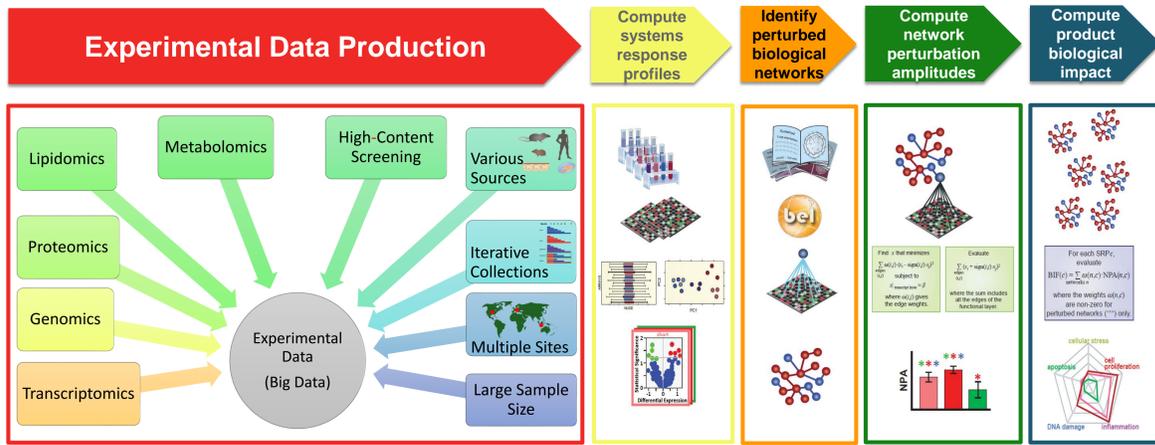


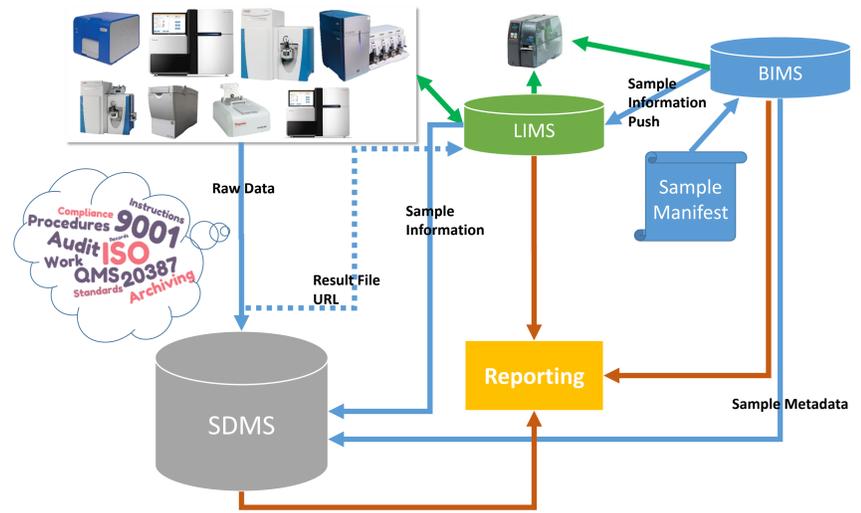
# Enabling Systems Toxicology Assessment Studies with State-of-the-Art Biospecimen Information Management Systems

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## Our Systems Toxicology Assessment Approach



## Our Implementation



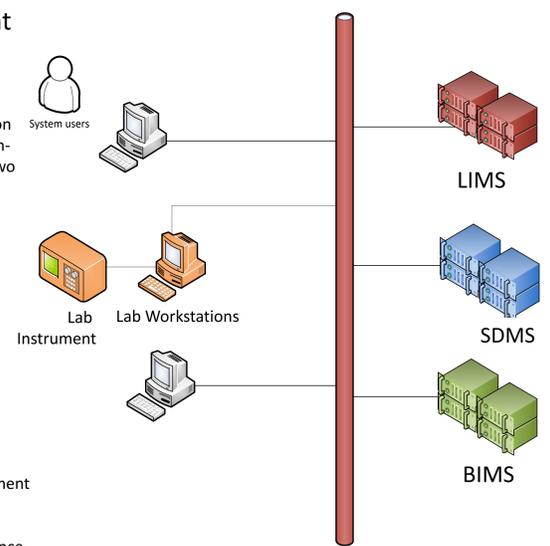
## Resulting Sample Management Workflow



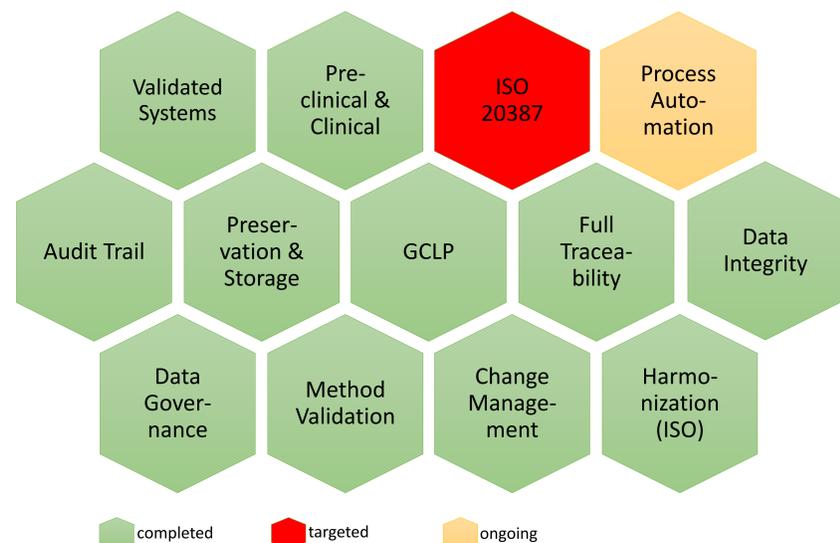
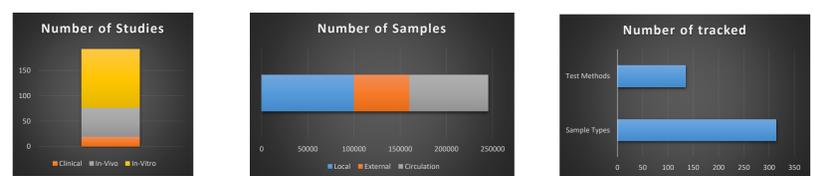
BIMS	LIMS	SDMS	Reporting
<ul style="list-style-type: none"> <li>LabVantage 6.1</li> <li>Manages sample:                             <ul style="list-style-type: none"> <li>Annotations</li> <li>Relationships</li> <li>Events</li> </ul> </li> <li>Provides sample data to other systems</li> <li>Does not store raw data or experimental data</li> </ul>	<ul style="list-style-type: none"> <li>Illumina Clarity LIMS 4.2</li> <li>Receives sample information from BIMS</li> <li>Manages:                             <ul style="list-style-type: none"> <li>Experimental data</li> <li>Link to raw data</li> <li>Reagents and consumables</li> </ul> </li> <li>Does not store raw data</li> </ul>	<ul style="list-style-type: none"> <li>Agilent OpenLAB Enterprise Content Manager</li> <li>Receives sample information from BIMS</li> <li>Automatically fetches raw data from instruments</li> <li>Does not manage any experimental data</li> </ul>	<ul style="list-style-type: none"> <li>INTERVALS</li> <li>Online platform to share data openly</li> <li>Flexible data format to enable interoperability</li> <li>Controlled vocabularies</li> <li>Full sample traceability and access to raw data and processed data</li> <li>Integrates information from internal systems</li> </ul>

## 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.pmscience.com>