Lab Medicine (Pathology) Information Standards – UK Approach & Specification(s)

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Information and technology
for better health and care

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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 – 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 were deprecated (April 2016) therefore there is a need to move to a new SNOMED CT based coding scheme for pathology tests.

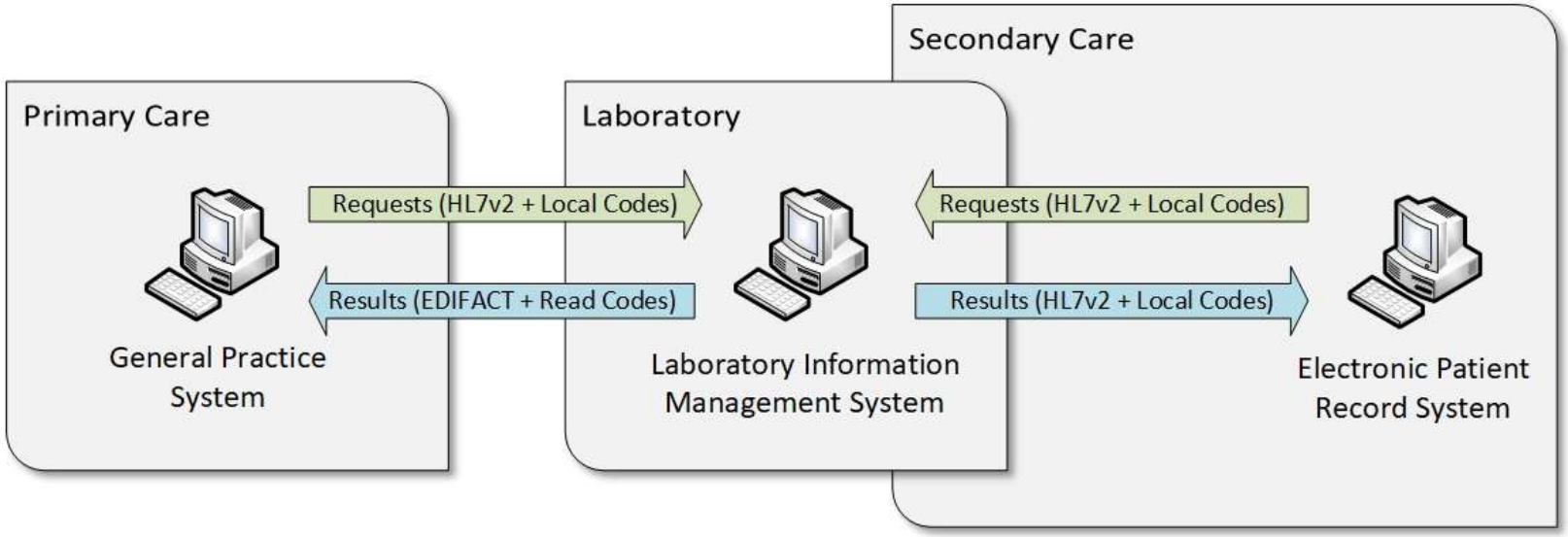
  e.g. 1107861000000100 – Sodium substance concentration in plasma

- 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.

Pathology – Current Information Flows and Standards (Simplified)



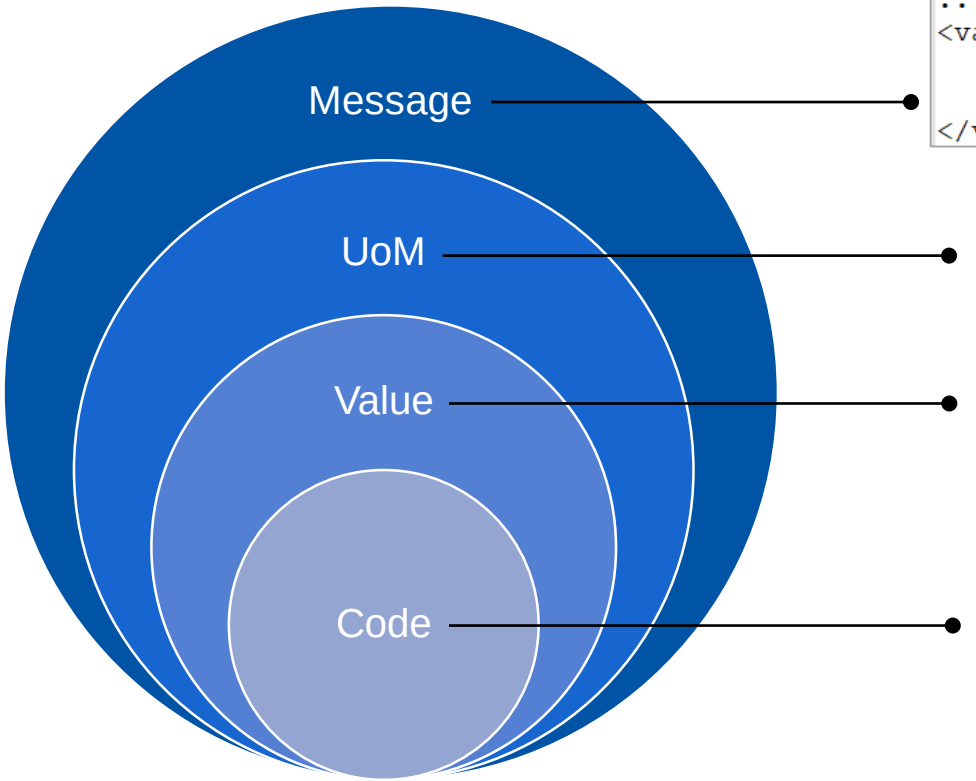
- The diagram provides a very simplified, generic view of the key pathology request and result information flows and standards that are currently used in the UK.
- Other types of systems that are typically involved are not shown e.g. middleware, integration engines, order comms systems.

- 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.

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

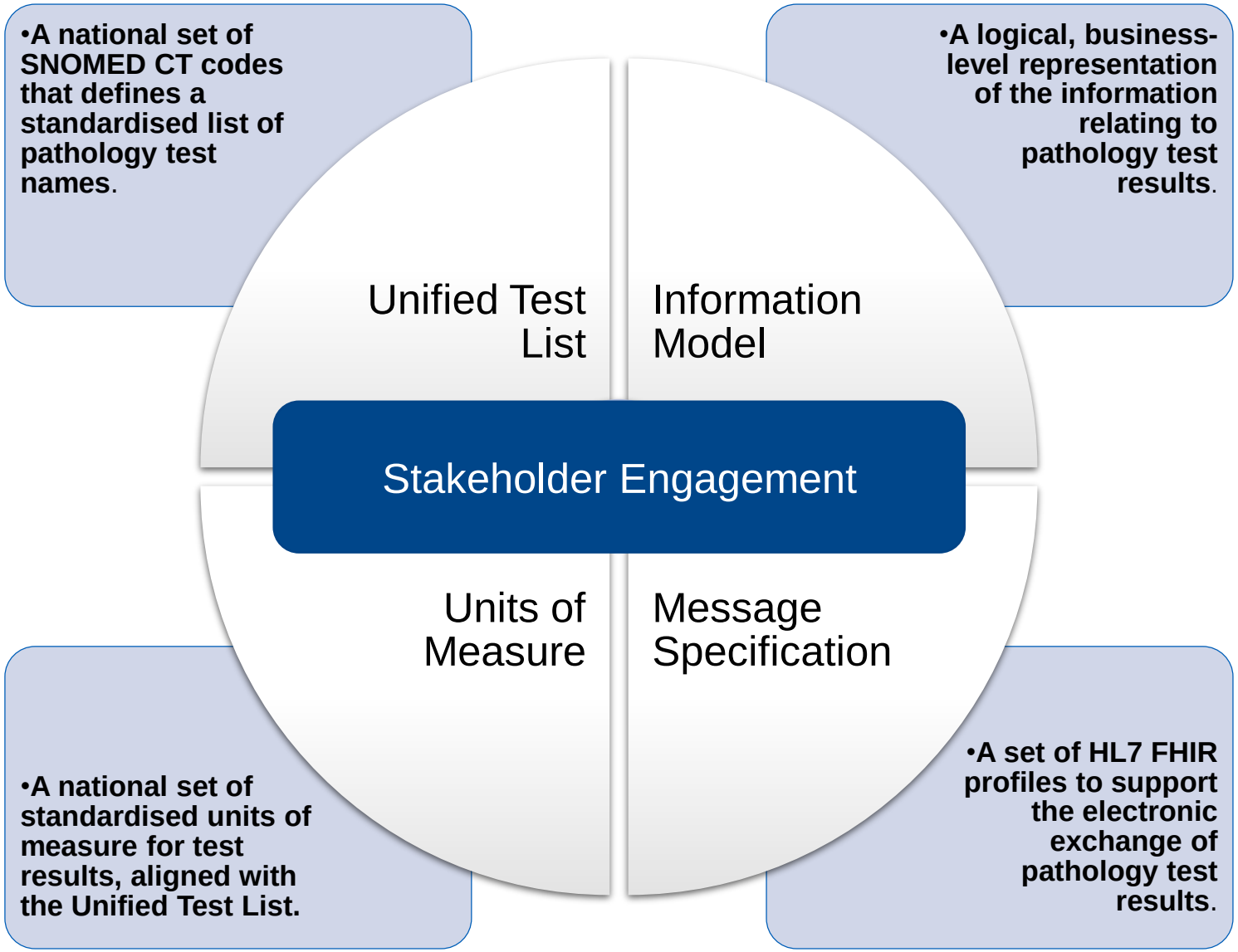
Qualitative values:
High/Low
Absent/Present
Ordinals

142

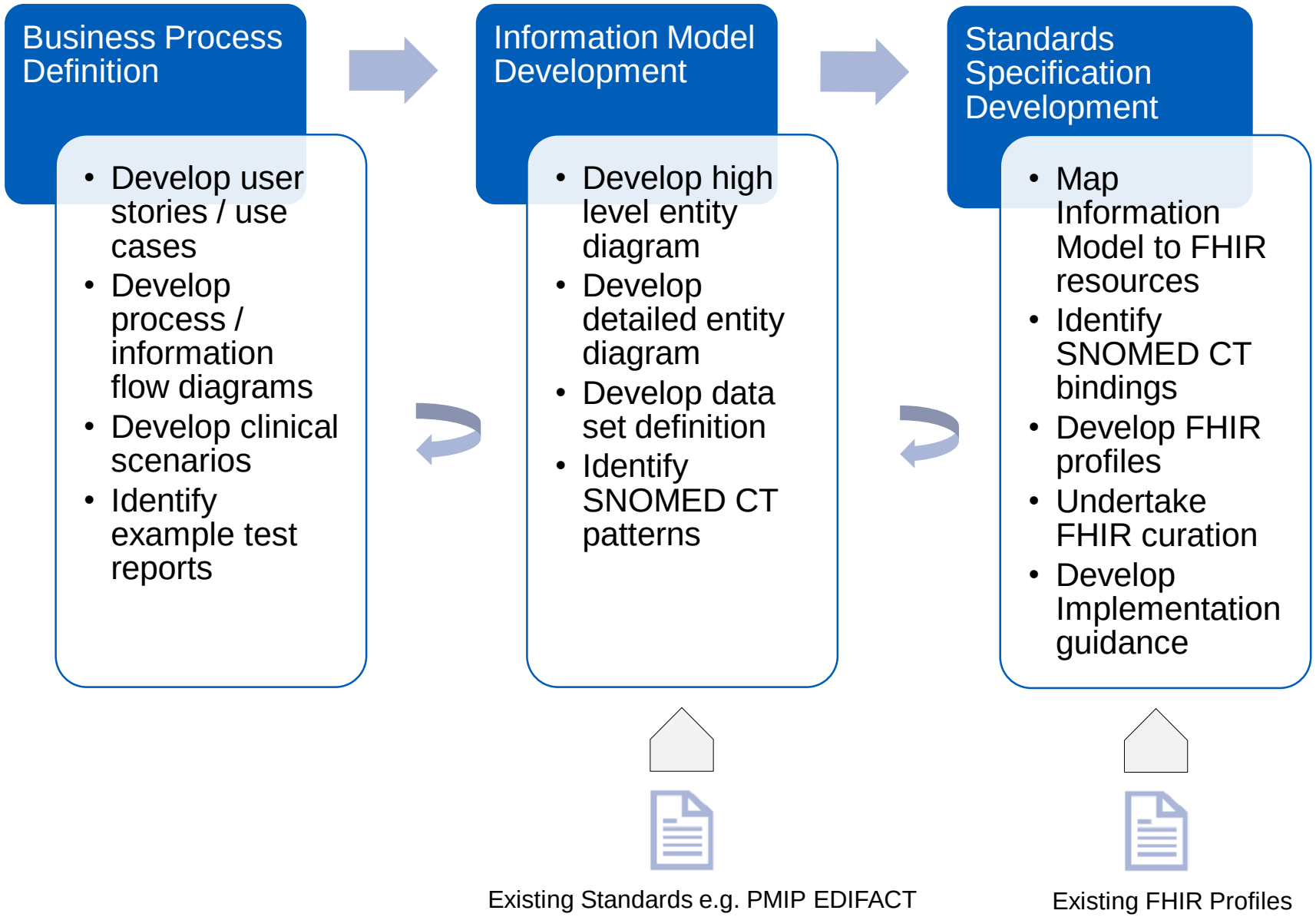
11078610000
Sodium substance concentration in plasma

Approach

NHS Digital – Inter-related Pathology Workstreams



Standards Specification Development Approach



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.

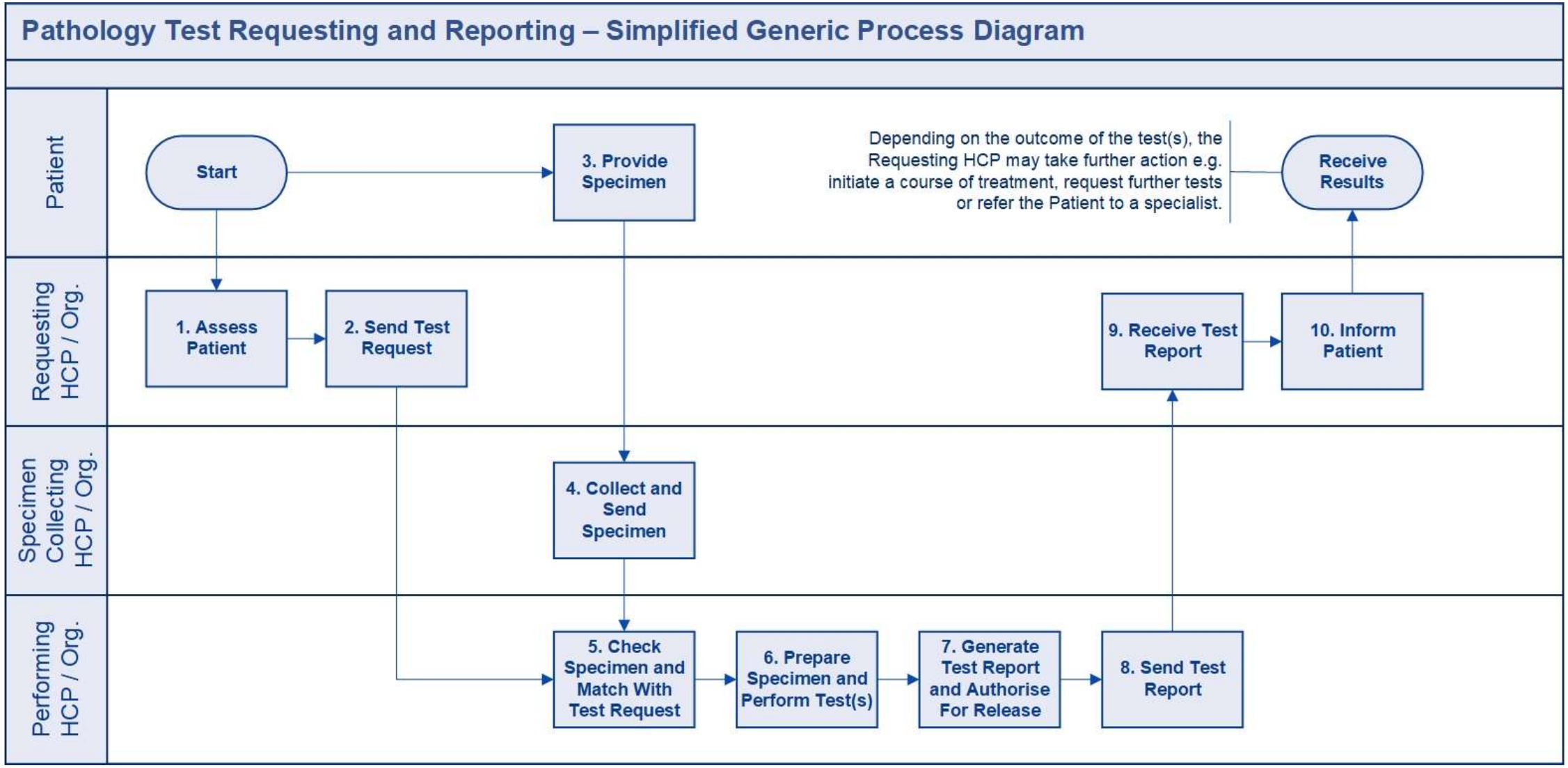
Based on the outcome of the tests, Lisa's GP determines that additional action is not currently required and advises Lisa to continue her current medication and attend her next review.

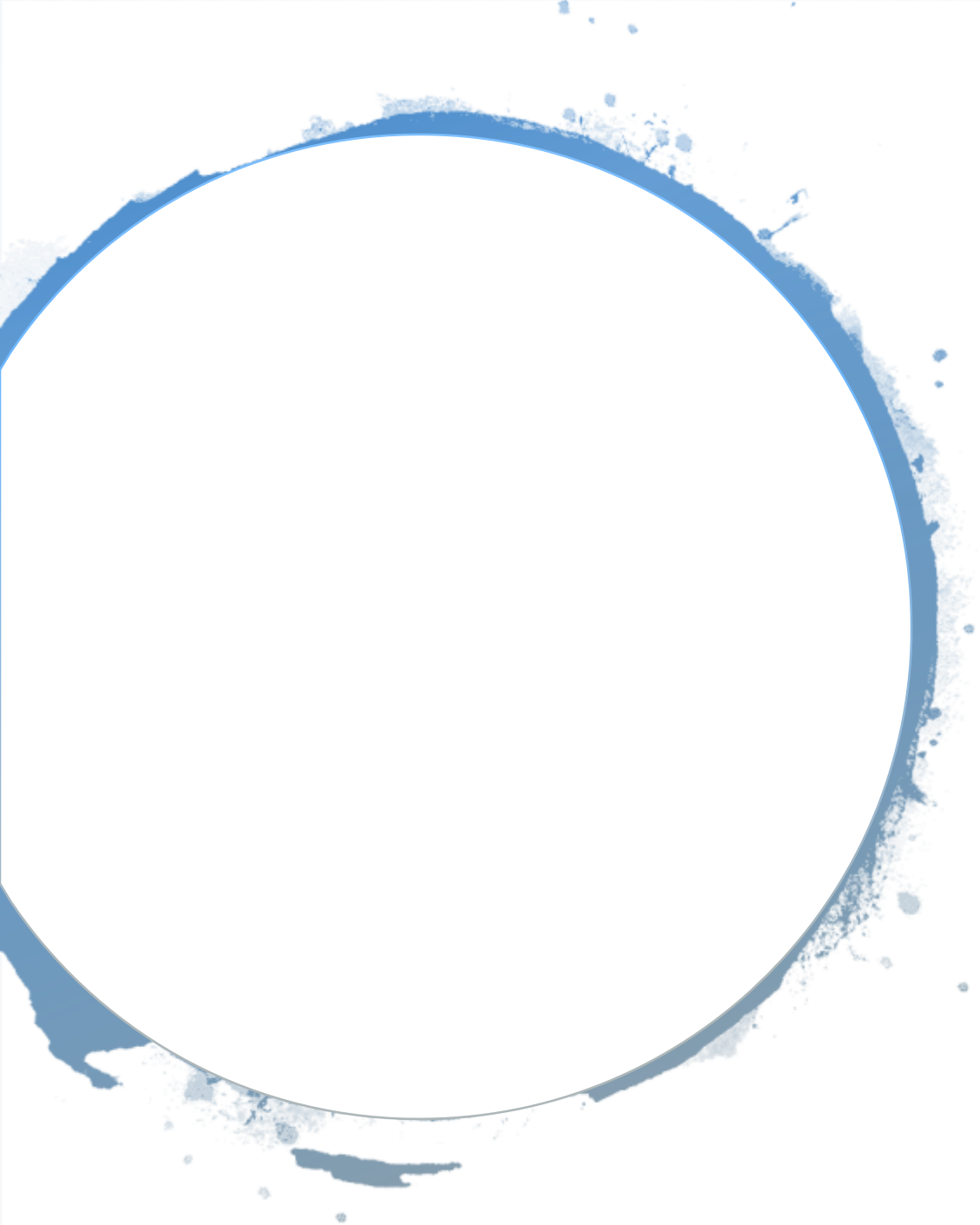
Business Process Definition – Example Test Report

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.

Business Process Definition – Simplified Generic Process Flow





Unified Test List

Unified Test List – What Is It?

- Unified Test List (UTL) – a catalogue of SNOMED CT coded laboratory test result terms.
  - Based on the SNOMED ‘observable entity’ type.
  - Naming convention for terms/descriptions is based on ‘patterns’.

- Core pattern is the triad of **Property-OF-Thing-IN-Specimen.**
  - An extension to this pattern includes **Method**.

- Other patterns will be identified and applied as work on the UTL progresses.

- Examples:

  Creatinine substance concentration in **serum**
  (substance + property + specimen)

  Creatinine substance concentration in **serum by enzymatic method**
  (substance + property + specimen + method)

SNOMED Model + Message Model (FHIR)

Test Name	SNOMED Attribute Model ('observable entity' type)					Message Model (FHIR) (relative to SNOMED model)			
	COMPONENT	PROPERTY	DIRECT SITE	TECHNIQUE	RELATIVE TO	UoM	Time	Patient/ Specimen Precondition	Reference Range
SNOMED Term	*substance etc. being measured*	*constrains **UoM** Field*	*specimen*	*method*	*second component of ratio, % etc.*				
REPORTED RESULT VALUE FROM TEST: *n*									

Creatinine substance concentration in serum *by enzymatic method*

Unified Test List – Development Approach

- Existing pathology test lists used as input:
  - national test catalogues e.g. PBCL (Pathology Bounded Code List) – based on Read codes
  - hospital Trusts – based on local codes
- Design patterns identified and applied.
- Human readable list used for initial authoring and clinical review.

- Currently published in SNOMED CT RF2 format and also in human-readable (HTML) format to aid stakeholder review.
- Latest release (published October 2019) contains approximately 1600 concepts.
  - Expectation in April 2020 release ~3,000 concepts!
  - But really, we do incremental releases - ~ monthly… ☺
  - So how do we do this quick turnaround?

Governance & Maintenance of UTL

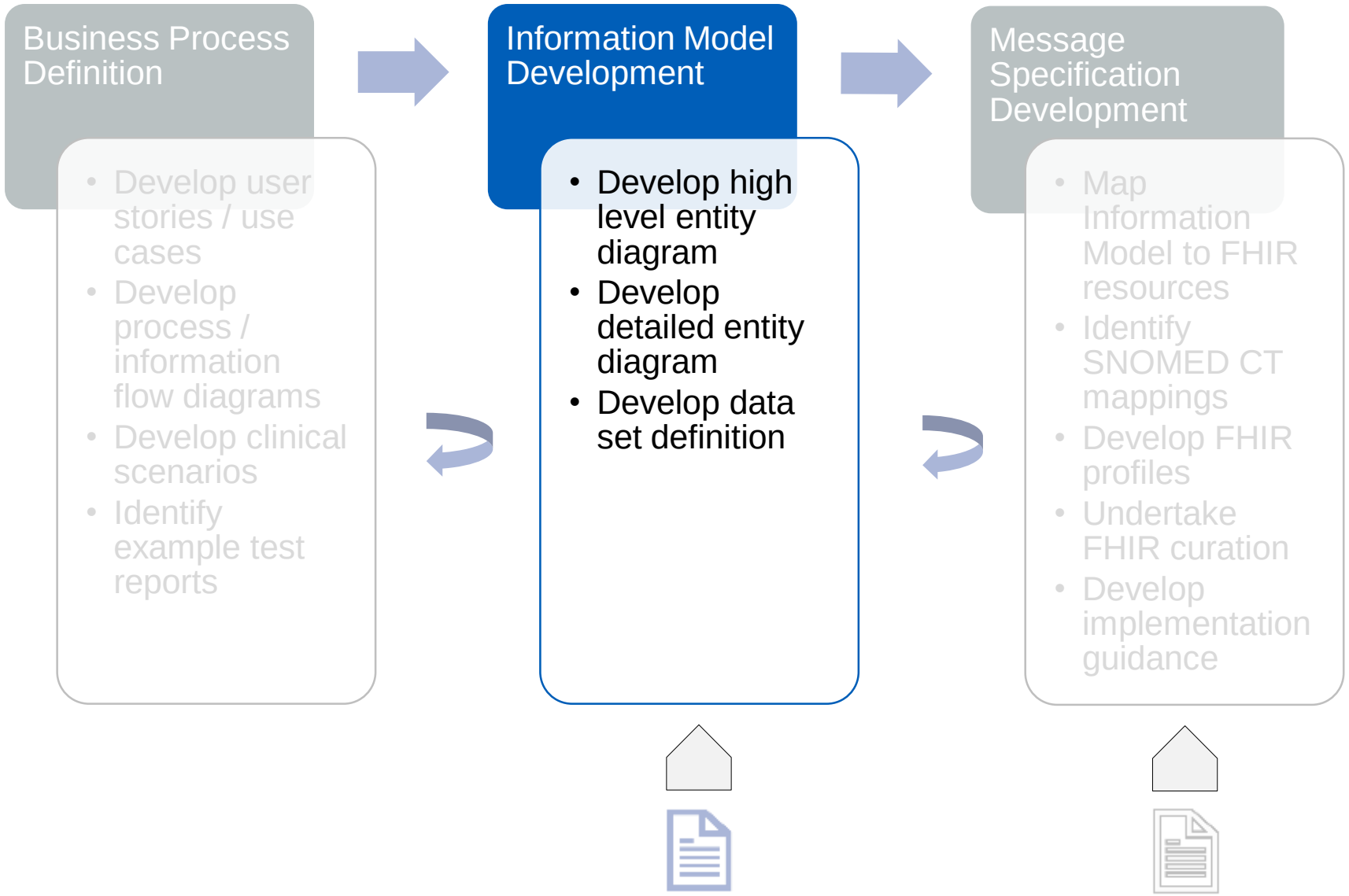
- **Content Creation**
  - Editorial Principles have been created for current work – blood sciences.
  - Design Principles created to cover both UTL and Information Model
  - Identify and apply further design patterns.

- Scale up the build/review process – explore use of SNOMED CT templating.

- **Governance of UTL Content**
  - National Pathology Information Standards Governance Board
    - Professional/clinical bodies, supplies, national organisations
      - RCPath, FCI, NHSI, PHE, PRSB – extending to all of UK
    - Use SNOMED International PaLM Group – not as active at the moment

Information Model

Information Model / Message Specification Development Approach

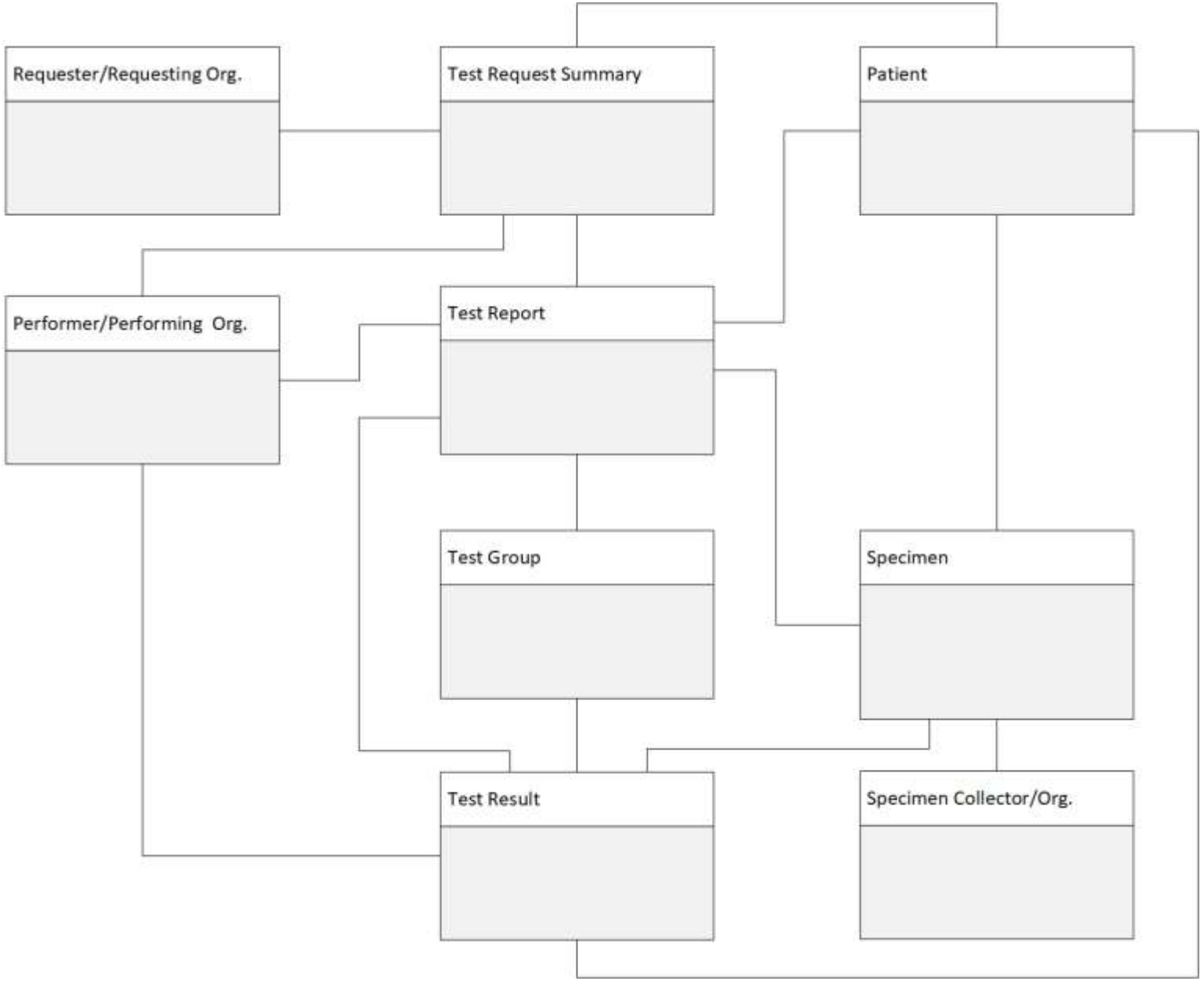


Information Model – Overview (continued)

- 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 – 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 – Development

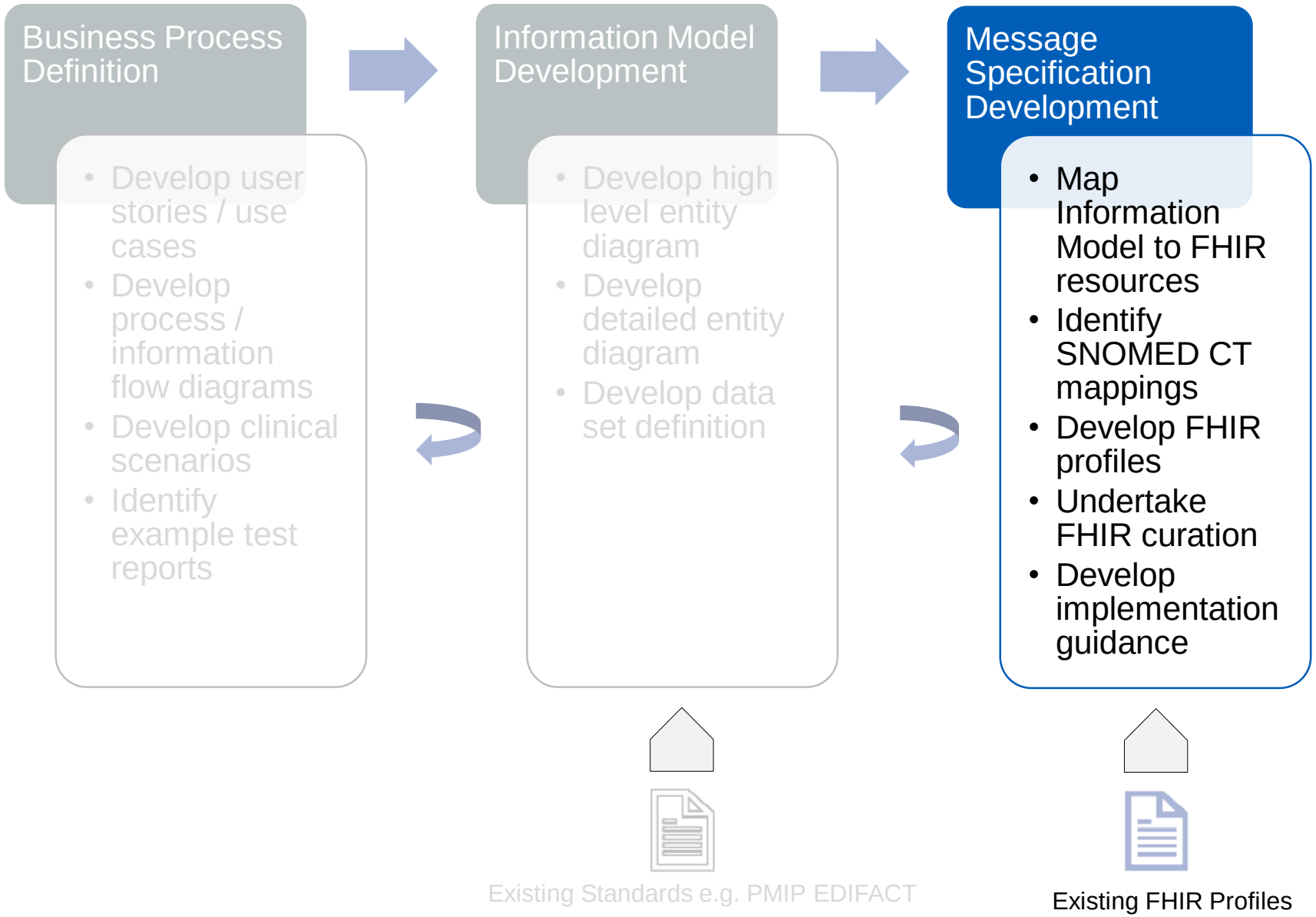
- Development of the Information Model was clinically-led, with input from a range of stakeholders including clinicians, professional bodies, standards organisations, system suppliers and a national pathology user group.

- 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

Message Specification

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.

But what about:

UoM

Other specialties

My favourite topic X

No time… but please see next slide

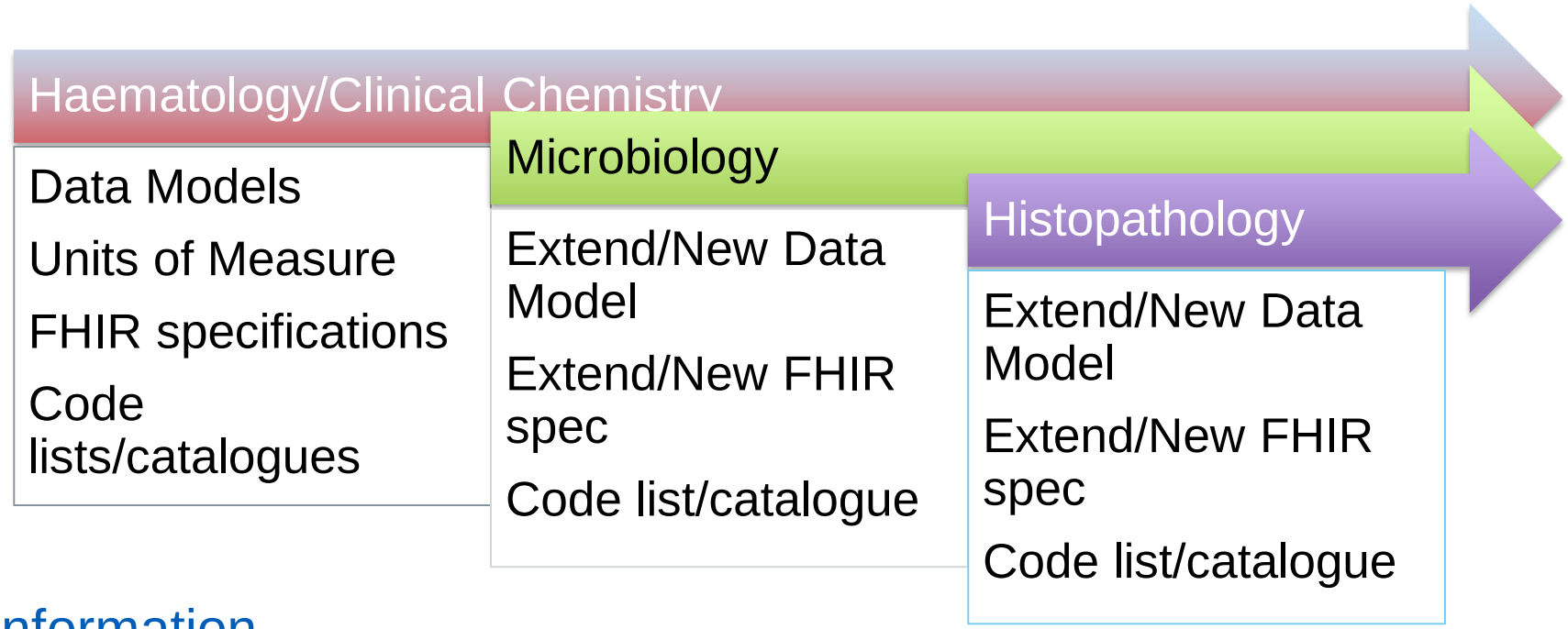
Next Steps and Further Information

Next Steps

- **Unified Test List**
  - Formalise design and editorial guidance.
  - Identify and apply further design patterns.
  - Support additional pathology specialities e.g. microbiology,
  - Scale up the build/review process – explore use of SNOMED CT templating.
  - Target of 3000 UTL entries by April 2020.
- **Message Specification**
  - Undertake First of Type testing of pathology FHIR message specification, in conjunction with adoption of the UTL.
  - 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.

Next Steps and Further Information

Next Steps



Further Information

- Unified Test List: https://hscic.kahootz.com/connect.ti/PathologyandDiagnostics/view?objectID=13047024

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

Any Questions?

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