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BIOBANKING FOR GLOBAL CHALLENGES

Implementation of the new ISO norm in a regional biobank – First experiences

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Introduction

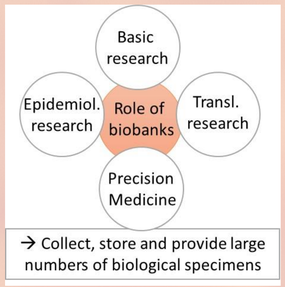

Figure 1: Role of biobanks

To obtain **comparable levels of high-quality biospecimen** and associated data, the **ISO 20387:2018** norm "Biotechnology — Biobanking" was created. It provides a set of requirements to match biobanking activities in all biobanks so that biobanking entities can operate competently in all areas (Fig. 1), and that they are able to provide biological resources of appropriate quality.

Goal of the **Central Biobank Regensburg (ZBR)** is the **accreditation** according to the new norm to make biobanking in Regensburg valid and reliable: Therefore, the ZBR adapted and changed procedures to implement the requirements into the workflow.

Method

Categories were created, existing Standard Operation Procedures (SOPs) were revised on basis of ISO 20387:2018 and categorized. Additional guidelines (OECD Guidelines or ISBER Best Practices) were taken into consideration and GBN quality management (QM) documents were used supportively [2-4] (Fig. 2).

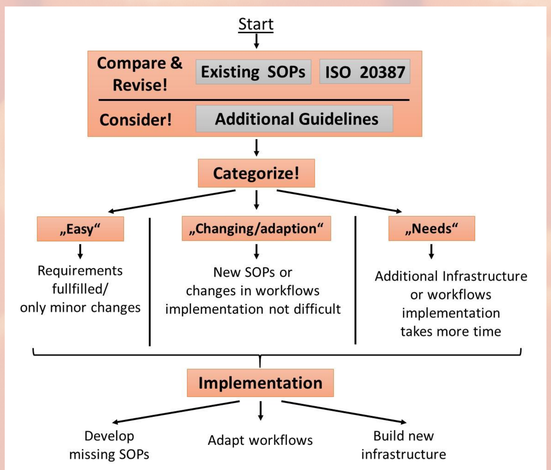

Figure 2: Workflow of SOP categorization and ISO implementation

Results

→ **Categorization** of the existing SOPs revealed important issues, that should be implemented into our local QM system (Fig. 3).

→ With this, the **implementation** of the requirements according to the ISO 20387:2018 is possible during ongoing biobanking operations

→ Use of categories saves time as **long lasting procedures can be recognized and started** at the earliest possible time point – e.g. new IT infrastructure with new equipment

→ In addition, **procedures involving cooperating hospitals and partners can be determined,** and an appropriate time plan for the changes can be made with the cooperation/partner

→ The implementation of SOPs in the **category "Easy" can be performed in practical timeslots** throughout ongoing biobanking operations

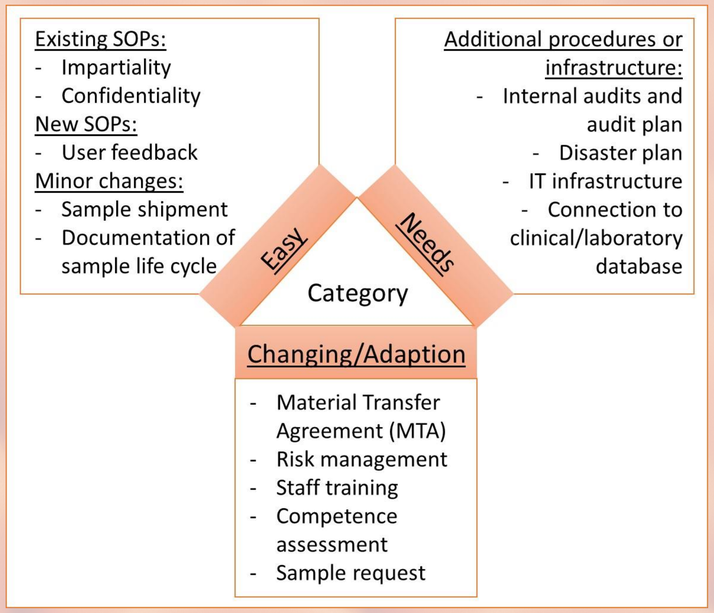

Figure 3: Categorization of existing SOPs and the requirements of the ISO 20387 in the categories "Easy", "Changing/Adaption" and "Needs" with respective examples.

Conclusion

- Precise identification of all processes and the examination of all SOPs is crucial for adapting all workflows and documents with smallest effort.
- Some modifications need to be implemented in accordance with cooperating hospitals and partners.
- Identification and documentation of all pre-analytical variables that effect the integrity of samples are crucial for making biobanking valid and reliable.

In summary, implementation of the ISO 20387:2018 is possible during ongoing biobanking operations, but for some modifications it might take time to put all innovations into practice.

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4. ISO 20387:2018-08

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