ABSTRACT BOOK
POSTER PRESENTATIONS
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TOPIC 2: ENVIRONMENT, BIODIVERSITY AND HUMAN HEALTH

P2_01 - Generation of A Type-2-Diabetes Prediction System Based on Epigenetic Markers from Human Bio Bank Samples

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Introduction

Type-2-diabetes (T2D) is the seventh leading cause of death with increasing global prevalence. Disease manifestation is characterized by persistent hyperglycaemia, hyperinsulinemia and finally the inability of the pancreas to produce sufficient insulin. The underlying molecular mechanism are still incompletely known, hence effective long-term therapies are missing. Since it is known that environmental factors, life style habits and obesity contribute to T2D development, we analysed whether epigenetic changes which influence hepatic expression of IRS2 can be used for disease stratification and subgroup prediction.

Material and Methods

DNA methylation of IRS2 was measured by bisulfite pyrosequencing in liver biopsies of 101 obese human subjects. All subjects were genotyped for a known T2D polymorphism rs4547213 within IRS2. Furthermore, hepatic and serum miRNA hsa-let-7e-5p levels were measured by qPCR. Results were evaluated by linear regression and random decision forest regarding T2D prediction and subgroup stratification.

Results

Non-linear prediction models based on common risk factors age, BMI and gender were able to significantly stratify obese subjects with T2D and non-diabetic subjects. Classification was improved upon addition of hepatic DNA methylation and miRNA expression, which both influences IRS2 expression. Replacement of hepatic markers with serum miRNA concentration and genotype information improved stratification further.

Conclusion

Human liver and serum samples were collected for establishment of a human bio bank for metabolic diseases. Downstream applications including laboratory and computer-based techniques enable the generation of disease models which can be used to prevent T2D manifestation.

P2_02 - Hunt One Health – A Resource to Study the Health Impact of Human-Animal Contact


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Hunt One Health is an expansion of HUNT (the Nord-Trøndelag Health Study), a large Norwegian human population-wide project that commenced in the mid 1980-ies. The objective of HUNT One Health is to facilitate research to understand interaction between and subsequently improve human and animal health. A large-scale population-wide study of human-animal health interactions commenced in Norway in 2017 with sampling completed in 2019. Among 15000 sampled humans included in HUNT4, animal owners have provided dried fecal samples from 3000 animals (63% dogs, 20% cattle, 7% sheep, 6% horse and 4% pigs). Shotgun sequence data and fecal sample materials will conditionally be made available for a global research community along with associated metadata. Additional health data and biological samples are available for the humans enrolled in HUNT4. Further sampling efforts are foreseen in the future stage II of HUNT One Health. Humans and animals affect each other’s health in many ways. The term “One Health” highlights that the health of humans and animals is tightly interwoven, and affected by their shared environments. The ability to link human and animal microorganisms and other health parameters on a large scale makes this project unique.
P2_03 - The Methylarginines In Human Serum: Effects of Age, Gender, Total Cholesterol And C-Reactive Protein

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Introduction
Methylarginines, including asymmetric dimethylarginine (ADMA), are known as markers for endothelial dysfunction and independent risk factors for cardiovascular diseases. Here, we evaluated whether ADMA concentration varies in correlation with gender, age, serum total cholesterol (tChol) and high-sensitivity C-reactive protein (hsCRP) levels in 400 healthy volunteers (200 females, 200 males).

Methods
Blood samples were collected during PORT Biobank study (2015-2018). Levels of tChol and hsCRP were assayed on Cobas Integra® 400plus System (Roche Diagnostics GmBH). All measurement steps were performed according to the manufacturer's protocols. ADMA concentration was evaluated by validated UHPLC-MS/MS method (QTRAP 4500, ABSciex).

Results
We divided the cohort into several subgroups based on the hsCRP (hsCRP<1, hsCRP<2 and hsCRP>2mg/mL) and tChol serum levels (<190 and >190mg/dL). No differences were observed in the serum ADMA concentrations between gender and age in the group <190mg/dL of tChol for hsCRP<1mg/mL (0.65μM) and hsCRP<2mg/mL (0.66μM), but there was significant difference for hsCRP>2mg/mL (0.71μM) group. Cohort with >190mg/dL of tChol resulted in increased ADMA (0.68 μM) level even for hsCRP<1 and has grew up to 0.71 and 0.72μM for hsCRP<2 and hsCRP>2mg/mL respectively.

Conclusion
There was no significant difference in the serum ADMA concentrations between both gender groups, but the slightly elevated serum ADMA concentrations were observed in groups with the serum levels higher than 2mg/mL for hsCRP and 190mg/dL for tChol. Independent testing of ADMA, tChol and hsCRP serum levels can be a promising tool to distinguish between general organism inflammation and early stage of cardiovascular diseases.

TOPIC 3A: PRE-ANALYTIC IMPACT ON SAMPLE QUALITY – MEANS & MEASURES

P3A_01 - Pre-Analytical Quality Assessment in the Biospecimen Collection of the First Portuguese National Health Examination Survey (INSEF 2015)


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Introduction
The First Portuguese National Health Examination Survey (INSEF) was a cross-sectional epidemiological study representative of the Portuguese population aged between 25-74 years old (n=4911). Quality assurance was a major concern during the INSEF fieldwork (in particular regarding the collection of blood samples).

Materials and Methods
Blood samples were collected according to the European Health Examination Survey (EHES) guidelines. Information regarding these procedures was recorded and a pre-analytical audit was performed by trained professionals. Quality control was based on: Number of tubes collected and reason for their absence; Proportion of haemolysed samples; Processing conditions and proportion of samples processed under 24 hours and; Blood sample collection record quality.

Results
Preliminary data suggest that all tubes were collected from 95% of participants. The main reason for the absence of a total or partial blood collection was technical impossibility and less than 3% of the blood
samples were haemolysed. Over 95% of all samples were processed under 24 hours. Record quality and missing information check was performed daily through validation routines, and corrected whenever possible upon contact with the fieldwork team. The pre-analytical audit revealed no nonconformities.

**Discussion and Conclusion**

The overall quality of the blood samples collected is very good. Only a minority of samples are haemolysed or were processed over 24 hours. In addition, information regarding the blood collection is thoroughly documented for nearly 100% of the samples. The EHES procedures were strictly followed by the fieldwork personnel, since no nonconformities were observed during the pre-analytical audit.

**P3A_02 - Evaluation of PBMC Isolation Protocols**

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**Introduction**

The isolation of peripheral blood mononuclear cells (PBMCs) is relatively time-consuming and requires a certain level of skills and expertise. The process is based on the density-gradient-based separation of blood into plasma, PBMCs and polymorphonuclear fractions.

**Material and Methods**

A manual PBMC isolation protocol was compared against protocols using commercially available tubes. The Greiner Bio-One Leucosep tube contains a porous barrier incorporated into the centrifuge tube which prevents the mixture of sample material with the separation medium simplifying the loading process while also preventing recontamination of the enriched cell fraction during the harvesting step. The BD Vacutainer® CPT™ tube contains an anticoagulant, liquid density medium and inert gel barrier, the latter forming a physical barrier retaining the mononuclear cells in plasma. The blood of 15 healthy volunteers was collected, divided in 3 fractions and processed using the various protocols. The protocols were evaluated based on total processing time, cost and ease of use of the procedure and the efficiency in isolating PBMCs as measured using the HoriBA ABX Micros 60 (AxonLab).

**Results**

The average processing time of the manual and CPT protocols was about 2/3 compared to the Leucosep protocol. PBMC counts were significantly higher for the CPT and manual protocols (4.7x10^4 cells/ml) compared to the Leucosep protocol (2.6x10^4 cells/ml).

**Conclusion**

Although the commercial tubes tested simplify the process and increase the robustness of the protocol, experienced lab technicians are capable of isolating equal amounts of PBMCs in the same amount of time and at a significantly lower cost.

**P3A_03 - Protein Biochip Assessment of Pre-Analytical Impact of Storage on Serum Samples**


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**Background**

Pre-analytical conditions like sample storage can impact the serum proteome and therefore influence biomarker discovery. A novel multiplex protein biochip was used to investigate effects of different storage temperatures in relation to the time of storage to ensure marker quality for further multicentre studies.

**Methods**

The used biochip, based on simultaneous chemiluminescent sandwich immunoassay and composed of C3a desArg, CD26, M-CSF and S100A11 was applied to a pool of serum samples collected from healthy donors (n=5). All aliquots were either stored at room temperature, -80°C or liquid nitrogen (LN2).
(gradient freezing and shock freezing). Serum samples were analysed directly and without storage (0h) and after 3 days, 2 weeks, 3 months and 1 year. The biochip was subsequently applied to pancreatic adenocarcinoma samples, stored at -80°C (n=296) and in the gas-phase of LN2 (n=135).

Results
C3a desArg showed a trend for decreased expression levels after storage at all the temperatures analysed (P<0.05), CD26 and S100A11 resulted in stable concentrations at -80° and LN2 storing conditions over the complete analysis period, and M-CSF showed altered levels only when stored at -80°C for 1 year. When comparing the marker serum levels between -80°C and LN2 for pancreatic adenocarcinoma samples, M-CSF and S100A11 showed statistical significant differences (P<0.05).

Discussion
Pre-analytical factors like temperature of storage could affect the biomarker analyses. This highlights the importance of preserving the quality of the samples, since it will also influence the quality of the data obtained.

P3A_04 - Analysis of Hypoxia Markers in Colorectal Cancer and Uninvolved Margin Using Targeted High-Throughput Parallel Sequencing
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Recently, transcriptomics has experienced a strong growth and its importance has increased significantly. The wide variety of molecular studies on biological material demands proper procedures for sample collection and storage and is especially challenging for clinical samples acquired during surgery treatment. The aim of our study was the analysis of cold ischemia time on RNA quality and transcriptomic profile. The colorectal cancer tissue and uninvolved margin from adjacent areas were sampled using six time points (0, 10, 20, 30, 45 and 60 minutes) from the resection and snap-frozen in liquid nitrogen. After measurement of RNA concentration and integrity a transcriptomic profile targeted high-throughput parallel sequencing (RNA-Seq) was assessed. STAR was used for alignment (with hg19 as reference genome), and Cufflinks package for transcript assembly, abundance and differential expression analyses. Targeting RNA-Seq showed the directional tendency for 11 genes. Three types of expressional patterns were observed. First one, in which both cancer and healthy margin showed upregulation in all ischemia time points was found for ANGPTL4 and VEGFC genes. Second one was characterized by downregulation of ADORA2B, CTSA, F10, HNF4A genes in both tissue types and all time points. Third type of expression changes showed an upregulation in cancer and a downregulation in healthy tissue for EGLN2, FOS, PFKFB3, PFKFB4, SL2A3 genes. The changes in genes expression suggest that cancer tissue displays higher adaptation to hypoxia and lack of nutrient compound comparing to healthy tissue. Those observations are of clue importance for biobanking of clinical material.

P3A_05 - Innovation in Biobanking: Reducing Errors in Sample-Kit Manufacturing and Sample Aliquoting through Automation
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Despite advances in sample processing automation, generating sample-kits for multi-centric studies is still done manually, as no system so far could select, label, scan, pack, and seal primary sample tubes as well as pre-barcoded cryotubes into separated sealed bags. Although aliquoting robots exist, they require manual selection of protocols. Manual steps are not only time-consuming but also represent a considerable source of error, reducing significantly the quality of biospecimen collections. Regarding the reproducibility of research results, a high level of accuracy during these first steps of biobanking is key. Here, we present two robotic systems improving those limitations for the healthcare-integrated biobanking process of the Liquid Biobank Bern, Switzerland. For sample-kit manufacturing, a newly designed SampliKit robot - designed in collaboration with Samplision – automatically prints barcoded labels, labels primary tubes, scans and picks cryotubes, prints labels on bags, packs labware into bags, and finally seals sampling bags. By replacing monotonous error-prone manual packing, errors in kit
manufacufuring are avoided and hands-on-time is limited to reloading of labware. The data of the kits can be exported and transferred to any LIMS or trial database. For optimization of aliquoting, the processing of a Hamilton Star system was redesigned to enable a sample-by-sample processing, requesting for each loaded sample its own specific profile from central LIMS. Thus, we can process an infinite number of protocols on the same aliquoting system without a user having to select a protocol. Aliquoting errors– as they occur with manual selection - are avoided with this system.

P3A_04 - Analysis of Hypoxia Markers in Colorectal Cancer and Uninvolved Margin Using Targeted High-Throughput Parallel Sequencing

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Recently, transcriptomics has experienced a strong growth and its importance has increased significantly. The wide variety of molecular studies on biological material demands proper procedures for sample collection and storage and is especially challenging for clinical samples acquired during surgery treatment. The aim of our study was the analysis of cold ischemia time on RNA quality and transcriptomic profile. The colorectal cancer tissue and uninvolved margin from adjacent areas were sampled using six time points (0, 10, 20, 30, 45 and 60 minutes) from the resection and snap-frozen in liquid nitrogen. After measurement of RNA concentration and integrity a transcriptomic profile targeted high-throughput parallel sequencing (RNA-Seq) was assessed. STAR was used for alignment (with hg19 as reference genome), and Cufflinks package for transcript assembly, abundance and differential expression analyses. Targeting RNA-Seq showed the directional tendency for 11 genes. Three types of expressional patterns were observed. First one, in which both cancer and healthy margin showed upregulation in all ischemia time points was found for ANGPTL4 and VEGFC genes. Second one was characterized by downregulation of ADORA2B, CTSA, F10, HNF4A genes in both tissue types and all time points. Third type of expression changes showed an upregulation in cancer and a downregulation in healthy tissue for EGLN2, FOS, PFKFB3, PFKFB4, SL2A3 genes. The changes in genes expression suggest that cancer tissue displays higher adaptation to hypoxia and lack of nutrient compound comparing to healthy tissue. Those observations are of clue importance for biobanking of clinical material.

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Froehlich, T.K., Fiedler, M.G., Largiadèr, C.R.

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P3A_06 - AMH Preanalytical Conditions - Stability Tests According to the ISBER Protocol

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Background
Pre-analytical conditions for blood collection are critically important. Based on the protocol of the International Society for Biological and Environmental Repositories (ISBER), various pre-analytical conditions were tested to identify the optimal one.

Materials and Methods
Serum and plasma from 5 volunteers, AMH levels 3.92-6.39 ng/ml, were used. Peripheral blood was collected, aliquots were prepared in the same volume and stored under different conditions. We created four groups of samples: serum, plasma, serum separated after whole blood freezing in gel collection tubes, and serum separated after centrifugation from gel tubes using a second collection set. The first 6 aliquots from each group were exposed to 1-5 cycles of re-freezing at -80°C. Additional 6 aliquots from each group were stored at room temperature (RT), next 6 aliquots in the fridge at 4°C, for 1, 2, 4, 24, 72 and 168 hours. The last aliquot was placed at -20°C for 30 day Results The effect of re-freezing cycles was not significant (NS). The coefficient of variation (CV) was in serum: 2.55%, in plasma: 2.65%, in the gel tube after freezing: 3.73%, in the serum separated by the second collection set: 3.01%. Changes in AMH at different temperatures were also NS with CV in serum: 4.86%, in plasma: 2.22%, in a gel tube after freezing: 5.50%, in serum separated by a second collection set: 2.80%.

Conclusion
Changes in AMH concentrations at different conditions were non-significant and AMH levels remain stable. The worst CV% was observed in group of freeze-thaw whole blood gel tubes.

P3A_07 - Impact of Long-Term Storage and Freeze-Thawing on Circulating Micrornas in the KORA Study


Sample collection, processing, storage and isolation methods constitute pre-analytic factors that can influence the quality of biosamples used in research and clinical practice. Regarding good biobanking practices, a critical point in biospecimen’s life chain is the long-term storage. Since most studies examine the influence of different temperatures (4°C, RT) and a delay in sample processing on sample quality, there is only little information on the effects of long-term storage at low (-80°C) and ultra-low temperatures on biomarker levels. Circulating miRNAs have been reported as biomarkers for diagnosis or prognosis for a variety of diseases, and are thus of high interest in several scientific questions. We therefore investigated the influence of long-term storage on circulating miRNA levels from 10 participants from the population-based cohort study KORA. Samples were collected during the baseline survey S4 and the follow-up surveys F4 and FF4, from 1999 to 2014. The influence of freeze-thaw (f/t) cycles on miRNA stability was investigated using samples from voluntaries (n=6). All plasma samples were profiled using Exiqon’s miRCURY real time PCR profiling system. ANOVA was used to check for storage or f/t effects. Our results show that the studied nine miRNAs, showed no changes in detection levels when stored at ultra-low temperatures for up to 17 years. Freeze-thawing of one to four cycles showed only an effect in one miRNA, indicating a high stability and robustness even under stress conditions. The stability of circulating miRNAs even after decades of storage and several f/t cycles is higher than assu

P3A_08 - Why Biomarker Validation Can Help Researchers and Industry?

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After a huge hype with some innovative and clinically useful biomarkers, after considerable amounts of investments in H2020 “omics” calls or IMI consortia such as “safety” biomarkers, it is time for disappointment on both sides of academic research and health industry. Every year, thousands of biomarkers are published through an abundant literature, but less than 5% of those are used clinically mainly because they are not properly validated. This issue has led -particularly in Europe- to a delay in using new biomarkers e.g. in translational
Cryopreservation is a useful process in medicine. However, it is complicated and if not done correctly, it could lead to many problems including cryo-injury. This paper discusses some of the methods of preventing these problems, which could result from the freezing or thawing process. Since most of the injuries occur during freezing and thawing, controlling these processes could help protect the tissue. The methods of preventing these injuries include altering the cooling process to prevent rapid freezing of the tissue and water in it. Secondly, addition of preservatives could reduce the chances of injury to the tissue during the two risky phases. Failure to adding these agents could cause the tissues to break during the anomalous expansion of water during cooling. In the cryopreservation of semen, it is important to preempt the injury of some of the cells, and therefore, to act in advance. Appropriate actions include selecting the best cells for preservation to reduce the chances of death. Moreover, that increase motility could be added to the cells to ensure that they do not die during the processes. Another factor that increases the injuries to the cells during this preservation process is the presence of cytoplasmic lipids. Therefore, this paper states that removing them could help prevent them from injury, which would be advantageous to the process. Finally, this paper highlights the advantage of using dimethyl sulfoxide and Ficoll 70, which makes the cells to have good life after a long preservation period of over one year. The use of these methods could increase the success of the cryopreservation leading to healthier cells after preservation.

P3A_10 - Quality Control Methods in Biobanking: Pre-Analytic Impact on Sample Quality in the Context of Gene Expression Studies

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Background
Gene expression profiling of blood cells is a widely used tool in clinical diagnostics and health research. Pre-analytic phase represents a crucial step of the process: the identification of factors influencing RNA stability is mandatory in the context of biobanking, to ensure the accuracy and reproducibility of results.

Methods
Blood specimens collected in EDTA tubes (n=10) were processed for PBMCs isolation either immediately after blood drawn (T0) or following 2, 4, 6 hours and overnight (ON) incubation (at RT and at 4°C). Blood samples collected in Tempus Tubes (n=5) were processed at T0 and following 5 days incubation, either at RT or at 4°C. RNA yield and quality were determined in all experimental conditions. RNA expression levels of 8 candidate genes (CD14, IL10, TNF, TNFAIP3, NR4A2, CD20, CD19, MxA) and 4 housekeeping (HK) genes (GAPDH, HPRT1, B2M, CASC3) were evaluated by Real Time PCR. Results: 1) RNA from Tempus Tubes was stable across all the experimental conditions; RNA yield and purity from EDTA tubes were marginally reduced after ON incubation. 2) In EDTA samples RNA expression was affected by pre-analytic conditions in a target- and housekeeping gene related manner. 3) Inter-individual variation in EDTA tubes was observed throughout the study.
Discussion

RNA expression levels of analysed genes were affected by pre-analytic factors. Biobanking of blood samples for gene expression studies should be performed using RNA-specific tubes. When generic blood collection device are used, time-course studies are mandatory to evaluate the impact of pre-analytic factors on analyzed genes.

P3A_11 - Probe Electrospray Ionization (PESI) Allows Fast Detection of Compromised Blood Quality from Minimal Sample Amounts

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Placenta biological samples may be used in biomedical research, to investigate normal development and pathologies, and in pharmacy, as a source of stem cells and bioactive substances. In this context, placenta-oriented biobanks play a decisive role but do lack agreed storage standards. Herewith, the below-zero temperatures do not always insure the transition of all liquid phase in tissue into solid state, leading to sample quality lowering, mainly due to oxidation processes and salt hyperconcentration during prolong storage. Human placentas collected after normal pregnancies were divided into equal parts and stored at -20°C, -80°C, -170°C. Tissues were analyzed: without treatment (control), after freeze-thawing, after storage for six months. Placenta antioxidant status was evaluated using ABTS+ radical decolorization assay. The liquid phase in tissues at certain temperature was detected using low temperature differential scanning calorimetry (DSC). Storage at -20°C for 6 months leads to placenta antioxidant status lowering down to 50± 6% compared to the control. Interestingly, placenta antioxidant status increases up to 35±8% compared to the control after 6 months' storage at -80°C. No significant changes were detected after placenta storage at -196°C. The data were confirmed with the DSC method. DSC revealed that the main part of water in placenta crystallizes before reaching -29°C. The remaining unfrozen water is transferred into the solid state in between -81.5°C and -77°C, and a small part of the bound water between -108°C and -97°C. The results shows the necessity of strict SOPs for placenta quality preservation while biobanking.
Comparing Data from Different Surveys in a Large Cohort Study

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Introduction
In general, biomarkers are considered objectively measurable indicators for biological and pathological processes. However, analytical results may be affected by preanalytical conditions and analytical variability. The present study will address the inter- and intra-assay variability of blood marker analysis found between different surveys in a large cohort study in children.

Material and Methods
Biomarkers, including adiponectin (n=478), leptin (n=509), c-reactive protein (crp) (n=4131), and insulin (n=3871) were measured for each individual with two different methods and inter-assay variability was analysed. In addition, levels of adiponectin, leptin, crp, insulin were established in different surveys with the same method and will be compared on an age-specific non-individual level, to determine intra-assay variability (n>5000).

Results
In general MSD assays revealed higher concentrations for adip and crp and lower ones for insulin compared with other laboratory methods. A high correlation was found for leptin measurements only. During the first survey age-specific crp and adiponectin concentrations were higher and insulin and leptin levels lower than in a second follow-up of the study when measured with MSD assays, while the crp concentrations were lower and insulin values higher than in the first follow up when measured with the other methods.

Discussion and Conclusion
We discuss how to handle laboratory data from different surveys of population based cohort studies and address possible factors, affecting laboratory values. Still, even with a highly standardized implementation of biosample collection and processing in epidemiological studies we face a great variability of laboratory outcomes, that have to be reviewed carefully.
P3A_15 - Assessment of Sample Quality after Freezer Breakdown

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Freezer breakdowns are critical emergencies for biobanks as the quality of precious samples is endangered by an interruption of the cooling chain. One option in such an emergency case is often to cool the samples with liquid nitrogen while waiting for freezer replacement or repair. Filling of the defective freezer with liquid nitrogen until the bottom is covered completely results in a temperature gradient where parts of the samples are located in the liquid phase and others in the gas phase. The emergency case was simulated in a controlled setting to assess the effect of this procedure on the sample quality. Equally-sized pieces of pig liver were fresh frozen and stored in a defective freezer filled with liquid nitrogen. Reference samples were stored in a functional -80°C freezer. After 24 hours, all samples were transferred to -80°C until further processing. Tissue quality was assessed by histological examination using HE-stained sections as well as qualitative and quantitative RNA analysis. Finally, usability for downstream analyses of the RNA was analyzed by qPCR. The results are expected to provide information on how temperature perturbation during an emergency case might influence the quality of cryo-conserved tissue samples. This may give rise to the development of standardized emergency protocols and procedures.

Methods

Postoperative tumor tissues (T) and adjacent normal tissues (AN) from 50 HCC patients were randomly selected from May 5, 2017, to June 15, 2017. Postoperative tissue specimens from each HCC patient were stratified by tissue type (T or AN), ischemia time (min), and ischemia temperature (°C) into 16 groups. RNA integrity was detected by RNA integrity number (RIN) and 1% agarose gel electrophoresis. Results: At an ischemia temperature of 4°C and ischemia time of >30 min, the RIN of T began to decrease. RIN also gradually decreased in T at an ischemia temperature of 4°C and in both T and AN at an ischemia temperature of 24°C for ischemia times 15 min, 30 min, 60 min and 120 min. For ischemia time ≤ 15 min and ischemia temperature 4°C or 24°C, the RINs of T and AN were significantly different. Furthermore, at ischemia temperature 4°C and ischemia time 30 and 60 min or ischemia temperature 24°C and ischemia time 30 min, the RIN of T was higher than that of AN. However, there was no significant difference in RIN between T and AN under other treatment conditions.

Conclusion

Tissue quality is adversely affected by ischemia time and ischemia temperature. Therefore, temporary ischemia time (≤15 min) before snap freezing is key for maintaining high-integrity RNA in HCC tissues.

TOPIC 3B: ACADEMIC-INDUSTRIAL PARTNERSHIPS FOR A HEALTHIER WORLD

P3B_01 - Transbioline - Biobanking at the International Level

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Introduction

Harmonized and overarching biobanking in heterogeneous research consortia is a challenge. Diverse data structures, different local conditions and procedures need to be brought to a comparable level. In addition, agreed legal, ethical and formal frames are required.
Material and Methods
The Innovative Medicines Initiative supports a Translational Safety Biomarker Pipeline (TransBioLine) project, a five-year program to generate exploratory and confirmatory data supporting regulatory qualification and acceptance of novel safety biomarkers for five target organ systems (kidney, liver, pancreas, vascular, central nervous system) for application in drug development. To guarantee this quality across different locations a harmonization of standard operating procedures and the correct implementation of processes should be highest priority.

Results
For the Transbioline project, the Central Biomaterial Bank Charité (ZeBanC) is coordinating the sample-related processes, the provision of sample kits, storage and distribution of samples to the analysis laboratories. By means of this project, we demonstrate the important role of a biobank as a central instance for harmonization among the various partners and the different work packages. We show how to deal with the many challenges, the tasks to coordinate the sample management in a large European project, and the requirements to ensure that process and sample quality are executed under optimal conditions.

Conclusion
Harmonized central biobanking is key for the successful scientific work of research consortia. These efforts are time consuming, require broad expertise and should not be underestimated. Establishment of a concise sample and data management also ease the cooperation amongst the partners.

P3B_02 - Biobank’s Inferno, the Nine Levels of Autofreezers
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The parallels between Dante’s nine concentric circles of torment and getting an operational autofreezer are quite striking. With genuine respect to suppliers and indeed Dante, we take the liberty of reinterpreting the classic text to reflect modern times in the hard-pressed lives of biobankers. Vestibule of Hell – tendering process begins “Abandon all hope ye who enter”. Tender is awarded, move to hell proper. First circle (Limbo) – installation and SAT. Although not dysfunctional enough to warrant damnation, not functional enough to pass SAT. Second circle (Lust) – the desire for your autofreezer to work better than anyone else’s, allows your appetite for success to sway your normally sound reasoning. Third and fourth circle (Gluttony and Greed) – testing the system excessively – mutual indulgence slowly declines into mutual antagonism as you become increasingly aware of the inability of the instrument to do what it should. Fifth circle (Wrath) – anger at the system as the fixes being implemented are causing more problems. Sixth circle (Heresy) – you stand against the dogma all your colleagues hold dear to their hearts that “the system will never work”. Seventh circle (Violence) - autofreezer robotics still crashing and destroying samples. You and your colleagues hear the anguished but plausible explanations. Eighth circle (Fraud) – renegotiation of contract and the promise of a working instrument from the now Uncommitted. Ninth circle (Treachery) - eyes frozen open for eternity staring at your ramshackle autofreezer, wondering how you are going to pay the service contract that you cannot afford…

P3B_03 - Shared Value and Sustainability Gained through Data Partner Collaborations in a Secure Platform BCRQUEST.Com

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Rapidly developing technology and the explosion of big data hold untapped potential for drug discovery and personalized healthcare studies. However, the full power of this data is yet to be unlocked, due to both industry and academia grappling with challenges in managing, harmonizing, and integrating data and resources. This opens the door for a global network that can guarantee a confidential environment for data reservoirs to share their data with pharmaceutical researchers who seek diverse patient cohorts for clinical research and drug development projects. BC Platforms has established a global network of Data Partners (biobanks, hospitals, cohorts) to collaborate with industry and provide data for research and development. The network operates through the BCRQUEST.com platform, providing secure federated access to anonymized data sources and scalable technology for analytics. Currently, over 300,000 patients with clinical and genomic data are represented through the network, estimated to grow to over 5 million by 2020. BCRQUEST.com features
availability and feasibility queries and meta-analytics capabilities, secured and processed so that access to the data is compliant with local policies and user rights. The network creates shared value for its Data Partners by supporting data generation and discoveries in biomedicine. Additionally, use of the platform by drug developers creates revenue streams that are directly allocated to the partners whose data is used for research purposes through the platform. Ultimately, the goal of having such a system is to accelerate informed, personalized treatment development and health innovations.

P3B_04 - Fishing in a Data Lake. Are We There Yet?

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Problem

Biobanks operate where academia, healthcare and industry meet. They have the opportunity and responsibility to ethically collect information about patients or respondents whose biomaterials have been biobanked, for example, socioeconomic factors, lifestyle and nutritional habits, medical history and various phenotypic traits and metrics. The recent digital revolution in biobanking has created the need for an environment which would allow to concentrate, harmonize and correlate the heterogeneous data obtained from various sources. A data lake of a national scale is of vital importance for future biomedical research and precision medicine.

Solution

All of the parties have been involved in discussions to identify the requirements and applications for a data lake of national scale. Safety measures are addressed, data handling tools are being prototyped, such as automatic and semi-automatic collection, anonymization, normalization, transformation and retrieval.

Discussion

We have observed a growing interest among involved patients and respondents in research project results. The infrastructure, which will be either updated or developed in order to take advantage of the possibilities offered by a data lake, will create opportunities for better patient education and more streamlined and transparent involvement in studies via the biobank network. Extensive involvement from industry was observed which coupled with universities and state hospitals has succeeded in jumpstarting the development of a data lake at a national level. This sort of collaboration has started discussions which identify various issues in current system such as, data safety and effective anonymization and medical data storage in machine learning friendly formats.

P3B_05 - Cooperation between Academic Biobanks and Industry: Position of the German Biobank Node/Alliance


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Background

Cooperation between academic biobanks and industrial partners represents a very important component in the advancement of precision medicine. However, the conditions under which such cooperations should take place are only vaguely defined. Therefore, the German Biobank Node (GBN) and representatives of the German Biobank Alliance (GBA) developed recommendations for academic biobanks.

Methods

Informal discussions with GBA biobank directors and industry representatives at the beginning of 2018 informed a GBN Workshop in June 2018. The workshop combined expert-talks and open discussions. 17 participants discussed possible forms of such cooperations, as well as financial, ethical and legal aspects, and challenges.

Results

As an outcome of the workshop, a position paper summarising the key points was written. It considers general framework conditions and procedures in the German biobanking environment and raises ethical, legal and procedural questions that need to be taken into account when establishing cooperations with industry partners. This position paper intends to create a basis for
further activities to foster cooperation with the industry and to promote an orchestrated national process.

Discussion
Based on the position paper, GBN/GBA have formulated specific recommendations for cooperations between academic biobanks and industrial partners. These recommendations offer a framework for German academic biobanks and the foundation for further discussions with industrial partners.

P3B_06 - Cooperation between Academic Biobanks and Industry: The Industry’s Point of View

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Background
The cooperation between academic biobanks and industrial partners represents a very important component in the development of precision medicine. The German Biobank Node is conducting an interview study, addressing representatives of the pharmaceutical and diagnostic industry to better understand their views, needs and experiences.

Methods
A qualitative study with twelve semi-structured telephone interviews is scheduled for June 2019. We ensured that different companies and branches are represented (maximum variation sampling). The participants were recruited with the help of a gatekeeper, the association of research-based pharmaceutical companies (VfA), and via our personal network. Interviews will be recorded, transcribed in anonymous form and analysed using qualitative content analysis.

Results
The questions address the use and acquisition of biosamples and data as well as current experience by the industry in cooperations with academic biobanks. The results of this survey will provide relevant information about the perceptions and needs of the pharmaceutical and diagnostic industry. The collected data should serve as background information for further joint workshops with academic biobanks and industry.

Discussion
Supporting industry with biosamples and related data is important for developments in diagnostics and therapy and deserves encouragement. A better understanding of actual needs of users from the industry will bring valuable input for further communication and will help to foster the process of harmonisation within the German biobanking community.

TOPIC 3C: RARE DISEASES: THE NEXT BIG STEP

P3C_01 - Promotion of Rare Disease Biobank Services, Sample Findability and Accessibility through Dedicated Training Workshops

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Introduction
Access to rare disease (RD) biological samples is a challenge due to the intrinsic rarity and sparsity of patients. Recent developments in the RD-Connect Sample Catalogue*, a flagship platform listing over 66.500 RD samples and metadata, allow users worldwide to find specific specimens for research. Its subsequent link with BBMRI-ERIC Negotiator opens the way to initiate sample requests. However, despite significant tool developments to improve RD sample access, biobanks did not have sufficient training opportunities to be able to exploit these technological advances. Similarly, researchers remain unfamiliar with biobank services and its potentials.

Methods
The recently launched European Joint Programme on Rare Diseases (EJPRD) encompasses a comprehensive program addressing training needs of RD community. It includes a dedicated biobank stream offering capacity
building in 1) RD sample data management for biobanks and 2) sample management via biobanks for researchers. The program will see the organisation of 10 training workshops in 8 European countries between 2019 – 2023.

Results
The first workshop targeting biobanks took place in Milan 1-2 April 2019. The workshop consisted of interactive sessions using the Problem-Based-Learning approach to stimulate awareness in biobank and sample findability/accessibility, practical sessions on data harmonisation and tool demos. Participants were biobank staff and patient representatives. Feedbacks were positive, where 88% would strongly recommend it to their colleagues and 93% rated it as excellent or very good.

Conclusion
A rich, dedicated training program to promote biobank accessibility can moreover stimulate interactions between biobanks and its stakeholders. * https://samples.rd-connect.eu/

P3C_02 - Biobanking, a Tool for Rare Disease Research: Mitochondrial Disorders

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Blood samples from Maltese patients suspected of having a mitochondrial disorder were banked at the University of Malta’s biobank.

The analysis was part of a collaborative BBMRI-Large Prospective Cohort (BBMRI-LPC) project focused on mitochondrial disorders. The full mitochondrial genome sequencing, whole exome sequencing (WES) and data processing were carried out at Centro Nacional de Análisis Genómico (CNAG-CRG). Phenotypic data was recorded in the RD-Connect PhenoTips instance, and variant filtration and prioritization was undertaken using the RD-Connect Genome-Phenome Analysis Platform.

In one patient, a rare nuclear homozygous mis-sense variant c.308C>T (rs749249430) in NDUFAF3 on chromosome 3, three INDELs in NDUFS1, intronic variants in NDUFA10 on chromosome 2 and a heterozygous intronic variant c.408+6468C>T (rs752756523) in NDUFB9 on chromosome 8 were identified. In another patient, a mitochondrial DNA (mtDNA) mis-sense mutation in MT-ATP6 c.163A>G at m.8689 and a splice donor variant c.207+2T>G (rs782792601) and two mis-sense splice region variants: c.206A>G (rs781909386) and c.205A>G (rs782503581) in NDUFB11 were identified on the X chromosome. NDUFAF3 is a complex I (C1) assembly factor. mtDNA m.8689 is associated with mitochondrial ATPase deficiency and Leigh syndrome while NDUFB11 is associated with mitochondrial C1 deficiency. Functional validation of disease alleles could identify disease-causative variants in mitochondrial respiratory chain complexes. The RD-Connect platform is a resource for biobank-led research.

This initiative was supported by EuroBioBank and the National Alliance for Rare Diseases Support – Malta.

TOPIC 4A: HARMONISATION AND STANDARDISATION: WHAT IS NEEDED, WHAT IS POSSIBLE?

P4A_01 - How Good is Your Chosen Biobank? - Second Party Evaluation of Human Research Biobanking Organisations

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Introduction
Research using human biosamples (HBS) requires legitimacy, compliance and quality for reproducibility of results. Prior to ISO 20387:2018, no international standard for governance and quality of biobanks (“suppliers”) existed, therefore, Novo Nordisk implemented evaluations of its suppliers of HBS.
Methods
Evaluations include 64 mandatory requirements, derived from existing laws and regulations, declarations, best practices, guidelines, conventions and quality standards. Requirements relate to: legal and ethical, quality and HBS integrity, donor recruitment, consent, confidentiality, contracting, document control, infrastructure and outsourcing.

Results
Sixty-two suppliers from 12 countries were invited. Invited suppliers were from both public and private sectors including biobanks, contract research organisations and research collaborators. Fifty-one agreed to be evaluated. There were no significant differences in the types of suppliers that agreed to participate, or their location, except for UK where participation was significantly lower. Twenty suppliers were in full conformity on initial evaluation. Thirty-one suppliers were initially non-compliant, with an average number of non-conformities (N/Cs) of 4.3. Twenty-eight of these suppliers became compliant after correcting N/Cs. The rate of N/Cs did not vary by the types of supplier or the ownership type. Suppliers in USA had a higher N/C rate compared to suppliers in other countries. Most N/Cs related to safety, packaging and transportation, absence of SOPs, payments to donors and inadequate consent documents.

Discussion and Conclusion
Novo Nordisk’s use of “second party” evaluations fosters high international standards. This helps Novo Nordisk select suppliers responsibly. These results suggest that ISO 20387:2018 will benefit biobanks and stakeholders, particularly researchers.

P4A_02 - Implementation of the New ISO Norm in a Regional Biobank and Resulting Impact
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Background
The implementation of the new ISO norm is an important and inevitable process for making biobanking valid and reliable. The Central Biobank Regensburg met this challenge and begun to integrate the new requirements into the workflow.

P4A_03 - Interdisciplinary Biobank and Database Frankfurt IbdF: A Network of Hospital-Based Biobanks at the University Hospital Frankfurt
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At university hospitals a vast number of decentralized sample collections with different approaches on governance, IT-infrastructure and sample allocation were established over time. For scientists seeking biomaterial and clinical data for research purposes this causes problems - especially when material or data is needed that encompasses more than one specific entity. Then a multitude of requests forms might have to be
submitted to several sample collections with different time frames and approaches to sample and data allocation. One possible solution is the centralization of all sample collections and the establishment of a biobanking core unit. At the university hospital Frankfurt a different approach was taken and the interdisciplinary Biobank and Database Frankfurt (iBDF) founded. The iBDF is a network of currently ten biomaterial and data collections that has set itself the task of harmonizing the diverse entity specific collections at the site and facilitating coordinated access to biomaterials and clinical data for scientific purposes. The independent collections are linked by an overarching governance structure, where every collection is represented and general requirements such as IT, quality or project management are discussed and decided. The legal basis for the use of biomaterial and clinical data is the recently established “broad consent” comprising all clinical entities. The network uses shared IT infrastructure (CentraXX) and has a generalized request-management with decisions in currently four entity specific scientific boards. Every collection that is part of the iBDF and every clinic that is involved in biomaterial assurance is represented in at least one scientific board.

P4A_04 - Polish Biobanking Network – Characteristics and Collections Specification

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Poland’s access to BBMRI-ERIC was the beginning of nationwide project which main goal is to create a Polish Biobanking Network (PBN) bringing together entities interested in professional, harmonious and standardized biobanking of biological material. The first task was to identify biobanks that already exist in Poland. To achieve this goal, many promotional and informational activities were carried out. We contacted many biobanks and researchers and we invited them to participate in the survey, developed specifically to obtain basic information about Polish biobanks. We collected data from 62 centers, of which 42 are banking mainly human biological material and decided to join the PBN. Polish biobanks collect variety of material types - most of which are medical and research data, blood, DNA/RNA and cells. Majority of Polish biobanks have implemented or are currently in the process of implementation of QMS for collected samples (30 units), they also take care of obtaining consents from donors (34 units) and bioethical commissions (31 units) for the use of biological material. 69% of PBN members declare their willingness to share their collections. Most Polish biobanks are localized at universities (43%) but there are also 5 units (12%) located in private companies. Dynamically conducted project resulted in detailed the characteristics of Polish biobanks/biorepositories. Members of PBN are interested in cooperation and compliance with the highest principles related to biobanking, also with new ISO standards on biobanks. We are continuously striving to encourage remaining biobanks to join the Network. This work was supported by MNSW, grant DIR/WK/2017/2018/01-1.

P4A_05 - Harmonization of Biobanks of the Italian IRCCS Cardiology Network

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Problem
Cardiovascular disease is the main chronic “killer” worldwide, accounting for 45% of all deaths in Europe in 2017. Risk factors, incidence and gene–environment interactions vary considerably among populations, therefore, to reach a critical mass of data, institutions should collaborate for an integrated and interdisciplinary research infrastructure.

Solution
The Italian IRCCS Cardiology Network is the largest Italian organization for cardiovascular research, established by the Italian Ministry of Health, consisting of 19 high standard institutes for comprehensive patient care and research (IRCCS). The Cardiology network promotes research in three main areas:

1) molecular and cellular mechanisms;
2) diagnosis and therapy of cardiac and vascular disorders;
3) cardiovascular prevention.
To achieve these aims, collaborative work among specialized institutions is instrumental for an optimal exploitation of resources. Biobanking represents a critical cornerstone for biomarker discovery/validation, a fundamental aid for personalized medicine and the necessary tool for the follow up of clinical trials, thus to establish a network of biobanks within Cardiology institutes appears mandatory. A project was designed for harmonization of the repositories already available or in progress at the participating institutions to share the principles of governance, regulations, technical standardization, ethical and legal issues.

Discussion
The first step of this project has been a survey among biobank representatives of all the institutions, through a detailed questionnaire released by BBMRI.it. These efforts are useful to implement hospital-based biobanks into clinical routine; their interconnection will yield huge amounts of data (analyzed by conventional and AI approaches) with remarkable saving of healthcare costs.

P4A_06 - QMS Standards in Polish Biobanking Network
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Introduction
The Wrocław Medical University (WMU), as a BBMRI.pl consortium member, is responsible in project for the task: “Verification of SOPs that exist in Polish biobanking institutions, implementation of common solutions”. Extremely important goal for BBMRI.pl was to create, implement and maintaining a uniform and harmonized Standards in the QAMS based on TQM, which must be consistent for all biobanks in Poland and compatible with international requirements, guidelines and recommendations.

Materials and Methods

Results
QSPB consist 15 chapters divided into thematic areas. The originality of QSPB lies in the fact that the guidelines give examples that explain all requirements, so-called “good practices”, contain the most frequently asked questions, together with given answers. Thus, it is not only the presentation of the requirements which must attend to operate correctly within the research and development processes, but it’s also precise explanation and suggestions how each part of standards can be implemented.

Discussion
QSPB will have a positive impact on biobanks, e.g. by implementing TQM in practice. More efficient work will reduce errors, operating costs and improve quality of biological material and data storage. Presented advantages directly improve biobanks activity in the scientific and research area. Acknowledgements: This work is supported by Grant from the Polish Ministry of Science and Higher Education (DIR/WK/2017/01 and DIR/WK/2017/2018-01).

P4A_07 - Improvement of QMS through the Process of Audits in the Polish Biobanking Network
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Background
The role of the audit is an extremely important aspect for improving the Quality Management System in Biobanks, and improving the quality of samples and data.

Materials and Methods
The input data for the audit process in the Polish Biobanking Network are the Quality Standards for Polish Biobanks and Auditor Manual Handbook, which have been prepared as a part of work packages of QM Task in BBMRI.pl project.

Results
Until the end of 1Q 2019, the team conducted 35 audits. The audit results showed that the biobanking units present different level of QMS implementation. After the
QMS audit no 1, each biobank received an audit report with recommendations for implementation or improvement of the QMS. BBMRI.pl QM team supports Polish biobanks by trainings and workshops as well as individual consultations in addition to improving the audit process. Audit no 2 confirms compliance with the QSPB which confirm high quality of technical process in Biobank. This is the first, most important step to unify biobank repository in an organization such as the Universities as exemplified by the Wroclaw Medical University Biobank, belonging to the Polish Biobanking Network.

Discussion
The audit process is an effective tool to verify the adequacy and effectiveness of the quality management system / integrated quality management system and contributes to the improvement of these systems in Biobanks. Acknowledgments The project is supported by the Polish Ministry of Science and Higher Education (DIR/WK/2017/01 and DIR/WK/2017/2018-01).

P4A_08 - ISBER Tools to Facilitate Quality Biobanking


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Problem
Biobanking has expanded in the last twenty years and has become a key underpinning of molecular and clinical. Developments in medical, environmental, microbial and veterinary fields have benefitted from the knowledge, experience and activity of biobanks around the world. Research and biobanking has been instrumental in facilitating new discoveries, the implementation of new process and creating innovative ways of approaching and solving problems.

Solution
The International Society for Biological and Environmental Repositories (ISBER) is a global biobanking organization that creates opportunities for networking, education, and innovations, harmonizing approaches to evolving challenges in biological and environmental repositories. ISBER fosters collaboration; creates education and training opportunities; provides an international showcase for state-of-the-art policies; processes; research findings; and innovative technologies, products and services. Together, these activities promote consistent, harmonized high-quality standards, ethical principles, and innovation in science and management of specimen collection, processing, storage distribution and use.

Discussion
ISBER provides a host of tools and resources to the global biobanking community to harmonize best practices and quality of samples. Webinars, biobanking courses and science policy and standards development are key initiatives sponsored by ISBER along with the following tools on our website (www.isber.org): Best Practices Ed. 4; Self-Assessment tool (SAT) for Repositories; Biorepository Proficiency Testing (PT) Program; Pre-analytical Biorepository External Quality Assessment (EQA) Survey; International Repository Locator (IRL); Standard Pre-analytical Code (SPREC); Biospecimen Stability Testing Calculator (STABCALC); etc. The biobanking community challenge is to keep processes relevant and harmonized by sharing resources, tools, technologies and evolving biobanking practices.

P4A_09 - Bioscoop – Advances and Improvements

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Introduction
BioSCOOP is a sample communication protocol, created as an useful tool in data interchange and information flow between biobanks. The use of BioSCOOP includes two applications: the transfer of information about the sample and donor as well as the searching and presenting the sample sets and data sets of a particular biobank to others. First version of BioSCOOP contained the list of attributes describing the donor with particular emphasis on the phenotype, anthropological measurements,
medical data and sample material. Advanced version of BioSCOOP is going to be realised with a new set of features relevant to biobanks, especially clinical ones. Furthermore, the current work aims to integrate the protocol with available laboratory and biobank management systems.

**Materials and Methods**

The programming work is carried out in Swagger Editor and rely on extending the source code with new data. Additionally, the work involves wide consultations within Polish Biobanking Network to develop the best solution for the integration of BioSCOOP with LIMS and BIMS. Results and finding from your jobs: BioSCOOP has been deposited on Github, as YAML file and can be easily imported to Swagger Editor or any other text editor as a described JSON. Advanced version of BioSCOOP has been processing.

**Discussion and Conclusion**

Implementation of BioSCOOP will allow for an efficient work within a biobank and between biobanks especially in two applications: to transfer the information between different biobanks and to allow the searching and presenting the sample and data sets.

**P4A_10 - BBMRI.PL Quality Management Expert Centre**

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**Introduction**

BBMRI.pl Consortium was established as a part of the BBMRI-ERIC. The main goal of BBMRI.pl is to build a platform for scientific cooperation and research development.

**Material and Methods**

The main tasks in BBMRI.pl project are: establishment of the Polish Biobanking Network (PBN), coherent IT solutions, uniform Quality Assurance and Management System, formation of National Node, ELSI aspects and introduction to the Quality Control. Results: Task 3 of BBMRI.pl project “Verification of SOPs that exist in Polish biobanking institutions, implementation of common solutions” consists 8 packages. The task is performed by the team of high-qualified specialists with experience in the biomedicine and biobanking area, management and quality assurance in healthcare entities, diagnostic laboratories, tissue and cell banks. They are representatives of Polish Committee for Standardization, Ministry of Health, BBMRI-ERIC QM WGs.

**Discussion**

One of the solutions prepared by QM Task is Quality Standards for Polish Biobanks and Auditor’s Manual Handbook. Moreover, a detail planned audit process within the PBN is also determined. Three types of audits during BBMRI.pl project sustainability are performed. Individual CAP are prepared with audit reports for each PBN Member/Observer. Simultaneously consulting activity, trainings and workshops are organized.

**Conclusion**

The QMS Expert Centre provides a wide range of solutions to improve the quality of biological material and data in PBN. Acknowledgement: The project is supported by the Polish Ministry of Science and Higher Education (DIR/WK/2017/01 and DIR/WK/2017/2018).

**P4A_11 - BBMRI.it and Regional Biobank Networks: From Coexistence to Interaction**

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BBMRI.it is a distributed infrastructure including more than 90 Biobanks, biological resource centers and sample collections, located in different Italian regions. Most Italian biobanks and biological resource centers participate in National, European and international thematic networks. In Italy biobanks, for the most part, are located and operate in facilities and institutions (e.g. hospitals, clinical research centers) included in (or connected to) the national health system and are therefore directly or indirectly supported by the Regions. The Regional Authorities are responsible within the area of competence for the authorization of biobanks. On the basis of this panorama, the Italian Node proposes a matrix architecture model for the network of biobanks including each biobank in thematic networks (genetics,
population, oncology etc.) and in the regional networks. According to this matrix model, BBMRI.it has set up a pilot project with several Regions, that have expressed interest to cooperate on issues of common interest, such as: institutional recognition and reduction of fragmentation (Biological Resource Centers, reorganization of collections), quality (management, samples, data), sustainability (cost efficiency, centralization, public / private collaboration, cost recovery policies), service unit function (clinical trial services, repository, sample distribution), role in the pipeline of translational research, from basic research to public health (programming of biobanks functional to all phases of research / development, starting from the preclinical phase). Within the project, a BBMRI.it national meeting to debate models and activities at regional level will be conducted. The results of the pilot project with six Regions will be presented.

P4A_12 - ISBER Best Practices to Support Quality Management System of Biobanks

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Background
ISBER has developed and published 4 editions of its Best Practices (BP) during the last 15 years. The recently published 4th edition (BP-4) saw some important updates and expansions and has been translated into multiple languages.

Methods
Beyond a general comprehensive review and revision of BP-4, two major areas of expanded focus were added-QMS and LN-based cryogenic storage (LN addendum). Related tools, addressing self-assessment and internal audits, are also being updated or developed to support implementation of BP.

Results
Launched in January 2018 BP-4 has been downloaded 2317 times (1/3 ISBER members) as of April 2019. The LN addendum had 418 downloads (50% ISBER members) during its first month after launch. Supported by native speaking biobankers BP-4 was translated in different languages (Chinese, Japanese, Korean, Russian, Farsi, Spanish, and French) to enable access for biobankers worldwide. Translation of LN addendum will also be available soon. ISBER’s Self-Assessment Tool was updated based on BP-4 and new BP-4-based tools will be developed that will further improve the quality of biorepositories.

Conclusion
The implementation of BP-4, the LN addendum and related tools serve the global biobank community. All these documents and tools will improve the quality of biomedical research but will be associated with additional costs. However, given the rising global costs of non-reproducibility as well as new requirements from the authorities (e.g. EU regulation 2017/746), there are strong incentives for investing in the QMS of a biorepository. In addition, there is evidence that standardization of innovative methodologies enhances GDP.

P4A_13 - Survey Amongst the Downloaders of the ISBER Best Practice 4th Edition

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Background
ISBER Best Practices 4th edition (BP-4) and its translations are available to download from the ISBER website for free (www.isber.org/bestpractices). The goal of this survey was to evaluate the impact of BP-4 on biobanking practice.

Methods
When downloading the BP-4, requestors provided their email addresses, which were used, with requestor permission, to re-contact the downloaders to ask additional in-depth questions. This survey was conducted in January / February 2019. Results The survey was sent out to 2146 people; 74 (3.4%) responded (39.2% ISBER members). The number of samples stored in the respondents’ biobanks ranged from 40 to 11 million samples (mean 61777, median 75500). The majority of responders represented multiple disease-oriented biobanks with a broad scope in an academic setting in a mature phase. 66% had used a previous edition of ISBER Best Practices whilst 69.6% of those who answered used the BP to develop or review their own practices. Overall, 71.6% consider the BP useful in their biobank. For more than 50% of the
responders, the BPs gave a noticeable improvement to the biobank. Almost 66% of the responders need to implement only minor changes to meet the BP recommendations while about 25% already met the requirements. More than 50% the responders refer at least every 3 months to the BP.

Conclusion
The follow up survey will collate stakeholders’ views and assess the use and impact of BP at a local level. Feedback will help to inform future editions and the development of ISBER’s suite of educational tools.

P4A_14 - Sample Quality in Biomedical Research: One Goal, Two Languages?
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Background
The lack of standardisation in Biobanking has been blamed for hindering reproducibility in research and the ability to pool samples across institutions. Implementation of new standards seeks to address these issues. In order for these standards to be of use, however, their value must be understood by the researchers who use the samples.

Methods
Five focus groups were held with post-doctoral researchers in the UK. The factors surrounding the sourcing of human samples online were discussed in the groups. The discussions were recorded, transcribed and analysed using NVivo coding software. Several key themes were identified, of which sample quality was one.

Results
We found that researchers used a number of ways to determine the quality of samples and of these, official standards were the least frequently cited. A number of participants found it difficult to express sample quality outside of reading SOPs, trust and having a relationship with the sample provider. Researchers used factors such as perceived reputation, track record or a colleague’s referral to assess sample quality.

Discussion
We found that researchers are either unable or unwilling to use formal sample quality measures in discussions about sample quality. While this could be for a variety of reasons, our discussions indicated a lack of knowledge in this area. A key take home from this work is that a coordinated effort to engage researchers with technical standards is needed. Without these engagement efforts, expenditure on such standards may be wasted.

P4A_15 - Establishment of the National Association of Biobanks and Biobanking Specialists (Nasbio) in Russia

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Problem
While over 300 biomedical research centers operate in Russia, only a few of them have biobanks and there is almost no coordination between existing biobanks. In December 2018, the National Association of Biobanks and Biobanking Specialists (NASBio) was established. Association aims uniting professionals and scientific centers to create and develop a network of biobanks in Russia; providing specialized services in the field of biobanking; implementing various research projects utilizing biobanks’ infrastructure.

Solution
Initially, 21 medical research centers, 2 commercial organizations related to biobanking and 32 specialists joined NASBio; the number of participants is constantly increasing. The first conference of NASBio (with Russian
and international speakers) was held in Moscow in April 2019. The activities of NASBio includes: organization of biobanks’ network in Russia; creation of regulations for researchers’ access to biobanks; development and implementation of recommendations, best practices, standards, regulations, operating procedures and forms for biobanks; creation of a common information field; expert activity in the field of biobanking; organization of training courses, schools, educational programs, conferences. With NASBio support, the quality management system of ISO 20387:2018 will be implemented in Russian biobanks.

Discussion
Establishment of NASBio on the basis of international experience of ISBER and BBMRI-ERIC makes a foundation for the development of biobanking and modern biomedical science in Russia. Creation biobanks’ network in Russia will allow to collect large number of biological samples for research, effectively cooperate with academia, pharmacological and biotechnology companies on both national and international levels, improving quality and efficiency of biomedical studies.

P4A_16 - Using ISO 9001 as a Basis for Further Certification and Accreditation within ISO 27001 and ISO 20387 at HUNT Research Centre

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Background
ISO 9001 determines requirements to quality systems, such as quality objectives, quality policy, internal/external audits, non-conformance management, risk management and management review. A certification in accordance with ISO 9001 will be a good starting point for further implementation of ISO 27001 Information security management and ISO 20387 Biobanking.

Methods
By having an ISO 9001 certificate it presuppose that both the planning work and management take place in accordance with given quality objectives, and that these are in accordance with a documented quality policy. The main processes within the organization, such as collection, application management, storage and deliveries, are evaluated to provide continuous improvement.

Results
HUNT was approved for a certification in accordance with ISO 9001 in 2011 and in accordance with ISO 27001 in 2017. During 2019-20, we plan to submit an application for accreditation in accordance with ISO 20387. Our use of standardised procedures promotes data and biological material of high quality, and further strengthen the possibilities for researchers in getting their publications accepted for high-ranked scientific journals.

Discussion
The main vision for HUNT is to perform better public health by being a supplier of knowledge about causes of diseases and health. Ownership and involvements during implementation of a quality system in addition to have employees with the right expertise and good working systems are all important factors.

P4A_17 - Implementing the ISO 20387: The LPCE Biobank (BB-0033-00025, Nice, France) Experience, Transition from NF S96-900 to ISO 20387

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Introduction
To improve quality of samples and optimize management procedure as well as for well-controlled ethical constraints, biobanks should adopt the same international standard. However, each country referred to its own Biobanking guidelines making international collaboration complicated. Consequently, the ISO 20387 standard emerged in 2018 aiming to harmonize international biobanking activity. Our Biobank BB-0033-00025, is already certified by the French standard NF S 96-900 since 2010. Here we demonstrate how to implement this new international standard to optimize activities and to maintain the high quality of our biological resources.

Material and Methods
Both standards, NF S96-900 and ISO 20387 have been compared to each other and key differences were
Results
The ISO 20387 focuses on the quality management system, mostly on operation processes. Additionally, it includes “impartiality” which ensures the transparency and the absence of conflict of interest during the treatment of biological resources. Unfortunately, this was hard to establish and difficult to prove. However, many of the ISO 20387 requirements were already applied in our biobank through the NF S96-900, such as the processes concerning confidentiality, environment or satisfaction of the stakeholders.

Discussion
Here we report the challenges but also opportunities that arose during the implementation in our biobank. This new standard will allow us to increase visibility at the international level leading to the initiation of new partnerships. Consequently, we expect that biobanks around the world will rapidly participate in empowering the scope of this standard.

P4A_18 - Standardization to Achieve Fitness for Purpose in Biobanks
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Background
Biobanking standards and best practices are critical for ensuring that biospecimens are fit for purpose and that the results of studies using biospecimens from biobanks are meaningful and reproducible. Many standards and best practices for biobanking have been developed, such as the ISBER Best Practices (4th Edition), ISO 20387, an international standard for biobanking, and other related programs and tools. However, biobanks vary widely and it may be challenging to determine how best to implement these standards and best practices.

Methods
ISO 20387 General requirements for biobanks is a recently published international standard that provides access to a number of tools of standardization, including quality management and conformity assessment. An analysis of ISO 20387 was performed to identify some of the many considerations that might be explored while implementing this standard for various types of biobanks.

Results
Some of the many considerations that might be explored while implementing ISO 20387 include client requirements, risk tolerance, biobank size and resources, the need for interoperability, and many other factors reflecting the diversity of needs among biobanks.

Conclusion
ISO 20387 was developed to be applicable to a vast array of biobanks and tailorable to individual needs. This presentation will describe the components of ISO 20387 and its partial or complete implementation. It will also address various considerations in plotting the best path for implementation of the standard for different types of biobanks to ensure fitness for purpose.
The finished IT strategy is a comprehensive document outlining a number of strategic focus areas, as well as proposed means in order to successfully cultivate them.

Impact
The journey undertaken by Biobank Sweden in identifying a need for penetrative consensus in the IT area, to organizing and establishing a foundation on which to build it on, should be of interest for most movements aiming for bi-lateral cooperation and lasting infrastructures – be they digital or organizational.

P4C_2 - MIABIS Core V3: How to Better Represent Data-Driven Biobanks in Different Biobank Catalogues


Background
The Minimum Information About Biobank data Sharing (MIABIS) promotes interoperability and facilitates biobank data sharing. The MIABIS Core consists of components defining biobanks, sample collections and studies on aggregate-level. Currently, MIABIS terminology is focused around biological samples. However, some biobanks may not have biological samples, but are rather built around data. Such data-driven biobanks are becoming more common while biobank samples are converted into data, and new digital sample types emerge through biological imaging techniques. Thus, the concepts ‘digital samples’ and ‘data-driven biobanks’ need to be accommodated.

Methods
Several state-of-the-art biobanks and research groups participate as use-cases in the identification of required updates. A consensus on revisions is achieved through expert discussions, after which an initial update proposal is prepared jointly. Following review by BBMRI-ERIC’s nominated domain experts, the suggestion is modified and submitted to BBMRI-ERIC Management Committee for approval. Voting determines whether the update is accepted or if additional refinement is required.

Results
The work for revising MIABIS Core components started in May 2019. The scope of the work and initial results will be presented in the European Biobank week. The work will include updated definitions of sample collection, biobank and sample, and possibly addition of attributes that describe digital samples.

Conclusion
The updated MIABIS Core v3 will allow better description of ‘data biobanks’ and ‘digital samples’ in biobank registers and catalogues, and in biobank information management systems. The Core revision promotes semantic interoperability also through generic data-modelling and serialization.

P4C_3 - PALGA Portal, the Dutch National Tissue Portal; A Nationwide Infrastructure for Requesting Pathology Data and Tissue Blocks

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Background
PALGA, the nationwide Dutch pathology registry, delivers pathology data for diagnostics, observational research, medical quality control and evaluation of screening programs. PALGA contains over 73 million pathology records, the accompanying FFPE blocks and tissue slides are stored in 45 pathology labs.

Methods
The PALGA Portal was built in collaboration with BBMRI to stimulate secondary use of pathology data and tissues for research. It allows researchers easy, fast and safe requests of pathology data or material from all 45 Dutch diagnostic pathology labs. Laboratory requests are forwarded to the designated labs and track-and-traced. HUB-employees, stationed in each academic lab and
serving the non-academic labs, aid in collecting, registering and sending blocks.

Results
Before the start of the PALGA Portal in roadshow 1 all pathology labs were introduced to the PALGA Portal. In 2018, 35 of 45 pathology labs were revisited to evaluate the use of the PALGA Portal (roadshow 2). Over 100 pathologists and laboratory staff discussed the use of the PALGA Portal and the consequences of GDPR for pathology research, and suggested improvements. In addition, the portal delivered process information, e.g. total number of requests through the portal. In 2018, 324 PALGA requests were made and 172 requests for ‘PA material’ were sent to the laboratories, consisting of 17,874 PA numbers (13,690 FFPE blocks, 4,184 pathology reports).

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

P4C_4 - Implementation of an Open Source Database in Navarrabiomed Biobank as a Tool for Personalized Medicine
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Problem
Biobank business is moving forward from sample focus to data focus, due to personalized medicine. Biobanks should adapt their operations in order to serve the investigators and stake-holders requested services.

Solution
Navarrabiomed Biobank has implemented in 2019 OpenSpecimen, which is user-friendly, adaptable and configurable, enabling our Biobank to satisfy properly researcher’s needs.

Discussion
OpenSpecimen allows including data and samples from patients that give consent, projects are registered as specific collection protocols. Each collection protocol can be configured and adapted to project specifications. Roles to everyone can be given, assuring that every person who accesses the database has its specific permission for editing, data entry, viewing, etc. Data protection ethically and legally for participants is guarantee. OpenSpecimen can also be integrated with other databases, for example clinical trial databases as REDCap, allowing the researchers and the Biobank traceability and to share pseudonimized data with researchers from other institutions. OS allows us to manage in Navarrabiomed Biobank all type of samples from tissue to liquid specimens, from our neurological, tumor tissue and population banks to associate disease and projects samples collections. Indeed, we have implemented the database in a multicenter genomic study for personalized diagnoses and treatment in chronic heart failure and kidney disease (CHF and CKD), enrolling 800 patients. We are not only the samples managers, but the database designers and providers. Large amount of clinical data, from hematology and biochemistry parameters, to comorbidities, medications, follow-up data is being registered in OpenSpecimen as specific designated forms.

P4C_5 - MOLGENIS Catalogue - Towards a Unified Application for Data and Sample Catalogues
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Background
To implement the ‘Findability’ of ‘FAIR’, many are now creating catalogues to promote reuse of valuable data and samples. However, isolated development of these different catalogues is a large burden and hinders interoperability to pool information together in more comprehensive catalogues. Therefore we present MOLGENIS/catalogue, a unified catalogue application that generalizes best practices from many biobank, population, (rare) disease, and cohort catalogue communities, e.g. BBMRI, RD-connect, LifeCycle, Lifelines, Maelstrom.

Methods
We compared catalogue data models from many existing initiatives and standards (MIABIS) and consulted our many stakeholder projects to identify common data structures and elements. Then we implemented a unified
but modular data model to accommodate the needs of different communities using MOLGENIS software suite, optimized for flexible data models and independent development of web user interface ‘apps’, to allow ‘agile development’ with frequent releases.

Results
A first version of the unified catalogue data model has been created for evaluation. In addition we have defined a list of user requirements, based on broad community consultation. This ‘backlog of user stories’ is now being prioritized by the stakeholders to create a community supported roadmap for implementation. We designed MOLGENIS/catalogue to be highly configurable and extensible to attract community contributions in data model extensions, tools and user interfaces.

Discussion
We believe that focus of efforts into one unified catalogue application will greatly improve development speed and promote interoperability, and invite the biobank community to feedback and steer its development to meet all their needs.

P4C_6 - Supporting Patient Research Engagement Based on a Mobile Consent Tool Integrated into a Comprehensive Sample and Data Sharing Framework

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The German Biobank Alliance aims to establish a cross-site biobank network, supporting both researchers and the participation of sample donors. Regarding donor empowerment, the focus is on managing their consent (and potential withdrawals) as well as informing them about the sample/ data usage. Similar processes are to be established within the German Medical Informatics Initiative, whose requirements should also be considered. This underlines the need for a digital communication interface that connects researchers and donors. Since such consent/withdrawal functionality must be provided by university hospitals aiming at biomaterial collaboration and associated sample/data sharing projects, we envision this as part of an EHR-integrated patient portal. Furthermore, sample/ data sharing projects, including research results/publications, must be tracked with a project management tool. Moreover, data protection regulations require the integration of identity management functions between the clinical EHR and the research/biobanking environment. We designed a framework that integrates a mobile EHR-linked patient portal with consent functionality and a consent management database, an ID management tool, a project management tool and an exemplary research database. Based on an analysis of the patient consenting processes and the research processes, the information flow between these components was modelled using BPMN. For a subsequent evaluation, a prototypical consenting application was developed and integrated with the mentioned components. Providing not only a personalised consent management interface to the patient, but also critical information and restrictions for data usage in the research context, such a portal needs to be linked to various research IT components.

P4C_7 - Bioface - A New Approach to Data Sharing

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There are more and more services/catalogs available for sample search for scientific purposes. These solutions are undoubtedly needed and are able to solve many problems of scientists. The main principle of their operation is to provide information about the entire collection. For some applications (including for the purposes of our research) this information is too general – clarification requires additional effort. It involves contact with the curator of the collection and clarification of information, in some situations requires additional analysis. To meet these needs, we want to come up with a new approach to the exchange of information about samples. BioFACE is an IT solution that allows to search for information at the level of a single sample. On one hand it is an easy search tool for researchers. On the other hand data security for biobanks is also offered. To enable easy data transfer there is incorporated BioSCOOP – data transfer protocol about sample and collection in JSON format. Bioface has distributed infrastructure and will be available as open source solution. Thanks to that data never leave the biobank. Biobank does not lose control over data and the access to data itself can be regulated by independent
determination of the access level for data and scientists. The system was designed in such a way that it would be possible to use its own or any other authentication service provider, e.g. BBMRI-ERIC AAI service. The study was financed by Polish Ministry of Science and Higher Education no. DIR/WK/2017/01.

P4C_8 - E-Consent as Means to Expanding Donor Population Coverage and Increasing Sample Numbers

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Background
As a hospital biobank, Finnish Clinical Biobank Tampere (FCBT) has primarily obtained biobank consents and samples from Tampere University Hospital's inpatient and outpatient clinics. With newly-developed electronic biobank consent, FCBT aims to increase the number of potential sample donors and to reach wider population coverage than provided by the previous paper-based system. Updating the consent management process through the use of electronic biobank consent therefore brings FCBT to a modern age and provides access to a larger and wider population base.

Methods
Tampere University Hospital's electronic patient portal is utilized as the platform for the electronic consent. FCBT's electronic consent register is automatically updated with new e-consents and subsequently generates sample requests for all new consentees to the laboratory management system. New potential donors who are not patients at Tampere University Hospital are expected to represent population segments (younger donors, healthy donors) underrepresented in the biobank's sample collection. Marketing is used to bring awareness of the portal to the general public.

Results
Implementation of the FCBT electronic consent functionality was initiated in January 2019. With the launch of the e-consent during Autumn 2019, the number of new donors is expected to increase. The donors are also expected to be more representative of younger and healthier population segments than the general hospital patient population.

Discussion
Introduction of e-Consent both increases and expands the donor population coverage for FCBT. Automating consent management processes optimizes the use of personnel resources. The end result is a more sustainable biobank

P4C_9 - The Integrated EUTRO Database for Projects, Datasets and Biobanks

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Problem
The General Data Protection Regulation (GDPR) was implemented in the EU in May 2018, with the main purpose of increasing the protection of personal data. For biobanks, GDPR entails higher standards for processing and management of biological material and associated data. Main challenges for biobanks include increasing the transparency for research participants through traceability of data and samples. Simultaneously, biobanks and host institutions must ensure accountability toward government authorities. All the while, new legal demands should not hinder exploitation of collected sample material, and streamlining the identification of eligible participants and samples for researchers is desirable.

Solution
The locally developed EUTRO database consists of three comprehensive and fully integrated modules: Projects, Datasets, and Biobank. The Project module is a record of all biomedical research projects at our institution, and includes ethical approvals, required documentation, functionality for deadline reminders, etc. The Dataset module allows researchers to order and retrieve data, it logs dataset changes, and provides overview statistics. Finally, the Biobank module contains a comprehensive biobank inventory, it logs the history of each sample, and it is fully searchable.

Discussion
The seamless integration of the Projects, Datasets, and Biobank modules in EUTRO enables improved
exploitation of collected sample material, as well as the fulfillment of GDPR and national legislation through:
- Traceability and transparency for participants
- Identification of eligible participants and samples for specific research questions
- Convenient reporting on biomedical research activities for the host institution

P4C_10 - Usability Analysis of the GBN Sample Locator for the Federated Search for Biomaterials and Related Data


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Introduction
The heart of the IT infrastructure, provided by the German Biobank Alliance (GBA), is the federated search for biomaterials and related data. For this purpose, the so-called Sample Locator was developed. In order to ensure a sustainable use of such a tool, it is crucial to involve end-users in the development process. This is achieved by a usability analysis of a search interface prototype.

Methods
To develop a prototype ready for an evaluation we needed the input from GBA IT-experts. Thus, we conducted a two-day workshop with eight GBA IT-team members. Focus was on the respective steps of a user-centered design process. With the acquired knowledge, the participants designed low fidelity mockups. Of these mockups the main ideas were discussed, extracted and summarised into a comprehensive prototype using MS PowerPoint. Furthermore, we created a questionnaire on the usability of the prototype including the System Usability Score, questions on negative/ positive aspects as well as typical tasks to be fulfilled with the tool. Subsequently, the prototype was pre-tested on basis of this questionnaire with researchers with biobank background.

Results
The pre-test testified that the prototype generally has an intuitive operability. Individual imprecise formulations in prototype and questionnaire were noted which needed to be revised. Based on the feedback of the pre-test, we refined and finalised the prototype.

Future Work
The adapted prototype will be evaluated in May/ June 2019 by researchers that are familiar with sample requests. Results and feedback from this evaluation will then support the productive tool development.

P4C_11 - Bioscoop Ver. 2.0 – Advances and Improvements

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Introduction
BioSCOOP is a sample communication protocol, created as an useful tool in data interchange and information flow between biobanks and related software. The use of BioSCOOP includes transfer of information about the sample and donor as well as the searching and presenting the sample sets and data sets of a particular biobank to others. First version of BioSCOOP contained the list of attributes describing the donor with particular emphasis on the phenotype, anthropological measurements, medical data and sample material. BioSCOOP ver. 2.0 is going to be realised as an extended version with a new set of features relevant to biobanks, both clinical and anthropological. Furthermore, the current work aims to integrate the protocol with available laboratory and biobank management system within Polish Biobanking Network (PBN). Materials and Methods

The programming work is carried out in Swagger Editor and rely on extending the source code with new data. Additionally, the work involves wide consultations within PBN to develop the best solution BioSCOOP with LIMS and BIMS.

Results
BioSCOOP available on Github, as YAML file and can be easily imported to Swagger Editor or any other text editor as a described JSON. BioSCOOP in version 2.0 has been processing.

Discussion and Conclusion
Implementation of BioSCOOP will allow for an efficient work within a biobank. Proposed new, anthropological attributes provides unique set of data description which could be used in classical anthropology communication protocols and expand the possibility of exploring this type of data in the future.

**P4C_12 - EUCAN-Connect - A Federated FAIR Platform Enabling Large-Scale Analysis of Biobank and Cohort Data between Europe and Canada**

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On January 1st 2019 EUCAN-Connect project started, on a mission to unify federated data analysis infrastructures for cohort and biobank data analysis. Rapid progress in information and biotechnologies incite the promise of better, personalized prevention and healthcare. Both Europe and Canada have long-term investments in population-based prospective cohort and biobank studies providing essential longitudinal data. These data must be analysed in unison to reach statistical power, however, presently these data are locked in fragmented repositories because they don’t use universally compatible data standards and experience difficulties to share the data because of privacy protection, data security and regulatory issues. EUCAN-Connect will enable large-scale integrated analysis of individual, environmental, population and omics data via an open, scalable data platform for cohorts, researchers and networks to share data, according to FAIR principles (Findable, Accessible, Interoperable, Reusable). We will therefore synergize the best elements of DataSHIELD, MOLGENIS, Opal, and major international cohort network and infrastructure initiatives such as BioShARE, InterConnect, LifeCycle and RECAP Preterm. The solution is centered on federated analysis technologies, where sensitive data are kept locally and only results are shared and integrated, in line with good governance principles, taking into account the ethical, legal and societal challenges of such an endeavour. First widespread uptake will be promoted via demonstrator studies with leading cohort networks, focused on early-life origins of cardio-metabolic, developmental, musculoskeletal and respiratory health and disease impacting human life course. Further dissemination through BBMRI-ERIC (EU) and Maelstrom Research (Canada) to sustain long-term benefits to science and researchers worldwide.

**P4C_13 - Architecture Approach to the Polish Biobank Network Central IT Tools**

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Recent developments in information technologies and unparalleled expansion of hardware capabilities have set the new boundaries of the amount of data collected and processed automatically on a daily basis. The availability of these technological developments together with new discoveries in the omics science and medical diagnostics, provide the rationale for recent efforts to acquire and process large amounts of medical and biological data, and allow for massive data sharing. Therefore, there is need to find the most effective way to integrate databases containing data from different specialties and to provide potential researchers with a complete information about analyzed cases. Our team at the Medical University of Gdansk, began working on the development of central IT tools for the BBMRI.PL. We analysed available databases, their data structures, and communication protocols of different biobanking systems in Europe, Polish registries for rare diseases, and clinical and national medical databases. In addition, we are preparing on-line tools for processing and sharing research data. Our IT architecture is central-driven, where permitted datasets are reproduced at the central database and combined with other data sources. Our system design provides the investigators with tools not only to find appropriate samples, but also to obtain associated donor medical data including experimental, examination and diagnostic results. We have successfully developed IT technologies and workflows for storing and sharing biobanking data. Our expertise and the results can aid other groups in the process of
preparing national biobanking systems to store, deliver and share biomaterial and donor information.

P4C_14 - BBMRI-ERIC Directory 5.0

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Background

The Directory is BBMRI-ERIC’s publicly accessible tool to find and request 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.

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 to evaluate and improve the user experience of the Directory.

Results

We released version 5 of the Directory, based on MOLGENIS 7.2.14, which sports further refinements to the user interface and search capabilities, such as an improved diagnosis search facet and the ability to search on the quality marks issued in the BBMRI Quality Program. To support the National Nodes, we improved the mapping service and validation of the provided data, and enabled Single Sign-On login based on the BBMRI-AAI. Together with the BBMRI User Forum and CS-IT WP6 we have identified further areas of improvement in the user interface and user interaction, which we plan to address in minor releases over the coming period.

Discussion

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

P4C_15 - Launching of the SBP E-Catalogue: How to Federate Users and Promote Scientific Collaboration?

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Background

Swiss Biobanking Platform (SBP) is the Swiss National Node of the BBMRI-ERIC infrastructure. Among its most important achievements, the biobank SQAN (Biobank Solution for Quality Assessment and Normalization) provides an IT tool for the biobanking community to enable stakeholders to monitor the quality of their biobanks and create the first national directory. Next objective is to allow visibility at the sample level.

Methods

The recurring issue for the adoption and use of catalogues is the willingness of users to share biological samples and to initiate scientific collaborations. Aware of these challenges, SBP is developing a platform that will take into accounts these needs. Flexibility and freedom of choice to publish catalogues according to the target audience are the main criteria.

Results

Through a pilot project, PathoLink, involving the Swiss Institutes of Pathology, a platform has been set-up and is being implemented. This platform allows the creation of catalogues offering granularity in terms of access rights. Users keep the control of data, and can limit, or open their access. This tool is intended to be user friendly, with simplified administration interface to load data from different flows, with a harmonized framework trough SBP datasets.

Discussion

Usefulness of catalogs at a sample level is often controversial due to the balance between resources and expected benefits. We aim to shift the actual paradigm of showing high numbers of samples towards a more personalized approach focusing on starting collaborations around those ready-to-use resources.

TOPIC 5A: 500 DAYS INTO THE GDPR
P5A_1 - A Pilot Study, including Biobanks and Patient Organizations, for the Implementation and Testing of the BBMRI.It National Informed Consent Matrix in TNGB

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The European Regulations changed our ELS horizon. In 2017-2018, the BBMRI.it Common Service (CS) ELSI facilitated a working group on informed consent (IC) composed by all stakeholders of the biobanking field (i.e. patient representatives, biobankers, research institutions, ELSI experts) aimed at drafting through a participatory approach a matrix of IC for biobanking research, as an ELS co-produced framework for a dynamic informative process. The Telethon Network of Genetic Biobanks (TNGB) composed of 11 RD-biobanks, to be GDPR compliant, needed to remodel its IC model. Thus, BBMRI.it CS ELSI and TNGB, activated in 2018 a laboratory composed by biobankers and patient representatives, including UNIAMO -RD Italian Federation- where the TNGB IC model became a training ground to implement the BBMRI.it matrix. The matrix was the laboratory concrete framework, a participatory approach based on dialogue, multidisciplinary, pluralism and progressive co-production, the methodological horizon was applied through several teleconferences and a joint work on a collaborative platform. Turning-points were the achievement of common language, content articulation and link between information and governance. It was critical to discuss the sample preservation time, depletion of the last aliquot and minor re-consent. The next steps: sharing the outcome with BBMRI community, digitalizing the BBMRI.it/TNGB model and revising from a legal expert. In conclusion, the new TNGB IC model confirms how joint, equal and participative method involving all RD-biobanking stakeholders and infrastructures is a successful approach for producing documents and good practices not only legally but also ELSI compliant as well as patient-centred.

P5A_2 - How to Transform a Public Consultation in a Community Building and in a Normative Suasion Action: the GDPR, the National Prescriptions and BBMRI.It

Casati, S., Lavintrano, M., on behalf of BBMRI.it Group on Public Consultation

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On December 13, 2018, the Italian Data Protection Authority launches a public consultation concerning the compatibility between national provisions - relating to the processing of genetic data and personal data carried out for scientific research purposes – and the GDPR. The extended community of BBMRI.it considers this public consultation as a great opportunity both to launch a useful collaboration with the Authority and to empower an all community within a normative suasion horizon (Italy has not a Biobank Law). Through a coral working group coordinated by CS ELSI BBMRI.it, the public consultation becomes a vector to bring the collegial perspective of the multiple actors (Patient Organizations, Ethics committees, Biobanks, Research Institutions) who with different roles and responsibilities are at the forefront in promoting, guaranteeing and developing biobanking research within a practical horizon of Responsible Research. The proposed contribution plays its normative role highlighting the specificity and relevance of the biobank as a service structure in processing and custodianship of samples and related data, recalling the utility of distinguishing instruments from structures, both in the treatment of genetic data and in biological samples governance. Turning-points have been the need for a shared language, especially in expressions originating from research having for the genetic data/samples treatment an immediate impact in science, as well as the appreciating the substantial difference between concepts such as biological samples, data generated by their study (genetic data), data...
generated by their processing (metadata): due to their peculiarities they would require dedicated and different regulatory models.

P5A_3 - The Impact of Research-Related Derogations on Biobanks: Filling the Gap between Legal and Ethical Compliance

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Problem
One of the main implications of GDPR for research biobanks concerns research-related derogations from a set of participants’ rights such as the right to consent, to withdraw, to access. Even though it is provided that technical safeguards must put in place when those individual rights are denied, the GDPR is not very enlightening on how to accommodate the ethical concerns that the suspension of individual rights generates and what are the standard ethical requirements that should be adopted as additional safeguards. This ambiguity arises the legitimate question of whether what is legally compliant under GDPR is also ethically compliant with the fundamental rights and freedom of biobank participants.

Solution
As Recital 59 demands, biobanks should facilitate the exercise of data subject rights. A solution for strike a balance between the derogations and the individual rights would be recognizing the key role of participants in biobanking. In this regard, the effort to enhance ethical safeguards under research exemptions should focus on empowering participant as active partners through participant-centric initiatives, dynamic consent tools and e-involvement.

Discussion
I critically examine the challenge that the legal compliance to GDPR raises to participants’ rights and roles in the context of research biobanks. I argue that an extra effort should be put in place in enhancing the role of participants in order to implement the ethical compliance with their individual rights and interests. In this way, the loss of control over personal data should be counterbalanced with an active engagement in governance mechanisms.

P5A_4 - Challenges of Harmonized Patient Consent in the Light of the New European Data Protection Regulation in the German Centre for Cardiovascular Research E.V.

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Background
Since 2014, the German Centre for Cardiovascular Research e.V. (DZHK) is building up a comprehensive data and biomaterial collection for secondary use in the context of 20 multicentric clinical studies using an overarching infrastructure platform.

Methods
Harmonized patient documents for these 20 widely differing clinical studies have been presented to 50 German ethics committees. In at least one third of the submissions we had to discuss numerous process points with the corresponding ethics committees. To evaluate this submission processes, we categorized contents of the 42 written votes from 16 ethics committees in 2017 and 2018. These related to 11 DZHK multicenter studies.

Results
Since the introduction of the GDPR, topics related to data protection legislation increased noticeably while general procedures of the DZHK research platform decreased. Main points raised were storage limitation, purpose of data and biomaterial use and transfer of data to non-EU-countries. Due to a lack of binding guidelines for dealing with the new regulation, the response to the comments was extremely difficult and very individual. Nevertheless in all but one consultation joint solutions were found.

Discussion
These experiences were incorporated into the “Ethics Concept of the Clinical Research Section of DZHK e.V., Version 4”. For a deeper insight, a more detailed evaluation of the content of votes and discussions is
ongoing. One of the critical questions remaining is the transfer of not anonymized data and biomaterial to non-EU countries.

**P5A_5 - Cross-Border Transfer of Samples and Data in the EU and GDPR**

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(a) It has been a year since the beginning of the application of GDPR. The purpose of the regulation was to harmonize legal regulations concerning the processing of personal data. However, after a year of application, it is clear that the interpretations of the GDPR regulations in individual member states differ from each other.

(b) The most important discrepancy in this area is visible when determining when the recipient of data is their controller and when only the processor, what to do in a situation where the basis for processing data in the country that sends samples is statutory regulation and in the country that receives the consent of the donor, what information obligations towards the donor has an entity that sends data to the receiving entity and, finally, what are the rules of responsibility for the data of the sending entity being processed and which recipients. These issues will be considered on the basis of the GDPR regulations, templates of MTA agreements as well as the draft of the Polish code of conduct. Concluding the considerations, it should be point out the need to adopt a code of good practices or a code of conduct at the level of BBMRI.ERIC and until then, to develop common standards for the cross-border transfer of samples and data in the EU.

**P5A_6 - The General Data Protection Regulation and the ISO20387: Anatomy of a Partnership**

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The General Data Protection Regulation (GDPR) has been established to regulate the access and use of person data. Transition time is long gone, compliance is now mandatory and fines have already been dished out to unfulfilling companies: the time for ‘wait and see’ is over. Biobanks have a lot a sensitive information to manage and protect, in the light of all the challenges posed by GDPR. With service-users becoming even more powerful, as they continue to understand the rights and mechanisms that regulations like the GDPR have made available to strengthen their ability to manage and protect their data, it is always worth remembering the importance of ensuring person data is secured. Compliance with GDPR seems to be easier in companies which have a management system that supports daily practice. Biobanks may then take a structured approach to support and maintain compliance with GDPR. GDPR provisions may be integrated with the management system from ISO20387 or ISO 9001 standards, sparing efforts and resources and making it easy for the biobank and personnel to understand and apply.

**P5A_7 - ELSI-Help Desk**

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ELSI-Helpdesk The Swedish Research Council-funded research infrastructure Biobank Sweden supports healthcare providers and universities with medical faculties working towards national harmonization in biobanking. Research on human tissues raises ethical, legal and social issues. For example, how do we protect data when sharing samples? How do we protect the integrity of research participants? To assist researchers and biobanks navigating through the ethical, legal and societal landscape, Biobank Sweden launched an ELSI Helpdesk in October 2018. This support service offers researcher and biobankers in Sweden advice on ethical topics relevant in biobanking and biomedical research, such as informed consent and data protection. The ELSI Helpdesk also offers trainings in ELSI related questions, research ethics and provides preparatory materials to support universities and research consortia in their dialogue with Swedish authorities, such as answers to referrals on government inquires and policy documents. The ELSI Helpdesk is managed by researchers and experts of biomedical ethics, administrative law and public law connected to the Centre for Research Ethics.
& Bioethics (CRB) at Uppsala University. By sharing their expertise through the ELSI Helpdesk, Biobank Sweden will contribute to the integrity of biobank research.

**P5A_8 - Empowering Biobanks to Comply with the EU GDPR for Personal Data Protection Using a Cloud-Based LIMS**

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**Problem**

Biobanks collect, process, store, and provide high-quality annotated biospecimens to researchers for clinical and translational research. For sharing high-quality biospecimens and associated metadata obtained from the European Union (EU) citizens, biobanks need to comply with the EU General Data Protection Regulation (GDPR). The main purpose of EU GDPR is to harmonize data privacy laws across all 28 member states that constitute the EU and to safeguard personal data obtained from EU citizens. The EU GDPR has special guidelines for processing of data concerning health and genetic data. The EU GDPR recommends ‘Privacy by Design’ approach which necessitates the implementation of appropriate data safeguarding mechanisms into a biobank's services and use of techniques such as pseudonymization and encryption for data protection. The new regulation requires biobanks to maintain records of all processing activities and to implement necessary security measures to prevent infringement of privacy rights of subjects.

**Solution**

A LIMS can play a crucial role in meeting the new regulatory requirements. A LIMS can help in pseudonymization of sensitive data and can help data processors in maintaining automated records of all processing activities such as data collection, organization, storage, alteration or retrieval. Furthermore, a cloud-based LIMS helps in transnational data transfer without compromising data integrity.

**Discussion**

A LIMS can help biobanks to protect privacy rights of data subjects and to process sensitive health and genetic data of the EU citizens in accordance with the EU GDPR guidelines.

**P5A_9 - GDPR and Clinical Trials: Implications for Innovation and Sharing for Biobank Based Research**

R. Neethu  Acknowledgment to all authors of the original paper R. Neethu, Timo Minssen and Marcel Bogers

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This paper focuses on the interrelationship between the Clinical trial and the EU's new General Data Protection Regulation 2016/679 (GDPR). Recently there have been increased EU initiatives and legislation towards public access to clinical trials data (CTD). These are generally much welcomed developments for the enhancement of science, trust and open innovation. However, they also raise many questions and concerns on the interface between CTD transparency and other areas of evolving EU law concerning the protection of trade secrets, IPRs, privacy and most importantly GDPR about which the paper focuses. By examining the interphase of GDPR and Clinical Trials in EU specific concerns emerge which has impact for advanced research in context of personalized medicine and rare diseases. This paper examines (1) the genesis of the EU Clinical transparency regulations, including the incidents, developments and policy concerns that have shaped them; (2) the features and implications of the GDPR in the context of clinical trials; and (3) the tensions between the GDPR and the policy goals of CTD transparency and its implication for data sharing and open innovation. Ultimately, it is stressed that researchers involved in clinical research must be carefully consider such challenges and address them to reap the full benefits of CTD transparency.

**P5A_10 - Implementing a New Consent Procedure: Successes and ‘Lessons Learned’**


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Introduction
In the Netherlands, hospital-based biobanks collecting residual tissue samples and related data commonly offer patients an opt-out procedure. However, changing societal values, our research findings on patient information needs, and the GDPR, motivate many hospitals to reconsider this consent procedure. The Netherlands Cancer Institute is the first hospital in The Netherlands to implement an opt-in procedure for general secondary use of residual tissue samples and data for scientific research.

Implementation process
Implementing a new consent procedure affects hospital procedures on different levels. The management level needs to be involved to be able to take decisions. At the organizational level, IT systems need to be adjusted, and employees need to be informed about the urgency for getting the consent from the patient and instructed about the new procedure. At the legal level, laws and regulations need to be translated into new procedures that can be used in practice. Moreover, the patient information needs to be adjusted to inform patients about the new procedure.

Successes and ‘lessons learned’
During the first months, we evaluated the implementation process by monitoring consent percentages, and by interviewing both patients and employees. We identified several successes and ‘lessons learned’ that might help other hospitals when changing their consent procedure. Examples are the development of an information brochure that is both legally sound and easy to read for patients, and internal and external communication. All steps taken and lessons learned will be shared with the community through an extensive implementation document.

P5A_11 - Legal Regulations and Social Perceptions of Genetic Genealogy Databases
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Background
Donating of own biological samples for genetic testing is an increasingly common practice among people seeking knowledge about their ancestors. Genetic research allows expanding the family tree, finding ancestors. The collection of biodata in the genetic genealogy databases is associated with legal and social problems. The scientific literature mentions the fears of possibilities of police accesses to genetic genealogy databases.

Methods
The aim of the study was to examine, according to the ELSI model, the existing legal regulations in the EU countries and to examine the social perception concerning genetic genealogy databases. The EU regulations were analyzed. In the field of social perception research - the study was conducted on a representative all-Polish nationwide group of over 600 adults (CI = 0.95) by Lickert scale questionnaire.

Results
Most of the respondents accepted conducting research in the field of genetic genealogy and collecting biodata in databases. Among the restrictions on this type of scientific activity there were concerns about unauthorized disclosure of biodata to law enforcement agencies and insurance institutions and disclosure of genetic relatedness incompatible with historical genealogy.

Discussion
The conducted research revealed the need to make legal regulations both in Polish and EU legislation. It would be desirable to conduct a nationwide information campaign on the possibilities of genetic genealogy.

P5A_12 - Data Sharing and Protection in Biorepositories: Perspectives from a Small LMIC Biorepository in SA and Other African Countries
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With the implementation of GDPR and soon to be implemented, Protection of Personal Information, Act 4 of 2013 (POPIA), biorepositories in SA is revising data
sharing and protection policies to ensure compliance. Since data privacy policies are in place for some biobanks, the question remains how many other are POPIA/GDPR ready and take into account their African partner’s data sharing and protection legislation.

Methods: Using NSB as a case study, both current and prospective partner’s regulatory frameworks along with POPIA and GDPR guidelines will be reviewed. Data sharing and protection legislation from Kenya and Nigeria will also be reviewed to account for differences. A SA/African data sharing and protection summary of do’s and don’ts taking into account all the required national and international legislation will be developed.

Preliminary results: Using POPIA/GDPR as a reference, a coded sheet was generated of key points. These include: 1) informed consent and REC roles, 2) MTA and DTA’s, 3) the use of secondary data, 4) long term storage, 5) protection, 6) IT/LIMS perspective and 7) in between countries sharing along with 8) whom takes responsibilities in case of data breaches.

Discussion and conclusion: For researchers and biobankers, the GDPR and/or POPIA legislation is a challenge to interpret. Therefore the summarised guideline for LIMC African countries that would be generated focusing on the do’s and don’ts related to data sharing and protection aims to help researchers and biobankers to become POPIA/GDPR complaint and to create awareness within their own setting.

P5A_13 - Leftover Sera Obtained during the Health Care Process Can Have a 2nd Usage in Research

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Background

Obtaining prospective samples is a big challenge for a hospital-based Biobank because physicians or health care personnel are not interested in obtaining these samples if they are not involved in the project. On the other hand, the Hospital Clinical Analysis Departments and also Biotech companies need very often samples (mainly sera) from patients, to check new equipment or analyzers, or to test or validate new diagnostic kits. Despite that these protocols cannot be strictly considered research projects, nobody knows if in the future, from these technical protocols could derive patents or scientific publications. Ethical and legal conditions must be fulfilled in front of any situation.

Methods

Facing these two challenges, MARBiobanc has designed a strategy where it takes the responsibility of storing and managing leftover samples obtained during the healthcare process, after a security period of 8 months. This time is reserved for reanalyzing samples if necessary for the patient care.

Conclusion

If the informed consent for research is available the Biobank opens the possibility of acceding to thousands of prospective samples without specific external collaborations. It is based on a long storage of leftover sera obtained routinely at the hospital during the health care process. These samples can be transferred not only to research projects but to the Clinical Analysis Departments and external Biotech Companies for their technical tests and validations, accomplishing all the ethical and legal rules.

TOPIC 5B: QUALITY ASSESSMENT AND MANAGEMENT OF SAMPLES

P5B_1 - Bioresource Center Ghent: Quality Control Frozen Tissue Tumorbibank with DNA & RNA Extraction

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Background

Since 2001, tumor samples have been frozen and stored at the UZ Gent Tumor Biobank, which is funded through the National Cancer Plan (Onkelinx 2008, Action 27). These samples are collected during diagnostic or therapeutic surgery procedures or specific for research purposes. To test if the samples are useful for research purposes, 5% of the tumors collected during the year undergo systematic quality control. The quality control procedures are essential to evaluate the potential use of
tissue received in the tumor biobank, and to identify possibilities for improvement by correlation with their pre-analytical factors.

**Methods**

Frozen tissue, collected in 2017, was selected in the database for quality control. Care was taken that no rare samples were selected and that the selection was representative of the global tumor type content of the biobank. DNA was extracted using the Maxwell RSC tissue DNA kit (Promega). RNA with a manual method using TRI Reagent®. The quantity and quality was determined by the Lunatium.

**Results**

The results are very varied. Some samples have little to none yield. Others give good results. We compare the results with the tissue type. Soft tissues has the lowest yield. Lymph node for example gives a good result. Liver gives different results.

**Discussion**

Some tissues have a low content of RNA & DNA dependent on the tissue type. A cause of this low yield is the freezing delay of the tissues. How longer this delay, the lower the yield even if the tissue should have a high yield.

**P5B_2 - Improvement of Automated DNA Extractions from Various Types of Biological Materials on a Prime (PerkinElmer)**

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The CEPH biobank is a high throughput human Biological Resource Center involved in the establishment of large collections of samples for research programs. The aim of the biobank was to implement an automated integrated solution to extract up to 96 DNAs per day from different types of biological material fresh or frozen, saliva, blood, buffy-coats, cell pellets and from a large range of volumes varying from 0.4 mL blood to 10 mL to finally recover extracted DNAs in 2D barcoded tubes. The magnetic bead technology was chosen to enable an immediate concentration measurement impossible when DNA pellets have to be homogenized after extraction with the salting out method. The Prime (Perkin-Elmer) was selected to 1) enable completely automated DNA extractions, 2) guarantee the quality and stability of extracted DNAs for years, 3) provide traceability of samples during the extraction by the communication between Prime and CEPH LIMS. DNA extraction protocols were optimized on the Prime 1) to guarantee to non-contamination from to sample to sample during the initial transfer of samples from collection tubes to extraction plates even for very viscous samples (freshly collected saliva samples on DNA Genotek OG-600 kits, buffy-coats, cell pellets from lymphoblastoid cell lines), 2) to optimize DNA yields, 3) to get high quality DNAs. Protocols’ improvement was fruitful allowing the extraction of high quality DNA with proper DNA yields from 48 4 mL blood or buffy-coat in about 4h and of 48 highly viscous 20 M cell pellets or saliva 4 mL samples in 6h.

**P5B_3 - Italian National Institute of Health Initiatives to Promote Quality Management and Assessment in Research Biobanking**

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**Introduction**

The Istituto Superiore di Sanità (ISS), the Italian National Institute of Health and Governative Member in BBMRI-ERIC, supports quality of the research and in particular of studies based on biological materials; promotes good practices for the standardization of reporting the use of biobanking services in scientific articles; contributes to the normation process for research biobanking.

**Material and Methods**

Definition of requirements to have suitable samples for each intended purpose associated with communication and dissemination are appropriate methods to increase awareness of necessity and of benefit deriving from quality assessment of biobanking.

**Results**

Experts from ISS have been contributing to the activities of the Working Group 2 “Biobanks and bioresources” of
the ISO/TC 276 Biotechnology, since the early phases of the process. After publication of the ISO 20387, ISS supported the adoption of the standard by the National Standard Body (UNI) and in collaboration with UNI and the Italian Accreditation body (ACCREDIA) organized an event in Milan on March 5th with the aim of disseminating a correct information on ISO 20387 requirements, implementation and competence assessment for research biobanking. About 100 people attended and to fulfill exceeding participation requests the event was repeated at ISS, in Rome, on May 22nd.

Discussion
Success of these events, analysis of received questions show effectiveness of actions performed and interest of Italian biobanking community in the improvement of quality management of biological materials as well as in the assessment of its implementation.

Acknowledgement: Minister of Health, MIUR, BBMRI.it, Ente Italiano di Normazione (UNI)

P5B_4 - Implementation and Optimization of Automated Protocols for Sample Management Using Tecan Freedom EVO Work Station: A New Kind of Biobanking

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Introduction
Management of samples and quality assessment are critical aspects in biobanking since the quality of biospecimens is necessary to produce reliable data for basic and clinical research.

Material and Methods
Taking advantage of the advanced Tecan Freedom EVO™ liquid handling work station we set-up and optimize automated protocols for serum/plasma processing and mononuclear cells isolation by density gradient centrifugation from peripheral blood (PBMC) and bone marrow (BM-MNC) using SepMate™ tubes according to datasheet protocol.

Results
All the protocols described in our SOPs have been adjusted for being processed using the Freedom EVO work station integrated with Hettich™ centrifuge. Thanks to Tube-eye SciRobots™ and Ziath™ 2D barcode scanner, sample tracking is fully automated. All the protocols have been set-up and optimized, PBMC and BM-MNC isolation in particular. The optimum pipetting height following gradient centrifugation for the collection of mononuclear cells was fixed to allow efficient isolation of PBMC/BM-MNC while reducing the number of granulocytes in the final preparation. The flow velocity during cell resuspension as well as the number of controlled aspiration/resuspension cycles was determined to obtain a single cell suspension while limiting shear stress and cell membrane damage. Finally, we optimized sample management in order to minimize the entire duration of the procedure.

Conclusion
Automated Freedom EVO™ platform allows the prospective implementation and standardization of uniform protocols for the collection, processing and storage of clinical samples. Moreover built-in sample tracking, audit trails and user access control helps to ensure process integrity.

P5B_5 - Quality Assessment of DNA Obtained from Blood Clots for the Creation of Strategic Collections of High Interest in Biobanking

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Background
Preliminary studies on blood clots obtained after clinical laboratory tests showed in previous studies the potential in order to create collections of some pathologies such as pediatric or neurological diseases (Alzheimer). However, quality studies with flurimetry and long PCR are necessary to determine the viability of this matrix as a source of nucleic acids.

Methods
In this study, blood clots were extracted from 10 healthy volunteers. The extraction of DNA was performed using
the Gentra Puregene Blood Kit (Qiagen, Germany). DNA was analyzed using the Quant-iT™ Picogreen® dsDNA assay to determine the integrity and concentration of double-stranded DNA. Functionality was assessed by Long-PCR amplification, a fragment of 3396 base pairs from HLA genes respectively, were amplified in all samples.

Results
Quality of DNA extracted from blood clot was assessed by fluorimetry and compared with the previous results obtained by spectrophotometry. Results showed certain differences in the samples evaluated which corresponded with those previously obtained by spectrophotometry. Functionality performed for HLA gene was positive in all samples tested.

Conclusion
Quality study performed in blood clots showed that these samples are a good alternative when it is very difficult to obtain a sample for research, so that the clinical laboratory samples could be used. This allowed the creation of pathological collections of rare diseases when the collection of the sample is difficult because it is limiting or there is difficulty in accessing this type of population.

P5B_6 - Evaluation of GAPDH and ACTB Genes 3'5' Assay as an Alternative Technique to RIN for MRNA Integrity Analysis

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Ensuring quality of human samples is a great challenge in order to ensure the reproducibility of scientific results. The low availability of standardized and validated techniques to evaluate tissue molecular integrity makes difficult to guarantee its quality. In this study we aimed to evaluate the usability of a 3'/5' fragment RT-qPCR assay to assess integrity of mRNA derived from human tissue samples as a complementary technique to RIN. Molecular integrity was evaluated with paired samples from 10 donors of healthy colon tissue preserved as snap-frozen OCT (SF-OCT) and formalin-fixed paraffin embedded (FFPE). RNA integrity was evaluated in parallel by 2100 Bioanalyzer (Agilent) and qRT-PCR (Illumina). RT-qPCR assays were carried out with specific probes for GAPDH and ACTB genes, amplifying regions of 3’ and 5’ ends in addition to a central amplicon. dCq was calculated by subtracting Cq values obtained for the 5’ end between those obtained for 3’. Lower dCq values were obtained in SF-OCT samples (average of 5.83±0.46) in comparison with FFPE samples (average of 11.9±1.48), which is an indicative of major mRNA degradation on formalin-fixed samples. These results agree with the values obtained from RIN, which were higher in the case of SF-OCT samples compared to FFPE (R=0.61). Significant results of mRNA quality were obtained by studying dCq 3'/5' values, especially for the ACTB gene. A new methodology in biobanks has been tested as a tool for quality control for tissue samples based on mRNA integrity. This quality control method correlates with RIN results.

P5B_7 - Tissue-Safe as an Alternative Method for the Conservation of Blood Clots in Order to Obtain High Quality DNA

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Background
In the last decade, human biorrepositories have storage problems due to the high number of samples stored in ultra-freezers of -80ºC, so they are looking for storage alternatives. In addition, some studies seem to show that freezing could be a non optimal method to maintain the quality of the samples used in research, this is another reason for the search for new matrices that allow storage at 4ºC or room temperature. Aim Tissue safe as a means to conserve blood clots at 4ºC and room temperature in order to obtain high quality DNA is proposed.

Methods
In this study, blood clots were extracted by venopunction from 10 healthy volunteers, and used fresh and stored in different conditions: freezeed, at 4ºC, processed in tissue safe and stores at 4ºC or room temperature. After 1
month DNA were obtained from each matrix and condition. The extractions of these nucleic acids were performed using the Gentra Puregene Blood Kit (Qiagen, Germany).

**Results**
Quality of the nucleic acids obtained was assessed by spectrophotometry and agarose electrophoresis. Functionality was assessed by PCR. Results obtained showed significance differences between the conditions tested. However, the functionality of the samples was not altered with the storage time.

**Conclusion**
Data obtained in this study showed differences between the storage conditions evaluated. This could be of great interest to optimize storage systems in biobanks, and to offer high quality samples with a low cost. However, studies on long-term storage would be of great interest in this area.

**P5B_8 - How NMR Spectroscopy Can Contribute to Quality Control in Biobanking and Provide Additional Information in Downstream Analytics**

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**Background**
Nuclear magnetic resonance (NMR) spectroscopy is one of the main analytical techniques in metabolomics. Advantages of NMR spectroscopy are the identification and quantification of a multitude of diagnostic metabolites in a single experiment, minimal sample preparation effort, and targeted and untargeted analysis approaches. More precisely, NMR enables quality control of biobank input samples and provides additional analytical information at the same time.

**Methods**
SOPs comprising the full in vitro diagnostic research (IVDr) workflow from sample collection to postprocessing procedures for urine, plasma, serum and CSF samples are provided by Bruker Corporation, enabling worldwide standardization. Main elements of these SOPs can be implemented in the biobank.

**Results**
Taking advantage of the university’s NMR metabolomics infrastructure and employing Bruker Corporation’s IVDr standardized platform for preclinical research, first analyses could be performed with urine and blood samples. In the quality report parameters like the spectral fingerprint confirm sample identity. Interesting findings are detection of drugs and the discrimination of tea and coffee consumers.

**Discussion**
NMR spectroscopy and Bruker Corporation’s IVDr screening analyses have the potential to upgrade quality control in biobanks and at the same time deliver valuable additional diagnostic parameters. Implementing this workflow in the biobank routine, however, remains a challenge.

**P5B_9 - Sample Quality Control Assessment of Long Read Sequencing and Low Input Libraries**

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**Background**
Long-read sequencing and miniaturization of library preparations are becoming increasingly common as new next-generation sequencing workflows are developed. Traditional quality control methods do not provide the required sizing accuracy of DNA greater than 50kb or the sensitivity allowing for sample conservation during the quality control assessment steps.

**Methods**
The Femto Pulse system by Agilent Technologies works to streamline quality control by separating genomic DNA up to 165kb in as little as 70 minutes, down from the 16+ hours required for traditional agarose PFGE. The unparalleled single cell gDNA sensitivity of the Femto Pulse allows for preparation of low input NGS libraries from cDNA, RNA, and miniaturized traditional DNA NGS libraries. Quality control metrics such as the RNA Quality Number (RQN) and user defined Genomic Quality Number (GQNN) aids in the determination of sample quality/integrity.

**Results**
This poster shows the unique use of the Femto Pulse System in high molecular weight gDNA separation and
low input library preparation with subsequent analysis features highlighted.

**P5B_10 - Sample QC With the Cell-Free DNA Screentape Assay**

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**Background**

Quality control of nucleic acid starting material is essential to ensure the success of downstream experiments. Especially, Next Generation Sequencing (NGS) developed to a powerful tool in almost all genetic research and diagnostic areas. Due to the establishment of low input library protocols for NGS workflows sequencing of cell-free DNA (cfDNA) became possible. Since the downstream applications are often time-consuming and expensive, tight QC steps are required to ensure that samples are “fit for purpose”. These QC steps can be performed with automated electrophoresis systems.

**Methods**

Different cell-free DNA samples were evaluated for sample quality with an Agilent 4200 TapeStation system and the Agilent Cell-free DNA ScreenTape assay.

**Results**

Depending on preanalytical sample treatment or extraction methods the quality of cfDNA can vary. The results include a score to qualify cfDNA samples according to their contamination level with high molecular weight material. This allows defining a threshold for objective sample qualification prior to library preparation. Moreover, accurate quantification of cfDNA samples is essential to determine suitable input amounts for cfDNA library preparation prior to sequencing.

**Conclusion**

Quality control of cfDNA is essential to ensure the success of downstream experiments. Automated electrophoresis systems standardize sample quality control and enable objective sample integrity assessment as well as the establishment of quality thresholds.

**P5B_11 - Quality Control of DNA and RNA Samples Using the 4150 Tapestation System**

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**Background**

Quality control (QC) of RNA and DNA samples is key for the success of any downstream experiment. Especially, Next Generation Sequencing (NGS) developed to a powerful tool in almost all genetic research and diagnostic areas. Since the downstream applications are often time-consuming, expensive and generate a lot of data, tight QC steps are required to avoid a “garbage in-garbage out” situation.

**Methods and Results**

The ideal QC solution is easy-to-use, economical and provides fast and unambiguous results also for very low concentrated samples. Nucleic acid quality assessment can be standardized using automated electrophoresis systems to ensure that samples are “fit for purpose”. Quality scores enable impartial sample comparison and allow defining a quality threshold for specific types of samples or preparation. For the objective quality evaluation of gDNA and RNA, the quality scores DNA integrity number (DI	extsubscript{N}) for gDNA and the RNA integrity number equivalent (RIN	extsubscript{e}) for RNA can be assessed providing numerical values from 1 (degraded) to 10 (intact) for classification of samples. This poster exhibits the latest developments in nucleic acid sample QC and gives application examples – from gDNA and RNA to NGS libraries - evaluated with an Agilent 4150 TapeStation system.

**P5B_12 - A Comprehensive Portfolio for Quality Testing of Clinical Samples to Test Novel Automated Stage Systems**

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**Problem**

The development of an automated cryogenic storage system for organic samples (AKELOP) is a joint research project funded by the European Union and the state Schleswig-Holstein. The project aims to develop a novel, highly flexible, integrated and highly energy-efficient
system for the permanent storage and fully automated handling of biomedical samples in the cryogenic sector. Research of preanalytical parameters in the context of clinical biobanking by means of DNA, RNA and protein analysis enables quality testing of clinical tissue and fluid samples for downstream molecular biological analyses of routine diagnostics and clinical research.

Solution
We established a comprehensive portfolio of methods to investigate the quality of biomedical samples under various storage modalities on a molecular basis at different regulation levels. This portfolio covers analysis on DNA (OD260/280 ratio, OD230/280 ratio, dsDNA amount, degradation), RNA (RIN) and protein level (chelation, SOD level, catalase level, LC-ESI-MS/MS).

This data will be faced to samples stored in AKELOP to examine effects of a discontinuous cold chain caused by manual sample handling on sample quality.

Discussion
It is of outstanding importance to provide standardized methods for quality testing to ensure reliable results of routine diagnostics and scientific research on clinical samples. This might be even of more importance for hospital integrated biobanks enabling precision medicine.

P5B_13 - FTA as an Alternative in Biomedical Research for Obtaining Nucleic Acids from Blood Stored at Room Temperature

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Background
Cold as a method of long-term conservation of biological samples for research purposes has been questioned in recent years. This item, together with the storage problems that human samples biobank repositories have at present, has produced the search for alternative matrices which can be conserved at room temperature. Preliminary studies on FTA card have shown that this matrix can be a good alternative in biomedical research.

In this study, blood for FTA cards was obtained from 10 healthy volunteers. DNA and RNA extractions were performed using two different methods: QIamp DNA mini kit (Qiagen, Germany) and a manual method, for DNA; and Monarch Total Miniprep RNA Kit (NEB, USA) and Trizol method (Invitrogen, USA), for RNA. Nucleic acids purity and integrity were analyzed by spectrophotometry and agarose gel, respectively. Functionality was assessed by PCR amplification.

Results
Quality of DNA extracted from FTA was assessed by spectrophotometry. Results showed statistical differences between methods used for both nucleic acids. However, functionality performed was positive in all samples tested regardless of the extraction method.

Conclusion
Quality study performed in FTA showed that manual methods are better to obtain a better performance in the obtained nucleic acids. However, the quality markers seem to be somewhat better in the extractions performed with the commercial kits. However, deeper studies with different methods should be done to optimize the technique.

P5B_14 - High Quality DNA Samples in FinnGen Project

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The FinnGen research project, launched in autumn 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. The project will benefit all parties; genomic data produced will be returned to the biobanks and can be widely used in future projects. Data also remains available for researchers and companies. Sample management in FinnGen project meets high requirements because large cohorts of population and disease samples have 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. During the first year of FinnGen project, THL Biobank has received nearly 60K DNA samples from other Finnish biobanks and has normalized, plated and distributed over 100K DNA samples for genotyping. Depending on weather old decades ago extracted samples or newly extracted ones from ongoing researches are being processed, different techniques in quantity and quality controls are needed. On average almost 99% of the THL processed samples have passed the quality control of genotyping analysis provider. THL biobank has been a pioneer in biobanking collecting large cohorts of samples since the 70’s. Strong experience, skilled professionals and well-designed infrastructures are all needed to handle sample logistics on such a large scale as in FinnGen project.

P5B_15 - Mitigating the Risk of ‘Lost Labels’ on Biobanked Samples

Thurogood, M
Brooks Life Sciences

Prior to biologic samples being stored in a biobank, collection sites can record specific tracking information on a primary vessel using labels, referenced here as ‘Custom Information’. This custom information can be; patient specific, site specific or even internal custom tracking numbers and can be crucial to retain when storing and tracking a sample. Upon reaching a biobank or store, these primary vessels are often aliquoted into smaller volume sample tubes, with the custom information from the primary vessel printed on labels and affixed to the new, aliquot tubes. This creates a highly labour-intensive tracking and retrieval process when specific samples relating to a specific collection, recorded on a label, need to be retrieved. Using printed labels also creates reliability issues if labels are lost, damaged or unreadable. Using non-coded tubes with a printed label can pose multiple risks if the label is damaged, lost or unreadable:

- Sample waste due to the inability to guarantee sample ID
- Lack of audit traceability
- Throughput restrictions based on highly manual processes

P5B_16 - Maintaining Optimal Sample Quality During Transportation

Wolfenden, C., Montano, D.
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Cryogenic samples such as eukaryotic cell-based therapeutics require storage at temperatures below the threshold for the glass transition phase of water (Tg-H2O, approximately -135°C). Storage under those conditions avoids biological activity and minimizes loss of post-thaw cell viability. Keeping eukaryotic cell solutions at temperatures higher than Tg-H2O introduces serious risks. When encapsulated liver cell spheroids were stored at -80°C, decreased viable cell numbers and cell function were detected after just one month of storage compared with the same cells stored at -170°C. Liquid nitrogen (LN2) and its vapor phase provide a safe environment for such samples, maintaining temperatures at around -170°C or lower. LN2, first produced in 1883 by Polish physicists, is now used as a coolant in many industrial environments from computers to cameras – and superconductors to vacuum pumps. It is indispensable in any research that involves cryogenic samples. Cryopreservation allows researchers to store biological samples for years without compromising sample integrity.

P5B_17 - A Comparison between Automated Storage Refrigeration and Manual ULT Technology Identifying Improvements in Temperature Uniformity to Protect Sample Integrity

Wolfenden, C., Montano, D.
Brooks Life Sciences

Problem
Exposing samples repeatedly to temperatures above -80°C for prolonged periods of time can degrade sample integrity. Sample storage technology usually involves temperature recovery following a door opening. Prolonged periods of temperature elevation due to lengthy recovery periods can affect your samples' viability. Surprisingly, it is quite common for upright ULT freezers to have temperature variances of up to 30°C between the top and bottom. Samples should be stored at uniform ULT temperatures to maintain viability.

Solution
A comparison study between manual upright ULT -80°C Freezers using compressor-based technology was compared with ULT chest freezer technology and the
MaxCool Refrigeration in an automated sample storage system. Technology used in an automated store has many benefits over Typical 2-Stage Refrigeration, as the MaxCool Cryochiller washes samples with cold air and can achieve -150°C without going below 1 bar. Temperature recovery is also superior, due to exposing less than 1% of the storage environment, for less than 8 seconds per tray pick, reducing time needed for recovery back to operating temperature.

Conclusion
This results in a high level of sample temperature stability, air temperature uniformity and is more consistent, with less than 1% of the surface area of the tile wall opens at any time when removing samples from the -80°C storage environment. This process, which is thermodynamically more efficient than a multi-stage cascade process when compared with manual ULT freezer technologies, offers greater sample and environment temperature stability, more favourable operating conditions, lower maintenance and greater reliability.

P5B_18 - Pathway to SBP Compliance Review Program
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Background
SBP compliance review program is a recent development. Preparing biobanks for accreditation to the new ISO 20387:2018 may be difficult, as many elements required need to be established for the first time.

Methods
SBP compliance review program is a national initiative designed to address minimum standards in biobanking across Switzerland. The compliance review methodology is based on the ISO 19011:2018, including the principles of auditing, managing an audit programme and conducting management system audits.

Results
SBP has developed a 3-step approach to implement its program. The first step introduces the primary tool at the basis of the compliance review, the biobankSQAN. The biobankSQAN serves as a tool for organizing thoughts, an outline for findings, and a focal point for discussion among team members on the progress of the work. The second step assures that the compliance reviews are performed in accordance with the Ethical and Legal requirements and the Good Biobanking Practices and provides guidance on documenting the compliance review. The third step bring a compendium of standard operating procedures (SOPs) templates for documenting the findings and are proposed after each compliance review to support biobanks meeting the SBP minimal requirements.

Discussion
Conducting compliance reviews assure that biobanking practices are consistently applied for the good management of samples, ensuring their high quality and reliability. Proper biobank organizational and procedural work, evaluated through SBP compliance review program, will make biobank eligible for the new ISO 20387:2018.

P5B_19 - Comparative Study of DNA Obtained from Whole Blood and Buffy Coat using Two Different Extraction Protocols
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Background
Whole blood (WB) and buffy coat (BC) are usually stored in biobank repositories and are very appreciated by researchers because DNA and RNA can be obtained from this type of samples. Some preliminary studies on DNA/RNA extraction from human samples have been performed, but a comparison between different extraction methods would be of great interest to researchers.

Methods
In this study, peripheral blood was extracted by venipuncture from 10 healthy volunteers. Then DNA was obtained from BC and WB. Nucleic acid extraction was performed using two methods: a) using Gentra Puregene
Blood Kit (Qiagen, Hilden (Germany)) and b) a method based on this same protocol but with some modifications to process buffy coat.

Results
Quality of the DNA obtained was assessed by spectrophotometry and agarose electrophoresis. Functionality was assessed by PCR. Results showed significance differences in the efficiency of the DNA extracted from BC and WB with the first method. No statistical differences were found with the modified method. Additionally, the integrity and functionality of the samples were not altered with the method used.

Discussion
Data obtained in this study showed that WB is better than buffy coat to obtain nucleic acids in samples using Qiagen method, but when the modified method is applied, the origin matrix does not matter. However, modified method is more efficient and has a lower cost than Qiagen method. This could be applied at the biobank repositories to optimize the storage conditions, and at the scientific advisory process of the researchers in their projects.

P5B_20 - STR Profiling for Cell Line Authentication Service at the Interlab Cell Line Collection of CRB-HSM (Genoa), a Biobank of the Italian Node of BBMRI-ERIC

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Cell lines are a useful model to study biology and physiology of normal cells and mechanisms of disease development. Their correct identification is essential to ensure experimental rigor and to avoid errors caused by cell line misidentification. The International Cell Line Authentication Committee (ICLAC), a voluntary scientific committee, aims at promoting the authentication testing as effective way to combat the problem and to disclose false or misidentified cell lines to researchers and cell line biorepositories. It curates the Database of Cross-Contaminated or Misidentified Cell Lines (http://iclac.org/databases/cross-contaminations/), including more than 480 cell lines. To reduce the impact of misidentified cell lines in research, scientists should check the database before they start working with a new cell line. Misidentified cell lines can be detected by authentication testing, that became mandatory for publication in scientific journals. Short tandem repeat (STR) genetic profiling has become the international standard (Standard ANSI/ATCC ASN-0002-2011 Authentication of Human Cell Lines: Standardization of STR Profiling). The Interlab Cell Line Collection of CRB-HSM in Genoa provides the service of cell line certification according to the standard. Fifteen highly polymorphic STR loci plus amelogenin are used. Detection of amplified fragments is obtained by ABI PRISM 3100 Genetic Analyzer and data analysis is performed by GeneMapper software, version 4.0. The STR profile obtained is checked against the Cell Line Integrated Molecular Authentication database (http://bioinformatics.hsanmartino.it/clima2/). Each new profile is compared with all profiles contained in the database (4,485 distinct names, 5,587 distinct profiles).

P5B_21 - Cord Blood Serum Quality Assessment after Biobanking

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Human cord blood serum (CBS) is a noninvasive source of protein biomarkers. CBS accumulates the cells secretion and decay components associated with the pathological processes progress or regress. Moreover, CBS is simple in obtaining, thus it is promising in monitoring the human health state from the birth moment and studying the external factors influence. Thus, CBS cryopreservation is of great necessity. However, the low-temperature storage may cause protein damage, leading to wrong conclusions in biomarkers research. Therefore, development of the adequate methods for cryopreserved CBS quality assessment is urgent. CBS samples (n=7) was aliquoted and frozen down to −20 °C (1–2 deg/min) and −196 °C by plunging in liquid nitrogen and stored for 6, 12 and 24 months. CBSs were separated on a 24 cm column with Sefadex G75 using gel-chromatography method. Protein structure stability in obtained CBS fractions were studied, analyzing protein intrinsic fluorescence spectra. It was shown that freezing down to −20 °C and subsequent storage led to significant
changes in the protein composition distribution by molecular weights and changes in fluorescence parameters. The freezing of the CBS to −196 °C and subsequent storage allowed us to keep the CBS in a state close to the native one. Gel chromatography and analyzing protein intrinsic fluorescence spectra allowed us to determine differences between samples stored at different temperatures confirming their possible applicability for biobanked CBS quality assessment.

**P5B_22 - Assessment of the Suitability of RNA Extracted from Archived FFPE Cervical Tissue Blocks for Use in qRT-PCR**

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Formalin-fixed paraffin-embedded tissue (FFPET) is a potentially invaluable source of tumour RNA. Although available commercial kits may yield RNA of adequate quantity and quality for molecular assays, the variation between kits requires verification for RNA extraction from FFPET. This study used archived FFPET blocks from between 2015 and 2017 to assess the suitability of the Qiagen® miRNeasy FFPE kit for extracting mRNA and miRNA for use in quantitative real-time PCR (qRT-PCR). RNA was extracted from sections of 40 FFPE cervical tissue blocks with a diagnosis of cervical intraepithelial neoplasia or invasive squamous cell carcinoma or adenocarcinoma and quantified with a Qubit fluorometer. The RNA quality was assessed using spectrophotometry and micro-capillary-based electrophoresis. Human GAPDH mRNA expression was used for detection of high abundant transcripts, whereas HPV 16 and HPV 18 E6/E7 mRNA expression was used to detect lower abundant transcripts. Expression of U6 miRNA, miR-21, and miR-595-p was also investigated. Seventy-five percent of the samples yielded sufficient concentrations and quality of RNA. GAPDH mRNA was measured in all samples. HPV 16 and HPV 18 mRNA transcript expression occurred in 20% and 8.5% of samples respectively. Only 71% of samples were suitable for miRNA detection, showing U6 and miR-595-5p in 100% and miR-21 in 69% of the samples. The quantity and quality of mRNA and miRNA isolated from the FFPE cervical tissue blocks were sufficient for the detection of high and low abundant mRNA transcripts and miRNAs using qRT-PCR.

**P5B_23 - Biorepository Management at Clinical Laboratory Services**


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Management systems are required to uphold accepted standards and ensure stringent regulatory requirements are met. The use of advanced technologies, integrated informatics solutions and the adoption of standardized, validated protocols are critical in biorepository operations. Clinical Laboratory Services (CLS) biorepository is an entity that receives, processes, stores and distributes biospecimens. The biorepository is a custodian of biospecimens and plays a vital role in the clinical trial space in South Africa by processing, storing and providing biospecimens of high integrity and quality. A robust quality assurance system is the corner stone of biorepository management at CLS and is in place to ensure that the quality and integrity of biospecimens are maintained. The quality assurance system extends to the planning, implementation, documentation, risk assessment, and improvement of the biorepository processes. A quality management system that monitors processes will lead to efficiency in operations and in costing and ultimately promote long term development and sustainability. Laboratory Information Management Systems (LIMS) are essential in biorepository operations. CLS makes use of the following LIMS: Meditech, LDMS and STARLIMS. These are purpose built customized LIMS for the biorepository and offers chain of custody tracking, security, interconnectivity, instrument integration and data management capabilities. These are necessary to manage an ever increasingly complex research requirements and large-scale biospecimen collections. Biorepository management requires a quality assurance system for: • policy and procedure development • stringent review of documents and procedures • Assessments and audits These processes provide the assurance that traceability and sample integrity is maintained throughout

**P5B_24 - Monitoring Sample Quality in Serum and EDTA Plasma, Through 25 Years, Stored By - 80 °C**
Background

Biobanks are an important resource in research. The quality of the materials stored in a biobank is crucial. To document the integrity of samples after both short time and long time storage, we have started a project for monitoring the sample quality up to 25 years, stored at -80 °C.

Methods

In this first step of the project, we have collected blood samples from 12 patients, both serum and plasma. 9 parameters were measured in serum, and 8 in EDTA plasma, due to that Potassium is added in the tubes. The parameters are; Na, K, Asat, Albumin, IgG, T.Bil, CRP, and Fe. The first measurement was at baseline, the same day as collection. The total amount of material was divided into 25 alliquots of 250 ul, to avoid extra thawing and freezing cycles. The second measurement was done after 6 months, the 3th after 12 months, and then analyzed every other year up to 10 years, and then subsequently every third year up to 25 years. Statistics; paired t-test with Bonferroni coecction. The measurement was done by the accredited laboratory at the Department of medical Chemistry, Oslo University Hospital, Rikshospitalet.

P5B_26 - Introduction of a Uniform Quality Control System for All Stages of the Functioning of National Biobanks

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Background

A uniform quality control system is a key step for controlling all stages of Biobank's operation. The implementation of such a solution will ensure that the samples and data collected by Biobank are of high quality and can be used for scientific purposes.

Methods

As part of the project implementation 5 Biobanks will collect a minimum of 500 samples of biological material. Quality control will take place in two stages. In the first stage, material assessments and collected data will be performed by internal teams in each of the biobanks. Then, the National Lead Center will conduct an analysis of the quality control results from each unit. A complement to this validation will be participation in the external laboratory quality control program for biobanks and biorepositories.
Results
The project activities will result in the creation of standard operating procedures which will describe every step starting with collection of material, through, transport, preparation and storage. SOPs will also include technological and technical quality control records regarding i.a., transport temperature, fractionation conditions. In addition, a report about the health condition of inhabitants of individual regions of Poland will be published.

Discussion
The development of a uniform quality control system will not only ensure the integrity of solutions in the field of Quality Management System, but also the use of consistent processing methods and ultimately enable minimization of errors during material processing.

Acknowledgments
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TOPIC 5C: IS YOUR BIOBANK HEALTHY?

P5C_1 - Increasing the Visibility of Biobanks Using Public Relations – Experiences from the Leipzig Medical Biobank

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Problem
Visibility is one of the major challenges even for sustainable biobanks. Various tools are needed to address different stakeholders to gain knowledge about and awareness for biobanks and their sample collections.

Solution
The main instruments used at the Leipzig Medical Biobank (LMB) are guided tours and lectures addressing students, staff and the general public. The LMB also participates at public events like “the long night of sciences”, open house days or the seniors academy. Together with the University Leipzig and Business Development Saxony also workshops with industry partners have been conducted to foster contacts.

Discussion
Within the last months more than 220 people participated at guided tours for staff of the University Leipzig and the University of Leipzig Medical Center. Professions ranged from employees from administration, PhD students and researchers to work group leaders. Such tours were also conducted for industry. The main aim is to advertise the sample collections of the LMB and to show how important standardized sample collection, processing and storage are for research purposes. Lectures for medical/science-oriented students and medical staff mainly focus on preanalytical problems in research and aim to improve awareness of upcoming generations of researches and staff collecting biological samples. In public events mainly potential sample donors were addressed to inform about biobanking in general and how biobanks can help for future developments in the diagnostic and therapeutic area. Our public relation efforts got good feedback and also some new projects have been realized due to the tours.

P5C_2 - SBP Labels as an Incentive for Swiss Biobanks’ Fundings?

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Background
Swiss Biobanking Platform (SBP) is the national coordination platform which supports the research community for the optimal usage of its biological resources by fostering quality and harmonization of practices. The term sustainability often refers to financial self-sustaining. However, in the evolving field of biobanking, this restricted definition needs practical solutions, tools and strategies to also address its operational and social dimensions.

Methods
Using the biobank SQAN, biobanks are evaluated for their compliance with the ethical/legal requirements and their quality standards (e.g. ISO 20387:2018). This compliance review issues three possible labels (i.e. Vita, Norma, Optima) reflecting the biobank compliance level with the SBP requirements. The labellisation process is completed by the evaluation of the preanalytical data documented by the biobank using SBP datasets to support sample quality and biobanks’ interoperability.
Results
By using these labels as a basis to a funding incentive, SBP proposes a framework to allow more effective discussion and actions around approaches for supporting high quality biobanking and sample sharing. This strategy will be developed with the Swiss National Science Foundation (SNSF) whose goals are the promotion of FAIR samples in reference with the principles applied for Research Data Management and the submission of a Data Management Plan as a prerequisite of the SNSF funding application.

Conclusion
Labellised biobanks will serve the research community by increasing users’ trust and enable reliable and high quality research. This funding process paves the path towards the professionalization of biobanking activities and will contribute to Swiss biobank sustainability.

P5C_3 - Comparative Study on Different Sub Banks in Platform-Based Biobanks of General Hospitals
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Background
With more scientists’ awareness of the importance of biobank resource, biobanks are facing an issue about large quantity and small utility. Especially in Chinese general hospitals with a huge number of patients. As a result, it is vital to find a way to evaluate the comprehensive performance of different sub banks in platform-based biobanks of general hospitals. After finding out the reason that make a sub bank perform better, we could guide scientists to manage their biobank resource more efficiently.

Methods
We conducted a comprehensive analysis of all these sub banks from three aspects, including specimen incoming, specimen application and specimen quality as well.

Results
A total of 77 sub banks were included in this study, with 22 (28.57%) project-based banks and 55 (71.43%) reserve banks. There was no significant difference in specimen incoming score between project-based banks and reserve banks. Project-based banks scored significantly better than reserve banks in specimen application [(50.7±30.1) vs. (47.6±29.9), P=0.1614] and specimen quality [(100.0±0.0) vs. (94.5±22.9), P=0.0444]. Project-based banks had a significantly higher comprehensive score than reserve banks [(62.5±14.8) vs. (57.9±17.9), P=0.0077].

Discussion
Project-based sub banks’ comprehensive performance is better than reserve banks. Steady staff and well-directed SOP might be two factors which influence performance. Further regression analysis would help us find more factors that make a sub bank have better performance.

P5C_4 - The Value(S) of/in Infrastructuring the Biosciences: Reflecting Biobanking from a Social Science Perspective
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Biobanks have become core facilities that collect, store, and organize access to a large variety of human/biological materials and data. Being a technological infrastructure it is not simply based on a predefined set of ethical/value related principles to be followed, it also takes part in shaping and realizing them. This presentation puts the concept of infrastructuring at the core of our reflections in order to focus attention to the processes that bring biobanks to life. This means being attentive to the many practices related to the life of a biobank such as anticipating, designing, donating, transforming, maintaining or standardizing. Looking at these practices, we will specifically reflect how values get expressed or how value is generated through them. This poster thus seeks to foreground these ways in which values matter in biobanking. It maps the multiple value generation and valuation practices involved in the process of building and sustaining biobanks, and discusses the dynamic relations between them. Its arguments will be grounded in a review of the social science literature, but also in the engagement with those building/running, donating to or using biobanks in Austria. Value-related practices have implications for
our understanding of biobanks and for their governance. In particular, we will argue that understanding the expectations and concerns different actors voice, why they might find it worth contributing to, using or supporting it, but also the work invested in creating these “value-able” resources for biomedical research, is essential to make biobanks societally and scientifically sustainable.

P5C_5 - Evaluation of Regular User Satisfaction Survey in the German Biobank Alliance

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Introduction
To ensure continuous improvement of biobanking quality as requested by the DIN EN ISO 9001 and 17020, the biobanks of the German Biobank Alliance (GBA) conduct regular user satisfaction surveys with researchers and clinicians.

Methods
In 2017 a GBA-wide user satisfaction survey was developed and send to all user of 11 biobanks. After minor revision a second round of this survey was conducted in 2018 asking the user in addition how they got in contact with the biobank and the impact of the biobank service on their project. By now, the survey results of 460 users of eight biobank sites were analysed by themselves. The German Biobank Node compiled an overall evaluation of all biobank sites also including the data from the biobanks missing so far.

Results
More than 80% of the users stated that the samples and data contributed to the success of their research projects. In comparison, the importance of the biobank’s certification and accreditation is regarded as high by 64%, which is similar to the results of 2017. The proportion of first-time user who got aware of the biobank through colleague recommendations is still very high.

Discussion
The majority of users are very satisfied with the biomaterials, data and service provided by the biobanks. However, more awareness of existing biobanks is needed since a large proportion of users are attracted based on the advise of colleagues. Quality management of biobanks has gain much interest and certification/accreditation is increasingly regarded as important. An expansion of biobank services was wished by many researchers.

P5C_6 - Business Plan Biobank Antwerpen

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Introduction
Biobank Antwerpen was established in 2018 and harbours a wide variety of human biological sample collections. The biobank integrates the existing collections within the University of Antwerp (UAntwerpen) and the Antwerp University Hospital (UZA), estimated to amount several millions of samples. Its main objective is to contribute to translational, biomedical and clinical research.

Methods
The Biobank Antwerpen builds on Tumorbank@UZA which was set up in 2009 in the context of the Belgian National Cancer Plan Initiative and integrates the Center for Medical Innovation which was funded with the support of the Flemish Government. As the size and scope of the Biobank Antwerpen significantly increased, a business plan was developed.

Results
The Biobank Antwerpen was established as a centralized biobank with decentralized hubs which could be located within the own institutions, but were offered as a platform to neighboring hospitals, pharma and biotech. Funding was obtained from the supporting institutions to set up the biobank, but with a clear aim to reduce this centralized funding, to make a partial cost recovery from local researchers and to generate income through collaborations with third parties, including industry.

Conclusion
Today the Biobank Antwerpen is an independent service facility integrated within the department of Tissue-, Cell- & Biobank. The biobank works according to standard
operating procedures (SOPs) for collection, processing and storage of high-quality frozen and fixated tissue and body fluid samples, based on international guidelines.

**P5C_7 - Monitoring of Biological Sample Cohorts: Keep an Eye on Your Collections!**

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**Background**
Epidemiologically relevant cohorts are not always monitored in terms of patient number, incoming and outgoing samples as well as related costs and scientific output. To ensure adequate use of samples and long-term sustainability, Biobank Graz undertook a comprehensive monitoring of the liquid sample cohorts.

**Methods**
The “cohort monitoring” was initiated to determine and record the number of incoming and outgoing samples for each year as well as related costs for some of the most important cohorts managed by Biobank Graz.

**Results**
In total, twenty one liquid sample cohorts have been monitored yet. The rate of sample use has been very low for some cohorts (under 1%) and rather high (up to 19.4%) for some others. However, we keep in mind that the sample use is usually more important after collection. The average cost recovery of the monitored cohorts reached 11%.

**Conclusion**
This initiative has been very useful to readapt the collection setting. For example, we reduced for some cohorts the set of aliquots generated during collection. Biobank Graz is an academic non-profit biobank, however 11% of cost recovery found trough the investigation is still low. Consequently, several actions have been undertaken (update of the user-fee calculation, renegotiation of the cooperation agreement) in order to optimize the cost recovery and ensure long-term sustainability.

**P5C_8 - Highlighting the Biological Resources Through Cohort Profile**


Radboud Biobank, Radboud university medical center, Nijmegen, The Netherlands Strategic Management at Business Administration,
The Radboud Biobank (RB) is a non-profit research facility in a medium-sized university hospital which supports the collection, storage, and use of biomaterials of well-documented patients. Currently, the RB has about 500,000 aliquots comprising different biomaterials from near 40,000 unique participants of 60 sub-biobanks. In the current business model, participating departments cover all costs related to patient sampling and collection of biomaterials. The RB covers the costs of sample preparation, management, and storage. A fee based on the quantity and type of samples applies upon request for biomaterials. All revenues are used as return on investment. Our goal is to achieve a coverage of 30% of the total variable costs through income from issuances. However, is the current business model sustainable in the long-term? In collaboration with the Nijmegen School of Management of the Radboud University, we used the stakeholder engagement approach to develop the current business model based on a causal loop diagram. The advantage of this approach is that we not only show the components of the business model, but also we are able to display all cause-effect relationships related to the issuances. We also test the robustness of the business model given changes in funding of the RB and IT landscape. Our results showed that the legitimacy and viability of RB depend on the strategic options within the scenarios. Our approach identified the critical success factors in redesigning the business model towards a sustainable one. The approach and results will be discussed at the European Biobank Week.

P5C_10 - Social Sustainability of Biobanks in Latvia: Results of a Survey on Public Attitudes

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Background
Addressing information needs and concerns of donors, as well as building trust and raising awareness about biobank research in society is crucial for the successful functioning of research biobanks. The 2010 Eurobarometer study indicated a low level of public knowledge on biobanks in Latvia. We decided to repeat the survey in 2019 to explore public attitudes, concerns, and trust in biobanking and to monitor changes in public attitudes.

Methods
Conducted in March 2019, the survey included a sample (n=1017) representing the adult general population of Latvia aged 18 to 75. The survey questionnaire included questions on biobanks from the 2010 Eurobarometer study and some additional questions to analyse the public’s awareness on biobanks, general attitude towards biobanks, and hypothetical willingness to donate biological samples and provide personal data.

Results
The results of the survey indicate that public awareness on biobanks in Latvia has increased, e.g. in 2010, only 22.0% of respondents had heard about biobanks to compare with 25.6% in 2019. There is also an increase in readiness of respondents to provide personal data and biological samples to biobanks.

Discussion
Although the public awareness and trust in biobanks in Latvia has increased since 2010, it remains low in comparison with many other European countries. To ensure social sustainability of biobanks, the public awareness and trust has to be increased. Based on the analysis of the survey results, we have developed recommendations for increasing social sustainability of biobanks in Latvia, as well as proposals for future policies and legal framework.

P5C_11 - What are High-Quality Lighthouse Collections?

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Introduction
The benefit of biobanks emerges from linking high-quality samples to high-quality data. Access of academic/industrial researchers to cutting-edge samples/data is often hampered by missing transparency regarding the availability of samples and data. Despite huge BBMRI-ERIC efforts (e.g. BBMRI-ERIC Directory, Sample Locator/Negotiator), the support of local researchers and biobanks is needed to feed the
platforms with valuable information. BBMRI.at aims to engage highly motivated partners by highlighting “lighthouse sample collections” (LHCs) that serve as best-practice examples and highlight the benefits of (inter-)nationally visible high-quality collections. This abstract describes the development process of a criteria catalogue that enables the assessment of potential LHCs candidates.

**Material and Methods**
To develop a criteria catalogue for evaluating and identifying LHCs, the following steps were conducted: (1) Nomination of high-quality collections by BBMRI.at partners, (2) SWOT-analysis of nominees and identification of LHC criteria, (3) aggregation of LHC criteria catalogue (initial version), (4) discussion of LHC criteria catalogue in BBMRI.at consortium, (5) refinement of LHC criteria catalogue, and (6) documentation and dissemination of the LHC criteria catalogue. Results
The resulting criteria catalogue for LHCs tackles the following criteria dimensions of collections:

1. translational/international impact,
2. sample quality,
3. sample access,
4. number/types of samples,
5. data availability/quality,
6. legal/ethical standards, and
7. additional characteristics, such as governance, Open Science or a Unique Selling Proposition.

**Discussion and Conclusion**
A criteria catalogue for LHCs was developed that highlights financial, operational and social sustainability of sample collections and enables the evaluation and promotion of LHC candidature.

P5C_12 - Strategic Financial Sustainability Planning for Biobank in Latvia
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Introduction
Strategic planning of biobank activities is crucial for sustainable long-term financial stability and increased utilization of samples. The development of the business plan of the biobank is one step towards sustainable operation. Our aim was to develop a strategic plan for National Biobank – Genome Database of Latvian population to encompass national specifics and design plan to attain sustainable operational status in future that could help to integrate in larger international collaboration.

**Methods**
In-depth literature review was performed regarding biobank sustainability, business planning and operational models. The model that could ensure most operational stability and future development was created by combining several principles from the literature and integration of local level issues. The national features regarding local legal norms, financial availability and sample obtainment and processing procedures were taken into consideration to create the best prospective option using resources available.

**Results**
Our designed model of National biobank includes several adjustment to operational proceedings: (1) increase utilization of the samples and data, (2) optimize sample and data collection process, (3) adjust informed consent of the biobank to gain more flexibility in terms of sample types, data and use, (4) increase added value of the samples, (5) improve biobank quality management, (5) perform regular financial planning.

**Conclusion**
In Latvia, the biobank sustainability depends on flexibility to gain the most added value of the samples and data using the limited financial resources that could be achieved by careful financial planning and enrichment of initial collection or more strategic collection of new samples.

P5C_13 - Valuing Biobanks to Improve Sustainability
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Introduction
Despite the recognized importance of biobanking, sustainability challenges are common, and there are few published comparisons of biobank costs and outputs. Establishing an overall biobank value through costs/investments (‘economic value’), internal metrics (‘operational value’), and outputs (‘social value’) provides an opportunity to address biobank sustainability threats.

Material and Methods
An interview template was developed and invitations were emailed to 17 Australian cancer biobanks, of which 12 biobanks participated (open-access: n=6; restricted-access: n=6). Ratios of monetary to in-kind contributions, numbers of publications and clinical trials supported, and costs per supported publication were compared according to biobank access policy, funding sources and biobank size, during a defined reporting period.

Results
Preliminary analyses (n=2 open-access; n=1 restricted-access) indicate that ratios of monetary to in-kind support were higher for the two open-access biobanks (7:1 and 32:1) than for the restricted-access biobank (1:1). Open-access biobanks reported more research applications (n=13 and n=26 versus n=7), and higher estimated costs per publication (AUD $45417 and $40303 versus $18188). The number of supported publications (n=8 and n=18 versus n=8), median journal impact factors (6.68 and 12.05 versus 6.9), and clinical trials supported by open- versus restricted-access biobanks (n=10 and n=10 versus n=8) were comparable. Similar analyses will be presented for the remaining biobank cohort.

Discussion and Conclusion
Comparisons of biobank costs and outputs can provide useful measures of biobank value, and could also illuminate differences in the operations and contributions of open- and restricted-access cancer biobanks. These data can inform biobanks and their stakeholders on sustainability challenges.

P5C_14 - Introduction to Business Planning for Biorepositories
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Problem
Quality specimens from biorepositories are key resources required to support reproducible research. Sustaining biorepositories and these valuable resources requires robust management. There is a clear imperative for the use of quality human biological samples and associated data in basic, pre-clinical and clinical research. Importantly, the biorepository infrastructures themselves, which are often based in clinical and academic setting, must plan to meet and sustain ongoing and emerging needs for a range of quality specimen types and associated data for the stakeholders they serve. Consequently, biorepositories must ensure ongoing sustainability through sound business planning with the ability to adapt to future market requirements.

Solution
Based on recently published survey results on biobank business planning, it is clear biobanking business acumen is still in its infancy. We recently ran a workshop to highlight how Biobank business planning enables identification of future development opportunities for the biobank and potentially to the organization. In the business plan, the objectives of the biobank should be formulated and the measures to achieve them should be detailed. The core elements of the business plan include: a vision and mission, a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, information about the products & services the biobank is providing, marketing activities including stakeholder engagement, and risk and cost analysis.

Discussion
There is a need to establish biobank business plans to engage stakeholders, collection smartly, utilize specimens, and by doing so increase sustainability – financially, operationally and socially. This can be supported by educating biobanks about business planning techniques and processes.

P5C_15 - Cost Calculation as Prerequisite to Ensure the Sustainability of Biobanks within the German Biobank Alliance (GBA)
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Background
Biospecimens and related data are mostly collected in a healthcare and clinical research environment. Such activities for research purposes in general are not funded by health insurers but instead on an institutional or a project-related basis. However, the high investments that are necessary to run a modern biobank are only rational if sustainability of operations can be ensured. As basis for this, a detailed cost calculation is essential for every biobank. However, previous activities including a survey within the German biobank community have revealed that many biobanks do not deal with this topic in a systematic way.

Methods
To raise awareness amongst GBA biobanks, two workshops on cost calculation and cost recovery were organized with the aim to develop operational concepts including economic elements. Representatives from all 11 GBA biobanks were invited to share their experiences and knowledge.

Results
First, biobank-specific processes and services were defined and delineated against standard healthcare and research activities. Detailed cost analysis for biobank-related tasks, like sample processing, sample storage, DNA isolation or project management were discussed and a number of critical points were identified, e.g. cost recovery for indirect costs. Best practice models how to deal with these were discussed.

Discussion
The results of this analysis served as a common basis for the subsequent development of an aligned bottom-up cost calculation model that shall sustain and support the exchange of sample and data within the German biobanking community and other biobanking shareholders and help to ensure sustainability of the German biobanks.

P5C_16 - Transition from Collections to Biobanks: The Role of a Biological Resource Center
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Introduction

IRCCS San Raffaele Hospital is a clinical-scientific-university structure of international importance and of high specialization for several important pathologies with intense research activity. A Biological Resources Center (CRB) has been set up to support and coordinate the collection and storage of biological material for research purposes: a central biobank for processing, storage and redistribution of samples.

Methods
The model is based on a central biobank that processes biological samples and coordinates the activities of the hospital’s autonomous biobanks. Every new collection is subject to Ethics Committee approval, the biological material is sent to CRB by pneumatic post accompanied by a form and signed Informed Consent. Samples are processed according to SOP described and mapped in the San Raffaele Hospital quality system and to existing national and regional regulations of biobanking. All samples are tracked from their preparation to delivery and stored at controlled temperatures. Researchers apply for samples through a material transfer form both for prospective and retrospective studies. A Scientific Committee of pathology evaluates the requests for samples submitted to the CRB and releases the biological material, a clinical referent follows the project during its course. Using a WEB based platform, researchers can consult the lists of available biological material, book and share samples.

Results and Conclusion
Organized and shared collections of biological material are increased. The transition from multiple “collections of biological material” to “institutional biobanks” under a single coordination is proving to be a winning strategy for a correct optimization of economic and scientific resources.

P5C_17 - The Biobank Perspective: Gathering Input for Overarching Dutch Preconditions to Improve Biobank Sustainability
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Background
Many Dutch biobanks struggle with their sustainability. The resulting continuity problems are degrading preconditions for high-quality research. We need to create an environment that promotes sustainability by setting the right overarching national preconditions. To identify main challenges and potential solutions we collected the perspectives of Dutch academic biobanks.

Methods
We conducted two workshops with 22 professionals working at Dutch biobanks. Groups of seven or eight participants rotated along the workshops. In workshop one, participants discussed challenges and best practices. In workshop two, participants performed a problem mapping exercise to identify causes and sub-causes for a lack of sustainability.

Results
The main challenges the participants identified were: finding sufficient funding; deciding on older collections; obtaining long-term stakeholder commitment; handling regulatory changes; and differences in access, review, and sample release policies between institutes. During the problem mapping exercise the six main causes for a lack of sustainability were: 1) lack of a long-term business model; 2) variable sample/data quality; 3) current scientific reward system and focus on new instead of reuse; 4) constantly changing external factors; 5) too many biobanks; and 6) mostly project-based funding instruments. Furthermore, the participants discussed the poor image biobanks currently have and the lack of incentives for researchers to share their collections.

Discussion
In the next step we will conduct focus groups with users, to gain insights on their perspective. The results from both biobanks and users serve as input for multi-stakeholder follow-up events aimed at finding suitable overarching Dutch preconditions to improve biobank sustainability.

P5C_18 - The User Perspective: Gathering Input for Overarching Dutch Preconditions to Improve Biobank Sustainability

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Background
Many biobanks struggle with their sustainability. The resulting continuity problems lead to poor preconditions for high-quality health research. However, some challenges that prevent sustainability cannot be solved by individual biobanks. Instead they have to be addressed at an overarching level. But what challenges should we address at this overarching level? And what are potential solutions? To answer these questions we gathered the perspectives of academic and industrial biobank users. These perspectives serve as input for determining suitable Dutch overarching preconditions that promote the sustainability of individual biobanks.

Methods
We organised four focus groups of four to eight participants each, using a semi-structured approach. Three focus groups consisted of academic researchers from Dutch university medical centres and research institutes and one focus group consisted of researchers from the pharmaceutical industry.

Results
We gathered challenges, needs, and requirements from the user perspective. These insights can help increase the use of individual biobanks. Furthermore, the preliminary results show that users experience institutional and national policy obstacles (e.g. ethics approval, issuance policy) and funding problems that can only be addressed on an overarching level.

Discussion
This research is part of a larger project aimed at setting suitable overarching preconditions, additional to the efforts necessary at the level of the individual biobanks. We have now mapped the perspectives of the supply-side (BBMRI-NL Workshop, April 2018) and the user-side. The results from both sides serve as input for multi-stakeholder follow-up events aimed at finding suitable overarching preconditions that improve biobank sustainability.

TOPIC 6: BIOBANKING FOR PRECISION MEDICINE

P6_1 - Qatar Biobank
Qatar Biobank is a platform that will make vital health research possible through its collection of samples and information on health and lifestyle from large numbers of members of the Qatari population. Qatar Biobank, Qatar’s long-term medical health initiative, was created to give Qatar’s people better chances of avoiding serious illnesses, and to promote better health for our future generations. The Attached abstract aim to highlight Qatar Biobank effort in recruiting the right candidates (Qataris and long-term residents) using the right tools (strategic communication and social media) in order to create awareness among the Qatari community.

P6_2 - Electronic Patient Path (EPP) – A Systems Medicine-Based Therapy Decision Support System for Colorectal Cancer


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Background
The biggest challenge for personalized medicine remains the integration and interpretation of heterogeneous data sources to obtain the optimal therapy decision for a given patient. Here, we describe the concept and implementation of the Electronic Patient Path (EPP), a systems medicine-based therapy decision support system for colorectal cancer (CRC), which integrates clinical, biosample and research data.

Methods
For method development, a clinical data set of 3,325 colorectal cancer patients was available. The biobank management system CentraXX served as the backbone for an integrated database containing the different data types. A CRC “cause and effect” disease model was established by querying manually created CRC terminology with the semantic search engine SCAIView and encoding the results using the Biological Expression Language OpenBEL. To create topic graphs from publically available abstracts the Doc2Vec algorithm was used. Backward feature elimination and the random forest algorithm were applied for patient classification.

Results
The EPP software combines user-friendly visualisation of patient data with text mining analyses on scientific literature and classification algorithms using machine learning. The implemented text mining analyses include an interactive CRC disease model representing causal relationships between different biomedical entities (e.g. genes, drugs, pathways) and patient-specific topic graphs to discover alternative therapy options and relevant scientific literature. Furthermore, patients can be classified and compared to prototypical patients in an interactive principal component analysis.

Conclusion
The EPP software integrates CRC data from heterogeneous data sources and provides a user-friendly software solution to support physicians in the therapy decision for CRC patients.

P6_3 - Versatile 96-SNP Genotyping Panel Enables DNA Fingerprint and Sample Integrity Assessments in a Streamlined and Economical Microfluidics-Based Workflow

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The importance of reputable, well-managed biorepositories continues to grow. In 2017, EuroBioBank Network was made up of 25 biobank members from Canada, France, Germany, Hungary, Israel, Italy, Malta, Slovenia, Spain, Turkey and United Kingdom. Approximately 13,000 new samples are collected each year and 7,000 samples are distributed in Europe and beyond. The identity of samples and the integrity of the genomic data produced from their analysis are critical for execution of superior research. Particularly with complex, multi-phase studies, aliquots from a single specimen may be shared among researchers within a laboratory or with external collaborators and service providers, and move into and out of storage on numerous occasions. Standard operating procedures for sample traceability have been implemented by biorepositories for many years, but these practices are often limited to labeling, barcoding and careful storage of sample
The purpose of this study was to evaluate biomarkers such as stress-related hormones and brain markers in atopic dermatitis (AD) model. A researcher donated a model of atopic dermatitis, a C57BL/6J mouse treated induced AD by serum biochemical tests C-reactive protein (CRP), ELISA of stress-related hormones (Cortisol, Corticosterone), skin/brain histopathology and immunohistochemistry. Serum CRP levels were increased in the DNCB group and typical skin pathologic features of dermatitis were observed. The levels of cortisol and corticosterone increased in the DNCB group. In hippocampus, expression of inflammatory factors (Cox2, BDNF, GFAP) was higher in DNCB group. These results suggest that atopic dermatitis may cause stress and affect the brain by stimulated inflammation. This study was carried out using the resources of LAREB without sacrificing animals, showing that the resources of LAREB could be useful in the future.

P6_5 - The HROC-Xenobank - A High Quality Assured PDX Biobank of >100 Individual CRC Models

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Problem
Recent years’ research established that best to conserve the original tumor’s biological features in experimental models, and to predict individual treatment success, is using patient-derived xenograft (PDX) model panels. Due to their recognized importance for translational research and late-stage preclinical testing, there is a clear need for more academically-run PDX-biobanks containing high numbers of individual tumors.

Solution
Basing on our working group’s large biobank of colorectal cancers (CRC), we here describe the activities to establish a high quality assured PDX biobank of more than 100 individual CRC cases, including not only sufficient numbers of vitally frozen (N>30 aliquots), snap frozen backups (N>10) – “ready to use” and also paraffin embedded PDX tumor pieces. This resource allows histopathological examinations, molecular characterizations, gene expression analysis and the like, aiming at different interests. Especially the application of low-passage cryopreserved PDX for in vivo studies guarantees reliability of results due to the largely retained tumor microenvironment. For all cases, the molecular subtype was determined, a cancer hot spot mutation analysis was performed, and the genetic identity to the original tumor tissue was confirmed. The latter allows exclusion of ambiguity errors between the PDX and the original patient tumor.

Discussion
All relevant CRC molecular subtypes identified so far are represented in the HROC-xenobank. Of note, all models are available for cooperative research. Even more
important, matching patient-derived tumor and normal tissue samples are stored in the biobank of the original patient cases which served as starting platform.

**P6_6 - Prognostic Implication of Tumor Infiltrating CD3+, CD8+ and Foxp3 T Regulatory Lymphocytes in the Molecular Subtypes Gastric Cancer**

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**Background**

For gastric cancer, several studies have shown the strong evidence that intra tumor lymphocyte infiltration has direct effect on the prognosis of gastric cancer. However, the exact role of immunecells in gastric cancer remains unclear.

**Material and Methods**

In this retrospective study, Tumor-infiltrating leukocytes were measured using immunohistochemistry the subsets of T lymphocytes mainly, CD3,CD8 and Tregulatory cells forkhead box P3 (FOXP3) were performed on tissue microarrays (TMA) of a cohort of 183 intestinal type gastric adenocarcinoma patients treated in Turku University Hospital between years 1993 and 2012. The cohort clinical information was retrieved from the clinical database of Auria Biobank-Turku, Finland. Tumor classified into; Epstein-Barr virus (EBV)-associated (N=17), microsatellite instability (MSI) (N=18), Ecadheren related tumors (N=146), and Tp53 subgroups (N=17).

**Results**

Absolute numbers of CD3, CD8 and foxp3 positive T lymphocytes together with the average CD8/FOXP3 and CD3/FOXP3 was significantly correlated with the four molecular subtypes. EBV and MSI tumors were the most infiltrated tumors by the T lymphocytes. CD3+ and CD8+ T lymphocytes the most privilege immune cells (P=0.041), and in the EBV gastric cancer subtype were a predictive factor for prognosis (P=0.027).

**Conclusion**

Simple quantification of lymphocyte infiltration correlates differentially with different molecular subtypes, have different prognostic significance in each type, and helps in patient selection for future immunotherapy for patients with gastric adenocarcinoma intestinal type. Keywords: Tumor-infiltrating immune cells. Molecular subtypes gastric cancer. Overall survival

**P6_7 - Establishment of Cancer Biobank in Molecular Medicine Center, Medical University of Sofia for the Purposes of Precision Medicine**


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**Background**

The collections of high-quality human biospecimens such as tumour tissues, blood and other bodily fluids along with associated patients clinical information provides a fundamental infrastructure for cancer research and treatment. In precision medicine biobanks are the main resources for molecular profiling of solid tumour samples using highly throughput “omics” technologies.

**Methods**

In the frame of research projects we have collected biological samples from patients with solid tumours following the recognised standard operating procedures for processing and storage of biospecimens. In parallel we have built a database including patients’ clinical and epidemiological data. Sample tracking, workflow and overall biobank management has been guaranteed by LIMS. The biobank have been approved by the Ethics Committee, MU-Sofia. All participants confirmed their agreement for participation upon signing an informed consent. This work was supported by DUNK01/2/2009/NSF/MES.

**Results**

The cancer biobank of MMC has been accumulated as a product of the research activity of the oncogenetics group in collaboration with medical specialists from the major University Hospitals, National Specialised Hospital.
for Active Treatment in Oncology and Hospital “Nadejda”. The biobank consists of DNA/RNA, plasma and tissue samples from patients with colorectal, endometrial, breast, ovarian, prostate, lung, laryngeal cancer, brain tumours etc. Establishment of cfDNA and CTC biobank is on the way.

Discussion
The established cancer biobank will serve as a base for high throughput "omics" analyses for molecular profiling of solid tumours, stratification of patients for targeted therapies and for the discovery of new biomarkers for better diagnosis, prophylaxis and treatment.

P6_8 - Lower Saxony Unified Biobank
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Lower Saxony is the second largest federal state in Germany with the fourth largest population. Thus, it is necessary to join forces for precision medicine, especially in the case of oncology. Therefore, the Hannover Medical School and the University Medical Center Göttingen have to collaborate closely to set standards for cancer treatment and aftercare. In particular, this includes the area of biomedical research, where sourcing of high-quality samples with structured annotated data is a prerequisite for reliable research results. For this purpose, the well-established centralized biobanks at both university hospitals need to maximize cooperation. Because of the aforementioned requirements, the Lower Saxony Unified Biobank (LSUB) with the two sites Hannover and Göttingen enables the simultaneous search for samples and data from both locations and thus offers its users a wider spectrum of samples and data. The data sets and the sample collection and storage processes are standardized and coordinated, as both sites are also partners within the German Biobank Alliance. The LSUB uses a uniform broad informed consent based on the template of the national Working Group of Medical Ethics Committees. For greater acceptance among patients and users, however, it is necessary to have locally separate Use and Access Committees in place that operate according to agreed criteria. Establishment of a joint LSUB increases the use of high-quality samples and data. At the same time, involved clinicians decide on the release of these valuable resources, which increases the acceptance of the biobank.

P6_9 - BBMRI.It Working Group Related to "Biobanks and Precision Medicine"
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BBMRI.it has promoted three National working groups (WG) on different topics related to Biobanks and precision medicine: Human microbiota and biobanking, Metabolomics and biobanks, Liquid biopsy: types, techniques and perspectives. The online meetings are attended by 80 biobankers and researchers. The collection and storage of microbes from gut, mucosal tissues, respiratory system and other districts, along with their genetic and metabolic profiles is becoming increasingly important for therapeutic approaches and for researching a wide range of diseases. The “human microbiota and biobanking WG” aims to define procedures and protocols for the maintenance of Microbiota Biobanks with reference to clinical samples (eg. faeces, aspirates, biopsies, urine, blood) and derivative products: DNA, proteins. During the meetings, standardization procedures for human, veterinary microbiota biobanks and IT “ad hoc devices” are debated. Moreover, this WG allows to promote a survey on the Italian biobanks that collect microbiota samples and to activate a scientific-clinical collaboration network between microbiota biobanks. The focus of the “Metabolomics and biobanks” WG is on use of biobanks collections for metabolomics, development of preanalytical SOPs for different biosamples, data standards in metabolomics and quality control of biobanked samples. The “Liquid biopsy” group is focused on: nucleic acids (pre-analytical and analytical procedures, techniques for data normalization), circulating (tumor) cells (enrichment, isolation, molecular characterization), exosomes, quality of the results (how to safeguard and verify it), also involving Italian Scientific
Societies (position and guidelines, and options about prime time to clinics). The results achieved by the WGs will be presented.

P6_10 - Share and Utilize Laboratory Animal Resources with the Laboratory Animal Resources Bank (LAREB) on the 3R Principles

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The need to use laboratory animals is a large part of medical research and contributes greatly to scientific development, so the use of laboratory animals is steadily increasing. Likewise, as the use of laboratory animals increases in diverse studies, interest in the 3R (Replacement, Reduction, Refinement) principles has also been focused. Sharing of resources is an issue in many fields, and it is also in the field of experimental animals. Most researchers know that once they are done, they need a system that saves and shares various types of resources from laboratory animals. These systems and facilities that need to be shared and utilized with laboratory animal resources were made up of the Laboratory Animal Resources Bank (LAREB), which belongs to the National Institute of Food and Drug Safety Evaluation (NIFDS, Korea). Research using laboratory animals can result in high financial, physical and temporal cost for researchers. Considering these conditions, research using laboratory animals has many limitations in its accessibility. Therefore, recent movements have been made to reduce the use of laboratory animals and replace animal experiments. We believe that the resource sharing system that we provide meets the 3R principles of laboratory animal research and will help researchers in new ways.

P6_11 - The Europdx Research Infrastructure: Building a Distributed High-Quality Biobank of Patient-Derived Tumour Models for Precision Oncology


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Background
Most novel anticancer drugs fail during clinical trials, due to poor efficacy or limited number of responding patients. Faithful preclinical models to reliably predict treatment efficacy and discover biomarkers are needed for optimal development of new personalized treatments.

Methods
Patient-derived cancer xenografts (PDXs), developed by transplanting tumour fragments into immunodeficient mice, are increasingly recognised as clinically relevant models (Byrne, Nat. Rev. Cancer 2017). PDXs retain characteristics of original patients’ tumours and effectively recapitulate human cancers heterogeneity. Population-scale correlations between therapeutic response in PDXs and extensive molecular annotation has enabled biomarkers identification with immediate clinical relevance. Founded in 2013 as an initiative toward European integration of PDX collections, the EurOPDX Consortium now teams up with other academic and SME partners to build a cutting-edge Research Infrastructure for PDX research (H2020 grant 731105, www.europdx.eu).

Results
We are establishing a biobank of well-annotated PDXs in 6 state-of-the-art facilities, to offer access to these models to academic and industry researchers. This necessitates the harmonization of procedures for handling, analyzing and reporting PDX models (including metadata, molecular and pseudonymized clinical data), in order to deliver high-quality and reliable samples. Standards related to data tracking, biobanking of cryopreserved samples, health monitoring, and quality control, are established in collaboration with BBMRI.QM. Model annotation will be summarized in a PDX Passport. Standards will be disseminated widely in order to increase predictability and reproducibility of preclinical data in oncology.

Conclusion
We aim to improve preclinical and translational cancer research and promote innovation in precision oncology.

P6_12 - Application of Biobanked Specimens in Development of Exosomal Mirna Biomarker of Prostate Cancer


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Biobanks are essential for scientific breakthroughs in precision medicine leading to new treatments. Precision medicine research is based on the analysis of samples with clinical data- and, because the associations are often weak, we need these samples in large quantities. The implication is clear: if more, well-characterized, high-quality samples are available through biobanks, the faster research will advance and impact upon the faster delivery of precision healthcare today. The systematic collection of human samples of high quality is a key element for the success of future treatments. Furthermore, biobanks are already part of molecular tumour board process chains thus improving patient treatment individually. During this session, we will show examples and discuss how biobanks can facilitate and improve precision medicine now and in the future.

P6_13 - Primary Care Based Biobanking: A New Concept?

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Less than 1% of the population is seen in university based hospitals while most of the population seeking medical care are seen in a primary healthcare setting. Primary care (PC) fills a huge gap between the general healthy population and the university teaching hospital in provision of healthcare services. 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. 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. 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.

TOPIC 7A: HOW DO BIOBANKS SUPPORT CLINICAL TRIALS & PRECISION MEDICINE?

P7A_1 - How a New European Paediatric Translational Research Infrastructure (EPTRI) Could Support Personalised Medicine in Children


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Background

Personalised medicine is based on implemented developmental technologies derived by the use of biological products that are appropriately stored, managed and processed. Biological resources of paediatric interest are many but dispersed and
underestimated. Thus, innovative biological-based medicines in children are very few while promising in many fields (oncology, neurology, neonatology and over all rare diseases).

Objectives: to identify existing biological resources in the EU and establish a research network to implement personalised medicine in children and develop innovative medicines.

Methods
In the framework of ID-EPTRI, a new EU-Research Infrastructure focused on children, a large survey has been launched to identify competences, technologies, facilities and services to develop new biological medicinal products.

Results
73 Research Units (RUs) in 20 EU/ non-EU countries, able to provide the following services:
  1. Validation of biomarkers for paediatric use;
  2. Access to/ deposit of annotated human paediatric biological samples;
  3. Identification/ characterisation of biomarkers for paediatric use, adhered to the survey.
46 RUs currently collect biosamples of paediatric interest, with 20 institutions having biobanks exclusively dedicated to paediatric biosamples (Serum, Plasma, Cells, DNA, saliva, blood, stool, urine). For each RU, a detailed report on available core-facilities (genomics, transcriptomics, proteomics, high-throughput screening, etc.) will be available at EPTRI central Hub level.

Discussion
This analysis demonstrated the scientific relevance of the paediatric research in EU in the sector of personalised medicine. It will serve as a valid contribution for the design study of the new paediatric research infrastructure EPTRI.

P7A_2 - Biobanking Contribution in an Intensive Neurorehabilitation Hospital
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A Biobank strongly supports the scientific progress in the stratification of the population and in the discovery and validation of biomarkers in the context of Personalized Medicine. For these reasons Casa di Cura Privata del Policlinico (CCPP), a high intensive neurorehabilitation hospital in Milan, established the CCPP Biobank in 2015 as part of BBMRI.it, national node of BBMRI-ERIC. Our Biobank contains biological samples, such as plasma, serum, PBMCs, CSF, DNA and relative data from patients with neurological diseases, both of cerebrovascular and neurodegenerative type. Clinical, neuropsychological, motor functional evaluations are obtained at different timepoints. In addition, complete biological profiles are also obtained through the analysis of biological samples collected before and after specific treatments (i.e. cognitive and physical rehabilitation, or neuromodulation such as Transcranial Direct Current Stimulation). One of the main research aims of CCPP is the discovery of diagnostic and prognostic biomarkers in order to better characterize patients for Personalized Medicine. In the future CCPP Biobank will extend the collection of biological samples in the context of clinical trials to eventually predict how individuals will respond to therapies.

P7A_3 - Parel snoer – The National Infrastructure for Clinical Biobanks in The Netherlands
Parelsnoer Institute, partner of Health-RI, Utrecht, The Netherlands

Parelsnoer has started in 2007 as a collaborative biobanking initiative of the eight University Medical Centres (UMCs) in the Netherlands. Over the past decade, Parelsnoer has offered an infrastructure and harmonized procedures for the establishment, expansion and optimisation of clinical biobanks for scientific research. The UMC’s benefited from the developments within Parelsnoer by setting up their own local infrastructures for biobanking and research data. In order to work together to a national infrastructure for personalized medicine & health research, the so-called Health-RI, and to remain a valuable asset in life science research, Parelsnoer initiated a process that will result in an organization that is facilitating rather than steering multicenter clinical cohorts. Key to this will be two platforms directed at biobanking and IT/data in which all UMCs participate. These platforms will assist the UMC’s
with challenges, that are beyond the level of the individual UMCs. A cornerstone of the new design will be a federated data infrastructure, which not only collects but also stores the clinical data in the individual UMCs and brings them together only upon request. The decentralized data infrastructure will improve the data collection process for the researcher and will facilitate access to the collected data in a more easy and efficient way, which also complies with the FAIR principles. With these changes, the new Parelsnoer Infrastructure aims to meet the needs of the academic, biomedical research community and thereby becomes an important component of Health-RI for the development of multicenter clinical biobanks.

P7A_4 - Challenges and Pitfalls of Interoperability in Biobanks

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Background

Cooperation within the biobanking community is more and more crucial. Multicenter clinical trials, large national cohorts and the increased attention of the funding bodies - especially to tools that share and aggregate information about biospecimens to optimize their use for researchers - make it necessary for biobanks to assess the quality of samples and harmonize their protocols. However, despite all the standardization and harmonization efforts, interoperability between biobanks has its pitfalls and bottlenecks.

Methods

To validate and refine the processes across twelve biobanks, a ring trial concept was designed to control the quality of liquid biospecimen from whole blood and to assess the interoperability within the German biobank alliance during a use-case scenario. This concept included evaluating the initialization phase of the ring trial, compliance with preanalytical specifications, determining, and measuring quality biomarkers as well as evaluating SOPs from the individual biobanks.

Results

Despite general instructions and specifications, preanalytical conditions were still highly heterogeneous within biobanks - especially transport processes and temperature control before freezing proofed to be highly variable. In order to analyze quality biomarkers, workflows were established to deal with the diversity of cryogenic tubes and the resulting lack to use automatic sample picking. Interestingly, sample randomization was a significant bottleneck for analysis of liquid biospecimen from various biobanks.

Conclusion

Interoperability between biobanks of the GBA has proven to be very successful. However, to ensure high-quality biospecimen and easy usability for users of liquid samples from multiple biobanks, further harmonization, and standardization of equipment should be promoted.

P7A_5 - Rare Disease Biobank & Registry, Patient Association and Biopharmaceutical Company: A Successful Collaboration for Multiple Osteochondromas Disease


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Multiple Osteochondromas (MO) is an autosomal dominant disorder characterized by benign cartilage-capped bone tumours, (osteochondromas - OCs) causing pain, deformities and functional limitations that might develop a malignant transformation in 1 to 5% of the cases. MO is caused in 90% of patients by heterozygous mutations in EXT1/EXT2 genes implicated in the cartilage growth during endochondral ossification. Since 2003, Medical Genetic Department has initiated a process of biosamples storage and maintenance leading to the Biobank for Genetic Samples (BIOGEN) with a synchronous collection of patient information flown into the Registry for Multiple Osteochondromas Disease (REM). These two entities are working in concert to provide high-quality samples connected to high-quality data within a RRI horizon. The procedures for biospecimens and data collection and governance (according to ELSI standards) have been implemented
P7A_6 - Biobanks and Traumatic Brain Injury: Experience from CENTER-TBI


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The Comparative European Neurotrauma Effectiveness Research (CENTER-TBI: www.center-tbi.eu) is a large-scale observational study that, amongst others, aims to develop classification schemes to inform precision medicine approaches in traumatic brain injury (TBI). TBI is a field in medicine with huge unmet needs. In Europe, over 2 million people are admitted to hospital annually with a diagnosis of TBI, of whom more than 80.000 die. CENTER-TBI has enrolled over 4500 subjects with acute TBI and established repositories for neuro-images and blood/serum samples (Pecs, Hungary) for genetic and biomarker analyses. Biomarkers may aid an objective diagnosis of TBI, support triage for CT scanning, facilitate identification and tracking of disease processes and inform prognostic estimates. The CENTER-TBI biobank contains over 55.000 aliquots from over 3500 patients. Serum samples are being analyzed for a panel of 6 biomarkers: NSE, S100B, GFAP, UCH-L1, total tau and NFL. Preliminary results show a clear association of biomarker levels with care pathway, with CT abnormalities, and with clinical severity. Ongoing analyses aim to determine the best (panel of) biomarkers, differentiated by study question and to explore if biomarker levels may predict the occurrence of residual complaints after mild TBI. Detailed results will be presented. We anticipate that many outstanding questions in the field of biomarkers in TBI can be addressed in CENTER-TBI. The greatest opportunity may, however, lie in legacy research and collaboration with other biobanks, which may serve to promote standardization of sample processing and accelerate advances by facilitating meta-analyses in larger numbers.
results of the laboratory to take or not the treatment. Also, because some of the samples require to be processed in a specific time to be completely useful for the study.

Conclusion
The Biobank Platform has opened 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. Always guaranteeing the quality and traceability of the samples.

P7A_8 - Experience from Recruiting Finnish Biobank Donors for New Clinical Studies

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Introduction
THL Biobank (located in Helsinki, Finland) hosts 26 sample and data collections from ca. 180,000 sample donors. These versatile collections are divided into: (1) Legacy collections (1965-2013) transferred to THL Biobank following on a legal procedure, and (2) new collections based on donor’s written informed biobank consent. The biobank can contact donors to invite them to participate in new clinical studies, for which they are selected by using biobank data to meet project-specific criteria.

Methods
We developed a recruitment process, which ensures the rights and privacy of biobank donors. The process includes both ethical and biobank approval of the proposed study; agreement between the study PI’s institute and the biobank; contacting selected biobank donors by letter, and requesting permission to provide their contact information and specific data to study PI.

Results
We have conducted three recall studies and the fourth is underway. The criteria used for selection of donors included genotype, age, gender, lipid values, exclusion of certain diseases, smoking status, existence of previous samples, and place of residence. So far, THL Biobank has contacted >220 donors, and permission was obtained from 56% of them. Positive response was higher among donors who had given written biobank consent (75%) compared to donors in legacy collections (48%).

Conclusion
THL Biobank can greatly facilitate identification of suitable individuals for new clinical studies and help in the recruitment process. Finnish biobank donors are very supportive of research and are ideal participants in new clinical studies.

P7A_9 - From Samples to Data. From Biobank to Genomics

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Introduction
The Hospital-based biobanks are at the intersection of diagnostics, research, genomics, society, ethics and law. The development of patient samples’ patient collections with well annotated clinical and pathological data is one of the main requirements of personalized medicine advancement. Furthermore, emerging analytical technologies have resulted in complex processing workflows. Nowadays, genomic medicine is seen as a prerequisite for more personalized healthcare. Core Facilities of IMIM (Hospital del Mar Medical Research Institute) has a hospital integrated biobank (MARBiobanc) since 2011 and recently developed a new platform (MARGenomics) integrating all phases of genomic analysis: initial advice, nucleic acids extraction, genomics sample processing and final data analysis and results interpretation.

Methods
In order to integrate and interconnect these platforms, a Centralized Management Unit (CMU) has been created to take care of all MARBiobanc/MARGenomics requests sent via electronic platform opened to both internal and external researchers. The CMU staff schedule a meeting with researchers to design the project considering 4 main points of advisement (type of samples requested and ethic-legal aspects, nucleic acids extraction, genomic
processing and data analysis). Once designed it the CMU coordinates different steps of the genomic analysis from the beginning, preparing samples in the MARBiobanc, to the final data analysis in MARGenomics.

Conclusion

This kind of organization improves technical workflows between these two different platforms and laboratories. It ensures all ethic-legal requirements and a great feedback between different professional profiles allowing the process optimization in benefit of the biomedical research and future patient’s health.

P7A_10 - NMR as a Tool for Biobanks in Support of Clinical Trials and Precision Medicine

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NMR used under complete standardization allows fully automatic QC for biobanks, delivering a large number of relevant quality checks with one measurement. Adding spectral information and quantification to the metadata kept in a biobank, allows to retrieve spectra to be used in clinical trials e.g. as controls, such reducing the need to use new aliquots. Under standardization, multiple biobanks can deliver NMR spectral information worldwide to be integrated into one clinical trial. This means using spectra instead of aliquots for the trials. If longitudinal collections of human cohorts are available in biobanks, personalized metabolic profiles can be built from the NMR data, generating a health trajectory, whose deviations can be identified at very early time points, allowing e.g. dietary intervention to re-establish healthy metabolic trajectories.

P7A_11 - CASCADE: A Cancer Tissue Collection after Death Programme to Improve our Understanding of the Progression from Primary Stage Cancer to Metastatic, Treatment-Resistant Disease

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Background

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

Methods

Autopsies provide an opportunity to obtain a comprehensive survey of tumour deposits and relatively large amounts of material. For the past 7 years we have run a rapid autopsy in cancer patients called CASCADE and created a bank of metastatic tumour tissue matched with primary tissue and clinical data from 101 cancer patients to investigate mechanisms of resistance, discordant treatment response, metastasis, and cancer evolution using genomic and biological tools to facilitate precision medicine. Results: We conducted rapid autopsies on patients that died of advanced cancer and extensively profiled multiple lesions, which were compared to biopsies taken whilst patients were alive. We aimed to reconstruct the relationship between different metastatic lesions and understand the tumour cell subpopulations that make up metastatic lesions. Our findings reveal significant heterogeneity and evolution over time, which was shaped by treatment, mutational processes, and the interaction of these factors with alterations in cancer-promoting driver genes. Conclusions: Our study highlights various mechanisms that shape the genome of metastatic cancer. Treatment drives significant genomic heterogeneity in cancers which has implications for disease monitoring and treatment selection in the personalised medicine paradigm.

P7A_12 - Genotype First Breast Cancer Precision Prevention and Management, Initial Lessons from a National Pilot Project


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Background
Breast cancer screening is in transition from age- to risk-based management. The genetic component of breast cancer risk is caused by monogenic variants, as well as polygenic risk. In 2018, a national pilot study for genetics-based breast cancer screening and follow-up management in female participants of the biobank was initiated.

Methods
The study consists of monogenic and polygenic arms and involves two central hospitals in Estonia. Our primary aim is to estimate the feasibility of genetics first approach in a clinical setting, involving consenting participants, secure data transfer, counselling in different centers, etc. We also test the subject compliance and psychosocial aspects. In monogenic arm, cascade screening of relatives will maximise the impact of pre-existing genetic data in biobank. The study group consists of female participates 22-74 years.

Results and Discussion
In monogenic arm, 128 subjects with causative variants in 11 genes were identified. The clinical follow-up is based on adapted international guidelines. In polygenic arm, the participants with top 5% threshold were selected as high-risk group (HR 2.73, 95% CI 1.92-3.9). The females (n ~1300) will receive information about their genetic risk and biennial mammography will be initiated from age 40 to those below 50y age. To date, approximately 60 subjects have been counselled in monogenic arm and 350 in polygenic arm. We will present the data on study progress and compliance, cancer prevalence and age of onset in the study groups, as well as discuss the practical lessons learned along with perspective on public healthcare.

P7A_13 - Specimen Management in the PREVAC Clinical Trial

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Introduction
Partnership for Research on Ebola Vaccination (PREVAC), a phase II clinical trial assessing immunogenicity and durability of three Ebola vaccine strategies in adults and children, was conducted in Guinea, Liberia, Sierra Leone and Mali. Five years’ follow-up of 4,789 participants recruited in 6 country sites is ongoing. Approximately 300,000 aliquots consisting mostly of serum, but also peripheral mononuclear cells, total blood and saliva samples, will be generated throughout the trial. A portion of these specimens is expected to stay in countries for biobanking purposes.

Method
A working group that includes representatives of each organizations involved in PREVAC supervises specimens’ processing, storage and shipments.

Results
PREVAC samples are stored at -80°C. Sustainable storage structures with strong cold chain monitoring were installed in the 4 countries. Specimens are regularly shipped to analytical laboratories in Liberia, Mali, France, UK and USA. Shipments are organised in close collaboration with country authorities and framed by 8 material transfer agreements. Staff has been trained in performing shipments with IATA standards compliance. Thanks to a rigorous labelling system, specimens are easily tracked and reconciliation is performed after each shipment by Inserm-Euclid, the clinical trials unit.

Conclusion
It is essential to capitalize on the PREVAC experience for conducting large-scale multicentre future clinical trials in low resource settings. While potentially infectious specimens’ management was extremely challenging during the 2014-2016 Ebola epidemics, PREVAC has contributed in strengthening capacities in specimen management and has fostered collaborations between governments, research institutions, and pharmaceutical companies for specimen collection, storage and sharing.
P7A_14 - Centralized Biobanking Supports Hematology Clinical Trials: The New Challenge of the University of Torino

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Introduction
Academic and sponsored clinical trials need to rely on laboratory facilities expert in handling biological samples and data. The hematology division of the University of Torino (UNITO) has kicked-off a biorepository system, for specimens’ collection, from patients affected by Multiple Myeloma (MM), Non-Hodgkin Lymphoma (NHL) and Waldenstroem Macroglobulinemia (WM). Herein we present the first overview of data collected from February 2018 till April 2019.

Methods
Patients were enrolled in longitudinal multi-center clinical-trials after providing informed consent. Patients’ data were pseudonymized according to the GDPR. The reference laboratory collected data in ACID database. Data included: patient and center ID, withdrawal date, specimen type (mononuclear cells [MNC], CD19+/− and CD138+/− cells, plasma, serum and urine). Samples stock was performed according to trial-established procedures for clinical correlation with genetic and phenotypic analyses: FISH to predict cytogenetic risk, flow cytometry and molecular techniques for screening and minimal residual disease monitoring.

Results
Biospecimens were collected from 359 patients: 155 MM, 102 NHL and 102 WM for totally 6048 vials. MNC from both bone marrow (BM) (1352/2966) and peripheral blood (PB) (1614/2966), plasma (1910) and CD19+/− (395). Moreover, all samples were organized in dedicated boxes tagged according to each ancillary sub-study: e.g. liquid biopsy, clonal evolution and genomic profiling.

Discussion
We present the first biobank platform at of UNITO designed for clinical data merging. This project provides an effective strategy to optimize the sample storage and the selection of biological data retrieved from translational multi-centric clinical trial. A computerized integration with clinical data for precise prognostic analysis is ongoing.

TOPIC 7B: QUALITY ASSESSMENT AND MANAGEMENT OF DATA

P7B_1 - Opendataclinica as a Platform for the Exchange of Open Data from Clinical Studies and Biomedical Information

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Problem
Biomedical research makes it essential to integrate, standardize and harmonize the information that each node collects for its particular objectives. The use or lack of specialized programs makes it difficult or impossible to exchange data to generate new knowledge.

Solution
Opendataclinica is a new proposal for a web-based platform, for institutions and researchers, with emphasis on the management of biomedical research projects, their resources and the analysis of information. This platform available as a Software as a Service (SaaS) allows to collect and organize the information of any research project or clinical study through flexible forms and databases. It allows you to track your progress and manage informed consents. It uses pre-configured analysis tools directly from this platform or allows data sets to be exported in a wide range of formats for analysis with external programs. Export data using a series of predefined or custom filters. From the point of view of a biobank, it generates the collection and management of clinical medical information, as well as the storage of patients’ informed consent for compliance with safety regulations and current legislation. Each one is associated with the patient's clinical history and can be consulted to comply with the conditions defined therein.
Discussion
Opendataclinica is currently being used in a joint clinical study between a public hospital and a private clinic. The objective is to implement shortly the recommendations generated by the Research Data Alliance and the European Open Science Cloud to expand and standardize a truly open data integration.

P7B_2 - Medical Research Institute

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Background
Alexandria Cancer Registry (ACR) is a well-established central hospital based cancer registry collecting data from university hospitals , MOH, and health insurance hospitals to cover almost 90% of diagnosed cases with cancer. Data is collected active and passive ways and reviewed by well trained cancer registrars.

Methodology
Data abstracts include the minimal adequate items. Cancer registrars in ACR attended several continuous training activities in abstracting, case ascertainment and TNM coding to allow competence, reliability and accuracy of data through pathologists, oncologists, surgeons and radiologists in the registry board. Data manipulation and analysis are routinely by CANREG 5,0

Results
The last report in 2017, shows a total of 4550 confirmed registered cases. with a male to female ratio 1:1.1. The report shows the frequency of cases by systems, age and gender, followed by affected organs within systems. The most affected system was connective tissues and soft tissue including female breast cancer. The second most affected system was gastrointestinal system. Primary liver cancer replaced urinary bladder as the most frequent cancer among males with young age presentation. As a data bank, several research activities has been done in ACR as case control studies in collaboration with IARC. Several interesting findings will be discussed and explained during the presentation. We joined BCNet-LMIC. We also joined Egypt Biobank Network to fulfill targets of enhanced understanding of cancers.

Discussion
The appropriate data quality of cancer patients in cancer registry along with good biological specimens are considered a pillar to establish a biobank .

P7B_3 - A Documentary Workflow Solution for Hospital-Based Biobank Data Management

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Several challenges are encountered in efficiently managing a large-scale hospital-based biobank for research. We proposed a centralized documentary management system to provide a sure linkage between international biobanking regulations and health data integration, on the road to personalized medicine. Following the International Project Management Standards, we used a web-interface to collaborate and share information about project's tasks. Visio™ was used for diagramming the biobank workflow, based on what described in the SOPs. We adopted an enterprise content management platform (OpenText™ Documentum™) – currently used to build customer-specific applications for clinical data management – that allows us to manage contents while putting them to work. For each step of the biobank process (storage demand, consensus gathering, sample/data collection, delivery, processing, storage, and access demand), we defined requirements and constraints about: functionality; performance; quality; user-demand; process. We developed a documentary workflow solution based on Documentum™, which manages: the creation, review, and approval of storage/access demands, quality requirements for preparing SOPs, quality control and processing documents; and the integration of other software solutions (sample traceability system, Electronic Health/Medical Records, research data repositories and registries) already used in the biobank processes. According to our Hospital regulations, business attributions and policy rules define the pattern architecture and level status. We suggested a homebrew-document management system for improving the monitoring and sharing of aggregate data about biospecimens of a hospital research biobank. A further development will be the access to the documentary
workflow system from the outside, implementing a new interface with the hospital web-portal.

**P7B_4 - Integrated Biobanking and Tumor Model Establishment of Colorectal Carcinoma Provides Excellent Tools for Modern Precision Medicine**

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**Problem**

Establishment of tumor models has a long standing history. The first tumor cell line was established in the early 1950s. In vivo tumor models followed suit in the 1960s. Currently, patient derived xenograft models are very popular for preclinical drug development by mimicking clinical trials. In parallel, the generation of large biobanks, enabling individualized therapy approaches, at least on a patho-molecular level of the tumor, has become standard in comprehensive cancer centers.

**Solution**

Over the time period from 2006 to 2018, consecutive patients operated on at the university medicine of Rostock participated in this comprehensive biobanking and tumor-modelling approach: the HROC collection. Samples were collected using strict SOP including blood (serum and lymphocytes), tumor tissue (vital and snap frozen) as well as adjacent normal epithelium. Patient and tumor data including classification, molecular type, and results of model establishment are the essential pillars.

**Discussion**

The more than 400 patients and over 150 tumor-models encompass all colorectal carcinoma anatomic sites, grading and staging types, molecular classes, hereditary forms (especially Lynch) as well as rare cases including Crohn’s-associated, neuroendocrine and duodenum carcinoma. The HROC collection representing one of the largest model assortments from consecutive clinical CRC cases worldwide is available for research projects.

**P7B_5 - Application of Computational Intelligence Methods for Biobank Data Quality Assurance**

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Biobanking software capabilities are no longer related only to sample location management but instead the capabilities are becoming a distinguishing factor in the ability of a biobank to provide appropriate data quality. In biobanks along with the biological sample, stored are the related data. That are sample annotations, analysis and transformation of samples to other derivatives, such as genetic information that in turn allow the meaningful study of the collection. Delivering mechanisms to support data quality assurance is one of the most important issues in the biobanking industry. A number of best practices, guidelines and standards have been proposed over the years including ISO TC276 or ISBER Best Practices. Along with these efforts very important work has to be done by biobanking software vendors. There is an increasing requirement for biobanking software systems in two most important aspects: consistency and quality. With the increase in the number of innovative solutions based on artificial intelligence, they are still not recognized in the quality assurance process in biobanking. In this paper presented are the results of work on application of computational intelligence methods for biobank data quality assurance. Real life use cases are demonstrated to prove the concepts. Identified and summarized are selected relevant research papers on the topic and proposed are problems that require more work.

**P7B_6 - The BIMS You Get and the BIMS You Deserve**

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The digitalization proliferates into all areas of life. Especially in laboratories we can profit from automated processing to transform the working environment into a paperless and organized lab. Here, the laboratory management system becomes the heart of the lab as powerful platform to process the challenges linked with the digitalization process. Lab and biobank software must face the permanently changing individual requirements. Therefore, simple solutions with flexible
structure which can handle large data sets in a short time period get mandatory. There are many reasons why software adaptability is beneficial for a smart realization of your individual requirements. Reorganizations of any kind or the introduction of new workflows, procedures and sample management can be easily implemented. Already existing working procedures can be automated and logged parallel to get the current working state anytime. Interactions with the user interface get intuitive and self-regulated. For instance, data fields and user interfaces can be self-editable and expandable according to the roles and rights. Despite all flexibility, the system must be sustainable and secure with high data integrity. Here, we present a powerful and universal applicable lab organization software which can be operated highly flexible. The software ensures a fast performance for database search tasks and can be expanded anytime with your own data. Comfortable and easy connection between future interfaces and software will become prospective challenges for the lab software. Further automated features shall be applicable such as optical character recognition, especially for handwriting, as well as intelligent image processing by artificial intelligence.

P7B_7 - Illustrating the Sample Life Cycle at an Hospital Integrated Biobank


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Background

Biobanks collect high-quality biological material, donor-specific data, and sociodemographic information about the donor. Sample-specific data such as sampling time, processing conditions or sample location should all be documented in a Biobank Management System. The hospital-integrated biobank ICB-L uses the software CentraXX from KAIROS ® to enable sample and data management.

Methods

To proof the quality of processing and storage, we developed a sample-life-cycle BIRT-report (Business Intelligence and Reporting Tools) and made it available in CentraXX. This analysis contains information about donors, medical-conditions, acquisition and storage. With the distribution of the sample the monitoring process ends. All information is processed at the individual sample level from sampling to storage.

P7B_8 - Bioresource Center Ghent: Strategies for Defining Essential Datasets for Biobanking Combined with Dynamic Options for Additional Detailed Information Capture

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Data collection is inherently linked with storing biospecimens. Because datasets vary between different biobanks, several initiatives have tried to identify common dataset parameters and suggested minimal requirements for data collection. As a large hospital-integrated biobank, samples are captured for different clinical related research domains. We set out to rationalize the datasets linked to the samples by exploring the vast information on biobank datasets and suggested minimal requirements. Our goal is to develop datasets with information on preanalytical factors, essential for quality determination and potential usability.
of samples, combined with minimal essential sample data and expanded with clinical data and other data that can dynamically alter according the subdomain of interest.

Solution
Data fields defined in multiple proposed datasets (BRISQ, MIABIS, SPREC, HL7 FHIR, CTN…) were compared and evaluated based on the type of information captured, relevance for research purposes and feasibility to obtain. After evaluation, three different datasets – a cell line, liquid and solid - were established based on the essential data fields from existing datasets in combination with sample type specific additions. These three datasets consist of crucial pre-analytical data, essential sample, legal and storage information and can be coupled with extended datasets, which will be stored separately from our BIMS to maintain a clear structure.

Discussion
The datasets were implemented in our BIMS system. Through dynamic use and linkage of systems, the datasets can effortlessly be expanded with extended clinical, laboratory or even environmental information by coupling our BIMS system with specific designed registries in REDCap.

P7B_9 - The Belgian Virtual Tumourbank (BVT)
Project: Availability of Childhood Cancer Samples

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The Belgian Virtual Tumourbank (BVT network) 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. High quality of the data is guaranteed by automatic and manual controls performed by the BVT project team at the Belgian Cancer Registry. Currently, more than 93,000 registrations are available in the catalogue for researchers in the oncology field. The majority of the samples available in the catalogue originate from adult patients. However, each year about 320 children and 180 adolescents in Belgium face the diagnosis and treatment of cancer. Therefore, we investigated the availability of samples originating form children (<15 years) and adolescents (15-19 years) in the BVT catalogue. In total, 2,967 samples originate from children (1,917) and adolescents (1,050). The highest number of samples from children are from central nervous system tumours (CNS, 28%), while we have most samples of lymphomas (25%) in the adolescents. Besides tumour samples also other available material can be stored and registered by the local biobanks, such as normal tissue samples (8.7%), DNA (5.6%) , plasma (1.8%) and blood (1.8%). Our data illustrate the great value of the BVT catalogue for cancer research, in particular for research on rare cancers such as childhood cancers.

P7B_10 - Central Acquisition and Visualization of Temperature Logs of Various Biobank Storage Systems


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Background
Quality-assured biobanks are obliged to keep a complete sample documentation. The appropriate storage temperature is particularly responsible for the sample quality. Storage systems either have internal temperature recording or are equipped with such systems. Having this information available in a uniform format and in one place facilitates overview and access.

Methods
In this project, the -80°C Thermo Fisher freezers, the automated storage systems HS200 from Askion and BIO Store III from Brooks and the conventional tanks using T-Tracker are taken into account by ICB-L. This selection results in four different temperature measurement systems and different formats, which need to be harmonized.
Results
Not all storage systems have a direct connection to the network of the biobank software, they have to be read and transferred manually. We have developed an interface that reads the formats and transfers the specific xml format. All temperature logs of these devices are then stored as measurement series in the BIMS and can be used for further analysis. Errors and other logging system specific events are stored and considered separately. An automated analysis of the temperature data, over the different systems becomes now even possible.

Discussion
We can continuously retrieve and use the logs of the automated systems to identify deviations and promote an early reaction. But also the non-automated storage systems can be better controlled by automatic instead of manual verification. This specific information can then be used to calculate curves on single tube level.

TOPIC 8A: HOSPITAL-BASED BIOBANKS

P8A_1 - Challenges in a Worldwide Unique Repository for Orthopaedic Rheumatological Samples
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Background
The “Centre for Rheumatopathology” in Mainz represents a worldwide unique repository of 90,000 orthopaedic samples, complemented by clinical observations, laboratory values, imaging data and surgical reports. This collection includes surgical specimens after therapies, which are no more performed nowadays.

Methods
Since 1974, we collected 90,000 orthopaedic rheumatological samples with histopathological diagnosis linked to clinical-, laboratory- and imaging data. Within 20 years, we were able to cover the whole western, German speaking part of Europe, by collecting tissues from 143 German and 24 Swiss surgical centres.

Results
The review of the samples and linking to clinical- and histological data is in progress. In addition, digitization of our findings is in progress to create a unique biobank-like structure, to permit researchers access to these data. This process is already completed for the synovectomy specimens from 1994, allowing new insights into the genesis and early stages of rheumatoid arthritis.

Summary
We were able to create a unique repository of approximately 90,000 samples of orthopaedic pathology, in which clinical symptoms as well as laboratory values and imaging data are brought together. A comparison of the histological findings and the clinical data is aim of an ongoing study. In the course of digitization and as part of the "BRoTHER" network project, the repository gives innovative insights how to handle archive material with modern digitization techniques.

P8A_2 - Biocor Biobank Establishment
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Introduction
A research biobank does not directly carry out a research activity, but an activity at the service of researchers and allows to conduct wide-scale research by the professional collection of biological specimens and correlated clinical data. At the IRCCS Policlinico San Donato we are establishing a biobank that is a Research Biobank named BioCor, which will be included among the projects of the Cardiological Network of the Italian IRCCS. We received a loan from the Italian Ministry of Health, which concerns the establishment of a Research Biobank. BioCor Biobank will be managed by Operative Unit of Clinical Pathology with University management.

Material and Methods
We intend to act as follows: - popular science activities (GSD Magazine) - database managed by BioBank BioCor directly within the institution - ad hoc information conferences on research and cardiovascular activity - any scientific publications designed to confirm the usefulness of the biobank in basic and applied clinical research.
Results and Discussion
The BioCor Cardiovascular Biobank will be established to investigate the molecular and genetic basis of vascular dysfunction, cardiovascular disease and stroke. BioCor will collect blood and tissue specimens for DNA, RNA, proteomics, metabolomics, and biomarker assays. In addition, clinical data and family history of patients will be collected. The establishment of BioCor does not only give benefits to the scientific community, but also for a patient health participating in the development of the precision medicine, a medical approach that aims to diagnose and treat in a personalized way.

P8A_3 - A New Biobank is Born – The IRCCS Istituto Ortopedico Galeazzi Experience
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Background
Our goal was to establish a tissue biobank of biological materials to be used in specific studies aimed at defining the pathophysiological mechanisms and/or new diagnostic/prognostic markers and/or therapeutic targets of pathologies of the musculoskeletal system.

Methods
The study includes the collection of biological specimens from patients undergoing surgical procedures in the routine diagnostic and/or therapeutic path, following informed consent sign. Blood and its derivatives are stored at -80°C while tissue samples at -150°C. We developed an IT platform for biobank database able to provide a QR-coded label. At the end of the process all the cryoboxes are stored in a proper repository with the best quality standards, after a dedicated transport.

Results
From May 2017 we collected samples from 185 patients, for a total of 1444 vials (last update, 13/05/19): 1162 were stored at -80°C while tissue samples at -150°C. We developed an IT platform for biobank database able to provide a QR-coded label. At the end of the process all the cryoboxes are stored in a proper repository with the best quality standards, after a dedicated transport.

Discussion
Our system is now flowing smoothly and we are planning to include other medical teams soon. Furthermore, we are working on IT platform version updating, according to the ongoing needs. We started to release samples and many researchers plan to exploit our biobank for their future studies. We will enter in the BBMRI network soon.

P8A_4 - Study of the Improvement of the Production Systems of BBSSPA Located in Málaga After 3 Years of the Merge of the Local Nodes
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3Costa del Sol Sanitary Agency, Sanitary District of Málaga.

Background
Working cooperatively on many occasions leads to a better productivity than work as an isolated structure. In this line, the three local nodes belonging to the Andalusian Public Health System Biobank (BBSSPA) located in Málaga was merged in 2016. For this, aim of this study has been to assess the progress achieved as a single entity.

Methods
Different questionnaires were carried out to determine the progress in 4 different areas after the merge: A) At the level of biological sample and service to researchers, B) Research lines, C) Participation in research projects, D) Personnel and infrastructure calls.

Results
Results showed an exponential increase in at least 3 of these areas. Until before the merge of the three local nodes BBSSPA located in Málaga, this node did not have research lines or led any research project. After the merge, the international scientific productivity of Málaga Biobank has been consolidated, being focused on improving the management of the biological sample and the researchers service. In the same way, it has allowed it to compete at a national level to win national calls for personnel and infrastructure.

Conclusion
Local nodes fusion in BBSSPA located in Málaga has consolidated the structure allowing it to become more competitive in different areas and allow a visualization of
this node at an international level through publications and contributions in international congresses.

P8A_5 - CSUR (Collection De Souches De l'Unité Rickettsies)
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IHU Mediterranee Infection (Institut Hospitalo-Universitaire) possesses a large Biobank allowing us to preserve at -80°C any samples of interest. Those samples are diverse body fluids (such as stool, urine, saliva, biopsies, blood) and bacterial isolates that are conserved in the CSUR (Collection de Souches de l'Unité Rickettsies). Each isolate is attributed a unique number. Prior to storing isolates, we test the absence of contamination using MALDI-TOF MS. In case of pure culture, all colonies on the agar plate are harvested and placed in a croutube containing ceramic beads and glycerol. Tubes are labelled and one vial is preserved in a safety collection as a failsafe. To date, the CSUR hosts more than 7000 bacterial isolates, representing recently described new human-associated species. We are in the process of developing a fully automated-80°C biobank that will limit the risk of accidental loss of bacterial isolates. From biosafety level 2 to 3, we have a large panel of bacteria, actually those species are available to commercialization.

P8A_6 - Healthcare Integrated Biobanking – A Prerequisite for Equitable and Quality-Assured Collection of Samples for Research
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Background
Within Biobank Sweden, a project was initiated in 2015 with the aim to implement healthcare integrated biobanking (HIB) for blood and liquid-based research samples in all regions of Sweden. HIB is a standardized model for the collection and management of samples that result in comparable samples with known quality. Data related to the sample management is stored in biobank LIMS.

Methods
HIB means that the healthcare routines are used to manage also the collection of research samples. An inventory of current routines has been carried out at all hospitals that offers HIB. The purpose of the inventory is to identify routines that need to be harmonized between hospitals to ensure that the samples have comparable quality regardless of the location for collection.

Results
In May 2019, HIB was implemented to a varying degree at 26 hospitals in Sweden. The inventory shows a further need for national harmonisation and for facilitating the exchange of information between different LIMS. It also calls for guidelines for pre-analytical management of samples to ensure compliance to the quality requirements of sensitive analysis methods.

Discussion
The long-term value of the project is to create a simpler and a more cost-effective way to manage research samples that can create benefits for patients by facilitating research on biobank samples and thereby contributing to medical research in Sweden.

P8A_7 - Stakeholder Surveys as a Tool for Public Relations and Quality Management
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Background
Patients at the University Hospital Würzburg have the opportunity to have biomaterial samples stored in ibdw for future research purposes. Their willingness to participate usually depends on the level of information of those affected.

Aims
Surveys offered by the ibdw to interested participants have two aims: First, to inform potential future patients and study participants about the biobank itself. Secondly, the surveys provide information on the participants' interest in specific topics relating to biobanks. The question of the quality of the information provided by the Biobank can also be determined.

Methods
Through targeted surveys, future and current patients are made aware of the work of the biobank. For this purpose, surveys are usually held in the context of larger events, which ensures direct contact with biobank
employees; printed survey forms as well as wireless response devices are used. Advantages: Quantitative surveys allow patients to deal with the topic of biobanks without major entry barriers, as well as simple distribution, good comparability and relatively low time and personnel expenditure. A disadvantage is that one only receives quantitative results. For the collection of qualitative results, these surveys must be combined with other methods, e.g. longitudinal studies.

Results
The questionnaires have already been used to conduct over 200 surveys of potential and current patients and study participants. The results are incorporated in the field of PR and quality management. They are used in the development of targeted information measures, such as the creation of advertising flyers and the ibdw's homepage.

P8A_8 - Relevance of the Establishment of Biobank in the National Medical Research Research Center of Cardiology of the Ministry of Healthcare of Russia (NMRCC)

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Problem
NMRCC is one of the largest federal medical research institutions in Russia that solves actual problems of diagnosis and treatment (including surgical) of major cardiovascular diseases (CVD). NMRCC consists of: 1. Institute of Clinical Cardiology named after A.L. Myasnikov; 2. Institute of Experimental Cardiology; 3. Experimental pharmaceutical production of unique drugs. One of the important goals of NMRCC is the creation and preservation of a unique collection of standardized biological samples of different types and full database, with the observance of ethical and legal standards.

Solution
Biobanks are the important resources for personalized medicine, experimental cardiology, as well as for the development of the production of biomedical drugs. Biobanks provide an access to the high-quality samples for researchers. Directorate of NMRCC in 2017 decided to establish such an important unit as Biobank. In the beginning of 2019 reconstruction of premises was carried out, the equipment was purchased and software was installed. We developed regulations and special standard operating procedures (SOPs). NMRCC joined the National Association of Biobanks and Biobanking Specialists (NASBio).

Discussion
Biobank of NMRCC is an integrated department that gives opportunities for: - study of the mechanisms (molecular, genetic, and epigenetic etc.) of CVD; - development of innovative drugs for cardiology and other areas of medicine and new research on methods of regenerative medicine (gene and cell therapy, tissue engineering). Biobank of the National Medical Cardiology Research Center is a young division and it has a promising and interesting future.

P8A_9 - Interactive Cloud Platform & Quick Acquisition of High Quality Clinical Samples

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Every day a large number of bio-specimens from the clinic, but most of them are not preserved in standardized way or effectively used. This is undoubtedly a huge waste of resources. Here, we developed an interactive cloud platform for promoting sharing and effective use of clinical samples. Our biobank was designed in a distributed model. All samples are collected by the front-end acquisition module and stored in distributed biobanks. Sample and sample source information are sent/recorded to the cloud platform. In order to acquire high quality samples, all procedures must be done according to the relative SOPs which have been uploaded to the platform previously. The platform offers member registration and bonus points system. Researchers and doctors can report their resources and projects on the cloud platform. Anyone who contributed samples can earn the bonus from the project owner, which is the possibility to exchange bio-specimens. In addition, statistical analysis of big data can also be performed on the cloud platform. Based on distributed biobanks, the interactive cloud platform allows fast
collection and standardized sample management. It improves sample utilization efficiency and enables regional sharing of clinical resources.

**P8A_10 - Amsterdam UMC Biobank**

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Amsterdam UMC is one of the largest university hospitals in the Netherlands with over 10,000 employees providing integrated patient care, education, and fundamental and clinical scientific research. Research is supported by core facilities, including a central biobank department. Amsterdam UMC Biobank provides comprehensive logistic support and biospecimen storage services for patient materials and related data. The Biobank works in close collaboration with the departments of Clinical Chemistry, Genetics, and Pathology. Currently Amsterdam UMC Biobank hosts numerous collections containing overall millions of samples including various Parelsnoer cohorts, shared with other Dutch university medical centers, the HELIUS study on health differences among residents of Amsterdam with different ethnic origin, the MARS study on molecular diagnosis and risk stratification of sepsis, the Liquid Biopsy Center (LBC) initiative, which goal it is to design novel non-invasive methods for detecting cancer in biofluids, and biobanks from the Alzheimer Center Amsterdam focusing on cause, prevention, diagnosis, and cure of dementia. Samples are managed using biobank information management systems, and metadata of all collections are accessible through the national BBMRI-NL catalog. Amsterdam UMC Biobank focuses on a quintet of goals: ethical-legal assurance, optimal pre-analysis, proper registration, reliable technique, and durability. These shared values, a common biobank policy, and customized services and prices must ensure that researchers are supported at a high level. By applying the best practices, the Biobank will help maximizing the scientific potential of patient material collections of Amsterdam UMC in order to improve quality and create added value for researchers and patients.

**P8A_11 - Biobank Sample Collection as Part of Routine Procedure in Maternity Clinics**

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**Introduction**

Primary healthcare provides opportunities for biobank consent and sample collections. In Finland all pregnant women visit maternity clinic which can be utilized in collecting biobank samples.

**Objective**

The aim was to establish and routinize biobank sample collection in all maternity clinics at Pirkanmaa area Finland.

**Methods**

The nurses and midwives at maternity clinics ask for the biobank consent during the first maternity clinic visit. Blood samples (serum, plasma, DNA) are collected during 1st trimester (9th-11th gestational weeks) at the same time as the national infection screening of the pregnant women. Blood samples are drawn in outpatient clinics and transported using cold chain protocol with optimal temperature between +2°C and +8°C.

**Results**

The biobank consent and sample collection was initiated 1st of March 2019. During the first two months 70% of the pregnant women gave biobank consent. From these women approximately 95% also gave their blood samples to biobank. The clinical data from the maternity clinics will be electronically available. The process for successful sample collection included close collaboration between primary healthcare professionals and biobank. The sample collection is on-going and implemented as routine procedure at maternity clinics.

**Discussion**

The biobank consent and sample collection process was successfully implemented to maternity clinics and together with the clinical data will constitute a valuable collection for researchers in the future. Successful sample collections requires close co-operation between biobanks and the healthcare professionals.

**P8A_12 - Uniform Sample Flow**

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Introduction
The Biobank Antwerpen was established in response to the new Belgian royal decree on biobanks as a collaboration between the University Hospital and the University of Antwerp. The biobank integrates the existing collections at both institutions, estimated to amount several millions of samples. For that purpose, a data management system was set up in collaboration with Genohm (now part of Agilent). Soon after its implementation, the hospital decided to use the system to track all research related samples, including those used in the framework of clinical trials, thus creating a uniform sample flow.

Material and Methods
The sample management system (SLIMS, Genohm) is a webbased system that ensures full traceability and generates a full audit trail. Shielding of data can occur on various levels, making it suitable for multiple independent users. Export and connectivity functions allow to integrate with equipment and various data management systems.

Results
In Belgium, all research related samples of human origin need to be registered in a biobank with the sole exception of samples from clinical trials with investigational medicinal products (IMP). Within the framework of the Clinical Trial Centre in the hospital, a uniform sample flow was established to register all study samples including those with IMP and using the biobank registration system. This strategy fitted the harmonization of study flows, reducing the burden on hospital staff.

Conclusion
In addition to a full audit trail, the establishment of a uniform sample flow proved cost effective and significantly simplified the work flow.

P8A_13 - From Projects to Biobank: Development of the MRC/UVRI and LSHTM Uganda Research Unit Biorepository in the Last 10 Years (2008-2019)
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Problem
The biorepository was started in mid-2007 under Clinical Diagnostic Laboratory to support biobanking of samples from different research programs and projects across 4 research sites of the unit. We had 2 staff in one freezer room with a few -20 and -80 freezers belonging to different projects housed in different laboratories. Protocol specific excels and access databases existed in different lab sections each managing their “own” samples and data for long term storage. Samples and associated data management was decentralized.

Solution
Freezer rooms were set up and all samples initially housed in the different labs were pooled together. Sample reorganisation and inventory creation started with implementation of sample management software in mid-2012. More staff were recruited and trained on sample management. SOPs were developed and put in place. Access control, sample pre-authorization for use, use of barcoded labels for sample collection and storage were adopted. Sample management was centralized.

Discussion
The biorepository has evolved over the last 10 years with adequate infrastructural capacity and existing large collections. Standardized sample management workflows prior to storage has improved sample traceability, data management, storage and TAT. Over 90 protocols with over 1m aliquots have been documented to date. Staff have got training through our professional memberships, international biobanking networks and forums. This has improved collection,storage, distribution and accountability of samples attracting biobanking collaborations such as the H3A.

P8A_14 - Creating a Tissue Biopsy Collection from FFPE Lung Cancer Samples beyond the Initial Clinical Care Objective: A New Opportunity for Research Projects on Late Stage Non Small Cell Lung Carcinoma (NSCLC)
Background

Biological resources collected from lung cancer patients for the development of translational and clinical research, not only from early stage but also from late stage lung cancer patients, are increasingly requested. However, collections from stage IIIB/IV lung cancer patients are rarely available. Since 2004, the LPCE Biobank (BB—0033-00025, Nice, France) focused particularly on collecting samples from lung cancer patients. Additionally, it is integrated in the Clinical and Experimental Pathology Laboratory (LPCE, ISO 15189 accredited). Formalin-Fixed Paraffin-Embedded (FFPE) tissue biopsies, initially dedicated to clinical care are stored within the LPCE. These samples, together with their associated molecular and clinical data, represent a significant resource of strong scientific interest. Therefore, the goal was to establish a sub-collection of lung tumor samples for research purpose.

Methods

Transthoracic and bronchial biopsy samples were re-evaluated by senior pathologists being experts in lung cancer to store the FFPE blocks safely at 4°C (% of tumor cells; area of necrosis). Their associated genomic and clinical data was securely integrated into the biobank database. Patients already signed an informed consent allowing the research use of their samples.

Results

1567 FFPE blocks were selected corresponding to 56% bronchial biopsies and 44% transthoracic biopsies and included as new collection in the biobank. Thorough quality management was implemented to guarantee sample integrity.

Discussion

Implementation of routine FFPE samples in a biobank is feasible and our new collection of biopsies can be of strong interest in lung cancer research for the characterization and/or validation of new diagnostic, prognostic and theranostic biomarkers.

P8A_15 - Establishing a Collection of Biological Fluids from Patients Undergoing Thoracic Surgery For Lung Cancer: Why and How?

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Problem

Collecting biological samples from patients undergoing thoracic surgery remains to be challenging, importantly as strict quality management is necessary to allow the standardized collection of those samples. The LPCE Biobank (BB-0033-00025, Nice, France) is integrated in the Laboratory of Clinical and Experimental Pathology (LPCE) and was established in 2004 at the University Côte d’Azur to store tissue samples (frozen, FFPE). Thanks to the close proximity and the strong collaboration with the department of thoracic surgery, the LPCE Biobank systematically collects biological fluids (blood, urine) since 2012. This thoracic collection is associated with molecular and clinical data enriched with a complete survey on personal/professional exposures and family history as well as the information concerning the follow up.

Solution

The blood samples of the biobank comprise not only whole blood, but also include and store its derivatives, such as plasma, serum, pellets obtained after plasma preparation, platelets and Peripheral Blood Mononuclear Cells (PBMCs). Samples are either stored at -80°C or in liquid nitrogen. Processed derivatives are also prepared from the blood samples such as germline DNA extracted from whole blood and cell free circulating tumor DNA extracted from plasma. A strict quality management has been implemented to document and harmonize sample collection.

Discussion

We here demonstrate how a sample collection from biological fluids can be implemented in a hospital-related biobank and how this wide variety of samples and can be of strong interest for the scientific community to develop research projects and finally to improve lung cancer therapy.

P8A_16 - Requirements for a Hospital Integrated Biobank - Managing the Heidelberg Cardiobiobank (HCB)

Sandke, S., Heimberger, T., Weis T.
In the era of precision and personalized medicine, clinicians and experimental researchers are focusing on analyzing genomics, proteomics and metabolomics of human patients to identify promising therapeutic targets or novel biomarkers. To facilitate this intention, hospitals establish biobanks with collections of biosamples annotated with their clinical data. The Heidelberg CardioBiobank (HCB) operates as a hospital integrated Biobank, mainly for the Department of Cardiology as well as a core Biobank for several national and international studies. To ensure highest quality of biosamples, we evaluated and optimized entire workflows for sample collection, logistics, and storage. In addition different procedures of sample processing were tested. Recording biosamples results in large datasets, which requires an IT-system enabling efficient and secure handling of data information. We therefore aimed for a customized solution, fitting our requirements. To reach highest and consistent standards we Standard Operating Procedures were developed for all preanalytical processes, starting with the collection of biomaterial until their final storage. This resulted in a significant improvement of sample quantity and quality. For data collection, we established an individualized IT-solution using a customized research portal for biobanking and clinical studies named CentraXX (KAIROS GmbH). The introduction of standardized and almost fully automated sample processing systems into the HCB produces the highest quality and integrity of biomaterials, which is essential for translational research. Embedding the customized CentraXX system into the workflows allows functional data modeling and enables an efficient search between clinical, study and sample related data.

P8A_17 - Establishing Swiss SCI Biobank – A Multicenter Collaboration Platform


Swiss Paraplegic Research SCI Population Biobanking & Translational Medicine Group Guido A. Zäch Strasse 1 6207 Nottwil Switzerland

Introduction
The condition of spinal cord injury (SCI) can accelerate the onset of common multifactorial diseases and survival of persons with SCI still remains below that of the general population. A biobank for research in SCI was launched in 2016 as a strategic resource in the context of the Swiss Spinal Cord Injury cohort study (SwiSCI).

Methods
Currently the primary biomaterials are blood and urine samples as they are readily available and can be taken routinely or by indication. The stored blood products are serum, plasma, leukocytes, DNA, and RNA. Urine is stored as a sediment pellet and filter sterilized liquid. Standard Operating Procedures (SOPs) for the sample collection, transport, processing and storage were first installed at the SCI center in Nottwil, and in 2017, the inclusion of the other Swiss Paraplegic Centers was started. The biobank database is connected to the database of the SwiSCI study center.

Results
Sample quality is continuously monitored and periodically controlled, involving the use of time stamps and specific experimental SOPs. The biobank was accredited for compliance with ethical and legal standards by the Swiss Biobanking Platform (SBP) with the VITA label and is listed as an SBP member.

Discussion and Conclusion
We provide biobanking infrastructure and services to all Swiss Paraplegic Centers and research groups in Switzerland in order to investigate the underlying biological mechanisms of such conditions and the possibilities for new therapies. Collaborations within and outside of the Swiss Paraplegic Group are steadily growing after the establishment of the SwiSCI biobank.

P8A_18 - A Specialized Tissue Collective for a DZIF Cohort Study

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The tissue bank of the German Center for Infection Research (DZIF) is a hospital-based biobank located at the University Hospital Heidelberg. It supports translational infection research within the national DZIF consortium by providing tissue sample collections of infectious diseases for research projects. Localized at
the Institute of Pathology, the DZIF tissue bank mainly provides formalin-fixed paraffin-embedded tissues, originally obtained for histomorphological routine diagnostic analysis in the course of clinically indicated interventions. After completion of all diagnostic testing, left-over material of biopsies, resections or explantations is made available to research projects under strictly defined ethical and legal requirements. In the frame of a pilot project, the DZIF tissue bank aims to make available tissue samples to complement the liquid biosample pool of a large-scale multicentric DZIF cohort study on infections in transplanted, immunocompromised patients (the DZIF Tx-cohort). Including tissue samples from a hospital-based biobanking setting allows for the investigation of additional research questions such as opportunistic infections that escape serogenic analysis (e.g. fungal or parasite infections). The goal of the pilot project is to assess the ability to identify additional infectious events and to analyze the availability of relevant tissue samples. Collaborating closely with the Department of Infectious Diseases, Microbiology and Hygiene, the tissue bank aims to set up the relevant processes to link tissue samples and data on validated pathogen identifications, to identify and validate infectious events during follow-up.

Methods
LBC samples are collected using ThinPrep (Hologic) methodology and aliquoted in 96-well plates (500ul) using the Freedom Evo 150 (Tecan) automated robot before long term storage in minus 25°C freezers. All information regarding the samples is processed by the regional laboratory information management system LabWare-LIMS™.

Results
The sample collection currently holds close to 400 000 samples that have been collected, aliquoted and stored in the same standardized manner. Of the 500ul that is biobanked, 200ul is reserved for the patients’ own care while 300ul is available for research. This population based sample collection includes the majority of age groups (ranging from 23 to 65+ yrs) which enables genetic-, registry-, methodological and quality studies.

Discussion
Several research groups are using this sample collection and numerous papers have been published within the research field. We invite additional research groups to utilize the samples in both national and international collaborations.

P8A_20 - Improving the Quality of Fresh-Frozen Samples of Finnish Clinical Biobank Tampere

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Introduction
Finnish Clinical Biobank Tampere initiated fresh-frozen (FF) tumor sample collection in 2018. However, soon after the initiation it was realized that the process to manage the removed organs and resectate samples was not optimal for high quality analysis, such as RNA sequencing, due to long stay in room temperature.

Objective
The aim of the study was to speed up the systematic process of FF sample collection at the hospital and implement a process enabling collection of high-quality tumor samples for research and future diagnostics.

Methods
We narrowed to scope of the study into clinics which showed most enthusiasm during the pilot and
concentrated into solid gynecological, gastroenterological, and urological tumors. We invited the surgeons, operating room personnel and pathologists into a joint meeting. Together we recognized several procedures critical for the waiting time before the sample was managed and frozen.

Result
As result of the multidisciplinary work group, a new enhanced procedure was developed with better yield. The new process focuses on ensuring shorter cold ischemia time. Operation room personnel was re-trained to prepare tumor and ship it in ice as soon as possible to pathologist.

Discussion
Old procedure are not always applicable for new needs of diagnostics. High quality FF tissues can be used in wider range of analysis methods compared to traditional FFPE samples. The new implemented process will improve sample quality for both research and diagnostic purposes. The new process will be implemented as part of hospital routine to other specialities in the future.

P8A_21 - Melanoma Biobank for Research Purpose: Fresh Tissue, Blood and Dermoscopy
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Background
With an overall mortality rate of around 20%, melanoma is responsible for the 80% of skin cancer-related deaths worldwide. As dermoscopic examination helps clinicians in distinguish benign from malignant lesions to be excised, molecular analysis has an important role in clarifying progression mechanisms. Therefore in 2012, we established an hospital-based biobank collecting both fresh samples and dermoscopic images from melanoma patients.

Methods
We prospectively recruited patients with a clinically malignant skin nodule or a flat lesion >1 cm and/or metastases >0,5 cm in diameter. Tumour samples and a normal counterpart were snap frozen in liquid nitrogen. Peripheral blood was collected the day of surgery and plasma and mononucleated cells were stored. All the data on samples traceability were registered in a tracking & inventory System (SMARTY BIOBANK), together with the most relevant dermoscopic images.

Results
This study enrolled 103 subjects (60% male; median age 66). We collected fresh frozen tissue from 94 patients (68 primary lesions and 26 metastasis) and blood derivatives from 70. Dermoscopic images were available for all patients. We stored skin samples and corresponding blood samples in 61 cases. Among them, in 4 cases we stored matched primary lesion and metastasis. Sample data (pre-analytical conditions, storage and demographic information) and signed consent were uploaded in the software and progressively updated with histological diagnosis and dermoscopic images.

Discussion
This experience poses the base for a systematic collection of tissue and images correlated with pathological and molecular data, that will provide researchers with highly annotated samples.

TOPIC 8B: NOVEL MOLECULAR & MEDICAL IMAGING TECHNOLOGIES IN BIOBANKING

P8B_1 - Imagebanking for Deep Understading of Cellular Progression
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Problem
High throughput imaging of individual cells for example from imaging flow cytometry promises far more detailed understanding of cellular development and disease progression than is currently available. Detection of first steps in normal development or disease progression is crucial to dissect what are the determinants of such processes. Machine learning techniques such as deep learning promise computational classification techniques that make fluent analysis of thousands of individual cells from a person feasible. However, to develop such methods imagebanks of thousands images of
individuals’ cells of different types in different stages are required.

**Solution**

Finnish Red Cross Blood Service (FRCBS) has acquired Amnis ImageStream X Mark II (EMD Millipore) imaging flow cytometer for use of research and the Blood Service Biobank the FRCBS hosts. Through the blood donation activity (~ 200 000 donations yearly) the Blood Service Biobank has ample access to samples of healthy normal individuals. As a pilot project FRCBS will start to image peripheral blood mononuclear and natural killer cells and develop deep learning methods to describe their normal variation and later detect abnormal cells from hematological cancer patients.

**Discussion**

Public imagebanks and associated public code of classifiers are a prerequisite to a quantitative definition of what is a normal cell of a certain type and stage and hence to automated detection of abnormalities. Detection of abnormal cells from for example bright field images of cells promises simpler early detection of disease than for example DNA sequencing where manipulations are required to extract and process the DNA.

**P8B_2 - Application of the Tissue Microarray (TMA) Technology to Study 3D Grown Spheroids**

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We introduce the Tissue microarray (TMA) as a high throughput platform useful to analyse 3D grown spheroids/organoids. TMA allows to examine combined protein expression profiles in differentially grown aggregates and determine the relevance of specific markers in relation to growth condition, differentiating procedures and culturing time. The methodology can be scaled up in two dimensions: (i) in the number of specimens that can be analyzed at once and (ii) in the number of consecutive sections that can be produced for analysis with different probes and antibodies. Using multi-parametric analyses, TMAs can provide a ‘profile’ for protein targets and genomic/genic alterations occurring as the organoids mature toward the pre-determined cell fate. Given the importance that the organoid and TMA technologies are acquiring in basic research we combined the two approaches to explore the generation of cerebral speroids starting from hiPSCs.

**P8B_3 - An Interface Between Tumor Histology, Clinicopathological Features and MALDI Imaging Data for Precision Medicine**


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**Background**

A challenging task for biobanks is to provide an interface between research phenotype data and clinical features of individual patients. We established a workflow to analyze multiple tissue samples simultaneously, link the protein profiles assessed by MALDI imaging mass spectrometry (IMS) to histological images as well as clinical features and present the results in the biobank management system CentraXX.

**Methods**

A tissue microarray of normal and tumor tissue from 50 patients with invasive prostate carcinoma was analyzed by MALDI IMS. Obtained data were analyzed with SCIb Lab 2015b. For all samples, research profiles containing the m/z spectra were created in CentraXX. Additionally, the corresponding histological images were uploaded.

**Results**

Per individual spot in each TMA core, 1023 peaks corresponding to 1023 m/z values could be detected by MALDI IMS. For every patient, the m/z values of all spots were exported to a CSV file and added as a research profile to the respective patient record in CentraXX. Images of the corresponding haematoxylin and eosin stained tissue sections were added to correlate the spectra with histological features of the tissue.

**Conclusion**

Our approach allows the simultaneous analysis of multiple tissue samples and can be used to, e.g. identify new biomarkers in cancer research. The data storage in CentraXX which is accessible by researchers and clinicians provides the possibility to include the obtained results in future studies and treatment decisions. The
next aim is the automatization of the export process as well as the inclusion of corresponding protein data.

**P8B_4 - Digitizing the Proteome from Big Tissue Biobanks**

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Tissue biopsies have been preserved and stored in biobanks for more than a century in the hope that their future analysis will provide a better understanding of health and disease. One of the most common methods of preserving these tissue samples is by formalin-fixed paraffin-embedded (FFPE). These samples are often very well characterized by classical pathological methods and provide great potential for precision medicine and the discovery of new diagnostic/stratification markers and therapeutic targets. A powerful way to take advantage of this repository is to quantify large numbers of proteins across all the samples so that correlations can be made with respect to various health and disease states. Such an endeavor would require highly reproducible sample preparation, a robust analytical platform for high throughput sample analysis, as well as robust data analysis. Current LC-MS/MS proteomics tools now allow for the reproducible quantitation of 1,000s of proteins in a single run. In particular, SWATH® Acquisition has been shown to provide the very good data completeness, reproducibility, and quantitative precision in comparative studies.

**P8B_5 - Evaluation of Novel Platform for the Digitization of Image Data (PDID) as a Tool for Examining the Role of Dietary Advanced Glycation End Products in Prostate Cancer**

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**Background**

Overexpression of the receptor for advanced glycation end-products (RAGE) and high levels of its ligands (AGEs) within prostate cancer (PCa) microenvironment is associated with poor patient survival. The aim of the study was to develop and evaluate the Platform for the Digitization of Image Data (PDID) to implement specialized workflows for biological samples collection, processing, digitization, and sharing. PDID is part of our efforts to develop IT tools to support Polish biobanks network and integration with BBMRI.ERIC and other scientific and industrial units.

**Methods**

The impact of dietary AGEs on PCa was studied in murine xenografts evaluated with serial PET-CT imaging with RAGE-targeted probe. PCa xenografts were explanted, preserved using standardized protocols, and shipped to the Medical University of Gdansk Biobank for cryostatted sectioning, staining, and digitization using PDID platform. Multidimensional imaging data were securely transmitted to Beckman Institute for Advanced Science and Technology in Urbana, IL for image processing and analysis.

**Results**

We demonstrated the feasibility to utilize PDID for interdisciplinary studies with two or more geographically distant institutions which provided distinct but complementary expertise in the fields of biopreservation, imaging and genomics/proteomics to support personalized and targeted medicine.

**Discussion**

Our study has indicated that multimodal strategy targeted at RAGE/AGE axis to diagnose and monitor PCa using newly developed PDID could significantly support both local and remote investigators and potentially impact PCa management.

**TOPIC 8C: IVD, GMP & CELL THERAPIES: NEW SERVICE**

**P8C_1 - Trehalose Cryopreservation of Human Cord Blood Mesenchymal Stem Cells**

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Adequate hypothermic storage of human multipotent mesenchymal stromal cells (hMSCs) is of fundamental importance since these cells are being explored in several regenerative medicine initiatives. The use of hMSCs, however, necessitates hypothermic storage for long periods prior to their clinical application, processes that require the use of nontoxic and efficient cryoreagent able to maintain high viability and differentiating properties. In this study, we describe a simple and effective trehalose-based solution to cryostore human umbilical cord blood (hUCB-MSCs) in liquid nitrogen (LN2). Cells viability, identity, and differentiating properties were assessed after cryostorage. Here we show that trehalose stored MSCs provided lower cell recovery rates but good differentiating potential. There were no differences in the osteogenic, adipogenic and chondrogenic differentiation capacity of MSCs in these solutions. All together these results in addition to ascertained therapeutic properties of trehalose, provide sufficient evidence to consider trehalose-based medium as a low-cost and efficient solution for the storage of hUCB-MSCs cells and substitute DMSO-based cryoreagents.

P8C_2 - Temperature and Time Delay on Fibroblast Cultures

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Background

Fibroblasts are valuable samples as they represent an excellent resource of biological material and they allow performing functional studies. In pediatric hospitals it is remarkable as the quantity of samples is limited. It is important in those cases that patient has died and it is impossible to obtain more biological samples.

Material and Methods

A skin biopsy was obtained from an amputated leg. The biopsy was separated into 7 portions. One of them was processed immediately. The other fragments were stored in culture medium during 24 or 48 hours at room temperature, at 4°C and at 37°C respectively, and then processed normally.

Results

We wanted to evaluate how time prior processing the biopsy, as well as the exposure to different temperatures, affected to the viability of the fibroblast culture. Fibroblasts of the immediately processed skin biopsy started growing at day 2-3. The ones stored at 4°C, 37°C and room temperature for 24 hours started growing at day 5-6, and the one stored for 48 hours at day 8-10. Fibroblasts stored at room temperature grew more rapidly and showing less young fibroblasts around skin fragments edges than the ones stored at 4°C and 37°C, reaching 80-100% of confluence like the biopsy processed immediately.

Discussion

Although time until the culture processing is an important factor, the storing temperature is more relevant. The growth of fibroblasts is better in biopsies stored at room temperature, reaching a confluence of 80-100% at the same time that the biopsy processed immediately, regardless of the time.

P8C_3 - Influence of Cryopreservation on Bone Cells Quality Parameters


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Background

Bone fragments containing mesenchymal stromal stem cells (MSC) are discarded as waste during routine bone
fracture operations. The aim of BONEBANK is to harvest these cells and to store them in a cross-border biobank. To evaluate different models for sampling, the aim of this study was the quality comparison of: a) direct cultivation of MSCs, b) storing whole bone fragments with subsequent isolation / cultivation of MSCs and c) cultivation MSCs after isolation and storing.

Methods
Trabecular bone samples from eight patients were collected after surgery and divided into smaller pieces to isolate MSCs through a gradient density centrifugation. While subsequent isolated cells were directly cultured and used as a reference for the analysis, parts of the bone and isolated cells were frozen in liquid nitrogen for comparative analysis. The quality of the cells was assessed by means of CFU assays, proliferation assays as well as osteogenic and adipogenic differentiation.

Results
The cryopreservation did not seem to affect the clonogenicity of the cells, however their proliferation ability was significantly poorer after freezing (P<0.05). MSCs directly frozen after isolation had a better differentiation ability than MSCs extracted from the frozen bone.

Discussion
For acquisition of bone samples, it is possible to isolate and cultivate MSCs from frozen bone pieces as well as to cultivate MSCs that were frozen directly after the isolation. However, MSCs that were frozen directly after the isolation show better clonogenicity, multiplication rate and differentiation ability than the cells isolated from the frozen bone.

P8C_4 - Fibroblast Culture Using Old Skin Samples
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Background
Pediatric Biobanks has to take full advantage of biological samples due to their size and because some rare diseases are cause of child death. In those cases, it is impossible to obtain samples after death and there remains a need to investigate biological mechanisms and physiological background of the diseases.

Material and Methods
Skin biopsies obtained from trivial operations were frozen at different conditions of temperature and using or not cryopreservation medium or histological mounting medium (OTC). One week later all of them were defrosted and processed as normally. A piece of each skin biopsy was processed immediately, as a basal conditions control. All the samples had been obtained under ethical and legal framework.

Results
We observed that cryopreservation medium was not crucial for fibroblast growing, and that previous skin OTC embedding affected them. Temperatures of frozen process were strongly linked to the success of fibroblast culture. The skin biopsy frozen at liquid nitrogen directly did not grew and the ones frozen at -80ºC and 45ºC grew more slowly than the basal ones.

Discussion
The possibility of using old skin biopsies (stored for other purposes) to obtain fibroblast culture could be a new approach in pediatric rare disease research, especially in those cases of child death. Skin biopsies without cryopreservation medium could be a starting point for further studies where fibroblasts cultures will be needed.

P8C_5 - Influence of Cryopreservation Process on The Quality of Advanced Therapy Investigational Medicinal Products
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The cells used to prepare the Advanced Therapy Investigational Medicinal Products (ATIMP) should strictly meet the requirements of Good Manufacturing Practice. The use of previously tested and frozen cells in clinical trials greatly facilitates the process of cell-based ATIMPs preparation. The aim of this study was to
evaluate the process of freezing the cells several times on the quality of the prepared product. Adipose-derived stem cells (ADSC) were processed in 4 different ways after isolation: continuously cultured, cultured and cryopreserved (one or two times), cultured after cryopreservation and additional passage. The experiment was repeated on cells from 4 donors. The preliminary results indicated no significant differences in cell viability after culture in different experiment models. There were also no differences in cell number/proliferation between continuous ADSC culture and cells culture with additional passaging after one round of cryopreservation. In contrast, we observed lower proliferation of cryopreserved cells in relation to ADSC cultured without cryopreservation. After two rounds of cryopreservation, proliferation was higher compared to cells after one round of cryopreservation. Above results indicate that two rounds of cryopreservation do not reduce the quality of ADSC cells. This can greatly facilitate the process of cell-based ATMP preparation. Considering the fact, that mesenchymal stem cells are applied usually at early passages, cryopreservation routine can allow more flexibility and widen a window of opportunity for application of the product. The work was supported by the National Centre for Research and Development grant STRATEGMED2/267976/13/NCBR/2015 and by MNSW, grant DIR/WK/2017/2018/01-1.

P8C_6 - Microbiological Characterization of Lipoaspirate Used in Cell Therapies

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Liposuction is one of the most commonly used fat removal procedures. Liposuction can be performed not only to improve body shape but also to obtain stem cells. Collected fat is excellent source of ADSC which can be used in cell therapies as active substance of ATMP. However microbiological safety of the must be ensured. Therefore, before administration of ATMP product liposapirate is examined for presence of microbial pathogens and in case of positive signal the identification of pathogens must be performed. Here, we present results of our 2-year long monitoring process of contamination incidences after liposuction and results of characterization of most common microorganisms. The microbiological analysis from 89 lipoaspirates, derived from two clinics, were conducted and results of microbiological examination were collected. More than 40% of lipoaspirates were contaminated with thirteen different microorganisms. The most commonly isolated were S. epidemidis, P. acnes, S. capitis. Almost all identified pathogens belong to group of physiological flora of human skin, hence most probably they come from patients themselves. Hence, thanks early identification of these microorganisms we are able to prevent contamination of in vitro culture by using the appropriate antibiotic solution and prepare sterile ATMP product. Microbiological control of material intended for clinical trials is one of the key processes carried out in biobanks preparing ATMP product. Adhering to GMP rules and following the proposed procedures, we are able to obtain specimen that can be used both in the clinic and for other biobank research purposes. This work was supported by STRATEGMED2/267976/13/NCBR/2015

P8C_7 - Challenges in iPSC Biobanking – Solutions by the Radboud Biobank

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The Radboud Biobank is a hospital integrated Biobank and access to tissue and cells from diseased donors is often limited, induced pluripotent stem cells (iPSC) have the potential of providing researches unlimited access to large quantities of cells (and tissues). iPSC are derived from a simple blood sample, fibroblasts or urine and reprogrammed into a pluripotent state. In collaboration with our specialized laboratories, we searched for the optimal routing to provide our investigators with high quality materials that can be used for future development of iPSC. This resulted in the offer of two options: i) Storage of whole blood in liquid nitrogen, on demand isolation of white blood cells and their subsequent immortalization with EBV virus, ii) Isolation and storage of PBMCs. The first option requires less blood and processing and storage costs are low, samples are only processed when needed for specific studies. The second option, direct isolation of PBMCs, is more expensive
because laboratory processing takes place before storage without assurance of sample usage for specific studies. However, a plus of this latter option is that the second step in the process (reprogramming iPSC) is faster and consequently less expensive. Based on the comparison of pros and cons of both approaches we conclude that a professional hospital Biobank needs both options in their portfolio and that a flow-chart is needed to sort out which of the two is most cost-effective in specific situations. At EBW we will present the detailed processes, arguments and a proposal for the flow-chart.

TOPIC 10A: FUTURE-PROOF SAMPLE AND DATA ACCESS

P10A_1 - BROThER – Elements for an Innovative Collaboration of Biobanks

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Background
Bio-banking represents a pivotal prerequisite for further developments in personalized medicine. Therefore, building networks represent a crucial element to cooperate. On the European level the “Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium” (BBMRI-ERIC) is an important network for biobanks in Europe. However, regional biobank-networks could significantly improve the translational and basic research within the connected regions. To enable an optimal collaboration of regional biobanks, web based tools for data exchanges are mandatory to guarantee a long-term success of such a network.

Methods
The aim is to create a prototype of a digital pathology framework in which secondary consultations regarding biobank-specimens could be conducted remotely for accurate tissue diagnosis and the potential use in a research project (i.e. tele-pathology). Furthermore, we implemented a student exchange program to introduce students from medicine and natural sciences in the biobank idea and the different methods involved in biobanking. Finally, we set-up events to inform the public about the need and the potential of Biobanking to optimize personalized medicine and to encourage participation.

Results
We successfully set-up a pathology framework which enables whole slide imaging even optimized for small screens. We integrated up to 10 students in our exchange program who were involved in the development of the pathology framework and in the different methods use in the partner sites. Finally, different public events informed highly successful regarding personalized Medicine and biobanking.

Discussion
The BRoTHER project opens innovative perspectives to overcome hurdles in biobank cooperations over different medical systems.

P10A_2 - How to Practice Stakeholder Engagement in a Large EU Biobank-Based Research Project – Experiences from the Lifebrain Consortium

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Stakeholder engagement ensures that a research project addresses the stakeholders’ needs. It is critical for increasing the transparency and legitimacy of the research and the impact of research findings. However, knowledge regarding best practices and which forms of stakeholder engagement are most efficient is still limited. Lifebrain is an EU research project that integrates neuroimaging, cognitive, mental health, blood biomarkers, and genetic data from a pool of 5300 European research participants collected from 11 European brain-imaging cohorts and biobanks. Lifebrain aims to identify environmental, social, occupational, and lifestyle factors influencing brain health. Lifebrain is committed to engage its stakeholders to increase awareness about brain, cognitive and mental health maintenance, risks, problems as well as potential, and secure translation of research into hands-on health policy, including prevention strategies. Lifebrain stakeholders include research participants in the European cohorts, patient organisations, health
policymakers at local, national and EU levels, clinicians and basic scientists. We will present and discuss the methods of engagement used in the “stakeholder engagement” work package since the start of Lifebrain in January 2017. Employed methods include stakeholder workshops, public lectures, conferences, and consultations with cohort participants and the public. We will draw preliminary lessons from our experiences and address challenges and opportunities related to stakeholder selection, form of collaboration, and continuity of action. Finally, we will outline preliminary recommendations for stakeholder engagement in biobank and health research.

P10A_3 - Access and Sharing in a Participatory – ELSI/FAIR/RRI Horizon. For a Best Practice of Sharing, from Data to Results

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The ELS working groups based in a participatory approach are an alive infrastructure of the Italian Common Service ELSI, designing dynamically, through the co-produced process, the new ELS challenges to face in terms of services and tools. In 2017-2018, working on informed consent process as a good practice, two critical issues remained open: an effective sharing of data/samples and the access governance, inclusive of patient/citizen representatives. The ideal biobank is empty of samples but full of shared and shareable results, this was recognized as a common milestone. And these were the pillars of the current national ELS group “Access and sharing. For a best practice of sharing, from data to results”. Meanwhile, the hardcore is the assumption and the implementation of data/samples/results sharing as the driving force and purpose both of biobanking and of research infrastructures. This process is possible within a shared ELSI/FAIR horizon in which everyone has a decisive role, institutions, biobanks, ethical committees as guarantors, researchers using and returning results to patients, citizens and their representatives, who through the provision of data/samples are partners throughout the process. Both Regulations, Reg EU 536/14 and GDPR, redefine the ELS criteria and requirements for research based on data/samples as they propose co-responsibility in sharing. Within a co-production process, we plan as deliverables: a DTA/MAT matrix, a FAIR access matrix between ethics committee and biobank, a guideline for sharing, pooling together governance models, ELS requirements and best practices. The work is going on

P10A_4 - Bioresource Center Ghent: Exploring the Researcher’s Perspective on the Informed Consent Process to Enhance Biobank Participation

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Introduction

Different types of informed consent exist for biobanking practices, resulting in a multitude of informed consent forms, formulations and procedures that are applied in clinical research. However, few data is available about the researcher’s perspectives concerning the currently used informed consent procedures for biobanking. An in-depth understanding of researcher’s views concerning the informed consent process allows us to tailor the informed consent process to the needs of researchers and to develop consent tools that can be used efficiently in everyday practice, with respect to the patients autonomy and rights.

Methods

A REDCap survey was developed based on literature review and sent out to the research community of Ghent University Hospital. The survey is designed to explore views concerning current practice, feasibility and communication methods. All data was combined to discover the pros and cons of the currently used process and to identify opportunities to optimize the informed consent procedure.

Results

An overview of researcher’s perspectives towards the current informed consent approach for biobanking was obtained through the survey. The results give insight into the difficulties related to the current informed consent procedures and help us understand the researcher’s burden and difficulties.
Discussion
In overviewing researcher's perspectives towards the current informed consent approach, we have gained important knowledge for improvement of the informed consent procedures. This allows us to develop new tools for communication/information and consent that can be applied in everyday clinical practice and allow us to evolve to a more participant-centered informed consent approach.

TOPIC 10A: FUTURE-PROOF SAMPLE AND DATA ACCESS

P10A_5 - Project Approval and Sample and Data Allocation at the UCT Biobank

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With the new biobanking norm DIN ISO 20387 a biobank has to safeguard impartiality. This includes governance as well as biomaterial allocation for scientific requests. As sample numbers are limited, the allocation of biomaterial has to be transparent for all parties involved. At the UCT Biobank investigators have to submit a project proposal to gain access to biomaterial and clinical data. There, detailed information on the scientific purpose and specification of samples and data are given. These proposals are then evaluated in a scientific board and the local ethical committee. The scientific board was established in 2014 as a central committee for project approval within the UCT. It is chaired by the UCT's scientific director during its quarterly meetings and is composed of representatives of involved tumor-specific clinics and institutes, the biobank project management and the UCT director. Here, the project proposals are evaluated regarding quality, feasibility, scientific relevance, material demand and availability, as well as potential for third party funding. In the case of competing projects the scientific board will prioritize. The project management functions as the central contact for scientists with questions regarding project submission, the approval process and delivery of biomaterial and clinical data. Progress of scientific projects will be tracked and documented annually by the project management as well. Benefits of the UCT process:

- Simplified and structured access to materials and data
- Increased quality of projects due to board discussion
- Inclusion of all collecting disciplines in the distribution
- Evaluation of request creates transparency in the approval process

P10A_6 - Reaching Out to Researchers – Campaign to Promote Biobank Services and a Cross-Biobank Online Search Tool for Samples

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German Biobank Node (GBN), Charité – Universitätsmedizin Berlin Campus Virchow Klinikum Augustenburger Platz 1, 13353 Berlin Germany

Background
Many scientists carry out biomedical research without using high-quality biobanks because of lack of experience or knowledge. This calls for communicative efforts among this target group. Also, the newly developed “Sample Locator” of the German Biobank Alliance (GBA) – an IT tool that enables cross-biobank online searches for quality-assured samples and associated data – needs promotion. Methods Interviews with German scientists allowed to determine their expectations towards biobank services and possible barriers to cooperation. A quantitative online survey conducted among medical staff at university hospitals targeted researchers who had not (yet) cooperated with biobanks and asked them for their reasons. Moreover, focus groups with researchers in the UK discussed strategies to search for samples as well as possible ways to advertise a biobank directory.

Results
Using the feedback provided through the interviews, online survey and focus groups, key messages could be developed to convince researchers of the value of high-quality biobanks and explain the possibilities a cross-biobank online search tool holds e.g. for research projects on small disease subgroups. These key messages were then adapted to be used in a communication campaign. The information obtained
from researchers also allowed to identify most suitable components for the campaign and its channels.

Discussion
No biobank service and innovation has value without users knowing about it – targeted communication is necessary. Increasing the number of researchers using high-quality biobanks and GBA’s “Sample Locator” could accelerate biomedical research in Germany, contribute to replicable research findings and enable a faster delivery of precision healthcare.

Discussion
We propose here a structured workflow for incidental findings in the context of Hospital-based biobanking. Many aspects (ethics, GDPR) have been addressed; however, further testing in daily practice will show whether this workflow might be useful for other hospital-based biobanks, too.

P10A_8 - Biobank Issues - Put a Sample Service Coordinator into Your Research Life

Bergenstråhle, K.1,2, Demirel, I.1,3, Enquist-Olsson, K.1,4, Isaksson, H.1,3, Johansson, A.1,4, Lindström, I.1, Mori, M.1,5, Ortega-Paino, E.1,6, Ridell, E.1,7, Sarwari, W.1,8, Thysell, E.1,4

1Biobank Sweden; 2Uppsala node; 3Örebro node; 4Umeå node; 5Stockholm node; 6South node; 7South East node; 8West node

Biobanking is a complex field and it requires knowledge in the field to start new studies and to get access to existing collections, fulfilling all the requirements established by the Swedish Biobank in the Medical Care Act. Biobank Sweden has established the role of Sample Service Coordinators (SSC) to support researchers in biobank issues. SSCs are spread in the seven different universities with university hospitals, are employed by the Medical Faculties, and serves and acts in their correspondent biobank facilities. Therefore, SSCs are located in Gothenburg, Linkoping, Lund, Örebro, Stockholm, Umeå and Uppsala. The main SSC role is to guide and support researcher interested in starting a new national study involving new sample collection or cohorts. It is a logistical challenge to ensure that sampling and handling is performed in a uniform way to assure comparable sample quality independent of site. Moreover, SSC will provide researchers with advice and guidelines to get access and retrieve samples from existing sample collections/cohorts, as well as to encourage the scientific community to collaborate, use and give value to all the existing collections. SSCs will also have a regional strategic function by developing a local workflow, which fits in a tight manner within the national coordinated biobank services. All this together make the SSC a key resource for researchers to create, find, access and retrieve samples for local, regional and national research studies that could lead to the discovery of relevance re-contact the former patient/donor (clinical confirmation of the “finding”).
of better biomarkers and therefore, to better health and quality of life.

**P10A_9 - #Wecare_Ye Project: A New EU Initiative to Promote the Paediatric Patients Engagement**


TEDDY European Network of Excellence for Paediatric clinical Research, Via Luigi Porta 14, 27100 Pavia – Italy (TEDDY)

CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE (CVBF), Via Putignani 178, 70122, Bari, Italy

CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE – Dege e shoqerise se huaj (CVBF-AL), Rruga Prokop Myzeqari 9 1000 Tirana, Albania

UNIVERSITAIR ZIEKENHUIS ANTWERPEN (UZA), UNIVERSITEIT ANTWERPEN (UA), Address in WILRIKSTRAAT 10, 2650 Edegem, Belgium

FUNDATIA ROMANIAN ANGEL APPEAL (RAA) address in 52 Rodiei Street, sector 3 Bucharest, Romania

MASARYKOVA UNIVERZITA (MU), Zerotinovo namesti 9, 60177 BRNO STRED, Czech Republic

GREEK CARERS NETWORK EPIONI (EPIONI), address in Victoros Oguko 15, 104 37 Metaxourgio, Athens, Greece

**Background**

Over the last years, Patient Engagement and Advocacy have taken hold in the scientific community. This vision aims to draw on patients knowledge in order to reach more easily clinical achievements and address unmet medical needs. Engaging early in research process is the aim of #wecare_ye project, funded within the Erasmus + programme with the aim to create four Young Persons Advisory Groups (YPAG) in partner countries following the experience of KIDS Bari and KIDS Albania developed by Consorzio per Valutazioni Biologiche e Farmacologiche, with the TEDDY Network and the local University Hospital. YPAGs are groups of youths actively participating as advising partners in many research activities.

**Methods**

To achieve this goal, a youth exchange will be organized in Bari (8-18 July) with people responsible for the setting up of the group and every organizations will select youngsters, aged 13-18 years, chosen among young patients, patients’ relatives, youngsters interested to health. The youths will follow a training characterized by “peers education” and “learning by doing” approaches, aimed to increase their engagement on health and research issues and learn how to be actively involved in the decisions concerning their own health, but also the management of clinical research.

**Results**

Sharing best practices on youth engagement among partners will affect positively the quality and management of health services.

**Discussion**

Through the creation of new YPAGs, the youths will be able to take an active part in clinical studies, awareness campaigns and development of educational materials for various age groups.

**P10A_10 - Migrating from Opt-Out to Opt-In Consent for Residual Samples: A Solution-Oriented Approach**

Lutomski, J.E., Oord, A.V., Rebers, S., Zielhuis, G.A.

**Problem**

Residual samples, i.e. leftover biomaterials from standard clinical procedures, constitute a critical resource for the biobanking community. Patient consent for the use of residual samples frequently relies on an opt-out method, which means such samples are available for scientific research unless the patient explicitly refuses. However, in the current ethical-legal environment, there are widespread concerns that this method undermines patient autonomy. An opt-in method, where the patient explicitly consents to the use of residual samples, has been regarded as the preferred standard. With this backdrop, the Netherlands Federation of University Medical Centres has proposed a strategic plan to evaluate the feasibility of migrating from an opt-out to an opt-in method for new patients. The Radboud Biobank Radboudumc Geert Grootenplein 10, 6525 GA Nijmegen The Netherlands

**Solution**

Residual samples, i.e. leftover biomaterials from standard clinical procedures, constitute a critical resource for the biobanking community. Patient consent for the use of residual samples frequently relies on an opt-out method, which means such samples are available for scientific research unless the patient explicitly refuses. However, in the current ethical-legal environment, there are widespread concerns that this method undermines patient autonomy. An opt-in method, where the patient explicitly consents to the use of residual samples, has been regarded as the preferred standard. With this backdrop, the Netherlands Federation of University Medical Centres has proposed a strategic plan to evaluate the feasibility of migrating from an opt-out to an opt-in method for new patients. The Radboud Biobank Radboudumc Geert Grootenplein 10, 6525 GA Nijmegen The Netherlands
Forming a strong collaboration between various departments is essential; this includes representatives from registration/medication check-in desks, patient communication and information management. The optimal point of contact to discuss consent for use of residual material during the patient journey is a critical factor. Consideration should also be given to how consent is carried out for patients undergoing different treatment pathways.

Discussion
The Radboudumc will launch this feasibility study in September 2018. The process will be routinely evaluated; underlying reasons why some patients are uncertain or refuse consent will also be investigated.

P10A_11 - The Cost of Benefit Defining Benefit Sharing in the Context of African Biorepository Services

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H3 Africa Biorepositories Clinical Laboratory Services De Korte Street Braamfontein Johannesburg South Africa

Introduction
Biorepositories are a key resource for longitudinal population-based studies as sources of high quality biological material for rare diseases and to foster innovation across the biological-value chain. Historically, biological material has been transported outside Africa’s continental borders without tangible benefit accruing to African subjects. As the regional Human Heredity and Health in Africa (H3Africa) biorepositories based in Nigeria, South Africa, and Uganda, we have engaged with stakeholders across the continent to define benefit sharing for African participants in African biorepository services. The primary purpose of the project was to investigate how to increase the value of samples collected within healthcare, for medical research.

Methods
Comments and experiences were gathered during the autumn of 2018, through round table discussions as well as survey.

Results and Conclusion
It was emphasized that stored samples are necessary for medical research to improve knowledge of diseases and how to treat them. However, there are limitations mainly concerning to get access to and information about stored samples. Suggestions to increase the value of stored samples were; dedicated personal categories within biobanks, visualization of sample collections, increased information about samples’ quality, and facilitated industry and community-based interactions including return of research results.

Conclusion
The H3Africa policies for secondary transfer of biological material form a key resource for biorepository scientists engaged in work on the African continent and who wish to engage with the biorepositories which have been established through H3Africa as a resource for sample sharing to advance science.

P10A_12 - How to Increase the Value of Swedish Sample Collections?

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Biobank Sweden, Region Jönköping County, Jönköping, Sweden.

Introduction
Sweden has good conditions for medical research including human biological samples. There are national quality registers, national health data registers and biobanks with millions of stored samples that, after an approved ethical vetting, may be useful for medical research. The largest sample collections consist of samples collected within healthcare and stored in the county councils’ biobanks for the purposes diagnostics and treatment (approximately 95% of all stored samples). These samples can be used in medical research after an approved biobank application, approved ethical vetting, and consent from the donor in accordance with ethical vetting. The primary purpose of the project was to investigate how to increase the value of samples collected within healthcare, for medical research.

Methods
Comments and experiences were gathered during the autumn of 2018, through round table discussions as well as survey.

Results and Conclusion
It was emphasized that stored samples are necessary for medical research to improve knowledge of diseases and how to treat them. However, there are limitations mainly concerning to get access to and information about stored samples. Suggestions to increase the value of stored samples were; dedicated personal categories within biobanks, visualization of sample collections, increased information about samples’ quality, and facilitated
consents from sample donors. The main conclusion is that stored samples are of great value but that it can be increased through several actions. To receive full impact of those actions and a common biobank structure, a national collaboration between county councils, universities and industry is of the utmost importance.

**P10A_13 - Biobank Sample Collection in Psychiatric Care Units - How Do We Ensure Ethically Sound Recruiting?**

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**Background**

Finnish Clinical Biobank Tampere (FCBT) collects samples based on the donor’s informed consent from most inpatient and outpatient clinics of Tampere University Hospital. Until now, psychiatric care units have been excluded from sample collection. Most patients in psychiatric inpatient clinics at Tampere University Hospital are in involuntary treatment and might intermittently be unable to consent. However, most of the patients are competent to give their consent during care or later. In order to collect samples from psychiatric care units ethically and legally fair, mental health personnel would benefit from training targeted to assess the patients’ ability to give their informed consent during treatment. The objective of this study is to design training material that meets these needs. Methods: FCBT together with clinicians/nurses will identify training needs of psychiatry personnel in interactive workshops. Based on workshops and existing literature, training material will be designed. Training material will be tested in the selected units.

**Results**

Personnel of selected units will be trained to assess patients’ ability to consent, inform patients about biobanking and ethically sound recruiting and informed consent process. Systematic sample collection will be started after education.

**Discussion**

Having the possibility to consent to biobanking increases patient’s autonomy to decide about their own care. Collecting samples from psychiatric care will increase research conducted in the field of psychiatry. This might benefit the patients to receive personalized care. Moreover, experiences from this pilot study could encourage all other hospital-based biobanks to expand their sample collection into psychiatric units.

**P10A_14 - Research Ethics Between Science and Security: The Case of Biomedical Research**

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The EU has been one of the key proponents of knowledge economy, driven by cutting-edge research and innovation. The investments in science are however increasingly accompanied by calls for bringing research and innovation closer to the society, its values and needs. The practices of research ethics (whether in the form of ethics self-assessment or ethics committees) have become an important intermediary between science and the society in this regard. Yet what kind of social and political institutions do ethics practices in science mediate, how, and with what effect? This presentation will focus on ethics practices within BBMRI-ERIC, which brings together key actors involved in biomedical research in Europe and works towards harmonisation and globalisation of research. The paper argues that the newly established - or empowered - knowledge institutions in biomedical research increasingly translate demands for security into the language of privacy and practices of research ethics, education, and awareness-raising. As such, this development contributes to the transformation of security knowledge and reconfiguration of the political debate through which security and insecurity can be problematized.

**P10A_15 - Promoting Access to Biobank Samples and Data – THL Biobank as an Example**

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National Institute for Health and Welfare, THL Biobank P.O. Box 30, 00271 Helsinki, Finland

**Background**

THL Biobank aims to promote the research use of its vast sample and data collections. For the biobank to be FAIR (findable, accessible, interoperable and reusable), we have considered different approaches to better
showcase our sample collections and data resources. In addition, we have developed various routes for being accessible to researchers making sample/data queries and feasibility study requests. To complement this, we have streamlined the process for responding to researchers and providing accurate availability information.

Methods
Our sample collections are showcased on BBMRI-ERIC’s Directory and KITE availability system and extensive details are found on biobank’s webpages. Researchers may contact THL Biobank through different portals and channels: THL Biobank Inquiry form (Webropol), REMS2 application system by CSC, Negotiator by BBMRI-ERIC, BC|RQUEST by BC Platforms (for pharmaceutical companies), Fingenious query portal by FINBB; via biobank network members or strategic partners; or by direct communication (e-mail, phone, congress presentations, brochures etc.).

Results
During the last 12 months we have obtained over 30 different queries. A significant number of these queries resulted from congress presentation/ personal communication or came through strategic partners, illustrating the importance of being visible and actively networking. A team with different expertise is compiling the response to the queries to allow rapid and reliable reply.

Conclusion
Developing the access process to better serve the researchers is a continuous effort. It is essential that all related processes are fluent and potential customers receive a prompt and professional answer to any presented query, regardless of the method of their approach.

P10A_16 - Identifying the Rate of Participation Among a Socio-Demographic Triangle and Understanding the Barriers between Science and Society

R. Singh
K-RITH Tower Building, Nelson R. Mandela Medical School, 719 Umbilo Rd, Umbilo, Durban, 4001,AHRI,South Africa

The current participation rate in Research studies are a major concern in providing answers to questions in medicine, which leads to better ways to prevent, detect, diagnose, control, and treat illnesses. Not every study aims at patient benefit or providing a positive outcome, however it is imperative to understand how this affects participation rate as well as how we can maximize patient benefit to possibly increase participation and create more advantages for current and future clinical trial participants. Method To conduct a survey in the form of a Questionnaire in three demographical areas Rural (Ngwelezane), Urban public (Addington Hospital) and Urban private (St. Augustine’s). The survey will approach Study Research Health workers who are already part of an HIV and TB Research study to better understand what different rates of participation are and why. keys areas to focus on:

- The demographical information
- Understanding of the research
- Communication skills
- Does level of education influence participation
- Understanding the decision-making process and possibly involving an individual’s cultural beliefs and how science researchers can become more culturally aware.

Results and Conclusion
All these key areas will help in evaluating how the rate of participation is dependent on specific key areas which may improve the process and possibly increase the participation rate. This will help in designing a tool for participation in those demographic regions, as well as helping the health workers to improve on their skills.

P10A_17 - Biobank Sweden – The Implementation of a New Swedish Biobank Infrastructure

Eaker Fält, S., Sjöblom, T., Beskow, A., Thunell, L.
Biobank Sweden

Problem
In Sweden, over 150 million samples are stored in biobanks with a yearly increase of 3-4 million. Thanks to the use of unique personal identifiers, biobank samples can be linked to nationwide health data registries. In order to fully utilize this, we now focus on national harmonization.

Solution
We are organized into a national biobank infrastructure; Biobank Sweden. This is a joint initiative founded by Swedish healthcare and universities with medical faculty, including industrial partners and patient advocacy groups. Biobank Sweden is a member of BBMRI-ERIC. Our work is in the intense implementation phase. Our overall goal is to build a sustainable national biobank infrastructure where we provide a nationally accessible, cost effective biobank network securing access to high quality samples. To attain this, we work on national harmonization of several aspects of biobanking. We have a joint web portal, a communication strategy, and a biannual national biobank conference. The regulatory support function has been expanded with an ELSI helpdesk for research support. Operative support is established through Sample Service Coordinators and Hospital Integrated Biobanking. We address the question of how to increase the value of healthcare biobanks for research and a national IT strategy has been created. Much effort has also been put into enhancing sample utilization through support of local projects.

Discussion
The implementation of the plans within Biobank Sweden is an important building block on the way to fulfilling the goal of offering coordinated access to biological samples and data for medical research and clinical trials.

P10A_18 - Valorization Of Hospital-Based Biobank Resources Through Samples And Data Sharing Policy: Example Of The Toulouse Bioressources Biobank

Vigné, V., Chassang, G., Rial-Sebbag, E.

Inserm, UMR1027, F-31000 Toulouse, France 37 allées Jules Guesde 31000 Toulouse

Valorization of Hospital-based biobank resources through samples and data sharing policy: example of the Toulouse BioRessources biobank Valentine Vigné123, Gauthier Chassang1234, Emmanuelle Rial-Sebbag123. 1 Inserm, UMR1027, F-31000 Toulouse, France. 2 Université Paul Sabatier Toulouse 3, F-31062 Toulouse, France. 3 Plateforme « Œtique et Biosciences », Genotoul Societal, F-31000 Toulouse, France. 4 Inserm, US13, Infrastructure Nationale Biobanques (BBMRI.FR), Institute for Public Health, Clinical Research Department, F-75013 Paris, France. Hospital-based biobank hold a particular spot in the French biobanking landscape. Firstly, they outnumber other structures, secondly they are at the crossroad of treatments and research, which places them at the center of modern innovative public health policies. The access and use of biomaterials (samples/data) is essential in developing precision medicine, technological, epidemiological and fundamental health researches. However, French biobanks face challenges regarding the fragmented national regulation, lack of standardized operational process and still have to be sustainably funded. Therefore, to increase the value of biological material, without compromising patients’ rights, biobanks tailored their legal and ethical framework to their needs. The Toulouse BioRessources multithematic biobank (TBR), hosted by Toulouse hospital, which collects biological resources from diseased people or through research procedures, is taken as an example of this phenomenon. How does TBR organize valorization at national and European level? How does it Frame access to biosamples? What are the results and the remaining issues/needs? This poster results from an empirical onsite research (access to documents and interviews), realized in partnership between Genoutoul Societal (Ethics and biosciences) and Genotoul CRBh (hospital-based biobanks).

P10A_19 - Blockchain Technology: Implementing Benefit Sharing

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Benefit Sharing is a concept that strives to give research participants or tissue donors a more equal position in research by trying to implement tools to fairly distribute research results developed from their tissue, such as therapies, technology, profits or patents. The implementation of benefit sharing for human tissue donors, however, causes conflicts of legal and practical nature, for example prohibition of commercialization of bodily substances, data protection and informed consent for future research, ownership rights to results, administrative effort and costs for tracing donors and maintenance as potential obstacles for research. Blockchain technology would be a means to counter or at least mitigate practical as well as legal reservations: Blockchain technology can design digital information units that contain elements of a property right (according
to civil law concepts) to which an owner has direct and exclusive access. It contains the tools to program a unique set of information that attributes property. Blockchain would also offer the potential of a shared data platform that decentralizes (health) data without compromising the security of protected (health) information. A crypto token could serve as proof or certificate that a person has actually participated in a research project and in so doing facilitate traceability as well as potential entitlement of tissue donors with relatively little effort. Applied in biobanks blockchain technology could enable research participants to participate in research more actively and benefit from its results as a sort of stakeholder and, therefore, equalize the power imbalance between researchers and research participants.

TOPIC 10B: POPULATION BIOBANKS – WHAT CAN WE LEARN FROM LARGE COHORT STUDIES IN DIVERSE POPULATIONS?

P10B_1 - How to Engage 10% of a Population in a Biobank with Limited Resources and within Limited Time

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Estonian Genome Center, University of Tartu, Riia 23B Tartu, Estonia

Introduction
In 2018, as part of Estonian republic's centennial celebrations the government launched a program to map the genotypes of 100,000 citizens from its population of 1.3 million. The goal of this initiative is to use this genetic data as the basis for transforming Estonian healthcare system to deliver personalized medicine.

Methods
In order to recruit nearly 10% of the adult population of Estonia as biobank participants tools of traditional marketing were applied to gain public support for the benefit of the nationwide project with a minimized budget. Methods used included publishing best case examples of the potential benefits of genetic information in health care, getting youtubers involved, increasing opportunities to get involved by involving a wide network of pharmacies as recruitment centers, volunteers as informers in public events and fairs, etc.

Results
By the end of the year, 100K new biobank participants were recruited increasing the population biobank cohort from previous 50K to 150K participants.

Conclusion
A lot can be done in nine months! The methods used and experiences gained throughout the project can be from the Estonian biobank can be used in other countries.

P10B_2 - Population and Genetic Isolate Biobanks: A New Working Group (WG) if BBMRI.It for 2019

Donati, M.B.,1 Napolitano, M.,2 De Curtis, A.,1 Bravo, E.2

1Neuromed Biobanking Centre, Department of Epidemiology and Prevention, IRCCS Neuromed, Pozzilli (IS) and 2Research Coordination and Support Service, Istituto Superiore di Sanità, Roma (RM), Italy

Background
Biobanking involves not only cryotechnology and clinical issues but also social, legal and ethical implications. The whole body of issues may differ according to the type of biobank, f.i. disease or population/genetic isolate-based. The latter have peculiarities, poorly recognized and defined so far in the Italian scenario. Within the 2019 Work Program of BBMRI.It, a new WG has been launched to cover specific needs of population and genetic isolate biobanks and to promote their collaborations as a research network.

Methods
Representatives of all Italian biobanks belonging to BBMRI.It were invited to take part in the WG activity: consisting in 4 two-hours call conferences and two one-day meetings (Pozzilli and Rome). Web platform for call conferences is made available by Bicocca University.

Results
WG activity plan includes: citizen empowerment to provide samples and personal data for better public health; common strategies for recognition by regional, national and international institutions; definition of peculiar needs and tools, such as pre-analytical and
storage variables; implementation of the ISO 20387; ad hoc remodelling of ethical and legal documents (i.e.: Consents, Transfer Agreements, Business Plan); common strategies of access/sharing and cost recovery; activities of public understanding for science to increase the visibility of biobanks.

**Discussion**

Work is in progress with the help of epidemiologists, statisticians, clinical and laboratory investigators, bioethics experts towards better public health strategies and prevention of chronic degenerative disorders. Acknowledgement: Italian Ministries of Health and Research, BBMRI.it.

**P10B_3 - Reuse of Data for Research: Challenging a Global Governance through the CINECA Project**

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**Problem**

Data sharing has become an essential and powerful tool for public health research. It reduces the need for dangerous and burdensome research protocols, avoids unnecessary replication, optimizes resources and promotes the gathering of diverse and rare information. However, sharing and processing of data also exacerbates risks of violations of fundamental rights of research subjects and patients like privacy or non-discrimination, all the more so when the data is sensitive as is the case for genomic and health related data.

**Solution**

The H2020 funded project CINECA aims to create a Common Infrastructure for National Cohorts in Europe, Canada and Africa. The goal is to enable the exchange of population scale health data across international borders to allow and promote reuse of data for research. The CINECA project is a particularly interesting illustration of the obstacles of putting into place such a broad infrastructure of health data sharing. The public health opportunities are all the more promising that the virtual cohorts assembles 1.4 million individuals from populations, longitudinal and disease studies from countries of Europe, Canada, and Africa.

**Discussion**

Nevertheless, with this richness and diversity of data come even more challenging issues of compatibility of personal data protection frameworks in the three continents. The goal of this presentation is to introduce the project and to use it as a case study for an ethical and legal reflexion on the balance between the protection of personal data and the promotion of public health interests in a global context.

**P10B_4 - Fargen – A Population Based Initiative towards Precision Medicine**

Guðrið Andorsdóttir, Leivur Nattestad Lydersen, Ólavur Mortensen, Katrin Didriksen Apol, Bjarni á Steig and Noomi Oddmarsdóttir Gregersen

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**Background**

We propose a population based initiative towards precision medicine, by exploring the isolated population of the Faroe Islands as a model-population for integrating genomics with national health registry data. With the FarGen-Health study we will construct an infrastructure with multidimensional data comprising genetic, biochemical, microbiome and body measurements that will give an overall knowledge about the health of the Faroese people. By incorporate the multidimensional data with health information from medical records, pharmaceutical records, socio-demographics and genealogy we aim to describe the relationship between genes and other health/risk factors for common and rare diseases in the Faroese population. **METHOD** We will recruit 3500 individuals in addition to the 1500 individuals already in the FarGen-infrastructure. The project will involve collecting blood samples for genetic and biochemical analysis, stool samples for microbiome analysis, as well as collecting health status information through body measurements and questionnaires. Access to medical and pharmaceutical records will be required for the multidimensional analysis.

**Results and Conclusion**

The project will increase the knowledge of the genetic variation within the Faroese population i.e. knowledge of known, unknown and de novo mutations. Further, the multidimensional data will be available for combined analysis in order to describe and predict polygenic risk scores for various diseases in the Faroese population.
This information will be essential for the development of precision medicine aimed for the Faroese population, however, in the long-term it will contribute to the development of precision medicine in general.

**P10B_5 - The Norwegian Mother, Father and Child Cohort Study, an Infrastructure for Research**

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**Background**
The Norwegian Mother, Father and Child Cohort Study (MoBa) is a large ongoing prospective population-based cohort aimed at studying causes of diseases.

**Methods**
Between 1999 and 2008, pregnant women and their partners were invited to participate when attending ultrasound examination around 17 weeks’ gestation. 114,500 children, 95,000 mothers and 75,000 fathers were recruited based on consent. This includes 16,400 mothers with more than one pregnancy (i.e. siblings) and 1,900 pairs of twins. The parents responded to questionnaires on physical and mental health at regular intervals during and after pregnancy (mothers n=11, fathers n=2). Collection of questionnaire data is ongoing. The children respond to questionnaires from age 13. MoBa is linked to the Medical Birth Registry of Norway, and linkage to other national registries is possible. Biological samples were obtained from parents during pregnancy, and from mother and child (umbilical cord) after birth. Samples of DNA, RNA (child), whole blood, plasma, urine (mother) and teeth (child) are stored in biobanks.

**Results and Discussion**
The family design enables analyses of mother, father and child trios. Genetic data is available from participants through the research infrastructure MoBa Genetics. Genotyping is in progress. As a birth cohort MoBa offers a unique frame for studying environmental factors, by self-report measures or biomarkers, during pregnancy and their effect on child development and health status during adolescence and adulthood. MoBa has resulted in >650 publications. Researchers may apply for access to data and samples at www.fhi.no/moba.

**P10B_6 - Taiwan Biobank: A Valuable Resource Incorporating Health Data with Biospecimens Representative of Han Population**

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**Background**
The prevalence of chronic diseases becomes challenging. To identify the cause of these common diseases in Taiwan, we established the Taiwan Biobank (TWB), a national database collecting biological specimens and personal information from general Taiwanese population.

**Methods**
We aim to recruit 200,000 Taiwanese nationals, approximately 1% of total population, between 30 and 70 years of age with no history of cancer to 29 recruiting centers across the nation. In a 1-2h reservation slot, the participants will be explained in detail about the biobank, their rights, obligations, and risks before signing a consent form, followed by a physical examination, blood and urine collection, and filling out an electronic questionnaire. The participants are invited to come back for a follow-up every 2-4 years. By using biological samples, we are carrying out whole genome genotyping, whole genome sequencing, HLA typing, epigenomics, metabolomics, and, urine plasticizer levels.

**Results**
TWB has more than 110,000 participants so far. Among these, the gender ratio of male to female is about 1:1.8, and the age distribution is more even. The number are expected to reach 200,000 by 2024. To make the database more regionally and ethnically representative, at least 1% of qualified nationals in each county will be encouraged to participate.

**Discussion**
The composition of Taiwanese population is unique and representative as it includes all the subgroups of the Han ethnicity. The community-based population cohort study helps researchers to clarify the complicated factors related to the development of chronic diseases and thus improves their prevention, diagnosis and treatment.
P10B_7 - Exploring the Link Between Cancer Registries and Biobanks Information in European Breast Cancer Research

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Background
The burden of breast cancer is increasing worldwide. Advances in molecular diagnosis and the personalised therapies are improving the outcomes. The link of the information contained in the biobanks, clinical records and population-based cancer registries permits longitudinal follow-up of cohorts to study health outcomes at population level. The goal of this study is to explore how the link between these sources has been used in breast cancer research in Europe. The role of the cancer registries in this process is also highlighted.

Methods
Searches were done in Pubmed for studies regarding the use of biobanks in breast cancer research and involvement of the cancer registries in this process. Studies published until March 2019 with an abstract in English were included.

Results
The searches retrieved 20 studies fulfilling the inclusion criteria. Cancer registries were used to identify retrospectively the cancer cases in 11 studies, to link clinical data or other information with the biobanks in 5 studies. In 4 studies the cancer registries were used to prospectively investigate cancer occurrence and follow-up for a cohort.

Conclusion
In Europe, the link of the cancer registries and biobanks information for breast cancer research is limited. Population based cancer registries are used mainly to identify and follow-up subjects. Linkage of different data sources including cancer registries and biobanks should be further promoted, as a valuable source of information to possibly understand the effects of genetic, environmental and lifestyle factors on cancer incidence and mortality and thus boosting clinical and epidemiological researches.

P10B_8 - The Population Biobank of the Istituto Superiore Di Sanità: The CUORE Project Collection for Epidemiological Research in Italy

Donfrancesco, C., Lo Noce, C., Di Lonardo, A., Morsilli, O., Tocaccelli, V., Scipione, R., Veronesi, G.a, Strazzullo, P.b, Giampaoli, S., Vanuzzo, D.c, Palmieri, L.

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Background
The population biobank of the Istituto Superiore di Sanità (ISS) is an Italian research infrastructure, which stores biological specimens of longitudinal epidemiological studies since ‘90s. The biological material is linked with data on life-styles, risk factors, and high risk conditions provided by donors who agree to participate to research projects. Procedures for collecting, storing and preserving biological specimens follow international standards. The ISS biobank is part of the BBMRI-IT in the BBMRI-ERIC. Within the ISS biobank collections, CUORE Project includes serum, plasma, buffy coat, red cells and urine of over 25,000 persons, aged 20+ years, examined in 8 longitudinal studies with the aim of estimating the predictive role of new risk factors in the development of chronic degenerative and ageing related diseases. The CUORE Project was approved by the ISS Ethics Committee.

Methods
Biological specimens are preserved in liquid nitrogen, urine at -30°C, whole blood at -80°C. Follow-up of cardiovascular events are available up to 2004; currently all cause and specific mortality follow-up is ongoing. International collaborations have been set up (MORGAM, BiomarCaRE, CHANCES, euCanSHare).

Results
Within BiomarCaRE lipid-related markers, markers of renal function, metabolic disorders, vascular functions, inflammatory processes and necrosis were measured on stored samples of 1,735 men and 2,706 women; data were pooled with 21 European cohorts for cardiovascular risk prediction.

Conclusion
Data and biological samples of the CUORE collection are available for public health purposes and epidemiological
research, under the provisions of international ethical guidelines and the European personal data treatment regulation (GDPR 679/2016).

P10B_9 - The Population Biobank of the Istituto Superiore Di Sanità: 24h-Urine Collection for Epidemiological Research in Italy

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Background
The population biobank of the Istituto Superiore di Sanità (ISS) is an Italian research infrastructure included in BBMRI, which stores biological material collected from population epidemiological studies since ’90s. The biological material is linked with data on life-styles, risk factors, and high risk conditions provided by donors. Procedures for collecting, storing and preservation of serum, plasma, buffy coat, red cells, urine and other specimens follow international standards. Among collections belonging to ISS biobank, CUORE Project stored 24h-urine samples collected within 4 population studies, aimed at monitoring sodium and potassium intake of Italian adult population.

Methods
Sodium and potassium intake was assessed in frozen urine, and performed by a central laboratory at the University Federico II in Naples; specimens are preserved at -30°C in the ISS population biobank; follow-up of mortality of the examined population is planned.

Results
Between 2008 and 2014, 24h-urine were collected for 8,787 persons aged 35-79 years, resident in all 20 Italian Regions, showing a mean sodium excretion of 10.6g/die in men, 8.2g/die in women. A new survey covering 2000 persons, ages 35-74 years, resident in 10 Regions, is ongoing and results will be available soon; up to now 24h-urine have been collected from 1,454 persons.

Conclusion
These researches are partly funded by the Ministry of Health-CCM; it is just an example of the opportunities that a population biological bank may offer. The ISS population biobank is a precious source for public health purposes and for future epidemiological research in chronic and ageing related diseases.

P10B_10 - Lifelines, a Three-Generation Cohort Study and Biobank

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Introduction
Lifelines is a large three-generation population-based cohort study and biobank that aims to facilitate research on Healthy Ageing. A wide range of data is being collected from 167,000 participants in the Northern part of the Netherlands,. As such, Lifelines is a valuable resource for multidisciplinary research on complex interactions between environmental, phenotypic and genomic factors in the development of various (chronic) diseases.

Methods
Lifelines aims to follow participants over a 30-year period. So far two study waves were completed in the periods 2007-2013 and 2014-2017. The third wave is planned for October 2019, 155.000 participants will be re-invited. Biomaterials, physical measurements and questionnaire data are gathered. Characteristics of dropouts are being analyzed.

Results
Lifelines received over 480 applications for data access from a wide variety of disciplines worldwide. Including over 50 requests for additional assessments leading to ‘in depth’ knowledge about specific subgroups in Lifelines participants. Furthermore, Lifelines has procedures for data linkage with Statistics Netherlands (CBS), pharmacy database IADB, PALGA, and GIS data, which has proven to be scientifically powerful. This has thus far resulted in almost 300 published papers.

Conclusion
Taken together, Lifelines is a valuable resource for national and international multi-disciplinary research in the field of healthy ageing. Lifelines offers the opportunity for personalized medicine with sufficient power,
ultimately leading to improvements in health care and disease prevention. The Lifelines website provides details on how to apply for data and/or samples, the available data in our online catalogue and an overview of publications with Lifelines data.

**TOPIC 10C: BIOBANKS DRIVING ARTIFICIAL INTELLIGENCE FOR A HEALTHIER WORLD**

**P10C_1 - In the Era of Translational Research: Biobank and Precision Medicine**

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**Background**

The biobank at Regina Elena National Cancer Institute (BBIRE) is an integral part of the strategic plan of the Institute. BBIRE is involved in a growing number of projects, and as a member of the European research network of Biobanks and Biomolecular Resources (BBMRI-ERIC) participates with European groups (EORTC) to large-scale multicenter projects. BBIRE may be defined as the collecting, storing and distributing biological material according to specific ‘Standard operating procedures’ (SOPs); in order to implement, clinical and translational cancer research. The availability of well annotated, high-quality human samples linked to accurate diagnostic and clinical information is essential in the research and development of new biomarkers and drugs in the overall goal of precision medicine.

**Methods**

The BBIRE has collected more than 8500 solid human tissue samples, and about 36000 fluid samples as well as associated clinical data of patients and their follow-up with a high quality level.

**Results**

In all cases we assess the tissue morphology with Aperio Image system analysis, that represents the most used solution for digital pathology, to verify the correspondence with the final pathological diagnosis, and stored for molecular analyses. We performe Next-generation sequencing (NGS) by S5 by Thermofisher (NGS), which can allow simultaneous determination of hundreds of target genes.

**Conclusion**

Our BBIRE can provide medical and scientific research and infrastructure support, in the era of personalized medicine. High throughput data are available due to the NGS sequencing capability and expertise in data analysis and thanks to the, sharing and advanced networking model.

**P10C_2 - Data Science Tools for Healthcare-Integrated Biobanking**

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**Background**

Healthcare-integrated biobanking connects highly automated routine patient care with institutional or study-specific sample collections. Sample-related information is retrieved during the sampling procedures, while disease-related and patient-centered information is usually retrieved within the clinical setting and IT infrastructure. Frequently, these systems are neither made for being queried nor for data science evaluations. With our unified data platform we offer data extraction for patients having biobank samples, standardized reporting and a broad range of data evaluation methods to optimize the utilization of patient data and samples.

**Methods**

Our general data platform structure comprises many source systems (e.g. lab, biobank, hospital information, survival data, diagnoses, medications etc.) that are preprocessed via ETL (extract, transform, load) processes and form a large database, that can be queried using state-of-the-art tools like R and python.
Results
Markdown-based scripts automatically extract and evaluate the data, delivering e.g. key performance indicators, publication-ready graphics, and self-adjusting summaries. For specific requests, we can flexibly assemble data from the source systems and generate data files for further statistical assessment. Depending on the ethics approval, data can also be pseudo- or anonymized.

Conclusion
A comprehensive data platform together with modern data science tools enables vast and flexible script-based evaluation of patient-related data in the context of healthcare-integrated biobanking.

P10C_3 - AI or not AI that’s the Answer

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The problem with AI in health care lies in the artificial simulation of intelligent structures and disease models. Independent learning must be part of intelligent information processing right from the start. Only by digitizing and harmonizing data can an intelligent system meet the demands of society. However, this development faces several hurdles: The lack of an IT infrastructure in hospitals is accompanied by outdated, paper-based data processing. At the same time, digitized data stocks are untapped for medical research due to technical hurdles. Different standards, semantics as well as ontologies lead to “communication deficits”. The result is an increasing fragmentation of data. Big-Data must contribute to these developments. The fact that this kind of learning brings great advantages or even solves problems that the disruptive factor human intelligence simply cannot solve has already been proven in many technical areas. For this, however, AI systems must access a pseudonymized data pool, which must be provided by the health care systems. At present, almost every institution insists on its own system solutions and definitions. As a result, the data does not flow where it is actually needed. Data must be understood as common property, which is made available and used in a generally beneficial manner in accordance with data protection regulations. The data protection that is often used as an excuse must not be used to prevent this. This must not give patients the impression that data protection is superfluous, but the argumentative use of data protection to prevent it costs lives.

TOPIC 10D: BECOMING A BIOBANKER: YES WE CAN!

P10D_1 - Implementing a CCFDNA Extraction Workflow as Part of an Internship Project in the Interdisciplinary Center for Biobanking-Lübeck (ICB-L)

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Background
Cancer patients show elevated circulating cell-free DNA (ccfDNA) concentrations in their blood system. Thus, ccfDNA levels are high-potential, sensitive biomarkers for cancer diagnosis and therapy monitoring.

Methods
As an internship project we aimed at implementing ccfDNA extraction from cancer patient plasma as a routine service in the ICB-L. The performance of two different commercial kits was evaluated: a manual (MK) and an automated (AK) ccfDNA extraction kit. For the latter, we use an existing purification robot. In total, 12 study participants were recruited. The sample quality was assessed employing concentration measurement by UV absorbance and dsDNA-dye fluorescence, and ccfDNA fragment size determination using the Bioanalyzer microfluidic electrophoresis instrument (Agilent).

Results
For AK, we observed with dsDNA-dye fluorescence a ccfDNA concentration range between 0.11-1.21 ng/ul (p25: 0.19 ng/ul; p50: 0.23 ng/ul; p75: 0.44 ng/ul), and for MK a range between 0.13-1.70 ng/ul (p25: 0.20 ng/ul;
For both kits observed ccfDNA fragment sizes were in the expected range of ca. 200 bp. Peak integrals were slightly higher for samples processed with MK. However, the kits differ regarding manual processing time and costs. MK requires a manual processing time of 70 min, while AK using a robot requires just 5 min. Including technician salary, ca. 48 €/sample for MK face ca. 18 €/sample for AK.

**Conclusion**

Considering the comparable performance, but lower costs using the existing infrastructure, and lower manual preparation time, AK is identified as most efficient method for the ICB-L.

**P10D_2 - Biobanking Education: To Whom it May Concern?**

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Education in biobanking is very complex and requires a detailed needs assessment before setting-up specific training sessions. Topics of interest vary according to the profile of the target group. Thus, it is impossible to set up a general training for all types of learners. In this context, a question arises: What should be taught to whom? In order to identify commonalities and differences among interests, Biobank Graz has surveyed former learners from the different training sessions: 3-day Biobanking course and 2-year Master Program. Learners have been asked through online surveys about their preferences in different biobanking topics. Two surveys have been sent, first to the 3-day biobanking course learners and second to the graduates of the Master program. The response rate for both surveys reached over 30%. Three topics were equally preferred by both groups: Quality, ELSI and Business Plan/Cost Calculation. However, some topics were preferred by one group more than the other and vice versa. In one hand, MSc graduates expressed their interest in infrastructure and sample workflow. In the other hand, biobanking course learners expressed their interest in practical work (lab technics) and data management/IT. The results suggest that learners from short-term courses are more interested in specific technical aspects of biobanking while the Master graduates are more interested in managerial aspects including biobanking workflow. Each group is intended to hold specific positions in the field; in this context, tailor-made education in biobanking is necessary while keeping important topics, such as quality and ELSI, in both programs.

**P10D_3 - Medical Informatics in Biobanks: Experiences from an Interdisciplinary Internship from the Student’s Side**


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**Background**

Students choose to study Medical Informatics because it is scientifically oriented and at the same time practice-related. The tasks in the research field between medicine and computer science serve to further improve medical care and patient treatment in the future.

**Methods**

The practical course in the master's program can be done in research institutions or companies in Germany or abroad. This internship lasts six months and is carried out at the IT Center for Clinical Research, Lübeck in close cooperation with the Interdisciplinary Center for Biobanking-Lübeck at the campus.

**Results**

During the internship two main areas of the clinical infrastructure, biobanking and study administration can be explored. In the laboratory of ICB-L collecting, processing and storage of samples are demonstrated, especially the different automated storage systems. Regarding the samples, the cut of tissue samples is examined in the pathology. Getting to know these biobank relevant processes is particularly instructive to transfer them to mobile sample documentation. In the field of study management different approaches for automated study recruitment on the basis of inclusion and exclusion criteria were evaluated.
Discussion
The practical course had a positive influence on my professional and personal development. In particular, the interaction with other international interns of other disciplines was very educational. I think the internship is a good preparation for my future professional life. The wide-ranging ethical and data protection requirements were both a challenge and an opportunity.

P10D_4 - The Advantage of Combining Two Worlds: Scientists and Lab-IT

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In the course of digitalization, the working environment changes significantly. Meanwhile, scientists and lab members need extensive knowledge not solely about the lab equipment but also about lab organization software and biobanks. The demand for well-trained employees increased drastically but society still lacks specialists connecting two worlds - lab workflows and their special requirements facing the lab IT. Comprehensible communication between these two worlds is often complicated. Professional trainings for scientists and lab members on IT basics and more detailed the IT environment in the lab help to understand the benefits of a digitalized lab and the processes behind. We established an academy that trains future employees or already established coworkers with diverse methods such as webinars, seminar-days and even personal coaching. We train the participants irrespective of a certain system which means the training focuses entirely on basic IT knowledge and understanding lab organization software and biobanks in general, not a specific software. Moreover, depending on the requests, participants have the possibility to improve their soft skills or optimization of professional self-portrayal for their application process to become even more successful. With such an advanced training, employees can rise to a valuable interface between lab and IT world and serve as knowledge multiplicator in their company. They can also provide highly qualified input for future IT projects in the course of the digitaliz.