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The International Society of Biological and Environmental Repositories Presents Abstracts from Its Annual Meeting

Breaking Down Walls: Unifying Biobanking Communities to Secure Our Sustainability

April 5–8, 2016
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The abstracts that follow demonstrate the broad range of timely issues addressed in the contributed oral and poster presentations at ISBER's 2016 Annual Meeting & Exhibits.

INTERNATIONAL SOCIETY FOR BIOLOGICAL
AND ENVIRONMENTAL REPOSITORIES

ORAL ABSTRACTS

Biobanking Profiles

O4-21 Experiences of the First 3 Years and Future Topics for Biobanking in the German Center for Infection Research (DZIF)

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Background: In 2013 the German Center for Infection Research (DZIF) was founded with the mission to coordinate and strategically align translational infection research with the aim of developing new diagnostic, preventative and therapeutic methods for treating infectious diseases. Within DZIF the Translational Infrastructures (TI) biobank has been established to provide fast and standardized access to biomaterials which is nowadays mandatory for multisite and translational research.

Methods: For better coordination while using the existing expertise, the platform was divided into 3 columns (tissue, liquid and pathogens). To build up the biobanking platform, pre-existing biomaterials as well as respective expertise and technologies at different partner sites were integrated.

Results: A stable communication through telephone conferences and the biobanking homepage (www.biobanken.de) was built up between all DZIF sites. The development of a generic ethical and data protection concept has strengthened the harmonization in ELSI aspects. More than 100 biobanking projects were executed and documented at the different DZIF sites at present. In addition, the connection to the national biobanking community was tightened (strong connection to the other German Centers for Health Research (DZGs), the German Biobanking Node (GBN)).

Conclusion: In the course of the first phase (2013–2015) it was recognized that human tissue and liquid samples and pathogen biobanking are structurally too different and therefore the TI was divided into the human biobanking and pathogen biobanking part. For the second phase (2016–2018), the main focus of the TI is to support the DZIF Transplantation (Tx) cohort, a large multisite study on infections in transplanted patients. One of the central tasks will be the implementation of a central data and sample management system for Tx and other prospective biobanking projects in DZIF. Moreover, a harmonized quality management system (SOPs) for a standardized collection of biomaterials at the DZIF Tx-cohort sites will be set up. Additionally, the training of local staff for internal audits and audit coordination will be provided, as well as ongoing support in ELSI questions. In addition, future work for the DZIF biobanking platform includes extending the networking within the national (DZGs, AG BMB TMF, GBN) and international (e.g. ESBB) biobanking community.

Biodiversity/Environmental/Repositories

O4-23 Determining Sample Suitability for Genomics Applications of Samples from the National Marine Mammal Tissue Bank

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The National Institute of Standards and Technology (NIST) began banking specimens for contaminant trend monitoring in 1979. Based on these initial collections, NIST protocols for collection, processing, and banking biological tissues and fluids have been primarily for environmental contaminants analysis, with operations centralized at the Marine Environmental Specimen Bank (Marine ESB), Hollings Marine Laboratory, Charleston, SC.

The National Oceanic and Atmospheric Administration's (NOAA's)/National Marine Fisheries Service (NMFS) Marine Mammal Health and Stranding Response Program established the National Marine Mammal Tissue Bank (NMMTB) in 1990 as a resource of tissue samples for chemical analysis, to determine exposure to contaminants and retrospective research on exposure history of populations to emerging contaminants. Maintained by NIST at the Marine ESB, the NMMTB tissues are collected and banked from fresh-stranded marine mammals, animals taken incidentally in fishing operations, and from Native Americans for subsistence.

NIST is working with NOAA and its collaborating partners to expand the scope of the specimen bank and develop it as a resource of samples for animal health research. Currently, efforts are being made to evaluate sample suitability for genetics and protein research. Initially, total RNA isolates from liver samples collected at a mass stranding event of Atlantic white-sided dolphins (Lagenorhynchus acutus) in 1998 will be analyzed using qPCR and Next-Generation RNA sequencing. The success, or failure, of these downstream applications will be correlated to RNA quality indicators to determine if the current inventories of samples at the Marine ESB are suitable for molecular biology research. In the future a range of collection conditions, species, tissue types, and storage conditions will be included to determine sample limitations.

Biospecimen Research and Science

O4-26 Laser Scanning Microscopy and Micro-Spectroscopy for Cryobiology and Cryopreservation

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In order to preserve a biological product from degradation, storage at very low temperatures is a common strategy. This will considerably slow most (bio-) chemical reactions down to almost stagnancy and furthermore drastically increase the viscosity throughout the sample to virtually stop any diffusion. Unless the cooling process is extremely fast and yields a vitrified state, the sample will disaggregate into a complex texture of phases upon freezing: Ice, salt hydrates, precipitated additives, biological matter and the remaining fluid in a liquid or glassy form. Not only is the physiological and molecular state of the biological matter determined by the cooling speed but also the phase texture and composition of the surrounding medium, which again influences the environment the biological matter is stored in.

Most established experimental methods of biology require a liquid aqueous medium and are not applicable to a solid matrix. So the effects of cryopreservation - freezing, storage & thawing - are studied in accumulation after frozen storage. Microscopic techniques applied to cryopreserved samples are predominantly consumptive (cryo-EM) or yield only morphology information (cryo transmission microscopy).

Since laser scanning microscopy techniques provide ways to gain molecular and physicochemical information with sub-micron three-dimensional resolution, we adapted two conductive laser scanning methods to cryogenic samples: two photon microscopy (TPM) [1] for structural and functional investigations as well as confocal Raman microscopy (CRM) [2] for chemical imaging. Using TPM we investigated the volume progress of cells in interdendritic channels during the freezing process, formation of intracellular and intranuclear ice crystals, recrystallization and the distribution of cells and phases over a vial cross section. CRM enabled us to observe water and DMSO fluxes over the cellular membrane during freezing, to identify and localize salt hydrates within and around cells and to confirm the glassy state of the cytoplasm of successfully stored cells.

The advances and potential as well as the limits of the laser scanning imaging technologies regarding their use in cryobiology will be discussed. Prospects for novel biobanking technology based on the present results are given.

[1] D. Doerr, M. Stark, F. Ehrhart, H. Zimmermann, F. Stracke, Biotechnol. J. 4 (2009) 1215–1221.
[2] A. Kreiner-Møller, F. Stracke, H. Zimmermann, Cryo Lett. 34 (2013) 248–254.

Ethical, Legal, and Social Issues

O3-16 Return of Research Results from the Laboratory to the Clinic – the Increasing Role of Biobanks

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Background: Current research, including high throughput DNA interrogation of whole genome and exome sequencing, provides an increasing opportunity for results that may be of clinical significance to research participants or their families. The complexities associated with the disclosure of individual research results and incidental findings are the subject of current debate. In Australia the National Health and Medical Research National Statement on Ethical Conduct in Human Research recommends that where research involving the use of biospecimens may reveal information that may be important for the health of donors, their relatives or their communities, researchers need to prepare an ethically defensible plan (EDP) to describe the management of any proposed disclosure or non-disclosure of that information. In circumstances where biospecimens are obtained through a biobank, the biobank has an important role in the development and enactment of an EDP as they hold the patient identifying information and are often the conduit between the researcher, clinician and donor.

Methods: The GynBiobank at Westmead has developed an EDP in conjunction with clinicians and researchers. A key component of the EDP is assembly of a panel, comprised of the treating clinician, a familial cancer specialist, a social worker, a pathologist and a biobank representative, and other specialties depending on the nature of the research finding returned to the biobank. The panel determines whether the finding is clinically significant and 'actionable' and oversees validation of the research finding. If these conditions are met, the panel determines the appropriate course of action, including confirmation of the result on an independent sample in an accredited clinical testing laboratory either via the clinician, or in the case of a germline mutation, via the familial cancer service.

Results: A number of potentially 'actionable' research results have been returned to the biobank to date, including a BRCA1 tumour mutation, which was not verified in the matched germ-line sample, hence no further action was taken; a BRAF tumour mutation, which led to participation in a Phase I clinical trial; and a PMS2 mutation that led to referral of the next of kin to the familial cancer service.

Conclusion: Biobanks need to be prepared for an increasing role in the development of strategies to manage the disclosure of research results in line with an increase in genomic research and personalised medicine.

O3-17 Knowledge & Attitudes of Healthcare Providers and Medical Students in Saudi Arabia Toward Biobanking and Biospecimen Donation

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Background: The post-genomic era has been marked by the emergence of biobanking as a new discipline to support effective OMICs scale research. Biobanks are hence the central core facility which provides researchers with high-quality and fully annotated biospecimens to foster the transition towards Precision Medicine. Such transition requires comprehensive interactions

between all the stakeholders involved in biobanking field. In Saudi Arabia, awareness about the concept, importance and the scale of biobanks remains the bottleneck challenge, even with healthcare providers, in order to implement efficient biobanking system and to recover precious biospecimens, chiefly those collected from large consanguineous families and highly inbred populations. The objective of this study is to perform a suitable assessment of knowledge and attitudes of healthcare professionals towards biobanks and the factors affecting their willingness to donate, in order to establish effective biobanking outreach programs.

Materials & Methods: A cross-sectional study was conducted among consented healthcare students and medical staff at King Abdulaziz University, Saudi Arabia. Data were obtained using an English self-administered questionnaire, which assessed the general knowledge about biobanks, the willingness to donate tissue, as well as various socio-demographic and biobanking-related characteristics.

Results: So far, more than 1000 students and medical staff have been included in this ongoing study. Partial results showed a general percentage knowledge score of 55%. About 46% of students have heard about the ''Human Genome Project'' but only 28% heard of the term ''biobank.'' Around half the students were willing to donate biospecimens to biobanks. Better general health, previous blood donation and higher knowledge of biobanking scores were significantly ($p < 0.05$) associated with the willingness to donate. The main reason for willing to donate was to advance medical research and benefit the society. Misuse of biospecimens and/or biodata confidentiality were the main concerns.

Conclusions: An insufficient knowledge about biobanking and a moderate willingness to voluntary donate biospecimens were reported. More educational and awareness programs dedicated to medical students, focusing on both biobanking and genomic medicine are highly recommended to bridge the gap between clinicians and scientists, foster state-of-the art biomedical research, and speed up the move towards Precision Medicine.

O3-18 How Well Do Study Participants Understand the Concept of Biobanking in Medical Research? Results of a Survey Among Sample Donors in Germany

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Background: Biobanks are essential resources of future medical research. Neither the term nor the activities and aims of a biobank are very well known in the public and among patients. Given the growing importance of biobanks, experts demand a greater involvement of the public and of donors in order to create a better understanding of the purpose and the future benefits of biobanks for medical research. The ''German Biobank Node'' addresses this issue in one of its projects.

Methods: Between July 2014 and June 2015 187 patients and healthy study participants at four university hospitals in Germany, who had agreed to donate their biomaterial, were asked to respond to a standardized questionnaire. The main objective of this exploratory survey in a cross-sectional design was the scientific investigation of donors' attitudes towards biobanks and their understanding of the notion of a biobank.

Results: In general, the willingness to donate biomaterial is rather high and the attitude towards sample donation is mostly positive. The majority of the sample donors want to support science and research as well as other patients and next patient generations. However, when participants were asked to explain what a biobank is and what is happening to their donations, many of them had no (44%) or an imprecise idea (24%) about the scope of biomedical research and the use of their donated biomaterials, even if they were previously informed about it. Nevertheless, the respondents showed a great demand for information about the usage of their sample: The majority would like to receive feedback on the research results (73%). In the case of incidental and/or supplemental findings 70% of the donors expect feedback: 50% generally wish to get feedback and 20% only in case of a possible intervention.

Conclusions: Given the increasing centralization and thus anonymization of large biobanks it seems advisable to create more transparency for the public and for patients. Information needs of donors should be addressed with a target group and specific communication measures. Additionally, there is a need for improved patient education: place, time and context of the delivered information should be evaluated and external web-based information services should be established, where patients can receive simple and valuable background knowledge on biobank-based medical research. In addition, regular reports on research studies and their results would help satisfy the interest of patients and donors.

O3-19 Human Specimen Usage Policies at Kyoto University: How to Utilize Human Specimens in Collaborative Research

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In Japan, promotion of regenerative medicine is emphasized as a national strategy, particularly since 2012, when Prof. Shinya Yamanaka won the Nobel Prize for Physiology or Medicine. Two years later the Act on the Safety of Regenerative Medicine was enacted, and this is expected to encourage developments in the field of regenerative medicine. Kyoto University hosts the Center for iPS Cell Research and Application (CiRA), and hopes to make progress in regenerative medicine using iPS cells. Although clinical studies are crucial for the development of new therapies, human specimens available for research are critically insufficient nationwide. The key factor affecting this is informed consent (IC) concerning the use of human specimens. Traditionally, consent was obtained by medical doctors or researchers within the scope of particular research projects. However, more recently, ''carte blanche'' consent has garnered criticism from both patients and researchers.

In 2013, we proposed a new informed consent framework. 1. This new ''biobank-type consent'' seeks active participation in medical research by permitting the use of donors' blood, tissue, and so on. Donors are offered the position of collaborators in research. 2. With this IC form, biospecimens can be used for various medical and life-science research and education purposes, under certain conditions, by researchers belonging to Kyoto University and their collaborators. 3. This has become the standard system used within the university; doctors in every

department of diagnosis and treatment can use the same framework. Thanks to these features, patients and researchers can now avoid the difficulty of giving and obtaining multiple consents. This has a direct, positive effect on promotion of clinical research and development of regenerative medicine.

Based on the above IC system, Kyoto University Graduate School of Medicine this year drew up the ''Common Guidelines for the Transfer of Human Specimens to External Institutions'' and detailed regulations. 1. These guidelines outline policy on transferring human specimens to private companies and so forth. 2. Collaborative research agreements are the standard context in which human specimens are used outside the university, not just by the Graduate School of Medicine but also in the iPS cell stockpiling project by CiRA. 3. This framework guarantees that Kyoto University can responsibly handle withdrawal of IC or inquiries from donors.

O3-20 Developing Models for Biobanking with Indigenous Peoples in New Zealand

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Internationally there is a significant body of work focusing on the Ethical, Legal and Social Implications (ELSI) related to clinical research, biobanks and genomic analyses. To date the cultural dimension of these debates has not been present, but the Health Research Council (New Zealand) funded project 'Te Mata Ira' has been exploring Maori views on biobanking and genomic research. Methods included, (a) meetings and interviews with five tribal groups, (b) interviews of Māori individuals that participated in genomic studies, (c) experts in Māori values and knowledge, (d) interviews with non-NZ indigenous experts in genetic research and/or biobanking, and (e) workshops with medical genomics researchers and health researchers. Key themes that have emerged include:

A need for protection of Māori interests; Focus on Māori health priorities; Expectations of consultation & engagement; Accessibility to public education resources; Māori control over samples and data; Ongoing communication with, and feedback from, researchers;

Expectations of consent; and Fair and equitable benefit sharing that recognizes community contributions.

This presentation will outline the cultural parameters for best practice next generation biorepository research with Indigenous Peoples and how these are being implemented at governance and operational levels in New Zealand.

Hot Topics

O2-8 Emerging Opportunities to Sustain and Develop Biospecimen Curation: Sustaining Biorepositories and Training the Next Generation of Research Professionals

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Background: Growing funding crises at the federal and state level make the financial stability of repositories increasingly problematic. Laboratories are reducing staff, hours of operation or closing entirely as the funds required to maintain preservation are reduced or eliminated as the need for specimen preservation only increases, with many repositories operating at or beyond their storage capacity. Addressing this crisis requires a unified effort to illustrate the value added that well run repositories bring to research dollars, and the need for training the next generation of repository scientists.

Methods: The NACDA Program on Aging is the world's largest electronic repository on aging, health and medical data. Funded by a P30 Center Grant by the National Institute of Aging since 1978, NACDA has continuously grown as the preeminent repository for electronic measures of aging and health and the biological life course. Increasingly, the NACDA mission embraces collaborations with repositories that specialize in specimen preparation, preservation and distribution. Working with NIA and NIH, NACDA builds collaborations with biorepositories, seeking the development of sustainable funding to support the work of biorepositories as well as identifying resources essential to growth and to training of next generation of biological curation experts.

The presentation will draw upon this experience to focus on the current funding situation within the NIH environment. We will review changes in funding line and identify emerging opportunities for funding, particularly in light of the recent Alzheimer's initiatives.

Results: Sustainable funding is the result of not only good research, but an ongoing review of funding trends and new opportunities. Building partnerships across biorepositories and other research centers is key to achieving sustainability and growth.

Conclusions: NACDA has a long history of working closely with researchers to identify opportunities and to discuss ways in which the best practices in the preservation sciences can be translated into competitive grant applications. With its partners, including ICPSR and the UM science community, NACDA has developed a well-established infrastructure focused on building sustainable research that involves the preservation of information, both electronic and specimen based. We seek to expand our relationship with the Biospecimen community and to engage in collaborative funding opportunities to maintain the important mission of biorepositories.

Human Specimen Repositories

O1-2 German Biobank Node: Establishing a National Biobanking Research Infrastructure to Accelerate Biomedical Research

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The German Biobank Node (GBN/ bbmri.de) aims to establish a state-of-the-art biobanking infrastructure in Germany and to increase cooperation and harmonization between biobanks. These are prerequisites to facilitate access and foster the use of biological samples and data for academic and industrial research. Biologic samples and data collected in biobanks are valuable resources for innovations in personalized medicine, development of biomarkers for diagnostics and therapeutics as well as for prevention of diseases.

The main goal of GBN is to set up a focal point for national biobanks and simultaneously act as the national hub for the European biobanking research infrastructure BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure).

GBN will thus comprise the representation of Germany in BBMRI-ERIC by the national coordinator who takes part in the BBMRI negotiations and instigate Germany's role in BBMRI-ERIC.

Being the central point of contact and exchange for the German biobank community GBN aims:

- to facilitate exchange of experiences between biobanks
- to develop standards for quality assurance
- to develop an IT concept for the sample and data exchange
- to inform the public about biobank activities

The core of GBN is the central office, which is located close to the national coordinator at the Charité in Berlin. An annual national biobanking symposium serves as the central scientific meeting for all German biobanks and enables a continuous exchange of GBN with all national biobanks and federated networks that operate in the biobank community. Most important, working groups for IT, quality management and public engagement are actively developing concepts and strategies to reach the above mentioned goals. These concepts are in close alliance with the activities pursued in BBMRI-ERIC.

This is especially true for the IT approach. GBN has taken a major role in the common service IT of BBMRI and will contribute significantly to the progress of the European IT infrastructure. One major issue is the development of a sample locator which is already in a pilot phase in GBN and will be developed further in the European network.

With a new funding period starting in summer 2016 the Federal Ministry of Research will fund GBN together with a German Biobank Alliance in order to establish important structures based on the currently developed concepts, and to connect the German biobanks seamlessly into all BBMRI-ERIC activities.

O1-3 The German Environmental Specimen Bank: Making the Most of Archived Human Samples – Benefits of Better Knowing Your Donors

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Human samples cryo-archived in bio banks provide important information for scientists and policy-makers in the field of environmental health. Analyzing these samples by human biomonitoring (HBM) allows for retrospectively investigating time trends of human exposure to various pollutants. These results are essential for evaluating environmental regulation and for tackling unforeseen research questions. However, in addition to environmental pollution, concentrations found in an archived human sample are also influenced by the donor's individual behaviors, like smoking as well as anatomical/physiological factors, e.g. sex and total volume of the 24-h urine collection. This must be taken into account when assessing HBM data derived from archived human biosamples in environmental health research.

The German Environmental Specimen Bank (ESB) regularly collects human samples which are analyzed for a set of substances before being cryo-archived over liquid nitrogen and – retrospectively – for emerging pollutants. Physiological parameters, e.g. urinary creatinine, are also quantified. Each year samples from 480 adults (20–29 years) from four cities are collected. Participants report on their behaviors and anthropometrics.

Recent findings underline the additional value of individual information acquired from ESB donors for exposure and risk management: (i) Multivariate evaluation of Hg in urine resulted in significant associations with dental amalgam and fish consumption, explaining more than 50% of variation. (ii) Bivariate analysis yielded significant correlations between levels of perfluorinated compounds (PFAS) and protein in plasma. No association resulted for PFAS and body-mass-index. PFAS are significantly higher in males. (iii) Mainly due to reduced emissions, lead in blood (PbB) decreased on average from 77.5 in 1985 to 11.7 µg/L in 2013. Smokers tend to have higher PbB levels. PbB is also significantly higher in males. (iv) Mean Cu in blood differs substantially by sex (2013: females 1.4 vs. males 0.9 mg/L), with oral contraceptives as one possible reason. For urinary Cu no such differences are observed.

ESB data allow for analyzing associations between HBM data, environmental levels, physiological/anatomical parameters, and individual behaviors. They support further improvement of HBM study designs and comparability of HBM results. Experiences from ESB data evaluation may also support the improvement of donor questionnaires used by bio repositories.

O1-4 A Standard Procedure Ensures Good Quality of MiRNAs in Plasma and Serum

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Background: Standardization and stability are the most vital principles of biobanks. MicroRNAs (miRNAs) are known as post-transcriptional regulators of gene expression and promising biomarkers of various human cancers, including pancreatic adenocarcinoma (PDAC). In this study, we chose miR-16, miR-93, miR-103a, miR-425 as housekeeping genes, to investigate the quality and stability of miRNAs in plasma and serum collected and stored in our biobank.

Methods: Blood samples from PDAC inpatients were collected at the time when patients were admitted to the hospital. Blood samples were centrifuged, isolated and stored at −80 degrees centigrade within two hours of venipuncture. Thirty cases were randomly chosen every year from 2010 to 2014, and five healthy human controls and thirty fresh not frozen samples collected from patients in 2015 with the same processing protocol were chosen as controls. MicroRNAs were extracted from 200 µl plasma and serum samples using a mirVana PARIS Kit (life technology). After thawing and centrifugation, the plasma and serum were disrupted with Cell Disruption Buffer provided in the kit. Five nM cel-miR-39 as an exogenous control was added for normalization of each gene of interest. Other steps were implemented according to manufacturer's instructions. Quantitative RT-PCR were utilized to evaluate the expression of these miRNAs. Relative quantification was calculated by delta delta CT method and

normalized based on the designated control. Statistical significance between PDAC patients and healthy controls was determined by the Wilcoxon test, and Kruskal-Wallis test was utilized among the blood samples collected from PDAC patients for different storage periods. P values < 0.05 was considered as statistically significant.

Results: First, levels of different miRNAs from healthy controls and PDAC patients were compared. The qRT-PCR showed no significant differences between these two groups ($P = 0.5879$). Furthermore, compared to the samples collected in 2015, miRNA levels in PDAC samples collected from 2010 to 2014 indicated no statistical significance ($p = 0.2836$).

Conclusions: The data showed that miRNAs in plasma and serum were relatively stable at -80 degrees centigrade over time. If collected and processed with our standard operative procedure strictly, blood samples can be preserved with high quality for a long period of time, and suitable for miRNA evaluation.

O1-5 HOVON Pathology Facility and Biobank: Pathology Support of Lymphoma Clinical Trials

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Background/Information: HOVON (the Hemato Oncology Foundation for Adults in the Netherlands) is a collaborative clinical trial organization for comprehensive treatment studies in lymphoma. Pathology review is an integral part of all clinical trials. Obtaining of this material for review is time consuming and expensive. The HOVON Pathology Facility and Biobank (HOP) aims to provide a professional infrastructure to improve logistics and efficiency of collecting, storing and managing samples from patients who are treated in HOVON clinical trials.

Methods: To achieve this we create a web-based portal (HOP system) in close collaboration with the CTMM TraIT Biobanking team and CSC developers. After randomization in a clinical trial, the patient is entered by the HOVON Datacenter into the HOP system and the pathology material is semi-automatically requested from the original pathology laboratory. After receiving the material, the biopsies are processed for pathology review and stored for future research purposes. This may include additional assays for classification and (biomarker) stratification if needed, TMA production and DNA/RNA extraction. Subsequently, original materials are sent back to the original pathology laboratory. All process and actions are registered in the HOP track & trace system which is provided with time frames for all the different steps in the process, and gives reminders if the time frames are exceeded. All time frames are adjustable for the various HOVON lymphoma trials to maintain flexibility.

Results: In June 2015 the new sample request/tracking portal was launched and almost 200 patients have been processed via this portal. Using HOP, we have been able to reduce the requesting time and the revision results are now available during the trial, allowing full analysis immediately after closure of the trial and with interim analysis if needed. The monitoring of the material from the different trials is now transparent and organized in one system. This system now allows us to support a simple biomarker-based clinical trial (HOVON130 for MYC+ lymphoma) and will be crucial to perform a planned complex multi-armed biomarker-based clinical trial that will be launched in the near future.

Conclusions: The HOP and the HOP system have improved the logistical process for requests, processing and returning of material from clinical trials in a transparent and monitored manner. Allowing modern pathology to contribute to HOVON lymphoma clinical trials.

O1-6 Leveraging Established Collection and Biorepository Infrastructure in the Development of Pregnancy Cohort Sites in Low- and Middle-Income Countries

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Background: Developed in 2009, the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Repository is an open source biobank dedicated to the advancement of maternal and child health research. The biobank houses specimens and data that are longitudinally collected across pregnancy with the goal of maximum utilization by investigators. Critical to this aim is a suite of carefully protocoled onsite processing and storage procedures, rooted in best practices for quality control and assurance.

Methods: The value of the GAPPS Repository model is its rigor in quality and flexibility and adaptability for collection of specimens and data. It has also become a platform to provide consultative services and training for new cohort and project development worldwide. We have since leveraged the program to supply guidance and standardization to the BMGF InterBio 21st Site Network. We report here on the development of the Preventing Preterm Birth Cohort Sites in Zambia and Bangladesh where we utilized the Repository's strengths for rapid deployment of standardized and harmonized collection and biorepository systems.

Results: The effort included development and implementation of data capture, management and visualization tools, project protocol, collection and processing SOPs, collection kit production, training and certification, specimen storage and archiving, regulatory compliance, and centralized distribution. The project was operationalized beginning in October of 2014 with first collections beginning in May 2015. To date the sites have recruited over 800 participants, with a goal of 6000.

Conclusions: The efficiencies gained by using an established infrastructure model accelerated project implementation at both sites, which are now fully operational. We detail here the successes as well as the unique challenges and lessons learned in implementing GAPPS Repository systems in low resource settings.

01-35 Specimen Collection for a Contemporary and Nationwide Cancer Prevention Study

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Background: The American Cancer Society (ACS) has a long history of conducting large nationwide prospective studies on the etiology of cancer. In the most recently enrolled cohort, Cancer Prevention Study-3 (CPS-3), we enrolled approximately 304,000 geographically diverse cancer free men and women. At enrollment, participants completed a survey and provided a blood sample with written consent. Internationally, there are efforts to enroll large cohorts for a broad spectrum of outcomes. Herein, we describe methods of collecting and aliquoting blood specimens outside of a clinical setting.

Methods: Participants enrolled at one of 2,833 venues across the US and Puerto Rico. Venues ranged from outdoor events with broad temperature variability to indoor climate controlled sites. Trained phlebotomists drew 36 ml blood (three-10 ml EDTA and one 6-ml heparin vacutainers) and were instructed to submerge samples into an ice-water bath within 20–30 minutes of draw. From the venues, specimens were transported to one of 22 contracted laboratories for centrifuging, aliquoting and initial storage at −80°C; per protocol from vein to freezer was required to occur within 24-hours. Samples were then shipped on dry ice to the ACS biorepository where they were transferred to liquid nitrogen tanks for long-term storage.

Results: Of those enrolled, blood was collected from 96.8%. For the vast majority (97.3%), the process from collection to freezer was completed within 24 hours. The average time to aliquoting was 13 hours 50 minutes. The primary source for delayed specimen aliquoting was transport between enrollment venue and the closest laboratory. Standard Operating Procedures (SOPs) were created to minimize pre-analytic variability, however, there was not a defined system to clearly document when adherence to SOPs failed such as the time to submergence of samples into the ice-water bath.

Conclusions: Despite the variability in field conditions, transport time, and geography, we successfully collected a large number of blood samples in non-clinical settings. Because all specimens were date/time stamped at collection/aliquoting/receiving, those data are clearly documented. While SOPs existed to minimize pre-analytic variability in the blood collection methods, future collections should identify additional processes for documenting SOP failures and subsequent corrective actions.

Repository Automation Technology

O4-25 How the Uppsala Biobank Automated Hospital Integrated Biobanking Became a Model for the National Project for Collection of National Cohorts in Sweden

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Background/Information: In 2010, the Uppsala Biobank saw a need for collection of samples for research, within the health care system, in a high through put manner. The normal procedure at the time was to set up a solution specific for each project. In order to handle the large scale routine biobanking that was requested, the development of a standardized and highly automatic hospital integrated biobanking process was initiated.

Methods: The Uppsala Biobank developed a process that made it easy to collect and store patient samples without the need of study specific staff and solutions for sample management. Initially, Uppsala Biobank had to ensure that the right IT freeways were accessed for each clinic and their staff. The solution was to use the patient medical record system and the electronic referrals used to order any other ordinary laboratory analysis. The next step was to implement automatic liquid handling by installing a robot at the Clinical Chemistry Department. Information concerning the sample collection and handling is sent via the electronic referral system and the robotic software to the biobank Laboratory information management system (LIMS).

Results: Since 2011, twelve different liquid based sample types (including e.g. whole blood, plasma, serum, urine, saliva, and cerebrospinal fluid) are processed twenty-four-seven at the Clinical Chemistry Department using an automated process. The samples are aliquoted into 2D barcoded micro tubes, which are stored in low temperature freezers and a LIMS connected automated −80-freezer. Since its beginning in 2011, the sample collection process has increased by approximately 70%. Now nearly 20,000 primary tubes (165,000 aliquots) are collected yearly from around 3,500 sample donors. Sampling is taking place at over 50 clinics; it includes more than 30 projects with a range of research areas including cancer, cardiology, psychiatry, neurology, infectious diseases, and neonatal care among others.

Conclusions: Through the unique hospital integrated biobanking program developed by Uppsala Biobank, there is now an easy way to collect and store samples in a simple, efficient, safe, and qualitative way.

The model has also been implemented in the Uppsala-Örebro region, and at other Swedish biobanks. It is now becoming a model in Sweden through The Swedish Innovation Programme for Life Science against widespread diseases-SWELife (national cohorts).

Repository Management

O1-7 Developing and Implementing a Three-Day Course on Biobanking for BCNet Members from Low and Middle Income Countries

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Background: IARC, in collaboration with its NCI-CGH and BCNet international partners, conducted a biobank course in Lyon, France 3-5th November 2015. Programs were developed following a needs assessment survey of 22 BCNet member institutions for their biobank status, expertise and educational needs. A three-tiered approach to building sustainable biobanking competencies was recommended based on a) online training, b) face-to-face and c) in-country site visits.

Aim: To provide training on information that is lacking or requires updating to build robust competency strengthening in the basics of biobanking, best practices for sample collection, processing and storage, quality control and assurance, information technology, ethical and legal issues in BCNet members' institutions.

Method: The Online Training included access to the CTRNet training through the ISBER portal. IARC hosted a SharePoint site for the pre and post–test exercises; a pre-requisite for attendance

to the face-to-face training. Participants also had to upload documents on their local ELSI framework governing their biobanking activities.

The face-to-face training consisted of lectures and interactive discussions in break-out sessions for the sharing of knowledge and experience. Presentations were on key aspects of biobanking and the discussions focused on country-specific challenges presented in posters on country-specific rules/regulations/laws that govern biobanking in research and clinical settings. Segments of the sessions were recorded and will be made available online as support for BCNet members to use in disseminating training in their individual institute.

Results: A total of 25 participants from 16 LMIC attended, including biobank managers, technicians, pathologists, biologists and researchers. A post-test exercise and course evaluation will be conducted to assess the impact of the training.

Conclusions: Key recommendations put forward by LMIC participants include the need to address ELSI constraints in LMICs, in particular consent procedures and practices; addressing education for organization and country leadership on the benefits of biobanking for their citizens' public health; the need for clarity on expectations for patients, biobanks and researchers, including the request for patronage from IARC in addressing country specific issues.

BCNet membership remains OPEN to additional LMIC member organizations. Please see details at www.bcnet.iarc.fr.

O2-9 Progressive Consent and Specimen Accrual Models to Address Sustainability: A Decade's Experience at an Oregon Biorepository

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Background: The National Cancer Institute and the International Society for Biological and Environmental Repositories have published best practices for biorepository operations, while the College of American Pathologists (CAP) has created a biorepository accreditation program modeled on their successful clinical laboratory accreditation program. However, these guidelines and accreditation requirements still leave biorepositories with many challenges related to infrastructure and procedural design. The Legacy Biorepository is a CAP accredited biorepository that has been operating within a six-hospital community healthcare system for the past decade. After prioritizing quality management and accreditation, we evaluated our own challenges in sustainability. We identified certain operational changes, including informed consent and specimen accrual and distribution that we predict will improve our sustainability and institutional flexibility while increasing our scientific impact.

Methods: Until 2015, informed consent was performed primarily by biorepository staff at an estimated time of one hour per case. System-wide, we successfully changed our informed consent process to a front-door model, with use of material and data for research as an opt-in or opt-out selection on the institutional patient informed consent form across all six hospitals.

Results: Saving approximately 200 hours annually as a result of front-door consent, this progressive model allows us to maintain our frozen sample collection, while greatly increasing the availability of paraffin-embedded tissue and bodily fluid. Additionally, we found that augmenting our tissue collection in this way adds little expense per case (approximately half that of each frozen tissue aliquot) and increases the range of biospecimens collected. We have also been able to capture many additional specimens that were previously uncollectable due to issues surrounding acquisition.

Conclusion: There are many ways to address financial sustainability within a biorepository. Through a Lean process improvement exercise, a thorough evaluation of existing procedures and collection models, as well as cost recovery initiatives were modified to translate into savings. Fortunately, sustainability, process improvement, and scientific impact broadly overlap; it is possible to achieve all three through operational critique and implementation of strategic changes.

O2-10 Research Sustainability by Implementation of Collaborative Departmental Core Initiatives

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Advancing research depends on the ability to have sustainable resources to support comprehensive clinical and translational studies. To optimize these resources in the current resource-constrained environment, our Substrate Services Core (SSC) serves as a biorepository and research support service that partners with researchers for the collection and distribution of required samples. The SSC implemented a process for infrastructure efficiency across institutional and multicenter studies to reduce cost and increase productivity.

Our biorepository utilizes centralized sample collection, processing, receiving, transfer and shipping to support multiple IRB-approved protocols. Protocol standardization has been validated and routine quality control is in place for monitoring sample receipt through a laboratory information management system. Appropriate samples are transferred to researchers to support ongoing research and generate preliminary data for funding opportunities. The systematic standardization of these processes also allows for efficient incorporation of this core resource into grant and contract applications.

In the first year, this collaboration has supported over 20 clinical trials and collaborative studies, including the National Institutes of Health, Food and Drug Administration, Department of Defense and industry studies. Our SSC serves as a core facility for multicenter studies, providing a single point of contact for feedback in protocol development, standardized collection, processing methods, sample preparation and sample shipping, receiving and distribution. Over 32,000 biological aliquots from over 1,400 patients have been received, processed and/or shipped through the SSC. The biorepository serves as the foundation for the core, providing retrospectively collected and clinically profiled samples for funded studies and preliminary studies for grant and contract submissions. Through collaborative efforts of the SSC, we have been able to reduce redundancies in staff duties and increase throughput of samples and overall research, leading to growth in the funding of the SSC and basic research.

The SSC serves as a sustainable model for biobanking and support for clinical and translational research. We show how the implementation of a bank of high-quality, well-characterized biological samples can be utilized to assist in securing funding and enabling researchers to pursue research findings that ultimately translate to clinical care.

O2-11 Adopting Elements of Lean Six Sigma to Address Biobank Sustainability

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Background: The Wales Cancer Bank (WCB) consents cancer patients to donate surplus tissue and blood samples to be banked for future research. Reductions in core funding and the evolving requirements for sustainability have initiated reviews into the biobank's processes and procedures to ascertain where efficiencies can be made, efforts streamlined and costs can be reduced. Lean Six Sigma is a set of principles, powerful tools and techniques designed to improve efficiency and productivity by focusing on customer value and eliminating defects and time wastage in processes. Although designed and used in big corporations, the core ideas and elements of Lean Six Sigma are applicable to all organizations wanting to reduce waste from business processes and boost customer satisfaction.

Methods: All biobank staff (consenting nurses, laboratory technicians, administrative and IT staff) were asked to draw out process maps to document their workflows and timelines. A training session was held to introduce staff to the basic concepts of Lean Six Sigma and clarify the desired end product – better customer satisfaction. Staff adapted their process maps with greater detail and participated in group discussions for brainstorming particular issues.

Baseline measurements were taken from several years of data to show the average time taken from receipt of application to supply of samples. Data was grouped by sample type to allow for variation due to length of time required for processing. The three issues deemed to have the most potential impact on improving the ability to deliver fit-for-purpose biosamples to researchers in a timely manner, were chosen for shadowing sessions. Two experienced project managers, with no involvement in the biobank, shadowed the three processes and reported back to the biobank.

Results: The process engaged all staff and gave them ownership of the whole process, allowing them the opportunity for input into areas of the biobank operation not normally within their remit. Data is currently being collected to ascertain early indicators of impact on the time to supply, but it will be several months before meaningful data will be available.

Conclusion: Focusing on the end user and how to ensure a good customer experience has changed the way the biobank management and team think and operate. Using business principles to address sustainability can be alien to the healthcare or academic centers involved in biobanking, but they can be very powerful tools.

O2-14 Economic Consideration of a Vapor Phase Nitrogen Biobank by Means of an Example Calculation

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Background: Damage-free freezing, cold handling and long-term storage of biological samples, such as cells and tissue, are the most important factors of successful establishing cell therapies and tissue engineering. The crucial factor in a biobank, besides the sample quality, is to minimize storage costs.

Methods: Different cost models, like ''Total Costs of Ownership (TCO)'' and ''Life Cycle Costing (LCC)'', will be introduced. Key influence aspects, like consumables, different operational costs, usage pattern and degree of biobank capacity usage, will be presented.

Results: The specific contributions of the above-mentioned aspects and the influence of different stages of the Biobank automation to the economics will be demonstrated. The combination of high capacity and fully automated sample processing leads to a significant drop in both acquisition and running costs. Based on those facts, general guidelines for a Biobank design will be given. One specific cost calculation example will be shown in the end.

Conclusion: An effective reduction of costs can be achieved if the presented influencing factors are taken into account properly. The introduced basic pattern can be adapted and used for individual cost calculations.

O2-36 US NCI's Center for Global Health Regional Centers for Research Excellence Program to Support Infrastructure Including Biobanks, for Research in Non-Communicable Diseases, Mental Health and Injuries (NCDs)

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Background: In many low and middle-income countries (LMICs), there is a marked need to build or enhance research infrastructure to support basic, translational, clinical, and population science on non-communicable diseases, mental health and injuries (NCDs). One of the key infrastructures required are biobanks in these regions.

Methods: To support this growing need, The NCI's Center for Global Health recently invited investigators throughout the world to apply for Planning Grants for Regional Infrastructure Centers (RCREs) for the coordination of research on NCDs, in low and middle-income countries (LMICs). http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-15-007.html The purpose of the funding opportunity (FOA) is to facilitate the planning and designing of RCRE (including biobanks) that will build on collaborative partnerships among investigators from institutions in high-income countries (HICs)/ Upper Middle Income Countries (UMIC) and low- and middle-income countries (LMICs).

Results: The presentation will provide details of the opportunity for funding from the NCI, how partnerships can be created, the requirements for the application to the program, its multiple funding timelines and early information about the program's global reach.

Conclusion: The NCI Center for Global Health encourages the ISBER community to examine and become involved in this important support opportunity for biobanking infrastructure as primary or partner applicants.

O4-22 An Opt-in Self-administered Video Consent for Subject Enrollment into the Biobank of a Large Tertiary Care Center

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Background: Cedars-Sinai Medical Center is a 1000 bed tertiary care hospital in Los Angeles. There are many private practice physicians who are associated with the hospital, and there is no central location where patients can be approached for consenting to the Biobank. Therefore, we developed a self-administered electronic consent form that can be signed through a web portal on a home computer or on a tablet in a doctor's office and that does not require an explanation by a health care official.

Methods: The consent structure is fully automated and integrated with EPIC, RedCapTM and OnCore® software programs. The IT requirements are provided by the marketing and electronic data services divisions. All parts of the consent are developed in partnership with the IRB, HIPAA compliance and legal groups at Cedars-Sinai. For the tablet consent, patients are approached by office staff.

Results: The electronic opt-in consent structure consists of a patient education video, a 3-page global consent, a survey to reinforce the main concepts in the consent and link to deliver the signed consent with an accept/decline decision to the Biobank staff for validation. Individuals can decide to give permission for the use of their medical data, to storing their remnant specimens for up to 15 years, to providing urine samples as well as additional blood draws solely for research purposes, and to being contacted in the future. Permission is also obtained to analyze samples on a broad range of analytical platforms, to generate immortalized cell lines and to share samples and data with for-profit commercial companies. Both acceptance and decline are tracked and flagged in the medical chart and no partial opt-out choices are granted. Multiple options are provided to contact the Biobank with questions or to withdraw from enrollment.

Conclusions: We demonstrate that it is feasible to develop a self-administered automated consent, which reduces the burden on the healthcare provider and does not restrict opportunities for utilization of biological specimens and data. The system is designed to evaluate patient and physician satisfaction and to compare consent decisions with historical data from the conventional paper consent mechanism. We anticipate that the self-administered consent will significantly increase the number of biospecimens in the Biobank.

O4-24 Global Catalogue of Microorganisms (GCM)—A Global Information Platform for Accessing, Tracking, Monitoring and Benefit Sharing of Microbial Resources

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Microbial resources are one of the most important natural resources in the world, and the scientific basis to support the development of biotechnology and life sciences. Culture collections, as the libraries of these living microbial materials, are urgently required to combine into a worldwide alliance. The World Federation for Culture Collection (WFCC) is such community with long term conservation and research facilities that bring together more than 600 collections in 68 countries. WFCC-MIRCEN World Data Centre of Microorganisms (WDCM), the heart of WFCC, which was once hosted in Australia and Japan, plays a crucial role in providing a database of microorganisms, analysis of the function and establishing a platform of international communication. To date, 714 international culture collections from 72 countries have registered with WDCM.

WDCM has developed an online reference strain catalogue which helps users to find local sources of the reference strains by asking all collections to supply contact information, as well as the unique reference of their most appropriate one or more collections. Furthermore, WDCM is developing the Analyzer of Bio-Resources (ABC) as one of the most effective software products provided to WFCC members, which offers searching and statistics tools for culture collections or strains.

WDCM launched an international project called the Global Catalogue of Microorganisms (GCM) to construct a data management system and a global catalogue to help organize, unveil and explore the data resources of its member collections. GCM is expected to be a robust, reliable and user-friendly system to help culture collections to manage, disseminate and share the information related to their holdings. It also provides a uniform interface for the scientific and industrial communities to access the comprehensive microbial resource information. Up to now 77 international culture collections from 35 countries have joined GCM, and by the end of 2015, over 350,000 microbial strains were included in GCM. For the culture collections in developing countries, homepage and an online strain catalogue will be developed based on the GCM platform. Meanwhile, for others in developed countries which have already had online catalogues, GCM could also provide Culture Collection Reports for strain data mining and analysis.

Repository Standards

O2-13 The CAP Biorepository Accreditation Program: Results from the First Four Years of the Program

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Background: The College of American Pathologists (CAP) developed the Biorepository Accreditation Program (BAP) in 2012. This program integrates guidelines and best practices from the International Society for Biological and Environmental Repositories, the National Cancer Institute, the Organisation for Economic Co-operation and Development, the Center for Medicare & Medicaid Services and the College of American Pathologists Laboratory Accreditation Program. This program provides the means to attain and maintain standardization in biorepository processes, resulting in high quality specimens that can be used to support research, drug discovery, and personalized medicine. At this time 42 biorepositories are fully CAP BAP accredited and 13 are in the process of obtaining accreditation.

Methods: The CAP uses a peer inspection model to ensure the inspectors have proper expertise and to promote educational efforts through information sharing. Lead inspectors are Pathologists, PhDs and Managers of biorepositories, and they are often supported by CAP staff inspectors. Accreditation is a three-year continuous cycle of quality assessment, with a peer inspection occurring at the start of year 1 and a self-inspection with CAP desk assessment at the start of years 2 and 3.

There are 273 established standards and inspection checklists are customized based on the scope of activities performed by a biorepository as defined in their initial application.

Results: A total of 64 inspections were completed between May 2012 and September 2015. Forty-seven (47) were initial inspections and 17 were re-inspections. A total of 405 deficiencies were identified in the areas of Information Technology (20%), Equipment/Instrumentation (19%), Specimen Handling and QC (16%), Quality Management (15%), Personnel (12%), Safety (11%), Facilities (5%) and Regulatory (2%).

Conclusions: The CAP BAP establishes an organized set of standards and a common set of measures for biorepositories that is based on a biorepository's scope of services. Through tracking and monitoring trends of common deficiencies, the CAP is able to identify common areas of focus for continuous improvement and educational opportunities for the biobanking community.

Innovative Technologies

IT-27 SecureConsent: An e-Consent System for Biobanks

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The SecureConsent e-Consent system provides a robust flexible approach for the collection and maintenance of patient consents for collection and use of biobank specimens. This Technology Presentation will provide insight into how the use of an e-consent platform can address current and upcoming issues with biobank informed consent, including general consent for all uses, specific consent, specimen withdrawal by patient, specimen matching to consent and patient notification. The presentation will consist of a short demonstration of how the SecureConsent e-Consent system can facilitate patient education and consent, and maintain the consent for the long-term. The presentation will end with a short discussion of communication with specimen management systems to provide real time access to research specimens with identified appropriate patient consent.

IT-28 CryoID Adding the p-Chip to FluidX Labware: Ultimate Sample Provenance Is Possible

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Background: Labware evolution in the past decade has focused on sample quality, increased storage density, tracking and annotation. There have been many innovations, but the perfect combination of labware quality, capability and cost remains elusive. Add in challenges related to frost and the desire to minimize freeze thaw cycles and the challenge becomes even more apparent. Brooks Life Science Systems is focused on creating this solution by combining FluidX labware with p-Chip permanent tagging technology from Pharmaseq.

Methods: Labware available on the market today includes many options. Volume, cap type, cost, storage method and identification are the primary considerations in selecting labware. Additional options of including RFID have been cost prohibitive and unsuitable for ultra low temperatures (-196°C). Building on the widely recognized FluidX brand, Brooks Life Science Systems has established a licensing agreement to incorporate the benefits of p-Chip (silicon-based micro transponder) to its existing labware offering, making an affordable option of labware with electronic tracking ability.

Results: p-Chip will be integrated into the FluidX tube for use with various devices and the Brooks BioStore system. This chip is 500 μm × 500 μm and light activated. p-Chip is a light activated ''RFID'' IC solid state chip with an integrated antenna, 64-bit architecture and is virtually impossible to copy or destroy. Light activation allows identification through frost while the employment of fused memory eliminates any chance of data loss or tampering, providing an absolute audit trail. Memory and temperature tracking are also targeted benefits of this technology. Lastly, it is planned to be offered at a cost at least 75% less than previous RFID options.

Conclusions: Combining FluidX CryoID labware with p-Chip technology will be the first affordable, integrated labware solution to offer electronic tagging of samples along with memory and sample temperature tracking ability.

IT-29 Automating Entire Workflows with Multiple Labware Types Using LabElite AutoSwap

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In the current market, biobanks can fully automate their entire workflow from pre-processing to liquid handling to sample storage when using one type of labware. Using a second type of labware would require manual intervention, such as changing adapter sets on a decapper to decap a different set of tubes.

However, with the new AutoSwap™ feature on Hamilton Storage's LabElite line of decapping devices, biobanks can process multiple tube types in the same workflow, as the AutoSwap automatically switches labware adapters without manual intervention. This allows workflows to proceed with different types of 96- or 48-well tubes while saving time and effort.

This is beneficial for biobanks that have changed or are planning on changing labware, as they are no longer bound to one type of labware in an automated workflow. The process of reformatting samples is also simplified, as liquid handlers can reformat from one tube type into another because of the ability to decap/cap multiple tube types with the AutoSwap.

Overall, this new technology provides biobanks with more flexibility in their choice of labware, whether they are reformatting samples or running multiple workflows with different labware in an automated workflow.

IT-30 The ThawSTAR Automated Cell Thawing Platform: De-Risking Thawing: From Research to the Clinic

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Biobanks are an increasingly important resource for medical research and cellular therapeutics. The need to bank temperature sensitive biological materials necessitates improved methods to cryopreserve and resuscitate cells in a reliable, quality-controlled manner. While significant effort is placed on optimizing cell freezing techniques, few methods exist for optimizing cell thawing techniques.

Thawing rate and temperature affect cell viability and recovery. In an industry where reproducibility is a concern and

samples can be extremely precious, it is crucial to ensure that the cryopreservation process has as little impact as possible on the integrity and value of banked samples. BioCision's CFT2 ThawSTARTM Automated Cell Thawing System introduced standardized cell thawing in a single 2.0 ml cryogenic vial format. This vial format is commonly used for cryopreserving cells in both research and clinical settings, making the ThawSTAR CFT2 a useful tool for de-risking thawing of clinical trial, clinical research, or translation research samples.

Building on broad interest in the ThawSTAR Platform, BioCision has introduced additional formats (the AT6 for 6 ml cell therapy vials and the NG1.5 for 1.5 ml cryovials) and improved the ThawSTAR Platform functionality with next generation features (improved load detection, RFID reading, connectivity). The ThawSTAR AT6 utilizes the same proprietary thermal sensing technology of our first generation CFT2 system, and extends that technology to a system capable of thawing between 2 and 6 ml. In addition to monitoring vial temperature, this second generation format incorporates upgraded hardware and software that results in better load detection and thaw time determination. Celgene plans to use this format for their Phase 2 clinical trial work on an allogeneic cell therapy to treat symptoms of diabetes.

These recent modifications in the ThawSTAR Platform are important for the adoption of the ThawSTAR in biobanking workflows because improved load detection will be critical for thawing large volume formats such as cryobags, (a common format for e.g. cord blood) and the ability to read e.g. RFID chips is critical for sample tracking and handling histories.

The ThawSTARTM Automated Cell Thawing Platform provides users within research, clinical and biobanking settings a thawing solution that is intuitive, standardized, reproducible and traceable.

IT-32 TempAura Remote Environment Monitoring: Using IoT to Enhance Sample Storage Monitoring

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Background: Maintaining the correct sample storage condition is key to maintaining sample quality, hence periodic checking of temperature, humidity and physical security of storage locations is a crucial activity within any facility. For smaller distributed labs, the choice of systems for remote monitoring is limited and cost prohibitive. Often labs resort to manual protocols where a member of staff visits each storage location and records environmental parameters multiple times each day.

Brooks Life Science Systems has recognized this need and brought to the market remote connected, low cost, self-deployable environment monitoring specifically for labs who previously would consider this a luxury.

Methods: The development of network connected technology, referred to as the ''Internet of Things'', has resulted in sophisticated electronics with wireless communication being available at consumer level prices. Combining different sensor capabilities with a wireless data logging solution and cloud based technology, Brooks Life Science Systems has a solution for the distributed laboratory that can be easily deployed by lab users. Data can be viewed from any web browser or mobile device via a secure web site.

The TempAura remote monitoring system includes wireless temperature and humidity sensors, door closure monitors, network gateways, cables and power adapters sufficient for a fully functioning monitoring system.

Results: TempAura remote monitoring collects data every minute from each monitor and sends it to a cloud based host, which means no local software installation is required. Data is displayed on a private web portal which allows near real time checking of each storage location. Limits for each monitor reading can be set and a configurable dashboard displays the status of monitors and historic readings. Each monitor has on board data logging, which has the capacity to buffer results for over 2 days in the event of a network failure, and automatically reconnects when the network is restored.

Conclusions: By combining the Internet of Things with sophisticated, low cost technology, Brooks Life Science Systems is bringing remote monitoring capabilities to smaller, distributed labs, where this technology was previously out of reach. Smaller facilities can now afford to follow best practices for their storage locations and make best use of precious time and resources.

IT-33 E-Consent: A Way Forward for Management of Patient Consent and Specimen Verification of Consent

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The multiple research uses of specimens, use of opt-in consents for specific research projects, and multiple checkbox options provided to the patient on a consent form complicate the process of determining consent for use of a stored sample while maintaining patient confidentiality. As patients and biobank staff become more comfortable with use of technology, the use of an e-consent system for patients asked to provide tissue specimens is becoming an important consideration for expanding biobanks.

This presentation will provide the parameters for a robust flexible e-consent system for the collection and maintenance of patient consents for biobank specimens. Examples of how an e-consent platform can address current and upcoming issues with biobank informed consent will be provided, including patient education, front door consent, disease-specific consent, consent withdrawal, specimen matching to patient parameters consent and patient notification.

A discussion of integration with specimen management systems to provide real time access to research specimens with appropriate patient consent will provide guidance on the issues to be addressed in a choice of an e-consent system for a biobank.

The presentation will end with an analysis of significant elements to be considered in an e-consent system and process for various consenting situations (e.g. tumor registries, general biobanks, clinical trials).

IT-34 Cloud Based Tools for Efficient and Low Cost Biobanking

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A rapid increase in the amount of molecular data being generated from biosamples has resulted in the necessity for appropriate data storage solutions. Precision Medicine Initiative, in particular, is calling for IT systems which allow for collection, storage and sharing of large volume of data in pro-

tected ways. Such data is typically multi-factorial, both large in sample size and heterogeneous in context which needs to be integrated in a standardized, cost-effective and secure manner. This requires technical solutions and administrative support that are not usually available for small and medium-sized research labs. As a result, such labs end up in using spreadsheets and lab notebooks for storing and managing data, which are error-prone, making the data difficult to retrieve. Cloud based data management technologies are emerging as alternatives to traditional on-premise software on a global scale. Cloud-enabled systems are often low on total cost of acquisition, have maintenance outsourced, and are scalable to help meet the ever-changing business and regulatory compliance needs.

IT-37 Optimization of Skin Biopsy Processing for Isolation of Viable Dermal Fibroblasts

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Background: Coriell processes tissue to isolate viable fibroblasts that can be grown in standard cell culture laboratory conditions. As a biorepository for these important research resources, Coriell continually seeks to improve its protocols. This study was designed to optimize a protocol for obtaining fibroblasts with robust growth traits and evaluated key parameters; mechanical dissociation and concentration of collagenase (col.). While the initial objective of this experiment was to evaluate the combination of manual dissection with automated dissociation, automated dissociation without manual dissection was also evaluated. The expected outcome was that the use of the gentleMACS™ Dissociator would standardize the process and provide reliable, reproducible results compared to manual dissection alone, and that the higher collagenase concentration would improve tissue break-down leading to a more hardy fibroblast recovery.

Methods: Samples of human skin from 4 separate donors were obtained from the CHTN. All biopsies were collected in growth medium and shipped for next day delivery to Coriell. The samples were divided into 4 test groups and a control, processed, and frozen in quadruplicate as follows:

Control: Manual dissection, then digestion with 0.5 mg/ml col.

Test 1: Manual dissection, then digestion with 1.5 mg/ml col.

Test 2: Manual dissection, then digestion with 0.5 mg/ml col. and disruption on the dissociator.

Test 3: Manual dissection, then digestion with 1.5 mg/ml col. and disruption on the dissociator.

Test 4*: Digestion with 0.5 mg/ml col., then disruption on the dissociator.

*This was only evaluated on 1 tissue donation.

Results: Tests 1 and 3 yielded the least number of cells at freeze, with averages of 87% and 68% fewer cells than the control, respectively. Test 2 exhibited improved yields as compared to the control, with an average of >35% more cells at freeze. Test 4 yielded the most cells with an average of >50% more cells than the control.

Conclusions: Processing the skin samples using the gentleMACS™ yields consistently more cells on average when the samples are not dissected. Based on the final test it appears that manual dissection adversely affects cell recovery. The best practice determined from this study includes digestion of the tissue with 0.5 mg/ml collagenase followed by disruption on the dissociator to liberate the cells gently, preserving the viability of the recovered cells.

POSTER ABSTRACTS

Biobanking Profiles

BP-1 Biobanking Experience in Saudi Arabia

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Saudi Biobanking project was initiated and is conducted by King Abdullah International Medical Research Center (KAIMRC), King Saud bin-Abdulaziz University for Health Sciences (KSAU-HS), and funded by the NGHA and King Abdulaziz City for Science and Technology (KACST). It is a large-scale prospective study of the combined effects of genes, environment and lifestyle on common diseases of adult life, with nested case-control studies within the cohort. Its goal is to increase the quality of patient care and accelerate the impact of research on such care. It will implement the highest standards of biological banking to provide outstanding clinical, medical, demographic and analytic data through the use of upfront broad consent forms.

This study is concerned with two biobanking groups: (1) population-based study group, with an expected sample of 100,000 people of all ages, and (2) disease-specific biobanking group of 100,000 of patients with certain common diseases such as: cancer, diabetes, hepatitis, chronic renal impairment/failure and stroke allocated from the specialized clinics. Disease registries are being conducted for these conditions under study.

Initially, the public attitude and perception of the Saudi public towards Biobanking was investigated in a cross-sectional study of a sample of subjects representing the different sectors of the Saudi population. Positive attitude towards Biobanking was prevalent in 69% of all subjects who participated in the study. The actual study is in the form of an interview to collect data on lifestyles, quality of life and co-morbidities, followed by various anthropometric, biochemical and physiological investigations. Annual examinations will be conducted in the surviving original cohort to obtain information on physical activity, blood pressure, diet, body weight, occupational history, psychosocial factors and personal habits such as smoking. Information about any diseases which develop during the follow-up period is collected via NGHA-electronic medical records. Subjects are targeted for fluid and solid body tissue samples, while DNA/RNA capacity 1.8 million matrix tubes for genetic diseases seen in day to day clinical practice. Endpoints include coronary heart disease, stroke, hypertension, congestive heart failure and peripheral arterial disease. Analysis of the genetic and non-genetic data will be done to cover areas such as the lifetime risk coronary heart disease, prevalence and determinants of selected conditions.

BP-2 The Power of Biobanking: Leveraging Biobanking Within Consortiums

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Refining Vascular Composite Allotransplantation (VCA) for therapeutic option for patients in need of advanced tissue reconstruction and replacement depends on the ability to have access to biological specimens and data to support comprehensive clinical and translational studies. Small samples sizes in VCA have driven the need to augment sample collections. The Vascularized Composite Allotransplantation Collaborative Initiative (VCAci) Biobank is an established joint effort of five outstanding institutions that provides access to high quality pre-clinical, clinical tissue and blood samples facilitating enhanced statistical power for clinical and translational studies. A process had been developed across institutions allowing for standardization and centralization of specimen and data collection.

The VCAci utilizes standardized sample collection, processing, receiving, transfer and shipping across the consortium. Protocol standardization has been validated and routine quality control is in place for monitoring sample receipt and storage. A VCA-specific REDCap database has been developed and implemented to collect standardized data sets for human, non-human primate, swine, and murine studies. Specimen and data collected under the VCA consortium are transferred and housed in a central location to maintain integrity and security. The systematic standardization of these processes allows for specimens and data acquired through this consortium to establish a library of tissues and fluids representative of the scope of immune-related conditions in VCA with significant power to be studied.

The VCAci will share an estimated 20,000 samples, increasing the power of VCA clinical and translational studies compared to an individual site. Samples include pre-clinical ($\sim$5000) and clinical ($\sim$15,000) VCA allograft biopsies with corresponding native biopsies from skin, muscle, nerve, vein and artery, as well as blood and urine. Through collaborative efforts of the VCAci, we will be able to increase the significance of VCA clinical and translational studies to support hypothesis-testing and hypothesis-generating evaluations.

The VCAci Biobank serves as a model for comprehensive support for clinical and translational research in VCA. The VCAci contributes to a bank of high-quality, well-characterized biological samples combined to develop a comprehensive library of VCA relevant disease processes facilitating the study of VCA.

BP-3 Durrer Center for Cardiovascular Research

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Background: The Durrer Center for Cardiovascular Research (Durrer Center) is a non-profit national multi-disciplinary collaboration of academic research institutes in the field of cardiology, genetics and biostatistics partaking in cardiovascular

genetic and epidemiological studies and associated biobanks. Durrer Center is an independent unit within the Interuniversity Cardiology Institute Netherlands (ICIN) located at the AMC in Amsterdam.

Durrer Center facilitates high-quality sample/data collection and storage for the Principal Investigator and facilitates maximizing its scientific potential by providing a transparent mechanism for sample and data access to benefit the scientific community and society as a whole.

Methods: The Durrer Center provides autonomous and secure storage of both samples and data as well as tools for a) logistic support, b) research support on molecular biology and bio statistical analysis and c) trial management for the development of registries and standard e-CRFs for clinical data collection using OpenClinica.

Results: At the moment Durrer Center manages the samples and/or data of 35 (multi) center studies covering more than 250.000 samples and developed 13 eCRFs. It is the preferred biobank for CVON (CardioVascular Research the Netherlands) and ICIN projects and collaborates with national and international partners such as CTMM (Center for Translational Molecular Medicine) and A*STAR (Singapore).

Conclusions: The Durrer Center has gained an authoritative and leading role in the handling and organization of fractionated and scattered stored samples plus the accompanying data in the Netherlands. The Durrer Center combines existing cohorts and provides a web-based portal to exhibit available collections as well as guaranteed secure, independent and high quality storage of samples and/or data.

BP-4 Bimetra Biobank: A High Quality Biobank Facility Integrating Biobank Initiatives

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Background/Information: The Bimetra Biobank was initiated as one of the platforms of Bimetra - the Clinical Research Center Ghent – in order to facilitate and stimulate translational biomedical research by providing a preparation/storage biobank facility with elaborate quality management procedures, a clear ethical-legal framework and powerful data management. The Bimetra Biobank is linked to different biobank initiatives such as the Flemish Biobank Initiative and the Tumorbiobank Initiative, all present in BBMRI.be.

Methods: A high quality biobanking facility was established. An ethical-legal framework was implemented with transparent biobank access flows involving all stakeholders. A service cost model was developed based on preparation and storage costs, with reduced fees for strategic biobank initiative collections and cost options for research collaborations with industry.

Results: The Bimetra Biobank focuses on the storage of biobank collections for (academic) research with a translational finality. The Bimetra Biobank has a state-of-the-art biobank, where both a fraction of the local existing retrospective and prospective collections are managed under a clear operational plan. At this facility, samples are processed according to high quality standards (CMI-CRC guidelines based on ISO 9001:2008, ISBER and OECD guidelines for biobanks and NF S 96-900) and stored in various storage devices, in a continuous monitored environment.

The Bimetra Biobank uses an integrated sample and data management system, Slims (Genohm). All collections are registered using a minimal data set (MDS), allowing full traceability of samples. The MDS is based on international parameters (OECD and BRISQ dataset) combined with SPREC (Standard Pre-analytical code). Additionally, extended and project specific datasets can be kept in the data management system, allowing further enrichment of the data.

Through a clear ethical-legal framework (access flows, template MTAs and collaboration agreements) stakeholders are involved in the biobank processes and the forthcoming research. These workflows enhance transparency and collaborations in a larger (national – international) context.

Conclusions: The Bimetra Biobank has evolved from a small biobank supporting a few collections into a highly organized, specialized and valued biobank, supporting multiple strategic collections. By pooling knowledge and expertise a high quality sample and data biobank, linked to BBMRI. Vlaanderen is realised.

BP-5 Live Up to Life! Biological Resource Preservation and Utilization in the Era of Big Data, Big Science, and Big Industry

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In recent years, as people have begun to realize the importance of protecting the Earth's bio-diversity, together with our increased demands on the development and utilization of biotechnology in precision medicine, precision agriculture and precision poverty alleviation, along with the outburst of meta-datasets of bioinformatics brought by the revolution of sequencing technology, biobanks and bioinformatics databases have been readily established and developed into applications. Establishing a biorepository with unified standards and codes will accelerate the realization of global genetic resource sharing, and ultimately promote sustainable development of biotechnology.

A large number of China's unique biospecimens and genetic resources are not properly preserved and systematically managed, which poses as a potential risk to our country's genetic resources and a potential threat to China's genetic data security, but can also significantly cause the loss of industrial development of life science and bio-economy in China.

How to protect and utilize our national genetic resources, how to remain competitive globally within current frameworks of biotechnology industry, how to integrate existing biobank and bioinformatics resources, and how to provide supporting platforms for China's bio-industry to flourish, are some of the most important strategic demands of Chinese government agencies and industrial governing bodies. China National GeneBank (CNGB) is a direct result of these demands.

CNGB will become a state-of-art, highly efficient genetic information database, traceable biorepository, and the national standard of operation for genetic data and biospecimen collection, storage, and management.

CNGB take part in numerous international and national collaborations, aiming to establish a fundamental supportive platform for biomedical, bio-agricultural, and marine biology research.

CNGB will protect precious and unique genetic resources in China. By stimulating genetic and bioinformatics data sharing and utilization, and improving our genetic data storage, analysis,

and management capabilities, CNGB will promote further development of life sciences and biotechnology industries, seizing the strategic advantage of bio-economy and genetic resource for the future.

BP-39 Construction of a Prospective Osteoporosis Bio-Bank in China

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We aimed to construct the osteoporosis bio-bank and provide the bio-samples for the clinical, basic or public health study on osteoporosis. Materials and methods bone mineral density was measured at the lumbar spine, femoral neck, wards region and total hip, using dual X-ray absorptionmetry in 5000 subjects of Chinese people ages older than 45 years. Osteopenia or osteoporosis were defined as bone density between 1 and 2.5 or more than 2.5 standard deviations below the mean value for young adult Chinese women at the LS (L2–L4), TH and femoral neck (FN) based on T scores according to World Health Organization (WHO) criteria. Patients with degenerative changes in the spine and vascular calcifications in the aorta were excluded from evaluation. Fasting urine samples and peripheral blood of all participants were collected according to the sample collecting rules of ISBER. Meanwhile, information about the participants at the time of physical examination was recorded: participant's ID card number, name, gender, age, duration of osteoporosis, sleep quality, exercise habit, dietary structure and harmful habits etc. The genotypes of rs1032128 in OPG gene and rs2292910 in cry2 were measured also. Results The OP bio-bank including 3000 subjects with BMD, epidemiological and some genetic information have been constructed. There are 600 osteoporosis, 1800 osteopenia and 600 normal BMD subjects in the OP bio-bank. Conclusions of the OP bio-bank were suitable for the prospective or intervention study of OP in Chinese cohort. It was the first time that the sleep quality and sleep genetic information has been collected in the OP bio-bank and especially suitable for the study the influence of sleep to osteoporosis.

Biodiversity/Environmental/Repositories

BER-8 From Rookery to Research Lab: Collecting Northern Fur Seal (Callorhinus ursinus) Liver and Blubber Samples to Investigate Trends in Environmental Contaminants and Vitamins for the Alaska Marine Mammal Tissue Archival Project (AMMTAP)

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Northern fur seal (Callorhinus ursinus) blubber and liver samples were collected following standardized protocols developed for the Alaska Marine Mammal Tissue Archival Project (AMMTAP). The AMMTAP was established in 1987 and protocols were developed by the National Institute of Standards and Technology (NIST) for collecting and archiving tissues that are designed to: (1) provide sufficient material for multiple analyses, (2) minimize the possibility of sample change and/or loss during storage, (3) minimize inadvertent contamination during sample handling and ensure sample integrity, (4) provide for long-term sample stability through cryogenic techniques, and (5) track and maintain a record of sample history. Samples are maintained at the NIST Marine Environmental Specimen Bank (Marine ESB) at the Hollings Marine Laboratory in Charleston, SC. Forty-nine liver and 50 blubber samples were collected from sub-adult male Northern fur seals during Alaska Native subsistence harvests on St. Paul Island, AK, USA, from 1987 to 2007. Prior to analysis, samples were cryogenically homogenized using standardized protocols in order to produce multiple homogenous aliquots of fresh, frozen powder. One aliquot from each blubber sample was analyzed for legacy persistent organic pollutants (POPs), including polychlorinated biphenyl congeners (PCBs), dichlorodiphenyltrichloroethane (DDT), chlorobenzenes, chlordane compounds, and mirex; and recently phased-out and current-use POPs, including flame retardants, polybrominated diphenyl ethers (PBDEs) and hexabromocyclododecanes (HBCDs). One aliquot from each liver sample was analyzed for perfluorinated alkyl acids (PFAAs), trace elements, and Vitamins A & E. The results from this study are also being used to develop and test Phase II of the Marine Sample Tracking and Analytical Reporting (STAR) data platform (presented at ISBER 2015). An overview of the sample collection and processing protocols, results of the analyses, and an update on Marine STAR will be presented.

BER-9 Egg Viability of Red-spotted Apollo Butterfly, Parnassius bremeri (Lepidoptera: Papilionidae) in Korean Peninsula

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The Apollo Butterfly (Parnassius bremeri) is a beautiful white butterfly, decorated with large black spots on the forewings and red eye-spots on the hindwings and a high altitude butterfly which is found in Russia, Korea and China and it is a member of the Snow Apollo genus Parnassius of the Swallowtail (Papilionidae) family. The Apollo butterfly has been designated as endangered species in Korea since 1989, classified as Vulnerable (VU) on the IUCN Red List, and listed on Appendix II of CITES. SCPs on larvae and eggs of red-spotted apollo butterfly, P. bremeri were measured according to the method of Kim and Kim (1977) with a thermocouple, BTM-4208SD (LT Lutron, Taipei, Taiwan), to detect the release of the latent heat of fusion as body water freezed. SCP of larvae during December goes below -35.0 ± 0.9 Celsius and egg SCP during November goes -47.2 ± 1.0 Celsius. In order to identify the reason of the difference (-12 Celsius) between egg and larva we took photographed egg through scanning electron microscope (COXEM EM-30, Korea). Chorion of P. bremeri were 0.1001mm, Papilio machaon and Sericinus montela in same family was 0.0108mm, 0.0055mm respectively. P. bremeri was 10 times, 20 times thicker than another species within Papilionidae.

Biospecimen Research and Science

BRS-10 Data Harmonization Is the Key Step to Biospecimen Sharing Across Biobanks

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With the increasing number of birth cohorts with longitudinal studies in China, it has rapidly accumulated a wealth of research resources (questionnaires and biobanks). In the real world practice, design and information collection vary with the individual cohort studies. Like other biobanks, samples in cohort biobanks also need to be characterized via sample annotation appropriately before the banked samples are possibly shared across cohorts. Data heterogeneity of the cohorts thus creates a roadblock for data and sample sharing across the cohort biobanks. The initiative on the study is designed to adopt a feasible solution: harmonize variables to form a dataset that can meet the basic interest and needs for sharing resources of multiple cohorts. This model could be also applicable for more collaboration in clinical research. Key to the model is data sharing without taking any physical data from any component databases in a federated model.

By the joint effort, Canadian and Chinese teams have launched the initiative aiming to capitalize on this situation by strategically positioning the proposed collaboration between teams at the intersection of the cohort studies and networks complementary research, providing new opportunities for national and international collaboration. The work was supported by International S&T Cooperation Program of China (ISTCP) Funding (Grant No. 2014DFG31460).

BRS-11 The Quality Control of Nucleic Acids and Protein of Freeze-preserving Gastric Cancer Samples

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Background: To explore the quality of inventory samples of biobank stored in deep freezer at 0 ~ over 10 years in Shanghai Ruijin Hospital.

Methods: We extracted 24 pairs of gastric cancer samples between 2003 to 2014 stock. A 1% agarose gel electrophoresis was used for analysis of DNA and RNA purity and integrity, while adding the RIN (RNA integrity) as precise analysis. BCA assay was used for protein concentrations evaluation. Coomassie brilliant blue method was used for protein integrity assay.

Results: The samples were divided into four groups according to preserving periods (<2-year, 3-5-year, 6-8-year and >9-year). There is no significant difference of DNA integrity between the groups ($P > 0.05$), but the degradation of DNA in normal gastric mucosa is severer than that in gastric cancer tissue ($P = 0.023$). The RIN values was significantly declined when the storage-period is over 5-year or more ($P = 0.018$). There is no significant difference on protein concentration between different groups. By Coomassie brilliant blue method, we found significant differences on preserved proteins with different molecule weight. In over 9-year group only a few low molecule weight (average 36.5KD) proteins were detected. In preserving 6-8-year group, the proteins with medium molecule weight (average 65.63KD) were detected. In 3-5-year group, the proteins with higher molecule weight (average 127.5KD) were detected. In cryopreservation <2-year group, the proteins with large molecule weight (average 160KD) were still detected.

Conclusion: Effect of cryopreservation on DNA is not obvious. If the frozen period is more than 5 years, the serious degradation of RNA should be appeared, and the degradation of proteins with higher molecular weight should be appeared too.

BRS-12 A Critical Evaluation of the PAXgene Tissue Fixation System: Morphology, Immunohistochemistry, Molecular Biology and Proteomics

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Background Information: PAXgene tissue fixative has recently been developed as an alternative to formalin and marketed by PreAnalytiX as offering immunohistochemistry comparable to formalin, but, unlike formalin, also the recovery of high quality DNA, RNA and protein from biospecimens. We present an independent evaluation of the PAXgene tissue fixation system using clinical biospecimens, comparing it with the appropriate Gold Standard (formalin for immunohistochemistry/histomorphology and cryopreservation for molecular biology and proteomics).

Methods: Clinical biospecimens were divided into PAXgene-fixed paraffin-embedded (PFPE), formalin-fixed paraffin-embedded (FFPE) and fresh-frozen (FF) blocks. PFPE and FFPE ($n = 29$ patients) were compared for histology (H&E staining) and immunohistochemistry (14 clinically-relevant antibodies) using tissue microarrays. PFPE, FFPE and FF samples ($n = 37$) were evaluated for RNA quality (RNA integrity number, PCR amplicon length and qRT-PCR), DNA quality (gel electrophoresis and methylation profiling) and protein quality (LC-MS/MS).

Results: For immunohistochemistry, protocol optimisation was required in most PFPE cases, after which PFPE and FFPE sections were usually equivalent. H&E staining was more eosinophilic in PFPE than in FFPE sections but similar in terms of detail. Some tissue shrinkage was evident in a few PFPE sections. RNA extracted from PFPE sections was less degraded than that from FFPE sections but more degraded than that from FF blocks. Genomic-length DNA was extracted from PFPE and FF biospecimens, and methylation profiling showed PFPE and FF biospecimens to be almost indistinguishable. Only degraded DNA was extracted from FFPE sections. PFPE sections yielded peptides that were slightly less amenable to LC-MS/MS analysis than FFPE sections, with FF returning the best results.

Conclusions: It is difficult to envisage that PAXgene will ever replace formalin in routine pathology. However, PAXgene is a viable option for specific projects or immunodiagnostics where immunohistochemistry or histologic staining is of paramount importance and additional DNA or RNA analyses are required. However, as RNA is more degraded in PFPE sections compared with FF samples, we think that FF remains the best option where RNA quality is crucial and immunohistochemistry is not required. For studies using immunohistochemistry and LC-MS/MS proteomics, FFPE can be used.

BRS-13 An Evaluation of Room Temperature Storage of DNA Using Two Commercially Available Products

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Background: Storage at ultra-low temperatures has been the standard for preservation of DNA. This has downsides, including reliance on mechanical freezers and high energy costs. New products have been developed for ambient temperature (RT) storage of DNA. We evaluated two of these products: DNAstable Plus® (Biomatrica®) and GenTegra® DNA (GenTegra®).

Methods: DNA was extracted from five different serotypes of Streptococcus pneumoniae using Qiagen DNA blood mini kit spin columns (clean prep) and a boil and spin method (crude prep). Each sample was stored at 25°C and 50°C (accelerated aging) in cryovials with O-ring seals under the following conditions: in liquid and dried form with no product, in liquid and dried form with DNAstable Plus® and in dried form with GenTegra® DNA. Samples were also stored at −30°C with no products. Evaluation occurred at the following time points: 0, 1 2, 4, 8, 16, 32 and 64 weeks. DNA concentration was determined using the NanoDrop and samples were tested by real-time PCR for pneumococcal-specific gene targets, lytA and psaA. There was little difference between each of the five serotypes, so for analysis, data from all samples were combined to give a single mean for each storage condition and test.

Results: Samples stored in liquid form, with and without product, evaporated over time so were not included in further analyses. The mean DNA concentrations did not change over time for samples stored dried or at −30°C ($p > 0.11$ for all). The cycle threshold (Ct) mean from time 0 to time 314.9 weeks (accelerated aging) for the clean preps treated with DNAstable Plus® and tested for the lytA target ranged from a low of 19.5 at 2 weeks to a high of 21.7 at 32 weeks giving a range of 2.2 Cts across all time points. All other DNAstable Plus® treated preps had mean ranges of ≤3.1 Cts for both gene targets. All GenTegra® DNA treated preps had mean ranges of ≤2.9 Cts for both gene targets. These compare with a mean range of ≤3.0 Cts for preps stored at −30°C and a mean range of ≤5.0 Cts for preps stored at RT without a product added.

Conclusions: These data show that DNAstable Plus® and GenTegra® DNA can protect dried DNA samples stored at room temperature with similar effectiveness as −30°C storage. Accelerated aging experiments show that dried DNA samples can be preserved using these products for at least 6 years and 11 months (extrapolation of 64 weeks at 50°C).

BRS-14 Chemical Imaging in Cryobiology Using Confocal Raman Microscopy

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Transmission microscopy is commonly used in order to study the mechanisms of cryopreservation, but due to the nature of this only information related to morphology can be measured. More advanced microscopy methods can however be applied in this field to obtain further information and thus help understanding the underlying mechanisms of cryopreservation. One such promising microscopy method is Confocal Raman Microscopy (CRM) (1). The wavelength of inelastically scattered laser light in a sample depends on the vibrational mode of the scattering molecule allowing for laser scanning microscopy with a chemical contrast. One of the main advantages of this method is that staining is not required in contrast to most fluorescence microscopy techniques. In the post-processing of the data virtual filters can be applied to image different chemical compounds and distinguish between liquid/amorphous and crystalline water.

By applying CRM we discovered that in the absence of cryoprotective agents (CPA) hydrated salt crystal hydrohalite (NaCl 2 H2O) form in slowly frozen cell suspensions of mouse fibroblasts (2) or human induced pluripotent stem cells. In diluted saline solutions without CPAs hydrohalite can only form through eutectic crystallization, which previously has been correlated to extensive cell death (3). In the presence of CPAs hydrohalite can also form by continuous precipitation at before an eutectic point is reached. The absence of hydrohalite is however still a strong indicator for supercooling beyond the eutectic point leading to a glassy state in interdendritic channels and cytoplasm.

Hydrohalite forms complex structures in the proximity of the investigated cells and by means of image statistics we identified three distinct cases: Extracellular, intracellular and shell hydrohalite. Shell hydrohalite forms just outside the cellular membrane. This study gives the first evidence that intracellular eutectic crystallization can take place, which was uncertain up until now.

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BRS-15 CPTAC: A Biospecimen Collection Optimized for Proteomics

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The National Cancer Institute's Clinical Proteomic Tumor Analysis Consortium (CPTAC) is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of robust, quantitative, proteomic technologies and workflows. CPTAC collects prospective samples, qualifies, processes, and distributes them to genomic and proteomic characterization centers. Data scientists then integrate, analyze, and visualize the multi-faceted CPTAC data sets seeking to understand the relationships between genomic aberrations, protein content, and cancer biology.

Essential to the CPTAC enterprise is a high quality process of biospecimen collection and qualification. To date CPTAC has collected over 500 tumors with plans to collect 3,000 more. Tissue Source Sites prospectively collect tumors according to a protocol optimized for proteomics which includes strict ischemic time limits. A Biospecimen Core Resource then qualifies each specimen according to pathology and molecular criteria. This entire process is held accountable through a Quality Management System (QMS), which seeks to integrate each institution's QMS with the overall CPTAC QMS.

The presentation will focus on the scientific motivations for CPTAC as well as the scientific basis for the proteomics-optimized

protocol. Also included will be accrual and qualification details as well as a description of the implementation of the QMS.

BRS-16 Investigating Pre-analytical Effects of Anesthesia and Tissue Ischemia

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Background: Clinically relevant biomarkers from blood and tissues promise to revolutionize cancer diagnosis and therapy. Specific biospecimen preanalytical factors have been shown to influence the detection, qualification and validation of biomarkers.

Methods: We summarize research projects sponsored by the NCI Biospecimen Research Network (BRN). One project investigated potential effects of surgical anesthesia on blood samples, in order to understand whether anesthesia might affect detection of biom arkers. Plasma from pre- and post-anesthesia blood samples was analyzed using NMR metabolic profiling, while PBMCs and plasma were analyzed using global mass spec proteomic analysis. A second project investigated the effects of post-operative ischemia time changes on colorectal tumor and matched normal tissue, using NanoPro 1000 technology to interrogate protein phosphorylation/isoforms. Selected genes were analyzed by RT-PCR on the same tissues in order to validate ischemia-responsive transcripts identified in previous BRN studies.

Results: For studies pertaining to the effect of anesthesia, 4288 and 549 proteins were quantified in PBMCs and plasma samples respectively. Of these only 9 were differentially expressed in PBMCs and one in plasma samples. However, comparison of NMR metabolomics profiles of patients treated with etomidate or propofol anesthetics demonstrated significantly decreased plasma levels of several NMR-detectable metabolites. In the tissue ischemia studies, changes in overall phosphorylation of selected proteins in response to ischemia revealed minor variations in both tumor and adjacent normal colorectal tissue, while significant changes were identified in individual isoforms. Regarding gene expression, post-operative ischemia reproducibly revealed up-regulation of RGS1 expression and stable expression of EEF1A1 in both tumor and adjacent normal tissue.

Conclusions: Anesthesia affects the concentration of plasma metabolites, but does not seem to impact the global plasma proteome significantly. Post-operative ischemic time significantly affected protein phosphorylation isoforms with minor changes in overall phosphorylation. RGS1 and EEF1A1 were validated as colorectal post-operative ischemic markers. The research results will contribute to the development of evidence-based best practices for the collection, processing and storage of biospecimens, as well as the development of blood and tissue quality biomarkers.

BRS-17 Characterization of Somatic Mutations in Liver Cancers from the Mayak Production Association Worker Cohort Using Whole-Exome Sequencing

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Background: The Mayak Production Association facility was established by the Soviet Union in the late 1940s to manufacture nuclear weapons. Exposure to the plutonium isotope 239Pu, used in the production of nuclear weapons, has been associated with increased risks for cancers of the lungs, liver and bones. The Mayak worker cohort is unique in that following an initial period of high occupational exposure to 239Pu (1948–1959), improved industrial hygiene practices resulted in a chronic low-dose exposure scenario over a period of >40 years. In this study, our goal was to characterize somatic mutations in biobanked liver cancers from Mayak workers to elucidate DNA variations associated with chronic, low-dose exposures to ionizing radiation.

Methods: Tumor samples from Mayak workers were collected and stored in the Russian Radiobiology Human Tissue Repository (Ozyorsk, Russia). Subjects in this study include seven workers with liver cancer: three with hepatocellular carcinoma, two with cholangiosarcoma, and two with angiosarcoma. Tumor samples were processed into formalin-fixed paraffin-embedded (FFPE) tissue on slides, and immunohistochemistry and pathological review confirmed the diagnosis. Demographic data including age, sex, occupation, smoking status, and radiation dose levels (external exposure, absorbed dose for liver, and Pu body burden) were recorded. For each subject, total DNA was extracted from FFPE sections from both tumor and adjacent non-tumor tissue. The DNA quality and quantity was estimated with UV-VIS using the NanoDrop spectrophotometer, and fluorometry using the Qubit 2.0 Fluorometer. Indexed, paired-end sequencing libraries were prepared using the Agilent SureSelectXT Human All Exon V6 + COSMIC kit. Sequencing was performed on the Illumina HiSeq 4000 platform using PE 150 bp reads.

Results: We obtained sequencing data with an average depth of 400x per base, and 362x per base for tumor samples and adjacent non-tumor samples, respectively. Data are currently being analyzed, and a final list of annotated variants (somatic mutations, indels and structural variants) and their association with ionizing radiation dose and tumor type will be presented at the meeting.

Conclusion: The results of this study from this unique cohort will provide novel information on DNA mutational signatures related to chronic, low-dose ionizing radiation exposure in liver cancer to inform future radiation safety standards to protect workers in nuclear industries.

BRS-18 Mass Spectrometry Imaging of Brain Tumor Tissues in Tissue Bank

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Background: Few proteomic studies have been conducted to examine the human brain tissues of glioma and glioblastoma in Repository of Kyoto University, Kyoto, Japan.

In this study, we used a novel proteomic approach to examine brain tissues for the determination of the molecular changes at the tumorigenesis.

Methods and Results: An imaging mass spectrometry (IMS) system was used to obtain multiple mass spectra for specific cardiac peptides at a high m/z range. Direct in situ tandem MS analysis

enabled the identification of proteins in the glioma. IMS data revealed that the Glial fibrillary acidic protein (GFAP), a cell cycle related protein Ki67, a tumor suppressor gene p53 in the glioma and histone H2A in the metastatic carcinoma from the lung. Immunohistochemistry examination confirmed the IMS data.

Conclusion: IMS revealed the range of the AMI. IMS is a promising technique for the identification of biomarkers for brain tumors.

BRS-19 Circulating Free Nucleic Acid (cfNA) Extraction

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Circulating Cell free DNA (cfDNA) and miRNAs could be a valuable source of biomarkers in cancer research, by targeted sequencing or qPCR respectively. cfDNA can be collected from easily accessible bodily fluids, like serum or plasma, however only at low yields (<20 and up to >200 ng/ml plasma for healthy donor and CRC patient respectively). The inter-laboratory pre-analytical variations in cfDNA production is a challenge for cfDNA use as a biomarker. In this study, we optimized and validated various pre-analytical steps in the cfDNA extraction process.

Cancer patient plasma is difficult to obtain in sufficient quantities for statistically significant studies. More easily obtainable healthy donor plasma, for effective use in method validation, was spiked with artificial cfDNA. For this we used micrococcal nuclease digested DNA from healthy donor PBMCs or HT29 (adeno carcinoma) cell line. The digested DNA was gel excised in a size range of approximately 150 to 210 bp, corresponding to native cfDNA size ranges. 100 to 200 ng of artificial cfDNA was spiked in 1 ml plasma or whole blood, depending on the validation parameter.

Combined extraction of miRNA and cfDNA is possible by use of specialized commercial circulating nucleic acid kits. Yield comparison between combined and individual extraction methods of miRNA and cfDNA, showed a substantial reduction for both cNA types in combined extraction methods. If sufficient starting material is available, individual cfDNA and miRNA extraction methods are preferred.

The addition of glycogen, a DNA extraction facilitator, and the impact of different centrifugation steps for plasma isolation or cell debris removal, prior to cfDNA extraction were evaluated.

The optimized extraction procedure is being validated for reproducibility and robustness to different cfDNA dedicated blood collection tubes, with or without stabilizers. The pre-centrifugation delay of blood from 4h to two weeks and the impact of plasma freeze-thaw cycles (1 to 9 cycles) are being validated.

This study demonstrates how technical challenges in cfNA extraction are overcome through method validation and subsequent, evidence-based standardization. The work has been conducted within the context of the Innovative Medicines Initiative (IMI) consortium CANCER-ID (www.cancer-id.eu).

BRS-20 Overcoming Challenges in Sequence Analysis of FFPE Tissue: A New Approach to Understanding Complex Cancer Genomics

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Background: Large sample collections, most in form of Formalin-Fixed, Paraffin Embedded (FFPE) tissue specimens, with long clinical follow-up and associated genetic data are an invaluable resource for translational medicine research. However DNA from archival FFPE tissue is largely degraded and low tumor cellularity is an exclusion criteria preventing genetic characterization for biomarker research. Here we have validated a specimen-to-sequence workflow from tiny clinical specimens combining FFPE tissue disaggregation and fluorescent staining with isolation of pure and homogenous tumor cells for high-quality genomic data.

Methods: We disaggregated into cell suspension 0.6 mm diameter FFPE tissue cores or 50 micron FFPE tissue sections from 23 archival FFPE samples with tumor cellularity between 5% and 60%. Cell mixtures were stained with anti-Keratin and anti-Vimentin, for identification of tumor and stromal cells, and DAPI. We sorted by DEPArray™ pure homogenous cells populations and we generated libraries of sorted cells and unsorted samples using IonTorrent AmpliSeq™ Cancer Hotspot Panel v2 then sequenced with IonTorrent™ PGM. Low-pass whole genome sequencing was performed for detection of genome-wide chromosomal copy number alterations (CNA).

Results: We detected somatic mutations with 100% variant frequency, only observable as heterozygous in the unsorted samples and as wild-type in stromal cells. Loss-of-heterozygosis (LOH) and CNA detected in tumor cells were confirmed through low-pass profile. The diploid stromal population shows a flat profile consistent with normal diploid cells, whereas the tumor population shows several somatic CNAs in forms of gains and losses. By contrast, in the unsorted sample the signal is diluted by the contamination of normal diploid cells, therefore all losses and most of the gains are missed. Moreover, within DEPArray™ workflow we obtain a ploidy estimation of the recovered tumor cells, which can be input to the low-pass CNA algorithm to set appropriately the baseline.

Conclusion: We achieved 100% purity, also from tiny clinical specimens with low tumor cellularity, reverting the DNA composition to a germline-like situation and different classes of genetic alterations are readily resolved. In addition, the capability of sorting pure stromal cells provides a convenient internal control when matched normal tissue is unavailable, as may be the case for archival samples.

BRS-21 The Quality Advantage of Using CryoXtract's CXT350 to Core Frozen Pediatric Thyroid Tissues

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Most biorepositories around the world freeze tissues as a standard protocol for long term human specimen preservation. The methodology behind freezing tissue at an ultralow temperature is that it preserves nucleic acids in their natural state and protects against enzymatic degradation. The widely accepted limitation to the advancement of nucleic acid-based research is the deterioration of nucleic acids upon removal from this natural state. Traditionally, various molecular, biophysical, and biochemical analytic studies use thawed tissues as opposed

to frozen tissues due to lack of adequate technology. However, the CryoXtract CXT350 Frozen Tissue Aliquotter addresses the need for tissues to remain frozen by allowing for the specimen to be mounted to a frozen fixture maintained at −80°C and below. There is no thawing of tissue, therefore degradation is minimized.

To study the effect of freeze-thaw aliquotting vs frozen aliquotting on previously frozen tissues, we randomly selected 10 pediatric thyroid tissues obtained between 2012 and 2015 from our freezer. These tissues were divided between two conditions—freeze-thaw aliquotting and frozen aliquotting. To check the impact of each aliquotting method on RNA quality, we extracted RNA and assessed its integrity by obtaining RIN scores and performing rt-PCR for each tissue and condition over multiple time points.

It was determined that compared to freeze-thaw aliquoted tissues, frozen aliquoted tissues show minimum degradation. Additionally, it was noted that repeated rounds of frozen aliquotting did not affect the quality of the parent sample. By using the CryoXtract CXT350, tissues are kept in their originally preserved state, reducing the loss of integrity. Another application of the CXT350 is to maximize opportunities to distribute cores of the parent sample. This is because minimal amounts of tissue can be cored in multiple rounds, which is crucial for samples that are rare or hard to obtain. Frozen aliquotting of tissues is a valuable resource for the maintenance of high quality specimens in all biorepositories.

BRS-22 Examining RNA Integrity in Post-Mortem Tissues Preserved in Liquid Nitrogen, Dry Ice, or PAXgene Tissue® Identifying Best Practices for Tissue Preservation and Maintenance of RNA Integrity: The Biospecimen Methodological Study (BMS)

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Background: Traditional methods for human tissue preservation and stabilization such as freezing in liquid nitrogen (LN2) or on dry ice are often considered the ''gold standard'' for preservation, yet the effectiveness of these methods as compared to newer technologies remains unclear. The National Cancer Institute's Biorepositories and Biospecimen Research Branch (BBRB) conducted a study to better understand tissue preservation methods to inform BBRB's biospecimen collection efforts for the Genotype-Tissue Expression (GTEx) program, a National Institutes of Health Common Fund program.

Methods: The Biospecimen Methodological Study (BMS) was developed to provide an evidence-based structure to support future tissue collection and data analysis methods by comparing characteristics of three different preservation methods: PAXgene Tissue® (Qiagen); LN2; and dry ice. The study also investigated whether the time between cardiac cessation and tissue preservation altered RNA integrity. Four collection time points using six tissue types were analyzed for each preservation method in biospecimens from 32 post-mortem donors. RNA quality was assessed by RNA Integrity Number (RIN) and RNA sequencing analysis.

Results: The use of PAXgene Tissue® was highly successful in preservation and maintenance of RNA quality. In fact, for tissue types prone to rapid degradation, PAXgene Tissue®-preserved samples produced RNA with higher RINs compared to LN2 and dry ice. Histology and RIN analyses demonstrated that biospecimens preserved with PAXgene Tissue® had fewer artifacts and produced a higher percentage of samples with RINs ≥6. Although RIN was modestly correlated with post-mortem time, tissue type had a strong influence. Furthermore, RNA sequencing results indicated that between 800 and 3000 genes were differentially influenced by the postmortem interval.

Conclusions: The study has helped define optimal tissue processing parameters for studies that use human tissue by identifying artifacts associated with three different preservation methods at four different post-mortem collection time points. The identification and utilization of superior biospecimen preservation methods will, in the future, help identify patient-specific changes in gene expression and ultimately contribute to the development of targeted molecular medicine.

BRS-23 Pre-analytical Impacts on RNA and DNA Quality and Next Generation Sequencing from Formalin-Fixed Paraffin Embedded (FFPE) Tumor Tissue

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Background: The Biorepositories and Biospecimen Research Branch (BBRB) at the National Cancer Institute (NCI) developed the Biospecimen Pre-analytical Variables (BPV) Program to systematically evaluate the effects of pre-analytical factors on the molecular integrity of biospecimens. We report here the results of experiments examining the effects on RNA and DNA analysis of cold ischemic time (delay to fixation (DTF)) and time in fixative (TIF) in FFPE tissues.

Methods: We collected BPV specimens from cancer patients under surgical treatment at four medical centers. A total of 364 tumor tissue cases were collected from four tumor types: kidney, ovary, lung and colon. Each specimen was annotated with 300+ data elements that cover steps in the collection, handling, and processing procedures, pathological review, and clinical information. Case-matched experimental blocks were treated differently based on the pre-analytical factors of interest; matched frozen blocks were collected to serve as ''gold standard'' controls. The impact of DTF and TIF on the quality of DNA and RNA from FFPE samples was assessed prior to whole exome sequencing (WES) of DNA and RNA sequencing.

Results: DNA and RNA quality of FFPE samples is significantly lower than that of frozen tissues, as measured by RIN and KAPA assays. 72 h TIF samples showed a significant drop in both RNA and DNA quality compared to shorter time points (6, 12, or 23 h TIF), as measured by DV200 and Kappa assays. No significant differences in RNA/DNA quality were observed between the shorter TIF time points or between the DTF time points (1, 2, 3, 12 h DTF). In addition, substantial differences in RNA-seq and WES data were observed between FFPE and frozen tissues. RNA sequence reads from all FFPE tissues tested

showed a significant decrease in mapping to the transcriptome as compared to data from frozen tissues, while the percent of reads mapping to intronic regions more than doubled.

Conclusions: The data from this study along with other BPV studies provide strong evidence that pre-analytical factors can cause significant variations in the molecular profiles of tissues measured by specific analytical platforms. These data will be widely shared with the research community through publication and deposition in a public data repository. The results from these studies will be used to develop evidence-based best practices for fit-for-purpose collection, processing, and storage of biospecimens.

BRS-24 Developing Melanoma Cell Lines: Immortalizing from a Cancer Biobank

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Background: The establishment of melanoma cell lines from biopsy and surgical specimens has allowed for an enhanced understanding of the complex interactions that occur in vitro between tumor cells, gene expression, drug sensitivity, and histopathology.

Methods: The International Melanoma Biorepository and Research Laboratory (IMBRL) was established at the University of Colorado Anschutz Medical Campus in 2005. We have successfully established and characterized over 36 human melanoma cell lines. The development of an efficient and effective method of tissue procurement for the subsequent establishment of long-term melanoma cell lines has been a central goal for our biorepository. All viable melanoma specimens collected at surgery are transported immediately for processing. Tumors are cut into small fragments $\sim$4-5 mm in length and are dissociated using the GentleMACS system. After seven days in culture – if viable – cells are: frozen in liquid nitrogen (low passage), passaged, and made into cell pellets for FFPE blocks and immunohistochemistry analysis.

Results: As of January 2016 over 14 melanoma cell lines derived from metastatic tumors have been used in research studies here at the University of Colorado and 36 have been stored permanently in our biorepository. The experimental investigations utilizing our melanoma cells lines have looked at the etiology, progression, and treatment of melanoma. Further, these cells have been used to understand the stepwise progression from primary melanoma to metastases. Recently several of our cell lines have been discovered to harbor oncogenetic genomic rearrangements that may be therapeutic targets and possibly open a new paradigm in melanoma treatment.

Conclusion: The establishment of melanoma cell lines has been an invaluable aspect to our biorepository. As a model for experimental investigations, human melanoma cells in culture play an important role for the biological analyses of cancer. As biobanks play an increasingly important role in medicine, the use of human cell lines developed by biobanks will grow in significance as well.

BRS-25 Serum Metabolome Changes in Healthy Subjects with Different Genotypes of NOS1AP in the Chinese Population

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Background: Nitric oxide synthase 1 adaptor protein (NOS1AP), regulates the neuronal nitric oxide synthase activity and has an effect on nitric oxide release by binding N-methyl-d-aspartate receptors. Our previous study showed evidence that rs12742393 in NOS1AP was involved in type 2 diabetes susceptibility in the Chinese population, with C allele as the risk allele. In this study, we report a comprehensive metabonomic study of different genotypes (AA and CC) of rs12742393 using two complementary analytical platforms, GC-TOFMS and UPLC-QTOFMS.

Methods: Fifty-five healthy participants with normal glucose regulation were selected for metabolomic investigation, including thirty CC homozygote and thirty AA homozygote individuals. All the individuals for the metabolomic analysis were matched for with age, sex, BMI, glucose. For all the subjects, venous blood samples were obtained after overnight fasting for at least 10 hours and subjected to GC-TOFMS and UPLC-QTOFMS. The GC-TOFMS data was analyzed by ChromaTOF software. The UPLC-QTOF-MS ES+ and ES- raw data were analyzed by the MarkerLynx Applications Manager version 4.1 (Waters, Manchester, U.K.) and then metabolites were identified by comparing the accurate mass, mass fragments, characteristic ions with the available reference standards and published reports, to the web-based resources such as the Human Metabolome Database. The data sets were then analyzed and validated by uni- and multi-variate statistical methods, separately. Principle component analysis (PCA) and orthogonal partial least squares-discriminant analysis (OPLS-DA) were carried out (SIMCA-P 12.0, Umetrics, Umeå, Sweden) and Wilcoxon-Mann-Whitney test was selected to measure the significance of each metabolite.

Results: A total 258 metabolites were identified and seven significantly altered serum metabolites identified in AA carriers relative to CC carriers were selected according to the VIP threshold (VIP >1) in OPLS-DA model coupled with the Mann-Whitney U test ($p < 0.05$). These including malic acid, inosine, maltose, adonitol, ribitol, serine and glycine.

Conclusion: We detected four metabolites showing significant differences between CC and AA carriers of rs12742393 in NOS1AP. These metabolites might associate with the development of type 2 diabetes in subgroup of patients through the crosstalk with NOS1AP protein, which might provide us a new perspective to the mechanism of type 2 diabetes.

BRS-26 Mass Spectrometry Imaging of Cardiac Tissues in Human Bioresource Repository of Kyoto University

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Background: Few proteomic studies have been conducted to examine the human cardiac tissue after an acute lethal infarction. In this study, we used a novel proteomic approach to examine cardiac tissues for the determination of the molecular changes at the very early phase of acute myocardial infarction (AMI).

Methods and Results: An imaging mass spectrometry (IMS) system was used to to obtain multiple mass spectra for specific cardiac peptides at a high m/z range. Direct in situ tandem MS analysis enabled the identification of proteins in the acute ischemic area. IMS data revealed that the mitochondrial and several sarcomeric proteins showed intense signals in the infarcted endocardium of the left ventricle. Immunohistochemistry of these proteins confirmed the IMS data.

Conclusion: IMS revealed the range of the AMI. IMS is a promising technique for the identification of biomarkers for AMI and heart failure.

BRS-37 Biobank Study: Stability of the Selected Tumor Markers

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Aim of study: The aim of this project was to monitor the stability of the tumor markers stored in the biobank in relationship to the temperature and storage period.

Methods: Stability of the selected tumor markers of the mucine type - CA 15-3, CA 19-9, CA 125, cytokeratine polypeptide antigen (TPA), tissue specific polypeptidic antigen TPS and MonoTotal (MT) and Cyfra 21-1, oncofetal tumor markers CEA and AFP was monitored for the period of 24 hours, 48 hours, 1, 3. 6, 12, 24 and 36 months at the temperature −20°C and −80°C.

Results: No significant decrease was found at 24 and 48 hours period and 1 month at both –20°C and −80°C temperature. Longer periods had an impact on the stability of the tumor markers based on the tumor markers. Significant decrease at the temperature −80°C was found only for the 36 months period for all the selected mucinous tumor markers. Their decrease was dependent on the marker level – between 15-25%. No significant decrease was found for all the other selected tumor markers. But significant decrease was found at the temperature of −20°C within 3 months period by 5% dependent on the level. The levels decreased progressively in relation to the time of the storage up to 50-75% dependent on the marker level. Significant decrease of 10% of the oncofetal and cytokeratine markers was found for the period of one year and a further decrease of 30% for the period of three years.

Conclusions: Based on our results we have found that the serum samples are stable at the temperature −80°C. Stability at the temperature −20°C was significantly worse.

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Ethical, Legal, and Social Issues

ELSI-27 Systemic Stabilization of Biospecimen Science Using Latourian Actor-Network Theory in the Emerging Era of Precision Medicine

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The emerging era of precision medicine necessitates the combining of biospecimen science, advanced sequencing technologies, bioinformatics analyses, and the translation of analytical outcomes to clinical settings. This paradigm places human biospecimens in an actant role, converged upon by a complex socio-technical network of technologies, scientists, and clinical practitioners whose role(s) involve a complex set of negotiations and activities. What is emerging constitutes a progressive network in which both human and non-human actors assume identities according to their prevailing strategies of interaction. This process can be understood within the framework of Bruno Latour's Actor-Network Theory, in which both actors and actants share construct the prevailing network of interactions leading to the stabilization of the system. From a biospecimen science perspective, socio-political norms and architectures are being created around biospecimen science, allowing the furtherance of the emerging era of precision medicine. In my presentation, I will seek to delineate these structures, actors, and to provide context of biospecimen science as it relates to the larger paradigm of precision medical advancement.

ELSI-28 Evaluation of Biospecimen Donors' Response to Informed Consent: An Experience of ICMR National Tumour Tissue Repository, Tata Memorial Centre, Mumbai, India

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Background: ICMR National Tumour Tissue Repository (INTTR) was established as the first biorepository in India in the year 2005 at Tata Memorial Centre, Mumbai, India, to provide sufficient and properly preserved tissues to researchers in the field of translational medicine. Informed and understood consent is an essential component for collection of human biospecimens for translational research. The aim of the present study was to evaluate response to informed consent administered to the specimen donors.

Methods: An informed consent for biospecimen donation is administered by INTTR Personnel with the help of nurses and doctors either on the previous day of the scheduled operation or on the day of biopsy procedure. In case of out of scheduled operations, delayed consent is obtained from the patient. The specimen donors' response to informed consent was evaluated during the period between May 1, 2014 and October 31, 2015.

Results: During the period between May 1, 2014 and October 31, 2015, 3,652 patients were administered informed consent. Of whom 3,051 (83.54%) willingly signed informed consent document to donate the biospecimens and did not have significant queries, 366 (10.02%) patients asked pertinent questions and signed informed consent document only after their questions were satisfactorily answered by repository staff.

Ninety five (2.60%) agreed to donate tissue but refused to donate blood. Nine (0.25%) patients consented but refused to give permission to send tissues abroad for collaborative research.

One hundred and thirty one patients (3.59%) refused to give consent. Reasons for refusal included unwillingness to participate in any kind of research, repository collection not being a diagnostic test, no immediate impact on patient's treatment and no monetary benefit involved in the process. Some patients were distressed and unwilling due to disease itself.

Conclusion: Our data suggest that it is possible to administer informed consent by biorepository staff with the help of nurses and treating doctors to most patients and a majority of patients agree to donate biospecimens in an oncology setting.

ELSI-29 Qatar Biobank: Participant Feedback and Observations

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Qatar Biobank (QBB), is designed to build a powerful research infrastructure for future investigations of the lifestyle, metabolic and genetic risk factors for the most frequent medical conditions in Qatar. The recruitment approach provides a model

for public involvement in biomedical research. Qatar Biobank offers its participants feedback for all the measurements and tests they get done at this prestigious facility. At the end, they are requested to fill in an 'Overall Visit Feedback Form', which consists of 11 questions and a comments/suggestions section. The participants are required to fill in the form, rating the questions on a scale of 1 to 10, 1 being poor and 10 being excellent. Seven hundred and twenty out of one thousand six hundred sixty three participants (43%) filled the form. Analysis of the data showed that 97% of the participants appraising quality of our services as excellent, regarding the speed at which our services are delivered, 84% of the participants grade it as excellent. However, a few of the participants (less than 5%) are not satisfied with the delivered performance, showing room for improvement. 93% of the participants grade the time taken for clarification and respond to their inquiries as excellent. More than 96% of the participants rate the courtesy of our staff as excellent, 97% of the participants state that the staff's understanding of their needs and requirements is excellent, 95% of the participants feel that our staff response to their complaints or problems is excellent. More than 96% of the participants think that the information and instructions provided to them are sufficient, rating them as excellent, 89.2% of the participants are happy with the effectiveness of our communication and coordination, grading it as excellent, 58.6% of the participants rating their satisfaction with the duration after which they receive their results as excellent while 28.2% rating it as above average, however, 12% of the participants rate this question as average or below average, showing that this is clearly an area for improvement. 97% of the participants are satisfied with the explanation of their results, appraising it as excellent; more than 96% of the participants are happy and content with our services. At the comments section 14% of the participants have suggested further tests, 13% of the participants said that the results take too long to be prepared.

ELSI-30 Attitudes Towards Biospecimen Donation for Cancer Research: A Cross Section Survey Among Chinese Cancer Patients

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Background: High quality biospecimens collection from consented patients is crucial for cancer research activities. To a certain extent, patients' attitudes and willingness towards specimen donation would influence biospecimens collection for biobanking. Therefore, we conducted a comprehensive survey to know attitudes and perceptions of Chinese cancer patients towards biospecimens donation for cancer research.

Methods: We carried out a cross-sectional study among randomly selected patients from 11 cancer departments of Tianjin Medical University Cancer Institute and Hospital between August 2014 and August 2015. A total of 784 patients were included in the study to complete a 30-item self-administered survey. Then we evaluated their willingness to consider providing leftover sample and additional samples for cancer research purposes.

Results: 683 (87.1%) of 784 patients would consider donating leftover tissue samples. 653 (83.3%) of 784 patients would consider donating surplus blood after diagnosis. 411 (52.4%) of 784 participants consider both donating leftover tissue, blood sample and related clinical data for cancer research purposes.

For blood samples donation, elder patients ($\geq$50y) are less willing than younger patients (<50y) to provide additional blood samples for biobanking (OR = 0.59, 95%CI: 0.41-0.86). Compared with male patients, female patients' willingness to donate blood samples for research were much lower (OR = 0.48, 95%CI: 0.35-0.64).

For leftover tissue donation, similarly, female patients showed less willingness to donate leftover tissue after diagnosis (OR = 0.62, 95%CI: 0.41-0.94). However, patients with higher education level were more likely to donate leftover tissues after diagnose for research purposes (OR = 2.33, 95%CI: 1.45-3.76). Patients who were hospitalized first were more unwilling to provide leftover tissues for research after biopsy (OR = 0.58, 95%CI: 0.35-0.97). Patients who have received biopsy had a significantly higher willingness to donate leftover tissues after biopsy (OR = 1.57, 95%CI: 1.04-2.37).

Conclusions: In the survey study, most Chinese cancer patients showed a higher willingness to consider donating blood and tissue samples for cancer research. Several factors influenced the willingness of patients to donate different type of sample. Further research is required to understand reasons for nonparticipation might help to improve understanding of patients in biobanking activities.

ELSI-31 Legislation on Biobanks in Spain

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Spain has enacted specific legislation concerning biobanks. This legislation regulates how biobanks should be set up, how they should work and what kind of requirements they need to comply with. There are 89 biobanks on the Spanish National Registry. Many of them were founded in last 6 years. The main objective of this legislation is to keep a good balance between scientific progress and respect for rights and freedom of individuals participating in research. This legislation lays down a series of basic principles, for instance, the principle to inform donors accurately i) on the deposit of samples in objectives and implications of their donation and on the need to present written consents, ii) on the obligation to establish consistent procedures to guarantee the confidentiality of personal data associated with and obtained from biological samples, iii) on a free sample donation either by donors or by biobanks, iv) on the need of consistent procedures to deposit samples and data in biobanks, and for acts of donations and data for research projects to be performed correctly. Although this Spanish legislation fulfills its objectives, it has some drawbacks; mainly it overprotects research participants. Therefore, our objective was to analyze of main points of the Spanish legislation on biobanks and to show their strengths and weaknesses, to find the ways to improve and to maximize the efficiency and utility of these support platforms for research, keeping in mind always in mind the strict legal procedures on collecting and keeping donor's data.

ELSI-32 Donor Registry of Samples for Biomedical Research

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Andalusia is a region with approximately 8 million people and with a unique Public Health System (SSPA) which serves the entire population. The Andalusian Biobank, is a network structure with 32 nodes which attends an average of 300 research applications and distributes 20,000 samples per year. The society itself and through patients societies, asks for participation in a more direct way in the support to investigation. This has been properly detailed by the EU in the H2020, program, Social Challenges. This weakness has also been reflected on literature with initiatives as British Columbia BioLibrary. We have also noticed this demand of healthy citizens in our Biobank.

For this reason the Andalusian Government has taken the initiative to organize the Andalusian Donor Registry of Samples for Biomedical Research. The registry allows citizens, sick or healthy, to be identified as donors. The Andalusian Biobank is the responsible of the management of this registry. When researchers apply for samples and associated data, which we cannot provide, we go to the registry, identify the candidate donors and we ask for their agreement for obtaining the specific sample.

We present the organization and results of this registry, unique in its nature, and a comparative meta-analysis with similar initiatives.

ELSI-33 Protecting Genetic Data from Re-identification Threats Through Anonymization

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Biosamples are collected in an ever-increasing rate in order to allow a broad range of uses, especially new form of analyses, such as those based on next generation sequencing technologies. In order to protect the privacy of individuals to whom the analyzed genetic data belongs, many security mechanisms exist (for example, anonymization, cryptographic methods or data usage controls).

There are no global standards for privacy protection yet. The question whether anonymization is a proper means to protect donor's privacy raises many unresolved issues. Whereas major draft guidelines (WMA, Council of Europe) have proposed anonymization as preferred means regarding samples and genetic data, many stakeholders in Europe see anonymization in a critical light for several reasons. One reason is related to the fact that the donors/patients cannot be contacted in the future in case of incidental findings. Another reason is the question of whether anonymization is feasible for genetic data in view of the unique and complex nature of many genetic profiles. For example, the Art 29 Working Party under the EU Data Protection Directive has stated in its Opinion on Anonymization Techniques (p.10): ''It has already been shown in the literature that the combination of publically available genetic resources (e.g. genealogy registers, obituary, results of search engine queries) and the metadata about DNA donors (time of donation, age, place of residence) can reveal the identity of certain individuals even if that DNA was donated 'anonymously'.''

Feasibility of anonymization means that algorithms lead (in a reasonable time) to data sets that are still useful for the applications. Whether anonymization is feasible or not for genetic necessitates first the clarification of the term ''genetic data''; more and more DNA and RNA profiles are available, and anonymization might be feasible for one kind profile and not for other ones. Such a lack of clarity might be one reason why genetic data is not seen as personal data in the sense of data protection law in some jurisdictions. Then, usefulness has to determined, which has to be done in view of the context.

Finally, alternatives such as cryptographic methods or data usage controls and their possible combinations with anonymization will be discussed.

Hot Topics

HT-34 Electronic-Catalogue-Based Database of National Center Biobank Network

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National Research Centers for Advanced and Specialized Medical Care (NCs) have organized the National Center Biobank Network (NCBN) in order to utilize human biological samples, i.e. bio-resources, which each NC collects and uses for academic research, drug discovery research, development of new diagnostic method, and individualized medicine. NCBN is also constructing a common platform for bio-resource collection of the NC biobank. In part, we have developed an electronic-catalogue-based database (ECD) which has the disease name, the type of bio-resources, shared interview sheet of patients and others. The database is expected not only for medical researchers but for the pharmaceuticals to contribute an innovative drug development. We have thus developed a retrieval function of the ECD, as shown in http://www2.ncbiobank.org/Search/Search_en. The catalogue data consists from a set of de-identified individual data, extracting from the NC biobank database. Because NC bio-resources are donated by outpatients and inpatients, the disease name is a mandatory item of the ECD, and is coded by the ICD-10 classification, adopted in major biobanks like BBMRI. In the retrieval system of Japanese version, however, we provide both of the check-box method to select from the ICD-10 classification and the text-data-entry method, because the ICD-10 classification is rather coarse for disease classification in Japan. In the future, we can hope to cooperate with overseas biobank databases as well as in Japan. As a fundamental mission, each NC biobank is in charge of a principal diseases category (cancer, cardiovascular diseases, psychoneurotic and neuromuscular diseases and others). It is emphasized that each NC biobank collects high-quality bio-samples with high-accuracy clinical information. The ECD can show that a bio-sample diagnosed with a certain disease of interest has an additional clinical information of the relevant patient.

HT-35 Mobile Lab-Units Support Multicentric Studies and Standardized Collection of Human Specimen

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Background: Multicenter sampling campaigns are the basis for human biomonitoring and epidemiologic studies worldwide. Standardized conditions are the key for high quality in sample preparation, analysis, and biobanking and handling of potentially infectious material requires additional safety features. Obviously individual laboratories at all sampling sites will meet those requirements. However, operation and maintenance of those facilities is cost intensive and changing locations or scope of studies is not easily realizable. Mobile units are a promising approach since one unit is able to serve several locations with the same equipment. But establishing safe and ergonomic operations in the restricted space of vehicles is only possible with dedicated solutions with properly optimized workflows.

Methods: Tailored mobile units are designed starting from critical analysis of existing procedures and requirements followed by constructing the vehicle and laboratory deploying 3D modeling of all analytical and medical instruments. Vehicles range from pick-ups over vans to semi-trailers and containers all complying with both the requirements of public transport and laboratory admission. Laboratory equipment is integrated with remote access into higher-level control systems. Operation conditions are logged and analyzed to predict potential failures and to assist trouble-shooting from the distance. Setting up of the mobile units is designed to require minimal technical staff.

Results: Mobile units based on semi-trailers have been designed, built and tested in epidemiologic studies. Integrated laboratories have received approval for the handling of infectious samples complying to biosafety level two and three. Campaigns have been carried out and best practice guidelines have been derived. Routine operation of one mobile unit in the framework of the German Environmental Specimen Bank (ESB) has been successfully demonstrated and were accredited according to the general requirements for the competence of testing and calibration laboratories (DIN EN ISO/IEC 17025: 2005).

Conclusions: Mobile units are the key for highest quality integrated biobanking workflows from sampling to specimen repository. They provide flexible support of multicentric studies supplying identical technical and laboratory boundary conditions at any site. Integrated biobanking facilities allow for seamless transfer of samples from sampling site to final repository without breaking the cold chain.

HT-36 Cryopreservation Causes the Changes of RNAs and Protein Expression in Hep-G2 Cells

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Introduction: It is important and necessary to know the quality of the specimens changes in preservation to ensure accuracy of the research. Compared with DNA, RNA and protein are easier to degrade under the influence of various external factors.

Biobanks will have higher application value if the tumor tissues can be cryopreserved alive. But the cryopreservation may produce the injuries of DNA, RNA and protein. The study of molecular modifications potentially produced by cryopreservation is necessary for CPAs application. The objective of this research is to study the expression levels of RNA and protein in cells after exposure to CPA solutions or cryopreservation. The human liver carcinoma Hep-G2 cells were chosen as model to provide research basis for the CPAs' application in biobanks.

Methods: Hep-G2 cells were treated with no CPA solutions, Dimethyl Sulphoxide(DMSO)-based cryoprotectant solutions or trehalose + DMSO-based cryoprotectant solutions, and cryopreserved at $-80°C$ or in liquid nitrogen for 7 days. The effects of cryopreservation were assessed by cell viability assay, qPCR assay for genes expression of CRK and CD44v6, and western blot assay for protein expression of CD44v6.

Results: Cells were all dead after cryopreservation with no CPA, whereas more than 75% cells were alive after exposure and cryopreservation in CPA solutions.

The expression levels of CRK and CD44v6 changed more after exposure and cryopreservation in 10% DMSO solution, but less in 5% DMSO + trehalose solution.

The protein was seldom determined in the cells after cryopreservation with no CPA. But the affects on CD44v6 protein expression of CPAs was not significant.

Conclusions: Cryopreservation has proved to be an effective technique to keep cell and tissue viability, but causes the changes of RNAs and protein expression. But trehalose could protect several RNAs from degradation. Our findings provide a new strategy for the biobanking. Long term storage and more genes should be studied in further research.

Human Specimen Repositories

HSR-40 Production of Tissue Microarrays (TMAs) of Cervical Cancer for Korea Gynecologic Cancer Bank

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Abstract: The cause and progression of gynecologic cancer is extremely diverse. Thus, for any basic and translational study of gynecologic cancer, there is the need to use patient-derived specimens and clinical information to identify genetic changes involved in the development and progression of gynecologic cancer and to apply the best diagnostic as well as therapeutic methods.

Korea gynecologic cancer bank aims to increase the diagnosis and treatment rates by providing various specimens donated from patients and sharing research resources, information, and results among researchers.

Human tissues are usually stored as formalin-fixed paraffin-embedded (FFPE) samples in biobanks. However, its application for clinical research use has been limited.

Herein, we production of TMAs of cervical cancer using FFPE in our Korea gynecologic cancer bank. Korea gynecologic cancer bank has been made by well-designed tissue microarrays from the archival paraffin-embedded tissues blocks of cervical cancer.

This tissue microarrays would be the basis for the translational studies in cervical cancer.

Materials and Methods: During 2012-2014, we made 12 TMA blocks from 200 cervical cancers, 327 high-grade cervical intraepithelial neoplasias (CINs), 99 low-grade CINs, and 541 matched nonadjacent normal cervical epithelial tissues and compared the data with clinicopathologic variables, including the survival of cervical cancer patients.

Results: The overall mean age of patients was 40.6 ± 9.8 years for low-grade CIN, 38.9 ± 11.2 years for high-grade CIN, and 49.4 ± 11.7 years for cervical cancer. The distribution of FIGO staging for the 200 cases of cervical cancer is as follows:

138 stage I, 53 stage II, and 9 stage IV. The following cell types were assigned according to World Health Organization (WHO) criteria: 164 squamous cell carcinomas, 30 adenocarcinomas/adenosquamous carcinomas, 4 small cell carcinomas, 1 neuroendocrine, and 1 clear cell carcinomas. HC2-confirmed HPV infection rate was 78.7% (74/94) in low-grade CIN, 92.2% (226/245) in high-grade CIN, and 93.9% (92/98) in cervical cancer.

Discussion: Almost all these tissue microarrays are ready to be used in the related translational studies. In addition, we experienced the work related to making tissue microarrays. So, this experience will facilitate our efforts to make the next collections of tissue microarrays.

HSR-42 Key Roles of the Korea Gynecologic Cancer Bank (KGCB)

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Background: To develop effective targeted therapy for gynecologic cancer, the need to understand molecular mechanisms related to the tumor generation, metastasis and treatment resistance is increasing. Human specimens are the core resources that include these molecular information. Securing quality specimen can be considered an essential for drawing out quality research result. This study seeks to review the current status of the database, the cooperation system with other institutions and to evaluate the utility degree of the stored specimens as research sources of KGCB.

Methods: Human specimen and data stored in the bank target primary gynecologic cancer cell line, tissue, serum, plasma, urine, saliva and pelvic ascites. Specimen extraction was administered starting from 2012, and it was administered before or during the treatment using the low-invasive method with the patients agreement. Specimen quality and quantity was identified by classifying specimen by cancer type, acquired year and characteristic. The amount of specimen that was lent and distributed was verified, and published papers that were studied with these specimen were checked. Moreover, institutions that signed work agreement with the bank for collection of the specimen and academic interaction were verified.

Results: The KGCB currently maintains a collection of over 38,000 specimens that have been isolated from Korean gynecologic cancer patients since 2012. The KGCB has distributed approximately 3,934 specimens to many other researchers both at home and abroad. As for the paper using the distribution of research sources, there are 11 papers published on SCI journals from 2012 to 2015. Institutions that signed work agreement include 9 institutions and hospitals in Korea and NIH of the US.

Conclusion: Resources of gynecologic cancer bank is continuing to grow steadily since 2012, and quality resource is being developed through proper management. As such, these resources are utilized to publish a number of outstanding research papers. Likewise, request for distribution and lending for new researches is increasing. It is necessary to continue to acquire and manage resources continually to establish the mechanism and the treatment method of the gynecologic cancer that are not confirmed to this point. It is judged that it would be necessary to provide resources actively according to the fair and appropriate procedure of the related research institutions and academic community.

HSR-43 The Evolution of Specimen Processing from Manual to Full Automation

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Our tissue repository started as a disease-specific (oncology) biorepository more than 10 years ago. Gradually, the repository evolved into a multi-disease, population-based repository over time. The amount of specimen processed daily increased multifold. Here we described the process of adaptation of the repository to the ever increasing specimen numbers. When we first started blood processing, the whole process was performed manually by our medical technologists. As our specimen number increase, a liquid handler was acquired to semi-automate the process. With the purchase of the Tecan Evo system in 2015, the repository now processes blood and liquid specimen in a fully automated fashion. The chart of specimen processing progression over time and the pro and cons of full automation in our biorepository will be discussed.

HSR-44 Biobank of Birth Defects: Sample Collection and Information Management

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Background: China is one of the world's most populous countries. China also has high incidence of birth defects. According to the data of Chinese birth defects prevention report 2012, the birth defect rate was as high as 5.6%. The Obstetrical Department of Nanjing Drum Tower Hospital has annual deliveries of 5,000. Since 2010, investigate birth defects and related diseases, the department of obstetrics and biobank established a specialized biobank of birth defects.

Methods: Pregnant women with birth defects who provided informed consent were screened in obstetrics. The peripheral blood, cord blood, amniotic fluid of pregnant women, fetus and placenta specimens were taken by a serial of special medical orders and sent to the biobank. Biobank staff separate the peripheral blood of pregnant women and umbilical cord blood into plasma and leukocytes, amniotic fluid into supernatant and precipitation then store at −80 degree centigrade. According to the guidance of pathological doctors, specimens of fetus and placenta were photoed with standard posture, then measured and dissected. Tissue samples: placenta, umbilical cord, alar skin, liver, kidney, lung, thymus, and heart tissue, including left atrium, right atrium, left ventricular, right ventricular, aorta, pulmonary (3 copies) were collected and quick freezing in liquid nitrogen then stored in −80 degree centigrade. The information system of biobank obtained clinical information of cases enrolled through data interface from the electronic medical records of hospital, including family history and past marital and fertile history of pregnant women, current pregnancy related index, ultrasound results and pregnancy outcome.

Results: There were 800 birth defect cases in the biobank until now, the sum of all kinds of birth defect specimens were about 26 thousand. Information of all cases and specimens were managed by the information system of biobank. For each specimen, information system can supervise its location precisely.

With the information system, researchers can also screening interested cases by any one or more data index.

Conclusions: Standard Operation Procedures of birth defects specimen reservation were established. Biobank of birth defects with completely matched specimens, comprehensive cases information and convenient management provide a solid foundation for the research of birth defect related diseases.

HSR-45 Biobank Data Standardization for NCBN Catalogue-Based Dataset: A Feasibility Study on Using CDISC

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The National Center Biobank Network (NCBN), consisting of six national centers (NCs) for advanced and specialized medical care, was launched in Japan in 2012 to collect biological specimens and health-related data. The common data formats of the six NCs are, however, not widely known outside the NCs. Therefore, we investigated whether the data elements collected by the NCBN could be made to conform to the international standards of the Clinical Data Interchange Standards Consortium (CDISC). We attempted to map the NCBN data elements onto the Study Data Tabulation Model (SDTM), a set of CDISC standards on the submission format of electronic clinical data approved by the Food and Drug Administration. The results showed that all items of the NCBN data could be mapped onto the SDTM and fulfilled 50–70% of the required items of each domain specified in the SDTM. We also attempted to map the NCBN data elements onto the Analysis Dataset Model (ADaM). The results showed that all items of the NCBN data could be mapped onto the ADaM. We concluded that, while the standardization of biobank data according to the CDISC standards is possible, there is a need to consider whether additional items must be included in the NCBN and to have experts familiar with the CDISC standards review the standardization needs.

HSR-46 The Association Between Dyslipidemia and Obesity Indices in Chinese Adults in Beijing

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Background: To evaluate the association of anthropometric indices of obesity including the body index mass (BMI), waist circumference (WC), waist-to-height ratio (WHtR) and waist-to-hip ratio (WHR) with dyslipidemia in the population residing in Beijing.

Methods: We conducted a study in a sample of 453 Beijing residents aged 18 years or older. Body weight and height, WC, and hip circumference were measured and BMI, WHtR, and WHR were calculated. Overweight/obesity was defined as BMI ≥ 25 kg/m2, while abdominal obesity was defined as WC $\geq$90cm/80cm (men/women), WHtR ≥ 0.5 or WHR $\geq 0.9/0.85$ (men/women). Dyslipidemia included any one of the following: total cholesterol (TC) ≥ 6.22 mmol/L, triglyceride (TG) ≥ 2.26 mmol/L or high density lipoprotein-cholesterol (HDL-C) <1.04 mmol/L.

Results: We calculated the correlation between the anthropometric measurements and lipid profile. It was shown that BMI, WC, WHtR and WHR correlated with lipid profile (TC, TG and HDL-C, respectively). The majority of the correlations were relatively weak, but significant. After adjusting for age and gender using logistic regression, the probability of developing dyslipidemia was significant higher for participants with overweight/obesity [odds ratio (OR): OR: 2.58; 95% confidence intervals (CIs) CI: 1.64-4.06)] or abdominal obesity which was measured by WC (OR: 2.83; 95%CI: 1.79-4.47), WHtR (OR: 2.09; 95%CI: 1.28-3.41) or WHR (OR:2.43; 95%CI: 1.56-3.80), respectively.

Conclusion: Dyslipidemia is one of the most important risk factors for atherosclerosis which is likely to play a role in disc degeneration. Our study has shown that these anthropometric indices were associated with the risk of dyslipidemia. Further researches will be needed to identify the best anthropometric index in population to predict dyslipidemia risk.

HSR-47 The NINDS Repository: A Large Public Collection of Biomaterials for Neurological Disease Research

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Neurological disorders are a serious health concern that presents massive challenges to healthcare systems globally and their multifactorial pathological mechanisms are not completely understood. The National Institute of Neurological Disorders and Stroke (NINDS) -part of the USA National Institutes of Health (NIH)- sponsors the NINDS Repository which was established in 2002 at the Coriell Institute for Medical Research with the mission of supporting the identification of the genetic risks and causes for neurological disorders. The NINDS Repository collects blood samples as well as de-identified clinical data from a diverse patient population diagnosed with cerebrovascular diseases, Parkinsonism, motor neuron diseases, epilepsy, Tourette syndrome, Dystonia, and neurologically normal controls. The collection features patient-derived DNA and cell lines including many samples annotated with well-defined mutations. Since the NINDS Repository inception, biomaterials and clinical data from more than 46,000 individuals have been received. More than 38,000 unique samples are available through an online catalog at http://catalog.coriell.org/1/NINDS and during 2015 more than 7,000 unique samples were distributed to investigators worldwide.

The NINDS Repository aims to standardize the collection and processing across all samples while protecting patient safety and privacy. In an effort to ensure the quality of these valuable biological resources, the NINDS Repository has established well validated standard operating procedures (SOPs) for the collection, reception, processing, storage, and worldwide distribution of biological specimens. These SOPs include rigorous quality control assessments for each sample type. The NINDS Repository aims to provide rapid feedback to sample submitters regarding sample integrity and appearance at the time of receipt and status after completion of all required in-house processing. Essential to all this is a customized secure and highly user-integrated biobanking laboratory information

management system, including sample-data association by cross-referencing with other NIH resources such as dbGaP.

The development of such a centralized collection of human biospecimens and their associated de-identified clinical data allows the NINDS Repository to provide a vital resource for research designed to discover and validate genetic and molecular biomarkers relevant for the study and treatment of neurological disorders prevalent in our society.

HSR-48 The Association of Human Cervical Disc Degeneration and Lipid Levels

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Background: Atherosclerosis and cardiovascular risk factors were suggested as one of possible underlying factors for disc degeneration. The aim was to assess the association between the lipids levels and the risk of cervical disc degeneration.

Methods: We established a standardized case-control study of cervical disc herniation. One hundred and one cases and 102 controls were enrolled in Beijing Jishuitan hospital from Jan. 2012 to May 2013. The data of demographics, history of hypertension and type 2 diabetes, smoking and drinking status were collected from each individual. All subjects had lipids testing at the time of hospitalization. Levels of total cholesterol, triglyceride, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol in fasting blood were measured by automatic biochemical analyzer.

Results: No differences were found in the term of gender and age between cases and controls. Compared with controls, the levels of total cholesterol and triglyceride were significantly higher in cases, with the means of 4.88 mmol/L vs. 4.47 mmol/L ($P = 0.002$) and 1.89 mmol/L vs. 1.28 mmol/L ($P = 0.003$), respectively. Triglyceride levels were significantly related to cervical disc degeneration after adjustment for multiple covariates through logistic regression. The summary odds ratio (95% confidence interval) per 1-mmol/L increase of triglyceride was 2.11(1.26, 3.54), respectively.

Conclusions: Lipids levels were associated with the risk of cervical disc degeneration. However, the causality should be needed more evidence.

HSR-49 ISO9001: 2008 Quality System Certification in National Children Biobank of China: Standardized Biospecimen Samples Collection

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Pediatric disease is abundant in China with an immense children population base, which makes it necessary to establish a standard national children biobank to control the systematical and standardized collection of pediatric specimen. The collection work has been in process in National Children Biobank affiliated to Beijing Children's Hospital since early 1980s. Beijing Children's Hospital is a pediatric medical center integrating medical services, scientific research, education, and healthcare, unparalleled by any other children's hospital in China and even in Asia. Biospecimen samples (healthy as well as hospital participants), including blood (children and parents when necessary), urine, tumor, skin, nail, hair and the related clinical data were collected to National Children Biobank, and then stored at liquid nitrogen freezers or ultra-low temperature freezers.

To standardize the collection process, National Children Biobank has passed ISO9001:2008 quality system certification in November, 2014, which deals with the fundamentals of quality management systems on specimen collection through continuous improvement. ISO9001: 2008 quality system certification for biobank is an exploration to guarantee the quality of specimen. Our certification is the first in the biobank field in China, which has been a successful promotion to other biobanks.

Up to now, 43,434 specimen were collected included pathogenic specimen, anaphylactic disease, hemopathic specimen, solid tumor and so on. The scientific research output in Beijing Children's Hospital was mostly based on the systematical collection of pediatric specimen.

The standardized biospecimen samples collection process which improved the specimen quality is well carried out in the National Children Biobank.

HSR-50 The Study of Orthopaedic Degenerative Diseases in China: Construction of Clinical and Biospecimen Information Integration Platform

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Background: Our aim was to establish an orthopedic high-quality biobank in accordance with international standards, which includes clinical information and biospecimen, to provide a resource platform for early diagnosis and early warning systems of orthopaedic degenerative disease.

Methods: First we determined constructive and developing mode; confirmed facility location. Second, we set up the organization, informed consent procedure, standard operating procedures and biological information platform. According to the standard operating procedures, biological samples and clinical information were collected from inpatient who suffered from orthopaedic degenerative diseases and healthy volunteers.

Results: We completed the construction of biological sample library for orthopaedic degenerative disease, including organizational and managing system, standardized process, infrastructure, information system and entitative specimen library. Up to December 2014, clinical data of 6,819 patients and 36,403 samples of blood and tissues have been collected. 29.3% of the samples from Biobank were used for research projects. Moreover, a cohort study was initiated in 2013 and 453 volunteers with their data of imaging have been included.

Conclusions: To establish international standardized and high-quality Biobank for orthopaedic degenerative disease, is the important guarantee for improving the level of the orthopaedic basic research and clinical medicine and realizing ''precision medicine.''

HSR-51 BioKEP Pilot-Study: Generating the Framework for a Collaboration Between Publicly Funded and Private Biobanks (Public-Private-Partnership)

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Background: For the understanding of the pathogenesis and development of a disease, biomaterials and patient data prior to diagnosis would be invaluable. The IDBW collects biomaterials and associated data from patients diagnosed and/or treated in the University Hospital Würzburg (UKW) based on a broad consent. The Bavarian blood donor service (BSD) retains from each donor a plasma sample for follow-up analysis which can be broadly used for medical research after expiry of the statutory period if the donor consents.

Methods: By linking donor and patient identities we attempt to merge bio-samples and data to obtain a contiguous longitudinal time series. In this aim BioKEP, a TMF funded project, was set up to establish a generic framework comprising legal, ethical, and technical issues for public/private biobank-collaborations.

Results: All documents and work-flows developed for BioKEP are designed in a generic manner allowing for a straightforward implementation in different public/private biobank constellations. BioKEP is based on a cooperation-agreement covering all relevant aspects of biobanking including ELSI-issues. Data and privacy protection are regulated as well as handling of intellectual property and/or liability limitations. Patient information and consent forms meeting all current ethical standards have been developed. However, the matching of patients with blood donors poses a major challenge, however. This has been solved by a secondary level of pseudonymisation linking the pseudonyms of each project partner. Biomaterials and data are exchanged between the partners exclusively based on the secondary BioKEP pseudonym.

Conclusion: By solving a number of ELSI- and administrative issues/challenges BioKEP may serve as a (generic) model for the successful establishment of public-private-partnerships in the field of biobanking.

HSR-53 BBMRI.vlaanderen: Bridging Biobanks with Research Communities in Flanders

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Background/Information: Recently a new interuniversity consortium - BBMRI.vlaanderen - was set up to continue to operate the existing Flemish interuniversity Biobank infrastructure (initiated in 2009, Center for Medical Innovation), maintain and expand the interuniversity biobank catalogue and enhance collaboration between researchers in the institutions.

Methods: BBMRI.vlaanderen comprises of all Flemish Universities and University Hospitals, with a team of liaison officers ensuring an effective integration of expertise and coordination of efforts in establishing of an interuniversity Flemish Biobank Network.

The Flemish biobank infrastructure includes four decentral biobank facilities with dedicated premises and equipment, operating under strict quality and harmonization criteria (conform international OECD standards) for human samples and their pseudonymized clinical data sets, with an online catalogue of these samples built on a decentralized backbone system.

This ICT backbone connects the decentral local databases of the individual biobanks and is queryable through the website: https://bbmri.vlaanderen. A minimal data set (MDS) for the central catalogue based on international standards was implemented, while harmonized material transfer agreements between both academic and non-academic partners were approved.

Results: The Flemish Biobank project has achieved important milestones in its initial phase (2013–2015). In 2013 a Belgian node was established, the BBMRI.be, as a founding partner within the BBMRI.eu. We are expanding the activities of the Flemish Biobank to bring all Flemish Biobanks together on a single harmonization and data sharing platform and strengthen its participation in BBMRI.be and BBMRI.ERIC.

The expansion of our ICT system consists of the addition of data sharing features between collaborating researchers in different institutions to the existing catalogue. A solution where data is not replicated between partner sites, but specific datasets are shared through a system of ''remote views'' maintains the integrity of the data.

Conclusions: The catalogue is an important tool to accelerate the translation of innovation in several disease domains based on scientific, quality, volume and strategic criteria.

The possibility of data sharing is an important differentiator compared to other existing biobank networks, and will further leverage the Flemish interuniversity collaboration to the European context.

HSR-54 Biobank Collaboration Generates Biospecimen Collection Network in Rural Maine

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Background: According to the National Cancer Institute, one of the most significant roadblocks to progress in cancer research is the lack of standardized, high-quality biospecimens. Maine has two major medical centers that are geographically separated and serve patient populations of approximately 500,000. Each medical center has a unique human tissue biorepository. The Maine Medical Center (MMC) BioBank, which operates within the Dept. of Pathology, has an inventory of >100,000 FFPE and frozen tissue specimens available for research to an established network of academic and commercial collaborators. The Eastern Maine Medical Center (EMMC) BioBank is based within a clinical oncology practice and has expertise in patient consent, clinical practice integration, and prospective collection and processing of liquid biopsy specimens, especially from hematologic malignancies. A collaboration between these two distinct and independent biobanks has been formed to expand and facilitate access to specimens available for biomedical research.

Methods: The goals and activities of the partnership including the communication infrastructure, financial obligations, regulatory considerations and data capture for collaboration assessment were outlined in a Memorandum of Understanding that was signed by each medical center. The Maine Cancer

Biospecimen Portal (MCBP) website, which serves as the hub of the collaboration, was established to expand cancer research in Maine by facilitating access to biospecimens and to navigation services which aid investigators in study design and sample selection. Specimen requests from this website are jointly evaluated and filled by both biobanks. Material Transfer Agreements allow for bi-directional transfer of specimens between the biobanks and to investigators making the requests.

Results: With grants awarded by the Maine Cancer Foundation, each biobank has begun to put infrastructure in place to expand the inventory and management of prospectively collected cancer biospecimens. Awareness of the collaboration and the MCBP, have been communicated through poster presentations at local basic science research and clinical oncology conferences. Strategic planning for biospecimen collections for 2 major studies has begun.

Conclusions: The EMMC and MMC BioBanks have established a collaboration that leverages the complementary strengths of each organization in expanding the number and variety of tumor specimens available for biomedical research.

HSR-56 The Management of Clinical and Follow-Up Information for Morden Biobanking

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Background: A biobank is an entity that collects, processes, stores, and distributes biospecimens and relevant data for use in basic, translational, and clinical research. Biobanking of high-quality human biospecimens such as tissue, blood and other bodily fluids along with associated patient clinical and follow-up information provides a fundamental scientific infrastructure for personalized medicine.

Methods: Clinical information collected for donors should be as comprehensive as possible and mainly include basic information, operation information, laboratory examination, imaging tests and pathological information. For specific patients, it should also include postoperative chemotherapy or other relevant treatment options information such as targeted therapy strategy. The follow-up information mainly includes the basic living conditions, presence of recurrence or metastasis, and survival. The methods of collect information are based on five major components: (a) Extracted detailed electronic medical records, test results, the pathological diagnosis from hospital information system (HIS); (b) The questionnaires; (c) Telephone follow-up; (d) Counseling; (e) Query the residents' health records. For more completely understand and obtain the donors' information, we put to use biobank information management system and do system interface with HIS, laboratory information system (LIS), picture archiving and communication systems (PACS), the pathological system and Nanjing residents' health records. While we have collected biospecimens, the information of sample source will be extracted or updated directly. Furthermore, we established follow-up module in our system. We set the time and content of follow-up for different kind of diseases, referring to the follow-up standard from NCCN guidelines and clinician's advice. In addition, we set notifications in the system and regularly remind the biobank staff implementing follow-up.

Results: The management of clinical and follow-up information allow the researchers quickly and easily review details, sources, and specifics of biospecimens.

Conclusions: The biospecimens with complete clinical and follow-up information are valuable that can be used for the discovery of biomarkers, cohort study, epidemiological study and can provide favorable conditions. So information technology plays a major role in management of biobanks. We believe that we will provide useful information for researchers and personalized medicine advancement.

HSR-57 The Clinical Database and Biobank of Cardiovascular Disease in HMU

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Coronary arterial disease (CAD) became a leading cause of death and morbidity among the adults around the world. The pathological foundation is atherosclerosis, which is considered as a chronic inflammation slowly progresses over decades until clinical symptoms arise. The severity evaluation of atherosclerotic plaques guides clinical management and it is always relies on clinical manifestation and stenosis degree assessed by coronary angiography (CAG). Iconographic methods like intravascular ultrasound (IVUS) and optical coherence tomography (OCT), with its high resolution images taken from coronary artery, could provide detailed plaque features, including fibrous cap, lipid deposits, calcium, thrombus and macrophages. The Clinical Database and Biobank of Cardiovascular Disease (CDBCD) of 2nd hospital of Harbin Medical University (HMU) is established in May, 2012. All of the participants enrolled in CDBCD underwent CAG and most underwent OCT and IVUS. Total number of sample is 44,192 from about 3,000 participants. The participants enrolled in early stages by now are stable and unstable angina, acute myocardium infarction (AMI) patients and healthy individuals. Sample types included serum, plasma, DNA, RNA and PBMCs (peripheral blood mononuclear cells). About half of all these participants are severe CAD (stenosis degree $\geq 70\%$ or AMI) and underwent stent-implantation. These participants were followed up 3 to 12 months and provided free medical consulting from the cardiology department. Clinical database included medical history obtained from hospital information system (HIS), laboratory information system (LIS), picture archiving and communication system (PACS) and follow-up system. With detailed information about the plaques and biospecimen, we could conduct researches aimed to personalize medicine.

HSR-58 Establishment of Beijing Biobank of Clinical Resource (BBCR) for Mental Disorders

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Background: In 2009, funded by Beijing Municipal Science and Technology Commission, under the organization of Capital Medical University, the Beijing Biobank of Clinical Resource (BBCR) construction started. Ten kinds of major diseases such

as cancer, cerebral vascular disease, cardiovascular disease and mental disorders were included. In September 2010, BBCR for Mental Disorders (BBCR-MD) initiated construction by Beijing Anding Hospital. We want to report construction process and current state of BBCR-MD.

Methods: According to the third edition of Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research and certification documents of International Organization for Standardization (ISO 9001) to establish BBCR-MD, including quality control, informed consent, clinical resource and specimen collection and preservation. Special standardized operational procedures for BBCR-MD were developed, we also collected clinical data and venous blood samples after sign informed consent. Specimens were stored at −80°C refrigerator. A special database system suit for mental disorders was designed to management of clinical data and specimens.

Results: Between June 2012 and October 2015, more than 5,300 participants were enrolled in BBCR-MD, most of them with major depressive disorder. In July 2014, other disorders such as bipolar disorder, schizophrenia, anxiety disorder were start to enroll. From the beginning, high risk population of mental disorders and health control were also taken into account. Over 40,000 tubes of blood derivatives were collected and stored. Specimens including plasma, serum, erythrocyte, leukocyte and DNA.

Conclusion: The construction of BBCR-MD is a systematic work. Its functions will be increasing in exploring pathogenesis, developing technological innovation for early detection, novel therapeutic strategies and individualized therapy.

HSR-59 Federated Biobanking with Corporate Service Unit: The Munich "Biobank Alliance" Blueprint

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From October 2010 until March 2015, the German Federal Ministry of Education and Research funded the m4 Biobank Alliance project, as part of the Munich cluster program m4 ''Personalized Medicine and Targeted Therapies''. It was designed as a ''structural project'', partnering BioM Biotech Cluster Development GmbH with the Helmholtz Centre Munich (HMGU), both Institutes for Pathology at Ludwig-Maximilians University (LMU) and Technical University Munich (TUM) as well as the surgical clinics of University of Munich Medical Centre (KUM) and of TUM-Medical Centre ''Rechts der Isar'' (MRI). Its aim was the harmonization and expansion of existing biobank activities and formation of a biobank network providing access to a standardized collection of samples and data, both for in house research as well as, on a ''fee for service'' base, for research and development in pharma and biotech companies, thus optimizing the use of biosamples and data with the prospect to co-finance biobanking activities.

This Biobank Alliance project has successfully rooted participating biobanks in a common ethics and privacy/data protection framework as well as in TQM and has refined biobanking processes towards common standards, also clarifying the scope of these processes and their ownership. However, the attempt to relocate process ownership among stakeholders in favor of a unified biobank design failed. Continuing challenges include unsettled strategies of involved public institutions and missing openness towards inclusion of existing cooperation and private initiative into an integrated infrastructure.

BioM GmbH as cluster management organization assumed a neutral positon and established ''Biosample Services'' as a central service unit, contracting qualified biobanks and in consequence offering central access, shared collection standards and comprehensive project management. This presentation shows the compiled contractual framework and project workflow as well as related documents as a blueprint for networking independent biobanks. Only this kind of joint promotion of research usage, leveraging scientific biobanking will lead towards biobank sustainability.

HSR-60 Construction of Beijing YouAn Hospital HBV Biobank: Background and Methods

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Background: Beijing YouAn Hospital HBV biobank aims to collecting clinical and biological information as well as blood specimens from Chinese HBV patients, to further investigate this disease's causes, risk factors, pathogenesis and prevalence patterns etc. To date, we have collected 10,000 chronic hepatitis B cases, 300 acute hepatitis B cases, and 5,000 hepatocellular carcinoma cases. Among all follow-up chronic hepatitis B cases we collected, 95 cases developed into hepatocellular carcinoma. The clinical, biological and specimens information are used for different research in order to find early diagnosis biomarkers and to promote new pathogenic insights.

Methods: Between October 2009 and December 2015, 10,000 hepatitis B cases and HBV related cases were enrolled in the study of HBV Biobank. Detailed clinical and biological information was collected, including patient's name, gender and age, profession, family history, and diet, lifestyle, when and how get HBV, and HBV DNA level, HBsAg, HBsAb, HBeAg, and HBeAb, HBcAg, and biochemical indicator, etc. These cases were followed up once every three months The blood specimens collected were stored in line with Standard Operating Procedures. Carcinoma and paracancerous tissues were collected. PBMCs separated from blood and tissues were stored in liquid nitrogen for future research. The whole collection and storage process was obtained by ISO9001: 2008 certification.

Results: 10,000 Hepatitis B cases with complete pathological data and blood specimens at different disease stages were collected and stored. As a research platform, the HBV Biobank has supported almost 50 national key projects. The research direction is mainly about hepatocellular carcinoma biomarker at early stage and new pathogenic insights of HBV progress.

Conclusions: As research platform, the HBV Biobank has collected 10,000 cases not only including biological specimens, but also containing the general and clinical information. HBV Biobank will provide rich resource for early-stage hepatocellular carcinoma biomarker as well as new pathogenic insights for HBV progress study.

Keywords: HBV Biobank, chronic HBV, hepatocellular carcinoma, biomarker, HBV progress.

HSR-62 Tissue Microarray Facility at CEGMR Biobanking Unit: Enhanced Management of Clinical FFPE Biospecimens Towards Effective Biomarkers Research

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Background: Despite the advancement of OMICs technologies, several polygenic and complex diseases are still challenging the scientific community and their molecular pathogenesis remain poorly understood. Thus, additional high quality and fully annotated biospecimens processed using the best biobanking practices are still needed to deliver individualized healthcare. Millions of Formalin Fixed Paraffin Embedded (FFPE) blocks are routinely constructed every year and worldwide as a tissue preservation gold standard and occupying large spaces at biobanks/hospitals. The development of Tissue microarray (TMA) as an advanced technology of tissue tininess and processing has modernized the management of these FFPE blocks. In addition to tremendous reduction in biobanks space storage dedicated to these FFPE blocks, TMA technology has allowed a high throughput analysis of many tissues at once under similar experimental conditions and in a cost-effective manner. Aims of study are to provide an overview of the TMA facility at CEGMR Biobanking Unit (CBU) - King Abdulaziz University, Jeddah - as an adjunct and useful tool for solid tumor profiling, validation and biomarkers discovery.

Material & Methods: Fully automated TMA technology (TMA Master, 3DHISTECH) has been implemented at CBU since 2012 to make thousands of FFPE blocks from the western region of Saudi Arabia with their full annotations data available for medical research.

Results: More than 7723 FFPE blocks of different types of solid tumors archived at the department of pathology, KAU Hospital were successfully transferred to approximately 180 TMA FFPE recipient blocks. Additionally, validation between conventional full sections versus TMA slides was performed using both Immunohistochemistry (IHC) and Hematoxylin & Eosin (H&E) staining techniques. Several biomarkers were therefore investigated using the TMA platform for either proteinic and/or genetic profiling using IHC and/or Bright-field Double In Situ Hybridization (BDISH) respectively.

Conclusions: The TMA facility is a time, space and cost-effective technology that allowed the processing and analysis of large number of biospecimens under similar experimental conditions. Given the tremendous number of available FFPE blocs worldwide, we recommend the integration of this technology as a permanent component of tissue biobanks' platforms for better availability, transfer, packaging and shipment of fully annotated biospecimens readily available for scientists.

HSR-63 Freezerpro to Limfinity: Developing an Extensible Lab Management System Based on Biorepository Data Management

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With the rapid development of the post-genomic era and the advent of information technology, the traditional sample information collection cannot meet the needs of today's biobank development, information technology rapidly improved the speed of sample collection and processing, improved the working efficiency and the utilization rate of the samples, which can satisfy the needs of large-scale, efficient collection, management and utilization of sample information, clinical and epidemiological information. Freezerpro devote itself to biospecimens data management. More recently, the Freezerpro continues to evolve as an all-around system known as Limfinity. In addition to manage biospecimens data, limfinity provides comprehensive, high-standard information management capabilities for the sample management process when refer to equipment, personnel, project, reagents and other supplies.

International standardization of biobank information repository require normalized collection, procession and preservation, meanwhile, reserve diversified information associated with biospecimens, such as clinical, pathology, medical history, informed consent, family pedigree information. Limfinity users access to different types of sample information through the data interface between the applications, such as diagnosis, laboratory and imaging examination, treatment, medication and surgery information. So that samples can be related to diagnostic information, treatment follow-up information dynamically and extended to sample correlation information simultaneously, which can also facilitate the intelligence screening of biospecimens under different conditions for follow-up studies. Intelligent docking between the databases minimize the error rate of information management and extraction paperless.

Considering the needs of tracking all activities and related information for biospecimens, biobanks need a comprehensive management system to deal with all these sample related data. Therefore, limfinity adopts an ideal metadata model to deal with the integration of heterogeneous data set, thus realize the collection, storage, management and retrieval of research and high-throughput experimental data information. This application can adapt to diverse scenarios and biobanking workflows, which can catalyze advances in biomedical research and operations.

HSR-64 Head and Neck Cancer Biobank in Shanghai Jiaotong University School of Medicine

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The establishment of biobanks to hold frozen blood and tissues from patients with primary head and neck cancer was made possible by a donation from Shanghai Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine in Shanghai. Since the Department of Oral and Maxillofacial-Head Neck Oncology has long experience of surgical and pathological examination, the quality of the sample is guaranteed. A group of pathology and statistical experts was established and made specifications for data registration and technical advice for the handling of blood and tissue and produced a draft handbook on quality assurance. Furthermore, an open access database providing cancer related Bioinformatics was established. In the future this biobank is going to connect to the nationwide cancer bank and supply service for the whole country.

HSR-65 A Project of a Biobank for Oncological Serum and Plasma Samples in the Czech Republic

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Background: The Medical Faculty in Pilsen, Charles University of Prague, has joined the national network of biobanks of clinical samples (BBRMI_CZ.). The Central Laboratory for Immunoanalysis has been charged to build up and manage the biobank of serum and plasma samples of selected oncological diseases (prostate, breast, colorectal and lung cancer).

Methods: Since the laboratory is part of of the Teaching Hospital in Pilsen and serves the whole Pilsen region (more than 575,000 inhabitants), a large number of blood samples from oncological patients are collected (about 200 blood samples of selected oncological diseases per month). The laboratory is equipped with several freezing units, an automated system for sample storage and retrieval, analytical instruments for IVD as well as for research (immunoassays and molecular biology) and an interpretation software. The serum and plasma samples stored in the biobank will serve for analysis of protein biomarkers, DNA expressions and microRNA.

Results and Conclusion: The results of biomarker analysis, together with the interpetation software, can help in the treatment optimisation and long-time prognosis estimation. The goal of the biobank is to provide a large number of data which can help in the management of diseases and treatment, in the prevention, prediction and prognosis of oncological diseases and eventually in improving the quality of life.

HSR-66 Human Specimen of the German KompNet HIV/AIDS: An Extensive Research Tool for Patient-Oriented Research

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Introduction and Objectives: HIV/AIDS causes a high burden of disease worldwide. Leading German researchers on HIV collaborate on interdisciplinary level in the scope of the HIV patient cohort and the biomaterial banks of the Competence Network (KompNet) for HIV/AIDS.

Methods: The KompNet HIV/AIDS patient cohort is a multicentre cohort study, providing nationwide data on HIV/AIDS, relevant co-infections, concomitant diseases and medication. Data and biomaterial has been collected prospectively from 2004 to 2011. The KompNet cohort is the largest cohort study on HIV and other infectious diseases in Germany, comprising a total of ~16,500 adult patients (15% women, 85% men.)

Results: Biomaterial banks have become a central component of biomedical research. Consequently, tissue specimens, blood samples (serum samples = 56.000, collected 2/year of each patient, DNA samples = 16.000) and cerebrospinal fluid are made available in the long-term for scientific studies. Stored samples are linked to the sociodemographic and clinical dataset (~290 variables) of each particular patient of the cohort. The data comprises in total ~62,900 person years (PY) including retrospective data, patients under antiretroviral therapy (ART) 55.860 PY and 8.9% were ART-naïve. Patient under antiretroviral therapy are documented in mean 6.7 years. The proportion of men in the cohort is 85% due to the inclusion criteria of HIV, mean age at enrolment for men is ~43 years, women ~38 years.

The research in KompNet HIV focuses e.g. on long-term pharmacovigilance issues, on the genetic impact on therapy outcomes towards individualised therapy approaches as well as on interactions between HIV and other coinfections e.g. hepatitis. For more information, publications and application form for samples see http://www.kompetenznetz-hiv.de. Patient consented to provide pseudonymised data and samples as well to the industry or foreign scientist outside the German KompNet community.

Conclusion: The KompNet biomaterial banks linked to the extensive cohort data bank offer great potential for interdisciplinary science to find answers to urgent questions within medical research. Researchers are invited for collaborations.

HSR-67 Fraunhofer Metabiobank: Locate and Stratify Human Biospecimens on a Case-by-Case and Sample-by-Sample Basis

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Introduction: Biomarker research requires a large number of human tissue samples, all comprehensively annotated, preserved and stored following unified standard operation procedures (SOPs). The initial partners of the Fraunhofer Metabiobank achieved this requirement man exemplary manner: The German Prostate Cancer Consortium's (DPKK) virtual biobank[1] provides information about the DPKK members' available data on samples and cases. The North German Tumor Bank of Colorectal Cancer's (ColoNet) biobank provides a comprehensive tissue, blood and clinical data collection[2]. Common SOPs are used for sample collection as well as clinical data collection.

Still, neither the partners' highly granular data, nor their sample quality, can be accessed adequately for the scientific community via existing biobank registers or catalogs.

Materials & Methods: Based on Fraunhofer IZI-BB's CRIP Toolbox[3], the new Fraunhofer Metabiobank is built up with use cases DPKK and ColoNet as initial partners. Its query interface provides access across indications while selectable search parameters are dynamically shown or hidden instantaneously – as soon as an indication is selected, specific parameters will instantly appear in the query interface.

Basis for the data transfer between the partners' biobanks and the Fraunhofer Metabiobank are the then closed contracts between Fraunhofer and the biobank's institutions [4].

Results: We present the Fraunhofer Metabiobank prototype: Parameter stratification in the query interface (including information about patients' informed consents, sample & storage quality, therapy and research data) allows instant refinement by showing live-calculated results and delivers pools of matching cases available in the partner biobanks. The refined search profile is then transmitted to the biobank site – and only there this search profile delivers the corresponding single case data required to start the research project.

Conclusion: The Fraunhofer Metabiobank increases visibility for the partner biobanks and their data. The scientific community has access to a comfortable online query tool for a case-specific parameter stratification and project refinement for an envisioned research project allowing detailed feasibility

requests. At the same time the patients' and the biobanks' data is protected by a proven data protection scheme.

[1] http://www.dpkk.de/
[2] http://www.northgermantumorbank-crc.de/
[3] http://crip.fraunhofer.de/en/toolbox/
[4] Becker C (2015).

HSR-68 The EORTC SPECTA Program: A Model of Quality Assured Biobanking in Clinical Research

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Background: The EORTC SPECTA (Screening Patients for Efficient Clinical Trial Access) is a standardized, quality assured molecular screening program for tumor characterization, including clinically annotated biobanks with longitudinally collected information, for optimized patient access to therapeutic biomarker-driven clinical trials and new biomarker discovery.

Methods: After informed consent, FFPE tumor material is collected in central biobanks for quality assessment, sample processing for subsequent analysis by next generation sequencing and long term storage. Associated clinical and pathological data is collected at patient entry and during follow-up (every 3 or 6 months, depending on each SPECTA platform). QA/QC criteria is applied all along the process from biobank selection to NGS data reporting. Within SPECTApath(ology), a forum to address biomarker and biological material related transversal issues in all SPECTA, there are two expert working groups. The Biorepository Working Group is responsible for biobank assessment, harmonization of preanalytical procedures and QA/QC in the preanalytical phase, while the Molecular Advisory Board helps with NGS data reporting and monitors QA/QC during sequencing and data processing/interpretation.

Results: Launched in 2013, SPECTAcolor, the first SPECTA platform for colorectal cancer, counts over 850 registered patients and close to 900 centralized samples as of mid-November 2015. 30 samples were rejected due to insufficient quality (tumor cellularity <30%) and less than 1% of the histologically adequate samples failed to yield sufficient amount of DNA for NGS. SPECTA biobanks were successfully evaluated by the EORTC Biobanking self-assessment questionnaire and physical audits. Relevant SOPs from each biobank have been compared toward maximum possible extent of harmonization and biobanks participate in ISBER-endorsed proficiency testing schemes for preanalytical methods (tissue histology and DNA extraction/quantification from FFPE tissue). SPECTAlung (thoracic cancers) was launched in May 2015, and additional platforms for melanoma (SPECTAmel), neurological (SPECTAbrain), prostate (SPECTApros) and rare (SPECTArare) tumors are about to open.

Conclusions: The successful implementation of SPECTA proves that a logistically complex infrastructure including quality controlled HBM collection and management to conduct next generation clinical research in multitumor and multinational settings is feasible.

Repository Automation Technology

RAT-70 Implementation and Management of Biobank Lims Databases System - South Africa National Biobank Experience

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National Biobank in South Africa based in the National Health Laboratory Services, recently implemented the Biobank Lims databases system as an information management tool for effective traceability of biobank specimen. The Lims system was implemented by two processes where first we installed databases and secondly the Lims system after all databases were successfully installed. The aim of the process is to able to do sample tracking, allocation of storage space and improving traceability of samples. The system will trace samples, locate them in freezer shelves according to their categories and then it groups them into rack order number. Equipment required to accommodate Biobank Lims system require enough memory and ram, and processor and hard disk to accommodate all databases together with Lims system.

Installation of Database, Client Set up for database and Lims system an Oracle Standard edition is initially required as first installation, afterwards install Client Set up then lastly install Lims Systems and all installation must be successfully. Problems encountered during installation are errors about account rights not allowing installation for software, and then we solve it by logging into local account using Administrator rights for the system. In conclusion the Lims system was installed successfully and its the best application for Biobank that will work on how to trace samples and backing them up for future records of research studies.

RAT-71 Sample Warming During Innocent Exposures from an LN2 Freezer – Comparing Temperature, Time and Workflow Using Manual vs. Automated Systems

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Background: Storing samples in liquid nitrogen (LN2) vapour phase freezers is very common and performed throughout the biobanking industry. These freezers are chosen primarily because they maintain a sub −150C storage environment and thus, keep the samples below −135C, the glass transition temperature of water (Tg). This cryogenic storage practice preserves sample viability. The concern is what happens to innocent samples (the ones not intended to be thawed) during routine rack exposures. Thousands of innocent samples may be exposed multiple times per day. Constant thawing/freezing through the glass transition phase may cause irreversible sample damage and affect sample functionality when thawed.

Method: Using typical operating procedures with a manual LN2 storage freezer, samples from five different locations are removed from the freezer. During the rack removal, innocent sample temperatures, exposure times and workflow are monitored and later analyzed. The experiment is repeated with the

identical sample removal workflow, but using an automated LN2 storage freezer. Again, multiple innocent sample temperatures, exposure times and workflow are monitored and later analyzed.

Result: The innocent sample temperatures, exposure times and workflows will be compared and contrasted for both manual and automated procedures. Attention will be given to samples that cross Tg during an innocent exposure and further investigated to determine the variables that cause and may prevent it. Based on this experimental evidence, best practices will be recommended to protect Tg when using both manual and automated LN2 freezers.

Conclusion: It is critical that samples stored in LN2 freezers remain safely below Tg at all times, until they are thawed for use. Repeatedly crossing the glass transition temperature may permanently damage sample viability. Manual vs. Automated innocent sample temperatures, exposure times and workflow are compared and contrasted. Best practices are listed for protecting Tg when using both manual and automated LN2 freezers.

RAT-72 Standardized Workflow for Bio-Material Requests

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Background: The exchange of samples from biobank/lab to researcher or from hospital/lab to biobank is traditionally administered through e-mails, fax or telephone. This approach lacks a proper track-and-trace and audit trail of specimens, impeding a fast recovery of lost samples. Within the TraIT (Translational Research IT) project a workflow for requesting and distributing samples was developed. This workflow supports all process steps typically needed in a sample workflow: request of bio-materials from a biobank, evaluation and approval of a request, track and trace of the sample during shipment. Next to this workflow implemented within TraIT, several other Dutch initiatives developed workflows for data or sample request (DNTP, HOVON, GO-NL, Lifelines). All these initiatives now collaborate within the BBMRI-NL 2.0 project where we will compare existing workflows that should lead to a blueprint for a generic sample/data request workflow for biobanks in the Netherlands.

Methods: The Trait workflow tool has been developed in collaboration with CSC using the OpenText BPM platform in a use-case driven approach. The various steps in the workflow are implemented as separate building blocks, and can be customized to the specific needs of any organization or multi-center collaborative network with biobank activities. Through the incorporation of approaches and methods from the other available workflows in The Netherlands we are now working towards an extended generic model for data and sample requests.

Results: The workflow was developed as a cloud-based solution to monitor requesting, dispatching, collecting, and processing bio-specimens from collections under full control of audit trails. Time constraints can be set and attachments can be added at every step in the workflow (e.g. Material Transfer agreements). The tool is now hosted in a production environment (hosted by Vancis) and is actively used in TraIT projects.

Conclusions: A methodized cloud based generic workflow application for requesting, dispatching and collecting bio-materials and data from collections enables the users to work according to a standardized process, improving quality, reliability and accountability. Every process step is logged and location and/or status of the samples can be monitored at any point in the sample exchange process. Phone calls, fax and e-mails, used in the traditional sample logistics workflow, can be eliminated or at least greatly reduced.

RAT-73 Automated Circulating Cell-Free DNA Purification from Large Volume Samples

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Circulating, cell-free DNA (ccfDNA) has emerged as an important tool in the research for biomarkers of health and disease. Because it is highly fragmented, present in small quantities, and highly susceptible to degradation, purification of ccfDNA poses unique challenges to researchers. While plasma is the main focus of many researchers for ccfDNA, recent work has shown that it is present in other biological fluids.

Promega has developed a unique chemistry to selectively purify ccfDNA from plasma. The Promega ccfDNA purification chemistry is a completely automated system that allows purification of ccfDNA from 1ml of plasma. To add flexibility, we adapted the chemistry to automated platforms in 24-well configurations. These platforms include the Hamilton Microlab STAR series and the KingFisher Flex Processor. Because the biomarkers in ccfDNA can be of very low frequency, many researchers prefer to process volumes of samples >1ml which can exceed the capacity of many purification systems. Using a sequential bind strategy, we demonstrate that ccfDNA can be purified from at least 8ml sample draw using a fully automated method. Sample types tested include plasma and urine. DNA quantity was assessed by qPCR using an autosomal target, and quality was assessed using an internal PCR control.

This study shows the flexibility and robustness of the Promega ccfDNA purification chemistry. We successfully adapted it for purification from relatively large volume liquids in a fully automated manner making this a convenient option for early biomarker research.

RAT-74 The Nottingham Health Science Biobank (NHSB) Moving Beyond the Firewall a Strategy for Collaborative Data Management

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Background: Stratification of patients with a defined clinical and molecular phenotype permits greater mechanistic insights which will ultimately lead to individual personalised medicines with targeted diagnostic tests, therapies and optimised intervention outcomes. Realising these benefits requires precise/accurate definition of phenotype by linkage of clinical

data and informative samples sets. Critically this requires flow of information across existing technical and information governance 'firewalls' between partner organisations in hospital, academic and commercial sectors.

Methods: The Nottingham Health Science Biobank (NHSB) sits within the UK National Health Service (NHS). The NHS is a uniquely powerful source of clinical, pathological, imaging and outcome data of enormous value to personalised and translational medicine. The key challenges are to access, order this data and render it discoverable for research purposes whilst rigorously preserving patient anonymity. The NHSB has taken an innovative approach to these challenges by developing the capacity to securely export a 'mirror' of its internal databases beyond the NHS firewall in an automated format.

Results: NHSB have worked in partnership with Interactive Software Ltd. (ISL), the developer of the Achiever NHSB management system, University of Nottingham (UoN) and Nottingham University Hospitals (NUH) ICT teams to set up a new and fully synchronised informatics system hosted by UoN. The infrastructure implemented to deliver the system includes a load balanced network to 4 web front end servers which in turn connect to a backend Microsoft SQL server, which also contains a mirrored partner in a secondary data centre. All sample/clinical data available in the NUH biobank are automatically pushed via a one-way anonymised link to the UoN server, where they can be accessed externally, browsed and sample/data requests raised. The link uses web services that strip any identifiable data from the feed. The UoN synchronised and NUH systems share a single Achiever configuration which permits external researchers to share the full functionality of the NHSB system for their own tissue management and HTA compliance.

Conclusion: This to our knowledge is the first time a Biobank has created a platform for partnership by making its internal directory of biosamples and linked clinical data visible to external PIs and other research staff, and sharing the full functionality of its biobank management systems.

Repository Management

RM-75 Biobanking Partnerships for Sustainable Collections

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Background: There is a gap between the understanding that researchers have about clinic operations, and that of clinicians in what researchers needs are for quality tissue collection. The subsequent creation of silo workflows results in lost opportunities to gather optimal numbers of quality cases, thereby limiting research utility. With a view towards addressing this gap, the OHSU Knight BioLibrary has been developing strategies for partnering across institutional departments, with the goal of enhancing research outcomes and fostering sustainability.

Methods: The BioLibrary has developed models for interdepartmental relationships, with consideration of strategies for analyzing the impact of biobanking activities and enlarging the added value (both financial and non-financial) of these partnerships within OHSU.

These models include working with clinical department chairs and principal investigators to establish Memos of Understanding that outline the responsibilities of each party in patient consenting, tissue collection, and distribution procedures (including any revenue sharing), and instating liaisons across the groups.

Results: By maintaining an interconnected presence in these disparate environments, we have been able to increase donor catchment, collection efficiency and data accuracy. Similarly, there has been an increase in the number of principal investigators that the efforts may support, and generation of value through increased publications, grants and revenues.

Conclusions: Institutions should consider different relationship models for biobanking partners, financial sustainability and profit sharing, and strategies for analyzing the impact of biobanking activities when designing their internal processes, with a view towards bridging gaps between the clinic and research arenas.

RM-76 The Pros and Cons of Moving Towards a Modern Method for the Storage of Blood Samples in a Research Biorepository

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Background: The Australian Prostate Cancer Research Centre-New South Wales (APCRC-NSW) has an established biorepository containing over 49,000 blood derivatives from consented men with localized prostate cancer. The APCRC-NSW currently uses a printer that produces thermo-resistant 1-dimensional (1-D) barcoded labels that are manually attached to the cryovials for cataloguing. This method is ageing and is prone to issues such as label becoming detached and illegible barcodes being printed. This along with single tube scanning makes auditing biospecimen collection labour intensive. We investigated the use of 2-dimensional (2-D) pre-coded cryovials as an alternative to improve labeling, auditing and storage systems.

Aim: To determine the feasibility and cost of using 2-D pre-coded cryovials as an alternative to the use of 1-D thermo-resistant printed labels placed manually on cryovials.

Method: Information was collected on variables including consumables, time spent in processing, data entry and freezer space capacity. A cohort of 300 men, which is part of our biorepository was selected. One off equipment set up cost for the 2-D cryovials (e.g. capper/decapper, box and individual scanner costing >AU$30,000) was excluded and only operational costs assessed in the cost analysis.

Results: The use of 2-D pre-coded cryovials reduced labour costs (AU$39.45/pt Vs AU$45.19/pt, 12.7%), decreased storage costs (AU$5.55 Vs AU$7.46, 25.60%) and increased storage capacity (80,640 Vs 60,000 cryovials, 34.4%) compared to current 1-D labeled cryovials. This is due to thinner size of the 2-D cryovials and the elimination of time spent on the label entry, production and sticking to the cryovials of the 1-D labels and preparation of the cryovials. However, there is a higher consumables cost associated with 2-D pre-coded cryovials (AU$54.33/pt Vs AU$33.46/pt, 62.37%), resulting in AU$15.13/pt more to use the 2-D pre-coded cryovials compared to the conventional labeling.

Conclusion: The use of 2-D pre-coded cryovials is a feasible alternative compared to 1-D thermo-resistant printed labels placed manually on cryovials. However, the cost per patient is substantially higher than the older method even after excluding the significant start-up costs. Larger biorepositories like UK biobank have successfully adopted these technologies. Established and smaller biorepositories will need to carefully consider the potential benefits compared to the significant cost implications.

RM-77 Harnessing Cloud Technology for Biobank Informatics in the Age of Precision Medicine

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A rapid increase in the volume of molecular data being generated from biosamples has resulted in the necessity for appropriate data storage solutions. Precision Medicine Initiative, in particular, is calling for IT systems which permit the collection, storing and sharing of a huge volume of data in protected ways. This requires technical solutions and administrative support that are usually unavailable for small and medium-sized research labs due to limited funds. Hence, they end up in using spreadsheets and lab notebooks for storing and managing data, which are error-prone, making the data difficult to retrieve.

In recent times, the cloud-based technologies are playing an emerging role in streamlining the heavily regulated biobanking operations, specifically in optimizing the way samples from multiple sources are collected, stored, archived, and shared. The cloud has the potential to transform this labor-intensive process into one in which information exchange is efficient, secure, and controlled. With appropriate security measures in place, document-centric processes involving internal and external stakeholders can be centralized, automated, and monitored in the cloud, which greatly improves operational efficiency.

In order to address the challenges faced by small and medium-scale biobanks concerning regulatory compliance, data security, storage space, cost of maintaining the data management system and trained healthcare IT professionals (HCIT) to provide tech support, we have developed BioTracer, a cloud-based data management software. It uses 256-bit AES encryption SSL (HTTPS) protocol, providing secured data transmission between the client and the server. The software is HIPAA and SAS 70 compliant.

RM-78 Biobanking in Primary Care: A Prelimenary Process

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Quebec's healthcare system is focused on the well being of Quebecers and ensuring they receive the best care possible. Innovative health research plays a critical role in not only understanding disease but also unique features within our population and the disease, leading to personalized treatment plans. Primary care (PC) fills a huge gap between the general healthy population and the university teaching hospital in provision of healthcare services. 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. Patients seeking medical care in a primary setting present with symptoms that do not always render towards diagnosis. These characteristics provide a unique population for translational research. Pivotal to translational research are biobanks, in which biospecimens are procured and used in the discovery and development of new drugs in addition to study disease mechanisms and processes. With standardized governance planning, sharing and access policies specific for biobanks, the roadblock to samples/ data have been lifted, leading to not only increased usage of specimens/data but also help build retrospective studies with large cohorts of patients. Having a biobank in PC is key in studying trends, susceptibilities to disease and obtaining population data. With the current reforms in the Quebec primary health care system there is a unique opportunity to integrate a biobank that can be used for prospective and retrospective research that will also advance research in chronic disease, health services and health structures in PC. This project evaluates the benefits of an integrated biobank within Quebec's PC system, its impact on promoting access and sharing of clinical data/biospecimens to the research community and how this will allow for a better understanding of the patient population followed in Quebec's PC setting. In this project, we propose a four steps procedure: explore the benefits and impact of such a program by reviewing literature of existing biobanks in PC worldwide; understand and design a patient flow schematic. This includes evaluating its feasibility through stakeholders and public engagement with a deliberation with stakeholders and the public similar to British Columbia's public deliberation in biobanking in 2007. Finally, we propose a biobank framework and establish a sampling procedure of biobank recruitment.

RM-79 Comparison of the Quantity and Quality of Mononuclear Cells Isolated by the Conventional Density Gradient Centrifugation Method Versus Using SepMate Isolation Tubes for Biobanking Purposes

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Background: Providing high quality biospecimens to researchers while saving cost is important in biobanking practices. Isolation of mononuclear cells is an expensive and time consuming practice. The objective of this study was to compare the quantity and quality of mononuclear cells isolated using the traditional density centrifugation method versus a recently developed method using SepMate isolation tubes.

Methods: We isolated mononuclear cells from blood using the traditional density gradient centrifugation method or SepMate isolation tubes. The mononuclear cell yields were determined manually using a hemocytometer using a Crystal Violet dye and an automated cell counter. Cells were frozen and stored at $-80°C$. Cells were then thawed and the cell yield, recovery, purity and viability were evaluated. Flow cytometric analysis was performed to determine mononuclear composition and viability.

Results: There was no significant difference in the mean mononuclear cell yield obtained with Ficoll and SepMate method ($n=26$, $p=0.7369$). Flow cytometry showed that the two methods were comparable in terms of total lymphocyte yield (Ficoll: $44.6\pm14.3\%$ vs SepMate: $43.6\pm13.6\%$), total CD3+ T-cell yield (Ficoll: $29.0\pm15.5\%$ vs SepMate: $30.3\pm14.3\%$), and within the CD3+ population, the CD4+ T-cell yield (Ficoll: $46.1\pm18.3\%$ vs SepMate: $45.1\pm19.2\%$) and CD8+ T-cell yield (Ficoll: $43.4\pm17.8\%$ vs SepMate: $44.2\pm18.7\%$). Also, the lymphocyte viability from the Ficoll method of ($90.9\pm1.74\%$) was comparable with the SepMate method of ($91.2\pm1.35\%$). After freeze-thaw, the mononuclear cell recovery and purity between the Ficoll and SepMate method were not significantly different (recovery, $n=22$, $p=0.151$; purity, $n=16$, $p=0.5789$). Lastly, we found that using the SepMate tubes was more time efficient and cost effective for isolating mononuclear cells from blood.

Conclusions: We conclude that using SepMate tubes can be a time and cost effective method for the isolation of mononuclear cells for Biobanking purposes.

RM-80 Application Programming Interface for the National Cancer Institute Specimen Resource Locator

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The National Cancer Institute (NCI) Specimen Resource Locator (SRL) (https://specimens.cancer.gov/) is a biospecimen resource database that helps investigators to locate available human tissue specimens needed for research. Currently the SRL has two methods to enter biospecimen collections depending on the amount of data. One method uses a web-based (drop down menu) form that allows a resource to describe its collection. Another method is via a comma-separated values (CSV) file upload, where biospecimen collection information is uploaded by parsing it line by line in the provided file. More recently NCI launched a new open source application programming interface (API) as a third way to easily upload large data sets. The API comprises of instructions and tools for programmatically accessing a web service, such as the SRL. Unlike a user interface, such as the web-based forms, an API operates on a software-to-software level, providing a means for the information collection and retrieval of information between software applications. The SRL API leverages frameworks written in Python to expose its available data structures, allowing outside systems to both read data out of and write data to the SRL database with minimal user interaction. To enter the data into the SRL the biospecimen resources simply need to format it in the Javascript Object Notation (JSON) defined and expected by the SRL API. Once formatted properly, a system may send the JSON message to the SRL API and the API will answer with its own JSON message, informing the outside system of the status of the request. APIs offer several advantageous features including support for high data throughput, consistent and automated data transmissions, and the ability to configure frequent data updates for active biorepositories. An additional advantage of the API is that once the two-way communication is set up, an outside system no longer needs to manually ensure that its data are periodically added and updated, thereby reducing administrative overhead. The system administrator can schedule automatic data additions and updates as often as he or she feels is necessary. With large data sets, the API is a particularly helpful approach for biorepositories that wish to load their data into the SRL database.

RM-81 Assessing Which is the Right Ultra-Low Freezer to Use: An Evaluation of −80°C Ultra-Low Storage Units in the NHLBI Biorepository

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Background: Ultra-Low (UL) freezers that are designed to maintain specimens at −80°C use different technologies for cooling and have different storage configurations (upright or chest). The time to retrieve specimens is dependent on the number of specimens and the number of times a freezer can be accessed before the temperature falls outside of the acceptable range. This time varies between the different UL freezer designs.

Methods: Chest and upright UL freezers that use traditional compressors to cool the unit and were <1 year, 6–8 years and 14–16 years and energy efficient −80°C upright freezers that were <1 year old that used stirling motors or LN2 to cool the UL freezer were evaluated. The cost of ownership for each type of UL freezer was compared. An accessibility assessment was also performed by measuring the elapsed time for the air temperature to increase 15°C when the unit is accessed and the time for the unit to recover after that warming. This was performed on both empty units and full units that contained samples planned for discard. The air temperature was measured at six different points within the storage chamber following our standard freezer mapping protocol. In full freezer assessments the sample temperature was also measured.

Results: There were no significant differences found in the cost of repair and maintenance between upright and chest UL freezers. The operating expense associated with energy efficient models (stirling motor or LN2 cooled), along with the increase in life expectancy and lower repair costs for the LN2 cooled units, offset the increased capital expense. Conventional and stirling upright UL freezers warm >15 times faster than chest units when accessed, limiting the number of samples that can be retrieved from a unit. The LN2 cooled unit did not warm 15°C with an extended door opening (>30 minutes). Recovery time for the conventional upright, chest, and stirling units ranged from 25 to 150 minutes.

Conclusions: The cost of ownership for different types of UL freezers is similar when taken over the full life expectancy of the unit. Labor efficiency associated with accessing samples from UL freezers that maintain temperature longer when accessed and recover quickly is increased. Repositories should take the expected access frequency and associated labor expense into consideration when determining which type of UL freezer is best for their repository.

RM-82 Maximizing Storage Efficiency in the NHLBI Biorepository: Using Technology to Drive Continuous Improvement

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Background: The US NIH National Heart, Lung, and Blood Institute's Biologic Specimen Repository (NHLBI Biorepository) has served as a valuable scientific resource for four decades. The Biorepository acquires specimens from NHLBI funded clinical studies and distributes them online through the NHLBI Biologic Specimen and Data Repositories Information Coordinating Center (BioLINCC) to qualified investigators from all sectors of the life sciences community. Currently, 43 contemporary and historical specimen collections comprised of 3.8 million specimens and their associated data are available at www.biolincc.nhlbi.nih.gov.

The NHLBI Biorepository receives specimens as bulk transfers. Many of the freezer boxes received were not consolidated prior to transfer and had partially filled boxes. In addition, non-consecutive unoccupied spaces occurred as vials were requested and distributed. This has resulted in many locations having occupancy rates of <75%.

Methods: Study specimen profiles were evaluated, including material, vial type and request history to assess potential future utilization. Studies were prioritized based on the activity level for each collection. Reports were then run for each selected study to determine if there were any specimens marked for discard and to determine the size and number of containers with available usable specimen occupancy rates of <25%, <50% and <75%. The cost to consolidate specimens at each occupancy tier was then compared to the cost of storage, based on freezer ownership costs, including costs to run, maintain and replace the units. Collections that had a return on investment (ROI) of <5 years were added to the queue for consolidation.

Results: Over the course of 8 months the NHLBI Biorepository evaluated 35 collections that consisted of 1.8 million biospecimens. Twenty-five studies had ROI <5 years when evaluated at the <75% occupancy threshold and consolidation activities commenced. A total of 1.2 million specimens located in 21,355 storage boxes were consolidated, resulting in a savings of approximately 10.5 freezers' worth of space.

Conclusion: The cost to store an archive biorepository increases over time as the occupancy level of storage containers decrease. ROI tools to evaluate the labor to consolidate versus the cost to store inefficiently packed boxes are an effective mechanism for determining when to consolidate archive collections.

RM-83 Towards a Unified Query Interface for Distributed Biobanks

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Modern digital patient and sample management rely on software systems within biobanks that hold the corresponding metadata. Each biobank contains a manifold of sample data used in different research aspects. Connecting these information repositories and granting access to authorized scientists can significantly enlarge study data. This is especially useful when investigating very specific research topics where samples are rare.

The BB-IT-Boost project aims to implement a system for unified access to distributed data repositories (such as, but not limited to, biobanks). The system will enable users to formulate their research data requirements. These requirements are distributed to on-site search components that will find and aggregate matching sample records and return them to the user.

The main challenge for the described tasks is to query data from the different biobank systems. Due to the lack of approved standards each biobank provides proprietary data structures and interfaces for data access. Therefore the herein presented approach addresses the problem of data harmonization between biobanks. The introduced solution utilizes so called ''attribute mapper'' and ''data modifiers'' that can be applied to specific records selected from the biobanks. The ''attribute mapper'' uses techniques like ontologies or mapping tables to convert domain specific data record attribute names to the standard naming domain (e.g. SPREC or MIABIS). After transferring the data records into the shared naming domain the record itself needs to be harmonized (e.g. to share a common unit across records). This task is handled by the ''data modifiers''. These specific functions must perform tasks from simple unit conversion (like °C to °F) to complex data generation from potentially multiple other attributes of the data record.

To enable the user to aggregate result records even if there are no predefined attribute mappers and data modifiers for his or her use case, our architecture allows the upload of custom data modifiers to the search middleware at the remote data source. This map-reduce-like paradigm of user generated workload execution at the remote endpoint enables sample data processing on-site instead of transferring all information for aggregation back to the query interface. Besides the requirement of preventing reidentification of patients through data aggregation, the architecture must ensure system stability alongside custom query and data modifier submission.

RM-84 Maintaining an Open Scientific Resource of Archival Collections Without Cost Recovery: The NHLBI BioLINCC and Biorepository Tool Chest

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Background: The National Heart, Lung, and Blood Institute's Biologic Specimen Repository (NHLBI Biorepository) was established in 1975 to address emerging blood-safety concerns. Towards the end of the 1990s the scientific value of maintaining archival collections for future scientific research was recognized and the mission was expanded to include NHLBI studies with unique patient populations. Currently, 3.8 million vials from 43 studies are available online to qualified investigators at no cost beyond shipping through the Biologic Specimen and Data Repositories Information Coordinating Center (BioLINCC) www.biolincc.nhlbi.nih.gov.

Funds to support this open scientific resource are limited. As a result, three strategies that leverage BioLINCC IT expertise and biorepository management expertise were applied to efficiently expand and optimize the collections without implementing cost recovery from recipients.

Methods: All new collections undergo a rigorous application process to assess potential scientific utility using an initial

questionnaire followed by a full review of the study documents and data to assess biospecimen quality. Freezer contents were mapped to a vial level and IT tools to visualize box space were developed to integrate vial consolidation and/or reduction into standard workflows. BioLINCC request data on collection use were compiled and a process to assess collections with <5% use established.

Results: The application process provided the necessary framework and quality measures to identify collections with potential scientific utility. Over the past two years, 3 collections were accepted and 3 collections with inadequate data and potential quality issues were not. The costs to consolidate versus maintain were estimated for 35 collections and vials in storage boxes with >25% unused space were flagged for consolidation. BioLINCC reports identified 9 collections with <5% usage over five years and after discussions with the NHLBI and original study members over 500,000 vials were flagged for removal. Approximately 240 cubic feet (10.5 freezers; 4,200 boxes) will be recovered from consolidation efforts and 315 cubic feet (13.75 freezers; 5,500 boxes) will be recovered from reductions. This reduces the number of freezers maintained and improves vial retrieval efficiency.

Conclusions: Identifying key areas and coordinating IT and biorepository management expertise is reducing operating costs and optimizing the scientific utility of a biorepository.

RM-85 Experience of Organizing the First ICMR National Tumour Tissue Repository (INTTR) in India

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Background: INTTR was established in 2005 to store all types of disease as well as normal tissues and components of blood, and distribute the biospecimens to researchers. Standardized methods are used for collection, long term storage, retrieval, and disbursement. Clinical information and follow up record of all patients whose biospecimens are maintained in the biorepository are provided to investigators, whenever required, while protecting confidentiality of data and privacy of specimen donors.

Methods: The process of organizing INTTR was classified into various tasks including operational, administrative, and ethical/legal aspects. Standard operating procedures were established for collection, storage, retrieval, disbursement, and quality control. The biospecimens are collected following an administration of informed consent. Indigenously developed software is being used to anonymize the biospecimens and facilitate storage and retrieval of biospecimens. An online biobank form is developed on intranet to collate clinical and follow up data. Disbursement of tissues is done for institutional review board approved projects through INTTR Technical Authorization Committee. A Material Transfer Agreement is sought for disbursement of biospecimens to non-institutional investigators.

Results: During the period of 10 years from May 2005 to October 2015, a total of 32,176 tissues were collected from various anatomic sites from 26,110 patients following administration of informed consent and 2,223 pairs (Tumour & Normal) were disbursed to investigators for various Institutional review board approved projects. Clinical information was provided as per the investigators' requirement after due validation.

Conclusions: Central tissue repository has many advantages like better control of biospecimens, easy availability of various types of tissues, and an increased opportunity to participate in intramural and extramural research. A repository can be easily implemented in a pathology laboratory. High quality and well annotated biological samples are valuable institutional assets for translational research.

RM-86 A Biobanking Case Study: Advancing Research with an Advanced Medical Informatics Platform

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Technological advancements in sample inventory management, data virtualization, and intelligent visualization platforms, and the growing use of secure cloud data storage offers opportunities to advance the development of personalized therapies. The Indiana Clinical and Translational Sciences Institute (CTSI) partnered with BioStorage Technologies to develop strategies and solutions that enabled the connection and integration of biological sample and research data among disparate research groups for improved sharing across the research enterprise using an advanced medical informatics technology platform.

Learn how the Indiana CTSI has enable improved sharing and optimization of biobank samples and data to advance bioscience discoveries. The Indiana CTSI will present four specific use case examples demonstrating the value of a collaborative informatics approach within an academic medical school, medical care center and research foundation. The case studies will highlight how an advanced medical informatics technology is:

- Enabling researchers to visualize the availability of, and publicizing, specific subsets of samples within a shared database to improve sample asset sharing across the research enterprise.
- Providing researchers with the ability to isolate availability data of different types of tissue and enabling them to match specific tissue samples with bio-macromolecules to support various types of experiments.
- Delivering a centralized data dashboard for querying and reporting sample collections within a multi-center study and enabling researchers to identify if the overall study collection goals are being met, and whether each study center is contributing as planned.
- Producing a visual dashboard for querying and reporting the demographics of normal donor samples collected within a research foundation, including demographic and phenotypic data enabling improved valorization of samples with requesting researchers and organizations.

This case study demonstrates that an advanced medical informatics platform enables the virtualization of biological research sample data. When combined with the development of an advanced visualization dashboard, this platform enables research to be accomplished more efficiently with greater opportunities for sample asset sharing across the research enterprise and with collaborative partners.

RM-87 Utilizing Open-Source Technologies to Save Resources in a Biobank: A Case Study

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Background: As biobanks strive to be sustainable, opportunities to identify cost effective operating solutions become increasingly important. Integration of software components for laboratory and administrative devices can be costly to implement. The philosophy of open-source software (OSS) is that all benefit through shared technology/information. By utilizing OSS and incorporating it into Laboratory Information Management System (LIMS), many integration challenges can be inexpensively solved.

The Cooperative Human Tissue Network Eastern Division (CHTNED) maintains multiple Thermal Labeling Devices (TLD) for label printing at sample collection sites at multiple institutions. Integrating and accessing all TLDs through CHTNED's web based LIMS originally required expensive software licenses that required routine renewal and upgrades. Using 4 pieces of OSS, the CHTNED developed a more cost effective solution that served the original purpose and also provided more functionality than the commercial software license.

Methods: OSS, most of which is licensed under the General Public License, allows the product to be used and modified. CHTNED uses Brady BBP-81 and BBP-11 printers to print biospecimen labels on differing media types (chemical, heat and/or freeze resistant labels). These printers, like many commercial printers use a component language called Zebra as a control language. Using Zebra and OSS components, a TLD service is easily built.

Results: CHTNED developed a mechanism to send print commands from any collection site to any devices through a web based LIMS by combining a series of OSS. A Linux-based server hosts 2 different Java Runtime Engine (JRE) programs. Each JRE has a particular function: the first monitors a MySQL database (open-source data engine) for print requests. When a print request is submitted, the second JRE formats the request for the specific label media being requested. This JRE then uses the Linux-embedded Line Printer Daemon protocol/Line Printer Remote protocol to print raw data directly to the TLD using Internet Protocol.

Conclusion: Through a combination of OSS components, CHTNED developed a printing solution with dual benefits; economizing resources and providing previously unavailable functionality of internet printing. This allows a user to initiate a print request via the internet, including remote location printing capabilities. Open-source technologies can drive process improvement through software and device integration.

RM-88 A Comprehensive Ontology for Biobanking Developed for and with Biobanking Domain Experts

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Background: The field of biobanking, including the concept of informed consent, is in profound need of harmonization for the sharing of specimens and data. Academic medical institutions commonly maintain multiple biobanks created for diverse research needs with numerous data representations developed in silos. These disparities, compounded by variations in informed consent regarding research use of specimens, make it challenging to query for samples across biobanks. Well defined terms are the first step towards integration of data and knowledge management. Ontologies build upon the value of linear data elements by further defining what they are about and the relationships between them, thereby enabling computational processing. The Ontology for Biobanking (OBIB) was built from the Ontology for Biomedical Investigations, the Ontologized Minimum Information About BIobank data Sharing (OMIABIS) and related ontologies following documented design principles. The Informed Consent Ontology (ICO) was similarly developed, and focuses on data elements related to the ethical obligation to adhere to participants' permissions and restrictions regarding use of their specimens. Research has shown that definitions from ontologies do not always rate well with domain experts, highlighting the need for closer collaboration between ontology curators and domain terminology experts regarding definitions and real life applicability.

Methods: The intersection of these vital topics has led to a multi-center research collaboration between several academic research institutions and the Biorepositories and Biospecimen Research Branch (BBRB) of the National Cancer Institute (NCI). The OBIB is being extended to establish a single biobank ontology that encompasses the Lifecycle of the Biospecimen as defined by the NCI. The collaborators will now integrate OBIB with ontologies relevant to informed consent (ICO, d-acts), all of which have been developed based on the same design principles. This will lead to the ability to not only query for specimen types and populations, but also for the participants' consent-status.

Results: First steps of the collaboration has led to further refinement of existing definitions in OBIB and creation of new classes. The existing informed consent ontology (ICO) will be extended to cover Biobanking informed consent terms.

Conclusions: OBIB is developed in an open community-driven effort and is located at https://github.com/biobanking/biobanking.

RM-89 The Coriell Biorepository Collections: Greater than 40 Years of Biobanking Sustainability as an International Resource for the Study of Mendelian Genetic Diseases, Aging, and Neurological Disease

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Coriell Institute has been committed to providing the worldwide scientific community with high-quality, well-characterized

cell cultures, DNA and associated phenotypic and clinical data since 1969. The Institute's founder, Dr. Lewis L. Coriell, M.D., Ph.D., pioneered techniques in the use of the laminar flow hood in cell culture laboratories to provide aseptic conditions and the use of cryogenics as a cellular preservation technique. Coriell Institute has expanded on this legacy of innovation and excellence and has optimized many best practices for the collection, storage, retrieval and distribution of biospecimens.

Coriell is recognized as the world's largest and most diverse biobank, maintaining close to 300,000 unique cell lines representing diagnoses such as autism, Huntington's disease and other neurological disorders, as well as melanoma, diabetes, diseases of aging and inherited genetic disorders. Furthermore, Coriell's broad collections also encompass apparently healthy control samples, which are essential for research studies across all specialties. Coriell has shipped more than 750,000 vials of DNA and close to 200,000 cell lines to 66 countries, and Coriell cell lines have been cited in more than 8,000 peer-reviewed scientific publications.

Through government contracts and grants, and collaborative partnerships with top pharmaceutical and academic organizations, Coriell's financial history reflects its strong and stable financial position. Other funding is derived from support contributed by foundations and other private organizations and from income earned on invested funds. Coriell recently advanced its commitment to human genetic research and human heath by adding a state-of-the art high-throughput genotyping center and continues to expand and modify its custom-designed repository information management system (RIMS) to meet evolving business and scientific requirements and enhance and streamline tracking, documentation, and distribution of biomaterials.

RM-90 B3Africa - Bridging Biobanking and Biomedical Research Across Europe and Africa

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The management of biobank resources require IT infrastructure and the implementation of minimum standards to store, process and share data and information. Such infrastructure is costly to set up and maintain for an emerging biobank. Therefore, new hard- and software solutions will be developed by the B3Africa project to provide an ''out-of-the-box'' informatics tool that can immediately be used under challenging conditions to preserve valuable material and secure related information.

The African continent is home to the greatest genomic diversity on the planet and provide a unique resource of information to advance fundamental understanding of health and disease. With the eB3Kit developed by the B3Africa project we will be able to support a rapidly emerging biobanks in a networked community to support research on the continent. The system is configured to secure data but makes it possible for each biobank to independently decide on what data to share and what data to maintain internally or within a national jurisdiction. Thereby enabling international collaboration but without compromising national law or the independence of researchers using the system.

The system will be based on the ''Biobank in a box'' (BiBBoX) concept developed at the Medical University of Graz. The BiBBoX will integrate the BIKA LIMS, the eBiokit bioinformatics toolset and a novel surveillance system developed at the International Livestock Research Institute in Kenya as well as tools for secure data sharing. Together these tools allow researchers to establish sample collections, track the samples and analyse the data generated from the samples.

The project takes place over 3 years and interested researchers can visit www.b3africa.org to learn more about the project and its outreach program.

RM-91 Building a Centralised, Global, Biological Sample Management Platform in R&D – Challenges and Rewards

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Biological samples and particularly human biological samples (HBS) play a vital role in drug discovery by helping us to build a deeper understanding of human disease processes and their underlying mechanisms, provide earlier and better predictions about the effectiveness and safety of new chemical and biological entities and increase our confidence in developing new effective medicines to treat diseases with current high unmet therapeutic need.

Acquiring samples, assessing quality, archiving them and making them available to researchers within an acceptable timeframe can be challenging. This challenge is magnified due to fluctuating supply demands and through increasing third party interactions with suppliers, external collaborations and contract research organisations.

For coordinated utilization of Biological Samples in our drug discovery process at GSK, a centralised approach drawing on wide expertise can help. Our aim is to streamline this process by forming a group with expertise in biological acquisition and supply, biological archiving and HBS compliance including agreements, consent and ethics approval.

We discuss the challenges of third party sourcing and collaborations, investigate sample storage options and provide an example of addressing the changing needs from our researchers through a flexible approach to sourcing and assessing the suitability of different supply types of blood, including fresh blood, blood cones and leucopacs.

Moving forward, we have a one-stop group to supply all types of biological materials to GSK scientists world-wide, with a single point of contact arranging all ethical and consent requirements, with line of sight to compliance, shipping and storage coordination and supply.

RM-92 Development of a State-Wide Framework for Biobanking in New South Wales, Australia

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Background: A major strategic review into Medical Research in New South Wales (NSW) determined that high quality biobanking is essential for NSW to support excellence in medical research. The NSW Ministry of Health responded with a commitment to support a human biobanking strategy. Funds were allocated via the NSW Health Office of Health and Medical Research (OHMR) to develop a strategy that would rationalise current biobanking activity and ensure that world best practice is followed.

NSW Health Pathology (NSWHP) is the largest provider of diagnostic pathology services in NSW, primarily supporting the public health care system with more than sixty laboratories including those in all major hospitals. As pathology is integral to disease based biobanking OHMR engaged NSWHP to develop a more coordinated service delivery model for biobanking across the State.

Methods: We first identified areas of focus via:

- Analysis of the currently very diverse biobanking landscape
- Measurement of biobanking activities currently performed within NSWHP diagnostic services
- Assessment of current standards
- Engagement with stakeholders and operators of biobanks

Results: We developed the following strategies:

- Stakeholder engagement and governance model
- Build on existing base of well-established well governed biobanks
- Development of mechanisms to improve and standardise quality
- Recommendations on operational methods to streamline current activities
- Identification of priorities and establishment of pilot projects
- Standardisation of documentation e.g. a common consent form; standard MTAs
- Formation of a broad based reference group
- Opportunities to leverage off work undertaken by cancer agencies
- Opportunities to leverage off NSWHP infrastructure and support

From these strategic areas we have:

- Performed an analysis of current operations within NSWHP with recommendations on how to increase efficiencies
- Engaged with the Office of Biobank Education and Research in Canada to develop and deliver a certification program for biobanks in NSW
- Assisted OHMR to develop a standard consent process and documentation
- Led the development of a standard MTA which will be applicable state wide

Conclusions: We have just completed the first year of this three year initiative and have identified additional areas of focus for the coming year(s), in addition to actively following implementation of processes and mechanism identified during this first year.

RM-93 Managing Biological Samples: Moving from Manual to Automated Sample Storage Efficiently and Effectively

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Background: Successfully managing one's growing biorepository manually takes time to sort, catalog and pull samples when required for use, not to mention the possibility of compromising your samples when adding and subtracting samples from storage. With the development of automated sample storage systems, many of these processes can be streamlined to maximize sample integrity, efficiently manage your collection and improve turnaround times when pulling samples. However, the path from manual to automated storage poses some challenges that can be easily addressed by proactive planning.

Methods: Our lab manages 50,000 mononuclear cell samples from cancer patients which grows by 30-50 samples and decreases by 10-20 samples per week due to use. We currently collect all of our cells in 2mL non-barcoded cryovials, labeled with a readable ID and the location of each vial is written down in a 3 ring binder. Although everything is well documented, currently it takes one person approximately one week to find and pull out 20 samples to run an experiment. Our challenge to move toward automation becomes the lack of barcodes on our already stored samples and time required to move sample information from paper into a computer storage program.

Results: Due to space and expenses, we are moving our samples into an automated system in two phases: phase I is our partially automated legacy samples and phase II is our fully automated prospective samples. Since our legacy samples are already frozen and thawing to put into barcoded tubes is not an option, we will move the samples into a barcoded box which can be cataloged on our server and linked with the biobanking system. This will not allow us to do individual picking of samples; however, sample pulling efficiency will be improved. Then, we will begin to change over our collection tubes with individual barcodes for phase II. With barcoded tubes, we will be in position to be fully automated to pick single tubes much more accurately and efficiently than our current system.

Conclusions: Although changing from a manual to automated biobanking system does present some challenges, many of these challenges can be addressed and processes can be designed to implement this change smoothly and efficiently. We look forward to the increased efficiency, ease of sample management, and decrease in human error as well as improved sample integrity that comes with better practices to manage sample storage with an automated system.

RM-94 Biosample Distribution of Cancer Center Biobank

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Subject: To support the basic and clinical research projects by distributing the samples collected between 2006 and

2014 at the Tissue Bank of Fudan University Shanghai Cancer Center.

Methods: Blood and tumor tissue samples were collected for research purpose. All patients signed informed consent forms. Altogether 135,144 samples were collected including 93,375 blood samples and 41,769 tissue samples. After approval of three different authorities, i.e., Department Director, Chief Scientist of Multi-Discipline Treatment Group and Biobank Director, requested samples would be distributed to the sample requesters. Sample types requested included serum, plasma, genomic DNA, as well as RNALater preserved tissue, frozen tissue matched or not matched by normal tissue.

Results: Total 85,615 samples have been accessed for 351 scientific research projects. Most requests focused on WBC/PBMC (34,626) for extracting DNA. DNA extracted from whole blood became a highly requested sample after DNA is extracted ready for aliquoting. Plasma (4,199) and serum (6,436) were also frequently requested for protein and soluble circulating DNA, miRNA studies. For solid tumor sample request preserved in RNALater and the frozen tissue were in dire need (17,057 and 16,260). Scientific findings using theses samples have been published in 884 articles.

Conclusions: Institutional biobank should encourage investigators to use the collection aimed for research and contribute by providing high quality samples and good service in biobank activities.

RM-95 Better, Faster, Cheaper – How a Biobank Can Have All Three on Its Data Using a Data Warehouse

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The collection of specimens in a biobank is far more valuable when accompanied by comprehensive data that describes the collection accurately and fully, and can be shared with researchers as needed.

The Australian Breast Cancer Tissue Bank (ABCTB) tracks its collection using a customised version of Caisis, an open source tool. Caisis provides strong data capture, but requires complicated Structured Query Language (SQL) to extract data. To overcome this, the ABCTB is applying commercial data warehousing techniques to enhance the quality and consistency of its data, and simplify data extraction.

The ABCTB is building a data warehouse, separate from the operational system that houses the specimen collection. This warehouse uses dimensional modelling to create an alternative view of the data, which greatly simplifies grouping and summarizing of data in different ways, and biobank staff can use this without knowledge of the specifics of the Caisis data model or SQL programming. Biobank tasks that have so far been prototyped using this approach include: the identification of specimens matching specific criteria, tracking the collection of follow-up clinical data for patients who comprise the bank's cohort, and confirming that data provided to researchers with samples have been audited against source documents.

Creating the data warehouse provides an opportunity for data cleansing. Data can be manipulated automatically as it is transferred. The format in which individual data fields have been stored can be changed to facilitate more powerful queries and reports. Reference data that are inconsistent in the source system can be made consistent in the data warehouse. Anomalies that cannot be corrected programmatically within the warehouse can be flagged for correction in Caisis. This improves the accuracy of data extracted. Examples where ABCTB is applying this include consistency of immunohistochemistry (IHC) markers for individual specimens, and consistency of clinical information.

In some cases, Caisis configuration can be adjusted to prevent recurrence of errors and anomalies discovered, improving the quality of data captured.

The upfront investment to create this facility is making it possible to extract information that previously required multiple queries and manual processing, with a single, reusable query. Information that previously required manual work can now be derived via real time. The outcome is data of higher quality extracted for less effort.

RM-96 The Need for Biobanking: A Newcomers' Course

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Background: Building up a biobank is challenging since biobanking is a very interdisciplinary field and specific education is rare. Particularly the very first steps in development are fundamental for defining focus and providing a future vision. Hence information, training and know-how transfer is needed from experienced biobanks to newcomers. At the same time, there are few of biobanking courses.

Methods: Biobank Graz has extensive experience in coaching and consulting of emerging biobanks and decided to provide a biobanking course to offer know-how transfer for biobanking newcomers in a structured frame. The course 'How to build a biobank – Learning by doing' was held at Biobank Graz in September 2015. This course delivered the theoretical, practical and hands-on comprehensive knowledge essential to enable the activities of emerging biobanks. It transferred basic best practice principles for all interested individuals working in biobanks. Furthermore, it encouraged principle-based exchange of knowledge and skills crosswise between different biobanking activities involved in biospecimen preservation, storage, handling and research. Amongst others, the main topics were: governance types, services of a biobank, ethics, cost calculation, quality management, sample collection, processing, storage and retrieval, biobank data systems and biobank networking (e.g. BBMRI-ERIC, ESBB, ISBER).

Results: This interactive 3 day course has generated great interest in the biobanking community and was fully booked within short time. 20 participants from 8 countries attended the first biobanking course at Biobank Graz.

To evaluate this course, the participants were asked to anonymously fill in a questionnaire. The feedback was very positive and was graded 1.19 on average (1 = excellent, 4 = insufficient). In detail, the theoretical part (trainers, lectures, structure of the lectures) was graded with 1.19 on average. The evaluation of the practical part (hands-on training, guided tour) averaged 1.22.

Conclusions: The consistent positive feedback from course participants and the further demand for education – already numerous biobanking newcomers are on the waiting list – encouraged Biobank Graz to plan the next course, which will take place November 23rd–25th, 2016.

RM-97 The First Postgraduate Master Study in Biobanking Offered as Distance Learning Course in English

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Background: The number of projects using biobank samples for research is increasing constantly. At the same time, requirements on quality of biobanking samples are increasing because of the growing spectrum of potential methods for different analyses and applications. The further development of biobanking processes depends on a deeper understanding of biobanking processes, to keep quality of biobank resources up-to-date with research. Hence, there is an essential and demanding requirement for training of experts in the field of biobanking, e.g. of well-structured postgraduate training programs.

Methods: An overview of biobanking education opportunities has shown that currently only three such Master courses are offered: (1) 'Management and Biobanking' at the Catholic University of Lyon in French, (2) 'Master en biobancos UCV' at the Catholic University of Valencia in Spanish and (3) 'Research Biobanking' at the King's College in London in English. As all three courses are offered as a classic study course with regular attendance, we decided to design a master course in biobanking in English as a distance learning course.

Results: The master distance learning course 'Biobanking' should be completed within four semesters (90 ECTS Credits) and the curriculum is comprised of 14 modules. The goal of this course is to acquire knowledge, experience and practical skills which will qualify for the work in the multidisciplinary field of biobanking. Therefore, knowledge and skills that will be educated include areas such as (1) organisation of a biobank, (2) implementation of a biobank in the health care system and in existing research infrastructures, (3) critical view on research questions, (4) representing a local biobank in national and international networks, and others.

Conclusion: The extensive growth of biobanks requires training of highly qualified personnel in the field of biobanking and different disciplines linked to it. To meet this developmental needs this postgraduate master distance learning course will educate in knowledge and practical know-how on organisation, management, infrastructure and emerging challenges in biobanking.

RM-98 Analysis of Economic Cost and Technical Criteria to Include Samples of Hematopoietic Precursors Not Valid for Clinical Use in a Biobank to Research Use

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Background: Numerous hematopoietic progenitors' units (HP units) are discarded for clinical use because the transplant for which they were collected wasn't carried out. Due to the enormous value and potential interest of these samples, the SSPA (Andalusian Public Health System) Biobank did recover them for their possible use in research. With this purpose we evaluate the viability of hematopoietic cells; most of them were long-term stored and validate the preservation process and the best final storage format for its possible splitting and final distribution.

Methods: We first analyzed the initial viability of cells after thawing and then we studied the effect of the preservation process on freezing and defreezing recovery and viability under different conditions: DMSO concentration (7% or 10 %) and the freezing method (freezing ramps with refrigerant containers at −80°C or programmable freezers equipment with liquid nitrogen). Finally, we analyzed the economic costs of the different process.

Results: We observe an average viability of 70% after hematopoietic cells initial thawing, so the samples would be suitable for research purposes. Regarding the preservation process we did not observe any difference related to cell viability between the DMSO concentrations and freezing methods. However, we find differences in the economic cost associated with each of these methods of freezing, resulting cheaper the preservation method with refrigerant containers at −80°C.

Conclusions: PH units discarded for clinical use can be splitted and derived for research applications. Furthermore, the technical and economic analysis of the different processes indicates that the best method is a freezing ramp with refrigerant containers at −80C and a 7–10% of DMSO, only due to economic reasons, since no technical differences are observed.

RM-99 Is an Expiration Date Useful for Biobanks?

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Background: The use of biospecimens and respective data from biobanks enables cost-effective and fast retrospective studies. At the same time, it enables prospective studies with high quality samples following standardized processes and work flows for handling and storage. However, access to long-term funding for biobanks is rare and strategies to recover costs of data and sample processing and retrieval are emerging.

Methods: The diversity of biobanks is enormous. Many biobanks pursue prospective collections based on multiple projects. A considerable number of biobanks collects samples population-based, storing samples almost without any limitation in terms of time for retrospective and epidemiological studies. Accordingly, it is unknown if and when a biobank will spend all the biospecimens for biomedical research. So far, an expiration date for a biobank has not been discussed. However, what are the costs for closure of a biobank?

Results: The following questions were addressed: (1) What kind of existent funding can support the sustainability of a biobank? (2) Is long-term funding possible? (3) Has a biobank to be able to recover all costs itself? (4) Does an expiration date according to the period of funding make sense? (5) How much would it cost to terminate a biobank?

As an example, Biobank Graz was investigated. Analysis of national and international funding acquisition for Biobank Graz was performed by the publicly available Boston-Consulting-Group Analysis and a Strengths-Weakness-Opportunities and Threats Analysis. Costs for processing and storage of biospecimens were calculated by a transparent cost calculation for academic and non-academic researchers. Costs for termination and sample destruction of a biobank were calculated as well.

Conclusions: As Biobank Graz includes a disease-specific and a population-based collection it is not possible to plan an expiration date without losing a large number of epidemiological data. However, there are no long-term funding options

and the total recovery of costs seems difficult in light of the aim to provide researchers high-quality samples/data for their projects independent of acquisition of third-party funds. Costs for a shutdown of Biobank Graz were estimated to be about €700,000 without reconstructing of infrastructure and premises for use by another institution. For clinical biobanks a long-term funding and cost recovery strategy seems to be necessary for sustainable operation.

RM-100 Biobank in Diagnostic Laboratories: A Model for Translational Research

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Background: The new challenge for Diagnostic Laboratories (DL) is to serve as a bridge between the clinic and the research, through the organization of a systematic biorepository. The Clinical Cancer Pathology Unit and the Pathology Department of CRO Aviano National Cancer Institute accepted this challenge demonstrating the feasibility of the management of an institutional biobank.

Methods: CRO-Biobank is a structured facility aimed at collecting human biological samples for cancer research purposes. Tissue and blood samples are collected from patients affected by different cancer pathologies before and during treatments. The preparation of samples in a certified DL implies the standardization of the method of collection, processing and storage, and is therefore a guarantee of quality, homogeneity and stability of samples. All procedures have been implemented in accordance to ISBER guidelines; we also implemented Quality Control procedures, mainly concerning timing and method to obtain optimal freezing, prevention of hot and cold tissue ischemia and accuracy in the embedding process.

Samples and personal data are managed by a software which is integrated with an external registry platform, allowing to safeguard the privacy upon encoding of the patient's personal data. The storage room is provided with a fingerprint recognition system to protect the access, and with a wireless temperature monitoring system which records the temperature of freezers during years.

We designed a multisource informed consent system for patients' enrolment, which allowed a high rate of understanding and awareness of study participation (<95%). This system relies, among others, of a dedicated biobank nurse who collects patients information and give information to patients.

Results: During the first 9 years of activity, DL collected and prepared more than 70.000 samples to be stored by the CRO-Biobank. Part of these samples has been collected ''on demand'', i.e. based on specific needs of requesting researchers. A Steering Committee for the evaluation of samples requests was established. We also drafted a Material Transfer Agreement to regulate the transfer of banked samples.

Conclusions: The creation of an institutional biobank coordinated by DL, has allowed to systematically collect a large series of biological samples from the Structures of the Cancer Center. Therefore it represents a quality service that plays a fundamental role in improving cancer research.

RM-101 Increasing Efficiency of Rare Diseases Biobanks via Risk Management Tools

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Background: The Genetic Biobank BIOGEN, born in 2008 at the Medical Genetics Department of Istituto Ortopedico Rizzoli, aims to develop and strengthen high-quality research in rare skeletal disease; to date, it stores more than 5000 biospecimens (DNAs, RNAs, blood samples and derivates, tissues).

Risk Management is a governance tool that aims to avoid (or reduce) the occurrence of adverse factors that oppose the achievement of the proposed objectives.

Due to the lack of specific regulations on the risk biobanks, BIOGEN performed a comprehensive risk assessment through:

- Identification of risk factors and risk sources
- Risk Reduction
- Ongoing monitoring

Methods: Many methods have been identified as useful tools for work supervision. For BIOGEN we have identified two useful systems:

- a voluntary reporting of undesirable events based on the error-tracking system of Incident Reporting (IR) - that includes adverse events and near-miss - and Non Conformities (NC). This system estimate all collected IR/NC and their risk level evaluated in terms of probability and severity, to then identify improvement actions.
- the 'Failure mode and effect analysis/Failure mode and effect criticality analysis' (FMEA/FMECA): a predictive technique for a proactive risk analysis in order to prevent potential errors/incidents before they happen.

Results: BIOGEN applied an integrated risk management system, which aims to promptly detect – with a spontaneous reporting form - risk situations or incidents and then introduce corrective actions for preventing their recurrence. Moreover, in order to trace and monitoring the entire sample process – from the collection to the final storage – including also all relative data, a BIOGEN-dedicated interdisciplinary working group (WG) was established. This WG precisely mapped all biobanking processes (flows and activities) and performed a FMEA/FMECA analysis, identifying the customized assessment scales of detectability, probability and severity for failure mode analysis in the BIOGEN scenario.

Conclusions: The IR registration and FMEA/FMECA analysis allowed us to identify all risks related to the BIOGEN management, prioritize and carry out the corrective actions and improvements, thus obtaining a risk reduction. In our experience, the continuous monitoring of process activities ensures a high quality management of samples with the ultimate purpose to improve the research, the diagnosis and the treatment of these diseases.

RM-102 Improving Laboratory Workflow, Records Management and Sample Tracking in the eyeGENE® Biorepository

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Background: The CLIA-certified eyeGENE® Laboratory receives whole blood from participants with certain inherited eye conditions, isolates DNA, stores blood and DNA, ships DNA to clinical genetic testing and research laboratories, and performs a short tandem repeat-based quality assurance and quality control (QA/QC) procedure on the original blood and its derived DNA. Until recently, these operations were managed manually using a combination of paper and custom computer systems which were time-consuming and error-prone. To improve laboratory workflow, records management and sample tracking, the eyeGENE® Biorepository chose to customize a web-based commercial laboratory information management system (LIMS), Sampleminded Laboratory System.

Methods: The eyeGENE® and Sampleminded teams worked together to analyze the eyeGENE® Biorepository's processes. This analysis led to the development of LIMS requirements and an overall project plan. Using eyeGENE® standard operating procedures as a guide, existing Sampleminded Laboratory System tools were configured and new tools were developed as necessary to meet the eyeGENE® LIMS requirements. Iterations of releases were tested by the eyeGENE® team and corrections and improvements were made before launching the live system.

Results: Sample receiving, processing, storage, QA/QC, retrieval and distribution are now being managed by the customized LIMS. This system has increased the efficiency of the eyeGENE® Laboratory workflow by approximately 40%. Using a robust barcode scanning system, the LIMS has improved sample tracking and automated chain of custody by recording the location and annotating data from each workflow event for every sample in the biorepository. Additionally, a reduction in manual data entry combined with the LIMS double entry requirements and data validity checks have improved data quality. Paper records have been dramatically reduced and completely eliminated for most procedures.

Conclusions: Developing and maintaining records management and computer-based sample tracking systems are best practices for all repositories. With thoughtfully drafted requirements, adequate time and optimized communication between the repository and LIMS development teams, adherence to these recommendations can be accomplished with a customized commercial LIMS. This method has proven effective in improving efficiency, productivity and quality in the eyeGENE® Biorepository and serves as an example for other repositories.

RM-104 Selecting and Configuring a Web-Based Application to Manage Data and Specimen Requests Across Multiple Epidemiological Studies

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Background: Since 1994, we have managed data and specimen requests for studies conducted by the National Institute of Environmental Health Sciences' Epidemiology Branch (NIEHS EB). Over the last two decades, more than 5 million biological samples have been collected from 70 studies, along with anthropometric, clinical, environmental, and questionnaire data. As investigator and collaborator requests for specific data and sample sets have increased for these studies, so too have the challenges associated with fulfilling requests in an efficient and effective manner. We anticipate additional challenges as more studies begin to make their resources available to scientists outside of the institute. The purpose of this presentation is to describe our experience selecting and configuring a commercially available, web-based application to standardize and automate the management and fulfillment of requests.

Methods: Requirements for the application were developed by a multi-disciplinary team that included project managers, data managers, and laboratory staff. The team first reviewed similar applications used by other federal research groups, as well as the features of the applications and the ways in they were configured and utilized. Based on this review some of the key application requirements for the NIEHS site included: compliance with federal security/accessibility requirements; features that allow for sharing study protocol, manuals, questionnaires, and codebooks and up-to-date information about data and sample resources; workflow features to control submission and approval of requests and tracking of fulfillment statuses; and capability to post datasets for retrieval in an access-controlled environment within the application.

Results: After an extensive review process, we selected Information Management Systems, Inc.; (Rockville, MD) to configure an existing application currently in use by other institutes within the National Institutes of Health. The NIEHS website is tentatively named ''BioShare''. The configuration phase of the project took 6 months to complete. Following final review and approval by the NIEHS EB, we plan to launch a pilot version of the application in the spring of 2016 and to assess the extent to which the current configuration reduces the time and effort required to fulfill requests.

RM-105 PANDORA© 2.0: A Customized, Flexible Data Management System for Efficient Biobanking in an Academic Hospital Setting

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Biobanks play a crucial role in translational research. Likewise, providing high-quality biospecimens with appropriate clinical annotation in a timely and efficient fashion requires a reliable data management solution.

As part of our ongoing childhood leukemia genomics research program, we have been recruiting childhood acute lymphoblastic leukemia patients since 1994. Until recently, an in-house database called PANDORA was used to store specimen-related information, including sample collection details, patient demographics and clinical data. With the advent of high-throughput technologies, the sheer size of projects has grown exponentially. To cope with information growth, we developed PANDORA© 2.0, an innovative biobank software system based on Drupal, a flexible open source content management system. While the platform itself solves most of the implementation details, all the biobank-specific requirements are met by extending the core system capabilities through the addition of custom modules. Consequently, we developed the PANDORA Suite, a collection of four major components that, together, provide our biobank staff with many of the key functionalities offered by other commercial off-the-shelf products: 1) entity management (including patient consent forms); 2) specimen/inventory tracking; 3) clinical data integration; and 4) highly customizable

querying/reporting. Additionally, we extended Drupal's built-in system of permissions to limit content access, and we modeled complex access rules based on user roles and patient consents to enforce security of confidential data. Drupal contributed modules were also integrated to fulfill other non-functional requirements such as usability and performance.

As of now, our biobank houses over 9,300 biospecimens from 750 patients, 900 parents and 600 healthy control individuals, and leverages research in pediatric oncology, bone marrow transplantation, personalized medicine and immunotherapy. All data and patient information relating to these cohorts are efficiently managed by our customized system using appropriate security measures. PANDORA© 2.0 is an invaluable tool for promoting translational research in an academic hospital setting and provides the ultimate combination of functionality and flexibility to meet the research community's needs.

RM-106 RD-Connect/EuroBiobank/BBMRI-ERIC: Tackling Rare Diseases Together

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RD-Connect is a six-year EU project that joins researchers across the world to develop an integrated research platform in which complete clinical profiles are combined with -omics data and sample availability for Rare Diseases (RD) research, in particular research funded under the IRDiRC.

EuroBioBank is a European biobank network supporting research on RD by facilitating access to quality human biological resources (DNA, cells and tissues) and their associated data from patients with RD. EuroBioBank is a key resource in RD-Connect in view of the integration between biobanks and registries and contributing to the development of legal and regulatory frameworks in rare disease biobanking.

BBMRI-ERIC, one of the largest Health Research Infrastructure in Europe, is establishing, operating, and developing a pan-European distributed research infrastructure of biobanks and biomolecular resources that will facilitate the access to biological resources as well as biomedical facilities and support high-quality biomolecular and medical research.

The RD-Connect/EuroBioBank/BBMRI-ERIC strategic collaboration will produce an effective use of resources and guarantee sustainability of projects such as RD-Connect and EuroBioBank. The produced services, tools, bioresources and knowledge will be maintained, forward developed and made available to the biobanking and research communities by the BBMRI-ERIC infrastructure. At the same time, BBMRI-ERIC would build a solid ground for RD research biobanking in Europe.

The key collaboration areas related to the IT domain are: cataloguing bioresources (biobank, sample collections, samples), sample request workflows and harmonized biobank data representation by using a common semantic: Minimum Information About Biobank data Sharing (MIABIS 2.0).

As a result, RD-Connect counts on a Biobank Catalogue (ID-Card) populated with RD biobanks and sample collections willing to share their samples and a Sample Catalogue where researchers can search for samples in the biobanks. The produced software and data would be transferred to BBMRI-ERIC along with the technology and experience gain in the project. For instance, the sample catalogue is developed using the Molgenis platform that shares code with BBMRI-NL, CTMM TraIT. The ID-Card code is already reused by the BBMRI-ERIC Directory. Both software use MIABIS 2.0 as the basic semantic for modeling the data.

RM-107 Legacy Data Migration and Workflow Redesign Increase Operational Efficiency and Data Utilization in the Biorepository

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Background: The Cohorts Biorepository currently houses biospecimens and data from large study cohorts dating back as far as 30 years. With close to 3 million specimens in inventory matched to participant level data, these collections represent an irreplaceable resource for cutting edge biomarker and genomic studies in relation to risk of multiple chronic diseases. The biorepository currently is meeting the challenges of updating systems while maintaining support for scientific aims.

Methods: The predominant challenge faced by the biorepository is the modernization of legacy inventory management systems. After nearly 30 years of continuous use, migration of inventory data to a modern system is a source of risk for loss of data and operational functionality. To mitigate this risk, planning and testing for data migration and physical inventory verification are being employed. Preparation of legacy records for migration includes a logic check and issue resolution of 23 unique data points for each participant and specimen. Additionally, definitions of participant subgroups are being established to provide greater definition within the 250,000 participants within the repository. Post migration data is quality controlled on both data structure and user interface levels to ensure complete capture of legacy information.

Results: Project management and risk mitigation approaches were used for inventory verification and transfer to modern recordation systems. Employment of workflow analysis, issues tracking, and strategic operational planning were used to mitigate risks to operational flow and data loss. To date, over 300,000 records have been migrated for use in newly established workflows. On-going and new collections have been established with the new recordation system exclusively, and are adding hundreds of new records weekly.

Conclusions: Operational challenges incurred in modernization of cohort biorepository systems can be mitigated by evaluation, planning, and quality monitoring plans. Utilization of relational database models for biospecimen inventory and meta data management result in greater ease of use, transparency, and data sharing among biospecimen users and collaborators.

RM-108 Implementing Best Practises in Transferring of Large Scale Banked Specimen to National Biobank in South Africa

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A good systematic management system is needed to ensure the transfer of over 500,000 specimen to the National Biobank. Biobank best practices must be applied in order to preserve the integrity, cold chain and value of biospecimen. The National Biobank encompasses components of multiple biobanks such as blood, genetics, histology and cytology specimens. Biobank received large number of specimen from researchers, pharmaceuticals' industry and the government laboratories. Project planning for transfer of 500,000 specimen in 3 months was required. Cold chain and specimen integrity had to be maintained by planning transport, thermometers, dry ice and shipping manifestos. Each sample had to be tracked at all times and it is essential to record every minute of transportation stage and temperature. During transportation the temperatures increase and dry ice is used to ensure the transporting temperatures are below −40 degrees Celsius using calibrated mobile thermometers. This successful large scale biobank project had challenges and successes that kept specimen data and integrity intact.

RM-109 MIABIS Connect: Biobank Federation Through MIABIS 2.0

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Biobanks use informatics management systems as LIMS for managing biological samples. Nevertheless, samples that could be available for research are not often visible to the biomedical research community not only due to ethical and regulatory constraints, but also because there is not a standard software tool that allows biobanks exposing their resources without requiring a time-consuming process or economical investment.

On the other hand, BBMRI-ERIC has developed the MIABIS 2.0 (Minimum Information about Biobank data Sharing), which is its de facto standard for sharing biobank data. MIABIS has been widely accepted by other biobank networks and research projects as BCNet, BiobankCloud, BioMedBridges and RD-Connect.

MIABIS Connect federation framework is a solution to the difficulty of searching for the most valuable bio-resource in biobanks: the sample. The main function of this software is to create federations of biobanks using MIABIS 2.0 as central semantics. The main features of this software are:

- Open-source software framework that can be easily adopted by the biobank and research communities.
- Allows biobanks keeping their idiosyncratic semantics and at the same time be able to share data using MIABIS 2.0 semantic. The harmonization process is data model agnostic.
- Biobank data stays in the biobank. Only the results of queries are fetched from the biobanks to be viewed through the common web query interface.
- Requires a minimum involvement of biobank staff or IT support in order to deploy and maintain the federation framework.
- A flexible and very friendly web client allows researcher all over the word search for samples in all the biobanks participating in the federation.
- We will present MIABIS 2.0, the BBMRI-ERIC de facto standard for biobank data sharing and MIABIS Connect, the federation framework that allows to share sample data using MIABIS 2.0 as central semantic to represent biobank data.

RM-110 Going Beyond Data Virtualization: Advancing Sample Intelligence Through a Transformational Informatics Platform

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Due to the growth in personalized medicine and translational research, the demand for integrated biological sample inventory and research data has never been greater. Research organizations are in need of flexible data integration solutions to improve the global visibility and optimization of biological sample assets. This poster will show examples of the process and journey taken to achieve optimal utilization and identification of the best biological samples for future research.

Learn more about how a major biopharmaceutical company worked with a leading genomic academic center to integrate and connect sample bioprocessing and inventory data within a central global database. Understand how this advanced technology solution supported the identification of the best biological samples for conducting future genomic research.

Discover how a leading medical academic research institution integrated clinical R&D, EHR, EDC, donor and biological sample data across the research enterprise. Gain an understanding on how an advanced and customized visualization platform was built to support researchers and internal biobank service personnel in accelerating access to and optimizing sample research assets.

Understand the journey, process and considerations taken in each scenario to build a centralized transformational technology solution and learn how to apply this knowledge to your research organization.

RM-111 Resources for the Research Community from the NIH's Genotype-Tissue Expression (GTEx) Program: Normal Biospecimens, Data, and SOPs

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Background: The Genotype-Tissue Expression (GTEx) program is a National Institutes of Health (NIH) Common Fund study which examines the relationship between human genotype and gene expression in multiple tissue types of non-diseased individuals.

Methods: Normal tissues were collected from nearly 1,000 postmortem donors and genomic analysis was performed on all tissues with the resulting data deposited into the database of Genotypes and Phenotypes (dbGaP) at NIH. Additional information imported into dbGaP for each donor includes clinical and genotype data, pathology review and gene expression data from each tissue, and data from expression quantitative trait loci (eQTLs). Biospecimens were obtained with the consent of donor families through partnerships with Organ Procurement Organizations. Researchers are encouraged to apply for access to utilize residual GTEx biospecimens. A new, open access GTEx histological image library is available. No software is required, and images can be viewed with zooming capability. Lastly, the GTEx program developed and has made publicly available the Standard Operating Procedures (SOPs) detailing the collection infrastructure.

Results: Public resources available from GTEx include:

1. GTEx Portal: an open access database of GTEx expression data and analysis results: http://www.gtexportal.org
2. Access to residual GTEx biospecimens: http://www.gtexportal.org/home/samplesPage
3. dbGaP: controlled access of comprehensive GTEx clinical and raw sequencing data: http://www.ncbi.nlm.nih.gov/gap
4. SOPs from GTEx biospecimen collections: http://biospecimens.cancer.gov/resources/sops/library.asp
5. GTEx histological image viewer: http://biospecimens.cancer.gov/resources/tissue_image_library.asp
6. GTEx donors' families: a lay description of the GTEx project tailored to the GTEx donors' families: http://www.genome.gov/gtex
7. Various manuscripts detailing the GTEx program available through PubMed

Conclusions: Data from GTEx is already being used in numerous projects to better understand predisposition to disease, with several high profile studies already published. The breadth of the program has afforded multiple, varied public resources from biospecimens to molecular analyses datasets to standardized operational documents. The full potential of GTEx resources has yet to be determined; however, based on results thus far, there is confidence that these resources will be useful tools for biospecimen-related science immediately, and in future years.

RM-112 Roadmap to Selecting a Biorepository Information Management System (BIMS)

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Background: The Houston Methodist Research Institute Biorepository (HMRI) is a centralized biorepository at the Houston Methodist Hospital System (HMHS) which is a non-profit healthcare organization. The system has a network of community based hospitals and is academically affiliated to Weill Cornell Medical College. The HMRI Biorepository has been collecting varied human biomaterials for last ten years, with data on excel sheets. It has been decided to upgrade the biorepository by acquiring a robust Information Management System.

Methods: A thorough review of available biorepository information management systems was undertaken. Seven vendors were identified based on general system requirements for a LIMS/biorepository management software. A committee consisting of Biorepository Director, Biorepository Manager, Director IT Development, Clinician Informaticist, Director EHR System Implementation and an IT Staff was formed. A Request for Information was sent to seven vendors. All seven responded. RFIs were assessed based on institutional requirements, federal regulations and ISBER checklist, and the 3 fulfilling most of these were selected for further review. The three had previous experience of implementing biorepository information management system at academic medical center/s and interfacing with electronic health records system similar to the upcoming one at HMHS. The three vendors presented an onsite 90 min. demo which included an overview of the system and connected scenarios encompassing specimen workflow in the biorepository. The evaluation committee was joined by a senior physician/former CMIO, and a member from the institution's Research Protection Office for these presentations. Request for Proposal was then generated for the top two vendors asking for detailed proposal plan, including resources, estimated cost of the system, implementation timelines and client references. Technical knowledge of presenting staff, functionality of the system, backend IT specifics in sync with HMHS' current applied technology were some of the features that committee members looked at. Proposed costs were considered to an extent. Client reference calls, with a pre-set questionnaire, were made to the top two vendor client sites. Site visit/s are next on agenda.

Results: The selection process is in its final stages.

Conclusion: The above roadmap presents a comprehensive, yet practical approach, to similar biobanks planning to embark on purchasing a BIMS.

RM-113 Collaborative Models for Specimen Repositories: The Creation of Metadata Linkages That Reflect the Presence, Use and Application of Biospecimen Repository Inventories in Research

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Introduction: This presentation contributes to an ongoing debate over how to best identify, define and share biomedical specimen information maintained in repositories. The collection of biomedical information represents an increasingly important element of research for both the biological and social sciences. Many repositories increasingly collect not just biospecimens, but information about these materials and their research use. Evidencing the growing importance of specimens and biomarker information is the growing research literature that uses this information within a multidisciplinary framework. What remains lacking is a commonly accepted way to define, identify and centralize information on biomedical materials, test results and inventories.

Methods: The presentation will discuss an organizational framework initiated as part of the NACDA Program on Aging at the University of Michigan that establishes metadata standards that can describe specimens, assign universal tracking IDs and link the specimens to publications and research use.

Results: The state of best practices for identifying, cataloguing and sharing information on the presence of biospecimens and biomarkers in archives and repositories remain decentralized. Currently numerous databases and methods catalogue the existence of biospecimen inventories, data records and publications that report analysis of biospecimen data but these are rarely linked to the BioRepository of origin. This is a concern as BioRepositories do not receive due credit a source of research generation. Emerging tools can help organize these independent sources of information into an integrated resource for BioRepositories and its users.

Conclusions: Our goal is to create systematic definitions that classify biomedical information in the public domain. The potential for integrated systems clearly exists. Examples such as the SWAN biorepository at the University of Michigan show that this process is already being done for individual research projects. New metadata management tools being developed at NACDA show how this process can be extended to multiple collections, housed and maintained at independent sites. The creation of information resources that reflect not only the presence of biospecimens, but their use and contri-

butions to science offers great promise for the future. It requires a multidisciplinary approach but it will ultimately add considerable marginal value collections in biospecimen repositories.

RM-114 Retrospective Modelling to Build Biobank System at Universitas Gadjah Mada, Indonesia

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Background: To start a biobank system, Faculty of Medicine UGM used retrospective cancer samples collected in one −80°C freezer started from the year 2000 until 2014.

Method: Retrospective modelling was done from March-October 2015. The process followed was: Determining inclusion criteria; physical identification of samples and its principle investigator (PI); requesting demographic and parallel samples information to PI in excel format. Further, we built an in-house web-based database. A 12-digit barcode for tube identifier, box and rack position were determined automatically by database based on inclusion to database, type of samples, type of analyte, and physical position in the freezer, based on data provided from spreadsheet.

Results: All samples were included in the format of tissue, buffycoat, whole blood, and epithelial exfoliates. Five PIs comprising 8 different studies were agreed to be included. Information sent back was then inputted based on determined position of sample tubes in 9x9 box format. Application web-based made using code igniter framework and Mysql programming system. Further, data was loaded from spreadsheet to the database format, that automatically assigned 12 unique identifier, and labelled onto tubes printed using ID barcode. In the end, 12,298 tubes were inputted. They belong to 8 studies, comprised of nasopharyngeal carcinoma, breast cancer and acute myeloid leukemia. We documented the process in retrospective SOPs as requested by GCLP applied in the institute.

Conclusion: Retrospective system was successfully done. Prospective samples collection will be started in 2016 by considering: the use of direct database without the use of spreadsheet. SOP for standardized method for samples collection, intermediate storage and transportation to the biobank will be provided for researchers.

RM-115 The Challenge of Capital Faced by the Establishment and Continuous Operation of Multicenter Biological Specimen Banks–Case Study of Nanjing Multicenter Biological Specimen Bank

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Biological Specimen Banks (hereafter referred to as Biobank) that can provide high-quality biological samples serve as a foundation for research on translational medicine. However, the continuous operation of Biobanks still face the major challenge of capital.

We tried to establish a high-quality Biobank and keep it operational in China's economic environment. The maximum value of Biobank lies in the specimen itself together with the quality and integrity of information, while the cost of these resources is also the most expensive. On the premise of ensuring the quality, the cost is saved to the maximum extent. We set up a Biobank in the pathology department of a large hospital in an administrative way. There are three purposes, including: 1. the fluency of Biobank work can be guaranteed to the greatest extent by integrating their work, thereby ensuring the quality of Biobank; 2. Integrated information and richer and complete specimen can be conveniently obtained; 3. Clinicians in general hospitals are both providers and demanders of specimen. By sharing and cooperating with them, the costs of obtaining resources can be minimized. In this mode, we store samples respectively, carry out centralized management of information, and set up a multicenter Biological Specimen Bank under one standard operating procedures.

The key to recovering the cost is to balance the quality and quantity of specimen and information. In the early establishment, the cost of infrastructure, human resources, specimen acquirement, information system and quality control of samples accounts for 44.9%,20.5%,18.5%,11.5% and 4.6% of the total costs respectively. Later, after three to five years of rapid development of specimens, the annual cost invested into the Biobank is 31.1% of total cost in early construction period, when the sample number and quality of Biobank can basically satisfy over 90% of the applications. Later on, the Biobank enters a cycle of stable operation, where the annual cost is 12% of the total cost in early construction period. The cost of human resources, energy, information system, specimen acquirement and quality control of samples accounts for 41%, 40.3%, 9.3%, 8.2% and 0.61% of the total costs respectively. In this mode, our Biobank can be operated sustainably. Although the cost cannot be recovered completely, a large amount of cost for repeated construction and human resources can be saved, which is conducive to the overall development.

RM-116 Biospecimen Repository Administration Graduate Certificate Online Program at Arizona State University

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The collection, storage and distribution of high quality biospecimens is seminal to the success of translational research and precision medicine. Biorepository administrators are tasked with overseeing operations that meet the qualitative and quantitative needs of current and future research modalities – specimens that exhibit molecular integrity, clinical relevance, and are collected according to ethical standards and biobanking industry guidelines. To meet the demand of specialized knowledge across different biospecimen disciplines, the Clinical Research Management Programs at the College of Nursing and Healthcare Innovation at Arizona State University created the Biospecimen Repository Administration Certificate program. The academic certificate is focused on the business oversight of biospecimen repositories and provides a basic understanding of biopreservation science and technology; biospecimen and data management; and the ethical, social, and legal regulations and guidelines in biobanking. Clinical research professionals benefit by learning more about biorepository science and technology, while lab technologists benefit by learning more about human subject protection regulations and trial management. The program offers the following courses: (1) The Foundations in Biospecimen Administration: This in-

troductory class is offered as an elective to a variety of undergraduate and graduate students to complement their knowledge in biospecimen repository science and potentially create a long-term interest in the biobanking field. (2) Management of Biospecimen Repository Operations: This course examines the biospecimen repository industry from an operational perspective. (3) Biospecimen Resource and Technology Management: This course is instrumental to the planning and selection of technology and resources for the support of the start-up and long-term maintenance of a biospecimen repository. (4) Regulation and Ethics in Biospecimen Repository Administration: This course examines the biospecimen repository industry from an ethical and regulatory perspective. Students learn the ethical and consenting challenges of biospecimen collection, storage, and disbursement. (5) Scientific Innovation and Biospecimen Repository Administration: The course examines tracking pre-analytical variables, adequate preservation, and storage methods. https://asuonline.asu.edu/online-degree-programs/certificates/graduate-certificate-biospecimen-repository-administration

RM-117 The Study of How to Make Best Practices in Bio-Bank in China

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After years of study on how to maximize the function of biobank, we realized that there are many factors we may make better in order to present best practices in biobank. We summarized couple of important aspects to improve the performance of biobank in China. First: improvement of quality control and specimen collection. It is well-known that the quality of tissue specimens can be detected by testing integrity of DNA, RNA, HE staining. However, that is not enough. There are always factors to affect the quality of specimens but these tissues have more meaningful to clinical applied study. For example, the situation of preoperative chemo or radio-therapy may decrease the cell counts significantly and make tissue fibrotic. We should recognize the difference from each collection, and use them accordingly. Second: establishment of information sharing network, and the needs of software for managing specimen international wide. Establish a network based intra-hospital virtual cancer biobank in a single hospital or institute is very important. It allows different users to share information without time delay or confusion. In the process of building this network, the whole community reached an agreement to follow the best practices of biobanking and accept minimum standards for data sharing. This infrastructure design for a virtual biobank network, which integrates information the patient, will result in a broader virtual network for data and even specimen exchanges, to expedite clinical and basic investigations in the future. Third: the standard operating procedure on bio-specimen is essential. Human error can hardly be avoided. Automation allows for quicker and repeatable processing. It helps reduce the risk of human error. Therefore, by following above recommendations, the performance of biobank has significant improvement in the past practices. We recommend above suggestions in the future establishment of biobanks.

RM-118 Integrating Tissue Microarray and Laser Capture Microdissection into Biorepository for Biomedical Research

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Background: An important need of many biomedical research projects is the availability of human tissue biospecimens. Biorepository is an entity that collects, processes, stores, and distributes biospecimens and relevant data for use in basic, translational, and clinical research. In order to accurately identify and define the biologically important processes in actual pathologic lesions and validate the protein expression pattern, it is essential to analyze the pure specific cells isolated from tissue biospecimens by laser capture microdissection (LCM) and assess molecular targets rapidly and simultaneously by tissue microarray (TMA).

Methods: LCM was used to isolate pure tumor cells from cancer tissues including Hodgkin's lymphoma tissue. Sanger sequencing was used to detect DNA mutations in microdissected tumor cells. TMAs were constructed using multiple cancer tissues. Protein expression patterns were further analyzed on cancer TMA slides using immunohistochemistry.

Results: ATR gene mutations were successfully detected in microdissected Hodgkin's lymphoma cells but not in the whole tissue samples. TMA slides were subsequently used to validate the ATR protein expression.

Conclusions: Our results demonstrated that LCM can reduce heterogeneity within tissue. TMA allows rapid and simultaneous assessment of molecular targets in large sets of cancer tissue specimens. Integrating LCM and TMA into biorepository has opened ways to identify and validate biomarkers to facilitate biomedical research. Together they will provide even greater potential for disease investigation and facilitate the rapid translation of molecular discoveries to clinical application.

RM-119 A Novel Approach Towards Identity Management and Pseudonymization Service

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Background: Modern research infrastructures require the protection of the research subjects' privacy. At the same time researchers have to rely on the comprehensive and correct linkage of the data that their research is based on. The basis of a reliable data protection system is the use of de-identifying methods such as pseudonymization or anonymization. Research data is generally being pseudonymized to enable enrichment of the sample data with clinical information. In order to allow linkage of multiple identifiers associated with the same individual an identity management system is indispensable.

Methods: We have developed a pseudonymization service using a two-stage pseudonymization method. The first stage is based on an algorithm which deterministically codes any incoming ID into a stage-1 pseudonym. In order to manage identical IDs coming from different sources or from the same source but relating to different items IDs are expanded with tags identifiying sources and types of IDs. In a secured table the coded ID is mapped to an unique identifier. Stage-1 pseudonyms pertaining to the same object are mapped on the same

unique identifier. In a subsequent step a unique random number is generated and translated into a 10 character string using a 21 character alphabet thus allowing more than 1013 combinations. For validity checks a checksum is added to the string as an 11th character. The resulting identifier is mapped to the unique identifier from stage-1 in a further secured table. Both mapping tables are protected and only accessible for an external trustee service who safeguards data protection according to the data protection law.

Results: The pseudonymization service is sufficiently powerful to serve up to 10 pseudonymization requests per millisecond. The service is scalable and provisions have been taken that performance does not degrade with management of an increasing number of IDs. The multi-pseudonym management can take any kind and length of identifier supplied and handle overlapping ID ranges In addition the system can automatically link IDs for the same object in different contexts.

The identity management combined with a powerful and flexible pseudonymization service covers the needs of a local research infrastructure adhering to the data protection regulations. However, the design of the service and its ID-type and ID-context concepts makes it ready to be used even in a networked, i.e. multi-centric research infrastructure.

RM-120 Sample Management of Research Study Collections in the Biospecimen Repository and Processing Laboratory at the Lunenfeld Tanenbaum Research Institute

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Background: The Biospecimen Repository and Processing Laboratory processes, stores, and distributes human biospecimen collections from research studies that are both internal and external to the Lunenfeld Tanenbaum Research Institute. Since 1997, we have provided biospecimen processing services to over 30 research studies, processed over 120,000 specimens, and have banked over 780,000 samples.

Information: Research study groups must collect biospecimens for specific research purposes to meet the research goals for which grant funding has been obtained. The sample collection, REB, and consent are managed by the Research Study Group, and the sample processing and storage are managed by our facility.

Understanding the research goals of each study is the first step to providing quality biospecimen processing services. A thorough review of the participant population, collection schedule, biospecimen type, and testing algorithm with the research study manager will help facilitate successful downstream biospecimen processing, management, storage, and distribution.

Processing and storing biospecimens in a laboratory that operates exclusively to provide these services ensures quality by standardizing biospecimen management with respect to data capture, processing, storage, and distribution. Parameters around these activities will be outlined.

Due to the diverse nature of the various collections, we have developed different cost models to help meet the budget constraints of both large and small collections. Having multiple models has allowed us to maintain core staff and accommodate fluctuation in demand. Considerations regarding labour, consumables, operation, and overhead will be described.

RM-121 A Novel Consent and Collection Process for Use of Remnant Clinical Specimens in Research at a Large Academic Medical Center

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Background: Utilizing patient remnant specimens for research not only makes efficient use of valuable resources, it can be done at a scale that is unmatched by prospective invasive collections performed solely for research. As such, the consent process for remnant specimens is typically far simpler than the alternative. It has been our goal to develop an enterprise wide remnant collection infrastructure for research, with a consent process that is acceptable to conservative institutional review boards (IRBs). In the next sections we describe these efforts thus far.

Methods: We will collect remnant specimen aliquots (e.g., blood, body fluids, and tissues) for research use from patients who have ''opted-in'' to the Cedars-Sinai biobank during the admissions process. We will retrieve these aliquots from our pathology clinical laboratories and attach a custom clinical data set to each specimen and anonymize them prior to distribution to researchers.

Results: We worked with our IRB to develop a simple one page opt-in consent that will be administered as an electronic form during the admissions process and allows patients to accept or reject participation. The opt-in consent also allows for distribution of remnant specimens for research to commercial companies. Aliquots of remnant specimens will be collected within 24 hrs after analysis in order to preserve biochemical intactness. Specimens will be labeled with barcoded biobank IDs and tracked into our OnCore® Forte database (HIPAA approved for specimen management). Stored specimens will be annotated with custom clinical data in a separate internal database linked to OnCore®. Desired specimens will be identified based on laboratory values, or other clinical parameters via a ''real-time'' database copy of our EMR (EPIC®). A limited extracted custom dataset will be associated with the biobank ID for each stored specimen. Specimens and data will be permanently anonymized prior to distribution.

Conclusions: The remnant consent structure described is one that can withstand rigorous IRB review, while also allowing access to the most patient specimens via incorporation into the admissions process. Trained personnel for daily specimen retrieval on a large scale must be accounted for and implemented. Annotation with appropriate clinical data is the final key as this will determine the extent and usefulness of research that may be performed. We have accounted for all these parameters to ensure a successful remnant biobank.

Repository Standards

RS-122 Qatar Biobank: One Year Post ISO 9001 and ISO 27001 Certification Experience

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Background: Qatar Biobank is a large-scale, long-term medical research initiative for the population of Qatar.

Methods: The process of implementation of ISO 9001 and ISO 27001 standards has greatly enriched the knowledge of the staff in terms of quality performance and continual improvement. A) Improving Internal Process and Procedures, B) Improving Product/Service Quality, C) Improving Customer Satisfaction and D) Improving Performance Measures.

Results: Inventory Checklists to monitor consumables; Clinic & Laboratory Procedures and Quality Manual were developed and implemented, to streamline interdepartmental as well as intradepartmental processes. Equipment checklists to track service contracts, breakdowns were created. Various working instructions and checklists for Clinical and Laboratory equipment were created after thoroughly reading the operator's manual. Calibration and verification criteria were discussed with manufacturer and this enhanced the technical knowledge of end users. ISO raised the importance of obtaining intense technical and maintenance training by manufacturer service engineers to assure quality results, and this has now become part of QBB routine training activity. Validation methodology were developed for Freezers, Blood pressure and BMI instruments, to assure excellence in output. Qatar Biobank is a customer driven center and ISO 9001 raised awareness of value of customer satisfaction. QBB enhanced its feedback and complaint processes thus enabling QBB to positively reach to its customers, both the participants as well as researchers. Performance measures were developed and closely monitored by the management. Key Performance Indicators (KPI) helped achieve targets and this increased the commitment of staff.

In Quarter 1 it was found that all CAPA were closed within target completion date, however in Quarter 2 only 20% was completed. This led to further investigation which increased awareness among QBB external vendors, e.g. Replacement of defected blood tubes. Maintain zero customer/participant complaint level with regard to service was one of the Key Performance Indicators (KPI), with a target of less than 5% of the number of participants per Quarter.

RS-123 Participation of SSPA Biobank in IBBL Biospecimen Proficiency Testing Program: A Global Report

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Background: The biospecimen Proficiency Testing (PT) program provided by the Integrated Biobank of Luxembourg (IBBL) and endorsed by the International Society for Environmental and Biological Repositories (ISBER) offers multiple benefits to biobanks: methods validation, results comparing with other laboratories, testing problems identification, accreditation requirements compliance, biobank credibility. The SSPA (Andalusian Public Health System) Biobank selected this PT program in 2012 as a tool for evaluating its procedures and has increased progressively its inscription in different inter-laboratory testing and processing schemes.

Methods: Reported results for each scheme along the editions were analyzed. Results different to ''very satisfactory'' were classified in specific internal errors, improvement opportunities and scheme participation review. A global report was elaborated.

Results: The SSPA Biobank participated in 4 from 5 available schemes in 2012 and 2013, 5 from 8 in 2014, and 9 from 12 in 2015. In 2012, an improvement opportunity was identified for the Tissue Histology scheme obtaining in 2013 a ''very satisfactory''. In 2014 several specific internal errors were detected in different schemes and corrective actions are in progress. 2015 results will be the consequence of corrective actions established. Additionally, participation in new schemes during 2015 will allow us validation of RNA extraction from FFPE cells and PBMC extraction methods. Participation review in DNA extraction from whole blood scheme based in 2013, 2014 and 2015 results is being analyzed.

Conclusions: PT program participation allows us to evaluate our procedures and to validate new selected methods. Visibility of certificates in our facilities support the services offered by the SSPA Biobank. Improvement opportunities identified and corrective actions initiated from obtained results have allowed the best participation in next editions. Besides of the benefits showed, new necessities are identified and will be discussed.

RS-124 A Biospecimen Proficiency Testing Program for Biobank Accreditation: 4 Years of Experience

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Background: Biobanks produce and distribute biospecimens, ensuring their fitness-for-purpose and accurately qualifying them before distribution. In their efforts towards professionalization, biobanks can seek certification or accreditation. One of the requirements of accreditation standards is regular participation in Proficiency Testing (PT) programs.

Method: An international PT program has been developed and provided to biobank- and other laboratories that utilize biospecimens to assess their performance for specific tests that can be applied to qualify different types of biospecimens. This PT program includes biospecimen testing schemes, and biospecimen processing inter-laboratory exercises.

Results: The ISBER biorepository PT program was first implemented in 2011 and has been provided every year since. The number of implemented schemes has increased from 2 in 2011 to 7 in 2014 and the number of participants has also constantly increased over the years. Performance analytics

demonstrate that laboratories regularly participating in PT programs improve their performance over time. These observations show that PT programs represent a very important component of a laboratory's quality management system and a valuable tool supporting biobank certification/accreditation.

Conclusion: The ISBER PT program supports biobank certification and accreditation by providing the means to assess biobank laboratory performance and by providing useful insights into biobank laboratory method performance characteristics. In the future, as more and novel biospecimen quality control assays are developed, the PT program will progressively implement corresponding schemes to support them.

RS-125 A Simple and Cost-Effective Method for Cold-Chain Monitoring During Transport and Handling of Deep-Frozen Samples

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Background: Continuous monitoring of the environmental conditions is fundamental to maintain sample quality. While the temperature of a container or the ambience of the sample can easily be monitored by electrical devices, the actual temperature of individual sample tubes may significantly differ due to nonuniform cooling. Particularly, when low or ultra-low temperatures are to be maintained, measurement of the ambient temperature is insufficient. During the handling of frozen samples the sample temperature can only by estimated or inferred from general assumptions. We aimed at developing a straightforward and cheap method enabling the control of cold chain maintenance during transport and handling of deep-frozen samples and the validation of sample handling workflows.

Method: Temperature changes are detected by the melting of probes with a distinct melting point. As temperature probes ethanol/water mixtures of defined composition and safe substances with appropriate melting points are used. The substances are filled in the appropriate sample tubes and shock frozen in liquid nitrogen. The detection of sample melting is achieved by placing a miniature metal ball on the frozen test solution. During melting of the sample the ball sinks in the sample. The distance the ball travels down is proportional to the time the sample experienced warming above the melting point. The melting temperatures were validated with probes equipped with calibrated micro sensors.

Conclusions: The probes were exposed to different conditions and monitored by recording a video. The distance the metal ball traveled was determined from the video stills. The observed melting of the probes perfectly correlated with the temperatures recorded. The method was used to investigate the temperature change of frozen samples ($-80°C$) when exposed to $-20°C$ or $20°C$. A workflow for registration and consolidation of frozen samples on SBS racks as well as the transport of frozen samples on dry ice were validated with this method.

The method described is cost-effective, easily implemented, and calibrated. As the authentic sample format is used the method reflects the actual temperature effects and can also indicate temperature dependency on the sample position on a rack or in a sample container. In addition, the probes contain only safe chemicals and can be recycled repeatedly. The temperature probes presented here allow for an immediate detection of deviations from according guidelines.

RS-126 Method for Evaluation of the Tightness of Cryo Tubes and Leakage from Cryo Tubes

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Background: During temperature changes, repeated screwing and unscrewing or longterm storage cryo tubes may become leaky. We sought for a method to detect and quantify cryo tube leakage under changing conditions.

Method: As a measure for the loss or gain of substance in the sample tube we used the concentration of a dye solution. Upon evaporation of solvent the concentration, thus the optical density should increase; if water vapor would condense in the tube the concentration should decrease, consequently reducing the optical density. Water and water/iso-propanol were used as solvents to mimic different volatilities. To correct for concentration effects on volatility three different dye concentrations were chosen, ranging from .3 to .01 mM. The test solutions were pipetted into four sets of cryo tubes for storage at $20°C$, $-20°C$, $-80°C$ and $-160°C$. The tubes were either kept at the respective storage temperature or subjected to up to five freeze-thaw cycles. The effect of repeated screwing/unscrewing was investigated with cryo tubes which had been screwed and unscrewed for up to 50 times with a automated decapper, filled with the test solution as mentioned and then stored at room temperature for up to 3 months.

Results: No significant loss of solvent from the test tubes could be observed. It appears that the loss of volatile solvent only occurred during opening of the tubes. In some cases a gain of solvent could be detected which most probably resulted from condensation of water in the sample tube. Multiple un-/screwing cycles did not show any immediate effects.

Conclusion: The method described is easily implemented and the data can be recorded and analyzed with standard laboratory equipment with reasonable precision.

Our pilot experiments indicate that no immediate loss of sample material from cryo tubes occurs, even under frequent temperature changes and with a volatile solvent. Multiple screwing/unscrewing as well had no immediate effect. However, long term experiments are necessary to verify these observations.

RS-127 The National Cancer Institute's Biospecimen Research Database: A Biobanking Resource to Improve Biospecimen Quality

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Standard operating procedures (SOPs) used for human biospecimen collection, processing and storage can vary greatly across institutions, and this absence of harmonization can confound analytical comparisons across sample sets. In an effort to minimize preanalytical variability and improve the quality of biospecimens used for research, the National Cancer Institute's Biorepositories and Biospecimen Research Branch (BBRB) developed the Biospecimen Research Database (BRD; http://biospecimens.cancer.gov/brd). The BRD is a free and publically accessible online database that aims to (i) improve

access to peer-reviewed articles that investigate the impacts that biospecimen collection and handling practices can have on clinical, molecular, and proteomic endpoints, (ii) facilitate transparency between institutions and researchers by promoting SOP sharing and distribution, and (iii) improve the quality of biospecimens through the development of evidence-based procedural guidelines. The BRD currently houses more than 2,300 articles that are meticulously categorized and annotated by a team of Ph.D.-level scientists to highlight the type of biospecimen and technology platform used and the preanalytical factors investigated. Literature contained within the BRD serves as the foundation for internally developed reviewed papers as well as evidence-based procedural guidelines, termed Biospecimen Evidence-Based Practices, that focus on biospecimen collection, preservation, and processing. The BRD's SOP library presently accommodates more than 200 SOPs from 32 participating institutions. SOP topics include preacquisition preparations; biospecimen acquisition, processing, preervation, shipment, storage, analyte extraction; as well as assay-specific methods. Approximately 80% of these SOPs were provided by non-profit, private, and international biobanks and biorepositories. BBRB has invested a substantial and continued level of effort in the establishment of this scientifically accurate and robust database. Contributions from the biobanking community in the form of article suggestions and SOP submission are greatly appreciated and can be submitted directly through the website or via email to biospecimens@mail.nih.gov.

RS-128 The Creation of the World's First Whole-Genome Reference Material to Ensure DNA Testing Accuracy

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With advancements in precision medicine there is an increased need to have accurate genetic results and standardizing the ever changing technology of genome sequencing is becoming critical. Previously, large collections of well-characterized DNA samples have not been readily available to clinical laboratories sequencing patient genomes and to researchers studying complex human diseases.

In May of 2015, through an initiative spearheaded by the Genome in a Bottle Consortium, an academic trust co-organized by the National Institute of Standards and Technology and the U.S. Food and Drug Administration, the first DNA standard was released to the public. It is now possible for investigators to verify their results against a reference value of a well-characterized DNA sample. The DNA was isolated from an NIGMS HGCR human lymphoblastiod cell line and was homogenized in a large batch with rigorous quality control.

Over 100 samples have been distributed to researchers thus far, and the release generated sizeable industry and scientific interest and was featured in the New York Times and by other news organizations. Coriell's high quality biobanking program and their expertise in the area of precision medicine combined with NIST's commitment to standards development create a unique collaboration that can facilitate the availability of more reference samples in the future. Coriell has provided NIST with additional samples for use as genetic reference material that will be available in the future including samples from an Ashkenazi Father-Mother-Son trio and from the son from the Asian (Han Chinese) Father.

RS-129 Quality Control and Reporting Practices in an Australian Cancer Biobank Cohort

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Background: Inadequate quality of research biospecimens may adversely impact research translation to clinical practice. Despite the development and endorsement of external quality control (QC) programs and biospecimen quality reporting tools, there has been little examination of relevant biobank practices.

Methods: An online survey was designed to describe the use and communication of biospecimen QC measures by an Australian cancer biobank cohort (n = 21), classified according to access policy. Survey questions examined the development and maintenance of Standard Operating Procedures (SOPs), biospecimen QC activities, and the communication of biospecimen quality results to researchers.

Results: Over three quarters of biobanks utilised regularly-reviewed, best-practice-referenced SOPs, and the majority of biobanks undertook at least one form of biospecimen QC analysis. Whereas all open-access biobanks (n = 11) utilised SOPs, practised biospecimen QC, confirmed diagnoses using histological techniques, and performed database audits, these practices were significantly less frequent in restricted-access biobanks (n = 10). There were overall low rates of recording the SPREC code, with increased but incomplete recording of Tier 1 BRISQ data. Open-access biobanks were significantly more likely to provide biospecimen QC results to researchers, and to also report receiving queries from researchers regarding biospecimen quality.

Conclusions: Improved biobank resourcing and staff education may both be required to boost current levels of biospecimen QC and reporting by cancer biobanks.

RS-130 How the Spanish Biobanks Work with Peripheral Blood Mononuclear Cells: An Overview

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Biobanks conform to the highest standards and provide researchers with samples of consistently high quality. The Spanish Hematic Derivatives Group (SHDG) was established in 2011 in the context of the Spanish National Network of Biobanks (www.redbiobancos.es). The SHDG consists of 26 biobanks. In this article, we show how the Spanish biobanks work to provide material for comparative multicenter studies, to avoid possible inter- and intra-biobanks assay variability in the analysis of isolated fresh samples and to develop the best strategy to freeze and to thaw peripheral blood mononuclear cells (PBMC) in order to retain biological viability and functionality in their responses, especially in the processes between their cryopreservation and shipment. We present an overview of Spanish biobanks, which work with PBMC. We also analyzed the Functional Standard Operating Procedure (SOP) established as safety measures for collecting, processing and

storing PBMC, emphasizing the fact that the viability of thawed cells in all the Spanish biobanks was higher than 70%, which indicates consistent proliferative T cell responses. Finally, we show how we have applied the SOP to all the Spanish biobanks than work with PBMC through theoretical and practical courses.

RS-131 COSTS OF QUALITY: Analysis of the Effectiveness of Quality Control in the "Collection Samples Kits"

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Background: The participation of Public Health System Biobank of Andalusia (BBSSPA) as central and co-coordinating Biobank in charge of sample collection and management of multicenter projects is progressively increasing. Besides, number and complexity of the collection processes is also rising, more patients and higher diversity and number of samples per patient. A proper preparation of the collection kits as well as the adequate instructions for sample collection will ensure a more adequate sample testing and analysis.

Biobank activity involves sample's collection, including the organization of paths for donor's recruitment, processing, preservation and intermediate and final packaging and transportation. A delicate piece of this phase of recruitment is the design and its of "collection samples kits" to centers.

The objective of this work is to perform a comparative analysis of the cost of implementing new quality control in the last phase of implementation of recruitment plans: information and materials for donors and procurement and the complete preparation of "collection samples kits", against the cost of the corrective measures to be applied after possible incidents may arise. Hence a quality control technician was dedicated to review all kits produced before being shipped.

Methods: Two major projects of sampling conducted in the BBSSPA one at a regional level (670 kits distributed to all Andalusia) and one at European level (1225 kits distributed to 9 countries) have been evaluated taking into account the following items:

- Transport costs from the Biobank destiny
- Fungible costs because of the incidents detected
- Kits costs for incidence correction (fungible and transportation of new kits)
- Cost of consumables kits made
- Cost of Quality Technician dedicated to check kits before departure.

Results: The results show the incidents detected in the preparation of the "collection kits", 9% in the regional project and 6% in the European project, and of course cost savings by providing quality controls facing the costs without quality, 5% in the regional project and 3% in the European project.

Conclusions: Quality controls performed to collection samples kits helped to:

Identify defective kits, anticipating more serious incidents, such as the need of kit's its, as well as kit recipient.

Significantly reduce the costs in the first and often forgotten phase of kit's preparation.

RS-132 Quality Assessment of the Preanalytical Workflow in Liquid Biobanking: Amino Acids as Potential Markers for Pre-Centrifugation Delay

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Background: It is well known that large sample collections, clinically well-characterized, quality controlled and readily available, are an indispensable prerequisite for successful development of novel diagnostic and therapeutic tools in the field of personalized medicine. Process variations, as a source of error, must be considered carefully when interpreting the impact of inter-individual differences on the effectiveness of personalized medicine. The development of a quality assurance and quality control concept for biobanking might help in this regard to ensure as great a degree of consistency as is achievable. However, evidenced based quality markers addressing the majority of relevant preanalytical variations are still lacking.

Methods: To investigate whether changes in amino acid concentrations might be indicative for pre-centrifugation delay in serum and plasma samples, blood was drawn from 28 healthy volunteers and kept at RT for 30, 60, 120 and 240 min. After centrifugation samples where aliquoted and stored at −80°C until analysis. Amino acid where quantified by using either LC-MS/MS or a Biochrom 30+ amino acid analyzer.

Results: We observed significant time-dependent changes of several amino acids in serum as well as in plasma samples. Taking into account the high inter-individual variability of amino acids we decided to use amino acid ratios rather than single cut-off values for monitoring time to centrifugation. Preliminary results suggest that the ratio of ornithine/arginine as well as the serum-plasma difference of taurine will allow for discrimination of samples with different pre-centrifugation delays.

Conclusions: Time dependent changes in amino acid concentrations might be useful as quality indicators for monitoring of pre-centrifugation delay. However, due to the small samples size and the fact that we have used samples from healthy volunteers, results have to be validated e.g. by analysing well-characterized blinded specimens from patients with several common diseases with known processing history. Studies are under way for application of the proposed quality indicators in a larger set of samples collected in a multicenter clinical trial.

RS-133 Use of the ULT Transport in Biorepository Processing to Reduce Thermal Excursions

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Background: As the efficacy of cell based therapies has improved, demand exists for greater controls for processing of materials while maintaining cryogenic temperatures. Standard cell products are contained inside cryoboxes stored in LN2 vapor-phase freezers at temperatures below −150°C to preserve their viability. Many publications have shown that cells preserved and maintained below the glass transition (Tg) temperature show highly reduced degradation and metabolic ac-

tivity. However, when vials are transferred from their storage environment of the LN2 freezer for inventorying, characterization, or label manipulation, the vials experience thermal excursions with warm-up rates of several degrees per second potentially impacting the quality of the cellular material by unintentionally crossing the Tg.

Through use of the ULT Transporter developed by Biocision, we were able to perform a variety of common biorepository activities while maintaining the environmental conditions of the vials below the Tg while at the bench.

Methods: Standard fiberboard cryoboxes containing eighty-one 1.8ml cryovials filled with a salt solution to mimic the heat capacitance of whole blood, were precooled to −170°C in a standard LN2 storage environment. Select vials contained an embedded thermocouple for temperature sensing during the experiment. Data was captured using a Fluke 2638A Hydra Series III capturing at 1 second intervals. Vials were transferred within a closed cryobox to reduce thermal impact due to convection. Once in the ULT Transport product, the vials underwent standard scanning, delabeling and relabeling activities, and visual characterization.

Results: The vials experienced a net elevation in temperature of 16°C during the processing occurring over a 3 minute period per vial. The maximum temperature reached was −153°C well within the Tg threshold demonstrating successful stabilization of the processing environment through use of the ULT Transporter.

RS-134 Careful Management Helps to Improve the Value of Sample

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Bio-specimen quality has become the main indicators of biobank. Quality not only refers to the biomaterial specimen itself, but also including all production procedures of biological samples. Compared with the quality control, quality design and quality supervision is more important. Because biosamples are precious, there are some difficulties in getting samples. Moreover, the study found that biological samples since in vitro, many factors will affect its quality. What are the key factors? How to obtain these key factors? Our team study set of access. We have designed form files through in the flow of the sample link. First, when establishing disease depots, there is a need to fill in an application form including diseases and sample type, as well as clinical follow up plan. Then, each sample there is a need to fill in the registration form, record type of sample, collect time and handling time, storage temperature, sample transportation temperature, cold ischemia time, fixation time onal. This information helps sample library managers to judge its value and determine whether the sample will be used. So, we believe careful management methods can help improve the value of a sample, as well as help with future quality control.

Biobank Education Tools

BET-136 Creating Successful Training Programs for Repository Technicians

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Background: The ability to effectively train repository staff to fulfill required roles and responsibilities is essential to ensure the availability of high quality specimens for research. Training should include safety, laboratory operations, personnel, and project management as well as other repository-related activities. The Certified Repository Technician (CRT) Task Force was established by the ISBER Education and Training Committee to develop a series of educational modules for the training and eventual certification of entry-level biorepository technicians.

Methods: Biorepository mission fulfillment and successful operation begins with careful explanation of tasks to be performed by staff. Failure to effectively train staff can impact the quality and suitability of specimens for use in research efforts. Effective training begins with a thorough understanding of the tasks to be performed. A successful training program includes documentation to ensure that tasks are well described, suitability of the trainee to the tasks being performed, suitability of personnel conducting the training, overview of the task, observing the procedure (task), performing the procedure while supervised, recognizing and communicating problems when they arise, planned and unplanned deviations, periodic evaluation, cross training, and balancing consistency and productivity with quality. A series of training modules and exams were developed, tested and evaluated by a group of experts in the field of biospecimen banking management for the ISBER CRT Workshops. These modules were audited and improved utilizing ISBER's Best Practices for Biorepositories.

Results: Two of the ISBER CRT modules, Selecting the Best Storage Environments for Biospecimens and Process Improvement in Repositories, were presented as workshops during the 15th Annual ISBER Meeting and Exhibits. Surveys completed at the conclusion of the two workshops indicated that the modules were well-attended and received.

Conclusion: The collaboration among ISBER Members from various biospecimen banking backgrounds allowed for the development of modules which are widely applicable and appealing to a broad audience of repository personnel. The work of the CRT Task Force demonstrates the ability to build upon a shared interest in promoting consistent, high quality standards, ethical principles and innovation across the global biospecimen banking community with a common goal; biospecimen-related education.

BET-137 An Educational Video Showing How to Use the CoBRA Guideline

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Background: Standardized and retrievable citation of bioresources is paramount for the recognition of the work needed for setting and maintaining them. Here we present an educational video to help researchers and biobankers to correctly use the CoBRA guideline, when writing a scientific paper in which the bioresources used in the study have to be cited.

As in the acronym, CoBRA is a guideline for the Citation of BioResources in journal articles and it sets a standard for citing bioresources (including biobanks) in scientific articles, whenever a study based on the use of a bioresource is published. The core of the CoBRA guideline regards the reference section, where each individual bioresource used to perform the study has to be cited as an individual ''reference [BIORESOURCE]'' according to a delineated and standardized format.

Researchers are often unfamiliar with implementation of new reporting guidelines and this slows the process of adoption and diffusion of best reporting practices. This video aims at being a multimedial educational tool to show, by several practical examples, how to adopt the CoBRA guideline during the reporting process and how to build the ''reference [BIORESOURCE]'' for the different types of bioresources.

Methods: Full HD (1080p) video and audio tracks were recorded in MPEG-4 Part 10 (H.264) digital multimedia format, by using a screencasting and video editing software (Camtasia Studio trial version, TechSmith Corporation, Okemos MI, US).

Results: The main features of CoBRA are explained throughout the video, examining the various sections of a scientific paper which are influenced by the guideline. The bioresource has to be cited as a single bibliographic ''reference [BIORESOURCE]'' following a specific format and the video analyzes in detail how to build the reference that mentions the bioresource USED for performing the work. This format is explained in deep detail, along with practical examples.

Conclusion: Applying CoBRA as a standard citation scheme for bioresources will improve the quality of reporting and will facilitate the retrieval of journal articles based on the USE of biological samples/data and their tracing in the scientific literature. The process of reading and learning how to use a guideline can be speeded up through training and educational tools. This video helps the endorsement and the adoption of the CoBRA guideline by authors, editors, researchers and bioresource policy stakeholders.

BET-138 Post-Graduate Biobank Courses: A Road from the Auditorium to BOOC (Biobank Open Online Courses)

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Background: Given the relevance of the discipline Biobanking and the increasing demand of trained interdisciplinary expertise within this field, BBMRI.se, in collaboration with Lund University (Sweden) and University of Copenhagen (Department of Public Health, Denmark) have been arranging post-graduate courses.

Whereas the previous courses (Biobanking and Personalised Medicine and Interdisciplinary Aspects in Biobanking) were mainly classroom courses, this year's course, ''Biobanking and Big Data: possibilities and challenges'' was available not only as a classroom course but also as a Open On-line Course under the name of BOOC (Biobanking Open Online Course) provided by BBMRI.se (booc.bbmri.se).

Methods: The format of the classroom course (with students from 7 different European countries), was based on lectures developed around a 2-day open symposium. The course offered a first day of lectures for the students, a field trip visit to the Danish National Biobank and the Beijing Genomics Institute Headquarters in Copenhagen. The assignment of the course to obtain 3 ECTs was a group presentation on a chosen topic as well as answer the questions stated by their peers in the classroom.

The lectures and the 2-days symposium's presentations were streamed live and kept on the on-line platform BOOC. The material provided were the lectures (recorded and slides) and selected reading material chosen by the teachers. The assignment to get the 3 ECTs for the on-line students was an essay based on a selected topic.

Results: Fifty students from all over the world (30 on-line and 20 on-site) registered to attend the course. Thirty four of them logged into the site. Slides were browsed 215 times in total, 76 video recordings were watched and documents such as course syllabus, reading list and online course instruction, were read in total 137 times. The slides were viewed to a higher extent by students from European countries, and the video recordings were watched mostly by students from the host country Sweden.

Conclusion: We believe that the BOOC format is an efficient tool to reach and teach larger numbers of students from many countries. This tool opens doors to broad global education, interaction and debate within the field of biobanking - without borders - and will allow educating new scientists from all over the world on how to optimally exploit the accessible global biobank infrastructure.

BET-139 From the Human Genome Project to Biobanking Industry, Where Are We Now?

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Introduction: Biobanking is a new concept and knowledge about it is still limited in many developing countries including Egypt. Public engagement and enhancing social acceptability is fundamental for success of biobanks. Medical personnel represent a specific segment of the public since they represent potential customers for the biobank and they come in direct contact with potential participants. Raising awareness about biobanks in this segment could have a positive effect on the future of biobank work in these countries.

Objectives: This video is a presentation about the general concepts of biobanks. It is created to increase awareness about biobanks and their importance. The objectives of this video are to:

- Explain the meaning of biobanks to medical personnel.
- Create a link between history of genetics, medical research and personalized medicine on one side and biobanks on the other side.
- Briefly address the challenges facing biobanks to achieve their goals.

Method: The video is divided into three sections; the first part is discussing a brief history of genetics from the era of Mendel till the human genome project. The second part is discussing the need for biobanks in for improving medical research. The third part is discussing the value and challenges facing biobanks to carry out their functions.

Expected results: Using different forms of educational materials in different occasions including lectures, posters, group discussions, multimedia and case studies is expected to increase awareness among undergraduates and postgraduates in the medical field about biobanks and their role in creating the change in the medical field. This will help the creation of the supportive culture needed for biobanks to perform their functions in collection and distribution of samples and data and in the development of a new environment of research in developing countries.

BET-140 Gamify Your Biobank: Raising Public Awareness Through Social Game Play

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Background: The aim of the project was to create an innovative educational tool to increase public awareness of biobanking. We have, therefore, created a board game that challenges players' strategic thinking while simultaneously learning about biobanking.

We felt that gamification, or the use of game design elements in non-game contexts, could motivate people to learn about biobanking (because they enjoy playing games) and then promote corresponding positive attitudes and behaviours. This was inspired by the growing popularity in the UK of playing tabletop games.

Methods: The creation of a prototype game involved two aspects of translating biobanking: first, identifying and refining key biobanking messages; and second, identifying and refining game design and mechanics which accurately simulate real life biobanking.

Members of the public were asked to give feedback on prototypes based on their experiences of playing tabletop games, during workshops in games cafes and an arts festival. The participants suggested alternatives and improvements to prototypes and discussed how aspects of the game might be interpreted by others. The prototypes were also presented to biobanking professionals to test whether it provided an accurate reflection of real-life biobanking.

Results: Surveys conducted before and after the public workshops showed an increase of self-rated knowledge of biobanking and confidence in explaining biobanking to others. Additionally, feedback from biobank professionals suggested that the game would be useful in educating other stakeholders directly involved with the biobanking pathway, including clinicians, researchers, bioinformaticians and regulators. Both of these groups suggested that the game would be a valuable tool in increasing biobanking knowledge generally.

Conclusions: We now have a novel tool for engaging the public and professionals in biobanking through accurately simulating biobank management and its critical contribution to biomedical research. We will explore developing this concept into a mobile gaming app for wider reach. By increasing their understanding how biobanking works, we hope that players will apply their learning to real-life situations positively, such as becoming involved in research.

BET-141 Engaging Students, Teachers and Artists to Promote New Models of Education in Biobanking. A Tale of Specimen Donation to Biobanks Based on the 3P Approach: Posters, Paints and Pictures

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The use of human biological materials for research contributes greatly to the advancement of biomedical science. The sources of these materials can be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead humans, body wastes (including urine, saliva, sweat) or abandoned tissue. Biological materials may also be sought from individuals for use in a specific research project. Once collected, biological materials may be held in biobanks to serve as a research resource for many years. In addition to human biological materials, information related to the specimens (namely, clinical, life style and environmental data) can be collected and stored for research. The key word of this process is the donation of specimen and information to biobanks. The main scope of this abstract is to report a new educational approach suitable in the biobanking science consisting of the use of illustrations, paints and pictures as additional tools to describe the process of specimen donation and related data for research aims. Here we report the engagement of students of an undergraduate institute (the European Institute of Design), academic teachers and artists to describe the donation of human samples and data to research biobanks. From our perspective, illustrations and comics as well as paints and pictures are crucial to storytell the sample donation process in easily comprehensible manner. We believe that new approaches of education using alternative tools to teach the biobanking science can contribute significantly to open the doors of this discipline to ''lay people'' involving students, teachers, scientific communicators, industries (e.g., marketing) and the general public. We also think that this approach can launch the basis for a culture of specimen donation to biobanks bridging sciences and society broadly.

BET-142 Biobanks and Public Awareness. Target Audiences and Local PR Concepts

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A currently performed patient-survey (2014/2015) at the University Hospitals of Hannover, Heidelberg, and Würzburg supports the public perception of biobanks as some kind of ''black box''. Two-thirds of the respondents had no or just a vague idea of what a biobank is and what the aims and tasks of a biobank are, even if they were previously informed about it.

In addition, the survey revealed that communication is a challenging task for biobanks. Central issues are the heterogeneity of the potential stakeholders, the difficulties in assessing their attitudes, and the variety of influences that can only partially be controlled by the sender of information. In addition, much care should be taken that the information to transmit has neither an excessive nor an insufficient degree of abstraction, and that appropriate communication-channels are chosen.

''Public relations'' and/or ''public information'' aim to build relationships between a ''sender'' and various stakeholder groups (''receiver''). Besides this, many other ways of communicating products and/or issues to the public exist. In the context of biobanking a differentiation of communication tools and/or procedures and the various intended or desired responses and/or reactions still require some in-depth analysis and adapted/optimized solutions.

One key aim of the ongoing PR-activities is to communicate a positive image, explain the public benefit and create an intelligible view on biobanking in Germany. This is a pre-requisite for a broad acceptance, positive public perception and support of biobanks as important infrastructures for the progress of biomedical research in Germany and across Europe.

BET-143 Donating Your Tissue for Research

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NCI, United States

NCI's video ''Donating Your Tissue for Research'' is intended to inspire prospective biospecimen donors and to serve as an educational tool for patients and their families, as well as the general public, about the impact of donating residual clinical specimens to medical research in the era of precision medicine. The three-minute video portrays, through moving real life stories, why tissue donation can be so meaningful to cancer patients and researchers. The video highlights perspectives from a cancer survivor, a physician-researcher, and a pathologist/cancer survivor, each of whom describes what tissue donation has meant to him or her personally. It is designed to be shared with hospitals, cancer centers, surgery clinics, free-standing biobanks, community advisory boards, patient advocacy groups, and clinical trial organizations. Sites should be prepared to advise individuals who view the video and are motivated to donate how they can proceed to donate remnant tissue from clinical procedures within their respective institutions or within their local community. Our hope is that the video will educate, inspire and engage people from multiple and diverse communities regarding the critical role of tissue donation in furthering precision medicine.

We wish to emphasize that the NCI video does not, and is not intended to, supply the breadth of information necessary for research participants to consent to donate tissue for future research. It was developed as a visual format to precede and supplement the standard information about research biobanking communicated during typical informed consent encounters, which is limited and not always effective. The NCI has also developed a printed brochure for prospective research participants containing additional important information about donating tissue, including privacy risks and data protection concerns. The brochure is freely available in both English and Spanish and may be accessed on NCI's website at http://biospecimens.cancer.gov/global/pdfs/MedicalResearchPatientBrochure-508.pdf (English) and http://biospecimens.cancer.gov/content/docs/como-contribuir-a-la-investigacion-medica.pdf (Spanish). At the end of the NCI video, viewers are referred to this printed brochure as an additional information resource, as well as to the NCI's Cancer Information Service 1-800-4-CANCER telephone number.