

**MINUTES from the online meeting (1/2022)**

**of the Scientific Board of the Ministry of Health, Slovak Republic  
(hereinafter referred to as “SB, MoH SR”), which took place on 29th June 2022 (Wednesday) at  
9:00 am online**

*Present:*

**Prof. MUDr. Peter Valkovič, PhD.**, Presidium Chair, SB, MoH SR  
**Assoc. Prof. MUDr. Richard Imrich, DrSc.**, Presidium Vice Chair, SB, MoH SR  
**Prof. MUDr. Lukáš Plank, CSc.**, Presidium member, SB, MoH SR  
**Prof. MUDr. Peter Zvara, PhD.**, Presidium member, SB, MoH SR  
**Prof. RNDr. Shubhada Bopegamage, CSc.**, member, SB, MoH SR  
**Prof. MUDr. Andrea Čalkovská, DrSc.**, member, SB, MoH SR  
**MUDr. Beata Čečetková, PhD.**, member, SB, MoH SR  
**Prof. MUDr. Alexandra Kolenová, PhD.**, member, SB, MoH SR  
**Assoc. Prof. MUDr. RNDr. Ing. Peter Celec, DrSc., MPH**, member, SB, MoH SR  
**Ing. Igor Lacík, DrSc.**, member, SB, MoH SR  
**Assoc. Prof. MUDr. Juraj Maďarič, PhD., MPH**, member, SB, MoH SR  
**Prof. MUDr. Michal Mego, DrSc.**, member, SB, MoH SR  
**Prof. MUDr. Daniel Pella, PhD.**, member, SB, MoH SR  
**Prof. MUDr. Juraj Šteňo, DrSc.**, member, SB, MoH SR  
**Assoc. Prof. RNDr. Zuzana Danková, PhD.**, Director, Biobank for Cancer and Rare Diseases,  
Jessenius Medical Faculty Comenius University in Martin  
**Ing. Martina Lutterová, PhD.**, external expert, MoH SR /Institute of Research and Development  
(hereinafter referred to as “IoR&D”), key team member of the BIOHUB SK platform  
**RNDr. Ivica Kvietiková, PhD., MAS ETH IP**, Head, “IoR&D” at the MoH SR  
**Mgr. Iveta Hermanovská**, SB, MoH SR; “IoR&D” at the MoH SR

*Absent (excused)*

**Prof. RNDr. Silvia Pastoreková, DrSc.**, Presidium member, SB, MoH SR  
**Prof. Maria Amparo Acker – Palmer, PhD.**, member, SB, MoH SR  
**Prof. Dr. phil. nat. Martina Muckenthaler PhD.**, SB, MoH SR  
**Prof. Prof. h. c. D. med. vet. Max Gassmann**, member, SB, MoH SR  
**Prof. MUDr. Miloš Jeseňák, PhD., MBA, Dott. Ric., MHA**, member, SB, MoH SR  
**MVDr. Ján Rosocha, CSc.**, member, SB, MoH SR

*Communication language: Slovak*

Agenda of the SB, MoH SR meeting:

1. Introduction: Welcome by Chair of the SB, MoH SR
2. Approval of the Agenda of the SB, MoH SR
3. Biobank Infrastructure in Slovakia – Projects BIOFORD and DIGITAL BIOBANK (Zuzana Danková)
4. Biobank Legislation (Ivica Kvietiková)
5. SLOVACRIN Activities (Beáta Čechťková)
6. Discussion
7. Conclusion

**Add 1 – Introduction: Welcome by Chair of the SB, MoH SR**

The SB, MoH SR meeting was opened and led by the Chair Prof. Valkovič, who welcomed all participants.

**Add 2 – Approval of the Agenda of the SB, MoH Meeting**

Agenda of the SB, MoH SR meeting was unanimously approved by all present members of the SB, MoH SR.

**Add 3 – Biobank Infrastructure in Slovakia – Projects BIOFORD and DIGITAL BIOBANK**

Assoc. Prof. Danková presented the BIOFORD and DIGIBIOBANKA projects reflecting a long-term efforts of biomedical community stakeholders (especially Prof. Lukáš Plank and Prof. Ján Sedlák) as well as the initiative of the MoH of the SR via IoR&D since 2017. These activities were translated into the two complementary projects financed by the European Structural and Investment Funds (hereinafter referred to as "ESIF"): "Systemic Biobank Infrastructure in Slovakia" and "Digital Biobank", wherein the major contribution on the preparation of said projects reflects work and performance of Mgr. Martina Antoňová, PhD., MBA. Subsequently, Assoc. Prof. Danková introduced the cooperation of Biobank Consortium Partners namely their unique and main activities as well as the common goals. She emphasized the importance of Slovakia's entry into the pan-European ESFRI research infrastructure consortium BBMRI-ERIC (one of the activities of the MoH, SR/ IoR&D), which would have major impact on the quality of biomedical research and increases the potential success of projects funding in the Horizon Europe to 50%.

**Add 4 – Biobank legislation**

Dr. Kvietiková reported on one of the key activities of the MoH, SR regarding the Slovak Biobank Consortium – preparation and implementation of the legislative and non-legislative amendments supporting biobanking, including the certification of biobank facilities. An important part represents the Informed Consent, wherein a General template thereof will contain all possible variations and conditions for providing samples with associated data. The proposal of said General template will also be provided to the SB members, MoH SR for revision with a deadline of July 13, 2022.

Based on remarks and comments, a specified form of the Informed Consent will be completed and processed in the form of a Decree in parallel with the aforementioned legislative amendments. Another crucial part represent biobanking Standard Operating Procedures (SOPs) - the collection of patient samples. Within the BIOFORD project the SOPs are primarily focused on the collection of tissue, blood and cell lines (the uniqueness of the expertise of the team of Dr. Ján Strnádel, Biomed Martin) and will be updated as necessary in the form of Decree.

The legislative amendments were originally planned to be submitted to the Government of the SR in fall of 2022, however in connection with the preparation of the Clause on impacts and material and technical

securing (hereinafter referred to in Slovak as “MTZ”), a date of the internal comment procedure (hereinafter referred to in Slovak as "VPK") has been moved to the beginning of October 2022. Another reason of said delay are foreseen project activities of further development of the biobank infrastructure in Slovakia, which requires discussions and meetings at the interministerial/ governmental level initiated by Jessenius Medical Faculty Comenius University in Martin (with support of the MoH SR/ IoR&D).

As part of Slovakia integration into the aforementioned BBMRI-ERIC consortium, a personal meeting was held in Graz in Austria in June 2022 with the BBMRI Board members as well as with a founder of said pan-European consortium - Prof. Kurt Zatloukal - Head of the Diagnostic and Research Center for Molecular Biomedicine (Diagnostic and Research Institute of Pathology at MedUNi Graz), who has offered help and support in development of biobanking in Slovakia. Prof. Zatloukal is ready to come to Slovakia and have discussions with all relevant stakeholders who decide on financing and further development of the biobank infrastructure.

In conclusion, Dr. Kvietiková emphasized that systemic support and continuity are inevitable for such important projects, which is also reflected in the Summary Report from EDP in context of SK RIS3 2021+ (one of essential documents for exploiting EU Funds in a program period 2021-2027 for research and innovations in SR), wherein in so-called transformation maps of the Domain No. 4 "Healthy Society", there is listed a continuity of biobank activities in specified areas of socially significant diseases. The IoR&D will provide SB members, MoH SR with links to all relevant strategic documents (in Slovak/ English).

#### **Add 5 – SLOVACRIN activities: Clinical trials - Benefits and Perspectives**

Medical director MD Čečetková presented the activities of SLOVACRIN - the Slovak national infrastructure, which are in line with the scope of ECRIN and the aforementioned BBMRI - ERIC. In order to support academic clinical research and innovative projects of small start-ups, it is essential to have the same set of established standards as well for clinical trials sponsored by the pharmaceutical industry, so that we can bring innovative treatments to patients. SLOVACRIN plays an important role by providing its experts for specific key areas so that clinical research, in this case an academic clinical trials (hereinafter referred to in Slovak as "AKS"), can be implemented. However, we constantly encounter lack of systematic governmental funding of these infrastructures in Slovakia. In contrary, in the Czech Republic, every scientific research ESFRI infrastructure is financed from a state budget, has its own rules, is evaluated at certain intervals, and its financing does not depend on the political change. This systemic approach, which will guarantee the continuity of infrastructure, financing and facilitate patients' access to treatment, needs to be introduced in the Slovak Republic as well.

The importance of clinical trials is also confirmed by the economic impact of the introduction of new prescription drugs that help in the treatment of incurable diseases (88 new drugs were added in the Czech Republic between 2017 and 2020). According to Association of Innovative Pharmaceutical Industry in Czech Republic (hereinafter referred to in Czech as “AIFP”) their members generated savings of 3.5 million CZK by implementing clinical evaluation and in 2020 saved health insurance companies 1.1% of the funds spent on health care. The topic for further discussion is closer cooperation with insurance companies in the SR regarding the support of AKS. These discussions are already underway in the Czech Republic, primarily in the field of oncology. On 31 January 2022, new European legislation was implemented to facilitate and simplify the administrative process for the approval of clinical trials. In this context, MD Čečetková highlighted cooperation with the MoH SR (a national template for a tripartite agreement within the framework of clinical trials), as well as continuous support of SLOVACRIN's activities from 2019 via Action Plans of the National Oncology Program directed to research, development and education. At the end, she summarized the added value of SLOVACRIN for Slovakia:

- support and enabling of realisation of multicenter clinical trials

- strategic advice to academic clinical partners
- increasing the quality of results
- support for the education of academic research centers.

The discussion reflecting the above presentation was devoted to mutual cooperation and the possibility of expanding SLOVACRIN's activities within the scientific community. Dean of the Medical Faculty, Comenius University, Prof. Šteňo emphasized the importance of state university health care as the vanguard of health care as such, including clinical research that brings patients a better quality of life.

Furthermore, Prof. Valkovič suggested to elaborate on this issue SB, MoH SR written position and sent it to all relevant stakeholders, including the Ministry of Education, Science, Research and Sport of the SR – Slovak Research and Development Agency - hereinafter referred to in Slovak as “APVV”), Government Office of the SR, Ministry of Finance of the SR, Ministry of Investments, Regional Development and Informatization of the SR, etc.

Dr. Kvietiková highlighted that this issue was/ is repeatedly communicated to the former as well as to the current executive management at the MoH SR, while Minister Lengvarský fully agrees with this position. Vice-chair of the SB, MoH SR, Assoc. Prof. Imrich suggested diversifying a support into the AKS projects through a strategic agreement with the APVV and also into the Calls for R&D issued by the MoH SR, wherein there is currently an ongoing problem with financing.

Assoc. Prof. Celec, who is a member of the APVV Presidium, informed that this option is not feasible within the APVV grant schemes. MD Čečetková stated that in the Czech Republic, within the framework of the Agency for Medical Research, they are currently working on this issue and searching for ways how to finance projects, which includes non-commercial clinical studies projects.

Prof. Valkovič, Assoc. Prof. Maďarič and Assoc. Prof. Celec discussed the possibilities of financing AKS by insurance companies.

Dr. Kvietiková proposed a meeting at the highest level with the representatives at the Government Office of the SR/ Section for Research, Development and Innovation and SLOVACRIN.

Prof. Kolenová stated that we do not have defined academic clinical research implemented in the legislation and the related problems of reimbursement of costs for AKS are not solved. Dr. Kvietiková informed on establishment of the Working group at the MoH of the SR lead by the Section of Pharmacy and Drug Policy, which works on legislative changes in this area (novelization of the Codes 362/2011 and 576/2011 in Slovak legislation), wherein on behalf of the IoR&D - Mgr. Katarína Kováčová (a key member of the BIOHUB SK team) is preparing the final amendments. As part of the planned novelization, issues of non-commercial clinical trials fees are included. In line, Mgr. Kováčová will inform the members of the SB, MoH SR with a current status of the foreseen implementation of said legislative changes.

#### **Add 6 – Discussion**

The SB, MoH SR Chair informed about the meetings of the SB Presidium, MoH SR, its members and with support of the IoR&D with the executive representatives of the MoH of the SR – with the Minister and the State Secretary, which were devoted to several key topics, especially to a lack of funding from 2019 of the Call of the MoH SR for research and development in healthcare, including activities of the SB, MoH SR and of the IoR&D/ BIOHUB SK, insufficient support for a systemic development of the biomedical research ecosystem, failure to exploit funds from past ESIF calls, possible delays of exploiting EU funds within the current program period 2021-2027, opportunities from the Recovery and Resilience Plan in the field of research and innovation. The question of essentiality of supporting research workplaces, especially in the university hospitals, at the Medical Faculties and the Slovak Academy of Sciences and their linkage was opened. The necessity of building new hospitals in Bratislava and Martin was also emphasized. The Minister of the MoH SR and the State Secretary expressed their unequivocal support for the financing and continuity of the above-mentioned Call of the MoH SR and asked for the

preparation of summary of arguments to be prepared by the IoR&D/ SB, MoH SR for discussion with the Ministry of Finance of the Slovak Republic.

The Chair of the Scientific Board opened the issue of interim project outputs evaluation (calls from 2018 and 2019). The absence of the appointment of the SB, MoH SR from April 1st 2020 to November 30th 2021 caused the situation that the funded projects (specifically, the 2nd and the 3rd year of the Call 2018; and the 1st - the 3rd year of the Calls 2019) were not continuously evaluated by the SB, MoH SR in 2020 and 2021. Prof. Valkovič invited the members of the SB, MoH SR to cooperate, i.e. readiness to participate in the projects evaluation of the above-mentioned calls. However, in the context of the long-term inoperability of the entire process, this evaluation will be formal.

The IoR&D will provide members of the SB, MoH SR with the above-mentioned presentations (in English).

#### **Add 7 – Conclusion**

After discussing all points of the Agenda, the Chair of the SB, MoH SR thanked all for their participation.

Minited by	<b>Mgr. Iveta Hermanovská, v. r.</b>	
	Scientific Board Secretary, Institute of Research and Development, MoH SR	
Approved by	<b>RNDr. Ivica Kvietiková, PhD., MAS ETH IP, v. r.</b>	
	Head, Institute of Research and Development, MoH, SR	
Endorsed by	<b>prof. MUDr. Peter Valkovič, PhD.</b>	
	Chair, Scientific Board, MoH SR	