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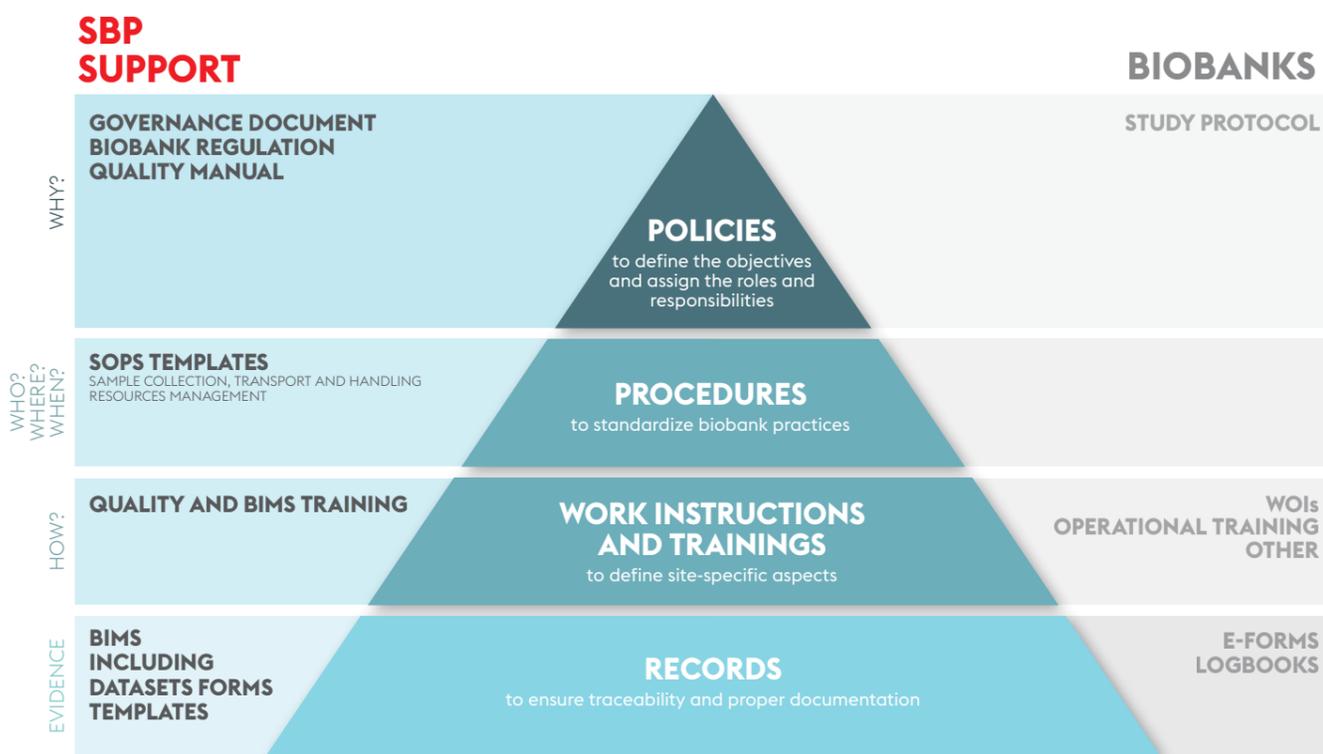
# SWISS HEALTH STUDY PILOT PROJECT: TOWARD A MULTICENTER QUALITY STRATEGY FOR BIOBANKING

## 1 / CHALLENGE

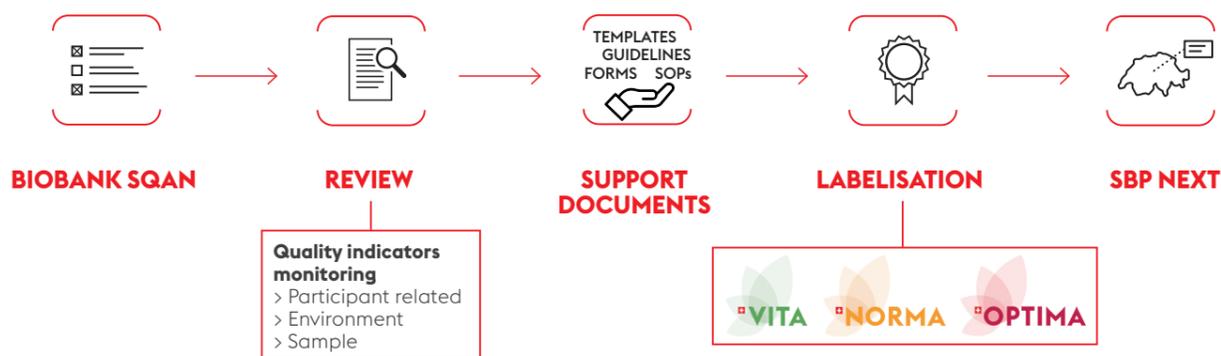
Lack of biobanking practices harmonization is a key challenge that face multicenter studies, such as the Swiss Health Study (SHeS) project. This problem can directly affect the sample quality and thus the research conducted with the biological resources collected across the centers. Swiss Biobanking Platform (SBP), the national coordination platform for biobanks and node of the Biobanking and

BioMolecular resources Research Infrastructure- European Research Infrastructure Consortium (BBMRI-ERIC), was appointed to support the recruitment centers for the harmonization and coordination of the study. SBP proposes a quality strategy based on documented information at every step of the biobanking processes.

**Fig. 1 / Quality Management System (QMS) setup to support harmonization across study centers**



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



## 3 / CONCLUSION

To foster the harmonization of the biobanking practices between different sites, SBP developed an evidence-based strategy, with common core documents and central records of operational aspects in a custom BIMS. Additionally, on-site compliance reviews are performed to ensure compliance with good practices and ethical/legal requirements. To date, SBP performed the VITA compliance check for the lead biobank (Vaud), while the NORMA compliance review is in the pipeline for Fall 2020. Bern biobank is currently

implementing the proposed strategy. Concomitantly, the quality program will soon include the monitoring of Quality Indicators, 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 the pilot project. In the end, SBP strategy should serve as a blueprint for a future, larger scale nationwide population-based cohort.

## 2/ SBP STRATEGY TO SUPPORT HARMONIZATION OF BIOBANK PRACTICES

### 2.1 / Evidence-based approach (Fig. 1)

Quality objectives were inferred from the study protocol as a pillar to design two core documents: the biobank regulation and the quality manual. SBP SOPs templates were proposed to biobanks to develop operational aspect of sample collection, transport and handling, and resource management. In parallel, to ensure an evidence-based approach, a BIMS based on SBP datasets was designed, which includes the preanalytical factors impacting sample quality. Finally, SBP provided personnel training on BIMS and quality to support harmonization of practices across the study centers.

### 2.2 / 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 across the different sites involved. 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.