BIMS GUIDELINES

SBP RECOMMENDATIONS

WHO ARE THESE GUIDELINES FOR ?

This guidance document is intended for Swiss Biobanking Platform (SBP) partners who wish to acquire a Biobank Information Management System (BIMS) to manage their biological resources. SBP will not favor any commercial solution, but will support biobanks in their software choice by ensuring that the implementing software meets their needs and facilitate their long-term operational management.

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1) BIMS BACKGROUND

A) BIMS DEFINITION

As per SBP, a BIMS is an IT solution managing the main biobank operational processes. Note that a Laboratory Information Management System (LIMS) can also address the biobanks' requirements and can thus be used for the same purpose. Its main feature shall ensure the complete sample/associated data life cycle traceability and possibly manage other processes. The BIMS can thus be considered as a real Enterprise Resource Planning (ERP) for the management of the daily biobanking activities. However, it is important to stress that a BIMS only reflects the organization and quality of a biobank and cannot replace the rigor and commitment of the personnel while applying the professional standards in their daily practice.

B) BIMS IMPLEMENTATION

Successful implementation requires the allocation of sufficient resources and the involvement of the key stakeholders including commercial solution providers, information systems support services, and end users. Each party must be involved from the beginning of the project in order to clearly understand the expectations and needs of others. The implementation of a BIMS is a transversal project which will require a strong coordination and the establishment of detailed specifications which clearly identify the needs of the key stakeholders. To this end, a comprehensive review of all biobank activities as well as an in-depth analysis of the project shall be performed.

This analysis shall at least cover:

1. SCOPE DEFINITION

For which needs is this tool designed?

- Ensure the traceability of samples and their associated data
- Ensure the quality of samples
- Host sensitive data (e.g. personal data and/or clinical data)
- Host preanalytical data
- Integrate research data
- Integrate information from other systems (e.g. patient records, laboratory systems, equipment)

SBP RECOMMENDATION

Determine the BIMS features including its functions, the type of data that will be stored and the possible interface with the information system. These features are key factors when choosing the infrastructure that will host the BIMS.

Who are the responsible persons of this project?

The overall progress of the project requires the availability of persons whose responsibilities are clearly established and recognized by the key stakeholders.

Below are listed the more common responsible actors' assignments:

- A project manager coordinates and monitors the entire project with the various actors as well as being responsible of reporting. He/She ensures that resources are used optimally and is responsible of reporting
- An operational manager ensures that the BIMS corresponds to his/her needs. He/She participates in the definition and drafting of the specifications, which can be supported by a business analyst
- A coordination manager is the link between the project manager and the other involved departments (e.g. institutional project)

  Note that the same person can handle several roles.

SBP RECOMMENDATION

Identifying and integrating the principal actors (including users) as well as developing custom project specifications are the fundamentals for fitness for purpose and good decision-making of the envisioned solution. The consultation of specifications from similar projects should help to define the strategy but not influence decisions. The specifications must ultimately be reviewed and validated by key stakeholders.

SBP RECOMMENDATION

Project management must include performance indicators to monitor the progress of the BIMS implementation.

By which users will this tool be used?

- An investigator managing biological resources for his/her research projects
- A dedicated department/service/unit (e.g. the Institute of Pathology)
- IT services of the Institution
- An organizational structure ensuring the management of multiple biobanks within the Institution. This structure can serve different investigators, departments or services
- A type of users (e.g. laboratory technicians)

Which access rights should be allowed?
Depending on the roles, different levels of access will be assigned based on the Create, Read, Update, Delete (CRUD) principles.

Examples of roles for a biobank infrastructure:
- Administrator: Can add new users. Can create, read, modify, delete data stored and generated by all users
- Biobank Manager: Can create, read, and modify data from all users
- Biobank Technician: Can create and modify his/her own data. Can read data from other users
- Investigator: Can read data intended for him/her

SBP RECOMMENDATION
Define the scope of the BIMS to clearly assign the roles and responsibilities, as well as the access rights to the system.

Who are the stakeholders involved in the BIMS selection?
At the institutional level, many actors can be involved for the BIMS selection:
- Software provider must be involved in the discussion with the other stakeholders since having the best knowledge about the product
- IT services sets up the infrastructure hosting the BIMS solution, performs maintenance and ensures IT security
- Legal department validates contracts with suppliers, ensures that the BIMS solution and data are hosted in compliance with the applicable legal framework
- Purchase department manages the purchase of the BIMS solution including price negotiation and funds transfer
- Technical service may take part of the process if the BIMS solution integrates monitoring modules as temperature tracking for freezers

SBP RECOMMENDATION
Due to the complexity of its implementation and the sensitivity of the data it may host, a BIMS must be installed and hosted by trusted professionals. SBP recommends to establish a close collaboration with them and follow their recommendations.

SBP RECOMMENDATION
To clarify the roles and responsibilities of each party, SBP recommends the development of Service Level Agreement(s), even within the same institution.

2. DEDICATED RESOURCES

The implementation and integration of a BIMS within an Institutional framework requires dedicated resources:

a) Financial resources
- Purchase of the product
- Cost of the initial licenses and additional cost for annual renewal
- Product configuration to meet specific requirements
- Training of users
- Additional costs for further developments (e.g. updates)
- Infrastructure hosting the solution (e.g. physical server, virtual machine)

SBP RECOMMENDATION
The initial license is at relatively low cost compared to the long-term investment. SBP recommends to plan realistic annual budgets to ensure BIMS sustainability.

b) Human Resources
In addition to the above-mentioned managers, the implementation and use of a BIMS requires additional human resources.
- System Administrator designs and operates the infrastructure hosting the solution (e.g. maintenance and security of the networks, databases, servers)
- Application expert is responsible for the daily usage (e.g. creation of new users, roles assignment, data extraction) and the long-term improvement of the tool (i.e. development of new features)

SBP RECOMMENDATION
The specifications are the central element guaranteeing a good cohesion between the different actors. Strong support and commitment from the top management is essential to ensure the legitimacy and success of the project.

3. EXPECTED QUALITY LEVEL

It is important to determine the quality level to be achieved by the biobank. The BIMS shall comply with the quality requirements. The main standards that could affect a BIMS are: ISO 20387, ISO 27001, NFS 96-900, HIPAA Act.

SBP RECOMMENDATION
The BIMS compliance with the main quality standards should be part of the strategy from the beginning of the project.

4. INFRASTRUCTURE

The BIMS is hosted either on a physical server or a virtual machine. The main solutions currently available are:

1) web-based solutions, accessible from a web browser for user friendliness, and without the need to install a software per machine. Despite being accessible from a web browser, the accessibility of the solution may be limited to exclusive intranet access within your Institution. A majority of solutions offers the integration of Lightweight Directory Access Protocol (LDAP) which allows to automatically identify yourself by your institutional identifiers once logged in.
In the case of a local hosting supported by IT services, it is important to ensure that the room is secure and the data regularly back up to another location. Depending on the type and quantity of data to be hosted, IT services are informed and should be able to respond to the increasing capacity needs.

2) cloud-based solutions whose deployment and maintenance are under the provider's responsibility. These solutions must not contain sensitive data whose security relies entirely on the provider.

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A local hosting infrastructure supported by your organization's IT services is preferred over a cloud-based solution. If the latter solution is however chosen, SBP recommends to find out where the data are stored, and avoid storage abroad which may be governed by other applicable laws (e.g. Cloud Act in the United States). The possible supplier's bankruptcy should also be taken into account in the long-term sustainability of the BIMS.

5. INTEROPERABILITY

This feature enables a system to work with others and is key for the harmonization of practices and the promotion of biological resources sharing.

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SBP recommends using Ontology systems (ICD-10 / ICD-11 / SNOMED CT / LOINC) or fit for purpose datasets (e.g. SBP Datasets) to facilitate interoperability. If you aim to develop your own data structure to describe your biobank, SBP recommends the use of the MIABIS or FHIR data model.

Refer to SBP datasets available in our website for human and veterinary samples (i.e. liquid, tissue) and for bacterial samples
https://swissbiobanking.ch/tissue-and-liquid-data-sets/
https://swissbiobanking.ch/dataset-veterinary/
https://swissbiobanking.ch/dataset-bacteria/

II)
DATA SECURITY

Data security refers to the protective measures applied to prevent unauthorized access and data corruption. Protecting data from compromise and ensuring data privacy are key components of data protection. While privacy is protected by the duty of confidentiality of those involved in the management of health databases and biobanks, security strategies ensure proper data handling.

The following points address the technical and organizational measures to be applied for secured BIMS. The responsibilities for the implementation of these measures are shared between the defined stakeholders.

A) TRAINING

The training shall ensure the proper use of the BIMS solution. Users' awareness should be raised for the management of data over the whole lifecycle.

SBP RECOMMENDATION
Users must be trained for all aspects of data processing including the legal aspects on data protection (e.g. Data Protection Law, General Data Protection Regulation).

B) CONFIDENTIALITY

In compliance with the applicable legislation, confidential data are securely collected, stored and processed with a higher security level.

SBP RECOMMENDATION
If personal data are planned to be hosted in the BIMS, SBP recommends to store them in a coded form. The key must be kept in a different IT system by a person who is independent of the research project.

SBP RECOMMENDATION
SBP recommends to record the list of authorized persons having access to the BIMS.

SBP RECOMMENDATION
A confidentiality agreement has to be signed 1) by anyone having access to the system, and even if an IT charter is already in place within the Institution; 2) with the supplier if a commercial solution has been purchased.

C) INTEGRITY

The information system shall be protected from data loss and data corruption to prevent unintentional changes of information. Data integrity is closely related to the data security aspects previously described.

1. USERS AUTHENTIFICATION

Each user has a unique login. The password associated with the login complies with specific rules (including character length, special characters, upper and lower case, no personal data, regular redefinition).

2. DEFINITION OF ROLES AND ACCESS MANAGEMENT

Roles and responsibilities have to be defined. Depending on the roles, different levels of access will be assigned based on the CRUD principles.

3. AUDIT-TRAIL

The audit-trail function ensures the full traceability of access and modifications to the database over time. In particular, this function allows to record:

- Log system connections and disconnections by date/time/user/IP address
- Data reading, creation, modification, and deletion by date/time/user/IP address

4. SECURED WORKSTATION

The security strategy must include:

- an automatic log out after a period of inactivity
- a system lock if the user attempts to access it too many times

5. EXTERNAL ACCESS TO THE SYSTEM

If necessary, a VPN access to the internal network with a strong two-factor authentication has to be allowed.

6. BACKUPS

Backups are essential to ensure BIMS sustainability. These backups should be:

- scheduled automatically at fixed intervals
- stored in another location, whose access shall be secured
- tested and validated regularly

SBP RECOMMENDATION
It is essential for a biobank to design a data security strategy to maintain the BIMS activity even in the event of a disaster. Defined responsible persons must be able to know where the data are stored and what to do in case a damage occurs in the system.

III)
DATA QUALITY

Data quality refers to the condition of a set of qualitative and quantitative variables whose values shall serve data fitness to its purpose in a given context. For biobanks, data are considered of high quality when they fit for their intended use (e.g. research, diagnostic).

A biobank's IT system must meet the following criteria to guaranty the quality of its data:

A)
ACCURACY

Data entered into the system must be correct.

- Standardized processes as well as training of personnel are key to minimize error for data entry.

B)
RELIABILITY

To be confident on reliability of data stored, they must be collected consistently (i.e. coherent whoever collects them).

- Datasets are key to promote standardization of data collection and should be used to increase the quality of documentation.

C)
PRECISION

The information system must provide sufficient detail information to characterize the data.

- A data has to be linked to metadata, datatype and units (e.g. "20"; "Age"; "Integer"; "Years")

D)
COMPLETENESS

Data must be complete. An incomplete field could lead to a biased interpretation (e.g. Omission or filled later?).

- Be clear when using N/A. It can be interpreted as Not Applicable or Not Available.

IV)
CONCLUSION

The implementation of a BIMS requires an efficient project management to set up the predefined BIMS specifications. The commitment of the actors, the adequacy of resources, the training of users and the monitoring of the project are key elements to ensure its success. Each project is unique due to its specificities and SBP remains at your disposal to advise you in your BIMS choice and its implementation.

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