

A photograph of three scientists in a laboratory setting. A man with glasses and a white lab coat is on the left, looking at a computer monitor. A woman in a white lab coat is in the center, looking at the monitor. Another person is partially visible on the right. The background is a blurred laboratory environment.

## Feature

# Insight and advice for a successful LIMS deployment

**CliniSys has created a deployment model based on the tried and tested PRINCE 2 methodology. It works, but there are plenty of things that Biomedical Scientists can do to help, as Moira Johnston, Matt Foreman and Tony Oliver explain.**

Our delivery experts argue that a good implementation project depends on planning, stakeholder engagement, harmonisation, resourcing, and testing, but it's attention to detail and getting the right people in the right place at the right time that are key to success.

Pathology is working through a period of profound change. Following the well-known report by Lord Carter of Coles, that suggested hospital laboratories should collaborate to improve efficiency and quality, NHS England / Improvement has been working to create hub and spoke networks.

These networks have many requirements, including strong leadership, new ways of working and, in many

cases, new equipment and IT systems. CliniSys Group has been working hard to make sure that its laboratory information system WinPath Enterprise, can meet their requirements.

Our LIMS is now in use in more than 60% of NHS trusts and has been chosen to support 34 pathology networks in England. However, we know that a great IT system is not enough. Networks and the laboratories need to be able to deploy their new LIMS and deploy it in a way that delivers on the support, efficiency and quality benefits outlined in the business case.

To make sure that happens, CliniSys Group has developed a 'master build' for WinPath Enterprise, that incorporates best practice workflows from around the country. It means new customers have a good foundation to build on, while still being able to accommodate local requirements.

We have expanded our deployment team and created a structured model to get new project managers up to speed quickly, that includes

'buddying up' with more experienced colleagues. And we have created a deployment model for our customers that is based on the tried and tested PRINCE 2 project management methodology.

The deployment model creates a structure that sets out the stages and stage gates – or checkpoints – that need to be cleared to go live. We know it works, because we have seen networks go-live over the two years, despite the huge pressures that have been placed on pathology by the Covid-19 pandemic and the unprecedented demand for health services that has followed.

Even so, there are plenty of things that pathology networks, laboratories, BMSs and their IT colleagues can do to make sure the process runs smoothly. So, here are some of our top pieces of advice:

## Planning

Big projects can be exciting and rewarding, but they can also be challenging and exhausting. Over time, communication can diminish and progress can stall. The antidote to this is good planning: both at the beginning of the project and at each stage.

In the initial eagerness to get on, you may be tempted to skip, or rush through, this part of the project: but taking the time to plan well, at the beginning and at each stage, helps to make sure that everyone is on the same page, and that everyone knows ahead of time what it will take to get to the next milestone.

Good planning underpins good communication and stakeholder engagement. It helps to make sure that people know their role and what's needed from them at any given time, making it easier to help as and when that's needed. Which brings us to:

## Stakeholder engagement

Stakeholders are the people who are involved in the project or affected by its outcome. It's important to understand who the stakeholders of your project are, and what involvement or information they might need to have.

A RACI matrix helps you to define who will be involved in the project. RACI stands for Responsible, Accountable, Consulted, and Informed. If you take the time to complete it during the planning stage, it can be used to drive communication throughout the project. Bear in mind, though, that a stakeholder's needs and interests can change throughout the life of a project, so it's important to review your RACI matrix regularly.

Once you know who your stakeholders are, it's important to understand them. An executive stakeholder might see project success as a project delivered on time and on budget, but an end-user might care more about the workflow they will be using or whether they have had enough training.

It can be easy when driving a project to become very task focused, but as experienced project managers we can tell you that balancing the needs of the project with the needs of its stakeholders will be key to success.

## Harmonisation

Harmonisation is about bringing multiple sites and systems together into a single way of working. A critical success factor for a LIMS deployment is whether the network has been harmonised onto a single way of working before the project starts or, at least, whether harmonisation business change activity is well underway, and sufficiently advanced to ensure that the system design is not delayed by decisions on ways of working.

Really, it's best to secure alignment ahead of your LIMS implementation, to reduce the risk of potentially costly delays, and to describe it as a Target Operating Model. Defining the Target Operating Model is a clinical activity that will need to be led by the pathology service management and domain subject matter experts. It requires early engagement and regular discussion, with decisions being made and captured effectively.

As with most things related to LIMS projects, you'll find that the devil is in the detail. Seemingly innocuous differences can become magnified into project showstoppers if they are not flushed out and addressed head on: the earlier the better.

So, make sure there is strong direction from the project governance structure, so difficult decisions can be readily escalated and resolved quickly. It's also important to look beyond current ways of doing things. Don't think: 'how do I recreate what we have now?', think: "What would be the most efficient way of using the LIMS to solve a clinical workflow challenge?"

Facilitating this kind of business change is a skill, so it's worth considering whether to bring in professional change management people. Which brings us to resourcing:

### Examples of harmonisation considerations: Blood – Electronic issue

#### Blood Transfusion – Electronic issue

- Do you perform this on your site?
- Are the methods the same on all sites?
- What specimen criteria do you use?
- What exceptions to electronic issue do you have?

#### Blood Science – Test profiles (or sets)

- Are you using the same contents within each profile or set?
- Does the set or profile contain the same number of tests and also same types?

## Resourcing

Another critical determinant for success of any project is the ability of an organisation to accurately recognise and address the resourcing needed to complete it within an agreed timescale. In a LIMS contract, the deployment timescale is fixed and the scope of work is fixed, so the business case needs to allocate resources to meet these constraints.

It's tempting to believe that your supplier will do the build and the testing and present you with a fully functional system that everybody will just start using at go-live. When in reality, as with most things in life, you will get out what you put in.

As indicated above, it's a high level of engagement, with good people sustained throughout the project, and particularly during design and user acceptance testing, that will result in a well built, clinically safe system; and a smooth go live that will run to the project timeline.

CliniSys provides a guide to the resources required at each stage of a LIMS implementation project as part of our standard methodology. The number of days of customer effort can range from 1,000-3,000 days depending on the scope of the project.

That's a lot, and that, plus the complexity of the work, underlines how project/programme managers are critical appointments. It's no longer sufficient for the pathology IT manager or a lab manager to try and do this "on the side of their desk"; it requires time, experience and training.

The customer effort requirement will vary at each stage of the project, but it tends to peak during the design phase and again during user acceptance testing, when a given department may need to have 1-2 whole time equivalents working on the project full time for a number of months.

We've already explained how subject matter experts in the clinical domains will need to be involved. But ICT networking, infrastructure architects, and integration engineers will also be needed, particularly in the early phases.

It may be painful to 'lose' some of your best people to a LIMS implementation project for a while, but as project experts we will tell you that it is more painful to have an overrunning project that draws resource for way longer than it needs.

Also, don't forget about third party suppliers. The analyser/diagnostic equipment suppliers, the electronic patient record and clinical system vendors, any legacy LIMS providers, will all need to be engaged at the right time to provide testing for instrumentation, integration, and the provision of data for migration.



## Testing

"Don't underestimate the testing phase" is another, key message and one that we always communicate at project kick-off. A meticulous testing strategy and testing plans are required not just to ensure quality, but to preserve project budget and resource levels and to keep those project timelines on track.

CliniSys uses CATS to reduce testing resource requirements by at least 50%. But CATS, which stands for CliniSys Automated Testing System, doesn't negate the need for a plan and test scripts, so it's never too early to start defining them.

In fact, designing the test scripts should start during the low-level design phases, when you can consider whether you will attempt to cover every single workflow and combinations, or whether you'll stick to common workflows, without disregarding fragmented or less frequent workflows.



This scope of testing is key and should not change once the project and testing has begun: the in scope and out of scope items should be clearly defined and the test activities set out in a Test Plan.

The time it will take to complete the Test Plan activities should be clearly communicated to everyone involved before testing commences. That way, any delay can be communicated within the structure of the project governance model.

We talked about resourcing above, but testing is so important that an experienced testing manager should be assigned to lead the test teams and to manage the whole testing phase and process. This is another area in which it is best to have a dedicated resource, rather than someone taking this on as an assumed role.

### Key test parameters: coverage, quality and time.

#### Coverage:

- All 'critical' and 'high' importance level scenarios have been executed and passed, meaning that they have met the expected outcome.
- Coverage objectives have been achieved for 'medium' and 'low' importance level scenarios.

#### Quality:

- Probability of issues remaining has been reduced to an acceptable level.
- No 'open' severity 1 or severity 2 issues.
- Coverage objectives have been achieved for severity 3 and 4 issues.

#### Time:

- End of acceptance test project date has been met.

## Plan for after the go-live event

To ensure a smooth transition from the go-live event to business as usual it's important to plan for what our pathology network's standard business operational model will look like.

That will mean reviewing what is currently in place, as an individual trust SOPs are likely to be different to the Standard Operating Procedures required for working with a pathology system designed for a network. One thing to think about is whether a new, centralised service desk will need to be introduced or whether the trusts coming together in the network will continue to triage calls locally.

Many networks are using a mixed model, but if that's where you end up, the model should be mapped out from an early stage. That way, only authorised users will log incidents with the CliniSys Helpdesk, after they have been triaged with the end users.



## Final thoughts: it's all about building and sustaining momentum

A LIMS deployment project is no different to any other, major project. To succeed, you need leadership, and stakeholder communication, and structure, and resources. You also need to make sure that you are continually making decisions and looking ahead to the next stage, to maintain momentum.

Our deployment model is all about building momentum and making sure that the right people are in the right structure to do the right things at the right time. That generates confidence.

It means the energy that comes from a LIMS procurement is captured and channelled into a project that can demonstrate that progress is being made, that everything is on track, and go-live is going to happen.

Many networks are planning LIMS deployments over the next few years, so you are very likely to find yourself involved in a go-live project at some point.

Our final piece of advice: if you get the chance, get involved and enjoy it!

This is a rare opportunity to make a contribution to the development of a network and to creating a better service for your colleagues, clinicians and patients. A LIMS deployment is a huge amount of work, it's challenging, it's exhausting. But it's also hugely rewarding, particularly on go-live day, when everything clicks into place.

Pathology networks are now forming at pace and many are choosing the WinPath Enterprise LIMS. CliniSys Group has responded by expanding its deployment team and creating new resources to help customers run effective implementation projects. A LIMS implementation can be challenging, but if you're going to be involved in a go-live project, our article will help you understand what's required and how to get involved at this exciting time.

### About the authors:

#### **Moira Johnston, Programme director:**

"I'm a recent recruit to CliniSys. My background is in project management, and I've worked in both the NHS and business. I'm passionate about continuous improvement. CliniSys has a deployment methodology, but we're always looking to make it more productive."

#### **Matt Foreman, Programme director:**

"I have been with CliniSys Group's parent company, Roper, for many years. I used to work for Sunquest and now I work on LIMS delivery. We have worked hard on our master build and our deployment methodology, so we know what needs to be done: my job is to make sure that it works."

#### **Tony Oliver, Programme director:**

"I am a clinical virologist by training. I've been at CliniSys for four years and my focus is always clinical safety, ensuring effective risk management as well as maximising clinical efficiency for our customers."