



The International Society for Biological
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Abstracts from Its Annual Meeting

“Come As You Are: Building Biobanking Bridges”

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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 2023 Annual Meeting & Exhibits.



INTERNATIONAL SOCIETY FOR BIOLOGICAL
AND ENVIRONMENTAL REPOSITORIES

Oral Abstract

O-01 Accelerating Translational Research by Enabling Access to Specimens and Datasets

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Statement of the Problem: Finding appropriate clinical specimens and associated data often causes bottlenecks in the translational research pipeline. Often investigators procure specimens through only one or a small number of sources which often have limited volume of participants and demographics of the patient population. Seemingly paradoxical, groups with large numbers of banked specimens often struggle to increase awareness and use of their collected specimens, which can lead to limited return on investment for high infrastructure costs.

Proposed Solution: To address the above-mentioned challenges the Specimen & Data Acquisition Network (SAN) was formed in 2019 to increase opportunities for resource exchange in the Pacific Northwest region (Oregon, Washington, and British Columbia). The concept of SAN, a hub and spoke network to speed sharing of resources and ideas, originated in response to sparse specimen resources within our translational research program which was a key bottleneck to research endeavors. Building on existing local connections and those from our research network in other academic institutions, we began collaborations with 7 additional institutions that were aligned with our objectives and goals. SAN serves as a liaison for investigators to leverage collective resources and works to support researchers in their biobanking activities. SAN is a conduit for collaborative science across the regional translational research community.

Conclusions: Currently, the SAN consists of 10 member organizations, each with representation on the governance committee. SAN began serving investigators in 2020 and, to date, has received 80 requests and connected more than 40 investigators to critical project resources spanning 12 institutions. SAN works with researchers to provide support across 6 service areas: 1) Access to specimens, 2) Access to datasets, 3) Data Management Support, 4) Research Connections, 5) Regulatory Guidance, and 6) Resource Lifecycle Management. These supportive services are catered to give researchers more time to focus on their next big discovery. Five SAN member institutions are signatory to an umbrella material/data transfer agreement that has expedited resource sharing. We envision that this will be a valuable resource for the translational research community.

O-02 Power of Consortium Shared Resources When External Threats Occur

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Statement of Problem: The Eastern Health Tissue Bank (EHTB) is a hospital-integrated cancer biobank and a member of Victorian Cancer Biobank (VCB) Consortium. In 2021, the biobank responded to several external threats that affected daily operations. These included a cyber-threat incident at the hosting institution and multiple COVID-19-related disruptions as the city experienced one of the longest pandemic lockdowns globally.

Unplanned events can severely and suddenly restrict biobanking activities, and small biobanks require support to ensure sustainability and business continuity.

Proposed Solution: As part of the VCB Consortium, the EHTB has a strong resilience and ability to respond to external threats or incidents. As a hub-and-spoke Consortium (comprising a central lead agency with five cancer tissue banks), the VCB utilises shared resources to strengthen business continuity.

This presentation depicts two scenarios (cyber threat and pandemic) which demonstrate the combined use of tools across a networked biobank to reduce risks and impacts from large-scale organisational disruptions.

Three Consortium-wide tools were utilised:

- 1) A robust Business Continuity Plan, incorporating key stakeholders' responsibilities in risk management.
- 2) A Consortium Business Plan with local (institution) and networked (consortium) goals.
- 3) Implementation of harmonised Standardised Operating Procedures (SOPs).

Scenario Outcomes Included:

- 1) Central Operations "Hub" provided immediate contingency support as part of a framework for rapid response/recovery, including facilitating communications with stakeholders.
- 2) A partner "Spoke" Site allowed EHTB staff access to Biobank shared databases, group business communication platforms, and shared biospecimen storage.
- 3) Harmonised Consortium SOPs allowed large-scale multisite dispatches to still be completed.

Conclusions: In responding to external threat incidents, a robust business continuity plan and immediate access to shared resources enabled the EHTB to retain some functionality. If the EHTB had been a standalone biobank, capacity to operate would have been diminished, resulting in the loss or suspension of activity.

The resources described cannot be underestimated in their effectiveness when an external threat occurs.

O-03 The Qualification in Biorepository Science (QBRs) Examination: Progress Report on its Global Reach

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Background: The importance of quality parameters in biobanking of biological materials like human tissues has been emphasized in the past: Biobanking standards by ISO (ISO 20387), CAP accreditation, Best Practices (ISBER Best Practices 4th ed.), OECD standards, and Standard Operating Practices and Policies by CTRNet were developed to address these challenges.

While these procedures are proving invaluable to biobanks to ensure that their processes for accessing, processing, and distributing biobanked materials result in reproducibility and quality performance, they do not address the question of quality performance in the biobanking professionals themselves.

Methods: The International Society for Biological and Environmental Repositories (ISBER) and ASCP BOC (American Society for Clinical Pathology Board of Certification) as two leading organisations in their fields joined forces to develop the QBRs (Qualification in Biorepository Science) examination, in order to further enhance reproducible and sustainable quality biobanking in biobanking professionals. The exam is administered online and is unique in its field.

Well trained and skilled staff are essential to ensure high quality biospecimens for reproducible results in precision medicine, biomarker development, and biomedical research as a whole, while aiming for sustainable biobanking activities.

Results: To date, over 58 individuals in Australia, Hong Kong, Singapore, Ireland, Wales, Nigeria, Saudi Arabia, UAE, Costa Rica, and the USA have taken and passed the exam to qualify for the QBRs, demonstrating its global appeal.

Conclusions: The QBRs has become the standard which defines the required level of knowledge and skill in biobanking professionals that will assure sustained quality and reproducibility in biobanking laboratories worldwide. Successful applicants have acknowledged that achieving the QBRs makes them more desirable in hiring competitions and enhances their career trajectory. Conversely, biobanks that hire a QBRs qualified biobanker have acknowledged that they are striving for quality in their biobanking operation. The QBRs qualification establishes that the biobank in which the qualified biobanker works is one that promotes and establishes quality within its biobanking staff. Biobank directors have indicated that the QBRs exam provides further impetus for professional training for their staff.

O-04 A New Tool to Match Organ, Tissue, and Eye Post-mortem Donors to Research Project Criteria

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Background: Post-mortem repositories recover organs, tissues, and eyes for research from authorized donors. However, due to the rapid nature of the donation process conflicting with the laborious task of matching donors to research project criteria, organizations miss opportunities to identify donors for prospective recovery. The ReSync app was developed by the

Precision Ocular Biobank to assist in the real-time identification of research donors at the initial point of the referral call.

Methods: ReSync is an app built in Claris FileMaker 19, a low-code relational database engine. Although ReSync is a closed system, open-source functionality of Claris FileMaker allows it to universally connect to external donation referral databases. Research project criteria are entered into a table in ReSync prior to activation. Exclusion and inclusion criteria in categories such as donor demographics, medical history, and referral status act as triggers to match with donor information. Once active, referral coordinators enter donor information into the host database during the initial call from the hospital with a recent or impending death. Filtering occurs through connecting pairs of fields in tables in ReSync and the host database to validate or invalidate a donor candidate against each project. When a match between a project and donor occurs, a flag alerts the coordinator in real-time. Matching projects appear in a pop-up window, and referral coordinators can then consult with research specialists or directly assign the case to one of the projects and initiate recovery dispatch.

Results: Since its employment, ReSync has allowed the Precision Ocular Biobank to expand its open research requests from 3 to 18 at any given point, representing a six-fold increase in concomitant projects. This also led to a dramatically decrease in the time a donor was matched to a project, from twenty minutes to five (400% decrease). Even with more projects open simultaneously, request fulfillment time decreased by 25%.

Conclusions: Low-code, automated donor matching solutions allow post-mortem repositories with limited software developing capability to better fulfil prospective research requests. While simultaneously reducing missed opportunities and eligibility times, programs like ReSync allow for the expansion of enrolled projects.

O-05 Determining Pre-analytical Variables and Molecular Determinants to Ensure High Quality of Luxor Biobank

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Background: Biobank sample preparation methods must ensure long-term functionality of the products obtained. Pre-analytical variables affect the integrity of the biospecimens, and results of analyses. The quality of nucleic acids has a major importance for molecular biology techniques used in genetic analysis. Quality indicators are the tool to measure these parameters; purity and integrity are the determinants for DNA quality. This study aims to determine the quality of SOH Biobank (SOHB) by independently evaluating the preanalytical variables in terms of measurement of processing time, aliquots position audit, and the quality of DNA samples.

Methodology: SOHB biospecimen collection is performed after SOH-IRB approval. Standard operating procedures (SOPs) were written with strict adherence by the team. Blood samples are collected after participant recruitment in the biobank program and obtaining informed consent. After blood collection, the blood is processed within one-hour and stored in -80 degree Celsius freezers. Quality control was determined first, through recording sample withdrawal, receiving, and processing time. Second, aliquots position audits were performed manually on recruited patients for the last 6 months of 2021 to ensure 100% accurate aliquots position. Finally, DNA extracted from buffy coat samples was stored in the duration of 01-2017 to 02-2022

using QIAamp DNA kit (Qiagen). Concentration and purity are measured by spectrophotometer (Multiscan, ThermoFisher). Pure DNA ratio should be between 1.8 to 2.0; a higher ratio reveals DNA degradation, while a lower ratio indicates protein contamination.

Results: Mean value of processing time for 6600 samples is calculated to ensure that samples are processed and stored in -80 degree Celsius freezers within 1 hour of sample withdrawal. Results showed the mean value is 23 ± 0.08 minutes. Manual aliquots position audit was performed for samples stored from July to December 2021; 1087 cases showed 96% accuracy, while 4% aliquot misassigned position inside box. Purity detection for 980 samples out of 6600 samples were analyzed and showed a mean of A260/A280 ratio of 1.8 ± 0.025 .

Conclusion: SOHB quality control results are satisfactory ensuring that SOHB can provide high-quality samples for genomic studies. Quality control should be performed in a regular manner to ensure the appropriate management of the samples, avoiding low confidence in results, high costs, and sample wasting.

O-06 MIRRI-ERIC: A Pan-European Research Infrastructure for Making Microbial Science and Innovation Happen

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Statement of the Problem: Several hurdles hamper microbial research and cause inefficient, ineffective, and costly science and innovation: difficulty to access strains cited in papers and databases; sharing of unverified strains; gaps in the current offer; fragmentation of resources, data, services, and expertise; and deficient support to individual culture collections (CCs).

Proposed Solution: The Microbial Resource Research Infrastructure - European Research Infrastructure Consortium (MIRRI-ERIC) has been created as a pan-European distributed research infrastructure, with the goal of solving/mitigating these bottlenecks, promoting complementarity, reducing redundancy, and continuously improving the capacity of its Partner Microbial domain Biological Resource Centres (mBRCs). MIRRI brings together ~50 mBRCs, CCs, and research institutes from ten European countries working for the preservation, systematic investigation, provision, and valorisation of microbial resources and biodiversity, with a special focus on the domains of Health & Food, Agro-Food, and Environment & Energy.

MIRRI serves the bioscience and the bioindustry communities by facilitating the access, through a single point, to a catalogue of 400,000+ high-quality microbial resources, such as bacteria, cyanobacteria, archaea, yeasts, filamentous fungi, micro-algae, bacteriophages, viruses, and other microbiological material, such as microbiomes, plasmids, and genomic DNA. The MIRRI Information System will also provide users with resources' associated data, as available – e.g., taxonomy, ecology, pathogenicity, morphology, physiology, chemical characterization, DNA barcoding, or genomics.

Based on its partner organisations' state-of-the-art facilities/equipment and top-level expertise, MIRRI also offers its

users a diverse catalogue of high-quality services, including pipelines of integrated, product-oriented services made available as tailor-made, turnkey solutions.

Conclusions: The resources, services, and expertise provided by MIRRI and its partners can help researchers and bioindustries deliver the maximum value and impacts from their projects, technologies, and products.

MIRRI is continuously engaged in enlarging its coverage in Europe and beyond. EU Member States, associated countries, third countries other than associated countries, and intergovernmental organisations may become a Member or an Observer of MIRRI-ERIC. Individual organisations may become Partners of MIRRI-ERIC.

O-07 Developing Genomic and Biomaterials Resources for Establishing Nonhuman Primate Models of Human Disease

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Background: Animal models of human disease play a vital role in biomedical research and therapeutic development. Nonhuman primates, in particular rhesus macaques, share behavioral, anatomical, physiological, and genetic similarities with humans that make them excellent translational models. The wealth of information developed on these animals through diverse research efforts can be leveraged through interconnected repositories of phenotypic data, biomaterials, and genomic information. Through the development of a centralized framework it is possible to accelerate the generation of non-human primate models of human disease and effect vital synergies that go beyond individual laboratories or research programs.

Methods: The macaque Genotype and Phenotype (mGAP) resource serves as a repository for genomic data derived from rhesus macaques, largely those found at NIH-funded Primate Research Centers. A standardized bioinformatic pipeline is used to call single nucleotide variation (SNV) and to cross reference human data on regulatory elements, disease-associated variation, and evolutionary conservation. SNVs are also annotated using variant effect prediction tools. Data are made openly available to the research community both in aggregate as well as at the individual animal level. This information can then be tied back to specific animal health records, phenotypic information, and biomaterials through the contributing centers.

Results: mGAP currently houses genomic information from 2,985 rhesus macaques including nearly 52 million variants. Of these, 11.5 thousand overlap with human ClinVar annotations and 33.2 thousand overlap with GWAS associations housed in GRASP. Many more, 125 thousand, are predicted deleterious by Polyphen2 or high impact by SnpEff. Coupled with phenotypic information derived from animal health records and pathology reports, spontaneously occurring genetic models of multiple rare human diseases have been identified and are being used for novel therapeutic development and biomarker discovery.

Conclusions: Through the integration of genomic and phenotypic information, rhesus macaques are being developed and

harnessed for translationally important nonhuman primate animal models. These efforts can occur at scale only through resources that bring together diverse data and research expertise while still allowing for the connection to individual animals and samples.

O-08 AI in Medicine Based on Biobank Data - New Opportunities and (Not) Known Risks

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The possibilities for improving effectiveness and interoperability clearly show the directions in which BBs will develop soon. Today, virtual links between different DAs allow an exchange of data and samples, which previously could only occur with great effort and long waiting times or even rejections of queries, have decreased. Furthermore, the notion of a biological “sample” is extended to imaging samples, which multiplies the amount and dimensionality of the data obtained and thus provides biobanks with a more complete picture of individual patients and entire disease patterns. With the integration of digitalization into biobanks, a steady flow of data is ensured that, in the best case, does not cease for the duration of a patient’s lifetime. This steady flow of data updates and exchange enables better tracking of the health status of individual patients and populations and can provide far-reaching and as yet unknown information for the epidemiology of certain diseases in terms of course, treatment response, and prognosis. Particularly concerning genotype-phenotype predictions, there is the potential to use genetic traits to develop new personalized therapies or targeted therapies and to identify subgroups that, for example, have an increased risk of developing certain diseases based on their genetic features or to facilitate the early detection of the respective diseases and, among other things, to single out non-responders and to focus more specifically on their specific needs. The consent forms that patients and donors have to fill out and accept with their signature and consent when providing samples to clinical institutes or biobanks, or similar repositories will also evolve into more flexible, dynamic, digitally accessible forms that enable patients/donors to track their own samples and their informative value or usefulness in research whenever and wherever they are. They can withdraw their consent at any time and thus exercise complete control over their genetic material processing. Thus, they will be better treated, yet better informed, and educated.

O-09 Biobanking during War: Experience of Audubon Bioscience

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On February 24, 2022, the large-scale Russian army invasion severely interrupted the operations of our biobank in Ukraine. Our team globally and especially in Ukraine faced and is still facing many challenges. Before the events occurred (when risks of the war escalation increased), we prepared our contingency and business continuity plans. They were partially executed. We have since been able to resume operations in Ukraine.

On the first day of the large-scale war, the Operations team, together with Revenue and HR teams, organized the evacuation of the staff with all documentation and laptops, as well as laboratory equipment and ambient storage specimens to the Western region of Ukraine. We were able to eventually move the ambient specimens to the US. Once in our US operations facility, we reorganized and cataloged every specimen and re-established our biobank there. For frozen specimens, since we can’t relocate them due to the lack of proper transportation at that time, we decided to seal all freezers with specimens and installed surveillance cameras to keep them safe. Together with our temperature monitoring system, we were able to keep track of our freezers’ temperature and ensured that the specimens were properly stored during the 2-month period when only a few members of our team remained at the biobank.

Ongoing Ukrainian projects were immediately transferred to other countries of operations such as Turkey, USA, Armenia, etc. In three months (May 2022) we achieved financial break-even (monthly) confirming the fact that global organization was stabilized. After two months, when active warfare was stopped in the Kyiv region, new logistic chains were organized and we started to rebuild our workflow. By August 2022, the Ukrainian operations reached the level of pre-war collection rates. However, we continue to distribute projects among all of our affiliates in other countries to minimize risks for our partners.

In conclusion, the operations of Ukrainian biobanking have been faced with severe difficulties due to the Russian-Ukrainian war. Although we were not able to execute our contingency and business continuity plans in full, right planning together with good execution and improvisation helped minimize the negative effect. Solutions that we put in place to ensure proper specimen storage were implemented and proved to be effective. Our ability to redistribute projects globally enabled us to continue supporting precision medicine researchers.

O-10 Survey of Adolescents Regarding Their Opinion of Research and Vaccination During the COVID-19 Pandemic

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Background: The COVID-19 pandemic has emphasized the importance of research into disease biology, prevention, and treatment of emerging diseases and pathogens. Currently, there is limited understanding on adolescent perceptions towards biobanking, research participation, vaccinations, and how the pandemic has altered these perceptions. The BC Children’s Hospital BioBank (BCCHB) surveyed Grade 8-12 students in British Columbia (BC) to determine perceptions before and after the pandemic about topics such as research, pediatric biobanking, vaccinations, and public health policies.

Methods: A voluntary, anonymous, 15-question online survey was distributed through student emails, online school portals, and parent newsletters. Phase 1 of the survey was conducted from May to June 2021 and Phase 2 was conducted from Sept 2021 to June 2022. Questions were edited between Phases 1 and 2 to reflect vaccine availability for adolescents, and the emergence of new variants of COVID-19.

Results: We received a total of 1,022 completed survey responses, from participants aged 12-19 years in 13 BC school districts and compared the findings to a previous completed school survey [1]. The majority of participants (94%) agreed that COVID-19 is a serious disease and 95% stated that the pandemic has shown them how important medical research is. While many (95%) agreed on the importance of research before the COVID-19 pandemic, this increased to 97% after pandemic onset. This desire to contribute to research was reflected by the 80% of participants willing to donate an extra blood sample for biobanking purposes during the COVID-19 pandemic, compared to 64% from a 2016 school survey conducted among the same age group [1]. Participants (97%) also agreed that research participation would allow them to help others. Of the adolescents surveyed, the majority (85%) were comfortable with making the decision on their own to donate a sample specifically to research. Considering the current public health climate, 92% of participants stated that they will be vaccinated, for reasons such as knowing vaccines are safe, allowing them to engage in social activities, and protecting them from COVID-19.

Conclusion: Adolescents across BC were found to be more willing to participate in research after living through the COVID-19 pandemic. They also were found to be more willing to donate leftover samples towards biobanking after knowing the importance of research in disease diagnosis and treatment.

Reference: [1] Kong CC, Tarling TE, Strahlendorf C, Dittick M, Vercauteren SM. Opinions of Adolescents and Parents About Pediatric Biobanking. *J Adolesc Health*, 2016; 58(4):474-480. doi: 10.1016/j.jadohealth.2015.12.015. PMID: 27013273.

O-11 Tissue Microarrays: Turning Hidden Resources in Research Gems

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It is expected that biobanks provide critical tissue resources to researchers to conduct fundamental investigation into disease states and to ensure the best research use of all tissue biospecimens by linking them to key questions being asked in research. Recognizing the rarity of childhood cancers, small tumour specimen volumes, and the burgeoning need for tissue-directed research, we describe here the impact of a research-focussed biospecimen resource. The Tumour Bank at The Children's Hospital at Westmead (TB-CHW) has initiated alongside the main source of all such tissue, our histopathology department. In 2012 we leveraged the hospital's formalin-fixed paraffin-embedded (FFPE) tissue block archive to commence a tissue microarray (TMA) construction program. Our purpose was to provide rationalised access to FFPE tissue whilst not impacting on the availability of blocks for future diagnostic or medico-legal review. Construction of the TMAs that represented a single childhood cancer subtypes required a deep dive into the block archives with blocks selected covering sample collected over a couple of decade-long periods or more. This resulted in a tissue resource where enough rare paediatric tumours representing all patients seen at a single centre are drawn together to provide meaningful results in their own right. The TB-CHW TMA selected blocks from the

past two or more decades, establishing a workable pipeline for the construction of TMAs involving block selection, pathologist review, block construction, and QA processes; staining and review; digital microscope; and downstream image analyses. The program constructed 25 TMAs which have subsequently supported 21 international studies with a total of 828 individual slides released novel technical evaluation, image analyses, and biological assessment that have shifted beyond routine chromogenic and immunohistochemical staining into spatial assessment of targeted regions for protein and gene expression activity as well as deep learning and artificial intelligence.

O-12 Genomic Taxonomy of Bacterial Strains in a Microbial Biorepository: The Instance of the Collection of Institut Pasteur (CIP)

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Background: Around 500 bacterial strains preserved at the CIP date from the first half of the last century; nowadays this repository includes >26000 strains from various sources representing more than 1000 genera and 5000 species. Most of the strains have been classified and phenotypically characterised by using traditional microbiological methods. For improving characterisation and taxonomy of the holdings, a whole genome sequencing (WGS)-based workflow has been implemented at CIP with the GIPhy group.

Methods: A standard operating procedure was set up for genomic analyses. Illumina paired-end reads generated at the Institut Pasteur sequencing facility are de novo assembled using the in-house developed pipeline fq2dna. Acceptance criteria are based on absence of sequence contamination and contiguity metrics corresponding to the typical values of the species. The highly curated Genome Database Taxonomy (GTDB) is then used for assigning taxonomic classifications calculating ANI distances with GTDB-Tk. The strains' curated metadata and the genomes are deposited on the BIGSdb-Pasteur platform (bigsdb.pasteur.fr). This web service offers analysis tools, genomic libraries, and strain nomenclature databases for bacterial pathogens of public health concern.

Results: Outdated or pending species classification were (re)defined for several strains. When applied on 36 strains previously identified as *Chryseobacterium* sp. from the 1970s/80s, the pipeline confirmed that only 18 strains were *Chryseobacterium* (or affiliated species *Epilithonimonas*) among which three represented novel *Chryseobacterium* species. Another project involved the categorization of 44 *Clostridium perfringens* (CPE) strains according to the recently revised toxinotype scheme by using a versatile in-house tblastN search program that stratifies results by gene coverage and amino acid identities. These strains were classified as 30 CPE type A, 1 CPE type B, 3 CPE type C, 1 CPE type D, 1 CPE type E, 5 CPE type F, and 3 CPE type G. High amino acid sequence diversity of the $\beta 2$ toxin was observed in the selected panel that will be soon visible in our online catalogue.

Conclusion: A standardized pipeline for genomics analysis is crucial in a biobank for purposes of operational efficiency, high added value annotations, avoidance of taxonomic redundancy, and accurate representation of Earth's biodiversity of the micro-organisms.

O-13 Reassessing Historical Collections: Finding Novel Uses for Archived Specimens

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Biobankers are regularly required to make decisions regarding perpetuation of archived collections due to financial, staffing, and space limitations. This can be exceedingly difficult, particularly when the collections may represent valuable resources to help answer future research questions. At the National Institute of Standards and Technology (NIST) Biorepository located in Charleston, SC, staff are continually investigating potential uses for archived collections to help management make these difficult decisions. Recently, a collection of fresh frozen human livers was accessed to explore the development of a metabolomics reference material suite. In partnership with the Environmental Protection Agency (EPA), these livers were collected from decedents between 1980 and 1994 using strict sampling protocols to monitor environmental contaminants in human populations across the United States and have since been stored at the Biorepository. NIST researchers surveyed the historical data to identify subjects from different life history categories (age, sex, health status, etc.) and accessed liver tissues from these subjects to generate three cohorts of fresh frozen liver homogenate: Normal, Fatty, and Congested. Sub-samples from these homogenates were extracted and analyzed using nuclear magnetic resonance (NMR) and liquid chromatography high-resolution mass spectrometry (LC-HRMS/MS). Results from these analyses demonstrate this reference material suite can be used as a quality control material to harmonize measurements across laboratories and benchmark instrument performance for differential metabolomic analysis. Because NIST researchers have access to this valuable collection of tissues, the metabolomics community will soon be provided with a vital tool for standardizing measurements, thereby instilling greater confidence in their analytical results.

O-14 An Ethico-Legal Analysis of Broad Consent for Biobank Research in South Africa: Towards an Enabling Framework

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The South African National Department of Health Ethics Guidelines for health research allows the use of biobank research broad consent while section 13(1) of the Protection of Personal Information Act 4 of 2013 seems to prohibit the use of this consent model because it stipulates that the purpose for personal information collection (which includes biobank sample-associated data) should be for a specific, lawful purpose that is explicitly defined. This discord creates room for divergent views in interpretation of the latter. The study therefore seeks to answer the question of whether South Africa's current regulatory framework permits the use of broad consent for biobank research. The research question is answered through an analysis of the regulatory framework relevant to broad consent for biobank research. Ethical principles and theories are also used to construct arguments in support of and against broad consent use. Arguments in support of broad consent use for

biobank research include: beneficence, autonomy as not being specific to the scope of choices, participant non-maleficence ensured through biobank ethics committee review, and ongoing communication with participants on material use. Counter-arguments include: interference with participant autonomy, understanding of information and ethical participant protection, broad consent withdrawal, and limitations of sample anonymisation. Briefly, the regulatory framework amendments that I propose include rectifying the regulatory ambiguity pertaining to broad consent use, ensuring adequate safeguards for research participants through specifying rules for data access, and processing of personal information as well as amendments of the consent template of the Ethics Guidelines.

O-15 Challenges and Opportunities for mBRCs in the Era of Regulated Access Policies

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Statement of the Problem: Microbial Biological Resource Centers (mBRCs) ensure access to authenticated and quality-controlled microbial resources. To meet this valuable goal, mBRCs must preserve a large and diverse collection of microorganisms and authenticate them before making them available for distribution upon request for teaching, quality control, and scientific purposes. Easy and unrestricted availability of cultures (including the type strains) directly from mBRCs has been a standard practice among researchers. However, the implementation of biodiversity regulations, particularly the Nagoya Protocol on Access and Benefit-Sharing (NP-ABS), has forced mBRCs to modify their policies to access microbial resources. Differences in the process of ABS among the countries further complicate the development of a universal access policy and pose serious challenges for mBRCs in ensuring restriction-free access to microbial resources. The introduction of mandatory prior approval for a few countries on all kind of access are at odds with the rules of the International Code of Nomenclature of Prokaryotes (ICNP).

Proposed Solution and Conclusions: Several mBRCs are putting forward robust mechanisms in compliance with biodiversity regulations, including specific documentation to comply with NP-ABS, such as PIC, MATs, and IRCC. However, these evolving requirements incur novel costs for mBRCs, which may in some cases represent existential challenges. Application of fast and low-cost techniques like MALDI-TOF MS for de-replication* and authentication of microbial resources and establishing collaborations with biotechnological industries can contribute to cost recovery of the mBRCs.

Abbreviations:

ABS = Access and Benefit-Sharing

ICNP = International Code of Nomenclature of Prokaryotes

IRCC = Internationally Recognized Certificate of Compliance

MALDI-TOF MS = Matrix Assisted Laser Desorption Ionization time-of-flight mass spectrometry

MAT = Mutually Agreed Terms

mBRC = Microbial domain Biological Resource Centers

NP-ABS = Nagoya Protocol on Access and Benefit-Sharing

PIC = Prior Informed Consent

*De-replication here refers to the identification of similar strains so that the curator can make a rational decision to keep or remove the replicates of the same microbes.

O-16 How Can and Should Biobanking Governance Structures Respond to (Inter)national Political Contexts?

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Statement of the Problem: Biobanks provide invaluable resources for biomedical research but require ongoing attention to participant consent, access procedures, data usage, and accountability mechanisms. Good governance is an important route by which these concerns can be examined and addressed yet the focus on this governance in scholarly debate has been around the biobank itself. Yet biobank governance structures embed into larger macro-political and -economic structures, and multi-directional relationships exist between these, biobanks, and their participants. In contemporary society, these structures are becoming increasingly dominated by issues of nationalism and human rights. Questions arise about how biobanks should address these issues, and specifically, how they should respond to access requests by researchers who work within jurisdictions that are perceived to be untrustworthy or politically dubious. This is an issue for large-scale population-based biobanks that have relatively open access procedures internationally, and for which participant data is increasingly linked to health records and/or other information.

Proposed Solution: Discussion is required to better understand the challenges posed by such political landscapes and if/how biobank governance structures should respond. We describe what these discussions should involve using two case studies: (a) a country has invaded another country, resulting in a range of human rights violations, and (b) scientists based in a country reported to be violating human rights are accessing biobank data. Questions that need addressing include whether changes in the political landscape affect the legitimacy of consent provided by participants, particularly when that consent has been provided at a time before these political changes; how biobanks should respond to concerns raised in the media about such changes in the landscape; how participants might be given a voice to raise their concerns; and how/who decides whether the biobank should sanction access, and whether this should be based on reasonable suspicion or actual knowledge that any associated biobank data may be used to further violations in some way.

Conclusion: Biobank governance structures need to consider the challenges that national and international landscape changes may raise, and do so from a range of perspectives.

WITHDRAWN

O-18 Surveying the Biobanking Landscape

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Background: Biobank sustainability is a hot topic for many around the world and biobanks are increasingly being asked to justify their existence and provide evidence of impact. There is a lack of data to help biobanks benchmark and, because of the variety in operating models, it is often difficult to provide direct comparison. Without the ability to compare like with like, biobanks are in danger of being unfavourably compared to others even when non similar. To help inform strategic planning for the Wales Cancer Biobank (WCB), data were required to place the biobank's operation and outputs in context, both in comparison to other UK biobanks, other cancer biobanks, and biobanks worldwide. To account for the different biobanking models around the world and to stratify the responses and allow more nuanced groupings, an in-depth survey was proposed to provide a snapshot benchmark that could be used for WCB's internal purpose but also as a wider tool for the community.

Methods: An online survey was designed and gained ethics approval. The survey was targeted to biobanks collecting from human participants. Three biobanks piloted the survey and adjustments were made prior to wider circulation. The final version of the survey had 34 questions, some with multiple parts. The survey was circulated; via the UKCRC Tissue Directory distribution list in the UK, via the ABNA network in Australia, via the ISBER general forum, in the October BBMRI-ERIC newsletter, on a personal

WITHDRAWN

LinkedIn page and on the WCB's Twitter account. Reminders were sent and the survey was open for 6 weeks.

Results: Seventy-nine responses were received, 39 from the United Kingdom, 38 from other countries, and 2 respondents did not specify a geographical location. Biobanks ranged in size and remit with some consenting fewer than 20 participants per year and some upwards of 3,000. Just over half (54%) of the biobanks are disease or condition specific, and half are based in academia. 53% reported being asked to justify existence.

Data will be analysed for two purposes: specific benchmarking for the WCB, and for publication to create a reference work useful for all biobanks collecting human biospecimens. Analysis is ongoing and results will be presented.

Conclusions: There is clearly a need for robust benchmarking and the difficulties in achieving comparability are not to be underestimated. It is hoped that (future) publication of these data will help biobanks to place their operations and outputs in a wider context.

O-19 Evolution of Risk Management in Qatar Biobank (QBB)

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Background: Since QBB's founding in 2012, an analysis that identifies and prioritizes strategic risks with the potential to impact the completion of milestones was monitored annually. QBB obtained ISO 9001:2008 & ISO 27001:2013 in 2014. QBB's approach to review risk evolved drastically with a more risk-focused ISO 9001: 2015. Risk analyses were conducted to control unlikely events for operations and future (service/product) expansions. QBB created Quality/Strategic (QMS) & information security management (ISMS) risk registers to mitigate risks.

Methods: Risk is subjective, based on experience & knowledge. Hence, QBB Director, Department Manager/HOD, Scientist, and Risk Champions meet to analyze/mitigate risks.

In 2014, ISMS Risk Register (RR) was implemented. IT asset register provided inputs to assess risks & treatments. RR was categorized into physical, software, information, people, and service assets. Risk assessment was based on asset register values by grouping similar assets, identifying threats and vulnerabilities to grouped assets, and calculating risk rank. Residual risks were monitored if high. This methodology was used until 2020. In 2020, ISMS risk process was revamped and did not depend on asset register. Firstly, risk is identified and its source is submitted in ISMS risk register e-form. Then, risk is assigned to process owner for evaluation and treatment. In 2021, monitoring of residual risk after treatment was re-introduced.

In 2017, QMS (Strategic) Risk Register was implemented. 4 strategic objectives were the frameworks of RR. Risks were categorized into Operational, People, Hazard, Financial, Legal, Strategic, and Reputation. Risks were further linked with KPI and KRI for objective analysis.

In 2020, during the pandemic, QBB strategic RR was revamped and risks were reevaluated into Operational (data/facility/equipment), People, Hazard, Financial, Environmental, Strategic, Legal, and Technology. In 2021, residual risk monitoring was introduced.

Results: ISMS Risks – 112 risks were identified in 2014, which systematically decreased to 34 in 2020 and 30 in 2021.

QMS Risks – 10 negative risks +1 positive were reported in 2017. 12 strategic risks were reported in 2021.

Conclusions: Continuous risk monitoring ensures smooth operations. During audits, root causes of various deviations were found in RR, indicating risk-evaluating competencies in QBB. Risk analysis is implemented into processes, e.g., reporting non-conforming products/services. QBB is considering risks from many perspectives

O-20 Costs and Publication Outputs of an Academic Cancer Biobank Cohort

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Background: Sustainability for biobanks represents an ongoing economic challenge, with numerous closures of high-profile facilities. We have previously discussed the lack of focus on valuing biobanks and their associated outputs, and the threats to sustainability that this may confer[1]. To better understand the biobank costs and outputs that contribute to biobank value, we performed an in-depth analysis of annual monetary and in-kind support, and supported publications and their metrics, for a cohort of 12 academic cancer biobanks in New South Wales, Australia.

Methods: Through a combination of interviews and desktop analysis, comprehensive costing and supported publication data were obtained. Biobanks were grouped and compared according to two classifications: open- versus restricted-access[2], and high- versus low-total annual costs.

Results: Median total costs, as well as median staffing and in-kind costs, were comparable for open- and restricted- access biobanks, as were the quantity and journal impact metrics of supported publications. High- and low-cost biobanks supported similar median numbers of publications; however, high-cost biobanks supported publications with higher median Journal Impact Factor and Altmetric scores. Overall, 9 of 10 biobanks had higher Field Weighted Citation Impact scores than the global average for similar publications.

Conclusions: To our knowledge, this is the first analysis of the costs and supported publications of any academic biobank cohort. Through assessing explicit cost and output data, academic biobanks can engage in or support informed re-direction of resourcing and/or benchmark setting, particularly in light of the range of available collection and access models. Funders and policymakers can also benefit through greater accountability for decision making enabled by evidence-supported business models of biobank operations.

- [1] Rush A, Catchpoole DR, Ling R, Searles A, Watson PH and Byrne JA. Improving biobank sustainability through an outputs focus. *Value in Health*. 2020; 23(8): 1072 - 1078
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Innovative Technology

IT-01 An Analytical Method to Determine Quality of Fixation Using Vibrational Spectroscopy and Machine Learning

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Background: Modern histology is built on the century-old process of formalin fixation, which arrests molecular degradation by crosslinking a tissue's biostructure. Despite being critically important, there are no analytical methods of measuring fixation quality. The level of tissue fixation significantly impacts detected protein expression, which drives medical opinion on diagnosis, prognosis, and treatment. Mid-infrared spectroscopy (MID-IR) is a powerful non-destructive optical technique that probes the vibrational state of individual molecules in the tissue and is very sensitive to the conformational state of proteins. Using MID-IR spectroscopy, this work demonstrates that fixation significantly alters tissue's biochemical state and uses the discovered spectral fingerprint of formalin fixation to build a predictive model to determine the fixation time of unknown biospecimen.

Materials and Methods: One hundred and five individual pieces of human tonsil were differentially fixed in room temperature formalin for between 0 and 24 hours, then were processed and embedded. Each paraffin block was sectioned in duplicate and all 210 slides were imaged with a MID-IR microscope (Bruker Hyperion 3000). Approximately 100 regions throughout each slide were imaged ($\nu=900\text{--}4000\text{cm}^{-1}$, $\text{deltav}=8\text{cm}^{-1}$, averages=16) and the average spectra were used for analysis. Adjacent tissue sections were stained for BCL2 and FOXP3 to assess each tissue's preanalytical quality via orthogonal IHC staining.

Results: A partial least squares regression model was trained on 158 slides and its performance was evaluated on the remaining 52 slides. Among the holdout tissues, the model accurately determined fixation time to within 1.4 hours, indicating the model had deciphered the true molecular fingerprint of formalin fixation. Additionally, the fixation status of tissue specimens was confirmed with FOXP3 and BCL2 staining, which was compromised with low fixation times (e.g., time <6h).

Conclusions: This study details the novel ability to quantitatively measure fixation time and quality using an objective and standardized metrology. This technology could enable an analytical quality check of tissue blocks, help laboratories assess their preanalytical procedures, or be used to identify and study preanalytically sensitive cancer biomarkers.

IT-02 Electromagnetic Heating Technology for the Fast and Uniform Rewarming of Cryopreserved Large-Volume Samples

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Background: Complexity is increased significantly in both cooling and rewarming when the cryopreserved sample is scaled up to large volume. Recent research has successfully vitrified samples up to 1 L with high-concentration solutions such as M22, but the vitrified samples currently cannot be rewarmed back without devitrification even when the volume decreases to 100 mL. The challenge is that the rewarming must be fast and uniform, which is difficult to achieve by the conventional water bath method or any conductive heating. Electromagnetic (EM) heating is a promising rewarming solution for large samples due to its ability to heat the samples volumetrically. Specifically, dielectric heating (DH) and Magnetic Heating (MH) are the two main methods for converting the electric and magnetic energy, respectively, to heat the cryopreserved samples.

Method: This work will experimentally and numerically compare the rewarming performance of DH and MH in terms of the heating rate and uniformity. The testing sample is a 20 mL vitrification solution including 40% (w/v) DMSO plus 0.5 mg/mL PEG-coated magnetic nanoparticles (MNPs). The single-mode electromagnetic resonance (SMER) system is designed to rewarm the sample either by DH or MH efficiently. The signal input is amplified to 500 W by an amplifier. Due to the special dimensions of the SMER cavity, the maximum electric field and magnetic field locates at the center and edge of the cavity, respectively, where the sample would be placed to measure the rewarming rate of DH and MH. To further understand the rewarming uniformity, a finite element analysis with COMSOL is developed to analyze the temperature distribution in the samples during heating. The effects of MNPs and the influence of MNP concentration is also studied in the simulation.

Results: Compared to MH, DH could achieve faster and more uniform heating when the concentration of MNPs is as low as 0.5 mg/mL. The higher concentration of MNPs can further improve the performance of both the MH and DH significantly.

Conclusion: Compared to the conventional water bath, both DH and MH perform significantly better especially for large samples, owing to their high energy density and volumetric heating mechanism. For DH, MNPs works as the auxiliary heating component. In comparison, MH cannot work without MNPs due to its heating mechanism.

IT-03 OMICS-QC: Integrative Model of Quality Control of Plasma and Serum Samples for Multi-omics Approach

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Statement of the Problem: Development of biobanks entailed improving technological hinterland for efficient management in the fields of large amounts of samples, clinical data, and big data from multi-omics assays. It is clear that the reliability of data obtained from research directly depends on the quality of starting material. To ensure that biospecimens provided by biobanks are omics-grade and meet the requirements of high-throughput assays, we developed the OMICS-QC, a precise and affordable molecular-based model of quality control (QC) for serum and plasma.

Proposed Solution: Within the OMICS-QC model, we established a process composed of successive steps with hemolysis monitoring and control of RNA extraction. The model was developed and tested using 347 serum and 694 plasma samples stored in the Biobank at the Medical University of Białystok, Poland.

The first step (1)- visual hemolysis assessment is performed according to the three-point scale that indicates an absence of hemolysis, suspected hemolysis, or hemolysis at different degrees. The second step (2), a quick, low-cost technique to monitor hemolysis in serum/plasma, is the spectrophotometric analysis based on oxyhemoglobin absorbance measurements at $\lambda=414$ nm and $\lambda=385$ nm. Distinct values of hemolysis score indicate the presence of free hemoglobin and can be used to disqualify samples affected by hemolysis before time-consuming and expensive processing. The third step (3) is performed following RNA extraction from serum/plasma and includes the analysis of the efficiency and correctness of RNA purification process using the qPCR method based on a set of synthetic RNA spike-ins and endogenous microRNA assays. The assessment of RNA Integrity Number represents a critical step for selecting biospecimens, and isolates with $RIN \geq 7$ are qualified for omics analysis only. Key QC parameters of RNA isolated from the serum/plasma samples include the efficiency of RNA extraction, absence of nucleases, and any inhibitors of enzymatic reactions.

Conclusions: Advanced research applications require access to biospecimens with confirmed omics-grade quality. Accordingly, we developed a molecular-based model to ensure the reproducibility of high-throughput assays performed using samples provided by biobanks. An established OMICS-QC model can be recommended in the process of specimen qualification before the multi-omics assays for reproducibility and replicability in research.

IT-04 Spa Biobank: A New Type of Biobank

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Background: Modern health care systems give more attention to spa health care that consists of prevention, treatment, rehabilitation, wellbeing and healthy diet, and healthy lifestyle. Taking in the consideration the requirements of both clients/patients and medical doctors, evidence-based and personalised results of spa stay become more important, especially in the post-covid pandemic time with enormous effects on health and mental health off all: children, elderly, and people back from home offices to their real offices.

Methods: That is why spa stay plays a greater role than before. Personal health status before an after-spa stay gives important information about spa importance for patients' health. To have a complete picture of the patient, beside general information, the selected biomarkers for a given diagnosis (diabetes, CVDs, cancers, etc.) from blood are crucial to identify

and compare before- and after-spa stay. For these types of analysis, no spa has its own laboratory, equipment, and staff educated enough, that is why collaboration with hospital laboratories is necessary.

Results: The connecting point between spa houses and the hospital is a purpose-based spa biobank. For every single spa facility it is necessary to prepare standardized procedures for acquiring, short-time storing, and safe transporting samples to the central facility with "biobank" to ensure a high quality of samples, from where samples are once a day transported to the hospital laboratories for analyses. The associated data must be in a unified form to be common for all and acceptable for the hospital information system. Special informed consent and other ELSI issues need to be adjusted to the spas' requirements. Spa biobank is a new challenge for the science of biobanking.

Conclusions: Spas Karlovy Vary, Mariánské Lázně, and Františkovy Lázně—all UNESCO "Great Spa towns of Europe" in the western part of the Czech Republic—are almost ready to build the spa biobank. General requirement for this type of biobank was expressed by spa houses. The close situated University Hospital in Pilsen with well-equipped laboratories and its own well-established biobank is opened to start the initial steps. More information will be in the presentation.

IT-05 AI and the Metaverse as the Drivers of Change for Biorepositories

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Temperature is without a doubt one of the elements that rule the world of biorepositories.

To manage an effective specimen's Cold Chain and be compliant, you must monitor the temperature while the specimens are in storage and transit, and log the results for future review. Today, Cloud-based technology allows you to manage this from a distance for added confidence, and this is no longer enough.

Artificial intelligence can provide revolutionary methods for material examination that would ensure optimum storage solutions. The large amounts of data processed by AI combined with the performance of leading-edge computers could open up a world of opportunities and change the face of industrial temperature management forever. As a merging of virtual, augmented, and physical reality, the Metaverse can provide the means to achieve fully integrated cold storage technology and would facilitate access to infographics, data, feedback results, and other accurate information to make smart data-driven decisions. This could change the way biorepositories handle their samples, enabling them to track their products all throughout their journey. What the Metaverse brings to the table is a greater overlap of the digital and physical life, whether that's through virtual reality, augmented reality, or a computer screen. The data provided through virtual and augmented reality on Meta's platform for real-time commercial feedback can facilitate the decision-making process for cold storage users. Information on product delivery, stock, rotation, dispensary, and disposal can be easily accessed at any time, allowing the user to monitor and control any service or operation and make better data-informed decisions. The mere task of investigating specimen management can turn into an immersive experience. In the event of a critical stock delivery delay, an alarm, or a simple deviation in the freezer's functionalities, Meta could provide instant feedback on the nature of the service interruption.

Therefore, its capabilities go beyond monitoring ultra-cold temperatures of bio-freezers, giving businesses full control over their operations.

But the one thing we know for sure is that Meta is going to be a real gamechanger for both organizations and users in all industries. Businesses will be able to address many of their current issues by simply taking advantage of the data and information in the Cloud, and thus ensure higher quality products and services for their consumers.

IT-06 Bridging the Gap Between Biobanks and Industry

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Statement of the Problem: Pharmaceutical and biotechnology companies are increasingly using human tissues, human cells, and human biospecimens of all types (e.g., saliva, DNA, blood, tissue) in their efforts to respond to global health emergencies like the recent COVID-19 pandemic. This renewed emphasis on accessible, ethically-sourced samples has led to an urgent need to make hundreds of thousands of human biospecimens rapidly available to researchers across the globe. To date, the interactions between non-commercial biobanks and biopharmaceutical organizations (“Industry”) have been limited due to complications brought about by lengthy contract negotiations, misalignment on roles, and due diligence assessments by both parties.

Proposed Solution: Scientist.com has worked with Industry to create a solution that allows biobanks to provide human biospecimens, under a pre-negotiated contract designed specifically for the provision of human biospecimens, which has been accepted by over 140 pharma, including 24 of the top 30. Scientist.com has established a rigorous, award-winning legal and compliance framework, called COMPLi®, that ensures that all aspects of the project are addressed by the authorized individuals (e.g., legal, procurement, compliance, biobank) within each organization and allows direct interactions between the parties. Furthermore, it enables biobanks to maximize the use of the banked biospecimens and provides a sustainable pathway for non-for-profit organizations to work with Industry, driving innovation and therapeutic advancement. COMPLi also ensures that all human biospecimens undergo the necessary ethical considerations that govern the collection and respect the wishes of the donor.

Conclusions: Currently, COMPLi is the cornerstone of Scientist.com’s biospecimen outsourcing capabilities, supporting ~15000 projects. COMPLi enables Industry to easily acquire the necessary biospecimens to complete ongoing studies ensuring compliance is at the heart of the process. Most importantly, COMPLi reduces the administrative burden on biobanks and other providers, enabling effective relationships to be formed that speed up scientific research and increase visibility, traceability, and control over human biospecimens.

IT-07 Biobanking as a Foundational Component of NIH Research: Sampled Provides a Critical Resource for Research into the Genetics and Epigenetics of Substance Abuse in Humans through its National Institute of Drug Abuse (NIDA) Centers

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From 1999 to the present, Sampled, formerly known as RUCDR Infinite Biologics®/ Infinity BiologiX, has continuously been the federal grantee or contractor for a number of NIH institute biobanking awards including NIDA, NIAAA, and NIMH. Sampled established and serves as the NIDA Center for Genetic Studies (NGC) and the biobank for the Adolescent Brain Cognitive Development (ABCD) study. While the NGC was conceived as a cell, DNA and clinical data repository designed to facilitate cost-effective sample sharing among researchers, it has surpassed that original mandate by consistently providing the latest technological services to NIH grantees. This is demonstrated by the implementation of services including cutting-edge genomics (e.g., genotyping, methylation and transcriptome microarrays, next-generation sequencing including methylseq and single cells), clinical diagnostics, and iPSC derivation.

To date, the NGC has received more than 100,000 samples from NIDA and NIAAA subjects, producing more than 825,000 aliquots of nucleic acids, plasma, PBMCs, and other biomaterials. NGA analytical services has run and analyzed more than 60,000 samples on Smokescreen arrays, and sequenced >30,000 whole exomes and >1 million samples on Infinium and Axiom arrays. We will consider examples of how these data, available in dbGAP, have contributed to critical progress in important areas such as opioid dependence, addiction susceptibility, and behavioral issues relating to addiction.

As it expands to a new 200,000 square foot facility in 2023, Sampled looks to its partnership with NIH and the future of substance abuse research with excitement, with new projects such as the Healthy Brain and Child Development (HBCD) study coming online. Through the application of a number of modalities, including genomics, toxin and drug exposure assays, imaging, and behavioral assessments, the HBCD study will study a large cohort of pregnant women from regions of the country significantly affected by the opioid crisis and follow them and their children through early childhood. The study will collect information beginning at birth and continuing through early childhood. The central role of the biobank and SMART Lab at Sampled in this effort will be discussed.

IT-08 Two-for-one: Optimizing Histologic Quality Control of Fresh Tissue Disbursement and Simultaneously Banking for Future Use

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Background: The Cooperative Human Tissue Network (CHTN) of the National Cancer Institute provides human biospecimens to researchers. Since it began in 1987, CHTN has focused not only on patient safety and efficient sample procurement and distribution, but also on optimal sample quality. One hundred percent of tissue samples released through CHTN receive histologic quality review, including tissues which are released fresh. In the era of increasing requests for fresh tissue (for single-cell RNA sequencing, organoid cultures, and other research modalities), quality control for fresh tissue releases becomes even more important. The CHTN model of sectioning the tissue and formalin-fixing and paraffin-embedding (FFPE) a “mirror-face” piece of tissue provides an H&E top-slide that is representative of the FFPE block and also representative of the fresh tissue that was immediately released.

Methods: CHTN investigators are able to place specific requests for human tissue samples processed in different ways (fresh, frozen, FFPE, etc.). Research staff access requests,

identify upcoming surgical procedures, consent patients, and attend surgical pathology to collect and begin processing tissue. At the Southern Division of CHTN (Duke), the mirror-face FFPE QC procedure is employed for all fresh tissue releases. The FFPE QC block and the fresh specimens are linked in the LabVantage biobanking information management system (BIMS). Histologic review data (diagnosis, site of origin, % necrosis, and % tumor nuclei) are recorded in the BIMS and a QC report issued to the investigator.

Results: Fresh tissue releases have increased year-over-year for CHTN at Duke with a 5.8-fold increase from CY2020 to CY2021. The trend toward increasing fresh tissue releases is

also reflected across the entire CHTN network. All fresh tissue releases result in the creation of dedicated research FFPE blocks to facilitate quality control.

Conclusions: Mirror-face FFPE blocks created to facilitate histologic quality control of freshly-released tissues are stored in the biobank and are available to investigators as dedicated research-only blocks. Dedicated research-only blocks at our institution can be released in full and are not subject to the same restrictions as archival surgical tissue blocks from non-consented patients. Quality control for freshly-released tissue specimens is logistically challenging, but this approach is highly efficient and provides added value to the biorepository.

Poster Session

Biobanking Tools

PA-01 Design and Implementation of Nasopharyngeal Specimen Storage in Straws during the Covid-19 Pandemic in Ivory Coast

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The Institute Pasteur of Ivory Coast in its mission of surveillance and support to public health participates in the response to the Covid-19 pandemic in west Africa. It is involved in the diagnosis by RT-PCR of SARS-CoV-2. Through his Biological Resource Center (biobank) which is the regional biobank of ECOWAS, Institute Pasteur of Ivory Coast keeps a priori or a posteriori nasopharyngeal samples of the Covid-19 pandemic and associated data. This study aims to characterize the key issues driving the high-security straw storage of Covid-19 pandemic nasopharyngeal specimens in Ivory Coast, the key determinants of the process (economic, political, and logistical) and the final storage protocol. Planning was used to examine the technical, economic, logistical, and political aspects of the project. This study was designed to include 100,000 samples from Abidjan, the economic capital, and the interior of the country. The biobanking process of nasopharyngeal samples in straws from a primary tube was carried out using two technologies: manual and semi-automatic. The manual and semi-automatic technologies performed respectively by SYMS (system manual sealing) and PACE machine (CryoBioSystem, Saint Ouen sur Iton, France) permitted to put in high-security straws of the biological samples. The average monthly performance of the straws obtained is 1,685 for the manual technique versus 2,820 for the semi-automatic technique. This performance is in line with the objective set during the design of the present study. The acquisition of the semi-automated technique (PACE) has allowed the biobank of Ivory Coast to reinforce biosafety measures concerning the handling of samples.

PA-02 Conducting an Internal Audit Using ISO/IEC 20387

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How is your management system performing to meet client and stakeholder needs? How has your biobank's SOPs and technical systems been operating? How is your biobank assessing the performance of these items to verify conformance and to support the organization's overall objectives?

Performing an internal audit is a great way to see what actions your biobank is taking to address these questions. One of the main concerns when performing an internal audit is where

to begin and how to review all avenues efficiently and effectively. Here is where ISO/IEC 20387 can help. ISO/IEC 20387 clauses 8.8.1 and 8.8.2 provide an outline of information relevant to performing an internal audit. These clauses are written to provide biobanks with a framework on what to record, implement, perform, and maintain to successfully determine the competency and success of the management system.

While ISO/IEC 20387 sections 8.8.1 and 8.8.2 provide a solid framework, there are other methods that go into a successful internal audit. There are two different methods of audit a biobank can apply under ISO/IEC 20387; one can perform either a vertical audit or a horizontal audit. In addition, there are methods of gathering information a biobank should consider, optimizing the outcome of their internal audit: observations, interviews, and review of records/documentated information.

The overarching purpose of an internal audit is to determine the degree to which stated requirements are being met. In this presentation, I aim to discuss the benefits of an ISO/IEC 20387 internal audit along with touching on some methods to make your internal audit more impactful.

PA-03 How Qatar Biobank is Engaging Young Minds and Supporting Future Biobankers

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Problem: The high school students of today are our potential biobankers of tomorrow, as well as our future research study participants; however, in Qatar, awareness of biobanking as a career amongst this group is low. Qatar Biobank has developed an internship program to engage young minds about the role biobanks play in research while increasing the awareness of Qatar Biobank.

Proposed Solution: Over the past 10 years Qatar Biobank has cultivated and developed a team of competent, professionally qualified staff with a mix of technical and leadership skills that have supported and enabled the growth of the biobank; these people are now supporting high school students interested in biobanking. The current internship opportunities available are designed for students with an interest in laboratory sciences aged 15-18 years (grades 10-12) and offer the opportunity to follow two learning pathways, a wet lab experience or an epidemiological pathway. The wet lab experience will focus on procedures used in Qatar Biobank related to DNA extraction and how DNA is the key to the development of future precision medicine initiatives and offers the students hands-on opportunities with theoretical learning to support their experience while researching future downstream applications of extracted DNA. The epidemiology internship allows students to develop their statistical analysis and interpretation skills using data relevant to a hypothesis. Each learning pathway has expected outcomes for the students that involve reporting their findings to both their school and to the biobank.

Conclusion: While the success of this program may not be determined immediately, it is garnering a lot of interest from

local schools. What is evident is that schools and their students are desperately seeking opportunities that give students a supervised experience with access to data that can produce tangible outcomes, and Qatar biobank is happy to support that while introducing biobanking and the science behind it. In the future, we hope to expand this program to students with interests in other areas such as information technology. While many STEM schools are available in Qatar, this program is available for enthusiastic young minds from a common core educational program as well. Through engaging young minds and raising the profile of biobanking, it is hoped to attract the next generation of biobankers to continue the groundbreaking work of Qatar Biobank.

PA-04 Successful Customer Satisfaction Indices as a Biobank Metric

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Statement of the Problem: A key component and best practice of a Quality Management System is to obtain feedback from users to ensure customer satisfaction.

Efforts to obtain feedback can vary, but a common vehicle for gauging satisfaction has been online surveys. Response rates to these surveys can be statistically low. Methods to increase response rates can often be labor intensive.

Proposed Solution: Customer satisfaction indices (CSI) have been an integral part of the utilization and quality programs of the Cooperative Human Tissue Network (CHTN) since its inception. A survey link is sent to correspond with every biosample shipment.

Originally a mail-back postcard survey was included with each shipment. Then, with the advent of quality email services, the surveys were emailed shortly after a biospecimen shipment was sent. Response rates to these surveys remained lower than industry standards. Several efforts to raise response rates (shortening the survey; increasing follow-up emails, etc.) did not produce favorable results. Current response rates are less than 2%.

We were able to achieve a higher and statistically actionable response rate through the use of a Likert scale single-click survey question which minimizes the time and effort of the respondent. The user opens an email and is asked to click on a 5-star rating system. The option to click-thru to a longer survey and provide more feedback is an option but not required to submit the survey.

Along with this new survey format, a computerized, multi-pronged audit program and the standard operating procedure were implemented. The server communicates daily and quarterly with the technical staff to alert them of CSI metrics and issues. SOPs are in place to immediately address any low-score responses that are received.

Conclusions: Analysis of a Likert scale survey measures the most frequent response to understand the overall sentiment of respondents. It does not require mean analysis, making it an accurate measure for a customer service index.

Since implementing this single-click survey system over the past year, the response rate to surveying has been approximately 17.9% which is consistent with industry standards for statistically accurate customer service indices.

PA-05 A Robust Quality Management System is Essential for High-Quality Tissue Acquisition in Biobanking

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Background: Biobanking is fundamental in the development of new diagnostic and therapeutic strategies, including personalized treatments for patients. At the Princess Margaret Cancer Biobank (PNCB) with an oncology focus, we have been able to bank, utilize, and distribute over 1.3 million high-quality biospecimens and related patient data from myriad cancer types and tissue sites.

Methods: With increasing advances in genomic and molecular techniques that enable cost-effective research at a level of a single cell, the demand for well-annotated and high-quality biospecimens is accelerating globally. To meet this challenge and be able to deliver high-quality specimens for academic and industry research, PNCB has implemented a robust quality management system (QMS) with periodic audits to ensure consistent sample quality across the program. In this 3-pronged approach, we:

- 1) Developed an extended library of standard operating procedures and guidance documents for specimen acquisition.
- 2) Conducted an audit of a randomized sample of flash-frozen specimens banked at different time points, for nucleic acid quantity & quality.
- 3) To ensure that the audited samples, have adequate cellularity to provide a valid genomic result, we prepared hematoxylin-eosin (H&E) slides and assessed the total cellularity, tissue size, and percentage of neoplastic and necrotic cells.

Results: The standardized workflow ensured tracking and reduced ischemic time, prevented tissue contamination, and standardized fixation time. Additionally, there was high yield and no reduction in DNA and RNA integrity numbers (RIN) following extraction across different tissue sites providing high-quality specimens for downstream Next Generation Sequencing. Similarly, pathology review of the same cohort revealed representative H&E slides to have at least 40% neoplastic cellularity to enable a valid molecular result. The tumor assessment was also consistent with the clinical assessment conducted by the clinical pathologist at the time of tumor resection.

Conclusion: We show that establishing a strong Quality Management System in the Princess Margaret Cancer Biobank that processes specimens from across multiple cancer types and tissue sites is essential in delivering high-quality samples, representative of tissue sites of interest, well suited to downstream genomic analysis essential in the development of personalized therapeutic and diagnostic strategies which are the gold standard in cancer research today.

PA-06 Evidence-Based Biobanking: Hit the Ground Running with NCI's Biospecimen Evidence-Based Practices

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Statement of Problem: The quality of a human biospecimen is affected by how it is collected, processed, and stored, concerns that are well known within the biobanking community. The majority of biobanks have implemented standard operating procedures (SOPs) developed in-house to minimize variability introduced during the pre-analytical phase. While adoption of handling practices founded on scientific evidence is a logical step in improving specimen quality, time and monetary investments to identify such practices for inclusion in new or revised SOPs can make this approach impractical on an institutional level.

Proposed Solution: The National Cancer Institute (NCI)'s Biorepositories and Biospecimen Research Branch (BBRB) has developed a document series to address the need for both evidence-based practices and harmonization across biobanks with the release of data-driven, expert-vetted guidance for the collection and handling of several biospecimen types. The aim of each NCI Biospecimen Evidence-Based Practice (NCI BEBP) document is to enable the development of evidence-based SOPs by individual biobanks. NCI BEBPs contain a level of detail that is sufficient for SOP development or revision and include optimal and acceptable practices to accommodate for institution-specific needs and constraints as well as topic-specific summaries of evidence with citations that allow users to review and make modifications based on findings relevant to their specific needs. To date, four NCI BEBPs are freely available to the public on BBRB's website (<https://biospecimens.cancer.gov/resources/bebp.asp>) and through NCI's Biospecimen Research Database (BRD) (<http://biospecimens.cancer.gov/brd>); these BEBPs address snap-freezing tissue specimens; nucleic acid extraction from formalin-fixed, paraffin-embedded (FFPE) specimens; and blood collection and processing practices tailored for either cell-free DNA or cell-free microRNA analysis. Two additional BEBPs on FFPE processing tissue and blood collection and handling for mass spectrometry proteomic analysis are in development.

Conclusions: The NCI BEBP series has been well-received by the scientific community, with more than 66 journal articles citing the document series as a resource and more than 2,000 downloads from NCI's BRD. Community involvement such as serving on an expert panel or sharing a user story relating to how an NCI BEBP was applied at your biobank is welcome and can be submitted to ncibbrb@nih.gov.

PA-07 Evaluation of Collections for Automated Sample Handling and Storage in a Biobank with Diverse Sample Sets

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Background: Clinical biobanks have used automated sample handling and storage solutions for more than a decade supporting large observational and population-based studies. They have accomplished this by use of standardized consumables. However, many clinical biobanks have diverse collections that change over time. The biobank is not typically empowered to use select consumables and must be able to accommodate multiple types. Furthermore, common practice at the clinical sites processing the samples is to add handwritten information to 'sticky' labels applied to the vials that are often not automation friendly.

Method: A multivariate analysis was performed that took into consideration storage temperature, vial volume, vial size,

label format, label application practices, and expected utilization. Volume and vial size were obtained from the sample management system (SMS), while vial type required a physical assessment to capture manufacture and catalog number of the vials being received. Sample utilization was evaluated taking into consideration the age of the sample in the biobank.

Results: Seventy percent of the samples received were in 2-mL vials from 5 different vial manufactures. Different color High-Density (HD) trays were designed to allow for easy visual segregation of the vial types by biobank technicians in the automated store to ensure effectiveness of the tube pickers used in the sample handling process. Specific collections were chosen for prioritization of automated storage based on utilization practices. It was found that 85% of samples requested for retrieval were requested within 3 years of sample receipt.

Conclusion: Automation of sample handling and storage is possible in clinical biobanks that support diverse studies. Through analysis of physical properties associated with samples received and assessment of utilization patterns, automation can be employed to reduce labor efforts and improve efficiency in biobanks.

PA-08 Comparison of Spectrophotometric and Fluorometric Findings on DNA Isolated from Shefa Al Orman Biobank Blood Samples

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Background: Estimation of nucleic acid concentrations is a major critical step prior to downstream several molecular biology applications like sequencing. This study was conducted to compare DNA yield and quality from buffy coat samples using spectrophotometer and fluorometer.

Most mutation analysis kits existing in the market do not identify method of DNA estimation in their methodology for preparation of amplification mix. So, we aim to select a reliable quantification method, to avoid wasting low-volume samples, and to determine the contributors of the differences. This will save the time and the cost of measuring DNA integrity.

Methods: The study was conducted in upper Egypt at Biobank of Shefa Al Orman oncology hospital. Where a total of 125 blood samples obtained from cancer patients (n = 125) and DNA was isolated manually from the buffy coat using QIAamp DNA Mini kit (Qiagen, Hilden, Germany), according to the manufacturer's instructions, the DNA was eluted in 200 μ L buffer.

DNA was quantified by two optical methods using fluorometric through Qubit4 (by qubit TM ds HS Assay Kit) and spectrophotometric (by Multiskan Sky-high microplate instrument) where DNA quality was detected using 230/260 and 260/280 absorbance ratio.

Results: We estimated the concentrations of isolated DNA using two different quantification methods (Micro drop spectrophotometry, Qubit Fluorometry). Hence each method reported a different result of DNA concentration.

Micro Drop reported higher estimates than Qubit, where the measurements were (mean: 45.4 ng/ μ L, median: 42.1 ng/ μ L; range, 4-118 ng/ μ L), (mean :36.3ng/ μ L, median: 36.5 ng/ μ L, range, 4- 85 ng/ μ L), respectively.

The ratio of DNA quantity conducted by spectrophotometer and fluorometer was found to be QS/QF 1.25.

In addition, we examine absorbance readings at both the 260/280 and 230/280 ratios for samples by micro drop plate, as the average of results was found to be 1.8 and 1.76, respectively.

Conclusion: The results demonstrated that fluorometry-based estimation of DNA is more accurate than spectrophotometer because of specific fluorescent dye that directly binds to double strand (ds)DNA. Furthermore, spectrophotometers did not distinguish between dsDNA, RNA, and proteins and this led to overestimation of DNA content resulting from contamination of the sample.

PA-09 Cost Recovery at The Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit Biobank

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Statement of the Problem: The MRC/UVRI and LSHTM Uganda Research Unit Biobank acts as the main storage center for biospecimens for the different projects that store samples within the unit. For sustainability purposes, the biobank was entirely depending on the core funds provided by the MRC.

With the increased number of research projects and growing collections at MRC, the biobank has had to attain more equipment and staff to support biospecimen handling and storage. This led to a constraint on the budget plans that had already been established. Despite financial support from MRC, the long-term sustainability of the biobank remained a major concern.

Proposed Solution: In 2019 a cost recovery scheme was developed. All the biobank processes were assessed to draw up a costing charge for each process. The processes that were highly considered were those directly involved with biospecimen handling/processing, biospecimen retrieval, biospecimen storage, consumables, sample management software, and electricity, which all contribute to the categories of costs. Storage charges were developed and were categorized based on the temperatures the biospecimens were stored at. The storage charges were incorporated into the biobanks' storage request application form. All projects planning to store samples at the unit's biobank are required to complete this form. For biospecimens stored in freezers, the charges include: £0.99 for initial storage service per vial per year, £0.082 for initial storage per vial per month, £0.24 for subsequent fee per vial per year, and £0.02 for subsequent fee per vial per month. For biospecimens stored in liquid nitrogen, the charges include: £1.30 for initial storage service per vial per year, £0.108 for initial storage per vial per month, £2.40 for subsequent fee per vial per year, and £0.20 for subsequent fee per vial per month. Retrieval of biospecimens from freezers costs £0.28 and retrievals from liquid nitrogen cost £0.29.

Conclusions: The cost recovery scheme is now a new added stream contributing to the funding of the biobank. Although the recovered costs do not completely cover the average annual operational costs of the biobank, there has been a slight relief on the core funds that have always been relied on. The current costing tool used is subject to periodic reviews to cater for changes in the economy as well as the inflation and tax rates on the consumables and equipment used in supporting all the biobanking activities.

PA-10 Quality Management Framework of Biobank: Raising the Standards for Cancer Research

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Background: The introduction of an effective quality management system (QMS) into biobank activity warrants high-quality samples and data. Quality is the main foundation for sustainable development of biobank.

Methods: We aimed to devise a practical and effective method which can achieve high-quality samples using available risk assessment tools produced by ISBER. In this paper we will discuss how an implementation of QMS can change the business metrics of a biobank struggling for sustainability. Our strategy to ensure quality include: 1) Standardization of procedures based on published guidelines, 2) our own experience of biospecimen management, and 3) a server-based laboratory management system (Matrix-Gemini-LIMS) that supports biospecimen circulation, securing exact workflow and data tracking. This approach forms a common standard for all the projects and indicates joint responsibility of all involved biobank staff.

Results: Quality checks can be performed at three levels, i.e., pre-analytical (major source for poor sample quality), analytical, and post-analytical levels. Variability at different levels can impact downstream analysis and need to be monitored as per ISBER-2020. Assessment of the following needs to be done: A) samples, B) data, C) equipment, and D) infrastructure.

During sample processing both internal and external quality assurance systems (EQAS) should be in place. This paper elaborates in detail the internal quality procedures to be followed for duration of all projects. Hemolysis reference palette is followed during plasma separation. QC-checks for FFPE blocks are performed by two board-certified pathologists. Re-blocking for tumor enrichment is part of FFPE blocks quality control process. Gross examination of specimen during collection and checking cryopreserved DTCs and PBMCs for viability and contamination is part of internal quality checks. Feedback from researchers for RNA integrity/protein contamination of frozen samples is part of EQAS. Server-based LIMS outlining the way that the information produced, stored covers security, ethics and regulation for personal data protection, storage and analysis to big data by making high-throughput analyses using different modules and audit trail for tracking data manipulation.

Conclusions: Using ISBER-2020 and various risk assessment tools provided by ISBER we have developed our own quality management approach which has helped our biobank in a resource-limited setup to not only sustain but also escalate our business metrics.

PA-11 Maintaining Manual Laboratory Skills in a World of Automation - The Qatar Biobank Perspective

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Problem: The output of Qatar Biobank laboratory processes has the potential to impact the quality of future research in Qatar. In Qatar Biobank, automatic robotic liquid handlers with integrated devices are replacing all critical procedural steps, which can significantly decrease the risk of discrepancies during preanalytical, analytical, and post-analytical stages. The positive impact of laboratory automation is evident, with increased

sample throughput improved consistency and quality of samples and reduced in sample turnaround time from collection to storage. However, there are concerns that staff are becoming deskilled with decreased competency through relying on automation; it is important that manual skills and related theory are maintained if in the event of automation process downtime, a manual backup can be implemented while resulting in the same sample quality.

Proposed Solution: To ensure manual wet lab skills and knowledge is not lost, Qatar Biobank has embarked on a knowledge/practice exercise for the laboratory staff to ensure they are competent in all aspects of our processes and that the quality of our output does not decrease if we are required to revert to a manual process because of out-of-date knowledge and skills. Working closely with the senior laboratory staff, a series of knowledge gap exercises was created; each technologist was given a topic related to a process in Qatar Biobank, resulting in 14 exercises. The aim was to expand the scope of learning to create a deep understanding regardless of the applied protocols and to include the device integration, data integrity flow, and sample traceability and preservation.

Conclusion: Automation of laboratory processes have created a new type of laboratory technologist who is required to have blended skills with basic wet lab skills and a good understanding of automation processes that include validation and software/hardware technical troubleshooting. While automation may remove many of the repetitive tasks, staff must work hard to ensure their basic laboratory skills and knowledge remain up to date in the event their manual skills are called upon as a backup, ensuring uninterrupted workflow leading to preservation of each of the precious samples fulfilling the core role for every biobank. Comprehensive educational programs for biobankers should cover a broad range of skills, with emerging use of technology laboratory science no longer limited to wet lab processes anymore.

PA-12 Utilizing Strategic Communications and Social Media to Drive Qatar Biobank's Public Recruitment

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Background: Qatar Biobank aims to recruit 60,000 Qatari nationals and long-term residents, 18 or older. More than 37,000 participants have already been recruited through its cohesive recruitment strategy. Qatar Biobank has recently started follow-up visits for those who have completed five years since their first registration and launched MRI to its portfolio of check-ups to generate more insights about the participants' health.

Qatar Biobank has been using a multi-pronged participant outreach strategy, powered with proactive public relations activities, to disseminate the underlying messages to the right target audience. The core pillars of the participant's outreach strategy include: participation in conferences/seminars/symposiums, awareness programs, and national events, sustained media outreach, and continued social media activities.

Methods: In addition to monthly social media campaigns, Qatar Biobank participates in monthly media interviews with both broadcast media and print media. Qatar Biobank regularly attends relevant industry events and global awareness campaigns to raise awareness about biobanking. It has been providing opportunities for media and social media influencers to take tours of the facility and personalize their stories. A series of

campaigns around the main national events such as Qatar's national day, the national sports day, and the country's landmark national sports day were launched to humanize the Qatar Biobank story, allowing the population to understand the concept better, encouraging people to register.

Results and Discussion: Qatar Biobank's public participant recruitment strategy and methods successfully enrolled more than 50% of the targeted population in 10 years (with almost 2 years of COVID-19 pandemic interceptions). Qatar Biobank has over 6500 potential participants on a waiting list. Basing the core messages of the communications activities on the benefits personalized medicine brings to the people of Qatar has been of utmost help to the success of the campaign.

PA-13 Towards Virtual SSPA Biobank: New Functionalities Integrated and Tools Developed to Improve Communication with Stakeholders

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Statement of the Problem: Since biobanks are infrastructures for research involving multi-disciplinary teams and an increasing number of stakeholders (donors, end-users, clinicians, funders, personnel), the Andalusian Public Health System Biobank (SSPA Biobank) has the purpose of reporting and communicating them its activity as part of its transparency policy.

Proposed Solution: The SSPA Biobank has implemented a global management system called nSIBAI, co-developed by personnel from the SSPA Biobank and the company Biosoft Innovation S.L., made up of different modules that allow the recording, traceability, and monitoring of all the information associated with the biobank operations. In order to make the activities and results of the SSPA Biobank accessible to their stakeholders, nSIBAI has been completed by different tools and functionalities according to a virtual biobank:

Donors: real-time donations and interface for dynamic consent; participation in the Andalusian Registry of Donors for Biomedical Research.

End-users: services and projects managed, and samples and associated data provided.

Clinicians: contribution of patients' recruitment and collection rate.

Funders: activity and quality indicators of the SSPA Biobank, cost recovery.

Personnel: processing and storage of samples, incidents management.

The data model is being designed in a standardized and normalized way in compliance with international initiatives on data harmonization.

Conclusions: Through nSIBAI as an integrative solution for the management and traceability of the biobank operations thanks to its great capacity and versatility to incorporate new processes and adapt the data model, the SSPA Biobank allows to show and/or report selective information to distinct stakeholders in response its transparency policy.

PA-14 Introducing Scientific and Student Communities to the World of Biobanks Through a Massive Open Online Course: The Experience of the Institut Pasteur

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General information about biobanking can be easily found online. However, there are only a few available online courses that can give the scientific and student communities more practical information on biobanking. The Institut Pasteur develops digital educational courses, through the production and the replay of Massive Open Online Courses (MOOC), as part of its strategic plan, focusing on the development of courses targeted to strategic scientific priorities.

The Biological Resource Centre of the Institut Pasteur (CRBIP) is a biobank which brings together four entities specialized in collections of biological materials, such as bacteria, viruses, cyanobacteria, and human samples. The mission of the CRBIP is to preserve and provide access to qualified, historical, and newly collected microbiological and human resources, primarily for research in the field of human diseases and quality control.

The “MOOC Biobanking” organised by the CRBIP aims to confront the scientific and student communities to the daily work of a biobank, giving examples related to the application of legislation, the characterization of samples, and the organization of a biobank. It is a transdisciplinary program that includes biobanking of bioresources of both human and microbial origin. Topics such as the operational aspects of sampling, collection, transport, and preservation of different types of biological resources are discussed, as well as the organization and management of a biobank and its equipment. Several sessions are devoted to the quality control, and ethical and safety issues. Likewise, legal, and organizational issues related to the provision and the use of biological resources are addressed.

The “MOOC Biobanking” was offered for the first time in 2021, with 2,319 participants from 101 countries having registered in a first season and 1,829 participants from 97 countries in the second season. Participants had access to expert videos, quizzes, and a forum animated by community managers. In addition, a webinar was organised with a live Q&A session. Registered participants had the possibility to obtain an authenticated certificate upon a successful MCQ exam.

In conclusion, the format of this course allows a wide audience to benefit from it regardless of the place where participants are located. Also, the content and the way of presentation were satisfactory to the great majority of the participants. We intend to significantly expand the contents of this MOOC in the coming years.

PA-15 Quality Assurance Through Biobanking Standards

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Statement of the Problem: The use of biobanks in medical research has grown significantly, enabling numerous contemporary research fields like genomics and personalized medicine. Getting access to high-quality, clinically-annotated samples

might be challenging and there is a need for higher informatics capabilities. The requirement for informed consent is seen as an ethical cornerstone of all research involving human subjects; it has been argued that broad consent increases the risk of exploitation of research populations from developing countries. Standard operating procedures (SOPs) are components of good laboratory practices that are necessary for the successful implementation of a laboratory information management system (LIMS) in a biobank. However, as biospecimen collections grow, so do biobanks and there comes a challenge of quality management standards.

Proposed Solution: It is crucial to implement strong quality assurance and quality control systems in biobanks by adhering to previously established standards like the International Organization for Standardization (ISO) 20387. Additionally, it is important that samples are handled in accordance with SOPs for sample collection, labeling, preparation, transport, and storage. Documentation and record keeping support quality assurance by ensuring that every minor but crucial aspect is maintained under control and outputs are consistently of high quality. Additionally, audits, interlab comparisons, benchmarking, and the validation of procedures are crucial. Furthermore, it is necessary to set up cold chain management systems and alarms to track the temperatures of each freezer and refrigerator and to alert lab staff right away if any of them deviate from the ideal standard temperature. This keeps biospecimens' integrity and thus enables the biobank to offer outstanding, dependable services.

Conclusions: Biobanks have a pivotal role in maintaining the integrity of research studies by supplying great quality samples and associated data to researchers. Quality must be implemented in all areas of the biobank at all phases of the biobanking procedures since the quality of the results is only as good as the quality of the samples utilized.

PA-16 To Examine Unapproached/Refusal Metrics Against Self-Reported Ethnic Diversity of Participants of the McCain GU Biobank

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Background: Data have shown that biobanks lack diversity in samples, with the majority of samples coming from patients with European ancestry. Increasing ethnic diversity in biobanks is necessary to understand how diseases may differ across various ethnicities. It is possible that language barriers may influence likelihood of participation. Understanding whether and how language barriers impact participation could be helpful in optimizing participant recruitment in biobanks.

Methods: A retrospective review of unapproached/refusal metrics was conducted. The reasons why patients did not consent to participate in the MGB between 2018, 2019, and 2022 were calculated. These reasons for refusal were then compared to ethnic diversity of participants who consented to participate at those time points. Years 2020 and 2021 were not considered since recruitment was paused due to COVID-19.

Results: For the years 2018, 2019, and 2022, the proportion of patients who were unapproached or refused to participate in MGB due to language barriers were 2.1%, 7.7%, and 1.6%, respectively. In those years, 32%, 18%, and 26% of patients refused to participate in MGB due to “other or no reasons.” The proportion

of MGB participants who reported to be of White/Caucasian ethnicity were 79%, 78%, and 81.5%, respectively. The remainder of ethnicities included South Asian, East/Southeast Asian, Blacks/African Americans, and Hispanic/Latino.

Conclusion: To increase diversity in Canada's largest Genitourinary BioBank would involve applying a multifaceted approach. Approximately, 18%-32% of the population included no reasons as their rationale for declining participation. This would mean that although language barriers only accounted for 2.1%-7.7% of reasons for refusals/unapproached, it could still be a hindrance in active participation.

Additionally, use of translational services has been a cornerstone of diversity; however, having informed consent forms only available in English limits inclusivity. Furthermore, the ongoing pandemic shifted healthcare entirely virtual which meant missing patients were having their bloodwork collected at community labs. Increasing diversity would therefore entail increasing accessibility. Another proposed solution is to reflect on ethnicity metrics and try to meet a targeted approach for clinics. Inclusivity, accessibility, and using targeted approaches based on metrics, provide just the rudimentary pathways to optimize diversity in biobanks.

PA-17 Prior-Knowledge Assessment of Biobank Science Among South African Health Sciences Postgraduate and Senior Medical Students: Integration of Knowledge in Instructional Design and Curriculum Planning

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Problem Statement: There is a noteworthy scarcity of qualified biobank professionals who have been systematically educated & trained in South Africa (SA). Africa's most common topic within international biobank communities is the need for education & training. Education and training will influence a new generation of biobankers who are fluent in the language and competent in the methodology of future research involving biorepositories. The current gap of implementation of biorepository education and training programs in places of learning in SA should encourage the development of contextual programs with respect to challenging aspects such as affordability, applicability, and accessibility unique to the country. Despite the challenge, the development of a suitable range of biorepository education and training programs to match the diverse needs of professionals from various backgrounds is needed. A student-focused research study investigating the level of biobank science knowledge amongst SA health sciences postgraduate and senior medical students has not been undertaken. Outputs of education and training initiatives conducted by biobank professionals at university institutions are not enumerated in literature in SA. This is further perpetuated by the lack of formal biobank science education and training courses in SA. Consequently, this compromises the visibility of the value of biorepositories and the understanding of their relevance in promoting modern biomedical research that seeks to address the burden of diseases in SA and the African continent.

Proposed Solution: The proposed solution is to conduct a research study with the aims to assess awareness of biobank science among South African health sciences postgraduate

students and senior medical students and to develop an integrated biobank education and training program (IBETP) for targeted stakeholders

Conclusions: The envisaged outcome of the study is development of a university-level IBETP on specific biobank science knowledge areas that adapts to students' direct or indirect role in biospecimen science and their existing knowledge on the subject. Furthermore, the development of IBETP is envisaged to be a stepping stone for an educational framework for national curriculum planning through the Medical Collection Cluster of the National Scientific Research Collections Platform (NSRCP) through the Department of Science and Innovation (DSI).

PA-18 Biorepositories and Risk Assessment: Incorporating a Novel Tool of Combining Risk Strategies. A Proactive Approach

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Statement of Problem: Providing high-quality research material is challenging due to the intrinsic nature of activities involved throughout the biospecimen's lifecycle. Investigators need confidence that biospecimens meet standards for fitness for purpose. Components of a biospecimen's lifecycle include but are not limited to activities involved in collecting, accessioning, storing, processing, shipping, destroying, and tracking. Each activity possesses a level of risk to the biospecimen. Current "-omic"- type research utilizes complex platforms and requires high-quality biospecimens to produce reliable data. Challenges include preserving biospecimens stored for "future, unspecified research" where requirements may not be defined as apriori. Biorepositories have an opportunity to proactively identify and respond to risks by incorporating risk assessments as part of their quality management system.

Proposed Solution: Adopting a dynamic risk management method identifies and mitigates potential adverse events before they impact biospecimens and related processes. The proactive design used by the Veterans Affairs Albuquerque Central Biorepository utilizes a team of subject matter experts to determine the scope and classify risk based on biospecimen type. The risk level is assigned using likelihood and severity matrices. Detectability is also considered. Each risk is identified and ranked to its detectability and risk, then categorized by likelihood and severity. A control plan is established based on known factors. Severity and likelihood are reassessed considering the mitigation strategy; then, a determination is made. Significant findings are recorded, and each risk assessment undergoes continuous cycles of improvement through formal review at regularly defined intervals to assess overall effectiveness.

Conclusions: Quality processes and controls in biorepositories play a critical role in research by providing investigators with biospecimens fit for their intended purpose. Confidence in the associated data from high-quality biospecimens provides greater assurance in answering research questions.

Robust quality control steps are needed at every stage of the biospecimen's lifecycle to support the goal of maintaining fitness for purpose. Continuous improvements made through identifying and managing risks can help biorepositories successfully manage biospecimens for valuable research.

Biobanking Profiles

PB-01 BC COVID-19 Biobank Network; Critical Infrastructure to Support Provincial Research

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Statement of Problem: In 2020, amidst the rise of the COVID-19 pandemic, the University of British Columbia (UBC), Canada identified the critical need for a provincial biobank focused on COVID-19. The BC COVID-19 Biobank Network (BCCBN) was established in response to support and enable COVID-19 research.

The province of British Columbia is made up of five health authorities, all of which function independently. Historically, it has been challenging to conduct research across health authorities but in recent years a harmonized research ethics board review has enabled this possibility.

The COVID-19 pandemic highlighted the importance, as a province, to pivot and to develop networked approaches across our health authorities to better understand the disease and more rapidly translate the findings from enhanced collaboration.

Proposed Solution: Under the BCCBN infrastructure, all health authorities are partners to facilitate the coordination, collection, and storage of standardized biospecimens and associated data to enable high-quality research across BC.

The BCCBN has multiple benefits to the research community: decreased duplication of biobanking research infrastructure; improved standardization and annotation of biospecimens and their storage across sites; full compliance with local Research Ethics Board (REB) and regulatory requirements; a transparent biospecimen procurement process, which ensures equitable access to biospecimens by all researchers; and high-quality biospecimens and accompanying phenotypic data.

We developed a provincial recruitment and collection strategy utilizing an electronic consent and data collection form. Biospecimens can be collected in either hospital or private laboratories and subsequently funneled into processing and storage sites across the province and then be distributed for research.

Conclusion: By creating a multi-site networked biobank, we have been able to collect biospecimens more efficiently and effectively across the province and have the potential to include outreach into smaller communities where until now it was hard to participate in research. We have logged all participants and their biospecimens into an OpenSpecimen database which collates inventory at all sites, allowing for building of cohorts across all sites.

With the COVID-19 pandemic potentially declining but forever evolving, we have the tools in place to maintain our provincial approach and address other issues facing the province in addition to COVID-19.

PB-02 The Busselton Health Study Biobank

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The Busselton Health Study (BHS) Biobank is a 57-year database and biospecimen collection on over 30,000 children and adults with in-depth cross-sectional and longitudinal data. Established in 1966, the biobank is one of the longest running epidemiological research programs in the world. It has been described by public health experts as a “national treasure.” It currently has over one million biological samples including serum, plasma, DNA, RNA, sputum, throat swabs, and urine stored in -80C freezers. Detailed self-report (e.g., demographics, smoking history, alcohol consumption, general health, diet and nutrition, medication, medical history, ears and hearing, eyes and vision-, respiratory, food and allergies, sleep, back pain, mood and well-being, depression, physical activity, information technology, community values), objective clinical measures (e.g., lung function; hearing testing; eye testing; full blood picture; urea and electrolytes; glucose, lipid, and liver function tests), genetics, metabolomics, lipidomics, and microbiome data are stored. Linked health data (hospital morbidity data collection, emergency department data collection, deaths, cancer registrations, and mental health data) are also available on samples in the BHS biobank for approved projects. The BHS data and specimen biobank have provided local, national, and international researchers with a diverse, unique, and immediate resource for targeted studies. The BHS biobank is world-renowned in scientific circles, as evidenced by the over 500 peer reviewed research publications and ongoing collaborations with international genetics and normative data consortia. In its role as a “population laboratory,” the BHS biobank is a collaborative resource and is almost unique in its capability to accelerate important and topical population health studies and provide translational outcomes in risk prediction, diagnosis, treatment, and patient care. In an economic evaluation on social return of investment conducted in 2017, it was estimated that the annual increase in Australian Population Health attributable to BHS research is equivalent to AUD \$24,363,178. BHS also contributed directly to a number of significant career advancements and collected data have been used in education and training of undergraduate and postgraduate students.

PB-03 The New Fiocruz Covid-19 Biobank Will Bring Together Human and Non-Human Biological Materials for Research and Development

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Statement of the Problem: In response to the Covid-19 pandemic, the Oswaldo Cruz Foundation (Fiocruz) of Brazil was responsible for initiatives, such as the construction of a Hospital Center and two Diagnostic Units. In addition, Fiocruz has reference laboratories working with SARS-CoV-2, as well as a Genomic Network that is sequencing new coronavirus throughout the national territory. Thus, there was a generation of thousands of human clinical samples related to Covid-19 and isolates of SARS-CoV-2 and its variants of interest for future research and development that needed an adequate repository infrastructure.

Proposed Solution: Fiocruz had dedicated efforts to establish a Biological Resource Center in Health (BRC-Health),

constituted by pathogenic microorganisms and those with biotechnological potential. Additionally, since 2015, the Fiocruz Biobanks Network was created in order to establish and maintain biobanks of human biological material. Both initiatives support research projects that are of benefit and interest to public health.

Recently, ISO 20387:2018 was published, which specifies general requirements for the operation of biobanks. It is applicable to all organizations performing biobanking, including storage of biological material from multicellular organisms and microorganisms.

Within this context, with financial support from the Health Ministry, the Fiocruz Covid-19 Biobank (BC19-Fiocruz) started its operations, on an emergency basis, in December 2021. BC19-Fiocruz will store, preserve, and distribute both human and non-human biological material. BC19-Fiocruz Human Samples Collection is derived from patients hospitalized or tested for Covid-19. BC19-Fiocruz Virus Collection is constituted from the isolation of potentially existent pathogens in the human samples received, as well as the deposit of previously isolated viruses.

Conclusions: BC19-Fiocruz was a quick response to the difficulties encountered in storing different biological materials produced by services recently installed at Fiocruz. Pre-existing projects were incorporated into this initiative, offering expertise and human resources. This structure remains in the institution as an important tool for facing new pandemics and as a component for the preparedness strategies of Brazil, including the storage of other viruses, bacteria, fungi, protozoa, and other representatives of the Brazilian biodiversity, besides human samples associated to other diseases.

PB-04 Value of Biobank Non-Cancer Samples

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Background: Biobanks perform a significant role in research and accurate diagnosis of diseases by collecting high-quality biospecimen. Biobanks establishments have been in increase since the 1970s, reaching a rate of 42% in 1990-1999 and look likely to continue to expand for scientific research. We target to enrich the number of participants in order to investigate the role of genetic factors, lifestyle, and environmental exposures in the development of major genetic diseases of adults and pediatrics. We are tracking patients and obtaining samples for our biobank before they start any type of treatment. In Shefa Al-Orman oncology Hospital (SOH) system, patients start medication within two weeks, and this is the main reason for our missing several patients in SOH biobank. Therefore, we modified the eligibility criteria to track the underdiagnosed patients to enroll a large number of participants and their samples in SOH-Bio.

Methods: At SOH-Bio, eligibility criteria depend on sampling from patients who did not undergo tumor surgery or medical treatment whether chemotherapy or radiotherapy. Therefore, in 2020 we started targeting new cases, specifically underdiagnosis patients instead of diagnosed patients and obtain an informed consent from them before sampling to be able to enroll a huge number of participants before starting treatment.

Results: With our modification criteria, we succeeded in enriching the biobank samples with less cost burden:

In 2018 we collected 1040 biobank cases from a total of 5789 SOH cases with a rate of 17.9%.

In 2019 we collected 1043 biobank cases from a total of 5993 SOH cases with a rate of 17.4%.

In 2020 we collected 1715 biobank cases from a total of 4143 SOH cases with a rate of 41%.

As a result of the modified criteria cases increased more than one-fold.

In 2021 we collected 2130 biobank cases from a total of 5615 SOH cases with a rate of 37%.

In 2022 we collected 1264 biobank cases from a total of 3540 SOH cases with a rate of 35% in 10 months until now.

The consideration that the challenging point faced is the collection of samples from non-cancer cases. The percentage of non-cancer cases in SOH biobank is 4.7% (about 365 cases) from 7700 total biobank cases.

Conclusion: The presence of non-cancer samples is a benefit, as these samples can be used in the progression of clinical and academic research in many cancer studies by being a control group. Their presence will help in decreasing the cost, effort, and time of the researchers.

PB-05 Integration and Synergies of Scientific Core Facilities – a Place for Biobanking? The Westmead Experience

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The Westmead Research Hub (WRH) is a consortium of over 1,400 researchers that study disease mechanisms affecting children and adults. WRH is a long-standing joint venture of over 11 health and medical research partners. WRH receives grant funding of >\$25 million annually across the disease spectrum. A major strength is integration of research with clinical treatment centres, resulting in strong collaborative links between researchers and clinicians, and the hub is recognised for successfully translating its research discoveries into diagnostic, prognostic, and therapeutic solutions. Currently several biobanks are located across the Precinct.

Operationally the hub supports a Scientific Platform model. This comprises 10 core facilities providing cutting edge technology, state-of-the-art instruments, and training and education programs to ensure the best possible scientific support to researchers and beyond. The Westmead Biobank (WB), which operates as a service-model, is one of the core facilities in the Scientific Platform.

Based on the needs of the biobanks at the Westmead Precinct, the WB was established in September 2018 to consolidate activities into a centralized model to further improve the biobanking quality, efficiency, cost-effectivity, and sustainability over the long term. It has subsequently evolved to a fully-fledged service-model biobank offering sample processing and management of biospecimen collections.

A 5-year plan was established that will focus on areas such as infrastructure/services, ethics/governance, QM, and certification.

WB works closely/together with the other core facilities in the Scientific Platforms, under a unified governance structure, building interrelated services, equipment, and relationships to deliver biobanking support and connect end-to-end scientific services to process and analyze biospecimens. Central biospecimen storage facilities, biospecimen processing services, data management, and other biobank services provided by WB will promote quality and sustainability of biobanking activities at Westmead.

So, what does the future hold for the Westmead Biobank? In line with the 5-year plan, the WB is undertaking the following activities: certification (specific for New South Wales), expansion of services to cover the management of multiple collections, implementation of a new LIMS and streamlining researcher access to materials to ensure the strengths in biobanking at Westmead are maximally translated into research outcomes.

PB-06 A Biospecimen and Biomarker Program of the National Biobank of Korea: An Application to the Korea National Health and Nutrition Examination Survey

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The National Biobank of Korea (NBK) established the Biospecimen and Biomarker Programs (BBP) to provide high-quality biological samples and related biomarker panel data sets for various national health survey studies and cohorts. Here we describe one of the NBK Biospecimen and Biomarker Program for the Korea National Health and Nutrition Examination Survey (KNHANES). In 2005, the NBK BBP was first launched for the KNHANES in order to collect biological samples from the participants who consented additionally for the NBK BBP. Until 2021, we had collected biospecimens (DNA, serum and plasma) from over 90,000 participants in NBK BBP for the KNHANES. The NBK generated biomarker panel data sets from 8,248 serum samples that collected in the NBK BBP for the KNHANES VI (2013-2015) in an effort of increasing the value of biobanked samples. Genetic variant data sets were also produced using the Korean Biobank Array for 16,612 participants in NBK BBP of KNHANES VI and VII (2013-2018). These biospecimen and biomarker panel data sets can be linked to KNHANES data to be distributed to researchers for the NBK-approved studies. More than 80,000 vials of biospecimens from the NBK BBP were provided for 41 studies from 2011 to 2021. The NBK BBP will contribute to the advancement of biomedical research and the improvement of the health and welfare of Koreans.

PB-07 Biobank Mississippi – A Biobank Enriched For African Americans

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Background: To report on design and progress of Biobank Mississippi after 5 years of enrollment at the University of Mississippi Medical Center (UMMC).

Methods: Biobank Mississippi is a partnership between UMMC and the Mayo Clinic Center for Individualized Medicine to encourage collaborations across institutions and to build

a new biospecimen and data repository that includes 10,000 participants for biomedical research representative of the UMMC population. Recruitment sites include the UMMC Pavilion, Rapid Care Clinics, and Medical Mall in Jackson, MS. Pop-up recruitment locations in high traffic areas of the main campus have also helped to boost enrollment. Eligible participants are age 18 years and older, able to give written informed consent, and U.S. residents. Collected blood samples are processed into DNA, serum, and plasma. Surveys collect information on personal and family health history, demographics, and education. Clinical data are available from electronic health records for care provided by UMMC. This biobank has governance of an institutional biospecimen access committee that includes a community advisory board. Genomewide association study was performed using the Illumina Global Diversity Array on over 3,500 participants and provides genome-wide genotyping to the researchers.

Results: After a little more than 5 years of recruitment, over 5,200 participants have consented to the project and provided samples and data. Among enrollees, 76% of participants self-reported being African American, 20% white, and 60% female. The mean age is 44 years (range: 19-68). Some self-reported conditions include hypertension (30%), depression (24%), anxiety (22%), osteoarthritis (22%) gastroesophageal reflux (18%), and HIV (13%). The most common cancers reported at enrollment were breast (4%), lung (2%), and colorectal (2%) cancer. The subset with genome-wide genotyping includes 83% African Americans, 15% whites, and 2% other racial groups estimated from genome-wide SNPs.

Conclusions: Biobank Mississippi is a newly established resource for biomedical research with translational value. The access to this large, well-annotated clinical and biological data with diverse samples may lead to innovative and personalized approaches. This will contribute to advances in the precision medicine field and support studies that address health disparities in Mississippi with potential global applications.

PB-08 The Aswan Heart Centre Biobank: A Powerful Resource for Precision Medicine in Cardiovascular Science and Practice

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Background: Aswan Heart Centre (AHC) is a state-of-the-art cardiac care facility to provide high-quality treatment to the underprivileged. The Research Program contributes to solving one of the biggest challenges in Egypt and Africa: cardiovascular disease (CVD). Our aim is to promote a better understanding of disease mechanisms and enhance early prediction and diagnosis of CVD, with the ultimate aim of developing innovative personalized therapeutic solutions and advanced healthcare management strategies. The AHC biobank was established to serve the clinical and research program, which caters continuum of population science, translational, and basic science research.

Methods and Results: The AHC biobank comprises specimens collected from 16,500 individuals (80,000 aliquots) processed and stored from 2014–2022. There are currently 75,437 plasma and serum samples, 7,000 frozen whole blood stored, 6,000 nucleic acid samples, 3,152 cardiac fibroblasts, 2,500 FFPEs, 1,500 frozen tissues, and 926 iPSCs, all from different etiologies (cardiomyopathies, valvulopathies, and arrhythmias). Integrated workflows and protocols were established for specimens' acquisition upon patient consent and in coordination with disease and population-based specialized clinics at AHC. Collected specimens include patient- and healthy subjects-specific tissues and blood, in addition to their derivatives. Specimens inventory and clinical data are translated into REDCap, the electronic data capture tool. Specimens' retrieval for research workflows occurs upon an approved material transfer agreement. A customized cloud-based laboratory information management system (LIMS) is currently under deployment that enables seamless data capture and management, automation, collaboration, and integration. Standard operating procedures are deployed for various sample processing workflows, following documented optimization cycles.

Conclusion: Powerful biobanks are a critical component of a Centre of Excellence in Science and powerful biobanks are essential to ensure global representation and diversity in precision medicine initiatives and biomedical research on regional and global levels. AHC Biobank continues to exponentially grow to accommodate the development of population studies and patient cohorts. Global programs and networks are essential to identify and align lighthouse biobanks and large-scale infrastructure. This is crucial to ensure globally inclusive digital and precision medicine initiatives.

PB-09 University of Mississippi Medical Center Biobank: Growing Biorepository for Collaborative Research

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Background: University of Mississippi Medical Center (UMMC) Biobank was established with an aim to provide high-quality biospecimens with reliable clinical information to investigators to facilitate translational research. Biobank also has collaboration with Mississippi Organ Recovery Agency (MORA) to receive, process, and bank unutilized donated organs for research. Adult and pediatric COVID-19 Biobank was established in March 2020. UMMC Biobank has recently started stem cell collection, culture, and banking project.

Methods: All the biobanking projects at UMMC Biobank are IRB approved and permitted to collect biospecimens like adipose tissue for stem cell retrieval, cancer tissue, and blood samples. Biobank has trained specialists to consent patients using either paper consent form or e-consent using Redcap. For stem cell biobanking, patients are selected who undergo either abdominoplasty, deep inferior epigastric perforators flap surgeries (DIEP), or antero-lateral thigh free flap (ALT) Procedures. Biobank staff obtain informed consent in the presurgical unit and then the fresh tissue following the institutional regulations. Stem cell isolation procedure is performed in the lab dedicated specially for stem cell processing. The stem cell and all other biospecimen processing for research is carried out according to Institutional Biosafety Committee (IBC) and best practices by International Society for Biological and Environ-

mental Repositories (ISBER) for handling of biospecimen. Enrolled participants are registered in the epic beaker database maintained by biobank with demographics and de-identified samples banked in 24-hr. alarm-monitored freezers.

Results: There are nearly 8000+ biospecimens well-maintained at UMMC Biobank available for all research collaborations. The UMMC Biobank is governed by institutional Biospecimen Access committee. UMMC biobank has provided biosamples with relevant clinical data to a number of academic and industry researchers through expertise developed by biobank staff. UMMC Biobank aims to be the largest biorepository research facility in the state of Mississippi.

Conclusions: UMMC Biobank has a mission to use preserved biosamples for future research including studies focused on stem cell utilization research and on the pathophysiology of all types of cancer. In addition, this biobank is keen on collaborations with the scientific community to share the biospecimen for enhancements in the promising field of precision medicine.

PB-10 The Regional Prospective Observational Research in Tuberculosis (RePORT) Brazil Biorepository and its Role in Tuberculosis Research

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Statement of the Problem: Tuberculosis (TB), a disease caused by *Mycobacterium tuberculosis* (Mtb), is present in all countries and approximately 25% of the worldwide population is infected. In 2021, 1.6 million people died from TB. Infected people have a 5–10% lifetime risk of developing active disease, and the risk is higher in people living with HIV (PLWH). Rapid molecular tests improved early TB detection; however, diagnosis remains challenging for certain groups (children, PLWH, extrapulmonary TB). Moreover, treatment adherence is difficult because of the 4–6-month regimen with 4 antimicrobial drugs.

Proposed solution: RePORT-Brazil was established in 2013 with funding from the Brazilian Ministry of Health and the United States National Institutes of Health. One of the main objectives of RePORT is to identify biomarkers that predict progression from latent to active TB, as well as TB treatment cure, relapse, or failure. Cohorts were established in several countries with high TB burdens, enabling a platform for cross-national collaborations that includes data and specimens from thousands of TB patients and their close contacts. In Brazil, enrolled participants are from three different regions (Rio de Janeiro, Bahia, and Amazonas). Participant demographic and clinical data as well as biological specimens are collected and stored at different timepoints. To date, data from 3,300 enrolled participants and 275,000+ samples are available. Specimens

stored at the biorepository are linked to a well-characterized database containing clinical, epidemiological, and laboratory information, allowing researchers to identify such biomarkers. Hosted in Salvador, our biorepository contains 13 -80-degree Celsius freezers storing samples such as whole blood, plasma, DNA, RNA, urine, sputum, Mtb isolates, and QuantiFERON plasma supernatants; and 2 nitrogen tanks containing peripheral blood mononuclear cells (PBMCs). All samples are registered in an inventory system (FreezerPro® Sample Management System) that tracks location and freeze/thaw events. There are 2 backup power options (a generator and a CO2 system), computers, temperature and CO2 monitors, security and remote monitoring systems, biosafety cabinet, stand-by on-site electrician, and 2 staff members.

Conclusion: The RePORT-Brasil TB biorepository is a specific TB biorepository in Brazil. The data and samples from this cohort are linked and stored properly, which allows investigators to address critical TB research needs.

PB-11 Predict, Prevent, Reverse, Cure – The Benaroya Research Institute Biorepository

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Background: Benaroya Research Institute (BRI) is a non-profit research organization in Seattle, Washington affiliated with Virginia Mason Franciscan Health. BRI's mission is to predict, prevent, reverse, and cure immunological disease.

Methods: The BRI Biorepository was formed over two decades ago. BRI collects biological specimens and associated participant metadata from participants with a variety of diseases related to immune function including allergies, asthma, diabetes, infectious disease, cancer, Down syndrome, inflammatory bowel disease, multiple sclerosis, and rheumatic diseases. BRI also collects samples from participants without disease to serve as controls in our studies. Participants are recruited from the surrounding area through online and traditional advertising, targeted recruitment, and partnerships with other institutions such as Virginia Mason Franciscan Health, University of Washington, and Seattle Children's Hospital.

Results: In total, almost 350,000 samples from approximately 14,000 participants are currently contained in the BRI biorepositories. Available sample types include serum, plasma, peripheral blood mononuclear cells, DNA, RNA, whole blood, bronchoalveolar lavage, and urine. 27% of these samples are from participants with Type 1 diabetes, 22% are from healthy controls, 17% are from participants with rheumatic disease, 10% are from participants with inflammatory bowel disease, and the remaining samples are from participants with a variety of other immunological diseases. Last year, investigators accessed over 11,000 samples from our biorepository; over 25% of those were part of collaborations between BRI investigators and academic or industry partners. These samples are essential to the important work done by BRI investigators and external collaborators to understand the underpinnings of immunological disease.

Conclusions: The BRI biobank is a valuable resource for investigators studying immunological disease. The BRI biobank contains samples from a variety of participants and is continuing to grow.

Biobanking Structures

PC-01 The Role and Challenges for Office of Bio-Resources Planning at the Cluster of Biological Resource Centers

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The bio-resource is the key material for biotechnological studies and industries. Due to the importance of the bio-resource, many countries have been encouraged in collection and management of bio-resources. Recognizing the importance of bio-resources, Korea has made a considerable effort to acquire these resources since the 2000s. As a result, by 2021, Korea had amassed 16,667,579 bio-resources and had established 237 biological resource centers. However, due to changes in domestic and international circumstances, such as the forced entry into the Nagoya Protocol and the global pandemic crisis, it is necessary to change the quantitative policies for the acquisition of bio-resources and the establishment of biological resource centers. The 3rd Korean national strategy for bio-resources is announced in July, 2020. The main changes of 3rd strategy are the acquisition of biological information and the utilization of bio-resource. Due to the utilization of bio-resources, biological resources centers are clustered in 14 units such as human tissues, pathogens, cell lines, experimental animal model, microorganism, plant extracts, and so on. Due to the national strategy for bio-resources, 14 bio-resources clusters and 1 general support unit (Office of Bio-Resource Planning, OBRP) are organized and work together for enhancing the utilization of bio-resources in Korea. In this presentation, we introduce changes after 3rd national strategy for bio-resources. In addition, we introduce a harmonized national measure for biological research resources in Korea and the roles of the OBRP for enhancing utilization of bio-resources.

PC-02 Biobank Networks in Korea

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A national project of the Republic of Korea for supplying qualified bio-resources had begun in 1995. As the number of biobanks had been increased, the central center controlling the biobanks had been established in 2008. In the need of legal basis, all related ministries had managed their biobanks and organized the 'Korea Biological Resource Center Alliance' to manage the biobanks on a national level. However, over the past 10 years, the function of biobank had been supposed to focus more on utilization in the related fields than supply to them. 'The 3rd Master Plan for National Biological Research Resources' was established to promote the environment for the users and utilization of bio-resources.

One of the strategies for the users and utilization of bio-resources is to organize and promote 14 national bio-resource fields, which we called a 'cluster.' The 14 clusters include human-derived material, stem cell, pathogen, animal model, etc. The 3rd master plan has been established for bio-resources to be efficiently utilized in research and industry with categorizing biobanks in the related fields into a cluster. Each cluster is composed of central banks and branch banks. The central banks,

as control towers which would be more than one, support and manage branch banks in their cluster. For example, animal model cluster has two central banks, which deal with animal, mouse, and related research data. Their branches are primate, drosophila, zebrafish, xenopus bank, etc. Each branch bank collects and manages its own resource for supplying to research and industry fields. Their central banks collect the data of their branches for the integrated system for public service and manage the projects of their branches.

The environment of clusters is supported by the related ministries. For example, the ministry of science and ICT holds 'network day' with their central and branch banks to communicate for the political and budgetary supply. Also, the banks in the ministry hold the meetings for the subcommittee for practical issues such as data integration, biobanking standards, and promotion. There is another committee in the banks to list-up agenda for the network day. Finally, all banks from the related ministries have the government department meeting to communicate their annual performances and plans.

The biobank network in Korea has been expected for the joint response national issue and global network and the convergence project

PC-03 A Non-Traditional Approach to Biobanking: When a Non-Profit Meets a Large Pediatric Medical Center

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Statement of Problem: Down syndrome (Ds) is the most commonly diagnosed chromosomal condition. Yet, access and availability to high-quality, well-annotated biospecimens to help drive clinical and translational research are extremely limited. This has hobbled the pace of scientific discovery in Ds research in the U.S. and globally. In 2019, research advocacy group DownSyndrome Achieves (DSA) partnered with the Discover Together Biobank and the Division of Human Genetics at Cincinnati Children's Hospital Medical Center (CCHMC) to launch a national, dedicated biobank for Ds with the goal of addressing this very problem. DSA Biobank aims to not only solve the problem of limited biospecimens, but also provide a resource where families feel comfortable participating in research, particularly for a community with no historical or cultural grounding in research at all.

Proposed Solution: A targeted procurement model that diverges from more conventional biobank models, including: 1) collection of biospecimen types based specifically on researcher needs vs traditional un-targeted collection; 2) expansion of REDCap utilization for e-consent structure, database tracking for medical questions, and dashboard reporting; 3) engagement of third-party phlebotomy service for home/remote collection; and 4) adoption of lab operations supporting IRB approved protocols with third party phlebotomist services.

Conclusions: Adoption of non-traditional processes enabled engagement and outreach to rare populations such as Ds. Moreover, this hybrid partnership approach enhanced long-term sustainability, increased efficiency from a single IRB site, and provided a solid foundation for collaboration between a non-profit charitable organization and large pediatric medical center.

PC-04 Nuts and Bolts of a Cancer Moonshot Biobank for Precision Medicine

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Statement of the Problem: There is a lack of longitudinal biospecimens collected from diverse patients representing the US population and there is a lack of annotated, high-quality samples collected with a single SOP and an infrastructure. This is needed to understand and combat mechanisms of tumor resistance and to explore tumor sensitivity to anti-cancer therapies.

Proposed Solution: The Cancer MoonshotSM Biobank (moonshotbiobank.cancer.gov) is a National Cancer Institute (NCI)-sponsored study that aims to accelerate cancer research through the collection of longitudinal blood and tissue biospecimens from patients with advanced cancer receiving standard of care therapy. To ensure that the collection represents the diversity of the US population, the biobank has teamed up with NCORP community hospitals across the US to enroll participants for the study. Biospecimens are collected from a diverse set of participants representing several cancer types. Efforts have focused on biobank governance, protocol development, clinical data management, biospecimen source sites, and participant and provider engagement. The program utilizes electronic informed consent. A third-party single IRB serves all sites. To provide value back to participants and their medical providers, clinical biomarker assays are performed in a CLIA-certified laboratory on tumor samples; a report detailing clinically relevant genomic alterations is sent to participants and their provider. An interactive, web-based platform has been developed to facilitate secure communications and engagement in the program from all involved – patients and health care providers. A portion of eligible fresh tumor specimens are used to establish patient-derived models for future research needs. Extensive clinical data and biospecimen data, along with molecular profiling data generated from the donated specimens, is deposited into an NIH data repository, the NIH Database of Genotypes and Phenotypes (dbGaP), under controlled access to protect patient privacy. Specimens collected will be available for researchers to request through an online catalog. Clinical and imaging data collected for the first 50 participants have been released in dbGaP and The Cancer Imaging Archive (TCIA), respectively, with a pipeline established for subsequent data releases.

Conclusion: The Biobank will provide a networked biospecimen resource which will serve the goal of the Cancer Moonshot to accelerate research progress in cancer.

PC-05 MBRIO Project: Identification of Technical and Non-Technical Needs to Implement Biobanking Practise for Health Research in Indonesia

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Introduction: Biobank concept and practise needs to be improved in Indonesia, not only about its role as infrastructure in research or clinical service, but also non-technical issues on ethic, legal, and social (ELSI). MBRIO (Medical Biobank for Health Research in Indonesia) Project of Universitas Gadjah Mada (UGM) Biobank is funded by Indonesia Endowment Fund for Education for 2 years (2019 and 2022) with the objectives: 1. To identify ELSI of biobanking in Indonesia; further used for 2. To develop hospital-based biobank concept into a basic model for Indonesia practise.

Methods: For objective one, series of in-depth discussions and focus group discussions among different stakeholders were done to identify expectation and gaps for biobanking in health research to develop in Indonesia. For objective two, a biobank model was developed and detailed into 4 modules: governance, informed consent, biospecimen collection, and data management system; this model is further tested prospectively in hospital based setting, by employing case report form (CRF) to ensure the completeness of the process. We aim for 20 subjects (hospital patients) following complete process from inclusion, collection of tissue and blood samples, processing and storage in biobank facility.

Results: For objective one, we could identify the gap in legal and ethical aspects, including sample and data long-term storage in use and sharing, as well as data ownership. These issues require to be formally discussed and managed to ensure the growth of biobanking in Indonesia. Further, academic paper is finalized to be proposed to the authorities as one resource for development of national regulation. For objective two, the four modules were further developed into protocols and standard operational procedures (SOP), tested in UGM Academic Hospital. By walking through the process, (so far) we can identify that: 1. Understanding of stakeholders on the importance of biobank is the primary key; 2. continuous communication among different hospital departments ensures conformity to the protocol; 3. understanding on regulation of patients' data sharing will enable the use of samples and parallel data. Further we will use results of the MBRIO project as basic recommendation to build alike structure in Indonesia.

PC-06 Qatar Biobank Connecting Nodes Building Networks in the Pursuit of Precision Health

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Statement of the problem: In the field of medical care, we are living in a transition era aiming towards Precision Health. In this transition, biobanks play a key role, from scientific research to the development of new treatments, diagnostic procedures, and prevention approaches. Biobanks are important assets for the healthcare infrastructure, ensuring the standardized collection of specimens and annotated data enabling the precise diagnosis and treatment. The failure to efficiently translate research findings into healthcare delivery is mainly due to the challenge of miscommunication between the various stakeholders in a healthcare system. This is a showcase on how Qatar Biobank (QBB) works toward bridging the gap between medical research and clinical practice.

Proposed Solution: QBB management regularly re-visits and reviews the operational plan to meet the requirements of its stakeholders, trying to meet their expectations and align them with QBB strategic objectives. QBB as an integrated research platform provides a research environment that may foster multidisciplinary research. Mechanisms are in place to

strengthen the communication and the collaboration between the different stakeholders by providing a framework warranty-ing and manage ethical issues, privacy, data sharing, etc. QBB was able to coordinate national collaborative efforts, bringing together the healthcare providers (Sidra Medicine, Primary Health Care, and Hamad Medical Corporation), Academia, and Research infrastructures to facilitate the translation of research findings into precision medicine practices within its healthcare system (i.e., Q-Chip), building and setting the expectations of the management of precision health in the country. Moving forward, QBB is continuously exploring various partnership opportunities at the international level. The goal is to create long-term business relationships that offer high value and serve its objectives as well as to have an impact in the research and health ecosystems worldwide. QBB extended network includes collaborations with countries in the EU (i.e., Spain, Cyprus, etc.), Malaysia, and India. It is also worth mentioning that we have started to curate QBB data to be used for AI models.

Conclusions: QBB is continuously trying to achieve trusting governance relationships by providing appropriate environment for collaboration, build collaborative networks, and pursue engaging activities to enhance trust and connect research to clinical practice enabling precision health.

PC-07 One-Stop Shopping: Aligning Biobank and Clinical Laboratory Tissue Services to Optimize Quality, Efficiency and Investigator Experience

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Background: The Biorepository and Precision Pathology Center (BRPC) relies on a strong partnership with Duke Health Clinical Laboratories (CL) to safely procure patient biospecimens for research. BRPC also provides researchers with a wide menu of biospecimen services including immunohistochemistry (IHC). CL provides its clinical assays to researchers at a fraction of clinical cost. Investigators needing services from both facilities have historically had to navigate two different systems within Duke. Greater alignment of BRPC and CL has raised the quality standard for research IHC to the level of clinical testing, prevented redundant infrastructure, and allowed the development of a unified store-front to optimize investigator experience.

Methods: Investigator requests for IHC were previously separately routed through BRPC and CL by complex email communications to confirm separate test menus and billing structures. In 2020, BRPC (1) ceased IHC testing that was redundant to CL testing, (2) validated all new IHC assays to the standard set by the College of American Pathologists (CAP), (3) offered to investigators a combined test menu of CL and BRPC IHC assays, and (4) established a "BRPC submitter code" allowing BRPC to route investigator payments for CL IHC through BRPC. In addition, in 2021, BRPC's CAP accreditation was renewed, confirming clinical standard for IHC testing.

Results: In 2019, BRPC did not centralize IHC testing for investigators. In 2020, BRPC routed \$5,512 worth of IHC testing to CL as a service to investigators who were using both BRPC and CL to support their research. In 2021, BRPC routed \$24,826 worth of IHC testing to CL. In the first 10 months of 2022, BRPC routed \$95,111 worth of IHC testing to CL. The BRPC currently offers 55 IHC antibodies and CL offers 237 separate antibodies; there is no redundancy, and all assays are covered under CAP accreditation that includes IHC assay validation to the CAP/clinical standard.

Conclusion: Alignment of IHC testing for research through both BRPC and CL has optimized and aligned quality to the clinical standard, prevented redundant infrastructure, and improved the investigator experience by aligning test ordering, specimen handling, and billing infrastructures within our large academic medical center. This is a model that could be expanded to other similarly-structured academic medical centers.

PC-08 Overview of Strategic Planning and Progress of Korea Biobank Project (KBP4.0)

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Korea Biobank Project (KBP) is one of the first government-led human biobank initiatives to foster nationwide biobanking ecosystems for eventually promoting biomedical and healthcare research. Here we describe the evolution of the KBP from the initial phase of the project (KBP 1.0) to the latest phase of the project (KBP 4.0), especially focusing on a strategic plan of KBP 4.0. Since KBP started in 2008, the KBP has supported biobanking of over one million participants in the National Biobank of Korea and hospital-based biobanks. The KBP 4.0 envisions biobank-driven R&D innovations in biomedical research and healthcare. Major strategic goals of KBP 4.0 include: strengthening functions, roles, and leadership of the National Biobank of Korea; fostering specific target disease-oriented biobank subnetworks with encouraging public-private partnerships; and establishing sustainable biobanking ecosystems to support standardization and education as well as ELSI frameworks. To achieve these goals of KBP 4.0, we designed five funding programs to support 1) the Collaborative Subnetworks for Specific Target Disease-based Future Biobanking (n=10 subnetworks), 2) the Biobank Innovation Consortia for Biomedical and Healthcare Research including BICWALZS (n=2 consortia), 3) the Establishment of Integrated Biobanking Service Platforms for the Korea Biobank Network (n=2 platforms), 4) Data Generation and Utilization of Legacy Biobanked Samples, and 5) Biospecimen Science and Biobanking Technology Development. The first three of these programs was funded to start in 2021, but the others are underway for funding. The KBP continues to evolve to address national and global challenges and trends in biobanking in order for KBN to become an invaluable bioresource infrastructure to accelerate future medicine.

PC-09 Implementation and Continual Enhancement of a Biospecimen Information Management System at an Academic Medical Center

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Background: Establishing a biospecimen information management system (BIMS) is essential when creating a new institutional biorepository. In an academic medical center with a decentralized organizational structure, cross-functional teams

allow for subject matter experts to collaborate, share knowledge, implement, and enhance information technology solutions. Leveraging past experiences at Weill Cornell Medical College (WCM), the Institutional Biorepository Core (IBC; part of the Office of the Research Dean) and Research Informatics (RI; part of Information Technologies & Services) formed a core team to oversee the selection, delivery, and support of a BIMS.

Methods: The core team consisted of an engineer, a project manager, a business analyst, the IBC director, and the RI director. For BIMS selection, we developed a request for proposal (RFP) process which included sessions with the working group to identify system requirements and other factors to consider in the selection process. The core team and other key stakeholders attended vendor presentations before selecting a final vendor. Due to the efficient performance of the core team, we maintained the same structure for delivery. The group worked closely with the BIMS vendor and held in-depth working sessions to understand the core functionality of the BIMS, the outcome of which was a set of refined requirements for the desired configuration. The vendor configured and delivered the BIMS to the core team for testing. After the implementation and go-live of the BIMS, the team expanded the core microstructure to two business analysts, two engineers, the IBC director, and the RI associate director. This transition from project to operational support and continuation service improvement (CSI) followed IT industry best practices (ITIL ITSM and PMI PMBOK). The senior business analyst performs the ITIL role of Service Owner and oversees the technical roadmap of the BIMS, such as determining when to apply software patches, impact analysis of version upgrades, etc.

Results/Conclusion: Vendor selection took 8 months of effort spread over two years. Changes in senior institutional leadership delayed the process; having a consistent core team sustained the effort. Successful vendor selection was due to the strength & engagement of the core team. Forming a functional microstructure focused on biobank informatics ensured the delivery of a high-quality BIMS and a framework for efficient enhancement and operational support.

PC-10 Streamlining the Collaboration Process for Industry and Academic Requestors

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Statement of the Problem: To accelerate collaborative research and fulfill the growing needs of the biomedical community, biobanks have a responsibility to develop efficient pathways for requestors to gain access to consented, well-annotated, and appropriately stored biospecimens and data.

Solution: UHN Biospecimen Services, in order to increase efficiency, promote sample utilization, and decrease timelines, has established a 6-step standardized workflow to streamline the collaboration process.

1. Initial Request: Established multiple avenues for requestors to discover and connect with the program such as through global biobanking directories, multiple online websites, or through social media pages. All communication channels are integrated through a shared email account that is reviewed daily.
2. Feasibility: Standardized Sample Request Form (SRF) is forwarded to potential requestors to provide information

on specimen requirements, data, ethics, and timelines. The SRF is reviewed and confirmed by four internal teams: The Data team, Specimen team, Ethics team, and lastly the Financial team to develop a cost-recovery model.

3. Confidentiality Disclosure Agreement (CDA): CDA is executed to allow both programs to exchange confidential documents with respect to the project or requested services.
4. Research Ethics Board (REB) application: REB template provides a detailed summary of all the information and documents required for the REB application.
5. Material Transfer Release: Approval from REB allows the program to then coordinate material and data transfer and confirm cost recovery of services from the client/collaborator.
6. Client Survey Feedback: The Client Survey Feedback is completed following the delivery of the requested services. Feedback on sample quality, delivery, and collaboration process ensures that the biobank continues to develop according to industry standards.

Conclusion: UHN Biospecimen Services, by streamlining the collaboration workflow, has been able to significantly increase the number of collaborations received, decrease timelines, increase transparency, as well as communicate clear and efficient pathways to both industry and academic requestors that are interested in biobanking services. To date, over 60% of requests received have been approved or are currently in progress.

Biodiversity/Environmental/Animal Repositories

PD-01 The First Biobank Internship in Egypt: Focusing on Undergraduates' Hands-on Experience in LIMCs

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Introduction: Biobanking techniques and regulations are relatively new concepts in Egypt. Spreading the knowledge by targeting undergraduate students would positively affect research by increasing the future educated biobank specialists. A free program was designed to engage undergraduate life sciences students in the biobanking field, starting from preparing standard operating procedures (SOPs) and criteria for choosing participants to appropriate storage conditions and managing possible errors. In this poster, details of the program and its content will be discussed as a guide for other organizations involved in biobanking education.

Statement of Problem: Lack of hands-on experience opportunities in the field of biobanking in Egypt and unknowing about the biobanking concept itself among undergraduates.

Solution of the Problem: A one-month internship program was designed to help students to get their roadmaps in the scientific research field through structured and connected sections working on state-of-the-art instruments with minimal costs. First, they were introduced to biobanking basic legal, ethical, and technical regulations and needed knowledge to start a biobank unit. Secondly, there was the creation of SOPs and hands-on experience with sample processing. Finally, they got familiar with handling storage equipment and practicing Problem Based Learning (PBL) Sessions on Real-Life Scenarios in Biobanks. Along with basic knowledge, they were introduced to comparative studies by comparing three DNA extraction kits from blood and the concept of nano-cryopreservation through

the synthesis of three nanomaterials. They also were introduced to academic writing through summarizing and presenting biobank-related articles and reviewing possible therapeutics based on small interfering RNA. Clinical biostatistics and bioinformatics were part of the internship to have an overview of the whole clinical research process.

Conclusion: A well-tailored curriculum covering both theoretical and practical sides was created to cover the fundamentals of biobanking and cryopreservation. The program was conducted for the first time at a MARC summer internship. It will be generalized to all science-related students for the sake of adding value to the initiatives of biobanking education as a successful model.

PD-02 Biorepository Capacity for Emerging Infectious Disease Outbreak Research

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Background: Emerging infectious disease (EID) outbreaks require rapid research with high-quality samples to characterize pathogens, discern transmission dynamics, and develop medical countermeasures. The Centers for Research in Emerging Infectious Diseases (CREID) Network assesses and strengthens biorepositories in more than 20 countries with elevated risk for EID outbreaks.

Methods: In 2021 the CREID Network surveyed more than 40 biorepositories' capacity to support EID outbreak research. Topics included sample types stored, procedures, equipment, biosafety, shipping, and quality assurance. The survey was deployed via RedCap in early 2021. Participating institutions reviewed and updated their responses in mid-2022.

Results: The survey was completed by CREID Network biorepositories across Africa, Asia, the Americas, and Europe. Nearly all store human and/or animal samples and almost half store arthropods. Sources include livestock, wildlife, research and companion animals, and markets. More than half store viral isolates with pandemic potential. Sixteen sites are qualified at or above biosafety level three (BSL-3).

Many CREID Network sites are in areas with limited infrastructure. More than half reported power outages or mandatory utility throttling. Equipment is connected to backup generators in many but not all sites. Thirty-three sites have liquid nitrogen on-site. Fuel for generators, LN-2, replacement parts, and funding to maintain equipment remain serious challenges in lowest resource settings.

Twenty-five sites reported using SOPs or protocols to collect, process, and store samples. Many agreed to share and train other sites on them. Fifteen sites participate in regular external audits and 11 operate under formal quality systems. Most sites have access to international couriers and can obtain import/export permits. Their priorities for support include material transfer agreements, import/export permits, and biosafety.

Conclusion: The CREID Network identified a range of sample types, sources, and capacities for EID outbreak research support across its biorepositories. Since 2020 these sites have enabled studies on arboviral spillover in Latin America, animal-to-human COVID-19 transmission in Asia, and Rift Valley Fever risks in Africa. These biorepositories have requested training and resources to ensure they can handle samples safely and preserve them with fidelity. Many have also offered to share tools and knowledge through South-to-South training and support.

PD-03 Epicatechin Affects Sperm Cryocapacitation through Changes in the Levels of Reactive Oxygen Species

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An attractive option to prevent sperm cryocapacitation lies in the administration of biologically active substances with motility-promoting, membrane-stabilizing, and antioxidant properties. Out of these, epicatechin (EPI), a plant-derived secondary metabolite, has shown promise in the prevention of the sperm plasma membrane, mitochondria, and DNA deterioration. As such, the aim of this study was to assess the effects of selected EPI doses on the motility and capacitation status of cryopreserved bovine spermatozoa alongside its effects on the production of major reactive oxygen species (ROS), namely superoxide, hydrogen peroxide, and hydroxyl radical. Semen samples from 12 breeding bulls were cryopreserved in a commercial extender containing 25 μ M, 50 μ M, and 100 μ M EPI or carrying no supplement. Sperm motility was evaluated with computer-assisted semen analysis while the capacitation status was assessed with the chlortetracycline assay. Quantification of superoxide was performed by the nitroblue tetrazolium test, hydrogen peroxide production was assessed with the Amplex Red assay, while the concentration of hydroxyl radical was quantified using the aminophenyl fluorescein reagent. Our results indicate that the presence of 50 and 100 μ M EPI resulted in a higher sperm motility ($P < 0.001$; $P < 0.0001$) and a concomitant decrease of prematurely capacitated spermatozoa ($P < 0.01$; $P < 0.001$). Exposure of cryopreserved spermatozoa to particularly 50 and 100 μ M EPI lead to a significantly lower concentrations of hydrogen peroxide ($P < 0.01$; $P < 0.001$) and hydroxyl radical ($P < 0.01$). We may suggest that EPI as an alternative cryosupplement may offer higher protection to premature sperm capacitation, particularly by stabilizing the levels of ROS that may promote cryodamage to male gametes. This publication was supported by the Operational program Integrated Infrastructure within the project: Creation of nuclear herds of dairy cattle with requirement for high health status through the use of genomic selection, innovative biotechnological methods, and optimal management of breeding, NUK-LEUS 313011V387, co-financed by the European Regional Development fund, by the Slovak Research and Development Agency grant no. APVV-21-0095 and by the CeRA Team of Excellence.

PD-04 The STAMP Egg Collection at the NIST Biorepository

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Seabird tissues, particularly seabird eggs, have demonstrated a valuable role in the monitoring of environmental pollutants. As such, in 1999, the Seabird Tissue Archival and Monitoring Project (STAMP) was established as a long-term collaboration between the National Institute of Standards and Technology (NIST) and a multitude of local, state, and federal agencies to monitor trends in Alaskan marine environmental quality. To do

so, standardized protocols and practices were implemented including (1) the collection of seabird eggs with minimal contamination, (2) the processing of eggs and cryogenic archival of egg tissue subsamples to ensure chemical stability during long-term (decadal) storage, (3) the maintenance of sample history records, and (4) the analysis of archived subsamples for monitored contaminants. Since STAMP's inception, target Alaskan species have included common murre (*Uria aalge*), thick-billed murre (*U. lomvia*), black-legged kittiwake (*Rissa tridactyla*), glaucous gull (*Larus glaucescens*), and glaucous-winged gulls (*L. hyperboreus*).

In 2010, the 111th US Congress provided funding to NIST in an effort to expand its capabilities and resources into the Pacific region. In response, NIST, in partnership with Hawaii Pacific University, expanded the specimen banking components of several ongoing programs, including STAMP, to the Pacific Islands (i.e., the Hawaiian Islands, and Midway and Palmyra atolls). Target Pacific species have included Laysan albatross (*Phoebastria immutabilis*), black-footed albatross (*P. nigripes*), wedge-tailed shearwater (*Ardenna pacifica*), sooty tern (*Onychoprion fuscatus*), gray-backed tern (*Sterna lunata*), masked booby (*Sula dactylatra*), and brown booby (*S. leucogaster*).

Over these last 20 years, STAMP has amassed approximately 1850 individual eggs spanning 45 Alaskan colonies and 750 individual eggs spanning 28 Pacific Island colonies. Through its use in many research endeavors, the STAMP egg collection has proven an invaluable resource in environmental monitoring and will remain so for years to come. Use of these samples is highly encouraged and may be requested through STAMP's online tissue access policy.

PD-05 Implementing the ISO 20387: The Animal Resource Bank Experience, Transition from the ISO 9001 to ISO 20387

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Statement of the Problem: Due to the importance of model animal resources, Ministry of Science and ICT(Korea) has established an animal core center as central bank and 7 animal resource banks. Animal resource banks are committed to establishing a scientific research infra by providing resources and related information. For standardization of animal resources, the standardization team of the central bank improved QMS and introduced ISO 9001. Nevertheless, standardization of animal resource is still difficult and insufficient. In the standardization of animal resources, the most important thing is to decide what standard to use for standardization, and the standard should be applicable to various animals.

Proposed Solution: To optimize management process of animal resource as well as for well-controlled ethical constraints, animal resource banks should adopt the same international standard. The standardization team implemented the ISO 20387 for the first time in the field of animals of Korea at Laboratory Animal Resource & Research Center, a mouse resource bank. The ISO 20387 focuses on the QMS, 'impartiality,' and 'confidentiality,' but these requirements were already applied in mouse resource bank through the ISO 9001. Most of the ISO 20387 requirements are process related to life cycle of

resources. During the introducing ISO 20387 process, the mouse resource bank encountered some challenges and paid attention to the singularity. First, the animal itself is not capable of storage activity. Conversion of a resource to another type enables preservation or storage. Second, factors involved in the integrity of resources should be monitored during the transport. Monitoring process should be established in a proper way to satisfy both the provider and the recipient. Third, examination and testing methods for the management of resources are often based on experience. In this case, it may make it difficult to implement the ISO 20387 requirements 'verification' and 'validation'. Finally, various management experiences for each animal can be documented as process, and that process is very scalable.

Conclusions: We reviewed the process of firstly introducing the ISO 20387 in the field of animals, in Korea. We have implemented this new international standard to optimize resource bank activities and maintain the high quality of animal resources. Thereby, according to our mission and vision, we can increase our international activity and cooperation as animal resource bank.

PD-06 Role of Reduced Glutathione in Extender for Liquid Storage of Ring-Necked Pheasant Semen

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Background: Artificial propagation of ring-necked pheasant through semen preservation is of significance as this species is facing enormous threats in its natural habitat. Semen preservation inevitably induces oxidative stress and exogenous antioxidants need to be investigated for preservation of ring-necked pheasant semen. Therefore, the current study was conducted to investigate the role of GSH in extender on the liquid storage of ring-necked pheasant semen.

Methods: Semen was obtained from ten sexually mature males, evaluated for sperm motility and pooled. Pooled semen was aliquoted for dilution with Beltsville poultry semen extender (1:5) at 37°C having GSH levels of 0.0mM (Control), 0.2mM, 0.4mM, 0.6mM, and 0.8mM. Extended semen was gradually cooled to 4°C and stored in a refrigerator (4°C) for 48 hours. Semen quality, including sperm motility, membrane integrity, viability, acrosomal integrity, and DNA integrity, was assessed at 0, 2, 6, 24, and 48 hours.

Results: Sperm motility (%), plasma membrane integrity (%), viability (%), and acrosomal integrity (%) were recorded higher ($P < 0.05$), while DNA fragmentation (%) was recorded lower in extender supplemented with 0.4mM GSH up to 48 hours of storage compared to 0.2mM, 0.6mM, 0.8mM GSH concentrations and control.

Conclusion: It is concluded that 0.4mM GSH in extender improves sperm quality parameters of ring-necked pheasant during liquid storage up to 48 hours at 4°C.

PD-07 The MARS PETCARE BIOBANK: Establishing a Longitudinal Study of Health and Disease in Dogs and Cats

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Background: The veterinary care of cats and dogs is increasingly embracing innovations first applied to human health, including an emphasis on preventative care and precision medicine. Large-scale human population biobanks have advanced research in these areas; however, few have been established in veterinary medicine. The aim of the MARS PETCARE BIOBANK™ (MPB) is to establish a longitudinal study and biobank, recruiting 20,000 healthy domestic cats and dogs, at a target rate of ~1000/species/year, over a 10-year period, following them as they age and develop disease. Recruitment of dogs launched in March 2022 and cats in June 2022. Here, we describe the MPB and discuss its potential as a platform to increase the understanding of why and how companion animal diseases develop and to advance individualised veterinary healthcare.

Methods: Recruitment is through Mars Veterinary Health hospitals (VCA™ Animal Hospitals, Banfield® Pet Hospitals and BluePearl™ Specialty and Emergency Pet Hospitals) in the USA. After informed consent, pets attend an annual veterinary examination where biological samples are collected for plasma and serum separation, whole blood stabilised for RNA extraction, and feces stabilised for DNA extraction. At enrollment, a cheek swab is also collected for phenotypic and disease variant genotyping (Wisdom Health, Vancouver, WA, USA). Biological samples are transported to local Antech Diagnostics laboratories, where blood biochemistry and hematology are performed and plasma, serum, and fecal material are prepared, aliquoted, and frozen at -80°C for long-term storage in a central biobank facility. DNA is extracted from blood samples for whole genome sequencing and from feces for shallow shotgun metagenomic analysis. To assess activity levels, dog owners are provided with a collar-worn accelerometer (Whistle™, San Francisco, CA, USA). Owners complete regular quality of life, diet, health, and lifestyle surveys and allow access to their pet's electronic medical records.

Conclusion: Over the coming years, the MPB will provide the longitudinal data and systematically collected biological samples required to generate important insights into companion animal health. Areas for future research include the early detection and progression of age-related conditions, the influence of the microbiome on health and disease, and the identification of risk factors for common conditions.

PD-08 Ukrainian Tissue Sample Bank, the Newly Established Zoological Institution

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The Ukrainian Tissue Sample Bank (UTSB), including the National Banks of Cetacean and Bat Samples, was established in 2020 in the Schmalhausen Institute of Zoology of National Academy of Sciences of Ukraine in Kyiv, Ukraine. This is the first zoologically oriented tissue bank in the region. The main storage is the freezer facility supporting -80°C regime and the emergency power supply capable for 72 h of operations. Also

the Bank includes -20°C freezers and room-temperature facilities. Its mission was identified as a regional collection, research, and expert center, the core of a future center of excellence. Good practices for sample sharing were introduced. Promoting the new facility included networking with other tissue banks, communication activities, and listing in the professional lists of institutions and labs. Cooperative agreements on sample treatment were signed with other Ukrainian institutions. Ongoing and planned applications included research projects on pathology, toxicology, population genetics, evolution (including genomics and transcriptomics), embryology, life history, and environmental studies (eDNA analyses). Also, the facility played a critical role for sample collection during the investigation of the environmental crimes. Collecting and archiving the samples included creating an inventory of old collections and samples, obtaining of samples from nature, obtaining of environmental samples (e.g., eDNA), and initiating the system of exchange and backup between tissue banks. Appropriate storage conditions include low (-80°C, -20°C, +8°C) and room temperature under climate control; frozen, RNA later, ethanol, cryoprotector media and other buffer solutions. Future developments will include developing routine, secure, and rapid procedures of samples sharing and cooperative research, following the best standards and providing sustainable environment for conservation research.

PD-09 Sclerochronology Applications in Sea Turtle Scutes Sourced from Historical Archives

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Conservation scientists have realized that modern datasets are frequently too short to adequately characterize ocean management challenges. This problem contributes to an abbreviated ecological memory, known as “shifting baselines,” and limits our ability to manage ecosystems effectively. The field of historical ecology aims to correct this problem by augmenting contemporary scientific data streams with reliable information mined from historical documents and cultural ephemera. In this seminar, I will review several ways to amend historical ecology research through the sclerochronology (diagnostic analysis of hard tissues) of sea turtle scutes from natural history repositories. I will discuss protocols, tissue preparations, omics techniques, costs, and applications for sea turtle conservation. Here, basic questions of life history, migrations, and habitat use—while critical for defining management priorities—are constrained by inaccessible habitats, low survivorship, late maturity ages, and technological limitations. Multi-institutional partnerships between researchers, repositories, and resource agencies are important for advancing this field and accelerating basic science and applied use in the conservation of these protected species.

Biospecimen Research, Science, and Outputs

PE-01 ONCOPassport Diagnostic Service for the Improvement of Lung Cancer Targeted Therapy

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Statement of the Problem: The management of oncological therapy for lung cancer patients represents a significant challenge due to the distinct genetic landscapes between different tumors. Genetic alterations play a crucial role in tumor development and predicting the malignancy potential; therefore, identifying driver mutations is vital for targeted treatment administration.

Proposed Solution: To facilitate the decision-making process in selecting individual therapy following the current recommendations for lung cancer treatment, we established the ONCOPassport service. This service was created thanks to the access to the standardized resources of Biobank at the Medical University of Białystok combined with data stored in the SmartBioBase database designed for the implementation of personalized lung cancer therapy.

The diagnostic algorithm that allowed the formulation of ONCOPassport is based on the results of full-genomic sequencing and immunohistochemical (IHC) analyses.

The ONCOPassport is built of two main parts with the following panels:

I. ONCOSUP DIAGNOSTICS:

- 1) NGS_Lung_Cancer_DNA focused on the detection of 31 driver mutations in lung cancer diagnostics at the DNA level.
- 2) NGS_Lung_Cancer_RNA for detecting driver mutations at the RNA level, including fusion genes and exon-skipping isoforms of alternative splicing in 14 genes associated with the development of lung cancer.
- 3) Assessment of PD-L1 expression by IHC.

II. ONCOSUP ANALYTICS PROTOTYPE with miRNA panel for diagnosis and histopathological evaluation of cancer:

- 1) Morphological panel of 425-miR microRNA signature in serum to investigate expression differences between lung adenocarcinoma and squamous cell carcinoma.
- 2) Panel for the early diagnosis of lung cancer of 28-miR microRNA signature in serum for expression differences between NSCLC patients and non-cancer patients.

The tests run within ONCOPassport services are carried out using a custom-tailored Next Generation Sequencing technology that has been properly optimized and certified for the service. The primary samples used for these assays are formalin-fixed paraffin-embedded tissue samples.

Conclusions: The ONCOPassport has been implemented as the routine assay run for lung cancer patients that require adjuvant treatment. The result of such an extensive analysis represents a critical element of the complex diagnostic procedure in selecting an appropriate molecularly targeted therapy regimen.

PE-02 WITHDRAWN

PE-03 Preliminary Study for SNP Array Analysis of DNA Derived from Blood Smears Stored for More Than 50 Years

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Since 1958, the Radiation Effects Research Foundation and its predecessor, the Atomic Bomb (A-bomb) Casualty Commission, have been conducting the Adult Health Study (AHS) of 25,000 people, including A-bomb survivors, with biennial health examinations in Hiroshima and Nagasaki, and a large number of biological specimens, including blood specimens, have been collected and are stored and maintained. Among those blood specimens, the blood smears (smears) of all AHS subjects have been preserved since 1958. Since the specimens of cases who developed cancer immediately after the A-bombings are also stored, genome analysis using these specimens will enable us to elucidate the mechanisms of radiation-related cancer development in detail and to identify individual differences in susceptibilities to these cancers. Therefore, a genome analysis of all AHS subjects, including A-bomb survivors, is planned. For this to happen, it is necessary to investigate the availability of smears prepared from trace amounts of blood specimens, although ethical, legal, and social issues (ELSI) must be solved. In this study, call rates and concordances of single nucleotide polymorphisms (SNPs) in DNA obtained from the blood specimens of six in-house volunteers (W-DNA) and DNA extracted from smears prepared from the blood specimens and amplified with the QIAGEN REPLI-g DNA amplification kit (amplified-DNA) were examined using two SNP arrays designed for SNP analysis in a Japanese population, the Axiom Japonica Array NEO (AJAN, about 670,000 SNPs) and Infinium Japanese Screening Array (IJSa, about 710,000 SNPs). As a result, the average call rates of W-DNA and amplified DNA for AJAN were 99.3% and 97.0%, respectively, and those for IJSa were 99.9% and 96.3%, and the average concordance rates between W-DNA and amplified DNA were 93.7% for AJAN and 99.7% for IJSa, both of which exceeded 90%. There were 435 SNPs with different identification results in the two SNP arrays, which were identified by the Taq-Man assay method and were consistent with the results obtained by IJSa. These results showed that whole-genome amplified DNA prepared from smears represents a similar copy of the genomic DNA template and that a comparable call rate was obtained using high-throughput SNP genotyping assays, suggesting that smears can be used for GWAS. However, the applicability of old preserved smears for genomic analysis and the selection of the SNP array to be used require further validation.

PE-04 Cost Assessment of Cryogenic Preservation of Biocollections during the COVID Pandemic at CeReB 2020-2021

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Aims: Coronavirus 2019 (COVID-19) is a new human disease caused by the Coronavirus SARS-COV-2. It was classified as a pandemic by the World Health Organization (WHO) on March 11, 2020. The Institute Pasteur of Côte d'Ivoire (IPC), through its specialized units and its Center National of Reference (CNR) for respiratory viruses, has been entrusted with the mission of coordinating the diagnostic and conservation efforts of COVID-19 for the country.

The objective of this study is to evaluate the costs of cryogenic conservation of biocollections during the COVID pandemic at the Côte d'Ivoire Biological Resource Center (CeReB) from 2020-2021.

Methodology: Cost and sample data were collected using a questionnaire administered to the IPC administration, the

Supply Management Unit (UGA), and CeReB staff that ensured data quality.

Results: For our study period, of the 1,225,710 SARS COV 2 samples collected by National Surveillance, 92.7% (1,137,210/1,225,710) were received in IPCI laboratories for diagnosis.

Variable costs are higher than fixed costs in both cryovial and chaff collection production. The total production cost of the straw collection is 3.5 times the total production cost of the cryovial collection

Conclusion: This study establishes a generic analysis of the capital and operating costs required to integrate nasopharyngeal specimen cryopreservation and can serve as a model for the implementation of cryopreservation programs.

PE-05 Plasma miRNA Profile in High Risk of Preterm Birth during Early and Mid-Pregnancy

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Background: Prospective biobank studies provide better opportunities to explore and study the predictive value of biomarkers. Of particular difficulty is the search for biomarkers of pregnancy complications, since pregnant women are a difficult cohort to study. We hypothesized that the miRNA profile in blood plasma may change in pregnant women at risk of preterm birth. We have performed a prospective study of the miRNA profile in the blood plasma during the first trimester in pregnant women who were later found to be at high risk of preterm birth. Also, we evaluate the miRNA profile in these same women in the second trimester after the diagnosis.

Methods: Samples were taken prospectively in the first (9-13 weeks), second (22-24 weeks), third (32-34 weeks) trimesters, and at birth, and then the outcomes of pregnancy and childbirth were analyzed. We have performed a prospective study of the miRNA profile in the plasma during the 1st and 2nd trimesters in pregnant women with high risk of preterm birth (n = 13 cases and n = 11 controls). For the study group plasma blood samples at 9-13 weeks before diagnosis and at 22-24 weeks after start of therapy were selected. For miRNA profiling we used high-throughput sequencing, which allows de novo miRNA analysis with high resolution and accuracy

Results: We created "The Bioresource Collection for the Detection of Early Biomarkers of Pregnancy Complications," which houses about 17,000 biosamples of various types of biomaterial from 355 pregnant women in different stages of gestation, in biobank "Genofond" from the D.O. Ott Research Institute of Obstetrics, Gynecology, and Reproductology. Using high-throughput sequencing technology we detected differences in the levels of 15 miRNAs (3 upregulated - hsa-miR-122-5p, hsa-miR-34a-5p, hsa-miR-34c-5p; 12 downregulated - hsa-miR-487b-3p, hsa-miR-493-3p, hsa-miR-432-5p, hsa-miR-323b-3p, hsa-miR-369-3p, hsa-miR-134-5p, hsa-miR-431-5p, hsa-miR-485-5p, hsa-miR-382-5p, hsa-miR-369-5p, hsa-miR-485-3p, hsa-miR-127-3p) ($\log_2(\text{FC}) \geq 1.5$; $\text{FDR} \leq 0.05$) during the first trimester compared with control. All downregulated miRNAs in the first trimester from placenta-specific C14MC cluster. During the second trimester no differentially expressed miRNAs were found. Our results suggest that the miRNA profile in plasma during early pregnancy may predict a high risk of preterm birth, which is important to prevent gestational problems as early as possible.

PE-06 The Mathison Centre Neurogenetics Biobank and Advancing in Precision Mental Health

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Background: The Matheson Centre Neurogenetics Biobank is an academic health research biobank within a neurogenetics research network that includes international collaborators, hospitals, research institutes, and community-based studies. The aim of the biobank is to support gene discovery and knowledge translation in child and youth mental illness and to develop next-generation research for a precision medicine approach that will contribute to prediction, prevention, and early intervention in child and youth mental health.

Method: Our biobank system features state-of-art technology; controlled rate freezing, sample storage, and transfer; ethics and biosafety; data preservation; documentation; and consultation. As an ongoing development process, the Matheson Centre Neurogenetics Biobank is currently focusing on two (2) major areas 1. Developing an outline of the types of biospecimens (saliva, blood, buccal swab) regularly collected, stored, retrieved, and distributed in a biobank (<https://www.bcplatforms.com>) system and the procedures involved with strict standard operating procedures (SOPs) to ensure sample quality fits the purpose of use. 2. Implementing a specimen data and record management system for internal and external stakeholders, using an automated method, which ensures secure collection, storage, and retrieval of genetic and phenotypic data.

Research Involvement with Biobank: 1. Genetic and Environmental Influences on Behaviour and Cognition in Childhood Neuropsychiatric Disorders. 2. PGx -Spark: the discovery of Pharmacogenetics markers and tools for Child and Youth Mental Health. The aim of this project is to implement Canada's first Pharmacogenetics testing service to improve drug treatment outcomes in children receiving mental health care. 3. Harnessing the Power of Population-Based Samples for Detecting Gene x Environment Interactions. 4. Brain Function and Genetics in Pediatric Obsessive-Compulsive Behaviors. Funding NIH, CIHR, and Alberta Children's education fund.

Results: To date, our biobank has successfully stored 4062 out of 5455 clinical bio-specimens from five different sites. Our biobank system has also established a database system focused on sample tracking, phenotype-genotype linkage, and health information.

Conclusion: The Mathison Centre Neurogenetics Biobank applies dynamic approaches to gene discovery and precision medicine. We emphasize project engagement and return of value to participants, collaborators, and other stakeholders.

PE-07 Precision Medicine in Childhood Cancer: From Tiny Biospecimen to Big Possibilities!

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Despite improvements in risk-stratified treatments, ~20% of childhood cancer patients do not respond to current therapies and ultimately succumb to their disease. It remains the first cause of death by disease among children. However, no significant progress has been noted over the last decade, urging the need for new and more effective therapeutic alternatives. To address these issues, we have launched TRICEPS, a Childhood Cancer Precision Medicine program, which targets hard-to-treat pediatric cancers by offering in-depth multi modal -omics investigation of tumour material to identify patient-specific alterations within a reasonable timeframe (8 weeks). One of the key components was the availability of a biobank containing high-quality human biospecimens such as tumour material, blood, and saliva along with well-annotated clinical data. Our Biobank collected, preserved, and provided access in a transparent and quality-controlled manner in compliance with ethical, legal, and regulatory requirements. This was made possible by a close collaboration between scientists, oncologists, surgeons, pathologists, biobankers, ethicists, and clinical research assistants. From 2014 to 2022 we collected 501 biospecimens from 221 patients enrolled at the 4 main pediatric oncology centres in Québec, Canada. We have faced numerous challenges to offer the study to as many patients as possible. For instance, fresh-frozen tissue samples (tumour resection [74%], needle biopsy [16%]), although limited in size, are better suited for molecular profiling, downstream application. For 11% of cases we had to develop protocols to isolate DNA from tissue samples in formalin-fixed paraffin-embedded (FFPE) blocks when it was the only source of material. An increasing number of specimens are obtained by needle biopsies, leading to sparse material for diagnosis and potential use for research. We also developed protocols to isolate tumour cells from biopsies and bone marrow with tumour content <25% (6% of cases). In conclusion, biobanking played an important role in our precision medicine program. We demonstrated the feasibility of incorporating genomic sequencing into the management of hard-to-treat childhood and adolescent cancers. The genomic-driven molecular profiling led to the identification of potentially therapeutic actionable alterations in most patients tested (86%). The systematic collection of human samples of high quality is a key element to the success of future treatments.

PE-08 Quality Analysis of Residual Genome DNA in Red Blood Cell Samples from Anticoagulated Whole Blood

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Background: Anticoagulant blood (ACB) can be sorted into different fractions after centrifugation. Red blood cell (RBC) contamination in buffy coats and residual leukocytes in RBC samples is inevitable during this process. Buffy coats and whole blood are preferred options for obtaining genome DNA (gDNA), and the RBC samples are usually discarded. This program is designed to investigate the quality of gDNA in RBC samples and the effects of RBC Lysis Buffer treatments on gDNA yield.

Material and Methods: Whole blood was collected in EDTA blood collection tubes, and the sample volume was 2-4 ml. The buffy coat (leukocytes) isolation and the plasma and RBC separation were performed using the Hamilton Microlab STAR Liquid Handling platform. Genome DNA was isolated from 4 groups (Group 1 was RBC samples stored for more than 4 years. Group 2 was fresh RBC samples. Group 3 was RBC Lysis Buffer-treated fresh RBC samples, and leukocytes were collected. Group 4 was fresh buffy coats) using Magen HiPure Blood DNA Mini Kit. There were 50 samples in each group and the sample volume was 250 µl. The purity, concentration, and integrity of the gDNA obtained were assessed by Nanodrop One, Qubit 4, and Agilent 4200 TapeStation. Results were analyzed using the Wilcoxon Signed Rank Test or the Mann-Whitney Test (SPSS 20.0).

Results: Genome DNA with high purity and integrity was obtained from frozen RBC samples. All samples had a DIN number above 7.0, and the ratio of A260/A280 was 1.92 ± 0.08 . Genome DNA yields were similar by three instruments (range 0.18-27.28 ng by Nanodrop One; range 0.31-21.91 ng by Qubit 4; range 0.99-28.35 by 4200 TapeStation). No significant difference was found in gDNA yield between cryopreserved and fresh RBC samples ($Z = -1.682$, $P > 0.05$), but RBC Lysis Buffer treatment can significantly decrease the gDNA yield in fresh RBC samples ($Z = -6.077$, $P < 0.001$). Genome DNA yields of 50 fresh buffy coat range from 4.10-51.90 ng. 4200 TapeStation is a good choice for qualitative and quantitative analysis, especially when a high-integrity sample is required for research.

Conclusions: A few leukocytes were left in the residual RBC samples after the isolation of plasma and buffy coat in the anticoagulated blood processing cycle. It is possible to extract high-quality gDNA from RBC samples. Despite the need for more storage space and cryogenic vials, the preservation of RBC samples for future analyses in repositories can make better use of blood samples.

PE-10 Assessment of the Stability of Metabolic Parameters for Creation of Pre-Analytical Guidelines for Metabolomics

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Background: Assessing the sample quality is an important aspect of BioBank Dresden // Germany. Using metabolomics in combination NMR spectroscopy has shown to provide extended information to characterize the pre-analytics of liquid samples. Here, we performed a series of experiments to determine the rate of change of up to 152 different metabolic parameters, depending on pre-centrifugation delay, post-centrifugation delay, as well as the overall time-to-freeze. Specific time-delays were chosen to simulate a realistic scenario of a working central biobank (0-8h). The main goal was to investigate the stability of a large parameter panel (40 metabolites, 112 parameters from lipidoprotein subfraction analysis) and how fully characterized pre-analytics of biobanks can be employed to filter unstable metabolites for potential studies.

Methods: Blood was drawn from healthy volunteers in different coagulation tubes (EDTA, Serum, LiH). The samples were left at room temperature at specific intervals (0-8 h and 24h) with either a constant pre-centrifugation delay or constant post-centrifugation delay. Isolated plasma or serum aliquots were immediately frozen and were thawed to the measurement using NMR Spectroscopy. The measured parameters range from amino acids and organic acids to lipoproteins.

Results: ANOVA was used to determine the metabolic parameters with the biggest correlation to the time-delays. The stability was assessed using linear regression and optimal pre-analytical conditions were calculated for each parameter before it reached a change of 30% from its original value at 0 hours. For example, pre-analytical effects heavily influence lactate metabolism. The concentration of lactate is altered by more than 30% in just 0.8 hours, making it necessary to investigate lactate metabolism carefully if the pre-analytical conditions are not fully known. These analyses were performed for all measured parameters.

Conclusion: In automated biobanks the pre-analytics of samples are often fully characterized, including time-stamps for collection and pre- and post-centrifugation delays. The data presented here allowed us to characterize the pre-analytical effect for a large variety of different metabolic parameters as well as create guidelines under which pre-analytical conditions certain metabolic parameters should be excluded from research studies and also highlighting the importance of having fully characterized pre-analytical conditions for every deposited sample.

PE-11 Method Validation for PBMC Isolation and Cryopreservation: Old and New Preanalytical Variables

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Peripheral blood mononuclear cells (PBMC) are elements of interest to the research community, particularly in the fields of immunology and tumor biology. The methods used for their isolation and freezing vary significantly between different biobank laboratories with subsequent variability in the quality attributes of the PBMCs. These include the yield of cells isolated from whole blood, their viability, as well as the conservation of cell sub-populations so that they are as close as possible to the physiological state.

In the process of validating our method, we compared different parameters: anticoagulant (EDTA, sodium citrate, lithium heparin and sodium heparin), isolation method (Ficoll[®], Sepmate[®], Leucosep[®], and CPT[®]), and freezing medium supplemented with 10% DMSO (autologous serum, decompartmented autologous serum, autologous plasma, and fetal calf serum), in order to identify the best combination of conditions. To do this, blood samples were collected from 11 healthy donors.

For each of the methods, consisting in a combination of the above-mentioned parameters, we measured the PBMC viability using Muse[®] equipment, and compared by ANOVA. Flow cytometry analyses were carried out on Cytoflex S[®] to verify the effective preservation of the sub-populations: Leukocytes (CD45), T lymphocytes (CD3/CD4/CD8), B lymphocytes (CD19), and Monocytes (CD14).

Our first results suggest that the isolation yield, before freezing the PBMCs, is significantly different, in favor of the CPT separation device (SepMate[®]: 0.841×10^6 PBMC/mL; Leucosep[®]: 0.693×10^6 PBMC/mL Ficoll[®]: 0.936×10^6

PBMC/mL, CPT[®]: 1.047×10^6 PBMC/mL). We did not observe any difference in pre-freeze PBMC viability. Furthermore, we did not observe any significant difference in yield or viability between the different anticoagulants used (SepMate[®]: 99.36%, Leucosep[®]: 99.35%, Ficoll[®]: 99.24%, CPT[®]: 99.15%). We will present the corresponding post-thawing results, as well as results from comparison of cryopreservation in autologous plasma, with different platelet concentrations, a parameter that has barely been studied until now.

PE-12 Characterization of Process for Isolation of Peripheral Blood Mononuclear Cell (PBMC) Using a Custom Layering Tool and a Custom Hourglass Tube

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Investigation of peripheral blood mononuclear cells (PBMCs) responses remain one of the most important steps in the development of pharmaceuticals and invitro diagnostics. However, these studies are often inconclusive because of the poor reproducibility of the isolation process for PBMC. The use of density gradients (still the gold standard) for isolations involves a step for layering diluted blood and a second step for harvesting of the PBMC band that are large contributors to the hands-on time and poor reproducibility of the overall process. In this study, we evaluated the use of 1) a custom layering tool and 2) an hourglass-shape tube as a simpler solution to increase reproducibility and reduction of hands-on time for both critical steps. These two components were evaluated and compared to the results from a 50mL centrifugation tube manually prepared using the standard method for Ficoll-Pique PLUS. Performance was assessed based on hands-on time, cell recovery, cell viability, and overall process time. Results showed that the layering tool reduced hands-on time and overall process time by >95% and 70%, respectively, without an impact on the cell recovery and viability. Similarly, the hourglass-shape tube showed cell recoveries and viability of >90% and >99%, respectively, when compared to the standard 50mL centrifugation tube. This configuration also reduced the harvest volume and Ficoll volume by 60% and 65%, respectively. Overall, these results showed significant improvement in hands-on time and overall process time without impacting cell recoveries and viability. Furthermore, this hourglass-shaped tube may be used with liquid handlers to achieve additional improvement in process/hands-on time and overall reproducibility.

PE-13 Optimization of Vitrification Solutions for Dielectric Heating of Cryopreserved Biospecimens

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Background: Dielectric heating is one of the promising approaches to rewarming the large-scale cryopreserved biospecimens since it has the ability to rewarm the samples volumetrically. The rewarming rate and uniformity mainly depend on the dielectric and thermal properties of the cryopreserved specimens, especially the vitrification solution (VS) that consists of the majority of the specimens. However, the current VS

compositions are selected according to the vitrification tendency and toxicity, lack of the consideration for ultrafast and uniform rewarming. In this study, we propose to optimize the VS holistically, achieving high vitrification tendency and low toxicity, and optimal rewarming based on the measurements of dielectric and thermal properties, and the potential effects of additional nanoparticles on dielectric heating.

Method: The measurements of dielectric and thermal properties are conducted on several VSs (M22, VS55, VS83, and DPVP). A dielectric property measurement system is developed based on cavity perturbation theory and used to measure the dielectric properties of the VSs. The thermal properties including critical cooling rate, critical warming rate, and specific heat are determined by differential scanning calorimetry. The thermal conductivity is determined by our designed thermal conductivity meter. Our study also considers different nanoparticles (magnetic nanoparticles [MNPs, e.g., Fe₃O₄], dielectric nanoparticles [DNPs, e.g., SiO₂], or thermal nanoparticles [TNPs, e.g., CuO]) as the additional components to improve the heating effects.

Results: The absorability of electric field power depends mainly on the dielectric loss. DPVP shows the highest dielectric loss compared to other VSs from -150 C to 0 C. Another special property of DPVP is that the dependence of the dielectric loss on temperature showed an inverted “U” shape, which is critical to avoid the “thermal runaway” phenomenon in heating. The additional MNPs, DNPs, and TNPs can improve the EM power absorability and thermal conductivity even with relatively low concentrations.

Conclusion: DPVP shows the potential to have better-rewarming performance. Owing to its relatively high dielectric loss and the inverted U shape of temperature dependence, DPVP is promising to achieve ultrafast and uniform rewarming by dielectric heating. MNPs, DNPs, and TNPs are also potential cryoprotectant components specifically for dielectric heating.

PE-14 Impact of Serum Indices on Serum Metabolite Profiles and Its Association with Pre-Analytical Variables of Biobanked Samples

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The serum indices of hemolysis, icterus, and lipemia (HIL) are known to be important interference factors of clinical chemistry assay results. Here we describe the assessment of the impact of HIL indices on serum metabolite profiles, and an association of HIL indices with pre-analytical variables of serum samples. To study associations of HIL indices with clinical laboratory test results and pre-analytical conditions, we selected serum samples (n=12,196) of the KoGES cohort with measurements of HIL indices and pre-analytical variables (SPREC parameters). In addition, metabolite profiles were analyzed using Absolute IDQ p180 for the case groups of hemolysed (n=60), Icteric (n=60), and lipemic (n=60) samples with the non-HIL control samples (n=60). The hemolysis index was found to be related with over 20 metabolites of glycerophospholipids, and the third (pre-centrifugation-delay between processing) and sixth (post-centrifugation) elements of SPREC. This study would provide an evidence-based quality control process of serum samples for an application of serum indices to data interpretation in clinical chemistry assays or downstream biomarker assays using biobanked serum samples.

PE-15 Biobanking in the COVID-19 Times: Research on Serum Cytokine Profile and Tumor Biomarkers in Relation to Disease Severity Prognosis

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Background: In 2020, the Biobank Pilsen initiated acquisition of blood serum and plasma samples from COVID-19 patients which then have been stored in standardised conditions and were available for research. The pilot investigation focused on potential biomarkers which would help to assess the disease severity and therefore to decide on the suitability of aggressive treatment such as supportive mechanical ventilation. Serum inflammatory cytokines were selected as biomarkers of inflammation extent. Selected serum tumor markers were assessed as well since their levels might increase due to the COVID-induced lung fibrosis.

Methods: A retrospective non-randomised study was conducted which included three groups of coronavirus-positive patients: 1/ 60 patients with mild to moderate disease course, 2/ 60 patients on mechanical ventilation who recovered, 3/ 60 patients who were deceased due to COVID-19. Cytokine profile of pro-inflammatory (IL-1beta, IL-12p70, IL-2, IL-4, IFN gamma, TNF alpha, IL-6) and regulatory (IL-10) cytokines were measured in patients' sera using the ELLA microfluidic platform. Tumor markers (CEA, CA 15-3, CYFRA 21.1, HE4) were measured using automated immunoassays (CLIA). Cytokine levels and tumor marker levels were compared among groups.

Results: Levels of IL-10 were significantly higher in group 3 compared to group 2 and 1 ($p=0.014$). IFN gamma levels in group 1 were higher than in groups 2 and 3, although non-significantly ($p=0.062$). IL-6 levels were higher in group 3 than in groups 1 and 2 (mean 97.4 pg/mL vs. 63.8 and 63.0, respectively). CEA, HE4, and CYFRA 21.1 levels were significantly higher in group 3 than in groups 1 and 2.

Conclusion: According our data, serum levels of cytokines IL-10, IFN gamma, and IL-6 and tumor biomarkers CEA, HE4, and CYFRA 21.1 might predict the life-threatening outcome of COVID-19 disease and help in treatment decisions. Studies with larger patient groups are needed in order to support these findings. The Biobank Plzen is ready to provide specimens for such a larger study.

PE-16 Long-Term Stability and Qualification of an Historical Fungal Collection

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Background: Microbial culture collections hold qualified and diverse microorganisms, ensuring their availability and thus

playing a pivotal role in research, education, and innovation, as well as supporting our response to current and emerging public health and societal challenges.

However, such precious holdings, when not integrated in the context of professional biobank infrastructures, may be exposed to major risks, ensuing staff's retirement or changes in the institutional strategy with redefined priorities.

Several successful stories of rescued 'historical' collections have been reported, and of their utilization towards new discoveries.

At the Biological Resource Center of Institut Pasteur (CRBIP), we undertook the challenge of rescuing the dormant legacy collection of fungal strains, including freeze-dried and mineral oil-conserved yeasts and filamentous fungi, by using a polyphasic approach combining morphological features and multi-locus sequence (MLS) molecular data.

Methods: We assessed the viability, purity, and authenticity of 70 selected strains (yeasts $n=37$, filamentous fungi $=43$) isolated from multiple sources (e.g., human, animals, and plants), and maintained in storage for a period of over 60 years, spanning from the 1930s to the early 2000s.

Results: Our preliminary results promisingly show long-term stability of the selected strains and successful qualification with regards to purity and authentication. More specifically, 34/ 37 yeasts and 42/43 filamentous fungi are viable and pure and could be authenticated using the polyphasic approach. Moreover, we could update the taxonomic assignments, based on the most recent revisions, where applicable.

Conclusions: These results confirm the high potential of reviving historical microbiological collections for biobanking and research activities, as well as for supporting and complementing pre-existing collections and catalogues at national and international levels and consortia, such as the Microbial Resource Research Infrastructure (MIRRI) and World Data Centre for Microorganisms (WDCM).

PE-17 Supporting Diagnostic Research and Development with Biobanking Activities for Infectious Diseases Endemic in Low- and Middle-Income Countries

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FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. Diagnostic research and development for infectious diseases require the availability and accessibility of well-characterized, high-quality clinical specimens. However, this remains a challenge, and biomaterials from diseases that are of pandemic potential or endemic in low- and middle-income countries (LMICs) are often difficult to source.

To contribute to more equitable access to specimens, since 2007 FIND has been building a biobank with fit-for-purpose collections of specimens, mainly from LMICs. During this time, FIND biobanking activities have been continuously supporting areas of health inequalities and providing the global health community with a transparent means of sharing clinical specimens.

More recently, in response to the lack of biobanks in LMICs, FIND has also deployed a strategy aimed at building local capacity and investing in on-site, in-country infrastructure to deliver a long-term, sustainable, and adequate biobanking service. FIND integrated biobanks (FIBs) comprise a network of biobanks coordinated by FIND, which conducts specimen collections to support the development of diagnostic tools. Within the FIB network, sites based in LMICs are proactively equipped to

rapidly scaleup activities for an efficient response to future pandemics. To ensure standardization of operations, FIND manages FIB sites and FIND centralized biobank as one.

Within the centralized biobank and FIB sites, FIND currently stores more than 600,000 clinical specimens covering 6 disease areas: acute febrile illnesses, antimicrobial resistance, COVID-19, hepatitis C, malaria, and tuberculosis. Specimens in FIND biobanks were collected in almost 30 different countries and are distributed to a variety of institutions globally, both in high-income countries and LMICs, and for all stages of diagnostic development and exploratory research.

FIND biobanking activities have been a major asset for the global health community and its efforts in diagnostic research and development. FIND is engaged in an ongoing assessment of the gaps in biobanking and continuously re-evaluating the inclusion of new diseases and sample types. FIND is also highly in favour of network-based biobanking systems, an approach that enhances the value of biobanks by increasing their visibility and distribution of specimens as well as fostering collaborations.

PE-18 Functional DNA Quality Control Implementation in Qatar Biobank Laboratories

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Background: Sample misidentification is a common problem in biomedical research and can eventually result in the publication of incorrect data. Qatar Biobank implemented the SNP trace panel 96*96 technology because it is a fast, reliable, and cost-effective genotyping platform used to assess genomic DNA quality and identity, as an addition to standardize analytical QC assessment. SNP Trace panel is a set of 96 SNPs assays that enable sample tracking and fingerprinting. This panel generate data in a single run of 3,5 hours with minimal hands-on steps and provides data for genetic gender identification, contamination, quality issues, and sample viability for downstream applications.

Methods: A total of 9,559 collected genomic DNA samples were genotyped using 96*96 SNP Trace panel dynamic Array. The DNA extraction was performed using a fully automated robotic liquid handler with magnetic bead technology and was checked for analytical quality control using fluorometric and spectrophotometric methods of DNA purity and concentration measurements. Determining the genotype calls for gender was based on k-means clustering. The genotyping output data were compared against the demographic data to generate a functional quality report.

Results: All SNPs with a call rate and accuracy rate greater than 99% were used for analysis. The gender concordance rate between the genotyped DNA samples and the demographic data of the participants was equal to 91%. Among 9,559 samples, 4,085 were determined as 'Female' while 4621 were identified as 'Male.' The results showed that SNP-based genotyping detected a gender failure with rate equal to 7%. 2% were identified as Klinefelter male 'K-Male'.

Conclusion: Implementing a functional quality control workflow in Qatar Biobank has resulted in the production of high-quality DNA samples which complies with stringent requirements for downstream applications. It also allows biobanking of participant DNA while producing a unique database which currently includes nearly 10,000 samples. With this approach Qatar Biobank is reducing the preanalytical sample processing uncertainties which will serve as a foundation resource for research and clinical initiatives that play a key role in precision medicine.

PE-19 Automatic and Robust Extraction of Genomic DNA from Various Leftover Blood Samples

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Background: Genomic DNA (gDNA) is used to diagnose a variety of diseases by utilizing restriction enzyme analysis, polymerase chain reactions (PCR), or DNA sequencing modalities. The development of high-throughput genomic sequencing techniques coupled with bioinformatics technology has enabled large-scale and lower-cost DNA sequencing. Genomic DNA sequencing provides greater possibilities for personalized medicine. With the development of genomic technologies, isolation of gDNA from clinical samples is requested for clinical diagnostics and research studies.

Method: Blood samples were collected in seven types of blood collection tubes, including EDTA Tube, Heparin Tube, BD P800 Tube, Plasma Separator Tube, Serum Tube, Serum Separator Tube, and CPT Mononuclear Cell Preparation Tube. All blood samples were extracted on the automated platform QIAasympathy with its programs and the commercial DSP DNA midi Kit.

Results: We extracted and compared the gDNA from seven types of leftover blood with an automatic and robust method. Average yields of gDNA ranged from 4.44 ± 1.41 to 22.12 ± 4.91 μ g. In addition, we obtained gDNA from blood samples stored at 4 °C for up to 13 weeks with the yield of 8.62 ~ 56.53 μ g, or at -80 °C for up to 78 weeks with the yield of 9.65 ~ 68.08 μ g. Using a 96-well format for large-scale extraction, the leftover blood samples from Serum Separator Tube (n = 157) and EDTA Tube (n > 3000) were tested. Sequenceable gDNA was obtained from the Serum Separator Tube with a yield range of 0.24 ~ 28.52 μ g, and from EDTA Tube with a yield range of 3.94 ~ 215.98 μ g.

Conclusions: We show that leftover blood samples from routine clinical tests are a good source of gDNA. Our results suggest that sequenceable gDNA can be obtained from the leftover blood samples of whole blood, plasma-collected blood, serum-collected blood, or the erythrocytes and granulocytes layer after the isolation of peripheral blood mononuclear cell (PBMC) with adequate and sufficient yield. We suggest that gDNA can be extracted from various leftover blood collection tubes with any automated and high-throughput DNA extraction platform.

PE-20 A Case Study: Extending Downstream Applications for a Stabilized Whole Blood Collection Tube

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Statement of the Problem: For a whole blood biospecimen pre-analytical variables, such as tube type, processing delays, and centrifugation time and temperature, are critical factors known to alter the quality of the obtained blood derivatives. Stabilization technologies for blood collection tubes have been developed over several years and provide various solutions for sample quality preservation. For example, widely used PAX-gene RNA/DNA blood collection tubes help to overcome the potential impact of pre-centrifugation delays, thus maintaining

sample fitness for purpose for downstream applications. However, for plasma and serum, the maximum pre-centrifugation time limit for an accurate measurements of the most clinical parameters is 24h. Therefore, there is a need for plasma and serum-specific stabilization systems to guarantee sample quality when the processing delay time is above 24h.

Proposed Solution: Whole blood collected in PAXgene circulating cell-free DNA (ccfDNA) tubes, is suitable for purification of ccfDNA from plasma and gDNA from the cellular fraction. The tube minimizes haemolysis and stabilizes blood cells by inhibiting their apoptosis. Due to these specific characteristics, there may be limitations pertaining to plasma downstream analysis, RNA extraction, and/or peripheral blood mononuclear cell (PBMC) isolation. We have therefore investigated whether PAXgene ccfDNA stabilization system interferes with reliable measurements in plasma, while we compared tube performance versus the commonly used EDTA vacutainer. Pre-centrifugation delay was evaluated at 24h and 48h and compared with the immediate processing post-collection.

Conclusions: In the scope of extending the use of the PAXgene ccfDNA whole blood collection tube we faced some processing challenges when isolating PBMCs; however, it was still possible to obtain viable cells when the tube was processed immediately after collection. We evaluated the effect of sample 'aging' considering the established pre-centrifugation delays on ds gDNA yield extracted from PBMCs, along with DNA/RNA purity and integrity; gene expression; and IL-16/IL-8 cytokines, previously reported as quality control markers. We measured plasma HIL-indexes to evaluate the haemoglobin, total bilirubin, and sample turbidity, which is associated with hyperlipidaemia. Our results would show if it is possible to extend fitness for purpose for additional downstream applications for samples collected in this tube.

PE-21 Discovery Through Biospecimen Sharing: The NASA Biological Institutional Scientific Collection (NBISC)

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Sharing of non-human biospecimens from spaceflight and ground experiments has been an ongoing enterprise since the 1960s, with NASA Ames Research Center leading the effort toward fostering collaborations with other NASA Centers, Universities, and international academic institutions. As a means of promoting awareness of space bioscience research, NASA Open Science initiatives make these unique biospecimens available to researchers worldwide through a formal biospecimen request and proposal review process. In this presentation, we will demonstrate the progress made utilizing these biospecimens in developing measures to safeguard long-term human space exploration and their contributions to the advancement of life sciences. An initial step in understanding these insights begins with an online request at the NASA Life Sciences Portal (NLSP) for select biospecimens from various NASA flights and studies related to space biosciences research. We will describe the meticulous planning and coordination required to ensure the collection of high-quality, well-preserved tissues while practicing modern biobanking methods that provide a comprehensive database of scientific and administrative metadata. By providing 90,000+

unique biospecimens for scientific research, NBISC not only serves as a biorepository for storing and distributing non-human biospecimens but provides a pathway for future discoveries that will benefit NASA and humankind.

PE-22 Enhancing RNA Quality from FFPE Tissue through Ultrasonication

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Background: RNA obtained from formalin-fixed, paraffin-embedded (FFPE) tissues is usually highly degraded and chemically modified, which limits its use for RNA sequencing (RNA-seq), Next Gen sequencing, and other downstream assays. Enzymatic lysis allows total RNA to be effectively purified from FFPE tissue sections, although often it's sub-optimal for RNA-seq. Its quality may be significantly improved by using adaptive focused acoustics (AFA) ultrasonication that provides regulated cell lysis. To standardize and improve RNA extraction services at the Moores Cancer Center Biorepository, we compared the common method of enzymatic dissociation (ED) with the ultrasonication dissociation (UD) of FFPE tissue for RNA extraction.

Methods: Six 10-µm-thick sections of human FFPE tissues were loaded into ML230 focused-ultrasonicator for AFA-enhanced paraffin emulsification using truXTRAC FFPE total NA kit, followed by manual spin column purification. Tissue replicates were processed through QIAcube Connect, an automated system using enzyme-based dissociation and spin column purification with RNeasy Kit. Quality analyses were performed by the Agilent TapeStation, Invitrogen Qubit, and Thermo-Scientific Nanodrop.

Results and Discussions: The DV200 values of RNA from UD were significantly higher than RNA yielded by ED of tissue ($P=0.001$). The extracted RNA from UD method yielded a DV200 range of 45.05%-61.48% whereas the extracted RNA from ED had a DV200 range of 22.49% -39.17%. RIN values, 260/280, and 260/230 were not significantly different between the ED and UD of FFPE tissue. All UD-RNA samples qualified for RNA-seq per Illumina DV200 standards, in which 4 of 6 samples were medium quality (DV200 range of 50-70 %) and 2 of 6 samples had low DV200 quality (DV200 range of 30-50 %). Only 4 ED-RNA samples qualified for RNA-seq with low quality. DV200 values show that ultrasonication dissociation of FFPE tissue significantly improves quality metrics defined by Illumina for RNA-seq, a significantly higher percentage of extracted RNA fragments exceeded 200 nucleotides. Here we report that ultrasonication is a viable method for amplifying the quality of RNA.

PE-23 Pre-Implementation Qualification Study of Blood-Based Biomarker Assay Precision to Establish Consistent and Reliable Data Return

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Background: Biomarker studies in Alzheimer's Disease (AD) research samples are pivotal to increasing our ability to not only diagnose the disease, but also characterize prognosis. Blood-based biomarkers, such as neurofilament light chain (NfL), phosphorylated tau 181 (Ptau181), glial fibrillary acidic protein (GFAP), and beta-amyloid 1-40 and 1-42 (A β 40, A β 42), allow researchers to investigate AD biomarkers in studies with stored historical plasma samples. The National Centralized Repository for Alzheimer's Disease and Related Dementias Biomarker Assay Laboratory (NCRAD BAL) performs qualification studies on each commercially available assay of interest to assess key parameters of performance prior to implementation. Studies on analyte stability and performance bridging when key reagents are changed are critical to deliver reliable and consistent data over time. This study assessed the precision of commercially available assays implemented in the NCRAD BAL.

Method: Blood was collected from AD (N=14) and healthy control (N=19) subjects by the Indiana Biobank and processed to plasma. Plasma was assayed on the Quanterix Simoa HD-X platform using the Simoa Nf-Light, P-tau 181v2, Neurology 2-Plex B (N2PB), and Neurology 4-Plex E (N4PE) Advantage Kits. Five samples were chosen for each assay independently to span high, medium, and low concentrations for the qualification studies. Sets of 3 plates were run on two separate days using kits of the same lot number. Precision of each assay was assessed.

Results: The average total coefficient of variation (CV) was calculated to determine the precision of each assay. This calculation included the data collected from each of the two runs. The CV for the Nf-Light and Ptau 181v2 advantage kits were 7% and 6.6%, respectively. The CVs for NfL and GFAP within the N2PB Advantage Kit multiplex were 6.4% and 7.4%, respectively. The CVs for NfL, GFAP, A β 40, and A β 42 within the N4PE Advantage Kit multiplex were 8.2%, 9.4%, 6.0%, and 4.4%, respectively.

Conclusion: The qualification study of commercially available NfL, Ptau 181v2, N2PB, and N4PE Advantage Kits demonstrates precision that met the NCRAD BAL criteria of total average precision CV of 10% or less and have been implemented in the lab. The stability and bridging study illustrates that NCRAD BAL can maintain stability of the assays and demonstrate that performance over time will be consistent to deliver reliable data for researchers submitting samples for analysis.

PE-24 A Multispectral Fluorescence Lifetime Imaging (FLIM) System for Rapid Biochemical Assessment of Fresh and Frozen Tissue Specimens in Biobank Settings

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Statement of the Problem: There is an increased appreciation for well-designed biobanks for procuring and maintaining a repository of high-quality specimens for patient-oriented research, and a number of organizations (academic and non-academic) are gearing their resources toward this direction. Research dissemination of specimens from the repositories need to be quality-controlled and associated with metadata that are compliant with the ethical and regulatory principles that govern the biobank workflow. One of the quality-control (QC) processes entails maintaining the specimen integrity by minimizing

the time between the tissue collection and its storage in appropriate temperature conditions ($\sim 80^\circ\text{C}$ or lower). Between tissue collection and its storage, a pathologist's assessment (often frozen sections) can be valuable; however, this method has limited scope due to narrow sampling of the entire tissue.

Proposed Solution: A rapid assessment of the entire tissue to get a snapshot of biochemical and metabolic signatures of the tissue before it is frozen can be an excellent framework for a standardized and reproducible biobanking practice. In this study, we will describe the development, calibration, and validation of a compact, hand-held, multispectral fluorescence lifetime imaging (FLIM) system that can provide high-speed (~ 3 -5 seconds) biochemical maps of endogenous fluorescence (autofluorescence) in surgical tissues.

Conclusions: We will describe the operational principles of this system along with our preliminary validation of this system using selected human repository tissue cohort. We envision that this system can be used not only for obtaining FLIM images from fresh tissues but also for assessing the tumor content in archived (frozen) tissues without compromising tissue integrity. This feature can significantly increase the value of archival specimens by providing a standardized way of quality assessment in tissue specimens banked at different time points of organizational biobanks. We will also demonstrate how the approach described here can facilitate cohort building for research groups.

PE-25 Role of Biospecimen Science in Cancer Biomarkers: A Funding Opportunity for Basic and Clinical Researchers

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Introduction to the Problem: There is a lack of standardization and annotation when studying biomarkers in basic and clinical research. There is a need for creating best practices to standardize biospecimen-handling practices for emerging and developing biomarkers. The Biorepositories and Biospecimen Research Branch (BBRB) of the U.S. National Cancer Institute (NCI) has designed a funding opportunity to support extramural research to study preanalytical challenges facing biomarker assay development. Investigators can propose work performed on variety of biospecimen types and molecular platforms used in biomarker research.

Proposed Solution and Methods: Core tissue biopsies, needle aspirates, blood, urine, saliva, breast milk, feces, tissue exudates, sweat, cerebrospinal fluid, and biospecimen aspirates can be utilized to investigate and standardized several biomarker assays. Funded grants include integration of biospecimen science in both solid and heme malignancies using both tissues and liquid biopsies. 13 grants have been funded to date that include breast cancer, glioblastomas, lung cancer, bladder cancer, prostate cancer, and cutaneous and peripheral T-cell lymphoma. There is a steering committee that meets bi-annually which consists of investigators, NCI, FDA, NIST, and patient advocates. Several working groups have also been formed that works on addressing specific topics.

Conclusions: The funding opportunity will help build a solid foundation of biospecimen science in clinical research with collaborative activities, sharing of biospecimens, cross validation, and development of biospecimen best practices. Applications are being accepted for this funding opportunity with future receipt dates of Jan 11, 2023, and June 07, 2023.

<https://grants.nih.gov/grants/guide/pa-files/PAR-22-049.html>

PE-26 Effect of Different Cryopreservation Temperatures on Recovery of Postmortem Goat Skin-Derived Fibroblast Cell Populations

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Background: Skin fibroblasts are ideal cells for conservation of germplasm and animal cloning due to their easy accessibility and reprogramming potential. Cryopreservation is an important technology to preserve livestock germplasm for future use, specially at a time when climate change is real. It is well known that lower the temperature, longer the cells and tissues can survive. However, the effect of different freezing temperatures on recovery of cells is not precisely known. Here we show isolation of live fibroblast cells from goat skin, after 14 days of animal death, and the effect of 4 different freezing temperatures on their post-cryopreservation cell recovery.

Methods: We cultured small (2-3 mm²) skin explants (n=10) from goat ear in DMEM media supplemented with 10% FBS, 50 units/mL of penicillin, 50 µg/mL of streptomycin, and 2.5 µg/mL of fungizone. Outgrowing cells were recovered by trypsinization and dispensed in cryovials (50,000 live cells/vial) in 1.0 mL media with 10% DMSO and stored at 4 different freezing temperatures, in triplicate, for each group. After two weeks the cells were thawed at 37°C, cultured in 12-well microtiter plates in CO₂ incubator, and analyzed for growth morphology, comparative confluence, and cell viability using trypan blue assay.

Results: We established a fibroblast cell-line from an accidentally deceased goat kid skin after 14 days of its death. The cells were cultured for 3 passages and cryopreserved at -20°C, -80°C, liquid nitrogen (-156°C; LN₂), and -80°C overnight followed by storage in LN₂ (-80°C/LN₂ group). After two weeks of storage, cryovials in triplicate for each group were thawed, cultured, and analyzed. Mean and standard deviation of live cells recovered after 5 days of in vitro culture was $1.0 \pm 0.71 \times 10^5$, $7.60 \pm 2.88 \times 10^5$, $1.40 \pm 0.55 \times 10^5$, and $14.80 \pm 1.30 \times 10^5$ cells / mL for -20°C, -80°C, LN₂, and -80°C /LN₂ groups, respectively. Recovery of cells stored at -80°C/LN₂ group was significantly higher than -80°C (p<0.0007), -20°C (p<0.0001), and LN₂ (p<0.0001) groups. Recovery was least upon freezing cells directly into LN₂. These results agree with cell confluence images, captured prior to recovering cells.

Conclusion: We conclude that step cooling (-80°C overnight followed by LN₂) is most effective for cryopreservation of goat fibroblast cells. Although storing cells in -80°C was significantly higher than -20°C (p<0.0002) and LN₂ (p<0.0003) groups, it was less than -80°C/LN₂ group.

PE-27 The Need for Standardized Cryoprocessing on Preservation Outcomes

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Background: Recent literature indicates that the characteristics of ice formation during cryopreservation can impact preservation outcomes in eukaryotic cells. Ice formation can be modulated by various chemical approaches, such as anti-freeze proteins or reagents, and other physical means, such as high temperature ice nucleation and controlled rate freezing. Certain

non-adherent human cell lines have poor post-cryopreservation outcomes characterized by significant loss of viability 24 hours post-thaw which could be due to variation of ice formation characteristics during cryoprocessing. It is a common practice to use passive freezing containers for small-scale cryopreservation. However, such freezing conditions have limited scalability and offer very little control over the freezing process. The current work highlights the need for standardization in freezing processes in cryopreserving biomaterials in production environments.

Methods: In this study, preservation outcomes of THP-1 human monocytes isolated from a monocytic leukemia patient (ATCC TIB-202) were compared from multiple controlled rate freezing (CRF) temperature profiles using an identical cryopreservation medium. Cell recovery was measured using standard viability, growth, and metabolic activity. Finally, the thermal characteristics of each CRF profile were analyzed using differential scanning calorimetry.

Results: All recovery metrics recorded were moderately lower when compared to the non-frozen control. Additionally, there was statistically no difference in viability and metabolic activity between the different freezing methods. However, there was a reduction in the variability between the CRF profiles when compared to the passive freezing container. We also report differences in the thermal characteristics between the different freezing profiles.

Conclusions: This work reconfirms that batch-to-batch variability remains a concern in cryopreservation outcome of mammalian cells; standardization of CRF profile could be an important strategy to address the issue. Further investigation is required to identify the exact mechanisms of variability reduction during cryoprocessing.

PE-28 The Value of a Gift - Understanding the Perceived Value of Post-Mortem Brain Donation for Research

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Statement of the Problem: Of adult patients diagnosed with glioblastoma multiforme (GBM), only 5% survive 5 years. GBM research remains hampered by an incomplete understanding of brain tumour biology, partially attributed to limited access to human brain tumour samples. Post-Mortem Brain Donation (PMBD) programs allow researchers a unique insight into the pathogenesis of glioblastoma and address the challenge posed by tissue shortages.

There are available data for motivations and barriers to PMBD in neurodegenerative and psychiatric diseases, but not for primary brain cancers such as GBM.

Proposed Solution: Our aim was to conduct a systematic review of existing literature to identify and characterise the perceived benefits and harms posed by PMBD programs to better understand the potential psychosocial value of PMBD in GBM.

A systematic search of Embase, Medline, PsycINFO, Psychology and Behavioural Science, and Scopus extracted relevant studies investigating the motivations, barriers, psychosocial impact, or personal experiences of PMBD among patients, family, and carers. Thirty-eight studies were identified

for data extraction with quantitative and qualitative data grouped into key perceptions of benefit and harm.

The perceived benefits of PMBD were characterised into key themes including: altruism, contributions to science/medical research, comfort/consolation, and control/empowerment. An aversion to 'waste' was a key benefit identified across multiple participant groups. Perceived harms included physical harm and emotional distress, disfigurement, delay to funeral, and withdrawal of clinical care to accelerate donation timelines.

Conclusions: Some perceived harms reflect misconceptions of the brain donation process, indicating the need for increased education and outreach to patient communities. Understanding patient experiences with inter-disciplinary PMBD programs will allow for an evidence-based, best practice model to support the GBM clinical research programs. Recognising the variability within respondent groups confirms the need for further investigation, particularly with respect to brain donation in the setting of glioblastoma multiforme.

PE-29 Assessing the Quality of Plasma Obtained from Blood Plasma Separation Microdevice for Liquid Biopsy Application

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Liquid biopsy is rapidly emerging as a promising diagnostic, prognostic, and predictive tool in cancer patient care. Currently, plasma is ubiquitously used as a standard sample for the downstream processing of potential biomarkers such as ctDNA. Therefore, obtaining ctDNA in its pristine state is contingent upon the high quality of plasma. It's also observed that centrifugation-induced WBCs lysis increases background production of cfDNA, thereby adding to the noise during downstream detection. Hence, the preparation of a good quality sample is an important step in liquid biopsy application.

The Blood Plasma Separation (BPS) micro-device is a microfluidics chip that extracts plasma from undiluted blood input using hydrodynamic techniques. We propose that low stress involved in plasma separation in BPS may reduce the WBCs lysis and improve the detection of ctDNA in the sample. Our pilot clinical study aims to assess the quality of plasma obtained from BPS and compare it against standard centrifugation. We further proposed that the technology has the potential to reduce the time of the pre-analytical sample workflow while minimizing manual operation and the human errors and contamination that may be caused by the same.

PE-30 Δ S-Cys-Albumin as a Biomarker of Pediatric Biospecimen Integrity

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Background: Blood plasma storage is a crucial element of pediatric biobanking. Improperly stored or handled specimens (e.g., at $> -30^{\circ}\text{C}$) can result in altered biomolecular composition

that no longer reflects in-vivo reality. Monitoring biospecimen integrity in pediatrics is crucial because, compared to adults, fewer and lower volume samples are typically available for children, due to the ethical and practical challenges of conducting pediatric research. We report application of a previously developed technique in adults, the Δ S-Cys-Albumin (Δ SCA) assay, to a population of pediatric plasma samples to determine its applicability, estimate a reference range, and test initial pre-centrifugation time at 0°C , as well as plasma thawed-state exposure to a range of times at 23°C , 4°C , and -20°C .

Method: S-Cysteinylation-albumin (SCA) is a post-translationally modified form of albumin that increases in relative abundance in thawed plasma/serum ($> -30^{\circ}\text{C}$), as unmodified albumin spontaneously undergoes oxidative S-cysteinylation ex vivo. The relative abundance of SCA eventually plateaus below 100% in all specimens. To quantify Δ SCA, the baseline relative abundance of the SCA proteoform is measured using dilute-and-shoot LC/MS, an aliquot incubated at 37°C for 24 hrs to intentionally drive S-cysteinylation to its maximum plateau, after which SCA relative abundance is remeasured. The difference, Δ SCA, is used to assess the exposure of specimens to thawed conditions.

Results: Using 109 pre-collected and processed pediatric EDTA plasma specimens grouped into six-time bins, we found no difference in Δ SCA under conditions of pre-centrifugation delay for up to 10 hrs at 0°C . This lack of change allowed us to estimate a pediatric reference range for Δ SCA of 6.4-19.3% ($12.8 \pm 3.2\%$), with a modest Pearson correlation between Δ SCA and age ($r=0.22$; $p<0.05$). We also evaluated Δ SCA stability in six specimens at 23°C , 4°C , and -20°C , finding that plateaus were reached by 1 day, 7 days, and 14-28 days, respectively.

Conclusions: Pre-centrifugation delays of up to 10 hrs at 0°C did not impact Δ SCA in specimens from pediatric patients, 0-18 years of age. The pediatric reference range observed was lower than previously observed in 180 adults 12.3-30.6% ($20.0\% \pm 3.8\%$) and the slope of the age correlation was twice as steep, but the rate of Δ SCA decay was similar to adult plasma.

Ethical, Legal, and Social Issues

PF-01 Oversight of Tissue Banking Activity in Clinical Trials by SingHealth Tissue Repository

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Statement of Problem: When clinical trials are conducted in healthcare institutions, human tissue is collected for the purpose of the clinical trial. Extra human tissue is often collected for future research purpose according to the agreement between the institution and the sponsor.

The Human Biomedical Research Act (HBRA) came into effect in Singapore in November 2015 and serves to regulate the conduct of human biomedical research (HBR) and the use of human tissue in research. With the implementation of the Human Tissue Framework (HTF) of the HBRA in November 2019, tissue banking activity (TBA) is defined as an organized activity involving collection, storage, procurement, supply, import, or export of human tissue. If human tissue is collected to meet clinical trial objectives and endpoints, such collections are governed by the Health Product Act or the Medicines Act. However, human tissue collected beyond the scope of Health Sciences Authority-approved clinical trial protocol or for future

unspecified research is regulated by HTF and must be undertaken or overseen by a tissue bank.

Proposed Solution: SingHealth Tissue Repository (STR) has established a workflow to oversee such tissue collections for clinical trials involving the collection and supply of extra and/or leftover human tissue for unspecified future research. STR oversees the TBA by ensuring that all relevant documents and approvals are in place. These include appropriate consent from study subjects, clinical trial agreements indicating the supply of human tissue for future research, and accurate documentation of transfer and receipt of human tissue or derivatives.

Conclusion: With the implementation of oversight workflow, STR is able to provide a tissue banking and oversight service to researchers for clinical trial in compliance with HBRA. The workflow is necessary to ensure that TBA carried out in clinical trials follow the law and regulations in Singapore and that the fundamentals of good clinical practice relating to ethics and science are upheld to protect the rights, safety and well-being of research subjects.

PF-02 Incorporating Equity, Diversity, and Inclusion into a Canadian Biobank

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Background: Equity, diversity, and inclusion (EDI) is an important issue in the research environment including biobanking. EDI initiatives, in Canada, are providing awareness and guidance, along with education and tools to meet new guidelines. We set out to review the concepts of EDI and determine how to integrate EDI principles into biobanking from 3 perspectives: our biobank team, biobank participants, and researchers who access our biobank. Our aim was to develop and implement a formal biobank EDI plan.

Methods: One member of our team was assigned to investigate the concepts of EDI and report back to the team at weekly team meetings held over 6 months. EDI material was accumulated and reviewed from a variety of sources including: Canada Research Chairs; Federal and Provincial legislation; and institutional policies and guidelines using relevant internet search terms, e.g., equity, diversity, inclusion, research, Indigenous, race, ethnicity, gender, disabilities, and cultural safety.

Results: A list of glossary terms and EDI learning resources guided the development of a formal biobank EDI plan. Included in this plan:

- determine a defined glossary;
- develop a team awareness and learning plan;
- develop EDI objectives;
- implement EDI sound bites at weekly team meetings (e.g., definitions, institutional EDI information);
- update team electronic signatures with pronouns and a land acknowledgement;
- create a statement for addition to our websites;
- conduct a human resources review (job postings, interview questions, orientation, training);
- determine a checklist with an EDI focus for reviewing biobank documents, websites, and offered educational material and use to develop, improve, or modify biobank material to reflect our enhanced understanding of EDI;
- share our EDI knowledge.

Conclusion: Many perspectives and experiences influence EDI in biobanking; therefore, our biobank team has developed a formal biobank EDI plan. We have determined a glossary and implemented an EDI soundbite at our weekly team meetings. We have initiated a team awareness and learning plan. Our next steps for implementation will be the additions to our electronic signatures and initiating the review of our biobank documents, websites, and educational material with an EDI lens. We are committed to implementing EDI principles within our team and for our biobank participants and researchers that access our biobank.

PF-03 Efforts to Scale Return of Research Results in the Mayo Clinic Biobank

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Background: The Mayo Clinic Biobank (N=53,000+) is tasked with responsibly returning pathogenic/likely pathogenic (P/LP) variants within the ACMG78 secondary findings gene set. Many challenges must be overcome to scale return of research results to large populations, including: data storage, large-scale variant interpretation, removal of previously reported mutations, scheduling of genetic counselor (GC) visits, and subject preparedness. We have utilized multiple approaches to overcome these challenges.

Methods: Genomics data (N=53,000+) is stored in a secure, centralized data warehouse to ensure data security, proper authentication protocols, and protection of intellectual property. To reduce manual variant interpretation, we developed and validated Semi-Automated Variant Interpretation (SAVI) software. SAVI uses a rules-based Python algorithm which uses variant annotation, variant databases, and ACMG guidelines to prioritize potentially reportable variants by imputation of an InDepth Score and Range of Pathogenicity Classification for every variant in a sample VCF within the ACMG78. Only those variants meeting a defined likely reportable threshold are prioritized for manual review. To identify those with electronic health record (EHR)-documented ACMG78 P/LP variants, we used an NLP tool to develop rule-based algorithms to extract all mentioned gene mutations in a reference cohort. Algorithms were modified until recall reached 100%, then applied to and refined for positive predictive value (PPV) within the entire biobank. Sentences mentioning mutations were extracted from the EHR for manual validation. To expedite GC visit scheduling and subject preparation, we developed a chatbot with input from community members.

Results: In a pilot of 983 subjects, SAVI prioritized 258 discrete variants in ACMG59 genes (0.006% of all variants) within 335 samples that were manually reviewed, resulting in 40 subjects with a reportable variant. The NLP algorithm and subsequent review led to identification of 384 subjects with documented P/LP variants that do not need to be returned. In a small pilot of the chatbot, 87% used the chatbot to schedule a GC visit. Among chatbot users, 85% completed personal and family history, 96% indicated high satisfaction.

Conclusions: Multipronged efforts are needed to enhance the scalability of the return of research results to subjects. Results demonstrate the potential role of technology in scaling biorepository disclosure obligations.

PF-04 A Multi-Prong Operating Model for Balanced Application of Ethical & Religious Directives, Federal Regulations, and Virtual Biobank Operations at CHRISTUS Virtual Biobank

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Background: Established in 2018, CHRISTUS Virtual Biobank (CVB) does not physically store human biospecimens, but utilizes an integrated international network of ethical sources to provide a convenient, structured, on-demand, single point of access to a wide range of high-quality, richly annotated, fit-for-purpose biospecimens on a fee-for-service basis from diverse donors for multidisciplinary research and development. Driven by the mission to extend the healing Ministry of Jesus Christ, CHRISTUS Health is formed from the convergence of three faith-based congregations and ranks among the top ten Catholic health systems in the United States.

Methods: To preserve our Catholic mission and identity, and to ensure integration of The Ethical and Religious Directives for Catholic Health Care Services (ERDs) over the continuum of the biobanking research protocols, CVB has designed, drafted, developed, and deployed a multi-prong operating model. For overall success, it was highly important to engage the relevant list of stakeholders during each step. These multi-prongs are abbreviated as 'FIRE CONTROL' and their details are described as: A] Feasibility Review, B] Informed Consent Review, C] IRB/Ethics Review, D] Contract Review, E] Policies and Standard Operating Procedures, F] Initial and Ongoing Education, G] Language Access Services. Our operating model has been meticulously developed with a practical approach while maintaining the delicate balance between ERDs, federal regulations, and virtual biobank operations.

Results: Since the adoption of FIRE-CONTROL operating model, CVB has expanded significantly by developing strategic collaborations and robust business pipeline with leading global researchers while hardwiring mission, identity, and teaching found in sources such as the ERDs.

Conclusions: The applicable clinical research regulations as set forth by HHS and FDA must be followed by all clinical research institutions, faith-based or not. The teachings of the church have been developed over more than 2,000 years, but sometimes conflict with the current federal regulations related to clinical research, such as pregnancy prevention/birth control, gene therapy research, selection of subjects, etc. Our operating model has struck the harmonious balance between all these requirements. Similar biobanks associated with faith-based organizations may consider adoption of our FIRE-CONTROL operating model as-is or a customized version of it to meet their business needs.

PF-05 WITHDRAWN

PF-06 A Successful Minority Outreach Model for Biobanking

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Despite current efforts to increase minority representation in research, therapeutic trials, mainly biospecimen collection, have historically yielded lower percentages of minority populations in their studies. Academic interest in increasing minority populations has not waned, but there has been little discussion in how to systematically improve representation across research for biospecimen collection. Barriers to participation, like lack of access to research facilities, contribute to this gap in representation. Our current effort is to increase minority outreach in the catchment area of Moore's Cancer Center by developing a collaboration model under the California Initiative for Advanced Precision Medicine (CIAPM) for Hispanic triple negative breast cancer (TNBC) patients. This pilot program may enable future biospecimen collection partnerships between minority-rich community medical centers and comprehensive cancer centers.

The CAP-accredited UCSD biorepository (BR) developed a successful collaboration with El Centro Regional Medical Center (ECRMC), located in a rural border region with a high proportion of Hispanic residents. This collaboration was enabled by an existing clinical research infrastructure at ECRMC and BR under an IRB-approved protocol. Standard operating procedures were established for patient enrollment and biospecimen collection from remote collaboration sites. An ECRMC oncologist identified Hispanic TNBC patients. The ECRMC bilingual coordinator then arranged an appointment for remote consenting. The BR coordinator facilitated the informed consenting process in the presence of a licensed medical provider and a certified bilingual translator over Zoom. Consented patients provided a 10mL of blood. The ECRMC coordinator also requested remnant formalin-fixed paraffin-embedded (FFPE) tissues from the pathology archival collection. The anonymized blood samples, FFPE tissue blocks, pathology reports, and associated medical records were collected.

This successful collaboration resulted in the collection of biospecimens from 19 Hispanic TNBC patients over a period of 13 months. In all 28 patients were approached for consenting, 4 patients declined consent and 5 patients are still pending appointment. This pilot project established the groundwork for partnerships with regional community centers and may serve as a model for other BRs to improve collection of biospecimens to promote minority participation in cancer research.

PF-07 Biobank-Specific Regulatory Requirements and How to Address Them

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Statement of the Problem: UHN Biospecimen Services is a large-scale biospecimen storage and sample information management group, which facilitates the use of high-quality samples and associated data to drive health research. The unique nature of biobanking necessitates regulatory considerations. Samples are stored long-term, often for several years, prior to their use for research. Samples may be used months or years after consent to participate in a biobank. The research techniques that make use of the biospecimens may not yet exist at the time of consent. Biobanks must ensure that participants understand how their samples may be used and that true informed consent is obtained.

Biobanking presents unique legal and contracting requirements, such as determining what constitutes identifiable information regarding patient privacy, and whether this includes tissue and genetic information. This creates challenges in determining

the economic value of banked samples when drafting a contract with a collaborator or negotiating intellectual property.

Many of the researchers that collaborate with biobanks perform genetic analyses, including whole genome sequencing. These collaborators may be located outside of Canada and the laws governing genetic research differ by country.

Solutions: The informed consent forms used by biobanks must be developed to ensure true informed consent is obtained. Patients are made aware of the potential time interval between the collection of biospecimens and their use in research, and of the types of research that may make use of the specimens.

Identifiable information is defined differently in different countries. Tissue and genetic information are not likely to be able to identify patients at the current level of sequencing technology.

Contracting issues and genetic laws are addressed on an individual basis in collaboration with the institutional legal team to ensure that our program can continue to operate sustainably.

Conclusions: Appropriately addressing biobank-specific regulatory requirements can ensure the effective and timely use of biospecimens, allowing UHN Biospecimen Services to continue to support high-quality oncology research both locally and globally.

PF-08 Differences and Similarities Between Local and Global Genetic Information Law and Regulatory Considerations

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Statement of the Problem: Genetic analysis, including whole genome sequencing, is an important component of many modern research studies. Many researchers that collaborate with UHN Biospecimen Services utilize genetic information in their analyses. UHN Biospecimen Services collaborates with researchers not only within Canada but also internationally. Each of these areas is governed by different laws regarding genetic research and information.

Collaborating with researchers outside of Canada requires consideration of these different laws.

Solution: Researchers in different countries are governed by different laws regarding genetic information: The Genetic Non-Discrimination Act in Canada, the Genetic Information Non-Discrimination Act in the United States, and the General Data Protection Regulation of the European Union. There are similarities and differences between these laws. Understanding the nuances of each is key to obtaining Research Ethics Board approval of proposed research projects, contracting, and prompt initiation of research activities.

Conclusions: Genetic analysis is a quickly growing field of research. Understanding the laws governing genetic research in different countries is essential to the support of research on a global scale.

PF-09 What Egyptians Think! Knowledge, Perceptions, and Attitude of Egyptian Stakeholders towards Biobanking

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Background: Biobanking is a relatively new concept in Egypt. Building a successful relationship with different stakeholders is essential for the social sustainability of biobanks. To establish this relationship, it is necessary to assess the knowledge and attitude of different groups towards this concept. The objective of this work is to assess the knowledge, perceptions, and attitude of Egyptian stakeholders, namely, patients, physicians, and medical students, towards biobanking issues.

Methods: We designed three surveys to be administered to each of the three groups in 3 university hospitals in Egypt. The surveys included questions estimating the level of knowledge about the term "Biobank," together with questions about the attitudes and opinions about ethical and other related issues of biobanking.

Results: Knowledge about the term "biobanking" was quite limited among the different groups, and was lowest among patients (81% never heard the term before). However, there was a general positive attitude towards the concept, where most patients (85%) were willing to participate with their samples and data in biobanks, and the other two groups had a general positive attitude towards the value of biobanks in research. While a great majority of patients (87%) thought that sample donation does not contradict their religious beliefs, only 30% of physicians agreed on the same statement. A limited number of patients were supportive of participation in genetic research (58%), fewer supported sharing their sample with pharmaceutical companies (27.8%), and 32.4% agreed to share their samples with institutions abroad. A higher percentage of physicians and students supported sharing biospecimens with international research organizations, but lower percentages supported collaboration with pharmaceutical companies. There was a general agreement that research results and incidental findings should be returned to participants in research supported by biobanks.

Conclusion: Although there is limited knowledge about biobanking among different stakeholders, many had a positive attitude towards the concept and didn't show religious concerns against it. However, they had concerns regarding sharing samples with pharmaceutical companies (commercialization issue) and some had concerns regarding participation in research with institutions abroad. Education about biobanking is necessary to sustain the developing field, taking into consideration the specific cultural and legal framework in Egypt.

PF-10 Consent Tools for Pediatric Research Involving Databases and Biobanks

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Statement of Problem: Research increasingly relies on the use of rich sets of data and biological samples. In the past, children were often excluded from research, mainly due to

ethico-legal concerns and limited resources. While pediatric research warrants the implementation of special safeguards, overly protectionist policies deprive children of their right to benefit from science. Consent forms should therefore prospectively address the key issues in pediatric research today. First, pediatric-specific clauses should be used to facilitate the collection and sharing of data and biological samples from children over time while addressing relevant ethico-legal issues. Second, with consent, existing clinical resources, such as leftover tissues and newborn bloodspots, can be leveraged for ongoing research use. These are being used by initiatives such as the Human Cell Atlas and can serve as models for future research.

Proposed Solutions: Pediatric consent forms must address a number of key issues. Two relevant “participation” issues are assent and recontact. Obtaining assent from children who are able to understand the general purpose of the research is an ethical requirement. It ensures that children are included in decision-making processes in developmentally appropriate ways. Furthermore, ethical guidelines require that when children reach the age of consent, whether at the age of legal majority or medical maturity, researchers should either recontact or notify them to obtain permission for the continued storage and use of their data and biological samples.

Rather than being discarded, residual tissues from clinical procedures, such as biopsies or resections, can be used for research purposes. The same is true for newborn bloodspots. In both cases, consent can be used in conjunction with clinical procedures to harness these resources which provide valuable developmental insights into child health.

Conclusions: Research involving data and biological samples is key to advancing our understanding of human health and well-being. However, such resources are limited in pediatric populations, often due to ethico-legal concerns and limited resources. Special consent clauses can help address these issues and make data and samples more readily available for research. Anticipating the use of special consent forms can help leverage existing clinical resources for research use. These tools may serve as models for future pediatric research initiatives.

Hot Topics

PG-01 The Importance and the Specific Method of Education and Training in Biobanking

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It is widely recognized that global developments in the multidisciplinary field of biobanking are linked to the rising shortage of specialized biobanking workers. Comprehensive education should be provided to address these needs and translate knowledge and experience into applied biobanking science. Exceptional opportunities for integrated and multi-partner study opportunities in biobanking are created at several universities.

The lecturers are dedicated to transferring their knowledge and first-hand experience with practical implementation and management of biobanks to educate the next generations of biobankers. Significant is the transfer of the knowledge not only theoretically but in practical active work within biobanks as well in workshops and interactive group work. The main ad-

vantage of the method in biobanking education is the involvement of specialists in the management of national and international biobanks, quality management, risk assessment, sustainability, budgeting, and cooperation (academic and industrial).

The specific modular education offers to secure the future of successful and sustainable biobanks, cooperating within networks and with international partners, representing the best confirmation of the benefits of education and practice.

PG-03 Prostate Tumor Collection for the National Tumor Bank of the National Cancer Institute – INCA/RIO DE JANEIRO/BRAZIL: Our Experience with the Validation of a New Protocol

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Introduction: Tumor banks are responsible for collecting, recording, storing, and distributing tissue and fluid samples, used by researchers to identify diagnostic molecular markers, prognostic indicators, and therapeutic targets. The objective of this work is to describe a simple, safe, and consistent protocol for obtaining and storing fresh frozen samples of prostate cancer tumors, due to the difficulty of collection for this type of topography.

Materials and Methods: Prostate tumors were collected by surgeons from the Urology Section of the National Cancer Institute. A horizontal cut was performed in the region with the greatest tumor volume, based on a previous biopsy report (base, apex, or middle). A section measuring approximately 1.0×1.0×0.5 cm was cut by the technician from the Tumor Bank, and these fragments were placed on a glass slide and sectioned in a mirror-like manner. A fragment was placed in a cryovial. They were evaluated by the pathologist, the % tumor in the collected specimen was estimated, and they were immediately placed in liquid nitrogen and then stored by cryopreservation (-80°C). A mirror fragment was fixed in 10% formalin and HE slides were prepared for retrospective pathological evaluation. Samples with more than 70% tumor tissue were considered suitable for future research.

Results: During the period from September 2020 to March 2022, INCA's National Tumor Bank processed 80 samples with this protocol and 76 were evaluated for tumor content. 71/76 samples were considered adequate in 93.4%. In none of the cases did it compromise the pathological evaluation.

Conclusions: The technique described is effective and innovative, producing frozen tumor tissue in 93.4% of the samples, without compromising the clinical diagnosis. Having access to well-characterized and available biological samples, along with clinical patient information, provided an integrated picture of patients and their diseases, facilitating advances in molecular biology. It also promoted the development of translational research, improving cancer diagnosis and treatment methods.

PG-04 Pre and Post-COVID-19 Biospecimens Trend at Princess Margaret Cancer Biobank

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Background: Since the COVID-19 pandemic, biobanks have been a fundamental resource, allowing researchers to request and utilize high-quality biospecimens. The entire process of requesting, storing, and/or distributing biospecimens is complex and requires precise timelines, onsite staff, and adequate logistics. As the pandemic crisis deepened and the government started to implement lockdowns, all nonessential research was shut down and UHN was not an exception. This measure changed the type of requests received in our biobank, going from prospective biospecimen cohorts to mostly retrospective requests. Here we describe the type of biospecimens that were distributed and collected during the 3 different periods starting in March 2019 up to February 2022.

Methods: We have compiled the metrics related to total requests, distribution, and banking for tissue and biofluid biospecimens during three different periods ranging from 2019 until 2022. These data were obtained from our internal platform and analyzed to compare the different biospecimens banked and distributed.

Results: The major impact on the supply and demand chain was on fresh tissue distributions, falling from 455 requests in 2019 to an almost 50% reduction in 2020. We outline that the distribution for genito-urinary and thoracic tissue sites was not affected during the pandemic. In contrast, breast, gyne, gastro, and head and neck tissue distributions were the most affected sites with less than 10 distributions during this period. For biofluid specimens, we reported an increase in distribution and banking during the COVID-19 period, with the majority being study-specific and showcasing the shift in the study's priorities to adapt to the pandemic scheduling challenges.

Conclusion: The supply-side reduction for tissue was mainly due to the cancellation of surgeries during the COVID-19 lockdown and the shortage of staff at surgical pathology, leading to a low collection of surgical tissue during this time. However, the PMCB biobank was able to distribute and bank around 28,000 tissue and biofluid specimens not related to COVID-19 during the pandemic. Our success is attributed to a consolidated workflow as well as the rapid identification of barriers and adaptability.

PG-05 The Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit Biobank Experience and Continuation during Coronavirus Disease of 2019 in Uganda

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Statement of the Problem: The MRC/UVRI and LSHTM Uganda Research Unit biobank stores biospecimens for the different research projects or collaborative projects at the unit. In March 2020, Uganda reported its first COVID-19 case. A few days later the President declared 14 days' nationwide curfew from 7pm to 6:30am. The country later announced a strict lockdown as the number of confirmed cases increased. Public transportation was suspended and restrictions placed on private

vehicle movements. This restricted people to stay in their homes and work remotely. The operation of the unit's biobank drastically changed. It had to plan for the continuity of its operations while observing safety measures. The world-wide travel bans and restrictions also slowed down the delivery of consumable orders.

New opportunities and challenges were faced by the biobank at the unit. The biobank supported ethically approved COVID-19 research projects by availing storage space for the collected biospecimens and temperature monitoring of the storage equipment. With the influx of biospecimen collections that required storage, the workload increased as the biobank still supported other research studies at the unit.

Proposed Solution: The MRC biobank management and the unit's COVID-19 Business Continuity Team had to put measures in place that minimised the risk to the staff who had to go in physically to work. At the unit, there was a strict prioritization of the staff who had to physically go for work during the lockdown.

The unit received a limited number of movement permits from the Ministry of Health which were handed out to some of the prioritized staff. The biobank's emergency plans focused on maintaining the cryopreservation of the biospecimens in their custody and continuing temperature monitoring of equipment.

One new biobank staff was hired to specifically handle biospecimen storage of the approved COVID-19 research project that requested to store biospecimens with the unit biobank. The biobank was also able to outsource consumables that were available in the country.

Conclusions: The unit's management and business continuity team were supportive and prompt in addressing the needs of the biobank. The Biobank was able to continue and sustain its operations despite the few challenges that were faced during the pandemic. Learning from the situation, the biobank has since then worked to develop contingency plans on keeping its operations during any pandemic.

PG-06 Harmonization of Electronic Medical Records Diagnoses Between Hamad Medical Corporation and Qatar Biobank

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Introduction: Biobanks collect and store a vast amount of data including medical history and diagnosis. Assessing the medical history of a participant in a biobank is usually through self-reported questionnaires, which is what is being done at Qatar Biobank (QBB). However, QBB is taking it one step further. QBB has received access to electronic medical records (EMR) from Hamad Medical Corporation (HMC) of participants of QBB who have consented to have their data used for research purposes.

Now that access to EMR is available to QBB, data harmonization between the medical records and QBB data is necessary to enable QBB to have as much information about the medical history of a participant to be used for research purposes.

Method: A unique health card number or a national identifier is used to register a subject to participate in the QBB cohort study. This identifier was also used to obtain the EMR data for these subjects. The EMR data was then merged to QBB data using one or both unique identifiers.

A master diagnosis catalog was provided from HMC with 13 different diagnosis standards for all the subjects. SNOMED CT and ICD-10 diagnosis standards represented the biggest amount

of diagnoses codes in the master catalog. ICD-10 CM was used for the classification of diseases and all diagnosis standards were harmonized against it. Challenges identified related to the formatting of the codes, multiple ICD-10 CM codes for a single diagnosis code, and mismatch between the code ID and the diagnosis name were curated after applying Mapping files found for ICD-9 CM, ICD-10 CA, ICD-10 AM, and SNOMED and/or by discussion between the two reviewers. QBB Data catalog was updated, including the description and the business rules related to the harmonized data.

Results: EMR data for more than 8,000 subjects have been harmonized against ICD-10 CM. Of the 13 diagnosis standards, 9 were found to be either procedure codes or drug names and were not harmonized to the diagnosis codes. Approximately 107,300 diagnosis codes were provided by HMC for these 8,000 subjects and approximately 129,000 ICD-10CM codes were harmonized to the given diagnosis standard from HMC.

Conclusion: Harmonization for 8,000 subject was accomplished between EMR from HMC and QBB, which is providing QBB with more detailed data of a subject's medical history than ever before and can provide researchers with diagnoses based on ICD-10 codes for their research interest.

PG-07 Biospecimen and Data Resources from the Cancer Moonshot Biobank

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Statement of the Problem: Advances in precision medicine research have fueled the need for high-quality biospecimens from diverse participants and their associated structured clinical data. While national biobanks have been established to manage the collection, storage, and distribution of biospecimens and accompanying patient data, streamlining the biospecimen and data-sharing process remains a challenge due to underdeveloped infrastructure and the lack of a user-friendly interface.

Proposed Solution: Under the U.S. Cancer MoonshotSM initiatives, the Biorepositories and Biospecimen Research Branch (BBRB) at the National Cancer Institute (NCI) has established the Cancer Moonshot Biobank (Biobank) Program to support cancer research on drug resistance and sensitivity. The main aim of the program is to collect longitudinal tumor tissues and matched blood samples from approximately 1,000 cancer patients receiving standard of care treatment. Specimens are being collected by community hospitals across the U.S. from a diverse set of participants diagnosed with one of eight targeted cancer types. A searchable web-based catalog called the Cancer Moonshot Biobank Online Catalog (Catalog) will allow researchers to locate available samples based on specified criteria; returned results also contain links to associated digitized histopathology and standard of care radiology images that are hosted at The Cancer Imaging Archive (TCIA) (<https://www.cancerimagingarchive.net/research/cmb/>) under open access. The Catalog system also manages sample requests and the distribution process in accordance with the access policy established by the program. Extensive clinical and biospecimen processing data, along with the molecular profiling data gen-

erated from donated specimens, are available under controlled access through the NIH's Database of Genotypes and Phenotypes (dbGaP) (https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs002192.v1.p1) to protect patient privacy.

Conclusions: Clinical data from the first 50 participants in the Biobank Program were released from dbGaP in August 2022. Incremental releases of data will occur quarterly. Biospecimens will be available for request through the Catalog when preset accrual thresholds are met. The well-annotated and diverse set of specimens available through the Biobank provides the resources needed to accelerate cancer research and ultimately optimize patient treatment options by personalizing healthcare.

PG-08 What Happens to Recruitment Rates at a Biobank When Healthcare Goes Virtual?

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Background: The COVID-19 pandemic has prompted a shift towards virtual healthcare whereby patients frequently attend clinic visits via phone and have their bloodwork collected at third-party laboratories. This has posed a challenge for the McCain GU Biobank (MGB), the largest genitourinary (GU) oncology biobank in Canada, where patients historically had their research bloodwork collected at the time of their in-person clinic visits at the Princess Margaret Cancer Center (PMCC) in Toronto, Canada. To adapt to this change in workflow, the MGB began to consent patients virtually in 2022. Though this was possible, we hypothesize that there has been a decrease in the number of patients being approached to participate in the MGB post-COVID-19 in comparison to pre-COVID-19 due to the rise in virtual healthcare. We aimed to investigate metrics of patients who were not approached for participation in the MGB due to them having their bloodwork done externally or not attending in-person clinic visits at the PMCC.

Methods: The number of GU surgical oncology patients who were not approached for the MGB due to their bloodwork being collected externally between the months of July-August in 2019 (pre-COVID-19) was compared to the number of patients who were not approached in those months in 2022 (post COVID-19).

Results: Pre-COVID-19, 2.45% of GU surgical oncology patients were not eligible to be approached for the MGB because either 1) their bloodwork was done outside UHN or 2) they did not attend in-person visits at the PMCC. Post-COVID-19, 70.16% of GU surgical oncology patients were not eligible to be approached for the MGB for the same reasons. Although there was still a high number of patients who had their bloodwork done externally pre-COVID-19, this was not considered an ineligibility criterion because blood collections could be done in clinic when the majority of patients were coming to their appointments in person.

Conclusions: Post-COVID-19, patients are more likely complete their bloodwork outside of the PMCC, resulting in challenges in recruiting participants and collecting longitudinal samples. This could be due to external blood labs being closer to home, smaller crowds, and shorter wait times. Virtual con-

senting may help overcome this issue, but it is only effective if the patients complete their bloodwork at the hospital. Partnering with third-party laboratories that may assist with sample collections at locations throughout Toronto may be necessary.

PG-09 A Proposal to Investigate the Impact of the COVID-19 Pandemic on Willingness to Participate in Scientific Research Among Participants of a Biobanking Initiative

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Statement of the Problem: The COVID-19 pandemic has immensely impacted scientific research activities, particularly those involving in-person interactions with vulnerable populations, such as cancer patients. Research institutions worldwide have been challenged to find a balance between continuing to advance high-quality scientific knowledge while maintaining the safety of patients by implementing methods of data collection that promote social distancing. As a result of this, clinical research as we know it has changed dramatically over the course of the last two years. Simultaneously, it is well known that the pandemic has posed tremendous impacts on patient mental health and wellbeing, factors which may be linked to trust in the healthcare system and willingness to participate in scientific research. Indeed, recent studies have observed that people may be less willing to participate in research initiatives, even observational studies, during the pandemic. However, this topic remains narrowly explored to date, particularly in the context of biobanking. We propose to investigate what factors are associated with willingness to participate following the COVID-19 pandemic. Our research proposal and preliminary findings will be presented at ISBER 2023.

Proposed Solutions: A questionnaire will be administered to previously consented participants of the McCain GU Biobank to investigate whether and how their beliefs and willingness to participate in scientific research have changed as a result of the COVID-19 pandemic. The questionnaire will be used to investigate whether willingness to participate in research is influenced by several factors, including: methods of data collection (in-person vs. remote), attitudes toward the healthcare system, sources of information during the pandemic, whether participants were severely affected by COVID-19 infections/vaccines, and sociodemographic factors.

Conclusions: Investigating what factors are influencing public interest to participate in scientific research will be beneficial in optimizing research methods as we continue to adapt to a post-COVID-19 reality.

PG-10 Rationale for a Hybridized Consent Workflow in a Biobank Adapting to Virtual Health Care

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Statement of the Problem: The McCain GU Biobank (MGB) is a biorepository historically operating in an entirely face-to-face manner to recruit, consent, and collect longitudinal samples from genitourinary patients seen during standard of care appointments at Princess Margaret Cancer Center. However, the COVID-19 pandemic created a dramatic shift towards virtual medicine. As a result, the MGB has seen a significant decline in participant recruitment due to difficulties in consenting potential participants outside of their regular clinic visits. While conducting a literature review to support the creation of a new informed consent workflow, evaluations of adapted consent processes in other biobanks highlighted challenges in enrolling diverse patient populations when offering only remote methods for obtaining informed consent. This is largely due to barriers surrounding technology, healthcare education, and an inability to develop trusting relationships remotely, particularly with patients from ethnic and cultural backgrounds that have been previously underrepresented in scientific research.

Proposed Solutions: The MGB has endeavoured to create an informed consent workflow that hybridizes both remote and face-to-face consent modalities to uphold participant recruitment following the pandemic while ensuring that a diverse population is represented within our biorepository. This includes the development of new guidance documents with detailed instructions on the administration of an external REDCap platform, used in the completion of electronic consent documents by patients seen virtually while simultaneously speaking to a biobanker to address any questions on the phone. The deployment of an internal REDCap electronic capture database allows for a seamless integration of consent and patient demographic information obtained both via electronic and face-to-face methods, which follow similar workflows for either patient visit scenario to maintain consistency in recruitment efforts. Regardless of consent modality, the REDCap internal participant tracker database follows both collected and outstanding specimens for every participant to ensure timely and quality sample collection.

Conclusions: Incorporating both electronic and face-to-face informed consent processes at the MGB addresses the needs of patients with differing consenting preferences and allows for the collection of a diverse array of specimens at multiple timepoints throughout a longitudinal pathway.

PG-11 Refining Approach Strategies Using Pre- and Post-COVID Consent Metrics at the McCain GU Biobank

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Background: McCain GU Biobank (MGB) houses high-quality specimens (such as tissue, blood, and urine) collected longitudinally from over 16,000 consenting participants in genitourinary oncology division at UHN, Canada's major hospital network. MGB has supported clinical trials and biomarker research internationally and in Canada since its inception in 2008, while maintaining an industry-leading consent rate of 93%; however, this consent rate has dropped to 79% in the immediate time period following the onset of the COVID-19 pandemic. The objective of this project was to investigate the observable causes of this decreased willingness in biobank participation, to see whether reasons for refusal to participate in the MGB have changed following the COVID-19 pandemic, and to generate strategies to address this issue.

Methods: We abstracted consent data from our pre- and post-COVID-19 consenting efforts, beginning from Aug 2019 till Sept 2022, to see if there were differences in the reasons for refusal among the approached individuals who declined to participate in the MGB. Consent trends were also correlated with global events surrounding the COVID-19 pandemic, restrictions to research in clinics at UHN, and patient attendance in clinics. These metrics are applied to shape new patient engagement initiatives within our program.

Results: While many of the common reasons provided for refusing participation remained constant, we saw an increase in patients who refused to participate in MGB due to 1) lack of interest in research initiatives (38% to 50%) and 2) feeling overwhelmed when approached (10% to 15%). While a number of factors are implicated, further investigation will be conducted to determine whether these changes in reasons for refusals were directly related to the COVID-19 pandemic. We aim to address this issue through various initiatives including initiating a virtual consenting workflow, implementing communication strategies with corresponding physicians to generate interest in clinical research, and adjusting our consenting language to best present the biobank to potential participants.

Conclusion: The post-COVID-19 era in clinical research has demonstrated the importance of vigilance and adaptability. Through consistent monitoring of patient sentiment and implementation of the aforementioned strategies, we aim to continue the MGB's industry leading consent rate of 93% while ensuring a diverse range of high quality biospecimen to research collaborators.

PG-12 Lessons Learned from the COVID-19 Pandemic: The Need for Flexible Biobanking of Healthy Control Samples

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Statement of the Problem: The McCain GU Biobank (MGB) is a cancer biorepository containing samples from both genitourinary patients and healthy control cohorts. Specimen requests from external collaborators is a cost-recovery stream crucial to maintaining sustainability. Historically, recruitment strategies for our healthy control cohort reflected a “reactive” banking modality, allocating resources in response to specific specimen requests. However, during the COVID-19 pandemic, the elimination of non-essential clinical research activities halted recruitment, resulting in no healthy control sample procurement over several quarters. Coupled with an increased demand from researchers, this resulted in a severe depletion of healthy control specimen availability, which persists through our phased return to clinic since Spring of 2022.

Proposed Solutions: In response to this depletion, it has become a goal of the MGB to optimize recruitment efforts of healthy control participants. Based on available metrics, as well as to balance allocated staffing resources and storage costs, we established a maintenance threshold of 440 healthy control cases with banked specimens based on the historic maximum demand of the most highly requested specimen type. We have then devised two strategies to achieve this threshold: the first is a short-term strategy for a recruitment “push” of about 52 healthy volunteers per month to procure adequate specimens to

fulfill the pending requests gathered during the pandemic within the next year. This historically high healthy control recruitment target at MGB may be achievable with practical strategies including attending more clinics, hiring more consenting staff, and remote consenting of healthy volunteers. We then propose a long-term “proactive” banking strategy that sets in motion a baseline recruitment rate of about 32 healthy volunteers per month to support the health of the biobank in meeting healthy control sample requests for the foreseeable future according to the historical average demand per year.

Conclusion: The COVID-19 pandemic presented an unforeseen challenge that illustrated the need for flexible recruitment and proactive resource allocation to support healthy control sample requests at the MGB. To address this need we propose strategies to optimize healthy control recruitment and sample procurement to adapt to the needs of our collaborators and ensure the sustainability of the biobank in the years to come.

PG-13 Whole Community Living Microbiome Biobanking

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Statement of the Problem: Biodiversity declines are accelerating. While protection and restoration initiatives are crucial for ecosystems, they will not be a complete solution. We're seeing new funding and awareness, but we're still stretching resources over an ever-expanding field.

Cryobanking offers hedges against rapid biodiversity declines. Repositories of tissue and gamete samples can be used to improve genetic bottlenecks in captive breeding. Stored seeds and shoots can help restore forests and agricultural crops. Repositories can also be sources of vouchered reference samples for research. For example, biobanked collections of marine samples give us the comparison data to allow for in-time monitoring of ecosystem health.

Biodiversity biobanking must expand in scope. We are still at the start with regards to what biodiversity material is chosen and how it is stored. And there are important gaps. We know that most ecosphere and living organism functions are mediated by microbes. Microbiome dysbioses are implicated in aquaculture damage, coral diseases, severe mammal and amphibian health issues, and more. As yet, most collections preserve the host part of a holobiont, but not the associated microbial communities. And when microbiomes are biobanked, it is often as genomic and metabolomic sequences, rather than living material.

Proposed Solution: Species and ecosystems restoration will depend on all parts of the system being available in storage. For holobionts, the associated microbial communities will need to be collected and preserved. Because a single animal's holobiont may include tens of thousands of microbial Operational Taxonomic Units (OTUs) from all evolutionary domains, preservation is a problem of scale, necessitating best-case solutions and technical innovations. The microbiome sample must be frozen as a whole, preserving the community structure, an interesting cryoprotection challenge. To prevent degradation over time and keep samples alive, microbial collections must be stored at liquid nitrogen temperatures.

Conclusions: Microbial communities are almost never preserved whole, ready to be brought back. Future directions in biodiversity protection must augment current cryobanking with microbiome collections.

Human Specimen Repositories

PH-01 Synergizing Biobanking Processes Between Academia And Commercial Biobanks

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Academic and commercial biobanks have their strength and weaknesses. Here we described a multi-center study in Singapore whereby academic biobanks in hospitals, research institutions, and cancer consortium worked in tandem with a commercial biobank. The CADENCE (Cancer Detected Early can be CurEd) study, a large 10,000-participants cohort 3-year study, coordinates across multi-centers for participants recruited, with a central biobanking process for the development of a blood-based multi-cancer screening test for the detection of the nine most prevalent cancers in Singapore: lung, breast, colorectal, liver, stomach, esophageal, ovarian, pancreatic, and prostate.

PH-02 Biobanking in East and Central Africa: A case of the Integrated Biorepository of H3Africa Uganda

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Biorepositories are essential because they guarantee the proper storage and distribution of biospecimens and their associated data for current and future research. In Eastern and Central Africa, the Integrated Biorepository of H3Africa Uganda (IBRH3AU) at Makerere University in Uganda was the first of its kind. It is strategically located at Makerere University College of Health Sciences, which is home to some of Uganda's most relevant and impactful infectious and non-infectious disease research. Since its inception as a pilot project in 2012, the IBRH3AU biorepository has grown into a state-of-the-art facility serving the H3Africa consortium and the rest of the scientific community. IBRH3AU has built a solid infrastructure over the past 10 years with cutting-edge methods and technologies for the collection, processing, quality control, handling, management, storage and shipment of biospecimens. H3Africa researchers, local researchers, postgraduate and postdoctoral students, and the greater scientific community in Eastern and Central Africa and beyond have benefited from IBRH3AU's exceptional biobanking services.

PH-03 Audit of Biospecimens at Medical Research Council/Uganda Virus Research Institute and London School of Hygiene and Tropical Medicine Biobank in Uganda

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Background: The MRC/UVRI and LSHTM Uganda research unit is an internationally recognized center of excellence for research on HIV, emerging and re-emerging infections and non-communicable diseases. The unit has a biobank that houses a collection of over 30 years: with various samples ranging

from whole blood, serum, plasma, urine, saliva, and PBMCs, among others. These samples have been collected from the various projects conducted at the unit in either diseased or healthy populations. Initially samples were managed by projects but were later pooled together to form the current biobank collection. These constituted the legacy collection whose storage was initially not properly done. With the increase in number of projects, there arose shortage of storage space in terms of floor space for expansion and freezers. With little to no actual numbers of stored samples from the legacy collection, the biobank faced limited budget funding and space constraints. Data was stored using access and excel databases which were not well updated. Utilization of the biospecimens was so low thus the need to assess how best these samples could be availed for utilization. This justified the need to conduct a sample audit to evaluate the collection.

Method: The sample audit was conducted. The audit process involved a physical walk in all the freezers to identify the sample types, visual status checks, and capture of the available data as per sample labelling; merging of the available data with the access database and uploading into the sample management software; and filling of positions in the boxes that were found empty or with missing samples.

Results: Some samples did not have sufficient data, were not identifiable; and could not be easily linked to any study. We had samples that were crystallized, contaminated, and those with very small volumes. All samples identified as not fit for purpose were listed for the discard. Samples were properly compressed for all boxes with empty positions.

This created space in the freezers, a clean database was created, and an actual count of the number of stored samples was established.

Conclusion: The sample audit exercise has now been incorporated in the 5 years' review plan by the sample access committee to track of the growth and utilization of the collection. Storage application requests have also been reviewed to ensure that proper storage requirements are met covering all aspects of the national guidelines for long-term biological sample storage.

PH-04 Overview of Shefa Al Orman Hospital Biobank in Upper Egypt

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Background: Shefa Al Orman Hospital (SOH) Provides free treatment to cancer patients in Upper Egypt. The hospital facilitates and supports scientific research to treat and prevent cancer in its earliest stages. Cancer research relies on a supply of human samples. SOH established a scientific research department, including the biobank, which is the first step in supporting scientific research. SOH-BIO was established in 2017 for collecting biospecimens from cancer patients, for future research.

Methods: Voluntary participation by patients is a main factor in the success of the biobank. The candidate patient for the biobank is asked to sign an appropriate informed consent form, previously approved by the SOH research ethics committee. After the patients are accepted to participate, the phlebotomist withdraws the blood. The blood samples are processed and separated into two serum, two plasma, and two buffy coat aliquots. The aliquots are stored at -80°C. Tissue samples are

collected from patients only if the tissue is in excess of what is required for pathological assessment. We collected tumor and adjacent normal tissue samples and stored them in liquid nitrogen. Then, samples information is stored in the SOH database. The time of sampling, arrival, and processing are recorded to ensure the quality of all samples. Peripheral blood mononuclear cells are manually isolated by density gradient method and stored in triazole reagent for later extraction of RNA. DNA is extracted from buffy coat by QIAamp DNA Mini Kit.

Results: Starting from September 2017 to October 2022 a total of 7770 newly diagnosed cancer patients were recruited in SOH-BIO. There are approximately 49,490 aliquots collected and stored, including 7 different types of samples (plasma 15,267, serum 14,617, buffy coat 14,781, triazole 1848, DNA 2002, tumor tissue 495, and normal tissue 480). The SOH-BIO contains biological samples from different types of cancer; the most common types of cancer are breast 1456, liver and intrahepatic bile duct 402, bladder 402, lymph nodes 399, lung 391, colon 270, thyroid gland 266, rectum 253, and pancreatic 218.

Conclusion: SOH established the first biobank in Luxor which provides a huge number of samples to facilitate and support clinical and scientific research. SOH-BIO is provided with high-quality samples that serve as an essential infrastructure for current and future research useful for humans. Cancer research lead to new approaches for better diagnosis, early detection, and reduction of cancer burden.

PH-05 An Experience of Organizing and Maintaining the First National Tumour Tissue Repository (NTTR) in India

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Background: NTTR was established in the year 2005 to bank all types of diseased as well as normal tissues and components of blood and distribute biospecimens to researchers. Standardized methods are used for collection, processing, long-term storage, retrieval, and disbursement for retrospective as well as prospective research initiatives. Clinical information and follow-up record of all patients whose biospecimens are maintained in the biorepository are provided to investigators while protecting confidentiality of data and privacy of specimen donors.

Methods: NTTR functions are classified into various tasks viz. operational/technical, administrative, and ethical/legal aspects. SOPs were established and periodically updated for collection, storage, retrieval, disbursement, and quality control. Biospecimens are collected following administration of broad informed consent. Indigenously developed software is used to anonymize the biospecimens and facilitate storage and retrieval of biospecimens. An online biobank form is developed to collate clinical and follow-up data. Preanalytical variations are documented in the biorepository computerized system. Validation of various procedures viz. collection, processing, storage of biospecimens is being accomplished by correlation with histopathology, DNA/RNA quality, and integrity of random samples since 2005 to date biannually. Feedback from recipient

scientist is sought. Disbursement of tissues is done for Institutional Ethics Committee (IEC)-approved projects through the NTTR Technical Authorization Committee. A material transfer agreement is sought for disbursement to non-institutional investigators.

Results: During the period of 16 years from May 2005 to September 2022, a total of 73,614 tissues were collected from various anatomic sites from 46,989 patients and 10,320 biospecimens disbursed for various IEC-approved projects. Clinical information was provided as per the investigators' requirement. More than 30 peer-reviewed publications have acknowledged valuable contribution by NTTR.

Conclusions: A central tissue repository has many advantages like efficient control of biospecimens, easy availability of various types of tissues, and increased opportunity to participate in intramural and extramural research. A repository can be easily implemented in a department of pathology. High-quality and well-annotated biospecimens are valuable institutional resource for basic and translational research in current era of precision medicine.

PH-06 To Keep or Not to Keep – Minimizing Biohoarding in a Resource-Limited Setting

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Statement of the Problem: The low- and middle-income biobanking community faces serious challenges in terms of funding. Biobank designing and infrastructure entails expertise and added costs. An ideal biobank stores biosamples across various indications and in multiple biosample formats like snap frozen tissues, blood and its derivatives, formalin-fixed paraffin-Embedded (FFPE) blocks, tumor microarrays (TMAs), and the list is endless if we go by a researcher's need. However, hospital-based biobanks/disease-oriented biobanks in a resource-limited setting need to be cautious in storing samples. Limited deep freezers, liquid nitrogen supply hindrances, and lack of adequate storing cabinets and space can be a limiting factor in adhering to good biobanking practices. FFPE blocks are the most widely used sample types owing to ease of availability and logistic stability; however, their storage in cool and well-lighted cabinets in pest free areas can be harrowing for some with limited space.

Proposed Solutions: Assess the critical areas of research and associated biosample need. Multiple preanalytic variables can help in judicious selection of biosamples for storage. Careful gross examination of the tissue to be snap frozen and making multiple small aliquots for researchers can be done for ease of disbursement and usability. Histopathological confirmation of tumor percentage and necrotic content can help identify usable blocks versus non-usable blocks. Maintaining a Biospecimen Reporting and Improved Study Quality (BRISQ) indicator sheet for every biosample stored ensures clear-cut segregation of samples as usable and non-usable for various downstream applications like the “-omics” studies. Assessing hemolysis in blood derivatives using a hemolysis chart can ensure that the right sample set is stored for cfDNA analysis studies. Biohoarding of samples is best avoided.

Conclusions: Biohoarding of biosamples is a common phenomenon in most biobanks, but can be a rate-limiting factor in the growth and sustainability of a small-sized biobank. Judicious selection of biosamples for storage can be rewarding and can pave to a small but mighty biobank.

PH-07 Recruitment Strategies for a Non-Hospital-Based Academic Biobank in South Africa: The Journey of the CHM Biobank

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Statement of the Problem: South Africa (SA) and many other developing countries face the reality of unequal health-care systems within their diverse societies. The concept of biobanking and the use thereof in rare disease (RD) research receive limited acknowledgement in the African medical community. The Centre for Human Metabolomics (CHM) established SA's first "exclusive" RD biobank in 2019 and have since experienced numerous challenges, more specifically in terms of awareness and participant consent. The activities of the CHM Biobank are further complicated through its placement in a province without an academic hospital and within a university not associated with any hospitals. Recruitment difficulties are mostly due to the lack of prioritisation in the diagnosis of a RDs, the poor acknowledgment of its burden on the national healthcare system, and obtaining consent. It is estimated that RD affects approximately 4 million people in SA, with most patients not receiving support they desperately require.

Proposed Solution: The CHM Biobank has implemented various models for recruitment, trying ultimately to bridge the various gaps faced in this biobank journey. It has partnered with various stakeholders in SA, attempting to overcome challenges experienced to date. The goal of the CHM Biobank is to promote RD awareness and to increase scientific and innovative outputs called for by the SA Department of Science and Innovation (DSI). Implementation of recruitment drives and rare disease projects resulted in the growth of the CHM biobank. Ultimately, an African RD biobank is a valuable resource in identification of the local genetic diversity and may inform treatment-naïve patients of clinical trials which may lead to the development of competitive treatment options. The CHM Biobank and collaborators (commercial and academic) strive to increase the scientific outputs to showcase the enormous worth that a RD biobank have and continue to offer.

Conclusions: The value of working together with multiple stakeholders and establishing good trust relationships have been proven as effective measures to bridge some gaps faced by the CHM biobank. The CHM Biobank aims to continue its work in South Africa and Sub-Saharan Africa, by providing education and promoting awareness in RD and continue to build a robust, locally relevant evidence base resource that is able to respond to the ever-changing genetic landscape in Africa.

PH-08 Evaluating the Efficacy of Density Gradient Centrifugation for the Biobanking of Malignant Cells in Patients with Hematological Disorders

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Background: To complement a new acute leukemia referral service, the Sunnybrook Hematology Biobank opened Jan. 2021, prioritizing new diagnostic cases of acute myeloid leukemia (AML). Given the biological heterogeneity of AML, we asked how standard density gradient centrifugation (DGC) of bone marrow aspirates (BMA) performed for monocytic AMLs, a subtype of AML with a variable proportions of myeloblasts, monocytic blast-equivalents, and often morphologically abnormal monocytes. This information may help to guide automated bone marrow processing for AMLs as well as other hematological neoplasms.

Methods: We selected 6 cases of monocytic AMLs by review of clinical bone marrow pathology reports, clinical BMA smears, and clinical flow cytometry (FC) plots. BMA were processed using DGC and differential counts from Giemsa-stained smears performed pre-freeze. Pre-freeze mononuclear cells (MC) and expected blast, promonocyte, and monocyte yields were calculated from clinical BMA smears assuming a 100% enrichment efficiency. MCs were defined as myeloblasts, promonocytes, monocytes, lymphocytes, and plasma cells.

Results: Post-DGC, MC enrichment was >90% for 50% (3/6 patients). For the cases with <90% MC enrichment, the additional cell types present in pre-freeze smears were: promyelocytes > myelocytes > metamyelocytes > neutrophils. In order to determine if promonocytic blast equivalents were also recovered by DGC, we reviewed the blast proportions (i.e., myeloblasts and promonocytes) and specific differential subtypes in the primary clinical BMA smears and compared this to pre-freeze differential counts. Our data show that in some monocytic AML cases (67%, 4/6), preferential enrichment of mature monocytes is favored over promonocytes since monocytes on average represented 198% of expected recovery. This compared to enrichment of promonocytes between 17%-75% of expected recovery. Conventional myeloblast enrichment was >84% for 4/6 cases and 22%-25% for 2/6.

Conclusion: Biobanking of AML cases is often focused on viable preservation of blasts. While conventional myeloblasts are often enriched, it is uncertain how routine DGC techniques may selectively enrich MCs in monocytic AML cases with variable proportions of myeloblasts, promonocytes (blast-equivalents), and abnormal monocytes. Our pilot data shows promonocytes in particular appear to be underrepresented. We will confirm these findings with additional cases and post-thaw FC-based lineage assessment.

PH-09 Ensuring Sustainability for Clinical Laboratory Support of Biospecimen Procurement

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Background: In the Duke University Health System (DUHS), the Biorepository and Precision Pathology Center (BRPC) has worked alongside Clinical Laboratories (CL) to provide excellent care to patients for over a decade. The number of patients who consent to biospecimen collection and the number of biospecimens released for research has increased

significantly since BRPC was established in 2012. Expansion was facilitated greatly after BRPC received funding to become the National Cancer Institute's Cooperative Human Tissue Network (CHTN) Southern Division. The increased demand for CL-facilitated biospecimen procurement required the creation of a sustainable, flexible model of CL support.

Methods: During initial CHTN funding, BRPC used direct salary support for CL staff to provide support to in return for their involvement in patient sample procurement. This model did not translate into additional effort available for research. To improve on this model, BRPC and CL leadership worked together to create a fee-for-service shared resource within CL called the Duke Labs Clinical Research Center (DLCRC). Chargeback rates were established for simple and complex tissue procurement services, archival slide and block pulls from the clinical warehouse, and releases of residual blood and body fluids post-clinical testing.

Results: Calendar year 2021 saw a 44% decrease in the number of surgical pathology collection events that were unable to be dissected for research based on insufficient clinical staff effort compared to CY2019. In CY2021, a 16% increase in archival slides/blocks pulled is shown compared to CY2019. At the same time, CY2021 saw a 50% increase in the number of blood-based biospecimens released by the clinical laboratories to BRPC/CHTN and ultimately, to investigators, compared to CY2019.

Conclusion: Direct salary support of specific CL personnel involved in research may not be an optimal model for ensuring success in procuring clinical samples for research. Rather, broad involvement of CL and establishment of a flexible fee-for-service model establishes buy-in, and a trust that increased research requests across multiple clinical work centers (surgical pathology, archival slide/block warehouse, and blood testing laboratories) will be met with increased levels of support. This is even more important to ensure availability of research specimens as clinical revenues tighten.

PH-10 Van Andel Institute's Biospecimen Core Resource for the NCI Cancer Moonshot Biobank

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Background: The Cancer MoonshotSM Biobank (moonshotbiobank.cancer.gov) is an NCI-funded project in collaboration with NCORP community hospitals across the US to collect longitudinal blood and tissue biospecimens from cancer patients receiving standard of care therapy. Participants donate tumor tissue, blood samples, and clinical health and biospecimen data at multiple timepoints for this research. In return, participants may receive tumor biomarker CLIA test results to help identify additional treatment options. The Van Andel Institute's (VAI) Pathology and Biorepository Core (PBC) serves as the Biospecimen Core Resource (BCR) for the Cancer Moonshot Biobank. The BCR provides centralized services to the community hospitals to collect biospecimens, and serves as the Biobank's core facility to process, store, and distribute biospecimens.

Methods: The VAI PBC laboratories for histology, molecular processing, kit preparation, and biorepository, and a robust quality management program serve large research and clinical trial projects. The PBC a) provides and manages SOPs, biospecimen collection kits tailored specific to each project; b) monitors specimen shipment and receipt including weekend arrival; and verifies protocol compliance; c) provides specimen processing, such as plasma, serum, cell separation, and tissue pathology verification with downstream extraction of nucleic acids, tissue pulverization for proteomics, and various tumor enrichment strategies to meet project goals; and d) maintains chain of custody for CLIA purposes. The VAI PBC BCR uses the Biological Specimen Inventory system developed by Information Management Systems and uses the Leica Biosystems Aperio digital pathology platform for slide imaging and review. The VAI PBC is accredited by College of American Pathologists for both the Biorepository Accredited Program and CLIA.

Results: As of November 1st, 2022, the BCR has sent 775 kits to 49 participating hospitals in 20 states and received 1452 specimens from 143 patients, covering 8 cancer types. The BCR has shipped samples from 54 patients to the Molecular Characterization CLIA Lab. The biospecimens will be available to researchers via an online catalog.

Conclusions: The VAI PBC provides comprehensive core resources that can support large-scale biobanking efforts, including CLIA services. It serves the NCI Cancer Moonshot Biobank and other federally-funded and foundation-funded basic, clinical trial biorepository and other precision medicine programs.

PH-11 Rapid Establishment of a Biospecimen Resource to Study the Global Impact of COVID-19 Vaccines

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The emergence of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in late 2019 and its subsequent explosive spread highlighted the need to rapidly develop curated biobanks containing specimens that can be used to inform etiology, diagnosis, and treatment options for such large-scale global outbreaks of communicable diseases. Recently, we undertook a project to develop a repository of biospecimens from individuals aged 12 and older who were scheduled to be vaccinated against coronavirus-19 (COVID-19) with one of the vaccines whose development was supported by the United States (US) Government. We planned to establish 40 or more clinical study sites in at least six countries and associated territories to collect biospecimens from approximately 1,000 individuals, at least 75% of whom were to be SARS-CoV-2 naïve at the time of enrollment. These specimens would be used to: 1) ensure quality control of future diagnostic tests; 2) serve as standards to calibrate serologic assays; 3) provide reference reagents in the development of new assays, new drugs, new biologics, or new vaccines in response to SARS-CoV-2; 4) understand immune response to multiple COVID-19 vaccine platforms; and 5) be available for future, as yet undetermined, uses. Biospecimens to be collected included: serum, plasma, and whole blood by venipuncture, and nasal secretions by mid-turbinate nasal swab. Large-volume collections of peripheral blood mononuclear cells (PBMCs) and defibrinated plasma by apheresis were also planned for a subset of study subjects. Repeat sampling of those consenting to participate was planned

at pre-defined intervals prior to, and following, receipt of designated COVID-19 vaccines over a one-year period. Here, we describe the selection of global clinical sites for specimen collection and processing, SOP development, design of an informatics system to track participant metadata, design of training materials and systems for tracking specimen quality, and transport of specimens to a central repository for interim storage. Our approach allowed us to enroll our first participants within 21 weeks from the study's initiation. Lessons learned from this experience should benefit the development of biobanks in response to future large-scale global epidemics.

PH-12 Translational-ANZGOG (TR-ANZGOG): Enhancing Translational Research Capacity in Gynaecological Cancer Clinical Trials to Optimize Research Impact

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Background: Translational aspects of clinical trials are accelerating changes in clinical practice and increasing the impact of trial results. This is resulting in a fundamental change in the clinical trials landscape with increased reliance on biospecimens, both in selection of patients for molecularly directed trials and to characterise factors associated with response to treatment. Recognising the need for a strategic approach to drive the changes that will be needed to fully integrate translational research into all trials, the Australia New Zealand Gynaecological Oncology Group (ANZGOG) established the TR-ANZGOG initiative.

Translational ANZGOG, 'TR-ANZGOG,' aims to support collection of ANZGOG trial biospecimens, provide enduring custodianship, and maximise trial outcomes by facilitating future translational research.

Methods: TR-ANZGOG is a national platform, with planned expansion to New Zealand, comprising four components:

- 1) Support for ANZGOG Trial Investigators to plan and manage translational research aspects of clinical trials.
- 2) A national network of laboratories to support biospecimen collection, processing, and management.
- 3) A mechanism for researchers to access trial biospecimens and data.
- 4) An online Information and Resource Portal.

Results: Key policies, processes, and resources needed to integrate TR-ANZGOG with prospective ANZGOG trials were developed in consultation with consumers and sector experts across diverse specialties.

Following TR-ANZGOG's launch in 2020, the implementation stage demonstrated multiple ethical, legal, and operational barriers, highlighting the challenges of this initiative, to build translational research capacity and enable maximal research from ANZGOG trials for optimal impact.

The first ANZGOG trials to implement TR-ANZGOG are in start-up. Next steps will include the procurement and development of IT platforms and processes for sample tracking and data management, to establish a valuable biospecimen resource with associated study data.

Conclusions: The ability to further interrogate biospecimens from clinical trials will add enormous value to the contributions that patients have made by identifying factors associated with

treatment response, identifying ways to improve treatment, and contributing to the design of future trials. TR-ANZGOG is an exciting opportunity to improve outcomes for women with gynaecological cancer by stimulating new translational research projects and clinical trials, and by promoting collaboration.

PH-13 Effective Biobanking of Tissue Biopsies through Vacuum Sealing Method

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Background: To enable precision medicine initiatives and cancer research at Karkinos Healthcare, a biobank infrastructure has been established in the central laboratory. To facilitate the fresh tumor collection from the partner network hospitals, we adopted a novel method of vacuum sealing and cold shipment at 4 degrees Celsius. The method was validated for tissue and nucleic acid (NA) integrity for further molecular pathology and biobanking applications.

Methods: Routine cases in daily practice were collected, vacuum sealed within 30 min of resection of tumor, and transported in cold bags at 4 degrees Celsius. The specimen was grossed, cut open to collect tumor tissue (at least 5mm²) in RNA later, and stored at -86 degrees Celsius. The remaining tissue is fixed then in formalin for 12 to 24 hours and processed. The quality of the specimens was evaluated by tissue morphology, protein expression by immunohistochemistry, and NA integrity. Formalin-fixed tissues from the same tissues were compared for NA quality and quantity with that of vacuum-sealed tissues. We have also tested the effect of the transport duration on the RNA integrity.

Results: We have collected 30 different tumor tissues for the study. The vacuum and temperature inside the cool bag were maintained up to 24 hours after collection. In general, the tissue gross morphology and viability were well preserved without being compromised by autolysis. Protein and RNA analysis showed good preservation of antigen epitope and RNA integrity number (RIN), respectively, in all samples. The quantitative RT-PCR showed that RNA extracted from the tissues collected in vacuum bags was as good as that collected from fresh tissue by gene expression profiling.

Conclusions: Our preliminary data suggest that the refrigerated vacuum sealed transport system of fresh specimens represents an excellent technology for maintaining tissue integrity for routine diagnostics, as well as immunohistochemistry, molecular diagnostics, and biobanking. This will play a critical role in taking diagnostics forward into the molecular era and precision world. It has also proved to be an effective method for ensuring fresh tissue bio-banking as the sampling was done by a pathologist without affecting the diagnosis of the patient.

PH-14 Cancer Screening and Biobanking: Insights from Community Wellness Initiative in India

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Background: Biobanking has become an integral component of cancer research and provides high-quality specimens which are essential in the discovery and validation of cancer biomarkers. While numerous cancer biobanks have been established in North America and Europe, biobanking in India still has a long way to go. Apart from the need for cancer-oriented biobanks, there is an acute need for community screening programs for prevention and early detection of cancer in the country. There was a 21% increase in the number of recorded cancer cases in India from 2019 to 2020. In this study, we describe the implementation of paired biospecimen collection with community outreach programs to tackle the need for both community screening as well as specimen collection for a cancer biorepository.

Methods: We set up community wellness camps for women in the Chikkaballapur district in Karnataka. In addition to testing for signs/symptoms of major cancers as part of the community-screening initiative, we also collected biospecimens: saliva, blood, and buccal smear. The specimens collected were processed and stored in our biorepository.

Results: Over a three-month duration, nearly 5000 women were screened and we collected 573 blood specimens and 650 saliva and buccal specimens. There were 159 oral cancer suspicious and 11 breast cancer suspicious subjects which needed further longitudinal follow-up. Participant demographics, cancer risk assessment, and medical history was also recorded.

Conclusions: Integrating community wellness programs with biospecimen collection provides a unique opportunity to tackle two issues: detection of cancer at a very early stage through community outreach and collection of precancerous/early cancer biospecimens. A close follow-up of the high-risk participants will help in the early detection and provide the opportunity to collect relevant longitudinal biospecimens. Future molecular tests on these specimens could potentially accelerate biomarker research to gain a better understanding of the effects of genetic, environmental, and lifestyle factors on cancer incidence and mortality.

PH-15 Biobank at Indus Hospital & Health Network, Pakistan

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Background: Indus Hospital & Health Network (IHHN) is a not-for-profit healthcare network across Pakistan, with the mission of providing quality healthcare free of cost to the patient. IHHN serves around 400,000 patients per month through its primary, preventive, secondary, and tertiary care healthcare services. The institution has recently established a biobank for potential future research, diagnostic assay development, and validation and verification of clinical diagnostic assays.

Methods: Planning encompassed evaluation of expected future use of specimens and outlining of the requisite processes and procedures. Multi-disciplinary involvement of clinical, laboratory, biobank, electronic medical record (EMR), and research staff enables coordination for consent-taking, sample flow, data collection, and management. Approval from the Institutional Review Board (IRB) is obtained for a broad consent for the use of these samples for research. Depending on the specimen type, consent is either obtained separately or incorporated into the general hospital procedure consent form. Data relating to these specimens are stored electronically, as well as in MS Excel files. A dedicated biobank Management Information System (MIS) is also under development. Space for liquid

nitrogen storage fulfills the College of American Pathologist (CAP) requirements. SOPs for all processes implemented thus far have been aligned with CAP, International Society for Biological and Environmental Repositories (ISBER), and World Health Organization (WHO) Biosafety and Biosecurity guidelines.

Results: The biobank at IHHN has stored a total 7036 clinical specimens including 256 malignant tissues and 181 acute leukemia patient specimens. Microbiological collections include 3398 *Mycobacterium tuberculosis* isolates out of which 2266 isolates are multi-drug resistant. Others include 798 *S. typhi*, 194 mycobacteria other than tuberculosis, 87 *Vibrio cholerae*, 46 rare bacteria, 37 colistin-resistant isolates, 10 rare yeast, 5 molds, 9 *Neisseria gonorrhoeae*, 2000 SARS-CoV-2, and 15 samples with rare antinuclear antibody (ANA) patterns. Immortalized cell lines, microbiological strains, and other resource material have also been added and further expansion is underway.

Conclusion: The biobank at IHHN is an integral part of a healthcare system that facilitates research, independent validation, evaluation, verification, diagnostic assay development, analysis, and investigation.

Informatics & Technology

PI-01 Implementing Natural Language Processing Technology in the Department of Pathology and Biorepository Using the eLearning for Staff Training

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Introduction: One of the current, used educational methods is eLearning, in which information is delivered electronically. A variety of online learning platforms can be used by hospitals to train employees. Natural language processing (NLP) is a branch of computational linguistics and artificial intelligence that includes algorithmic processing of text. The education and professional development of a new generation of lab and biorepository professionals in this area are limited. The work presented here aims to compile a course "Digital speech recognition in an Anatomical pathology practice" to cover basic operational activities associated with NLP technologies. To be able to widely implement this course we use the MediaLab platform. **Methods:** For this eLearning course, we reviewed the appropriate modern literature and built the study materials in several modules: the background of speech-recognition technology, equipment for speech recognition, general principles of gross descriptions and terminology. To test the participants' knowledge, there were quizzes and tests with multiple-choice, fill-in-the-blanks, and true or false assessments. **Results:** We developed and implemented a course for pathology residents, lab specialists, pathologists' assistants, and biobank staff. After a one-year duration on the MediaLab, this eLearning course was reviewed by 110 participants. To measure the quality of the course we used several scores. Customer Satisfaction Score - showed the overall satisfaction, which was 90% for this course. Net Promoter Score - showed whether the customer recommended

this course to a friend or colleague, which was 90.2%. Customer Effort Score - measured how interesting and easy the interaction course was. This course was rated 4.57 out of 5 stars by 81 students that responded to the survey. **Conclusion:** Analysis of the course survey scores demonstrates that the course is in demand. Reviews of customers suggest that it is a “great tool for teaching beginners and new residents.”

PI-02 Application of Natural Language Processing in the Current and Future Work in the Department of Pathology and Institutional Biorepository

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Introduction: Natural Language Processing (NLP) is widely used in medical practice for data abstraction. NLP techniques extract information from structured data (images/genetic data) and unstructured data (clinical notes/pathology reports). NCI Metathesaurus and Ontology for Biobanking are useful tools for the standardization of medical terminology used in protocols. Automatic speech recognition systems (ASRS) accurately convert the operator's speech into meaningful text and use natural language for interaction with a computer, two interrelated processes. Using standard medical lexicons for data entry increases extraction efficiency. Utilization of standard templates/terminology is crucial to the surgical pathology report. Little published practical guidance on template creation in pediatric pathology exists. This work aims to build and incorporate into the department NLP system the templates for the common nosological entities using a pathology thesaurus. **Methods:** Dragon Medical One version 2021.2 with the standard CoPath, Natural Language Search (Sunquest CoPathPlus Version 7.1.0032) and data from modern literature were used to generate standardized reporting templates for pediatric pathology, which incorporated AJCC staging criteria, elements of the College of American Pathologists cancer protocols, and instructions for tissue procurement for Biorepository. **Results:** Seven user profiles were created to have access to the ASRS and up to 50 templates for specimen reporting of pediatric patients and tissue procurement for research to implement an integrated histo-molecular diagnosis. All pathologists' assistants, residents, and fellows were trained to use Dragon Medical One and templates for the description of pediatric surgical specimens through on site or online courses, created by department staff. **Conclusions:** The templates contain imperative elements in order of importance to aide decision-making, facilitate diagnostic accuracy, and tissue procurement. The templates built into ASRS increase documentation efficiency and significantly reduce workload for a biorepository's personnel to extract information for sample annotation. Furthermore, standardized processing enables future research efforts to perform NLP on collected notes.

PI-03 SIMBIOX, an In-House Data Management System for Biobanks in Indonesia

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Statement of the Problem: A biobank is a repository system that has a massive role in storing biological samples for use in research. It is still relatively young in Indonesia so not many institutions have this facility. A comprehensive management system in a biobank is crucial to quickly trace records and collect comprehensive information on the samples and the data associated with the patients. For managing information systems of biobanks, open sources or paid software are indeed available. However, since the paid software is usually expensive, while open source software is sometimes difficult to fit, a simple in-house information system that is designed based on the particular need of the biobank is required.

Proposed Solution: Biobank of Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada (FMPHN UGM), was initiated in 2015 and developed its data management system, called SIMBIOX. It is a web-based system, a PHP with framework Codeigniter 3. x, supporting MySQL, PostgreSQL, and graphical user interface (GUI), based on bootstrap and completed with a log module as monitoring and security features. SIMBIOX has been used to generate a 2D barcode indicating research and subject code, sample type, storage condition, and sample position in the freezer. These allow the biobank to manage sample storage, tracing, transaction, and reporting. Currently, SIMBIOX has been adopted by the Indonesian Minister of Health to help many hospitals throughout the country establish hospital-based biobanks. It has been available as open-source software in Github for developing and improving the health system in Indonesia.

Conclusions: An in-house data management system for a modest biobank in FMPHN UGM can be scaled up to a national level, supporting other institutions as open-source software to initiate a hospital-based biobank.

PI-04 pccm_db: A Sophisticated High Granularity Breast Disease Dataset Created Utilizing an Easily Implementable Data Entry Too

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Background: Breast cancer is a rapidly increasing cancer among women in India. Incidence rates are relatively low but are increasing with a high mortality rate. While clinical and

omics data-rich datasets are available for breast cancers from primarily Caucasian populations, such datasets are few and far between for breast cancers from the Indian population. Datasets representing the varied ethnic groups that make up the globally substantial Indian population are the future to advance our knowledge of the disease, its clinical management, molecular drivers, and therapeutics.

Method: A comprehensive breast disease database was required to support a retrospectively established tissue biobank. Critical treatment and diagnostic modules and data points in the workflow of breast disease patients from presentation through treatment and follow up were identified. A tool was built in base python with a command line interface and SQLite backend for data entry of these data points. Each module was evaluated and refined for clinical and translational research data collection. Individual data management tools, workflows, and systems were created to digitize, classify, and manage available data resources. Pattern-matching algorithms were created to extract report identifiers and key diagnostic data points.

Results: A database of 860 breast disease cases has been created to date using the described tool. Local SQLite databases allowed for frequent changes in database structure and vocabulary in the initial stages of implementation but presented hurdles in the creation of a unified database. Maintaining unique entries for each case was a challenge with multiple entries for cases over time for evolving data structures. Parallel experiences with multiple experienced information system vendors highlighted the need for complex domain understanding to create and accurate dataset.

Conclusion: While the nature of the data entry tool and use of individual local databases imposed a technical challenge in creating a curated and accurate dataset, the simplicity of the implementation allowed us to create a dataset which had high domain complexity without technological complexity. This allowed the technology to grow as the dataset size increased, preserving the domain complexity. The resulting dataset has been finessed with the successful use of the data in translational and clinical research projects.

PI-05 Data Profiling of HuBIS_Sam SPREC data of the Korea Biobank Network

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The Korea Biobank Network (KBN) is one of the pioneering infrastructures to support the Korea Biobank Project. The KBN consists of various hospital-based biobanks and a central government-affiliated biobank (National Biobank of Korea). Since 2013, the KBN has used the self-developed biospecimen inventory system (HuBIS_Sam, currently version 3.8) to manage storage information and pre-analytical variables (SPRECs) of KBN biospecimens. In order to examine the data quality of the SPREC records, we conducted data profiling of the SPREC records housed in the HuBIS_Sam database. As of December 2020, the inventory data for 17 million biospecimen vials were housed in the HuBIS_Sam database. Of these vials, SPREC-containing biospecimen vials account for about 44% (4.3 million vials out of 9.72 million vials) in the central biobank and 30% (2.45 million vials out of 8 million vials) in the KBN biobanks. Among 6.75 million biospecimen vials with SPRECs, about 499k biospecimen vials (131k vials for hospital-based biobanks, and 367k vials for

NBK) were found to have a specific code of 'ZZZ' or 'Z' in one or more elements of the SPREC. Therefore, about 7.4% (499k/6750k) of biospecimen vials with SPRECs remains unmapped to the SPREC 3.0. Data profiling of the HuBIS_Sam inventory data would improve data quality of the SPREC records for the KBN biospecimens.

PI-06 A Review of COVID-19 Lockdown Across Different Countries During 2020: Characterization of Risk Factors and Severity of COVID-19 in Egyptian Patients

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On March 12, 2020, The World Health Organization (WHO) announced the new coronavirus 2019 as a global pandemic. In January 2022, the number of COVID-19 cases reached 300 million confirmed cases with a total death count of 5.5 million cases. Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was identified in a seafood wholesale market in Wuhan, China. At the time of the outbreak, there was no effective treatment to protect from the novel coronavirus; the only way to control the pandemic was through reducing person-to-person contact and taking preventive measures based on the severity of the disease among the population. The first aim of this thesis is to visualize the confirmed cases, deaths, and recovered cases across the most affected countries and to analyze if non-pharmaceutical interventions (NPI), such as government interventions, are effective in flattening the curve. The second aim of this thesis is to use machine learning models to predict the severity of COVID-19 and clinical outcomes based on demographic, epidemiological, comorbidities, and laboratory findings among the Egyptian population during the lockdown period.

Innovative Technology

PJ-01 Investigating the Labeling Workflow and Incorporation of Automation for Increased Collaborations

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Statement of Problem: Identification and sharing of samples is a crucial function of biobanking. Labeling of the samples plays a key role in ensuring samples can be correctly identified and allows for increased collaboration. Labeling can be as straightforward as handwritten notes to using automation and 2D barcodes. However, handwritten labels are limited and can be easily misinterpreted, with those mistakes carrying on and leading to bigger issues. While 2D barcodes can include more information, it can also be expensive to implement. Figuring out how to merge both is a crucial need.

Proposed Solution: Matrix 1.0 mL tubes (with white space, 1D, and 2D barcodes) were labeled with handwritten notes. These labels were then transferred by two different scientists. The handwritten labels were compared to identify readability and errors. At the same time, the VisionMate HSX High Speed Barcode Reader was used as an automation tool to intake and identify matrix 1.0 mL tubes. Comparison of repeatable sample

entry with the 2D barcode was conducted. The time needed to read both handwritten and 2D barcode tubes were compared to judge efficiency.

Conclusion: Incorporation of the 2D barcode and reader allows for more accurate collection and processing of sample information. Not only were there fewer errors in the transferring of samples, but more data could be associated with each sample and samples were read faster. The 2D barcode also allows for redundant labeling, leading to better organization and accessibility storage. With a modest investment compared to other automation options, the automation setup is highly scalable and helps improve workflow and manage samples while also facilitating research. No matter the lab size, this incorporation of automation helps position biobanks better for collaborations: accessing, identifying, and transporting samples.

PJ-02 An Analytical Method to Determine Quality of Fixation Using Vibrational Spectroscopy and Machine Learning

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Background: Modern histology is built on the century-old process of formalin fixation, which arrests molecular degradation by crosslinking a tissue's biostructure. Despite being critically important, there are no analytical methods of measuring fixation quality. The level of tissue fixation significantly impacts detected protein expression, which drives medical opinion on diagnosis, prognosis, and treatment. Mid-infrared spectroscopy (MID-IR) is a powerful non-destructive optical technique that probes the vibrational state of individual molecules in the tissue and is very sensitive to the conformational state of proteins. Using MID-IR spectroscopy, this work demonstrates that fixation significantly alters tissue's biochemical state and uses the discovered spectral fingerprint of formalin fixation to build a predictive model to determine the fixation time of unknown biospecimen.

Materials and Methods: One hundred and five individual pieces of human tonsil were differentially fixed in room temperature formalin for between 0 and 24 hours, then were processed and embedded. Each paraffin block was sectioned in duplicate and all 210 slides were imaged with a MID-IR microscope (Bruker Hyperion 3000). Approximately 100 regions throughout each slide were imaged ($\nu=900\text{--}4000\text{cm}^{-1}$, $\text{deltav}=8\text{cm}^{-1}$, averages=16) and the average spectra were used for analysis. Adjacent tissue sections were stained for BCL2 and FOXP3 to assess each tissue's preanalytical quality via orthogonal IHC staining.

Results: A partial least squares regression model was trained on 158 slides and its performance was evaluated on the remaining 52 slides. Among the holdout tissues, the model accurately determined fixation time to within 1.4 hours, indicating the model had deciphered the true molecular fingerprint of formalin fixation. Additionally, the fixation status of tissue specimens was confirmed with FOXP3 and BCL2 staining, which was compromised with low fixation times (e.g., time <6h).

Conclusions: This study details the novel ability to quantitatively measure fixation time and quality using an objective and standardized metrology. This technology could enable an analytical quality check of tissue blocks, help laboratories assess their preanalytical procedures, or be used to identify and study preanalytically sensitive cancer biomarkers.

PJ-03 Sensitive Internal Thermal Monitoring Provides an Indication of Tank Health and Advance Alert for Impending Tank Failure

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Objective: To assess liquid nitrogen (LN2) thermal dynamics in failing cryostorage Dewars to develop an early warning system using proprietary, sensitive, internal temperature sensors.

Materials and Methods: Two experimental models were used to assess whether minor, dynamic thermal fluctuations can assess Dewar's health and impending failure. Model 1, Experimental Dewar Failure (EDF): a 21-liter MVE Dewar was fitted with a vacuum gauge and a vacuum of -27.5 in Hg was applied, which provides sufficient insulation to maintain suitable internal temperatures for an average of 96 hours. Model 2, Spontaneous Dewar Failure (SDF): a 47-liter MVE Dewar in active cryostorage use with known increased consumption of LN2. An intact, monitored tank in the same room was used as a control (CON). Internal temperatures were monitored with PharmaWatch Direct RTD measurement solution. Temperature change following filling and stabilization was monitored at five-minute intervals. The temperature change was tracked for 3, and 2 replicates for EDF and SDF, respectively.

Results: CON, EDF, and SDF tanks had a stable baseline temperature of $-198.10 \pm 0.03^\circ\text{C}$. CON maintained this temp consistently throughout the trial with a maximal deviation of $\pm 0.05^\circ\text{C}$. At an average of 72 hours after filling, temperatures for EDF and SDF increased above -197°C (vs -198.1°C for CON). A deviation of $+1.30 \pm 0.26^\circ\text{C}$ for EDF occurred $11.4 \pm 4.0\text{h}$ before the internal tank temperature reached -180°C , when the probe is no longer submerged in liquid. A deviation of $+0.60 \pm 0.1^\circ\text{C}$ for SDF occurred $10.25 \pm 2.0\text{h}$ after tank filling and stabilized at -196.3°C until the subsequent LN2 refill.

Conclusions: Sensitive, cellular-based continuous monitoring of internal Dewar thermal dynamics shows that a shift of $0.5\text{--}1.5^\circ\text{C}$ indicates deteriorating tank performance due to sub-optimal vacuum/insulation. This early event provides at least 10 hours of advance notice before the standard temperature alert at -180°C .

Impact Statement: Most current methods for monitoring cryostorage Dewar performance do not provide insights into Dewar health and do not provide significant lead time in the event of a Dewar failure, exposing patient samples to the risk in the event of a loss. The novel findings presented here present a robust and easily integrated internal system for 24/7 monitoring of each Dewar's health and performance.

PJ-04 A New Cohort Study Management Application: Improvements to Efficiency and Morale in the Two Months Following Adoption

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Statement of Problem: Since the 1950s, the American Cancer Society (ACS) has conducted cohort studies on hundreds of thousands of participants. Findings from these have contributed to policies reducing exposure to tobacco and air pollution, as well as guidelines around obesity, physical activity, and diet.

Workflows and data management associated with running such cohort studies are highly complex and labor-intensive. Although the past decade has seen rapid advances in tools for data management (such as participant management and synchronization of data captured from a variety of sources including participant reports, triennial surveys, sub-studies, and pre-/post-analytical biospecimen data), scientific organizations like ACS have continued to use practices that lack adoption of cutting-edge tools and technologies due to lack of funding, capacity, or expertise to develop, implement, and maintain modern data infrastructure for research-based systems.

Proposed Solution: ACS partnered with Manifold to modernize the software used for participant management, resulting in development of the Participant Relationship Management application (PRM). The PRM aims to streamline ACS study workflows by condensing 16 pages of information into a single interface, enriching participant information search capabilities, enabling tracking of participant information history, empowering study staff to edit fields and batch upload information within the application, and linking to data sources needed to confirm participant-reported medical information.

Conclusions: In the two months following the ACS Study Management Team's adoption of the PRM, results included reduced workflow disruptions and costs stemming from reduction in manual effort to synchronize data between operational and analytical systems, as well as elimination of duplicative data storage and single-user access during data imports. In addition, the PRM saw a 2.5x increase in usage relative to the previous homegrown solution, and team members reported significant improvements in productivity, live participant interactions, and morale. In conclusion, these results suggest that participant management tools like the PRM may improve cohort study management teams' efficiency and capacity, removing distraction from focus on organizations' core missions and increasing time dedicated to research efforts.

PJ-05 Fully Automated, Non-Destructive Processing and Imaging of Intact Tissue Samples

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Statement of Problem: Users searching biorepository inventories would benefit from access to histology images to help choose the most relevant samples. However, making H&E slides for every sample incurs processing costs and reduces available tissue, while digitizing the image data requires additional costs and labor. Sample choice is also complicated by potential differences between the recorded clinical diagnosis and actual sample content. Even with a single section image, the residual tumor content within a given tissue sample remains unknown. In addition, small samples have variable yield for morphology and DNA/RNA analysis, while paraffin embedding reduces nucleotide quality and the alternative of freezing affects morphology.

Proposed Solution: Applika Technologies has developed CHiMP (Clearing Histology with MultiPhoton microscopy), a fully-automated tissue processing and digital imaging platform that produces high-quality H&E-like digital images directly from fixed but otherwise intact tissue specimens without the need for embedding, cutting, and slide preparation. CHiMP enables imaging multiple levels at arbitrary depths up to 1 mm into samples and is completely non-destructive. Using CHiMP,

biorepositories can pre-scan through the depth of samples to provide users with more complete histologic evaluation for assessing tumor content and other relevant morphological parameters. In addition, because CHiMP does not require rigid samples for physical slicing, tissue can be processed with an abbreviated fixation step for better preservation of DNA/RNA. And since CHiMP does not consume tissue, more is left for ancillary studies, including nucleotide analyses as well as immunohistochemistry and specialty stains. Finally, the complete automation of the CHiMP platform avoids the cost and labor requirements typical of digital pathology and can result in much lower labor expenses even compared to conventional processing without slide scanning.

Conclusion: Applika's CHiMP platform provides a unique opportunity to provide enhanced histological information to users for better sample selection, all while preserving precious tissue and enhancing DNA/RNA yields.

PJ-06 Justifying an Automated Biobank in Your Business Plan

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Statement of the Problem: While automated processes are known to reduce manual error and provide cost savings for high throughput tasks, it is important to justify a new automated process both operationally and financially. Barriers to automation include the costs associated with equipment purchase, plus the significant changes to infrastructure and process that are required. The cost and benefits analysis within this poster explore these in more detail to help ascertain whether full automation, partial automation, or manual operation best supports the current and future requirements of varying sized biobanks.

Proposed Solution: Automation systems offer high-density storage capacity, sample registration and tracking, random access, and rapid cherry picking, all of which improve the speed and organization of biobanking workflows. Automating some, or all, of these steps can significantly minimize the costs associated with wasted employee time manually searching for samples.

Initial investment, service costs, and infrastructure changes attributed to automated systems can be hard to justify; however, other factors to consider when weighing the advantages and disadvantages of automation. Labor costs, energy costs, and space considerations are easily assessed by quantitatively evaluating current usage and predicting future needs. Other "softer" factors such as sample security and integrity are more difficult to quantitate yet are extremely significant to the biobank's success. Advances in automated sample storage and processing have focused on improving these more intangible needs to ensure that biobanks are able to contribute the highest quality samples to research.

Conclusions: With funding circumstances constantly evolving, capital investment costs versus anticipated returns are integral to analysis when considering automation. To assist in the justification process, the manual processes versus automation cost analysis outlined within this poster can be customized to represent any biobank. Building an operational cost model for the working life of a system that considers library size, throughput requirements, and the value placed on the intangible benefits of automation can help to determine whether full or partial automation is the right approach.

Repository Management

PK-01 Brain Tumor Biobanking in the Postmortem Setting

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While biobanking brain tumor specimens is common across many institutions, collecting matched tissue in postmortem cases is much rarer. Yet, such tissues are valuable, as they can provide a unique perspective on end-stage, post-therapy gliomas. Such material yields insights into patterns of disease spread and why all currently employed therapies inevitably fail. However, the logistics of postmortem tissue collection are complicated, requiring the coordination of teams outside of the biobank as well as the patient's family and/or loved ones. The Nervous System Tumor Bank (NSTB) at Northwestern University established a postmortem tissue collection protocol in 2015, focusing on glioma patients. Our postmortem glioma program designed standard operating procedures that are implemented by the hospital teams, the funeral homes, and the patient's families. Each of these aforementioned groups receives role-specific instructional documents and communication prior to the patient's passing. Since 2015, the NSTB has collected biospecimens from 70 adult brain and spinal cord autopsies. These materials have already led to a surprising discovery regarding how most gliomas spread at the end stages of disease, which was published in 2020 (PMID: 31711239). (A follow-up study involving the genomic and epigenomic patterns of end-stage gliomas is ongoing.) Furthermore, many patients and their families have embraced the program with great enthusiasm. Thus, with the appropriate infrastructure and protocol in place, postmortem biospecimen collections are feasible for human tissue biobanks and can serve as invaluable resources.

PK-02 Implementing Technology to Enhance Sample Quality and Expedite Workflows at the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)

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Alzheimer's disease and related dementias (ADRD) pose a growing public health crisis that requires a collaborative effort by both public and private stakeholders to meet the challenge. The National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) was established in 1990 at Indiana University with the mission to support research focused on the etiology, early detection, and development of therapeutics for ADRD. NCRAD has been funded by the National Institute on Aging (NIA) since 1990 and is an international resource for

clinical information and biological materials. As ADRD research has advanced, NCRAD and the NIA have worked together to expand the number and type of biological samples available to the research community. Use of NCRAD samples has resulted in over 700 peer reviewed publications. NCRAD currently houses DNA, RNA, CSF, plasma, serum, stool, brain tissue, LCLs, PBMCs, fibroblasts, and stem cells from individuals with ADRD as well as healthy controls. Additionally, NCRAD and the NIA have invested in technologies to standardize sample processing, enhance sample quality, and increase the number of samples distributed to researchers. Since 2017, all DNA samples are run on a custom SNP fingerprinting platform (Standard BioTools, Inc.) upon intake and distribution to ensure sample identity is maintained. In 2019, APOE genotyping was added to provide researchers banking samples with valuable ADRD-related genetic information. As part of a standardization effort, all DNA extractions from various source materials were moved to the Chemagic360 platform (PerkinElmer, Inc.) in 2020, resulting in increased throughput and better DNA quality. Recently, the NIA funded the construction of a Hamilton BIOS M automated storage system at NCRAD to manage the increasing number of samples. Limited building space is an ongoing issue and the automated high-density format permits storage of more samples, allowing for onboarding of additional studies. Compared to a manual -80C freezer, automation reduces the daily handling of samples that could introduce warming events, contributing to confounding preanalytical variables. Most importantly to many researchers, the automated picking and placing of samples reduces the time from proposal approval to sample distribution, supporting faster research discovery. Recent investments in new technologies will allow NCRAD to accelerate ADRD research to reduce risk, increase detection, and raise care.

PK-03 Increased Requests for Fresh Samples Impact the Workflow for The Cooperative Human Tissue Network (CHTN) Midwestern Division

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Background: Cooperative Human Tissue Network (CHTN), funded by the National Cancer Institute (NCI), provides access to human tissue for approved researchers from academia, government, and industry. The Midwestern Division, one of six in the network, is based at OSU with subsites at Case Western Reserve University and University of Pittsburgh. OSU's Tissue Procurement organization prospectively procures and ships samples for CHTN investigators within their region as well as Networked CHTN investigators from other CHTN Divisions. Rush samples (fresh and others that must be shipped overnight such as floating in formalin) are increasingly important, affecting the number of shipments handled daily.

Methods: We compared biospecimen distribution statistics for quarters from eight years (3Q14 – 3Q22) for which data is stored in the OSU-developed Research Tissue Procurement – Information System (RTP-IS). For each quarter, we used:

total number of shipped samples and shipments;
number of investigators receiving samples and number receiving rush shipments (samples that are fresh or floating in formalin);

number of rush vs. non-rush shipments and number of samples in rush vs. non-rush shipments.

Results: The number of shipped non-rush samples has steadily decreased from 2014 to 2022 (a high of 2,147 in 1Q17 and a low of 183 in 2Q20), while there has been a sharp increase in rush samples (a low of 376 in 4Q14 and a high of 1,199 in 3Q22). From 1Q19 to 3Q22 the percentage of rushed shipments has remained high (ranging from 88.5 - 95.5%).

Although the overall number of investigators receiving rushed samples each quarter has remained steady during this period (ranging from 42 – 68 setting aside 2Q20 with 27 when the pandemic began), the number of rushed samples has increased 205.0% (from 393 in 3Q14 to 1,199 in 3Q22) as have rushed shipments increasing 218.7% (from 283 in 3Q14 to 902 in 3Q22), with the largest increase occurring in the most recent two quarters of 2022.

Although the overall number of shipments per quarter has increased 165.1% (from 364 in 3Q14 to 965 in 3Q22), the number of non-rush shipments per quarter has declined 62.8% (from 121 in 3Q14 to 45 in 3Q22).

Conclusions: The number of shipments tracks closely with the number of rush samples shipped. The sum of numbers of non-rush samples roughly tracks with the average samples per cart/shipment. The increase in the number of small rush shipments is affecting how the operation is run and increasing the shipping overhead.

PK-04 A Robust, Inexpensive Solution for Alarm Monitoring of Freezers, Incubators, and Other Biobank Equipment Based on Readily Available, Easy to Deploy Home Alarm Equipment

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Problem: Sample/specimen preservation demands active unattended monitoring of biobanking equipment (“freezer monitoring”). Unfortunately, monitoring solutions are often provided by niche companies using custom hardware and protocols at premium price points. While often incredibly granular in data logging and alerting capabilities, the bespoke nature of these products can result in obsolescence within a relatively short period of time. Additionally, these solutions can require significant configuration as well as physical and IT infrastructure to function properly – deployed solutions can become silently unreliable if not regularly tested. The end result is that precious samples and workflows are left unmonitored with the concomitant risk to samples/specimens when equipment or power failures are noticed too late.

ALL of these issues are compounded in academic and non-profit institutions that cannot afford routine replacement of monitoring infrastructure.

Proposed Solution: This presentation describes the process in which readily available residential “burglar alarm” systems can be easily repurposed to provide inexpensive, 24/7, reliable active monitoring of freezers, incubators, and other equipment which have intrinsic set points and alarms. With minimal effort the system can be further interfaced to provide temperature range monitoring for cold rooms, equipment rooms, and refrigerators.

When connected via cellular networks or WiFi to an alarm company, equipment status can be monitored via web browsers

and cell-phone apps and the response to alarms becomes highly configurable, everything from sending text messages and emails through triggering a human to work through a call list until a person acknowledges the alarm.

These systems are easy to install (often wireless), inexpensive, and highly tolerant to failure. They use interchangeable sensors and controllers that have been supported for decades. They are battery powered and actively monitored (low batteries and disconnected wires/sensors all trigger alarms).

This presentation will walk through all the steps and configuration required to deploy this solution.

Conclusions: Our deployment monitored 11 incubators, 7 - 80 freezers, 3 refrigerators, a cold room, and an equipment room at a cost of ~\$500 + \$10/month. With all alarms going to SLACK, email, and text we caught everything from open freezer doors to empty incubator water trays to the occasional compressor failure. It is true democratized biospecimen protection.

PK-05 Satellite Lab Concept to Reduce Processing Turnaround Time

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Background: The mission of the Mayo Clinic Biorepositories Program is to support Mayo Clinic Principal Investigator research initiatives through state-of-the-art biospecimen processing and storage, with a focus on quality and service. To meet industry and study standards, processing turnaround times (TAT) of less than two hours are required. Due to a multitude of variables, two-hour processing TAT was unattainable with the current model. The goal was to meet the protocol requirements for sample processing TAT.

Methods: Key stakeholders with the common goal of this project included research group Principal Investigators and Program Managers, Biorepository Program Directors, Operations Manager, Lab Supervisors, Quality Coordinator and Project Manager, and a Health Systems Engineer from the department of Management Engineering and Internal Consulting. The requirements from the research group, current process flows, and available TAT data were collated and analyzed.

Results: BAP baseline measurements for processing TAT were measured over a three-week timeframe. On average automated processing TAT was 8.2 hours while manual processing TAT was 5.7 hours. Factors contributing to a higher TAT for processing of samples included sample collection workflows, the location of the collection site and proximity to processing lab, the extended travel route for sample movement, and updates to the regulatory guidelines for processing samples within a two-hour timeframe. The project team implemented a satellite lab as well as several other interventions to decrease TAT for sample processing and increase customer satisfaction. Re-measurement of sample TAT that were initially conducted

at one month post go-live demonstrated a decrease in average manual processing to 1.6 hours. Four-month post implementation TAT showed an even further decrease to 1.2 hours. TAT continues to be measured on a monthly basis to ensure TAT reduction is being maintained.

Conclusions: The largest contributor to savings in TAT was the time spent in transporting the samples from the collection site to the lab. This transportation time was significantly decreased due to the satellite lab implementation resulting in an overall decrease in TAT. Other interventions were implemented as routine workflows within the satellite lab. Monthly measurements demonstrated a need for additional staffing and increased/more streamlined laboratory space. BAP Leadership and key stakeholders confirmed improved customer service.

PK-06 An Inside Look into Biobank Sustainability at UHN Biospecimen Services

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Background: Biobanks are a growing resource for biomedical research as they are poised at a unique standpoint of providing standardized services paired with high-quality associated data. With the growing impact of biobanks in health sciences, biobank sustainability is an important topic to consider. UHN Biospecimen Services (UHN BSP) comprises 3 different programs, the McCain GU BioBank, Princess Margaret Cancer Biobank, and UHN COVID-19 biobank, that focus on different disease cohorts. UHN BSP implements various sustainability strategies that can be analyzed using the biobank sustainability framework proposed by Watson et al. (2014).

Method and Results: Based on Watson et al. (2014)'s framework for sustainability, a sustainable biobank optimizes the operational, social, and financial dimensions of the organization.

Operational Dimension: Optimizing input and output efficiency by utilizing data capture tools, centralizing the Biobank Information Management System and sample storage, implementing automation, and performing sample and data quality checks. Additionally, through centralization of the biobanks, workflows between programs are shared to ensure optimization and consistency.

Social Dimension: Improving biobank acceptability and standards by undergoing biobanking accreditation; ensuring compliance with institutional safety, privacy, and ethical guidelines; supporting education via co-operative education programs; and developing a strategic plan to increase global visibility, engage patients as partners in the biobanking process, and drive collaborations within the research community.

Financial Dimension: Considering the value of biospecimen and optimization of biobank resource utilization, UHN BSP incorporates targeted and general biobanking to meet the needs of the research community. Feedback surveys are used to measure program strengths and identify research demands. Automation and centralization of resources can significantly reduce the cost of operation.

Conclusion: Operational, social, and financial dimensions of a biobank need to be considered and improvements along any axis will result in greater biobank sustainability. Presently, UHN BSP has banked about 2 million samples and distributed over 110,000 samples globally. Next steps include achieving Biorepository Accreditation Program accreditation across all programs, further integrating automation, and developing a more comprehensive survey to assess biospecimen demand in precision medicine.

PK-07 The Utilization of Sample Confirmation Testing (SCT) in Improving Quality Assurance and Quality Control in the eyeGENE Biorepository

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Background: The National Ophthalmic Disease Genotyping and Phenotyping Network (eyeGENE®) is a clinical biorepository created for the advancement of research on rare genetic eye disorders. Blood is received from participants, DNA is extracted and stored, samples are shipped to diagnostic labs for genetic testing or to researchers, and results are returned to participants. Quality assurance and quality control (QA/QC) procedures ensure sample integrity when returning results. In 2012, sample confirmation testing (SCT) was implemented as an internal QA/QC. SCT utilizes short tandem repeat (STR) marker analysis to verify a participant's original blood has the same genotype as all related DNA samples. SCT assists in identifying biobanking processing errors and serves as a model for maintaining sample quality.

Methods: STR marker analysis was performed using the GenePrint24 kit (Promega). Samples were amplified by polymerase chain reaction and analyzed via capillary electrophoresis. Alleles were called using GeneMapper (ThermoFisher) and the profile of each sample was uploaded to a laboratory information management system (LIMS). The LIMS verified the participant's gender, a unique profile, and identified genotype inconsistencies. Issues were flagged and prompted sample investigations. Sample issues that impacted clinical test results were reported to the Institutional Review Board (IRB).

Results: SCT was completed for all available original blood (n=5,369) and DNA (n=14,178) in the biorepository and resulted in 25 sample investigations with 15 IRB-reportable events. Overall, investigations identified 17/25 (68%) profile mismatches caused by a sample switch, 5/25 (20%) by contamination with a secondary profile, 1/25 (4%) by clinic error, and 2/25 (8%) from unknown reasons. Following these investigations, 75/19,547 (0.38%) of total samples were destroyed.

Conclusion: SCT relies on the ability to compare STR profiles between blood and DNA samples to confirm identity and gender. Mismatched DNA profiles were found for 25/5,329 (0.46%) of samples corresponding to 5,308 participants. Further investigation is warranted to confirm the nature of genotyping errors. When sample switches are identified, affected samples are destroyed and fresh samples are sent for re-analysis. This procedure is a vital component of our QA/QC and leads to improved diagnostic and biorepository operations. As such, we recommend SCT be performed as a part of biorepository management best practices.

PK-08 Communication with Participants: From the Report of the 3rd Biobank Open Forum "Biobank and Participation" Held in Japan

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Background: Biobank has stakeholders such as "biobank users" and "biobank participants." Biobank projects can work

as social infrastructures only when academia, industry, and the public are united in their commitments. In this context, we organized an open forum, the first of its kind in Japan, where several “biobank participants” took the stage to speak. Based on the planning process and results of the forum, this paper will provide an overview of the potential of biobank projects by incorporating citizens’ perspectives.

Methods: This event was organized as part of the Biobank Open Forum, which was designed to promote the utilization of biobanks, and to provide a place for discussion among stakeholders. The planning committee of five members was organized to plan the Open Forum. We decided that the theme of our twelfth forum would be “Biobanks and Participation,” and decided to have several “biobank participants,” i.e., stakeholders who are not directly involved in research and development, appear to speak. For this rather sensitive purpose, meetings were held more frequently than those for past forums.

Results: The web-based forum was held on September 13, 2022, and 317 of 408 registrations attended. From the comments on the biobank participants’ side, it became clear that for a smoother biobanking project, there has to be a deeper understanding of the role of biobanks, including processes such as the elimination of barriers caused by terminology, the understanding of whether or not there is any disadvantage to the individual, and the alleviation of concerns about personal identification. The post-questionnaire survey yielded a maximum of 130 responses. Many of them mentioned that it was the first time for them to be exposed to diverse opinions from various biobank participants and that it was a good opportunity for them to get in touch with the actual situation.

After the forum, we compiled these results and published them as a report on the website (<https://biobank-search.megabank.tohoku.ac.jp/v2/>). We also shared the post-forum questionnaire with the speakers to provide feedback on the forum.

Conclusions: Here we organized a forum that provides a precious opportunity to biobank operators and biobank users for dialogue with “biobank participants.” The forum gives a fresh insight to biobank operators and biobank users about what they may have to do for sample donors, possibly contributing to the development of both domestic and worldwide biobank businesses.

PK-09 Fuelling Local Cancer Research by Establishing Biorepository Best Practices for Quality Samples at The University of Texas at El Paso

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Statement of the Problem: Cancer is a major public health death problem in the United States (US) and it is the leading cause of death among the Hispanic population. The University of Texas at El Paso (UTEP) is committed to investigating molecular and physiological signatures from Hispanic-origin cancer samples in the El Paso/Juarez border region. This area has a particular demographic with wide variances in the economic, social, and institutional living conditions of the population being ideal to evaluate health disparities since it has some poorest rural areas and at the same time urban-poor dwellings as well as some very affluent urban neighborhoods. As research has shown, such variations cause health disparities that con-

tribute to the incidence, prevalence, development, severity, and even burden of cancer. Health disparities have been linked to the higher incidence and mortality rates of cancer in the Hispanic population. The UTEP Border Biomedical Research Center (BBRC) is committed to address health disparities in the Borderplex region by establishing a regional Cancer Biorepository to expand research on this issue. The main challenge of UTEP-BBRC was to establish biorepository best practices to ensure that the quality of samples collected meets internationally acceptable standards.

Proposed Solution: The University adopted ISBER Best Practices and NCI Best Practices for the collection, use, and storage of quality biospecimens in the biobank, geared toward cancer research. The University staff were trained on the adopted biobanking best practices and SOPs were created to ensure compliance with these best practices. The University automated its operations by deploying an informatics solution to support compliance with the biobanking best practices. They decided to use a cloud-based Laboratory Information Management System (LIMS), CloudLIMS, for their informatics needs.

Conclusion: Cancer has a detrimental effect on the Hispanic population which has been attributed to the prevailing cancer health disparities in the US. UTEP-BBRC Biorepository facilitates cancer research in this unique El Paso/Juarez border region and strives to reduce Mexican cancer-related health disparities in the region and beyond. The biobanking best practices guarantee the authenticity of cancer research at the institution as well as the accuracy and reliability of the clinical research conducted using the biorepository samples.

PK-10 Evacuation of the Cryobank during Military Aggression

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Cryobank management is known to affect the success of infertility treatment by the assisted reproductive technology using cryopreserved biological material.

Effective management involves constant monitoring of the processes, ensuring safe and efficient storage of biological samples. Selection of cryopreservation equipment and documentation of biomaterial storage processing, together with audit of components, all need to be properly and regularly managed.

However, military aggression against Ukraine has significantly impacted the routine management of cryobanks in many clinics of our country.

Honestly, such a procedure as an emergency evacuation of the cryobank was not prescribed in the standard operating procedures and we simply did not know what to do. Everything was done quickly with one purpose, thanks to the bank, which stores hundreds of lives of future Ukrainians.

The aim of the report was to supplement the existing requirements for quality management biobanking, namely the procedure for organizing the evacuation of cryopreserved samples during military operations based on our own experience.

If there is a threat or need to evacuate the cryobank, a disaster recovery algorithm should be developed, to maintain normal storage conditions for oocytes, spermatozoa, and embryos.

The first main problem was lack of an amount of LN in the storage. Thus, the following conclusions were made: Thus, the following conclusions were made. There was a need for: access

to equipment for liquid nitrogen generation; access to a back-up source of liquid nitrogen for emergency evacuation; and making a clear decision about sample packing density of the container because of the possibility for liquid nitrogen overconsumption.

At the time of evacuation, all the documents were placed into a separate container. Therefore, we made another conclusion about the mandatory maintenance of the electronic register of the cryobank. So the next point for emergency of cryobank transportation is that: all bank databases should be in electronic version and stored at independent server.

We believe that due to our experience, the documents regulating the cryobanks management should be supplemented with the above items for proper and safe storage of specimens.

PK-11 Risk Management of Total Inventory and Operations Transfer to a New Biobanking Space: A Case Study

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Statement of Problem: Over five months, the AstraZeneca (AZ) US Biobank Team planned and executed the relocation of biobanking operations and human biological sample (HBS) inventory from Massachusetts to Maryland. Relocating the Biobank operations was a complex operation, involving updating HBS sources of active clinical trials, commercial HBS vendors, and academic and hospital collaborations. The HBS inventory relocated varied in storage temperature from ambient to frozen and required auditable monitoring. The plan for operations, inventory transfer, and the associated risk assessment and risk mitigations that were conducted to successfully complete the relocation are outlined.

Operations relocation risks included: a) active clinical trials requiring co-ordinated updates to statements of work globally without disrupting study delivery, b) outdated contact information with commercial HBS vendors, c) HBS users not identified who required notification, and d) organizing short timelines.

Inventory relocation risks included: a) sample integrity compromise; b) multiple transportation method/timeline possibilities; c) safety, health, and environmental considerations; d) sample inaccessibility to researchers; e) database updates reflecting move; and f) staffing coverage interruptions.

Proposed Solution: The relocation of biobanking operations required a mass data revision to the clinical trial central lab database, updates to the Statements of Work for 39 active global clinical trials, identification of and notification to relevant stakeholders responsible for clinical trial setup and oversight, and updates to central lab database and training. The AZ US Biobank updated its roster of commercial vendors and HBS users across the R&D sites and created a notification timeline.

Initial planning for the relocation of samples required a comparison of different transportation methods taking into account carbon-negative goals, minimizing sample compromise, research timelines, and space constraints. A mass single-day transfer was selected and numerous companies specializing in biologics shipping were consulted to compare logistics. Throughout the move, the US Biobank partnered with AZ Safety Health and Environment, Laboratory Operations, Shipping and Receiving, and Procurement to ensure success.

Conclusion: AZ US Biobank's collaborative and detailed planning, risk assessment, and mitigation made for a successful relocation of biobank operations and inventory.

PK-12 Data Management Pipeline Implementation as a Tool to Foster 3.0 Biobanking

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Background: To contribute significantly to scientific knowledge it is necessary to provide investigators with demographic, clinical, quality, and traceability data linked to the biological samples. We aim to detail the challenges and achievements that HCB-IDIBAPS Biobank underwent during the transition to biobanking 3.0 by incorporating data management tools.

Methods: The biobank enables dataset registry by customizable options, such as hardcopy datasheets or direct LIMS upload. A Python-coded computational pipeline has been designed to ensure: i) data annotation compliance, ii) clean-up of mismatches and duplicates, iii) filling of empty variables and missing data, and iv) assessment of sample incidental events. This pipeline is nourished by scripts that are trained and refined by using increasingly complex datasets.

Results: First, databases have been cleaned and informative variables and minimal datasets have been identified. Second, massive sample redistribution has led to an increase in storage capacity by the equivalent to a whole -80 ultra freezer. Third, a complementary database has been curated and migrated to the Laboratory Information Management System (LIMS), resulting in a centralized database that allows access to samples information, filtering options, and sample procurements registry. Finally, the occurrence of incidental events has been monitored by the workflow to establish corrective actions. These actions avoid any possibility to compromise the quality of the sample or its derivatives or further implications in downstream applications. Overall, a consolidated pipeline that includes 7 quality checkpoints has been established and is currently being used to evaluate the whole Biobank data catalogue.

Conclusions: The data management pipeline is successfully applied at HCB-IDIBAPS Biobank. This pipeline includes checkpoints for the monitoring of data annotation, sample incidental events and follow-up for all existing collections in the Biobank. Likewise, it allows the monitoring and optimization of technical activity, and provides the means to calculate several performance quality indicators. This workflow has changed the Biobank organization from the computational and bench work to the human resources management and has led to interdisciplinary collaboration across various institutional stakeholders. These results are promising and will be upgraded by means of machine learning tools to foster cost-efficiency measures and biobank sustainability.

PK-13 Alessandria Biobank. Creation of Breast Cancer Collection

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Background: At the Research Training Innovation Infrastructure of the Azienda Ospedaliera SS Antonio e Biagio e Cesare Arrigo is located "Alessandria Biobank" which includes the collection of malignant mesothelioma; Alessandria Biobank began a journey to collect biological samples of breast cancer and associated data with the aim of serving biomedical research in the fight against cancer.

Methods: A multidisciplinary team including biologists, breast surgeons, pathologists, oncologists, and radiation oncologists of the hospital has collected inside the hospital a considerable number of biological samples and data from breast cancer patients. This is a descriptive, prospective, single-center observational study, whose recruitment criteria include:

- patients older than 18 years of age
- patients with breast cancer
- signing of informed consent

The exclusion criterion is the lack of informed consent.

Anonymized data collection was structured through the creation of a new database on the user-friendly web interface REDCap.

Results: Biological samples include breast cancer biopsy, blood, plasma, and serum sampling.

A total of 270 patients, comprised 2 males, with breast cancer were included in the database, and of these there were 51 biopsies, stored at -80°C.

According to the database it turns out that the most frequent tumor type is ductal carcinoma followed by invasive lobular carcinoma. This result is in line with the worldwide incidence. In our study, we evaluated the province and municipality of both birth and domicile, trying to identify a geographical arrangement of incidence.

From our data, there is an average age of 64.5 years, with the youngest patient being 27 years old and the oldest being 93 years old.

Conclusions: The breast collection allowed the biobank to increase the number of samples stored and to further open up to new collaborations arising precisely from studies focused on breast cancer. The increasing collection of high-quality samples and associated data plays an important role in biomedical research and health care betterment.

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PK-14 Utilization of Study Specific Workflows in Conjunction with Standard Operating Procedures and/or Study Specific Laboratory Manuals to Manage Multiple Studies in a GCLP Biorepository

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Problem: Substrate Services Core and Research Support (SSCRS) was developed in June 2014 to serve as a departmental biobank within the Department of Surgery at Duke University. From the beginning, SSCRS supported only 14 studies. SSCRS began to grow and expand. 2015 brought more studies and implementation of GCLP and in 2016, SSCRS made the transition from a departmental biobank to a School of Medicine Core Facility with 42 active studies. At present, SSCRS supports over 100 different studies, of which 81 are actively collecting, with an average of over 350 collections events from 40 different studies each month. Of these active studies, 50 utilize SSCRS standard operating procedures (SOPs), 27 have study-specific lab manuals or

study SOPs, and 4 use a combination of both SSCRS SOPs and study-specific lab manuals. The enormous complexity of managing a combination of multiple studies with different study requirements is a challenge that must be met to ensure the integrity of the samples that are received and processed in the biorepository.

Solution: Through trial and error, we have streamlined our processes to ensure that each study utilizing SSCRS is treated in a personal manner, with the ultimate goal of maintaining sample quality and integrity. Prior to activation of a study within SSCRS, the study and SSCRS teams meet to go over the requirements and logistics of the study plan, discussing timelines, processing needs, SOPs, and lab manuals. Based on these meetings the study-specific workflow (SSW) is drafted. SSWs are documents that provide key linkage to study-specific information and SSCRS expectancies. This includes recommendations for maintaining sample quality, SSCRS rejection criteria, scheduling and notification instruction, and sample collection and handling expectations, ultimately providing a single source of reference. The final document is then approved by both the study team and the SSCRS laboratory. SSWs are distributed to both the study and SSCRS teams, and are maintained in a version-controlled manner to ensure that all parties are following current defined processes.

Conclusion: Study-specific workflows were developed specifically to address the challenge of managing the complexity of multiple studies with differing sample handling and processing requirements. These documents are key to ensuring that all samples that move through SSCRS are managed in such a manner that sample quality and integrity are maintained.

PK-15 Intraoperative Collection of Neurosurgical Biorepository Tissue

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High-quality biospecimens are critical to research. To deliver useful tissues to researchers, it is necessary to develop strategies for increasing the viability of human biospecimens while preventing their contamination. One method involves flash freezing biospecimens as close to their resection as possible. This will decrease the amount of time biospecimens are exposed to environmental factors, but it will also arrest their metabolic functions—preserving cellular proteomes and transcriptomes. In the Biobank Core Facility (BCF) at Barrow Neurological Institute (BNI), we have implemented an intraoperative collection procedure to markedly decrease the time to freezing. While still in the sterile field, OR staff divide tissue for clinical diagnosis and biobanking. Biobank portions are immediately frozen in LN2. To accomplish this, we established a satellite biobank adjacent to the OR suites, sourced sterile collection kits, and collaborated closely with OR staff to ensure their compliance. Currently, greater than 75% of neurosurgical specimens are flash frozen in under three minutes; of those biospecimens more than 66% are frozen in one minute or less.

PK-16 A Collaborative Communication Model to Support Quality Culture

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Statement of Problem: Installation of a culture of open communication is very important to enable a growth mindset. When this is insufficiently present, important information may be not reaching management, and may not be acted upon. Profound risk analysis (RA) and root cause analysis (RCA) are key drivers of continuous improvement. Biobanks may miss out on opportunities for improvement if their organizational culture doesn't sufficiently support open communication to express contributions and report issues.

Proposed Solution: Non-Violent Communication, developed by M. Rosenberg, is based on the principles of nonviolence (1). It originates from concepts used in person-centered therapy and has been applied in a variety of contexts including organizational settings (2).

This model creates clarity by the separation of observations from judgments, feelings from thoughts, needs from strategies, requests from demands. It proposes self-empathy, honest expression, and empathic listening. Shifting from a paradigm of power-over to power-with, it promotes collaboration.

The poster/talk illustrates the application of the model in a biobank context with an example of an incident during sample storage. A non-judgmental honest expression (cfr meeting theme 'come as you are') facilitates mutual empathic listening (cfr meeting theme 'building bridges'). Focusing on the needs at play supports a profound understanding of the issue. This facilitates addressing the root causes of the issue whilst engaging the personnel in the quality culture.

Conclusions: The collaborative communication model can install a context that fosters the sharing of knowledge and cooperation. During RA and RCA, focusing on this underlying need supports thorough understanding of all aspects and can help with choosing a strategy that better addresses the actual issue. Alignment with the meaning and value behind the work can promote employee engagement and encourage personal responsibility for quality.

1: Mann J et al. (2020), DOI: 10.1080/13561820

2: Azgin, B. (2018). DOI: 10.7596/taksad.v7i2.1550

PK-17 A Ten-Year Review of a Prospective Procurement Biospecimen IRB and the Influence on Specimen Procurement and Distribution at the Cooperative Human Tissue Network (CHTN) Midwestern Division

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Background: The National Cancer Institute (NCI)-sponsored CHTN MWD provides human tissue and associated clinical data as approved by Institutional Review Board (IRB) review for basic and applied research. The OSU Dept. of Pathology Tissue Procurement Service collects biospecimens for CHTN MWD as well as OSU Comprehensive Cancer Center (CCC) investigators and the OSU Total Cancer Care (TCC) Biorepository. The MWD IRB was approved under a Waiver of Consent prior to March 2015. Anticipated changes to the Common Rule, and initiatives from NCI for the new competitive grant cycle, created a significant effort to move to patient consent. In collaboration with the TCC, CHTN MWD created a new IRB protocol approved in March 2015 to operate under

patient consent. In April 2020, the protocol was amended to allow procurement under waiver of consent for researcher projects determined non-human subjects by their IRB. CHTN MWD has two subaward sites that have procured samples during the study period, CWRU and UPITT (starting in 2019). Both sites have their own IRBs that include a general surgical consent.

Methods: We compared biospecimen procurement and distributions totals from a 10-year period (2012 through September 2022) to examine the impact of IRB rule changes on CHTN MWD biospecimen operations. More detailed consent tracking data for the most recent 7 years was used.

Results: Procured samples overall decreased by 17% in 2015 and 31% in 2016 (patient consent), leveled off in 2017-19, and then increased by 20% in 2020 and 16% in 2021 (waiver non-human subjects). Consented procurement remained relatively stable in 2015-19 with a decrease in 2019-21 (53%).

Distributed samples overall decreased by 22% in 2015 and 20% in 2016 (patient consent), leveled off briefly with a sharp decrease in 2018 (38%) before showing a 28% increase in 2019 and 19% increase in 2021 (waiver non-human subject).

Conclusions: IRB changes over the 10-year period have impacted trends in procurement and distribution for the CHTN MWD. Peak numbers are reflected under full waiver of consent in years just prior to the change to patient consent. However, with the implementation of non-human subjects-determined research, numbers are gradually trending up. The sharp decline in distribution in 2018 coincided with an overall decrease in frozen and fixed-tissue sample requests. The downward trend in procurement from TCC-consented patients (2019-21) coincided with Covid-19 pandemic restrictions.

PK-18 The Development and Implementation of an Overhauled Biospecimen Collection Database Within a Mature Biobank

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Statement of the Problem: The McCain GU (Genitourinary) Biobank at the University Health Network (UHN) in Toronto, Canada, was founded in 2008 to collect liquid biospecimens from prostate, kidney, and bladder cancer patients at hallmark clinical time points throughout their journey. Participant consent and sample collection information were initially stored using a Microsoft Access database. In the past decade, the scope of the biobank has expanded to include comprehensive clinical data annotation and collections for testicular cancer, penile cancer, and healthy participants. The needs of our expanding biobank outgrew the functionality provided by the original database, and challenges with database instability, scalability, and limited customizability emerged.

Proposed Solution: The recent centralized implementation of REDCap (Research Electronic Data Capture) at UHN provided us with an opportunity to build a more flexible, comprehensive, and robust database for the biobank. REDCap is a secure, web-based software platform designed to support validated data capture for research studies. The platform is equipped with data validation and data quality rules, granular user-rights control, a complete audit trail, and is compliant with personal information protection legislations, such as PHIPA/HIPAA and GDPR. The customizable nature of the platform facilitates the easy incorporation of new data forms and vari-

ables with no system downtime. Capturing data longitudinally in a centralized system for sample annotation will reduce redundant data abstraction. REDCap's survey functionality will replace our current manual transcription of patient-reported data, reducing data-entry errors and the need for additional staffing resources. One challenge posed by this transition is the disruption to the clinical workflow that will occur during the implementation period, as staff must switch between the old and new databases for patient screening and data entry, respectively.

Conclusion: The updated database structure will contribute to future scalability and interoperability with other digital healthcare platforms such as Epic and the planned centralized biospecimen information management system at UHN. This database migration increases the utility of our biospecimens in clinical research, broadens the scope of our potential collaborations, and enables us to meet the evolving demands of our research partners.

PK-19 Moving the Duke Human Vaccine Institute (DHVI) Accessioning Unit and Biorepository During the COVID-19 Pandemic

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The Duke Human Vaccine Institute (DHVI) Accessioning Unit and Biorepository is a multipurpose unit that has two different functions: 1) receipt, accessioning, processing, and storage of fresh and frozen human and non-human primate specimens and samples (Accessioning Unit) and 2) maintenance of the over 1,000,000 samples stored in multiple cold-storage units (Biorepository).

To accommodate the needs of new funding awards, the DHVI Accessioning Unit and Biorepository started planning to move to a bigger facility off campus. The planning involved the design of shipping and processing labs along with a larger biorepository space. The process began in 2019, and design work initially involved in-person meetings with architects, facility planners, movers, and vendors. Infrastructure planning included specifying electric load requirements and the locations for outlets, piping for water and gasses, and space needs. With the start of the COVID-19 pandemic, these meetings became virtual and the timeline was stretched due to pandemic restrictions, including limited construction materials.

The move commenced in July 2021. For the Accessioning Unit we moved laboratory equipment and the Biorepository we moved 40 ULT cold-storage units, 10 refrigerators, and 14 LN2 cold-storage units over the span of 3 days. There were no interruptions of Accessioning Unit and Biorepository operations. In general, the move went smoothly; however, when moving in the 40 ULT cold-storage units we discovered the power in the ULT freezer room was not working. Facility management quickly restored power and the remaining movement of cold storage units proceeded without interruptions. The startup of our piped LN2 system revealed a low-pressure problem which was quickly resolved and there were no further problems with the LN2 freezer room.

In order to move laboratory equipment and cold-storage units for the Accessioning Unit and Biorepository we undertook extensive planning and coordination. This work was made more difficult during the COVID-19 pandemic due to restrictions on in-person meetings and limitations in supply chains which delayed renovations. Despite planning and coordination, multiple

problems were identified during the move that required rapid response from all involved parties, highlighting the need to have facilities, movers, and lab staff involved throughout the process.

PK-20 Metamorphosis in an Online Era: Migration of Consent Collections to a Paperless System by Digitization of Information

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Introduction: A challenge that biobank programs face in an era of digitization is the implementation of digital tools into existing, antiquated workflows. Paper-based data recording and archiving methods remain preferred due to their success and reliability. However, during hospitals' ongoing shift to digital records, consent for biobanking collections, previously established using a paper-based format, also need to be transitioned. Centralized digital consent databases can be used to enhance consent workflow at UHN Biospecimen Services Program (UHN BSP). These databases have proven crucial in the transition to electronic recordkeeping.

Methods: UHN BSP consists of three biobanking programs with separate systems for their consent workflow. Prior to the digital databases' implementation, physical documents had to be checked before collecting from a consented participant.

As a biobank affiliated with regional hospitals, the workflow for accessing and uploading consent information was restricted due to the availability of the physical consent documents by hospital staff and the COVID-19 pandemic. Additionally, if these consents were unavailable during upload, the program's consented individuals were missed, or biobank staff were required to undergo prolonged means of verifying this information.

To improve the current workflow, centralized digital consent databases were established. Guidance documents and example cases were used to train staff prior to the new system's implementation, ensuring a smooth transition. The data fields in the consent databases were edited to include more options as the workflow evolved; this highlights the flexibility of the digital platform to match the varying biobanks' consent forms and form versions. In June 2022, participant records were digitized which removed uploading restrictions.

Results: The centralized online consent databases' implementation enabled over 1500 consents to be registered since its inception in August 2021. De-identified information gathered from over 6200 participants approached for consent was used to streamline the system and to determine changes to improve the workflow. Archived consent data starting from 2012 were also digitized and uploaded.

Conclusion: Digital tools offer great potential to improving the accuracy of the consenting process at UHN BSP. Increasing efficiency, accessibility, and security are one of the many reasons which warrant the need for digitizing consents and using centralized databases.

PK-21 Exhuming Forgotten Treasures: Digitizing Archived Samples for the Future Generation

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Background: As biobanks have moved towards using biobank information management systems (BIMS) to log their samples, many longstanding programs encounter the same issue: archived samples not being utilized due to the nature of the sample information, paper rather than digital. While conversion to digital records and sample digitization sounds simple, it belies a tedious initiative which can take years to complete. By employing different strategies and tools, the digitization of these archived samples into BIMS can be expedited.

Methods: In preparation for accessioning onto the BIMS, the development of standard operating procedures (SOPs) were key for training staff and ensured that the information added was uniform. Resources were allocated towards the physical evaluation of the archived samples to create accurate digital records and progress trackers improving accessibility, as compared to the paper format. Data collected from the physical evaluation were digitized to ensure precise documentation into the BIMS platform, making updates and corrections to sample volumes and conducting distributions to study teams possible. Incorporation of new tools such as bulk accessioning using Microsoft Excel Macros were implemented to transform participant and sample information from the digital records into a format which could then be uploaded onto the BIMS.

Results: Implementation of bulk accessioning of sample information onto BIMS was extremely effective in improving digitization output and optimizing the time spent inputting participant data. Through the use of said strategies, one cohort with over 10,000 derivatives was accessioned in 4 months; another with over 27,000 derivatives was accessioned in 13 months. With samples collected from more than 7100 participants and 48 disease sites, over 6400 frozen tissues, 5000 plasmas, 3500 serums, and 1250 buffy coats were annotated and digitized for future research studies and endeavors.

Conclusions: Creation of standard operating procedures along with proper training were essential to completing this project. Furthermore, implementation of bulk accessioning improved the efficiency of sample digitization exponentially to reduce time spent on uploading information into our BIMS. Movement towards the automation of archiving samples has led to numerous derivatives being added onto BIMS such that requests and utilization of these specimens can empower future research.

PK-22 Building a Better Biorepository, Block by Block

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Background: Can a basic design be developed that can be applied to all types of sample repositories? A model repository can be designed and built that can be easily adapted for sample storage requirements and site conditions (i.e., capacity, temperature, sample format, or access).

Method: Using a list of targeted questions, a repository can be designed that will meet the facility requirements for the storage of any type of sample. Some foundational design questions include:

What square footage will the facility occupy?

Will activities beyond sample storage occur within the facility or within the storage area, i.e., sample preparation or laboratory space?

How many people will occupy each section of the facility? The sample storage area?

Will there be intermittent workers in the facility?

What are the access and egress requirements for the facility/sample storage area?

What are the temperature requirements for the storage of the samples?

What are the power requirements for the facility/sample storage area?

The responses to the questions are converted to building blocks, which represent a requirement for the design. The building blocks are then arranged in a graphical representation to meet the user's needs and to meet building code and access/egress requirements. The use of this graphic compilation of responses to the initial/foundational design questions informs the final project architectural scope. This integrated block-by-block approach generates an informed down selection presented to the user for the final facility design options.

Results and Conclusions: Establishing the needs and requirements for a repository are critical for the development of the overall design. The user needs to assess current state and anticipate potential future growth and changes when designing a repository to ensure that the repository can be flexible and adaptable.

PK-23 When the Decision to Close a Repository Is Reversed: The Ontario Tumour Bank Experience

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Statement of the Problem: The Ontario Tumor Bank (OTB) is a bioresource of high-quality biospecimens comprehensively annotated with clinical data. The OTB has a central office at the Ontario Institute for Cancer Research (OICR) with four hospital-based collection centers. Founded in 2002, over 21,800 patients have participated, nearly 200,000,000 samples have been accrued, and more than 50,000 samples have been distributed. Sample types include snap frozen tumors and adjacent normal tissue, paraffin-embedded blocks, and matched blood derivatives.

In the spring of 2021, OICR was faced with a significant budget shortfall. The decision was made to wind down OTB operations and search for a Canada-based biorepository to assume custody of the OTB collection. However, a suitable organization could not be identified. Other factors resulted in a reversal of the decision to close in 2022. There were expressions of concern from the research community about the loss of this important bioresource, OTB's cost recoveries surged to their highest level ever in 2021, and potential opportunities for charitable fundraising were identified.

Unfortunately, uncertainty around OTB's future had consequences. Exacerbated by personal and work disruptions caused by the COVID-19 pandemic, the Director and other staff left OTB to pursue other opportunities. Further adding to the challenges was an urgent need to identify a new bioinformatics information management system (BIMS) as vendor support of the existing BIMS was ending.

Proposed Solution: A new Steering Committee was launched and OICR managers were seconded to support remaining OTB staff and operations. Increased fulfillment of biospecimen requests allowed for investment into a new BIMS, former employees were retained on a contractual basis and OICR Lea-

dership secured new funding. The collection sites restarted accrual and a new Associate Director was hired. New initiatives have begun including an expanded Association of Ontario Tumor Biobanks, updated services such as viable tumor for living models and renewed marketing to relaunch OTB to patients, academic researchers and industry.

Conclusions: The difficult decision to close the OTB, despite its reversal, resulted in disruption of business continuity. Work is on-going to rekindle community engagement, rebuild OTB's reputation, and continue to honor the wishes of those who donated their samples under the expectation that they would be used in essential medical research.

PK-24 Use of The College of American Pathologists Competency Assessment Program to Maintain and Document Staff Training

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Background: The CDC Biorepository (CBR) was accredited by the College of American Pathologists (CAP) Biorepository Accreditation Program in 2019. To retain accreditation, CBR must provide and document training and competency assessments to demonstrate that CBR staff are properly trained and are performing activities correctly and consistently. The CBR previously used a manual, paper-based system for tracking 1) which trainings were required for each of 26 CBR personnel roles, 2) which staff were designated to provide and document trainings, 3) due dates and required frequency of each training, and 4) completion of previous competency assessments. This system was inefficient and labor intensive, requiring meticulous oversight and introducing risks for possible deficiencies.

Method: To better manage and document staff training, CBR selected the CAP Competency Assessment Program (CAPCAP) software. Implementation required the development of over 150 training and competency assessment profiles composed of training materials including procedures or other documents to read and acknowledge, PowerPoint presentations, training and competency assessment checklists, and written evaluations: all with initial and annual requirements. Furthermore, over 30 of the profiles required unique combinations of training materials specific for different CBR staff roles depending on job duties.

Results: The conversion from CBR's manual training system required the creation and definition of new roles and responsibilities for the entire CBR staff. Staff met regularly to identify requirements and training formats, provide feedback and input, and answer questions. The system was designed to not only meet CAP accreditation requirements but would also include documentation of mandatory trainings required by CDC.

Conclusions: Utilization of the CAPCAP software and creation of specific trainings and competencies allowed CBR to ensure that staff are proficient in CBR policies, process, and procedures and comply with CAP accreditation requirements. Use of the system also improved methods for performing and documenting in person and online trainings and assessments, increased visibility and awareness of requirements by CBR staff, minimized the risk for staff to miss assignments, improved communication to CBR staff through CAPCAP auto-generated email notifications and reports, and reduced the training time needed for new staff.

PK-25 How Collections Management Helped Transform the CDC Biorepository

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Background: The CDC Biorepository (CBR), established in 1997, serves as a centralized biorepository resource to preserve valuable samples from the Centers for Disease Control and Prevention (CDC) and to provide ongoing support and other services to CDC programs. In 2016, CBR set a goal of transforming its sample collection management. Methodologies for how data were collected, electronically managed, and archived were antiquated. Standards were minimal, and very little data were available. Communications with subject matter experts (SMEs) for older collections were not informative.

Methods: In 2017, CBR conducted a survey to update information about its collections. In 2018, CBR initiated a data gap analysis by reviewing policies, best practices, and conducting interviews with SMEs across CDC. Revised standards were established for new collections, and a process was developed to apply them retroactively to legacy collections and ensure uniform management of all collections moving forward. CBR created an online Annual Collection Review (ACR) form to gather collection data and supporting documentation.

Results: Collection reviews were conducted in 2017, 2020, and 2022. The 2017 review revealed a need for a comprehensive survey, leading to the development of the ACR form in 2020 to consist of over 100 data fields to gather collection data (e.g., geography, secondary use) and a call for associated documentation (e.g., project proposals, IRB information, permits, publications). Robust data were successfully obtained (e.g., geographic information: 30% before, 80% after; project period: 60% before, 100% after), and a simplified ACR was used in 2022. New documentation was obtained for 50% of collections and newly collected records were assessed, scanned, referenced, and archived following each review. Accession numbers were assigned to all collections.

Conclusions: The ACR has provided a significant amount of information that will help to preserve CDC's valuable collections and mitigate risks associated with data loss that could affect sample value. Like all federal institutions, CDC strives to improve the development, preservation, management, and accessibility of its holdings. The ability of CDC to share its resources in the future with the broader scientific community depends upon samples with robust, supporting metadata and complete documentation.

PK-26 Biobanking in Challenging Times: Sustainability Plan of Research Guidance

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The costly kind of unique samples/cell lines, data, and also other high-pitched value biobanking products and services such as cell-based drugs and biologically active pharmaceutical materials call for tremendously precise planning—including the full spectrum of risks.

So what happens if your biobank suddenly finds itself in the middle of a dangerous situation like an earthquake or even a war zone?

Well, let's look at our biobank again. Based on our experience, we have identified the main tasks and challenges that the Biobank faces in an emergency. The highest need is TIME.

Statement of the Problem: The first person on the scene of an accident must set the emotional stage for both the personal and other arriving responders. All biobanking workers are highly encouraged to obtain CPR and first aid training:

- a) Give the location of the emergency: building; specify the wing, if known.
- b) Give the extent and nature of injury, if known.
- c) Provide any details that may be relevant: building integrity, availability of water and electricity, backup generators running, whether toxic fumes are present, etc.

The second task is the place of evacuation of the biobank: evacuation within the country or abroad.

At the evacuation stage, you have to solve a number of tasks: 1. Transport and driver, as well as transport boxes, dry ice, liquid nitrogen, temperature control during transportation, compliance with sterility conditions, and contamination prevention; 2. Compliance with ethical and legal standards; 3. Compliance with safety for personnel; 4. Evacuation and uninterrupted operation of the biobank database; 5. Analysis of SOPs and documentation to determine the temperature regime and the maximum amount of time for transporting various types of biological samples.

The primary task during the evacuation of the biobank is the sorting of biological material and collections. We have applied the principle of "sorting" the wounded in relation to bio-samples. This principle is the most complex measure of the military medical administration. At the Ukrainian Association of Biobanks, sorting bio-samples proved to be the most difficult task and required clinical thinking and medical composure.

Conclusion: You must know how to react before a crisis arises. We believe that the creation of a biobank for the emergency evacuation of bio-samples from any country on the ISBER or ESBB platform is a top priority for the biobank community.

Repository Standards

PL-01 Qatar Biobank's (QBB) Journey for ISO 20387:2018 Accreditation

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Background: As QBB's diagnostic lab is CAP accredited, we faced a dilemma of pursuing CAP or ISO Biobanking accreditation. After much deliberation, QBB began its quest to obtain ISO 20387:2018 certification in June 2021.

Methods: Due to limitation of acquiring a training and certifying body in Qatar for ISO 20387:2018, QBB purchased awareness training from A2LA Workplace Training in January 2022 and 85 staff were trained online in March 2022. QBB approached A2LA for accreditation. A2LA is the world's first conformity assessment accreditation body to be recognized for ISO 20387 for biobanks.

Mar 22, 2022: QBB registered itself as a customer in the A2LA portal.

March 27, 2022: QBB formulated a working group consisting of the director, functional managers, lab quality officer, research and training specialist, scientists, and ISO coordinators and met weekly until all mandatory clauses were met. In the

initial gap assessment, it was found that out of 355 clauses, 215 (61%) were met, 11 (3%) were unmet, 78 (22%) were partially met, and 48 (14%) were to be confirmed.

March 29, 2022: The working group met for the first time to discuss noncompliant clauses. Clauses were assigned to relevant managers to embed the new requirements in their processes and accordingly create/update required manuals, procedures, work instructions, and templates.

April 11, 2022: As some clauses needed more focus, sub-working groups were created, e.g., the Lab & Research Office met to develop a detailed report to satisfy clauses 7.12.2.1. content of the report for samples provided to the researchers. QBB's Action Request committee initiated their group meetings to revise the procedures and incorporate risk assessments.

June 01, 2022: Clauses were assigned to relevant managers and were given two months to fulfill the requirements.

August 08, 2022: Out of 355 clauses, 320 (90%) were met and 36 (10%) were partially met. Partially met were not mandatory clauses.

August 18, 2022: QBB submitted its documents to the A2LA portal and awaited document review assessment.

August 24, 2022: QBB submitted the scope of accreditation to the A2LA portal.

Results: October 24-26, 2022: A2LA conducted an online initial certification assessment. QBB received two findings and is in the process of closing with root cause analysis, corrective action, and plan.

Conclusions: QBB aims to close two findings by 25 November 2022 and awaits a successful certification process. QBB's competence with ISO 9001:2015 and 27001:2013 gave confidence and experience to approach this journey quickly.

PL-02 High-Quality BioBanking in Belgium: The Road Towards ISO20387 Accreditation (B3-ISO)

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A large part of the irreproducibility of research on human body material originates from the biospecimens used and has been identified as a major undermining factor regarding the translation of research results into clinical applications. As, since the new Royal Decree on the biobanks in 2018, all human body material used for research has to pass via a Belgian biobank, such biobanks can play an important role in reducing research variation by providing high-quality, fit-for-purpose samples and associated data.

The European infrastructure for biobanking BBMRI-ERIC is reflected in the National Node BBMRI.be, established in 2013 at the Belgian Cancer Registry and connects 18 Belgian biobanks. Many of these biobanks arose from existing sample collections, sometimes with limited quality management systems (QMS). These biobanks are now aiming toward further professionalization and implementation of a QMS according evidence-based guidelines and/or standards. The biobank standard (ISO 20387), which was recently published but not yet

included in the portfolio of the Belgian accreditation organization BELAC, will allow biobanks to formalize their competences and because of its international recognition will allow the Belgian biobanks to demonstrate their readiness to support (inter)national translational research.

To harmonize and enhance the quality management activities of the BBMRI.be biobanks, BBMRI.be will develop a stepwise quality improvement program that can be implemented at the individual biobanks. This quality improvement program will facilitate the road towards ISO 20387 for the BBMRI.be biobanks by guiding them step by step. At the same time, an accreditation program will be established together with BELAC, ultimately leading to ISO accreditation. The setup of this program and the implementation of the ISO 20387 standard will substantially contribute to (inter)national translational research and foster collaborations between industry and academia in the biomedical sector.

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PL-03 Biorepository Processing Data Standards and Data Validation as an indicator of Standard Operating Procedure Compliance and Biospecimen Quality

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Problem: Appropriately annotated biorepositories containing high-quality biospecimens are critical to translational research efforts. Standardization and repetitive application of systems, processes, and methods will result in fewer errors. Failure to follow standardization can result in high failure rates and poor performance. It is common practice for biorepositories to implement standard operating procedures (SOPs) but it is difficult to assess SOP compliance and the impact on sample quality in real-time. The impact of SOP non-compliance on biospecimen quality is often not realized for months or years, if at all.

Solution: Substrate Services Core & Research Support (SSCRS), a Duke School of Medicine biorepository service center, established a processing data entry standard of <2% major error and <5% minor error rate. Major errors have the potential to adversely impact downstream uses or present a billing risk. Minor errors are missing values or errors that are easily corrected and unlikely to adversely impact downstream uses. For a baseline, one month of data entries into the LIMS and REDCap®-based eProcessing form were reviewed and errors were noted. These data, common errors, and a re-training plan were presented to each technician. The team major error rate was 15.45% (range: 6-32.2%). During a 6-month provisional period the team major error rate dropped to 2.23% (range: 0-7.6%). Error rates above the standard were isolated to specific technicians. The first 4 months after the provisional period, despite performance improvement plans, major error rates ranged from 0-13.1% and were isolated to specific technicians and resulted in terminations. The team major error rate now consistently remains below 1.7% (range: 0-1.68%). To assess the utility of the standard to predict biospecimen quality, 18 PBMC specimens were sent to the Duke Immunology and Virology Quality Assessment Center for assessment of % recovery and viable recovery. Three of 4 samples processed prior to the data standard failed QC, 2 of 6 specimens processed during the provisional period failed QC, and 2 of 4 specimens processed after the provisional period failed QC. The failed specimens were isolated to the same technicians identified in the data standard reviews.

Conclusion: Specimen processing data standards and validation methods serve as an indicator of SOP compliance and

specimen quality in real-time and allows for early training and performance intervention to mitigate negative sample quality.

PL-04 The National Institute of Diabetes and Digestive and Kidney Diseases Central Repository Resources for Research (NIDDK-CR R4R): Enabling FAIRness and TRUSTworthiness with Data & Specimen Standards

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Background: The NIDDK-CR R4R was established to expand the usefulness of multi-center clinical study-generated resources by providing access to data and specimens for secondary research. In 20 years of service, it has expanded its portfolio and includes more than 15.5M specimens representing more than 150,000 unique participants with over 200 data packages across 177 studies. Its visibility to the research community requesting specimens and data, has increased accordingly.

R4R continues to make significant system and process improvements, it and its users can benefit from additional steps that streamline these processes, improve data and specimen annotation, and encourage wider recognition of its achievements by the scientific community. New technology advances and informatics capabilities offer an opportunity to expand the research community's awareness of the existence and increases reuse in innovative research.

Methods: We implemented relevant portions of the Desirable Characteristics of Repositories to better position the R4R for the updated NIH data management and sharing requirements with the goal of strengthening the repository's adherence to FAIR and TRUST principles, securing Core Trust Seal (CTS) certification and enhancing data and specimen annotation using NIH-endorsed CDEs stored in the NIH CDE Repository.

Results: Several key results were realized based on the implementation of desirable repository characteristics and applying for CTS certification including: established workflow and metadata mapping to assign digital object identifiers (DOIs) to R4R studies and packages; generated schema.org mappings and implemented code to publish R4R metadata in schema.org format; developed a CDE implementation plan that included a variable mapping to standard terminology and overall improved data quality, validation, and preservation of information stored within the R4R.

Conclusion: The work performed continues to enhance the R4R's ability to support enhanced data discovery, sharing, and analysis. Persistent DOIs will improve data citation, reusability, and accessibility; the CDE plan defines an implementable strategy for using CDEs and standardized terminology and can facilitate data reuse by implementing standardized annotation and enabling meta-analysis across studies. This work also lays the foundation for applying FAIR principles to specimens and enables R4R to support NIH's new data sharing policy that takes effect Jan. 25th, 2023.

PL-05 Preparation of panels for the External Quality Assessment of COVID-19 laboratories in Côte d'Ivoire: Pilot Phase

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Background: A pilot External Quality Assessment (EQA) study of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleic acid amplification tests and antigenic tests was conducted in Côte d'Ivoire. During this study, the preparation of the panels for the EQA was performed at the biobank of Pasteur Institute of Côte d'Ivoire. In this paper, we present the preparation of the panels for the SARS-CoV-2 QEE carried out in the framework of a project funded by the American Society for Microbiology (ASM).

Methods: Twenty two PCR- and antigen-positive nasopharyngeal samples were used to prepare the EQA panels.

Results: A total of 720 samples were obtained after preparation of the EQA panels with dilutions ranging from 10-1 to 10-5 for PCR test and from 10-1 to 10-2 antigenic test. Subsequently, the allocation of the samples resulted in 112 panels.

Each panel consisted of 8 samples, i.e., a parent sample, a sample diluted to the 10th, 100th, 1000th, 10000th, 100000th, and 2 negative controls. Of the 112 panels, 28 were analysed using the GeneXpert. And the results showed that 69.05% of the samples were positive and 30.95% were negative. For the antigenic test, half of the 16 panels were analysed using the SD Biosensor kit and the results showed respectively that 100% of the parent samples analysed were positive, 50% of the 10th diluted samples were positive and 12.5% of the 100th diluted samples were positive. Moreover, when going from 10-1 to 10-5 and from 10-1 to 10-2 there was a progressive decrease in the number of positive samples.

Conclusion: The preparation of the panels made it possible to obtain samples for the External Quality Assessment of SARS-CoV-2 in Côte d'Ivoire.