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Using a LIMS to Support HTA and MHRA Compliance

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Together with people, processes, systems and oversight, data management forms an integral part of regulatory and quality standards compliance. Critical decisions and outcomes rely on data. The Medicines & Healthcare products Regulatory Agency (MHRA) in its 2018 publication, 'GXP' Data Integrity Guidance and Definitions, uses the acronym ALCOA when talking about data; that data should be Attributable, Legible, Contemporaneous, Original, and Accurate. The MHRA goes on to detail that "data governance measures should also ensure that data is complete, consistent, enduring, and available throughout the lifecycle, where;

- Complete – the data must be whole; a complete set
- Consistent - the data must be self-consistent
- Enduring – durable; lasting throughout the data lifecycle
- Available – readily available for review or inspection purposes."

GOOD RESEARCH ENSURES INTEGRITY, QUALITY AND TRANSPARENCY …

UK Policy Framework for Health and Social Care Research

When considering compliance principles, auditors are most concerned with data quality. There are many reasons why a laboratory will fail their audit. Some of the most common data-related compliance issues include:

- Users having more access to data than permitted in accordance with procedures
- Missing data or source data not retained for validation
- Users permitted to change the default audit trail
- Lack of / missing audit trail to reconstruct changes to data
- Inability to access the audit trail.

A fundamental part of the quality of any data set is to minimize risk; how do you manage oversight to ensure risk is mitigated? Furthermore, a critical aspect of date compliance is how to protect patients' confidentiality, the data that you have on file for a patient and how the patients or donors wishes are met in relation to what consent they have provided.

Making sure that all information recorded is complete and accurate is also an essential element of the auditing process. This requires all laboratory personnel involved with data management to be familiar with and understand the importance of data recording. Again, when a laboratory has Standard Operating Procedures (SOPs) in place all staff must adhere to these SOPs in order that data quality is preserved.

A laboratory management system (LIMS) is a useful and arguably critical tool both for managing sample data and the laboratory auditing process; helping to simplify data recording and ensuring that information held is accurate and complete.

Minimising Risk

One of the first areas that needs to be understood when minimizing risk is how data is being used in decision making. When considering oversight, laboratories, biobanks etc. collect a plethora of data and not all of this information has the same level of priority. Some data is more critical and more important for the decision-making process and, as a result, auditing process. It is essential to understand how data is going to be used, what data is going to be used, when and where.

Also, there are many ways in which data can be transcribed and transferred between teams, labs, and systems. Each of which poses a risk to its quality as well as its security. When identifying oversight and data management risks take into account:

- Inaccuracies due to transcript errors during migration or transfer
- Integrity issues due to missing/lost information or data manipulation
- Unauthorised access to information
- Undetected deletion, amendment, or exclusion of data
- Incomplete/lost information due to inconsistent/disconnected processes and systems.

How can a laboratory information management system be used to mitigate and help reduce risks associated with data management?

Table 1 details common risks associated with the handling and processing of laboratory and patient information and how a LIMS can help in overcoming these issues.

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Table 1: How a LIMS can be used to minimize data management risks

Risk	LIMS
Inaccuracies due to transcript errors	• Data transfer tools • Portals and controlled system access for internal and external users
Integrity issues	• Mandatory data prompts and notification • Relational database reducing duplication and dynamically updating metadata • Dynamic, accessible audit trail to view source data and reconstruct changes • Links to a copy of the source data
Unauthorised access	• Username and password protected system • Assignment of roles to manage data access and actions • Data encryption 'at rest' to protect Personally Identifiable Information (PII) • Configurable user inactivity timeout
Undetected deletion, amendment, or exclusion	• Controlled access to data and actions • Delete request and review/restore system • Automated alerts/notifications to monitor critical data changes • Dynamic auditing (who, when, what and why) • Secure, saved queries and dashboards for data oversight
Inconsistent/disconnected processes and systems	• Centralised system connecting labs • Data migration and transfer tools (SOAP Web Services, RESTFul APIs, Import Tools) adhering to data and metadata protocols • Inbuilt, configurable workflows mirroring SOPs • Barcode label generation and links to scanners • Links to study documents and protocols

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Some LIMS now incorporate a Laboratory Execution System (LES) to help standardize operations and procedures involved with data management. A LES supports LIMS users by guiding them step by step through laboratory workflows. These systems help to reduce risks associated with data processing by enforcing SOPs, improving consistency and compliance, increasing efficiency, and reducing or eliminating paper-based systems (digitalising processes) which can cause errors in procedure as well as operational inefficiencies.

Protecting Confidentiality and Data

Protecting a patient or donors' confidentiality and the data held about them within a laboratory or biobank is of paramount importance. The system administrators and managers have a duty of care to ensure that patient data is safe and treated with the highest confidentiality.

A common compliance issue concerns users having access to more data than they need. A LIMS uses roles to control access to functions and data. To prevent unauthorized access to patient information, a well-designed LIMS will ensure that entry to the LIMS is username and password protected, which together with assigning Role Based Access Control (RBAC) restricts who has the right to view and process patient data. Username and password protected systems with RBAC can prevent unauthorised alteration/deletion of patient data by ensuring access to features, workflows and actions is only for those users who require them. Some LIMS use modern authentication methods to manage system access. Modern authentication further minimizes risk by securely controlling and managing access to the LIMS using sophisticated authentication protocols such as password strength, maximum login attempts, automatic timeout after a defined period of user inactivity, audit of failed login attempts, CAPTCHA, and multi-factor authentication. There are many benefits in using modern authentication including increased cybersecurity centralising and standardising system access management and improved compliance through auditing and managing failed login attempts. End-to-end encryption of personally identifiable information (PII) also helps to guard patient confidentiality.

The ability to export certain types of data can be controlled by protecting information from users who shouldn't have access to it and managing who can export information from a LIMS. Whenever there is any migration or transfer of patient information, data within the LIMS can be protected during transfer between different systems via Secure File Transfer Protocols (sFTP), security tokens and HTTPS. Additionally, ensuring all information is protected with a comprehensive data and audit trail guarantees complete traceability of samples and allows both system users and auditors to see where the data has been accessed and amended and by whom.

Some LIMS systems are now utilising AES-256, the most secure encryption method currently available to protect sensitive data 'at rest' with support for key rolling. AES-256 can work in conjunction with Attribute Based Access Control (ABAC) which offers protection at database level and allows only those users who are working on particular studies or trials to access samples and patient information relating to that research, providing an additional level of security.

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Protecting Patient Wishes

Every laboratory storing, processing, and using patient data is under obligation to only use that information based on the consent and wishes of the patient or donor. A LIMS can help to mitigate the risk of patient samples being used without the appropriate level of consent. Within a LIMS, consent protocols can be defined at project and/or study level and links can be set up to consent documents as well as eConsent forms. The system can be set up so that samples are searchable by consent and actions restricted based on consent status. The LIMS will also notify users when the consent expiry date is due.

Patient samples are, for various reasons, withdrawn from a trial or research study. Laboratories fail audits in this scenario for not managing data in accordance with patient wishes.

A LIMS is able to support laboratory and biobank managers to prevent patient information being used after samples and data have been withdrawn from a study. The LIMS can manage the consent status of patients and dynamically audit consent status and expiry dates. The LIMS allows a user to manage disposal using a process to track samples and record critical information required in an audit e.g., date, person, method, and reason. This provides the auditors with full traceability for those samples where patient consent has been withdrawn and provides information how and why they have been disposed.

Configurable consent within a LIMS enables different consent options to be defined and managed for individual trials and studies so users can adhere to specific study or trial protocols. The benefits of configurable consent within a LIMS include:

- Improvements in data quality
- Provision of evidence for compliance
- Increased flexibility to manage different consent requirements.

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Data Completeness and Accuracy

Data quality relies on information being recorded completely and accurately. Incomplete data, missing or inaccessible audit trials and audit trials that are user editable can result in downstream issues in the laboratory auditing process.

A LIMS can support data quality and integrity by ensuring that data is recorded as required by:

- Facilitating the setup of mandatory data fields by administrators
- Prompting and notifying users to input missing mandatory data
- Designing relational databases with links to metadata
- Prompting users for reason for change on key events
- Tracking approval status on critical outcomes
- Dynamically creating and managing a record audit trail
- Reconstructing records using details in the audit trail
- Restricting data creation/amendments to authorised users only
- Providing data migration and connectivity tools.

In addition, a LIMS dynamically creates and manages an audit trial which is read-only, yet searchable and viewable by authorised users only. This helps quality and compliance managers review individual data records to identify any discrepancies in process or data and prevent missing or inaccessible audit information.

Some LIMS also provide offer Record Versioning that dynamically captures a version of a record when created, updated, deleted in a read-only, searchable xTimePoint table. Record Versioning offers improved data quality and integrity, provides evidence for compliance, and increases confidence in outcomes and results.

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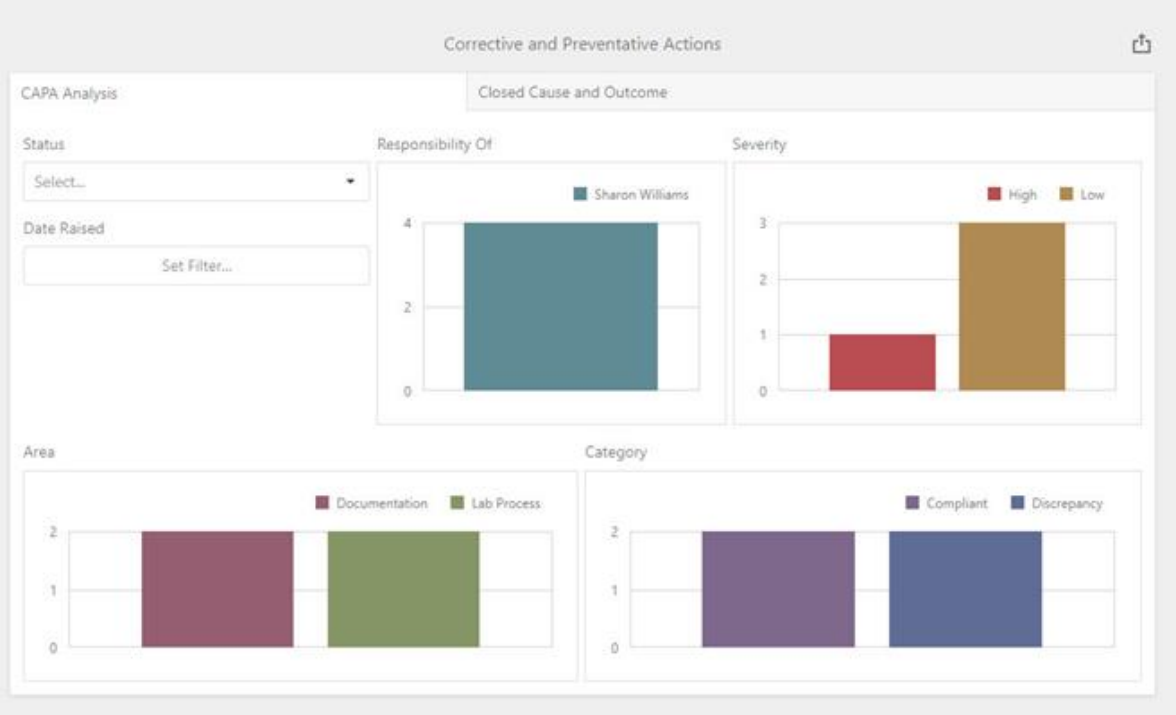
Protocol Adherence and Oversight

Critically, and above all else, a LIMS delivers oversight for data governance by providing a centralised, accessible, searchable data and audit trail. Dashboards and reports allow information to be monitored as well as the management of queries and incidents. A LIMS also provides Corrective Action Preventive Action (CAPA) for tracking non-compliance and allows administrators and users to track supplier and partner visits.



A LIMS offers laboratory and biobank managers a dependable tool to conduct proactive, internal auditing, quality assurance and data governance activities on:

- Samples, storage and consent randomly selected by LIMS
- Audit trail data, data and meta data
- System access (including failed login attempts).

These activities can include query management, CAPA activities, documents, and dashboards to track and manage non-compliance actions and outcomes.

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Compliance Support in LIMS

A well-designed LIMS can provide managers, administrators, and users with a robust and useful data management tool, supporting HTA and MHRA compliance by giving access to accurate, timely and complete data in an easy and comprehensible manner.

Data Integrity Compliance Requirement	Support
Data – Complete, consistent, enduring, and available	✓
Raw Data – Reconstruct activities	✓
Metadata – Defining data	✓
Data Integrity – Secure and available throughout its lifecycle	✓
Data Governance – Quality assurance and monitoring	✓
Data Lifecycle – View data at all phases to destruction/archive	✓
Recording and Collection of Data	✓
Data Transfer and Migration	✓
Data Processing	✓
Audit Trails	✓
Computerised System Transactions	✓
Audit Trail	✓
Data Review and Approval	✓
Computerised System User Access/System Administrator Roles	✓
Data Retention	✓

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Interactive Software Limited

Interactive Software Limited provides Laboratory Information Management Systems (LIMS), Biobanking software and Sample Management Systems that improve quality and compliance and instil good practice through effective processes.

For over 20 years Interactive Software Limited has been helping life science organisations implement successful software solutions that transform the way they work and deliver greater insight into their data. Achiever Medical is a modern, configurable web-based Laboratory Information Management System (LIMS) that centralises lab data and supports pre-clinical, clinical research, academic research and biorepository processes and compliance needs. Managing all sample life-cycle events, the LIMS gives complete traceability of all sample activities providing evidence for compliance and quality assurance.

With the Achiever Medical Laboratory Information Management System (LIMS), our aim is to support labs to get the most out of every valuable sample. This means giving users simple tools to record, search and analyse data so researchers can easily find samples within their inventory and use them for their intended purpose.

Learn more about Achiever Medical LIMS

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