

Pathology and Laboratory Medicine Reporting Information Standard

Requirements Specification



Data Alliance Partnership Board

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a new information standard for publication under [section 250 of the Health and Social Care Act 2012](#).

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB).

This information standard comprises the following documents:

- Implementation Guidance
- Requirements Specification (this document)

An Information Standards Notice (DAPB4101 Amd 63/2023) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled copies of these documents can be found on the [NHS England website](#). Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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| Version | Date | Summary of Changes |
|---------|------------|---|
| 0.1 | 30/01/2024 | Initial draft |
| 0.2 | 22/02/2024 | Minor editorial corrections – move to updated templates |
| 1.0 | 15/04/2024 | Final |
| 1.1 | 16/04/2024 | Minor editorial corrections |

Contents

| | | |
|-----------|---|-----------|
| 1. | Introduction | 5 |
| 2. | Key requirements | 5 |
| 3. | Related documents | 5 |
| 4. | Related Information Standards, APIs and message specifications | 6 |
| 5. | Data exchange mechanism | 6 |
| 6. | Scope | 7 |
| | 6.1. Healthcare settings affected | 7 |
| | 6.2. Pathology specialism coverage | 7 |
| | 6.3. Out of scope | 7 |
| 7. | Requirements and conformance | 8 |
| 8. | Implementation approach | 10 |
| | Appendix A: Useful web links | 11 |

1. Introduction

The Pathology and Laboratory Medicine Reporting Information Standard (DAPB4101 Amd 63/2023) supports the interoperable sharing of pathology reports from laboratories to Primary Care for the purpose of direct care.

DAPB4101 has been designed to replace the legacy [ISB 1557 EDIFACT Pathology Messaging Standard \(Amd 39/2003 EDIFACT v1.003\)](#), thereby replacing the [Pathology Messaging EDIFACT](#) integration with the [Pathology Messaging - FHIR](#) integration.

The purpose of this document is to specify the functional requirements to support conformance with DAPB4101. Specifically, this document is intended to inform health and care organisations and system suppliers of the required functionality to enable a system to electronically communicate and exchange a generic pathology report.

2. Key requirements

In the pathology report sent from laboratories to GP practices, and to support complex pathology reporting structures containing fully atomic, coded results, DAPB4101 mandates the use of:

- [Pathology FHIR specification](#).
- Concepts included in [SNOMED CT](#) Pathology specific Reference sets:
 - ❖ Pathology Bounded Code List (PBCL) observables simple reference set
 - ❖ PaLM (pathology and laboratory medicine) procedure simple reference set
 - ❖ PaLM (pathology and laboratory medicine) observable entity simple reference set
- Additional mandatory data elements such as patient demographic information, report identifiers, and organisational data. These are governed by their own Information Standards and the Pathology FHIR specification details their use.
- The target date for conformance with DAPB4101 is April 2025.

3. Related documents

This document should be read alongside:

- DAPB4101 Pathology and Laboratory Medicine Reporting Information Standard Implementation Guidance

4. Related Information Standards, APIs and message specifications

- [SCCI0034 SNOMED CT](#) - the information standard for clinical terminology.
- [ISB 1557 EDIFACT Pathology Messaging Standard \(Amd 39/2003 EDIFACT v1.003\)](#) – the legacy information standard that governs the use of PMIP EDIFACT.
- [DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems](#) - this standard is designed to help manufacturers of health IT software evidence the clinical safety of their products.
- [DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems](#) - this standard is designed to help health and care organisations assure the clinical safety of their health IT software.
- [FHIR](#) - the interoperability standard identified to facilitate the exchange of all healthcare information across the NHS.
- [Pathology Messaging – FHIR](#) – an integration for exchanging pathology test results from laboratories to GP practices.
- [Pathology Messaging – EDIFACT](#) – the legacy integration for exchanging pathology test results from laboratories to GP practices.
- [ISB 0149 NHS Number](#) – the Information Standard that sets out the scope and the use of the unique identifier for a patient, the NHS number.
- [Organisation Data Service API](#) - for obtaining ODS codes and organisation information.

5. Data exchange mechanism

NHS England's [Message Exchange for Social Care and Health](#) (MESH) service supports the ability to share data directly and securely between health and care organisations. MESH is the nationally recognised mechanism for message-based data sharing and is currently used to transport PMIP EDIFACT reports from laboratory systems to GP systems.

In addition to MESH, FHIR supports other methods of exchanging data, including the use of [RESTful APIs](#). This approach may be considered for pathology reporting in the future, but until an alternative national messaging architecture is mandated, MESH will be used to transport FHIR UK Core R4 pathology reports.

6. Scope

6.1. Healthcare settings affected

DAPB4101 supports the implementation of the Pathology Messaging – FHIR integration between laboratories and GP practices.

6.2. Pathology specialism coverage

In terms of specialisms, SNOMED CT pathology reporting content currently covers:

- clinical biochemistry (also known as chemical pathology)
- haematology
- immunology
- transfusion medicine
- microbiology – this includes bacteriology, virology, and serology

Further pathology specialism coverage is under review and will be considered based on the need of health and care providers and patients.

6.3. Out of scope

In its initial iteration, DAPB4101 allows, but does not mandate how pathology laboratory test result values, interpretations, units of measure, and specimens are represented in the pathology FHIR UK Core R4 profiles. If, however, the Pathology Standards Programme is commissioned to standardise [these elements](#), DAPB4101 would be amended to support this requirement.

DAPB4101 does not govern how variants of the EDIFACT messaging standard (e.g., NHS002, NHS004 messages) are used to exchange pathology data, such as in [Bowel Cancer Screening – EDIFACT](#) or [Cervical Screening – EDIFACT](#).

7. Requirements and conformance

This section describes what is expected of health and care providers and system suppliers to comply with DAPB4101 and the tests that can be measured to indicate that DAPB4101 is being used correctly.

MUST requirements are mandatory, SHOULD requirements mean there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course. [RFC-2119](#) (Requirements for Change) provides additional information about these categorisations.

For each requirement there is a corresponding conformance criterion which defines the measures used to assess success.

| Reference | Requirement | Conformance criteria |
|-----------|---|--|
| R1 | Providers MUST review their system compatibility against this standard to identify any changes required to current practice and systems to ensure compliance with the standard by 31 March 2025. | Review the documents to identify any systems or processes that will be affected. |
| R2 | Providers MUST, where the need for change is identified, ensure their systems are changed to be conformant with the standard by 30 April 2025. | Ensure your system supplier has plans, where the software does not meet the standard, to upgrade it before 30 April 2025. |
| R3 | Providers MUST instruct their IT system supplier to develop the capability to transfer / ingest pathology laboratory test reports using pathology specific FHIR UK Core R4 profiles by 30 April 2025. | System suppliers MUST confirm to providers they have the capability to transfer / ingest pathology laboratory test reports using pathology specific FHIR UK Core R4 profiles by 30 April 2025. |

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| <p>R4</p> | <p>Providers MUST instruct their IT system supplier to develop the capability to transfer / ingest pathology laboratory test request and result code data, and report identifier data using SNOMED CT by 30 April 2025.</p> | <p>System suppliers MUST confirm to providers they have the capability to use SNOMED CT Observable entity, Procedure, and Record artifact concepts in the report sent / ingested by 30 April 2025.</p> <p>This content is published in SNOMED CT reference sets and included in the SNOMED CT UK Clinical Edition:</p> <ul style="list-style-type: none"> • Pathology Bounded Code List (PBCL) observables simple reference set • PaLM (pathology and laboratory medicine) procedure simple reference set • PaLM (pathology and laboratory medicine) observable entity simple reference set • 721981007 Diagnostic studies report (record artifact) <p>System suppliers MUST evidence use of the latest version of the SNOMED CT UK Clinical Edition to ensure they can send / ingest newly introduced concepts and no longer send / ingest outdated concepts.</p> |
| <p>R5</p> | <p>Providers MUST instruct their IT system supplier to develop the capability to transfer / ingest associated mandatory pathology report data by 30 April 2025</p> | <p>System suppliers MUST confirm to providers they have the capability to use associated mandatory data in the report sent / ingested by 30 April 2025.</p> <p>NB. These are governed by their own Information Standards (see section 4)</p> |
| <p>R6</p> | <p>Providers SHOULD instruct their IT system suppliers to use NHS England’s assurance and testing processes.</p> | <p>System suppliers can evidence to providers by providing reports from NHS England’s assurance and testing processes.</p> |

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| <p>R7</p> | <p>Providers SHOULD work with their IT system suppliers to complete a local risk and clinical safety assessment before the Pathology Messaging – FHIR integration is used to transfer live patient data.</p> | <p>A self-assessment should be completed between the IT system supplier and the provider to ensure all risks have suitable mitigations in place and are agreed between both parties.</p> |
| <p>R8</p> | <p>Providers MUST ensure appropriate guidance is made available to their users if changes implemented to achieve compliance affect how a user interacts with the system.</p> | <p>Ensure user guidance is available to support any changes to the software and local process.</p> |
| <p>R9</p> | <p>Providers MUST ensure when procuring new systems or modifying agreements with existing IT system suppliers that their supplier complies with existing clinical safety standards DCB0129 and DCB0160.</p> | <p>Check your system supplier complies with clinical safety standards DCB0129 and DCB0160.</p> |

8. Implementation approach

Implementation of the Pathology Messaging – FHIR integration will be determined and managed locally.

The Pathology Standards and Implementation team are available to offer informatic support. Please contact the team via pathology.standardsandimplementation@nhs.net.

Implementation guidance, advice, and supporting artefacts will be regularly updated and published on the NHSE <https://simplifier.net/guide/Pathology-FHIR-Implementation-Guide/Home> and [Pathology Standards and Implementation website](#) throughout the period between initiation and conformance with DAPB4101. Please bookmark these websites and check for the latest updates.

Appendix A: Useful web links

| Content | URL |
|---|---|
| Bowel Cancer Screening - EDIFACT integration | https://digital.nhs.uk/developer/api-catalogue/bowel-cancer-screening-edifact |
| Cervical Screening - EDIFACT | https://digital.nhs.uk/developer/api-catalogue/cervical-screening-edifact |
| Choosing an Organisation Data Service API | https://digital.nhs.uk/services/organisation-data-service/organisation-data-service-apis/choosing-an-organisation-data-service-api |
| DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems Information Standard | https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems |
| DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems | https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0160-clinical-risk-management-its-application-in-the-deployment-and-use-of-health-it-systems |
| FHIR | https://digital.nhs.uk/services/fhir-apis |
| Harvard requirement for change | https://www.ietf.org/rfc/rfc2119.txt |
| ISB 0149 NHS Number Information Standard | https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/isb-0149-nhs-number |
| ISB 1557 EDIFACT Pathology Messaging Standard (Amd 39/2003 EDIFACT v1.003) | https://webarchive.nationalarchives.gov.uk/ukgwa/20150107154542/http://www.isb.nhs.uk/documents/isb-1557 |
| Message Exchange for Social Care and Health | https://digital.nhs.uk/services/message-exchange-for-social-care-and-health-mesh |
| Our API technologies | https://digital.nhs.uk/developer/guides-and-documentation/our-api-technologies |

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| Pathology Messaging EDIFACT integration | https://digital.nhs.uk/developer/api-catalogue/pathology-messaging-edifact |
| Pathology Messaging - FHIR integration | https://digital.nhs.uk/developer/api-catalogue/pathology-messaging-fhir |
| Pathology FHIR Implementation Guide | https://simplifier.net/guide/pathology-fhir-implementation-guide?version=0.1 |
| SCCI0034: SNOMED CT Information Standard | https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/scci0034-snomed-ct |
| SNOMED CT for pathology reporting | https://digital.nhs.uk/services/pathology-standards-and-implementation/snomed-ct-for-pathology-reporting |