Regulatory Challenges in Biobanking: Informatics Makes it Easy

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Agenda

The Importance of Regulatory Compliance for Biobanks

Regulatory Framework for Biobanks Across the Globe

Major Compliance & Best Practices for Biobanks

How Informatics can Help Biobanks Meet Compliance

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Compliance & Best Practices: An Overview

- A set of laws, regulations and guidelines that a biobank needs to follow.
- Regulatory compliance acts as the moral compass to ensure a biobank is legally and ethically competent.
- Regulatory compliance applies to all types of biobanks (in-house biobanks, third-party biobanks, & commercial biobanks).
- Compliance is governed both nationally and internationally.

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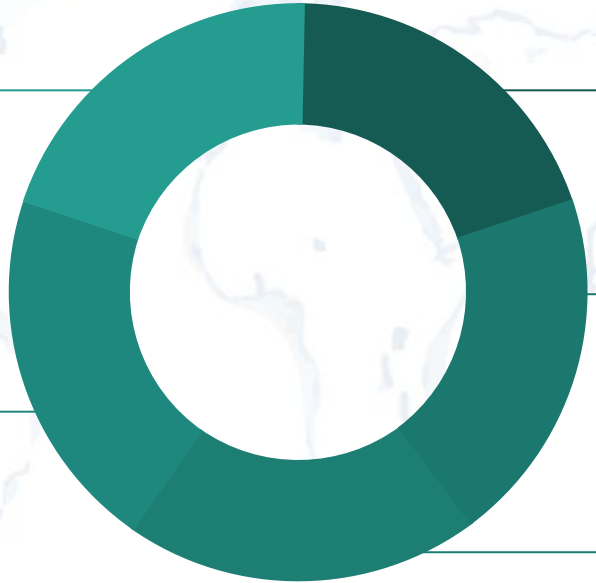
Why is Compliance Important?



Standardizes operations

Safeguards PHI of sample donors

Supports transnational collaboration

Helps maintain high-quality, fit-for-purpose samples

Builds trust within community

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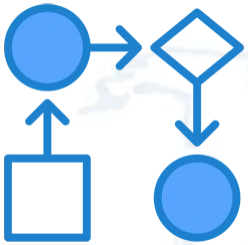
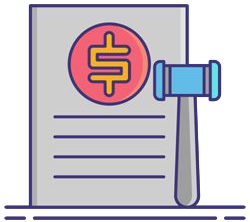
Risks of Non-compliance



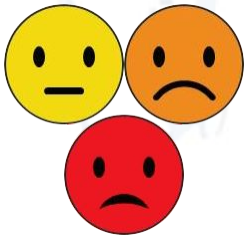
Non-standard Workflows

Compromised Sample Quality

Legal and Ethical Issues



Hefty Fines and Penalties



Loss of Reputation

License Cancellation

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HIPAA

HIPAA sets standards to protect privacy of health information

Technical, administrative & physical safeguards.

Covered entities include biobank staff and their business associates.

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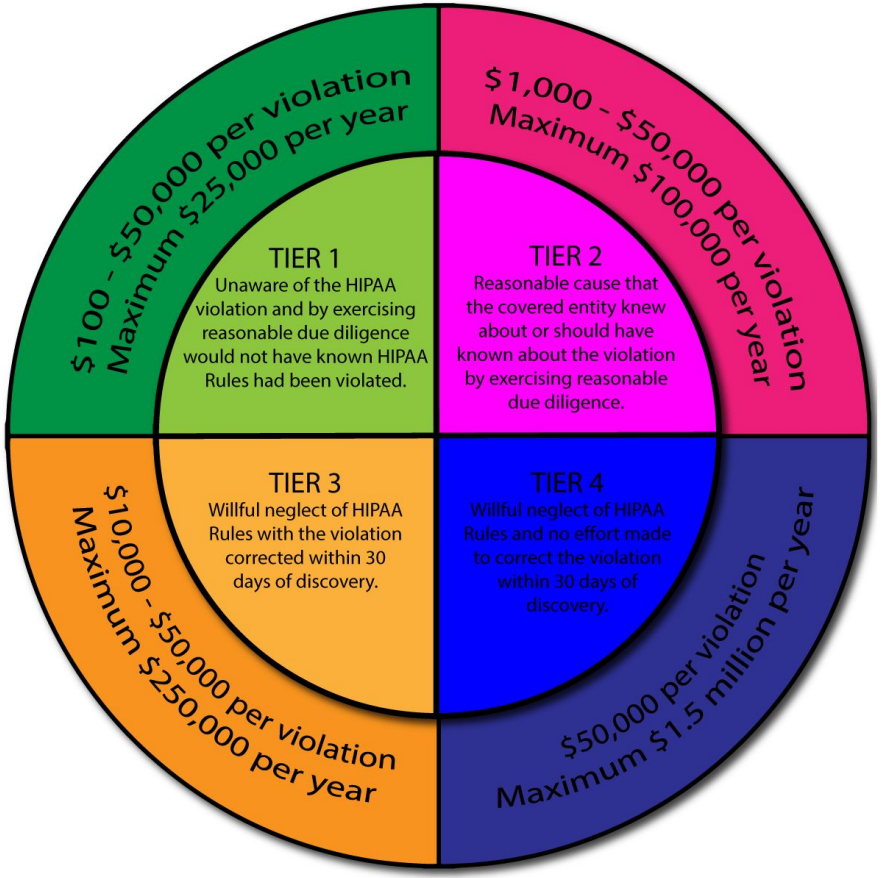
Penalties for HIPAA Violations



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HIPAA Compliance Requirements

- Assign role-based access permission to staff.

- Encrypt data transmission and data security.

- Maintain an audit trail of PHI changes.

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Solution to Regulatory Challenges

How can a biobank successfully navigate through the complex regulatory patchwork?

Informatics is the key

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21 CFR Part 11

Stipulates handling of records in electronic forms

Protects personal information in electronic form

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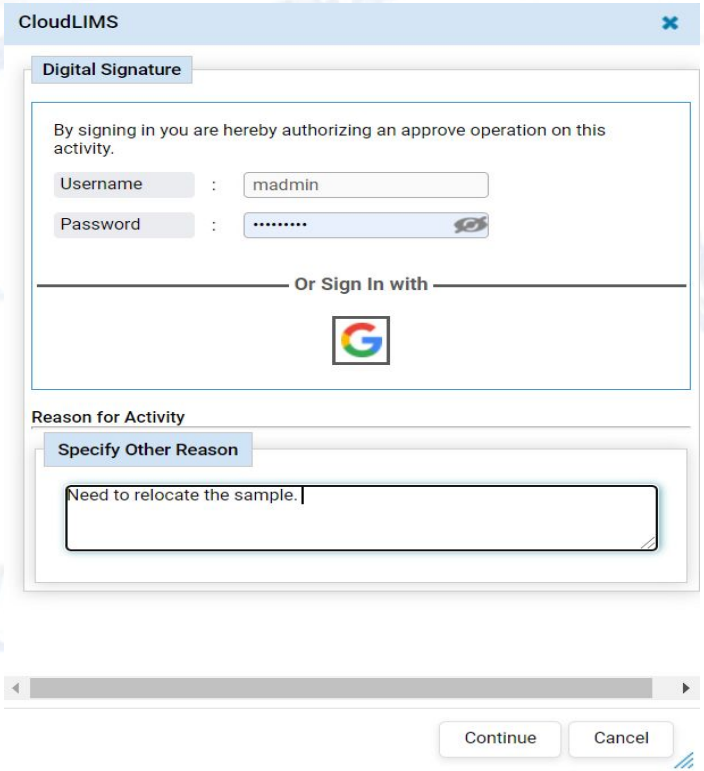
Authenticating Key Activities

Enforce staff to authenticate key activities using electronic signatures



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Penalties for HIPAA Violations

- HIPAA imposes certain penalties on covered entities for non-compliance.
- HIPAA violations are categorized in tiers (1-4) based on their severity.
- The OCR can waive a penalty if necessary.

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EU GDPR

The EU GDPR safeguards the data and privacy of EU citizens

EU GDPR governs how biobanks collect, store, and use biospecimens

EU GDPR applies to all biobanks that store samples or data of EU citizens

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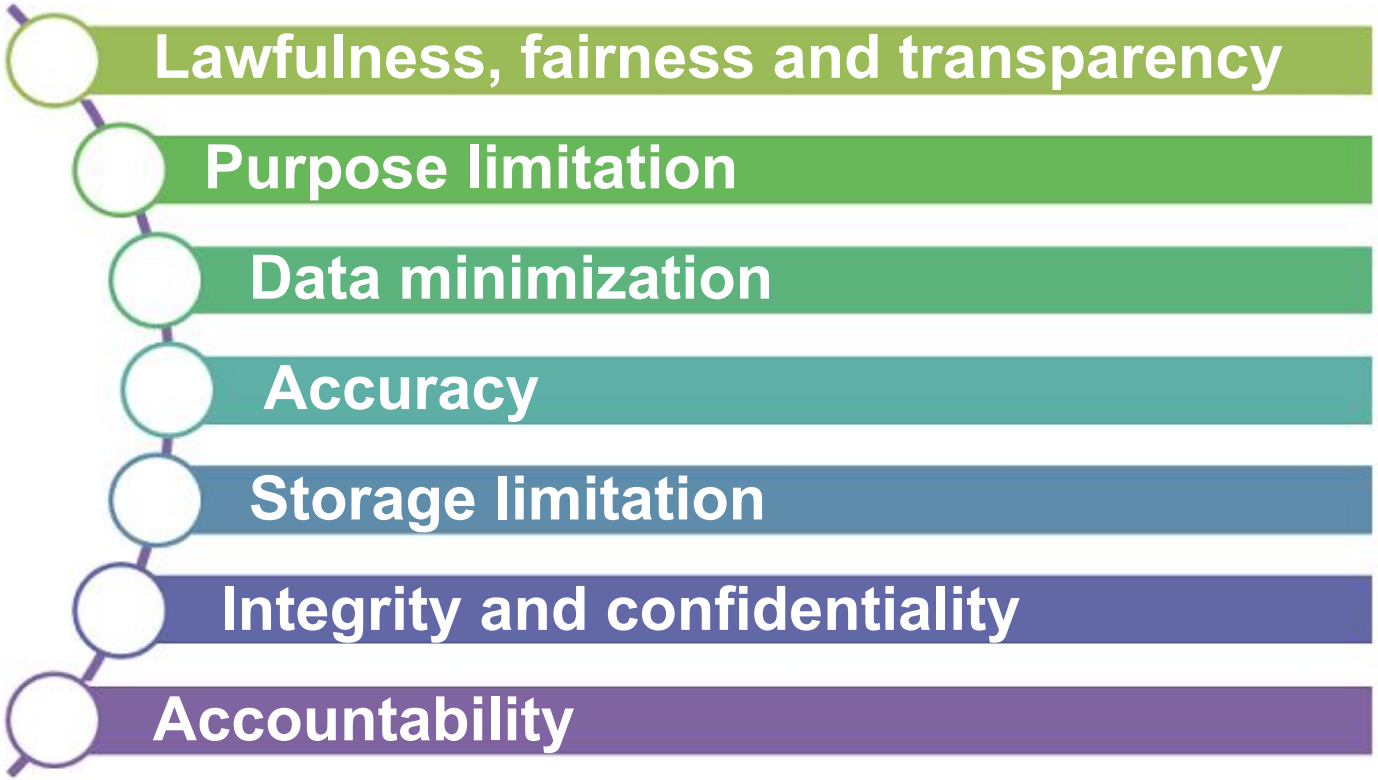
EU GDPR: Data Protection Principles

The **7** Principles



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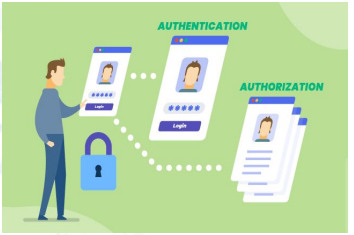
EU GDPR Requirements

Maintaining Records of All Processing Activities

Protecting Sensitive Information of EU Subjects

Authenticating Key Biobanking Activities



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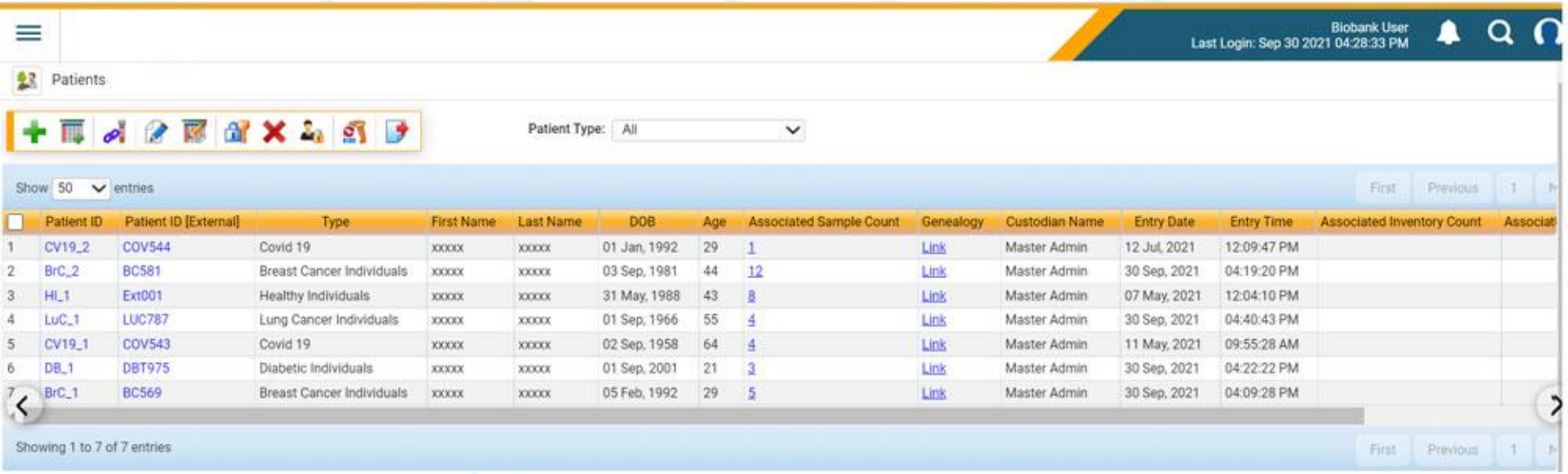
Safeguarding PHI of Patients

Anonymize sensitive PHI and limits PHI access to authorized staff



	Patient ID	Patient ID [External]	Type	First Name	Last Name	DOB	Age	Associated Sample Count	Genealogy	Custodian Name	Entry Date	Entry Time	Associated Inventory Count	Associat
1	CV19_2	COV544	Covid 19	xxxxx	xxxxx	01 Jan, 1992	29	1	Link	Master Admin	12 Jul, 2021	12:09:47 PM		
2	BrC_2	BC581	Breast Cancer Individuals	xxxxx	xxxxx	03 Sep, 1981	44	12	Link	Master Admin	30 Sep, 2021	04:19:20 PM		
3	HI_1	Ext001	Healthy Individuals	xxxxx	xxxxx	31 May, 1988	43	8	Link	Master Admin	07 May, 2021	12:04:10 PM		
4	LuC_1	LUC787	Lung Cancer Individuals	xxxxx	xxxxx	01 Sep, 1966	55	4	Link	Master Admin	30 Sep, 2021	04:40:43 PM		
5	CV19_1	COV543	Covid 19	xxxxx	xxxxx	02 Sep, 1958	64	4	Link	Master Admin	11 May, 2021	09:55:28 AM		
6	DB_1	DBT975	Diabetic Individuals	xxxxx	xxxxx	01 Sep, 2001	21	3	Link	Master Admin	30 Sep, 2021	04:22:22 PM		
7	BrC_1	BC569	Breast Cancer Individuals	xxxxx	xxxxx	05 Feb, 1992	29	5	Link	Master Admin	30 Sep, 2021	04:09:28 PM		

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ISO 20387:2018: An Overview

ISO sets quality standards for different sectors.

ISO 20387 defines the general, structural, resource, process, and quality management system requirements.

ISO published a new standard for biobanks in 2018 - ISO 20387.

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Inside ISO 20387:2018

Manual section	*Corresponding ISO section*	*Content*
General requirements	4	Impartiality and confidentiality
Structural requirements	5	Organizational structure
Resource requirements	6	Personnel responsibilities Personnel training and competency Facilities Equipment maintenance and calibration External providers
Process requirements	7	Life cycles of biological materials and associated data Specific procedures for collection, reception, transport, preparation, preservation, testing, analysis, storage, and distribution Traceability Validation and verification of methods Data management Material and data certificates (reports) Nonconforming output Complaints
Quality management system	8	Control of documents and records Identification of risks and opportunities Corrective actions following nonconforming outputs Internal audits and quality management review

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ISBER Best Practices

ISBER BP provide guidelines to biobanks on:

- Collection, storage, and allocation of samples
- Specimen tracking & retrieval
- Document control & management
- Equipment calibration and management
- Distribution & shipping of samples
- Inventory management

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ISBER Best Practices

ISBER requires biobanks to maintain records of:

- Standard Operating Procedures (SOPs)
- Staff training & competency
- Equipment maintenance
- Sample procurement, handling, storage, & transfers
- Sample & inventory procurement
- Informed consent of patients

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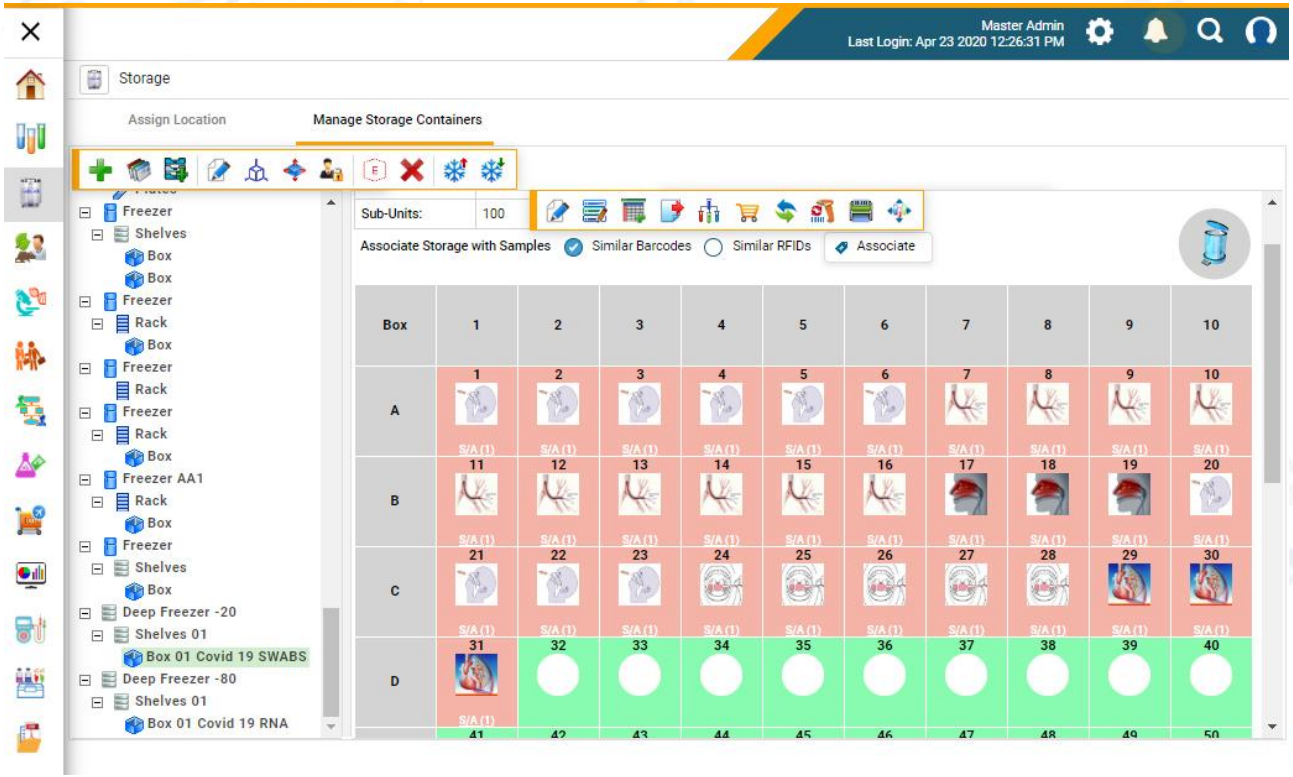
Managing & Locating Stored Samples

Mirror storage inventory and locate stored samples with ease



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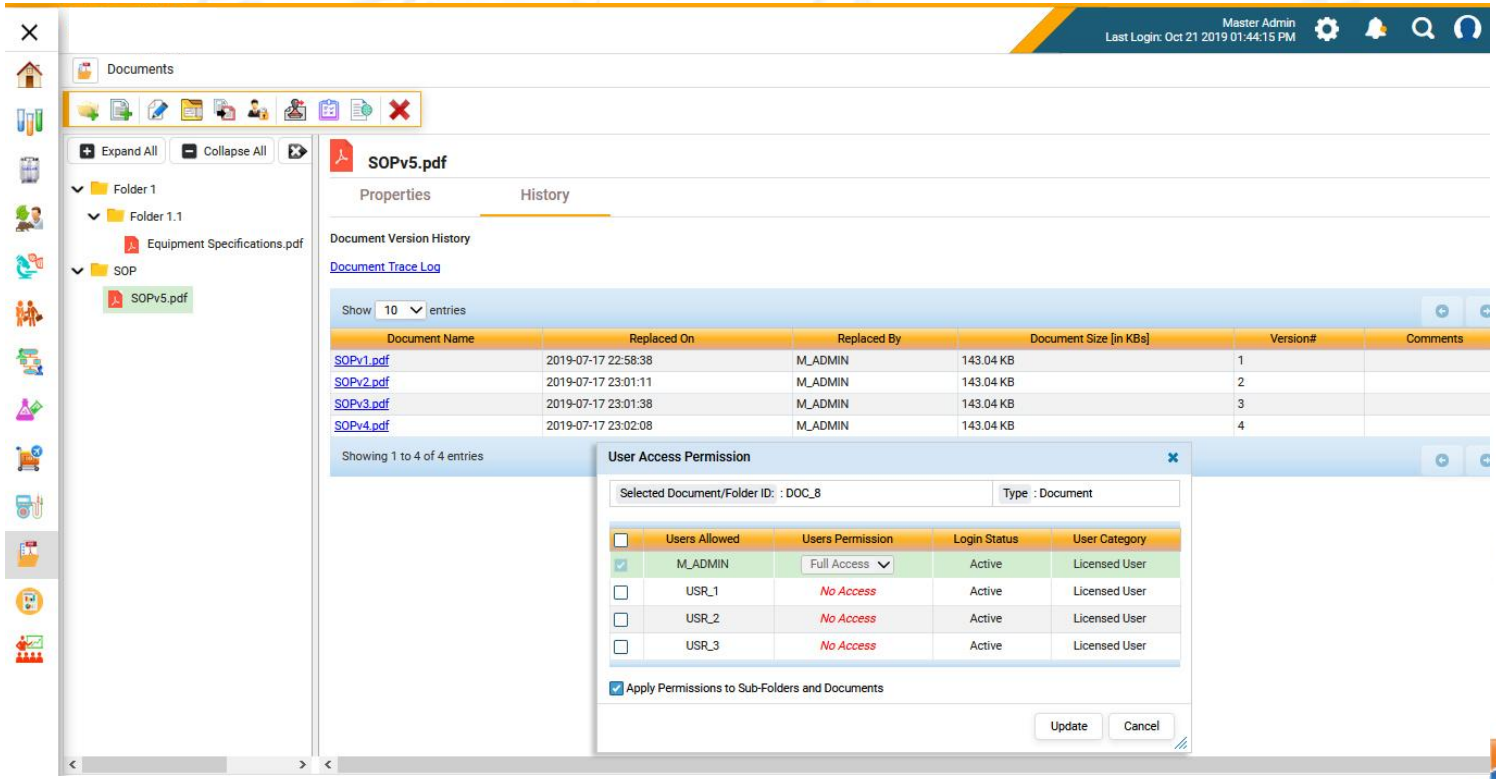
Managing Documents

Manage documents, such as Standard Operating Procedures (SOPs), and provide quick access of documents to all authorized users



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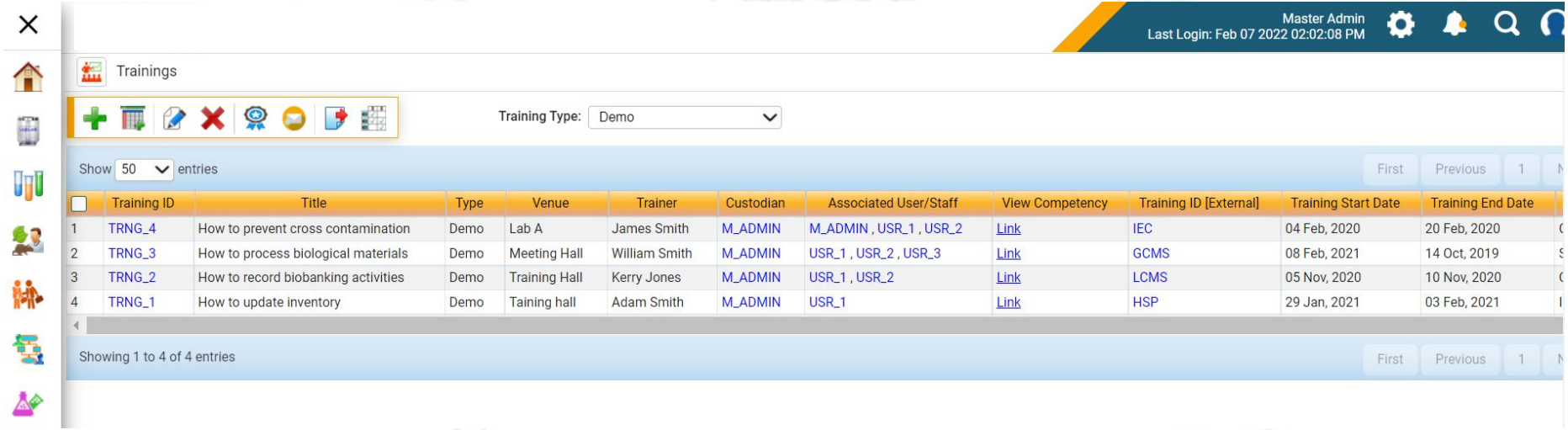
Managing Staff Training

Manage staff training & their competency



Training ID	Title	Type	Venue	Trainer	Custodian	Associated User/Staff	View Competency	Training ID [External]	Training Start Date	Training End Date
1	TRNG_4	How to prevent cross contamination	Demo	Lab A	James Smith	M_ADMIN	M_ADMIN , USR_1 , USR_2	Link	IEC	04 Feb, 2020	20 Feb, 2020
2	TRNG_3	How to process biological materials	Demo	Meeting Hall	William Smith	M_ADMIN	USR_1 , USR_2 , USR_3	Link	GCMS	08 Feb, 2021	14 Oct, 2019
3	TRNG_2	How to record biobanking activities	Demo	Training Hall	Kerry Jones	M_ADMIN	USR_1 , USR_2	Link	LCMS	05 Nov, 2020	10 Nov, 2020
4	TRNG_1	How to update inventory	Demo	Taining hall	Adam Smith	M_ADMIN	USR_1	Link	HSP	29 Jan, 2021	03 Feb, 2021

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NCI Best Practices

The NCI Best Practices include principles that:

- Define state-of-the-science biospecimen resource practices.
- Promote quality of biospecimens and associated metadata.
- Enable biobanks to meet ethical and legal requirements.

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Biobanking Policies in India

Biobanking in India is supported by three agencies:

icmr
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

Department of BioTechnology, Government of India
सत्यमेव जयते

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Biobanking Policies in India

- India does not have specific laws to govern biobanks.
- The ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants govern biobanking in India.

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Biobanking Policies in India

- Personal data is protected by the Personal Data Protection Bill (not yet approved).
- The health ministry of India has a separate data protection bill.
- However, this bill needs to work in tandem with the general data protection law.

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Choose Right

Checklist for Biobanking Software:

- ✓ Securely manage samples, metadata, patient consent
- ✓ Assign role-based access to authorized users to safeguard PHI
- ✓ Anonymize sensitive patient data to safeguard PHI
- ✓ Store SOPs, control documents and records digitally and securely
- ✓ Track samples and maintain a chain of custody

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Choose Right

Checklist for Biobanking Software:

- ✓ Manage staff training and their competency
- ✓ Schedule instrument calibration & manage maintenance data
- ✓ Maintain an audit trail
- ✓ Enforce authentication of key activities through digital signatures
- ✓ Optimize freezer management and sample utilization

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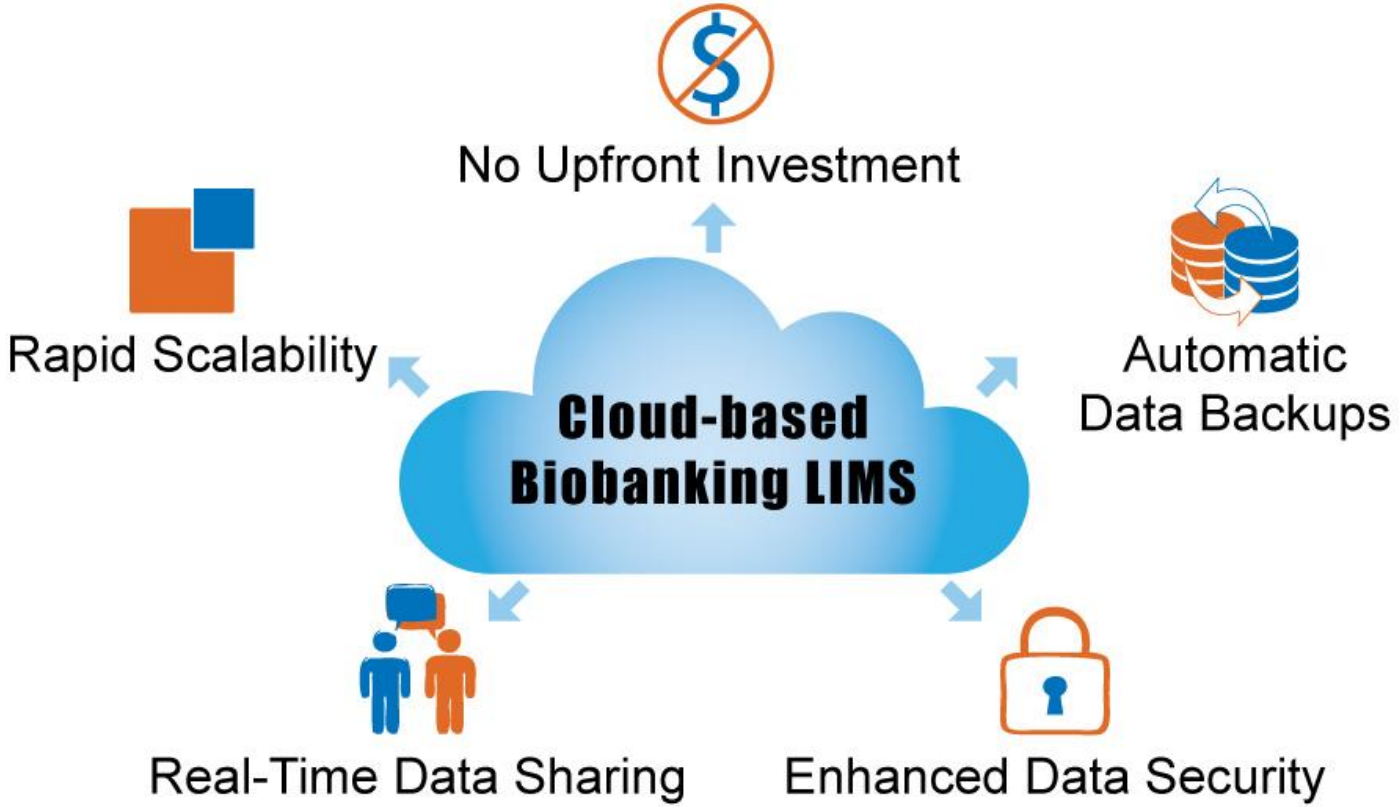
Benefits of Cloud-based Informatics



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Key Takeaways

- An overview of regulatory compliance and best practices for biobanks across the globe.
- How Informatics helps biobanks meet compliance and follow best practices to stay ahead of the curve.
- Key benefits of a cloud-based informatics tailored to biobanking

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