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TRACK 1. Navigating the Future of Biobanks: Challenges and Innovations

3A: One Health: Non-human biobanking

287: Biobank at Biomedical Primate Research Center, The Netherlands: Attractive Alternative Source for Scientific Research

by Kondova-Perseng I. | Feo Almagro M. | Langermans J. | de Groot N. | Bruijnesteijn J. | Langelaar M. | BPRC, The Netherlands | BPRC, The Netherlands | BPRC, The Netherlands | BPRC, The Netherlands BPRC, The Netherlands | BPRC, The Netherlands Topic: 3A: One Health: Non-human Biobanking Presenter Name: Kondova-Perseng Ivanela Keywords: biobank, nonhuman primates, one health

Kondova-Perseng I.[1], Feo Almagro M.¹, Langermans J.¹, de Groot N.², Bruijnesteijn J.², Langelaar M.¹

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Nonhuman primates (NHPs) are routinely used in biomedical research because of their anatomical, physiological and genetic similarities to humans. Nonhuman primate tissue banks represent a valuable resource for scientific research, guarantee the reduction of animals used in experiments and enable the efficiency of pre-clinical studies. The nonhuman primate biobank of the Biomedical Primate Research Center is the biggest in Europe and is based on the principals of the 3Rs: refinement, reduction and replacement. The aim of the biobank is to provide rare and valuable primate specimens for scientists working in biomedical and evolutionary research.

BPRC's primate biobank consists of:

- Organs and tissues. Samples without morphological alterations from clinically healthy retired animals include snap frozen samples stored at -80 C, and formalin fixed paraffin embedded (FFPE) tissues. The short post-mortem interval guarantee the best quality of the specimens.
- Blood, serum and blood derived material: DNA, RNA, cDNA samples are adequately stored at +4, -20 or -80 °C. The species identity and the quality of the materials are tested by standard laboratory-based technologies. PBMCs and/or immortalized B-cell lines of macaques, marmoset and chimpanzees are stored in liquid nitrogen.

The samples represent the following primate species: Rhesus macaques, Long-tailed macaque, Common marmoset, and Common chimpanzee.

278: VMF Biobank, Latvia University of Life Sciences and Technologies: A repository for clinical animal biospecimens and data

by Stelfa Gundega | Latvia University of Life Sciences and Technologies, Clinical Institute Topic: 3A: One Health: Non-human Biobanking Presenter Name: Stelfa Gundega *Keywords: animals, comparative medicine, one health, translational research, veterinary biobank*

Veterinary biobanks are specialised repositories that systematically collect, process and store biological samples and associated data from animals, facilitating cutting-edge research in veterinary and comparative medicine. Establishing an animal tissue biobank offers several advantages: 1) using stored samples, researchers can minimise the need for live animal experiments, reducing ethical concerns and lowering costs associated with housing and care; 2) provides access to samples collected from various disease stages, particularly from animals in longitudinal studies, enabling crucial insights into disease progression; 3) availability to the collections of samples from rare diseases or difficult-toobtain species, allowing researchers to study conditions that might pose ethical, legal or financial challenges; 4) promotes One Health approach by supplying valuable samples for spontaneous disease models found in companion animals, facilitating cross-species research and improving understanding of zoonotic disease transmission and antimicrobial resistance; 5) provide samples from diverse animal populations, capturing biological variations essential for generalising research findings. These advantages make animal-tissue biobanks a powerful tool for advancing scientific knowledge in an ethical, cost-effective, and collaborative manner.

At the Latvia University of Life Sciences and Technologies (LBTU), Faculty of Veterinary Medicine, we are establishing a VMF Biobank. This initiative aims to implement a long-term biobank to support high-quality research using residual biological samples from veterinary patients. The LBTU VMF Biobank will support the 3R principles, promote collaboration among researchers, and contribute to advancing One Health-focused science.

276: Implementation of the Standard ISO 20387 for Genetic Resources Conservation in a Biobank

by Edgar Torres García | Carlos Hugo Avendaño Arrazate | Centro Nacional de Recursos Genéticos INIFAP | Centro Nacional de Recursos Genéticos -INIFAP

Topic: 3A: One Health: Non-human Biobanking Presenter Name: Edgar Torres García Keywords: Biobank, conservation, genetic resources

Genetic resources for food and agriculture encompasses all those vegetal, animal, DNA and microbial material, which possess functional hereditary units and holds a potential value for world's food safety. Its diversity has sustained humanity for centuries and has facilitated the continuous growth of cultures. The CNRG has been functioning since 2011 as the central biobank in Mexico holding five different but interconnected collections of biological material: seeds, plants, DNA, zoogenetic resources and microorganisms. Therefore, a consistent and well stablished conservation procedures of genetic resources is of vital importance for present and future generations.

ISO 20387 has been gradually implemented in the CNRG as follows:

- 1. Standard ISO 20387,
- 2. Training on ISO 20387 (BBMRI-ERIC),
- Creation of manuals, work flows, formats,

- 4. Implementation and validation of documentation,
- Audit (March 2025 documentary audit -Sep. 2025 internal audit)

Due the use of standard NMX 17025 at the CNRG since 2015, the foundation for ISO 20387 was already in use. Nevertheless, there was the need to adapt some documents and create others. As of January 2025, 200 documents plus are in use on the five collections.

Despite 13 years of work at the CNRG, ISO 20387 has helped standardize the processing of genetic resources and involve staff in an international environment. It has assisted on a better traceability of genetic resources conservation as well as an improvement of the quality management system. Once the accreditation under ISO 20387 is obtained, it will benefit the CNRG on its internal daily activities and on its recognition worldwide.

4A: Clinical biobanks: Bridging research and patient care

439: Gap analysis of RWD and consent coverage of Neuromuscular Disease Biobank using registration at the source principles

by Y.D. Krom | R.J.A. Hoek | U.A. Badrising | C.S.M. Straathof | M.R. Tannemaat | J.J.G.M. Verschuuren | F. Slingerland | M. van der Holst | R.R. Snijder | E.H. Niks | LUMC, Duchenne Center Netherlands | LUMC | LUMC | LUMC | LUMC | LUMC , Duchenne Center Netherlands | LUMC , Duchenne Center Netherlands | LUMC Biobank Organisation, Duchenne Center Netherlands | LUMC , Duchenne Center Netherlands

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: R.R. Snijder Keywords: Biobank, FAIR, Informed Consent, Neuromuscular diseases, Real World Data, Registration at the source

At LUMC, Duchenne Center Netherlands has developed and adopted a conceptual framework, FISMA, that allows capturing Real World Data (RWD) as relevant, re-usable and semantically interoperable data. FISMA was originally drafted for dystrophinopathies (Duchenne and Becker muscular dystrophy, DMD and BMD, respectively), but at the same time, with expansion in mind: to other neuromuscular diseases, and in future to other (rare) diseases, too. FISMA allows data exchange and pooling of RWD with minimal post-hoc curation, thereby achieving I and R from FAIR (Findability, Accessibility, Interoperability, and Reusability).

Having successfully implemented FISMA in a whole array of data-capture related solutions in a variety of applications, such as an EHR (HiX), a BIMS (Sample Navigator) and an EDC solution (Castor EDC), we will perform a gap analysis to see how many of the subjects stored at the LUMC Biobank for Neuromuscular disease, are covered by automatically collected data, such as informed consent, diagnoses, lab results, and biomaterials.

As the systems aren't yet fully tailored to accommodate neuromuscular diseases other than DMD and BMD, we expect to find gaps, but also already useful information, as we attempted to work as generically as possible from the start, and also because FISMA is flexible enough to allow for similar, if unanticipated, data.

[to the Scientific Committee: we are currently preparing data for analysis; preliminary results show coverage well beyond DMD/ BMD as well as excellent coverage of informed consents]

432: New perspectives in cancer biomarker use - role of biobanks

by Marie Karlíková | Ondrej Topolcan | Martina Pestova | Michal Jirasko | University Hospital Pilsen and Charles University Faculty of Medicine in Pilsen | University Hospital Pilsen and Charles University

Faculty of Medicine in Pilsen | University Hospital Pilsen and Charles University Faculty of Medicine in Pilsen | University Hospital Pilsen and Charles University Faculty of Medicine in Pilsen

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Marie Karlikova

Keywords: cancer biomarkers, diagnostics, treatment optimisation, tumor aggressiveness

The use of cancer biomarkers in the clinical mangement of cancer has changed significantly over time, from the originally intended use for primary diagnosis to the current use for treatment optimisation. In primary diagnostics, cancer biomarkers have proven a minor utility, they have been mostly used for diagnosis of relapse and disease progression, and more recently for determination of tumour aggressiveness and selection of optimal therapy, adjuvant, neoadjuvant, surgical or oncological. All these new applications require the availability of large series of specimens from a single patient, collected over a long time period, in order to to enable comparisons over time and, most importantly, the use of new cancer biomarkers that were not available in the past. Such approach requires a biobank involvement because of its storage facilities and especially for a huge database of clinical parameters connected to individual samples.

346: The Biobank of Institute of Hematology and Blood Transfusion in Prague presents an infrastructure for hematooncological research of adult patients

by Adela Benesova | Adela Cirbusova | Robert Telicak | Katerina Machova Polakova | Institute of Hematology and Blood Transfusion Prague | Institute of Hematology and Blood Transfusion Prague |

Institute of Hematology and Blood Transfusion Prague | Institute of Hematology and Blood Transfusion Prague

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Adela Benesova Keywords: leukemia, leukocytes, oncohematology research

The Biobank IHBT Prague is a novel research infrastructure which mission is to collect the samples of patients with haematological disorders. The Biobank collects and processes samples from patients with acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, and myelodysplastic syndromes. The stored materials include cryopreserved cells, plasma and DNA. Data for all samples are available and can be used for the creation of research cohorts of patients.

At the beginning of 2025, samples from 1 164 patients have been processed, with a total of 16 550 aliquots stored. Samples are preserved in gas phase of nitrogen in automated Askion C-line[®] systems, which enable tracking of samples and provides stability of the environment. Since the biobank's short existence, 180 samples have been issued for focused projects on research of immunotherapy of AML, utilization of specific inhibitors in the treatment of AML, treatment of Ph-negative ALL, study of the hypoplastic

form of myelodysplastic syndrome and study of acquired aplastic anaemia.

Since 2023, the IHBT Biobank has been part of the research infrastructure BBMRI.cz, network connecting eight Czech biobanks. Thank to this membership, the Biobank of ÚHKT Prague offers samples and data via the BBMRI Directory catalogue and the BBMRI Negotiator communication channel. The Biobank's equipment allows to expand research using multi-omics analysis including information about phenotype and genotype at the singlecell level.

The IHBT Biobank is open for various research projects and also serves as a training facility, regularly organizing excursions for students and offering internships for undergraduate and graduate students.

330: Precision Biobanking for Children: Unlocking Molecular Insights with Cell Sorting

by Luigi Coppola | Alessandra | Pasquale Primo | Alessandra Macrì | Giovanna Maisto | Giuseppe Menna |

Rosanna Parasole | Peppino Mirabelli | AORN Santobono-Pausilipon, Naples, Italy | AORN Santobono-

Pausilipon, Naples, Italy | AORN Santobono-Pausilipon, Naples, Italy | AORN Santobono-Pausilipon,

Naples, Italy | AORN Santobono-Pausilipon, Naples, Italy | AORN Santobono-Pausilipon, Naples, Italy | AORN Santobono-Pausilipon, Naples, Italy | AORN Santobono-Pausilipon, Naples, Italy

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Peppino Mirabelli Keywords: Pediatric biobanking, cell sorting, molecular biology

<u>Introduction:</u> The establishment of pediatric biobanks is crucial for advancing medical

research, particularly in pediatrics, where biological samples are often scarce. At Santobono Pausilipon Children's Hospital an institutional biobank (endorsed by BBMRI.it) is being developed to optimize the collection, processing, and analysis of pediatric biological specimens. Here we present the usefulness of electronic cell sorting for the purification of live cells for downstream analysis using sensitive molecular analysis techniques.

Materials & Methods: BBMRI.it has been essential in providing common services for the biobank setup, including informed consent documentation for parents, adolescents, and children aged 6–12 years. The BD FACS-Melody was used for the purification of CD4 and CD8 Tcells, CD19 positive B cells, and CD56 positive NK cells from 10 PB samples. RNA extraction and reverse transcription are performed using the Cell-to-CT Express Kit and gene expression analysis was performed using both TaqMan[™] and SYBR[®] Green technologies.

<u>Results:</u> Cell sorting enabled the purification of viable cell populations, including CD4+ and CD8+ T lymphocytes, naïve B lymphocytes, and NK cells from all samples. RNA was successfully extracted from all sorted populations. The gene expression levels of Beta-2Microglobulin (B2M) were successfully obtained even from 1500 total live purified cells.

<u>Discussion & Conclusion:</u> Optimizing laboratory methods for pediatric sample analysis is crucial due to limited specimen availability. Cell sorting enables the isolation of viable and specific cell populations enhancing downstream laboratory test. The integration of cell sorting with omics-based analyses facilitates biomarker discovery and therapeutic target identification, ultimately contributing to personalized treatments for pediatric disease.

325: A pilot cohort study on MASLD in Switzerland.

by Dr. med. Beatrice Barda | Chiara De Luca | Rossella Forlenza | Maurizia Bissig-Canevascini | Claudia

Di Bartolomeo | Mario Uhr | Andreas Cerny | Fondazione Epatocentro Ticino, Lugano, Switzerland |

Fondazione Epatocentro Ticino, Lugano, Switzerland | Fondazione Epatocentro Ticino, Lugano,

Switzerland | Fondazione Epatocentro Ticino, Lugano, Switzerland | Fondazione Epatocentro Ticino,

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Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Beatrice Barda Keywords: MASLD, cohort study, steatosis

Introduction: The definition of metabolic dysfunction-associated steatotic liver disease (MASLD) includes the steatotic liver disease related to a systemic metabolic disregulation. Patients with MASLD do not have a history of relevant alcohol consumption and have been screened for other causes of liver steatosis.

Material & Methods: We collected clinical data and biological samples from patients at baseline and follow up visits. At each visit, patients fill a questionnaire on quality of life, physical activity and nutrition habits. The study is intended to be a long-term cohort study.

Results: At the time of submission of 70 eligible patients, 64 were included from 19th July 2023 untill 21st of January 2025. Nine patients underwent the 1st follow-up visit. The mean age

of patients was 56.6 (18-84) years old. Most participants are male (64.3%). All patients enrolled had a genetic test performed, to spot the PNPLA3 I148M, TM6SF2 E167K or HFE mutation. The study has been selected by the Council of the Swiss Association for the Study of the Liver to become a Swiss national muticenter cohort project.

Discussion: We show the feasability of a pilot project of cohort study with a complete clinical, laboratory and biometric data set, a biobank with a extended set of biosamples and patient reported outcomes. This will lay the ground for future studies such as those adressing pathogenesis, the role of life style and other factors on disease progression, the development of novel predictive tests as well as studies focussing of quality of life and other patient reported outcomes.

323: Alessandria Biobank: A Resource for Skin Cancer Research and Personalized Medicine

by Libener Roberta | Amore Valentina | Oliveri Giulia | Ghiglione Marco | Morello Alice | Maconi Antonio | Alessandria Biobank - Research and Innovation Department (DAIRI) - SS Antonio e Biagio e Cesare Arrigo

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Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Libener Roberta Keywords: Biobank, Biological Samples, Personalized Medicine, Research, Skin cancer

A biobank is a nonprofit organization involved in the management of biological samples and data for research purposes. Biobanks ensure high-quality standards for samples and data, ethical compliance, privacy protection, and transparent access procedures. The availability of samples and data constitutes an essential raw material for research and the development of personalized medicine. Within the AOU Antonio e Biagio Arrigo, there is the Alessandria Biobank, where biological samples and data of oncological pathologies are stored. The protocol has been developed for the collection of samples from patients affected by skin tumors, managed by a multidisciplinary team, including the Biobank. The associated data are recorded in REDCap. The skin tumor collection began in 2023 and contains samples and data from 88 patients, 56 are affected by cutaneous melanoma, 16 by squamous cell carcinoma, 3 by basal cell carcinoma, and 13 with a dual diagnosis, generally represented by the association of melanoma and basal cell carcinoma. The data collection includes medical history, treatment details, tumor classification, and staging. The biological samples collected consist of 462 aliquots of whole blood, 713 plasma, 867 serum, and 85 PBMCs, all stored at -80°C. The skin tumor collection has allowed the Alessandria Biobank to expand the number of collections, opening greater opportunities for up new collaborations and the activation of studies on

skin cancer. Through this collection, we aim to support biomedical research on skin tumors.

324: Archipelago of Ovarian Cancer Research; a Dutch nationwide IT infrastructure and biobank for ovarian cancer.

by Marlou Heeling | Mignon D.J.M. van Gent | Amsterdam University Medical Centre, Amsterdam, The

Netherlands. (CCA, AR&D, department Pathology) | Amsterdam University Medical Centre, Amsterdam, The Netherlands. (CCA, AR&D, department Gynecological Oncology)

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Marlou Heeling | Mignon D.M.J van Gent Keywords: Ovarian cancer, clinicopathological data, fundamental research, nationwide biobank

Objective: The development of effective ovarian cancer treatments requires high-quality, standardised data and biomaterials. To facilitate this, the multicentre, interdisciplinary Archipelago of Ovarian Cancer Research (AOCR) infrastructure was established, incorporating a nationwide biobank¹.

Infrasture: The AOCR integrates existing software through a cloud-based registration tool, Ldot, for secure pseudonymisation. Clinicopathological data are automatically retrieved from the Netherlands Cancer Registry and Dutch nationwide pathology databank (Palga). Tissue samples (paraffin-embedded and fresh frozen) are locally collected during diagnosis and surgery. Blood samples are obtained from patients who are treatmentnaïve and from those undergoing (neo)adjuvant therapies, prior to and following treatment administration. Biomaterial

metadata are stored in Biospecimen Management System, OpenSpecimen. SlideScore, a web-based application, is used for digital pathology, and genomic data will stored in cBioPortal. The AOCR provides an integrated IT framework that enhances data accessibility, and research efficiency while adhering to the FAIR (Findable, Accessible, Interoperable, and Reusable) principles².

Results: Over four years, 1,523 patients were enrolled across 17 hospitals. Among the 1,080 patients with complete clinicopathological data, 82% (n=880) had primary ovarian cancer. In 60% of cases, the histological diagnosis was high-grade serous carcinoma, and 69% of patients presented with advanced-stage disease. Surgery was performed in the majority (92%) of the patients and in 77% chemotherapy was administrated.

Conclusion: The AOCR biobank provides a scalable, cost-effective infrastructure adaptable across multiple tumour types, setting the new standard for biobanking³. Future developments include expansion to all gynecologic malignancies and integration of qualityof-life metrics, facilitating prospective studies to ultimately improve patient outcomes.

308: Feasibility and diagnostic accuracy of ctDNA fragmentome combined with risk factors for multicancer early detection; the ESCALATION study

by A. Broeks | 1Department of Pathology, Netherlands Cancer Institute, Amsterdam, the Netherlands

Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: A. Broeks **Background:** Early detection of cancer can significantly reduce morbidity, mortality, healthcare costs, and quality of life loss. Multicancer blood tests based on circulating tumor DNA (ctDNA) have shown potential, but their applicability in the Dutch population remains unclear. This study aims to evaluate the feasibility, validity and requirements of ctDNAbased multi-cancer screening in the Netherlands, combined with polygenic risk scores (PRS) and environmental/exposome risk scores (ERS) to enhance predictive accuracy.

Material and methods: The study involves a prospective observational cohort and a nested case-control design, targeting 125,000 Dutch blood donors aged 50–75. Blood samples (~10mL Streck tubes) will be collected and processed for plasma and buffy coat storage at the NKI biobank. Participants will also complete questionnaires on general health, lifestyle and on attitudes towards ctDNA screening. By linking to the Dutch national cancer registry, we anticipate identifying 1,500 cancer cases diagnosed within a year. In a nested casecontrol study of 6,000 participants (1:3 case-control ratio) we will assess the relation between presence of cancer and ctDNA, PRS, and ERS. The study will also explore the ethical, legal, and societal implications (ELSI) of population-based cancer screening as well as the impact and costeffectiveness of such approach.

Expected results: ESCALATION will provide a benchmark of the potential of ctDNA analysis combined with PRS and ERS in population-based multi-cancer screening. Additionally, the study will create a large, well-annotated biobank for future research.

265: Establishing a Prospective Biobank for Cervical Cancer: A Comprehensive Approach to Sample Collection and Data Integration for Translational Research

by Marta Barba | Angela Maria Cozzolino | Camilla Nero | Marianna Buttarelli | Francesca Alcaro | Tina Pasciuto | Enrica Martinelli | Maria Gabriella Ferrandina | Francesco Fanfani | Denis Querleu | Giovanni

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Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Marta Barba | Angela Maria Cozzolino Keywords: Biobank, Cohort, cervical cancer, personalized medicine

Introduction:

Cervical cancer is the third most common cancer in women. Despite lower mortality due to better screening, early detection, and HPV vaccination, the increasing incidence in younger women with fertility concerns underscores the need for new treatments. The Cervical Cancer Biobank aims to collect biological samples and clinical data from patients to support research on the disease's molecular characterization, with the goal of identifying prognostic biomarkers, therapeutic targets, and fertility preservation strategies.

Methods:

We enrolled patients with cervical cancer who access care at our institution. Biological Samples are collected only after obtaining specific informed consent for biobanking from each patient. The collected samples include whole blood, OCT biopsies, plasma for ctDNA analysis, serum, PBMCs. Clinical data are gathered by clinicians through a dedicated REDCap project, ensuring compliance with GDPR regulations.

Results:

Since 2022 we enrolled 273 patients with cervical cancer. A total of 737 PBMCs, 483 plasma, and 725 serum and 484 whole blood and 143 OCT biopsies have been collected. The biological samples undergo rigorous quality control processes to ensure that the collected samples meet the required standards for downstream analyses.

Discussion:

The establishment of this large cohort, which will be further expanded through longitudinal follow-up of patients and the application of omics analyses on the collected samples, represents a valuable resource for advancing cervical cancer research. By integrating clinical data and biological samples, we aim to foster interdisciplinary collaboration and drive progress in precision medicine in oncology and fertility preservation for affected patients, ultimately improving patient outcomes.

264: Centralized biobanking in a multicenter research organization: harmonized samples and data for precise medicine in diabetes

by Amélie Schellenbauer | German Center for Diabetes Research (DZD) Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Amélie Schellenbauer Keywords: Centralized/decentralized biobanking, biomarker research, clinical studies, precise medicine, research network

Successful strategies for more precise prevention and treatment of diabetes are still lacking. The German Center for Diabetes Research (DZD) conducts several multicenter studies across Germany to develop precise prevention and therapy measures.

The DZD Biobank offers a unique collection of liquid samples, tissues and clinical data from deeply phenotyped individuals, including those with prediabetes, type 1 or type 2 diabetes, gestational diabetes, or control subjects. It collects biological samples at eleven partner sites utilizing its excellent clinical infrastructure for long-term sample and data collection. Aim is to classify (pre-)diabetes and metabolic diseases into subtypes and to identify specific biomarkers.

One key achievement of the DZD is the identification of prediabetes subtypes based on large DZD datasets. DZD researchers are now characterizing these subtypes through proteome analyses of 1,500 biobank samples.

To ensure high-quality standards the DZD transitioned from decentralized collections to a centralized biobank model, overcoming challenges such as:

- Standardization of data collection with the introduction of the DZD Diabetes Core Data Set. It comprises 146 strictly defined clinical parameters collected for all samples in the DZD Biobank.
- Implementation of a central web-based
- LIMS and cross-site monitoring
- Standardization of collection processes,
- materials, and logistics at 11 collection sites.

Stakeholder management with a clear communication strategy Centralized biobank administration

The DZD Biobank is a critical resource for diabetes and metabolism research. Its centralized structure now enhances quality, accessibility and transparency and it streamlines operations to support precise medicine.

261: BB-CRESM: a structured institutional biobank for quality research in Multiple Sclerosis

by Cecilia Irene Bava | San Luigi Gonzaga University Hospital Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Cecilia Irene Bava Keywords: biobank structure, disease-specific, multiple sclerosis

Background

Biobanks are increasingly demonstrating a crucial role in clinical/scientific research. The Regional Reference Multiple Sclerosis Center (CRESM, AOU San Luigi Gonzaga) has been operational in transforming its "historical collection" of biological samples into a structured biobank (BB-CRESM).

Methods and Results

1) Establishment: in 2020, BB-CRESM received formal Institutional commitment into AOUSan Luigi. Legal and ethical (ELSI) documentation was approved and BB-CRESM governance was defined. BB-CRESM is involved in BBMRI network.

2) Participants engagement: about 2700 patients and 150 healthy participants (HC) areinvolved according to ELSI procedures.

3) Samples and data: about 30000 biospecimens (serum plasma, RNA, whole blood, bloodcells and cerebrospinal fluid samples) are currently stored, collected from MS patients at different disease stages, from patients with other neurological diseases and from HC. Each biospecimen is aliquoted in barcoded tubes, according to privacy/quality requirements.

Specific GDPR-based procedures for personal data protection are applied.

4) Quality: quality controls on biological samples (RNA integrity/purity), data(completeness/consistency/relevance) and equipment were defined and applied. BB-CRESM guarantees its personnel competence through training activities/working groups.

5) Access policy/cost-recovery: researchers can have access to BB-CRESM samples/dataaccording to definite procedures. A cost-recovery policy was defined.

6) Sample requests/collaborations: since 2020, more than 1000 samples/data have beendistributed for external research studies; several projects were carried on at CRESM; additional collaborations are ongoing.

Conclusions

BB-CRESM is the first italian biobank focused on MS. Its activity, founded on rigorous quality standards, represents a crucial service to boost quality research studies, in the respect of involved participants.

225: Enhancing Donor Engagement for Longitudinal Genetic Studies: Lessons from the Diverse Israeli Population

by Adelina Ovcharenko | Yehudit Cohen | Shimon Reisner | MIDGAM | MIDGAM Topic: 4A: Clinical Biobanks: Bridging Research and Patient Care Presenter Name: Adelina Ovcharenko Keywords: clinically significant results, collaboration, diverse multicultural population, donation, inform consent, longitudinal, privacy, receiving study results

Biological samples are crucial for longitudinal genetic studies but are difficult to acquire, particularly from a diverse multicultural population.

A survey of 1,607 potential donors, 922 representing the general population, 384 in the ultra-Orthodox Jewish sector, and 301 in the Arab sector, assessed the willingness, preferences, and concerns regarding samples and data collection for longitudinal genetic studies.

About half of the participants (52%) were willing to donate, but this figure decreased to 44% when free access to their medical records was indicated. Forty-one percent agreed to donate samples and data repetitively for the whole study's duration, 18% annually, and 23% whenever needed. The main concerns were fears of personal data breaches (51%), and doubts regarding donation impact (35%), and 14% of the respondents claimed they were short of time. Willing donors were typically non-Orthodox Jewish men of higher socioeconomic status, individuals with chronic illnesses, or those with severe medical conditions. The Ultra-Orthodox Jewish and the Arab sectors as well as young women with lower education and income were more reluctant to donate. Among the willing donors, 88% expressed interest in receiving study results, and 68% prefer to receive only the clinically significant results.

In countries with a diverse and multicultural population, the biobank team must focus on underrepresented populations, address privacy concerns, communicate the study's goals transparently, and establish mechanisms for sharing findings. By doing so, they can build trust and foster a culture of collaboration.

5A: Rare Disease Biobank Insights

382: National Cancer Institute Biobank: A Key Scientific Biobank in Lithuania's Network, Advancing Personalized Medicine and Rare Cancers Research

by Daiva Dabkeviciene | Dominyka Breimelyte | Monika Drobniene | Vita Zeromskiene | Jurgita Usinskiene | Sonata Jarmalaite | National Cancer Institute, Lithuania | National Cancer Institute, Lithuania

Topic: 5A: Rare Disease Biobank Insights Presenter Name: Daiva Dabkeviciene Keywords: AI/ML-driven radiogenomic biomarkers,

> Personalized medicine, global collaboration, oncology biobank, rare oncological variants Introduction

The National Cancer Institute (NCI) has launched a joint Lithuania-Japan project, dedicated to radiogenomic modeling of breast cancer and rare genetic variants. Also, researchers at NCI Biobank are conducting studies on rare oncological variants in prostate cancer. The modernization of the NCI Biobank infrastructure, enhanced large-scale data analytics capabilities, and strengthened collaboration with clinical departments have significantly increased the capacity and efficiency of such research, further reinforcing Lithuania's role in international oncology and rare disease investigations.

Material & methods

For breast cancer, radiological image analysis is performed using medical software, and collected samples undergo NGS sequencing for rare coding variants. A multi-layered dataset combining clinical, genetic, and radiological data analyzed using Python and R-based statistical analysis and ML. For prostate cancer, rare oncological variants were identified by multifactorial survival analysis and are planned for NGS analysis.

Results

A key outcome of these projects has been the development of a workflow for joint sample collection, data standardization, and scientific research optimization, which will undoubtedly streamline and accelerate the execution of future multicentric biomedical projects.

Discussion

By sharing international knowledge, valuable experience and cutting-edge technology, scientists are expected to significantly enrich the data on rare genetic variants in breast cancer and other oncological diseases, leading to a better understanding of the relationship between tumor heterogeneity and outcomes, development as well as the and implementation of innovative non-invasive tumor dynamic profiling methods in clinical settings.

388: TNGB onwards: Two Decades of Advancing Rare Disease Biobanking

by Calzolari, M | Casareto, L | Locatelli, M | Sangiorgi, L | for the Telethon Network of Genetic Biobanks | IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy |

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Topic: 5A: Rare Disease Biobank Insights Presenter Name: Calzolari, M Keywords: biobanking, networking, rare diseases

The Telethon Network of Genetic Biobanks (TNGB, <u>http://biobanknetwork.telethon.it/</u>) is the first Italian non-profit network of rare disease (RD) biobanks, founded in 2007 with the mission to support RD research by providing high-quality biospecimens and associated data to the scientific community.

TNGB's uniqueness resides in the adoption of a centralised IT platform that enhances biospecimens accessibility and manages entire network workflow.

TNGB has always coped with ELSI topics to protect participants' confidentiality as well as to enhance their awareness and trust in biobanking by designing comprehensive Informed Consent and Material Transfer Agreement templates. TNGB increases its impact by collaborating with RD Patient Organisations and several European RDrealities.

The centralised IT platform integrates the partner biobanks enabling standardisation and harmonisation of procedures, creation of the online catalogue and sample access managed via a request control panel, ensuring transparency and equity in accessing samples.

The catalogue lists now 130,500 RD-samples and over 1,500 RDs. In nearly 20 years, the network has distributed over 55.000 worldwide both for diagnosis and research purposes, proving the TNGB an invaluable resource in RD research, contributing to over 800 publications. TNGB's commitment to patient engagement has led to the creation of an innovative agreement model allowing sample centralisation and enhancing trust and global access to valuable resources.

The development of TNGB's infrastructure has demonstrated the critical importance of networking, especially in RDs, implementing common policy and procedures respecting ethical standards and maintaining transparency and finally, collaborating with similar entities and patient organisations.

398: SATELLITES: An Innovative, Sustainable and Shared Model for Harmonizing Rare Disease Biobanking

by Alisia Madè | Laura Valentina Renna | Lavinia Curini | Alba Di Pardo | Maurizia Grasso | Eloisa Arbustini | Ferdinando Squitieri | Amalia De Curtis | Maria Benedetta Donati | Massimo Chessa | Rosanna

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> Topic: 5A: Rare Disease Biobank Insights Presenter Name: Alisia Madè Keywords: Rare diseases, network

Introduction. Rare diseases (RDs) are complex clinical conditions affecting fewer than 1 in

2,000 people (1). With over 6,000 RDs identified—most of them genetic and currently incurable-there is an urgent need for diagnostic and innovative therapeutic strategies (2). However, in Italy the collection of biological samples for RDs remains fragmented, with small or medium-sized biorepositories operating without integration into a coordinated network (3). To address these challenges, the SATELLITES project aims to organize already existing RDs biorepositories into a coordinated network and to create new well-organized and standardized biobanks, ensuring the integrity, accessibility, and longterm usability of biological samples for highquality research.

Material & methods. The creation of the SATELLITES network to enhance the collection of high-quality samples and data will start with the harmonization and standardization of biobanking processes in 4 Italian RD Referral Centres through the development of common Standard Operating Procedures (SOPs), shared databases, unified ethical/legal frameworks and the creation of a Quality Management System. An active involvement of Patient Organizations will be essential for the success of the network.

Results. The development of shared SOPs and quality control methods can lead to minimize inter-laboratory and inter-centre variability in sample collection and processing. This harmonization will enable the creation of a Biospecimen Inventory Catalogue, providing an accessible repository of biospecimens and associated data to support future research initiatives.

Discussion and conclusion: The SATELLITES network represents a significant step forward

in fostering collaboration among Italian reference centres, paving the way for largescale epidemiological and clinical studies on RDs.

401: Developing a Biobank network among sarcoma treatment centers to improve biomedical research: the PANORAMA project

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> Topic: 5A: Rare Disease Biobank Insights Presenter Name: De Palma, G Keywords: Sarcoma

Introduction

Sarcomas are rare tumors affecting the musculoskeletal system, with more than 120 histotypes. Their diagnosis and treatment are complex. As part of the PNRR PANORAMA project, four Italian hospital institutions are creating a network for collection and sharing of samples and data with improved quality, in accordance with current legislative requirements for biobanks.

Material & methods

All cases included in this project will be diagnosed in the Pathology Unit of the 4 participating institutions according to the current criteria of the WHO Classification of soft and bone tumor tissue. The tumor samples and their matched unaffected tissues (when available) will be stored in biobank along with clinical data and radiological images. In order to share all information on samples, each institution will have specific software for registration and traceability of tumor samples, with relative qualitative and quantitative evaluation of the material. Furthermore, we will create a protocol to generate a FAIR metadata repository ensuring the easy deployment of the federated indexing/searching mechanism.

Results

PANORAMA project focuses on creating a common data collection form and standardizing the collection processes in each biobank, linked to a digital archive of high-quality radiological images and related digital pathology slides.

Conclusion

The project presented here provides basis for a national network of biobanks for patients with musculoskeletal sarcomas.

References

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- ISO 20387

- Developing a Biobank network among major sarcoma treatment centers to improvebiomedical research (PNRR-MCNT2-2023-12378098) funded by EU - Next Generation EU - NRRP M6C2 - Investment 2.1 Enhancement and strengthening of biomedical research in the NHS

411: Integrating Standardized Biobanking into Rare Disease Research: Insights from the ACURARE Biobank

by Ilayda Sahin | Fatma Merve Antmen | Ceren Erdogan | Gizem Onder | Gulsah Sebnem Ozkose-Iyigel | Julide Ceren Yilmaz | Aybike Bulut | Cansu Portakal | Eylul Aydin | Semanur Ozdemir | Huma Gunay |

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> Topic: 5A: Rare Disease Biobank Insights Presenter Name: Ilayda Sahin Keywords: ACURARE, Rare disease biobank,

Standardized Biobanking, Translational Research

Introduction

Rare disease biobanks are essential for translational research, facilitating the collection, preservation, and analysis of biospecimens under standards. Acibadem University Biobank Unit was established to address the challenges of undiagnosed and rare diseases by integrating standardized biobanking practices with advanced analytical processes. In 2021, we presented the feasibility of establishing the Acibadem Rare Disease Research Biobank. Today, we highlight the implementation of standardized biobanking protocols at Acibadem University Biobank.

Materials & Methods

The biobank successfully developed standardized preanalytical workflows for sample collection, processing, and storage. The workflows were designed to accommodate:

- DNA, RNA, and viable cell
- banking for omics and
- functional research, Triobased biobanking for rare variant detection and inheritance analysis, Protocols ensuring longterm sample viability.

Results

Between 2022-2024, the ACU Biobank collected 1,075 biospecimens from 205 individuals, consisting of DNA, RNA, fresh frozen white blood cells, and cryopreserved cells. The samples were obtained from patients with rare or undiagnosed diseases, rare pediatric cancers, and their affected/unaffected family members. Additionally, we archived 28 shortread for reanalysis in a sequencing data decentralized setup aligning with GDPR. The collected samples have been integrated into translational research projects of ACURARE, contributing to the genetic diagnosis and treatment strategies for undiagnosed and rare diseases.

Discussion & Conclusion

Harmonization of biobanking protocols demonstrates the importance of standardization, ethical compliance, and interinstitutional collaboration in rare disease research. Wellstructured biobanks provide high-quality biospecimens that support advanced genomic studies, ultimately enhancing the diagnostic and therapeutic landscape for rare diseases.

440: A Decade of Biobanking and Supporting Hematooncological Research at the University Hospital

by Lucie Broskevičová | Jana Klepáčová | Hana Križňanská | Roman Hájek | 1Department of Haematooncology, University Hospital Ostrava, Czech Republic 2Department of Haematooncology, Faculty of Medicine, University of Ostrava, Ostrava, Czech Republic | 1Department of Haematooncology,

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> Topic: 5A: Rare Disease Biobank Insights Presenter Name: Lucie Broskevičová Keywords: Bone marrow, Immunomonitoring,

Monoclonal gammopathies, Rare diseases,

peripheral blood

Introduction

The Biobank at the University Hospital Ostrava, established in 2013, is a key resource for collecting and storing biological samples from patients with hematological malignancies, especially monoclonal gammopathies, with a focus on rare diagnoses. It is actively involved in the latest research trends, including precision medicine and immunomonitoring.

Material & Methods:

After obtaining informed consent, bone marrow (BM) and peripheral blood (PB) samples were collected from patients with newly diagnosed or progressing disease during routine clinical visits. Plasma, serum, and DNA were archived, and bone marrow and peripheral blood mononuclear cells were isolated by density gradient centrifugation and cryopreserved. In certain diagnoses, specific pathological cells were separated, including plasma cells (CD138+) in multiple myeloma, CD19+ cells in chronic lymphocytic leukemia, and CD34+ cells in acute myeloid leukemia, all using magnetic-activated cell sorting (Figure 1), with purity assessed by flow cytometry. All samples were pseudonymized and stored at -80 °C or in liquid nitrogen for long-term preservation.

Results

By the end of 2024, more than 74,000 samples were archived in the biobank, with significant growth noted (Graph 1). The distribution of individual diagnoses is shown in Graph 2. Since 2023, samples from patients treated with modern immunotherapies (Table 1) have been archived.

Conclusion

The Biobank plays an essential role in research through longitudinal studies, while adapting to scientific demands. It has the latest significantly advanced hematological malignancy research, particularly by establishing a cohort of rare diagnoses such as AL amyloidosis (ALA) and Waldenström's macroglobulinemia (WM), as well as biobanking patients treated with modern immunotherapies.

7A: Green Biobanking: Paving the Path to Sustainable Practices

266: Challenging the -80°C Gold Standard: A Case for Sustainable Biobanking at Higher Temperatures

by Corrie Lynne Madsen | Nicolai Sode Mikkelsen | Estrid V. Høgdall | Department of Pathology, Bioand GenomeBank Denmark, Herlev Hospital, Herlev | Department of Pathology, Bio- and GenomeBank

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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Corrie Lynne Madsen Keywords: -70, Green biobanking, sustainability

Introduction: The current practice of storing biological samples at -80°C is considered the gold standard for preserving sample integrity in biobanking¹. However, this approach is energyintensive and environmentally unsustainable^{2,3}. This study evaluates the feasibility of storage at warmer temperatures by assessing temperature stability and energy use in Haier DW-86L959W ultra-low temperature freezers (ULT's).

Material & Methods: Temperature was measured in three ULT's filled with empty racks set at -80°C, -70°C and -60°C. Temperature stability was measured using data loggers for 2x12 hours at 10 min intervals placed in outer and middle positions of each shelf at the front and back of racks. Each freezer was turned off to simulate power failure and temperatures were logged every 10 minutes. Finally, energy consumption was measured for each storage temperature.

Results: The mean temperature was measured and is given as mean (sd, maximum, minimum). The mean temperature was -74.9°C (2.0, -72, -77.4) at -80°C, -65.7°C (1.0, -64, -66.8) at -70°C and -58.5°C (3.4, -53.3, -61.7) at -60°C . Depending on set operating temperature, the ULT's reached -20°C after 14-18 hours of power failure and 0 degrees after 30-33 hours. Energy consumption measurements revealed a ~32% reduction in power usage at -70°C compared to -80°C.

Discussion and conclusion: Results show that -70°C storage maintains samples below the critical degradation threshold (-60°C to -63°C)⁴. These findings highlight the possibility for biobanks to transition to more sustainable practices without compromising sample integrity, calling for a re-evaluation of standard protocols to address both research needs and environmental responsibilities.

279: Greening the ULT storage of biomaterials at Amsterdam UMC

by A Kromhout | Amsterdam University Medical Center

Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: A Kromhout Keywords: Greening, Sustainabilty, ULT-storage

Introduction – Long-term storage of biomaterials for research and innovation at ultra-low temperature (ULT) significantly impacts the environment due to high energy consumption. Amsterdam UMC participates in the International Laboratory Freezer Challenge to increase energy efficiency in cold storage. After winning the competition in the category Hospital/Clinical we have started new initiatives to further green the storage of biospecimens at ULT.

Methods – We focused on specific aims including the implementation of -70°C as set point for all ULT freezers and the exchange of existing ULT freezers by more energy-saving equipment across Amsterdam UMC.

Results - In 2024, (1) -70°C became the setpoint for all ULT freezers at Amsterdam UMC, not only at the central biobank facility, but at all departments, (2) a large, energyefficient freezing installation, equivalent to 36 conventional ULT freezers, has been installed, (3) a process for the replacement of older ULT freezers by newer, more economical models has been initiated based on a business case (accounting e.g. for the depreciation and the electricity costs of old ULT freezers in comparison to new ones), and (4) the developing a ULT-freezer tender model has been initiated in which sustainability is more heavily integrated including a calculation on energy consumption and ecological damage.

Conclusion – Amsterdam UMC is taking various measures to increase the sustainable storage of biospecimens at ULT. Of critical importance is the dedication of various partners, including the biobank core facility, technical service departments, green teams, and decisionmaking boards.

283: Effect of fluorinated greenhouse gases regulation on biobanks – a case study using the example of Biobank Graz

by Monika Valjan | Veronika Perz | Sabrina Kral | Biobank Graz, Medical University of Graz, Austria | Biobank Graz, Medical University of Graz, Austria | Biobank Graz, Medical University of Graz, Austria Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Monika Valjan Keywords: F-gas regulation, cooling agent, greenhouse gas, greenhouse warming potential, hydroflourocarbons, refrigerants

Introduction: Hydrofluorocarbons (HFCs) are used as refrigerants in freezers or automated storage systems and exhibit strongly divergent but mostly very high greenhouse warming potentials (GWP). The European Union's "F-gas Regulation (EU) 2024/573" aims to significantly reduce emissions of climate-damaging fluorinated greenhouse gases. This regulation, effective March 11 2024, prohibits the production of certain refrigerants, including those used in Biobank Graz (R508B and R507).

Material & Methods: To implement the regulation in Biobank Graz, a partner of BBMRI.at, collaborated with the Austrian Academy of Refrigeration Technology and the "Environment Agency Austria" to secure a solution for the existing storage systems. This included ensuring EU approval for the ongoing use of Refrigerants R508B and R-507 in existing systems until 2030, as well as accumulating an adequate supply of refrigerant through a fast tendering process.

Results: A feasibility study is currently planned to detect environmentally sustainable storage solutions that can replace existing storage systems and guarantee the security of already collected samples. The study will also explore how the existing system could be adapted to sustainable coolants with lower GWPs, with the goal of improving both sustainability and sample storage security.

Discussion & Conclusion: Existing storage systems cannot be easily replaced within short time making interim solutions essential for planning sustainable storage facilities that will meet future requirements. Biobanks should consider the greenhouse warming potential of the used cooling agent, when issuing tenders for a low-temperature storage or buying new freezers and automated freezer systems.

284: Applying "R" strategies to foster environmental sustainable practices in biobanking

by Monika Valjan | Veronika Perz | Sabrina Kral | Biobank Graz, Medical University of Graz, Austria | Biobank Graz, Medical University of Graz, Austria | Biobank Graz, Medical University of Graz, Austria Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Monika Valjan Keywords: R strategies, environmental sustainability, recovering, recycling, reducing, repairing, rethinking, reusing

Introduction: Biobanking generally is sustainable due to highly organized centralized logistics, storage, and retrieval of samples. Additionally, it fosters collaboration between institutions and industries, reducing research duplication, optimizing resources and maximizing sample utility. Nevertheless, it is important to acknowledge, that biobanks require substantial amounts of energy and other resources. "R" strategies can help to explore environmental sustainability measures in biobanking.

Material & Methods: We adapted the framework proposed by Zorpas including up to 100 potential R's strategies, focusing on reducing, rethinking, reusing, recycling, repairing and recovering to find suitable sustainability measures. Through an intensive literature review and analysis of Biobank Graz, a partner of BBMRI.at, we identified several actionable improvements.

Results: By applying the 'R' strategies to Biobank Graz processes, we have identified several measures for improvement. These include reusing materials, such as unsuitable or outdated consumables for sample transport, reducing our carbon footprint through the transition to renewable energy and overall power consumption reduction, rethinking the use of refrigerants with high global warming potential, and maximizing consumable recycling.

Discussion & Conclusion: Implementing these "R" strategies help to find sustainability measures in your biobank and save energy, resources and costs. Biobanks and related institutions can make significant strides toward sustainability, benefiting both the environment and operational efficiency.

320: Sustainability in Biobanking: Legal Framework and Practical Implementation

by Catarina Almeida | Katarzyna Barud | Nikolaus Forgo | Sabrina Kral | Klaudia Kwiatkowska | Veronika

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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Catarina Almeida | Monika Valjan Keywords: Environmental Protection, European

Union, Legal Framework, Sustainability

Introduction

As biobanks' value for scientific research has steadily grown, the environmental impact of processing and storing increasingly larger numbers of samples cannot be ignored. Despite some biobanks - including Biobank Graz (partner of BBMRI.at) - implementing institutionally enacted policies for environmental protection, there are legal acts that can guide biobank stakeholders into pursuing green biobanking, which is a key consideration for long-term sustainability of these repositories and aligns with the European Commission's aim of making Europe climate-neutral by 2050.

Material & methods

We have performed legal desk research, such as resorting to published materials on the topic. Moreover, interview partners working in research and consulting elucidated their experiences with e.g. reporting and CO₂ balancing for companies that fall under the new directives. The current regulatory framework for environmental protection at both national and EU levels is, as of now, largely not applicable to biobanks. Recommendations proposed by the scientific community as best practices for biobanks to reduce carbon emissions can often be difficult to implement, since fundamental changes in locally established processes are necessary.

Discussion & conclusion

Compliance with existing legislation, most of which is currently optional for biobanks, can prepare them for future regulatory intervention. Additionally, biobanks, as key of contemporary scientific actors advancements, should lead by example in environmental adopting measures for protection.

Consent models that allow sample reuse are an example of a potential regulatory pursuit that aligns with environmental protection. Ethical and legal guidelines to dispose of unused, surplus samples can further reduce the environmental strain.

383: Fifteen years of real-time stability data at room temperature: validation of encapsulation for sustainable biobanking

by Marthe Colotte | Aurélie Luis | Delphine Coudy | Magali Milhau | Jacques Bonnet | Imagene, France |

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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Marthe Colotte Keywords: Cold chain-free logistics, Hermetic metallic container, Inert atmosphere encapsulation, Longterm sample stability, Room

Results

temperature storage, Sustainable storage solutions

Introduction

The exponential increase in biospecimen collection by clinical laboratories and biobanks has intensified the challenges associated with traditional cold storage, including high energy costs, safety concerns, limited space, and complex maintenance. Imagene's innovative **RNAshell**[®] and **DNAshell**[®] technology addresses these issues through the confinement of dried biospecimens under an inert atmosphere (helium or argon) within a hermetic metallic container. Validated over 15 years through accelerated and real-time aging, this solution sets new standards in biospecimen preservation.

Materials & Methods

Biospecimens of various types, including DNA, RNA, blood, and lysed cells, were encapsulated for long-term room-temperature storage. Samples stored for up to 15 years were recovered by adding water and purified when needed. The quality and quantity of the retrieved samples were evaluated using methods such as RT/qPCR and electrophoresis (capillary or gel).

Results

Analyses revealed that samples maintained excellent integrity and yield, even after a decade or more of storage under unregulated temperature and humidity conditions. Remarkably, RNA, which is notoriously fragile, demonstrated extreme stability over long periods.

Discussion & Conclusion

breakthrough technology effectively This shields biospecimens from moisture and other degrading factors, enabling mid-to-long-term energy-free storage. By eliminating the need for cold storage and logistics, RNAshell/DNAshell provides a reliable, costeffective, and sustainable alternative for biobanks, research institutions, and clinical laboratories. This solution not only ensures biospecimen integrity but also supports environmentally responsible storage practices.

441: The CSR DNA-Library project

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Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Sylvia Bruneau Keywords: NGS, agro-environmental DNA matrices, ambient storage, epi-genomic sequencing

Preserving the genetic resources of diverse biomes is essential in the context of global climate change and biodiversity erosion. Capturing epigenomic referential picture times in longitudinal research programs will allow retrospective studies to unravel the molecular mechanisms at stake in species adaptation to global warming and environmental changes such as pollution, food, the emergence of pathogens, or resistance.

Biomolecules will be stored as a patrimonial legacy to the next generations to anticipate the

co-evolution of research fields (epigenetics, eDNA, nc RNA, etc.), holistic dimensions (pangenome, holobionte), and technologies (NGS and IA). Moreover, compared to classical freezing conditions, biomolecules will be stored at ambient temperature to fulfil CSR goals.

The pilot experiment includes various environmental DNA matrices, from very low (eDNA) to high molecular weight (plancton, salmon, pig). We selected three promising RT storage technologies based on their reusable and scalable properties. Aging of the stored DNA samples will be accelerated based on the Arrhenius equation. Comparison of storage conditions will be assessed by full DNA quality control, short-and/or-long reads sequencing and analysis of; deamination, metabarcoding, metagenomic, WGS and methylome will be performed.

The CSR DNA-library project, led by the environment pillar of the French Research Infrastructure RARe, brings together the resources and expertise of French genomics and bioinformatics Infrastructures, France Genomique.

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463: Automated vs. Manual Ultra-Low Temperature Sample Storage: A Comparative Analysis of Space Efficiency, Power Consumption, Labor Efficiency, Running Costs, and Carbon Emissions

by Cristiana Bercea | Azenta Life Sciences, Massachusetts, USA

Topic: 7A: Green Biobanking: Paving the Path to Sustainable Practices Presenter Name: Cristiana Bercea Keywords: Ultra-low temperature (ULT) freezers, automated storage and retrieval systems, biobank automation, carbon footprint, cold-chain logistics, cost savings, energy efficiency, environmental sustainability, green lab practices, laboratory automation, manual sample storage, operational efficiency, refrigerant gases, research workflow, space utilization, temperature stability

Manual ultra-low temperature (ULT) freezers pose challenges for sample storage and retrieval. Manual freezers have low energy efficiency, and frequent door openings lead to temperature fluctuations and increased energy consumption as the freezer works harder to maintain the required temperature. This, coupled with the use of refrigerant gases, contributes to a high carbon footprint. Moreover, freezer capacity is not optimally utilized due to the need for access aisles and the constant rearrangement of samples, leading to wasted space. The manual retrieval process is time-consuming and labor-intensive, requiring researchers to physically locate and retrieve samples, further slowing down research workflows.

This model simulates the impact of replacing a large manual ULT freezer collection with an Azenta Life Sciences automated storage and retrieval system. By modeling time, power, space, carbon emissions, and running costs, we demonstrate a 77% reduction in electricity

consumption and carbon emissions, an 83% reduction in floorspace, and a 40% reduction in labor hours.

Therefore, significant improvements can be obtained in operational efficiency, cost savings, and environmental sustainability by replacing manual sample storage with automation.

8A: The Transformative Role of Biobanks in Public Health

258: The Historical Development of Biobanking: From Strange Curiosities to Saving Lives

by Ian Kasper Kjelsgaard | Estrid Høgdall | Department of Pathology, Bio- and Genome Bank Denmark,

Herlev Hospital, Herlev | Department of Pathology, Bio- and Genome Bank Denmark, Herlev Hospital, Herlev

Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Ian Kasper Kjelsgaard Keywords: Bio- and Genome Biobank Denmark, biobank, cabinents, curiosity, development, history

Introduction:

The earliest biobanks were operating as cabinets of curiosities for the purpose of entertainment. In the 17th and 18th biobanks increased the size of their collections and became increasingly associated with medical education and pathology. Later, in the 19th century and 20th century, biobanks became increasingly modern as they gradually became more and more important for medical research. In the latter part of the 20th century, biobanks had to adapt to the greater data requirements of medical research, to provide the high-quality biospecimens and data that facilitate the complex analyses requested.

Material & Methods:

Will use examples to illustrate the historical development of biobanks, beginning with the earliest examples of biobanks (cabinets of curiosity) and ending with an example of a modern biobank. The development of the Danish Biobank, Bio- and Genome Bank Denmark (RBGB), will serve as the example of a modern virtual biobank.

Results:

Providing a timeline and graphical overview of the general trend in the development of the biobank.

Discussion and conclusion:

Even though the purpose of the biobank has changed, the biospecimens it possesses always seem to excite its audience with novelty. Originally, onlookers saw the objects as a source of wonder and entertainment. Later, students saw them as educational and examples of the "real" thing. Today, researchers see their potential. These differences underline how the biobank has remained relevant by adapting to its changing circumstances.

297: Medically actionable findings of the Cypriot population: a silent threat to public health

by Fanidis D | Moutsouri E | Malatras A | Polydorou C | Argyrou C | Papagregoriou G | Deltas C | University of Cyprus, biobank.cy Center of Excellence in Biobanking and Biomedical Research, Nicosia,

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Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Fanidis D Keywords: Actionable genetic findings, Biobank, CYPROME, Genetic diagnosis, Prevention

Background: Acquiring knowledge of a population's genetic landscape is crucial for informing public health policies. Notably, the identification of medically actionable variants can guide therapy interventions and reduce morbidity and mortality in a population. For the first time, we report on the occurrence of ACMG actionable findings [doi: https://doi.org/10.1016/j.gim.2023.100866], as identified in Cyprus general population (CYPROME). The CYPROME is an initiative of the Cyprus Biobank to canvass the Cypriot reference genome, by harvesting exome and genome data from volunteers.

Methods: Exome sequencing data from 1446 general population samples (*CYPROME*) were examined *in silico* to identify actionable genetic changes as termed by ACMG criteria. Variant pathogenicity was assessed using three distinct strategies for increasing stringency: Franklinby-Genoox, local InterVar installation and ClinVar classification. (Likely) pathogenic variants were filtered using *ad hoc* scripts.

Results: The strictest pathogenicity classification strategy used revealed the presence of at least one actionable (likely)

pathogenic variant in 2.63% of Cypriots. As expected, cardiovascular disease associated variants are overrepresented in the Cypriot population with variants on *MYH7*, *MYH11* and *APOB* genes occupying the top positions, in accordance with the larger number of actionable genes published by ACMG. Other genetic diseases, including cancer and inherited types of diabetes, are also represented.

Conclusion: Our analysis suggests the presence of latent yet actionable genetic diseases similar to other populations [doi: https://doi.org/10.1038/s41431-024-01656-1]. This molecular-based phenotype identification could improve populationspecific disease diagnosis, prevention, and eventually treatment. In addition, a detailed examination of accompanying metadata could reveal phenotype biomarkers further supporting timely therapeutic interventions.

328: Analysis of selected obesity risk biomarkers in the PICTURE pediatric population

by Oliwia Piaskowska | Mateusz Sikora | Emilia Spyrka | Agnieszka Matera-Witkiewicz | Katarzyna KiliśPstrusińska | Anna Medyńska | Agnieszka Bargenda-Lange | Anna Jakubowska | Wroclaw Medical

University, Faculty of Pharmacy, Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland | Wroclaw Medical University, Faculty of Pharmacy, Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland | Wroclaw Medical University, Faculty of Pharmacy,

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University Biobank, Poland | Wroclaw Medical University, Faculty of Pharmacy, Screening of **Biological** Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland | Clinical Department of Paediatric Nephrology, Wroclaw Medical University, Wroclaw, Poland | Clinical Department of Paediatric Nephrology, Wroclaw Medical University, Wroclaw, Poland | Clinical Department of Paediatric Nephrology, Wroclaw Medical University, Wroclaw, Poland | Clinical Department of Paediatric Nephrology, Wroclaw Medical University, Wroclaw, Poland Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Emilia Spyrka Keywords: Biomarkers, Childhood obesity,

Metabolic disorders, Public health

Introduction

According to the World Health Organization, childhood obesity is a growing public health concern. Biomarkers are gaining attention for analyzing metabolic and inflammatory processes associated with obesity. Such analysis could accelerate diagnosis and prevent disease progression.

Material & methods

From the PICTURE study (Population Cohort Study of Wroclaw Citizens), blood and urine samples were selected from 268 children aged 8–18. The analysis included 200 children with excessive body weight and 68 children with normal weight. The classification was made based on the OLAF scale. The criterion for overweight was a BMI value above the 85th percentile and for obesity above the 97th percentile. The potential obesity predictors were examined: visfatin, resistin, isthmine from blood, and acidic alphaglycoprotein/creatinine (AAG) indicators from urine. All analysis we performed using ELISA tests.

Results

Small differences in the mean levels of isthmin, resistin, and visfatin were observed between healthy and affected children. However, a statistically significant difference was found between the study groups for the AAG index.

Discussion and conclusion

The AAG index may serve as a potential predictor of obesity and overweight in children and adolescents. To validate this method, the study should be repeated with a larger sample size. Early detection of metabolic disorders in children enables the prevention of disease development in adulthood.

References

Acknowledgement:

The research was supported by project: Biomarkers of obesity risk level in the pediatric population in the PICTURE study (Population Cohort Studies of Wroclaw Citizens) no. SUBK.C210.24.002

Grant from the Medical Research Agency ABM.D250.24.001.

361: Unlocking the Potential of Biobanks: Assessing the Value of Historical Plasma Samples for Molecular Diagnostics

by Winnie Rytter | Corrie Lynne Madsen | Christina Demuth | Lars Dyrskjøt Andersen | Iver Kristiansen Nordentoft | Mads Heilskov Rasmussen | Tenna Vesterman Henriksen | Amanda Frydendahl Boll Johansen | Claus Lindbjerg Andersen | Cecilie Mondrup Jacobsen | Luisa Matos Do Canto Alvim | Rikke Fredslund Andersen | Torben Frøstrup Hansen | Caroline Emilie Brenner Thomsen | Estrid Høgdall | Bioand Genome Bank Denmark, Department of Pathology, Herlev Hospital, Herlev, Denmark | Bio- and Genome Bank Denmark, Department of Pathology, Herlev Hospital, Herlev, Denmark | Department of

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Hospital, University of Southern Denmark, Denmark | Bio- and Genome Bank Denmark, Department of Pathology, Herlev Hospital, Herlev, Denmark

Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Estrid Høgdall Keywords: biomarker, ctDNA, historical samples, long term storage, plasma

Introduction: Plasma samples, stored within long-standing biobanks, may offer a unique opportunity for clinical studies. Bio- and Genome Bank Denmark (RBGB), implemented in 2010, provides an exceptional resource for retrospective studies. Samples collected in Denmark are handled and stored using national standard operating procedures with realtime registration ensuring high quality data and biological samples¹. In this study we investigate if historical plasma samples from RBGB can be used for ctDNA analyses after long time storage.

<u>Material and Method</u>: Results from primary analysis^{2,3} was compared to results performed using identical material stored at -80°C for 5 to 8.5 years. Analyses was conducted on two cohorts of patients diagnosed with colorectal cancer: A) 22 patients (7F/15M, age 35-76)² and B) 25 patients (8F/17M, age 68-78)³. Plasma was analysed using either ddPCR or UmiSeq.

<u>Results:</u> The study confirms reproducibility of the primary results of ctDNA analysis. In cohort A, there is 100% concordance with the original analytical result, while 96% concordance in cohort B (24/25). The one sample representing a discrepancy in cohort B, may be due to low DNA concentration (expected total tumour molecules <1, quantified by Qubit[™] dsDNA BR Assay Kit, Thermo Fisher).

<u>Discussion/Conclusion</u>: The results are crucial in presenting the reliability of using archived biobank samples in molecular diagnostics. Thus, material collected and stored in RBGB is a highly valuable resource, which can help researchers save money, increase the effectiveness of their studies, and speed up clinical studies or trials aiming faster translational research to be implemented in clinic.

373: The Evolving Role of Nurses in Qatar Biobank: Addressing Challenges and Innovations

by Ghada Deyab | Qatar Biobank for Medical Research

Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Ghada Deyab Keywords: Genetic Fragile Syndrome (GFF), Qatar Biobank (QBB), as Cystic Fibrosis (CFO), multiple sclerosis (MS)

Introduction

Nurses are integral to the operation of Qatar Biobank (QBB), supporting various tasks from participant recruitment and informed consent data validation and biospecimen to management. With the introduction of a new cohort study focusing on chronic diseases such as Cystic Fibrosis (CFO), Genetic Fragile Syndrome (GFF), and Multiple Sclerosis (MS), alongside existing population-based and disease-specific cohorts, nurses are playing a critical role in advancing biobank research. This expansion introduces challenges, including the integration of multi-omics data, the need for

continuous professional development, and ensuring sustained participant engagement.

Materials & Methods

At QBB, nurses are fully involved in biobank operations, including informed consent, sample management, and data collection. They ensure data accuracy by cross-referencing selfreported information with electronic health records. Specialized training equips nurses to handle the evolving demands of multi-omics data integration, while continuous professional development ensures they remain up to date with new technologies.

Results

Nurses' active participation has enhanced data accuracy, reflected in a reduction of discrepancies between self-reported and verified medical data. Their oversight in biospecimen collection has also reduced sample rejection rates, indicating improved adherence to protocols. Furthermore, nurses' engagement with participants has fostered trust, improving retention and study completion rates.

Discussion & Conclusion

Nurses' evolving role at QBB is crucial to maintaining high standards of biobank research. Their contributions to data validation, sample quality control, and participant engagement ensure the success of current and future initiatives. Strengthening nurse training and incorporating new innovations will be essential as research expands, particularly in chronic disease studies.

409: Cardiovascular Biobank at the German Heart Center in Munich (KaBi-DHM): From unravelling gene expression signatures to biomarker discovery

by Sabine Seeler | Elda Dzilic | Felix Wirth | Karl-Christian König | Muamer Kameric | Rupert Öllinger | Roland Rad | Teresa Trenkwalder | Harald Lahm | Stefanie A. Doppler | Markus Krane | Martina Dreßen |

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Topic: 8A: The Transformative Role of Biobanks in Public Health

Presenter Name: Sabine Seeler Keywords: Cardiovascular Biobank; Ascending thoracic aortic aneurysm; Acute type A aortic dissection

Introduction: Cardiovascular diseases remain the leading cause of death in Europe and worldwide. Thus, research concerning genetic risk factors, disease pathologies, and diagnostic markers is indispensable. The KaBi-DHM has been collecting various types of biospecimens of patients undergoing cardiac surgery. Ongoing studies address amongst others gene expression changes in the aorta and aortic valves (AVa) of patients with ascending thoracic aortic aneurysm (ATAA) and the biomarker potential for acute type A aortic dissections (TAAD) patients.

Materials & Methods: To identify gene expression changes in patients with ATAA, we performed 3'-poly(A)-RNA sequencing on

aortic and AVa tissues with aortic stenosis (AS) or insufficiency (AI). Moreover, to discover novel plasma biomarkers in patients with TAAD, we currently conduct high-throughput proteomics using the SomaScan platform.

Results: Bulk RNA sequencing of aortic tissue from ATAA revealed differentially expressed genes associating with inflammatory responses and immune cell migration. Further subgroup analysis of AS and AI patients identified specifically dysregulated genes for the respective patient cohort. AVa tissue from ATAA patients with AS compared to AI showed gene alterations that associated with ossification and BMP signalling.

Conclusion: The present studies give insights into gene expression changes that could further contribute to identify mechanisms in the interplay of AVa pathology and the development of ATAA. We plan to overlap these findings with plasma proteome data from TAAD in order to obtain a comprehensive picture of aortic diseases and potentially develop a novel biomarker. Research benefits from the sample diversity of biobanks, which allows obtaining an overall understanding of the disease.

462: EULAT Eradicate GBC: Building a unique Biorepository and IT platform towards Eradication of Preventable Gallbladder Cancer

by Kirsten, R | Scherer, D | Barahona Ponce, C | Colombo, A | Donoso, G | Bermejo J. L. | Integrated Biobank Mannheim, Medical Faculty Mannheim of Heidelberg University, Germany | Statistical Genetics

Research Group, Institute of Medical Biometry, Heidelberg University, 69120 Heidelberg, Germany | Statistical Genetics Research Group, Institute of Medical Biometry, Heidelberg University, 69120 Heidelberg, Germany | Biobanco de Tejidos y Fluidos, Departamento de Anatomía Patológica, Facultad de Medicina, Universidad de Chile | Servicio de Anatomía Patológica, Hospital Clínico de la Universidad de Chile | Statistical Genetics Research Group, Institute of Medical Biometry, Heidelberg University, 69120 Heidelberg, Germany Topic: 8A: The Transformative Role of Biobanks in Public Health Presenter Name: Kirsten, R Keywords: Gallbladder Cancer; Personalized Prevention; Risk Prediction; Biorepository

Introduction

Gallbladder cancer is a relatively rare but aggressive disease with enormous potential for prevention. GBC incidence and mortality rates vary widely around the globe, with about 65% of cases occurring in less developed countries. In order to improve the prevention of GBC, we have established a European-Latin American research consortium –EULAT Eradicate GBC– funded by the European Union's Horizon2020 programme, with the ambitious goal of eradicating preventable GBC.

Methods

EULAT Eradicate GBC members are building a biorepository integrated into a tailored IT platform with high quality data and samples from GBC cases and gallstone disease controls in high-incidence regions of northwestern Argentina, Bolivia, Chile, and Peru. Samples are collected following standard operating procedures and taking advantage of an application for electronic collection of sociodemographic, sample, clinical, and lifestyle information. This collection will be complemented with data and samples from

the large European prospective cohorts to identify epidemiological and genetic-molecular risk factors and to develop multifactorial GBC risk scores tailored to low (Europe) and high (South America) GBC incidence regions.

Results

The information generated will facilitate the identification of individuals at high risk of GBC, guiding surveillance and decisions on the potential benefit of prophylactic cholecystectomy in low and high GBC incidence regions, and new data on genomic alterations in incidental GBC will pave the way for future clinical trials. The EULAT Eradicate GBC biorepository and IT platform are already important resources for translational research into precision prevention, personalised early detection, and targeted therapy of GBC.

10A: Organisational Profiles

231: Gender in biobanking: A survey on biobankers' perception

by Benna, C | Huppertz, B | Department of Surgery Oncology and Gastroenterology, University of Padova,

Padova, Italy | Division of Cell Biology, Histology and Embryology, Gottfried Schatz Research Center, Medical University of Graz, Graz, Austria

Topic: 10A: Organisational Profiles Presenter Name: Benna, C Keywords: Biobank, biobanking, discrimination, gender, job satisfaction, survey

Background: Extensive data on gender inequality in science and medicine has led to the conclusion that gender discrimination is negatively affecting public health worldwide. Biobanking was born as a tool for health research. The conditions of women in the biobanking field have never been studied. The purpose of this study was to describe the relationship between gender and biobanking by assessing the views of biobank employees.

Methods: Biobanks were surveyed to appraise employees' working conditions.

Results: Overall, a total of 212 (21.9%) biobankers completed the questionnaire. The main respondents were from Europe, in leadership n=85 (40.3%), and in a public setting n=164 (77.4%). Females accounted for 69.8% of the respondents with 33% of them being managers; of the 28.3% male responders, 57% were managers. No gender differences were identified in the contractual working hours per week, the monthly overtime hours, and the overall job satisfaction and dissatisfaction. A highly significant difference was identified in the perception of discrimination. Women felt negatively discriminated against in hiring opportunities, career opportunities, and the superiors' behavior toward them in how ideas/proposals, and needs/complaints were taken into consideration.

Conclusions: These results support the hypothesis that there are gender biases in biobanks; however, this study should be considered a pilot study, which might help design a possible future main study.

303: Enhancing research opportunities through collaboration between the Biobank and Clinical Biology in a hospital

by Yentl Wouters | Biobank Antwerp Topic: 10A: Organisational Profiles Presenter Name: Yentl Wouters Keywords: 24/7 processing, Clinical Biology, Interdepartmental, operational efficiency

Introduction

The Clinical Biology lab and the Biobank are two different departments within the hospital. While the Clinical Biology lab uses samples for diagnostic purposes, the lab can contribute significantly to research aspects governed by the Biobank. Integrating these services requires overcoming several operational and logistical challenges.

Material & methods

Residual material and associated diagnostic data generated through accredited workflows and tools prove a major asset to biobank customers. In addition, contrary to the biobank lab, the clinical biology lab allows 24/7 processing of samples facilitating prospective collection.

Results

Standardized workflows and good coordination and communication as documented in a service level agreement ensure alignment of operational procedures and compliance with ethical and regulatory requirements while guaranteeing sample quality and accessibility. Trough participation of the clinical biology lab in 35,61% of studies, the partnership has increased the number of studies in which the Biobank can take part.

Discussion and conclusion

The collaboration between the Biobank and the Clinical Biology lab has optimized the use of available resources and facilitated broader participation in clinical trials. A shared return on investment makes this worthwhile for both partners. Similar partnerships are being set up with the pathology and medical genetics departments.

322: Measuring Impact: Implementing Key Performance Indicators to Monitor BBMRI.be's National Biobank Network

by Annelies Debucuoy | Stéphanie Gofflot | Manon Huizing | Pieter Moons | Caroline Rombouts | ELke Smits | Kim Vande Loock | Elke Berneel | Belgian Cancer Registry, Brussels | Biothèque HospitaloUniversitaire de Liège, CHU de Liège | Biobank Antwerpen, Antwerp University Hospital & University of

Antwerp, Belgium | Biobank Antwerpen, Antwerp University Hospital & University of Antwerp, Belgium |

Biobank Institute of Tropical Medicine, Antwerp | Biobank Antwerpen, Antwerp University Hospital & University of Antwerp, Belgium & Clinical Research Center Antwerp, Antwerp University Hospital & University of Antwerp, Belgium | Belgian Cancer Registry, Brussels | Biobank University Hospital Gent

> Topic: 10A: Organisational Profiles Presenter Name: Annelies Debucquoy Keywords: BBMRI.be, KPI's

Introduction

The BBMRI.be network connects 21 Belgian biobanks affiliated with public institutions, including hospitals, universities, and research centers. During 2023, the Networking & Valorisation Working Group of BBMRI.be identified 20 Key Performance Indicators (KPIs) to systematically monitor and evaluate the activities and impact of BBMRI.be.

Methods

The 20 KPIs represent a blend of five KPIs defined by BBMRI-ERIC and 15 KPIs developed at the national level. These KPIs capture the performance of BBMRI.be's Working Groups (IT, ELSI, Quality, Sustainability, Stakeholder Involvement, Network & Valorization) as well

as the coordination activities of the National Node. Eight of the KPIs required input from local biobanks, while the remaining KPIs were centrally assessed at the National Node.

Results

The 2023 KPIs were collected for the first time in early 2024 and summarized in the BBMRI.be annual report, establishing a baseline for future comparisons and trend analysis. The results highlight a high number of sample requests, well-represented collections in the Directory/Negotiator of BBMRI-ERIC, active engagement with various stakeholder groups, and effective outreach through numerous events and publications. However, areas for improvement include increasing the response rate to Negotiator requests and enhancing the number quality labelled biobanks in the Directory of BBMRI-ERIC.

Conclusions

The implementation of KPIs by the BBMRI.be Board of Directors offers a structured approach to measure the network's achievements and impact. These KPIs will support the visualization of BBMRI.be's added value, both nationally and internationally, while driving continuous improvement and alignment with strategic goals.

370: A platform for monitoring the KPIs of BBMRI.it

by Marco Moscatelli | Matteo Gnocchi | Luciano Milanesi | Andrea Manconi | CNR-ARMI4, Italy | CNRARMI4, Italy | CNR-ITB | CNR-ITB

> Topic: 10A: Organisational Profiles Presenter Name: Andrea Manconi Keywords: Key Performance Indicators

Introduction- Entered the ESFRI Roadmap 2006, BBMRI was established as a ERIC in 2013.

The ESFRI developed a common approach across RIs to monitor their performance based on Key Performance Indicators (KPIs). RIs are required to collect data and periodically calculate the KPIs to be evaluated by ESFRI. BBMRI.it, the Italian node of BBMRI-ERIC, is required to collect data from the node to calculate the KPIs. The Common Service IT (CS-IT) of BBMRI.it, implemented a platform to collect and monitoring KPIs.

Methods- The monitored KPIs measure the performance of BBMRI.it at organizational node level and at biobank level. As for node level data are continuously collected with specific sensors on the infrastructure. As for biobanks level, dedicated forms have been built that allows to the representatives to submit the data for their biobanks. Information collected from different sources is analyzed through a monitoring platform. Monitoring is organized according to specialistic views associated with the objectives of relevance for RI. For each view it is possible to monitor the trend of the KPIs as a function of time.

Results- The proposed platform implements a service aimed at measuring the impact of BBMRI.it through a set of KPIs. The service can easily be adapted to consider new KPIs.

Discussion and conclusion- The platform is now in a testing phase and is planned will be released by the first half of 2025.

This activity is supported by the funding of the European Union (NextGenerationEU), Italian NRRP project code IR0000031-Strengthening <u>BBMRI.it</u>-CUP B53C22001820006.

423: Internal Quality Audits in BBMRI.it Biobanks

by Monica Forni | Enea Ferlizza | Filippo Papa | Antongiorgio Tognoli | Angela Bozza | Daniela Pistillo | Giuseppina Bonizzi | Simone Lapi | Donatella Conconi | Domenico Coviello domenicocoviello@gaslini.org |

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Mater Studiorum , Italy | University of Bologna Alma Mater Studiorum , Italy | University of Bologna

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Topic: 10A: Organisational Profiles Presenter Name: Monica Forni Keywords: ISO19011 guidelines, Internal Quality Audit, peer cooperation

Internal audits are a cornerstone of a Biobank's Quality Management System (QMS), crucial for identifying potential issues, ensuring compliance with standards and regulations, and fostering a culture of continuous improvement.

Auditor roles can be assigned to any employee within the organization, provided they are not directly involved in the quality management processes being audited. Regardless of their role, auditors must be trained, qualified, and competent, with critical thinking skills and a strong sense of confidentiality and ethics. Effective internal auditors objectively and impartially assess organizational processes, understanding strategic objectives, risks, areas for improvement, and clearly communicate their findings to staff and executives maintaining integrity and transparency.

In smaller biobanks, assigning internal auditors can be challenging. While ISO standards allow for reasonable independence within specific contexts (ISO 19011:2011, Section 3.1), outsourcing audits to external parties may offer a practical solution.

The BBMRI Italian National Node has developed a network-based auditing system and supported the ISO 19011 certification of a group auditors working in biobanks, available to visit other facilities. BBMRI.it has also established a registry of auditors creating clear procedures for the process, ensuring transparency and mitigating conflicts of interest.

A group of ten certified figures are already enrolled and, also thanks to the support of the BBMRI-ERIC Quality Label, will be able to put theory into practice through hands-on auditing training within biobanks.

431: Developing a University Hospitalbased Tissue Biobank

by DI Dr. Philipp Hofer | Medical University of Vienna, Department of Pathology

> Topic: 10A: Organisational Profiles Presenter Name: Jennifer HSU | Lisa RAINER Keywords: ISO 20387, hospital, project based, tissue biobank

Authors:

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Institution:

Medical University of Vienna

Introduction:

The Medical University of Vienna Biobank is a joint initiative of collaborating clinical departments at the General Hospital of Vienna (AKH), supporting researchers by providing multiple biobank services. The Department of Pathology (KIP) provides services for processing and storage of tissues and viable cells, addressing various requirements of clinical researchers.

Materials and Methods:

Since 2018, over 30 ongoing biobank projects were established, leading to a diverse sample collection. These include fresh frozen tissues, tissue-derived single-cell suspensions, PBMCs, FFPE tissue blocks, H&E slides, frozen sections, and cryo molds, stored under according conditions (RT, -80 °C, -130 °C). Samples are submitted by collaborators or generated within the Department of Pathology by the biobank team in collabotation with specialized pathologists.

Results:

Since 2018, our collection expanded to ~37,000 samples, with ~3,500 samples provided for diverse research projects.

The MedUni Vienna Biobank KIP is a partner of the Austrian national node of BBMRI-ERIC, also participating in the national cross-audit program established within BBMRI.at.

Discussion and conclusion:

Throughout continuously improving our quality and risk management system (ISO 9001:2015) we aim to achieve a ISO 20387 accreditation in the medium-term future.

Until then, we are motivated by expanding numbers of ongoing projects, services we can offer to our partners, and increasing numbers of samples provided for research projects.

TRACK 2. Bridging the Gap: Biobanks and Data-Driven Research

3B: Biobanks in Big Data Research and Al

458: The Geneva Brain Bank: towards data driven research in a historical tissue collection.

by Christophe Lamy | Department of Psychiatry, Hôpitaux Universitaire de Genève

Topic: 3B: Biobanks in Big Data Research and AI Presenter Name: Christophe Lamy Keywords: Brain Bank

Introduction

The Geneva Brain Bank is a large collection of brain tissues dating back to the early 20th century. It contains formalin fixed and paraffin embedded tissues, autopsy reports and histological slides representing a broad variety of brain pathologies over more than 10'000 donors. The access to the material and data it contains is however limited by the lack of digitization.

Material & methods

Digitizing this brain bank first requires making an inventory of pre-existing material, acquiring digital images of documents and histological slides, training AI-based tools to identify and classify informative elements in those sources and establishing a database to accommodate this information. A registry has then to be built to reference the brain bank's entries and link them to the database of digitized biobank material. For recent cases, pipelines need to be devised to retrieve health, pathology and medical imaging data from the electronic health record. Eventually, an interface is necessary to enable users to mine this large digital brain bank.

Results

Digitizing the brain enables large-scale multicriteria searches in brain bank, thus facilitating the identification of cases of interest. It also helps run AI tool to refine diseases' classification. Eventually, it permits relating clinical and biological features of diseases on large datasets.

Conclusion

Digitizing large autopsy tissue biobanks offers an opportunity to run data-driven approaches, which is fundamental in disorders with no clearly identified origin such as neurodegenerative or psychiatric disorders. Future evolutions would include integrating genomic or environmental data originating from outside the biobank and interacting with other brain banks.

389: Using whole slide images and AI algorithms to enrich biobank sample annotation

by Julia Bein | Kristina Götze | Daniel Brucker | Nadine Flinner | Christian Brandts | Peter Wild | interdisciplinary Biobank and Database Frankfurt | interdisciplinary Biobank and Database Frankfurt | Dr. Senckenbergisches Institut für Pathologie und Humangenetik | University Cancer Center Frankfurt | Dr. Senckenbergisches Institut für Pathologie und Humangenetik

Topic: 3B: Biobanks in Big Data Research and AI Presenter Name: Julia Bein Keywords: AI, TMA, WSI

Nowadays digitization plays an increasingly important role in biobanking and patient health care. This development will eventually replace the manual diagnostic process with the help of AI for a fast and precise cancer cell detection. Therefore big data is needed to train algorithms to recognize cellular structures or histological pattern.

The first step during the digitization is the scanning procedure of histologically stained slides By using high-resolution scanners it is possible to obtain whole slide images (WSI), which can be utilized to annotate biobank samples with a microscopic overview image of the stored tissue. With the help of an image management software (IMS) with additional AI solution, the slides are analyzed for parameters like tumor cell content, immunophenotypic markers, growth pattern and others (Darling et al. 2024, Stoll et al. 2024). This information can also be annotated to biobank specimen and enables the biobank to easily search for suitable samples for predefined scientific cohorts.

Additionally, the images can be used to select regions of interest for the following preparation of tissue micro array (TMA). TMAs can then be used for different scientific approaches such as the analysis of large patient cohorts or as a training set for convolutional neuronal networks (CNN) (e.g. Meyer et al. 2024). Combining WSI with genomic and proteomic data (e.g. from other scientific projects) will lead to a comprehensive characterization of the biobank samples.

371: A digital infrastructure based on HPC and AI methodologies to enhance the BBMRI.it computing facility

by Tania Bobbo | Alice Chiodi | Maria Milanesi | Matteo Gnocchi | Marco Moscatelli | Andrea Manconi | CNR-ITB, Italy | CNR-ITB, ITaly | CNR-ITB, Italy | CNR-ARMI4, Italy | CNR-ARMI4, Italy | CNR-ITB, Italy

Topic: 3B: Biobanks in Big Data Research and AI Presenter Name: Andrea Manconi Keywords: Computing platform, HPC, big data, deep-learning

Introduction- Innovative biobanks will produce huge amounts of clinical, omics and imaging data that require robust computing and large storage infrastructure and suitable analysis tools -also based on artificial intelligence (AI)offering compute density, performance, and flexibility to support research. Providing access to such infrastructures is essential to support research.

Material & method- The Common Service IT (CS-IT) of BBMRI.it is implementing an innovative infrastructure based on HPC and AI methodologies to support Biobanks. The platform also supports Deep Learning (DL) which is ever increasingly used in biomedical research. Currently, the platform is configured to be accessible through an instance of Galaxy and Jupyter notebooks. The CS-IT is also working to implement and make available specific workflows (e.g., medical imaging, structural bioinformatics, omics analysis) that can be easily run on the platform.

Results- This activity will enhance the BBMRI.it computing facilities with suitable environment for big-data analysis, including resources to deploy ML and DL models. To help the researchers to easily implement scalable algorithms the computing environment is equipped with an HPC engine for large-scale data processing on HPC clusters, able to ensure high scalability.

Discussion and conclusion- The platform and services are under development and testing pending the completion of the strengthening of the infrastructure through the NRRP project. This activity is supported by the funding of the European Union (NextGenerationEU), Italian NRRP project code IR0000031 - Strengthening <u>BBMRI.it</u> - CUP B53C22001820006.

365: THE BASQUE BIOBANK AS A TOOL FOR THE GOVERNANCE OF DATABASE REUSE

by OIHANA BELAR | Roberto Bilbao | Ainara Egia | Francisco Polo | Angel José Calderón | Artzai Picón | Cristina LÓPEZ | José Blas PAGADOR | Luisa F. SÁNCHEZ-PERALTA | Basque Biobank-BIOEF | Basque

Biobank-BIOEF | Basque Biobank-BIOEF | OSI Bilbao Basurto/OSAKIDETZA, IIS BIOBIZKAIA | OSI Bilbao

Basurto/OSAKIDETZA, IIS BIOBIZKAIA | TECNALIA | TECNALIA | Centro de Cirugía de Mínima Invasión Jesús Usón | Centro de Cirugía de Mínima Invasión Jesús Usón

Topic: 3B: Biobanks in Big Data Research and AI Presenter Name: OIHANA BELAR Keywords: DATA REUSE

After analyzing the samples and the data that the biobanks transfer to research projects, new databases are created that may have secondary uses in other projects. However, it is not common sharing this data with third parties. In contrast, open data science promotes free access to research data, facilitating the use of it for any purpose, replicability or reproducibility.

Biobanks are perfect tools to collect these databases and offer them to the scientific community, maintaining quality, traceability, and privacy rights of the donors.

The Basque Biobank launched a pilot with the idea of reusing medical images database generated in PICCOLO, a European research project (H2020), from biological samples with the approval of The Basque Country Ethics Committee.

This database contains 3,433 images of 76 colon lesions from 40 codified patients with clinical information. The procedure for access to the databases are detailed in the BasqueBiobank e-catalogue.

Thanks to this initiative that began in 2020, 81 research groups from 28 countries have requested access to PICCOLO dataset and 61 citations in scientific literature have been generated. The latest review about Open Access databases has classified it as a useful and complete database among the 22 most used databases in the field of AI research in colonoscopy imaging. This experience demonstrates that Biobanks can play an important role in open science policies as a tool for the application of the FAIR principles.

280: Metabolic Risk Analysis in the Lower Silesia Healthy Donors Cohort: Statistical Insights and Machine Learning Classification

by Przemysław Wieczorek | Magdalena Krupinska | Agnieszka Matera - Witkiewicz | Wroclaw Medical University, Faculty of Pharmacy, Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland | Wroclaw Medical University, Faculty of Pharmacy, Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland | Wroclaw Medical University Biobank, Poland | Wroclaw Medical University Biobank, Poland | Wroclaw Medical University, Faculty of Pharmacy, Screening of Biological Activity Assays and Collection of Biological Material Laboratory, Wroclaw Medical University Biobank, Poland

Topic: 3B: Biobanks in Big Data Research and AI Presenter Name: Magdalena Krupinska Keywords: Logistic regression, Machine learning, Metabolic Syndrome (MetS), Risk factors

Introduction:

Metabolic Syndrome (MetS) is a group of risk factors linked to cardiovascular diseases and type 2 diabetes. The "Healthy Donors" project in the Lower Silesia region collected health data, enabling statistical analyses to explore the relationships between metabolic factors and MetS risk.

Materials & Methods:

The study consited of 957 participants in the "Healthy Donors" database, collected from 2012 (BC 73/2012 POIG.01.01.02-02-003/08, BioMed project). All statistical analyses were performed using R software (version 4.3.0). A machine learning pipeline was implemented to classify participants. Five algorithms were evaluated: CatBoost, XGBoost, LightGBM, Random Forest, and Logistic Regression.

Results:

Significantly higher glucose and insulin levels were observed in the overweight group compared to the normal BMI group. HDL levels were lower in the overweight group, and the HOMA index was higher in participants with increased waist circumference. The logistic regression model demonstrated strong predictive power, with systolic blood pressure, triglycerides, and glucose levels identified as key predictors using SHAP values.

Discussion & Conclusion:

Logistic regression revealed a 1.13-fold increase in MetS risk with each unit increase in BMI. Systolic blood pressure and triglycerides were positively associated with MetS, while HDL levels were inversely related. The findings highlight the need for targeted public health strategies to reduce MetS prevalence in Lower Silesia.

Acknowledgement:

The ananysis was performed within Project: Digital Medicine: an Innovative approach for SuppoRt and UPgrade of the diagnosis and Therapy based On Research (RCMC "DISRUPTOR" at WMU 2023/ABM/02/0003-00) using data from POIG.01.01.02-02-003/08, BioMed project WCB EIT+, now Research Network Łukasiewicz – PORT Polish Center for Technology Development.

5B: Ensuring Data Security in Biobanks: Strategies and Best Practices

241: Implementing a Trusted Research Environment in Taiwan Biobank: Enhancing Data Security and Enabling Ethical Biomedical Research

by You, Yu-FU | Academia Sinica

Topic: 5B: Ensuring Data Security in Biobanks: Strategies and Best Practices Presenter Name: You, Yu-FU Keywords: Taiwan Biobank, Trusted Research

Environment, data security, privacy safeguard

Introduction

The Taiwan Biobank (TWB) is advancing toward a cloud-based Trusted Research Environment (TRE) to enhance data security, streamline management, and support collaborative biomedical research. This initiative addresses key privacy and security issues as biobanks expand in scope. The survey provides critical insights into user needs, ensuring the TRE is designed to effectively meet expectations and drive its successful implementation.

Materials and Methods

A survey was conducted among TWB users, including Principal Investigators and data analysts, to assess computational resource needs, data security preferences, regulatory compliance, and system performance expectations, focusing on privacy safeguards, encryption, and user permissions.

Results

The survey received a 24% response rate, gathering input from researchers in diverse

fields such as genomics, epidemiology, and AI. Key findings indicate that 80% of users prioritize robust security measures like encryption, and 96% emphasize regulatory compliance (e.g., GDPR, Taiwan's Personal Data Protection Act). Preferred tools include RStudio (80%), Excel (64%), and PLINK (58%), with 76% requiring scalable resources for large-scale genomic analyses. Additionally, 79% support intuitive interfaces and user guides.

Discussion and Conclusion

The survey highlights user awareness of data privacy, supporting TWB's efforts to prioritize security in the TRE framework. By integrating advanced protocols, regulatory compliance, scalable resources, and analytical tool compatibility, the TRE will enhance research efficiency and reproducibility. Its user-friendly design and educational support ensure accessibility, establishing a secure foundation for impactful biobank research and biomedical advancements.

427: Privacy by design of the data journey in AlmaMicrobiome biobank

by Giulia Caldoni | Filippo Papa | Marco Fabbrini | Gabriele Conti | Enea Ferlizza | Antongiorgio Tognoli | Matteo Pallocca | Patrizia Brigidi | Monica Forni | University of Bologna Alma Mater Studiorum , Italy |

University of Bologna Alma Mater Studiorum , Italy | University of Bologna Alma Mater Studiorum , Italy

| University of Bologna Alma Mater Studiorum , Italy | University of Bologna Alma Mater Studiorum ,

Italy | University of Bologna Alma Mater Studiorum , Italy | 3Istituto degli Endotipi in Oncologia, Metabolismo e Immunologia "G. Salvatore" (IEOMI), Naples, Italy. | University of Bologna Alma Mater

Studiorum , Italy | University of Bologna Alma Mater Studiorum , Italy Topic: 5B: Ensuring Data Security in Biobanks: Strategies and Best Practices Presenter Name: Giulia Caldoni Keywords: GDPR, data journey, systems integration

The University of Bologna's guidelines for research data management embody a strong commitment to fostering responsible, highquality research aligned with FAIR principles and Open Science.

Ethics, as a cornerstone of research integrity, is vital for ensuring reliability, quality, and transparency. When it comes to biobank data, the involvement of individuals makes ethical principles related to privacy a key consideration, requiring thoughtful and proactive management.

Adopting a "privacy by design" approach is critical in addressing potential privacy challenges. This entails designing data processing activities with meticulous attention to the principle of minimization, collecting and processing only the personal data necessary for achieving scientific objectives. Striking a balance between research collaboration and data protection involves using storage systems that adhere to the General Data Protection Regulation (GDPR). Additionally, robust protocols for managing access, encryption, anonymization, or pseudonymization of data are essential.

To comply with University of Bologna regulations and Italian law, the AlmaMicrobiome biobank has outlined a clear data processing framework. Although initially dealing with sensitive personal data, the biobank transitions this information into microbial data after specific processing. The designed "data journey" underscores the biobank's readiness to uphold both scientific rigor and legal compliance.

Scheduled to commence operations by the end of 2025, the AlmaMicrobiome biobank will be equipped to manage samples and data efficiently, despite the presence of some local technical challenges, ensuring it aligns with ethical standards and supports the advancement of research in a responsible and sustainable manner.

445: IZSAM's software for the management of veterinary biobank samples

by Marco Caporale | IZS AM

Topic: 5B: Ensuring Data Security in Biobanks: Strategies and Best Practices Presenter Name: Simonetta Ulisse Keywords: Biobank, Veterinary, management, software

Introduction

Veterinary biobanks are crucial for global disease control, preserving biological samples enable detailed for research. They epidemiological studies, tracing infectious disease pathways, and studying zoonotic disease transmission. Biobanks also reduce animal testing by allowing shared sample use, promoting ethical research practices. Key challenges include ensuring accurate cataloguing, traceability, and standardized management of biological materials to support research and vaccine development.

Material & methods

IZSAM developed software to address these challenges, featuring a virtual warehouse for cataloguing biological materials based on international taxonomic standards. The system facilitates mass acquisition, standardized data collection, and efficient searches. It ensures traceability by recording transactions, monitoring user activities, and adhering to standard operating procedures (SOPs). Secure access is restricted to authenticated users.

Results

The software has enhanced the management of veterinary biobank samples by improving traceability and data quality. It streamlines the process of sample requests and supports epidemiological research by providing wellorganized, accessible resources. This strengthens efforts to study zoonotic diseases and supports vaccine development.

Discussion and conclusion

The IZSAM software is a model for efficient biobank management, fostering collaboration across institutes and ensuring sample comparability globally. It promotes a One Health approach, supporting multidisciplinary research and advancing the fight against zoonotic and endemic diseases.

7B: Data Flows in Healthcare Integrated Biobanking

269: Association of clinical data in samples from the Biobank of the Aragon Health System through the BIGAN Platform.

by Recalde, D | Montolio, A | Arenaz, I | Naval, J | Encabo-Berzosa, Marimar | Mora, I | Giraldo, C | González-García, J | Telleria, C | Biobank of the Aragon Health System, IACS, Spain | Biocomputing Unit, IACS | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biocomputing Unit, IACS | Biocomputing Unit, IACS

> Topic: 7B: Data Flows in Healthcare Integrated Biobanking Presenter Name: Recalde, Delia Keywords: BIGAN, biocomputing, clinical data

INTRODUCTION

The Biobank of the Aragon Health System (BSSA) collaborates with the IACS Biocomputing Unit to optimize sample selection based on specific clinical criteria, ensuring high-quality associated datasets.

OBJECTIVES

- Maximize the efficient use of Biobank
- samples.

Improve the association of quality clinical data according to research needs.

MATERIAL AND METHODS

Since 2018, the Biocomputing Unit has managed the BIGAN Platform, a proprietary technological infrastructure of the Government of Aragon that captures, anonymizes, stores, and analyzes health data.

BSSA registers a minimum dataset for each sample (age, sex, main diagnosis) in its Bioebank database (VITRO SA). When samples meeting specific clinical criteria are requested, BIGAN enables rapid and efficient data filtering. Additionally, for transfers requiring extended datasets beyond the Biobank's minimum records, BIGAN facilitates secure data association. For prospective sample collection with specific clinical data, the Biocomputing Unit also assists in designing dedicated databases using REDCap forms.

RESULTS AND CONCLUSION

This collaboration has significantly reduced the time Biobank staff spend on data association while improving data quality assurance. It has also enabled access to sample assignments that were previously unfeasible, such as selecting samples with precise clinical conditions.

8B: Best Practices for Biobanking Data Integration

236: Recruitment Strategies for the Taiwan Biobank: Driving the Success of a National Cohort Study

by Yi-Ching Chung | Academia Sinica, Taiwan Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Yi-Ching Chung Keywords: Tawian Biobank(TWB), Health data integration, Precision medicine, Biorepository system, Longitudinal data

Introduction

The Taiwan Biobank (TWB) is a national biomedical resource aimed at improving disease prevention, treatment, and health policy planning. By collecting biological samples and health data from individuals aged 20 and above across Taiwan, TWB set a goal of recruiting 200,000 participants to support precision medicine research. Ensuring cohort diversity and high-quality data are central to this initiative.

Methods

TWB employed diverse recruitment strategies, including collaborations with local health centers, community events, targeted outreach, and digital pre-registration. Nationwide recruitment stations, flexible scheduling, educational outreach, and mobile units were established to enhance accessibility and retention. A centralized online system enabled realtime data integration, reducing errors and ensuring high data quality. Biological samples were transported to a central storage facility via specialized freight services to maintain sample integrity.

Results

TWB successfully recruited 203,041 participants and conducted over 288,000 follow-up interviews, achieving demographic diversity. Participants consented to link their data with the national health insurance database, significantly expanding the utility of the dataset. To protect data security and privacy, TWB obtained ISO27001 and ISO27701 certifications and provided ongoing staff training, strengthening its data ecosystem.

Conclusion

With adaptive recruitment strategies and robust infrastructure, TWB has established an efficient national cohort. Its dedication to transparency, education, and long-term followup has created a comprehensive longitudinal data and biorepository system. This achievement advances Taiwan's biomedical research capabilities, driving progress in precision medicine and public health at both national and global scales.

255: Analyzing the current biobank IT landscape at Austrian BBMRI Node partners

by Georg Göbel | Volodymyr A. Shekhovtsov | Franz Gruber | Helmuth Haslacher | Patrick Neff | Monika Valjan | Ingrid Walter | Robert Primschitz | Medical University of Innsbruck, Austria | Medical University of Innsbruck, Austria | Johannes Kepler University, Linz, Austria | Medical University of Vienna, Austria |

Medical University of Innsbruck, Austria | Medical University of Graz, Austria | University of Veterinary Medicine, Vienna, Austria | Medical University of Graz, Austria

Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Volodymyr A. Shekhovtsov Keywords: IT landscape, biobanks, communication

interfaces, data flow, questionnaire, stored data

Introduction: As part of the BBMRI.at project we analyzed the current biobank IT landscape at Austrian BBMRI Node biobanks. This is the initial step of implementing the solution which will connect the Austrian Biobank-IT systems to BBMRI-ERIC Platforms.

Methods: We performed the analysis by means of distributing a self-developed indepth questionnaire consisting of 67 questions covering the following topics: (1) the biobank system as a whole, in particular, its main components, the biobank IT team and its duties, and the available system documentation; (2) the stored data, in particular the biobank data model, the internal regulations and external standards, data security and privacy; (3) the communication Interfaces, in particular system input and output and external data sources; (4) the data flow, in particular the events occurring in the biobank system, and the standardized processes for data input, output, or management.

To supplement the questionnaire with live questioning, interviews with the IT representatives of the Biobanks were organized covering system components and interfaces, biobank data, communicating with external systems, IT team organization, and external regulations.

Results: The biobank representatives provided detailed answers to both questionnaire and live interviews. The IT infrastructures and architectures are very heterogeneous, and an indepth analysis is currently planned. New standards like OMOP or FHIR are currently low prioritized at the local sites due to the lack of resources.

Discussion: the answers to the questionnaire and the results of the interviews will be used to form the requirements to the NN Biobank Data Communication Platform and to guide its implementation.

263: MIABIS - behind the scenes

by Cäcilia Engels | Andrzej Strug | Błażej Marciniak | Gabriele Renate Anton | Heimo Müller | Michael Neumann | Niina Eklund | German Cancer Consortium (DKTK), partner site Charité, Berlin, a partnership between DKFZ and University Hospital Charité, Berlin, Germany | Gdańsk Medical University, Gdańsk, Poland | Biobank Łódź, University of Łódź, Łódź, Poland | Biobank Ostwestfalen-Lippe, University of Bielefeld, Bielefeld, Germany | BBMRI-ERIC, Graz, Austria | University Hospital Würzburg, Würzburg, Germany | BBMRI-ERIC, Graz, Austria

Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Cäcilia Engels Keywords: Biobank, Biosample, Data sharing, Interoperability, Research This overview presents the backend operations of the Minimal Information About Biobank Data Sharing (MIABIS) framework. MIABIS is an evolving system that goes beyond a semantic model and involves continuous monitoring, development and integration of new components. We also aim to consolidate the position of terminology with a plan to ontologise of biobank-related terminology.

Methods

We have reviewed the governance structure and open licensing policies to ensure appropriate stakeholder involvement, including biobanks, data experts, and researchers in the development of the terminology. This work focuses on the ongoing evaluation of the MIABIS components to identify and address the need for updates such as the recent developments, including the Biobank Services component, the Dataset Type extension, Digital and the Pathology component. All relevant information is openly available in a publicly accessible GitHub repository, encouraging collaborative growth through shared resources such as attribute tables and mappings.

Results

Significant progress has been made in refining MIABIS, particularly in improving the attribute data structure, adding new components or even extensions, and streamlining governance. Updates have improved functionality and interoperability as well as the development workflow, while new components such as Digital Pathology support descriptions. The GitHub repository has proved instrumental in promoting transparency and accelerating update. Further work is planned to include a

Objective

quality assurance component, provenance information, and the resolution of stalled components such as Standard Operating Procedures (SOPs) to ensure that MIABIS remains a comprehensive tool for biobank collaboration.

Discussion

MIABIS is a dynamic, evolving framework driving real-world improvements in biobank data interoperability.

305: BBMRI Federated Platform ETL: A flexible framework for biobank data conversion

by Vittorio Meloni | Giovanni Delussu | Alessandro Sulis | Cecilia Mascia | Luca Pireddu | Aneas Hodselmans | Esther van Enckevort | Morris Swertz | Francesca Frexia | CRS4 - Center for Advanced Studies, Research and Development in Sardinia | CRS4 - Center for Advanced Studies, Research and Development in Sardinia | CRS4 - Center for Advanced Studies, Research and Development in Sardinia |

CRS4 - Center for Advanced Studies, Research and Development in Sardinia | CRS4 - Center for Advanced Studies, Research and Development in Sardinia | UMCG - University Medical Center Groningen

| UMCG - University Medical Center Groningen | UMCG - University Medical Center Groningen | CRS4 -

Center for Advanced Studies, Research and Development in Sardinia

Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Vittorio Meloni Keywords: ETL, Federated Platform, Framework, HL7-FHIR, MIABIS, OMOP-CDM

Introduction

The BBMRI-ERIC Federated Platform (FP) allows researchers to search for samples and data meeting precise characteristics -- e.g. age, disease -- through two services: Locator and Finder. To make their collections findable through the FP, biobanks must export their data in HL7-FHIR and OMOP-CDM. It is paramount to provide the BBMRI community with models and tools that can facilitate this process. In this work, we present an ETL framework that provides a plug-in solution to extract biobank and sample (meta)data and map them to the FP data models.

Methods

BBMRI-FP-ETL uses a representation based on MIABIS 2.0 as a translation layer between biobank-specific input and standardised output. Two output formats are supported: HL7FHIR, to populate Locator, and OMOP-CDM, to populate Finder. To create the ETL process, biobanks only need to develop a script that extracts data from their data source and fills the framework's MIABIS classes; then, the framework automatically generates the FHIR resources or the OMOP data to populate the Locator or the Finder respectively.

Results

We validated the framework with two different kinds of sources: the RD-Connect Sample Catalogue, that exposes data via a Molgenis REST API, and the BBMRI CRC-Cohort, which is persisted in an openEHR-based repository. BBMRI-FP-ETL is available as open-source (https://github.com/crs4/bbmri-fp-etl).

Conclusions

The BBMRI-FP-ETL framework facilitates connecting biobanks to the BBMRI-ERIC Federated Platform, independently of their internal data models. Further developments include the option to add an additional output serializer towards the Fact Tables of the BBMRI Directory's Star Schema.

364: Towards increased findability of datasets and collections available in the Netherlands

by Lucie Kulhankova | Hannah Neikes | Ana Konrad | Niek Van Ulzen | René Oostergo | Robin Verjans | Health-RI | Health-RI | Health-RI | Health-RI | Health-RI; UMCG | Health-RI

Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Lucie Kulhankova Keywords: catalogue, interoperability, metadata, metadata standards

Introduction

The National Health Data Catalogue, developed by Health-RI, is an integrated resource designed to enhance the secondary use of health and life sciences data in the Netherlands. By providing metadata of datasets, the Catalogue aims to make health and life science data from the Netherlands Findable, Accessible, Interoperable, and Reusable (FAIR). Metadata is obtained from a variety of data sources, including biobanks, cohorts, registries, data collections, or electronic health records, and is structured using a Health-RI metadata schema, based on DCAT-AP v3 a European standard for, enabling connection with other DCAT-based, national or European catalogues.

Results

In 2024, the onboarding process was piloted, resulting in the integration of the first datasets using the v1 core metadata schema. Metadata are shared with the catalogue via a FAIR data

point ensuring scalability and enabling automatization of the process. In December 2024, an expanded version of the metadata schema, incorporating health-specific metadata, was prereleased. Mapping of metadata from diverse (meta)data sources is underway in collaboration with the research community. For 2025, dataset expansion with local, regional, and national partners is planned.

Discussion and Conclusion

The National Health Data Catalogue simplifies metadata sharing across platforms, reducing redundancy while promoting FAIR principles. Its interoperability and scalability enable integration of datasets at both national and international levels. Future plans include introducing domain-specific metadata for areas like and a dataset request platform. The Catalogue is a key tool for organizing and sharing life science and health-related data, supporting research and innovation in the Dutch research community.

385: Leveraging Open-Source Solutions for Biobanking: Implementing GRIST for Sample and Data Management

by Markus Ulrich | Anup Kumar Raha | Dominic Bläsing | Helmholtz Institute for One Health | Helmholtz Institute for One Health | Helmholtz Institute for One Health

Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Markus Ulrich Keywords: FAIR, One Health, Open Source, Sample Management, Software

Effective biobanking and sample management require adaptable, cost-efficient, and userfriendly digital infrastructure. However, many commercial sample management systems are either standalone solutions, prohibitively expensive, or require advanced technical expertise, limiting accessibility and integration. GRIST, an open-source, no-code database management tool, addresses these challenges by providing a highly flexible, communitydriven platform with customizable templates.

At the Helmholtz Institute for One Health, we are developing a digital ecosystem centered around GRIST to support the entire scientific value chain, from field sample collection to laboratory data documentation. GRIST's Excellike interface facilitates user adoption, enhances data management efficiency, and ensures high compliance with database maintenance. The system is designed following FAIR, CARE, and TRUST principles, promoting interoperability, data reusability, and ethical research data governance. Furthermore, selfhosting capabilities significantly reduce costs, making GRIST a viable solution for low- and middle-income countries.

Our objective is to establish a replicable framework by developing standardized templates and a comprehensive white paper to guide other research institutions in implementing GRIST. This initiative aims to foster an open, scalable, and sustainable approach to biobanking and sample management, ultimately advancing collaborative scientific research.

406: Enhancing Data Quality and Reproducibility in BBMRI.it network: The Impact of the BB4FAIR Digital Maturity Assessment

by Federica Rossi | Davide Fragnito | Antonella Cruoglio | Ramona Palombo | Alice Massacci | Alessandro Sulis | Vittorio Meloni | Sara Casati | Antonella Mirabile | Andrea Manconi | Luciano Milanesi | Gennaro

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Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Matteo Pallocca Keywords: Data Management, Digital Framework, FAIR Principles

Introduction:

Data FAIRness is essential to improve research reproducibility by ensuring that data are findable, accessible, interoperable and reusable. To achieve these principles, biobanks need to establish appropriate processes for data collection, storage and sharing, which should be managed by trained staff and comply with international standards and legislation.

Results:

As part of the BBMRI.it, in the project "Strengthening the Research Infrastructure on Biobanks and Biomolecular Resources in Italy" we developed a framework for Biobank Digital Maturity, BB4FAIR. Piloted in 37 Italian biobanks, this tool comprises of a structured survey and an automated R/Shiny system to analyse responses and generate visual data representations

(https://bbdataeng.shinyapps.io/bb4fair_app/). A scoring table facilitated digital maturity tiering, highlighting areas requiring corrective action. Finally, The BBMRI.it community is contributing by providing outreach materials and supporting the recruitment and training of Data Engineers specialized in biomedical data management.

Discussion and conclusion:

The framework has been preprinted as a metholodogical resource according to Open Science practices (https://zenodo.org/records/14012403), and is currently in advanced review process on the Journal of Biomedical Informatics. We will launch a second survey that will offer a more detailed and comprehensive assessment of digital resources. This will enable biobanks to track and demonstrate progress in enhancing the security and quality of their data and biological resources management. Improved data quality and management will foster the collaboration across research networks and accelerate the generation of more accurate insights in public health and disease research.

420: FHIR-Facade and SampleXChange: A Reference Implementation for Transforming Biobank Data into Sample Locator Format

by Patrick Skowronek | Miriam Rößner | Dominik Boehm | Johanna Schwarz | Stefanie Köhler | Matthias

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> Topic: 8B: Best Practices for Biobanking Data Integration Presenter Name: Patrick Skowronek Keywords: , BBMRI.de, Data Integration, FHIR, Sample Locator

The Central Biobank Erlangen (CeBE) processes and stores samples collected across various clinical departments. Integrating associated clinical data across multiple organizations is challenging, especially consent management and diverse data formats. To address these issues, Data Integration Centers (DIC) were established in German university hospitals. These centers integrate clinical data from a variety of data sources in a common data format used nationwide. Patient data is strictly separated from sample-specific information, leaving CeBE with access only to sample quality data and pseudonyms of associated patients. Patient- and sample-related data are joined in the DIC solely for research purposes, such as filling the Sample Locator.

The DIC Erlangen integrates the STARLIMS sample data with patient data from multiple

systems into a unified data store. The nationwide data format is the MII Core Data Set while the Sample Locator relies on BBMRI.de definitions. To bridge this gap, we implemented an automated data integration pipeline using the FHIR-Facade (a consent-based data filter) and SampleXChange (a conversion tool from MII KDS to BBMRI.de).

We successfully tested the combination of both tools. The FHIR-Facade ensures compliance by checking for signed consents, while SampleXChange(part of samply.TransFAIR) converts selective, approved data into the BBMRI.de format.

Using open-source tools we established a reference pipeline for the integration of biobank sample data and clinical information from multiple sources. Concludingly, we advise the freely available solution, reducing the need for custom data integration jobs in DICs. Additionally, the pipeline avoids data duplication by reducing the data to a minimal set.

10B: Ensuring Excellence: Elevating Data Quality in Biobanking

275: Support of biobank operations at Amsterdam UMC by a biobank information management system

by Erik van Iperen | Aran Hartlooper | Maureen van der Arend | Jörg Hamann | Adrie Kromhout | Amsterdam University Medical Center, Amsterdam, The Netherlands Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Erik van Iperen Keywords: BIMS, FAIR, Standardization, workflows

Introduction – Amsterdam UMC Biobank currently stores over 500 collections containing > 3 million biospecimens. In 2023, a new biobank information management system (BIMS) went live, which boosted the quality of collection, storage and the efficacy of work processes.

Methods – During the first year of OpenSpecimen's use, the final phases of data migration were completed, and the majority of newly collected biospecimens were processed by the pre-analytical laboratory within Amsterdam UMC. This lab integrated the workflow module from OpenSpecimen in their processing procedures, which facilitates efficient and accurate data entry. Data from biomaterials, originating from external sources, was added to OpenSpecimen using the system's bulkimport functionality.

Results – During its first year of implementation, OpenSpecimen facilitated the intake and management of 241.268 new biospecimens. Additionally, over 80.000 samples were distributed to researchers. The workflow module proved highly effective in reducing data entry errors and enhancing the traceability of samples throughout their lifecycle. Through integration with the Research Data Platform (RDP), metadata for biospecimens in OpenSpecimen became accessible, enabling linkage between biospecimens and clinical data, significantly improving data usability and supporting multidisciplinary studies.

Conclusion implementation The of _ OpenSpecimen has improved the management, accessibility, and quality of historical and recently started collections. Moving forward, efforts will focus on providing researchers direct access to OpenSpecimen, enabling them to search and request biosamples and publish metadata in the national Health-RI catalog, increasing visibility and usability of the biobank's resources. here.

306: The Belgian Virtual Tumourbank (BVT) Project: data quality control on lung cancer tumour tissue samples

by Kim Vande Loock | Belgian Cancer Registry Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Kim Vande Loock Keywords: data quality, network, oncology, tumours

Introduction: The Belgian Virtual Tumourbank (BVT) is a collaborative network of 11 biobanks associated with Belgian university hospitals. To facilitate the search for tumour samples scattered among different institutions, one central database compiles data from residual human tumour material. Following extensive quality control analyses, the coded data are available to researchers in the online BVT catalogue (BVTc). A study will be conducted using data from lung cancer tissue samples collected in 2022 and registered in the BVT.

Methods: Data quality control within the BVT follows a two-step process. Initially, an automated quality control system checks the format and content of uploaded data fields within the BVTr application. Subsequently, experienced BVT data analysts manually verify the data for inconsistencies across fields. Once validated, the data is published in the BVT catalogue in a coded format. Researchers with access to the catalogue can query samples of interest. When tumour samples are requested by researchers, a comparison can be made between the data of these requested tumour samples available in the BVT central database and the Belgian Cancer Registry database, which contains overlapping information. The records from 127 patients with the lung cancer tissue samples registered in BVT will be crossreferenced with the database of the Belgian Cancer Registry.

Results: The results of this study, focusing on data quality control outcomes, will be presented.

Conclusion: The upcoming pilot study will provide further insights into data consistency and completeness, strengthening the BVT's role as a critical resource for cancer research in Belgium.

311: Enhancing Biobanking Data Quality: A Survey-Based Approach to Prioritisation

by Niina Eklund | Stella Antoniou | Nadja Palko | Andrea Wutte | BBMRI-ERIC, Graz, Austria | BBMRI-

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Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Niina Eklund Keywords: Data quality, data management, interoperability, process improvement, staff competence

Introduction

Improving data quality and strengthening data management frameworks are critical for biobanking when promoting replicability and reliability of research. Over the past year, BBMRI.QM has focused on advancing these areas through active participation in Europeanlevel projects, such as ISIDORe, QUANTUM, and EvolveBBMRI. Additionally, we produced a structured data quality plan for the biobanking quality community. This plan, introduced at a Data Quality Working Group (WG DQ) kick-off meeting in October, serves as a roadmap to support biobanks in optimising their data management and data quality processes when striving towards biobank standard ISO 20387 accreditation.

Material and Methods

To refine the data quality strategy and establish priority areas, we conducted an eightquestion survey via Microsoft Forms among WG DQ kickoff meeting participants. A total of 38 responses were collected from 10 countries, ensuring broad geographic representation across Europe.

Results

Survey findings revealed already existing data quality measures within biobanks and highlighted critical areas for improvement. Key challenges were categorised into two domains: (1) enhancing staff competencies and (2) improving processes and tools. The highestpriority training needs included data quality improvement software and relevant data quality standards. Process-related priorities encompassed the development and monitoring of data quality metrics, implementation of standardised tools, and enhancement of IT system interoperability through common data models and structured data frameworks.

Discussion

The identified priorities will inform future training initiatives and guide WG DQ activities focused on data quality improvements. Addressing these critical areas is essential for ensuring high-quality, interoperable biobank data.

372: Creation of the Standard Pre-Analytical Code System (SPREC) Refset in SNOMED CT for use in biobanks and biomedical research

by Santiuste, I | Armendáriz, J | Gómez-Romano | Aguilar-Quesada, R | Abril-Tomo, C | Biobanco Valdecilla-Instituto de Investigación M. de Valdecilla-IDIVAL | Biobanco Universidad de Navarra | CIBER de Enfermedades Infecciosas, Instituto de Salud Carlos III | Biobanco del Sistema Sanitario Público de Andalucía | Spanish SNOMED CT National Release Center

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Santiuste, I Keywords: Interoperability, SNOMED CT, SPREC

Introduction

Pre-analytical variables, such as sample collection, processing, and storage conditions, are crucial in biobanks to ensure the quality and reproducibility of research results. Variations in these processes can introduce biases in experimental outcomes, affecting the validity of studies. Interoperability between biobanks and research groups is also essential to facilitate data exchange and enhance global collaboration. To address these challenges, the Semantic Interoperability Observatory (OISIB), in collaboration with Spanish SNOMED CT National Release Center, mapped the SPREC (Standard Pre-Analytical Code) to SNOMED CT, aiming to standardize and facilitate tracking pre-analytical variables in biobanks and improve interoperability.

Material and Methods

The team conducted a systematic review to identify existing SNOMED CT concepts related to SPREC codes. Since there were few preexisting concepts (less than 18%), new descriptors were created and aligned with SPREC requirements. The process followed SNOMED CT's editorial policy, ensuring the localization of terms into Spanish.

Results

The SPREC mapping to SNOMED CT resulted in 170 new concepts, 380 descriptors, and 190 new "is a" relationships. These additions complete the SPREC implementation in SNOMED CT, enabling standardized tracking of pre-analytical factors.

Discussion & Conclusion

Mapping SPREC codes to SNOMED CT improves interoperability between biobanks and research groups by providing a standardized way to record and share pre-analytical factors. This standardization reduces biases in research results, promoting more reproducible and efficient biomedical research globally.

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377: Verifying annotation of study samples according to a predefined rack layout

by Kristina Götze | Timo Schneider | Jaqueline Patzek | Daniel Brucker | interdisciplinary Biobank and

Database Frankfurt | interdisciplinary Biobank and Database Frankfurt | interdisciplinary Biobank and Database Frankfurt | interdisciplinary Biobank and Database Frankfurt

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Kristina Götze Keywords: Data quality, pre-defined rackannotation

In a study setting where different patient samples are collected and processed locally and stored in one central biobank, samples are usually stacked in a predefined rack layout.

In this example, a patient's samples are arranged on a rack in such a way that both the visitation number and the material type can be clearly derived from the position of a tube. This information is entered by hand in the biobank information system (BIMS, CentraXX) with the sample information when the samples are scanned by study personnel at the biobank where the samples are stored.

quality assurance of the manual For documentation, the material type and visitation number derived from the position of the samples were compared with the information stored manually in the BIMS. This resulted in an - albeit low - rate of incorrectly entered sample annotations. These were subsequently corrected. In order to continuously check the documentation quality, the comparison described above is carried out as an automatically triggered report in CentraXX.

This study shows that manual documentation can be prone to errors and that automated annotation of the samples would be an advisable option, especially in a study setting with a predefined rack layout.

378: Improving sample annotation by algorithm- based mapping of diagnoses and sample types using surgical codes (OPS) from the local cancer registry.

by Daniel Brucker | Timo Schneider | Julia Bein | Jaqueline Patzek | Kristina Götze | interdisciplinary Biobank and Database Frankfurt | interdisciplinary

Topic: 10B: Ensuring Excellence: Elevating Data Quality in Biobanking Presenter Name: Daniel Brucker Keywords: Data quality, automated sample annotation, cancer registry, searchability, surgical codes

In everyday clinical practice, oncological diagnoses are often only established some time after an initial operation. Therefore, a final diagnosis cannot be assigned to some tissue samples at the time of storage. This process must be carried out subsequently and is timeconsuming. In order to be able to implement the missing annotation of the samples afterwards in a resource-saving manner, an algorithm was developed which assigns the samples to the corresponding diagnosis from the local cancer registry. For this purpose, all operations that could presumably generate tissue samples for the biobank were compiled in a comprehensive OPS catalog. The samples are assigned to suitable operations based on the operation and sample receipt date. Subsequent annotation of the samples is

carried out with the diagnosis from the cancer registry associated with the operation.

In contrast to fresh tissue samples, the paraffin samples from the pathological archive are not routinely recorded for the biobank. Therefore, the formation of cohorts of suitable patients for scientific research projects is only possible to a limited extent. To address this problem, virtual paraffin samples were generated on the basis of the OPS catalog described above, which are not directly stored in the biobank, but are also available for research questions via the pathology archive.

By using these algorithms, the UCT Biobank was able to significantly increase the findability of suitable samples for research projects and thus provide scientists with better access to suitable tissues.

TRACK 3. Biobanks -Pathways to Quality and Efficiency

3C: Biobank Automation: Challenges, Opportunities and Solutions

329: The Path to Fully Automated Sample Documentation in the Healthcare-Embedded Biobank at UKSH

by Samer Kadibalban | Antje Torge | Hao Qian | Heike Lehmann | Andre Franke | Ralf Junker | Jeanette Franzenburg | University Hospital Schleswig-Holstein | University Hospital Schleswig-Holstein |

University Hospital Schleswig-Holstein | University Hospital Schleswig-Holstein | University Hospital Schleswig-Holstein | University Hospital Schleswig-Holstein | University Hospital Schleswig-Holstein Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions Presenter Name: Samer Alban | Jeanette Franzenburg Keywords: HEB, Kiel University, Kiel uniklinikum, UKSH, precision medicine

Advancing precision medicine depends on extensive clinical data and biomaterial collections from diverse patient groups. To regulate these efforts, the Healthcareembedded Biobank (HEB) at the University Hospital Schleswig-Holstein (UKSH) integrates biobanking services directly into hospital operations. This is achieved through a projectindependent broad consent, enabling more effective data and sample management, which in turn improves medical research. The HEB database system is integrated with the hospital's order entry system, laboratory information system and laboratory automation for routine diagnostics. This has significantly improved the accessibility, efficiency, and reliability of biobank data. To date, the HEB at UKSH has accumulated over 350,000 samples, including serum, plasma, buffy coats, urine, saliva, and PBMC. Moreover, 30,000 samples have been provided for 50 research projects. Managing vast datasets from multiple sources while ensuring data integrity presents a considerable challenge. To overcome this, the biobank has made automation a key priority, progressively enhancing its processes with inhouse scripting and third-party services towards the end goal of achieving full automation. By implementing automated workflows, the HEB not only reduces manual labour and human error but also accelerates sample processing and data retrieval. As a result, this enables researchers to access highquality, standardized data more efficiently. Looking ahead, the biobank aims to integrate artificial intelligence algorithms to further optimize data integrity and data management, and enhance sample traceability. This will strengthen the biobank's role as a central component of precision medicine at the UKSH, supporting medical research and improving healthcare outcomes.

256: iPSC Factory: an automated cell factory for the production of iPSC

by Silvia Pellegrini | Giusy Di Giuseppe | Clarissa Meoni | Cristina Tresoldi | IRCCS Ospedale San Raffaele- Centro Risorse Biologiche | IRCCS Ospedale San Raffaele - Centro Risorse Biologiche | IRCCS Ospedale San Raffaele - Centro Risorse Biologiche | IRCCS Ospedale San Raffaele - Centro Risorse Biologiche

> Topic: 3C: Biobank Automation: Challenges, Opportunities and Solutions Presenter Name: Cristina Tresoldi Keywords: facility, iPSC, reprogramming

Background

The iPSC Factory_Biological Resource Center integrated (CRB-OSR), established in 2022, specializes in producing, characterizing, and biobanking high-quality induced pluripotent stem cell (iPSC) lines using high-throughput automated platforms. Over the past two years, we refined protocols for reprogramming somatic cells into iPSC with automated procedures, focusing on reproducibility, efficiency, and rigorous quality control.

Materials and Methods

Our workflow involves fibroblast preparation and iPSC reprogramming. Fibroblasts, isolated from skin biopsies, are expanded and characterized via karyotype analysis, Short Tandem Repeat (STR) profiling, Mycoplasma testing, and cryopreservation. Reprogramming employs non-integrating RNA-based methods with reprogramming factors under low oxygen conditions to enhance efficiency. After 10–14 days, iPSC colonies are enriched for TRA 1-60 expression using magnetic beads. Single cells are plated at low density, and compact, round iPSC colonies are manually picked and expanded as individual clones using the automated platform. Quality control includes karyotype analysis, STR profiling, Mycoplasma testing, and flow cytometry for pluripotency markers (OCT4, SOX2, TRA-1-60, SSEA-4). Differentiation potential is validated by inducing differentiation into three germ layers, confirmed via flow cytometry of lineagespecific markers: PAX6 (Ectoderm), CXCR4 (Endoderm), and CD144/CD140b (Mesoderm).

Results

Our automated protocol reliably generates high-quality iPSC lines, averaging three clones per donor. Anti-TRA 1-60 bead sorting enriches pluripotent cells, while manual picking isolates compact, morphologically typical clones. Quality control confirms genomic stability, identity, and pluripotency, with trilineage differentiation validating the potential to form all germ layers.

Conclusions

The iPSC Factory's standardized, automated pipeline ensures stable, genetically intact, pluripotent iPSC lines, enabling scalable biobanking and supporting diverse regenerative medicine applications.

4C: Implementing and Securing Quality Control in Biobanking

234: THE IMPLEMENTATION OF A BIOLOGICAL SAMPLES QUALITY CONTROL SYSTEM IN A RESEARCH BIOBANK – THE EXPERIENCE OF THE UNIVERSITY HOSPITAL OF PADOVA

by D'Angelo, E | Benna, C | Aita, A | Sciacovelli, L | Spolverato, G | Agostini, M | Montagnana, M | Pucciarelli, S | Basso, D | Department of Surgery, Oncology, and Gastroenterology, University of Padova,

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Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: D\'Angelo, E Keywords: biobanking, biomarker, pre-analytical standard, quality control, survey

Quality controls and standardized protocols ensure reliable and reproducible data from specimens stored in biobanks.

The study aimed to examine analyte stability over time under different pre-analytical storage and handling conditions in two steps.

 A survey was designed to provide a snapshot of the pre-analytical procedures followed by clinical wards (CWs) of the University-Hospital of Padova (Italy) that actively enroll patients. The collection of blood samples from 11 healthy volunteers. The samples were kept uncentrifuged for 1, 4, 8, and 24h. At each time point, samples were centrifuged at 3500g for 5 min, and the following seven biochemical markers were analyzed in plasma: ALT, AST, γGT, glucose, LDH, K+, C-Reactive Protein (CRP), and HIL (hemolysis-icteruslipemia) index.

Concerning the results:

- 16 CWs participated in the survey, showing substantial differences in the time from collection to centrifugation (T1) and centrifugation parameters. Only 13% of CWs completed T1 within 2 hours. Centrifugation speeds ranged from 400g to 3800g, introducing potential variability in sample quality.
- AST, ALT, γGT, and CRP remained stable regardless of separation time. K+ and glucose showed significant changes after a 4-hour delay and continued to decrease significantly at an 8-hour delay compared to the reference (p<0.0001 for both). LDH concentration increased significantly after a 24-hour delay (p<0.05). All HIL indices were negative for all specimens at each time point.

This study emphasizes the need for unified protocols and quality control to ensure suitable specimens, offering a framework for optimizing blood processing and enhancing data integrity in biobanking research.

248: The accreditation of the Integrated Biobank Jena (IBBJ) – Aiming for highest quality standards and controls of biological samples and data

by Christine Hess | Juliane Kaufmann | Julia Köhler | Cora Richert | Kay Stötzer | Sabrina Rehbein | Daniel Barth | Marcus Martin | Michael Kiehntopf | Integrated Biobank Jena, University Hospital Jena | Institute for Clinical Chemistry and Laboratory Diagnostics, University Hospital Jena | Integrated Biobank Jena, University Hospital Jena | Institute for Clinical Chemistry and Laboratory Diagnostics, University Hospital

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Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Christine Hess Keywords: Accreditation, DIN EN ISO 20387, QMS

The Integrated Biobank Jena (IBBJ) demonstrated a certified quality management system (QMS) according to DIN EN ISO 9001 since 2018. The IBBJ aimed to receive accreditation for their processes, including all liquid specimens handled and quality controls performed as well as competence assessment according to the DIN EN ISO 20387.

In 2022 the IBBJ obtained an "accreditationworthy biobank status" as result of several GBA/GBN Friendly Audits. Still, a huge effort was exaggerated to prepare for accreditation: (a) QM topics were set priority and small teams worked on re-validation (including improvement and development of workflows) of critical infrastructure, responsibilities, data protection and risk management. (b) Core processes were reviewed internally. (c) A new QM tool was introduced and the QMS reorganized. Documents were revised and reassigned. (d) The data management system (CentraXX) was evaluated and extended. The German Accreditation Body (DakkS) appraised the IBBJ in May and November 2024. In total, nine minor deviations were documented.

The IBBJ proofed their processes for all biological liquid materials received and all methods applied to be comprehensive to the DIN ISO EN 20387. The final assessment and certification by the DAkkS is currently awaited.

In reflection, the whole project was truly a team effort that was worth is. By critical consideration of requirements and "real life" biobanking, the team created a balance between not getting lost in small-scale documentations and improving the workflows serving our goals. We would like to encourage other biobanks to discuss the matter with us and share experiences.

288: Get Ready for Biobank Accreditation with the Biospecimen Proficiency Testing Program

by Olga Kofanova | Integrated Biobank of Luxembourg (IBBL), Luxembourg Institute of Health (LIH)

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Olga Kofanova Keywords: biospecimen, external quality control, proficiency testing

A participation in Proficiency Testing (PT) program is one of the crucial component in any laboratory's quality system. The Biospecimen PT program, developed by the Integrated Biobank of Luxembourg (LIH IBBL) in 2011, was designed to assess the performance and capabilities of biobank laboratories. It especially evaluates the performance of laboratories in processing, handling and storing, ensuring that biospecimens meet the quality standards required for clinical and research applications. The IBBL PT program evaluates processes, such as DNA and RNA extraction from various biospecimens like whole blood, buffy coat, FFPE and frozen tissue, stool, saliva, as well as cell-free DNA/RNA extraction and viable PBMC or circulating tumour cell isolation.

By providing independent assessments of laboratory performance, the PT program helps identify variables that affect the quality of biospecimens and provides insight into potential sources of error, such as method imprecision, systematic errors, and/or human factors. Different quality metrics, such as yield, purity, integrity, viability and biospecimen fitness for purpose, are assessed. These evaluations help the standardization of biobank processes, enhancing the quality, reliability, and consistency of biospecimens, thus ensuring the reproducibility of research and clinical studies. Regular participation in the PT program can improve a laboratory performance over time.

The PT program represents an essential tool in the mission of standardization of biobank laboratories. A participation in PT program helps laboratories demonstrate compliance with regulatory standards, which are essential for meeting the expectations of regulatory bodies and for acquiring or maintaining accreditation.

316: Essential storage safety precautions in a biosample vault *by Andreas Nessel | DZNE e.V.*

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Andreas Nessel Keywords: Biobanking, Biorepository, DZNE, Safety

Setting up a biobank takes time and one critical part is the safety of your samples. The DZNE Biorepository has implemented several levels of precautions in case of emergencies.

To begin, a well-setup data surveillance is crucial. Abnormalities trigger an alarm via several ways of communication. Some alarms have an automatic reaction in place for predefined emergency protocols.

Every sample location has 3 levels of security; any alerts are carefully analyzed with protocoldefined decisions taken.

With only a small team on site, detailed and precise training procedures to be refreshed yearly are crucial and leave less room for human error.

Sample safety is priority number one.

338: Management of incidents and nonconformities through the Biobank Information Management System (BIMS) in the frame of the quality management system (QMS) of the SSPA Biobank

by Ana María Sánchez López | Enrique Cano | Manuel Gómez | Jose Manuel Puerta-Puerta | Rocío Aguilar-Quesada | Andalusian Public Health System Biobank, Coordinating Node, 18016 Granada, Spain, and Instituto de Investigación Sanitaria Ibs.Granada, 18012 Granada, Spain | Biosoft Innovation, S.L. | Biosoft Innovation, S.L. | Andalusian Public Health System Biobank, Coordinating Node, 18016 Granada, Spain and Unidad de Gestión Clínica Hematología y Hemoterapia, Hospital Universitario Virgen de las Nieves, 18014 Granada, Spain. | Andalusian Public Health System Biobank, Coordinating Node, 18016 Granada, Spain

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Ana M. Sánchez-López Keywords: BIMS (Biobank Information Management System), QMS (Quality Management System), incidents, non-conformities

Introduction: The Andalusian Public Health System Biobank (SSPA Biobank) works in the frame of a network well-implemented quality management system (QMS) certified by ISO 9001:2015, which addresses any activity that impacts on the quality of samples and their associated data. The QMS is a requirement of the 20387:2018 standard focused on biobanking. Until recently, the SSPA Biobank process for reporting and recording of incidents and non-conformities as well as the monitoring and analysis of corrective actions, was performed in an independent commercial software. In order to facilitate and improve the efficiency and involvement of the Biobank personnel, the SSPA Biobank has implemented this process into its comprehensive BIMS, nSIBAI.

<u>Material & Methods</u>: The data model and the workflow were reviewed to include the necessary information, records and forms into the BIMS, nSIBAI.

<u>Results</u>: The data model and fields have been established for incidents and non-conformities, corrective or preventive actions, and tasks and alerts to the personnel involved. Moreover, a manual and a semi-automatically way for reporting of incidents and non-conformities have been implemented as well as the possibility of printing reports for audits.

<u>Discussion</u> and <u>Conclusion</u>: The implementation of this process in a unique

BIMS has led to an increasing in the reporting of incidents and non-conformities of 26%. In addition, this improvement permits that all professionals of any node of the SSPA Biobank can see all incidents and non-conformities and their corrective actions, which promotes networking, learning and opportunities for the SSPA Biobank.

391: Implementation of a Quality Management System for a new adult adipose tissue-derived stem cell Biobank

by Ramona Palombo | Antonella Nicolò | Alessia Leone | Daniela Criscuolo | Maria Marotta | Domenico Conza | Marialuisa Moccia | Michele Campitelli | Martina Chiacchiarini | Valentina Fioretti | Mauro Miele

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Immunology CNR | Institute of Endotypes in Oncology, Metabolism, and Immunology - CNR | Institute of Endotypes in

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> Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Rocco Caggiano

Keywords: Adipose Tissue-Derived Stem Cells (ADSCs), BMRI QUALITY LABEL, Biobank, ISO20387, Quality Management System (QMS), Regenerative Medicine

The increasing significance of biobanks in biomedical research demands high-quality standards to ensure the reproducibility of scientific results. These biological repositories must adhere to national legislative frameworks and meet necessary legal and administrative requirements. Implementing a quality management system (QMS) is a critical step for guaranteeing sample quality and integrity.

As part of the project "Strengthening the Research Infrastructure on Biobanks and Biomolecular Resources in Italy" (BBMRI.it), a new biobank 4.0 will be established for the collection of adipose tissue-derived stem cells (ADSCs). This initiative aims to support studies on predictive features for regenerative therapies, with all biobanking processes designed to meet the highest quality standard in the field. For this purpose, the program includes the recruiting of personnel who will receive specialized training and will be supported by the QMS.

Objectives

Comprehensive staff training in ISO 20387 guidelines in general biobanking procedures Establish standardized procedures for the collection, processing, and storage of ADSC samples.

Conduct regular internal audits to assess potential risks and evaluate biobank performance.

Expected Results

This approach will ensure the establishment of standardized and traceable processes from the

outset and will mitigate many operational and compliance challenges commonly encountered by newly established biobanks. It will also foster the achievement of the BBMRI quality label and facilitate the future accreditation of the biobank to ISO 20387.

Conclusions

The final aim is to ensure that all the procedures for the new biobank of ADSCs will be sustainable and reliable to establish a prominent position in the scientific community.

396: Optimizing Standard Operating Procedures for PBMC Isolation in Biobanks: A Quality Control Approach

by Lavinia Curini | Chiara Zara | Alisia Madè | Rosanna Cardani | Laura Valentina Renna | Biobank BioCor, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy | Miltenyi Biotec SRLU Italy |

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Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Lavinia Curini Keywords: PBMC, cell isolation, cryopreservation, flow cytometry

Introduction. Peripheral blood mononuclear cells (PBMCs) play a crucial role in immunological research, serving as a model for cell proliferation and transcription factor expression. These cells are frequently collected and stored in biobanks. Since biobanks are specialized infrastructures aimed at preserving high-quality biological samples, ensuring the integrity of PBMCs during their isolation, storage, and cryopreservation is crucial for

supporting reliable and reproducible research outcomes. Common isolation methods, like Ficoll® and SepMate tubes, can leave residual red blood cells (RBCs) in the PBMCs fraction, leading to contamination that may interfere with cell sorting. In this study, we aimed to compare PBMCs isolation and freezing methods to define the best procedures for obtaining high-quality samples in terms of purity and viability.

Methods. To optimize purity, we compared PBMCs isolation with and without RBCs sedimentation step, which helps remove erythrocytes selectively. Additionally, three cryopreservation methods—storage at -80°C, liquid nitrogen, and planer freezing—were tested to determine the best approach for preserving PBMCs viability and integrity.The 8-Color Immunophenotyping Kit, (Miltenyi Biotec), and the MACSQuant[®] Analyzer flow cytometer were used to assess the PBMCs fraction in both conditions.

Results. Flow cytometry analysis revealed an increase (average 1-3%) in the proportions of classical dendritic cells, monocytes, eosinophils, neutrophils, and NK cells in RBC-removed samples, although total cell numbers and viability were lower compared to non-sedimented samples.

Discussion. This procedure brought improvements in terms of sample purity and quality, but still requires refinement to enhance cell yield and viability. Nevertheless, holds significant potential for experimental applications.

400: Quality assurance along the biobanking cycle of tissue samples

by Carolin Kaufhold-Wedel | Peter Schirmacher | Alexander Brobeil | Tissue Bank of the National Center for Tumor Diseases (NCT) Heidelberg, Germany | Institute of Pathology, Heidelberg University Hospital,

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> Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Carolin Kaufhold-Wedel Keywords: ISO 20387, compliance, quality assurance, tissue biobanking

Quality assurance is essential in biobanking, particularly for tissue samples, as it ensures their integrity, stability, and fit for purpose for research and diagnostics. Tissue samples are valuable biological resources that have to be collected, processed, stored, and transported under strict and quality-controlled conditions to preserve their structural and molecular integrity. Without rigorous quality control, morphological and molecular degradation or misidentification can occur, compromising the reliability of scientific studies and clinical applications. Additionally, data quality in terms of traceability, ensuring each sample's history—from collection to delivery—including entire documentation, is just as important as sample quality. This is particularly vital for personalized medicine and clinical trials, where data accuracy directly impacts patient outcomes.

The highest level of quality assurance can be achieved through accreditation according to ISO 20387 confirming the biobank to provide fit-for-purpose biological samples. Quality assurance measures must be implemented in diverse life cycle stages of a tissue sample within a biobank. Here, we present a collection of meaningful measures, which facilitate sustaining high-quality tissue samples such as entry and exit control for identity verification, monitoring of storage conditions and sanity check of data.

By implementing rigorous quality management, biobanks ensure trust among researchers, clinicians, and regulatory bodies. Ensuring quality at every step maximizes the scientific and clinical value of tissue samples, strengthening their role in advancing medical research and patient care.

449: Continuous Surveillance and Internal Quality Control: A Case Study of Viable PBMCs Isolation and Cryopreservation Processing Methods

by Pauline Lambert | Wim Ammerlaan | Alexander Hundt | Olga Kofanova | Integrated Biobank of Luxembourg (IBBL), Luxembourg Institute of Health (LIH) | Integrated Biobank of Luxembourg (IBBL), Luxembourg Institute of Health (LIH) | Integrated Biobank of Luxembourg (IBBL), Luxembourg Institute of Health (LIH) | Integrated Biobank of Luxembourg (IBBL), Luxembourg Institute of Health (LIH)

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Pauline Lambert Keywords: ACQA, Internal Quality Control, PBMCs Isolation

For biobanks that also offer sample processing services, like IBBL, the consistent production of high quality, fit-for-purpose derivatives is of primary importance. One of the main challenges is continuously monitoring and controlling factors that impact quality of samples and derivatives. This is particularly significant in production of viable PBMCs for functional assays and elucidating the dynamic phenotypical status of donors. Hence, it is crucial to control and monitor the viability and cellular yields to ensure they are fit-forpurpose.

The quality of cryopreserved PBMCs produced cannot be monitored in the study samples themselves, as this would require sacrificing study samples. As an alternative approach, IBBL implemented the **ACQA** (<u>Annual Control</u> <u>Quality Assessment</u>) monthly collection program to provide, amongst others, viable PBMC samples dedicated to quality control monitoring.

This approach enables regular assessment of cell viability, yield, and recovery from whole blood before and after cryopreservation. By integrating these quality control samples into our workflow, we can monitor and validate the entire biobanking process (from blood collection to PBMC isolation, cryopreservation, storage, redistribution and final use) on a monthly basis.

Over the course of three years, the study has demonstrated that IBBL's standardized processing ensures consistent PBMC viability and yield, confirming that both parameters are fit-for-purpose for downstream applications. Furthermore, data analysis allowed the characterization of differences between automated and manual processing methods using CPT blood tubes, providing valuable insights for processes optimization. These results highlight the benefits of a systematic approach to internal quality control of processing methods.

453: Achieving Precision in Biobanking: Trend Analysis of DNA Quantification Methods to Boost Lab Performance

by Monika Markovic Bordoski | Linda Hannigan | Eiman Al Khayat | Dr. Fatima Qafoud | MSc | MSc | MBA | Dr

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Dr. Fatima Qafoud Keywords: Coefficient of Variation (CV%), DNA quantification, Lewy-Jennings QC charts, Quality control, lab process effectiveness

Introduction: In Qatar Biobank, as part of ongoing quality control, DNA testing performance was monitored using Lewy-Jennings QC charts to ensure high-quality control and accuracy in DNA quantification. Data analysis, including standard deviation (SD) and coefficient of variation (CV%), helped identify deviations and implement corrective actions.

Methods: The analysis used raw data from QC charts for DNA quantity, over four years, calculating SD and CV% monthly from in-house positive controls. The SD and CV were assessed for three DNA quantification methods: spectrophotometric, automated fluorometric, and manual fluorometric. Deviations were tracked, and corrective actions were taken.

Results: Automated Fluorometric: SD and CV% showed significant improvement, with CV% decreasing from 8.6% in 2021 to 2.7% in 2024. **Manual Fluorometric:** SD and CV% reduced from 9.8% in 2021 to 3.98% in 2024. **Spectrophotometric:** SD and CV% decreased from 7.2% in 2021 to 4.12% in 2024. The average CV% was reduced from 8.5% in 2021 to 3.6% in 2024, reflecting overall improvement. **Discussion:** The automated method showed significant reduction in CV% and SD, indicating better consistency. Manual method showed

higher variability, attributed to technique and reagent handling inconsistencies. Root cause analysis identified areas for improvement in staff training and reagent management. Automation minimized human error, enhancing reliability and reducing variability. Conclusion: Monitoring CV% and SD is essential for evaluating lab process effectiveness. As manual method continued to show variability, corrective actions addressed the identified challenges. The laboratory will continue to monitor and refine quality control processes to ensure ongoing reliability and accuracy of DNA testing procedures.

464: Thermal excursions of cryogenically frozen vials (below -150°C) and the risk of rising above Tg,H2O: analyzing warmup rates from cryogenic storage to both dry ice and ambient temperature environments

by Erica Waller | Azenta Life Sciences, Massachusetts, USA

Topic: 4C: Implementing and Securing Quality Control in Biobanking Presenter Name: Erica Waller Keywords: Cryogenic storage, LN2 vapor, biological sample preservation, cold-chain handling, dry ice transport, finite element simulation, glass transition temperature, thermal excursions, vial thermal response., warm-up rates

Biological samples are often preserved at cryogenic temperatures (below -150°C) in liquid nitrogen (LN2) vapor-phase freezers to minimize degradation and metabolic activity. This preservation is based on maintaining the sample below the glass transition temperature (Tg). However, when samples are handled or temporarily removed from LN2 storage, they may undergo rapid thermal excursions, with warm-up rates of several degrees per second, potentially breaching the Tg threshold and compromising sample integrity.

This study characterizes the thermal behavior of single cryogenically frozen vials filled with water (H_2O) during such transient temperature events. Water-filled vials are used as proxies to approximate the thermal response of a variety of bio-materials. The focus is on evaluating warm-up conditions when a vial transitions from an LN2 vapor environment to either room temperature (RT) or a dry ice (-80°C) environment.

Key factors influencing heat transfer include environmental temperature, exposure duration, vial size and shape, water volume, cryobox positioning, and handling method (manual or automated). Experimental measurements are complemented by calibrated finite element simulations to quantify typical warm-up rates. These findings enable the identification of best-practice time constants for safe vial handling, minimizing the risk of exceeding Tg for H_2O (Tg, H_2O).

Ultimately, this work provides practical guidelines for optimizing cold-chain procedures and ensuring the thermal safety of cryopreserved biological samples during handling and transfer.

5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

242: Quality of human body material samples for potential use in scientific research evaluated after been stored for long time at Sciensano – Fit for purpose project

by David Triest | Pauline Pauss | Marina Mukovnikova | Alexandra Vodolazkaia | Sciensano, Scientific Directorate Infectious Diseases in Humans, Laboratory of Medical Microbiology | Sciensano, Scientific

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: David Triest Keywords: Assay positivity, Fitness, Long-term storage, Pathogen stability

High-quality human body material (HBM) samples are required for valid scientific research. However, the effects of long-term sample storage on their future research potential are not well-known. Particularly for HBM samples studied in the context of human infectious diseases, an important domain of expertise of the Belgian health institute Sciensano. The objective of this project is to evaluate the fitness of long-term (> 1 year) stored HBM samples at Sciensano for their potential use in future research concerning human infectious diseases of interest to Sciensano. Depending on the HBM sample type, these samples are stored in (ultra-)low temperature freezers or cryo-tanks, several of them already for many years. An extensive literature study on this subject has been performed and the gaps of knowledge were identified. In this project, samples that have been positively analyzed in the past at

Sciensano for a pathogen of interest, will be evaluated. The applied quality control biomarker to evaluate the fitness will be the loss of assay positivity per storage year, determined after re-analysis of the samples according to the assay that was applied for obtaining the initial study or diagnostic / surveillance result. Different assays (PCR, immuno, ...) will therefore be used. By comparing the previously obtained assay results of the selected HBM samples with their re-testing results, the duration of long-term sample conservation without loss of quality can be assessed. This will lead to the setting-up of guidelines on storage duration of our HBM samples, depending on the sample type and pathogen analyzed.

257: Optimizing pre-analytical conditions: the impact of sample handling in hypoxia studies on gene expression and proliferation in cellular models

by Agnieszka Mroczko | Stefan Rudziński | Ilona Szabłowska-Gadomska | Laboratory for Cell Research and Application, Medical University of Warsaw, 02-097 Warsaw, Poland | Laboratory for Cell Research and Application, Medical University of Warsaw, 02-097 Warsaw, Poland | Laboratory for Cell Research and Application, Medical University of Warsaw, 02-097 Warsaw, Poland

Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Stefan Rudziński Keyword

s: cell culture conditions, hypoxia, oxygen level,

standarization

Introduction

This study underscores the necessity for standardization in the terminology related to

hypoxia in cell culture research to assure the pre-analytical quality of *in vitro* samples. We aimed to investigate how cell cultures respond to continuous hypoxia condition compared to intermittent hypoxia condition, called "semihypoxia".

Materials and methods

Mesenchymal stem/stromal cells (ADSC and BMSC), and the osteosarcoma U-2 OS cell line were used. The cell culture process was divided into two phases, incubation and preparation, each subjected to varying oxygen levels: 21% O₂ (ambient level for both), 5% O₂ (the BioSpherix system for both), and 5/21% O₂ (5% O₂ and 21% O₂, respectively). Cell activity was assessed through the expression of *Ki67*, *H2AX*, *POU5F1*, and *VEGFA*. Various housekeeping genes, *B2M*, *RPLPO*, *GAPDH*, and *YWHAZ*, were evaluated for oxygen-related deviations. Cell proliferation was assessed by the Presto Blue assay.

Results

The expression levels of *Ki67*, *H2AX*, *POU5F1*, and *VEGFA* exhibited mixed trends that varied depending on the oxygen conditions, while B2M demonstrated stability across conditions, serving as a reliable housekeeping gene. The Presto Blue analysis indicated that both 5% O2 and 5/21% O2 conditions promoted higher proliferation rates in BMSC and U-2 OS, particularly at the 48-hour and 96-hour time points. In contrast, ADSC demonstrated the highest proliferation rate in 21% O2.

Discussion

Our findings showed the discrepancy between proliferation rate and *Ki67* expression levels in

5% O₂ and 5/21% O₂. This emphasizes the necessity for the precise definition of conditions used in cell culture throughout the entire process.

332: Sustainable organization of biobank freezing infrastructure to be a safe harbor for biomaterials

by Gruber, Franz | Doppler, Christian | Ivek Propadalo, Elena | Kubasta, Christa | Langer, Rupert | Liebmann, Eva | Spiegl-Kreinecker, Sabine | Bernhard, David | Center for Medical Research, Johannes

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Franz Gruber | Ivek Propadalo, Elena Keywords: biobank emergency system, risk

prevention, temperature control

Introduction

A key task of biobanks is to guarantee that biomaterials are stored under safe temperature conditions, which includes permanent maintenance of the cold chain under predefined temperature values. We report our undertaking to set up an emergency system from scratch and our experiences in the follow up period. The system contains technical components, computer and communication tools and trained staff.

Methods

The following measures were implemented

- Connection with facility the management system and а communication tool notify to emergency staff as central part of the emergency system. In parallel, an independent alarm monitoring system was used.
- Equivalent reserve equipment was
- installed.

A data logger system was placed inside storage racks in order to document biomaterial temperature during transfer between freezers.

• Comparison of the temperature robustness of nitrogen cryogenic tanks and freezers.

Findings

Diverse risk factors were identified with the potential that the worst case happens, i.e. unintended thawing of samples. Preventive measures were implemented to circumvent risks.

Some relevant risk factors are

- Failure in alarm chain and emergency
- staff is not notified
- Reserve equipment not ready for use
- Blackout: insufficient backup electricity
- Fast temperature increases in ULT freezer
- Uncontrolled biomaterial temperature in case of emergency transfer

Conclusion

Risk factors were identified and considered in setup of the emergency system.

A bundle of emergency and control measures was implemented to maintain and document safe and constant cold chain conditions and conceptual approaches to minimize temperature risk for biomaterials were identified (e.g. temperature robustness in cryovessels versus storage in electrical driven freezers).

342: Evaluating cryopreservation methods in biobanking: impacts on biomarker integrity and OMICS data reliability

by Annamaria Antona | Valentina Bettio | Jacopo Venetucci | Silvia Vittoria Cracas | Eleonora Mazzucco |

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of Pre-analytics

Presenter Name: Valentina Bettio Keywords: OMICS, biobanking, blood biomarkers, cryopreservation, cryovials, sample quality, sample storage, straw

Introduction: Personalized medicine relies on genetic screening and biomarker assessment. Biobanks support this effort by providing highquality biospecimens. This study investigated optimal long-term storage by evaluating plasma and serum samples cryopreserved in cryovials and straws at the UPO Biobank. The goal was to determine the impact of these storage methods on various analytical methodologies.

Material & methods: Samples were subjected to standard biochemical laboratory analyses, targeted lipidomics, untargeted proteomics, and targeted metabolite quantification via UHPLC-MS/MS.

Results: Lipidomic analysis revealed minor abundance differences, primarily affecting specific fatty acid species. Proteomic and metabolomic analyses uncovered abundance variations in a small but significant fraction of analytes between cryovials- and strawderived samples.

Discussion and conclusions: This study provides insights for optimizing biobanking practices and understanding factors influencing cryopreserved biospecimen integrity and data reliability. Both cryovials and straws offer convenient and efficient cryopreservation, proving essentially equivalent for robust, lower-sensitivity standardized analyses. Critically, the findings emphasize caution when interpreting OMICS data from samples subjected to different cryopreservation methods, as subtle variations can arise even with different container types.

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345: The Role of Biobanks in PFAS Research: Standardized Sample Management in the SCENARIOS Project

by Libener Roberta | Giacchero Fabio | Farotto Marianna | Amore Valentina | Oliveri Giulia | Bolgeo Tatiana | Dondero Francesco | Maconi Antonio | Bertolotti Marinella | Research and Innovation

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Libener Roberta Keywords: Biobank, Biological Samples, PFAS, Research

Introduction: Perfluoroalkyl substances (PFAS) are aliphatic compounds in which hydrogen

atoms are replaced by fluorine, creating a strong bond resistant to heat and degradation. These substances persist in the environment and accumulate in the food chain, raising concerns for human and environmental health.

As part of the European SCENARIOS project, two studies aimed to identify and quantify PFAS in biological and non-biological samples and investigate their relationship with the postvaccination COVID-19 immune response. To ensure reliability, a structured approach to sample collection, processing, and storage was essential. The Alessandria Biobank played a key role in preserving biological materials under controlled conditions.

Material & Methods: Blood, urine, and drinking water samples were collected, placed in thermally insulated containers with dry ice, and delivered to the Alessandria Biobank. Samples were processed and stored at -80°C within one hour, following standardized protocols to maintain integrity.

Results: Samples from 239 individuals were collected over a year, yielding approximately 1,022 aliquots cataloged in the biobank's repository.

Discussion & Conclusion: Proper sample processing and storage are critical for data reliability. The Alessandria Biobank ensured standardized handling, minimizing variability. These procedures require expertise and resources, which must be considered in research design. The collaboration between SCENARIOS and the biobank highlights the importance of biobanks in environmental health studies, ensuring high-quality, reproducible research. Standardized sample management significantly enhances the

reliability of epidemiological and environmental investigations.

353: THE IMPORTANCE OF LONG-TERM SERUM BIOBANKING FOR FUTURE CARDIOVASCULAR RESEARCH AND BIOMARKER DISCOVERY

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Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Laura Valentina Renna Keywords: biobanking, biomarkers, cardiovascular diseases, quality control

Introduction. Biobanks represent a resource for research, storing high-quality samples and related data. Although it is known that multiple preanalytical factors and long-term storage can affect human samples integrity, objective markers that can measure samples stability still have to be defined. In this work we analyse the stability over time of biomarkers commonly analysed in cardiovascular (CV) patients by clinical chemistry assays.

Methods. In 2022, along with the Italian Cardiology Network, a research project was started aiming to compare different interventions in reducing CV risk and to create an important collection of high-quality biosamples for future research. A total of 1091 subjects were enrolled and performed at baseline various clinical chemistry assays related to CV risk before biobanking. Among them, sera from 367 subjects were re-tested after storage in BioCor Biobank to analyse blood markers variation over time (glucose, cholesterol, triglyceride, NTproBNP, TSH).

Conclusions. Results and Glucose measurement was significantly lower after frozen storage in biobank when compared to fresh samples (p<0.0001). Interestingly, these differences were more evident in samples stored for more than 551 days compared to samples stored for less days (p=0.0003 vs p=0.0008). On the contrary, TSH, triglyceride, total cholesterol and NTproBNP showed no difference in measurements over time. suggesting that freezing processing and storage in BioCor didn't affect sample quality for those measurements. Our results demonstrate that long-term biobanking of serum samples is invaluable for future cardiovascular research, as it enables retrospective analyses and the discovery of novel biomarkers, supporting advancements in prevention, diagnosis and treatment.

354: EU Horizon Europe no. 101057129: REACT – Respiratory host pathogen interaction – Setup of a prospective sample collection in Denmark

by Nina Drøjdahl-Ryg | Maria Vistrup-Parry | Karina Meden Sørensen | Lydia Viekær | Cathrine Hansen | Ramona Trebbien | Ria Lassaunière | Morten Rasmussen | Amanda Bolt Botnen | Sofie Hørlyck | Máiréid

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National Biobank | Statens Serum Institut – The Danish National Biobank | Statens Serum Institut – The

Danish National Biobank | Statens Serum Institut -Department of Virology and Microbiological Preparedness | Statens Serum Institut -Department of Virology and Microbiological Preparedness |

Statens Serum Institut - Department of Virology and Microbiological Preparedness | Statens Serum Institut - Department of Virology and Microbiological Preparedness | Statens Serum Institut - Department of Virology and Microbiological Preparedness | Statens Serum Institut - Department of Virology and Microbiological Preparedness | Rigshospitalet Denmark - Department of Infectious Diseases | Rigshospitalet Denmark - Department of Infectious Diseases | Rigshospitalet Denmark - Department of Paediatrics and Adolescent Medicine | Statens Serum Institut – Digital Infrastructure | Technical University of Denmark - Department of Health Technology | Technical University of Denmark -Department of Health Technology | Technical University of Denmark - Department of Health Technology |

Hvidovre Hospital - Department of Infectious Diseases | Hvidovre Hospital - Department of Infectious

Diseases | Centro Nacional de Investigaciones Oncológicas - CNIO biobank | Centro Nacional de Investigaciones Oncológicas - CNIO biobank | The REACT Consortium

Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics

Presenter Name: Nina Drøjdahl-Ryg Keywords: , Covid, EU Horizon Europe, Influenza, LRL, PBMC, REACT, RSV, airway secretion, blood, collection, general practice, hospitals, immunology, logistics, patients, samples, virus The REACT project is conducted by 12 partners from 5 countries (https://react-euproject.eu) exploring in-depth virus-host interactions and disease outcomes for influenza virus, SARSCoV-2, and Respiratory Syncytial Virus, by integrating samples, data and new analyses from de-novo collected samples and existing cohorts. Within work Package 2 of the project, a Danish prospective cohort was established, collecting samples within 4-8-hour from venipuncture to processing. The project is currently ongoing.

Patients with Influenza-Like Illness are enrolled during the respiratory viral seasons of 2023-2025, by recruiting patients from general practice (GPs) (adults) and hospitalized patients (adults and children 0-15 years). Blood and airway material are collected for immunological, genetic, and viral analyses. Participating hospitals (Rigshospitalet and Hvidovre Hospital) and 6 GP clinics are located in the Copenhagen area in the 4-12 km vicinity of The Danish National Biobank at Statens Serum Institute (SSI), and daily fixedschedule transport to SSI ensures rapid transport enabling same-day processing for virus identification, and storage of peripheral blood mononuclear cells (PBMCs), plasma, whole blood, and virus. Children's samples are collected only if part of planned examinations/treatment, with Lung Resident Lymphocytes (LRL) isolated from childrens' airway secretion when possible. Data collection includes questionnaire, laboratory, clinical, and registry data.

By January 2025, 135 patients (126 adults/9 children) were included (86 hospitalized/49 patients from GP).

We have implemented an efficient same-day procedure for collection and processing of samples enabling multiple types of laboratory analyses. However, challenges in recruiting GPs were encountered. Inclusion numbers are expected to rise this season with increasing infection numbers.

367: Analysis of Plasma Sample Quality: Best Practices for Biobank Management and Assessment

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Via Maugeri 4, 27100 Pavia, Italy - Nanomedicine and Molecular Imaging Lab, Istituti Clinici Scientifici

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Nanomedicine and Molecular Imaging Lab, Istituti Clinici Scientifici Maugeri IRCCS, Via Maugeri 4,

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Nanomedicine and Molecular Imaging Lab, Istituti Clinici Scientifici Maugeri IRCCS, Via Maugeri 4, 27100 Pavia, Italy | Breast Unit, Surgery Department, Istituti Clinici Scientifici Maugeri IRCCS, Via Maugeri 4, 27100 Pavia, Italy - Department of Biomedical and Clinical Sciences, University of Milan, Via

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Maugeri 4, 27100 Pavia, Italy - Nanomedicine and Molecular Imaging Lab, Istituti Clinici Scientifici Maugeri IRCCS, Via Maugeri 4, 27100 Pavia, Italy Topic: 5C: Samples Fit-for-Purpose – Optimisation

of Pre-analytics Presenter Name: Francesca Piccotti Keywords: Sample quality - Preanalytical factors -Preanalytical controls - Plasma samples - Analytical opportunities

Introduction

Biobanks play a pivotal role in advancing translational research by providing access to highquality biological materials. The international standard ISO 20387:2018 states that biobanks must demonstrate the quality of the biological material throughout its entire lifecycle, from collection to distribution (doi: 10.1089/bio.2019.0126). Consequently, the standard operating procedures (SOPs) that biobanks adopt must be able to guarantee this quality. Our goal was to develop a method to assess both adopted SOPs and plasma sample quality at the "Bruno Boerci" Biobank (BBB), a certified ISO 9001:2015 biobank, member of the Italian Node of BBMRI-ERIC.

Material and methods

Blood samples from 50 breast cancer patients referred to the EUSOMA-accredited Breast Unit at IRCCS Istituti Clinici Scientifici Maugeri were collected and processed at the BBB. Two different plasma isolation protocols (direct centrifugation versus density gradient centrifugation) were tested for a comparative purpose. Sample quality was evaluated by spectrometry for haemolysis and lipemia (doi: 10.4155/bio.13.344), biochemical analysis for icterus, electrolytes, and proteins, and flow cytometry for cellular debris.

Results and discussion

No significant differences were observed between the two groups for pre-analytical factors. While red and white blood cells were absent in all samples, platelet residues were higher in density gradient-separated plasma. Significant differences were observed for albumin and cholesterol levels, suggesting an influence of the density gradient method. These findings underscore the critical role of quality control in biobanks, where the selection of the processing method can impact sample quality and reliability of subsequent research data.

381: Evaluating Fitness-for-Purpose of Archival Serum Samples for Biomarker Analysis in the Cancer Biobank

by Amina Arar | Oliver Carroll | Heidi Annuk | Sonja Khan | Nicola Miller | Institute for Clinical Trials, School of Medicine, University of Galway, Galway, Ireland and Lambe Institute for Translational

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Institute for Translational Research, University of Galway, Galway, Ireland | Institute for Clinical Trials,

School of Medicine, University of Galway, Galway, Ireland and HRB Clinical Research Facility, School of Medicine, University of Galway, Galway, Ireland | Discipline of Surgery, Lambe Institute for Translational Research, University of Galway, Galway, Ireland Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Amina Arar Keywords: Archival Serum Samples, Biobank Quality Assurance, Cryopreservation for Biomarker Analysis., Protein and miRNA Stability

Long-term preservation of biological samples in biobanks is essential for advancing cancer research and biomarker discovery. This study evaluated the fitness-for-purpose of archival serum samples stored for over two decades in the Cancer Biobank, University of Galway for biomarker analysis, focusing on their suitability for assessing proteins and miRNAs associated with breast cancer.

Archival (n = 7, collected and cryopreserved 1999–2002) and recent (n = 7, collected and stored for less than 6 months) serum samples were analysed for protein integrity using SDSPAGE, BCA assays, and ELISA for cancer antigen 15-3 (CA 15-3), while miRNA stability was assessed via qPCR and the Agilent Bioanalyzer system.

Archival serum samples showed comparable protein integrity to recent samples, with SDSPAGE analysis confirming similar banding patterns. BCA assays showed no significant difference in protein concentrations between archival and recent samples, with a 2.25% difference at 1/200 dilution (p = 0.8882) and 12.9% at 1/800 dilution (p = 0.1289). CA 15-3 levels in archival samples (4.30 ± 0.95 mU/mL) remained stable and were not significantly different from recent samples (3.98 ± 1.88 mU/mL, p = 0.695). Archival samples showed lower RNA integrity compared to recent samples, despite no significant difference in CT values for miR-425 and miR-16 (p=0.185). Archival serum samples from the Cancer Biobank are fit-for-purpose for biomarker analysis, with preserved protein and miRNA integrity after decades of cryopreservation.

410: Usefulness of the BD BACTEC system for assessing the quality of cellular material samples

by Stefan Rudziński | Agnieszka Mroczko | Marta Bochyńska-Czyż | Ilona Szabłowska-Gadomska | Laboratory for Cell Research and Application, Medical University of Warsaw | Laboratory for Cell Research and Application, Medical University of Warsaw | Laboratory for Cell Research and Application,

Medical University of Warsaw | Laboratory for Cell Research and Application, Medical University of Warsaw

Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Agnieszka Mroczko Keywords: , cell culture, quality control, sterility,

validation

Introduction

In biobanking, ensuring high-quality biological samples is essential for reliable research results. For cell samples, one crucial aspect of pre-analytical quality assessment is the sterility of the thawing batch. The aim of this study is to demonstrate the process of validation of the BD BACTEC FX40 system for assessing the quality of cell culture media in biobanks.

Materials and methods

The validation process was conducted in four steps: i) sterility testing, where the BACTEC media were incubated alone to assess the quality of provided reagents; ii) growth promotion test for positive control of inoculated BACTEC media; iii) suitability testing for compatibility with culture media and cryopreservatives; iv) confirmation with standard microbiological tests. All inocula used for growth promotion testing complied with the recommendations of the European Pharmacopoeia (Table 2.6.27-1).

Results

The validation results showed that the BD BACTEC system consistently and accurately detected microbiological contamination in investigated media. For each of the tested strains used in the growth promotion assessment process, satisfactory results were obtained within the acceptance criteria range of < 100 CFU. Additionally, the suitability of the BD BACTEC system was confirmed with the standard method for sterility testing.

Discussion

The validation of the BD BACTEC system highlights its usefulness in quality control of cellular material upon its introduction into the biobank. This approach guarantees the high quality of biological samples and their reliability for use in future research.

414: Fitness for purpose of chicken blood according to sampling and conservation conditions

by Jardet D. | Gruet C. | Houel B. | Tixier-Boichard M. | Muller D. | INRAE, GABI, Jouy-en-Josas, France | INRAE, GABI, Jouy-en-Josas, France

Topic: 5C: Samples Fit-for-Purpose – Optimisation of Pre-analytics Presenter Name: Muller D. Keywords: DNA, chicken, conservation, quality, whole blood Introduction- In domestic animals, blood samples are kept frozen as a source of DNA extraction for genetic studies, that make necessary to keep samples over many years. Here, we aimed at testing the effect of preservation conditions on DNA quality obtained from frozen whole blood samples of chickens.

Methods-We analysed 570 chicken blood samples from research projects differing in sampling conditions. Collection and storage took place between 1991 and 2014, at -25° or -80°C, without a conservation buffer or with a solution containing sucrose or glycerol. Some samples were collected abroad and shipped to us. We used a Chemagic Star™ Hamilton robot for DNA extraction with Perkin Elmer DNA kit B400. DNA quantity and quality were determined by spectrophotometry with a Nanodrop™ and integrity was assessed by capillary electrophoresis on a Fragment Analyser™.

Results-We obtained DNA from 562 samples. Blood samples that were frozen without any buffer were more difficult to pipet after thawing and yielded the lowest DNA concentration, with a mean value of 100 ng/µl, which is still sufficient for genotyping studies. DNA quality, as measured by OD ratios, was satisfactory and was not affected by storage conditions. DNA fragment length was most often above 10 kb, which is suitable for short read sequencing. DNA quality was more heterogenous for samples coming from different sites and sampled by different operators.

Discussion-We recommend conservation with a PBS+glycerol buffer of whole chicken blood. Long-term storage is possible at -25 °C . Sampling conditions appeared as important as conservation conditions for results homogeneity.

7C: Innovative Quality Concepts

247: One blood draw, two samples: novel coisolation method for plasma and PBMCs

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> Topic: 7C: Innovative Quality Concepts Presenter Name: Inga Laurinaitytė Keywords: PBMC, coisolation, plasma

Introduction

This study investigated the feasibility of a coisolation method for simultaneously isolating plasma and peripheral blood mononuclear cells (PBMCs) from a single blood sample. This method aims to provide high quality samples from a single blood draw, offering a more efficient and patient-friendly approach.

Material & methods

Blood from 12 healthy donors was processed using traditional (separate) and coisolation methods. In the traditional method, plasma was obtained by centrifugation, and PBMCs were purified using SepMate tubes. For the coisolation method we used an additional centrifugation step (300 g 20 min), after which the supernatant was processed as traditional plasma, while the sediment was reconstituted to the original blood volume using PBS + 2% FBS and before the SepMate PBMC purification. Plasma analytes were measured using methods described in Table 1. Cell viability, RNA integrity (RIN), RNA concentration, and complete blood count (CBC) parameters were measured to evaluate PBMC quality.

Results

Slightly less plasma volume was collected with the coisolation method (≈20%). Plasma analyte measurements, CBC analysis (leukocyte, lymphocyte, and monocyte yields), PBMC viability, and RIN values were assessed. No statistically significant differences were found between the methods for any of these parameters.

Discussion and conclusions

Our study demonstrates that the coisolation method offers several advantages over traditional methods: improved patient experience by collecting smaller amounts of blood, and potentially wider applicability in research settings due to the ability to analyze both plasma and PBMCs from a single blood draw. This coisolation method holds promise for streamlining blood-based research while maintaining sample quality.

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249: Stepwise Quality Engagement: A Pan-European Collaborative Approach to Advancing ISO 20387 Implementation

by Sabine Bavamian | Joséphine Uldry | Lou Walder-Ferraton | Christine Joye | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform

Topic: 7C: Innovative Quality Concepts Presenter Name: Sabine Bavamian Keywords: Harmonized Quality Framework, ISO 20387 Implementation, Stepwise Quality Engagement

Swiss Biobanking Platform (SBP) has developed a stepwise quality engagement strategy to address the diverse needs of biobanks in implementing the ISO 20387. Aligned with BBMRIERIC quality strategy and 10-Year promotes Roadmap, this approach reproducible research by enhancing data traceability and quality management. Recognizing varying readiness for quality, the strategy offers tailored support while fostering harmonization across National and European networks.

SBP offers three progressive labels — VITA, NORMA, and OPTIMA — enabling biobanks to incrementally implement the ISO 20387 requirements. This framework accommodates biobanks aiming to improve practices as well as those preparing for accreditation. Ongoing discussions with BBMRI-ERIC explore linking SBP stepwise strategy with BBMRI audit Programme to create a unified Quality Management framework that will be applicable across interested Nodes.

This stepwise approach allows SBP to assess ISO 20387 compliance across its labels with around 100 biobanks in its network. A pilot evaluation is aligning SBP OPTIMA label with BBMRI Quality Programme, supporting collaborative pathways toward the BBMRI Quality label. By implementing this strategy, SBP expanded its outreach, increased biobank participation, and improved network visibility while achieving biobank targeted quality levels.

In conclusion, this stepwise quality provides biobanks with engagement manageable progression toward ISO 20387. Harmonizing quality strategies across Nodes will enhance mutual understanding of achievements and strengthen the European biobanking landscape. Building on the Swiss approach, SBP will collaborate with other Nodes facing similar challenges to establish a harmonized framework, advancing the biobanking community toward unified, higherquality standards and increasing the visibility and trust for the researchers.

312: BBMRI-ERIC Quality Management services

by Niina Eklund | Stella Antoniou | Nadja Palko | Maike Tauchert | Andrea Wutte | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | BBMRIERIC, Graz, Austria

Topic: 7C: Innovative Quality Concepts Presenter Name: Niina Eklund Keywords: Quality Management, auditing, quality assurance, quality control, service portfolio BBMRI-ERIC Quality Management (QM) department is providing a comprehensive service portfolio to support the biobanking delivering community in high-quality biospecimens and associated data for biomedical research. Standardised processes essential for quality management; are therefore, our QM services have been developed based on international and European standards from the outset.

Our service portfolio is structured into distinct pillars. The **Knowledge Hub** offers fundamental resources, including information on biobankrelevant standards, qualityfocused events, working groups, QM templates, and access to an expert network. To enhance biobank operations, we provide **Training and Support** led by domain experts in accessible virtual formats. As part of our BBMRI-ERIC Academy, participants can earn Continuing Medical Education (CME) credits through selected live webinars.

For biobanks seeking to implement the requirements of selected ISO standards and achieve accreditation for their biobanking processes, we facilitate the process through initiatives such as our Audit Programme. This programme assesses compliance with relevant standards via a series of Self-Assessment Surveys. Upon successful completion, biobanks receive certification, confirming their adherence to best practices. To date, 55 biobanks have been awarded a Quality Label in the BBMRI-ERIC Directory following а successful audit.

Sustainable development of biobanks is essential and therefore we drive **Continuous Improvement**, where we engage experts to exchange on quality assurance (QA) and to quality control (QC) measures. Our commitment to quality ensures that biobanks are equipped with the necessary tools and expertise to maintain high operational standards and support innovative biomedical research.

397: Database for Equipment Logging in Compliance with ISO 20387

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Topic: 7C: Innovative Quality Concepts Presenter Name: Jeanett Stephansen Keywords: Documentation of critical equipment activities

INTRODUCTION

Documentation of critical equipment activities is required in order to comply with ISO 20387. According to the standard, biobank shall maintain documented records for critical equipment, including the maintenance plan and completed maintenance, any damage, malfunctions, modifications, or repairs. E-log is a database in development with the ability to collect equipment-related information and provide a comprehensive overview of each equipment unit's lifecycle.

MATERIAL & METHODS

E-log will integrate automatically collected data and manual logs of equipment actions, creating a unified database for equipment management. This enables users to track and analyze performance metrics across units, ensuring all relevant information is easily accessible and actionable.

RESULTS

By centralizing data, E-log will enhance equipment oversight, optimizes maintenance strategies, and reduces operational risks. Potential applications of the collected data include recommending maintenance to prevent breakdowns, notifying users of possible equipment failures, and assessing the viability of repairs.

DISCUSSION AND CONCLUSION

E-log is being developed as an essential tool for biobanks aiming to enhance equipment transparency, efficiency, and decision-making by enabling easy comparison of performance across devices. Once implemented, E-log is expected to enhance stability and contribute to ensuring the operation of critical equipment.

444: High Quality BioBanking in Belgium: the Road towards ISO20387 Accreditation (B3-ISO)

by Annemieke De Wilde | Annelies Debucquoy | Johan Guns | Ahmad Merhi | Loes Linsen | Pieter Moons | Manon Huizing | Katia Emmerechts | Elke Smits | BBMRI.be - Belgian Cancer Registry | BBMRI.be Belgian Cancer Registry | Central Biobank, UZBrussel | IPG BioBank and Laboratory of Translational

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University Hospital & University of Antwerp | Biobank Antwerp, Antwerp University Hospital & University of Antwerp | BBMRI.be - Belgian Cancer Registry | Biobank Antwerp, Antwerp University Hospital & University of Antwerp

Topic: 7C: Innovative Quality Concepts

Presenter Name: Annemieke De Wilde Keywords: ISO20387, accreditation, harmonization

Introduction

BBMRI.be, the Belgian node of BBMRI-ERIC, connects 21 Belgian biobanks. The inclusion of ISO20387 'General Requirements for Biobanking' in the portfolio of the Belgian accreditation organization BELAC, will allow biobanks to formalize their competences.

Methods

To harmonize and enhance the quality management activities of the BBMRI.be biobanks, a stepwise quality improvement program (funding BELSPO/ESFRI-FED call) is being implemented at the individual biobanks. In cooperation with the participating biobanks, BBMRI.be coordinates the development of guidelines, templates and policies, the organization of webinars, and Frequently Asked Questions. BBMRI-ERIC Quality tools such as the SAS and audit program are being supported, and an ISO20387 accreditation program is being established together with BELAC. Overviewing committees, and periodical evaluation (surveys/discussions) provide feedback and support continuous improvement of the project.

Findings

Templates have been harmonized and integrated in the domains of IT, ELSI and sustainability. These project deliverables received positive feedback from participating biobanks and are being validated by both biobanks and stakeholders. In contrast to the kickoff survey findings, less biobanks aim for ISO20387 accreditation within the project timeline (mid-2026). The biobanks estimate that more implementation time will be needed as compared with their initial planning at project kickoff. The interest in achieving the consecutive quality improvement steps including ISO20387 accreditation remains high.

Discussion

The setup of this program and the implementation of ISO20387 will substantially support the BBMRI.be biobanks in achieving their quality-related ambitions. Furthermore it will contribute to (inter)national translational research and foster collaborations between industry and academia in the biomedical sector.

8C: Special Samples, Special Needs

290: Blood Collection for Biobanking: Experiences from the Slovenian Institute for Transfusion Medicine

by Maja Černilec | Natalija Lampreht | Valerija Kovač | Melita Gracar | Marjana Šprohar | Jugoslav Njenjić | Dražen Franić | Slavica Stanišić | Irena Razboršek | Polonca Mali | Tadeja Režen | Katarina

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> Topic: 8C: Special Samples, Special Needs Presenter Name: Vladka Čurin Šerbec Keywords: blood samples, healthy donors

Biobanks are valuable repositories of human biological material. Many diseased-oriented and population-based biobanks exist, whereas biobanks containing samples of healthy donors remain scarce.

In the scope of the Interreg V-A Italy-Slovenia project C3B, we first examined the demand for blood samples of healthy donors in research, education, and clinical studies in Slovenia. After we received approval for establishment of a pilot biobank of healthy donor blood samples at the Slovenian Institute for Transfusion Medicine (BTCS) from the National Medical Ethics Committee, implemented we biobanking protocols into standard blood management processes at BTCS. When blood donors enrolled for regular blood donation, we invited them to donate an additional sample of their blood to our pilot biobank. After signing an informed consent, we performed the collection, processing, and storage of the blood samples from healthy blood donors according to standardized protocols. Plasma samples were additionally analyzed for selected biomedical markers. Biobanking activities were supported by an information system that ensures the traceability of the handling of samples and enables the protection of personal data.

We successfully integrated biobank-specific processes into pre-existing BTCS blood banking protocols and established a pilot biobank of blood samples of healthy donors. The lack of biobanking regulatory framework in Slovenia results in difficulties with biobank establishment and governance. Nevertheless, based on our experience and good practices in blood banking, we prepared the prerequisites to establish and operate a national biobank of blood samples of healthy donors.

Acknowledgements: The study was supported by Interreg Europe and Slovenian Research and Innovation Agency.

339: Implementation of a Biobanking Pipeline for High-Quality Spleen Mononuclear Cells (SMCs) to Support Research in Immune Regulation and Pathology

by Helene Kraus | Marei-Theresa Bott | Anita Delor | Anna-Verena Stell | Stephan Rusch | Gerhard Kindle | Peter Bronsert | Julia Huber | Martin Werner | Julius Wehrle | Marta Rizzi | Carola Focke | Stefan

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Freiburg, Germany. | Department of Medicine I, Medical Center-University of Freiburg, Faculty of Medicine, University of Freiburg, Freiburg, Germany. Topic: 8C: Special Samples, Special Needs Presenter Name: Helene Kraus Keywords: Biobanking Workflow, Cryopreservation, Quality Management Concept, Spleen Mononuclear Cells, Tissue-derived Cells

The Center for Biobanking (FREEZE-Biobank) is a Central Facility of the Faculty of Medicine of the Albert-Ludwigs-University of Freiburg and the University Medical Center Freiburg operating since 11/2018. One of the key strengths of the FREEZE-Biobank is the advanced biobanking of blood and bone marrow-derived immune cells, supporting multiple research projects in the area of immune- and infection-based diseases.

Due to technical and scientific progress e.g. in the area of single cell technologies and respective high-dimensional data analyses, tissue-derived immune cells are of emerging interest for a variety of cutting edge projects. To meet these needs, we established a biobanking workflow involving all stakeholders from the clinic, pathology, data integration center (DIZ), biobank to the bench. We will outline the implemented pipeline, from the patient information and consenting process to the software-supported tracking of all sampling steps -starting at the site of surgery all the way to the release of clinically annotated tissuederived cell suspensions from our biobank for innovative research projects in cancer immunology.

We will demonstrate that the recovery and cryopreservation of spleen mononuclear cells are both efficient and reliable, providing a valuable resource for studying spleen-derived cells (e.g. natural killer T cells) using techniques such as FACS, CyTOF, and the isolation of single cell populations for various *in vitro* experiments.

Furthermore, the set-up of a fit-for purpose quality management concept shall be discussed, as well as possibilities and challenges to upscale workflows and adapt to other tissues.

340: Establishing a new hiPSC Biobank for disease modelling and drug discovery: standardization and quality control processes.

by Alessandro Cutarelli | Marina Cardano | Paola Gasperini | Angela Bozza | Veronica De Sanctis | Roberto Bertorelli | Chiara Valentini | Paolo Cavallerio | Giorgia Zappacosta | Alessandro Quattrone |

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Topic: 8C: Special Samples, Special Needs Presenter Name: Alessandro Cutarelli Keywords: Biobank, Disease modelling, Induced pluripotent stem cells, Quality control

Disease modelling completely was revolutionized in 2007 when Yamanaka successfully reprogrammed human fibroblasts to human induced pluripotent stem cells (hiPSCs)¹. Since then, different somatic cell types including skin biopsies and blood cells were used to generate hiPSCs by overexpressing the so-called Yamanaka factors (KLF-4, Oct-4, Sox2 and c-Myc)². During the last decade, multiple and more efficient delivery methods were developed, giving access to this new promising technology to researchers working in the field of drug discovery and personalized medicine³. Indeed, hiPSCs have the unique ability to differentiate towards the three germ layers endoderm, mesoderm, and ectoderm, and potentially further differentiate into every cell type of the human body⁴. In 2022 the CIBIO department of the University of Trento, supported by funding from the European Union (NextGenerationEU), Italian NRRP project code IR0000031 - Strengthening BBMRI.it - CUP B53C22001820006, took advantage of its Core Facilities' expertise to set the first hiPSCs Biobank hosted by an Italian University. In particular, the Cell Technology Core Facility (CTF), the Next Generation Sequencing Core Facility (NGS) and the recently established Biobank Core Facility (BCF) teamed up to design and standardize the procedures required to eventually generate and distribute high quality hiPSCs. To achieve this goal, the team is working on different topics including

patient's recruitment in compliance with European and Italian legislation, somatic cell reprogramming and downstream characterization of the obtained cell population. Here we summarize the setup and quality control implementation processes for hiPSCs biobanking: cell reprogramming, phenotypic assessment, pluripotency potential, Karyotyping and cell identity.

360: Hospital-based solid tissue sample collections for research needs: integration of biobanking activities in clinicaldiagnostic routine

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> Topic: 8C: Special Samples, Special Needs Presenter Name: N. Pagani

Keywords: cancer, hospital biobank, quality control, solid tissue Introduction – The institutional biobank of IRCCS Ospedale San Raffaele called Biological Resource Center (CRB) is composed of a Liquid Biobank and a Solid Tissue Biobank, which operates in collaboration with the Pathology department thus supporting the clinical and translational research activities performed by the Comprehensive Cancer Center.

Methods and Results – Almost 25% of the protocols involving sample collection and storage for future scientific research managed by the CRB for biobanking activities (reception and registration, processing, storage, distribution and disposal) involves the Solid Tissue Biobank.

Tissue sample collection is performed within dedicated research protocols upon approval by the Ethical Committee and signing the informed consent both during surgery or biopsy procedures for diagnostic and/or therapeutic purposes. Tissue sampling is always evaluated and performed by a dedicated pathologist trained for the protocolspecific procedures who takes care of samples for diagnostic and, if possible, makes the leftover material accessible for research. According to protocol-specific procedures, this material is sent to CRB and directly distributed to research groups after registration and pseudoanonimization and/or directly processed and stored by the CRB for subsequent analysis and distribution. CRB, in collaboration with the Pathology department, performs quality control on 100% of the OCT tissue through Hematoxylin & Eosin staining evaluated by the pathologist for tumoral or pathological area, cellularity, necrosis. inflammation and fibrosis and shares the data with the users. Pathology department tissue

archive remains available for research purposes.

Conclusions – The coordinated interaction between CRB and the Pathology department supports and promotes research needs and strategies.

413: Biobanks help tracking the interferences in immunoassays

by Marie Karlikova | Ondrej Topolcan | University Hospital Pilsen and Charles University Faculty of Medicine in Pilsen | University Hospital Pilsen and Charles University Faculty of Medicine in Pilsen Topic: 8C: Special Samples, Special Needs Presenter Name: Marie Karlikova Keywords: HAMA antibodies, immunoassay, interference

Immunoassays are methods of choice for measuring many low-level biomolecules in biological fluids, both in the clinical routine and in the biomarker research. They are sensitive, robust, easily automated and affordable even for small laboratories. However, currentl there is an increasing number of issues with false results caused by interferences which either hamper the in vitro antibody-antigen reaction or the detection of investigated molecule. These interferences mainly originate from biological treatment in oncology (HAMA antibodies, imaging methods using antibodies or increased biotin use. Storing aliquots in the biobank allow to study the interferencies, f.i. with the help of different technology. Case studies will be presented.

Biobanking of historical samples: an interesting challenge

by Evi Mampaey | Valérie Hostens | Caroline Rombouts | Maartje van Frankenhuijsen | Institute of

Tropical Medicine Antwerp | Institute of Tropical Medicine Antwerp | Institute of Tropical Medicine Antwerp | Institute of Tropical Medicine Antwerp Topic: 8C: Special Samples, Special Needs Presenter Name: Evi Mampaey | Valérie Hostens Keywords: biobanking, domestic animals, ethical committee, historical samples, human clinical samples, infectious diseases, leftover material, livestock, pathology, tropical medicine., zoological samples

Introduction

Cataloguing historical tissue and cell samples is crucial for preserving valuable scientific material and fostering global research collaboration. Thisproject, which started at the end of 2021 and still ongoing, focuses on inventorying and digitising a unique collection of tissue and cell specimens, along with the corresponding original clinical files and lab notebooks, collected by pathologists, Dr E. Van Marck, Dr P.L. Gigase and colleagues, at the Institute of Tropical Medicine Antwerp.

Material & methods

The collection consists of leftover material of about 107.000 samples taking for routine care and was collected from 1963 to 1994. It represents a repository with high research potential, primarily comprising pathological samples from infectious diseases, but also from non infectious diseases worldwide. In addition, this project involves cataloguing samples from various zoological gardens, domestic animals and livestock. The digital archiving process involves documenting of each specimen, including detailed (clinical) metadata such as sample origin, histological analysis and associated diagnostic outcomes. Before utilizing the samples, ethical approval will be obtained from relevant local ethical committees in the country of origin to ensure compliance with current ethical standards.

Discussion

This project enhances the potential for genomic time-series studies and genetic epidemiology, enabling the exploration of how genetic factors interact with environmental influences over time. By linking the physical collection to advanced digital technology, the project contributes to global health research and fosters a deeper understanding of genetic factors in diseases affecting populations worldwide.

References

Institutional Review Board of the institute of Tropical Medicine Antwerp.

Contact details

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10C: Samples Ready for Multi-omics Research

Results

250: Generation and molecular characterization of an organoid collection (Biobank of the Aragon Health System, Spain)

by Encabo-Berzosa, Marimar | Giraldo, Cindy | Mora, Irene | Arenaz, Izaskun | Bermúdez, Paula | Naval, J | del Agua, C | Martínez-Gimeno, L | Torcal, MP | Giménez, I | Subira, J | Recalde, D | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Biobank of the Aragon Health System, IACS, Spain | Hospital Clínico Universitario Lozano Blesa | IACS | IACS |

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> Topic: 10C: Samples Ready for Multi-omics Research

Presenter Name: Recalde, Delia

Keywords: PDO characterization, kidney, organoid

Our Biobank has generated a collection of organoids derived from tumor and tumoradjacent human tissue, with particularly relevant success in the case of healthy renal tissue. Currently, we offer to the scientific community healthy kidney organoids, in different passages and formats, from twelve donors. The characterization of these cultures is key to ensure their quality and usefulness in various scientific projects.

OBJECTIVES

Characterize by H&E, IHC, IF and RT-PCR the renal organoids generated.

MATERIAL AND METHODS

After parafin-embedding the organoid culture, 3 μ m sections were cut and H&E and IF staining of LTL (proximal tubule), UMOD (distal tubule) and Podocin (glomeruli) proteins was performed. On the other hand, RNA was extracted from the cultures and RT-PCR was performed to evaluate the expression of Megalin, KSP-Cadh, DPP4, THP, aSMA, SGLT2, APN, GAPDH, GGT1, AQP2, NKCC2, NCC, NGAL, Ki67, KIM1, PAX8, PROM1, PODXL, NPHS1, SOX9 and WT1 genes.

RESULTS AND CONCLUSIONS

H&E showed structures morphologically assimilable to distal tubules, proximal tubules and glomeruli. There was verified by the expression of the genes NCC and THP, involved in the functioning of the distal tubule, NPHS1, related to glomerular function and Megalin, DPP4, SGLT2-SLC5A2, APN, GGT1, expressed in the proximal tubule. IF were also positive for proteins representative of distal (UMOD) and proximal (LTL) tubules.

The generated organoids thus appear to show a representative culture of all renal structures.

274: Targeted Proteomics and Digital Transformation of the SwiSCI Biobank

by Ramona Schaniel | Simona Capossela | Sebastian Sonntag | Alexander Stacul | Bjoern Zoerner | Franziska Singer | Xavier Jordan | Margret Hund-Georgiadis | Gerold Stucki | Jivko Stoyanov | Swiss

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(CRR), Sion, Switzerland | Rehab Basel, Basel, Switzerland | Swiss Paraplegic Research, Nottwil, Switzerland | Swiss Paraplegic Research, Nottwil, Switzerland

Topic: 10C: Samples Ready for Multi-omics Research Presenter Name: Ramona Schaniel Keywords: OLink, SwiSCI study, digitalisation, spinal cord injury, targeted proteomics

Introduction

Targeted proteomics offers precise identification and quantification of proteins, while keeping costs manageable, serving as a start for the digital transformation of the SwiSCI Biobank that was established in 2016. This initiative addresses challenges such as limited accessibility and the degradation of physical samples over time. The SwiSCI Biobank has adopted the Olink platform, leveraging Proximity Extension Assay (PEA) technology alongside specialized protein panels for advanced data analysis.

Methods

The biobank houses serum, plasma, PBMCs, RNA, DNA, urine, and urine sediment. For proteomic digitalization, serum samples from longitudinal donors were prioritized. A total of 119 proteins are being analysed using the Olink T48 Cytokines, Olink T48 Immune Surveillance, and a custom designed Olink Flex panel.

Results

As of January 2025, the SwiSCI Biobank comprises 376 donors, including 221 with longitudinal serum samples. Proteins critical to spinal cord injury (SCI) and related conditions are emphasized. The Olink T48 panels facilitate analysis of 89 immune mediators linked to inflammation and immune function. A custom Olink Flex panel was developed to include 30 additional proteins associated with SCI recovery across subacute, chronic, and longterm phases.

Discussion and Conclusion

The establishment of a proteomics platform using Olink technology marks an advancement

in the digitalization of the SwiSCI Biobank. This strategy enhances data preservation and enables detailed protein analyses, driving progress in SCI research. By supporting precision medicine, this work has the potential to improve SCI rehabilitation outcomes and accelerate translational research.

298: DwarnaBio – Insights from the population biobank of the Maltese islands

by Nikolai Paul Pace | University of Malta Topic: 10C: Samples Ready for Multi-omics Research Presenter Name: Nikolai Paul Pace Keywords: clinical collections, populaiton biobanks

Background: DwarnaBio is the Maltese national genomic biobank. DwarnaBio is establishing a reference databank of phenotypic data collected at baseline, with corresponding biospecimen storage with consent for downstream multi-omic analysis. DwarnaBio has commenced whole genome sequencing of its collection, aiming to develop a reference Maltese genome as a publically available resource. DwarnaBio uses a dedicated webportal (dwarna.mt) designed to prioritise public engagement in research and facilitate return of relevant findings to study participants where indicated.

Results: Several previous studies provide preliminary support for a distinct genetic architecture in the Maltese population, with strong evidence for a genetic affinity with the Middle East. We will present a preliminary analysis of clinical and phenotypic data from the first year of operations of DwarnaBio, and an analysis of aggregate genomic data from the first batch of genomes obtained from this population biobank. Conclusion: DwarnaBio aims to leverage the power of a small island state characterised by a centralised health care system and a single national tertiary research institute. DwarnaBio is the seed for a multi-omic longitudinal cohort study that will enable researchers to investigate different clinical outcomes. It will facilitate the annotation and analysis of a reference Maltese medical genome, thus contributing to genetic diversity datasets in the public domain. Through genomic analysis of this representative cohort, DwarnaBio will also seek to evaluate the population burden of polygenic risk scores, identify variants of potential disease relevance and carrier frequency for recessive Mendelian disease in an island population.

380: Rare diseases collection in BBMRI.bg for diagnostics and personalized medicine in Bulgaria

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Topic: 10C: Samples Ready for Multi-omics Research

Presenter Name: Daniela Kostova Keywords: Rare diseases, biobanking, networking, targeted therapies

Introduction: There are currently over 7,000 rare diseases (RDs). BBMRI.bg is the National biobank node of Bulgaria that has already uploaded 22 collections including over 1,600

RDs samples to the BBMRI-ERIC directory. There is a need to improve the diagnostic rate of genetic testing to enable better patient management, genetic counseling, and therapeutic intervention. Valuable collections of patients' biomaterials are critical in these efforts.

Material and methods: In the past decade, more than 4,400 samples of patients and their relatives were collected through 124 national, 6 international scientific, and 5 infrastructure projects, as well as through routine diagnostics. More than 2,600 RD patients have signed an informed consent and underwent clinical/whole exome sequencing in both research and diagnostic setting.

Results: The patients with positive genetic findings spanned a wide range of neurological, neurosensorial, renal, metabolic, skeletal, etc. disorders. Notably, best rates were seen in eye (82%), followed by rasopathy (67%), and renal diagnoses (62%). Variants in diseaseassociated gene/s were identified in 1,339 patients, resulting in an overall diagnostic yield of 47%. The undiagnosed cases will need further more in-depth genomic and multi-omics approaches.

Discussion and Conclusion: Large cohort studies have shown that exome sequencing has a consistent diagnostic yield in the range 30-50%. Whole genome sequencing adds further improvement. Biobanking of DNA, RNA, buffy coats, plasma, urine etc. from patients and relatives with wide spectrum of rare phenotypes, provides excellent basis for further collaborative OMICs studies for the undiagnosed cases in the frame of ERDERA and other international partnerships.

References:Slaba et.al,2024

403: The Importance of Tissue Biobanking for Spatial Analysis in Research

by Alexander Brobeil | Carolin Kaufhold-Wedel | Tilman Pfeffer | Peter Schirmacher | Tissue Bank of the National Center for Tumor Diseases (NCT) Heidelberg, Germany; Institute of Pathology, Heidelberg

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> Topic: 10C: Samples Ready for Multi-omics Research Presenter Name: Alexander Brobeil Keywords: methods, spatial analysis, tissue biobanking

Tissue biobanking plays a central role in biomedical research, especially in precision medicine and systems biology approaches. Modern biobanks must increasingly support cutting-edge technologies such as spatial transcriptomics, spatial proteomics and spatial metabolomics to capture the spatial heterogeneity of biological and tumor samples in detail. These technologies enable highresolution analysis of the molecular landscape within tissue sections and open up new perspectives for research into disease mechanisms, biomarker identification and therapy development.

However, the integration of these methods places high demands on sample quality, fixation, storage and technical expertise of the tissue biobank staff. Using the established processes of the NCT tissue bank and cooperation projects, we describe examples of efficient tissue processing for the aforementioned methods. For example, since these methods can be very cost-intensive, the sample arrangement on the used material carrier, usually special slides, should be designed as efficiently and space-saving as possible. Furthermore, the nature of the tissue samples and the possible use in routine pathological diagnostics pose a further challenge to the correct use within these cutting-edge methods.

In the future, biobanks will not only function as passive sample storage facilities, but as highly networked platforms with high methodological expertise. The combination of optimal sample management and expertise in state-of-the-art analysis methods will significantly advance translational research and further optimize personalized therapy approaches.

7E: EP PerMed – Unlocking biobanks for personalised medicine

259: Standardizing Procedures: Key Indicators to Maintain and Monitor Standard Procedures Across Regions in a National Biobank

by Ian Kasper Kjelsgaard | Rasmus Adalbert Meldgaard | Estrid Høgdall | Department of Pathology, Bioand Genome Bank Denmark, Herlev Hospital, Herlev | Department of Pathology, Bioand Genome Bank

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> Topic: 7E: Unlocking biobanks for Personalised Medicine Presenter Name: Rasmus Adalbert Meldgaard

Keywords: Bio- and Genome Bank Denmark, biospecimen, key indicators, key metrics, quality, sample quality, standardization, uniformity

Introduction:

Biobanks have been hailed as an essential component in modern medical diagnostics and research as complex procedures have created a need for high-quality samples. To achieve this goal, biobanks are constantly improving their procedures to provide biospecimen of the highest quality. As such, Bio- and Genome Bank Denmark (RBGB) uses quality metrics to monitor the various biobank centers to ensure uniformity and compliance with SOPs across Denmark.

Material & Methods:

We use the Danish biobank, Bio- and Genome Bank Denmark, as a case study to examine the key indicators from the two largest biobanks in order to understand how well the standard procedures are maintained and monitored nation-wide.

Results:

The different key metrics successfully highlight inconsistencies and irregularities between regions in various categories such as sample quality, data registration consistency, data quality, sample parity, and sample usage. Furthermore, they highlight the activities of the biobank: how many new biospecimens have been added, how is their quality, and how are they used.

Discussion and conclusion:

By using standard operating procedures and key indicators, RBGB, is able to intervene with location-specific solutions when key targets are not satisfactorily met. The key indicators are a practical approach to monitor and harmonize procedures across multiple regions and different localities to ensure high-quality samples without regional differences.

309: Enhancing Research Discoverability: The UMCG Research Data Catalogue

by K. Meijer | C.E. Boorsma | University Medical Center Groningen | University Medical Center Groningen

> Topic: 7E: Unlocking biobanks for Personalised Medicine Presenter Name: K. Meijer Keywords: Catalogue, FAIR, Findability

At the University Medical Center Groningen, The Netherlands (UMCG), we want to enhance reuse of existing collections following FAIR principles by building the UMCG Research Data Catalogue. With this Catalogue, we aim to improve the findability, accessibility, and reusability of available research data.

The catalogue (umcgresearchdatacatealogue.nl) is a public metadata registry that provides a structured and searchable overview of available data- and biobank collections and study data- and samples sets at the UMCG. Researchers can explore datasets using filters based on data and sample categories, collection type, age groups, and available information (e.g., lab results, medication, lifestyle). Furthermore, each dataset profile includes details about cohort design, contributors, data and sample types, access conditions and application procedures. The platform also facilitates collaborations by providing direct contact options for researchers.

Additionally, we performed a survey among researchers to study their search behavior and preferences when looking for available data and samples. Data catalogues are widely used to find potential datasets, especially by earlycareer researchers, followed by connections through networks and conferences. When using catalogues, researchers value information about disease areas, available data collection methods. variables. access conditions and application procedures, which is largely in line with the current design of our catalogue. We will proceed to use the finding of this survey to further improve functionality and visibility of the UMCG Research Data Catalogue.

317: Development of Latvian National Genome Data Information System

by Vita Rovite | Normunds Kante | Ivars Silamikelis | Rolands Strazdins | Janis Klovins | Latvian Biomedical Reserch and Study centre | Latvian Biomedical Reserch and Study centre

Topic: 7E: Unlocking biobanks for Personalised Medicine Presenter Name: Vita Rovite Keywords: biobank, genomic data infrastructure, personalized medicine

The Latvian National Biobank – Genome Database of the Latvian population has been a national hub for genomic projects since its establishment in 2003. In 2023, the biobank began implementing the Latvian Genome Reference Development project within the European One Million Genomes initiative, generating whole genome sequences for 3,500 individuals from the Latvian population. To manage and facilitate the use of the generated genomic data for personalized medicine, the development of the Latvian National Genome Data Information System was launched.

At the core of the genome data infrastructure is the biobank's dynamic informed consent and survey system (DECIDE), which is linked to a specific genomic data repository, an electronic signature, and a connection to the Latvian National e-Address system. Access levels for various user groups—administrators, researchers, medical professionals, and participants—have already been introduced in the DECIDE system. Consequently, the genomic data infrastructure has defined user roles and access levels according to the rights of each user group. Additionally, there are plans to develop a secure data processing environment compliant with the EHDS regulation to ensure further reuse of the data and to provide services using genomic data for personalized medicine purposes.

We have been able to leverage the existing biobank IT system for dynamic consenting and surveys to develop the National Genome Data Information System, which is currently being enhanced through the integration of various security measures and services to become the national hub for the use of genomic data in personalized medicine.

399: Raman Spectroscopy as a Novel Tool for Acute Myeloblastic Leukemia Diagnostic

by Piotr Mrówka | Paulina Laskowska | Sylwia Orzechowska | Patrycja Leszczenko | Anna Maria Nowakowska | Aleksandra Borek-Dorosz | Wiktoria Korona | Maciej Szydłowski | Przemysław Juszczynski

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> Topic: 7E: Unlocking biobanks for Personalised Medicine Presenter Name: Piotr Mrówka Keywords: AML, Acute myeloblastic leukemia, diagnostics, personalized medicine, raman specrtoscopy

Introduction: Acute myeloblastic leukemia (AML) is a heterogeneous malignancy characterized by the clonal proliferation of progenitor stem cells. Traditional classification systems, like the French-American-British (FAB), have evolved to incorporate genetic and molecular data for better diagnostics. Despite advancements. current methods remain complex and resource-intensive, lacking direct information on AML cells' metabolic features. Recent studies indicate that metabolic signatures in blood cancer cells, such as increased glycolysis and mitochondrial biogenesis, can be detected using Raman spectroscopy (RS). This study evaluates RS's utility in identifying AML subtypes based on metabolic profiles and genetic alterations.

Material & methods: We analyzed primary AML blasts from 30 patients collected in the IHiT

Biobank alongside various AML cell lines using RS to capture molecular fingerprints. Principal component analysis (PCA) and partial leastsquares discriminant analysis (PLS-DA) were employed to differentiate between peripheral blood mononuclear cells (PBMC) and AML, as well as among various AML subtypes.

Results: Our findings demonstrate that RS can accurately distinguish AML blasts from PBMC. PCA revealed significant spectral differences among AML subtypes M0, M1, M5, and M5a. Spectral markers associated with cytochromes and lipids were identified as distinguishing features of AML. Furthermore, genetic mutations such as MLL or FLT3 exhibited distinct biochemical signatures detectable by RS.

Discussion & conclusion: RS presents a promising label-free method for the rapid identification of AML subtypes based on unique metabolic signatures and genetic profiles, potentially enhancing diagnostic accuracy and facilitating personalized treatment strategies. Future research will focus on validating these findings in larger patient cohorts.

438: NMR Metabolomics: Elevating Biobank Standards for Personalised Medicine

by Claire Cannet | Bruker BioSpin GmbH & Co KG Topic: 7E: Unlocking biobanks for Personalised Medicine Presenter Name: Michele Zani Keywords: biobank, large cohorts studies, metabolomics, metadata, omics, quality control, sample preparation optimization

Introduction: Advances in personalised medicine (PM) depend on the availability of

highquality health-related data and corresponding biofluid samples. Quality control of biofluids stored in biobanks, along with additional metabolomics information, is crucial.

Methods: NMR-based Material 8 metabolomics analysis of biofluids is essential for personalised medicine. High-quality and reliable data are paramount. Stringent and standardized quality control on sample input ensures effective characterization of samples. NMR can validate if newly incoming samples meet quality requirements for biobank storage. Using standardized workflows, biobanks benefit from outstanding NMR reproducibility and transferability, achieving compatibility with biobanks worldwide.

Results: Highly standardized and high-quality spectra generation offers substantial value for biobanks. The quality of urine, plasma/serum, CSF, and saliva samples can be determined alongside additional quantitative metabolic information, including Lipoprotein Subclass Analysis, metabolites, and inflammation parameters for plasma/serum, and metabolites for urine, CSF, and saliva. Retrospective analysis of the NMR spectra obtained and stored in the biobank can be performed without remeasuring samples.

Discussion and Conclusion: Examples will be presented on quality control and data analysis performed on samples from different biobanks measured with standardized NMR metabolomics protocols. High-quality NMR spectra can be used in combination with AI to develop new algorithms empowering personalised medicine.

TRACK 4. Education, ELSI Insights, Stakeholder Collaboration and Patient-Centered Partnerships

3D: Empowering the Next Generation: Education and Training in Biobanking

430: The new Master "Research Biobanks in the Scientific Ecosystem"

by Monica Forni | Daniela Capello | Valentina Ancarani | Valentina Bugani | Sara Casati | University of Bologna Alma Mater Studiorum, Italy | UPO Biobank, University of Piemonte Orientale, Novara, Italy |

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Ufficio formazione, IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST) "Dino Amadori", Meldola, Italy | 3Istituto degli Endotipi in Oncologia, Metabolismo e Immunologia "G. Salvatore" (IEOMI), Naples, Italy.

Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Monica Forni Keywords: Quality Assurance, Research, Training

Training personnel for Research Infrastructures (RIs) requires a specialized approach to effectively address current challenges. The EUfunded RItrainPlus project explored this need, by aligning its efforts with Levels 6 (Bachelor), 7 (Master), and 8 (PhD) of the European Qualification Framework (EQF) helping students gain familiarity with RIs and consider them as career opportunities.

In the field of biobanking, this need is particularly evident due to the strong ties between biobanks and research institutions such as universities and hospitals. The EU- funded EvolveBBMRI project aims at bridging this gap by developing a comprehensive career and training for RI staff in biobanking and biomedical research to educate the next generation of biobank professionals while expanding career opportunities in the field.

Building on RItrainPlus results and adhering to Higher Education Area quality assurance principles, the University of Bologna, in collaboration with the University of Eastern Piedmont and with the support of IRCCS - IRST and BBMRI.it, designed and delivered the master's program Research Biobanks in the Scientific Ecosystem. Open to EQF Level 6 graduates, this program addresses key aspects of strategic management and innovation in biobanking-based activities. Drawing from the BBMRI.it "Biobanking Skills Map", the program is tailored for both aspiring biobank professionals and researchers utilizing biobanking resources. It covers topics such as research reproducibility, quality assurance, strategic planning, human and material resource management, and economic sustainability. Ultimately, the program aims to equip the next generation of biobank professionals with the skills necessary to address the evolving challenges in the field.

415: National legal framework and ELSi impact in Biobanks' activity: Italy vs Spain comparison

by Margherita Carpani | Monica Forni | Marialuisa Lavitrano | Nùria Montserrat Pulido | Alma Mater Studiorum - University of Bologna | Alma Mater Studiorum - University of Bologna | Università degli studi

Milano Bicocca | Institute for Bioengineering of Catalonia (IBEC)

> Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking

Presenter Name: Margherita Carpani Keywords: GDPR, Italy, Spain, Training, data management, interdisciplinary skills, sensitive data

Biobanks' activity implies the management of a great amount of sensitive data. Given the fastpaced evolution of technology, ever-changing skills and knowledge are required by professionals operating in these infrastructures. The lack of efficiency in laws and regulations in keeping pace with the upcoming challenges, leaves researchers and managers in a grey area of uncertainty and risk. After the introduction of the GDPR every country has adopted its own approach in further regulating the subject: Italy a "hibryd model" that combine general national and international provisions with a decisive role of the italian DPA (Data Protection Agency); Spain a specific regulation on scientific research and Biobanks'.

The work has been conducted analysing the qualitative data collected through frontal semistructured interviews to managers, researchers, bioethicists and lawyers from both countries.

Main results have been the understanding of present needs and challenges that biobanks' professionals face in their everyday activity and if they are receiving coverage through the legal framework of their country, in addition to identifying possible improvements in regulation and interdisciplinary skills needed. Biobanks' network and community have proven to be, in both countries, the most effective tool to solve uncertainties and provide support.

The pathway to a career in biobanking can have different backgrounds and requires interdisciplinary skills, along with flexibility and attitude toward progress and collaboration. Specific and institutional trainings are proving to become more and more effective to bring researchers and clinicians closer to this environment with the necessary skills to operate in this complex context.

407: Capacity building for rare disease biobanking: results and lessons learned from the European Joint Programme on Rare Diseases

by Artuso, I | Casareto, L | Carta, C | Wang, CM | for the EJP RD WP 14.4 partners | Fondazione Telethon

ETS, Milan, Italy | Istituto Ortopedico Rizzoli, Bologna, Italy | Istituto Superiore di Sanità, Rome, Italy |

Fondazione Telethon ETS, Milan, Italy Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Casareto, L Keywords: biobanking, rare diseases, trainings

Biosamples and linked data are pivotal for RDresearch and such RD-biobanks are key infrastructures. The importance of RD-biobank training is therefore critical to fulfill the unmet needs of the RD-biobanking community.

Within the European Joint Programme on Rare Diseases, ten biobanking training workshops were successfully delivered. All workshops, open to all RD-biobanking stakeholders, were designed to be delivered in-person applying the problem-based learning method. The COVID-19 pandemic situation, however, required to move six workshops online in favor of more traditional lecture format.

The in-person workshop had the limit of 25 participants to allow effective implementation of the problem-based learning methodology

that was increased to up to 45 in the online editions.

The trainees' feedback was highly positive (+90%), indicating the curriculum appropriateness and reconfirming the demand for high-quality training in biobanking.

From 2019 to 2023, two annual workshops were organized, training 259 participants who came from 44 different countries and represented different professional profiles, including patient representatives. One-third of them were already working in biobanking.

The workshops stimulated thinking and awareness in sharing RD samples and data, as well as best practices in data management, ethical awareness and enabled networking in RDresearch.

Although several educational opportunities in the biobanking field are available, they do not offer training addressing the needs of RD resources and research. This training series has contributed to underlining the importance of making biosamples available for research and sharing them in proper conditions, ensuring reliable results for researchers and protecting participants' interests and privacy.

348: Development of a Training Framework for Biobanking Research Infrastructures: Insights from Task 4.1 (Evolve BBMRI)

by Elena M Molina Roldán | CNIO Biobank Quality Manager

Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Elena M Molina Roldán Keywords: Competency matrix, biobank training

Introduction

Evolve BBMRI Task 4.1 aims to conceptualize a training and career curriculum for research infrastructure (RI) staff in biobanking and biomedical research. The objective is to identify training needs, map existing programs, and align them with RI competencies to address gaps and support development.

Materials and Methods

• Competency Matrix Development:

A biobank-specific competency matrix was created using RItrain and RItrainPlus as references. This first version (V1) will evolve with feedback.

• Survey Design:

A 22-question survey was developed to assess training programs, covering:

- Biobank information and training
- availability
- Existing training (title, type, format,

 language, duration, providers)
Training content (thematic areas, learning outcomes, accreditation)
Target groups

It was distributed to BBMRI-ERIC (24 National Nodes, IARC/WHO, and 400+ biobanks) from Dec 2024–Feb 2025. A workshop (M24) will engage academic training coordinators to refine findings. **Results**

• Competency Matrix: Version(V1)

• provides a structured framework for training needs. Survey Analysis: Ongoing

analysis supports a training catalogue (M15) and highlights gaps (M18).

Discussion and Conclusion

Task 4.1 bridges training programs and biobank needs through a structured skilldevelopment approach. The competency matrix and survey results will shape a tailored training catalogue. The M24 workshop will refine outcomes, ensuring alignment with stakeholder needs. This initiative addresses key challenges in European Research Infrastructure Consortiums (ERICs), integrating One Health, datafication, and sustainable biobanking.

313: BBMRI-ERIC Academy: New ERA for biobanking training

by Stella Antoniou | Eleanor Shember | Nadja Palko | Andrea Wutte | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria | BBMRI-ERIC, Graz, Austria

> Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Stella Antoniou Keywords: BBMRI-ERIC Academy, biobanking

> training, knowledge transfer, staff proficiency

Introduction

BBMRI-ERIC has extensive experience in setting up training in core services (QM, IT, ELSI, ERIC Forum, and others) at headquarters and National Node levels. This training, conducted by field experts, is largely non-university based. To adequately train research infrastructure staff in managerial and technical skills and enable knowledge transfer to the biobanking community, BBMRI-ERIC is evolving by offering novel training and career path concepts to address current scientific challenges, EU policy priorities, and respond to future training needs. The focus is on emerging topics like Datafication (WP1), Green Biobanking (WP2), and One Health (WP3), complemented by training needs identified in the EVOLVE BBMRI-ERIC project task 4.1.

Material and Methods

The BBMRI-ERIC Academy is under development, branding, and preparing to launch with the purpose to transfer knowledge in the community by combining practical hybrid (on-site) on<u>-</u> demand trainings complemented by thematically related online modules in a blended learning format.

Results

BBMRI-ERIC worked on conceptualizing and integrating a transparent structure to function as an educational organisation, adhering to ISO 21001:Management systems for educational organisations criteria. It is also building a pool of international trainers to cover emerging topics such as Datafication, Green Biobanking, and One Health and engaging with researchbased pharmaceutical and medical technology industries and industry clusters.

Conclusion

The BBMRI-ERIC Academy represents a major step forward in biobanking training. This initiative not only enhances knowledge transfer in the community but also aligns with EU policy priorities and industry needs, ensuring high educational standards and fostering collaboration within the biobanking community.

296: Ethical Tissue: A Not-for-Profit Model for Human Tissue Supply. Cell and Tissue Banking, 12(1), 9-10.

by Kevin Adams | Previous Board Member and Employee of the University of Bradford

> Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Dr Parisa Naeem | Joanne Mullarkey

Keywords: Biobank, Bradford, CPD, Ethical Tissue, Ethics, Human Tissue, Professional training, University

Introduction: High-quality biobanks are essential for biomedical research, requiring staff skilled in lab techniques, ethics, and compliance. Ethical Tissue at the University of Bradford developed **P.U.L.S.E** programme (Phlebotomy, Understanding Laboratory Skills, and Ethics) to address the gap in structured training programs for biobank professionals.

Materials and Methods: P.U.L.S.E was created by biobank experts, educators, and regulatory bodies. Specifically, P.U.L.S.E provides ethics and compliance training (GCP, cultural sensitivity, informed consent, regulatory frameworks); certified phlebotomy training (venepuncture, cannulation); and advanced lab skills training (immunohistochemistry, qPCR, cell culture). The programme is CPDaccredited and tailored for biobank managers, technical staff, and researchers. Participants undergo hands-on training, simulations, and assessments to ensure proficiency. The programme's concept and curriculum were presented to colleagues and students who provided valuable feedback through surveys.

Results: Although set to launch in Spring 2025, initial feedback indicates that 90% of respondents are enthusiastic and optimistic about its ability to enhance the efficacy of biobank training. Colleagues have praised the

curriculum for its novel and comprehensive approach. Staff anticipate it will be a highly valuable resource for staff within the biobanking industry.

Discussion and Conclusion: The enthusiastic response to **P.U.L.S.E** underscores the demand for structured biobank training. Participant feedback has been instrumental in refining the curriculum to meet industry standards. By bridging the gap in biobank education, **P.U.L.S.E** is poised to enhance biomedical research. Strong support further highlights its potential impact. Moving forward, efforts will centre on launching the programme to equip participants with the essential skills needed to excel as biobank professionals.

238: Comprehensive Training Program for the Implementation of a Research Biobank at University-Hospital of Padova (Italy)

by Benna, C | D'Angelo, E | Cassandro, G | Segato, S | Tasca, T | Rossato B | Agostini, M | Pucciarelli, S | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova | UniversityHospital of Padova | Department of Surgery Oncology and Gastroenterology, University of Padova,

Padova, Italy | Department of Surgery Oncology and Gastroenterology, University of Padova, Padova, Italy

Topic: 3D: Empowering the Next Generation: Education and Training in Biobanking Presenter Name: Benna, C Keywords: biobank awareness, biobanking, employees' engagement, survey, training course

Background:

The University-Hospital of Padova (AOUP) implemented a comprehensive training program to support the establishment of a state-of-the-art research biobank. The program aimed to raise awareness of the biobank's relevance and equip personnel from various operational units and different disciplines with the necessary knowledge and skills to contribute effectively to the biobank's operations.

Methods:

The training program lasted from February to December 2024 and consisted of several phases, including introductory modules that describe the objectives, challenges, and opportunities of the project, as well as in-depth modules on ethical, legal, and social implications (ELSI), quality management (QM), quality control (QC), and information technology (IT). As part of the QM and QC modules, a survey was designed to assess the complexity of pre-analytical procedures followed by clinical wards actively enrolling patients. A crucial phase involved individual meetings with each operational unit involved in the biobank project to share sample collection protocols, align expectations, assess learning outcomes, and gather feedback.

Results:

60 participants from 26 operational units accomplished the entire course. Participants obtained 50 ECM credits, recognizing their professional development efforts. The personalized approach through individual meetings with operational units ensured effective implementation and active participation from all stakeholders. The training initiative laid a strong foundation for excellence, compliance, and collaboration within the AOUP biobank. Its multidisciplinary approach and tailored strategy equipped staff to excel and uphold biobanking best practices. The program underscores the value of investing in staff training and will be held annually as part of AOUP's standard curriculum to ensure a steady flow of qualified personnel.

4D: Balancing Ethics and Innovation: ELSI in Biobanking

239: The Nature of Public Communication of Biobanks and Genomic Research: A Japanese Perspective

by Jusaku Minari | Uehiro Research Division for iPS Cell Ethics, Center for iPS Cell Research and Application (CiRA), Kyoto University

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking Presenter Name: Jusaku Minari Keywords: Public Perceptions, and Bioethical Frameworks

Since around 2000, large-scale biobanks, such as the UK Biobank, have been established and developed. These activities have increasingly facilitated genomic research. However, in general, large-scale biobanks and genomic research must make significant efforts to advance basic and translational research, where the societal benefits to clinical care and healthcare may not be immediately apparent.

Based on this premise, this presentation focuses on the nature of public communication and engagement in the sustainable development of large-scale biobanks and genomic research from a Japanese perspective.

Conclusions:

To clarify the challenges and opportunities in public perceptions regarding large-scale biobanks and genomic research, key Japanese academic articles were analysed. Relatedly, an attempt to raise public awareness of these initiatives was explored from the perspective of art and design.

The main findings highlight public preferences and ambiguities regarding these initiatives, which may stem from uncertain social values and norms. In particular, the widening gap between public perceptions and bioethical frameworks and practices—such as informed consent, biospecimen ownership, and ethical review—could be seen as an emerging challenge. To address this challenge, our team has initiated a novel project using artwork to raise public awareness of the relationship between cells and society.

From the public's perspective, the societal significance and benefits of basic and translational studies of large-scale biobanks and genomic research may be of greater interest than the research itself due to their relevance to everyday life. It is therefore essential that both research and its societal applications are recognised by a wider public.

289: Strengthening Biobank Practices: The Experience of INMI Biobank

by Maestripieri Claudia | Antonelli Valentina, Caparrelli Claudia, Prota Gianluca, Rossi Alberto, Carrara Stefania and Fontana Carla Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking Presenter Name: Claudia Maestripieri Keywords: ELSI in biobank; SOP; INMI biobank

Ensuring quality and efficiency in a biobank is crucial for regulatory compliance and

preserving the value of biological samples. High sample quality directly influences the validity of scientific research. This abstract highlights the key improvements our biobank has implemented, including developing Standard Operating Procedures (SOPs), participant awareness initiatives, and a thorough review of governance documents related to ethical, legal, and social issues (ELSI).

Ongoing training for our technical staff, combining technical and regulatory expertise, addresses current and future biobanking challenges. As part of the European BBMRI-ERIC network, our biobank has strengthened the management of biological samples and data. Adopting up-to-date SOPs has standardized processes and improved data reliability, with clear documentation accessible on our website for other biobanks.

Additionally, we engage in awareness-raising events like 'Research Night' to promote informed donor participation, ensuring clarity informed consent and transparent in communication. Our ISO:9001-2015 certification affirms our commitment to quality, and building trust within the biobanking ecosystem. In the meantime, we working to achieve ISO 20387 are accreditation, in order to improve our competence, impartiality and quality control requirements to ensure biological material and data collections of appropriate quality. These initiatives enhance sample management and reinforce the biobank's vital role in supporting the scientific community.

In summary, our efforts solidify the biobank as a key resource for researchers, maintaining high standards of quality and reliability while promoting sustainable and innovative biobanking practices.

337: Brain donation in Italy: is it possible?

by Riccardo Rocco Ferrari | Vittorio Bolcato | Giuseppe Basile | Annalisa Davin | Giulia Negro | Arcangelo

Ceretti | Antonio Guaita | Mauro Colombo | Mauro Ceroni | Livio Pietro Tronconi | Tino Emanuele Poloni |

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University of Rome, Department of Human Science, Rome, Italy & GVM Care and Research, Maria Cecilia

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Department of Rehabilitation, ASP Golgi-Redaelli, Abbiategrasso, Italy

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking Presenter Name: Riccardo Rocco Ferrari Keywords: body donation, brain banking, health regulations, post-mortem brain donation **Introduction:** Brain banking represents a crucial frontier in the field of neuroscience. Nevertheless, current Italian law does not comprise brain donation programs. We propose strategies to effectively regulate brain donation and brain banking in Italy.

Material & methods: A review of the Italian legal context about this issue was performed.

Findings: The most important rules are dictated by the following laws: 1) Law 12 1993, n.301 regulates August death ascertainment, based on the verification of the "irreversible cessation of all brain functions" through thanatography (20-minute flat ECG); 2) Law 10 February 2020 n.10 ("directives on own body and post-mortem tissues disposal for study purposes") represents the most important legal advancement, enhancing individual's will expression. However, the law considers only those facilities that can manage the entire body, without mentioning the management of individual post-mortem tissues, which is highly specific for brain.

Discussion & Conclusion: Death ascertainment by thanatography, conceived for cornea donation, should be extended to brain donation, for which a timely harvesting is crucial to avoid rapid tissue deterioration. The peculiarity of brain harvesting allows to quickly return the body to the family for the funeral, carefully recomposed and visible. Instead, whole-body donation is conceived for didactic anatomical dissections, possibly leading to a negative emotional impact. Moreover, this activity is not suited for brain handling since there is a huge difference between the brain and the entire body or other tissues. Brain banking should have a specific regulation to ensure ethical and effective collection,

characterization, storage and distribution of brain samples.

390: Efforts to Discuss Challenges Among a Wide Range of Biobank Stakeholders – Biobank Open Forum in Japan

by Fuji Nagami | Junko Ikeda | Makiko Inoue | Tsutomu Tomita | Takayuki Morisaki | Soichi Ogishima | Tohoku Medical Megabank Organization, Tohoku University | Council for Industrial use of Biological and Environmental Repositories | Tohoku Medical Megabank Organization, Tohoku University | National

Cerebral and Cardiovascular Center | Institute of Medical Science, University of Tokyo | Tohoku Medical Megabank Organization, Tohoku University

Topic: 4D: Balancing Ethics and Innovation: ELSI in Biobanking Presenter Name: Fuji Nagami Keywords: discussion, forum, stakeholder

Biobanks are sustained not only by its operators but also by the contributions of various stakeholders, including users, donors of biospecimen and information. While biobank operators occasionally receive requests from users, there are few opportunities to discuss the universal challenges involved, beyond the boundaries of individual positions. In Japan, efforts have been made to create a forum where these issues can be openly discuss with various stakeholders, such as donors to biobanks (patients/general residents), biobank operators, academic researchers, industrial users and associations, and governments. Here we report on the progress of these initiatives.

The Biobank Open Forum, which started in August 2021, has been held eight times so far. This forum has been organized through the efforts of a small organizing committee, and it continues to be held primarily online. Feedback has been gathered through surveys after each event.

The Biobank Open Forum has attracted a total of approximately 2,500 participants. Nearly 1,500 individuals have registered email addresses, forming the largest community around biobanks in Japan. There has also been interaction with European biobanks, with BBMRIERIC giving lectures at two of the events.

Through these forums, various challenges surrounding biobanks have been identified, and they have provided a starting point for initiatives aimed at resolving these issues. By creating an open platform and fostering discussions, the forum has played a role in advancing the biobank community.

5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability

281: Striving towards a bio- and tissue bank department with multi-deployable personnel

by Jeroen Caremans | Natascha Perales Selva | Yentl Wouters | Pieter Moons | Manon Huizing | Biobank Antwerp, Belgium | Biobank Antwerp, Belgium | Biobank Antwerp, Belgium | Biobank Antwerp, Belgium | Biobank Antwerp, Belgium

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability Presenter Name: Jeroen Caremans Keywords: biobank, efficiency, harmonization, tissue bank

Introduction: In our hospital, the formerly separated biobank and tissue bank were merged into one department. One of the goals was to harmonize processes within the two departments and to share personnel and processes. Now, we want to verify to what extent this can be made possible.

Materials & methods: A comparison between biobank and tissue bank processes was made. Topics for the comparison were chosen based on the process flow of human body material and on the requirements from legislation, good practice guidelines, the ISO20387 norm and QMS documents. Topics were grouped as sample flow and quality topics.

Results: The general sample flow from collection to distribution is the same for biobank and tissue bank, but the only process steps that have parallel requirements are receipt, storage and distribution. The quality topics show more similarity.

Discussion: Currently in Belgium, the law on human body material of 2008 is the only common regulatory requirement for biobanks and tissue banks. The new European regulation on substances of human origin (SoHO) does not include biobank requirements and will require a new Belgian law. Still there are many parts of the processes that have quite similar requirements. Therefore it is useful to streamline biobank and tissue bank processes, especially when considering moving both departments to a common location in the future, and considering the efficiency of shared personnel. Suitable topics for harmonization include mainly the quality processes (not related to the human body material flow), like personnel and training, consumables, equipment (storage), validation management and quality management.

368: The Service Catalogue of BBMRI.it

by Matteo Gnocchi | Marco Moscatelli | Valentina Adami | Luciano Milanesi | Andrea Manconi | CNR-

ARMI4, Italy | CNR-ARMI4 | University of Trento, Italy | CNR-ITB | CNR-ITB

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability Presenter Name: Andrea Manconi Keywords: biobank services, core facilities

Introduction- BBMRI.it Biobanks offer ondemand services for sample processing and data analysis.

A public catalogue describing the infrastructure services would help to promote accessing infrastructure resources according to an Open Science mechanism.

Material & method- We implemented an online catalogue to effectively and consistently engage biobanks and industry who need to access the infrastructure services. The catalogue is implemented in the NextGenerationEu "Strengthening BBMRI.it" project.

The data model underlying the catalogue defines two main entities: ServiceProvider and Service. The descriptive fields of these entities include information useful for evaluating the services. For example, it is possible to describe the type of collaboration, the access method and the scientific instrumentation used to implement a given service.

Results- A dedicated platform with controlled forms has been implemented to allow service providers to submit and/or update information describing themselves and the offered services. The public interface of the catalogue allows to search for services according to different features. Specific filters have been implemented to support the search for. The catalogue is available at the address <u>https://servicecatalogue.bbmri.it/</u>.

Discussion and conclusion-The catalogue promote accessing infrastructure resources according to an Open Science mechanism. Currently, 100 services provided by 32 service providers are published in the catalogue.

This activity has been supported by the fundingof the European Union (NextGenerationEU),Italian NRRP project code IR0000031 -StrengtheningBBMRI.itB53C22001820006.

375: Strengthening BBMRI.it by enhancing synergies between biobanks and core facilities

by Valentina Adami | Mirella Collini | Angela Bozza | Marco Borra | Daniela Capello | Monica Forni | Andrea Manconi | Matteo Pallocca | Marialuisa Lavitrano | University of Trento | University of Trento |

University of Trento | Stazione Zoologica Anton Dohrn, Napoli | University of Piemonte Orientale | University of Bologna | Institute of Biochemical Technologies, CNR, Milano | Istituto degli Endotipi in

Oncologia, Metabolismo e Immunologia G. Salvatore (IEOMI), Napoli | University of Milano Bicocca

Topic: 5D: Securing the Future of Biobanks: New Collaboration Models for Sustainability Presenter Name: Valentina Adami Keywords: BBMRI.it, Core Facilities, services

Introduction

Strengthening <u>BBMRI.it</u>, a project funded by NextGenerationEU (Mission 4 Component 2, CUP B53C22001820006) supports the BBMRI Italian Node by integrating a Core Facilities (CFs) network to enhance the Research Infrastructure portfolio with services for omics analysis, microscopy, cytometry and other key technologies for characterization of BBMRI.it collections towards the development of Virtual Cohorts. CFs are technology-based labs with advanced equipment managed by expert personnel, offering services to internal and external researchers.

In 2022, 11 academic institutions signed a Memorandum of Understanding to establish the Network of Italian Core Facilities (<u>NICo</u>), promoting best practices in managing technology platforms. NICo partnered with BBMRI.it to foster service provision to biobanks in accordance with institutional activities and regulations. Participating facilities commit to quality standards, ELSI compliance, and scientific community guidelines for developing SOPs and protocols.

Methods & Results

To strengthen the BBMRI.it-NICo collaboration, the following activities were undertaken:

- Training CF staff on financial and legal aspects of service provision, such as fee calculation, contracts, privacy, material and data transfer.Providing management software for service tracking and cost recovery.
- Developing a service catalog to integrate NICo and biobank services.
- Mapping academic CFs within the BBMRI.it network via surveys.
- Launching public calls for BBMRI.it collection characterization via CF and for interlaboratory quality and reproducibility testing.
- Involving BBMRI.it in NICo's annual conference

Conclusion & Discussion

This project enhances synergies between biobanks and CFs, ensuring high-quality service provision alongside robust sample and data distribution. The collaboration strengthens resource sharing, expertise, and best practices, benefiting both communities and advancing Italian research.

7D: Patient-Centric Biobanking: Strategies for Engagement and Participation

232: use MY data – Patients Driving Tissue Sample Use

by Richard Stephens | Alison Stone | Patient and Donor; Chair, use MY data; past Chair BBMRI-ERIC Stakeholder Forum | Head of Programmes & Engagement, use MY data

Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation Presenter Name: Richard Stephens Keywords: Patient activism; patient leadership; data; samples;

Background

use MY data (uMd) is the only independent UK movement of patients and carers campaigning for the use of patient data to save lives and improve outcomes.

The UKCRC Tissue Directory and Coordination Centre estimates that only 15% of samples in UK biobanks are ever used, and that one challenge in using samples was lack of easy linkage to patient/donor health care data.

Method

use MY data facilitated a workshop with partners, to seek solutions and identify key areas for campaign activity about biobanking. The workshop brought together stakeholders from patient groups, researchers, industry and tissue banks, aiming to agree specific recommendations for improving the use of human tissue samples, including removing barriers to linkage with patient/donor data.

Results

The workshop published its report in January 2020 - *"The Issue With Tissue: Recommendations for the use of human tissue samples."* (*) It outlines ten recommendations that can be achieved by voluntary actions within the UK biobanking research community, and elsewhere too. One is to create a citation acknowledging that, without patients donating tissue samples, research would not be possible.

Conclusions

Patients donate samples to facilitate research and to discover new treatments. *The Issue With Tissue* is a call to action for researchers, institutions, funders and regulators each to make these things happen. Patient advocates are themselves driving change by campaigning for their tissue to be used, to help the next generation - "When I donate, I want to give an instruction. Use my tissue to benefit others!" *(*)*

<u>https://usemydata.org/content_db.php?page=</u> <u>1641</u>

233: use MY data – The Donation Citation

by Richard Stephens | Alison Stone | Patient and Donor; Chair, use MY data; past Chair BBMRI-ERIC

Stakeholder Forum | Head of Programmes & Engagement, use MY data Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation Presenter Name: Richard Stephens Keywords: Patient activism; patient leadership; donation citation; samples;

Background

use MY data (uMd) is the only independent UK movement of patients and carers campaigning for the use of patient data to save lives and improve outcomes, both now and for the future.

To emphasise the importance of data access for health research generally, uMd members created the patient data citation:

"This work uses data provided by patients and collected by the NHS as part of their care and support."

Discussion

This citation has proved popular with researchers across the UK. It featured on 29 of the 103 posters at Cancer Research UK's (CRUK) Data-Driven Cancer Research Conference (2024), and it is incorporated into all posters produced by the doctoral researchers at the Leeds University CDT for AI in Health Care.

Many uMd members are also biobanking donors and want their tissue to be used for research. They have helped create a specific citation to emphasise the importance of this point:

"This research was possible only because patients have donated their tissue."

Patient advocates can (and do) now ask researchers to promote using tissue samples by

using the Donation Citation when reporting their work. As with its predecessor, it is easy to use on existing posters (e.g. added as a sticker), it is a simple addition to acknowledgements in journal papers, and it can be amended or expanded if wished.

Conclusions

The principle and practice of using the Donation Citation can be promoted widely by patient groups, including the members of BBMRI Stakeholder Forum's Patient Pillar.

300: Digital Media for optimizing the collection of Informed Consent in pediatric and adult patients

by Locatelli, M | Boarini, M | Magagnoli, G | Assirelli, E | Casareto, L | Mordenti, M | Pedrini, E | Calzolari, M | Trisolini, G | Sangiorgi, L | Biological Resource Centre, IRCCs Istituto Ortopedico Rizzoli | Department of Rare Skeletal Disorders, IRCCS Istituto Ortopedico Rizzoli | Biological Resource Centre,

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Disorders, IRCCS Istituto Ortopedico Rizzoli | Department of Rare Skeletal Disorders, IRCCS Istituto Ortopedico Rizzoli | Biological Resource Centre, IRCCs Istituto Ortopedico Rizzoli | Pediatric Orthopedics and Traumatology, IRCCS Istituto Ortopedico Rizzoli | Department of Rare Skeletal Disorders, IRCCS

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Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation Presenter Name: Manuela Locatelli Keywords: Biobank, Digital Media, Engagement,

Informed Consent, Registries, Survey

Introduction

Research in the medical field requires highquality biological samples and data. To meet this need, a Biological Resource Center and Disease-specific Registries were established at IOR to ensure the quality of samples and data for research. The project aims to enhance Informed Consent collection through multimedia systems that guarantee an informed entrustment of samples to biobanks and data for registries, promoting patient participation and contributing to the advancement of knowledge in early diagnosis and personalized medicine.

Material & methods

Informational content was delivered through video materials tailored for both adult and pediatric audiences. The videos' effectiveness in improving comprehension and engagement was evaluated via survey assessing their impact on participants.

Results

The project created educational videos for both adults and children, covering biobank activities, disease registries and Informed Consent. The videos, featuring engaging visuals, voiceovers, and keywords, were designed to work together while remaining independent. A cartoon-style video was produced specifically for children. A survey assessed the tool's efficacy.

Discussion and conclusion

The study included 59 participants both patients (30% minors), and caregivers. Participants had good knowledge of informed consent but limited understanding of biobanks and disease registries. The educational video content was perceived as engaging, clear, and helpful. The Informed Consent video was particularly valuable during the consent process. Participants showed strong support for the use of new technologies and educational videos in Informed Consent procedures.

Founded by the Italian Ministry of Health -5×1000

315: Participant Experiences with an Al chatbot for Guidance of Selfmeasurements at a Biobank Research Site.

by Fennie van der Graaf | Alexandra Matei | Giuseppe Marinelli | Aevai Health | Aevai Health | Aevai Health

Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation Presenter Name: Fennie van der Graaf Keywords: AI, Chatbot, Empowerment, Engagement, Large Language Models, Selfmeasurements

Self-measurements for biobank data collection can improve participant empowerment and workflow efficiency (1), however offering support during autonomous data collection can be challenging. A population biobank in the Netherlands recently implemented several selfmeasurements on site, such as a SECA machine which measures body composition, to improve the efficiency of the visit and reduce staff burden. However, participant guidance still heavily relied on staff. With the rise of large models, AI chatbots have language demonstrated human-like performance as assistants in healthcare (2). Aevai Health B.V. developed ALVA to guide and assist participants during their biobank visit by answering questions about the biobank, the research, and the measurements.

Participants (median age 69) who used ALVA for 5 weeks provided anonymous feedback about their experience and also evaluated ALVA's AI responses. To evaluate the significance of "good/very good" ratings, a onesample proportion z-test was conducted.

From a total of 183 feedback responses, 80% of participants significantly rated their experience as good/very good, while 20% rated it as neutral/bad. Positive qualitative feedback included feeling independence, and finding it an informative and fun experience. Negative feedback included the low speed of chatbot messages and the increased focus on the phone. Participants had a 93% satisfaction rate with the AI answers.

This study demonstrated that participants had a positive experience using an AI chatbot for assistance with data collection at a biobank site. Further evaluation is needed to demonstrate the potential of the AI chatbot to reduce staff burden and improve operational efficiency of the site.

351: Innovating biobanking: the Golgi Cenci Biobank challenge

by Annalisa Davin | Riccardo Rocco Ferrari | Chiara Calatozzolo | Alessandra Canazza | Giulia Negro | Arcangelo Ceretti | Mauro Colombo | Antonio Guaita | Tino Emanuele Poloni | Laboratory of Neurobiology and Neurogenetics, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Laboratory of Neurobiology and Neurogenetics, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci

Foundation, Abbiategrasso, Milan, Italy & School of Medicine and Surgery and Milan Centre for Neuroscience (NeuroMI), University of Milano-Bicocca, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation, Abbiategrasso, Milan, Italy | Department of Neurology and Neuropathology, Golgi Cenci Foundation & Department of Rehabilitation, ASP Golgi-Redaelli, Abbiategrasso, Milan, Italy Topic: 7D: Patient-Centric Biobanking: Strategies for Engagement and Participation Presenter Name: Annalisa Davin Keywords: biobanking, engagement, longitudinal

study, social participation

Introduction: Biobanking is a promising frontier for human research and an opportunity for the diffusion of a scientific culture. Thus, dedicated efforts for conscious and participatory biobanking are essential to address the challenges of scientific research in a community-based manner. Believing in this type of approach, we created the Golgi Cenci Biobank along the lines of the "InveCe.Ab", the first Italian longitudinal cohort study including a brain donation program.

Materials and Methods: The "InveCe.Ab" study, launched in 2009, involved crosssectional and longitudinal assessments of individuals born between 1935 and 1939 in Abbiategrasso, Milan, Italy. Assessments included medical and neuropsychological evaluations, anthropometric measurements, social and lifestyle interviews, blood analyses, and the collection of blood-derived samples. Additionally, brains of consenting subjects were collected.

Results: In 2009, the participation rate for "InveCe.Ab" was 80.4%. This rate has remained constant over time and the study now includes multidimensional data from 1321 elderly subjects across five follow-ups over the last 15 years. Furthermore, 181 subjects consented to brain donation.

Discussion & Conclusion: The success of the "InveCe.Ab", in terms of people's participation, is due to a human-centered approach, promoting social inclusion and citizens engagement. The Golgi Cenci Biobank aims to enroll "InveCe.Ab" participants following this model that include face-to-face meetings with trained staff and a continuous relationship with participants through birthday cards, year-end reports, Christmas greetings, and medical support. This approach is also the key to obtain a wide variety of data (psychological, sociocultural, nutritional, biological, genetic, clinical, neuropathological) essential to generate multiple interesting correlations.

8D: Connecting Forces: Effective Stakeholder Management

293: Building Public Trust: Informing 1.3 Million Danes About Their Stored Samples

by Karina Meden Sørensen | Cathrine Hansen | Lydia Viekær | Ruben Bjerregaard Nielsen | Anne-Marie Vangsted | Statens Serum Institut Topic: 8D: Connecting Forces: Effective Stakeholder Management

Presenter Name: Anne-Marie Vangsted | Karina Meden Sørensen Keywords: National legislation, citizens right, sample destruction The Danish National Biobank and the local laboratories at SSI house millions of biological samples collected from both research projects and diagnostic analyses performed at SSI. All samples are collected in accordance with the applicable legislation, but most citizens were unaware that their samples are stored at SSI, as informing them was not considered a legal obligation prior to 2024. Recently, the Danish Data Protection Agency ruled that all citizens with diagnostic samples stored at SSI must be informed.

Material and methods

Letters were sent to approximately 1.3 million citizens via Danish national electronic post or mail. The letters were sent in bundles according to the types of samples and age groups. Citizens were instructed to contact SSI with questions, requests for access to personal data or sample destruction.

Results

Out of 6 million Danish citizens approximately 1.3 million received a letter regarding storage of their sample. The response rate was 0.2%.

Discussion and conclusion

The response rate was lower than expected, with an anticipated 0.6% based on information letters sent by Copenhagen Hospital Biobank. We distributed letters in three phases, with the highest response in the first phase, likely influenced by a critical TV report and the targeted age group.

Our low response rate reflects a high level of trust in Danish society towards the healthcare system and authorities, while underscoring the importance of transparency, a key objective for SSI. Additionally, the response data offers insights into how the information can be customized for different demographic groups.

270: Developing a Collaborative Communications Toolkit to Improve Stakeholder Engagement in Biobanking

by Verena Huth | Mariangela Masiello | Cornelia Specht | Eleanor Shember | German Biobank Node (GBN) | BBMRI-ERIC | German Biobank Node (GBN) | BBMRI-ERIC

Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Verena Huth Keywords: BBMRI-ERIC Taskforce 9, Communication, EvolveBBMRI, National Nodes, Toolkit, Transparency, Trust

Introduction: Effective communication is essential to foster trust, transparency and collaboration among biobanking stakeholders. As part of the EU project EvolveBBMRI Work Package 4 ("Strengthened approach to training and outreach activities to maximise impact"), BBMRI-ERIC is developing a communication toolkit. This resource aims to streamline outreach efforts and support its National Nodes and biobanks across Europe in engaging their stakeholders.

Materials and Methods: The toolkit is being developed collaboratively by the BBMRI-ERIC Taskforce 9 (Communications and Outreach), which includes representatives from various BBMRI-ERIC National Nodes. The Taskforce assesses community needs, sources existing best practice materials and provides ongoing feedback to ensure that the Toolkit meets the diverse needs. Existing outreach materials contributed, e.g. by the German Biobank Node (GBN), Task Leader for outreach-related activities in WP 4, will be transformed into reusable templates.

Results: The first version of the toolkit, to be released in summer 2025, will provide flexible,

standardised resources to improve communication and stakeholder engagement. It will include e.g. customisable poster, flyer, and social media post templates, a free image database and other tools.

Discussion: The conference poster will preview the toolkit and invite further feedback from participants to refine its development. It will also serve as an opportunity to raise awareness of Taskforce 9 and encourage participation, ensuring that the toolkit develops as a community-driven resource.

299: Effectively Showcasing Success and Impact: Tailored Communication for Engaging Biobanks and Researchers in Switzerland

by Claudia Lagier | Christine Joye | Sabine Bavamian | Louise Roy | Swiss Biobanking Platform | Swiss Biobanking Platform | Swiss Biobanking Platform |

Swiss Biobanking Platform Topic: 8D: Connecting Forces: Effective Stakeholder

Management Presenter Name: Claudia Lagier Keywords: Biobank Network, Biobanking Community, Communication & Outreach, Empowerment, Engagement Strategies, European Collaboration, Research Community, Researcher Engagement,

Stakeholders, Success Story

As the national research infrastructure coordinating biobanking activities, Swiss Biobanking Platform (SBP) has strengthened its communication efforts to solidify its leading position in Switzerland, foster European collaborations, and demonstrate its impact to key stakeholders.

Since 2021, SBP has focused its communication strategy on reaching first its primary users, the biobanking community, by creating a network of over 100 biobanks making their samples and data Findable, Accessible, Interoperable, and Reusable (FAIR) for the research community.

SBP has developed engagement strategies with monthly newsletters in four languages, expanding its audience with a great average open rate of 45%. In parallel, SBP maintains a highly active presence on LinkedIn featuring informative and educational posts, as well as targeted campaigns, attracting more than 1100 followers since 2021.

Building on this successful biobank empowerment, SBP now aims to engage the research community more specifically, promoting and improving the use of samples stored in its growing biobank network. To better serve researchers, the website will be revamped with a dedicated page featuring tailored materials.

SBP will leverage its proven approach for biobanks using the same core structure to attract researchers and will collaborate with BBMRI-ERIC to empower this target group. By showcasing success and impact stories, expanding our newsletter outreach and gathering insights via LinkedIn, we will communicate more effectively with this key audience.

327: Developing a Set of Biobanking Frequently Asked Questions for BBMRI.be: A Collaborative Approach in Belgium

by Elke Smits | Elke Berneel | Veronique De Keyser | De Wilde Annemieke | Manon Huizing | Patrick Miqueu | Ilse Gutierrez-Roelens | Maartje Van Frankenhuijsen | Peter Vermeulen | Natasha Wauters | Stephanie Gofflot | Clinical Research Center Antwerp, Antwerp University Hospital & University of

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Jules Bordet | UCLouvain university | Biobank Institute of Tropical Medicine, Antwerp | enhuis Aan de

Stroom, Antwerpen | Biobank VITO | Biothèque Hospitalo-Universitaire de Liège, CHU de Liège Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Elke Smits Keywords: biobank costs, cost calculator

Introduction

The BBMRI.be Stakeholder Involvement Working Group fosters collaboration between BBMRI.be biobanks and key stakeholders, including patient organizations, researchers, and industry professionals. To address common inquiries, a helpdesk was established at the BBMRI.be National Node as part of the B3-ISO Quality Improvement and Harmonisation project, leading to the development of a comprehensive FAQ resource. This initiative aimed to develop and maintain а comprehensive set of Frequently Asked Questions (FAQs) tailored to the needs of BBMRI.be stakeholders.

Methods

A structured process was designed to collect, evaluate, publish and periodically update FAQs. FAQs were collected from biobanking websites, webinars, guidelines, and direct inquiries via email, phone, and BBMRI.be meetings. Candidate FAQs were screened for relevance to the Belgian context and refined by BBMRI.be working groups based on predefined priorities.

Results

A total of 311 candidate FAQs were identified, with 76% sourced from international biobanking resources, 9% from direct inquiries, and 7% from discussions at BBMRI.be events. Despite offering a dedicated email and website submission tool, no FAQs were received through these channels, leading to a decision against investing in additional interactive tools. Following review and prioritization, 52 FAQs will be published on the BBMRI.be website in two iterative updates, followed by annual revisions. Additionally, 33 FAQs have been integrated into B3-ISO SOP templates.

Conclusions

The FAQs cover a wide range of biobanking topics, improving stakeholder engagement and understanding. By providing accessible information, this resource supports patients, researchers, healthcare professionals, and industry partners in navigating biobank processes in Belgium.

352: Empowering Biobank Users Through Simplicity, Training, and Community Collaboration

by Louise Roy | Swiss Biobanking Platform Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Louise Roy Keywords: Community, collaboration, design, education, training

Biobanking professionals often face challenges when adopting new tools, such as lengthy training and complex implementation processes, often driven by the need for extensive customization. Our innovative approach addresses these barriers bv combining intuitive design, universal applicability, and a strong commitment to training and knowledge sharing. As part of Biobanking Platform's Swiss broader educational mission, SMPL supports biobanks in adopting structured and efficient sample management practices. Designed with usability at its core, its intuitive interface reduces cognitive load, allowing users to navigate the system effortlessly and focus on their core work. Instead of requiring complex configurations, the tool provides a structured yet flexible environment, where users can quickly adapt workflows to their specific needs. Ready-to-use presets further streamline adoption, reducing setup time while ensuring consistency across biobanks.

To complement this simplicity, we propose a user-driven community where biobanks can share experiences, explore how others have addressed similar challenges, and co-develop solutions. This peer-exchange model fosters continuous learning and process optimization while reducing reliance on direct support. Feedback gathered through community discussions and shared experiences enhances the user guide and helps refine the tool to meet evolving biobank needs.

By combining intuitive design, training, and collaborative learning, we simplify tool adoption and help harmonize biobank practices while creating a sustainable and empowered network that fosters collaboration and drives innovation.

356: Connecting forces and competences since the initial idea of a sample collection protocol is key factor to support and advance scientific research

by E. Cantarelli | E. Dugnani | V. Maselli | E. Zino | C. Tresoldi | F. Ciceri | Centro Risorse Biologiche, IRCCS Ospedale San Raffaele (Milan, Italy) | Ufficio Qualità Ricerca, IRCCS Ospedale San Raffaele (Milan, Italy) | Ufficio Qualità Ricerca, IRCCS Ospedale San Raffaele (Milan, Italy) | Clinical Trial Center,

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Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Elisa Cantarelli Keywords: CTC, GDPR, protocol, user

Introduction – The Biological Resource Center (CRB) is the institutional biobank of IRCCS Ospedale San Raffaele. As hospital-integrated biobank, the main users are clinicians and researchers belonging to OSR clinical departments and research laboratories involved in clinical research protocols with sample collection.

Methods and Results – In collaboration with Clinical Trial Center (CTC), Quality Research Office (UQR), Legal Office and Data Protection Office, the CRB prepared template protocols for disease-driven sample collection or а observational study and informed consent including biobank and databank description as well as declaration of informed consent for collection, storage and use of samples and associated data for research. These forms are compliant with ISO 20387, GCP/GCLP standards and relevant legislation (e.g. GDPR) and codified in CRB and CTC QMS. Moreover, the CRB developed a protocol-specific agreement called Protocol Plan to define the biobanking activities and the management of samples and associated data to have samples suitable for the intended use thus aligning the CRB's work with the needs of our users. The Protocol Plan is prepared before protocol submission to the Ethical Committee and requested by CTC as it promotes transparency and collaboration and guarantees that biobanking activities are carried out using standardized methods and in compliance with OSR/CRB procedures. The Protocol Plan also represents an agreement between CRB and users signed by both parties for role and competence.

Conclusions – CRB engagement since the initial idea of a sample collection protocol builds trust in CRB, ensures the adherence to ethical-legal-social issues, sustainability and guarantees high-quality samples.

358: Establishing the Piedmont Regional Biobanking Network: A Model for Sustainable and Standardized Biobank Collaboration

by Oliveri Giulia | Libener Roberta | Bava Cecilia Irene | Di Sapio Alessia | Sorbini Monica | Ruggeri Marina | Deaglio Silvia | Novelli Francesco | Camusso Elisa | Bettio Valentina | Capello Daniela | Casale

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Piemonte | Integrated Activities Regional Research and Innovation Department (DAIRI-R), Azienda Sanitaria Zero Regione Piemonte

Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Libener Roberta Keywords: Biobanking; Regional Biobank Network; Harmonization; Sustainability; Research Collaboration

Introduction Biobanks have become essential resources for research, providing highquality samples and associated data. Standardized processes and sustainability are critical for their success. In this context, major public biobanks in the Piedmont Region, Italy, established a Working Group (WG) coordinated by the Department of Integrated Activities for Research and Innovation (DAIRI) to create a Regional Biobanking Network.

Materials and Methods The network includes Alessandria Biobank, CRESM, ENOAPA, TESEO, UPOBiobank and BB-DNS. The WG aims to promote harmonized activities among Piedmont's biobanks, establish a regional population biobank, improve public health, and foster biobanking-related research. Activities involved monthly meetings, training events, and collaborative projects. Key objectives include the design of multicenter studies and collaboration in drafting manuals and scientific articles.

Results Over a year, the network organized two public awareness events: one during BiotechWeek to introduce the WG and its objectives, and another focused on pediatric biobanks. The WG developed a Regional Manual on the introduction to biobanking, published in Working Paper of Public Health.

A shared Recovery Cost model, accounting for sample value and time sensitivity, is under development, alongside the structuring of multicenter studies on biobanking education for medical students and patient engagement. The WG is also supporting the development of emerging biobanks.

Discussion/Conclusion The Piedmont Regional Biobanking Network fosters collaboration among biobanks, promoting sustainable and standardized practices. Its initiatives enhance public understanding of biobanking, support research, and lay the groundwork for future population biobanks. This coordinated approach serves as a model for the development of regional biobanking networks.

394: A pilot study, including biobanks and Patient Organizations, for the implementation and testing of the BBMRI.it national informed consent matrix in TNGB

by Casati, S | Baldo, C | Casareto, L | Locatelli, M | for BBMRI.it-TNGB informed consent laboratory group | Common Service ELSI BBMRI.it | Istituto Giannina Gaslini, Genova, Italy | IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy | IRCCS Istituto Ortopedico Rizzoli, Bologna, Italy

Topic: 8D: Connecting Forces: Effective Stakeholder Management Presenter Name: Baldo, C Keywords: ELSI, biobanking, informed consent, partecipative laboratory, rare diseases

The European Regulations changed our ELS horizon. In 2017-2018, the BBMRI.it Common Service (CS) ELSI facilitated a working group on informed consent (IC) composed by all RDbiobanking stakeholders (i.e. patient representatives, biobankers, research institutions, ELSI experts) aimed at drafting through a participatory approach a matrix of IC for biobanking research, as an ELS co-produced framework for a dynamic informative process.

The Telethon Network of Genetic Biobanks (TNGB) composed of Italian RD-biobanks, to be GDPR compliant, needed to remodel its IC model. Thus, BBMRI.it CS ELSI and TNGB, activated a laboratory composed by twentyfive experts, including biobankers and patient representatives where the TNGB IC model became a training ground to implement the BBMRI.it matrix. The matrix was the laboratory concrete framework, a participatory approach based on dialogue, multidisciplinary, pluralism and progressive co-production, the methodological horizon was applied through several teleconferences and a joint work on a collaborative platform. Turning-points were the achievement of common language, content articulation and link between information and governance. It was critical to discuss the sample preservation time, depletion of the last aliquot and minor re-consent.

In conclusion, the new TNGB IC model proves how joint, equal and participative method involving all RD-biobanking stakeholders and infrastructures is a successful approach for producing documents and good practices not only legally but also ELSI compliant as well as patient-tailored.

10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives

260: Mutual recognition of multicenter biobank assessment in the Netherlands

by Ellis Niemantsverdriet | LUMC Central Biobank Facility, Leiden University Medical Center (LUMC), Leiden, The Netherlands

Topic: 10D: Emerging EU Regulations Unveiled: Latest ELSI Developments and National Perspectives Presenter Name: Ellis Niemantsverdriet Keywords: , Assessment, Ethics, Review

INTRODUCTION

Currently, the ethical review assessment of biobanks is organized differently across all centers in the Netherlands. As a consequence, each multicenter biobank has to go through a different process at each center, with different templates being used. This inefficient assessment, high regulatory burden is addressed in the mutual recognition project, with the ultimate goal to provide a Dutch framework for the assessment of initiation and distribution of material from biobanks.

MATERIAL & METHODS

To address the differences between the centers, multiple hackathons were performed to draft model-templates (participant information folder (PIF), collection protocol, and research protocol) and create a set of assessment criteria. Thereafter, pilots were introduced to the ethical review committees to provide input the developed on modeltemplates and assessment criteria, which led to the mutual recognition in the Netherlands for multicenter biobank assessment.

RESULTS

Deliverables of the project are **modeltemplates** and the mutual recognition in which the assessing biobank committees will review each assessment with the same set of assessment criteria. In addition, the full assessment for multicenter biobanks is only required at the submitting center, the other center(s) will carry out a local feasibility check.

DISCUSSION

The mutual recognition contributes to a less regulatory burden, for both researchers and ethical review committees, and harmonizes the ethical assessment of biobanks within the Netherlands.

More information concerning this project, frequently asked questions, and the modeltemplates are available at the **Health-RI ELSI Service Desk** (Toetsing van onderzoek | Elsi Servicedesk).