. To date, KHCCBIO along with its partners have worked closely in establishing an ISO Quality Management System (QMS) under which the biobank will operate. A Quality Policy Manual, Validation and Training plan have been developed in addition to the development of standard operating procedures (SOPs) for consenting policies on ethical issues, data privacy, confidentiality and biobanking byelaws. These have also been implemented for the donation, procurement, processing, preservation & distribution of tissues and blood samples according to best international practices. Dissemination of KHCCBIO and capacity building in order to sustain KHCCBIO through international networking is envisaged over the duration of this 2-year programme.

KHCCBIO will provide standardised human biospecimens and anonymised clinicopathological data to the cancer research communities and aid in the integration of Jordan's scientific and medical communities with its European neighbours in Horizon 2020.

ELSI

ID number: 041

How much factual information is necessary for an optimal informed consent in the field of biobanking?

Tanja Macheiner, Nathalie Lanner, Berthold Huppertz, Karine Sargsyan

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The individual level of education as well as life-experience leads to different requirements regarding the preparation of content of an informed consent for medical research. To optimize this transfer of knowledge a repeated evaluation of such informed consents is mandatory. There is no other way to proof that the donors have understood and memorize the information about e.g. risks and rights.

Aims: Our study aimed at investigating the recollection of participants after informed briefing to proof the comprehensibility of the informed consent.

Methods: We developed a questionnaire about the content of our informed consent as a multiple choice questionnaire for Biobank Graz donors. Recurred donors were asked to fill out the questionnaire more than a week after they had signed the informed consent.

Results: More than 120 Biobank Graz donors filled out the questionnaire. The results show that specific contents were understood incompletely by a large number of subjects. However, in large parts the information of the informed consent was reproduced quite well by the donors.

Conclusion: The results show that the informed consent of Biobank Graz is well conceived by the donors. However, there is still room for improvement as we also found weak aspects that will undergo revision to improve the informed consent.

ID number: 044

Development of an open informed consent for biobanking

Tanja Macheiner, Sebastian Fuchs, Michaela Bayer, Karine Sargsyan, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The amount of information in combination with the explanatory power plays a crucial role for the practical application of an informed consent in medical research. Moreover, too much as well as too little information for donors can hinder a trustful relationship between researcher and donor. Hence, our project aimed at developing an applicable informed consent procedure, which enables an uncomplicated management for the biobank as well as full protection of personal rights and privacy of donors.

Approach: A broad, one-time informed consent was developed by Biobank Graz based on the biobanking report of the Austrian Bio-Ethics Committee and taking into account the guidelines for human biobanks and genetic research databases published by the OECD. This informed consent and the associated information folder for donors are undergoing an annual re-evaluation by the local ethics committee. Furthermore, the informed consent status of donors is displayed in the clinical information system of cooperating clinical departments of the University Hospital Graz. If the patient has not yet signed the informed consent form it will be printed automatically.

Result: The informed consent developed by Biobank Graz enables researchers to do any kind of study with the samples if they show an ethical approval to perform such methods with the respective samples. This approach has been positively evaluated by the local ethics committee each year so far. The number of signing donors is steadily increasing and the disclaimer rate is nearly zero percent.

ID number: 072

Challenge: implementation of an open consent for donors of a disease-oriented biobank at one of the National German Biobanks - the ibdw experience

Jahns R, Neumann M, Geiger J, Störk S, Lohmueller R, Frölich G, Wölfel R, Stolberg M

The Interdisciplinary Bank of Biomaterials and Data Würzburg (ibdw), Straubmühlweg 2a, Building A8/A9, 97078 Würzburg, Germany

Aim: The implementation of an open consent for the disease-oriented National German Biobank located at the University of Würzburg, Bavaria (ibdw).

Methods: As a joint venture of the local Ethics Committee (EC), the data protection officer, and the legal departments of both the University & the University Hospital Würzburg, we developed an open consent document based on the recommendations of the National Ethics Council (NEC). It accomplishes the five NEC key-issues for biobanks storing human samples for unlimited time and unrestricted use. We implemented (1) measures to secure donors' privacy, (2) the right of withdrawal of consent at any time without any restrictions, (3) release of biosamples/data subject to the condition of an unrestricted vote of the respective reviewing ethics committee, (4) measures to secure quality control of data privacy, and (5) transparency of ibdw-processes including public involvement (internet-platform). In order to save time for the treating & informing physicians, an abridged version (flyer) was developed to inform patients & patient-families on the key issues of the ibdw.

Summary: The approved ibdw information/consent document clearly states that biomaterials & clinical data donated for medical research will serve both (a) to address current research questions, and (b) to meet future challenges in medical science. These comprise disease entities as cancer, heart-, brain-, skin-diseases, but may also extend to hitherto unknown diseases or genetic disorders. In addition to the vote of the reviewing EC, any delivery of ibdw biomaterials or data requires approval by the management board (feasibility), scientific advisory board (scientific merits), and executive board (decision).

ID number: 081

Sharing and Making Use of Digitalized Slides Obtained from Biobanked Human Tissue Samples for BIOPOOL: Legal and Ethical Issues

Bas de Jong1, Oihana Belar2, Arantza Bereciartua3, Elena Muñoz4, Fabienne Gandon5, Francesco Moscone6, Concha Alonso7, Peter Riegman1, Roberto Bilbao2

1 ERASMUS MC Tissue Bank, department of Pathology, 's Gravendijkwal 230, 3015 CE, Rotterdam, The Netherlands
2 Basque Biobank for Research-O+Ehun FUNDACIÓN VASCA DE INNOVACIÓN E INVESTIGACIÓN SANITARIAS (BIOEF), Plaza Asua s/n, Sondika, Bizkaia, Spain
3 FUNDACIÓN TECNALIA RESEARCH & INNOVATION, Parque Tecnológico de Bizkaia, Edificio 202, 48179, Zamudio, Bizkaia, Spain,
4 EMEDICA S.L., Ribera de Axpe 11 D1, 48950, Erandio, Bizkaia, Spain,
5 PERTIMM, 51, Boulevard Voltaire, 92600, Asnières-Sur-Seine, France
6 BRUNEL UNIVERSITY, Kingston Lane, Uxbridge (Middlesex), UB8 3PH, United Kingdom
7 CULTEK S.L.U., Av. Cardenal Herrera Oria, 63, 28034, Madrid, Spain

In the BIOPOOL system pools of digitalized slide images with associated clinical data are created. Users of the web-based BIOPOOL system can search for specific images by either a text query on clinical data or by uploading their own morphologically representative image to search for BIOPOOL images with a content-based image retrieval application.

All images and clinical data used in the BIOPOOL project are double coded; no identifiable personalized data is available for both project partners and end-users.
Processes carried out in the BIOPOOL project are performed at three legal and ethical levels. 1. National regulations: collection of samples, digitalized slides and clinical data by each biobank, currently BIOEF in Spain and Erasmus MC Tissue Bank in The Netherlands, but expansion with biobanks from other countries is foreseen. 2. The European Directive 95/46/EC: all actions on images and data performed in BIOPOOL to build the system. 3. International level: data entry to BIOPOOL from any country (biobanks sending images and clinical data to the central BIOPOOL system) and data exit from the central BIOPOOL system to users in any country when searching on the BIOPOOL system.

Images and associated clinical data remain within the BIOPOOL project: users searching on the image pools receive low-resolution images of each matching image together with contact information of the biobank of origin. Users may request for the original images and/or samples directly at these biobanks Therefore, the legal and ethical regulations of each involved biobank are respected while still enabling new services, using the full potential of digital pathology.

ID number: 086

A Specific Biobanks' Ethics Committee: The "CEBCI" Of Hospital La Fe

RAQUEL AMIGO (1); Elena Bellmunt (1); Ana-Belén Martín (1); M.J Gómez-Lechón (2); Serafín Rodríguez (3); Beatriz Alcayde (3) and José Cevera (1).

(1): Biobanco La Fe - Hospital Universitari i Politècnic La Fe (IIS La Fe) - Bulevar Sur, s/n, 46009 - VALENCIA (Spain).
(2) Department of Experimental Pathology - Hospital Universitari i Politècnic La Fe (IIS La Fe) - Bulevar Sur, s/n, 46009 - VALENCIA (Spain).
(3) Legal and Ethical Services - Hospital Universitari i Politècnic La Fe (IIS La Fe) - Bulevar Sur, s/n, 46009 - VALENCIA (Spain).

The Spanish legislation regulates, since the coming into force of the law 14/2007 about Biomedical Research, the biobanks' judicial framework. The chapter IV states, among other things, the biobanks' authorisation, their register and organization.
According to this regulation, every biobank must be ascribed to a Ethics Committee and a Scientific Committee. The medical centres have accredited and collegiate Committees of Clinical Research (CEIC, Spanish acronym); but biobanks need new frames and structures with competences more diverse, such as the Second Transitory Article notes.
With the authorization of the Biobanco La Fe, the CEIC of Hospital Universitari i Politècnic La Fe would accept responsibility for the Biobank's assessments; this fact would delay the validation reports of samples' transfers a lot. In order to avoid this, its aim was to set up an External Ethics Committee of Biobanks and Samples Collections for Research (CEBCI, Spanish acronym), which is part of the Hospital's Ethics Committee Research (CEI, Spanish acronym).
The CEBCI is in charge of evaluating the sample and information trasnfers, consulting to Scientific Director and helping in any ethical-legal issues (RD 17163/2011, Spanish law). It has its own Internal Rules and mechanisms to guarantee the independence and the lack of conflict of interest.
The goal of this communication is to show the proceedings of CEBCI's establishment, the different situations which are evaluated and some activity indicators.

ID number: 089

The Brazilian Regulatory Framework on Biobanking for Health Research compared with other International Regulations: some (but not total) consensus

Paulo H. Condeixa de França, Gabriela Marodin, Antonio Hugo Campos

Brazilian National Committee for Ethics in Research (CONEP) - Ministry of Health of Brazil; Esplanada dos Ministérios, Bloco G, Ed. Sede, 70058-900 Brasília - DF, Brazil

Background: Uniformity in biobanking regulations is needed to facilitate international collaborations and protect research subjects when samples are sent across national borders. In 2011, a new Brazilian regulatory framework on biobanks for health research came into effect. Comparison with other international regulations is warranted.

Materials and Methods: we have compared the new Brazilian legislation with guidelines from Spain, Australia, and Germany looking for points of consensus and controversies in main biobanking issues.

Results: There is some consensus concerning the need of written informed consent (and right to withdraw); the need to protect research subjects' privacy in all stages of the process; the need of ethical analysis of projects that require access to samples and related data; and the need to establish a national biobank register containing relevant technical, operational and organizational information about existing biobanks.
There is also a consensus on separating biobanks from restricted, duration-limited collections, although there is yet no uniformity on how to define both collections and, consequently, establish the scope of their functions and limits. This is particularly true concerning research subject's protection internationally. Not all regulations provide standards of international collaboration, covering the sending and receiving of foreign samples. The return of research results is also a matter of controversy that needs a minimum agreement.

Conclusions: There should be a concerted international initiative towards uniformity in biobanking regulations, particularly covering the protection of research subjects, the use of samples and data and the return of research results. Only then international collaborations involving biobanks will flourish.

ID number: 090

Personalized assent for pediatric biobanks

Noor A.A. Giesbertz, Annelien L. Bredenoord, Johannes J.M. van Delden

University Medical Center Utrecht, huispostnummer 6.131, P.O. Box 85500, 3508 GA UTRECHT

Assent is a relatively young term in research ethics, but became an often mentioned ethical requirement in current pediatric research guidelines. Also the European Society of Human Genetics considers assent an important condition for the inclusion of children in biobanks. Although many emphasize the importance of assent, few explain how they understand the concept. In this paper we will discuss the concept of assent and its different underlying ethical principles.
In the first category, assent appears to be a substitute for informed consent, grounded in respect for autonomy and protection against harm. We conclude that this interpretation of assent is not of added value as a majority of children cannot be considered competent to make autonomous decisions. In addition, other safeguards are more appropriate to protect children against harm. The grounds from the second category can be classified as engagement grounds. These grounds do justice to the specifics of childhood and are of added value. Furthermore, we argue that it follows that both the content and the process of assent should be adjusted to the individual child and the study at hand. This can be referred to as personalized assent. Personalized assent is an appeal to the moral responsibility and integrity of the researcher. In addition, we will discuss how personalized assent should be implemented in pediatric biobanks research.

ID number: 093

Biobanking for genetic research: ethical legal and social issues beyond traditional bounds

Karen Melham

HeLEX Centre for Health Law and Emerging Technologies, University of Oxford, Rosemary Rue Building, Old Road Campus, Oxford OX3 7LF

Biobanks are fundamental resources for biomedical research. They are particularly useful for research requiring large sample sizes, such as genetic studies. This poster addresses core ethical, legal and social (ESLI) issues that arise in biobanking for genetic research. Delving more deeply into the usual – and still necessary – considerations of consent, withdrawal, privacy, feedback, benefit sharing and governance, this poster addresses the particular issues raised by the very intersection of biobanking and genetics within the regulatory oversight of medical research. While not claiming exceptional status for either, it argues that both biobanks and genetic research represent specific instances where the established ethical norms and practice of medical research may not be fit for their purposes. From the fiction of anonymity to the conflation of requirements for banking with those for invasive or interventional research, this poster reassesses the ethical, legal and social requirements – and possibilities – of biobanking for genetic research.

ID number: 111

Balancing the rights and obligations of stakeholders in relation to access to biobanks

Michiel Verlinden and Isabelle Huys

Research Centre for Pharmaceutical Care and Pharmacoeconomics, KU Leuven, O&N 2, PO Box 521, Herestraat 49, 3000 Leuven, Belgium

Access in an efficient way to human biological materials (hereafter 'HBM') and associated data is crucial for biomedical research. Biobanks and biobank networks, as custodians, need to exercise a certain control on access to their resources to guarantee its long-time sustainability and the scientific, ethical and legal correctness of its use. The study intends to investigate whether (a) the social constructivist theory of ownership as applied to HBM by B. Björkman and/or (b) the ethical model of custodianship can enable us to determine in a balanced manner the bundles of rights (and/or obligations) held by different stakeholders – the patient/donor, the custodian and the applicant – in relation to access to HBM and/or data collected for biomedical research.

The empirical study starts with an inductive content analysis of (a) legislation on biobanking, custodianship of data and custodianship within clinical trials; (b) legal theories and studies on ownership and custodianship of HBM;(c) tables summarizing data on the concepts of ownership and/or custodianship resulting from a comparative analysis of 52 access policies and agreements of biobank networks and biobanks.

References: 1. Björkman, B. Different types--different rights. Distinguishing between different perspectives on ownership of biological material. Science and engineering ethics 13, 221–33 (2007); 2.Yassin, R. et al. Custodianship as an ethical framework for biospecimen-based research. Cancer epidemiology, biomarkers & prevention 19, 1012–5 (2010).

ID number: 114

Biobanking Challenges in Illiterate and Low Resources Context: Case of Mali

Samba DIOP, Mahamadou DIAKITE, Awa KEITA and Seydou DOUMBIA

Faculty of Medicine, University of Bamako, BP 1805 Bamako, Mali. Contact: saibd@icermali.org

Background: The development of new scientific and therapeutic knowledge related to genetic and genomic research requires ethical, legal social context of individuals and communities under study. In absence of such a formal structure in Mali a study of a holistic approach to these issues requires the utmost importance for the development of ethical standards and fair procedures transparent and impartial. This study, a pilot study in Mali context where our University actually faces issues related to biobanking dilemmas.

Method: Understanding Community- engagement of the genetic and genomic studies performed by public and academic researchers is the biggest ethical and legal challenge for continuous production and use of human biobank. In societal context where there is a big gap between educated people and illiterate people in Mali.

Results: This qualitative study among local actors demonstrates the cultural gap on human genetic and genomic research. It appeared relevant to ELSI public health Issues of genetics/genomics research where national actors are facing challenges related to – lack of regulation and law related to genetics research and also lack of preparedness and awareness of EC members on how to deal with current genetics/genomics by providing guidelines; and stigmatization / discrimination related to genetics disorders.

Conclusion: Identify and documents those gaps provided evidence basis for improving ethic review of genetics protocols by EC, providing appropriate communication strategy for researchers in local socio cultural environment, improving community awareness and understanding of risk and benefits related to genetics research relevant for ethics education specific to genetic research in the country.

ID number: 132

Easy! Requesting and sharing reagents, biospecimens and data through the new Technology Agreement Dashboard at the US National Institutes of Health

Marianne K. Henderson, M.S. and Lisa Finkelstein, Ph.D. National Cancer Institute, NIH, DHHS, USA

National Cancer Institute, NIH, DHHS, USA; 9609 Medical Center Dr., Rockville, MD USA 20850-9777

In 2010, the Policy for the Transfer of Materials from NIH Intramural Laboratories (http://www.ott.nih.gov/PDFs/Policy-for-the-Transfer-of-Materials.pdf) was approved to outline material transfer processes and to strengthen the procedures for the transfer of human samples. Concurrently, several efforts to streamline the processes of requesting and sharing biospecimens, reagents and data were undertaken at the US National Institutes of Health. NIH also finalized a model human MTA template with specific terms for transfers of human materials with or without accompanying data (http://www.ott.nih.gov/index.aspx). With input from staff across the NIH, a web-based system was developed and launched that manages and tracks MTAs (Transfer Agreement Dashboard (TAD)) to streamline the transfer of research materials between the NIH and the biomedical research community. NIH has also launched the electronic Research Materials catalogue (eRMA), an analogous system for licensing unpatented research materials to for-profit entities. The two systems are expected to reduce dramatically the transaction time for transferring biospecimens, reagents and data. The systems are in the dissemination and enrollment phase to allow more universities, academic and research centers worldwide to access the rich collections at the US NIH as well as to support collaborative research with NIH scientists. The presentation will show the capabilities of the system including how to enroll in the system, the ease and what type of biomaterials and data that be exchanged.

ID number: 138

Biobanking towards a participatory agreement among scientists and society as innovative standard of quality

Sara Casati, Maria Marcheselli, Annalisa Scopinaro, Renza Barbon Galluppi,

UNIAMO FIMR San Marco 1737, 30124 Venice, Italy

2013 is a special year for biobanking: the European infrastructure BBMRI-ERIC becomes operative, the Council of Europe renews the "Recommendation on research on biological materials of human origin" and both initiatives consider crucial citizens' active involvement and public information, which changes the perception of citizenship concerning conservation and scientific use of human biological materials. If in 2010, 67% of Europeans declared to the Eurobarometer not to have ever heard of biobanks, in May 2013, at Dubrovnik, Eurordis presented a survey of European Rare Disease associations: about 80% of them opted for the databases destruction, in case of change of their conservation venue. It should be a participatory agreement among citizens, patients, and researchers, mediated by health professionals, that represents also a responsibility agreement among all the actors at stake, from patients to researchers, mutually necessary for this new innovative model of scientific research. UNIAMO FIMR has identified this deep need during the pilot initiative ATTIVAMENTE INSIEME PER LA RICERCA performed at ARC-NET, in Verona, and at CNR, in Naples. Rare Diseases Associations have required to be part active in biobanking: through deliberative workshops patients associations with researchers and biobankers have worked on a proactive inclusion of patients into the biobanking infrastructure itself, sustained a permanent interaction towards a cognitive/decisional conflicts resolution and a scenario of quality and co-production of knowledge. UNIAMO in partnership with Welfare Ministry and the principal research institutions will work to promote participation as standard of biobanking good practice, thanks to Determinazione Rara, a training national programme

New Technology

ID number: 014

Network based biobanking for biomarker discovery

Zsolt Torok

Astrid Biosciences GmbH., 888 Avenue Road Toronto, ON M5P2K6, Canada

The concept of personalized medicine in drug research and development is more than ten years old. However, its impact on daily clinical routine is invisible in many therapeutic areas. The reason behind this failure is related to the shortage of good quality biomarkers that call for large scale translational research studies with the involvement of well-defined patient groups. Existing biobank projects usually do not record clinical, lifestyle and environmental data. On the other side, clinical research management systems and hospital information systems have been designed for different goal, therefore relevant information is missing for biomarker research.
Our Smartbiobank project attempts to provide solution for the above problem. Its web based bioinformatics platform standardizes the processes of biobanking including clinical and experimental data collection, storage, integration, and interpretation. The freely available biobank information system highly relies on network effect. Foreseeably, large number of research project will use the system in the future, thus researcher will be able to share data or merge independent projects. The Smartbiobank system was launched in April, 2013. By the end of the first month 30 research groups have registered from 4 continents.

ID number: 030

eagle.trace - Software for Biological Sample Tracking in a Biobank

Davide Nocentini

Linde AG, Linde Healthcare, Seitnerstrasse 70, 82049 Pullach, Germany

The eagle.trace platform is a web-application developed using the latest technologies, and responds to the needs of traceability management in the increasingly developing sector of biobanks. It is the first system capable of tracking the lifecycle of any biological sample, in accordance with GAMP 5 and CFR 21-11 (FDA) standards and recommendations, integrating seamlessly with biobank automation software used for managing cryovessels, mechanical freezers, incubators and other equipments.

Each facility is requested to register at the ICCBBA, the organization that has created a standard terminology and developed a coding standard called ISBT128, standard upon which this software is based.

The system allows you to customize data types that can be used within the software, always keeping within the standards, and is designed to manage information about patients and samples even automatically, interfacing with Your platform. It includes: donor identification, collection, preparation / handling, cryopreservation and transplantation, or where applicable, release of product.

A biological sample can be registered from a collection request, or on research purpose, specifying manipulations to be performed, and all the tests already carried out. It is also possible to accept every kind of biological samples from other centres, labelled according to ISBT128 standards or not.

For each biological sample is possible to view actual and historical placements, processing history, trend of biopreservation temperatures and related alarms. It is also possible to create any type of label specified in the ISBT128 standards and even custom-sized labels in case of sterile packages of non-standard dimensions.

ID number: 043

Biobank Graz: Automated pipetting with direct freezing

Michaela Bayer, Skaiste Riegler, Karine Sargsyan, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: Biobank Graz at Medical University of Graz, Austria, is the largest of its kind in Europe and aims to advance research through collection, processing and storage of human samples and their associated clinical data.

New technology: To facilitate collection of body fluids like serum, plasma or urine, Biobank Graz defined an interface for data transfer in cooperation with two companies, one for the pipetting robot and one for the LIS-system. Pre-programmed methods (volume and number of aliquots) are used as templates and performed automatically for each sample in a "real time request" manner. The robot scans barcodes of primary tubes, transmits these to LIS and gets back the pipetting information.
The robot is equipped with four pipetting channels and special tools for opening, closing and transporting 2D Data Matrix coded target tubes without any interaction of an operator. An integrated camera creates images of the primary tubes. An image processing software recognizes the buffy coat and generates scripts to automatically separate fractions into target tubes. Afterwards, the samples are frozen at minus 20°C immediately after pipetting by an integrated freezing system on a single tube level. Samples are stored in an automated minus 80°C sample storage system.

Benefit: Automated handling of samples combined with all process information leads to increased process reliability and stability. Due to systematic direct sample freezing, variations in processing at room temperature are dramatically reduced. Both aspects are essential for answering research questions which are becoming more and more complex in the future.

ID number: 047

Biobank Graz: Semi-automated FFPE sample storage

Michaela Bayer, Karin Konrad, Robert Primschitz, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The core asset of Biobank Graz is one of the largest collections of clinical samples in Europe, comprising millions of tissue and blood samples. The tissue samples are freshly frozen and stored in the gas phase of liquid nitrogen or formalin-fixed, embedded in paraffin (FFPE) and stored at room temperature. The FFPE samples are derived from diseases at their natural frequency of occurrence, representing diseases from all organs and all age groups over the last 30 years.

New technology: To cope with the huge amount of samples and data, Biobank Graz has advanced storage of FFPE samples with corresponding slides. A semi-automated storage system has replaced the processes of manually handling incoming and outgoing samples in daily routine.
To store large sets of samples, an optimized use of space is required. One central item is a specific storage box developed in the context of a master work at the Technical University of Graz. Each sample (FFPE and the corresponding slides) is labeled with a 2D Data Matrix code, scanned during the storage process, and linked to clinical data. Each incoming and outgoing sample is documented in specific databases.

Benefit: The scientific value of the existing tissue collection is based on its size, technical homogeneity, and its population-based character. These features provide ideal opportunities for epidemiological studies and allow the validation of biomarkers. Using the semi-automated storage system, easy and fast access to samples is ensured and guaranteed.

ID number: 050

Case Study: Creating a successful facility for large-scale extraction of DNA

Carita Björkman, Gunnel Tybring, Mark Divers, James Thompson

KI Biobank, Medical Epidemiology and Biostatistics, Nobels väg 12A, Box 281, SE-171 77 Stockholm, Sweden

Driven by the needs of several large population cohorts, we have implemented a large-scale facility for rapid purification of high quality DNA from human whole blood at KI Biobank. We routinely obtain 10-15 μg of DNA from 0.4 ml whole blood with a throughput of up to 1000 samples per day on two parallel automated systems. Automation and modern extraction chemistry has given many benefits, and since starting the operation in May 2011 we have extracted DNA from over 100,000 individuals in 4 major cohort studies. These modern studies are investigating the interplay between genes and environment in some specific diseases and are making use of advanced genotyping techniques.

Our early experience clearly demonstrated the potential of the new systems in speed, quality and cost. We gained significant process improvements that would have been impossible in our previous semi-automated systems. But we also experienced several difficult challenges with the approach. The modern genotyping platforms have also developed rapidly and we found that some of them are very sensitive to DNA quality parameters we didn't anticipate. We also experienced working environment problems due to the larger scale of operation.

We have now devoted much effort to solving the problem, and have learnt many lessons, which we will present here. We will also present examples of progress from the cohort studies and our plans for future development to handle other applications such as RNA extraction.

ID number: 071

BIOPOOL PROJECT: A new approach to look for samples across worldwide biobanks

Oihana Belar (1), Bas de Jong (2), Arantza Bereciartua (3), Rebeca Ruiz (4), Maria Amparo Viguri (4), Ricardo Rezola (5), Eduardo De Miguel (6), Sara Fernandez (7), Ayman Gaafar (8), Blanca Catón (9), Javier Aguirre (9), Alberto Saiz (6), Michael Doukas (10) , Elena Muñoz (11), Fabianne Gandon (12), Peter Riegman (2), Roberto Bilbao (1)

(1)Basque Biobank for Research_BIOEF, Plaza de Asua s/n-48150, Sondika, Spain (2) Erasmus MC Tissue Bank, Dr. Molewaterplein 50, 3015 GE Rotterdam, Netherlands; (3) Tecnalia, Ibaizabal Bidea, 202 – 48170 Zamudio (Bizkaia) -Spain; (4) Basque Biobank_Txagorritxu Universitary Hospital, C/ Jose Atxotegi, s/n - 01009 Vitoria-Gasteiz, Araba/Álava; Spain (5) Basque Biobank_Onkologikoa, Paseo Doctor Begiristain, 121, 20014, Donostia, Spain; (6) Basque Biobank_Galdakao Hospital, Barrio Labeaga, s/n - 48960 Usansolo, Spain (7) Basque Biobank_Basurto Universitary Hospital, Avenida de Montevideo, 18 - 48013 Bilbao, Spain; (8) Basque Biobank_Cruces Universitary Hospital; Plaza Cruces s/n, Barakaldo, Spain; (9) Basque Biobank_Santiago Hospital, C/ Olaguibel, 27 - 01004 Vitoria-Gasteiz, Araba/Álava, Spain (10) Erasmus MC department of Pathology, Dr. Molewaterplein 50, 3015 GE Rotterdam, Netherlands; (11) eMedica, Paseo Mikeletegi 57, 20009, Donostia, Spain; (12) Pertimm, 51, boulevard Voltaire – 92600 Asnières-sur-Seine - France

Searching human samples across Biobanks is a hard task due to the geographically dispersed biobanks distribution and the lack of online accessible robust samples catalogues. Therefore, a new web-based approach to provide a virtual view across multiple sites is desirable. The BIOPOOL consortium (www.biopoolproject.eu; 7PM EC) has developed an innovative web search to look for samples located at different biobanks. In the BIOPOOL web search engine, a researcher can find the localization of the requested samples in a biobank network by either inserting clinical text data or/and by uploading a morphologically representative image. For the latter, new technologies for a content-based image retrieval application have been developed to find histomorphological similarities between the uploaded image and images from the requested samples, stored in biobanks of the BIOPOOL network. For this aim, pathologists involved in Basque Biobank and Erasmus MC Tissue Bank have selected the representative regions of interest within scanned slides and defined the minimum associated data based on a pool of colon carcinoma samples. Prototype validation has been done from both a technical and user's point of view. The Proof-of-Concept has been done in the first year of the project. Developments now proceed by adding more pathologies, especially rare diseases, and by offering biobanks the possibility to join the BIOPOOL network as sample-image contributor. BIOPOOL is a new approach to build up a virtual network of samples reservoirs located in worldwide biobanks based on innovative technologies by exploiting the full potential of digital histological images and the data associated.

ID number: 076

Exploring Sample Preparation Techniques that Optimize Biospecimen Collections for Prospective and Retrospective Research

Kai-Alexander Wiemer

BioStorage Technologies, Im Leuschnerpark 1B, 64347 Griesheim Germany

Recent advancements in molecular biology, genetics and pathology presents unprecedented research opportunities for scientists to apply biomarkers to better understand the origin and diagnosis of diseases and their subsequent prevention and treatments. Much of this progress has been propelled by access to high-quality biospecimen samples and advancements in sample preparation and bioprocessing techniques, which support pharmacogenomics and biomarker research. Given the intrinsic value of these materials, high standards for sample management from the point of collection, and throughout the complete sample processing and/or storage lifecycle, to destruction has become critical for prospective and retrospective biomarker analyses.

The availability of high-quality samples are vital to the development of new drug therapies and can help speed molecules to the market faster while supporting reductions in clinical development costs. Further, analytical and pre-analytical variables introduced during the sample collection and processing can contribute significantly to errors in testing if not mitigated upfront. As such, sample processing and preparation requires careful coordination and planning to reduce the variability that can degrade sample integrity.

The presenter will review the following components of comprehensive sample management and detail how these techniques can optimize sample inventories:

- Best practices for sample collection, registration & accessioning
- Considerations for long-term sample storage
- New sample bioprocessing methods that are emerging to support research and development
- Best practices for reducing pre-analytical variables through sample preparation
- Implementation of a virtual sample management database to track stored and shipped samples
- Global regulations impacting sample management

ID number: 096

New Instrumentation for Sustainable and Cost Efficient Long-Term Storage of Biospecimens at Ambient Temperature

Marthe Colotte1, Loïc Cessot1, Jacques Bonnet1,2, David Georges de Souza1, Sophie Tuffet1.

1:Imagene, production platform, Rue Henri Desbruères, Genopole campus 1, Bât 6, 91030 Evry, France, 2: Institut Bergonié, U916, 229 Cours de l'Argonne, 33076 Bordeaux, France

Background/information: As biobanking activities and storage volumes increase, the need for efficient biospecimens long-term preservation solutions grows accordingly. Although cold storage currently remains the most widely used technology, ambient temperature storage solutions are becoming available. Those methods aim at providing cost effective and easy to handle solutions for the storage of nucleic acids and/or biospecimens from which they can be extracted when needed. This fundamental change in storage conditions makes it possible to avoid all the well-known limitations of cold storage: storage space requirements, time-consuming and cumbersome access to samples, costly and complex thermo-regulation logistics, deleterious freeze/thaw cycles, costs in energy, maintenance and infrastructure, exposure to natural disasters. Nevertheless, mid- to long-term storage at ambient temperature has specific and mandatory requirements which must be not overlooked.

Methods: In order to meet these requirements, Imagene has developed breakthrough preservation solutions for long-term, stand-alone storage of dried biospecimens. Once desiccated, samples are kept in airtight stainless steel capsules, under an anhydrous and anoxic atmosphere; that way, full protection from deleterious factors (oxygen, ozone, moisture, and light) is achieved. These tamper-proof capsules are 2D-bar coded and placed in 96-well racks allowing fully automated upstream and downstream processes.

Results/Future developments: Initially offered as a service solution, this procedure can now be carried out "in-house", thanks to medium to high-throughput instruments, allowing laboratories and biobanks to conveniently and economically benefit from such a powerful technology.

ID number: 129

A novel technology for stabilizing eukaryotic cells dry at room temperature

Albert Perez-Ladaga (2), Vasco Liberal (2), Senait Ghirmai (2), Carina Wimer (3), Kai Brewer (1), Robert Lothringer (1), Paul W. Diaz (1), John C. Reed (1), Judy Muller-Cohn (1,2) and Rolf Muller (1,2)

1) Cyternity, Inc., 5627 Oberlin Drive, Suite 120, San Diego, CA 92121
2) Biomatrica, Inc., 5627 Oberlin Drive, Suite 120, San Diego, CA 92121
3) Sanford-Burnham Medical Research Institute, 10901 N. Torrey Pines Rd., La Jolla, CA 92037

We have developed novel biostability molecules that allow for the preservation of live eukaryotic cells in the dry state at ambient temperatures. We demonstrate that exposure of mammalian cells to the biostability molecules protects them from cell death during dehydration. Both primary and immortalized or transformed cells stabilized in this fashion recover rapidly during the revitalization process with high yields of proliferative and functional cells. These findings open the door to the development of long-term, room temperature stabilized, eukaryotic cells and their use in biomedical research, product development and direct applications in diagnostics, blood supply logistics, regenerative medicine and cell transplantation.

ID number: 147

Interconnecting biobanks to their partners, collaborators and contributors using an open science platform

Joe Yeager, Mary Napier

Cliqr Technologies.530 Lakeside Drive, Suite 110; Sunnyvale, CA 94085

Modern biobanks are important platforms for technology integration between genomics, the patient and the medical sciences. Biobanks bridge two very different worlds: they connect to patients at a human scale, but also aggregate information and are at the cutting edge of scientific discovery. Biobanks affiliated with large multi-institutional studies face a significant volume of data and medical records associated with each sample. To store, manipulate and manage sample information requires a powerful laboratory information management system, yet the lack of a common platform , database, or standards hindered many groups from sharing information about their collections.

The CliQr Open Science Platform simplifies the access to the necessary IT tools for researchers and institutions to access such software and capabilities. We will describe a case study using an open source and proprietary biobanking tools developed at multiple locations for use in real world biobanks such as for The Cancer Genome Atlas program. By making the software cloud based it significantly reduces the upfront cost to biobanks who need a sophisticated LIMS software or a secure environment for sharing data.

We will discuss the technical challenges in the creation of this platform, issues around Cloud computing and bioinformatics, and how computation and storage requirements drive choice of Cloud. Use of multiple applications taking data from its raw form through to final presentation will be demonstrated. The benchmarking capabilities of the Open Science Platform will be presented, and the rapid transition of applications between Clouds to allow for optimum performance or cost behaviour..

ID number: 158

New phenol-free technology for simultaneous DNA/ RNA/miRNA extraction from difficult-to-lyse and FFPE tissue

Stefanie Schroeer, Christiane Baeumer, Devika Mathur, Friederike Kraemer, Martin Schlumpberger

QIAGEN GmbH, QIAGEN Str. 1, 40724 Hilden

The demand for simultaneous purification of different analytes from the same sample is increasing, especially in research fields such as translational medicine and biomarker studies. In applications such as genomics or transcriptomics studies, there is also an elevated need for simultaneous purification of miRNA, in addition to DNA and RNA. The development of standardized and reliable procedures for sample storage and simultaneous purification of these analytes is therefore crucial. The combination of Allprotect and AllPrep® technologies provides a complete solution for sample preparation in systems biology. Allprotect Tissue Reagent delivers immediate stabilization of DNA and RNA in tissue samples for long-term storage without freezing, while AllPrep Kits allow simultaneous purification of DNA and total RNA, including miRNA from the same precious tissue sample, including lipid- and fiber-rich tissue. The purified DNA and RNA/miRNA are eluted separately and are ready for use in a variety of downstream applications such as qRT PCR, qPCR, and next-generation sequencing.

ID number: 162

DNAQual: an index of human DNA quality validated in different degradation models

Bruno Tschirret 1, Mohit Parekh 2, Denis Fortier 3, Diego Ponzin 2, Nadine Martinet 1 and Marie-Claude Amoureux 3,4

1: Institut de Chimie de Nice, Parc Valrose, Nice 06108 Cedex, France
2: Fondazione Banca degli Occhi del Veneto Onlus, Padiglione Rama, 30174 Zelarino, Venezia, Italy
3: Eurobio, 7 Avenue de Scandinavie, Les Ulis, Courtaboeuf Cedex B, France
4: Aix-Marseille University, CNRS, Institut de Biologie du Développement de Marseille-Luminy UMR 7288, 13288 Marseille, France

DNA quality is of paramount importance to interpret results in genetics, forensics and sequencing studies. Bio banking has gained increasing interest and potential for epidemiologic investigations, personalized medicine, and evaluation of therapeutic targets. Despite great care in sample preservation, different factors such as post mortem time, storage temperature conditions, light exposure, affect DNA quality. Therefore, there is a need to accurately qualify bio preserved samples, were they be tissue or DNA samples. The present study describes a DNA quality index, named DNAQual, which allows in a single duplex quantitative Polymerase Chain Reaction (qPCR) assay to quantify the quality of human DNA. DNAQual index is independent of the amount of starting material within the range of 5 to 200 ng DNA. The test can use small amounts of DNA material (down to 5 ng), which is an advantage, particularly well suited for rare samples. The quality of the DNA samples is evaluated against freshly prepared DNA from whole blood, dehydrated and encapsulated. This control DNA is shown to be stable for at least 5 years. DNAQual index was evaluated after heat, DNase and Ultra Violet treatment, and correlated with the size of DNA fragments. In the current study, it is applied to DNA freshly extracted from blood clinical samples or human donor cornea tissues preserved in hypothermic conditions.

ID number: 167

Development of cell-based arrays to characterize stem cells and their derivatives

Alberto La Spada1, Aikaterini Ntai1, Jacopo Turri3, Luca Pavesi2, Alessandra Storaci2, Miriam Aresi2,Simona Baronchelli3, Monica Cattaneo3, Andrea De Blasio1, Pasquale De Blasio1, Ida Biunno 2,3

1Integrated Systems Engineering srl, Via Fantoli, 16/15, 20138 Milan, Italy; 2Institute for Genetic and Biomedical Research, Via Fantoli, 16/15, 20138 Milan, Italy; 3IRCCS Multimedica, Via Fantoli 16/15, 20138 Milan, Italy

The assembly of in vitro cultured cells into a tissue microarray-like block facilitates the analysis of protein expression in a range of different experimental settings, where cells have been manipulated prior to fixation. Cell-based microarrays are particularly important to: quickly test new antibodies with unknown staining patterns; immunophenotype stem cell populations; assess treatments performance and as a quantitative control tool. Here we will describe the application of cell line microarray to characterize neuronal derived human stem and cancer stem cells.

ID number: 179

Improved storage system for liquid nitrogen tanks

Beate Tiran, Christian Amon***, Karine Sargsyan**, Andreas Tiran**

Clinical Institute for Medical and Chemical Laboratory Diagnostics and Biobank**, Medical University of Graz, Universitätsplatz 3, 8010 Graz, Austria; M&R Automation GmbH***, Teslastrasse 8, 8074 Grambach, Austria*

Storage of biological samples in tanks cooled by liquid nitrogen is generally considered the method of choice for subsequent analysis of most of the sensible biomarkers. However, despite the increasing evidence that such samples are very sensitive to temperature changes even far below the thawing temperature, conventional, widely used storage systems can not guarantee uniform and constant temperature especially when frequent access to the system is required for insertion or retrieval of samples. An automated cryogenic storage device is available that eliminates these drawbacks, however the system is very expensive and very slow in operation.
We developed a new storage system to resolve the shortfalls of the systems currently available. Samples are not stored in boxes stacked up in racks with shelves, but in vertically accessible chains. In this way, the amount of samples moved during storage and retrieval processes are reduced to a minimum. Handling of samples can be performed much faster without the need of removing whole racks from the cooled environment of the tank. In this way, the temperature fluctuations in manipulated as well as close-by stored samples can be kept to a minimum while the hands-on work time can be reduced by approximately 50%. A quantitative evaluation of the technical performance of the system is under way. We will present the features of the system with respect to temperature constancy, liquid nitrogen consumption and handling times in comparison to a conventional storage system.

ID number: 180

The Impact of Preanalytical Variables in Blood: Enabling High Quality Protein Analysis

David Craft, Daniel Marchiarullo, Jizu Yi, Priyanka Apte

1 Becton Drive, Franklin Lakes, NJ, USA 07471

The scientific efforts on biomarker discovery research in the past five years have resulted in numerous potential biomarker candidates. These biomarkers, however, require further investigation by verification and validation in the clinical setting prior to specific application. One major hurdle in the transition from the research lab to the clinical lab is high quality banked samples. Preanalytical variability, most notably, time and temperature can have a significant impact on analyte stability. This presentation will address the potential impact of sample handling on protein and peptide stability and how this variability can be controlled through the use of protease inhibitors. Mass spectrometry will be used to demonstrate protein instability in conventional serum and plasma (citrate, heparin, EDTA). The same techniques will also be applied to plasma containing protease inhibitors clearly displaying stabilization.

In addition to mass spectrometry, antibody based accurate measurement of BNP in blood with protease inhibitors will also be presented. BNP was compared in EDTA vs EDTA + protease inhibitors using ADVIA Centaur immunoassay by Siemens Healthcare. Degradation of BNP due to protease activity was quantitatively examined in both blood collection tubes. Other examples of peptide instability overcome with DPP-IV protease inhibitors covered in this presentation will include Glucagon-like peptide-1 (GLP-1), Gastric inhibitory polypeptide (GIP), Glucagon, and Oxyntomodulin. These four plasma peptides are of particular interest in biobank storage for metabolic disorder research, especially diabetes drug research.

Stabilization of the aforementioned peptides is vital prior to biobank storage to ensure high quality samples for future analysis. Further, stabilization of proteins and peptides could improve the success rate of transitioning biomarker candidates from discovery research to clinical applications.

Other Topics

ID number: 009

Radboud Biobank: a central facility for prospective clinical biobanking in the Radboud University Medical Centre, Nijmegen

P. Manders, A.E. Siezen, W.L. Koevoets, C. Smit, D.W. Swinkels, G.A. Zielhuis

Radboud Biobank (440), Radboud University Medical Centre, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands

There is a growing need for large-scale data and biobanks for biomedical research. Therefore, a central biobank facility at the Radboud University Medical Centre, Nijmegen, the Netherlands, was established to contribute to biomedical research and innovation by creating an infrastructure for collecting, storing and managing biomaterial and associated clinical data. The Radboud Biobank was conceived from the standards that were laid down in the String of Pearls Initiative (PSI), a unique partnership between the eight University Medical Centers (UMCs) in the Netherlands, that contributes to innovation in health care by facilitating biomedical research.

The Radboud Biobank has set procedures for handling, storage and release of samples and data. These procedures are generic and established with a view on standardization, quality and efficiency, transcending the interests of single departments. Furthermore, (quality) standards are set in the field of ICT, legal and ethical aspects, communication and distribution. The establishment of the Radboud Biobank creates an efficient and high quality facility for scientific research and medical innovation.

ID number: 028

The Australasian Biospecimen Network Association – Building links for biobanking across Australia and New Zealand

Tas Stylianopoulos, Lisa Devereux, Megan Ellis, Trina Yeadon, Catherine Kennedy, Rhonda Huynh, Helen Morrin, Jane Carpenter

ABNA 2013 Executive Committee, c/o Research Department, Peter MacCallum Cancer Centre,Locked Bag 1, A'Beckett St, East Melbourne, VIC 8006, Australia

The Australasian Biospecimen Network Association (ABNA) is a professional organisation established in 2001 and incorporated in 2009. ABNA provides a forum for discussion of technical, ethical, legal, societal, and managerial issues relevant to the supply and use of human biospecimens in medical research.

A number of Australian scientists engaged in biobanking activities recognised that a 'gap' existed in opportunities for sharing of information and practices amongst people engaged in this young and emerging speciality.

The ABNA's main focus areas are:
* Supporting new and emerging biobanks through protocol sharing and collegiate support
* Promoting biobanks throughout Australia and New Zealand to ensure high quality biospecimens are provided to support high quality research
* Networking co-operatively and collaboratively with funding bodies and regulators to promote the interests of biobanking

ABNA serves the biobanking community, research community and the general public and is managed by a committee structure elected by the membership.

Each year a conference committee is convened from the membership. A professional meeting has been held annually since 2003 in various states of Australia. The 2014 meeting will be held in New Zealand, the first time we have met outside of mainland Australia.

The ABNA meeting has a unique focus from year to year to reflect the ever changing landscape in biobanking.
We are very proud to have over 120 members. The ABNA website was launched in 2012 and functionality will expand to include a chat room style forum in 2013.

www.abna.org.au

ID number: 049

CIBERER Biobank: A support platform for research into rare diseases.

Salvador Martí Pérez1, Virginia Corrochano James1, José María Millán Salvador1,2, Francesc Palau Martínez1,3.

(1) CIBERER Biobank, Centro Superior de Investigación en Salud Pública (CSISP), Valencia, España; (2) Unidad de Genética, Instituto de Investigación Sanitaria-La Fe, Valencia, España; (3) Centro de Investigación Príncipe Felipe (CIPF), Valencia, España.
CIBERER Biobank - Av. Cataluña, 21 - 46020 Valencia - SPAIN - Tel. +34963484380/Fax. +34963485362

CIBERER Biobank (CBK) is a public-non-profit-making biobank set up by the Centre for Biomedical Network Research on Rare Diseases (CIBERER) and located at the Centre for Public Health Research (CSISP) in Valencia, Spain. The CBK is currently offering different types of services to the scientific community and working in the implementation of new protocols to support research on Rare Diseases (RD). In addition, the CBK is closely working with several research groups and collaborating in different projects, both national and international, to enhance its added value as a biobank operating in the field of RD. The services offered are DNA extraction, fibroblasts culture from skin biopsies, B cell immortalisation from peripheral blood, myoblast isolation and culture from muscle biopsies and, in a foreseeable future, iPS cells generation from fibroblasts. In this sense, the participation in different projects related to RD and the increase on the number of service requests received by the CBK show up the importance of the CBK as a support platform for the scientific community in the field of RD. To summarise, though the aim of the CBK is to constitute a repository of human biological samples related to RDs, it additionally provides different services to the scientific community, working closely with research groups to offer technical support and services to those researchers interested in this wide and diverse group of low prevalence pathologies.

ID number: 054

Pathology lab accreditation stimulates tissue research support, leading to better research results.

L. de Vogel, P. Riegman

Erasmus MC, The Netherlands

Research on tissue specimens requires specialized knowledge, trained personnel, and dedicated equipment and procedures. In the Erasmus MC, researchers, within the institute, have been making use of the expertise and equipment of the clinical pathology department for years. Because of our recent ISO15189:2007 accreditation and to provide better histotechnical services we started the Tissue Research Support Unit (TRSU) as part of our tissue bank facilities. TRSU services include tissue processing to paraffin blocks, preparing blank slides, (immuno)histochemical stainings, plastic techniques, coordinating request for clinical trials etc. Next to this, TRSU enables making use of the diagnostic archive (under strict conditions), and assists with making TMA's and scanning of virtual microscopy images. The Erasmus MC now has one place where researchers can request for histotechnical assistance, whatever meets their needs. To cover expenses, a small fee is charged. Due to the level of training of the routine technicians, availability state of the art equipment with sufficient extra capacity and bulk discounts on reagents, these services will be cheaper and of a higher quality than if small research groups, often represented by inexperienced PhD candidates, do the work themselves.

ID number: 083

Analysis of Yeast and Mould Species Commonly Found in High Risk Units of C.H.U. Oran, Algeria

Zakaria BENMANSOUR

Department of Parasitology and Mycology C H U, Faculty of Medicine, University of Es- Senia Oran, Algeria. Mail: benzakarion31@yahoo.fr
Tel 00213770321576

The aim of the present study was to study and identify the causative agents, fungal frequently found in many spaces in high risk area of hospital .The aim of the present work was to compare the identification of yeast isolates from patients and environment and mould performed with API ID 32C and Auxacolor II (Biorad) and(PCR) identification of fungal DNA.

ID number: 099

Italian Network of Genetic Isolates Biobank: a good instrument to study complex diseases.

Ulivi S, Gasparini P

Institute for Maternal and Child Health - IRCCS "Burlo Garofolo", via dell'Istria 65/1, Trieste, Italy.

Background: Susceptibility to the complex diseases is due to the combined effect of multiple interacting genes and environmental factors. Using isolated populations to reduce disease and environmental heterogeneity of complex disorders is an interesting and powerful instrument to study the genetic basis of complex diseases. For this purpose we developed Italian Network of Genetic Isolates (INGI)-Carlantino Biobank and INGI-Friuli Venezia Giulia Biobank. The research projects respected all the Italian laws and rules in term of privacy and biological samples. A consent form either for clinical and genetic studies has been signed by each participant in the studies.

Method: We have developed a biobank (INGIB) that ensures the privacy protection and the participant confidentiality, and the quality throughout the entire process of biobanking that includes collection, storage and related data recording. INGIB collects various types of biological materials: DNA, RNA, blood, serum, urine, saliva. The traceability is guaranteed by the "Micronic" system based Ab-Analitica Biobanker software, in particular it allows to know the physical location of samples thanks to 2D-barcoded tubes.

Results: Clinical evaluation, personal data and biological materials from ~3200 subjects have been stored in INGIB. The Ethical Committee of IRCCS-Burlo Garofolo approved the projects and the protocols. Samples are collected under consents that allow a broad range of activities related to health surveys and genetic analysis.

Conclusion: Samples will be made available to users for research purposes in order to improve the knowledge of the genetic causes of complex diseases and traits.

ID number: 137

Circuit Stablishment For Quality Biological Samples Retrieval In A Third Level Hospital Biobank

Elena Bellmunt, Raquel Amigo, Ana Belén Martín Marco and José Vicente Cervera

Biobanco La Fe-IIS La Fe. Hospital Universitari i Politècnic La Fe. Av Bulervar sur s/n. Valencia. Spain

Quality samples are those that meet researcher's needs. Nowadays, scientists are demanding high numbers of well annotated biological samples together with vast clinical data to perform omics studies. Moreover, many of them claim more than one sample type to fulfill their research interests (mainly DNA, RNA, proteins and metabolites).
Biobanco La Fe is located in the Hospital Universitari i Politècnic La Fe, one of the biggest public hospitals in Europe and a reference center in many diseases. This is the ideal scenario for rich data-high quality biological samples recruitment, as clinical assistance, education and research live in peace.
There are many factors that would impact on sample quality and need to be registered. In fact, each sample type and containing biomolecules is going to be affected differently. All these variables, called pre-analytical, contribute enormously to erroneous interpretation of the results. Fortunatelly most of them are easily controlled by the biobank staff, conversely there are some important others that require clinical team collaboration to annotate them (nurses, surgeons, pathologists, clinicians,…). For these reason, before sample collection start, we meet with all the involved personnel and decide what, how, where, when and who participate in each step. With all these information a specific standard operating procedure (SOP) is documented and distributed to all the participants. Needless to say, informed consent process is imperative.
With the establishment and the rigorous coordination of these circuits we achieve the two mains aims of biobanks; to protect donors' rights and to provide high quality-well annotated biological samples for rese

ID number: 173

The Frozen Ark Project

A. Clarke (1), C. Wade (1), D. Lermen (2), J. MacKenzie-Dodds (3), P. Bartels (4), J. Astrin (5)

(1) The Frozen Ark Project, Dept. of Biology, University of Nottingham, NG7 2RD, UK;
(2) Fraunhofer-Institute for Biomedical Engineering IBMT, St. Ingbert, Germany; (3) Natural History Museum, London, UK; (4) NZG Biobank, Pretoria, South Africa; (5) Zoologisches Forschungsmuseum A. Koenig (ZFMK), Bonn, Germany

Despite the best conservation efforts, the United Nations Environment Programme, the International Union for the Conservation of Nature and The Royal Society of London have all concluded that at least 30% of all wild terrestrial, fresh-water and marine animals are expected to go extinct within the next 50 years. This is due, in large part, to the ever increasing growth of human populations with its concurrent climate change, habitat destruction, agricultural land needs, over-fishing and acidification of oceans.
The Frozen Ark Project is a global strategy to collect, preserve and store the genetic resources of the world's endangered wild animal species for the long term before they go extinct so these unique materials are not lost to future generations. The project, set up as a charity, is being co-ordinated from the University of Nottingham in the UK. It consists of a growing number of 23 Consortium Members from the world's Zoos, Aquaria, Natural History Museums, Universities and Institute biological departments dedicated to the task.
The stored genetic material will provide scientific knowledge of the biology, behaviour, ecology, physiology and evolution of the animals preserved and the means to prevent the loss of genetic diversity that causes infertility in conservation breeding programmes. It will also insure the material that has been used for the development of human and animal medicine throughout our history continues to be available for the future.
Many institutions around the world store gametes, tissues and viable cells of such animals but rarely in a manner that allows preservation of undamaged material, in collaboration with other institutions, aimed specifically at endangered species and including appreciable numbers of invertebrate taxa on which all larger animals, including mankind, depend and which, so far, have been largely neglected.

Resource Development

ID number: 004

Developing an Electronic Standard Operating Procedure Management Information System to Facilitate High Quality Research Within Biobank Networks and Collaborations

1) Dr. Brian Karisa Ngowa - (PhD Fellow) - University of Alberta, Canada
2) Mr. Davidson Ngibuini- Project Manager (HMIS) Future Groups Ltd, Kenya

C/O Simax Consultants Kenya, P.O Box 389 - 80108, Kilifi, Kenya.

Background: Biobank networks and networking are becoming an essential component in translational research projects and clinical studies. These networks require standardization to guarantee high quality medical research. While more emphasis has been placed on the scientific research aspect, very little effort has been focused on the management and usage of Standard Operating Procedures (SOP) within these networks. This has resulted in many biobanks facing challenges in managing traditional SOPs formats and the advent of Biobank Networks further necessitates harmonization and robust management.

Methods: This project is intended to develop an Integrated Electronic Standard Operating Procedure Network (e-SOPNet) Management Information System for Biobank networks carrying out similar research projects and clinical studies through collaboration over the next one year. A model e-SOPNet management information System will be focused on an existing biobank SOP structure and prototyped and replicated to an established network. The major steps in the development of this electronic SOP will be identifying lab setup/types, identifying similar studies, SOP metadata development, SOP development workflow, SOP change logs, SOP training logs and user validation, and SOP body. This project will involve various interested individual scientist and Information Technology experts

Results: The implementation of the e-SOPNet will enhance harmonization of SOP which will enhance quality in research through efficient and effective management of SOPs.

Conclusions: This initiative will help researchers to efficiently share and manage harmonized SOPs version controls, workflows, history logs and awareness logs. Further comparative analysis can be done on harmonized SOPs versus Traditional unharmonized SOPs.

ID number: 018

LifeLines Cohort and Biobank

S.Scholtens, S.J.L. Bakker, M. Bruinenberg, J.J. Duker, R.P. Stolk

LifeLines, University Medical Center Groningen and University of Groningen, The Netherlands

Background: LifeLines is a prospective population-based study that will follow 165,000 individuals for at least 30 years in the Northern provinces of the Netherlands. LifeLines collects high quality data and biomaterials to aid research on 'Healthy Ageing'.

Method: LifeLines employs a three-generation design, with inclusion of family members of participants. All participants receive an extensive baseline measurement. Every 1-2 years participants complete follow-up questionnaires and every 5 years a follow-up measurement is scheduled. Collected data include lifestyle factors, medical history, psychosocial characteristics, medical examinations (e.g. ECG, cognition, lungfunction) and biomaterials. Eight million tubes with plasma, serum, DNA, and urine are stored in an automated storage facility at -80°C. From 2014 feces and hair samples will be collected. For 13.000 participants genome-wide data are available. Linkage is established with environmental data and clinical registrations. Data and biomaterials are a resource for researchers worldwide. In addition to the routinely collected data and biomaterials, researchers can apply for additional data collection.

Results: Baseline measurements have been conducted in 145000 individuals and 55000 subjects returned the first follow-up questionnaires. Currently 112 applications for data have been granted and LifeLines contributed to 45 high-ranking scientific publications. The complete sample processing has been automated, a secure ICT infrastructure for sample and data storage has been accomplished and a sophisticated research portal has been setup for data access and sharing.

Conclusions: LifeLines is a unique research infrastructure and expert center that aims to facilitate scientists from public and private partners to push forward research on ‘Healthy Ageing’.

ID number: 024

Australian Breast Cancer Tissue Bank (ABCTB): Clinical Data Standardisation & Normalisation for Streamlining Data Retrieval Methods

Jane Carpenter1, Mythily Mariasegaram1, Matloob Khushi1, Deborah Marsh2 and Christine Clarke1

1Australian Breast Cancer Tissue Bank, Westmead Institute for Cancer Research, Westmead Millenium Institute, University of Sydney; 2Hormones and Cancer Division, Kolling Institute of Medical Research, University of Sydney.

The Australian Breast Cancer Tissue Bank (ABCTB) collects and stores clinical samples and data from consented donors across Australia and provides de-identified biospecimens and data to support breast cancer research. Currently, ABCTB collects pathology, clinical and longitudinal follow-up data using manual methods and the data is stored within its CAISIS database. The ABCTB has completed an assessment of the data that it collects and stores within its database of approximately 6,000 donors, by systematically examining the various data tables and identifying data fields that could be improved. The objective was to standardise and normalise data fields, and to streamline data retrieval for researcher enquiries and requests. To achieve our objective we will undertake a number of steps to standardise and normalise the data stored within our database:-

- develop a data dictionary to ensure that the data fields are defined accurately
- restrict data entry for various data fields with standardised drop down options
- minimise duplicate data fields within different data types
- identify and develop new data fields to better categorise and classify data

In summary, this work will simplify and improve data retrieval for research studies. Achievement of these goals will not only streamline data retrieval methods but will also allow researchers to search for de-identified clinical samples and data for their studies on the ABCTB website, using an increased number of data items.

ID number: 025

GCAT Genomes for life. Cohort Study of the genomes of Catalonia. Validation of the use of White cells Residue from a blood donation for biobanking purposes.

Anna Carreras, Gemma Valeta, Teresa Alonso, Lluís Puig Rovira, Manuel Perucho, Rafael de Cid

Institut de Medicina Predictiva i, Personalitzada del Càncer (IMPPC), Ctra. de Can Ruti, camí de les escoles, s/n, 08916 Badalona (Barcelona) - Spain, Tel. (+34)93 557 28 38, Fax: (+34)93 465 14 72 www.imppc.org

The GCAT is a long-term project that studies the role of genomic and epigenomic factors in the development of major common diseases in the general population to define the requirements for the management and personalized treatment of the patients. The GCAT will collect biological samples and information from 50.000 individuals in the region of Catalonia, and the information will be periodically updated through EHR (electronic health records) access as well epidemiological update.
The recruitment takes place through the National Blood and Tissue Biobank from Catalonia (BST). As part of the BST standard protocol, the blood donation (500ml) is fractionated; we collect a volume of a leukocyte concentrate, known as the Leukocyte Residue (RL) from this fractionation. This residue contains most of the nucleated white cells with a lower percentage of platelets, with a concentration of leukocytes that can reach 10E9/ml.
Even if genomic efficiency increases and low amounts of DNA is needed, for biobanking purposes a high DNA yield is preferred. We take advantage of the normal blood donor process to obtain high quantity of nucleated cells in an efficient manner, with a lower consumption of resources (material, personal time).
Due to the high number of samples we must deal with, we have established all protocols in an automated manner, to ensure greater homogeneity in the processes. We will present the current developed and validated Biobank protocols for DNA extraction and quality control using the Leukocyte Residue material.

ID number: 038

Biobanking Networks: Why now?

Berthold Huppertz, Karine Sargsyan

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The trend in modern medicine goes towards early detection of disorders and personalized medicine for better diagnostics, therapies and prognoses. Innovation is mainly addressing identification, validation and application of biomarkers with an increased stratification power.

Approach: Based on the rapid technological development, biomarker research has changed tremendously. On one hand technologies like NGS, single cell detection, and all -omics technologies combined with globally accessible databases and bioinformatics offer huge opportunities. On the other hand, international cooperation disclosed the urgent need for standardization and harmonization. One of the evident major challenges today, besides sample and data quality, is the increasing number of study participants required to set up sufficiently powered studies.

Answer: A single biobanking infrastructure on its own can never be sufficient to meet the challenges above. Therefore, networks of certified supra-regional biobanks are the answer. Such biobank networks sustain an efficient and purposive platform specifically designed to support system biology approaches, biomarker and drug discovery and public health.

Challenge: To meet the requirements of common sample quality standards in an ethical, legally adjusted environment is a great challenge for international biobank networks. Each biobank needs to explore its economic justification, perform effective reporting and quantify economic and often non-profit performance. Common standards need to be defined on a high rather than low level and hence, only few biobanks may be able to join such high-standard networks. Supra-regional biobanks such as Biobank Graz mostly meet international standards and can add innovative implementations in the field of maintaining sample quality.

ID number: 039

Development of biobanking in Central and East European Countries

Karine Sargsyan, Manuela Strahlhofer-Augsten, Gabriele Granitz, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Introduction: Due to the rapid progress in clinical, molecular and pharmaceutical research, biobanking - the structural collection of human biological samples and corresponding data - gained more and more attention in the last years. Coordination, consolidation and networking of existing European biobanks are central points for further development of biomedical sciences. The importance of networking of biobanks has been emphasized by many authors and there are several major biobank networking initiatives worldwide, such as the European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) initiative. As one of the leading biobanks in Europe, Biobank Graz intends to extend its network also towards emerging biobanks in Central-East-Europe (CEE).

Approach: The ultimate aim is to establish a sustainable biobanking community across CEE. This approach targets to optimise the ability of CEE biobanks to: communicate with each other, share ideas, information and data, and collaborate effectively in complex ethical guidelines to provide a solid biobanking network to advance biomedical sciences. A further objective of this study is to help setting up biobanks of CEE countries to become part of the European biobanking network providing rare biological material of high research relevance.

Conclusion: This initiative is already partly funded (CONEKT) and will facilitate CEE countries to develop their biobanking as well as bimolecular research profiles, ensuring a new level of understanding of the health effects of different risk factors, biochemical measurements, and genetic markers specific for the European population.

ID number: 042

Governing an academic biobank: What are the challenges?

Karine Sargsyan, Michaela Bayer, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: The implementation of an institutional biobank at Medical University of Graz started in 2007. It aimed at establishing an efficient and purposive research service facility specifically designed to support research approaches to human diseases, biomarker and drug discovery and public health. Combining the concepts of population-based and disease-based biobanking, Biobank Graz was founded based on a variety of different routine and research collections.

Difficulties:
- Juggle of individual interests and reconciliation into a joint global benefit
- Data/sample collections need to meet the requirements of clinical routine as well as quality standards in an ethical, legal and socially adjusted environment
- Cross linking and integration of all individual IT-subsystems of a hospital

The procedure of building a governance model needs to include the following:
- Are existing mechanisms appropriate and do they consider all involved bodies?
- Does the reconfiguration consider the relationships between different gatekeepers?
- How are samples and data shared between researchers from different institutions?
- How is the implementation of real benefit-sharing performed in practice?
- How can the governance structure support all this?

Solution: Biobank Graz is based on a four level model, which has been approved during the last six years. The model includes (1) a developmental, (2) an operation, (3) a decision and (4) a user level, and is directed and controlled by rectorate and scientific advisory board. This model has been implemented at the Medical University of Graz, an after proof of concept was evaluated, was announced as the official governance strategy of Biobank Graz.

ID number: 045

Pioneer in biobanking – hard work leading to success

Manuela Strahlhofer-Augsten, Karine Sargsyan, Michaela Bayer, Berthold Huppertz

Biobank Graz, Medical University of Graz, Stiftingtalstr. 3.1, 8010 Graz, Austria

Background: Biobank Graz started in 2007 comprising two people, rising to the biggest Biobank within Europe. At the moment more than five million human biological samples with respective clinical data are stored at Biobank Graz, with number and diversity steadily increasing. Handling and organization of this huge biological repository in combination with the aim of Biobank Graz to contribute to an improved and sustained healthcare for the general population requires a well-organized .

Results: The management of large sample numbers and high diversity within the last years entailed an increase in manpower resulting in 15 full time equivalents working at Biobank Graz today. Due to highly sophisticated research technologies, biological sample quality becomes more and more important. Achieving these requirements Biobank Graz has replaced manual working processes by implementing automation especially in liquid handling and storage systems. Biobank Graz also operates a quality management system according to ISO 9001:2008. The high quality of samples is reflected by an elevation of project requests rising from two in 2007 to more than 230 in 2012. Furthermore, the number of cooperation partners steadily increases. In turn, this results in a higher sample quality, quantity and diversity being useful for further cooperations supporting human medical research. Financial resources are gained due to the support by the Local Government of Styria and the Austrian Federal Government of Science and Research.

Conclusion: Biobank Graz demonstrates that a well-organized and continuous is key for being successful.

ID number: 051

The Janus Serum Bank of Norway- a prospective cancer biobank

Randi Gislefoss and Hilde Langseth

Cancer Registry of Norway, Institute of Population-based Cancer Research, Postbox 5313, 0304 Oslo, Norway

The Janus Serum Bank was launched in 1973 and is dedicated to cancer research. It contain a nationwide sample collection from health examination surveys in Norway and holds samples from blood donors and Janus donors that have been diagnosed with cancer. During 41 years of management, the serum bank has reached approximately 460 000 samples from 317.000 donors About 56.000 donors have developed cancer by thw end of 2010.
The Janus samples are stored at a constant temperature of 25 °C. A number of quality experiments in the Janus biobank have confirmed that many compounds are stable at this temperature.
In order to secure the best use of the material in the biobank, a multidisciplinary steering committee is responsible for the scientific evaluation of the project applications. All samples within a research study are given different codes, enabling blinded analyses that assures the privacy of the donors and prevents research misconduct.
Janus Serumbank has license from the Norwegian Data Inspectorate and information addressed to the donors is presented on our web site. The information includes consent, withdrawal of consent, central legislation and ongoing research projects.
The Janus Serum Bank has been a participant in several national and international biobank and research networks. During the last 10 years the biobank has delivered 2.000-10.000 samples yearly to researchers worldwide.
Future goals: Implementation of a new electronic web based tracking system "e-biobank" for handling of biobank material.
Increase the knowledge of sample quality by establishing a panel of samples reserved for quality studies

ID number: 059

Telethon Network Of Genetic Biobanks (TNGB)

Mirella Filocamo (1), Chiara Baldo (2), Stefano Goldwurm (3), Alessandra Renieri (4), Corrado Angelini (5), Maurizio Moggio (6), Marina Mora (7), Giuseppe Merla (8), Luisa Politano (9), Barbara Garavaglia (10), Francesca Dagna Bricarelli (11)

(1) UOSD Centro di Diagnostica Genetica e Biochimica delle Malattie Metaboliche, Istituto G. Gaslini, Genova, Italy; (2) SC Laboratorio di Genetica Umana, E.O. Ospedali Galliera, Genova, Italy; (3) Centro Parkinson, Istituti Clinici di Perfezionamento, Milano, Italy; (4) UOC Genetica Medica, Dipartimento di Biotecnologie Mediche, Università di Siena e Azienda Ospedaliera Universitaria Senese, Siena, Italy; (5) Dipartimento di Neuroscienze SNPSRR, Università di Padova, IRCSS San Camillo, Venezia, Italy; (6) UOD Diagnostica Malattie Neuromuscolari e Rare, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Italy; (7) Laboratorio di Biologia Cellulare, UO Malattie Neuromuscolari e Neuroimmunologia, Fondazione IRCCS Istituto Neurologico C. Besta, Milano, Italy; (8) Unità di Genetica Medica, IRCCS Casa Sollievo della Sofferenza, S. Giovanni Rotondo (FG), Italy; (9) Cardiomiologia e Genetica Medica, Dipartimento di Medicina Sperimentale, Seconda Università di Napoli e Azienda Ospedaliera Universitaria SUN, Napoli, Italy; (10) UO Neurogenetica Molecolare, Fondazione IRCCS Istituto Neurologico C. Besta, Milano, Italy; (11) Dipartimento Ligure di Genetica c/o E.O. Ospedali Galliera, Genova, Italy

TNGB, composed of 10 members, was founded in 2008 to coordinate biobanks supported as single core-facilities by Telethon since 1993. Currently, TNGB stores 75,900 biospecimens from over 750 rare genetic diseases. Governed by a Coordinator and all Biobanks' Directors (Network Board), TNGB is also supported by a Coordinator Emeritus and by an Advisory Board which includes ethical-technical experts and a representative of Patients' Associations. TNGB policies are defined in the Charter. TNGB has always focused on improving quality, visibility and catalogue access. Its interoperability is facilitated by an IT infrastructure, which greatly simplifies harmonisation and standardisation of all activities. The IT platform, managing samples' workflow, generates a centralised, continuously updated online catalogue and also enables coordinated management and common rules for catalogue access based on a unique "Request Control Panel". Hitherto, about 250 scientific publications resulted from research conducted using TNGB services. Through continued dissemination activities aimed at promoting TNGB services, the interest for the Biobanks is also enormously increased among patients/families. Indeed, several agreements have been formalised between TNGB and Patients' Associations. TNGB is a BBMRI-EU associated-member and is involved in the preparatory phase of BBMRI-IT-ERIC. Additionally, TNGB is a member of EuroBioBank and some Biobanks are also part of Regional Nets. Finally, TNGB is an associated partner of the RD-connect project. TNGB operates according to national and international regulations/recommendations and collaborates with qualified centres and regulatory bodies (Garante Privacy Authority) to review emerging ethical-legal and societal issues. General information and documents including the catalogue are available on www.biobanknetwork.org.

ID number: 060

Workflow for controlled collection and processing of patient samples

Geiger J, Neumann M, Froelich G, Lohmueller R, Kircher S, Rosenwald A, Jahns R

Interdisciplinary Bank of Biomaterials and Data Wuerzburg (ibdw), Straubmuehlweg 2a - A9, 97078 Wuerzburg, Germany

Aim: The Interdisciplinary Bank of Biomaterials and Data Wuerzburg (ibdw) as one of five German national biobanks aims to simultaneously collect liquid and solid biomaterials from patients based on a broad consent. The workflows for sample collection seamlessly integrate in clinical routine workflows. Sample collection and transport to ibdw are implemented based on standardized workflows used in clinical routine.
Concept: The consent form is generated automatically at patient admittance. Sampling of biomaterials for the ibdw is permitted immediately after signing the consent. Sample collection, transport and processing are tracked by time stamps and temperature monitoring at each step. Liquid biomaterials are processed, aliquoted and long-term stored in a separate building, equipped with air conditioning and continuous monitoring of temperature. Samples are stored in automated -80 C cryostores using tubes carrying a 2D barcode engraved in the bottom. Tissue collection starts with documenting the relevant time stamps (e.g. warm/cold ischemia). Subsequently, the tissue is transferred to the rapid section lab, documented by imaging, split if appropriate, and snap frozen. Tissue samples are stored in similar tubes also tagged with a 2D-barcode. The sample data are stored along with the information on the storage location in the Biobank Management System.
Summary: Standardized collection of liquid and solid biomaterials together with corresponding clinical data offers a unique professional service for both clinicians and researchers. Continuous monitoring of the samples, external conditions and timeline from acquisition to storage enables consistent and reliable sample quality.

ID number: 065

The Biological Library of the Université catholique de Louvain

Gutierrez-Roelens Ilse, Marbaix Etienne

Centre du Cancer, Cliniques universitaires Saint Luc, Université catholique de Louvain, Avenue Hippocrate 10, 1200 Bruxelles

The Biological Library of the Université catholique de Louvain was created in 2007 thanks to the National Cancer Plan launched by Mrs.L. Onkelinx, the Belgian Federal Minister of Social Affairs and Public Health. A team of two people collects and stores each year more than 450 well characterized specimens that complete the 3560 samples already stored in the Pathology Department since 1987. Nowadays, approximately 2600 frozen tissues have been collected following a standard procedure that ensures their high quality. Indeed, the surgical specimen reaches within a few minutes the pathology department, is analyzed by a pathologist and left-over tissue is rapidly stored at -80°C. FFPE samples are also available. Anonymized clinical information can be provided for each specimen.

The UCL Biological Library works in accordance with the Ethics Committee rules and national laws. All samples are coded to protect individual privacy.

The purpose of the Biological Library is to foster research by providing high quality material and hence to help progress in the treatment of cancer.

ID number: 080

Free reliable digital signatures

Hans van Nek

SampleNavigator . Weerribben 100. 8244 EZ Lelystad, The Netherlands

The use of digital signatures is mandatory for a professional Biobank: the only way to prove who created data about your samples, and nobody tampered with the data.
However digital signatures are very expensive, per byte maybe the most costly piece of data. Not because digital signatures are difficult. But because a whole industry has arisen that exploits your ignorance: they let you purchase a new signature each year, they allow you to use it only for one purpose. Some of them even let you pay per signature. The profit driven structure comes with a price: it is complex, and leads to unnecessary errors. For instance each time you replace a signature it can go wrong, leading to identity leak.
A handwritten signature is forever, you do not change it each year, you can use it for all purposes ,and it is totally free. Computers ought to make life easier, not more difficult. Why make an exception for digital signatures?
And indeed your organisation can create digital signatures yourself. You not only save money (each year). You also save a lot of work, by not replacing each year all those digital signatures. And no identity leak because of replacement errors: as a result with some care your system is better than a system based on purchased signatures.
We describe a system that you can make yourself, from open source or industrial components, and fulfils the requirements of European Directive 1999/93: legally at least as safe as a purchased digital signatures. It is amazingly simple.

ID number: 084

Biobanking data platform for translation research

David van Enckevort (UMCG), Erik van Iperen (Durrer Center for cardiogenetic research), Linda Mook (Parelsnoer Institute PSI), Chao Pang (UMCG), K. Joeri van der Velde (UMCG), Jan-Willem Boiten (CTMM), Morris Swertz (UMCG)

UMCG, Hanzeplein 1, 9713 GZ Groningen, The Netherlands

Within national and international biobanking networks there is an increasing need to use common standards for biospecimen to facilitate collaboration. The CTMM Translational Research IT (TraIT) project aims to develop a long-lasting national IT infrastructure that facilitates collection, analysis, archiving and securing of data generated in medical research projects. The project enables integration and querying of information across the four major domains of translational research: clinical, imaging, biobanking and experimental. Research from multi-site projects should be able to share and disseminate data and analyses from these domains in the TraIT translational research space.

In the biobanking workpackage, we have developed a platform that facilitates several processes around biospecimen for clinical studies. This has been done in line with other national biobanks and based on an stakeholder analysis and inventory of user needs.

Project deliverables are:
- A standard information model and data format enabling exchange of information between biobank information systems;
- A sample catalogue software allowing researchers to discover available samples and assessing feasibility of creating a study cohort;
- An electronic workflow to track the status of sample requisitions from the approval by the biobank coordinator until the delivery at the requestor;
- An integrated workspace where study data from different data domains can be analyzed across different studies.

The deliverables, software and summary data format are developed in collaboration with BBMRI-NL, the Parelsnoer Initiative PSI, Mondriaan and UMC Groningen, and international collaboration with BBMRI-EU, tranSMART, BioSHaRE, and BioMedBridges on the definition and use of a common dataset.

ID number: 101

TMF Represents an Interdisciplinary Platform for the Advancement of Biobanking in Germany

Michael Hummel1, Roman Siddiqui2, Sebastian Claudius Semler2, Michael Kiehntopf3 & Michael Krawczak4

1 Institute of Pathology, Charité Universitätsmedizin Berlin, Germany
2 TMF – Technology, Methods, and Infrastructure for Networked Medical Research, Berlin, Germany
3 Institute of Clinical Chemistry and Laboratory Diagnostics, University of Jena, Germany
4 Institute of Medical Informatics and Statistics, University of Kiel, Germany

"TMF - Technology, Methods and Infrastructure for Networked Medical Research" is a state-funded non-profit umbrella organization currently counting more than 80 academic medical research networks in Germany among its members [1]. The different TMF working groups have been geared to identify and solve organizational, legal, ethical and technological roadblocks with the objective of improving the infrastructural framework of clinical, epidemiological and translational research in the country. Established in 2004, the biobanking working group of TMF [2] has since surveyed the pertinent legal regulations of biobanking, developed specimen transfer contracts, quality assurance checklists and data protection concepts, and proposed informed consent declarations and generic guidelines for the establishment, operation and management of biobanks. Recently, the group set up a central registry for biobanks funded by the German Federal Ministry of Education and Research (BMBF), thereby allowing for the first time access to information on medically relevant biobanks in Germany [3]. TMF also supports the BMBF-funded National Biobanking Initiative destined to overcome the fragmentation of the national biobanking landscape and to create centralized biobank infrastructures [4]. The TMF provides a communication platform to the initiative and offers workshops as well as consulting services to them (e. g. on data protection issues). For further advancement and dissemination of biobanking expertise in Germany, TMF has launched the Annual National Biobanking Symposium in 2012. This symposium will continue to be held regularly in December each year [5]. To also promote international activities, TMF has become a member of major biobanking societies, including ESBB and ISBER.

[1] http://www.tmf-ev.de; 2013-06-27
[2] http://www.tmf-ev.de/EnglishSite/WorkingGroups/Biobankingworkinggroup.aspx ; 2013-06-27
[3]http://www.biobanken.de ; 2013-06-27
[4] http://www.gesundheitsforschung-bmbf.de/en/2638.php ; 2013-06-27
[5] http://www.biobanken.de/News/Termine/Symposium2013/tabid/212/language/de-DE/Default.aspx ; 2013-06-27

ID number: 102

Integration of biobanks into fully established molecular pathology programmes.

Claire Millar, Stephen McQuaid, Peter W Hamilton, Manuel Salto-Tellez, Jacqueline James

Northern Ireland Biobank & Northern Ireland Molecular Pathology Laboratory, Centre for Cancer Research and Cell Biology, Queen's University Belfast, BT9 7BL.

Biobanking of high quality, well annotated human tissue samples is recognised as the cornerstone of biomarker discovery and validation. In an era when drug discovery and diagnostics are rapidly evolving, biobanks are essential components of molecular pathology programmes, providing support for tissue based research and driving the delivery of personalised medicine for patients with cancer.

A comprehensive molecular pathology operation consists of four core components: molecular diagnostics, molecular translational research, digital pathology and biobanking. Integration of biobanks into molecular pathology programmes has mutual benefits for both organisations in terms of shared resources and manpower, increased clinical and academic collaboration, and creation of a hybrid biomedical scientist role incorporating clinical and research expertise. Biobanks also provide the infrastructure for the standardised collection of the large numbers of tissue samples required for biomarker studies within molecular pathology departments, thus reducing ethical and governance delays and ensuring maximum sample quality for validation studies.

In 2012 the Northern Ireland Biobank (NIB) was integrated into the newly restructured molecular pathology programme in the Centre for Cancer Research and Cell Biology (CCRCB) in Queen's University Belfast (QUB). This new department was purposely designed in partnership with the Belfast Health and Social Care Trust pathology laboratories to create a hybrid diagnostic and translational research operation. This partnership creates a sustainable, affordable translational research infrastructure which mutually benefits both healthcare and academia. Yet more importantly, it offers real potential to fully deliver on the promise of personalised medicine for patients with cancer in Northern Ireland.

ID number: 109

Services for the harmonization of the Italian biobank network

Barbara Parodi1, Mariagrazia Daidone2, Mirella Filocamo3 and Marialuisa Lavitrano4

1Banca Biologica e Cell Factory, IRCCS AOU San Martino-IST, Genoa, Italy, 2 Istituto Nazionale Tumori, Milano, Italy, 3Lab Diagnosi Pre-Postnatale Malattie Metaboliche, G. Gaslini Institute Genoa, Italy, 4University of Milano-Bicocca, Milano, Italy

The Italian node of BBMRI has established new services for the community of the Italian biobanks. As a first step, a survey has been designed to assess and select well established Italian biobanks in terms of the level quality and richness in samples and data. The survey also aimed at identifying biobanks available to provide services to the network. The health system in Italy includes a network of 47 IRCCS, institutions for hospitalization and care closely linked to translational research. This network is particularly rich in large and well established biobanks, most of which participate in the Regional and / or thematic National networks.
The second step is an on-line self evaluation form, followed by the creation, in the new web site of the node, of a web page for each biobank / biological resource centre of the network. This allows to provide visibility and to search biobanks and samples in order to facilitate collaborations and new studies, at a national and international level.
The information desk of the Italian node will respond to a toll-free number, providing support, advice and documents to those willing to set new biobanks and / or improve the quality of their collections of biological samples. A specific branch of the information desk is devoted to ethical, legal and social issues and relies on experts in the field.
The achievements of the network will be presented at the kick-off meeting of BBMRI Italy and the ESBB community is invited to participate.

ID number: 117

Validating The Use Of Under Vacuum Fresh Tissue Sealing And Cooling For Molecular Analyses

Veneroni S, Bongarzone I, Iorio E, De Bortoli M, Valeri B, De Cecco L, Miodini P, Taverna E, Ricci A, Pinciroli F, Dugo M, Canevari S, Pelosi G and Daidone MG.

Fondazione IRCCS Istituto Nazionale dei Tumori, Milan and Istituto Superiore di Sanità, Rome, Italy.

Standardization of pre-analytical tissue handling procedures represents a critical point in establishing robust infrastructures for biobanking to allow optimal morphologic and reliable antigenic preservation, and nucleic acid integrity enabling reliable molecular testing for personalized treatments, even in the context of multicentric studies. The evidence that formalin fixation, a widely adopted procedure for tissue preservation, may lead to extensive degradation of nucleic acids prompted the development of an alternative approach by under vacuum sealing (UVS) and cooling specimens at 4°C to transfer fresh tissues to pathology labs. We evaluated on a panel of 18 human normal and tumor samples (including breast, colon, lung cancers and sarcomas) the UVS approach in terms of: a) histomorphology, KI67 and vimentin expression; b) gene expression profiling (GEP) by Illumina HT12_v4 platform and gene set enrichment analysis (GSEA); c) high resolution NMR spectroscopy of metabolic content; d) peptidome analysis by SELDI and WB. Tissue specimens were UV sealed immediately after surgical removal: one aliquot was frozen and the others were kept to 4°C for 1h, 24h, 48h, 72h and then frozen. Morphology and immunohistochemical reactivity were preserved over time without necrosis or tissue degeneration. Tumor and normal tissue GEPs showed tissue-related changes over time while GSEA enlightened some pathways eventually deregulated. Degradomic behaviors by peptidome analysis revealed a negligible contribution of storage time on proteolysis, and stability of phosphorylation sites up to 24h. Conversely, metabolic changes occured after 1h of UV storage. Notwithstanding some tissue heterogeneity, the study confirms UVS validity for histologic and molecular analyses.

ID number: 122

The Value Of External Technical Support And Benchmarking To Evolving Centralised Biobanks In Africa

Carmen Swanepoel*†, Beverley van Rooyen†, Eyitayo Fakunle**, Ravnit Grewal*†, Alan Christoffels‡, Catherine Rossouw‡, ***Michael Sheldon, ***Andrew Brooks, Akin Abayomi*†

*National Health Laboratory Services, Stellenbosch University Faculty of Medicine, Cape Town, South Africa
†Division of Haematology, Stellenbosch University Faculty of Medicine and Health Sciences, Tygerberg, South Africa
‡South African National Bioinformatics Institute (SANBI), University of the Western Cape, Bellville, South Africa
**Department of Chemical Physiology, Centre for Regenerative Medicine, The Scripps Research Institute, La Jolla, Ca, USA
***RUCDR Infinite Biologics, Rutgers University, Piscataway NJ, USA.

Background: The development of centralised biobanks in Africa forms an important part of the H3Africa initiative as a resource to facilitate research development and sustainability in both SA and the African continent. As most biobanks are in the developed world, a benchmarking exercise of two international biobanks was performed to identify common practices that can be implemented at the NHLS-Stellenbosch–H3Africa Biobank (NSB-H3A).

Methods: An SOP on how to perform a benchmark was developed to collect information on best practices relating to biobanking operations, using an online interview tool compiled from the report "Case Studies of Existing Human Tissue Repositories: Best Practices for a Biospecimen Resource for the Genomic and Proteomic Era". Questions covered aspects related to specimen collection, transportation, storage, processing and annotation, consumer/user needs, bioinformatics and data management, business plan and operations, privacy, ethical concerns, consent issues, intellectual properties and other legal issues as well as public relations, marketing and education. Benchmarking was also performed via site visits, interviewing directors and technical staff, and e-mails.

Anticipated results: This exercise will allow us to determine our existing biobanking capacity, develop the envisioned scale up plans, and assist us in addressing unfamiliar issues and challenges that are unique to the African continent.

Conclusion: Performing such an exercise and utilising the external technical support on ground will aid in capacity building, technology exchange and will also assist in creating a benchmarking paper as a valuable resource to evolving biobanks on the African continent.

ID number: 128

Developing a state-of-the-art Biorepository in Uganda – The BioReMU

Samuel Kyobe, Misaki Wayengera, David Kateete, Edward M Wampande, Moses L Joloba

Department of Medical Microbiology,
2nd floor, Pathology/Microbiology BLDG,
School of Biomedical Sciences
College of Health Sciences,
Makerere University.
Box 7072, Kampala, Uganda.

Background: Enhancing the capacity of African researchers to conduct genomic studies addressing problems of African disease and health requires provision of adequate state-of-the-art infrastructure. The concept of genomic studies and biobanking are relatively new fields in Africa. Several issues will affect successful establishment of these concepts such as infrastructure development, access to well trained human resource, ethical and governance frameworks and availability of funding for sustainability. Africa faces an actue scarcity of well established biorepositories developed on international tenets of biobanking, no African biorepository is listed in the Global Directory of Biobanks. We proposed to establish a state-of-the-art biorepository in Uganda - The Makerere University Biorepository - BioReMU. Approach: The Departments of Pathology and Microbiology evaluated the available biobanking activities and resources and a needs assesment for biobanking. Results: Six laboratories conduct biobanking activities, no fresh tissue repositiong and specimen management below international standards. International and national demand for well annotated stored biospecimens is high. Recommendations: 1(a). Develop a governance and organization structure, 1(b) Examine national and international laws governing biobanking, 2. Perform benchmarking of international biobanks to establish industry standards, 3. Train personnel in biorepository management and science to equip them with the necessary skills and knowledge, 4. Develop centralized biobanking, a cost effective measure, 5. Improve the existing infrastructure for the biorepository, 6. Develop protocols for sample receipt, processing, storage and distribution, with rigorous quality assurance and control procedures as established by international standards, and 7. Identify sources and advocate for funding towards biobanking such as H3Africa Initiative

ID number: 139

Biobanco-IMM tumour collection: from the bedside to the bench

Pires R.; Ferreira A., Ortiz S.; Afonso A.; Zhao A.; Caetano-Lopes J.; Fonseca JE & Costa L.

Biobanco-IMM, Lisbon Academic Medical Center, Instituto de Medicina Molecular, Faculdade de Medicina da Universidade de Lisboa

Biobanco-IMM is integrated in the Lisbon Academic Medical Center (AMC), which brings together on the same campus a research institute (Instituto de Medicina Molecular, IMM), a medical school and a teaching hospital (Hospital de Santa Maria, CHLN).
The Biobanco-IMM tumours collection was originally created to support translational research projects in Lisbon AMC. Taking advantage of its location, we set up a multidisciplinary team including elements from Biobanco-IMM and from the Pathology Department of CHLN. We are also supported by a large team of nurses and surgeons, who are fundamental to run the complex flowchart of samples from the identification of the donor until the preservation of the sample.
In March 2012 we started collecting colorectal cancer samples and in July 2012 we added samples of breast cancer and all digestive cancers including pancreas. From each tumour we collect a fragment of the tumour and a paired fragment of healthy tissue. Paired samples of primary tumours and metastasis are also collected, representing and important asset of this biobank.
We have reached almost 400 samples (from 200 patients). These samples are collected and quality controlled making them available to all downstream applications. All samples have associated detailed clinical information, including follow-up, which is available through the national oncology registry.
Our vision is to enlarge Biobanco-IMM tumours collection not only by including more samples but also by increasing the repertoire to other tumours, such as sarcoma and melanoma, maintaining this an attractive collection for scientific research.

ID number: 140

Multidisciplinary working groups around the Virtual Biobank stimulates the Translational Biomedical Research Collaboration in Flanders, Belgium – a focused approach

Bekaert S.(1-2), Ectors N. (1-3), In 't Veld P. (1-4), Smits E. (1-5), Somers V. (1-3) , Degroote K. (1)

(1) CMI vzw, (2)CRC Ghent, (3)CRC Leuven-Hasselt, (4)CRC Brussels, (5)CRC Antwerp

In December 2009 the Center for Medical Innovation (CMI) was initiated with the support of the Flemish Government as a not-for-profit association with the final purpose of promoting and stimulating Translational Biomedical Research (TBR) in Flanders (Belgium).

The strategic objective of the CMI is to contribute to the translation towards (bio)medical innovations with societal and economic gains and to ensure that the Flemish region remains a strong basis for (clinical) research studies, by means of:
-setting up a uniform, high-quality Flemish Biobank in support of TBR;
-cooperation between the Flemish universities, the university hospitals and their clinical research centres (CRCs), and industry;

Collections of samples will be established in thematic domains in which the Flemish knowledge institutes and Flemish industry has a strong international position. The Flemish Biobank will be set up gradually: initially, a limited number of 'pilot' biobanks with high quality collections will be the substrate for strong research collaborations as they all have a clear translational focus within the predefined thematic domains, based on criteria such as excellence of research, industrial interest, and potential for valorisation, all in an international context.

5 initial multidisciplinary working groups were initiated focusing upon:
-sudden cardiac death
-hepatotropic pathogens
-inflammatory bowel disease
-rheumatoid arthritis
- diabetes

Collaboration of all partners enriches project proposals towards valorisation.

The inventory of these pilot biobanks will be included in a central catalogue through a central ICT backbone which will be developed.

ID number: 141

RNA stability in the human liver tissue and the ileum mucosa

Celine Schelcher, Serene M.L. Lee, Stefanie Schreiber, Wolfgang E. Thasler

Tissue Bank under the authority of Human Tissue and Cell Research (HTCR) Foundation, Department of Surgery, Grosshadern Hospital, Ludwig Maximilians University, Munich, Germany

Following medical procedures, usage of remnant tissues obtained from consented patients represents a valuable resource for biomedical research. Quality assessment of tissues after surgical removal is crucial for scientific investigation and pre-analytical study is necessary to determine whether the tissue is suitable for further study. As RNA is easily degradable, this study aims to examine whether the effect of processing time and temperature of the liver tissue can influence the transcriptome and whether ischemia has an impact on the RNA integrity of the ileum mucosa. Liver tissues and ileum mucosa were collected over a time course to analyse whether processing time, storage and temperature can have an impact on the RNA integrity and gene expression. Assessment of RNA integrity was performed with an Agilent Bioanalyser and gene expression profiles were assessed by RT-QPCR. RIN numbers were only significantly decreased after the liver tissue was stored for 24h at room temperature. However, cold ischemia time up to 24h, temperatures and with or without RNAlater did not demonstrate deleterious effect on gene expression levels in liver tissues. The effect of ischemia in the ileum mucosa up to 6h did not show a significant influence on the RNA integrity as the RIN number obtained were greater than 8. This study demonstrate that RNA from liver tissue and ileum mucosa is not as sensitive as previously thought and fresh tissues can still be used for scientific purpose up to 6h and 24h following surgical procedures for scientific projects requiring ileum and liver tissues respectively.

ID number: 142

Bimetra: integrative model for translational research

V. T'Joen, S. Bekaert

Bimetra, De Pintelaan 185 5K3, 9000 Gent (BELGIUM)

Bimetra is the Clinical Research Center from Ghent University (UGent) and Ghent University Hospital (UZGent).

Bimetra acts as a central point of contact facilitating and integrating several aspects of translational biomedical research (TBR), from basic funding opportunities and valorisation to biobank acces and clinical trial management. Its mission is to facilitate, stimulate and improve TBR, from bench to bedside and from bedside to community, bridging the gap between clinicians and researchers. The final aim is to reinforcing the leading scientific position of UZGent and UGent. In order to achieve these goals, bimetra is organised in 5 platforms, each covering a particular aspect of TBR and operating in an integrative manner:

bimetra valorisation: platform that informs and supports researchers regarding funding opportunities, IP, valorisation, technology transfer…

bimetra clinics: platform that coordinates clinical trial management and contracts (academic and commercial)

bimetra biobank: platform that facilitates biobanking by bringing together several biobank initiatives (tumour biobank- National Cancer Plan, Focus Biobanks of the Center for Medical Innovation (CMI) and local strategic collections) and offers high quality controlled biobank opportunities

translational data management: dedicated platform for integrated data management solutions, bringing together clinical data, scientific data and global biobank management data

translational core facilities: inventarisation and strategic management of core facilities on campus

ID number: 144

Bimetra biobank: bringing together different initiatives for high quality biobanking

V. T'Joen, M. Praet, S. Bekaert

Bimetra biobank, De Pintelaan 185 -1P8, 9000 Gent (BELGIUM)

In 2012, a central high-quality biobank facility was initiated at the Ghent University Hospital (UZGent), under the coördination of Bimetra, the Clinical Research Center of UZGent and Ghent University (UGent). The Bimetra biobank wants to facilitate and stimulate translational biomedical research by providing a high quality fully monitored preparation/storage facility with elaborate quality management procedures, a clear ethic-legal framework and powerfull datamanagement solutions.

Different biobanks have been centralized in this facility, funded by regional and national initiatives. The tumour biobank of the Pathology Department of UZGent , which was started in 2001, was one of the first biobanks to become integrated into the Bimetra biobank. In the tumour biobank, formalin fixed parafin embedded (FFPE) and snap-frozen tumor material is stored, together with corresponding normal tissue. The tumour biobank is a federal initiative (National Cancer Plan 27 - NKP27) and through the joint Belgian Tumour Biobank network, is connected with the "Virtual Belgian Tumour Biobank".

Our local biobank will also host specific biobanks within predefined disease focus areas in the context of a regional Flemisch initiative, the Center For Medical Innovation (CMI). The final purpose of the CMI is building inter-university/hospital translational research networks for which the collaborative biobank collections are only a means to that end. Bimetra, the Clinical Research Center Gent, is coordinating the focus biobank regarding "hepatotropic pathogens".

The bimetra biobank brings together these initiatives and is building out a strong quality managed and controlled facility for sample storage.

ID number: 151

QBB: The First QATAR Public Biobank , Participant Feedback and Observations.

N. Afifi*, A.Althani*, F.Qufoud*, G.Blakoe#, E.Kidher#, P.Elliott#, E.Riboli#,

* Qatar Biobank, Qatar Foundation, Doha-Qatar, # Imperial College London, UK

Qatar Biobank (QBB), the first very large scale, long-term public biorepository in Qatar, is designed to build a powerful research infrastructure for future investigations of the lifestyle, metabolic and genetic risk factors for the most frequent medical conditions in Qatar, namely diabetes, cardiovascular and respiratory diseases, obesity and cancer.

Qatar Biobank's recruitment approach provides a model for public involvement in biomedical research. Through inviting the public to contribute, Qatar Biobank promotes Qatar as dedicated to raising awareness and committed to engaging the community in shaping the health of their future generations.
During the pilot phase, between December 2012 and June 2013, 503 participants have completed their baseline visit at the QBB Center. 67.9% of participants are Qatari nationals, the remaining are Qatar long term residents (> 15 years). There is a balanced participation of males (51.8%) and females (48.2%).
Attitudes, perceptions and feedback are captured through a structured post-appointment participant questionnaire. Analysis of the feedback shows that upon giving consent the highest area of concern for participants is providing blood samples (47%), a further (46%) demonstrate concern over the physical measurements and (39%) are uneasy with contributing urine samples. An overwhelming (96%) of participants rate their experience at Qatar Biobank as very positive. A significant proportion (72%) of participants decide to contribute to Qatar Biobank due to word of mouth recommendations from friends (41.4%) and family (30.4%) emphasizing that the majority of participants value and enjoy their experience and are empowered to actively recruit within their communities.

ID number: 152

QBB: Milestones in building a successful biobank

N. Afifi*, A.Althani*,Z. Al -Kanaani,# F.Qufoud*, G.Blakoe#, E.Kidher#, P.Elliott#, E.Riboli#,

* Qatar Biobank, Qatar Foundation, Doha-Qatar, # Imperial College London, UK

Qatar Biobank (QBB), the first very large scale, long-term public biorepository in Qatar, is designed to build a powerful research infrastructure for future investigations of the lifestyle, metabolic and genetic risk factors by collecting comprehensive phenotypic baseline data among healthy volunteers, including ECG, blood pressure, anthropometry, spirometry, retinal imaging, carotid 3D ultrasound, arterial stiffness, total body iDXA, in addition to detailed personal lifestyle and clinical data. QBB collects and stores blood samples subdivided in 68 aliquotes for different future research purposes. Qatar Biobank understands that building a successful biobank depends on the willing participation of the public to come forward to contribute. The recruitment of participants requires insight into the public's existing knowledge of biobanking, level of willingness and an understanding of the motivators and barriers to participation.
From December 2012 to June 2013, 503 participants completed anonymously a feedback form to evaluate their experience. The aim of this specific survey is to gain insight into recruitment methods, incentive to participate and satisfaction with various aspects of the visit. This will enable assessment of the processes of registration, scheduling, checking in, consent and reporting back results.
Around 75% of those who completed the feedback form participated in QBB to improve the health of future generations and to have a comprehensive health checkup. 95% were willing to participate again if needed and 85% would recommend participation to friends and family. 87% and 95% thought the length of the questionnaire was appropriate and the questions not too intrusive, respectively.
Finally, 91% found the staff welcoming, 89% rated the check-in process as "good" and 76% found scheduling an appointment straightforward. Further comments from participants suggested appreciation of the protection of confidentiality and privacy that was displayed throughout the process and that the process was smooth and enjoyable.

ID number: 159

Development of a pilot project of data sharing between partners of the Italian Hub of Population Biobanks (HIBP)

Mariarosaria Napolitano1, Filippo Santoro2, Maria Puopolo2, Chiara Donfancesco3, Lucia Galluzzo3, Amalia De Curtis4, Alessandro De Grandi5, Federica Sevini6, Elisa Cevenini6, Luigi Palmieri3, Deborah Mascalzoni5, Paolo Roazzi7, Maria Antonia Stazi3, Licia Iacoviello4, Emanuele Scafato3, Peter Pramstaller5, Claudio Franceschi6, Simona Giampaoli3, Maria B. Donati4, Filippo Belardelli1, Elena Bravo1

1Department of Haematology, Oncology and Molecular Medicine, 2Department of Cell Biology and Neurosciences,3National Center for Epidemiology, Surveillance and Health Promotion,Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy;4Fondazione di Ricerca e Cura "Giovanni Paolo II", Università Cattolica del S. Cuore of Campobasso L.go A. Gemelli 1, 86100 Campobasso, Italy; 5Center for Biomedicine, EURAC Research, Bolzano, Viale Druso 1, 39100 Bolzano, Italy; 6C.I.G Interdipartimental Center L.Galvani, University Bologna, Via San Giacomo 12, 40126 Bologna, Italy; 7Information Technology, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy.

The Italian Hub of population biobanks (HIBP) is the network of the Italian population biobanks including both ongoing and completed studies heterogeneous for purposes and collected specimens, aiming to share and synergize the existing bioresources patrimony. Heterogeneity of starting conditions make sharing data studies very difficult because of technical, ethical and collection rights that hamper collaboration and synergism possibilities. With the aim of overtaking these difficulties and to achieve the «proof of concept» that sharing studies are actually achievable among Italian collections, a data sharing pilot project has been agreed by HIBP' Founder Members. Participants agreed methodology and signed a shared Data Transfer Agreement (DTA). Each biobank such as EURAC (MICROS-study), C.I.G (GEHA-project), CNESPS (FINE, MATISS, MONICA, OEC1998, Italian Twin Register, and IPREA collections), MOLI-BANK (Moli-Sani project) uploaded in a common database a minimum of 1000 data-samples. Subject were grouped in three geographical residence areas (North, Centre and South Italy). After the harmonization process of demographic data, physical, haematochemical and education parameters, 3882 of the initial 5071 personal records, were analyzed by a multivariate logistic regression model to assess influence of shared data on lipemic pattern. Odd ratios (confidence 95%), calculated by gender, show several geographical differences mostly regarding HDL, which may be a base for further deeper, sample-based, studies. More interestingly the HIBP pilot experience is the proof of the feasibility of collaborations and express a methodological prototype for future epidemiological studies based on well established, quality collections participating to the partnership.

ID number: 161

Qatar Biobank, a valuable resource for future healthcare initiatives

H.Abderrahim*, A.Althani*, N. Afifi*, F.Qufoud*, G.Blakoe#, E.Kidher#, P.Elliott#, E.Riboli#,

* Qatar Biobank, Qatar Foundation, Doha-Qatar, # Imperial College London, UK

Qatar Biobank project has been launched by Qatar Foundation in collaboration with Hamad Medical Corporation and Supreme Council of Health, with the expert support of scientists from Imperial College London in order to enable medical research on health issues that prevail in Qatar. A first pilote phase has been achieved , leading to completion of methodology, setup as well as establishment of procedures and quality systems.To date, over 500 participants have enrolled in Qatar Biobank as part of this pilot study. This effort is set to increase over the next 5 years, the foreseen goal being to reach 60.000 participants from the Qatari adult population.The recruitment process involves a battery of biometric tests, lifestyle and health data collection as well as imaging and fitness evaluation. A comprehensive set of biological samples (Blood, urine and saliva) is collected and a clinical chemistry and haematology analysis are performed before an initial feedback is provided to the participant. This resource will constitue a reference for an epidemiological evaluation as well as a longitudinal follow-up of the participants.

ID number: 166

Biobanking in Financial Crisis

Zdenka Prodanovic

Monash Health, 246 Clayton Road, Clayton, Vic 3168, Australia

Biobanking is an evolving entity and requires a lot of care from early stages of its development. I have joind Victoria Cancer Biobank late in 2007 and have been continously working on its improvement and expansion.
To set up a biobank/biorepository initial capital is usually funded by the governement. Biobanks are established, samples are collected and what is next? Government expects that the biobank will be able to cost recover some expenses as to contribute to the governement funding (not necessarily to recover invested funds in its set up). With the financial hardships research community as a whole is faced with, biobanks are having an extreme difficulty to manage own existence.This presenatation may give you an idea on how to ensure biobank's existence; how to improve your overall standing in the research community (clinical trials, academia) and how to be able to raise more revenue to create sustainable biobanking environment.Basis of this presentation is current status of biobank I am managing since 2009.

ID number: 168

Biobank and everything around….

Giuseppina Bonizzi1, Salvatore Pece1,2, Massimo Monturano1, Giuseppe Renne1, Giuseppe Viale1,2 and Pier Paolo Di Fiore1,2

European Institute of Oncology1 and University of Milan2, Milan, Italy

The Biobank of the European Institute of Oncology (IEO Biobank and Biomololecular Infrastructure, IBBRI) was born as an institutional infrastructure within the broader scenario of the Molecular Medicine Program (MMP) of IEO. In this context, IBBRI mission is to support biomedical research working in a highly integrated fashion with a number of centralized core infrastructures, such as the Primary Cell Culture and Stem Cell Unit, the Xenotrasplantation Unit, the Clinical Biomarkers Laboratory, the Biocomputational Unit, which constitute the pillars of the IEO MMP. One of the key qualifying aspects of IBBRI is the integration of its activity with that of the Department of Pathology, which ensures the continued and centralized supervision of a dedicated pathologist in the processing of biomaterials in an ad hoc structured core facility. We collect and store biological specimens only from patients who have signed our specially designed informed consent form for research purposes. All patients are offered the choice of samples being held anonymously or of being anonymized with encryption. Audio-visual materials have also been prepared to explain the main features of the informed consent and to help patients make fully informed decisions to participate to our research programs by donating biological samples. To ensure maximum compliance, trained Biobank research nurses are always on hand to explain to patients the impact and implications of their decision. All biobanked samples are managed through a software that is fully integrated with the hospital medical records database, pathology database and central registry of patient demographic information.

ID number: 170

DNA extraction for long-term storage: our experience

Chvatovic Genovefa, Gudleviciene Zivile

Institute of Oncology, Vilnius University (Vilnius, Lithuania) and Bureau of Forensic Medicine Investigatios (Vilnius, Lithuania)

Background. To date there are wide variety of different techniques, methods or protocols available for extraction and purification of DNA from the blood samples, each method have its own advantages and disadvantages. In our research we tried to determine which DNA purification method is the most appropriate quality in terms of cost and time, extracting DNA from the blood remaining after routine blood tests – usually frozen, often coagulated blood samples.

Material and methods. The patient's blood taken into tubes with EDTA and the remaining after routine blood tests, were divided into five tubes of 200 μl. DNA was purified by phenol chloroform method in a laboratory approved methodology and a set of commercial support and automated extraction – according to manufacturer's recommendations and protocols. Four manual extractions and one automated DNA purification and extraction methods were compared in order to determine the effectiveness of each method on quantity and purity of DNA.

Results. Two of the four manually performed the purification of DNA concentration was good enough (from 57 to 126 μg/ml), the other two were of poor quality (from 8 to 47 μg/ml). In the same samples purified automatically DNA concentrations ranged from 15 to 95 μg/ml.

Conclusions. Summarizing it can be said that DNA from the blood remaining after routine blood tests can be efficiently and easily extracted by phenol-chloroform method. When working with commercial companies offered kits its necessary to test them before on various old blood samples.

ID number: 174

Piccolipiù biobank: an Italian resource for children's health

Nisticò L (1), Penna L (1), Brescianini S(1), Toccaceli V(1), Medda E(1), Farchi S(2), Culasso M(2), Richiardi L(3), Merletti F(3), Rasulo A(3), Fiorini LM(3), Grasso C(3), Trevisan M(3), Fiano V(4), Todros T(4), Ronfani L (5), Vecchi Brumatti L (5), Volpi P(5), Piscianz E(5), Tognin V(5), Bin M(5), Loganes C(5), Rusconi F(6), Montelatici V(6), Poggesi G(6), Rapisardi G(7), Mugelli I (7), Frizzi A(7), Gagliardi L(8), Martini V(9), De Bartolo P(9), Fioritto A(9), Di Bernardini F(9), Nibbi A(9), Baccaro G(9), Bernardini T(10), La Rosa F(10), Badaloni M(10), Pallanch C(10), Fede A(10), Forastiere F(11), Porta D(11), Stazi MA(1), Di Lallo D(2)

(1) Genetic Epidemiology Unit, CNESPS, Istituto superiore di sanità, Rome, Italy
(2) Public Health Agency, Lazio region, Rome, Italy; (3) Department of Medical Sciences, University of Turin and CPO-Piemonte, Turin, Italy; (4) Department of Surgical Sciences, University of Turin, Italy; (5) Institute for Maternal and Child Health-IRCCS "Burlo Garofolo", Trieste, Italy; (6) Meyer Children's University Hospital, Florence, Italy; (7) Ospedale Santa Maria Annunziata, ASF 10, Bagno a Ripoli, Florence, Italy; (8) Department of Woman and Child Health, AUSL 12 Viareggio, Ospedale Versilia, Viareggio, Italy; (9) “Città di Roma” Clinic, Rome, Italy; (10) Cristo Re Hospital, Rome, Italy; (11) Department of Epidemiology, Lazio Regional Health System, Rome, Italy

Piccolipiù is a population based prospective cohort of 3000 Italian newborns, started in October 2011. It aims to investigate the effects of environmental exposures, parental conditions and social factors acting during pre-natal and early post-natal life on infant and child health and development. The biobanking of mothers' peripheral blood, infants’ cord blood and umbilical cord pieces has been set up according to ethical international guidelines and national legal requirements. Information on exposures and outcomes are collected from the mothers at baseline (delivery) by interview and self-administered questionnaire and at 6, 12 and 24 months by follow up questionnaires. Overall, 23 aliquots including serum, plasma, buffy coat, erithrocytes and slices of umbilical cords from each mother-child are frozen within 24h from sampling at delivery. Moreover, heel blood spots are collected 48h after delivery during the mandatory neonatal screening test. Samples are then transferred from the five maternity units (Ospedale Santa Maria Annunziata, Bagno a Ripoli (Florence); Ospedale ostetrico e ginecologico Sant’Anna, Turin; Clinica Ostetrica e Ginecologica IRCSS Burlo Garofolo, Trieste; Casa di cura Città di Roma, Rome; and Ospedale Cristo Re, Rome) to the biobank of the Istituto superiore di sanità and stored in -80° refrigerators and in vapoeur nitrogen tanks. Integration of longitudinal data with those deriving from biological material testing is a valuable resource to advance knowledge on factors influencing child’s health. Pooling and comparison with other birth cohorts data (www.birthcohorts.net) will increase scientific evidence and soundness of results.

ID number: 178

CASCADE: A CAncer tiSsue Collection After DEath programme to improve our understanding of the progression from primary stage cancer to metastatic, treatment resistant disease.

Heather Thorne1, Kathryn Alsop1, Paul Waring2, Gillian Mitchell1, Odette Spruyt1, Orla McNally3, Grant McArthur1, Mark Shackleton1 and David Bowtell1,2

1The Peter MacCallum Cancer Centre, East Melbourne VIC; 2Tthe University of Melbourne, Parkville VIC; 3 The Royal Women's Hospital, Parkville VIC.
With the support of the Victorian Institute of Forensic Medicine (VIFM) and Tobin Brothers Funerals.

Background: Cancer tissue collected for research purposes is commonly obtained from resected primary tumours. Comparatively few samples are collected from metastatic deposits. It is becoming apparent that multiple cancer genomes can exist within individual patients and even within a single tumour. Relationships between inter- and intra-tumoural genetic heterogeneity and cancer evolution are presently unclear, but likely to profoundly influence patient outcomes. Understanding these genetic determinants would be greatly facilitated by multiple spatially- and temporally-separated tumour samples from individual patients.

Methods: Recent work has highlighted the value of rapid autopsy in pancreatic and prostate cancer. Autopsies provide an opportunity to obtain a comprehensive survey of tumour deposits and relatively large amounts of material. We are piloting a 24/7 programme, called CASCADE, of rapid autopsy in cancer patients, with an initial focus on breast, ovarian, prostate cancer, and melanoma. CASCADE aims to create a bank of metastatic tumour tissue matched with primary tissue and clinical data to investigate mechanisms of resistance, metastasis, and cancer evolution using genomic and biological tools.

Results: CASCADE leverages existing infrastructure through the Kathleen Cunningham Foundation Consortium (kConFab), Australian Ovarian Cancer Study (AOCS) and Melbourne Melanoma Project (MMP), involving senior pathologists, palliative care specialists, medical oncologists, familial cancer clinicians, and scientists with extensive experience in biobanking and cancer cohort studies. Twelve participants have been enrolled to date.

Conclusions: CASCADE has presented ethical, logistic and scientific challenges. A large amount of metastatic tissue has been ascertained across and within multiple sites in individual participants, supporting the validity of this approach.