SBP RECOMMENDATION

WHICH IT-SOLUTION TO MANAGE BIOLOGICAL RESOURCES ?

April 17, 2020

1. TOPIC

Our recommendation addresses the question why biobanks should invest in a specific dedicated IT system and propose a comparison between Biobank Information Management System (BIMS) and broad solutions, such as Excel, to manage their biological samples.

2. OUR RECOMMENDATION

To comply with the legal requirements and foster quality, the IT system in which the data are processed must meet the necessary quality standards and security criteria. In this regard, Swiss Biobanking Platform (SBP) supports the implementation of a BIMS as the appropriate data management systems for biobanks. Therefore, the BIMS is part of the minimal requirements assessed by SBP when the biobanks go through the compliance review process for the NORMA label.

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3. LEGAL ANALYSIS

Traceability is essential, in particular to guarantee the right to information of the individual.
To follow best practices and comply with the applicable ethical and legal requirements, a robust IT system is necessary to ensure security and traceability.

WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (Declaration of Taipei) [1]
"Article 21. Governance arrangements must include the following elements:
(…)
- *Arrangement for how the data and material will be **documented and traceable** in accordance with the consent of the concerned persons;*
(…)
- ***The security measures** to prevent unauthorized access or inappropriate sharing;*
(…)"

Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordonnance) [2]
"Article 5. Storage of health-related personal data and biological material
- *Any person who stores health-related personal data for research must take **appropriate operational and organizational measures** to protect it […]"*

Federal Act on Data Protection (FADP) [3]
"Article. 8 Right to information
1 *Any person may request information from the controller of a data file as to whether data concerning them is being processed.*
2 *The controller of a data file must notify the data subject:*
   a. *of all available data concerning the subject in the data file, including the available information on the source of the data;*
   (…)"

IARC Technical Publication No. 44 [4]
IT systems must ensure complete traceability of samples and data:
- *Data security systems should be adequate to ensure confidentiality and safety.*
- *Access to IT systems must be managed so that they can be accessed only by authorized personnel*

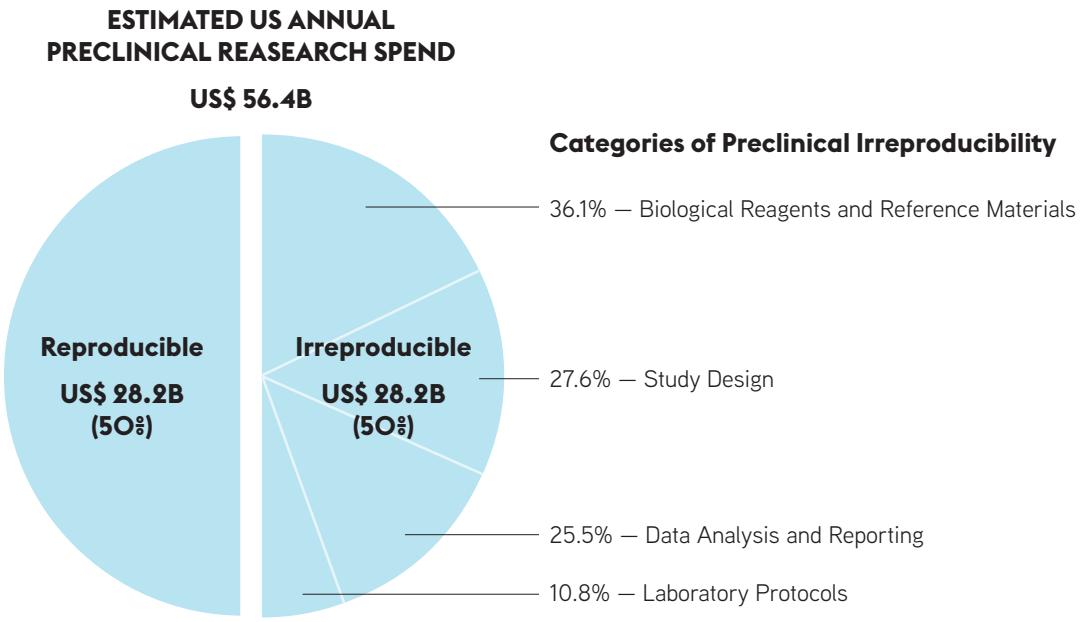
4. TECHNICAL ANALYSIS

Data management is an integral part of biobank's management tasks, and is a critical activity for which daily work can be significant. Whether it involves managing the traceability of samples, ensuring compliance with legal and ethical aspects, or collecting data, a Biobank Information Management System (BIMS) is at the core of the biobank operational management and is one of the main pillar in the promotion of high-quality samples and data.

To date, biobanks currently use IT tools from different sources for the management of their data, resulting in a great variability, both from an institutional standpoint and on an individual scale.

In the absence of tools promoted by the Institutions, biobanks are often limited to non-specific solutions at a lower cost. In the current practice, the main solution chosen is a spreadsheet type, such as Excel. These solutions are unfortunately not fit for biobanking purpose and present many limitations, including a risk of bias.
Through this report, Swiss Biobanking Platform explains why biobanks should not use broad solutions, such as Excel, and why IT systems dedicated to biobanking are key for a suitable management.

In a 2015 meta-analysis, Freedman et al. [5] estimated that 50% of pre-clinical studies were not reproducible. Interestingly, within this 50%, 25% is due to improper data analysis and reporting, including data management.



WHAT IS THE ADDED VALUE OF USING A BIOBANK MANAGEMENT SOFTWARE (BIMS) OVER EXCEL?

IT systems for biobanks have to offer a wide range of functionalities. The following table lists the most important ones and provides a comparison between Excel and a BIMS.

	Excel	BIMS
Audit-Trail	No	Yes
User account	No	Yes
Simultaneous inputs	No	Yes
Granularity of access	No	Yes
Security	Depends where the file is stored	Yes
Data validation	Poor	Yes
Data integrity	No	Yes
Backup	Should be planned	Planned
Data leakage	High risk	Low risk
Ergonomic	Less	High
Complex requests	Requires a lot of handling	Facilitated

Table 1 : Overview of main differences between Excel and a BIMS solution

DETAILS OF THE TABLE

Audit-Trail: The audit trail provides a logbook of all the actions that took place in the information system (Who?, When?, What?, Where?). This function ensures security to a database, in addition to guaranteeing the full traceability of the data.

User account: User accounts, directly linked to the audit trail, allow identifying and controlling users access to the system.

Simultaneous inputs: A BIMS allows data entries by several people simultaneously, thus avoids locking documents when being edited by other users ("read-only" files).

Granularity of access: The definition of specific roles allows a high level of granularity to control access to the data.

Security: Security depends on the database storage location. For an Excel file or an Access database, it is extremely easy to copy the file or to send it to an unsecured device, whereas a BIMS will make this kind of operation impossible.

Data validation: Storing reliable data is only possible using validations to ensure that data are reasonably complete and accurate, meet the intended purposes, and are not subject to inappropriate alteration [6]. Following are few examples of basic validations:
- Make an attribute required
- Define data format, for instance: date, number or text.
- Lower and upper limits for dates and numbers

Although spreadsheets can offer some validations, end-users can easily divert them and input false data. On the other hand, BIMS validations have the required out of the box robustness.

Data integrity: Each element entered in a BIMS is uniquely identified, voluntarily or not. Additionally; it creates links and constrains between related elements and thus participating in the referential integrity to ensure that the data "makes sense". Using both, data validation and referential integrity, a BIMS guarantees the database coherence, which is not possible with a spreadsheet file.

Backup: The backup of a BIMS is usually part of the services provided, whereas with a file, you have to plan it and track the versioning of your file to ensure appropriate use.

Ergonomic: The BIMS ergonomic is designed to facilitate and support data management, as opposed to a two-dimensional file.

Complex requests: The friendly usage of the data is facilitated by the management of complex queries. Such requests or queries cannot be handled as easily in Excel files.

In addition to these key features, a BIMS offers the ability to cover an entire biobanking workflow through simple and intuitive forms. Depending on the processes covered, it is even possible to automate specific actions in order to limit the risk of error. Along the same line, and to increase the data entry reliability, it is also possible to define logical rules, for example the rule according to which the sum of the aliquots of a primary tube cannot be greater than the volume of derived aliquots.
All these functions are important in increasing the quality of data associated to samples by ensuring well annotated and documented biological material.

5. REFERENCES

[1] WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53 WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67 WMA General Assembly, Taipei, Taiwan, October 2016

[2] Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) of 20 September 2013, CC 810.301

[3] Federal Act on Data Protection (FADP) of 19 June 1992, CC 235.1

[4] International Agency for Research on Cancer. Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research. IARC Technical Publication No. 44

[5] Freedman LP, Cockburn IM, Simcoe TS, 2015. The Economics of Reproducibility in Preclinical Research. PLoS Biol. 2015 Jun 9;13(6):e1002165.

[6] https://itlaw.wikia.org/wiki/Data_reliability