BIOBANKING IN SLOVAKIA: A QUALITATIVE SURVEY OF ACADEMIC AND CLINICAL STAKEHOLDERS ON PERCEIVED BENEFITS

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Abstract

Current literature describes many different types of benefits obtained from biobanking operations. However, whether these benefits will actually be realized depends on the large extent of various external and internal factors. The main goal of this study is to perform an impact analysis of an emerging biobanking program funded by EU grants (European Regional Development Fund), from the perspective of physicians and researchers, and also identify factors that could influence the achievement of these benefits. First, we briefly describe the concept of the ”BIOFORD” and “DIGIBIOBANK” projects and present a concise literature review of the benefits of biobanks identified in the scientific literature. Second, we investigate the perspectives of individual stakeholders, that are the closest to the biobank through a qualitative survey, namely semi-structured interviews. The interview confirms the need for a systemic biobanking infrastructure in Slovakia. It is perceived as a key facility for advancing research and healthcare and as an accelerator of new opportunities and international collaborations. Among the most important factors influencing its success is the ability to ensure high-quality processes, availability of bio-samples and medical data as well as provision of technical expertise.

Keywords

Biobanking infrastructure in Slovakia, Biobanking, Benefits of biobanks, Qualitative survey

I. Introduction

From an external point of view, biobanking is primarily related to the physical infrastructure and processes for collecting and archiving bio-samples. However, with an in-depth look from within, a number of complex human interactions can be revealed. Professional biobanks must be subject to quality standards and constantly reassure the public and patients that there are no risks associated with donating bio-samples. They must build an image of a trustworthy institution. It is crucial for the biobank to build a relationship with patients as well as the public. As physicians are in close contacts with patients during routine diagnosis and therapeutic interventions obtaining all kinds of bio-samples and medical data; and as researchers are primary users of the biobank, they have the greatest influence

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on its outcomes and impacts on basic and translational research. Therefore it should be important to know their individual needs and perspectives, respectively. These may vary between regions or countries due to cultural differences, various developmental stages of biobanking systems, unique research applications and awareness of biobank operations among other factors.

The latest data regarding public awareness of biobanks in EU countries are derived from a survey conducted in 2010 (European Commission, 2010). Individual countries differ greatly in this regard. Only 34% of respondents in Slovakia answered in this survey that they had heard about the biobank before. Respondents from Scandinavian countries such as Iceland (80%), Sweden (75%), and Finland were significantly better informed (European Commission, 2010). More recent numbers may be found in regional or national surveys. According to a survey in Germany conducted in 2018, only about 31% had previously heard of biobanks (2 p.p. higher than in 2010) (Bossert *et al*., 2018). In Latvia, according to a survey conducted in 2019, it was only about 26% of participants (20 p.p. lower than in 2010) (Mezinska *et al*., 2020). In Slovakia, an online survey conducted in 2022 also revealed a decrease in awareness (16,6 p.p less compared to Eurobarometer 2010). Despite continuing low public awareness of biobanks in selected countries, the overall public attitude towards such organizations can be described as open-minded. Support for biobanking activities was identified by 53,6% of respondents from Poland, 77% of respondents from Finland, and 82% of respondents from Scotland (Domaradzki and Pawlikowski, 2019). In the USA, 84% of respondents said that biobank is very or extremely valuable (Simon *et al*., 2011). Support for biobanking is demonstrated also by a willingness to donate bio-samples, which was found in 70% of respondents in Germany and 86% of respondents in Italy through recent surveys (Bossert *et al.,* 2018; Porteri *et al*., 2014).

One critical factor in successfully building a biobanking system, in general, is to find a way to connect physical assets with expertise and health innovations. Establishing formal or informal platforms supporting innovators in biomedical and clinical research could be advantageous in connection to a biobank system. Close cooperation, e.g. in the form of incubators or supporting hubs, provides wide-angle help to any researcher aiming to develop new treatments or diagnostics. Business, intellectual property, scientific, clinical and entrepreneurial expertise and skills present and delivered close to building systemic public research infrastructure will thus, in the end, increase the benefits of such infrastructure for the health system in a country.

Further, European countries differ in their number of established biobanking operation. There are currently 20 EU countries listed within the BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium) Directory. According to BBMRI-ERIC Directory data, the highest density of biobanks is in the UK, Sweden, the Netherlands, France, Italy, and Germany (BBMRI-ERIC, 2022). These countries also lead in terms of the number of publications related to biobanking, with the highest numbers coming from England, the Netherlands, Denmark, Sweden, Germany, and Scotland (as for Europe) (Wu *et al*., 2021). Among the countries most active in participation of top-notch research projects financed by the European Commission (from Framework programs and Horizon 2020) that were related to biobank or biobanking in the period 1994-2021 were Great Britain, Germany, Italy, France, the Netherlands, and Spain, as well as Sweden, Finland, Norway, and Denmark. And after the population size adjustment, the top countries also included Iceland, Luxembourg, and Finland (Kotorova Slušná *et al*., 2021).

In contrast to these findings, Slovakia is not a member of the BBMRI-ERIC yet. It is planned that Slovakia within the BIOFORD project will become a member of this pan-European network in 2023 at the latest. However, currently, it offers a fragmented landscape of individualized biobanking organizations mainly associated with a university and general hospital units (e.g. National Institute of Rheumatic Diseases (in Slovak *NURCH*), National Cancer Institute (in Slovak *NOU*), St. Elizabeth Cancer Institute). The need to establish systemic biobanking infrastructure in Slovakia reflects a multi-stakeholder initiative from 2016 being followed in 2017 under the leadership of the Ministry

of Health Institute for Research and Development (Glasa *et al*., 2019; Glasa *et al*., 2020). Legislative activity aimed at updating biomedical research and healthcare legislation started in 2018. However, the draft law on biobanks was ultimately not included in the legislative process (Glasa 2020; Glasa 2020a). The BIOFORD and DIGIBIOBANK projects started operations officially in January 2020 with a multi-factorial consortium of leading academic and clinical institutions and governmental organizations (Slovak Academy of Sciences: Biomedical Research Center of the Slovak Academy of Sciences and Centre of Social and Psychological Sciences; National Institute of Rheumatic Diseases; Comenius University Bratislava: Faculty of Medicine and Jessenius Faculty of Medicine in Martin; University of Žilina; National Cancer Institute, and the Ministry of Health of the Slovak Republic).

The main goal of the BIOFORD project is to build a modern, systemic, public research infrastructure, providing effective biobanking based on the international standards and foreseen implementation of the amended legislation on biomedical research as a form of providing of healthcare. Existence of such infrastructure represents basic pillars of excellent biomedical research.

Within the BIOFORD project, there is included BIOHUB SK as a mentoring incubator to support innovative biomedical research activities and education of the community in healthcare.

DIGIBIOBANK comprises digital banking of medical data associated with a human donor. These are data from hospital information systems - clinical anonymized data, data from the laboratory information management system, data from the research information system and data from the PACS (picture archiving and communications system). The obtained data can be analysed by bioinformatics, biostatistics and artificial intelligence algorithms, further supporting new digital pathology solutions in Slovakia

In this paper we present a brief literature review of the benefits of biobanks in general. Secondly, we describe the methodology and findings of the qualitative research we conducted in 2022. In our research, we selected and approached future users of emerging biobank facility, namely scientists and physicians (e.g oncologists), and asked them about current biobanking practices, interest in cooperation with the professional biobank, beneficial impact on society, and which factors could potentially limit the expansion of its benefits.

II. Literature review

The literature provides overall two perspectives on the perception of benefits; one an individual biobank perspective (Bemmels *et al*., 2012; Conradie *et al.,* 2021; Matharoo-Ball and Thomson, 2014; Sudoi *et al*., 2021; Von Walcke-Wulfen, 2009) and the other a national biobank or network of biobanks (Gee *et al.*, 2013; Rogers *et al*., 2011).

The first focuses on the benefits stemming from the provision of bio-samples for research. In the area of research and development (R&D), biobanks may contribute to new scientific knowledge resulting in, for example, new scientific publications, new therapeutic and diagnostic regiments or breakthrough innovations. Further, biobanks may contribute to new discoveries in science, new platform technologies and tools. In the life science sector, providing bio-samples for industrial applications or turning research into products or services are potential benefits that could result in the following output: new patents being filed; spin-off companies, businesses, and jobs being created; strategic expansion of existing corporations; financial resources flowing from industry to research; biobanks providing education and training to the commercial sector. These factors could directly benefit the community by bringing in new investments for infrastructure, creation of jobs, and the state would benefit from increased tax revenues and higher market rankings within EU countries (Von Walcke-Wulfen, 2009; Gee *et al.*, 2013). Sudoi *et al*. (2021) also discussed the broad range of direct and indirect beneficiaries. Starting with those closest to the biobank, there are biobank staff, donors, their families, and communities, and then local community members, local researchers and experts, , healthcare providers, pharmaceutical companies, the government, and the public (populations from

which the samples are derived and the civilization overall, if research results are transformed into clinical practice). In healthcare, donors could directly benefit from research results; for example, if a biobank conducts a genomic based analysis with donated bio-samples, important results could be communicated to the donor. Students in health-related fields could also benefit from a biobank by using samples and data for research projects and taking advantage of any collaboration between a biobank and an associated university (Fthenou *et al.,* 2019). Students, doctors, and researchers could benefit from having access to state of the art biobank technologies such as equipment for genome analysis (Campos *et al.,* 2012). Patient-derived biobanks have particularly significant impacts because of their focus on the patient; better collaboration, and communication between stakeholders (Edwards *et al.*, 2016).

The second perspective is focused on network effects arising from the operation of several biobanks within a network or operating under the hub and spoke model. These benefits include increased transparency, information sharing, efficiency, consistency and standardization, higher bio-sample quality, and optimization of IT and capital infrastructure. Other benefits include implementing best practices, improving professional recognition and accreditation, and reducing duplication and transaction costs; these lead to greater efficiency in scientific experiments, shorter and less costly clinical trials, more accurate patient diagnosis, more effective therapies, and, thus, higher quality of life through shorter treatment duration (Rogers *et al.,* 2011; Gee *et al.,* 2015). Professionally managed biobanks can act as centers of excellence and knowledge providers for smaller biorepositories or other stakeholders (Tarling *et al*., 2021).

Another group of scientific studies focuses on the benefits of biobanks in terms of specific types of research. In cancer research, a relatively high proportion of scientific studies about 40% have used bio-samples or biobank data for research (Tarling *et al.,* 2021; Meredith *et al.,* 2019). Several studies denote the role of biobanks in cancer research by providing insights in the origin, evolution, and prognosis of cancer (Campos *et al.*, 2012; Waldmann *et al.,* 2014; Zhang *et al.,* 2016). Human bio-samples are typically applied to investigate disease mechanisms and validate such biomarker data for diagnosis, disease progression, and response to treatment (Zhang *et al*., 2016; Schneider *et al.*, 2016). This may include the identification of genes associated with tumor progression or prediction of responders/non-responders to chemotherapy (Edwards *et al*., 2016), studies on cancer development and genetic heterogeneity (Waldmann *et al.,* 2014; Al Diffalha *et al*., 2019; Vora and Thacker, 2015). By knowledge of molecular structures novel target interactions can be developed (Zatloukal and Hainaut, 2010). Given the high variability of rare diseases, their low prevalence rate, and the high proportion of rare diseases with genetic origins, it is clear that biobanks play an even greater role. Namely, improving the quality and quantity of epidemiological data, enabling local genotypic and phenotypic correlations, improving the assessment of disease burden and treatment, and supporting informed decisions (Conradie *et al.,* 2021) Rare disease biobanks are particularly important for studying the biology, analyzing the cause of disease by genetic testing, and supporting clinical trials (Graham *et al*., 2014; Rubinstein et al., 2017); they can also aid the understanding of drugs and their mechanism of action (MOA), improving their safety and efficacy profile (Welinder *et al.,* 2013). For biobanks focused on rare diseases, the role of patient organizations and linkage to registries is particularly important (Conradie *et al*., 2021; Schneider *et al.*, 2016). The central role of patients and their contribution to biobanking is increasingly recognized (Mitchell *et al.,* 2015).

This literature review was focused only on a qualitative description of biobank benefits. The lack of studies devoted to the quantification of benefits, the impact of biobanks, or the absence of a methodology for their evaluation are pointed out, for example, by Rush *et al*. 2020, Tarling *et al.* 2021, Rogers *et al*. 2011 and Byrne *et al.* 2021. Certain quantitative data can be found within case studies of individual biobanks and from their monitoring of measurable indicators. Rogers *et al*. (2011) attempted to quantify the impact of a national biobanking framework in the US. The authors use analogies, examples, or scenarios in the study to compensate for the lack of data. The calculation

of the total economic benefits in the amount of $188 million per year thus needs to be interpreted very carefully.

III. Methodology

The qualitative design of our research was chosen mainly due to the lack of quantitative data as well as the depth of the knowledge that qualitative data were able to provide. In order to identify the potential effects of the emerging biobanking program and the factors that can influence them, a deeper understanding of the attitudes, environment, and complex interactions is crucial. During the interviews, we used the term national biobank, which was more understandable for the respondents, and we also used the thematic analysis that does not require quantification of findings and allows us to incorporate the context (Vajsmoradi *et al.,* 2013).

Qualitative research focused on two groups of stakeholders who present the main user profile of such biobank infrastructure, namely researchers and physicians. The qualitative research method was semi-structured interviews.

We used purposive sampling method in order to get the heterogeneous sample in terms of geography, institutional attribution, and expertise, preferably from non existing biobank project partners.

Interviews were arranged according to the interviewee's choice either by telephone, online or in person. Semi-structured interview design was used and respondents were incited to provide any comments or suggestions and introduce additional issues. Respondents were assured about the anonymization of the survey. Interviews lasted 30 minutes on average. Transcripts were not provided to participants for additional corrections or comments.

Verbatim notes taken during the interview were organized in order to follow the interview format. Interview transcripts were thoroughly screened for meaningful patterns. The analytical process followed the procedure outlined in Braun and Clarke (2006). A descriptive overview of findings is presented through quotations.

Demographics of respondents

Scientific respondents were recruited from three scientific research organizations (Slovak Academy of Sciences, Faculty of Medicine UPJŠ Košice, Biomedical Centre Martin). They operate on various departments focused on biomedicine, genomics, prenatal diagnostics, molecular medicine, experimental oncology, genetics, and medical biology located in three different regional territories, namely Martin, Bratislava, and Košice. Interviews were conducted from May 26 to August 10, 2022; in total eight researchers were interviewed alongside with four physicians specializing in oncology and onco-hematology working in medical facilities located in the cities of Trenčín, Košice, Bratislava, and Banská Bystrica.

IV. Results

With the aim of identifying the potential effects of emerging biobanking program, we asked participants a set of questions focused on four areas:

1. Mapping the current state
2. Cooperation opportunities
3. Potential effects of the national biobank
4. Factors important for the success of the national biobank

1. Mapping the current state

The scientists who were approached in the survey used different types of human biological material in their research including blood, healthy and tumorous tissues, adipose tissues, pap smear (cervix), plasma, peripheral blood, bone marrow and covid cohorts. Biological specimens from patients, i.e. clinical samples represent a key source for their research activities. The conditions in which samples are stored, depend typically on the type of bio-sample. Most often, bio-samples are stored in freezers or as FFPE (formalin-fixed, paraffin-embedded) tissue blocks and slides at room temperature.

All respondents mentioned the hospital as the main source for obtaining bio-samples. Researchers collect bio-samples individually as part of their research project. The researcher usually approaches hospitals located in the region where she/he works. Several respondents described their access to bio-samples as relatively simple while others said that obtaining clinical samples is extremely difficult. The reason for two different opposing points of view is the presence of subjective factors such as good relationships, previous cooperation, and the goodwill of physicians. All respondents stated that they currently cooperate or have cooperated with doctors in hospitals. Respondents stated that good relationships and previous collaborations are very important and often they would not have been able to access clinical samples without them. As an obstacle in obtaining biological material, they mentioned the overloading of clinical workers who are dedicated to health care and do not have the time capacity for research-related activities, as well as problems in obtaining data for samples.

"Oncologists do not have time to collect samples, it is up to their goodwill that they are willing to give us samples." The researcher

They often have to devote time to collect the data for the samples individually, as one respondent stated *"sometimes spending afternoons in the clinics"*.

Only in one case, the respondent mentioned the acquisition of bio-samples from abroad, and two respondents mentioned obtaining bio-samples from a foreign partner as part of an international project. Confirmation of the statement below would require further investigation:

"Scientists have to acquire bio-samples outside of Slovakia, for example in Germany. I might be forced to follow this path in the future as well." The researcher

All respondents stated that they use premises at their workplace or another workplace within their institution to store bio-samples. Space for archiving samples is usually procured within a grant for a specific research project. These are mostly freezers or nitrogen containers. Three respondents mentioned a lack of space. One respondent stated that they have little space for bio-samples that must be stored at -80 °C: *"Several colleagues share one space, the capacity is filling up, it is necessary to look for alternatives."*

Physicians stated that bio-samples of their patients most often go to laboratory departments for a short time during their analysis and to pathology departments. One respondent stated that bio-samples were also sent abroad where clinical studies were carried out.

2. Cooperation opportunities

All respondents with the exception of one person expressed themselves positively regarding their interest in cooperating with the biobank organization.

Most of the respondents were aware of the BIOFORD project. Only two respondents had not heard about the emerging biobank but declared high interest in participating with scientific projects. In response to this question however one respondent stated:

"We do, but there is a lack of awareness, no one knows about the biobank project." The researcher

One respondent outlined the topic of financial recovery related to establishing a biobank infrastructure and accessing bio-samples for academic research:

"Cooperation yes, as long as they have bio-samples and associated data available. It will be necessary in the future to take into account the sustainability of such infrastructure by applying for grant funding at the national /international level."

One respondent stated high enthusiasm about the establishment of the national biobank as such and with regards to cooperation stated:

"Yes, definitely. My lifelong goal is to create a national biobank, we miss it a lot." The researcher.

Interest in cooperation was solely positive among approached physicians. All approached physicians expressed their support by providing clinical samples for R&D applications, getting integrated into such novel type of biobanking network. Moreover, they stated an interest for medical partnership programs and systematic monitoring of patient examinations. As crucially important they indicated the compliance with the code of ethics.

3. Potential effects of the national biobank

We have categorized potential effects into two categories: social and direct benefits.

- Social benefits

Improving the lives of patients

Among social benefits, most emphases were on the effect of improving the lives of patients. The first thing that came to the minds of most respondents when asked about the potential effects of the biobank was the benefit for the patient. This suggests that biobank is perceived as a public good and socially beneficial facility. Several quotes support this:

"The physician, the scientist, the patient will benefit. In the long term, primarily the patient. Every single person will benefit." The physician

According to the researchers, the trend in research is to move toward the patient:

"From a scientist's point of view, I can say that research from patient samples is more relevant, we are closer to patients. In the end, the patient gets the biggest benefit." The researcher

Physicians expressed their willingness to participate with biobanking programs, where histological bio-samples are taken regularly, and repeatedly for patient follow-up typically performed by pathology. For fresh samples, it would be necessary to ensure transfer and logistics. One respondent stated: *"Samples are given to private pathology for expert analysis, older samples are thrown away. If someone lives with a tumor for 10 years, which is rare, it is not possible to look back at the sample. The biobank would thus have a great benefit for translational research, new treatments."*

Another physician stated in a similar expression:

"I see the biggest benefit in the fact that the bio-samples can be searched back, you can return to them. The research potential here is high."

Information obtained from genetic data to determine tumor cells group is important for oncologists who can better adjust treatment options. According to the respondents, the availability of clinical data in the biobank would make it possible to determine tumor types, speed up diagnosis and improve treatment.

According to respondents, benefits to health care will be achieved, through the possibility of making predictions for patients based on medical analysis, better examination of diseases, provision of data

for physicians to better adjust treatment, acceleration of diagnostics based on the availability of data and analysis, translation of scientific results into practice and last but not least new therapeutic options. The above points have the potential to reflect on lower costs for health care and treatment.

Prestige and new opportunities

Respondents frequently mentioned benefits in the form of shifting towards market standards and an improvement in Slovakia's scientific capabilities not only in basic research but also in applied R&D programs. They are aware that professional biobanks have been operating for many years in most western countries. These effects will be reflected in the form of higher quality scientific outputs which can bring more financial resources for the research organization and a higher reputation for Slovak research. The importance of a systemic biobanking infrastructure is described in the following statements:

"I am an enthusiastic supporter of the creation of such an initiative, I consider the biobank to be very important. I think we're doing it right on time if not 5 minutes past twelve."

"Slovakia is at the tail end in medical research, we don't have a biobank, and it could certainly bring us more opportunities for cross-border partnerships, involvement in international projects, networks."

Membership of a biobank in the international biobanking community is perceived as important, primarily in terms of involvement in international projects, and gaining experience and prestige.

Among other impacts, respondents included the benefit in educational and academic ecosystem. By providing access to standardized bio-samples, it would increase the application rate and quality of publications and give access to international grant funding schemes e.g. Horizon 2020.

Effects on clinical trials

According to respondents, biobanking operations could increase the number of clinical trials for Slovakia. One respondent stated that the bio-samples and data stored in the biobank could be supplied to pharmaceutical companies that could conduct clinical trials. He does not perceive it as providing a benefit to a private company, but as improving access to effective treatment, i.e. benefiting patient care.

" Corporate research in oncology is ongoing in Slovakia, but currently without a centralized source." The physician

Unification of the whole biomedical eco-system

The national biobank is seen as an important unifying element that is essential for Slovak research:

"Slovakia is a small country. Cooperation between individual subjects with a limited number of samples can increase the statistical power and thus the quality of the research."

"As soon as the teams have to share something, a problem arises. The biobank should act as a unifying element."

- Direct benefits

The biobank was also perceived as beneficial for researchers and physicians themselves.

Researchers emphasize the importance of collecting and archiving bio-samples under standardized conditions which will relieve them from such work packages.

When obtaining tissue and blood samples from hospitals, the researchers are not capable to supervise this process due to the complex condition: methods of fixation, transport of biospecimens, and other factors significantly affecting the quality.

Regarding the need for high-quality samples, one respondent stated:

"The research from our own bio-samples is most of the time sufficient for us in terms of the quality of the bio-samples, but there were several cases when we did analyses on bio-samples and we could not continue with further research because SOPs (standard operating procedures) that would ensure sufficient quality were not used."

Regarding the need for statistically significant cohort sizes, one respondent stated:

"During our research, it may happen that it is found that x% of the samples do not meet the criteria - e.g. low quality or hemolyzed plasma and y% of the samples lack data and so from the original e.g. 300 samples are ultimately 80 usable, which may not be enough for a scientific study." The researcher

"If we want to sequence the genome of Slovak patients with covid and monitor the progression of infection, which is typically financed from a project, it is necessary to write a proposal, wait for financial approval and by the time the implementation begins, it may happen that the study has lost its meaning. If such samples were available in the biobank, the research could begin immediately. In this way, other countries are far ahead of us." The researcher

According to the researchers, detailed characterization of medical data in anonymized form is necessary. One researcher stated:

"Biobank is important if it allows processing a large amount of data".

The physicians see also the benefit for their professional development, their clinics, and the expansion of their opportunities from research collaborations. At the same time, however, they mentioned a lack of time for engaging in research.

4. Factors important for the success of the biobank

Achievement of the above-mentioned benefits depends, according to our respondents, mainly on the quality of the biobank and its processes, availability of bio-samples and medical data, additional expertise, and ability to cooperate.

- Ensuring the highest quality of processes

One of the main factors that influence the choice of a bio-sample source is the quality and storage parameters – ideally under identical technical conditions. Respondents explained that the quality of the bio-sample is significantly affected by compliance with the SOP, or ensuring proper processes before accepting the sample to the biobank. First, we present several quotations from scientific respondents:

"Standardization and certification of the processes of tissue and blood samples are important. It is necessary to be able to rely on the biobank, that the samples are taken and stored under the same conditions."

"We do basic research, which means that the correct characterization of the sample is very important for us, so that the sample reaches us in sufficient time, quality, vitality and of course also anonymized and with clinical data."

"The purpose of the biobank is to collect samples and data as main responsible institution, i.e. systematically with validated protocols."

Every single process, including the collection itself, is important and must be done professionally. For example, the quality of human tissue samples depends on several factors, f.e. the cold and warm ischemia time. In this process, not only the pathologist himself is important, or the doctor who takes the sample but also, for example, the paramedic who transports the sample.

- Sufficient offer of samples and data

The next topic that was frequently mentioned by respondents is the sufficient supply of bio-samples and medical data. This is, after all, one of the main and fundamental roles of a biobank organization. According to respondents, complete histopathological and medical information for bio-samples and sufficient availability are crucial. They agree that the bio-samples should be characterized in as much detail as possible and a complete patient case report form should be created. Several respondents stressed that the collection of clinical data should take place on a unified national protocol and that it is necessary to collect the same clinical data.

- Expertise

The third topic goes beyond the fundamental role of biobanking. Respondents do not see a biobank only as a storage facility, but also as knowledge center with expertise in bioinformatics, biostatistics, biochemistry etc. and qualified service provider. Several respondents stated the importance of proper sample processing with trained personnel to carry out the work objectives. One respondent drew attention to increased physical infrastructures established and funded by EU grants, but personnel capacities remain insufficient. One respondent stated that they currently have two clinical trials running where analytical support would be of great benefit. Another respondent added:

"Clinical research is underdeveloped. It works so far only at one institute. It is necessary to carry out research and analysis in the biobank. It would be necessary to perform analysis such as gene alterations, genetic profiles, monitor circulating cells, and DNA analyses." The physician

According to physicians, technology and laboratory equipment are also of key importance. Technologies for genetic analysis, which are very expensive, would be of great benefit.

- Networking

Respondents emphasized that collaboration and networking will have a great impact on whether the biobank is going to be successful and sustainable. Networking with other institutions, especially hospitals and research facilities, will be a key factor in achieving the highest possible value for money. Some researchers mentioned the reluctance to share and cooperate on the part of physicians or a lack of openness as a possible problem. Respondents emphasized the necessity of cooperation:

"If there is a willingness to cooperate, there will be benefits throughout Slovakia." The physician

"Willingness to work together will be very important." The researcher

"Funding will be important for sustainability, but so will openness." The researcher

- External factors

The lack of medical workers in the health sector and their overload remains a key obstacle. Clinical research requires staff to deal with protocols, record time, etc. However, the respondents agree that there is a lack of clinical workers who would have time to devote to research and a lack of clinical research workplaces.

V. Discussion

In a recent survey by Massett *et al*., 2011, only 9% of respondents perceived the creation of a national cancer biobank in a negative way. Within this survey, they also identified a relatively high willingness to cooperate with the biobank (62% of respondents were interested in sample acquisition and 53% were willing to contribute to the biobank)

Attitudes towards biobanks and to the specific BIOFORD program were solely positive among the stakeholders we approached. They perceived the described biobank project as a key facilitator in improving research and health care.

Despite not having a well-developed biobanking system in Slovakia, respondents were aware of the wide range of benefits that the existence of a biobank will bring. Patients and scientists were identified as the main beneficiaries as well as research organizations and physicians. The key benefit was an increase in the quality of research due to higher availability and quality of samples and data, a shift of research toward the patient, and the ability to complete unfinished research programs. A higher quality of research will be reflected in increasing studies published in peer reviewed journals. Higher quality outputs will also benefit the scientific community and research in Slovakia. Biobanking has the potential to contribute to the advancement of research through the availability of diseased and healthy control bio-samples. A professional biobank is perceived as an organization that brings prestige and greater involvement in international projects and collaborations. Other identified benefits include support for the educational system and students, who could improve the quality of their diploma and dissertation theses.

Surprisingly, none of the respondents mentioned the impact on life science industries, e.g. spin-off companies or expansion of existing businesses. This may have been omitted due to the respondents coming mainly from academic or clinical backgrounds, but also due to Slovakia´s lagging in technology transfer in general. For illustration, according to the 2022 European innovation scoreboard, performance in PCT patent applications in Slovakia was only 38,5 relative to the EU (European Commission, 2022). The positive impact on the business environment was documented e.g. in the study of Von Walcke-Wulfen (2019), which is based on data from the Fraunhofer Bioarchive biobank for the period 2003-2008, during which the biobank participated in more than 25 patent applications and the creation of 3 spin-off companies.

Despite the small size of Slovakia, cooperation was seen as the main challenge among respondents. On the one hand, respondents proclaimed an interest in cooperation, on the other hand, they expressed concerns about cooperating on behalf of other researchers or physicians. Collaboration however seems to be one of the key ingredients for success in biobanking. Personal relationships and previous collaborations with the sample sources were identified as significant factors for researchers in Australia, Germany, and the UK (Klingler *et al.,* 2021, Lawrence *et al.,* 2020; Rush *et al.,* 2022). The preference for local and known sources in the UK was based on quality concerns and also on additional scientific and logistical input from known sample sources (Lawrence *et al.,* 2020).

Among the most important factors that influence UK biomedical researchers when choosing certain sources of samples were the availability of associated clinical data, geographic location, and previous collaboration (Lawrence *et al*., 2020). The key factor that influenced the choice of bio-sample source by Australian researchers were the costs and the most required data types were longitudinal, clinical data linked to governmental registries (Rush *et al.,* 2022). Among the factors that would convince German researchers to collaborate with biobank were the availability of data, high quality of bio-samples and medical data, and prompt access to bio-samples. The high quality and availability of bio-samples, additional clinical data, and previous collaboration convinced those who already obtain samples from an academic centralized biobank (Klingler *et al.,* 2021). Patient treatment outcomes

and information, and quality assessment of the sample were identified as the most desired information among the US researchers (Massett *et al*., 2011).

Surveys from abroad also confirmed that the application process needs to be efficient and access to samples must not be perceived by participants as demanding and difficult, so as not to discourage researchers from collaborating with the biobank (Lawrence *et al*., 2020; Rush *et al.,* 2022). These surveys also revealed that the percentages of researchers who actually use bio-samples from biobanks are not high. According to a survey among US researchers, on average respondents obtain approximately 50% of their biomaterial by themselves from patients and only 10,4% is obtained from a biobank (Massett *et al*., 2011). A survey among German researchers revealed that only 12% of respondents (researchers from institutions where a centralized academic biobank was located) obtain biomaterial from a centralized academic biobank (Klingler *et al*., 2021). In Australia, 62% of respondents stated that they have their own collection, mostly due to the unavailability of existing samples and data, but they also stated personal relationships as a reason (Rush *et al.,* 2022). According to the NCI survey, 81% of respondents said they needed to limit the scope of their research because of lack of available samples and 60% of respondents questioned their findings due to the sample quality concerns (Massett *et al.,* 2011). Mapping of researcher´s needs is crucial (Klingler *et al.,* 2021). Lack of awareness of these factors resulted in closure of the National biobank in Singapore after 8 years of operation. Singapore´s researchers preferred their own repositories to this biobank. Wai (2012) concluded that most biomedical researchers were clinicians, who could easily approach patients directly and avoid high administrative burdens. Mapping the perspectives and needs of scientists can be also helpful in dealing with low utilization rates and sustainable business operations (Klingler *et al*., 2021).

A literature review by Domaradzki and Pawlikowski (2019) identified benefits related to knowledge about many diseases, and to the development of novel therapies as the most frequently stated biobanks´ benefits by the general public. Benefits for families of respondents, donors, and future patients were among the stated factors as well. A study of Buhmeida *et al*. (2022) revealed that healthcare providers were more willing to support biobanks if they had good knowledge about biobanks, positive attitude towards biomedical research and if they were involved in medical research. External communications, active involvement of the public and dissemination of information about biobanks is equally important (Klingler *et al*., 2021; Goisauf *et al.,* 2019; Bosser *et al.,* 2018). A recent survey among biobankers and researchers from 32 predominantly European countries however revealed that many biobanks do not implement any activities for engagement with their participants (50% of respondents stated no activities of the biobank they work with) due to lack of funding and time (Goisauf *et al.,* 2019). Tupasela *et al.* (2015) emphasized the role of historical, political, and scientific aspects on public or donors' perception of the biobank.

VI. Conclusion

The results of our qualitative research pointed to the perception of the biobank as a highly important subject in research (especially biomedical, clinical, and translational) and the health sector. The results also confirmed the need for the existence of a professionally managed biobanking system that would unify all stakeholders. Clinical samples are essential for excellent biomedical research. Obtaining bio-samples from biobanks would grant the researcher community easier, efficient access to bio-samples and data. The survey identified requirements for additional storage facilities and the overall need for a systematic biobank infrastructure. A large supply of certified samples and data would significantly increase the quality of academic studies. Further, the need to complement the physical infrastructure with expert services and analytical support was identified.

There was specific interest expressed in cooperating with the current BIOFORD and DIGIOBIOBANK projects and future programs. If these projects are to have effects across the whole

of Slovakia, awareness of them must be spread to all regions. The need for active external communication of the biobank has been also identified in many foreign studies.

Even though the survey respondents expressed a high interest in cooperation, the willingness to cooperate was identified as the most pressing challenge. For any biobanking project continuous activities supporting its visibility and promotion are inevitable for future success. Building trust with all the stakeholders, mapping the needs of its users and decreasing administrative burden as much as possible to make a biobank preferred source for their research is no less important.

Further research into biobank stakeholders´ needs, viewpoints, and preferences is needed to complement the findings of our study and provide a comprehensive picture.

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