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A Guide to Mapping Laboratory Workflows into a LIMS

Maximise the benefits and avoid common pitfalls

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Introduction

Within a LIMS it is possible to use a combination of processes, workflows, and procedures to simplify and standardise data inputs and outputs. These processes and workflows guide users step-by-step to complete a series of tasks and are often set up to mirror a labs' Standard Operating Procedures (SOPs). Some of these may include automation. For example, in the case of donor registration, a LIMS may present the user with the next steps, while in the background the system is dynamically auditing changes to records.

Other examples include:

- Managing the patient experience. The process could consist of a series of independent workflows that, when connected, map the patient journey.
- Laboratory sample analysis. This process may contain a series of steps or procedures that must be completed sequentially.
- Administrative processes. These could consist of independent tasks that are not necessarily sequential and are restricted to users with specific permissions and roles.
- Reporting and quality management processes. These may happen dynamically in the case of data versioning and auditing, or user triggered in the case of creating Corrective and Preventative Actions (CAPA). The CAPA procedure itself will follow a series of sequential steps and escalation and approval depending on severity.

There are many benefits to using workflows and automated procedures in a LIMS and conversely, several pitfalls that can be avoided with the right guidance.

This white paper details how to get the best from standardising workflows in a LIMS whilst avoiding common, and sometimes costly, procedural mistakes.

Processes, procedures, and workflows

The terms procedures, workflows and processes are often used interchangeably but there are subtle differences in their meaning.

Procedures, Workflows and Processes

- A procedure is a particular way of accomplishing something i.e., a series of steps that must be completed in a set order to achieve an end result,
- A workflow is a series of actions, tasks and procedures that achieve a set outcome,
- A process is a series of workflows, procedures and tasks that contribute towards a high-level outcome.

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Critically, procedures, workflows and processes all involve a set of linked activities.

> *'Set of interrelated or interacting activities that use inputs to deliver an intended result.'*
> **ISO 9001:2015 Definition of a process**

Automation and digitalisation

Many laboratories are moving away from manual, paper-based forms and systems that are onerous and often administration-focused and are instead looking towards modern technologies and solutions to digitise, connect and automate laboratory activities. The aim is to provide a frictionless experience for laboratorians. This journey is often referred to as 'digital transformation.'

The first step in digital transformation is to digitise data. This may include transposing text currently written on paper into a digital format and/or storing images and documents digitally. This helps to structure and standardise information making it easier to search and query information. In addition, by entering data into systems, administrators can control access to that information which helps protect it from unauthorised access.

Once data is in a digital format, it is possible to use technology to digitalise activities. This may include creating procedures and workflows to manage data entry, programming instruments to perform certain tasks as well as connecting systems and instruments to receive and transfer information.

Digitalised processes, workflows and procedures may be performed:

- Manually, where the user enters all the details in the system as each step is completed,
- Automatically for example, in the case of connecting systems to receive and transfer information,
- A combination of both where the user enters some data, and the system then uses that information to perform the next steps.

Automation also can be simply presenting the user with the next step to complete a task, procedure, or workflow, as well as the system dynamically conducting repetitive tasks in the background.

In addition, there are various levels of automation:

- Workflow automation uses rule-based logic to automate or guide users through a series of steps to complete an action for example, donor consent withdrawal,
- Process automation is a more holistic automation of a series of workflows and tasks to achieve a macro-level goal for example, patient experience.

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Digitise Data | Digitalise Processes | Digital Transformation

Benefits of mapping processes in a LIMS

There are numerous benefits of mapping processes in a LIMS, including increased efficiency, productivity, and data consistency which can be achieved by guiding people through standardised workflows and automation.

Mapping processes also facilitates reproducibility as well as improving data integrity and quality as laboratory staff are prompted to enter information at critical points in the process.

All of this supports compliance with regulatory requirements, especially GxP, HTA and MHRA, as the processes maintain data consistency, facilitate repeatability, and promote transparency.

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Potential issues and pitfalls of mapping processes in a LIMS

Despite the many benefits of mapping processes in a LIMS, there are mistakes which can creep in and pitfalls to be aware of.

One of the potential disadvantages in mapping processes in a LIMS is that following workflows can be time-consuming. There are often valid as well as avoidable reasons why some workflows can take longer to complete than before. It is inevitable that some processes will take longer to complete than previously for a variety of reasons such as the way in which data is being formatted and structured, or the fact that more data is now being recorded.

Sometimes processes and workflows are so rigorous that users must enter a value at a specific stage to get to the next step even if they do not have the information or the correct data. This can lead to spurious data being added by the user just to get to the next step in the process.

Likewise, once the benefits of workflows are known, there can be a tendency by users to try and workflow everything which can lead to confusing and complicated processes or simply too many workflows.

Workflows may be out of touch with reality for several reasons including:

- The workflow was designed by individuals who are not hands-on in the day-to-day tasks who do not have a clear picture of the practicalities of the process,
- Regulations change and new regulations are introduced over time. These regulatory changes, together with the introduction of new equipment and personnel, could mean the workflow no longer matches what is actually happening in the laboratory.

Finally, guiding users step-by-step through a process can offer many benefits, but what if they have collected data that is not catered for in a process, or based on the variability in the process, they need to conduct additional steps? How can they manage this?

Whatever the reasons for failure, the result is that the system and or technology usually gets the blame. If laboratory staff do not like the system, it will make compliance difficult.

Why processes fail

When processes fail it is important to understand the cause of the failure to resolve them successfully and avoid making the same mistakes when planning new systems or extending existing practices. Generally, process failure is related specifically to the software, the people involved with the process, or process design and implementation.

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1. Software/technology

Occasionally processes fail due to the software and technology adopted by the laboratory. It may be that the system does not have the configuration tools and flexibility to mirror the actions users currently perform. Critically, in some LIMS, processes and workflows can only be created using code and require users to have certain development skills. This can make it difficult, costly, and time-consuming to enhance or create new processes or manage changes.

2. People

Processes can also fail as a result of the people administrating and using the LIMS.

One of the biggest problems with processes, from a user perspective, is not being clear on what system planners and managers are trying to accomplish. It is important that users understand what the objectives and outcomes are for new processes. If laboratory staff are unclear on what the process is trying to improve or achieve, it will be challenging to gain system acceptance as well as difficult to measure whether those benefits have been achieved.

When designing a new process, laboratories need to prevent too much involvement by management in the detail. Although management buy-in is important, too much involvement in the detail, by people who are not involved in the day-to-day processes, can result in unrealistic processes. Involve both the people who conduct the process, as well as those managing and monitoring the outcomes, to get a realistic view of what happens, how it can be improved and to encourage user buy-in.

Processes can fail because people will not or do not follow them. This is usually because they have not been told the reasons for changes and the benefits to them and/or the organisation. Communicating to those people impacted by the process as well as those who conduct the process is key. Giving laboratory staff who use and are impacted by a process the opportunity to be involved and provide feedback means they will be more likely to accept and support the new method of working.

A lack of defined responsibilities will make it difficult to understand whether the process is successful or not. If people do not understand why they are involved, what they can do, what decisions they can or cannot make, then it becomes challenging to work out who needs to be included and what they should be offering.

3. Process design and implementation

The way processes are designed and implemented will influence their ultimate success or failure. For example, mapping an inefficient process into a system will not make it efficient. It is important to understand where the inefficiencies are and remove them prior to designing the process.

It is not possible or useful to workflow or automate every task. There are some tasks which should remain manual including those that require user intervention and decisions along with those that would take longer to do if they were part of a workflow. Processes should not be designed for rare workflows or those with no benefit. Too much focus on these scenarios can cause projects to derail and teams to lose confidence in the system.

Similarly, processes should not just cater for 'sunny day scenarios.' There should be valid exits, roll backs and negative paths as part of a workflow to prevent users from just entering anything to get out of the system; leaving processes abandoned and data incomplete.

Creating workflows that are unrealistic or overly optimistic can be a side effect of involving the wrong people in the design of the processes. Workflows need to reflect reality and support achievable improvements. Creating workflows to capture the data that would be useful but rarely, if ever, received is certain to cause data issues and negative feelings about the software.

Technology and people change. If your workflows and processes are out of date with the reality of day-to-day data and information flowing into a laboratory, then the system will become increasingly inefficient, lessening its value to the business.

Finally, and mostly importantly, it must be possible to measure the impact of the workflow to know whether it has been successful and delivers the required benefits. Understanding this will also help shape design improvements for the future.

Guidance on LIMS process mapping

Before mapping new processes, it is useful to understand what is already available in the LIMS that can be used, adopted, adapted, or extended to meet the workflow requirements. It may be that there is already a process in place in the LIMS that meets or partially meets the requirements for the workflow being designed.

The next step is to decide what processes to map into a LIMS. There are certain factors that will dictate this.

1. What types of processes to map in a LIMS

- Activities subject to regulatory compliance/auditing
- Time-consuming activities carried out regularly
- Documentation / audit onerous activities
- Repetitive but necessary workflows
- Procedures requiring steps to be completed in a particular sequence
- Activities involving data transfer between systems

2. Who to involve

Deciding who to involve in process mapping can be tricky but whoever is involved needs to have their roles and responsibilities clearly defined.

Management should set out clear goals and guidelines for expected outcomes. Keeping their input at high-level allows them to clearly focus on ensuring perceived benefits and outcomes are realised.

It may be tempting to just include key users who respond positively to change in any process mapping activities. However, to ensure change is well received and adopted it is important to make sure everyone impacted is 'involved.' This could mean including them in progress updates, inviting impacted laboratory staff to review meetings or providing mechanisms to provide feedback.

Therefore, deciding who to involve as part of process mapping needs to be given careful consideration. It will likely include managers to set clear goals and outcomes and key users involved in inputting and receiving outputs from the process.

3. Identifying impact measurements - 'When' and 'How'

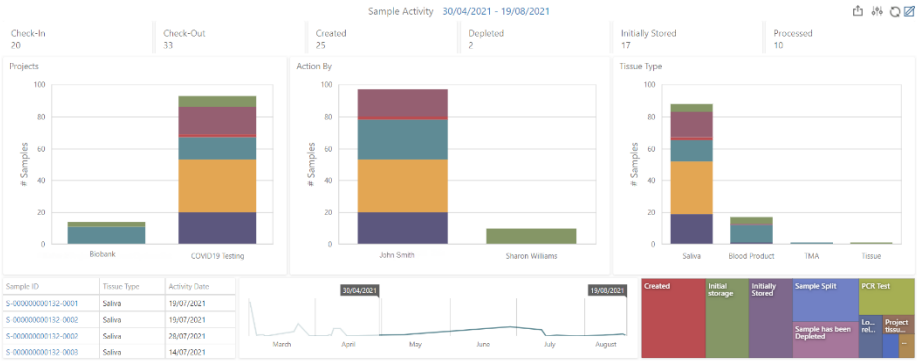
When it comes to identifying impact measurements, it is always important to understand when, how and, at what regular time points to start measuring impacts and benefits, for example, 3 months, 6 months, a year after initialization?

Consideration also needs to be given as to how to measure impact. What measurements will be used? Will feedback come via a form from system administrators? Who will be involved in this process? Is the resource in place to ensure meaningful impact measurements are captured?

The following are examples of potential impact measurements that need to be recorded regularly:

- Has the process improved the quality of the data available?
- Does the system allow for data to be measured in new ways?
- Is the data more consistent and in line with regulatory requirements?
- Are there fewer issues from people or systems from a training perspective etc?

It is also important to realise that these measures need to be reviewed regularly to support continuous improvement and to ensure workflows remaining current and relevant.



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4. Creating a communication plan

Creating a communication plan for those involved and impacted by process mapping allows laboratory staff and system administrators to keep up to date on new workflows and ongoing progress.

It is vital to feedback the benefits that will come from process mapping to the right people. Often the people who will see the benefit are not those involved in the process, but it is important that users buy-in to the overall process.

5. The devil is in the detail

When it comes to putting processes into a LIMS, beginning with high-level processes is the logical starting point. After listing these processes, tasks need to be assigned - whether they are manual, user-driven in the system or automated.

Unlike manual processes, implementing a workflow in a LIMS requires information such as:

- Where your starting point is and what the inputs are,
- What data and functionality the user and system have access to at each point in the process,
- What data needs to be captured for the next step,
- What other data and processes are impacted,
- What are the outputs.

The practicalities of different procedures and workflows vary. It may be that once a procedure has started it has to keep going to the end. However, there are workflows and procedures that involve multiple steps, instruments, and individuals. Understanding these and whether they can be split into smaller workflows and procedures will help identify repeatable workflows that can be reused and hook into larger processes – this maximises resources and reduces support and configuration.

Questions to ask to help identify these:

- Is it possible to split out individual workflows and procedures to create natural breaks?
- Will the information required be available at the point in the process?
- Is the process completed in one step or should part A be completed and then part B picked up later?
- If the process is started towards the end of the day and the user runs out of time is there a convenient place to stop, store the samples and pick up again in the morning?
- Is this procedure or workflow included as part of multiple processes?

Conclusions

Mapping processes in a LIMS delivers benefits including increased data efficiency, productivity, and consistency for regulatory compliance.

On a practical level, consideration must be given to who is going to be involved in mapping the process, their specific roles and responsibilities and the feedback mechanisms in place to provide useful and meaningful impact measurements on a regular basis.

By following the correct guidance from system specialists, it is possible to design a LIMS for the particular and unique requirements of any given laboratory.

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. Making every Sample matter.

Learn more about Achiever Medical LIMS

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