Pathology Test and Results Standard Consultation Report
Version 1.0 FINAL

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NOTE: From 1 February 2023, Delen - the information sharing and collaboration platform for Terminology and Classifications products - has migrated from https:///hscic.kahootz.com to https://nhsengland.kahootz.com. URLs in this document have been corrected to ensure continuity of access. No other changes have been made.

1. Background

As part of NHS England CCIO7 work streams, NHS Digital is delivering the ability to share pathology results across health and care. Within the scope of this work, NHS Digital is defining Pathology Information Standards aligned with clinical, commissioning and patient needs to support the sharing of pathology tests and results across care settings and organisational boundaries.

The Pathology workstreams are defined as three broad areas of information standards to meet future NHS needs for interoperability and secondary care use:

- Unified Test List (UTL) – a national catalogue of Pathology test requests and results to replace the Pathology Bounded Code List (PBCL), based on SNOMED CT.
- Units of Measure (UoM) – an unambiguous representation of commonly used units, aligned with the UTL, based on Unified Code for Units of Measure (UCUM).
- Pathology Message Specification – for interoperable data exchange of Pathology information, based on Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR).

The NHS Digital Pathology Business Product team is looking to establish collaborations in interoperability and information standardisation for key pathology initiatives across Health and Social Care to agree an approach for moving existing pathology estate and infrastructure to a future state based on updated national standards.

2. Key Stakeholders

To enable the above the Pathology team has multiple workstreams in place to support consultation and development of future pathology standards. The objectives of the stakeholder management workstream is as follows:

- To consult and to seek direction from the existing stakeholder community and inform on updates via proposed solutions. Encourage a two-way dialogue to allow innovation and to retain and expand knowledge around the projects.
- To promote, raise awareness and build the reputation of the benefits the workstreams offer, communicating key messages and ensuring decision makers remain engaged and informed.
- To ensure that communications are appropriately approved following internal practices.
- To outline the plan for all communications and engagement over the current financial year.
- To ensure that the team has a consistent approach for engagement with suppliers. This will help to ensure demonstrate transparency and equitability.
- To incorporate new and innovative ways to communicate with stakeholders.

We have completed a large-scale Stakeholder Landscape Discovery project to identify and manage all our key stakeholders and to ensure we are consulting with and informing of design decisions at the right stages of development. See below:

1. Stakeholder discovery Pathology.docx

2. Pathology stakeholder landscape 16_10_2020.xlsx
3. Pathology Stakeholders Mind Map August 2020.docx
4. Stakeholder list (in conjunction with strategy).docx

We have a detailed list of all LIMS suppliers, Professional Bodies and Middleware identified to support the programme of work. We have mapped our stakeholders in terms of priority and influence to evidence the type of consultation that would be required and put in place stakeholder plans over the course of the year, to enable effective consultation periods to support development.

The key messages which stakeholders need to be aware of that are taking place within this workstream are as follows:

- Development and endorsement (where possible) of the use of national data standards for test names and units across diagnostic areas.
- Development of data sets (i.e., the clinically relevant patient data required to accompany a request / result for the best diagnostic decisions), using the pre-defined data standards.
- Development and implementation (where possible) of messaging standards to support interoperability across information systems in community, primary, secondary, and tertiary care.

This should lead to the following long- term objectives:

- **Patient care:** Achievement of efficiency savings from the electronic automation of diagnostic requesting and reporting, measured by fewer repeat tests; reduced time to diagnose, treat and improve outcomes.
- **Performance Improvement:** Benchmarking and performance assessment looking at diagnostic outcomes assessment.

Several User Needs have been identified in relation to our work including Primary Care, NHS England and NHS Improvement, NHSX and Public Health England. You can find more information about content and topics to be developed by viewing our Pathology and Diagnostics Roadmap and timeline here.

We have an active and ongoing User Centred Design workstream, which focuses on engaging with the wider community to gain collaborative feedback to integrate within design decisions. See User Centred Design - Pathology & Diagnostics Information Standards Collaboration Space - NHS Digital (kahootz.com).

3. Approach

Please see the below table of daily activities currently in place and routinely undertaken to manage the stakeholder community we engage with.

3.1 Ongoing Comms and Stakeholder Management

Type of delivery	Activity	Role description	Responsibility
Digital media: reactive and proactive	Team– review all direct and indirect communications and action and record. Mailbox: pathologyanddiagnostics@nhs.net. Link: Mailbox Stakeholder Queries Tracker	Routine and ad-hoc email correspondence with stakeholders – either via individual team members or via the team mailbox, as appropriate. 1. Development of content. 2. Supporting and approval Advice, delivery, evaluation, and reporting.	• Project support • Pathology lead (for advice / guidance) • Project team (for advice / guidance)
	NHS Digital corporate external website/s. Pathology website legacy content	Revamp and maintenance upkeep of NHS Digital external webpage. Create an overview regarding the project workstreams, presented in a clear and non-overwhelming way. Delen page to be assessed and created aligned with the above.	• Pathology lead • Project support • Web team • Terminology and classifications
	NHS Digital intranet articles	Create and publish articles to publicise important news and key bulletin articles.	• Pathology lead • NHS Digital corporate comms
	Supplier communications Links - SNOMED CT Engagement Tracker	Supplier communications, message development and supplier management. Ensuring correct messages are developed and delivered to the supplier community and objectives are understood by the supplier community	• NHS X • NHS Digital corporate comms • Pathology project team • Pathology lead
Publications	Collaborative workspaces Links - Pathology & Diagnostics Information Standards Collaboration Site	Creation and management of online collaborative workspaces to encourage stakeholders and internal team members to partake in cross working. The following collaborative workspaces are being assessed, and if appropriate for the project will be created and maintained: SharePoint (in use) / Kahootz/Delen.	• Pathology project team (all) • Pathology lead • Project support
	Core narrative Publication pending on Intranet	Coordinating messages across the organisation to maintain a core narrative and key messages are coherent and coordinated.	• Pathology project lead

Type of delivery	Activity	Role description	Responsibility
	Surveys Ad-hoc	Produce content for surveys, design and deliver, using SurveyMonkey as a toolkit. Manage delivery and analysis of results.	• Pathology project team • Pathology lead • Project support
	Presentations Links - Pathology Information Representation SharePoint Site	A standard/generic presentation that can be used as a basis for all event presentations, conferences, and meetings. Include slides which can relate specifically to individual stakeholder groups or individual workstream area, which can be edited as appropriate.	• Pathology project team • Pathology lead • Project support
	E-bulletins / Newsletters Links - Pathology and Diagnostics news - Pathology & Diagnostics Information Standards Collaboration Space - NHS Digital (kahootz.com) Pathology Information Representation - 2020 - All Documents (sharepoint.com)	NHS England Bulletins and e-newsletters e.g., CCG bulletin.	• NHS England/NHS X comms team • NHS D corporate comms team • Pathology lead
		NHS Digital programme team e-bulletins – where possible, utilising existing (and relevant) programme team e-bulletins, including GP IT Futures, Terminology and Classifications etc.	• Pathology lead • NHS Digital programme teams (various)
		Pathology E-bulletin, IRES Newsletter. Update stakeholders on advances within the Pathology workstreams. Design and deliver using suitable mail build service.	• Pathology lead • Project support
	User case studies Links: PRSB Final Report	Design and creation of use cases designed to promote the benefits of the Pathology Service workstreams, in the eyes of key stakeholders.	• Pathology lead • External stakeholders • Project team (all)
	Education and Training - Infographics / Animations Links - https://nhsengland.kahootz.com/PathologyandDiagnostics/view?objectID=15848208 https://nhsengland.kahootz.com/PathologyandDiagnostics/view?objectID=581220	Design and creation of a package of infographics / animations to promote the benefits of the workstreams through visual aids.	• Education and Training Lead • Project support • Project team (all)
Events, workshops, and meetings	Workshops / User groups Links - Pathology Information Representation SharePoint Site/ Comms & Stakeholder Engagement/ Workshops	Face-to-face or virtual meetings of invited participants to discuss a specific topic. This could be either hosted by NHS Digital or an event where NHS Digital is invited to present.	• Project team (all) • Pathology lead (for guidance)

Type of delivery	Activity	Role description	Responsibility
		Virtual tools such as WebEx and Skype will be used where appropriate for smaller workshops and to facilitate remote meetings. Ensuring correct messages are developed and delivered to the user communities at the right time. Arranging and promoting events; ensuring correct level of engagement; capturing and publishing outputs.	
	Pathology National User Group (PINUG) Links - Pathology & Diagnostics Information Standards Collaboration Space (Kahootz) - Stakeholder Engagement Pathology & Diagnostics Information Standards Collaboration Space (Kahootz) - PINUG Collaboration Area	A long standing virtual (WebEx) user group which meets every two months to update internal and external stakeholders of ongoing workstream advances and allows stakeholders to share work and important updates in the Pathology community. Management of distribution list, stakeholder list, meeting management and minute / action logging. Advice, delivery, evaluation, and reporting	• Project support • Pathology lead
	Healthcare events	Speaker slots and / or exhibition stands at relevant third-party events and exhibitions, including but not limited to the following: • Health + Care Commissioning Show • Supplier User Group conferences • Health and Care Innovation Expo (TBC) • RCGP Annual Conference • Best Practice (TBC) • EHI Live (TBC) Note: this should only take place when projects have enough clarity around plans and have important detail to share	• Programme lead • Project team (various) • Pathology lead • NHS Digital corporate comms team
Networks	PRSB (various clinical organisations) Pathology & Diagnostics Information Standards Collaboration Space (Kahootz) - PRSB	Ongoing Consultation	• Programme lead • Project team (various)

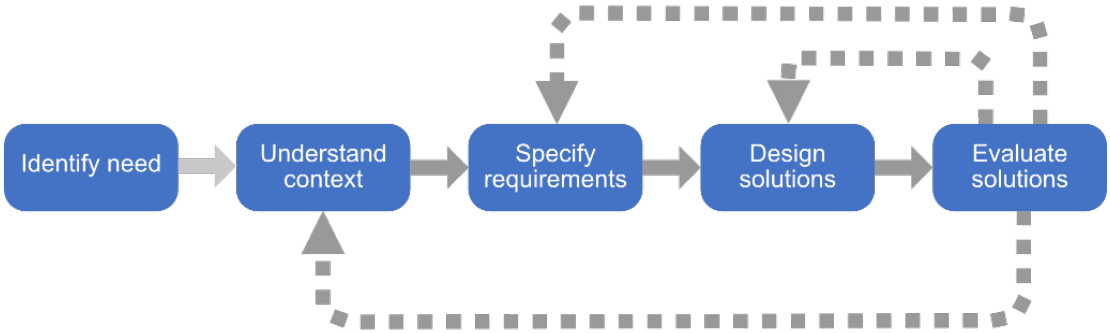
Type of delivery	Activity	Role description	Responsibility
	Primary Care special interest group (mainly GPs) Example link: Microbiology sub-group forum	Ongoing Consultation	• Programme lead • Project team (various)
	Royal College of General Practitioners	Ongoing Consultation	• Programme lead • Project team (various)
	Royal College of Pathologists	Ongoing Consultation	• Programme lead • Project team (various)
	Suppliers	Ongoing Consultation	• Programme lead • Project team (various)
Internal Communications	Reporting and senior executive liaison NHS X	Monthly Board Reporting on progress, maintaining engagement and supporting, facilitating approvals, and providing briefings.	• Programme Head • Programme Director • NHS X SRO • Project Support
	NHS Digital internal events	Information sessions to inform other NHS Digital programmes of progress, to lift the profile of the project and to enable indirect communication with the stakeholder groups of other programmes.	• Project team (all) • NHS Digital corporate comms
	Programme team away day	To disseminate and share workstream information and raise awareness / promote interest internally within the Information Representation Services (IReS) directorate.	• Programme lead • Project Team • Project support

3.2 User Centred Design

This Pathology Terminology Authoring Process is intended to bring it in line with GDS Agile methodology, User Centred Design and to support the use of Test-Driven Development (TDD).

The changes applied will support processes that allow for rapid user feedback that allow NHS Digital to fail fast, learn from stakeholders and respond to user needs.

UCD involves expertise and methodology to understand and deliver what the user really needs, not necessarily what they want. UCD is an iterative process which focuses on the users and their needs in each phase of the design process (see below).



Development teams involve users throughout design and development life cycle via a variety of research and design techniques (e.g., surveys, interviews, brainstorming), to create an understanding of user needs to construct highly usable and accessible products. Design is based upon an explicit understanding of users, tasks, and environments. Development is driven and refined by user-centred evaluation, addressing the entire user experience.

Further information can be found at: User Research - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com) including:

Personas

Personas are fictional characters that represent a group of users with the similar behaviours, motivation need and goals. Good personas are realistic, give actionable insight and reference for future decisions.

User needs

A user need is an actionable problem statement used to summarize who a particular user is, the user's need, and why the need is important to that user. It defines what you want to solve before you move on to generating potential solutions. They are high level, broad in scope and timeless and do not suggest specific solutions.

User Stories

The purpose of a user story is to articulate how a piece of work will deliver a particular value back to the customer.

Journey Map 1

Journey Map 2

A journey map is a visualization of the process that a person goes through to accomplish a goal. In its most basic form, journey mapping is a series of user actions mapped into a timeline. Then user thoughts and emotions are fleshed out to create a narrative that helps build empathy and understanding for a user within the delivery team.

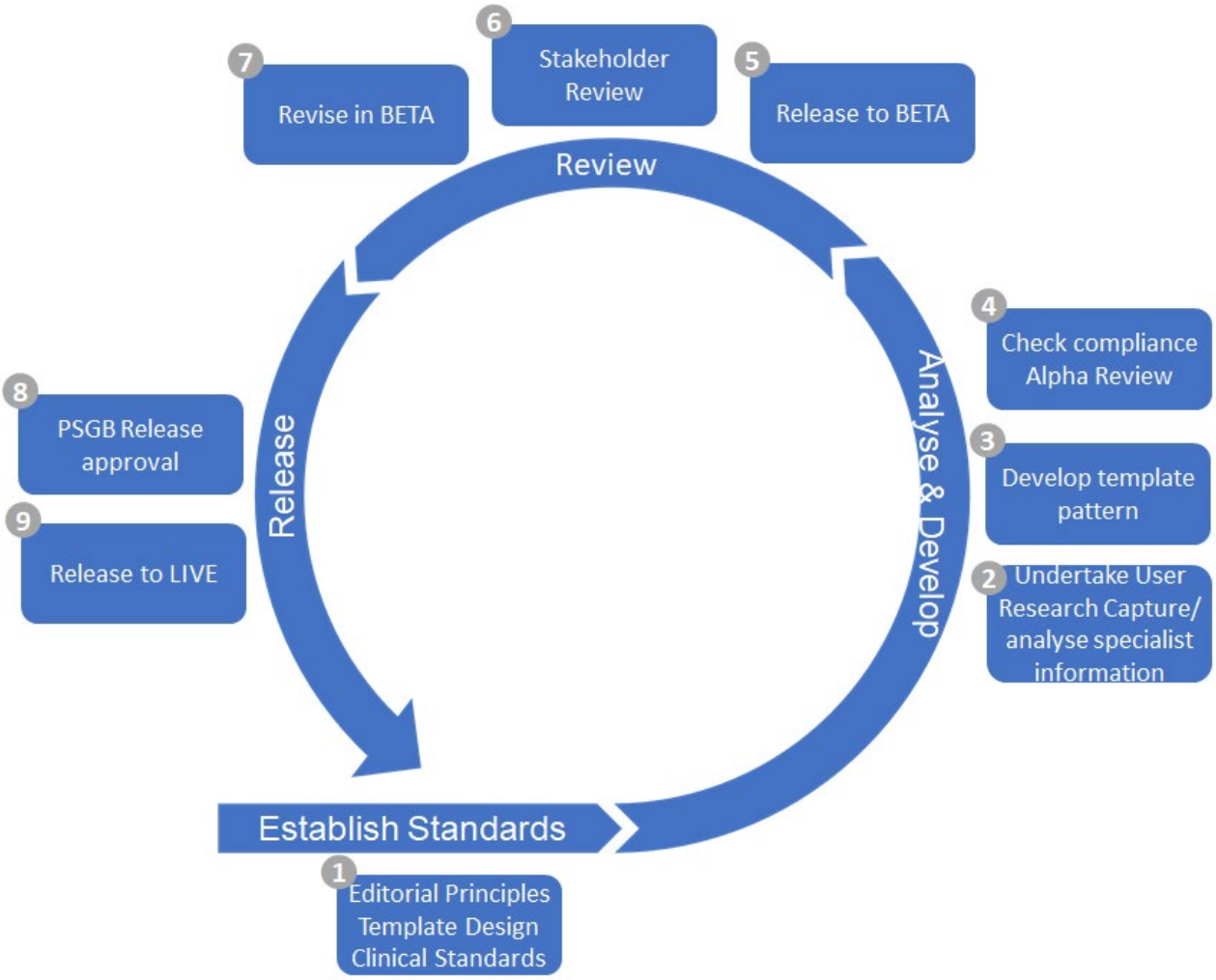
Agile Framework

This document will outline the standards for how Agile is best utilised for the NHS Digital Pathology and Diagnostics Team.

3.3 Peer Reviews

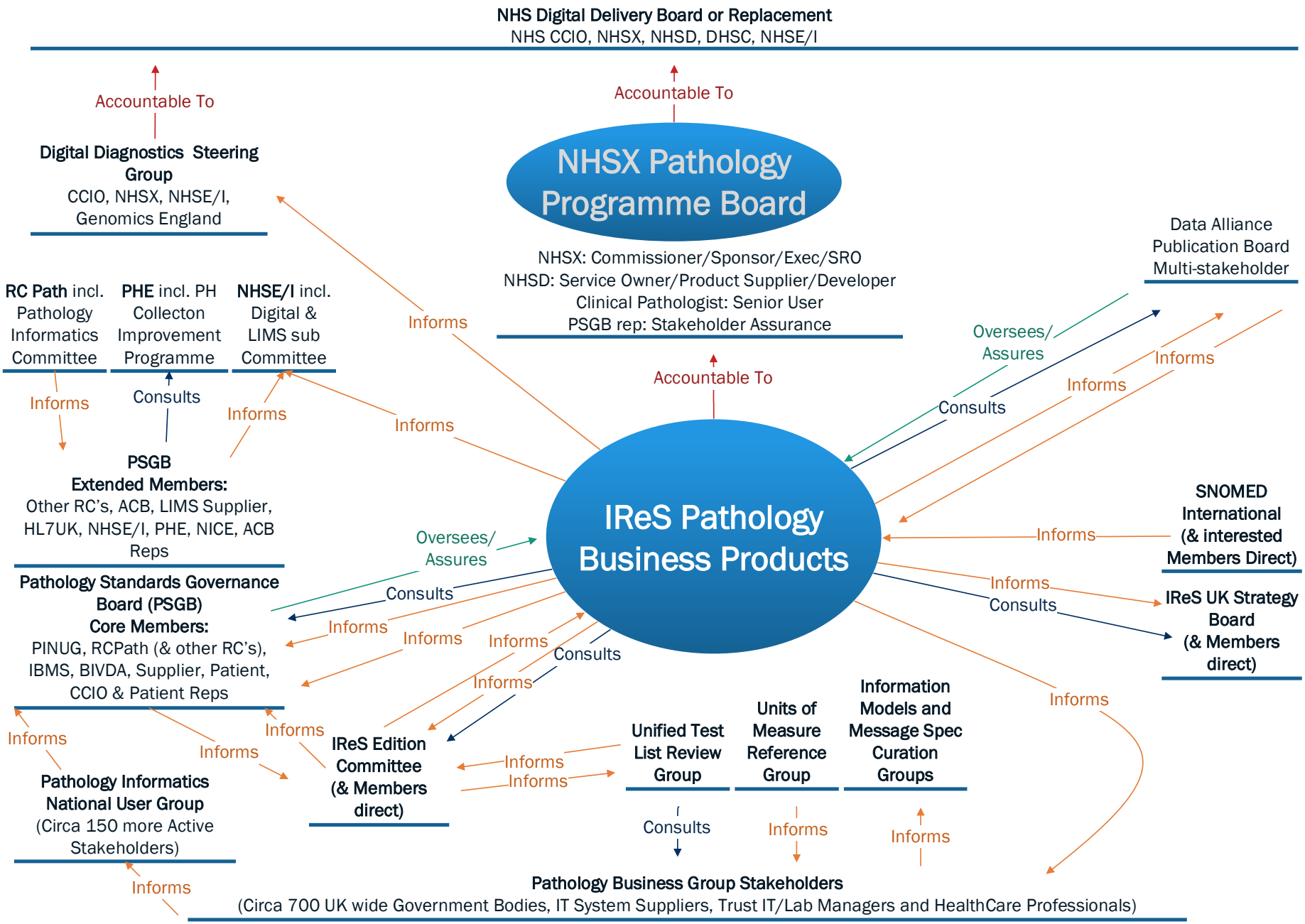
During development of concepts the following reviews take place: a terminology peer review, an alpha review with clinical SME's - either targeted stakeholder groups or PINUG subgroups. Alpha

reviews should be based upon template patterns and a small number of examples to provide context. The wider beta review is completed with a kick-off and review workshop to inform users of what has been released and to solicit feedback. Further detail can be found at Pathology Terminology Authoring Process v0 4.docx (sharepoint.com). The below image illustrates the authoring process and how stakeholder feedback is incorporated into the review and development cycle.



3.4 Dissemination and Engagement

As part of the wider engagement and consultation piece, there are bodies in place that support the programme of work in its development through to implement phases and influence the direction of travel and provide assurance that the key objectives of the programme will be delivered. Please see below multiple stakeholder bodies of influence and consultation.



4. Consultation Groups Overview

4.1 The Pathology Informatics National User Group (PINUG)

The Pathology Business Product team at NHS Digital are working closely alongside other key strategic partners to enable the sharing of Pathology results across all healthcare settings. To make this happen we are looking to engage with as many key stakeholders as possible to provide updates, share knowledge and potentially collaborate on the work we are undertaking.

The Pathology Informatics National User Group (PINUG) aims to encourage a two-way dialogue between NHS Digital and other interested parties, allowing us to successfully align with all stakeholder group requirements.

The group meets every two months via MS Teams and consists of clinicians, diagnostic professionals, and system suppliers. The meeting is chaired by our lead clinician, who is member of the Royal College of Pathologists (RCPath). The forum allows us to provide parties with key updates and encourages stakeholders to share relevant news and information with us.

Please visit the collaboration area below for previous PINUG minutes and supporting documents.

4.1.1 PINUG sub-groups

We have set up sub-groups to focus on pathology specialisms and address development questions relating to our Pathology information standards in development (UTL, Units of Measure and FHIR message specification). Please visit the collaboration area below to find out more.

PINUG collaboration area - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com).

Currently requesting and tests sets have been presented with a current position on requesting to the PINUG and PSGB for feedback. Feedback received from members of the PINUG here:

UTL Line Item and General Feedback (SharePoint)

Requesting and test sets discussion forums have been set up for general questions and discussion about the Requesting and Test Sets project itself, and on the broader aspects of business process and technical architecture in Pathology Requesting and Reporting in the UK.

4.2 Professional Record Standards Body

More than 1 billion test results are reported across the NHS each year, making pathology reporting a crucial part of the health and care system. The standards used for primary care test results now are based on a retired coding standard, and a transport standard which does not support the NHS approved terminology standard. Across the rest of the NHS there is no single set of standards used for pathology results.

Different laboratories use different test lists and different units to measure and report results. For clinicians this can mean they need to interpret results for the same type of test differently depending on which laboratory has carried out the testing and reported the results. This can lead to misinterpretation and errors.

NHSX/Digital have a programme to implement new standards for pathology test requests and results across the NHS. PRSB was commissioned to support this programme by developing demonstrators to show the feasibility of implementing the new standards. PRSB were then asked to engage with stakeholders to gather their feedback on the feasibility of implementing those standards.

The PRSB report is now published. The work is based on the clinical terminology, SNOMED CT, to define test requests and results, and machine-readable standards for units of measure. These will all be shared between systems digitally using FHIR (fast healthcare interoperability re-sources) messaging, the technical standards for sharing information between systems.

4.3 Unified Test List

We have identified the need for a single coded list to replace the primary care reporting standard PBCL (Pathology Bounded Code List) and meet hospital reporting needs across more specialised areas.

The Secretary of State vision document describes guiding principles that we should maintain to make this work and one of those is interoperability and openness. It is not just about technology – agreeing and adhering to clinical data standards will give us much better and more granular detail with which to fight disease and prevent and treat illness.

Our technology infrastructure should allow systems to talk to each other safely and securely, using open standards for data and interoperability, so people have confidence that their data is up to date and in the right place, and health and care professionals have access to the information they need to provide care.

We extend the iterative development, testing, publication and ongoing maintenance of nationally applicable test and result descriptions aligned with the international clinical terminology standard (SNOMED CT). Version 0.7.0 of the Unified Test List has been published both in human-readable form on our collaboration space and as machine-readable (RF2) format on TRUD. UTL_v_0.7.0_20210317 - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com). Version 0.8.0 was released in human-readable and machine ingestible tab-separated values (TSV) format on 28th May 2021.

Following the Government Digital Services Framework, we have iteratively engaged with and incorporated feedback from users into all stages of Discovery, Alpha and Beta development, for three new Pathology products/proposed standards (see: Authoring Process. Units of Measure will be presented later). The standards will be iteratively discovered, designed, developed, tested, approved, released, and maintained for the seventeen Pathology specialist areas.

Release comms are sent out after every UTL release to all Pathology stakeholders on our stakeholder directory. Invited members to provide feedback on the release as a whole via the UTL discussion forum or by emailing pathologyanddiagnostics@nhs.net. We are also using a mechanism to allow users to easily send feedback or questions to us on a specific UTL concept, via a link on each item in the downloadable HTML-format review copy of the UTL. We have held release kick-off sessions for each release, followed by focussed workshop sessions 2 weeks after each release date to provide an overview of the content and log any feedback received relating to the UTL content.

General feedback on each release and line-Item level feedback was logged for review by the content development team.

UTL Line Item and General Feedback (SharePoint)

Unified Test List (UTL) - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com)

4.4 Units of Measure

For producers and consumers of pathology diagnostics within the NHS, who need safe reliable communication of diagnostic results for both human (clinician + patient) and computer interpretation.

The UoM project will analyse both the current state and future needs for describing units of measure in Pathology, to deliver a solution that meets the need for a fully computable pathology message structure, without compromising patient safety or usability for clinicians or patients.

Unlike current practice the future UoM solution will support the FHIR and UTL projects in delivering a pathology reporting capability that is understandable and processable by computational means, allowing for new healthcare tools and processes to be developed and used safely.

We continue to engage with Professional Bodies and Standards to establish and align the units used in the NHS with the international standard (UCUM). Consultation with stakeholders via forum about the UoM project itself, and on the broader topic of Units of Measure in Pathology, including support in IT systems and related technologies including FHIR, SNOMED, UCUM and others can be found below.

Units of Measure (UoM) - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com).

4.5 Message Specification

The Pathology Message Specification defines a set of draft HL7 FHIR STU3 profiles to support the electronic exchange of pathology test results. Together with the Unified Test List and standardised Units of Measure, the specification aims to provide an interoperable and machine-readable mechanism for sharing pathology test results.

The initial objective is to use the FHIR message specification (in conjunction with the Unified Test List and standardised Units of Measure) to replace the existing PMIP EDIFACT messaging standard that is used for Primary Care requested test results. We maintain, extend, and publish the Logical Model of Pathology information flow requirements and message specifications to exchange including, tests, results, and units.

1. FHIR Message Specification - National Pathology FHIR Messaging Specifications | ITK-FHIR-Pathology (developer.nhs.uk)

2. FHIR Implementation Guidance - https://developer.nhs.uk/apis/itk3nationalpathology-1-1-0/

4.6 Information Model

Work has been undertaken to develop a generic logical data model for pathology test reporting. The model provides an implementation agnostic representation of the key business entities and data elements that are used to support the sharing of pathology test results between laboratories and requesting organisations.

In line with the other areas within the Pathology workstream, the scope of the current model focuses on haematology and clinical biochemistry (also known as chemical pathology) test reporting.

The model is defined in a Microsoft Excel spreadsheet and comprises:

- a tabular definition of the business entities and data elements, together with associated attributes such as data type and cardinality
- a class diagram that illustrates the relationships between the business entities and summarises the data elements within each one.

The data model has been used as the primary input into the development and curation (via INTEROPen) of a set of HL7 FHIR STU3 profiles to support the electronic exchange of pathology test results.

Information Model - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com)

4.7 Engagement and Preparation for Implementation

Ongoing collaboration with multiple impacted stakeholders including NHS ALB's, Royal Colleges, Pathologists and other clinicians, IT Managers, System Suppliers, and alignment with the UK and internationally.

Strategic User Needs were identified in relation to our work including Primary Care, NHS England, NHSX, Public Health England and NHS Improvement.

Clinical user needs were identified with the Greater Manchester Partnership as a digital exemplar Trust, iteratively building from the Top 100 high volume Blood Science Tests and results in their clinical systems to develop national test and result descriptions and assess their fitness for use with the requestors and nationally with a Consultant Chemical Pathologist from Calderdale & Huddersfield NHS Foundation Trust and via members of the Pathology Informatics National User Group

An open collaboration was made available: Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com) with an associated mailbox to manage all stakeholder engagement including feedback: pathologyanddiagnostics@nhs.net

In addition, the Message specifications were curated with multiple stakeholders in partnership with INTEROPen:

- **During February 2019**, NHS Digital worked with INTEROPen and a range of clinical, technical, and business stakeholders to develop and curate a set of HL7 FHIR STU3 profiles to support the electronic exchange of pathology test results. Three new INTEROPen CareConnect FHIR profiles were developed (DiagnosticReport, ProcedureRequest and Specimen) and the existing Observation profile was updated.

- The profiles can be found here: https://fhir.hl7.org.uk/StructureDefinition

- To support adoption of these profiles, draft technical implementation guidance aimed at suppliers and Trust IT departments is available here: National Pathology FHIR Messaging Specifications.

- In addition to the FHIR profiles and implementation guidance, a logical data model for test reporting has been published. The model provides an implementation agnostic representation of the key business entities and data elements that are used to support the sharing of pathology test results between laboratories and requesting organisations.

  It was used as the primary input for the development of the FHIR profiles described above. The data model is available to download from the NHS Digital Pathology and Diagnostics website here: a) Data Model; b) FHIR Curation.

Since then, we have worked with several digitally mature Trusts to identify their information flows and content that is required by Clinicians and incorporated their feedback and any changes required in our iterative development methodology.

Proof of Concept: NHS Digital engaged with South, Central and West CSU in April 2021 to conduct end-to-end testing with key GP and Laboratory Information Management System (LIMS) suppliers to

further prove the standards. The resulting Case Study and Test Results were published in late July 2021.

5. Governance

5.1 Pathology Standards Governance Board

We have also commissioned the Professional Records standards body to establish a multi-stakeholder Governance Group Pathology Standards Governance Board (PSGB) to assure our work, Demonstrators and Consultation. The board is made up of the following group see the following link: Core and extended members.xlsx (sharepoint.com) covering a wide range of representation and input from specialist fields. The terms of reference and objectives of this governing group can be found at PSGB role remit and membership v0.1.docx (sharepoint.com).

5.2 Pathology Programme Board

The Pathology Programme also has a board in place to provide direction and accountability for the work that has been initiated. This board is reported into every month in terms of progress/risk and issues and escalation. Below are the objectives for this board and the terms of reference can be found below:

- Providing overall direction for the CCIO7 Pathology Programme, ensuring clear objectives and defined deliverables are set.
- Committing resources to ensure the successful completion of the programme.
- Prioritising, deliverables, and resources.
- Resolving strategic and directional cross-organisational/stakeholder issues or dependencies.
- Ensuring effective engagement and communications with external stakeholders across the NHS.
- Informing the Senior Responsible Owners, Decision Making.

See Link - Pathology Information Representation - Terms of Reference - All Documents

6. High Level - Timeframe

Timeline	High Level Deliverable
2018/19	System wide Discovery based on the high-volume Blood Sciences tests and results used in current clinical systems of Digital Exemplars, learning lessons from previous work Pathology Standards: The Past 30 Years
2019/20	Definition of the three inter-related Products/Future Standards clinically reviewed as Alpha releases and widely as Beta release for human readable feedback as well as machine-readable drafts for trial use. System wide consultation and collaboration resulting in; cross organisational agreements including multi-stakeholder Governance established and agile development approach and standards validation.
2020/21	Tactical COVID solution delivered and transitioned back to strategic work with key stakeholder Programme Board established.

2021	Proof of concept testing, standards approval as fit for iterative system implementation and standards development transition to iterative live service development of Pathology specialist, Backlog needs.

7. Stakeholder Engagement Workshops and Information Sharing Events

To date there have been 5 major Information Sharing evented hosted by the NHS Digital Pathology team across the UK, please see below links to view the event information summaries, feedback and content which was shared with wider stakeholder groups that attended.

7.1 Leeds and London 2018

Leeds / London November 2018 - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com)

We presented an overview on enabling the sharing of pathology results across the NHS. This was a joined-up workshop with strategic partners including NHS E/ NHS I, PHE and Royal college of Pathologists. We used Voxvote, a live voting system to gain feedback on:

- Which Pathology specialty should be our next priority?
- Should we model immunology and virology next?
- Should there be a multidisciplinary approach to UOM?
- Message Specification: Should we use INTEROPen to curate the FHIR message specification rather than engaging via the National User Group?

Link to Pathology Information Standards Workshops Feedback Summary Report

7.2 Pathology Laboratory data collection

In December 2018, NHS Digital's National Pathology and Diagnostics team invited members of the Pathology Informatics National User Group (PINUG) and wider Pathology laboratory contacts to participate in an ongoing electronic survey devised by our clinical lead who is also a member of RCPath. The Survey enabled us to obtain up to date, real life data on various aspects relating to coding and IT systems used in Pathology laboratories, including lab details and specialities, LIMS, EHR and messaging details, clinical coding systems and clinical terminologies used. Pathology laboratory contacts from 24 different trusts have participated in the survey to date.

Collaborating with our strategic partner, NHS Improvement, we combined the results from our electronic survey with data from the IT and Equipment section of the NHS I 2017/2018 annual Pathology Survey. The survey was completed by 100 different trusts throughout the UK, and provided nationwide data on trust LIMS providers, major technology providers for software relating to Pathology sub-disciplines within trusts and statistical information on the distribution of electronic requests and reports.

In February 2019 NHS Digital held a Stakeholder engagement workshop on Terminology Migration attended by Pathology laboratory staff from various trusts throughout the UK, this provided an opportunity to collate further information on Clinical coding systems and terminologies used by those in attendance. A composite slide set of the presentations delivered at the workshop can be found

here. In total, data from 104 different trusts relating to coding and IT in Pathology Laboratories has been collated. Should you wish to contribute to our survey, please use this link to access the online form.

7.3 Birmingham February 2019

Birmingham February 2019 - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com)

Following feedback from our collaborators and attendees at the workshops that we hosted in Leeds and London in 2018, we identified several strategic themes that needed further exploration to progress our work to enable the sharing of Pathology Results across the NHS.

Following feedback from stakeholders, discussions at the workshop focussed on the following sub-areas:

Terminologies:

- Migration from Local codes &/or LOINC &/or Read/PBCL to Unified Test List.
- Migration from antecedent versions (SNOMED II, SNOMED RT) to SNOMED CT
- SNOMED CT Pre &/or post co-ordination, Reference sets

Messages:

- Local and/or EDIFACT &/or HL7v2 &/or v3 to FHIR
- Role of alternative information models – openEHR archetypes

Units of Measure:

- Migration from local &/or LSR to IUG
- Representation of IUG in SNOMED &/or UCUM as a National Standard
- Information Standards Publication of new standards and withdrawal of old standards/products Read Codes, EDIFACT, PBCL, NLMC.

High level requirements were captured from those in attendance at the workshop including LIMS and middleware suppliers, Pathology IT managers and Laboratory staff, clinicians, and representatives of ALB's and our strategic partners and added to our product backlog for prioritisation.

Pathology Birmingham Workshop User requirements for backlog.docx (sharepoint.com)

The high-level requirements and questions raised by those in attendance relating to terminology migration were captured in the below report and addressed by workstream leads in the document:

Terminology Migration Workshop: Stakeholder requirements/feedback

The questions raised relating to the content discussed at the event was then formally published on our Kahootz site in the form of an FAQ database:

Pathology & Diagnostics Information Standards Collaboration Space (Kahootz) - Frequently Asked Questions

Output of general questionnaire sent to those who attended:

Birmingham Terminology Workshop Feedback Summary

7.4 Leeds and London 2020 events stakeholder engagement workshops

Leeds / London 2020 - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com)

At this event we shared highlights/key achievements since the 2018/19 events. Topics covered included: SNOMED & Information Models working together, Potential Requesting Model, UTL as a successor to PBCL, UTL Release Schedule and Feedback on the proposed roadmap for change.

We engaged with stakeholders involved across the Pathology eco-system to establish consensus on standards being defined and ways to roll them into the ecosystem in discussions with NHSX, NHSI, NHSE and PHE. There was a cross-organisational governance board commissioned for the proposed Pathology information standards being created and international interest in adopting or aligning with our work.

Outcomes included:

1. Agree Clinical Leadership.
2. Agree with PHE, Reportable Diseases & Antimicrobial Resistance Stewardship.
3. International Agreements
4. Continue multi-organisational engagement to prepare for Implementation & use.
5. Create and engage closer via focussed reference groups.

At the workshop we shared a proposed forward view/Roadmap for stakeholder feedback to identify any gaps and inform prioritisation. Stakeholder feedback on roadmap prioritisation published on our collaborative workspace following the events: Pathology Standards Implementation Roadmap: Stakeholder Feedback

Dedicated Requesting and Panels area for stakeholder engagement and shared with attendees and wider stakeholders: Requesting and Test Sets (Kahootz)

UTL Beta Releases are published current in HTML file format with human readable links for providing feedback. Discussion about alternative options such as spreadsheet format for filtering, browsing, etc, Online browser based for browsing and feedback was sought from audiences.

Feedback form following events: NHS Digital National Pathology Information Standards Discussion Group Feedback

5 Point Outcomes for each of the workstream leads to follow up with stakeholders were output, following the Leeds and London Events can be found here: Information Sharing Consolidated Team Feedback

8. Summary of Consultation Feedback

PRSB was commissioned to support the NHSX/Digital programme and asked to develop demonstrators to show the feasibility of implementing the new standards and then to engage with stakeholders to gather their feedback on the feasibility of implementing those standards. The work was conducted in 2 phases. The full report can be found here: Pathology-Final-Draft-Report-V1.1.pdf (theprsb.org)

Phase 1 - Developed demonstrators to show how the 3 standards below could work.

- A Unified Test List (UTL) using SNOMED CT (the NHS approved standard for terminology) to define the list of test requests and results for everyone across the NHS. The UTL available only contains results for blood sciences and microbiology, and so the focus was in those areas rather across the full range of pathology disciplines.
- The Unified Code for Units of Measure (UCUM) as the coded primary Unit of Measure, together with a human readable version of that code.
- A technical standard (HL7 FHIR) to electronically transport the details of the test, the result and its Units of Measure across the NHS and other organisations needing the information.

Phase 2 - Engaged with stakeholders using the demonstrators or the outputs of them to gather feedback on the feasibility of implementing the new standards.

8.1 PRSB Consultation

Overall, 63 stakeholders attended one or more of the six webinars with good coverage across the targeted range of disciplines and organisations. The three streams were:

1. **Technical stream.** Aimed at technically aware clinicians, pathologists, lab scientists, and those implementing the standards including system suppliers, IT staff from labs and provider organisations. Three webinars were held with largely the same attendees and the discussion continuing across all three.
2. **Clinical users of test results** including research and public health. Aimed at understanding the needs of users, the benefits, issues, and risks of implementing the standards.
3. **Citizens.** A single webinar was held with a small group of knowledgeable patients so the benefits and implications for patients could be understood and used to inform the development and implementation.

8.1 Conclusions and Results

The findings are reported in the following four chapters of Pathology-Final-Draft-Report-V1.1.pdf (theprsb.org).

- Chapter 4: Mapping PBCL to UTL tool
- Chapter 5: The proposed methodology for identification and implementation of the preferred UoM for a test result and the options for sending the UoM in the FHIR message
- Chapter 6: The feasibility of sending the test result using HL7 FHIR and issues to be considered to ensure a safe and effective transmission, receipt, and end user interpretation.
- Chapter 7: Patient consultation

The overall outcome from the stakeholders were very keen to engage and support the programme and use their front-line knowledge and lived experience to help shape the standards and guide the implementation so that it can deliver new standards resulting in safe and effective implementation which will make a real difference to pathology testing and care. It is strongly recommended that further and continued stakeholder engagement is used to validate the development and shape the plans for testing and implementation.

8.2 Benefits

The pathology standards will act as an enabler for the following benefits:

- Standardised, semantically interoperable, and unambiguous data makes data machine-readable, enabling secondary uses like analytics or machine learning.
- Enable Clinicians to access pathology tests and results across health and care – right time right place.
- Interoperability, from employing the same clinical coding as utilised in other national datasets, will improve outcomes from areas such as population health and research.
- Efficiency gains from the reduction of duplicate testing by clinicians forced to repeat tests when they are unable to interpret tests correctly.
- Improve clinical decision making and patient safety with the ability to unambiguously communicate and interpret pathology results.
- Patients don’t have to repeat their medical history or care needs to different people
- NHS England can review commissioning and costs across the board due to a reduction in the need for local codes and standardisation.
- NHS Improvement will be able to benchmark tests being carried out by providers and associate them with applicable tariffs (Carter report recommendation).

- Public Health England will be able monitor results for emerging trends in antimicrobial resistance or routine surveillance.

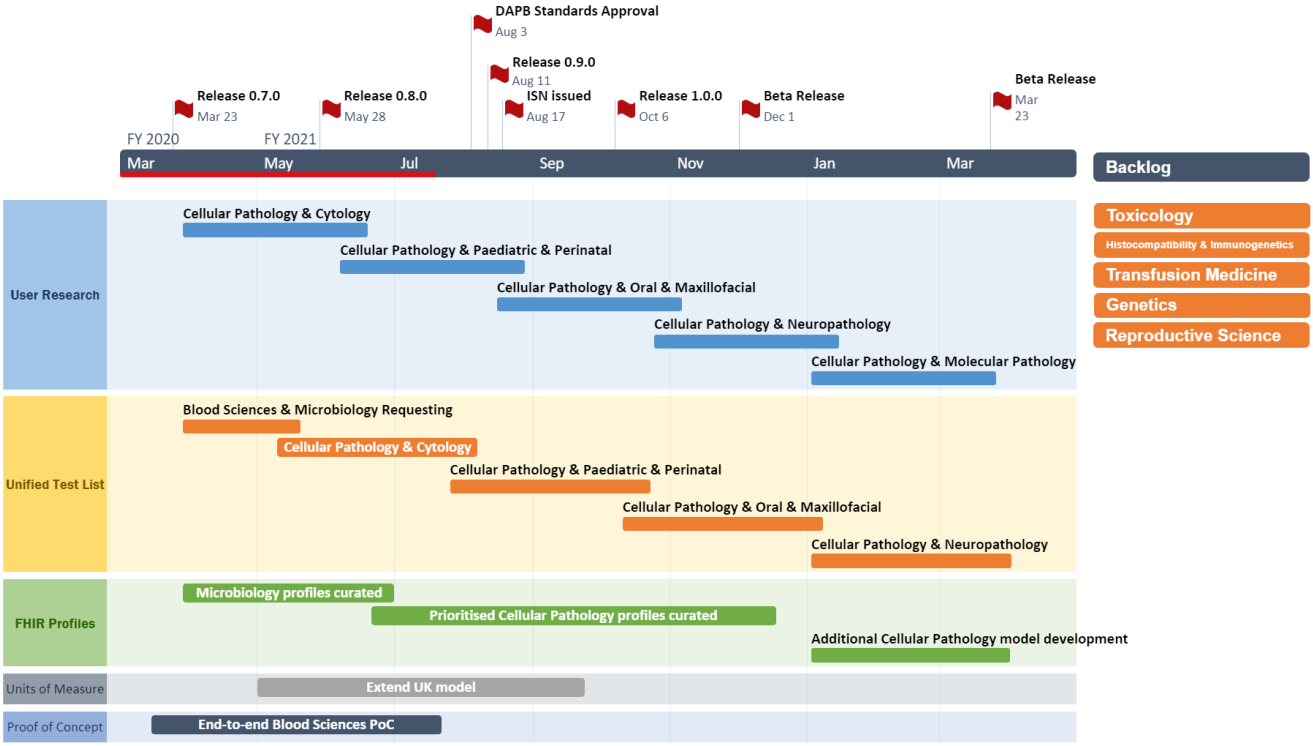
8.3 Next Steps

There is a plan to produce further case studies as part of our Training and Education plan. We will continue to iteratively develop content and standards in line with Agile development to ensure we are considering stakeholder feedback and consultation at all key points of development, along the journey to produce fit for purpose pathology standards.

For further detail see Pathology and Diagnostics Roadmap - Pathology & Diagnostics Information Standards Collaboration Space - NHS England (kahootz.com).

8.4 Roadmap

In line with the next steps and recommendations from the PRSB consultation, the following roadmap has been prioritised with input from Professor Jo Martin, the PSGB & PINUG, and approved by the NHSX Pathology Programme Board.



8.5 Website glossary

In order to tailor information to the stakeholder audience a number of web sites have been utilised to ensure communication is presented in as an efficient manner as possible. These include the following:

Website	Audience / Content
NHS Digital	Key stakeholder-facing corporate site, describing pathology alongside corresponding diagnostic data services.
Pathology collaboration space (Kahootz)	Key stakeholder collaboration site for users, supplier, PINUG and PSGB.

	Includes publicly available published deliverables including latest news, training, forums, surveys, user research and agile delivery artefacts.
Technology Reference data Update Distribution (TRUD)	Distribution site hosting UTL releases for supplier download, test, and implementation.
API Hub	Key developer resource providing specifications, examples, and profile information for system suppliers.
HL7	Developer hub providing documentation, profiles, and resources for system suppliers.