Europe Biobank Week

Abstracts book

Poster presentations

Topic 3: Environment, Biodiversity & Human Health

PS3-1: Population-based cohort screening of cardiovascular diseases biomarkers in Lower Silesia – implication of biobanking does matter.

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Introduction: Population biobanks are essential tools for the development of the public health screening due to the improvement of personalized medicine. Since 2012, Biobank EIT+ has collected more than 120000 biological samples from the healthy volunteers of Lower Silesia inhabitants, together with variety of demographic, anthropometric, life style and health information.

Material and methods: Patients were screened for cardiovascular, diabetic and inflammatory biomarkers, such as lipid profile (total cholesterol, triglycerides, HDL, LDL), glucose and insulin levels. Moreover, insulin resistance factor (HOMA) and insulin sensitivity check index (QUICKI) were calculated and compared with anthropometric parameters. LDL level was correlated with the level of CRP.

Results: The preliminary study comprised 4098 patients (during 2012-2016), divided into: individuals without any chronic disease (2318 patients), women (1425 patients), men (893 patients), both divided into age groups.

Our results have shown that the concentration of particular lipid metabolites were associated with the age. The first changes were noticed in the group of patients between 30-39 years old (increase in total cholesterol and LDL, decrease in HDL) . In the same group, increased HOMA factor, body mass index, waist to hip ratio were also observed. Moreover, significant correlations between QUICKI index, LDL and triglycerides level, between LDL and CRP were noticed.

Conclusion: Our study demonstrated that the age of metabolic breakthrough leading to cardiovascular diseases may occur in individuals above 30 years in Lower Silesia inhabitants. Further follow-up studies are needed to not only confirm this observation, but also to give an answer about dynamics of metabolites level changes during the aging.

PS3-2: Biobanking at VITO: population biobanks of healthy people.

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Introduction: For more than fifteen years, VITO has been working on the development of a human biobank. VITO manages a biobank in which residues of human blood, serum, urine, hair, saliva and exhaled breath condensate are preserved. These biospecimen were collected in different human biomonitoring studies.

Material and methods: Since 2002, the Centre for Expertise on Environment and Health, at the request of the Flemish Government, has been using human biomonitoring to detect the presence of polluting substances in babies, adolescents and adults and to monitor the general health of the population.

Results: The Centre is now working on its fourth campaign. VITO is also participating in other biomonitoring campaigns e.g. the 3xG project, a large-scale health monitoring in a birth cohort in three Flemish municipalities (Dessel, Mol and Retie) since the autumn of 2009. In each campaign, additional samples were systematically taken and stored in a biorepository. The registration, preservation and management of the samples in the biobank are done using a computer-based inventory system (LIMS, Labvantage software) . Each sample in the biobank has a tremendous information backbone on the lifestyle, environment and health status of the donor.

Conclusion: The biological samples in the biobank are invaluable to address specific policy questions in the future, to test old samples with new technology and according to the latest methods and insights or to identify recently identified pollutants in old samples to identifying longer-term trends.

PS3-3: The Biobank of the Norwegian Influenza Cohort Study (NorFlu)

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Introduction: The Norwegian Influenza Cohort Study (NorFlu) is a prospective population-based pregnancy cohort study conducted by the Norwegian Institute of Public Health (NIPH) . The study will examine the consequences of influenza A (H1N1) 2009 infection during pregnancy.

Material and methods: Pregnant women in the second half of their pregnancy were recruited February-September 2010. In addition non-pregnant women were recruited as controls.

At the age of 4, some of the children participated in a clinical study. Blood samples were obtained the mothers and children at birth and at the clinical appointment.

Results: The cohort includes about 3200 mother and child pairs and 327 controls. 614 of the children participated at the clinical study at the age of 4.

The children was tested with regard to language, motoric precision and cognitive processes among others.

The NorFlu biobank consists of 2542 sample sets collected from the mothers at birth, 2681 sets from the umbilical cord, 327 from non-pregnant women, and 596 samples from the mothers and 467 samples from the children taken at the clinical appointment.

Conclusion: The NorFlu biobank is a valuable research resource to study consequences of influenza A (H1N1) 2009 infection during pregnancy. A number of cells, serum and plasma samples has already been retrieved for research purposes.

PS3-4: VDR polymorphisms in colorectal cancer patients

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Introduction: Vitamin D and its receptor (VDR) play an important role in etiopathogenesis of cancer. Vitamin D deficiency is a known risk factor for colorectal carcinoma and its deficiency is associated with a worse survival in

metastatic colorectal cancer. VDR polymorphisms were associated with various diseases including various types of cancer.

Material and methods: We investigated selected polymorphisms of VDR gene (rs11568820, rs2228570, rs1544410, rs7975232, rs731236) in genomic and tumour DNA of 60 metastatic colorectal cancer patients (mCRC) and in 55 noncancer subjects of control population to assess their impact on CRC risk and clinical outcome of mCRC patients treated with bevacizumab plus chemotherapy.

Results: Polymorphisms of VDR gene did not differ between genomic and tumour tissue DNA. None of the investigated VDR polymorphism was associated with mCRC risk. Homozygotes TT a CC of VDR rs2226570 (FokI) polymorphism had significantly longer PFS with median 12 months (95% CI 8–21) compared to heterozygotes CT with median PFS 7.5 months (95% CI 4–14) (p = 0.010) . C allele in VDR rs7975232 (ApaI) polymorphism was associated with shorter OS with median OS 27.5 months (95% CI 18–N/A) for CC genotype and median OS 47 months for AA genotype (95%CI 34–N/A) (p = 0.026) .

Conclusion: VDR is an important factor determining vitamin D response. VDR polymorphisms may affect its expression and transcriptional activity thus modulating the risk and clinical outcome of several cancer types.

PS3-5: Status of the FarGen-infrastructure

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Introduction: The Faroe Islands is a North Atlantic archipelago with 50,000 inhabitants- a population considered genetically isolated. The FarGen-project is building an infrastructure of genomic data for research purpose. 1500 individuals have been recruited and exome-sequencing of their blood samples is in progress. The vision is to include all Faroese 18+.

Material and methods: Recruitment has primarily taken place through a marketing effort. All participants complete a questionnaire (in accordance with MIABIS) concerning their health status, demography and motivations to participate in FarGen. Participants sign up for the project voluntarily and they do not receive any feedback on their data.

Results: We present the status of the FarGen project. FarGen is the first project of its kind in the Faroe Islands, and we present the characteristics of a typical FarGen-participant. We point out what distinguishes these early adopters in terms of health-information and demography. In addition, we present results that show, that the motivation for participating in the project is primarily based on the interest of developing research capacities in the Faroe Islands, on a solidarity principle and a national sentiment.

Conclusion: The collected data from the questionnaires is a valuable basis for planning future recruitment and communication strategies for the expansion of the FarGen project. It also provides us with significant information that is useful for planning future research projects.

PS3-6: BBMRI-MENA Consortium: Bridging Biobanks in MENA Countries to Promote Research and Healthcare

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An international workshop on “Biobanking for Rare Diseases” and a symposium on "Bridging Biobanks in MENA Countries to Promote Research and Healthcare” took place in Izmir, Turkey between 2-4 May 2018. Both meetings were funded by the “Biobanking and Biomolecular Resources Infrastructure in European Research Infrastructures” (BBMRI-ERIC) through its European Commission Horizon 2020 project “BBMRI-ERIC-ADOPT”, and were organised by BBMRI.tr, the Turkish node of BBMRI.

The event hosted by IBG (Izmir Biomedicine and Genome Center) brought together a total of 132 participants and experts from 14 different countries. These meetings aim to establish and strengthen existing collaborative biobanking networks in MENA countries, as well as to facilitate their integration with pan-European counterparts.

After the inspiring and informative talks, the establishment of a MENA biobanking network was discussed. The panelists addressed some critical questions such as which field the Consortium should primarily focus on, which funding sources could be used, and so on. The consensus was that it is essential to create a BBMRI-MENA Consortium, and that future efforts should focus on its planning. For analyzing the outputs of this section for all participants we prepared a short questionnaire. We asked them “What is their opinion on the creation of BBMRI-MENA Consortium?” and “Are they want to be a part of this BBMRI-MENA Consortium, if it is formed?” If their answer is NO, we asked “Why?” And if their answer is YES, we asked, “On which field should the Consortium focus?” “To which working group would you like to contribute?” And “Which source should be used to raise necessary funds for the creation of BBMRI-MENA Consortium?”

As a summary of some of the results; 63,6% of participants were said it is necessary to create a BBMRI-MENA Consortium and 80,6% of them are want to be a part of this Consortium. The top 3 field that the Consortium should be focused on are cancer at the ratio of 72%, precision medicine 56% and rare diseases 52%.

Topic 4A: Impact of Policies and General Data Protection Regulation (GDPR) on Biosharing

PS4A-2: Material transfer agreement: a fundamental tool for sharing biospecimens

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Introduction: Sharing biospecimens and linked data between biobanks and researchers is a common, and much needed, practice.

Material Transfer Agreements (MTAs) are legal contracts between the provider and the recipient of samples and data defining the condition of transfer and use as well as ensuring the traceability of sample and data.

Material and methods: The Telethon Network of Genetic Biobanks (TNGB) has worked to draft an exhaustive MTA template, applicable to both non-profit and for-profit organisations. The MTA has been built to define the rights, obligations and restrictions for both the recipient and the provider with respect to the samples and data exchanged.

Results: The TNGB averagely processes about 200 requests per year and has always been careful to appropriately manage such type of transfer.

The implementation of the MTA procedure has therefore contributed to ease the sample and data international exchange across different national jurisdictions.

The TNGB, being aware of the important contribution of for-profit entities in developing treatments has also focused on the policies to be implemented with them. Among these, a devoted recovery cost list for sample access has been defined to ensure the biobank partial sustainability as well as to avoid unreasonable requests of such precious rare samples.

Conclusion: In conclusion, to protect patients' rights, TNGB can relies on a comprehensive MTA which regulates sample and minimum dataset exchange with the scientific community. The MTA therefore represents an effective tool for promoting a responsible sample sharing that is crucial for scientific research, especially in the field of rare diseases.

PS4A-3: Consent management in THL Biobank - Developing process for managing biobank consents

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Introduction: For THL Biobank, as research infrastructure hosting biological samples of human origin and linking personal data from the donor to these samples, a proper consent management is crucial. Consents also contain personal information on research participants, and their management must be subject to different data protection regulations, i.e. the GDPR.

Material and methods: Two different questionnaire surveys of biobanks and other research organizations in Finland and Europe were performed to collect data on consent management. The results were analysed using both quantitative and qualitative methods. Additionally, the regulatory framework on consents in national and international level was reviewed, accounting for GDPR.

Results: The outcome of the development work is a semi-automated process for administrating consent information. The process covers all steps of administration, from giving consents and receiving consent forms, registering consent data in a database, recording consent withdrawals and consent limitations, to archiving consent forms. The consent information is recorded in THL Biobank's electronic code registry, from which the relevant consent information is pushed to other THL Biobank databases querying the registry. Additionally, we developed a process for harmonising consent attributes between different legacy collections from the field of biomedical research, such that the consent data would be interoperable.

Conclusion: A good consent management is an important element supporting biobank's operations. It is essential for achieving sustainability in biobanking and meeting the requirements set by research ethics. While being compliant with GDPR, the biobank participant's privacy and right to give or withdraw their consent at any time is ensured.

PS4A-4: How does a biobank prepare to GDPR, THL Biobank as an example

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Introduction: The EU General Data Protection Regulation (GDPR), effective from May 25, 2018, contains new regulations that affect all operators who deal with sensitive data. From a biobank's perspective, this regulation affects various different operations and practices. Here we present how THL Biobank has revised its operations according to the GDPR.

Material and methods: To prepare for the GDPR, we surveyed all the biobank's standard operating procedures, administrative processes and documents, data workflow schemas, databases, and sample donor related issues. We noticed that modifications are needed in all those aspects to comply with GDPR. Also biobank personnel and customers need to be trained accordingly.

Results: The biobank's accountability in all aspects of personal data handling has been highlighted and enhanced, including privacy impact assessment of all biobank procedures, which led to many activities. We have upgraded the database tools to better reflect new requirements, such as extensive audit trails, higher data safety grade, and better tools for data handling to minimize human error. The biobank's agreement template has been updated to include new responsibilities for data controller and data processor, and similarly, material transfer agreements for ongoing projects have been updated. The informed consent documents have been revised to include additional rights for sample donors.

Conclusion: The development work based on the privacy impact assessment is ongoing. Biobank's personnel have been trained, but familiarizing the customers with the new data safety aspects is a continuing effort. This work has been beneficial for our biobank since it has forced us to examine and improve all biobank processes.

PS4A-5: Health Databases Governance: Towards an Harmonised Global Policy?

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Introduction: Data governance is becoming an important topic for biobanks and scientific research, in particular after the adoption of the EU General Data Protection Regulation (GDPR) in 2016 entered into force in May 2018. This topic shall equilibrate with individual's privacy and other legitimate interests in using the data.

Material and methods: We analyse policy documents adopted by several international organisations for reforming health and research data governance systems, namely, the WMA Declaration of Taipei (2016), the last Council of Europe draft modernized Convention n°108 on personal data protection (2016), the OECD Recommendation on the next generation of Health Reforms (2017) .

Results: Our comparative study will first briefly remind the different backgrounds and objectives of the organisations that issued the studied documents. Secondly it will highlight shared features and differences in the approaches for reforming health and research data governance in order to figure out if a global policy on the topic is possible.

Despite the differences between these organisations it seems that there is no fundamental discrepancies in the proposed trajectories to follow in order to benefit from the informational value of the data while efficiently ensuring human rights, such as privacy protection, and allowing economic development.

Conclusion: These works are some examples of complementary visions which could lead to the design of a global policy for health and research data governance for the benefit of the populations.

PS4A-6: Indian Biobanks: Biosamples and Data sharing

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Introduction: Biobanks, a key research infrastructure, has become very attractive among researchers because of its unique quality for sample storage and data processing. Global exchange of biosamples and data are fundamental in research and growth of biobanking. However, sharing is based on the consent of donor and national guidelines.

Material and methods: India has a gold mine of biosamples and data because of enormous genetic, geographical, cultural and linguistic diversity. Researchers are looking for Indian biosamples for research and discovery. Due to high demand and suggestions from CROs, the Indian Government reviewed, relaxed and updated its guidelines for biosample and data sharing.

Results: The Indian government has allowed hassle-free share of various biological samples by removing the mandatory requirement of a license for these samples by Notification number 19/2015-2020 by DGFT director general, on 4th August 2016.

ICMR, the apex body of India for the formulation, coordination and promotion of biomedical research has drafted the revised version of its ethical guidelines titled "National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017." First time included biobank and states that biobanks should have well-structured SOPs and clear guidelines for collection, coding, anonymization, storage, access, retrieval and sharing of biospecimens and data.

Conclusion: It's become ease for Biotech companies, CROs, research centers to export/import samples. As per ICMR research data is valuable and needs to be shared worldwide. It also state to de-identify and to closely inspect ethical issues related to data security, sharing, rights, benefit sharing and others surrounding big data.

PS4A-7: Linking Biobanks with National Health Registries in Latvia: Policy Challenges and Solutions

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Introduction: National health registries (e.g., causes of death, registries related to infectious diseases) are valuable source of research data when linked with biobank data. At the same time an important prerequisite for the use of this data for medical research is that personal data protection requirements and ethical principles are followed.

Material and methods: The paper will utilize policy analysis to explore regulation of linking health registries data and biobank data in Latvia for research purposes. The aim of the analysis is identification of the strengths and weaknesses, incl. gaps and inconsistencies in the existing policies.

Results: The analysis shows that there is a number of risks which must be eliminated by ethical governance of registry-based research in Latvia, e.g. risk of identification of study participants, loss of control on which projects use the data, breach of confidentiality, loss of public trust to medical research. So, the governance policy must aim at safeguarding integrity and protecting research subjects. At the same time there is lack of policy documents and regulations in this field in Latvia.

Conclusion: There is a growing interest in using data from national health registries and combining them with biobank data in Latvia; however, the existing policy lack ethical guidelines and limits for use of these resources. The new policies must be developed and introduced to enable research using health registries in Latvia.

PS4A-8: Discrimination on the basis of genetic features in the context disability and health - in quest for uniform standards

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Introduction: The issue of discrimination on the grounds of disability, health and genetic features raises doubts in the sphere of interpretation of law. At the legislative level, there is no terminological uniformity. These lead to lack of common standards both on the EU and country level.

Material and methods: Analysis of legal acts and practice of equality bodies of the EU countries (over 40 equality bodies have been asked a question on the premises: "genetic feature", "health" and "disability") . International, EU law and national legal acts will be discussed.

Results: European Union Member States were required to include disability criteria in their law in response to Council Directive 2000/78 / EC of 27/11/2000. The lack of implementation of the other two criteria led to a situation in which the lack of a criterion of health and genetic features is

compensated by the widening an interpretation of the concept of disability. At the same time, some Member States have decided to introduce in its legislation expressis verbis the prohibition of discrimination on grounds of health and genetic features. In the equality bodies' practice there is lack of common approach.

Conclusion: There is lack of uniform standard of understanding terms "genetic feature", "health" and "disability" both at the EU and national level. The practice shows that there is a need to introduce new criteria in the EU law in order to harmonize that field. A new directive can be discussed.

Topic 4B- Animal and Agricultural Biobanking and Preservation

PS4B-2: Estimation of Stress Markers in Inflammatory Bowel Disease Model using Resources from Laboratory Animal Resources Bank

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Introduction: The aim of this study is evaluating the biomarkers such as stress-related hormones (Cortisol, Corticosterone, Dehydroepiandrosterone; DHEA and Kynurenine) and brain in inflammatory bowel disease (IBD) model. A researcher donated IBD model that is C57BL/6J mouse, which is treated 3% dextran sulfate sodium (DSS) for 1 week, through the DGMIF.

Material and methods: The researcher received frozen serums and brain paraffin blocks. This study confirmed inflammation and stress responses of the DSS group and control group by serum biochemistry test (C-reactive protein; CRP), enzyme-linked immunosorbent assay (ELISA) of stress-related hormones (Cortisol, Corticosterone, DHEA and Kynurenine), brain histopathology and immunohistochemistry (Cox2, BDNF and GFAP) .

Results: Serum CRP level were increased in DSS group, and it indicates that DSS-induced IBD model were established well. The levels of stress-related hormone (Cortisol and Corticosterone) increased in DSS group. In hippocampus, the expression of inflammation-related makers (Cox2, BDNF and GFAP) were showed higher in DSS group.These findings suggest that inflammatory diseases, including IBD, may cause stress, and it affects the brain by stimulated inflammation.

Conclusion: DGMIF transferred these resources to Laboratory Animal Resources Bank (LAREB, Korea), and finally it was distributed to the researcher of this study. This research was conducted using resources from LAREB without sacrificing animals, and it showed the resources of LAREB could be useful in the future.

PS4B-5: Assessment of sterlet juvenile obtained with using frozen-thawed sperm

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Introduction: Currently, there is an increased interest in methods of cryopreservation of fish semen for use in fish farming. However, these methods have not been widely applied in practice to date, perhaps because of the fear of fish growers that the resulting juveniles will differ from those obtained by traditional technology.

Material and methods: One individual (pre-larvae, larvae, juveniles) placed in a special installation, with coordinate grid, registering the number of intersections of the object coordinate lines. The fish were affected by the following stimuli: light, illumination 20 Lx and 100 Lx; signal frequency 20 Hz and 300 Hz; vibroacoustic stimulus.

Results: When fertilized in production conditions with defrosted sperm of starlet (Acipenser ruthenus), the percentage of fertilization in the pilot batch was 67%, in the control – 83%. Fish obtained with the use of cryosperm in the analysis of morphometric indicators had an advantage compared to individuals obtained by traditional technology. The test was subjected to 30 individuals in the experimental and control groups in 1st, 8th and 15th day after hatching. In assessing the totality of the reactions of pre-larvae, larvae and juveniles, obtained by traditional technology with the use of cryopreserved semen, differences were revealed.

Conclusion: The use of cryopreserved sperm makes it possible to obtain resistant juveniles and can be recommended for use in artificial reproduction hatchery. The publication was prepared with the use of the Bioresource collections of rare and endangered species of SSC RAS No. 73602.

PS4B-7: Potato cryopreservation at the German ex situ gene bank in Gatersleben

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Introduction: The Gatersleben federal ex-situ gene bank of agricultural and horticultural plants houses ~1,800 cryopreserved accessions. The accessions held at -196°C include back-ups for the vegetatively propagated genetic resources, such as garlic and mint. With ~1,600 potato cultivars, the Gatersleben cryo-vault maintains also one of the world's largest potato collections.

Material and methods: The aim of the study was to analyze changes in soluble sugars and the viability marker adenosine triphosphate (ATP) during potato cryopreservation. To decipher detailed processes, the metabolites were investigated during the cryopreservation procedure of DMSO droplet freezing and PVS3 droplet vitrification in 4 out of 28 gene bank accessions.

Results: Regrowth varied in 28 genotypes and ranged from 5-100%. Regrowth was higher after PVS3 droplet vitrification than after cryopreservation using DMSO. Significant increases of soluble sugars were measured in the selected genotypes after PVS3 or DMSO and liquid nitrogen treatment and were reduced during regeneration. In contrast, ATP reached its minimum concentration after cryoprotection and liquid nitrogen treatment and recovered most quickly after PVS3 droplet vitrification. A reduction of the explant pre-culture period dramatically reduced the regrowth after PVS3 vitrification. However, correlations between the shoot tip regrowth and sugar concentration were absent and significant at a low extent with ATP.

Conclusion: In conclusion, the cryopreservation protocol, genotypes and pre-culture period affect the regrowth ability of explants, which was best estimated by the ATP concentration after low-temperature treatment. Due to the superior performance of PVS3, the routine potato cryopreservation at the Gatersleben gene bank was changed to PVS3 droplet vitrification.

Topic 4C - Quality Assessment and Management of Samples and Data

PS4C-1: Promising bank for specific therapeutic cells: Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF)

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Introduction: The Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF) has superior hospital infrastructure, abundant human resources and educational infrastructure, and the best settlement conditions compared to other regions. The DGMIF develops global-level new drugs and medical devices, and provides information for evaluating the effectiveness and safety of advanced new drugs and medical devices.

Material and methods: Laboratory animal center (LAC) in DGMIF has facilities for a variety of animals, ranging from mice to monkeys, and has complete systems for cell extraction and storage from various species. In LAC, studies are performing to analyze their characteristics and identify their ability for diseases treatment using cultured cells.

Results: Currently, the LAC has diverse cells such as adipose derived mesenchymal stem cells (AD-MSCs) and bone marrow mesenchymal stem cells (BM-MSCs) of mouse and rat, Wharton's jelly derived mesenchymal stem cells (WJ-MSC) and amniotic membrane mesenchymal stem cells (AM-MSCs) of feline, and WJ-MSCs and thymus AD-MSCs of human. Most of their cells were confirmed the basic information of cells through the expression of specific genes and markers and differentiation experiment. Especially, because we has a variety of stem cells, it is useful for study of disease treatment.

Conclusion: We plan to continue extracting and storing various types of cells from more diverse species, and try to be a pivotal institution in study of diseases treatment using cells of humans and animals by accumulating a lot of various cells and their information.

PS4C-4: German Biobank Alliance - Work Package Quality – A ring trial concept for tissue sample handling in biobanking

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Introduction: One of the objectives within the work package “Quality” of the German Biobank Alliance (GBA) is the development of a ring trial program for the handling of liquid and tissue biomaterial. For tissue samples the identification of critical parameters during sampling and storage processes influencing sample quality will be essential.

Material and methods: As trial material fresh pig liver was selected, dissected into equally sized pieces by a board-certified pathologist and concurrently distributed to the participating GBA biobanks. Upon arrival, the liver pieces were processed according to the respective local Standard Operating Procedure.

Results: After different periods of storage, quality and quantity of nucleic acids were determined. In parallel, tissue sections as well as extracted nucleic acids were sent to an independent reference laboratory for analysis. The results of the measurements at the reference laboratory and the biobanks as well as the different sampling and storage conditions at the participating biobanks are now being analyzed and evaluated to allow for conclusions concerning the different processes at the respective biobanks and sample quality.

Conclusion: Intra- and interlaboratory comparison of processes and regular repetitions of this ring trial scheme will enable the identification and optimization of critical elements influencing sample quality. This will be achieved by a customised evaluation of the respective biobank`s processes and consulting service organised by the GBA QM Core Team.

PS4C-5: Never lose track of a task again: applying SharePoint workflows to biobank tasks and processes.

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Introduction: The Radboud Biobank, a hospital integrated biobank, has a small team of 12 employees scattered across various departments at a Dutch University Medical Center. We needed an efficient system to manage day-to-day tasks, ensure these tasks are not forgotten and are completed within the time constraints.

Material and methods: Microsoft SharePoint has a workflow system offering solutions for allocating tasks either consecutively (one employee at a time) or parallel (more than one at a time) and for tracking progress. A completion deadline can be set and allocated time subdivided amongst employees. The initiator and employees receive automatic e-mail reminders.

Results: The Radboud Biobank implemented workflows for gathering information when starting a new sub-biobank, making quotes, issuances, and reviewing documents. Tasks are implemented and processes streamlined with the help of task forms. When each sub-task has been completed the workflow is sent on to the next employee and returns to the initiator on completion.

The automatic reminders ensure that an uncompleted task cannot be forgotten. Unnecessary cluttering of mail boxes can be avoided by good planning at the initiation of a task. This method also offers the added benefit of tracking performance indicators for the tasks.

Conclusion: SharePoint workflows are a readily accessible, useful and efficient tool to assist with the day-to-day running of a biobank and maintaining a high quality of service. Employees need instructions on working with workflows and (self) instruction is necessary for those initiating workflows.

PS4C-6: Blood sample quality assessment alongside NMR metabolomics for large biobanks and trials

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Introduction: NMR spectroscopy of serum and plasma is a sensitive method to detect signs of sample degradation. Nightingale Health Ltd has developed a high-throughput NMR metabolomics platform that captures molecular signatures of sample degradation and other sample quality measures alongside the quantification of >220 metabolic biomarkers from each sample.

Material and methods: The automated sample quality assessment includes screening of irregularities across multiple metabolic pathways, including

degradation of lipoprotein particles, decreased protein levels, as well as molecular substrates and products from enzymatic reactions.

Results: One such example is conversion of glucose into lactate and pyruvate, a common problem for biobanked samples collected from the clinical workflow. Other use cases include quality assessment of samples with multiple freeze-thaw cycles or stored temporarily in suboptimal conditions.

Simultaneously with the sample quality assessment, Nightingale's biomarker platform measures standard lipids, lipoprotein subclasses, fatty acids and amino acids, all quantified in mmol/L. The combined biomarker quantification and sample quality assessment becomes especially cost-effective for large biobank collections, with prices comparable to routine lipid testing.

Conclusion: These aspects have spurred widespread use of metabolic profiling in European biobanks and clinical trials, with almost 500,000 blood samples analysed thus far.

Recent improvements in throughput now allows screening entire national biobanks. What was recently feasible in small research cohorts is becoming the new standard for biobank blood testing.

PS4C-7: Process management of QMS audit in BBMRI.pl

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Introduction: In the BBMRI.pl-Polish Biobanking Network project Wroclaw Medical University is responsible for Task3 titled "Verification of SOPs that exist in Polish biobanking institutions, implementation of common solutions". As a part of Task 3 QMS audits are carried out in the Polish biobanking entities, that joined to the Polish Biobanking Network

Material and methods: The audits are conducted in accordance with ISO19001.Moreover, the internal documentation was created specifically according to BBMRI.pl project requirements.

A following procedures were prepared:

PS-02Audits within the BBMRI.pl Consortium and Polish Biobanking Network,

2S-11Algorithm procedure for remote and working visits in the Polish Biobanking Network entities,

IN-PS-02-01Instruction of audit proceeding.

Results: An audit process is a well-planned and described trial in the above-mentioned BBMRI.pl documentation. Presented forms are used for entries creation (i.e. schedules and audit orders) . The auditors are chosen in according to the commonly accepted competence of BBMRI.pl auditors. Furthermore, a competent person is allocated directly to the particular audit area. As a result, for each Biobank an Audit Report with recommendations for implementation and QMS improvements is prepared.

Conclusion: During the subsequent audits the Task 3 team will verify all the QMS improvements which have been performed by previously audited Biobanks.

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PS4C-8: Quality assessment of cells in biobanking – a systematic review

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Introduction: Ensuring high quality biobank samples is crucial for good research. However, standardization of cell biobanking is in its infancy compared to standardization in liquid biobanking. We evaluated the existing peer-reviewed literature in the field of cell cryopreservation by performing a systematic review to identify the state-of-the-art, potential improvements and challenges.

Material and methods: The systematic review was done in accordance with PRISMA, to identify biobank variables influencing the viability of peripheral blood mononuclear cells (PBMC) and mesenchymal stem cells (MSC), and to compare used protocols for assessing cell quality. Literature search was performed using PBMC, MSC, biobanking and quality management related key terms.

Results: A total of 623 studies were initially identified of which 100 were screened in detail and finally 20 (12 PBMCs and 8 MSCs) met the inclusion criteria and were eligible for the systematic review. Results showed that the procedures differ as the quality management systems of the biobanks do, even if internal standard operation procedures (SOPs) of PBMCs/MSCs exist. Generally, the knowledge of best cryopreservation and storage practices for cells is not harmonized and there is a need for standardized protocols and biobanking practices in terms of evaluating viability, purity, integrity, and functionality for different types of cells.

Conclusion: Additional research - to be coordinated with biobanking needs - is still required to clarify the effects of preanalytical variables on the quality of biobanked cells, along with the effects on downstream analyses.

PS4C-9: Implementation of an ISO9001 certified quality management system in the Bristol Bioresource Laboratories.

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Introduction: The Bristol Bioresource Laboratories (BBL) were established to manage samples from the Avon Longitudinal Study of Parents and Children in 1991. BBL has expanded to provide a biological sample processing and storage service for several British cohort studies. A quality management system has recently been implemented and achieved ISO9001:2015 certification.

Material and methods: Requirements of certification were determined and a project plan put in place to ensure progress. This included staff training, a review of governance procedures, definition of scope, establishing quality

objectives, policies and monitoring procedures. Gap analysis, stage 1 and 2 audits were carried out by the British Standards Institution (BSI) .

Results: An initial scoping exercise identified the Quality Management System scope, processes, quality objectives and monitoring requirements. A top management structure was established and project plan implemented. Staff training sessions were instigated to ensure the whole team understood the process, their responsibilities and the value of obtaining certification.

The initial gap analysis was invaluable as it identified several areas which required further development.

Stage 1 and 2 audits were completed in June and October 2017 respectively and in December 2017 The Quality Management System was ISO9001:2015 certified by BSI under certificate number FS 651591.

Conclusion: Obtaining ISO9001:2015 certification of a Quality Management System in an academic environment is achievable and an invaluable asset for biobanking laboratories offering a service. The provision of sufficient resources to manage the process of implementation is essential and some cultural and operational changes may be required.

PS4C-10: Improvement of genomic DNA and RNA quality controls on parallel capillary electrophoresis

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Introduction: Evaluation of the quality of nucleic acids is a key issue for biobanks involved in the selection of samples for Whole Genome/Exome Sequencing or Transcriptomic studies. DNA and RNA quality depends mainly on type of samples, delay and temperature of shipment to the biobank, extraction methods and storage conditions.

Material and methods: In biobanks quality of genomic DNA is usually evaluated by determining its integrity using either an agarose gel or a chip based method. Conformity with announced gender, capability of DNA amplification, homology profiles using microsatellites can be checked by PCR fragment analysis. RNA quality is commonly evaluated on a chip.

Results: At the CEPH-Biobank, we decided to improve nucleic acid quality controls (QC) in a context of a limited investment budget and an yearly average throughput of about 2000 DNA integrity and gender checks, 200 DNA fingerprints and 500 RNA controls. Our aim was to identify a single user-friendly system that could be used for both DNA and RNA QC, would improve reproducibility of our QC results and finally would limit the operator's involvement. We tested a parallel capillary electrophoresis based method on the Fragment Analyzer (AATI) to perform our DNA and RNA QC and compared with our reference methods.

Conclusion: Robustness, ease of use and cost-effectiveness were evaluated and will be presented. The use of this single system allows real improvements on all QC performed at the CEPH-Biobank on DNA and RNA in terms of reproducibility, efficiency, sensitivity with a guaranteed traceability.

PS4C-11: MedUni Wien Biobank – Pre-analytical protocol for liquid biospecimens

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Introduction: Poor reproducibility of biomedical research is frequent and to a good extent caused by inappropriate, low-quality biomaterials, which could be overcome by professional biobanks. However, despite their qualitative impact, quantitative contribution of academic biobanks to research output was so far only rarely disclosed.

Material and methods: Performance dynamics (including publication output) from prospective fluid collections of the MedUni Wien Biobank between 2010 and 2017 were reported and tested by correlation analyses according to Spearman.

Results: Annually stored aliquots rose from 68,500 to 151,966 (ρ=0.810, p=0.015), although numbers did only constantly increase until 2012 (>2012: p=0.266) . The number of requested aliquots climbed from 2,401 to 9,342 (ρ=0.929, p=0.001), and the access rate (requested/stored aliquots within the same year) nearly doubled from 3.5% to 6.1% (ρ=0.857, p=0.001) . As a consequence, the number of annual publications grew from 2 (total impact: 8.6) to 16 (total impact: 69.0), which was a statistically significant overall increase (ρ=0.857, p=0.007), although the curve presented with a cyclical trend showing two low points (2012, 2015) . Aliquots were accessed mainly by internal cooperation partners.

Conclusion: In conclusion, the MedUni Wien Biobank reports growing adoption and has already contributed to considerable scientific output at cost-efficient expenses (costs per requested aliquot are currently ~€20,- at 15-20-fold overproduction) . However, external access could be improved. The reported figures might serve as a benchmark for other academic, hospital-based biobanks.

PS4C-12: From Manual Sample Handling to Fully-automated Pipetting Robots: Technological Developments of Liquid Sample Processing Workflows

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Introduction: As the number of samples in biorepositories increases, more and more biobanks are turning to automation. By this means, they standardize their procedures and thereby maintain sample quality. Also, a reduction of labour and saving of time for sample processing and management are evident benefits of automated sample processing Systems.

Material and methods: We used different generations of sample processing workflows for the handling of fluid samples. Therefore, based on our wide experience with diverse systems, their advantages and disadvantages we assessed the technologies to provide a review and evaluation of the technological developments of liquid sample processing workflows in biobanking.

Results: Ten years experience including manual handling, the first simple pipetting robot with manual report files and a fully automated liquid handling robot with integrated freezing carrier (freezing -20°C directly) were analysed. Typical problems like inaccuracy of volumes, errors in reports and difficulties with the identification of tubes as well as integration of fully automated solutions were comprised. The huge advantages of the new system are the integrated barcode scanner, the tube capper/decapper and the after sample aliquoting. Documentation of all steps of sample processing (CEN-TS) and direct access to data in database is an enormous benefit of novel pipetting robots.

Conclusion: Fully automated robots enable high speed sample processing and are essential for large liquid samples biobanks. For smaller biobanks, semi-automated or manual sample processing is still a good choice. The decision of the best suitable system can be made with the help of the developed critical factor pattern and algorithm.

PS4C-13: Tumor biobanking: Sample quality assessment of historical collections

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Introduction: Since 2001, tumor samples have been frozen and stored at the UZ Gent Tumor Biobank. In 2012, Bimetra Biobank took over the operational management of the UZ Gent Tumor Biobank and has thus far introduced new standard operating procedures for freezing of tissue, based on best practices.

Material and methods: Over the years different freezing methods were applied and tissue samples have been frozen by multiple operators. As the quality of the material is essential for the success of future analysis, we set out to validate the value of the older tumor samples in this collection for molecular analysis.

Results: Samples from three common tumor types were selected from each year, with comparable pre-analytical variables, as far as these were registered or could be traced back. Cryosections were made to evaluate the amount of freeze damage in the samples. Through virtual microscopy, the cryosections were digitized and a quality number was assigned according to the rate of visual freeze damage that occured. Next, DNA and RNA extraction were performed using our standard procedures. The quantity and quality of DNA and RNA was measured using a DropSense16 by Trinean. Additionally, DIN and RIN scores were calculated using an Agilent BioAnalyzer.

Conclusion: The results of the samples are correlated to samples collected in more recent years (2015-2016-2017), giving an indication of the changes in quality and their usability for molecular analysis.

PS4C-14: Biobanking for the development of regenerative medicine: a problem of cell material heterogeneity

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Introduction: Postnatal human stem/progenitor cells, often preserved by biobanking, are required for regenerative medicine. However, high variability of cells, both phenotypical and functional, reflects dynamics and heterogeneity of stem/progenitor cells within tissue and could be a critical issue for the development of therapeutically effective and reproducible cell-based products.

Material and methods: These problems were explored within the scope of the project working on scientific basis of living systems depository “Noah’s ark” (Lomonosov Moscow State University, Russia) . Several approaches for cell material standardization, including single-cell analysis, potency test development and computational methods, were used.

Results: We have shown the diversity of cultured human multipotent mesenchymal stromal cells (MSC) population and revealed some mechanisms of their functional heterogeneity based on differential expression of hormone receptors and cell response to the regulatory signals. Considering that the benefits of MSC therapy was mediated mostly by producing multiple bioactive components, including soluble factors and extracellular vesicles, we have extensively studied the secretome of cultured MSC from many donors and showed the pronounced variability in the secretion of several proteins. Development of specific quality control methods and prediction computational models were used to overcome this variability.

Conclusion: Taken together, the development of comprehensive and well-reasoned approaches for the standardization of cell-based regenerative medicine products to provide the reproducible pattern of cell heterogeneity is crucial for their effective translation into clinical practice and can be a challenging concern for biobanks working in the field of regenerative medicine.

PS4C-15: Non-Compliance in Biobanking and Possible Mitigations

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Introduction: In modern biobanking compliance of both patient or donor subjects as well as biobank staff and other personnel being involved in the collection, packing, transporting, processing, and storing of biomaterials is a key component for high quality biomaterials. Non-compliance may lead to lower sample quality or even to sample loss.

Material and methods: We have been analyzing different players within as well as players outside the biobanking organization for sources of non-compliance. Our focus was on patients and/or donors of biomaterial, physicians, nursing staff collecting biomaterial, logistics staff, biobank laboratory staff. We have tried to identify causes for non-compliance among the mentioned groups.

Results: Causes for non-compliance are:

Patients / Donors do not understand the purpose of biomaterial collection. Physician staff does not support clinical research and does not encourage patients to consent. Collecting biomaterial is a burden for the nursing staff. Logistics staff does not understand the urgency of the biomaterial delivery. Specific sample processing procedures not followed by laboratory staff.

Mitigation by:

Detect false positive consents, correct them, and destroy samples collected based on invalid consents. Train and Re-train staff to comply with biobank goals and to understand quality demands of today's biobanking. Create suitable SOPs for high quality sample processing.

Conclusion: Non-compliance may be caused by very different circumstances among various players within and outside a biobanking organization and it is important to identify and address their reasons. A key mitigation strategy is training and information of the relevant players whereas some issues can also be resolved by sophisticated technical solutions.

PS4C-16: TQM in practice - proces of QMS audit in BBMRI.pl

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Introduction: In the BBMRI.pl project Wroclaw Medical University is responsible for Task3 "Verification of SOPs that exist in Polish biobanking institutions, implementation of common solutions".

As a part of Task 3 QMS audits in the Biobanks are performed. Furthermore, Standards for Biobanks and Auditor's Manual are created within the Taks 3.

Material and methods: Over the period 2017-2021 three types of audits are planned to be performed: 1st audit concerning current state of QMS level; 2nd audit and 3rd so-called evaluating/estimating audit.

Results: The following standards as input data for 1st audit are proclaimed: ISO19001, ISO9001, ISO/DIS 20387 and Audit Programme as a final proposal of WG06 BBMRI-ERIC.

For 2nd audit (1) the recomendations for Biobank after 1st audit, (2) first Standards for Biobanks version and Auditor's Manual, (3) ISO19001, ISO9001, ISO/DIS 20387 standards as input data have been considered.

Finally, for 3rd audit following input data are taken into account: (1) the recomendations from the previous audits, (2) Standards for Biobanks and Auditor's Manual (3) ISO19001, ISO9001, ISO/DIS 20387 standards, respectively.

Moreover, a consulting activity from QMS area is proceeded as well.

Conclusion: Primary audit's aim is the confirmation and suport of QMS improving complience, presented in Biobanks with accepted guidelines.

The output data from QMS audit are analyzed and used during QMS trainings in Biobanks.

Acknowledgements: This work is supported by Grant from the Polish Ministry of Science and Higher Education (DIR/WK/2017/01) .

PS4C-17: Introducing a new Tool in Qualifying Temperature Assurance Packaging System for a Safe and Reliable Transport of Health Matters

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Introduction: Careful management of resources is important and special care is required upon transportation. Blood and other biological products are extremely sensitive and become less effective, or even destroyed, when exposed to temperatures outside the recommended range. Because every degree matters, defining appropriate transport conditions is mandatory.

Material and methods: Operational and performance qualification are essential parts of quality assurance through equipment validation steps, but there are no standards for the suitability of transport conditions for sensitive products. Assistance in recommending the appropriate parcel for transportation would be beneficial to all of us.

Results: A variety of different parcels are now available to transport biological samples at constant optimal temperature. However, selecting the right shipping equipment for the job is cumbersome, time-consuming and very costly. Worst, parcels may not have been tested against a representative product volume, nor has been challenged against extreme temperatures that may be experienced outside of the standard shipping lane or location and number of loggers used for testing have not been indicated. Here, we propose a mix of tools that would help you choose the most appropriate packaging product among thousands that would just fit to your query.

Conclusion: Raising awareness is mandatory, because a parcel is not just a parcel. We firmly believe that this tool could revolutionize the packaging industry. A thorough understanding of temperature-controlled packaging needs will ensure the best packaging system is chosen to provide the necessary protection for valuable temperature-sensitive shipments.

PS4C-18: Needs and Requirements in Biobanking – Facing Challenges far beyond Biosamples

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Introduction: Recording of biosamples results in large datasets, which requires an IT-system enabling efficient and secure handling of data information. Tracking demographic and analytical data associated with these samples claims high standards. The Heidelberg Cardiobiobank developed an individualized solution using a customized research portal for biobanking and beyond named CentraXX (KAIROS) .

Material and methods: The focus of our information system is the structured data acquisition by using the modules “Biobanking” and “Study Management” of the CentraXX System. All collected sample information, clinical data and all study related data will be aggregated in the electronic patient record within CentraXX.

Results: Beside sample and study information further structured data like diagnoses or data from hospital stays (clinical data) and informed consents are combined in one file. Additionally the standard CentraXX masks for collecting patient and sample data, the embedded form engine provides the flexibility to create forms to capture all additional documentation points needed. The hospital integrated Biobank uses the interface standards HL7 (health level 7) for direct data connection to the hospital information system. Other data transfer via interfaces such as those for liquid handling platforms (TECAN), automated cryogenic storage (LICONIC) and multiple scanners are integrated in the system.

Conclusion: Embedding the customized CentraXX into the Heidelberg Cardiobioank allows functional data modeling and enables an efficient search between clinical, study and sample related data. Even today features such as age, diagnosis, therapy, pathological descriptions and laboratory values are no longer sufficient to compare diseases in the context of personalized medicine.

PS4C-19: Testing Askion’s Hermetic Storage HS200M - Experiences from the Interdisciplinary Center for Biobanking-Lübeck (ICB-L)

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Introduction: The ICB-L focuses on automation particularly for sample processing and nitrogen storage. This allows high standardization resulting in high quality samples aligned with corresponding data. Based on our setup and in cooperation with Askion GmbH, the ICB-L was chosen as a test site for the new HS200M system.

Material and methods: Different handling protocols (e.g. sample storing/retrieval) and different cryotubes (0.7ml and 2.0ml FluidX; 0.5ml ThermoScientific) were tested and validated for more than nine months. Various errors were simulated (e.g. wrong sample format chosen) in order to improve the workflow and the user interface as well as the error management.

Results: Over a period of nine months 4200 samples were stored and 2600 samples were retrieved. The storage/retrieval of 96 samples on a SBS-rack takes about 30 min, while it takes 20 min to store/retrieve 48 samples. Based on the chosen sample format, the HS200M allows the storage of up to 200,000 samples. Furthermore, different cryotubes and SBS-racks of different companies can be stored in one system. If the user chooses a wrong sample format, the system recognizes a discrepancy and adapts to it. Manual handling is not intended anymore, but a camera allows the observation of the process.

Conclusion: Sample storage and retrieval is unproblematic and comparable to the processes using the HS200S. The software C-line® control has been updated and allows a “Put Away” function, which facilitates and accelerates the sample storage. The control panel became more intuitive, which allows a quick understanding of the handling.

PS4C-20: Korean Bio-resource Information System (KOBIS) : the nationwide infrastructure for collecting and integrating bio-resource information in Korea

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Introduction: Korean government has enacted the legislature for the collection, management and utilization of biological research resources, and as a follow-up, the Korean Bioinformation Center (KOBIC) has undertaken the mission to collect and integrate the scattered bio-resource information in Korea.

Material and methods: We first made a bio-resource standard data format for exchanging data through the peer reviews among government agencies.

Results: After that, Korean Bio-resource Information System (KOBIS) has been developed, available at http://www.kobis.re.kr. KOBIS is an integrated information system for efficient acquisition and systematic management of biological research resources. KOBIS contains 109,117 species and 12,106,077 biological research information of 107 integration institutions from 4 ministries. KOBIS provides Resource Catalog to enhance the understanding and utilization of resource information, Classification System Explorer to multi-tier exploration feature following standards for biological resource, and Resource distribution for easy access to be a resource of interest and the relevant ministries and institutions.

Conclusion: We will continuously concentrate our efforts to the management of KOBIS for facilitation of information sharing, distribution, and service towards mining bio-resource information.

PS4C-21: Assessment of buccal smear DNA samples extracted from FTA cards for GWAS using the Illumina platform

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Introduction: The collection of buccal smear samples as opposed to blood samples is non-invasive, requires less equipment and no health-trained personnel. Samples stored on FTA cards are stored at room temperature for years without DNA deterioration. For GWAS, genotyping sufficient quality is required to ensure integrity and high genotype call rates.

Material and methods: Buccal smear samples (n ~ 7000-8000) from adolescents (age 13-19 years) that participated in Young-HUNT3 (2006-08) was collected and stored on FTA cards (Whatman, GE Healthcare) . DNA was

eluted using the Maxwell 16 System (Promega) from 2mm punches. Quality assessments of call rate and integrity was performed using PLINK software.

Results: Mean DNA concentration of 10-15 x 2mm punches was ~ 5 ng. Of the ~1300 samples to be genotyped by a custom-made Human Core Exome Illumina chip with ~604 000 markers, 214 samples were QC-tested. When comparing sex determined by genotyping against registered, none were discordant within samples with call rate ≥ 95%. Concerning samples with call rate < 95%, missing rates for SNPs were higher and heterozygosity was lower than expected compared to the samples with adequate call rate. Quality and integrity of the ~1300 GWAS-genotyped Young-HUNT3 buccal smear/FTA samples will be further tested in a family-based setting.

Conclusion: DNA extracted from FTA cards by the Maxwell 16 System with the accompanying elution kit is of sufficiently high quality if call rate is ≥ 95% to produce GWAS results when assayed by the Illumina technology.

PS4C-22: Sample logistics in FinnGen project

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Introduction: The FinnGen project, launched in 2017, aims to get up to 500 000 Finnish individuals to participate in the study to achieve innovations and breakthroughs in disease prevention, diagnosis and treatment. This global personalized medicine project is based on public-private partnership between Finnish universities, biobanks, hospital districts and international pharmaceutics.

Material and methods: Sample management meets high requirements because large cohorts of population and disease samples has to be collected and processed for genomic analysis within a tight time frame. THL Biobank logistics team coordinates a majority of DNA extractions and all of the DNA normalization, plating and distribution in the project.

Results: In the first three months, THL Biobank has within FinnGen framework received nearly 13 500 DNA samples from other Finnish biobanks and has normalized, plated and distributed over 34 000 samples for genomic analysis. Depending on the age and quality of the samples, different techniques in quantity and quality controls are needed which requires a standardized and automated sample flow. Also it-infrastructure had to be developed and our in-house LIMS-system was remolded to suit the needs of project's sample logistics. The flexibility of this tailor-made database is essential as several implementations of importing, tracking and reporting tools has been made.

Conclusion: Strong experience, skilled professionals and well-designed infrastructures are all needed to handle a sample logistics on such a large scale as in FinnGen project.

PS4C-23: ISO 9001 certification at the National Health Laboratory Service (NHLS) Biobank, Johannesburg, South Africa.

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Introduction: The NHLS Biobank is within the National Institute for Occupational Health (NIOH), a division of the NHLS, which has accredited been for ISO 15189, 17020 and 17025. Implementation of ISO9001: 2015 is under way at the NHLS Biobank in ensuring a sound and effective Quality Management System (QMS) .

Material and methods: In preparation for South African National Accreditation System (SANAS) audit and certification, a gap analysis was conducted in 2017. Training of personnel was conducted as an initial step. An internal audit was conducted based on ISO 9001 scope namely; organizational context, leadership, planning, support, operation, performance evaluation and improvement.

Results: The results showed a 93% compliance in ISO 9001 QMS requirements. The deadline for resolving of non- conformities (NCs) was set for 60 days. Five NCs from the ISO 9001 checklist comprising of clauses 4- 10 were identified. The NCs identified were from clauses 4 (business environment and scope) and 8 (operational processes). Closing of the NCs involved documentation development and amendments. The non- conformities were resolved within the set deadline of 60 days.

Conclusion: The gap analysis proved to be a success for preparation of ISO 9001 certification by SANAS with all of the non- conformities being resolved. Furthermore ISO 9001 certification will be a very useful tool in preparation for biobank specific accreditation as soon as the standard has been adopted in SA.

PS4C-24: Comparative Study in Whole Blood and Buffy to Obtain Nucleic Acids of High Quality and Functionality

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Introduction: Whole blood (WB) and buffy coat (BC) are usually stored in human biobanks and are very appreciated by researchers, because DNA and RNA can be obtained from this type of samples. Some preliminary studies have been performed in animals, notwithstanding that would be interesting use human samples for deeper studies.

Material and methods: In this study, blood was extracted by venopunction from 10 healthy volunteers, and used fresh and stored in long-term (one year). Then DNA and RNA were obtained from BC and WB. The extractions of theses nucleic acids were performed using the AllPrep DNA/RNA Mini Kit (Qiagen, Hilden (Germany)) .

Results: The quality of the nucleic acids obtained was assessed by spectrophotometry, fluorimetry and agarose electrophoresis. Functionality was assessed by Multiple Long PCR. Other aspect tested in this study was based in the comparison between long-term storing at -80ºC (one year) and fresh samples from BC and WB, to evaluate the stored conditions in the biobank repositories. Results obtained showed significance differences in the efficiency of the DNA and RNA extracted in the samples stored for one year but not in fresh samples. However, the integrity of the samples and the functionality was not altered with the storage time.

Conclusion: The data obtained in this study showed that is better the whole blood to obtain nucleic acids in samples stored for a long time. This could be applied at the biobanks repositories to optimize the storage conditions, and at the scientific advisory process of the researchers in their research projects.

PS4C-26: Implementation of Laboratory Quality Management System in biobanking at National Tuberculosis Reference Laboratory (NTRL), Uganda.

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Introduction: Improved biospecimen handling practices are important for research and medicine. Therefore, greater attention to quality systems in biospecimen collection, processing, and storage is required. NTRL is accredited for ISO 15189 by SANAS. Although there is Laboratory QMS implementation, the implementation levels and relevance in biobanking is not known.

Material and methods: WHO AFRO SLIPTA checklist was used to assess the implementation level of the 12 QSEs. Observation, Interviews and document review methods were used. 120 tuberculosis isolates were selected using Systematic random sampling and analyzed for reproducibility. TAT and data completeness were used to the check the relevance of QMS.

Results: Total score of (237/275) points was obtained from the 12 QSE. The Average score was 86%. Elements of satisfactory performance using a cutoff point of 80% were occurrence management, management reviews, client management and customer satisfaction, equipment, process control, information management, identification of non-conformities, corrective and preventive action, facilities and safety and purchasing and inventory. Areas of improvement included assessment and audits, organization and personnel, and documents and records. For the 120 samples done, average time for isolate retrieval from the freezer was 3 minutes, 100% agreement was obtained using kappa statistics. 71% (85/120) of documents reviewed had complete data.

Conclusion: NTRL has implemented QMS in biobanking, Implementation of QMS in biobanking has proved relevant in preservation of sample integrity. Future plans of the NTRL Biobank should include implementation of the ISO 9001:2015 standard and ISO/ TC 276. QMS implementation is feasible in biobanking in developing countries.

PS4C-27: Standardized cold chain biobank sample collection in Finnish Clinical Biobank Tampere

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Introduction: Biobanks hold the key for future breakthroughs in medical research and development of diagnostics and therapeutics. Without proper protocols, the integrity and validity of biobank samples can be at risk. The aim is to establish and validate a standardized cold chain for biobank samples.

Material and methods: Blood samples are drawn in outpatient clinics and immediately stored in fridge until transportation. Samples are transported to the laboratory using thermos bottles with two cold gel packages (+4C and -20C) . The optimal temperature was defined between +2C and +8C. During piloting (n=25 clinics), the temperatures were measured continuously.

Results: During piloting the mean time in which the temperature decreased into the optimal temperature was 1.6 h (±0.8 h) . The mean minimum temperature was 2.9C (±2.3C) during transportation and the mean time of transportation was 6.4 h (±1.5 h) . The packing of the sample increased the temperature in the thermos temporarily on average by 1.9C (±1.7C) but during transportation the temperature decreased or remained stable until the sample reached laboratory premises.Piloting of the cold chain procedure was done with water samples. After piloting, the temperatures are measured using blood samples.

Conclusion: Cold chain utilizing thermos bottle and cold gel packages worked efficiently in decreasing and maintaining the optimal temperature of the sample. Currently all samples in Finnish Clinical Biobank Tampere are handled using cold chain except for DNA samples. Validation of sample integrity will be performed in the next stage.

Topic 5A - Achieving Long-Term Sustainability in Biobanking

PS5A-1: Development of a cost and services catalogue for a centralized hospital-integrated biobank

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Introduction: The need for biobanks to provide high quality biomaterial and data for research is accepted, although their costs are mainly neglected. Consequently, a transparent description of services and their corresponding costs is required to enable a partial refinancing by funders besides continuous financial support by medical faculties.

Material and methods: The centralised biobank of the University Medical Center Göttingen (UMG) identified its costs for staff and equipment, operation of the facility, different consumables and measured and estimated the duration of various biobanking processes. Different storage formats relevant to invoicing were evaluated as well as a discount for UMG internal researchers.

Results: These efforts resulted in a cost and service catalogue for 20 distinct services. These services range from biomaterial transport, through storage in manual vapour phase LN2 tanks and automated storage at -80°C, through IT advise for data documentation. Prices are based on full costs and are distinguished for internal use (80% reduction) and for use by proxy (plus 20% overhead) . Staff costs are the biggest part of service costs. Moreover, calculation of costs for services are based on racks not on samples. The catalogue also includes available equipment and an exemplary calculation. Invoices are generated on the actual consumption.

Conclusion: The cost and service catalogue of the UMG Biobank was passed by the medical faculty as part of the terms of use. It has been applied to several project proposals. Thus, funders need to provide money for these costs to achieve a financial relief. The catalogue is available at http://www.biobank.med.uni-goettingen.de/de/media/Anlage_05_Kosten_und_Leistungskatalog.pdf

PS5A-2: How to achieve a sustainable central facility for clinical biobanking

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Introduction: Since 2012 the Radboud Biobank offers disease-based biobanks a centralized facility to optimize the use and distribution of biomaterial for research. Currently, the Radboud Biobank has more than 350,000 aliquots comprising different biomaterials from over 32,000 unique participants of more than 45 sub-biobanks.

Material and methods: In order to become a sustainable biobank our goal is to achieve a coverage of 30% of the total variable costs through income from issuances and to prevent our initiative to become a biobank bubble. In 2017 we covered 12% of the total variable costs through income from issuances.

Results: As sustainability apparently remains a challenge we tried to identify key-drivers for successful issuing during a brain storm session with our management team. The following issues were identified and will guide us in our sustainability strategy. Concrete actions were initiated:

- Business model – redefine the model parameters;

- Entry criteria – guide the decision process to access a new sub-biobank by strict criteria;

- Periodic evaluation – guide the decision process to maintain a sub-biobank by strict criteria

- Visibility – implement tools to increase visibility (e.g. catalogue, papers, showcases) ;

- Market analysis – monitor potential (industrial) clients and potential competing biobanks, act accordingly.

Conclusion: At the European Biobank Week we will share details and our experiences in order to increase the common understanding of the success factors for sustainable biobanks.

PS5A-3: Reinvigorate human biospecimen samples use in biobanking: cracking the Da Vinci code by using tools from business model design

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Introduction: While biobanks still hold tremendous promise for discovery of biomarkers and new diagnostics, the biobanking community is slowly recognizing that the traditional financial model for biobanks isn't working. Achieving sustainability in biobanking is not just a simple matter of displaying the provisions of a business plan.

Material and methods: Basically, biobank managers have the know-how necessary to manage a biobank but their knowledge of economic issues is poor. Contrariwise, economists are accustomed with financial instruments however not often aware of a consolidated understanding of biobanking landscapes. And if we attempt to merge both sides for the sake of biobanks?

Results: Business model serves the strategy, while business plan explains the operational implementation of the business model. Business model design is about new ways of creating, delivering and capturing value. While the value proposition canvas helps you create value for your customer, the business model canvas helps you create value for your business. Among others, the environment map helps you understand the context in which you create, while prototyping, lean methods and lean market validation would help you to prototype and validate your concept before bringing the new product to market.

Conclusion: Here, to reinvigorate the human biospecimen samples use, we raise awareness on the existence of such financial instruments to biobankers community and we hope to provide enough hands-on basic guidelines. This is essential for correct management of such infrastructures like biobanks.

PS5A-4: Is a biobank fairly recognized by the scientific community?

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Introduction: By providing biosamples and data to the researchers, a biobank may or may not charges user fees but in either way the scientific community ought to cite or acknowledge the biobank in publications. An in-depth investigation was conducted aimed to determine whether the researchers recognize a biobank through its publications.

Material and methods: Scientific articles from a set of established researchers (biobank users) were analysed. This analysis consisted of the identification of the biological material used in the publications (correspondence to biobank requests), the eventual partner in Sample/Data provision and the contribution of the researcher in the article.

Results: Among the 561 publications found, we recorded only the scientific articles gathering these criteria: Articles published from 2008, which used human biomaterial and (might) involve samples from our biobank, no case studies, no retrospective data analysis. In total 170 articles were recorded on a table. The most used material in the studies is Formalin-fixed Paraffin-embedded tissues (56%) . Moreover, 34% of the publications mention a partner in sample and/or data provision. Biobank Graz was cited and/or acknowledged in 16% of the articles (27/170) and two researchers never cited it.

Conclusion: Undeniably, without provision of high-quality, well annotated and well defined biological samples by an established biobank, a research study cannot be performed according to the good practices. Through this investigation, we conclude that biobanks and biobanking in general should be better recognized by the scientific community.

PS5A-4: How Online Marketplaces Can Help Biobanks Achieve Sustainability

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Introduction: While 2017's focus on harmonization amongst the global biobank community was a necessary first step toward this year's goal of Biosharing for Scientific Discovery, I believe we must also address the challenges biobanks will be facing in the coming years.

Material and methods: Just a few of these obstacles include GDPR implementation, a rapidly evolving research landscape and perhaps most importantly, sustainability. With a heavy reliance on dwindling external grants to maintain expensive facilities, where can biobanks turn to guarantee consistent funding?

Results: Setting up a revenue stream involving contracts, sales and marketing only adds to tightening budgets and can be a daunting prospect. One solution is to utilise a commercial provider to drive revenue, yet a number of biobanks are prohibited from using them due to internal policies. Over the past few years a new option has emerged: a third-party platform that ensures all administrative requirements (such as contracting) are addressed while reducing overhead and maintaining full control of your samples. Platforms, aka online marketplaces are sprouting up in every industry, promising a streamlined, more efficient and cost-effective way of conducting business.

Conclusion: As these marketplaces become more established within the biotech and pharma industries, now is the ideal time to consider whether or not such marketplaces can support your biobank's short, medium and long-term goals whilst maintaining visibility, traceability, control and lastly, sustainability.

PS5A-6: Sustainable biobanking in the Netherlands: best practices, value and a sustainable infrastructure

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Introduction: Sustainability of biobank- and data infrastructures depends on the interplay between scientific, societal, operational, and financial aspects. For most, the financial aspects represent the largest challenge. Tackling this challenge requires the creation of value for multiple stakeholders. Best practices and shared solutions for the variety of infrastructures are needed.

Material and methods: Through literature studies and workshops with biobanks and associated stakeholders, we create awareness and share relevant solutions. Hereby, we aim to improve the sustainability of individual biobanks and work towards overarching (Dutch) funding and infrastructural solutions that promote sustainability.

Results: First, to serve as a starting point, we described the current Dutch state of affairs regarding sustainable biobanking and gathered international best practices from literature. Second, we organised a workshop with approximately 20 biobank- and data infrastructures, each varying in size and complexity. The workshop was aimed at gathering best practices and solutions, understanding the value of biobanks for particular stakeholder groups, and exploring the potential for collaborations. These activities offered individual biobank- and data infrastructures insights on how they could make their own biobank more sustainable. Furthermore, results will be used as input in a workshop with external stakeholders.

Conclusion: The sustainability of biobanks is a many-sided subject. By identifying and understanding the value that biobanks create for scientists, patients, policy makers, funders, and many other stakeholders new and innovative collaborations and boundary conditions for ensuring a sustainable Dutch biobank- and data infrastructure can be created.

PS5A-7: National BioService: creating a bridge between Russian biobanks network and global biopharmaceutical R&D - a successful experience

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Introduction: In last few years, several well-organized biobanks have been created in research/clinical centers in Russia. This development is important, providing major boost to local biotechnology R&D. However, the power of individual institutional biobanks to support R&D projects is limited and does not meet growing demand of biomedical research.

Material and methods: National BioService (NBS) concept is based on the development of a wide partnership network involving many clinical centers with diverse specializations, in which NBS plays coordinating role, ensuring standardization of key activities and providing laboratory and logistical support, essential training, quality management system and ethical procedures based on international guidelines.

Results: Since 2014, NBS has created a partnership network of >100 clinical centers, including medical schools, multidisciplinary and specialized clinics, out-patient clinics and private medical centers. Several biospecimen characterization laboratories have been established to support creation of meaningful collections. Systematic biospecimen collections in areas such as

hematology, immunology and oncology, and customized projects are ongoing in full compliance with national laws and ISBER guidelines. Over 600 projects of various levels of technical complexity and in diverse TAs have been completed. Established clinical network and laboratories also allowed NBS to launch its own R&D programs aiming at developing cell and tissue products.

Conclusion: NBS has successfully created a high-capacity and well-coordinated clinical network, supported by NBS' extensive laboratory capabilities and actively involved in collecting and characterizing biospecimens for R&D needs of local and international community. NBS activities are driven by science, united by principles of legality, ethics and quality and follow international guidelines.

PS5A-8: Concept and implementation of a FeeForService model for a research biobank

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Introduction: In 2014 the tissue bank of the National Centre for Tumor Diseases (NCT) in Heidelberg decided to start to work on a model for cost recovery of research applications. This model should insure long-term sustainable financing as well as fair allocation of rising expenses for biobanking services.

Material and methods: A survey on existing pricing methods was performed and a model selected that would be most suitable to the mode of operation at the tissue bank. Laboratory and administrative processes were systematically assessed and associated average costs were determined using statistical methods.

Results: The assessment revealed about 130 relevant processes that could be transferred into a cost-service-matrix. This matrix is the basis for the new price calculation of the individual research applications at the tissue bank. 4 categories (overhead, material, processing and shipping) are used to issue a comprehensible invoice form that is given to the applicant together with a project-specific material transfer agreement (MTA) . The customer acceptance of the model is monitored by an already established after-project survey tracking the general customer satisfaction as well as collecting feedback on the perceived price-performance within the research project.

Conclusion: The implementation of a FeeForService model in a biobank requires comprehensive preliminary works and planning. To apply a specific method of pricing analysis of costs and costumer need is required. Once implemented it can serve as a basis for sustainable financing and contribute to responsible use of valuable specimens.

PS5A-9: Can collaborating with Industry make Academic Biobanks sustainable? If so, what do they have to change to work with Industry?

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Introduction: Academic biobanks require multiple staff in addition to equipment and consumables, so annual running costs are typically in the hundreds of thousands of Euros. Unless these costs are covered by the biobank's host institution, external sources of income are essential for sustainability. Collaboration with industry provides one possible external source.

Material and methods: Working as a biospecimen procurement CRO, we have direct experience of liaison between academic biobanks and researchers in industry, and are familiar with the challenges and opportunities in this area. We have also conducted surveys in collaboration with ISBER, to identify the issues faced on both sides of the collaboration.

Results: Based on our experience, there are very often a number of ways in which academic biobanks need to change in order to work effectively with industry. First, biobanks need to collect the type of samples that are needed by industry to support their research and development. Second, biobanks need to simplify and shorten many of their administrative processes. Third, biobanks need to appreciate the requirements and timelines that researchers in industry must respect when developing and validating new biomarkers, in order to satisfy regulatory authorities.

Conclusion: Academic biobanks can certainly recover significant running costs by collaborating with industry. However, to do so in a sustained manner, they need to plan their operations appropriately. They also need to have realistic expectations about the different benefits that may be possible.

PS5A-10: Biobanking to innovation

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Introduction: The medical services in the world is steering towards precision medicine which is based on genomic medicine. One of the infrastructures of this environment is the storage and/or utilization of bioresources including data.

Material and methods: Current discussions regarding standardization have been started under the ISO framework. The direction of standardization was properly placed, standardization have had positive impacts on innovation. Although precision medicine seems to be a promising concept, some critics point out that it may produce medical inequalities based on individual economic backgrounds.

Results: One solution for such problems could be to set up the opened framework of biorepositories. Considering the roles of biorepositories, it is urgent for the current generation to prepare a workable framework and maintain it in a sustainable way. In the near future, public funds will no longer be able to provide full support to all the social infrastructures. Under these circumstances, users of biorepositories as private partners are expected to participate in this framework in a proactive and pre-competitive manner.

Conclusion: We who are mainly users of biorepositories, have decided to network horizontally and further set up a corporation of "Council for Industrial use of Biological and Environmental Repositories (CIBER) ", and commit to support a part of the roles of the medical infrastructure under international standards.

Topic 5B - IT Tools: Solutions and Visions for Biosharing

PS5B-1: Selecting a Laboratory Information Management System for Biorepositories in Low- and Middle-Income Countries: The H3Africa Experience and Lessons Learned

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Introduction: Biorepositories in Africa need significant infrastructural support to meet International Society for Biological and Environmental Repositories (ISBER) Best Practices to support population-based genomics research. ISBER recommends a biorepository information management system which can manage workflows from biospecimen receipt to distribution. The H3Africa Initiative set out to develop regional African biorepositories.

Material and methods: Three institutions in Uganda, Nigeria, and South Africa were successfully awarded grants to develop the state-of-the-art biorepositories. The biorepositories

carried out an elaborate process to evaluate and choose a laboratory information management system (LIMS) with the aim of integrating the three geographically distinct sites.

Results: The following are key recommendations for review while choosing a LIMS for LMIC should be: (1) easily customizable and usable; (2) interoperable with other LIMS; (3) have access to revisions, updates, patches, and maintenance releases; (4) of low cost and accessible to technical support services; (5) of low maintenance and associated costs; (6) enable multiuser/site support; (7) robust to handle large volumes of sample information as the repositories grow; (8) have tamper proof security systems (audit trail, user roles, and privileges, etc.) ; and (9) preferably open source though these are of limited value compared to the commercial LIMS.

Conclusion: In this article, we review the processes, African experience, lessons learned, and make recommendations for choosing a biorepository LIMS in the African context. A detailed checklist and description of the elements we considered to be key while choosing a biorepository LIM can be accessed via biorepository.h3africa.org website.

PS5B-2: Automation in Biobank Pilsen

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Introduction: Biobank Pilsen has been created in 2015 as a hospital-integrated biobank in the Department of Immunoanalysis of University Hospital Pilsen. It is member of BBMR-CZ network, together with 4 other biobanks in Czech Republic.

Material and methods: In Biobank Pilsen, liquid clinical samples are collected. The specimens are automatically aliquoted on an instrument AutoMate 1250, Beckman Coulter, USA, with the integrated tool I.S.B. (Intelligent Sample Biobank) . This tool provides the transferring specimens into coded tubes and registering the specimens into the software.

Results: Thanks to the automated system, the Biobank Pilsen has collected more than 400 specimens since November 2017. All specimens are stored in freezers -80oC and their traceability is assured in the software. The database of specimens is ready to be offered for research.

Conclusion: An automation is an important part of biobanking as it has several advantages: better traceability of specimens, better work flow, less errors in identification.

PS5B-3: Enabling Systems Toxicology Assessment Studies with State-of-the-Art Biospecimen Information Management Systems

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Introduction: Systems Toxicology is an emerging assessment approach that is based on a variety of high-throughput molecular measurements, including genomics, proteomics, metabolomics, lipidomics and others. These experiments are often associated with large sample sizes, require rich sample annotations, and involve many sample events leading to complex sample relationships and large datasets.

Material and methods: Sophisticated sample metadata management is key to a successful experimental outcome and allows complex study designs to address complex scientific questions. This introduces significant informatics challenges that not only lie in the management of rich annotations or large sample-counts but also in the large number of sample events and relationships.

Results: In the course of the past six years, and together with the establishment of a quality management system, we have integrated a solution that is adaptive to complex experimental designs with multiple-level sampling. It provides a global sample management solution that includes tracking of subject and sample information in pre-clinical and clinical studies, dense branching of sample relationships, and internal and external sample storage management as well as sample information transfer to downstream systems (e.g., laboratory information management systems, data management systems, or data warehouse) for reporting.

Conclusion: In conclusion, this Biospecimen Information Management System effectively addresses many of the sample management challenges in the biomedical and 21st Century Toxicology domains.

PS5B-4: Efficient curation and real-time querying of clinical and genomic data for 500.000 samples

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Introduction: Recent research on projects such as the UK Biobank has emphasized the power of large, well curated and harmonized sets of clinical, phenotypic and genomic data for making groundbreaking discoveries. Such cohorts are increasingly feasible to collect, but heterogeneity within and between data sources often requires prohibitively timeconsuming data curation.

Material and methods: Once data has been collected, the scale of managing and efficiently accessing data for 100.000:s of patients can be daunting. To solve the most common issues in curation and management of clinical and phenotypic data, we have developed the Accurate (TM), Phenius (TM) and Genius (TM) software solutions.

Results: We present results showing the significant time savings achieved with Accurate (TM) in data cleanup, standardization and ontology mapping of both structured and natural language data. Results include both specific benchmarking of the machine-learning natural language analytics on the MIMIC III data set, as well as of the whole data curation process on a large heterogeneous clinical dataset. In addition, we present results and methods for achieving efficient and low latency complex queries on clinical and genomic data of over 500.000 samples with Phenius (TM) and Genius (TM) .

Conclusion: In summary, we here present highly intuitive and efficient solutions for curation and management of clinical and genomic data for biobanking, biomedical research and healthcare, emphasizing enrichment of data using ontologies, fine grained access control, a full audit trail of all curation operations and scalability to over a million samples.

PS5B-6: The electronic systems of Taiwan Biobank

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Introduction: Through the recruitment and follow-up of 200,000 individuals from the general population without cancer from communities throughout Taiwan and 100,000 patients with chronic diseases from medical centers, Taiwan Biobank have provided biospecimens and information, including genetics, environmental factors, physiological examination, dietary factor and medical records to researcher.

Material and methods: To manage the status of recruitment and information, Taiwan Biobank has developed many kinds of electronic systems. The major one is the Central Authentication Management System (CAMS), which is composed of Subject Personal Information Management System (SPIMS), Subject Tracking Management System (STMS) and Clinical Data Management System (iQuestion) .

Results: SPIMS is used to manage confidential personal information; STMS is to manage the status of recruitment and biospecimens information; iQuestion is to manage questionnaire information. To address the importance of privacy protection issue, these systems depend on different authorizations to different staffs with different roles in Taiwan Biobank.

Conclusion: All information in Taiwan Biobank have been effectively managed by these electronic systems. Taiwan Biobank is continuing to optimize these systems to achieve it goals.

PS5B-7: Leveraging cloud-based LIMS for managing Sheffield Neurodegenerative Diseases Brain Bank: a major resource for neuroscience research

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Introduction: Established in 1993, the Sheffield Brain Tissue Bank (SBTB) serves as a repository for brain tissue donated by patients with motor neuron disease, Alzheimer, and dementia. Their primary goal is to provide an infrastructure to facilitate neuroscience research. To collate data, a Laboratory Information Management System (LIMS) was imperative.

Material and methods: Leveraging the benefits offered by a cloud-based LIMS for managing brain sample donations, the SBTB is able to overcome the challenges of consent management and real-time sharing of brain tissues with neurological research laboratories, to facilitate Cognitive Function and Ageing Study (CFAS) .

Results: Deploying a cloud-based LIMS at SBTB helps manage the complete life-cycle of brain tissue samples including long-term archiving, patient consent, clinical annotation, and sample location. Managing tissue requests and its distribution to neuroscience laboratories is now possible with CloudLIMS' client portal. With CloudLIMS' audit trail reports, the biobank is always ready for external inspection by the Human Tissue Authority. Furthermore, CloudLIMS uses the highest standard of data security, 256-bit AES encryption SSL (HTTPS) protocol, to store and transmit brain bank data.

Conclusion: Clinically assessed and neuropathologically characterized brain and spinal cord tissues are one of the most important resources for neuroscience research. Using CloudLIMS, SBTB is able to provide access to high-quality tissue for Sheffield-based neuroscientists and outside research laboratories, which is vital for the development of future clinical treatments.

PS5B-8: Biobank Sample searching tool - BioFace

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Introduction: In recently published papers GWAS analysis are being performed on hundreds of thousand samples. Therefore the most important in nowadays genetics is access to high quality samples. As a response for this needs we would like to present for the first time the new approach on data/samples sharing.

Material and methods: Basing on experiences of social media with its defined access to resources using network of trusts we have implemented information sharing and samples searching system. The system allows to import meta/phenotype data of collected samples and then share them within biobanking society. Range of information shared is defined by user.

Results: The main concern is information security. Therefore during the import phase, designed app (everything else is being served by web browser) performing data pseudonymization. This approach allows latter updates of data especially if concerning longitudinal studies. Key for pseudonymisation is known only for data curator/owner of dataset.

System has implemented searching engine, therefore data structure is no longer concern for end user. What is more “asking questions” about samples is being served with mechanism known from web searchers and should not be a problem for average user. To ensure high performance the system is scalable from node to cluster.

Conclusion: System is going to be implemented among BBMRI.pl members as an official data sharing system, creating abstraction layer and entry point for data access.

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PS5B-9: Further development of the BBMRI-ERIC Self-Assessment Surveys based on user feedback

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Introduction: In order to provide high-quality samples, quality-controlled sample-handling is essential. To offer support for biobankers, BBMRI-ERIC in collaboration with BBMRI.at developed the BBMRI-ERIC Self-Assessment Surveys (SAS) . They assist in assessing the compliance of established sampling-handling processes with the requirements defined within the CEN Technical Specifications for pre-examination processes.

Material and methods: After releasing Version 1 of the BBMRI-ERIC SAS a year ago, user feedback from persons completing the surveys was collected. This feedback was either provided by using the "Additional Notes" field of the PDF reports submitted to BBMRI-ERIC or emailed to the responsible persons at BBMRI-ERIC or BBMRI.at.

Results: User feedback targeted the I.) content of the SAS, II.) layout of the PDF report, and III.) reporting functionality. Regarding the content, ambiguities of questions within the surveys were eliminated according to the feedback. Where needed additional answering possibilities (e.g. "not applicable") were incorporated. Apart from layout adaptions regarding e.g. font, spacing, corporate design, document control items (e.g. document title, version numbering, created/approved by, date, page count) were included. The reporting functionality was adapted with special focus on the trigger for sending reporting mails to the responsible contact person and – if requested – to BBMRI-ERIC.

Conclusion: Version 2 of the BBMRI-ERIC SAS aimed to increase usability based on user feedback integration. The incorporated document control enables the integration of the SAS within the Quality Management Systems of the biobanks and facilitates the communication and support of the BBMRI-ERIC Quality Management with the contact person.

PS5B-10: Harmonizing European and German Biobank Request Workflows: BBMRI-ERIC and GBA – a Synergy!

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Introduction: Biobanking IT at the national level and on a European scale have almost the same needs. The BBMRI-ERIC project intends to connect European biobanks, whereas the German Biobank Node applies the concept to Germany. From a researcher's perspective, it is instrumental to access many biobanks using one single entry point.

Material and methods: The existing requirements, workflows and software modules of both networks were analyzed. Moreover, a wide group of stakeholders was consulted to collect further requirements. A harmonized workflow and software architecture was defined and consented in a collaborative effort. It should enable researchers to query biomaterial of all participating biobanks.

Results: A software suite has been consented that implements the previously defined workflow. Having logged in with the account of their home institution, researchers can create a sample and data request in the context of their planned research project. This request is distributed to all selected biobanks. Biobanks may configure their reply in accordance with local data protection concepts. By default this is the number of potentially matching samples. Based on these results, the researcher may select biobanks to discuss a cooperation for his research project. This negotiation is supported by a communication platform tailored to the needs of the participants.

Conclusion: A common biobank request workflow was consented and is being implemented by a cross-national team. While introducing organizational challenges, the synergy effects surpass the "costs" for the harmonization, as software from both projects can be merged. A comprehensive test and evaluation of this multinational query process is still required.

PS5B-11: RD-Connect Sample Catalogue adopts BBMRI-ERIC Negotiator for request management of rare disease biological samples

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Introduction: Rare disease (RD) biological samples are difficult to access due to their intrinsic rarity and scarcity. RD-Connect Sample Catalogue is a centralised online catalogue of individual RD biological samples, and is open to all to browse. Adoption of BBMRI-ERIC Negotiator facilitates the requesting management and access of these precious samples.

Material and methods: RD-Connect project partners shared a common vision to facilitate data and sample access for RD research. With this common goal, multiple teams worked together to maximise resources, to ensure that tools from different project contexts were built to be interoperable, synergic and user-friendly.

Results: In the initial phase, the workflow mapping every step of a sample request was designed and agreed. The request workflow starts from the RD-Connect Sample Catalogue (samples.rd-connect.eu) where users can browse and select samples of interest for which to proceed to open a request. The communication between the user and the biobanks are then supported by the BBMRI-ERIC Negotiator, where the request moves through stages of negotiation, offers, confirmation of request, delivery and conclusion of the research project. The implementation of the Negotiator extension and crosstalk of the tools is underway and expected to complete in 2018.

Conclusion: Access to high quality human biological samples is fundamental for research. RD-Connect Sample Catalogue with BBMRI-ERIC Negotiator extension represents a successful collaborative effort to realise a tool that

allows researchers to easily search and request for samples, and at the same time optimising request management for the biobanks.

PS5B-12: BBMRI-ERIC Directory 4.0

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Introduction: The Directory is BBMRI-ERIC's publicly accessible tool to find aggregated information about biobanks and the collections they hold. In the last year members of Common Services for IT have improved the Directory to provide significant added value for researchers as well as biobanks.

Material and methods: The Directory is built using the MOLGENIS platform which enables building of flexible online databases and we incorporated the data model of the MIABIS minimal information standard developed by BBMRI. A user panel helped us to evaluate and improve the user experience of the Directory.

Results: We have released a major new version of the Directory with an engaging new user interface that makes it easier to find the relevant biobanks and collections, while keeping the more complex search available in an Advanced view. We have extended the data with imaging biobank through a collaboration with the European Society for Radiology (ESR) . To facilitate keeping the data up to date we have collaborated with National Nodes to automate data ingest from BBMRI countries. To encourage reuse we provide a ready to use installation of the Directory in BIBBOX (http://bibbox.bbmri-eric.eu).

Conclusion: The Directory is an important first point of contact for engaging biobanks and researchers. Through the integration with the BBMRI-ERIC Negotiator it encourages better use of existing biobank collections and the expertise of the biobanks. We welcome feedback to improve the system to better serve the biobanking and research community.

PS5B-13: Quantitative imaging biomarker platform for multi-center studies: the Heart-Brain Connection use case

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Introduction: We developed a platform that facilitates standardized extraction of quantitative imaging biomarkers from medical image data and enables relating them to other data in biobanks. The platform was originally developed for population imaging studies (BBMRI-NL2.0-Imaging, Rotterdam Study), and was recently successfully used in the prospective multi-center CVON Heart-Brain Connection study.

Material and methods: The infrastructure supports the full imaging component of the study, including data anonymization, quality assessment (QA), manual annotations, automated image analysis and linking quantitative imaging biomarkers to other data . The infrastructure has previously been used successfully to analyze thousands MRI brain scans of the Rotterdam Scan Study.

Results: In the Heart-Brain Connection study, MRI scans are acquired at four medical centers, anonymized, sent to a central XNAT image database, and registered in the StudyManager. The StudyManager is built to track and guide the scans through a predefined workflow:

1. QA: the scans are matched to the clinical data, and the scan parameters are checked to evaluate adherence to the scan protocol.

2. Radiologists rate the scans and annotate infarcts. We created an integrated viewer which automatically downloads images from and uploads annotations onto XNAT.

3. Automated image analysis pipelines are used to compute brain-tissue types and cerebral perfusion.

Conclusion: For the CVON Heart-Brain Connection study we successfully processed 500 scans with the infrastructure. The infrastructure greatly improve the traceability and reproducibility of image analysis in multi-center studies. Because the infrastructure is built in a flexible way, it can be adapted and reused for other studies with different workflows.

PS5B-14: PALGA Portal, the Dutch National Tissue Portal; a nationwide infrastructure for requesting pathology data and material

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Introduction: PALGA, the Dutch pathology registry contains over 72 million pathology records. The accompanying materials, mainly paraffin blocks, are stored in more than 50 pathology labs. The PALGA Portal allows fast, easy and safe access to these resources and with that, stimulates secondary use of the tissues and data for research.

Material and methods: The PALGA Portal is a web-based portal that allows researchers to request pathology data or material (from different diagnostic pathology labs) . Requests are forwarded to the designated labs (and track-and-traced) . HUB-employees, stationed in every academic hospital and serving the non-academic labs, aid in picking, registering and sending the requested materials.

Results: Since launch in 2015, the number of requests increased and so far, the PALGA Portal has facilitated over 500 requests, involving more than 49.000 pa-numbers. For example, the Portal enabled identification and collection of data and material from rare disease patients spread over the Netherlands. It also allowed the collection of thousands of tumor/normal tissue pairs for the creation of tissue microarrays. The increased re-use of pathology material led to increased scientific publications involving PALGA. Besides facilitating researchers, the PALGA Portal supports the labs in tracing material, and provides information on the use of pathology data and material for research.

Conclusion: The PALGA Portal has streamlined and professionalized the request, delivery and use of pathology data and material for research. It has shown to increase efficiency and transparency for both the requesting researchers and providing pathology labs.

PS5B-15: TraIT, Translational Research IT, a nation-wide initiative providing an integrated suite of tools aligned with the workflow of translational scientists

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Introduction: Translating new technology and biology into clinical applications is hampered by insufficient data infrastructure. The Dutch Translational research IT (TraIT) initiative, embraced by BBMRI-NL, bridges this gap by organizing, deploying, and managing data and workflows in an on-line "office suite" for translational research, supplemented with efficient training and user support.

Material and methods: TraIT (http://www.ctmm-trait.nl) is organized as a multi-partner IT infrastructure with active participation of BBMRI-NL targeting specifically biomarker research. TraIT enables collection, processing, integration and interrogation of information across the four major domains of translational research: clinical, imaging, biobanking and molecular (omics) data.

Results: TraIT avoids duplication of efforts by adopting (and adapting) existing standards, technologies and operational procedures. In line with this principle, TraIT has adopted existing successful applications, often open source, to fill crucial slots in its workflow. Typical examples are OpenClinica (clinical), XNAT (imaging), tranSMART (integrated analysis), and MOLGENIS (sample data) . Users are supported by a helpdesk, documentation, training, a self-service portal, and targeted account management for more complex research programs. This additional layer of services has been key to the success of TraIT. Overall, TraIT has currently more than 3500 unique users, applying TraIT tools in 420 studies

Conclusion: Netherlands academia, funders, patients, companies, and government are now joining forces to establish a comprehensive infrastructure for health research, called Health-RI, which we envision to be the future landing zone for TraIT.

PS5B-16: Pros and Cons of using SeedDMS File Management system

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Introduction: In the year 2018, with the help of BBMRI,Malta Biobank received and installed a new IT program -SeedDMS- which has proved to be very useful for file keeping. I am glad to present our experience with SeedDMS in this Power Point presentation.

Material and methods: A few scientists under the supervision of Prof Alex Felice from Malta University participated in the Thalassemia Study.

The team was international, use of Google Drive or University Drive was restricted due to different email settings.

SeedDMS was installed and used during the study with excellent results.

Results: Usage of SeedDMS file management system enables Maltese scientist Charmaine Vella to share her files with the team that will continue research in the Thalassemia field in a safe way. Libyan scientist Aisha Benzetoon, who had no previous experience using SeedDMS will be using the same data and continue her research in the same field.

A Multinational IT team from different institutions locally and abroad can also help with this study using and sharing files in a most secure way.

It is no longer necessary to send important files back and forth by email.

Conclusion: SeedDMS File management system is the perfect file management system .Accounts are extremely easy to create and each person or team can be assigned to a specific folder or folders, without being visible to other teams or having access' to other teams' folders. Information is secure and private .

PS5B-17: OpenSpecimen - Experiences of collaborative development of an open source biobanking informatics platform

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(1) Krishagni

Introduction: Biobanking is a highly dynamic activity which faces many challenges, including the need to deal with ever increasingly complex demands of managing data and integrations with existing databases. The informatics platform will need to support complex workflows and data collection needs specific to each collaborator, disease or geography.

Material and methods: Open source (OSS) promotes collaboration, avoids single "vendor lock-in", more secure and reduces the cost of ownership. In comparison, proprietary software is does not promote "collaboration". OpenSpecimen is result of collaborative efforts of NCI (USA) and in the last 8 years has continued its evolution with industry and academic partnership.

Results: Krishagni has worked closely with its biobanking community to develop a robust, scalable and highly flexible open source biobanking informatics platform. We will demonstrate how collaboration with biobanks across the globe has allowed OpenSpecimen to expand and meet the ever-increasing needs of this domain. We will present examples of collaboration with Johns Hopkins, Memorial Sloan Kettering, Children's Hospital (Dallas), UT Southwestern (USA), University of New South Wales, SAHMRI (Australia), Singapore General Health and University of Leicester (United Kingdom) . The poster will also highlight the open source methodology and the enhancements developed in OpenSpecimen as part of these collaborations.

Conclusion: As a result, OpenSpecimen is today used in 65+ biobanks across 15 countries. In summary, this poster will highlight an increased need for informatics systems to stay apace with the changes being experienced by biobanking societies and how OpenSpecimen uses open source to achieve collaboration amongst biobanks across the globe.

PS5B-18: EDC-LIMS integration through MIABIS semantic annotation

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Introduction: In translational research, the combination of biorepository data and electronic data capturing in eCRFs is often required. LIMS systems seldomly lend themselves as an ideal tool for eCRF design, nor do EDC systems provide an ideal solution for sample management. Hence, this induces the need for two separate data sources.

Material and methods: A common solution could be to replicating parts of the data from one data source to another. Many such integrations highlight a common pattern: mapping one field to another. This yields a few challenges: changing the names of fields requires the mapping to be adjusted accordingly.

Results: The lack of interoperability hence implements a fragile system with very limited sustainability. Another challenge is harmonizing the exact meaning of a field and which options they have: e.g, a slight difference in interpretation of a field may have a deteriorating effect on data quality. As a means to fix this problem, fields in both the LIMS and EDC system are annotated using the Minimum Information About BIobank (MIABIS) standardized data elements1. This standard provides codes (e.g., MIABIS-PERSON-04) which indicates the exact meaning (vital status) and its options (alive, dead, not recorded) .

Conclusion: We will describe a reliable and robust system based upon these solutions, that can efficiently query for fields by annotation and can easily be configured and conveys an agile way of agreeing on data replication.

PS5B-19: Podium: an open source web-application for access to samples and data from biobanks and registries in the Netherlands

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Introduction: The Dutch consortium BBMRI-NL is working towards a national biobanking infrastructure to make samples and data more findable and accessible for research (F and A,of FAIR principles) . One of the aims is to improve efficiency of biobanking samples and data request processes for both biobanks and researchers.

Material and methods: The Hyve has built a request portal that facilitates submission and review of access requests especially in a multi-biobank setting, thereby increasing accessibility of biobanking data for researchers and addressing underutilization of samples for research. This request portal is an open source web-application, called Podium.

Results: Podium is developed using the latest technology stacks such as Spring Boot, Angular (web-application framework), and Elasticsearch (search engine). As Podium aims to support all national biobanks, registries and researchers, a microservices architecture was chosen to accommodate for potential high traffic and load balancing. The modularity and scalability makes it well-prepared for an international setting. Podium has been developed as an open-source application to stimulate collaborative development and thereby creating a sustainable solution for advancing research. Podium also integrates with the BBMRI-NL biobank catalogue, allowing researchers to use their search-query and biobank selection, when starting an access request in Podium.

Conclusion: Podium serves as a central place for researchers, to request samples and data from biobanks and registries in The Netherlands. New feature developments, such as being able to integrate with local existing request systems, are ongoing.

PS5B-20: Blockchain in research biobanking and databases: where the technology meets EU regulation purposes

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Introduction: With the adoption and entry into force of the EU General Data Protection Regulation 2016/679 (GDPR) actors of European research are adapting practices and IT systems to reach enhanced data privacy protection in their organization and research partnerships or collaborations.

Material and methods: The search for adequate solutions for ensuring legal compliance in terms of sensitive personal data protection while not undermining or slowing research activities and international collaborations naturally leads to envisage, develop, trial and adopt privacy enhancing technologies. In this context we will analyse the blockchain technology's potentials for research biobanking.

Results: Originally designed for the digital cryptocurrency bitcoin, the blockchain technology starts enlarging to other sensitive domains such as health and scientific research. What is a blockchain and how could this promising technology fits to biobanks and health research databases environment? What are the legal benchmarks in the GDPR favoring the setting up of blockchain systems in the European Reasearch Area? Which advantages and roadblocks can be identified in such an approach?

Conclusion: This work aims to present the potential of this technology applied in the research sector, its added value for building ethical governance systems complying with current legal state-of-art, and to identify remaining challenges for a wide spread application in Europe.

PS5B-21: Italy Imaging Biobank with Radiomics Integration

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Introduction: Current software solutions do not allow to manage medical imaging in repositories with associated clinical information. The aim of our work was to implement a software solution fulfilling the requirements of an imaging biobank: storage, association with EHR data and advanced image analysis algorithms for radiomics characterization.

Material and methods: The platform was developed in NodeJS language for back-end modules and Angular for front-end user interface. Database was built on MongoDB structure. The image analysis algorithms and plug-ins can be integrated in different languages: Matlab, Python, C++. All the platform modules were implemented in Microsoft Azure.

Results: A pilot evaluation of the imaging biobank was performed by including magnetic resonance (MR) examinations from rectal cancer cases and analysing texture features from all lesions. A total of 157 studies are stored and properly annotated in the biobank. Associated texture features were extracted from the lesion by the application of gray-level Co-Occurrence Matrix (GLCM) algorithm. The DataMiner included in the platform allowed for the exportation of radiomics data in .csv format for the analysis in statistical packages.

Conclusion: The architecture for an imaging biobank was properly implemented, allowing for the storage, management and radiomics analysis of medical images. The pilot test experience will be translated to new clinical scenarios to enrich the repository.

PS5B-22: IT and Biobank: Cataloguing samples to enhance the value of biobank resources

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Introduction: KEMRI-WELLCOME TRUST RESEARCH PROGRAMME has been collecting samples over the last 27 years, most from Kilifi County Hospital,

Kenya. There was no systematic way of storing these samples and this made their management chaotic especially sharing, retrieval and tracking of remaining volumes. Sample requests took a week to process.

Material and methods: We created a metadata template to catalogue all stored samples and enforced it for any samples deposited in the biobank. Minimum data was identifiers of the samples (patient identifier, sample type, date) wth additional room for more information. Alongside, we were creating a web-based system for curating this data.

Results: Within a period of 6 months, we managed to identify and electronically catalogue close to 90% of the samples whose details were previously on paper. Process of requesting for shared samples markedly improved with majority of the requests are serviced within a day and the search taking less than 10minutes. All users of the biobank are now utilizing the system to store, retrieve and ship samples.

We are now able to run multi-site network studies collecting large number of samples with Kilifi serving as the coordinating site.

Conclusion: IT plays a critical role in process improvements, and by working science - and in our case biobank- it is possible to enhance the value derived from scientific infrastrucure. This is through automation of unnecessary bureaucracy allowing science to concentrate of what they do best.

Topic 5C - Harmonisation & Standardisation: quo vadis?

PS5C-1: Standardized DNA and RNA Sample Quality Control

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Introduction: Sample quality includes concentration and integrity are both important parameters to ensure that nucleic acid samples are fit for purpose. Nucleic acid quality can be assessed using conventional gel or automated electrophoresis systems.

Material and methods: The Agilent 4200 TapeStation system with TapeStation Analysis software version A.02.02 was used. RNA ScreenTape (p/n 5067-5576) with reagents (p/n 5067-5577 and

5067‑5578) and High Sensitivity RNA ScreenTape (p/n 5067-5579) with reagents (p/n 5067-5580 and 5067-5581) Genomic DNA ScreenTape consumable (p/n 5067-5365) and Genomic DNA Reagents (p/n 5067-5366) were obtained

from Agilent Technologies (Waldbronn,Germany)

Results: This poster shows examples of DNA sample patterns and correlating DIN across a wide quality range for DNA originating from blood, fresh frozen tissue and formalin‑fixed paraffin‑embedded (FFPE) material. The quality scores DIN, RINe and DV200 reflect sample integrity independent of instrument, operator and sample concentration. They can be used as an objective measure for genomic DNA and RNA sample integrity.

Conclusion: The 4200 TapeStation System enables fast and user-independent QA of DNA and RNA samples from various origins.

The quality scores DIN and RINe provide a numerical value from 1 to 10 for gDNA respectively RNA samples.

DIN, RINe and DV200 reflect sample integrity independent of instrument, operator and sample concentration.

PS5C-3: The Radboud standard for biobanking – an example how to standardize your biobank

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Introduction: The Radboud Biobank has been installed by the Executive Board as a central, hospital-integrated facility for clinical biobanking. Many guidelines for the establishment of clinical biobanks place strong emphasis on handling and storage of biospecimens plus associated clinical data. Furthermore, ethical, legal and social issues (ELSI) have been discussed intensively.

Material and methods: However, there is currently no straightforward standard available to use as a practical guideline for those who are new in the field of biobanking. To address this issue, we defined the Radboud standard for biobanking for all new biobank activities.

Results: To compose this guideline, we used our experience gained in the design and implementation of sub-biobanks that are part of the Radboud Biobank. Compliance with the standard ensures donor safety, quality of biospecimens plus associated clinical data and compliance with legal requirements. In order to meet the standard, sub-biobanks have to meet the following criteria:

1. A clear project description – scientific ambition, intended patient population
2. Transparent governance with the involvement of patient associations
3. Compliance with ELSI standards
4. Professional processing and storage of body materials and images
5. Professional storage of clinical data
6. Transparent issuance procedure

Conclusion: The Radboud standard guides new sub-biobanks in the development and implementation of standardized practices. The ultimate goal is to achieve compliance of all biobank activities in the Radboudumc with the local standard (before 2020) . The Radboud standard contributes to demonstrably distinctive quality and compliance to formal criteria for scientific research.

PS5C-4: BBMRI.it working group on quality

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Introduction: BBMRI.it, the BBMRI-ERIC Italian node, established the quality common service with the aim of monitoring biobanks and biomolecular resources, providing information on guidelines and best practices and harmonizing operating procedures. In this context, a working group was set up in April 2017, aimed at building a National Quality notebook.

Material and methods: The working group includes forty researchers, officially delegated by twenty-nine National institutions, including Istituto Superiore di Sanità, Research Centers, Universities, Hospitals and companies. Six video recorded teleconferences were managed through a web platform, relevant documents were shared through a cloud computing service, and are now available to the BBMRI.it community.

Results: All the participants collaborated to the drafting of the National Quality notebook, which currently includes 44 sheets, useful for everyday use by biobankers. Three areas were identified: 1. guidelines and on-line tools; 2: policies and management documents; 3: Standard Operating Procedures. In addition, a section of the notebook is dedicated to biobanking success stories, examples "how biobanking makes a difference in society". The tool was presented to biobankers and stakeholders at the National BBMRI.it day in November 2017, and it is regularly updated by the BBMRI.it biobanking community with new sheets, which are validated by the group and subsequently published.

Conclusion: The BBMRI.it working group on quality has built the Quality notebook with the aim of: - making aware the Italian biobanks of international guidelines and useful on-line tools, developed by BBMRI-ERIC, NCI, IARC, ICLAC, CTRnet and many other recognized institutions, - harmonizing operating procedures and - acknowledging biobanking success stories.

PS5C-5: German Biobank Alliance: An Audit Concept for Continuous Improvement of Biobanks

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Introduction: Audits represent a key tool for analysis and continuous optimization of internal biobank processes and the underlying management system. Currently all applied standards require audits to ensure compliance and consequently improvement of the quality of biospecimens.

Material and methods: The GBA audit concept is based on the audit specific norm (DIN EN ISO 19011), the applied standards (DIN EN ISO 17025, 17020, 15189 und ISO 9001) and the preliminary ISO 20387. For realization of these audits, selected GBA auditors will be trained in cooperation with the TUEV Sued Academy.

Results: GBA is planning to perform annual friendly audits within the network. The audit team will consist of one lead Auditor, one co-auditor and the optional participation of trainees. Within the GBA community the audit concept represents a further step towards harmonization of the existing quality management system and offers the opportunity of GBA-internal counseling regarding their advancement. In summary the GBA audit programm will provide a platform for further development based on exchange of experience and tutorials regarding various biobank specific topics such as changes in EN ISO 9001:2015 or the improvement of the GBA-specific audit guidelines.

Conclusion: Additionally, this concept will be extended to other national networks such as the German Centers of Health Research and the National Cohort to initiate a mutual approach to integrate and harmonize audit activities on a national level. Ultimately, cooperation will be extended to the European level in coordination with BBMRI-ERIC.

PS5C-6: Identifying and mitigating difficulties in the correct application of CoBRA citation guidelines

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Introduction: The CoBRA guideline (Bravo et al, 2015, Developing a guideline to standardize the citation of bioresources in journal articles (CoBRA), BMC medicine, 13:33) was developed to promote uniform citation of bioresources used for research and development in peer reviewed literature.

Material and methods: In 2016, Biobank@UZA asked the researchers who had requested samples and/or data to implement this guideline using its BBMRI-ERIC ID. (e.g. in the reference section: BE 71030031000; Biobank@UZA, BBMR-ERIC, Belgian Virtual Tumourbank funded by the National Cancer Plan; No. Access: n, Last: Month, DD, YYYY. [BIORESOURCE])

Results: Throughout 2017, 11 publications resulted from researchers using samples and/or Data from biobank@UZA. In none of these publications, the citation was fully in accordance with the CoBRA guidelines. We analysed the citations and compared them with the CoBRA guideline, and contacted the corresponding authors for feedback.

Conclusion: The authors reported the following hindrances:

- I wasn't aware that I had to mention the bioresource this way
- It's difficult to remain within the allowed number of words in the introduction and the material & methods sections.
- The editors are not familiar with the format need more information (PMID nr.)

PS5C-7: BioSCOOP - Biobank Sample Communication Protocol. New approach for “biobank talks”

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Introduction: Dynamic development of Biobanking industry (business and science) resulted in an increased number of IT systems for samples and data management. The most bothering case for biobanking community was the cooperation between institutions, equipped with different IT systems, in the field of scientific research, mainly data interchange and information flow.

Material and methods: A solution most commonly offered by the speakers was a “unique IT solution” with all its pros and cons. However, is this really the way to go? Why not take other industries like banking (economy), automotive, informatics and many others as an example and create common standard for data interchange?

Results: We would like to introduce to a wide audience a core of this kind of a protocol for further development by the community - the result of work of the interdisciplinary team. The protocol is in a form of well documented JSON API. It is not another project, starting from scratch, existing standards like MIABIS, ICD10 and more were included.

Conclusion: Implementing this kind of a communication layer will organize and standardize data sharing and bring some space for new utilities for automation in data collection for scientific research purposes.

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PS5C-8: How BBMRI promotes harmonisation and standardisation within 19 European Member States.

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Introduction: Increasing demand and the use of high-quality samples, data and services place biobanks at the center of basic and applied research. The BBMRI-ERIC Quality Service (BBMRI.QM) support biobanks and researchers to meet the highest quality demands for their research efforts and the needs of their customers.

Material and methods: Since 2015, BBMRI.QM focus on improving the QMS of biobanks, and in particular the quality of sample collections, to promote scientific excellence and ensure harmonization and interoperability based on European and International standards. BBMRI.QM Service includes QM consultancy and a peer review audit service within the community, partners and projects.

Results: More than 117 experts and researchers from 19 different Member States and WHO/IARC are currently part of BBMRI expert working groups. One

of the key results are self-assessment questionnaires based on CEN/TS and ISO standards for biobanks. The BBMRI-ERIC Self-Assessment Surveys (BBMRI-ERIC SAS) provide biobankers and scientists with a foundation for 1) implement quality requirements and 2) assess performance. Biobanks or sample collections meeting the criteria of the BBMRI-ERIC SAS are recognized by being marked in the BBMRI-ERIC directory. This process is ensured in a peer review audit and reflect harmonised and standardised processes in biobanks.

Conclusion: The implementation of appropriate QMS (QA / QC) and the harmonization of preanalytical processes such as sample handling in biobanks and related disciplines, as well as the downstream diagnostic procedures will ultimately lead to improved clinical decisions and health outcomes for patients. BBMRI.QM Service supports harmonization/standardization at European level.

PS5C-9: Introducing Sample and Sample Donor Components in the Minimum Information About BIobank Data Sharing (MIABIS)

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Introduction: The Minimum Information About BIobank data Sharing (MIABIS) aims to standardize data elements used to describe biobanks, research on samples and associated data. The aim of the current work was to develop MIABIS components to describe sample donors and samples at an individual level, based on several use cases.

Material and methods: We used the following guiding principles: the components target human origin samples; the model should be applicable to all sample types and all sample donors; hierarchy structure is not defined; the model should capture the current status of samples stored in biobanks; existing data terminologies should be used.

Results: For the purpose of this work, all the use cases had in common the sharing of individual level data about samples and sample donors. The generalized data model should support different biobank catalog applications and availability queries, which require that the data is recorded similarly by all biobanks.

The attributes to be shared for sample donor include sex, age information, and data categories. The 'Sample' component includes detailed material type, based on SPRECv3 with certain extensions, and relevant sample storage and processing parameters aligned to SPREC. Sampling and diagnosis events are separately defined as 'events' linked to donor/sample.

Conclusion: We believe the MIABIS suggestion is consistent with the scope and use cases as accepted by BBMRI-ERIC Management Committee. Even though these components were extensively defined, we already recognize the need for further work for adjusting the models to upcoming standards and extending the components to support additional use cases.

PS5C-10: The Malta BioBank's participation in BBMRI ADOPT

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Introduction: BBMRI.mt is a full partner in BBMRI ADOPT, a Horizon 2020 EU funded project. The project enables well-established biobanks to connect with BBMRI-ERIC to provide data on 10,000 colorectal cancer cases across Europe for future research use. In Malta, it is estimated 300 colorectal cancer cases are diagnosed annually.

Material and methods: 450 colorectal cancer cases diagnosed in Malta were identified retrospectively from the National Cancer register. A comprehensive data set was defined by BBMRI-ERIC experts. Cases having a primary diagnosis for colorectal cancer and banked FFPE tissue samples were included in the study. Aggregate data was manually collected from hospital records.

Results: BBMRI.mt contributed a comprehensive data set on 300 colorectal cancer cases with banked FFPE tissue samples. Data attributes for each case included: sex, age at primary diagnosis: time of recurrence (metastasis), vital status and overall survival information, surgery, pharmacotherapy, targeted therapy, radiation therapy, response to therapy, molecular markers, histopathology and radiological imaging. Data was uploaded on the BBMRI Colorectal Cancer Data Collection (CCDC) database, "connector". The metadata was mapped and transformed into XML format. A "negotiator" allows access to more granular data and samples linked to any of the data can be accessed through the official access procedures of biobanks.

Conclusion: The BBMRI CCDC provides a sufficient pool of information for researchers to query and explore. The well defined data set could be used as a model for future disease data collections. BBMRI ADOPT demonstrates the importance of data harmonisation and standardisation as a biomolecular resource for research.

PS5C-11: International Harmonization and Standardization between Denmark and Germany: The German-Danish Interreg project BONEBANK

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Introduction: BONEBANK is a German-Danish biobank and innovation platform for stem cells in bone regeneration. Its cross-border biobank locations at Odense and Lübeck obtain human bone marrow mesenchymal stem cells (BM MSCs) from fracture-related routine operations. Samples and BM-MSCs are available for research through a common BONEBANK database.

Material and methods: To establish a cross-border biobank with a common database, which allows both participating biobanks to share pseudonymized data with their users, the relevant parameters for a harmonized data set and all necessary Standard Operating Procedures (SOPs) for standardization have to be determined.

Results: Both participating biobanks agreed on a common parameter set. This includes parameters for sample harvesting, processing, storage, and associated clinical data being integrated in the local software systems. For data transfer to the common BONEBANK database, an ethics approval has been obtained in Germany and Denmark. SOPs for e.g. isolating, culturing and storing BM-MSCs and quality assessment are constantly improved in harmonized fashion across both locations.

Conclusion: Based on harmonized cross-border process and SOPs, BM-MSCs and according clinical data are made available for research use through one common BONEBANK wide database. This is only possible since country specific data protection regulations and ethics were used as basis for this Danish-German biobank concept.

PS5C-12: Biobanking lessons learned from urine sample processing for a preeclampsia study

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Introduction: Urine is an excellent biospecimen to biobank. Pre-eclampsia (PE) is a pregnancy complication that affects both the mother and fetus and early identification would decrease the likelihood of maternal and perinatal mortality, improve antenatal care, management and treatment. Thus identification of potential biomarkers are of importance for PE.

Material and methods: The Calcium and Pre-eclampsia (CAP) study that forms part of the Pre-eclampsia and eclampsia monitoring, prevention and treatment (PRE-EMPT) program has been collecting urine in Argentina, Zimbabwe and South Africa. Urine were frozen at -80 degrees since 2013 and moved to a biobank (NSB) in Cape Town in 2017.

Results: In order to standardize and harmonize procedures urine biospecimens were relabelled with both 1D and 2D unique barcodes, reorganised and re-checked against the compiled database, as each site had their own guidelines for sample collection and data compilation. A number of issues were observed of which labelling and overfilled tubes were major concerns. Protein, calcium and creatinine are being measured as part of the CAP study protocol.

Conclusion: In conclusion urine have the potential to be a diagnostic tool in the diagnosis of preeclampsia. Access to quality biospecimens are of importance in biomarker identification studies. Harmonisation of biobanking procedures for the CAP study resulted in an excellent cohort that would be of benefit to the preeclampsia research community.

Topic 6A - Biosharing for Scientific Progress: Ethics and Stakeholder Engagement

PS6A-1: Health-RI – How to build the national infrastructure for personalized health & medicine

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Introduction: Closing the innovation gap by performing high quality and reproducible health research requires optimally support and facilities for researchers. The Netherlands is solving this by connecting research infrastructure activities into a national health research infrastructure – Health-RI.

Material and methods: In Health-RI, the Dutch nodes of BBMRI, EATRIS and ELIXIR, together with national initiatives have joined forces to create a shared service center for researchers to get access to data, images and samples, and provide them with the required best-practices, tooling and information to perform ELSI compliant and FAIR research.

Results: A wealth of knowledge and knowhow is already available, much of which is developed within European and national infrastructure initiatives. Nevertheless, this inadequately spreads to the broader health research community. Therefore, integrating these activities is an essential step, both national and international. The first concept for a Health-RI initiative was conceived in 2015 and since then we have made significant progress and gained experience on fundamentals and conditions for such a shared national initiative. By engaging all relevant stakeholders, we developed a business plan, that can count on broad support from over 70 partners in academia, industry and patient advocacy.

Conclusion: Building a shared national infrastructure for health research requires a vision on the future of health. To achieve this, we need long-term commitments and enthusiasm amongst the partners to work together.

PS6A-2: Cadaver specimen in Russian biobanking – legal aspects and stakeholder's positions

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Introduction: There are neither direct rules on using cadaver specimen for scientific purposes in Russia, nor legal doctrine on the point. Is it legally possible and ethically acceptable? To answer one should interpret legislation by analogy and compare results with sociological analysis of two main stakeholders' groups: researchers and lay people.

Material and methods: Two sociological surveys were conducted for each stakeholder's group. Apart from that deep legal search was made to set up a reasonable analogy for cadaver biomaterial use in scientific purposes.

Results: In Russia anyone is presumed to disagree with using their biomaterial for scientific purposes. Direct agreement on the point must be made in the form of a will. Any informed consent made by incapable person is void so no research with their biospecimen can be produced ethically.

Despite this the majority of researchers tend to ethically approve using cadavers without consent for research. Majority of lay people are unwilling to interrogate whether corpses are used for scientific purposes.

Conclusion: Strict principles of Russian law are incompatible with social reality where researchers prefer to skirt existing rules, and lay people are reluctant to fight for their rights.

PS6A-3: Evaluating the German Biobank Node as coordinating institution of the German Biobank Alliance: The perspective of partner biobanks

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Introduction: The German Biobank Node (GBN) coordinates the German Biobank Alliance (GBA) – a network of eleven biobanks that joined forces to develop common standards and infrastructure. The GBN's work processes and outcomes are evaluated from the perspective of the GBA biobanks as an important stakeholder group.

Material and methods: An online survey has been developed and pre-tested. It will be sent to all non-technical staff at the eleven GBA biobanks and analyzed using descriptive statistical methods.

Results: A high return is expected with an estimated number of 100 participants. Questions address the work of GBN including tools developed to communicate within and beyond the network (e.g. online work platform Confluence or GBN newsletter) . The survey also asks questions about collaboration within GBA and interactions with other participating biobanks as well as products and services developed within GBA (e.g. poster campaign for donors) . As GBN also represents German interests within BBMRI, networking on the European level is also included as a topic. Answers will provide insights into perceptions and attitudes of participants on the above named dimensions.

Conclusion: A profound understanding of perceptions, attitudes and needs of stakeholder groups is a prerequisite to improve processes effectively. Accordingly, the survey will generate important insights for GBN to improve coordinating activities and develop products and services tailored to the needs of GBA biobanks.

PS6A-4: Towards ethical biobank research in Africa: What lessons can we learn from Europe?

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Introduction: Biobanks are increasingly being established across the globe. Although common in the developed world, they are gaining prominence in Africa with the establishment of the Human Hereditary and Health in Africa (H3Africa) biobanks in South Africa, Uganda and Nigeria. Despite potential benefits, biobanks pose complex ethical issues and policy challenges.

Material and methods: This project aims to do a comparative study of biobank related policies, regulations and practices between Africa and Europe (namely Germany and UK) .

Results: Preliminary findings highlight that there is no common model of governance neither in Europe nor Africa. Most biobanks are regulated using 'soft laws' embedded within general nonbinding ethics guidelines rather than biobank-specific legislation. Furthermore, there was lack of consensus on key issues – particularly in relation to consent, transfer of samples and data to third parties, rights and ownership, and feedback of incidental health findings.

Conclusion: There is need for robust ethics and regulatory frameworks to support biobank research in an ethical manner that protects the rights and dignity of participants and enhance public trust.

PS6A-5: Development of a framework for an age-adapted "broad consent" template for children/adolescents willing to donate biomaterials/related data for medical research

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Introduction: Because bio-banks represent important resources for the progress in research, many paediatric departments/networks/registries collect biomaterials of diseased children -mostly using a narrow consent for specific disease-entities. However, the openness of future medical questions/need for novel targeted therapies in paediatrics should allow collecting bio-samples from children/adolescents also with a "broad consent".

Material and methods: Since 11/2017 the bio-bank task-force of the Working-Party of the German Medical Ethics-Committees (WP-GMEC) has developed a framework for an age-adapted master-template "for the broad use of biological materials and related data donated by diseased children/adolescents treated or followed in a hospital" (either hospitalised or ambulant) .

Results: For children/adolescents the unpredictability of the future use of donated bio-samples/related data must be compensated by a bundle of precautions/limitations & procedural methods as a pre-condition for the ethical/moral acceptability of the minor's act. To give legally valid consent individuals need to be major; thus, until children/adolescents reach majority, involvement of both parents/legal guardians in decision-making is mandatory: parents sign the broad consent after information by the treating paediatric physician, thereby acknowledging that their child did not show any doubt/opposition and voluntarily donates her/his biomaterials. The child's right of changing will/opinion at any time without any reprisal must be secured.

Conclusion: The nation-wide applicable age-adapted master-template "for the broad use of biological materials and related data donated by diseased children/adolescents treated or followed in a hospital" appears well-suited to serve as a model for an European-wide consent facilitating broad use of bio-samples and data donated by children/adolescents for children-specific medical research.

PS6A-6: A systematic engagement action, a national "Responsible Research Innovation"- RRI experience: the BBMRI.it ELSI working groups

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Introduction: 2 main cross Ethical-Legal-Societal-ELS issues: what shared matrix of informed consent for research biobanking understood as a participatory process and what requirements for good practice in the ethical review of biobank-based research, alongside an infrastructural need to strengthen a shared horizon for Responsible Research and Innovation - RRI.

Material and methods: BBMRI.it, the Italian node, took this challenge as an opportunity for the development of a RRI-national action, engaging all the principal actors, starting by patients and Ethics Committees. 3 ELSI-national groups, institutionally endorsed, worked together on the basis of a deliberative method, built on plural multidisciplinary setting and collaborative tools.

Results: Pooling expertise, good practices and insights together the WGs created a common consensus "Towards good practice in biobanking for research" and drew practical conclusions about a concrete RRI horizon of biosharing. On the basis of the mapped experiences and identified needs, they developed the 2 ELS matrices, the first for the informed consent process, highlighting requirements for a good inclusive informative practice, the second for the ethical review, including the minimum requirements for a positive ethical evaluation. Their working co-produced an engagement script to support scientific communities in societal engagement and Patient/citizen organizations in being active part of the system.

Conclusion: Some steps were crucial in shaping both the participatory process and the methodological outcome. Overall, the expertise enhancement, a transparent peer setting, the co-production of definitions and good practice requirements. We think that the engagement script tested could be useful and inspiring both in other contexts and for other communities.

PS6A-7: The Altruistic nature of Tuberculomas in Durban, South Africa

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Introduction: The Africa Health Research Institute (AHRI) conducts basic science research focusing on TB & HIV in KwaZulu-Natal (KZN), province with the highest HIV burden in South Africa. Working with the Department of Cardiothoracic Surgery at 2 hospitals, AHRI is studying the HIV-TB co-epidemic at the site of infection.

Material and methods: In establishing this partnership, we have incorporated the researcher into the doctor-patient relationship and are now studying the various aspects surrounding consent for both therapeutic surgical procedures

as well as consent from patients for human tissue collection, exploratory basic science research as well as tissue storage.

Results: The informed consent process facilitates surgical treatment of disease. This interaction occurs between the surgeon and patient, with the outcomes, complications and alternatives to surgery discussed. When this process occurs in conjunction with consent for basic science research utilising the excised surgical tissue, the potential exists for angst on the part of the patient and suspicion regarding the motives of either intervention. This sets the scene for a complex patient-doctor-researcher interaction which may compromise the ethical principles of autonomy, beneficence and maleficence. This led us to investigate health practitioners concerns at both hospitals, around the impact of the consent process.

Conclusion: Results obtained from this investigation will enable us to develop a tool to standardize the process to consent patients for surgical procedures, and research studies. A multidisciplinary approach to addressing and educating patients/surgeons/academics and researchers will enable us to improve and align research practices in South Africa and other countries.

PS6A-8: Towards the Fears of Biosharing Scale (FoBS-POL)

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Introduction: Sharing samples and data is an important condition in the development of biobanks. However, society and donors may have a number of different concerns and fears in terms of biosharing.

Material and methods: The aim of our research was to analyze fears and concerns connected with biosharing and development of the tool to measure the potential donors' fears of biosharing. The study was conducted on a representative nationwide representative group of over 1200 adults (CI=0.95) by the Osgood's semantic differential technique questionnaire.

Results: We identified different categories of fears and concerns and different levels of fears connected with biosharing of samples and data with foreign countries, private companies etc. We attempted to construct a useful tool for measure the fears and identified the factors of the new tool: "The Fears of Biosharing Scale (FoBS-POL) ". It still requires a standardization study for the Polish population.

Conclusion: The donors fears of biosharing can be important barrier in biobanks development. FoBS-POL can be useful tool in identifying fears and concerns of potential donors and providing better communication with donors and society. It can be used in the process of recruiting new donors by biobanks.

PS6A-9: Lifelines; Stakeholder engagement for the Third follow-up visit

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(1) Lifelines, The Netherlands

Introduction: Lifelines is a longitudinal general population cohort study and biobank among 167.000 people in the Northern part of The Netherlands. Lifelines facilitates research on Healthy Ageing. Lifelines is about tot start its Third follow-up visit in 2019. For this we engaged with all stakeholders.

Material and methods: Stakeholder information was collected by;

- Send questionnaires to 5.000 participants

- Send questionnaires to 240 Postdoc (+) researchers, National Institute of Health, Health (research) funds, National Research Funds

- Launch discussion platform

- Interviews with specialists

- Internal consulting

- Consult local governmental institutions

- Consult National government (funding)

Results: All information was collected and were needed responders were asked to clarify the input. A framework for the content was defined by the Scientific Advisory Committee. Internal knowledge on data- and sample usage and other available data was used. Specialists were interviewed for their knowledge on eg. motion, diet, skin problems and biomaterials. All information is used for specifying data- and sample collection for the Third follow-up visit of participants of the study. The plan was discussed with the Participants Advisory board for final check.

Conclusion: Lifelines generated a revised screening program for its Third Follow-up visit. It generated a program that is based on expectations and knowledge of all stakeholders. Lifelines expects to target its collected data and samples better for future use.

PS6A-10: Driving Qatar Biobank's Public Recruitment through the Effective Utilization of Nationwide Events and Social Media

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Introduction: Qatar Biobank, a long-term health initiative, was launched by Qatar Foundation in collaboration with the Ministry of Public Health and Hamad Medical Corporation, with an overarching aim to reduce the number of chronic illnesses in the population and to improve the health of future generations through medical research.

Material and methods: Qatar Biobank's communications team has been utilizing a multi-pronged approach to disseminate the underlying messages to the right target audience. The strategy focuses on using Qatar's domestic media landscape, social media, public and national events and direct stakeholders outreach to raise awareness about personalized medicine, encouraging people to enrol.

Results: In addition to monthly social media campaigns, Qatar Biobank participates in monthly media interviews with both broadcast media and print media. Qatar Biobank regularly participates in relevant industry events to raise awareness about biobanking. It has been providing opportunity for media and social media influencers to take tours of the facility and personalize their stories. A series of campaigns around the main national events such as Qatar's national day and the country's landmark national sports day were launched to humanise the Qatar Biobank story, allowing the population to understand the concept better, as a way to encourage people to register.

Conclusion: Qatar Biobank public participant recruitment strategy and methods successfully achieved to enrol 25% of the targeted population in less than 4 years with a 5000 potential participant waiting list.

PS6A-11: German Biobank Alliance: Implementation of a User Satisfaction Questionnaire and its Evaluation

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Introduction: In order to assess and improve the internal processes of biobanks, German Biobank Node (GBN) has developed - in cooperation with the German Biobank Alliance (GBA) - a standardized questionnaire for biobank users.

Material and methods: The questionnaire is based on experiences of GBA biobanks that already have a feedback process in place.

Inter alia, users were asked how they got in contact with the biobank, the impact of the biobank service on their project and about their overall satisfaction with the biobank services.

Results: Each biobank was responsible to contact their users active in 2017. More than 530 users of 11 German biobank sites have already been contacted, the return rate being more than 35% within six weeks. The results of their user satisfaction were evaluated by the respective biobanks, GBN compiled an overall evaluation of all biobank sites.

A preliminary selection of results is provided:

• the majority of the users not only requested samples, but in addition a variety of specific services like extraction of nucleic acids

• first knowledge of the respective biobank was most prominent through recommendations by colleagues

Conclusion: Furthermore, the survey will be optimized based on the recommendations of the users and the biobanks of the first round. An English version is available and the GBN offers the possibility to use the questionnaire to interested biobanks outside of GBA.

PS6A-12: Building trust and sharing: analysis of two different modes of Chinese biobank

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Introduction: Biobank construction has been paid a significant amount of attention in China.Different scales and different kinds of biobanks have been springing up in some large cities.Our aim is to study two modes of sample exchanges in two biobanks and is critical both at a theoretical level and for policy making

Material and methods: This paper focus on research-oriented use of biobanks and have carried out ethnographic filed work in two Chinese biobanks which are in north and south China respectively. We treated two biobanks anonymously and conducted observations interviews and investigations which were oriented to identify the diversity of the two modes.

Results: Biobank A and Biobank B represents two different modes of sample sharing. Biobank A constructed an online sharing platform and the researchers using the virtual credit to share with each other.It more like an open market and the platform serves as a contractual mediation. The researchers in Biobank B shared their samples according to the network of their personal relationship .This type of sample sharing involves in interests exchanging,like the ranking of authorship,as well as the intervention of external factors,such as the command decition.

Conclusion: While the biobanks are increasingly being conducted in the context of collaborations between researchers,the ethical guidelines of data sharing in China is lacking. Both modes of sample sharing are grounded on trust and we try to observe the actors involved in the shaping of sharing rules and ethics.

PS6A-13: Ethical issues of informed consent for genomic research and collection of biosamples from donors with mental disorders

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Introduction: The project goal was to make informed consent for research purposes clear for donors with mental disorders to help them in making decision, weather to participate. Their diseases require attention of not only lawyers, specialists in medical ethics and genetics, but also of psychiatrists and psychologists to protect donors' interests.

Material and methods: 10-year practice of the main Russian Psychoneurological Research Institute, scrutiny of majority of informed consent versions for donors with mental disorders used in Russia (more than 50 versions), independent surveys of 28 leading Russian specialists of ethics clinical research of mental disorders.

Results: A mental disorder often limits the donor's autonomy. Incompetence and vulnerability make it difficult for such a patient to protect their interests and clearly express consent or disagreement, leading to delegation of decision-making to the other persons (relatives, doctors, administration, etc.). It is shown that clinical and psychological characteristics of patients affect their perception of legal and medical information and the possibility of making a conscious and voluntary decision to participate in genomic research.

Conclusion: The level of understanding of medical and legal information provided by the psychiatric to a patient and, accordingly, their awareness and voluntariness of decision-making remains poorly understood. Further research and development are needed to create the best form of informed consent for patients with mental disorders.

Topic 6B - Data sharing in biobanking – Discoveries, Novelties, Realities

PS6B-1: The successful link between clinical data from a national biobank and data from a nationwide pathology registry in the Netherlands

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Introduction: Linkage of pseudonymized personal data from biobanks with other registries is of great scientific value. The Inflammatory Bowel Diseases cohort (n=4874) of the Parelsnoer Institute (PSI) aimed to link clinical data to the pathology data of PALGA, to study the prevalence and persistence of human papillomavirus infections in females.

Material and methods: PSI is a biobanking initiative of the eight University Medical Centers in the Netherlands, covering 35,000 patients and 608,000 samples. PALGA is a nationwide registry of pathology data, covering 71 million pathology reports. PSI data was linked to PALGA data despite different personal data collection protocols and different review boards.

Results: Experts in pathology, research, IT, data management, and privacy were involved to compose a procedure to link pseudonymized PSI and PALGA data. The clinical data of 90% of all female patients over 30 years in the PSI cohort could be linked to the cervical screening pathology data of PALGA. Essential success factors were a well specified protocol and involvement of all relevant parties in an early stage to ensure close collaboration and adequate communication between the different fields of expertise. Additionally, dedication and commitment facilitate the process as well as clear agreements about the timeframe.

Conclusion: The created successful linking infrastructure can be used for other PSI cohorts and biobank initiatives. Efforts are currently focused on 'uniform review' trajectory to ensure smooth and appropriate review for similar biobank/registry valorization proposals. Interconnecting biomedical resources matches the goal of Health-RI to empower personalized medicine and health research.

PS6B-2: Taiwan Biobank: An Open Access Resource for Conducting the Biomedical Research

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Introduction: To understand the cause for common disease is challenging. These conditions are caused by a combination of genetics, environmental exposure, and lifestyle. In order to clarify these complex interactions, the Taiwan Biobank (TWB) is establishing a scientific infrastructure accessible to biomedical researchers.

Material and methods: TWB is a prospective study with 200,000 participants, age 30-70 years, from the general population without history of cancer, and another 100,000 patients with chronic diseases. This study has collected details from participants, including questionnaires, physical examination, biomedical test, image inspection, experimental information, biospecimens, and longitudinal follow-up of health-related outcomes.

Results: In order to study the variance of molecular markers in a large number of participants, TWB aims to generate multi-omics experimental information to study the genome, epigenome, transcriptome, proteome and metabolome from a large number biospecimens of participants. In genomics, TWB has already accomplished 28,000 whole genome genotypings, 2,000 whole genome sequencings, and 1,100 NGS-based HLA typings. TWB has also done 1,300 DNA methylation chips in epigenomics and 500 NMR-based metabolites identifications in metabolomics. The genomic summary statistics have been released through a publicly accessible web-based calculation platform, Taiwan View (https://taiwanview.twbiobank.org.tw/) .

Conclusion: TWB is available for open access to researchers to conduct research. Additionally, most of participants have provided inform consent to authorize Taiwan Biobank to link their electronic health records. The release of this large-scale population data, omics information, and electronic health records will greatly benefit human biomedical research.

PS6B-3: The Belgian Virtual Tumourbank (BVT) Project: An overview of samples available in the catalogue

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Introduction: The Belgian Virtual Tumourbank encompasses the tumour biobanks from eleven Belgian university hospitals that collect and store residual human tumour samples locally. In order to facilitate the search for tumour samples scattered among different institutions, data collected at sample level is made available for researchers via the online BVT catalogue.

Material and methods: High quality of the data is guaranteed by automatic and manual controls performed by the BVT project team at the Belgian Cancer Registry.

Results: The majority of the samples available in the catalogue originate from breast tumours (27%) but also less frequent localizations as head and neck are available (4%) . As far as the conservation mode of the samples is concerned, the majority of the tumour samples (70%) are conserved at -80°C and more than one fourth (29%) are included in paraffin. Besides tumour samples also other available material can be stored and registered by the local biobanks. The most common type of other residual material is corresponding normal tissue samples (19%) . Other common available materials are plasma, blood, serum, DNA and buffy coat.

Conclusion: Currently, more than 84,000 registrations, including 85% primary tumour samples and 12% metastasis samples, are available in the catalogue for researchers in the oncology field.

PS6B-4: CCDC Data Provision in the Context of BBMRI-ERIC ADOPT CRC-Cohort

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Introduction: BBMRI-ERIC is a research infrastructure for biobanking and biomolecular resources aiming to facilitate access to samples and data in Europe. The ADOPT project - focusing on colorectal cancer - can be considered as pilot project. Therefore, BBMRI-ERIC has developed and made available a "Colorectal Cancer (CRC) Data Collection software" (CCDC) .

Material and methods: After identifying the relevant cases, the CCDC data set was compared with the locally available data. Missing data elements were recorded and the data accordingly complemented. Subsequently, the datasets of 300 colorectal cancer cases have been exported from the database and written into an XML document using Talend Open Studio.

Results: This approach let to successful documentation of cases that meet all the requirements. In order to verify the data, an XDS schema provided by ADOPT was used. Therefore, the XML file generated using Talend Open Studio will be uploaded via a web interface. This procedure ensures the highest data quality compared to manual data entry. All records were pseudonymized in accordance with the local data protection regulations and the data protection concept of ADOPT. Verification of the CCDC dataset was successfully performed and all local CCDC correspondence was provided in the ADOPT MDR. We will discuss challenges and solutions experienced.

Conclusion: The described approach of complementing local data records followed by data export and verification provides a simple and automated procedure for high-quality data integration. Structured data management, automated interfaces and IT tools simplify processes. Project specific adjustments to datasets are necessary and legal requirements need to be addressed.

PS6B-6: Lifelines – Statistics Netherlands linkage database: Enhancing multidisciplinary research aimed at healthy ageing

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(1) Lifelines, Netherlands

Introduction: The Lifelines Cohort Study is a large population-based cohort study and biobank, including 167,000 participants in the Northern part of the Netherlands. Data linkage with Statistics Netherlands is a powerful process for combining information from different databases on an individual level and enhances the possibilities for multidisciplinary research.

Material and methods: Statistics Netherlands (CBS) collects data about Dutch citizens from various sources. CBS allowed linkage with datasets from Lifelines, within its protected data warehouse, for research purposes only. CBS enables linkage between the stored datasets based on personal private information, using safe pseudonimization methods compliant with the Dutch privacy protection laws.

Results: The Lifelines linkage dataset at CBS enables 1) fast linkage on request, 2) multidisciplinary research connecting detailed socio-economic and socio-demographic data with health data, 3) continuous update of data and 4) required privacy protection of participants. The findable, accessible, interoperable, and reusable (FAIR) data is available on request through the remote access environment of CBS. For the access procedure see https://www.cbs.nl/microdata (CBS) or https://www.lifelines.nl/researcher/biobank-lifelines/application-process (Lifelines) .

Conclusion: Ultimately, the Lifelines linkage database at CBS will strongly stimulate (prospective) multidisciplinary research aiming at personalized medicine and health, ultimately leading to improvements in health care and disease prevention.

PS6B-7: The SUPER Study On Psychotic Disorders Provides Valuable Insight For Biobank Research

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Introduction: The Finnish SUPER Survey on Genetic Mechanisms of Psychotic Disorders (2015-2018), led by FIMM, is part of the International Stanley Global Neuropsychiatric Genomics Initiative. The goal of the study is to better understand genetic and biological background of psychotic disorders and provide basis for new therapeutic interventions. (https://www.superfinland.fi/english)

Material and methods: In Finland, at least 10,000 high-quality samples and information on patients diagnosed with psychosis are collected. In parallel to SUPER study, participants have also given an informed consent for THL Biobank, which allows gradually the use of this valuable research material also in biobank research. (www. thl.fi/biobank)

Results: Research nurses were trained to take samples, interviews, and clinical measurements identically in all recruiting areas, in order to ensure high-quality samples and phenotypic data for research use. Samples were collected for DNA, serum, plasma and PBMC isolation. The questionnaire and interview consist of questions related to life history, previous important life events (such as major childhood events, traumas, and abuse), current status of living, education, employment, comorbidities, current health (sleep, daily functioning) and medication. Participants performed a Cantab reaction test and a PAL test to assess cognitive performance.

Conclusion: High-quality samples and genomic data of the Super-project can be soon applied for research purposes from THL Biobank. Data can later be linked to phenotypic data collected by questionnaires and interviews. National register data (e.g. medication, diagnoses, hospitalization, etc.) can be combined with biobanked data with a separate application.

PS6B-8: BBMRI.mt participates in collaborative BBMRI-LPC project on Mitochondrial Disorders

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Introduction: The Malta BioBank (BBMRI.mt) participated in the BBMRI-LPC WES call. This was a collaborative research initiative jointly organised by BBMRI-LPC, EuroBioBank, RD-Connect and Centro Nacional de Análisis Genómico (CNAG-CRG) . The goal was to sequence 50 exomes from patients

with genetically undiagnosed mitochondrial disorders whose samples were banked within EuroBioBank.

Material and methods: A total of 50 patients from Malta and Turkey consented to participate in the study.The Maltese cohort included 13 probands. WES and bioinformatics analysis were carried out at CNAG-CRG. Phenotypic data of each participant was recorded on PhenoTips. Exome data was analysed on the RD-Connect Genome-Phenome Analysis Platform.

Results: A comparative analysis of rare autosomal recessive mutations shows that some patients share the same variants. Rare missense mutations in the mitochondrial cytochrome B gene (MT-CYB) at positions 14766 and 15326 were present in 7 and 12 probands respectively. The mtDNA mutation at position 15326 (rs2853508) was not present in the reference Maltese Exome database, whereas that at position 14766 (rs193302980; rs57236041) had a frequency of 59%.

Conclusion: The infrastructure for data sharing in rare disease research set up through RD-Connect will aid in establishing a genetic diagnosis for these rare disease patients. This initiative was supported by the National Alliance for Rare Diseases Support – Malta.

PS6B-9: The Swansea Neurology Biobank – Preparing for the Personalised Medicine Revolution

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Introduction: The Swansea Neurology Biobank (SNB) is a NHS-focused repository for biological specimens and clinical data based at Swansea University. It provides a framework for neurological genetics research in South Wales for patients with epilepsy, multiple sclerosis and movement disorders.

Material and methods: The rigorous analysis of biobank recruitment using electronic healthcare data, reveals regional patterns of biobank donation. Methodical investigation of these patterns with service delivery, regional geography, demographics and socio-economics will help predict future ascertainment and allow the efficient distribution of resources.

Results: Outcomes can help identify where patients are more likely to donate biological specimens, within hospital out-patient departments. Investigation of recruitment rate variations can help target resources at certain times or the month or year and the correlation of donor demographics with disease prevalence and incidence reveals areas where future recruitment could be taken into the community.

Conclusion: Biobank recruitment analysis can optimise prospective biobank collections. This example from a diseased focused biobank can be applied to other medical specialities to maximise ascertainment for research and future personalised medicine.

PS6B-10: PALGA, a nationwide pathology database with increasing research possibilities

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Introduction: PALGA, the Dutch nationwide network and registry of histo- and cytopathology, has national coverage from 1991 onwards, comprising >72 million pathology reports from >12 million patients. PALGA is a known valuable source of research, using pseudonymized individual data and left over pathology material by intermediating between researchers and pathology labs.

Material and methods: Synoptic reporting (SR) was successfully introduced in 2009 to improve patient care through more complete and high-quality pathology reporting (C. Sluijter et al., 2016) . In 2017, twenty-eight protocols were available, having already yielded over 1 million synoptic pathology reports. SR includes many standardized variables enabling answering of detailed research questions.

Results: Recently, a molecular diagnostics SR protocol was implemented, independent of cancer type for supporting differential diagnosis, clonal relatedness and therapy choice. Molecular outcome data, derived from next generation sequencing are integrated in the corresponding pathology reports and thus will be available for future research.

Another important possibility is a trial alert to identify specific patients to efficiently enter them prospectively in studies.

An additional advantage is the possibility of combined linkages with other registries such as the Netherlands Cancer Registry and Pharmo (pharmaceutics database) . PALGA can provide control groups that best resemble specific case groups contrary to general population control groups.

Conclusion: In total, 459 publications have been based on PALGA data, of which 56 articles in 2017 with a mean impact factor of 6.086.

PS6B-11: Accelerating access to biospecimens for rapid exploratory studies

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Introduction: AstraZeneca's focus on personalised healthcare demands rapid exploratory studies on biospecimens collected in ongoing clinical trials. However, Biobanks were not historically designed for fast turnaround times, and requested samples are often at different stages in their lifecycles and held at different locations, creating a challenge for sample visibility and access.

Material and methods: AstraZeneca is analysing full end-to-end sample lifecycles, and tracking individual sample requests to identify the source of bottlenecks and delays. We have also mapped sample and data workflows in the AstraZeneca Biobank and at our strategic partners to identify any areas where we can improve alignment or increase processing speed.

Results: Biospecimen requests from ongoing clinical trials are collated and fulfilled by the AstraZeneca Biobank to ensure ethics and compliance, even though samples may be at the collection sites, central labs, analysis labs or the Biobank. AstraZeneca are introducing the GlobalCODE® system to provide sample visibility throughout the lifecycle. However, different operating procedures and IT systems at each site (highly controlled and validated but consequently often inflexible) causes duplication of work and sample processing delays at each site-to-site interface. Our recent work identified a number of areas that we have been able to change to improve efficiency and overall turnaround times.

Conclusion: The introduction of GlobalCODE® will provide full sample visibility across sites, but improving the understanding and alignment of key working practices and IT systems between sites is the key to reducing delays in sample handling and data processing and, consequently, accelerating access to samples reaching scientists for critical exploratory studies.

Topic 6C - Biospecimen and Pre-Analytics Research – from Sampling to Scientific Discovery

PS6C-1: Archival May-Grünwald Giemsa stained bone marrow smears can be used as a source for molecular research

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Introduction: For biobanks, it is important to ensure sample quality after long-term storage. The University Biobank Limburg and Clinical Biobank (Jessa Hospital) contain a hematological collection of stained bone marrow (BM) smears, stored at room temperature since 1998. For their use in downstream applications, DNA quality of the samples was investigated.

Material and methods: The effect of long-term biobank storage on DNA quality was assessed in samples stored for 1, 5, 10, 15 and 18 years using gel electrophoresis, qPCR, and targeted Next-Generation Sequencing (NGS) (TruSight® Myeloid Sequencing Panel) . The stored BM smears were either May-Grünwald Giemsa (MGG) or Perls' Prussian Blue (PPB) stained.

Results: Overall, DNA quality decreased over time. But where DNA extracted from PPB stained samples immediately showed smeared patterns on gel, DNA from MGG stained BM smears exhibited less diffuse and more distinct bands. With qPCR, mean dCt values for HMBS and HBB were remarkedly higher in PPB stained samples. Generally, DNA isolated from PPB stained BM smears showed to be degraded independent of storage time, while DNA isolated from MGG stained samples were qualitatively suitable for downstream applications. Using the NGS panel, reliable results were obtained for MGG stained samples with a storage time of no more than 15 years.

Conclusion: Conclusively, DNA better preserved in stored MGG than in PPB stained samples. The MGG stained BM smears up to 15 years of storage still yielded DNA suitable for reliable NGS analyses. Therefore, the archival MGG stained BM smears can be used as a source for molecular research.

PS6C-2: Temperature matters – Differences in temperatures depend on level and position of stored samples in ultralow temperature freezers

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Introduction: Samples and data from biobanks have an increasing importance for research outcomes. Actually most of those samples are stored in ultralow temperature freezers at temperatures around – 80 °C. We aimed to identify temperature zones in ultralow temperature freezers and were to store temperature sensible samples.

Material and methods: Using USB temperature data loggers (TDL) (testo 184-T4) the temperature in ultralow temperature freezers from Thermo Scientific, Ewald, Sanyo and Panasonic was monitored. The TDLs were placed at different positions in each level of the freezers for 48 hours to detect different temperature zones even at the same level.

Results: The variation of the temperature measurement of the TDLs ranged from 0.1-1.5 %. A temperature gradient of up to 12 °C was observed in some freezers. The lowest temperatures have been measured at the bottom of the freezers. We also monitored the temperature in the front and the rear of the same level. In the most cases the rear of the ultralow temperature freezers was colder compared to the position in the front.

Conclusion: The temperatures in ultralow temperature freezers are different depending on the level and position of stored samples. Even in one level of a freezer different temperatures have been measured. Temperature sensible samples should be stored at the bottom and in the rear of a – 80 °C freezer.

PS6C-3: Stability study: Long-term storage of serum; three different -80 °C storage environments

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Introduction: When storing biological material on long-term basis, it's important to minimize changes in the samples. The purpose of this study is to investigate the effects on serum components during long-term storage up to ten years in three different -80 °C storage environments to mimic different storing environments in our biobank.

Material and methods: Serum from 32 adult donors were collected. The serum was stored at -80 °C with 1/3 from each participant in an automated store, 1/3 in a chest freezer that is rarely opened and 1/3 in a chest freezer that is opened on a daily basis.

Results: The long-term serum panel is established. One aliquot from each participant was analyzed on the collection day, and one aliquot from each of the three storage environments will be analyzed after 6 months, 12 months, and 2, 3, 5, 7 and 10 years.

Results after 6 months of storage will be presented.

Conclusion: This study will contribute to the knowledge about serum stability during long-term storage.

PS6C-4: Study of cell viability and RNA quality from lymphocytes frozen for 10 years

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Introduction: Human samples are commonly collected and long-term stored in biobanks for current and future analyses. Even though techniques for freezing human blood are well established, the storage time can compromise the cell viability and the yield and quality of the ribonucleic acid (RNA) extracted from them.

Material and methods: In this study, lymphocytes from 78 volunteers were purifed with Ficoll gradient and stored at -196 ºC until use. Samples from 2008 to 2012 were thawed and viable cells were calculated using a neubaeur chamber. Then, RNA from these samples were obtained using the Mini Kit RNAeasy (Qiagen, Hilden (Germany)) .

Results: Lymphocytes from 78 volunteers were purified and frozen at -196 ºC during the period from 2008 to 2012, with an average number of viable cells between 4-5 million, which were suitable for cell culture. RNA was extracted from these cells. The quality and performance of these nucleic acids was evaluated by spectrophotometry. The results obtained showed certain differences in the extracted RNA, although without significant differences. However, the quality of the RNA extracted was between 1.8-2 in all years studied.

Conclusion: The freezing protocol established by the Malaga Biobank shows that viable lymphocytes can be kept for a period of at least 10 years and the RNA extracted from these cells presents a good quality and performance, so frozen samples under these conditions are optimal for biomedical research.

PS6C-5: Impact of long-term storage and freeze-thawing on microRNAs in human plasma samples from KORA study

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Introduction: The preanalytical phase plays an essential role in biosample collection. However, the effects on the samples after freezing are only poorly investigated. Additionally, the impact of freeze-thaw cycles to sample quality is of high interest for researchers. Most studies do not adress storage at ultra-low temperatures for many years.

Material and methods: We investigated the influence of long-term storage on miRNA quality from n=10 participants taking part in the population-based cohort study KORA. Samples have been collected during the years 1999-2014. Plasma samples were analyzed using Exiqon real-time PCR profiling. Moreover, the influence of freeze-thaw cycles on miRNA stability was investigated.

Results: Choosing four miRNA references, we analyzed if their plasma levels were affected by two analytical variables, storage time (2, 9 vs 16 years) and freeze-thaw cycles (1, 2, 3, vs 4) using Exicon real-time PCR technique. We found no significant differences in CT values after storage at ultra-low temperatures between samples stored for two or 16 years. Additionally, we found no relevant influence of four freeze-thaw cycles on miRNA stability and detected only minor differences in Ct-values. The stability of the here studied miRNAs is at ultra-low temperatures higher than expected, fostering the stability of miRNAs.

Conclusion: Since storage over 16 years at ultra-low temperatures have no effect on miRNAs, we conclude, that miRNAs remain stable when stored in gas phase of liquid nitrogen. Also the effect of freeze-thawing has shown no critical effect on the here chosen miRNAs, indicating a higher stability and robustness as assumed.

PS6C-6: Searching for a suitable alternative to formaldehyde

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Introduction: Formaldehyde is the most commonly used fixative in tissue preservation. The formaldehyde-free alternative MorFFFix® (Morphisto) is described to be a harmless fixative suitable for the preservation of all kinds of tissues without risk of over-fixation and to provide the same properties regarding morphological imaging, and histological and immunohistochemical staining.

Material and methods: We tested this alternative by processing different tissues from mouse and rat in duplicates, treated identically except that one sample was fixed with 4% neutral buffered formaldehyde (NBF), the other sample with MorFFFix®. For this investigation different fixation times between 6 hours to >1 month were selected for histological analyses.

Results: Morphology was evaluated on HE-stains and immunohistochemistry was performed using antibodies covering different cellular expression localizations (nuclear, membranous and cytoplasmic) .No differences were observed in the routine handling of NBF- or MorFFFix®-fixed paraffin blocks. Whereas HE routine staining results were comparable between the two fixation methods, preliminary results indicate that longer fixation with MorFFFix® is critical for immunohistochemical staining with some antibodies and resulted in reduced staining intensities. This phenomenon was increasing with longer fixation times, demonstrating the dependence of staining results on fixation times with both MorFFFix® and formaldehyde.

Conclusion: Therefore, the large-scale use of MorFFFix® in routine diagnostics would need new extensive validation procedures in histological and immunohistochemical analyses.

PS6C-7: Microgradient separation improves profiling of N-glycans isolated from ovarian cancer sera

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Introduction: Protein glycosylation plays a crucial role in various biological and biochemical processes. Changes in the glycosylation processes were found in many diseases including cancer progression and metastasis. Detection of unusual complex N-glycan structures present in patients' sera may provide diagnostically and prognostically important information about human disease.

Material and methods: Sera samples from healthy women and patients with epithelial ovarian cancer were obtained from the Biobank at the MMCI, Brno, CZ. The samples were processed by enzymatic deglycosylation of proteins, followed by glycan purification, their permethylation, and fractionation. N-glycans were measured using mass spectrometer and obtained data were statistically evaluated.

Results: Presented methodology improved both detection and identification of complex N-glycan structures isolated from patients' sera. We used the reversed-phase microgradient chromatography for two steps of sample elution. In the first step, a gradient of acetonitrile up to 32% was applied for removing of more hydrophilic contaminants and in the second elution step a gradient of acetonitrile from 32% to 49.5% was set for N-glycan collection. This fraction was directly measured using mass spectrometer with MALDI

ionization. Higher mass N-glycans (up to m/z 6300) were detected within mass spectra in comparison with samples without fractionation.

Conclusion: We report an improved approach for N-glycan profiling in human blood sera with regard to detection of diagnostically and prognostically important large tri- and tetra-antennary glycans that are usually hidden in mass spectra of unfractionated samples.

PS6C-8: Antioxidant assessment as pre-analytical parameter for serum quality testing

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Introduction: Serum proteome composition is considered to be of a great value for understanding, predicting and treating various diseases. However, variations in pre-analytical conditions may affect serum sample quality, being crucial for the reliability and validity of research findings. We evaluated antioxidant status as a possible quality test for serum samples.

Material and methods: Pooled serum samples collected from healthy donors were stored at room temperature, -20°C, -80°C and -190°C up to six months. Samples were analyzed without storage as well as after eleven days, and one, two, three, and six months of storage. Enzymatic superoxide dismutase (SOD) and chelating ability were assessed spectrophotometrically.

Results: SOD activity was decreased significantly already after 11 days independent of storage temperature ($P<0.001$) . Additional decrease of the activity was observed after 6 months in samples stored at -20°C ($P<0.01$) compared to storage at -80°C and -196°C. Chelating activity increased ($P<0.001$) after 11 days of low-temperature storage without any additional changes during further storage. This increase was more pronounced in samples stored at -20°C ($P<0.006$) . Both enzymatic and chelation ability assays were able to distinguish room- and low-temperature storage ($P<0.001$) .

Conclusion: Our pilot study indicates that serum antioxidant status might be influenced by different storage temperatures. This result may be useful for sample quality testing in the future.

PS6C-9: Changes in Tissue bank sample requests: Less frozen tissue samples and more FFPE samples; hype or long term?

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Introduction: Frozen tissue has long been regarded as golden standard for preservation of tissues for research. We started to collected frozen tissue in 2001 and has now 95.000 high quality frozen and about 3 million FFPE well documented samples available for medical research.

Material and methods: Recent years we measured a significant decrease in the distribution of frozen, and an increase in the FFPE samples was noticed. One good reason is that technologies like NGS have made FFPE tissues more accessible for research. Another effect could be found in biobanked samples of common tumors readily available.

Results: However, tumors that are rare or typically very small exist mostly in FFPE pathology archives. Researchers interested in such samples, have to choose for FFPE.The decision to utilize FFPE pathology archival material in cancer research may be dictated by research questions and new analytical techniques. However, FFPE samples may suffer from variation in quality in comparison to frozen sample. This is due to a more extensive pre-analytical phase, including variations in fixation and tissue processing. This requires validation of FFPE results best to be performed on frozen tissues. Providing the frozen tissue samples are available.

Conclusion: The Tissuebank should take extra care to collect samples from rare specimen. However abandoning the collection of freezing common diseases is not recommended, because it is not known if using less frozen over more FFPE is a trend or long term effect. Maybe new techniques can give a sudden U-turn.

PS6C-10: Assessment of optimal quality indicators for stool samples

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Introduction: Determination of optimal quality indicators for DNA isolated from stool samples is essential for biobanks. It is even more important now that microbiome analysis is a challenge for biomedical research.

Material and methods: 24 stool samples collected in two different tubes were used to isolate DNA in the Chemagic MSMI automated system following the manufacture recommendations. Quantification, purity and integrity indicators were analyzed by using spectrophotometry, fluorimetry for DNA and RNA, 2200 TapeStation, SPUD and qPCR quantification for human and bacterial DNA.

Results: A yield between 75.7 µg and 442.8 µg was obtained based on TECAN and Nanodrop spectrophotometers. Furthermore, significance differences between spectrophotometry, fluorimetry, TapeStation 2200 and qPCR quantification values were observed in spite of low contaminants detected. On the other hand, samples collected in tubes with preserving liquid shown quantification and purity values more consistent than samples collected in tubes and preserved at -80ºC in anaerobic atmosphere. DIN values were obtained with a broad range cassette but this analysis using TapeStation 2200 system insufficient to detect the bacterial load on samples.

Conclusion: The comparative analysis of these results (including collection tubes comparison) provides a wealth of information to recommend the best quality indicators for DNA from stool samples to be included into the quality standards procedures.

PS6C-12: Quality control of biosamples collected within the frame of the Transplant cohort of the German Center for Infection Research

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Introduction: Quality control of biosamples is highly mandatory for large

multicenter cohort studies with biosample collection. The usage of SOPs helps to maintain an equal biosample quality. However, different procedures in different study centers as well as different technical staff and other local parameters may lead to deviations in biosample quality.

Material and methods: After conducting internal audits, quality control of biosamples (plasma) using metabolomics technique and miRNA experiments using real-time PCR were conducted from n=10 participants with solid organ tx per partner site. Inclusion criteria for samples were determined beforehand, preanalytical data were available.

Results: Quality control measures like metabolomics and miRNA detection used for our approach are both excellent techniques to screen the quality of biosamples. Investigating the biosample quality at an early stage of biosample collection will enable the improvement of procedures to prevent the occurrence of artefacts and thereby contribute to a higher biosample quality throughout the different partner sites of the Tx cohort. Moreover, the quality control of biosamples is a topic bothering a big biobanking community, since the biomarkers identified for sample quality conclusions are unfortunately rare.

Conclusion: Metabolomics analyses can show preanalytical deviations during sample processing, like delay in centrifugation and/or in time-to-freeze. miRNAs can also give a hint on e.g. hemolysis during blood sample retrieval and can serve as biomarkers and by using them patients could be better monitored and easily managed by clinicians

PS6C-13: A comprehensive model of DNA fragmentation for the preservation of High Molecular Weight DNA

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Title: A comprehensive model of DNA fragmentation for the preservation of High Molecular Weight DNA

Introduction: During DNA extraction the DNA molecule undergoes physical and chemical shearing. Under common laboratory conditions this fragmentation yields DNA fragments of 5-35 kilobases (kb) in length. This is insufficient for long-read sequencing ltechniques like Nanoprore sequencing and linked reads where 100s of kb may be desirable.

Material and methods: To understand DNA fragmentation during DNA extraction and storage it is necessary to untangle the potential pre-analytical variables an to identify the key molecular mechanisms contributing to fragmentation by looking at a wide variety of fields affected by DNA fragmentation.

Results: The influence of physical shear stress and chemical degradation are substantially different from each other. It is therefore necessary to use two separate measures to evaluate DNA integrity adequatly.

The characteristic fragment length (CFL) : The most abundant fragment length of the sample. In gel-electrophoresis (both conventional and capillary), this value corresponds to the peak intensity of the signal.

The smear ratio (SR) : The proportion of DNA with a fragment length of less than 500 bp. This value can be easily calculated using the imageJ open source software to integrate over the signal intensity curve.

Conclusion: Our work contributes to the understanding of DNA fragmentation which enables biobanks to extract high molecular weight DNA more effectively. By measuring the smear ratio and peak fragment length biobanks biobanks can provide a simple but reliable measurement of DNA integrity for quality management and evaluation.

PS6C-14: Optimized workflow for top-down and bottom-up protein isolation from solid tumors respecting sample quality and tumor heterogeneity

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Introduction: So far common techniques for isolation of proteins are unable to consider tumor heterogeneity of samples below temperatures of -120°C. As biomolecules become instable at room temperature, the aim was to establish a workflow for protein isolation from frozen tissue samples under constantly low temperatures with respect to tumor heterogeneity.

Material and methods: Tissue blocks with the highest tumor representativity were cored at specific sites using the CryoXtract CXT 350. As an alternate approach, tissue blocks were extracted by macrodissection with using either H&E or toluidine staining at room temperature. The proteomic workflow was further evaluated using two-dimensional gel electrophoresis and mass spectrometry.

Results: We were able to establish a protocol for protein measurements from frozen tissue samples below -120°C and respecting tumor heterogeneity. The quality and quantity of proteins are suitable to allow further assays, e.g. 2-DE and MS.

Conclusion: Our protocol allows to work in a constantly cold environment with being able to extract proteins out of samples with high tumor heterogeneity.

PS6C-15: Effect of pre-analytical plasma hemolysis on circulating microRNA

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Introduction: Circulating microRNAs (miRNAs) are promising non‑invasive biomarkers whose expression have been recently correlated with different diseases staging. Nevertheless, miRNA expression may be affected by pre-analytical variables that should be considered including hemolysis. The present study aims to evaluate the impact of hemolysis on the expression of circulating plasma miRNAs.

Material and methods: In-vitro serial hemolysis of 20 plasma samples using sonicated RBCs. we used 4 different methods to assess hemolysis and ROC analysis to identify absorbance cutoffs that could identify samples with no, low and high levels of hemolysis. The expression levels of 8 circulating plasma miRNA were done by real-time PCR.

Results: The degree of hemolysis and the sensitivity of the method used had a significant pattern of correlation with the expression of miRNA in hemolyzed and non-hemolyzed plasma samples.

Conclusion: Results propose a tool for the evaluation of the influence of plasma hemolysis in downstream miRNA biomarker research.

PS6C-16: Impact of different freezing methods on DNA and RNA quality of tumor samples

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Introduction: Since 2001, tumor samples have been frozen and stored at the UZ Gent Tumor Biobank. In 2012, Bimetra Biobank took over the operational management of the UZ Gent Tumor Biobank and has thus far introduced new standard operating procedures for freezing of tissue, based on best practices.

Material and methods: However, through comparison of different processing methods internationally, there is no reezing protocol based on validated observations of sample quality. In this study, we set out to validate our protocol and evaluate differences introduced in the freezing protocol on the outcome of the tissue morphology, DNA and RNA quality.

Results: Reference material (of animal origin) from three organs (lung, kidney and liver) was selected for the study. Four snap freezing methods with isopentane were selected: snap freezing in mechanically cooled isopentane, in liquid nitrogen, with dry ice and cooled in a CryoPod (portable LN2 carrier) . Cryosections were made to evaluate the amount of freeze damage in the samples. Through virtual microscopy, the cryosections were digitized and a quality number was assigned according to the rate of visual freeze damage that occured. Next, DNA and RNA extraction were performed using our standard procedures.

Conclusion: The quantity and quality of DNA and RNA was measured using a DropSense16 by Trinean. Additionally, DIN and RIN scores were calculated using an Agilent BioAnalyzer. The data was combined to evaluate if differences could be seen according to changes in the freezing method, hence validating our freezing protocol.

PS6C-17: Short term storage of peripheral blood mononuclear cells under minimized temperature fluctuations using automated devices

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Introduction: Cryopreservation of peripheral blood mononuclear cells (PBMC) is a widely used technique in basic research and clinical studies. We examined the influence of storage temperature and handling of samples on recovery and function of cells after thawing.

Material and methods: PBMC were isolated from buffy coats and stored in an automated -80 °C (Liconic) or below 132 °C (Askion) biobanks. We simulated repeated handling of the samples (160 cycles) under temperature-controlled conditions. Cell recovery and function was examined using flow cytometry after thawing.

Results: Compared to storage below 132 °C, storage in a -80 °C biobank did not result in significant changes in PBMC recovery or viability directly after thawing or after an overnight resting period. Cycling of the samples between <132 °C and <100 °C had no influence on these parameters, whereas cycling between -80 °C and -20°C showed a tendency to lower recovery. None of the storage conditions had profound influence on the response of T cells to stimulation (activation markers, cytokine production and degranulation) .

Conclusion: Our data show that, at least for the short term, storage and handling of PBMC under "conventional" conditions is possible with only minor impairment of sample quality

PS6C-18: Stability of lyophilized urine sample in long term storage

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Introduction: Urine has always been a useful source for proteins, bio markers discovery and assessment, as it is readily available, also can be obtained by non-invasive collection methods. We evaluated the protein content and stability of GATA-3 in lyophilized urine samples stored for 4 years.

Material and methods: Midstream urine sample (30ml) was collected in sterile containers after taking aseptic precautions. Samples were evaluated for pH level and uncentrifuged urine (5ml) was lyophilized and the powder was collected and stored at room temperature. Protein was extracted by RIPA lysis method and GATA-3 was estimated using Western blot.

Results: The levels of pH remained constant over time and showed a variation in 13% samples. GATA-3 was found positive by Western blot in 17% and found consistent in intensity compared to the control group over the time period.

Conclusion: Lyophilized urine samples can be stored at room temperature as the stability of protein and pH levels remain constant over a period of time.

PS6C-19: Compare different methods to extract PBMCs from whole blood

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Introduction: Peripheral blood mononuclear cells (PBMC) isolation is widely used for immunology research, but extraction by the traditional Ficoll method is time-consuming. Therefore, it is important to test alternative extraction methods with shorter processing time but at least comparable cell quality and quantity.

Material and methods: We isolated PBMCs using the Becton, Dickinson and Company (BD) vacutainer CPT cell preparation tube and the Ficoll method. We compared total processing time, number of cells and purity by FACs analyses, at different delays before processing and different temperatures, in 8-10 replicate isolations.

Results: The CPT method tended to yield a higher total number of PBMCs (75% [67 – 84] of PBMCs before isolation compared to the Ficoll method (64% [57 – 72]; p=0.070) . After a 24 hr isolation delay at room temperature (RT), PBMCs yield using Ficoll was slightly lower, but an even lower yield was obtained with both methods for delay at 4°C. The purity of both methods was comparable 97% [93% - 99%] at direct isolation and after 24 hr delay at RT. The novel CPT tube decreased the processing time from 4 hours to on average 2 hours.

Conclusion: In conclusion, the BD vacutainer CPT cell preparation tube yielded more PBMCs, and offers advantages with respect to reduction of processing time compared to the Ficoll method.

PS6C-20: The effect of sample storage temperature and time on integrity of DNA

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Introduction: DNA preparation is a critical step to provide high quality samples for further analysis. We investigated the effect of time and storage temperature prior the extraction of the EDTA whole blood sample to DNA fragmentation. Furthermore we examined the quantity and purity of the extracted DNA.

Material and methods: EDTA whole blood samples from four individuals were stored in RT, +4°C and -20°C prior the extraction for 24 hours or 72 hours. DNA extraction method was based on magnetic particle technology. Quality control analysis was performed with capillary electrophoresis. DNA quantitation was defined with spectrophotometer.

Results: We found a clear difference in the quality of the DNA stored in RT vs +4°C or -20°C for 72 hours. The storage temperature and time correlated to the fragmentation state of DNA. No significant difference was found in the DNA integrity, when the whole blood sample was stored in RT or +4C for 24h. The 1000 µl sample volume for extraction resulted in ~ 20 µg of DNA. No impurities or carry over chemical contaminants from the extraction were detected with spectrophotometric quantification.

Conclusion: The storage temperature is an important factor that affects the quality of DNA. To maintain the integrity of the DNA, the storage temperature should be low enough to prevent cell decomposition prior the extraction. Evaluation of the extraction method and sample volume is needed to provide sufficient yield of DNA.

PS6C-21: First-void urine: a potential biomarker source for cervical HPV infection and disease

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Introduction

The use of urine, in particular first-void urine, as a biospecimen for biomarkers is still relatively undiscovered. However, the so called contaminants in the initial urine stream (first-void) are valuable materials originating from the genital tract and washed away with the initial urine stream.

Material & Methods

Using urine from HPV-infected women, we optimized sample collection, storage, transport, and preanalytical testing. Additionally, HPV DNA analyses from paired (first-void) urine and cervical samples were performed, as well as proof-of-concept experiments identifying urine-biomarkers that could distinguish HPV-lesions that have the tendency to regress or progress to cervical cancer.

Results

The results showed that an optimized method for HPV DNA detection in urine should (a) prevent DNA-degradation during extraction and storage using a preservative, (b) recover both cell-free and cell-associated HPV DNA, (c) process a sufficient volume of urine, and (d) use a first-void sample. The latter was confirmed in a clinical study, also showing that first-void urine collected in the morning versus later during the day is equally performant. We found a good agreement for high-risk HPV DNA between paired first-void urine and cervical samples (Cohen's Kappa: 0.688; 95%CI: 0.542-0.835), and identified triage markers in these first-void urine samples.

Conclusion

Using proper sampling, transport, storage, and pre-analytical concentration techniques, first-void urine is expected to be a valuable source of biomarkers, offering primary HPV DNA-detection and triage in the same sample. A first-void urine collection device ensures a standardized sample volume, and allows immediate mixing of the biospecimen with a preservative

Topic 7A - Hospital-Based Biobanks, Clinical Trials & Precision Medicine

PS7A-2: 500,000 Finnish biobank samples made available for FinnGen project: quality and quantity

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Introduction: FinnGen is the first large-scale research project enabled by Finnish biobanks, and a model example of public-private partnership. FinnGen aims to reveal disease mechanisms by combining genome data and health registry data of 500,000 Finns, with seven pre-defined clinical focus areas (neurology, gastroenterology, rheumatology, pulmonary diseases, cardiometabolic diseases, ophthalmology, oncology) .

Material and methods: Participants are recruited in 2017-2023 using three complementary approaches: (i) existing population cohorts (N=225,000), (ii) hospital biobanks and Blood Service Biobank (N=250,000), and (iii) a private health care biobank (N=25,000) . DNA-samples are centrally processed at THL Biobank for genotyping. We further aim to enrich patients within the clinical focus areas.

Results: Many existing population cohorts have already been transferred to THL Biobank. 6,000+ new participants are recruited each month through six hospital biobanks and Blood Service Biobank, and we currently have 63,000+ new biobank samples collected. Participants from hospital biobanks typically represent patients enrolled in special health care units. As many participants have multiple diagnoses, we have 60,000+ relevant ICD-10 codes among 50,000+ hospital biobank samples. Participants recruited through Blood Service serve as healthy controls. Additional samples are acquired by a biobank request made to a private health care provider, with an emphasis on patients under-represented in special health care.

Conclusion: Our versatile recruitment strategy ensures accumulation of large numbers of relevant cases and controls, and adequate representation of all hospital districts in Finland. Samples are owned by Finnish biobanks and genotype data can later be combined by rich clinical data available at hospital biobanks, and utilized in future research projects.

PS7A-3: Latvian cohort of Type Two Diabetes patients - personalized medicine and improvement of health care system

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Introduction: The cohort of Type Two Diabetes (T2D) patients has been developed based on recruits participating in national biobank project Genome Database of Latvian population. This have been performed to unite fragmented knowledge, research results and information in order to combine efforts in improving individual and national health care.

Material and methods: All T2D recruits having E11 diagnosis were identified in national biobank (n=4056) . The information about research of samples and data were gathered and state registry medical records for patients were obtained. All available information was integrated in project specific data warehouse. Data was analysed on individual scale and epidemiological level.

Results: Although biobank holds only pseudonymization code for the samples and information, the code is traceable to personal ID number via State Genome registry. Via registry linking patients having genetic results for pharmacogenetic marker analysis were identified. These results were reported back to participants via visits to endocrinologist, that was qualified to explain the obtained results in context of patient health, heredity and response to therapy. During visits further health information and biological samples were obtained from participants' who consented. The initial and newly obtained patient specific data were used to study, mortality risks, complication development and health care systems shortcomings.

Conclusion: In this example of T2D patients' cohort use of biobanked samples and associated data has served to enhance individual life quality of patients, provide personalized treatment and indicate potential improvement strategies for health care system in Latvia.

PS7A-4: Association of cytoskeleton-regulating formin proteins with basal-like breast cancer

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Introduction: Triple negative breast cancer basal genes,can be identified by IHC detection of CK 5/6 and EGFR.This subgroup are aggressive.Actin is essential for invasion.In this study, we wanted to clarify whether expression of actincytoskeleton regulating formin proteins FHOD1,INF2 and FMNL1in this group,and whether they are associated with expression of basal-type markers.

Material and methods: FFPE samples from 96 patients,wasIHC stained for formins and basal markers.Staining intensity was classified from0-3,siRNA mediated knockdown was performed in the cell lines BT-549 and MDA-MB-231. Cells were plated in Boyden chamber with 8µm pores,after 48h migrate towards the serum gradient,stained and the amount of staining was quantified by spectrophotometer.

Results: In the triple-negative breast cancer cohort, 87 tumor samples (91%) stained positive for EGFR and/or CK5/6. 73% cases were positive for FHOD1, 65% for INF2 and 51% for FMNL1. Pearson correlation analysis indicated statistically positive significant correlation of FHOD1, INF2 and FMNL1 with EGFR expression.The expression of FMNL1 further correlated with CK5/6 expression.In vitro, knockdown of FHOD1 and INF2 expression individually resulted in reduced migration in the cell lines BT-549 and MDA-MB-231. The reduction was statistically significant in MDA-MB-231. No reduction was noted upon FMNL1 knockdown and no clear effect was observer when FHOD1 and INF2 are simultaneously knocked down.

Conclusion: FHOD1, INF2 and FMNL1 are expressed in triple-negative breast cancer. The expression of FHOD1 and INF2 correlates with markers of basal-like breast cancer. Functionally, formins participate in migration of basal breast cancer cell lines. FHOD1 and INF2 may play a role in the more aggressive behavior of basal-like breast cancer.

PS7A-6: Prevention of 5-fu toxicity by analysis of polymorphism of dpyd in biobanked blood from oncologic patients

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Introduction: 5-fluorouracil (5-FU) is an antimetabolite compound, used in chemotherapy in solid tumors and associated with cardiotoxicity, ranging from asymptomatic ECG-changes to cardiogenic shock.

Dihydropyrimidine dehydrogenase (DPD) is the rate-limiting enzyme of hepatic 5-FU catabolism. Polymorphisms in gene encoding DPD (Dpyd) can cause defective protein production/activity, increased drug half-life and toxicities.

Material and methods: Starting from 2011 we established an hospital-based biobank collecting blood samples from all the oncological patients who were planned to be treated with 5-FU. Upon patient informed consent, blood was stored and each patient was tested for polymorphism *2A (c.1905+1G>A) in gene Dpyd.

Results: So far, 2449 whole blood samples were collected (55,2% males) from patients with cancer in the stomach (21,1%), colorectum (47,7%), pancreas (10,5%), oropharynx (7,7%), breast (5,5%), and other sites: small intestine, liver, genital-urinary tract, biliary tract, lung (8,5%) . Thirty-nine patients (1,5%) showed a mutation in *2A (c.1905+1G>A) .

Among the non-mutated, 198 (8,2%) developed severe toxicities after therapy with 5-FU and were re-evaluated for the Dpyd variants c.2846A>T, c.1679T>G and c.2194G>A. Out of 198, 53 patients showed at least one polymorphism (5 in c.2846>T, 2 in c.1679T>G e 46 in c.2194G>A) .

Conclusion: The Biobank storage of material from oncologic patients ensures the long term availability of biological samples during the chemotherapy that can be used to improve patient stratification for 5-FU toxicities.

PS7A-7: A mandatory implementation of next-generation of biobanking in the future world of anticancer drug development

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Introduction: Cancer covers a complex and heterogeneous area of diseases. By 2025, there will be nearly 20 million new cancer cases per year posing a substantial economic burden to healthcare systems worldwide. Even though medical science is dynamic and making rapid progress, we need to make future cancer research more efficient.

Material and methods: New drugs development to treat cancer is a complicate, perilous and costly enterprise. Notably investigational drugs are failing to meet expectations. The reasons are complex and involve every discovery-development continuum aspect. “seven wonders” are designated for the future anticancer medicine world, one has been underestimated: access to good quality biospecimens!

Results: Biobanks store and catalog biological samples and associated medical and biomolecular data compliant with international quality standards and regulations. Overpromising the utility of new biomarkers without adequate evidence on the tissue quality will only hamper its usefulness in drug development and clinical therapy. Furthermore, high reproducibility of molecular techniques relies on good quality data and standardized procedure. Consequently, having good biospecimen and data for translational research is fundamental to personalized medicine. This presentation illustrates the next generation of biobanking 4.0 that fit-to-purpose to the changing word of drug development.

Conclusion: It is time to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world.

PS7A-8: Management of samples taken specifically for oncological clinical trials by the biobank platform

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Introduction: Clinical trials are the last phase of an investigation study, so they can test drugs, diagnosis techniques or products in humans.

Some of these studies sometimes need samples taken in a very specific moment of the treatment of the patient. This couldn’t be done until biobank started managing it.

Material and methods: The biobank manages the sample since it is taken from the patient until is ready to send to the laboratory, which is when we are sure that the sample is available for the study. Some of them need only a simple process; others, a specific way of stabilization and preservation.

Results: The results of the implementation of this circuit show a good coordination between the different professionals involved in this process, always following the guidelines of the current legislation.

In all the process, the biobank guarantee the patient’s privacy and the correct process of the samples and it traceability. The exit of the material is recorded in case the patient or the pathologist needs it again.

All of this is done in a very short time, which is something very important because the patient is waiting the results of the laboratory to take or not the treatment.

Conclusion: The Biobank Platform has open an effective and needed circuit to take and process fresh samples for the oncological clinical trials that are being undertaking in Málaga Hospitals; in coordination with the Anatomical Pathology services. Guarantying the quality and traceability of the material.

PS7A-9: Creation of collections of pathological samples with interest in research from independent clinical trials

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Introduction: Most of the independent clinical trials (IICCTT) carried out by Public Hospitals in Spain try to improve the quality of life of patients and

develop a personalized medicine. These tests require a specific design, procedures, supervision and surveillance. Samples from these patients are very interesting to create biobank collections.

Material and methods: This study pretend establish a circuit in biobank to collect the surplus of the blood samples of patients from IICCTT that are being carried out in the Hospitals of Malaga and thus be able to create strategic collections of different pathologies that can be used prospectively for research purposes.

Results: Blood samples were collected from IICCTT for different pathologies (diabetes, obesity...) . The donors were duly informed through the specific consent of biobank and the samples were processed by the specialized technician to obtain the different fractions. These samples were processed, stored and registered following the protocol established in the Provincial Biobank to guarantee their quality and traceability, following the indications established at the 1090/2015 Royal Decree.

The responsible technician registered and processed the samples from different IICCTT obtaining a representative number of donations with great interest for prospective investigations in different biomedical research areas.

Conclusion: Serum, plasma, whole blood and buffy coat collections of different pathologies were generated in the biobank repository from the surplus of the IICCTT, which have a great strategic value so that they can be used in other biomedical research projects and create more efficient medicines according to the studied disease.

PS7A-10: Whole-exome sequencing of a case-unaffected parent's trio using barcoded DNA from dried blood spots

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Introduction: The Faroese National Hospital has performed new-borns screening since 1986 using dried-blood spots (DBS) . To use the current 22.000 DBS for genetic research has retrospect advantages, however, laboratory challenging. We investigate the possibility to use DBS and linked-reads for detection of a disease-causing mutation (c.95A>G) in primary carnitine deficiency disease.

Material and methods: The case-unaffected parent's trio, was whole-exome sequenced using DNA obtained from DBS and whole blood (WB) . Chromium barcoded libraries were enriched using the SureSelectXT Human All Exon kit and sequenced on the NextSeq 500. The linked-reads were aligned to the reference genome (GRGh37/hg19) and variants were called using Freebayes.

Results: Due to the phenotype of the proband we explored the SLC22A5 gene in more detail. We observed 14 variants within the SLC22A5 gene, including the c.95A>G variant, which further was the only variant predicted to be pathogenic. In the DBS and WB data the c.95A>G variant was called as heterozygous (A/G) in the proband and father, while the mother was homozygous (A/A) for the variant. In the probands WB data we observe a phase block spanning most of the target region of the SLC22A5 gene. Moreover, all seven alternated alleles are located on the same haplotype, inherited from the father.

Conclusion: DBS can be used for mutation detection when WB is unavailable. We were unable to identify the probands second mutation; therefore, unable to fully explain the genetic component of the phenotype. Moreover, linked-reads may be essential for detection of specific diplotypes when compound-heterozygosity plays a role in the pathogenesis.

PS7A-11: A prospective, longitudinal, breast cancer biobank (PBCB) in western Norway

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Introduction: A population-based, longitudinal (10 years), collection of liquid biopsies (blood and urine) and Patient Reported Outcome Measures (PROM) -data from patients with early breast cancer in Western Norway was started in 2011; enrolling patients at two locations, Bergen and Stavanger, covering a catchment area of approx. 1 mill. people

Material and methods: We aim to enrol 1200 patients with early breast cancer who will be followed for a period of 11 years with blood and urine samples obtained every six months. PROM data (9 validated questionnaires) are obtained at baseline and thereafter yearly from all patients included in Stavanger (approx. 350 patients) .

Results: Currently 1296 patients have been enrolled, 1054 (81%) of these are still actively being followed. Average follow-up is 4.5 years. The "liquid biopsy kit" comprises various blood sample tubes (Serum, EDTA plasma, EDTA whole blood, PAX-gene and CPT-tubes) and urine. All samples are aliquoted and stored at -80□ C. Currently, data on tamoxifen metabolites, circulating tumour cells and exosomes have been isolated. The combination of long-term longitudinal biological samples and PROM data can be used to develop biomarkers for personalized monitoring of breast cancer patients in relation to quality of life, side effects of adjuvant treatment and prognosis.

Conclusion: The PBCB project will provide longitudinal real-world data allowing for discovery of novel prognostic and predictive biomarkers, including contemporary information on side effects of the adjuvant treatment. The collaboration between the two hospitals has led to more standardized biobank procedures and analysis. In summary, the PBCB welcomes bilateral collaboration.

PS7A-12: Mechanism of Endothelial Dysfunction in Pathogenesis of Atherosclerosis.

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Introduction: Decreased of nitric oxide (NO) bioavailability in the vessel wall that accompanies endothelial dysfunction is the earliest manifestation of atherosclerosis. This study was established to determine the molecular mechanism underlying decreased NO bioavailability in the endothelium covering atherosclerotic lesions in human arteries.

Material and methods: Fragments of atherosclerotic and non-atherosclerotic carotid arteries were isolated from patients undergoing carotid endarterectomy. Kinetics of NO/O2−/ONOO- radicals, were measured with highly sensitive electrochemical nanosensors near the surface of a single endothelial cell. Total eNOS mRNA and protein expression was analyzed with the use of quantitative RT-PCR and western blotting.

Results: In comparison to the control sample, endothelial cells from atherosclerotic lesions revealed a reduced release of bioactive NO (556 ± 38 nmol/L vs. 214 ± 19 nmol/L) with a parallel increase in the release of both O2- (230 ± 15 nmol/L vs. 710 ± 40 nmol/L) and ONOO- (288 ± 24 nmol/L vs. 648 ± 42 nmol/L) . In contrast, in the cells from atherosclerotic lesions eNOS mRNA and protein expressions were much higher than in the control cells (4,44 ± 0,99 vs. 1,00 ± 0.22 and 451 ± 62 vs. 298 ± 43, respectively), $p < 0.01$ each.

Conclusion: Based on analysis of biobanked carotid arteries, we have provided direct evidence that endothelial dysfunction developing in the atherosclerotic lesions results in a decrease of NO bioavailabilty despite an enhanced eNOS expression. This phenomenon can be attributed to an increase in endothelium O2- and ONOO- production by functionally uncoupled eNOS.

PS7A-13: Showcase studies of the Dutch Parelsnoer Inflammatory Bowel Disease Biobank provide new disease genotype-phenotype insights

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Introduction: The Inflammatory Bowel Disease (IBD) Biobank within the Parelsnoer Institute of the Netherlands facilitates research focused towards the prediction of individual disease course and personalized treatment options. Showcase research protocols enable studies on the complex relation between the heterogeneous clinical presentation and the underlying genetic, microbial and environmental factors.

Material and methods: All eight University Medical Centers (UMCs) participate in the Parelsnoer IBD Biobank currently encompassing 4874 patients. Patients are being enrolled and followed-up prospectively on 255 IBD-related clinical information items and a standard laboratory set collection, including DNA. DNA was analyzed by immuno-chip array, exome-chip array and targeted pooled next-generation resequencing.

Results: Given the huge variation in disease behaviour and drug responses we hypothesized that different genetic variants or associated pathways lead to different clinical subphenotypes or drug responses. Studies with the DNA data revealed specific inherited determinants of Crohn's Disease and Ulcerative Colitis phenotypes. Furthermore, population-specific associations of rare variants in the MUC2 gene were found in Ulcerative Colitis. In addition, disease-modifying genetic variants were found associated with recurrent fibrostenotic Crohn's Disease. Clinical data analyses revealed sex-related differences, impact of ethnicity and of country of birth, and prevalence of and risk factors for work disability in the IBD patients.

Conclusion: Showcase studies of the Parelsnoer IBD Biobank provided new insight in the etiopathogenesis of IBD with impact of genetic and environmental factors on the development of clinical subphenotypes. At present additional global screening array DNA studies are being executed to enrich the genetic dataset enabling even more detailed genotype-phenotype analyses.

PS7A-14: Effective Cooperation of Biobanks for the Conduction of Scientific Genetic Research on Obesity and Diabetes Mellitus Type 2 (DM2)

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Introduction: To date >70 genetic variants associated with obesity and >80 - with DM2 have been identified. The purpose is to perform exome sequencing to find new genetic markers of obesity and DM2. For such work it is necessary to collect biomaterial from a certain sample with the use of Biobank.

Material and methods: The study included 3 groups of patients: 1) obese with DM2; 2) obese without DM2; 3) control. Biospecimens from 68 patients were collected in Hospital №40 and the Biobank of Center for Preventive Medicine (NMRCPM) . Exome sequencing and bioinformatic analysis were performed in Biobank of St. Petersburg State University (SPbSU) .

Results: Biospecimens for groups 1 and 2 were collected in Hospital №40 during 12 months. In the search for rare patients (group 3), the researchers of Biobank SPbSU applied to Biobank NMRCPM, where project of biomaterial collection "Interesting clinical cases" is underway. After examining the

database of this project, the necessary samples were found. Scientific cooperation between biobanks was established and allowed immediately to proceed to the analytical stage. Because of the NGS and analysis of patient data from the three groups, the new genetic markers were identified for obesity and DM2; one new locus of DM2 was found.

Conclusion: Due to biobanking (standard regulations for collection and storage of biospecimens and data, including clinical) effective cooperation between scientific centers has become possible. As a result, terms of the study were minimal and reduced by more than a year; new genes associated with obesity and DM2 have been identified.

PS7A-15: Integrative approach by omic-analysis to discovery genetic biomarker of Precision Medicine in Incontinentia pigmenti

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Introduction: The phenotypic heterogeneity of Incontinentia Pigmenti (IP, MIM308300), a rare X-linked dominant disorder affecting neuroectoderm, suggests to search for molecular markers to aim personalized therapeutic strategies. Incontinentia Pigmenti Genetic Biobank, IPGB, first disease-oriented biobank dedicated to IP, collects DNA samples, harmonised clinical and biological data of IP-TRIOS families from worldwide.

Material and methods: Although the IP is caused only by NEMO/IKBKG mutations, the 30% of patients manifests neurologic and/or eye defects (IP-severe) . To identify what variations/genes/pathways may affect the IP severity, we used OMIC-strategy: Target Exome Sequencing of Metabolic Pathway in 80 IP cases (40IP-severe, 40IP-mild) ; Whole-Exome and Transcriptome Sequencing in 3 IP-severe.

Results: The Haloplex and Exome sequences gave a good mapping quality and the GATK variant calling pipeline was applied to identify high quality polymorphisms (SNPs and InDels) in each sample. More than 30,000 high quality variants were found across the haloplex samples, with an average of 430 variants/sample, and more than 300,000 across the exome samples, with an average of 40,900 variants/sample. Statistical analysis showed enrichment of mutations with higher rate of impact in the IP-severe respect to the IP-mild cases, although the association could not be considered “strong”. From exome-dataset analysis 12 genes were mutated among the 3 IP-severe cases.

Conclusion: The validation of variants and RNA sequencing results from the patient fibroblast cell lines will be integrated and the affected pathways will be shown. This research was supported by grant from the CNR-DSB Progetto-Bandiera "InterOmics".

PS7A-16: Global screening array analyses on DNA from Dutch Parelsnoer Biobanks to provide new genetic information on diverse diseases

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Introduction: The Parelsnoer Institute of the Netherlands is a collaborative Biobank of all eight University Medical Centers that facilitates research towards the prediction of individual disease course and personalized treatment options. Recent projects focus on the complex relation between the heterogeneous clinical presentation and the underlying genetic risk factors.

Material and methods: Four disease-specific Parelsnoer Biobanks participate in the Global DNA screening array genome-wide association project (GSA-GWAS), i.e., Inflammatory Bowel Disease (IBD), Neurodegenerative diseases (ND), Stroke and Type 2 Diabetes. Patients have been enrolled in the biobanks with collection of disease-specific clinical information and a standard laboratory set, including DNA.

Results: The GSA-GWAS studies focus on inherited determinants in Inflammatory Bowel disease (n>3900) of specific clinical subphenotypes, i.e., Crohn’s disease and Ulcerative Colitis. In the ND cohort (n>1110) research is focused on deciphering the missing heritability as part of the European Alzheimer’s disease DNA biobank. In Diabetes (n>6500) emphasis is on genetic factors associated with various clinico-physiological parameters, e.g., macro/microvascular complications, diabetic distress and neuropathy. In the Stroke cohort (n>1400) research is on specific gene loci related to ischemic stroke. Preliminary results indicate informative genetic information in 93.5% of the DNA samples with 6.5% loss due to low call rates.

Conclusion: GSA-GWAS DNA analyses in diverse clinical Parelsnoer Biobanks will provide new insights into the impact of genetic factors on the development of clinical disease subphenotypes. These DNA studies will enrich the genetic datasets in these chronic clinical conditions towards minute genotype-phenotype analyses.

PS7A-17: AMC Biobank: A central biobank in an academic medical setting

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Introduction: The Academic Medical Center of the University of Amsterdam is one of the largest hospitals in the Netherlands. Over 7.000 people work here to provide integrated patient care, teaching, and fundamental and clinical scientific research. Research is supported by core facilities, including AMC Biobank, which has been established in 2014.

Material and methods: AMC Biobank provides comprehensive logistic support and storage services for biological materials and related clinical data. The Biobank is part of AMC’s division Laboratory Specialisms and works closely together with the Durrer Center for Cardiovascular Research, hosted by the Netherlands Heart Institute.

Results: AMC supports the central storage of patient material for scientific research. AMC Biobank currently hosts more than 1 million samples for about 60 biobank collections, including various Parelsnoer collections, shared with other Dutch university medical centers, the HELIUS study on health differences among residents of Amsterdam with different ethnic origin, and the MARS study on molecular diagnosis and risk stratification of sepsis. Samples are managed using the LabVantage biobank information management system, and metadata of all collections are accessible through the national BBMRI catalog. Services of AMC Biobank are certified according to the ISO9001:2015 norm.

Conclusion: By providing ethical and legal supervision, proper registration, and technical services, AMC Biobank helps maximizing the scientific potential of biobank collections at AMC and creates added value for researchers and

patients, thereby contributing to the health research infrastructure (Health-RI) in the Netherlands.

PS7A-18: China on the Scheldt: biobanking of population with high prevalence of HBV

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Introduction: Viral hepatitis is a worldwide, important health issue. Asians have higher seroprevalence of Hepatitis B virus (HBV) infection, and presumably of Hepatitis C virus infection as well. This was unknown in the Belgian-Asian/Chinese migrant population. An epidemiological study was performed with biobanking to elaborate immunological markers in this population.

Material and methods: A community outreach screening program was performed in three major Belgian cities. Persons younger than 18 years were excluded. Serum, EDTA, Tempus Blood RNA and BD Vacutainer CPT (Mononuclear Cell Preparation Tubes) were collected. CPT tubes were centrifuged on-site and mononuclear cells collected within 24 hours. Informed consent was obtained.

Results: Using this protocol, 456 persons were successfully screened using venepuncture. A seroprevalence of 7.0% was found (32/456) for HBsAg and 0% of anti-HCV. Anti-HBcAb rate was 53.5% (244/456) . Of these persons, 298 individuals supplied all 4 sample types. All samples were delivered to the hospital biobank. Serum left-overs were delivered from the hospital clinical laboratory and isolated mononuclear cells were transfered from the Antwerp University Laboratory of Experimental Medicine and Paediatrics. Samples were stored at -150°C and all storage and derivatives were logged in the biobank's SLIMS database. Samples were subsequently used for immunological and biomarker studies for HBV-related studies.

Conclusion: This large screening study of a high-prevalence population for HBV entailed significant logistical effort from multiple parties but resulted in a 298-sample biobank with serum, EDTA, Tempus Blood RNA and mononuclear cells in a population with high HBsAg positive and anti-HBcAb prevalence.

PS7A-20: Parelsnoer Institute - Biobanking in the Netherlands

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Introduction: Launched in 2007 by the Dutch Federation of University Medical Centers (NFU), the Parelsnoer Institute (PSI) is a collaborative biobanking platform of all eight University Medical Centers in the Netherlands. PSI offers researchers an infrastructure and standard procedures for the establishment of clinical biobanks and their use for scientific research.

Material and methods: Human biomaterials are collected and stored according to nationally agreed standards. Related timelines and quantities are carefully aligned with the demands of the care process. To ensure patient privacy, clinical data and images are pseudonymized before being stored in a central database.

Results: Currently, PSI covers 19 disease specific, multicenter cohorts within the areas of cancer, auto-immune diseases, metabolic disorders, cardiovascular diseases and neurologic disorders, and new ones are being started. Within this platform, more than 608,000 biospecimens with annotated clinical data of over 35,000 patients are accessible for any scientist with a relevant research proposal. So far, more than 50 releases of data and/or samples have been requested for (multipurpose) research protocols, which has led to 39 peer-reviewed published manuscripts and 11 general biobank organization publications, and more are expected soon.

Conclusion: Over the years, the Parelsnoer Institute has been an example for biobanking in the Netherlands. It is collaborating with BBMRI-NL and Health-RI to further develop the Dutch research infrastructure, by participating in BBMRI-NL's catalogue and request portal, and by exploring the possibilities to connect data of different partners in Health-RI.

PS7A-19: Microbiome from stool, tumour and adjacent normal tissue swabs in the CRC patients: emerging concept in biobanks

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Introduction: Recent studies suggest a crucial role of the gut human microbiome in the development and aggressiveness of colorectal cancer. 16S rDNA sequencing revealed a number of bacterial species that are specific for colorectal carcinomas with Fusobacterium playing a prominent role.

Material and methods: Simple healthy tissue/adenoma/carcinoma correlation studies need to be followed by complex multimodal approaches that can efficiently combine all the modalities including molecular/clinical data/histopathology/immune response and microbiome. The identification of microbiome-immune-molecular CRC pathophenotypes can improve the stratification of patient population and lead to more effective patient care and improving disease prognosis.

Results: Here we present first results of a subset of our prospective study of colorectal cancer heterogeneity assessed from the immune, microbiome and histopathology perspective. We compared microbiome profiles of tumour swabs, swabs from adjacent healthy tissue and patient's stool to healthy individuals and correlate these profiles with clinical data and histopathological and immune assessment of tumours. Our analysis revealed important heterogeneity of microbial samples from CRC and intriguing correlations with histopathology, immune reaction and clinical variables. The stool composition of CRC patients differs significantly from healthy volunteers, however, stool from CRC patients remains heterogenous, starting at the class level.

Conclusion: Gut microbiota biobanks and the accompanying molecular information about its bacterial members may grow into a valuable health resource in the cancer field and beyond.

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PS7A-21: University Biobank Limburg – Successful collaboration between university and peripheral hospitals

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Introduction: The University Biobank Limburg (UBiLim) is a collaboration between Hasselt University, Hospital East-Limburg and Jessa Hospital, founded in 2010. It is established to support translational research carried out by the three partners, but makes its facilities also available to researchers from other hospitals or research institutes.

Material and methods: In both hospitals the biobank is embedded in the clinical laboratory and follows the corresponding quality standards (ISO15189), as well as several biobanking standards (Belgian law of 9/2/2018, ISBER guidelines, OECD guidelines,…) . To manage the samples and associated data a Biobank Information Management System (LabVantage Biobanking) is used.

Results: UBiLim consist mainly out of disease-specific samples collected at the hospitals for a specific study. The main research domains are oncology and autoimmunity. However, other research fields, such as cardiology, diabetes, gynecology/fertility, infectious diseases, obesity, pulmonary disorders and rehabilitation, are also represented in the biobank. Because our biobank is embedded in 2 hospitals, we can quickly meet the request of (doctor-) researcher to include certain sample types or enroll specific patient groups. At the moment, we have about 130.000 samples stored in our biobank, mainly plasma, serum and white blood cell pellets.

Conclusion: The number of sample collections set up in collaboration with UBiLim have increased from 14 collections in 2014 up to 25 collections in 2017.The request for samples stored in our biobank has also increased over the years, from 2.759 samples in 2014 up to 6.323 samples in 2017.

PS7A-22: The Biothèque Hospitalo-Universitaire from Liège: past, present and future

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Introduction: The availability of large collections of patient samples with well annotated data is one of the main requirements for life science research. That is why biobanks will definitely play an important role in future healthcare.

Material and methods: At CHU de Liège, biobanking has been in place since researchers have expressed their need to validate their in vitro research on human body material. Funding from the federal government since 2009 has helped the biobank to organize and implement a systematic collection of residual tissue material for research.

Results: More recently, the legal and ethical contexts motivated to concentrate efforts and to centralize resources by the constitution of the Biothèque Hospitalo Universitaire of Liège (BHUL) . This project integrates 6 thematic sub-units : pathology, hematology, gastroenterology, pneumology, cardiology and genetic. This biobank integrated in hospital activities collects, treats, characterizes and stores different types of human body material.

Conclusion: This institutional biobank has therefore been faced with several challenges in terms of harmonization of sample processing procedures, traceability of aliquots in database management software, and implementation of the quality management system.

Moreover, BHUL is part of different networks at regional, national and European level.

PS7A-23: Introduction of the CENTER-TBI Serum Biobank: current state – future challenges

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Introduction: The CENTER-TBI „Collaborative European NeuroTrauma Effectiveness Research in TBI" project includes a large scale observational study using precision medicine approaches and comparative effectiveness research to advance the care for patients with traumatic brain injury (TBI) . The study supported by the EU FP7 program.

Material and methods: The serum Biobank and proteomic lab in the János Szentágothai Research Centre of the University of Pécs, Hungary are cornerstones of the CENTER-TBI project. Serum sample collection was organized in 63 recruiting centers from 19 countries across Europe.

Results: To date (26.MAR.2018), 36575 0.5 ml serum aliquots from 31 different sites were banked derived from 4696 sampling time points of 2144 TBI subjects. According to the plans by December 2018 the Biobank will contain almost 100000 serum aliquots from different sampling points of more than 5000 TBI subjects. We will also bank whole blood samples for genomic analysis and plasma samples in a sub-set for coagulation studies. Planned blood-based biomarker assays include GFAP, UCHL-1, S100B, NSE, total tau and NF light and will be conducted at our proteomic lab as well as in the labs of partner institutes.

Conclusion: This Biobank for TBI is unique with a main goal to serve as a broad basis for different genomic, (protein) biomarker, and coagulation investigations in TBI. Collaboration with SME's for explorative studies of novel markers has been established, and we aim for long-term storage to provide for legacy research.

PS7A-24: Characteristics and specialization of Polish biobanks

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Introduction: Currently, knowledge about Polish biobanks is still insufficient. The main goal of the Polish Network of Biobanks and BBMRI.pl – after gathering information about Polish institutions dealing with the broader biobanking or storage of biological material, is to determine the type of samples collected and the nature of the biobank.

Material and methods: An information survey to collect data about Polish biobanks characteristics was created. The survey consists of 53 questions that depend one on another. The identified biobanks received the electronic questionnaire.

Results: Among the 50 identified biobanks, 45 units declare storage of human origin material. We can divide the units depositing human origin material according to the selected criteria: population biobanks - focusing on population research; specialist (researching or collecting material from people with specific diseases), mixed (population-specialist), clinical and other. The most units were identified as the specialist (26 units) and clinical (18 units) type. Specialist or mixed biobanks are focused on various diseases – cancer (27 units), rare (14 units) and autoimmune diseases (11 units) . Most Polish biobanks are localized at medical universities.

Conclusion: The received data is still being analyzed. Additionally, new biobanks are constantly joining the Network. However, it was observed that Polish biobanks specialized in selected diseases and many of them focus on cancers. This tendency and the availability of material from clinics can significantly strengthen the anti-cancer research.

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PS7A-25: Biobanking of samples of patients with psychiatric disorders within the framework of the Russian Psychiatric Genetics Concortium - RPGC

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Introduction: In Russia there are seven main scientific centers working in the field of psychiatric genetics. To promote further development of research in this field, they initiated the setting up of RPGC. In 2017 the Biobank of SPbU joined RPGC with the aim of processing, preservation and archiving of biological samples.

Material and methods: To date, several thousand DNA samples with detailed clinical information (patients with schizophrenia and affective disorders, together with population-matched controls) have been collected.

Results: To provide processing, long-term storage, transportation and research of biospecimens, the protocols, policies and standard operational procedures were developed. The specimens of patients and controls were used in studies with various designs. The genetic markers of psychiatric disorders specific for the Russian population were identified.

Conclusion: The medical research of psychiatric diseases requires the availability of biological samples with associated clinical data. Creation of RPGC and biobanking of samples with psychiatric diseases enables to preserve and archive patient samples for future multicenter research and to develop personalized diagnostic, prognostic and therapeutic approaches of psychiatric diseases.

PS7A-26: 10th year anniversary of Durrer Center for Cardiovascular Research: past, present and future

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Introduction: The Durrer Center for Cardiovascular Research (Durrer Center) is a facility that operates within the unique cooperation of the cardiology departments of all eight university medical centers in the Netherlands, called Netherlands Heart Institute. The Netherlands Heart Institute fosters excellent cardiovascular research on national and international level.

Material and methods: Durrer Center a) facilitates logistic support and storage services for biosamples and (imaging) data and b) provides data management support for new studies/projects following the FAIR principles (Findable/Interoperable/Accessible/Reusable) . Durrer Center is housed in the Academic Medical Center (Amsterdam) and works closely together with AMC Biobank.

Results: At the moment Durrer Center manages samples and data of 25 (multi) center studies covering more than 125,000 samples. An online catalogue visualizes data and biomaterials collections. Moreover, Durrer Center supports data management for 25 research projects including implementation of image archives, development of eCRFs (Castor/OpenClinica/REDCap) and catalogues at study and patient level. Durrer Center supports the Dutch Heart Foundation in implementing the Dare-to-Share policy on research data.

To guarantee control and continuous improvement on storage of biological materials and facilitation of data management/stewardship Durrer Center implemented a quality management system (according to ISO9001:2015), which has been certified in January 2018.

Conclusion: Durrer Center helps maximizing the scientific potential of cardiovascular research projects by providing reliable storage and transparent access for biosamples and data to create added value for researchers and patients. In cooperation with BBMRI, TraIT and PSI, Durrer Center contributes to the health research infrastructure (Health-RI) in the Netherlands.

PS7A-28: Constitution of the new biobank CRYO-LEA using the MBioLims BioBanking Information Management System

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Introduction: Patients treated in childhood for leukemia by chemotherapy or allogeneic hematopoietic stem cell transplantation suffer from long-term complications (metabolic syndrome, cardiomyopathy, secondary tumors, osteonecrosis…) . Consequently, the study of genetic susceptibility to treatments late adverse effects is a promising approach to develop personalized therapies and improve the survivals quality of life.

Material and methods: A collaboration, aiming to constitute a biological collection, has been initiated between the cohort LEA, dedicated to the Leukemia of Children and Adolescents, and the CRYOSTEM network, expert in biobanking, both located on the French territory. Modul-Bio has deployed the MBioLIMS CRYO-LEA to centralize the samples and associated data.

Results: Leaning on its network logistics and quality management system, CRYOSTEM coordinates the biobanking of the samples from patients included in the cohort LEA. Based on the therapy received by the patient, blood samples or skin biopsies are collected, from which viable cells, dried pellets and plasma are derived. The MBioLIMS CRYO-LEA has been deployed and configured to answer the specific requirements of the cohort LEA, mainly related to the recording of patients and the samples collected or derived. The collection is expected to begin in June 2018 and almost 2,000 patients to be included in this new collection.

Conclusion: The constitution of CRYO-LEA biological collection is a crucial step. Modul-Bio ensures a major role by deploying a functional BIMS Biobank Information Management System, tailored to the biobank specificities, centralizing a large number of samples and data, further used in genome-wide studies to identify genetic factors behind late side effects.

PS7A-29: Overview of Challenges in the Establishment of the IROPICAN Biobank

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Introduction: The IROPICAN biobank is a multi-center study established in 2016 to investigate the association between opium use and the risk of cancer. Herein, we report the study design and the challenges during the first 2-year period of the project.

Material and methods: Extensive data as well as biological samples are collected from 17 hospitals in 7 different geographical sites of Iran. Blood samples are collected and kept in each local center temporary in -20°C for one month and then shipped to the main center at Cancer Institute of Iran, for further processing.

Results: Currently, this precious resource houses more than 17000 samples (5 total samples including blood, plasma, serum, DNA and saliva per patient) of 1812 individuals with head and neck, lung, bladder and colorectal cancer and 1679 healthy individuals. So far, the quality of DNA for both local and distant samples was promising. However, the quality of serum, plasma, blood, and RNA samples remained to be examined.

Conclusion: Due to low resource setting, attaining the cold-chain requirements is a key issue which is remained to be solved. This report will further study the impact of our cold-chain strategy on the quality of samples. The results of our validation study will be presented at the conference.

PS7A-30: Introdoucing the Iran National Tumor Bank; Its Role in Cancer research, the Challenges and the Future Goals

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Introduction: Iran National Tumor Bank (INTB) was founded in 2006 with the aim to collect, store and distribute human tissues to facilitate advances in cancer research. The purpose of this report is to introduce INTB and the available services to create opportunities for International networking.

Material and methods: Quality, diversity and integrity are core principles in INTB. The high-quality biospecimens, derivatives and clinical data are collected according to the standard operating procedures. Fresh-frozen tumor, fresh adjacent normal tissue and their formalin fixed paraffin-embedded tissues, and blood products including plasma and buffycoat are stored in INTB.

Results: To date, INTB is the custodian of 34 different types of tumors from more than 2000 donors of which breast and gastric cancers are the 2 tumor types most issued. INTB has provided detailed information as well biological samples for more than 180 different cancer research projects from home and also internationally recognized centers, including International Agency for Research and Cancer (IARC) and the Karolinska Institute. INTB has also been a resource for over 60 research literature published in the prominent journals.

Conclusion: INTB provides a viable solution for cancer researchers who often face challenges in obtaining the quality and number of biospecimens required for their studies. Thus, INTB accelerates cancer research for the development of better patient diagnostics and therapies.

PS7A-31: Towards establishment of a biobank for translational medicine research

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Introduction: iBG-Biobank is a hospital integrated core unit collecting human biospecimens obtained from cancer and rare disease patients. The collections are ingenerated by fresh, frozen, FFPE tissue samples, blood, CSF with associated DNA, RNA, cfDNA, iPSC. And the SOPs are constituted under the guidance of BBMRI-ERIC criteria and CEN/TS documents.

Material and methods: According to the existing experiences of the expert centers the most leading challenges, that we must manage, are harmonization, standardization, combination of multidisciplinary approaches

and coordinating big data. Among these, harmonization and exchanging of data and biomaterials have great importance from our point of view.

Results: Best researches are demands larger number of samples and these samples are representative broad populations not just the locals. But results from the biospecimens that collected, stored and processed by the researchers in each case were done different. And the samples, which are done in-house protocols with narrow audits on their own labs and their close colleagues. The major aim is establishment of an international and centralized biobank that collects the biospecimens and biomolecular resources together with the all clinical data and lifestyles. This is the only possible way to link clinic and the wet-lab/basic sciences, phenotype and genotype.

Conclusion: By the comparison patient cohorts and an established background general population it is possible to; characterize cancer of unknown primary, personalized medicine for developing therapeutics tailored to patient and disease characteristics like obesity, immunotherapies, identification of new biomarkers,Human PDX organoid models for drug research and to determine the best treatment.

Topic 7C- Education Tools and Programs for Biobankers

PS7C-1: Student exchange program of the BRoTHER project of cross-border collaboration

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Introduction: The project, BRoTHER (Biobank Research onTelemedical Approaches for Human Biobanks in a European Region), is a project of cross-border Bavarian-Czech collaboration supported by a grant of the Bavarian-Czech University Agency with funding from the Bavarian State Ministry of Finance. Student exchange program is one of the aims of the project.

Material and methods: Student exchange program was prepared based on actual needs of students, current state of art in some aspects of biobanking, and the partnering institutions activities. First course organised by University Hospital Pilsen "Intensive course in immunochemistry, biobanking and personalised medicine" offered the students basic information, practical introduction and routine practice.

Results: Programme was structured to the following sections:

1. overview of research topics, and introduction to laboratories of molecular biology and microscopy, real-time PCR and the importance of molecular biology methods in oncological research at University Medical Centre –Faculty of Medicine in Pilsen

2. ELLA – ELISA multiplex system and LUMINEX, introduction, principles, demonstration and practical exercising at Laboratory of Immunochemistry University Hospital Pilsen

3. biobanking, introduction, samples, registration system, aliquotation, storage and sample searching, ELSI at Department of Immunochemistry University Hospital Pilsen

4. personalised medicine in oncology, theoretical background, history and implementation into practice, personalised medicine at University Hospital Pilsen, international collaboration, research projects

Conclusion: First experience from both sides were positive, students were active and fully involved in all activities, especially in practical exercising, the team both of students and lecturers was opened and friendly, the cultural associated programme helped the cross border collaboration. Students´ evaluation of the course was excellent with innovative ideas.

PS7C-2: An innovative concept to educate and strengthen biobank governance at Swiss Biobanking Platform

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Introduction: Adherence to the highest ethical and legal standards is critical to run any biobanking activity and is one of the most important concerns Swiss Biobanking Platform (SBP) wishes to address. To tackle this challenge, transparent and strong governance has to be developed.

Material and methods: Building up a proper Governance through accountable mechanisms is key to foster trustworthiness and the pre-requisite for the appropriate use of health-related personal data and biological material.

SBP Governance strategy relies on three main documents :

- the consent form

- the Biobank Regulation

- the Material Transfer Agreement

Results: These documents can be developed by using SBP supporting tools dedicated to address this Governance strategy. Among them, biobank governance issues have been gathered into an innovative solution, the SBP Toolbox, including the essential biobanking key components a successful biobank has to integrate. Through specific questions, biobanks will be scored by assessing their level of compliance with ethical and legal requirements. Scoring will be translated into labels, the governance label being the mandatory one showing that ethical/regulatory criteria have been met.

Conclusion: Based on this evaluation, SBP proposes action plans to support biobanks reaching this label, as well as other services for those willing to achieve quality-related labels.

PS7C-3: "How to build a biobank" course : overall feedback and future interests

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Introduction: Starting from 2015, Biobank Graz has set-up an annual 3-days biobanking course called "How to build a biobank: Learning by doing". This course was designed to provide best practices, introduce state-of-the-art equipment and guide scientists willing to set up an efficient biobank.

Material and methods: With the objective of course refinement according to current biobanking challenges, an anonymous questionnaire survey was sent to the 59 former participants. The survey was created via 7 questions and a "free comments" field, with the aim to have a feedback on the course and potential future interests in biobanking.

Results: In total, 16 answers were collected which represents 27% of the former participants. On a scale from 1 (not useful) to 4 (very useful), an average of 3.13 was obtained regarding the usefulness of the course. In particular, the practical aspect was slightly preferred (43%) . As future interests, the most chosen field was "quality management, quality control and quality assurance" (88%) . Further, most of the participants would be interested in a course on modernization of biobanks (81%) and possible webinars covering specific issues (87%) . Regarding sponsor presentations, participants have mainly shown interest in "IT solutions for biobank database".

Conclusion: The results of survey have been positive and very supportive and enlightening regarding the course. Over this feedback and in accordance with current biobanking interests, changes will be made to better adapt the future programs. Participant satisfaction is one of the main priorities of Biobank Graz in conceiving this course.

Topic 9A - Academic – industrial partnerships to accelerate scientific discovery

PS9A-1: Global Availability Service, BC|RQUEST.com, provides a meeting place for biobanks and pharma industry

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(1) BC Platforms

Introduction: The last decade in medical research has seen major advances in the production and collection of data, as well our ability to effectively analyze and understand this new information. Big data is helping every industry to become more efficient and productive, drug development being no exception.

Material and methods: Biobanks are an essential tool for drug discovery with their rich datasets originating from diverse profile of individuals and populations. Yet the hurdles of harnessing these data sources effectively have largely been the inability to find and/or integrate those valuable to medical research.

Results: Research groups and industry demand an ecosystem that facilitates the sharing of data and information in a safe and secure environment. This opens the door for the role of data broker who can guarantee confidential environment for biobanks to share their data with pharmaceutical researchers. BC Platforms offers a technological solution, BC|RQUEST, for combining the datasets of biobanks globally and enabling analytical queries on aggregate genomic and clinical data.

Conclusion: The technical ability to adapt and structure phenotypic data in conjunction with genetic data in one technical system and database makes BC Platforms uniquely positioned to act as the common denominator for biobanks.

PS9A-2: Collaborations with the ETOP Lungscape iBiobank advances translational research

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Introduction: The European Thoracic Oncology Platform (ETOP) was founded in 2009 to promote and improve collaboration in clinical and translational research on thoracic malignancies. It is a not-for-profit foundation. The heart of the ETOP translational research activities is formed by the Lungscape program, a decentralized, 'virtual' biobank.

Material and methods: The Lungscape iBiobank consists of more than 2500 Non Small Cell Lung Cancer (NSCLC) tumor specimens with de-identified but fully annotated clinical data. The Lungscape investigators developed a series of study protocols to assess prevalence and identify prognostic biomarkers for NSCLC, to molecular profile the lung.

Results: The Lungscape iBiobank is unique in that it provides a platform to carefully selected, primarily European, lung cancer centers to conduct collaborative biomarker projects that would overwhelm a single center. Since the participating investigators, all highly specialized pathologists, are closely involved in study design, quality assessment, and operation, this acts as powerful endorsement for support of the iBiobank. Motivation is high as participating sites analyze their own cases rather than submitting biological material to a third party. The decentralized design furthermore promotes continuous training and empowers all participants in biobanking operation and biomarker study conduct.

Conclusion: The Lungscape iBiobank was first runner up at the ESBB Research Biobank of the Year Contest (RBYC) in Leipzig in 2014. Where do we stand four years later? Six translational research projects will showcase academic-industrial partnerships that helped accelerate scientific discovery.

PS9A-3: EIT Health - consortium to promote collaboration between biobanks/data registers and industry

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Introduction: EU funded innovation consortium EIT Health (www.eithealth.eu) promotes healthy living, active ageing and improvements in healthcare by leveraging big data and new technologies, identifying and removing barriers to innovation, including promoting more active use of big research infrastructures like biobanks and health registers.

Material and methods: EIT Health leverages the expertise of more than 140 leading organisations spanning key areas of healthcare, such as pharma, medtech, payers, research institutions and universities with the aim to develop new products and services.

Results: EIT Health Scandinavian node has particularly taken into the focus the collaboration between industry and academia by starting a program RABBIT (Register-data And BioBanks Implementation Token) with the key focus on speeding up innovation implementation, hypothesis testing and new technology/process/treatment monitoring through a clear access to register-data and biobanks. These processes normally take very long time and we believe that the EIT Health could provide the engine and "better" mechanisms for speeding up the implementation processes since all partners have signed a joint framework contract promising to drive "healthy aging" through the fast implementation of innovation in health and wellness.

Conclusion: The project welcomes biobanks and registers, who have done collaboration with industry to join the project and share their experience for better and faster industry-academia collaboration outcomes in the future.

Topic 9B - Patient Involvement & Empowerment

PS9B-3: A person-centred framework to support better use of the biobank samples and data and drive healthcare improvements across Europe

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Introduction: Research conduct and care practices centred on the person are increasingly receiving more attention. However, there remains a strong unmet need for a widely accepted person-centred-research-and-care (PCRC) framework, endorsed by all stakeholders, to allow for good communication, robust evidence generation and optimal outcomes.

Material and methods: Given data ownership and access issues, and ethical implications thereof, the objective of this work was to broker initial dialogue with stakeholders about their preferences and needs,opportunities and synergies, and assessing willingness to actively support a collaborative participatory initiative for the development, promotion and adoption of such a comprehensive framework.

Results: A series of national and international policymakers, regulators, academics, healthcare professionals and patient representatives were asked to provide feedback on collaboration plans to strengthen PCRC and examine the key elements that ought to drive the generation, promotion and adoption of such a framework. Current issues that still prevent successful PCRC practices were highlighted, i.e., poor training; limited knowledge/exchange between stakeholders; lack of common law, regulations and ethical guidance for multi-sourced biological and health data; lack of patient ownership of data, poor transparency and traceability, failure to protect people's rights and representation in bank-related activities.

Conclusion: The development and delivery of high-quality social&healthcare services encompasses individualised-care options, for which predictive and prognostic markers need to be considered along with epidemiological data and public-health priorities. A PCRC-framework to promote and adopt evidence-informed policy-making is needed and would lead to more resilience on persons, systems and society.

PS9B-4: Promoting Engagement of Cancer Patients with a Biobank and Future Research Studies

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Introduction: Collecting residual tissues for research purposes, without the explicit consent of individuals, implies to efficiently raise awareness on biobanking processes, and to provide adequate information on the biobank itself. Dedicated communication materials must be designed and made accessible to engage individuals or to allow them to opt-out upon their wish.

Material and methods: In order to raise awareness and to provide information on an institutional tumor bank, researchers of a comprehensive cancer center in Belgium, carried out a literature analysis on the best practices to communicate about biobanking activities.

Results: An animated video has been designed and produced. It details: 1) the purpose of research when integrated to cancer cancer; 2) the different steps of collection and storage of tissues in the tumor bank; 3) the process of consent and 4) additional procedures patients can consent to foster further researches. The emphasis of the animated video was put on providing patients with the opportunity to reflect upon their participation, while trying to stimulate autonomous decision making.

Conclusion: With the aim to provide all adequate information and awareness about a biobank, a video animation allows at the same time 1) validating of the overall opt-out procedure, and 2) engaging patients in a broader reflection about research: making the biobank's consent process a moment to learn and reflect.

PS9B-5: Information Campaign to Empower Donors and Promote Biobanks in the Public

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Introduction: Biobanks largely depend on the support of donors willing to provide biomaterials and data for research purposes. Previous research revealed that donors lack basic understanding about biobanks. A better level of knowledge is a prerequisite for a trustful relationship between biobanks and donors, and a necessary precondition for successful participation.

Material and methods: GBN wants to address this issue with an information campaign that launches in May 2018 in 11 partnering German university clinics that maintain large-scale centralized biobanks. The goal of this campaign is to 1. increase awareness about biobanking, 2. promote education, and 3. increase motivation to donate.

Results: To achieve these goals GBN has created and tested a series of posters, flyers, and a donor website (www.biobanken-verstehen.de) available starting May, 1st 2018. The messaging of this campaign is based on current research on donor knowledge, attitudes and motivations to donate biomaterial and aims to answer the most common questions about biobanking. The communication material is designed in a way that different target groups (age/sex) can be addressed in the appropriate setting of a clinic. GBN offers the material as a toolkit that every biobank can adapt for their individual use.

Conclusion: A first evaluation of the campaign will be presented in September 2018. We expect the campaign to positively influence donor knowledge and attitudes towards biobanking. Concurrently, the interaction of the centralized biobanks with various clinics in their university will improve internal communication and raise awareness for the biobanks services.

PS9B-6: From Engaging Publics to Engaging Knowledges: Enacting "Appropriateness" in the Austrian Biobank Infrastructure

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Introduction: Our paper synthetizes recent research on public engagement in order to describe the constitution of respective concerns as 'engagement of knowledges'. While there is consensus on the essential importance of publics' concerns in further developments of biobanking, the related investigations have not delved into the ways these concerns are constituted.

Material and methods: We analyze our three-year investigation of public views on biobanking in the form of citizen-expert panels (CEPs) in the Austrian infrastructure of biobanks (BBMRI.at) . CEP tool builds on group-based engagement methods which illustrate that group discussions can enable manifold interactive processes, thereby generating rich data on meanings behind certain assessments.

Results: We reflect on CEP as a methodological-cum-epistemological tool to follow how public attitudes toward biobanking are formulated through engagement of already available knowledge with the knowledge newly received during the CEP. We show through our examples that citizens provide important (local) knowledge on societal contexts and embeddedness of biomedical research not only in terms of concrete attitudes but, in particular, in terms of the knowledge process, through which they create these attitudes. The notion of appropriateness empowers publics by helping them to organize this knowledge process and to embed the new knowledge in the stock of knowledge they already possess.

Conclusion: By shifting from 'publics' to 'knowledges', we draw attention to the interaction dynamic through which citizens embed the new knowledge they receive during expert interactions into the stock of knowledge they already possess. We trace this dynamic through citizens' concerns that the research practices related to biobanking should be "appropriate".

PS9B-7: Communication strategy of the BBSSPA based on collaboration with public and private entities and associations of patients

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Introduction: The Andalusian Public Health System Biobank (BBSSPA) has the mission of promoting biomedical research. This goal needs the participation of donors and BBSSPA has established a communication strategy based on collaboration with entities and associations of patients to develop the social promotion of the samples donation for biomedical research.

Material and methods: The BBSSPA has contacted to institutions such as the Granada Football Club, the Andalusian Public Radio-TV, ... and associations of patients. The collaboration with the aforementioned institutions consists in carrying out joint dissemination activities, and the using by the biobank of dissemination and communication tools specific from each institution.

Results: So far, there have been outreach activities in different events such as science fair, coffee&science, thematic tours, informative talks and sports activities. The institutions have provided informative material such as digital information panels distributed throughout the city, information panels on the transport lines, advertising spaces during the broadcast of sporting events, publications in institution's own magazines and participation in television programs.

Conclusion: The communication and dissemination strategy of the BBSSPA in the Andalusian population has allowed to increase the number of sample donors for biomedical research.

PS9B-8: "The long night of sciences" as an example to gain public outreach for biobanks and biobanking in Germany

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Introduction: Biobanks are essential infrastructures for biomedical research providing high quality biosamples and data. However, the public (potential biosample donors) are not aware of the existence of biobanks and their role in biomedical research. Concepts of how to enroll the public are currently under development by the biobank-community.

Material and methods: "The long night of sciences" is a public bi-annual event in Leipzig (Germany) . The German Biobank Alliance (GBA) together with the LIFE-Biobank Leipzig takes advantage of this event to inform and educate the public employing a broad panel of presentations, a booth, discussion rounds, and guided tours through the LIFE-Biobank.

Results: In interactive lectures biobank experts explained the basics of biobanking focusing on the importance of biobanks for future medical research also including diagnosis and treatment of various diseases. Such information have been actively used for participative activities (the biobank "triathlon") guided by the LIFE-biobank and GBA. Participants also could visit the LIFE-Biobank and discuss the pros and cons of biobanks with basic and clinical researchers from the University of Leipzig. In GBA this serves as a best-practice example for other biobank sites which can re-use materials and ideas for their own future events.

Conclusion: "The long night of sciences" or comparable public events are being used to attract more attention on biobanks and biobanking. This could help to address urgent needs of our community and to gain public trust and awareness for future potential donors of biosamples.

PS9B-9: Citizens negotiating informed consent in biobanking

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Introduction: Biobanks have become core infrastructures for providing access

to human materials and health information for biomedical research. Processing these materials for research purposes is dependent on participants' agreement to donate and on the informed consent (IC) they are willing to give.

Material and methods: We draw on data from a public engagement method, addressing biobanking in Austria: 15 "Citizen-expert panels" (CEPs) brought together citizens, patient representatives and professionals from the field. Analytically, we go beyond the evaluation of CEPs' capability to engage publics and carve out how citizens (re) construct value of biomaterials and data.

Results: Making an informed decision about the use of samples/data is a particular challenge in the biobank context, fueling debates about ethically appropriate consent forms, control and ownership and data protection and privacy, as well as about how to improve the involvement of publics and patients in biobanking governance. When citizens relate to biobank-based research, they conceptualize this relationship in terms of responsibility and care, and regarding ideals of "gift-giving" for the common good. This happens within an imagination of reciprocity that requires mutual engagement instead of unidirectional information, which is codified in the IC.

Conclusion: By illustrating how biobanks are situated in a wider context of biomedical developments and societal debates, we conclude with discussing how this could inform a more value-oriented policy-making.

This research has been carried out in the framework of BBMRI.at (funding: BMWFW) .

PS9B-10: BBMRI-NL Patient and Public Advisory Council: Bridging health research and society

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Introduction: Biobank- and data infrastructures contain samples and data of many citizens and/or patients to facilitate personalized health research. Biobank research is largely dependent on voluntary participation, public trust and societal involvement. The Patient and Public Advisory Council of BBMRI-NL was founded in 2016 to bridge research and society.

Material and methods: Council members either represent societal organizations like patient organizations, or act in individual capacity. With that, the council is a mixture of professional and experience experts with affinity for biobank and health research. The council meets regularly to provide a societal perspective on current practices, problems, concerns and new developments.

Results: Various topics have been discussed, including over-arching societal themes concerning most biobanking research, such as public and patient communication; transparency; consent; and how to create tangible impact. Further topics with main outcomes include:

Self-recorded data for research: Criteria for participation are the concrete use for research, easy recording, a positive contribution to individual health, proper study information, and confidence in the researchers.

Policy on incidental findings: Since each research project has its own characteristics, discuss upfront with representatives of the participants group what the policy on incidental findings should be, and how you will communicate about this with the participants.

Conclusion: The Patient and Public Advisory Council initiated by BBMRI-NL gives voice to patients and public in health research infrastructure initiatives. The council enriches research scopes and outcomes, and thereby increases possibilities to translate research into better personalized medicine and health.

PS9B-11: Patient organizations as a partner in rethinking of both informed consent and governance in research biobanking

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Introduction: We need patient-citizen's systematic involvement and engagement to consolidate a good practice for a large-scale research based on publicity, individual awareness, and responsibility. Thus, overall it is critical both structuring an extended peer community, and dynamic conditions for public debate and engagement, to create a RRI horizon.

Material and methods: The 2 peer working groups with the Rare Disease and Cancer communities, including patient and caregiver, were among the pillars of the BBMRI.it Common Service ELSI work plan 2017. Both groups worked in parallel on an informed consent process based on understanding, awareness, engagement and regeneration of trust.

Results: Throughout 2017, in cooperation with Ricerc@, the Ethics Committees network, Uniamo F.I.M.R. and F.A.V.O, the Italian Rare Disease and Cancer Federations, some principal Patient Associations, together with the biobankers, modelled a matrix of informed consent and agreed on ELS requirements of a good inclusive practice in research biobanking, starting from the patient's information needs. Patient Associations made the difference in focusing contents and logic of the process. Key-points were: biobanking scope, balancing risk of profiling with rights due, respect and protection of genetic information, clear information on results returning and samples traceability, guaranteeing all players' involvement in the governance.

Conclusion: In the ongoing process of validating, Associations are promoting the outcomes within their communities, and are ready to test them in the field with committees and biobanks. But above all, after recognizing the groups as an empowerment vector, Associations propose to rethink together the governance of bio-banking, systematically including patients.

PS9B-12: Returning genetic data to participants of Estonian Genome Center

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Introduction: Estonian Biobank (EGCUT) holds genotype and health data of nearly ~52,000 individuals. In the end of 2017, EGCUT has started offering individual genetic risk predictions to its participants. The personalised standard reports include genetic risk scores for common diseases, carrier status, other hereditary risk factors, and pharmacogenetics.

Material and methods: 47,000 participants have been genotyped and ~5,000 individuals have whole genome or exome sequencing data available. Semi-automated report assembly and participant portal have been set up. Genetic risk scores are used for calculating the risk of common diseases. High-risk variants reported are based on ACMG guidelines. Participant responses are surveyed.

Results: Over 890 participants have expressed interest through logging in to patient portal and 341 have been to the genetic counselling session from November 2017 to March 2018. We currently perform counselling visits for at least 30 participants per week.

Conclusion: EGCUT initiative of return of results to population-based biobank participants provides insight on how healthy population responds to personalised genetic risk information. The long-term aim of the project is to to promote introduction of personalised medicine in Estonia, including genetic risk estimates as essential part in electronic health records.

PS9B-13: A multistakeholder dialogue to prioritize NASH research in relation to biobanking: mind the gap!

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Introduction: A multi-stakeholder dialogue (MSD) is an alternative way of consulting all stakeholders actively involved, or beneficiary of research outcomes, who are currently not involved in research prioritization. In general, it is a metodology in which citizens and patients work together with researchers, caregivers, and research sponsors to prioritize research topics.

Material and methods: The methodology of MSD is a multi-actor and iterative process that is being increasingly employed in different countries around the world (Netherlands and UK as pioneers) . Based on the state of the art, the King Baudouin Foundation (Belgium) has designed 3 pilot projects to evaluate and test the MSD methodology.

Results: In one of those, the central question in the MSD approach was defined as How can hepato-biobanks be optimally used in order to maximise their benefit for patients and society?.

Through a process of different rounds of stepwise information gathering and ultimately a MSD face-to-face consensus meeting, the Belgian King Baudouin Foundation and the BBMRI.be and BASL have brought together the voice of :

- donors,
- patients with liver diseases,
- health professionals providing care to liver patients,
- researchers,
- representatives from research sponsors and industry,
- Biobank managers,
- ELSI representatives

Conclusion: With this pilot project the MSD methodology was evaluated to induce a paradigm shift in research prioritization and identification of challenges, inspired by Belgian stakeholders in liver research, people involved in various aspects of biobanks, and patients and (potential) sample donors.

PS9B-14: Playing cards with biobanks: a tool for promoting public engagement

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Introduction: The assurance of public support is vital to the future sustainability of the biobanks. Therefore, recognising the importance to engage a liaise with public, three Ligurian biobanks, partners of BBMRI.it, organised a local initiative in Genoa (Italy) in collaboration with A.Li.Sa. (Regional Health Authority) within the European Biotech Week 2017.

Material and methods: The objective to disseminate the biobanks' services was pursued by developing an interactive ad-hoc card game which consisted of a deck of cards, each containing multi-choice questions on six main biobanking topics, represented by diverse colours. The cards were chosen by the player (s) by rolling a dice.

Results: The event was well-attended by approximately 50 people including citizens, students, health professionals and journalists. A news conference was also held by a regional councillor, giving therefore visibility to the event on local television. In order to be more effective, the various biobanking topics and activities were also tackled via poster presentations and videos concerning some projects such as BBMRI, Telethon Network of Genetic Biobanks and RD-Connect. In addition, a booklet was given to players to foster the spread of biobanking.

Conclusion: The closed-ended questions gave the player the possibility to interact and discuss with the game facilitators (i.e. biobankers) on the importance of biobanking and networking, especially in the field of rare diseases.

PS9B-15: Willingness to Donate Biological Material for Research and Knowledge About Biobanking of Parents and Children – a Polish Nationwide Survey

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Introduction: Polish Biobanking Network (BBMRI.pl) has gained a recognized position among Polish scientists, who understand the need for efficient storages and sharing of biological material for research purposes. However, the knowledge about biobanking of the general Polish population is not known.

Material and methods: We carry out a national survey about the personal intention of adults and children to donate own or own child's biological material for research purposes. Firstly, we assess the willingness to donate the biological material on the basis of personal opinion on blood and bone marrow/organs donation.

Results: Then, the questions deal with basic knowledge about biobanking. The survey takes into account potential incentives and obstacles of donating biological material for research purposes, such as chronic or rare illiness of the family member or a friend as well as a belief in positive or harmful impact of innovative research on personal health. The issues of informed consent, use and sharing of samples, also after donor maturity is explored. The results will be analyzed with regard to detailed demographic data, including child's age and health status and compared to general Polish teenagers and adult population.

Conclusion: The survey will be the first to present Polish general population knowledge and opinion about biobanking, with special regard to pediatric collections. It would help us to adjust the educational campaign about pediatric biobanking to our population. This work was supported by Ministry of Science and Higher Education grant DIR/WK/2017/01-27.01.2017

PS9B-16: Understanding Biobank Involvement among Patients – Experiences from the Interdisciplinary Center for Biobanking-Lübeck (ICB-L)

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Introduction: The need for biobanks as repositories for storing human biomaterials and corresponding clinical data to support biomedical research and contribute to the improvement of personalized health care is becoming more and more important. Nevertheless, there is still a lack of awareness amongst patients on what biobanks generally are.

Material and methods: 82 Patients visiting the UKSH Campus Lübeck were asked to fill out a questionnaire containing four different sections: 1) present knowledge of biobanks and the ICB-L, 2) aim of biobanks, 3) possibilities of biobanks and 4) usage of media.

Results: Among the interviewed patients, 20% knew what biobanks are and only 2% have heard of or knew the ICB-L. 78% of the surveyed patients have not donated biomaterials yet and just 1% donates regularly. Still, 62% considered biobanks as necessary. With regard to the willingness to donate, 63% of the patients would donate their biomaterials to the ICB-L, however, 37% conceive the patient information as insufficient. In terms of personal concerns, the majority of the patients is worried about data protection or the abuse of biomaterials.

Conclusion: In contrast to present findings, the ICB-L recorded three withdrawals out of 50,000 patients who had given consent for biobanking since 2015. By developing a „communication concept" (e.g. advertisement, public events), ICB-L will improve the awareness of biobanks among patients and the willingness to donate biomaterials to support biomedical research.

PS9B-17: Cancer patient views on clinical trial data sharing and involvement

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Introduction: Present-day, many initiatives and articles are devoted to clinical trial data (and to a lesser extent sample) sharing. In general, this is largely being debated by journal editors, pharmaceutical companies, funding agencies, governmental organization, regulators, clinical trialists… However, only little research has been conducted to unveil research participants' attitudes.

Material and methods: To substantiate the current debate, we interviewed 16 patients with cancer currently participating in a trial and inquired why they would approve/disapprove reuse of samples and data, and how they would like to express this.

Results: This study indicates a general willingness of patients with cancer participating in a trial to reuse their trial data and/or samples by the same research team, and a general open approach to share these with other research teams albeit with the provision of information. Despite divergent opinions about how patients prefer to be engaged, ranging from passive donors up to those explicitly wanting more control, participants expressed positive opinions towards technical solutions that allow to indicate these preferences.

Conclusion: To respect all attitudes, we recommend a stratified approach, for instance by e-consent approaches allowing individualization of data sharing preferences.

PS9B-18: Simulating the Genetics Clinic of the Future – Experiences of apparently healthy individuals undergoing pre-emptive whole-genome sequencing

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Introduction: We performed whole-genome sequencing on 14 apparently healthy individuals, with the aim to simulate a healthcare setting in which

individuals manage their own genetic data and related healthcare decisions. We provided each participant with an external hard drive containing all the necessary sequence data files (.BAM, .gvcf) .

Material and methods: To facilitate their exploration of the data, participants were invited to take part in various exercises that would simultaneously help to evaluate different challenges within the future genetics clinic, for instance, about the consent process and data policy. We performed pre- and post-project interviews with participants.

Results: Interviews revealed that participants were skeptical of the value of discussing results with their own doctor at this stage, and that the perspectives of some participants on access to and use of personal data had changed dramatically over the course of the project. It was envisaged that this first-hand experience of genome sequencing would provide a totally new different perspective on the power and utility of genome data for the experts and professionals involved in the project.

Conclusion: We therefore conclude that personal experience of sequencing provides an interesting alternative perspective for experts involved in planning, implementing and recommending genome sequencing, and that more experts should be encouraged to have their genome sequenced to gain a better understanding of the challenges their patients could face in the future.

PS9B-19: Biobanking and Pathology University Workshops for Children

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Introduction: The number of biobanks is increasing, accompanied by growing awareness among researchers. However, the public knowledge about biobanks, at least in Austria, is very low. Therefore, BBMRI.at partners actively engage in public events, such as the Austria-wide Long Night of Sciences, regional initiatives for students/pupils, open-house-events, and biobank tours.

Material and methods: BBMRI.at partner Medical University of Graz developed a concept for a children's "biobanking-and-pathology workshop" held in collaboration with the Austrian Society of Pathology. Aim is to familiarize children with the terms biobank and pathology and make them tangible in hands-on parts where children "become" biobankers and pathologists.

Results: The concept consists of

• an interactive introduction about: i) the workflow in a hospital (patient anamnesis, surgery, pathology, biobank, drug administration and development of a new drug) and ii) the organs of our body and their function.

• a practical, hands-on, part where children can perform classical work steps of a biobank and pathology laboratory in 3 stations. This includes pipetting blood (raspberry juice), freezing it in a 'biobank', snap-freezing tissue (sausage or pork liver) in liquid nitrogen, embedding tissue in paraffin, staining paraffin (mouse) tissue sections from different organs and viewing them under microscope.

Conclusion: The workshops are an excellent way of introducing biobanking and pathology to children: what they are, how they are embedded in health care and research, and why they are so important. They are easily combined with PR. This concept is suitable for differently aged children and events of different duration.

Topic 9C - Pitch Your Scientific Idea -Innovative Techniques and Methods in Biobanking - (no product pres)

PS9C-2: Collection of mild cognitive impairment samples created to evaluate diagnosis biomarkers by using raman technology.

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Introduction: In recent years, there has been a significant increase in mental diseases occurrence within elderly population, particularly mild cognitive impairment (MCI) . There is a close conceptual and clinical connection between MCI and Alzheimer Disease (AD), being considered sometimes MCI as an initial and prodromal phase of AD.

Material and methods: Currently, PET-FDG image technique is the main reference to MCI diagnosis. Accordingly, Raman spectroscopy provides a different approach, since it generates a "molecular fingerprint" that can be related to several pathologies. Aim: to evaluate the sensitivity and specificity of Raman biomarkers in plasma and serum as MCI degenerative etiology markers.

Results: To this purpose, 85 patients were referred for Neurology Service of Hospital Regional Universitario de Málaga (HRUM) suspected of MCI diagnostic, complying with inclusion criteria (60-85 age range, MMSE >24, episodic memory test, lack of dementia by CDR) . These patients were included in the study after signature of informed consent. Samples were extracted following assistance protocols and aliquoted according to established procedure for this study, preserving the extra fluids to create a Biobank strategic collection. Afterwards, patients were quoted to perform the PET-FDG F18 test as a reference to compare with Raman biomarkers.

Conclusion: In conclusion, results provided by PET-FDG along with collected samples were addressed to their analysis and validation by using Raman spectroscopy. Concurrently, a strategic and remarkable Biobank collection was created for this kind of pathology, with high added value in this biomedical research area.

PS9C-3: Multiplex immunoassay utility for sample pathogen characterization

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Introduction: Within the guidelines of the quality management initiative promoted by BBMRI-ERIC, robust infectious pathogen characterization of biological samples could allow more efficient resource allocation while maintaining safety standards.

Material and methods: Corresponding HIV-Ab and HCV-Ab assays from the PCL Hi3-1 system and the Abbott Architect system were compared at Seoul St. Mary's Hospital, CERBA (France), and Korea University Guro Hospital.

Results: Results indicate that the sol-gel protein microarray based Hi3-1 kit achieves a similar capability of detection for viral Ab compared to commercial Architect assays.

For Hi3-1 the sensitivity of both the HIV-Ab and HCV-Ab assays was 100.00% (n = 853 HIV-positive; n = 831 HCV-positive), and the specificities for the HIV-Ab were 99.98% (n = 12,185 HIV-negative) and HCV-Ab assays was 99.81% (n = 11,856 HCV-negative) . Concordance of the corresponding HIV-Ab and HCV-Ab assays between the Hi3-1 system and the Architect systems for negative specimens was 99.96% (n = 4479 HIV-negative) and 99.76% (n = 4150 HCV-negative) .

Conclusion: PCL's Hi3-1 system has high concordance with Abbott Architect systems and offers an affordable multiplex assay for pathogen detection in blood.

Routine characterization of sample pathogenicity could add significant value when transferring to third parties, enabling biobanks to reach higher levels of efficiency and self-sustainability.

PS9C-4: Achieving long-term sustainability in biobanking by means of introducing innovative tools: case of next-generation Tissue Microarrays

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Introduction: While reliable detection of tissue molecular targets is important for using their expression as biomarkers in medical diagnostics (a.k.a. companion diagnostics), some issues prevail, especially: the inherent biological complexity underlying diseases heterogeneity, inconsistent responses to treatment, and the lack of standardization in the sampling, processing and storage of biospecimen.

Material and methods: Tissue microarray still represents a powerful method for undertaking large-scale tissue-based biomarker studies but required revisions. To address this, Biobank-Wallonia-Brussels network and Auria Biobank join forces to present the next-generation TMA (ngTMA) technology as a powerful tool to improve the robustness and reproducibility of TMA-based studies in biomarker discovery.

Results: The ngTMA platforms combine histopathological skills with (semi) - automated tissue microarraying and cutting-edge digital pathology by using image analysis and high performance computing to acquire histological accuracy, enhance the precision of punching, and speed of construction. Further steps to ngTMA manufacturing and processing, as well as validation steps to assess quality assurance and quality control would be developed to support the TMA excellence. Furthermore, the standardization of specimen handling, the best practice of centralized optimized IHC-staining protocols, the full-automatic advanced IHC apparatus and the digital image analysis would be jointly used to complete the ngTMA technology and to strengthen their quality.

Conclusion: The merge of all these methodologies could constitute a genuine high-throughput analysis platform for TMA biomarker discovery significantly

enhancing the reliability for biomarker research to the benefit of both individuals and the healthcare system as a whole.

PS9C-5: A new procedure for DNA isolation from saliva samples and comparative analysis of quality indicators

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Introduction: Large population-based studies involving thousands of participants are needed for research on genetic diseases and epidemiologic studies. Saliva samples are a non-invasive and efficient DNA source for massive collection. The establishment of new optimized DNA isolation procedures and the determination of effective quality indicator are essential for this purpose.

Material and methods: DNA was extracted from 112 saliva samples with a novel method. Samples were pre-treated with Protease. Reagents from a kit for blood samples were used in the Chemagic MSM-I instrument with a specifically designed saliva protocol. Quality indicators were estimated by spectrophotometry, fluorometry, qPCR, SPUD assay and the 2200 TapeStation.

Results: An average DNA yield of 52,58 ± 33,77 µg was obtained with no significant differences between males and females. A260/A280 and A260/A230 ratios of 1,84 ± 0,123 and 1,56 ± 0,297 were obtained respectively. A DIN value of 6,83 ± 0,90 was observed with a satisfactory functionality resulted by qPCR analysis. Significant differences were observed between spectrophotometry, fluorimetry and qPCR quantification methods in spite of the low amount of contaminants detected.

Conclusion: Biobanks establish DNA cohorts that represent the whole population. The described non-invasive procedure guarantees a high amount of DNA from saliva samples valid for any downstream molecular application, with an important reduction in costs. Additionally, an innovative comparison between the DIN values and conventional DNA quality indicators is shown.

PS9C-6: Primary Care Biobank: A new concept?

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Introduction: Less than 1% of the population is seen in university based hospitals while most of the population seeking medical care are seen in a primary healthcare setting. Primary care (PC) fills a huge gap between the general healthy population and the university teaching hospital in provision of healthcare services.

Material and methods: Patients seeking medical care in a primary setting present with symptoms that do not always render towards diagnosis. However, having a biobank in PC is key in studying trends, susceptibilities to disease and obtaining population data.

Results: A PC biobank can consist of a collection of biological samples and data to investigate disease,symptoms,signs and the relationship between environmental factors and diseases before it leads to pathological changes. It can facilitate earlier diagnosis presented in the general practice as well as elucidate their mechanism of production and their significance for the patient. A population biobank has the power to translate genetic discoveries into clinical practice. However,it is donated by thousands of individuals from the general population who might or not have disease or use a healthcare service. But, the challenges we face in a PC biobank is multifaceted.

Conclusion: These can relate to the nature and organizational aspect such as patient sampling (population), governance and the type of collections (data and biospecimen) in a PC setting. A PC biobank can provide some reliable assessment of lifestyle, environmental and genetic factors as determinants of chronic disease.