LabWare e Biobancos 4.0: Rastreabilidade Total e Gestão Inteligente de Dados

LabWare and Biobanks 4.0: Total Traceability and Intelligent Data Management

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biobank Brasil summit

Presenter Info

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biobank Brasil summit

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About today

Building a collaborative network, standardized records, end-to-end traceability, data security and privacy, workflow automation, integrations and interoperability, and continuous improvement.

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Objective

Enhancement of scientific data quality, reduction of regulatory risk, and acceleration of researchers' access to reliable data.

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Biobanks 4.0

How we get there?

Risks and Impacts

Manual Records Paper, Decentralized Documents, Disconnected Systems

Risks

Impacts

Data Integrity Failures:

- Lack of demonstrable effective controls
- Decentralized Data
- Audit Failures
- Identification errors and losses due to QC failures
- Low visibility of pre-analytical and QC, compromising reproducibility

Low Operational Efficiency:

- Low Operational Efficiency
- No Interoperability
- Long Lead Times
- Slow Decision Making
- Inefficient Use of Damaged Labor
- Patent Difficulties

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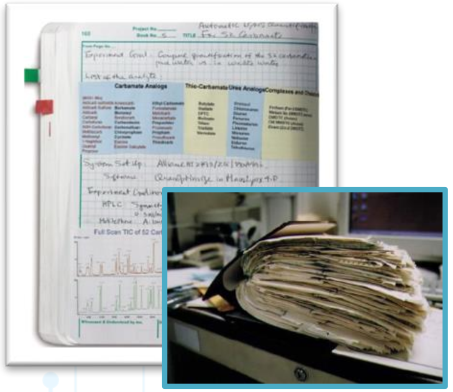
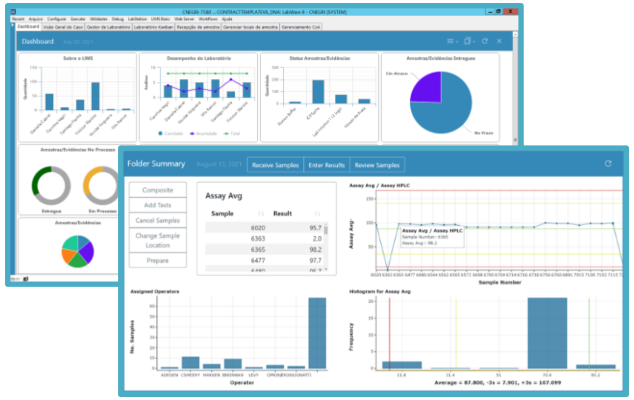
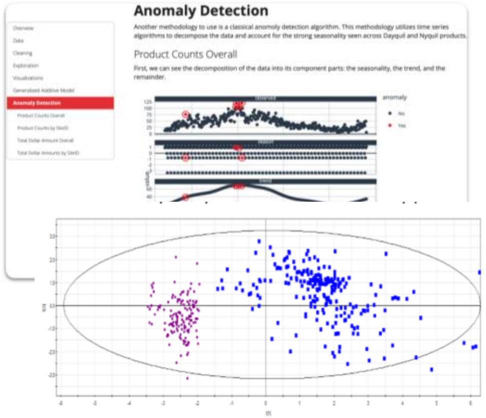
Data Evolution to Generate Value







DATA

INFORMATION

KNOWLEDGE

INTELLIGENCE

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Biobank 4.0 is not just a technological infrastructure,
but a platform for innovation and governance that connects science, market and state.

Biobank Pillars

SAMPLES

Ensuring full lifecycle management/tracking, from collection, stability, unique identification, and accessibility.

QUALITY

Validation, compliance, CAPA and change control, QC Dashboards, access hierarchy.

INTEGRITY

Traceability, Chain of custody.

INTEROPERABILITY AND STANDARDS

Consistent use of data standards, MIABIS, SPREC, ISBT 128, standardization terminology

SECURITY

Data Governance, Confidentiality, Access Hierarchy.

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Technologies for Biobank 4.0

Systems Supporting Routine Operations

System capabilities to support decision-making, problem resolution, and task execution.

Interoperability

Among Biobanks and in data collection via interface between systems and interconnected equipment, devices, and sensors.

Automation and Robotics

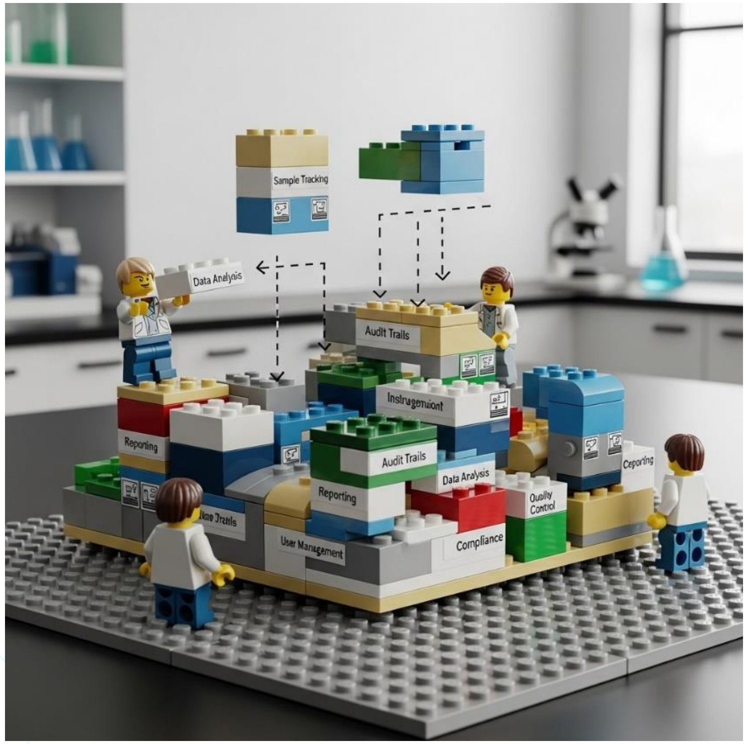
Automation through systems and equipment, transformation of routine manual processes.

Machine Learning and Predictive Analytics

System capabilities to guide decisions based on data stored in a centralized ecosystem.

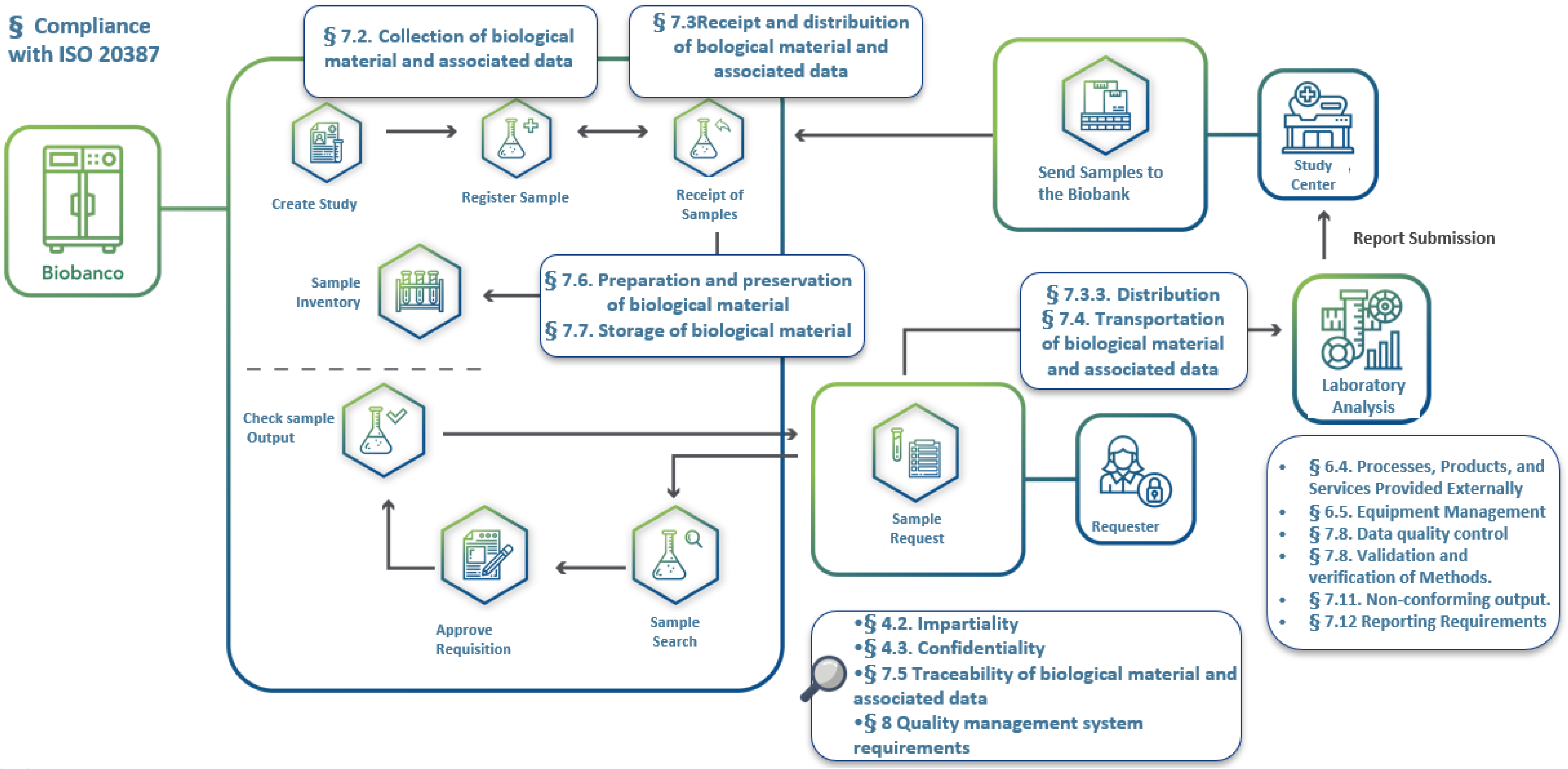
But how does all this work in practice?

Standardization + Flexibility



- Compliance with standards such as ISO 20387, ISO 17025, ...
- 21 CFR Part 11 (FDA), GxP/GLP/
- 2D Labels, QR Code, supporting ISBT 128
- End-to-end sample lifecycle management
- Movement, Distribution, and Storage
- Metadata and pre-analytical quality (SPREC)
- MIABIS Mapping
- Access logs and privacy reports (LGPD)
- Equipment integration
- Management of deviations, non-conformities, CAPA
- Validation according to GAMP5
- Documents, SOPs, and competency management
- Analytics, KPIs, and continuous improvement
- And much more....

LabWare - Generic Workflow



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Conclusion

Where We Can Go

Where We Can Go

Complete lifecycle management, from collection, stability, unique identification, and accessibility.

- **More agile research** and development and **intelligent data management**, ensuring greater precision in analyses and forecasts.
- **Regulatory compliance**, with assured traceability and digital security.
- **Intersectoral partnerships** that expand innovation capacity by connecting science, health, and technology, **facilitating evidence-based decision-making**.
- **Data integrity** with electronic records and automatic instrument data capture, eliminating errors from human intervention.
- **Integration with corporate systems**, eliminating the need for repeated information entry.
- **Optimization of public resources** by reducing redundancies and increasing efficiency in applied research.

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Thank you!

QUESTIONS?

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