WHITE PAPER

EFFECTIVELY STORING AND SHARING BIOLOGICAL DATA FOR CLINICAL RESEARCH

A biobanking LIMS can integrate, centralize, and safeguard specimen data

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INTRODUCTION

Though biobanking—the practice of managing biological specimens and data for current or future medical research—has been around for many decades, the field has changed significantly since the completion of the Human Genome Project in the early 2000s. Advanced analytical techniques, high-tech tools, and mountains of data have made their way into modern biobanking, with the rapid changes both inspiring and perplexing clinical researchers looking for answers.

Comprehensive information management is vital to biobanks seeking to improve how they manage and share biobank data. The International Society for Biological and Environmental Repositories (ISBER) has published a best practices guide for biopreservation and biobanking repositories for years. Among its recommendations is an effective system that tracks specimens throughout their entire life cycle, one that includes support for "unique specimen identifiers, appropriate specimen labels, electronic data inventory systems for specimen tracking, consent form and/or permit tracking," and other vital features.[1] In line with these guidelines, biological resource management facilities have increasingly turned to laboratory information management systems (LIMS) as their central biobanking data management software.

When paired with an effective quality management system (QMS), a robust yet flexible IT structure, and strong processes and procedures based on best practices and regulatory demands, a LIMS can prove to be one of the key elements to the success of a biobank. Not only can a LIMS manage biological specimens and associated data more efficiently, but it can, when prepared well, facilitate data sharing with clinical labs, accelerating research in the process. However, the rapid evolution of biobanking creates new challenges for the field, particularly as researchers increasingly tap into the potential benefits of having biospecimens and related data readily on hand.[2]

DATA SHARING, REGULATIONS, AND ETHICS DRIVING BIOBANK NEEDS

Biobank data sharing is exciting to many. Shared repositories provide researchers new avenues for accessing clinical specimens and data that are already collected and relevant to their research, saving them time and precious research funding.[2,3] With access to shared biomedical data, clinical researchers can also further drug discovery research and make new insights into diseases. Additionally, wider access substantially increases the potential to improve the four "Ps" of healthcare, making it more predictive, preventative, personalized, and participatory.[4]

Clinical researchers are increasingly turning to the likes of pathology laboratories, clinical research coordinators, and biobanks to expand their research efforts. From routine patient specimens sent to a lab for screening to study participant specimens collected for a clinical trial, researchers

see value in having access to specimen data relevant to their efforts. They can then make their own analyses and discoveries, such as how genetics drives risk for common diseases and how environmental exposure impacts health outcomes, in the process furthering development of personalized therapeutics.

However, the process of acquiring those specimens and data isn't straightforward; ethical guidelines and regulatory requirements determine how that data can be made available. Are biobank specimens being used in an inappropriate manner? Are specimens being under-utilized? Are the benefits of the research being returned to the donors? Is identifiable personal data being managed appropriately? Are all necessary informed consent documents available for review?[5] These questions and more are driven by standards and regulations. For example, the Health Insurance Portability and Accountability Act (HIPAA) Common and Privacy Rule demand that patient data be de-identified, and various federal bodies such as the Food and Drug Administration (FDA) address requirements for informed consent. Navigating this legal and ethical territory can be challenging, further compounded by the muddled and inconsistent nature of privacy protection rules governing U.S. biobanks and other laboratories wishing to share specimens and data.[5,6]

Other challenges also arise when attempting to put data sharing into practice, particularly for biobanks. Primary among them is striking a critical balance among the needs of researchers, donors, and funders. This turns into a complicated process of navigating workflow models, IT requirements, legal and ethical quandaries, and funding schemes. Woven into all those topics is how to efficiently, legally, and ethically collect, track, store, and share biological specimens and data throughout a biobank's workflow such that clinical researchers may more readily find the data and put it to beneficial use.

Are biobank specimens being used in an inappropriate manner? Are specimens being under-utilized? Are the benefits of the research being returned to the donors? Is identifiable personal data being managed appropriately? Are all necessary informed consent documents available for review?[5] These concerns and others drive policy, workflow, and information management at a biobank, requiring an adaptable information management system that not only meets workflow requirements but also helps biobanks meet the legal and ethical requirements of their field. Biospecimens will be managed, analysis requests will be made, custody transfers will be organized, data will be integrated and shared, and documentation will be well-controlled. Data entry, management, and transmission will occur at all of these stages, requiring logical and well-enforced data authentication, harmonization, and transfer policies, as well as a powerful information management system to handle it all.

LIMS FOR STORING AND SHARING BIOLOGICAL DATA

LIMS for biobanking are like other LIMS in many regards: they track specimen location, interface with analysis equipment, maintain history of modifications, and control access to data. But the special needs of the field require biobank software to have functionality beyond what you would find in a vanilla LIMS. One need not look further than the workflow of the typical biobanking facility to discover the additional functionality required.

Biobank specimens and data typically have clinical study context, requiring special data management considerations from biobanking software. Collections must follow specific, well-documented rules that define stakeholder roles, data formats, and ontologies. Study-related documents such as standard operating procedures (SOPs) and consent forms must be linked to specimen data, whether it is de-identified or original, and be version controlled. Support for master IDs, entity relationships, patient consent management, and storage management are also critical to the biobank. A well-designed biobanking LIMS takes all these needs and more into account.

Storing and sharing biobank data, with clinical researchers in mind, represents another major role of the biobank. Müller et al. emphasized this important point in 2017 while discussing the available software options for biobanks, noting "the biobanking community are required to work together in order to share knowledge and jointly build solutions to underpin the research infrastructure."[4] This mandate for storing and sharing can be more easily met with a robust biobanking LIMS. Biobanks benefit from a LIMS' ability to integrate, harmonize, centralize, catalog, and anonymize data objects while at the same time making metadata consistent and searchable, and maintaining access restrictions formed by consent and veto rights. An external portal may also be included with a LIMS, allowing clinical researchers role-based permission to better search for datasets relevant to their work.

As clinical researchers may also want direct access to stored specimens, a LIMS can aid in tracking specimens that are *en route* or being redistributed to authorized recipients, including the handling of transfer agreements and pick lists. Biobanks are also supported by a biobanking LIMS' ability to readily manage retention and destruction requirements, track personnel's qualifications, and record security logs.

BIOLOGICAL DATA MANAGEMENT IS NOT STRAIGHTFORWARD

A modern LIMS designed with the needs of biobanking in mind can help organize and support the complexities of storing and sharing biobank data while accelerating research for others. However, it's not as simple as picking any LIMS, installing it, and importing data. Several considerations and precautions must be taken

when choosing and using a LIMS for biobank data management.

First, setting up a biobank's information technology (IT) infrastructure is no simple task, one that can be complicated by lack of expertise within the organization. A 2014 survey conducted by Müller et *al*. revealed that eight of 10 French biobanks had little to no resources for developing biobanking IT projects, suggesting a significant need for outside consulting help.[4] Turning to an experienced consulting company may be critical to the success of a biobank that is otherwise understaffed or unfamiliar with data management and security aspects. For example, knowledge of the MIABIS biobank information standard — which is widely accepted in Europe and other parts of the world4 — as well as other standards and best practices is important to have, even before developing core business and data handling processes for quality management purposes. Ardini et *al*. emphasized this idea in their role as the biological data repository for the National Institute of Diabetes, Digestive and Kidney Diseases[7]:

"Use of data standards and common data elements during collection should allow for a more automated presentation of results. Such consistency must begin at the design stage and requires that the data repository be a partner right from the start to streamline processes and reduce the cost of post study data sharing."

Sharing data centralized within the LIMS comes with other difficulties as well. Does the biobank's approach to data formats and storage require additional repository staff to assist clinical researchers in determining whether or not the repository holds the required specimens and data, an aspect that is often looked for by less experienced researchers? These staffing and cost issues may be compounded further by handling omics data, which brings additional needs for storage and quality control.[7] Do the biospecimens and data that will be stored have missing documentation or linkage files? Problems may arise with accepting into the LIMS such biospecimen data that are lacking consent forms, subject ID, incomplete annotations, and missing linkage files that tie together study biospecimen IDs with de-identified subject IDs.[7]

Finally, how discoverable is the biobank's data? Pang et *al*. identified three significant needs in discovering (and making more discoverable) biobank data[3]:

1. Researchers need to find datasets that have relevant items to their research.
2. Researchers need to assess how well those datasets integrate for pooled analysis.
3. Biobanks need to identify other external biobank data collections similar in attributes to their own to better facilitate integration for larger research studies.

Meeting these needs will require a well-considered data management plan that includes careful LIMS

management, data curation, and specimen handling. Additionally, the methodical selection of a LIMS for biobanking will ideally assist with meeting the requirements of ethics committees, explaining how existing specimens will be used in the future, and exceeding the needs of donors who wish to make well-informed decisions about their personal data.[2]

CONCLUSION

Biobanking laboratories have additional responsibilities not commonly found in other labs. Their work is driven by a growing mandate to store biological specimens and data and make it available to clinical researchers seeking to improve healthcare and quality of life. Just as those researchers have regulatory guidelines and standards to follow in the use of biodata, so also do biobanks in the process of making biodata available to the researchers. Meeting necessary legal, ethical, workflow, and data management demands requires expertise, attention to detail, and well-designed data management software. That software must focus both on the traditional data management needs of a laboratory and the specific biospecimen management needs of a biobank. A dependable biobanking LIMS fills this role well. However, like any industry, simply throwing technology at a problem doesn't guarantee success. The challenges that come with storing and sharing biobank resources require additional considerations for how a LIMS is chosen and implemented. Technical and regulatory expertise, knowledge of industry standards, rigorous process and quality control, and an ability to balance the needs and expectations of the biobank with those of clinical researchers and donors are all required as part of ensuring the successful integration of a biobanking LIMS. However, when implemented well, the end result is biobanking software that provides long-term value to the biobank and researchers who depend on it.

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