



MEDICAL UNIVERSITY OF GDAŃSK

EUROPEAN JOURNAL OF TRANSLATIONAL AND CLINICAL MEDICINE



2021

Vol. 4

Suppl. 3

www.ejtcm.gumed.edu.pl

ISSN 2657-3148

e-ISSN 2657-3156

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80-211 Gdańsk, Poland

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E-mail: ejtcm@gumed.edu.pl
www.ejtcgumed.edu.pl

Publisher

Medical University of Gdańsk
M. Skłodowskiej-Curie 3 A
80-210 Gdańsk, Poland
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University of Gdańsk

Gdańsk 2021
e-ISSN 2657-3156

Online edition is the
original version of the journal



IV KRAJOWA NAUKOWO-SZKOLENIOWA KONFERENCJA BIOBANKÓW POLSKICH

**BBMRI.pl i BBMRI-ERIC
– partnerstwo dla nauki**

6 – 7 grudnia 2021 r.

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PATRON MEDIALNY



Poniedziałek, 6 grudnia 2021 r.

9:00-9:15

Otwarcie konferencji

BBMRI.pl – Polski węzeł krajowy w sieci BBMRI-ERIC

Piotr Zień, Sieć Badawcza Łukasiewicz – PORT Polski Ośrodek Rozwoju Technologii

9:15-10:00

Wykład plenarny

Key Success Factors of Biobanks

Karine Sargsyan, Medical University of Graz

10:00-10:15

Przerwa

10:15-11:25

Sesja 1. Pięć lat BBMRI.pl i Polskiej Sieci Biobanków

1. Biobankowanie materiału biologicznego w Polsce – rozwój i możliwości współpracy

Anna Chróścicka, Warszawski Uniwersytet Medyczny

2. Wprowadzenie jednolitego systemu kontroli jakości wszystkich etapów funkcjonowania krajowych biobanków

Michał Karpeta, Regionalne Centrum Naukowo-Technologiczne

3. Opracowanie i wdrożenie jednolitego Systemu Zarządzania Jakością w Polskiej Sieci Biobanków – podsumowanie 5 lat projektu

Agnieszka Matera-Witkiewicz, Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

4. Lokalne i rozproszone rozwiązania IT

Dominik Strapagiel, Uniwersytet Łódzki

5. Platforma Centralna – wspólne dobro dla PSB

Andrzej Strug, Gdański Uniwersytet Medyczny

6. Ochrona danych w biobankach – Kodeks postępowania w sprawie przetwarzania danych osobowych w biobankach

Dorota Krekora-Zajac, Uniwersytet Medyczny w Lublinie, Uniwersytet Warszawski

Moderator: Małgorzata Lewandowska-Szumieł, Warszawski Uniwersytet Medyczny

11:25-12:15

Dyskusja panelowa:

Rola BBMRI.pl i Polskiej Sieci Biobanków w rozwoju biobankowania w Polsce

Prowadzenie: Leszek Kalinowski, Łukasiewicz – PORT/Gdański Uniwersytet Medyczny

Uczestnicy:

1. Łukasz Kozera, BBMRI-ERIC
2. Mateusz Gaczyński, Ministerstwo Edukacji i Nauki
3. Małgorzata Lewandowska-Szumieł, Warszawski Uniwersytet Medyczny
4. Marcin Moniuszko, Uniwersytet Medyczny w Białymstoku
5. Piotr Orzechowski, Centrum Informatyczne Trójmiejskiej Akademickiej Sieci Komputerowej
6. Dorota Krekora-Zajac, Uniwersytet Medyczny w Lublinie/Uniwersytet Warszawski

PROGRAM KONFERENCJI

12:15-13:00

Przerwa

13:00-14:30

Sesja 2. Perspektywy członkostwa Polski w BBMRI-ERIC (j. angielski)

- 1. Biobanking as a vital element of scientific processes and healthcare system**
Mateusz Gaczyński, Ministerstwo Edukacji i Nauki
- 2. Biobanking and Biomolecular Resources Research Infrastructure – reaching the next level” – Jens Habermann, BBMRI-ERIC**
- 3. BBMRI-ERIC Quality Management Services – a very successful collaboration with BBMRI.pl**
Andrea Wutte, BBMRI-ERIC
- 4. BBMRI IT Services and Research – collaboration with BBMRI.pl**
Petr Holub, BBMRI-ERIC
- 5. Future directions for development of biobanking within BBMRI-ERIC**
Łukasz Kozera, BBMRI-ERIC

Moderator: Leszek Kalinowski, Łukasiewicz – PORT/Gdański Uniwersytet Medyczny

14:30-14:45

Przerwa

14:45-16:15

Sesja 3. Rozwój biobankowania i współpraca naukowa w oparciu o infrastrukturę BBMRI.pl

- 1. Biobank NIGRiR – nowoczesny Biobank z Systemem Zarządzania Jakością**
Diana Hasan, Narodowy Instytut Geriatrii, Reumatologii i Rehabilitacji im. prof. dr hab. med. Eleonory Reicher
- 2. Monitoring narażenia na substancje chemiczne w polskiej populacji**
Jolanta Gromadzińska, Instytut Medycyny Pracy
- 3. Współpraca Pomorskiego Uniwersytetu Medycznego w Szczecinie z BBMRI-ERIC konsorcjum**
Tomasz Wojdacz, Pomorski Uniwersytet Medyczny
- 4. Poszukiwanie wczesnych biomarkerów choroby Alzheimer’a we krwi**
Urszula Wojda, Instytut Biologii Doświadczalnej im. M. Nenckiego PAN

Moderatorzy: Agnieszka Matera-Witkiewicz, Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu; Dominik Strapagiel, Uniwersytet Łódzki

Wtorek, 7 grudnia 2021 r.

9:00-11:00

Sesja 4. Biobankowanie w praktyce

- 1. Bank Mózgów – kolekcja Instytutu Psychiatrii i Neurologii**
Tomasz Stępień, Instytut Psychiatrii i Neurologii
- 2. Praktyczne zastosowanie zbiobankowanych próbek glejaka wielopostaciowego w analizie występowania kodelekcji 1p/19q**
Anna Michalska-Falkowska, Uniwersytet Medyczny w Białymstoku
- 3. Znaczenie badań nad zmiennością genomu ludzkiego dla rozwoju nowych narzędzi kryminalistycznych**
Wojciech Branicki, Uniwersytet Jagielloński
- 4. Rola Biobanku w rozwoju badań genetycznych w chorobach nowotworach. Perspektywa Narodowego Instytutu Onkologii – Państwowego Instytutu Badawczego, Oddział w Gliwicach”**
Małgorzata Oczko-Wojciechowska, Narodowy Instytut Onkologii im. Marii Skłodowskiej-Curie, Państwowy Instytut Badawczy
- 5. Baby Biobanks w projekcie ERICONS – wykorzystanie systemu archiwizacji próbek i danych Polskiej Sieci Biobanków BBMRI.pl w wielośrodkowym badaniu klinicznym**
Aleksandra Żurowska, Gdański Uniwersytet Medyczny
- 6. Europejski wspólny program dotyczący rzadkich chorób – tworzenie zintegrowanego ekosystemu badawczego poprzez połączenie kluczowych zasobów**
Daria Julkowska, INSERM/European Joint Programme on Rare Diseases

Moderatorzy: Anna Chróścicka, Warszawski Uniwersytet Medyczny; Leszek Kalinowski, Łukasiewicz – PORT/Gdański Uniwersytet Medyczny

10:00-10:15

Przerwa

11:15-12:15

Sesja plakatowa

Moderatorzy: Ilona Szablowska-Gadomska, Warszawski Uniwersytet Medyczny; Monika Jarych-Szyska, Łukasiewicz – PORT; Jarosław Sak, Uniwersytet Medyczny w Lublinie

12:15-13:00

Przerwa

PROGRAM KONFERENCJI

13:00-15:15 **Sesja 5. Wyzwania dla biobankowania**

- 1. Główne wyzwania dla biobankowania z perspektywy agencji finansującej rozwój badań w dziedzinie nauk medycznych w Polsce (Agencji Badań Medycznych)**
Dorota Makarewicz, Agencja Badań Medycznych
- 2. Dawstwo danych jak dawstwo krwi – jak zapewnić dostęp do danych medycznych w celach B+R?**
Ligia Kornowska, Polska Federacja Szpitali
- 3. Akredytacja biobanków. Zasady i procesy oceny kompetencji**
Tadeusz Matras, Polskie Centrum Akredytacji
- 4. Wykorzystanie Ludzkiego Materiału Biologicznego w badaniach naukowych**
Błażej Marciniak, Uniwersytet Łódzki
- 5. Przetwarzanie danych szczególnych kategorii w świetle zasad RODO”**
Krzysztof Król, Urząd Ochrony Danych Osobowych

Moderator: Dominik Strapagiel, Uniwersytet Łódzki

15:15-15:30 **Zakończenie konferencji, ogłoszenie wyników sesji plakatowej**

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Collaboration of the Pomeranian Medical University in Szczecin and the BBMRI-ERIC Consortium

Tomasz K. Wojdacz

Head of Independent Clinical Epigenetics Laboratory in Pomeranian Medical University, Szczecin, Poland

Abstract

From 2020, the biobank of the Department of Genetics and Pathology, Pomeranian Medical University, Szczecin, Poland, joined the BBMRI-ERIC consortium as an observer, and is currently in the process of the standardization required for full quality certification. In parallel to this process, the Independent Clinical Epigenetics Laboratory, which leads epigenetic research at the Pomeranian Medical University, established a collaboration with dr Dominik Strapagiel, prof. UŁ, Biobank Lab, University of Lodz, with the goal to access the infrastructure of BBMR. The collaboration so far has resulted in a number of projects with the outcome that two of them are being currently published. One of them is a clinical trial registered under the number: NCT04520724, in which we investigated the involvement of the epigenetic mechanisms in the effects of diet change in non-alcoholic fatty liver disease. The second project is an example of an effective collaboration that allowed us to fast react to the SARS-CoV-2 pandemic, recruit patients and investigate the response of the blood cells epigenome to the infection. In my talk/this paper, I will review the current state of the process of standardization of our biobank and present the results of our successful collaborations with the BBMRI infrastructure.

Citation

Wojdacz TK. Collaboration of the Pomeranian Medical University in Szczecin and the BBMRI-ERIC Consortium. Eur J Transl Clin Med. 2021;4(Suppl.3):12.



Search for Early Biomarkers of Alzheimer's Disease in the Blood

Urszula Wojda

Laboratory of Preclinical Testing of Higher Standard, Neurobiology Center, Nencki Institute of Experimental Biology of Polish Academy of Sciences, Warsaw, Poland

Abstract

The mission of the Laboratory of Preclinical Testing of Higher Standard at the Nencki Institute launched in 2014 is the translation/transference of discoveries from basic neuroscience to clinical trials. The Laboratory conducts its own research and provides the core-facility services for the Nencki Institute and other scientific and R&D institutions in accordance with the principles of Good Laboratory Practice (GLP) and higher standards. The core facility offer includes comprehensive preclinical in vitro and in vivo testing of the safety and activity of potential new therapeutic substances for cancer and diseases of the nervous system. Our own studies aim at the elucidation of early molecular mechanisms of Alzheimer's disease (AD), one of the main threats in ageing societies, for the identification of new therapeutic targets and early non-invasive biomarkers. The processes underlying AD are being studied at the level of gene expression, protein signalling, and behaviour, using cellular and animal AD models. We also search for non-invasive blood-based early AD biomarkers in human blood cells and plasma, focusing mainly on microRNA*. We collaborate with multiple investigators and clinical groups within Polish and European research programmes. The growing collection of samples from over 200 AD patients obtained due to this cooperation has been deposited in our biobank. Since 2018, the biobank belongs to the Polish Network of Biobanks BBMRI.pl and continuously improves aspects such as ethical, security and management quality in accordance with the requirements of the Quality Standards for Polish Biobanks.

**Grants: EU H2020 FET OPEN 737390 (ArrestAD) and Polish National Science Centre OPUS 2018/29/B/NZ7/02757*

Citation

Wojda U. Search for Early Biomarkers of Alzheimer's Disease in the Blood. Eur J Transl Clin Med. 2021;4(Suppl.3):13.



Tracing the fate of fluorescent drugs in normal and cancer breast cell lines using confocal microscopy

Anna Pogorzelska¹, Maciej Mazur², Katarzyna Wiktorska¹

¹ Department of Drug Biotechnology and Bioinformatics, National Medicines Institute, Warsaw, Poland

² Faculty of Chemistry, University of Warsaw, Poland

Abstract

Doxorubicin is an oncological drug used as a first-line treatment in chemotherapy of breast cancer. Except for its anticancer efficacy, it exhibits cytotoxicity toward normal tissue and organs, e.g. high cardiotoxicity, which significantly limits its use. The doxorubicin fluorescent properties enable its efficient visualization within a single living cell. This phenomenon was exploited to compare the target sites of various drug formulations in normal (non-malignant) and cancer cells.

The normal (MCF10) and breast cancer (MDA-MB-231) cell lines were stored and cultured in the NIL-Biobank with accordance to the Quality Assurance System in order to ensure solid and repeatable test results, which is particularly important when working with biological material – characterized by high variability depending on the culture and experiment conditions (e.g. passage number, pH, temperature). Cellular imaging was performed in living cells using an Olympus IX70 FV500 confocal microscope, and an additional cytotoxicity test was performed with MTT assay.

The study revealed a difference in the location of the drug. It has been shown that in normal cells, doxorubicin does not penetrate the cell's nucleus, unlike in cancer cells, where by binding to DNA it interferes with the cell division and exerts the desired cytotoxic effect in neoplastic cells.

Citation

Pogorzelska A, Mazur M, Wiktorska K. Tracing the fate of fluorescent drugs in normal and cancer breast cell lines using confocal microscopy. *Eur J Transl Clin Med.* 2021;4(Suppl.3):14.



Central IT Platform – a Common Good of the Polish Biobanking Network BBMRI.pl

Andrzej Strug^{1,2}, Nikola Bulman^{1,2}, Thierry van de Wetering^{1,2},

Jarosław Skokowski^{1,3}, Leszek Kalinowski^{1,2,4}

¹ Division of Medical Laboratory Diagnostics – Fahrenheit Biobank BBMRI.pl, Medical University of Gdańsk, Gdańsk, Poland

² BBMRI.pl Consortium, Poland

³ Department of Surgical Oncology, Medical University of Gdańsk, Gdańsk, Poland

⁴ BioTechMed Centre, Department of Mechanics of Materials and Structures, Gdansk University of Technology, Gdańsk, Poland

Abstract

An internal work of a contemporary biobank should be supported by the IT system that helps to organize biomedical samples and data handling. On the other hand, the essence of the biobank existence lies in offering its resources to the researchers who need them in vast amounts to run scientific experiments. If there are many small biobanks, as is the case in Poland, a diversity of the local BIMSs does not pose a problem for the biobankers using them, that is, until we look at it from a researcher's perspective.

Scientists would like to have access to the information about the biobanks' samples and data in a unified and orderly way that fosters the preparations of their project collections. Therefore, the Medical University of Gdańsk's main idea at the time of the BBMRI.pl project planning was an implementation of a Central IT Platform – a common IT portal for all Polish biobanks, where they could publish in a standard way the data about the collections offered by them for scientific collaboration.

Now, at the end of the first phase of the BBMRI.pl project, the Platform is ready for use, with its initial, most important functions. It gives the researchers who want to use it, insight into information about the collections of the Polish biobanks. But, moreover, thanks to an export tool based on the API, it gives our biobankers an easy way of uploading the relevant data to the European catalogue of bio-samples – the Directory – significantly extending a range of potential partners.

Citation

Strug A, Bulman N, van de Wetering T, Skokowski J, Kalinowski L. Central IT Platform – a Common Good of the Polish Biobanking Network BBMRI.pl. Eur J Transl Clin Med. 2021;4(Suppl.3):15.



Evaluation of BBMRI.pl QM trainings over the period 2017-2021

**Małgorzata Witoń^{1,2}, Patrycja Sitek^{1,2}, Magdalena Krupińska^{1,2},
Joanna Gleńska-Olender^{1,2}, Michał Laskowski^{1,2}, Karolina Zagórska^{1,2},
Agnieszka Matera-Witkiewicz^{1,2}**

¹Screening Biological Activity Assays and Collection of Biological Material Laboratory; Wrocław Medical University Biobank, Faculty of Pharmacy, Wrocław Medical University, Wrocław, Poland

²BBMRI.pl Consortium, Poland

Abstract

Training sessions in the field of quality management systems and Quality Standards for Polish Biobanks, were one of the objectives of Task 3, carried out within the framework of the Project *Organisation of the Polish Biobanking Network within the Biobanking and Biomolecular Resources Research Infrastructure BBMRI-ERIC*

Initially, training sessions were conducted in a stationary version, during the first audits and during scientific and training conferences. Their goal was to further develop the knowledge of the Members and Observers of the Polish Biobanking Network in the field of implementing and improving the Quality Assurance and Management System in Biobanks. The training gave an opportunity to exchange experiences and provide provision for frequently asked questions. Each training ended with an evaluation questionnaire. Thus, based on the survey results analysis, in response to a great need reported by employees of biobanks in this area, the number of training courses was intensified. Training sessions began to be conducted on a monthly basis. Hands-on training was added, which included exercises from the QSBP area and case studies.

The Covid-19 pandemic forced to conduct training online. The consequences in 2021 resulted in weekly training in the area of QMS (theoretical and practical webinars) and less formal meetings within the QMS Caffee, where current topics that biobank employees in Poland face in their routine work were discussed.

The final presentation how QM training has evolved in response to audience needs and technical capabilities, as well as the results of the analysis of audience satisfaction surveys, are presented in the poster session.

Citation

Witoń M, Sitek P, Krupińska M, Gleńska-Olender J, Laskowski M, Zagórska K, Matera-Witkiewicz A. Evaluation of BBMRI.pl QM trainings over the period 2017-2021. *Eur J Transl Clin Med.* 2021;4(Suppl.3):16.

Five-year follow-up changes in the lipid profile in the Lower Silesian population

Marta Obremaska^{1,2,3}, Agata Świdarska^{2,3}, Beata Wałęsa^{2,3}, Weronika Wangert-Mądzik^{2,3}, Magdalena Grodecka^{2,3}

¹ Medical University of Silesian Piasts in Wrocław, Wrocław, Poland

² Łukasiewicz Research Network - PORT Polish Center for Technology Development, Wrocław, Poland

³ BBMRI.pl Consortium, Poland

Abstract

The assessment of the prevalence of dyslipidemia in general populations is used to evaluate public health. The changes in the lipid profile show the effectiveness of treatment and provide public education in reducing the risk of developing atherosclerosis. The aim of the study was to evaluate changes in the lipid profile of the Lower Silesian population after a 5-year follow-up.

The study was part of a project carried out by Łukasiewicz-PORT Biobank concerning the assessment of the prevalence of atherosclerosis risk factors in the population of Lower Silesia. People who first visited the Biobank in 2012-2016 and consented to take part in this project received an invitation for a 5-year follow-up visit. Out of 4803 originally examined, 492 participants (10.24%) 55.9±18.8 years of age, 62% female, responded to the invitation. In the study group, the concentration of triglycerides was similar after the 5-year follow-up, while the concentration of total cholesterol (TC), and high and low-density lipoproteins (respectively HDL, LDL), decreased significantly (respectively 214.96 vs 194.75 P<0.001, 65.20 vs 61.73 P=0.002, 126,71 vs 111,86 P<0.001). However, the same analysis in the six age groups (20+ to 70+) showed a significant reduction of TC and LDL in the 50+ study group, who constituted 61% participants in the study.

An improvement of the lipid profile after a 5-year follow-up in the Lower Silesian population was observed. The favourable changes concerned people over 50 years of age. The low number of patients returning for the follow-up visit could be due to relocations, low social participation in research and to the COVID-19 pandemic and introduced lockdown.

This project has been funded by decision of the Ministry Education and Science, decision DIR/WK/2017/01 i DIR/WK/2017/2018/01-1.

Citation

Obremaska M, Świdarska A, Wałęsa B, Wangert-Mądzik W, Grodecka M. Five-year follow-up changes in the lipid profile in the Lower Silesian population. Eur J Transl Clin Med. 2021;4(Suppl.3):17.



The strategic role of Risk Management in biobanking

Anna Michalska-Falkowska¹, Gabriele Hartl², Karine Sargsyan²

¹Department of Clinical Molecular Biology, Medical University of Białystok, Białystok, Poland

²International Biobanking and Education, Medical University of Graz, Graz, Austria

Abstract

Every project and daily activity undertaken during the process of biobanking is combined with risks. Therefore, biobanks' correct functioning depends on a holistic, complex approach to managing the potential risks that can arise due to the multiple issues. Active Risk Management should be identified as a core biobanking expertise, to have well-defined procedures in the case of an emergency. A specific Risk Management strategy designed exclusively for a particular biobank is crucial to address the individual environmental conditions, demands for specific sample types, potential stakeholders, national and international regulations, and ethical aspects. The general purpose of Risk Management planning is to minimize the impact of harmful events, improve risk communication and risk awareness within the biobank, and support the biobank continuity. According to the ISO 31000 group of standards, the process of building a Risk Management plan consists of several basic steps, including communication and consultation, establishing the context according to the biobank's individual risk tolerance and appetite, risk identification, analysis, evaluation with arranging the response to the risk when it occurs, risk treatment techniques, monitoring, and periodical review. It is recommended to directly merge Risk Management with the overall biobanking process since it represents an essential concept connected with maintaining the safety and financial stability of the biobank. Implementing Risk Management at every level of biobanking activity is combined with multiple benefits, including an increase of the risk awareness among all employees, improvement in workplace safety, and better operational capability due to coherent control over the risk.

Citation

Michalska-Falkowska A, Hartl G, Sargsyan K. The strategic role of Risk Management in biobanking. Eur J Transl Clin Med. 2021;4(Suppl.3):18.



Practical Application of Biobanked Glioblastoma Samples in 1p/19q Co-deletion Status Analysis

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Abstract

Glioblastoma, the most common type of malignant primary brain tumour, is an extremely aggressive lesion with an infiltrative growth that hinders total surgical resection. Among the important indicators used to administer the appropriate therapy, assessment of the deletion of the short arm of chromosome 1 (1p) and the long arm of chromosome 19 (19q) is applied. Unfortunately, the practical use of this test in the glioblastoma has not been clearly defined to this day. For this reason, as part of the MINIATURA 3 project, occurrence analysis of 1p and 19q deletion in tissue samples was collected within the biobanking process during surgery of brain tumours, which were then diagnosed as glioblastoma multiforme WHO G4. Fluorescence in situ hybridization (FISH) was used to detect mutations in the analyzed tissue samples retrieved from the Biobank at the Medical University of Białystok. Determination of 1p and 19q deletion in tumour cells was possible with the use of DNA probes, and changes in the signals compared to the controls were applied to determine the presence of mutations. After examining 160 slides with a fluorescence microscope, mutations of 1p and 19q were found in two tissue samples taken from one patient. The remaining 158 slides showed the presence of two orange signals, indicating that the probe was linked to the matching DNA sequence within chromosomes 1p and 19q of the analyzed cells. The obtained results are consistent with the current literature reports showing a low frequency of 1p/19q deletions among glioblastoma multiforme WHO G4.

Citation

Michalska-Falkowska A, Mariak Z, Nikliński J. Practical Application of Biobanked Glioblastoma Samples in 1p/19q Co-deletion Status Analysis. *Eur J Transl Clin Med.* 2021;4(Suppl.3):19.



Verification of ex vivo expanded $\gamma\delta$ T cell cytotoxicity against glioblastoma 3D cultures

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Abstract

Glioblastoma multiforme (GBM) is the most aggressive brain cancer, with a poor survival rate. Current therapy is ineffective as tumours recur in more than 90% of cases, which proves that new therapeutic approaches against GBM are needed. One novel strategy can be an intracranial infusion of ex vivo expanded $\gamma\delta$ T cells, which may destroy cancer cells. In our research, we compare effector functions of two major $\gamma\delta$ T cell subpopulations ($V\delta 1+$ and $V\delta 2+$) toward established and primary GBM cell cultures. Human $\gamma\delta$ T cells were expanded from cryopreserved peripheral blood mononuclear cells by 20-day culture in media supporting the growth of desired $\gamma\delta$ T cell subsets. Glioblastoma organoids (GBOs) and neurospheres were generated from resected tumour tissues and cultured in an optimized media, maintaining the cellular heterogeneity of the parent tumours. Each culture was biobanked for future expansions and assays. The $\gamma\delta$ T cell and GBM culture phenotypes were verified by flow cytometry and fluorescent microscopy, respectively. Cytotoxic activity of $\gamma\delta$ T cells toward GBM cell cultures was assessed by viability assays and live-fluorescent imaging. Tumor infiltration and the killing efficacy of $\gamma\delta$ T cells was evaluated by immunofluorescence (IF) of cleaved-caspase-3 and Ki67 antigen. Our in vitro data suggest that both $\gamma\delta$ T cells subsets were able to destroy GBM cells. IF staining showed T cell invasion, decreased proliferation and increased apoptosis of tumour spheres as a result of co-culture with $\gamma\delta$ T cells.

This project has been funded by the National Science Centre Poland, grant no 2019/35/B/NZ6/03748.

Citation

Mączyńska J, Toporkiewicz M, Skulska K, Kupczyk P, Woźniak J, Miś M, Ziółkowski P, Tabakow P, Chodaczek G. Verification of ex vivo expanded $\gamma\delta$ T cell cytotoxicity against glioblastoma 3D cultures. Eur J Transl Clin Med. 2021;4(Suppl.3):20.

Development and Implementation of a Unified Quality Management System in the Polish Biobanking Network – 5-year summary

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Abstract

The creation of the Polish Biobanking Network (PBN) within BBMRI.pl started in 2017 on the basis of a Polish governmental decision about joining the BBMRI-ERIC infrastructure as a full member. The main idea was to unify a distributed infrastructure based on a precise biobank registry, where quality management and an assurance system integrated with ELSI aspects would be implemented, which would allow for cooperation both at the national and international levels. From 2017 BBMRI.pl QM Experts have performed many activities and prepared supporting tools and solutions to help biobanks from PBN to form and improve quality systems to fulfil the requirements of high quality samples and associated data for scientific cooperation purposes.

The list of the results includes: (1) a QMS audits system, (2) the preparation of QMS document templates, (3) consulting (4) workshops and training, (5) three Handbooks: Quality Standards for Polish Biobanks, Biobank's Internal auditor-a practical guide and Auditor's Manual Handbook. Moreover, a close cooperation with national (The Polish Committee for Standardization) and international (International Organization for Standardization-ISO) strategic institutions and the QM BBMRI-ERIC community, determined the best knowledge exchange.

All QM actions prepared within BBMRI.pl as carefully designed plans dedicated to PBN, determine the unification and harmonization of a common solution, which are convergent with the BBMRI-ERIC general outline. The prepared concept of a comprehensive and consecutive outline have directed biobanks toward a uniform QMS implementation and improvement, which is noticeable after 5 years of the BBMRI.pl project's execution. But it is not over yet – the BBMRI.pl project shall be continued and reinforced by the BBMRI-ERIC infrastructure.

Citation

Matera-Witkiewicz A, Zagórska K, Laskowski M, Sitek P, Witoń M, Gleńska-Olender J. Development and Implementation of a Unified Quality Management System in the Polish Biobanking Network – 5-year summary. Eur J Transl Clin Med. 2021;4(Suppl.3):21.



Key Biobanking Challenges from the Point of View of the Agency that Finances the Development of Medical Research in Poland (the Medical Research Agency)

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Abstract

The Medical Research Agency is a modern institution supporting the development of clinical trials and health sciences. The situation analyses in this area indicate the need to consolidate the existing biobanks and collections and to increase the efficiency of usage collected data for research, diagnostic and therapeutic purposes, for scientific and commercial applications. In order to meet the increased needs of the Beneficiaries regarding the cooperation with professional biobanks, the Agency took up the challenge of designing directions for the development of biobanks. We propose the transformation of dispersed places for collecting samples into units operating in a common infrastructure, allowing the integration of resources and data, and offering investigation facilities for research and implementation units. The main tasks planned are the unification of standards for collecting and identifying samples, and the management system in the context of medical sample information, and the effective protection of the rights of people who are depositing biomaterial.

The Agency will develop and implement a programme enabling the financing development of biobanks. We expect that the projects selected in these programmes will concern the active search for long-term cooperation with other organizations and the sharing of resources gathered in accordance with the implemented standards, according to the established rules. We will recommend legislative steps aimed at better management of the patient's data. We will start testing the developed concept of the system by implementing it in selected units of the Polish Clinical Research Network and for future Beneficiaries who will declare their readiness to cooperate in creating collections of central biobanks.

Citation

Makarewicz D, Sierpiński R. Key Biobanking Challenges from the Point of View of the Agency that Finances the Development of Medical Research in Poland (the Medical Research Agency). Eur J Transl Clin Med. 2021;4(Suppl.3):22.



Practical Aspects of Quality Control in the Biobank

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Abstract

Quality control (QC) of biological material, associated data and related processes ensures that a biobank demonstrates competences in operations and the ability to provide biobanking products where appropriate quality for research and development is assured.

The biobank shall establish procedures and conduct QC in accordance with the requirements of the Quality Standards for Polish Biobanks (QSPB) and ISO 20387:2018, dedicated standard for biobanking. The biobank is responsible for the determination of the approach to QC. QC shall be carefully planned at specified intervals and shall be documented. All results must be analyzed on an ongoing basis and as part of the periodic trend analysis.

Despite the lack of standardized QC solutions for biobanks, there is an approach that seems to be the most comprehensive. The biobank can carry out quality control in a triple system: 1) current internal QC, i.e. control activities performed during routine work (e.g. visual assessment of hemolysis), 2) periodic internal QC (e.g. once a quarter, determination of the stability of the tested parameter in a stored material), 3) participation in proficiency testing schemes or external quality assessment, usually carried out once a year.

The data processed in the biobank shall also be related to QC. Completeness, integrity and consistency of data shall be checked. This can be done by periodically verifying the data contained, for example, in paper questionnaires, with the data entered into the biobank's IT system. The biobank can also compare the "raw" data generated by the test equipment with the processed data stored in the biobank's database.

Citation

Laskowski M, Kantor M, Witoń M, Sitek P, Gleńska-Olender J, Zagórska K, Matera-Witkiewicz A. Practical Aspects of Quality Control in the Biobank. Eur J Transl Clin Med. 2021;4(Suppl.3):23.



PopulatIon CohorT stUdy of wRoclaw citizEns – a PICTURE of the health condition within Wroclaw families population

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Abstract

The main purpose of the project PICTURE is to conduct a comprehensive survey study and laboratory analysis of children and their parents regarding their health status and lifestyle. Rich resources of biological material and associated data for future projects are collected in the Wrocław Medical University Biobank.

The project involved 1,250 children with their parents to be examined during the 2-year project period. Every participant underwent medical examination and a set of laboratory assays, ECG, spirometry, audiometry, tympanometry, blood pressure measurement, anthropometric measurements, hand grip strength, body height, body mass and body composition.

Since September 2019, 1,868 participants, including 475 boys, 463 girls, 621 women and 309 men have been examined. A total of 34,982 samples of biological material, including 17,496 samples of blood, 5,539 of saliva, 4,249 of urine and 3,465 of stool have been collected. Project results will be a valuable contribution and a starting point for the development of the health report of the study participants. Moreover, all biological material and associated data are collected under rigorous supervision, fulfilling the requirements of the certified ISO 9001:2015 quality management system and also the ISO 20387:2018 external positive BBMRI-ERIC assessment, as the first biobank within the BBMRI-ERIC community. Thanks to the availability of PICTURE resources, the duration and costs of future potential research are significantly reduced. It is possible by obtaining broad consent from the patient for future scientific purposes. Also, thanks to the highest quality standards at the pre-analytical stage, the repeatability and reproducibility of the planned analysis can be assured.

Citation

Kantor M, Krupińska M, Laskowski M, Matera-Witkiewicz A. PopulatIon CohorT stUdy of wRoclaw citizEns – a PICTURE of the health condition within Wroclaw families population. *Eur J Transl Clin Med.* 2021;4(Suppl.3):22.

Personalized medicine perspectives revealed by *The Thousand Polish Genomes Project* – the First Database of Variant Allele Frequencies in the Polish Population

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Abstract

Although Poland is a country of over 38 million citizens, no centralized reference database of genetic variation exists to date. Such data is crucial for research in biomedicine, population genetics, advancing personalized medicine, as well as for archeological and historical studies. The aim of the present study was to create a national database of the Polish genomic variant allele frequencies and to demonstrate its potential significance for clinical genetics and biomedical research.

The DNA samples of 1222 individuals were collected in collaboration with the Polish Biobanking Center. Deep Whole Genome Sequencing (WGS) followed by comprehensive genomic analyses was used to identify and genotype a wide spectrum of genomic variation, such as small and structural variants, mitochondrial haplogroups and Mendelian inconsistencies. Similarities to other publically available, European and continental populations were analysed using PCA and ADMIXTURE.

The analyses of Polish genomes confirmed the genetic homogeneity of the Polish population and its similarity to north-western Europeans. A precise detection of rare variants enriched in the analysed cohort allowed to show the allele frequencies for known pathogenic variants related to cancer and rare diseases. Allele frequen-





cies for small and structural variants calculated for 1,076 unrelated individuals were released as The Thousand Polish Genomes database.

The Thousand Polish Genomes database is the biggest WGS-based dataset for a single Slavic population created to date. This unique genetic picture of the Polish population will contribute to the worldwide genomic data resources helping to advance personalized medicine and cancer treatment.

Citation

Kaja E, Lejman A, Sielski D, Sypniewski M, Gambin T, Suchocki T, Dawidziuk M, Golik P, Wojtaszewska M, Stępień M, Szyda J, Lisiak-Teodorczyk K, Wolbach F, Kołodziejaska D, Ferdyn K, Szopa A, Woźna A, Żytkiewicz M, Bodora-Troińska A, Elikowski W, Król Z, Zaczyński A, Pawalk A, Gil R, Wierzba W, Dobosz P, Zawadzka K, Zawadzki P, Sztormwasser P. Personalized medicine perspectives revealed by The Thousand Polish Genomes Project – the First Database of Variant Allele Frequencies in the Polish Population. *Eur J Transl Clin Med.* 2021;4(Suppl.3):25-26.



The NIGRiR Biobank – a Modern Biobank with Quality

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Abstract

The biobank of the Molecular Biology Department is a unit of the National Institute of Geriatrics, Rheumatology and Rehabilitation (NIGRiR) in Warsaw. NIGRiR is a scientific institute with an established position internationally, with clinics that treat patients with autoimmune rheumatic diseases (i.a. rheumatoid arthritis, systemic lupus erythematosus, scleroderma) and geriatric diseases (i.a. sarcopenia, frailty syndrome). Biological material obtained from NIGRiR clinics is immediately transported to the Biobank. Close cooperation with clinicians ensures the appropriate selection of patients and the constant expansion of the collection.

We are aware of the importance of the quality of biological materials in scientific research, which can affect the reliability and reproducibility of the results. Our biobank, wanting to offer the highest quality biological materials for research, decided to implement a quality system. For this purpose, we have joined the BBMRI.pl Polish Biobank Network of the European Research Consortium BBMRI-ERIC. Together with BBMRI.pl QMS Team we have created 19 procedures and 80 prints according to the Quality Standards for Polish Biobanks, the guidelines compatible with ISO 9001: 2015 and ISO 20387: 2018. Our biobank's infrastructure, professionally qualified personnel and procedures ensure the highest quality biological samples.

The biobank collects high-quality biological material such as: blood, serum, plasma, PBMC, synovial fluid, SFMC, saliva, muscle fragments, as well as clinical and multi-omics data. Scientific research are conducted on the molecular mechanisms of ageing and inflammatory processes and the etiology of rheumatic/geriatrics diseases, as well as for other research and service activities. We are currently storing material from over 2,000 volunteers.

Citation

Hasan D, Wajda A, Kmiełek T, Zajęc G, Pradowska-Gorycka A. The NIGRiR Biobank – a Modern Biobank with Quality. Eur J Transl Clin Med. 2021;4(Suppl.3):27.



Biomonitoring of Exposure to Chemicals in the General Population

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Abstract

Exposure to environmental pollution remains a major source of risk to human health. The associations between environmental pollution and health outcome are poorly recognised. According to an analysis by WHO from 2002, about 8-9% of total disease is attributed to pollution, mainly polluted air and water. Industrial emissions, contaminated water and food, inadequate waste management, and outdoor and indoor air pollution, affect big groups of people. The measuring of chemicals (metals, organic substances) or their metabolites in the human body, specifically in urine, serum, blood, hair or saliva collected from general populations and occupationally exposed groups, is necessary to estimate the risk to health in different parts of the population (children, pregnant women, adults) and to investigate the new selective biomarkers. Biobanking of biological samples from big populations living in different conditions and different geographical regions is necessary to estimate the rate of exposure and its changes from year to year. These biomonitoring results are/may be used to adjust policy and legislation performance and to protect people from dysfunctions, diseases or even death.

Citation

Gromadzińska J. Biomonitoring of Exposure to Chemicals in the General Population. Eur J Transl Clin Med. 2021;4(Suppl.3):28.



The Role of Tutors from QM BBMRI.pl Expert Group in the Creation and Implementation of Uniform Quality Systems in the Polish Biobanking Network

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Abstract

The main goal of BBMRI.pl infrastructure is to build a platform for scientific cooperation and research development. One of BBMRI.pl activities in the past 5 years was the formation of the BBMRI.pl QM Expert Group, where dedicated tools for the Polish Biobanking Network (PBN) have been proposed, resulting in the effective implementation and improvement of QMS in Polish biobanks. One outcome from this was consulting and supporting activities regarding the individual approach to the consequent quality system launched and sustained in each biobank from PBN.

After the 1st audit, a dedicated tutor has been assigned to each specific biobank. The cooperation consists of meetings, document templates preparation and sharing, documentation consultations and corrections to achieve optimal solutions within the QMS unification.

The role of the QM BBMRI.pl expert was defined to assist and support biobanks in the process of preparing procedures, and providing consultations and guidance in specific biobanking areas. The consultant, together with the Biobank, determines the scope and limitations of the management system, analyzes individual processes in terms of the development and implementation of documented information, and prepares the necessary documents in accordance with the work schedule. Checking and monitoring the progress and timeliness of the work to prepare the Biobank for the audit for compliance with the Quality Standards for Polish Biobanks followed the preceding steps of the system's implementation. In the future, this cooperation may result in the accreditation of the Biobank for compliance with the ISO 20387 standard and ISO 9001 certification.

Citation

Gleńska-Olender J, Witoń M, Zagórska K, Sitek P, Laskowski M, Matera-Witkiewicz A. The Role of Tutors from QM BBMRI.pl Expert Group in the Creation and Implementation of Uniform Quality Systems in the Polish Biobanking Network. Eur J Transl Clin Med. 2021;4(Suppl.3):29.



Quality Management and Project Management Methodologies in the Biobank

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Abstract

Efficient organization management is one of the main concentration areas in biobanks, and the proper selection of quality methodology and tools is a key factor in the quality of work. The Biobank Laboratory of the University of Lodz has implemented a quality management system based on the ISO 9001: 2015 standard and the Quality Standards for Polish Biobanks. The system in the Biobank Laboratory is based on the TQMS (Total Quality Management System) methodology and its processes on the Deming PDCA (Plan Do Check Act) cycle. The FMEA (Failure Mode and Effects Analysis) methodology has been used in the analysis of risk and opportunities while corrective actions have been based on the 5 Why methodology and the Ishikawa diagram. The Pareto-Lorenz method has been used in storage management. The basis of the system in project management at the Biobank Laboratory is the Kanban methodology, which allows for the reduction of work in progress and its improved visualization. As a result, project teams are not overloaded with tasks, and the information related to the implementation of projects is generally available and legible. This method can be used for the simultaneous management of many projects and it also allows for the integration of all project elements: tasks, resources, information, stakeholders. The project management process in accordance with the Kanban methodology enables the implementation of four basic groups of activities in the project, i.e. planning, organizing, motivating, and controlling. In the Biobank Laboratory, it is carried out on the basis of the Enovatio IT platform, which is dedicated to this purpose.

Citation

Dobrowolska-Broniarek S, Kostrzewa D, Strapagiel D. Quality Management and Project Management Methodologies in the Biobank. Eur J Transl Clin Med. 2021;4(Suppl.3):30.



Pomeranian Voivodeship Population-based Collection of Samples and Related Data

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Abstract

As a member of BBMRI.pl Consortium, Fahrenheit's Biobank at the Division of Medical Laboratory Diagnostics, Medical University of Gdańsk took part in the task entitled: "Introduction of a uniform quality control system for all stages of the functioning of national biobanks". The main goal of the task was to establish and implement uniform standard operating procedures among members of the BBMRI.pl Consortium. The created procedures referred to the collecting, transport and processing of biological material, and were implemented in practice by conducting a population-based study.

Fahrenheit's Biobank created a population-based collection from 500 healthy donors from the Pomeranian Voivodeship. The collection includes samples of biological material (whole blood, plasma, serum, DNA) biobanked in standardized, strictly controlled conditions in accordance with the procedures developed by the BBMRI.pl Consortium, regarding survey data and the results of laboratory parameters related to cardiovascular diseases (hsCRP, glucose, insulin, lipid profile, homocysteine).

The collection was published both on the Central IT Platform of the Polish Biobanking Network and in the Directory BBMRI-ERIC. The collection has already been used for a set of quality control analyzes and in a bioequivalence study. We compared the applied LC-MS/MS method with the immunochemiluminescent method (ChLIA) used to determine the concentration of homocysteine in certified diagnostic laboratories.

Our Pomeranian Voivodeship population-based collection consists of high quality biological material and extensive, complete data, related to the samples and the donors. This enables an effective cooperation between current and future members of the European and Polish network of biobanks associated under BBMRI.eu-ERIC.

Citation

Bulman N, Jendernalik K, Pelikant-Małecka I, Radulska A, Płoska A, Skokowski J, Kalinowski L. Pomeranian Voivodeship Population-based Collection of Samples and Related Data. Eur J Transl Clin Med. 2021;4(Suppl.3):31.



The Importance of Human Genome Variation Research for the Development of New Forensic Tools

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Abstract

Forensic genetics has good tools for human identification, but their use requires the comparative analysis of evidence and reference material. It appears that the lack of reference samples limits the ability to solve many serious criminal cases around the world despite the availability of biological traces collected from crime scenes. Importantly, the human genome contains information about a person's appearance, biogeographical ancestry and even age, which can be very helpful for intelligence purposes in the process of identifying suspects. Research to date indicates that developing appropriate DNA-based predictive tools requires the large-scale analysis of DNA and phenotypic variation in various human populations. It is clear that sufficiently large genomic and epigenomic datasets and prediction modelling using machine learning methods provide opportunities for method development to accurately predict the phenotype of unnamed individuals, facilitating the process of their identification and contributing to better law enforcement and justice.

Citation

Branicki W. The Importance of Human Genome Variation Research for the Development of New Forensic Tools. Eur J Transl Clin Med. 2021;4(Suppl.3):32.



The Platform for the Digitization of Image Data

Marika Bolcewicz^{1,2}, Kamila Jendernalik^{1,2}, Nikola Bulman^{1,2}, Thierry van de Wetering^{1,2}, Agata Płoska^{1,2}, Iwona Pelikant-Małecka^{1,2}, Lawrence W. Dobrucki^{1,2,3,4}, Jarosław Skokowski^{1,2,5}, Leszek Kalinowski^{1,2,6}

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Abstract

Division of Medical Laboratory Diagnostics (DMLD) at the Medical University of Gdańsk, as a member of the Polish Biobanking Network (PBN), is concerned with providing a specialized IT environment of modern solutions that will integrate Polish biobanks with BBMRI.ERIC and other scientific organizations. For this purpose the Platform for the Digitization of Image Data (PDID) has been developed, which gives an opportunity to store and share information about sample collections, digitized images and related data.

To ensure the platform's development and large amounts of data acquisition, DMDL includes an IT and laboratory infrastructure that contains advanced software and equipment, with a fully automated device line that improves the bio-preservation, processing and staining of tissue specimens.

Advanced slide scanners which combine optical microscope and digital camera functions and technology based on high-speed and high-capacity solutions with high requirement imaging gives an opportunity to obtain the best quality digital scans. As a result, DMDL provides digital scans of slides and associated data, including of oncological collections as well as of rare diseases.

Combining technology and interdisciplinary experience supports the expansion of PDID and cooperation between research units, which enables a wider use of scientific resources. The platform meets the needs of the modern model of science among European recipients.

Citation

Bolcewicz M, Jendernalik K, Bulman N, van de Wetering T, Płoska A, Pelikant-Małecka I, Dobrucki LW, Skokowski J, Kalinowski L. The Platform for the Digitization of Image Data. Eur J Transl Clin Med. 2021;4(Suppl.3):33.



The Bridge of Data

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Abstract

BRIDGE OF DATA – Multidisciplinary Open Knowledge Transfer System – stage II: Open Research Data is a project centered around the collecting and sharing of scientific resources that are made available to view, download and analyze for a wide range of recipients. The Division of Medical Laboratory Diagnostics (DMLD) at the Medical University of Gdańsk, as a participant, undertook the gathering of over 20,000 digitalized slides and 120 TB of data described by pathologists during the project. To achieve this purpose, the DMLD and the Centre of Informatics Tri-city Academic Supercomputer and network (CI TASK) within the Gdańsk University of Technology developed a web application called “Virtual Microscope” to present and share high resolution digital slides of Digital Tissue and the Cell Atlas.

Through cooperation with various research institutes and hospital departments, DMLD obtained a large number of histopathological slides providing digital scans, enriching the platform with various collections of wide range oncological and non-oncological diagnoses. Datasets transferred using a dedicated direct network connection between DMLD and the CI TASK data center contain digitalized images and related metadata, presented further in the application.

The platform provides an opportunity to access a rich database, with high-resolution and high quality images in the universal DICOM format, along with related research data and anonymized clinical information. Its extensive user interface, contextual searching and browsing tools combined with the functionality of the image browsing using the microscope and presenting detailed descriptions of particular records – these are only a few mentioned features of the application.

“Virtual Microscope” itself is a solution suitable to the individual requirements of future users from the scientific community, and the private education research sector, that provides advanced services in digital resources availability.

Citation

Bolcewicz M, Jendernalik K, van de Wetering T, Proficz J, Skokowski J, Kalinowski L. Eur J Transl Clin Med. 2021;4(Suppl.3):34.

EUROPEAN JOURNAL OF TRANSLATIONAL AND CLINICAL MEDICINE

(ISSN: 2657-3148, e-ISSN: 2657-3156)



Nowe czasopismo naukowe
Gdańskiego Uniwersytetu Medycznego
/półrocznik, wydawany od 2018 r./



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EUROPEAN JOURNAL OF TRANSLATIONAL AND CLINICAL MEDICINE

(ISSN: 2657-3148, e-ISSN: 2657-3156)



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