

A Highly Configurable Biobanking LIMS

OpenSpecimen is a highly configurable web-based Biobanking Laboratory Information Management System (LIMS). used in 70+ clinical research centers across 20+ countries - including many of the world's leading research centers. OpenSpecimen helps you collect High-quality Biospecimen Data and track biospecimens from Collection to Utilization.

- Find out why OpenSpecimen is best suited to manage your biospecimen data.
- Get a comprehensive look at the *major features* and some of our *upgrade plugins*.
- Read some important *customer case studies*.

Need more info? Visit our website or write to us.

Managing Millions of Specimens Across Thousands of Studies in

70+ customers and

20+ countries

Five Reasons to use OpenSpecimen

Global Adoption:

Used in <u>70+ biobanks</u> across 20+ countries, including the leading centers like Johns Hopkins, Pittsburgh, Emory, Oxford, Cambridge, Melbourne, University of New South Wales.

High Configurability:

Configure screens, data entry workflows, forms, and fields based on your needs with minimal IT support.

Data Collection and Reporting:

Collect disease/study-specific data at Participant, Visit, or Specimen level, and use the Reporting module to look for "specimens of interest".

Community Driven:

The OpenSpecimen Community meets regularly in web-meetings, and online forums, and provides feedback on features, pain-points, and improvements.

Keeping up to date:

New version every 3-4 months, based on community's needs

What Customers Say About Open-Specimen?

Our customers talk highly about OpenSpecimen. We will be happy to provide you with customer references to speak directly with them about their experiences with OpenSpecimen.



OpenSpecimen is a cost-effective solution for us. We were previously locked into proprietary software. With extremely large upgrade costs which we were not able to meet. This is no longer the case with the increasing use of opensource software solutions."

JOHN MILLER, **OXFORD BIOBANK (UK)**



We considered OpenSpecimen to be the most complete solution of the six we were offered. It scored consistently highly, particularly because of its flexible configuration, with the ability to collect very varied types of information in a very user-friendly way and configurable access controls to ensure the data is protected. We also noted (although this wasn't one of our evaluation criteria) that there would be no limit on the number of users."

LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE



The user interface is extremely intuitive and streamlined the data entry flow - so that the real time data entry is possible. We were also impressed by the querying and reporting module. We find the developers to be responsive and helpful with any issues, questions, or requests that arise."

TARA MCSHERRY-HURST, UNIVERSITY OF PENNSYLVANIA (USA)



OpenSpecimen's flexible user interface (UI) works very well for the different biorepositories and workflows at our institution. The ability to easily configure the user interface creates streamlined 'screens' so technicians spend less time entering data."

DAVID MULVIHILL, WASHINGTON UNIVERSITY (ST. LOUIS, USA)

Introduction

About Krishangi

Established in 2009, we are an Indiabased company exclusively working with academic research centers worldwide to manage their clinical research data.

We are focused solely on OpenSpecimen, i.e., we have no other products or business priorities. This focus enables us to make rapid progress in improving the product and provide timely support.

Worldwide Adoption

OpenSpecimen is used in 70+ biobanks across 20+ countries, including leading centers like



Penn





OXFORD (





Click here to see the complete customer list.

Evidence of our recognition as the "Go-to Biobanking LIMS" in the academic world is getting selected via a competitive RFP process in centers like:

WEILL CORNELL MEDICAL CENTER

OXFORD UNIVERSITY

LONDON SCHOOL OF HYGIENE AND **TROPICAL HEALTH (LSHTM)**

UNIVERSITY OF BASEL (SWITZERLAND)



EMORY



THE UNIVERSITY OF BRITISH COLUMBIA

Features



User Management Control user privileges at a granular level.



Collection Protocols Design study calendar and track specimen collection and lineage.



Consents

Collect and track patient consent and validate during specimen distribution.



Freezer Management Create containers to track

any type of freezers.



Distribution

Track specimen distribution to researchers. Manage distribution invoicing.



Shipments Ship specimens among collaborating sites.



Custom Forms and Fields Create custom fields and forms

based on the study needs using a UI form builder.



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Specimen Carts
Create carts (picklists),
share with others, and
perform bulk operations.
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Printing Auto-generate uniqe specimen IDs and print labels.



CSV Import

Import CSVs for every object to add, edit or delete data.



Audit & Security

Every operation us audited for regulatory compliance. LDAP/ SAML integration.

Specimen Catalog & Requests

Easily share data with researchers

in one or more online catalogs and

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Dashboards

manage requests.

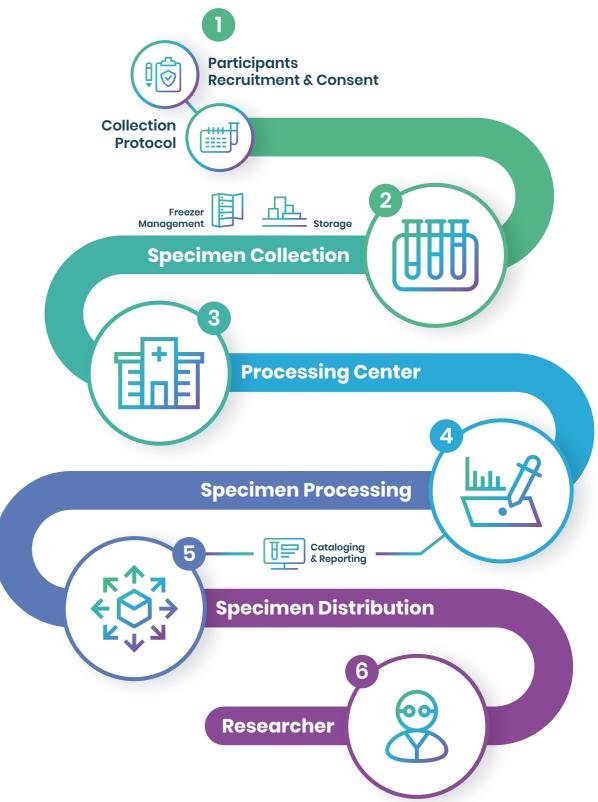


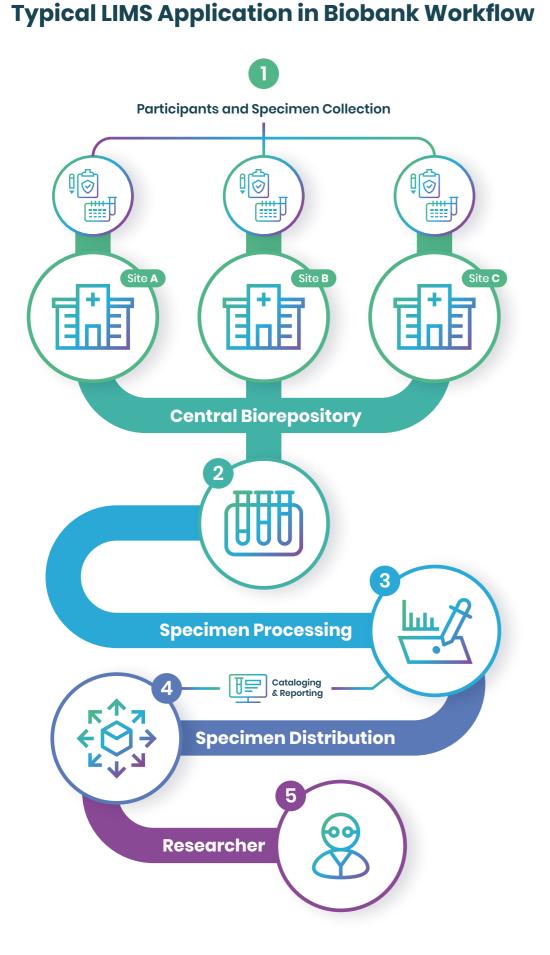
Create visually appealing dashboards per study, catalog, or system level.



TMA & Gels Track DNA gel loading and tissue microarray.

Typical LIMS Application in Biobank Workflow





🖄 Users and Roles

OpenSpecimen allows controlling the user privileges at a granular level - per study or group/site. For example:

- John is a Technician for "Breast cancer protocol."
- Jane is an Administrator for "all" protocols in Dr. Jack's lab.

Administrators can assign multiple "roles" to a user and customize the privileges associated with these roles.

Collection Protocols (CP)

A CP is equivalent to a study or a collection project. Administrators can define the collection events, primary specimens, and processing details. There can be different types of CPs:

Longitudinal CP - Multi or Single Sites

- A longitudinal CP contains a specimen collection calendar and specimens collected in each time-point and their processing details.
- The collection time points could be Screening Day 0, Surgery Day 30, Pre-Operative.
- Specimen processing details can include creating plasma and serums from blood.

Users can also configure things like label formats, printing, consents, monthly reports, catalog, custom forms/fields, and questionnaires.

Article: Managing Longitudinal Collections In OpenSpecimen

Disease Based or Left-over Samples Collections

Users can define prospective CPs to track disease-based collections. For example, collections in breast cancer biorepository or HIV biorepository. These can be defined as participant-centric or specimen-centric.



Configure consent questions within a CP and collect responses for each participant. The consent responses are useful for reporting and validating during specimen distribution.

Article: Consent management for Biobanks

Freezer Inventory Management

OpenSpecimen all types and sizes of freezers. Administrators can configure any type of freezers, LN2s, or other storage compartments.

Highlights:

- Predefine "container types" to create a complete hierarchy in a single click.
- Restrict containers by specimen type or study.
- Create containers in bulk.
- Transfer boxes or racks from one freezer to another.
- "Dimensionless" containers, i.e., with no predefined dimensions.
- Auto-allocation boxes to specimens during collection.

Distributing Specimens to Researchers

You can distribute specimens to researchers. When distributed, the location of the specimen is vacated and marked as closed. It also allows for generating invoices for distributed specimens.

Shipping Specimens between Sites

Often, in large repositories, the specimens are stored in offsite locations for long-term storage. In the case of multi-site collections. Specimens are collected in one site and shipped to another place for processing and storage. These specimens are then shipped back and forth from the storage locations to the biobanks. The shipping module supports tracking specimens from one place to another - sending, receiving, and storage.

Custom Forms and Fields

Apart from the default data entry workflows, users need to collect additional clinical and pathological data like smoking history, family history, pathology annotations, test results, or other information. These data may be different for individual CPs. Users can create custom data entry forms or questionnaires with various field types and associate them with one or more CP. This feature also allows adding custom fields to default data entry pages and is used in reporting.

Specimen Carts

A "specimen cart" allows users to shortlist specimens of interest for further use. A user can:

- Create multiple carts and save them.
- Share them with other users.
- Perform bulk operations like shipping, distribute, add annotations, delete, transfer, and more.

🖻 Label Generation and Printing

Users can auto-generate specimen labels and print them from OpenSpecimen. The label can contain various details like study code, visit code, sample type, collection year. You can configure this at the study level.

NOTE: OpenSpecimen is compatible with printing software like Bartender, NiceLabel, and others.

CSV Import

OpenSpecimen supports importing CSV files for (almost) all objects, including the custom fields and forms. This feature is useful for legacy data migration and high throughput workflows, where each specimen's manual entry is time-consuming.

Security

OpenSpecimen audits every action of a user from login to logout. The audit information includes the date-time, user id, IP address, old value, and the new value. You can generate audit reports from the user interface per study or user.

Security:

Following security measures are available in OpenSpecimen:

- 1. HTTPS for SSL-based encryption for data to and from the server.
- 2. Integrate with institute's LDAP/SAML.
- expiry, and other password-related security measures.

Article: Is OpenSpecimen CFR Part-11 Compliant?

LDAP/SAML Integration

You can Integrate with your institution's identity providers (e.g., Active Directory) for better security. It enables users to use their existing login credentials to log in to OpenSpecimen as well. Thus, it eliminates the hassle for the users to remember two different sets of usernames and passwords.

3. For local accounts (non-LDAP/SAML), OpenSpecimen allows configuring password complexity,

Inactivity for a certain number of days or incorrect password attempts locks the user account.

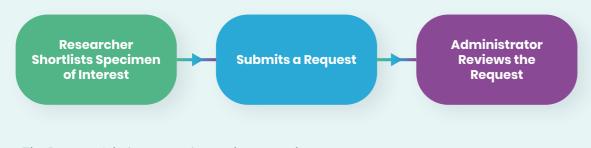


Specimen Catalog is an online display of your specimens that improves the utilization of the specimens in your biobank. Create configurable displays and request forms for researchers to filter and request specimens of interest.

Article: OpenSpecimen's SpecimenCatalog Helps Researchers Find Biospecimens of Interest

Specimen Requests

Researchers can search for specimens of interest and submit a request using the SpecimenCatalog. A researcher can shortlist the specimens using the easy to use catalog user interface and add these specimens to a cart. Once ready, the research can fill in a request form customized per catalog.



The Request Admins can review and approve the request.

Reporting & Dashboards

Reporting is one of the most powerful features of OpenSpecimen. It does not require any IT-support. With an easy-to-use interface, the reporting module allows users to query any data related to a specimen, subject, or user.

Example queries:

- Show all participants who have consents.
- Show pairs of primary & relapse tumors collected at various time points.
- Aliquots that are processed within 30 minutes of collection.
- List of visits scheduled for the next month.
- Count based report on the number of specimens collected by type and site.
- Inventory reports: based on freezer or boxes.
- Distribution reports: based on specimens distributed, reserved, or invoiced.

Reporting features:

- Count-based based reports (e.g., count of samples per anatomic site subdivided by specimen type)
- Save queries for future use, organizing in folders, and sharing with other users.
- Export and import query definition.
- Export data into CSV files.
- Add specimens to a picklist to distribute, ship, or perform any other bulk operation.

Dashboards

Dashboards are a graphical representation of the current status of the CP. Each CP can have its dashboard, which the administrator can configure (without any programming changes). You can also embed the graphs in a website to display live data, e.g., on the website for biobank or study.

Tissue Microarray (TMA) & Gels

This plugin allows the creation of specimen arrays with existing specimens to be tracked, processed, and created into slides. Additional annotations can be captured by creating custom forms and fields.

Gels

Track DNA gel loading with the image and its associated specimens.

Available **Upgrade-Plugins**

Project Tracker

The Project Tracker module helps biobanks track projects, specimen requests, services, timelines, and their statuses. It also supports email notifications and messaging to ensure that information is not lost in emails. It reduces the communication gap between biobanks and researchers and eliminates the need for using Excel sheets outside OpenSpecimen. Finally, the reporting module enables biobanks to query for projects related data and download reports.

Article: Track Biobank Projects Using "Project Tracker" Module

Supply Management

The Supply module allows tracking the inventory of supply items (like tubes, vials, kits, gloves, labels, reagents) across multiple studies and sites. Supply items get deducted as specimens are collected or processed. It also sends notifications for low quantity and expiry date.

Article: Manage supply items inventory

Integration

OpenSpecimen is 100% REST API-enabled software. Thus, it is easy to integrate OpenSpecimen with other databases and instruments. Following are the integration plugins supported in OpenSpecimen

REDCap (RC) and OpenClinica (OC)

OpenSpecimen can be integrated with RC and OC to enable users to query data across the two systems. For instance, biospecimen data is in OpenSpecimen, and clinical data is in OpenClinica/RedCap.

This plugin pulls the complete dataset of the study, including Case Report Form (CRF) data from RC/OC into OpenSpecimen. The RC/OC CRFs get duplicated in OpenSpecimen such that they are now available via the OpenSpecimen reporting module. Thus, it enables users to execute highly powerful queries to search for specimens of interest.

Article: OpenSpecimen-OpenClinica Integration

Link Missing

Epic (or any EMR)

The goal of integration with EMR is to eliminate duplicate data entry and human errors. The integration is possible via three different methods. The same approach applies to any other EMR system:

- a. HL7 feed
- b. Direct web service call to EMR
- c. A nightly feed from the EMR

Article: OpenSpecimen EPIC integration

Pathology Reports from Cerner/CoPath

Pathology reports can be loaded in OpenSpecimen manually or via an HL7 message from Cerner, CoPath, and other databases. These reports can also be de-identified either manually or using de-identification algorithms.

Automated Freezers

IOpenSpecimen can be integrated with automated freezers from Hamilton, Liconic, TTP Labtech, Brooks, and others. The integration will provide an "one-click" option to store or retrieve specimens from the freezer.

Link Missing

Customer Case Studies

• The University of California Davis Adopts OpenSpecimen to Manage Large Biospecimen Projects

• Johns Hopkins OpenSpecimen Adoption Over the Years

• OpenSpecimen Helps Streamlining Biobanking at Washington University

• How Tumor Bank at the University of Pennsylvania benefited from adopting OpenSpecimen?

• OpenSpecimen adoption at University of Leicester

• How does the Oxford Biobank manage 400,000+ specimens using OpenSpecimen?

• Victorian Cancer Biobank goes live with OpenSpecimen

• OpenSpecimen Helps SAHMRI (Adelaide) Manage Large Sample Inventory

OpenSpecimen-OpenClinica Integration Poster by FIND Diagnostics

Adopting an Organized and Queryable Biospecimen Database







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