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A Generic Pathology Information Model for Laboratory Test Result Reporting in the UK (FHIR and SNOMED CT)

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Information and technology
for better health and care

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What's covered in this presentation

- What is Pathology?
- What are the key Pathology related standards that are currently used in the UK and why do these need to change?
- What is NHS Digital's role?
- What is the Pathology Information Model?
- How was the Pathology Information Model developed and how does it relate to the Message Specification?
- Next steps and further information

What is Pathology?

- Pathology is the study of disease.

- It is central to many aspects of patient care, including diagnostic testing, screening, disease prevention, treatment advice and the monitoring and management of conditions.

- Pathology encompasses a range of specialties, including:
  - Chemical Pathology (also known as Clinical Biochemistry)
  - Haematology
  - Microbiology
  - Histopathology
  - Virology
  - Immunology, and several others…

- The volume of use of pathology services is high. In the NHS (England and Wales):
  - around 95% of clinical pathways rely on patients having access to pathology services
  - pathology is involved in 70% of all diagnoses made
  - nearly 800 million tests are performed annually

Pathology – Drivers For Change

Strategic Drivers

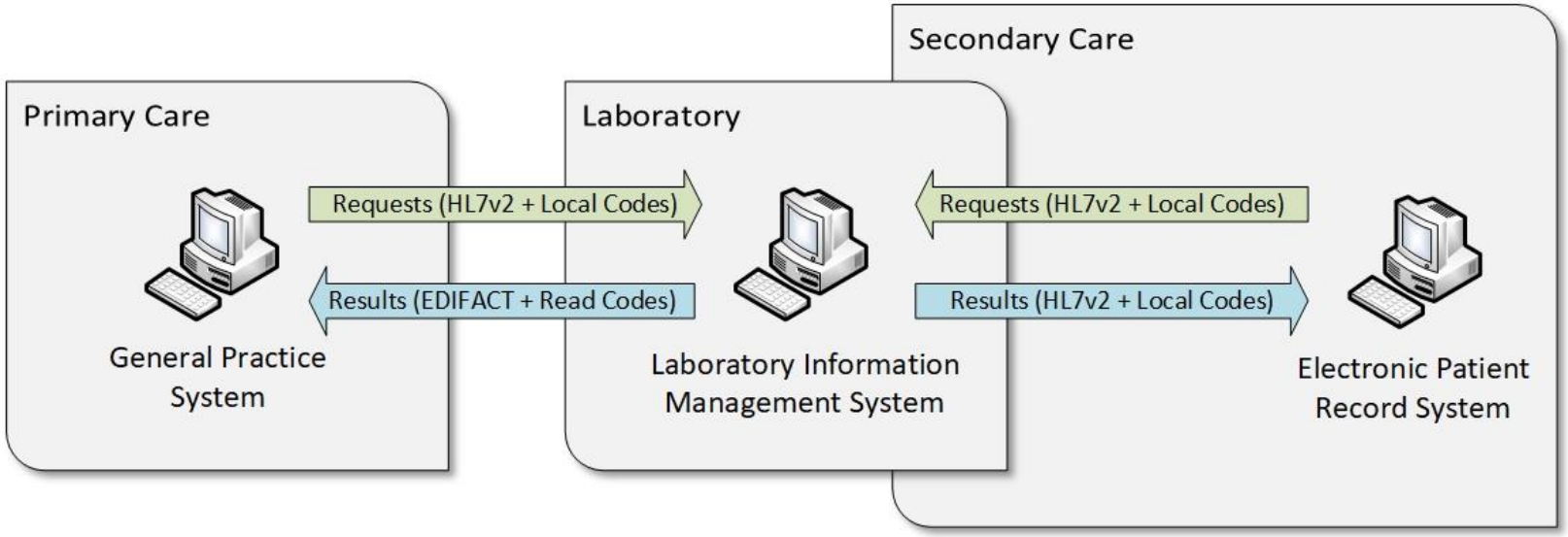
- Recently published NHS vision and strategy documents such as the NHS Long Term Plan and The Future of Healthcare state the need for clinicians, patients and carers to have access to information using clear and consistent standards.

- Interoperability, enabled by open data standards, is a key building block to help achieve that vision.

- Within pathology, there is an increasing need to standardise the ways in which test requests and test results are defined and shared between health care professionals and patients.

- This will enable a range of benefits, including:
  - improved clinical decision making and patient safety due to the ability to unambiguously communicate and interpret pathology test results
  - the ability to establish managed networks of pathology laboratories
  - opportunities for using the data to support secondary uses such as analytics
  - the ability for commissioning organisations to consistently compare and manage costs

Pathology – Current Information Flows and Standards (Simplified)



- The diagram provides a very simplified, generic view of the key pathology request and result information flows and standards that are currently used in the UK.
- Other types of systems that are typically involved are not shown e.g. middleware, integration engines, order comms systems.

- Primary Care
  - Test requests are typically sent from the GP system via an Order Comms system (not shown) using HL7v2 format messages and local codes for the requested tests.
  - Test results are returned from the lab using a nationally defined messaging standard based on EDIFACT. Test names are coded using a nationally defined catalogue based on Read codes.
- Secondary Care
  - Test requests and results are sent using HLv2 format messages. These vary depending on system supplier. A variety of locally defined codes are used for test names.

Pathology – Drivers For Change (continued)

Retirement of Read Codes

- Test results sent from labs to primary care currently use a coding scheme for test names based on Read codes rather than SNOMED CT. This is known as the PBCL (Pathology Bounded Code List).

  e.g. 44h6 – Plasma sodium level

- Read codes are in the process of being retired therefore there is a need to move to a new SNOMED CT based coding scheme for pathology tests.

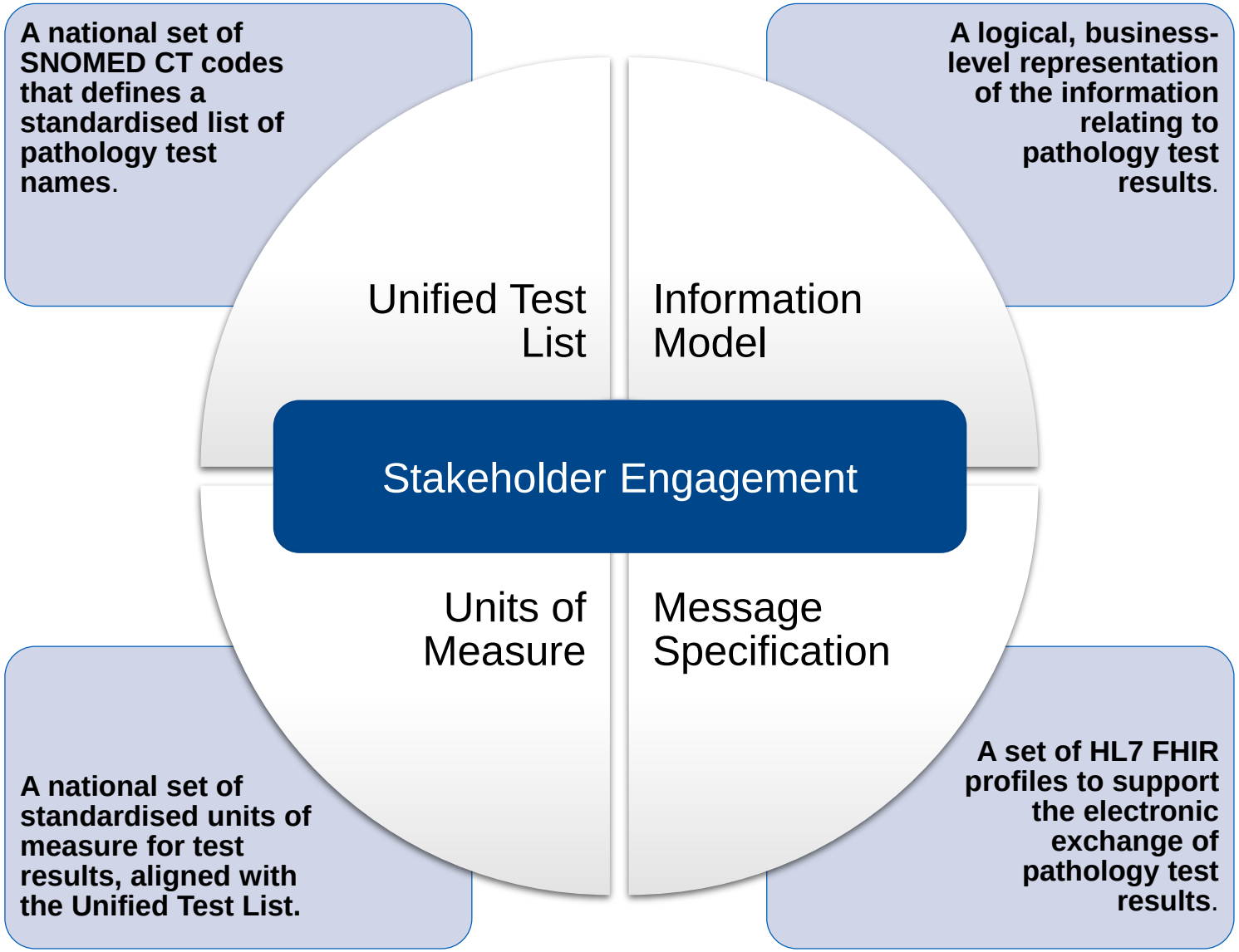
  e.g. 1107861000000100 – Sodium substance concentration in plasma

- The new SNOMED CT based pathology test coding scheme is being developed by NHS Digital and is called the Unified Test List.

Legacy Messaging Standard

- The current lab to primary care interface for sending pathology test reports uses a legacy messaging standard based on EDIFACT. This uses the PBCL (based on Read codes) for coding test names.

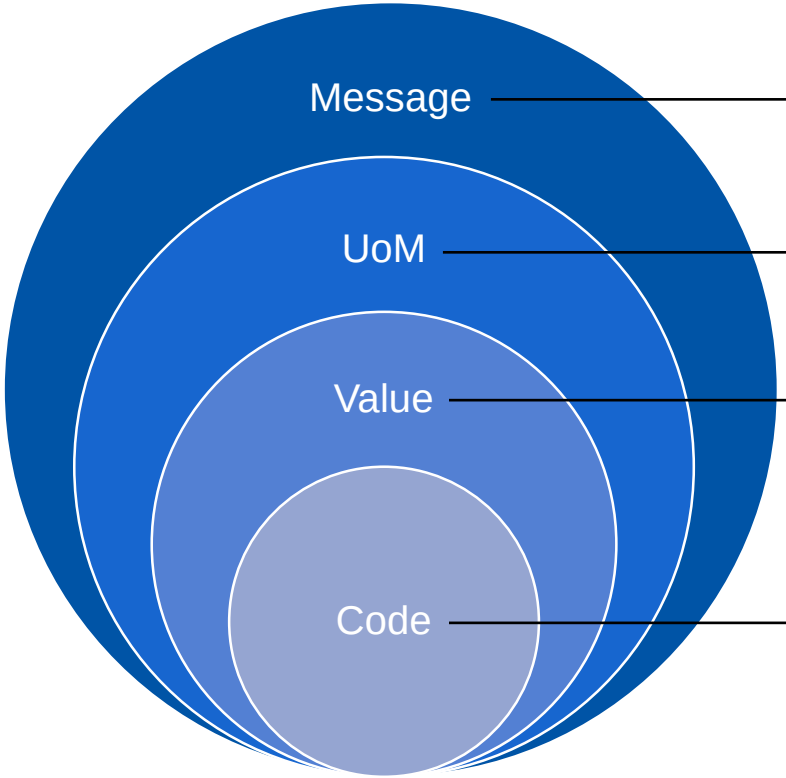
NHS Digital – Inter-related Pathology Workstreams



NHS Digital – What are we trying to create?

Transfer clinical statement → Sodium substance concentration in plasma 142 mmol/L

```
<code>
    <coding>
        <system value="http://snomed.info/sct"/>
        <code value="1107861000000100"/>
        <display value="Sodium substance concentration in plasma"/>
    </coding>
</code>
...
<valueQuantity>
    <value value="142"/>
    <unit value="mmol/L"/>
</valueQuantity>
```



mmol/L

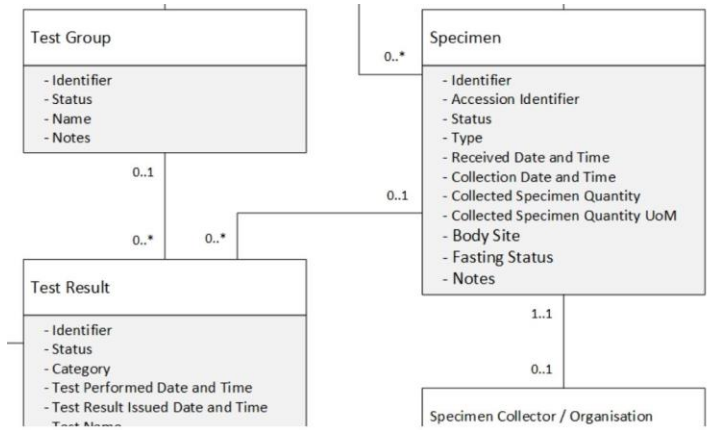
142

11078610000
Sodium substance concentration in plasma

Information Model – Overview

- The model provides a logical, business-level representation of the information relating to pathology test results.

- It includes business entities (e.g. Patient, Test Result, Specimen), relationships between business entities and entity level data items. For example, the data items in the Test Result business entity include:
  - Status
  - Category
  - Test Performed Date and Time
  - Test Result Issued Date and Time
  - Test Name and Code
  - Test Result Value

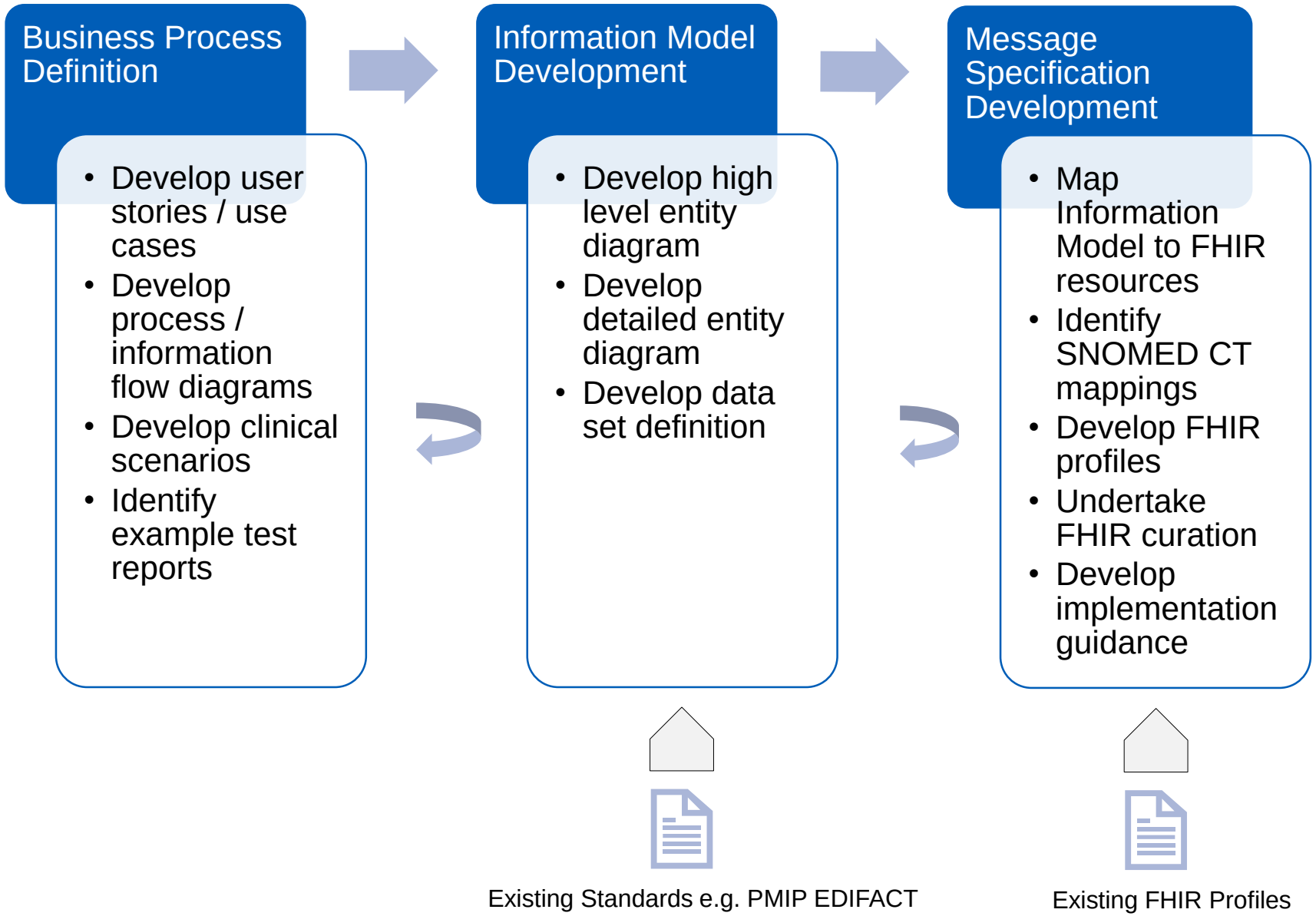


- The model consists of:
  - a diagram illustrating the business entities, relationships and data items (as per the fragment shown above)
  - a tabular definition of the business entities and data items, together with associated properties such as data types, value sets and cardinalities

Information Model – Overview (continued)

- The current version of the model focusses on test reporting, however to provide context it also includes a reference to a summary of the test request.
- Future iterations of the model will cover test requesting in more detail.
- A key objective is to ensure that the model is generic enough to apply to a range of primary and secondary care settings.
- This allows the model to be ‘mapped’ to different technical messaging standards that can then be implemented e.g. using HL7 v2.x, PMIP EDIFACT, HL7 FHIR (this is covered in more detail later).
- It also allows the use of terminologies (such as SNOMED CT) and simple coded value sets to be decoupled from the core Information Model.

Information Model / Message Specification Development Approach



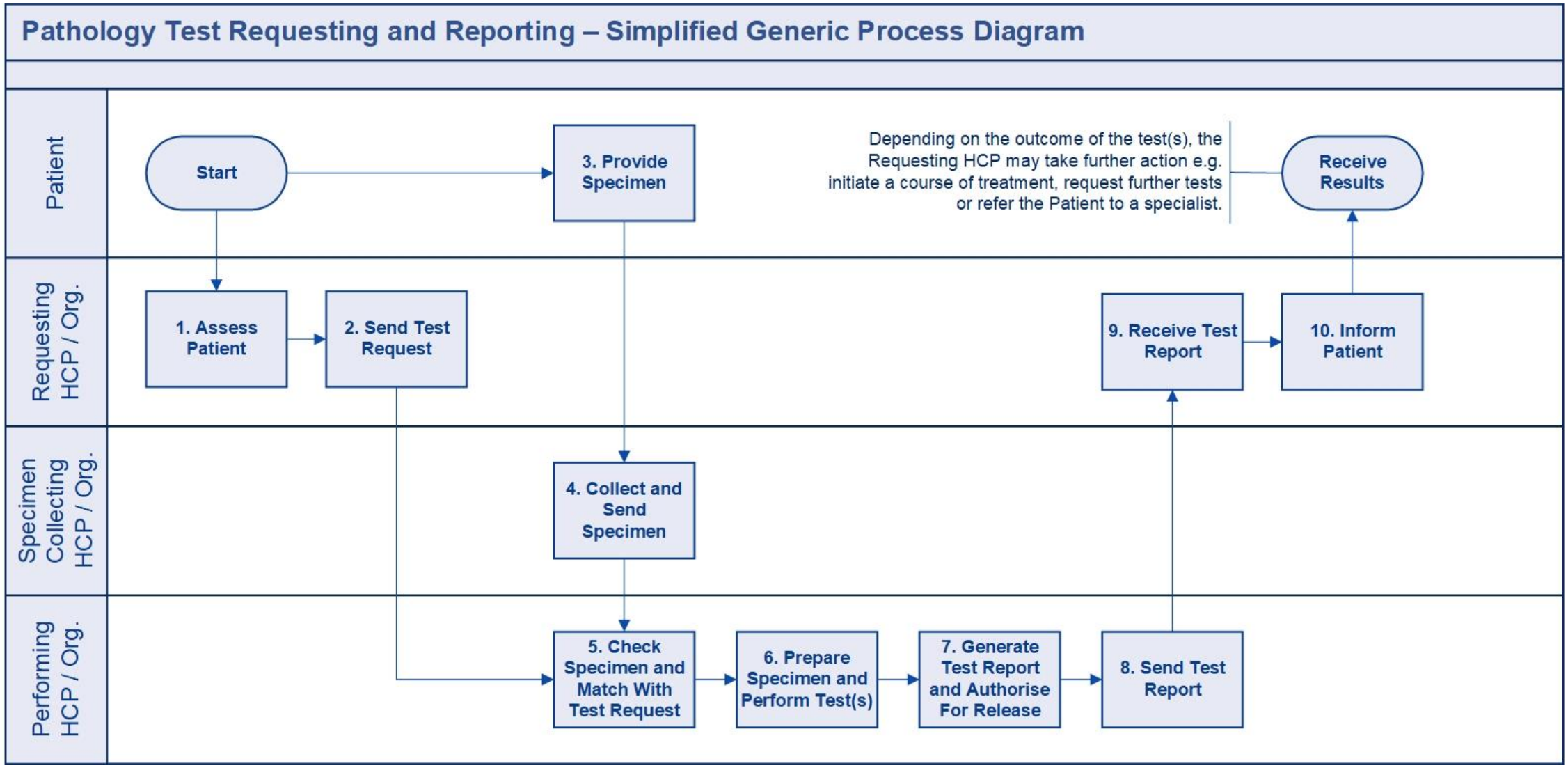
Business Process Definition – Overview

- Work was undertaken with a range of stakeholders to understand the current state (“as-is”) business processes, information flows and data requirements associated with pathology test reporting and requesting.

- Various outputs were produced, including:
  - Process / Information Flow Diagrams
  - User Stories / Use Case Descriptions
  - Clinical Scenario Descriptions
  - Example Test Reports

- The following slides provide examples of the artefacts that were produced.

Business Process Definition – Simplified Generic Process Flow



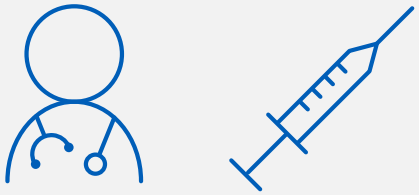
Business Process Definition – Example Use Case

Scenario	A Health Care Professional (HCP) in a primary care setting (e.g. a GP in a GP practice) determines that a patient requires a pathology test, for example to aid the diagnosis of a suspected condition or monitor an existing condition.
Actors	Patient, Requesting HCP, Specimen Collecting HCP, Performing HCP, Medical Courier Service GP system, Order Comms system, Laboratory Information Management System (LIMS)
Main Flow	1. The patient attends an appointment at their GP practice and the HCP determines that a pathology test is required. 2. The Requesting HCP sends a test request to a designated pathology laboratory (typically based in a hospital trust). The request is sent electronically using an order comms system, accessed via the GP system. **(Alternative Flow a)** 3. The patient provides a specimen e.g. blood, urine. Depending on the type of test and local processes, blood specimens may be taken by the patient's GP or, more typically, by a GP Practice Nurse or similar Health Care Professional in a follow-up appointment. The specimen is sent via a specialist medical courier service to the laboratory. **(Alternative Flow b)** 4. Upon receipt at the laboratory, the specimen is prepared and matched with the test request. The details are recorded in the LIMS. (**Exception Flow a)** 5. The test is performed against the specimen and the results authorised for release. 6. The tests results are sent electronically to the GP system. 7. The patient is informed of the test results and, if required, the Requesting HCP takes further action e.g. initiates a course of treatment, requests further tests or refers the patient to a specialist.
Alternative Flows	a. An order comms system is not used - the test request is sent via another method e.g. paper form. **(Main Flow Step 2)** b. The specimen is collected in a different care setting, for example a phlebotomy clinic at a hospital. **(Main Flow Step 3)**
Exception Flows	a. The specimen is damaged or not received. **(Main Flow Step 4)**

Business Process Definition – Example Clinical Scenario

Lisa, a 60 year old woman, was diagnosed with hypertension several years ago.

She attends her GP practice regularly so that her GP can monitor her condition.



Lisa's GP requests renal function tests to help monitor her condition.

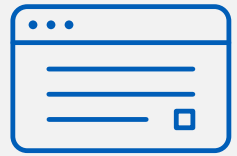
The test request is sent electronically from the GP practice to the test lab.

The GP practice nurse takes a blood sample from Lisa. This is sent via a courier to the lab.

The sample is received by the lab, matched with the test request and the details are booked into the lab system.

The tests are performed.

The test results are authorised for release and sent electronically to the requesting GP.



The test results are received by the GP practice.

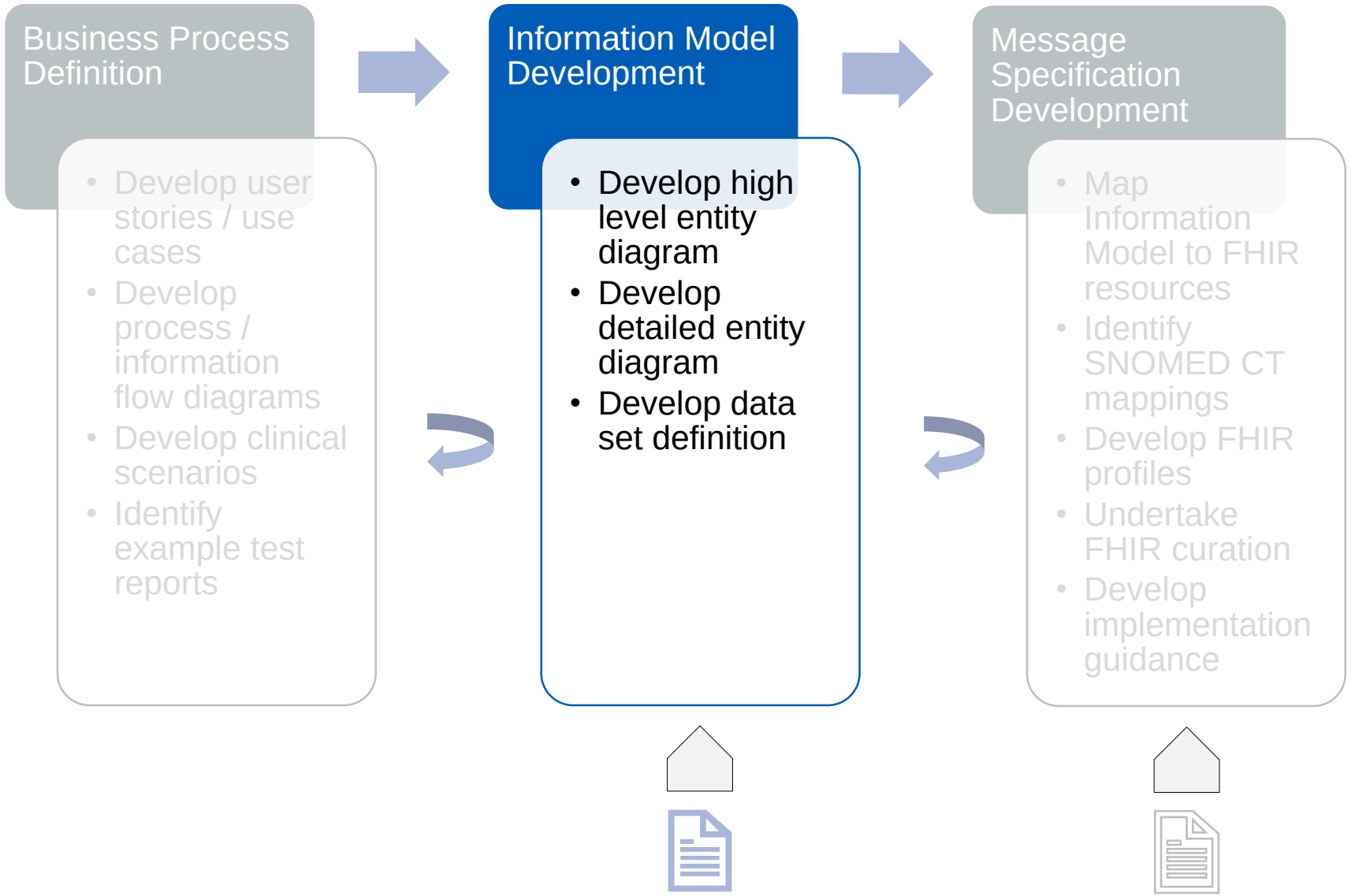
Based on the outcome of the tests, Lisa's GP determines that additional action is not currently required and advises Lisa to continue her current medication and attend her next review.

Business Process Definition – Example Test Report

Electrolytes and Creatinine Profile		
	Value / Unit of Measure	Reference Range
Sodium	142 mmol/L	(133 to 146)
Potassium	4.8 mmol/L	(3.5 to 5.3)
Chloride	105 mmol/L	(95 to 108)
Creatinine	64 umol/L	(48 to 128)
EGFR	87 mL/min/1.73m*	
Comments: The EGFR quoted above must be multiplied by 1.2 if the patient is of Afro-Caribbean origin.		

- This example illustrates a test report based on a test request for a set of related tests.
- Various terms are used to refer to sets of related tests, including **profile**, **panel** and **battery**.
- Within the context of the Information Model, the term **Test Group** has been used.

Information Model / Message Specification Development Approach



Information Model – Development

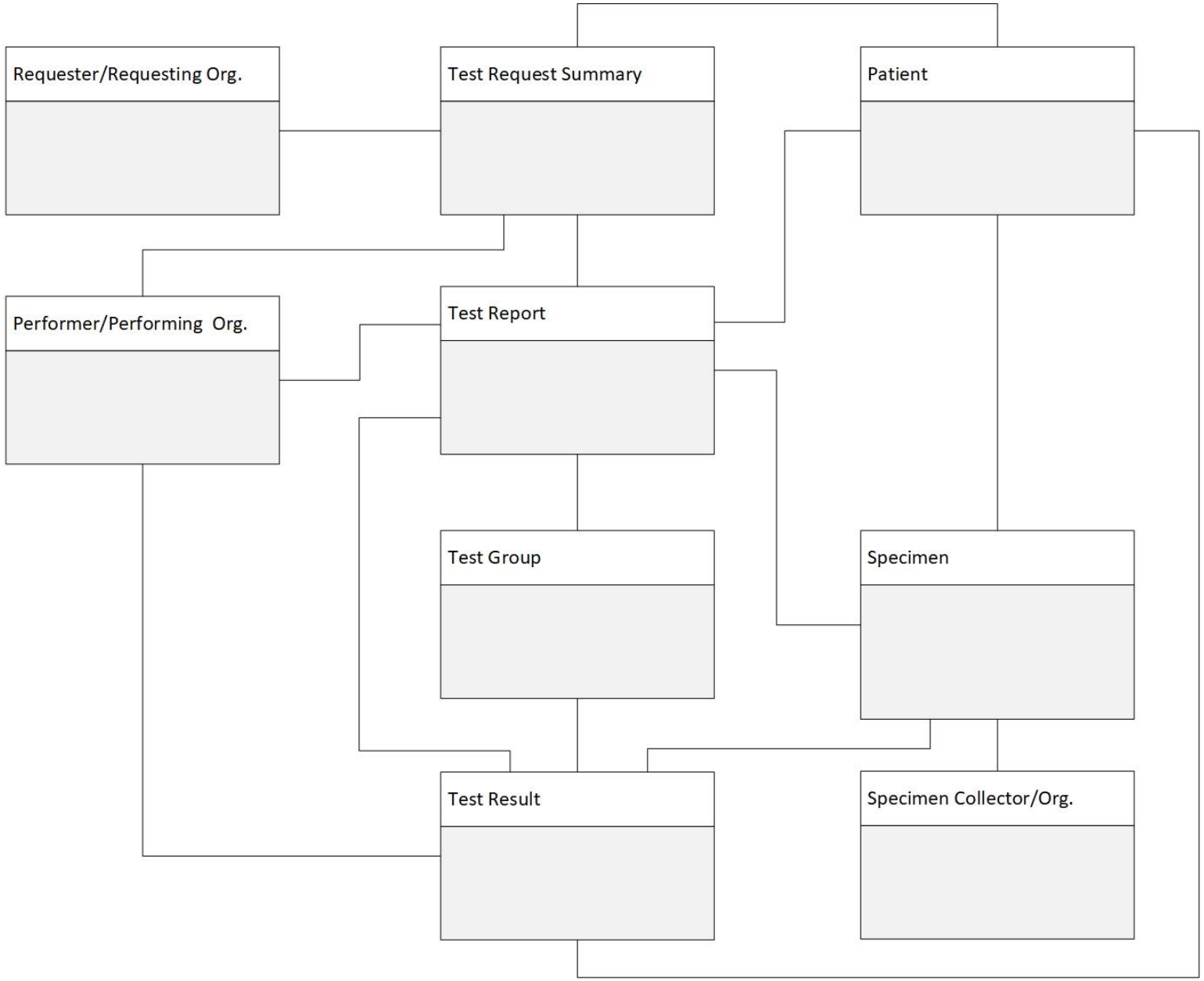
- Development of the Information Model was clinically-led, with input from a range of stakeholders including clinicians, professional bodies, standards organisations, system suppliers and a national pathology user group.

- In addition to the outputs of Business Process Definition phase, development of the model was informed by reference to existing pathology messaging standards:
  - PMIP EDIFACT (in primary care)
  - HL7v2 (in secondary care)

- An incremental and iterative development approach was adopted:
  - a high level view was developed first, depicting key business entities and the relationships between them
  - this was then developed into a more detailed model that included entity level data items and relationship cardinalities
  - finally a tabular data set definition was produced to provide a detailed description of entity and data item properties, such as data types and value sets

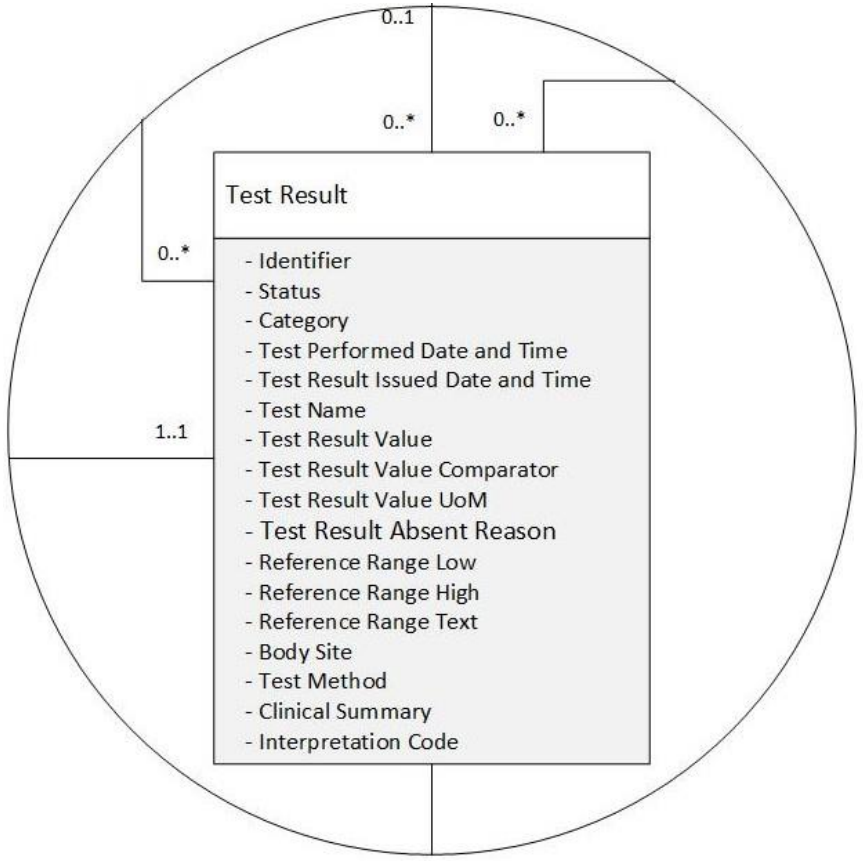
Information Model – High Level

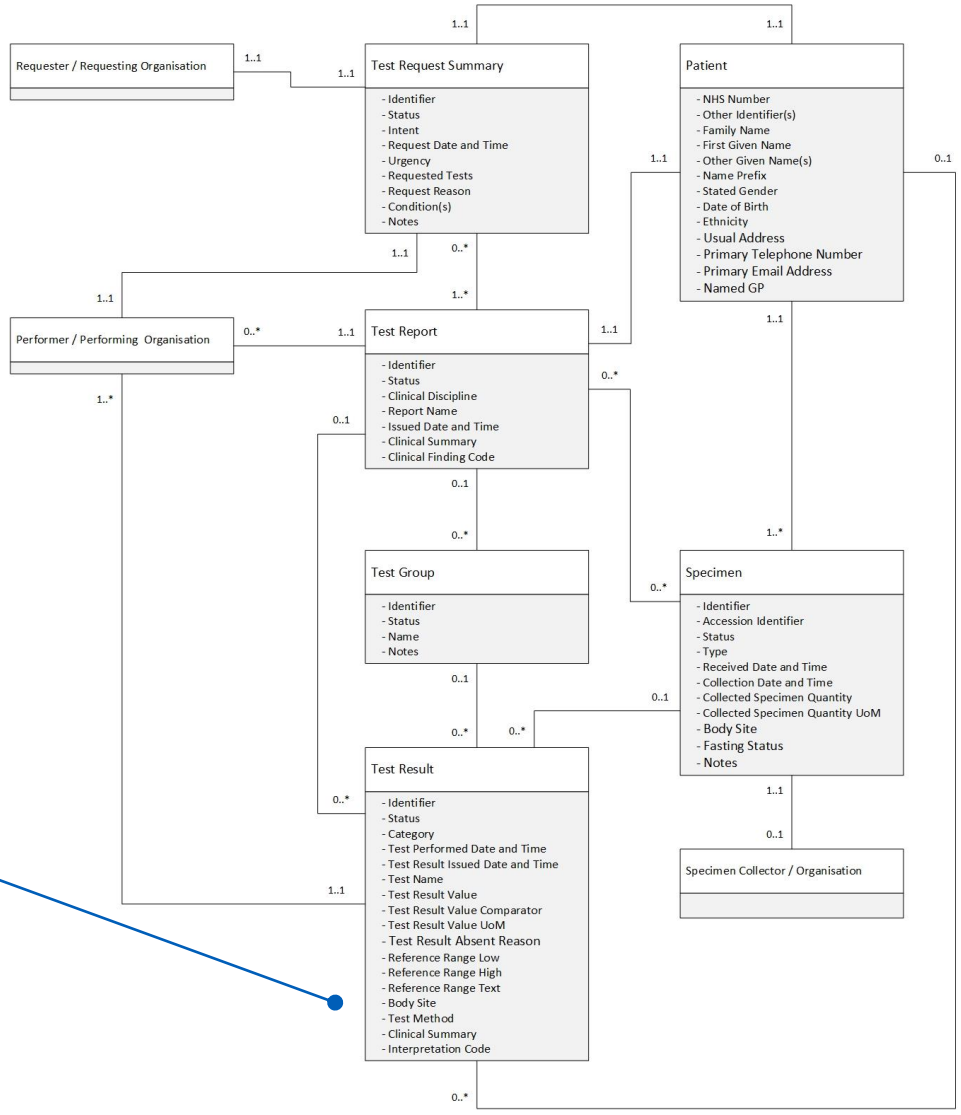
- High level model depicts the key business entities and relationships between them but does **not include data items or cardinalities**.
- Incorporates business entities identified during the Business Process Definition phase.
- A Test Result may optionally form of a Test Group (a.k.a. Profile, Panel, Battery).
- Note: to aid clarity, Individual level and Organisation level type entities (e.g. Performer / Performing Organisation) have been combined in this version of the diagram.



Information Model – Detailed

- Detailed model includes entity data items and relationship cardinalities.
- Further detail is provided in a data set definition spreadsheet (see next slide).



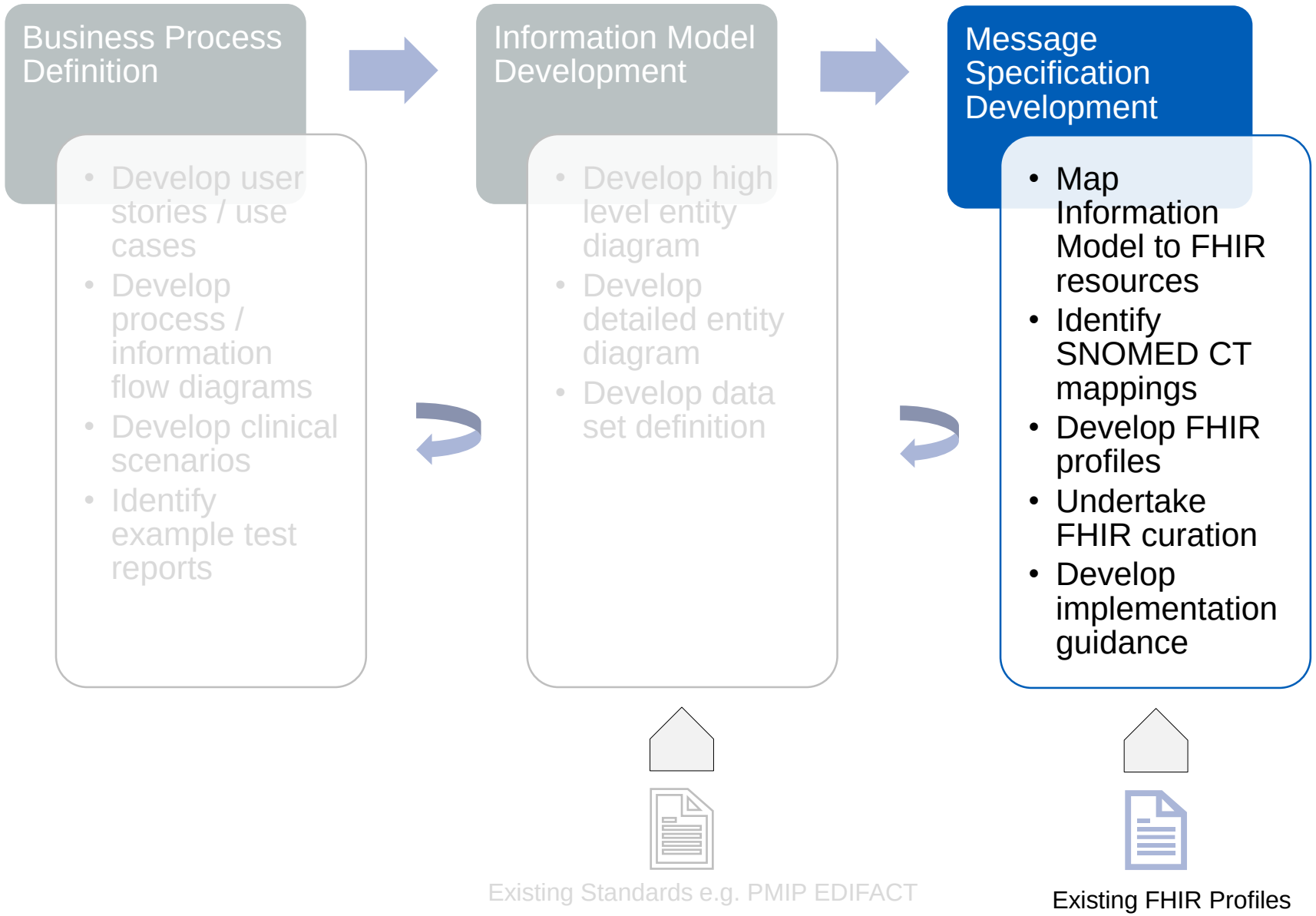


Information Model – Data Set Definition

- Provides a detailed tabular definition of business entity and data item properties.
- Extract below is taken from the ‘Test Result’ entity.

Data Item Name	Description	Cardinality	M/R/O	Data Type	Values
Identifier	A business level identifier for the test result.	1..1	Mandatory	Identifier	
Status	The status of the test result.	1..1	Mandatory	Code	registered | preliminary | final | amended | corrected | cancelled | entered-in-error | unknown
Category	The general type of test result.	0..1	Required	Code	social-history | vital-signs | imaging | laboratory | procedure | survey | exam | therapy
Test Performed Date and Time	The date and time that the test was performed.	0..1	Required	DateTime	
Test Result Issued Date and Time	The date and time that the test result was issued to the requesting organisation.	0..1	Required	DateTime	
Test Name	The name and code of the test that was performed.	1..1	Mandatory	CodeableConcept	SNOMED CT concept (observable entity)
Test Result Value	The test result value.	0..1	Required	Multiple	
etc.					

Information Model / Message Specification Development Approach



Message Specification – FHIR

- The Message Specification is based on the HL7 FHIR (pronounced FHIR – Fast Healthcare Interoperability Resources) standard.

- FHIR is an XML based standard for exchanging healthcare information electronically. It builds on previous HL7 standards such as HL7v2, HL7v3 and CDA.

```
<code>
    <coding>
        <system value="http://snomed.info/sct"/>
        <code value="1107861000000100"/>
        <display value="Sodium substance concentration in plasma"/>
    </coding>
</code>
...
<valueQuantity>
    <value value="142"/>
    <unit value="mmol/L"/>
</valueQuantity>
```

- A key feature of FHIR is the inclusion of **resources** – these are predefined but extensible groups of data elements.

- A range of clinical and administrative resources are provided as part of FHIR e.g. Patient, Practitioner, Sample, Observation, DiagnosticReport.

- Resources can be constrained and/or extended using **profiles** to meet local requirements.

Message Specification – Development

- The business entities in the Information Model were mapped to FHIR resources. For example: Test Report -> DiagnosticReport

- The data items in the business entities were mapped to elements within the FHIR resources. Where mappings could not be identified, extensions were created e.g. Specimen Fasting Status.

- Data items with coded lists of values were mapped to SNOMED CT concepts and FHIR value sets.

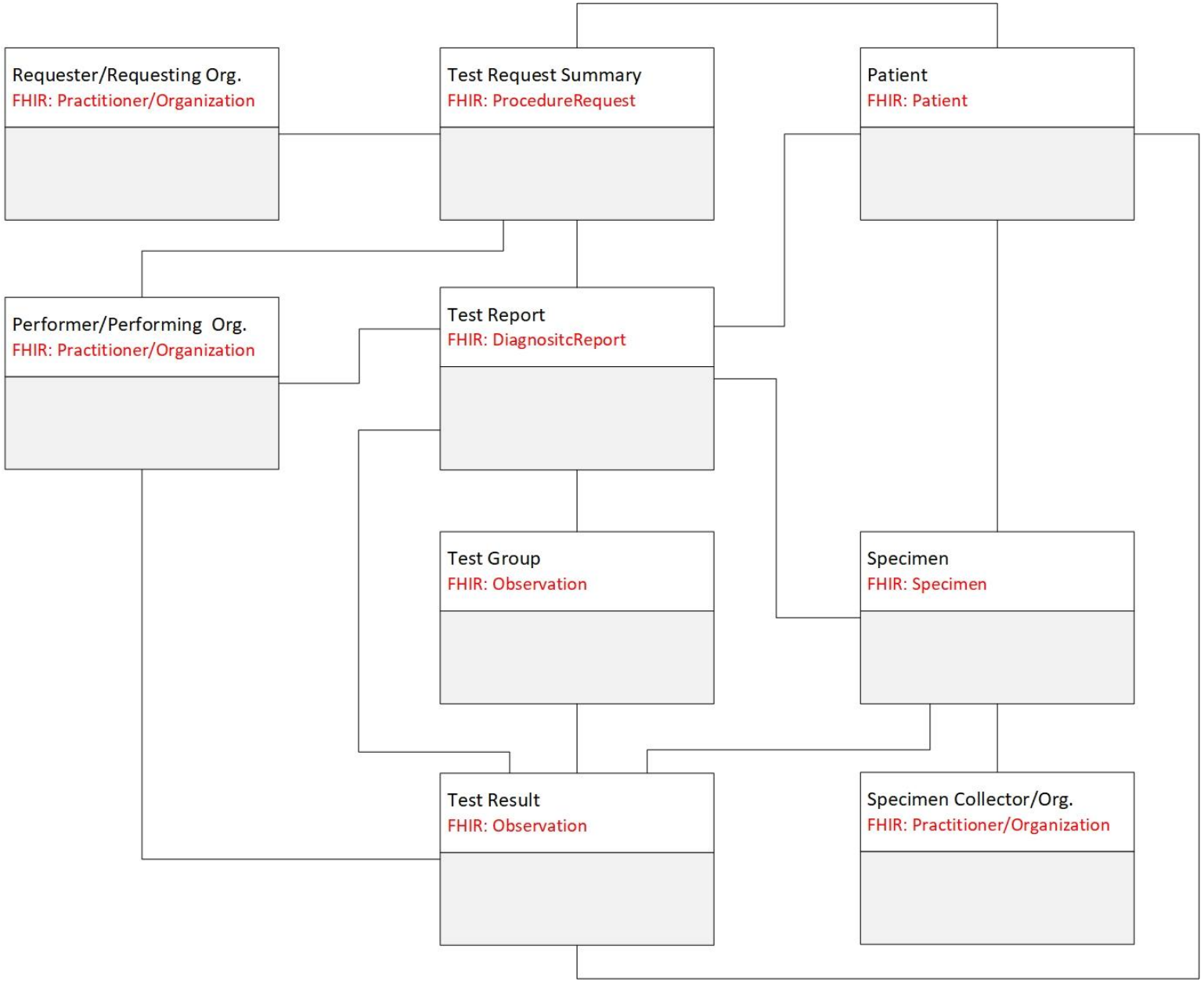
- For some of the core business entities (e.g. Patient, Requesting Organisation / Practitioner), existing, previously defined FHIR profiles were used, otherwise new profiles were created based on the base FHIR resources.

- The draft FHIR pathology profiles were reviewed and refined as part of a clinical and technical assurance process known as FHIR Curation, led by INTEROPen

- To aid adoption of the FHIR profiles, Implementation Guidance has been developed.

Information Model to FHIR Resource Mapping (High Level)

- Diagram illustrates high level mapping between the Information Model business entities and FHIR resources.



Information Model to FHIR Resource / Element Mapping

Provides a mapping between the Information Model data items and, where available, the corresponding FHIR resources and data elements.

Information Model		FHIR
Data Item Name	**Description**	**FHIR Resource / Element**
Identifier	A business level identifier for the test result.	Observation.identifier
Status	The status of the test result.	Observation.status
Category	The general type of test result.	Observation.category
Test Performed Date and Time	The date and time that the test was performed.	Observation.effectiveDateTime
Test Result Issued Date and Time	The date and time that the test result was issued to the requesting organisation.	Observation.issued
Test Name	The name and code of the test that was performed.	Observation.code
Test Result Value	The test result value.	Observation.value.valueQuantity.value
etc.		

Message Specification – Example FHIR Profile Content

```
<resource>
    <DiagnosticReport xmlns="http://hl7.org/fhir">
        <id value="efae5859-28df-4e7d-be91-6df56d8215e4"/>
        <meta>
            <profile value="https://fhir.nhs.uk/STU3/StructureDefinition/CareConnect-DiagnosticReport-1"/>
        </meta>
        <!--Test Request Summary-->
        <basedOn>
            <reference value="urn:uuid:d9df1431-22ac-462a-946a-f195f6c639af"/>
        </basedOn>
        <status value="final"/>
        <code>
            <coding>
                <system value="http://snomed.info/sct"/>
                <code value="721981007"/>
                <display value="Diagnostic studies report"/>
            </coding>
        </code>
        <subject>
            <reference value="urn:uuid:8d6c2cd5-0eec-496a-88d0-3785a135df09"/>
            <display value="REARDON, John"/>
        </subject>
        <issued value="2019-04-03T12:00:00+00:00"/>
        <performer>
            <actor>
                <reference value="urn:uuid:d6407de7-0e86-45eb-93cb-035094aaa49e"/>
                <display value="GREENTOWN GENERAL HOSPITAL"/>
            </actor>
        </performer>
        <specimen>
            <reference value="urn:uuid:756a8361-79ce-4561-afcb-a91fe19df123"/>
        </specimen>
        <result>
            <reference value="urn:uuid:dacb177a-9501-4dcc-8b22-b941791ae0db"/>
        </result>
    </DiagnosticReport>
</resource>
```

Message Specification – FHIR Profile Linkages

The following provides a simplified, schematic view of the key pathology related FHIR profiles and elements, and the relationships between them.

ProcedureRequest (Test Request Summary)	
id	d9df1431-22ac-462a-946a-f195f6c639af
status	active
intent	order
code.coding.code	63476009
code.coding.display	Prostate specific antigen measurement (procedure)

DiagnosticReport (Test Report)	
id	efae5859-28df-4e7d-be91-6df56d8215e4
basedOn	d9df1431-22ac-462a-946a-f195f6c639af
status	final
code.coding.code	721981007
code.coding.display	Diagnostic studies report
issued	2019-03-03T12:00:00+00:00
specimen	756a8361-79ce-4561-afcb-a91fe19df123
result	dacb177a-9501-4dcc-8b22-b941791ae0db

Specimen (Specimen)	
id	756a8361-79ce-4561-afcb-a91fe19df123
status	available
type.coding.code	53130003
type.coding.display	Venous blood (substance)
receivedTime	2019-01-29T15:00:00+00:00
collection.collected	2017-11-01T11:00:00+00:00

Observation (Single Test Result)	
id	dacb177a-9501-4dcc-8b22-b941791ae0db
status	final
code.coding.code	1030791000000100
code.coding.display	Prostate specific antigen level (observable entity)
effectiveDateTime	2017-11-01T15:00:00+00:00
valueQuantity.value	5.9
valueQuantity.unit	ug/L
referenceRange.low	0
referenceRange.high	4
specimen	756a8361-79ce-4561-afcb-a91fe19df123

To aid clarity, the FHIR profiles for Patient, Practitioners and Organizations have not been shown. Similarly, not all of the required data elements have been shown. The arrows indicate the links between the FHIR profiles, using the local ids assigned to each resource instance. SNOMED ids are highlighted in yellow.

Key Challenges

- Cost and time constraints meant that we couldn’t tackle the whole pathology domain at once, therefore:
  - we have taken an agile and iterative approach, focussing initially on high use pathology specialities (chemical pathology and haematology)
  - we expect the Information Model and Message Specification to evolve as we progress through First of Type testing of the first release and go on to support other pathology specialities.

- FHIR is an evolving standard. The most recent version is v4, however the pathology Message Specification is based on v3. This is because currently the majority of existing FHIR profiles developed by NHS Digital are based on v3, including those defined for Patient, Practitioner and Organization.

- Some aspects of the Information Model could not be mapped directly to FHIR, for example Specimen Fasting Status. These were resolved by introducing localised extensions to the relevant FHIR profiles. In this case the extension was based on functionality introduced into FHIR v4.

Next Steps and Further Information

Next Steps

- Undertake First of Type testing, working with healthcare organisations and suppliers.
- Use the feedback gained from First of Type testing to enhance the Information Model and Message Specification.
- Support additional pathology specialities (e.g. microbiology), extending the Information Model and Message Specification as required.
- Explore pathology test requesting processes in more detail, expanding the Information Model and Message Specification as required.

Further Information

- Information Model: https://hscic.kahootz.com/connect.ti/PathologyandDiagnostics/view?objectID=13047120

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

- NHS Digital Pathology Service mailbox: pathologyanddiagnostics@nhs.net

Any Questions?

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