

Integrating the Healthcare Enterprise



5 **IHE Quality Research and Public Health
(QRPH)
White Paper**

10 **IHE SDC on FHIR®**
 HL7® FHIR® Release 4
 Using FHIR® Resources at FMM Levels 3 and Normative

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Foreword

This is a white paper of the IHE Quality Research and Public Health (QRPH) domain.

- 30 This white paper is published on October 1, 2021. Comments are invited at any time and can be submitted at https://www.ihe.net/QRPH_Public_Comments.

General information about IHE can be found at www.ihe.net.

- 35 Information about the IHE QRPH domain can be found at https://www.ihe.net/ihe_domains/quality_research_and_public_health.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and <http://ihe.net/Profiles>.

The current version of the IHE QRPH Technical Framework can be found at http://ihe.net/Technical_Frameworks.

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1 Introduction

Note: White papers are, by definition, INFORMATIVE. White papers cannot be normative

This document, the IHE Quality Research and Public Health Domain IHE Structured Data Capture (SDC) on FHIR^{®1} White Paper, describes recommendations on how to transform IHE SDC forms into FHIR resources that can be used for a variety of use cases, including, but not limited to: pre-population of clinical data in forms, display of data in patient portals, and data analytics. As this is a white paper, none of these recommendations are normative, but do provide guidance on some best practices when converting data to FHIR from IHE SDC.

1.1 Purpose of the IHE Structured Data Capture (SDC) on FHIR White Paper

IHE SDC has been built on XML and ISO standards. FHIR has been gaining traction over the last several years in the health technology space. As SDC has recently gone live as the new format for the College of American Pathologists (CAP) electronic Cancer Checklists (eCCs) there is a need for interoperability with data in other formats. FHIR can be a layer to create that interoperability. By creating a pattern to parse SDC into FHIR we can enhance interoperability between data captured by SDC and other tools.

IHE Structured Data Capture (SDC) on FHIR uses a form driven workflow to capture and encode data by creating FHIR Observations from the captured data. The primary use case for this implementation guide is point of care reporting for clinicians using structured forms to capture high quality data for care and reporting purposes. Structured data can enable easier auto-population of future medical documents, easily queryable data, and high-quality reporting for quality measurement and evaluation, and research.

The SDC initiative was established by the ONC in 2013 to develop two implementation guides:

- [IHE SDC Technical Framework Supplement](#)
- [HL7^{®2} FHIR SDC Profile](#)

On March 30, 2017 both initiatives transitioned into community led projects focused on data capture. The ideal scenario is that data captured in any manner can exist in FHIR for maximum interoperability. Both initiatives focus on improving data capture within healthcare. The CAP has already developed and implemented IHE SDC for their collection of [electronic Cancer Checklists \(eCCs\)](#), and being able to extract data from these cancer checklists to create FHIR Observations will enhance interoperability.

¹ FHIR is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.

² HL7 is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.

There is a defined need to use the information captured in any standard in modern health systems without human intervention to manually extract the data. Structured data capture can help automate data collection, while FHIR can ensure that the collected data is more interoperable downstream.

105 **1.2 Intended Audience**

The intended audience of this paper is anyone looking to implement IHE SDC for a specific data capture use case, but requires interoperability with other systems. This audience will include healthcare institution IT departments, technical staff of vendors participating in IHE, experts involved in standards development with an interest in data capture, and researchers who are
110 interested in decoupling data from its initial collection source.

Integration engineers may be particularly interested if they need to interoperate SDC form data with FHIR systems.

1.3 Open and Closed Issues

1.3.1 Open issues

- 115
1. Should Observations be validated or is that out of scope for this white paper?
 2. How should FHIR Bundles be handled? What type of Bundle should be used?
 3. If Bundles are included, should a Provenance resource be a standard part of that package?

1.3.2 Closed Issues

None

2 Background

This document highlights a key pattern that leverages the strengths of two standards i.e., HL7 FHIR and IHE SDC to make the sharing of data more fluid and applying this data to various use-cases such as analytics and data pre-population. For many use cases, structured and coded data removes the necessity of human intervention to read, interpret and utilize the data. Structured data combined with interoperable standards can lead to more automated process, faster, and more accurate results.

Irrespective of the data capture tool, by choosing to represent the captured data as FHIR resources, opens a plethora of scenarios that break down barriers between siloed health information. SDC has a strong data capture capability, and can be leveraged to get information into FHIR so that it can exist as an interoperable part of a patient's shared health record (SHR).

2.1 Problem Description

The SDC Profile is built on the IHE Retrieve Form for Data Capture (RFD) Profile and the ISO/IEC 19763-13 Meta-model for Framework Interoperability (MFI). FHIR has been gaining traction over the last several years in the health technology space. As SDC has recently gone live as the new format for the College of American Pathologists (CAP) electronic Cancer Checklists (eCCs) there is a need for interoperability with data in other formats including North American Association of Central Cancer Registries (NAACCR) based on HL7 V2.5 and FHIR.

FHIR can be a layer to create that interoperability through the RESTful architecture. By creating a pattern to parse SDC into FHIR interoperability between data captured by SDC and other tools is greatly improved. This pattern enables organizations using SDC to interoperate with other FHIR systems and leverage other FHIR based standards, profiles, implementation guides, and technical frameworks to deliver higher quality data for patient's health records.

2.2 Current Workflow and Approach

Synoptic reporting is a process of reporting specific clinical findings in a structured format. Using a structured format not only ensures that all reports contain the necessary information but also makes the maintenance of reports easier and increases the level of interoperability for exchange purposes.

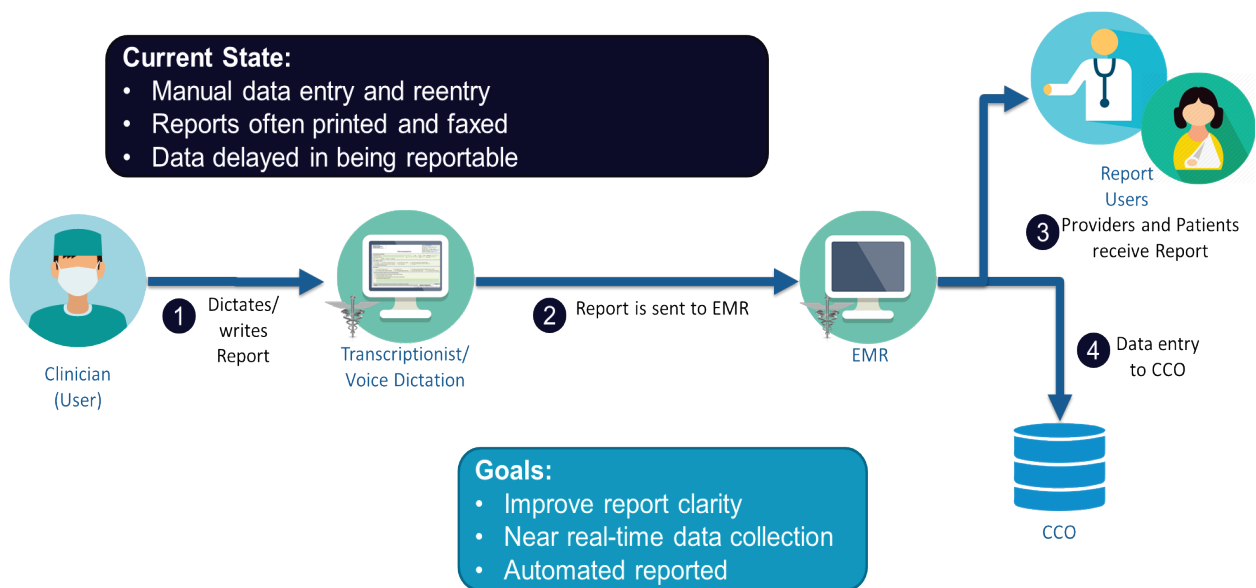


Figure 2.2-1: Typical Manual Reporting Entry Process

150 In the current workflow model, a clinician orally dictates reports that are later transcribed and
 151 sent to primary care systems or other jurisdictional repositories. Since the reports are either faxed
 152 or printed, there is a fair bit of manual labor in data re-population where necessary.

153 After a careful analysis of one of the CAP reporting forms, keeping in mind the nature of the
 154 underlying data and clinical domain, it was clear that the context of the question and the answer
 155 could be captured independently as an observable artifact, i.e., a FHIR Observation. At the same
 156 time, the existing IHE SDC Report could be collated along with the patient demographic
 157 information to form a reporting package of independently queryable objects.

158 One of the design principles of FHIR is that the base specification contains 80% of the data
 159 elements required by most use-cases. In our approach we decided to make use of this feature and
 160 therefore the FHIR resources used for this proof of concept do not contain an extension; were
 161 able to satisfy our requirements completely without extending FHIR based on our use case being
 162 part of the 80% Conventions and Data Models. Ultimately, we were able to completely satisfy
 163 this use case without the use of extensions.

164 In this section, we describe the IHE SDC and FHIR data model, their key elements and attributes
 165 that were used to map information from the CAP and Ontario Health (Cancer Care Ontario)
 166 forms. SDC has been deployed by the CAP for the electronic Cancer Checklists, and OH is
 167 testing SDC's capability for Lung Cancer Screening and Lung Surgery use cases. We also
 168 describe the Terminologies used to encode the data and the use of FHIR resources to encode
 169 similar clinical concepts.

2.2.1 IHE SDC Data Model

The following table highlights the IHE SDC XML elements and their corresponding attributes. The formInstanceVersionURI is of importance as it is a unique identifier that is used to identify a specific version of a form that is filled out. A snippet of an existing CAP form can be found in Appendix A and more detail can be found in the [IHE QRPB SDC Technical Framework Supplement in Section Q.6.2.6.](#)

2.2.2 FHIR Data Model

This section describes the structural patterns that were used to convey the context described in an IHE SDC form into a FHIR object. Depending on the nature of the underlying data and its domain, it may be necessary to use other FHIR resources when conveying information and therefore not limited to the resources mentioned in this document.

The table below highlights the resources and their purpose

Table 2.2.2-1: FHIR Resource Mapping

FHIR Resource	Element	Cardinality	Purpose
Observation	Observation.code	1..1	Capture the IHE SDC form question. Here, the use of the coding element allowed to the context of question to be represented in different terminologies with equivalent concepts if necessary.
	Observation.value[x] [x] = valueCodeableConcept	0..1	Capture the corresponding IHE SDC form answer in response to the question. This is used for a single answer response. Again, the use of the CodeableConcept allowed the same concept to be interpreted using different terminologies.
	Observation.component.value[x] [x] = valueCodeableConcept	0..*	Captures multiple answers in response to the question. Each component element encoded as a valueCodeableConcept represents an answer. Multiple answer implies multiple component elements.
DocumentReference	DocumentReference.masterIdentifier	0..1	Place holder for the formInstanceVersionURI.
	DocumentReference.content.attachment	1..*	The DocumentReference resource serves as the package wrapper that will house the IHE SDC Form (either base64 encoded within the resource or will be referenced via a URI).

FHIR Resource	Element	Cardinality	Purpose
	DocumentReference.context.related	1...*	The DocumentReference will reference generated Observations, the Patient the corresponding Practitioner and any other resources that are deemed clinically relevant to the patient.

2.2.3 Terminology

185 To capture semantic meaning of the concepts from the forms to the FHIR resources, this proof of concept created FHIR ValueSets and ConceptsMaps. The ValueSets allow capturing of the context and domain specific information while the ConceptMap helped represent equivalent concepts in different terminologies.

190 Each question and answer pair should be represented in a ValueSet. In the ValueSet, the code and the display value should be the unique identifier and title of the element as described in the IHE SDC form. These codes and titles in the ValueSet are mapped to standardized terminologies (e.g., SNOMED CT³) using a ConceptMap. It is valuable to map any terms so that they can be retrieved using FHIR search queries.

For an example of this mapping, see Appendix B.

195

³ SNOMED CT is a registered trademark of the International Health Terminology Standards Development Organisation, all rights reserved.

2.3 Future Workflow

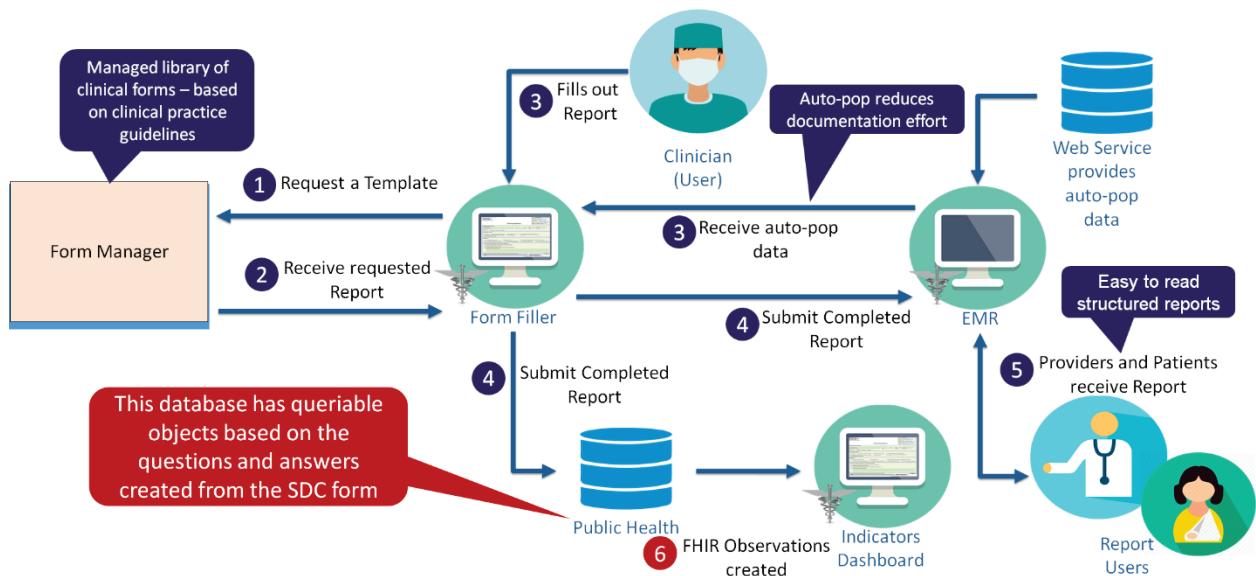


Figure 2.3-1: Potential Future Workflow with SDC

In this future-state workflow, a clinician will request a template from an SDC Form Manager. The template will be shared through a standards based API, and may use a profile such as IHE Non-Patient File Sharing for Mobile (NPFSm). The form is now available in the local system. The Form Filler will extract the form from the package and display it to the user. The user will fill in the form, and submit the data to the applicable endpoint(s).

2.4 Practical Applications and Use-cases.

IHE SDC on FHIR can be used for a number of applications and use cases regarding reporting, where structured data must be captured, and interoperated with other health data.

2.4.1 Laboratory reporting to Public Health Agency

Laboratories will use the existing FHIR REST API to request, using GET, a blank SDC form to be populated by the hospital/laboratory system acting as the SDC Form Filler.

Form Manager FHIR Server will host SDC forms and upon receiving the GET command, will return a FHIR DocumentReference with the blank SDC form included as an attachment.

Hospital/laboratory system populates received blank SDC form with existing data from the EMR and user input.

The Hospital/laboratory system will save the completed SDC form, and create FHIR Observations which will serve as searchable objects that can be used to find the original report or insights about the encounter.

Hospital/laboratory system uses FHIR REST API to POST the completed SDC form in a new FHIR DocumentReference, with updated identifiers, with populated SDC form as an attachment Public Health FHIR server.

220 Public Health FHIR server will store the completed SDC form in a database for the cancer registry program to query data; FHIR Observations can be queried and linked for additional information.

The FHIR Observations are linked to the completed SDC form, patient, practitioner and other important contextual information.

225 2.4.2 COVID-19 Reporting

A use case that was explored, but not implemented was COVID-19 autopsy reporting. An IHE SDC form can be quickly created and deployed to Form Managers. Once the forms are available on the Managers, the templates can be downloaded and implemented by Form Fillers for clinical use.

230 Data entry at healthcare sites can commence quickly, and forms can be submitted as FHIR Document References along with FHIR Observations to appropriate public health agencies. These agencies can leverage the coded Observations to do advanced analytics based on the standard terminologies available within the Observations.

235 Clinicians, and patients will also receive highly structured reports digitally through their provider and patient portals respectively.

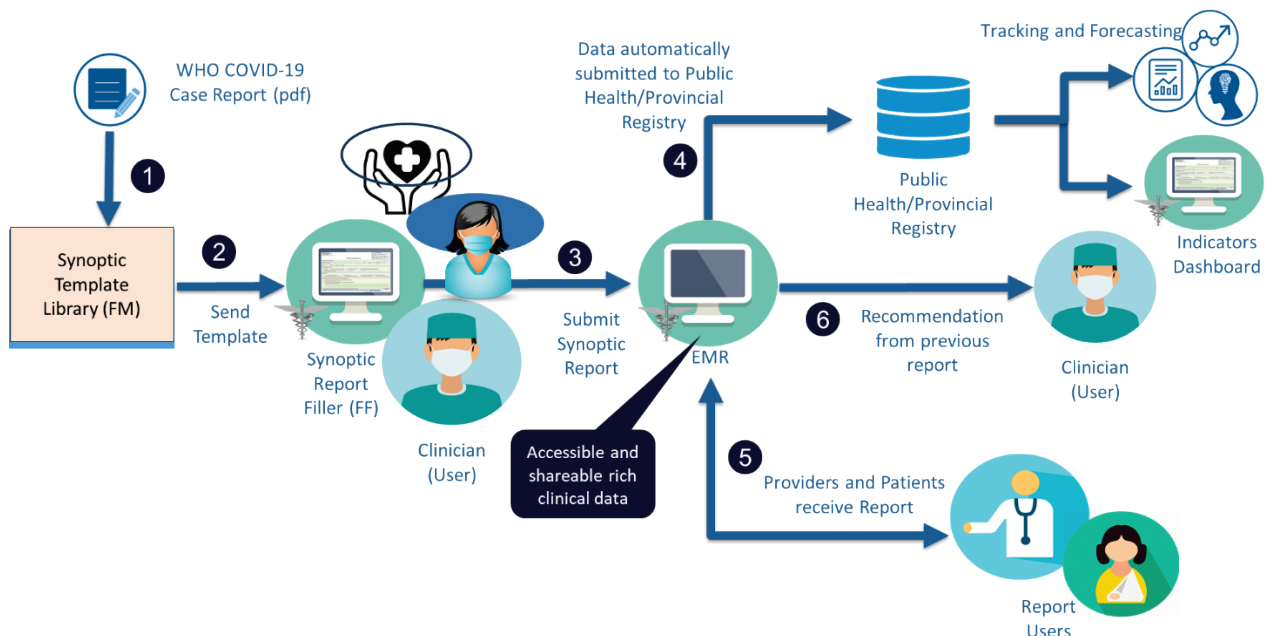


Figure 2.4.2-1: Potential COVID-19 Reporting Model Using SDC

2.4.3 Lung CCG Use Case

240 IHE SDC on FHIR can be applied to clinical reasoning within FHIR. One such example is the IHE Computable Care Guidelines Profile. Data captured in SDC forms can be transformed into FHIR Observations. Those Observations can then be utilized to help suggest decision.

245 A clinician may see a patient with a given symptom, captured as a FHIR Observation. The standard terminology code in that Observation can be read, and a determination can be made against a CCG if a next step is applicable. For example, a clinician may note a patient coughing up blood (hemoptysis), and may record that in a form. That data is written into an Observation where it is read by the CCG system.

Once the data has been read, it can be used to trigger a notification for the clinician of the next step. This methodology can be applied to each step in the process, where data is captured, processed at point of care, and decision support is delivered to the clinician.

250 In this workflow, the SDC form is also be saved as a FHIR DocumentReference; however, the Observation is used to drive the guideline decision support.

The complete FHIR Implementation Guide can be found here: <https://simplifier.net/sdconfhir>

2.5 Areas of Research

255 The QRPH SDC Profile has several areas of further research that have been captured in the Open Issues section of this document. Namely, the use of FHIR Bundles will be tested in future FHIR Connectathons to establish a clear pattern that can be aligned with existing IHE profiles such as Mobile Health Documents. Additionally, the authors will explore the use of FHIR Document and Composition in order to align the products of this paper with the [International Patient Summary](#) (IPS), which already widely recognized as a potential baseline for the exchange of meaningful patient data. The findings of this white paper will inform this future profile development.

260 As part of the exploration of FHIR Bundles, there will be an investigation in using other FHIR resources such as Condition or Procedure, as these resources better represent certain questions from IHE SDC forms. Currently the authors have only tested IHE SDC forms transmission in a FHIR DocumentReference and transformable into FHIR Observations. Standard terminology and complex mappings may need to be leveraged in order to facilitate these transformations as all data is represented in a question/answer format in IHE SDC. Therefore an IHE SDC Question/Answer pair can be represented as one of many FHIR resources, increasing the complexity of the mappings.

270 Other areas of future research may include the use of the developing FHIR Bulk API and support for the future IHE Computable Care Guidelines Profile.

2.6 Benefits and Conclusion

The decoupling of form data into independently queryable objects have a direct impact on the following use cases:

- 275
- Assisting with data pre-population thus saving administrative time, costs and preventing any errors due to manual intervention
 - By capturing and anonymizing the observations, it is possible to generate analytics for quality indicators and research
 - Assisting in the adherence to clinical care guidelines using computable care guidelines there by improving the health outcomes for all patients
- 280
- This white paper has leveraged the work of two different standards bodies and created a synergy between the various efforts. The paper has discussed applicable use-cases and potential benefits. The eventual aim of the pattern is to break down any barriers for data silos and promote the sharing of semantically interoperable data thus promoting better outcomes for all patients around the world.

Appendices

Appendix A – DocumentReference resource with form referenced via a URL example

```
<DocumentReference xmlns="http://hl7.org/fhir">

  <meta>

    <profile
value="http://ihe.net/fhir/StructureDefinition/IHE_MHD_Provide_Minimal_DocumentRefer
ence"/>

  </meta>

  <text>

    <status value="generated"/>

    <div xmlns="http://www.w3.org/1999/xhtml">Adrenal Pathology form about
Frederick SDC-ONE</div>

  </text>

  <masterIdentifier>

    <system value="https://cap.org"/>

    <value value="Adrenal.Bx.Res.129_3.002.011.RC1_sdcFDF1.f96d3fea-62b3-47e9-
8443-f199c2f946f0.ver1"/>

  </masterIdentifier>

  <!-- ID for this resource appended FormID.FormInstanceVersionURI -->

  <identifier>

    <system value="https://cap.org"/>

    <value value="Adrenal.Bx.Res.129"/>

  </identifier>

  <!-- Matches SDC Lineage -->

  <identifier>

    <system value="https://cap.org"/>

    <value value="3.002.011.RC1"/>

  </identifier>

  <!-- Matches SDC form Version -->
```

```

<identifier>
  <system value="https://cap.org"/>
  <value value="Adrenal.Bx.Res.129_3.002.011.RC1_sdcFDF1"/>
</identifier>
<!-- Matches SDC FormID; should be unique to this Form -->
<identifier>
  <system value="https://cap.org"/>
  <value value="f96d3fea-62b3-47e9-8443-f199c2f946f0"/>
</identifier>
<!-- Matches SDC FormInstanceURI -->
<status value="current"/>
<docStatus value="final"/>
<!-- Must us FHIR statuses for docStatus -->
<type>
  <coding>
    <system value="http://loinc.org"/>
    <code value="60568-3"/>
    <display value="Synoptic Report"/>
  </coding>
</type>
<category>
  <coding>
    <system value="urn:oid:1.3.6.1.4.1.19376.1.2.6.1"/>
    <code value="REPORTS"/>
    <display value="REPORTS"/>
  </coding>
</category>
<subject>

```



```
<reference value="http://fhir-read-write:8080/fhir/baseR4/Patient/2"/>
<display value="Frederick SDC-ONE"/>
</subject>
<date value="2018-12-24T09:43:41+11:00"/>
<author>
  <reference value="http://fhir-read-
write:8080/fhir/baseR4/Practitioner/138"/>
  <display value="Robert Robertson"/>
</author>
<securityLabel>
  <coding>
    <system value="http://terminology.hl7.org/CodeSystem/v3-
Confidentiality"/>
    <code value="N"/>
    <display value="normal"/>
  </coding>
</securityLabel>
<content>
  <attachment>
    <contentType value="application/xml"/>
    <language value="en-US"/>
    <!-- likely en-US or en-CA -->
    <url value="/Binary/SDCpkgAdrenal.f96d3fea-62b3-47e9-8443-
f199c2f946f0.ver1"/>
  </attachment>
  <format>
    <system value="http://ihe.net/fhir/ValueSet/IHE.FormatCode.codsystm"/>
    <code value="urn:ihe:pcc:crc:2008"/>
    <display value="Cancer Registry Content (CRC)"/>
  </format>
</content>
</entry>
```

```
</format>  
</content>  
</DocumentReference>
```

290 **Appendix B – Observation resource with questions and answers example**

```
<Observation xmlns="http://hl7.org/fhir">

  <identifier>

    <value value="Adrenal.Bx.Res.129_3.002.011.RC1_sdcFDF.f96d3fea-62b3-47e9-8443-f199c2f946f0.ver1.49275.100004300"/>

    <!-- check if FormInstanceVersionURI already includes the FormID -->

  </identifier>

  <status value="final"/>

  <code>

    <coding>

      <system value="https://CAP.org"/>

      <code value="49275.100004300"/>

      <display value="Tumor invades into other adjacent organ(s)"/>

    </coding>

  </code>

  <subject>

    <reference value="Patient/bibata.amidou@chudequebec.ca"/>

    <display value="Bibata Amidou"/>

  </subject>

  <issued value="2018-12-24T09:43:41+11:00"/>

  <performer>

    <reference value="Practitioner/f202"/>

    <display value="Luigi Maas"/>

  </performer>

  <valueCodeableConcept>

    <coding>

      <system value="https://CAP.org"/>
```

```
<code value="53603.100004300"/>
<display value="Low grade (less than 20 mitoses/50 high-power fields)"/>
</coding>
</valueCodeableConcept>
<derivedFrom>
  <reference
    value="DocumentReference/Adrenal.Bx.Res.129_3.002.011.RC1_sdcFDF.f96d3fea-62b3-
47e9-8443-f199c2f946f0.ver1I"/>
    <!-- referencing Document Reference to SDC Form -->
  </derivedFrom>
</Observation>
```

Glossary

- 295 Please see the IHE Technical Frameworks General Introduction, [Appendix D - Glossary](#) for the IHE Glossary.