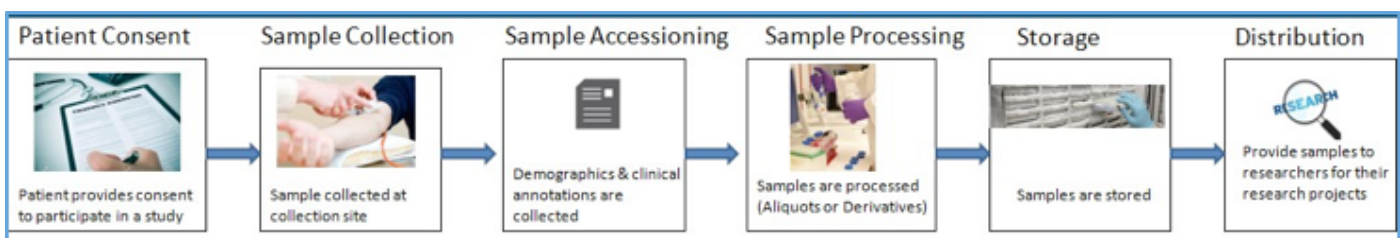


# Overcoming Biobanking Informatics Challenges with a Purpose-Built COTS LIMS

By: Terrence R. Smallmon, MBA

Biobanks play a crucial role in biomedical research by storing and distributing a wide array of biospecimens and the clinical information linked to those samples. Tracing these biospecimens and the data accurately and efficiently can be challenging, taking into consideration the diversity of sample types, the choice for processing technologies, and the variety of storage conditions associated with the biospecimens. Ethical factors and consent tracking provide for added complexity, requiring additional steps during the process. Security and patient privacy need to be carefully considered, with great care given to protecting the personal health information of participants enrolled in a study. The process also needs to consider compliance with regulations relating to audit trails, electronic signatures and chain of custody as these impose additional data capture requirements during the process. A purpose-built, commercial-off-the-shelf (COTS) Biobanking LIMS solution can help address many of these challenges by providing built-in workflows, electronic data capture, improved data accuracy, increased process efficiency and enabling compliance with regulatory requirements.

## Typical Biorepository Process



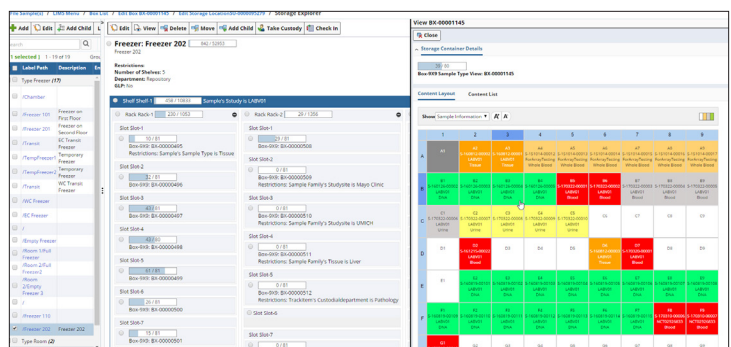
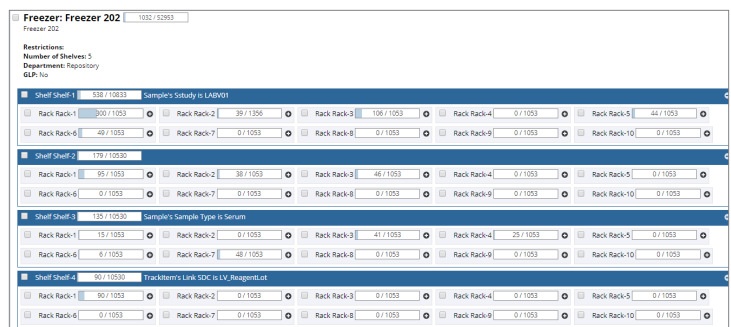
Typical challenges encountered include:

1. Efficiently store & track the biospecimens and the associated clinical data
2. Tracking the chain of custody and the patient consent associated with a sample
3. Securely managing patient privacy data to ensure compliance with regulatory agencies

Benefits of a purpose-built COTS LIMS are shown graphically below:

## Visualization of Storage Inventory

A view of lab's floor, depicting each freezer and the boxes/plates that are stored in it, can help optimize storage space.



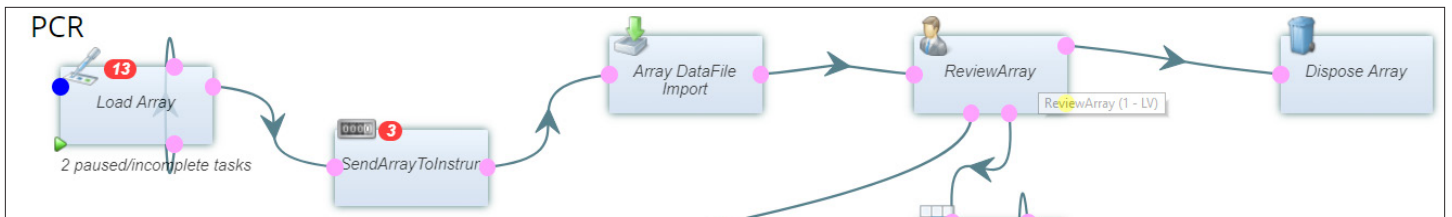
## Specimen Accessioning

Being able to record specimen and subject information using controlled vocabulary ensures everyone is accessioning the samples using the same language, including clinical diagnosis, microscopic diagnosis, tissue types, organs, metastasis and species.

Expected Samples									
<span>← Back</span> <span>Next →</span> <span>✖ Cancel</span> <span>Tools ▾</span> <span style="float: right;">Event (3) Receive (3) Accessioning</span>									
Study		Site		Cohort					
NCT02926833		Kite Pharma		Drug Dose					
Subject: (ST-0000217)								External Participant ID MRN-4521131	
Visit: Collection 1									
<input type="checkbox"/>	Status	Sample Type	Container	Amount	Collection Date	Kit	Instructions	Sample Alias	
<input checked="" type="checkbox"/>	Not Received	Urine	10 ml Urine Tube	43 ml	9/27/17 2:40 PM	KIT-00000001		EXT-123	Clinical Site
<input checked="" type="checkbox"/>	Not Received	Whole Blood	10 mL Blue Top	10 ml	9/27/17 2:40 PM	KIT-00000001		EXT-124	Clinical Site
<input checked="" type="checkbox"/>	Not Received	Whole Blood	10 mL Red Top	10 ml	9/27/17 2:40 PM	KIT-00000001	Ship to Genentech for Processing	EXT-125	Clinical Site

## Built-in Workflows

Pre-configured workflows developed specifically for biobanks helps improve the efficiency by guiding lab technicians and lab managers through their daily tasks.

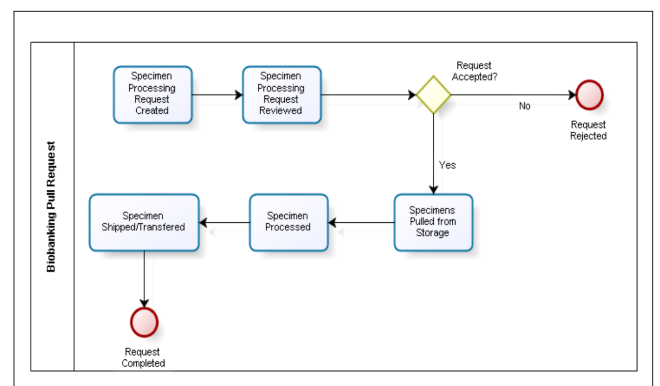


## Request Management

Researchers approach biobanks when they need a specimen with specific traits for their research.

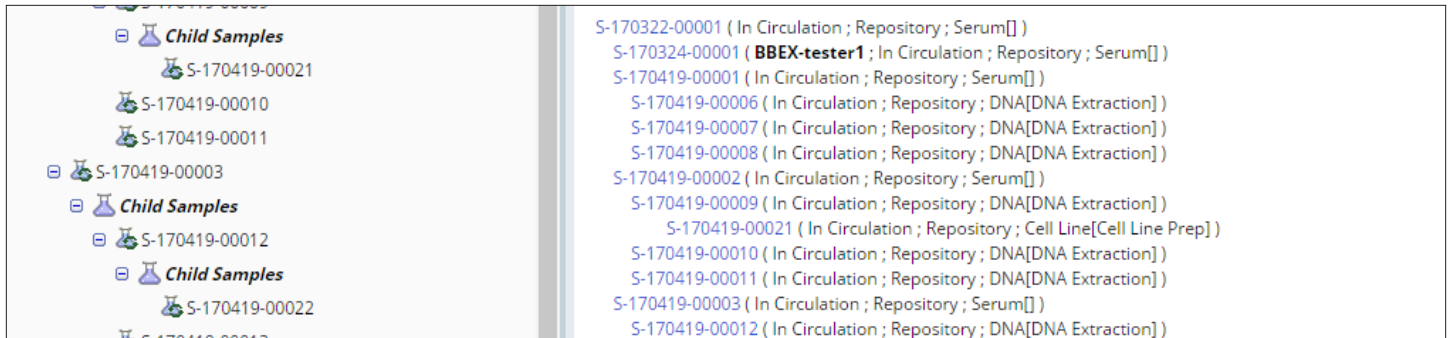
A LIMS solution can facilitate sample sharing by providing an interface for researchers to search specimens, submit requests and track all requestor correspondence. It can also help biobanks manage these specimen requests and process them in order of their priority.

Checkout Fulfillment Dialog					
Checkout & Fulfillment					
<span>Take Custody</span> <span>Ship Samples</span> <span>Cancel Fulfillment</span> <span>Close&amp;Refre</span>					
S-161017-00011		<input type="button" value="Scan"/>			
[ 3 selected ] 1 - 32 of 32					
<input type="checkbox"/>	Status	Sample	Study	Custodian	
<input type="checkbox"/>	Pending	S-160819-00104	LABV01	jwebb	<span>●</span> <span>?</span>
<input checked="" type="checkbox"/>	Pending	S-160819-00105	LABV01	jwebb	<span>●</span> <span>?</span>
<input checked="" type="checkbox"/>	Pending	S-160819-00106	LABV01	jwebb	<span>●</span> <span>?</span>
<input checked="" type="checkbox"/>	Pending	S-161012-00002	Histology Study	jwebb	<span>●</span>
<input type="checkbox"/>	Pending	S-161017-00011	Histology Study	jwebb	<span>●</span>



## Genealogy Viewer

Protocol-driven specimen collection, handling, storage, aliquoting and testing along with an ability to track complete genealogy of aliquots, derivatives and pooled samples fully complements biorepository activities.



## Consent Management

Being able to track patient consent information ensures that biological specimens are handled as per regulatory requirements and in accordance with donor preferences.

## Privacy and Security

A LIMS enables compliance with 21 CFR Part 11 and HIPAA by providing an ability to capture electronic signatures along with audit trails and maintaining patient privacy while ensuring chain of custody.

<input type="checkbox"/>	Question	Answer Style	Consent
<input type="checkbox"/>	I give me consent for samples to be used for Cancer research	Yes/No/NA ▼	Cancer R
<input type="checkbox"/>	I permit my medical records to be shared.	Yes/No/NA ▼	Record K
<input type="checkbox"/>	I permit my samples to be tested externally.	Yes/No ▼	External
<input type="checkbox"/>	I permit contact from the institution in case further information is required.	Yes/No ▼	Recontact

## Conclusion

A LIMS designed specifically for biobanks, like LabVantage 8.2 from LabVantage Solutions, resolves most of the informatics challenges inherent in biobanking. It offers a standardized solution to meet the data management requirements of both large biobanks and small laboratories while enabling compliance with strict regulatory requirements and improving sample traceability.

## About LabVantage

LabVantage Solutions, Inc., the leading global laboratory informatics provider, is headquartered in Somerset, NJ and has offices around the world. LabVantage's industry-leading solutions and world-class services are the result of 35+ years of experience in laboratory informatics.

LabVantage offers a comprehensive portfolio of products and services that enable companies to innovate faster in the R&D cycle, run labs more efficiently, improve manufactured product quality, achieve accurate recordkeeping and comply with regulatory requirements. LabVantage serves thousands of labs across the globe from industries such as pharmaceutical, biotech, food & beverage, chemicals, CPG and more.

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