Enabling Systems Toxicology Assessment Studies with State-of-the-Art Biospecimen Data Management Systems

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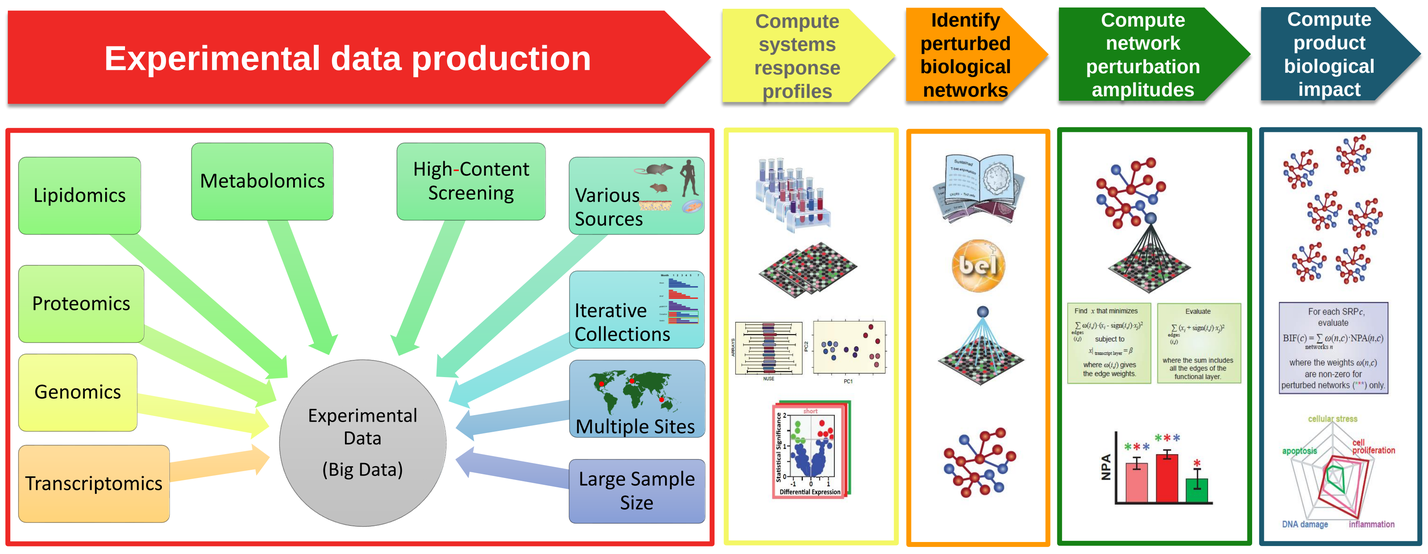
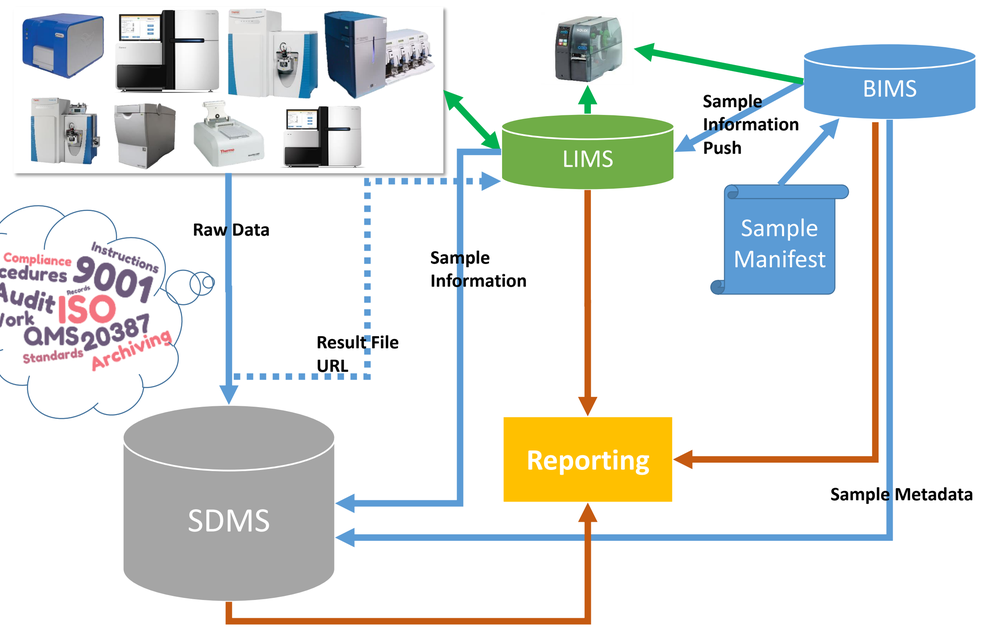
Our Systems Toxicology Assessment Approach



Our Implementation



Resulting Sample Management Workflow

Study Planning
- Import study, subject, sample annotations into Biobank Information Management System (BIMS)
- Retrieve unique sample IDs

Sample Collection
- Follow collection protocols referenced in the Study Plan and apply labels provided by BIMS
- Track custody and storage locations to BIMS

Sample Relocation
- Track shipment of samples in BIMS
- Track custody status and new location in BIMS
- Confirm receipt in BIMS

Sample Storage
- Temporally store samples under suitable conditions
- Track location and storage conditions in BIMS

Sample Processing
- Create extracts from samples
- Simulate sample extraction in BIMS for sample relationships racking
- Push sample annotations into Laboratory Information Management System (LIMS)

Sample Analysis
- Track experimental events in LIMS
- Push sample information into LIMS
- Manage plates and reagents for analyses in LIMS
- Store instrument output and results into Scientific Data Management System (SDMS)

Study Report
- Create consolidated sample reports from the systems with reference to the raw data
- Finalize Study Report

Sample Archive
- Ship samples to long-term repositories and track shipment and relocation in BIMS
- Retrieve samples from long-term repository on demand and track relocation in BIMS

Sample Disposal
- Dispose samples when requirements are met
- Track disposal status in BIMS
- Create disposal report

Control of confounding effects
Rich subject and sample annotations

Excel Templates
Study Generation Tools
Master Data Management

LabVantage

Complex collection: tissue regions
Randomization at each step
Operator and time tracking

Multiple sites across the globe
Large sample numbers
Handling of customs

WORLD COURIER
An AmerisourceBergen Company

Storage of large sample lists and retrieval of single samples
Ensuring stable and secure storage conditions

Brooks LIFE SCIENCE SYSTEMS
BioStorage TECHNOLOGIES

Tracking rich sample relationships through derivation, aliquotation, and pooling

LabVantage

Retrieval of full sample annotations and history
Tracking of experimental parameters
Management of large data output

Clarity LIMS
Intuitive Lab Management

Consolidation across multiple systems and instruments
Compliance with submission formats

INTERVALS
ADVANCING SCIENCE FOR A SMOKE-FREE WORLD

Retrieval from the long-term repository
Maintaining stable and secure storage conditions

Brooks LIFE SCIENCE SYSTEMS
BioStorage TECHNOLOGIES

Disposing samples but keeping sample life cycle data

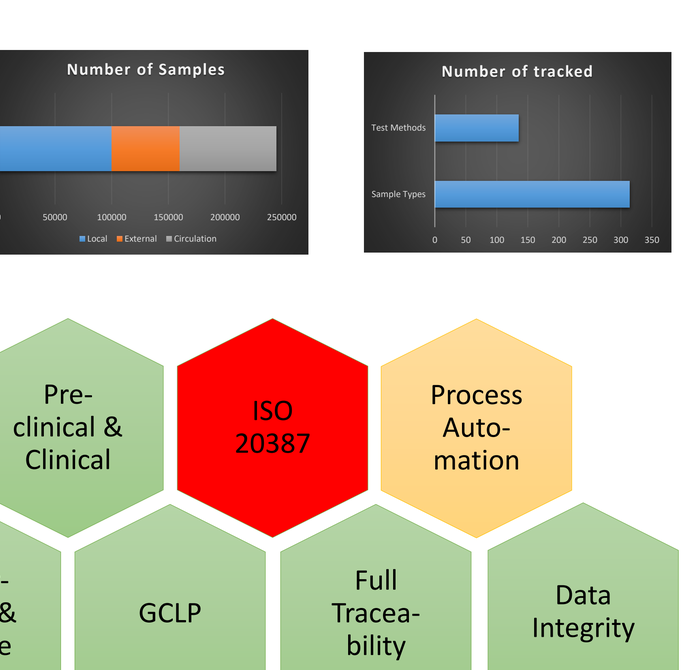
BIMS	LIMS	SDMS	Reporting

• LabVantage 6.1
• Manages Sample:
  • Annotations
  • Relationships
  • Events
• Provides sample data to other systems
• Does not store raw data or experimental data
	• Illumina Clarity LIMS 4.2
	• Receives sample information from BIMS
	• Manages
	  • Experimental data
	  • Link to raw data
	  • Reagents and consumables
	• Does not store raw data
		• Agilent OpenLAB Enterprise Content Manager
		• Receives sample information from BIMS
		• Automatically fetches raw data from instruments
		• Does not manage any experimental data
			• INTERVALS
			• Online platform to share data openly
			• Flexible data format to enable interoperability
			• Controlled vocabularies
			• Full sample traceability and access to raw data and processed data
			• Integrates information from internal systems

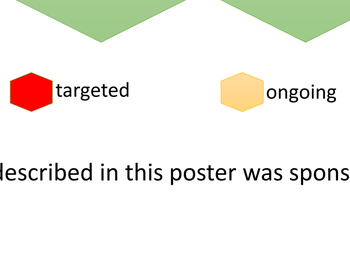
LabVantage	Clarity LIMS Intuitive Lab Management	Agilent Technologies	INTERVALS

Quality Management System

- ✓ According to ISO 9001
- ✓ Computerized System Validation
  - ✓ Four environments, two non-controlled (DEV, STG) and two controlled (QA, PRD)
  - ✓ Electronic validation
  - ✓ Risk-based approach
  - ✓ Full change control
  - ✓ Audit trail
  - ✓ e-signature or e-approval implemented
  - ✓ System access control
  - ✓ Defined roles
- ✓ Data Governance
- ✓ Data Integrity
- ✓ GCLP
- ✓ Service Agreement
- ✓ Training Management
- ✓ Electronic document management
- ✓ Instrument Validation
- ✓ Method Validation
- ✓ Upcoming: **ISO 20387** compliance



Facts & Summary



http://intervals.science

https://www.pmiscience.com

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Competing Financial Interest

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