

WHITEPAPER

BIOFORTIS

a Q²Solutions Company

NEXT GENERATION BIOBANKING

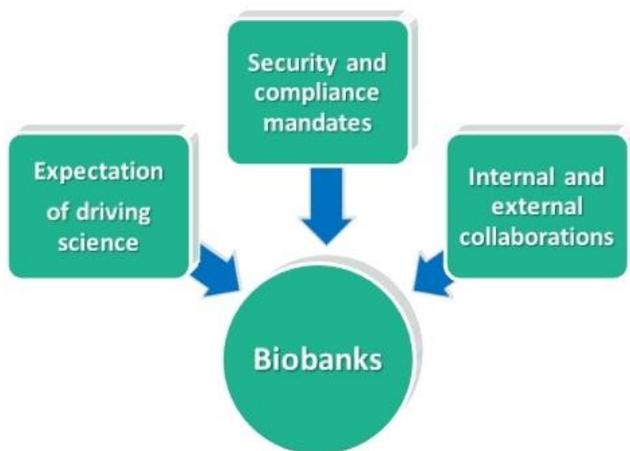
INTRODUCTION

Precision Medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle¹. Precision Medicine generates increased awareness of the value of biospecimen in biomarker-driven clinical research. In concert, research utilization of human samples requires strict compliance to study subject informed consent. While the practice of “broad consent” is becoming more widespread, regulatory agencies are placing higher standards onto biobanks and research teams to adopt robust IT systems so that information and biospecimen privacy safeguards are followed².

CHALLENGES

A biobank is a liability, not an asset – unless and until it can provide significant value for scientific research. Traditionally, organizations have invested in conventional biobanks: building out infrastructure in hardware (freezers, automation, etc.) and first-generation LIMS software that emphasizes in-house operational efficiency in sample collection, processing, and storage.

However, biobanks are no longer measured by how many samples they store, but by the actual utilization of these samples to drive investigational research. This shift poses the following critical challenges for traditional, “first-generation” biobanks:



Challenges Faced By Biobanks Today

Increased expectation for biobanks to drive science – Biobanks must expand from just focusing on operational and in-house sample inventory management activities (hoarding samples) to also driving scientific insights by enabling optimal utilization of samples. With the advent of “big data” from new assay technologies, as well as large quantities of electronic medical record based healthcare data, the accurate linkage of biospecimen data with patient

clinical and molecular data is now critical. While traditional LIMS is optimized to capture rigid, repeatable biospecimen processing workflows, they are not set up for users to explore and gain new insights by interconnecting scientific knowledge from new technologies and data sources.

Increased security and compliance mandates – The sensitive nature of clinical research requires privacy control and regulatory compliance. Greater scrutiny is placed upon stringent adherence to governing standards such as HIPAA, 21CFR Part 11, GxP, CAP, and CLIA. For example, the 2017 Common Rule revision encourages human sample use through broad consent, but mandates escalated stakeholder accountability via publishing publically-accessible patient enrollment consent forms. Biobanks must properly manage complex patient consent and sample details to allow timely response to regulatory inquiries on biospecimen chain-of-custody and research utilization. This puts pressure on biobanks to implement processes that enable patient informed consent reconciliation and sample lifecycle audit trail tracking. Conventional biobanking and LIMS software often lack such functionality.

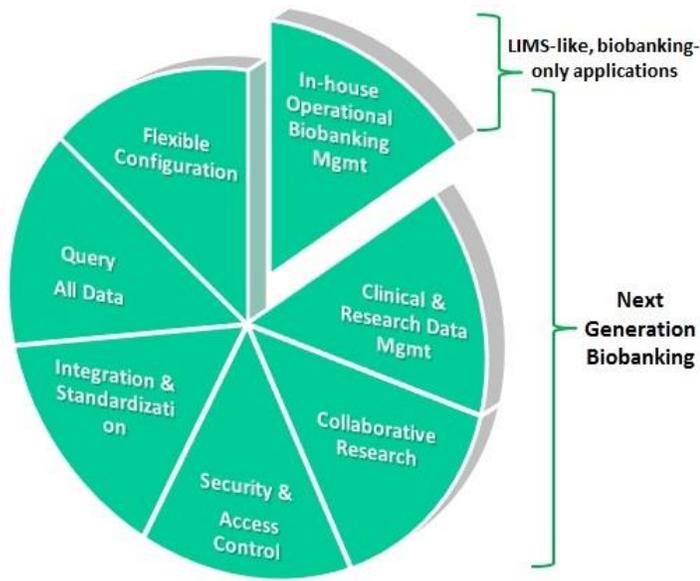
Increased trend for multi-investigator, multi-site collaboration – Many research programs are now performed within a distributed network of investigators, labs, biobanks, and other collaborators. As a result, getting control over data security, integration, and harmonization is critical. LIMS software may be sufficient within a local facility, but they lack scalability and support for the new research ecosystem of external collaborators and data sources. Therefore, research programs are hindered due to over-expenditure on system integration, data standardization, and IT management resources.

OUR SOLUTION

We have conceived the term “Next Generation Biobanking” to describe the attributes required to solve the critical challenges faced by precision medicine biobanks. Next Generation Biobanking not only supports biospecimen operational activities, but also functions as the knowledge hub for an integrated translational and clinical research ecosystem. With the Next Generation Biobanking approach, you will reap the benefits of a well-annotated patient and sample database that supports precision medicine, clinical trials, translational research, and patient registries. Here are the key attributes of Next Generation Biobanking:

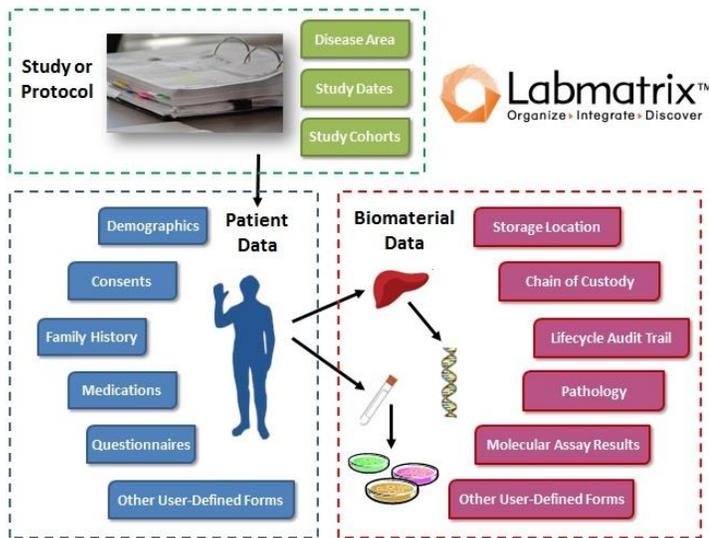
- Harmonization of biospecimens with clinical and molecular information to generate scientific insights
- Enhanced security and compliance
- Support for multi-site, multi-investigator collaborative studies

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Next Generation Biobanking vs. Traditional Biobanking

Our Next Generation Biobanking solution, Labmatrix™, is a web-based, clinical and translational research platform that captures critical concepts such as study, subjects, and biospecimens, which are tightly coupled to clinical, molecular, assay, diagnostics, and outcomes data. These concepts are complemented by powerful data import and export capabilities, flexible API and system integration & standardization options, comprehensive study planning, data access control, privacy and identity protection, lifecycle audit trails, patient consent management, biospecimen operational workflows, chain-of-custody tracking, storage management, and reporting.

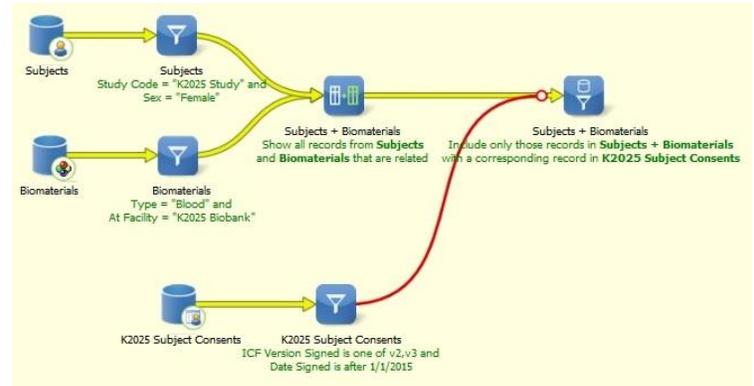


The Labmatrix Next Generation Biobanking Data Hub

Demonstrated below is how Labmatrix addresses key attributes in Next Generation Biobanking.

Harmonization of biospecimen with clinical and molecular information – In order for researchers to better gain scientific insights from banked samples, Next Generation Biobanking tightly links biospecimens with the multitude of molecular and clinical data to create a precision medicine information hub. Investigators across the research ecosystem can then have a holistic view of all the data collected during the course of a research program. It is also critical that this information hub be as flexible as possible, allowing users to harmonize and integrate data from disparate sources.

Labmatrix's data exploration tool allows all stakeholders in the research ecosystem to ask sophisticated questions without requiring any IT help or programming skills. Since scientists are able to run ad hoc inquiries on all available data, they are empowered to, for example, seek out suitable samples for a new study, delve into biomarker-based hypothesis, or stratify patients for clinical research based on their clinical and molecular profile. These self-documenting inquiries provide transparency in complex query logic, allowing users to easily share, update, and troubleshoot existing queries.

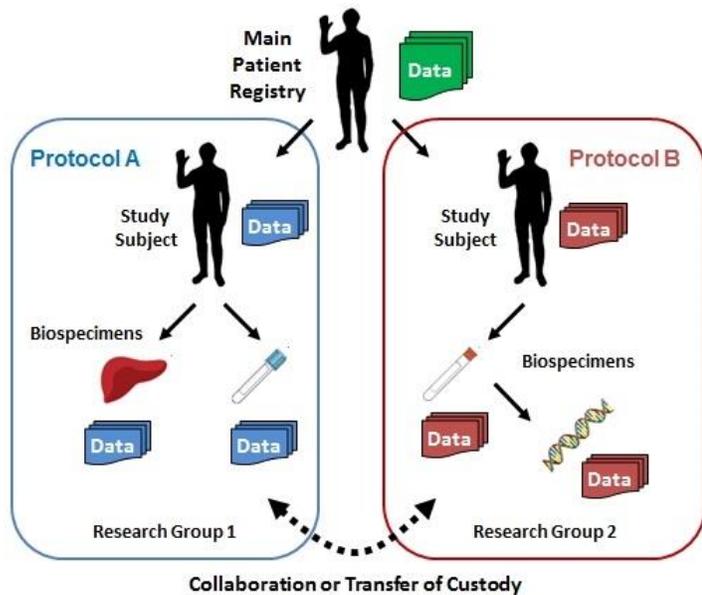


Graphical Data Exploration – Connecting Subjects, Consents, and Biospecimens with *ad hoc* Parameters

Support for collaborative research programs – Next Generation Biobanking provides the critical information infrastructure to effectively manage a distributed precision medicine research ecosystem and its network of stakeholders. Labmatrix not only supports sample-centric workflows of traditional biobanking software, but also extends its scope to accommodate full scale precision medicine studies, each with different collaborators, scientific goals, workflows, and data models that are easily setup and administered. Next Generation Biobanking requires a high degree of flexibility to meet the demands of a wide variety of study data and access control mandates. Organizations must effectively manage multiple local and

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virtual biobanks, where sample collections are processed, analyzed, or stored.



Share Common Resources (e.g. Patient Clinical Data), But Segregate Individual Group Research Data Via Access Control.

Enhanced security and compliance – The consequence of chain-of-custody problems or donor consent issues on clinical research samples can be disastrous for a research program. Labmatrix is designed with extremely fine-grained access and security controls that extend to all the data linked to a biospecimen, ensuring compliance with regulatory and local IRB guidelines. Comprehensive consent and biospecimen reconciliation processes ensure that both ongoing study and future-use samples can be managed effectively. The system is completely configurable in terms of study data access permissions via user-definable roles, allowing each research partner to have full control over which data elements to share and with whom.

Administration

Access Management | Steve Chen (schen) | Save | Actions

Users
Roles
Security Groups

Configuration
Studies
Forms
UI Configurations
Barcoding
Biomaterial Types
Container Types
Aliquot Templates
Facilities
Notifications

Study	View	Update	Create	Delete
102-15852 (MEL IST)	✓	✓	✗	✗
Atopic Dermatitis	✓	✗	✗	✗
BF-201	✓	✓	✓	✓
BioFortis Tissue	✓	✓	✓	✗
Breast Cancer - 001	✗	✗	✗	✗

Fine-Grained Data Access Control with Flexible User Roles and Permissions

Subject Consent | Save | Export...

Fields | Properties | Associated Studies

Add field... Remove field Import fields from file

Name	Datatype
<input type="checkbox"/> Consent Version	Text
<input type="checkbox"/> Consent Signature Date	Date
<input type="checkbox"/> Consent Location	List
<input type="checkbox"/> Consent Document Location	Text
<input type="checkbox"/> Patient Recruiter	List + Other
<input type="checkbox"/> Legally Authorized Representative	List
<input type="checkbox"/> Representative Identifier	Text
<input type="checkbox"/> Consent Status	List
<input type="checkbox"/> Consent Status Date	Date
<input type="checkbox"/> Detailed Consent Parameters	Child Form
<input type="checkbox"/> Post-Collection Consent	Yes/No
<input type="checkbox"/> Subject agrees to be contacted for...	Yes/No
<input type="checkbox"/> Consent Notes	Large Text

Consent Version: IRB#2235v-1.1
 Consent Signature Date: 11/18/1995
 Consent Location: BioFortis Hospital
 Consent Document Location: STE 410 Rm 355A
 Patient Recruiter: User1
 Legally Authorized Representative: Adult - Spouse
 Representative Identifier: Thomas Jefferson T2-01
 Consent Status: Enrolled
 Consent Status Date: 11/18/1995

Detailed Consent Parameters:

Applicable Biomaterial Type	Applicable Assay Type	Consent
<input type="checkbox"/> Buccal Swab	Genetic Testing	Yes
<input type="checkbox"/> Blood	Genetic Testing	Yes
<input type="checkbox"/> Urine	Studies Related to Disease	Yes

Add Detailed Consent Parameter...

Manage Patient ICF (via User Configurable Forms) to Ensure Biospecimen Regulatory Compliance

CASE STUDIES AND OUTCOMES

Government research institute – Since 2006, the National Cancer Institute has been utilizing Labmatrix as the precision medicine information management platform that serves all of its intramural research groups. Labmatrix supports the entire lifecycle of patient and biospecimen management, from clinical and research information management of the originating patient (study subject), to barcode label generation, to tracking of internal/external custody transfers for samples. Patient demographics are synchronized from the institutional electronic medical record (EMR) system; subsequently, additional study subject information is captured from a multitude of research activities and study-centric clinical observations that are not captured by the EMR (such as questionnaires, disease scoring, and clinical events). Prior to patient procedures, investigators attach pre-generated Labmatrix barcode labels to biospecimen containers, and provide them to phlebotomists and/or surgical staff for sample collection. With the acquisition of the biospecimens, this clinical event is associated with other downstream processing information such as pathology results, custody transfer, storage inventory, sample aliquots, downstream derivatives, slide images/annotations, and experimental or molecular assay results from the samples. Individual patient reports combine real-time clinical, molecular, and study protocol data in Labmatrix, which provides a precision medicine overview of the patient. This overview is presented to physicians in weekly grand rounds, and serves as reference material for clinical and research purposes.

Academic research hospital – A prominent academic research university with an ongoing study focused on genetic alterations in esophageal cancer uses Labmatrix for biobank management as well as the collection of patient clinical, phenotypic and molecular data. All data for the study, including patient demographics, familial relationships, medical history, pathology reports, and biomaterial processing/tracking information are stored and immediately accessible by all team members with

appropriate permissions (including PHI protection). Since the study spans a dozen collaborative research groups across the United States, access to data and proprietary information from each group is controlled with flexible, precise user roles. This type of real-time controlled sharing enables the research groups to work as a cohesive unit to achieve faster generation and validation of scientific insights.

The successful implementation of this project led to the adoption of Labmatrix as the biospecimen and clinical/research information data management solution at the Institute for Computational Biology, an academic collaboration between Case Western Reserve University, University Hospitals Case Medical Center, and the Cleveland Clinic Foundation.

Non-profit research organization – Catalysis Foundation for Health (CFH) engaged in a large-scale international tuberculosis biomarker discovery project with a target enrollment of more than 200 human subjects and acquisition of many thousands of samples. This study, sponsored by the Bill and Malinda Gates Foundation, includes the collection of five types of biofluids per timepoint over 10 timepoints for the initial study phase, and a data-driven reduction of collection timepoints and samples as the study progresses. The multi-year project utilizes 2 biofluid collection sites and 2 assay labs across 3 continents. Labmatrix serves as the central, web-accessible database collecting patient clinical information, tracking sample shipments, and managing sample data, all of which can be viewed in real-time with precise data query reports. Effective communication for this type of large collaborative projects is complicated but essential. Labmatrix allows CFH to easily retrieve data, assess progress, and identify problems that need to be addressed, thus providing the essential, real-time link between the central project management team and all clinical and assay sites.

Pharmaceutical company – Bristol-Myers Squibb's BIOSTORE program utilizes Labmatrix as the enterprise IT platform for managing its global biospecimen inventory. Critical biobanking activities and details from a sample's lifecycle (study setup, patient clinical profiles, biomaterial registration, patient consents, barcoding, physical storage, order request, order approval, order fulfillment, laboratory processing, annotation, return of unused samples, issue management, reporting, material/freezer usage projections, chain of custody, audit trail, and sample destruction) are unified in a global Labmatrix information hub, serving hundreds of BMS scientists worldwide with role-based permissions. In addition, staff members at multiple biobank locations manage all operational workflows within the same Labmatrix instance, leveraging standard workflows and ready-built integration systems with the company's multiple research and clinical IT systems. With

the implementation of Labmatrix, millions of samples located at BMS internal and vendor/partner facilities are now centrally tracked with the same level of rigor and traceability. Labmatrix is the information backbone of new processes that drastically improved BMS's ability to retrieve sample information, reduced turnaround time of sample requests, and increased sample utilization, while minimizing biospecimen operational issues and compliance risks.

CONCLUSION

A biobank is a liability, not an asset – unless and until it can provide significant value for scientific research. Traditional LIMS and biobanking software offers a standard set of well-established operational sample management functions, so much so that these features can be regarded as commodities. In comparison, Labmatrix is an advanced, Next Generation Biobanking solution that provides a central unifying information hub for all precision medicine data, *in addition to* the standard operational biobanking workflows. Labmatrix bridges the gap between existing operational biobanks and precision medicine research. After all, Next Generation Biobanking is not only about how many samples you can collect, but more importantly about how you can best utilize these samples to advance science.

REFERENCES

1. Precision Medicine Initiative Cohort Program.
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2. Final Revisions to the Common Rule
www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html

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