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Turning Hope Into Help™

Using Labmatrix® at a big biopharma company to reduce clinical trial delays, costs, and regulatory risks

Background

For biomarker-driven precision medicine clinical trials, the increased importance of samples (biospecimens) has resulted in an increase in trial complexity and operational burden for the sponsors and their lab partners. Existing tools used to track patients, protocol documents, consents and samples have rapidly become outmoded and insufficient, resulting in delayed trials, regulatory risks, and cumbersome or non-existent reporting capabilities.

Challenge

Our client, a global biologics R&D company, had a laboratory information system (LIMS) that was unable to track necessary clinical sample data to support precision medicine trials. For these biomarker-driven trials with complex sample collection and analysis requirements, it is critical to have the capability to link and harmonize data sets, which include: study design parameters, study meta data, consent templates, sample regimen, routing, subject consent choices, specimen tracking and processing metadata. The clinical trial ecosystem generates large amounts of data from different sources, such as eClinical, sites, central labs, testing labs, and biorepositories. These data tend to be non-standard and error-prone, making it difficult to derive actionable insights. The absence of intra- and cross-study insights from a sample-centric perspective results in milestone delays, increased regulatory risks, and increased operational costs (see Table 1 for examples).

Table 1: Example issues and impacts

Issue	Milestone delays	Additional costs	Regulatory risks
Lack of ongoing visibility into sample operations	X	X	
Inability to perform timely Sample Reconciliation (Expected vs. Actual Collection)	X	X	X
Inability to fully track subject consent choices and Allowable Use at the Sample level		X	X
Lack of system-wide controlled vocabulary, posing issues with tracking and reporting	X	X	
Inability to project sample accrual rates to help budget and planning assay runs	X	X	

Solution

The client's primary objective was to establish a central environment for the life-cycle management of its clinical samples. BioFortis' Labmatrix® software was configured to acquire, standardize, and aggregate the multitude of data, in various formats, from its study partner sources.

Study metadata, including the Biospecimen Collection Plans, Sample Routing Plans, and Informed Consent document templates were loaded into Labmatrix®. Relevant eClinical and vendor data sets were automatically imported into Labmatrix® via the Data Staging Area (see Figure 1) on a scheduled basis. Data validations were run on the incoming files; records that failed validation were compiled into Validation Error alerts. When the necessary corrections were made by the study/vendor team, the corrected data records were loaded again. Error-free data records were "conditioned" into standardized data, which were then loaded into Labmatrix®. By validating and conditioning the incoming data, Labmatrix® harmonized disparate data sources, and furthermore, contributed to establishing controlled vocabulary across all data sources.

> ***We don't know where or what is happening with our samples right now. We need to establish a single source of truth and accountability for the lifecycle management of clinical samples.***
>
> Director, Clinical R&D IT

Figure 1: Labmatrix® clinical trial sample and consent tracking solution

Arrow key: Bi-directional sample transfer · Unidirectional data transfer · Bi-directional data transfer

1 Biospecimen collection plan
Study information
Cohort information
Sample types and quantities
Sample routing
Scheduled visits
Assay information

Sponsor

Sites

Labs

2 Biospecimen collection reality
Actual patient visits
Actual sample collection
Actual routing
Actual tests performed

3 Patient consent
Type of consent obtained
Geographic restrictions
Allowable future use
Protocol amendment number

Storage

Labmatrix logo placeholder

Data staging area

Corrected data

Qiagram®
Data Validation → Pass? → Yes → Data conditioning
No → Validation errors

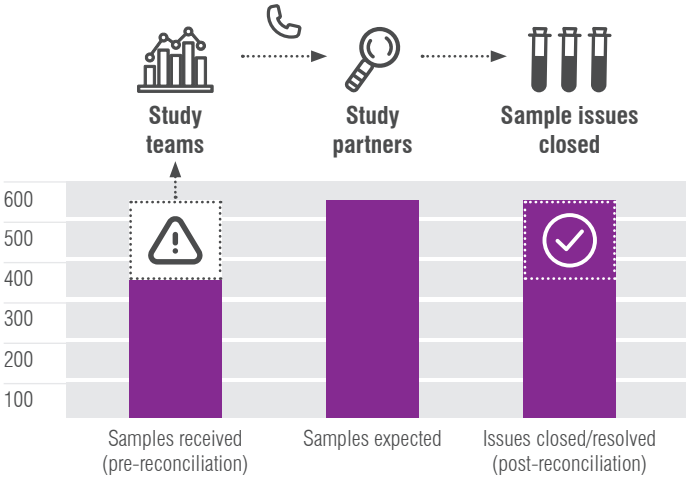
Standardized data
Clinical trial specimen reports and dashboards

Impact

With Labmatrix®, facilitated by the automated capturing of study metadata, the Biospecimen Collection Plan and Patient Consents were reconciled against Biospecimen Collection Reality (Figures 1 and 2), and quickly identified a multitude of sample-related issues. Labmatrix®-based monitoring and sample reconciliation reports exposed a significant percentage of samples for a specific study had issues (e.g. uncollected or missing). Once identified, the client's clinical research organization (CRO) partner confirmed and rectified where possible. Other sample deviations identified via Labmatrix® included: insufficient sample volume collected, thawed sample, sample instability, incorrect shipment, and mislabeled identifiers.

Figure 2: Sample Reconciliation is performed by comparing the Samples Received to the Samples Expected. When deviations were identified, Study Partners were alerted, and issues were rectified where possible.

Sample reconciliation

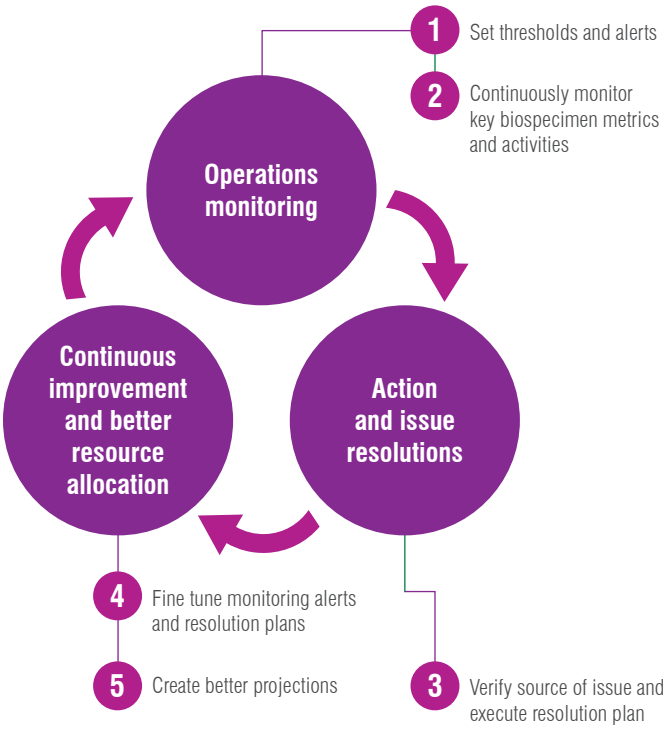


Impact (cont.)

In applying the Labmatrix® monitoring and reporting capabilities throughout the duration of the trials (Figure 3), the client gained the ability to:

- More efficiently detect sample issues on an ongoing basis (allowing remediation of existing issues), which also acted as a mechanism for continuous improvement
- Better estimate projections for sample-related activities, allowing for more accurate allocation of time and resources

Figure 3: Biospecimen operations monitoring lifecycle



Labmatrix® allowed flexible sample and consent reconciliation with either pre-defined or ad-hoc reports. Here are some examples of the information made available to the client through Labmatrix®'s out-of-box and configurable dashboards and reports:

- What is the variance between the Collection Plan and Collection Reality?
- Are these missing samples optional, or required?
- What consent types and protocol amendment numbers are on file for the subjects in this study?
- Are the associated samples cleared for future use?
- When do the samples expire (and must be destroyed) per signed consent?
- What samples are projected to be collected?

> ***After putting Labmatrix® in service, we gained new abilities to review and analyze sample data, including 1) trends by site, country, or vendor, 2) full chain of custody across our vendors, and 3) sample expiry and other consent-driven activities.***
>
> Director, Clinical Operations

Summary

By fulfilling the primary objective to centralize the lifecycle management of clinical trial samples, the client now has the ability to access meaningful reports at the cross-study, study, site, subject, and sample levels – and can identify sample issues earlier and resolve them more effectively. Having critical information readily and easily accessible reduced cost and labor burdens for conducting clinical trials. It also enabled analytics that were either previously not possible, or too cost-prohibitive to obtain. With the implementation of Labmatrix®, the client is better positioned to meet the complexity of today's biomarker-driven clinical trials through a sophisticated sample-centric data solution.

If you have questions or comments, we can be contacted at info@biofortis.com

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