

TOWARDS A QUALITY STRATEGY FOR MULTICENTER BIOBANKS

J. Uldry¹, S. Bavamian¹, J. Virzi¹, S. Nacia¹, L. Chapatte¹, C. Currat¹
¹ Swiss Biobanking Platform, Lausanne



INTRODUCTION

Lack of biobanking practices harmonization is a key challenge that face multicenter studies. This problem can directly affect the sample quality and thus the research conducted with the biological resources collected across the centers. Swiss Biobanking Platform (SBP), the Swiss coordination platform for biobanks and the national node of BBMRI-ERIC, develops a quality strategy applicable to multicenter biobanks to foster the harmonization of practices.

METHOD

SBP quality strategy includes optimized controls of the biobanking processes with the development and implementation of a centralized Biobank Information Management System (BIMS), a document management system (DMS), routine control measures, and the compliance to SBP review programs. This strategy is applied to the Swiss Health Study (SHeS) pilot phase, as a proof of concept study.

CONCLUSION

To foster the harmonization of the biobanking practices, SBP developed an evidence-based strategy, with common core documents and central records of operational aspects that are followed in a BIMS. Additionally, on-site compliance reviews are performed to ensure compliance with good practices and ethical/legal requirements. Concomitantly, the quality program will soon include the monitoring of Quality Indicators inferred from the literature^{1, 2, 3, 4}, which is essential to test the validity of the approach, and to propose corrective actions when needed. This global strategy is meant to help forecasting issues related to governance, IT and Quality aspects of biobanks embedded within SBP network. In the end, SBP strategy should serve as a blueprint to increase the overall research quality.

RESULTS

EVIDENCE-BASED APPROACH FOR SAMPLE MANAGEMENT — (FIG.1)

Quality objectives shall be defined from the study protocol as a pillar to develop two core documents: the biobank regulation and the quality manual. SBP SOPs templates are proposed to the biobanks. To develop operational aspect of sample collection, transport and handling and resource management SBP proposes SOP templates to support biobanks in their daily activities. In parallel, to ensure an evidence-based approach, a BIMS based on SBP datasets is proposed, which includes the preanalytical factors impacting sample quality. Finally, SBP provides biobank compliance review to support harmonization of their practices and increase the overall quality of samples.

QUALITY MONITORING WITH BIOBANK SQAN TOOL — (FIG. 2)

SBP uses its compliance review program through its online tool, the Biobank SQAN, to monitor the biobanking practices. This web-based solution includes the essential components that biobanks need to integrate to be compliant with the ethical/legal framework (VITA label) and professional standards (NORMA and OPTIMA labels). This program starts with the biobank registration on the SQAN database, followed by an on-site compliance review by SBP to evaluate the standardization of the processes. To consolidate the strategy, Quality Indicators will be monitored to increase sample quality over-sites.

FIG. 1 AND 2: APPLICATION TO THE SWISS HEALTH STUDY (SHeS) PILOT PHASE, THE NATIONAL STUDY ALIGNED WITH THE HUMAN BIOMONITORING PROJECT.

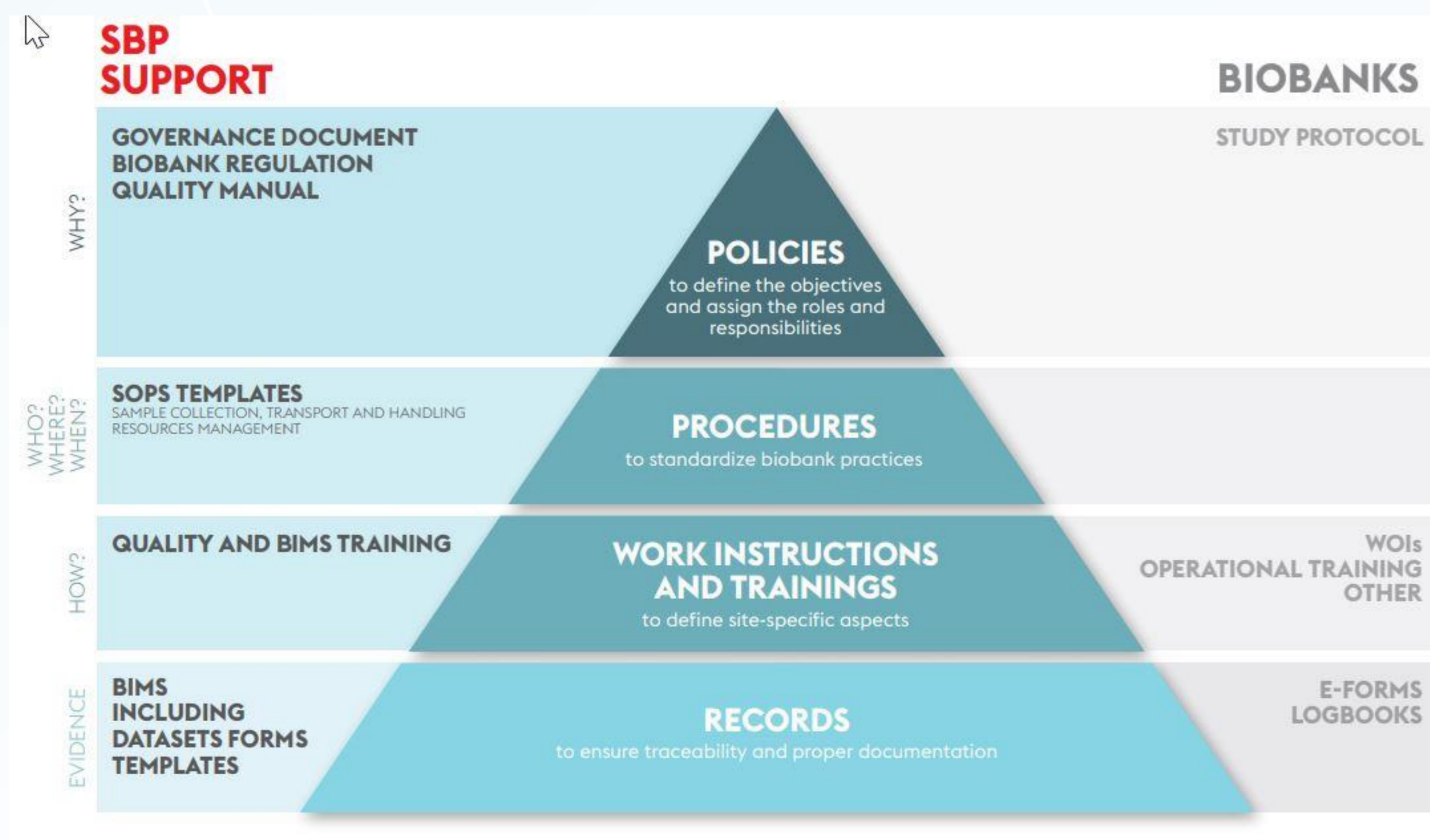


Fig.1 / Quality Management System (QMS) setup to support harmonization of biobanks activities.

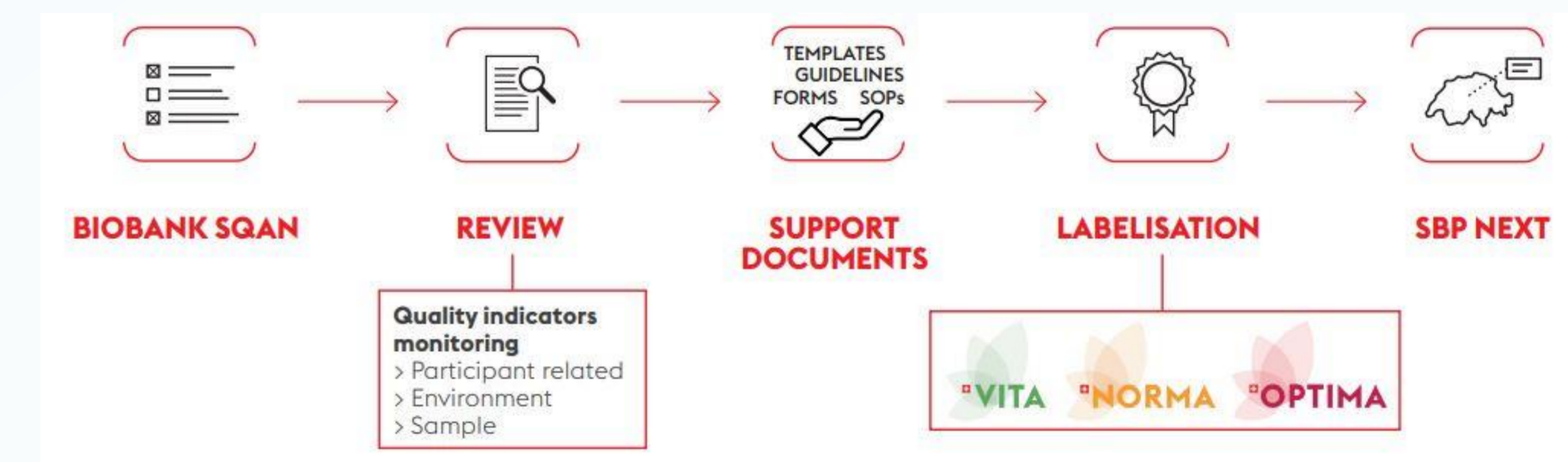


Fig.2 / Monitoring of biobanks practices through SBP Biobank SQAN.

REFERENCES

- [1] Esteve-Socias, M., Artiga, M., Bahamonde, O. et al. In search of an evidence-based strategy for quality assessment of human tissue samples: report of the Tissue Biospecimen Research Working Group of the Spanish Biobank Network. J Transl Med 17, 370 (2019).
- [2] Charlotte Gils, Mads Nybo, Quality Control of Preanalytical Handling of Blood Samples for Future Research: A National Survey, The Journal of Applied Laboratory Medicine, Volume 5, Issue 1, January 2020, Pages 83-90.
- [3] Lippi, G., Betsou, F., Cadamuro, J., Comes, M., Fleischhacker, M., Fruekilde, P., Neumaier, M., Nybo, M., Padoan, A., Plebani, M., Sciacovelli, L., Vermeersch, P., von Meyer, A., Simundic, A., & on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). (2019). Preanalytical challenges – time for solutions, Clinical Chemistry and Laboratory Medicine (CCLM), 57(7), 974-981.
- [4] Sciacovelli, L., Panteghini, M., Lippi, G., Sumarac, Z., Cadamuro, J., Galoro, C., Pino Castro, I., Scolnik, W., & Plebani, M. (2017). Defining a roadmap for harmonizing quality indicators in Laboratory Medicine: a consensus statement on behalf of the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases", Clinical Chemistry and Laboratory Medicine (CCLM), 55(10), 1478-1488.

ACKNOWLEDGEMENTS



CONTACT INFORMATION

Swiss Biobanking Platform (SBP)
 Av. d'Echallens 9, 1004 Lausanne
 Switzerland
 +41 21 314 52 84
info@swissbiobanking.ch
www.swissbiobanking.ch

