BIOFORTIS
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Labmatrix®

Tracking clinical trial samples and consents to support total sample lifecycle management

Clinical samples have complex lifecycles

Clinical trials can be envisioned as distributed ecosystems of sites, laboratories, vendors, and biobanks, with patient samples and data representing the lifeblood of the enterprise. A successful study must manage specimens throughout their lifecycle, from initial patient consent to final delivery of formatted data. However, following specimens through the course of a trial requires integrating data from multiple sources and systems. A centralized trial sample management system that can track samples over time will facilitate in-study analyses and improve regulatory sample and data reviews.

Labmatrix®: A comprehensive system for sample lifecycle support

The Labmatrix® Clinical Trial Sample and Consent Tracking (CTST) system is a configurable and upgradable system that provides comprehensive sample lifecycle support for in-study sample and sample consent management and tracking, including future-use virtual or physical biorepositories (next generation biobanking) and data mining. Utilized in more than 1,000 trials to date, Labmatrix® offers sample-centric monitoring across a clinical trial's entire ecosystem.

Labmatrix® enables oversight of all samples in a trial, thereby facilitating:

- Data integration among electronic data capture (EDC) systems for central and third-party testing laboratories, repositories, and shipping carriers
- Ongoing sample tracking through the chain of custody and reconciliation
- Projection of subject visits and sample collections
- Consent tracking to support collection compliance and allowable future use

Standard Labmatrix® CTST features include dashboards, study-, subject-, and sample-specific reports, study setup/configuration plans, integration with central and third-party laboratories and biobanks, and user training. Labmatrix® can be upgraded as new features are released and configured to meet client specifications. All CTST releases come validation-ready.

Data Integration

EDC, central labs, third-party testing labs, repositories, shipping carriers

Projection

Projected subject visits and sample collections

Sample Tracking

Chain of custody and reconciliation

Consent Tracking

Collection compliance and allowable future use

Turning Hope Into Help™

Using Labmatrix® to solve sample tracking challenges

Designed to support today's healthcare and research needs, Labmatrix® facilitates a wide variety of studies, including biomarker/precision medicine studies, trials that incorporate two or more laboratories, companion diagnostics studies, proteogenomics applications, and studies in which samples may have intended future use.

Labmatrix® enables organizations to create rich, integrated, and fully accessible "information hubs" that provide holistic views of research data. Labmatrix® provides complete biospecimen and consent lifecycle management that supports regulatory efforts on multiple fronts by reducing costs, efforts, and risks from trial noncompliance.

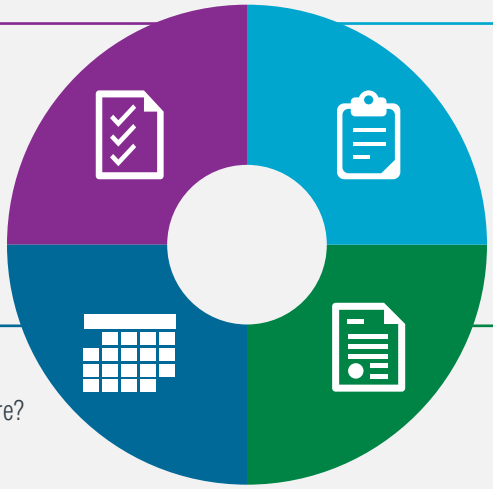
Labmatrix® CTST report families capture key narratives that illustrate the flow of study resources.

Reconciliation

- Were samples collected as planned?
- Were samples properly consented?
- Are there unexpected samples?
- What samples are missing?

Summaries

- What samples are currently available?
- Where are the samples now?
- Which samples have been processed?
- Where has this sample been shipped?



Projection

- What samples are planned in the future?
- When should samples arrive?

Consent

- What can be done with the samples?
- Which samples are impacted by a subject's consent withdrawal?
- When do samples expire?

To learn more about how Labmatrix® can drive scientific insights and support meaningful decisions for your study, visit www.BioFortis.com/labmatrix.

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