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Diagnostic Data Services FHIR Profiles Design

Document Management

Revision History

Version	Date	Summary of Changes
0.1	27-Jan-2016	First Draft
0.2	11-Feb-2016	Second Draft follows internal review Added Diagram for all resources used Added XML Example for each FHIR resource Added the rest of the FHIR resources Device, Supporting Information and substance.

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Richard Kavanagh		Head, Data Dictionary and Messaging		
Laura Sato		Head, Diagnostics Data Service		

Glossary of Terms

Term / Abbreviation	What it stands for
FHIR pronounced "Fire"	FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's v2, v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability.

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Contents

1 Introduction

1.1 Background

The National Information Board (NIB) roadmap published in September 2015 Work_Stream_2.1_Final.pdf cited the National Laboratory Medicine Catalogue (NLMC) as one of the highest priority national information standards to complete and use within the next 1-3 years. The NLMC is thus planned to replace the current primary care pathology data standard, the Pathology Bounded Code List (PBCL). PBCL is a subset within the Read V2 terminology, and Read V2 is being nationally withdrawn in 2017. The NLMC will also address current gap areas in PBCL, including setting data standards for use across all care settings, for all pathology disciplines (e.g. including microbiology, histopathology, cytology, genetics and blood transfusion), for both requesting and reporting, and including fully-approved standard units of measure per quantitative test. The NLMC is currently planned to adopt international technical standards wherever fit for purpose, including SNOMED CT, LOINC and UCUM.

The move to adopting the NLMC as a single set of pathology data standards for use across all care settings, addressing current content gaps and standardising pathology data across care settings requires the current national primary care pathology report message (profiled in EDIFACT) to be replaced to facilitate this change.

The HL7 standard FHIR is proposed to be used for Diagnostic Data Services messaging. FHIR uses a set of pre-defined structures called “Resources” which can be constrained or extended for local implementations. These constrained structures are called “Profiles”.

For more information on FHIR, readers should consult the FHIR website.

1.2 Purpose of Document

This is a consultation document about the design of the FHIR Profiles proposed for use with Data Diagnostic Services. It will be used to document the following:

- Assumptions
- Issues
- Questions
- Design principles
- Decisions
- Comparison of FHIR to other standards, documents etc.
- Other information required for FHIR messaging design decisions.

This initial draft copy may be lacking sufficient detail in some areas and it is acknowledged that some of the assumptions, questions etc. will require further provision of information or analysis to be carried out to enable the necessary design decisions to be made. This additional information will be added to the document as and when required.

1.3 Format of Document

This document has been written for an audience where readers will have wide-ranging areas of clinical expertise, technical expertise or interest. Therefore, not all the information contained in this document is of interest to everyone. However, all the information is included for completeness.

Within this document, there is a table for each FHIR profile with column headings as below:

- Name - the name of the FHIR element
- Flags – currently ignore this column for the purpose of this document
- Card - Cardinality of the FHIR element which is of no relevance unless an element is mandated in FHIR
- Type – The data type used for the FHIR element
- Description & Constraints - description of the FHIR element and any constraint imposed by FHIR on the element
- FHIR - Information on the element usage in FHIR (mandatory, optional etc)
- Edifact - Information on whether the FHIR element is a data item supported in Edifact
- ISO 15189:2012(E) - Information on whether FHIR element is a concept that is supported in the ISO standard for pathology labs.
- Example System - Information on whether supported in an example secondary care pathology system
- Comment - any associated comment

The comment is linked to a footnote, which details one of the following:

- Assumptions indicated by **A**
- Issues indicated by **I**
- Questions indicated by **Q**
- Decisions indicated by **D**

1.4 Comparison of FHIR to Other Standards

The comparison is done on a “best as” approach because the various inputs (documents, standard specifications etc.) vary so much in format and level of detail. Therefore, some comparisons should not be seen as definitive, but more of an indication as to the reasoning for an assumption as to why a FHIR element should be included.

1.4.1 Comparison of FHIR to Current Edifact Report Message

For the comparison of FHIR to Edifact, a direct mapping of some data items is not possible because FHIR has an element defined for each individual data item. Whereas Edifact has, for some types of information, multiple data items concatenated into a single free text item.

1.4.2 Comparison of FHIR to ISO 15189:2012(E)

For the comparison of FHIR to ISO, a direct mapping of many data items is not possible because FHIR has an element defined for each individual data item for the purpose of message requests and reports, whereas the ISO document does not deal with messaging but is about best practice within laboratories.

1.4.3 Comparison of FHIR to Example Secondary Care System

For the comparison of FHIR to the example secondary care system a direct mapping of many data items was not possible because FHIR data elements are not structurally the same as the example system used.

1.5 XML Examples

The current assumption is that XML messaging will be used, and not JSON **A**[1]. This assumption will need to be validated and agreed. Therefore, only XML examples are included in this document. The example XML instance fragments contained in this document all come with the following caveats in that they:

- Are provided for illustrative purposes only.
- Have not been clinically validated.
- May contain incorrect or unsuitable coded values.
- May contain incorrect or unsuitable terminology.
- May conflict with a message specification or schema previously published.
- May contain elements and attributes which are not suitable for use in the NHS in England.
- May have missing elements and attributes

[1] **Assumption** The current assumption is that XML messaging will be used, and not JSON

2 FHIR Resource Overview Diagram

This diagram Figure1 gives an overview of how the various FHIR resources would be used in a HSCIC Diagnostic Data Services message. Its purpose is to show how the various profiles fit together to make up the message. This is to allow readers to understand how the profiles documented later in the document fit within the overall Diagnostic Data Services message.

Note: To improve readability, resources may be repeated and some relationships between the resources have been omitted.

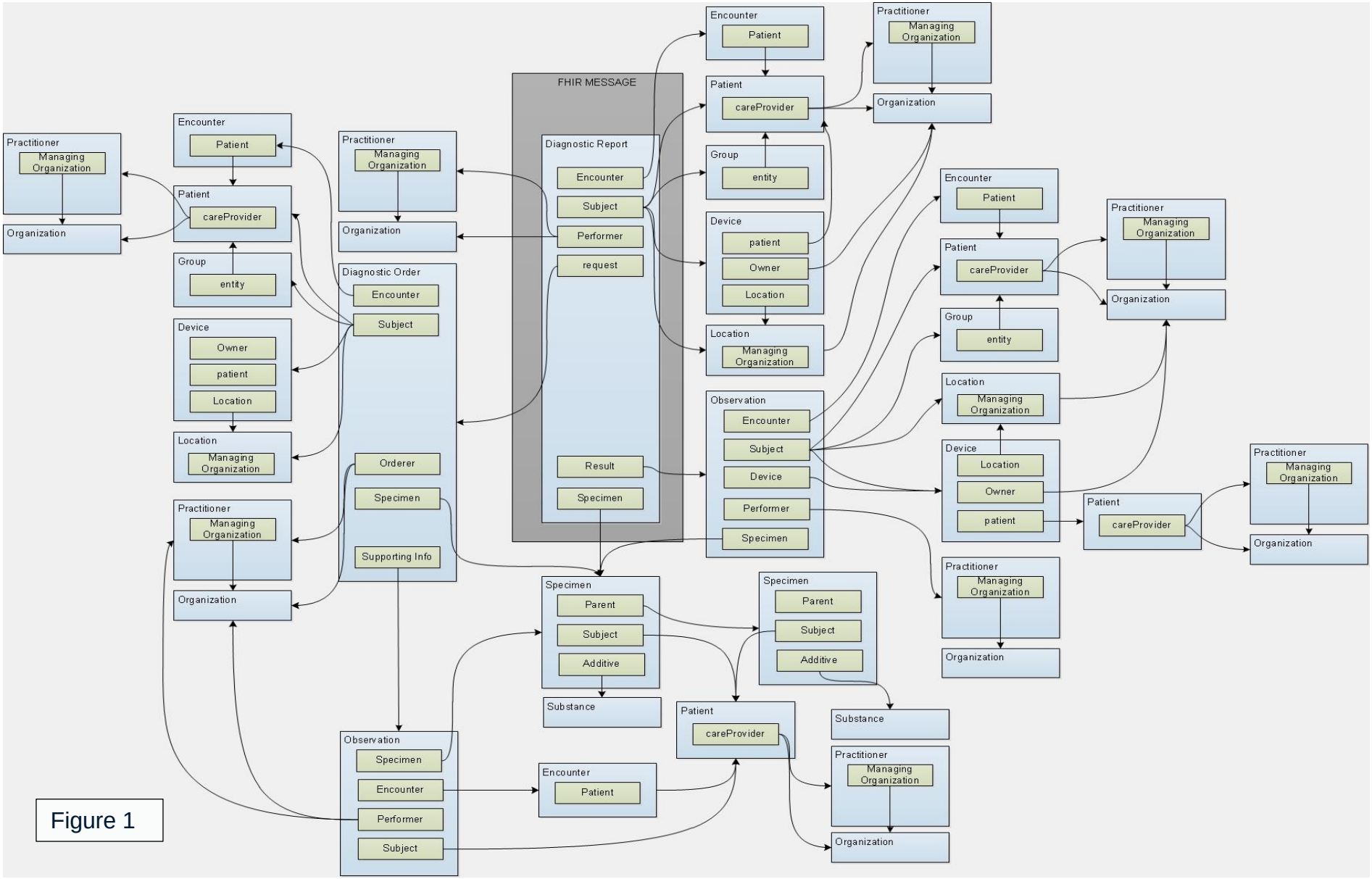

Figure 1

3 FHIR Patient Profile

3.1 FHIR Patient Resource Description

In the FHIR standard, the Patient Resource covers data about patients and animals involved in a wide range of health-related activities, including:

- Curative activities
- Psychiatric care
- Social services
- Pregnancy care
- Nursing and assisted living
- Dietary services
- Tracking of personal health and exercise data

The data in the Resource covers the "who" information about the patient: its attributes are focused on the demographic information necessary to support the administrative, financial and logistic procedures. A Patient record is generally created and maintained by each organisation providing care for a patient. A patient or animal receiving care at multiple organizations may therefore have its information present in multiple Patient Resources.

Not all concepts are included within the base resource (such as race, ethnicity, organ donor status, nationality, etc.), but may be found in profiles defined for specific jurisdictions (e.g., US Meaningful Use Program) or standard extensions.

Such fields vary widely between jurisdictions and often have different names and valuesets for the similar concepts, but they are not similar enough to be able to map and exchange

This resource is referenced by **DiagnosticOrder**, **DiagnosticReport**, Encounter, ImagingObjectSelection, ImagingStudy, Person etc.

In the FHIR standard, this resource has a maturity level of:

- FMM2 + the artefact has been verified by the work group as meeting the DSTU Quality Guidelines and has been subject to a round of formal balloting with at least 10 implementer comments drawn from at least 3 organizations resulting in at least one substantive change

3.2 HSCIC FHIR Patient Profile

The HSCIC FHIR Patient profile is derived from this existing DTSU2 FHIR patient resource. It has a much larger scope than the current Edifact message. The support for animals will also be removed

3.3 HSCIC FHIR Patient Profile Design Principles

Currently the design approach is for a patient profile based on a constrained patient resource as per the assumptions list but this will need to be validated as suitable for Diagnostic Data Services.

3.4 HSCIC FHIR Patient Profile Elements

PATIENT									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Patient			DomainResource	Information about an individual receiving health care services.					
..identifier	Σ	1..*	Identifier	An identifier for this patient	supports multiple identifiers	NHS number only	NHS Number and locally assigned identifiers	NHS Number and locally assigned identifiers	Will support NHS number and multiple local identifiers **A**[2]
..active	?! Σ	0..1	boolean	Whether this patient's record is in active use	optional	not supported	not supported	not supported	**A**[3]
..name	Σ	0..*	HumanName	A name associated with the patient	optional	supported	is mentioned in section 5.4.3	supported	
..telecom	Σ	0..*	ContactPoint	A contact detail for the individual	optional	not supported	is mentioned in section 5.4.3 request	not supported	**A**[4]
..gender	Σ	1..1	code	The gender of a person used for administrative purposes. male | female | other | unknown AdministrativeGender (Required)	optional male female other unknown	supported	supported	typically uses “M”, “F”, “U” not clear if U maps to unknown	**A**[5]
..birthDate	Σ	1..1	date	The date of birth for the individual	supported	supported	supported	supported	**A**[6]

[2] **Assumption** Support for NHS number and local identifiers is required and patient identifier is a mandated element.

[3] **Assumption** The optional record active flag will be included in the profile.

[4] **Assumption** The optional contact details for patient will be included in the profile.

[5] **Assumption** The patient gender is mandatory and uses a required vocabulary and therefore vendors will have to map to the FHIR coded Values.

[6] **Assumption** The birth date element will be mandated and used as per FHIR.

PATIENT									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..deceased[x]	?! Σ	0..1		Indicates if the individual is deceased or not	optional	not supported	not supported	not supported	**A**[7]
….deceased ….Boolean			boolean		As above	As above	As above	As above	As above
..deceased DateTime			dateTime		As above	As above	As above	As above	As above
..address	Σ	0..*	Address	The address of the patient.	optional	supported	supported	supported	**A**[8]
..maritalStatus		0..1	CodeableConcept	The domestic partnership status of a person.	optional	not supported	not supported	not supported	**A**[9]
				Marital Status Codes (Required)	As above	As above	As above	As above	As above
..**multiple Birth[x]**		0..1		Whether patient is part of a multiple birth	optional	not supported	not supported	not supported	**A**[10]
….multiple BirthBoolean			boolean		As above	As above	As above	As above	As above
….multiple BirthInteger			integer		As above	As above	As above	As above	As above
..contact	I	0..*	BackboneElement	A contact party (e.g. guardian, partner, friend) for the patient	optional	not supported	not supported	not supported	**A**[11]
				SHALL at least contain a contact's details or a reference to an organization	optional	not supported	not supported	not supported	As Above
….relationship		0..*	CodeableConcept	The nature of the relationship between a patient and a contact person for that patient.	optional	not supported	not supported	not supported	As Above
				PatientContactRelationship (Extensible)	optional	not supported	not supported	not supported	As above
….name		0..1	HumanName	A name associated with the contact person	optional	not supported	not supported	not	As above

[7] **Assumption** Retain the deceased flag for now as optional, but validate whether there is a use case for this element.

[8] **Assumption** For structured addresses, vendors will need to map to FHIR address structure that is slightly different to current messaging solutions.

[9] **Assumption** Retain marital status for now as optional, but validate whether there is a use case for this element.

[10] **Assumption** Retain multiple births flag for now as optional, but validate whether there is a use case for this element.

[11] **Assumption** Retain contact details for now as optional, but validate whether there is a use case for this element.

PATIENT									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
								supported	
….telecom		0..*	ContactPoint	A contact detail for the person	optional	not supported	not supported	not supported	As above
….address		0..1	Address	Address for the contact person	optional	not supported	not supported	not supported	As above
….gender		0..1	code	The gender of a person used for administrative purposes. male | female | other | unknown AdministrativeGender (Required)	optional	not supported	not supported	not supported	As above
….organization	I	0..1	Reference(**Organization**)	Organization that is associated with the contact	optional	not supported	not supported	not supported	As above
….period		0..1	Period	The period during which this contact person or organization is valid to be contacted relating to this patient	optional	not supported	not supported	not supported	As above
..communication		0..*	BackboneElement	A list of Languages which may be used to communicate with the patient about his or her health	optional	not supported	not supported	not supported	**A**[12]
….language		1..1	CodeableConcept	The language which can be used to communicate with the patient about his or her health Language (Required)	optional	not supported	not supported	not supported	As above
….preferred		0..1	boolean	Indicates whether the patient prefers this language (over other languages he masters up a certain level).	optional	not supported	not supported	not supported	As above
..**careProvider**		0..*	Reference(**Organization**| **Practitioner**)	Patient's nominated care provider, for example the GP practice that the patient is registered with.	optional	supported	supported 5.4.3		**A**[13]
managing Organization	Σ	0..1	Reference(**Organization**)	Organization that is the custodian of the patient record	optional	not supported			**A**[14]

[12] **Assumption** Retain communication element for now as optional, but validate whether there is a use case for this element which would be dependent on whether patient contact details are carried in the message.

[13] **Assumption** The care provider details are required in the profile as they are used in the Edifact message.

[14] **Assumption** The managing organisation details are required in the profile.

PATIENT									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
.. link	?!	0..*	BackboneElement	Link to another patient resource that concerns the same actual person	optional	not supported			
.... other	?!	1..1	Reference(Patient)	The other patient resource that the link refers to	optional	not supported			
.... type	?!	1..1	code	replace | refer | see also - type of link LinkType (Required)	optional	not supported			

3.5 HSCIC FHIR Patient Profile XML Example

```
<Patient>
	<!--Identifies the profile being used-->
	<meta>
		<profile value="http://fhir.nhs.net/StructureDefinition/dds-patient-1-0"/>
	</meta>
	<!--Primary patient identifier i.e. NHS number and code to indicate its been verified-->
	<identifier>
		<use value="official"/>
		<type>
			<coding>
				<system value="http://fhir.nhs.net/ValueSet/nhs-number-Status-1-0"/>
				<code value="01"/>
				<display value="Verified NHS Number"/>
			</coding>
		</type>
		<system value="http://fhir.nhs.net/Id/nhs-number"/>
		<value value="9900000276"/>
	</identifier>
	<!--secondary patient identifier i.e. locally defined-->
	<identifier>
		<use value="secondary"/>
		<type>
			<coding>
				<system value="http://fhir.nhs.net/ValueSet/local-patient-identifier-type-1-0"/>
				<code value="local"/>
				<display value="Locally Assigned Patient Identifier"/>
			</coding>
		</type>
```

```
            <system value="http://fhir.nhs.net/Id/local-patient-identifier/V014"/>
            <value value="PI1112345"/>
            <assigner>
                  <display value="BRISTOL CITY HOSPITAL"/>
            </assigner>
      </identifier>
      <!--Whether this patient's record is in active use-->
      <active value="true"/>
      <name>
            <use value="official"/>
            <text value="William Arthur Smith"/>
            <family value="Smith"/>
            <given value="William"/>
            <given value="Arthur"/>
            <prefix value="Mr"/>
      </name>
      <gender value="male"/>
      <birthDate value="1956-05-15"/>
      <!--Flag to indicate this patient is not deceased-->
      <deceasedBoolean value="false"/>
      <address>
            <use value="home"/>
            <!-- Distinguishes between physical addresses (those you can visit) and mailing addresses (e.g. PO Boxes) Most addresses are both.-->
            <type value="both"/>
            <!-- Unstructured address-->
            <text value="1a Muirfield Crescent, Sampletown, BB1 1BB"/>
            <!-- Structured address-->
            <line value="1a Muirfield Crescent"/>
            <city value="Sampletown"/>
            <postalCode value="BB1 1BB"/>
            <country value="United Kingdom"/>
      </address>
      <maritalStatus>
            <coding>
                  <system value="http://hl7.org/fhir/valueset-marital-status.html"/>
                  <code value="M"/>
                  <display value="Married"/>
                  <!-- If this coding was chosen directly by the user -->
                  <userSelected value="true"/>
```

```
            </coding>
            <text/>
        </maritalStatus>
        <multipleBirthInteger value="1"/>
        <!-- Patients NOK contact -->
        <contact>
            <relationship>
                <coding>
                    <system value="http://hl7.org/fhir/valueset-patient-contact-relationship.html"/>
                    <code value="partner"/>
                    <display value="Partner"/>
                    <!-- If this coding was chosen directly by the user -->
                    <userSelected value="true"/>
                </coding>
                <text/>
            </relationship>
            <name>
                <use value="official"/>
                <text value="Margaret Kate Smith"/>
                <family value="Smith"/>
                <given value="Margaret Kate"/>
                <prefix value="Mrs"/>
            </name>
            <telecom>
                <system value="phone"/>
                <value value="01254783568"/>
                <use value="home"/>
                <!--Specifies preferred order of use of the phone number (1 = highest)-->
                <rank value="1"/>
            </telecom>
            <address>
                <use value="home"/>
                <type value="both"/>
                <line value="1a Muirfield Crescent"/>
                <city value="Sampletown"/>
                <postalCode value="BB1 1BB"/>
                <country value="United Kingdom"/>
            </address>
            <gender value="female"/>
```

```
        </contact>
        <communication>
                <!--The patient's preferred language-->
                <language>
                        <coding>
                                <system value="http://fhir.nhs.net/ValueSet/human-language-1-0.html"/>
                                <code value="en"/>
                                <display value="English"/>
                                <userSelected value="true"/>
                        </coding>
                </language>
                <preferred value="true"/>
        </communication>
        <careProvider>
                <!-- A reference to the patient's care provider (GP) details elsewhere in the message-->
                <reference value="Practitioner/4BFCA0EF-85D0-4C5E-B662-D4910BB83D82"/>
                <display value="Dr. Jones"/>
        </careProvider>
</Patient>
```

4 FHIR Health Care Professional (Practitioner) Profile

4.1 FHIR Practitioner Resource Description

In the FHIR standard the Practitioner resource is defined as a person who is directly or indirectly involved in the provisioning of healthcare.

Practitioner covers all individuals who are engaged in the healthcare process and healthcare-related services as part of their formal responsibilities and this Resource is used for attribution of activities and responsibilities to these individuals. Practitioners include (but are not limited to):

- physicians, dentists, pharmacists
- physician assistants, nurses, scribes
- midwives, dieticians, therapists, optometrists, paramedics
- medical technicians, laboratory scientists, prosthetic technicians, radiographers
- social workers, professional home carers, official volunteers
- receptionists handling patient registration

- IT personnel merging or unmerging patient records
- Service animal (e.g., ward assigned dog capable of detecting cancer in patients)

The Resource is not used for persons involved without a formal responsibility like individuals taking care for friends, relatives or neighbours.

Practitioner performs different roles within the same or even different organizations. Depending on jurisdiction and custom, it may be necessary to maintain a specific Practitioner Resource for each such role or have a single Practitioner with multiple roles. The role can be limited to a specific period, after which authorization for this role ends. Note that the represented organization need not necessarily be the (direct) employer of a Practitioner.

This resource is referenced by **DiagnosticOrder, DiagnosticReport, Encounter, Observation, Patient, and Specimen**,

In the FHIR standard, this resource has a maturity level of:

- FMM0 + the artefact produces no warnings during the build process and the responsible WG has indicated that they consider the artefact substantially complete and ready for implementation

4.2 HSCIC FHIR Health Care Professional Profile

The HSCIC FHIR Health Care Professional profile is derived from the existing DTSU2 FHIR Practitioner resource. It has a much larger scope than the current Edifact message.

4.3 HSCIC FHIR Health Care Professional Profile Design Principles

Currently the design approach is for a Health Care Professional profile based on a constrained practitioner resource as per the assumptions list but this will need to be validated as suitable for Diagnostic Data Services.

4.4 HSCIC FHIR Health Care Professional Profile Elements

HEALTH CARE PROFESSIONAL									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Practitioner			DomainResource	A person with a formal responsibility in the provisioning of healthcare or related services					
..identifier	Σ	0..*	Identifier	A identifier for the person as this agent	optional	supported		supported	**A**[15]
..active	Σ	0..1	boolean	Whether this practitioner's record is in active use	optional	not supported			
..name	Σ	0..1	HumanName	A name associated with the person	optional	mandated		supported	
..telecom	Σ	0..*	ContactPoint	A contact detail for the practitioner	optional	not supported			
..address	Σ	0..*	Address	Where practitioner can be found/visited	optional	not supported			**A**[16]
..gender	Σ	0..1	code	male | female | other | unknown AdministrativeGender (Required)	optional	not supported			**A**[17]
..birthDate	Σ	0..1	date	The date on which the practitioner was born	optional	not supported			**A**[18]
..photo		0..*	Attachment	Image of the person	optional	not supported			**A**[19]
..practitioner Role		0..*	BackboneElement	Roles/organizations the practitioner is associated with	optional				
..managing Organization		0..1	Reference(**Organization**)	Organization where the roles are performed	optional	supported	mentioned in section 5.8.3	supported	**A**[20]

[15] **Assumption** The laboratory personnel when identified will use SDS codes only.

[16] **Assumption** The address element will not be support as the laboratory personnel will use the address of the laboratory and this will be carried in the organisation profile.

[17] **Assumption** The gender element will be supported.

[18] **Assumption** The birthdate element will not be supported.

[19] **Assumption** The photo element will not be supported.

[20] **Assumption** The managing organisation will carry pathology laboratory information.

HEALTH CARE PROFESSIONAL									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….role	Σ	0..1	CodeableConcept	Roles which this practitioner may perform PractitionerRole (Example)	optional	supported		supported	**A**[21] **Q**[22]
….specialty	Σ	0..*	CodeableConcept	Specific specialty of the practitioner PractitionerSpecialty (Example)	optional	supported			**Q**[23]
….period	Σ	0..1	Period	The period during which the practitioner is authorized to perform in these role(s)	optional	not supported			**A**[24]
location		0..*	Reference(Location)	The location(s) at which this practitioner provides care	optional	not supported			**A**[25]
healthcareService		0..*	Reference (HealthcareService)	The list of healthcare services that this worker provides for this role's Organization/Location(s)	optional	not supported			
..qualification		0..*	BackboneElement	Qualifications obtained by training and certification	optional	not supported			**A**[26]
….identifier		0..*	Identifier	An identifier for this qualification for the practitioner	optional	not supported			
….code		1..1	CodeableConcept	Coded resupportedation of the qualification	mandatory	not supported			
….period		0..1	Period	Period during which the qualification is valid	optional	not supported			
….issuer		0..1	Reference(**Organization**)	Organization that regulates and issues the qualification	optional	not supported			
..communication		0..*	CodeableConcept	A language the practitioner is able to use in patient communication	optional	not supported			**A**[27]

[21] **Assumption** The role of the person such as Screener, Clinical Authoriser will be supported.

[22] **Question** How is the role of the person such as Screener, Clinical Authoriser be coded ? Will we need a suitable value set defining is this SNOMED CT? This is not straightforward because of issues with terminology for example, 2548447016 primary screener is in SNOMED CT but Clinical Authoriser is not.

[23] **Question** Is the speciality of the person required, if so we will need a suitable value set defining. Is SNOMED CT suitable?

[24] **Assumption** The period of time the performer is authorized to perform role is not required and will be removed from profile.

[25] **Assumption** The location of the managing organisation is not required and will be removed from the profile.

[26] **Assumption** The qualification elements are not required and will be removed for the health care professional profile.

[27] **Assumption** The communication elements are not required and will be removed for the health care professional profile.

4.5 HSCIC FHIR Health Care Professional Profile XML Example

This example shows the practitioner (Health Care Professional) profile used to carry the patient's GP.

```
<Practitioner>
	<meta>
		<!--Identifies the profile being used-->
		<profile value="http://fhir.nhs.net/StructureDefinition/dds-Health Care Professional-1-0"/>
	</meta>
	<identifier>
		<system value="http://fhir.nhs.net/Id/SDS"/>
		<value value="9900000276"/>
	</identifier>
	<name>
		<family value="Jones"/>
		<given value="Tim"/>
		<prefix value="Dr"/>
	</name>
	<practitionerRole>
		<managingOrganization>
			<!-- A reference to the GP practice profile-->
			<reference value="Organisation/4BFCA0EF-85D0-4C5E-B662-D4910BB83D82"/>
			<display value="MGP Medical Centre"/>
		</managingOrganization>
		<!-- Indicates the practitioners role i.e. Patient's GP-->
		<role>
			<coding>
				<system value="http://fhir.nhs.net/Id/snomed.info/sct"/>
				<code value="24841000000106"/>
				<display value="Usual general practitioner"/>
			</coding>
		</role>
	</practitionerRole>
</Practitioner>
```

5 FHIR Organisation Profile

5.1 FHIR Organization Resource Description

The FHIR Organization Resource is defined as a formally or informally recognized grouping of people or organizations formed for the purpose of achieving some form of collective action. Includes companies, institutions, corporations, departments, community groups, healthcare practice groups, etc.

This resource may be used in a shared registry of contact and other information for various organizations or it can be used merely as a support for other resources that need to reference organizations, perhaps as a document, message or as a contained resource. If using a registry approach, it is entirely possible for multiple registries to exist, each dealing with different types or levels of organization.

The Organization resource often exists as a hierarchy of organization resources, using the part-of property to provide the association of the child to its parent organization.

This resource is referenced by, **DiagnosticReport**, Encounter, **Observation, Patient**, and **Practitioner**

In the FHIR standard, this resource has a maturity level of:

FMM0 + the artefact produces no warnings during the build process and the responsible WG has indicated that they consider the artefact substantially complete and ready for implementation.

5.2 HSCIC FHIR Organisation Profile

The HSCIC FHIR organisation profile is derived from this existing DTSU2 FHIR “Organization resource”. It has a much larger scope than the current Edifact message.

5.3 HSCIC FHIR Organisation Profile Design Principles

Currently the design approach is for an organisation profile based on a constrained “Organization resource”. Note: that this will be a profile for a typical NHS organisation and therefore may have optional elements that are not applicable to Diagnostic Data Services.

5.4 HSCIC FHIR Organisation Profile Elements

ORGANISATION									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Organization			DomainResource	A grouping of people or organizations with a common purpose The organization SHALL at least have a name or an id, and possibly more than one					
..identifier	Σ I	0..*	Identifier	Identifies this organization across multiple systems	optional	mandated		supported	**A**[28]
..active	?! Σ	0..1	boolean	Whether the organization's record is still in active use	optional	not supported			
..type	Σ	0..1	CodeableConcept	Kind of organization OrganizationType (Example)	optional	not supported			**A**[29]
..name	Σ I	0..1	string	Name used for the organization	optional	supported		supported	**A**[30]
..telecom	I	0..*	ContactPoint	A contact detail for the organization The telecom of an organization can never be of use 'home'	optional	not supported		supported	
..address	I	0..*	Address	An address for the organization An address of an organization can never be of use 'home'	optional	not supported		supported	
..partOf	Σ	0..1	Reference(**Organization**)	The organization of which this organization forms a part	optional	not supported		supported	**A**[31]
..contact		0..*	BackboneElement	Contact for the organization for a certain purpose	optional	not supported			**A**[32]

[28] **Assumption** This identifier element will carry an ODS code

[29] **Assumption** The type of organisation is required in the profile

[30] **Assumption** The name of organisation is required in the profile and will be the ODS name

[31] **Assumption** The part of element and associated elements which is represented as another instance of the same organisation profile will be supported in the profile.

[32] **Assumption** The contact element and associated elements will be supported in the profile.

ORGANISATION									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….purpose		0..1	CodeableConcept	The type of contact ContactEntityType (Extensible)					
….name		0..1	HumanName	A name associated with the contact					
....telecom		0..*	ContactPoint	Contact details (telephone, email, etc.) for a contact					
....address		0..1	Address	Visiting or postal addresses for the contact					

5.5 HSCIC FHIR Organisation Profile XML Example

This example shows the Organisation profile used to carry the patient's GP practice.

```
<Organization>
	<meta>
		<!--Identifies the profile being used-->
		<profile value="http://fhir.nhs.net/StructureDefinition/dds-organisation-1-0"/>
	</meta>
	<identifier>
		<system value="http://fhir.nhs.net/Id/ODS"/>
		<value value="H81010002"/>
	</identifier>
	<name value="MGP Medical Centre"/>
	<telecom>
		<system value="phone"/>
		<value value="01634111222"/>
		<use value="work"/>
	</telecom>
	<telecom>
		<system value="email"/>
		<value value="jlorenzo@MMC.co.uk"/>
		<use value="home"/>
	</telecom>
	<address>
	<type value="both"/>
		<line value="1 MGP House"/>
		<line value="Overtown"/>
		<line value="Leeds"/>
		<line value="West Yorkshire"/>
		<postalCode value="LS21 7PA"/>
	</address>
</Organization>
```

6 FHIR Specimen Profile

6.1 FHIR Specimen Resource Description

The FHIR Specimen Resource is defined as a sample to be used for analysis.

Scope and Usage is any material sample:

- taken from a biological entity, living or dead
- taken from a physical object or the environment

Some specimens are biological and can contain one or more components including but not limited to cellular molecules, cells, tissues, organs, body fluids, embryos, and body excretory products (source: NCI Thesaurus , modified).

The specimen resource covers substances used for diagnostic and environmental testing. The focus of the specimen resource is the process for gathering, maintaining and processing the specimen as well as where the specimen originated. This is distinct from the use of Substance that is only used when these other aspects are not relevant.

This resource is referenced by **DiagnosticOrder**, **DiagnosticReport** and **Observation**

In the FHIR standard, this resource has a maturity level of:

- FMM0 + the artefact produces no warnings during the build process and the responsible Working Group (WG) has indicated that they consider the artefact substantially complete and ready for implementation.

6.2 HSCIC FHIR Specimen Profile

The HSCIC FHIR Specimen profile is derived from this existing DTSU2 FHIR specimen resource. It has a much larger scope than the current Edifact message.

6.3 HSCIC FHIR Specimen Profile Design Principles

Currently the design approach is for a specimen profile based on a constrained specimen resource as per the assumptions list but this will need to be validated as suitable for all Diagnostic Data Services disciplines.

6.4 HSCIC FHIR Specimen Profile Elements

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Specimen			DomainResource	Sample for analysis					
..identifier	?! Σ	0.*	Identifier	External identifier	optional	supported	part of request	not supported	A[33]
..status	?! Σ	0..1	code	available | unavailable | unsatisfactory | entered-in-error (SpecimenStatus (Required)) This element provides details of the status/availability of a specimen	optional	Not supported	Is mentioned in 5.8.2 b) comments regarding sample suitability with respect to acceptance/rejection criteria;	Not supported	**A**[34]
..type	Σ	0..1	CodeableConcept	Kind of material that forms the specimen (v2 Specimen Type (Example))	suggested codeable concept of SNOMED CT Subset Original subset ID:1381000000136 Specimen Material Type	reflected as (Specimen Characteristic) as a free text field	Not supported	type and source as single text field	**A**[35]

[33] **Assumption** The specimen identifier will be mandated in the profile.

[34] **Assumption** The specimen status code will be retained in the FHIR profile as optional and the list of codes will be reviewed for suitability for NHS use. The list is required in FHIR and therefore cannot be amended.

[35] **Assumption** The specimen type code will be retained in the FHIR profile as optional and the SNOMED CT subset reviewed for suitability for NHS use.

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..parent		0..*	Reference(Specimen)	Specimen from which this specimen originated		Not supported	Not supported	Not supported	Laura Sato: GPs can sometimes have trouble tracing results received to the original specimen they sent to the lab - should this be the original GP (parent) specimen barcode reference **A**[36]
..subject	Σ	1..1	Reference (**Patient** |Group | Device | **Substance**)	Where the specimen came from. This may be from the patient(s) or from the environment or a device	supports patient , group of patients , devices or substances	only patient supported	can only find reference to patient	only patient supported	**A**[37]
..accession Identifier		0..1	Identifier	Identifier assigned by the lab	optional	supported	cannot find any reference	cannot find any reference	**A**[38]
..collection		0..1	BackboneElement	Collection details			Mentioned in 5.4.4.3 recording of the identity of the Health Care Professional collecting the primary sample and the collection date, and, when needed, recording of the collection time;		**A**[39]

[36] **Assumption** Following comment from user group the specimen parent will be retained in the profile as optional to allow tracking when the report goes back to requester.

[37] **Assumption** Subject scope is limited to one patient in Edifact message however; group of patients, device and substance will be supported in this profile.

[38] **Assumption** The accession identifier will be included as optional in the profile.

[39] **Assumption** Retain in FHIR Profile, collection is optional and some elements are reference for ISO and time element is in Example system.

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….collector	Σ	0..1	Reference(**Practitioner**)	Who collected the specimen	optional	Not supported	Mentioned in 5.4.4.3 recording of the identity of the Health Care Professional collecting the primary sample and the collection date, and,		**A**[40]
….comment		0..*	string	Collector comments	optional	Not supported	when needed, recording of the collection time;		**A**[41]
….collected[x]	Σ	0..1		Collection time	optional	Not supported	Mentioned in 5.4.4.3 recording of the identity of the Health Care Professional collecting the primary sample and the collection date, and,	supported	**A**[42]
….quantity		0..1	SimpleQuantity	The quantity of specimen collected	optional	supported	not mentioned	not mentioned	**A**[43]
….method		0..1	CodeableConcept	Technique used to perform collection (SpecimenCollectionMethod (Example))	optional	not supported	some mention of collection as part of clinical practice in 5.4.4.3	not mentioned	**A**[44]

[40] **Assumption** Retain in FHIR Profile, collector is optional and elements are reference for ISO.

[41] **Assumption** Retain in FHIR Profile, comment is optional and elements are reference for ISO.

[42] **Assumption** Retain in FHIR Profile, collected is optional and some elements are reference for ISO and time element is in Example system.

[43] **Assumption** quantity is required to be in the specimen profile to support the Edifact message.

[44] **Assumption** Retain in FHIR Profile as there is a reference to method in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….bodySite		0..1	CodeableConcept	Anatomical collection site (SNOMED CT Body Structures (Example))	optional	not supported	mentioned in 5.4.3 as part of request	supported	**A**[45]
..treatment		0..*	BackboneElement	Treatment and processing step details	optional	not supported	mentioned in 5.4.4.3 instructions for collection activities	not mentioned	**A**[46]
….description		0..1	string	Textual description of procedure	optional	not supported	mentioned in 5.4.4.3 instructions for collection activities	not mentioned	**A**[47]
….procedure		0..1	CodeableConcept	Indicates the treatment or processing step applied to the specimen (SpecimenTreatmentProcedure (Example))	optional	not supported	mentioned in 5.4.4.3 instructions for collection activities	not mentioned	**A**[48]
….additive		0..*	Reference(**Substance**)	Material used in the processing step	optional	not supported	mentioned in 5.4.4.3 instructions for collection activities	not mentioned	**A**[49]
..container		0..*	BackboneElement	Direct container of specimen (tube/slide, etc.)	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[50]

[45] **Assumption** Retain in FHIR Profile as there is a reference to body site in ISO document. However, terminology needs defining i.e. do we use SNOMED CT and if so we need a subset defining.

[46] **Assumption** Retain in FHIR Profile as there is a reference to treatment in ISO document.

[47] **Assumption** Retain in FHIR Profile as there is a reference to procedure in ISO document.

[48] **Assumption** Retain in FHIR Profile as there is a reference to procedure in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.

[49] **Assumption** Retain in FHIR Profile as there is a reference to additive in ISO document.

[50] **Assumption** Retain in FHIR Profile as there is reference to container in ISO document.

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….identifier	Σ	0..*	Identifier	Id for the container	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[51]
….description		0..1	string	Textual description of the container	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[52]
….type		0..1	CodeableConcept	Kind of container directly associated with specimen (SpecimenContainer (Example))	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[53]
….capacity		0..1	SimpleQuantity	Container volume or size	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[54]
….specimen Quantity		0..1	SimpleQuantity	Quantity of specimen within container	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[55]
….additive[x]		0..1		Additive associated with container (v2 Additive/Preservative (Example))	optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[56]

[51] **Assumption** Retain in FHIR Profile as there is reference to container identifier in ISO document.

[52] **Assumption** Retain in FHIR Profile as there is reference to container description in ISO document.

[53] **Assumption** Retain in FHIR Profile as there is reference to container type in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.

[54] **Assumption** Retain in FHIR Profile as there is reference to container capacity in ISO document.

[55] **Assumption** Retain in FHIR Profile as there is reference to container specimen quality in ISO document.

[56] **Assumption** Retain in FHIR Profile as there is reference to container additive in ISO document and use default FHIR vocabulary.

SPECIMEN									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
……additive CodeableConcept			CodeableConcept		optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[57]
……additive Reference			Reference(**Substance**)		optional	not supported	mentioned in 5.4.4.3 instructions for collection	not mentioned	**A**[58]

[57] **Assumption** Retain in FHIR Profile as there is reference to container in ISO document and use default FHIR vocabulary.

[58] **Assumption** Retain in FHIR Profile as there is reference to container in ISO document.

6.5 HSCIC FHIR Specimen Profile XML Example

This example is for a blood test taken by a practice nurse.

```
<Specimen>
	<meta>
		<!--Identifies the profile being used-->
		<profile value="http://fhir.nhs.net/StructureDefinition/dds-specimen-1-0"/>
	</meta>
	<identifier>
		<use value="official"/>
		<!-- Unique identifier of the specimen assigned by requester - UUID is used as an example only -->
		<value value="83BF8C17-9B27-465A-84B2-CEC6E4977A1E"/>
		<assigner>
			<!-- This can be a reference to the profile elsewhere in the message or just text -->
			<display value="MGP Medical Centre"/>
		</assigner>
	</identifier>
	<!-- The specimen type -->
<!-- The specimen type -->
	<type>
		<coding>
			<system value="http://snomed.info/sct"/>
			<version value=" 20150731"/>
			<code value="119297000"/>
			<display value="blood specimen"/>
		</coding>
	</type>
	<subject>
		<!-- Reference to the patient profile carried elsewhere in the message-->
		<reference value="Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
		<display value="William Arthur Smith"/>
	</subject>
	<accessionIdentifier>
		<!-- Identifier assigned by the lab-->
		<value value="ECC4D353"/>
		<period>
			<start value="2016-01-03T09:00:00+09:00"/>
		</period>
```

```
        <!-- This can be a reference to the profile elsewhere in the message or just text -->
        <assigner>
            <display value="QUIK Screen Ltd"/>
        </assigner>
    </accessionIdentifier>
    <receivedTime value="2016-01-03T09:00:00+09:00"/>
    <collection>
        <!-- This is reference to the practitioner profile elsewhere in the message -->
        <collector>
            <reference value="Practitioner/856F14A7-5323-4998-930A-A63E29B79F2F"/>
            <display value="Nurse Brown"/>
        </collector>
        <quantity>
            <value value="6"/>
            <unit value="mL"/>
        </quantity>
        <method>
            <coding>
                <system value="http://snomed.info/sct"/>
                <code value="32564009"/>
                <display value="arterial specimen collection for laboratory test"/>
            </coding>
        </method>
        <bodySite>
            <coding>
                <system value="http://snomed.info/sct"/>
                <version value=" 20150731"/>
                <code value="53120007"/>
                <display value="Arm"/>
            </coding>
        </bodySite>
    </collection>
    <treatment>
        <description value="Treated with anticoagulants."/>
        <!-- This is reference to the substance profile elsewhere in the message -->
        <additive>
            <reference value="Substance/B2D4B85D-AC24-4E9C-A368-588C3F34F960"/>
        </additive>
    </treatment>
```

```
        <container>
                <identifier>
                        <value value="08FC96C4-EB3A-46D3-93C5-4B23792DCC1C"/>
                        <assigner>
                                <!-- This can be a reference to the profile elsewhere in the message or just text -->
                                <display value="MGP Medical Centre"/>
                        </assigner>
                </identifier>
                <type>
                        <coding>
                                <system value="http://snomed.info/sct"/>
                                <version value=" 20150731"/>
                                <code value="434746001"/>
                                <display value="Specimen vial"/>
                        </coding>
                </type>
                <capacity>
                        <value value="10"/>
                        <unit value="mL"/>
                </capacity>
        </container>
</Specimen>
```

7 FHIR Substance Profile

7.1 FHIR Substance Resource Description

A medication is a substance that is packaged and used as an administered medication. The medication resource uses the substance resource to represent the actual ingredients of a medication.

This resource is referenced by **Specimen**.

For substances in Diagnostic Data Services, it would be used for medication that the patient is / has been prescribed or for substances used for/during processing of a specimen.

In the FHIR standard, this resource has a maturity level of:

- FMM0 + the artefact produces no warnings during the build process and the responsible Work Group has indicated that they consider the artefact substantially complete and ready for implementation.

7.2 HSCIC FHIR Substance Profile

The HSCIC FHIR Substance profile is derived from the existing DTSU2 FHIR substance resource.

7.3 HSCIC FHIR Substance Profile Design Principles

The design of this profile is currently awaiting confirmation of the use cases applicable for Diagnostic Data Services.

7.4 HSCIC FHIR Substance Profile Elements

SUBSTANCE									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Substance			DomainResource	A homogeneous material with a definite composition					**A**[59]

[59] **Assumption** This profile will be required to carry substances used to treat specimens and for medication that the patient has been prescribed or is currently taking.

SUBSTANCE									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
. identifier	Σ	0..*	Identifier	Unique identifier	optional	not supported			
.category	Σ	0..*	CodeableConcept	What class/type of substance this is Substance Category Codes (Extensible)	optional	not supported			
.code	Σ	1..1	CodeableConcept	What substance this is Substance Code (Example)	mandated	not supported			
.description	Σ	0..1	string	Textual description of the substance, comments	optional	not supported			
.instance	Σ	0..*	BackboneElement	If this describes a specific package/container of the substance	optional	not supported			
..identifier	Σ	0..1	Identifier	Identifier of the package/container	optional	not supported			
..expiry	Σ	0..1	dateTime	When no longer valid to use	optional	not supported			
..quantity	Σ	0..1	SimpleQuantity	Amount of substance in the package	optional	not supported			
.ingredient	Σ	0..*	BackboneElement	Composition information about the substance	optional	not supported			
..quantity	Σ	0..1	Ratio	Optional amount (concentration)	optional	not supported			
..substance	Σ	1..1	Reference(**Substance**)	A component of the substance	optional	not supported			

7.5 HSCIC FHIR Substance Profile XML Example

This example shows the substance co-amoxiclav 875mg/125mg tablet.

```
<Substance>
        <!--Identifies the profile being used-->
        <meta>
          <profile value="http://fhir.nhs.net/StructureDefinition/dds-substance-1-0"/>
        </meta>
        <contained>
                <Substance>
                        <id value="ingr1"/>
                        <code>
                                <coding>
                                        <system value="http://snomed.info/sct"/>
                                        <code value="372687004"/>
                                        <display value="Amoxicillin"/>
                                </coding>
                        </code>
```

```
            </Substance>
        </contained>
        <contained>
            <Substance>
                <id value="ingr2"/>
                <code>
                    <coding>
                        <system value="http://snomed.info/sct"/>
                        <code value="395938000"/>
                        <display value="Clavulanate potassium"/>
                    </coding>
                </code>
            </Substance>
        </contained>
        <category>
            <coding>
                <system value="http://hl7.org.fhir/substance-category"/>
                <code value="drug"/>
                <display value="Drug or Medicament"/>
            </coding>
        </category>
        <code>
            <coding>
                <system value="http://snomed.info/sct"/>
                <code value="392259005"/>
                <display value="co-amoxiclav 875mg/125mg tablet"/>
            </coding>
        </code>
        <description value="Augmentin 875"/>
        <ingredient>
            <quantity>
                <numerator>
                    <value value="875"/>
                    <unit value="mg"/>
                    <system value="http://unitsofmeasure.org"/>
                    <code value="mg"/>
                </numerator>
                <denominator>
                    <value value="1000"/>
```

```
                        <unit value="mg"/>
                        <system value="http://unitsofmeasure.org"/>
                        <code value="mg"/>
                    </denominator>
                </quantity>
                <substance>
                    <reference value="#ingr1"/>
                </substance>
            </ingredient>
            <ingredient>
                <quantity>
                    <numerator>
                        <value value="125"/>
                        <unit value="mg"/>
                        <system value="http://unitsofmeasure.org"/>
                        <code value="mg"/>
                    </numerator>
                    <denominator>
                        <value value="1000"/>
                        <unit value="mg"/>
                        <system value="http://unitsofmeasure.org"/>
                        <code value="mg"/>
                    </denominator>
                </quantity>
                <substance>
                    <reference value="#ingr2"/>
                </substance>
            </ingredient>
</Substance>
```

8 FHIR Request Profile

8.1 FHIR Request Resource Description

The FHIR Request resource is defined in the standard as a record of a request for a diagnostic investigation service to be performed.

A Diagnostic Order is a record of a request for a set of diagnostic investigations to be performed. The investigation will lead to a Diagnostic Report that summarizes the outcome of the investigation, and includes any useful data and/or images that are relevant to the treatment/management of the subject.

The principal intention of the Diagnostic Order is to support ordering diagnostic investigations on patients. However, in many contexts, healthcare related processes include performing diagnostic investigations on groups of subjects, devices involved in the provision of healthcare, and even environmental locations such as ducts, bodies of water, etc. Although these such things may be out of scope for Diagnostic Data Services, the FHIR Diagnostic Order resource supports all these usages.

The DiagnosticOrder supports references to the numerous other resources that define information about the subject - the orderer, associated encounter, specimen, body site and other supporting information. For example, Patient, Practitioner, Specimen and Condition are all referenced in this resource.

This resource is referenced by **DiagnosticReport**.

. In the FHIR standard, this resource has a maturity level of:

- FMM0 + the artefact produces no warnings during the build process and the responsible Working Group (WG) has indicated that they consider the artefact substantially complete and ready for implementation.

8.2 HSCIC FHIR Request Profile

The HSCIC FHIR Request profile is derived from this existing DTSU2 FHIR DiagnosticOrder resource

Important Note: please see the design principles section below regarding use of the request profile.

8.3 HSCIC FHIR Request Profile Design Principles

Although the request (order) message is currently out of scope the FHIR request resource is a mandated reference in the FHIR diagnostic report resource. This means that any Diagnostic Data Services message that is developed is required to reference a request profile that will

contain some mandated elements. Therefore, the request profile will be included in the Diagnostic Data Services message specification. Any implementation that makes use of the HSCIC FHIR Diagnostic Data Services report message must support the HSCIC FHIR request profile with respect to mandated elements. A potential list of elements that will need to be supported are highlighted in yellow in the table below.

8.4 HSCIC FHIR Request Profile Elements

REQUEST									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
DiagnosticOrder			DomainResource	A Diagnostic Data Services Request.		mandatory			See design principles section for more information **A**[60] **Q**[61]
..subject	Σ	1..1	Reference(**Patient** | Group | Location | Device)	The patient from whom the specimen is taken.					This will reference the Patient profile within DDS
..orderer	Σ	1..1	Reference(**Practitioner**)	The practitioner responsible for ordering the Diagnostic Data Services Request.	mandated	mandated			
..identifier	Σ	1..2	Identifier	Diagnostic Data Services Request identifier.	mandated	mandated			
..encounter	Σ	0..1	Reference(Encounter)	The encounter that this diagnostic order is associated with	optional	not supported			
..reason		0..*	CodeableConcept	Explanation/Justification for test Condition/Problem/Diagnosis Codes (Example)		supported			

[60] **Assumption** The elements highlighted in yellow in this table must be present in the request profile referenced in the report message.

[61] **Question** Should the request profile be constrained down to just the mandated items?

REQUEST									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..supporting Information		0..*	Reference(**Observation** | Condition | DocumentReference)	Additional clinical information about the Diagnostic Data Services Request.	.	supported			**A**[62]
..specimen		0..*	Reference(**Specimen**)	If the whole order relates to specific specimens					This will reference the Specimen profile within DDS.
..status	?! Σ	0..1	code	proposed | draft | planned | requested | received | accepted | in-progress | review | completed | cancelled | suspended | rejected | failed DiagnosticOrderStatus (Required)		not supported			
..priority	Σ	0..1	code	routine | urgent | stat | asap DiagnosticOrderPriority (Required)		not supported			
..event		0..*	BackboneElement	A list of events of interest in the lifecycle		not supported			
….status	Σ	1..1	code	proposed | draft | planned | requested | received | accepted | in-progress | review | completed | cancelled | suspended | rejected | failed	.	not supported			
….description	Σ	0..1	CodeableConcept	More information about the event and its context Diagnostic Order Event Codes (Example)		not supported			
….dateTime	Σ	1..1	dateTime	The date at which the event happened		not supported			
….actor		0..1	Reference(**Practitioner | Device**)	Who recorded or did this		not supported			
..item		0..*	BackboneElement	Items requested for the Diagnostic Data Services Request.		supported			

[62] **Assumption** The supporting information observation is to be used to carry information such as patient fasted. Condition and Document reference will also be supported.

REQUEST									
Name	**Flags**	**Card.**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..code	Σ	1..1	CodeableConcept	Code to indicate the item (test or panel) being ordered LOINC Diagnostic Order Codes (Preferred)		supported			
..specimen		0..*	Reference(**Specimen**)						If this item relates to specific specimens
..bodySite		0..1	CodeableConcept	Location of requested test (if applicable) SNOMED CT Body Structures (Example)		supported			
..status	Σ	0..1	code	proposed | draft | planned | requested | received | accepted | in-progress | review | completed | cancelled | suspended | rejected | failed DiagnosticOrderStatus (Required)		not supported			
..event	Σ	0..*	see event	Events specific to this item		not supported			
..note		0..*	Annotation	Additional notes added to the Diagnostic Data Services Request.		Supported			

8.5 HSCIC FHIR Request Profile XML Example

This example is for the request information that would be carried in the request profile with the Diagnostic Data Services report message.

```
<DiagnosticOrder>
        <meta>
                <profile value="http://fhir.nhs.net/StructureDefinition/dds-request-1-0"/>
        </meta>
                <subject>
                <!-- This is reference to the patient profile elsewhere in the message -->
                <reference value="Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
                <display value="William Arthur Smith"/>
        </subject>
        <orderer>
                <!-- This is reference to the practitioner profile elsewhere in the message -->
                <reference value="Practitioner/4BFCA0EF-85D0-4C5E-B662-D4910BB83D82"/>
```

```
        <display value="Dr. Jones"/>
    </orderer>
    <identifier>
        <!-- Request identifier -->
        <value value="D4910BB83D82"/>
    </identifier>
    <reason>
        <coding>
            <system value="http://snomed.info/sct"/>
            <version value=" 20150731"/>
            <code value="1758111000000113"/>
            <display value="Fasting blood test due"/>
            <userSelected value="true"/>
        </coding>
    </reason>
    <specimen>
        <!-- This is reference to the specimen profile elsewhere in the message -->
        <reference value="Specimen/83BF8C17-9B27-465A-84B2-CEC6E4977A1E"/>
    </specimen>
    <status value="requested"/>
    <priority value="routine"/>
    <event>
        <status value="requested"/>
        <dateTime value="2016-01-02T10:15:15"/>
    </event>
    <item>
        <code>
            <coding>
                <system value="http://snomed.info/sct"/>
                <version value=" 20150731"/>
                <code value=" 2661284019"/>
                <display value="Diagnostic blood test"/>
                <userSelected value="true"/>
            </coding>
            <coding>
                <system value="http://snomed.info/sct"/>
                <version value=" 20150731"/>
                <code value="313835008"/>
                <display value="Hemoglobin A1c measurement aligned to the Diabetes Control and Complications Trial"/>
```

```
                        <userSelected value="true"/>
                    </coding>
                </code>
            </item>
            <note>
                <text value="patient is afraid of needles"/>
            </note>
</DiagnosticOrder>
```

9 FHIR Report Profile

9.1 FHIR Report Resource

The FHIR standard defines the result resource as the findings and interpretation of diagnostic tests performed on patients, groups of patients, devices, and locations, and/or specimens derived from these. The report includes clinical context such as requesting and provider information, and some mix of atomic results, images, textual and coded interpretations, and formatted representation of diagnostic reports.

A diagnostic report is the set of information that is typically provided by a diagnostic service when investigations are complete. The information includes a mix of atomic results, text reports, images, and codes. The mix varies depending on the nature of the diagnostic procedure, and sometimes on the nature of the outcomes for a particular investigation.

The DiagnosticReport resource has information about the diagnostic report itself, and about the subject and, in the case of lab tests, the specimen of the report. It can also refer to the request details and atomic observations details or image instances. Report conclusions can be expressed as a simple text blob, structured coded data or as an attached fully formatted report such as a PDF.

The DiagnosticReport resource is suitable for the following kinds of diagnostic reports:

- Laboratory (Clinical Chemistry, Hematology, Microbiology, etc.)
- Pathology / Histopathology / related disciplines
- Imaging Investigations (x-ray, CT, MRI etc.)
- Other diagnostics - Cardiology, Gastroenterology etc.
-

Diagnostic Report Names.

The words "tests", "results", "observations", "panels" and "batteries" are often used interchangeably when describing the various parts of a diagnostic report. This leads to much confusion. The naming confusion is worsened because of the wide variety of forms that the result of a diagnostic investigation can take, as described above. Languages other than English have their own variations on this theme.

This resource uses one particular set of terms. A practitioner "requests" a set of "tests". The diagnostic service returns a "report" which may contain a "narrative" - a written summary of the outcomes, and/or "results" - the individual pieces of atomic data which each are "observations". The results are assembled in "groups" which are nested structures of Observations (traditionally referred to as "panels" or “batteries" by laboratories) that can be used to represent relationships between the individual data items.

In the FHIR standard, this resource has a maturity level of:

- FMM2 + the artefact has been verified by the work group as meeting the DSTU Quality Guidelines and has been subject to a round of formal balloting with at least 10 implementer comments drawn from at least 3 organizations resulting in at least one substantive change.

9.2 HSCIC FHIR Report Profile

The HSCIC FHIR Report profile is derived from the existing DTSU2 FHIR report resource. It has a much larger scope than the current Edifact message.

9.3 HSCIC FHIR Report Profile Design Principles

There are no design principles at the present time.

9.4 HSCIC FHIR Report Profile Elements

REPORT									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Diagnostic Report			DomainResource	A Diagnostic report - a combination of request information, atomic results, images, interpretation, as well as formatted reports					

REPORT									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..identifier	Σ	0..*	Identifier	Id for external references to this report	optional	Mandated			**A**[63]
..status	?! Σ	1..1	code	registered | partial | final | corrected | appended | cancelled | entered-in-error. DiagnosticReportStatus (Required)	mandated	Required			**A**[64]
..category	Σ	0..1	CodeableConcept	Service category http://hl7.org/fhir/ValueSet/diagnostic-service-sections Diagnostic Service Section Codes (Example)	optional	Mandated			**A**[65]
..code	Σ	1..1	CodeableConcept	Name/Code for this diagnostic report LOINC Diagnostic Report Codes (Preferred)	Mandated	not supported			**Q**[66]
..subject	Σ	1..1	Reference(**Patient** | Group| Device | Location)	The subject of the report, usually, but not always, the patient					
..encounter	Σ	0..1	Reference(Encounter)	Health care event when test ordered	optional	not supported			**A**[67]
..effective[x]	Σ	1..1		Clinically Relevant time/time-period for report	Mandated	not supported			**A**[68]

[63] **Assumption** The report identifier is mandated.

[64] **Assumption** The status code in FHIR is mandated and therefore this element will be included in the HSCIC report profile and the values are suitable for NHS use.

[65] **Assumption** The category element is required and the values are suitable for NHS use.

[66] **Question** The FHIR spec recommends that http://hl7.org/fhir/ValueSet/report-codes are used to name the report. These are LOINC codes. Should we use SNOMED CT and if so do we need a subset?

[67] **Assumption** The link to the health care event (encounter) when the order was made is not required. This will be removed in HSCIC FHIR report profile.

REPORT									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….effective DateTime			dateTime		Mandated	not supported			A[69]
….effective Period			Period		Mandated	not supported			
..issued	Σ	1..1	instant	DateTime this version was released	Mandated	Mandated			A[70]
..performer	Σ	1..1	Reference (**Practitioner** |**Organization**)	Responsible Diagnostic Service	Mandated	Mandated			A[71] A[72]
..request		0..*	Reference(**DiagnosticOrder**	ProcedureRequest |ReferralRequest)	What was requested				A link to the request
..specimen		0..*	Reference(**Specimen**)	Specimens this report is based on					A link to the specimen
..result		0..*	Reference(**Observation**)	Observations - simple, or complex nested groups	optional	Mandated			Q[73]
..imaging Study		0..*	Reference(ImagingStudy |ImagingObjectSelection)	Reference to full details of imaging associated with the diagnostic report	optional	not supported			A[74]
..image	Σ	0..*	BackboneElement	Key images associated with this report	optional	not supported			
….comment		0..1	string	Comment about the image (e.g. explanation)	optional	not supported			
….link	Σ	1..1	Reference(Media)	Reference to the image source	required	not supported			
..conclusion		0..1	string	Clinical Interpretation of test results	optional	supported			

[68] **Assumption** The Clinically Relevant time/time-period for report is mandated in FHIR and therefore will be mandated in the HSCIC FHIR report profile.

[69] **Assumption** The Clinically Relevant time is as a time stamp and a period. Is required to be supported?.

[70] **Assumption** The report issued time is mandated in FHIR and will mandated be in the HSCIC FHIR report profile.

[71] **Assumption** The performer of the tests is mandated in FHIR and will be mandated in the HSCIC FHIR report profile.

[72] **Assumption** The performer of the tests can be an organisation or a person.

[73] **Question** The results are carried in a generic observation resource. Should an individual result profile be created for each discipline/ result type?

[74] **Assumption** Although imaging not supported in the current messing solutions it may be a requirement in the future and therefore, is supported.

REPORT									
Name	**Flags**	**Card**	**Type**	**Description & Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..coded Diagnosis		0..*	CodeableConcept	Codes for the conclusion SNOMED CT Clinical Findings (Example)	optional	supported			Q[75]
..supported Form		0..*	Attachment	Entire report as issued	optional	not supported			Q[76]

9.5 HSCIC FHIR Report Profile XML Example

This is the report profile example. Note: it is not a complete Diagnostic Data Services report message.

```
<DiagnosticReport>
        <!--Identifies the profile being used-->
        <meta>
                <profile value="http://fhir.nhs.net/StructureDefinition/dds-report-1-0"/>
        </meta>
        <identifier>
                <!-- The report identifier issued by the lab -->
                <value value="LAB1234">
                </value>
                <assigner>
                        <!-- This is reference to the lab carried in the organization profile elsewhere in the message -->
                        <reference value="Organization/B2D4B85D-AC24-4E9C-A368-588C3F34F888"/>
                        <display value="QUIK Screen Ltd"/>
                </assigner>
        </identifier>
        <!-- Indicates this is a final report-->
        <status value="final"/>
        <category>
                <!-- A code(s) that classifies the clinical discipline, department or diagnostic service that created the report (e.g. cardiology, biochemistry, hematology,
MRI). This may be used for searching, sorting and display purposes.-->
                <coding>
```

[75] **Question** What SNOMED CT concepts are required for Coded Diagnosis, and should a subset be used, is the current messaging subset useable?

[76] **Question** Report presented form, Should we limit the format of the actual report to HTML PDF etc.? If so what is the allowed list of formats?

```
                    <system value="http://snomed.info/sct"/>
                    <code value="15220000"/>
                    <display value="Laboratory test"/>
                </coding>
                <coding>
                    <system value="http://hl7.org/fhir/v2/0074"/>
                    <code value="LAB"/>
                </coding>
        </category>
        <code>
                <coding>
                    <system value="http://snomed.info/sct"/>
                    <code value="104177005"/>
                    <display value="Blood culture for bacteria, including anaerobic screen"/>
                </coding>
        </code>
        <subject>
                <!-- This is reference to the patient profile elsewhere in the message -->
                <reference value="Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
                <display value="William Arthur Smith"/>
        </subject>
        <effectiveDateTime value="2013-03-11T03:45:00+01:00"/>
        <issued value="2013-03-11T10:28:00+01:00"/>
        <performer>
                <!-- This is reference to the lab carried in the organization profile elsewhere in the message -->
                <reference value="Organization/B2D4B85D-AC24-4E9C-A368-588C3F34F888"/>
                <display value="QUIK Screen Ltd"/>
        </performer>
        <request>
                <!-- Request identifier -->
                <display value="D4910BB83D82"/>
        </request>
        <result>
         <!-- The reference to the result carried in an observation -->
                <reference value="Observation/B2D4B85D-AC24-4E9C-A368-588C3F34F548"/>
                <display value="Results for staphylococcus analysis on Roel&amp;#39;s blood culture"/>
        </result>
        <conclusion value="Blood culture tested positive on staphylococcus aureus"/>
        <codedDiagnosis>
```

```
                <coding>
                        <system value="http://snomed.info/sct"/>
                        <code value="428763004"/>
                        <display value="Bacteremia due to staphylococcus"/>
                </coding>
        </codedDiagnosis>
</DiagnosticReport>
```

10 FHIR Result Profile

10.1 FHIR Observation Resource

In FHIR, results are carried in an observation resource. The FHIR standard states that Observations are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics. Most observations are simple name/value pair assertions with some metadata, but some observations group other observations together logically, or even are multi-component observations. Note: the DiagnosticReport resource provides a clinical or workflow context for a set of observations. Expected uses for the Observation resource include:

- Vital signs: temperature, blood pressure, respiration rate
- Laboratory Data
- Imaging results like bone density or foetal measurements
- Devices Measurements such as EKG data or Pulse Oximetry data
- Clinical assessment tools such as APGAR
- Health Care Professional characteristics: height, weight, eye-colour
- Social history: tobacco use, family supports, cognitive status
- Core characteristics: pregnancy status, death assertion

In the FHIR standard, this resource has a maturity level of:

- FMM2 + the artefact has been verified by the work group as meeting the DSTU Quality Guidelines and has been subject to a round of formal balloting with at least 10 implementer comments drawn from at least 3 organizations resulting in at least one substantive change.

10.2 HSCIC FHIR Result Profile

The HSCIC FHIR Result profile will be derived from the existing DTSU2 FHIR observation resource. It has a much larger scope for coded information than supported by the current Edifact message.

10.3 HSCIC FHIR Result Profile Design Principles

The current plan is to create one or more result profiles based on the FHIR Observation Resource.

At the present time, there can be no other design decisions due to the large number of outstanding questions.

10.4 HSCIC FHIR Result Profile Elements

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Observation	I		DomainResource	Measurements and simple assertions SHALL only be supported if Observation.value[x] is not supported					**Q**[77]
..identifier		0..*	Identifier	Component code SHALL not be same as observation code Unique Id for this particular observation	optional	supported			**A**[78]
..status	?! Σ	1..1	code	registered | preliminary | final | amended + ObservationStatus (Required)	mandated	supported			**A**[79]
..category		0..1	CodeableConcept	Classification of type of observation Observation	optional				

[77] **Question** The result resource in FHIR is a generic observation, for the purpose of validation should we create multiple result profiles for each type of result/discipline? i.e. microbiology, histopathology, cytology, genetics, blood transfusion etc.

[78] **Assumption** The identifier of the result will be mandated.

[79] **Assumption** The status code which is mandated and a required value set in FHIR is suitable for NHS use.

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
				Category Codes (Example)					
..code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)	mandated	supported			Q[80]
..subject	Σ	1..1	Reference(**Patient** | Group| D evice | Location)	The subject of the report, usually, but not always, the patient					
..encounter		0..1	Reference(Encounter)	Healthcare event during which this observation is made	optional				Q[81]
..effective[x]	Σ	0..1		Clinically relevant time/time-period for observation	optional				
….effectiveDate Time			dateTime		optional				
….effective Period			Period		optional				
..issued	Σ	0..1	instant	Date/Time this was made available	optional				
..performer	Σ	0..*	Reference(**Practitioner** | **Organization** | **Patien**t | RelatedHealth Care Professional)	Who is responsible for the observation	optional	supported			
..value[x]	Σ	0..1		Actual result	optional	supported			Q[82] Q[83]
….valueQuantity			Quantity		optional				

[80] **Question** The type of result is mandated in FHIR and uses LOINC. What code system will be used for the NHS?

[81] **Question** Do we need to reference an encounter? Note this is dependent on whether the encounter is supported in the request.

[82] **Question** Does this value element structure support all the results that need to be reported in the NHS?

[83] **Question** Can we constrain the value element for the various types of results?

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….value Codeable Concept			CodeableConcept		optional				
….valueString			string		optional				
….valueRange			Range		optional				
….valueRatio			Ratio		optional				
….value Sampled Data			SampledData		optional				
….value Attachment			Attachment		optional				
….valueTime			time		optional				
….valueDate Time			dateTime		optional				
….valuePeriod			Period		optional				
..dataAbsent Reason	I	0..1	CodeableConcept	Why the result is missing Observation Value Absent Reason (Extensible)	optional				Q[84]
..interpretation		0..1	CodeableConcept	High, low, normal, etc. Observation Interpretation Codes (Extensible)	optional	supported			Q[85]
..comments		0..1	string	Comments about result	optional	supported			
..bodySite		0..1	CodeableConcept	Observed body part SNOMED CT Body Structures (Example)	optional	supported			Q[86]
..method		0..1	CodeableConcept	How it was done Observation Methods (Example)	optional	supported			Q[87]

[84] **Question** Do we need to support the reason why data is absent?

[85] **Question** How do we define the value set for interpretation?

[86] **Question** Do we need to support this bodysite element, if so how is it coded and what are the values?

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..specimen		0..1	Reference(**Specimen**)	Specimen used for this observation					
..device		0..1	Reference(Device | DeviceMetric)	(Measurement) Device					
..reference Range	I	0..*	BackboneElement	Provides guide for interpretation Must have at least a low or a high or text	optional	supported			
….low	I	0..1	SimpleQuantity	Low Range, if relevant	optional				
….high	I	0..1	SimpleQuantity	High Range, if relevant	optional				
….meaning		0..1	CodeableConcept	Indicates the meaning/use of this range of this range Observation Reference Range Meaning Codes (Example)	optional				**Q**[88]
….age		0..1	Range	Applicable age range, if relevant	optional				
….text		0..1	string	Text based reference range in an observation	optional				
..related	Σ	0..*	BackboneElement	Resource related to this observation	optional				**Q**[89]
….type		0..1	code	has-member | derived-from | sequel-to | replaces | qualified-by | interfered-by Observation Relationship Type (Required)	optional				

[87] **Question** Do we need to support this method element, if so how is it coded and what are the values?

[88] **Question** Is support for this meaning element required, if so how is it coded and what are the values?

[89] **Question** Is support for this related element required, if so how is it coded and what are the values?

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….target		1..1	Reference(**Observation** | QuestionnaireResponse)	Resource that is related to this one	optional				**A**[90]
..component	Σ	0..*	BackboneElement	Component results	optional	supported			**A**[91]
….code	Σ I	1..1	CodeableConcept	Type of component observation (code / type) LOINC Codes (Example)	optional				
..value[x]	Σ	0..1		Actual result	optional	supported			
……value Quantity			Quantity		optional				
……value Codeable Concept			CodeableConcept		optional				
……valueString			string		optional				
……valueRange			Range		optional				
……valueRatio			Ratio		optional				
……value Sampled Data			SampledData		optional				
……value Attachment			Attachment		optional				
……valueTime			time		optional				
……value DateTime			dateTime		optional				
……value Period			Period		optional				
….data Absent Reason	I	0..1	CodeableConcept	Why the result is missing Observation Value Absent Reason (Extensible)	optional				

[90] **Assumption** The reference observation will be supported Questionnaire Response will not.

[91] **Assumption** Component results are required.

RESULT									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
….reference Range	I.	0..*	BackboneElement	Provides guide for interpretation Must have at least a low or a high or text	option	supported			

10.5 HSCIC FHIR Result Profile XML Examples

```
<Observation>
        <!--Identifies the profile being used-->
        <meta>
                <profile value="http://fhir.nhs.net/StructureDefinition/dds-result-1-0"/>
        </meta>
        <!--   Identifier of observation (result)  -->
        <identifier>
                <value value="R121232"/>
        </identifier>
        <status value="final"/>
        <code>
                <!--   Kind of observation = Blood culture   -->
                <coding>
                        <system value="http://acmelabs.org"/>
                        <code value="104177"/>
                        <display value="Blood culture"/>
                </coding>
                <coding>
                        <system value="http://loinc.org"/>
                        <code value="600-7"/>
                        <display value="Bacteria identified in Blood by Culture"/>
                </coding>
        </code>
        <subject>
                <!-- This is reference to the patient profile elsewhere in the message -->
                <reference value="Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
                <display value="William Arthur Smith"/>
        </subject>
        <issued value="2013-03-11T10:28:00+01:00"/>
```

```
        <performer>
                <!-- This is reference to the lab carried in the organization profile elsewhere in the message -->
                <reference value="Organization/B2D4B85D-AC24-4E9C-A368-588C3F34F888"/>
                <display value="QUIK Screen Ltd"/>
        </performer>
        <valueCodeableConcept>
                <coding>
                        <system value="http://snomed.info/sct"/>
                        <code value="3092008"/>
                        <display value="Staphylococcus aureus"/>
                </coding>
        </valueCodeableConcept>
        <interpretation>
                <coding>
                        <system value="http://hl7.org/fhir/v2/0078"/>
                        <code value="POS"/>
                </coding>
        </interpretation>
        <method>
                <coding>
                        <system value="http://snomed.info/sct"/>
                        <code value="104177005"/>
                        <display value="Blood culture for bacteria, including anaerobic screen"/>
                </coding>
        </method>
</Observation>
```

11 FHIR Supporting Information Profile

11.1 FHIR Observation Resource

In FHIR, supporting information is carried in an observation resource. The FHIR standard states that Observations are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics. Most observations are simple name/value pair assertions with some metadata, but some observations group other observations together logically, or even are multi-component observations. Note that the DiagnosticReport resource provides a clinical or workflow context for a set of observations. Expected uses for the Observation resource include:

- Vital signs: temperature, blood pressure, respiration rate
- Laboratory Data
- Imaging results like bone density or foetal measurements
- Devices Measurements such as EKG data or Pulse Oximetry data
- Clinical assessment tools such as APGAR
- Health Care Professional characteristics: height, weight, eye-colour
- Social history: tobacco use, family supports, cognitive status
- Core characteristics: pregnancy status, death assertion

In the FHIR standard, this resource has a maturity level of:

- 1. FMM2 + the artefact has been verified by the work group as meeting the DSTU Quality Guidelines and has been subject to a round of formal balloting with at least 10 implementer comments drawn from at least 3 organizations resulting in at least one substantive change.

11.2 HSCIC FHIR Supporting Information Profile

The HSCIC FHIR Supporting Information profile will be derived from the existing DTSU2 FHIR observation resource. It has a much larger scope for coded information than supported by the current Edifact message.

11.3 HSCIC FHIR Supporting Information Profile Design Principles

There are no design principles at present due to lack of clarity regarding requirements for what supporting information is required.

11.4 HSCIC FHIR Supporting Information Profile Elements

SUPPORTING INFORMATION									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Observation	I		DomainResource	Measurements and simple assertions SHALL only be					**Q**[92]

[92] **Question** The observation resource in FHIR is a generic observation. What is the total of the supporting information to be sent? How will it be coded?

SUPPORTING INFORMATION									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
				supported if Observation.value[x] is not supported					
..identifier		0..*	Identifier	Component code SHALL not be same as observation code Unique Id for this particular observation	optional	supported			
..status	?! Σ	1..1	code	registered | preliminary | final | amended + ObservationStatus (Required)	mandated	supported			
..category		0..1	CodeableConcept	Classification of type of observation Observation Category Codes (Example)	optional				
..code	Σ	1..1	CodeableConcept	Type of observation (code / type) LOINC Codes (Example)	mandated	supported			
..subject	Σ	1..1	Reference(**Patient** | Group| D evice | Location)	The subject of the report, usually, but not always, the patient					
..encounter		0..1	Reference(Encounter)	Healthcare event during which this observation is made	optional				
..effective[x]	Σ	0..1		Clinically relevant time/time-period for observation	optional				
….effectiveDate Time			dateTime		optional				
….effective Period			Period		optional				
..issued	Σ	0..1	instant	Date/Time this was made available	optional				
..performer	Σ	0..*	Reference(Practitioner | Organization | Patient | RelatedHealth Care Professional)	Who is responsible for the observation	optional	supported			
..value[x]	Σ	0..1		Actual result	optional	supported			
….valueQuantity			Quantity		optional				
….value Codeable			CodeableConcept		optional				

SUPPORTING INFORMATION									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Concept									
….valueString			string		optional				
….valueRange			Range		optional				
….valueRatio			Ratio		optional				
….value Sampled Data			SampledData		optional				
….value Attachment			Attachment		optional				
….valueTime			time		optional				
….valueDate Time			dateTime		optional				
….valuePeriod			Period		optional				
..dataAbsent Reason	I	0..1	CodeableConcept	Why the result is missing Observation Value Absent Reason (Extensible)	optional				
..interpretation		0..1	CodeableConcept	High, low, normal, etc. Observation Interpretation Codes (Extensible)	optional	supported			
..comments		0..1	string	Comments about result	optional	supported			
..bodySite		0..1	CodeableConcept	Observed body part SNOMED CT Body Structures (Example)	optional	supported			
.. method		0..1	CodeableConcept	How it was done Observation Methods (Example)	optional	supported			
specimen		0..1	Reference(**Specimen**)	Specimen used for this observation					
device		0..1	Reference(Device | DeviceMetric)	(Measurement) Device					
..reference Range	I	0..*	BackboneElement	Provides guide for interpretation Must have at least a low or a high or text	optional	supported			

SUPPORTING INFORMATION

Name	Flags	Card.	Type	Description&Constraints	FHIR	Edifact	ISO 15189:2012(E)	Example System	Comment
….low	I	0..1	SimpleQuantity	Low Range, if relevant	optional				
….high	I	0..1	SimpleQuantity	High Range, if relevant	optional				
….meaning		0..1	CodeableConcept	Indicates the meaning/use of this range of this range Observation Reference Range Meaning Codes (Example)	optional				
….age		0..1	Range	Applicable age range, if relevant	optional				
….text		0..1	string	Text based reference range in an observation	optional				
..related	Σ	0..*	BackboneElement	Resource related to this observation	optional				
….type		0..1	code	has-member | derived-from | sequel-to | replaces | qualified-by | interfered-by Observation Relationship Type (Required)	optional				
….target		1..1	Reference(**Observation** | QuestionnaireResponse)	Resource that is related to this one	optional				
..component	Σ	0..*	BackboneElement	Component results	optional	supported			
….code	Σ I	1..1	CodeableConcept	Type of component observation (code / type) LOINC Codes (Example)	optional				
……value[x]	Σ	0..1		Actual result	optional	supported			
…..value Quantity			Quantity		optional				
……value Codeable Concept			CodeableConcept		optional				
……valueString			string		optional				
……valueRange			Range		optional				
……valueRatio			Ratio		optional				

SUPPORTING INFORMATION									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
……value Sampled Data			SampledData		optional				
…..value Attachment			Attachment		optional				
…..valueTime			time		optional				
……value DateTime			dateTime		optional				
……valuePeriod			Period		optional				
….dataAbsent Reason	I	0..1	CodeableConcept	Why the result is missing Observation Value Absent Reason (Extensible)	optional				
….reference Range	I	0..*	BackboneElement	Provides guide for interpretation Must have at least a low or a high or text	option	supported			

11.5 HSCIC FHIR Supporting Information Profile XML Example

```
<FamilyMemberHistory>
        <!--Identifies the profile being used-->
        <meta>
                <profile value="http://fhir.nhs.net/StructureDefinition/dds-supporting-information-1-0"/>
        </meta>
        <text>
                <status value="generated"/>
                <div xmlns="http://www.w3.org/1999/xhtml">Mother died of a stroke aged 56</div>
        </text>
        <patient>
                <!-- This is reference to the patient profile elsewhere in the message -->
                <reference value="Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
                <display value="William Arthur Smith"/>
        </patient>
        <status value="completed"/>
        <relationship>
                <coding>
                        <system value="http://hl7.org/fhir/familial-relationship"/>
                        <code value="mother"/>
```

```
                </coding>
        </relationship>
        <condition>
                <code>
                        <coding>
                                <system value="http://snomed.info/sct"/>
                                <code value="371041009"/>
                                <display value="Embolic Stroke"/>
                        </coding>
                        <text value="Stroke"/>
                </code>
                <onsetQuantity>
                        <value value="56"/>
                        <unit value="a"/>
                        <system value="http://unitsofmeasure.org"/>
                </onsetQuantity>
        </condition>
</FamilyMemberHistory>
```

12 FHIR Device Profile

12.1 FHIR Device Resource

This resource identifies an instance of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The device may be a medical or non-medical device. Medical devices includes durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Non-medical devices may include items such as a machine, cell phone, computer, application, etc.

This resource is primarily used for recording which device performed an action and can also be used to track device location. It is also used for prescribing and dispensing devices for patient use. If the device is implanted in a patient, then the patient element will be present, and there would be no location.

In the FHIR standard, this resource has a maturity level of:

- FMM0 + the artefact produces no warnings during the build process and the responsible WG has indicated that they consider the artefact substantially complete and ready for implementation.

12.2 HSCIC FHIR Device Profile

The HSCIC FHIR Device profile will be derived from the existing DTSU2 FHIR observation resource. It has a much larger scope for coded device information than supported by the current Edifact message.

12.3 HSCIC FHIR Device Profile Design Principles

There are no design principles at present due to lack of clarity regarding requirements regarding use of devices.

12.4 HSCIC FHIR Device Profile Elements

DEVICE									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
Device			DomainResource	An instance of a manufactured that is used in the provision of healthcare					
..identifier		0..*	Identifier	Instance id from manufacturer, owner, and others	optional				
..type		1..1	CodeableConcept	What kind of device this is DeviceKind (Preferred)	mandated				
..note		0..*	Annotation	Device notes and comments	optional				
..status	?! Σ	0..1	code	available | not-available | entered-in-error DeviceStatus (Required)	optional				
..manufacturer		0..1	string	Name of device manufacturer	optional				

DEVICE									
Name	**Flags**	**Card.**	**Type**	**Description&Constraints**	**FHIR**	**Edifact**	**ISO 15189:2012(E)**	**Example System**	**Comment**
..model		0..1	string	Model id assigned by the manufacturer	optional				
..version		0..1	string	Version number (i.e. software)	optional				
..manufacture Date		0..1	dateTime	Manufacture date	optional				
..expiry		0..1	dateTime	Date and time of expiry of this device (if applicable)	optional				
..udi		0..1	string	FDA mandated Unique Device Identifier	optional				
..lotNumber		0..1	string	Lot number of manufacture	optional				
..owner		0..1	Reference(**Organization**)	Organization responsible for device	optional				
..location		0..1	Reference(Location)	Where the resource is found	optional				
.. patient		0..1	Reference(**Patient**)	If the resource is affixed to a person	optional				
..contact		0..*	ContactPoint	Details for human/organization for support	optional				
.. url		0..1	uri	Network address to contact device	optional				

12.5 HSCIC FHIR Device Profile XML Example

```
<Device>
	<!--Identifies the profile being used-->
	<meta>
		<profile value="http://fhir.nhs.net/StructureDefinition/dds-device-1-0"/>
	</meta>

	<text>
		<status value="generated"/>
		<div xmlns="http://www.w3.org/1999/xhtml">
			<p>
				<b>Generated Narrative with Details</b>
			</p>
			<p>
				<b>id</b>: example-pacemaker</p>
			<p>
				<b>identifier</b>: 1234-5678-90AB-CDEF</p>
			<p>
				<b>type</b>: Performance pace maker for high octane patients <span>(Details : {http://acme.com/devices code
&amp;#39;octane2014&amp;#39; = &amp;#39;??&amp;#39;, given as &amp;#39;Performance pace maker for high octane patients&amp;#39;})</span>
			</p>
			<p>
				<b>manufacturer</b>: Acme Devices, Inc</p>
			<p>
				<b>model</b>: PM/Octane 2014</p>
			<p>
				<b>lotNumber</b>: 1234-5678</p>
			<p>
				<b>patient</b>: <a>Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570</a>
			</p>
			<p>
				<b>contact</b>: ph: ext 4352</p>
		</div>
	</text>
	<identifier>
		<system value="http://acme.com/devices/pacemakers/octane/serial"/>
		<value value="1234-5678-90AB-CDEF"/>
```

```
        </identifier>
        <type>
                <coding>
                        <system value="http://acme.com/devices"/>
                        <code value="octane2014"/>
                        <display value="Performance pace maker for high octane patients"/>
                </coding>
        </type>
        <manufacturer value="Acme Devices, Inc"/>
        <model value="PM/Octane 2014"/>
        <lotNumber value="1234-5678"/>
        <patient>
                <reference value=" Patient/B2D4B85D-AC24-4E9C-A368-588C3F34F570"/>
        </patient>
        <contact>
                <system value="phone"/>
                <value value="ext 4352"/>
        </contact>
</Device>
```

13 List of Assumptions and Questions

13.1 Patient Profile Assumptions

No	Assumption	Status
1	The current assumption is that XML messaging will be used, and not JSON	
2	Support for NHS number and local identifiers is required and patient identifier is a mandated element.	
3	The optional record active flag will be included in the profile.	
4	The optional contact details for patient will be included in the profile.	
5	The patient gender is mandatory and uses a required vocabulary and therefore vendors will have to map to the FHIR coded Values.	

No	Assumption	Status
6	The birth date element will be mandated and used as per FHIR.	
7	Retain the deceased flag for now as optional, but validate whether there is a use case for this element.	
8	For structured addresses, vendors will need to map to FHIR address structure that is slightly different to current messaging solutions.	
9	Retain marital status for now as optional, but validate whether there is a use case for this element.	
10	Retain multiple births flag for now as optional, but validate whether there is a use case for this element.	
11	Retain contact details for now as optional, but validate whether there is a use case for this element.	
12	Retain communication element for now as optional, but validate whether there is a use case for this element which would be dependent on whether patient contact details are carried in the message	
13	The care provider details are required in the profile as they are used in the Edifact message.	
14	The managing organisation details are required in the profile.	

13.2 Health Care Professional Profile Assumptions

No	Assumption	Status
15	The laboratory personnel when identified will use SDS codes only.	
16	The address element will not be support as the laboratory personnel will use the address of the laboratory and this will be carried in the organisation profile.	
17	The gender element will be supported.	
18	The birthdate element will not be supported.	
19	The photo element will not be supported.	

No	Assumption	Status
20	The managing organisation will carry pathology laboratory information.	
21	The role of the person such as Screener, Clinical Authoriser will be supported.	
24	The period of time the performer is authorized to perform role is not required and will be removed from profile.	
25	The location of the managing organisation is not required and will be removed from the profile.	
26	The qualification elements are not required and will be removed for the health care professional profile.	
27	The communication elements are not required and will be removed for the health care professional profile.	

13.3 Health Care Professional Profile Questions

No	Question	Status
22	How is the role of the person such as Screener, Clinical Authoriser coded ? Will we need a suitable value set defining is this SNOMED CT? This is not straightforward because of issues with terminology for example, 2548447016 primary screener is in SNOMED CT but Clinical Authoriser is not.	
23	Is the speciality of the person required, if so we will need a suitable value set defining. Is SNOMED CT suitable?	

13.4 Organisation Profile Assumptions

No	Assumption	Status
28	This identifier element will carry an ODS code	
29	The type of organisation is required in the profile	
30	The name of organisation is required in the profile and will be the ODS name	
31	The part of element and associated elements which is represented as another instance of the same organisation profile will be supported in the profile.	

No	Assumption	Status
32	The contact element and associated elements will be supported in the profile.	

13.5 Specimen Profile Assumptions

No	Assumption	Status
33	The specimen identifier will be mandated in the profile.	
34	The specimen status code will be retained in the FHIR profile as optional and the list of codes will be reviewed for suitability for NHS use. The list is required in FHIR and therefore cannot be amended.	
35	The specimen type code will be retained in the FHIR profile as optional and the SNOMED CT subset reviewed for suitability for NHS use.	
36	Following comment from user group the specimen parent will be retained in the profile as optional to allow tracking when the report goes back to requester.	
37	The accession identifier will be included as optional in the profile.	
38	Retain in FHIR Profile, collection is optional and some elements are reference for ISO and time element is in Example system.	
40	Retain in FHIR Profile, collector is optional and elements are reference for ISO.	
41	Retain in FHIR Profile, comment is optional and elements are reference for ISO.	
42	Retain in FHIR Profile, collected is optional and some elements are reference for ISO and time element is in Example system.	
43	quantity is required to be in the specimen profile to support the Edifact message.	
44	Retain in FHIR Profile as there is a reference to method in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.	
45	Retain in FHIR Profile as there is a reference to body site in ISO document. However, terminology needs defining	

No	Assumption	Status
	i.e. do we use SNOMED CT and if so we need a subset defining.	
46	Retain in FHIR Profile as there is a reference to treatment in ISO document.	
47	Retain in FHIR Profile as there is a reference to procedure in ISO document.	
48	Retain in FHIR Profile as there is a reference to procedure in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.	
49	Retain in FHIR Profile as there is a reference to additive in ISO document.	
50	Retain in FHIR Profile as there is reference to container in ISO document.	
51	Retain in FHIR Profile as there is reference to container identifier in ISO document.	
52	Retain in FHIR Profile as there is reference to container description in ISO document.	
53	Retain in FHIR Profile as there is reference to container type in ISO document. However, the terminology needs defining i.e. do we use the default FHIR example vocabulary.	
54	Retain in FHIR Profile as there is reference to container capacity in ISO document.	
55	Retain in FHIR Profile as there is reference to container specimen Quantity in ISO document.	
56	Retain in FHIR Profile as there is reference to container additive in ISO document and use SNOMED CT concepts	
57	Retain in FHIR Profile as there is reference to container additive in ISO document and use SNOMED CT concepts	
58	Retain in FHIR Profile as there is reference to container additive in ISO document.	

13.6 Substance Profile Assumptions

No	Assumption	Status
59	This profile will be required to carry substances used to treat specimens and for medication that the patient has	

No	Assumption	Status
	been prescribed or is currently taking.	

13.7 Request Profile Assumptions

No	Assumption	Status
60	The elements highlighted in yellow in the table must be present in the request profile referenced in the report message.	
62	The supporting information observation is to be used to carry information such as patient fasted. Condition and Document reference will also be supported.	

13.8 Request Profile Questions

No	Question	Status
61	Should the request profile be constrained down to just the mandated items?	

13.9 Report Profile Assumptions

No	Assumption	Status
63	The report identifier is mandated.	
64	The status code in FHIR is mandated and therefore this element will be included in the HSCIC report profile and the values are suitable for NHS use.	
65	The category element is required and the values are suitable for NHS use.	
67	The link to the health care event (encounter) when the order was made is not required. This will be removed in HSCIC FHIR report profile.	

No	Assumption	Status
68	The Clinically Relevant time/time-period for report is mandated in FHIR and therefore will be mandated in the HSCIC FHIR report profile.	
69	The Clinically Relevant time is as a time stamp and a period. Is required to be supported?.	
70	The report issued time is mandated in FHIR and will mandated be in the HSCIC FHIR report profile.	
71	The performer of the tests is mandated in FHIR and will be mandated in the HSCIC FHIR report profile.	
72	The performer of the tests can be an organisation or a person	
74	Although imaging not supported in the current messaging solutions it may be a requirement in the future and therefore, is supported.	
75	What SNOMED CT concepts are required for Coded Diagnosis, and should a subset be used?	

13.10 Report Profile Questions

No	Question	Status
73	The results are carried in a generic observation resource. Should an individual result profile be created for each discipline/ result type?	
76	Report presented form, Should we limit the format of the actual report to HTML PDF etc.? If so what is the allowed list of formats?	

13.11 Result Profile Assumptions

No	Assumption	Status
78	The identifier of the result will be mandated.	
79	The status code, which is mandated, and a required value set in FHIR is suitable for NHS use.	

No	Assumption	Status
90	The reference observation will be supported Questionnaire Response will not.	
91	Component results are required.	

13.12 Result Profile Questions

No	Question	Status
77	The result resource in FHIR is a generic observation, for the purpose of validation and ease of implementation should we create multiple result profiles for each type of result/discipline? i.e. microbiology, histopathology, cytology, genetics, blood transfusion etc.	
80	The type of result is mandated in FHIR and uses LOINC. What code system will be used for the NHS?	
81	Do we need to reference an encounter? Note this is dependent on whether the encounter is supported in the request.	
82	Does this value element structure support all the results that need to be reported in the NHS?	
83	Can we constrain the value element for the various types of results?	
84	Do we need to support the reason why data is absent?	
85	How do we define the value set for interpretation?	
86	Do we need to support this bodysite element, if so how is it coded and what are the values?	
87	Do we need to support this method element, if so how is it coded and what are the values?	
88	Is support for this meaning element required, if so how is it coded and what are the values?	
89	Is support for this related element required, if so how is it coded and what are the values?	

13.13 Supporting Information Profile Questions

No	Question	Status
92	The observation resource in FHIR is a generic observation. What is the total of the supporting information to be sent? How will it be coded?	

13.14 Device Profile Questions

No	Question	Status
93	Is device required? if so, what level of device information is required?	