Integrating the Healthcare Enterprise

Quality, Research and Public Health (QRPH)

Technical Framework Supplement

Physician Reporting to a Public Health Repository – Cancer Registry (PRPH-Ca)

Trial Implementation

Date: November 4, 2010

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Foreword

This is a supplement to the forthcoming IHE Quality, Research, and Public Health Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of November 4, 2010 and will be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the forthcoming Quality, Research, and Public Health Technical Framework. Comments are invited and may be submitted on the IHE forums at http://forums.rsna.org/forumdisplay.php?f=371or by email to qrph@ihe.net.

This supplement describes changes to the existing technical framework supplement documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

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

Information about IHE Quality, Research, and Public Health can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current versions of the IHE Technical Frameworks can be found at: http://www.ihe.net/Technical_Framework/index.cfm

CONTENTS

Preface

This supplement is written for Trial Implementation. It is written as changes to the documents listed below. The reader should have already read and understood these documents:

1. PCC Technical Framework Volume 1, Revision 6.0
2. PCC Technical Framework Volume 2, Revision 6.0

This supplement also references other documents[1]. The reader should have already read and understood these documents:

1. IT Infrastructure Technical Framework Volume 1, Revision 7.0
2. IT Infrastructure Technical Framework Volume 2, Revision 7.0
3. IT Infrastructure Technical Framework Volume 3, Revision 7.0
4. The Patient Identifier Cross-Reference (PIX) and Patient Demographic Query (PDQ) HL7 v3 Supplement to the IT Infrastructure Technical Framework.
5. HL7 and other standards documents referenced in Volume 1 and Volume 2
6. Dilbert 2.0: 20 Years of Dilbert by Scott Adams, ISBN-10: 0740777351, ISBN-13: 978-0740777356
7. The Effectiveness and Efficiency of Agglomerative Hierarchic Clustering in Document Retrieval (Technical report. Cornell University. Dept. of Computer Science) [Unknown Binding] Ellen M Voorhees

Introduction

Until recently, complete and high quality cancer reporting has been achieved primarily through hospital cancer registries. Traditionally cancer patients receive diagnostic testing or work-up and/or treatment in hospitals. However, advances in medicine now allow patients to obtain their care outside the acute care hospital setting. Data collection systems from other sources such as physician offices are not as consistent with reporting. This leads to under-reporting of certain types of cancers, typically those now diagnosed and treated outside the acute care hospital setting. Both melanomas and prostate cancers, for example, have been shown to be under-reported when central registries rely only on hospital reporting.

[1] The first four documents can be located on the IHE Website at http://www.ihe.net/Technical_Framework/index.cfm#IT. The remaining documents can be obtained from their respective publishers.

In many states, these non-hospital data sources are only minimally involved in reporting to the central cancer registry although the numbers are increasing each year. When reporting does occur, it may be through a manual process of identifying reportable cases and submitting copies of the medical record, or the central registry may send certified tumor registrars (CTR) to clinics or physician offices[2] to manually abstract the information from the paper-based medical records. These processes are very resource-intensive, time-consuming, and vulnerable to errors in transcription.

The need to access the data contained in clinics/physician offices with only limited resources is driving the effort to develop an automated electronic process to identify and report cancer cases using the clinic/physician office electronic medical record (EMR).

The Physician Reporting to a Public Health Repository – Cancer Registry Profile provides a means through which physician office EMR systems can report information on cancer patients to the public health cancer registry. A single, consistent method allows efficient and accurate exchange of information while reducing the burden on EMR system-specific or registry-specific implementations.

Open Issues and Questions

1. The US-Realm specific constraints for Header Content is used in this profile. Will need to accommodate international constraints in future versions. The Constraints are taken from HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes (U.S. Realm) Draft Standard for Trial Use (Release 1 Levels 1, 2, and 3)
2. Need to determine how to list value sets for AJCC Staging Manual, a proprietary coding scheme used internationally.

Closed Issues

[2] For purposes of this profile, clinic/physician offices has been defined as any health care practitioner, e.g., physician or dental offices, who would be required by state regulation to report a cancer case to the central cancer registry.

Volume 1 – Profiles

Add the following to section 1.1.5

1.1.5 Copyright Permissions

Add the following to section 2.5

2.5 Dependencies of the QRPH Integration Profiles

<Profile Name>	<?>	<?>	<->

This profile requires:

1) One of the following:

a) Cross Enterprise Document Sharing (XDS.b);

b) Cross Enterprise Document Media Interchange (XDM);

or c) Cross Enterprise Document Reliable Interchange (XDR)

or
2) Retrieve Form for Data Capture (RFD)

Add the following to section 2.7

None.

2.7 History of Annual Changes

Add Section X

X Physician Reporting to a Public Health Repository – Cancer Registry Profile

The Physician Reporting to a Public Health Repository – Cancer Registry Profile provides a means through which physician office EMR systems can report information on cancer patients to the public health cancer registry. A single, consistent method allows efficient and accurate exchange of information while reducing the burden on EMR system-specific or registry-specific implementations.

This profile defines the data elements to be retrieved from the EMR and transmitted to the cancer registry.

X.1 Purpose and Scope

Until recently, complete and high quality cancer reporting has been achieved primarily through hospital cancer registries. Traditionally cancer patients receive diagnostic testing or work-up and/or treatment in hospitals. However, advances in medicine now allow patients to obtain their care outside the acute care hospital setting. Data collection systems from other sources such as physician offices are not as consistent with reporting. This leads to under-reporting of certain types of cancers, typically those now diagnosed and treated outside the acute care hospital setting. Both melanomas and prostate cancers, for example, have been shown to be under-reported when central registries rely only on hospital reporting.

In many states, these non-hospital data sources are only minimally involved in reporting to the central cancer registry although the numbers are increasing each year. When reporting does occur, it may be through a manual process of identifying reportable cases and submitting copies of the medical record, or the central registry may send certified tumor registrars (CTR) to clinics or physician offices[3] to manually abstract the information from the paper-based medical records. These processes are very resource-intensive, time-consuming, and vulnerable to errors in transcription.

The need to access the data contained in clinics/physician offices with only limited resources is driving the effort to develop an automated electronic process to identify and report cancer cases using the clinic/physician office electronic medical record (EMR).

[3] For purposes of this profile, clinic/physician offices has been defined as any health care practitioner, e.g., physician or dental offices, who would be required by state regulation to report a cancer case to the central cancer registry.

The scope of this profile is for clinic/physician office reporting to a public health cancer registry[4]. Within this scope are the following activities:

- Report required information on all new cancer patients;
- Report treatment and cancer status on all existing cancer patients;
- Report referrals to other clinicians, treatment centers, facilities and/or hospitals;

The following activities are out of scope for this version of the profile:

- Physician reporting to a **hospital** cancer registry;
- Public health cancer registry reporting to the national cancer registries.
- Re-engineering public health cancer registry processes to handle multiple event reports;
- Physician querying the public health cancer registry for patient information;
- Assessing and/or providing guidance for modifying state legislation related to cancer reporting.

X.2 Process Flow

X.2.1 Use Cases

Scenario:

Patty Patient visits her physician complaining of fatigue and a slight temperature. David Doctor orders a complete blood count (CBC) lab test which is performed within the clinic's laboratory. Along with other clinical information, the laboratory results indicate that Patty Patient has cancer – chronic lymphocytic leukemia. David Doctor records the information in the EMR, triggering reporting to the public health cancer registry.

Use Case 1

The Clinic EMR automatically populates the registry report with information from its system and sends it directly to the public health cancer registry.

Use Case 2

The Clinic EMR does not contain sufficient data to generate the registry report. The EMR automatically populates a form with available information and presents the form to the physician

[4] In the USA extension of this supplement, the scope is restricted to clinician reporting to a state/territorial cancer registry. State/territorial cancer registry reporting to the national cancer programs (CDC and SEER) are out of scope.

to complete the remaining required information. The completed form is sent to the public health cancer registry.

X.2.2 Diagrams

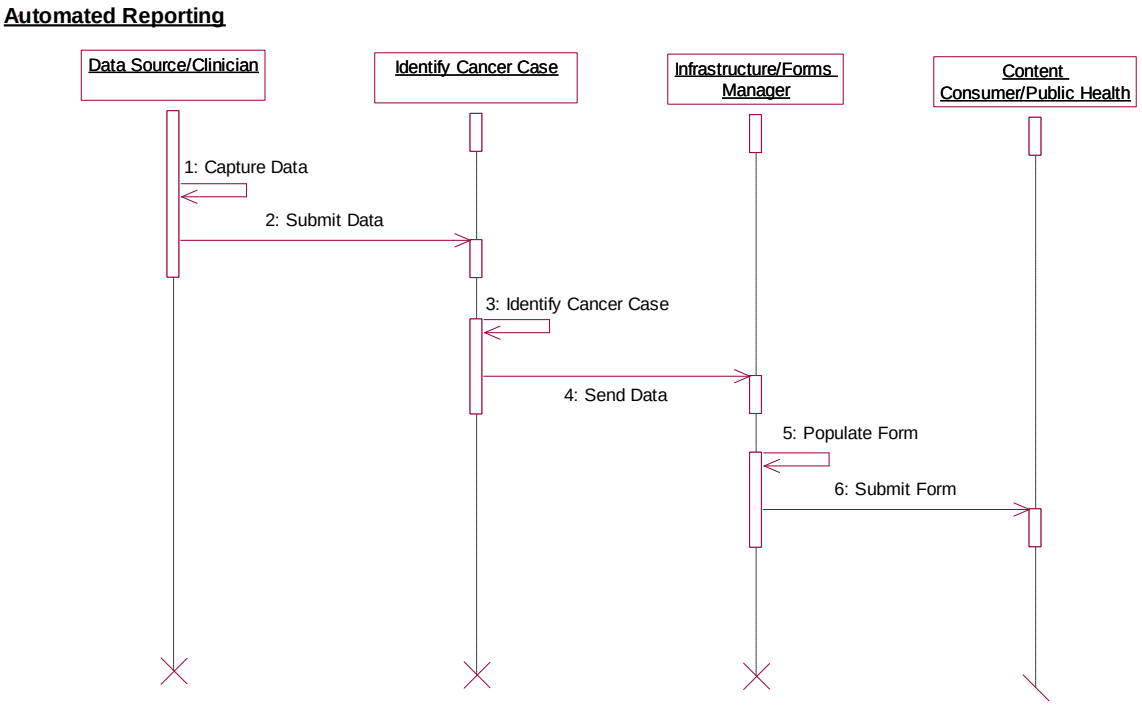


Figure X.2.2-1 Use Case 1: Flow in Physician Reporting to Public Health Repository – Cancer Registry Profile

Clinician Interaction Reporting

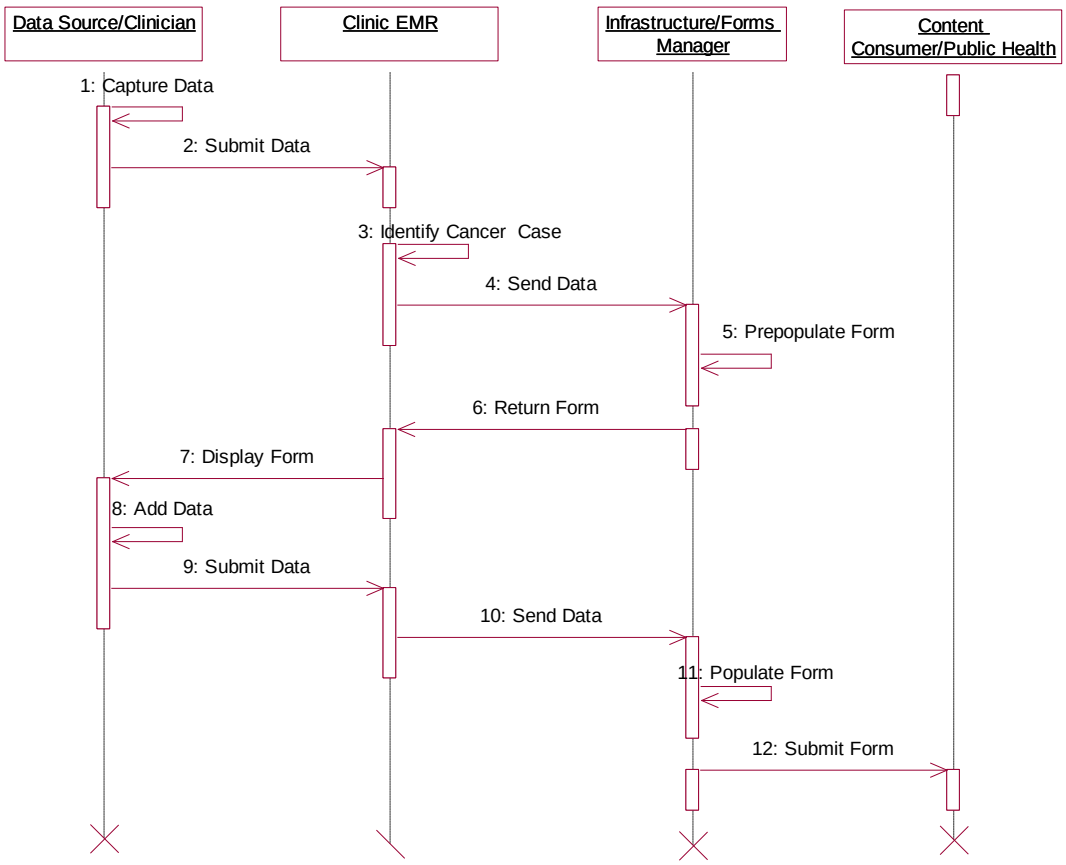


Figure X.2.2-2 Use Case 2: Flow in Physician Reporting to Public Health Repository – Cancer Registry Profile

X.3 Actors/Transactions

There are two actors in this profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. Transmission of

content from one actor to the other is addressed by grouping these actors with actors from other IHE profiles[5].

Figure X.3-1 Actor Diagram

X.3.1 Requirements of Actors

This section describes the specific requirements for each Actor defined within this profile.

X.3.1.1 Content Consumer

1. A Content Consumer shall be able to consume a Cancer Reporting Extract by implementing the Document Import option.
2. A Content Consumer may implement the Discrete Data Import option.
3. A Content Consumer that implements the Discrete Data Import Option may offer a means to import structured data from one or more sections of the document.

X.3.1.2 Content Creator

1. A Content Creator shall be able to create a Cancer Reporting Extract according to the specification Physician Reporting to Public Health Repository – Cancer Registry Profile found in QRPH TF-2:.

X.4 Options

Options that may be selected for this Profile are listed in the table X.4-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

[5] Profiles described in the section on Grouping with XDS, XDM,XDR and RFD.

Table X.4-1 Physician Reporting to Public Health Repository – Cancer Registry Profile Actors and Options

Actor	Option	Section
Content Consumer	View Option (See Note 1)	PCC TF-2: 3.1.1
	Document Import Option (See Note 1)	PCC TF-2: 3.1.2
	Section Import Option (See Note 1)	PCC TF-2: 3.1.3
	Discrete Data Import Option (See Note 1)	PCC TF-2: 3.1.4
Content Creator	No options defined	

Note 1: The Actor shall support at least one of these options.

X.5 Groupings

X.5.1 Infrastructure supporting XDS.b, XDM, and XDR shall be available

It is expected that reporting will occur in an environment where the clinics/physician offices have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS.b) and other IHE Integration Profiles such as patient identification (PIX & PDQ) and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework. Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles.

X.5.2 Required Grouping with Actors from Cross Enterprise Document Sharing, Media Interchange, Reliable Messages or Retrieve Form for Display

A Content Creator or Content Consumer SHALL be grouped with at least one pair of actors from the XDS.b, XDM or XDR profiles, and the metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile.

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms by a Form Filler from a Form Manager optionally using pre-population data sent from the Form Filler. RFD further describes display and completion of a form, and return of instance data from the Form Filler to the Form Receiver as well as optionally to a Form Archiver. [For more details on these profiles, see the IHE IT Infrastructure Technical Framework].

At least one of the following four pairs of groupings is required:

Profile Actor	Groups with (see note 6)
Content Creator	XDS.b/ Document Source
Content Consumer	XDS.b/ Document Consumer
Content Creator	XDR/ Document Source
Content Consumer	XDR/ Document Recipient
Content Creator	XDM/ Portable Media Creator
Content Consumer	XDM/ Portable Media Importer
Content Creator	RFD/ Form Filler,
Content Consumer	RFD/ Form Manager

Note 6: Actors grouping with actors from RFD, XDS.b, XDM and XDR require grouping with actors from the ATNA profile. ATNA requires groupings with Actors in the CT profile.

X.5.3 Notification of Document Availability (NAV)

A Document Source may provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer may provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

X.5.4 Document Digital Signature (DSG)

When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content

Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

X.5.5 Shared Value Set (SVS)

A Content Creator Actor and Content Consumer Actor may support the Shared Value Set (SVS) Integration Profile to receive a common, uniform nomenclature managed.

X.6 Security Considerations

Security considerations are discussed within the appropriate transaction documents.

X.7 Content Modules

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in. Detailed information on the content for this profile can be found in IHE QRPH TF-2.

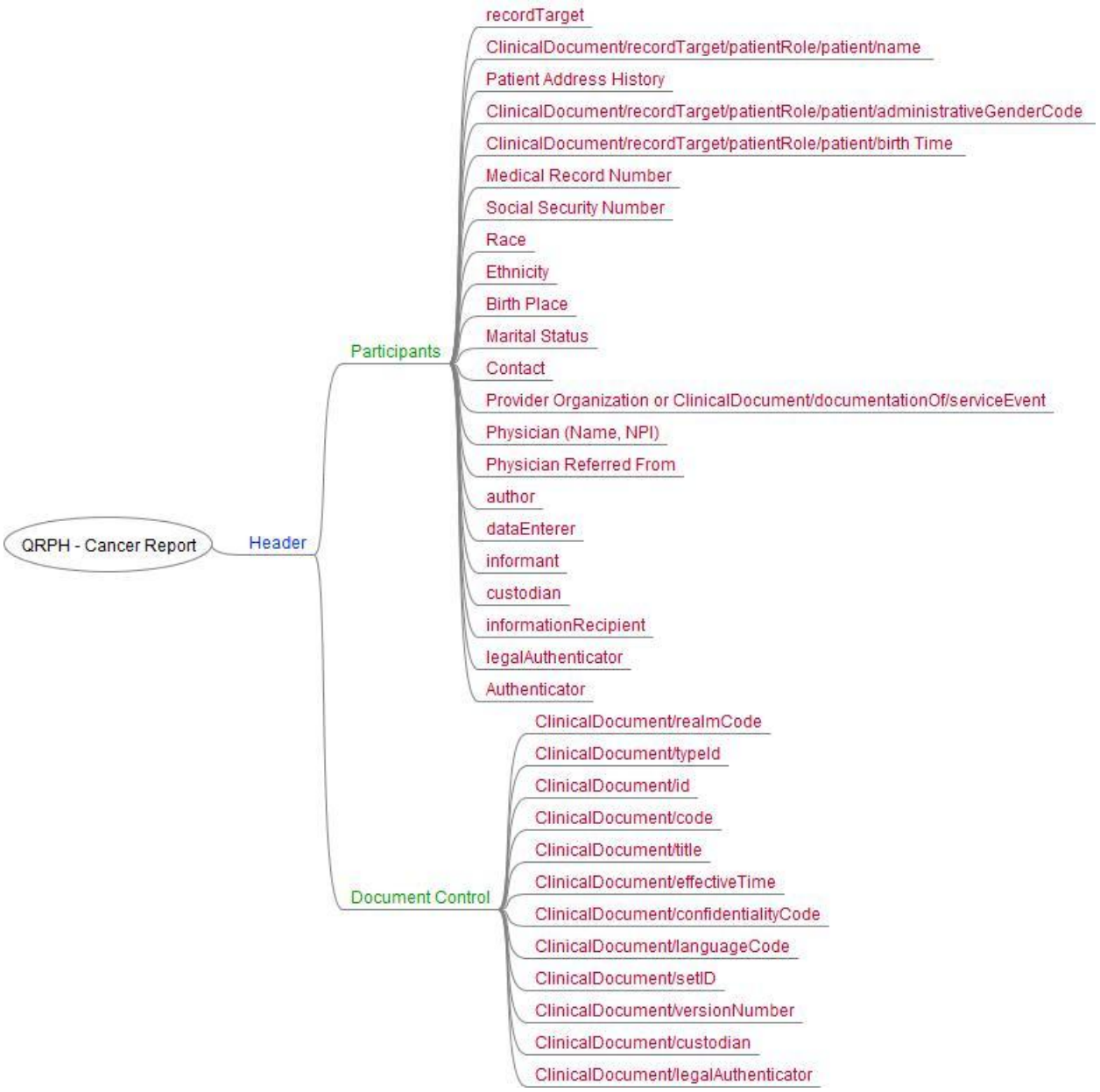


Figure X.7-1 Data Element Diagram of CDA Header

(CDC National Program of Cancer Registries Advancing e-Cancer Reporting and Registry Operations (NPCR-AERRO) Use Case: Clinician/Physician Office Prepare and Transmit Event Report : Data Element List for CDA Header.)

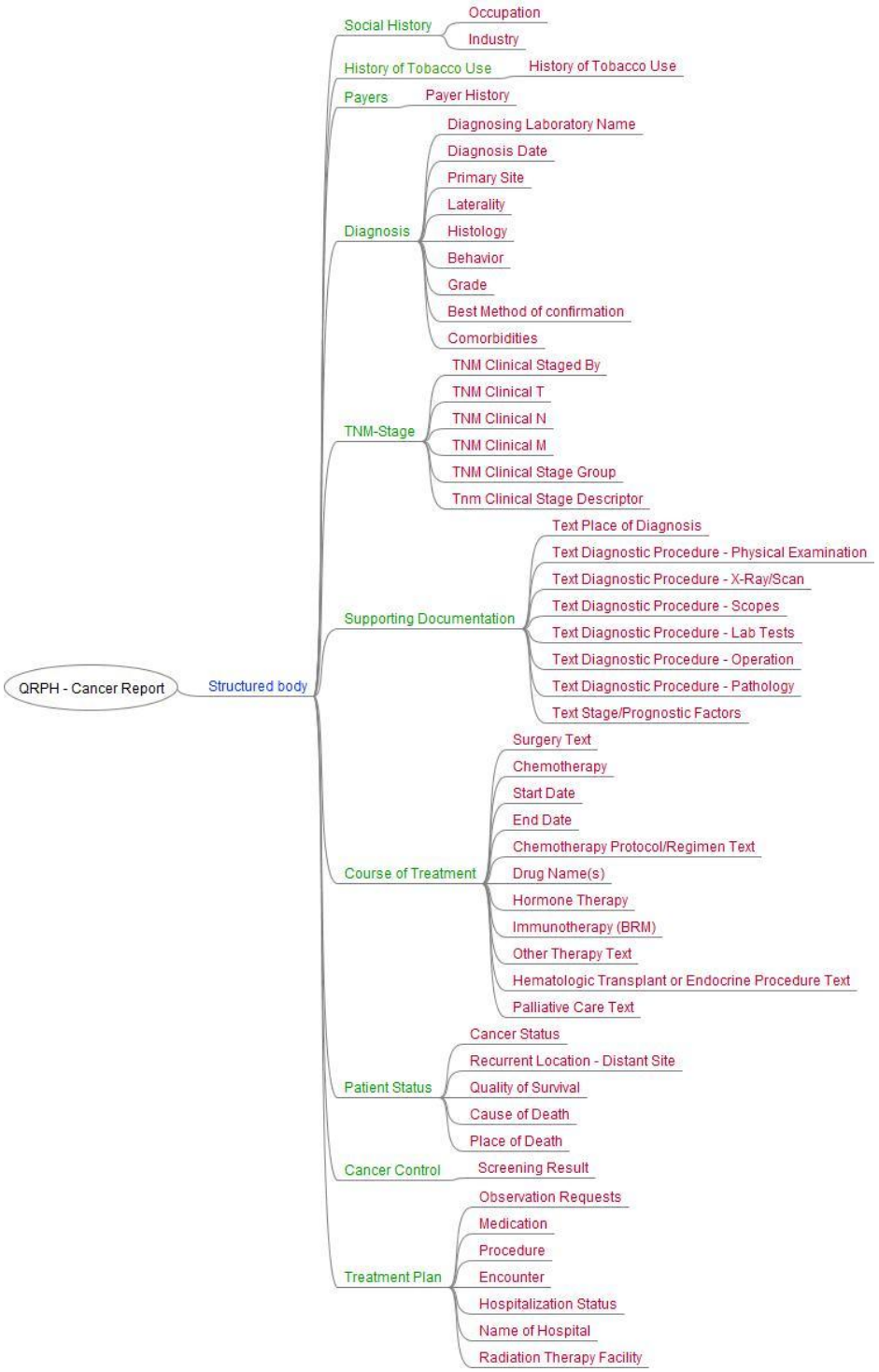


Figure X.7-2 Data Element Diagram of CDA Body

(CDC National Program of Cancer Registries Advancing e-Cancer Reporting and Registry Operations (NPCR-AERRO) Use Case: Clinician/Physician Office Prepare and Transmit Event Report: Data Element List for CDA Body.)

Appendix A Actor Summary Definitions

No new actors are defined for this profile.

Appendix B Transaction Summary Definitions

No new transactions are defined for this profile.

Glossary

Add the following terms to the Glossary:

Actor – An entity within a use case diagram that can perform an action within a use case diagram. Possible actions are creation or consumption of a message

AJCC – American Joint Commission on Cancer – Author of the TNM staging system (See TNM Stage)

Cancer case – A summary of all submitted information. It contains the final best information regarding a patient and his or her cancer and includes patient demographic, medical, staging, treatment, and service information.

Cancer Control – Actions taken to reduce the frequency and impact of cancer, both financially and medically.

Cancer reporting – Actions taken to notify a public health agency of a case of cancer.

Cancer reporting extract – A CDA document containing required and recommended information about a patient's cancer diagnosis and treatment, submitted by a physician to a public health cancer registry.

Certified Tumor Registrar – A nationally certified data collection and management expert with the training and specialized skills to provide the high quality data required in all avenues of cancer statistics and research.

Chemotherapy regimen – A collection of drugs administered in a highly organized manner for treating cancer. It includes information on doses, scheduling, and duration of administration.

Chronic lymphocytic leukemia – A malignant disorder of the bone marrow.

Comorbidity – The presence of one or more disorders (or diseases) in addition to cancer.

Content Binding – A content binding describes how the payload used in an IHE transaction is related to and/or constrained by the data elements contained within the content sent or received in those transactions.

Cytology – Microscopic examination of cells.

Endoscopy – A medical test to examine the interior of a hollow organ or cavity of the body

First course of treatment – Includes all methods of treatment recorded in the treatment plan and administered to the patient before disease progression or recurrence.

Histopathology – Microscopic examination of tissues.

HL7 – Health Level Seven

Hospital Cancer Registry –Collects information on all cancer patients who use the services of a hospital. It may be required to report cancer cases to the central registry, to respond to inquiries from the central registry, or to allow central registry access to its records.

IHE – Integrating the Healthcare Enterprise.

Immunotherapy – Treatment that stimulates the body's immune system to fight tumors. Also called biological response modifier (BRM) therapy.

Interaction Diagram – A diagram that depicts data flow and sequencing of events.

IT – Information Technology.

Logical Observation Identifiers Names and Codes (LOINC®) – A vocabulary developed by the Regenstrief Institute aimed at standardizing laboratory and clinical codes for use in clinical care, outcomes management, and research. Additional information found at http://www.regenstrief.org/medinformatics/loinc/.

Metastasis – The spread of cancer to other parts of the body.

NAACCR – North American Association of Central Cancer Registries. A collaborative umbrella organization for cancer registries, governmental agencies, professional organizations, and private groups in North America interested in enhancing the quality and use of cancer registry data.

Public Health Cancer Registry (Central Cancer Registry/State cancer Registry) –A registry for a defined geographic location that collects cancer information from more than one facility and consolidates multiple reports into one record.

Stage – The extent of involvement of organs and tissues by tumor (e.g. how far the cancer has spread in the body.

Systemic therapy – Treatment that affects the entire body, rather than a localized area. Types of systemic therapy include chemotherapy, hormone therapy, and biological therapy. Systemic therapy enters the bloodstream to destroy or control cancer throughout the body.

TNM Stage – Tumor/Nodes/Metastasis – A system to classify the extent of disease based mostly on anatomic information on the extent of the primary tumor, regional lymph nodes and distant metastasis.

Volume 2 – Transactions and Content Modules

2.3.1 Content Modules

The Patient Care Coordination Technical Framework organizes content modules categorically by the base standard. At present, the PCC Technical Framework uses only one base standard, CDA Release 2.0, but this is expected to change over time. Underneath each standard, the content modules are organized using a very coarse hierarchy inherent to the standard. So for CDA Release 2.0 the modules are organized by document, section, entry, and header elements.

Each content module can be viewed as the definition of a "class" in software design terms, and has associated with it a name. Like "class" definitions in software design, a content module is a "contract", and the PCC Technical Framework defines that contract in terms of constraints that must be obeyed by instances of that content module. Each content module has a name, also known as its template identifier. The template identifiers are used to identify the contract agreed to by the content module. The PCC Technical Committee is responsible for assigning the template identifiers to each content module.

Like classes, content modules may inherit features of other content modules of the same type (Document, Section or Entry) by defining the parent content module that they inherit from. They may not inherit features from a different type. Although information in the CDA Header is in a different location that information in a CDA Entry, these two content modules are considered to be of the same type, and so may inherit from each other when necessary.

The PCC Technical Framework uses the convention that a content module cannot have more than one parent (although it may have several ancestors). This is similar to the constraint in the Java™ programming language, where classes can derive from only one parent. This convention is not due to any specific technical limitation of the technical framework, but does make it easier for software developers to implement content modules.

Each content module has a list of data elements that are required (R), required if known (R2), and optional (O). The presentation of this information varies with the type of content module, and is described in more detail below. Additional data elements may be provided by the sender that are not defined by a specific content module, but the receiver is not required to interpret them.

Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data is not available.

Data elements that are marked required if known (R2) must be sent when the sending application has that data available. The sending application must be able to demonstrate that it can send all

required if known elements, unless it does not in fact gather that data. When the information is not available, the sending application may indicate the reason that the data are not available.

Data elements that are marked optional (O) may be sent at the choice of the sending application. Since a content module may include data elements not specified by the profile, some might ask why these are specified in a content module. The reason for specifying the optional data elements is to ensure that both sender and receiver use the appropriate semantic interpretation of these elements. Thus, an optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element.

Other data elements may be included in an instance of a content module over what is defined by the PCC Technical Framework. Receivers are not required to process these elements, and if they do not understand them, must ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the framework. This allows value to be added to the content modules delivered in this framework, through extensions to it that are not defined or profiled by IHE. It further allows content modules to be defined later by IHE that are refinements or improvements over previous content modules.

For example, there is a Referral Summary content module defined in this framework. In later years an ED Referral content module can be created that inherits the constraints of the Referral Summary content module, with a few more use case specific constraints added. Systems that do not understand the ED Referral content module but do understand the Referral Summary content module will be able to interoperate with systems that send instances of documents that conform to the ED Referral content module. This interoperability, albeit at a reduced level of functionality, is by virtue of the fact that ED Referrals are simply a refinement of the Referral Summary.

In order to retain this capability, there are a few rules about how the PCC Technical Committee creates constraints. Constraints that apply to any content module will always apply to any content modules that inherit from it. Thus, the "contracts" are always valid down the inheritance hierarchy. Secondly, data elements of a content module will rarely be deprecated. This will usually occur only in the cases where they have been deprecated by the base standard. While any specific content module has a limited scope and set of use cases, deprecating the data element prevents any future content module from taking advantage of what has already been defined when a particular data element has been deprecated simply because it was not necessary in the original use case.

2.3.1.1 Document Content Module Constraints

Each document content module will define the appropriate codes used to classify the document, and will also describe the specific data elements that are included. The code used to classify it is specified using an external vocabulary, typically LOINC in the case of CDA Release 2.0 documents. The set of data elements that make up the document are defined, including the

whether these data elements must, should or may be included in the document. Each data element is typically a section within the document, but may also describe information that is contained elsewhere within of the document (e.g., in the header). Each data element is mapped into a content module via a template identifier, and the document content module will further indicate whether these data elements are required, required if known or optional. Thus, a document content module shall contain as constraints:

- The template identifier of the parent content module when there is one.
- The LOINC code or codes that shall be used to classify the document.
- A possibly empty set of required, required if known, and optional section content modules, and their template identifiers.
- A possibly empty set of required, required if known, and optional header content modules, and their template identifiers.
- Other constraints as necessary.

The template identifier for the document will be provided in the narrative, as will the legal LOINC document type codes and if present, any parent template identifier.

The remaining constraints are presented in two tables. The first table identifies the relevant data elements as determined during the technical analysis, and maps these data elements to one or more standards. The second table actually provides the constraints, wherein each data element identified in the first table is repeated, along with whether it is required, required if known, or optional. Following this column is a reference to the specification for the content module that encodes that data element, and the template identifier assigned to it. The simple example below completes the content specification described above.

Sample Document Specification SampleDocumentOID

Sample Document has one required section, and one entry that is required if known

2.3.1.1.1 Specification

Data Element Name	Opt	Template ID
Sample Section Comment on section	R	SampleSectionOID
Sample Entry Comment on entry	R2	SampleEntryOID

Table 0-1

2.3.1.1.2 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='SampleDocumentOID'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Sample Document</title>
  <effectiveTime value='20080601012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component><structuredBody>
    <component>
      <section>
        <templateId root='SampleSectionOID'/>
        <!-- Required Sample Section Section content -->
      </section>
    </component>

  </structuredBody></component>
</ClinicalDocument>
```

2.3.1.1.3 Schematron

```
<pattern name='Template_SampleDocumentOID'>
 <rule context='*[cda:templateId/@root="SampleDocumentOID"]'>
   <!-- Verify that the template id is used on the appropriate type of object --
>
   <assert test='../cda:ClinicalDocument'>
     Error: The Sample Document can only be used on Clinical Documents.
   </assert>
   <!-- Verify the document type code -->
   <assert test='cda:code[@code = "{{{LOINC}}}"]'>
     Error: The document type code of a Sample Document must be {{{LOINC}}}
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The document type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "SampleSectionOID"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Sample Document must contain Sample Section.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
   <assert test='.//cda:templateId[@root = "SampleEntryOID"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Sample Document should contain Sample Entry.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
 </rule>
</pattern>
```

2.3.1.2 Section Content Module Constraints

Section content modules will define the content of a section of a clinical document. Sections will usually contain narrative text, and so this definition will often describe the information present in the narrative, although sections may be wholly comprised of subsections.

Sections may contain various subsections, and these may be required, required if known or optional. Sections may also contain various entries, and again, these may be required, required if known, or optional. A section may not contain just entries; it must have at least some narrative text or subsections to be considered to be valid content.

Again, sections can inherit features from other section content modules. Once again, sections are classified using an external vocabulary (again typically this would be LOINC), and so the list of possible section codes is also specified. Sections that inherit from other sections will not specify a LOINC code unless it is to restrict the type of section to smaller set of LOINC codes specified by one of its ancestors.

Thus, a section content module will contain as constraints:

- The template identifier of the parent content module when there is one.
- The LOINC code or codes that shall be used to classify the section.
- A possibly empty set of required, required if known, and optional section content modules, and their template identifiers for the subsections of this section.
- A possibly empty set of required, required if known, and optional entry content modules, and their template identifiers.
- Other constraints as necessary.

These constraints are presented in this document using a table for each section content module, as shown below.

Sample Section

	SampleSectionOID	
	foo (SampleParentOID)	
	Desription of this section	
	Opt	**Description**
XXXXX-X	R	SECTION NAME
Entries	**Opt**	**Description**
OID	R	Sample Entry
Subsections	**Opt**	**Description**
OID	R	Sample Subsection

Table 0-1

Table 0-2

Table 0-3

Table 0-4 LOINC Codes

Table 0-5 General Description

Table 0-6 Parent Template

2.3.1.1.4 Parent Template

The parent of this template is foo.

```
<component>
  <section>
    <templateId root='SampleParentOID'/>
    <templateId root='SampleSectionOID'/>
    <id root=' ' extension=' '/>
    <code code=' ' displayName=' '
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
      Required and optional entries as described above
    </entry>

    <component>
      Required and optional subsections as described above
    </component>

  </section>
```

2.3.1.3 Entry and Header Content Modules Constraints

Entry and Header content modules are the lowest level of content for which content modules are defined. These content modules are associated with classes from the HL7 Reference Information Model (RIM). These "RIM" content modules will constrain a single RIM class. Entry content modules typically constrain an "Act" class or one of its subtypes, while header content modules will normally constrain "Participation", "Role" or "Entity" classes, but may also constrain an "Act" class.

Entry and Header content modules will describe the required, required if known, and optional XML elements and attributes that are present in the CDA Release 2.0 instance. Header and Entry content modules may also be built up using other Header and Entry content modules. An entry or header content module may also specify constraints on the vocabularies used for codes found in the entry, or data types for the values found in the entry. Thus, an entry or header content module will contain as constraints:

- The template identifier of the parent content module when there is one.
- A description of the XML elements and attributes used in the entry, along with explanations of their meaning.
- An indication of those XML elements or attributes that are required, required if known, or optional.
- Vocabulary domains to use when coding the entry.
- Data types used to specify the value of the entry.

- Other constraints as necessary.

An example is shown below:

Sample Entry

Some text describing the entry.

```
<observation classCode='OBS' moodCode='EVN'>
   <templateId root='foo'/>
</observation>
```

3.0 IHE Transactions

None.

5.0 Namespaces and Vocabularies

The following vocabularies are referenced in this document. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/frames.cfm. Realm-specific vocabularies are included in the related appendix.

codeSystem	codeSystemName	Description
2.16.840.1.113883.5	HL7	This is the root OID for HL7 v3 code systems
1.3.6.1.4.1.19376.1.5.3.1	IHE PCC Template Identifiers	This is the root OID for all IHE PCC Templates. A list of PCC templates can be found in CDA Release 2.0 Content Modules.
1.3.6.1.4.1.19376.1.7.3	IHE QRPH Template Identifiers	This is the root OID for all IHE QRPH Templates.
1.3.6.1.4.1.19376.1.5.3.4	IHE Extensions to CDA Release 2.0	Namespace OID used for IHE Extensions to CDA Release 2.0
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9* CM (diagnosis codes)	International Classification of Diseases (Realm-Specific)
2.16.840.1.113883.6.3	ICD-10* (diagnosis codes)	International Classification of Diseases (Realm Specific)
2.16.840.1.113883.6.43.1	ICD-O-3	International Classification of Diseases for Oncology, Version 3
	ILO	International Labor Office International Standard Classification of Occupations 2008 (ISCO-08)

5.1 IHE Format Codes

The table below lists the format codes, template identifiers and media types used by this profile.

Profile	Format Code	Media Type	Template ID
2006 Profiles			
Physician Reporting to Public Health – Cancer Registry	urn:ihe:qrph:prph:2009	text/xml	1.3.6.1.4.1.19376.1.7.3.1.1.14.1

6.0 QRPH Content Modules

6.1 Conventions

Various tables used in this section will further constrain the content. Within this volume, the follow conventions are used.

R

A "Required" data element is one that shall always be provided. If there is information available, the data element must be present. If there is no information available, or it cannot be transmitted, the data element must contain a value indicating the reason for omission of the data. (See PCC TF-2: 5.3.4.2 for a list of appropriate statements).

R2

A "Required if data present" data element is one that shall be provided when a value exists. If the information cannot be transmitted, the data element shall contain a value indicating the reason for omission of the data. If no such information is available to the creator or if such information is not available in a well identified manner (e.g. buried in a free form narrative that contains additional information relevant to other sections) or if the creator requires that information be absent, the R2 section shall be entirely absent. (See section PCC TF-2: 5.3.4.2 for a list of appropriate statements).

O

An optional data element is one that may be provided, irrespective of whether the information is available or not. If the implementation elects to support this optional section, then its support shall meet the requirement set forth for the "Required if data present" or R2.

C

A conditional data element is one that is required, required if known or optional depending upon other conditions. These will have further notes explaining when the data element is required, et cetera.

Note: The definitions of R, R2, and O differ slightly from other IHE profiles. This is due in part to the fact that local regulations and policies may in fact prohibit the transmission of certain information, and that a human decision to transmit the information may be required in many cases.

6.2 Folder Content Modules

None.

6.3 HL7 Version 3.0 Content Modules

This section contains modules that describe the content requirement of documents used within the Cancer Reporting profile.

6.3.1 CDA Document Content Modules

Add section 6.3.1.A

6.3.1.1 Medical Documents Specification 1.3.6.1.4.1.19376.1.5.3.1.1.1

This section defines the base set of constraints used by almost all medical document profiles described in the PCC Technical Framework.

6.3.1.1.1 Standards

CDAR2	HL7 CDA Release 2.0
CDTHP	CDA for Common Document Types History and Physical Notes (DSTU)
XMLXSL	Associating Style Sheets with XML documents

6.3.1.1.2 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Medical Documents</title>
  <effectiveTime value='20081004012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component><structuredBody>

  </structuredBody></component>
</ClinicalDocument>
```

Figure 6.3.1.1.2-1 Sample Medical Documents Document

```
<!-- Verify the document type code -->
<assert test='cda:code[@code = "{{{LOINC}}}"]'>
  Error: The document type code of a Medical Documents must be {{{LOINC}}}
</assert>
<assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
  Error: The document type code must come from the LOINC code
  system (2.16.840.1.113883.6.1).
</assert>
```

Figure 6.3.1.1.2-2 Sample Medical Documents Schematron Rules

6.3.1.1.3 Specification

The constraints for encoding of the CDA Header (Level 1) can be found in the CDA for Common Document Types History and Physical Implementation Guide, in the section 2. CDA Header -- General Constraints.

- IHE Medical Documents **SHALL** follow all constraints found in that section with the exception of the constraint on realmcode found in **CONF-15.**
- IHE Medical Documents which are implemented for the US Realm **SHALL** follow ALL constraints found in that section, and **SHALL** use both the IHE Medical Document templateId (1.3.6.1.4.1.19376.1.5.3.1.1.1) and the HL7 General Header Constraints templateId (2.16.840.1.113883.10.20.3).}}

Realm	Constraints	Template IDs Required
Universal	**CONF-HP-1** through **CONF-HP-14** **CONF-HP-16** through **CONF-HP-52**	1.3.6.1.4.1.19376.1.5.3.1.1.1
US	**CONF-HP-1** through **CONF-HP-52**	1.3.6.1.4.1.19376.1.5.3.1.1.1 2.16.840.1.113883.10.20.3
DE	**TBD**	TBD

6.3.1.1.4 Distinctions of None

Information that is sent **MUST** clearly identify distinctions between

None

It is known with complete confidence that there are none. Used in the context of problem and medication lists, this indicates that the sender knows that there is no relevant information that can be sent.

None Known

None are known at this time, but it is not known with complete confidence that none exist. Used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.

None Known Did Ask

None are known at this time, and it is not known with complete confidence that none exist, but the information was requested. Also used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.

Unknown

The information is not known, or is otherwise unavailable.

In the context of CDA, sections that are required to be present but have no information should use one of the above phrases where appropriate.

6.3.1.2 Physician Report to Cancer Registry 1.3.6.1.4.1.19376.1.7.3.1.1.14

The Physician Cancer Report contains a record of a patient's encounter for diagnosis and/or treatment of cancer. This content module inherits from the Medical Documents content module, and so must conform to the requirements of that template as well.

6.3.1.2.1 Parent Template

This document is an instance of the Medical Document template

6.3.1.2.1.1 LOINC Code

The LOINC code for this document is **x-physician-cancer-rep**

6.3.1.2.2 Standards

CDAR2	HL7 CDA Release 2.0
LOINC	Logical Observation Identifiers, Names and Codes
NAACCR	North American Association of Central Cancer Registries
CDTHP	CDA for Common Document Types History and Physical Notes (DSTU)

6.3.1.2.3 Specification

Note: Refer to the appendices for realm-specific optionality and templateIDs.

Table 6.3.1.2.3-1 is a list of the elements of the CDA header with further constraints on optionality for the Physician Report to Cancer Registry Document.

Table 6.3.1.2.3-1 CDA Header Elements for Physician Report to Cancer Registry Document

Data Element Name (Section)	Option-ality	Template ID
ClinicalDocument/realmCode	R	2.16.840.1.113883.10.20.3
ClinicalDocument/typeId	R	2.16.840.1.113883.10.20.3
ClinicalDocument/id	R	2.16.840.1.113883.10.20.3
ClinicalDocument/code	R	2.16.840.1.113883.10.20.3
ClinicalDocument/title	R	2.16.840.1.113883.10.20.3
ClinicalDocument/effectiveTime	R	2.16.840.1.113883.10.20.3
ClinicalDocument/confidentialityCode	R	2.16.840.1.113883.10.20.3
ClinicalDocument/languageCode	R	2.16.840.1.113883.10.20.3
ClinicalDocument/setId	R	2.16.840.1.113883.10.20.3
ClinicalDocument/versionNumber	R	2.16.840.1.113883.10.20.3
ClinicalDocument/custodian	R	2.16.840.1.113883.10.20.3
ClinicalDocument/legalAuthenticator	R	2.16.840.1.113883.10.20.3
Participants (all participants will have name, address and telephone number)	**R**	2.16.840.1.113883.10.20.3
recordTarget	R	2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/**patient/name**	R	2.16.840.1.113883.10.20.3
Patient Address History	O	1.3.6.1.4.1.19376.1.5.3.1.1.1
ClinicalDocument/recordTarget/patientRole/patient/**administrativeGenderCode**	O	2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/patient/**birthTime**	O	2.16.840.1.113883.10.20.3
Medical Record Number	O	1.3.6.1.4.1.19376.1.5.3.1.1.1
Social Security Number	O	
Race	O	2.16.840.1.113883.5.104
Ethnicity	O	2.16.840.1.113883.5.50
Birth Place	O	1.3.6.1.4.1.19376.1.5.3.1.1.1
Marital Status	O	2.16.840.1.113883.10.20.3
Contact	O	

Data Element Name (Section)	Option-ality	Template ID
Provider Organization	O	2.16.840.1.113883.10.20.3
Physician (Name, NPI)	O	
Physician Referred From	O	
Author	R	2.16.840.1.113883.10.20.3
dataEnterer	R	2.16.840.1.113883.10.20.3
Informant	O	2.16.840.1.113883.10.20.3
custodian	R	2.16.840.1.113883.10.20.3
informationRecipient	O	2.16.840.1.113883.10.20.3
legalAuthenticator	O	2.16.840.1.113883.10.20.3
Authenticator	O	2.16.840.1.113883.10.20.3

Table 6.3.1.2.3-2 is a list of the sections defined for the Physician Report to Cancer Registry Document. These sections are recorded in the StructuredBody of the CDA document.

Table 6.3.1.2.3-2 Section Requirements for Physician Report to Cancer Registry Document

Data Element Name (Section)	Opt	Section Template ID / Location	Value Set Template ID
Occupational History Section	**R**	2.16.840.1.113883.3.520.2.1 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.50	
History of Tobacco Use Section	**R**	**1.3.6.1.4.1.19376.1.5.3.1.1.9.8** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.29	
Payers: Ca Section	**R**	**2.16.840.1.113883.3.520.2.2** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.37.5	
Diagnosis Section	**R**	**2.16.840.1.113883.3.520.2.3** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.8	

Data Element Name (Section)	Opt	Section Template ID / Location	Value Set Template ID
TNM-Stage Section	**R**	**2.16.840.1.113883.3.520.2.4** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.9	
Cancer Supporting Documentation Section	**R**	**2.16.840.1.113883.3.520.2.5** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.10	
Cancer Course of Treatment Section	**R**	**2.16.840.1.113883.3.520.2.6** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.6.18	
Patient Status Section	**R**	**2.16.840.1.113883.3.520.2.7** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.51	
Cancer Control Section	**R**	**2.16.840.1.113883.3.520.2.8** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.52	
Cancer Treatment Plan Section	**R**	**2.16.840.1.113883.10.20.1.25** PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.6.19	

6.3.1.2.4 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below. A CDA Document may conform to more than one template. This content module inherits from the Medical Document content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <templateId root='1.3.6.1.4.1.19376.1.7.3.1.1.14.1'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title> Physician Report to Cancer Registry </title>
  <effectiveTime value='20100506012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>



  <!-- one or more patient -->
  <recordTarget><patientRole> .. </patientRole></recordTarget>

  <!-- one or more author -->
  <author> .. </author>

  <!-- one or more person who provided information as input to this document -->
  <informant> .. </informant>

  <!-- the organization issuing this report and in charge with its lifecycle -->
  <custodian> .. </custodian>

  <!-- zero or more intended recipient other -->
  <informationRecipient> .. </informationRecipient>

  <!-- the person legally responsible for this report, who may have signed it -->
  <legalAuthenticator> .. </legalAuthenticator>

  <!-- one or more physicians who validated the content and contributed to the conclusion -->
  <authenticator> .. </authenticator>



  <component>
   <structuredBody>
    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.1'/>
        <!—Required Cancer Occupation History -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.2'/>
        <!— Required Payers -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.3'/>
        <!—Required Diagnosis -->
      </section>
    </component>
```

```
    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.4'/>
        <!—Required TNM-Stage -->
      </section>
    </component>

    <component>
      <section>
       <templateId root='2.16.840.1.113883.3.520.2.5'/>
        <!—Required Cancer Supporting Documentation -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.6'/>
        <!—Required Cancer Course of Treatment -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.7'/>
        <!—Required Patient Status -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.3.520.2.8'/>
        <!—Required Cancer Control -->
      </section>
    </component>

    <component>
      <section>
        <templateId root='2.16.840.1.113883.10.20.1.25'/>
        <!—Required Cancer Treatment Plan  -->
      </section>
    </component>


  </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 6.3.1.2.4-1 Physician Report to Cancer Registry Document

6.3.2 CDA Header Content Modules

Add section 6.3.2.B

6.3.2.B Header Content Module Specification Name

Data Element Name (Section)	Option-ality	Template ID

Data Element Name (Section)	Option-ality	Template ID
ClinicalDocument/realmCode	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/typeId	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/id	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/code	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/title	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/effectiveTime	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/confidentialityCode	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/languageCode	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/setId	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/versionNumber	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/custodian	**R**	2.16.840.1.113883.10.20.3
ClinicalDocument/legalAuthenticator	**R**	2.16.840.1.113883.10.20.3
Participants (all participants will have name, address and telephone number)	**R**	2.16.840.1.113883.10.20.3
recordTarget		2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/patient/name	R	2.16.840.1.113883.10.20.3
Patient Address History	R	1.3.6.1.4.1.19376.1.5.3.1.1.1
ClinicalDocument/recordTarget/patientRole/patient/**administrativeGenderCode**	O	2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/patient/**birthTime**	O	2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/patient/**Medical Record Number**	O	2.16.840.1.113883.10.20.3
ClinicalDocument/recordTarget/patientRole/patient/**Social Security Number**	O	2.16.840.1.113883.10.20.3
Race	O	2.16.840.1.113883.5.104
Ethnicity	O	2.16.840.1.113883.5.50
Birth Place	O	1.3.6.1.4.1.19376.1.5.3.1.1.1
Marital Status	O	2.16.840.1.113883.10.20.3
Contact data (Current Address and telephone number)	O	2.16.840.1.113883.10.20.3
Provider Organization	O	2.16.840.1.113883.10.20.3
Physician (Name, NPI)	O	
Physician Referred From	O	
Author		2.16.840.1.113883.10.20.3
dataEnterer		2.16.840.1.113883.10.20.3

Data Element Name (Section)	Option-ality	Template ID
Informant		2.16.840.1.113883.10.20.3
custodian		2.16.840.1.113883.10.20.3
informationRecipient		2.16.840.1.113883.10.20.3
legalAuthenticator		2.16.840.1.113883.10.20.3
Authenticator		2.16.840.1.113883.10.20.3

Figure 6.3.2.B-1 Specification for Header

The header describes the document itself (e.g., unique ID, document type classification, version), the participants (e.g., care physicians, authors, patients) and the document's relationships to orders and other documents.

typeId

The typeID element identifies the document as an instance conforming to CDA release 2.

Example

```
<typeId root='2.16.840.1.113883.1.3' extension='POCD_HD000040'/>
```

templateId – Physician Cancer Reporting Extract

This templateId element identifies the document instance as conforming to the constraints for a physician cancer report.

Document Template ID = '1.3.6.1.4.1.19376.1.7.3.1.1.14.1'

id (instance identifier)

The document's id element is an instance identifier data type. The root attribute specifies the scope of the extension attribute.

Example

```
<id root="1.3.6.1.4.1.19376.1.7.3.1.1.14.1"/>
```

code

The code element at the document root specifies the document type code that classifies the document as a Physician Report to a Cancer Registry.

Example

```
<code codeSystem="2.16.840.1.113883.6.1"
```



```
      codeSystemName="LOINC"
      code="x-Physician Report to a Cancer Registry"/>
```

title

The title is a display string that identifies the type of document.

Example

```
<title>Physician Report to a Cancer Registry</title>
```

relatedDocument

Example

```
<relatedDocument typeCode="RPLC">
  <parentDocument>
    <!-- Previous document's file id-->
    <id root="xxx"/>
    <!-- Previous document's setId and version -->
    <setId root="xxx"/>
    <versionNumber value="x"/>
  </parentDocument>
</relatedDocument>
```

Participants

The Patient: ClinicalDocument/recordTarget

The `recordTarget` element represents the patient whose health history is described by this cancer report. The CDA `patientRole` element can record patient identification:

- ID,
- name,
- address,
- gender,
- birthdate,
- marital status and
- contact data (current address and telephone).

Example

```
  <recordTarget>
    <patientRole>
      <!-- Patient ID - Hospital -->
      <id root="2.16.840.1.113883.4.6" extension="123456"/>

      <!-- Medical record number for the patient -->
```

```
      <sdtc:patient><sdtc:id root=' ' extension='221234-7'/></sdtc:patient>

      <!-- Patient's Social Security Number -->
      <id root="2.16.840.1.113883.4.1" extension="999-99-9999"/>

      <addr>
        <streetAddressLine>17 Daws Road</streetAddressLine>
        <city>Blue Bell</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
      </addr>
      <telecom value="tel:(888)555-1212"/>

      <patient>
        <name>
          <family>Henry</family>
          <given>Levin</given>
          <given>D.</given>
          <suffix>the 7th</suffix>
        </name>

        <birthTime value="19320924"/>
        <birthplace>
          <place>
            <addr>
              ...
            </addr>
          </place>
        </birthplace>
      </patient>
    </patientRole>
  </recordTarget>
```

Patient Identifiers

A patient identifier consists of an identifier and the OID of the authority that issued it as a unique identifier within its scope. An OID in itself is not sufficient to specify the kind of identifier being recorded[6], therefore an ID element for each identifier must be present in the specified order.

[6] For example, the hospital's patient ID and medical record number would both be scoped by the OID identifying the hospital. Some facilities assign an OID specifically to their Medical Record Numbers; however, relying on this would require the receiver of the document – for example, a Public Health Cancer Registry – to be able to interpret the OIDs of all facilities which submit records to it. That is not always viable: the submissions may be unanticipated, and the sender's OIDs may be unpublished.

Address History

Address History documents all of the addresses on file for the patient, along with the dates the address was used. The element is of type AD, and each patient address is entered as a distinct element. Address History shall be present and contain at least one address, the most recent/current address.

Example:

```
<!—Australian home address with usable period -->
<addr use="H">
      <streetAddressLine>1 Clinician Street</streetAddressLine>
      <city>Nehtaville</city>
      <state>QLD</state>
      <postalCode>5555</postalCode>
      <additionalLocator>32568931</additionalLocator>
      <useablePeriod xsi:type="IVL_TS">
            <low value="01012001" />
            <high value="01012012" />
      </useablePeriod>
</addr>
```

Gender Observation

This observations codes the patient's administrative gender.

Race Observation

This observation codes the patient's race.

Ethnicity (/Hispanic Origin Observation)

This observation codes the patient's ethnic status.

Provider Organization

The serviceEvent element records the ID of the reporting facility and the dates of first and last contact.

Provider Referred From: /ClinicalDocument/participant

This observation records the provider that referred the patient to the reporting facility.

Example

```
   <participant typeCode="REFB>
      <associatedEntity classCode="SDLOC">
        <id root="xxx"/>
```



```
        <code codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC"
              code="22021-0"
              displayName="Provider Referred From"/>
     </associatedEntity>
  </participant>
```


6.3.3 CDA Section Content Modules

Add section 6.3.3.C

For this profile each section is required to be present. It may be empty based on optionality of the entries within the section.

Table 6.3.3.C-1 Section Templates

Section	Optionality	Cardinality	Section Template ID / Location
Occupational History	R	[0..*]	2.16.840.1.113883.3.520.2.1 PCC TF Supplement CDA Content Modules (TI)
History of Tobacco Use	R	[0..*]	1.3.6.1.4.1.19376.1.5.3.1.1.9.8 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.4.54
Cancer Payers	R	[0..*]	2.16.840.1.113883.3.520.2.2 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.7.5
Diagnosis	R	[0..*]	2.16.840.1.113883.3.520.2.3 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.8
TNM-Stage	R	[0..*]	2.16.840.1.113883.3.520.2.4 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.9
Cancer Supporting Documentation	R	[0..*]	2.16.840.1.113883.3.520.2.5 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.5.10
Cancer Course of Treatment	R	[0..*]	2.16.840.1.113883.3.520.2.6 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.6.18
Patient Status	R	[0..*]	2.16.840.1.113883.3.520.2.7 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.51
Cancer Control	R	[0..*]	2.16.840.1.113883.3.520.2.8 PCC TF Supplement CDA Content Modules (TI) Vol 2: 6.3.3.2.52
Cancer Treatment Plan	R	[0..*]	2.16.840.1.113883.10.20.1.25

Example

```
<ClinicalDocument>
  ... [header elements]

  <component>
    <structuredBody>

      <component>
        <section>
          <templateId root="...">
          <code codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC"
                code="..."
                displayName="..."/>
          <title>...</title>

          ...  [section content here]

        </section>
      </component>

      <component>
        <section>
          ...
        </section>
      </component>

      ...
    </structuredBody>
  </component>
</ClinicalDocument>
```

6.3.4 CDA Entry Content Modules

Diagnosing Laboratory Observation: /ClinicalDocument/participant

This observation records the name, address and ID of the laboratory which provided the cancer diagnosis.

Example

```
<participant typeCode="PRF>
   <associatedEntity classCode="SDLOC">
     <id root="xxx"/>
     <code codeSystem="2.16.840.1.113883.6.1"
           codeSystemName="LOINC"
           code="xxxxx-x"
           displayName="Diagnosing Laboratory"/>
   </associatedEntity>
</participant>
```

6.5 QRPH Value Sets

Add section 6.5.A

6.5.A <Value Set Name>

Primary Site Value Set

Code System: ICD-O-3 2.16.840.1.113883.6.43.1	
Code	**Meaning**
	A code from ICD-O-3 (Topography Section)

Histologic Type Value Set

LOINC = 31205-8	
Code System: ICD-O-3 2.16.840.1.113883.6.43.1	
Code	**Meaning**
	An ICD-O-3 code (Morphology Section)

TNM Clinical Tumor Value Set

Code	**Description: Site specific descriptions prevent listing of text equivalents.**
Ta	
Tis	
T0	
T1	
T1mic	
T1a	
T1a1	
T1a2	
LOINC = ????	
Value Set: ????	
T1b	
T1b1	
T1b2	
T1c	

T1d	
T2	
T2a	
T2a1	
T2a2	
T2b	
T2c	
T2d	
T3	
T3a	
T3b	
T3c	
T3d	
T4	
T4a	
T4b	
T4c	
T4d	
T4e	
Tx	

TNM Clinical Node Value Set

LOINC = ????	
Value Set: ????	
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
N0	
N1	
N1mi	
N1a	
N1b	
N1b1	

N1b2	
N1b3	
N1b4	
N1c	
N2	
N2a	
N2b	
N2c	
N3	
N3a	
N3b	
N3c	
Nx	

TNM Clinical Metastasis Value Set

LOINC = ????	
Value Set: ????	
Code	**Description: Site specific descriptions prevent listing of text equivalents.**
M0	
M1	
M1a	
M1b	
M1c	
M1d	
M1e	
Mx	

TNM Clinical Stage Group Value Set

LOINC = ????	
Value Set: ???? Code System:	
Code	**Description: Site specific**

	descriptions prevent listing of text equivalents.
Okk	
0	
0a	
0is	
I	
IA	
IA1	
IA2	
IB	
IB1	
IB2	
IC	
II	
IIA	
IIA1	
IIA2	
IIB	
IIC	
III	
IIIA	
IIIB	
IIIC	
IS	
IV	
IVA	
IVB	
IVC	

TNM Clinical Stage Descriptor Value Set

Item 980
LOINC = 21909-7

Value Set: Code System:	
Code	**Meaning**
0	None
1	E (Extranodal, lymphomas only)
2	S (Spleen, lymphomas only)
3	M (Multiple primary tumors in a single site)
4	Y (Classification during or after initial multimodality therapy)—pathologic staging only
5	E & S (Extranodal and spleen, lymphomas only)
6	M & Y (Multiple primary tumors and initial multimodality therapy)

Appendix A Realm Constraints for the United States of America (USA)

A.1 Name Space and Vocabularies for the United States

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)	International Classification of Diseases, Clinical Modification.
2.16.840.1.113883.4.6	NPI	National Provider Identifier (US)
2.16.840.1.113883.4.1	SSA	Social Security Administration (US)
2.16.840.1.113883.6.243	SOC	Standard Occupational Classification (US)
2.16.840.1.113883.6.240	US_COC	United States Census Occupation Codes (US)
2.16.840.1.113883.6.85	NAICS	North American Industry Coding System (US)
2.16.840.1.113883.6.101	NUCC	National Uniform Claim Committee for Provider Types
2.16.840.1.113883.3.520	NAACCR	North American Association of Central Cancer

codeSystem	codeSystemName	Description
		Registries
2.16.840.1.113883.3.221	PHDSC	Public Health Data Standards Consortium
2.16.840.1.113883.6.12	C4	Current Procedure Terminology 4 (CPT-4) codes
2.16.840.1.113883.6.88	RxNorm	RxNorm

A.2 Entry Constraints for the United States of America

(CDC National Program of Cancer Registries Advancing e-Cancer Reporting and Registry Operations (NPCR-AERRO) Use Case: Clinician/Physician Office Prepare and Transmit Event Report.)

NAACCR Data Item #	Data Element Name (Section)	Option-ality	Template ID
	ClinicalDocument/realmCode	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/typeId	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/id	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/code	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/title	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/effectiveTime	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/confidentialityCode	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/languageCode	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/setId	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/versionNumber	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/custodian	**R**	2.16.840.1.113883.10.20.3
	ClinicalDocument/legalAuthenticator	**R**	2.16.840.1.113883.10.20.3
	Participants (all participants will have name, address and telephone number)	**R**	2.16.840.1.113883.10.20.3
	recordTarget		2.16.840.1.113883.10.20.3
2230, 2240, 2250, 2280, 2290	ClinicalDocument/recordTarget/patientRole/**patient/name**	R	2.16.840.1.113883.10.20.3
1810, 1820,	Patient Address History	O	1.3.6.1.4.1.19376.1.5.3.1.1.1

NAACCR Data Item #	Data Element Name (Section)	Option-ality	Template ID
1830, 2355, 2360			
220	ClinicalDocument/recordTarget/patientRole/patient/**administrativeGenderCode**	O	2.16.840.1.113883.10.20.3
240	ClinicalDocument/recordTarget/patientRole/patient/**birthTime**	O	2.16.840.1.113883.10.20.3
2300	Medical Record Number	O	
2320	Social Security Number	R	
160	Race	R	2.16.840.1.113883.5.104
190	Ethnicity	R	2.16.840.1.113883.5.50
250	Birth Place	R	1.3.6.1.4.1.19376.1.5.3.1.1.1
150	Marital Status	R	2.16.840.1.113883.5.2.
	Contact	O	
	Provider Organization	R	2.16.840.1.113883.10.20.3
2440	Physician (Name, NPI)	R	2.16.840.1.113883.4.6
2420	Provider Referred To	R	2.16.840.1.113883.4.6
	author	R	2.16.840.1.113883.10.20.3
	dataEnterer	R	2.16.840.1.113883.10.20.3
	informant	O	2.16.840.1.113883.10.20.3
	custodian	R	2.16.840.1.113883.10.20.3
	informationRecipient	O	2.16.840.1.113883.10.20.3
	legalAuthenticator	O	2.16.840.1.113883.10.20.3
	Authenticator	O	2.16.840.1.113883.10.20.3
	Cancer Occupation History Section	**R**	**2.16.840.1.113883.3.520.2.1**
270	Occupation	R	2.16.840.1.113883.6.243 2.16.840.1.113883.6.240
280	Industry	R	2.16.840.1.113883.6.85
	History of Tobacco Use Section	**R**	**1.3.6.1.4.1.19376.1.5.3.1.1.9.8**
	History of Tobacco Use	R	1.3.6.1.4.1.19376.1.5.3.1.1.9.8
	Payers Section	**R**	**2.16.840.1.113883.3.520.2.2**
630	Payer History	R	2.16.840.1.113883.3.221.5
	Diagnosis Section	**R**	**2.16.840.1.113883.3.520.2.3**
	Diagnosing Laboratory Name	R2	

NAACCR Data Item #	Data Element Name (Section)	Option-ality	Template ID
390	Diagnosis Date	R	Date
400	Primary Site	R	2.16.840.1.113883.6.43.1
410	Laterality	R	2.16.840.1.113883.3.520.3.1
522	Histology	R	2.16.840.1.113883.3.520.3.2
523	Behavior	R	2.16.840.1.113883.3.520.3.14
550	Grade	R	2.16.840.1.113883.3.520.3.15
490	Best Method of Confirmation (Diagnostic confirmation)	R	2.16.840.1.113883.3.520.3.3
3110, 3120, 3130, 3140, 3150, 3160, 3161, 3162, 3163, 3164	Comorbidities	R	2.16.840.1.113883.6.103
	TNM-Stage Section	**R**	**2.16.840.1.113883.3.520.2.4**
990	TNM Clinical Staged By	R	2.16.840.1.113883.3.520.3.4
1060	TNM Edition	R2	2.16.840.1.113883.3.520.3.5
940	TNM Clinical T	R2	2.16.840.1.113883.3.520.3.6
950	TNM Clinical N	R2	2.16.840.1.113883.3.520.3.7
960	TNM Clinical M	R2	2.16.840.1.113883.3.520.3.8
970	TNM Clinical Stage Group	R	2.16.840.1.113883.3.520.3.9
980	TNM Clinical Stage Descriptor	R	2.16.840.1.113883.3.520.3.10
	Cancer Supporting Documentation Section	**R**	**2.16.840.1.113883.3.520.2.5**
2690	Text Place of Diagnosis	R2	
2520	Text Diagnostic Procedure – Physical Examination	R2	
2530	Text Diagnostic Procedure – X-Ray/Scan	R2	
2540	Text Diagnostic Procedure – Scopes	R2	
2550	Text Diagnostic Procedure – Lab Tests	R2	
2560	Text Diagnostic Procedure – Operation	R2	
2570	Text Diagnostic Procedure – Pathology	R2	
2600	Text Stage/Prognostic Factors	R2	
	Cancer Course of Treatment Section	**R**	**2.16.840.1.113883.3.520.2.6**
	Surgery Text	R	
700	Chemotherapy (Includes effectiveDate)	R	2.16.840.1.113883.3.520.1.10
	Chemotherapy Protocol/Regimen Text	R	
	Drug Name(s)	R	
710	Hormone Therapy	R	

NAACCR Data Item #	Data Element Name (Section)	Option-ality	Template ID
720	Immunotherapy (BRM)	R	
	Other Therapy Text	R2	
	Hematologic Transplant or Endocrine Procedure Text	O	
	Palliative Care Text	O	
	Patient Status Section	**R**	**2.16.840.1.113883.3.520.2.7**
1770	Cancer Status	R	2.16.840.1.113883.3.520.3.11
1860, 1871, 1872, 1873	Recurrent Location – Distant Site (Includes Recurrence Date)	R	
1780	Quality of Survival	R	2.16.840.1.113883.3.520.3.12
1910	Cause of Death	R2	
1940	Place of Death	R2	
	Cancer Control Section	**R**	**2.16.840.1.113883.3.520.2.8**
520	Screening Result (includes Screening Date)	R	2.16.840.1.113883.3.520.3.13
	Cancer Treatment Plan Section	**R**	**2.16.840.1.113883.10.20.1.25**
	Observation Requests	R2	1.19376.1.5.3.1.1.20.3.1
	Medication	R2	1.3.6.1.4.1.19376.1.5.3.1.4.7
	Procedure	R2	1.3.6.1.4.1.19376.1.5.3.1.4.19
2420	Encounter	R2	1.3.6.1.4.1.19376.1.5.3.1.4.14
	Hospitalization Status	R	
	Name of Hospital	R	
	Radiation Therapy Facility	R	2.16.840.1.113883.4.6
2410	Provider Referred From	R	2.16.840.1.113883.4.6

A.3 Value Set Constraints for the United States of America

Contact Physician Types Value Set

NAACCR Data Item Number: 2460	
Code System: LOINC 2.16.840.1.113883.6.1	
Code	**Meaning**
22025-1	Physician: Managing
22026-9	Physician: Follow-up
22027-7	Physician: Primary Surgeon
22028-5	Physician 3, Physician 4, ...

Ethnic Status Value Set

NAACCR Data Item Number: 190
LOINC = 21837-0
Value Set: Ethnicity Group Code System: PHVS_EthnicityGroup_CDC 2.16.840.1.114222.4.11.837

Laterality at Diagnosis Value Set

NAACCR Data Item Number: 410	
Code System: NAACCR Laterality at Diagnosis 2.16.840.1.113883.3.50.3.1	
Code	**Meaning**
0	Not a paired site
1	Right: origin of primary
2	Left: origin of primary
3	Only one side involved, right or left origin unspecified
4	Bilateral involvement, lateral origin unknown; stated to be single primary; including both ovaries involved simultaneously, single histology; bilateral retinoblastomas; bilateral Wilms' tumors
5	Midline of Tumor
9	Paired site, but no information concerning laterality, midline tumor

NAACCR Behavior Code Value Set

NAACCR Data Item 523	
LOINC = 31206-6	
Code System: NAACCR Behavior Code 2.16.840.1.113883.3.520.3.14	
Code	Meaning
0	Benign
1	Uncertain whether benign or malignant
2	Carcinoma in situ
3	Malignant, primary site

NAACCR Grade Value Set

NAACCR Data Item Item 440	
LOINC = 21858-6	
Code System: NAACCR Grade 2.16.840.1.113883.3.520.3.15	
Code	Meaning
1	Grade I

2	Grade II
3	Grade III
4	Grade IV
5	T-cell
6	B-cell
7	Null cell
8	NK (natural killer) cell

NAACCR Best Method of Diagnosis Value Set

NAACCR Data Item Number: 490	
LOINC = 21861-0	
Code System: NAACCR Diagnostic Confirmation 2.16.840.1.113883.3.50.3.3	
Code	**Meaning**
1	Positive histology
2	Positive cytology, no positive histology
4	Positive microscopic confirmation, method not specified
5	Positive laboratory test/marker study
6	Direct visualization without microscopic confirmation
7	Radiography and other imaging techniques without microscopic confirmation
8	Clinical diagnosis only (other than 5, 6, or 7)

TNM Clinical Staged By Value Set

Item 990	
LOINC = 21910-5	
Code System: NAACCR TNM Clinical Staged By 2.16.840.1.113883.3.520.3.4	
Code	**Meaning**
1	Managing physician
2	Pathologist
3	Pathologist and managing physician
4	Cancer Committee chair, cancer liaison physician, or registry physician advisor
5	Cancer registrar
6	Cancer registrar and physician
7	Staging assigned at another facility

Cancer Status Value Set

Item 1770	
LOINC = 21976-6	
Code System: NAACCR Cancer Status 2.16.840.1.113883.3.520.3.11	
Code	**Meaning**
1	No evidence of this tumor
2	Evidence of this tumor
9	Unknown, indeterminate whether this tumor is present, not stated in patient record

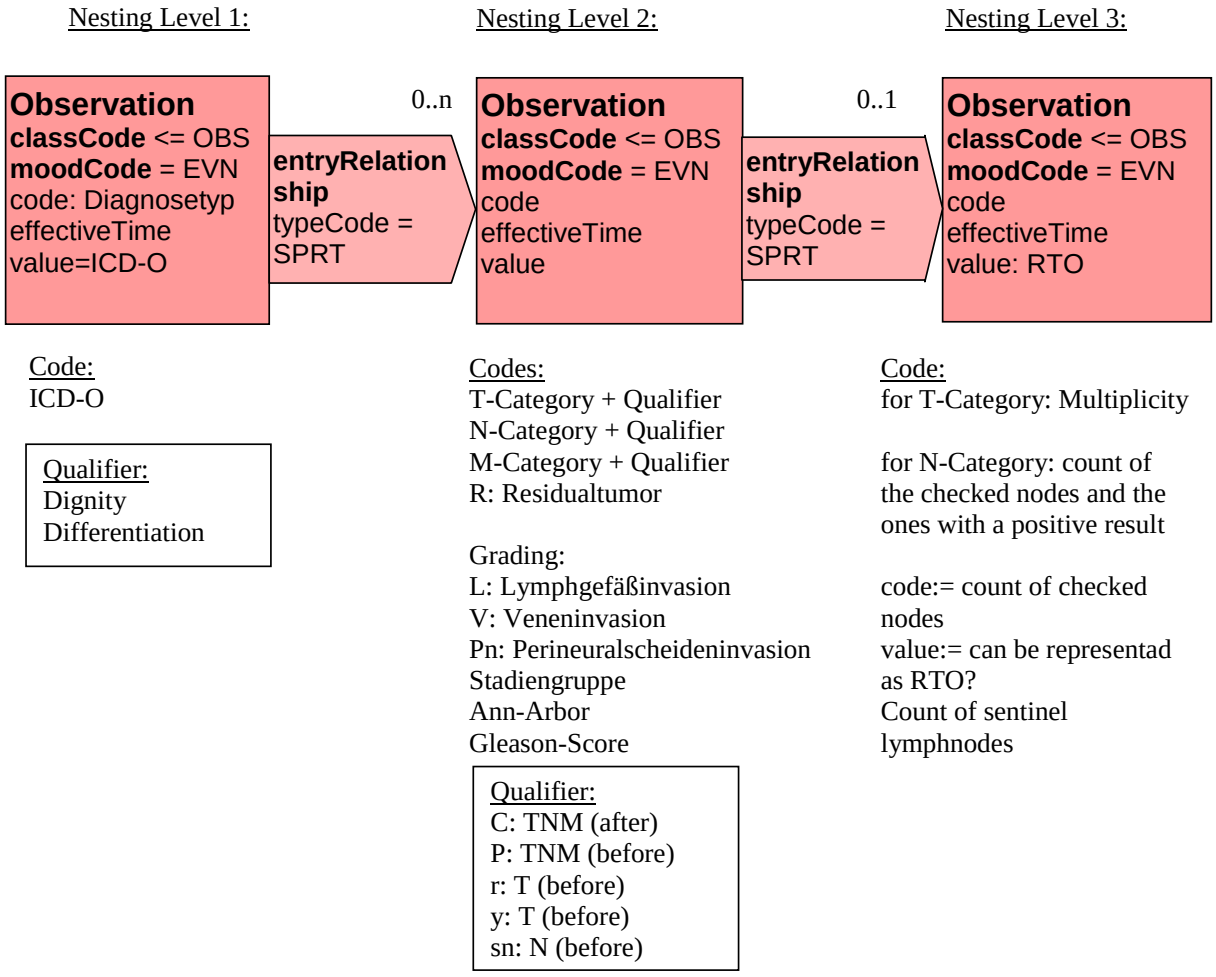
Quality of Survival Value Set

NAACCR Data Item Number: 1780	
LOINC = 21977-4	
Code System: NAACCR Quality of Survival 2.16.840.1.113883.3.520.3.12	
Code	**Meaning**
0	Normal activity
1	Symptomatic and ambulatory
2	Ambulatory more than 50 percent of the time, occasionally needs assistance
3	Ambulatory less than 50 percent of the time, nursing care needed
4	Bedridden, may require hospitalization

Screening Result Value Set

NAACCR Data Item Number: 520	
LOINC = 21864-4	
Code System: NAACCR Screening Result 2.16.840.1.113883.3.520.3.13	
Code	**Meaning**
0	Within normal limits
1	Abnormal-not suggestive of cancer
2	Abnormal-suggestive of cancer
3	Equivocal-no follow-up necessary
4	Equivocal-evaluation recommended

Appendix B Realm Constraints for Germany



Note: the remark «after» or «before» refers to the tumor formula expressing whether it is represented there, after or before the categories.

The codes which specify the contents of the observation class or a qualifier are listed in the following table.

Code	Codename	Class / Pfath	Representation (Observation or Qualifier)
DF	Differentiation	Observation (ICD-O)	qualifier.@name
DN	Dignity	Observation (ICD-O)	qualifier.@name
T	T	support-Observation	Observation/value.@code
M	M	support-Observation	Observation/value.@code

Code	Codename	Class / Pfath	Representation (Observation or Qualifier)
N	N	support-Observation	Observation/value.@code
MP	Multiplicity	support-Observation(T)-support-Observation	Observation/value.@code
CF	Certainty Factor	support-Observation(T, N or M)	qualifier.@name
RS	Residual tumor	support-Observation	Observation/value.@code
GR	Grading	support-Observation	Observation/value.@code
LI	Lymph invasion	support-Observation	Observation/value.@code
VI	Vene invasion	support-Observation	Observation/value.@code
SG	Stading	support-Observation	Observation/value.@code
AA	Ann-Arbor classification	support-Observation	Observation/value.@code

CONF-1: A TNM-classification Observation **SHALL** be represented with an `observation` element where the value of `@classCode` is `OBS` and the value of `@moodCode` is `EVN`.

CONF-2: A `value` element **SHOULD** be present where the value of `@xsi:type` is `CD` and the value of `@code` is from 1.2.276.0.76.5.???? ICD-O.

CONF-3: A `qualifier` element **SHOULD** be present where the value of `name/@code` is the qualifier from the above mentioned table and the value of `name/@codeSystem` is 2.16.840.1.113883.3.7.1.0.

CONF-4: An `effectiveTime` element **MAY** be present representing the date of diagnosis.

CONF-5: An `entryRelationship` element **MAY** be present where the value of `@typeCode` is `SPRT`, containing one of the TNM-classification values.

CONF-6: An `entryRelationship/observation` element **MAY** be present where the value of `@classCode` is `OBS` and the value of `@moodCode` is `EVN`.

CONF-7: A entryRelationship/observation/`qualifier` element **SHOULD** be present where the value of `name/@code` is the qualifier from the above mentioned table and the value of `name/@codeSystem` is 2.16.840.1.113883.3.7.1.0.

CONF-8: If a T-category value should be transmitted an entryRelationship/observation element **SHALL** be present where the value of `value/@codesystem` is coming from the `QRPH-T-classification value set`.

CONF-9: If a N-category value should be transmitted an entryRelationship/observation element **SHALL** be present where the value of `value/@codesystem` is coming from the `QRPH-N-classification value set`.

CONF-10: If a M-category value should be transmitted an entryRelationship/observation element **SHALL** be present where the value of `value/@codesystem` is coming from the `QRPH-M-classification value set`.

```
<observation classCode="OBS" moodCode="EVN">
                    ...
                    <value xsi:type="CD" code="8070"
codeSystem="1.2.276.0.76.5.????"
                                displayName="Plattenepithelkarzinom">
                                codeSystemName="icd-o-3">
                          <qualifier>
                                <name code="335"
codeSystem="2.16.840.1.113883.3.7.1.0"/>
                                <value code="0" codeSystem="1.2.276.0.76.5.335"/>
                          </qualifier>
                          <qualifier>
                                <name code="336"
codeSystem="2.16.840.1.113883.3.7.1.0"/>
                                <value code="1" codeSystem="1.2.276.0.76.5.336"/>
                          </qualifier>
                    </value>

                    <!-- Tumor Formula -->
                    <entryRelationship typeCode="SPRT">
                          <observation moodCode="EVN" classCode="OBS">
                                <!-- T-Code -->
                                <value xsi:type="CD" code="T1"
                                      codeSystem="1.2.276.0.76.5.337"
                                      codeSystemName="ausdehnung-tnm"/>
                                      <qualifier>
                                            <name code="341"
```

```
                  codeSystem="2.16.840.1.113883.3.7.1.0"/>
                                          <value code="C2"

                  codeSystem="1.2.276.0.76.5.341"/>
                                    </qualifier>
                              </value>
                        </observation>
                  </entryRelationship>

                  <entryRelationship typeCode="SPRT">
                        <observation moodCode="EVN" classCode="OBS">
                              <!-- N-Code -->
                              <value xsi:type="CD" code="N2"
                                    codeSystem="1.2.276.0.76.5.338"
                                    codeSystemName="nodus-tnm"/>
                              </value>
                        </observation>
                  </entryRelationship>

                  <entryRelationship typeCode="SPRT">
                        <observation moodCode="EVN" classCode="OBS">
                              <!-- M-Code -->
                              <value xsi:type="CD" code="M0"
                                    displayName="Fernmetastasen nicht vorhanden"
                                    codeSystem="1.2.276.0.76.5.339"
                                    codeSystemName="metastasen"/>
                              </value>
                        </observation>
                  </entryRelationship>

</observation>
```

B.1 ICD-O-Codes

B.1.1 Behavior

Behavior Value Set

LOINC = ????	
Value Set: ???? Code System: ??? OID 1.2.276.0.76.5.335	
Code	**Meaning**
0	
1	

2	
3	
6	
9	

B.1.2 Grading

The following table represents the gradings which are allowed at all. The column "entity" specifies the cancer entity where this grading is allowed.

Differentiation/Grading Value Set

LOINC = ????
Value Set: ???? Code System: Differenzierungsgrad/Grading – Codes (OID 1.2.276.0.76.5.336)

Code	Description	Entity
0	Primary acquired melanosis	Malignant Melanoma of Conjunctiva
1	well differentiated	All except Prostata, Malignant Melanoma of Conjunctiva
	Well differentiated (slight anaplasia) (Gleason 2-4)	Prostata
	Malignant melanoma arising from a naevus	Malignant Melanoma of Conjunctiva
2	moderately differentiated	All except Prostata, Malignant Melanoma of Conjunctiva
	Moderately differentiated (moderate anaplasia) (Gleason 5–6)	Prostata
	Malignant melanoma arising from primary acquired melanosis	Malignant Melanoma of Conjunctiva
3	poorly differentiated	All except Prostata, Penis, Kidney, Renal Pelvis and Ureter, Urinary Bladder, Urethra, Malignant Melanoma of Conjunctiva
	Malignant melanoma arising de novo	Malignant Melanoma of Conjunctiva
3-4	Poorly differentiated/	Prostata

	undifferentiated (marked anaplasia) (Gleason 7–10)	
	Poorly differentiated/ undifferentiated	Penis, Kidney, Renal Pelvis and Ureter, Urinary Bladder, Urethra
4	undifferentiated	All except Prostata, Penis, Kidney, Renal Pelvis and Ureter, Urinary Bladder, Urethra, Malignant Melanoma of Conjunctiva
L		
H		
X	grade of differentiation cannot be assessed	Alle

B.2 Codes for the TNM classification

B.2.1Topography (QRPH-T-classification)

All known T-categories (with specification of additions/qualifiers). The meaning varies according to entity:

CONF-11: For the German realm the `QRPH-T-classification value set` **SHALL** be bound to the following table (OID 1.2.276.0.76.5.337).

T-classification Value Set

LOINC = ????	
Value Set: ???? Code System: Topographie-Codes (Version 6, OID 1.2.276.0.76.5.337)	
Realm: German	
Code	**Meaning**
Ta	
Tis	Carcinoma in situ
T0	No evidence of primary tumor
T1	
T1mic	
T1a	
T1a1	
T1a2	

T1b	
T1b1	
T1b2	
T1c	
T1d	
T2	
T2a	
T2a1	
T2a2	
T2b	
T2c	
T2d	
T3	
T3a	
T3b	
T3c	
T3d	
T4	
T4a	
T4b	
T4c	
T4d	
T4e	
Tx	Primary tumor cannot be assessed

B.2.2 Nodes (QRPH-N-classification)

CONF-12: For the German realm the `QRPH-N-classification value set` **SHALL** be bound to the following table (OID 1.2.276.0.76.5.338).

N-classification Value Set

LOINC = ????
Value Set: ???? Code System: (N) Knoten-Codes (Version 6, OID 1.2.276.0.76.5.338)
Realm: German

Code	Description	Entity
N0	No regional lymph node metastasis	All
N1		
N1mi	Bilateral regional lymph node metastasis	Vulva
N1a		all
N1b		
N1b1		
N1b2		
N1b3		
N1b4		
N1c		
N2		
N2a		
N2b		
N2c		
N3		
N3a		
N3b		
N3c		
Nx	Regional lymph nodes cannot be assessed	

B.2.3 Metastasen (QRPH-M-classification)

CONF-13: For the German realm the `QRPH-M-classification value set` **SHALL** be bound to the following table (OID 1.2.276.0.76.5.339).

M-classification Value Set

LOINC = ????

Value Set: ???? Code System: Metastasen-Codes (Version 6, OID 1.2.276.0.76.5.339)
Realm: German

Code	Description	Entity
M0	No distant metastasis	Alle
M1	Distant metastasis	Alle
M1a		nur Ösophagus und Prostata
M1b		nur Ösophagus und Prostata
M1c		
M1d		
M1e		
Mx	Distant metastasis cannot be assessed	Alle

B.2.4 Residualtumor

Residualtumor Value Set

LOINC = ????
Value Set: ???? Code System: Residualtumor-Codes (OID ??????)
Realm: German

Code	Meaning
R0	No residual tumor
R1	Microscopic residual tumor
R2	Macroscopic residual tumor
R2a	
R2b	
Rx	Presence of residual tumor cannot be assessed

B.2.5 Stading

Staging Value Set

LOINC = ????
Value Set: ???? Code System: Stadiengruppierung (OID ??????)

Realm: German	
Code	**Meaning**
Okk	
0	
0a	
0is	
I	
IA	
IA1	
IA2	
IB	
IB1	
IB2	
IC	
II	
IIA	
IIA1	
IIA2	
IIB	
IIC	
III	
IIIA	
IIIB	
IIIC	
IS	
IV	
IVA	
IVB	
IVC	

B.2.6 Vene invasion

Vene Invasion Value Set

LOINC = ????
Value Set: ???? Code System: Veneninvasion-Codes (OID ??????)

Code	Meaning
V0	no venous invasion
V1	microscopic venous invasion
V2	macroscopic venous invasion
Vx	venous invasion cannot be assessed

B.2.7 Lymphsystem invasion

Lymphsystem Invasion Value SetLOINC = ????	
Value Set: ???? Code System: Lymphsysteminvasion-Codes (OID ??????)	
Code	**Meaning**
L0	no lymphatic invasion
L1	lymphatic invasion
Lx	lmphatic invasion cannot be assessed

B.2.8 Neuralscheideninvasion

Neuralscheiden Invasion Value Set

LOINC = ????	
Value Set: Neuralscheideninvasion-Codes (OID ??????) Code System: ???	
Code	**Meaning**
Pn0	
Pn1	
Pnx	Unknown

B.2.9 Qualifier

TNM qualifier Value Set

LOINC = ????
Value Set: ???? Code System: TMN-Qualifier (OID 1.2.276.0.76.5.340)

Code	Meaning
C	Clinical
P	Pathological
R	
Y	

B.2.10 Certainty

Certainty Value Set

LOINC = ????	
Value Set: ???? Code System: Certainty Factor-Codes (OID 1.2.276.0.76.5.341)	
Code	**Meaning**
C1	Evidence from standard diagnostic means (e.g., inspection, palpation, and standard radiography, intraluminal endoscopy for tumors of certain organs)
C2	Evidence obtained by special diagnostic means (e.g., radiographic imaging in special projections, tomography, computerized tomography [CT], ultrasonography, lymphography, angiography; scintigraphy; magnetic resonance imaging [MRI]; endoscopy, biopsy, and cytology)
C3	Evidence from surgical exploration, including biopsy and cytology
C4	Evidence of the extent of disease following definitive surgery and pathological examination of the resected specimen
C5	Evidence from autopsy

B.2.11Lokalisation von Metastasen

Metastasen-Localisation Value Set

LOINC = ????	
Value Set: ???? Code System: Metastasen-Lokalisation-Codes (OID 1.2.276.0.76.5.?????)	
Code	**Meaning**
PUL	Pulmonary
OSS	Osseous
HEP	Hepatic
BRA	Brain

LYM	Lymph Nodes
OTH	Others
MAR	Bone Marrow
PLE	Pleura
ADR	Adrenals
SKI	Skin

B.3 Codes für Gleason-Score

Gleason Score Value Set

LOINC = ????	
Value Set: ???? Code System: Entdifferenzierungsgrad nach Gleason-Score (OID 1.2.276.0.76.5.??????)	
Code	**Meaning**
1	
2	
3	
4	
5	

Wachstumsmuster according to Gleason Score Value Set

LOINC = ????	
Value Set: ???? Code System: Wachstumsmuster nach Gleason-Score (OID 1.2.276.0.76.5.??????)	
Code	**Meaning**
1	
2	
3	
4	
5	

Grading according to Gleason Score Value Set

LOINC = ????

Value Set: ???? Code System: Grading nach Gleason-Score (OID 1.2.276.0.76.5.??????)	
Code	**Meaning**
2	
3	
4	
5	
6	
7	
8	
9	
10	