# LINC

## The latest news from the Laboratory Information Network Cymru Programme (LINC)



## A new laboratory information system for Wales

Welcome to the LINC Newsletter, keeping you up-to-date with the Programme that will enable Pathology modernisation through the delivery of end-to-end systems and services to include a new laboratory information management system (LIMS) for Wales.

It has been some time since we sent out a newsletter but there has been a lot happening and we thought that the time was right to bring you up-to-date with the programme.

LINC began the procurement of a new LIMS Service in January 2020 and has now chosen a preferred supplier. The aim is to put a contract in place in the autumn after the full business case is approved but discussions with the supplier have started already.

LINC has completed an amazing exercise to extract and document all the configuration of the current LIMS, totalling 14,000 configuration items. Nearly 80% is standardised and work is now progressing to complete the standardisation of mainly test set workflows.

LINC has established a permanent Quality Management Team to maintain validation of the new LIMS service and standardisation within an ISI9001 quality management system.

LINC is investing in the improvement of tools for electronic test requesting and increasing uptake to 90% by December 2022. This will deliver real benefits and a project to help the development of local health board and trust benefits plans is making good progress.

Next steps after the contract award is also set out.

If you have any queries or feedback, please do not hesitate to get in touch with me or one of the team.

**Adrian Thomas**
**Senior Responsible Owner**
**LINC Programme**

# PROCUREMENT OF A NEW LIMS SERVICE

The aim was to procure a new LIMS Service that meets current and future Pathology service requirements. Digital Health and Care Wales (DHCW)* Commercial Services led the procurement supported by three procurement teams comprising 50 staff, more than half from the pathology service. These teams were responsible for functional/technical, operational/governance or commercial/legal/financial aspects of the requirements.

A contract notice was published in January 2020 advising bidders across the world of the opportunity. In March 2020, from eight initial bidders, the procurement teams longlisted five suppliers, just as the global pandemic took hold. All five longlisted suppliers were asked if they were happy to proceed remotely to which they agreed, and more time was allowed for them to submit their initial tender responses. In the end, the whole process took place virtually.

Three suppliers were shortlisted in August 2020 and subsequently engaged in two rounds of competitive dialogue in September and November 2020. Following this the shortlisted suppliers were invited to submit trial final tenders by 12 February and their final tenders on 9 March 2021.

The final scoring took place over the next two weeks and findings presented to the LINC Programme Board in April 2021. However, at that stage, the Board felt further clarifications were needed from the preferred supplier. Subsequent to satisfactory clarification being received in May 2021, the Tender Evaluation Report was approved by the Board in June 2021.

An external Gateway Review took place in April 2021 to assure the procurement process and full business case. The review team commented; "we would like to acknowledge the exemplary way that the procurement was conducted through the pandemic. This is to the credit of all involved and the lessons learned should be shared widely." As they were unable to receive the tender evaluation report at that stage, the review was repeated mid-August 2021.

The contract will be signed with the preferred supplier once the LINC Full Business Case (FBC) has been approved by all health boards and trusts providing or using pathology services. Welsh Government also have to approve the FBC and is considered by their Digital Scrutiny Panel. When all the approvals have been confirmed, the Minister for Health and Social Services gives approval for the contract to be awarded, currently planned for the autumn 2021.

* formerly NHS Wales Informatics Service (NWIS)



**Karis Jones**
**Senior Project Manager**
**LINC Programme**

# QUALITY MANAGEMENT PROJECT

As part of the scope of the LINC Programme, a National Quality Management Service has been established. This permanent team will lead the validation of the new LIMS throughout its life cycle and will support the standardisation of the Pathology service across Wales.

The Quality Management Team has developed a new national Quality Management System to ISO 9001, which is currently going through the certification process and has had two successful visits by the appointed Notified Body, Lloyds Register. The final certification audit will be conducted when enough evidence of the Validation activities of the LIMS system is available to demonstrate conformity with the existing processes and procedures.

This Quality Management System is underpinned by iPassport, an electronic Quality Management System (eQMS) to maintain controlled documentation for accreditation and validation purposes. This system was procured, and contract awarded back in March in 2020 and it is available for use primarily to NHS Pathology services in Wales. The eQMS account and its validated state is maintained by the LINC Quality Management team.

The Quality Management System will provide a robust framework for the following activities:

- Validation and accreditation of the new LIMS Service throughout its life, including user acceptance testing. This will be done in accordance with Good Automated Manufacturing Process (GAMP) 5.
- Clinical risk management, to ensure the LIMS is clinically safe before going live. This will be signed off by the discipline Clinical Leads, qualified Clinical Safety Officer and the Welsh Informatics Assurance Group.
- Supplier audits, to ensure that the supplier meets a range of quality, information governance, information, validation and technical standards.
- Training activities to cover testing, end users, service management and configuration.
- Support the Standardisation Strategy Group and discipline-specific standardisation groups to maintain standardisation throughout the life of the Contract.



**Quality Management Team (from left to right)**

**Stacey Richards – Quality Management Officer**
**Bhavani Shangalla – Pathology Test Analyst Trainer**
**Ana Maldonado – Quality Manager**
**Scott Bevan – Pathology Test Analyst Trainer**
**Callum McCormack – Pathology Test Analyst Trainer**
**Mark Korankye – Senior Project Support Officer**

# BENEFITS REALISATION PROJECT

The purpose of the project is to identify the benefits of the LINC Programme, establish their value and recognise how they'll be achieved and measured.

Benefits stem from the investment being made through the LINC Programme, for example:

- A new LIMS Service, updating and reconfiguring our digital approach to pathology
- Standardisation, simplifying and standardising data and workflows to allow greater cooperation between health boards
- Quality management to maintain validation of the new LIMS Service and standardisation of services
- Enabling Electronic Test Requesting (ETR) take up to increase to 90% by December 2022 through funding to DHCW to improve the tools and health boards to support take up
- Development of business intelligence including real time operational dashboards to manage workload in the laboratory

A benefits group was formed with benefit leads for each health board, PHW and DHCW. This group held workshops to define LINC benefits and discuss how to measure them from tangible financial and efficiency savings, to more abstract concepts like patient care and business intelligence. The result was a national benefits register comprising all the possible benefits that could be realised.

Each health board has now agreed which benefits they can own and include in their own benefits register and local benefits plans are being developed.

A benefit by definition needs to have a measurable effect, but this can be difficult to realise in the real world where data can hard to obtain. Our benefits leads have helped immensely in gathering the data required. This has included use of LIMS data, staff surveys and case studies within labs.

One such benefit is the time saving involved in reception processing test requests due to the increased uptake of ETR. A case study found that paper requests take on average 49 seconds to process with ETR requests only taking 18 seconds. The difference in cost was calculated using the expense of reception staff and the volume of tests being processed, some 11.5 million episodes. We then calculated ETR rates across health boards from 2020 all the way until LINC's input in April 2021 as shown in the dashboard. LINC's contribution is estimated at half the savings made from 45-90% of ETR nationally, to be completed by December 2022. This was costed to save around £303,000 in efficiency savings, allowing staff to be released to another tasks.



**William Brailsford**
**Pathology Informatics Officer**
**LINC Programme**

| LINC Benefits Register | | | |
|---|---|---|---|
| **Business Need** | **Ref** | **Benefit** | **Benefit Type** |
| ETR | B1 | Reduction in number of repeat tests | Cash releasing |
| End to end solution (NPEx) | B2a | Reduced time spent process tests outside of Wales | Cash releasing |
| | B2b | Income for external tests retained | Non-cash releasing (Cost avoidance) |
| ETR | B3 | Reduced time spent processing referrals | Non-cash releasing |
| BI | B4 | Service has capacity to meet growing demand | Cash releasing |
| ETR | B5 | Improved clinical safety | Quantifiable |
| ETR / End to End Solution | B6 | Optimise diagnostics on single cancer pathway contributing to 62-day target and improved patient outcomes | Quantifiable |
| Standardisation | B7 | Patient results easier to compare as standardised reference ranges across laboratories | Quantifiable |
| End to End Solution | B8 | Improved national helpdesk services | Quantifiable |
| End to End Solution / Integration | B9 | Improvement user interaction and experience | Quantifiable |
| End to End Solution | B10 | Managed service will reduce DHCW activities on supporting the solution | Quantifiable |
| End to End Solution / Standardisation | B11 | Reduced time for "clinical validation" (e.g. in Clinical Biochemistry) | Quantifiable |
| End to End Solution / Integration | B12 | Segregation of blood transfusion functions | Quantifiable |
| Business Intelligence | B13 | Transparent and usable KPI's | Quantifiable |
| Business Intelligence | B14 | Better Business Intelligence reports and dashboards | Quantifiable |
| Laboratory Processing / BI | B15 | Improved MHRA compliance | Quantifiable |
| Laboratory Processing / BI | B16 | Improved UKAS compliance | Quantifiable |
| End to End Solution / Standardisation | B17 | Single, standardised LIMS configuration across Wales | Quantifiable |
| Standardisation | B18 | Improved capacity to support LIMS service upgrades | Quantifiable |
| Business Intelligence | B19 | Improved performance management | Quantifiable |
| End to End Solution | B20 | Increased availability of the system | Quantifiable |
| Standardisation | B21 | Single legacy database | Quantifiable |
| End to End Solution / ETR / BI | B22 | Demand Optimisation | Quantifiable |

# STANDARDISATION AND DESIGN PROJECT

One of the major objectives of the LINC Standardisation and Design Project has been the extraction and documentation of all the configuration items contained within the current WLIMS1 (TrakCare Lab 2016), called the 'Current State'. This has never been attempted before, so it has not been possible for the service to readily review this configuration since it was first implemented in WLIMS1 nearly 10 years ago.   A 'Current State' organisational unit has been created in the iPassport electronic Quality Management System eQMS) to store all extracted configuration items.

| Current state configuration item (CSCI) | Total No and % of CSCI & TSW extracted/ documented | | No and % of CSCI and TSW Items no longer required OR For New Supplier to define. | | No and % of CSCI & TSW Items in standardised form | |
|---|---|---|---|---|---|---|
| **Business Intelligence** | 282 | 100% | 90 | 32% | 192 | 100% |
| **Code Tables** | 118 | 100% | 4 | 3% | 114 | 100% |
| **Core Functionality** | 9921 | 100% | 290 | 3% | 9631 | 97% |
| **Reference Ranges** | 16198 | 100% | 5988 | 37% | 10210 | 100% |
| **TSW Workflows** | 1656 | 100% | 31 | 11% | 523 | 32% |
| Andrology | 3 | 100% | 0 | 0% | 2 | 67% |
| Blood Transfusion | 33 | 100% | 0 | 0% | 33 | 100% |
| Biochemistry | 773 | 100% | 12 | 2% | 14 | 2% |
| Cellular Pathology | 21 | 100% | 0 | 0% | 5 | 24% |
| Haematology | 213 | 100% | 13 | 6% | 29 | 14% |
| Immunology | 161 | 100% | 6 | 4% | 0 | 0% |
| Microbiology | 401 | 100% | 0 | 0% | 401 | 100% |
| Screening | 51 | 100% | 0 | 0% | 39 | 76% |
| **Grand Total** | **28175** | **100%** | **6403** | **23%** | **20670** | **73%** |

The Current State Master Catalogue lists all the configuration items, and a dashboard has been developed to track the progress with this work showing 28,000 configuration items covering business intelligence, code tables, core functionality reference ranges and test set workflows. Documenting the current state was a very complex and laborious piece of work and has taken two years to complete. The test set workflows are particularly complex and preparing the current state involved several steps, from extracting and analysing the raw data, and converting into an MS Visio diagram to represent the process in a way that makes sense to a pathologist to review. Blood transfusion, microbiology and screening workflows are standardised, leaving 1,256 for the team to produce.

The project is led by Kevin Williams, Lead Pathology Subject Matter Expert (SME) and managed by Greg Ead, Senior Project Manager. The current state work has been led by Gabriel Kumar, LIMS SME who manages a small, skilled team with intimate knowledge of the current LIMS data and processes as well as a general knowledge of pathology disciplines is required comprising Andrea Abbott and Rhys Williams, both Pathology Business Analysts and Simon Watton Programme Support Officer supported by Phil Waters, BI SME, Juber Islam, Pathology informatics Officer, DHCW WLIMS1 Configuration Team and Steve Williams, Aneurin Bevan UHB, who helped to finish the Haematology workflows.
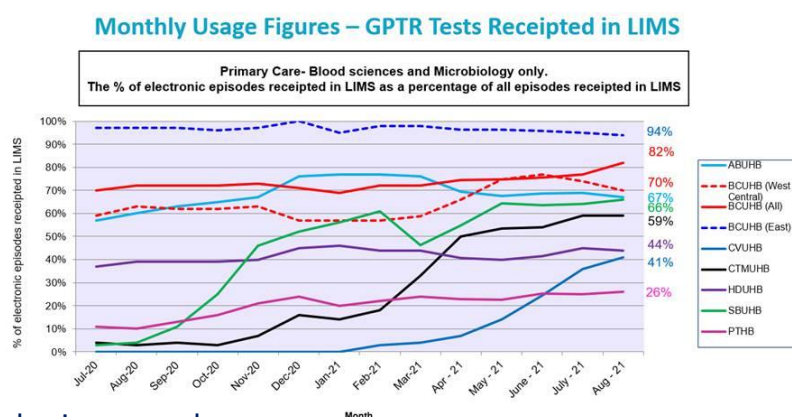
This is an amazing achievement, and the standardisation leads, and groups have already started reviewing and standardising the test set workflows to be implemented in the new LIMS Service and, where feasible, initially in WLIMS1.

# ELECTRONIC TEST REQUESTING

LINC is enabling the uptake of electronic test requesting (ETR) across NHS Wales by funding development of in-house tools and paying health boards to increase the uptake in primary and secondary care. The aim is to achieve 90% ETR by December 2022.

DHCW set up an ETR Project Board chaired by Dr Robert Bleasdale, Consultant Cardiologist, Cwm Taf Morgannwg UHB (CTMUHB) and have set up a subject matter expert group of test requesters and pathology staff to plan future development.

DHCW created a roadmap for the development of ETR and improvements included enabling Powys Teaching Health Board to use ETR, results notifications and the graphing and tabulation of results. A release was due in the autumn 2021 to include a new e-form in the Welsh Clinical Portal (WCP) that will be easier to use and Histology reporting. This development is now ready to be integrated into the WCP and Welsh Results Reporting Service, but the team who need to do this have to prioritise covid work and so the release is delayed until the New Year 2022.



The take up in primary care is increasing although the highest use in Betsi Cadwaladr UHB (BCUHB) East is because the GPs are using ICE. The aim is to improve in-house tools to be as good as a commercial tool. Swansea Bay UHB (SBUHB) GPs are the most improved from almost 0 to 64% over the last year.

Uptake in secondary care has always been high in BCUHB and CTMUHB, but the latter's figures now include the Princess of Wales Hospital. Velindre NHST is the most improved but Cardiff and Vale UHB have to be applauded for the amazing progress they have made. LINC is preparing a case study on their experience.
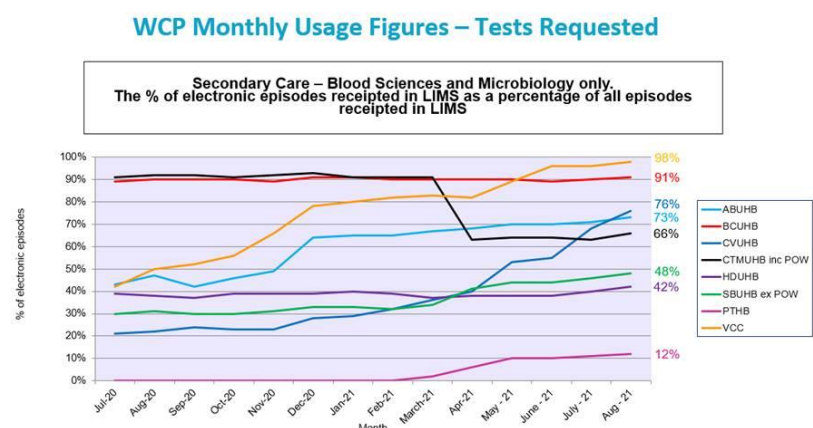
# NEXT STEPS

Over the next 18 months, after the award of the contract, the focus will be on developing, testing, and validating the new LIMS service to deliver intended requirements, ensure it is fit for purpose and clinically safe to go live.

This work will be taken forward by the National Development Projects:

- ***Standardisation Project*** will complete the standardisation of the configuration to define the future state requirements, managed by Greg Ead.
- ***LIMS Service Project*** will manage everything the supplier has to deliver, managed by Jon Savill.
- ***Quality Management Project*** will lead validation, testing, training, supplier audits and clinical safety, managed by Lucy Poole.
- **National Deployment Project** to ensure all the NHS services are in place to support the new LIMS Service after deployment, managed by Karis Jones.
- ***DHCW LIMS Project*** to ensure DHCW prepare for the new LIMS Service, managed by Louise Gregory.
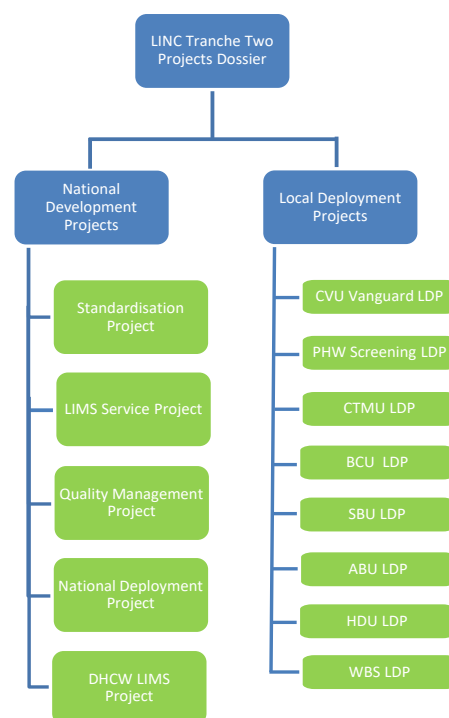


In addition, ***Local Deployment Projects*** are being put into place to contribute to the development, testing and validation and to prepare for and deploy the new LIMS Service. Cardiff and Vale University Health Board will be the first to go live as a vanguard for the rest of Wales.

| Tranche 0 | Tranche 1 | Tranche 2 | Tranche 3 | Tranche 4 |
|---|---|---|---|---|
| Pre-procurement | Procurement | Development | Deployment | Close |
| Apr18-Dec19 | Jan20-Sep21 | Oct21-Mar23 | Apr23-Dec24 | Jan25-Mar25 |
| Outline business case Contract documentation Standardisation approach Quality management | Procurement Benefits specification Standardisation design Business change Full business case | Hosting LIMS Service - development - Testing - UAT - Validation Once for Wales Preparation for deployment | 1. CAV & PHW Screening (6 mths) 2. CTM (3 mths) 3. BCU (3 mths) 4. SBU (3 mths) 5. ABU (3 mths) 6. HDU (3 mths) | Handover to operations Programme closure |

Once the new LIMS Service is ready for operations, deployment is expected to take 21 months until December 2024, as set out in the plan above.

## We want to hear from you

In 2019, LINC carried out a survey of staff to find out what you knew about LINC and what you thought about standardisation. You can find out the results of this survey on the [LINC internet site](#).

LINC planned to repeat this survey each year to see how views change but did not repeat the survey last year due to covid. But following the roadshows that LINC held earlier this year, it is planned to run the survey again in September and we hope that you will take part and encourage colleagues to also respond.

We have kept all the questions the same so we can compare the results with the previous survey. We hope you take part as we are keen to know your views.

## Goodbye to Mark



The LINC team would like to thank Mark Korankye for his contribution to the LINC Programme. Mark left us on Friday 20 August 2021 for pastures new. He is going to work closer to home at the University Hospital Bristol and Weston NHS Foundation Trust as a Digital Services PMO Officer.

We all wish him well in his new role!

## Goodbye to Stacey



On Friday 17 September 2021, Stacey Richards will be leaving the LINC team to work for Maximus UK who deliver employment and skills programmes across England, Scotland and Wales as the Quality and Continuous Improvement Lead.

The LINC team thanks Stacey for all her hard work and wish her the best for the future.

# Join the Team



LINC will be advertising soon for Test Leads (band 7 backfill) and Test Analyst Trainers (band 6) in Blood Sciences and Cellular Pathology. We need staff with laboratory experience and welcome staff on secondment or fixed term. Training will be offered as laboratory experience is more important. If you are interested, then please contact Gabriel Kumar: Gabriel.Kumar@wales.nhs.uk

We will also be advertising for a Senior Pathology IT Officer (band 6). If you are interested, then please contact Jon Savill: Jonathan.Savill@wales.nhs.uk.

# Contact LINC

LINC are keen to get your views on the newsletter and the programme. If you have any questions that we can answer in future editions, then please do ask one of the team.

You can contact us at LINC.PMO@wales.nhs.uk or directly:

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